ADOPT BBMRI-ERIC
GRANT AGREEMENT NO. 676550

DELIVERABLE REPORT

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PROCEDURE AND CHECLIST FOR ON-SITE VISIT EVALUATION

Executive Summary

In relation to Task 1 on mapping and selecting established biobanks in Europe that are complying with BBMRI-ERIC procedures, the parameters for measuring the quality level and richness in samples and data in biobanks have been defined. A self-evaluation tool for helping National Nodes to identify biobanks within their network which give assurance of quality of samples and data, service to the scientific community, interoperability, compliance with best practices has been set up in a form of questionnaire for biobanks to describe themselves .A more specific on-line tool for pre-analytics evaluation of biobanks will be done in WP6 (D6.3).

The questionnaire for the biobanks to describe themselves have been applied to all parameters in compliance with the BBMRI-ERIC Partner Charter[1]. This takes into account areas of primacy, access policy, data protection and management policy, informed consent, infrastructure and management, quality management as well as charges. Hence, all Partner Charter items were included in the questionnaire and a standardised method of evaluation was defined (parameters and scores for assessment were defined).

The procedure and checklist for on-site visit evaluation of the biobanks have been set up. The work towards mapping and selecting the established biobanks in Europe was realized within M1-M8 time of the ADOPT project.

[1] BBMRI-ERIC Partner Charter: http://goo.gl/zhSYGx

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Document log

Issue	Date (yyyy-mm-dd)	Comment	Author/partner
D2.1_Rev1	2017-10-24	Revised: -Details on the onsite visits -Insights on how BBMRI-ERIC supports the biobanks in improving their quality -Conclusions and future work -Compliant with the GA art 29.4	Marialuisa Lavitrano, Outi Törnwall

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Methods and Results

The parameters for measuring the quality level and richness in samples and data of the European biobanks have been defined by the WP2 working group (Table 1.). The assessment tool (Biobank questionnaire Table 2., and the WP6 D6.2 pre-analytics evaluation tool, delivered in M18) is built up on the needs of biobankers, and takes into account Quality Management System in general, pre-examination processes, performance evaluation (Product specification report). The results are also reported to in the BBMRI-ERIC Work Programme 2016 (the Work Stream 2 Quality, of the 2016 Work Programme of BBMRI-ERIC, Work Stream 2.1: Molecular In-vitro Diagnostic Examination of CEN/TC and Work Stream 2.2 Self Assessment Tool for Biobanks)[2]. The work takes into account the documents and guidelines specifically referred to in the BBMRI-ERIC Partner Charter[1],OECD best practice guidelines for Biological Resource Centres and WHO/IARC guidelines for biological resource centres for cancer research, and additional National and International Guidelines (NFS 96-900 Certification des Centres de Resources Biologiques, ISBER Best practices for Repositories, ISO 9001:2015 Quality management systems requirements, ISO 15189:2012 Medical laboratories – Requirements for quality and competence, ISO 17025:2005 General requirements for the competence of testing and calibration laboratories, ISO 19011:2011 Guidelines for auditing management systems)[3]. All parameters for compliance with the BBMRI-ERIC Partner Charter[1] have been applied primacy, access policy, data protection and management policy, informed consent, infrastructure and management, quality management, charges.

Already available tools produced by the Italian Node (questionnaire BBMRI.it) and by the Austrian Node (Pre-An Tool)[4] were also analysed, with the aim of a) building a self-evaluation questionnaire, taking into account all parameters relevant to the quality management of biobanks; b) defining a standardized method of evaluation, by giving a score to each parameter and by weighing the items under evaluation on the basis of their respective importance; c) providing the self-evaluation tool to the National Nodes, in order to adapt it to specific requirements; d) assessing the efficacy of this evaluation system through on-site audits of biobanks.

In order to validate the information gained through the questionnaire/ on-line self assessment tool for the biobanks, on-site visits to biobanks by members of the BBMRI.it Committee for biobank evaluation have been planned. The Committee includes experts in quality, ELSI and IT issues in biobanking, and covers population biobanks as well as disease-oriented biobanks. The means to effective validation are:

- to verify the quality management system implementation within the visited biobank
- to define the characteristics of the expert evaluators, their methods and frequency of the visits, procedures for conducting the visits
- to standardise the checklist containing the set of questions/topics to be covered during the on-site visit

  The check-list for evaluation has been created for on-site visits (Table 3.)

