QUALITY MANAGEMENT IN BIOBANKING

BBMRI-ERIC®
biobanking for a healthier world

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BBMRI-ERIC

European Research Infrastructure Consortium
for biobanking and biomolecular resources
established in 2013 under EU legislation (ERIC)

BBMRI-ERIC enables the development of innovative technology and processes, as a cross-domain network, that facilitates responsible access to **high quality samples, data and biomolecular resources**

AGENDA

01. BBMRI-ERIC IN A NUTSHELL IN THE VIEWPOINT OF QM
The distributed Research Infrastructure

02. QUALITY IN BIOBANKING
International Standard ISO 20387

03. QUALITY OF SAMPLES AND DATA (PRE-ANALYTICS)
International pre-analytical Standards

04. BBMRI-ERIC QUALITY MANAGEMENT SERVICE
BBMRI-ERIC QM SERVICE | AUDIT PROGRAMME | QUALITY LABEL

05. QUIZ
7 Questions to be answered

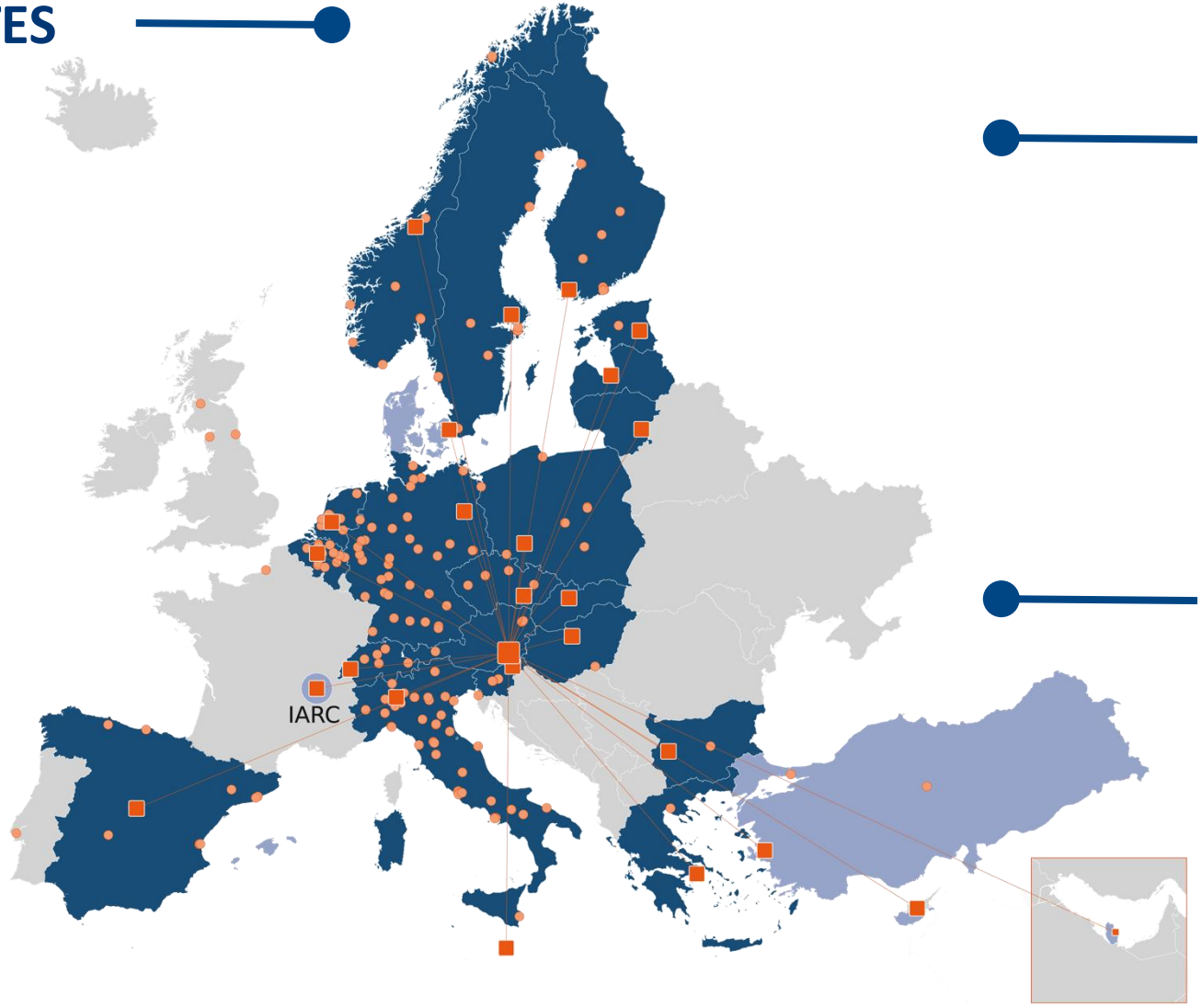
01.

BBMRI-ERIC IN A NUTSHELL

BBMRI IS A DISTRIBUTED ERIC IN HEALTH AND LIFE SCIENCES

22 MEMBER STATES

Austria
Belgium
Bulgaria
Cyprus
Czech Republic
Estonia
Finland
Germany
Greece
Hungary
Italy
Latvia
Lithuania
Malta
Netherlands
Norway
Poland
Slovakia
Slovenia
Spain
Sweden
Switzerland



4 OBSERVERS

Denmark
IARC/WHO
Qatar
Türkiye

COMMUNITY

~ 500 biobanks
+ Affiliated partners
25 National Nodes + IARC/WHO
1 Headquarter
3 Biotech Expert Centres
ELSI, QM, IT Expert Groups

02.

QUALITY IN BIOBANKING

QUALITY IN BIOBANKING

"If we want researchers to be able to achieve reliable research results, we need to make sure that they have access to **samples and data of well-defined quality that fit for their research purpose.**

