



Conference

Putting **Science** into **Standards**:  
evidence-based **quality assurance**  
– an example for **breast cancer**

Hosted by EARTO, CEN/CENELEC  
and the JRC

JRC Ispra • Italy • 20-21 October 2015



Joint  
Research  
Centre

## Context

The Directorate-General Joint Research Centre (JRC) of the European Commission, together with the European Association of Research and Technology Organisations (EARTO), the European Standards Organisations (ESO) CEN and CENELEC, and the European Commission Directorate-General Internal Market, Industry, Entrepreneurship and SMEs (DG GROWTH) have launched an initiative to bring the scientific and standardization communities closer together entitled 'Putting Science into Standards'. The initiative is in line with article 9 of the Regulation (EU) No 1025/2012<sup>1</sup> which states that the Commission's research facilities shall [...] provide European standardization organisations with scientific input, in their areas of expertise, to ensure that European standards take into account economic competitiveness and *societal needs* such as environmental sustainability and safety and security concerns'. Such event, where communication can occur between science, services (and respective users) and standards, would be the ideal environment to address the challenge of common benchmarking for quality of care in breast cancer care services. This would facilitate the creation of a framework for an evidence-based screening of emerging science and technology, identification of research gaps and prioritisation needs, and agreement on areas which should be introduced early into the process of standardization in order to enable innovation and facilitate improved breast cancer care services.

## Background

The European Commission's Initiative on Breast Cancer (ECIBC) aims at establishing a set of essential and evidence-based quality requirements for breast cancer care across Europe while developing the evidence underpinning the scheme, namely the *New European guidelines for breast cancer screening and diagnosis*. This initiative responds to the Council Conclusions on reducing the burden of cancer<sup>2</sup> and it aims to mitigate the risks connected to inadequate quality of prevention and care.

In addition, within the context of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare,<sup>3,4</sup> in order to help patients make an informed choice when they seek to receive healthcare in another Member State, Member States need to ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on which healthcare providers are subject to these standards.

1. 32012R1025: Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardization, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1025&rid=1>.

2. Council of the European Union: *Council Conclusions on reducing the burden of cancer*, 2876<sup>th</sup> Employment, Social Policy, Health and Consumer Affairs Council Meeting, Luxembourg, 10 June 2008.

3. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>.

4. [http://ec.europa.eu/health/rare\\_diseases/european\\_reference\\_networks/index\\_en.htm](http://ec.europa.eu/health/rare_diseases/european_reference_networks/index_en.htm).

The JRC was assigned by DG SANTE with the coordination of ECIBC with the support of working groups and is in the process of developing a *European quality assurance scheme for breast cancer services (European QA scheme)*. It will be based on evidence (via guidelines) and underpinned by the Regulation (EC) No 765/2008 on Accreditation,<sup>5</sup> ensuring its consistent application in all countries; placing the woman/patient at the centre of the process and ensuring that appropriate communication and involvement in decisions occur whenever possible.

The *European QA scheme* will encompass all breast cancer stages: from the first invitation to screening, to diagnosis, surgery, treatment and post-treatment, including rehabilitation, palliative and psychosocial care.

The implementation of the requirements of such a scheme would be not only important for auditees (breast cancer services, *e.g.* hospitals, medical and screening centres, etc.) and auditors, but mainly for patients, policy makers and reimbursement systems, industrial and academic research and many other stakeholders. Standardization could play a role in helping in this implementation process and ensuring that inequality of national and cross-border care is minimised.

Understanding how to do it is one of the main objectives of this Conference, which is fully in line with:

- the European Commission Work programme for European Standardization for 2015,<sup>6</sup> that has included healthcare services in the framework of Directive 2011/24/EU, as one of the potential topics for future standardization requests;
- the declared objective of CEN and CENELEC to develop a common strategy on how to approach healthcare services.

