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## Deliverable n. D5.3

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A proposal for quality assurance processes specific for rare cancers and consistent with ERN requirements focusing on improving quality of care, based on peer review and patient involvement.

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# 1. DESCRIPTION

## 1.1 The Joint Action on Rare Cancers

The Joint Action on Rare Cancers (JARC) is aimed to integrate and maximize efforts of the European Union (EU) Commission, EU Member States and all stakeholders to advance quality of care and research on rare cancers.

The public health challenges posed by rare cancers include the limited professional expertise in the community, the difficulties in clinical research, the need of a timely and appropriate diagnosis and optimal treatment from the very beginning of the patient's journey. An accurate clinical, pathologic and biological assessment of the disease of the individual patient is key to survival and cure, as well as an expert clinical decision provided by a multidisciplinary team. To this end, proper referral of patients and effective clinical networking are crucial in rare cancers. This is the main reason why JARC decided to shape its efforts around the new European Reference Networks (ERNs) with the following objectives:

1. Improving epidemiological surveillance of rare cancers in the EU
2. Identifying standards of care for all families of rare cancers to ensure sharing of best practices and equality of care for rare cancers across Europe, particularly through clinical networking
3. Improving the implementation at local level and within ERNs of clinical practice guidelines on rare cancers
4. Promoting integration of translational research innovations into rare cancer care
5. Improving education on rare cancers for medical and non-medical experts to ameliorate management of rare cancers and to improve rare cancer patients' empowerment in the EU
6. Identifying core strategies to incorporate in National cancer plans and Rare disease plans to address the specific needs of rare cancers across EU MSs

The JARC is structured in 10 work packages (WPs). Three cross cutting WPs (WP1 coordination, WP2 dissemination, WP3 evaluation) and 7 specific WPs based on the JARC objectives: WP4 epidemiology, WP5 quality of care, WP6 clinical practice guidelines, WP7 innovation and access to innovation, WP8 medical education, WP9 childhood cancers and, WP10 rare cancers policy. Patients work across all work packages, driving the JARC efforts along the needs of the only end users of all what we can do, in care and research as well.

## 1.2 Work Package 5

Within the framework of JARC, WP5 main objectives are:

Objective 1- To map existing networks of care for all 11 families of adult rare cancers across all Member States and identify gaps in current scenario and inequalities of patient access to resources.

Objective 2- To propose consistent and Europe-wide systems-based Standards for all families of rare cancers and the networks serving them.

Objective 3- To design Quality Assurance systems or processes (e.g. accreditation/audit/improvement plan) specific to rare cancers.

### **1.3 Aim and purpose of deliverable**

To design Quality Assurance (QA) processes for Rare Cancer Networks (RCNs) in tandem with the Standards in Objective 2 above. These QA processes would be recommended (a) for National RCNs and (b) offered for consideration to the ERN Monitoring Group for the AMEQUIS system in development (Assessment, Monitoring and Evaluation for Quality Improvement System) for ERNs. This QA process will focus on maintaining and improving expert-agreed best practices for rare cancer centres of excellence and networks, including ongoing peer review, a cycle of improvement plans, and patients' involvement.

### **1.4 The target groups of the specific deliverable**

This document represents a guide for National Health Authorities (e.g. Ministries of Health) which wish to set up a Quality Assurance programme for RCNs within their national boundaries. Target groups are:

- 1- National or regional (within countries) Rare Cancer Networks (RCNs).
- 2- Healthcare Providers (HCPs)
- 3- Regional (within countries) or National Health Authorities (e.g. Ministries of Health).
- 4- The ERN Monitoring Group of the European Union.
- 5- Policy Makers for Cancer in Member States.
- 6- Patient Organizations for Rare Cancers.

### **1.5 Summary of the main conclusions of the deliverable**

The present document describes the proposal for a QA process to evaluate and monitor an RCN. The QA herein proposed is based on a 5-year evaluation process. This consists of a self assessment and then an independent evaluation performed by an Independent Evaluation Provider (IEP). The process uses as a backbone for the evaluation the Qualitative and Quantitative Standards developed in this WP (Objective 2, Deliverable 5.2) and experts in the field as auditors of the RCN and HCPs. Key outputs from the IEP process are: a Final Report and Recommendations delivered to the RCN and the National Health Authorities; and an Improvement Plan drawn up by the RCN and approved by the IEP. The form in which an Accreditation Certificate might be recognised is a matter for decision for the National Health Authorities working with the IEP, and patient involvement in this strategic decision is recommended.

At the present time, the European Union is setting up a continuous monitoring system for European Reference Networks - the Assessment, Monitoring and Evaluation of Quality Improvement System - AMEQUIS. The present document has primarily a different objective (i.e. QA of regional or national RCNs), However, its conclusions may offer useful insights to the ERN monitoring group.

