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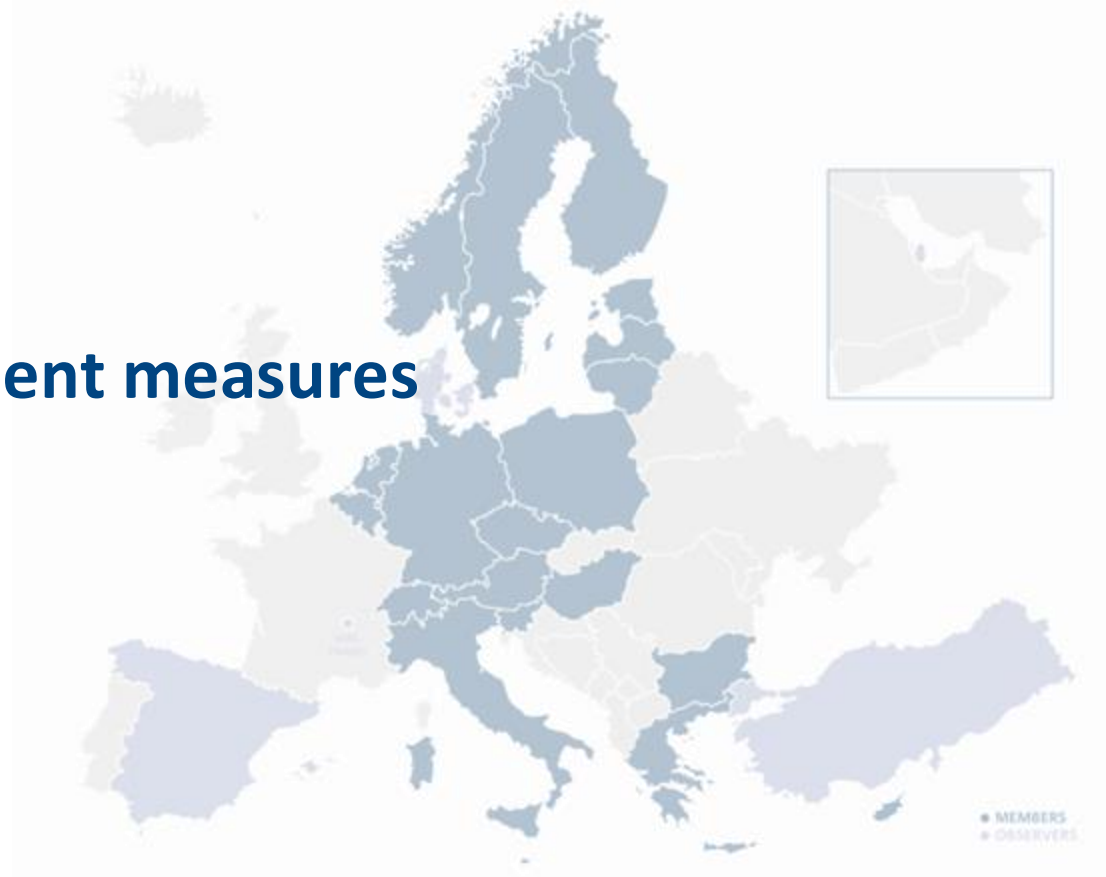
The European research infrastructure for biobanking and biomolecular resources in health and life sciences

For better quality in biobanks – Audit programmes support improvement measures

BIOBANK OPEN FORUM JAPAN
29 AUGUST 2023

Andrea Wutte

Head of Quality Management Department



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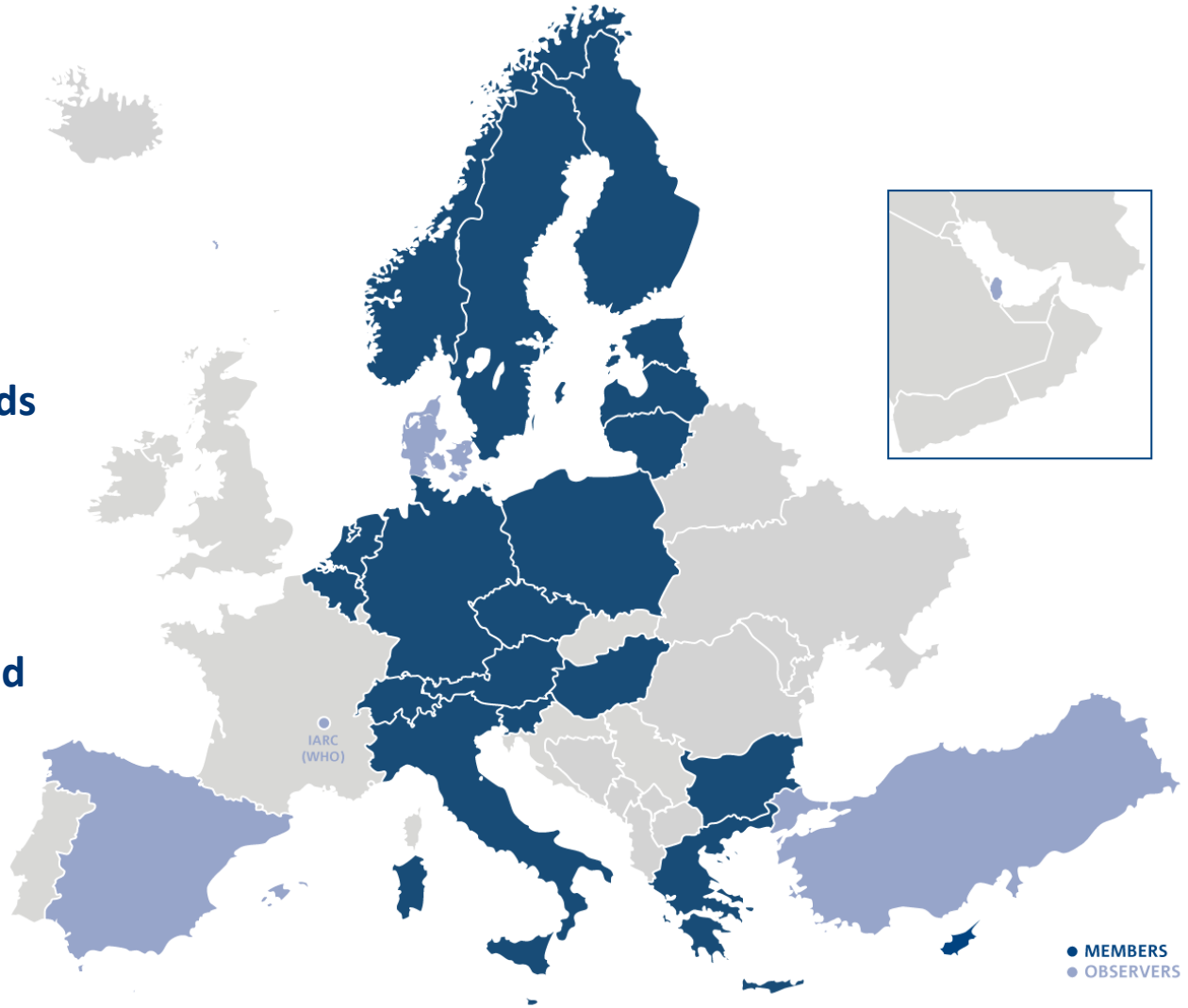
WE ARE 25

20 Members

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



5 Observers

Denmark
IARC/WHO
Qatar
Spain
Turkey

- > 400 biobanks
- 3 Expert Centres
- Headquarters in Austria
- 25 National Nodes
- and affiliated partners

- 25 active projects
- 19 submitted projects (2023)
- 20 completed projects

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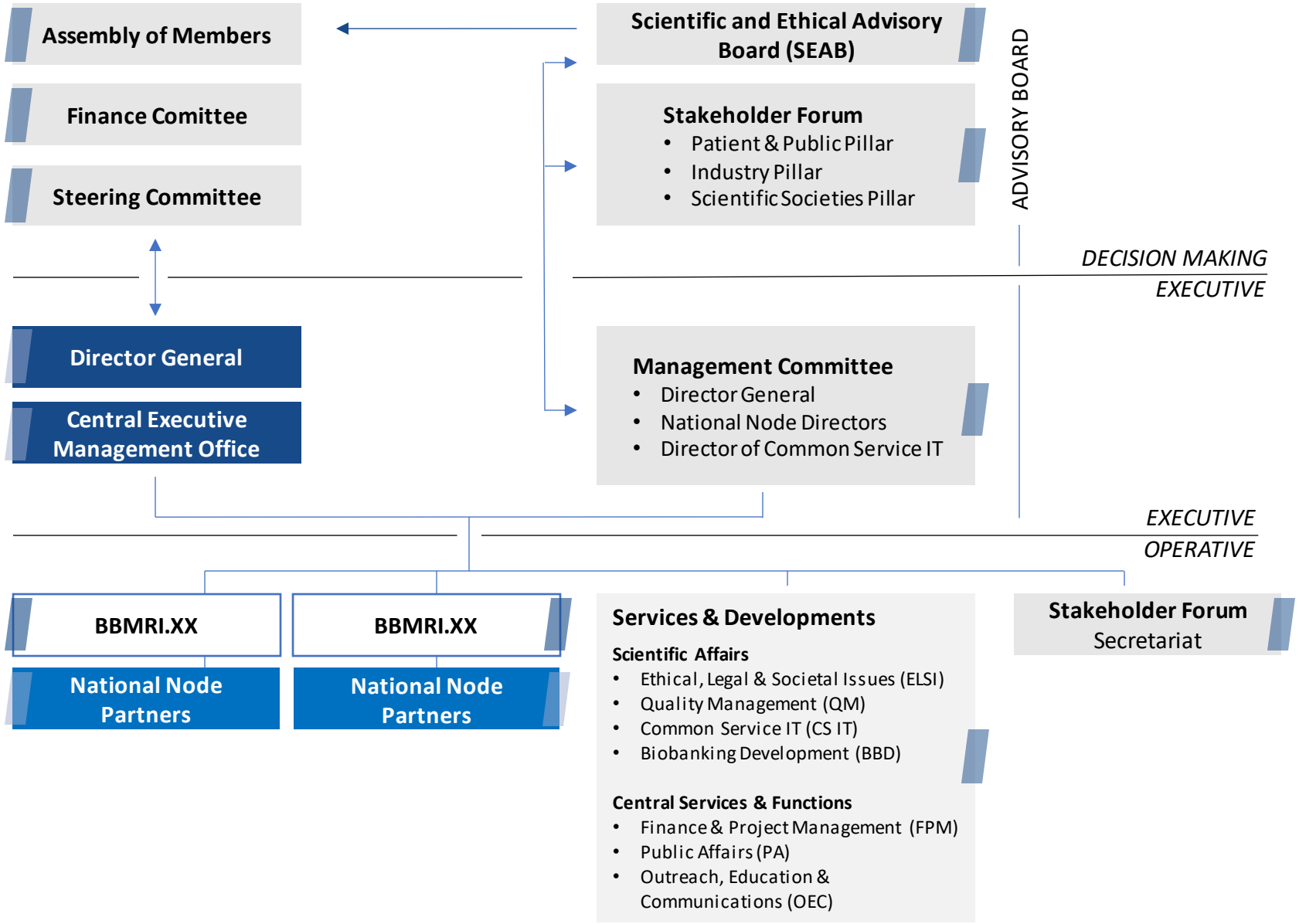
GOVERNANCE