Therefore, the proposal of developing a standard based on evidence (via the guidelines and the QA scheme to be developed in parallel on breast cancer under JRC scientific coordination) and with a good potential of uptake, as linked to a European-wide project, can be considered as a basis for an enlarged and inclusive discussion on the way forward and the possible blue-print for other areas, like health technology assessment, health(care) data and health-related tools (*e.g.* satisfaction questionnaires, apps, etc.), and a bridge towards other already active standardization fields, like the one on e-health/health informatics.

EARTO contribution aims at supporting CEN-CENELEC and the JRC in detecting and filling of research gaps. The anticipation of new technologies is key to ensure that the guidelines and, in cascade, the *European QA scheme* and the standard, will reflect in a timely manner the scientific evolution of therapies and technologies, including evidence on organisational aspects.

5. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93: *OJ L218/30-47 of 13.08.2008*.

6. See item 3.2.23 of COM(2014) 500 *The annual Union work programme for European standardisation for 2015*.

## Key topics for the event

The following overarching questions (horizontal aspects) should be tackled and consensus reached on the way forward.

- Would a European approach help in minimizing and avoiding duplications of local/regional/national/international entities developing guidelines and sometimes associated QA schemes, with the assumption that if evidence has a unique series of sources, guidelines can be produced at an international level and adapted at local level? Can we agree on the best approach for improving economic and quality aspects of healthcare, *e.g.* a pan-European versus a national one?
- What are the benefits for a European versus a national approach in terms of trust of patients, reliability of accreditation, comparability of the quality of care, expectations of the public authorities? What can we learn from the different existing schemes?
- Both for developing Guidelines and for setting-up QA schemes (and potentially for standards development), would an outsourcing of evidence, based on a clear selection gate and grading methodology, be an acceptable and useful solution? Would it help granting a higher degree of transparency and neutrality, *e.g.* the experts involved in the development will receive from a third party the summary of existing evidence instead of being directly involved in the selection of papers and reviews?
- Could a transparent and inclusive mechanism for the selection of experts in developing guidelines and quality assurance schemes (and eventually standards) be proposed and agreed at European level?
- What could be the role of standardization in this framework? To which extent should a standard cover the elements of care? How can a voluntary European standard facilitate the implementation of the Guidelines and the Schemes?
- Would the cascade model: *guidelines* → *QA scheme* → *standard* proposed for ECIBC be a useful and applicable blueprint in the healthcare sector?

## The event

The scope of the event is to address the key topics and questions described above in dedicated sessions.

Each session is moderated by a recognised expert in the field, with speakers from research, professional profiles, stakeholder community (mainly citizens – potential patients, but also health authorities, e.g. the ECIBC National Contacts network) and standardization. The speakers will be followed by a moderated discussion with all participants. Rapporteurs will contribute to the round table with a summary for each session.

The outputs will be:

- i. a joint, publicly available report, and
- ii. an agenda for action in the breast cancer services area and anticipating topics of potential interest in the same area for future events in the same stream, to be implemented by the relevant bodies and authorities.

The event is by invitation only, with 60-80 experts from research, stakeholders, standardization and policy in attendance, in addition to the participants from the three organisers.

The JRC Ispra site, with its facilities and visitors' centre, in the middle of the famous Italian Lake District and close to Milano Malpensa airport, hosts the event.<sup>7</sup>

### For further information please contact:

For JRC: Donata LERDA or Zuleika SAZ-PARKINSON ([jrc-PSIS@ec.europa.eu](mailto:jrc-PSIS@ec.europa.eu))

For CEN/CENELEC: Alberto SIMEONI ([ASimeoni@cencenelec.eu](mailto:ASimeoni@cencenelec.eu))

For EARTO: Kadija TAFFAH ([taffah@earto.eu](mailto:taffah@earto.eu))

A helpdesk for practical information will be set at JRC and in due time you will receive all details.

Additional information on the *European Commission Initiative on Breast Cancer* is retrievable at the dedicated webpage of JRC Science Hub <https://ec.europa.eu/jrc/en/research-topic/healthcare-quality>.

