



BBMRI-ERIC

Biobanking and
BioMolecular resources
Research Infrastructure

BBMRI-ERIC Quality Management QM Strategy for European biobanks

Andrea Wutte

Biobank Workshop Medical University Innsbruck, Partner of BBMRI.at

13 June 2017

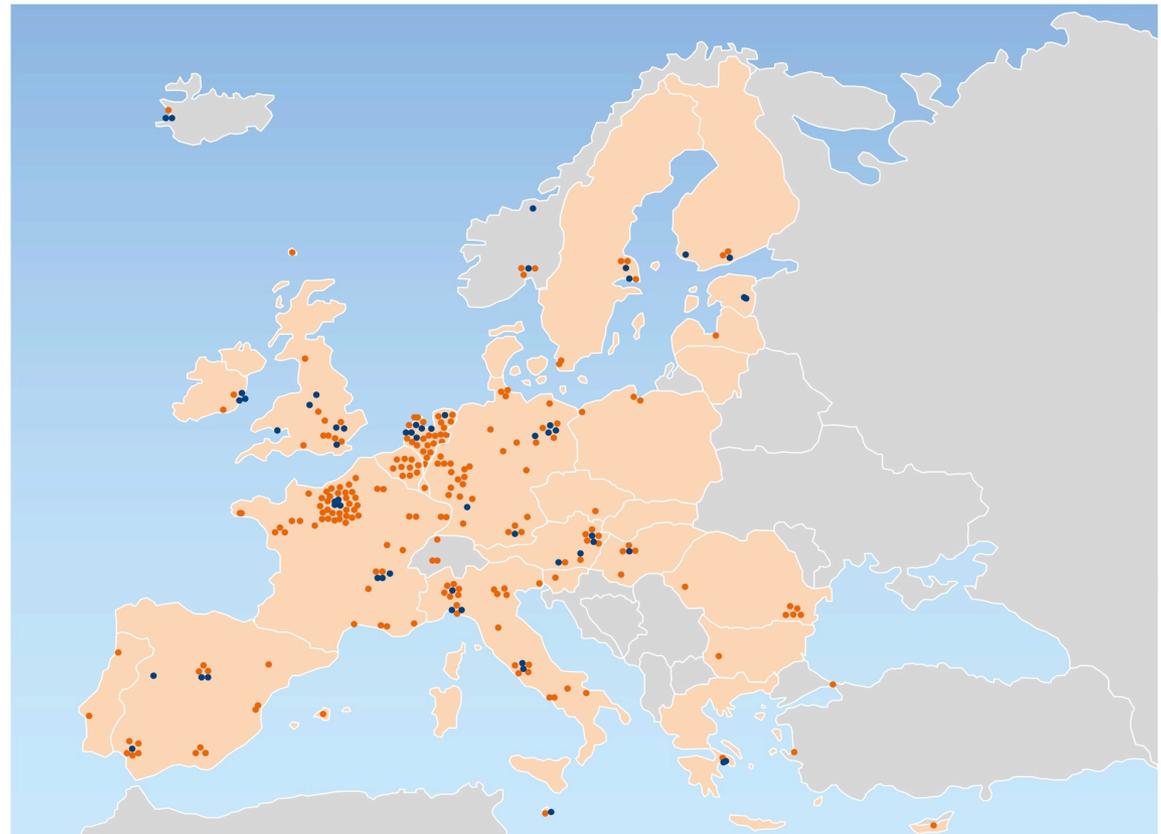
BBMRI-ERIC History of origins

1st ESFRI Roadmap

This roadmap proposes research facilities of pan-European interest
Among BBMRI



The Preparatory Phase of BBMRI 2008 - 2011



Preparatory Phase: 2008-2011

Funding: 5 million (FP7, GA 212111)

33 Countries

54 Participants

225+ Associated Organisations

BBMRI-ERIC History of origins

The Interim Phase 2011-2013

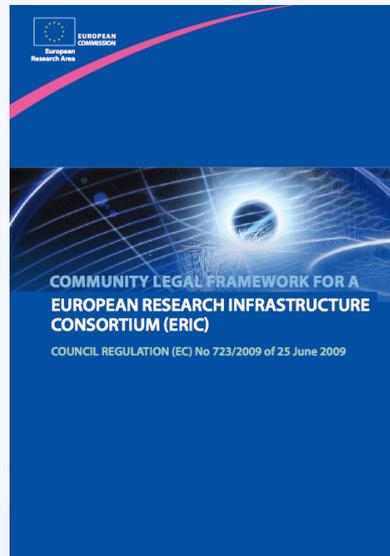
31 January 2011

7 July 2013

3 December 2013

Application

Awarded legal ERIC Status



BBMRI-ERIC 20 Members & Observers

Members (16)