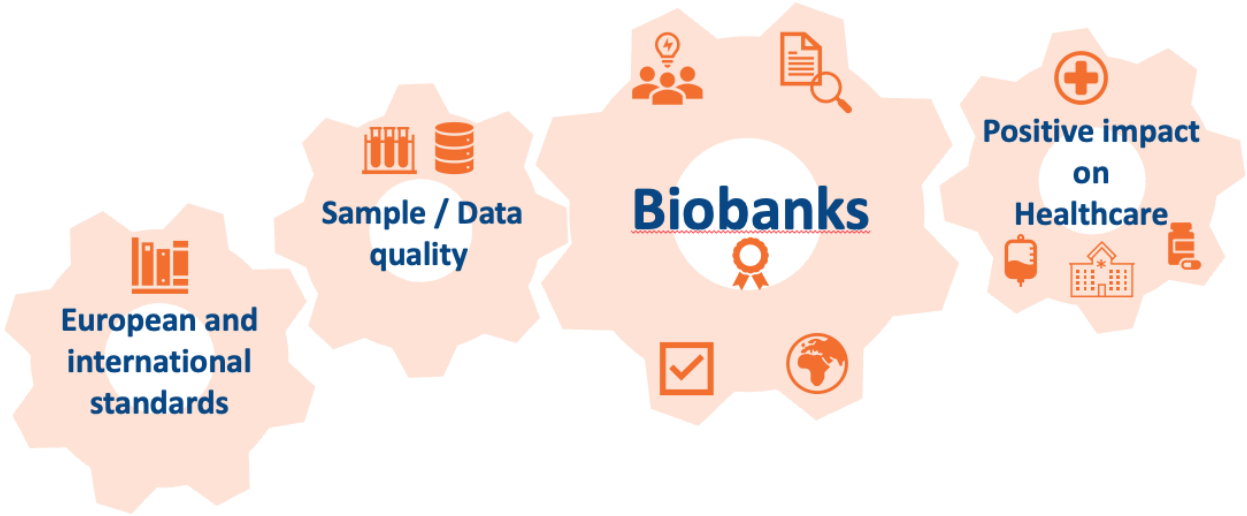
As a European Research Infrastructure, our key objective is to ensure the **comparability of samples and data across** different countries and various biobanking and research systems"

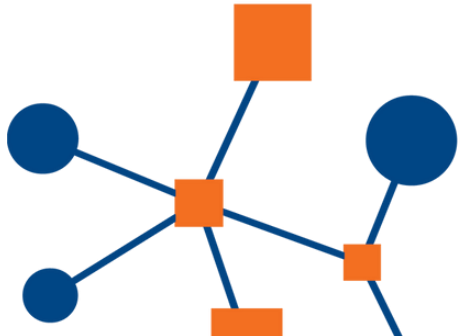
QUALITY IN BIOBANKING

Biobanks play a pivotal role in

collecting, tagging, accessioning, cataloguing/classifying, examining, preparing, preserving, storing, destroying, packaging, distributing and transporting of biological material and associated data.

Biobanks have the overall aim of supporting medical translational research and increasing the quality of the research output and positive impact on the health care system.

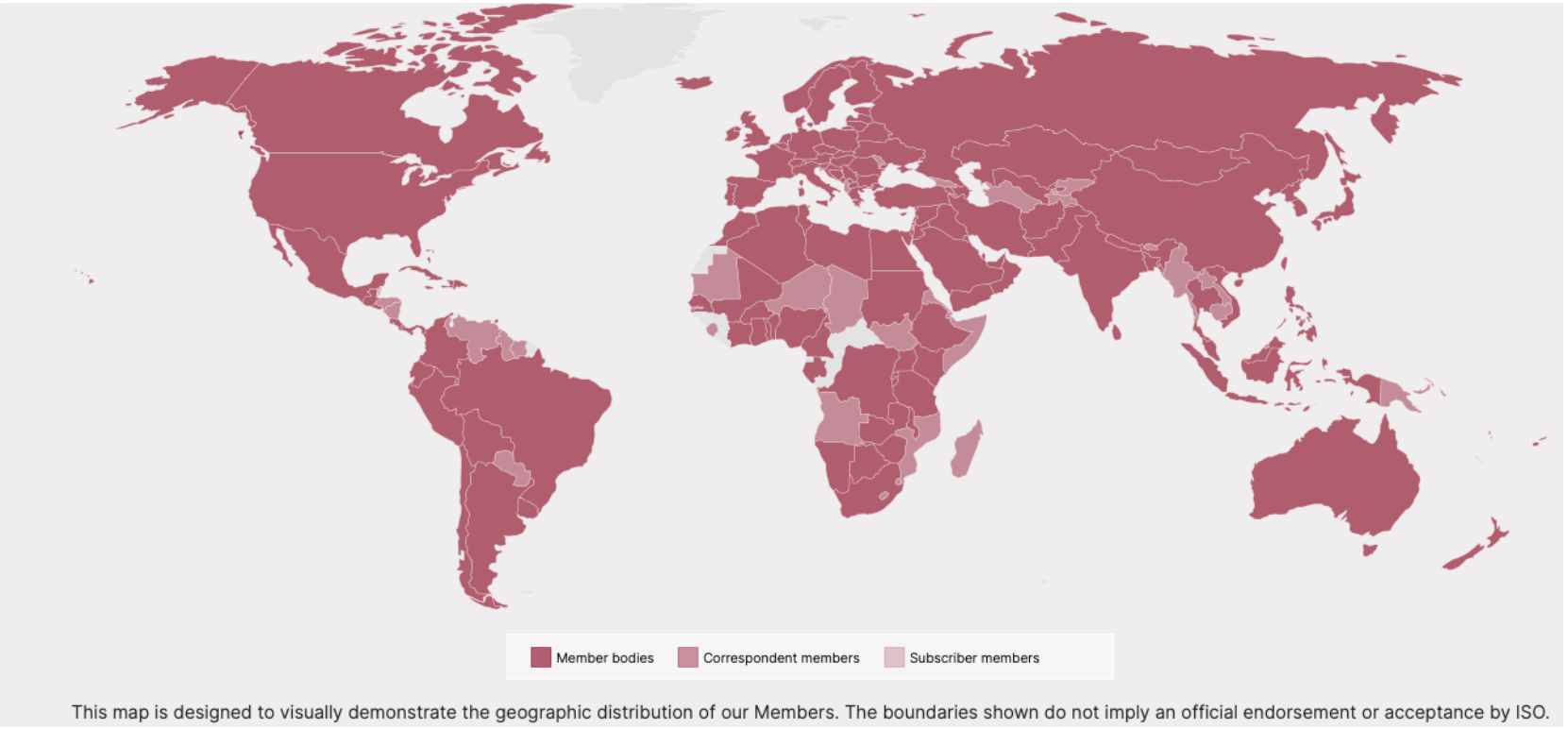




BIOBANKS A PARTNER FOR RESEARCH AND DEVELOPMENT

Quality Assurance / Quality Control (QA/QC)

BBMRI-ERIC LIAISON WITH ISO SINCE 2015



Facts and Figures:

- **ISO = International Organization for Standardization**
- Independent, non-governmental international organisations with a membership of **174** national standards bodies
- ISO collaborates with over **700** international organizations (& Liasons)
- **275 Technical Committees** comprise experts from national committees

- **ISO/TC 276**: Biotechnology
  Biobanking / Provenance data
- **ISO/TC 212**: Clinical laboratory testing and in vitro diagnostic test systems
  Pre-examination processes
  Quality of the
  biological material and data
- **ISO/TC 215**: Health Informatics
- **ISO/TC 215**: Health Informatics **CEN/TC 140**: In vitro diagnostic medical devices

