SEVENTH FRAMEWORK PROGRAMME

ICT-Call 1

FP7-ICT-2007-1

REMINE

Grant Agreement for: Large Scale Integrating Projects – CP – (IP)

Annex I - "Description of Work"

Project acronym: REMINE

Project full title: High performances prediction, detection and monitoring platform for patient safety risk management

Grant Agreement n°: 216134

Date of preparation of Annex I: 27 November 2007

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TABLE OF CONTENTS

Part A

A1. Budget breakdown and project summary

A.1.1 Overall Budget Breakdown of the project

Grant agreement Preparation Forms

EUROPEAN COMMISSION
7th Framework Programme on Research, Technological Development and Demonstration

Collaborative Project

A3.2: What it costs

Proposal number (1)	216134	*Proposal acronym (2)*	REMINE

ONE FORM PER PROJECT

Participant number in this project	Organisation short name	Estimated eligible costs (whole duration of the project)				TOTAL A+B+C+D	Total receipts	Requested EC contribution
		RTD / Innovation (A)	Demonstration (B)	Management (C)	Other (D)			
1	GMD	531.111,00	97.619,00	187.011,00	48.623,00	864.364,00	0,00	549.999,00
2	REGLOM	231.000,00	126.000,00	26.249,60	87.500,80	470.750,40	0,00	350.000,40
3	SEK	156.637,00	75.659,00	19.154,00	25.539,00	276.989,00	0,00	200.000,25
4	TRFT	174.704,00	110.555,00	27.297,60	36.396,80	348.953,40	0,00	249.999,90
6	QSC	487.822,40	134.644,00	34.086,40	22.724,80	679.277,60	0,00	490.000,00
7	HP	146.751,00	42.802,00	32.611,00	32.612,00	254.776,00	0,00	159.999,50
8	SO	622.549,00	51.934,00	9.892,00	42.866,00	727.241,00	0,00	389.999,50
9	TUW	169.328,00	31.211,00	21.524,80	35.875,00	257.938,80	0,00	200.001,30
10	RAMIT	133.113,60	81.321,60	19.834,80	39.668,40	273.938,40	0,00	199.999,20
11	Q&R	673.308,80	66.683,20	20.858,40	20.819,20	781.669,60	0,00	580.000,80
12	LINK	425.105,00	11.122,00	18.539,05	37.074,00	491.840,05	0,00	380.002,80
13	ICCS	319.846,40	148.064,00	17.216,00	68.865,60	553.992,00	0,00	399.998,40
14	MIP	295.105,60	348.923,20	75.240,00	68.968,00	788.236,80	0,00	539.998,80
15	INFO WORLD	318.316,80	89.067,00	18.364,80	18.364,80	444.113,40	0,00	320.000,70
16	AMINIO	391.748,60	52.465,60	34.977,60	34.977,60	514.169,40	0,00	389.999,45
TOTAL		5.076.447,20	1.468.070,60	562.857,05	620.875,00	7.728.249,85	0,00	5.400.000,00

A2 Project Summary

Grant agreement Preparation Forms

EUROPEAN COMMISSION

7th Framework Programme on Research, Technological Development and Demonstration

Collaborative Project

A1: Our Project

Project number (1)	216134	*Project acronym (2)*	REMINE

ONE FORM PER PROJECT

GENERAL INFORMATION

Project Title (3)	HIGH PERFORMANCES PREDICTION, DETECTION AND MONITORING PLATFORM FOR PATIENT SAFETY RISK MANAGEMENT		
Starting Date (4)	01/01/2008		
Duration in months (5)	36	*Call (part) identifier (6)*	FP7-ICT-2007-1
Activity code(s) most relevant to your topic (7)	ICT-1-5.2 -		-
Free keywords (8)			

Abstract(9) (max. 2000 char.)

According to recent studies, Risks Against Patient Safety (RAPS) represent one of the most important factors of dead in hospitals: during therapy, more then 8% of patients recovered in hospitals suffer for additional disease that in almost 50% of the cases produce either dead or significant additional health problems. RAPS occur in any stage of the patient care process.
REMINE project idea originates from the common difficulty in conducting a analysis, early identification and effective prevention on RAP when there are significant mass of inhomogeneous data sources, stored in multimedia databases, and a distributed environments with different care professionals contemporary involved.
To contrast the RAPS trends and the malpractices diffusion, REMINE prosecutes a number of main objectives. a new technological platform, new care process organizational requirements. Main elements are: mining of multimedia data; modeling, prediction, detection of RAPS, RAPS management support system and info broker patient safety framework.
Main outcomes of REMINE will be: time reduction in collecting data, time reduction in RAPS analysis, standardization of common language, evolution in the interaction model, reference framework, patient safety improvement, health care cost saving (within an estimated RAPS reduction between 6% to 9% of RAPS.

A3 List of Beneficiaries

Participant no. *	Participant organisation name	Part. short name	Country	Date enter project	Date exit project
1 (Coordinator)	GMD Gesellschaft fur Medizinische Datenverarbeitung mbH	GMD	D	M1	M36
2	Regione Lombardia- Direzione Generale Sanità	REGLOM	I	M1	M36
3	Federation of Municipalities for Economic Development in Suupohja	SEK	FI	M1	M36
4	The Rotherham NHS Foundation Trust	TRFT	UK	M1	M36
6	Quality AND Systems Consulting LTD	QSC	UK	M1	M36
7	Hewlett-Packard Italiana Srl	HP	I	M1	M36
8	SOLUZIONA, A.S.	SO	CZ	M1	M36
9	Technische Universitaet Wien	TUW	AT	M1	M36
10	Research in Advanced Medical Informatics and Telematics (vzw)	RAMIT	BE	M1	M36
11	Quality & Reliability Sa – High Tech Applications Industrial & Commercial Societé Anonyme	Q&R	GR	M1	M36
12	Link Consulting, Tecnologias e Sistemas de Informação, S.A.	LINK	POR	M1	M36
13	Institute Of Communication And Computer Systems - National Technical University Of Athens	ICCS	GR	M1	M36
14	MIP Consorzio per l'innovazione e la Gestione delle Imprese e della Pubblica Amministrazione	MIP	I	M1	M36
15	S.C. Info World S.R.L.	Info World	RO	M1	M36
16	AMINIO AB	AMINIO	SWE	M1	M36

Part B Concept and Objectives, progress beyond state of the art, S/T methodology and workplan

B1.1 Concept and Project Objectives

According to recent studies Risks Against Patient Safety (RAPS) represents one of the most important factors of dead in Hospitals: just in the phase of therapy, it is assessed that more than 8% of the patients recovered in Hospitals suffer for additional disease due to RAPS that in almost 50% of the cases produce either dead or significant additional health problems. RAPS occurs in any stages of the patient care process: from admission to demission and home therapy and rehabilitation too, and even if most of them are predictable (around 50% of them as recent estimation1), they happen due to the lack of proper communication amongst different actors of the patients care chain.

Looking at available data, it seams evident that non much progress has occurred during the last six year. The table below, which shows data processed in 2001 by the Royal Society of Medicine1, demonstrate that error happen during all patient way, from admission to demission:

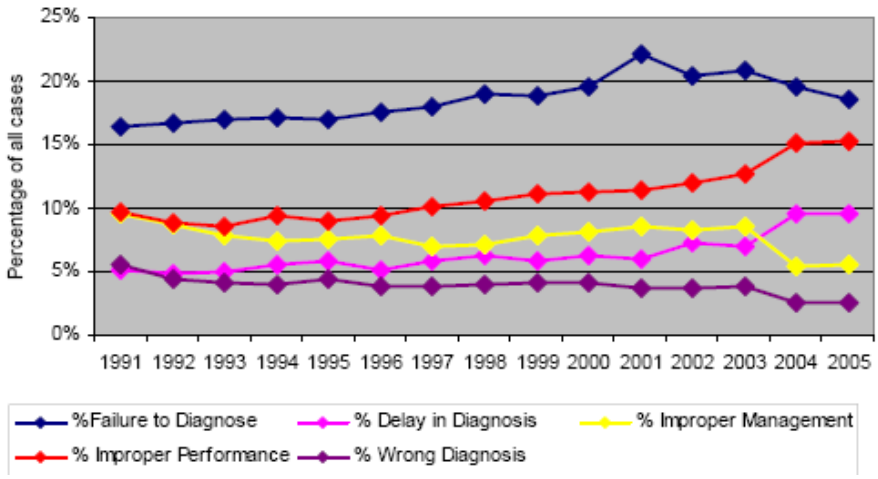
1%	admissions with incorrect diagnoses
28%	postoperative problems
1%	urethral catheterization
41%	during an operation or an invasive procedure (including anaesthesia)
12%	intravenous fluids
3%	cases of overtransfusion
14%	demission procedures

Source: The Royal Society of Medicine

The next table, which refers to data elaborated in 20072, clearly demonstrate that the proportion of most common errors over the time has been almost constant:

[1] Exploring the causes of RAPS in NHS hospital practice, *Graham Neale* FRCP, Maria Woloshynowych PhD, Charles Vincent PhD, *Clinical Risk Unit, Department of Psychology, University College London, London WC1E 6BT, UK ; J R Soc Med* 2001;*94*:322-330 © 2001.*The Royal Society of Medicine*

[2] The Great Medical Malpractice Hoax: NPDB Data Continue to Show Medical Liability System Produces Rational Outcomes. Public Citizen's Congress Watch 2007



Proportion of most common errors over the time

However, understanding the sources of an RAPS it is not so easy: it may happens for a wrong application of procedures, or simple for the absence of procedures itself or even more for not application of them at all. For example it is assesses that from 5% to 8% of the patient recovered in hospitals gets nosocomial infections and more of the 40% of these infections are predictable: recent international studies have shown how more than 50% of infections are due to negligent behaviour of hospitals personnel2.

Other sources of RAPS are related to drugs interactions: since middle of 90th it is known how more then 60% of RAPS in hospitals are due to this phenomena and more then 10% of hospitalizations is due to it. However drugs interactions it is not the only RAPS due to the drugs usage. It became more and more important the selection of the right drug at the right time. One example is the usage of antibiotics than in most of the case they are used more on empirical bases rather than standardized one. By the matter of fact, the so frequent usage of antibiotics in hospitals produce a selective process of bacteriological flora that became hard to fight. Thus, choosing the right antibiotics to the right time became more and more important and this process require both a clear procedure to be applied and a contemporary involvement of several experts in the field such as virology expert and expert about antibiotics together. All of this experts and care professional as well requires data and context information before to decide any actions.

Summarizing these examples we can see that RAPS in patient care and quality of care in more general sense:

- should involve all the care process: diagnosis, treatments/operations, post treatments/operations, de-hospitalisations, home therapy;
- should be based of the specific patient characteristics;
- should involve contemporary experts and specialists in various fields ;
- should be based on as much as possible information;
- should be supported by clear and recognized procedures.

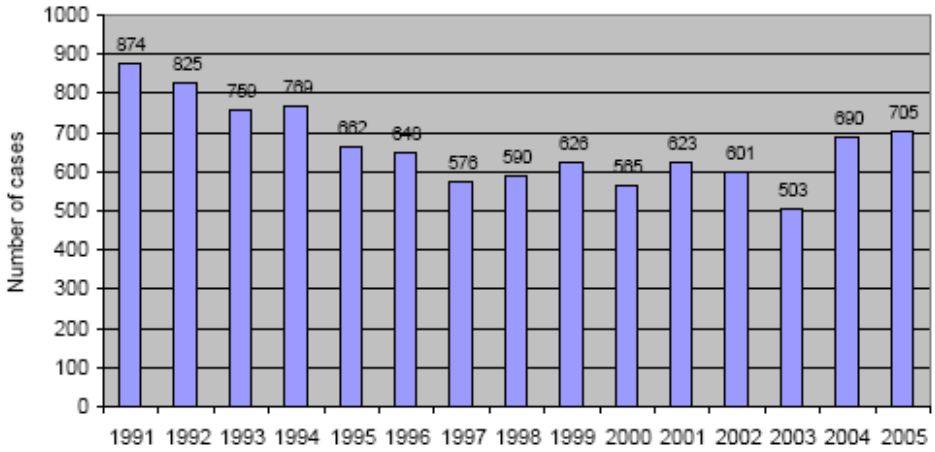
On the contrary the effect on both the Patient Safety and the socio-sanitary expenses will continue to grow, together with the insurance costs and the legal actions due to care professionals malpractices.

For what concern the consequence of a RAPS on Patient Health, the risk unit of the Department of Psychology, University College3 classified RAPS with the following breakdown of the produced effects:

66%	minimal impairment (or recovered within one month);
34%	injury or complication;
19%	moderate impairment;
6%	permanent impairment;
8%	contributed to death.
48%	RAPS were judged preventable.

Source: Risk Unit, Department of Psychology, University College 2006

The number easily avoidable errors, such as leaving a foreign object inside a patient, or operating on the wrong body part, fell from 874 in 1991 to 576 in 1997, and then remained relatively constant until 2004, when incidents increased dramatically. The most recent data, showed in the figure below, reflect the highest number of such errors in 11 years4., more than 40% of them are preventable errors.



Easily preventable errors: Up 40 percent since 2003

While, the same analysis shows how RAPS brings about elevation of health expenditure, this because patient has to recovery an higher number of days, ranging from 8,5 to 10 extra beds days (on overage) per RAPS occurrence. The only Italian health care system suffers every years of 32.000 victims due to RAPS and more than 300.000 between minimal to permanent impairments5. The overall cost of these damages goes over 260 million euros every year for the Italian Heath Care System.

3 Risk Unit, Department of Psychology, University College 2006

4 The Great Medical Malpractice Hoax: NPDB Data Continue to Show Medical Liability System Produces Rational Outcomes. Public Citizen's Congress Watch 2007

5 Sources ISTAT statistics Feb. 2007 and "La Repubblica" 6 of May 2007.

Current approaches against RAPS early identification and effective prevention, suffer from two major problems: lack of RAPS information at the right time in the right place and absence of standardize procedures easily accessible and usable.

REMINE project idea originates from the common difficulty in conducting a detailed analysis, an early identification and an effective prevention on RAPS when there are significant mass of inhomogeneous data sources, stored in multimedia databases, and a distributed environments with different care professionals contemporary involved.

In order to contrast the RAPS trends and the widespread care malpractices diffusion, REMINE prosecutes a number of main objectives, which can be distinguished into two categories: technological and socio-economical as follows:

- A new technological platform able to perform an automated/semi-automated RAPS management and prevention through:
    - An effective RAPS identification and analysis by means of acquisition and mining of relevant multimedia data present in an hospital care processes information boundary;
    - Use of the above results for modeling, prediction, detection and monitoring of RAPS related to single/multiple patient safety profile;
    - An efficient reaction procedure based upon both RAPS management process support System and the contemporary involvement of several different care professionals in a common RAPS management strategy, based upon a RAPS info broker patient safety framework.

- A new care process organizational requirements which succeeds in producing new added value by means of:
    - The RAPS modelling and clinical risk management process;
    - The envisioning of a new active role of RAPS manager;
    - The identification of a new way for interactions among different health care professional along patient care management process and belonging to different socio-sanitary units in a local health care system.

Conceptually, REMINE will contribute to the RAPS management process in a local heath care system through the definition of a **framework architecture**, instantiated and validated in a proof-of-concept, enabling a **collection and analysis of RAPS-related data**, through a **semantic approach** that allows a fast and secure extraction of data and **correlation of the information across several domains**. In this respect the REMINE platform will promote an **early RAPS detection and forecast by** supporting the process of RAPS management from both the moment:

- when the RAPS is foreseen to the determination of the best possible preventive actions and the way of communicating it to the key actors of the patient care process;
- when the RAPS is detected to the **determination of the best possible reaction**, the secure and reliable **distribution of the related action-list** to all the involved parties and the **monitoring of the reaction effectiveness**.

This will be achieved by means of the creation of a **methodology and platform for integrated RAPS description/collection/analysis/response**. The overall structure assumes the presence of one or more "info broker patient safety framework", strictly connected with the Hospital Information system (in the following called "ERP") which collect, aggregate, mine, assess data and distribute advise and or provide actions against RAPS occurrence. The underlying **ontological system** which carries out the process of reaction determination basing on the aggregated data is going to **evolve basing on the measured effectiveness** of the suggested reaction to the identified RAPS.
The project activities will include also the creation of a **reference implementation** as well as the issuing of **best practices, procedures, recommendation and guidelines** for implementers and users.

Therefore REMINE aims at enhancing the efficiency, effectiveness and security of the means used to carry out the RAPS internal investigation in an hospital as well as its local heath care environment (e.g. regional clinical data; social sanitary units information, etc.) and increasing the quality level of analysis procedures, as well as allowing a joint reaction from the different involved ICT infrastructures, even if independently administered.

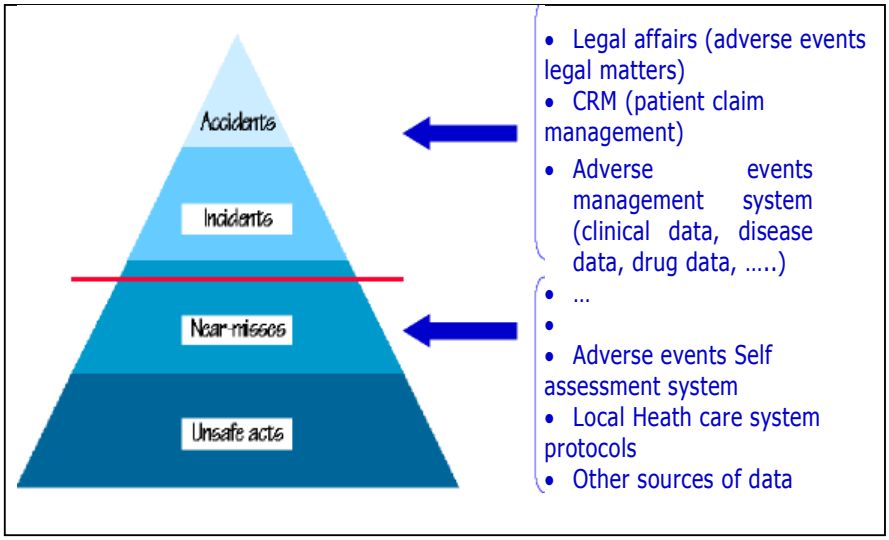
For better understanding how REMINE can support the RAPS management processes, the following table should be analyzed.

Current RAPS management practices	**REMINE technological innovations**	**REMINE organisational innovations**
RISK IDENTIFICATION – This is the first step of a RAPS management process. According with the figure below, many information sources exists for detecting RAPS situations. The sources can be multiple and can be provided with different multimedia data formats. In the same figure it is also evident that there are two different groups of RAPS and	**Integrated multimedia data acquisition** (including RFID) **Data enrichment through:** Metadatabase semantically	**New organizational models** for data collection about RAPS in hospital health care environment

related risk factors: • the visible risk factors, that allows to determine a clear RAPS, due to the legal affairs; patients claims; ….; • the invisible risk factors, that don't allow to foreseen any RAPS. Today these ones can be determined only on voluntary bases.	developed RAPS taxonomy RAPS ontology	
RISK ANALYSIS – today for the risk analysis of RAPS is used the so called: • "clinical audit": this implies confrontation meetings among health care professional, than on the bases of clinical qualitative and quantitative data, provided in the risk identification process, make an open confrontation of their current practices and the existing guidelines in the risk domain under observation. The results of this confrontations could be a modification of the current practices according with the outgoing standards. • Morbidity and Mortality audit. This is a current weekly of by-weekly practices for assessing the mortality and morbidity cases occurred in the period. The main objectives in this case is to preserve an high level of attention in the care management process carried out by all the care professionals. (Failure Mode and Effect Analysis methods is usually used - FMEA)	**Knowledge extraction algorithm** and methodologies for: • Mining • Pattern discovery **Modelling system for RAPS:** • Prediction • Detection • monitoring	• international Heath Quality Standards definition and assessment mechanism improvement • local Heath care systems procedures definition and assessment mechanism improvement • specific hospital work flows definition and assessment mechanism improvement

ALLERT PROVISIONING - It represents the final step of the RAPS management process. Generally speaking is composed by a "risk report" and an "improvement plan". These two documents all together have the scope of identify the RAPS management priorities, the major countermeasures and the care personnel responsible for their implementation. An assessment	• RAPS info info-broker patient safety framework able to provide the best possible reaction, using advanced Businss Process Modelling	• New organizational models for dynamic health care professionals interaction for RAPS reductions
		• New business model for RAPS management including
		  • RAPS manager role and responsibilities
		  • Insurance costs reduction

schema about the implementation action results is also foreseen in the documents.		• Relational model amongst heath care units in and outside hospital and local heath care authorities



The final goal of REMINE project is the harmonization of RAPS detection and reaction methodologies; the identification of the main risk factors and the continuous revisions of the effectiveness and efficiency of the foreseen countermeasures; the continuous alignment of the countermeasures with the RAPS management guidelines; the promotion of a multisources-multidisciplinary RAPS management process in relation with the provision to right time – right place decision in respect to each single patient safety profile.

Following the project concepts expressed above, the expected outputs of REMINE are:

Expected output	Expected delivery time
• The development of a integrated multimedia data acquisition framework (including RFID usage) about RAPS	M12 and M32
• The development of a specific taxonomy and related ontology domain for the risk factors and related RAPS classification and correlation, supporting distributed RAPS analysis and classification.	M12 and M24
• The development of a high performances knowledge extraction tool based upon evolutionary mining and pattern discovery algorithms and methodologies	M12 and M33
• The development of a modelling systems for RAPS prediction, detection and monitoring based upon knowledge extraction results (real time alerting tool, post process alerting tool, patient treatment, black list tool).	M12 and M33
• The implementation of a specific dynamic knowledge rule-base risk management support system of the possible RAPS and related risk factors, each one classified according to the international Heath Quality Standards, the local Heath care systems procedures and the specific hospital work flows	M24 and M34
• The development/configuration of an info-broker patient safety framework able to provide the best possible reaction to each RAPS identified as in proactive or in post occurrence situation for each of the main organizational management domain of an hospital (disease management; nosocomial management; drug management; clinical pathways management) and for them all together, and for single and/or cluster of patient safety profiles	M12, M24 and M36
• The creation of suitable interfaces for the distributed reaction diffusion, giving the people entitled of administrative responsibilities the possibility of interacting with the reaction task-lists	M12, M24 and M36
• The deployment of a secure infrastructure for the communication among all the involved entities, including both the data gathering phase and the reaction distribution and monitoring phase.	M24 and M33
• The definition of a suitable business model in order to address the research and development activities and exploit the project results	M12 and M36

Main outcomes of REMINE, once the solution will be deployed, can be summaries as follows:

- Drastic time reduction in collecting data and classifying RAPS from days to minutes
- Sensible time reduction in carrying out RAPS analysis procedures: from hours to minutes
- definition and standardization of a common language for the RAPS description, thus promoting and enhancing the interoperability among different tools
- a significant evolution in the interaction model among patients, doctors, nurses, health care specialist, others relevant heath care process stakeholder in and outside the hospital to transform an Hospital and its related local health care system into a cooperative organization network for RAPS reductions and quality of care improvement.
- a reference framework leading to the proper definition and simulation of RAPS policies and environment enabling secure scenarios
- a significant patient safety improvement (see box below)
- a significant health care cost saving (see box below)

Expected patient safety improvements with REMINE platform usage.

This session is aimed at **quantify which can be the impacts of REMINE platform** usage for RAPS reductions.

As it is presented in the paragraph 1.2, nowadays already exist risk management programs, which have incident reporting systems, wide database with possibility to insert notes and to extract statistics. The recent literature shows how the introduction of these type of software in hospital department, reduced RAPS of notable percentage.

In order to provide evidence on it can be considered three very recent studies, from different part of world, showed which can be the range of major improvement in protecting patients from risks in hospital, through existing ICT tools.

% of RAPS reduction has been reported below:

3,00% Risk Management Piemonte Region – Italy (1)
4,28% Risk Management Melbourne – Victoria (2)
0,61% Agency for Healthcare Research and Quality – USA (3)

(1) Homerus Project c/o Hospital of Nizza-Monferrato (Asti), Italy 2005
(2) Wimmera Project c/o Wimmera Base Hospital of Horsham (Melbourne), Victoria 2004
(3) Few Hospital of USA – AHRQ Agency for healthcare Research and Quality, USA 2005

REMINE project represents a major ICT step ahead for protecting Patient from RAPS, thus taking into account that REMINE will perform incident reporting system and thanks to risk management processes support it will predict RAPS, it will integrate several tools and optimized ward function, Consortium attends to exceed the better results of past studies and to improve sensibly results. Thus the following % of RAPS reduction due to REMINE platform contribution can be collocated between 6% and 9% of RAPS reduction expected.

Starting from previous table, REMINE partners assume a scenario between these two list of results:

(Lowest) 6% of RAPS reduction	**REMINE project expected effects on RAPS**	**(Highest) 9% of RAPS reduction**
% of RAPS remaining		**% of RAPS remaining**
From 66% to 62%	minimal impairment (or recovered within one month);	From 66% to 58%
From 34% to 30%	injury or complication;	From 34% to 28%
From 19% to 14%	moderate impairment;	From 19% to 12%
From 6% to 3%	permanent impairment;	From 6% to 1%
From 8% to 4%	contributed to death.	From 8% to 1%
From 48% to 43%	RAPS were judged preventable.	From 48% to 40%

Thus the REMINE consortium considers that the major improvement on RAPS reduction due to REMINE platform can be:

- For the lowest impact of REMINE
  - a dramatic reduction on death (from 8% to 4%)
  - a dramatic reduction of permanent impairment (from 6% to 3%)
- For the highest impact of REMINE
  - a total reduction on death (from 8% to 1%)
  - a total reduction of permanent impairment (from 6% to 1%)
- For both lowest and highest impact of REMINE
  - a significant improvement on all the remaining impacts (as in the table above)

Expected cost saving in Regional Heath Care systems yearly expenses with REMINE platform usage.

This session is aimed at **quantify which can be the cost saving in regional health care systems thanks to REMINE platform** usage for RAPS reductions.

In the previous pages have been reported that in average terms each RAPS produce 8,5 exta bed/day for a patient subjected to it.

Furthermore as previously discussed REMINE consortium estimates that REMINE platform can contribute at reducing between 6% to 9% of RAPS in Hospital.

According with this numbers can be outlined the following consideration on each REMINE pilot.

Lombardy Region Heath care system.

Numbers of RAPS/year: 5.000 (it is constitute by and average of 2.500 litigation procedures/year for RAPS and 2.500 registered RAPS not under litigation processes). This number represent an underestimation of the RAPS problem.

Bed cost/day: 2.700€. (estimation of Regione Lombardia health care system).

Number of extra bed/days per RAPS: 8,5 extrabedday/RAPS

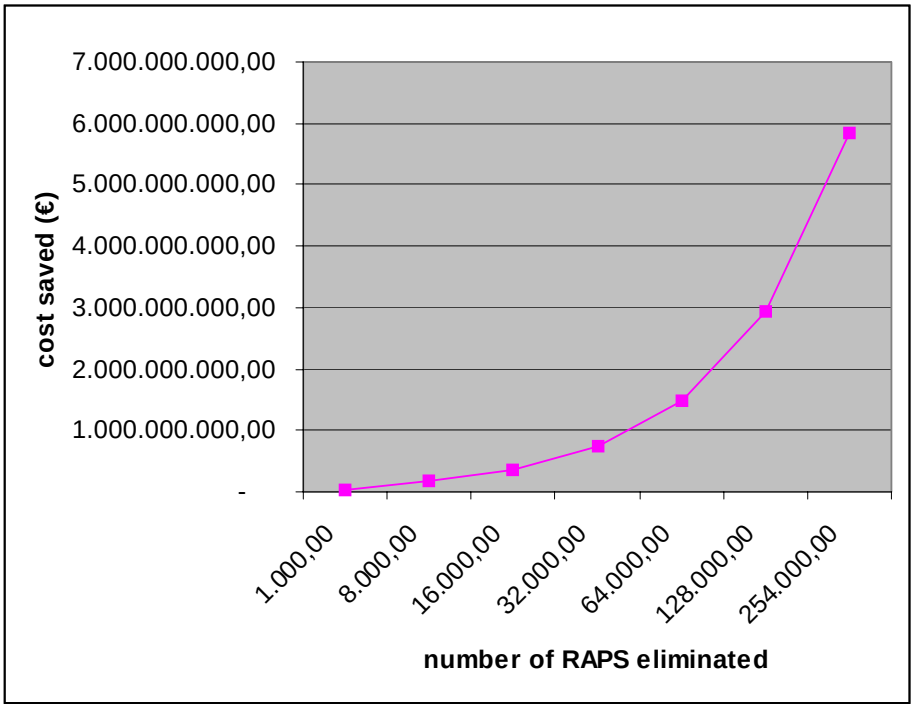
% of RAPS reduction: (lowest) 6%; (highest) 9%.

Number of RAPS reduced with REMINE platform: (lowest) 300 RAPS/year; (highest) 450 (RAPS/year).

Cost Saved for Lombardy Region Heath Care System: between 6.375.000 €/year and 9.562.500 €/year

Similar consideration can be done for the other REMINE pilots (in Finland and UK).

A more interesting consideration can be done in general terms considering the **average cost saving per number of RAPS reduced**, as reported in the following figure.



This will allow introducing a significant enhancement in the current methodologies and approach to the RAPS and related risk factors identification and to the reaction determination. The following table shows a comparison between the approach nowadays in use and the key innovations introduced by REMINE.

	Today	**Enabled by REMINE**
Application domain	Non integrated domains with poor communication	Potentially very large composition of different applications domains (such as nosocomial, labs, drugs, operational, clinical pathways, administrative)
RAPS-related data sources	Not well connected data sources, mainly localized at each organizational unit level	Integrated information from multiple-sources and multiple- formats, including multimedia formats
Achievable correlation level	Low, mainly paper based	High, with the introduction of mining, semantic and ontology which allow to extract knowledge for RAPS modeling and management
Analysis specificity	Clinical audit and Morbidity and Mortality audit, local and paper based	Context-aware analysis, where the RAPS are automatically categorized basing on the risk factors and the existing quality protocols, through specific dynamic knowledge rule-based risk management support system
Interoperability	Very poor	Maximum interoperability among different organizational management domains (lab, drug, clinical pathways, nosocomial), due to the development and configuration of an info-broker patient safety framework able to provide the best possible reaction to each RAPS identified as in proactive or in post occurrence situation and for single and/or cluster of patient safety profiles
Business models	Very limited and not shared	New organizational models for dynamic health care professionals interaction for RAPS reductions. New business model for RAPS management including. RAPS manager role and responsibilities Insurance costs reduction. Relational model amongst heath care units in and outside hospital and local heath care authorities.

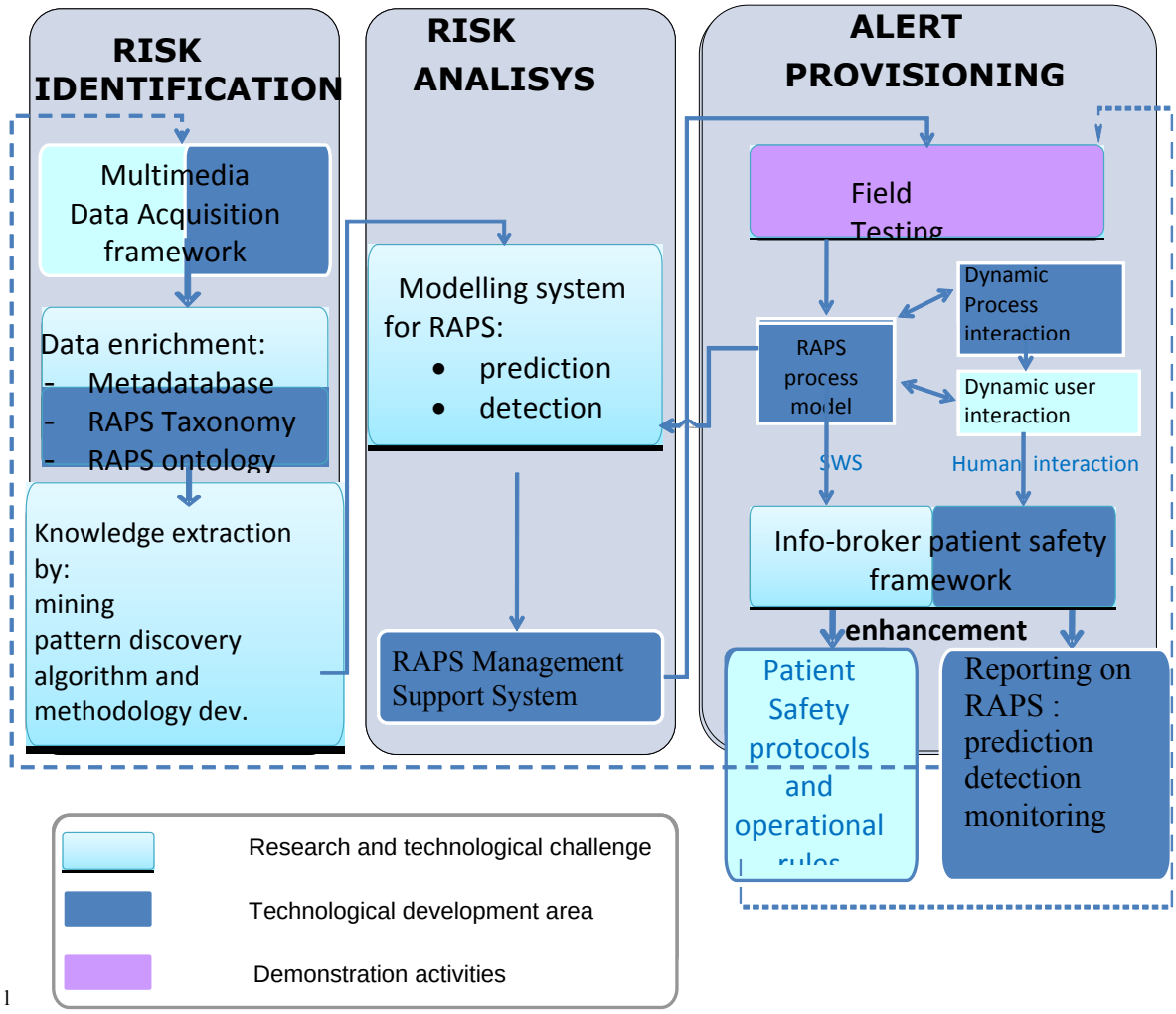
The overall project activities, which aim at realizing all the architectural blocks of the REMINE platform described above, as well as all the necessary support activities in terms of research, demonstration/validation, management, results management and exploitation, can be grouped into three main action areas, called "streams" in the following. These streams are:

- **Main streams 1: data modelling and pilot management**
  Activities that foreseen involvement of the users for their requirement definition; scenario-based design creation; RAPS management procedures definition and modelling; set up of the user-driven test beds in the regions involved in the project.

- **Main streams 2: Research and technological development**
  Research and development activities such as research, development, deployment, validation of the REMINE solution, that foreseen three major research challenges: RAPS data capture and knowledge extraction; risk management process support aimed at creating an advanced RAPS decision support system based upon an RAPS ontology; extended hospital interoperability layer for semantically manage REMINE solution together with the existing Hospital information system.

- **Main streams 3: Socio economic research and business model definition**
  Business scenario definition, socio economic analysis, business model and legal framework, exploitation strategy and plan including IPR are the main component of this steam. Training and capability development, standardisation, dissemination, community building, networking and collaboration are the enabling activities that are also foreseen in steam 3.

The following figure shows the main functional schema of REMINE project, including the distinction among the so called "research challenges" and the "technological development areas".



REMINE - Main architectural blocks

B1.2 Progress Beyond State of the Art

Since several years the risk management and patient safety related activities in health care have received great attention from politic institutions. The reasons are linked to:

- the widespread increase of complaints for malpractice,
- the changes in the patient-doctor relation,
- the characteristics of the information available, generally redundant on what concerns the curative power of medical therapy and superficial on its limits,
- the empowerment of the citizens on security matters.

Several initiatives have been promoted in this area by Scientific Institutions and Citizens associations, but it's still unclear how they will be integrated in the European Heath services frame. For the moment, there are no published studies that analyze the clinical risk management frame across Europe.

Risks Against Patient Safety (RAPS) in health care can roughly be classified into three main groups:

- injuries caused by medical management (negligence or substandard care),

- hospital acquired infections,
- adverse drug events (medication misuses, under-uses, overuses).

The issues have been systematically studied and the results have come into the public's consciousness mainly through three key sets of publications. First, the classic paper by Brennan[6] et al, "Incidence of adverse events and negligence in hospitalized patients, Results of the Harvard Medical Practice Study" laid the landmark to measure risks against Patient safety. Secondly; reports from studies in different countries show that about 7.5% to 16% of total hospital admissions experienced RAPS. 37% - 51% of these RAPS were preventable. Studies in this group include quality of Australia health care studies, Canada national survey , RAPS in British hospitals, and New Zeeland public hospitals . Reports of the Institute of Medicine revealed that RAPS in health care killed thousands of people per year, more than from traffic accidents, breast cancer, or AIDS. Thirdly, one study of outpatient visits shows that almost 27% of adult outpatients experience Adverse Drug Events (ADEs).

In the next five years, in the U.S., RAPS detection approaches are expected to emerge that combine knowledge based system with automated knowledge acquisition according to each patient's medical history. This will entail an automated combination of information from different sources, including diagnosis / progress notes, lab results and prescription. The system will generate alerts or flags to support the early detection and, possibly, prediction of RAPS and it will be equally important to integrate RAPS detection processes within the hospitals workflow management and risk management processes[7].

Work already carried out at European level

Lot of works has been conducted in the European research community in the field of eHealth trying to provide Health Care professionals and organizations with advanced tools aimed at easing the treatment of patients, the identification of diseases and the overall management of the process. That work has often lead to the creation of tools and procedures able to improve the management of all the knowledge that is involved in Hospital Assistance. The major amount of activity in this direction may be found in the output generated by the following projects, financed within the 6th Framework Programme:

- **ARTEMIS.** The objective of the ARTEMIS project is to develop a semantic Web services based interoperability framework for the health care domain. ARTEMIS takes a highly innovative approach regarding the interoperability of medical information systems with respect to the current approaches.
- **Doc@hand.** The aim Doc@Hand is to support Healthcare professionals in this changing environment, by providing a set of IT tools that help reducing the time and associated costs to collect the information and knowledge required, and more crucially, in making the best use of it for a more informed decision making (diagnoses, therapies, protocols).
- **PALLIANET.** Objective is to support knowledge driven collaborative practices in order to minimise risks in the context of palliative care. The project aims at conceiving an advanced solution supporting the needs of city professionals by combining a Community and Knowledge Management service, Advanced human-computer interaction features that makes access for caregivers easy and natural, and Coordination Facilities.

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[6] Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med 1991;324:370–6.

[7] "Adverse Events in Health Care and Challenges in Their Detections", Xiaohui Zhang Ph.D. Chief Scientist, Scientific Technologies Corporation

- **PIPS.** The PIPS project will make a significant step forward in the processes for healthcare (HC) delivery to the European Public by means of creating a new Health and Life Knowledge and Services Support Environment. This will improve current HC delivery models while creating possibilities for HC professionals to get access to relevant-updated medical knowledge and the European citizens to choose healthier lifestyles.
- **TACIT**. The vision of TACIT is to unlock the tacit knowledge of Europe's senior clinicians both by linguistically analysed multimedia recording and by expert location and communications. TACIT will be prototyped and piloted in cancer care where it will support the entire clinical process across primary and secondary care. It will specify, prototype and test Ambient Knowledge Elicitation integrated with an Expertise Browser and expert locator.

If compared to these projects, REMINE introduces several advances. To start with it deals with the modeling of all procedures and models relevant to security, designing a comprehensive approach to adverse events prevention. Then deals with the acquisition of data to be analyzed and matched with the above mentioned procedures. This match allows the identification of risks associated to the different situations health care professionals face in their everyday working life. Professionals receive alerts about arising risk and can further explore the issue by simulating the impact of different choices the may make, finding out the best possible solution. This process is iterative and leads to a continuous improvement of procedures.

State of the Art

Developing and maintaining a computerized screening system generally involve several steps. The first and most challenging step is to collect patient data in electronic form. The second step is to apply queries, rules, or algorithms to the data to find cases with data that are consistent with an adverse event. The third step is to determine the predictive value of the queries.

The data source most often applied to patient safety work is the administrative coding of diagnoses and procedures, usually in the form of ICD-9-CM and CPT codes. This coding represents one of the few ubiquitous sources of clinically relevant data. The usefulness of this coding—if it is accurate and timely—is clear. The codes provide direct and indirect evidence of the clinical state of the patient, comorbid conditions, and the progress of the patient during the hospitalization or visit. For example, administrative data have been used to screen for complications that occur during the course of hospitalization.

The coding suffers from errors, lack of temporal information, lack of clinical content, and "code creep"—a bias toward higher-paying diagnosis-related groups (DRGs). Coding is usually done after discharge or completion of the visit; thus its use in real-time intervention is limited. Adverse events are poorly represented in the ICD-9-CM coding scheme, although some events are present (for example, 39.41 "control of hemorrhage following vascular surgery"). Unfortunately, the adverse event codes are rarely used in practice. Despite their limitations, administrative data are useful in detecting adverse events, and have been largely represented in the report edited by OECD , "Selecting Indicators for Patient Safety at the Health Systems Level", which includes also the quality indicators defined by the Agency for Healthcare Research and Quality (AHRQ), Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in the USA, the Canadian Institute for Health Informatics (CIHI), and the Australian Council for Safety and Quality. To fill the gap of comparable information for what concerns technical quality of national health systems the OECD Health Care Quality Indicators Project (HCQI) has brought together 21 countries, the World Health Organization (WHO), the European Commission (EC), the World Bank, and leading research organisations, such as the International

Society for Quality in Health Care (ISQua) and the European Society for Quality in Healthcare (ESQH).

Pharmacy data and clinical laboratory data represent two other common sources of coded data. These sources supply direct evidence for medication and laboratory adverse events (e.g., dosing errors, clinical values out of range). Unlike administrative coding, pharmacy and laboratory data are available in real time, making it possible to intervene in the care of the patient.

Visit notes, admission notes, progress notes, consultation notes, and nursing notes contain important information and are increasingly available in electronic form. However, they are usually available in uncontrolled, free-text narratives. Furthermore, reports from ancillary departments such as radiology and pathology are commonly available in electronic narrative form. If the clinical information contained in these narrative documents can be turned into a standardized format, then automated systems will have a much greater chance of identifying adverse events and even classifying them by cause.

The state of the arte is shared in two part. The first analyzes the technological state of art approach, the second one analyzes the of Organizational State of the art approach.

Into the Technological aspect will be analyze the consolidated technology where the project is based, like:

- RFID technology
- RIS PACS
- H-ERP
- Ruled based system
- EHR
- Laboratory Information System
- While Organizational approach it will be analyze subjects like:
- EHR Workflow implications
- Incident Reporting Schemes
- Protocol PS usage

Technological State of the Art for patient safety

Data acquisition

RFID

In recent years automatic identification procedures (Auto ID) have become very popular in many service industries, purchasing and distribution logistics, industry, manufacturing companies and material flow systems. Automatic identification procedures exist to provide information about people, animals, goods and products. The omnipresent barcode labels that triggered a revolution in identification systems some considerable time ago, are being found to be inadequate in an increasing number of cases. Barcodes may be extremely cheap, but their stumbling block is their low storage capacity and the fact that they cannot be reprogrammed. More over it is not possible to use the barcode tags to identify movement object or long distant objects.

The RF-ID technology solve all problems describe above .The procedures used for the transfer of power and data in RFID systems (Radio Frequency Identification) is contact-less .
An RFID system is always made up of two components:

- the transponder, which is located on the object to be identified

- the detector or reader , which, depending upon design and the technology used, may be a read or write/read device
- RFID in healthcare

However, industry-wide spending on RFID is also poised to dramatically increase middle in 2007, driven by senior executives who view the technology as critical to helping achieve their organizations' business goals, especially improved patient safety. According to some surveys carried out in the EU and US, the results illustrates that most healthcare institutions believe RFID technologies are strategic to their business in a number of important aspects, from patient safety to operational improvement. Over the next 2 years, it is expected healthcare organizations will move from the strategy and pilot phases they are in today toward first-stage implementations where there will be a strong opportunity for return on investment.

RFID technology is already finding many uses in healthcare organizations, including medical equipment tracking using real-time location systems; patient safety systems such as for identification and medication administration; patient flow management; access control and security; supply chain systems; and smart shelving. In the following some examples where the RFID technology can be applied are shown.

RIS PACS

RIS-PACS systems are the instruments used today to manage digital data in the departments of diagnostics by images.

- RIS (Radiology Information Systems) are informative systems usually realized with a client/server technology which is now rapidly evolving towards web based technologies. Most common technological approach is to use Windows based OS together with Oracle databases. Anyway some solutions are based on either Solaris or other Unix operative systems.
- PACS (Picture Archive Communication System) are systems dedicated to the management of images and of all biomedical signals that can be produced within the operative units of the Department of Diagnosis by images.

RIS-PACS are characterized by integration protocols developed primarily with proprietary languages developed by procedures themselves, mostly HL7 languages. The communicate with the external environment in one of the following ways:

- Communication of RIS with Hospital Information Systems (HIS) in HL7 language for DB sharing (personal data, booking and so on).
- Communication between PACS and diagnostic tools for image acquisition, storing and processing in HL7 language.

In particular, diagnostic modalities (producer of diagnostic images) that can be now found on the market are digital systems, often using conversion systems between analogical and digital systems (e.g. Computhed Radiography) characterized by data management in DICOM language.

Diagnostic modalities are equipped by modules specifically conceived for data management.

- Interface Modules for acquisition of clinical data from RIS (DICOM Worklist).
- Interface Modules for printing images (DICOM print).
- Interface modules for the management fo image transmission to PACS for storing (DICOM store).

H-ERP

H- ERPs contain large amount of data that can be used for effective risk management. These systems are produced by almost all leading IT companies and some of them have versions and components that are specific for the medical sector (just to mention a few, the ones produced by Siemens, IBM, ORACLE and SAP). These systems are quit effective, but are not specifically linked to Adverse Events management and without this match no actual risk management is possible.

- IBM and CLinicare. CLINICARE provides Practice Management (billing and scheduling) and Electronic Medical Records applications to group medical practices and MSOs in Canada and the United States. CLINICARE is an Advanced level IBM Business Partner. Together, CLINICARE and IBM can deliver turnkey solutions, including hardware, software, installation, training and support. CLINICARE offers several versatile applications for healthcare, including TotalCare, the package of Practice Management Applications (PMA); ChartCare, comprising Electronic Medical Records (EMR) modules; and EliteCare, which provides both EMR and PMA applications.
- SAP for HealthCare. SAP for Healthcare can help you meet the challenges by streamlining and integrating your healthcare processes -- administrative and patient-centric -- on an open, growth-capable platform. Installed in more than 800 organizations, the SAP portfolio allows you to reduce costs and increase the amount of time spent on patient care.
- CISCO Electronic Health Records. Enable effective distribution of electronic health records to help caregivers improve care while allowing organizations to decrease expenses and increase productivity.

Ruled based system

Risk Management Support Tool

Risk management is the human activity which integrates recognition of risk, risk assessment, developing strategies to manage it, and mitigation of risk using managerial resources. In particular way, there are tools specifically designed for Risk Management whose focus is on tracking procedures and easing reports about events to ease the process of learning from mistakes. These tools have been seldom conceived for Hospitals.

Among these tools, the following deserve to be mentioned:

- Synergi[8]. Synergi is one of the worlds leading risk management software specialized in making reporting, improvement more targeted and effective by good management reports, experience transfer and action tracking.
- QPR[9]. Collaborative Risk Management is the solution for the most important aspects in risk management today – risk identification, risk assessment, risk response, risk control, risk communication, and risk monitoring..
- Metastorm[10]. Metastorm understands the unique needs of healthcare organizations and how they can better succeed with efficient process execution. Metastorm's BPM technology and proven expertise is helping organizations around the world achieve regulatory compliance, reduce risks, enhance customer service, retain and acquire customers, tie together silo processes and systems, and do more with less.

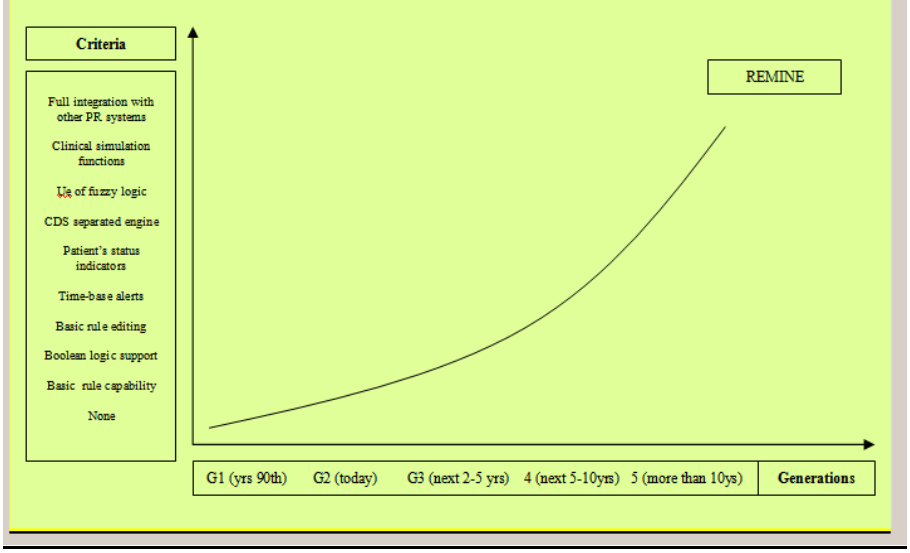
[8] http://www.synergi.com/

[9] http://www.qpr.com/

[10] http://www.metastorm.com/

According to Gartner Group*11*, clinical decision support (CDS) represents a critical capability as CPR systems, Computer-based Patient Record (CRP), become more sophisticated. It helps clinicians make complex decisions and can trigger appropriate early notification of possible untoward events. The CDS system thus is the agent where much of the medical knowledge embodied in evidence-based medicine is actually deployed during the provision of clinical care.

A given CPR product may have some increased functionality in certain areas, but to be considered an Nth-generation product, it must at least have all the basic capabilities listed for that generation. This evolution is represented in the following diagram which shows the main criteria used by Gartner Group to include CPRs in different "generations" and their evolution over time. REMINE positions itself well beyond the last generation identified by Gartner as it fulfils the required criteria and uses a wider range of data coming from the metadatabase, provides innovative knowledge extraction and discovery capabilities as well as semantic modelling of data, procedures and guidelines.

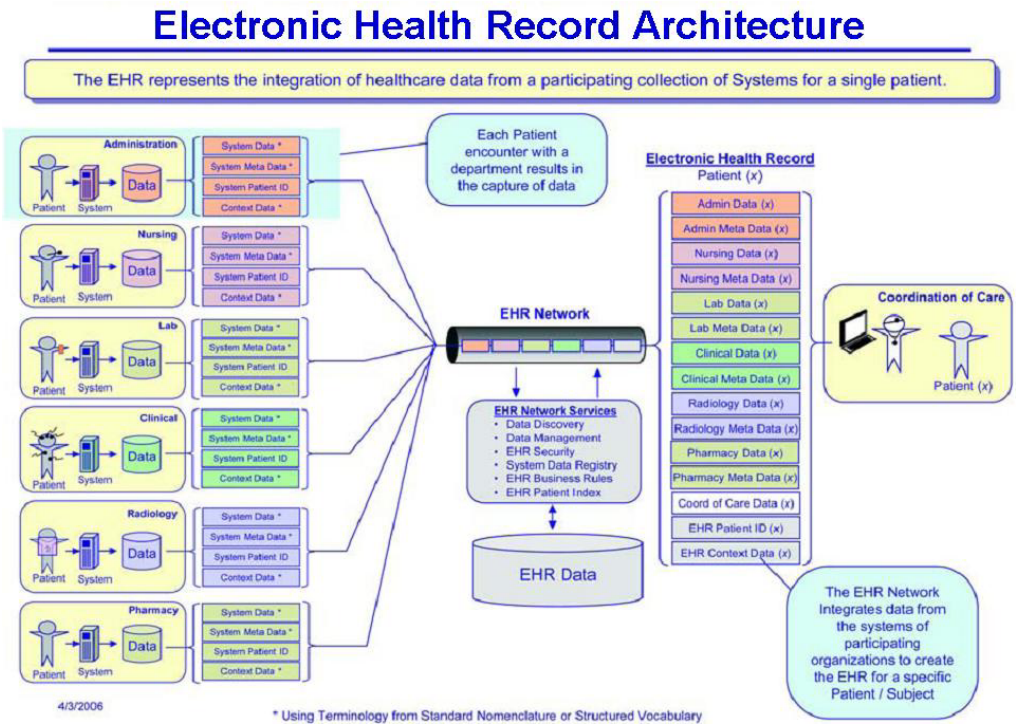


EHR

Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. The EHR information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. An electronic record may be created for each service a patient receives from an ancillary department, such as radiology, laboratory, or pharmacy, or as a result of an administrative action (e.g., creating a claim).

Each system in Figure below stores its own data locally. To share patient information, a system (or system user) must allow another system to access its files, or it must transmit a copy of the file to the other system. The EHR in figure below depicts the integration of healthcare data from a participating collection of systems for a single patient encounter.

11 2007 CPR Generation Criteria Update: Clinical Decision Support



Laboratory Information System

A Laboratory Information Systems (LIS), is a class of software which handles receiving, processing and storing information generated by Medical laboratory processes. LIS have been one of the first areas where IT has been applied to the Healthcare sector. In fact, since more than 10 years the production flow of Laboratories has been automated in order to speed up the availability and enhance the quality of Lab results which represent the most relevant data for the patient diagnostic and treatment.

Moreover in the last years LIS functions have been increasingly enhanced; both because of the changing way of working of Laboratories (which rely on new organizational models and more sophisticated analyzers for blood testing) and for the huge amount of tests that have to be performed every day.

LIS main functions and workflow can be summarized as follows:

- Pre-analytic phase à order management, specimens check-in, work planning.
- Analyzers connection à interface to analyzers.
- Analytical phase à scheduling, test execution, validation.

  Post-analytic phase à result viewing, result distribution, archiving.

Organizational State of the Art for Patient Safety

EHR Workflow impliations

EHR workflow implications*12* for healthcare clinicians (physicians, nurses, dentists, nurse practitioners, etc.) may vary by type of patient care facility and professional responsibility. However, the most cited changes EHRs foster involve increased efficiencies, improved accuracy, timeliness, availability, and productivity.

[12] Electronic Health Record Overview, National Institutes of Health, April 2006

Clinicians in environments with EHRs spend less time updating static data, such as demographic and prior health history, because these data are populated throughout the record and generally remain constant. Clinicians also have much greater access to other automated information (regarding diseases, etc.), improved organization tools, and alert screens. Alerts are a significant capacity of EHRs because they identify medication allergies and other needed reminders. For clinical researchers, alerts can be established to assist with recruitment efforts by identifying eligible research participants.

Incident Reporting Schemes

A first approach to Adverse Events relies on Incident reporting schemes that are increasingly being seen as a means of detecting and responding to failures before they develop into major accidents.

Incident reporting schemes are soft systems and every such scheme is different in implementation and use. The majority of incident reporting scheme studies (including those of reporting in non healthcare industries) involve a quantitative analysis of the issues reported, of reporting rates and/or of the effects on safety. Such studies offer evidence for the usefulness of such schemes. The reporting scheme is the organization of many parts and processes. A reporting scheme is more than the technologies of reporting, and is not about making factual accounts that mirror incidents. There is not a direct correspondence between an incident and a report: the report is a subjective account of the incident, and in turn the report is never static. The incident is told and re-told through reports, through analysis and categorization and through discussions in meetings. Actions to maintain or improve safety come after analysis and discussion, but the maintenance of safety often comes about directly through having a discussion and thus learning and reinforcing knowledge.

Protocol PS usage

Clinical Risk Managementl: experience in Denmark and UK

A recent report published by the Italian Ministry, underlined that only a limited number of hospitals (about 17%), created specific risk management units, or attributed the role of clinical risk manager. From the comparisons conducted between the different systems of several Countries (Denmark, France, Germany, USA, UK) has been concluded that the present situation is still undergoing a process of development and definition. Only in few models strongly oriented and specialized in the clinical risk management can be appreciated (Nuti, Tartaglia et Al. 2007).

In Denmark each hospital is managed by a Board of Directors, composed by a Health Director, an Administrative Director, and a Nurse Director. Inside the Board works a “Quality council” constituted by the Board of Directors, the Department Directors and the Risk Manager. The last one can be either a MD or a Nurse. Its function is to collect the adverse events reports, and to analyze them. In every report is identified the patient safety officer, whose task is to conduct the case analysis.

In the United Kingdom works the National Patient Safety Agency, a governmental Institution founded on 2001, that provides a guidance on the aspects of risk management, and patient security. The Strategic Authorities, institutions that coordinate several hospitals, and the hospital trust, refer directly to NPSA. At the SA level work the patient safety managers, that are the intermediate between NPSA and Trust, while at Trust level work the risk manager. The risk manager task is to manage the local incident reporting system, linked to the National Reporting and Learning System. The report management is coordinated together with clinical leaders, consultants and in particular cases with the medical director.

Progress beyond State of the Art

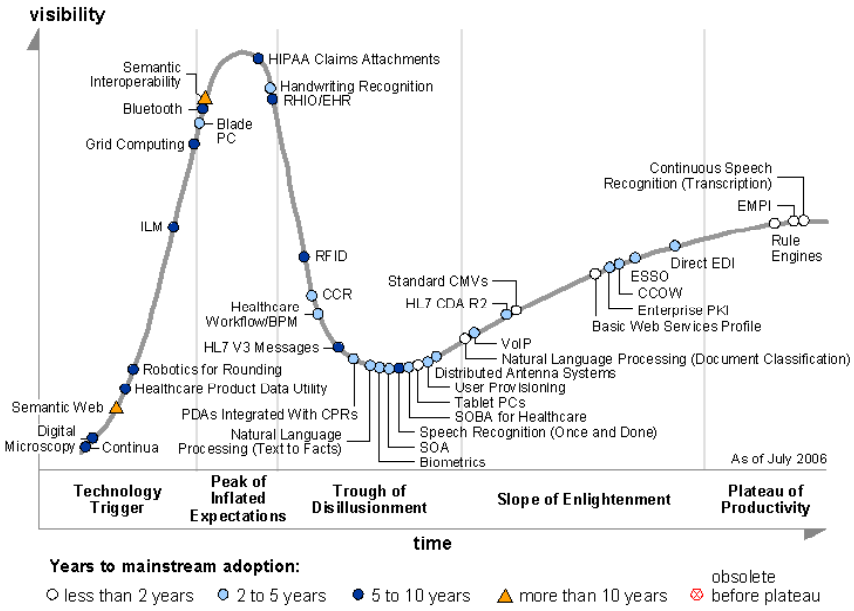
In a recent paper, Gartner Group*13*, listed the top priority action for Healthcare Information System in 2007. The strategies to be pursued according to Gartner Group are:

- Equip the CDO (Care Delivery Organizations) with a third-generation CPR (Computer-based Patient Record).
- Engage physicians early and on an ongoing basis.
- Adopt a formal continuous quality improvement methodology.
- Implement clinical business intelligence capabilities to enable measurement and analysis of clinical performance.

