

**The European Commission's
science and knowledge service**

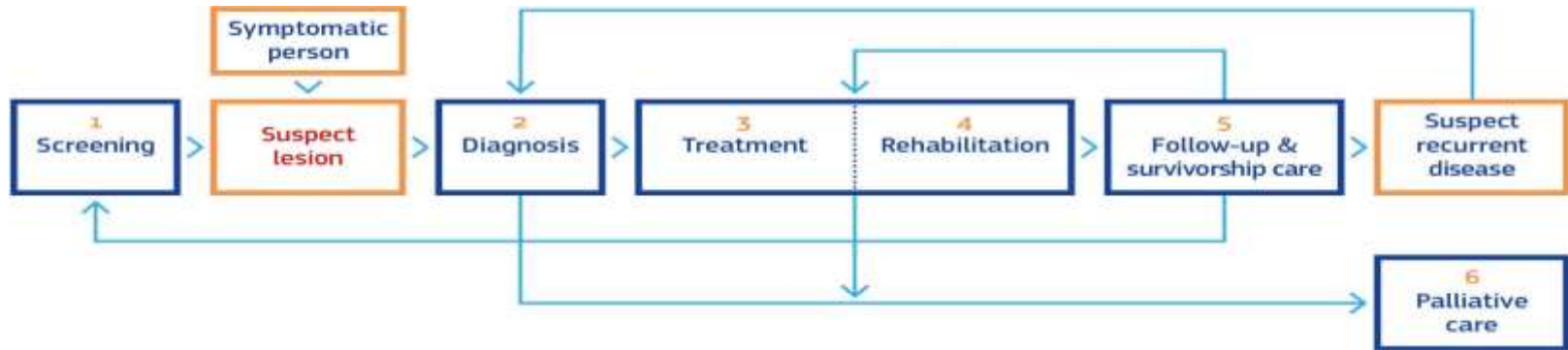
Joint Research Centre

**European
Quality Assurance Scheme
for Breast Cancer Services**

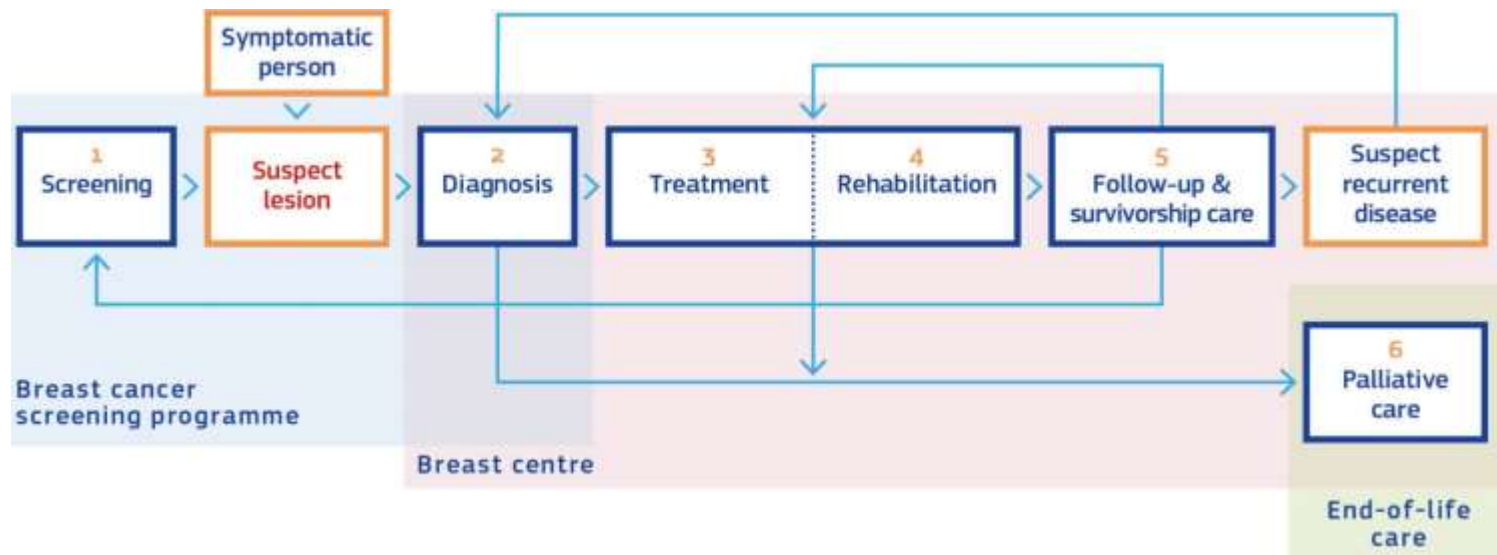
Robert Mansel, chair QASDG
ECIBC Plenary, Varese 24.11.2016