## 2. INTRODUCTION

The proposed quality assurance (QA) system in this deliverable aims to implement the Quality Standards developed by the WP5 of the JARC action (Objective 2, Deliverable 5.2), to establish a system of continuous quality improvement, to share best practices among Health Care Providers (HCPs) within Rare Cancer Networks, and ultimately to improve outcomes for rare cancer patients.

When this document was produced, the European Union ERN monitoring group was also developing a QA system for ERNs, the Assessment, Monitoring and Evaluation of Quality Improvement System - AMEQUIS. The proposed QA system in this deliverable may be offered to the ERN Monitoring Group as containing possible insights, but its primary focus is on National Rare Cancer Networks (RCNs). At the same time, the present proposal is designed to test compliance with the key chapters of the Qualitative and Quantitative standards proposed in JARC Objective 2, Deliverable 5.2 (i.e. Governance and co-ordination, Networking and Collaboration, Multidisciplinary approach, Quality Assurance, Patient-centeredness, Research and Education, Infrastructure and Data, Continuous and Evidence-based monitoring and Improvement) that largely follow the chapter headings of the ERN Operational Criteria [1, 2]. Therefore, the present QA system over time might assist, without guarantees, HCPs of RCNs to become ERN members.

The present QA system is based on 5-year independent evaluation process and cycles of improvement plans.

### 2.1 What is accreditation?

Accreditation is a process in which an Independent Evaluation Provider (IEP) would evaluate a RCN and certify that both the RCN and each constituent HCP meets certain Standards (Objective 2, Deliverable 5.2) [3]. Compared to current accreditation programmes in oncology, RCNs pose two challenges:

- (a) the accreditation process involves not just one HCP (e.g. oncology clinic or Comprehensive Cancer Centre) but several that work in co-operation. This challenge is being addressed for common cancers by the Organisation of European Cancer Institutes (OECI) in its nascent Network Programme and by WP10 of iPAAC in developing standards for Comprehensive Cancer Care Networks (CCCNs) [4];
- (b) rare cancers require highly specialised treatments, concentrated knowledge and resources that are more likely to involve collaborations of experts around specific patient cases.

The International Society of Quality in Healthcare (ISQua) published a useful guide to the domains which need to be provided by a best practice health accreditation programme [5]. They are:

- Developing Quality Standards: (this is satisfied by Deliverable 5.2).
- Developing assessment methodologies: this covers domains such as selection, training and evaluation of auditors, developing the survey management process, establishing the accreditation/certification process, and quality assurance of the process.
- Evaluating systems and achievements: this covers domains such as measuring performance internally, ensuring independence, accrediting the external evaluation bodies.

### **3. MATERIAL AND METHOD (E.G., SURVEYS, CONSENSUS MEETINGS)**

The quality assurance (QA) system herein proposed stands on the experience of the Accreditation and Designation programme of the Organisation of European Cancer Institutes (OECI) which has accredited 40 cancer centres across EU since 2008 [6]. In building this proposal, reference has also been made to the Accreditation Programme of the German Cancer Society [7], Accreditation Canada (now QMentum) [8], and the requirements of The French National Cancer Institute (INCa) [9].

The present document has been presented and consensus reached during the Consensus Meeting in Catania on the 27<sup>th</sup> of March 2019 (Task 5.4).

### **4. RESULTS**

#### **4.1 Recommendations on parties involved and their accountability in the QA programme.**

The accreditation programme for RCNs should include three main parties:

- The National Ministry of Health or other National Health Authority, which is accountable for guaranteeing that the QA programme for national/regional RCNs is in place and (preferably) financially supports it;
- The RCN, which is accountable for periodically completing the QA programme, and for developing and implementing improvement plans. Depending on the type of rare cancer and depending on the structure of the RCN, not all qualitative standards and indicators can be evaluated in all HCP members of the RCN. In addition, some standards only apply to the governance/co-ordination of the network; in a hub-spoke type of network, the majority of standards apply to hub HCPs.
- The Organisation or Agency (i.e. Independent Evaluation Provider – IEP), which performs the external evaluation of the RCN. The IEP is accountable for assessing the quality of RCNs in an independent and unbiased way and for reporting its findings to the RCN and the National Ministry of Health or other National Health Authority. The IEP is also accountable for the selection, training and evaluation of auditors. Auditors should be experts in the rare cancer field (ideally participating in an existing ERN). The audit team could be diversified by expertise and contain researchers, physicians (e.g. surgeons, pediatricians, oncologists, radiotherapists) and radiologists.