To support those strategies, the same research by Gartner suggests to do the following:

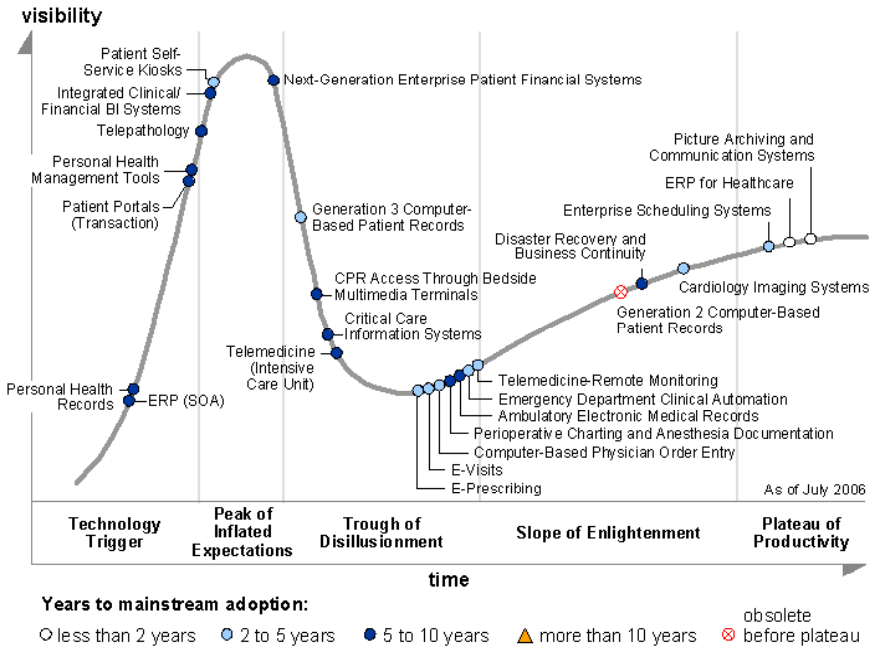
- Take advantage of semantic and ontologies to ease discovery information.
- Adopt instruments allowing continuous monitoring and improvement of processes.
- Involve Healthcare professionals as much as possible,
- Put the patient at the center of your action.
- Include data sharing and take care to use all relevant data available for more informed decisions.

The major project beyond state of the art foreseen both in terms of technological breakthrough and Heath care providers applications and systems one are presented in the next two figures.



Hype Cycle for Healthcare Provider Technologies, 2006 - Source: Gartner (July 2006)

[13] Gartner Industry Research, 26th February 2007, ID n° G00145752



Hype Cycle for Healthcare Provider Applications and Systems, 2006 - Source: Gartner (July 2006)

Amongst the issues foreseen in the next 2-10 years and listed in the two previous figures, the ones addressed by REMINE are listed in the next paragraph.

Technological progress beyond state of the art for Patient Safety addressed by REMINE

Metadatabase

The metadatabase REMINE component will manage all the data activities for REMINE project. It will contain:

- data that are directly acquired and produced inside the REMINE boundary
- data coming from other data sources .

When possible the REMINE metadata module will always contain the links to where the real data are. In this way REMINE will work only on copy of real data without effect any changes on data that not belong directly to REMINE.

The innovative aspect of the REMINE metadata module it is that all the data storage and usage will be executed in a semantic way thus also the external data label will be "transformed into an homogeneous semantic repository. In this way REMINE will avoid any kind of data misusing. Moreover the REMINE metadatabase will manage both "classical" data and Multimedia data so the mining application and decision support system can be applied not only on traditional data but on a set integrated data that will include:

- Traditional data
- Video data
- Audio data
- Image data
- Vectorial data

The developed data Metadatabase will contain data from multiple state-based and categorical programs, it will be risk -centred where reporting information is about a specific risk, such as in missing events case reports. It will implement the Public Health Conceptual Data Model HL7 Reference Information Model structure as appropriate. Moreover it will include the ability to associate incoming data with appropriate existing data in semantic form using the ontology engine (e.g., group information of a issue in a risk situation which had another condition previously reported or defined).

The Metadatabase will have the capacity to support data accumulated through various means (e.g., through web-based and thick client systems as well as electronic messages), and will function so that data can be accessed by standards-based interaction with REMINE module for reporting, statistical analysis, geographic mapping and automated outbreak detection algorithms as well as the processing of Data mining , knowledge support and decision support activities. The Metadatabase will actually perform an active data translation and exchange integration broker functionality. Moreover it will support data translation, data import and export, queuing and messaging for the dynamic bi-directional interchange of external data using Extensible Mark-up Language (XML).

Knowledge Extraction

REMINE system's components responsible for knowledge extraction will retrieve data from taking advantage of Data Mining and a Semantic Model providing the data necessary to meet the requests of the User Interface.

The innovations carried on by REMINE in the knowledge extraction process are to be found in the following issues:

- *Taxonomy*
- *Ontology*
- *Semantic mining and modelling.*

The approach chosen by REMINE allows a more complete way of information discovery thanks to a wider base of data of different kinds from different sources and innovative way to relate these data semantically so as to extract information from raw data.

Taxonomy

The REMAINE Common Classification System (RCCS) for adverse events in healthcare will combines existent taxonomy like the one developed for England's National Reporting and Learning System (NRLS) with ad hoc REMINE extensions. The REMINE taxonomy will provide a comprehensive mapping of the healthcare system that enables incident records to be partitioned into logical categories for REMINE use. Inside the Project we will focus on extensions that are particularly strong in the clinical specialties which are prone to the more serious incidents, including surgery, adverse drug events, infections, obstetrics and emergency medicine.

Ontology

An ontology is commonly defined as 'a shared and agreed upon conceptualization of a domain'. An ontology such as the UMLS Semantic Network correspondingly takes the form of a graph, whose nodes refer to concepts. The combinations of nodes and edges in such a graph provide both concept descriptions and also, in the best case, concept definitions.

In REMINE we present a novel methodology for calculating the improvements obtained in successive versions of biomedical ontologies*14*. The theory takes into account changes both in reality itself and in our understanding of this reality. The successful application of the theory

[14] Ceusters W, Smith B. A Realism-Based Approach to the Evolution of Biomedical Ontologies. Proceedings of AMIA 2006, Washington DC, 2006;: 121-125

rests on the willingness of ontology authors to document changes they make by following a number of simple rules. The theory provides a pathway by which ontology authoring can become a science rather than an art, following principles analogous to those that have fostered the growth of modern evidence-based medicine.

Semantic Mining

Data mining is a stage in the overall process of Knowledge Discovery in Large Databases (KDD). Data mining is a semi-automated process for finding undiscovered patterns and/or relationships in large databases. Data mining finds its roots in the Machine Learning community whereby academicians invented and developed artificial intelligence algorithms as a basis for machine learning. systems, in combination with data mining tools, now permit the development of new knowledge management processes to apply to meeting both corporate and scientific objectives.

As the evolution of data mining has matured, it is widely accepted to be a single phase in a larger life cycle of KDD. The field of KDD is particularly focused on the activities leading up to the actual data analysis and including the evaluation and deployment of results.

REMINE would use both clustering and classification methods. Data clustering-describes an exploratory technique that arises in the absence of a priori information about the data. Its goal is to group observations into similar groups in such a way that homogeneity within a group and heterogeneity between groups are both maximized. In other words, a clustering algorithm attempts to find natural groups of components (or data) based on some similarity.

Semantic Modelling

According to a recent paper by Gartner Group15, The semantic Web has the potential to revolutionize semantic interoperability in healthcare. However, for all but the most advanced healthcare organizations, it will not be implemented for many years.

The Semantic Web is a web of data. There is lots of data we all use every day, and its not part of the web. The Semantic Web is about two things. It is about common formats for integration and combination of data drawn from diverse sources, where on the original Web mainly concentrated on the interchange of documents. It is also about language for recording how the data relates to real world objects. That allows a person, or a machine, to start off in one database, and then move through an unending set of databases which are connected not by wires but by being about the same thing.

The semantic Web has the potential to revolutionize healthcare IT interoperability, helping to enable shifts in the business relationships among healthcare stakeholders.

Semantic Web standards include ways of using XML to express information that is much more amenable to precise interpretation by reasoning programs than freely written XML.

In REMINE, semantic is not only applied to data, but to processes as well. On one side that allows a better integration of data and processes, on the other it opens the door to process analysis and continuous improvement. Business Process Modelling (BPM) software is headed for mainstream adoption, but it's still a relatively small, immature market.

Most organizations gain efficiency just by turning ordinary processes into streamlined, connected, documented and tracked processes managed by BPM systems. But what thousands of users have yet to do is exploit the technology's closed-loop process control and continuous process improvement capabilities. Closed-loop process control means using operational statistics and higher-level BAM to better manage work in process. Continuous process improvement is about spotting patterns of problems and exceptions and revising the process accordingly. If advanced BAM and real-time decision support are the exception rather than the rule, rarer still are real-world examples of continuous process improvement. This state of affairs is ironic given

[15] Gartner Industry Research, 6th June 2006, ID n° G00140872

that much of the marketing hype around BPM is about "changing processes on the fly" to respond to changing business conditions.

Organizational progress beyond state of the art for Patient Safety addressed by REMINE

Predicting, alerting monitoring patient safety management process

In the international literature, the proves of efficacy, concerning the different organizational models adopted in the CRM (Clinical Risk Mangement), are limited and indicators, that prove to be significant in long term periods, still have to be identified (Ovretveit, 2006). However, the evidences coming form other safety-critical industries highlight the need for a network model capable of activating organizational resources at all levels to anticipate and control risks (Weick and Sutcliffe, 2001). The information technology infrastructure is crucial in the risk management network as professionals shall activate to identify, analyze and prevent risks. Also IOM (2004) recommends to establish patients safety systems that provide immediate access to complete patient information and decision support tool for clinicians and their patients and capture information on patient safety as by-product of care. In this sense, the automation of some information system (e.g. patient records, lab tests, etc.) may help the early identification of risks and therefore activate professionals on the sharp end to anticipating adverse events.
The medical facilities safety could obtain an enormous betterment by the development and the adoption of both conceptual frameworks, and application platforms and solutions, that allow the continuous integration of the various information sources and make the diffusion and benchmarking of betterment solutions possible. Integrated information and modelled procedures, combined with the right mining and knowledge discovery tools, can tremendously improve efficiency in Healthcare and reduce the impact of adverse events. Following this principle of providing an integrated approach to adverse events management, which is actually an advancement in itself, REMINE will a set of specific advances.

The innovations proposed by the REMINE approach can be summarized as follows.

- Innovative knowledge discovery tools and technologies.
- Integration of heterogeneous data with modelled procedures for total semantic integration.
- Innovative mining techniques for data analysis and information extraction, to identify relevant patterns among heterogeneous data. This would allow to synthesize Risk Patient Safety evidences, collecting and connecting events, starting from wards.
- An advanced rules-based system tool able to take advantage of the application of ergonomically modelled procedures to data, warning HR professionals about possible adverse events (Analysis and Reporting Tool) and allowing them to perform What if Analysis (Risk Management Support Tool)
- A detailed taxonomy and modeling of the existing clinical guidelines.
- An ontology to relate semantically data coming from different sources, along with guidelines and procedures.
- An adverse events interoperability layer (Lab, Drug and Nosocomial Management modules) capable of integrating REMINE with the organization’s ERP system.
- A data capture system that allows REMINE to gather the necessary data from different sources.

All that, as we have seen, will be achieved introducing significant progress beyond the current state of the art in the scientific/technological and methodological areas identified above.

The new approach developed by REMINE will produce concrete benefits and contribution in terms of adverse events identification, efficiency and effectiveness of the reaction. All that will introduce considerable improvements at organizational level.

Objectives	Metrics	State-of-the-art	Progress
Enhancement of efficiency and security	Reduction in collecting and classifying data: from months to seconds	ERP and Risk Management applications are not integrated. Data collected are often classified manually or semi-manually. Often the collection itself of data is made semi-manually.	Reducing the time for analysis and identification of Adverse Events using an integrated data collection approach based on semantic classification of data. Knowledge extraction from data is faster and more accurate.
	Time reduction in carrying out adverse events detection: from weeks to seconds	Data are often analyzed semi-manually and information extraction takes a lot of time.	Improved knowledge discovery speeds up Adverse Events detection and anticipation, thanks to a spread analysis and interpretation of a wider sample of events related data appropriately clustered thanks to the ontological engine of the system.
Enhancement of effectiveness of incident reaction	Considerable time reduction in implementing incident reaction: from months to seconds	Reaction to adverse events is nowadays based on skill of the people involved, in the analysis of the data produced by the adopted Risk Management tool. Countermeasures have to be planned and implemented. That can take literally months.	Having immediate and customized countermeasures for avoiding the Adverse Events (through Alerting).
	Constant evolution of the reaction strategies, in order to maximize effectiveness, leading to a reduction of the Adverse Events occurrence.	Reaction to event is nowadays based on skill of the involved people, who may not be aware of all the relevant information as they are produced every day.	Semi-automatic process improvement based on dynamic BPML. Semantic analysis of events and procedures allow to identify process improvements.

The REMINE project requires four different research streams to be carried on in order to achieve the expected results described above:

Macro-components to be enabled	Process addressed	Functionalities to be implemented	Research to be applied
Patient/user context and content semantic modelling	Acquisition and modelling of guidelines and procedures.	Modelling of procedures and guidelines to put them in a format readable by the system.	Semantic modelling of procedures and guidelines.
Data Mining and knowledge extraction	Acquisition of Data related to Adverse Events and knowledge extraction	Acquisition of modelled procedures. Acquisition of data form external sources and ERP system (through interoperability layer). Alerting and reporting.	Taxonomy of relevant data. Interpretation of modelled procedures through semantic analysis. Knowledge discovery through data mining techniques.
Risk Management process support	Risk Management decision making support. Semantic analysis of data. Ontology development.	Semantic interface. Ontology engine. Risk Management Support tool.	Ontology development of Adverse Events domain. Adverse Events scenario analysis. Development of innovative Risk Management support tool for decision support.
Enhanced interoperability layer	Integration and interaction with ERP systems.	Extended interoperability layer (Lab, Drug, Nosocomial management).	Semantic integration with Risk Management support tool and adverse events data capture and knowledge extraction modules leading to continuous improvement of procedures.

Within this framework and in order to achieve the established targets, as well as to create the required tools, REMINE will face the major challenge of improving Adverse Events detection and reaction from a point of view both scientific/technological and methodological. The two elements are closely connected and lead to increased efficiency and patient safety.

- Scientific/technological approach:
  - Development of specific event related data filtering, semantic-based collection interfaces and communication protocols among the relevant data sources.
  - Development of specific semantics for describing Adverse Events in terms of correlated data, suitable for the application of an ontology (to be created) allowing Adverse Events detection and classification
  - Development of specific semantics for describing procedures and guidelines.

- Development of a Meta-database capable of storing all required metadata.
- Development of specific techniques for data mining and knowledge discovery.
- Development of suitable interoperability layer between ERP systems and other REMINE components.
- Development of a suitable Risk Management support tool allowing users to assess impact of different actions on the faced scenario.
- Development of specific functionalities (within the Risk Management support tool) to support the decision process of MDs in relation with the analyzed case.

- Methodological approach:
  - Analysis of the current Adverse Events detection and reaction guidelines and procedures
  - Categorization of the different types of Adverse Events
  - Identification of the best methodology for a detailed analysis of each Adverse Event
  - Identification the best methodology of reaction for each Adverse Event
  - Evaluation of the effectiveness of the reaction which is going to be implemented (check before the actual implementation), and the effectiveness of the reaction once put in field.

Final considerations

The final objective faced from the two perspectives above is to allow a truly integrated approach to risk management in healthcare environments. This will be achieved introducing significant progress beyond the current state of the art in the scientific/technological and methodological areas identified above.

The following table outlines the areas which will mostly benefit of the expected progress

Project innovative elements	**Metrics for the measurable objectives**	**State-of-the-art in the area concerned**	**Progress beyond current state of the art introduced by the project**
Risks Against Patient Safety (RAPS) knowledge extraction. Semantic-based collection tools. Metadatabase	Definition of a semantic model of RAPS, and a suitable semantic language in order to describe it Set up of knowledge extraction tools. Set up of Metadatabase	Lack of a semantic model of RAPS and related procedures and guidelines	Introduction of a data collection platform and of a metadatabase with multimedia capabilities. Development of suitable data mining techniques for knowledge discovery.
RAPS identification and classification semantics definition and ontology creation	Setup a semantic engine for extracting useful data from what has been collected. Create an ontology for correlating semantic data and identify and categorize the RAPS	Lack of methods to find and correlate the required data.	Speeding up RAPS detection and categorization phase.
RAPS "best reaction" generation methodology	Define a database where reaction pattern to different kind of RAPS are stored in a suitable format to be customized for the specific event of	Reaction to adverse event is based on skill of the involved people.	Speeding up the reaction phase. Develop a decision engine (within the Risk Management Support Tool) to

	the selected category		provide MDs with options for action related to the specific case.
Taxonomy development and modelling of clinical guidelines	Define a Taxonomy of RAPS.	There is not a complete Taxonomy of RAPS.	The Taxonomy will allow the ontology to correlate semantic data efficiently.
InfoBroker patient safety framework	Design and develop and interoperability layer allowing semantic integration of ERP systems with other REMINE components.	There is no automatic relation between data stored in ERP systems and RAPS management.	ERP system will become an active element in the RAPS Management. Semantic integration will allow RAPS prevention and procedure improvement.
Mining Engine	Set up of a mining engine for analysis of semantically integrated data.	Data analyzed are not integrated.	Data Mining performed on semantically integrated data.
Rules-based system	The Analysis and Reporting tool will alert about possible adverse events before they occur. The Risk Management Support tool will allow to perform "what if" analysis to the risk scenario faced by MDs.	No system currently allow to perform these functionalities with the same depth of information (procedures, guidelines, HER, ERP system and so on).	REMINE will allow the integrated approach to risk management that it is now indicated by experts as the winning one.

Clinical Validation details

Validation on the following issues:

- quality of the alert or advice (effectiveness)
- quality of the tool (usability)
- impact of the system
    - (sustainability)
    - (efficency

All that will be performed at the beginning of the project, defining validation criteria under the guidance of a panel of experts (both in the clinical specialties involved and in risk management). An iterative evaluation will take place throughout the project an iterative.

B1.3 S/T methodology and associated workplan

B1.3.1 Overall Strategy and General Description

Overall Approach

REMINE project will base its approach on the following principles:

- User driven test beds involving leading Heath care authorities such as Lombardy, Tuscany, Suupoohja regional health care system and the Rotherham NHS foundation Trust setting up for all the project life long;
- Involvement of the major research player in the field of RAPS taxonomy, ontology, process modeling, mining such as MIP, RAMIT, ICCS, TUW.
- Tools must be conformed to existing and upcoming standard such as SOA principles
- The implementation of a self-assessment activity to assess the project

REMINE project has been developed on the basis of the following perception of user requirements in terms RAPS management and reduction:

Statement (user needs expression)	Vision	Mission/Intervention	Technological objective
RISK IDENTIFICATION – This is the first step of a RAPS management process	Current approaches against RAPS early identification and effective prevention, suffer from two major problems: lack of RAPS information at the right time in the right place and absence of standardize procedures easily accessible and usable.	Promoting a detailed analysis, an early identification and an effective prevention on RAPS when there are significant mass of inhomogeneous data sources, stored in multimedia databases, and a distributed environments with different care professionals contemporary involved.	Integrated multimedia data acquisition (including RFID) Data enrichment through: • Metadatabase semantically developed • RAPS taxonomy • RAPS ontology
RISK ANALYSIS – today for the risk analysis of RAPS is used the so called: "clinical audit			Knowledge extraction algorithm and methodologies for: • Mining • Pattern discovery Modelling system for RAPS: • Prediction • Detection • monitoring
ALLERT PROVISIONING - It represents the final step of the RAPS management process.			RAPS info info-broker patient safety framework able to provide the best possible reaction, using advanced Business Process Modelling

Statement (user needs expression)	Vision	Mission/Intervention	Technological objective
BUSINESS MODEL It represents the need of the users in defining the better way of organising the RAPS process management system and the way for empowering the health care professionals and the major stakeholder in this RAPS management and reduction			New organizational models for dynamic health care professionals interaction for RAPS reductions. New business model for RAPS management including. RAPS manager role and responsibilities Insurance costs reduction. Relational model amongst heath care units in and outside hospital and local heath care authorities.

The architecture underlying to the whole project, designed according to the basic principles and methodological framework mentioned above, is described below. Furthermore, a detailed description of the identified work packages is provided, along with all the related information.

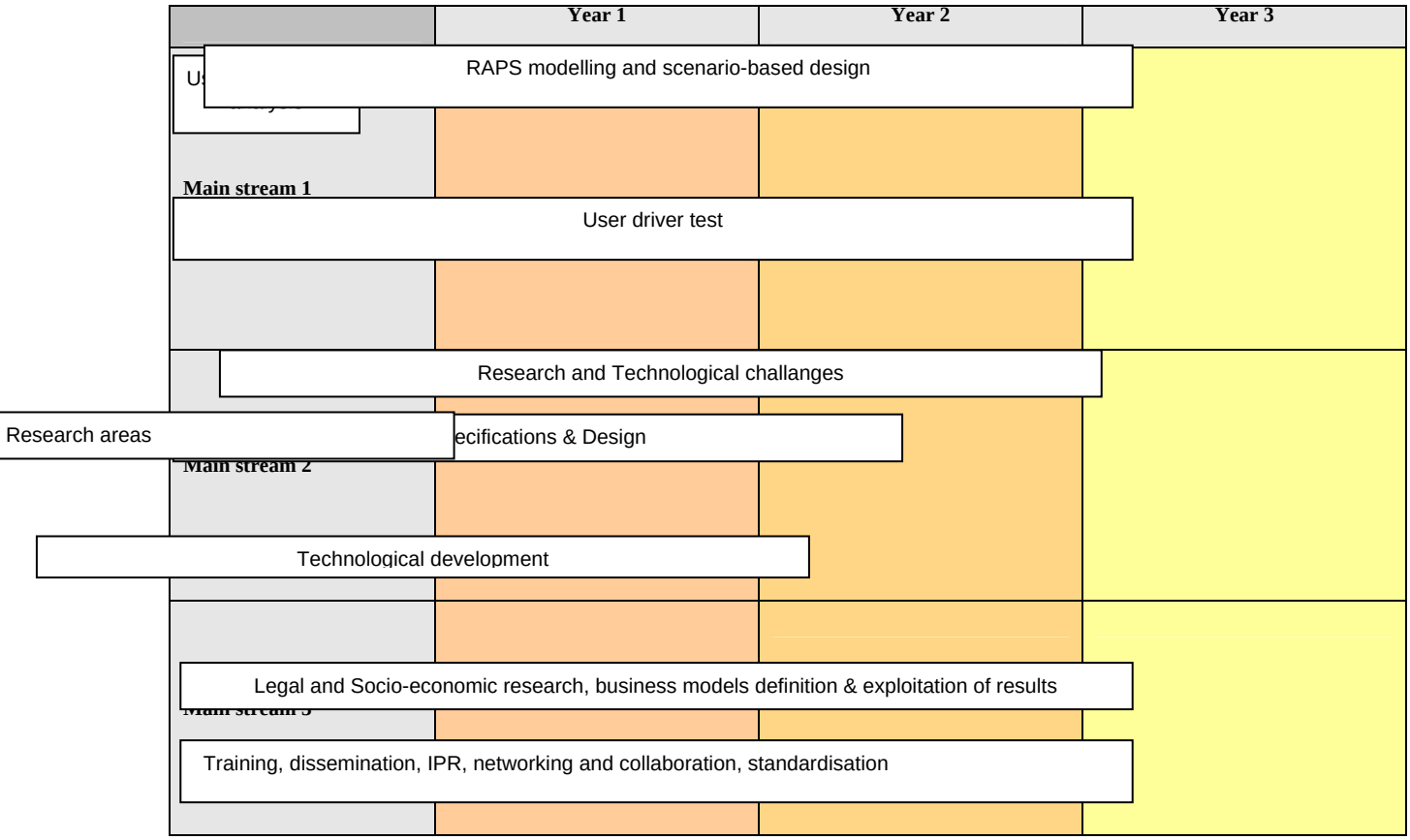
The overall project activities, which aim at realizing all the architectural blocks of the REMINE platform described above, as well as all the necessary support activities in terms of research, demonstration/validation, management, results management and exploitation, can be grouped into three main action areas, called "streams" in the following. These streams are:

- **Main streams 1: data modelling and pilot management**
  Activities that foreseen involvement of the users for their requirement definition; scenario-based design creation; RAPS management procedures definition and modelling; set up of the living pilots in the regions involved in the project.

- **Main streams 2: Research and technological development**
  Research and development activities such as research, development, deployment, validation of the REMINE solution, that foreseen three major research challenges: RAPS data capture and knowledge extraction; risk management process support aimed at creating an advanced RAPS decision support system based upon an RAPS ontology; extended hospital interoperability layer for semantically manage REMINE solution together with the existing Hospital information system.

- **Main streams 3: Socio economic research and business model definition**
  Business scenario definition, socio economic analysis, business model and legal framework, exploitation strategy and plan including IPR are the main component of this steam. Training and capability development, standardisation, dissemination, community building, networking and collaboration are the enabling activities that are also foreseen in steam 3.

The following graphical presentation of project main streams includes a Gantt for each main activity composing the streams themselves. In the following the exact matching between streams and work packages will be examined.



Roles and duties within the different streams

The following tables highlight the major contribution of partners to the three project streams.

	Contents	**WP**	**Partners**
Main stream 1- data modelling and pilot management **M1 – M36**	users requirement definition; scenario-based design creation; RAPS management procedures definition and modelling; set up of the living pilots in the regions involved in the project.	Wp1 – user requirement. Patient care process management modelling, business modelling and socio economical analysis	**MIP – leader** Main contributors: User partners; QSC, HP, AMINIO
Main stream 2 – research and technological development **M1 – M36**	development, deployment, validation of the REMINE solution together with three major project research challenges: RAPS data capture and knowledge extraction; risk management process support	Wp2 - data capure and RAPS alerting Wp3 – RAPS data processing integration Wp4 – RAPS manageemnt process support Wp5 – Infobroker patient safety framework WP6 – SOA and system integration WP7 - Demonstration	**GMD - leader** **INFOWORD - leader** **TUV - leader** **SO - leader** **GMD – leader** **MIP- Leader**

Main stream 3 – socio economic research and business model definition **M1 – M36**	PR. Training and capability development, standardisation, dissemination, community building, networking and collaboration.	wp8 – socio economic framework, dissemination and exploitation	**MIP – leader** Main contributors: GMD (validation and exploitation); user partners (dissemination); RAMIT (standardisation); NTUA (training)

In particular the responsibilities in Main stream 2 are the following.

	Technological Research Area	Research and Technological Challenge	Leader
WP2 Data Capture and RAPS alerting	• Data and Communication security	• Multimedia Data Acquisition	SO Q&R
WP3 RAPS data process integration	• Data Process Model	• Metadatabase • Data Mining • Knowledge extraction	InfoWord QSC QSC ICSS-NTUA
WP4 RAPS Management Process Support	• Taxonomy builder • Taxonomy manager • Ontology engine	• RAPS management process support system	TUW RAMIT RAMIT RAMIT
WP5 InfoBroker Patient Safety framework	• H-ERP component interface Coordinator • Web services Wrapper Framework	• RAPS process Model	GMD ICSS-NTUA LINK

Overall Scientific and Technological Approach

The base of REMINE Architecture a SOA Approach

Service-Oriented Architecture (SOA) is a new computing and software development paradigm in which software developers are grouped into three parties in terms of their responsibilities: the application builders (service requesters), the service brokers, and the service providers, which is referred as the standard SOA. Service providers develop services independent of potential applications by following the open protocols and standards. Service brokers publish the available services to the public. The application builders look up desired services and compose the target application using the available services. Thus a target application is built through service discovery and composing instead of traditional process of designing and coding software.

SOA software has the following characteristics that are different from traditional software:

Standard-based Interoperability

SOA emphasizes on stand-based interface, protocols, communication, coordination, workflow, discovery, collaboration, and publishing via standard protocols such as XML, SOAP, WSDL, UDDI, HTTP,CPP, ebXML, ebSOA, BPEL, FERA, and OWL-S.

These standards allow services developed on different platforms can interoperate with each other with the knowledge of service specifications only.

Dynamic Composition via Discovery

SOA provides a new way of application development by using services just discovered. Furthermore, the composition and discovery can be carried out at runtime.

Dynamic Governance and Orchestration

Execution of services needs to be controlled and several mechanisms are available. One is service governance by policy. More specifically, policies can be specified, checked, and enforced during development time and at runtime. The other is orchestration where process execution will be coordinated by a central controller and it is responsible for scheduling the execution of services that may be distributed across a connectivity network such as ESB (Enterprise Service Bus).

The three-party model of SOA is just a conceptual interaction model among participants of SOA application developers. An SOA application has its own architecture and architecture style [1]. In [1], an architectural template of an SOA application is 5-layered architecture, as illustrated in Figure 1, Presentation, Business Process Choreography,Services, Enterprise Components, and Operational Systems, as well as two supporting mechanisms, Integration Architecture and QoS, Security, Management & Monitoring, used in each of five layers. This architecture style is actually similar to conventional enterprise architecture, which often uses the layered architecture.

The reason of using an innovative architecture entirely based on SOA improvements are due to the increase of Complexity of interactions so :

- Common and normalized business semantics are needed for when describing processes internally and externally
- Quick and accurate response to business changes is needed while reusing functional and integration components
- The Service-Oriented Infrastructure is emerging as a critical value chain resource for managing global operations

A Proposed Standard for SOA is the FERA-based SOA that we would approach as standard in the REMINE project this because we see the following issues/benefits adopting this standard in the design process of the REMINE Architecture indeed FERA :

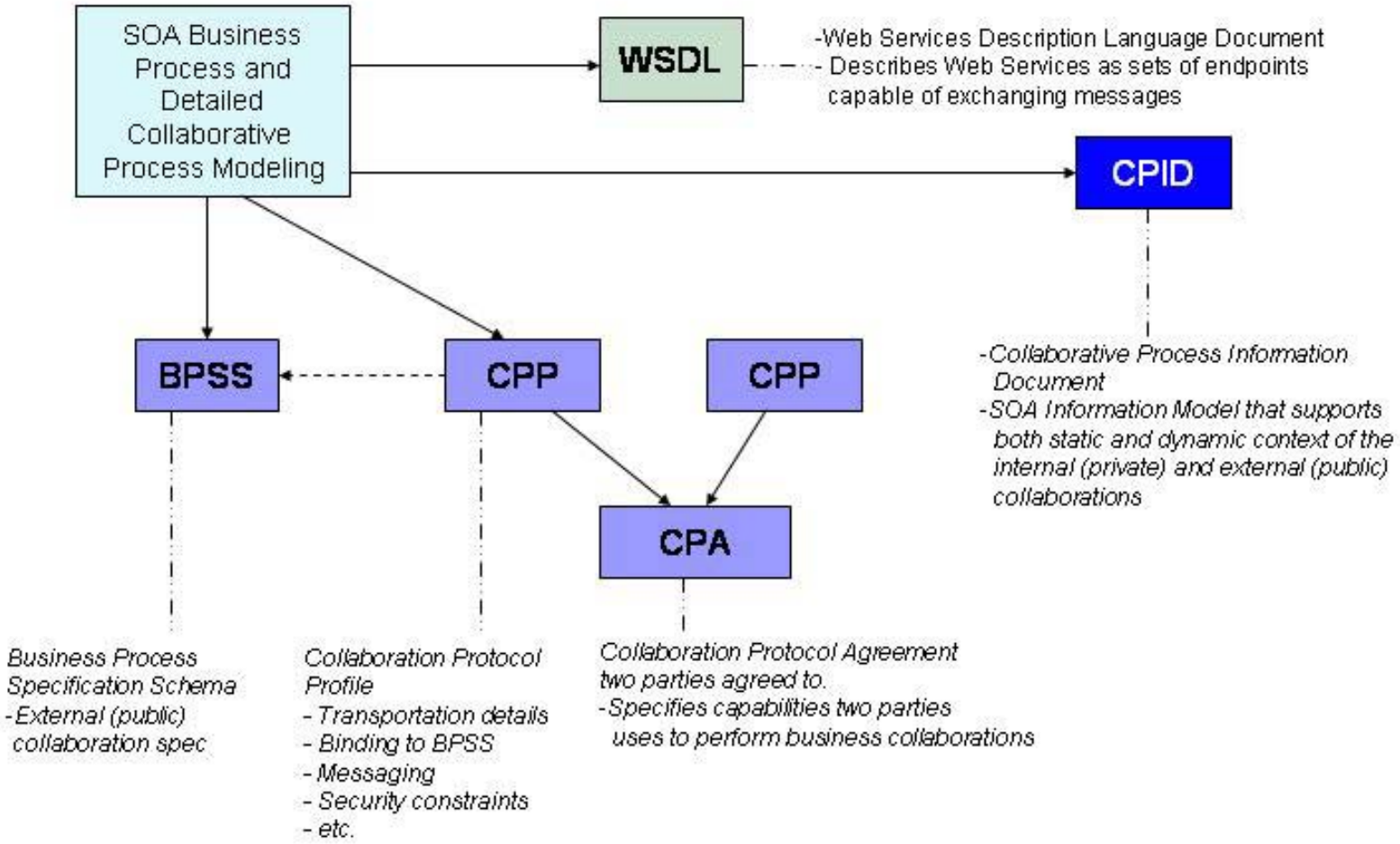
Provides semantic integration for today's SOA
Loosely coupled architecture that does not require coding
Defines complete run-time architecture
Currently in the process to be endorsed by OASIS as standard SOA architecture from its ebSOA TC
Based on Federated Enterprise Reference Architecture (FERA) reference model

FERA is also an architectural framework that defines principles and provides guidelines for a service oriented solution for value chain collaboration because FERA is based on loosely coupled business process integration, is agent powered and event driven and FERA is abstracted into reusable patterns for deployment and templates for configuration that can map to BPM reference models via Guidelines and it is ontology based.

Indeed with the usage of FERA it is possible to use eighteen defined patterns of collaborative process flow and we know as it is important in a even complex architecture using well know and defined pattern as starting point for future implementation.

So in Conclusions REMINE will be a Context-awareness Architecture for mapping SOA to SOI. SOI is infrastructure designed and built to be the Business Process Platform [BPP] for the enterprise that need to support a Integrated Process and Technology Framework that we can see

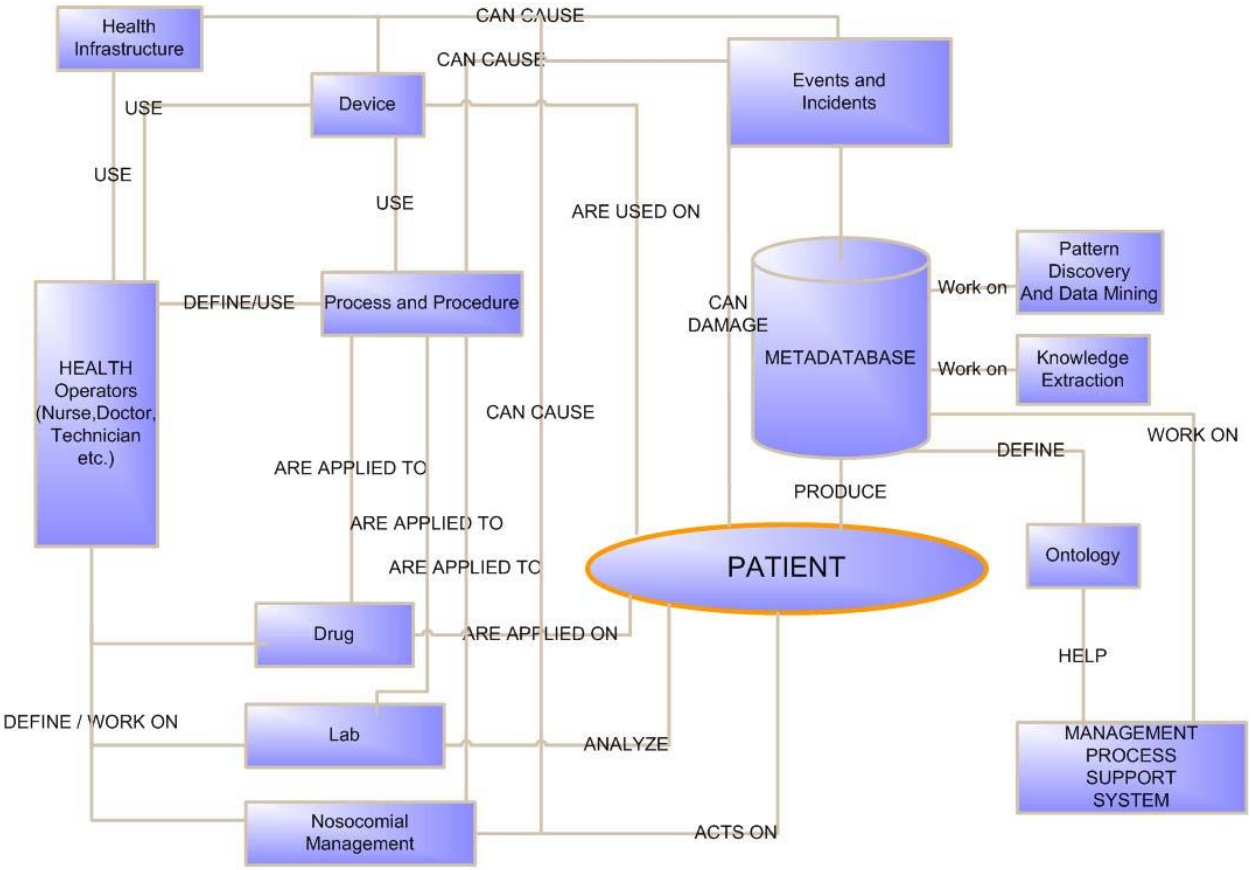
as a scalable, dynamic infrastructure which can respond to the demands of the business layer [Biz-SOA] – i.e. a Service Oriented Infrastructure – SOI
Indeed we have SOA that is an architectural style whose goal is to achieve loose coupling among interacting software agents - i.e. services from SOA we define a SOE (Service Oriented Architecture that in Health system is a structure that implements and exposes its business processes through an SOA and that provides frameworks for managing its business processes across an SOA landscape .


SOA Business Process and Detailed Collaborative Process Modeling
WSDL
-Web Services Description Language Document
- Describes Web Services as sets of endpoints capable of exchanging messages
CPID
-Collaborative Process Information Document
-SOA Information Model that supports both static and dynamic context of the internal (private) and external (public) collaborations
BPSS
CPP
CPP
CPA
Business Process Specification Schema
-External (public) collaboration spec
Collaboration Protocol Profile
- Transportation details
- Binding to BPSS
- Messaging
- Security constraints
- etc.
Collaboration Protocol Agreement two parties agreed to.
-Specifies capabilities two parties uses to perform business collaborations

The Key Principles/benefits adopting the above architecture in REMINE could be addressed in the following point.

Cheaper	The infrastructure must drive better Total cost of ownership (TCO)
Agile	The infrastructure environment must promote agility through scalable and dynamic provisioning
Distributed	The infrastructure must support service distribution – Geographically distributed execution, particularly for collaboration – Service partitioning, particularly "in house" and "out sourced" execution
Process Aware	The infrastructure must be abstracted and process aware

According to the SOA approach choose and according to REMINE concept and objectives of this project , as well all the additional consideration in the boundary that we are evaluating , all of them have lead to the definition of the overall REMINE logical schema , presented in Figure 1 and the following logical/functional view or the general layout (defined as an Architectural view) presented in figure 2.
For our architectural approach all the services need to be defined in a flow of data/operations , flow that need to be orchestrated in order that every services perform its activities in the right way according to the process defined, discovered yet implemented or to should be implemented.
The above logical schema illustrate a possible scenario of REMINE where we depicted the flow among the logical blocks that are involved in a REMINE-Like scenario, so in a sort of a holistic form we can see how every logic block it is directly or indirectly connected and, how REMINE can help to build a risk less environments.

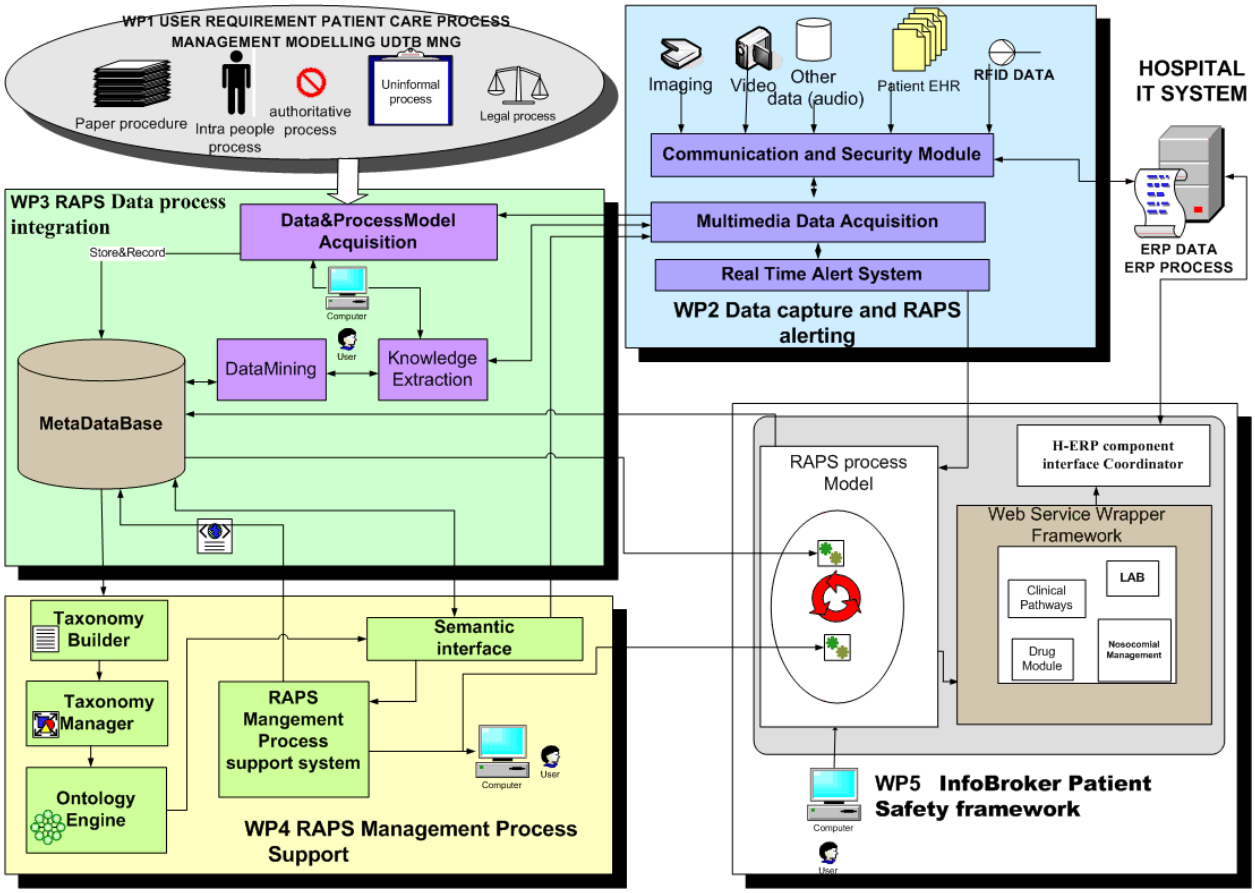

Health Infrastructure
CAN CAUSE
CAN CAUSE
Events and Incidents
USE
Device
USE
USE
ARE USED ON
Pattern Discovery And Data Mining
DEFINE/USE
Process and Procedure
CAN DAMAGE
METADATABASE
Work on
Work on
Knowledge Extraction
HEALTH Operators (Nurse,Doctor, Technician etc.)
CAN CAUSE
WORK ON
DEFINE
ARE APPLIED TO
PRODUCE
ARE APPLIED TO
ARE APPLIED TO
PATIENT
Ontology
Drug
ARE APPLIED ON
HELP
DEFINE / WORK ON
Lab
ANALYZE
MANAGEMENT PROCESS SUPPORT SYSTEM
Nosocomial Management
ACTS ON

The above logical schema it is the starting point that lead to the REMINE architecture design where in the picture some of the logical block are grouped in the REMINE Work package where inside lay the Technological and Challenge research activities , the Workpackages directly connected to the technological approach are :

- Data Capture and RAPS alerting (WP2)
- RAPS data process integration (WP3)
- Risk Management Process Support (WP4)
- InfoBroker Patient Safety framework (WP5)
-

	Technological Research Area	**Research and Technological Challenge**	**Leader**
WP2 Data Capture and RAPS alerting	• Data and Communication security	• Multimedia Data Acquisition	SO Q&R
WP3 RAPS data process integration	• Data Process Model	• Metadatabase • Data Mining • Knowledge extraction	InfoWord QSC QSC ICSS-NTUA
WP4 RAPS Management Process Support	• Taxonomy builder • Taxonomy manager • Ontology engine	• RAPS management process support system	TUW RAMIT RAMIT RAMIT
WP5 InfoBroker Patient Safety framework	• H-ERP component interface Coordinator • Web services Wrapper Framework	• RAPS process Model	GMD ICSS-NTUA LINK

This work packages grouped together shape the REMINE architecture that is depicted in the figure below



In the following there are a brief description of the REMINE architecture that should explain the overall vision of the system.

Data Capture and RAPS alerting, it is the framework that contains all the elements blocks that acquire digital information and data in the environment choose and defined in the WP1.
The collection of data and process in the form of "as-is process", usually defined in form of paper, verbal procedure, standalone IT system (excel, word, custom application) will acquired by the Data&ProcessModel Acquisition component inside the RAPS data process integration . The same component will run an harmonization data process, here with the use of standard like XML, BPL and HL7 all the information will be transformed and filtered in a common format in order to have a common "repository base" or better in a Metadatabase structure, moreover the same component will extract a first list of words that it will need as the base for the taxonomy build.
The Data&ProcessModel aquisition will also supply a tool on which the conceptual model will be transformed into digital process according to the input of the WP1 work.
As another module that behave as input for the Data&ProcessModel acquisition we will have the DataAcquisition , this module is depicted to acquire data from other kind of source as RFID data ,Electronic Health record data, and all the other data that the WP1 will define as useful for the project as for example video and audio file format.

On top of this 2 modules we have the communication security that will provide all the needs in term of security and data protection all the sensitive data.
In REMINE we will have a common language of data and process that will be stored inside the REMINE Metadatabase that , we can see as the working repository of the REMINE solution, it is important to know that data and process inside this repository are yet structured and defined in standard format so it could be possible that other solution outside the REMINE solution can benefits of this Metadata structure.
Directly connected with the Metadatabase there are two modules, the DataMining and the Knowledge extraction .
DataMining is the tool that using mining technique will work on the structured data and it will produce the output for the modules that require the mining work .Inside the DataMining module there will be predefined mining procedure but it also can work on the input of other modules (as the reporting tool) in order to build new mining procedure.
The knowledge extraction is the module that allow to produce and manage outcome using the data inside the Metadatabase. Knowledge extraction works in connection with the mining one because it can require mining activities and it can benefits form the mining module functions. Both a user interface and an Software Interface will be present as output in this module, one it allow the user to produce report and structured analysis , the other will allow the output of analysis and report to be used by other modules inside the REMINE architecture.
The TaxonomyList builder is a module that will extract the list of terms from the information inside the repository in order to let the repository be built and maintained on semantic bases , thus in order to facilitate the user the keep their lexical autonomy, the system will use the same user language also for define data and process.

Risk management process support

Another main logical area of the architecture it is the one that involve the modules connected to the Ontology and the Decision support system, indeed REMINE will overcome the output that can give a traditional support system tool ,indeed thanks to the cooperation with others REMINE components like the knowledge extraction it can improve the research innovation in the E-health risk management environment . REMINE it want give also a system that allow to evaluate the result and the outcome of the analysis and reporting in a decision support system in the form of "what if" so the outcome of the analysis and report will be used as input for decision support activities let the user play with different scenario , moreover in this main block we will have the module involved in the taxonomy ontology activities.
The taxonomy module is the module that work on the input of the taxonomy builder and contains all the functionalities in order to build ,maintain and manage the REMINE taxonomy , this module it is also the main input for the ontology module .
The ontology module it is the module that manage all the activities of REMINE ontology, it work in relation with other modules and it is the repository for all the ontology-related query .
The SematicInterface will drive the semantic structure of the REMINE repository so Repository will be build updated in a semantic structure that reflect also the lexicon of the Data/Process of the E-Health structure itself.
The Risk Management support tool module is the decision support engine module , it will perform all the activities of an inferential engine , engine that will also work in relation with the ontology engine in order to give a unique semantic structure inside the REMINE solution. Also the output of this module is double because it could be use from a GUI user interface but it can also produce an output in a form of file that can be used in BPM process . The output in BPL format it can be used in this way as input in an design process system so the final decision taken in the DSS environment if accepted can be became automatically a process or a procedure , the

advantages it is that process and procedure that derive from all the REMINE module will be enriched in information that prevent and reduce the risk and RAPS better the patient safety .

InfoBroker Patient Safety framework

The last main block of the architecture it is the interoperability layer that will wrap around the Hospital LAB Module the DRUG Module the Nosocomial management module and the clinical pathways a Semantic web services layers that will allow to connect this hospital IT Area with the other REMINE components .This module also will benefits of the input received in form of Automatic BPL process so the output of the REMINE processed information will drive the process that could be defined ,modified and ruled according to the decision taken from all the information that the REMINE process can supply in the boundary of the risk management.
Moreover the Hospital ERP can also be a part of the general input in the overall REMINE architecture indeed, ERP process and data can be evaluated by the DataAcquisition module present in the Main block1 , in this way REMINE will close a feedback loop with the Hospital ERP system in order to have a always update risk management approach so the Risk process will be monitored and evaluate even if any changes (also in form of near misses)it is introduced in the overall process chain.

Data Capture and RAPS alerting (WP2)

Multimedia Data Acquisition

Module category

Research and Technological Challenge (RTC)

Module description

The activity of Multimedia Data Acquisition described into REMINE domain can be split into two main areas: one more related to physically act that copies the natural acts of the Hospital Personnel (HP) during their work, while the second one is more concentrated to logical component that covert the physical environment in digital event of data comprehensible to REMINE Framework. These two different components permit to identifier “voluntary actions” and “clinical events” and to storage the patient clinical events in to hospital information system. More over this activity create a Digital Input Multimedia data Platform (DIMDP) that would allow a hospital personnel (HP) to interact with the patient and the RIMINE systems and to allow in real time to fill the HER in automatic way, without to surf within the innumerable menus of programs. The DIMDP will be able to create natural acts of HP directly in digital data acquisition.

In particular way, for what concerns the operations related to the “Multimedia Data Acquisition ” module, the Digital Input Multimedia Data Platform (DIMDP) will be responsible for the following tasks, providing the needed functional elements:

- Digital Multimedia Data Input system (DIMDS)
- RAPS Classification and Identification System (RCIS)
- Integration of RIMINE platform

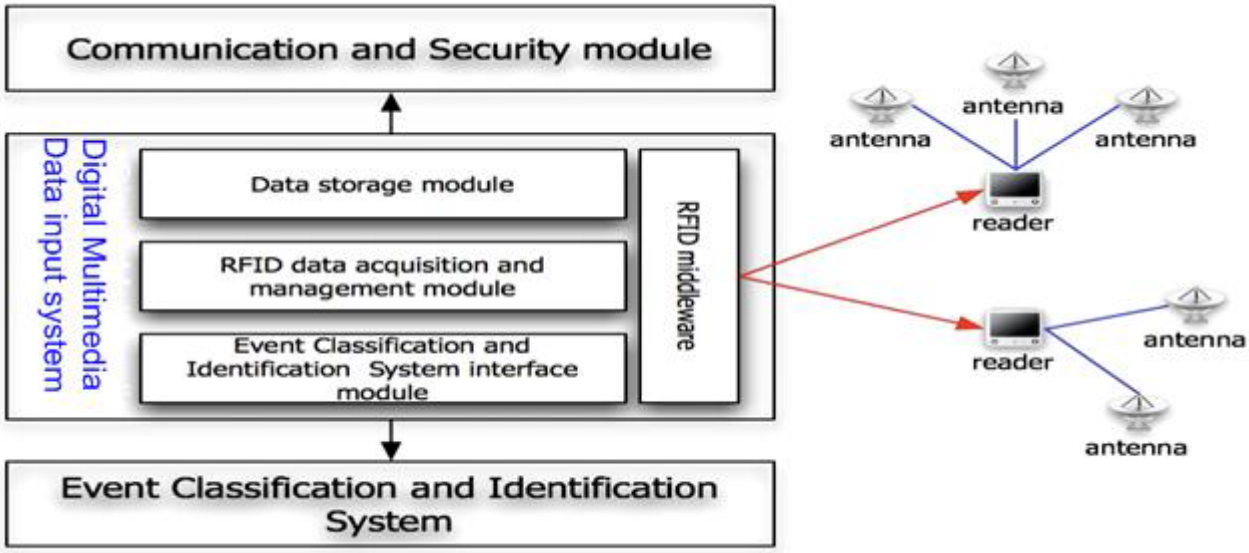
The part of DIMDP assigned to multimedia data acquisition: Digital Input Multimedia Data System (DIMDS) is focused on

- developing a multimedia data capture system to take hold of the patient events during the moving of the hospital personnel around to the patient. It will be possible by integration

of RFID and/or Barcode tag technology to identify hospital object like drugs, clinical device, Diagnostic Medical Imaging devices, medical instrument: stethoscope, thermometer, etc…. More over it will be possible to capture multimedia data from any kind of digital device like Diagnostic Medical Imaging devices (Computed Axial Tomography-CAT scan and multiscan devices, Magnetic Resonance Imaging-.MRI devices, Positron Emission Tomography-PET devices, X-Ray devices, Ultrasound devices, etc...), clinical digital device, digital medical instrument.

- integration DIMDS with Electronic Health records (automatic filling) to storage the patient events by integration with REMINE system.

The DIMDS will be made up of an hardware infrastructure controlled by software components that will specifically developed. The hardware infrastructure will be composed by antennas (both static and portable) and readers that will catch tags data when a tag comes in the reading range. The antennas and readers will be controlled by software modules (a RFID middleware for traditional data for health records and ad-hoc software for Diagnostic Medical Imaging) that allows to gather and manage the multi-medial data acquired. Moreover, a software component to store the multi-medial data in the REMINE database will be developed. A sketch of the module architecture is shown in the following Figure.



The element of RAPS Classification and Identification System (RCIS) is focused on

- identification "voluntary actions" of the hospital personnel during the moving around to the patient;
- freedom to refuse or to accept the patient events from hospital personnel;
- semantic classification and recognition of "clinical events" given to the patient by the identification of a items group: hospital items (drugs, clinical device, medical instrument: stethoscope, thermometer, etc…, Diagnostic Medical Imaging devices: Computed Axial Tomography-CAT scan and muliscan devices, , Magnetic Resonance Imaging-.MRI devices, Positron Emission Tomography-PET devices, X-Ray devices, Ultrasound devices, etc...), patients and hospital personnel supplied to DIMDS and clinical patient history storage on REMINE system;
- integration RCIS with REMINE system

These components constitute the basis for the overall clinical patient multi-medial data gathering in the REMINE architecture, and their design phase will take advantage of the studies carried out in parallel in an ad-hoc work package, whose results will be progressively incorporated into the REMINE architectural specification following specific integration procedures and milestones which will be defined in the work package itself.

Research/technological keywords

The compilation of EHR are done from a man that find the correct menu among innumerable menus and he fills the EHR modules. Usually the clinical activity consist in to fill the clinical paper document and after that to refill the same document in electronic way (EHR).
The RF-ID technology are used in logistic sector to collect data from pallet of objects through the warehouse gate. The RF-ID technology experimentations in hospital are used in the same way. The barcode technology are used in clinical aspect for example to identify the drug given to the patients, even if this way is more close to the first.
Instead, nobody have tried to relate clinical event with hospital objects.
The identification of clinical event by REMINE platform can be achieved with different steps:

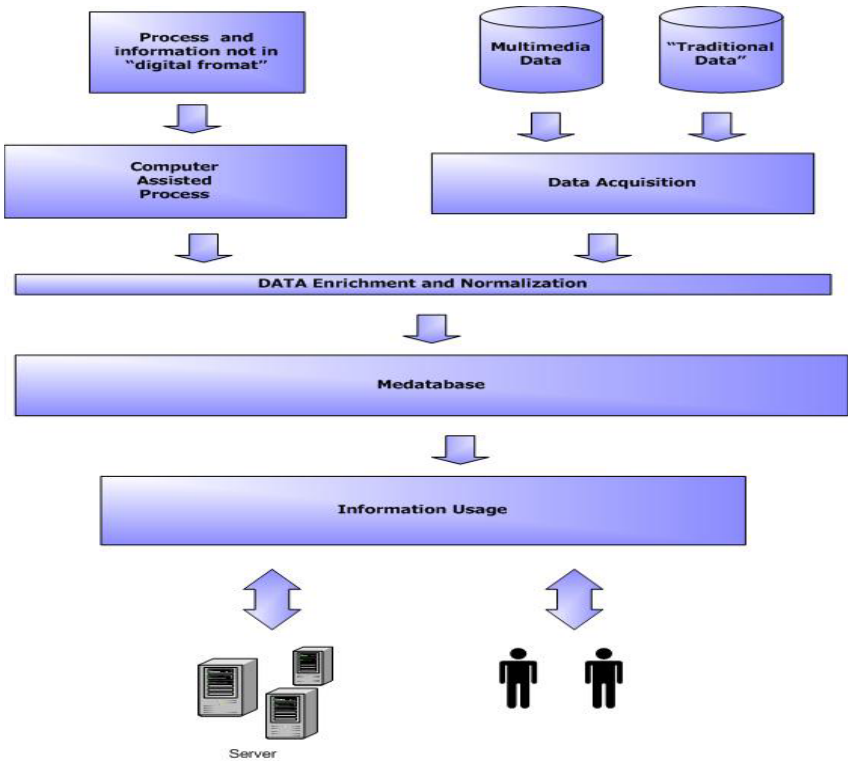
- to identify the hospital object around the patient during clinical event management and Diagnostic Medical Imaging.
- To Classify clinical objects (tolls and Diagnostic Medical Imaging devices) with clinical events.
- To relate the clinical history patient with clinical treatment, hospital object identification and Diagnostic Medical Imaging data.

For the identification of objects around the patient, it exists RF-ID technology that can be recognize multi object that stay in the same area and to track when they get in or out to the zone. However it will be necessary to relate this object tracking with a voluntary action done to the HP that want to be tracked.

