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

Event Report

Conference 20-21 October 2015

Zuleika SAZ-PARKINSON, Luciana NEAMȚIU,
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throughout the sessions and being able to identify the main points which they presented in the conclusions section. We wish also to thank to the co-organisers, to colleagues from DG SANTE for their inputs on how to optimise the conference design and content and to our colleagues Sandra CALDEIRA for reviewing the report and Manuel FLORENSA-MOLIST for his editorial support.

Foreword

Standards support many elements of our lives, from helping to create a level playing field that encourages investment in our industries thereby boosting competitiveness, through to helping to assure the quality and safety of our products and services. The timeliness of the production of standards is often the key to this process. To maximise competitiveness, quality and safety the preparation for standards, including pre-normative research, therefore needs to start as early as possible. Indeed it is often the case that those who identify and produce standards first can gain advantage internationally.

Science and technological development are key indicators of where new standards are needed. Scientists and technologists are a vital source of information about where new issues requiring standardisation effort are needed. Links between the science and technology communities, and the standardisation community need to be developed to facilitate the information flow. This has been recognised by Regulation (EU) No 1025/2012

of the European Parliament and of the Council of 25 October 2012 on European standardisation.

The ‘Putting the Science into Standards’ initiative responds to this need. Sponsored by the European Standardisation Organisations CEN and CENELEC, as well as by the European Commission’s science service, the Joint Research Centre, it seeks to bring scientists and technologists together with standardisers and other stakeholders including industry and policy makers to analyse the standardisation needs of a given subject. This document reports upon the third of the ‘Putting the Science into Standards’ series, focusing on a Quality Assurance Scheme for Breast Cancer Services. Previously the initiative has focussed on Eco-Innovation (2012) and Power-to-Hydrogen and HCNG (Hydrogen Compresses Natural Gas) (2014). As can be seen from this report the 2015 event has been equally productive for the future of the quality assurance scheme for breast cancer services.

Peter CHURCHILL

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on Scientific Development*

EUROPEAN COMMISSION
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Preface

Putting Science into Standards is a series of events co-organised by the Joint Research Centre (JRC), the European Committee for Standardization the European Committee for Electrotechnical Standardization (CEN-CENELEC), and the European Association of Research and Technology Organisations – (EARTO) each year focussing on a different emerging topic.

These events follow the recommendation included in article 9 of the Regulation (EU) No 1025/2012¹ that states that the Commission's research facilities shall '[...] *provide European standardisation 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*'. These events, aimed at facilitating consideration of emerging science topics for entering the standardisation process, were considered the ideal environment to address the challenge of common European benchmarking for quality of care in breast cancer care services; this benchmarking is the target of the European Commission's Initiative on Breast Cancer. For this reason the topic proposed for the 2015 edi-

tion of the events was 'Evidence-based quality assurance – an example for breast cancer' and the event was aimed at providing useful inputs for the European Commission's Initiative on Breast Cancer.

The JRC was asked to coordinate the European Commission's Initiative on Breast Cancer (ECIBC) by the Directorate General for Health and Food Safety (DG SANTE). The ECIBC aims to develop a voluntary *European Quality Assurance scheme for Breast Cancer Services* covering all processes of breast cancer care, including, in addition to screening and diagnosis, treatment, rehabilitation, follow-up and survivorship, and palliative care; it will be underpinned by the Regulation on Accreditation (765/2008), while respecting the country-specific organisational settings, and based on evidence. Such evidence will be provided by trustworthy guidelines: the *European guidelines for breast cancer screening and diagnosis*, for screening and diagnosis processes, and a Platform of evidence-based guidelines for all other processes of care.

The main objective of the 2015 edition of the *Putting Science into Standards* series was to understand the processes involved in the ECIBC, in particular with respect to the potential for integration of tools and reference documents to be made available for the development and implementation of the voluntary *European Quality Assurance scheme for Breast Cancer Services*.

1. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF>.

Participants agreed with the existence of a potential to implement quality assurance measures, also in support of efforts for reducing inequalities through a European level action. Participants expressed their support to the proposal of developing a methodology for developing standards of care (and/or regulatory frameworks/guidelines) for breast cancer services ensuring a structured and correct incorporation of evidence.

The need to have a more open discussion among standardisation and medical experts/citizens and patients/stakeholders in order to provide greater quality in prevention and care was emphasised.

Finally, the conference highlighted the urgent need of harmonising both the pre-analytical and analytical phases of diagnostic testing; the accuracy of diagnostic testing operations is crucially important to guarantee that treatments can be safely provided to those who will truly benefit the most from them. This includes availability of *e.g.* reference materials, tests, and, possibly, of reference networks.

1. Introduction

The *Putting Science into Standards* series is a series of events aiming to bring the scientific and standardisation communities closer together. Such an event, where communication can occur between science and standards, is the ideal environment to address the challenge of common benchmarking for quality of care in breast cancer care services, which is a main pillar of the ECIBC, coordinated by JRC, with the support of two working groups and under the auspices of the Directorate-General for Health and Food Safety (DG SANTE). This facilitates the creation of a framework for 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 standardisation in order to enable innovation and facilitate improved breast cancer care services.

The ECIBC aims at establishing a set of essential and evidence-based quality requirements for breast cancer care across Europe (a voluntary *European Quality Assurance scheme for Breast Cancer Services* – the *European QA scheme*). In parallel, the evidence underpinning the scheme, namely the *European guidelines for breast cancer screening and diagnosis* (the *European Breast Guidelines*) and a platform of high-quality guidelines (the *Guidelines Platform*) are as well developed under JRC coordination. This initiative responds to the Council Conclusions on reducing the

burden of cancer² and it aims to mitigate the risks connected to inadequate quality of prevention and care.

The *European QA scheme* will be based on evidence (via guidelines) and underpinned by the Regulation (EC) No 765/2008 on Accreditation,³ 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 when and as needed. It will encompass all breast cancer processes of care: from the first invitation to screening, diagnosis, treatment, rehabilitation, follow-up and survivorship, and palliative care.

The implementation of the requirements of such a scheme would be not only important for auditees (breast cancer services, e.g. hospitals, screening centres, etc.) and auditors, but mainly for patients, policy makers and reimbursement systems, industrial and academic research and many other stakehold-

2. Council of the European Union: *Council Conclusions on reducing the burden of cancer*. 2876th Employment, Social Policy, Health and Consumer Affairs Council meeting. Luxembourg, 10 June 2008. http://www.eu2008.si/en/News_and_Documents/Council_Conclusions/June/0609_EPSCO-cancer.pdf.

3. 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. *Of L218/30-47 of 13.08.2008*. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32008R0765>.

ers. The development of breast cancer care standards could play a role in helping implement the QA scheme.

Understanding how to do this was one of the main objectives of this conference, fully in line with the 2015 European Commission Work Programme for European Standardisation.⁴ The Work Programme highlighted the need to bring together the knowledge and experience of ‘*clinicians and representatives of regulatory authorities, research and development as well as accreditation and standardisation organisations*’ in order to develop relevant and fit-for-purpose European standards.

Therefore, within the ECIBC, the proposal of developing a scheme based on evidence and with a good potential of uptake, as linked

to a European-wide project, was considered as a basis for an enlarged and inclusive discussion on the way forward and a possible blueprint 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 standardisation fields, like the one on *e*-health/health informatics.

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

4. See item 3.2.23 of COM(2014) 500, ‘The annual Union work programme for European standardisation for 2015’. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52014DC0500>.

2 . Aim of the conference

The event aimed to address the questions and key topics described below in dedicated sessions.

The following overarching questions (horizontal aspects) were tackled and consensus was sought on the way forward.

- Would a European approach help in minimising and avoiding duplications of local /regional/national/international entities developing guidelines and the sometimes associated QA schemes? The assumption would be that, if evidence has a unique series of sources, guidelines can be produced at an international level and adapted at local level. Thus, would the best approach(es) for improving economic and quality aspects of breast cancer care be at pan-European or at national level?
- What are the benefits of a European (as opposed to a national) approach in terms of patients' trust, reliability of accreditation systems, comparability of the quality of care, expectations of public authorities? What can we learn from the different schemes which already exist?
- Both for developing guidelines and for setting-up quality assurance schemes (and potentially for standards development), would an outsourcing of evidence, based on a clear and neutral selection criteria and grading methodology, be an acceptable and useful solution? That is, would it help to have a higher degree of transparency and neutrality if, for example, the experts involved in the development receive the summary of existing evidence from a third party, instead of being directly involved in the selection of papers and reviews?
- Could a transparent and inclusive mechanism for the selection of experts involved in developing guidelines and quality assurance schemes (and eventually standards) be proposed and agreed at European level?
- What could be gained by using standards in this framework? To what extent can a standard cover elements of care? Could a voluntary European standard facilitate the development/implementation of the guidelines and of the quality assurance schemes?
- Would the cascade model: ECIBC guidelines → QA scheme → standard be a useful and applicable blueprint in other types of cancer or diseases?

3. Organisation and participants

The Conference dates were announced to invitees via email, describing the event’s scope, beginning on 5 June 2015. The official invitations to participants were sent out on 24 July 2015. Participants were invited to register and the registration page was open from 24 July 2015 till 5 October 2015.

Participants, as seen in *Figure 1*, represented 46 different institutions from 13 different European countries (18 participants were from various Institutes of the JRC and from its Headquarters, but they were counted as a single institution).

