



BBMRI-ERIC

Biobanking and
BioMolecular resources
Research Infrastructure

Next Generation Biobanking QMS improvement impacts research output

Andrea Wutte

ESBB satellite meeting, London, 29 September 2015

SAMPLE QUALITY

“Pre-analytical errors still account for nearly 60% - 70% of all problems occurring in laboratory diagnostics, most of them attributable to mishandling procedures during collection, handling, preparing or storing the specimens”.

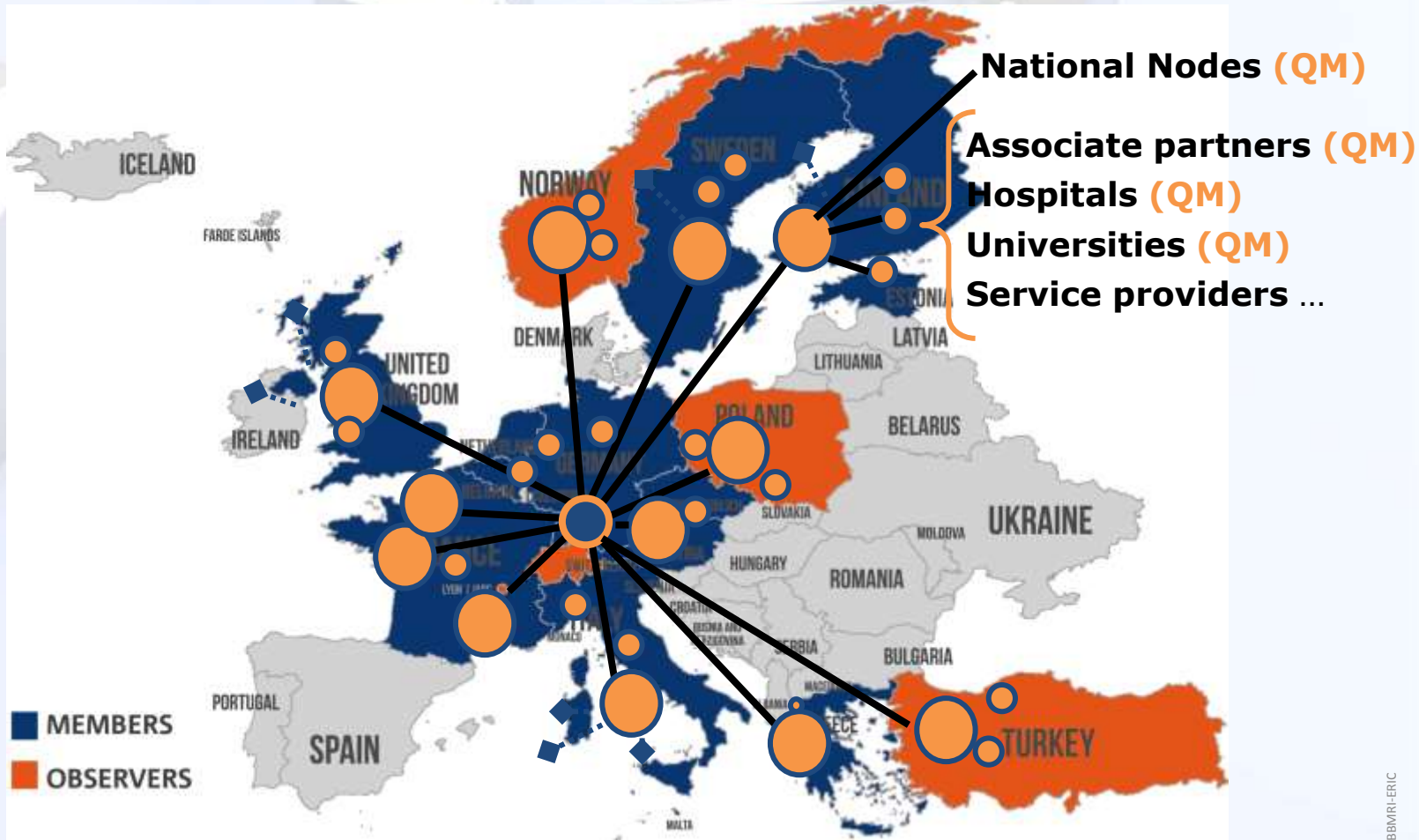
Lippi G. *et al.* Pre-analytical quality improvement: from dream to reality. *Clin Chem Lab Med.* **2011** Jul; 49(7):1113-26.