For the classification of clinical events related hospital object is more complicated. It depends from the analysis of clinical treatment and the classification of single object with single o multi steps in clinical treatment. However it possible to study the mapping with clinical event and hospital object with:

- Drawing the process of clinical events by analysis of specialist physician of that process
- Analyzing the clinical treatment during the running setup of DIMDS

For the relating of clinical history patient with clinical treatment and hospital object identification, it is possible to approach the problem with datamining analysis where identify the correlation with single step of clinical treatments and hospital objects. However it possible to study the correlation of events with the same methods above.



In this other schema we represent also how the part of the architecture that involve the RAPS data capture for patient safety, it is grouped in defined project tasks.

Data and Communication and security module

Module category

Technological Development Area (TDA)

Module description

This module has a central role in the multimedia data acquisition process from digital sources, which may be directly belonging to the hospital IT system (e.g. the ERP of the hospital) or other sources which are not pre-validated. This second condition mainly refers to input from RFID through suitable interfaces, to data import operations from other data sources, or to the Patient EHRs. All these sources suffer from the security issues which will be examined in details within task 2.3 description, namely a strong need for a data parsing and filtering in order to be completely sure that no risk for the inner system security is contained in the digital input acquired. This issue mainly apply to RFID data acquisition, where is well known but still under study the process of RFID malware.

This module is the only filter between the digital data imported into the system and the next multimedia data acquisition module, thus it must be granted of such features which maximize the up-time of the component. In particular:

- resilience should be granted through suitable redundant component deployment
- an alternative communication path should be provided among the different components of the module

- periodic or real-time monitoring routines should be applied to the module in order to verify the full operability

For what concerns the inner communication infrastructure of the module, at a first glance the currently existing network appliances and components are likely to be suitable for the role. In this case, a technology selection process needs to be issued in order to design the communication network, mainly considering:

- network topology
- capacity planning
- network resilience
- physical and protocol security
- compatibility with medical appliances (in terms of technological and legal constraints. e.g. restricted cellular devices usage, etc.)

Another important issue, considering the fact that the communication and security module has the capability of directly interacting with the Hospital IT System in both direction, within the design process of the module the access management matter has to be considered, in order to grant a suitable privacy level for the data contained into the Hospital IT System itself, as well a consistent feed of the Hospital IT System from the external sources

Research/technological keywords

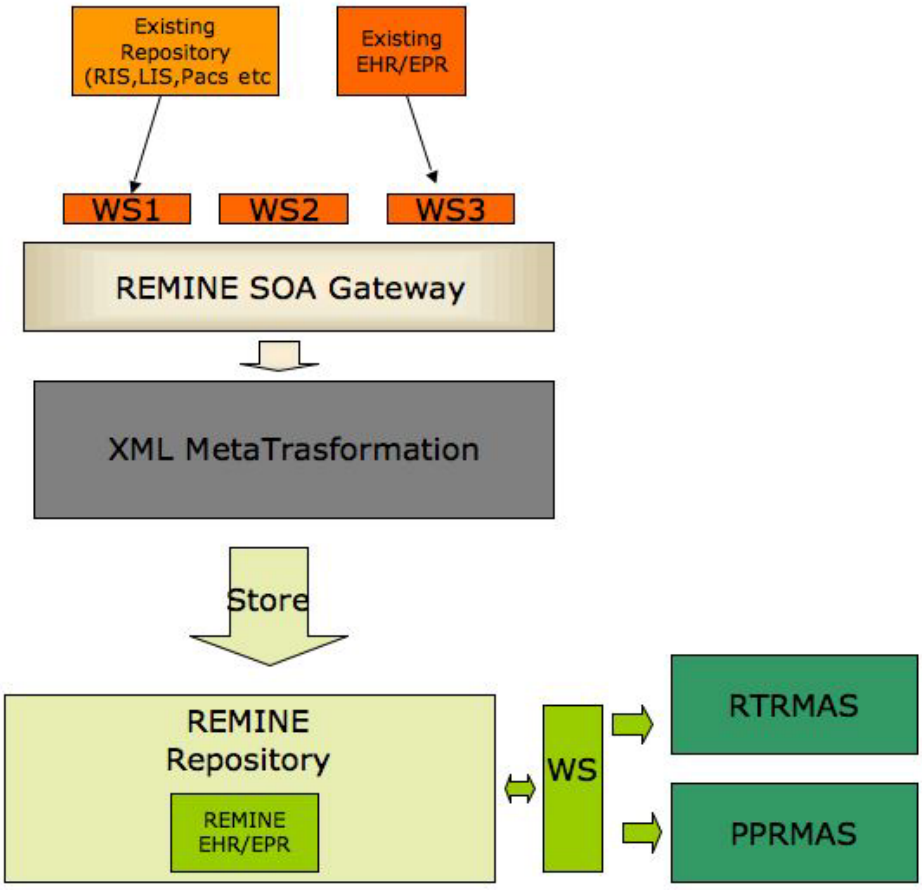
Some important issues to be faced during the design of the module, may be:

- code security rules for the application design
- input validation for the interfaces between the module and the external sources
- resilient layer 2 network through a suitable network topology design
- electromagnetic compatibility and compliance to law and/or rules
- secure layer 2 networks, involving the deployment of suitable protection mechanisms for the wireless portion of the network (WPA, certificates, etc...) and for all the network points in general (802.1x, etc...)
- secure transport protocols, e.g. by means of IPSec, SSL/TLS, etc.
- authentication, authorization, privacy, non repudiation to be granted in the data acquisition process
- Identity management for the connection to the Hospital IT System

RAPS Data Process Integration (WP3)

Integration of different data sources: REMINE approach

The process flow leading to the integration of data contained into existing HER/EPR systems and in other systems will be introduced into RTRMAS and PPRMAS is outlined in the following diagram.



Each WS depends on the proprietary HER/EPR repository source. RTRMAS (real time risk management alerting system) and PPRMAS (post process risk management alerting system) will use the data in the internal REMINE shape.

Implementation involves technology as well as operational and structural aspects of the workflow, thus allowing thorough understanding and acceptance of Laboratory needs and specific requirements. The LIS has to be designed in order to achieve the features, which Up to date laboratories are asking today: continuous workflow, specific specimen ID, tracking systems for samples, data and activities, specific bacteriology features and multi-site/ multi-laboratory management.

From the technological standpoint, the architecture, Relational Database (Oracle), windows graphic user interface that will be developed will follow solutions that are already considered as standards de facto for software applications in healthcare, and are open to future integration.
Features such as data integrity, consistency and security that distinguish Relational Databases will be employed for the management of archives and above all for the management of every single phase of day-to-day lab activity.

The data structure will be very flexible, leaving the system open to interaction with external systems (through data access ODBC). Authorized users will be allowed to perform custom SQL queries and export data in the most convenient format.

Laboratories are different one from another: regarding their specialization, dimensions (small, medium or large labs), functions within the pathology departments and operative models they

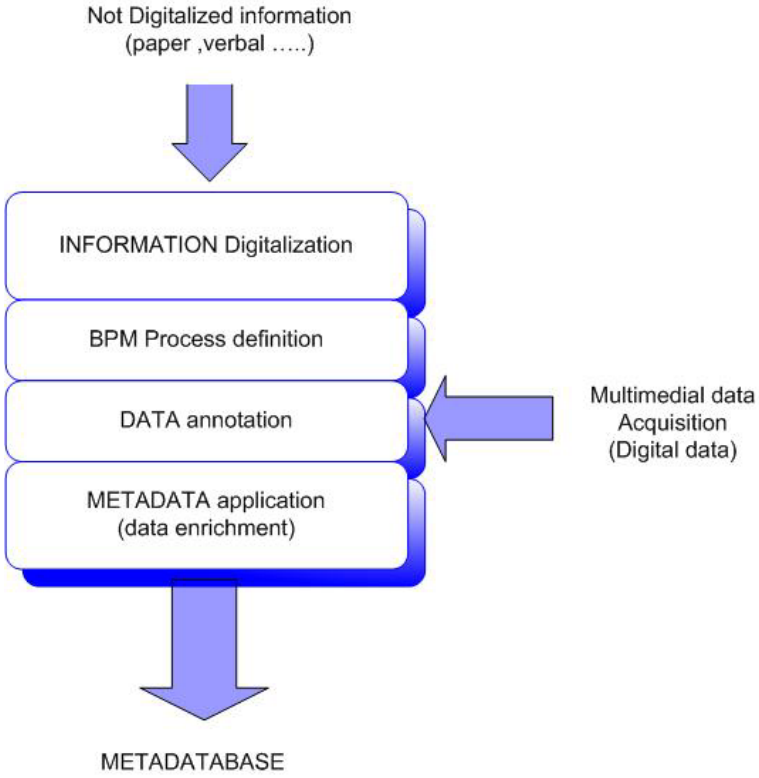
adopt. The REMINE approaches "differentiation" issues adopting organizational models specifically studied to meet each lab own demands. Also, whenever the lab structure, activity and workflow changes, the system flexibility allows easy and swift adjustments, customization. It's a system growing with the laboratory.

DataProcess Model

Module category

Technological Development Area (TDA)

Module description



The aims of this module are different but with a defined goal , thus transform heterogeneous information into a defined semantic structure ready to be stored inside the REMINE Metadatabase.
This module it can be seen as an information input enriched gateway . Indeed in this module it will be built a Web-based tool component for modeling and optimization of business processes moreover the same tool will be used for input inside the system all the issues defined in WP1 that need to better evaluated the risk process analysis . For example all the legal rules and or mandatory duty are most of the time in paper format and they are not in form that the system can take as "variable" to assess in the risk management thus in this module we will input in digital format whatever information need to better asses and evaluate the overall environment on which risk analysis should be managed. A initial core idea of our approach is that business process descriptions will be stored in a standardized XML-based format, which can be automatically transformed into a Business Process Modelling (BPM) format. BPM are used because they allow a formal analysis, evaluation, and optimization of business processes. This

module will consists of a collection of collaborating software components, which can be flexibly distributed and accessed over the internet so the users can directly work and asses the work that have to be done (translation what is not digital in a digital format) . The standardized XML based description format for business processes allows to easily collaborate with business process related tools of this area but it is very important to remember that this module need only to input information into REMINE system in a defined format so due to its behavior this module will not let the user work on the input information because this kind of activities will be performed in another dedicated module in the WP5.
The other components of the module will allow the data that come from the data acquisition module , and new digitalized ones to be enriched and semantically annotated in order to be stored inside the Metadatabase.
REMINE will use the standard Metadata DUBLIN Core in order to harmonize all the information that will be stored inside the Metadatabase so also dismogeneous information coming from different source will be integrated according a defined semantic schema in this way it will be more efficient also for other REMINE Module (for example Mining and Risk base support) work on a wide set of different data but that are view as an unique source of information.

Research/technological keywords

Some important issues to be faced during the design of the module, may be:

- Business risk rules for the process design
- Data integration using metadata structure
- Digital process on not digital information

Metadatabase

Module category

Research and Technological Challenge (RTC)

Module description

A metabase (sometimes called a metadatabase or metadata repository) is a database for storing metadata (data that describes data) for a specific purpose. For example, a metabase might include metadata about all configuration information in a system gathered from a number of sources. A physical metadatabase is one in which the metadata is actually collected into a single place before it is accessed. A virtual metabase is one in which metadata is gathered on the fly when it is needed, possibly when a program is executing.

This module will manage all the data activities for REMINE project. It will contain data that are directly acquired and produced inside the REMINE boundary and Data that comes from other data sources, where when it is possible the REMINE metadata module will contain the links where the real data are. In this way REMINE it will work only on copy of real data without effect any changes on data that not belong directly to REMINE.
The innovative aspect of the REMINE metadata module it is that all the data storage and usage will be executed in a semantic ways thus also the external data label will be “transformed into an homogeneous semantic repository. In this way REMINE will avoid any kind of data misusing .

Moreover the REMINE metadatabase will manage both "classical" data and Multimedia data so the mining application and decision support system can be applied not only on traditional data but on a set integrated data that will include :

- Traditional data
- Video data
- Audio data
- Image data
- Vectorial data

Functional description: The developed data Metadatabase will be integrated (i.e., contain data from multiple state-based and categorical programs), it will be risk -centered where appropriate (i.e., where reporting information is about a specific risk, such as in missing events case reports). It will implement the Public Health Conceptual Data Model HL7 Reference Information Model structure as appropriate, It will include the ability to associate incoming data with appropriate existing data in asemantic form using the ontology engine (e.g., group information of a issue in a risk situation which had another condition previously reported or defined).
Metadatabase will have the capacity to support data accumulated through various means (e.g., through web-based and thick client systems as well as electronic messages), and will function so that data can be accessed by standards-based interaction with REMINE module for reporting, statistical analysis, geographic mapping and automated outbreak detection algorithms as well as the processing of Data mining , knowledge support and decision support activities .

This element supports data translation, data import and export, queuing and messaging for the dynamic bi-directional interchange of external data using Extensible Mark-up Language (XML) to and from the integrated Metadatabase, other associated databases and, in some cases, the within health departments and with other public health agencies. Data integration functionality will be deployed with the ability to rapidly develop ad hoc data exchange interfaces without programming. XML messaging will also provide the messaging infrastructure for future versions of HL7 and X12 content and for some environments may be best achieved with interface engine technology such as in element

Research/technological keywords

-
- Semantic Multimedia database
- Multimedia data mining
- Semantic information integration
- Ontologies
- Data standardization
- Semantic interoperability
- Semantic information manager

Data Mining

Module category

Research and Technological challenge (RTC)

Module description

The REMINE Data Mining Module is dedicated to the extraction of useful patterns from heterogeneous clinical data with the aid of semantic modelling. It is a core of the system's decision support process, transforming the raw data gathered from the complex patient history stored in the REMINE databases into the set of weighted clinical guidelines. The output of the module; the structured medical directives are fed to the decision support logical reasoner for their further customization and prioritization.

The module primary functionality is to extract the most similar patient's profiles from the integrated and normalized complex clinical data stored in the REMINE Repository. This will be done in two steps; firstly the numerical and categorical data will be mined, and later the results will be fed to the semantic component describing the risk assessments connected with the specific medical symptoms.
The two main functionalities of the Data Mining Module will be clustering and rule extraction. The output of the clustering procedure will be the grouping of the patients into the properly identified most attribute-coherent groups. The Data Mining algorithms processing will be based on the input form semantic model which will define the particular features analytic characteristics. *The final output of this procedure will be the extraction of the centroids of the clusters that constitute the patient.*

Research/technological keywords: K-Means algorithm, Kohonen Networks, Mixture Models, Neural Networks, Genetic Algorithms, Decision Trees, Naive Bayesian Classifier, K-Nearest Neighbour (K-NN), Support Vector Machines.

Knowledge extraction

Module category

Research and Technological Challenge (RTC)

Module description

The Analytic and Reporting Module will posses two core functionalities:

- - The proposition and presentation of the final, personalized therapies and treatment for the patient
- The module will retrieve data from the Data Mining and Semantic Model serving data for the requests of the User Interface. It will be responsible for processing and managing the case-based information provided by the two dependent modules.
-
- - The automated generation of standardized clinical study reports

The set of flexible and easy-use reporting functions will be introduced. The tasks performed by all the system's reasoning modules: Data Mining, Semantic and Analytic modules can be documented in the form of prebuilt or customized templates.

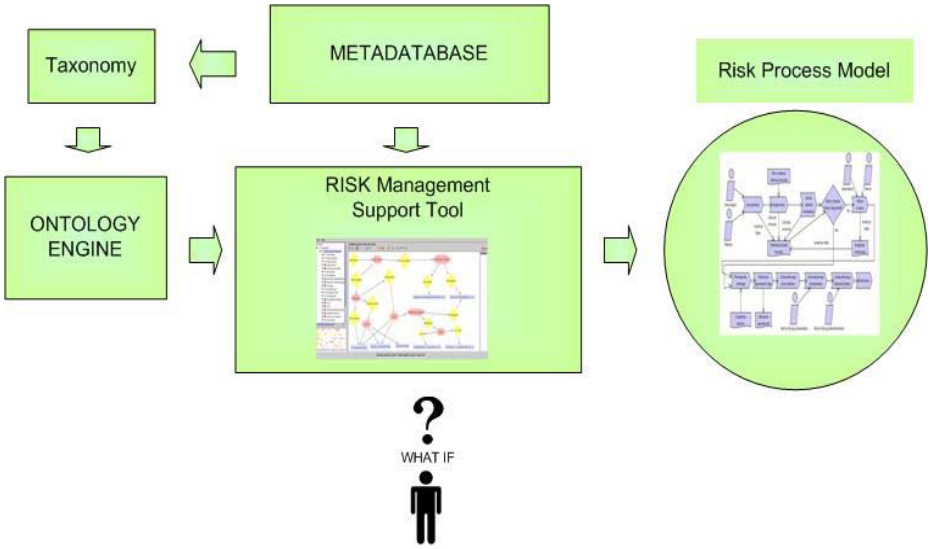
The Analytic part of the module will provide diagnostic and therapeutic information about a specific patients' record contained in the REMINE system. This will be done by performing comparisons to the cluster centroids obtained by the Data Mining Module. A ranking of the most similar clusters is achieved by utilization of analytic information provided by the semantic model.
The Analytic Module will interpolate between the User Interfaces, the Data Mining and the Semantic Interface assuring the system's output will be logically inferred from the REMINE medical knowledge base of risks factors.

The report generation will be based both on the data-mining techniques output, semantic enrichment and logically inferred personalized patient's guidelines. The target users of the system will be physicians, administrative staff, and the patients. Two major types of clinical reports will be incorporated: predefined and customized. The reports will be split into groups as the users will have differently specified access rights to this sensitive information. The reports will provide the statistically processed qualitative and quantitative information not only about the DM-derived patient's morbidity, mortality, and comorbidity but also about the personalized treatment options. Information will be visualized in the kind of chars as well as in the tabular form. The users will be able to interact with the system, dynamically changing the reporting and analytic parameters of the visualized data.

Research/technological keywords:
Information retrieval, semantic analysis, knowledge acquisition, risk management, risk analysis, decision support system, expert system, rating, ranking, prioritization, imprecision, consensus, similarity measure.

RAPS management process support (WP4)

The risk management process support is responsible for the “reasoning” and “decision” activities of the REMINE project The modules composing the macro block responsible of the Risk management process support are Adverse Capture and knowledge extraction are highlighted in the figure xx . This modules work around a Decision support system that takes data/information from the Repository and Data mining activities , take advantages of the ontology and produce elaboration of this information in away that they can be used both as “life process” and computer assist process.



Taxanomy builder

Module category

Technological Development Area (TDA)

Module description

The REMAINE Common Classification System (RCCS) for RAPS in healthcare will combines existent taxonomy like the one developed for England's National Reporting and Learning System (NRLS) with ad hoc REMINE extensions. The REMINE taxonomy will provide a comprehensive mapping of the healthcare system that enables incident records to be partitioned into logical categories for REMINE use. Inside the Project we will focus on extensions that are particularly strong in the clinical specialties which are prone to the more serious incidents, including surgery, adverse drug events, infections, obstetrics and emergency medicine.
The RCCS will be developed with consultation with Pilots representative and It will be incorporated in the software which is used by most of the REMINE components . We also anticipate incorporating the WHO taxonomy once this has been finalised.

The RCCS also will incorporate existing taxonomies such as ICD10 and OPCS4 where they are relevant, as well as taxonomies developed by some of the PILOT (if exist).

Merge the all the taxonomies and manage the integration is part of the functionalities of the taxonomy module that will manage all the category in a unique tree.
Basically the taxonomy module is composed by an advanced editor and some API that let others modules (e.g ontology module) work in junction with it.

Research/technological keywords
Semantic categorization; rules classification; medical classification and standard (e.g. Snowmed ICD9, OPCS4)

Taxanomy manager

Module category

Technological Development Area (TDA)

Module description

In order to facilitate the multilingual capabilities of the module , the editor will allow user to manage Vocabulary pages showing the node's content according to the language choose or with a mix of language, and will be able to show a list of terms (possibly the whole tree) within that vocabulary.
There will be a 'category' tab, which will allow users to quickly transform a node into a category, and to make it the child of another node that is already a term or a vocabulary. This is the same as the way that a node can currently be made the child of an existing page in a book hierarchy.
It will be possible to create a new vocabulary, and to make it the child of an existing term or vocabulary.
Taxonomy management is an area that still needs more attention. But for most people, the basic question about what practices are best suited to taxonomy use in the more full-featured . To pick the right method for creating taxonomies we will focus on a editor able to extract and display information reducing the effort that need to expend on maintaining it. The editor module it will give the flexibility we need in most cases for creating display rules.
The taxonomy module allows the categorization of content by assigning terms to a node. These terms are grouped in one vocabulary, where they can be structured optional in hierarchical order or related to each other. It depends on the type of vocabulary, whether it's possible for users to add new terms or whether only administrators have this permission.
The taxonomy module will provides a simple interface, where an user can add new terms at the one hand and edit existing terms on the other hand without the intervention of an IT specialist . For editing existing terms, the user can go through the list of all terms, which is generated for each vocabulary.
As we know many problems with an increasing number of terms within one vocabulary a user interface gets overloaded and it's nearly impossible to manage all the terms in an adequate way.
The main aim of this project is to increase the usability for editing terms, so what I want to do, is to write a complete module, which offers a better interface.
Taxonomy will implement a two way API , one in order to acquire new taxonomy elements from Data inside the Metadatabase and the other in order to provide Taxonomy functionality to other REMINE modules like :

- Functionalities that work with categories
- Risk management ontology System comparison focused on Taxonomy
- Taxonomy - guidelines for effective design of taxonomies
- Taxonomy : Managing Categories
- Taxonomy : Navigation by category
- Taxonomy : Organize content by category
- Understanding categories for new users
- Using taxonomy to organize risk RAPS
- Using vocabularies for navigation
- Vocabularies and terms
- Extraction Taxonomy
- Creating a Block with links belonging to certain taxonomy terms

Research/technological keywords
Semantic categorization; rules classification; medical classification and standard (e.g. Snowmed ICD9, OPCS4)

Ontology engine

Module category

Technological Development Area (TDA)

Module description

Medical errors are common, costly and preventable. They appear to occur in the setting of three major forces: Human/systems errors, information-seeking behavior, and clinical communication. It is possible to model this domain with an ontology engine that extends the concepts already contained in a defined taxonomy and defined in the ontology process building. The ontology engine will provide a tool that based on the defined ontology will support in a means of resolving coding disagreements, clarifying the role of communication in medical errors, development of a project database, targeting interventions, and promoting hypothesis-generation. Indeed Every ontology it need a software environment where ontology engineers can transform human knowledge in a digital format so the ontology engine inside REMINE will develop an ontology tool representing the intersection of medical errors, information needs and the communication space. We will use this ontology engine to support the collection, storage and interpretation of project data. The ontology's formal representation of the concepts in this novel domain will help guide the rational deployment of our informatics interventions. Moreover the rules based engine will work directly connected to the ontology engine in order to define the semantics of the concept and relation that it will use so cause-and-effect reasoning will use mainly concept derive from the ontology and taxonomy defined.
We will use one of the taxonomies were modeled as ontologies in for example Protégé-OWL or other support, and then aligned with one another through identification of semantic relations between concepts contained in the source ontologies. Once aligned, the source ontologies were merged to produce a single reference ontology with some multi-dimensional axes, the intersection of which, characterizes a medical error event. The classes and relationships in the reference ontology will implemented using a tool among the one that the open source community offer (Protegè, OpenCyc , Ontoweb ….), .

Ontology engine will be build on the following key point :

- Portability to the web: OWL format
- Development environment: Protégé 3.0 release or OpenCyc or othere researched open source framework
- Database: MySQL or other DB
- Consistency and inferencing: for example Classifiable by Racer
- Naming conventions: OWL-compatible and human friendly

The services that the ontology engine it will to provide ,in the operational context, are :

- It as a server it have to performs classification inferences on risk data to determine if a risk belongs to a particular category (e.g., high risk events).

- As a server in the maintenance context, the ontology engine manages changes in concept definitions over time (with an Ontology editor) .
- the Ontology engine also checks for inconsistency of some concepts or terminological cycles that might be created as a result of changes in the definitions.
-

Last things it will supply an API interface in order that other module can interact with it

Research/technological keywords
OWL, inference engine (e.g. Protegee, Ontoweb, OpenCyc)

RAPS management process support system

Module category

Research and Technological Challenge (RTC)

Module description

Main objective of the module are

- Using the acquired guidelines in semantic aspects computer-executable representation
- Providing a prototypical implementation of a guideline execution engine according to ontology rules
-

In order to build a Risk management process support toll we need a DataProcess Model consists of two main tasks:

(1) Formalizing the acquired guidelines in a computer-executable representation'

In WP 3 a repository of different kinds of guidelines in text form was developed. In this module we will explore, which guidelines are most suited to be formalized in a computer-executable representation. To select the guidelines we need to explore the structure and cmpleteness of the guidelines, their medical relevance, and their connection to the terminology and ontology.

To formalize guidelines into a guideline representation language two approaches are available: (a) model-centric approach and (b) document-centric approach [Kaiser 2007a]. In the model-centric approach, a conceptual model is formulated by domain experts. Thus, the relationship between the model and the original document is only indirect. In the document-centric approach markup-based tools are used to systematically mark-up the original guideline in order to generate a semi-formal model of the marked text part.

We will use a document-centric approach to formalize the guidelines, because it is very important that the links to the original guideline in text format are preserved. However, experiences in formalizing guidelines have shown that this can only be done semi-automatically and additional knowledge need to be modelled by domain experts. Therefore, we will add such a phase too, however, we will put much emphasize in the preservation of the links to the original guideline. Furthermore, the used terminology and ontology are essential to ease the modelling

process and to understand the derived conceptual model. Therefore, we will utilise the ontology engine and the used terminology and ontology.

(2) Providing a prototypical implementation of a guideline execution engine

According to the complexity of the formalized guideline and the used guideline representation language different guideline execution engine are available ([Clercq 2004], [Peleg 2003]). However, none of them are able to address the described problem characteristic in a reasonable way.

Therefore, we will start with the functionality provided by the AsbruInterpreter [Votruba 2006], which is based on the guideline representation language Asbru [Seyfang 2002] and complies abstraction rules and plans into a network of abstraction modules. We will prototypically implement such a guideline execution engine, which is able to handle the particular input streams, provide the functionality to execute a class of defined guidelines, and output the recommendations, suggestions, and observations in user adequate way. On the one hand, the user-interface has to be design very carefully according to the users' needs. Therefore, we will utilize the results and experiences from the other WP to design and develop an easy to use and simple user-interface. On the other hand, we will explore to utilize the results from the Data Mining and Reporting tools to ease the guideline execution engine.

Research/technological keywords

Clinical Guidelines and Protocols (CGPs), Formalizing Guidelines, Modelling Guidelines, Information Extraction, Terminology & Ontology, Plan Management, Guideline Execution Engines, (Temporal) Data Abstraction

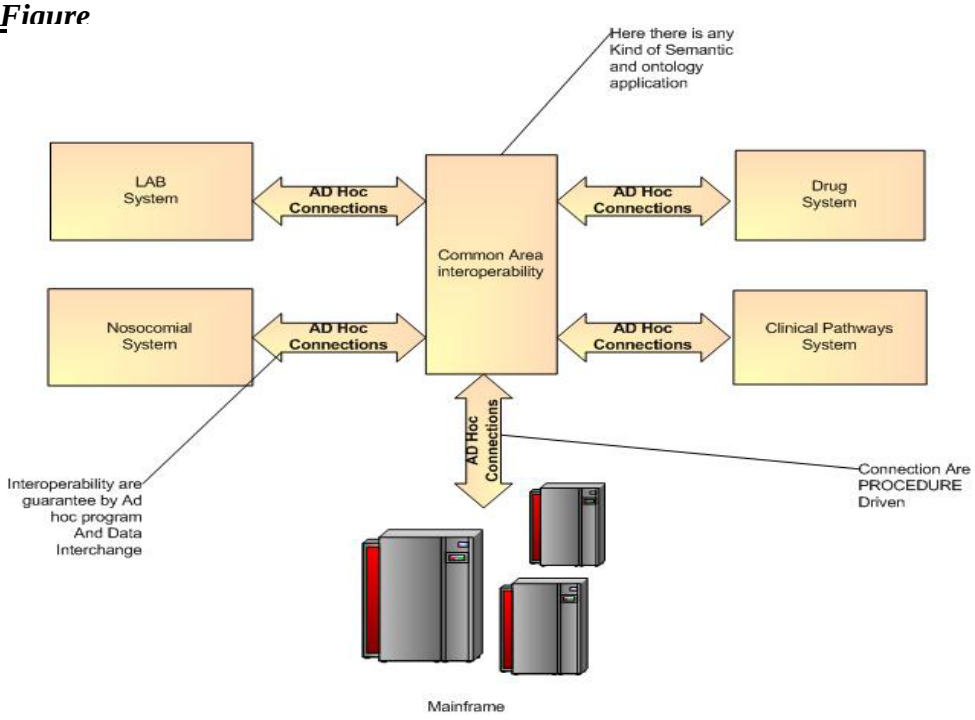
InfoBroker Patient Safety framework (WP5)

Business Process Management focuses on managing the execution of IT-supported business operations from a business expert's process view rather than from a technical perspective. The underlying motivation for BPM is that organizations need to continuously align their running business processes, as executed within multiple heterogeneous systems, with the required processes as derived from business needs.
In a hospital environment the area that control the LAB process , the drug process and the general nosocomial process are till today with a low level degree of mechanization and the use of BPM is currently very limited and without any integration in the different hospital area . Research and develop a general layer that could connect the last research in BPM , Semantic Web services and a traditional Hospital ERP (H-ERP) in the boundary of the risk management process is the topics that REMINE will focus on this Mina .
The major obstacle preventing a coherent view on business processes is that the business processes are not accessible to machine reasoning. Additionally businesses cannot query their process space by logical expressions, e.g. in order to identify activities relevant to comply with regulations and risk management issues.
Founded on ontologies Semantic Web technology provides scalable methods and tools for the machine-readable representation of knowledge ,and the case of REMINE here is the knowledge of a risk management process . Semantic Web Services (SWS) make use of Semantic Web technology to support the automated discovery, substitution, composition, and execution of software components (Web Services). BPM is a natural application for Semantic Web and SWS

technology, because the latter provide large-scale, standardized knowledge representation techniques for executable artefacts.

This Architectural block that belong entirely to Work package 4 is fully devoted to combine SWS and BPM and develop one consolidated technology in order to create am interoperability layer among this world and the traditional one of the Procedure/application of the H-ERP .
Specifically, we will create a set of interoperability Layer that will wrap actual component with a framework of semantic web services that which describe business processes in a ontology based risk system. The WP architecture is fully devoted in this goal.

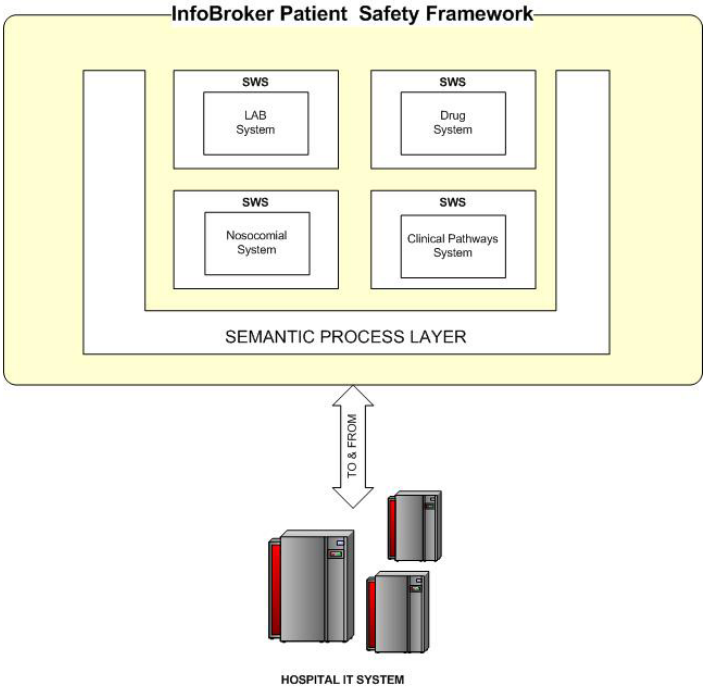
If we consider the traditional an common approach we have a situation as the one in the following Figure



Traditional Interoperabilty structure

In this case we have as usual a procedure approach thus system exchange data among procedural application so there is any kind of semantic interoperability among component , moreover also Web services are procedural one so it need some development in order to modify any part of this scenario. In this as is scenario only skilled technical people can work on the interoperability area and the People involved in any Process definition (e.g Risk management process) can not "manage" the operations.

In the following figure we represent the REMINE approach where in a common environment, Business relate people and IT technician can work side by side .



REMINE Semantic Interoperability Approach

Thanks to the ontologies and Semantic Web technology that provides scalable methods and tools for the machine-readable representation of knowledge the outcome of other REMINE work could be assed here and put in relation with the real Hospital It System (H-ERP). Semantic Web Services (SWS) make use of Semantic Web technology to support the automated discovery, substitution, composition, and execution of software components (Web Services).
So in REMINE it will not be necessary to rebuild entirely the components involved in the process but we will take all this operation at the SWS layer.
In other words REMINE will manage all the process involved in Risk Management issues drive traditional process in a new semantic approach.
Moreover BPM is a natural application for Semantic Web and SWS technology, because the latter provide large-scale, standardized knowledge representation techniques for executable artefacts , and used with SWS can lead to an integrated semantic approach.
One important point, that needs to be specified, is that REMINE does not aim at trying to implement some kinds of automatic reaction or similar concepts. It's a widespread opinion that the participating domain of trust or in general the involved actor would not accept any kind of automatic intervention on their managed infrastructure , in this case the procedure/process inside the H-ERP. The role of REMINE infrastructure is to identify the best possible overall reaction scheme and to suggest to the affected parties the proper tasks to execute in form of semantic web services in order to implement it, as well as to assist them during the deployment.
Anyway, a natural evolution of the architecture leads to the possibility of providing standard API which would allow (semi-)automatic system reconfiguration basing on REMINE alerts and decisions. This could be adopted or considered by the domain administrators on a voluntary basis.

RAPS Process Model

Module category

Research and Technological Challenge (RTC)

Module description

The RAPS process model is the system where Business E-Health Expert will work to merge all the information that REMINE could provide and where thanks to usage of Business Modeling & Integration a new Risk management approach will be explored .

Software modules contained in the RAPS process Model , provide functionalities for the assisted execution of a clinical process , the acquisition of the process instances and the evaluation among different process with the possibility to overlapping different risk layers. . The execution, performed through a graphical user interface constituted of web-based forms filled by users , it will assisted in two different ways:

• through the execution of a clinical process schema as workflow enactment where actors can be humans or machines
(e.g. legacy systems supplying results of medical examination).
During the workflow enactment the designed workflow schema is followed exactly producing clinical process instances where each of them contains the values of activities and events parameters related to a given cared patient.

• through a dynamic workflow composition. In this case, each activity or sub-process instance is acquired selecting the most appropriate one to execute in a given moment. The selection is supported by queries on the REMINE Metadatabase where all process, ontologies and information are enclosed

RAPS and errors prevention, risks and costs reduction and patients safety enhancement need, also, a monitored execution of clinical processes. Monitoring lets the application of prediction models to running process instances, to identify exceptions, unusual or undesired behaviorand and to inform the user.

The RAPS Process Model will help people to model process that will include all the information about RAPS that are collected , merged and analyzed inside the REMINE Platform additionally this module will also put in relation the REMINE Metadabase information with the capturing events taking place during the execution of semantic business risk related processes. It will be used for monitoring and management purposes although it also supports mapping logs from pre-existing Business Process Management software such as traditional ERP like SAP R3 used in Hospital environments (or others ERP Hospital System H-ERP) for their subsequent analysis. Events will be generated by the different REMINE process execution engines (i.e. real time risk engine RTRE and post process risk engine PPRE) and consumed by the analytical tools (i.e. monitoring and mining tools). It provides a generic and extensible framework for logging the execution of IT supported processes may them be totally automated or assisted by humans. It supports the Mining Module over specific processes, although additional domain specific analysis methods or techniques can be defined if necessary. Furthermore, by means of this genericity the very same methods can be applied to analyze the enactment of Processes at different levels of abstraction. For instance, business practitioners are given the means for focusing on the enactment of business processes whereas IT staff can focus on the technical

aspects of the service delivery which is a particularly relevant aspect in Semantic Web Services where services are discovered, selected and executed at runtime.

The RAPS process Model layer it is the interface among the each SWS wrapper and the rest of the REMINE architecture , thus the relationship between ontology and the SWS execution frameworks. Moreover here will reside the connection between the BPM Process and the ontology. Indeed the semantic links between business process models and Web services will enable us to implement automatic and semi-automatic update mechanisms. If a business expert changes a risk process description, in order to change process that could present an High risk situation , notifications can be sent to appropriate IT specialists who maintain the relevant Web services that consequently control the operation in the H-ERP system . Additionally, through the use of ontology-based constraints automatic warnings will notify the business expert if any alterations to a BPM will result in negative outcomes downstream. The combination of update and warning systems will facilitate the evolution of process descriptions both within and across organizational boundaries

Research/technological keywords
Business Process Model (BPM), Business Process Model Lenguage (BPML), Business Process Semantic Work Flow (BPSW), Business Process Management Initiative (BPMI)

H-ERP component interface Coordinator

Module category

Technological Development Area (TDA)

Module description

This module will connect automatically exposes H-ERP applications and process as ready-to-use Semantic Web services. The module will manage this main key features in order to provides a high-performance Web services integration capability for interfacing with H-ERP via SOAP

- Non-invasive development approach protects proven legacy logic
- Flexible choice in development environment supporting both major SW developer framework as Eclipse and Visual Studio
- Automated generation of XML from H-ERP data sources
- Internally transforms H-ERP data into a virtual RDBMS, enabling the use of industry standard SOAP calls
- Bi-directional Web services support on H-ERP, (publishing as well as allowing the mainframe to consume external Web services)
- Full support for SOAP over HTTP and eventually over MQ as transport options

The support transformation of other interface in case of custom H-ERP it will be evaluated and assessed , this component will also allow business logic implemented as stored procedures to be exposed using Web services. The advanced features available using the interface will be monitored and managed and any moment it should be possible switch –on and Switch-off the entire interface or some specific components..

H-ERP will implement the Security Optimization Management for optimizing security and performance associated with H-ERP web services deployments by reducing the overhead of authenticating loosely-coupled connections.
The H-ERP can with this component preserve the H-ERP Data Investment While Moving to an SOA Environment indeed this is the real connection between the H-ERP that let to use the data resources in new and innovative ways, incorporating the SOA model of reusable Semantic Web services (only in the RISK management boundary define in WP1) . The non-invasive development process gives the flexibility and efficiency in building applications, as well as many new options for integration, without requiring potentially disruptive changes to the underlying business logic.

Research/technological keywords

- Hospital ERP interoperability
- Hospital intra area communication
- Live component test on real application

Web services Wrapper Framework

Module category

Technological Development Area (TDA)

Module description

This module involve the creation of a layer around the existent hospital component identified in the Lab, Drug, Nosocomial and Clinical pathways this wrapper will develop the capabilities of the "atomic" process of this component to relate with the Semantic Web services.
After the identification of the process , procedure and data of each main component of the mentioned modules , their "atomic" components will be connect to the relative SWS that will lead the above software "components".
Due to the critical environment of an Hospital IT system the connection/relation between the SWS and the IT system component that they control can be switch-on or switch-off manually by the Hospital Governance ,so in any case the same operation on the IT system can be performed in a traditional way or run by REMINE SWS.

The activities related to the development of this module may be divided into two separated areas:

- Specification and design of suitable technological means related to the creation of the "task-lists", i.e. solutions in order to:
    - identify the software actors involved in the Hospital IT system schema deployment, also considering the difficulties which may be introduced by the anonymity of the information handled by REMINE at infrastructure level.
    - create proper "task-lists" for each one of the specified entities, derived from the overall strategy already established. These lists will deal at this stage with information which is semantic-based, leaving to subsequent modules the task of specify it for the context.
- Specification and design of the protocol for the distribution of the connection task lists, namely the "H-ERP component distributor". About this element, some considerations may be proposed:

- the component is likely to be referred to a end-point which is a standard procedure like input data , asses an IT simple process , print a report and so on , thus an "action" on the Hospital IT system having reduced elaboration of risk management capabilities if compared to a Risk management System as REMINE . This implies a careful design of the communication layer in order to be able to grant security and resilience even if the old system has some lacks.
- the available connectivity for the terminal elements may be reduced in some conditions, with expected impact on the connection protocol , as said before a mechanism of switch-on switch-off will be implemented.

Research/technological keywords

Semantic Web Services , Communication interoperability , Semantic architecture implementation.

- Semantic Web service
- Interoperability layer

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User Driven Test Beds descriptions

The different test beds of REMINE are described in detail in the following paragraphs. To start with, an outline of the different components of the test beds is provided. The following table explains the role of test beds, hospitals and regional authorities as well as the relationship between them within the project.

Country	Unit	Hospital	Regional Authority	Training/IT support
ITALY	Onco-Heamatology Unit Role: – Test bed	Niguarda Hospital Role: – Quality Continuous Unit is the coordinator inside the hospital – Supervise the possible integration with HIS	Health care Dept. Lombardy Region Role: – Identify the more strategic hospital for test bed – Collect Info generated – Supervise integration of the pilot produced inside the project, with Regional Informative data flows	HP Role: – Small tutorials – Practical training Addressed to the Unit/Hospital where pilot is tested
ITALY	Oncology Department Role: – Test bed	Careggi Hospital Role: – Clinical Risk Management Unit is the coordinator inside the hospital – Supervise the possible integration with HIS	Health care Dept. Tuscany Region Role: – Identify the more strategic hospital for test bed – Collect Info generated – Supervise integration of the pilot produced inside the project, with Regional Informative data flows	HP Role: – Small tutorials – Practical training Addressed to the unit/hospital where the pilot is tested
FINLAND	Oncology Department Role: – Test bed	Kuopio hospital Role: – Quality Elevation Unit is the coordinator inside the hospital – Supervise the possible integration with HIS	Heath care District Suuphoja region Role: – Identify the more strategic hospital for test bed – Collect Info generated – Supervise integration of the pilot produced inside the project, with Regional Informative data flows	AMINO Role: – Small tutorials – Practical training Addressed to the unit/hospital where the pilot is tested
UK	Haematology Depart. Role: – Test bed	Rotheramm general Hospital Role: – Supervise the possible integration with HIS	South Yorkshire-Rotherham Foundation Trust Role: – Identify the more strategic hospital for test bed – Collect Info generated – Supervise integration of the pilot produced inside the project, with Regional Informative data flows	QSC Role: – Small tutorials – Practical training Addressed to the unit/hospital where the pilot is tested

Heath Care Dept of LOMBARDY REGION – NIGUARDA HOSPITAL AND Heath Care Dept.TUSCANY REGION – CAREGGI HOSPITAL

The Health Care Department of Lombardy Region and Tuscany Region have a long established agreement of collaboration. Thanks to this agreement they will participate together at REMINE project, thus Lombardy Region will be the direct part of the project, while Tuscany Region will act as "supporting". In every case, both Lombardy Region and Tuscany Region will all the effort to participate at REMINE project.

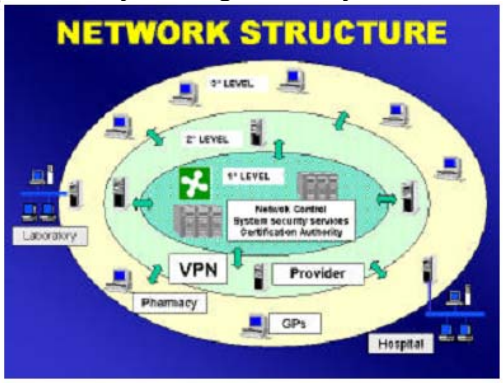
The REMINE project can count on two advanced Hospitals of these two Regions: Lombardy Region brings to the Project the participation of Niguarda Hospital, while Tuscany brings the participation of Careggi Hospital.

Lombardy Region (Niguarda Hospital)

In January 1997 the Regional Government of Lombardia started a large project to design and realise a new Information System for the regional Public Administration to improve the level of services provided and to manage, better, the Regional expenditure. This project named "Cards for Regional Services - HealthCare Information System" (or, in Italian, Carta Regionale dei Servizi - Sistema Informativo Socio-Sanitario referenced as SISS. here after) aims to obtain a modular open system able to grow with the needs of regional Public Administration with a first application to the Health Care environment. The first application of the project has been focused on Health Care environment and, from the beginning, an analysis of the processes of Health Care has been started and the final users (regional administrators, professionals, citizens, etc.) has been involved.

The project is based on the implementation of a Virtual Private Network able to support all the communications among the different actors, through the use of a "public network This network is actually covering a wide geographical area corresponding to a part of the region. The network provides a broad range of services aiming at connecting different levels of Heath care organisations among themselves and within the citizens. SISS is a part of a broader project of the Regione Lombardia, the "Service Regional Card" which will be the only way of access to the electronic services provided by the Region and by the Lombardy local Public Administration. Aim of the project is the development of info-telematics system highly innovative, based on a communication and co-operation advanced infrastructure, for the use of HC professionals to optimise and enhance their performance and thus the services to citizens.

Heath Care Dept. Lombardy Region – Niguarda Hospital	
Population:	Lombardy Region has around 9.300.000 citizens.
Health Care System:	Health Care system is constituted by: o Health clinics: 844 o Socio Sanitary Units: 15 o GPs 9.000 o Paediatricians 1.000 o Hospitals: 132 o Other public clinics: 66 o Hospices:381 o Research institutes:18 o Primary Care Clinics: 37 o Emergency Rooms: 99 o Beds in Hs: 45.849 o Beds in DHs: 4.294
Expenditure:	€ 14,5 billion budget for public healthcare.

	Incidence of RAPS on Total Expenditure in several countries: Harvard Medical Practice Study To err is human Australia New Zeland UK Adverse Events 3,7% 4% 16,6% 12,9% 10,8% Predictable Adverse Events 58% 53% 53% 35% 47% Mortality 13,6% 6,6% 4,9% <15% 8% Expenditure (billion per year) - $37,6 Predictable AE $17 $4,7 - £1 (due to increased n° of days inhospital) Source Leape et al., New Eng. J. Med. 1991-370-84 Kohn et al. 1999, Institute of Medcine Wilson et al., Med J Aust, 1995, 163, 158-71 Dais et al. 2001, Ministruy of Health Vincent et al. BMJ, 2001, 322, 517-9
HIS:	the Regional Government of Lombardia started a large project to design and realise a new Information System for the regional Public Administration to improve the level of services provided and to manage, better, the Regional expenditure. This project named "Cards for Regional Services - HealthCare Information System" (or, in Italian, Carta Regionale dei Servizi - Sistema Informativo Socio-Sanitario referenced as SISS. here after) aims to obtain a modular open system able to grow with the needs of regional Public Administration with a first application to the Health Care environment. The project is based on the implementation of a Virtual Private Network able to support all the communications among the different actors, through the use of a "public network This network is actually covering a wide geographical area corresponding to a part of the region. The network provides a broad range of services aiming to connect different levels of care between themselves and with the citizens SISS is a part of a broader project of the Regione Lombardia, the "Service Regional Card" which will be the only way of access to the electronic services provided by the Region and by the Lombardy local Public Administration.  "SISS" networks: the whole regional heath care system described above
Policy of RAPS Management:	To reduce RAPS Lombardy Region adopted a incident reporting system and every six month it promotes a round-table with General Director of Public Hospital. Lombardy Region has optimized a web database to monitor risk and to manage insurance.
Test Bed: Niguarda Ca' Granda Hospital	
Typology:	Niguarda Ca' Granda Hospital is a public hospital. Between the IX and XV centuries, due to the efforts of citizens, clergy, and hospital orders, many hospital were founded in Milano. In the first half of the *1400s, Francesco Sforza and Pope Pio II* united them to form the *Ospedale della Santissima Annunziata* (later called Ospedale Maggiore).

	It was not until 1932 that the long desired and planned *new big general hospital* was actually started. *Designed by the engineer Giulio Marcovigi and the architect Giulio Arata*, built on 336,578 square meters with 1500 beds, the Ospedale Niguarda ca' Granda was opened on *October 2, 1932*. *On June 14, 1993*, Niguarda Ca' Granda was recognized as a hospital of national scope. Niguarda is built on a *322,000 square metre* site. With its new buildings, buildings under renovation, gardens and flowers, streets, shuttles and parking lots, Niguarda is a *small city which hosts 9.000 people every day*, between workers, patients, relatives, suppliers, delegations, journalists, etc. Niguarda is located in the *northern part of Milano*, but it serves the whole Lombardy region. Niguarda is a *national point of reference* for treatment and health promotion.
Turnover:	Every day 6.000 people go to Niguarda for medical support. 3.000 people/day for blood test.
Structure:	Doctor: 800 Training physician: 400 Nurse: 3.000 Externals operator: 3.000 Sector: 11 Medical Department: 75 Operating Room: 34 Each medical dept. divides in several medical unit, these areas specialize in particular argument like bone marrow transplantation, or reconstruction of the woven ones.
HIS:	Niguarda adhered to "SISS" Lombardy project. The Hospital has a Information Technology Division, which manage the ERP system: SIAPRI. SIAPRI comprises to manage of case sheet, tele-medicine, communication, e-learning.
Policy of RAPS Management:	The S.S. "Clinical Risk Management Unit" coordinates work groups engaged for activities concerning clinical risk as to develop and the manage the insurance and the Guide Lines of Lombardy Region application. This commission is focus on cataloguing of RAPS happened, which catalogue is the base for implementation of business administration. Niguarda adopted in 2003 a IT system that allows to join the RAPSs and to collect anonymous signalling.
REMINE Test Bed: Niguarda "ualitytQQjgdbklòjbzjòlkfzdkjfzlknjsjhghdfsQuality Continuous Improvement Unit" (MCQ)	
MCQ Unit is the responsible of quality inside the organization. It controls the respect of RAPS procedure. MCQ adopts a incident reporting system in 2006, this software allows a employee to dismiss RAPS, but moreover it allows to dismiss RAPS and notes without any registration. This system is a elevation respect the past, when the RAPS were indicated on paper form, which dismissed in folders put in cellar. MCQ foresees that REMINE could develop the software used, to improve it, to transform it from only electronic archives to decision support tool for prediction and reduction the shown of RAPS.	
REMINE final user: Niguarda Onco-Haematology Dept. - Haematology Unit	
Choice of Haematology Unit	REMINE allows to manage RAPS in all level of organization. REMINE works as archives for collect all data, moreover thanks to risk management processes support and the interoperability among other departments (like chemistry' shop, ward, surgery, laboratories and operating rooms), REMINE could realize several scenarios. Doctor understands causes, he/she could predict the happening of RAPS and thus he/she could modify for example personnel shifts of nurses and doctors, could order drugs and so on.

<table>
<tr><td></td><td colspan="2">One of department joints with: 1) operating room, 2) laboratories, 3) chemistry' shop, 4) ward, 5) surgery and that involved many employee is Onco-Haematology department. Niguarda management choices Haematology Units for its size and number of patient turnover.

They have 45 room, 8 single, and 12 of which are ensuite isolation cubicles for patients receiving bone marrow transplantation, which suppresses the immune system.

People Involved:
Physicians: 18
Forward contract physician: 8
Physician specialised: 8
Grant-holder physician: 6
Training physician: 3
Nurse: 43
Forward contract nurse: 7
Technical Operator of lab: 5
Forward contract technical operator: 5
Ordinary beds: 30
Solvency beds: 4</td></tr>
<tr><td>IT infrastructure:</td><td colspan="2">Winpax for pathological anatomy.
SIAPRI for biochemical, microbiology and virology lab.
SIAPRI for case sheet.</td></tr>
<tr><td rowspan="3">Obj of pilot:</td><td>Databases ownerships:</td><td>All the data that will be use in the Pilot belong to Niguarda hospital. It has all the legal rights for using it in the pilot activities.
REMINE will use two type of data:
<u>First: Data Security</u>
o Electronic case sheet;
o Imaging of patient;
o Audio of patient;
o Patient' Anamnesis;
o Family' Anamnesis.
Electronic case sheet (jointed patient' anamnesis, family anamnesis') uses SIAPRI software.
Imaging and audio use WebAgfa software.
<u>Second: Common Data</u>
o Company Guide Line;
o Regional Guide Line;
o National Guide Line;
o Confederation Guide Line (e.g. World Heart Federation).
Niguarda has legal rights for modelling these data for communicating with H-ERP.</td></tr>
<tr><td>Expenditure:</td><td>8% of hospital medical department budget is spent by legal office for defending ward from RAPS accuses; and this amount is spent for mark up of suppliers caused by urgency orders.</td></tr>
<tr><td>Quantify Benefits:</td><td></td></tr>
<tr><td>OBJ of Test Bed:</td><td colspan="2">o To improve the quality of care
o To reduce RAPS and related costs (insurance, administrative and layers ones)
o To improve the cooperation amongst health care professionals in and within the hospital in terms of environmental and working conditions
o To improve the Multidisciplinary approach to health care,</td></tr>
</table>

	o To improve SIAPRI system not only to monitor RAPS but also to predict and prevent them. o To Support for clinical and managerial research.
Expected results:	In the project time scale the following objs need to be reached within REMINE pilot: o Evidence that RAPS can be reduced in significant ways. o minimal impairment (or recovered within one month) less then 40% o injury or complication less then 20% o moderate impairment less than 5% o permanent impairment less than 2% o contributed to death less than 1% o Proof that the cost of care and administrative one can be significantly reduced at least of 60% o Proof that the cooperation amongst heath care professionals in and within the hospital can be improved at least of 50%

Toscany Region (Careggi Hospital)

Regional Government of Tuscany started a project to design and realise a new Information System for the regional Public Administration to improve the level of infectious disease "Sistema di Sorveglianza Informatizzato (SIMI), and to manage better, the Regional expenditure. The follow year Tuscany Government realized the SST (Sistema Sanitario della Toscana), this is a web portal divided in three parts, one for citizen, one for physician, and the third pharmaceutical and industrial firms.

The project is based on the implementation of a network able to support all the communications among the different actors, Aim of the project is the development of info-telematics system, based on a sharing culture and events, each sanitary operators tagged its arguments, so other users could find information, and they could improve their culture.

Tuscany's public health service is subdivided in 3 wide area consortiums and 16 local healthcare trusts. Globally, we have 50.000 employees distributed in 34 acute care hospitals and hundreds of local wards. There are around 15.000 beds and 650.000 in-patients each year.

CRM centre, through a series of acts of the regional government, has outlined the goals each local healthcare units must achieve to reduce risks, improve patient safety and service quality. The activities for patient safety have been integrated in the Quality System of the Region. Some main requirements concerning clinical risk management and patient safety have been introduced in the institutional system for the accreditation of the healthcare organizations. Each healthcare trust will also implement a mechanism for the accreditation of good practices for patient safety.

In two years and half of work the system has achieved the following results.

A. Concerning the identification and analysis of risks:
   - 14 local trusts have conducted clinical audits inside their wards related to a report from a clinician;
   - 9 local trusts have implemented the Mortality and Morbidity review (M&M);
   - In 12 local trusts actions for improvement have been promoted after the analysis of RAPS;
   - 9 local trusts have conducted the analysis on sentinel events.
B. Thanks to the data collected with the informative system for the management of claims, we know that the litigation have increased in the last three years of 2,8% and that patient falls are the first cause of claims in our Region.
C. We conducted two main campaigns within the prevention of hospital infections and therapeutic errors.The evaluation of the campaigns showed that they produced a positive impact on the organizations: the washing hands practice increases of 25%, while the percentage of the drug prescriptions/for each inpatients which are completely retraceable increase from the 74,4% to the 88%.

D. 16 clinical risk managers, 800 facilitators/patient safety officiers, around 5.000 operators in the high risk areas have been training with specific programmes in patient safety, in cooperation with the University of Florence, Pisa and Siena and Sant'Anna School for Advanced Study.

The RAPS management system, is centralized at Regional Level, and data entry is performed by the facilitator of each hospital, who logs in in trhough username and password, and access the central database using a Smartcard. The system includes three different databases:

- Claims and complaints database: the system has been in use in the hospital since 1 year. The database is shared between the Hospital Legal Office, and the CRM group, who access the system at different levels. All the data used by CRM group are anonimsed.
- Voluntary incident reporting databases: Each report includes the dynamic reconstruction of the incident, and is evaluated by the CRM group, in order to define if it contains critical elements that worth a further study. This service is undergoing a technical assessment and is not in use yet.
- Alert report database: include the alert reports, performed by the CRM group for the incident reporting judged critical. This service is undergoing a technical assessment and is not in use yet.