Annex 1 contains a list of the final 70 participants (including speakers, moderators and

rapporteurs) to the event with their names and affiliations, and the group picture of participants is in *Figure 2*.

The short biographies and pictures of all the speakers, moderators and rapporteurs who participated in the conference can be found on the European Commission’s Initiative on Breast Cancer web page⁵ in the section dedicated to the event *Putting Science into Standards*.⁶ In addition, the abstracts of the presentations made during the event are available in *Annex 2*.

5. <http://ecibc.jrc.ec.europa.eu/home>.

6. <http://ecibc.jrc.ec.europa.eu/-/putting-science-into-standards-evidence-based-quality-assurance-an-example-for-breast-canc-1>.

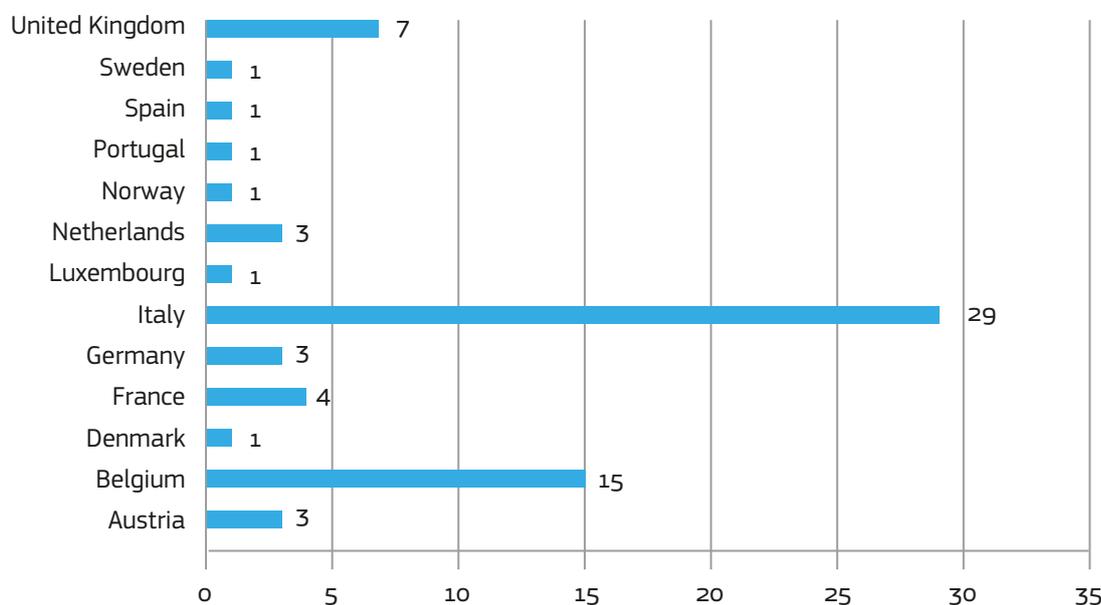


Figure 1. Countries’ distribution for participants.



Figure 2. Group picture.

The agenda and project concept were made available in the JRC Science hub. After the event, and upon their consent, presentations and the list of participants were posted on the European Commission's Initiative on Breast Cancer web page.⁷

Each session was moderated by a recognised expert in the field, with speakers from the research and standardisation fields, as well as from the stakeholder community (patient advocates, but also health authorities, *e.g.* some representatives of the ECIBC National Contacts network and of the Expert Group on Cancer Control of the EU). After the presentations, for each session a mod-

erated discussion with all participants followed. A rapporteur presented a summary of each session during the conclusive session of the event.

The outputs of this workshop were:

- i. a short report, sent only to participants, to gather their feedback on the event conclusions,
- ii. this publicly available report, and
- iii. an agenda for action in the breast cancer services area, anticipating topics of potential interest for future events in the same stream, to be implemented by the relevant bodies and authorities, based on the feedback received.

7. <http://ecibc.jrc.ec.europa.eu>.

4. Agenda and presentations



Figure 3. Welcome and Opening session.

The conference agenda foresaw keynote presentations, mostly dedicated to provide the different perspectives of the meeting from the three co-organisers of the event, JRC, EARTO and CEN-CENELEC.

Following, four different sessions, with five to seven speakers each, were dedicated to the following main topics:

1. European Policies in the healthcare area and the European Commission Initiative on Breast Cancer (ECIBC).
2. The methodological framework for incorporating evidence in healthcare policies: the example of ECIBC as a neutral and collaborative platform.
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?
4. Innovations, new technologies, future trends and perspectives.

Finally, an open discussion to identify and agree on next steps and a way forward concluded the event.

The full agenda with links to the presentations is available in *Annex 3*.

The four sessions addressing the key topics are summarised in the next pages of this chapter.

Session 1. European Policies in the healthcare area and the European Commission Initiative on Breast Cancer

The objective of this first session was to set the scene for the development of the ECIBC project, and point out the benefits of a European approach to setting essential quality requirements for breast cancer care across Europe.

There were presentations outlining the European Policies in the healthcare area. In particular, the work carried out by the Healthcare Quality Team of the Public Health Policy Support Unit of JRC to prepare the ground for the ECIBC project, was reported; for instance the results of surveys and reviews about the organisation of breast cancer care services across Europe, on the quality assurance schemes present in Europe and on ISO standards already in use in breast cancer services across Europe

were presented. Quality metrics in healthcare as an essential tool for determining whether a certain policy or process would be effective were explained, and an example from breast cancer surgery was provided.

The Accreditation framework and the general requirements of the *European QA scheme*, which will be person-centred and based on evidence, were presented by the European co-operation for Accreditation (EA). EA is recognised by legislation to be the coordinator of National Accreditation Bodies (NABs) ensuring a peer-reviewed, transparent and harmonised accreditation system across Europe.

Speakers contributed in outlining policies, at a European level, related to breast cancer care services. They also presented how these policies could facilitate the development of



Figure 4. Session 1.

a fit-for-purpose *European QA scheme* and enhance its uptake, in order to ensure a meaningful impact on the quality and equity of breast cancer care.

In this context, speakers highlighted the need for measuring critical outcomes that have an effect on the quality of services provided to breast cancer patients via key indicators. Those indicators, which are already collected in some European countries, should be monitored to control the quality of the care provided and plan improvements. This would grant an impact of ECIBC and other policies on breast cancer care in a person-centred perspective.

The discussion brought about by the different presentations of this session focused on the importance of bringing together all stakeholders as an occasion for constructive dialogue between CEN-CENELEC and the stakeholders of the ECIBC, including patients organisations, epidemiologists, methodologists, and clinical experts, to share best practice.

The importance of using patient reported outcome measures and patient satisfaction and quality of life tools was discussed. In addition, the positive impact of having adopted a multi-profile approach to develop the *European QA scheme* was emphasised; diverse professionals, methodologists and patients are collaborating with the JRC for setting appropriate requirements for infrastructures, resources and outcomes, quality improvement and quality management chain, collection of feedback, *e.g.* patient experience, safety and clinical effectiveness.

The conclusions of this session were that *participants agreed that there is potential to implement quality assurance policies, also in support of efforts for reducing inequalities through the European Commission Initiative on Breast Cancer*, though the details and modalities of such an approach still remain to be defined. Factors like the importance of transparently selecting the stakeholders participating in the definition of ECIBC guidelines and quality assurance scheme, as well as the need for quality assurance (and, when/if needed, standardisation) to be based on evidence and adapt to and manage change, were highlighted as key to develop an impacting and meaningful scheme.

Session 2: The methodological framework for incorporating evidence in healthcare policies: the example of ECIBC as a neutral and collaborative platform

This session focused on the methods currently used for ensuring that healthcare is, as much as possible, based on evidence. It presented the most rigorous approaches used as applied to: clinical research (randomised control trials–RCTs), guidelines development, development of quality indicators based on evidence, accreditation and standardisation.

The discussion points of this session focused on the importance of developing quality indicators simultaneously with guidelines (to incorporate the most updated evidence) and of selecting the measurable and most meaningful ones (that can adequately measure

the impact of critical outcomes) to ensure that the implementation of the *European QA scheme* will be useful.

The importance of incorporating in the ECIBC previous work on guidelines and quality assurance schemes in breast cancer was pointed out, while emphasising that only what fulfils key criteria (*e.g.* methodologies applied for evaluating the evidence) should be used for the development of the ECIBC objectives and in particular for the development/piloting/validating the *European QA scheme*. The use of modelling may provide help in cases where there is no direct evidence. The concept of ‘evidence-based’ was discussed in depth and clarified *e.g.* by pointing out that evidence does not come only from RCTs. Patient reported outcomes are becoming increasingly important in evidence-based medicine, as well as

the use of systematic ‘anecdotes’ (such as health insurance data linked to treatment data) providing narrative-type data collection which would be still ‘evidence-based’. The ‘Idealised structure’ for developing a QA scheme was presented by Martin Underwood, from the University of Warwick, UK who we kindly acknowledge for letting us use its proposed flowchart for *Figure 5*. The importance, of an ex-ante selection of indicators both to evaluate and monitor the impact of a scheme, and for the periodic assessment of the healthcare services covered by that scheme was emphasised. The ECIBC project is following this line of action.

Participants agreed that, in case standards (or regulatory frameworks) would be useful for the ECIBC, they should be developed using rigorous methodologies to ensure a structured and correct incorporation of evidence.