BBMRI-ERIC®
The European research infrastructure for biobanking and biomolecular resources in health and life sciences

BBMRI enabling personalised medicine through:

ELSI Services & Research

- Knowledge Base
- Helpdesk Network
- Ethics Check
- Training
- Code of Conduct for Health Research

Public Affairs & Stakeholder Engagement

- Member States & Strategic Partners
- EU & Global Affairs
- Patients & Public
- Scientific Societies
- Industry Collaborations

Biobanking Development

- Biobanks & Universities
- National Nodes
- Expert Centres
- Sustainability

Outreach, Education & Communication

IT Services & Research

- Discovery of biobanking resources
- Access to samples and data
- Data deposition, pooling, analyses
- Interoperability
- Data protection and access control
- Quality controlling & reusability
- Training & Support

Quality Management Services & Research

- Knowledge Hub
- Training & Support
- Auditing
- Quality Assurance

bbmri-eric.eu

QUALITY MANAGEMENT SERVICES – REVIEW AND OUTLOOK

- History and Quality Policy
- QM Engagement in International Organisations for Standardisation
- International standards relevant for biobanking
- BBMRI-ERIC Quality Management Services "Knowledge / Training / Audit Programme / Research"
- **BBMRI-ERIC Audit Programme**
  - BBMRI-ERIC Quality Label a quality indicator for biobanks and sample collections
- **BBMRI-ERIC Support Biobanks for accreditation**
  - Biobank Accreditation – by 3rd party – National Accreditation bodies

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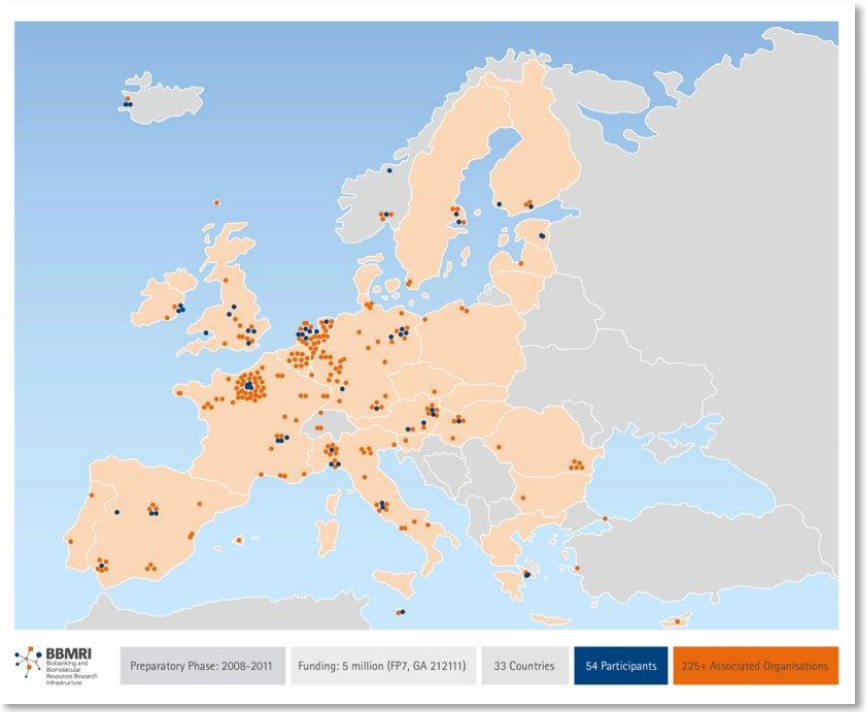
History

ESFRI ROADMAP / PREPARATORY PHASE 2008 – 2011 / **LEGAL STATUS DECEMBER 2013 – 10 YEAR ANNIVERSARY 2023**



BBMRI-ERIC QUALITY POLICY

All Partners should commit themselves to implement quality management/assurance procedures compliant with applicable European and International standards, OECD best practice guidelines for Global Biological Resource Centres Networks and WHO/IARC Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research.

SOPs should be established and made publicly available for all processes related to sample collection, processing, storage, retrieval and dispatch. It is recommended that SOPs should follow the procedures as specified in the WHO/IARC guidelines for biological resource centres for cancer research whenever feasible.

A biobank (collection) shall be provided a unique persistent identifier as a part of registering the biobank (collection) in the BBMRI-ERIC Directory. Partners are also encouraged to participate and benefit from the quality services of BBMRI-ERIC.

INTERNATIONAL BIOBANKING STANDARD

- **Biotechnology – Biobanking – General requirements for biobanking (ISO 20387:2018)**

This document 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.

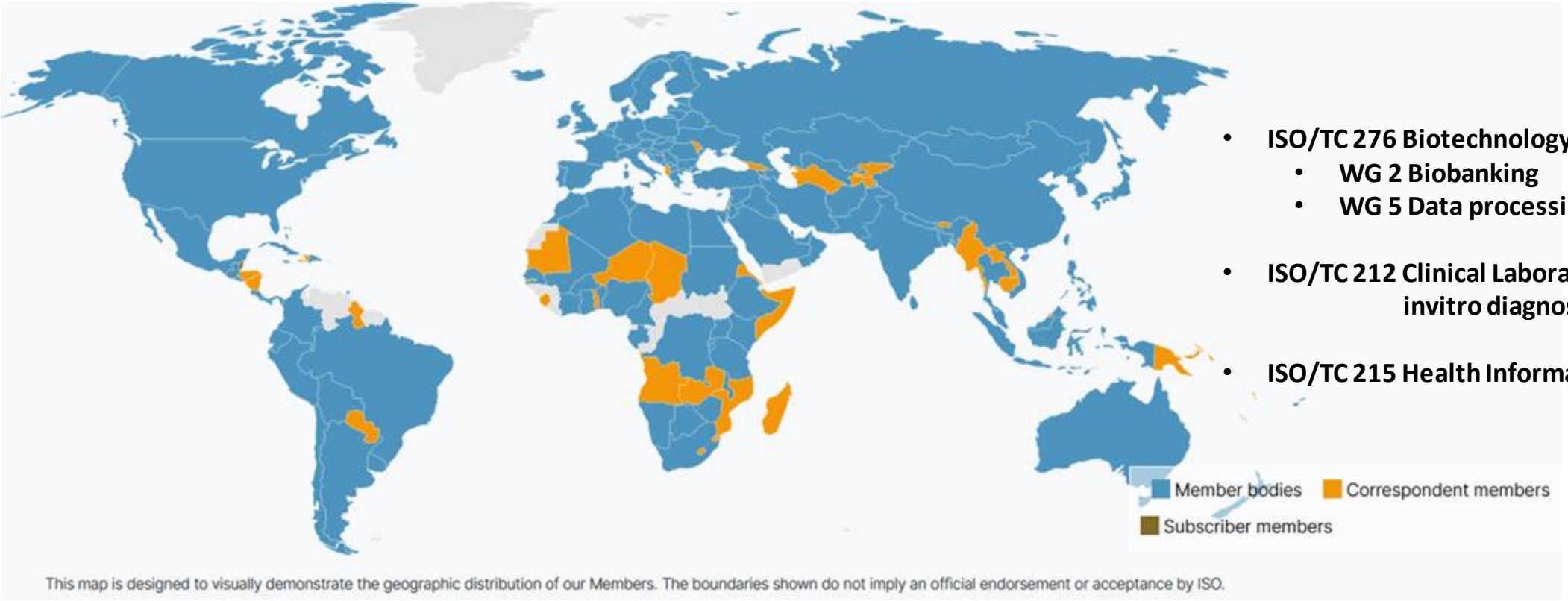
This document is applicable to all organizations performing biobanking, including biobanking of biological material from multicellular organisms (e.g. human, animal, fungus and plant) and microorganisms for research and development.

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.

- **Quality management systems – Requirements (ISO 9001:2015)**

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.This International Standard can be used by internal and external parties, including certification bodies, to assess the organisation's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organisation's own requirements.

