Rome, 10 April 2013

Project draft on a pilot European Reference Network on Rare Tumors

Pilot European Reference Networks in the Call 2013

4.2.2.7. Pilot networks of cooperation under Directive 2011/24/EU

- This action seeks to pave the way for European reference networks, as provided for by Directive 2011/24/EU
- European reference networks will link health care providers and centres of expertise in the Member States
- The aim is to improve access to diagnosis and provide high-quality health care to patients who have conditions that require a particular concentration of resources or expertise, especially where the expertise is rare and case volume low.

Pilot European Reference Network on pediatric oncology

- Work should cover concrete goals of and proposals for the concentration of low-frequency or high-complexity diagnostic and therapeutic procedures in services that have an adequate caseload and audited results. It also covers an evaluation of outcomes.
- The objective of a pilot network of cooperation on rare cancers is to develop and support the implementation of the Europe-wide standards of care

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Project definition: Policy context and relevance

Project draft: pilot European Reference Network on Rare Tumors

A.F. 4.2. Contribution to the Second health programme and the annual work plan

A.F. 4.4. Strategic relevance, EU added value and innovative nature

A.F. 4.3. Pertinence of the geographical coverage in relation to the scope

A.F. 4.1. Adequacy of the project with the social, cultural and policy context

Project draft: pilot European Reference Network on Rare Tumors

Policy context elements to use for the application form section 4:

- Cross border care directive (art.12)
- EU action in the area of Rare Diseases
- European Partnership for Action Against Cancer (EPAAC)

Policy context element ♯ 1: The cross-border care directive:

Art. 12: European reference networks shall have at least three of the following objectives:

- (a) to help realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies
- (b) to contribute to the pooling of knowledge regarding sickness prevention;
- (c) to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;
- (d) to maximise the cost-effective use of resources by concentrating them where appropriate;

Policy context element ♯ 1: The cross-border care directive:

- (e) to reinforce research, epidemiological surveillance like registries and provide training for health professionals;
- (f) to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks;
- (g) to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the network;
- (h) to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality.

Policy context element ♯ 1: The cross-border care directive:

The Commission shall:

- (a) adopt a list of specific criteria and conditions that the European reference networks must fulfil.

These criteria and conditions shall ensure, inter alia, that European reference networks:

- (i) have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes, as far as applicable;
- (ii) follow a multi-disciplinary approach;
- (iii) offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control;
- (iv) make a contribution to research;
- (v) organise teaching and training activities; and
- (vi) collaborate closely with other centres of expertise and networks at national and international level;
- (b) develop and publish criteria for establishing and evaluating European reference networks;
- (c) facilitate the exchange of information and expertise in relation to the establishment of European reference networks and their evaluation.

Policy context element ♯ 2: EU policies on Rare Diseases

- The EU Council recommendation on rare Diseases
- The EUCERD recommendation on criteria for European Reference Networks

EU Council Recommendation on Rare Diseases

Key areas of action:

- National plans and strategies
- Definition, classification, inventorying of RD
- Research on RD
- Centres of Expertise and ERNs
- Gathering the expertise and knowledge
- Empowering patients

EUCERD recommendation on criteria for ERNs in the area of RD

- Registries
- Quality assurance mechanisms for laboratory testing
- Mechanism for information flow for good practice guidelines
- Training/education tools
- Mechanisms for evaluation/indicators of performance
- Communications infrastructure
- Cross-border referral mechanisms
- Telemedicine core

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Policy context element ♯ 3: the European Partnership for Action Against Cancer (EPAAC)

The European Partnership for Action Against Cancer (EPAAC)

The general objective of this Joint Action is to contribute to the reduction of cancer burden in the EU by actions in the areas of:

- health promotion and prevention,
- screening and early diagnosis,
- cancer related health care,
- coordination of cancer research and
- cancer information and data.

The overall objective is to support Member States in the development of their National Cancer Plans (NCPs).