A QA scheme covering all processes



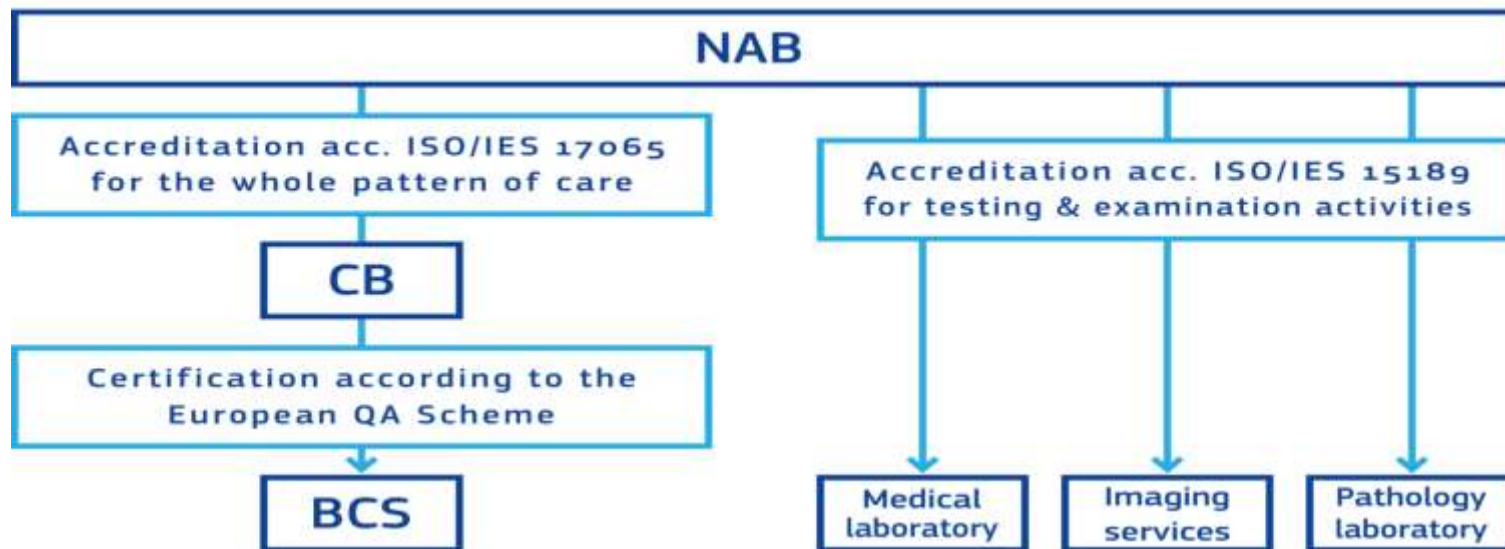
A modular QA scheme



The European QA scheme framework



Relation between NAB, CB and BCS (incl. testing and examination)