<table>
<tr><th colspan="2">Health Care Dept. Tuscany Region – Careggi Hospital</th></tr>
<tr><td>Population:</td><td>Tuscany Region has around 3.635.462 citizens.</td></tr>
<tr><td>Health Care System:</td><td>Health Care system is constituted by:
o Health clinics. 9
o Socio Sanitary Units: 12
o GPs: 3.5000
o Paediatricians: 600
o Hospitals: 42
o Other public clinics: 15
o Hospices: 270
o Research institutes: 4
o Primary Care Clinics: 8
o Emergency Rooms: 45
o Beds in Hs 13.870
o Beds in DHs 2.084</td></tr>
<tr><td>Expenditure:</td><td>€ 4.995 million budget for public healthcare.
Incidence of RAPS on Total Expenditure in several countries:

<table>
<tr><td></td><td colspan="2">Harvard Medical Practice Study</td><td colspan="2">To err is human</td><td>Australia</td></tr>
<tr><td></td><td>New Zeland</td><td>UK</td><td></td><td></td><td></td></tr>
<tr><td>Adverse Events</td><td>3,7%</td><td>4%</td><td>16,6%</td><td>12,9%</td><td>10,8%</td></tr>
<tr><td>Predictable Adverse Events</td><td>58%</td><td>53%</td><td>53%</td><td>35%</td><td>47%</td></tr>
<tr><td>Mortality</td><td>13,6%</td><td>6,6%</td><td>4,9%</td><td><15%</td><td>8%</td></tr>
<tr><td colspan="3">Expenditure (billion per year)</td><td colspan="3">- $37,6 Predictable AE $17</td></tr>
<tr><td></td><td>$4,7</td><td>-</td><td colspan="3">£1 (due to increased n° of days inhospital)</td></tr>
<tr><td>Source</td><td colspan="5">Leape et al., New Eng. J. Med. 1991-370-84 Kohn et al. 1999,</td></tr>
<tr><td>Institute of Medcine</td><td colspan="5">Wilson et al., Med J Aust, 1995, 163, 158-71 Dais et al.</td></tr>
<tr><td>2001, Ministruy of Health</td><td colspan="5">Vincent et al. BMJ, 2001, 322, 517-9</td></tr>
</table></td></tr>
<tr><td>HIS:</td><td>Tuscany Government realized the SST (Sistema Sanitario della Toscana), this is a web portal divided in three parts, one for citizen, one for physician, and the third pharmaceutical and industrial firms. The project is based on the implementation of a network able to support all the communications among the different actors, Aim of the</td></tr>
</table>

	project is the development of info-telematics system, based on a sharing culture and events, each sanitary operators tagged its arguments, so other users could find information, and they could improve their culture.
Policy of RAPS Management:	Tuscany Region Policy of RAPS Management led to institution of "Agenzia Regionale della Sanità" this standing committee has the goal to monitor and to report the RAPS manifestation. Tuscany Region would reduce the incidence of RAPS and this committee realized incident reporting system for inserting data.
Pilot Site: Careggi Hospital	
Typology:	Careggi Hospital is a public hospital and moreover it is university hospital.
Turnover:	Every day 4.000 people go to Careggi for medical support.
Structure:	Doctor: 200 Training physician: 50 Nurse: 1.000 Externals operator: 1.200 Medical Department: 14
HIS:	The Hospital has a Information Technology Division, which based on Oracle platform. At this moment the Hospital has being studied to improve electronic case sheet. The information system uses for collecting and for monitoring data.
Policy of RAPS Management:	The S.S. "Clinical Risk Management Unit" coordinates work groups engaged for activities concerning clinical risk as to develop and the manage the insurance and the Guide Lines of Tuscany Region application.
REMINE pilot: Careggi "URP" (Hospital Public Relation Office)	
A different System, implemented by Careggi teaching Hospital, manages the complaints arrived to the Hospital Public Relation Office (URP). The complaints classified as "technical-professional" are processed by the CRM regional group. Other users, different form Careggi Hospital access the service through the web.	
REMINE final user: Careggi Oncology Department	
Choice of Oncology Dept.	People Involved: Physicians: 25 Forward contract physician: 14 Physician specialised: 8 Grant-holder physician: 12 Training physician: 5 Nurse: 50 Forward contract nurse: 15 Technical Operator of lab: 8 Forward contract technical operator: 5 Ordinary beds: 1.500 Solvency beds: 25
IT infrastructure:	Oracle platform. Hospital is increasing the electronic case sheet and the PACS system

<table>
<tr><td rowspan="3">Obj of pilot:</td><td>Databases ownerships:</td><td>All the data that will be use in the Pilot belong to Careggi hospital. It has all the legal rights for using it in the pilot activities.
REMINE will use two type of data:
<u>First: Data Security</u>
o Electronic case sheet;
o Imaging of patient;
o Audio of patient;
o Patient’ Anamnesis;
o Family’ Anamnesis.
Electronic case sheet: Hospital is studying a integrated system.
Imaging uses RIS software.
Careggi uses Dianoema Italab software in laboratories.
Endobase software is used in endoscopi.
<u>Second: Common Data</u>
o Company Guide Line;
o Regional Guide Line;
o National Guide Line;
o Confederation Guide Line (e.g. World Heart Federation).
Careggi has legal rights for modelling these data for communicating with H-ERP.</td></tr>
<tr><td>Quantify Benefits:</td><td></td></tr>
<tr><td>Expenditure:</td><td>Careggi is not able to quantify the expenditure for RAPS. From Regional Study in 2006, Careggi collected data about incident and the analysis showed that lawsuit have increased in the last years of 3,5%.</td></tr>
<tr><td>OBJ of test Bed:</td><td colspan="2">o To improve the quality of care and patient satisfactions
o To reduce RAPS and related costs (insurance, administrative and layers ones)
o To improve leverage the reporting system and the knowledge of the heath care professionals on RAPS protection and prevention
o To develop a ICT for both monitoring RAPS and predicting and preventing them.
o To continuously improve RAPS guidelines of the Careggi Hospital.</td></tr>
<tr><td>Expected results:</td><td colspan="2">In the project time scale the following objs need to be reached within REMINE pilot:
o Evidence that RAPS can be reduced in significant ways.
o minimal impairment (or recovered within one month) less then 60%
o injury or complication less then 30%
o moderate impairment less than 8%
o permanent impairment less than 4%
o contributed to death less than 2%
o Proof that the cost of care and administrative one can be significantly reduced at least of 50%
o Proof that the cooperation amongst heath care professionals in and within the hospital can be improved at least of 70%</td></tr>
</table>

PILOT DESCRITPTION - SUUPHOJA REGION – KUOPIO HOSPITAL

Finland has a health care government organized in several levels. The country divides in regions and each region has autonomy, thus, prime responsibility for local health services rests with local authorities. Primary health care has health care centres, while secondary health care consists of central hospitals, university hospital and several institutes.

The Suupohja Region comprises 5 municipalities:

- Kauhajoki
- Teuva
- Jurva
- Isojoki
- Karijoki

SEK (Federation of municipalities) in Suupohja represents a region in Western Finland (about 200.000 citizens). The central hospital is in Seinäjoki www.epshp.fi.

SUUPHOJA REGION – SEINÄJOKI HOSPITAL	
Population:	Suupohja represents in REMINE a region in Western Finland of about 200.000 citizens. Presentation of the region is in *http://www.epliitto.fi/?page=index&lang=en*
Health Care System:	Health Care system is constituted by: o Primary health care o health centres o Secondary health care o 1 central hospital o Private health care
Expenditure:	€ 5.895 million budget for public healthcare. Incidence of RAPS on Total Expenditure amount to 12%.
HIS:	Finland Government realized a regional division in Health care government, each region chooses the main point of interest.
Policy of RAPS Management:	Each health institution has to have a quality system (SFS-EN ISO 9001:2000), and to use a incident reporting system. Each health institute at the end of year has to draw up a social annual report, highlighted incidence of RAPS like number, quality and expenditure.
Seinäjoki Central Hospital	
Typology:	Public hospital
Turnover:	Turnover: Hospital District of Etelä-Pohjanmaa, in western Finland. • 26 municipalities • 200 000 inhabitants • 1 central hospital • Total Beds: 590 • Conservative and operative treatment: 446 • Psychiatry: 164
Structure:	Personnel: 2.500 Doctor: 230 Research staff: 100

	Nurse: 900 Administration: 300	
HIS:	The Hospital has Oracle platform. They used electronic case sheet, database collection, and monitoring of RAPS.	
Policy of RAPS Management:	Has a special area of responsibility as a university hospital. Offers specialized services to the health care districts in the region and specialized nursing services to people in the local health care district	
REMINE pilot: Suupohja "Quality Elevation" (QE)		
QE Unit is the responsible of quality control, it manage the procedure of RAPS management.		
REMINE final user: Suupohja region		
Choice of Oncology Dept.	REMINE works as archives for collect all data, moreover thanks to risk management processes support and the interoperability among other departments (like chemistry' shop, ward, surgery, laboratories and operating rooms), REMINE could realize several scenarios. People Involved: Doctor: 3 Research staff: 1 Nurse: 2 Administration: 1	
IT infrastructure:	REMINE operations will be conducted in co-operation with the Regions eHealth research and service center www.eptek.fi	
Obj of pilot:	**Databases ownerships:**	All the data that will be used in the pilot belong to the regional hospitals, who have all the legal rights for using them in the pilot activities. REMINE will use two types of data: First: Data Security o Electronic case sheet; o Imaging of patient; o Audio of patient; o Patient' Anamnesis; o Family' Anamnesis. o Electronic case sheet (jointed patient' anamnesis, family anamnesis'), imaging and audio are based on GVD software. Second: Common Data o Company Guide Line; o Regional Guide Line; o National Guide Line; o Confederation Guide Line (e.g. World Heart Federation). The region has legal rights for modelling these data for communicating with H-ERP.
	Quantify Benefits:	
	Expenditure:	Expenditure: Legal expenditure and extra rectified budget amount to 4,5% of hospital medical departments budget.
OBJ of trial:	o to maintain and develop top-class know-how and expertise, o to develop continual progress in developing quality services for patients. o to develop Internationally recognized research work.	
Expected results:	In the project time scale the following objects need to be reached within REMINE pilot: • Evidence that RAPS can be reduced in significant ways.	

	• minimal impairment (or recovered within one month) less then 80% • injury or complication less then 50% • moderate impairment less than 15% • permanent impairment less than 1% • contributed to death less than 1% • Proof that the cost of care and administrative one can be significantly reduced at least of 70% • Proof that the cooperation amongst heath care professionals in and within the hospital can be improved at least of 80%

PILOT DESCRITPTION - SOUTH YORKSHIRE – THE ROTHERAM NHS FOUNDTION TRUST

Rotherham General Hospital is a modern, progressive hospital, situated two miles south of Rotherham town centre in pleasant suburban surroundings. The first phase of the development opened in 1978, phase two in 1984 and two major capital schemes, forming phase three, were completed towards the end of 1994. A major refurbishment of the main entrance area carried out in 1999 in partnership with the private sector resulted in the Trust now possessing some of the best reception facilities in the country; supported by cafes, major retail units and a cash-point machine. In addition the new 'Lord Scarbrough Macmillan Suite' has now been completed and has been helping patients since September 2005.

Another addition will be a pathology unit that will offer brand new accommodation and expansion to the department. The centre will be completed by 2007 and will offer much needed extra space for the Pathology unit's varied and vital work.
The hospital is a major provider of high quality health care in South Yorkshire and to the local population

SOUTH YORKSHIRE – THE ROTHERHAM NHS FOUNDATION TRUST	
Population:	Sputh Yorkshire has around 252.000 citizens.
Health Care System:	Health Care system is constituted by: • Primary health care o health centres • Secondary health care o 45 hospital districts o 10 university hospitals ° 15 central hospitals
Expenditure:	£ 20.895 million budget for public healthcare. Incidence of RAPS on Total Expenditure amount to £ 201.500.
HIS:	The South Yorkshire gave its institutes a microsoft windows environment, thus each institute extends its software.
Policy of RAPS Management:	Each organisation carries out research or technological development as one of its main objectives, for reduction of 7% of RAPS.
The Rotherham NHS Foundation Trust	
Typology:	NHS is a public hospital and moreover it is a research hospital and a community of GPs.
Turnover:	Patient visited annually: 73.000 Total Beds: 721
Structure:	Public Costituency:

	o Doctor: 1.305 o Nurse: 3.192 Staff Costituentcy: o Doctor: 103 o Nurses: 270 Other health medical personnel: o Professional: 120 o Supprto Staff: 135 o Other Staff Class: 377
HIS:	The Trust operates a predominately Microsoft Windows environment. The key Corporate IT systems include; Active Director Domain (Microsoft Windows 2000), Email (Microsoft Exchange 2005), Finance (Agresso) and Thin Client/Citrix. The Trust's major clinical systems are; Patient Administration System (McKesson's Totalcare PAS), Choose and Book, Radiology (McKesson's DM-Rad), Theatres (iSOFT's Galaxy Surgery system), Pathology (in-house), Picture-Archiving and Communications System (Accenture/AGFA PACS). Many of the clinical systems are linked via our Integration Engine (eGate's Interface Manager) For reporting and managing RAPS Trust adopts Accident & Emergency (Footman-Walker Associates' Symphony System).
Policy of RAPS Management:	NHS would offers always the best assistance to its citizens. Thus, Trust would remove RAPS.
REMINE pilot: The Rotheram NHS Foundation Trust "Accident & Emergency" (A&E)	
The Accident & Emergency Medicine Department provides care to people suffering from injury or illness requiring urgent treatment. The Rotheran NHS Foundation Trust sees approximately 73.000 patients a year, about 200 a day, this number having risen by a fifth (13,000) in the last five years. Whilst we will see anyone who attends the department, patients with long standing problems or minor illnesses should seek help from other areas such as their GP, Pharmacist or NHS Direct. If we feel you could receive treatment in a more appropriate place we will redirect you there.	
REMINE pilot: The Rotheram NHS Foundation Trust Haematology Dept.	
Choice of Haematology Dept.	REMINE collects data, from chemistry' shop, wards, surgery, laboratories and operating rooms, personnel shifts, then REMINE could monitoring the procedures respect and it could alert the anomalies. Doctor could create many scenarios modifying hypothesis (thanks to data collection, data mining, and risk management processes support), thus doctor could understand causes of error, predict possible of RAPS and reduce incident happening. One of department joints with: 1) operating room, 2) laboratories, 3) chemistry' shop, 4) ward, 5) surgery and that involved many employee is Haematology department. The Rotheran NHS Trust management choices Haematology Units for its size and number of patient turnover. The Clinical Haematology department caters for patients with diseases of the blood, both malignant and non-malignant. These can range from anaemia to complex leukaemias and lymphomas. The dedicated unit was created in 1997 and is made up of 9 inpatient beds, three of which are ensuite isolation cubicles for patients receiving in-patient chemotherapy, which suppresses the immune system. There are also facilities to accommodate day case patients in the Haematology Day Centre. The unit is very active caring for 650 in patient stays and 800 day cases per year. There are also 4.000 outpatient attendances each year. These numbers are increasing year on year. People Involved: Doctor: 5 Nurse: 10

<table>
<tr><td></td><td colspan="2">Lab technicians: 4
Administrative stuff: 2</td></tr>
<tr><td>IT infrastructure:</td><td colspan="2">The Trust's major clinical systems are:
Patient Administration System (McKesson's Totalcare PAS),
Choose and Book,
Radiology (McKesson's DM-Rad),
Accident & Emergency (Footman-Walker Associates' Symphony System),
Theatres (iSOFT's Galaxy Surgery system),
Pathology (in-house),
Picture-Archiving and Communications System (Accenture/AGFA PACS).
Many of the clinical systems are linked via our Integration Engine (eGate's Interface Manager).
As part of The Rotheran NHS Foundation Trust Health Informatics Strategy they will soon be implementing a new Corporate Information Data Warehouse (CACI) as well as conducting reviews of their Corporate Email, Integration Engine and Maternity system requirements.</td></tr>
<tr><td rowspan="3"></td><td>Databases ownerships:</td><td>All the data that will be use in the Pilot belong to Rotheran NHS Foundation Trust hospital. It has all the legal rights for using it in the pilot activities.REMINE will use two type of data:
<u>First: Data Security</u>
Electronic case sheet;
Imaging of patient;
Audio of patient;
Patient' Anamnesis;
Family' Anamnesis.
Electronic case sheet (jointed patient' anamnesis, family anamnesis') uses McKesson's Totalcare PAS.
Imaging and audio use Accenture/AGFA PACS.
<u>Second: Common Data</u>
Company Guide Line;
Regional Guide Line;
National Guide Line;
Confederation Guide Line (e.g. World Heart Federation).
The Rotheran NHS Foundation Trust has legal rights for modelling these data for communicating with H-ERP.</td></tr>
<tr><td>Quantify Benefits:</td><td></td></tr>
<tr><td>Expenditure:</td><td>The net effect of adverse error was to reduce the Trust's income by approximately £1.1M in 2005/06.
Balance sheet as at 31 March 2006 amounts to 92,598 (£000).</td></tr>
<tr><td>OBJ of trial:</td><td colspan="2">To improve the quality of care
To reduce RAPS and related costs (insurance, administrative and layers ones)
To improve the cooperation amongst health care professionals in and within the hospital in terms of environmental and working conditions
To improve the Multidisciplinary approach to health care,
To develop a ICT system to both monitor RAPS and predict and prevent them.
To Support for clinical and managerial research.</td></tr>
<tr><td>Expected results:</td><td colspan="2">In the project time scale the following objs need to be reached within REMINE pilot:
Evidence that RAPS can be reduced in significant ways.
minimal impairment (or recovered within one month) less then 50%
injury or complication less then 20%
moderate impairment less than 5%
permanent impairment less than 2%</td></tr>
</table>

	○ contributed to death less than 1% • Proof that the cost of care and administrative one can be significantly reduced at least of 60% • Proof that the cooperation amongst heath care professionals in and within the hospital can be improved at least of 60%

B1.3.2 Timing of Work Packages and their Components

REMINE project is made up of Work Packages each one lead by a project partner particularly experienced in the corresponding area, so as to ensure best practice and work efficiency. The Work Packages have been organized with the goal to keep the work divided into manageable units, small enough to be characterized by specific and measurable outputs.

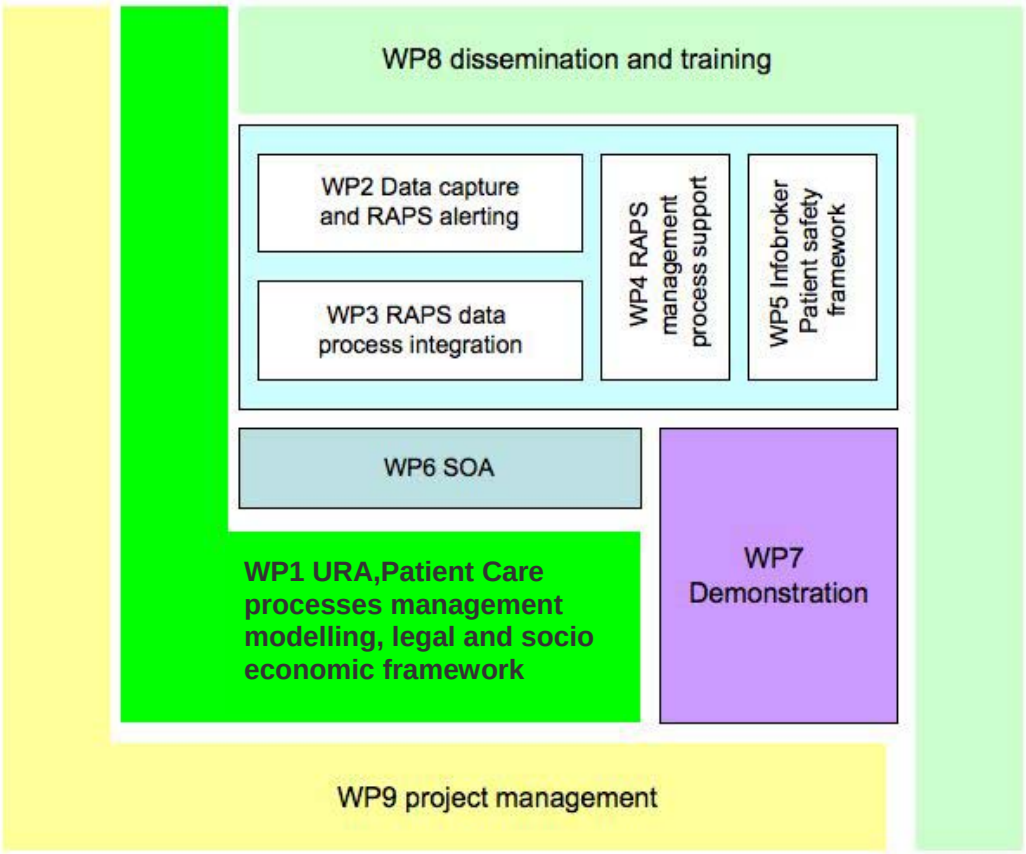
The identified Work Packages are:

- WP1 URA, Patient Care Processes Management Modelling legal and socio economic framework
- WP2 Data Capture and RAPS alerting
- WP3 RAPS data processing integration
- WP4 RAPS Management Process Support
- WP5 Infor Broker Patient Safety Framework
- WP6 Service Oriented Architecture and System Integration
- WP7 Demonstration
- WP8 Dissemination and training
- WP9 Project Management

The following paragraphs describe in detail the Workplan and the output to be produced.

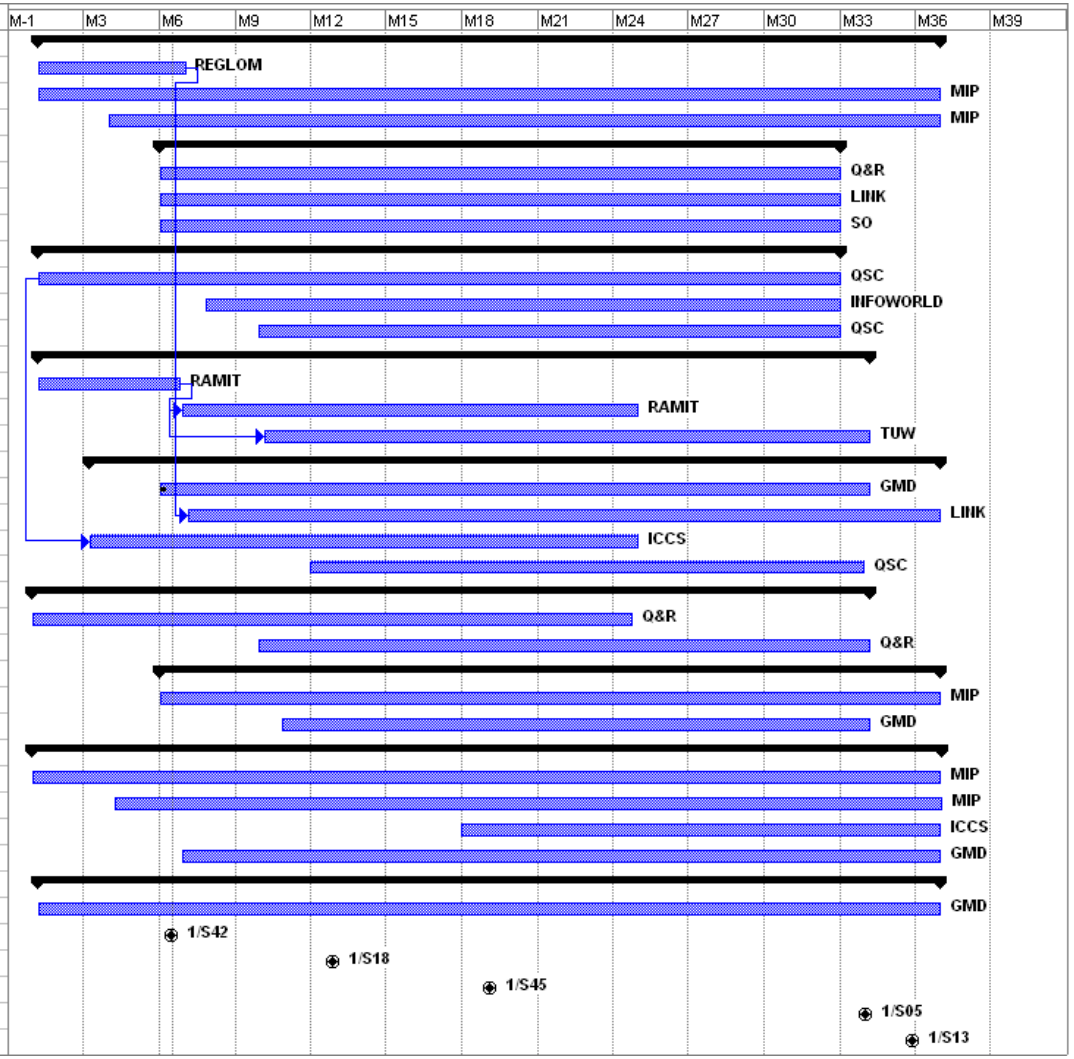
1.3.2.1 PERT Diagram

REMINE interrelation between work packages is give by the PERT diagram reported below.



1.3.2.2 Work package timing (GANTT Chart)

ID	
1	**WP1- URA, Patient Care Process Management Modelling, legal and socio-ec.**
2	T1.1 User needs and Requiremnts
3	T 1.2 Patient Safety Management Process modelling and scenario based design
4	T1.3 Remine Impact assessment, Legal and Socio-Economic Framework
5	**WP2 Data Capture and RAPS Alerting**
6	T2.1 RFID for data acquisition & identification of RAPS
7	T2.2 RAPS alerting for patient safety
8	T2.3 Data and Communication security
9	**WP3 RAPS Data process integration**
10	T3.1 Data and Process advanced store tool
11	T3.2 Metadatabase Semantic data integration def. And development
12	T3.3 Data Mining and Knowledge extraction
13	**WP4 RAPS management process Support**
14	T4.1 Develop and validate RAPS Taxonomy
15	T4.2 Ontology based error detection tool
16	T4.3 RAPS management Support System
17	**WP5 InfoBroker Patient Safety Framework**
18	T5.1 H-ERP Protocol and Operation definition interface
19	T5.2 Semantic Web services wrapper Framework
20	T5.3 RAPS Process Model
21	T5.4 RAPS Rules Model specialized for patient Safety
22	**WP6 Service Oriented Architecture and System Integration**
23	T6.1 Architectural Design
24	T6.2 Component Development Integration and QoS and test plan
25	**WP7 Demonstration**
26	T 7.1 UDTB deployment and assessment of organizational issues
27	T7.2 System Integration ,Testing and validation
28	**WP8 Dissemination, training and project exploitation**
29	T8.1 Dissemination Community Building, networking and standardisation actions
30	T 8.2 Assets and IPR management
31	T 8.3 Training and capability development
32	T 8.4 Project Explotation
33	**WP9 Project Management**
34	Project Management Activities
35	REMINE Milestone 1
36	REMINE Milestone 2
37	REMINE Milestone 3
38	REMINE Milestone 4
39	REMINE Milestone 5



B1.3.3. Work Package list/overview

Work-package No	Work package title	Type of Activity	Lead partic. no	Lead partic. Short Name	Person-months	Start month	End month
1	User requirement, Patient Care processes management modelling, legal and socio economic framework	RTD	5	MIP	112,2	1	36
2	Data Capture and RAPS alerting	RTD	1	GMD	90,4	6	33
3	RAPS Data processing integration	RTD	15	Info World	127,9	1	33
4	RAPS Management process Support	RTD	9	TUW	51,4	1	33
5	Info Broker Patient Safety Framework	RTD	8	SO	111,7	3	33
6	Service Oriented Architecture and system Integration	RTD	1	GMD	76,2	2	36
7	Demonstration	DEM	14	MIP	146,6	1	36
8	Dissemination, training and exploitation	OTH	5	MIP	64	1	36
9	PM	MGT	1	GMD	51,7	1	36
	TOTAL				**832,1**		

B1.3.4 Deliverable list

The following table contains the list of the deliverables that will be produced during the project. Multiple delivery dates mean the deliverable will be released in updated versions.

Del. No	Deliverable Name	WP No	MM	Nature	Dissemination Level	Delivery date (Project .month)
D1.1	User needs and requirements	1	50,4	R	PU	M6
D1.2	Patient Safety management process , modeling and scenario based design	1	50,6	R	PU	M12, M36
D1.3	REMINE legal implication	1	4,3	R	PU	M24, M36
D1.4	Impact assessment	1	7	R	PU	M24, M36
D2..1	First Revision of Digital Input Multimedia Data Platform (DIMDP)	2	6	O	PU	M12
D2..2	Third Revision of Digital Input Multimedia Data Plantform (DIMDP)	2	5	O	PU	M32
D2.3	First revision of real time RAPS alerting for patient safety	2	10	O	PU	M12
D2.4	Third revision of Real Time RAPS alerting for patient safety	2	9	O	PU	M32
D2.5	First, revision of data communication security	2	15	O	PU	M12
D2.6	Third revision of data communication security	2	9	O	PU	M32
D3.1	Data&Process model System Semantic specifications and rules	3	6	R	PU	M12
D3.2	Classification and identification of risk event using BPM process	3	6	R	PU	M12, M24
D3.3,	First revision of Data&Model process system framework	3	5	R	PU	M12,
D3.4	Third revision of Data&Model process system framework	3	5	R	PU	M32
D3.5	First revision of WP3 framework (including RTRMAS and PPRMAS),	3	31	O	PU	M12,
D3.6	Third revision of WP3 framework (including RTRMAS and PPRMAS),	3	25	O	PU	M32

Del. No	Deliverable Name	WP No	MM	Nature	Dissemination Level	Delivery date (Project .month)
D3.7	First revision of the data mining and knowledge extraction module	3	7	O	PU	M12
D3.8	Third revision of the data mining and knowledge extraction module	3	7	O	PU	M32
D4.1	RAPS Taxonomy approach and definition	4	4,6	R	PU	M6
D4.2	RAPS domain ontology	4	6	O	PU	M6, M18
D4.3	RAPS application ontology	4	6	O	PU	M6, M24
D4.4	Multilingual RAPS taxonomy	4	5,9	O	PU	M24
D4..5	Documentation of formalized guidelines	4	6	R	PU	M6
D4.6	Documentation of prototypal implementation of the guidelines Execution engine	4	6	R	PU	M12, M24
D4.7	First release of Adverse Risk Management Support System,	4	6	O	PU	M12,
D4.8	Third release of Adverse Risk Management Support System,	4	6	O	PU	M33
D5.1	H-ERP component interface coordinator first revision	5	15	O	PU	M12,
D5.2	H-ERP component interface coordinator third revision	5	8	O	PU	M33
D5.3	Wrapper engine for: Lab	5	4	O	PU	M12, M24, M36
D5.4	Wrapper engine for:Drugs	5	4	O	PU	M12, M24, M36
D5.5	Wrapper engine for: Nosocomial	5	4	O	PU	M12, M24, M36
D5.6	Wrapper engine for: Clinical. Path	5	3,8	O	PU	M12, M24, M36
D5.7	Technical Specification Adverse Clinical rules model specialized for patent safety	5	8	R	PU	M6, M12, M24
D5.8	First Revision of adverse clinical rules model specialized for patient safety component	5	8	O	PU	M12,
D5.9	Third Revision of adverse clinical rules model specialized for patient safety component	5	7,5	R	CO	, M33
D6.1	Remine architecture specification (general. Technical, environment and pattern, SW components)	6	32,3	R	CO	M12, M24

Del. No	Deliverable Name	WP No	MM	Nature	Dissemination Level	Delivery date (Project .month)
D6.2	SW component test plan and QoS evaluation metrics	6	10	R	CO	M12, M24
D6.3	First Platform REMINE prototype	6	10	O	PU	M12,
D6.4	Third Platform REMINE prototype	6	12	O	PU	M33
D7.1	UDTB deployment and assessment	7	73,2	R	PU	M12, M36
D7.2	Pilots test environment definition	7	20	R	CO	M12, M24
D7.3	REMINE first pilot platform	7	20	O	PU	M12
D7.4	REMINE third Pilots Platform	7	20	O	PU	M33
D8.1	Project Website	8	1,5	O	PU	M3
D8.2	Dissemination Plan	8	4,5	R	PU	M6
D8.3	harmonization plan for the REMINE framework	8	2	R	PU	M12, M36
D8.4	Promotional/informational materials and multimedia dissemination materials	8	1,2	O	PU	M12, M24, M36
D8.5	Report on the dissemination, a networking activities and dissemination activities on standardization bodies	8	4	R	PU	M12, M24, M36
D8.6	State of Art about the intellectual property rights	8	19,7	R	PU	M24, M36
D8.7	Skills analysis and training strategy and plan	8	3	R	PU	M12
D8.8	Accessible e-Training platform	8	3	O	PU	M12
D8.9	Report on Training activities	8	2,7	O	PU	M12, M36
D8.10	Business Modelling, market analysis, Individual consortium members and consortium as a whole exploitation strategies and plans	7	18	R	CO	M12, M36
D9.1	Quality control report	9	16	R	CO	Every six months
D9.2	Periodic Management reports at the time of each project financial costs statement as from grant agreement	9	16	R	CO	M12, M24, M36
D9.3	Final Project Report	9	8	R	CO	M36

- Effort for Deliverable list: **664,2 MM**
- Effort remaining for ID: **167,9 MM**
- **Total effort: 832,1 MM**

B1.3.5 Work Package Descriptions

WP number	**1**			**Start date or starting event:**		**M1**
WP title	**User requirement, Patient Care processes management modelling, legal and socio economic framework**					
Activity type	**RTD**					
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	15,2	6,2	5,2	3	4,9	2,1	11,5
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	2,1	3,6	8,8	13,6	9,2	16,7	6,4
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	3,9						

Description

This WP is responsible to provide:

- Definition of data available and to be included in the System
- In deep analysis of Clinical and non-Clinical Risk Management (C&nCR) experiences with their processes, workflows, rules
- Definition of the User Requirements

The main achievements at each milestone are:
M1: Data Model is envisaged in the development of task 1.2.
M2: User requirements will be completed within task 1.1, and will include complete specifications of the User requirements.

In the workpackage all data providers (Regional authorities as well as hospitals) are involved.

Task number	**1.1**			**Start date or starting event:**			**M1**
Task title	**User needs and requirements (RTD)**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	**REGLOM**	SEK	TRFT	QSC	HP	SO
Person-months per participant	7,6	2,3	1,7	0,7	2	1	5,7
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	0,6	0,9	4,4	6,3	4,1	8,1	3,2
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	1,9						

Objectives:

- to provide REMINE project user requirement analysis.

Description of work

S.ub.Task 1.1.1 Analysis of existing patient safety processes and workflows, and definition of users needs

- Comparative and in-depth analysis of existing patient safety workflows and processes, as implemented in the Hospitals involved in the pilot demonstration; analysis will return models and profiles for each informative system and procedure under analysis, and will be conducted according to .
- User needs analysis will be performed, to explicit high-level clinical risk management and decision-making needs to be supported by the system; user needs will be referred to key patient safety goals to be attained. The sub-task will specify high-level objectives to be achieved.

Sub. Task 1.1.2 Definition of organizational requirements

- An in-depth organizational requirements analysis will be produced; analysis will specify key profiles, working procedures and informative workflows to be implemented in healthcare local units and hospitals in order to reach user needs as from S.1.1.1.
- Organizational requirements will be modulated for each Hospital involved in the pilot demonstration, in order to specify the organizational gap to be filled up for a successful implementation of novel informative workflows as specified in S.1.1.1.

Sub. Task. 1.1.3 Definition of users requirements

- User requirements analysis and definition will specify both functional and non-functional requirements the overall system will conform to. User requirements will also specify required system responsiveness and interoperability. User requirements will be gathered by applying suitable methods such as interviews, focus groups and/or surveys and questionnaires to a proper representative panel of perspective users and/or domain experts.

Deliverables (brief description and month of delivery)

D.1.1 User needs and requirements (M6)

Task number	**1.2**			**Start date or starting event:**			**M1**
Task title	**Patient Safety management processes modelling and scenario based design (RTD)**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	5,7	3,8	3,4	2,1	3	1	5,7
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	0,6	0,9	4,4	7,3	3,1	4,5	3,2
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	1,9						

Objectives

- to Model of patient safety management processes.
- to design Scenario based.

Description of work

This task will be focused in the analysis and modelling of the data collected in real contexts of use, and will include the following subtasks

Sub.Task 1.2.1 Mapping of information sources: existing literature, and analysis of information flows from the content providers involved

- Evaluation of criteria for clinical risk assessment: Definition of criteria for the mapping of information sources: according to their impact on clinical *risk assessment*
- Evaluation *of criteria for non*-clinical risk assessment. Definition of criteria for the mapping of information sources: according to their impact on non-clinical risk assessment
- Evaluation of information sources reliability related to safety improvement in clinical and non-clinical critical areas: with special attention to Drug Management, Lab Management, Nosocomial infections management and Disease Management
- Definition for eventual new sources in the critical areas defined in S1.2, for the collection of data not covered by available information sources

Sub.Task.1.2.2 Data modelling once defined the map of information sources, data available in the existing informative systems will be collected and analyzed, in order to specify the rules for REMINE platform development.

Deliverables (brief description and month of delivery)
D.1.2 Patient Safety management process and modelling and scenario based design (M12; M36)

Task number	**1.3**			**Start date or starting event:**			**M4**
Task title	**REMINE impacts assessment, legal and socio economic framework (RTD)**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	1,9	0,2	0,1	0,1	-	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	**MIP**	INFO WORLD
Person-months per participant	0,9	1,8	-	-	2	4,2	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

- to develop an RAPS process management and legal framework;
- to facilitate the needed change and/or definition of the key organisational and institutional issues;
- to contribute to user requirements analysis and elaborate and implement an effective utilisation strategy;
- to produce an Evaluation and Measurement Conceptual Framework and its Implementation Methodology.

Description of work
This task is divided into two sub.task:

Sub-Task 1.3.1: Organisational and institutional and legal analysis and change management factors

- Organisational, institutional and legal analysis and implications will be conducted under this sub-task by extract list of key issues from the results of the state of the art review;
- to corroborate and improve the major findings elaborated from the state of the art review; will be conducted field studies through interviews and participants observation;
- Analysis of the future trends in terms of RAPS management processes implications by organisational, institutional and legal point of view will be also conducted.
- A change management and communication plan;
- Ad hoc workshops with the major stakeholder, in order to facilitate RAPS processes change management, will be carried out.
- Compliance with requirements set by Directive 95/46 confidentiality and privacy issues will be outlined;
- Clearance from local ethical committees will be obtained by each pilot sites before entering the demonstration phase.

Sub-Task 1.3.2: Multi-dimensional socio-economic framework for REMINE impact assessment
This activity is based first on meta-analysis of multi-disciplinary literatures reviews, combined with direct interviews within the major project stakeholders.
Then the second activities foreseen in this sub task is to develop and implement an Evaluation and Measurement Framework Analytical Model (EMFAM) for measuring the impact of the project and its potential. For achieving it the following steps are foreseen:

- Integrating the most promising contributions identified in the state of the art review elaborate a first Evaluation and Measurement Framework Analytical Model (EMFAM v. 0), identifying the main areas of outcomes and the logic model relationship between input, output, outcomes;
- Discuss the EMFAM with stakeholders and produce EMFAM v. 1 taking into accounts the results of stakeholder consultations;
- Add to the EMFAM v.1 the identification of the relevant metrics and of the needed data;
- Discuss with all stakeholders the relevance and feasibility of the identified metrics and data and produce EMFAM v.2 with revised metrics and data sources;
- Develop and implementation methodology and produce a manual for the application of EMFAM v.3, including: a) research design, processes and responsibility for data gathering; b) data elaborations techniques and protocols, c) sensitivity analysis techniques;
- Support the design of training programme aimed at enabling living labs of the project to implement EMFAM v.3 and its implementation methodology (wp8).
- Assess the results of the pilots demonstration (wp7) on economy' (spending less) and 'efficiency' (spending well) outcomes such as:
  - Avoided costs through less in-patients days due to re-admission and other effects of RAPS;
  - Less unit cost for diagnosing and treating patients with simple disease since the full proof alert and warning systems could convince hospitals to have such patients managed mostly but less expensive HCPs;
  - Decreased Cost of Quality, since the automated quality control functionalities embedded in REMINE will decrease the need of using personnel in the quality management system;
  - Decreased costs of hospital insurance from reduction of malpractice litigation;
  - Decreased opportunities for 'moral hazard' (unnecessary treatment prescribed only for receiving reimbursement) as alert and warning might spot inappropriate prescribed treatment given patient history.

Deliverables (brief description and month of delivery)
D1.3 REMINE legal implications M24; M36
D1.4 Impact assessment M24; M36

WP number	**2**			**Start date or starting event:**			**M6**
WP title	**Data capture and RAPS alerting**						
Activity type	**RTD**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	16,1	2,4	2,6	1,5	-	4,2	22,9
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	21,9	18,8	-	-	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Description

The WP aims to develop a "Data capture and RAPS alerting" that helps the hospital personnel (HP) to do their work and in the same way to guarantee the patient safety in relevant RAPS.
By creating of Digital Input Multimedia Data System (DIMDS) will be possible to develop new tools for prediction, detection and monitoring of Patient RAPS in real time (RAPS alerting for patient safety).
The WP will be organize in different tasks that will guarantee the achievement of the WP goals.
By RF-ID or Barcode technology, the responsiveness system can help the hospital personnel to fill the EHR in automatic way without to surf within the innumerable menus. More over by creating of RAPS alerting platform and integration with EHR and integration with clinical guide lines it will be possible to avoid clinical error or data entry error in real time to guarantee the patient safety.
Security issues within this WP will be faced through a multi-layer approach, starting from the low level security (integrated with the acquisition technology, i.e. RFID, or multimedia data acquisition), going through the communication security in terms of channel and in terms of protocols/languages/sessions. The next point above this faces the privacy, authentication, authorization and non repudiation issues related to the communication and to the alerting delivery. Finally, the complex interaction issues among different heterogeneous knowledge bases (including research activity in the IDM field) will be considered.

The Tasks to achieve this WP are:

- Task 2.1 RFID for data acquisition and identification of RAPS (Digital Input System).
- Task 2.2 RAPS alerting for patient safety
- Task 2.3 Data and Communication security

The main achievements are:

- Digital Input Data module
- RAPS Alerting module
- Security guide lines

Task number	**2.1**			**Start date or starting event:**			**M6**
Task title	**RFID for data acquisition & Identification of RAPS**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	0,8	0,9	0,4	-	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	21,9	-	-	-	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

This task aims at developing a Digital Input Multimedia Data Platform (DIMDP) that will allow a hospital personnel (HP) to interact with the patient and the REMINE systems and it will allow in real time to fill the EHR in automatic way, without to surf within the innumerable menus.

Focus will be on following aspects:

- To develop Digital Multimedia Data Input System (DMDIS)
- To develop RAPS Classification and Identification System (RCIS)
- To Integrate DIMDP with REMINE system

Description of work
The work of this task will be composed into the following subtasks

Sub-Task 2.1.1 Digital Multimedia Data Input System (DMDIS)
This subtask is focused on

- developing a multimedia data capture system to take hold of the patient events during the moving of the hospital personnel around to the patient. It will be possible by integration of RFID and/or Barcode tag technology to identify hospital object like drugs, clinical device, Diagnostic Medical Imaging devices, medical instrument: stethoscope, thermometer, etc…. More over it will be possible to capture multimedia data from any kind of digital device like Diagnostic Medical Imaging devices (Computed Axial Tomography-CAT scan and muliscan devices, Magnetic Resonance Imaging-.MRI devices, Positron Emission Tomography-PET devices, X-Ray devices, Ultrasound devices, etc...), clinical digital device, digital medical instrument.
- integration DIMDS with Electronic Health records (automatic filling) to storage the patient events.

Sub-T.2.1.2 RAPS Classification and Identification System (RCIS)
This task is focused on

- identification "voluntary actions" of the hospital personnel during the moving around to the patient;
- semantic classification and recognition of "clinical events" given to the patient by two things
  - the identification of a items group: hospital items (drugs, clinical device, medical instrument: stethoscope, thermometer, etc…, Diagnostic Medical Imaging devices: Computed Axial Tomography-CAT scan and muliscan devices, , Magnetic Resonance Imaging-.MRI devices, Positron Emission Tomography-PET devices, X-Ray devices, Ultrasound devices, etc...), patients and hospital personnel;
  - the data and information from Knowledge extraction (WP 4) and semantic interface (WP4)
- freedom to refuse or to accept the patient events from hospital personnel;
- integration RCIS with REMINE system.

Deliverables (brief description and month of delivery)
I.D. Digital Multimedia Data Input System (DMDIS) (M6)
I.D. RAPS Classification and Identification System (RCIS) (M6)
D.2.1 First Revision of Digital Input Multimedia Data Platform (DIMDP) (M12)
I.D. Second Revision of Digital Input Multimedia Data Platform (DIMDP) (M18)
D.2.2 Third Revision of Digital Input Multimedia Data Platform (DIMDP) (M32)

Task number	**2.2**			**Start date or starting event:**			**M6**
Task title	**RAPS alerting for patient safety**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	0,8	0,9	0,6	-	4,2	11,5
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	-	18,8	-	-	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

This task aims at developing RAPS alerting tool to help and support hospital personnel during their work and to guarantee patient safety. By Knowledge extraction (from REMINE system integrated with Digital Input Multi-medial Data Platform it possible to develop tools to prediction, detection and monitoring RAPS of the patients.
Focus will be on following aspects:

- to develop Incident alerting real time that helps and supports hospital personnel during their work in the ordinary work of the hospital personnel in real time in the hospital ward.
- to Integrate with hospital environment and REMINE system

Description of work

The task 2.2 Real Time RAPS alerting for patient safety is focused on

- Development of real time alert system that can capture clinical error of hospital personnel. It will develop comparing to data from Digital Input Multi-medial Data Platform with roles form real time Knowledge extraction
- Integration real time RAPS allerting for patient safety with Remine System to permit to identify in real time the RAPS for the specific patient.

This task needs to rules and data from Data Mining and Knowledge extraction (Task 3.3) and Digital Multimedia Data Input system (subtask 2.1.1).

Deliverables (brief description and month of delivery)

I.D. Real Time RAPS alerting for Patient Safety (RTASPS) (M6)
D.2.3 First Revision of Real Time RAPS alerting for Patient Safety (RTASPS) (M12)
I.D. Second Revision of Real Time RAPS alerting for Patient Safety (RTASPS) (M18)
D.2.4 Third Revision of Real Time RAPS alerting for Patient Safety (RTASPS) (M32)

Task number	**2.3**			**Start date or starting event:**			**M6**
Task title	**Data and Communication security**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	**SO**
Person-months per participant	16,1	0,8	0,9	0,6	-	-	11,5
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	-	-	-	-	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives
Objectives of this task are to provide:

- RFID Security
- Network security
- Communication Security
- Application security
- Security of infrastructural aspects
- Security related to access management aspects

Description of work

Sub-Task 2.3.1 RFID Security

For what concerns the security aspects related to RFID technology, the two main existing technologies bring different ranges of topics:

- For Passive RFID, a careful design of the interaction with the data acquisition points is required, in order to prevent the new RFID related menaces from exploiting
- Middleware weaknesses
- database weaknesses
- For Active RFID, additional issues arise in terms of interference (either malicious, with other RFIDs, or accidental, with the different medical appliances

In this task these aspects will be faced and guidelines for the RFID technologies application within the whole architecture will be issued, including solutions for these practical issues

Sub-Task 2.3.2 Network security, Communication Security and Application security

The topic of the network security is always present in the development of distributed applications/architectures. In particular, in the envisioned scenario which includes portable devices interacting with distributed databases, both the following infrastructures will exist and thus need to be designed according to the best practices, in particular facing the issues mentioned below:

- Wireless networks
  - the connection among the mobile terminals (involved in the process of data acquisition from RFID or barcodes) and the Health structure network has to be protected at layer 2 level
  - exploitation of currently available technologies, also considering new emergent compositions (on-the-fly ad-hoc network, etc.)
- Wired networks
  - A careful design of the infrastructure, joint with provisioning of physical security in order to prevent undesired accesses to the infrastructure itself (unauthorized modems/access points/etc.)

Once the infrastructure security is granted at a physical/link layer, the next necessary step is to be sure that channel/protocol security at transport and application level is achieved. In fact, most of the acquired data will be related to personal and sensitive information, thus there is a strong requirement for security in the data transfer, according to the classical approach for data subject (possibly) to loyal rules or constraints. In particular, the points to be assured within the overall architectural design are:

- Privacy
- Non-repudiation
- Authenticity
- Integrity

At a higher level, the whole application workflow (as well as the underlying process) will be carefully designed in order to take into consideration authentication/authorization aspects, namely giving an answer to the following questions:

- Who can interact with this patient?
- Who can access this document?

In this field, an approach based on profiles definition and data structuring will be adopted in order to grant the required privacy level.

Sub-Task 2.3.3 Security of infrastructural and access management aspects

Infrastructural aspects (mostly development and evaluation):

Since the aspects related to infrastructural security in interconnected/federated knowledge bases are well known and quite similar to many other kinds of large and distributed service infrastructures, this topic will be faced mainly from an "actual implementation" point of view, mainly for the three points below.

- Data persistency
- Disaster recovery
- Contingency planning.

The state of the art in these fields includes a number of possible solutions and methodologies for each of the considered aspects, but they have to be evaluated in terms of effectiveness and performance and a suitable composition among them has to be identified for each case. In particular, considered aspects will be related to:

Access Management aspects (mostly research):

The matter of the IDM (Identity management) can be faced by a twofold point of view, which includes:

- Administrative/ Applicative accesses (to be reduced as much as possible, due to high risk of data compromising and anonymity in operations)
- Personal accesses (carefully designed, with a rich log enforcement)

In particular, innovative solution will be studied and developed in the fields of:

- Identity management in a multi-DB environment, in particular studying and developing aspects of federated
- identity (thus considering current and evolving approaches)
- Semantic approach to security and access to information
    - Semantic-based anomaly detection
    - On-the-fly additional credentials
        - Emergency access to critical resources (the approach: do not think only about how to deny, but also on how to allow)
        - Personal involvement and responsibility assumption for temporary access

Deliverables (brief description and month of delivery)

- Guidelines for access technology security deployment
- Network security planning document
- Communication Security design document
- Guidelines Application security, including design and user access aspects
- Security of inter-database infrastructural aspects design document
- Report on identified methodologies for security related to access management aspects
- Overall security evaluation report

D.2.5 First Revision of Data and Communication security (M12)
I.D. Second Revision of Data and Communication security (M18)
D.2.6 Third Revision of Data and Communication security (M32)

WP number	3			Start date or starting event:			M1
WP title	RAPS Data process integration						
Activity type	RTD						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	3,2	4,3	2,7	16,7	-	31
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	**INFO WORLD**
Person-months per participant	-	-	20,8	-	15,2	-	24
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	9,9						

Description

The WP aims to develop the REMINE data environment, thus in this WP REMINE will integrate all the data need for the behaviour to build an risk management system for better the patient safety.
The Tasks to achieve this WP are:

- Task 3.1 Data&Process advanced store tool .
- Task 3.2 Metadatabase semantic data integration definition and development
- Task 3.3 Data Mining and knowledge extraction

The main achievements are:

- Digital Input information storage
- Development of a Metadatabase for data integration
- RAPS mining and semantic information integration
- Development of the component communication infrastructure layer

Task number	**3.1**			**Start date or starting event:**			**M1**
Task title	**Data&Process advanced store tool**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	**QSC**	HP	SO
Person-months per participant	-	0,8	0,9	0,9	8,1	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	-	-	7,1	-	11,7
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

This task aims at developing a technological infrastructure where it is possible store inside the metadatabase in a semantic format all the information that can not be acquired directly from the WP2 , thus process that are not in any digitalized form but that need to REMINE in order to achieve the overall goal to reduce risk and increase patient safety.

Description of work
The work of this Workpackage will be composed into the following tasks

Sub-Task.3.1.1 Semantic identification
This task is focused on

- Identification of the semantic structure to store the entire set of data arriving from WP2 and WP1)
- Definition and developing of the semantic API interface layer to and from the Metadata base "
- Usage and access of External data , Rules and process definition

Sub-Task.3.1.2 Information acquisition and storage (DIS)
This task is focused on

- Developing a tool that using BPM process allow not technical user to input and store inside the Metadabase all the information that are in paper format, human historical process (people common and ordinary process), oral procedures , de-facto rules. All this information will be stored using a semantic metadata structure and organization.
- developing all the API interface need to connect this module with other REMINE module in order to exchange data and process information .
- integration and storage of process building block using metadata structure

As a support to this activity, in order to strengthen its outputs, structured workgroup on living prototype with the main Hospital representatives (stakeholders such as doctors, nurses, hospital attendants) will be carried out. This activity will enhance a bottom-up approach and will provide a large amount of information for the validation of the data and process collected.
Finally, data and process standardisation and cataloguing through semantic classification will be performed.

Deliverables (brief description and month of delivery)

D.3.1 Data&Process model System Semantic specification and rules (M12)
D.3.2 Classification and identification risk event using BPM process (M12; M24)
D.3.3 First Revision Data&Process model System framework (M12)
I.D. Second Revision of Data&Process model System framework (M18)
D.3.4 Third Revision of Data&Process model System framework (M32)

Task number	3.2			Start date or starting event:			M8
Task title	Metadatabase semantic data integration definition and development						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	1,2	1,7	0,9	-	-	31
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	**INFO WORLD**
Person-months per participant	-	-	20,8	-	-	-	12,3
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	9,9						

Objectives:

This task aims at developing a metadabase structure where all the REMINE information will Focus will be on following aspects:

- to develop Incident alerting real time and Post process Incident alerting based on mining technique
- to develop a knowledge extraction system based on REMINE metadatabase
- Integration with wp2, wp4 and wp5

Description of work

This task is focused on

- Developing a Sofware and hardware structure that host the Metadatabase environment
- Develop a flexible structure for recording data
- Incorporate data from other relevant sources with attention to security and access
- Develop a structured framework for developing a data management system
- collect all the data that could be useful for analysis purpose- efficient and effective data collection and representation for the purpose of further data mining analysis.

A metadatabase is a tool that is used to access 'information about information'. At one level it can be described as a catalogue, but it can be much more than a simple listing of data sets. At a more complex level it can provide the means to easily share and access data between users and sites, to identify gaps and weaknesses in the data, to assess the value and need for new databases, and to monitor the currency and usefulness of data. Thus, it is an integral component of the research planning and management process and it does not stand alone. This last point is critical. A metadatabase that is not underpinned by a corporate policy on information management is unlikely

to achieve the goals of its creators. Without this support we may develop a very nice metadatabase, but not actually make effective use of it!
An important function of a metadatabase is to feed information about data back to the user (both human and software) . An efficient data management system should bridge the gap between collecting the data and making the datasets available for analysis or for use by other component . This includes the ability to query the database to identify data relevant to specific tasks or needs, some of which would not have been thought of when the data were collected. It also requires a mechanism to feed the information back to the users. The ease with which users can access the database is a critical factor. Training may be required to ensure that this is done with ease.
Given different needs for data and immense differences between the data that may exist in multi-disciplinary organisations such as Hospital , it may be necessary to establish tiers of information and detail for users. The tiers should be constructed to avoid burdening users with information that they do not require. Such tiers may also be useful for the exchange of information between metadatabases maintained by other organisations. The structure of the database should firstly serve the needs of the current users, but decisions that restrict future (and even unknown) uses should be very carefully considered. Security of data is necessary, but this should not be an excuse for limiting the usefulness of the data. It was specifically emphasised several times that eriss/oss should firstly identify its critical or core need for a metadatabase and then involve the users in the developmental process. With the users behind the process and with strong corporate support the reward should be a metadatabase that meets the needs of both the individual users and the hospital body. Once this basic planning process has been established those responsible for developing and implementing the task need to concentrate on the following:

- What data are available?
- Where are the data located?
- How are the data described?
- Who has access/possession of the data?
- What condition are the data in?
- Are the data secure?

This task will follow the establishment of a metadatabase it is essential to not only describe the data, but to also assess their quality and potential usefulness. Simply, are the data useable? Are they reliable? If there are question marks over the accuracy or usefulness of the data these must be attached to the entry in the metadatabase. If, for any reason, this assessment has not been done, or cannot be done, this should also be recorded. The level of documentation available with the data will prove critical in this process. Poorly documented data are extremely difficult to deal with. Any doubts about the data must be expressed. Where possible, contact names should be given, but it is recognised that if such people have left the organisation these may not be very useful.

Deliverables (brief description and month of delivery)

D.3.5 First Revision of the WP3 framework (Including RTRMAS and PPRMAS) (M12)
I.D. Second Revision the WP3 framework (Including RTRMAS and PPRMAS) (M18)
D.3.6 Third Revision of Adverse the WP3 framework (Including RTRMAS and PPRMAS) (M32)

Task number	**3.3**			**Start date or starting event:**			**M10**
Task title	**Data Mining and knowledge extraction**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	**QSC**	HP	SO
Person-months per participant	-	1,1	1,7	0,9	8,7	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	-	-	8	-	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives This task aims at developing a datamining procedure and structure and the relative structure of knowledge extraction in order to use the output of Mining and discovering both for a user interface dashboard and as input for others REMINE components.

Description of work
The work of this task will be composed into the following sub-tasks

Sub-Task.3.3.1 Mining and incident report system
This sub.task is focused on

- collect all the data that could be useful for analysis purpose- efficient and effective data collection and representation for the purpose of further data mining analysis.
- apply data mining and path discovery techniques in order to discover relation and "characteristic" among data- enhance data mining techniques for heterogeneous data sets.
- define a error reporting tool- reliable module responsible for presentation of the data mining results and also for sending alerts in case of high risk case discover.

Description of work
Health organizations in our modern society become large and complex to provide more advanced services due to the growing variety of social demands. Such organizations are highly efficient for the routine work processes but known to be weak to control unexpected matters. According to this observation, the importance of the organizational risk management has been noticed in recent years. On the other hand, the accumulation of a large amount of data on the work processes is going on under the introduction of information technology to the organizations. This data can be used to efficiently manage the risks in the organizations. This task focuses on the data mining techniques to detect and analyze the risks potentially existing in the organizations and to utilize the risk information for better organizational management and for use the same information as data for the Decision support Model.

Database management systems are the most effective way to document and communicate risk information using the latest information technology. This task is proposed to bring in both of the areas of data mining and risk management reporting, and to have intensive discussions on various aspects on the data mining based risk management.

Topics

- Data mining for risk management
- Chance discovery for risk management
- Active Mining for risk management
- Machine learning for risk management
- Other techniques for detection, analysis and utilization of risk information
- Semantic Mining validation on Multimedia DataBase

Moreover tools are required to support each step of the risk management process. Risk identification tools include questionnaires and analytical tools which focus on the threat areas. Risk analysis reporting tools are qualitative and quantitative instruments based upon the Key Performance Indicators. These same tools are also used to judge the predicted effectiveness of risk handling plans and to select the optimal portfolio of handling strategies. A system for reporting risk control metrics helps to ensure the consistency, completeness, and timeliness of risk control decisions.

The purpose of the Data Mining component for REMINE Project is to extract pathways of medical malpractice from the database that contains the range of data describing patient treatment and state of health. Such profile is a set of information that characterizes a group of patients with similar features. It's created using a clustering procedure. This procedure is based on the features that characterize the treatment. The final output of this approach is the extraction of the centroids of the clusters that constitute the patient treatment profiles. System matches most similar cases to reduce risk factor by preventing wrong diagnosis and treatment. To create the data mining based reporting module REMINE could use various methods for example -Bayesian networks that will allow modeling expert knowledge relative complete risk chain. It would exploit all the power of unsupervised learning to extract from patient health record data the set of probabilistic relations that are really significant, and then to identify the probabilistic links between risk factors. The module would exploit knowledge discovery to extend the understanding of the dependencies between particular treatment and possible threats. Supervised learning will allow characterizing main risk by finding the minimal subset of risk factors that are really important. The module will be able to take into account expert knowledge and experience feedback (with respect to outcome from data mining module applied to records from the data repository, as well as doctor's experience).

The module will enable testing various levers effects (e.g. action that can reduce the risk) by adding nodes to Bayesian networks. Risk analysis helps to understand probabilistic models: analysis of the strength of the relations, analysis of the interaction between main risk variable and the other variables, analysis of the relations linking all the variables with a
specific value of main risk variable, contradiction analysis to know if all the evidences support the same conclusion or if there are some contradicting evidences.
System will also be able to "play" with models to easily test new hypothesis by carrying out what-if-scenarios.

