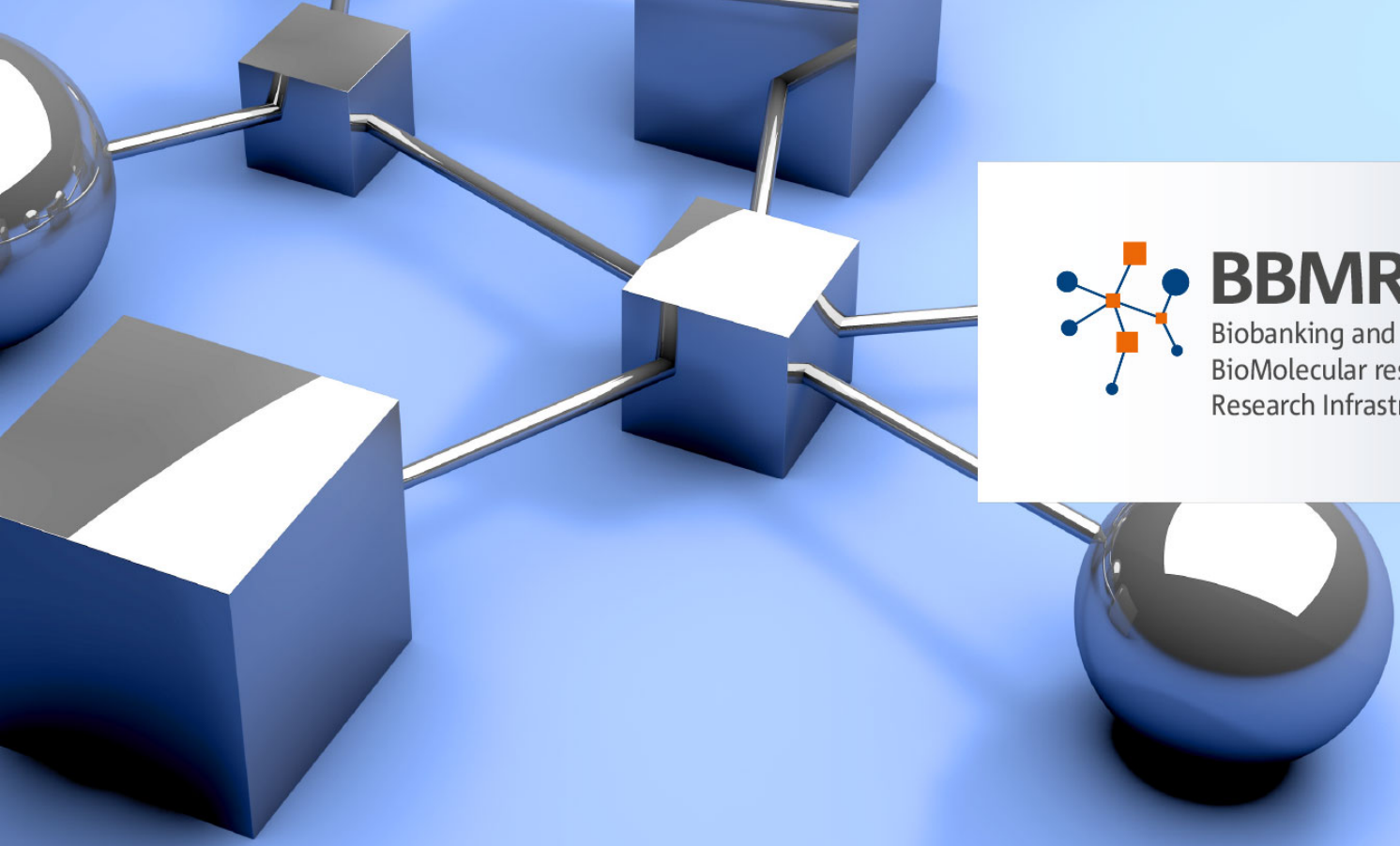


BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

BBMRI-ERIC Quality Management
QM Strategy for European biobanks

Andrea Wutte
Biobank Workshop Medical University Innsbruck, Partner of BBMRI.at
13 June 2017