NAB=National Accreditation Body

CB= Certification Body

BCS⁴=Breast Cancer Service

European QA scheme public call for feedback*



* Available soon online

- **What:** Scope of the *European Quality Assurance scheme for breast cancer*
- **When:** from 17 February 2016 to 8 March 2016
- **Who:**
 - Organisations
 - National accreditation bodies
 - ECIBC National contacts
 - Healthcare organisations
 - Professional societies or organisations
 - Individuals (*e.g.* Professionals, Citizens)
- **How:** EU survey

Results - 1

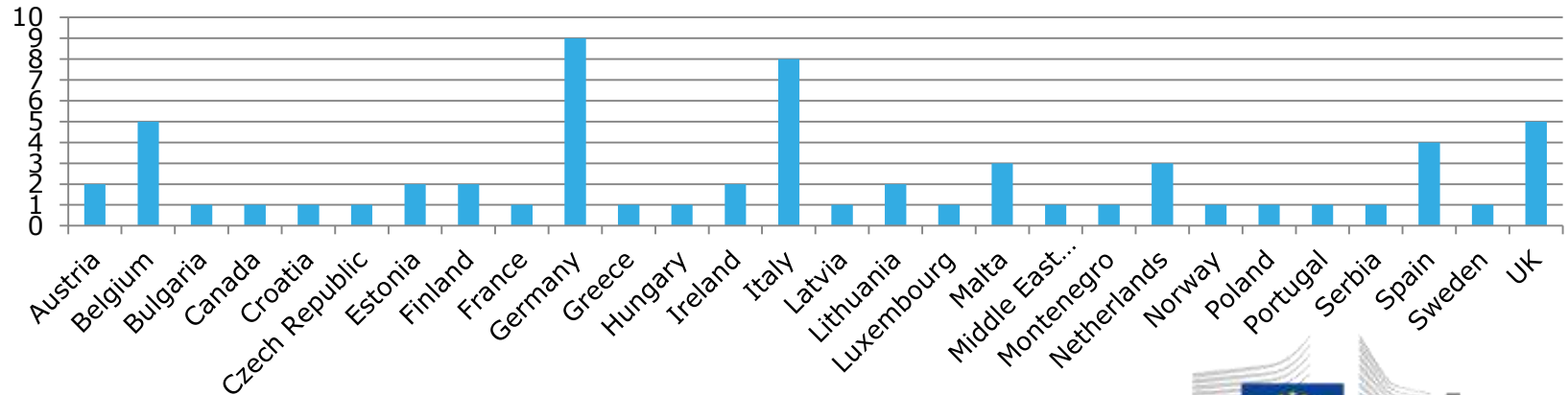


Number of valid responses: 63

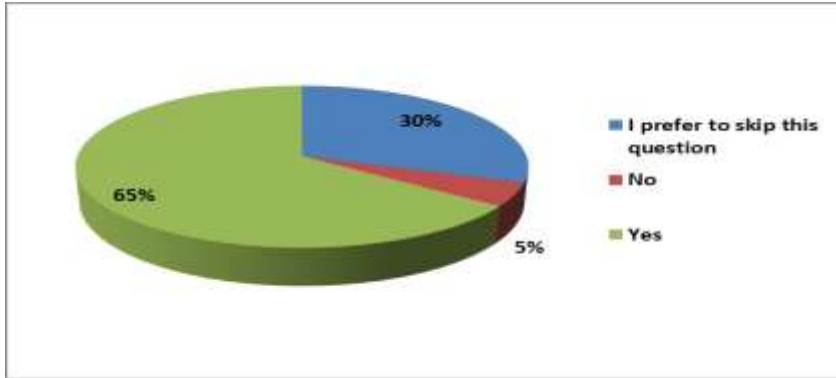
Organisations: 48 (76%)

Individuals: 15 (24%)

Countries' distribution (23/ 28 EU countries)