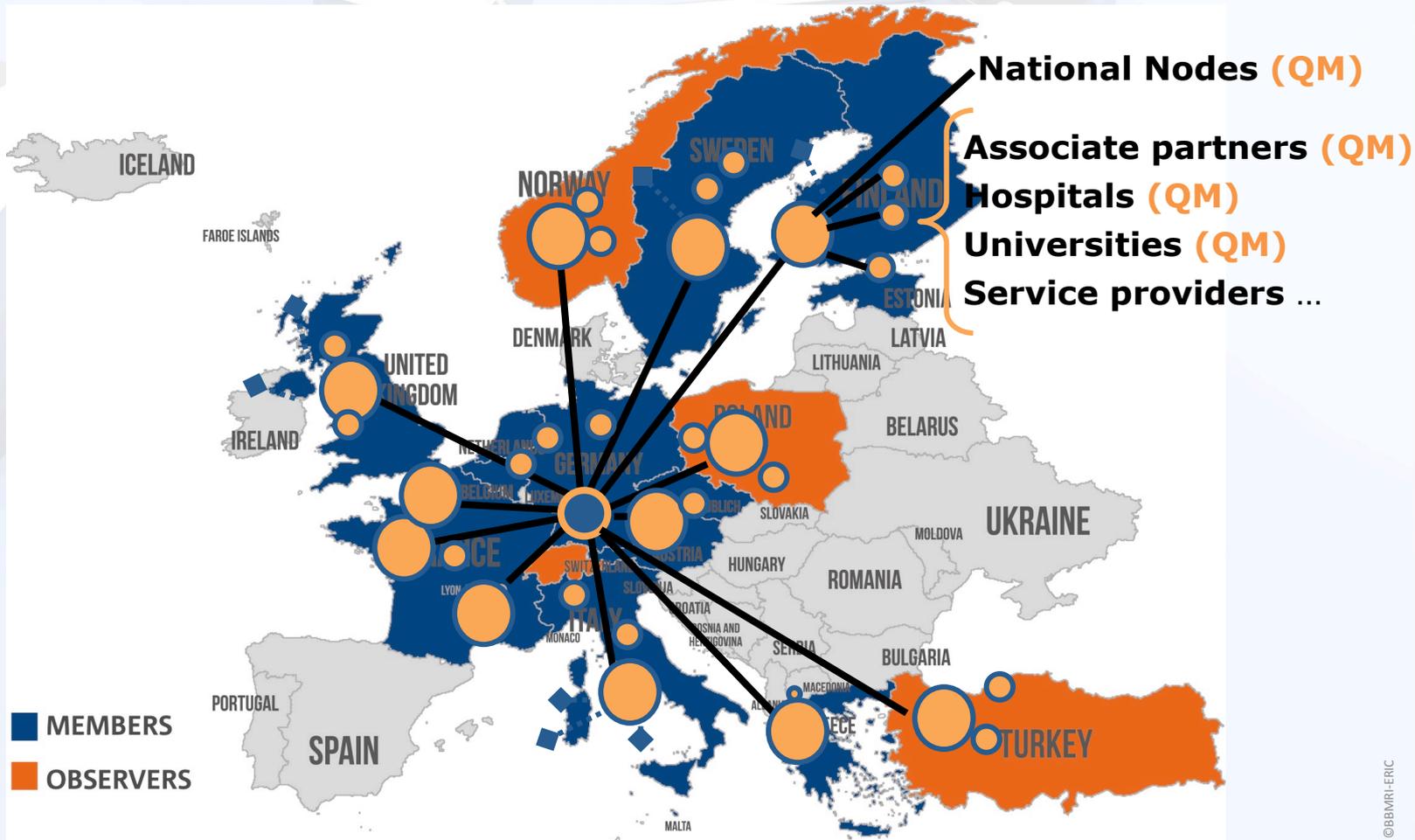
Republic of Austria
 Kingdom of Belgium
 Czech Republic
 Republic of Estonia
 Republic of Finland
 French Republic
 Federal Republic of Germany
 Hellenic Republic
 Italian Republic
 Republic of Malta
 Kingdom of the Netherlands
 Kingdom of Sweden
 United Kingdom of Great Britain and Northern Ireland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

Official Observers (4)

Swiss Confederation
 Republic of Turkey
 Cyprus
 IARC/WHO



BBMRI-ERIC Distributed Network



BBMRI-ERIC Work Programme 2017 - Quality



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)



8 Work Plans incl. 28 Work Streams

- 1) E-Infrastructure
- 2) **Quality**
- 3) ELSI and Stakeholder Engagement
- 4) Biomolecular Resources
- 5) Cohorts
- 6) Biomedical Imaging
- 7) Outreach
- 8) Continued Activities
- 9) Budget
- 10) **Project Active (12)**