SINCE 2015 BBMRI-ERIC LIAISON WITH INTERNATIONAL STANDARDIZATION ORGANISATION (ISO)



- ISO/TC 276 Biotechnology
  - WG 2 Biobanking
  - WG 5 Data processing and integration
- ISO/TC 212 Clinical Laboratory testing and invitro diagnostic test systems
- ISO/TC 215 Health Informatics

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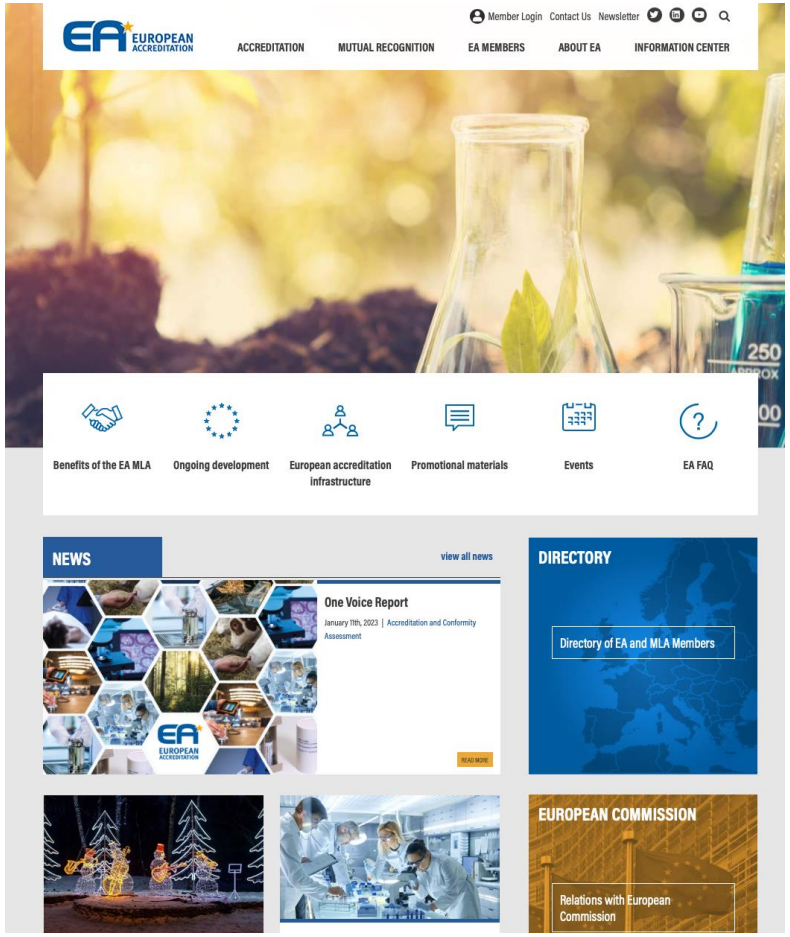
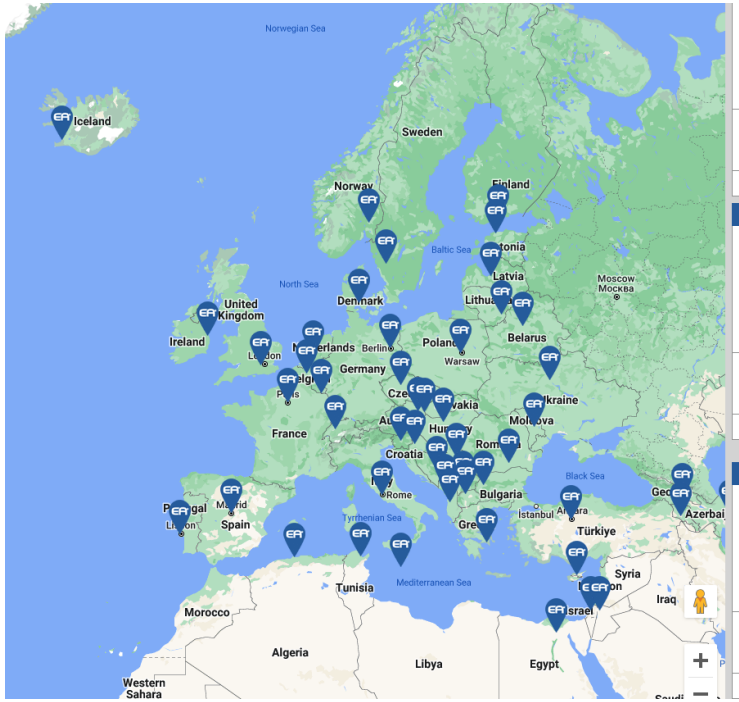
BBMRI-ERIC COLLABORATION WITH EUROPEAN ACCREDITATION (EA)



european-accreditation.org



Comité français d'accréditation
52 rue Jacques Hillairet
75012 - Paris

MLA signatory
Date of next re-evaluation: 2024-10
Date of last peer evaluation: 2021-01
Scopes ▾
Signatory : IAF - ILAC

GERMANY

DAkkS
Deutsche Akkreditierungsstelle GmbH
Spittelmarkt 10
10117 - Berlin
Phone: +49 (0) 30 67 059 10
Fax: +49 (0) 30 67 0591 90

MLA signatory
Date of next re-evaluation: 2022-09
Date of last peer evaluation: 2018-09
Scopes ▾
Signatory : IAF - ILAC

HUNGARY

NAH
National Accreditation Authority
Tétényi út 82
1119 - Budapest
Phone: +36 1 550-1007
Fax: +36 1 550-1036

MLA signatory
Date of next re-evaluation: 2022-05
Date of last peer evaluation: 2018-06
Scopes ▾
Signatory : IAF - ILAC

GAC - Unified National Body on Accreditation - Accreditation Centre
42a Kazbegi Av.
0186 - Tbilisi
Fax: + 995 32 239 93 48

MLA signatory
Date of next re-evaluation: 2022-11
Date of last peer evaluation: 2018-11
Scopes ▾

GREECE

ESYD
Hellenic Accreditation System
7 Thisseos str
17676 Kallithea - Athens
Phone: + 30 210 7204 502
Fax: + 30 210 7204 501

MLA signatory
Date of next re-evaluation: 2023-05
Date of last peer evaluation: 2019-05
Scopes ▾
Signatory : IAF - ILAC

ICELAND

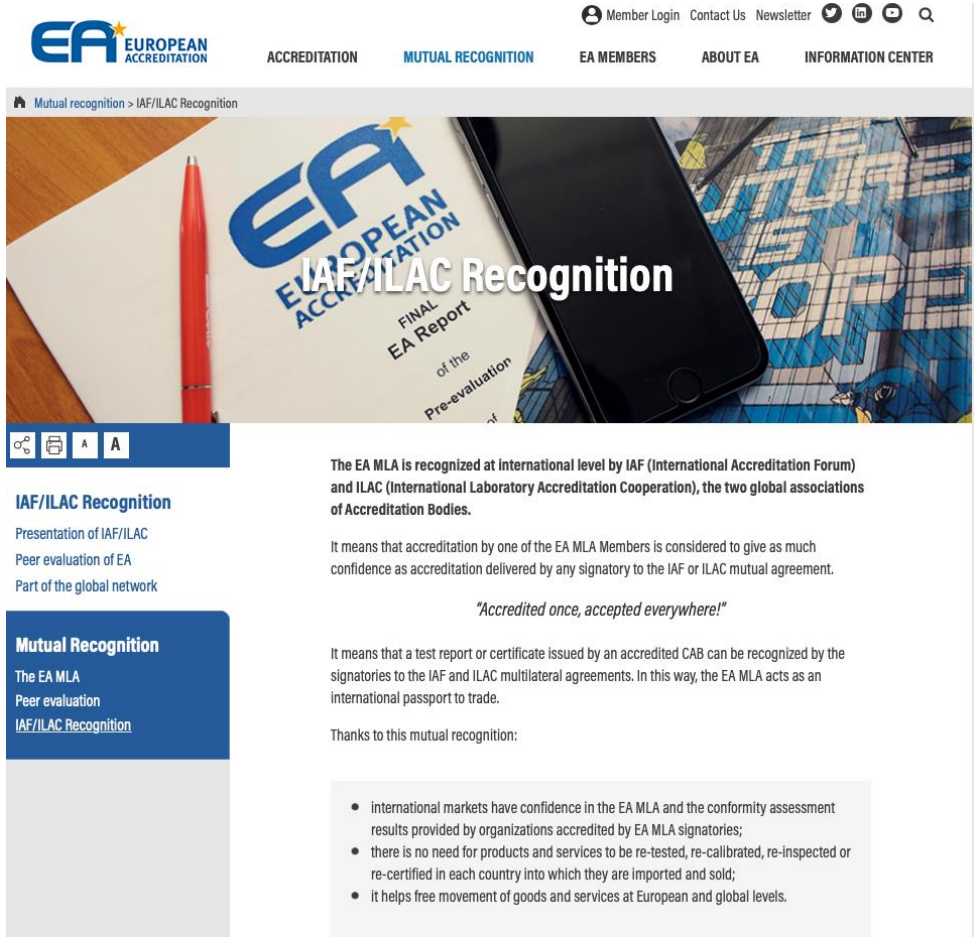
ISAC
Icelandic Board for Technical Accreditation
Hugverkastofan
Engjateigur 3
105 - Reykjavik
Phone: +354 580 9400
Fax: +354 580 9401

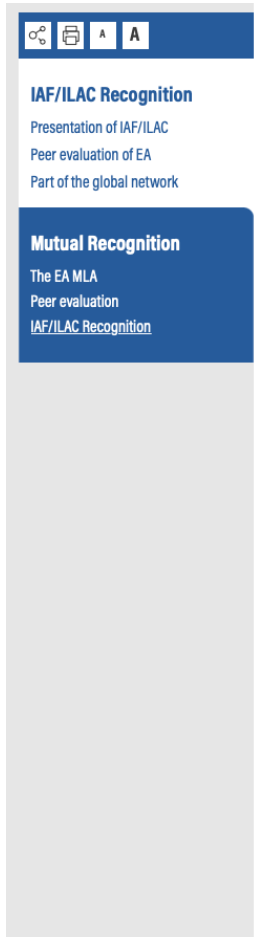
MLA signatory
Date of next re-evaluation: 2024-04
Date of last peer evaluation: 2022-04
Scopes ▾