In the Italian Node, the procedure of site visits of the biobanks that pass the self -ssessment test foresees the visits within six months after evaluation. The biobanks which do not pass the self

[2] BBMRI-ERIC Work Programme 2016: http://goo.gl/TKBGVs
[3] http://bbmri-eric.eu/standards
[4] https://redcap.i-med.ac.at/surveys/?s=8HP8HLWYXD

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assessment test are contacted by the common service quality and / or the common service ELSI in order to work together with the aim of filling the gaps in the implementation of a quality system compliant with the requirements of the infrastructure.

A standardised method of evaluation has been defined, by giving a score to each parameter and by weighing the items under evaluation on the basis of their respective importance (Table 4.). The criteria defined by the Parameters subgroup of the BioResource Impact Factor (BRIF)[5] initiative have also been taken into account in designing the questionnaire and in defining the method of evaluation.

Scores and sub-scores have been defined for seven features of the biobanks: quality, transparency, catalogue, usage, connectivity, innovation and scientific production, sustainability and impact. For each item sub scores have also been set and weighted. Quality includes 8 sub-scores (QMS, certification, QC/proficiency testing, SOPs, plan of improvements, staff competence, Regular audits/inspections, disaster recovery plan), Transparency includes 5 sub-scores (web site, annual report, access/priorization policy, donors' information and consent, involvement of donors/public); Catalogue includes 4 sub-scores (diffusion modality, sample variability, sample number, data availability); Usage includes 5 sub-scores (reality of supply, sharing procedure, numbers of requests, Material Transfer Agreement, ratio collected/used material); Connectivity includes 3 sub-scores (thematic network participation, regional network participation, infrastructure participation); Innovation and Scientific Production include 3 sub-scores (publications traceability, authorship and acknowledgements, data recovery); Sustainability and Impact include 5 sub-scores (institutional recognition, medium and long-term funding, grants obtained, cost recovery, dedicated staff).

As to the pre-analytical self evaluation tool, it is based upon the Molecular In-vitro Diagnostic Examination of CEN/TC, it is available on-line (https://redcap.i-med.ac.at/surveys/?s=8HP8HLWYXD) and it is being validated by the Austrian National Nodes.

[5] Cambon-Thomsen, Anne, et al. "The role of a bioresource research impact factor as an incentive to share human bioresources." (2011) Nature Genetics, Vol. 43, No. 6, p. 503.

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Table 1. WP2 working group

Country	BBMRI-ERIC Node coordinator	Additional person participating in WP2
Italy	Marialuisa Lavitrano	Barbara Parodi
BBMRI-ERIC	Jan-Eric Litton	Petr Holub Outi Törnwall
Austria	Kurt Zatloukal	Robert Reihs
Belgium	Karin Haustermans	Araceli Diez-Fraile Annelies Debucquoy
United Kingdom	Anne Carter	Balwir Matharoo M. Rodriguez Justo Parry Jonesa Philip Quinlan
Estonia	Andres Metspalu	Merike Leego
Check Republic	Dalibor Valík	
Finland	Anu Jalanko	Olli Carpen Iiro Hamalainen
France	Georges Dagher	
Germany	Michael Hummel	
Greece	Dimitris Thanos	Sissy Kolyva
Malta	Alex Felice	
The Netherlands	Gert-Jan van Ommen	
Norway	Kristian Hveem	
Poland	Łukasz Kozera	
Sweden	Joakim Dillner	Eva Ortega
Turkey	Nese Atabey	Sulen Sarioglu
IARC/WHO	Maimuna Mendy	Elodie Carboux
Switzerland	Stephanie Wyss Christine Currat	Laurence Chapatte Rainer Warth

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Table 2. Questionnaire for the biobanks to describe themselves

QUESTIONNAIRE BIOBANK
ID QUESTIONNAIRE:
1 **Name of the biobank**
2 **Biobank Acronym**
3 **Name of the Curator of the BB**
4 **Qualification of the Curator**
5 **Head office of the BB** Institute: University/Research Institute/Hospital/other: Department / Laboratory: Address: Region Area?: ZIP code: City: Country:
6 **Contacts of the BB** Phone: Fax: E-mail:
7 **Web site (if available)**
8 **The BB is officially recognized by the host institution?**
9 **The BB is active since (year)**
10 **The BB has dedicated facilities?**
11 **Aims of the BB**
12 **Certifications / Accreditations / International Recognitions**
13 **Networking** Regional: National: International:
14 **Data sharing** Network: What kind of data: Public Databases:
28 Operators working in the BB
27 Dedicated equipment for storage
26 **Description of the materials collected**
25 **Type of material**
24 **Number of Samples (not aliquots) collected per year Approximate number**
23 **Number of Subjects collected per year Approximate number**
22 **Number of Samples (not aliquots) collected per year**
21 **Number of Subjects collected per year**
20 **Dimension of the BB: Samples (not aliquots) Approximate number**
19 **Dimension of the BB: Subjects Approximate number**