<http://www.bbmri-eric.eu/publications/>

BBMRI-ERIC Sample Quality



Clin Chem Lab Med 2011;49(7):1113-1126 © 2011 by Walter de Gruyter • Berlin • Boston, DOI: 10.1515/CCM.2011.600

Opinion Paper

Preanalytical quality improvement: from dream to reality

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Abstract
Laboratory diagnostics (i.e., the total testing process) develops conventionally through a vertical loop, originally referred to as “the bean to bean cycle” by George Lundberg. Throughout this complex cycle, there is an inherent possibility that a mistake might occur. According to reliable data, pre-analytical errors still account for nearly 60%–70% of all problems occurring in laboratory diagnostics, most of them attributable to misdiagnosis procedures during collection, handling, preparing or storing the specimens. Although most of these would be “preventable” before inappropriate reactions are taken, in nearly one fifth of the cases they can produce inappropriate investigations and substantial increase in costs, while generating inappropriate clinical decisions and causing several unfortunate circumstances. Several steps have already been undertaken to increase awareness and establish a consensus of the internationally coordinated network of the world.

Introduction
Much has been written about the alarming number of preclinical studies that were later found to be irreproducible [1,2]. Flawed preclinical studies create false hope for patients waiting for likable cures; moreover, they point to systemic and costly inefficiencies in the way preclinical studies are designed, conducted, and reported. Because replication and cumulative knowledge production are cornerstones of the scientific process, these widespread accounts are scientifically troubling. Such concerns are further complicated by questions about the effectiveness of the peer review process itself [3], as well as the rapid growth of postpublication peer review (e.g., PubMed Commons, PubPeer), data sharing, and open access publishing that undermines the traditional model of preclinical research. Indeed, there are many different perspectives on the size of this problem, and published estimates of irreproducibility range from 5% to 15% to 80% [3]. Our primary goal here is not to pinpoint the exact irreproducibility rate, but rather to identify root causes of the problem, outline the direct costs of irreproducible research, and to develop a framework to address the highest priorities. Based on examples from within life sciences, application of economic theory, and reviewing lessons learned from other industries, we conclude that community-developed best practices and standards must play a central role in improving reproducibility going forward.

Abstract
Low reproducibility rates within life science research undermine cumulative knowledge production and contribute to both delays and costs of therapeutic drug development. An analysis of past studies indicates that the cumulative (total) prevalence of irreproducible preclinical research exceeds 50%, resulting in approximately US\$26,000,000,000 (US\$26B) spent on preclinical research that is not reproducible—in the United States alone. We outline a framework for solutions and a plan for long-term improvements in reproducibility rates that will help to accelerate the discovery of life-saving therapies and cures.

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Clin Chem Lab Med. 2011 Jul; 49(7):1113-26.

Stephen A Bustin.
The reproducibility of biomedical research: sleepers awake!
Biomolecular Detection and Quantification 2014, pp. 35-42

Freedman LP et al.
The Economics of Reproducibility in Preclinical Research.
Plos Biol. 2015 Jun 9;13(6):e1002165.



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BBMRI-ERIC Sample Quality

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



Variabilities of proteins and phosphoproteins in the pre-analytical phase

874 DOI 10.1002/prca.200800001 *Proteomics Clin. Appl.* 2009, 3, 874-882

Tissue is alive: New technologies are

Downloaded from clincancerres.aacrjournals.org on July 31, 2014. © 2014 American Association for Cancer Research.

Published OnlineFirst June 3, 2014; DOI: 10.1158/1078-0432.CCR-13-1507

Journal of proteome research

Article

pubs.acs.org/jpr

Influence of Delayed Times Phosphoproteo

Funda Meric-Bernstam,¹ Beatriz E. Adrada,² Gildy Babiera,² Isabe Ana Maria Gonzalez-

Sibylle Gündisch,^{1,†} Bilge Reischauer,^{3,§} M and Karl-Friedrich Beck

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

Sibylle Gündisch,^{1,†} Stefanie Hauck,[‡] Hakan Sarioglu,[‡] Christina Schott,^{1,◆} Christian Viertler,^{§,◆} Marcel Kap,^{||,◆} Tibor Schuster,¹ Bilge Reischauer,^{7,◆,¶} Robert Rosenberg,^{8,¶} Cornelis Verhoef,[○] Hans-Joerg Mischinger,^v Peter Riegman,^{||,◆} Kurt Zatloukal,^{§,◆} and Karl-Friedrich Becker^{9,7,◆}

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⁶Max Planck Institute of Biochemistry, Martinsried, Germany
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[◆]The SPIDIA Consortium, QIAGEN GmbH, QIAGEN Strasse 1, 40724 Hilden, Germany

Supporting Information

Reference K-F Becker

Technische Universität München

BBMRI-ERIC Work Programme 2017 - Quality

Enhance visibility of biobanks and sample collections in BBMRI-ERIC Directory

Facilitate Expert Working Groups

- WG1.2: FFPE and SF Tissue
- WG3: Venous Whole Blood
- WG4: Metabolomics
- WG5: QMS of Biobanks

