EUROPEAN COMMISSION
DIRECTORATE GENERAL
JOINT RESEARCH CENTRE
Directorate F – Health, Consumers and Reference Materials
Unit F1 Health in Society

European Commission Initiative on Breast Cancer (ECIBC)

Testing subgroup - Pathology

9 September 2017: 08:30 – 12:30

Minutes

Document history			
Version	**Date**	**Drafted by**	**Comments**
0	23/10/2017	Colin MACKAY	Initial draft version proposed by MOSTRA
1	31/10/2017	Silvia DEANDREA	JRC version for subgroup approval
2	13/11/2017	Silvia DEANDREA	Approved and published version

Presentations are available on the ECIBC web hub and/or on the CIRCABC dedicated space

List of Participants in Annex I

The Agenda is available at http://ecibc.jrc.ec.europa.eu/-/gdg-working-meeting.

Testing (pathology) subgroup meeting

19 September 2017: 08:30 – 12:30

The JRC, in the person of Ciarán Nicholl, welcomed all participants and opened the session.

A Healthcare Quality Team member gave a summary presentation from the subgroup (imaging) meeting of the previous day. She explained the definition of reference docs as well as how they should be selected, sourced, collected and assessed according to a list of criteria modified by the subgroup on the basis of a proposal by DG SANTE. The subgroup should follow the same process for pathology documents: transposition of DG SANTE criteria for best practices into the Reference Documents methodology, searches and assessment of reference documents.

The main topic for discussion in the meeting was the results of the systematic review performed by CCIb on the impact of accreditation (ISO 15189, ISO 17025, ISO 17020 or outside European legal framework) on pathology laboratories, complemented by a study of the grey literature conducted by a consultant, Dr. Ray Lambert. . Dr. Lambert presented the results of his search and a member from CCIb presented the Evidence-to-Decision (EtD) via teleconference. The study performed by Dr. Lambert allowed CCIb to add one additional study not retrieved applying the search string in the databases used.

Meeting participants commented on the EtD and all comments were registered by the notetakers. An amended version of the EtD integrating all comments will be distributed and discussed by the whole QASDG at the November meeting.

A major discussion took place on whether the cost of accreditation was captured by the EtD. As any outcome related to costs was not prioritized in the formal expert panel consultation prior to the search, analysis of costs could only be derived by information included in the papers selected on the basis of the prioritised outcomes of the EtD. Independently, neither the group nor Dr. Lambert was aware of any studies examining this. On the available evidence presented at the meeting, the group concluded that it was not possible to calculate the specific costs incurred by the accreditation process as, in the interest of best practice, some of these costs would also be incurred by laboratories undergoing certification and, indeed, by laboratories not undergoing either accreditation or certification. The group believed that this type of information might be useful to QASDG's decision-making. It was therefore agreed, that, in order to inform the QASDG, a table should be prepared to cover three laboratory types: not certified/accredited, certified and accredited. The costs incurred uniquely in moving from one status to the next (including payments for national accreditation boards (NABs) services or certification authorities) should be captured. This task will be allocated by the JRC to a contractor.

The JRC clarified that the outcome of this exercise would not be a *European Breast Guidelines* recommendation, since the PICO question was issued in order to inform the decision-making process on quality assurance for pathology laboratories in the *European Breast QA scheme*. Nevertheless, the process strictly follows the EtD rules and the exercise outcomes will be published.

In line with the usual EtD process as applied within the GDG, it was agreed that the QASDG will have the opportunity during the November meeting to review the EtD. The GDG Testing subgroup members that participated in the process will also join and participate in that meeting. Following this meeting of the

QASDG and the Testing Subgroup the QASDG will be asked to make a decision on quality assurance for pathology laboratories in the *European Breast QA scheme*.

Action points

Task	Who is responsible	Deadline
Amend EtD according to the changes discussed in the meeting	CCIb	By November meeting
Allocate the task of economic evaluation of accreditation costs	JRC	By November meeting

ANNEX I: Participating GDG-QASDG contributors (members, associated members and external experts)

Jane BEAUMONT, Miranda LANGENDAM, Annette LEBEAU, Elsa PEREZ, Niall PHELAN, Cecily QUINN, Holger SCHUNEMANN, Aliki STATHOPOULOU, Alberto TORRESIN, Francisco TRESSERRA, Ruben VAN ENGEN

Absent GDG-QASDG contributors (members, associated members and external experts)

Solveig HOFVIND (attending training subgroup), Cary VAN LANDSVELD-VERHOEVEN, Chantal VAN ONGEVAL

Participating ECIBC contractors and JRC staff

Pablo ALONSO, Jane BEAUMONT, Ray LAMBERT, Colin MACKAY, Silvia DEANDREA, Grazia FEDERICO, Donata LERDA, Sazan PAKALIN, Thomas PIGGOTT

ANNEX II: List of abstentions due to conflicting interests

No voting