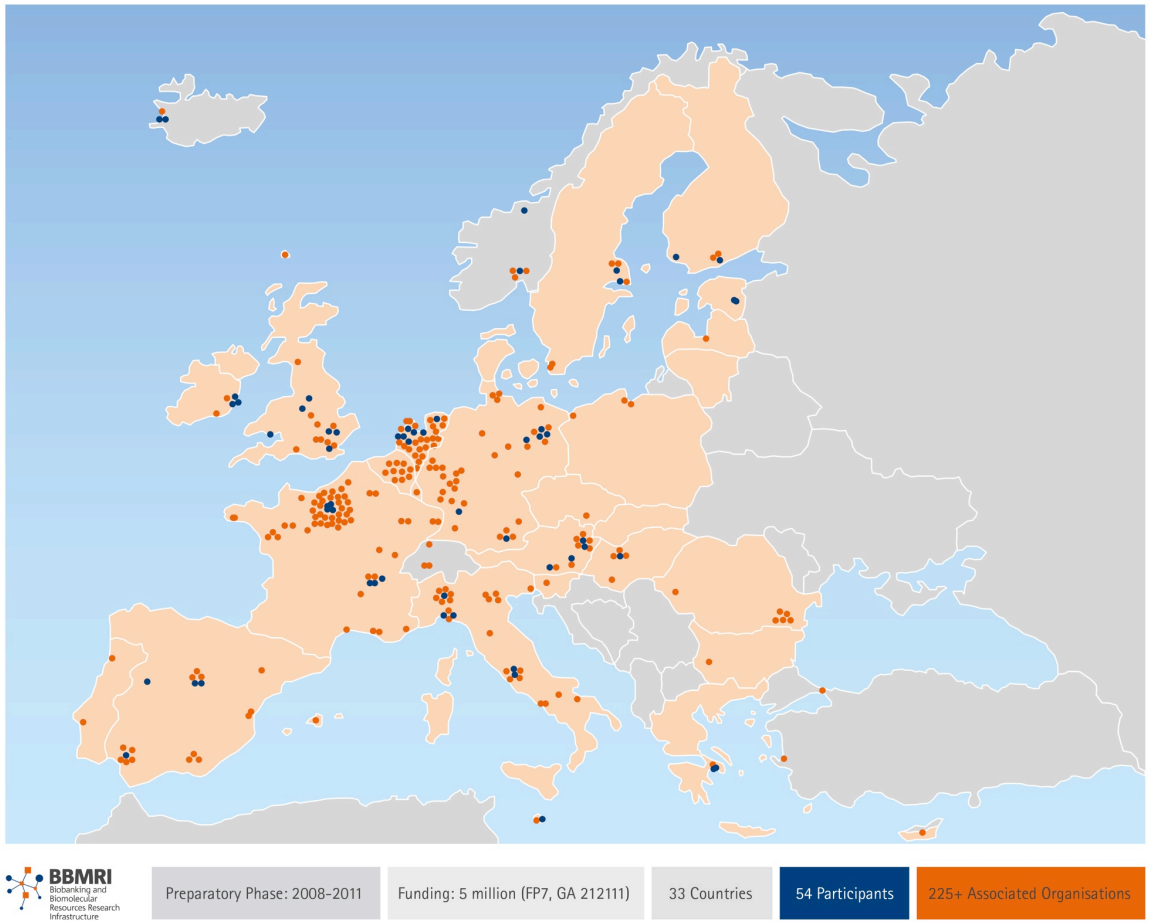
BBMRI-ERIC **History of origins**

1st ESFRI Roadmap

This roadmap proposes research facilities of pan-European interest

Among BBMRI

The Preparatory Phase of BBMRI 2008 - 2011



BBMRI-ERIC **History of origins**

The Interim Phase 2011-2013

31 January 2011

7 July 2013

Application

3 December 2013

Awarded legal ERIC Status

BBMRI-ERIC **20** Members & Observers

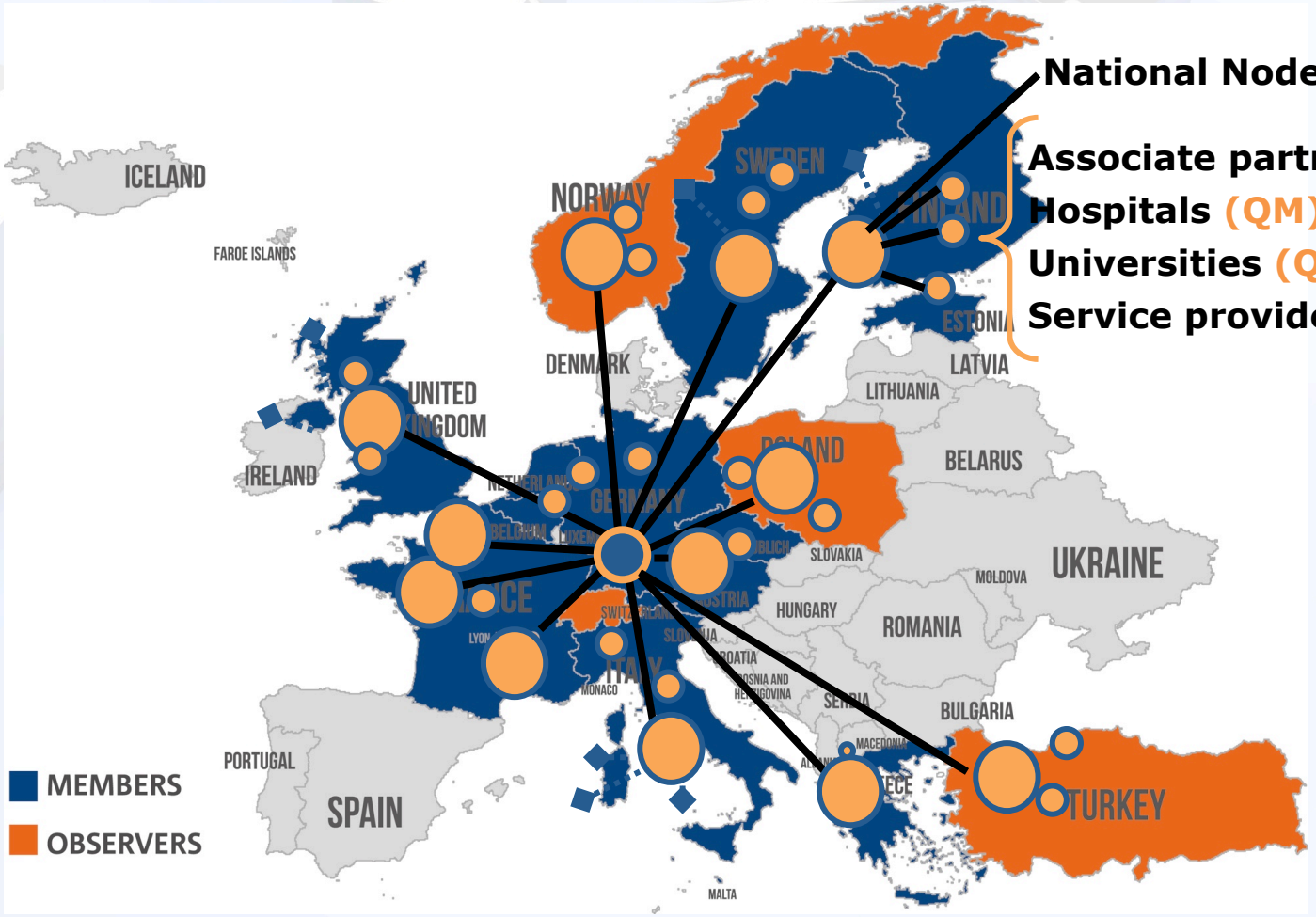
Members (16)

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**

Lippi G. *et al.*
Preanalytical quality improvement: from dream to reality.
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.