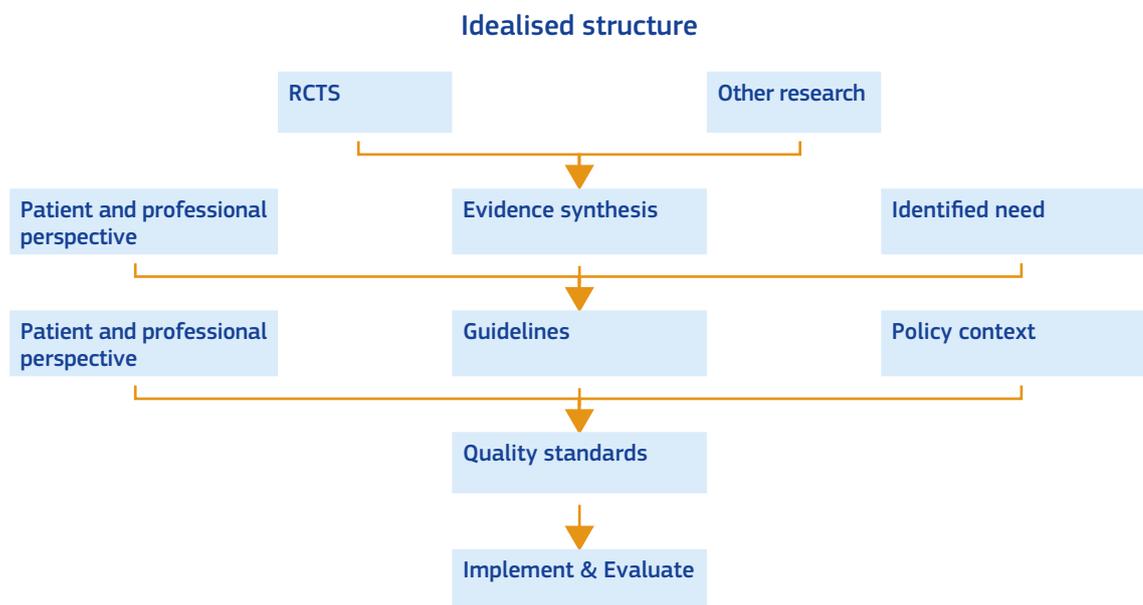


Figure 5. *Idealised structure for developing the QA scheme.*



Figure 6. Session 2.

Session 3: Stakeholder's views, needs and expectations on how to promote the implementation of the quality assurance scheme for breast cancer services

This session was designed to bring to the table the different stakeholders' views, needs and expectations on whether standardisation can be a useful tool, if correctly applied, to supporting the quality of breast cancer-related processes (*e.g.* testing, diagnostic activities, *e*-Health-related aspects).

There were presentations from the government perspective, medical professionals and the patient/consumer point of view. In particular, and linked to the *European QA scheme*, the description on how the legal framework will guide its development, implementation

and deployment, was provided by EA as an innovative proposal of how an accreditation /certification procedure could be set up for breast cancer screening and diagnosis.

It was important in this session to bring together all stakeholders in order to actually set a common ground for what is understood by standardisation, as its meaning (and perception) varies depending on the areas of application. In particular, there was discussion on what could be gained by standardisation from the patient perspective.

A definition that has been suggested for this field, and perhaps encompasses the process JRC is following for the ECIBC, is 'standardisation is the process by which healthcare products/services are chosen by a commit-

tee of key stakeholders, taking into account evidence-based results, to ensure quality patient care while adhering to fiscal responsibility'.⁸

Standardisation has been defined as a two-phase process (Botzen & Dobusch, 2012): generation and diffusion. Generation is where standardisation begins, bringing together key stakeholders to define the goals of the standardisation, and diffusion is where standardisation is disseminated among the individuals affected. These phases both feed off and develop from one another, in a dynamic way. The driving force for both phases is legitimacy, which gives authenticity to the standard.

International and European standards are documents developed on the basis of stakeholders' consensus and facilitated by standardisation organisations. They may be the basis for certification and accreditation of healthcare facilities, methods, and processes, if the parties involved wish to do so. Standards are voluntary in the sense that there is no obligation to comply with them, except in those cases where legislation mandates it.

Clinical guidelines addressing the diagnosis and treatment of patients are built on evidence-based medicine and developed by healthcare professionals, health professional bodies and other recognised institutions within the framework of specified procedures. Standards should not be considered

as an alternative to clinical guidelines until they are not evidence-based and a similar degree of transparency as is starting to be applied for guidelines development should be applied for developing standards.

Colorectal cancer screening was used as an example of population-based intervention in need of harmonisation (*i.e.* standardisation) in the testing area. While in Europe about 70 million Faecal Immunochemical Tests (FIT) are performed annually, the test performances and procedures are not harmonised (the instruments used to collect a sample collect varying quantities of it, the buffer concentrations for the sample collectors are different, the assay calibration is poorly defined and there is not an adequate external quality assurance service – *e.g.* proficiency testing), creating uncertainties which may lead to scepticism and concerns for citizens/patients.

The example of FIT within colorectal cancer screening well exemplified the overarching aim of the conference to foster an open discussion around the areas where harmonisation/standardisation can be of support in achieving quality cancer services.

Participants agreed, that the key objective for patients and carers is to be offered treatment based on the best available evidence which changes as scientific research develops, and that any tool supporting and improving treatment compliance to evidence would have a positive impact on outcomes.

The need for agreement on understandable terminology and concepts was highlighted

8. <http://www.mohawkssi.com/en/resourcesSection/Standardization.asp>.

by most participants. The discussion focused on the need to keep the development of guidelines and standards as separate items.

This session led to the final one, where the fruits of scientific research, innovations and new technologies, in the breast cancer field were discussed.

Session 4: Innovations, new technologies, future trends and perspectives

The final session was dedicated to present the current state of the art of different potential areas (genetic testing, biomarkers, new technologies, and precision medicine) that could benefit more from having standardised procedures, as well as to identify potential research gaps in this area.

There were presentations on how genetic-risk adjusted prevention strategies, molecular testing and genetic biomarkers could be used adequately and consistently to increase benefits for patients and reduce harms of incorrect diagnoses or treatments.

The rapid evolution of biomedical health research and its application in the clinical field was emphasised. In parallel, the importance of ensuring that the fast development of new technologies does not impede a rigorous approach was as well highlighted.

The added value of a rigorous approach for new technologies and research application to care would be to increase safety of the health systems. In this continuously changing environment, there is a need for a structured and methodologically rigorous update in the application of new evidence in clinical practice. This will ensure that patients receive the care that has been proven, through evidence, to have greater benefits and produce fewer harms.

The discussion points for this session focused on analysing the clinical utility of different tests. Particularly in the case of biomarkers (as predictive and prognostic tools for personalised/precision medicine), it was agreed that there is a lot of room for improvement. Risk-adjusted prevention strategies were suggested as possible tools for designing future cancer screening programmes.

The benefit of having both reference materials and reference methods in oncology was suggested, as their use (and co-use) is currently very limited. *Research towards harmonisation of both the pre-analytical and analytical phases of diagnostic testing could be extremely valuable. The accuracy of testing is crucial to guarantee that medications can be safely provided to those who will truly benefit the most from them. This includes e.g. reference materials, tests, and possibly reference networks.*

5. Conclusions

During the concluding session of the event, the main conclusions were brought forward and a set of questions were raised to encourage participants to send their feedback to the

event organisers via e-mail. Questions posed and feedback received during and after the event are reported below.



Figure 7. Conclusions session.

a. During the 2 day conference, the objective of *bringing together a rich set of stakeholders to discuss a possible role for using standards, in this case, to improve the quality of breast cancer care in Europe, was achieved*. It should be noted however, that it could have been even more enriching if regulators, insurance providers and funders, who were invited but could not attend, could have also participated.

Question:

Can you suggest any other stakeholders you think should be involved for future events of this type?

Feedback:

Some suggestions were received regarding the participation of stakeholders such as regulators, insurers (AIM), cancer networks, more patient representatives, and industry representatives.

b. There appeared to be general consensus regarding *the need for an agreed terminology for key concepts and processes*, so all stakeholders are able to speak and understand a common language within the field of healthcare quality vis-a-vis quality assurance, accreditation and standardisation.

Questions:

Do you think a glossary would be useful?

If this area of work were taken forward, would you (or another person or entity known to you) be interested in becoming involved?

Feedback:

Indeed, there was an overall agreement from the participants that a common glossary would ease the communication in this area. The glossary would need to draw on and combine existing definitions from authoritative sources. In addition, a translation of the interpretation of laboratory or clinical findings would be useful to ensure everyone is using the same terminology. Some names of individuals for participating in this work were suggested.

C. It was generally agreed that the application of the tools (guidelines/accreditation/standardisation) for breast cancer care services could be potentially useful also for other cancers (e.g. gastrointestinal and prostate cancers) and diseases. However, challenges and difficulties to extrapolate this model were highlighted, e.g. for the use of *standardised methods*, to *measure impact* and to *demonstrate validity of approaches*. The need to connect different information systems (*interoperability*, e.g. clinical databases, patients' dossiers) and *harmonise the coding* was particularly underlined for bio-informatics (e.g. precision medicine) and cancer registries.

Questions:

Do you think that there would be a need to develop further work in these areas?

