BBMRI-ERIC paves the way for reproducible medical research based on biological resources

Andrea Wutte

UK Biobanking showcase BBMRI.nl, London, 16 November 2016
BBMRI-ERIC 20 Members & Observers

Members (16)
Republic of Austria
Kingdom of Belgium
Czech Republic
Republic of Estonia
Republic of Finland
French Republic
Federal Republic of Germany
Hellenic Republic
Italian Republic
Republic of Malta
Kingdom of the Netherlands
Kingdom of Sweden
United Kingdom of Great Britain and Northern Ireland
Kingdom of Norway
Republic of Poland
Latvia

Official Observers (4)
Swiss Confederation
Republic of Turkey
Cyprus
IARC/WHO
BBMRI-ERIC Distributed Network

National Nodes (QM)
Associate partners (QM)
Hospitals (QM)
Universities (QM)
Service providers ...

MEMBERS
OBSERVERS
“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”.

Variabilities of proteins and phosphoproteins in the pre-analytical phase

Tissue is alive: New technologies are required for understanding its complex features.

Virginia Espinosa, Emanuel F. Perales

Influence of Biomarkers in the Pre-analytical Phase


Variability of Protein and Phosphoprotein Levels in Clinical Tissue Specimens during the Preanalytical Phase

Reference K-F Becker
BBMRI-ERIC Work Programme 2016

**8 Work Plans incl. 22 Work Streams**

1) Central Executive Management Office in Graz, Austria  
2) Biobank Outreach  
3) BBMRI-ERIC Common services  
4) Start pan-European and intern. fundraising efforts  
5) Quality  
6) Expert Centres  
7) e-infrastructure  
8) Finish work from BBMRI-PP

**6 Work Plans incl. 15 Work Streams**

1) A new gateway European Biobanks  
2) Quality  
3) Clinical Biobanks  
4) Population-based Cohorts  
5) Biobank Outreach  
6) Expert Centres

**10 Work Plans incl. 35 Work Streams**

1) E-Infrastructure  
2) Quality  
3) Healthcare integrated biobanking  
4) Population-based Cohorts  
5) Common Services for BBMRI-ERIC  
7) International standard developments  
7) Bioimaging  
8) Assessment and improvement of BBMRI-ERIC  
9) Biobank outreach  
10) Continued Work Streams  
11) Projects active ( 9 )
WP 2 QUALITY

Experts Evaluation of QMS for biobanks
- OECD best practice guidelines for Biological Resource Centres
- WHO/IARC guidelines for biological resource centres for cancer research
- NFS 96-900 Certification des Centres de Resources Biologiques
- ISBER Best practices for Repositories
- ISO 9001:2015
- ISO 15189:2012
- ISO 17025:2005
- ISO 19011:2011
- Evaluate already existing Questionnaires, Handbooks and docs

Experts Evaluation of 9 CEN/TS Pre-examination processes
- CEN/TS 16826-1, snap frozen tissue – Part 1: Isolated RNA
- CEN/TS 16826-2, snap frozen tissue – Part 2: Isolated proteins
- CEN/TS 16827-1, FFPE tissue – Part 1: Isolated RNA
- CEN/TS 16827-2, FFPE tissue – Part 2: Isolated proteins
- CEN/TS 16827-3, FFPE tissue – Part 3: Isolated DNA
- CEN/TS 16835-1, venous whole blood – Part 1: Isolated cellular RNA
- CEN/TS 16835-2, venous whole blood – Part 2: Isolated genomic DNA
- CEN/TS 16835-3, venous whole blood – Part 3: Isolated circ. cell-free DNA from plasma
- CEN/TS 16945  metabolomics in urine, serum and plasma

Facts::
86 Experts of 18 Member States
WP 2 QUALITY

- 4 Expert-WG for Evaluation of 9 CEN/TS pre-examination processes

<table>
<thead>
<tr>
<th>Deliverable</th>
<th>month of 2016</th>
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<tr>
<td>1. Set up WG</td>
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<td>2. Definition of evaluation tasks</td>
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<td>3. Nomination of experts for ET</td>
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<td>4. Evaluation process</td>
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<td>5. WG meetings</td>
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<td>6. Documentation for self-assessment tool</td>
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- 1 Expert WG for Evaluation relevant criteria for QMS for biobanks

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<tr>
<td>Building Working Group</td>
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<td>Implementation of results CEN</td>
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<td>Dissemination of self-assessment tool</td>
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WP 2 QUALITY 86 participants / 18 NN
WP 2 QUALITY 86 participants / 18 NN

- WG 1-5: initiation: 3 webcons
- WG 1: snap frozen tissues (34 p): 7 webcons
- WG 2: FFPE tissues (31p): 7 webcons
- WG 3: Venous whole blood (37p): 7 webcons
- WG 4: Metabolomics (27p): 3 webcons
- WG 5: QMS: 5 webcons (38p): 6 webcons