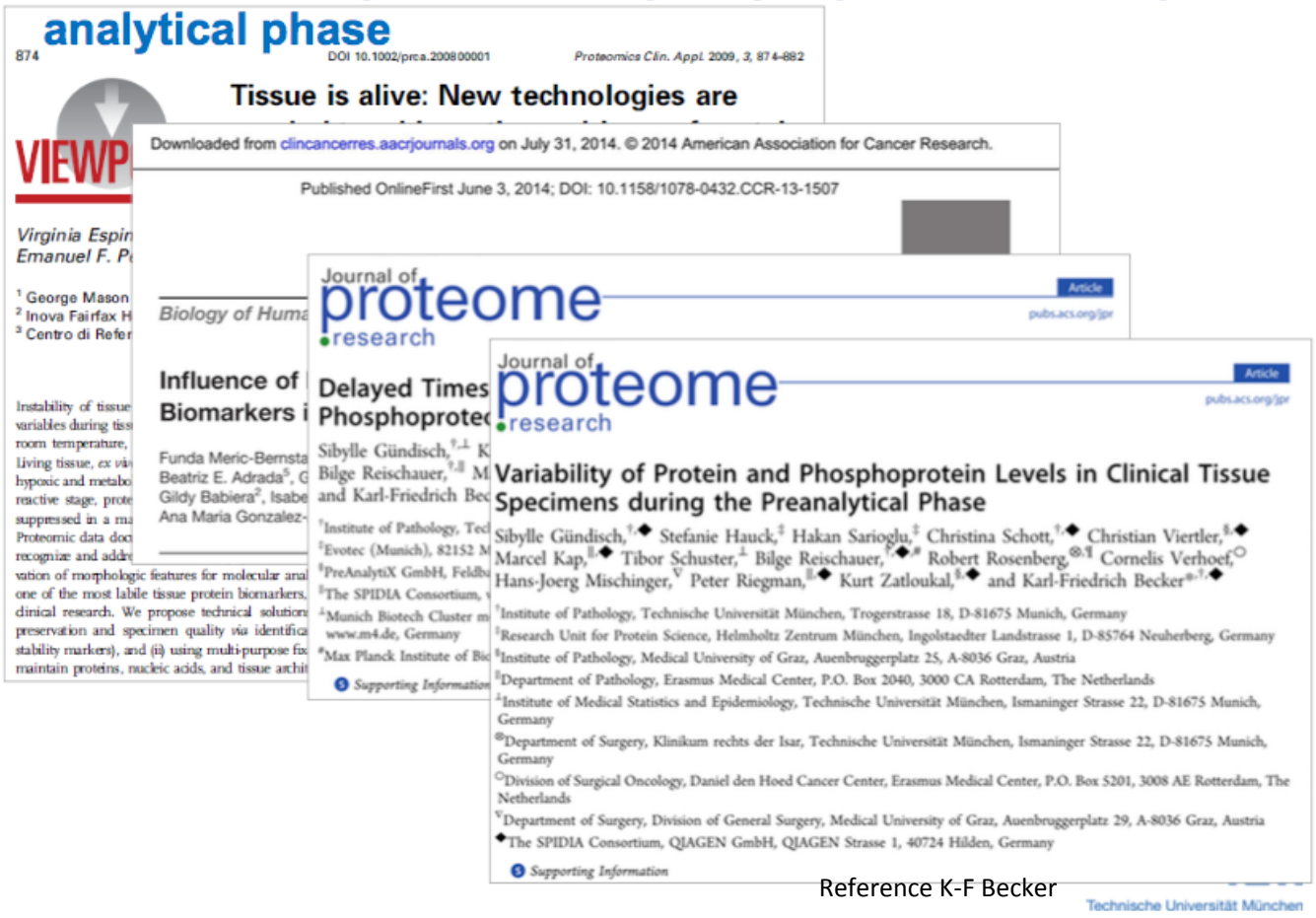
BBMRI-ERIC **Sample Quality**

"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 **Sample Quality**

Variabilities of proteins and phosphoproteins in the pre-analytical phase



Reference K-F Becker

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

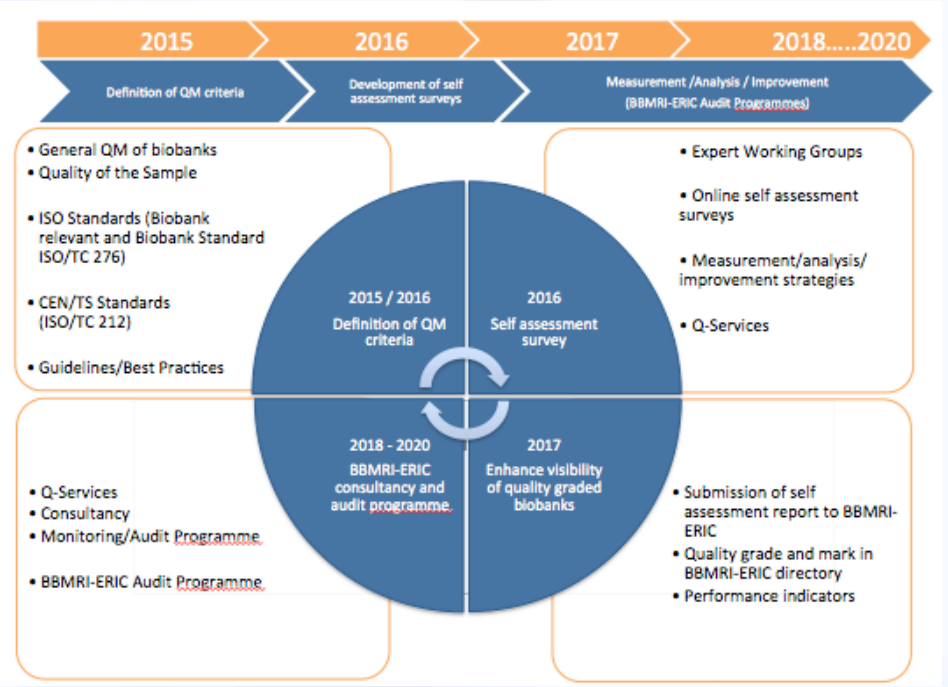
H2020-SC1-Project SPIDIA4P

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



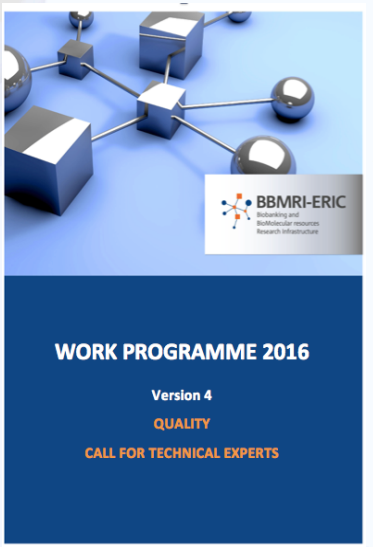
2.1.2 Expected Outcomes and Time Plan

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				
Foreseen outcomes 2018–2019: Continue 1–4 with a particular focus on the implementation (if consensus is reached) of the BBMRI-ERIC Audit Programme.				

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 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

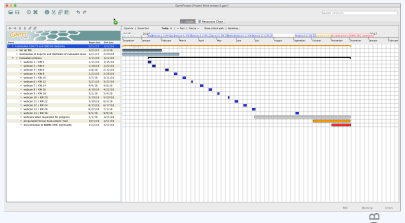


Facts of 2016::