Additional information on how breast cancer care is organised in Europe is available in the JRC report on Breast Cancer Services (<http://bookshop.europa.eu/en/report-of-a-european-survey-on-the-organisation-of-breast-cancer-care-services-pbLBNA26593/>).

7. <https://ec.europa.eu/jrc/en/about/jrc-site/ispra>.

# Draft agenda – Day 1

10:30-11:15 Coffee and Registration

## 11:15-11:45 Welcome and Opening

**K. MARUSZEWSKI**, Director, JRC-Institute for Health and Consumer Protection (IHCP)

Introduction to the Workshop

**P. CHURCHILL**, JRC – **A. GANESH**, CEN/CENELEC – **M. ATTANÉ**,\* EARTO

## 11:45-12:45 Key Note Presentations

(each speaker 15 minutes, with 15 minutes discussion)

Moderator: **K. MARUSZEWSKI**, Director, JRC-IHCP

*Speaker 1:* The JRC perspective – The ECIBC: a useful example on how Guidelines, QA schemes and, potentially, standardization can work together – **D. LERDA**, JRC-IHCP

*Speaker 2:* The EARTO perspective – Experience of the Austrian initiative for a nationwide screening program to detect breast cancer – Prof. **C. SINGER**, Professor of Obstetrics and Gynecology, Medical University of Vienna –AIT/EARTO

*Speaker 3:* The CEN/CENELEC Perspective – Standardization: an open and transparent process for the benefit of market and society – **K. GRÜN**, Austrian Standards Institute (ASI)

12:45-13:45 Lunch

## 13:45-15:40 Session 1: European Policies in the healthcare area and the European Commission Initiative on Breast Cancer

(moderator 5 min (outline and expectations); each speaker 10 min; up to 40 min discussion)

Moderator: **P. CHURCHILL**, JRC-Dir A

Rapporteur: **I. LADIGES**, Directorate-General for Health and Food Safety (DG SANTE)-C.1

*Speaker 1:* 2003 Council Recommendation on Cancer Screening and the European Initiative on Breast Cancer – **I. LADIGES**, Directorate-General for Health and Food Safety (DG SANTE)-C.1

*Speaker 2:* Activities on patient safety and quality of care under the new Commission – **K. NEUBAUER**, Directorate-General for Health and Food Safety (DG SANTE)-D.2

*Speaker 3:* Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)-B.3

*Speaker 4:* EA European Accreditation support to the European Commission – Regulation 765:2008 – NLF – **A. STEINHORST**, European co-operation for Accreditation (EA)

*Speaker 5:* The ECIBC – Overview of QA schemes and ISO standards in Europe for breast cancer care – **S. DEANDREA** and **A. ULUTÜRK**, JRC-IHCP

*Speaker 6:* Why the quality of quality metrics counts in healthcare: an illustration from breast cancer surgery – Prof. **S. CANO**, Plymouth University Peninsula Schools of Medicine and Dentistry and Prof. **L. PENDRILL**, Researcher, SP Metrology/SP Technical Research Institute of Sweden/EARTO

*Speaker 7:* An Independent Patient point of view: the European Breast Cancer Coalition – Europa Donna – **S. KNOX**, Europa Donna

15:40-16:10 Coffee/tea break

16:10-17:55 **Session 2: The methodological framework for incorporating evidence in healthcare policies: the example of ECIBC as a neutral and collaborative platform**

*(moderator 5 min (outline and expectations); each speaker 10 min; up to 40 min discussion)*

**Moderator:** **C. McLAUGHLAN**, Deputy Chief Executive and Director of Clinical Quality/  
BJA Education Editorial Office, The Royal College of Anaesthetists

**Rapporteur:** **M. UNDERWOOD**, Director, Warwick Clinical Trials Unit, Warwick Medical School,  
The University of Warwick

**Speaker 1:** Developing and implementing Guidelines based Quality indicators: the German experience – **M. FOLLMANN**, German Cancer Society (DKG)

**Speaker 2:** The GRADE approach: an emerging consensus to develop guidelines – **P.A. COELLO**,  
Iberoamerican Cochrane Center

**Speaker 3:** The role of clinical trials in establishing and refining standards – **J. BOGAERTS**,  
European Organisation for Research and Treatment of Cancer (EORTC)

**Speaker 4:** Health Technology Assessment (HTA) – A structured process of applied research  
to inform policies and decisions in healthcare – **F.B. KRISTENSEN**, EUNetHTA

**Speaker 5:** How can healthcare standards be standardised? – **C. SHAW**, former Program  
Director of CASPE Research

19:30 Workshop dinner

\* To be confirmed.