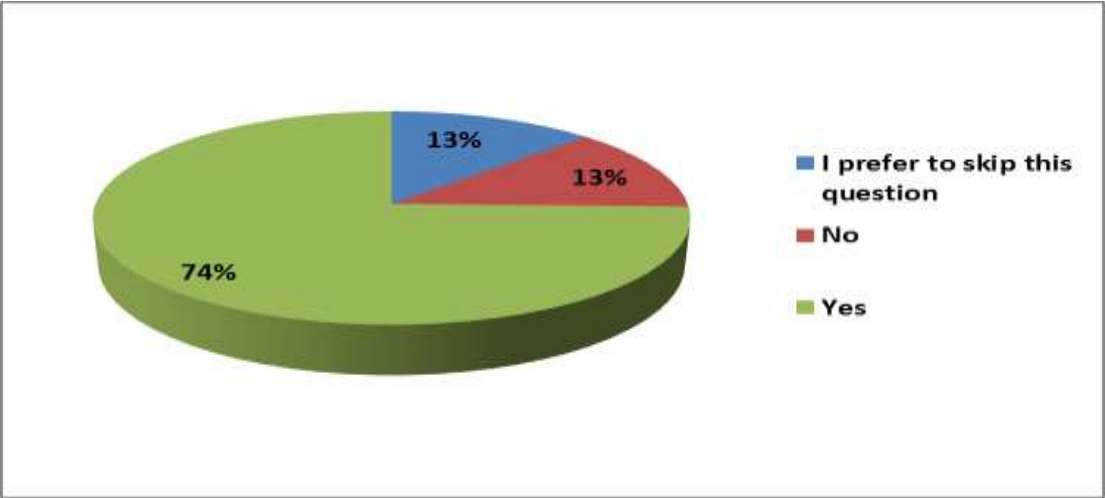


Q: Is the modular approach applicable in the health care system in your country

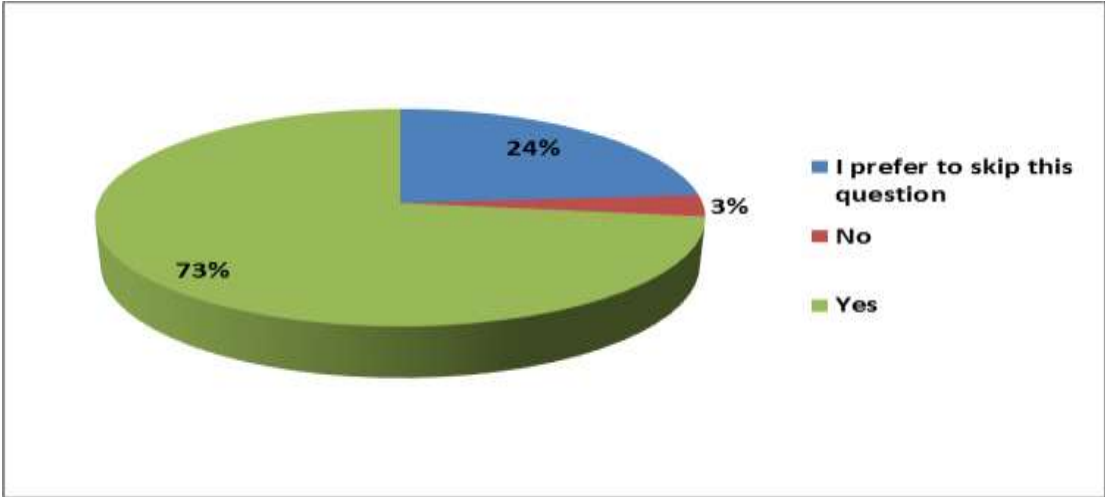


Austria	Yes
Belgium	Yes
Bulgaria	Yes
Croatia	NA
Czech Republic	Yes
Estonia	Yes
EU candidate country	Yes
Finland	Yes
France	Yes
Germany	Yes/ No
Greece	NA
Hungary	Yes
Ireland	Yes
Italy	Yes
Latvia	Yes
Lithuania	Yes
Luxembourg	Yes
Malta	Yes
Montenegro	NA
Netherlands	Yes
Norway	Yes
Poland	Yes
Portugal	Yes
Spain	Yes
Sweden	Yes
UK	Yes/ No