Concept development of a BBMRI-ERIC Audit Programme

Contribution to International Standard Developments

- ISO/TC 276 Biotechnology
- ISO/TC 212 Clinical Laboratory testing
- CEN/TS 140 Invitro diagnostics medical devices

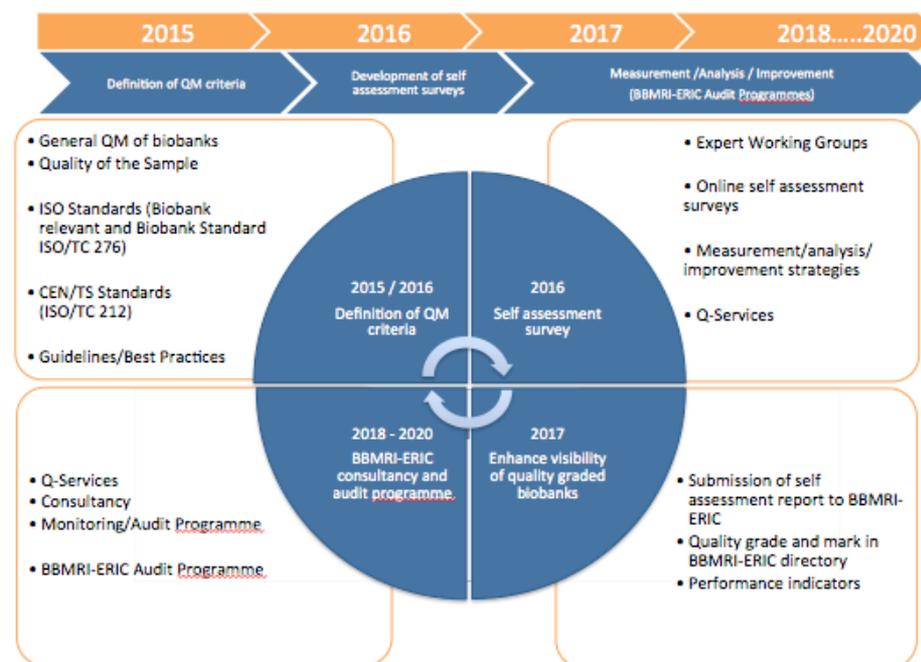
H2020-SC1-Project SPIDIA4P

Development of 12 new pre-analytical Standards

Global Biobank Week, 13-15 September 2017, Stockholm

Friday, 15 Sept 2017, 4 – 5.30 p.m. **SESSION 10C**

Quality Assessment: a key factor for successful biobanks and reproducible science



2.1.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Enhance visibility of quality graded biobanks and sample collections in BBMRI-ERIC Directory				
2. Concept development of Audit Programme				
3. Contribution to international standard developments				
4. Maintain Expert Working Group				
<i>Foreseen outcomes 2018–2019: Continue 1–4 with a particular focus on the implementation (if consensus is reached) of the BBMRI-ERIC Audit Programme.</i>				

BBMRI-ERIC Quality

Experts Evaluation of QMS for biobanks

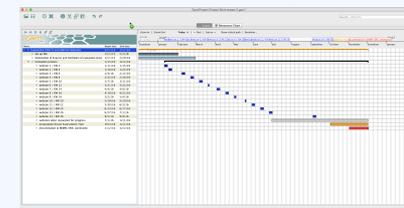
- OECD best practice guidelines for Biological Resource Centres
- WHO/IARC guidelines for biological resource centres for cancer research
- NFS 96-900 Certification des Centres de Ressources Biologiques
- ISBER Best practices for Repositories
- ISO 9001:2015
- ISO 15189:2012
- ISO 17025:2005
- ISO 19011:2011
- 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 of 2016::
86 Experts of
18 Member States