86 Experts of
18 Member States

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



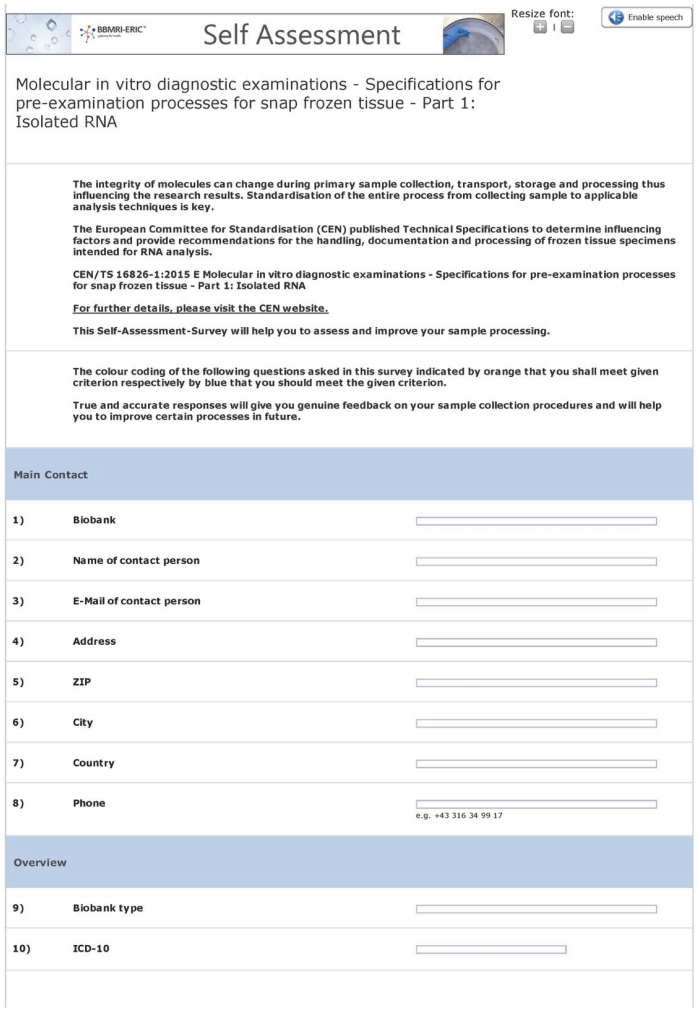
BBMRI-ERIC **Work Programme 2017 - Quality**

- 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

Resize font:

Enable speech

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**

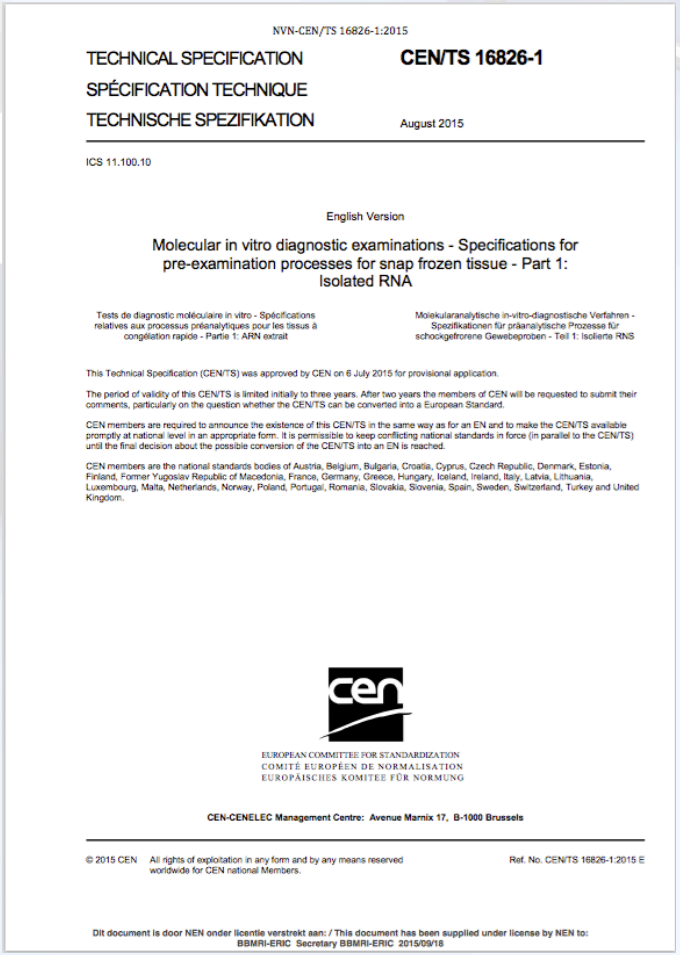
Scope of CEN/TS

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 RNS

This Technical Specification (CEN/TS) was approved by CEN on 6 July 2015 for provisional application.

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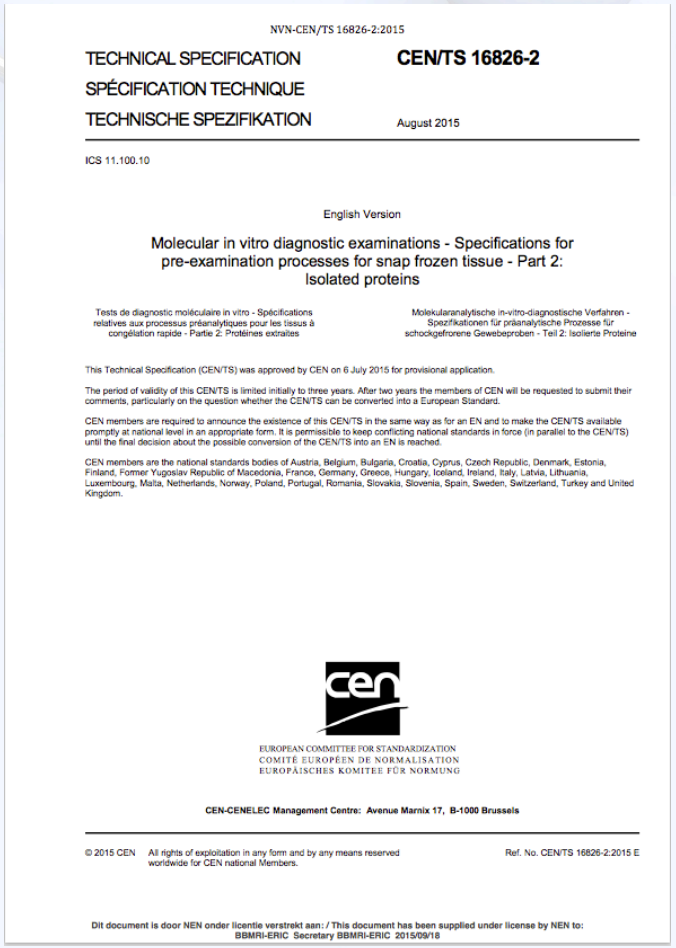
Ref. No. CEN/TS 16826-1:2015 E