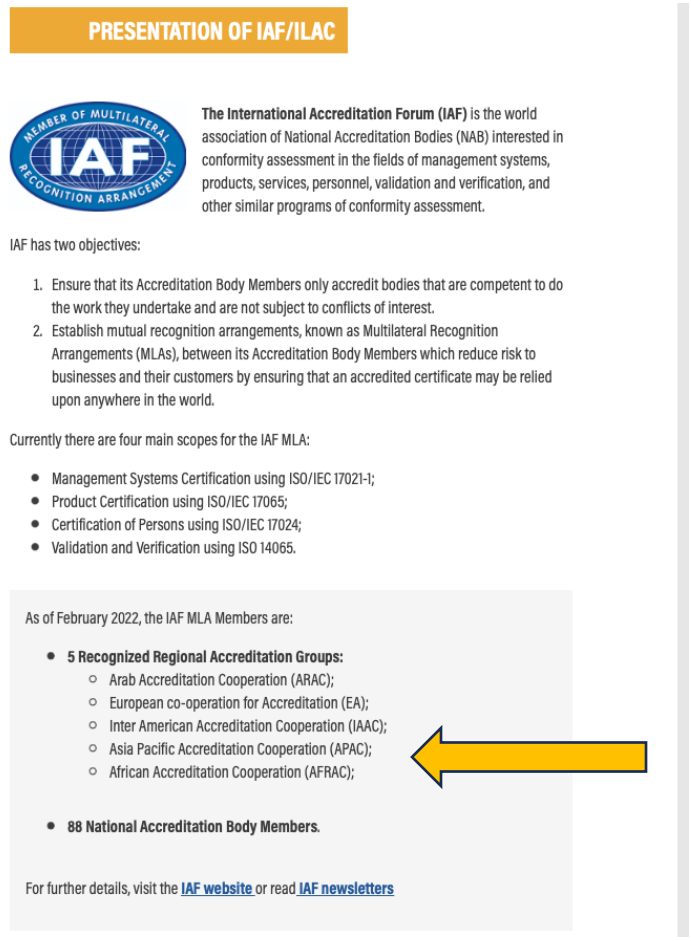
NETWORK OF ACCREDITATION BODIES

EA Multilateral Agreement (EA MLA) objective
'Accredited once, accepted everywhere'

MUTUAL RECOGNITION
EUROPEAN ACCREDITATION (EA) / ILAC / IAF







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Quality of biological material / data

Collaborate biological material / data in projects

Share knowledge harmonised / standardised procedures

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!**
- Working Group QMS
- Meet the QM Team

Consultation Hours:

- BBMRI.QM Newsroom

QM Documents:

- BBMRI.ch SBP Quality Manual
- BBMRI.de QM Biobank Manual
- BBMRI.pl Manual of Biobank QM
- Read our special issue of the Biobanks Europe Magazine on quality management

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 **Recordings available!** 🏆
- Training series about the biobanking standard ISO 20387:2018 **Recordings available!**

BBMRI.QM Academy:

- What is the BBMRI.QM Academy?
- Educational webinars **Recordings available!**

BBMRI.QM News and Events:

- Success stories of our BBMRI.QM community

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!

Process flow: From the SAS to a Quality Label in the BBMRI-ERIC Directory

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 Label in the Directory

- Quality Label in the BBMRI-ERIC Directory

BBMRI-ERIC Audit Programme

BBMRI-ERIC Quality Label

Training

#BBMRI_QM
@BBMRIERIC

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

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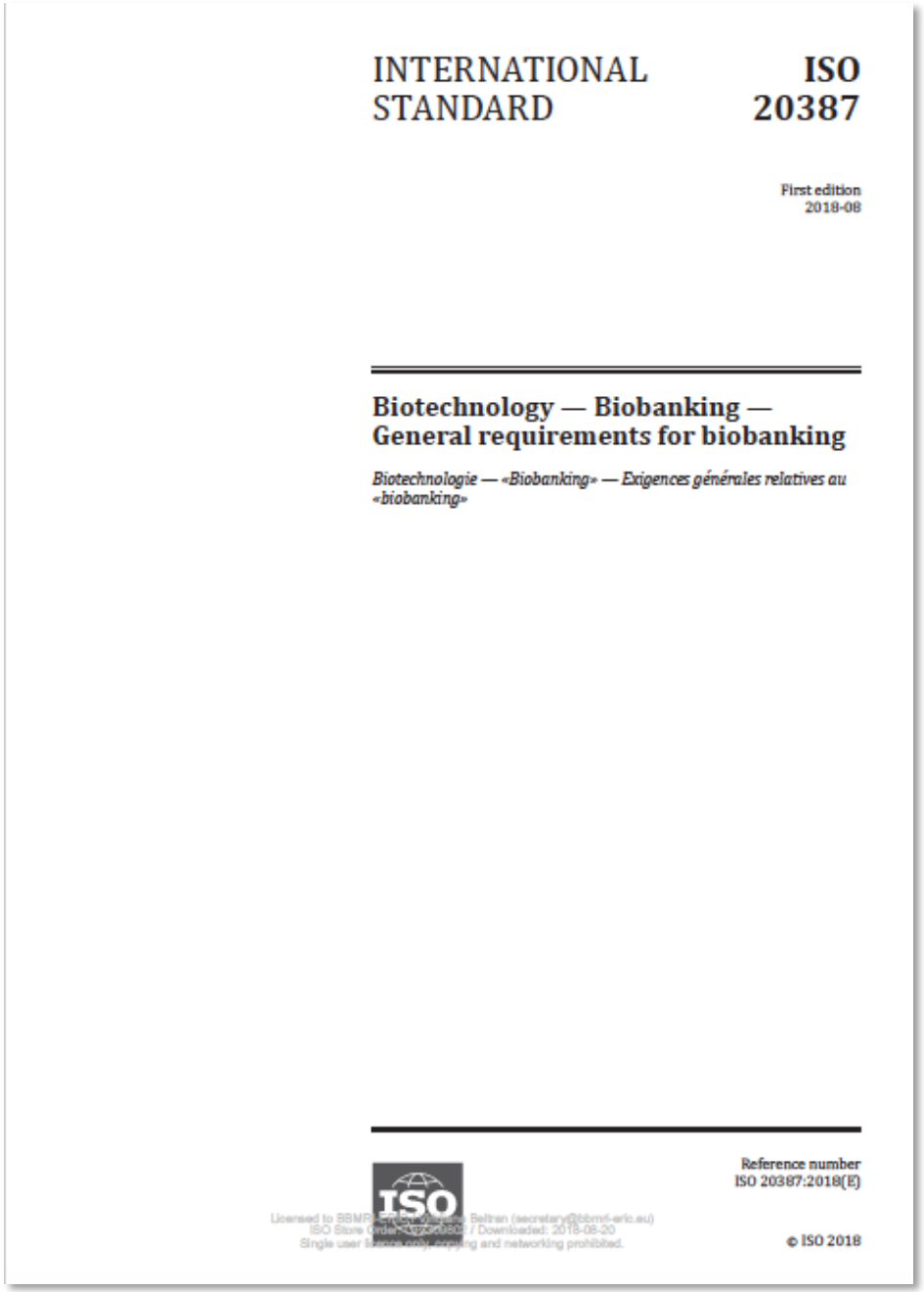
BUILDING BIOBANKING ACTIVITIES ON INTERNATIONAL STANDARDS

- Biobanking – General requirements for biobanking, ISO 20387:2018
- Quality management systems – Requirements, ISO 9001:2015
- Specifications for pre-examination processes for tissues, blood, serum, plasma, saliva, stool, body fluids *and more of these Technical Specifications for molecular in vitro diagnostic examinations
- Guidelines for auditing management systems, ISO 19011:2018
- !new! Provenance information model for biological material and data — Part 1: Design concepts and general requirements, ISO/TS 23494-1:2023



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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7 Process requirements

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

"21" ISO/CEN standards for pre-examination processes

Reference: www.iso.org

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.

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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/TS 21899:2020, Validation and verification of processing methods for biological materials in biobanks

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

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SPECIMEN PROCESSING

EUROPEAN STANDARDS

CEN/TS 17390-1:2020, circulating tumor cells (CTCs) in venous whole blood – Part 1: Isolated RNA
CEN/TS 17390-2:2020, circulating tumor cells (CTCs) in venous whole blood – Part 2: Isolated DNA
CEN/TS 17390-3:2020, circulating tumor cells (CTCs) in venous whole blood – Part 3: Preparations for analytical CTC staining

CEN/TS 17626:2021, human specimen – Isolated microbiome DNA

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 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 17811:2022, urine and other body fluids - Isolated cf DNA