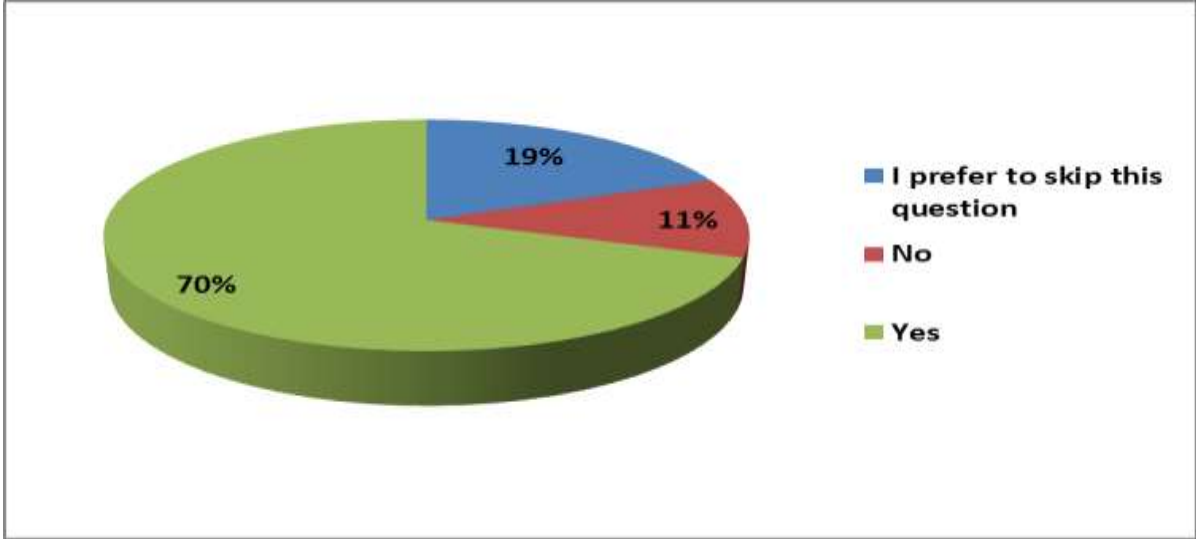
Q: Is the breast cancer treatment pathway applicable in your healthcare system?



Q: Do you agree with the use standard ISO17065:2012 for the accreditation of certification bodies?



Q: Do you agree with the use of standard ISO15189:2012 for testing and examination activities?



Public call for feedback – results



- Respondents represented the main categories of stakeholders and expressed acceptance and positive consideration of the main features of the *European QA scheme*
- Two critical points:
 1. the applicability of ISO 15189:2012 as an accreditation standard for pathology laboratories in Germany
 2. a lack of detailed information on the methodology proposed for the selection of requirements and indicators
- Critical points addressed in the new version of the Scope (published soon) and in the Methodology document (website)

What else has happened so far?



In respect to developing

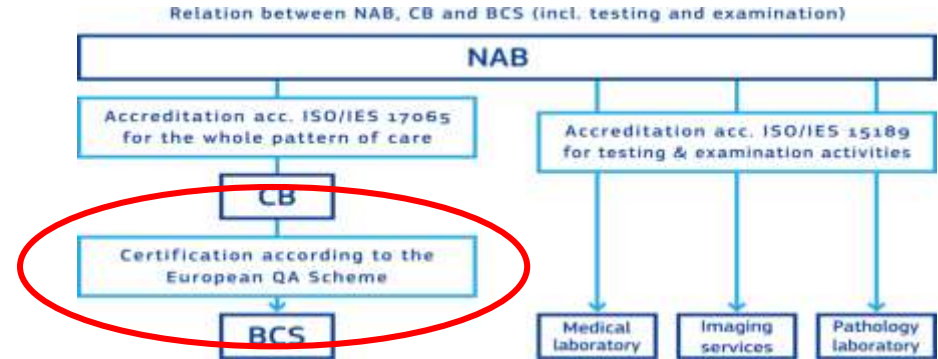
1. Certification of clinical processes
2. Accreditation of conformity assessment body
3. Accreditation of labs, imaging, pathology
4. Data assessment and reporting