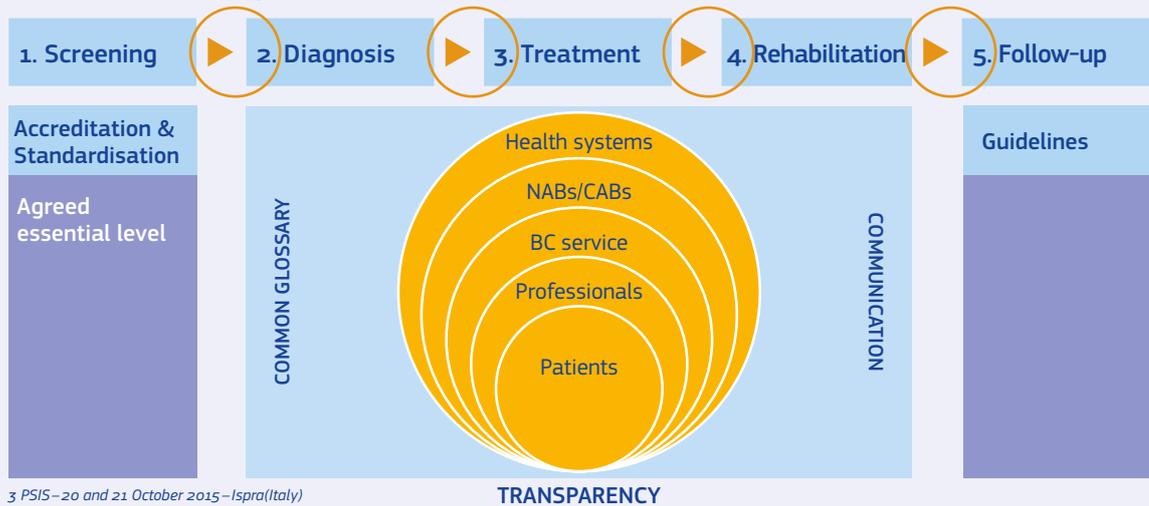
If this area of work were taken forward, would you (or another person or entity known to you) be interested in becoming involved?

Feedback:

There were suggestions towards further work in various areas such as trying to standardise computerised recording systems across administrations; work on developing instruments to measure the patient perspective/experience/satisfaction in relation to quality assurance or quality improvement guidelines; pooling ideas about cancer screening quality across several cancers, not focus on only breast quality standards that may or may not be applicable to others; a coordinated effort is needed to tackle challenges in the difficulties to measure and the need to demonstrate the validity of measurements as poor or inappropriate measurement can lead to wrong decisions. Some names of individuals for participating in this work were suggested.

d. The framework for the *European QA scheme* is accreditation. A variety of VOLUNTARY tools are planned to be used, aiming at ensuring not only accurate development, but, most importantly, a high implementation rate. Tools for the ECIBC-like guidelines, accreditation, and standards (ISO 17065 and 15189 are used for the scheme) – are neutral tools to be designed by the experts/stakeholders in the field and, most importantly, should be used in a fit-for-purpose way. Standards, like guidelines and QA schemes, need to be updated upon new needs/evidence/context.

ECIBC: the voluntary QA scheme, WHICH ARE THE KEY LEVELS?



3 PSIS – 20 and 21 October 2015 – Ispra (Italy)

Figure 8. ECIBC key levels.

Questions:

Would it be useful to see how the ECIBC project could apply all the above mentioned tools? For the ECIBC QA scheme in particular, a flexible accreditation standard (ISO 17065) could be used. It allows integrating specific requirements (e.g. based on guidelines-derived evidence) into the scheme. As there is not yet a methodological framework on how to proceed for integrating evidence into a QA scheme governed by ISO 17065, the ECIBC could develop it. Would you (or a person or entity known to you) be interested in collaborating to see how integration of evidence in the ECIBC, and in particular its QA scheme can be obtained?

Feedback:

There was a suggestion on the need for expert technical advice on the flexibility of ISO standards and on the potential relevant standards ISO 17021:2015 and EN 15224:2012, from those familiar both with ISO standards and healthcare accreditation, as well as preferably oncology. Integration of a QA scheme was considered useful, though it was suggested that the patient journey/service pathway aspects should be considered as a process. There was also a suggestion to look at other systems, perhaps not ISO (NICE, UK). Some names of individuals for participating in this work were suggested.

e. For patients, the most important aspect is that they receive high quality care and know what they can expect to get from prevention and care services. The importance of communication to/with citizens/patients was stressed throughout the conference, as well as the importance of measuring citizen/patient satisfaction and of taking the results into account in the quality plans of *e.g.* breast cancer services aiming at complying with a European scheme.

Questions:

Would it be useful to develop framework for measuring citizen/patient satisfaction for use in the quality assurance part of the ECIBC project?

If this area of work were taken forward, would you (or a person or entity known to you) be interested in becoming involved?

Feedback:

The feedback received was somewhat mixed on this issue, as there were some comments concerned with the cost/benefit of such work due to, among others, the difficulty in interpreting satisfaction data and the fact that the measured differences may be very small. There was a suggestion to measure patient experience as it was suggested to be a more reliable and measurable variable, but validated tools should be used. Involvement of the European Innovation Partnership on Active and Healthy Ageing was suggested. Another suggestion was to first begin the work on screening quality and later focus on patient satisfaction. Some names of individuals for participating in this work were suggested, and the OECD.

6. Evaluation of the conference

There were a total of 71 registered participants for the event and one speaker was unable to attend.

A total of 37 evaluations (52%) were provided to the organisers. Not everybody answered all questions, as some participants did not attend all sessions. The evaluation form used is presented in *Annex 5*.

There were 24 evaluations by individuals who had first been informed about this event through JRC, 10 evaluations from individuals who had first been informed about this event through CEN-CENELEC, one individual had been informed through EARTO and two individuals who did not answer this question.

In the event preparation, with regard to the Programme, 97% people felt the event met

(64%) or exceeded (33%) their expectations, with regard to the objectives, 94% felt this way. With regard to the usefulness of the meeting materials, 89% felt the event met or exceeded their expectations and 83% felt this way for the provision of additional resources.

With regard to the evaluation of the four main sessions of the event, in all cases the evaluations showed that more than 86% of respondents felt all the sessions met or exceeded their expectations.

In the first session 8% people felt that it was below expectations with regard to the discussion time/interaction between participants, and close to 6% felt this way with regard to the content and quality of the presentations. In the second session, close to 6% respondents thought the balance between presentations was below their expectations.

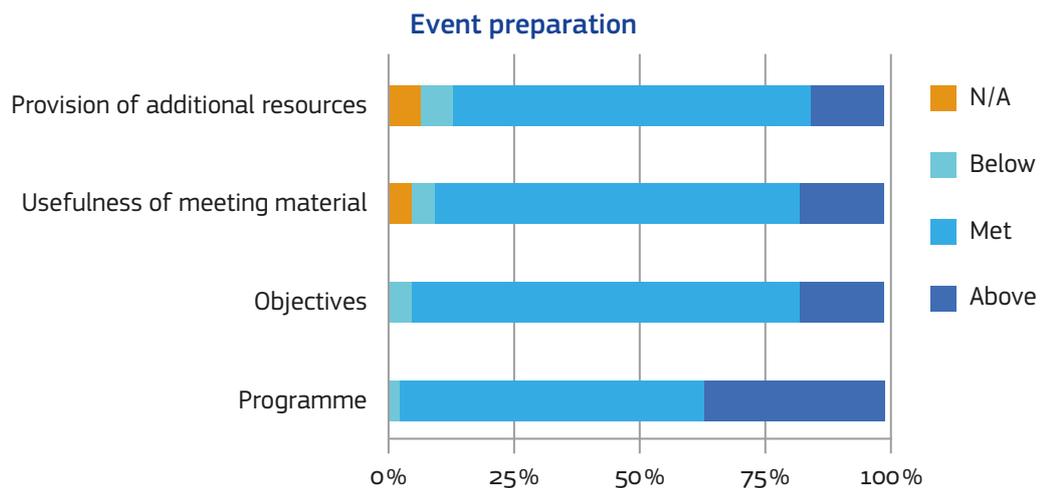


Figure 9. Event preparation.

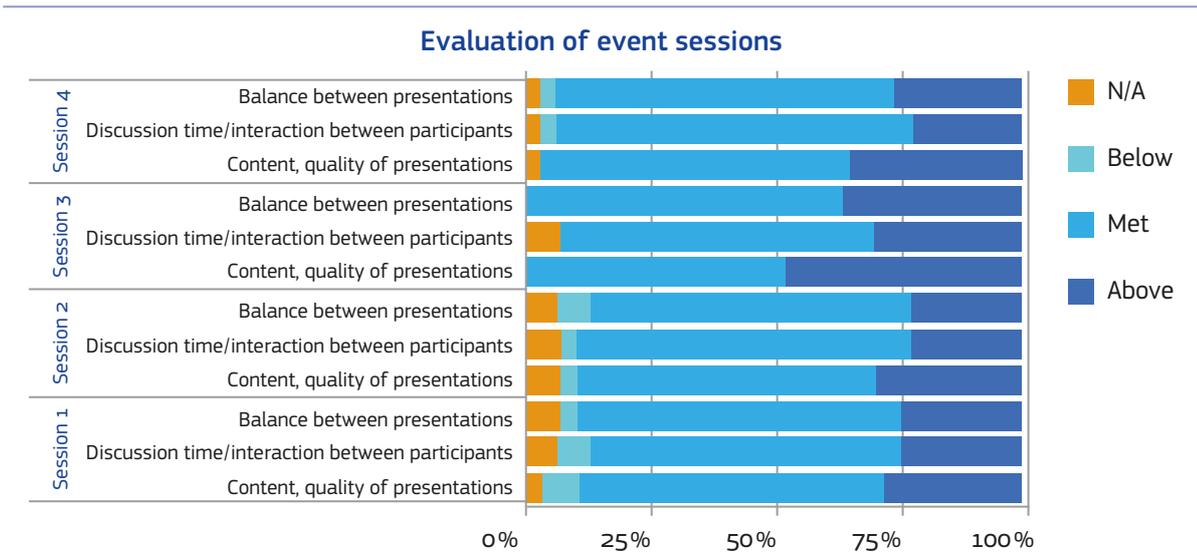


Figure 10. Evaluation of event sessions.