BBMRI-ERIC

takes it serious

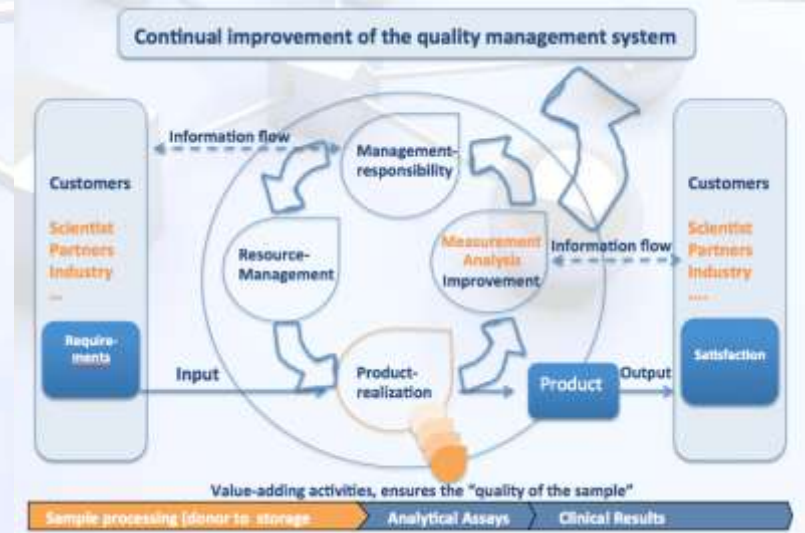
BBMRI-ERIC a distributed network



BBMRI-ERIC QMS

Quality of a Biobank

Quality Management System in general



Quality of the sample (Product realization)

Appropriate pre-examination processes for sample processing







BBMRI-ERIC QMS Requirements

Partner Charter

-  **OECD best practice guidelines for Global Biological Resource Centres Networks.**
-  **SOPs**
-  **WHO/IARC guidelines for biological resource centres for cancer research**

Relevant available international Standards

-  **ISO 9001:2008** Quality management systems Requirements
-  **ISO 15189:2012** Medical laboratories – Requirements for quality and competence
-  **ISO 17025:2005** General requirements for the competence of testing and calibration laboratories
-  **ISO 19011:2011** Guidelines for auditing management systems

BBMRI-ERIC Quality of the sample

for Molecular in vitro diagnostic examinations:

- snap frozen tissue – Part 1: Isolated RNA
- snap frozen tissue – Part 2: Isolated proteins
- FFPE tissue – Part 1: Isolated RNA
- FFPE tissue – Part 2: Isolated proteins
- FFPE tissue – Part 3: Isolated DNA
- venous whole blood - Part 1: Isolated cellular RNA

Soon available:


- venous whole blood - Part 2: Isolated genomic DNA
- venous whole blood - Part 2: Isolated circulating cell free DNA from plasma
- metabolomics in urine, serum and plasma


- And other examinations relevant for BBMRI-ERIC

A graphic consisting of a white speech bubble with an orange outline, containing the text 'Product-realization'. Below the bubble are four overlapping orange circles of increasing size.

**Product-
realization**

BBMRI-ERIC Observer Liaison ISO

 **International Standard for Biobanks and Bioresources**
ISO/TC 276 “ Biotechnology” **timeline 2017/2018**

 **International Standard for Pre-examination processes**
ISO/TC 212 “ Clinical laboratory testing and in vitro diagnostic
test systems” **timeline 2017/2018**

BBMRI-ERIC International Standard developments

WG 01 “Terminology”

Identification of currently used national and international standards, guidelines and other relevant documents, as well as terms and definitions, related to ISO/TC 276 Biotechnology.