Specific objective(s) of the joint action

#	Title	Description
1	To prepare guidelines for a high level standard NCP which includes the most significant areas	A National Cancer Plan is a tool for integrated and coordinated cancer control measures in MS. The specific goal in this field is to prepare guidelines for a high level standard NCP which includes the most significant areas.
2	To raise awareness about cancer prevention among targeted groups in Europe	Health prevention will focus on a re-launch of the successful European Week Against Cancer (EWAC) which took place across Europe between 1989 and 2005.
3	To improve implementation of the Council Recommendation on Cancer Screening of 2 December 2003	Screening and early detection will focus on alleviating the key barriers in order to make screening recommended by the Council of the EU accessible to all European citizens who may benefit.
4	To identify, assess and exchange best practices in cancer care across EU, including patient's perspective	New organizational perspectives in cancer care, specifically networks of cancer care at regional level and for low frequency tumors, issues of implementation of evidence-based guidelines in cancer for managers and clinicians and team working.
5	To develop a concerted approach for coordination of one third of research from all funding sources by 2013 in selected areas	To develop a comprehensive and collaborative approach to work towards coordination of one third of research from all funding sources by 2013 within selected areas of cancer research creating synergies with existing initiatives, avoiding duplication.
6	To make available and disseminate cancer burden indicators (incidence, mortality, survival and prevalence)across Europe	A European map of cancer information will be built, it will identify areas of data availability and data needs. Updated incidence and mortality data will be made available in the framework of current activities.

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Project definition: Technical content

Project draft: European pilot Reference Network on Rare Tumors

A.F. 3.1. Problem analysis including evidence base

A.F. 3.2. General objective of the project (link with art.12 of the Cross-Border care directive)

From general objective to the definition of activities and WP

A.F. 3.3. Specific objectives (SO)

Detailing the SO: the choice of methods leads to the definition of activities

From general objective to the definition of activities and WP

A.F. 3.6. Methods and means (link with 6.1. (WP definition) and description of WPs (6.2. Horizontal WPs and 6.3. Core WPs)

- Each of the SO will be linked to one WP and will include the appropriate methods/ activities to achieve this SO

The other key elements/ sections:

A.F. 3.4. Indicators

A.F. 3.5. Target groups

A.F. 3.7. Project outcomes

A.F. 3.8. Deliverables

Project draft: pilot European Reference Network on Rare Tumors

Technical content reference documents to use for the application form section 3:

- RarecareNet
- European Partnership for Action Against Cancer (EPAAC)
- Bench-can and OECI accreditation work
- Affordable cancer in the 21st century

Specific objective(s) of the project

#	Title	Description
1	To collect and disseminate information on the health care pathways for rare cancers and on updated epidemiological indicators.	Data on hospital of treatment and diagnosis will be collected from cancer registries to describe the health care pathway for rare cancers in EU. Updated epidemiology indicators, incidence and survival trends will be provided for rare cancers in EU.
2	To identify the qualification criteria for centers of expertise for rare cancers.	Following the criteria for European Reference Network for rare diseases, a list of qualification criteria will be developed in collaboration with major scientific societies and the European Cancer Patient Coalition (ECPC).
3	To identify and disseminate information on centers of expertise for rare cancers.	ECPC liaising with the Rare Cancers Europe(RCE)will build on the qualification criteria for centers of expertise previously identified and will ensure the engagement of patients to identify centers of expertise for rare cancers.
4	To produce and disseminate information on diagnosis and management of rare cancers.	Work will be undertaken by the project "State of the Art - Oncology in Europe" (which involves experts of oncologic societies)in collaboration with the RCE and the European Partnerships for Action Against Cancer (EPAAC).
5	To develop a clinical database on very rare cancers to provide new knowledge on these diseases and on their clinical management.	An online, prospective clinical database will be developed to pool clinical cases of very rare cancers from different EU countries. On the basis of the information collected, the best way to take care of these patients will be defined.
6	To develop and disseminate information for patients including a list of patients' associations dedicated to rare cancers.	Together with the partners, the ECPC (liaising with the RCE) will produce information material on rare cancers for the patient community and for the general public. Patients' associations dedicated to rare cancers will be identified too.