In session 3, 100% participants thought the content and quality of the presentations, and the balance between presentations met or exceeded their expectations. In session 4, these percentages were 97% and 94%, respectively. In both sessions 94% participants felt the discussion time/interaction between participants met or exceeded their expectations.

With regard to the organisation of the event, 61% felt the organisation, location, communication with participants, side events

exceeded their expectations and 36% met their expectations.

Finally, for the overall evaluation of the event, 42% thought it had exceeded their expectations and 58% felt it met their expectations.

In both these questions, organisation and overall evaluation, none of the participants felt the event was below their expectations.

Additional comments made by respondents can be made available upon a written request.

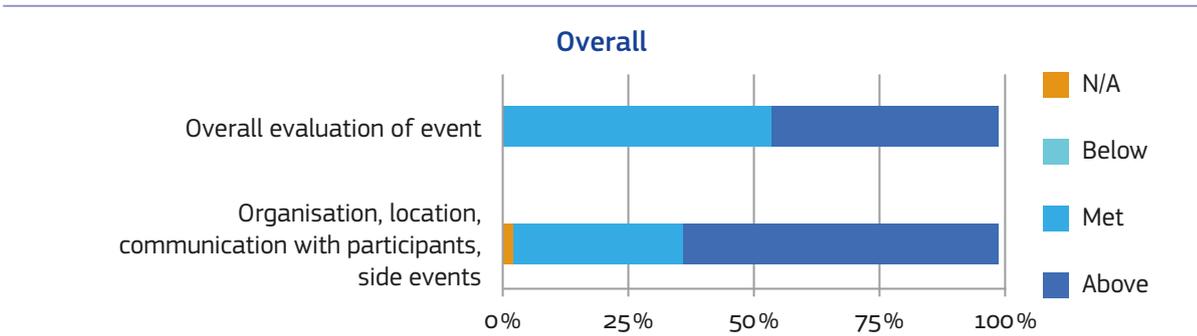


Figure 11. Overall evaluation of the event.

7 . Final remarks

The conclusions for this event, as seen in *Chapter 5* of this report, are structured according to the final session when participants were asked to provide feedback on the outcomes of the event proposed, often in the shape of a question, as many topics appeared to need further discussion.

On the 27th November, a short conclusion report was sent out to all participants asking their feedback on what they considered the main outcomes of the event. Specific suggestions to the questions posed were received from seven participants only, but some comments were included in the anonymous participation feedback forms they were asked to fill in during the event (see *Chapter 6*).

The overall clear message that came through with this event was that a dialogue between breast cancer care and standards should continue to be fostered. Working groups on

specific topics were proposed. The JRC will follow up carefully the indications received both during the meeting (including comments in the participation feedback forms) and after (via e-mail to the questions posed in the conclusion session).

In *Annex 4* there is a list of readings suggested by participants.

An agenda of possible actions will be developed in coordination with the organisers. In addition, those participants (or readers of this report) who would like to be involved in this work, are warmly invited to contact JRC at the e-mail below.

jrc-cancer-policy-support@ec.europa.eu

The JRC will ensure that messages will be also distributed to the other two co-organisers, CEN-CENELEC and EARTO as appropriate.

Annex 1: List of participants

Table 1. List of participants.

First Name	Last Name	Organisation
Pablo	ALONSO	Iberoamerican Cochrane Centre
Massimo	AMBROSIO	Joint Research Centre
Per	ANDERSEN	Norwegian Directorate of Health
Karen	BENN	Europa Donna
Christine	BERLING	Institut National du Cancer
Jan	BOGAERTS	European Organisation for Research and Treatment of Cancer
Hein	BOLLENS	European Commission
Anke	BRAMESFELD	Joint Research Centre
Erik	BRIERS	Europa Uomo
Stefan	CANO	European Institutions
Fatima	CARDOSO	European Society for Medical Oncology
Raquel	CARVALHO	Joint Research Centre
Peter	CHURCHILL	Joint Research Centre
Alberto	COSTA	European School of Oncology
Sarada	DAS	Standing Committee of European Doctors
E.G.Elisabeth	DE VRIES	University Medical Center Groningen
Silvia	DEANDREA	Joint Research Centre
Liesbet	DEPREZ	Joint Research Centre
Markus	FOLLMANN	German Cancer Society
Claudio	GALLI	Abbott Diagnostics
Ashok	GANESH	CEN-CENELEC
Franco	GATTAFONI	ACCREDIA
Paolo	GIORGI ROSSI	AUSL Reggio Emilia
Karl	GRUEN	Austrian Standards Institute
Nick	GULDEMOND	University Medical Centre Utrecht
Stephen	HALLORAN	NHS Bowel Cancer Screening Programme
Michael	HUEBEL	DG SANTE
Günther	JONITZ	Berlin Chamber of Physicians

Table 1. (cont.)

First Name	Last Name	Organisation
Henrik Lykkegaard	JØRGENSEN	DANAK
Anna	KARLSSON	Equalis
Susan	KNOX	Europa Donna
Isabell	LADIGES	European Commission
Donata	LERDA	Joint Research Centre
Lifang	LIU	European Organisation for Research and Treatment of Cancer
Jesús	LÓPEZ ALCALDE	Joint Research Centre
Carmen	MARTOS	Joint Research Centre
Charlie	MCLAUGHLAN	The Royal College of Anaesthetists
Fabienne	MENOT	HAUTE AUTORITE DE SANTE
Elena	NARDINI	Joint Research Centre
Luciana	NEAMȚIU	Joint Research Centre
Katja	NEUBAUER	European Commission
Ciarán	NICHOLL	Joint Research Centre
Frédérique	NOWAK	Institut National du Cancer
Maitane	OLABARRIA UZQUIANO	CEN-CENELEC
Simon	PAIN	Norfolk and Norwich University Hospital
Leslie	PENDRILL	SP Sveriges tekniska forskningsinstitut/EARTO
Mauro	PETRILLO	Joint Research Centre
Liisa	PYLKKÄNEN	Joint Research Centre
Maddalena	QUERCI	Joint Research Centre
Stefano	RAPI	AOU Careggi
Andrea	REDELSTEINER	Austrian Standards Institute
Patricia	RISCHITOR	Joint Research Centre
Anna	ROUILLARD	European CanCer Organisation
Tiziana	RUBECA	Ispo
Gianluca	SALERIO	UNI - Ente italiano di Normazione
Aleksandra	SANAK	Council of European Dentists
Francesco	SARDANELLI	University of Milan–Research Hospital Policlinico San Donato
Zuleika	SAZ PARKINSON	Joint Research Centre

Table 1. (cont.)

First Name	Last Name	Organisation
Rita	SCHMUTZLER	University Hospital Cologne – Center Hereditary Breast and Ovarian cancer
Charles	SHAW	Former Program Director of CASPE Research
Alberto	SIMEONI	CEN-CENELEC
Christian	SINGER	Center for Breast Health – Medical University of Vienna – General Hospital Vienna
Giorgio	STANTA	University of Trieste
Andreas	STEINHORST	European co-operation for Accreditation
Thecla	STERK	MedTech Europe
Alberto	TORRESIN	EFOMP and Niguarda Ca'Granda Hospital
Asli	ULUTÜRK	Joint Research Centre
Martin	UNDERWOOD	University of Warwick
Jan	VAN DER POEL	Raad voor Accreditatie
Michela	VUERICH	ANEC – The European Consumer Voice in Standardisation

Annex 2: Abstracts

Key Note Presentations

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

The European Commission (EC) launched the European Commission Initiative on Breast Cancer (ECIBC), a project to support European countries with a harmonised and benchmarked policy for improving quality while reducing inequalities.

Along the last 20 years, many guidelines were made available at national/regional/local level, and quality assurance (QA) schemes were developed and running across EU. However, an evidence-based approach was not always applied and the auditing systems are diverse.

The JRC, coordinator of ECIBC upon DG SANTE mandate, with the invaluable collaboration of ECIBC National Contacts, patients' associations and experts, has mapped out how BC services are organised in Europe, ISO standards applied for BC care, availability of BC data, and BC QA schemes. The next steps are (i) develop evidence-based guidelines, (ii) set-up a modular, flexible and voluntary QA scheme underpinned by that evidence and by Regulation (EC) No 765/2008 on accreditation, including training requirements and a dedicated website.

