BBMRI-ERIC®

MAKING NEW TREAT MENTS POSSIBLE

BIOBANKEN
PARTNER FÜR KLINISCHE STUDIEN - WEGE DER ZUSAMMENARBEIT

ANDREA WUTTE, BBMRI-ERIC QM SERVICE

BBMRI-ERIC

INCREASING THE VISIBILITY OF BIOBANKS AND SAMPLE COLLECTIONS

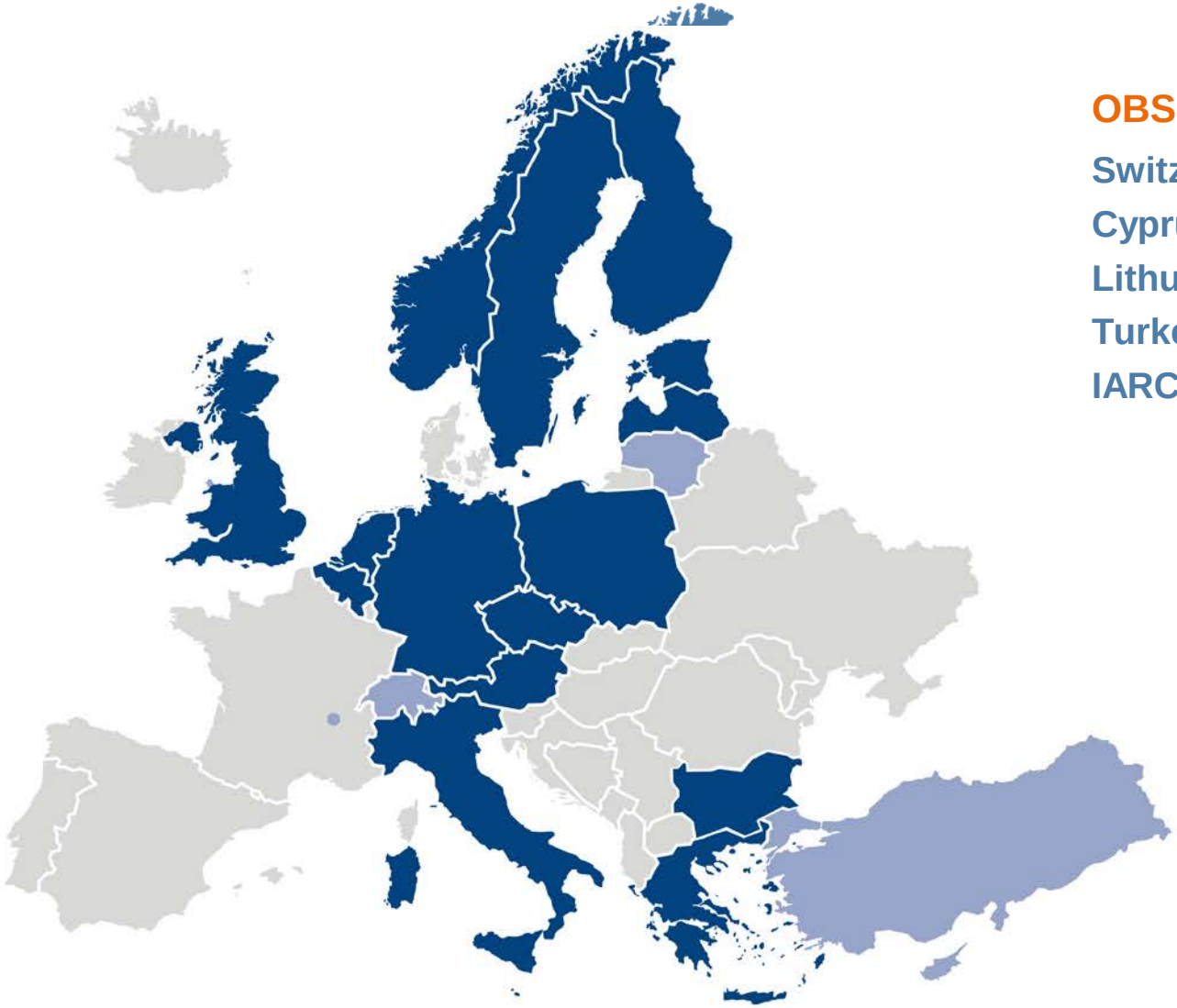
MAKING NEW TREATMENTS POSSIBLE

BBMRI-ERIC is a European research infrastructure for biobanking. We bring together all the main players from the biobanking field – researchers, biobankers, industry, and patients – to boost biomedical research. To that end, we offer quality management services, support with ethical, legal and societal issues, and a number of online tools and software solutions. Ultimately, our goal is to make new treatments possible.

WE ARE 21

MEMBER STATES

- Austria
- Belgium
- Bulgaria
- Czech Republic
- Estonia
- Finland
- Germany
- Greece
- Italy
- Latvia
- Malta
- Netherlands
- Norway
- Poland
- Sweden
- United Kingdom