#### **4.2 Recommendations on how the accreditation process might work.**

The RCN QA programme, similarly to other QA programmes, stands on:

1. A set of Qualitative and Quantitative standards (Objective 2, Deliverable 5.2) integrated in a web based e-tool. Ideally, the e-tool should be harmonized within Europe, and the ERN e-tool system could potentially be the common platform also for National Rare Cancer Networks. These standards

are at both the RCN level and the constituent HCP level and therefore require that all HCPs in the RCN are bound to take part in the accreditation process;

2. A self-assessment process where the RCN and all the constituent HCPs report using the qualitative and quantitative questionnaires in the e-tool; the RCN or HCP gives a score to each qualitative standard based on the degree of implementation (Plan-Do-Check-Act circle or Deming-circle) [3]. Four stages of implementation are translated in the following possible answers:
  - a. **Yes** means that the indicator of the standard has been implemented on a wide scale throughout the RCN and the Deming-cycle is completed at least twice (> in third cycle),
  - b. **Mostly** means that the indicator has been implemented in most of the critical HCPs of the RCN and the Deming-cycle is completed at least once (> in second cycle),
  - c. **Partially** means that the indicator is implemented on project bases or on a modest scale in the RCN or the Deming-cycle has not been completed,
  - d. **No** means that the indicator does not get attention or there are plans to start working on the indicator,
  - e. **Not applicable** means that the indicator is not applicable in the RCN.
3. An external evaluation managed by an IEP with an audit team visiting some or all of the HCPs belonging to the RCN; in a hub-spoke type of network it is highly recommended that the hub HCP is always audited.
4. A report made by IEP and delivered to the RCN and to the National Health Authorities;
5. A plan for improvement designed by the RCN, agreed by the IEP and satisfactory to the National Health Authorities.
6. The form in which an Accreditation Certificate might be recognised is a matter for decision for the National Health Authorities working with the IEP, and patient involvement in this strategic decision is recommended.

### 4.3 Proposed Timeline of the accreditation.

**Step 1:** The National Ministry of Health or other National Health Authority issues a tender proposal for the QA assessment, and awards the contract to an appropriate IEP to perform the external evaluation of the RCN (NB several Member States could combine in this process to ensure appropriate comparatives). The tender document may seek to specify the degree of external face to face assessment by the IEP, and determine the qualification of auditors for the evaluation (Steps 6 and 7).

**Step 2:** The National Ministry of Health or other National Health Authority works with the IEP to initiate the process with the RCN. Agreement is reached about the extent of external visits (to each HCP, or on a selected basis).

**Step 3:** The IEP contacts the RCN (on behalf of all constituent HCPs) to plan the accreditation process.

**Step 4:** The RCN and all the constituent HCPs self assess using the e-tool and upload all the required documents.

**Step 5:** The IEP evaluates the RCN and all the HCP self assessments uploaded in the e-tool.

**Step 6:** The IEP visits the RCN and the HCPs chosen in accordance with Step 2 to test compliance with the Quality Standards and acquire further evidence.

**Step 7:** The IEP reports about the degree of compliance with the Quality Standards to the RCN and the National Ministry of Health or other National Health Authorities, and produces a Final Report and Recommendations. The RCN works with constituent HCPs to develop an Improvement Plan accordingly, and agrees the Improvement Plan with the IEP and the National Ministry of Health or other National Health Authorities.

**Step 8:** The IEP or the National Health Authorities issues the accreditation certificate of the RCN to the RCN and the National Ministry of Health or other National Health Authorities. This accreditation certificate should last for 5 years.

**Step 9:** One year after the evaluation visit the RCN provides a written report to the IEP and the National Ministry of Health or other National Health Authorities describing the progress of the goals, actions and time-schedule set in the Improvement Plan.

## 5. DISCUSSION

The Joint Action on Rare Cancers (JARC) aims to integrate and maximise efforts of the European Union (EU) Commission, EU Member States and all stakeholders to advance quality of care and research on rare cancers. Proper referral of patients and effective clinical networking are crucial in rare cancers, and this is the main reason why JARC decided to shape its efforts around the Rare Cancer Networks. WP5 of the JARC action has focused on mapping existing RCNs and on proposing a QA system (including Standards and Processes) for national RCNs, with the aim to increase consistency of high quality diagnosis, treatment and care in rare cancers across EU member states.

The QA herein proposed is based on a 5-year accreditation performed by an Independent Evaluation Provider (IEP). The process uses as a backbone for the evaluation the Qualitative and Quantitative Standards developed in this WP (Objective 2, Deliverable 5.2) and experts in the field as auditors of the RCN and HCPs. Key outputs from the IEP process are: a Final Report and Recommendations delivered to the RCN and the National Health Authorities; and an Improvement Plan drawn up by the RCN and approved by the IEP. The form in which an Accreditation Certificate might be recognised is a matter for decision for the National Health Authorities working with the IEP, and patient involvement in this strategic decision is recommended.

The framework for setting up ERNs requires an initial quality assessment according to set criteria [2]. The ERN Monitoring Group of the Board of Member States is also setting up a Continuous Monitoring and Quality Improvement System for their members (ERN CMQS) [10-13]. The Quality Standards, Indicators and Programme in this paper are offered as suggestions for that CMQS. For instance, section 4.3 of the present document could be applied with suitable modifications to the Assessment, Measurement and Quality System

(AMEQUIS) being discussed during 2019-20 for the ERNs, and is offered to the EU as a set of ideas for consideration.

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