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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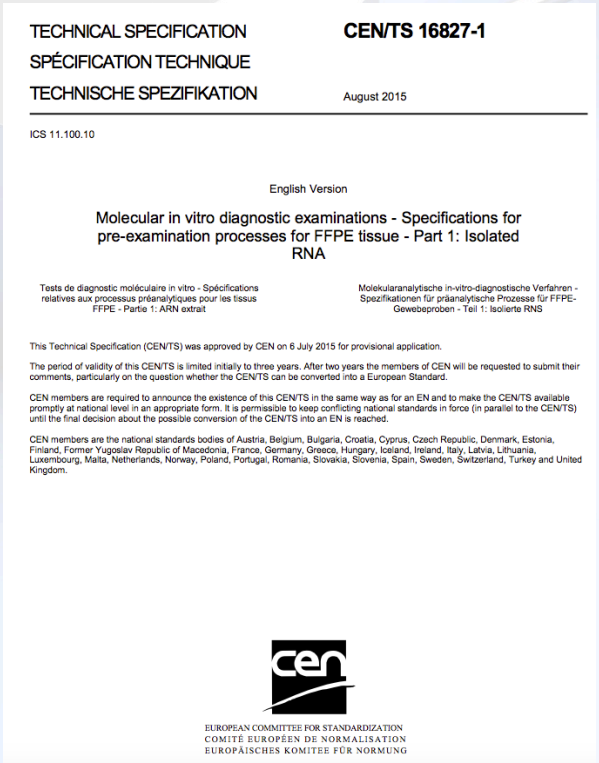
Ref. No. CEN/TS 16826-2:2015 E

CEN/TS **FFPE tissues**



TECHNICAL SPECIFICATION **CEN/TS 16827-1**
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION 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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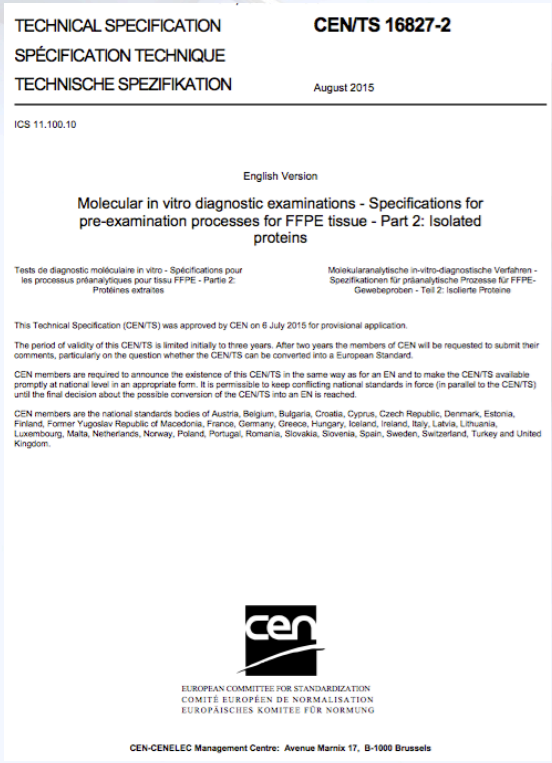

TECHNICAL SPECIFICATION **CEN/TS 16827-2**
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION August 2015

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 **CEN/TS 16827-3**
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION 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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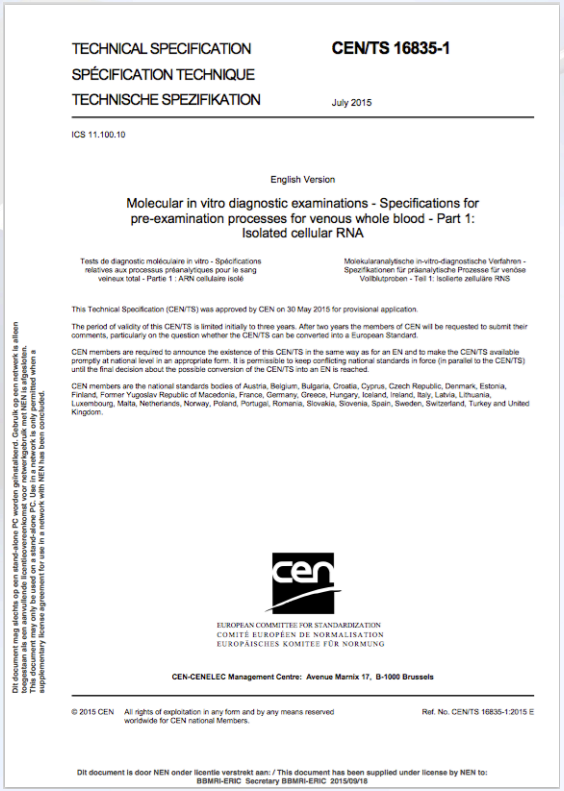
CEN/TS **Venous whole blood**



TECHNICAL SPECIFICATION **CEN/TS 16835-1**
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION 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 préanalytiques 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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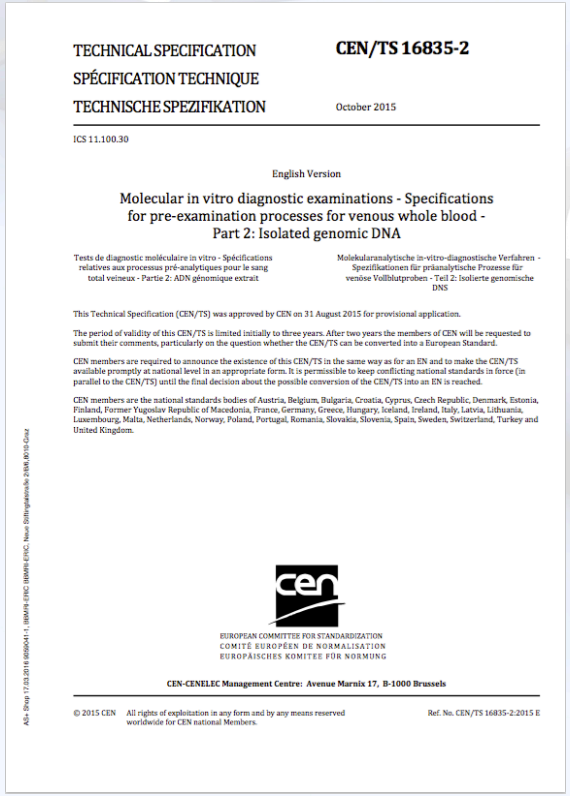

TECHNICAL SPECIFICATION **CEN/TS 16835-2**
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION October 2015

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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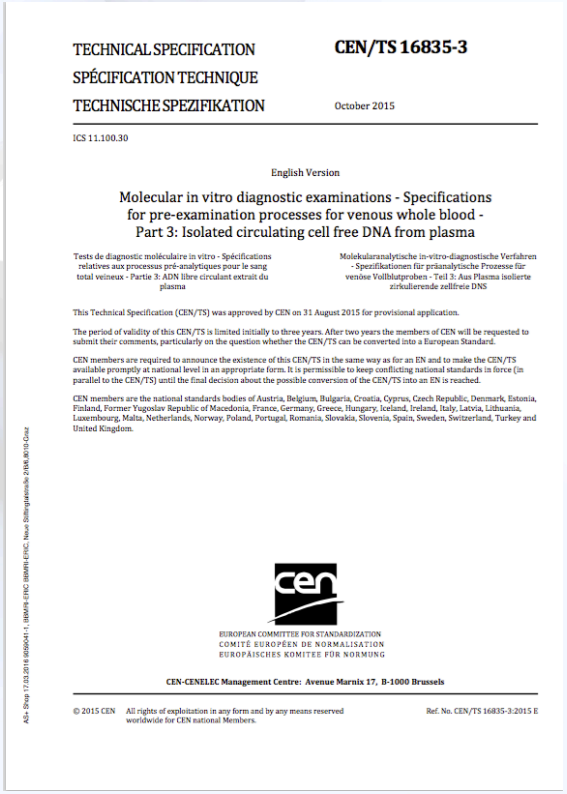
Ref. No. CEN/TS 16835-2:2015 E