OBSERVERS

- Switzerland
- Cyprus
- Lithuania
- Turkey
- IARC

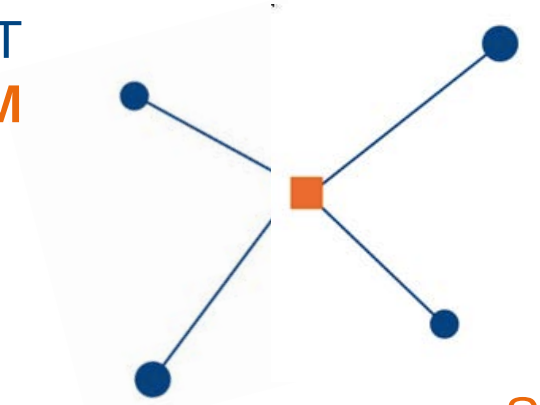
OUR SERVICES

PROVISION OF

BIOLOGICAL MATERIAL AND ASSOCIATED DATA

SUPPORT **QM**

SUPPORT **IT**



ENGAGE STAKEHOLDERS

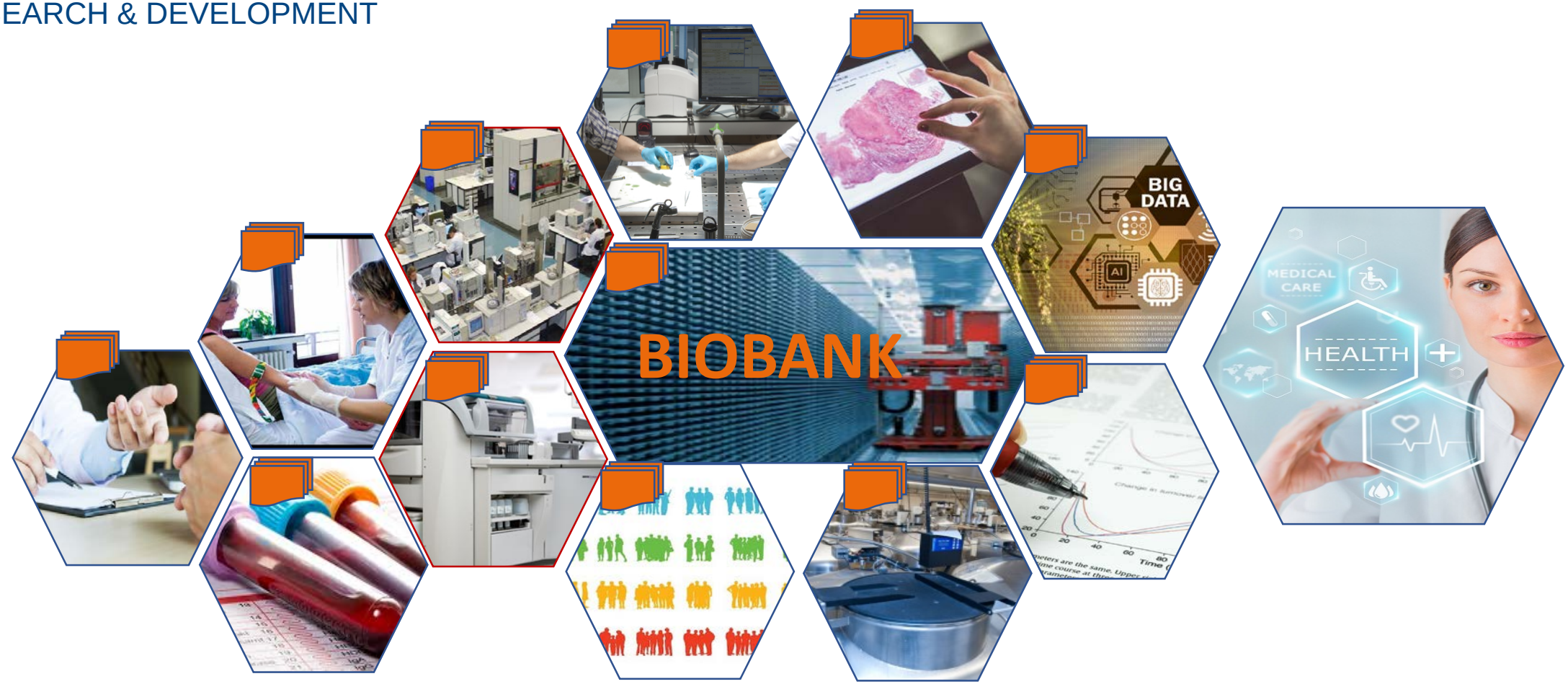
SUPPORT **ELSI**

PUBLIC HEALTH

CUSTOMER SATISFACTION

WORKFLOW IN PERSONALIZED MEDICINE

RESEARCH & DEVELOPMENT



BBMRI-ERIC LIAISONS WITH INTERNATIONAL STANDARDIZATION ORGANIZATIONS

Since 2015, BBMRI-ERIC has established and actively maintains liaisons to the International Organization for Standardization Technical Committees (ISO/TC).

ISO/TC 276 Biotechnology

Scope: Standardization in the field of biotechnology processes that includes the following topics:

– Terms and definitions;
– biobanks and bioresources;
– analytical methods;
– bioprocessing;
– data processing including annotation, analysis, validation, comparability and integration;
– metrology.

BBMRI-ERIC Delegates: Andrea Wutte and Petr Holub

ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

Scope: Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance.

BBMRI-ERIC Delegates: Andrea Wutte

Technical Committee ISO/TC 212 Health Informatics

Scope: Standardization in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.

BBMRI-ERIC Delegates: Andrea Wutte

Since 2016, BBMRI-ERIC has established and actively maintains a liaison to the European Standardisation Organization (CEN/TC)

CEN/TC 140 In vitro diagnostic medical devices

Scope: Standardization in the field of in vitro diagnostic medical devices which are reagents, reagent product, calibrators, control materials, kits, instruments, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: – concerning a physiological or pathological state or; – concerning a congenital abnormality or; – to determine the safety and compatibility with potential recipients, or; – to monitor therapeutic measures. Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination. Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

BBMRI-ERIC Delegates: Andrea Wutte

INTERNATIONAL STANDARDS

BIOBANKING – SPECIMEN PROCESSING - AUDITING

Biobanking – Requirements for biobanking, ISO 20387:2018

Quality management systems Requirements, ISO 9001:2015

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Frozen tissues, FFPE, Venous Whole Blood, Metabolomics …

Guidelines for auditing management systems, ISO 19011:2011

ISO 20387:2018

BIOBANKING – REQUIREMENTS FOR BIOBANKING

1 Scope

2 Normative references

3 Terms and definitions

4 General requirements

5 Structural requirements

6 Resource requirements

7 Process requirements

8 Quality management system requirements

Annex A (normative) Documentation requirements

Annex B (informative) Implementation guidance for Annex A

Annex C (informative) Quality management system options

Bibliography


INTERNATIONAL STANDARD

ISO 20387

First edition
2018-08

Biotechnology — Biobanking — General requirements for biobanking

Biotechnologie — «Biobanking» — Exigences générales relatives au «biobanking»