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INTERNATIONAL STANDARDS

DATA QUALITY, DATA SECURITY

- Data quality – Master data and Data quality management: ISO 8000 Series
- Information technology – Security techniques – Information security management systems – Requirements, ISO/IEC 27001:2022
- Information security, cybersecurity and privacy protection – Information security controls, ISO/IEC 27002:2022
- Information technology – Security techniques – Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors, ISO/IEC 27018:2019
- And more…

www.iso.org

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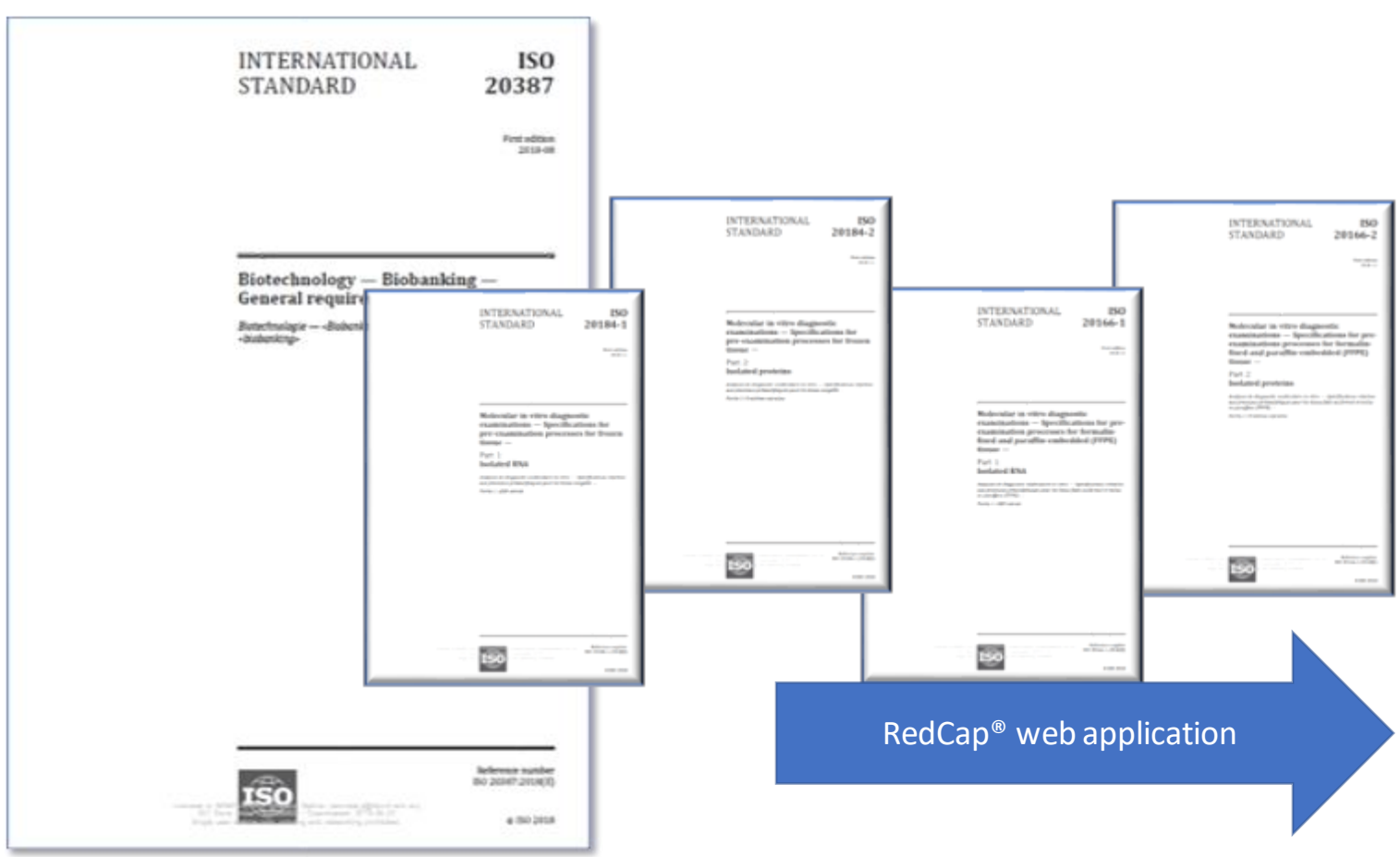
BBMRI-ERIC audit programmes support improvement measures

FROM STANDARD TO SELF-ASSESSMENT SURVEY (SAS)



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 AUDIT PROGRAMME

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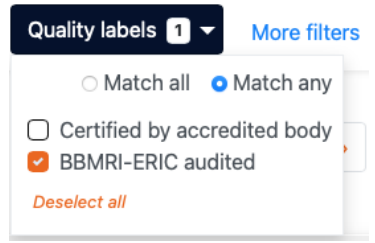
OVERVIEW: FROM THE BBMRI-ERIC SELF-ASSESSMENT SURVEY (SAS) TO QUALITY LABEL



Access	Evaluation	Quality Label
Access to BBMRI-ERIC SAS	**Evaluation of specifications**	**Award BBMRI-ERIC Q-Label in Directory**
Go to: https://www.bbmri-eric.eu/services/self-assessment-survey/	Completion: of BBMRI-ERIC SAS – create report	Biobank: Audit according to ISO 20387 and ISO 9001 "Quality of Biobank operations"
Fill out: Request form / tick off pre-conditions / send	Submit report: to BBMRI-ERIC Headquarter QM Department	Sample collection: Audit according to the respective pre-examination standards "Quality of biological material /data"
Get started: Receive the link to SAS	Be audited: by BBMRI-ERIC (**remote and/or on-site audit**)	Enhance visibility: Quality Label in the Directory https://directory.bbmri-eric.eu/

ACCESS TO BBMRI-ERIC SAS ON WEBSITE

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!

Process flow: From the SAS to a Q-mark in the BBMRI-ERIC Directory

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

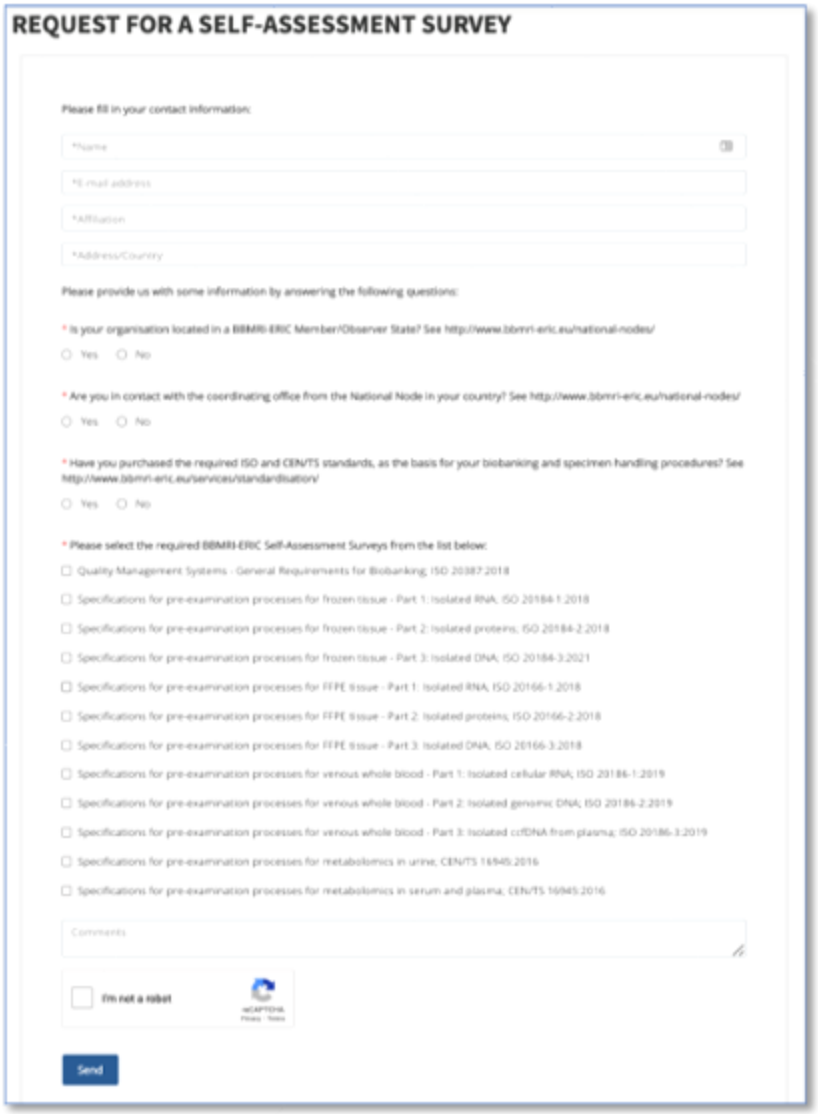
Step 2: Request a BBMRI-ERIC audit

- BBMRI-ERIC Audit

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

- Q-mark in the BBMRI-ERIC Directory

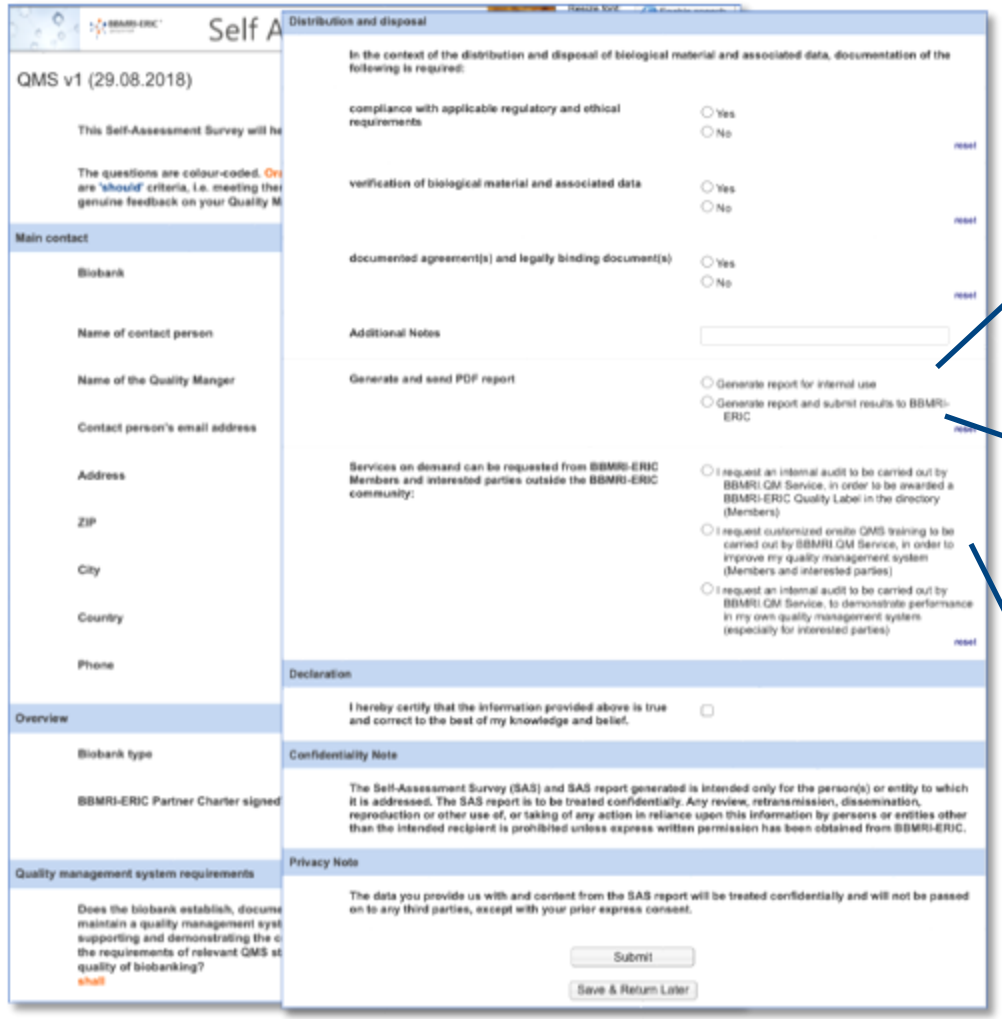
Access	Access to BBMRI-ERIC SAS
Go to	https://www.bbmri-eric.eu/services/self-assessment-survey/
Fill out	Request form / tick off pre-conditions / send
Get started	Receive @ with the link to SAS