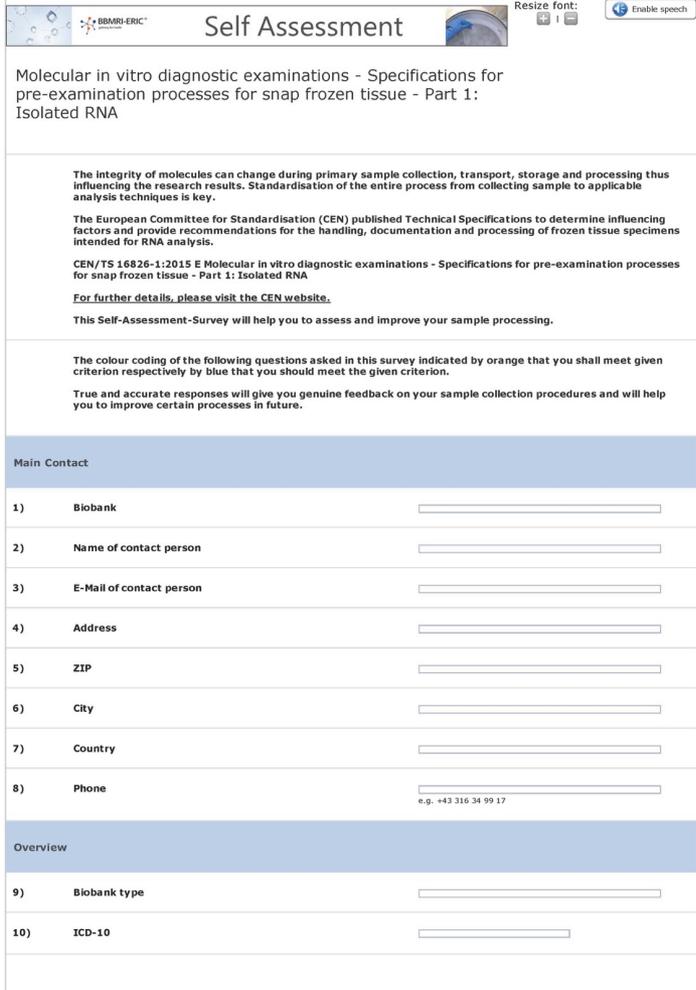
BBMRI-ERIC Work Programme 2017 - Quality

- 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



Self Assessment

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

The integrity of molecules can change during primary sample collection, transport, storage and processing thus influencing the research results. Standardisation of the entire process from collecting sample to applicable analysis techniques is key.

The European Committee for Standardisation (CEN) published Technical Specifications to determine influencing factors and provide recommendations for the handling, documentation and processing of frozen tissue specimens intended for RNA analysis.

CEN/TS 16826-1:2015 E Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for snap frozen tissue - Part 1: Isolated RNA

For further details, please visit the CEN website.

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

The colour coding of the following questions asked in this survey indicated by orange that you shall meet given criterion respectively by blue that you should meet the given criterion.

True and accurate responses will give you genuine feedback on your sample collection procedures and will help you to improve certain processes in future.

Main Contact

1) **Biobank**

2) **Name of contact person**

3) **E-Mail of contact person**

4) **Address**

5) **ZIP**

6) **City**

7) **Country**

8) **Phone**
e.g. +43 316 34 99 17

Overview

9) **Biobank type**

10) **ICD-10**

BBMRI-ERIC Sample Quality CEN/TS

Scope of CEN/TS

This Technical Specification gives recommendations for the handling, documentation and processing of **XXX** specimens intended for **XXX** analysis during the preanalytical phase before a molecular assay is performed.

This Technical Specification is applicable to molecular *in vitro* diagnostic examinations (e.g., *in vitro* diagnostic laboratories, laboratory customers, developers and manufacturers of *in vitro* diagnostics, institutions and commercial organizations performing biomedical research, **biobanks, and regulatory authorities**).

Reference CEN/TS page 5

CEN/TS Snap frozen tissues

NVN-CEN/TS 16826-1:2015

TECHNICAL SPECIFICATION **CEN/TS 16826-1**
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

August 2015

ICS 11.100.10

English Version

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

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus à congélation rapide - Partie 1: ARN extrait

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 1: Isolierte RNAs

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NVN-CEN/TS 16826-2:2015

TECHNICAL SPECIFICATION **CEN/TS 16826-2**
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

August 2015

ICS 11.100.10

English Version

**Molecular in vitro diagnostic examinations - Specifications for
 pre-examination processes for snap frozen tissue - Part 2:
 Isolated proteins**

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus à congélation rapide - Partie 2: Protéines extraites

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 2: Isolierte Proteine

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CEN/TS FFPE tissues

TECHNICAL SPECIFICATION
 SPÉCIFICATION TECHNIQUE
 TECHNISCHE SPEZIFIKATION

CEN/TS 16827-1

August 2015

ICS 11.100.10

English Version

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

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus FFPE - Partie 1: ARN extrait

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für FFPE-Gewebeproben - Teil 1: Isolierte RNS

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TECHNICAL SPECIFICATION
 SPÉCIFICATION TECHNIQUE
 TECHNISCHE SPEZIFIKATION

CEN/TS 16827-2

August 2015

ICS 11.100.10

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for FFPE tissue - Part 2: Isolated proteins

Tests de diagnostic moléculaire in vitro - Spécifications pour les processus préanalytiques pour tissu FFPE - Partie 2: Protéines extraites

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für FFPE-Gewebeproben - Teil 2: Isolierte Proteine

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TECHNICAL SPECIFICATION
 SPÉCIFICATION TECHNIQUE
 TECHNISCHE SPEZIFIKATION

CEN/TS 16827-3

August 2015

ICS 11.100.10

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for FFPE tissue - Part 3: Isolated DNA

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus FFPE - Partie 3: ADN isolé

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für FFPE-Gewebeproben - Teil 3: Isolierte DNS

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CEN/TS Venous whole blood

TECHNICAL SPECIFICATION
 SPÉCIFICATION TECHNIQUE
 TECHNISCHE SPEZIFIKATION

CEN/TS 16835-1
 July 2015

ICS 11.100.10

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 1: Isolated cellular RNA

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus pré-analytiques pour le sang veineux total - Partie 1: ARN cellulaire isolé

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 1: Isolierte zelluläre RNS

This Technical Specification (CEN/TS) was approved by CEN on 30 May 2015 for provisional application.