Reference number
ISO 20387:2018(E)

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ISO 20387:2018

TABLE OF CONTENT

7 Process requirements

7.1 General

7.2 Collection of biological material and associated data

7.2.1 Documented information requirements

7.2.2 Pre-acquisition information

7.2.3 Collection procedure

CEN/TS, ISO/TS pre-examination processes

7.3 Reception and distribution of biological material and associated data

7.3.1 Access principles

7.3.2 Reception

7.3.3 Distribution

7.4 Transport of biological material and associated data

Reference: www.iso.org

ISO 20387:2018

TABLE OF CONTENT

Reference: www.iso.org

ISO 20387:2018

EXCERPT

7 Process requirements

7.1 General

7.2 Collection of biological material and associated data

7.2.1 Documented information requirements

7.2.2 Pre-acquisition information

7.2.3 Collection procedure

CEN/TS, ISO/TS pre-examination processes

Reference: www.iso.org

QUALITY OF SPECIMENS

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.

SPECIMEN PROCESSING

INTERNATIONAL STANDARDS

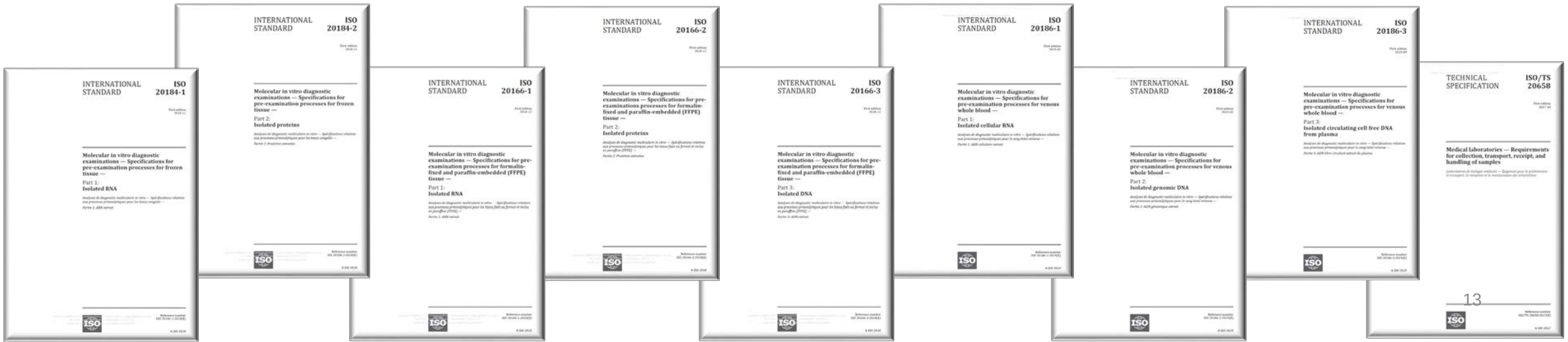
ISO 20184-1 frozen tissue – Part 1: Isolated RNA
ISO 20184-2 frozen tissue – Part 2: Isolated proteins

ISO 20166-1, FFPE tissue – Part 1: Isolated RNA
ISO 20166-2, FFPE tissue – Part 2: Isolated proteins
ISO 20166-3, FFPE tissue – Part 3: Isolated DNA

ISO 20186-1, venous whole blood - Part 1: Isolated cellular RNA
ISO 20186-2, venous whole blood - Part 2: Isolated genomic DNA
ISO 20186-3, venous whole blood – Part 3: Isolated circ. cell-free DNA from plasma

CEN/TS 16945 metabolomics in urine, serum and plasma

ISO/TS 20658:2017, Medical laboratories — Requirements for collection, transport, receipt, and handling of samples



NEW CEN/TS AND ISO STANDARDS

IN THE PIPELINE UNTIL 2021

4 CEN/TS for venous whole blood circulating Tumor and Organ Cells (DNA, RNA, Proteins, staining procedures)

1 CEN/TS for Venous Whole Blood Exosomes / cell-free circulating RNA

1 CEN/TS for Saliva (DNA)

1 CEN/TS for Frozen Tissues (DNA)

1 CEN/TS for Urine and other body fluids (cell-free DNA)

3 CEN/TS for Fine Needle Aspirates (RNA, DNA, Proteins)

1 CEN/TS for Saliva and Stool Microbiomes (DNA)

1 CEN/TS for FFPE Tissues (in-situ staining procedures)

H2020 Project SPIDIA4P, GA No. 733112

INTERNATIONAL STANDARDS

LABORATORY PRACTICES

Medical laboratories Requirements for collection, transport, receipt, and handling of samples, ISO/TS 20658:2017

Medical laboratories – Requirements for quality and competence, ISO 15189:2012

General requirements for the competence of testing and calibration laboratories, ISO 17025:2005

And others…

INTERNATIONAL STANDARDS

DATA QUALITY

Data quality - Master data: Exchange of characteristic data: Overview ISO 8000-100:2016

Data quality - Master data: Exchange of characteristic data: Syntax, semantic encoding, and conformance to data specification, ISO 8000-110:2009

Data quality - Master data: Exchange of characteristic data: Provenance , ISO 8000-120:2016

Data quality - Master data: Exchange of characteristic data: Accuracy , ISO 8000-130:2016

Data quality - Master data: Exchange of characteristic data: Completeness , ISO 8000-140:2016

INTERNATIONAL STANDARDS

DATA QUALITY

- Data quality - Master data: Quality management framework, ISO 8000-150:2011
- Data quality - Information and data quality: Concepts and measuring, ISO 8000-8:2015
- Data quality - Data quality management: Process reference model, ISO 8000-61:2016
- Data quality - Master data: Exchange of quality identifiers: Syntactic, semantic and resolution requirements , ISO 8000-115:2015
- Data quality - Data quality management: Process reference model, ISO 8000-61:2016
- Data quality - Information and data quality management process assessment, ISO 8000-60:2016

INTERNATIONAL STANDARDS

INFORMATION TECHNOLOGIES

Information technology – Security techniques – Information security management systems, ISO/IEC 27001