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*

On 1 January 2014, the Austrian Breast-Cancer Screening Programme 'Early Detection' was launched, which replaced nation-wide opportunistic mammography programmes for the early detection of breast cancer before 2014. The new programme offers numerous advantages for women: women between 45 and 69 make an appointment at a radiological facility participating in the programme and have to bring along just their e-card (national insurance card) to the early-detection mammography with the e-card being unlocked for early detection mammography every two years. In addition, women receive an invitation letter reminding them of the examination. No separate invitation or doctor's referral is required. Women between 40 and 44, as well as from the age of 70, can register for the pro-

gramme via the phone service or through an online form at www.frueh-erkennen.at. They have to bring along the invitation they receive about a week from registration and their e-card to the early-detection mammography. The national program meets comprehensive quality criteria for the examination – such as standardised double medical evidence based on the four-eyes-principle as well as the latest technology – and obligatory certification for radiologists participating in the early detection programme ensure the programme’s high quality. In addition, women with dense breasts are offered additional routine breast ultrasound examinations to overcome inherent shortcomings of mammography.

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

Standards can be seen as codes of good practice, with which compliance is not compulsory. They are the result of a multi-stakeholder process based on well recognized findings in compliance with internationally recognized principles of transparency, openness, impartiality and consensus, effectiveness and relevance, and coherence. Standards are initiated only upon reasoned requests. In the field of healthcare services the main reasons for these requests are cross-border mobility of patients, absence or lack of relevant national regulations in some EU Member States and uncertainty of both patients as well as healthcare service providers. Quality assurance, cost reduction, risk mitigation and increasing transparency are also the substantive drivers for such initiatives. But should this field already be well covered by legislation or by clinical guidelines, the added value of a standard must be challenged. Once a request for new work is approved the standard is drafted by representatives of those affected by the specific issue of interest. Challenges in the drafting and decision-making processes of European healthcare service standards are mainly due to misconceptions what a standard and what standardization is and due to the heterogeneity of national legislation in Europe. The policy of the European Union, *i.e.* national authorities are responsible for the organization of healthcare services, shall be clearly distinguished from the private autonomy of the European Standardisation System. Unlike European Standards for medical devices, European Standardization of healthcare services is relatively new and needs a due and careful care and consideration for the mutual benefit of healthcare professionals and especially for the protection and safety of patients.

Session 1: European Policies in the healthcare area and the European Commission Initiative on Breast Cancer

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

The European Union has been active on cancer prevention and control since 1985. Cancer screening is a cornerstone of this approach. In the 2003 Council recommendations on cancer screening, the Council set out set principles of best practice in the early detection of cancer, and invited all Member States to take common action to implement national population-based screening programmes for breast, cervical and colorectal cancer, with appropriate quality assurance. European Guidelines for quality assurance for breast, cervical and colorectal cancer screening have been developed as benchmarks on how to go about screening. Based on this work, DG Health and Food Safety have requested the Commission's Joint Research Centre to develop a new version of the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, and a voluntary European Quality Assurance scheme for Breast Cancer Services underpinned by accreditation and evidence-based guidelines – the European Commission Initiative on Breast Cancer.

EU activities in the area of eHealth, interoperability and standardisation – **K. NEUBAUER**, *Directorate-General for Health and Food Safety (DG SANTE)-D.3*

The Commission is committed to the provision of safe and high quality cross-border services to European citizens. Stakeholder consultation and involvement is a necessary part of European cooperation. It is in the interest of Europe's patients that health professionals, regulatory authorities and representatives from research and development, as well as accreditation and standardisation organisations, bring together their knowledge and expertise to consider the best methodologies and tools to ensure good quality healthcare.

In the field of eHealth, interoperability and standardisation developments – as part of the Digital Single Market Strategy – are on-going, creating the right conditions to exchange healthcare data between EU Member States. These developments are for the benefit of patients ensuring that eHealth solutions – electronic health records, telemedicine, electronic prescriptions – developed and deployed at national level are interoperable across borders. Member States are working together within the eHealth Network set up by the Directive 2011/24 on patients' rights in cross border healthcare and on the standardisation and improved interoperability of eHealth solutions and mHealth applications.

The best standard is the one you do not see – **H. BOLLENS**, *Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)-B.3*

The European Standardisation System is a system built by industry for industry. The EU is using this system for its legislative initiatives and EU policy objectives. The European Commission is particularly proud of the long standing and successful public-private partnership with CEN, CENELEC and ETSI. The European Standardisation System is

running under the European Standardisation Regulation [(EU)1025/2012], in force since 2013. It sets clear roles, competences and financing schemes for each actor involved in the process. In addition, it foresees the inclusion of SME and societal stakeholders in order to address the new challenges ahead. In this context, the European Commission has signed and is financially engaged in new public-private-partnerships with organisations representing, at European level, SMEs (SBS), consumers (ANEC), environmental topics (ECOS) and social/workers' interests (ETUC).

After having implemented the legal base and the operational as well as the financial frameworks until 2020, it is now time to focus on how European standardisation can deliver on the 10 Juncker Priorities for Europe. That focus has been stimulated following an in-depth Independent Review that the European Commission has carried out (2014-2015) on the European Standardisation System. There is common understanding that results can be delivered under the EU priorities when the long standing public-private partnerships are reinforced and particular attention is given to new areas, amongst others, such as to the Digital Single Market, services and the healthcare sector providing growth and more competitiveness to the EU.

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

In 2008, the European Parliament and the Council of the European Union adopted Regulation (EC) No 765/2008 that provides a legal framework for the provision of accreditation services across Europe. According to the Regulation each EU Member State has established a national accreditation body as the sole provider of accreditation services in that country. Each National Accreditation Body works in the public interest, ensuring that organisations supplying so-called conformity assessment services such as medical examination and certification are competent and fit to do so. The National Accreditation Bodies are organised and monitored under the auspices of the European co-operation for Accreditation (EA), the European, officially recognised infrastructure for accreditation.

Accreditation is gaining increased recognition as an important and practical tool in the delivery of objectives, in particular in the health care sector, but also in all areas related to environment, safety and security. That is demonstrated inter alia by the cooperation between EA and the European Commission for the elaboration of the EU scheme for breast cancer services underpinned by accreditation.

Breast cancer health care excellence is driven by the need to provide confidence and assurance in the delivery of a competent and reliable service to persons affected by cancer

diseases. Accreditation, based on the proposed EU scheme for breast cancer services, will support and strengthen this assurance. Accreditation will provide the appropriate tool for healthcare providers to demonstrate that they have undergone a rigorous process to ensure that their patients consistently receive high quality services delivered by competent staff.

The ECIBC – Overview of QA schemes and ISO standards in Europe for breast cancer care [1/2] – **S. DEANDREA**, *JRC-IHCP*

Background. The JRC was assigned with the task of developing a voluntary European Quality Assurance scheme for breast cancer services based on the European legal framework on accreditation. **Methods.** A search of external quality assessment schemes for breast cancer care already in place in Europe was carried out using different strategies in MEDLINE, website of relevant scientific societies, and EC Reports. **Results.** Seventeen schemes specifically addressing breast cancer were identified in Europe and thirteen countries have at least one scheme in place. The number of breast cancer services implementing such schemes goes from three to 277 with a median of 23. In some countries, more than one scheme is present, with a maximum of four schemes present in one country. **Conclusion.** European-wide scheme could help harmonise the situation in Europe and ensure that European citizens receive the same quality of care regardless of where they live.

The ECIBC – Overview of QA schemes and ISO standards in Europe for breast cancer care [2/2] – **A. ULUTÜRK**, *JRC-IHCP*

Background. The objective of this survey was to collect information from the National Accreditation Bodies in collaboration with European Cooperation for Accreditation on the accreditation status of the countries. **Methods.** The survey included two questionnaires and a data protection form distributed by e-mail. The participants were the members of EA. **Results.** Twenty-five out of 35 contacted countries responded, corresponding to a response rate of 71%. The most applied standard resulted to be ISO 15189 and the most covered stage of care diagnosis. **Conclusions.** Accreditation status is diverse across Europe; some countries don't harbor accredited/certified organisations on breast cancer care, and others use different standards in different stages of care. A harmonisation in quality benchmarking would enhance equality in patients' care.

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*

The need for the development of a new category of written standards—so-called 3rd generation—which includes a holistic view of added human value, can be found in breast cancer, person-centred healthcare. Clinical outcome measures in support of requirements and standards need to capture the pertinent health constructs in breast cancer care they claim to measure. Many variables, such as disability and quality of life, are however difficult to measure in this area, as illustrated with examples from the BREAST-Q project. Psychometric invariant measure theory is enabling some progress in the form of improved resolution, more quantitative scales and comparability need for better decisions about health. A coordinated European effort to tackle these challenges and investigation of potential symbiosis with major European programmes, such as the major EURAMET/EMPIR Art 185 Horizon 2020 European Metrology Innovation & Research programme, are recommended.

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

Advocating for standards, quality assurance and best practice—Europa Donna—The European Breast Cancer Coalition is a non profit, evidenced based advocacy organization. We promote best practice and seek to inform women, the lay public and policy leaders concerning this disease through policy, education and information programs. The best way to ensure that women receive the proper interventions carried out by properly trained medical professionals is for them to be diagnosed and treated in a specialist breast unit set up with defined quality standards. Women must know that the same standards for service prevail across all European countries.

Working with the EU Parliament, two resolutions and two Declarations have been passed describing the breast services that women in Europe should have a right to receive. These services were defined in the 2006 ‘European Guidelines on quality assurance in breast cancer screening and diagnosis’. ED has worked to disseminate the information contained in these Guidelines so that women across Europe would have access to the same high level of services. We advocate for the development of revised EU Guidelines and a quality assurance program that can be implemented and evaluated in each country. As a stakeholder we are working with the ECIBC to realize these aims.