Sub-Task.3.3.2 knowledge extraction system
This sub.task is focused on

- Develop a framework that using the information provided by the data mining module will allow the output management on the information stored inside the metadatabase.
- collect all the data that could be useful for analysis purpose- efficient and effective data collection and representation for the purpose of further data mining analysis.
- Let user relate with data mining and path discovery techniques in order to discover relation and "characteristic" among data- enhance data mining techniques for heterogeneous data sets.
- define a error reporting tool- reliable module responsible for presentation of the data mining results and also for sending alerts in case of high risk case discover.
- Develop a user interface tool on which Health operator can participate actively to the process of knowledge extraction
- Develop an infrastructure that manage the technical interface (API) for the real time risk management alerting system (RTRMAS) and for the post process risk management alerting system (PPRMAS)

Deliverables (brief description and month of delivery)
D.3.7 First Revision of the data mining and knowledge extraction module (M12)
I.D. Second Revision the data mining and knowledge extraction module (M18)
D.3.8 Third Revision of the data mining and knowledge extraction module (M32)

WP number	4	Start date or starting event:	M1
WP title	RAPS Management process Support		
Activity type	RTD		

Participant number	1	2	3	4	6	7	8
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	2,4	2,8	2,7	-	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	9,3	8,7	10,7	-	-	14,9	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Description

This WP it is entirely focus on the development of a risk management process support, thus a system that it is able to work on a rule based engine support the better decision process .
This Decision support system will work on an defined ontology and the rules will be based on the result of the "as is process " input from WP1 and the result of the work of the WP2 thus the data mining and the incidents and alerting .
The Task inside this WP are :

- T4.1 Develop and validate RAPS Taxonomy
- T4.2 ontology based error detection tool
- T4.3 RAPS management support system

Task number	**4.1**			**Start date or starting event:**			**M1**
Task title	**Develop and validate RAPS Taxonomy**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	0,6	0,6	0,6	-	,	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	**RAMIT**	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	2,9	-	-	-	-	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives :

- to define and validate a RAPS taxonomy

Description of work

The main activities foreseen are:

Multi-dimensional state of the art based on meta-analysis of multi-disciplinary literatures on:

- Classifications and Taxonomies;
- Organisational, institutional and legal analyses and implications;
- Socio-psychological and cultural barriers;
- Evaluation and measurement frameworks and implementation methodologies.

It is worth stressing that, while the main focus will be that of RAPS and the main fields of literature will be specialist ones, the meta-analysis must be broader in order to extract insights and knowledge also from contiguous and, by analogy and extension, also from non contiguous fields. For instance on Evaluation and Measurement the field of eGovernment is relatively more advanced than eHealth and some methodological solutions and implementations lessons can be derived. To make just another example, important lessons and insights can be extracted from the robust evidence existing on risk management and identification have not, within health organization in industrial sector affected by an high risk level, such as process industry or rail transport. From studies on such industries insights can found particularly as to key organisational issues and as to existing socio-psychological and cultural barriers.

For the remaining tasks, given the extensive consideration developed on all the relevant topics in the previous sub-paragraph, we limit ourselves to list the different activities they comprise without adding further comments and explanations

Develop and validate RAPS Taxonomy:

- Elaborate a preliminary internal Taxonomy from the results of the state of the art review;
- Validate and refine the taxonomy through interviews with internal users;
- Evaluate compatibility of internal taxonomy with classifications used in external databases ;
- Elaborate and validate with all stakeholders (internal and external) a Taxonomy integrating internal and external sources of information.

Deliverables (brief description and month of delivery)

D 4.1 RAPS Taxonomy: approach and definition (M6)

Task number	**4.2**			**Start date or starting event:**			**M7**
Task title	**Ontology based error detection tool**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	0,8	1,1	1,1	-	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	**RAMIT**	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	4,6	2,9	-	-	-	7,4	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives :

- to define an build an Ontology about the domain of the error connected to incidents and risk situation

Description of work

T4.2 Ontology based error detection tool

Scope: The purpose of this task is to develop a component that contains in a machine-understandable way all the domain knowledge that is required to be able to prevent, predict, detect or deal appropriately with RAPS in the context of the disease history of a patient. This component will consist of two parts.

One part is an ontology describing the portions of reality salient to the domain of RAPS occurring in hospitals. This ontology will itself consist of two different parts. One part is the "RAPS domain ontology" which will be developed following the principles of unqualified realism and therefore will be lined up with Basic Formal Ontology. This ontology will thus consist exclusively of (1) representational units that refer to salient universals in the domain covered, examples being person, drug, allergic reaction, and (2) relationships taken from the OBO Relation Ontology that has been developed under the same realist assumptions. The second part of the ontology is the "RAPS application ontology" that will use the domain ontology as a reference, but will differ from it in a few aspects: (1) it will contain defined classes to represent characteristics of groups of particulars that do not correspond with universals, (2) it will eliminate detail which is irrelevant for the purposes of the application.

The second part of the component is a taxonomy of terms in various languages that are commonly used as linguistic denotations for the universals, particulars, relationships and the more complex portions of reality of which the former three are constituents. Thus, whereas the ontology part describes (some aspects of) what is the case in reality, the terminology part describes (some aspects of) how humans communicate by means of language about reality.

Methods: Ontology and terminology development will be conducted in parallel: analyzing the terminology used in the literature on RAPS as well as case histories gives an idea about how the domain is structured and thus allows building the ontology. Developing the ontology according to the provisions of philosophical realism and the representational machinery offered by Basic Formal Ontology will help in identifying ambiguous terminology and will also avoid that other idiosyncrasies of language will lead to erroneous representations; as an example: whereas the term "life threatening RAPS" denotes a special kind of RAPS, the term "prevented RAPS" denotes no RAPS at all.

The domain ontology will be developed in a constrained form of first order language in which predicates can only range over relations and variables are strictly typed, and for which a referential rather than model-theoretic semantics will be defined. Axioms will be provided to restrict possible deviant interpretations.

The application ontology will be implemented in a suitable environment, whereby, because of the fast evolution in the domain of ontology engineering, suitability of available tools will be assessed only when the project starts. Candidate environments at this stage are Protégé, DAG-Edit and SWOOP.

The terminology will be implemented in the language extension modules that usually are provided with these tools.

Deliverables (brief description and month of delivery)

D.4.2: RAPS domain ontology – (M6; M18)

D.4.3: RAPS application ontology – (M6; M24)

D.4.4: Multilingual RAPS taxonomy (M24)

Task number	**4.3**			**Start date or starting event:**			**M10**
Task title	**RAPS management Support system**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	0,9	1,1	1,1	-	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	**TUW**	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	4,6	3	10,7	-	-	7,4	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

- to formalize the acquired guidelines in a computer-executable representation
- to provide a prototypical implementation of a guideline execution engine

Description of work

- Formalizing a guideline coming from WP1 (task 1.2)
- select a class of guidelines according to their structure and completeness, their medical relevance, and their connection to the terminology and ontology
- formalize the these guidelines using a document-centric approach and model additional knowledge by domain experts (in connection with the used terminology and ontology)
- examine the correctness of the guideline models
- Prototypical implementation of the guideline execution engine
- Specify the input and the output of the guideline execution engine
- Define and structure the functionality and coverage of the guideline execution engine
- Prototypical implementation of the guideline execution engine
- Test of the guideline execution engine (using test cases)
- Design of an easy to use and simple user-interface
- Prototypical implementation of an easy to use and simple user-interface
- Test of the user-interface with the guideline execution engine

Deliverables (brief description and month of delivery)
D.4.5: Documentation of the formalized guidelines (M6)
D.4.6: Documentation and prototypical implementation of the guideline execution engine (M12; M24)
D.4.7: First release of Adverse Risk management Support system (M12)
I.D. Second release of Adverse Risk management Support system (M18)
D.4.8: Third release of Adverse Risk management Support system (M33)

WP number	**5**			**Start date or starting event:**		**M3**
WP title	**InfoBroker Patient Safety Framework**					
Activity type	**RTD**					
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	**SO**
Person-months per participant	18	0,8	0,8	0,4	8,1	-	23,2
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	5,4	1,3	5,4	14,1	18,2	-	5,9
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	10,1						

Description

The aim of this workpackage is to connect the different output of REMINE components (Decision support system, Mining , Data integration and son on) with the Hospital ERP system using both Automatic and semiautomatic procedure (semantic web services) and traditional approach thus report and process . In this work package it is focus also the part of the definition of process model that take into account all the information about RAPS that the other component can provide. The Risk process model can in this way let user to compare the defined process with the ones enriched by the information given by the mining and Decision support allowing in this way to monitor and drive process without the direct intervention of technical people.
The main aspects under responsibility of this WP are:

- T5.1 H-ERP Protocol and operation definition Interface
- T5.2 Semantic Web Services wrapper framework
- T5.3 RAPS Process Model
- T5.4 RAPS clinical rules model specialized for patient safety

Task number	**5.1**			**Start date or starting event:**			**M6**
Task title	**H-ERP Protocol and operation definition Interface**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	**GMD**	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	18	-	-	-	-	-	23,2
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	-	-	-	-	2,9
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

- to define the environment where SWS, Real time Risk Alert and traditional H-ERP procedure/process can work together , due to the fact that the REMINE focus is Risk Management only the H-ERP procedure/process that are defined as HIGH- RISK (work performed in the WP1) will be taken into account.
- to connect between traditional H-ERP activities and WP5 will lead this operation process driven by Risk- Management process.

Description of work

This work package will create the runtime environment required to connect SWS , Real Time Alert Sytem and the relative component in the H-ERP moreover it will be develop a H-ERP library for storing and accessing models of semantic business processes will be created.
This library will provide efficient runtime support for discovering other business process models based on their functionality and it will connect functionality with semantic descriptions. Inside the runtime environment it will build a relation between the functionality atomic structure and its semantic meanings so in the case that in the H-ERP different functionality or names are defined with different “semantic value” this library will overcame the problem .
Corresponding functions will be prototyped in this task connected to a risks situation.
This task will evaluate and design a common bus among the Hospital module if this is not yet present , thus if the LAB. Drugs and Nosocomial can not talk each other REMINE will provide a prototype common bus.

Deliverables (brief description and month of delivery)
I.D. Design and functionality of specific Pilot Hospital ERP connection Interface (for each pilot Site) (M6; M12; M24)
D.5.1 H-ERP component interface Coordinator first revision (M12)
I.D. H-ERP component interface Coordinator second revision (M18)
D.5.2 H-ERP component interface Coordinator third revision (M33)

Task number	**5.2**			**Start date or starting event:**			**M6**
Task title	**Semantic Web Services wrapper framework**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	-	-	-	-	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	**LINK**	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	-	7,4	-	-	3
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	5,5						

Objectives

- to design and development of the environment where the SWS can be executed, a system of control and check will be also built in order to let them work in junction and not in contrast with the H-ERP.

Description of work

Task 5.2 is the wrapper engine of the defined H-ERP process defined in the task 5.1 , but in this task we will not only build some wrappers in form of SWS but also the Framework where this could happen.

In the framework the mail development activities are around the following elements :

- Design and develop a discovering and selection system thus what SWS need to be used in a defined contest , thus find the most suitable SWS for a particular Risk Management issue.
- Design and develop a SWS invocation and mediation , Therefore a service requester interacts with a SWS through the SWS execution infrastructure which provides the required functionalities in order to ensure seamless interactions.
- Design and develop a H-ERP instance identification thus SWS upon receiving a message to execute some action on the H-ERP components , the execution engine has to determine if the message is sent to an already running instance or it aims at creating a new instance (E-ERP it has always the ownership of the instance)
- Design and Develop an instance execution monitor ,thus a functionality that allows progressing a step forward on an instance execution. The execution engine could navigates through the instance control flow until its completion,
- reporting a fault or reaching a H-ERP task to be executed. .

Deliverables (brief description and month of delivery)

D.5.3 Wrapper Engine for Lab (with dedicated section for each pilot) (M12; M24; M36)

D.5.4 Wrapper Engine for Drugs (with dedicated section for each pilot) (M12; M24; M36)

D.5.5 Wrapper Engine for Nosocomial (with dedicated section for each pilot) (M12; M24; M36)

D.5.6 Wrapper engine for Clinical Pathways (with dedicated section for each pilot) (M12; M24; M36)

Task number	**5.3**			**Start date or starting event:**			**M3**
Task title	**RAPS Process Model**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	0,8	0,8	0,4	-	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	**ICCS**	MIP	INFO WORLD
Person-months per participant	2,6	0,6	-	-	18,2	-	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	4,7						

Objectives

The main objective here are to define a platform that allow user to work with BPM methodologies in order to work on the entire process that REMINE it have to manage in order to reduce the RAPS and better the patient safety.

Usage of graphical environment and easy notation let user not aware of technical skill (e.g Doctors) to work on the process in order to evaluate all the components in order transform a RAPS process analysis in real action inside the pilots environments. Moreover thanks to the real time alert system process variable and constant can be evaluated and inserted inside the design of the BPM process changing the process parameter of the BPM process.

Description of work

This task will develop the framework that will connect the BPM process methodologies, the ontological engineering
methodologies with the SWS environment .
The framework will allow both risk management process people and IT people to find a common environment where the risk process and the outcome from the DSS and the Mining will be managed in a Semantic Business Process Composer (SBPC) . In this task we will use a Business Process Modeling Notation (BPMN) in order to enable business user to
develop readily understandable graphical representations of business processes . The same graphical representation will allow the user to map , merge and confront different process introducing in overlapping session the outcome from the others REMINE modules , moreover BPMN will also supported with appropriate graphical object properties that will enable the generation of executable BPEL. Thus, BPMN creates a standardized bridge for the gap between the business process design and process implementation. The developing of a Monitoring and Management aims at providing relevant information about process deployment and execution to the Business Analyst through the observation and recording of the activities taking place during the execution of SBPC and the relevant activities of the SWS without the direct intervention of IT people. This framework , it should also support management functionalities allowing controlling process instances and connection with other REMINE Modules. We also include within this work package tasks associated with the evaluation of REMINE use cases deployment, and with preparing evaluation methods for REMINE deployment, after the project has finished.

Deliverables (brief description and month of delivery)

I.D. Design and functionality of specific Pilot Hospital ERP connection Interface (for each pilot Site) (M6; M12; M24)

Task number	**5.4**			**Start date or starting event:**			**M12**
Task title	**RAPS rules model specialized for patient safety**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	**QSC**	HP	SO
Person-months per participant	-	-	-	-	8,1	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	2,7	0,6	5,4	6,7	-	-	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

- to produce different outcome for single patients processed by REMINE system. Thank for information on RAPS process model, it will be possible to identify clinical roles specialize for any patient safety, that can be used form external e-health structures.

Description of work

The task 5.4 Real Adverse clinical rules model specialized for patient safety is focused on

- developing a component that using the information provided by the RAPS process model (Task 5.3) it will build clinical roles specialize for patient treated by REMINE System.
- Collect all relevant data and information to use to create the base of treatment roles those can be treated on patients
- Define the structure and the semantic of Patient treatment blacklist
- Developing an infrastructure that manage the technical interface (API) output of the Adverse clinical rules model specialized for patient

Deliverables (brief description and month of delivery)

D.5.7 Technical specification Adverse clinical rules model specialized for patient safety (M6; M12; M24)

D.5.8 First Revision of Adverse clinical rules model specialized for patient safety component (M12) I.D. Second Revision of Adverse clinical rules model specialized for patient safety component (M18)

D.5.9 Second Revision of Adverse clinical rules model specialized for patient safety component (M33)

WP number	6			Start date or starting event:			M1
WP title	Service oriented Architecture and system Integration						
Activity type	RTD						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	**GMD**	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	18	-	-	-	2	3,1	19,5
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	12,1	7,4	-	-	5,3
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	8,8						

Description

The functional specifications embodied in the REMINE User Analysis will lead to a full architectural design for a System Architecture dedicated to integrated system of Risk management. This activity will lead to a Common European Architecture, representing the design for a system that satisfied a large proportion of the common needs of users.

With the usage of UML (Unified Modelling Language) .We will use the current version of UML (early 2007) Version 2.1.1. UML consists of two parts, Infrastructure and Superstructure; associated with these are the Object Constraint Language (OCL) and Diagram Interchange specifications, a definition of principal scenarios will be reached illustrating system functionalities through the interaction of the components defined in the architecture. Scenarios, in fact, are specific sequences of actions describing the main system behaviours and are used to drive the definition of Use Case Model. In the REMINE design the use of UML, along with the *Meta Object Facility (MOF™)*, also provides a key foundation for OMG's *Model-Driven Architecture®*, which unifies every step of development and integration from business modeling, through architectural and application modeling, to development, deployment, maintenance, and evolution.

The main aspects under responsibility of this WP are:

- Design the Overall REMINE technological Architecture
- Define all the technological aspect for the implementation of REMINE system
- Develop according to the choose methodology an implementation plan
- Design the workflow of the entire project development

Task number	**6.1**			**Start date or starting event:**			**M1**
Task title	**Architectural design**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	9,5	-	-	-	-	1	10,3
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	**Q&R**	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	5,5	-	-	-	2,1
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	3,9						

Objectives

- to design the overall REMINE architecture

Description of work

This task involve the design of the architecture of the REMINE system , the design of the architecture it could see as a shorthand representation of "access to integrated information to support business process improvements" represents a desired state of an enterprise's infrastructure and is specific to the business needs of the organization.

The design of the REMINE architecture will be based on open standard components that provide services in a customer's extended enterprise that:

- Combine multiple sources of information
- Securely deliver the information whenever and wherever it is needed, in the right context for the people or systems using that information.

In the architecture design will be defined also the knowledge model, comprising the definition and development of formal ontologies to represent both the content and the decision making processes carried out by users in risk management applications.

The architecture, whose the design includes

A. the clear definition its layers,
B. the definition of required components like registries, catalogues, information and processing services, collaboration components, etc.,
C. a concept for a systematic approach for the integration of spatial and non-spatial information,
D. the management view of the overall system,
E. the most important interfaces at the conception level.
F. The meta-information model, necessary in order to have a clear understanding about how meta-information (modelled through ontologies) will be implemented and incorporated in the architecture
G. The enabling processes and tools, such as quality assurance processes and tools, methodology and tools for traceability of requirements among sub-projects, reporting templates and processes, dissemination and exploitation methodologies and tools, etc
H. the relationship and the connection between the main component of REMINE (ERP and Risk Management).

We stress that the architecture design it is directly connected to the business scenario that points out the need for access to integrated information in order to support business process improvements and emphasizes that interoperability of the infrastructure, which is a key enabler, is a main technical challenge. Today, many organizations have achieved a degree of boundarylessness between their people, only to find that the stovepipes are even stronger in the IT systems.

- Middleware Layer – This layer is characterized by the needed functionality of the platform, also including Communication manager, User Manager, Security manager, Service Manager and Discovery, Meta-model manager, Interoperability manager. Middleware offers to the users a transparent, integrated and fully customizable interface with the storage layer through the indexing and searching system.
- Application Layer - This is the layer of the Drug Management Process System that, through one or more services, can interoperate with other application's services through REMINE project.

Deliverables (brief description and month of delivery)
D6.1.REMINE Architecture Specification (general, technical, environment and pattern, SW components) (M12; M24)

Task number	**6.2**			**Start date or starting event:**			**M10**
Task title	**Component Development Integration and QoS and test plan**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	8,5	-	-	-	2	2,1	9,2
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	**Q&R**	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	-	-	6,6	7,4	-	-	3,2
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	4,9						

Objectives

- to develop all the software components and use a "lab" environment where assemble and run the system in a cycle of component assembling and testing .
- to define the environment of the overall component integration and the test plan in order to define the QoS of the technological components of REMINE Architecture.

Description of work

Define the "low level " functionality of every REMINE components , develop the single component ad define the QoS testing cycle for every components .
Define and develop the single Interface , API and services of every REMINE sub-object
Define the integration procedure and the environments where all the REMINE component where assembled and tested.
The planned procedure it will be to develop 3 different REMINE prototypes thus starting from Prototype1 with the elementary functionality that let to evaluate soon the Platform inpact and behaviour to arrive to Prototype3 with all the defined and final REMINE functionality.

The prototype designed that will pass the QoS Test will be deployed in the PILOT Site and it will became the REMINE Platform Pilot , once that a prototype will became a REMINE Platform Pilot it can not be changed in functionality but only fixed in bugs and malfuctions. The List of functionalities and can only be changed from a prototype release to another thus in order to avoid confusion and rushed implementation inside the PILOTS running enviroments.
Prototype can only be changed inside the REMINE development integration site .

Deliverables (brief description and month of delivery)
D.6.2 Sofware component test plan and QoS evaluation Metrics. (M12; M24)
D.6.3 First Platform REMINE Prototype (M12)
ID. Second Platform REMINE Prototype (M18)
D.6.4 Third Platform REMINE Prototype (M33)

WP number	**7**			**Start date or starting event:**			**M1**
WP title	**Demonstration**						
Activity type	**DEM**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	12	7,9	7,4	8,9	8,5	2,6	8,8
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	**MIP**	INFO WORLD
Person-months per participant	3	8	7,6	1,4	19	36,1	11,3
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	4,2						

Description

This work package is concerned with two main activities:

- the understanding of the business framework state of the art and its future trends, in where the project is facing off;
- the implementation of various instruments necessary to transfer the project knowledge, technologies, lessons learned and best practices to interested communities and thus to ensure their worldwide impact and long-term sustainability.

Therefore the objectives of the work package reflect these two main activities.
In particular, for understanding the business framework the major objectives are:

- to develop REMINE business model that will be utilised for both shaping the project exploitation activity and the user requirements (WP8);
- to validate REMINE platform in relation to the project business model and the related frameworks;
- to develop a consistent and sustainable REMINE project exploitation strategy and plan.

While for developing REMINE knowledge transfer instruments, the major objectives are:

- to provide the contents and establish the technical and organizational setting for training and capability development;
- to participate in the work of established standardization bodies and to contribute to the transfer of the results achieved in the project into

these standards bodies;
- to disseminate the project results in order to foster community building and to create an impact with European industry and research;
- to assurance the sustainability of the results and to support their transfer to the industry
  - asset and IPR management
  - legal and socio-economic implications
- to support the collaboration with related R&D initiatives at academic and industry level and to exploit the synergies emerging from such networking effects.

Task number	**7.1**			**Start date or starting event:**			**M6**
Task title	**User Driven Test Beds (UDTB) deployment and assessment of organisational issues (DEM)**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	5,1	6,6	6,2	7,7	5	0,9	8,8
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	**MIP**	INFO WORLD
Person-months per participant	0,9	1,8	3	0,7	7,5	8,5	6,3
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	4,2						

Objectives
- to set up and manage user driven test beds.
- to receive a continuous input from the user.

Description of work
This phase will start at the beginning of the project and will be concluded at the end of the project. It includes all activities meant to test the context in which the pilot will be developed and implemented. In particular it includes the following activities.
- Data collection: in the first phases of the project hospitals involved in the pilot demonstration will provide access to relevant informative systems and collected data, thus supporting S.1.1.1, S.1.1.2, S.1.1.3 and S.1.2.2 unrolling.
- Pilot test and validation

Deliverables (brief description and month of delivery)
D.7.1 UDTB deployment and assessment (M12; M36)

Task number	**7.2**			**Start date or starting event:**			**M11**
Task title	**System integration , testing and validation (DEM)**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	**GMD**	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	6,9	1,3	1,1	1,2	3,4	1,7	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	2,1	6,3	4,6	0,7	11,5	27,6	5
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

- to define and develop the "Running PILOTs Site " REMINE Platform , integrated with the all components and deployed in the PILOTS site , this that it will be called the "REMINE Production Prototype (RPP) it will the more stable platform and it will deployed in order to let the users work directly on the system in order to test the functionality and validate it since the beginning , We will deploy 2 prototype RPP1 and RPP2 and a final system RPF .

Description of work

Deploy a REMINE Platform that the user can test and validate , the REMINE platform will be released with the limited choosed beginning functionality in the RPP1 that will be increased in the RPP2 in order to arrive to the final release of the RPF. In this way users can soon start work on the system so all the eventual errors in the design phase.
On the same platform it will be performed user testing (different from the QoS Software testing) , and the functionality it will be validate by the users .

Deliverables (brief description and month of delivery)
D 7.2 Pilots Test environment definition (M12; M24)
D 7.3 REMINE First Pilots platform RPP1 (M12)
I.D. REMINE Second Pilots platform RPP2 (M18)
D 7.4 REMINE Final Platform RPF (M33)

WP number	8			Start date or starting event:		M1
WP title	Dissemination, Training and Project exploitation					
Activity type	OTH					

Participant number	1	2	3	4	6	7	8
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	6,1	5,6	2,5	3	1,5	2	7,3
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	**MIP**	INFO WORLD
Person-months per participant	3,5	4	2,4	4,6	9	7,3	2,4
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	2,9						

Description

This work package is concerned with two main activities:

- the understanding of the business framework state of the art and its future trends, in where the project is facing off;
- the implementation of various instruments necessary to transfer the project knowledge, technologies, lessons learned and best practices to interested communities and thus to ensure their worldwide impact and long-term sustainability.

Therefore the objectives of the work package reflect these two main activities.
In particular, for understanding the business framework the major objectives are:

- to develop REMINE business model that will be utilised for both shaping the project exploitation activity and the user requirements (WP1);
- to validate REMINE platform in relation to the project business model and the related frameworks;
- to develop a consistent and sustainable REMINE project exploitation strategy and plan.

While for developing REMINE knowledge transfer instruments, the major objectives are:

- to provide the contents and establish the technical and organizational setting for training and capability development;
- to participate in the work of established standardization bodies and to contribute to the transfer of the results achieved in the project into these standards bodies;
- to disseminate the project results in order to foster community building and to create an impact with European industry and research;
- to assurance the sustainability of the results and to support their transfer to the industry
  - asset and IPR management

- legal and socio-economic implications
- to support the collaboration with related R&D initiatives at academic and industry level and to exploit the synergies emerging from such networking effects.

Task number	**8.1**	**Start date or starting event:**	**M1**
Task title	**Dissemination , community building, networking and standardisation actions (OTH)**		

Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	2,3	1,1	0,6	0,7	-	0,5	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	**MIP**	INFO WORLD
Person-months per participant	1,4	1,3	-	1,5	2,2	1,3	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

The general objective of this task is:

- To provide awareness about the "to date" status of REMINE and outcomes, and about REMINE ultimate goals. Within this Task, efficient ways of communication with the scientific, business and general public communities will be identified, pursued and established.
- To develop a collaboration strategy with other similar and related initiatives;
- To cooperate with EC Information society and media initiatives.
- To adopt and use existing standards or pre-standards;
- To diffuse REMINE ongoing results at standardisation bodies level

Description of work
This task will be divided into three sub.task:

Sub.Task 8.1.1 Dissemination plans and actions (including EC initiatives) First, a dissemination strategy for the dissemination of the REMINE results will be set up. This strategy will consist of a preliminary research that will identify project stakeholders and the appropriate dissemination activities that need to be followed for the project's results effective communication. During this planning activities will be discussed with EC – e-Health Unit and EC Information
Society and Media how create mutual benefits in promoting REMINE in already foreseen initiatives during the project life cycle. Making REMINE results widely available outside the consortium will be achieved by a number of different dissemination activities. These will include a careful selection of workshops, conferences, journal publications and internet exposure, while parties to be targeted will include private and public healthcare organizations, industries, academia and research institutions.
Overall, this sub.task will coordinate the monitoring and participation in workshops on related areas for the presentation of REMINE results and achievements, as well as the submission and publication of consolidated results to selected journals and magazines. During the course of the REMINE project, the consortium will also organise and manage a number of workshops that will mainly target end-users. Publications in external conferences and journals would be used as good means for reaching academics, researchers, healthcare operators, and the consortium is committed to make full use of them. In addition, internet dissemination (such as the development of a web-site and the issuing of electronic newsletters) will allow a larger community of interested potential users to access REMINE for longer times and to keep them informed about the project's aims and progression.
Brochures, promotional/informational materials and multimedia dissemination materials (such as presentation CD-ROMs and DVDs) will be produced, having several levels of technical depth to target different types of intended audience. The project will also provide to the EC Communication manager regular updates on the project activities (one or two paragraphs), this will be included in the relevant EC newsletter. A link to the project websites will be also provided.

Sub Task 8.1.2 Networking strategy and actions. This sub.task will ensure that the work carried on in this project is aligned to similar and related initiatives in the field in order to increase its quality and its impact and visibility within the relevant communities. Networking and collaboration will be particularly targeted at members of the Project Scientific Board (PSB) and the Project partner will continuously keep track of related initiatives in the field in order to timely identify collaboration opportunities and will participate in the open exchange programme established within PSB in order to visit external institutions for joint research and development purposes. Moreover, REMINE project will participate in regular concertation activities (at least two per year) with other ICT projects, which will be organised to facilitate exchange of information and good practice and to discuss topics of common interest to all relevant projects.

Sub.Task 8.1.3 Harmonisation plan for the REMINE framework and dissemination activities towards standardisation bodies. REMINE will contribute to the standardisation activities concerning different aspects of networking. REMINE compliance with relevant standards will be crucial to provide the necessary architectural framework. Project contribution to standards will be achieved through a double-cross related approach:

- Adoption and use of existing standards or pre-standards, making them available to the market and providing feedback for those bodies with open activities in finishing or extending standards. Proceeding in that way and because of synergies with different SDOs, REMINE will help to extend the real use of standards by the industry, breaking the 'glass roof'. Therefore, this could serve as a test-bed for their feasibility and appropriateness, and reinforce their applicability as industry standards.
- Contributions to pre-standards and creation of new standards; during the project, needs and suggestions for improvement can be turned into recommendations, guidelines, annexes for pre-standards or even provoke new standards.

Deliverables (brief description and month of delivery)
D8.1 Project Website M3
D8.2 Dissemination Plan M6
D8.3 Harmonisation plan for the REMINE framework M 12 and M 36;
D8.4 Promotional/informational materials and multimedia dissemination materials M12; M24; M36
D8.5 Report on the Dissemination, networking Activities and promotional actions on standardisation bodies M12; M24; M36

Task number	**8.2**			**Start date or starting event:**			**M4**
Task title	**Assets and IPR management (OTH)**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	0,9	1,7	-	0,7	0,7	0,5	3,4
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	**MIP**	INFO WORLD
Person-months per participant	0,7	0,7	1,6	1,5	2,2	2	1,6
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	1,4						

Objectives

- to develop a strong barrier to intellectual property misuse during each phase of the development of the project, providing both a picture about new laws and political decisions among European Countries and a set of implications about the use of REMINE platform that will have an impact into the business model.
- to manage of the innovation produced by the project, both in terms of IPR allocation between contributing partners, and needed action to protect REMINE knowledge.

Description of work

To fulfil the completion of this task , the following activities are foreseen:

- a collection and analysis of laws, rules and policies of EU's Members to create a specific database. This database leads to the following step of analysis and provides the recovery and ordering of a large amount of data;
- a creation of a model to monitoring every legal and political innovation about IPR management.
- creation of a cause-effect map between the variables mentioned above and the REMINE scope. This will lead to underline the main critical aspects of the project and, probably, to re-define some variables of the strategy and the value proposition of the model itself.
- Suitable arrangements for protection and exploitation (as applicable) of the project innovation developed by the parties, as agreed in the Consortium Agreement and better defined in the Exploitation Agreement.

The approach used to carry out these activities includes parallel studies conducted with the following methods:

- literature review:
  - to develop a specific database related to laws and international political assets;
- a focus group in order to:
  - state the needs in terms of Intellectual Property Management;
  - conduct an in depth analysis ("why" and "how" questions) about the emerged Intellectual Property Management needs;
  - definition of a model to conduct longitudinal analysis in order to define and track the critical variables about Intellectual Property Management at a global level that can affect the development of REMINE platform.

Deliverables (brief description and month of delivery)
D8.6 State of art about the intellectual property rights (M24; M36)

Task number	**8.3**			**Start date or starting event:**			**M18**
Task title	**Training and capability development (OTH)**						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	-	1,1	1,3	0,7	-	-	-
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	**ICCS**	MIP	INFO WORLD
Person-months per participant	0,7	0,7	-	-	2,2	2	-
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	-						

Objectives

The main objective of this task is to provide accessible training material. It will be fulfilled by establishing a coherent training strategy at a European level and by developing appropriate training material. Parts of the training material will be served by an accessible e-training platform when appropriate. In addition, training will be provided to technology and content providers on how to benefit from project's applications. Training workshops will also be organized in order to give maximum visibility to the project activities and to train the trainers, i.e. user partners.

User requirements and a coherent training strategy will first be developed together with user partners participating in the project. Training material will be developed in parallel with the RTD work and we will identify which parts can be delivered through an accessible e-training platform integrating recommendations from other workpackages.

Description of work

Training workshops and user training will start at Y2 and will continue during the whole project lifetime, according to the following steps:

- *Developing a coherent training strategy*
  Training requirement is an intensive one-on-one process. A strategy should be developed early in the project cycle and be updated throughout the project period. The document should detail the anticipated training needs of specific technology solutions, and set up an optimal roll out, scope and schedule for training activities. The strategy should also identify synergy of anticipated training efforts, promote development of multi-lingual training material, and help coordination of user training and evaluation of project results on a European scale. User associations and all project partners are expected to contribute in setting up this strategy.
- *Preparation of training program and materials*
  Development of training programs and materials should be a priority item. Training insures proper use and evaluation of project results, which is vital to technology refinement, and for piloting future research efforts. Emphasis should be placed on maximizing synergy and reuse of training material.
- *e-training platform set up and management*
  Delivery of multi-lingual and multi-modal training material should be optimized. Training programs will be delivered on a variety of media. An e-training platform, available through REMINE website, will also be deployed to support the delivery of training material and program and for supporting, as much as possible, multi-lingual and multi-country training and evaluation activities. The platform serves also as a vehicle for continuous dissemination of training material to end users.
- *Coordinate training programs and workshops targeting the key user communities*
  Project partners will work closely with their local organizations for coordinating training, training activities and workshops targeting two major user groups:
  - Training system integrators, service and content providers. This insures a heightened awareness already in the production cycle.
  - Direct training to end-user associations and end-users. User associations and their technical staff are on the frontline of providing end-user service and training

Deliverables (brief description and month of delivery)
D8.7 Skills analysis and training strategy and plan M12
D8.8 Accessible E-training platform M12
D8.9 Report on Training activities M12; M24 **(ID)**; M36

Task number	8.4			Start date or starting event:			M7
Task title	Project Exploitation (OTH)						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	**GMD**	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	2,8	1,7	0,6	0,7	0,7	1	4
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	0,7	1,3	0,8	1,5	2,2	2	0,8
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	1,4						

Objectives

- To develop a market analysis and REMINE business model
- To support the consortium as a whole exploitation strategy and plan
- To develop consortium participants exploitation strategy and plan

Description of work
This task is aimed at both validating the on going results of REMINE project and developing proper exploitation strategy and plans for REMINE consortium as a whole and for each of its participants. Thus three major sub-task are foreseen.

Sub.task 8.4.1 Business Modelling. The development of an innovative business model involves the following activities:

- an analysis of REMINE scope in order to state the mission, the vision and the values steering REMINE activities. This analysis aims also to both fix the boundaries (products and markets) within REMINE will compete and to put in evidence the REMINE value drivers and the related critical success factors to control.
- a market analysis in order to increase the awareness about the market structure in terms of key stakeholders, competitors and potential suppliers, partners and coalitions;
- an internal analysis to define the competences, the assets and the core processes needed to reach strategic goals;
- an organization design in terms of key management processes and related tools.

The main result of these activities will lead to the formulation of REMINE exploitation strategy as outlined in WP8.

Sub-Task 8.4.2 Consortium Exploitation strategy and related plan
While, the exploitation activity is strategy outlines vital to evaluate how to fully exploit their potential – in terms of both technological and economical benefits –. The objective is to design a broad scheme of analysis showing the new technology solutions exploitation strategies best-suited for the REMINE business model and related legal and socio-economic implications.

Sub-Task 8.4.3 Individual exploitation strategy and plan
After defining an overall exploitation strategy for REMINE consortium and each of its member, it is time to put this strategy into effect, passing from the strategic level (where greater visioning and holism is required), to the operative one (which is made of plans, and where more attention paid to details). At this stage the main activities are on one side to provide guidelines supporting th e exploitation planning process, on the other to guide each consortium member in design its own exploitation plan.

Deliverables (brief description and month of delivery)
D8.10 Business modelling, market analysis, Individual consortium members and Consortium as a whole exploitation strategies and plans M12; M24 **(ID**); M36

WP number	9	Start date or starting event:	M 1
WP title	Project Management		
Activity type	MGT		

Participant number	1	2	3	4	6	7	8
Participant short name	GMD	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	22,3	1,6	1,5	1,7	1,6	1,3	0,8
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	1,5	1,6	1,6	2,3	2,3	7,7	1,4
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	2,4						

Description

Formulation and implementation of a solid project management plan, enabling both the contractor's project manager and the European Commission to gain rapid overview of the progress of the project, including financial elements; definition and adoption of sound impact metrics, to be tracked during the whole project, in order to evaluate project results.
In particular:

- Development and updating of a Project management plan
- Coordination and monitoring of the project activities
- Plan and implementation of reporting activities
- Definition of measurement metrics for quality control
- Establish and maintain effective communication between project partners, WorkPackage leaders and task leaders.

Task number	9.1	Start date or starting event:			Month 1		
Task title	Project management activities						
Participant number	**1**	**2**	**3**	**4**	**6**	**7**	**8**
Participant short name	**GMD**	REGLOM	SEK	TRFT	QSC	HP	SO
Person-months per participant	22,3	1,6	1,5	1,7	1,6	1,3	0,8
Participant number	**9**	**10**	**11**	**12**	**13**	**14**	**15**
Participant short name	TUW	RAMIT	Q&R	LINK	ICCS	MIP	INFO WORLD
Person-months per participant	1,5	1,6	1,6	2,3	2,3	7,7	1,4
Participant number	**16**						
Participant short name	AMINIO						
Person-months per participant	2,4						

Objectives

Design and updating of a Project management plan in order to guarantee rapid overview of the progress of the project including financial elements by regular PMP update and timely reporting to the European Commission. The formulation and the timely update of the Project Management Plan, together with the production of interim and final progress reports focused on the project results, will ensure the consistency of the actions to be undertaken with the specific and overall project objectives.

Description of work

REMINE project is a long-term project, and the people involved in it may change during its lifetime. Although a system of planning and organization is indispensable, project management must maintain the characteristics of a highly dynamic process. Clear Procedures assist newcomers joining the project and help them to become quickly operational. For the same reason, the proposed PM structure will be able to rapidly adapt to the involvement of new participants.

REMINE management is based on several principles that are important in inter-organizational collaboration:

- The REMINE Project participants are collaborating to achieve a common objective, share experience and know-how and develop results with complementary skills
- Work must be organized and planned in a result-driven way. Whilst the internal organization of each partner's work is his problem (as long as he meets his commitments), the interactions between partners working at distance must be based on the flow of results. Common planning must hence be a reference for everybody and must always be up-to-date
- The collaboration between participants is based on consensus and joint decision-making, involving different levels of decision-makers in different domains (strategic, technical, financial, and administrative). The rules for such decision making need to be clear
- The effectiveness of meetings between the partners is absolutely critical to the

progress of work. An inconclusive meeting can cause serious delays, risks and costs

- Effective collaboration requires central co-ordination and logistic support. The co-ordination mechanisms, communication flow inside and outside REMINE project are supported by REMINE Project Management structure.

In section 2.1 the proposed project management procedures that implement the mentioned principles are identified and described. The description of these procedures includes the management structure and organization, the form for reaching the internal consensus, the conflict resolution procedures and quality control strategy and procedures.

Deliverables (brief description and month of delivery)
D9.1 Quality control report, every 6 months (except M12, M24, M36)
I.D. Periodic Progress Report every three months (except for M12, M24, M36)
D9.2 Periodic Management Reports at the time of each project financial cost statement as from Grant Agreement (M12, M24, M36)
D9.3 Final project report M36

B1.3.6 Efforts for the full duration of the project

A summary of the staff effort is useful for the evaluators. Please indicate in the table number of person months over the whole duration of the planned work, for each work package by each participant.
Identify the work-package leader for each WP by showing the relevant person-month figure in bold.

Partic. No.	Partic. Short name	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	Total person months
1	GMD	15,2	16,1	-	-	18	18	12	6,1	22,3	107,7
2	REGLOM	6,2	2,4	3,2	2,4	0,8	-	7,9	5,6	1,6	30,1
3	SEK	5,2	2,6	4,3	2,8	0,8	-	7,4	2,5	1,5	27
4	TRFT	3	1,5	2,7	2,7	0,4	-	8,9	3	1,7	23,9
6	QSC	4,9	-	16,7	-	8,1	2	8,5	1,5	1,6	43,2
7	HP	2,1	4,2	-	-	-	3,1	2,6	2	1,3	15,3
8	SO	11,5	22,9	31	-	23,2	19,5	8,8	7,3	0,8	125
9	TUW	2,1	-	-	9,3	5,4	-	3	3,5	1,5	24,7
10	RAMIT	3,6	-	-	8,7	1,3	-	8	4	1,6	27,1
11	Q&R	8,8	21,9	20,8	10,7	5,4	12,1	7,6	2,4	1,6	91,4
12	LINK	13,6	18,8	-	-	14,1	7,4	1,4	4,6	2,3	62
13	ICCS	9,2	-	15,2	-	18,2	-	19	9	2,3	72,9
14	MIP	16,7	-	-	14,9	-	-	36,1	7,3	7,7	82,7
15	Info World	6,4	-	24	-	5,9	5,3	11,3	2,4	1,4	56,7
16	AMINIO	3,9	-	9,9	-	10,1	8,8	4,2	2,9	2,4	42,3
Total		**112,2**	**90,4**	**127,9**	**51,4**	**111,7**	**76,2**	**146,6**	**64**	**51,7**	**832,1**

B1.3.7 List of Milestones and planning of reviews

List and schedule of milestones					
Milestone number	**Milestone name**	**WPs nos**	**Lead participant**	**Delivery date from Annex I**	**Comments**
M1	User requirement and user driven test beds settled up	WP1 WP2 WP3 WP4 WP5 WP6	MIP GMD INFO WORLD TUW SO GMD	M6	User needs and requirements approved by pilots. Patient safety management process and modelling approved by pilots and by scientific and technical committee and ethical committee as well REMINE platform specifications (deliverables belonging to all technical workpackages) approved by scientific and technical committee and ethical committee as well
M2	First REMINE prototype and first REMINE platform released at test beds	All WPs	All leading participants	M12	REMINE platform first release approved by scientific and technical committee and ethical committee
M3	Second REMINE prototype and second REMINE platform released at test beds	All WPs	All leading participants	M18	REMINE platform second release approved by scientific and technical committee and ethical committee
M4	Third REMINE prototype and third REMINE platform released at test beds	All WPs	All leading participants	M33	REMINE platform third release approved by scientific and technical committee and ethical committee
M5	Project end	All WPs	All leading participants	M36	All REMINE deliverables approved by the General Assembly, Scientific and Technical committee, ethical committee and the European Commission

Tentative schedule of project reviews			
Review no.	**Tentative timing, i.e. after month X = end of a reporting period**	**planned venue of review**	**Comments , if any**
1	After project month: 12	Brussels	User Requirements Analysis and functional specification
2	After project month: 24	Brussels	System integrated and tested
3	After project month: 36	On site	Final review

B2 Implementation

B2.1 Management structure and procedure

Management structure and procedures

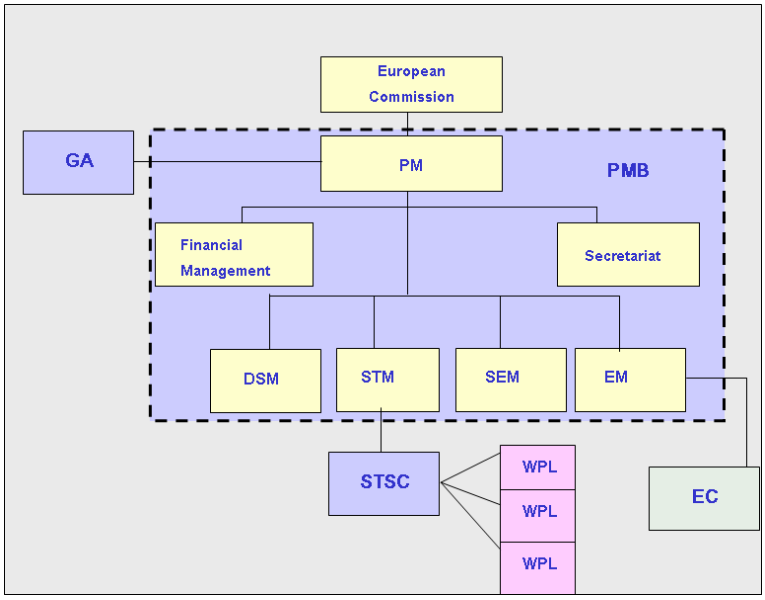
Project Management is an essential skill for the REMINE project to ensure a proper co-ordination across work activities, components and partners in achieving the overall project objectives within time and budget constraints. The management structure and organisation described below has been designed in order to support all partners' efforts in developing the REMINE system in a flexible way, thinking things through, having strategies for keeping control on all the activities and understanding and communicating the consequences of any changes made to the project.

The Project Management of REMINE will go through four main phases:

- Project Management Plan. A detailed Project Management Plan (henceforth PMP) is the first building block of Project Management. This is devised during project start-up activities to develop, obtain and maintain the approval of the project's operational plan and all of its components. It is important to highlight that PMP and Project Management are not the same thing; the former is only the starting point for the latter, which is a process activity unfolding throughout the life of the project which requires additional components. should identify starting from the project Work Plan, the specific activities to be performed to achieve the project objectives and produce project deliverables, schedule activities, properly allocate project resources within budget constrains, establish the principles and instruments for quality control and performance monitoring.
- Project Resources Organizations. Starting from the project Work Plan, these provide a deeper indication of activities and responsibilities (such as project deliverables responsible partners), the organisation of work teams is re-clarified and communication methods and schedules between work teams and team members are identified. These activities are all fine-tuned by consultation between the project manager, work package leaders and task leaders as the progresses.
- Project Monitoring Activities. When the project is running, Project Monitoring Activities defined in the PMP are introduced and refined. These include quality control and internal reporting activities.
- Project Completion. This phase covers the closure activities for the project, evaluation of project results as a whole and approval from the Commission. It also includes the release of the resources, the transfer of the final documentation produced and clarification of future activities to respond to enquiries and ensure further exploitation of results.

Management Structure

Being REMINE a complex project carried on by a number of organizations operating in different countries and each of them with their management structures and customs, the Project Management framework of the project has been designed to keep all the complexities of the work under control so as to assure the achievement of the project goals. The PM of REMINE require several functions and bodies that work according a set of predefined basic procedure. All that is described in the following paragraphs.



Project Management Structure

Due to the characteristics of the project, the management structure will be based on the collaboration of six lines of Management:

- Project Management (**PM**)
- Financial Management (**FM**)
- Socio-Economic & Exploitation Management (**SEM**)
- Scientific & Technical Management (**STM**)
- Dissemination & Standardisation Management (**DSM**)
- Ethical Management (**EM**)

One leader will be appointed to each line of Management. Collectively, they will share the project responsibility and will act under the structure of the Project Management Board (**PMB**), the ultimate authority within the project, chaired by the Project Manager (**PM**).
REMINE Project Manager will be Dr. Michele Carenini from GMD, that is supervisor and responsible of the quality and delivery of the overall project results through the WP9 activities. The PM is the contact point between the European Commission and the project. Chairing the PMB he is responsible for all the activities concerning the contractual, organisational and work-related project issues. Amongst the specific activities under the responsibilities of the Project Manager, the following can be further mentioned:

- Handling all communications with the Commission
- Proposing strategic orientations to Consortium members
- Monitor that the operational streams of activities are developed in a synchronised way

- Ensuring that all project deliverables are available on time (partner co-ordination for production of deliverables, monitoring against milestones and objectives in the project)
- Producing management documentation (progress reports, final report, documentation for project reviews)
- Creating conditions necessary for successful collaboration.
- Ensuring the compatibility of project management tools in use at each of the Consortium members.
- Convening the PMB (the PMB is expected to be convened every 3 months)

A Secretariat will provide secretarial, administrative, financial and legal support to the PM and partly to the Financial Manager. The Secretariat shall have a permanent contact person that also supports project participants. Several people may staff the Secretariat.

The Financial Manager (**FM**) will be closely working with the PM in order to synchronise the contractual and administrative items with the accounting and financial issues. The role of FM will be played by a selected trusted person at the coordination site. The principal responsibilities of the FM will be:

- Manage all procedures related to the accounting and financial relationship with the European Commission
- Co-ordinate the financial relationship between project partners
- Control that project activities are performed within budget constrains
- Co-ordinate the preparation of project cost statements
- Support project participant in the collection of the required financial data to be reported in each reporting
- periodically control the consistency of presented data

The Socio-Economic & Exploitation Manager (**SEM**) will co-ordinate activities related to socio-economic research, including the definition of business models. SEM is supervisor of the quality and delivery of the following task: T1.2, T1.3, T7.3 and he will report the results of those activities to the Consortium at large and to the PMB in particular, and will be responsible of ensuring that those results are properly taken in account in the steering of the project and of the other activities upon which they may impact, in the form of guidelines and recommendations. Consequently the SEM will be in charge of the design and implementation of the exploitation of REMINE results, as the project comes to its fruition. The SEM of REMINE will be Dr. Paola Fantini from MIP.

The Scientific & Technical Manager **(STM**) will co-ordinate the different research and technological activities foreseen in REMINE. STM is supervisor of the following tasks and work packages: T1.1; WP2, WP3, WP4, WP5, WP6, T7.1, T7.2. The STM takes also the role of the head of the Scientific and Technical Steering Committee of the project. The STM of REMINE will be Dr. Carsten Fehler from GMD. More specifically the activities will be undertaken by the STM can be summarised as follows:

- Synchronise and integrate the results achieved in each Research Activity
- Monitor all development plans for those Activities, and facilitate synergies among Activities
- Ensure a proper exchange of feedback between Research, Development, Piloting and Validation Activities.
- Report on scientific and technical progress of the project to the Project Manager and to the Consortium
- Decide together with the SEM and the DSM (see below) the strategies with respect to the outreach and the publicity of the Consortium, the Project and its major results.

The Dissemination & Standardisation Manager (**DEM**) will be in charge of REMINE dissemination strategy and roll out of the related activities as well as of standardization of REMINE results to ensure that the benefits of the new technologies developed in REMINE are utilized. DEM is supervisor of the quality and delivery of the WP8. This approach will be achieved through an active co-operating with the relevant standardization bodies. The DEM will be Prof. ANDREAS-GEORGIOS STAFYLOPATIS from ICCS.

The Ethical Manager (**EM**) EM is not supervisor of a specific task or work package in the project, but his responsibility it is to overlook the clinical side of the project, assuring that the field trials that will be roll out within the hospitals involved will respect good clinical practice as a legal requirement. In a sentence the Ethical Manager main roles are: advisory, supervisory, approving.
The Ethical Manager will also guide the work of the project Ethical Committee.
REMINE project Ethical Manager will be Tommaso Bellandi from REGLOM.

In addition to those managers grouped under the PMB, the project has identified a leader per each work package. They will closely work with the top-managers in order to match the expected project results with the strategic and research directions of the project. The Work Package Leader (**WPL**) will be responsible for the progress of the work in their respective work-packages being in charge of the co-ordination, planning, execution and monitoring of the tasks within that work package and for the detailed co-ordination of these tasks with the other tasks in the project. The WPLs of Research and Development Activities and Validation Activities, together with the appointed STM, form the Scientific & Technical Steering Committee of the project.
Within each work package, task leaders have also been appointed. Each task leader will directly report to the related work package leader.

Management Bodies

The highest-level authority of the project will be the Project Management Board (PMB), formally empowered to take binding decisions. It will be in charge of:

- implementing the strategy approved by Consortium members grouped under the General Assembly and for managing operations;
- definition of the IPR strategy;
- addressing the strategy for the exploitation of the project results;
- assuring the quality policy inside the project;
- approving the deliverables for release;
- solving difficulties and major problems eventually occurring during the project;
- solving conflicts that may eventually emerge during the project;

It will consist of the managers described above. Decisions in the PMB will be taken at the majority, the PM having a casting vote.

The General Assembly (**GA)** is composed by representatives from all partners of the consortium. Upon recommendation of PMB the GA takes the final decision on:

- the overall-policy of the consortium,
- modifications or extensions of the consortium agreement,
- modifications or extensions of the objectives of the project.

In case of conflict between the PMB and the Scientific & Technical Steering Committee, the GA takes the final decision. The PM will keep the GA informed about the progress and the achievements. Members of the GA shall have a differentiated voting power, which is based on their company's overall share of costs in the project. Decisions on the designation of the PMB, implementation plan, budget allocations, new members, revocation of the PMB, revocation of a Consortium Member, amendment to the EC Contract and alterations of the Consortium Agreement

need a 75% majority of all parties. For any other decision a majority of the votes and a majority of the parties is required. The GA constitutes a quorum if more than 50% of the parties are present or represented by a proxy. The overall REMINE size is determined by the total invested resources (work and financial) in the overall project as it has been defined in the detailed workplan. The PM, the STM are ex-officio members of the GA. It meets regularly at least once a year or more frequently if more than 20% of the GA members require it. The GA elects its chairperson from the GA members. Each partner shall appoint a representatives participating to the GA, empowered of voting.

The Scientific & Technical Steering Committee (**STSC**). STSC is an external group of 5 to 10 experts in the REMINE application domain, identified by the PMB during the first three month of the project. It will be set-up with the objective to define the strategic paths of the project, to assess the overall quality of the scientific and technical work carried out, and to update and verify the overall scientific and technical objectives and their relevance in the fast-moving context of the research field addressed by REMINE. More specifically, he STSC will be responsible for the following issues:

- Verifying the coherence and relevance of the research and technological objectives throughout the project
- Verifying the progress and work of the research and technological directions and of the technological development areas under the scientific and technical point of view
- Contributing to define and help resolve any problems regarding the need of scientific and technical competence
- Advising the PMB and reporting to the GA on all scientific and technical issues
- Further identifying proper application areas accordingly to the development of research and technological activities
- Assisting and monitoring in the definition of business model and REMINE exploitation plan
- Suggesting and evaluating dissemination and training actions

The STSC will be led and co-ordinated by the STM who will report decisions taken to the PMB for the final approval. Chairing the STSC, the STM will synchronise the activities with the PMB, being this board in charge to adopt the decision agreed within the SSC. The STSC holds at least four meetings during the project life time (M6 – after the REMINE project specifications; M18 after the first prototype testing results; M30 – after the second prototype testing results and M36 – for the final assessment of the project) to steer and to advice the STM and the PMB in their decision making process according with the REMINE expected outputs.

The project Ethical Committee (**EC**) will be composed by accredited exponents of each hospital internal ethical committee. Its main role will be to assure that Standard Operating Procedures will be applied in all the sites involved in the project demonstration activities. Moreover the project Ethical Committee will assure that the project demonstration activities will be developed fully respecting privacy and security issues from a legal point of view. In particular, the activities foreseen will be implemented in respect of the Data Protection Directive 95/46/EC. The project Ethical Committee will assist the Project Management Board in implementing the most compliant ethical and legal approach to project activities and will report to it.

Coordinating mechanism

The organizational structure described in the previous paragraphs and the management bodies identified will provide the right framework for managing the REMINE project appropriately. To assure that the designed framework will provide the right drive towards project goals' achievement, a set coordinating mechanism has been defined.

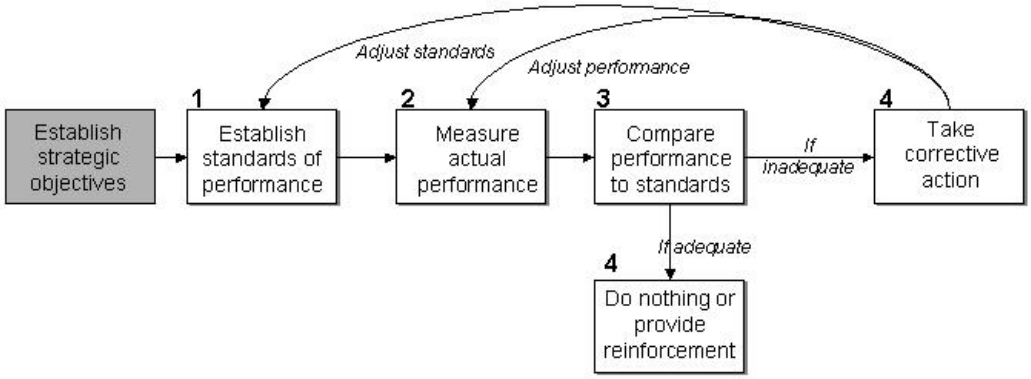
Direct supervision. Than means achieving coordination by having one person take responsibility for the work of others, issuing instructions and monitoring their actions. This form of coordination is quite effective for achieving specific goals and ease the attribution of precise responsibilities in large management structure allowing for accountability. In REMINE every partner will be required to identify an internal project manager who will be in charge for the work carried out within his organization with reference to the project. He will report directly to WP leaders and to the REMINE PM for all the issues related to his/her organization work.

Standardization. Using standardization the coordination is achieved "on the drawing board", so to speak, not during the action or "run-time". The coordination is pre-programmed. REMINE will achieve that through the precise definition of project work schedule, activities and output in the description of work. Standardized outputs means that there are specifications that work output must meet, but aside from that the worker is free to do as they wish. The output will be described as clearly as possible allowing for the necessary freedom to achieve results in a research process, of course, but characteristics and standards will be well defined in advance. Similarly, work process will be specified so to have a clear path to follow. That will ease coordination of activities in WPs as well as the coordinating work of the REMINE PM.

Mutual Adjustment. This mechanism is based on the simple process of informal communication. It is quite common in very small organizations, or for very, very complicated tasks. It's especially useful when nobody really knows ahead of time how to do what they're doing. In REMINE will be allowed and even fostered in small research groups at even at higher management level to identify solutions when facing particularly difficult problems.

Quality control procedures

Quality control is a mandatory requirement for REMINE project, so that a complete quality certification process has been developed in order to meet excellence standards. The various phases of the quality control activities that will became a consolidated practice within REMINE are visually represented in the following diagram.



Standards will be defined for each output as well as appropriate way of measuring the. This iterative approach will be applied on a regular base to all identified output and will be a primary concern of the PM to make sure that the process described has been gone through. The definition of an effective quality monitoring system is necessary for controlling the different phases of the project, in order to really understand if the project is proceeding as planned and to anticipate problems instead of solving them after. This important function of management has the goal of maintaining an adequate resource expense trace, in terms of consumed financial resources and work carried out according to the project progress. This is achieved through the use of adequate tools and control

instruments that ensure a good project progress in terms of timing, costs and quality. A review of all activities will be performed periodically to guarantee the minimisation of project deviation in comparison to criteria such as budget, quality, schedule. Any detected deviation, due to unexpected technical risks, Consortium disagreements, working problems, budgetary difficulties, will immediately lead to specific decisions, in order to adopt the necessary changes in the project workplan. This has been seen as an iterative process, where the identified changes established, in their turn, a new basis for the project assessment

Risk Management Methodology

General Approach

In addiction to the above described project monitoring and quality management instruments, the Consortium will ensure the internal control of the project outputs' quality through an assessed risk management methodology, with the aim of preventing operational bottlenecks of contributing to a first-level output delivery.
The chosen methodology is based on a three stage approach:

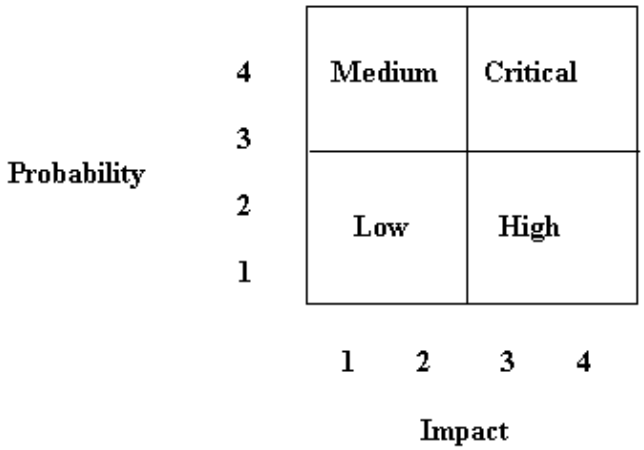
- Risk identification: quarterly and according to the current status of the project, possible risks will be identified, and evaluated according to their probability (how likely it is that each of them happens); this activity will be carried out by the PM supported by WP leaders.
- Risk Assessment: each identified risk will be evaluated considering its probability and the potential impact on the project; again the PM will be supported by WP leaders.
- Risk Response: the PM will identify possible actions to either aoid or mitigate the risks and evaluate these actions with WP leaders; a joint decision about how to precede will be taken.