Information technology – Security techniques – Code of practice for information security controls based on ISO/IEC 27002 for cloud services, ISO/IEC 27017

Information technology – Security techniques – Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors, ISO/IEC 27018

And others…

BBMRI-ERIC®

BBMRI-ERIC®

ABOUT ▿ SERVICES & SUPPORT ▿ EU GRANTS ▿ NEWS & EVENTS ▿ CONTACT ▿

- DIRECTORY
- SAMPLE/DATA NEGOTIATOR
- SAMPLE/DATA LOCATOR
- QUALITY MANAGEMENT
- ELSI: ETHICAL, LEGAL AND SOCIAL ISSUES IN BIOBANKING
- GDPR CODE OF CONDUCT

INCREASING THE VISIBILITY OF BIOBANKS AND SAMPLE COLLECTIONS

SPECIMEN PROCESSING

INTERNATIONAL STANDARDS

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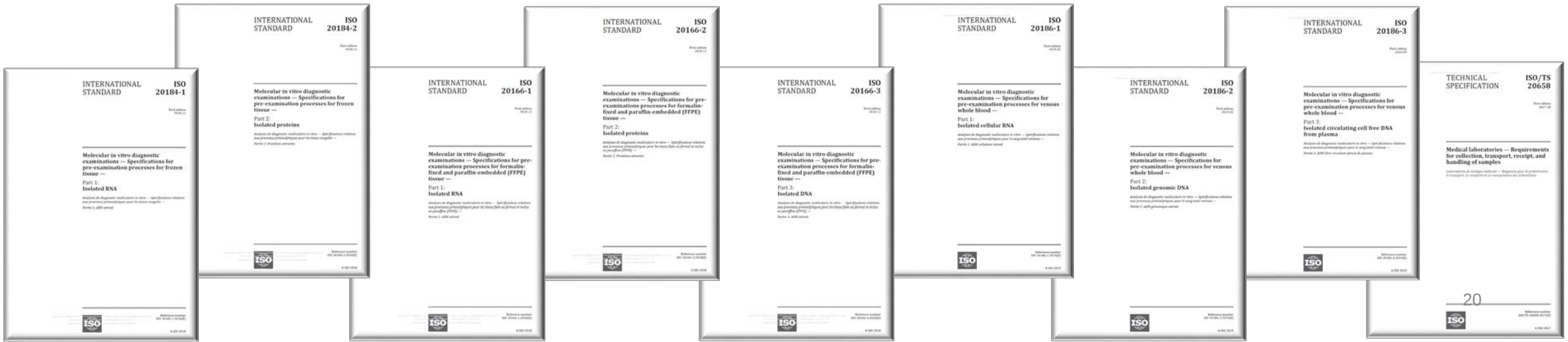
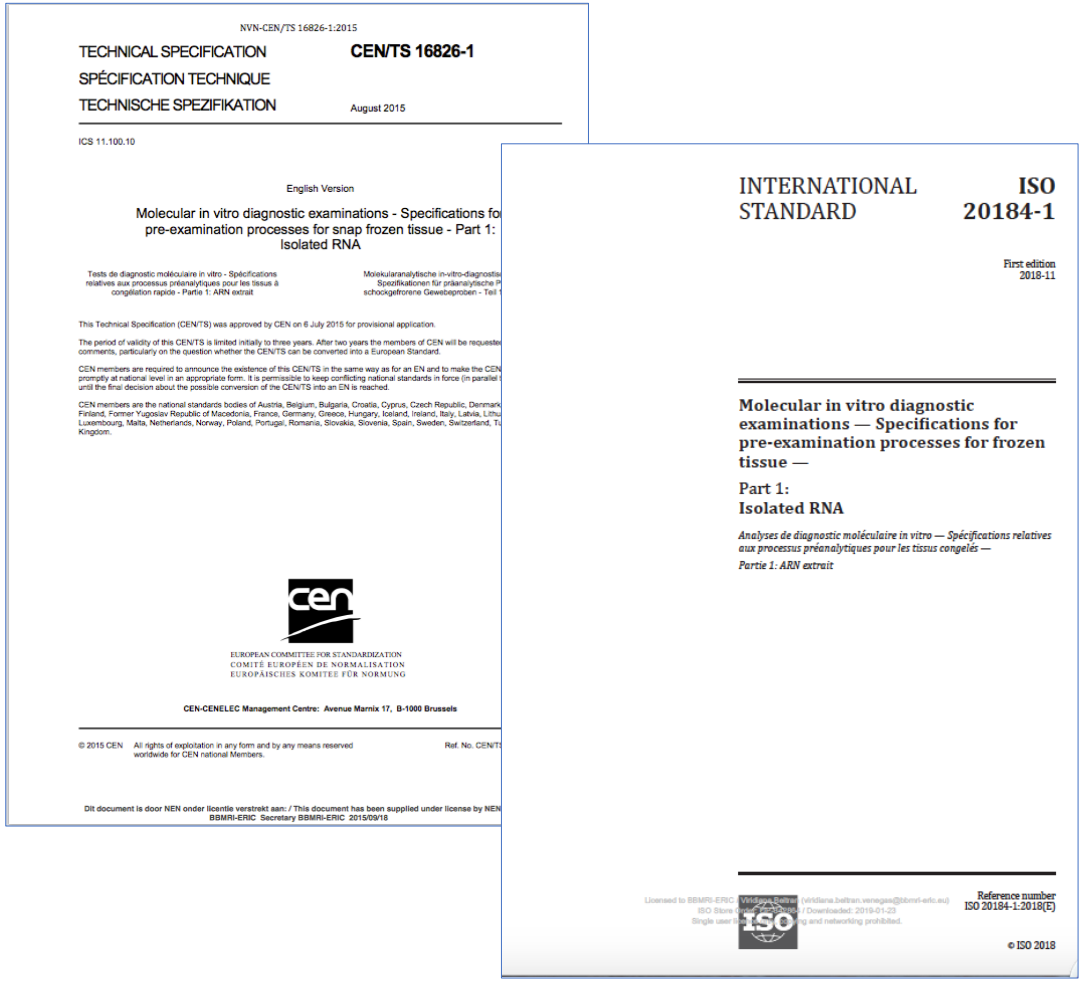