Session 2: The methodological framework for incorporating evidence in healthcare policies: the example of ECIBC as a neutral and collaborative platform

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

The presentation explains the interplay of evidence based guidelines, cancer registries and certified centres in order to create quality indicators within the German health care system. According to the German National Cancer Plan the German Guideline Program in Oncology (GGPO) coordinates and funds the development of clinical practice guidelines. A core tool for implementation and evaluation of guidelines recommendations are guideline based quality indicators (QI). The methodology how to develop these QI should be harmonized and transparently reported. In Germany a standardized process to generate and assess proposals of guideline based QI is practiced by two guideline programs (national disease management guidelines (NVL) and GGPO). The QI development Group should be composed interdisciplinary: patients, experts from the guideline development group, representatives from institutions involved in quality assurance, especially cancer registrations and certification, and methodologist are constant members of this working group. QI should be assessed for relevance, scientific soundness and feasibility and finally approved in a consensus process. A process for keeping QI up-to-date and for gaining the information of performance of QI in health care is important for keeping the quality circle in oncology alive.

The GRADE approach: an emerging consensus to develop guidelines – **P. ALONSO**, *Ibero-american Cochrane Center*

The Grading of Recommendations Assessment, Development and Evaluation (short GRADE) Working Group (www.gradeworkinggroup.org) has developed a common, sensible and transparent approach to grading quality of evidence and strength of recommendations. More than 80 organizations, such as the WHO or the Cochrane Collaboration, have provided input into the development of the approach, and have endorsed it and/or have started using it.

With the help of a European funded project called DECIDE (www.decide-collaboration.eu), GRADE has also developed and evaluated methods that address the targeted dissemination of guidelines. Examples of those methods include the interactive Summary of Findings tables (isof.epistemonikos.org) and the Evidence to Decision frameworks (ietd.epistemonikos.org/#/). Finally, an open-access software to facilitate the development of evidence summaries and health care recommendations using the GRADE approach has also been made available (www.guidelinedevelopment.org).

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

Clinical trials play a central role in Evidence Based Medicine. In oncology, the role of randomized trials is evolving due to the advance of knowledge. Driven by genomic and translational information, there is a tendency to split cancers into smaller segments. As a result, in the future there will be a higher need to glean information from non-randomized data, and spend more efforts on merging data sources.

Another element is that uptake of new ‘practice changing’ research may depend on resources put into dissemination. Whereas pharmaceutical drug access to market is highly regulated, the uptake of improved methods in other treatment modalities follows a different track. Especially in these areas, standard settings by national and international bodies can have a beneficial effect.

We will discuss some data that lead to the questions:

- how is a standard established
- how is it supported
- how can it be monitored.

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

While quality assurance or development is about doing things right, health technology assessment (HTA) is about doing the right things. Health technology is the application of scientific knowledge in health care and prevention. Examples of Health Technology are: Diagnostic and treatment methods, Medical equipment, Pharmaceuticals, Rehabilitation, Prevention methods, Organisational and supportive systems within which health care is provided. Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method. The origins of HTA are Evidence Based Medicine, health policy analysis, and health economics.

EUnetHTA was established to create an effective and sustainable network for HTA across Europe—we work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries. EUnetHTA supports collaboration between European HTA organisations that brings added value at the European, national and regional level through:

- facilitating efficient use of resources available for HTA
- creating a sustainable system of HTA knowledge sharing
- promoting good practice in HTA methods and processes.

An example of an HTA of prognostic tests for breast cancer recurrence (uPA/PAI-1 [FEM-TELLE], MammaPrint, Oncotype DX) will be presented.

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

International travel, medical tourism and trade have created a demand for reliable assessment of healthcare provision across borders, and for information which is accessible to patients, insurers and referring institutions. External assessment schemes for healthcare providers may be clustered into three types: statutory regulation and institutional licensing, International Standardization Organisation certification, and voluntary systems such as peer review and healthcare accreditation. Increasing complexity of healthcare provision, pressures for public accountability and expectations of professional self-governance place a burden on the inspectors and the inspected. If only to contain costs of external assessment and to increase access to reliable information for patients and insurers, the three approaches must work together rather than compete. This paper summarises the origins, aims, authority and methods of the three general models, describing current pressures and opportunities for convergence (between systems and across borders) in the UK and in Europe.

Session 3: Stakeholders' views, needs and expectations on how to promote the implementation of the quality assurance scheme for breast cancer services

How standardisation can contribute in Cancer care – **P.K. ANDERSEN**, *Norwegian Directorate of Health*

I will draw a line from the start of using health care standards in Norway through development of international standards for Management, Medical Devices and Systems, to the present discussions on standards for Health Care Services initiated from the EU-Commission. The attention is drawn to the resistance we see from important stakeholders and the strategic discussions on how to find a common platform to take advantage of using standards without interfering with an important and well established tradition for development of clinical guidelines.

I will give a presentation on the clinical cancer pathways established in Norway and point at the possibility to have this as standardized organizational structures using clinical guidelines as part of the structures.

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

ANEC will share its experience in consumer representation in European standardisation related to (healthcare) services with some examples of consumer relevant requirements that ANEC succeeded in including in existing deliverables.

ANEC will also present the consumer expectations from CEN strategy on possible further healthcare standardisation, as well as ANEC's views on what role standardisation could play in facilitating the implementation of the guidelines resulting from the European Commission Initiative on Breast Cancer.

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

The case for colorectal cancer screening is stronger than that for most other cancers. It is estimated that over 75000 lives are lost annually because Europe has not fully embraced population-based CRC screening. Whilst colonoscopy remains the definitive investigation for colonic cancer, screening for the presence of blood in stool is the RTC-proved mechanism to identify the high-risk group needing this invasive and expensive investigation. The faecal immunochemical test for haemoglobin (FIT) has now replaced the crude colorimetric guaiac faecal occult blood test and heralds markedly higher analytical sensitivity and specificity. The 2010 'EU Guidelines on Quality Assurance in Colorectal Cancer Screening' made FIT the preferred screening test; however, it is being adopted internationally without product standardisation and risks the credibility and effectiveness of CRC screening. Where are the deficiencies and what needs to be done?

Improving outcomes through quality certification of breast units – **A. COSTA**, *European Cancer Organisation (ECCO)*

A seminal paper by Cataliotti *et al.* published in 2000 in the *European Journal of Cancer* introduced the term 'breast unit' in the European cancer community. The authors took a firm position on the fact that breast cancer patients would receive a better treatment by an organized team of dedicated specialists than by single doctors. Rightly or wrongly they also decided the key numbers to define a Breast Unit: a clinical centre which treats at least

150 new cases per year with surgeons performing at least 50 procedures per year, radiologists seeing at least 2000 mammographies and dedicated specialists, including nurses, for the disciplines involved. But one thing is for a centre to declare itself a Breast Unit and another thing is to have its activity and quality certified by an external and independent body.

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

The emergence of quality surveillance for breast cancer services in England over the last ten years – **S. PAIN**, *NHS England*

The National Peer Review Programme is a quality assurance programme for NHS cancer services that reviews clinical teams and services to determine their compliance against national measures derived from national guidance, as well as the assessment of quality aspects of clinical care and treatment. The Programme, established in 2001, encompasses a whole systems approach to quality and safety in relation to the patient experience and clinical outcomes. The programme involves self-assessment by cancer service teams, external review by programme team members and visits to clinical services undertaken by professional peers and service users/carers.

The programme has been instrumental in reducing variation in practice and credited with highlighting significant opportunities for improvement, which have subsequently been implemented, including multi-disciplinary team-working, enhanced recovery programmes and the provision of nurse-led services.

Session 4: Innovations, new technologies, future trends and perspectives

Challenges of risk-adjusted prevention strategies for breast cancer – **R. SCHMUTZLER**, *Uni-Klinik Köln*

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

The development of precision medicine in oncology requires that molecular diagnostics be performed nationwide so as to ensure health care equity. To this end, France's Health Authorities, with the National Cancer Institute (INCa), have set up a network of 28 molecular genetics centers for the provision of selective molecular tests. They are accessible to all patients, irrespective of the cancer care establishment and the corresponding costs are wholly covered by the reimbursement system. Next Generation Sequencing technologies (NGS) are being implemented in daily practice in these centers and allow investigating panel of dozens of genes and identifying larger numbers of patients bearing actionable mutations in their tumor. Achieving and maintaining quality is crucial in a context of constantly evolving technologies and nationwide coverage. For this purpose, INCa fosters multidisciplinary and the development of a collaborative network between centers, and has set up a dedicated quality-assurance program.

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

In the 'classical' clinical trial patients are selected for inclusion. This means that patients are standardised for treatment during the trial. After receiving market authorisation there is only the question of disease and if the precise prescription conditions match the clinical trial conditions, if so the medicine is allowed pending reimbursement. But these patients are no longer selected for inclusion so for a proportion of patients the medicine may not work as in this stage 'wild type' patients are treated.

Same holds for disease markers that are tested on a selected population of patients. Further if more than one company offers the new marker the risk is that the results may differ in a relevant way and that treatments differ equally. Therefore we need standardisation of markers and their testing and a new model of clinical trials where third phase may 'use' less patients and the benefit and unwanted side effects (EudraVigilance) are monitored in 'wild type' patients.