## Draft agenda – Day 2

08:30-09:00 Welcome coffee

09:00-10:45 **Session 3: Stakeholders' views, needs and expectations: what could be the role of standardization in this area? How can it promote the implementation of the quality assurance scheme for breast cancer services?**

*(moderator 5 min (outline and expectations); each speaker 10 min; up to 40 min discussion)*

*Moderator: K. BENN, Europa Donna*

*Rapporteur: G.L. SALERIO, Italian Organization for Standardization (UNI)*

*Speaker 1: How standardization can contribute in the healthcare services – P.K. ANDERSEN, Norwegian Directorate of Health*

*Speaker 2: Standardization and societal needs: ANEC experience – M. VUERICH, The European consumer voice in standardisation (ANEC)*

*Speaker 3: Challenges for Colorectal Cancer Screening – A biomarker with no standards – S.P. HALLORAN, Professor Emeritus, University of Surrey*

*Speaker 4: European CanCer Organisation (ECCO)*

*Speaker 5: EC-JRC initiative on BCS: EA BCS WG accreditation/certification standards proposal for high quality care services: screening and diagnosis process – F. GATTAFONI, European co-operation for Accreditation (EA)*

*Speaker 6: The emergence of quality surveillance for breast cancer services in England over the last ten years – S. EDWARDS,\* NHS England*

10:45-11:15 Coffee/tea break

11:15-12:45 **Session 4: Innovations, new technologies, future trends and perspectives**

*(moderator 5 min (outline and expectations); each speaker 10 min; up to 40 min discussion)*

*Moderator: Prof. L. PENDRILL, Researcher, SP Metrology/SP Technical Research Institute of Sweden/EARTO*

*Rapporteur: S. RAPI, AOU Careggi, Toscana & SIBiOC*

*Speaker 1: Challenges of risk-adjusted prevention strategies for breast cancer – R. SCHMUTZLER, UniKlinik Köln*

*Speaker 2: Implementation of nation-wide molecular testing in oncology in the French Health care system: quality assurance issues & challenges – F. NOWAK, Institut National du Cancer*

*Speaker 3: From standardizing patients to standardizing for patients. Precision approaches to the 'holistic' patients – E. BRIERS, Past secretary Europa Uomo and patient advocate*

*Speaker 4: New technologies in diagnostics – K. MATÉ, European Diagnostic Manufacturers Association (EDMA)*

*Speaker 5: Standardisation needs for the measurements of genetic biomarkers – L. DEPRez, JRC-Institute for Reference Materials and Measurements (IRMM)*



12:45-13:45 Lunch

13:45-14:00 **Event's evaluation**

14:00-15:30 **Conclusions and open discussion for identifying and agree on a way forward and next steps**

*Moderator: C. NICHOLL, JRC-IHCP*

- Rapporteurs' presentations
- Round-table and open discussion (Different perspectives: Commission, Patients, Concerned services, Professionals, EA, CEN/CENELEC, etc.)
- Consensus on roadmap and agenda for action

15:30-15:45 **Closure of the meeting**

\* To be confirmed.





# Joint Research Centre

*The European Commission's  
in-house science service*

## **OUR MISSION**

As the Commission's in-house science service, the Joint Research Centre's mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle.

Working in close cooperation with policy Directorates-General, the JRC addresses key societal challenges while stimulating innovation through developing new methods, tools and standards, and sharing its know-how with the Member States, the scientific community and international partners.

Contact:

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