Work package #	7
Work package title	Healthcare
Work package description	Developed, reviewed and harmonized Clinical Guidelines (CG)regarding models of best practice in cancer-related care for managers and clinicians
Work package Leader	ICO

List of the acronyms of associated partners involved

IVZ/NIPH, HOPE, EHMA, INCa, FOD VVLD (FPS PH), SIOPE, PMH, IOL, RT, NCOD, EONS, ESPEN, NTNU.

Specific objectives of this work package

Specific Objective #	Specific objective title
4	To identify, assess and exchange best practices in cancer care across EU, including patient's perspective

List of deliverable(s) linked to this work package

Deliverable #	Outcomes / Deliverable title
6	Report 'Mapping the landscape of cancer care in Europe'

Milestones reached by this work package

#	Milestone title	Month of achievement
1	Conference to increase public and policy awareness of the need to develop standards for care of the children with cancer	18
2	Clinical guideline (CG) for nutritional care for cancer patients	24
3	Report 'Mapping the landscape of cancer care in Europe'	34
4	Report on the training workshops for communication skills and psychosocial care	36
5	Guide for implementation of CG ad self-assessment tool for organizations	36

Specific objective(s) of the project

#	Title	Description
1	To collect, compare and align by consensus formation the standards, recommendations and accreditation criteria of comprehensive cancer care in selected European countries.	Identify/assess recommendations, standards & accreditation criteria used in the EU for comprehensive cancer care. Discuss & agree key criteria with stakeholders. A database will be compiled & a consensus framework to compare best practices prepared.
2	To review and refine a benchmarking tool(s) that can be applied to comprehensive cancer care through interdisciplinary patient treatment	Engage key stakeholders (clinicians, management, patient organisations, funding agencies) to review & refine benchmarking tool(s). Scan what affects BM & quality improvement (organisational dynamics & external environment). Agree BM pilot process.
3	To pilot the benchmark tool with particular attention to operations management and best clinical practice.	Pilot the refined BM tool(s) with at least 6 OECI designated comprehensive cancer centers and 5 designated organ/tumour services. Conduct a budget impact analysis within 2-3 separate pilot sites. Identify/assess best practice from the pilot sites.
4	To maximise knowledge exchange and sharing of best practice between providers of comprehensive cancer care in member states and regions	Facilitate knowledge exchange by: preparing a BM manual to guide future BM exercises (WP6); building an publicly accessible best practice database (WP2); presenting pilot results & BM tool at events.
5	To ensure compatibility of the benchmarking tools with existing cancer care resources and services	A comparative analysis of the benchmark tool with relevant EU/international projects will be undertaken & specifically within existing services e.g. JACIE, OECI accreditation & designation scheme & the EurocanPlatform excellence designation system.
6	To ensure the sustainability and longer-term benefits of the project	A roadmap based on project learning will be prepared & Cancer Plans at national level invited to discuss/review use of the roadmap at MS level. A BM service that helps institutions in EU MS improve infrastructure & functioning will be a key element.

- Improve the information patients have to make decisions about and manage their care
  - Make available transparent quality metrics to help patients select their clinicians
  - Reimburse clinicians for communications with patients, including provision of accurate information on a patient's prognosis; the costs, potential benefits, and side effects of various treatment options; and palliative care and hospice care considerations
- Encourage clinicians to deliver affordable, high-quality cancer care
  - Ensure clinicians are well-trained to communicate with patients, interpret study results, and understand the financial repercussions of different treatment options
  - Promote adherence to the American Society of Clinical Oncology Top 5 list and encourage clinicians to stop using interventions with questionable value
  - Incorporate cost information in clinical practice guidelines and treatment pathways
- Promote and facilitate best practices in cancer care
  - Support team-based models of care that provide 24-hour support to cancer patients
  - Ensure early integration of palliative care in cancer care delivery and better use of hospice care
  - Improve the functionality and interoperability of electronic medical records
  - Provide feedback to patients, providers, and payers through population-based performance measurement of quality, outcomes, and costs
- Enhance research that informs clinical practice
  - Develop learning health care systems to collect point-of-care data that can inform personalized medicine, comparative effectiveness, health care redesign, and quality cancer care
  - Conduct pragmatic trials with real-world comparators and populations, as well as clinically relevant outcomes in pertinent patient subpopulations
- Reward the provision of affordable, high-quality cancer care through delivery system and reimbursement changes
  - Evaluate delivery system changes, including capitation, episode-related payments, medical homes, accountable care organizations, and shared savings programs
  - Support coverage with evidence development programs to assess new innovations in cancer care
  - Reimburse clinicians for performance on quality measures and for patient–clinician communication
  - Sever the relationship between treatment choice and physician income
  - Structure copayments based on the value of the service provided, to encourage patients to use higher-value treatments and discourage use of lower value interventions