33 / 1 to go 2016
WP 2 QUALITY participant expertise

- Scientist: 35%
- Biobank Manager: 16%
- Biobank Quality Manager: 23%
- Head of Biobank: 12%
- Head of Laboratory: 2%
- Chemist / Lab technician: 2%
- IT-Expert: 4%
- Pathologists: 6%
WP 2 QUALITY

**Procedure documentation**
- Handbook for Quality
- Pilot audit scheme

Acknowledgement:
Anne Carter

**Procedure documentation**
- ¹Self assessment template
- ²Web application REDCap™

Acknowledgement:
¹ Cornelia Stumptner and Kurt Zatloukal (Medical University Graz)
² Sabrina Neururer and Georg Göbel (Medical University Innsbruck)
WP 2 QUALITY

- CEN/TS 16826-1, snap frozen tissue – 1: Isolated RNA
- CEN/TS 16826-2, snap frozen tissue – 2: Isolated proteins
- CEN/TS 16827-1, FFPE tissue – 1: Isolated RNA
- CEN/TS 16827-2, FFPE tissue – 2: Isolated proteins
- CEN/TS 16827-3, FFPE tissue – 3: Isolated DNA
- CEN/TS 16835-1, venous whole blood – 1: Isolated cellular RNA
- CEN/TS 16835-2, venous whole blood – 2: Isolated genomic DNA
- CEN/TS 16835-3, venous whole blood – 3: Isolated circulating cell-free DNA from plasma
- CEN/TS 16945: metabolomics in urine, serum and plasma
### WP 2 QUALITY

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>11) BBMRI-ERIC Partner Charter signed</td>
<td>Yes</td>
<td>No</td>
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#### Primary tissue collection

- **> Information about the sample donor**

13) Donor/patient ID documented should

- **> Health status of donor/patient documented should**
  - e.g. health, disease type, concurrent disease

14) Medical treatment prior to tissue collection documented should

- **> Information on primary tissue sample**

15) Start of ischemia within the body (warm ischemia) documented should

16) Date of vessel ligation/arterial clamping time should

17) Time of vessel ligation/arterial clamping time should

18) Start of ischemia outside the body (cold ischemia) documented should

19) Date of tissue removal from the body should

20) Time of tissue removal from the body should

#### > Information on the primary tissue sample processing

21) Type and condition documented shell

22) Organ of origin and location within shell

- **Type and start of fixation documented:**
  - e.g. formalin, unclassified by the donor, Organ tissue of origin, reference to any marking applied by surgeon, radiologist or pathologist

23) Date of start shell

24) Time of start shell

25) Fixative type shell

26) Fixative condition shell

#### > Information on the primary tissue sample processing

27) Modifications after removal from body documented shell

28) Selection/use of transport containers and packages performed shell

29) Selection/use of stabilisation procedures for transport shell
WP 2 QUALITY

BBMRI-ERIC Survey

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for snap frozen tissue - Part 1: Isolated RNA

The integrity of molecular variances during primary sample collection, transport, storage and processing thus influencing the research results. Standardization of the entire process from collecting sample to applicable pre-examination criteria will increase the research quality.

The European Committee for Standardization (CEN) established Technical Specifications to determine influencing factors and provide recommendations for the handling, stabilization and processing of frozen tissue specimens needed for RNA extraction.


Further details, please visit the CEN website.

The Self-Assessment Survey will help you to assess and improve your sample processing.

The colour coding of the following questions asks for strenghts that you may meet lower criteria respectively. Blue than that you should meet the given criteria.

Your self assessment responses will give you guidance on your sample collection procedures and will help you to improve certain procedures in future.

Main Contact
1) Name
2) Name of contact person
3) E-Mail of contact person
4) Address
5) ZIP
6) City
7) Country
8) Phone

Overview
9) Molecular type
10) SID-ID

BBMRI-ERIC Directory
Quality self assessment and audit systems

1. Enhance visibility of biobanks and sample collections in Directory
2. Expert Working Groups
3. Concept development of a BBMRI-ERIC Audit Programme
4. Contribution to International Standard Developments
**BBMRI-ERIC Observer Liaison to ISO**

The central role of BBMRI-ERIC is to keep track and contribute to the biobank relevant international standard developments.

Act as an information hub by communicating Expert knowledge of the Working Group of ISO to the BBMRI-ERIC community and vice versa.

**International Standard for Biobanks and Bioresources**
ISO/TC 276 ‘Biotechnology’  
- **Terminology**
- **Biobanks** human, animal, plant and microorganism resources for R&D
- **Analytical Methods**
- Bioprocessing
- **Data processing and integration**

**International Standard for Pre-examination processes**
ISO/TC 212 ‘Clinical laboratory testing and in vitro diagnostic test systems’  
2017/2018
QUALITY MANAGEMENT

Standards and best practices for biobanking recommended

- Standardisation

Sharing QM expertise on a European scale

- See QM info & experts!

Self Assessment Surveys

- Forthcoming

Who to contact?
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andrea.wutte@bbmri-eric.eu

Stay informed: www.bbmri-eric.eu/BBMRI-ERIC/quality-management/