https://www.bbmri-eric.eu/services/self-assessment-survey/

SELF-EVALUATION

Evaluation	Evaluation of specifications
Completion	of BBMRI-ERIC SAS
Submit report	to BBMRI-ERIC
Be audited	by BBMRI-ERIC (remote and/or on-site)

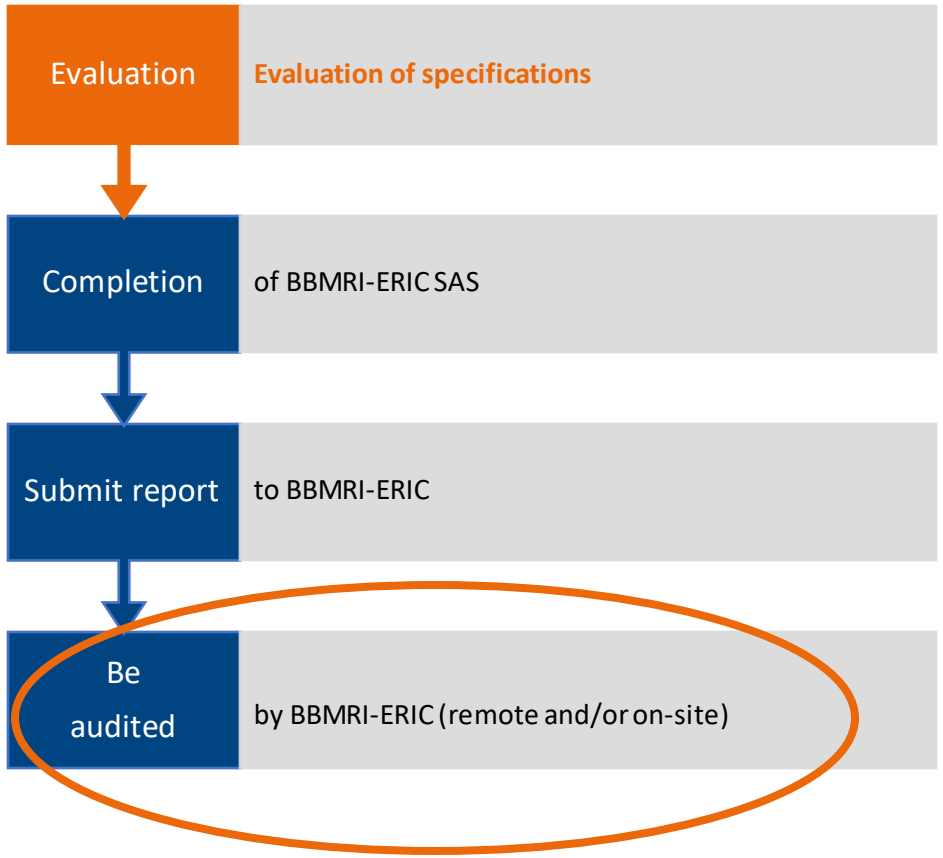


Generate report for internal use

Generate report and submit results to BBMRI-ERIC

Request Onsite-audit Training

EVALUATION OF SPECIFICATIONS



BIOBANK LEVEL

ISO 20387

1. conducting remote audit
2. Conducting **on-site audit**
   a) by auditors of the country
   b) by BBMRI-ERIC Headquarters QM
3. Positive assessment – Quality Label

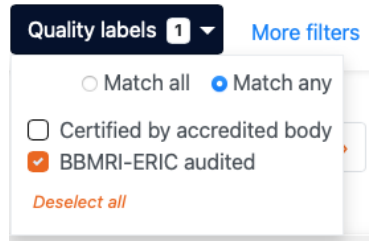
SAMPLE/COLLECTION LEVEL

PRE-ANALYTICAL STD'S

1. conducting a remote audit
   a) by BBMRI-ERIC Headquarters QM
   b) by auditors of the country
2. Positive assessment – Quality Label

BBMRI-ERIC AUDIT PROGRAMME

AUDIT PROCESS



Framework / Auditor competence		Conduct of the Audit		Quality Label / Directory	
ISO 19011	builds the framework of the BBMRI-ERIC Audit programme	Audit	Conducted by certified auditors	Audit report	Auditors provide report to BBMRI-ERIC QM
Certified	Lead Auditors and qualified audit team	Biobank	assessment according to ISO 20387 2-3 days on-site assessment of compliance	Approval	Auditors recommend Quality Label / BBMRI-ERIC QM approves (or disapprove)
Checklist	BBMRI-ERIC checklist / audit report	Collection	assessment according pre-examination Standards Remote assessment of compliance	Q-Label	Quality Label visible BBMRI-ERIC Directory

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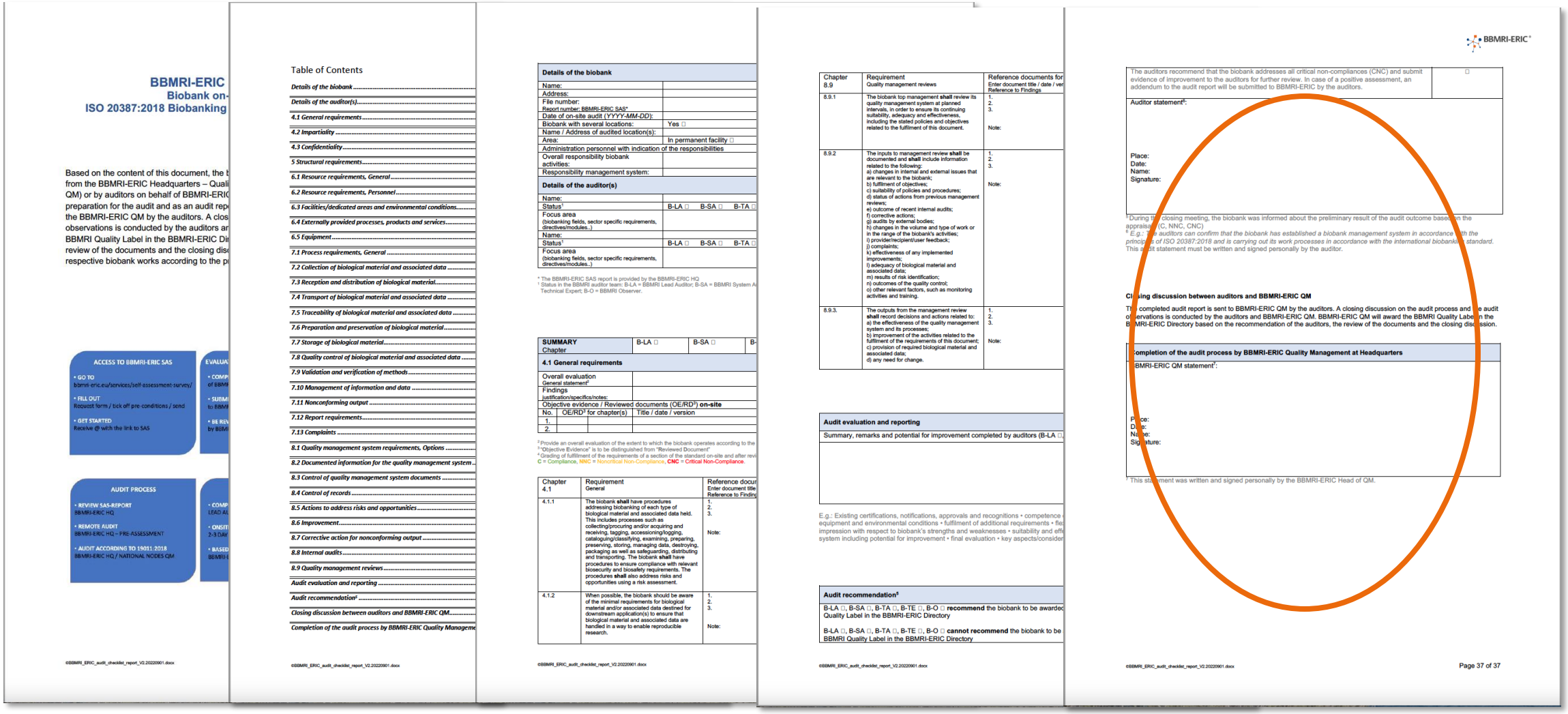
BBMRI-ERIC ONSITE AUDIT CHECKLIST / REPORT