New technologies in diagnostics – **C. GALLI**, *MedTech Europe*

The continuous efforts of R&D from medical technology companies have led to the implementation of breakthrough diagnostic devices in medical oncology. For breast cancer, the outstanding relevance of testing for HER-2neu in improving patients' care and survival has been demonstrated for quite some time, while more recently the identification of BRCA mutations has greatly improved the preventive strategies and clinical management options. Other promising biomarkers are clearing the way towards diagnostic use. Among these, many are seeking multiple markers to achieve better accuracy (*e.g.* molecular arrays

or multigene panels to be run on a single sample). Despite the possibilities offered by innovation, the majority of assays are only recommended for follow-up and monitoring, whereas the need for implementation for diagnosis and selective screening has also increased. A joint effort among diagnostic manufacturers, European regulatory bodies and health care authorities will guarantee the availability and appropriate use of diagnostics in this field.

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

During the past decade a large number of genetic biomarkers with potential diagnostics and therapeutic utilities in breast cancer have been identified and several companies have developed multigene prognostic tests for clinical use. In addition, advances in technologies like next generation sequencing and digital PCR have raised new possibilities for biomarker detection and quantification. In order for these biomarkers and technologies to move to wider clinical implementation international standardisation efforts are required. Reference materials are an essential tool for standardisation as they allow performance evaluation of the assays for biomarker detection or quantification and provide a measurement scale for the comparison of patient results from multiple clinical studies or multiple laboratories. The different aspects related to obtaining reliable and comparable measurement results by using certified reference materials are illustrated in an example of treatment monitoring in chronic myeloid leukaemia.

Annex 3: Agenda

DAY 1 Morning

Welcome and opening

Ciarán NICHOLL, *JRC*

Introduction to the Workshop

Peter CHURCHILL, *JRC* – Ashok GANESH, *CEN-CENELEC*

Key Note Presentations

- **Moderator:** Ciarán NICHOLL, *JRC* – Head of the Public Health and Policy Support Unit of the Institute for Health and Consumer protection (PHPS-IHCP)
- **Speaker 1:** The JRC perspective: The ECIBC: a useful example on how Guidelines, QA schemes and, potentially, standardisation can work together – Donata LERDA, *JRC*
- **Speaker 2:** The EARTO perspective: Experience of the Austrian initiative for a nationwide screening program to detect breast cancer – Prof. Christian 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 – Karl GRÜN, *Austrian Standards Institute – ASI*

DAY 1 Afternoon

Session 1: European Policies in the healthcare area and the European Commission Initiative on Breast Cancer

- **Moderator:** Peter CHURCHILL, *JRC*
- **Rapporteur:** Isabell LADIGES, *Directorate-General for Health and Food Safety (DG SANTE)*
- **Speaker 1:** 2003 Council Recommendation on Cancer Screening and the European Initiative on Breast Cancer – Michael HÜBEL, *Directorate-General for Health and Food Safety (DG SANTE)*
- **Speaker 2:** EU activities in the area of eHealth, interoperability and standardisation – Katja NEUBAUER, *Directorate-General for Health and Food Safety (DG SANTE)*

- **Speaker 3:** The best standard is the one you do not see – **Hein BOLLENS**, *Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROWTH)*
- **Speaker 4:** EA European Accreditation support to the European Commission – Regulation 765:2008 – NLF – **Andreas STEINHORST**, *European co-operation for Accreditation (EA)*
- **Speaker 5:** The ECIBC – Overview of QA schemes and ISO standards in Europe for breast cancer care – **Silvia DEANDREA & Asli ULUTÜRK**, *JRC*
- **Speaker 6:** Why the quality of quality metrics counts in healthcare: an illustration from breast cancer surgery – Prof. **Stefan CANO**, *Plymouth University Peninsula Schools of Medicine and Dentistry* & Prof. **Leslie 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 – **Susan KNOX**, *Europa Donna*

Session 2: The methodological framework for incorporating evidence in healthcare policies: the example of ECIBC as a neutral and collaborative platform

- **Moderator:** **Charlie MCLAUGHLAN**, *Deputy Chief Executive and Director of Clinical Quality, The Royal College of Anaesthetists*
- **Rapporteur:** **Martin 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 – **Markus FOLLMANN**, *German Cancer Society (DKG)*
- **Speaker 2:** The GRADE approach: an emerging consensus to develop guidelines – **Pablo ALONSO COELLO**, *Iberoamerican Cochrane Centre*
- **Speaker 3:** The role of clinical trials in establishing and refining standards – **Jan BOGAERTS**, *European Organisation for Research and Treatment of Cancer – EORTC*
- **Speaker 4:** How can healthcare standards be standardised? – **Charles SHAW**, *former Program Director of CASPE Research*

DAY 2 Morning

Session 3: Stakeholders' views, needs and expectations: on how to promote the implementation of the quality assurance scheme for breast cancer services?

- **Moderator:** **Karen BENN**, *Europa Donna*
- **Rapporteur:** **Gian Luca SALERIO**, *Italian Organisation for Standardisation – UNI*
- **Speaker 1:** How standardisation can contribute in Cancer care – **Per Kristian ANDERSEN**, *Norwegian Directorate of Health*



Figure 12. Lunch break.

- **Speaker 2:** Standardisation and societal needs: ANEC experience – **Michela VUERICH**, *The European consumer voice in standardisation – ANEC*
- **Speaker 3:** Challenges for Colorectal Cancer Screening – a biomarker with no standards – **Stephen P. HALLORAN**, *Professor Emeritus, University of Surrey*
- **Speaker 4:** Improving outcomes through quality certification of breast units – **Alberto COSTA**, *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 – **Jan VAN DER POEL**, *EA*
- **Speaker 6:** The emergence of quality surveillance for breast cancer services in England over the last ten years – **Simon PAIN**, *NHS England*

Session 4: Innovations, new technologies, future trends and perspectives

- **Moderator:** Prof. **Leslie PENDRILL**, *Researcher, SP Metrology/SP Technical Research Institute of Sweden/EARTO*
- **Rapporteur:** **Stefano RAPI**, *AOU Careggi, Toscana & SIBiOC*
- **Speaker 1:** Challenges of risk-adjusted prevention strategies for breast cancer – **Rita SCHMUTZLER**, *UniKlinik Koln*
- **Speaker 2:** Implementation of nation-wide molecular testing in oncology in the French Health care system: quality assurance issues & challenges – **Frederique NOWAK**, *Institut National du Cancer*

- **Speaker 3:** From standardising patients to standardising for patients. Precision approaches to the ‘holistic’ patient – **Erik BRIERS**, *Past secretary Europa Uomo and patient advocate*
- **Speaker 4:** New technologies in diagnostics – **Claudio GALLI**, *MedTech Europe*
- **Speaker 5:** Standardisation needs for the measurements of genetic biomarkers – **Liesbet DEPREZ**, *JRC*

Conclusions and open discussion

for identifying and agreeing on a way forward and next steps

- **Moderator:** **Donata LERDA** and **Peter CHURCHILL** (*JRC*)
- **Session 1 rapporteur’s** presentation – **Isabell LADIGES**, *Directorate-General for Health and Food Safety (DG SANTE)- C.1*
- **Session 2 rapporteur’s** presentation – **Martin UNDERWOOD**, *Director, Warwick Clinical Trials Unit, Warwick Medical School, The University of Warwick*
- **Session 3 rapporteur’s** presentation – **Gian Luca SALERIO**, *Italian Organization for Standardization (UNI)*
- **Session 4 rapporteur’s** presentation – **Stefano RAPI**, *AOU Careggi, Toscana & SIBiOC*
- **Round-table and open discussion** – Different perspectives: Commission, Patients, Concerned services, Professionals, EA, CEN-CENELEC, etc.
- **Consensus on roadmap and agenda for action**

Annex 4: Readings suggested by participants

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Annex 5: Participation feedback form

IHCP workshop/conference – participant’s feedback

Dear participant, please take a few minutes to fill out this feedback form. It will help us to assess how well this event met your expectations and will contribute to the improvement of future initiatives. Many thanks for your contribution.

Event:	Putting Science into Standards
Date(s):	20-21 October 2015
Location:	JRC Ispra
Organiser:	JRC Healthcare Quality Team/CEN-CENELEC/EARTO
Participant's name (optional):	
From what organization did you receive the first information about this Event:	CEN-CENELEC <input type="checkbox"/> EARTO <input type="checkbox"/> JRC <input type="checkbox"/>

Event’s preparation	Below expectations	Met expectations	Above expectations	N/A
Programme	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objectives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Usefulness of meeting material in folder	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Provision of additional resources (useful links, downloads, contacts)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session 1 delivery	Below expectations	Met expectations	Above expectations	N/A
Contents, quality of presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discussion time/interaction between participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Balance between presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Session 2 delivery	Below expectations	Met expectations	Above expectations	N/A
Contents, quality of presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discussion time/interaction between participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Balance between presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session 3 delivery	Below expectations	Met expectations	Above expectations	N/A
Contents, quality of presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discussion time/interaction between participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Balance between presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session 3 delivery	Below expectations	Met expectations	Above expectations	N/A
Contents, quality of presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Discussion time/interaction between participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Balance between presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Organisation and Logistics	Below expectations	Met expectations	Above expectations	N/A
Organisation, location, communication with the participants, side events	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
General Comments	Below expectations	Met expectations	Above expectations	N/A
Overall evaluation of the event	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any additional comment (especially for explaining the reasons for 'below expectations')				

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Table 1. List of participants

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