BBMRI-ERIC SELF-ASSESSMENT SURVEYS

Q-LABEL IN DIRECTORY



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 fo 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-diagnostis Spezifikationen für präanalytische P schockgefrorene Gewebeproben - Teil

This Technical Specification (CEN/TS) was approved by CEN on 6 July 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 requeste 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 promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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

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

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INTERNATIONAL STANDARD **ISO 20184-1**

First edition 2018-11

Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue —

Part 1: Isolated RNA

Analyses de diagnostic moléculaire in vitro — Spécifications relatives aux processus préanalytiques pour les tissus congelés —

Partie 1: ARN extrait

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Reference number ISO 20184-1:2018(E)

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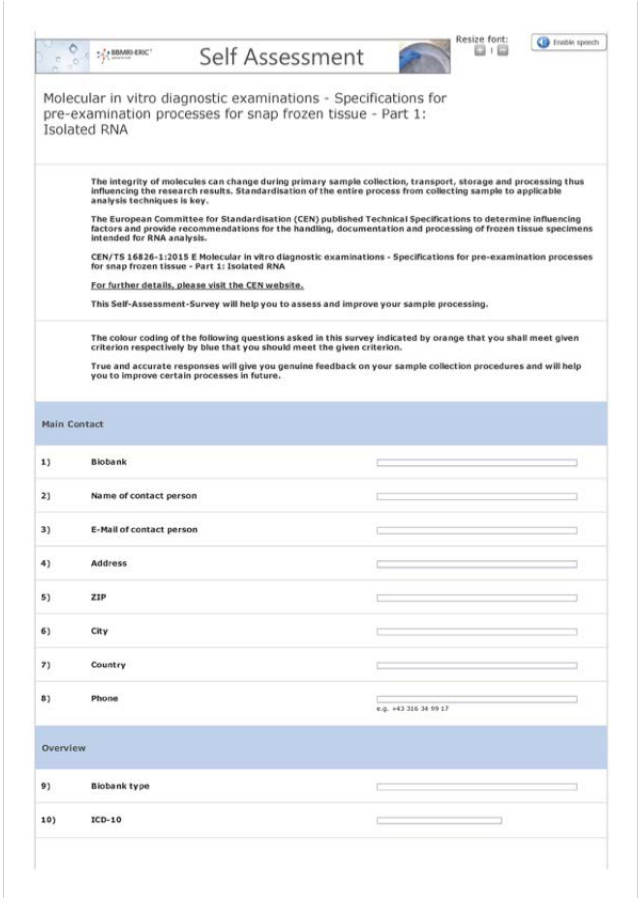


Self Assessment

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.

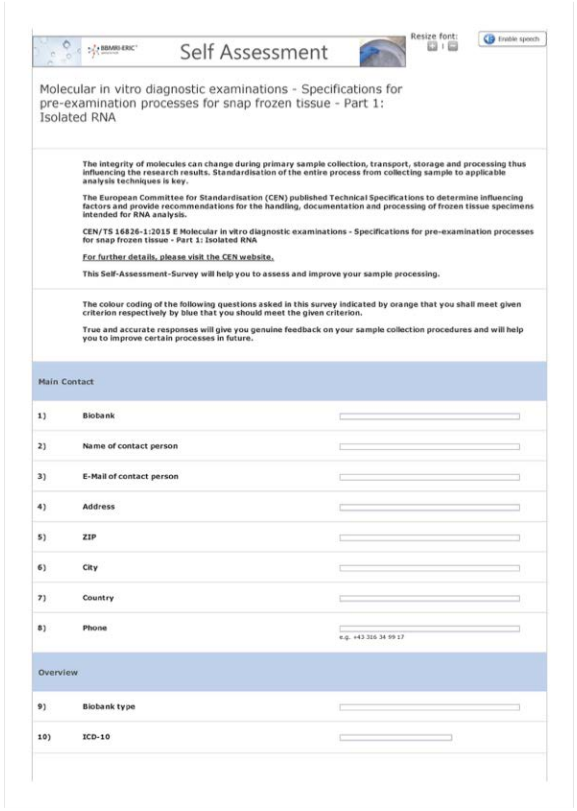
The colour coding of the following questions asked in this survey indicated by orange that you shall meet given criterion respectively by blue that you should meet the given criterion.