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18 **Dimension of the BB: Samples (not aliquots)**

17 Dimension of the BB: Subjects

16 **Pathologies handled** ***e/o studied***

15 **Typology of the BB (oncology, genetics, population, …, other)**

Permanent staff FULL TIME:

Permanent staff PART TIME:

Temporary staff FULL TIME:

Temporary staff PART TIME:

29 Operators working in the BB (Curator excluded): please specify the qualification (biologist, bioinformatician, lab technician, …, other

30 Availability of institutional economic support

31 Funds supporting the BB (last 5 years)

32 SOPs

33 Informed consent

34 Type of consent

35 Is the consent approved by the Local Ethics Committee?

36 The donor can withdraw his/her consent?

37 Data registration

38 Dedicated database

39 Types of data registered

40 Securing access to the database

41 Securing access to the paperwork

42 Online catalogue: static (descriptive), dynamic (automatically updated)

43 Users of the BB

44 Service of sample distribution

45 Number of samples distributed per year (mean value last 5 years)

46 Number of subjects distribuited per year (mean value last 5 years)

47 Number of samples distribuited Approximate number

48 Number of subjects distribuited Approximate number

49 Evaluation of requests (distribution service)

50 Registration of requests

51 Filing of requests

52 Communication of results to the donor / community

53 Number of publications resulting from the use of stored samples and in which the role of the BB is recognized (authorship, acknowledgements – last 5 years)

54 Comments

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Table 3. Check-list for evaluation of biobanks

Biobank Name	
Institution	
Country	
Head First Name	
Head Last Name	
Head Role	

Domain	Sub-domain	Docs analysed	Score*
Quality	Quality Management System		
	certification		
	QC/proficiency testing		
	SOPs		
	plan of improvements		
	staff competence		
	Regular audits/inspections		
	disaster recovery plan		
Transparency	web site		
	annual report		
	access/priorization policy		
	donors' information and consent		
	involvement of donors/public		
Catalogue	diffusion modality		
	sample variability		
	sample number		
	data availability		
Usage	reality of supply		
	sharing procedure		
	numbers of requests		
	Material Transfer Agreement		
	ratio collected/used material		

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Connectivity	thematic network participation		
	regional network participation		
	infrastructure participation		
Innovation and scientific production	publications traceability		
	authorship and acknowledgements		
	data recovery		
Sustainability and Impact	institutional recognition		
	medium and long-term funding		
	grants obtained		
	cost recovery		
	dedicated staff		

* 1=non-compliant or not applicable, 2= some progress towards compliance, 3=compliant with regard to most important features, 4=fully compliant

Table 4. Scores and weights of the items under evaluation

	Sub-Scores									Weight of Scores
Quality Scoring	Quality Management System	Certification	Quality Control / Proficiency Testing	Standard Operating Procedures	Plan of Improve-ments	Staff Competence	Regular Audits / Inspections	Disaster Recovery Plan	Other	Overall Quality Score (1 - 10)
Transparency Scoring	Web site	Annual report	Access / Priorization Policy	Donors' Information and Consent	Involvement of Donors / Public	Other				Overall Transparency Score (1 - 5)
Usage Scoring	Reality of Supply	Sharing Procedure	Numbers of Requests	MTA	Ratio Collected / Used Material	Other				Overall Usage Score (1 - 5)
Connectivity Scoring	Network Participation	Infrastructure Participation	Interfaces / APIs towards external ICT	Other						Overall Connectivity Score (1 - 3)
Innovation Scoring	Patents	New Methods	Services	Other						Overall Innovation Scoring (1 - 4)
Sustainability Scoring	Business Model	Invoice	Funding Applications	Grants Obtained	Cost Recovery Policy	Institutional Long Term Funding	Other			Overall Sustainability Score (1 - 6)

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Conclusions and future work

Self-assesment surveys (SAS, Figure 1.) are quality assessment tools, complementary to the CEN Technical Specifications, through which biobanks can evaluate the quality of their samples and collections (http://www.bbmri-eric.eu/services/self-assessment-survey/). SAS supports biobankers in their efforts to improve sample-handling processes, implement quality requirements and assess their performance. By completing the SAS, the biobanks can also gain visibility and prestige in European scale once the positive evaluation results are marked in the BBMRI-ERIC Directory. The researchers are able to search thereafter the biobanks whose quality is fit for their purpose by using the Directory.