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CEN/TS 16835-2
 October 2015

ICS 11.100.30

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus pré-analytiques pour le sang total veineux - Partie 2: ADN génomique extrait

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 2: Isolierte genomische DNS

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TECHNICAL SPECIFICATION
 SPÉCIFICATION TECHNIQUE
 TECHNISCHE SPEZIFIKATION

CEN/TS 16835-3
 October 2015

ICS 11.100.30

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 3: Isolated circulating cell free DNA from plasma

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus pré-analytiques pour le sang total veineux - Partie 3: ADN libre circulant extrait du plasma

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 3: Aus Plasma isolierte zirkulierende zellfreie DNS

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CEN / TS for metabolomics

NVN-CEN/TS 16945:2016

TECHNICAL SPECIFICATION

CEN/TS 16945

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

May 2016

ICS 11.100.10

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for metabolomics in urine, venous blood serum and plasma

Tests de diagnostic moléculaire in vitro - Spécifications
relatives aux processus préanalytiques pour l'analyse
du métabolome dans l'urine et le sang veineux (sérum
et plasma)

Molekularanalytische in-vitro-diagnostische Verfahren
- Spezifikationen für präanalytische Prozesse für
Metabolomuntersuchungen in Urin, venöses Blutserum
und -plasma

This Technical Specification (CEN/TS) was approved by CEN on 22 March 2016 for provisional application.

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BBMRI-ERIC Enhance visibility of biobanks and sample collections

Self-Assessment Survey

BBMRI-ERIC Self Assessment

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

The integrity of molecules can change during primary sample collection, transport, storage and processing thus influencing the research results. Standardisation of the entire process from collecting sample to applicable analysis techniques is key.

The European Committee for Standardisation (CEN) published Technical Specifications to determine influencing factors and provide recommendations for the handling, documentation and processing of frozen tissue specimens intended for RNA analysis.

CEN/TS 16826-1:2015 E Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for snap frozen tissue - Part 1: Isolated RNA.

For further details, please visit the CEN website.

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

The colour coding of the following questions asked in this survey indicated by orange that you shall meet given criterion respectively by blue that you should meet the given criterion.

True and accurate responses will give you genuine feedback on your sample collection procedures and will help you to improve certain processes in future.

Main Contact

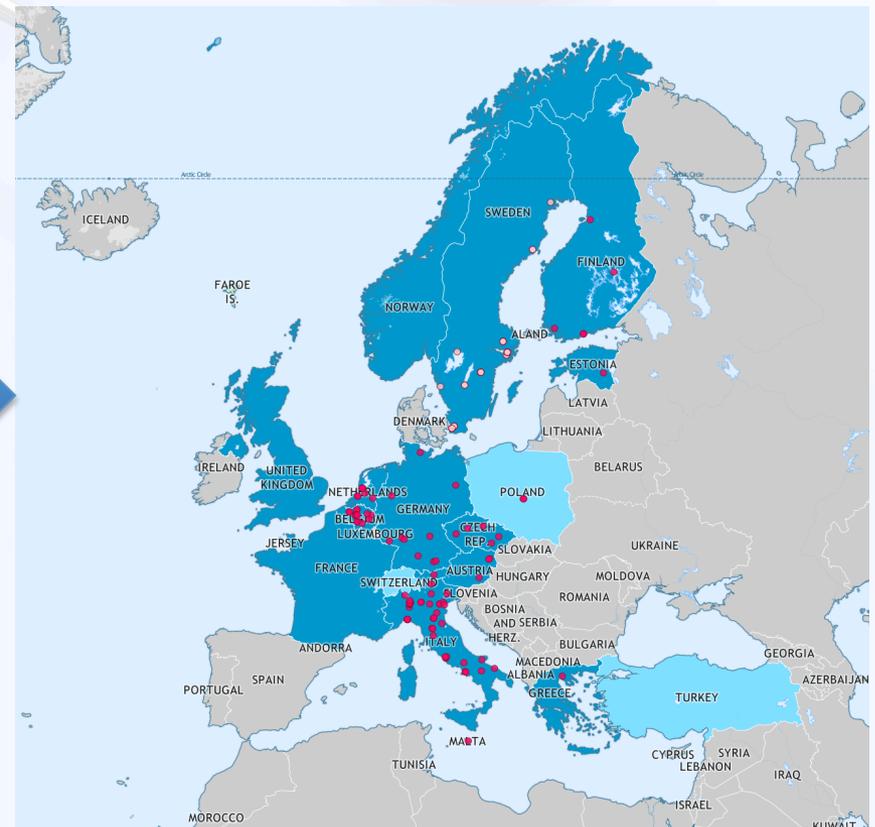
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2)	Name of contact person	<input type="text"/>
3)	E-Mail of contact person	<input type="text"/>
4)	Address	<input type="text"/>
5)	ZIP	<input type="text"/>
6)	City	<input type="text"/>
7)	Country	<input type="text"/>
8)	Phone	<input type="text"/>