BBMRI-ERIC
Biobank on-
ISO 20387:2018 Biobanking

Based on the content of this document, the b
from the BBMRI-ERIC Headquarters – Quali
QM) or by auditors on behalf of BBMRI-ERIC
preparation for the audit and as an audit rep
the BBMRI-ERIC QM by the auditors. A clos
observations is conducted by the auditors ar
BBMRI Quality Label in the BBMRI-ERIC Di
review of the documents and the closing disc
respective biobank works according to the p

ACCESS TO BBMRI-ERIC SAS
• GO TO bbmri-eric.eu/services/self-assessment-survey/
• FILL OUT Request form / tick off pre-conditions / send
• GET STARTED Receive @ with the link to SAS

AUDIT PROCESS
• REVIEW SAS-REPORT BBMRI-ERIC HQ
• REMOTE AUDIT BBMRI-ERIC HQ – PRE-ASSESSMENT
• AUDIT ACCORDING TO 19011:2018 BBMRI-ERIC HQ / NATIONAL NODES QM

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Details of the biobank	
Name:	
Address:	
File number: Report number: BBMRI-ERIC SAS*	
Date of on-site audit (*YYYY-MM-DD*):	
Biobank with several locations:	Yes ☐
Name / Address of audited location(s):	
Area:	In permanent facility ☐
Administration personnel with indication of the responsibilities	
Overall responsibility biobank activities:	
Responsibility management system:	

Details of the auditor(s)			
Name:			
Status[1]	B-LA ☐	B-SA ☐	B-TA ☐
Focus area (biobanking fields, sector specific requirements, directives/modules..)			
Name:			
Status[1]	B-LA ☐	B-SA ☐	B-TA ☐
Focus area (biobanking fields, sector specific requirements, directives/modules..)			

* The BBMRI-ERIC SAS report is provided by the BBMRI-ERIC HQ
[1] Status in the BBMRI auditor team: B-LA = BBMRI Lead Auditor; B-SA = BBMRI System A
Technical Expert; B-O = BBMRI Observer.

SUMMARY Chapter	B-LA ☐	B-SA ☐	B-
4.1 General requirements			
Overall evaluation General statement[2]			
Findings justification/specifics/notes:			
Objective evidence / Reviewed documents (OE/RD[3]) **on-site**			
No.	OE/RD[3] for chapter(s)	Title / date / version	
1.			
2.			

[2] Provide an overall evaluation of the extent to which the biobank operates according to the
[3] "Objective Evidence" is to be distinguished from "Reviewed Document"
[4] Grading of fulfillment of the requirements of a section of the standard on-site and after revi
C = Compliance, NNC = Noncritical Non-Compliance, **CNC** = Critical Non-Compliance.

Chapter 4.1	Requirement General	Reference docur Enter document title Reference to Findin
4.1.1	The biobank **shall** have procedures addressing biobanking of each type of biological material and associated data held. This includes processes such as collecting/procuring and/or acquiring and receiving, tagging, accessioning/logging, cataloguing/classifying, examining, preparing, preserving, storing, managing data, destroying, packaging as well as safeguarding, distributing and transporting. The biobank **shall** have procedures to ensure compliance with relevant biosecurity and biosafety requirements. The procedures **shall** also address risks and opportunities using a risk assessment.	1. 2. 3. Note:
4.1.2	When possible, the biobank should be aware of the minimal requirements for biological material and/or associated data destined for downstream application(s) to ensure that biological material and associated data are handled in a way to enable reproducible research.	1. 2. 3. Note:

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Chapter 8.9	Requirement Quality management reviews	Reference documents for Enter document title / date / ver Reference to Findings
8.9.1	The biobank top management **shall** review its quality management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.	1. 2. 3. Note:
8.9.2	The inputs to management review **shall** be documented and **shall** include information related to the following: a) changes in internal and external issues that are relevant to the biobank; b) fulfilment of objectives; c) suitability of policies and procedures; d) status of actions from previous management reviews; e) outcome of recent internal audits; f) corrective actions; g) audits by external bodies; h) changes in the volume and type of work or in the range of the biobank's activities; i) provider/recipient/user feedback; j) complaints; k) effectiveness of any implemented improvements; l) adequacy of biological material and associated data; m) results of risk identification; n) outcomes of the quality control; o) other relevant factors, such as monitoring activities and training.	1. 2. 3. Note:
8.9.3.	The outputs from the management review **shall** record decisions and actions related to: a) the effectiveness of the quality management system and its processes; b) improvement of the activities related to the fulfilment of the requirements of this document; c) provision of required biological material and associated data; d) any need for change.	1. 2. 3. Note:

Audit evaluation and reporting
Summary, remarks and potential for improvement completed by auditors (B-LA ☐

E.g.: Existing certifications, notifications, approvals and recognitions • competence
equipment and environmental conditions • fulfilment of additional requirements • fie
impression with respect to biobank's strengths and weaknesses • suitability and eff
system including potential for improvement • final evaluation • key aspects/consider

Audit recommendation[5]
B-LA ☐, B-SA ☐, B-TA ☐, B-TE ☐, B-O ☐ **recommend** the biobank to be awarded Quality Label in the BBMRI-ERIC Directory
B-LA ☐, B-SA ☐, B-TA ☐, B-TE ☐, B-O ☐ **cannot recommend** the biobank to be BBMRI Quality Label in the BBMRI-ERIC Directory

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The auditors recommend that the biobank addresses all critical non-compliances (CNC) and submit evidence of improvement to the auditors for further review. In case of a positive assessment, an addendum to the audit report will be submitted to BBMRI-ERIC by the auditors.	☐

Auditor statement[6]:

Place:
Date:
Name:
Signature:

[5] During the closing meeting, the biobank was informed about the preliminary result of the audit outcome based on the appraisal (C, NNC, CNC)
[6] *E.g.: The auditors can confirm that the biobank has established a biobank management system in accordance with the principles of ISO 20387:2018 and is carrying out its work processes in accordance with the international biobanking standard.*
This audit statement must be written and signed personally by the auditor.

Closing discussion between auditors and BBMRI-ERIC QM

The completed audit report is sent to BBMRI-ERIC QM by the auditors. A closing discussion on the audit process and the audit observations is conducted by the auditors and BBMRI-ERIC QM. BBMRI-ERIC QM will award the BBMRI Quality Label in the BBMRI-ERIC Directory based on the recommendation of the auditors, the review of the documents and the closing discussion.

Completion of the audit process by BBMRI-ERIC Quality Management at Headquarters
BBMRI-ERIC QM statement[7]:
Place: Date: Name: Signature:

[7] This statement was written and signed personally by the BBMRI-ERIC Head of QM.

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THE WORLD'S BIGGEST BIOBANK DIRECTORY

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.

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The European research infrastructure for biobanking and biomolecular resources in health and life sciences

CERTIFICATE

for the management system according to ISO 20387:2018

BBMRI-ERIC hereby confirms that, as a result of the internal audit, Biobank Väst, Sahlgrenska Universitetssjukhuset, 413 45 Göteborg

Biobank Väst
VÄSTRA GÖTALANDSREGIONEN OCH GÖTEBORGS UNIVERSITET

has established and operates a management system in accordance with the requirements of ISO 20387:2018.

Certificate ID: QMS/Quality Label/003
Date issued: 12 September 2022
Valid until: version change of ISO 20387:2018

Prof. Jens Habermann, M.D., Ph.D.
Director General

Andrea Wutte, M.Sc.
Head of Quality Management

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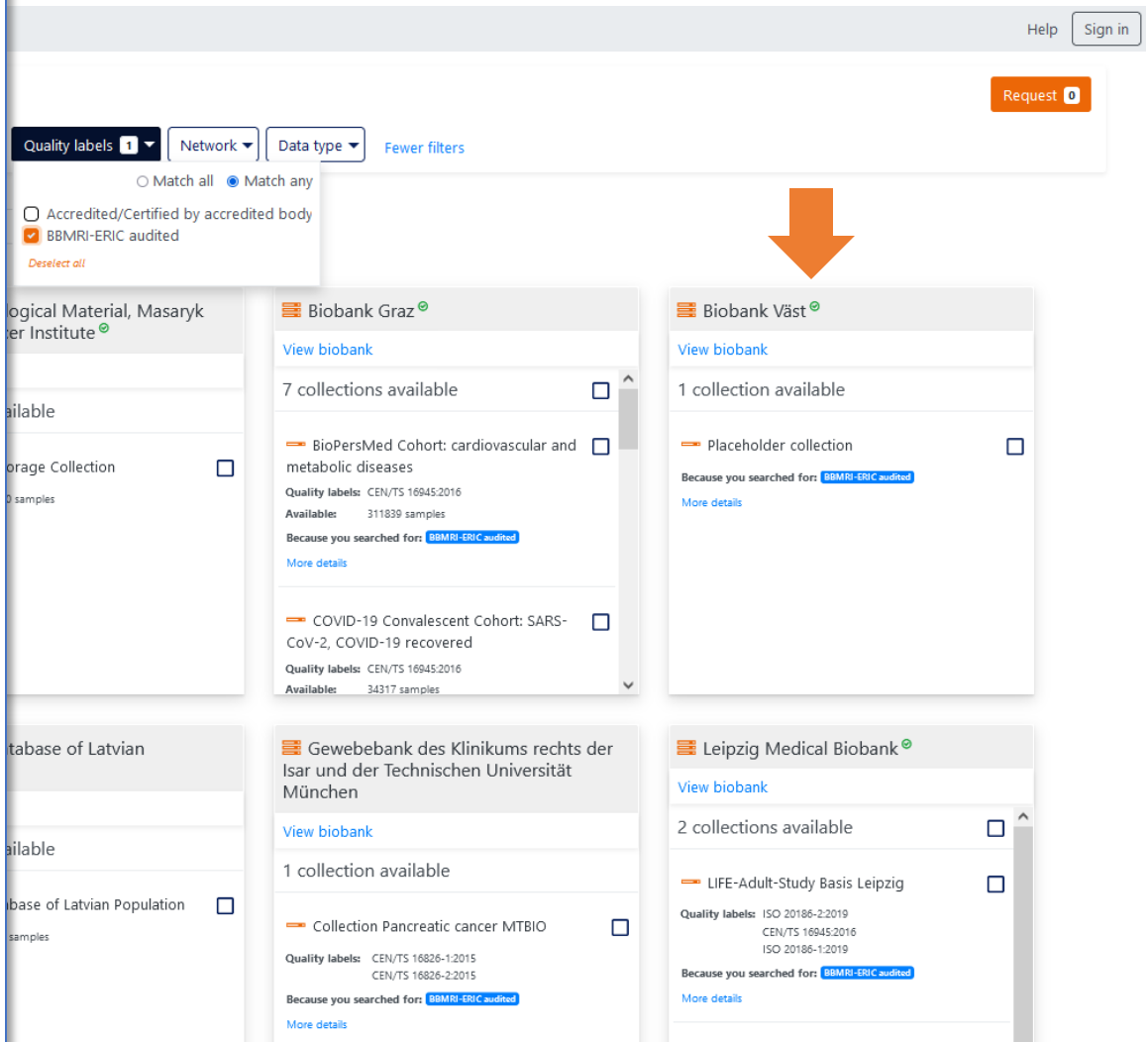