INTERNATIONAL STANDARDS
BIOBANKS and BIOMEDICAL RESEARCH

- Quality of Biobanking : **General requirements for biobanking, ISO 20387**
- ISO/TR 22758:2020 Implementation guide for ISO 20387
- Quality of the Samples / Data: Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for tissues, blood, serum plasma, saliva, stool, body fluids… **(21+ ISO pre-analytical standards) ,** Data Quality , Data Security , Data Provenance
- Guidelines for auditing management systems, ISO 19011

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

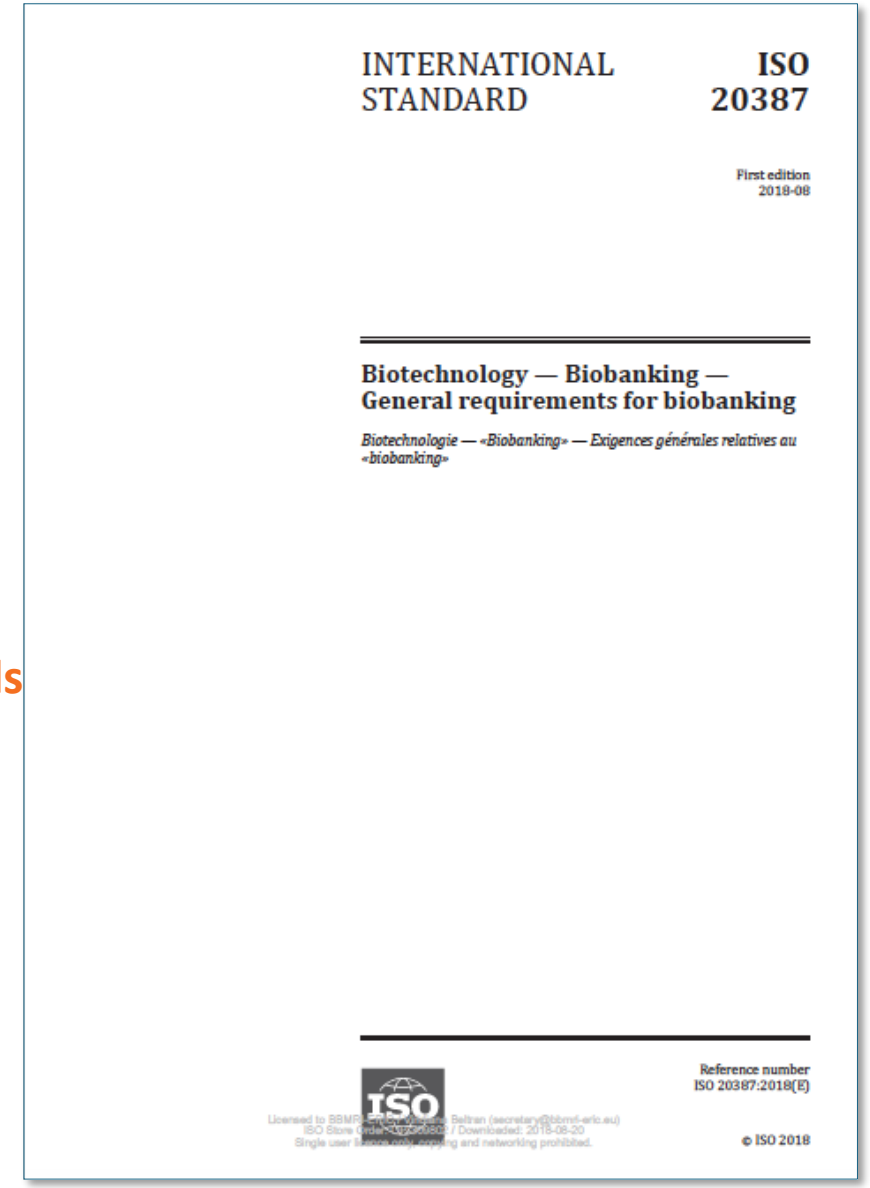
Annex A (normative) Documentation requirements

Annex B (informative) Implementation guidance for Annex A

Annex C (informative) Quality management system options

Bibliography

🔎🔎 **ISO and CEN Technical Standards**



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)

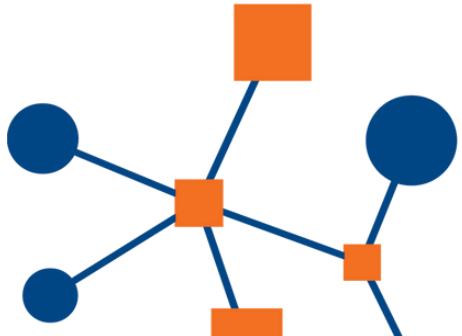
THE SCOPE OF ISO 20387:2018

Find training in biobanking standard, ISO 20387:
https://www.bbmri-eric.eu/services/bbmriqm-training-education/

The standard specifies general requirements for the competence, impartiality and consistent operation of biobanks including quality control requirements to ensure biological material and data collections of appropriate quality.

The standard is applicable to all organizations performing biobanking, including biobanking of biological material from multicellular organisms (e.g. human, animal, fungus and plant) and microorganisms for research and development.

Biobank users, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others can also use this document in confirming or recognizing the competence of biobanks.



ISO 20387:2018 OVERVIEW

Find training in biobanking standard, ISO 20387:
https://www.bbmri-eric.eu/services/bbmriqm-training-education/

3 Terms and definitions

Examples:::

biobank

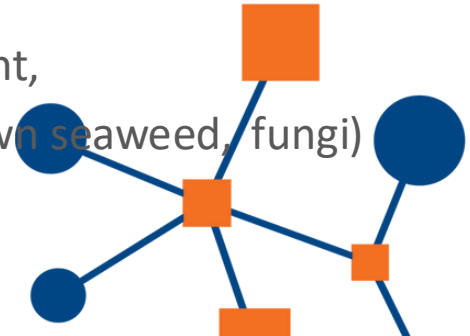
Legal entity or part of a legal entity that performs biobanking (3.6)

biobanking

Process of acquisition (3.2) and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analyzing and distributing defined biological material as well as related information and data

biological material

Any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is (are) neither animal nor plant (e.g. brown seaweed, fungi)



ISO 20387:2018 OVERVIEW

Find training in biobanking standard, ISO 20387:
https://www.bbmri-eric.eu/services/bbmriqm-training-education/

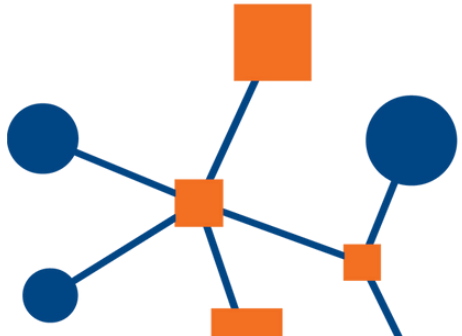
4 General requirements

- Impartiality
- Confidentiality

5 Structural requirements

6 Resource requirements

- Personnel
- Competence and competence assessment
- Training
- Facilities/dedicated areas and environmental conditions
- Externally provided processes, products and services
- Equipment