e.g. +43 316 34 99 17

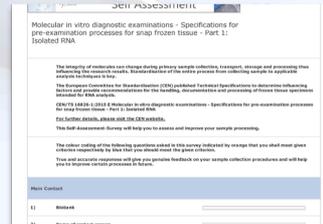
Overview

9)	Biobank type	<input type="text"/>
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BBMRI-ERIC Directory



BBMRI-ERIC Work Programme 2017 - Quality Service – Self-Assessment Survey (SAS)



Preliminary Access to SAS

- **Phase 1:**
 - BBMRI webpage
 - Request form
 - Pre-conditions
 - Email contact
 - Provide link to SAS
- **Phase 2:**
 - Parallel development: ACCESS via AAI prepared by CS-IT and MUI

Compliance Assessment

- **Use model 1:**
 - Biobank internal use (improving processes)
- **Use model 2:**
 - Biobanks submit report to BBMRI-ERIC
 - BBMRI-ERIC grading according to **shall/should** requirements

Biobank::Collection marked in Directory

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- Negotiator
- ..

Access to BBMRI-ERIC SAS

<http://www.bbmri-eric.eu/BBMRI-ERIC/quality-management/>

QUALITY MANAGEMENT

Standards and best practices for biobanking recommended

- | [Standardisation](#)
- | ["Quality Management Services" Flyer](#)

Sharing QM expertise on a European scale

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Self Assessment Surveys

- | [Access](#)



Access to BBMRI-ERIC SAS

<http://www.bbmri-eric.eu/BBMRI-ERIC/quality-management/>

Self-Assessment Survey

*Please type in your e-mail address

Please please provide us with some information by answering the following questions:

Is your organisation located in a BBMRI-ERIC Member/Observer state? See <http://www.bbmri-eric.eu/national-nodes/>

Yes No

Are you in contact with the coordinating office from the National Node in your country? See <http://www.bbmri-eric.eu/national-nodes/>

Yes No

Have you purchased the required CEN Technical Specifications as a basis for your sample handling procedure? See <http://www.bbmri-eric.eu/services/standardisation/>

Yes No

Please select the required BBMRI-ERIC Self-Assessment Surveys from the list below:

Specifications for Pre-examination processes for snap frozen tissue – Part 1: Isolated RNA; CEN/TS 16826-1:2015

Access to BBMRI-ERIC SAS

<http://www.bbmri-eric.eu/BBMRI-ERIC/quality-management/>

- Specifications for Pre-examination processes for snap frozen tissue – Part 2: Isolated proteins; CEN/TS 16826-2:2015
- Specifications for Pre-examination processes for FFPE tissue – Part 1: Isolated RNA; CEN/TS 16827-1:2015
- Specifications for Pre-examination processes for FFPE tissue – Part 2: Isolated proteins; CEN/TS 16827-2:2015
- Specifications for Pre-examination processes for FFPE tissue – Part 3: Isolated DNA; CEN/TS 16827-3:2015
- Specifications for Pre-examination processes for Venous whole blood – Part 1: Specifications for Pre-examination processes for Isolated cellular RNA; CEN/TS 16835-1:2015
- Specifications for Pre-examination processes for Venous whole blood – Part 2: Isolated genomic DNA; CEN/TS 16835-2:2015
- Specifications for Pre-examination processes for Venous whole blood – Part 3: Isolated circ. cell-free DNA from plasma; CEN/TS 16835-3:2015
- Specifications for Pre-examination processes for Metabolomics in urine; CEN/TS 16945:2016
- Specifications for Pre-examination processes for Metabolomics in serum and plasma; CEN/TS 16945:2016

Comments

PAWSON

TABORS



Type the text

Send

Access to BBMRI-ERIC SAS

<http://www.bbmri-eric.eu/BBMRI-ERIC/quality-management/>

Dear Peter,

please find the links to the SAS below:

BBMRI-ERIC Self-Assessment Tool (Snap Frozen - Part 1: Isolated RNA)