Risk identification

In this stage, we identify and name the risks. The best approach is a joint workshop with member of the team of different background (i.e. business and IT people) to carry out the identification. Use a combination of brainstorming and reviewing of standard risk lists. This will be done first at WP level with WP leaders identifying risks within their WP and then at project level by PM and WP leaders.

Risk Assessment

To be appropriately assessed, the identified risks have to be quantified in two dimensions. The impact of the risk needs to be assessed. The probability of the risk occurring needs to be assessed. For simplicity, rate each on a 1 to 4 scale. The larger the number, the larger the impact or probability. By using a matrix (see following picture), a priority can be established.



If probability is high, and impact is low, it is a Medium risk. On the other hand if impact is high, and probability low, it is High priority. A remote chance of a catastrophe warrants more attention than a high chance of a hiccup.

Risk Response

There are four things that can be done about a risk. The strategies are:

- Avoid the risk. Do something to remove it. Use another supplier for example.
- Transfer the risk. Make someone else responsible. Perhaps a Vendor can be made responsible for a particularly risky part of the project.
- Mitigate the risk. Take actions to lessen the impact or chance of the risk occurring. If the risk relates to availability of resources, draw up an agreement and get sign-off for the resource to be available.
- Accept the risk. The risk might be so small the effort to do anything is not worth while.

The PM supported by WP leaders will evaluate the situation and choose the most appropriate strategy that will be included into a risk response plan. A risk response plan should include the strategy and action items to address the strategy. The actions should include what needs to be done, who is doing it, and when it should be completed.
Risks will be continually monitored and reconsidered during the quarterly risk identification workshops, wih the goal to identify any change in the status, or if they turn into an issue.

Risk Description	Consequence	Inherent exposure		Current Preventative controls	Current Corrective controls	Residual Exposure		Assigned to
Risk Description	Description of the impact in worst case scenario	Likelihood	Outcome	Preventative Control Description	Corrective Control Description (*use this to correct/,mitigate the impact)*	Likelihood	Impact/ Consequence	Responsibility
Notes:.								
Is further action required: _____ Y/N Date: _____ Review Date: _____								

Datix*16*

In addition to the general approach described above. The Datix risk-management model will be used. DATIX is the UK's leading supplier of software for Patient Safety, Risk Management, incident and adverse event reporting. DATIX is used by more than three quarters of the National Health Service in the United Kingdom, serving a population in excess of 40 million. DATIX is also a favourite with private healthcare providers. DATIX has received a Queen's Award for Enterprise and Innovation.

The Datix framework provide a comprehensive set of tools for dealing with all the following Risk Management needs:

- Incident reporting
- Safety alerts
- Risk register
- Standards
- Complaints
- Patient Advise and Liaison Service
- Claims
- Inquest Management
- Training Records
- Classification of Safety Incidents

Drawing on international research and input from our users, DATIX has developed a standard coding system for clinical and non-clinical adverse events and near misses. DATIX has developed a standard coding system for clinical and non-clinical adverse events and near misses. This covers not only patient safety incidents, but also Health & Safety. Moreover the Datix Taxonomy will be an important part of the learning system within REMINE.

[16] http://www.datix.co.uk/

Risk and contingency plan

This paragraph is dedicated to a first analysis of possible risks which could affect the achievement of planned results and related contingency plan which might be implemented to properly face the out coming situation. Obviously, at this stage, this list should be considered just as a preliminary exercise which might be enriched or modified due to a clearer view of the reference market as well as of product characteristics and potentialities, during the following of the project activities and system development.

Risks	Contingency
Needs of very specific technical and scientific skills to fulfill the research and development effort necessary to realise the project backbone. Responsible: **STM**	REMINE scientific and technical partners represent a strong alliance of leading organisations that can boast the needed competences to realise and implement this ambitious venture. Moreover, the screen which has been already done of research projects and ongoing initiatives that can be useful to REMINE realisation, will aid this process giving the opportunity of taking out the most from already assessed research outcome.
Technical innovation needed is beyond project capacity Responsible: **STM**	Partners have been chosen to minimize the possibility of this risk as they have the full range of required skills and represent the most advanced European and International organisations in the fields related to REMINE innovation capacity. Consortium is aware of the rapid evolution of the eHealth market sector and for this reason has involved Internationally recognised Standardisation Organisations, such as CEN which will assure the prompt take up of innovative technological trends.
REMINE system does not fulfil user requirement and expectation Responsible: **STM**	The idea of REMINE has been born on a real need expressed by a group of Regions and related hospitals, timely become the REMINE project users, highly commitment in practically utilise the project product. REMINE users are playing and will play a fundamental role in the development of the system thanks to their knowledge in the field of application of REMINE. REMINE will relay its design and development on the fact that healthcare tools and services exist for the benefit of the user, and this assumption is reinforced in the case of innovative solutions: the development of a solution impacting on patient safety is an important focus when aiming to improve the quality and effectiveness of care.
Consortium ability of commercialising project results Responsible: **SEM**	The project consortium has the necessary commercial muscles to lunch and sustain the product in the reference market at pan-European and even International level. In particular this statement is reinforced by the fact that the Consortium can boast the presence of an industrial partner such as IFOWORLD, GMD and HP, that have a consolidated market presence in the medical field.

The profitability of the market may attract competitors Responsible: **SEM**	Being a first comer, REMINE will have the opportunity to establish itself and compete from a dominating position once other solutions will appear on the market.
Lack of cross cooperation with scientific communities Responsible: **DEM**	Presence of network of research centres linked with the healthcare users and domain experts. Continuous verification of joint research activities. STSC organized after three month of the project start. It will involve 5 to 10 key persons in REMINE domain in order to assure the proper cooperation with the scientific community.
Lack of data necessary for the testing phase Responsible: **STM**	The strong involvement of regions and related hospitals within the consortium grants that a large amount of data is available since the preliminary development phase, so that it is possible to complete a valid version of the framework, including the related knowledge. This will attract new actors, contributing with their internal knowledge.. The already selected hospital are already familiar with the use of new technologies and activities related to the scope of REMINE.
Lack of commitment from the health authorities Responsible**: PM**	REMINE idea has been and is actually fully sponsored by the regions involved in the project that are looking at the solution proposed by REMINE as a real answer to their actual needs.
Risk in involving hospital and related personnel in the project living labs Responsible: P**M**	Having chosen heath care regional authorities as partner of REMINE consortium, instead of hospital, it allows the consortium as a hole to be more flexible in the relationships with the final demonstration site. By the matter of fact, without changing the consortium composition, thus without running a time consuming project amendment, REMINE PMB, together with the regional authorities involved in the project, will be able to select the proper demonstration site and eventually to readjust the selection, according with the level of trust wll be recognised between REMINE consortium and the demonstration sites.
Risk related to RFID implementation at testing sites Responsible: **STM**	Some of the hospital involved through the regional authorities members of the consortium are already experimenting RFID. In any case HP together with STM will assess in advance each demonstration site in order to identify the possible risk and the needed countermeasures. All this information will be reported in the quality control report of the project.

Decision Making Structures

Decision Process

The Project internal consensus will be achieved through periodical PMB meetings. Within these meetings decisions will be taken both on managerial and technical issues.
It will be the responsibility of the Project Manager to encourage decision to be made by consensus.
Ordinary PMB Assemblies will be organised every four months to examine the completed activities and plans proposed for the future. Each consortium member will hold a number of votes proportional to its share of Project budget. Decisions will be taken at the majority (of votes and of members). Where unanimity is not possible, decisions can be made on the basis of a qualified majority of 75 % of the authorised representatives of those partners present represented by proxy.
Extraordinary PMB Assemblies may be organised at the request of the PM, of the PMB or of a group of Consortium members representing 25% of votes or of members in order to examine extraordinary issues (such as revocation of a Consortium Member, amendment to the EC Contract, …).

Information Flow

The information originated by the Project may have a technical or a managerial nature. Concerning the technical issues, information flow will be achieved through:

- Organisation of internal Workshops;
- Meetings of Scientific & Technical Team; Work Package participants and activity participants meetings will be held as necessary for the execution of the technical execution of REMINE Project .
- Distribution of monthly Technical progress by the Scientific & Technical Manager and regular discussion with the S&T Manager;
- Use of specific groupware to support collaborative work.

As far as managerial, administrative and financial issues are concerned communication and information flow will be achieved through:

- Consortium Meetings; they will aim to inform all Project Partners of project progress;
- Meetings of the Project Management Board;
- Distribution of reports by the Project Manager.

Intellectual Property Rights

The management of the Intellectual Property Rights will be considered within the exploitation WP and will consequently be under the responsibility of the SEM. The mechanisms that the Consortium will implement for managing knowledge and intellectual property comply with the rules defined by the EC for projects of the 7th Framework Programme.
They will deal with:

- Management of clear schedules of both pre-existing know-how brought in the Project by a participant and of knowledge generated through the Project;
- Establishment of contractual agreements between consortium members whenever the Consortium decides to use pre-existing know-how;
- Adequate dissemination of knowledge generated in the Project;
- Adequate protection of methods and technologies eventually resulting from the Project and having business potential.

At the time of drawing up the REMINE project, IPR intentions are the following:

- Any partner having conceived innovative methods and techniques will have the opportunity to protect the new knowledge through a European patent.
- Methodologies and research studies will be disseminated free of charge.
- Any software implementation that may occur within the project will remain the sole property of the partner having developed it.
- Software owners retain the right to develop commercial variants of their own production.

B2.2 Beneficiaries

Gesellschaft fur Medizinische Dataenverarbeitung mbh
GMD is the R&D software factory of NoemaLife's group. Noemalife Group consists of Dianoema, Italnoema, GMD, Noematica, Biosoft and NoemaLife Argentina. All companies jointly aim at understanding and anticipating the needs of health organizations in a continuous commitment to improve clinical processes. The Group's organization attaches a clear and specific mission to each company. Dianoema is responsible for diagnostic IT Systems, project execution and support to clients in Northern Italy and Group governance and joint services. Italnoema is handling project execution and support to clients in Central-Southern Italy. GMD develops and maintains the EMR platform and offers project execution and support to clients in Germany and on the international market. Noematica offers project execution and support to clients of Electronic Medical Record and Clinical Data Integrated Management in Italy. The latest addition to the Group are Biosoft and NoemaLife Argentina, while the Biosoft business is based on IT solutions for hospital processes with a product line focused on management systems for operating rooms, on the integration of biomedical equipment (in particular, for intensive care units), and on areas of medical specialty (cardiology, urology, oncology, gynaecology, etc.), NoemaLife Argentina develops the South American market coordinating NoemaLife partners and customers across the ocean. Established in 1996 Noemalife's success story is proved by its constantly growing figures: more than 250 healthcare organisations and 35 biotech companies as customers, 96 hospitals using EPR solution, 280 automated labs and more than 160 employees. All companies jointly aim at understanding and anticipating the needs of health organizations in a continuous commitment to improve clinical processes. The Group's organization attaches a clear and specific mission to each company.
Role in the project
A central point of improvement in REMINE project is the complete integration among all parts of health care system. In last years almost of health organization adopted ERP system, REMINE will be insert in HIS (Hospital Information System) and REMINE will interact with all hospital units. GMD thanks to its experience in realizing HIS and its skill in management project, is the better coordinator for REMINE. Dianoema worked and analyzed health problems from several years, and it knows health management requirements and procedures.
Description of the previous relevant experiences in the area of your organisation expertise
The group invests 10% of the turnover in research and development. As a matter of fact, a considerable team of professionals in Bologna and Berlin are committed to developing new projects, creating new technologies and implementing cutting-edge applications in collaboration with the best universities and research centres too. The latest market researches confirm our clients' very high satisfaction level towards Dianoema Group products and services. The keys to success are: strong focus on the clients and a constant presence to support them,

which allow us to operate as consultants for application optimisation too; the flexibility our systems boast to adapt to every single health institution's specific requirements; prompt and concerned help-desk service provided by a team of highly qualified specialists regularly and efficiently.
One of the projects realized in private market, it was WindoPath, a computerization system for the services of Pathological Anatomy.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Michele Carenini

After graduating in Computational Linguistics at the University of Pisa in 1989, Michele Carenini worked for the Dept. of Linguistics and the Institute for Computational Linguistics (National Research Council) in Pisa. In 1991 he set up AITech, a spin-off company specialising in Natural Language Processing and Artificial Intelligence applications. In 1996 he moved to Omega Generation, Bologna, where in 1999 he became R&D Manager. >From 1998 to 2004 he has also been a lecturer in NLP and AI at the Dept. of Psychology of the University of Bologna. He left Omega in 2004 to join the School of Informatics of the University of Edinburgh (UK) as Business Development Executive, focusing mainly on the School's relations with national and overseas industry. In September 2005 he returned to Bologna to join NoemaLife SpA as International Business Development Manager. Since January 2007 he is Knowledge Management Officer and Project Manager for all the companies of the group (GMD in Germany; NoemaLife, Noematica, Biosoft in Italy; NoemaLife Argentina). Since 1992 he is a member of the Society for Machines and Mentality. He has published more than thirty scientific papers on national and international journals, a book about Natural Language Semantics and one about Philosophy of Mind.

Gianpiero Camilli

Professional experiences:

- 2002–actual (NoemaLife's group) marketing manager EPR/EHR's projects and products; manager of the R&D business unit in GMD.
- 1998–2001 leader manager of the business unit health products.
- 1995–1997 marketing manager of Health Division.
- 1990–1994 (Logicasiel) marketing manager LIS products.
- 1985–1989 (GSO Informatica) R&D manager and product manager of a Unix-based LIS.
- 1980–1984 (General System) project and account manager in the implementation of LIS in European large hospitals.

Carsten Fehler

Education:

- 1991-1996 Open University (largest higher education institution in the UK) "Architectural Engineering" Degree awarded on July 17, 1996 with 100/100 Cum Laude. Stages and visiting periods at: Royal University of Gent (Belgium), Lehigh University (Pennsylvania, USA)
- 1996-2000 Open University (largest higher education institution in the UK) Ph.D. in "Structural Mechanics" Degree awarded on February 14, 2000 after discussion of a Doctoral Thesis on "FRP External Strengthening for Reinforced Concrete Beams" "Visiting scholar" at the CIES - University of Missouri Rolla (USA)
- 2001 McKinsey & Company - Mini MBA Program (SintMichielGestel, Netherlands) Intensive training program held by teachers of some of the best Business Schools (Harvard, Stanford, INSEAD) on Corporate Finance, Managerial Economics and Strategy

Professional experiences:

- Open University (largest higher education institution in the UK) Teaching assistant of

Structural Mechanics at the DISTART Structural Engineering Department and of Mathematics at the Economy Department

- Professional Engineer Design and consultancy as a Structural Engineer in Italy and in the United States with focus on repairing and strengthening existing structures. Main Clients: Wachovia Bank, Pittsburgh International Airport, Mitsubishi Chemicals, Ferrovie dello Stato, Regione Emilia Romagna, Prefettura di Venezia, Comune di La Spezia, Omnitel Pronto Italia, Wind
- 1999 Dianoema S.p.A.: External Consultant Development of software components in Visual Basic and HTML
- McKinsey & Company: Engagement Manager (joined as Junior Associate) Top management consulting on Corporate Finance, Strategy, Marketing Strategy, Organization and Operational Efficiency.
- 2003-2007 GMD: CEO and Vice President Business Development Partnership and alliances for the expansion in international markets.

HEALTH CARE DEPARTMENT OF LOMBARDY AND TUSCANY

Health Care Department of Lombardy Region is involved in REMINE together with Health Care Department of Tuscany Region,both have signed a cooperation agreement among them.
In this agreement Lombardy Region will be the direct part of the project, while Tuscany Region will act as "supporting" partner providing all the necessary efforts for carry out the project activities.

Lombardy Region has around 9.300.000 citizens. Health Care system is constituted by: nr. 844 Health clinics, nr. 15 Socio Sanitary Units, nr. 9.000 GPs, nr. 1.000 Paediatricians, nr. 132 Hospitals, nr. 66 Other public clinics, nr. 381 Hospices, nr. 18 Research institutes, nr. 37 Primary Care Clinics, nr. 99 Emergency Rooms, nr. 45.849 Beds in Hs , nr. 4.294 Beds in DHs. The Health expenditure amount to € 14,5 billion budget for public sector. In 2003 Lombardy Region adopted a Virtual network called SISS, a integrated database collecting all health structures. Tuscany Region has around 3.635.462 citizens. Health Care system is constituted by: nr. 9 Health clinics, nr. 12 Socio Sanitary Units, nr. 3.5000 GPs, nr. 600 Paediatricians, nr. 42 Hospitals, nr. 15 Other public clinics, nr. 270 Hospices, nr. 4 Research institutes, nr. 8 Primary Care Clinics, nr. 45 *Emergency Rooms, nr.* 13.870 *Beds in Hs*, nr. 2.084 *Beds in DHs*. Health expenditure amounts to € 4.995 million budget for public healthcare.

Lombardy and Tuscany have chosen as final pilots: Niguarda Hospital and Careggi Hospital with their RAPS office and a department chosen for completeness of medical path (e.g. laboratory, surgery, chemistry' shop, ward).

Role in the project

Lombardy Region by the light of its competence and previous experience, is be chosen as pilot, thanks to its advanced IT infrastructure, and its past experience.
Being Lombardy Region the greater of Italy and having all territorial data, the Lombardy Region Government could locate two final pilots in Niguarda Hospital and Careggi Hospital, and for using Careggi Hospital, Lombardy Region drawn up agreement.
Lombardy and Tuscany Regions have the competence as organization and management of project.
Niguarda Hospital is chosen for its features like size, number of patients, completeness of medical specialities. The living pilot will perform c/o MCQ Unit is the responsible of quality inside the organization. It controls the respect of adverse event procedure.
Careggi Hospital is chosen because is a public hospital and moreover it is university hospital. The living pilot will perform c/o Hospital Public Relation Office (URP).

Description of the previous relevant experiences in the area of your organisation expertise

The Lombardy Regional Government, in these last years, has introduced a new organisational model for the health-care service, based on the acknowledgement of the freedom to choose between public and private facilities. In addition, a distinction has been made between those that co-ordinate and manage the "demand", namely the local health-care centres that buy-in the services on behalf of the citizens, and those that ensure the "solutions", namely the accredited public and private facilities. Furthermore, the new regional social-health plan foresees an experiment to transform a number of public hospitals into foundations.

The group also participated to numerous European and national projects in the health-care field, a brief list follows: Co-Co (1), HECTOR (1), HANSA, STAR (1), Cardlink2 (1), Remedes (1), RHINE – AM, KIRHA Key Indicators for Regional HeAlth, DIDE DIdactic Distributed Environment, CAROLIN Cooperative Application for Remote OnLine INteractive diagnosis, VEPSY, CHARM, C-CARE; among them two are most significant INTERCARE The Interworking and Interoperability of networked services for Healthcare using Internet-based technology and SUN2 a integrated IT system for health functionalities.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Claudio Beretta

Degree in Physics (1981) at University of Studies of Milan. Qualified II level expert of the Labour Ministry Center Health Department.

At present. He is head of the Structure "Research and innovation technology" within the Regional Government Health Ministry. He co-ordinates and promotes the research activities of Regional Government Health Ministry and regional health structures. He defines the research development plan in order to promote the transfer of experience and know out, to create a critical mass of opportunities for the Lombard industry of healthcare information and network services, to encourage the co-operation of public administration, health structures, university and industry.

He holds the government of Regional Government Health Ministry information system and of the Regional Health Care Information Network. (SISS) He promotes the modernization of health hospitals information system in order to develop a regional network. He is a member of Tele-medicine working group within Italian University Ministry. This working group is responsible for co-ordination of Tele-medicine development in Italy, and for the promotion of health information transmission standard. He is the co-ordinator of the Regional Committee for the evaluation of Information Technology Projects of regional health structures. The committee evaluates projects, decides on their financing, and verifies their correct realization. He is the Regional responsible of European Project.

From 1999 to 2001 He holds refresher courses, within IREF (Training Regional Institute) courses, for Managers of Regional LHA (Local Health Authority) about Health Information and about European and Italian privacy laws. He is a consultant of Lecco Local Health Authority in the field of Health Information System.

From 1995 to 1999 He is responsible of Health Information System and EDP Manager at Vimercate Hospital. He manages the information system of 5 Hospitals in north Milano area. He is a consultant of Lecco Local Health Authority in the field of Health Information System He contributes to develop the hospital network, and to improve the connection with the community centres distributed across the territory.

From 1991 to 1994 He is responsible of Health Information System and EDP Manager at Desio Local Health Authority.

He manages 2 Hospitals and 4 Community Care Center information systems in north Milano area.

Tommaso Bellandi is a certified European Ergonomist (Eur.Erg.) and works as a project manager and human factors expert at the CRM centre. He has a PhD in Communications.

He has an experience of research, training and consultancy both with the public and the private

sector in safety issues, mainly in healthcare but also in transportations.
He teaches ergonomics, communications and risk management in many academic and professional courses around Italy and is author of scientific and professional publications in Italian and in English He is a member of the national commission on patient safety and of the board of the Italian Ergonomics Society.

Enrica Ferrari

Degree in Biology at University of Studies of Milan. Post degree in Biochemistry and Clinical Chemistry.
At present She works in the Structure "Research and innovation technology" within the Regional Government Health Ministry. She promotes the research activities of Regional Government Health Ministry and regional health structures. She is in charge of following European projects in order to promote the transfer of experience and know out, to create a critical mass of opportunities for the Lombard industry of healthcare information and network services.
From 1998 to 2000 She works in the Information System and Quality Office within the Regional Government Health Ministry. She is interested of hospital management and quality of care.
From 1994 to 1998 She is a research in the Desio Hospital. She is in charge of following some projects in Health care and environmental pollution.
From 1991 to 1994 She is a research in Desio Hospital Laboratory: She studies the cell cycle and its relationship with tumour.

Riccardo Tartaglia, MD, is the director of the CRM centre of the Tuscany Region. He is a Physician, registered in Occupational Medicine and in Public Health. He is also a certified European Ergonomist (Eur.Erg.). He was previously the head of the Centre for Research in Ergonomics, a consortium between the University of Florence, Siena and the Healthcare Trust of Florence metropolitan area.
He coordinates the national research on clinical risk management methods and solution at the Agency for the Regional Healthcare Services.
He teaches risk managemet and ergonomics in many academic and professionalcourses around Italy and is author of many scientific and professional publications in Italian and in English. He is currently the president of the Italian Ergonomics Society.

Francesco Venneri, MD, is the Clinical Risk Manager at the Florence Healthcare Trust. He is a surgeon, registered in Emergency Medicine and Neurosurgery. He has also a master in Clinical Risk Management. He teaches Risk Management in professional courses around Italy. He is a member of the Scientific Committee of the CRM centre and he is author of many publications in Italian and in English.

Sara Albolino is a Sociologist and works as a project manager and reliability expert at the CRM centre. She has a PhD in Organization Studies. She has an experience of research, training and consultancy both with the public and the private sector in organizational issues.
She teaches oragnization studies and risk management in many academic and professional courses around Italy and is author of scientific and professional publications in Italian and in English
She is a member of the national commission on patient safety and of the board of the Tuscany chapter of the Italian Ergonomics Society.

Matteo Fiorani works as a project manager and human-computer interaction expert at the CRM centre. He is a PhD candidate in Ergonomics at the University of Turin. He has been research assistant at the University of Siena from 2003, and he took part in national and EU-funded research projects, mainly in automotive and healthcare domains.
He teaches ergonomics, human-computer interaction and risk management in many academic and professional courses around Italy and is author of scientific and professional publications in Italian and in English. He is a member of the board of the Tuscany chapter of the Italian Ergonomics Society.

Suupohja region in West Finland

Finland has an health care government organized in several level. The country divides in region and each region has a autonomy, thus, prime responsibility for local health services rests with local authorities. Primary health care has health centres, while secondary health care consists of hospital, university hospital and several institutes.

The Suuphoja Region comprises 5 hospital district: Hospital District of Northern Savo (Kuopio), Hospital District of Central Finland (Jyväskylä), Hospital District of North Karelia (Joensuu), Hospital District of Southern Savo (Mikkeli), Hospital District of Eastern Savo (Savonlinna). Region population amount to 860.000.

Public healthcare has a budget for € 5.895 million, thus health is one of main point of interest in region government.

Suupohja region advises to adopt a H-ERP system, and a regional procedure regards quality system, thus each health instituted has to have a quality system (SFS-EN ISO 9001:2000).

Suuphoja Region choices like living pilot on of the greater hospital: Kuopio Hospital, it is a public hospital and moreover it is university hospital. Kuopio Hospital rises in Hospital District of Northern Savo, and it's the only hospital and the most research innovation oriented.

Hospital District of Northern Savo is composed by: 23 local authorities, 250.000 inhabitants, and 1 hospital: Kuopio University Hospital (KUH).

Personnel of Kuopio Hospital amounts to: 4.100, divided in nr. 500 Doctors, nr. 200 Research staff, nr. 2.500 Nurse, nr. 900 Administration, and Kuopio Hospital total beds are 800 (Conservative treatment: 300, Operative treatment: 360).

Kuopio Hospital pursues medical research as a value. The main areas of research are: chronic national diseases and their molecular background, prevention and cure, neurosciences, examination scans, musculoskeletal disorders, wide-ranging clinical research. Kuopio Hospital has a Quality Elevation (QE) Unit is the responsible of quality control, it manage the procedure of adverse event management.

Hospital adopted in 2005 a HIS system, which will integrated with REMINE.

Role in the project

Suupohja Region has the competence for managing a final pilot. Its precedent experiences in technological projects
allows Suupohja Region to have skill of pilot coordinator and it will be a essential user of REMINE.

Description of the previous relevant experiences in the area of your organisation expertise

Suupohja region in the Western Finland is one of the national regional centres of know-how. Suupohja Living Lab www.livinglab.fi is the innovation commitment and cluster for new IST-services. The organisation: The Federation of Municipalities for economic Development in Suupohja represents the region and is the development center in Suupohja www.suupohja.fi

The Federation of Municipalities for economic Development in Suupohja has worked in several development projects for eHealth, ICT for healthcare and personalized healthcare. The regions best know-how, biggest need and potential today is for the personalized health care records management system for the elderly people living still in their homes. The Suupohja region has co-operated and will co-operate in this project closely with our partner TietoEnator, the most innovative eHealth technology company in Finland.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Dr of Med, Ms Kirsi Kähärä, the head of Kauhajoki and Suupohja health care district. Dr Kähärä also represents the University of Tampere medical sciences faculty. She has a long experience as a trainer for advanced medical studies, working with the elderly patients, and of innovative eHealth solutions.

Mr Jari Iso-Koivisto, the head of Suupohja regions eHealth development sector and the Suupohja Living Lab's personal eHealth project of the regional centre of know-how.

Mr Jaakko Panula, international coordinator. Several years of experience with EU FP4, 5 and 6 projects as coordinator and partner.

THE ROTHERHAM NHS FOUNDATION TRUST

The Rotherham NHS Foundation Trust sites in South Yorkshire.
Health Care system is constituted by: primary health care with health centres, and secondary health care with 45 hospital districts, 10 university hospitals and 15 central hospitals.
The health care expenditure amounts to £ 20.895 million budget for public healthcare, and the incidence of RAPS on total expenditure is around £ 201.500.
The Rotherham NHS Foundation Trust provides a range of general and acute services at the main hospital site and at the Park Rehabilitation Centre on Badsley Moor Lane.
The Rotherham NHS Foundation Trust is a progressive acute Trust set in leafy suburban surroundings in the heart of South Yorkshire. The Trust provides a comprehensive range of hospital based Medical, Surgical, Paediatric, Obstetric and Gynaecological services, all located on one site. The hospital is a major provider of high quality health care in South Yorkshire and to the local population of 252.000. There are 721 beds on site and excellent modern facilities which include Intensive Therapy, Coronary Care Unit and Cardiac Suite, a Breast Screening Suite, a Day Surgery Unit and an Endoscopy Suite. The clinical services are supported by comprehensive Laboratory, Medical Physics and Diagnostic Radiology Departments. CT and MRI scanning are available on site.
The Rotherham NHS Foundation Trust has a "Accident & Emergency Medicine Department" that provides care to people suffering from injury or illness requiring urgent treatment. The Rotheran NHS Foundation Trust sees approximately 73.000 patients a year, about 200 a day, this number having risen by a fifth (13,000) in the last five years.

Role in the project

The Rotherham NHS Foundation Trust will use its Accident & Emergency Medicine Department like REMINE pilot, thanks to its IT innovation trend.
The Trust's major clinical systems are:

- Patient Administration System (McKesson's Totalcare PAS),
- Choose and Book,
- Radiology (McKesson's DM-Rad),
- Accident & Emergency (Footman-Walker Associates' Symphony System),
- Theatres (iSOFT's Galaxy Surgery system),
- Pathology (in-house),
- Picture-Archiving and Communications System (Accenture/AGFA PACS).
- Many of the clinical systems are linked via our Integration Engine (eGate's Interface Manager).

As part of The Rotheran NHS Foundation Trust Health Informatics Strategy they will soon be implementing a new Corporate Information Data Warehouse (CACI) as well as conducting reviews of their Corporate Email, Integration Engine and Maternity system requirements.
Thus The Rotherham NHS Foundation Trust is a perfect user for testing REMINE as all, in particularly for testing database hospital integration.

Description of the previous relevant experiences in the area of your organisation expertise

Thanks to Rotherham NHS Foundation Trust's very active IT development programme, (this year their plan to implement Order-Communications & Results Report for Pathology which will operate throughout the Trust and across the GP community plus a new Endoscopy System) NHS

took part in several international projects, among them there is a important plan to improve health and social care for patients, LIVE Project. NHS Live project involves in selected partners who offer their private sector expertise and project management support.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Brian James

is Chief Executive of The Rotherham NHS Foundation Trust. He has a Masters in Health Information Management from Manchester University. Brian has worked in the NHS for over 30 years, 20 of these at Director/Executive level. In his last post he was Director of Health Service Strategy & Innovation for South Yorkshire Strategic Health Authority, and prior to this was Director of Strategy & Operations at South Durham NHS Trust. He established the first Information Management and Technology (IM&T) Learning and Resource Centre for NHS staff in the UK, and has led the implementation and evaluation of one of the largest HISS (Hospital Implementation Support Systems) in the UK at Darlington in the mid 90's. Brian has chaired several National Committees associated with the development of National IM&T standards, including the educational standards and academic curriculum for IM&T professionals working in the NHS. He has extensive experience in evaluating and managing the commissioning of evaluations in relation to fitness for purpose and added value of healthcare systems.

Dr Mike Kesseler

is a Consultant Dermatologist in 1983. He is the Deputy Medical Director (previously Clinical Director for Specialist Medicine) and recent Hospital Medical Staff Committee Chairman His responsibilities for policy development at regional and national level have also provided a wide perspective on NHS issues. His passion about the Hospital alongside his in-depth knowledge of healthcare planning within the borough makes him a powerful advocate for staff at the Trust.

Q and System Consulting ltd

QSC Ltd is a Small to Medium Enterprise (SME) company based in the UK. QSC consultants have a wealth of ICT based project management skills in international arena. The team has extensive experience, in working with mid range systems to PLC (Programmable Logic Controllers), and PCs, etc. at the hardware level, as well as a variety of existing software platforms. QSC is the a core developer for SGI KM and e-security based applications. QSCs core competency include: ICT project management Total Network Solutions, Security Protocols, Web Services Architecture and Grid based computing. Moreover QSC Ltd provides a variety of specialized applications, services, and assistance to domain specialists in the application of data mining technologies to different kind of data analysis problems.

Role in the Project

As a technological partner QSC will be particularly involved in the application of Mining techniques to RAPS data.

Description of the previous relevant experiences in the area of your organisation expertise.

Over the years QSC and its consultants have worked on several projects applying different mining techniques to knowledge discover. The staff has worked on the application of mining techniques to business analysis and marketing. Work in the medical sector include use of data mining for prediction of the effectiveness of surgical procedures, medical tests and medications, and discovery of relationships among clinical and pathological data.

Profile of the most relevant staff members who will be undertaking the work.

Mehrdad Naderi

He is a Senior Manager in QSC. Mr. Naderi has a first degree in electronics Eng. a second degree in Applied Computing and an MSc in IT and Management. He has extensive experience (more than 20 years) in large ICT projects in central government and international corporate sectors. Mr Naderi has a working knowledge ISO 9000 procedure with professional certification from KARV.

As an eminent technical architect and IT project Director with more than 20 years hands one experience in enterprise wide system design and deployment projects, he is a position to contribute to the critical success factors of the project. Mr. Naderi was a lead architect in design and successful deployment of 20000 end-nodes C2 secure data network. In addition to the latter Mr Naderi has been extensively involved in distributed computing research including Grid based IST Framework V project (www.grace-ist.org). He has both technical and administrative skills for managing requirements of the Trust-ME project.

Richard Bertram.

He is a senior Project Manager in QSC. Richard is a Fellow of British Computer Scocity with more than 30 years of project management experience. He has BSc. C Eng. FBCS, CITP. He was employed as a Project Manager by British Steel during the 1970s, developing large scale IT systems with budgets of over 1m. He moved into academia where he became a Subject Leader in Information Systems, managing a group of up to 30 staff. Simultaneously he undertook consultancy projects, managing UK DTI grants for the development and implementation of IT systems. After retiring in 2003 from academia, he continues to be active with project managing consultancy projects for innovative product development in a range of companies.

Hewlett Packard

HP-IIC is one of HP's European Innovation Centers. Since 1999, it is carrying on applied research, technology transfer and innovative solutions integration in leading edge areas. It can rely upon an excellence level team of researchers, consolidated skills and methodologies, and a physical infrastructure supporting project development and demonstration.

Main technology interest areas include:

- RFID technology based end-to-end solutions for logistics, manufacturing, e-health
- IT Governance and software lifecycle management
- Service Oriented Architectures
- Vertical solutions for front-office banking
- Vertical solutions for mobile users (e.g. in tourism and e-health)
- Mobile device centralized management
- Ad hoc wireless networking
- Open Source technologies

HP IIC has a consolidated presence and experience within the EU sponsored research and innovation programs. It is participating to about 20 projects in the previous frame programmes.

Role in the Project

HP main role will be related to the set up of the tools necessary to exploit RFID technologies to achieve the goals of REMINE. RFID is used to collect RAPS related data from peripheral applicances through RFID middleware and bespoke software.

Description of the previous relevant experiences in the area of secure and reliable packet-based communication on mobile tiny devices (cellular phones, smartphones, PDA, etc.)

HP IIC has been involved in different innovation and commercial projects, targeted to security of IP-based communication among mobile devices. Among the application areas, we can mention:

- Mobile device management, centralized management of heterogeneous device groups, including global control on security features configuration of mobile devices;
- Specific security frameworks and features for PDA devices;
- Seamless roaming solutions based on secured Mobile IP protocol, maintaining security over different connection layers;
- IPSec based solutions for establishing secure connections (e.g. VPN over corporate enterprise networks).

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Marco Di Girolamo

Graduated in Electronics Engineering summa cum laude in November 1986. 20 years of working experience in R&D, IT and Consulting environments, in different Companies, both Italian and international.
In HP since 1993, covered positions in R&D as Development Engineer (hardcopy devices), in Customer Care as Back-end Support Engineer for enterprise systems, and in IT Department as Service Delivery Manager for client computing.
Since 2000, he is working in HPC&I Italy Innovation Center, where served as senior technology specialist, solution architect and project manager in different engagements, both internal and external.
Since 2002, he is fulfilling the role of HP Italy European programs manager. In this position, he is coordinating and leading all HP Italy initiatives related to European innovation programs, including IST FP5, FP6 and eContent project participations.

Lorenzo Ferigo

Lorenzo has been with HP since October 1994, and has 15 years of experience in the Computing Industry. His current focus is on developing and delivering innovative wireless technologies and solutions.
Prior to joining HP Italy Innovation Center, Lorenzo has worked for 5 years in HP R&D printer division, covering different roles. He started as a test engineer in the test team, then he covered the fw development engineer role for 4 years, having the responsibility of fw design end development of the HP Digital Sender product line. In addition, Lorenzo is a specialist in embedded sw design and development methodologies.
Before joining Hewlett-Packard, Lorenzo has been a R&D engineer for several Italian companies, mainly working in the area of manufacturing oriented computer hw and control, and access control devices.

SO

SO Slovak Republic is a subsidiary company of the SO Servicios Profesionales.
SO has been active on the Slovak Republic market since 1991. First it operated under the name of Energoinfo a.s.. and then under the international trademark SO.
SO´s milestones:

- 1991 first activities in Central Europe
- 1992 foundation of Energoinfo in the Slovak republic
- 2000 creation of the international trademark SO
- 2000 creation Software factory to support SO intenational projects
- 2007 closing of strategic partnership with SAP

In 1999 it was certified by AENOR that SO SR had established and applied a Quality Management System , for development, implementation and maintenance of information systems, Customization and implementation of SW and packages for support of process control, according to ISO 9001:2000.
SO´s customers are mainly in the sectors of Utilities. The company is focused on software development and maintenance the SO products OPEN UTILITIES.
Development, Implementation and Integration:

- Systems OPEN SGC, OPEN SGI, OPEN SGT, OPEN METERS, OPEN REPORTS
- Solutions based on the products of the partner companies (SAP)
- Training

Role in the project

Thanks to current research activities and the past experience, SO role in REMINE will be developer of integration of REMINE module and ERP systems.

Description of the previous relevant experiences in the area of your organisation expertise

Innovation is the driving force in many of the lines of work conducted by SO's various development groups, such as: Advanced localization systems, 3G/wireless networks and

services, Intelligent home and building networks and systems, E-administration and E-inclusion, Security, Advanced simulation and modelling and Virtual reality. Among the selected important relevant clients of SO in Europe belong Autonomous area Castilla-La Mancha, Regional government of the area of Castilla and León, Ministerial offices of the Canaria Islands, Office of the Prime of the Canaria Islands, Autonomous community of Madrid, Ministry of environment of the autonomous community of Madrid, Spanish Ministry of health of the Madrid, Health Institute of Carlos III, Ministry of health and social wellness of the autonomy area of Castilla and León and many other companies.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Juan Marcos is a graduate of the Electro-technical secondary school in Štúrovo, Slovakia and the University of Economics in Bratislava, Slovakia (Faculty of Economic Informatics).
He has been working at SO a.s. since 1997. From 1997-1999 at SO a.s., Bratislava, Slovakia (Union Fenosa group) as a Financial controller; from 2000-2002 at SO a.s (Union Fenosa group) as a Chief accountant and from 2002 to Up to date at SO, a.s. as a Financial Director
Palieskova Katarína is a graduate of the UCLES EFL, College of Bath. Previously she has been employed at AutoCont as an Accountant, at NR SYS s.r.o. as an Assistant, at MODERN STYLE s.r.o. and at Tendenza Slovakia s.r.o. as an Accountant. Since 2002 she is working as an Accountant at SO, a.s.

THE VIENNA UNIVERSITY OF TECHNOLOGY

The Vienna University of Technology (TU Wien) consists of eight faculties covering the entire range of engineering fields with more than 2.000 members of scientific staff and more than 15.000 students. The services of the TU Wien include a broad spectrum of know-how, encompassing both high-tech problem solving and expert evaluation.
The Institute of Software Technology & Interactive Systems is one of the main institutes of the TU Wien in the field of Computer Science. Beside its teaching activities for students in Computer Science and Information Systems, it is one of the leading institutes in research and development in the area of Software Engineering:

- Data Engineering: Data Warehousing, Data Mining, Non-standard Data Modelling,
- Information & Knowledge Engineering: Web Semantics, Information Visualization, Plan Management, E-Learning, Digital Libraries, Text Mining, Decision Support Systems,
- Process Engineering: adaptive workflows, inter-organisational workflows,
- Software Engineering: quality software engineering, verification and validation, security, project management,
- Web Engineering: ubiquitous web applications, integration of web and data base systems,
- Virtual Reality and Augmented Reality,
- Media processing; Visual Retrieval, Video Analysis.

Main application areas are business informatics, e-commerce, and medical informatics. The institute's research is based on tight cooperation with Austrian and international academic partner institutes on the one side and industrial partners on the other side. Currently, there are four full professors and 57 scientific researchers at the institute, whereas 38 are funded by third-party projects.

Role in the Project

TU Wien will bring its expertise in Computer Science and specific experience in medical informatics into the design and development of the rule-based system. The system will work on the data as processed by the mining engine and will support health professionals suggestion appropriate action to minimize the impact of Adverse Events and, whenever possible, to prevent it.

Description of the previous relevant experiences in the area of your organisation expertise

TU Wien contribute experience in the modeling of clinical guidelines and in developing methods

and tools to support the modeling (authoring, maintaining, and communicating/visualization) and execution of clinical guidelines and protocols trough the following projects.

- In national projects TU Wien further developed the guideline representation language Asbru, and we created a workbench of task-specific methods and tools for the authoring, maintaining, visualization, and execution of clinical guidelines.
- In other national projects TU Wien explores the application and the extensions of Information Extraction methods to support guideline authoring and maintenance.
- In previous EU-funded FET-open projects (Protocure-I, Protocure-II), TU Wien acquired significant expertise in constructing formal and semi-formal models of clinical guidelines and protocols, and in using these formal and semi-formal models for quality assessment.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Silvia Miksch

She is University Professor (Univ.-Prof.) in Information and Communication Technology. She is head of the Information and Knowledge Engineering research group (ieg), Institute of Software Technology and Interactive Systems (ISIS), Vienna University of Technology and head of the Department of Information & Knowledge Engineering with particular consideration of Health Care (ike) at the Danube-University Krems (DUK). She has acquired, led, and was involved in several research projects (national and international projects). For example, "Protocure I and II: projects on formal modeling and verification of medical guidelines and protocols" (EU-funded FET-open projects); "Gaining New Medical Insights Using Temporal Data Abstractions and Clinical Protocols" (funded by the "Fonds zur Förderung der wissenschaftlichen Forschung - FWF", Austrian Science Fond); "in2vis: Interactive Information Visualization: Exploring and Supporting Human Reasoning Processes"(funded by the Vienna Science and Technology Fund (WWTF)); and "EviX: Facilitating Evidence-based Decision Support Using Information Extraction and Clinical Guidelines" (funded by the "Fonds zur Förderung der wissenschaftlichen Forschung - FWF", Translational Research-Programm, Austrian Science Fond).
She severed on various program committees of international scientific conferences and has published more than 170 scientific publications (journals and conference contributions, contributions in books, and books). She was 2004 co-chair of the Symposium on Computerized Guidelines and Protocols (CGP-2004), 2005 Program Chair of the Conference on Artificial Intelligence in Medicine (AIME 05) and organized various other symposia and workshops.
Her main research interests are Information Visualization and Visual Analytics (in particular Focus&Context and Interaction techniques), Plan Management (in particular Information and Knowledge Engineering, Temporal Representation and Reasoning), and Evaluation of Knowledge-Based Systems in Real-World Environments (Health Care).

Andreas Seyfang

He studied Computer Science at the Vienna University of Technology specializing on Artificial Intelligence. His master thesis at the Institute of Medical Cybernetics and Artificial Intelligence involved the implementation of a web-based implementation of a knowledge-based system for the calculation of parenteral nutrition solutions for neonate developed by Silvia Miksch, Werner Horn, and clinical partners, which is still in daily use at the general hospital of Vienna. Later, he joined the Asgaard Project which developed task-specific problem-solving methods to support the design and execution of time-oriented skeletal plans where he specialized on further developing the plan representation language Asbru and on temporal data abstraction.
Afterwards, he joined the Protocure I and II projects to model clinical guidelines in Asbru, design an interpreter for it, and an intermediate representation to ease the modeling process.
At the same time he implemented a system to optimize the artificial ventilation in neonates using temporal data abstraction, which in a clinical evaluation study performed better than standard personnel and equally well as dedicated experts.

Katharina Kaiser

She is a postdoctoral research fellow at the Vienna University of Technology (PhD in 2005 from the Vienna University of Technology on the modeling of treatment processes in clinical guidelines using information extraction). Her research interests include Artificial Intelligence, Information and Knowledge Engineering (information extraction, transformation, and integration), temporal representation and reasoning and applications based on these methodologies with specific interest for clinical guidelines.

Research in Advanced Medical Informatics and Telematics

RAMIT, "Research in Advanced Medical Informatics and Telematics", is a non-profit association (Vereniging Zonder Winstgevend doel, Association Sans But Lucratif), established with the help of the State University of Ghent (Belgisch Staatsblad/Moniteur Belge, 16.01.1992, p 429-431), with the following objectives :

- Scientific Research and Development in Medical Informatics, including the development of Telematics Standards for the Healthcare sector.
- Participation, within the framework of objective 1, in the research-programmes of the CEU particularly DG Enterprise (DGIII), DG Information Society (DGXIII) and DG Research (DGXII).
- Participation, within the framework of objective 1, in the standardisation activities within CEN, CENELEC, ETSI, EWOS, WEEB, ISO, IEC and CCIIT.
- Certification of products, within the framework of objective 1.

Sponsoring or supporting initiatives that promote scientific developments, industrialisation and exploitation.

The working-team in RAMIT is multidisciplinary: medical doctors, engineers, computer scientists, statisticians and secretarial staff. Recent activities include successful national, European and international projects dealing with eg. electronic medical record systems, decision support systems, design and development of ontologies, electronic health data interchange, security, natural language processing in healthcare and computer assisted instruction in medicine.

RAMIT have participated successfully in more than 80 National and International R&D projects (often in a co-ordinating capacity) in both the framework of EU-Research Programmes and of national R&D Programmes. RAMIT's R&D activities resulted in the creation of five spin-offs. The membership of RAMIT is restricted. President is Prof Dr Georges J.E. De Moor and Directors are, amongst others, the Rector of the University and the Dean of the Faculty of Medicine (qualitate qua). RAMIT was from 1991 until 1996 in charge of Chairmanship and Technical Secretariat of CEN/TC 251.

Role in the Project

RAMIT will bring its most relevant contribution in the design and development of the ontology that will be used by REMINE to properly link RAPS, related data and procedures.

Description of the previous relevant experiences in the area of your organisation expertise

During the last three years RAMIT participated (or is participating) in following projects:

- 1. ACKNOWLEDGE (Accessible & Open Knowledge Infrastructure for Flanders)
- 2. ASSIST (Association Studies assisted by Inference and Semantic Technologies)

Recent trends in medical research combine genetic with clinical data and perform association studies among environmental agents, virus characteristics and genetic attributes, in order to identify new markers of risk, diagnosis and prognosis. While the number of studies describing phenotype-genotype associations is rapidly increasing, progress is hindered by the segmentation of various efforts and their corresponding datasets.

The main objectives of ASSIST are to:

- unify multiple patient record repositories;
- automate the process of evaluating medical hypotheses (association studies type);
- allow researchers to combine phenotypic and genotypic data;

- provide an inference engine capable of statistically evaluating medical hypotheses and producing medically important associations based on the collected data;
- offer expressive, graphical tools for medical researchers to post their queries.

3. BCFI (Belgian Center of Drug Information)

Implementing web applications for example i) to provide researchers in pharmaco-epidemiology and drug Utilization with a tool to explore validated and complete national registers of medicinal product packages, identified by a unique identifier, suitable for drug utilisation utilisation monitoring and research programs.

And ii) to provide a current and an historical view on the availability of medicinal product packages on the drug markets of participating countries.

4. COPLINTHO (Innovative Communication Platforms for Interactive eHomeCare)

The major goal of COPLINTHO was to study and develop ICT, which can support and improve the care process of home patients by using new technologies and services. It focuses on the home environment and the patient. The project was focussing on:

- Improving independent living
- Offering the possibility to patients suffering from different pathologies recovery after hospital stay, chronic diseases, pregnancy, ...) to directly interact with their healthcare team.
- Giving access to health care professionals and home patients to health-related information and services

5. INTERLIFE (Quality Healthcare Management and well-being through INTERLIFE Services)

INTERLIFE is a generic and modular contact center platform for the communication, management, processing and assessment of multimedia medical information, and the provision of high quality pervasive telehealth services to the citizens. It introduces new generation telemedicine services for home care to improve quality of health care and create a large new IT market by involving every single home and every single health care provider.

6. Q-REC (European Quality Labelling and Certification of Electronic Health Record Systems (EHRs))

The main objective of Q-REC is to create an efficient, credible and sustainable mechanism for the certification of EHR systems in Europe by addressing mainly:

- **EHR Systems Quality Labelling and Certification Development, thereby:**
- producing a State of the Art Report on EHR-Certification Schemas as already implemented in at least three European countries;
- performing a Pan-European Requirements Assay;
- proposing a Labelling Terminology and Functional Profiles for EHRs to be certified;
- comparing and harmonising the EHR-Certification Procedures at a European level;
- drafting Model Certification Guidelines and Procedures;
- planning the Validation of the Guidelines.
- **Resources for EHR Interoperability, including:**
- the register of Conformance Criteria and Guidance Documents for obtaining EHR Certification;
- an inventory and guidelines for EHR Archetypes;
- the registration of Coding Schemes in Europe (as mandated by CEN/TC 251);
- an inventory of relevant EHR related standards;
- a register of XML Schemas and Open Source components for EHRs.
- **Benchmarking Services:**
- Benchmarking Services Manual for Quality Labelling and Certification;
- preparing the Business Plan for new EHR-Certification related Services.
-

7. RIDE (A Roadmap for Interoperability of eHealth Systems in Support COM256 with Special

Emphasis on the Semantic Interoperrability).
RIDE is a roadmap project for interoperability of eHealth systems leading to recommendations for actions and to preparatory actions at the European level. This roadmap will prepare the ground for future actions as envisioned in the action plan of the eHealth Communication COM 356 by coordinating various efforts on eHealth interoperability in member states and the associated states. Since it is not realistic to expect to have a single universally accepted clinical data model that will be adhered to all over the Europe and that the clinical practice, terminology systems and EHR systems are all a long way from such a complete harmonization; the RIDE project will address the interoperability of eHealth systems with special emphasis on semantic interoperability. In order to create RIDE Roadmap, first the European best practices in providing semantic interoperability for eHealth domain will be assessed and the quantified requirements to create a valid roadmap will be identified. Based on these requirements, the goals, and the economical, legal, financial and technological challenges of the industry for the 21st century for achieving interoperability in eHealth solutions will be elaborated. RIDE will also focus on the limitations of the policies and strategies currently used in deploying interoperable eHealth solutions. A research portal for sharing resources addressing semantic interoperability in eHealth domain will be created and maintained; the key actors and stakeholders will be coordinated around RIDE special interest groups to create a wide consensus at the European level.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Georges De Moor

Professor Dr. Georges J.E. De Moor studied Medicine and specialised in Clinical Pathology and Nuclear Medicine at the State University of Ghent (Belgium), where he also obtained a PhD in Medical Information Science.
Currently, he is head of the Department of Health Informatics and Medical Statistics at the State University of Ghent, where he teaches Medical Informatics, Statistics, Decision Theory and Evidence Based Medicine.
As president of RAMIT (Research in Medical Informatics and Telematics), he has been involved in more than 80 European or International Research and Development projects, as well as in Standardisation activities. During seven years, Prof. De Moor acted as Founding Chairman of CEN/TC251, the official Technical Committee on standardisation in Health Informatics in Europe.
Prof. De Moor has also founded a number of spin-off companies (e.g. MediBRIDGE, GEMARAN, Language and Computing, Custodix and TeleTendo).He is also President of MSHUGe (Microsoft Healthcare Industry Users Group Europe, Asia and Africa) and of EuroRec (Certification of Electronic Health Record Systems in Europe).
Dr De Moor is also Head of the Clinical Pathology laboratory at the St Elisabeth Hospital in Zottegem. Prof. De Moor chairs a number of official Committees (e.g. the Health Telematics Committee and the Clinical Pathology Committee of the Belgian Ministries of Health and Social Affairs,), as well as a number of scientific and professional organisations (e.g. of the Belgian physicians specialised in Health Data Management). He has edited several books, and published over 200 articles in international peer reviewed scientific journals.

José Devlies

José is a Medical Doctor by training, specialised in Family Medicine at the Catholic University of Leuven (1969) and in Occupational Healthcare at the University of Ghent (1972). He has also a degree in the Management of Healthcare Data (2003). Practising General Practitioner, full time for over 30 years, and working for several years part-time in Occupational Healthcare, especially in the public sector, he started to be an entrepreneur. He has founded and chaired several companies, such as Medizorg C.V. and Datasoft Management N.V., founded in 1987, merged in

2002 into OmegaSoft, the largest provider of health information systems in Belgium, where he was responsible for business development, medical research and medical quality management. He was also co-founder and Member of the Board of MediBRIDGE N.V. He joined in 2006 RAMIT to be the medical director, addressing more specifically clinical aspects in eHealth research and development.
He is Member of the Board of the Belgian Scientific Society for Medical Informatics (M.I.M.), president of Prorec Belgium N.V. and member of EuroRec. He is co-author of the Belgian certification criteria for GP EHR systems. He has been a member of the EU 5th Framework Healthcare Telematics Requirements Board (DGXIII). He has also participated in several National and EU co-funded projects. Just some of them: Euclides, Patiënt en Dossier, Intranet Health Clinic, PharmDIS, eMed, C-Care, Share, eProLearn, PharmDIS-e+ and C³, coordinating some of them. He his actually actively involved in ePrescript and LiverDoc as well as in RIDE and QRec. He was generally involved in the product specification, product design, validation and business development with a special interest for the clinical aspects of those projects.
He was a member of CEN/TC251 Working Group 1 and 2, participated in several standardisation project e.g. on "Continuity of Care" and chaired the project team on the identification of medicinal products (ENV12610).

Pascal Coorevits, MSc, BICT, PhD

Pascal Coorevits received his master's degree in motor rehabilitation and physiotherapy from the Ghent University (Belgium) in June 1998. He obtained an additional bachelor's degree in ICT in June 2003. From August 1998 till December 2005 he has been working as a scientific researcher at the Department of Rehabilitation Sciences and Physiotherapy of the Ghent University. In January 2006 he has moved to the organization for Research in Advanced Medical Informatics and Telematics (RAMIT vzw), where he currently is involved in research and management of several national and international medical informatics R&D projects (e.g. ASSIST, QREC, Acknowledge, GA2LEN, …) and in teaching statistics at the Department of Medical Informatics and Statistics of the Ghent University. In February 2007 he obtained his PhD degree from the Ghent University.

Geert Thienpont

Geert Thienpont is a computer scientist and studied at the Industrial School of the State B.M.E. GENT. Since 1992 he has been involved in national and international R&D projects in the field of Medical Informatics & Telematics, e-Learning & e-Testing and Web Applications. Currently, he is the project manager of RAMIT for the European R&D projects and e-Learning applications. Project management includes technical, human resources, customer and financial follow-up.
Furthermore he is involved in the organization of national and European associations such as EuroRec (European Institute for Health Records), MS-HUGe (Microsoft Healthcare User Group Europe), and PROREC-Belgium. He also assists in preparing and giving courses in Medical Information Sciences. He co-organised several world-wide conferences in this field.
Geert Thienpont was working for two years (1994 -1995) in Luxembourg at the Centre de Recherche Public - Centre Universitaire. He was involved in a LRE project named ANTHEM ("Advanced Natural language Interface for Multilingual Text Generation in Healthcare") as IT researcher.

QUALITY & RELIABILITY S.A.

Quality & Reliability S.A. [Q&R] was established in 1992, with the aim of providing Integrated Information Technology Solutions to medium and large businesses of the Private Sector, as well as to the Public Sector.
The company's initial activity was the development of complete software packages for Sales & Retail Management and Financial Management for small and medium enterprises and

industries. Its quick development along with the rapid increase of its annual turnover, gave the company the ability to acquire know-how in the area of Databases and fourth generation languages (4GL).
The basic goal of the company is to provide high quality services in the field of IT and telecommunications.
Since 1993 Q&R opts for a strategic cooperation with Oracle Hellas, investing systematically in the development of know-how in Oracle Technology.The company's entrance in the field of relational databases had as an outcome the development of a group of software products, which was presented to the Greek market in 1993, with the commercial name ORAMA. These products are "ORAMA ERP" (Enterprise Resource Planning) and ORAMA HRM (Human Resource Management and Payroll). ORAMA has a wide recognition in the Greek market and is placed in the leading place, among other competitive products .

Role in the project

Q&R will provide to database and integration with potential Oracle ERP.

Description of the previous relevant experiences in the area of your organisation expertise

Towards the end of 1993, Q&R enters the IT market of the Public Sector (Ministries, Services, Organizations, State Organizations of Public Interest, etc). In such projects Q&R undertakes the development of the required software, the training/education, support and maintenance of Information Systems. Today, Q&R is one of the leading software and services suppliers for enterprises and organizations of the Public Sector.
In 2000, the company entered as an official member, the Athens Stock Exchange and received almost 16 million Euros to be invested in the further evolution of the company's activities as well as in exploitation of new business opportunities.
Since the beginning of 2000 has been ISO (9001:2000) certified by Lloyd's Register Quality Assurance.
Q&R is in a position where it can always bring any project to successful completion. Among Q&R's expectations is, continuing to offer high-standard services and developing specialized scientific information systems.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Dr Blathras Constantinos
Born in 1963, PhD in Computer Science and Informatics, Temple University Philadelphia, PA, USA
He is a Project Manager from 1983.
IT competence are:

- OS: Unix under a multitude of platforms (Solaris, Linux, AIX, OSF/1, EP/IX, IRIX), MS Windows 2003, XP, NT, 95-98-2000, VAX/VMS, IBM VM/XA - VM/CMS
- DBMS: Oracle (10g, 9i, 8i), Microsoft SQL Server, MySQL
- Programming Languages, 3GL: Java, C/C++ (Unix & PC environments), Perl, All ORACLE tools
- Case Tools : Network Technologies:
- Internet Technologies: HTML, CGI, XML, SSL, CSS, JavaScript
- Internet Tools: Macromedia Dreamweaver
- Methodologies: PRINCE2, UML, RUP,
- Web standards: W3C (WAI-compliance, etc),
- Office Automation: Microsoft Office

Blathras Evangelosnce
Born in 1969, Degree in Physics, University Of Athens
He is Senior Technical staff (Technical Expert), from 1992.