ISO 20387:2018 OVERVIEW

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7 Process requirements

Collection of biological material and associated data

- Documented information requirements
- Pre-acquisition information
- Collection procedure

ISO and CEN technical standards

Reception and distribution of biological material and associated data

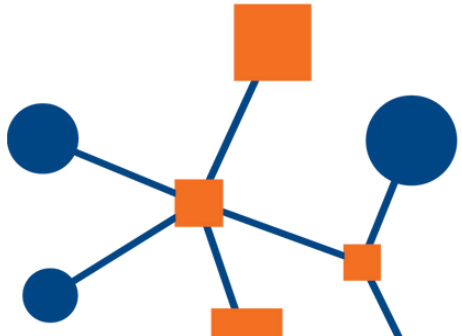
- Access principles
- Reception
- Distribution

Transport of biological material and associated data

Traceability of biological material and associated data

Preparation and preservation of biological material

Storage of biological material



ISO 20387:2018 OVERVIEW

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Quality control of biological material and associated data

- Quality control of processes
- Quality control of data

Validation and verification of method

- Validation
- Verification

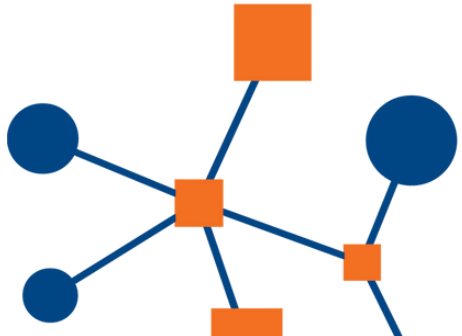
Management of information and data

Nonconforming output

- Control of nonconforming output

Report requirements

- Content of the report



ISO 20387:2018 OVERVIEW

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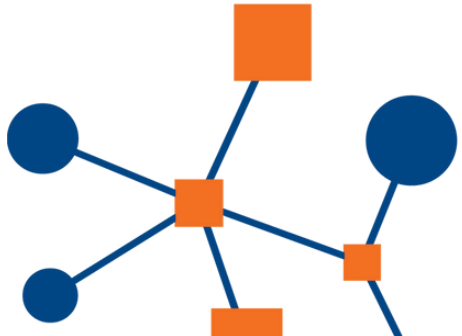
8 Quality management system requirements

- Documented information for the quality management system
- Control of quality management system documents (Option A)
- Control of records
- Actions to address risks and opportunities
- Improvement
- Corrective action for nonconforming output
- Internal audits
- Quality management reviews

Annex A (normative) Documentation requirements

Annex B (informative) Implementation guidance



ISO 20387:2018 – QUALITY OF THE BIOLOGICAL MATERIAL

7 Process requirements

Collection of biological material and associated data

Documented information requirements

Pre-acquisition information

Collection procedure

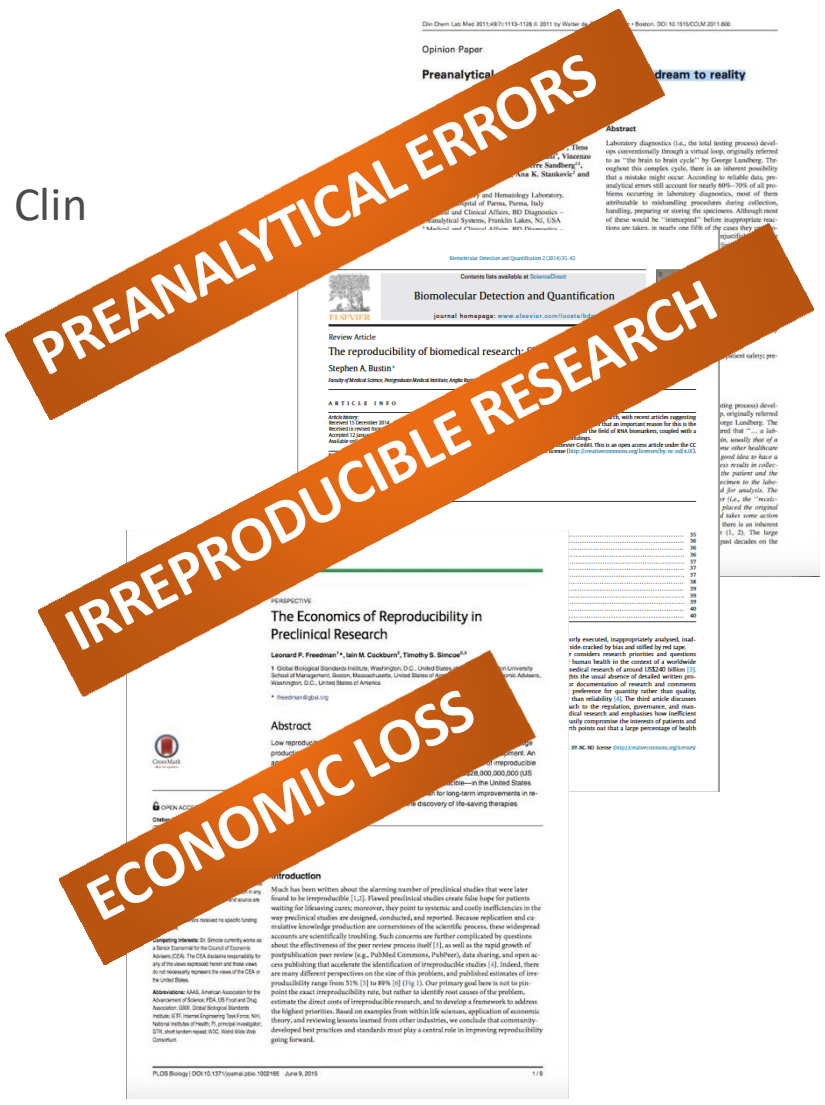
🔎🔎 ISO and CEN technical standards for sample collection and processing (pre-examination processes)

QUALITY OF BIOLOGICAL MATERIAL

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.



03.