<https://sas.bbmri-eric.eu/surveys/?s=Ho3Gm6aWKP>

BBMRI-ERIC Self-Assessment Tool (Snap Frozen - Part 2: Isolated Proteins)

<https://sas.bbmri-eric.eu/surveys/?s=s7oy58bLNB>

BBMRI-ERIC Self-Assessment Tool (FFPE Tissue - Part 1: Isolated RNA)

<https://sas.bbmri-eric.eu/surveys/?s=MSmFDZGTMe>

BBMRI-ERIC Self-Assessment Tool (FFPE Tissue - Part 2: Isolated Proteins)

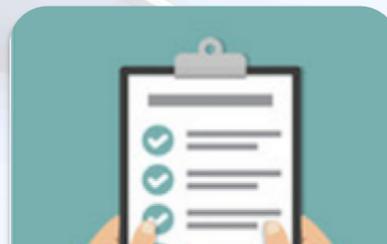
<https://sas.bbmri-eric.eu/surveys/?s=5QgIY7FNfn>

BBMRI-ERIC Self-Assessment Tool (FFPE Tissue - Part 3: Isolated DNA)

<https://sas.bbmri-eric.eu/surveys/?s=qtTD7spZQd>

BBMRI-ERIC Audit Programme

Concept development of a **BBMRI-ERIC Audit Programme**
 Start June 2017



Quality Services

- **BBMRI-ERIC level:**
 - Development of a jointly owned and used Audit Programme (Audit preparation, performance, reporting, follow up) ISO 19011
 - Budget
- **National Node level:**
 - Locate Auditors in the specific field
 - Translate Audit Documents

Compliance Assessment

- Audit preparation
- Audit performance
- Audit reporting
- Audit follow up
- **Report Audit to BBMRI-ERIC**

Biobank::Collection marked in Directory

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- ...

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' timeline 2017/2018

- **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

THE SPIDIA SUCCESS STORY

SLIDE FROM UWE OELMÜLLER



- 2014: 8 new projects for ISO Standards approved in ISO/TC 212 „Clinical laboratory testing and in vitro diagnostic test systems”



- 2015: 9 CEN Technical Specifications to be published
- 2013: 9 new projects approved in CEN/TC 140 „In vitro diagnostic medical devices“
- 2010: Start of standardization work

1. Problem - Errors in Diagnostics

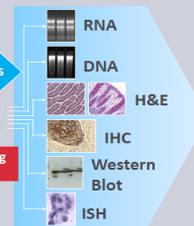


2. Technical Solutions

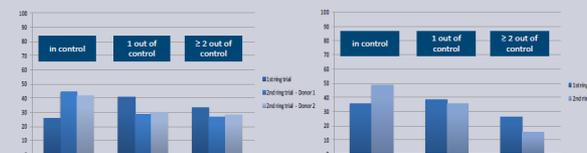
Resect & Gross → Fix → Stabilize → Process



Allows histomorphology and molecular testing from the same specimen



3. Ring-Trials – Blood RNA (l.) and DNA (r.)



European Conference. Standards: Your Innovation Bridge. Brussels (2014). SPIDIA Booth.

WP 2 QUALITY 2017 SPIDIA4P Excerpt

In summary, the main objectives for this project are:

12 new harmonized pan-European pre-analytical standards developed with the European Committee for Standardization (CEN) and implemented in European countries for in vitro diagnostics in Personalized Medicine:

- 4 new pre-analytical CEN/TS Documents for in venous whole blood circulating Tumour and Organ Cells (DNA, RNA, Proteins, staining procedures),
- 1 for Venous Whole Blood Exosomes / cell-free circulating RNA,
- 1 for Saliva (DNA),
- 1 for Frozen Tissues (DNA),
- 1 for Urine and other body fluids (cell-free DNA),
- 3 for Fine Needle Aspirates (RNA, DNA, Proteins),
- 1 for Saliva and Stool Microbiomes (DNA).

WP 2 QUALITY 2017 SPIDIA4P Excerpt

2 additional new harmonized international pre-analytical standards directly developed with the International Organization for Standardization (ISO) and implemented in European countries:

- 1 for FFPE Tissues (in-situ staining procedures),
- 1 for Metabolomics (urine, blood plasma, blood serum).

13 new External Quality Assurance Schemes corresponding to the pre-analytical standards portfolio

- Venous Whole Blood: Genomic DNA and cellular RNA, viable PBMC, Cell Free Circulating DNA(ccfDNA), Cell Free Circulating RNA (ccfRNA), Circulating Tumour Cells (CTCs)
- FFPE tissue : Genomic DNA, RNA, protein
- Frozen tissue: Genomic DNA, RNA, protein
- Saliva: DNA
- Stool: DNA

BIOBANKS EUROPE



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TWO SIDES OF THE SAME COIN

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STANDARDISATION IS KEY

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QUALITY ASPECTS IN ADOPT BBMRI-ERIC

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