1. Certification of clinical processes



Identify requirements/indicators for the quality of clinical care

1. Develop methodology
2. Train QASDG
3. Start identifying requirements/indicators
4. For surgery and organisational structure first



Indicator examples



Patients operated on in a defined time between
Diagnosis and Surgery

All patients undergoing
surgery

Clinical node negative patients undergoing surgery
having sentinel node biopsy

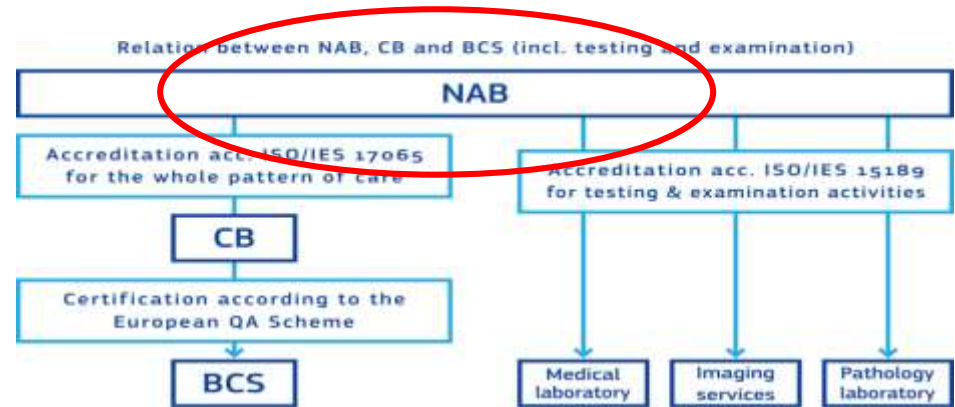
All clinical node negative
patients undergoing surgery

2. Accreditation of conformity assessment bodies



Define Scheme Owner (SO) requirements

- First draft of SO requirements under discussion with EA and Certification Processes subgroup