QUALITY OF SAMPLES AND DATA (PRE-ANALYTICS)

BIOTECHNOLOGY - BIOBANKING

INTERNATIONAL STANDARDS

ISO 20070:2025 Requirements for primary containers for storing biological materials in biobanks

ISO 21899:2020 Validation and verification of processing methods for biological materials in biobanks

ISO 24651:2022 Requirements for human mesenchymal stromal cells derived from bone marrow
ISO/TS 22859:2022 Requirements for human mesenchymal stromal cells derived from umbilical cord tissue

ISO 20012:2026 Requirements for human natural killer cells derived from pluripotent stem cells
ISO 18162:2024 Requirements for human neural stem cells derived from pluripotent stem cells
ISO 21709:2020 Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines

ISO 24603:2022 Requirements for human and mouse pluripotent stem cells

BIOTECHNOLOGY - BIOBANKING

INTERNATIONAL STANDARDS

ISO 24603:2022 Requirements for human and mouse pluripotent stem cells

ISO 20309:2025 Requirements for deep-sea biological material

ISO/TS 20388:2021 Requirements for animal biological material

ISO/TS 23105:2021 Requirements for the biobanking of plant biological material for research and development

ISO 16677-1:2025 Germplasm – Part 1: Agricultural animal species

ISO 18209-1:2024 Biobanking of parasites – Part1: Helminths

ISO 24088-1:2022 Biobanking of microorganisms – Part 1: Bacteria and archaea

SPECIMEN PROCESSING

INTERNATIONAL STANDARDS

ISO 20184-1 frozen tissue – Part 1: Isolated RNA
ISO 20184-2 frozen tissue – Part 2: Isolated proteins ISO 20184-3 frozen tissue – Part 3: Isolated DNA

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 20166-4 FFPE tissue – Part 4: In situ detection techniques

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

ISO 23118:2021 metabolomics in urine, venous blood serum and plasma

ISO 4307:2021 saliva – Isolated human DNA

ISO 18704:2026 urine, other body fluids – Isolated cell-free DNA

ISO/TS 7552-1 CTCs in VWB – Part 1: Isolated RNA
ISO/TS 7552-2 CTCs in VWB – Part 2: Isolated DNA
ISO/TS 7552-3 CTCs in VWB – Part 3: Preparations for analytical CTC staining

SPECIMEN PROCESSING

EUROPEAN STANDARDS

CEN/TS 17688-1:2021 Fine Needle Aspirates (FNAs) – Part 1: Isolated cellular RNA
CEN/TS 17688-2:2021 Fine Needle Aspirates (FNAs) – Part 2: Isolated proteins
CEN/TS 17688-3:2021 Fine Needle Aspirates (FNAs) – Part 3: Isolated genomic DNA

CEN/TS 17626:2021 human specimen – Isolated microbiome DNA
CEN/TS 17742:2022 venous whole blood – isolated ccf RNA from plasma

CEN/TS 17747:2022 exosomes and other extracellular vesicles in venous whole blood - DNA, RNA and proteins

CEN/TS 17742:2022 Isolated circulating cell free RNA from plasma

PROVENANCE INFORMATION, DATA QUALITY AND SECURITY

INTERNATIONAL STANDARDS

- Provenance information model for biological material and data — Part 1: Design concepts and general requirements – ISO/TS 23494-1:2023
- Data quality – Master data: ISO 8000 series, Syntax, Provenance, Accuracy, Completeness, etc.
- Information technology – Security techniques: ISO/IEC 270XX series, Information security, cybersecurity, privacy protection, etc.

A NEW QM SERVICE

BBMRI-ERIC - QUALITY LABEL FOR BIOBANK DATA MANAGEMENT MATURITY (DMM)

NEW TOOLS

SELF-ASSESSMENT SURVEY (DMM-SAS) / AUDIT PROGRAMME / QUALITY LABEL

The DMM framework provides biobanks with a structured instrument to design and continuously improve their data management systems. It enables to define clear governance, implement standards-aligned processes for data quality and interoperability, and systematically address maturity gaps,

Based on international standards including Biobank Standard ISO 20387, applicable Provenance standards and Data Standards.

Developed a new tool Self-Assessment-Survey (DMM-SAS)

Beta Testing EBW26 WG-QM-DQ Biobanks

Launch New tool DMM-SAS Q4/2026

Training Q4/2026

Include in BBMRI Audit Programme Q4/2026

BBMRI-ERIC Q-Label on Biobank level 2027

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- ✓ WG-QM-DQ Biobanks

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BBMRI-ERIC Q-Label on Biobank level 2027

04.

BBMRI-ERIC QUALITY MANAGEMENT SERVICE

BBMRI-ERIC QM SERVICE | AUDIT PROGRAMME | QUALITY LABEL

BBMRI-ERIC QUALITY MANAGEMENT SERVICES FOR BASIC AND APPLIED RESEARCH

Training

BBMRI-ERIC audit programme

KNOWLEDGE HUB

Find everything you need to know about quality management in biobanking and biomedical research right here! Our hub brings together a pool of experts who can assist you with:

- Standardisation in biobanking
- QM on Zenodo
- QM in EU Projects

Networking and exchange with QM experts:

- Meet the QM Team
- Participate in our QM Working Groups
- Stay updated with our QM Newsroom

Specific questions? Email us!

TRAINING & SUPPORT

Are you interested in quality management training or practical support? The QM team offers a variety of programmes to help you enhance your skills and knowledge in quality management. These programs cover different quality management systems and are designed to meet the needs of both beginners and advanced learners:

Training & Education Programmes:

- QM Training
- QM Academy

QM News and Events:

- Success stories of our QM community

AUDITING

If you operate a non-certified biobank and/or want to ensure that your stored samples meet specific quality standards, our QM team is here to help. We offer peer-review-style audits upon request, guiding you through the steps to improve your quality management practices.

Take the next step toward obtaining the BBMRI-ERIC Quality Label:

- Start by assessing your biobank operations with the BBMRI-ERIC Self-Assessment Survey (SAS).
- After completing the SAS, you can request a BBMRI-ERIC audit.
- If the audit is successful, your biobank will receive a Quality Label in the BBMRI-ERIC Directory.

CONTINUOUS IMPROVEMENT

Continuous improvement is central to the operation of the biobanks within BBMRI-ERIC and is important to be supported by enhanced quality assurance (QA) and quality control (QC) measures to safeguard the quality and integrity of biological materials and data. Furthermore, developing standardised technologies for proficiency testing, especially in the pre-analytical phase, is crucial for ensuring consistency and reliability.

This pillar will lead QA/QC initiatives to support biobanks remaining at the forefront of providing high-quality biological material and data for health research across Europe.