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	

REMOTE AUDIT FOR COLLECTIONS

Q-LABEL IN DIRECTORY



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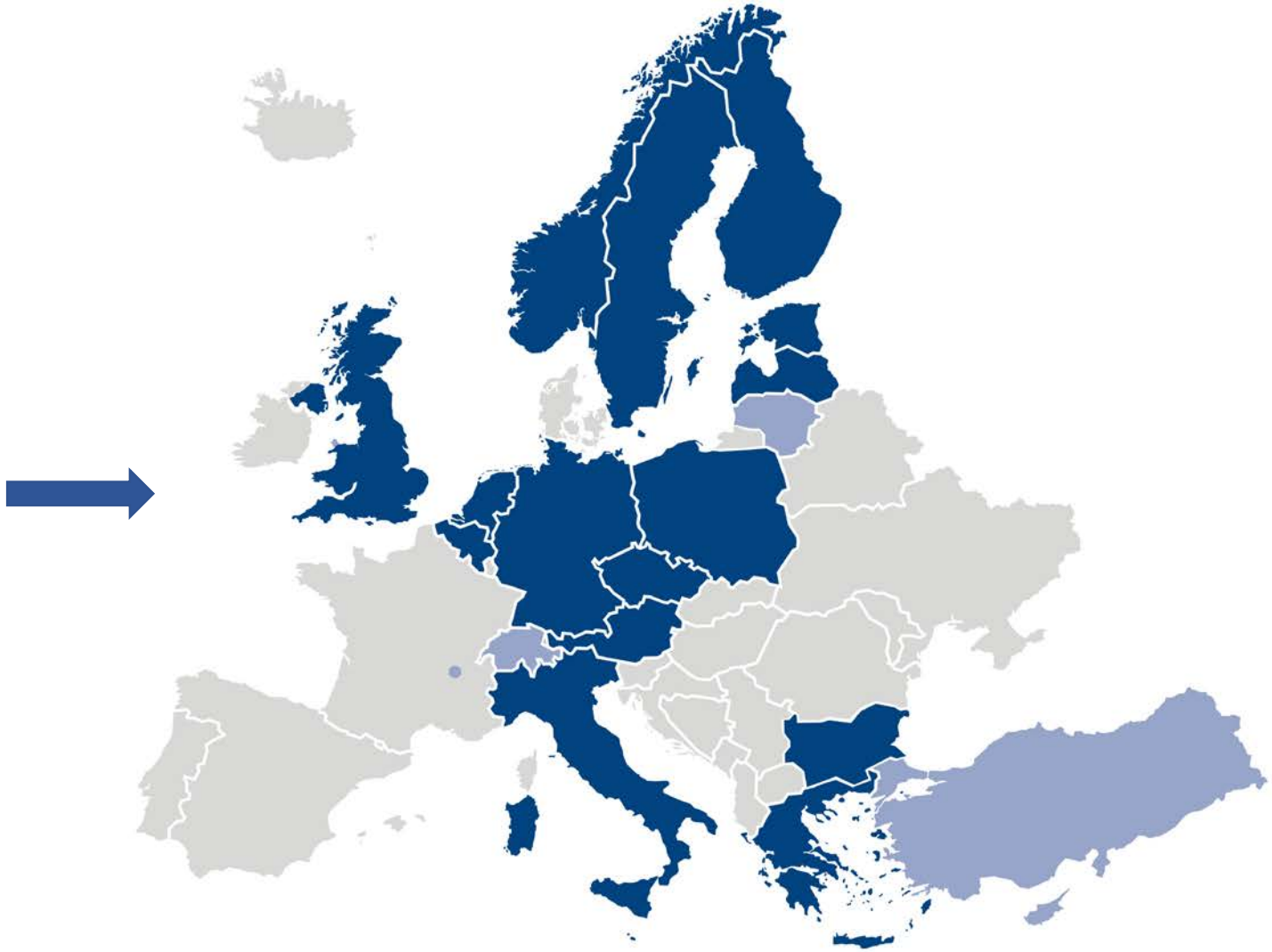

ONSITE AUDIT FOR BIOBANKS

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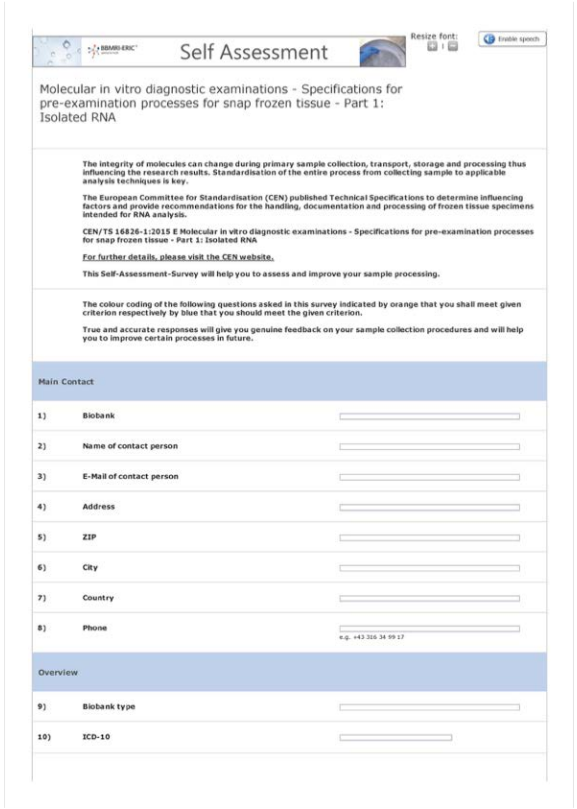