TECHNICAL SPECIFICATION **CEN/TS 16835-3**
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION 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

This Technical Specification (CEN/TS) was approved by CEN on 31 August 2015 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

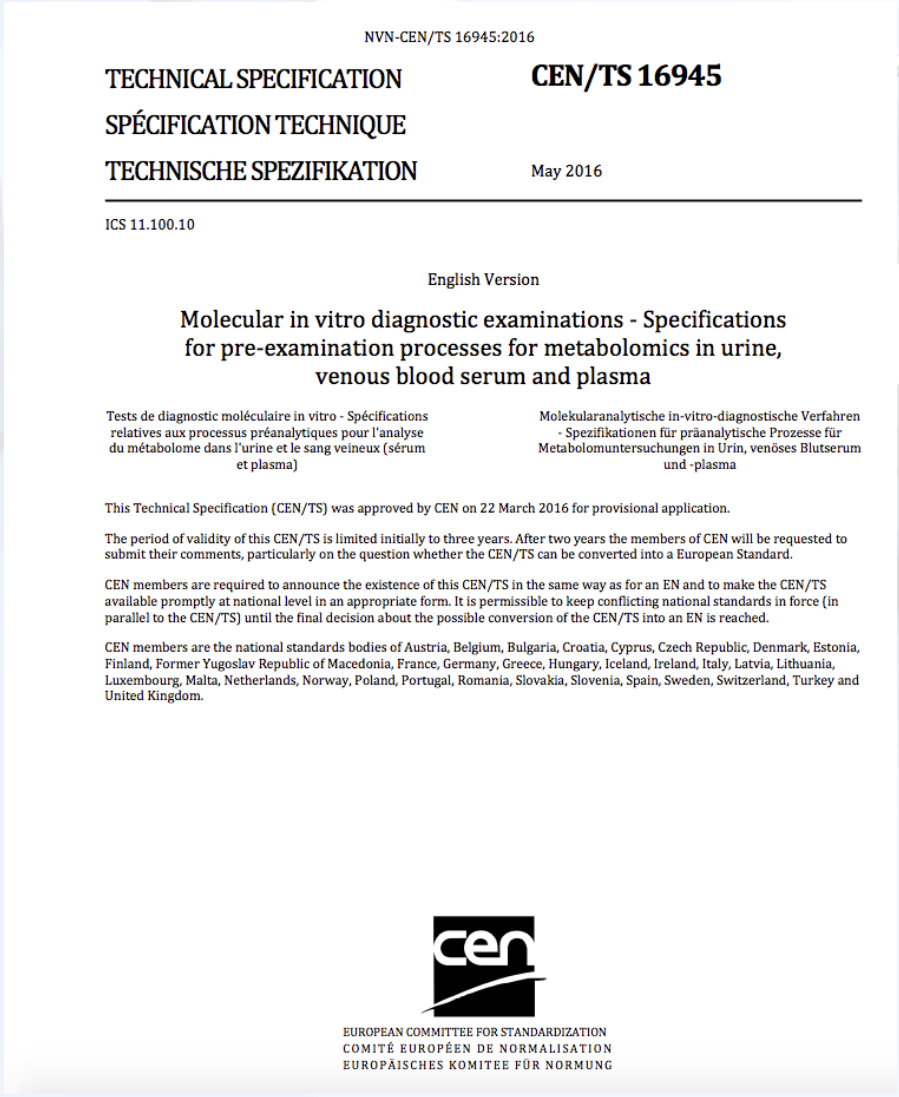
CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. CEN/TS 16835-3:2015 E

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.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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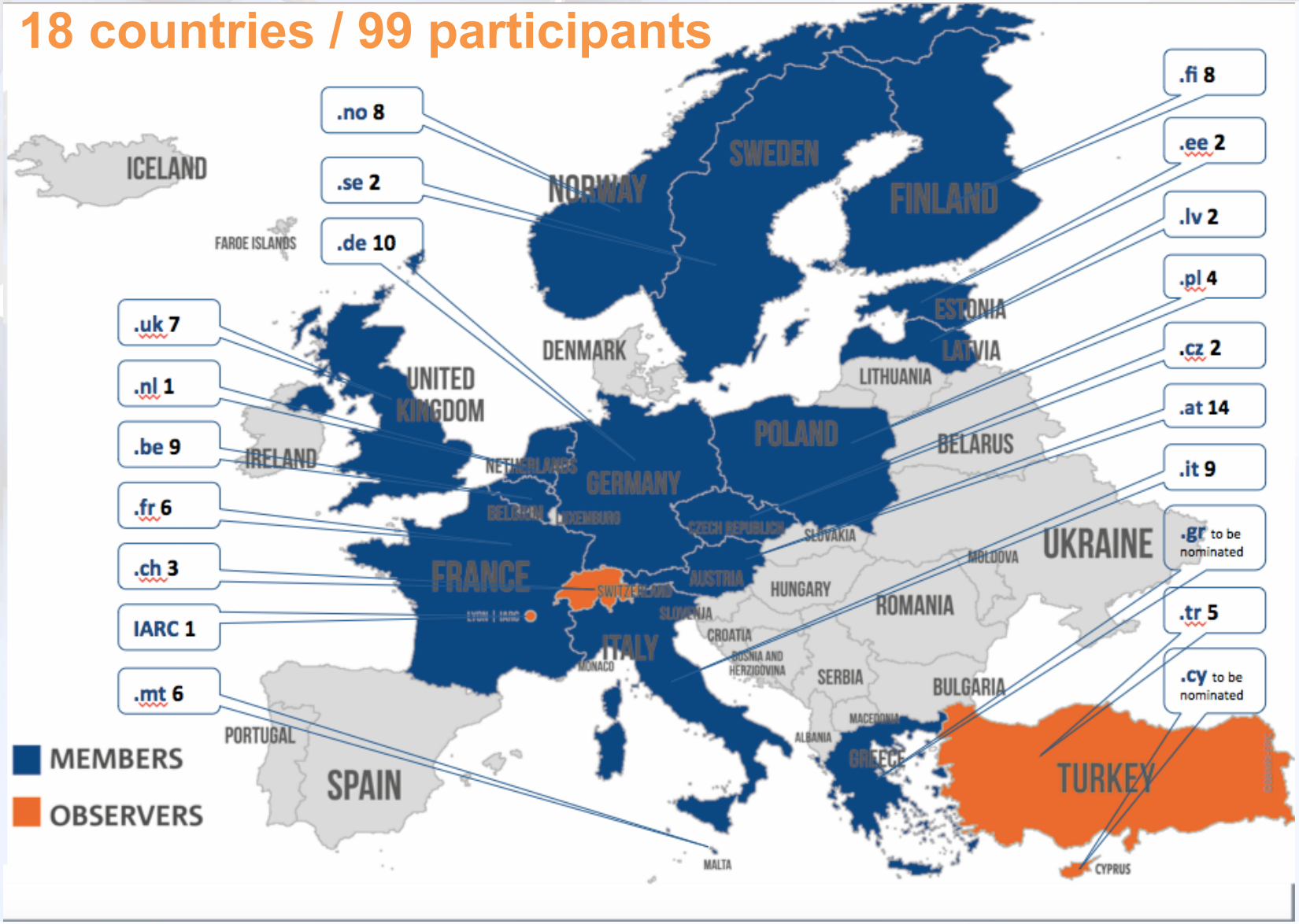
EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN/TS **Content structure**