Involvement in standards development

Collaboration on quality-related tasks in projects

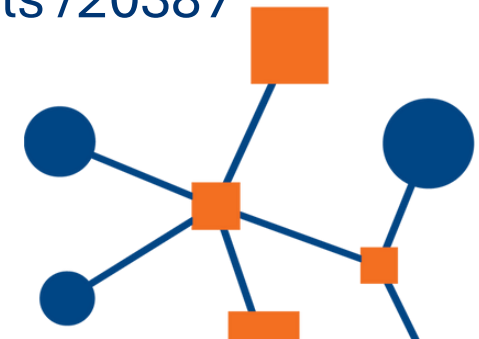
Share knowledge and harmonised/standardised procedures

BBMRI-ERIC Quality Label

#BBMRI_QM
@BBMRIERIC

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

- BBMRI-ERIC & National Node / Audit Programme
- The QC Pyramid
  - Biobank – National Node – BBMRI-ERIC – Accreditation
  - Audit scopes
  - Audit framework towards Quality Label
- Guideline for the Audit Programme
- Current Status of issued BBMRI-ERIC Quality Labels / 20387
- Current Status of biobanks with 3rd Party Accreditation Quality Labels /20387



BBMRI-ERIC / National Node / Audit Programme

Accreditation - Body
(3rd level audit)

BBMRI-ERIC Quality Label
QM/audit support
(second level audit)

BBMRI.National Node
QM/audit support **(available)**

Biobank internal audit
(1st level audit)

QC

BBMRI-ERIC / National Node / Audit Programme SCOPE

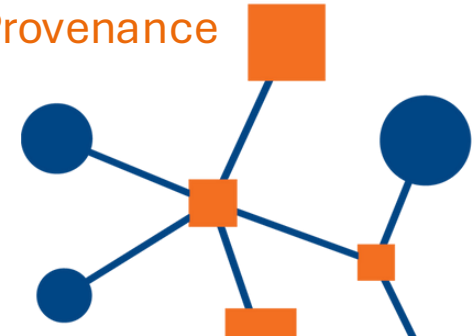
KNOWLEDGE HUB

TRAINING & SUPPORT

AUDITING

CONTINUOUS IMPROVEMENT

- Quality of Biobanking : **General requirements for biobanking, ISO 20387**
- Quality of the Samples / Data: Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for tissues, blood, serum plasma, saliva, stool, body fluids… **(21+ ISO pre-analytical standards) ,** Data Quality , Data Security , Data Provenance
- Guidelines for auditing management systems, ISO 19011
- OTHERS…



BBMRI-ERIC / National Node / Audit Programme FRAMEWORK

Framework

Based on the Guidelines for auditing management systems ISO19011:2018

1. Managing BBMRI-ERIC audit programme
2. Conducting the audit
3. Competence and evaluation of auditors

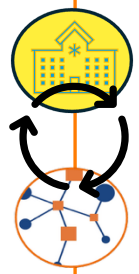
Audit Criteria (Scope)

1. European and international standards relevant for biobanking
2. Community standards relevant for biobanking

BBMRI-ERIC Quality Label

TOOLS AND AUDIT SERVICES

1. BBMRI-ERIC Self-Assessment Surveys (SAS)
2. Conduct the audit (on request by biobankers, Industry, interested parties)
3. BBMRI-ERIC Audit Checklist / Report
4. BBMRI-ERIC Quality Label / Certificate (visible in the BBMRI-ERIC Directory)



BBMRI-ERIC / National Node / AUDITORS / QUALITY LABEL

GUIDELINE FOR THE AUDIT PROGRAMME

- **Certified and Experienced Auditors**:

  Lead auditor must hold a valid auditor certificate (issued by external training provider)

  Minimum 2 years of biobank experience required

  Certificate and CV must be submitted to BBMRI-ERIC QM Headquarters before the audit

- **Audit Team**:

  Lead auditor may be assisted by technical experts, co-auditors, and auditors-in-training

  Co-auditors must provide proof of internal audit experience

- **Trainees and Observers**:

  Only invited with the agreement of the audited organization

- **Independence**:

  Auditors must remain independent from the audited organization and personnel

BBMRI-ERIC / National Node / AUDITORS / QUALITY LABEL

GUIDELINE FOR THE AUDIT PROGRAMME

- **Audit Planning:**

  Conducted by the lead auditor based on ISO 19011 principles

  Auditors should contact BBMRI-ERIC QM before the audit to discuss the plan

- **Document Review:**

  Comprehensive review of QMS documents

  Proof of evidence during the audit, duration of the audit depends on the number of auditors involved

- **On-Site-Visits**:

  Can take 2-3 working days (depends on the number of auditors involved)

  The audit visit may be conducted over multiple sessions on different time points

  - Especially when the National Node has a QM/audit service established

  The schedule is flexible but must be documented in the audit report

BBMRI-ERIC / National Node / AUDITORS / QUALITY LABEL

GUIDELINE FOR THE AUDIT PROGRAMME

- **BBMRI-ERIC Checklist:**

  Default document used for verification / provided to auditors by BBMRI-ERIC

  The auditors, in cooperation with the biobank, list the audited evidence (documents, forms, checklists, guidelines including document title and version number) in the checklist or refer to attached information.

  Completed and signed by lead and co-auditors → serves as Audit Report

- **Audit Report:**

  Sent to BBMRI-ERIC QM Headquarters after a positive outcome of the audit

  Final discussion between lead auditor and BBMRI-ERIC QM Headquarters

- **Outcome**:

  Quality Label awarded and published in BBMRI-ERIC Directory

  Certificate awarded (official award at EBW)