IT competence are:

- OS: Sun Solaris (2.7, 2.8), Linux, MS Windows 2003, XP, NT, 95-98-2000, VAX/VMS,
- DBMS: Oracle (10g, 9i, 8i), Microsoft SQL Server,
- Case Tools, 4GL: Power Designer, Rational Rose, Power Builder, JavaScript,
- Programming Languages, 3GL: C++, Java, Delphi, C, Basic (Visual), Pascal, Unix Scripts, Fortran. Perl, TCL/TK, Forth, Assembly (Intel x86, 6502), C Shell scripts, Bash Shell scripts,
- Internet Technologies: CORBA, RMI, XML (data exchange, content management), XSL, HTML (content presentation), ASP, JSP, Servlets, JavaScript,
- Internet Tools: Macromedia Dreamweaver, Microsoft FrontPage, Intershop IS4, TopClass Server,
- Multimedia Tools: Asymetrix Multimedia Toolbook,
- Internet Clients: Netscape Browsers & MailMicrosoft IE, Outlook,
- Web standards: W3C (WAI-compliance, etc),
- Office Automation: Microsoft Word, Microsoft Excel, Microsoft Access, Star Office, Dbase III+, WordPerfect for Dos.

Zografos Fotios

Born in 1967, University Degree in Software Engineering, University of Patras.
He is Senior Technical staff (Senior Analyst).
IT competence are:

- OS: MS Windows 9x, 2000, NT, 2003, XP, Solaris, SVR4, AIX, SCO, HP-UX, Linux, Novel,OS/2, MacOS, VMS, Zenix,
- DBMS: Oracle 7i, 8i, 9i, 10g, Oracle Context, Oracle Workflow, Informix, Ingres, SQL Server, SQL Base, Access, Clipper, DB/3, DB/4,
- Case Tools, 4GL: Oracle Developer, Oracle Designer, Oracle WebDB, Oracle Application Server, Oracle Context(Intermedia),Oracle Sql, Forms, Sql reportwriter,
- Programming Languages, 3GL: Visual C++, C++, C, Oracle PL/SQL, Perl, Pascal, Unix Scripts,
- Network Technologies: Sql*net, Net 8, FTP, NFS, ODBC, Unix advanced Server, TCP-IP,
- Internet Technologies: HTML, SGML, XML, ASP, Oracle Web server,
- Internet Tools: MS Frontpage, Intershop IS4, TopClass Server, Macromedia UltraDev 4,
- Office Automation: MS Office, MS Project, Lotus Notes, Adobe Photoshop,
- Data Warehouse: Oracle Discoverer, Oracle Express Server, Oracle Express Analyzer, Oracle Express Objects, Oracle Financial/Sales Analyzer.

LINK Consulting Technologias e Sistems de Informaciao

Link Consulting is a Portuguese SME with the mission of creating value through technological innovation on Information Technologies areas.
The company dates from 1999, and results from the enterprise automation of Technology Transference Centers associated to Public Universities. Nowadays, Aitec, SGPS, is the principal shareholder, integrating a holding of several technological based companies.
The staff consists on 165 collaborators and 30 trainees with expertise on the IT consulting and development, serving the offer structured on the following areas: Enterprise Architecture; IT Engineering; bespoke middleware applications for connecting to legacy systems; e-Solutions fro Health and Wellbeing; IT Services; Business Solutions. The clients are mainly Portuguese, with a crescent volume of services abroad (Brazil, Morocco, Spain, Israel, Belgium, EUA, Angola,

Mozambique, Cabo Verde and São Tome and Príncipe), in several segment areas, such as e-Government, Finances and Insurance, Telecommunications, Logistics and Distribution, Transportation, Forest and Natural Resources, Health, Justice and Utilities.

Role in the project

Link consulting, a technological partner will contribute to the development the REMINE system and, in particular, to the design and development of the RAPS management processes support system, the RAPS alerting.

Description of the previous relevant experiences in the area of your organisation expertise

Link has structured its Services, Solutions and Products offer based on a very close collaboration with customers facing complex challenges and with a vision for internationalization of their activities. It also privileges, INESC and other Research Institutions and is an active player in European R&D projects. Link has participated in several projects under the EU FP5 and FP6, namely:

- CALYPSO,
- ICARO,
- PLACEBO, @Home, USBone in areas of Health.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

The multidisciplinary team from Link on the project includes skills on project management, ICT applied to healthcare, SOA architectures development, SW development. As so, key staff members participating the project include:

Prof. Alberto Cunha (PhD)

He is an Associate Professor at Technical University of Lisbon and he olds the position of Director in Link Consulting. He is doctored in Computers and Electronic Engineer by the Technical University of Lisbon. One of the projects where he was involved (Smartcards for Lisbon transportation network project) received a premium of the ESIS (European Survey on Information Society), promoted by the Information Society Project Office of the European, for its relevance to the Information Society promotion. Profº Alberto Cunha was National Delegate in the European Programme Telematics Applications Programme), in the Information Engineer filed.

Prof. Pedro Sousa (PhD)

He is an Associate Professor at Technical University of Lisbon. He has more than thirty international publications and presentations on the topics of Enterprise Architecture, and Service oriented Architectures. He is also a senior consultant at Link Consult where has been involved in more than forty professional projects both in private and public sector for the past twenty years.

Armando Vieira

He is Electronic and Computer Engineering by Technical University of Lisbon. He is a Lead Consultant of Link Consulting SA. He has developed his activity in Project Manager, Enterprise Architectures, Business Process and Information Systems Architectures consultant and Auditor Coordinator ISO 9000.

- Joao Almeida is Electronic and Computer Engineering by Technical University of Lisbon and he olds a master in Electronics and computers Engineering. He is Director of Link, and project manager of international projects in the smartcards.

Institute of Communication and Computing System –National Technical University of Athens (ICCS)

Intelligent Systems Laboratory

The Institute of Communication and Computer Systems (ICCS), established in 1989, is a private law non profit Academic Research Body associated with the School of Electrical and Computer Engineering of the National Technical University of Athens (NTUA). Its aim is to carry out

research and development activity in all diverse aspects of telecommunications systems and techniques, computer systems and their applications, software and hardware engineering, telematics and multimedia applications, control systems, robotics and biomedical engineering. The personnel of ICCS consist of academic personnel (University Professors - about 80), a number of Research Scientists and more than 500 Associate Scientists (including PhD students). ICCS is very active in European co-funded research activities and has been the project manager of many EU projects in various programs in all of the above mentioned research areas. There are many research groups and laboratories presently active in ICCS. The ICCS is ruled by a five member board and its activity is co-ordinated by its Director being elected by the Senate of NTUA.

The Intelligent Systems Laboratory (ISLab) of ICCS constitutes a centre for research, development and education in the fields of computational intelligence (neural networks, fuzzy systems, evolutionary computation, hybrid systems), pattern recognition and machine learning. The Laboratory has developed rich research and educational activities during the last fifteen years. The research group is one of the first in Greece to work on the theory and applications of neural networks and has significant contribution at national and international level in the areas of computational intelligence and machine learning. The staff of the Laboratory currently includes 8 Ph.D. students and 4 post-doctoral collaborators.

The activities of the Intelligent Systems Laboratory concern the application of computational intelligence in data analysis, classification and diagnosis, scheduling and optimization, control and navigation tasks, as well as in data mining and knowledge discovery. For many of the above topics the members of the Laboratory have developed their own algorithms and software implementations, using both conventional and parallel hardware. The research group has extensive experience related to the use of intelligent techniques in biomedical applications (compression of medical images, cytological diagnosis, electrocardiogram analysis, classification of ultrasound images, sensor/mobile device networks etc), web applications and multimedia systems (educational systems, text characterization and classification, information mining, user profiling, intelligent agent architectures, user interfaces etc). The research activities of the Laboratory have been beneficial for educational tasks through the support of diploma theses and the dissemination of results to graduate and undergraduate activities.

Current research activities of ISLab also involve the development and implementation of hybrid intelligent systems, allowing the effective incorporation of knowledge and the synergy of subsymbolic and symbolic processing through combination of neural networks with fuzzy logic and conventional artificial intelligence techniques (e.g. rule-based systems).

The research group of the Intelligent Systems Laboratory has a rich publication record largely recognized in Greece and internationally. During the last years, more than 100 refereed papers of the group have appeared in international journals and conference proceedings.

Role in the project

Thanks to current research activities of ICCS also involve the development and implementation of hybrid intelligent systems, allowing the effective incorporation of knowledge and the synergy of subsymbolic and symbolic processing through combination of neural networks with fuzzy logic and conventional artificial intelligence techniques (e.g. rule-based systems). REMINE project will offer them the possibilities to improve and complete the research about rule-based system in health context.

Description of the previous relevant experiences in the area of your organisation expertise

The Intelligent Systems Laboratory has actively participated in many national and European Union funded research projects, including “Applications of Neural Networks for Industry in Europe (ANNIE)”, 1988-1991 (ESPRIT), “Knowledge Processing and Learning Systems on

Multitransputer Architectures", 1990-1992 (ESPRIT), "Novel Neural Networks", 1993-1996 (Human Capital and Mobility), "NeuroNet", 1993-1997, and "NeuroNet II", 1998-2001 (ESPRIT Network of Excellence), "Principled Hybrid Systems: Theory and Applications (PHYSTA)", 1998-2001 (Training and Mobility of Researchers), "Multimedia Organisation for Developing the Understanding and Learning of Advanced Technology in European Schools (MODULATES)", 1998-2000 (ESPRIT Educational Multimedia), "Cultural Journeys in the Information Society (CJIS)", 1998-2001 (INCO), "Modular Hybrid Artefacts with Adaptive Functionality (ORESTEIA)", 2001-2003 (IST), "A Wearable Platform for the Monitoring of Health Condition and Sport Performance of Athletes and the real-time Prevention of Sport Injuries (DROMEAS)", 2001-2004 (IST), "Teaching English as a second language to Deaf people, whose first language is the Sign Language, via e-Learning tools (DEDALOS)", 2003-2006 (LEONARDO), "Human-Machine Interaction Network on Emotion (HUMAINE)", 2004-2007 (FP6-Network of Excellence)..

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

ANDREAS-GEORGIOS STAFYLOPATIS

Andreas-Georgios Stafylopatis was born in Athens, Greece, in 1956. He received the Diploma degree in Electrical and Electronics Engineering in 1979 from the National Technical University of Athens and the Docteur Ingénieur degree in Computer Science in 1982 from the Université de Paris-Sud, Orsay, France. Since 1984 he is with the School of Electrical and Computer Engineering at the National Technical University of Athens, where he is currently a professor of computer science leading the Intelligent Systems Laboratory.

His research interests include computational intelligence, neural network theory and applications, pattern recognition, parallel and distributed computation, optimization techniques, information systems, modeling and performance evaluation of computer systems. His current research involves the use of hybrid intelligent techniques in classification and diagnosis, data mining and knowledge extraction, in multimedia systems and human computer interaction, in educational and biomedical applications. He has supervised 12 graduate students who completed their Doctorate and is currently supervising 8 graduate students working towards their Ph.D. degree.

Prof. Stafylopatis is the author or coauthor of about 150 refereed papers, 50 of which in international journals. He has been a member of the Program Committee of a large number of international conferences and an invited speaker/author in many conferences/books. In 2006 he was the co-chair and organizer of the International Conference on Artificial Neural Networks (ICANN 2006) and co-editor of proceedings volumes and journal special issues. He is an associate editor of the International Journal of Artificial Intelligence Tools and reviewer for several scientific journals (including Proceedings of the IEEE, IEEE Transactions on Systems, Man, and Cybernetics, IEEE Transactions on Circuits and Systems, IEEE Transactions on Neural Networks, IEEE Transactions on Biomedical Engineering, IEEE Communications Letters, Neural Networks, Neurocomputing, IEE Proceedings - Computers and Digital Techniques, International Journal of Neural Systems, Journal of Intelligent Systems, Journal of Intelligent and Robotic Systems, Information Sciences etc). He has been evaluator of research proposals for national and international organizations and has served as scientific consultant and member of advisory/evaluation committees concerning large computer system projects in various ministries and public sector organizations.

He has participated as leader or key researcher in about 40 national and European Union funded research projects. Prof. Stafylopatis is a member of the Technical Chamber of Greece, the IEEE Computer Society, the IEEE Systems, Man, and Cybernetics Society, the Association for Computing Machinery, the European Neural Network Society and the International Neural Network Society.

GEORGE SIOLAS, Ph.D.

George Siolas was born in Athens, Greece, in 1976. He graduated from the School of Electrical and Computer Engineering of the National Technical University of Athens in 1998. His dissertation was axed towards artificial intelligence, neural networks and rule extraction. In 1999 he obtained a Masters Degree in Cognitive Science at the School of Advanced Social Studies (EHESS) in Paris, France. His work was concerned consecutively with neurosciences, semantics and text mining. In 2003 he obtained his Ph.D. in Computer Science from the Université Pierre et Marie Curie (Paris 6) under the direction of Florence D'Alche-Buc. His thesis subject was the use of probabilistic models and kernel functions for information extraction from textual documents, but also included extensions to handling other kinds of structured information such as biological data. While working on his Ph.D. at the Laboratory of Computer Science of Paris he participated as a team member in the development of applied machine learning and pattern analysis methods in diverse fields, such as speech recognition, computer vision and biomedical engineering.

Dr Siolas is presently a Postdoctoral Researcher in the Intelligent Systems Laboratory of ICCS. His current research interests include adaptive systems, intelligent agents, recommender systems, biomedical decision making and probabilistic data modeling.

MIP – Politecnico di Milano

Since 1979, the MIP, the Business School of the Politecnico di Milano, has been one of the most prestigious schools offering business and management training to graduates from all disciplines. As a consortium, the MIP includes together with the Politecnico di Milano a number of national teaching institutions and various public and private sector industrial groups. As the Business School of the Politecnico di Milano, the MIP inherits the idea of appreciating technology as an essential tool to create, innovate and manage a company. In short, this is the main 'value' which characterises and differentiates the MIP-Politecnico di Milano. The MIP-Politecnico di Milano integrates the specialist know-how of the Politecnico with the concrete, practical and professional experience of companies and consultants. In collaboration with the department of the Politecnico di

Milano and its related consortia (such as CEFRIEL), the MIP promotes applied research addressing development needs in various markets. Projects are mainly related to themes which are crucial for service, manufacturing and public companies management. In this frame the main areas in which researchers and professors at MIP are involved in are: planning and control systems, process organization and management, organizational behaviour and human resources management, risk management, security and regulation, service networks management, eBusiness, IT, production and supply chain systems, strategy, marketing and CRM, innovation economics, project management. Moreover MIP will bring to the consortium the knowledge developed within its Health Area which focuses on research and consulting activities in the health-care field. The MIP Health Area places himself the aim of spreading a managerial culture oriented to the promotion of the change trials to the check on the costs and on the results, to the improvement of the service good quality and the user satisfaction, proposing a right mix of theoretical models and practical methods.

In particular the MIP is very well specialised in the recognition of the ever-growing role that Information and Communication Technologies (ICTs) were starting to play in the managerial innovation of business. Nowadays the MIP has organised 15 "ICT Observatories", with the mission of spreading the managerial culture of ICTs and increase the awareness of decision makers and managers with regards strategic and innovative role of ICTs for business. In almost 10 years activity the MIP's ICT Observatory have developed hundreds of on-field researches and carried out a continuous communication activity through several tools (i.e. 37 Research reports, 48 conferences and workshops, more than 500 international and national publications, 2 newsletters, etc..). The major ICT domains covered by the MIP Observatories are: New TV;

Intelligent Transport System; e-Procurement in public administration; Mobile and wireless business; Mobile Valued Added Services consumer; CIO community; B2b and B2c; ICT innovation as a strategic lever in SMEs.

Role in the project

The MIP brings to the project its expertise in organization models and the specific knowledge of the Health sector acquired also through the participation on other IST projects. In REMINE it will deal with the design of the Hospital organization model.
More specifically, MIP will be leader of both the Mainstream 1- data modelling and pilot management and Mainstream 3 – socioeconomic research and business model definition.

Description of the previous relevant experiences in the area of your organisation expertise

MIP has also a strong background in IST projects for both project management and applied research. The following is a short list of the latest ones: COCOON (MIP is the Main contractor), IP in 6FP-IST (Building knowledge driven and dynamically adaptive networked communities within European healthcare systems), TERREGOV, IP in 6FP–IST (Impact of eGovernment on Territorial Government Services), SUPER IP in 6FP–IST (Semantic Utilised for Process Management within and between Enterprises), RIGHT (MIP is the Main contractor) Strep in 6FP (Risk management in East European Health Care systems); SECSE (Services Centric System Engineering) IP in 6FP, CASCADAS (Binging autonomic services to life), IP in 6FP, PIM (MIP is the Main contractor) Strep in 6FP (Improving innovation in business process management of eastern Europe SMEs by using qualified process innovation managers), NOBEL (Next generation Optical network for Broadband European Leadership), IP in 6FP.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Alberto Savoldelli

He is contracting professor of Economy and Business Management of the Department of Economy and Business Management of the Milan School of Engineering. He is responsible of the International Applied Research group at the MIP and member of the MIP faculty.. He has been and actually is responsible of several applied research activities in the fields of knowledge management, change management and business modelling in the public and private domain. He is author of several studies and articles in the economic field. Having been responsible of several projects funded by European Commission under IST programme and LIFE programme Prof. Savoldelli gained extensive expertise in the management of the EU funded project. More specifically he is actually project manager of the COCOON (IP in Health care domain), PIM, RIGHT, projects funded under the FP6 .

Paola Fantini

She is currently responsible for several research activities developed under the MIP International Applied Research group. Her interest span over Societal & Economic relations, Business Modelling and Value Networking, Business Process and Services Management, Innovation Management, and Techno-economic Modelling. These topics applying to SMEs, Public bodies and Health Systems. She is contributing to several Projects within EU FP6.
She has been General Manager of an industrial company and has been holding managerial roles in SMEs for many years. She has also worked as Project Manager and consultant for several years in the field of organisation and accounting. She has been contract training at Politecnico and Scuola a Fini Speciali in Lecco e Como, teaching Economy and Business and Accounting. She graduated in Management Engineering at Politecnico di Milano, cum laude, in 1986.

INFO WORLD

Info World is a supplier of IT solutions dedicated exclusively to the health field. The company provides customized modular integrated solutions for both clinical and economic management of healthcare facilities. Info World also offers training, service and maintenance. Info World is currently active in Europe, America, Africa and Asia.

Info World offers very comprehensive information solutions, which cover the entire healthcare spectrum and responds to the demands of any type of healthcare institution. Info World systems are modular and can be combined into unique configurations to suit customer requirements and satisfy any need of Enterprise Resource Planning. Info World also provides a full range of services to assist our customers to develop maximum productive and cost-efficient clinical workflow and improve the quality of patient care.
Info World clinical solutions are supported by executive and financial tools which streamline processes and control costs and provide decision support. Info World owns a 30% market share from the total number of beds assisted with informatics management in Romanian Hospitals.

Role in the Project

Inforworld will be involved in the activities related to the creation of the interoperability layer necessary to allow REMINE to interact with the ERP system. Info World will be particularly involved with the ERP side of the work.

Description of the previous relevant experiences in the area of your organisation expertise

In Romania Info World is the HIS supplier for more than 70 healthcare units including: National Health Care Public System (including hospitals, blood banks, clinics, institutes, health insurance houses and others), Romanian Private Healthcare (various private Medical Centres, Policlinics and Laboratories), GP's consulting centres, pharmacies, etc.
Also, Info World developed partnerships with companies from Bulgaria, South Africa, U.S.A. and UK: EMC2 (USA), CACI (USA), USAID-AED (USA), KBC (South Africa), One Health Group (UK), Fornax (Hungary) and ICT Works (South Africa).
Other projects to which Info World has participated include:

- e-Hospital project in Târgovişte RITI – INFO WORLD (February 2005 – May 2005)
- National Critical Medicine Network – public-private Romanian partnership
- HEALTH OPTIMUM, an eTen project under current development

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Ion Perpegel
Ioni is an experienced programmer and system engineer. He has worked as a consultant for more then ten years participating at the development of different kind of solutions. He has developed mining solutions for business analysis and analysis of medical errors in surgery. He has managed several ICT projects. Before Inforworld he has worked for several IT companies and has been active as a freelance consultant as well. Ion speaks English, French and Russian. Known programming languages include: C#, Java, C/C++, VB6, JavaScript, HTML, DHTML, SQL
Catalin Branea
Catalin has Excellent programming abilities in C#, Visual C++, Visual Basic and SQL language. Solid OO design knowledge having a particular focus on design patterns. Distributed systems skills using n-tier architectures. He is a Brainbench Certified C++ developer and Master COM/DCOM (Visual Basic) developer (www.brainbench.com transcript ID 59391) Committed to excellent service and customer satisfaction.

AMINIO
AMINIO is a Sweden company operating in the Information & Communication Technology (ICT) business. Since the beginning its activities have been focused on helping enterprises with advanced technical consulting and complete development of innovative and successful business solutions. Its founders have gained a very deep knowledge of some specific markets (Retail and Consumer Goods, Finance) and completed various development projects for some of the leading companies in these market segments.
New technologies such as RFId and new business models such as e-commerce or Business

Intelligence and CPFR (Collaborative Planning, Forecasting and Replenishment) require a business partner that can implement the industry best applications, customise them in response to the company's specific needs, and then assist the company in the business development, growth and performance.
AMINIO has acquired a lot of knowledge and experience in the use of the RFId (Radio Frequency Identification) technology through the development of software projects for its costumers. Moreover, AMINIO is specialised in the development of software solutions with any mix of database management, web architectures, knowledge management, ontologies, advanced intelligent search engines interfaced with a large variety of physical signals and logical data coming from heterogeneous sources. AMINIO builds any size of personalized mono and multi ontology semantic engines for every kind of project, using mainly open source tools. Its development team supports customers in the developing of knowledge management projects with an in-deep analysis of the customer "scenario" and customer needs to deliver a usable, viable and cost effective KM solution.

Role in the project

AMINIO will take responsibility of integration. REMINE being a complex system made up of several modules will require accurate planning and execution of integration activities. Particular care will be put in the integration of different technologies to be used.

Description of the previous relevant experiences in the area of your organisation expertise

The activities of AMINIO have been initially focus on the Fast Moving Consumer Goods market and, in particular, on the Supply Chain Management.
Its main objective is to develop innovative software solutions that, through the collection, transformation and analysis of data produced by the logistic chain, can help each company to optimise its supply chain management.
AMINIO project to the market is mainly based on the highly innovative technology known as wireless digital identification (or RFID).
Applied to the FMCG (Fast Moving Consumer Goods) market, RFID allows creating electronic labels that are attached to the goods and are able to store a great deal of data about them.
AMINIO starts exploiting the experience gained in the Retail and Consumer Goods markets in others where the RFId technology can be effective. In the last year a promising field of application is the Healthcare and in particular the support to the Clinical Risk Management.

Profile of the most relevant staff members (at least 2 seniors) who will be undertaking the work.

Henrik Samuelsson

He is a Computer science expert, who obtained a bachelor in Information Technology.
He is an expert of the languages such as Java (Servlets, Tomcat, Hibernate, Struts, jsp), JavaScript, C/C++, XML, Delphi 6.0, ADA, Assembly, Visual Basic, MS-ASP, Lotus Notes, SQL, Windows, Linux, and has a deep knowledge of the Intel and Alpha's platforms.
Furthermore, he is an experienced expert of the software like Eclipse,Visual Interdev, Access, EMC2 Documentum, Captiva InputAccel, MS Sql Server, Oracle db.
His professional career started in April 1997 as a junior Software Developer devolping Delphi 3 and Microsoft FoxPro.
In January 1999 he started working on MS-ASP / Visual Basic technologies and also contributed for the development of a web analysis and reporting system of telephone exchange data.
From November 1999 to December 2003 he had several experiences as Lotus Notes/Domino platform developer for large accounts.
In 2004 he developed java projects using J2EE, Struts, Hibernate and tomcat technology. From January 2005 to date he is a Senior Developer and project leader of the EMC2 Documentum technology aimed at implementing additional features and customizations, for some large accounts as Bayer, Kone. Customizations have been developed using XML and extending java classes.

Jason Cane
Bachelor of Computer Science Engineering is technical project manager and information technology expert specialised in the field of software analysis, architecture engineering, software development, database engineering and managing. He is a serious analyst and a system administrator, since 2001 he manages and coordinates projects in the ambit of ontology and web semantic. He is Oracle Certified Professional Database Administrator 8i, his programming background is based on deep competencies in software engineering languages and object oriented ones such as C, C++, Java, Pl/Sql, Php. Because of his expertises in database administration and management (Oracle RDBMS, MySql, Microsoft SQL Server, PostgreSQL), he has been involved in several activities in the software/DB project area.

B2.3 Consortium as a whole

REMINE Consortium consists of allied partners willing to co-operate and share a diverse set of complementary technical skills and scientific expertise required for the development of REMINE solution. The Consortium is formed with strong commitment to maintain and develop an innovative direction in the provision of risk management, prediction, detection and monitoring of adverse and other relevant event impacting on patient safety. The Consortium has seen a constituency process aimed at realising an optimum example of complementarities, gathering together all the fundamental actors needed to develop such solution. The description of each participating organisation done in paragraph, gives evidence of their involvement and assignment on specific project research activities and different tasks, and how the presence of each of them if necessary to assure the goodwill and continuation of the project.

As far as specific skills are concerned, the following table provide an overview of the most relevant expertise of the Consortium in the field of patient safety and the projects where this experience has been used and increased.

Partner	Project/year	Description

GMD	Hospital Risk management system 2002-ongoing FORALL 2006 (EU project) ITACA 2002-2004 Saxon (D) region SAXTELMED	More than 50 hospitals in EU More than 30 hospital in Latin America Homecare patient safety monitoring EHR integration Risk management IT system
REGLOM SEK TRFT	COCOON 2004-2007 (together with MIP) INNOVATION IN PATIENT SAFETY 2005-2007	Risk management system for GPs National research project involving 11 regional healthcare systems
RAMIT	ASSIST COPLINTHO PANACEA – ITV TRUST Health	Data mining on cervical cancer retrieving genotype / fenotype data. Homecare patient monitoring Patient monitoring and patient education with safety related aspects Privacy enhancing techniques
TUW	Protocure I & II (EU-Project: IST-2001-33049 IST-FP6-508794) Asgaard/Asbru Project (national funding) EviX (national funding) VIE-PNN (national funding) VIE-VENT (national funding) Pulsoximetry (national funding)	Improving Medical Protocols by Formal Methods; development process of medical guidelines and protocols Guideline-based Care; Modeling, Verification and Execution Semi-automatical of Modeling Guidelines (Information Extraction) Expert System for Parenteral Nutrition Composition of Newborn Infants A Knowledge-Based Monitoring and Therapy-Planning System for Artificially Ventilated Newborn Infants Optimizing oxygen supply for neonates

Table below describes composition of the consortium based on the partners' organisational type. It is evident, from both the detailed partner description above given well as from the indication of the typology of organisations involved, how each project participant has been carefully chosen because it brings to the project specific skills that unified with the other participants competences compose the right set of complementary capabilities necessary to pursue and reach REMINE project objectives. In this context project activities have been attributed to individual participant, taking in full account the main experiences each partner had in each specific domain relevant to REMINE.

Participant name	Country	Organization type
GMD Gesellschaft fur Medizinische Datenverarbeitung	D	Big industrial organisation
Regione Lombardia- Direzione Generale Sanità	I	Public Authority
Federation of Municipalities for Economic Development in Suupohja	FI	Public Authority
The Rotherham NHS Foundation Trust	UK	Public Authority
Quality AND Systems Consulting	UK	SME
Hewlett-Packard Italiana	I	Big industrial organisation

SO	CZ	Big industrial organisation
Technische Universitaet Wien	AT	University/Research centre
Research in Advanced Medical Informatics and Telematics (vzw)	BE	University/Research centre
Quality & Reliability	GR	SME
Link Consulting, Tecnologias e Sistemas de Informação	POR	SME
Institute Of Communication And Computer Systems - National Technical University Of Athens	GR	University/Research centre
MIP Consorzio per l'innovazione e la Gestione delle Imprese e della Pubblica Amministrazione	I	University/Research centre
S.C. Info World	RO	SME
AMINIO	SWE	SME

Fact deserving to be mentioned is how SMEs will play a preponderant role in REMINE. In fact on a total of 9 industrial partners 6 are SMEs. Each of them has been selected taking in full account its ability to achieve the goals of the project and to assure the cohesion of the Consortium. The exact composition of the industrial partnership of the consortium is described in the table below.

	Sme qualification		**Characteristic of SMEs involved in REMINE**
Partner involved	**No**	**Yes**	1) Benchmarking and specialisation Each SME in the consortium is fully experienced in own specialisation for implementing the associated tasks of research and development. 2) SME's cooperation with Health Care organisations The consolidated experience in previous research projects is considered for ability to produce innovative knowledge for heath care organisation (Economic and Technological Intelligence) 3) International Network of SME's The presence of a collaborative environment among Centres of Research, SME's (industrial or consulting) and Institutional organisations is oriented to define a competitive consortium in the European market.
GMD Gesellschaft fur Medizinische Datenverarbeitung	X		
Quality AND Systems Consulting			
Hewlett-Packard Italiana	X		
SO	X		
Quality & Reliability		X	
Link Consulting, Tecnologias e Sistemas de Informação		X	
S.C. Info World		X	
AMINIO		X	
Total	**3**	**6**	

Such a partnership most certainly contains the critical mass of complementary scientific and technological expertise, as well as the industrial experience at the European level. These are qualities that are required in order to successfully complete the project and to continue the co-operation on the exploitation of its outcome upon its completion, having the Consortium all the necessary marketing power for the subsequent commercialisation of project results. REMINE Consortium members belong to eleven different countries: UK, Italy, Germany, Belgium, Greece, Romania, Portugal, Finland, Austria, Czech Republic and Sweden. In each of these countries REMINE has a considerable market potential. Moreover, the validation carried out by REMINE Pilots Group (which consists of various service providers directly interested in the project results) will also allow incorporating the "real-world" end-users' requirements and thus pave the way to an even larger market base.

The involvement of relevant industrial partners in REMINE is fundamental to enable timely and effective industrial exploitation. The project partners commit to apply the relevant results of this project in their activities or use them in order to enhance their worldwide competitiveness, to strengthen their product portfolios and to increase their network of customers. Some partners will expand their businesses by integrating the techniques, methods and standard practices in their commercial offers. Specific reference to REMINE exploitation strategy and methodology is given in section 3 of this project.

B2.3.1 Subcontracting

Subcontracting activities performed on behalf of partner number 4 (TRFT) by Sheffield Hallam University (SHU).

The work required is for sub-contracting of the following services to this TFT to support the project activities, with particular attention to:

- Identification of user requirements (WP1 – T1.1)
- Assisting with Structuring technical requirements (WP6)
- Technical Expertise regarding Risk Modelling (WP1 – T1.2)

These are technical skills that have been identified as potential gaps in TRFT capability. The value of any such sub-contract is not expected to exceed 48,000 Euro, and will be delivered by SHU that has all the required capabilities.

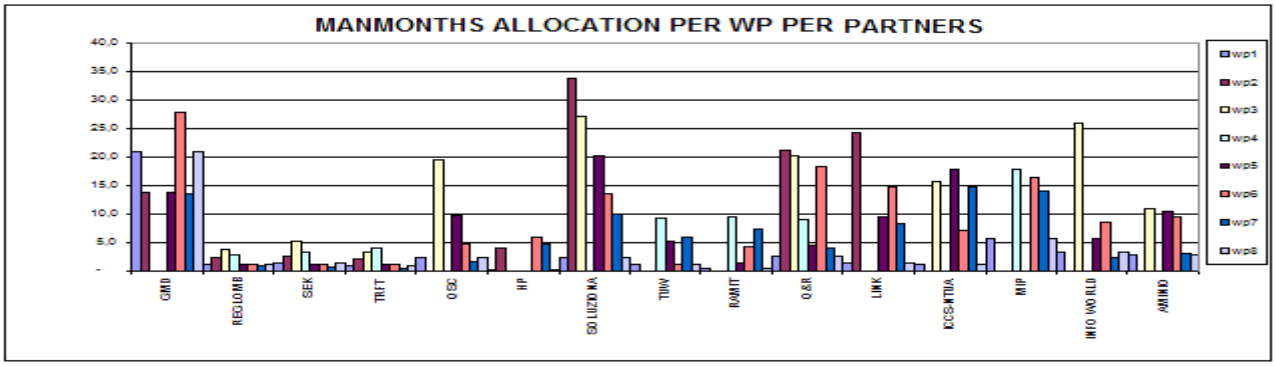
B2.3.2 Third Party

N/A

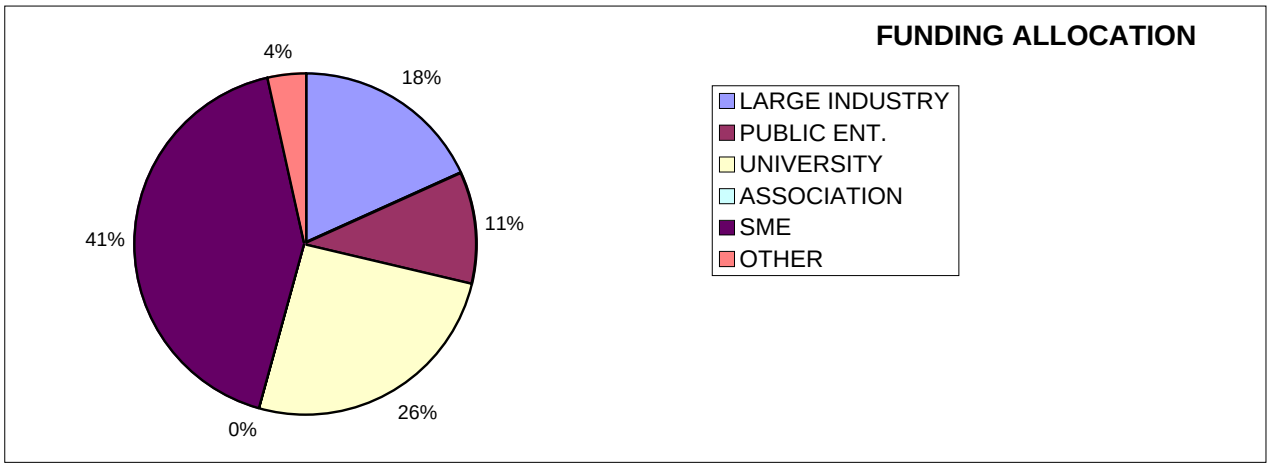
B2.4 Resources to be committed

The following diagrams show the allocation of man months per partners, the distribution of funding per partners, country and the distribution of costs per partner and activity.

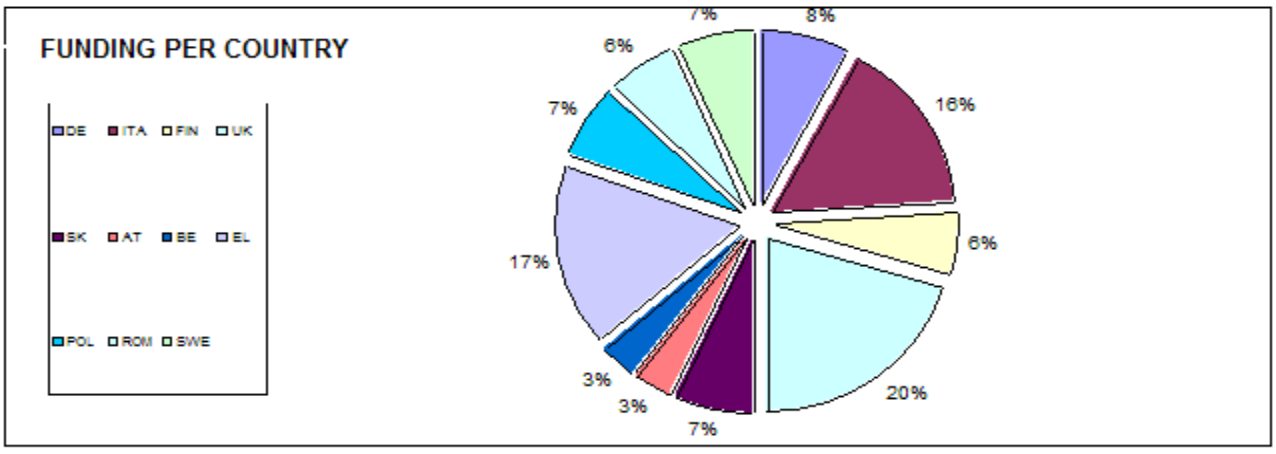
In particular the first graph is dedicated to the share of man effort between REMINE partners.



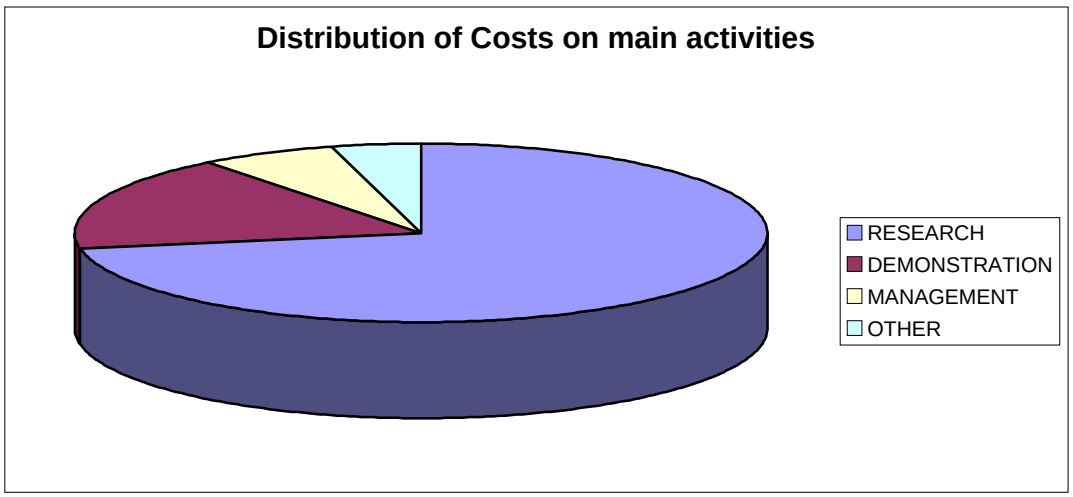
The following graph gives an idea of REMINE funding allocation between the different typologies of organizations involved in the project.



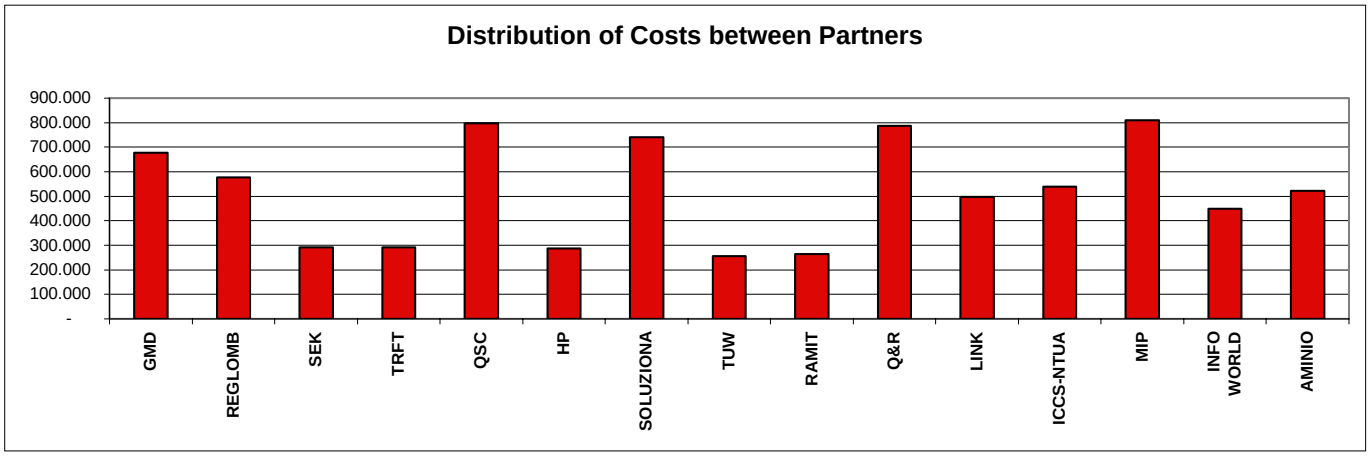
As reported in the description of REMINE consortium, the partners involved are belonging to 11 different European countries. The graph below gives an overview of percentage of funding dedicated to each participating country.

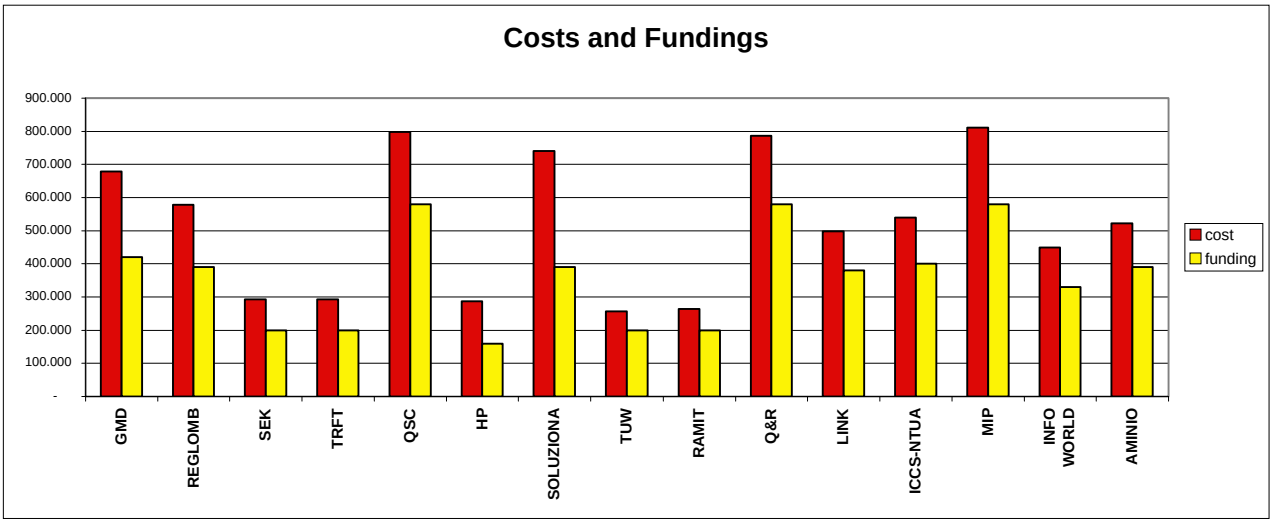


REMINE macro activities are categorized in four main typologies. The following graph gives a picture of costs distribution between the four main activities. As it is evident the main cost allocation is dedicated to RTD activities due to the intrinsic nature of the project.


Distribution of Costs on main activities
RESEARCH
DEMONSTRATION
MANAGEMENT
OTHER

The last two graphs are dedicated to the indication of total costs and funding distribution between REMINE partners.





B3 Potential Impact

B3.1 Strategic impact

REMINE project aims at providing a platform to predict and preventive the reduction system of RAPS. Remine project responds to the expected impacts described in the Work Programme 2007 of FPT-ICT-2007-1 - Call for: Towards sustainable and personalized healthcare, targeted to Advanced ICT for Risk Assessment and Patient Safety.

A study of Clinical Risk Unit, Department of Psychology, University College London*17* examines the main causes of errors in clinical practice, showing that there is at least a twenty-fold greater danger of dying from just being in hospital that being in traffic or flying in a commercial plane, and that being in hospital is only ten times less dangerous per hour of exposure than parachute jumping.

By analysing this and other more recent studies can be outlined a subdivision of RAPS that follows patient pre-during-post hospitalisation process:

- Problems arising at time of diagnosis. Around 1% of admissions are associated with incorrect diagnoses, all of which seem to have been made by trainee doctors. In all cases the errors occur during the early assessment of emergency admissions.
- Problems arising during preoperative assessment and care. In 30% cases there is a failure to guard against postoperative problems (possible deep vein thrombosis, infection and chest disease); in 0,5% cases unnecessary urethral catheterization led to urinary tract infection.
- Problems arising during an operation or an invasive procedure (including anaesthesia). This category yielded the highest number of problems 46% of which 10% are deemed preventable.
- Ward management. Problems in ward management (other than the use of drugs and intravenous fluids, which are dealt with separately) totalled 26% of all problems, of which 11% are thought to be preventable.
- Use of drugs and intravenous fluids. Problems arising from the use of drugs and intravenous fluids were identified in 12% cases, 9% of which are judged preventable. More than half the cases occurred in a medical ward. 3% cases of overtransfusion are identified.
- Discharge procedures. Poor clinical assessment at the time of discharge from hospital or failure to educate the patient and/or to liaise adequately with community-based carers (including general practitioners) are identified as important causes of RAPS in 14%.

Having REMINE project the scope of developing and implementing an RAPSs management platform and related methodology, this section wants to explain:

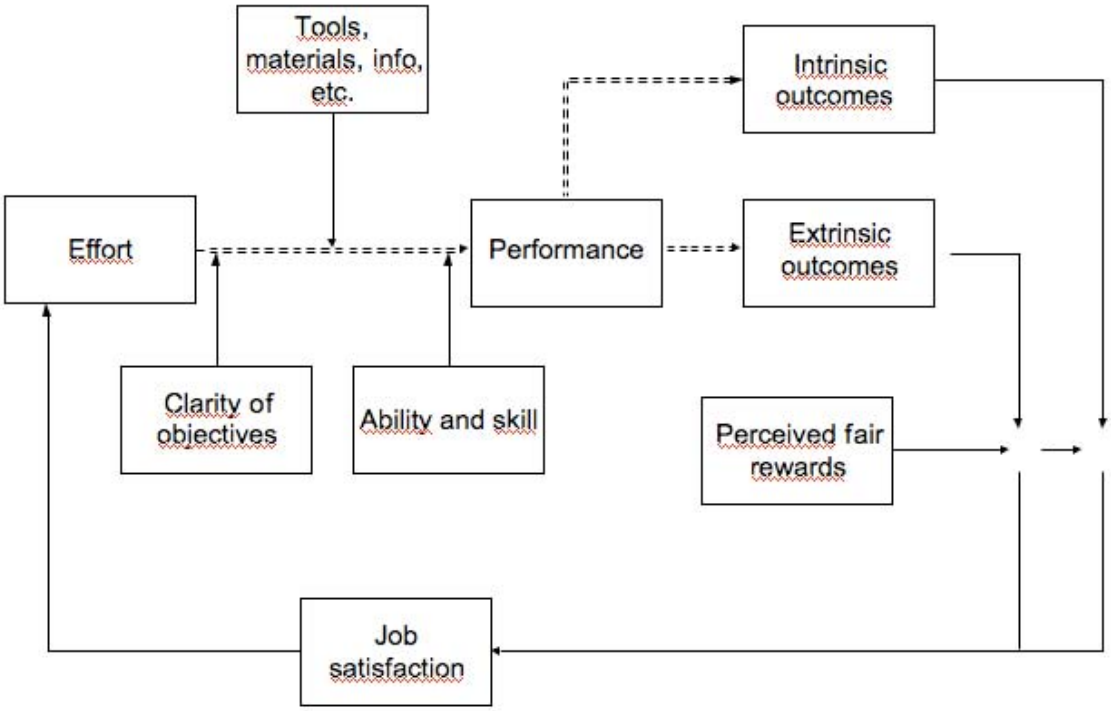
- Which REMAIN project is facing off;
- Which methodology will be implemented during the project (see WP1 and WP6 of the project) in order to assess and validate the project expected impacts.

How to convince hospital personnel of the importance of using REMINE

[17] Exploring the causes of RAPS in NHS hospital practice, ***Graham Neale*** FRCP Maria Woloshynowych PhD Charles Vincent PhD , *Clinical Risk Unit, Department of Psychology, University College London, London WC1E 6BT, UK ; J R Soc Med* 2001;***94***:322-330 © 2001 *The Royal Society of Medicine*

In order for REMINE to actually make the difference, it is important that people having to use the system actually understand that their contribution – willingness to use the system and comply with procedures – is necessary to get the most out of it. In other words, motivation is a key aspect.

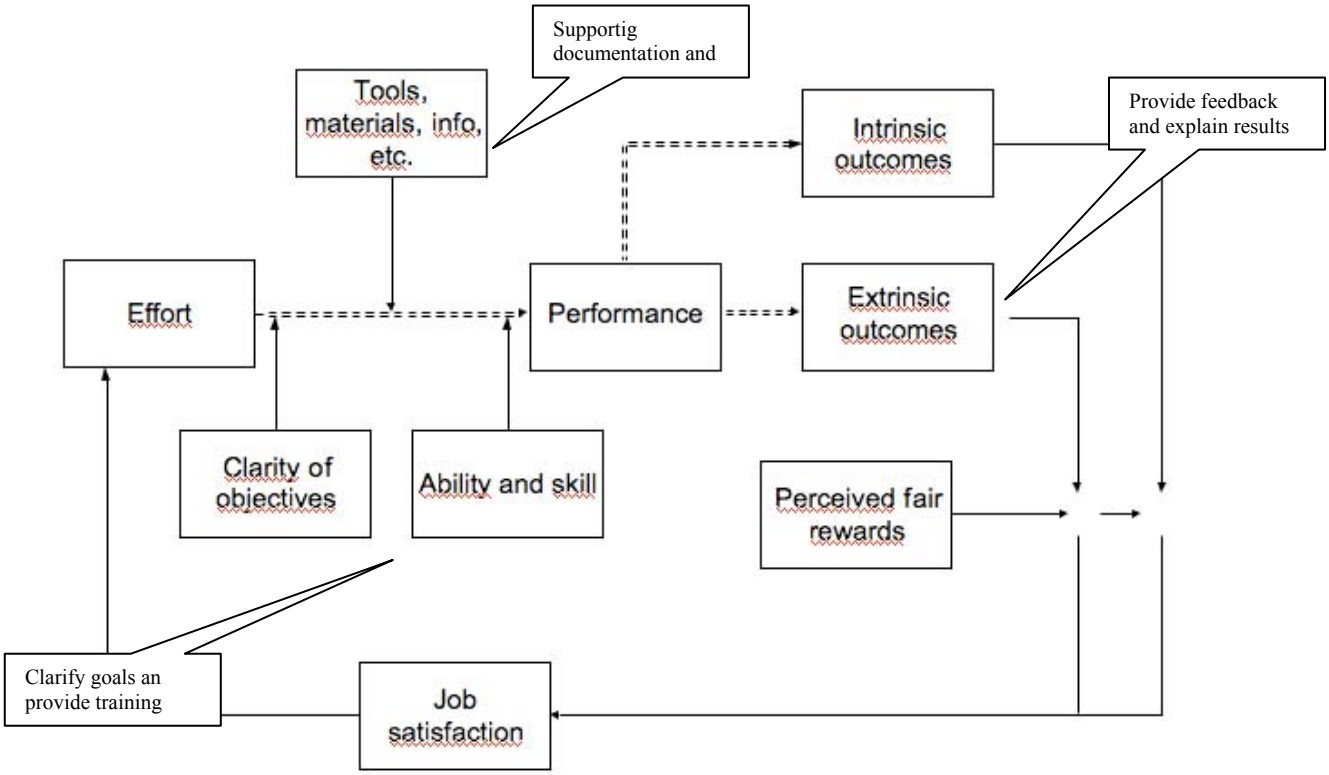
According to the Expectancy Theory*18* in order for someone to be motivated a set of actions and behaviours are required. The following tables summarizes the ideal procedure to be followed. Let's go briefly through the procedure and see how these principles will be used for improving motivation of REMINE users.



Anyone's effort, to be produced with appropriate motivation, has to be guided by goals clearly defined and should be performed with adequate skills as well as the necessary tools. The resulting performance, the outcome of the effort, will have on one side intrinsic outcomes, i.e. hoe the person perceives and evaluates the result of his/her job. On the other there will be an Extrinsic outcomes which is given by someone judging the performance from outside. Motivation is fostered if this outcome is given and is perceived as being fair. The arising job satisfaction boost motivation and effort.

REMINE will take these principles into account. Providing all the necessary supporting information coupled by appropriate training and support to users. The results of the evaluation and the increased benefits will be explained clearly and communicated to the users.

18 Proposed by Victor Vroom of the Yale School of Management



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Project contribution to expected impacts of the Work Programme topic/s

Starting from the requirements of Work Programme about Health care the following impacts can be foreseen as project outcomes:

- Improved productivity of healthcare systems in terms of 'economy' (spending less) and 'efficiency' (spending well) outcomes such as:
  - Avoided costs through less in-patients days due to re-admission and other effects of RAPSs;
  - Less unit cost for diagnosing and treating patients with simple disease since the full proof alert and warning systems could convince hospitals to have such patients managed mostly but less expensive HCPs;
  - Decreased Cost of Quality, since the automated quality control functionalities embedded in REMINE will decrease the need of using personnel in the quality management system;
  - Decreased costs of hospital insurance from reduction of malpractice litigation;
  - Decreased opportunities for 'moral hazard' (unnecessary treatment prescribed only for receiving reimbursement) as alert and warning might spot inappropriate prescribed treatment given patient history.
  - These are all very tangible benefits that can be assigned a monetary value and produce in the end a very compelling 'value for money' evaluation. Additionally intangible benefits can also be delivered in terms of 'good governance' in terms of transparency and of better image of hospitals vis-à-vis public opinion. Finally at the end of the cycle, when robust evidence as to the delivery of end outcomes is produced and disseminated this will increase the legitimacy of this project in particular and of eHealth in general and possibly lead to more public national and international funding.
- Savings in lives and resources by focusing on prevention and prediction rather than on costly medical interventions after symptoms and diseases have developed. This will be helpful in non overshooting/mismatch in resource allocation. Simple organisational

innovations supported by ICT can bring about cost effective ways of dealing with the least demanding segment of demand. For instance, a full proof integrated ICT supported RAPS system can enable less expensive practitioners to diagnose and treat patients with simpler diseases, freeing up the time of more expensive professionals, and thus reducing the unit cost of treating such patients*19*.

- Continuous and more personalised care solutions, addressing the informed and responsible participation of patients in care process, and responding to the needs of elderly people. REMINE project is a support at best the overall risk management activity, the regular monitoring of RAPS must reply to the need to addressing the informed and responsible participation of patients in care process. This project bases on a personalised care solutions of patient and on a data sources and documentary archives up-dated.
- Higher patient safety by optimising medical interventions and preventing errors by reducing fragmentation and overspecialisation (duplications and errors) in the patient care management process. REMINE supports patient centric preventive systems connecting several payers (patient, primary care, ambulatory, hospitals, ect) reduce duplication thus decreasing costs. REMIE supports RAPS systems, by better connecting the various information silos within an hospital, thus REMINE platform usage prevents errors in various areas, thus reducing hospitalisation costs and having various other impacts see above.
- Leadership of the eHealth and medical imaging/devices industry that is well rooted in Europe, and attracting back to Europe research activities of the pharmaceutical industry. The participation of several European partners will allow the project to improve Europe's overall healthcare system. The results of Remine project, in other terms, would constitute a further progress towards the achievement of the European strategy on life sciences an the Lisbon objectives**Error! Bookmark not defined.**, helping the increase the competitiveness of European healthcare biotechnology and medical technology sectors.
- Leadership medical devices to treat risk management. Remine benefits patients with better diagnostics, prevention and controll because it combines efforts of medical and industry. Through research, clinicians gain a greater insight in reporting incident system understanding, while industry is dragged by these achievements to develop more suitable medical devices to treat risk management.
-

<u>For what concern the objectives of the Call, REMIE is related to "Advanced ICT for Risk Assessment and Patient Safety". The following impacts can be foreseen as project outcomes:</u>

- Common patterns in safety-relevant events. Remine project intends to produce an integrated decision support tool for risk management (management support system), able to facilitate the identification of intervention priorities through the dynamic query of many information sources that contribute to specify the contexts, the contributing factors and the outcomes of RAPS. Most imaging procedures ordered by office-based clinicians, and some ordered by those in hospital-based ambulatory practices, are performed in external radiology centers. Connectivity between these organizations would reduce redundant tests and would save time and costs associated with paper- and film-based processes. Interoperability between outpatient providers and pharmacies would reduce the number of medication-related phone calls for both clinicians and pharmacists*20*. The RAPS costs are increasing in the last two

19 This is one example of disruptive innovations analysed by Christensen et al (op. cit, p. 106). Advances in diagnostic and therapeutic technologies matched with a full proof RAPS system preventing errors could allow nurse practitioners and physicians' assistants to diagnose and treat patients with simpler disease. An additional element cited by Christensen et al supporting this possibility are studies showing that nurse practitioners typically devote more time to patients during consultations than physicians do and emphasize prevention and health maintenance to a greater degree (i.e.). In other words they have a more patient-centric approach (ibid.).

20 The Value Of Health Care Information Exchange And Interoperability - There is a business case to be made for spending money on a fully standardized nationwide system.

years, as a study shown*21*, each RAPS led to an average of 8,5 extra bed days (range 0-70 days) with additional direct costs of National Health System (for example in a study estimates that around 5% of the 8.5 million patients admitted to hospitals in England and Wales each year experience preventable RAPS, leading to an additional three million bed days. The total cost to the NHS of these RAPS in extra bed days alone would be around £1bn a year).