WG 02 “Biobanks and Bioresources”

Elaborate a package of International Standards in the Biobanks field including human, animal, plant and microorganism resources for Research & Development aspects

WG 03 “Analytical Methods”

Develop standards for accurate, reproducible and robust measurement and analysis in support of biotechnologies. E.g. **Cell Counting**

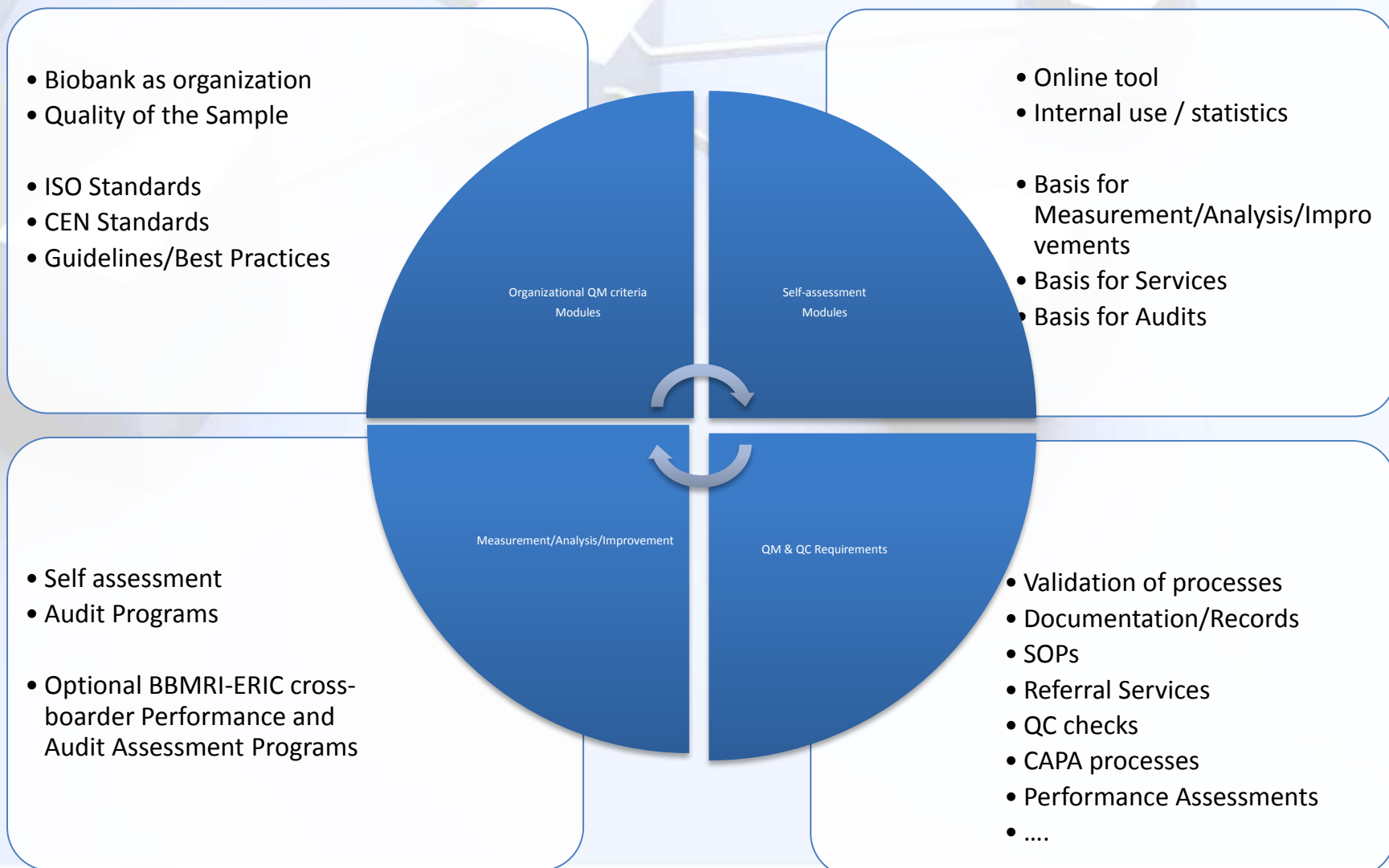
WG 04 “Bioprocessing”

Component Material control, Bioreactor processes

WG 05 “Data processing and Integration”



BBMRI-ERIC Q-Strategy





Q-news:
Q-@:

bbmri-eric.eu/at-a-glance
andrea.wutte@bbmri-eric.eu