BBMRI-ERIC / National Node / Nutshell / QUALITY LABEL

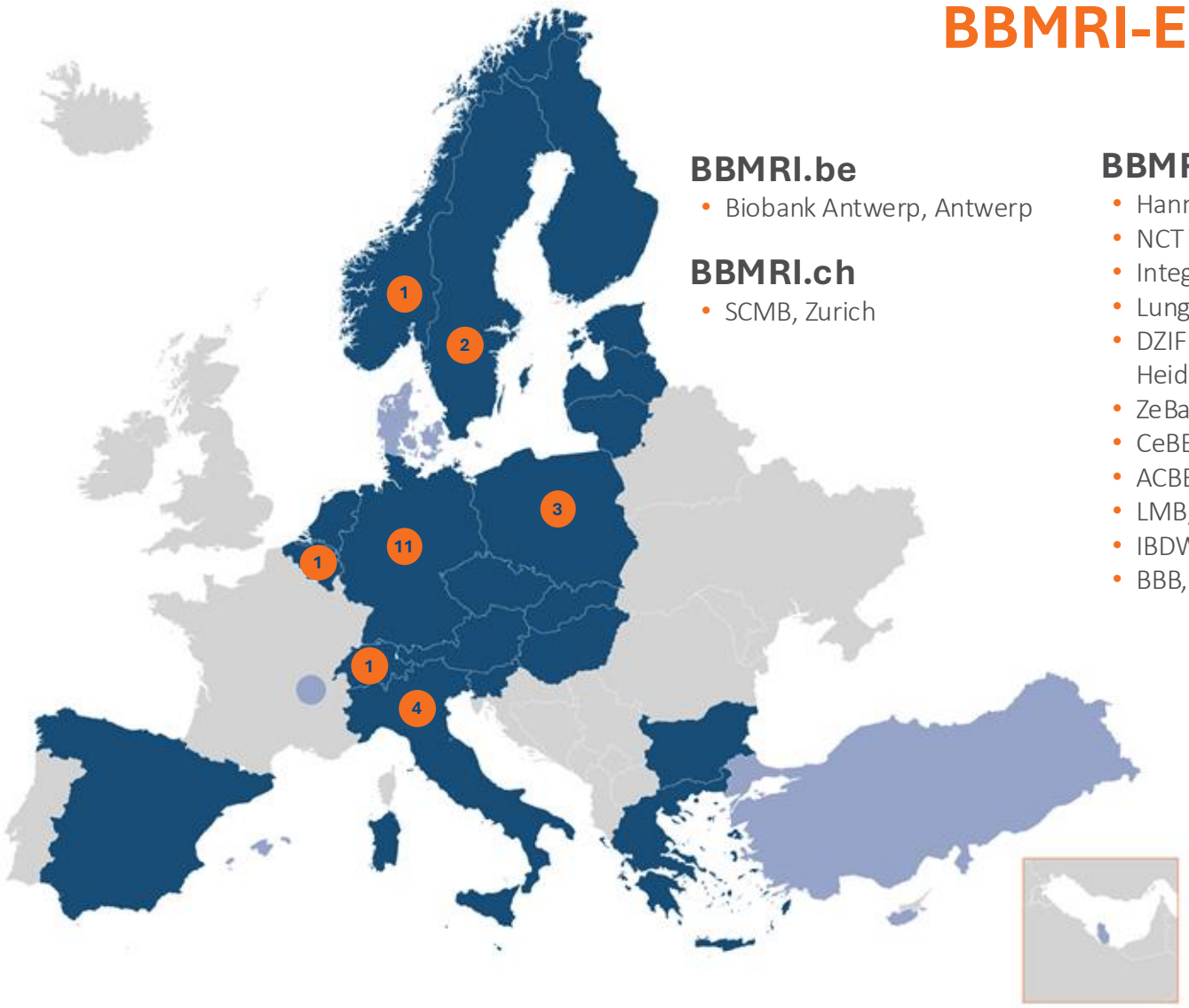
NUTSHELL

- **BBMRI-ERIC reviews documentation and biobank operations, it is not an accreditation**
  verifies that necessary documents and processes are in place, without providing formal accreditation.
- **Auditors offer guidance and training for biobanks in the audit procedures**
  Can suggest improvements and training, BUT only recommend the Quality Label, when processes meet ISO 20387 requirements.
- **Key focus on documented processes**
  Verifies that essential processes (ISO 20387) including pre-analytical standards, are well-followed and documented. Data Quality assessment coming soon!

- **BBMRI-ERIC Quality Label VALUE**
  - **Biobanks demonstrate operation according to (international) standards**
  - **A milestone towards 3rd Party accreditation by accreditation body**

BBMRI-ERIC Quality Labelled Biobanks (total 23)

ISO 20387:2018



BBMRI.be
- Biobank Antwerp, Antwerp

BBMRI.ch
- SCMB, Zurich

BBMRI.de
- Hannover Unified Biobank, Hannover
- NCT Tissue Bank, Heidelberg
- Integrated Biobank Jena, Jena
- Lungenbiobank Heidelberg, Heidelberg
- DZIF Tissue Bank Heidelberg, Heidelberg
- ZeBanC, Berlin
- CeBE, Erlangen
- ACBB, Augsburg
- LMB, Leipzig
- IBDW, Würzburg
- BBB, Bonn

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- BMS, Pisa
- Human Genetics Laboratory Biobank, Genoa
- BioCor Biobank, Milan
- CRB-OSR, Milan

BBMRI.no
- NIPH Department of Biobanks, Oslo

BBMRI.pl
- WMU Biobank, Wroclaw
- Stem Cell Biobank, Warsaw
- Port Biobank, Wroclaw

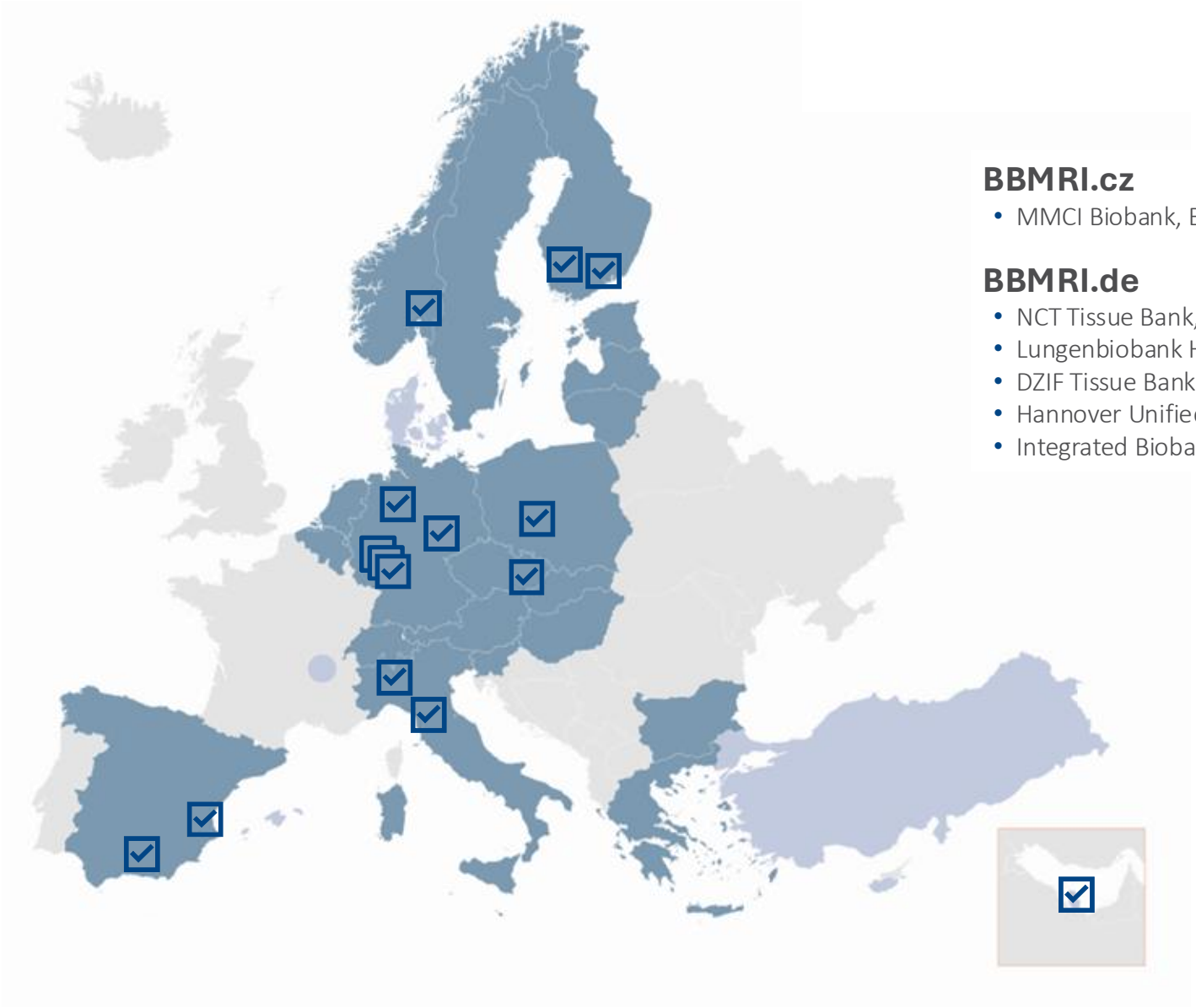
BBMRI.se
- Biobank Väst, Gothenburg
- Region Skånes Biobank, Lund