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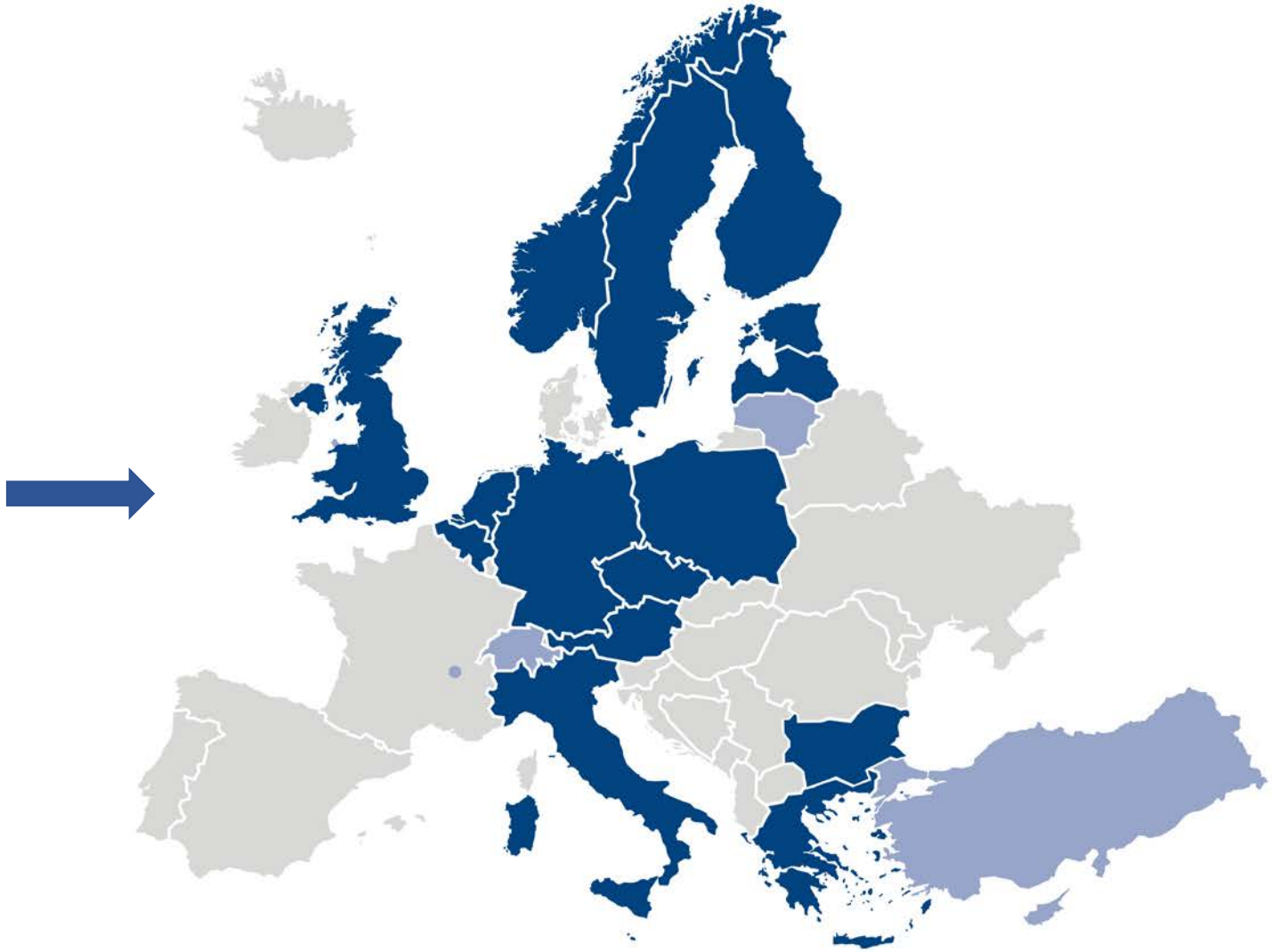
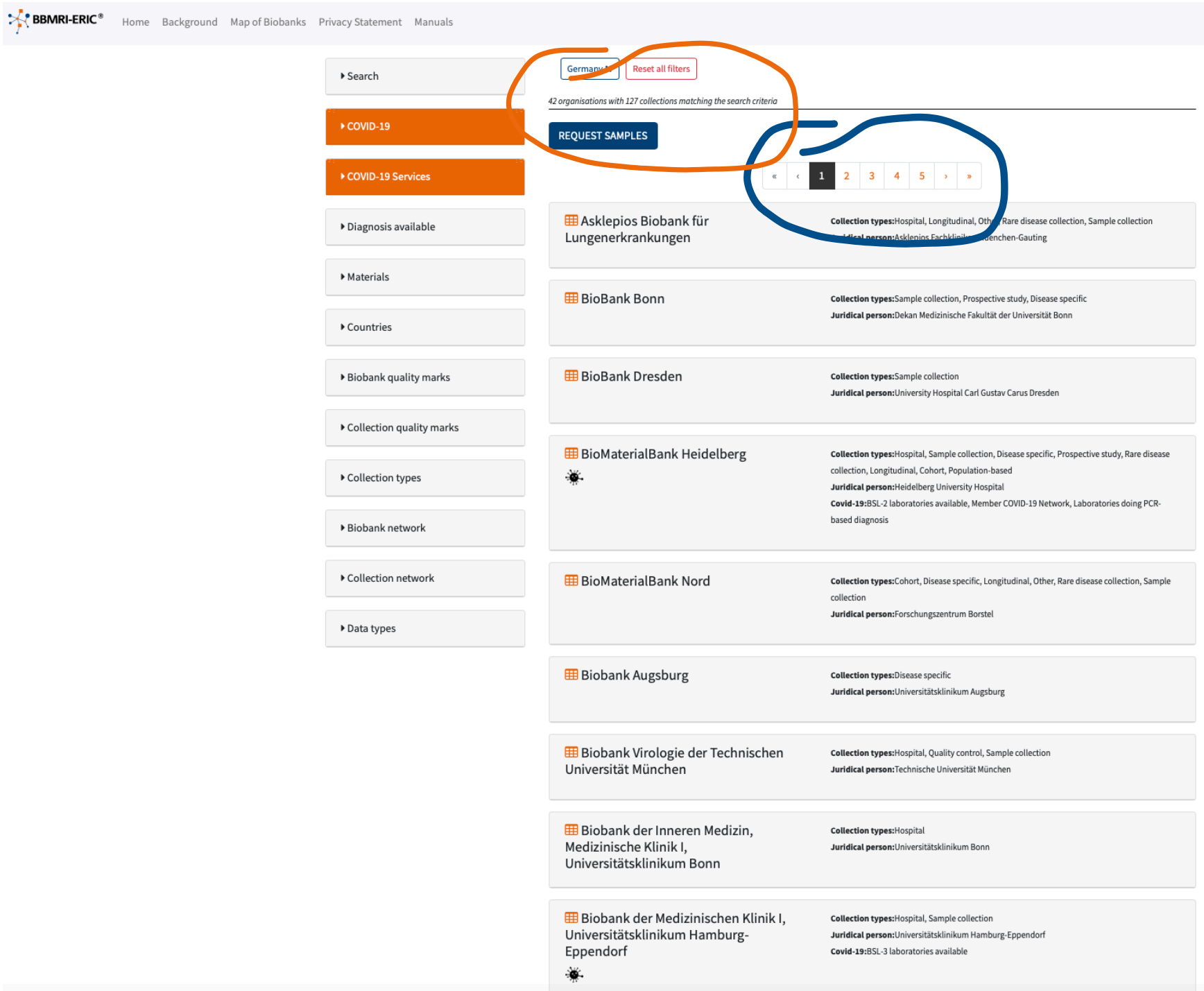