Contents

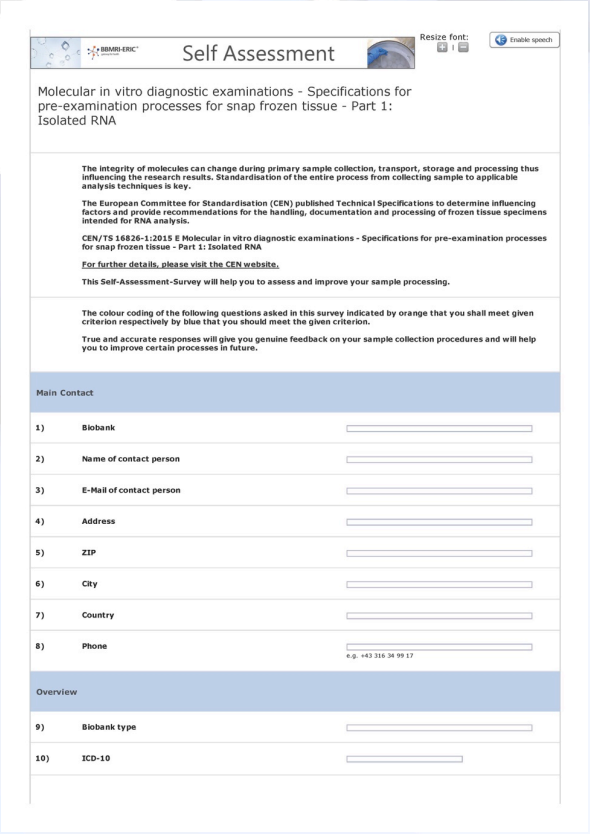
BBMRI-ERIC Quality Expert Working Groups

18 countries / 99 participants



BBMRI-ERIC Enhance visibility of biobanks and sample collections

Self-Assessment Survey



Self Assessment

Resize font:

Enable speech

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.

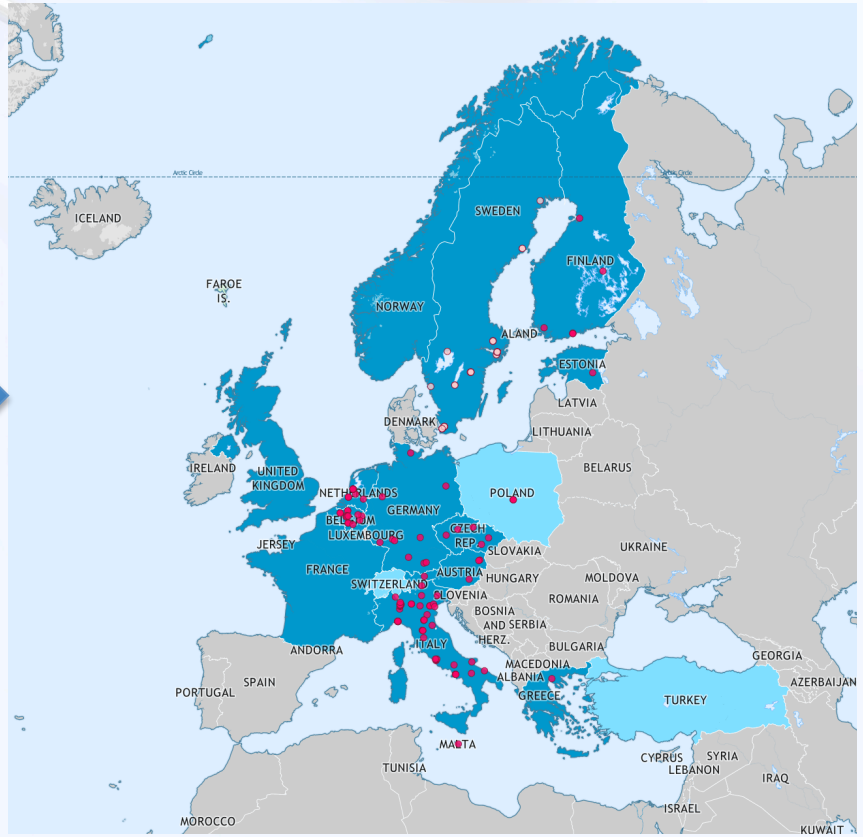
This Self-Assessment-Survey will help you to assess and improve your sample processing.

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.

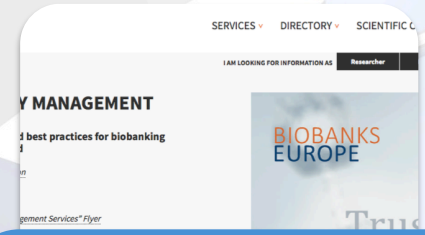
True and accurate responses will give you genuine feedback on your sample collection procedures and will help you to improve certain processes in future.