https://www.bbmri-eric.eu/services/auditing-and-quality-label/

Status 13 May 2026

Accredited Biobanks (15) ☑

Biobank Standard ISO 20387



BBMRI.cz
- MMCI Biobank, Brno

BBMRI.de
- NCT Tissue Bank, Heidelberg
- Lungenbiobank Heidelberg, Heidelberg
- DZIF Tissue Bank, Heidelberg
- Hannover Unified Biobank, Hannover
- Integrated Biobank Jena, Jena

BBMRI.es
- IVO Biobank, Valencia
- BBSSPA, Granada

BBMRI.fi
- Auria Biobank, Turku
- Helsinki Biobank, Helsinki

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- NIPH Department of Biobanks, Oslo

BBMRI.pl
- WMU Biobank, Wroclaw

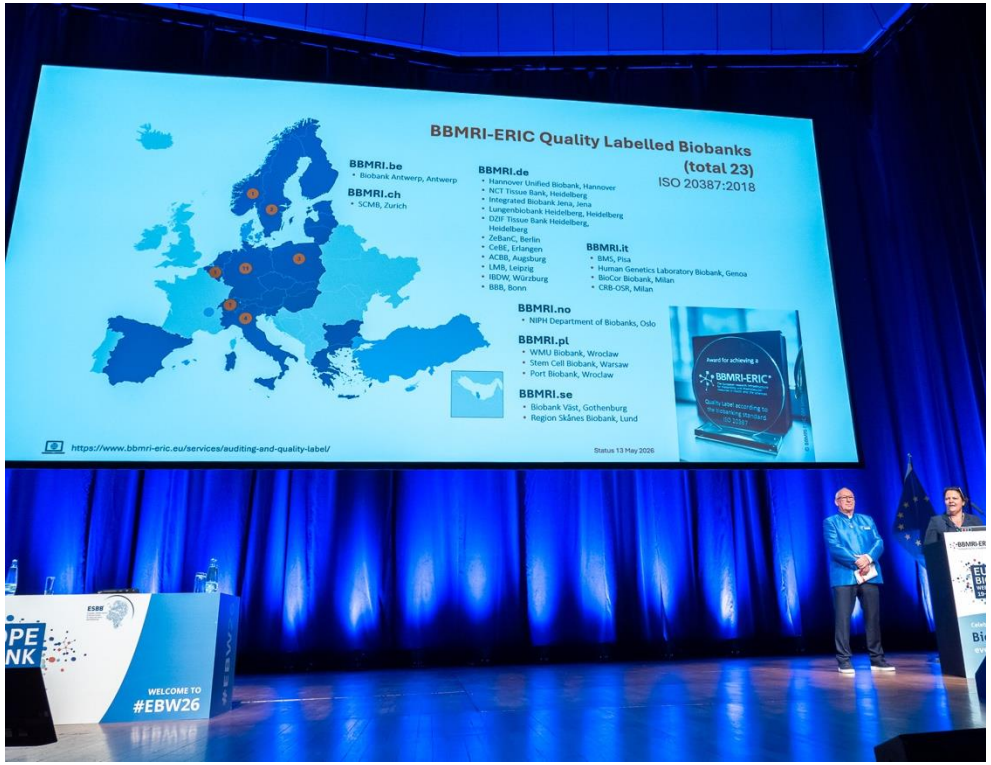
BBMRI.qa
- Qatar Biobank, Doha

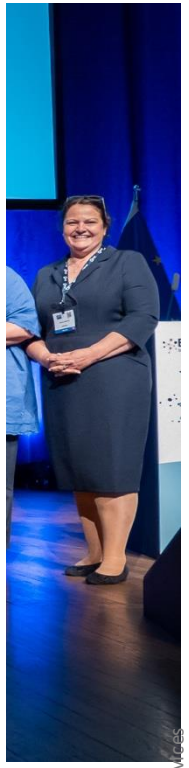
https://european-accreditation.org/ https://a2la.org/

Status 31 March 2026

EUROPE BIOBANK WEEK (EBW) 2026 TOOK PLACE IN PRAG

MORE THAN 750 PARTICIPANTS / BIOBANKERS, RESEARCHERS, INDUSTRY SPECIALISTS AND DECISION-MAKERS / ACROSS THE LIFE SCIENCES FROM 50 COUNTRIES





https://www.europebiobankweek.eu

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Co-funded by multiple Horizon and IHI projects

05.

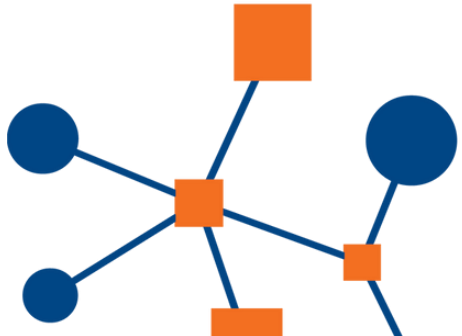
QUIZ

1. What is the main goal of quality management in biobanking?
    A. To increase the number of stored samples
    B. To ensure samples and data are fit for research purposes ✓
    C. To reduce operational costs

2. Which international standard specifies general requirements for biobanking?
    A. ISO 9001
    B. ISO 15189
    C. ISO 20387 ✓

3. What does ISO 20387 evaluate?
    A. Clinical diagnosis procedures
    B. Competence, impartiality, and consistent operation of biobanks ✓
    C. Pharmaceutical manufacturing

4. Why are pre-analytical standards important?
    A. They ensure the quality of samples before analysis ✓
    B. They reduce storage costs
    C. They replace quality control



5. Which consequence is associated with poor sample quality?
   A. Improved reproducibility
   B. Faster research
   C. Irreproducible research results ✓

6. What is the purpose of the BBMRI-ERIC Audit Programme?
   A. To verify compliance with relevant standards and best practices ✓
   B. To accredit laboratories
   C. To fund biobank infrastructure

7. Which statement about the BBMRI-ERIC Quality Label is correct?
   A. It is an international accreditation.
   B. It recognizes biobanks operating according to relevant standards and audited requirements. ✓
   C. It replaces ISO 20387 accreditation.