https://directory.bbmri-eric.eu

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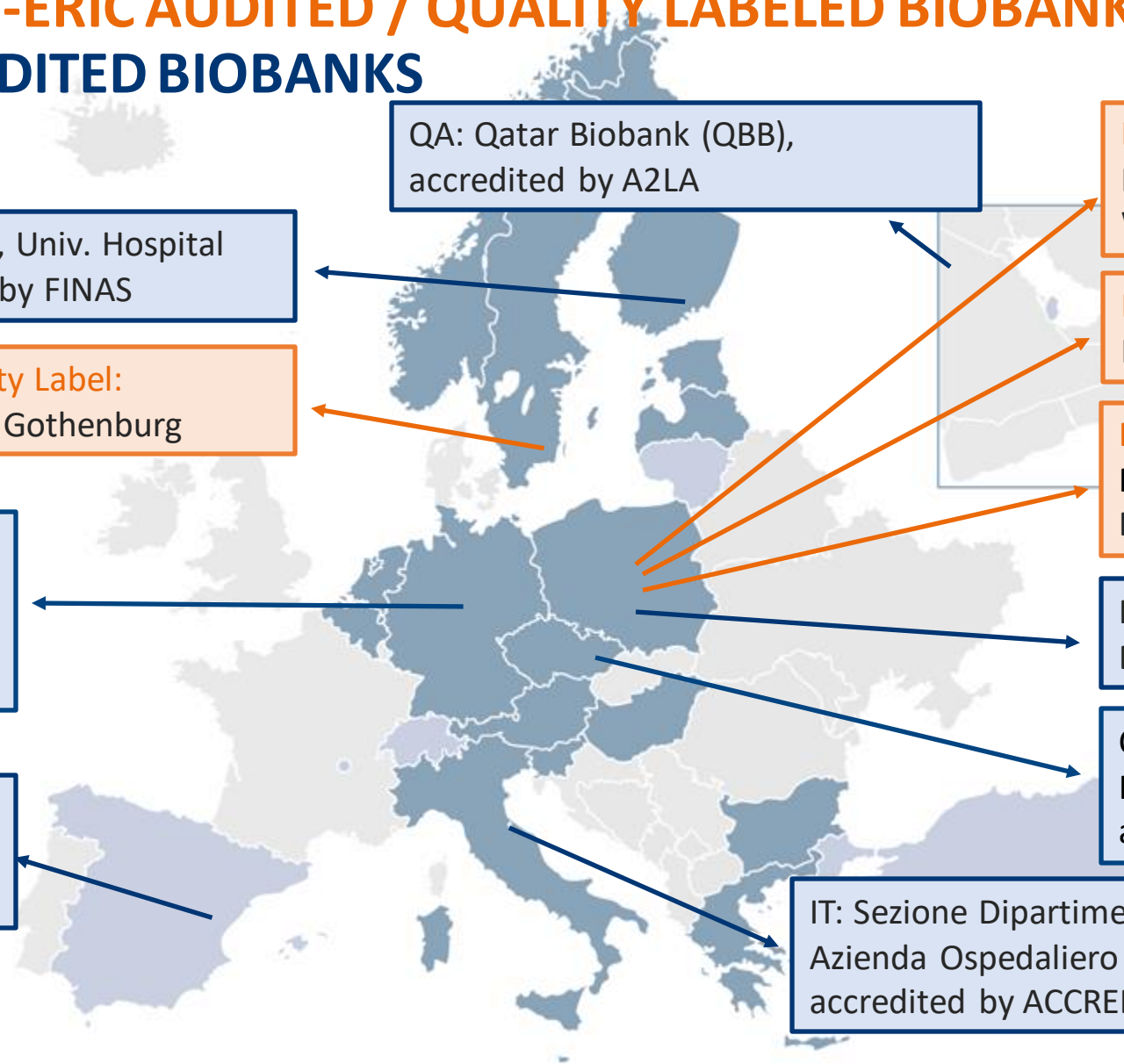
ISO 20387 BBMRI-ERIC AUDITED / QUALITY LABELED BIOBANKS
ISO 20387 ACCREDITED BIOBANKS



QA: Qatar Biobank (QBB), accredited by A2LA

FI: AURIA Biobank, Univ. Hospital Turku, accredited by FINAS

BBMRI-ERIC Quality Label:
SE: VÄST Biobank, Gothenburg

DE: NCT Tissue Bank, German Cancer Research Centre and Heidelberg University Hospital, accredited by DAkkS

SP: Fundación Instituto Valenciano de Oncología (IVO) Biobank, Valencia, accredited by ENAC

BBMRI-ERIC Quality Label:
PL: Stem Cell Biobank, Warsaw

BBMRI-ERIC Quality Label:
PL: Port Biobank, Wroclaw

BBMRI-ERIC Quality Label:
PL: Wroclaw Medical Univ. Biobank

PL: Wroclaw Medical Univ. Biobank, accredited by PCA

CZ: Masaryk Memorial Cancer Institute Biobank, Brno, accredited by CAI

IT: Sezione Dipartimentale Biobanca, Azienda Ospedaliero Universitaria, Pisa, accredited by ACCREDIA

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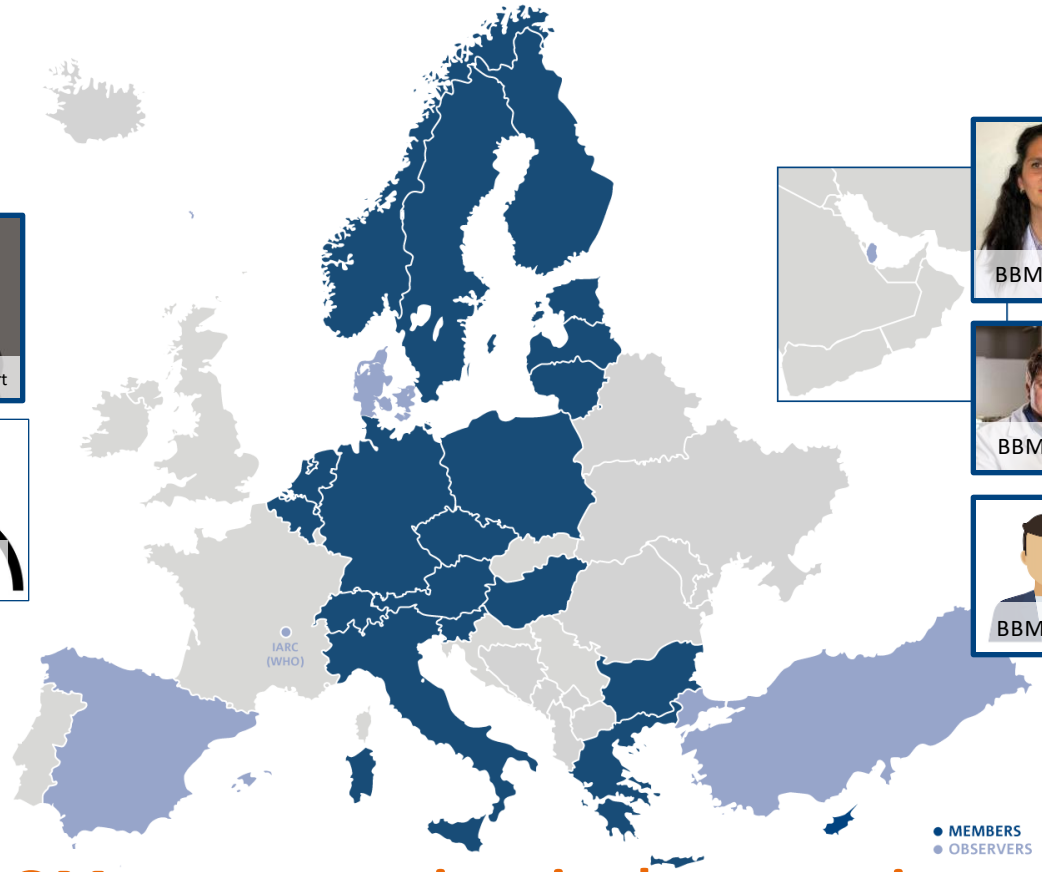
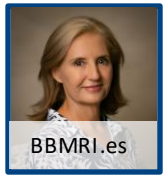
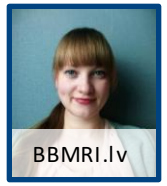
BBMRI-ERIC QUALITY MANAGEMENT TEAM (BBMRI.QM)

Quality Management Team
at Headquarters:



QM Leads
in National Nodes:





> 210 QM representatives in the countries

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ご清聴ありがとうございました。
THANK YOU FOR YOUR ATTENTION

contact@bbmri-eric.eu

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