GERMANY

BBMRI DIRECTORY



AW, December 10, 2020

GERMANY

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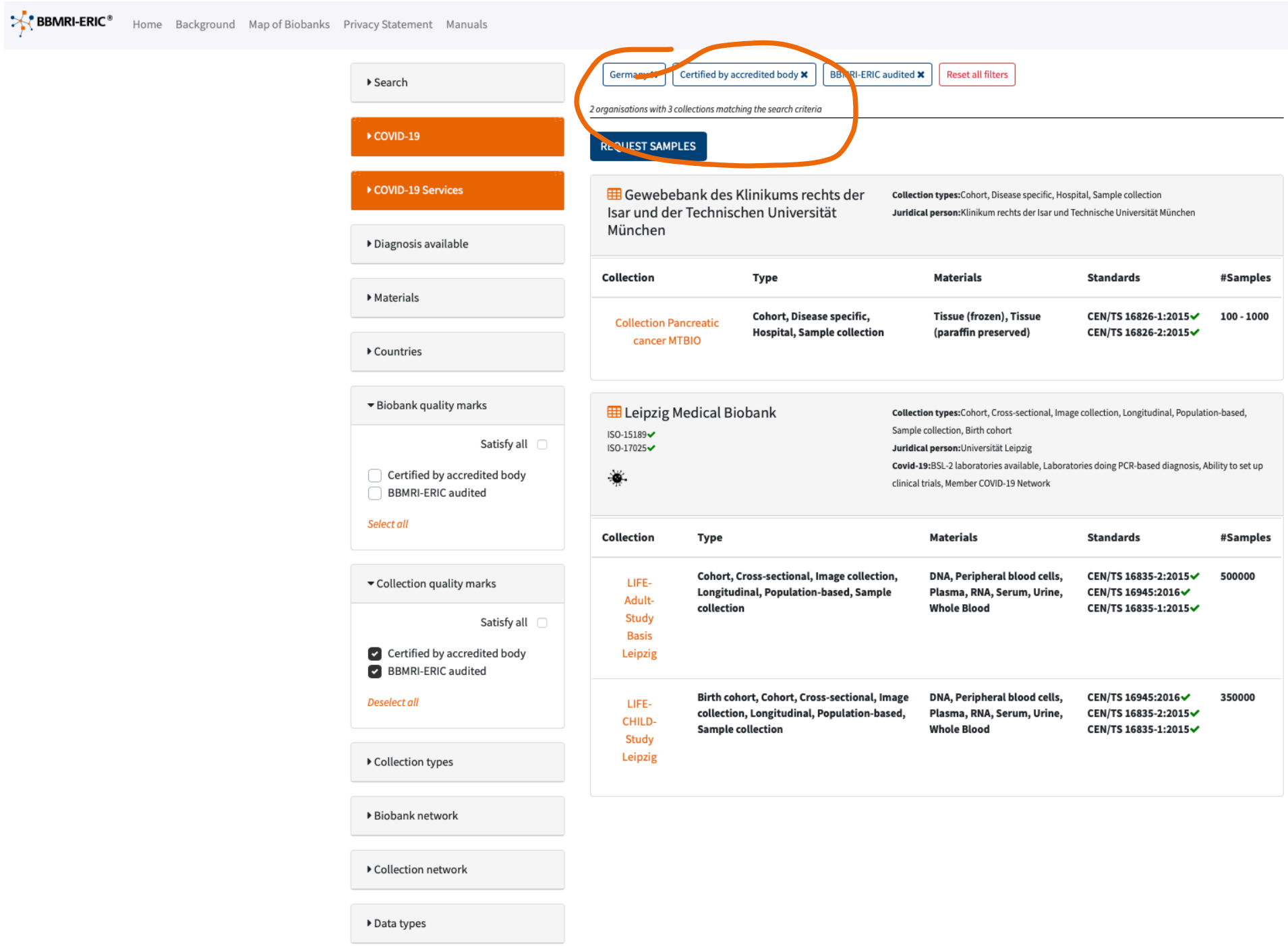

BBMRI-ERIC®

BBMRI-ERIC QUALITY MANAGEMENT SERVICES FOR BASIC AND APPLIED RESEARCH

Home - Services & Support - Quality Management

KNOWLEDGE HUB

Find everything you need to know about quality management in biobanking and biomedical research in one place: The BBMRI.QM Knowledge Hub consists of a pool of experts that can help you with any of the following:

- BBMRI-ERIC liaisons with international standardization organizations
- International standards relevant for biobanking and biomedical research
- Quality management tasks in EU projects
- Biobanking in times of COVID-19 **Recordings available!**

TRAINING & SUPPORT

Whether you are looking for training opportunities or practical support with your quality management – quality experts can provide you with a solution tailored to your needs.

Within the BBMRI.QM network, we offer in-house and online training, university courses, summer schools, short courses, workshops, and consulting services covering different quality management systems:

BBMRI.QM Training & Education Programmes:

- Training series about molecular in vitro diagnostic examinations – specifications for pre-examination processes **NEW**
- Training series about the biobanking standard ISO 20387:2018 **Recordings available!**

AUDITING

If you run a non-certified biobank and/or you want to know if the samples stored fulfill certain quality requirements, get the support of BBMRI.QM. We offer peer-review-style audits on request. Take the next QM improvement step together with us!

Step 1: Assess your processes with the BBMRI-ERIC Self-Assessment Survey (BBMRI-ERIC SAS).

- What is the BBMRI-ERIC SAS?
- Short explanation about access principles to the BBMRI-ERIC SAS
- Request the BBMRI-ERIC SAS

Step 2: Request a BBMRI-ERIC audit

- BBMRI-ERIC Audit

Step 3: A positive audit will lead to a quality mark in the Directory

- Q-mark in the BBMRI-ERIC Directory

QUALITY ASSURANCE

Task Force to define and provide biomarkers (intrinsic/extrinsic) that allow for standardized assessment of sample quality with a focus on liquid biopsies) through biospecimen research.

VISIT bbmri-eric.eu/services/quality-management

SHARE #BBMRI_QM @BBMRIERIC

THANK YOU

Co-funded within ADOPT BBMRI-ERIC, a project that has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 676550.

Co-funded within SPIDIA4P, a project that has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 733112.

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