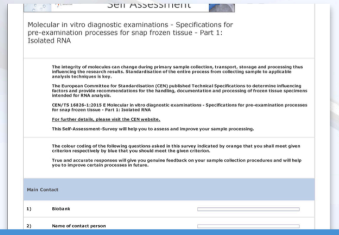
Main Contact		
1)	Biobank	
2)	Name of contact person	
3)	E-Mail of contact person	
4)	Address	
5)	ZIP	
6)	City	
7)	Country	
8)	Phone	e.g. +43 316 34 99 17
Overview		
9)	Biobank type	
10)	ICD-10	

BBMRI-ERIC 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)

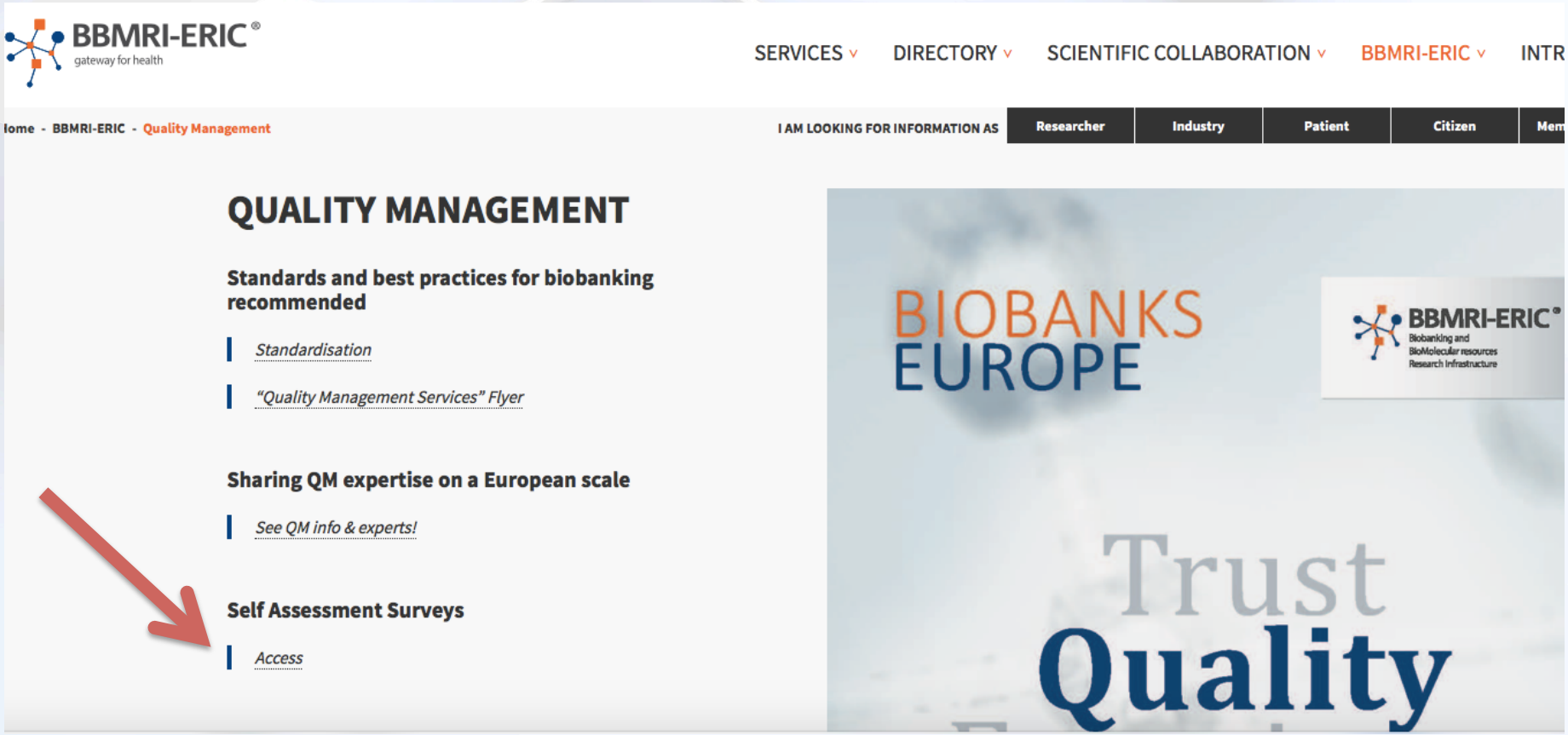
- **Use model 2:**
- Biobanks submit report to BBMRI-ERIC
- BBMRI-ERIC grading according to **shall/should** requirements

Biobank::Collection marked in Directory

- Directory
- Negotiator
- ..

Access to BBMRI-ERIC SAS

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



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

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

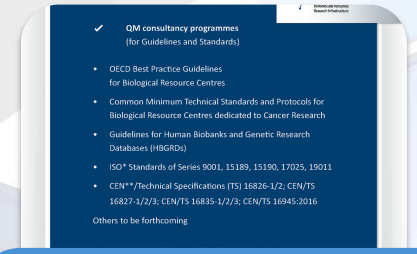
BBMRI-ERIC Self-Assessment Tool (FFPE Tissue - Part 1: Isolated RNA)
https://sas.bbmri-eric.eu/surveys/?s=MSmFDZGTMe

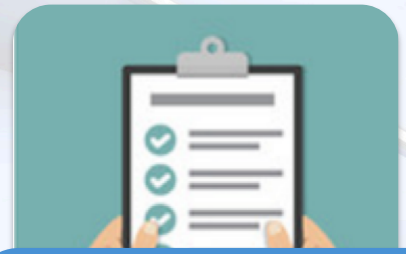
BBMRI-ERIC Self-Assessment Tool (FFPE Tissue - Part 2: Isolated Proteins)
https://sas.bbmri-eric.eu/surveys/?s=5QgIY7FNfn

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

- Directory
- Negotiator
- …

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

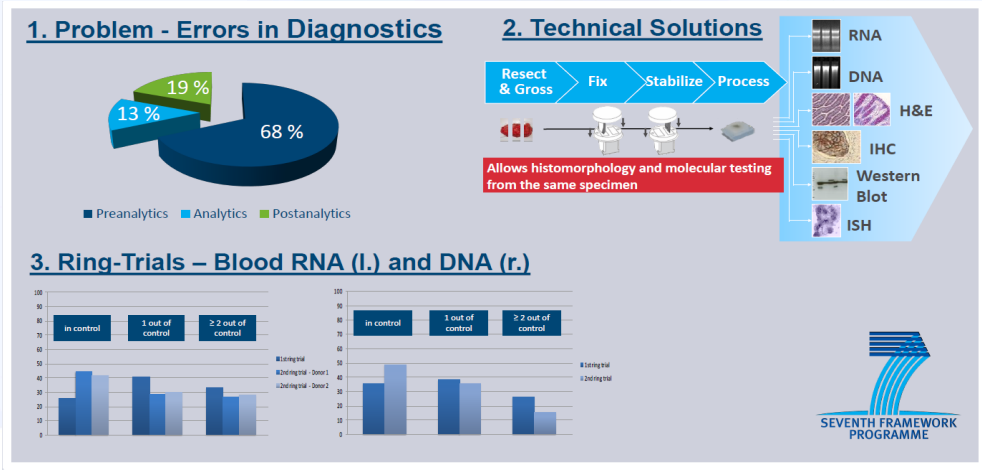
THE SPIDIA SUCCESS STORY

BBMRI-ERIC
gateway for health

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



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

CEN CENELEC

European Commission

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

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