- Redundant and mistaken data reduction. this process is integrated with a disease management systems. The outcome is as a matrix with patient's anamnesis and case history; this management system allows to prevent RAPS and optimise medical interventions. REMINE project will reduce the RAPS, positively impacting on the current breakdown of the incident typology showed below:
    - 66% patients who suffered RAPS had minimal impairment (or recovered within one month);
    - 34% patients developed an injury or complication;
    - 19% resulted in moderate impairment;
    - 6% resulted permanent impairment;
    - 8% contributed to death.
    - Overall, 48% RAPS were judged preventable.
- World-leading levels of patient safety with fewer medical errors and optimised medical interventions resulting in savings of lives and resources. Incident reporting is considered an important source of risk management data for identifying and addressing the causes of errors that occur in health-care organizations. An analysis*22* achieved that the RAPS reporting system had reduced the malpractice' incidence only when the reporting system was linked up stimulating learning opportunities, and the redundant and mistaken data erasing. Adverse incidents are typically caused by alignment of different factors, but good practice can prevent errors becoming incident. Careful analysis*23* of incidents reveals both the multifactor causes and the good practices that can help minimise repetitions, thus REMINE project will raise the operational procedures' quality. The continuing high incidence of medical errors suggest that eHealth approaches are struggling to acquire a clear understanding of the complex, dynamic and multi-layered nature of acute care settings and clinical practices, and to respond effectively to address the range of errors that actually occur.
- Early alerts and improved management of large scale health-related crises through effective and automated risk prediction, assessment and management. The value of electronic data flow, between providers (hospitals and medical group practices) and other providers, and between providers and stakeholders with which they exchange information most commonly: independent laboratories, radiology centers, pharmacies, payers, and public health departments, offers clinical benefits and financial benefits.
- Accelerated and wider adoption of future electronic health record systems. The expected impact of REMINE project, as for the Work Programme – Advanced computerised RAPS system -, should be achieved by the innovative ERP architecture and the new system of ontology. The greatest opportunities for improving health and health care lie in enabling information exchange between the three dimensions (areas – picture below) of the national health information infrastructure*24*. The full potential of REMINE systems will not be

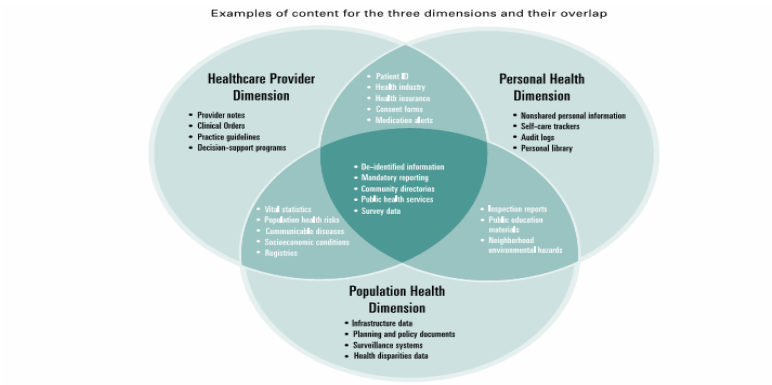
21 RAPS in British hospitals: preliminary retrospective record review, Charles Vincent, professor of psychology, Graham Neale, consultant physician, Maria Woloshynowych, research fellow, Clinical Risk Unit, Department of Psychology, University College London, London WC1E 6BT. Editorial by Alberti Letters p 548Reviews pp 562, 563

22 Identifying risk: the limitations of incident reporting. Burkoski V. University of Phoenix, Phoenix, Arizona, USA.

23 Education and debate: Quality improvement report - Learning from adverse incidents involving medical devices. John Amoore, clinical scientist, a Paula Ingram, sister. b a Department of Medical Physics and Medical Engineering, Royal Infirmary of Edinburgh, Edinburgh EH3 9YW, b Department of Nursing, Royal Infirmary of Edinburgh.

24 National Commitee on Vital and Health Statistics, Information for Health

realized until the leader of the three area (Healtcare Provider, Personal Health, Population Health) are capable of widespread exchange of information with eHealth and other sources of personal and other health data. REMINE project with the participation of several European partners will allow the improvement of electronic health record systems. REMINE project with the participation of several European partners will allow the improvement of electronic health record systems.



Source: National Committee on Vital and Health Statistics, *Information for Health: A Strategy for Building the National Health Information Infrastructure*, Washington, D.C., 2001.

- International cooperation between EU constituency and Latin America counterpart. Uptake of EU standards in the electronic Health Records area in Latin America. In the Latin America countries, broad allocation of health-care resources is primarily based on political criteria, historical records, geographical areas, and specific groups of patients and diseases. Public-health provision and inclusion of services in health-insurance package are responsibilities of the Ministry of Health. Decisions regarding the purchase of medicines are primarily made through public tenders, and mainly based on differences in clinical efficacy and the price of health technologies of interest[25]. To expedite the process of international cooperation between EU constituency and Latin America counterpart, REMINE project as a formal tool to inform decision-making processes within the health-care systems in Latin America countries, two main conditions need to be fulfilled. First, adequate resources and skills need to be available to conduct REMINE project of good quality. Second, decision-making procedures need to be modified to accommodate "evidence-based" approaches such as the project.

The Consortium is perfectly aware of the possible internal and external barriers that can arise against REMINE expected impact achievement. As to the internal barriers, the most significant threat could be the sudden coming out from the Consortium of one or more project partners, thus undermining the planned activities implementation. From this point of view, the Consortium relies on a well-built network of contacts, able to support such a risky situation in case of occurrence. Among the most relevant external ones, the existence of possible legal and ethical obstacles to the full deployment of the proposed platform. This is exactly the reason for which necessary investigation has been already made in order to prevent them (see WP6). At this stage, no legal/ethical obstacles subsists.
To cope with possible future barriers in these terms, REMINE partners will perform an adequate and continuous monitoring of the conditions that eventually could hamper the project work, within the general legal and ethical framework. In the following paragraph the impacts validation methodology has been described (see WP6 for its implementation planning during the project life cycle).

25 Health-care decision-making processes in Latin America: problems and prospects for the use of economic evaluation. Iglesias CP, Drummond MF, Rovira J; * NEVALAT Project Group. Centre for Health Economics/Department of Health Sciences, University of York, UK

Project contribution to expected impacts of the Work Programme topic/s

It is recognised*26* that OECD countries only 6% of health expenditure goes to collective goods such as Prevention (3%) and General Administration (3%). But is precisely in the fields of prevention and administration (where management, quality and risk control activities fall) that simple disruptive innovations, based on organisational changes and on Information and Communication Technologies (inexpensive if compared to sophisticated medical technologies) can maintain and/or improve the quality of services while at the same time decreasing the costs.
Below are summarised the seven factors contributing to rising health care costs.

- Ageing population. ICT supported RAPS systems can reduce re-admissions that are particularly frequent among the elderly;
- Increasing income. There is no way to impact the positive correlation between economic growth and health expenditure;
- Consumerism. If ICT supported RAPS systems enable a new patient centric approach this will respond to increase demands for quality and customer orientation;
- Nuclear families, work force feminization, mobility. Various other eHealth applications can facilitate access and reduce waiting times;
- Increasing capacity to cure (new costly medical technologies and/or pharmaceutical products). This structural feature is not impactable;
- Overshooting/mismatch in resource allocation. Simple organisational innovations supported by ICT can bring about cost effective ways of dealing with the least demanding segment of demand. For instance, a full proof integrated ICT supported RAPS system can enable less expensive practitioners to diagnose and treat patients with simpler diseases, freeing up the time of more expensive professionals, and thus reducing the unit cost of treating such patients*27*.
- Fragmentation and overspecialisation (duplications and errors). ICT supported patient centric preventive systems connecting several payers (patient, primary care, ambulatory, hospitals, ect) reduce duplication thus decreasing costs. ICT supported RAPS systems, by better connecting the various information silos within an hospital, will prevent errors in various areas, thus reducing hospitalisation costs and having various other impacts (see later).
- Cost inflation due to moral hazard / adverse selection. This is ingrained in utilitarian human behaviours leaning toward opportunism, which are difficult to change. Yet the optimised and distributed use of information can indirectly curb this behaviours. Full proof integrated ICT supported RAPS systems with warning on inappropriate treatment can make it more difficult for health care professionals within hospitals to provide unnecessary treatments for the sake of maximising reimbursements.

Above it has been stressed how REMINE can help in maintaining quality and reduce costs, and thus contain or substantially impact some of the seven factors and the other impacts already commented in paragraph 3.1.1. Needless to say eHealth as a whole, with its many application and services, can contain and impact these factors in several other way, but we here focused on the potential impact that project such as REMINE can deliver. In sum, thus, these are the promise of eHealth in general and of REMINE in particular that, however, to be delivered requires overcoming three challenges:

1) Organisational change;
2) Utilization (take up) strategy;

26 See http://www.oecd.org/document/37/0,2340,en_2649_37407_36986213_1_1_1_37407,00.html
27 This is one example of disruptive innovations analysed by Christensen et al (op. cit, p. 106). Advances in diagnostic and therapeutic technologies matched with a full proof RAPS system preventing errors could allow nurse practitioners and physicians' assistants to diagnose and treat patients with simpler disease. An additional element cited by Christensen et al supporting this possibility are studies showing that nurse practitioners typically devote more time to patients during consultations than physicians do and emphasize prevention and health maintenance to a greater degree (i.e.). In other words they have a more patient-centric approach (ibid.).

3) Impact/outcomes evaluation and measurement capabilities.

eHealth Impact, a study financed by the DG INFSO of the European Commission, has analysed the topic of the economic impact of eHealth in general and studied in depth 10 good practices cases showing evidence of having delivered substantive and tangible benefits. The conclusion of the study is that these benefits were not produced by ICT applications by themselves but originated in changes in organisational processes and working practices, triggered by the introduction of ICT*28*. This finding simply confirms what is by now already a consolidated wisdom, backed by robust empirical evidence, in the more general field of studies of ICT impact on organisations. Such a body of literature provides robust evidence on the importance of changes in business processes, organisational structures, human resource training, innovation in supply chain and customer relationship management, as crucial complementary inputs to fully leverage the potential of IT investments29. Systematic evidence presented in the work of the well-known MIT economist Erik Brynjolfsson and colleagues shows that organisation successfully leveraging ICT and obtaining the expected benefits, made substantial investment in complementary change termed "organisational capital" (subsuming together changes in business processes, organisational structures, human resource training, innovation in supply chain and customer relationship management)30. Besides organisational change, a utilisation (take up) strategy to maximise the usability and acceptance for all concerned users is crucial in general and particularly in the health sector, both ex ante in the design phase and ex post in assessment phase*31*: Is the technology usable in the intended environment and for the intended users groups and tasks? Do the different users groups (e.g. physicians, nurses, administrative staff, patients/users) accept the ICT and use it as intended? What are the patterns in the users' attitude towards the (future) system, and their pattern of behaviour? Have the users had sufficient training and guidance to be able to use the technology appropriately? Utilisation is a multiplier of the potential ICT benefits in the same way as organisational change, impacts grow proportionally to the utilisation of the new eHealth systems (internal applications by health care professionals) and services (by patients / users). eHealth Impact found that utilisation has been a key determinants of the benefits produced in the 10 good practices cases analysed*32*. The discussion on organisational change and utilisation strategy is summarised in the matrix reported below.

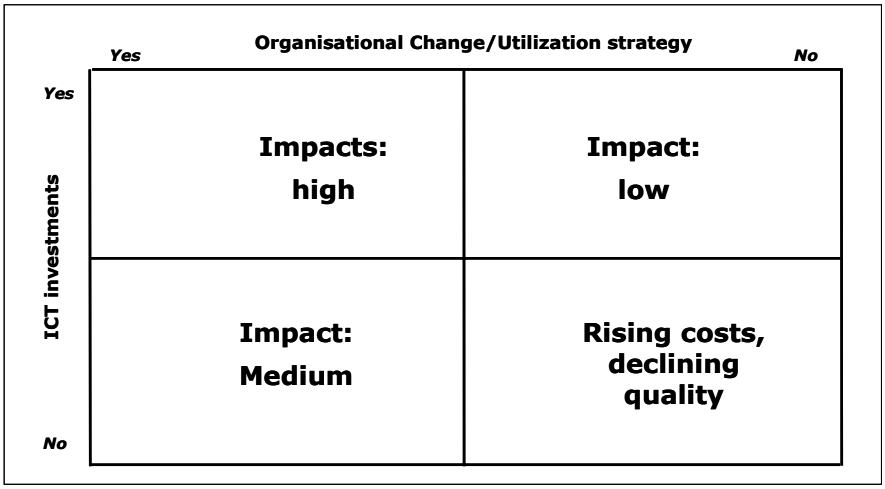
28 eHealth Impact, D6.2 Final Summary Project Report, February 2006 (*http://www.ehealth-impact.org/download/documents/D6_2_Final_Report_ext.pdf accessed April 2007*), p. 18.

29 For empirical evidence see Bresnahan, T., E. Brynjolfsson, and L. Hitt, "Information Technology, Workplace Organization and the Demand for Skilled Labor: Firm-level Evidence," Quarterly Journal of Economics 117:1 (2002), pp. 339–376. A general overview of such studies is presented in Brynjolfsson, E., and L. Hitt, "Beyond Computation: Information Technology, Organizational Transformation and Business Performance," Journal of Economic Perspectives 14:4 (2000), 23–48.

30 See for instance: Brynjolfsson, E. and S. Yang, "The Intangible Costs and Benefits of Computer Investments: Evidence from the Financial Markets", MIT Sloan School of Management Working paper, 1999 (*http://ebusiness.mit.edu/erik/ITQ00-11-25.pdf*, accessed January 2006); Brynjolfsson, E., L. Hitt, and S. Yang, "Intangible Assets: Computers and Organizational Capital", MIT Sloan School of Management Working paper, 2002 (*http://ebusiness.mit.edu/research/papers/138_Erik_Intangible_Assets.pdf* , accessed January 2006); Brynjolfsson, E., L. Hitt, and S. Yang, "Intangible Assets: How the Interaction of Computers and Organizational Structure Affects Stock Market Valuations," Brookings Papers on Economic Activity: Macroeconomics 1 (2002), 137–199; Brynjolfsson, E., and L. Hitt, "Computing Productivity: Firm-Level Evidence", The Review of Economics and Statistics, 85: 4 (2003), pp. 793-808.

31 On the importance of utilisation in the evaluation of health information systems see E. Ammenwerth, J. Brender, P. Nykanen, H.U. Prokosch, M. Rigby and J. Talmon, Vision and Strategies to Improve Evaluation of Health Information Systems, International Journal of Medical Informatics, 73 (2004), pp. 479-491.

32 eHealth Impact, op. cit., p. 6.



Source: exemplificative elaboration from various sources

The final challenge to justify existing investments and provide legitimisation and impulse for new ones is the capacity to demonstrate tangible impacts, which requires evaluation and measurement capacities. The earlier quoted EC financed eHealth Impact study, for instance, concludes that:

Despite the general availability of eHealth systems and services, they are not widely used in medical or healthcare environments across the EU. A major reason why European and national policy goals for eHealth applications have not been achieved so far is that very little reliable evidence is available on the economic impact of using ICT in delivering high quality healthcare. The impact is potentially enormous, but has been difficult to measure, especially some of the benefits. Evaluations often have only one perspective, such as financial, or the view of a single stakeholder33

The first and foremost challenge is the lack of a standardised and consensual taxonomy of RAPS as such and of how reporting them and the related causes and on the way to detect and avoid them. This evidently hinders the availability of comparable and homogeneous evidence. An interesting article published in Health Technology Assessment by Bruce et al on the measurement and monitoring of 'surgical RAPS' affirms that, while surgical RAPS contribute significantly to postoperative morbidity, 'yet the measurement and monitoring of events is often imprecise and of uncertain validity'. They attribute this mainly to the lack of a standard definition of surgical RAPS: in their systematic review of the literature through 30 separate search of core health and biomedical databases they identified, for instance, 40 different definitions and 13 grading scales of 'surgical infections' and over 40 different definitions of 'anastomic leak'.*34*
The concept of cost of quality (COQ) introduced as early as the 1950s in the industrial sector is very relevant for the topic of computerised RAPS systems. COQ includes: a) preventing failure; b) performing quality control; c) rectifying the internal and external failures*35* . While quality has a cost, the failure to provide quality can be even more costly because rectifying a situation can be more costly than preventing the quality failure causing it *36*. As stated, this approach would be appropriate for the health sector in general*37* and also for the peculiarity of dealing with RAPS (think of the cost of RAPS as a failure to ensure quality). This not withstanding the earlier cited

33 eHealth Impact, op. cit., p. 6.

34 J. Bruce, E.M. Russell, J. Mollison, abd Zh. Krukowski, The Measurement and Monitoring of Surgical RAPS, Health Technology Assessment, 5, 22 (2001).

35 D.M. Lundvall and J.M. Juran, Quality costs, in Juran J.M. (ed.), Quality Control Handbook, New York, McGraw-Hill, 1974, pp. 1-22.

36 S.A Finkler, Measuring the costs of quality, Hospital Cost Management Accounting, 7 (1996), pp. 1-6.

37 See A. Jarlier and S. Charvet-Protat, Can improving quality decrease hospital costs?, op cit., but also G. Ville, Challenges in the implementation of quality assurance in health care organisations (in French), Paris, IESTO, 1995.

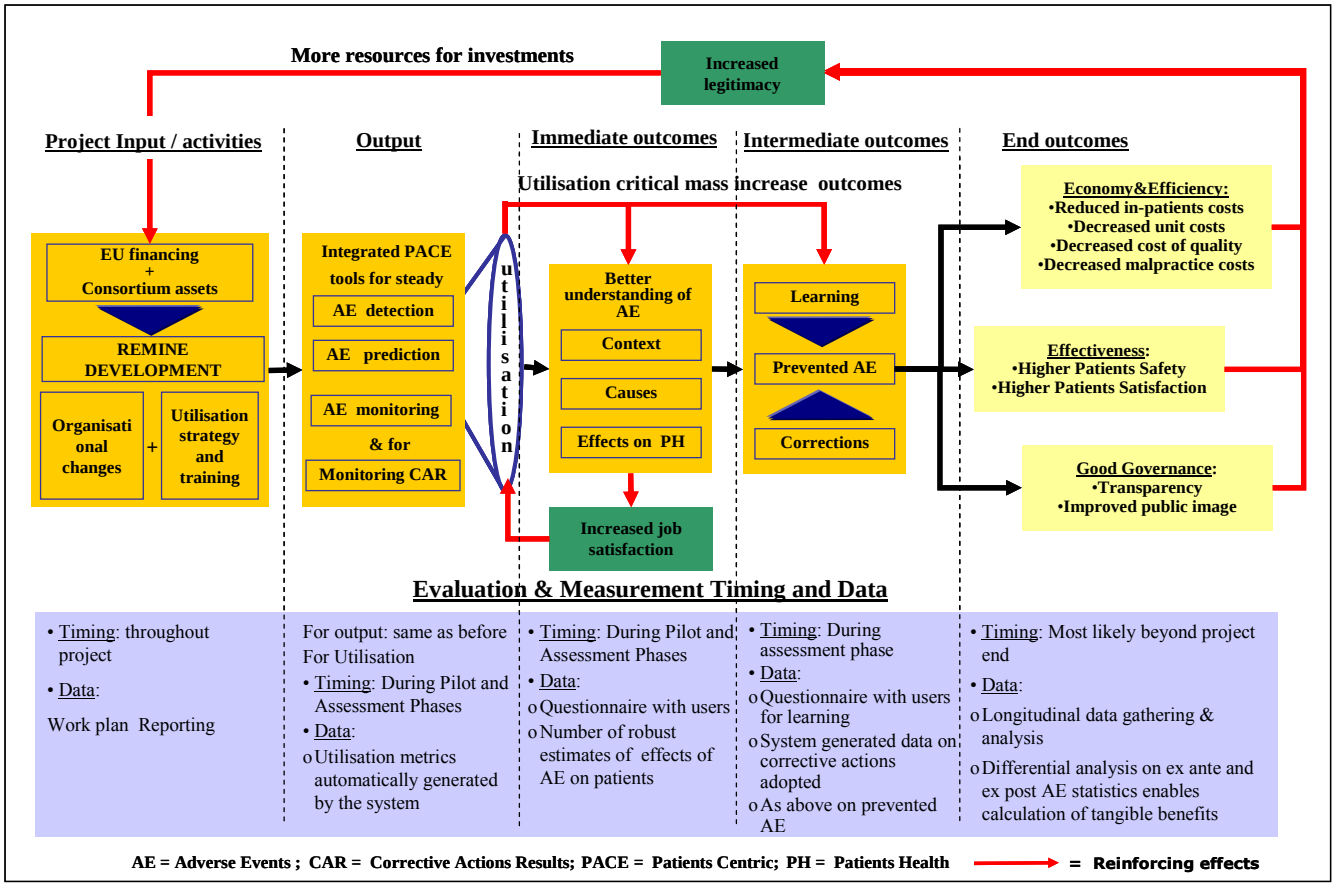
systematic meta-analysis conducted by Jarlier and Charvet-Protat found only 12 articles addressing this topic out of 554 retrieved*38*.
With respect to the evaluation and measurement of the cost of RAPS and, thus, indirectly of the potential benefits of avoiding them, the preliminary literature review conducted in preparation for this project seems to indicate that most studies concern the category of adverse drug reactions (ADR). In this very specific sub-field there is what seems to be a consolidated body of evidence on the costs of such events and on the benefits (cost avoidance) of preventing them. A cohort based longitudinal (18 months) pharmacoepidemiological survey conducted in a department of Internal Medicine at German University Hospital of Erlagen by Dormann et al, for instance, concluded using very robust evidence that ADR are one of the main cause of repeated readmission after discharge and, thus, of increased hospitalisation days and estimated that the preventable ADR are worth € 360.000 per year*39*. This in one department of one not very large hospital and only for one kind of RAPS!. If one goes beyond ADR only and transpose this to all types of preventable RAPS for all the departments of very large hospitals, it is clear that the benefits only in terms of cost avoidance can be very substantial. An aggregate estimate for Internal Medicine Departments in all of Germany is that 400 million € could be saved annually only from preventable ADR *40*. Other studies confirm such kind of findings for other countries such as for instance the USA where estimates of the increased cost per day for patients caused by ADR ranges from USD 2000 to USD 470*41*. Not surprisingly Dormann et al conclude their study with the recommendation to intensify ICT supported drug monitoring as this could substantially save hospital resources.

An integrated and advanced (through the use of semantic technologies and RFID supports) computer supported model of detection, monitoring, reporting and prevention of RAPS would produce a new model of hospital switching the focus from the professionals perspective and needs to that of the patients, implementing an holistic patient centric approach. This system, as other approaches such as evidence base medicine, are to some extent incompatible with organisational, socio-psychological and cultural entrenched clinical practices and will face therefore crucial challenges and barriers that must be deeply analysed in order to overcome them. The professionals common sense is that, since in most cases current practices are more or less effective if not efficient, why employing resources to find optimal procedures? Here again we must repeat the importance of supporting organisational change and utilization strategy to ensure usability and acceptance of the system.
Unfortunately the organisational analysis on the changes needed to accompany the introduction of an advanced computerised RAPS system, as well the socio-psychological study of the factors favouring or hindering its acceptance and subsequent utilisation, are key topics on which existing research is still scattered and scarce. Therefore, while for evaluation and measurement REMINE socio-economic research will at least partially leverage existing evidence, for organisational and socio-psychological and cultural analysis will mostly have to build new knowledge through field research thus filling the existing gap.

Figure in next page provide the comprehensive picture of the impacts assessment process that will be organised in WP6 activities in order to estimate the project outcomes (Input, Activities Output, Outcomes) matched with a preliminary and very tentative illustration of the timing and metrics that will be needed to monitor in input, activities and output and to demonstrate the delivery of tangible and intangible outcomes, and with the identification of reinforcing effects.

38 See A. Jarlier and S. Charvet-Protat, Can improving quality decrease hospital costs?, op cit..
[39] H. Dormann, A. Neubert , M. Criegee-Rieck, T. Egger, M. Radespiel-TroGer , T. Azaz-Livshits, M. Levy, K. Brune and E.G. Hahn, Readmissions and adverse drug reactions in internal medicine: the economic impact, *Journal of Internal Medicine*, 255 (2004), pp. 653-663.
[40] Schneeweiss S, Hasford J, Gottler M, Hoffmann A, Riethling AK, Avorn J., Admissions caused by adverse drug events to internal medicine and emergency departments in hospitals: a longitudinal population-based study, European Journal of Clinical Pharmacology, 58 (2002), pp. 285–291.
[41] See for instance Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP., Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality, *Journal of American Medical Association*(JAMA), 277 (1997), pp. 301–306; Bates DW, Spell N, Cullen DJ et al., The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. *JAMA* 277 (1997), pp. 307–311.

Leaving aside for the moment the left hand side of the figure (Input/ Activities), let us briefly read the logic going from output to outcomes. REMINE (see detailed technical description in paragraph 1.3) will produce as output a Patient Centric (PACE in the figure) integrated (using both external and internal databases for dynamic queries with the support of semantic ontologies and intelligent RFID tags) computerised RAPS System (RAPSS) providing tools for the detection, prediction and monitoring of all possible RAPS (RAPS in the figure), as well as for monitoring the results of the corrective actions (CAR in the figure) adopted to prevent RAPS. The actual capacity of this output to produce outcome is a direct function of the level of usage that hospital Health Care Professionals (HCPs) will make of the system, the figure clearly depicts 'Utilisation' as an amplifier.



As utilisation increases, the first immediate outcomes should be HCPs better understanding of the 'context (which work processes and at which stage) in which RAPS events occur', of 'the causes leading to them' and, last but not least, of 'the actual effects that RAPSs have on patients safety and health' and consequently on costs. This latter item is of fundamental importance for the eventual calculation of the end outcomes delivered, as they will result as differential analysis between the total effects of the numbers of RAPSs occurring before the full running of REMINE and the total effects after REMINE will have enables the prevention of many of them. If the system works well and produce such immediate outcomes for HCPs, job satisfaction should increase and further stimulate system utilisation , which in turn will further reinforce the delivery of outcome. So Utilisation is the corner stone for triggering a 'virtuous cycle'. While reality is not as clear cut and linear as in the conceptual framework depicted in figure 6, we can assume for the sake of argumentation that as system utilisation proceeds the immediate outcomes (in term of understanding) will then produce intermediate outcomes in the form of 'learning from errors', 'adoption of corrective actions', which together should lead to 'prevented RAPS'. This latter cannot be considered yet an end outcome because there is an evident time lag between when the first RAPSs start being prevented and when prevented RAPSs reach a critical mass producing tangible

benefits and also when enough longitudinal robust evidence has been gathered and analyse to provide reliable demonstration of benefits delivery. It is probably straightforward to say that advanced computerised RAPS systems are about quality of health care and patient safety. The institutional ultimate goal declared in the relevant section of the EU Framework Programme 7 is precisely 'Higher patient safety', that is to say an 'effectiveness' outcome (spending wisely). So also in the figure 'Higher Patient Safety' is included among the end outcomes of REMINE, but is not the only one. First of all, on the effectiveness side we can also include increased patients satisfaction, deriving not only from the avoidance of RAPSs but also for the more patient-centric approach to diagnose and treatment that REMINE functionalities and change management efforts should introduce in work practices. Moreover, REMINE is one one of those cases in which improving quality control and risk management for the sake of the higher goal to preserve human lives from preventable errors can be combined with more prosaic 'economy' (spending less) and 'efficiency' (spending well) outcomes.
These are all very tangible benefits that can be assigned a monetary value and produce in the end a very compelling 'value for money' evaluation. Additionally intangible benefits can also be delivered in terms of 'good governance' in terms of transparency and of better image of hospitals vis-à-vis public opinion. Finally at the end of the cycle, when robust evidence as to the delivery of end outcomes is produced and disseminated this will increase the legitimacy of this project in particular and of eHealth in general and possibly lead to more public national and international funding.
Needless to say this impact assessment model is very tentative and preliminary and also entirely theoretical, and will need in the course of WP 6 further refinement and 'real life validation through the living labs set up (see WP1).

Why a European approach

Among REMINE points of strength, the European vocation of the project is for sure one of the most influential. The need for a wider opening on the addressed topic, instead of limiting the research to a narrow screening within the local or national context, is mainly due to Consortium's strong belief in the enormous potentialities of a joint action of European Countries in Health care sector.
The main added value of the suggested international collaboration on REMINE project will rely on the concrete chance to stimulate and sustain multidisciplinary ICT research, being large scale cooperation an indispensable requirement to exploit the full potential of reporting incident system to underpin applications to human health.
The participation of several European partners will allow the project to improve Europe's overall health care system.
The results of RMINE project, in other terms, would constitute a further progress towards the achievement of the European strategy on life sciences and the Lisbon objectives*42*, helping to increase the competitiveness of European health care and medical technology sectors.

Consideration of other national and/or international research activities

The Consortium has carefully evaluated the current state of the art of research activities carried out at national and international level, within the field covered by REMINE project.
The project intends to introduce elements of novelty in the study of reporting incident system, with particular regard to interoperability and prediction of RAPS. To meet this objective, the complete awareness of the recent and on-going research activities constitutes an indispensable starting point for planning a solid scientific work.
Among the most important European projects centred on RAPS, a primary role is played by World Medical Association (WMA). It is a global federation of national medical associations, representing

[42] http://ec.europa.eu/growthandjobs/

the millions of physicians world-wide. Acting on behalf of physicians and patients, the WMA endeavours to achieve the highest possible standards of medical science, education, ethics and health care for all people and intends to provide an integrated decision support system to assess the risk of medical malpractice.
The REMINE project distinguishes as presenting a new paradigm to understand and manage risk, and developing a complete IT infrastructure for the management and processing of the vast amount of heterogeneous data acquired during diagnosis.
Another important European project is The International Pharmaceutical Federation (FIP), that proposes a new system to control the medical prescription of drug and the administering to patient in the ward
The system provides an automatic analysis of the drugs with quantitative and reporting of user.
The REMINE project will improve the FIP system, because FIP's regards only drug.

B3.2 Plan for use and dissemination of foreground

Dissemination strategy

REMINE project presents the facilities of the intervention priorities' identification through the dynamic query of many information sources that contribute to specify the context, the contribute factors and the outcomes of RAPS.
The last aim to communicate is represented by the pursuit of the EC' objective to spread the results of the research projects to the wider possible interested public.
In order to do improvement the style of life, the state of health of the European citizens and contemporarily decreasing the costs of maintenance of the system, is important disseminate the REMINE project and results.
The activities focusing on dissemination and exploitation, performed as part of the REMINE innovation-related activities, will identify factors and implications that could potentially influence the successful exploitation of the project's result.
REMINE' dissemination activities represents a articulated plan to diffuse the results (within medical practices and technological field of application) and to obtain public participation and awareness at European level.
The project partners delineated a dissemination plan whose main strengthening points can be summarized as follows:

- definition stakeholders;
- definition of communication needs for each stakeholder. This will be considered under three main headings:
- Mandatory communication, including regular Status Reports, statements of compliance with legal requirements (such as privacy legislation), financial reporting, etc. Selected aspects of this information will be pushed to recipients entitled to see it.
- Informational communication, meaning information people want to know or need to know. This information will be sent to some stakeholders, but in general it will be made available via a REMINE website and in other ways that require stakeholders to take the initiative, or pull the communication.
- Marketing communications. This type of information will be pushed out to selected stakeholders, both directly from the project coordinator and via the Public Relations (PR) departments of each REMINE partner.
- definition of the typologies of the events to be organized in the framework of the project including allocation of budget, geographic coverage, timing and expected attendance;

REMINE dissemination objectives are to:

- Diffuse interest in Health Care innovation technology, its incresing
- Activities and supporting materials that will promote REMINE to a wide-ranging pan-European audience.
- Pass on the information about EC' interest stimulating the research health market
- Inform the target audiences of the existence of the project, and its benefits, use and applicability in the different market segments
- Find potential customers and partnerships in REMINE' enforcement (hospital, ICT firm, pharmaceutical firm)
- Organize potential customers, users and collaborators for full product launch as REMINE commercial plans are finalized

To reach these goals the Consortium locates different public in dissemination plan. Each public category represents a specific target with which the Consortium would like interact and create relationship. These connections might develop directly REMINE or indirectly; directly as users, indirectly as buyer.

The Consortium singles out these Stakeholders:

- General public,
- Actors inside the research community;
- Local, National government public;
- Education public;
- Business

In detail:

- Generic public: EC would transmit knowledge, the Consortium would achieve this objective and at the same time dissemination plan would diffuse information concerning REMINE project, its goals, its improvement and innovations. The Consortium expects interest in initiative by this public, it expects questions about innovation, capability, application and place of installation of REMINE.
- Actors inside the research community: The Consortium would disseminate the reached goals, the results for creating workshops and it would debate about structural problems and news possibilities.
- Local, National government public: the Consortium would find participation for fatal adverse error, incident and the joined costs.
- Education public: The Consortium would training this public, it would yield responsibility about the problem of RAPS and the new possibility to reduce by REMINE, it would be consciousness people that approach for first time with risk management and about the real cost and social consequence.
- Business: interest in new services linked REMINE inoovation system. Request for implementation part of REMINE, purchase order of REMINE software, connection for future project.

Due to the technological and medical nature of the proposed project and the main orientation of the project results, the Medical and Business Community is the primary target' dissemination activities. Each partners will contribute in this phase providing the support to the whole Consortium.
Other ways to disseminate the project's results include the development of the web site of the project whose primary aim will be: the provision of general purpose information about the project's objectives and goals and for the announcement of the major results of the project.
Furthermore, the Consortium will publish a newsletter and brochure for the project (one with details on the project and partners and another one describing the major outputs).

At the end of the project a demonstration activity will e organized in an appropriately chosen European Health Conference, dissemination strategy and activities will commence at an early stage in the project.

Achieving these objectives will have the beneficial impact of:

- Increasing awareness and support for building the future REMINE customer base
- Early market penetration, user awareness and education and first stage contact with potential customers and partners
- Promotion of the real benefits of the service and understanding of the offering and benefits to reinforce the sales and marketing campaign
- World-wide awareness of the service and management of target audience contacts

Four distinct phases are envisaged:

Phase 1: Initial awareness:
The Consortium will decide on concrete actions for define communication integrated plan. The first step is the decision concerning what to communicate (idea, partial results, all results, step-by-step results, generic information, technical information). After the Consortium will have chosen like economical approach, technical approach, generic and informational one.
Close and replied to these arguments, the Consortium will chose logo, logotype, website, and all tools about its communication plan.
The objective of this first phase has the objective to create an initial awareness in potential users but also in the Research units.

Phase 2: Bring about approval:
Determined the communication tool, the Consortium will define the first package of activities for reach approval in the project. The goal is starting to find interested public in REMINE project. This will be a informational phase.
The communication has generic nature, REMINE will not tested yet.
The Consortium will refine the website, publish a Project brochure, issue the first releases and attend selected events.
The objective of this second phase is bring about approval in the project.

Phase 3: Pre-product launch:
Dissemination activities will focus on informing the selected target market of the REMINE benefits. First REMINE tests are available. The information in this phase become more precious, more technical; it is possible create a demo. Through workshops and round-table discussion the Consortium would reach a target more definite.
The objective is find interested industry and interested health care management.

Phase 4: Product launch:
Dissemination activities will intensify in this phase to reach much more possible main publics.
REMINE project is closed and the Consortium would diffuse results. The communications becomes technical and accurate.
The Consortium will decide on increasing with press release, publications, media briefing, direct e-mailing.
The objective is push up in information and communication to conclude the dissemination's phase, and find real final users of pilot, or find new promotions of the project.

The table below shows the steps of REMINE dissemination strategy

Step	Goal	Tool
Phase 1: Initial awareness	Initial awareness Put basis for communication plan Define roles of partners	Logo Logotype Integrated imagine Monitoring literature Create website
Phase 2: Bring about approval	Diffuse generic information Create expectation concerning the improvement of incident reporting system, of risk management, of ERP. Perceive by intuition new services joined with REMINE	Website Brochure Leaflet Abstracts Newsletter
Phase 3: Pre-product launch:	Disseminate first tests Create expectation about REMINE Find interested industry in improvement news services Find interested health care management in utilization in their hospitals	Demo Workshop Round-table discussion Papers Publications Events
Phase 4: Product launch	Find real final users of pilot, Find new promotions of the project Push up in information, communication	Papers Publications Events Media events Press Releases Direct e-mailing

Obviously, the Consortium would only foreseen the state of step in achievement of REMINE closing.
It is not unworkable that the Consortium might take part in events described in the table below:

Planned/Actual Dates	Type	Title	Type of audience	Countries addressed
January 30 – Feb 1, 2008	Exhibition, Congress, Conference	Health & Human Capital Management Congress	Business, and Health Management	Washington, DC
3-5 March 2008		World Health Care Congress Europe 2008	Industry and government leaders	Barcelona, Spain
on March 2008		Trade Event of Safety, Health and Ergonomics at Work	Business	in Amsterdam*http://www.eventseye.com/fairs/trade-shows-amsterdam_1.html* (Netherlands - Europe)
April 21-23, 2008		World Health Care Congress	Chief and senior executives' health care sector	Washington, DC

29 August until 4 September 2008		World Congress of Pharmacy and Pharmaceutical Sciences 2008	Health managementg	Basel, Switzerland

Standardization activities and training

Standardization of REMINE project results, as well as conformation to current standards is of decisive importance if they are indeed to be widely deployed. Hence, to ensure that the benefits of the new technologies developed in REMINE are utilized, there is a need to actively co-operate with the respective standardization bodies. This co-operation comprises the tracking of relevant innovations, the contribution to the standard process in relevant fields, as well as the provision of feedback from a deployment and user-oriented point of view.

Workshops will mainly target end-users and businesses, and the consortium may organize for example a number of workshops during the course of the REMINE project. Finally, internet dissemination (such as the development of a web-site and the issuing of electronic newsletters) will allow a larger community of interested potential users to access REMINE for longer times and to keep them informed about the project's progression.

In addition, the successful introduction of REMINE's results into a third-party organization will be supported and accelerated, through the organization of specific training workshops and sessions by the consortium, where potential end-users will be properly trained on all aspects relating to REMINE and its introduction to their current systems.

The consortium is also self-committed to promote REMINE results inside national and international standardization committees in order to enable the development of suitable standards and/or recommendations in all the technical areas that are relevant to the project.

Finally there is great importance in producing multimedia advertising and dissemination material (such as CD-ROMs and DVDs) with several levels of technical depth that are oriented to different types of intended audience and involved industrial partners will implement such a scheme.

Exploitation strategy

The Exploitation of REMINE will be based on an Exploitation Plan that will be realized early in the project and will be carried on throughout it as a living document, being updated taking into account the evolution of the work and the different results as they will become available.

The Exploitation will be conceived bearing in mind the need to achieve four major goals:

- A clear, detailed Market identification to give project partners definite data and reveal target needs;
- Clearly identify project output and specific form f exploitation;
- Define and regulate specific exploitation needs at partner level;
- Preparation of a business plan for the final exploitation of the project results.

The consortium as a whole will exploit the project results promoting the REMINE approach on the European market through a series of contacts with local partners. The plan, in fact, foresees the covering of each Member State potential market using local competencies and preferential relations with key players. Individually, instead, each consortium partner on the basis of its skills, competence and relationship will look for exploiting the project results within its peculiar target-market.

Let's now consider the results that will be produced by REMINE and how the consortium will implement them.

REMINE project satisfy the Work Programme's requests, FP7 – ICT- 2007 -1 to Call: Advanced ICT for Risk Assessment and Patient Safety. The following table describes the Remine contribution to achievement of Work Progamme. At the bottom of the table there are the activities used to reach Remine goals and the results they will produce. The achievement of these goals, conversely, contribute to the fulfilling of the goals of the Call.
The measurements of objective regards will happen with schedule deliverables and milestone.

GOALS	EXPECTED RESULTS	EVALUATION OF RESULTS
OVERALL OBJECTIVE: In the Work Programme, Challange FP7 – ICT – 2007 - 1 lists several objectives to reach with research project, Remine contributes to satisfy specifically, some of them: • Improved productivity of healthcare systems; • Savings in lives and resources by focusing non prevention and prediction rather than on costly medical interventions after symptoms and diseases have developed; • Higher patient safety by optimising medical interventions and preventing errors. Mori in particular, Remine answers to Call: Advanced ICT for Risk Assessment and Patient Safety and these are objectivites: • Common patterns in safety-relevant events; • Tools of prediction, detection and monitoring of RAPS and other relevant events impacting on patient safety.	• World-leading levels of patient safety with fewer medical errors and optimised medical interventions resulting in savings of lives and resources. • Early alerts and improved management of large scale health-related crises through effective and automated risk prediction, assessment and management. • Accelerated and wider adoption of future electronic health record systems. • International cooperation between EU constituency and Latin America counterpart. Uptake of EU standards in the electronic Health Records area in Latin America.	
SPECIFIC OBJECTIVES: Remine project will achieve the following goals.: • Allow to analyse RAPS based on available data coming form both inside and outside the Hospital where REMINE is working. • Perform risk management analysis supported by "what if" analysis.	• Design and develop tools and methodologies for RAPS data capture and knowledge extraction • Design and develop tools for supporting the risk management process using an ontology engine to ease the identification of correlation between data and a DSS engine to allow users (MDs) to perform simulations and "What if" scenario analysis.	The assessment of the results achieved will be based on the match of the deliverables produced and the milestones achieved against the standards set in the workplan and in the Quality assurance plan and validated by the Scientif and Technical Managers.

• Allow the interaction of Risk Managent support tools and data capture tools with all the relevant sectors of the Hspital (lab, drug…) so as to achieve an holistic approach to risk management.	• Produce an Extended Hospital RAPS interoperability layer to bridge REMINE with Hospitals' ERP. The components of this layer will allow REMINE to interact with all the relevant component of the Hospital structure: Laboratory, Drug managent and Nosocomial management.	
ACTIVITIES: Remine goals will be achieved thanks to three main research streams: • RAPS data capture and knowledge extraction • Risk management process support • Extended hospital RAPS interoperability layer	**MEANS:** • Consortium partners have leading skills in the necessary domains. • The research streams have been conceived to cover the different domains necessary to achieve project goals. • The work plan has been accurately designed and adequate effort has been allocated.	• The management structure and procedure of the project will allow the management to monitor the progress of the work and its adequacy to the stated goals (technological and scientific). • The Quality assurance plan that will be developed early in the project will allow to respect the desired standards.

The output produced throughout the project as explained in the previous paragraphs will be exploited, as previously mentioned, thanks to an exploitation strategy that will be designed an developed later on in the project. The guiding principles of that strategy are outlined as follows.

REMINE exploitation will be based on a "double-head package":

- Research and Development
- REMINE Prototype

In the first step (M12) the Consortium will decide to use knowledge developed, one is the competencies (consulting, training, methodologies) in the field of RAPS applied to the health/medical sector; other is the acquisition of specific technological skills in the ambit of risk management, data mining and data analysis and reporting system for medical sector.. In this phase of exploitation another decision regards in which way Consortium will decide to sell REMINE as whole product, or as partial modules. Consequently, partners will chose which legal patent selling REMINE between Licencing and ASP, or Consortium will chose to use both. At the end of the project in both cases (licencing and ASP), the result will not be a selling product, it is a prototype. Thus, the Consortium would invest to develop and to complete the final selling version of product.

In a second phase (M24) the exploitation responsible will analyse market and after he characterizes the potential markets (also niche market), the potential demand, the IT system analysis used, the competitors' analysis, the responsible will settle target and positioning of the products that will be defined (probably: complete REMINE solution, Single module exploitation, Training and Consultancy). REMINE will integrate the existing IT system and completed REMINE platform, they will work together allowed to lead a rational reasoning to a logical solution, a solution that only with human competence and knowledge could interpret. This project will indicate errors, RAPS, forgetfulness, it will eliminate dosage' error.
The research effort of the Consortium will thus focus on new reliable platform that support health professional in taking promptly the best possible decision for prediction, prevention better treatment.

At the end of the third REMINE platform release (M33) after Consortium will collect market data , Consortium will make provision for pricing decision and strategy of distribution of the product.

The exploitation strategy described above, will be deployed in three steps, as example below, during the first period Consortium is using round-table discussion for planning the marketing strategy. The second period keeps busy the Consortium to settle the connections for selling knowledge and demo (using publications, congress, brochure). As soon as REMINE will be ready, the operative exploitation will use tools like direct mailing, events, advertising, promotion following the marketing plan.

The exploitation plan starts from begin of project to five years after conclusion.

- In a first phase, the Consortium planning the activities.
- In a second phase on a national basis, each industrial partner will exploit the REMINE project starting from the developed demos in its own industrial association, enlarging then the market base to reach the whole national market. This phase is based on diffusion of knowledge.
- In the third phase (involving in knowledge and product), partners will offer services on a European basis. It is foreseen that this phase can start only and will depend on: commercial results obtained in the national market; support from the other industrial partners in the Consortium through the creation of a jointventure for this specific purpose. (IPR)

The exploitation plan will presume financial plan and results measurement (cash flow), the goal is selling, the conclusion step is going from a research prototype to a concrete product. The impact of the potential solution of REMINE could be such that business opportunities will be a lot. It is likely that additional products and services will also be possible, serving very specific information needs in other potential users.

The Consortium could locate two main markets.
The first health care system: the physician will use REMINE to reduce RAPS, to improve knowledge.
The second health industry: the pharmaceutical firm, the technological firm; REMINE will open new potential services.
Below, it's reported a standard services marketing plan, which exploitation strategy will foresee, of activities for REMINE selling and with the reference of corresponding project part. The objectives of marketing plan are knowledge diffusion, product distribution, health care improvement. The strategic marketing phase analyses market, competitor products, potential and existing product. In this phase Consortium will collect necessary data for selling REMINE, to be able to identify the targeted market.
The operative marketing phase concerns integrated communication, a plan described in dissemination paragraph.

At the end Consortium will use marketing mix for selling strategy and it will be measure effective goals.

	Activities	Reference
Strategic Marketing	Market Competitor products Potential and existing product	Exploitation strategy Exploitation plan Life cycle of product Quantity and quality data of market
Operative Marketing	Integrated communication	Dissemination plan integrated with sales strategy
Sales strategy	Marketing mix	Positioning Pricing Distribution
Measuring effectiveness of marketing plan to reach objectives	Financial reporting	Cash flow Sales analysis

Management of knowledge, of intellectual property, and of other innovation-related activities arising from the project

The REMINE Consortium will gave special consideration to Intellectual Property Rights (IPR) in order to identify all possible means protecting its research outcomes from potential plagiarists.
The management of IPR is very complex.
IPR important aspect is the management of database right used like Metadatabase sources.
It is important that Art. 29 WG recalls that the main data protection principles, established at the EU level in a well-consolidated regulatory framework, apply under all circumstances, therefore, also, within the framework of digital rights management and enforcement of copyright.
Indeed, Directive 95/46/EC (Data Protection Framework Directive) as well as Directive 2002/58/EC (for the e-communications sector) and their basic principles are of key importance to e-communications operators such as Telefónica, which appear to be, in many cases, the intermediary between the end users of copyrighted material available on the Internet and the right holders. As an intermediary, Consortium will require a clear legal framework, therefore we welcome Art. 29 WG efforts to provide some clarification concerning the application of the EU[43] data protection principles in the important areas of digital rights management and enforcement of copyright.
REMINE project is based on data provided by partners, thus, at the conclusive step of realization, Consortium would have to manage also IPR of these data.
It's a actual hypothesis, that the partners owner of database will have higher commission in distributing royalties of REMINE project IPR.
The success of intellectual property management relies on the development of solid framework of laws both at global and local level. The challenge for the successful development of REMINE will be maintaining constantly under control the level of usage of intellectual property which is, with no doubt, a key variable of success. As for the exploitation strategy is then necessary to start even from the first steps of analyses to protect all the knowledge created. Therefore the project will need a first phase of literature analysis, in which to define a framework for giving substance to the description of the status quo; then, a second phase will define a strategy to put intellectual property rights at the centre of the project, to protect all the process innovations created during its architectural model definition.

[43] Directive 2001/29/EC of the European Parliament and of the Council on the harmonisation of certain aspects of copyright and related rights in the Information Society (June 2001), implemented in the UK as the Copyright and Related Rights Regulations 2003.

The strategy on which REMINE IPR management will rely will be based on the ones that are outlined by the Commission for the VII Framework Programme and in the Consortium Agreement, as appropriate. Considering that each partner can bring into the project two kinds of contributions, which are background (pre-existing to the project) and foreground (developed in the project), some basic rules of exploitation have been already set up:

- The contributing member owns the Intellectual Property Right (IPR), regarding any original contribution or background knowledge brought into the consortium.
- The Intellectual Property Right (IPR) regarding any new knowledge (foreground) generated in the framework of the project as a result of a cooperative activity, is jointly owned by the members contributing to this knowledge. For joint ownership a default regime will facilitate the exploitation of jointly owned results in the absence of a clear agreement between parties.
- The Intellectual Property Right (IPR) regarding any new knowledge (foreground) generated in the framework of the project by each partner, is owned by the member that developed this knowledge.
- The rules related to Access for Use are as follows:
    - Access rights to background - For carrying out the project
        - Yes, if a participant needs them for carrying out it own work under the project
        - Royalty-free unless otherwise agreed before acceding to the grant agreement
    - Access rights to background - For use (exploitation + further research)
        - Yes, if a participant needs them for carrying out it own work under the project
        - Either fair and reasonable condition or royalty free-to be agreed
    - Access rights to foreground resulting from the project - For carrying out the project
        - Yes, if a participant needs them for carrying out it own work under the project
        - Royalty-free
    - Access rights to foreground resulting from the project - For use (exploitation + further research)
        - Yes, if a participant needs them for carrying out it own work under the project
        - Either fair and reasonable condition or royalty free-to be agreed

Further, IPR and revenues sharing rules can be defined (later in the project) in an Exploitation Agreement that will amend the first version of the Consortium Agreement and will detail the conditions related to ownership of the project results.
Therefore, a strategy for managing IPR will be properly designed, in close collaboration with experience consultants, in order to diminish future conflicts and ensure that the distribution of rights on the final product is fair for each partner.

The management of the Intellectual Property Rights will be considered within the exploitation WP and will consequently be under the responsibility of the SEM. The mechanisms that the Consortium will implement for managing knowledge and intellectual property comply with the rules defined by the EC for projects of the 7th Framework Programme.
They will deal with:

- Management of clear schedules of both pre-existing know-how brought in the REMINE by a participant and of knowledge generated through the Project;
- Establishment of contractual agreements between consortium members whenever the Consortium decides to use pre-existing know-how;
- Adequate dissemination of knowledge generated in the Project;

- Adequate protection of methods and technologies eventually resulting from the Project and having business potential.

At the time of drawing up the REMINE project, IPR intentions are the following:

- Any partner having conceived innovative methods and techniques will have the opportunity to protect the new knowledge through a European patent.
- Methodologies and research studies will be disseminated free of charge.
- Any software implementation that may occur within the project will remain the sole property of the partner having developed it.
- Software owners retain the right to develop commercial variants of their own production.

Theme	Responsibility	IPR allocation
Multimedia Data Acquisition	HP	100%
Data and Communication and security model	GMD	100%
Data Process Model	InfoWorl	100%
Metadatabase	InfoWord	100%
Data Mining	ICSS-NTUA	100%
Knowledge extraction	ICSS-NTUA	100%
Taxonomy builder	RAMIT	100%
Taxonomy manager	RAMIT	100%
Ontology engine	RAMIT	100%
RAPS management process support system	TUW	100%
RAPS process Model	TUW	100%
Web services Wrapper Framework	InfoWord	100%
H-ERP component interface Coordinator	GMD	100%

Besides IPR on single item composing the platform, the partners reached an agreement also on the exploitation of results coming from the commercialization of REMINE software. The shares were defined basing on the investment in research activities done in the project.

Partners	IPR allocation on REMINE system
GMD	16%
QSC	8%
HP	10%
SO	5%
TUW	4%
RAMIT	4%
Q&R	5%
LINK	9%
ICCS	9%
MIP	8%
Info World	17%
AMINIO	8%

More in general a qualitative exploitation is expected: REMINE project will enhance the consortium partners visibility in the context of RAPS risk management, will contribute to their know-how growth thus will have a direct impact on their businesses.
Besides, the dissemination of knowledge, by any appropriate means other than publication resulting from the formalities of protecting it will be granted if this does not adversely affect its protection or use.
The R&D costs for products/components specifically developed inside REMINE will not be charged by one partner to the other partners.

B4 Ethical issues

Ethical and legal issues are a delicate matter for an international project, even if "common sense" is shared throughout the globalized world, the interpretation of ethical aspects depends on multicultural, religious and political factors.

There are some public concerns related with the use of the technology in the data sharing in the medical domain like: the difficulty of respecting privacy and confidentiality when third parties have a strong interest in getting access to electronically recorded and stored personal health data, or the difficulty in ensuring the security of shared personal health data. There are also value conflicts on using it like, for example, Effectiveness versus confidentiality (the need to know and share patient personal health data, in order to provide good quality of care, creates a situation of shared secrecy, which may compromise confidentiality); or Privacy versus collective good (privacy may be traded for certain collective goods (research, administration, planning, prevention...) that benefit the community or population at large).

The legislative aspects of the medical practice in every country, and sometimes in each regional government depend directly of this interpretation. REMINE will develop a unique environment of knowledge exchange and confident relationships. The project will have to consider a unique ethical argument line from several national legislations (consortium members' nations). For many years, physicians have used communications technology such as telephone and telefax to benefit their patients. New electronic information and communication techniques are constantly being developed which facilitate the exchange of information between physicians. The World Medical Association recognizes that there are many ethical and legal issues arising from these new practices.
Because health and health care are critically important to people, the organizations and individuals that provide health information have special, strong obligations to be trustworthy, provide high quality content, protect users' privacy, and adhere to standards of best practices for online commerce and online professional services in health care. Regardless of the system under which the physician is operating, the principles of medical ethics, which are globally binding upon the medical profession, must never be compromised.

eHealth Code of Ethics

The "International eHealth Code of Ethics" endorsed by the Internet Healthcare Coalition in 2000 established the nature of e-health information, products and services. The project deals with the employment of medical product and services such as drugs, medical devices subject to regulatory approval by national agencies, and other products not directly subject to regulatory oversight. Services include medical care or advice, management of medical records, patients and health care facilities regarding treatment decisions.

Accountability and Responsibilities

The physician must be free and fully independent to decide whether or not to use or recommend REMINE. Not all doctors employ the same techniques or refer to the same socio-cultural

environment, especially in the field of biomedics and in the prescription of medicines. REMINE is designed to evaluate procedures. The physician assumes final responsibility for the case in question. This includes diagnosis, advice, treatment plans and direct medical interventions. The physician searching for an advice remains responsible for treatment and other decisions and recommendations given to the patient.

Patient Consent and Confidentiality

According to art. 8 of the Charter of the Fundamental Rights of the European Union, everyone has the right to the protection of personal data. Because of the risks of information leakage inherent to some types of electronic communication, the physician has an active obligation to ensure that all established standards of security measures have been followed to protect the patient's confidentiality. Since Directive 95/46/EC scientific developement and the growth of integrated information have posed new challenges to data protection both on technical and ethical level. Processing personal data, including medical data, must be "fair and lawful": meaning that personal data must be collected for specified, explicit and legitimate purposes and not further employed in a way incompatible with those purposes. The Directive also requires that data must be adequate, relevant and not excessive. They must be accurate, kept up to date and in a form which permits identification of subjects as long as necessary to accomplish the purposes data were collected for and further processed. Data processing must also comply with at least one of the criteria for legitimate data processing: for the processing of medical data there are special criteria assuring a legitimate approach. More freedom should be granted to health care professionals who are already subjected to a strict professional code in order to operate to save lives or reducing RAPS with a high - quality risk management and incident reporting system REMINE will search the best solutions for encrypting and/or encoding the information that could relate patient's identity to all the information registered in repositories, as image records, treatment effectiveness, etc. Patient data and other information that could identify him may be transmitted to a physician or other health professional, only on the request, or with the informed consent, of the patient, and to the extent approved by him. All the medical information needed for educational purposes, training and differential diagnosis, such as medical images, can be used and transmitted without consent only if it does not contain any kind of patients affiliation data.

In any case, REMINE will ensure that the relevant requirements on patient consent, confidentiality and privacy, as set by Directive 95/46 will be complied with.

Quality of care and safety

Quality assessment measures should be used regularly to ensure the best possible diagnostic and treatment. Quality indexes will be established within the project as a unique standard for all network participants. Routine controls and procedures should be used to monitor the accuracy and quality of data collected and transmitted.

Quality of data and information

The physician can only give medical opinions make medical decisions or give recommendations if the quality and quantity of data or other information received is sufficient and relevant to the case in question. If (s)he considers the quality and/or the quantity of the information is insufficient to express an opinion, the physician has the obligation to declare it. Furthermore, "no answer" or "no opinion" could not be considered as a default option like "normal", "no treatment", etc. The eHealth Code of Ethics declares some relevant aspects regarding the conduit professionals must follow to meet patients' needs: The necessity to put patients' interests first and protect patients' confidentiality The importance to disclose clearly any sponsorships, financial incentives, or other information that would affect the patient's perception of professional's role or the services offered.

It states also to declare what fees will be charged for the online consultation and how payment for services is to be made. Informing the patient about the limitations of online health care.

Network security

European Union has launched a comprehensive strategy based on network security (COM 298/6/2001), cyber crime prevention (COM 890/1/2001) and protection from attacks against information systems (COM 173 final 4/2002), assuring the end-user of a service with an high grade of protection. In 2002 a number of initiatives were taken to improve internet security that will develop in the creation of a secure European smart card infrastructure and in the establishment of a Cyber Security Task Force (CSTF), that should become operational by mid 2003 and was creatred to be a centre of competence on security. A "culture of security" plan is to be achieved By the end of 2005 to promote good practices both in the private and public sector. In REMINE will be used password, key word, antivirus and antintrusion. Possible solutions to respond to data's defence is the extreme cryptography that permits to make inaccessible and invisible files and folder in hard disk, local network or floppy disk.

Quality

The project will be realised obeying the quality's rules, the safety regulations on work place and the national (CEI, UNI), community (CENELEC, CEN) and international (IEC, ISO) certifications. In conformity with the quality system manage "Vision 2000" - ISO 9000" will be recognised the organisations EA - European co-operation for Accreditation and the IAF – International Laboratory Accreditation Co-operation. The conformation's evaluation will be realised by EOCT (European Organisation for Conformity Assessment). The proposed research does not involve:

- Research activity aimed at human cloning for reproductive purposes,
- Research activity intended to modify the genetic heritage of human beings which could make such changes heritable
- Research activity intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer;
- Research involving the use of human embryos or embryonic stem cells with the exception of banked or isolated human embryonic stem cells in culture.

Further information on ethics requirements and rules are given at the EU "science and ethics" website*44*.

[44] http://ec.europa.eu/research/science-society/page_en.cfm?id=3205

ETHICAL ISSUES TABLE

	YES	PAGE
Informed Consent		
Does the project involve children?		
Does the project involve patients or persons not able to give consent?		
Does the project involve adult healthy volunteers?		
Does the project involve Human Genetic Material?		
Does the project involve Human biological samples?		
Does the project involve Human data collection?		
Research on Human embryo/foetus		
Does the project involve Human Embryos?		
Does the project involve Human Foetal Tissue / Cells?		
Does the project involve Human Embryonic Stem Cells?		
Privacy		
Does the project involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)	X	78,82,84 ,87 (*)
Does the project involve tracking the location or observation of people?		
Research on Animals		
Does the project involve research on animals?		
Are those animals transgenic small laboratory animals?		
Are those animals transgenic farm animals?		
Are those animals cloned farm animals?		
Are those animals non-human primates?		
Research Involving Developing Countries		
Use of local resources (genetic, animal, plant etc)		
Benefit to local community (capacity building i.e. access to healthcare, education etc)		
Dual Use		
Research having direct military application		
Research having the potential for terrorist abuse		
ICT Implants		
Does the project involve clinical trials of ICT implants?		
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROJECT		

(*) Even if the running test beds of the project have in their information systems genetic information and personal data, as specified in test beds descriptions (see pages above), REMINE platform will exchange anonymised data with each hospital information system. In any case REMINE will ensure that the relevant requirements on patient consent, confidentiality and privacy, as set by Directive 95/46 will be complied with. Furthermore as described in session 2 of the DOW, Ethical manager and each local ethical committee will provide clearance on this issues during the project life time.