

# HOW BBMRI-ERIC PROMOTES HARMONIZATION AND STANDARDIZATION

Wutte Andrea, on behalf of 117\* European technical experts of the BBMRI-ERIC Working Groups for **Quality Management (BBMRI.QM)** (\* 08.2018)

**BBMRI.QM TOOLS** 

# **BBMRI.QM SERVICE**

#### **BBMRI-ERIC QUALITY MANAGEMENT SERVICE (BBMRI.QM)**

support biobanks and researchers to meet the highest quality

#### **KNOWLEDGE HUB**

Building up Quality Management Systems (QMS) according to International standards

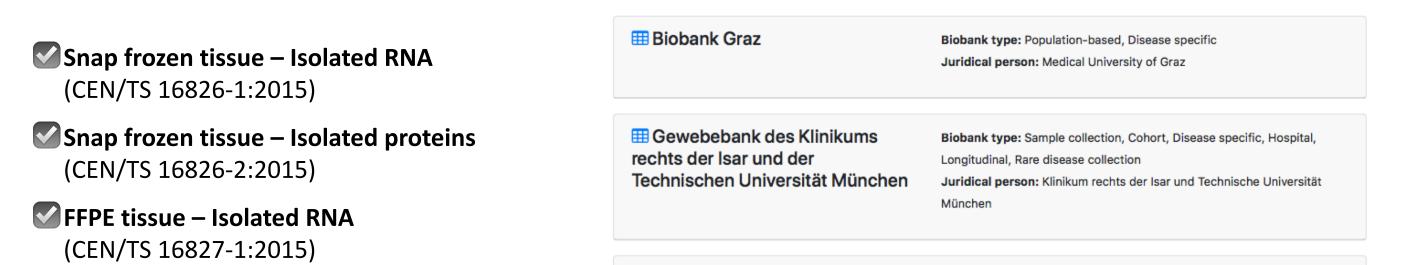
# **117 EXPERTS & RESEARCHERS JOIN WORKING GROUPS**

One of the key results are self-assessment questionnaires based on CEN/TS and ISO standards for biobanks.

**BBMRI-ERIC SELF-ASSESSMENT SURVEYS (BBMRI-ERIC SAS)** foundation for implement quality requirements and assess quality performance.

# **ENHANCE Q-VISIBILITY OF BIOBANKS AND/OR COLLECTIONS**

meeting defined quality criteria of the BBMRI-ERIC SAS, are being marked in the BBMRI-ERIC directory with the respective Quality label (Fig.1). This process (Fig.2) is ensured in a peer review audit and will reflect harmonized and standardized processes in biobanks





- **ISO 20387 Biobanking**
- ISO 9001 General QM Systems
- **Technical Specifications for sample handling processes**
- others



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## **TRAINING & SUPPORT**

Improving QMS within the European Network, offering tailormade services

- In-house and online training
- Webinars, Workshops, Master Courses, Summerschools
- **Consulting on how to combine multiple Integrated** Management Systems (IMS)
- others

FFPE tissue – Isolated proteins (CEN/TS 16827-2:2015)	Bank of Biological Material, Masaryk Memorial Cancer Institute	Biobank type: Other, Hospital Juridical person: Masaryk Memorial Cancer Institute
<b>FFPE tissue – Isolated DNA</b> (CEN/TS 16827-3:2015)	Integrated Biobank Jena	<b>Biobank type:</b> Cohort, Cross-sectional, Disease specific, Sample collection, Rare disease collection, Longitudinal <b>Juridical person:</b> University Hospital Jena
Venous whole blood – Isolated cellular		
<b>RNA</b> (CEN/TS 16835-1:2015	III MedUni Wien Biobank	<b>Biobank type:</b> Cohort, Longitudinal, Other, Disease specific <b>Juridical person:</b> Medical University of Vienna
Venous whole blood – Isolated		
<b>genomic DNA</b> (CEN/TS 16835-2:2015)	III THL Biobank	<b>Biobank type:</b> Cohort, Disease specific, Longitudinal, Population-based, Cross-sectional, Other <b>Juridical person:</b> National Institute for Health and Welfare
Venous whole blood – Isolated circ.		Surraical person, National Institute for Health and Weilare
cell-free DNA from plasma (CEN/TS 16835-3:2015)	🖽 Auria Biobank	<b>Biobank type:</b> Cross-sectional, Longitudinal, Population-based <b>Juridical person:</b> Hospital District of Southwest Finland
Metabolomics in urine, serum and		
plasma (CEN/TS 16945:2016)	III LifeGene	Biobank type: Other Juridical person: Karolinska Institutet

#### **AUDITING**

**Reviewing Biobanks QMS and Sample Quality, a** service provided on request

- **Remote Audit for BBMRI-ERIC SAS**
- **Onsite Visit / Audit on request**
- QMS Audit Guidance and Consultancy
- **BBMRI-ERIC Quality Label**
- others

Figure 1

# **ACCESS TO BBMRI-ERIC SAS**

# • **GO TO BBMRI-ERIC** website bbmri-eri.eu

#### • FILL OUT

# **EVALUATION OF SPECIFICATIONS**

 COMPLETION **BBMRI-ERIC SAS** 

SUBMIT REPORT

# AWARD BBMRI-ERIC Q-LABEL

# SAMPLE COLLECTION

meet the specifications of the particular international Standard 'fit for (standard defined) purpose'

Request form / fulfill pre-conditions

• GET STARTED @ link to SAS

 $\longrightarrow$ 

to **BBMRI-ERIC** 

• BE REVIEWED by **BBMRI-ERIC**  meet the specifications of the particular international Standard with documented deviations 'fit for purpose'

## • **BIOBANK**

BBMRI-ERIC audited (internal audits according to ISO 9001, ISO 20387 Biobanking, and others on request)

Figure 2



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