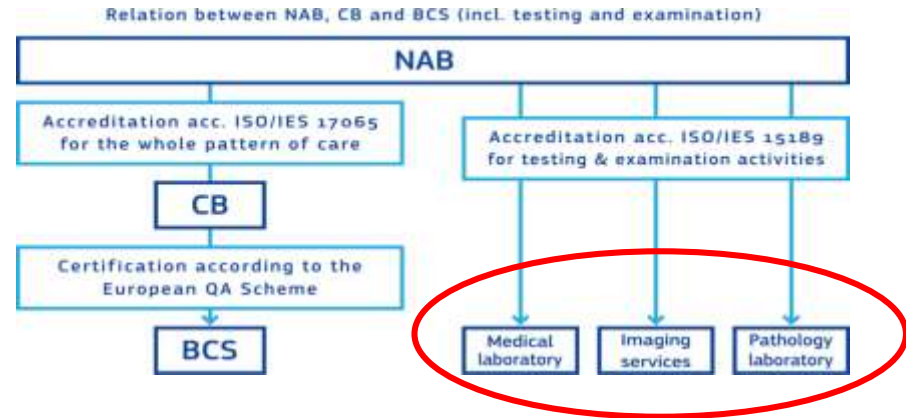


3. Accreditation of labs, imaging, pathology

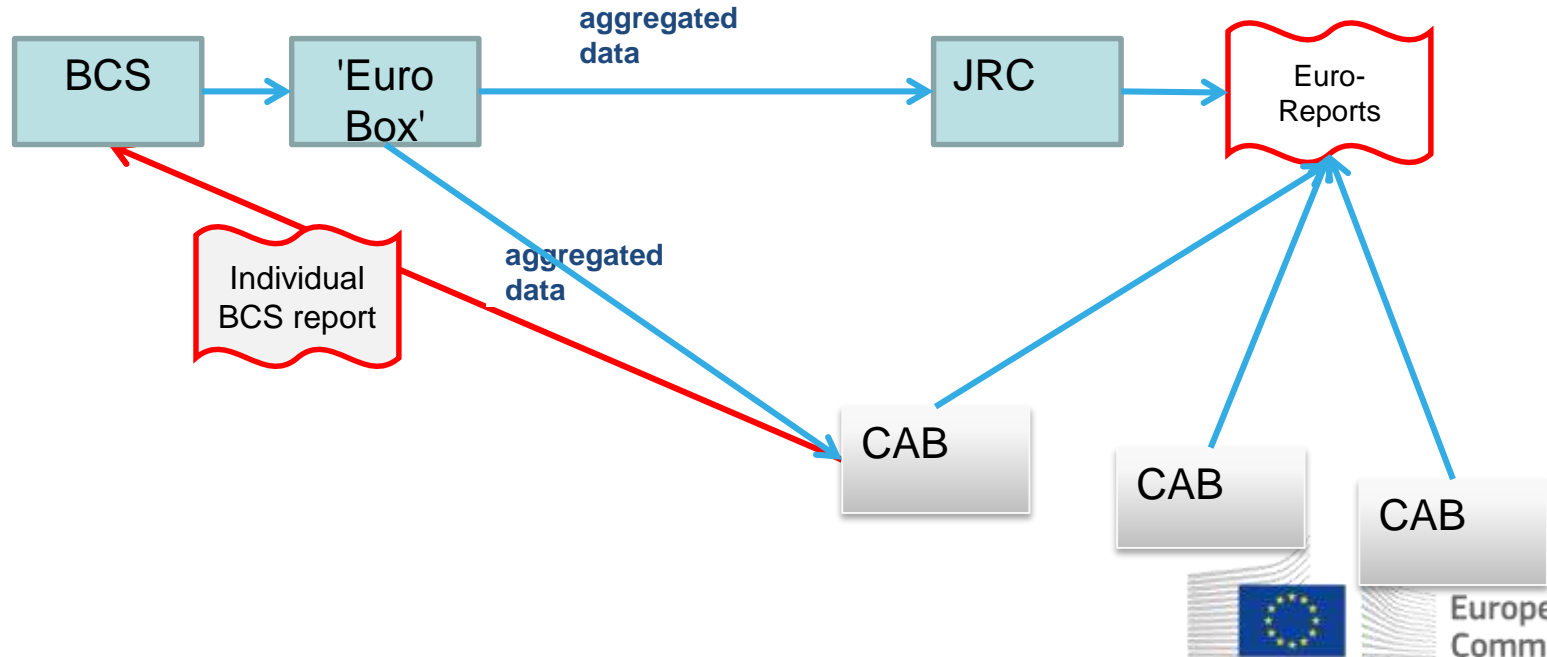


Give details on the use of ISO 15189 or equivalent standards

1. List of tests performed by BCS falling under accreditation
2. Reference documents needed:
 - **Reference documents for what**
 - **Criteria for acceptance of reference documents**



4. Data assessment and reporting: Idea



What is next?



- Requirements/indicators by 2018
- List of tests performed by BCS falling under accreditation by mid-2018
- List of reference documents for imaging and pathology
- IT data management
- Piloting 2018

Thank you and keep in touch!

European Commission Initiative on Breast Cancer
#ECIBC

ecibc.jrc.ec.europa.eu



BREAST
CANCER