Pilot European Reference Network on Rare Tumors

A.F. 3.1. Problem analysis including evidence base

- Significant burden of rare cancers (RARECARE)
- (Technical) rationale behind the ERNs

A.F. 3.2. General objective of the project (link with art.12 of the Cross-Border care directive)

- Contribute to improving quality of care/ quality of life of patients with rare cancers
- How: by “Pilot testing” the concept and technical components of an ERN

From general objective to the definition of activities

A.F. 3.3. Specific objectives

- SO1. Develop quality standards for diagnosis and treatment
- SO2. Ensure continuity of care as well as coordinated support between health and social sectors
- SO3. Develop tools for data collection on disease, treatments, outcomes and cost
- SO4. Develop the knowledge base on the selected diseases

Detailing the SO: choice of methods leads to definition of activities

A.F. 3.6. Methods and means (link with 6.1. (WP definition) and description of WPs (6.2. Horizontal WPs and 6.3. Core WPs)

- Each of the SO will be linked to one WP and will include the appropriate methods/ activities to achieve this SO

SO 1. Develop quality standards for diagnosis and treatment

Appropriate methodologies for:

- Drafting clinical practice guidelines (literature reviews; consensus writing process; validation process, etc.)
- Developing/ putting in place a QA scheme for diagnosis (central sample control; accreditation of labs)

Target groups:

- Primary: Healthcare professionals
- Secondary: Patients

SO 2. Ensure continuity of care as well as coordinated support

Appropriate methodologies for:

- Multidisciplinary approach in care setting (protocols for case review or referrals)
- Development of care pathways in care setting/ health system
- Developing integrated care between health and social sector (eg. Cooperation protocols; outreach programme development; integration of social services in care pathways, etc.)

Target groups:

- Healthcare and social service providers/ practitioners
- Policy makers, patients, carers

SO 3. Tools for data collection on disease, treatments, outcomes, cost

Appropriate methodologies for:

- Developing data set and quality control system
- Infrastructure development
- Data collection implementation support to include training of healthcare professionals (eg. EUBIROD Academy)

Target groups:

- Policy makers
- Healthcare and social service providers/ practitioners
- Patients

SO 4. Develop and share the knowledge base

Appropriate methodologies for:

- Developing research (eg. Development of a common bio-bank for genetic material?)
- Disseminating knowledge across the care system (systems for quality control/ accreditation of partner centres; tele-health development, etc.)

Target groups:

- Policy makers
- Healthcare and social service providers/ practitioners
- Patients

Work package specification

The analysis of the activities will help you fill the following sections on the WP description:

- A.F. 6.3.1. Specifications/ Description of the work
- A.F. 6.3.2 Specific objectives
- A.F. 6.3.3. List of deliverable(s) linked to this work package
- A.F. 6.3.4. Milestones produced by this work package

SO 1. Develop quality standards for diagnosis and treatment

Drafting clinical practice guidelines

- Milestones: a. completion of literature review; b. completion of the consensus/ validation process
- Deliverable: The Clinical Practice Guidelines document

Developing the QA scheme for diagnosis

- Milestones: a. completion of the documentation; b. timing of a first round of QA among participating centres
- Deliverables: a. the documentation supporting the QA scheme (SOP, protocols); b. A report on the first implementation round