Future work for ADOPT: all biobanks involved in the CRC collection should be involved in the SAS and to subsequent on-site visits.

Recommendations for BBMRI-ERIC: a procedure for audits should be defined and qualified auditors should be identified.

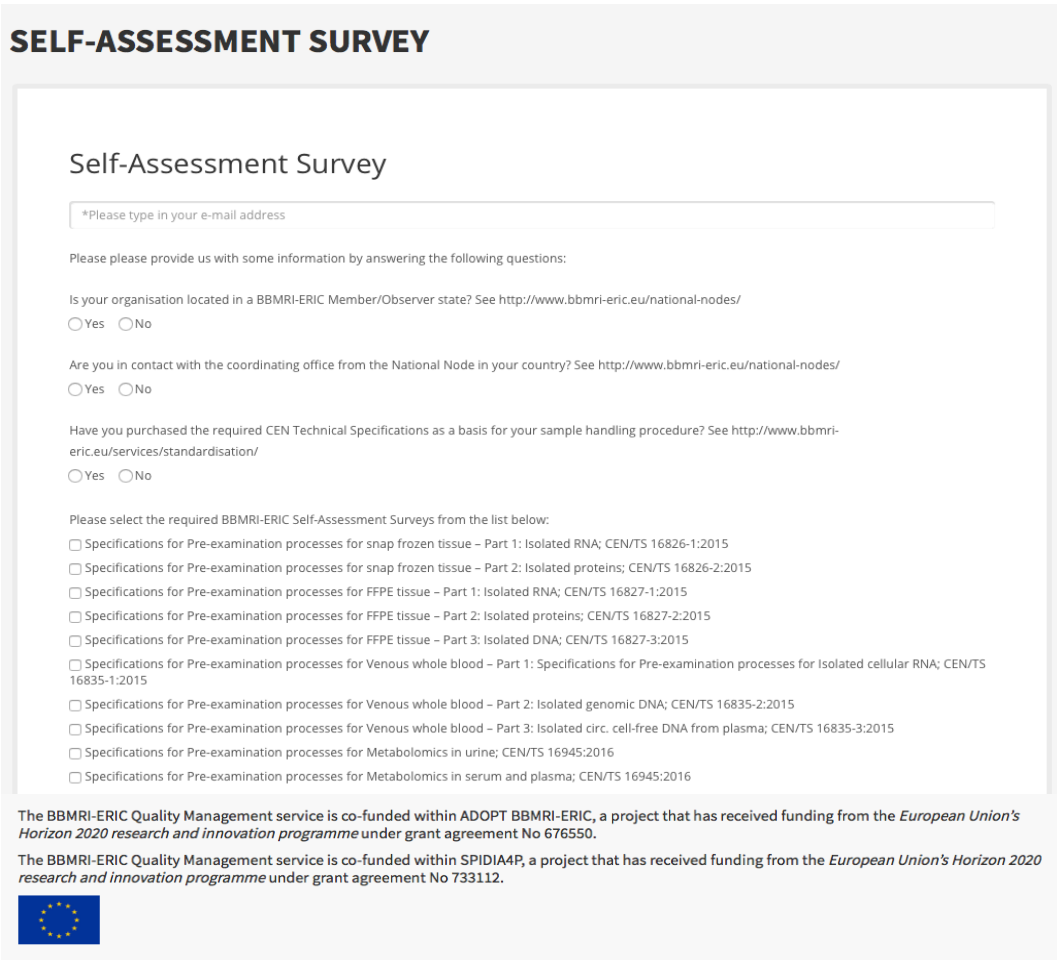

Fig 1. Self assessment survey entry on BBMRI-ERIC website: (http://www.bbmri-eric.eu/services/self-assessment-survey/

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BBMRI-ERIC provides guidance to establish and improve an appropriate Quality Management System for biobanks of human derived materials. Fig 2. Introduces the key pillars with timelines that contribute to the development of the Infrastructure in Quality Management (Self assessment survey, visibility of quality graded biobanks, consultancy and audit programme and the QM criteria). In 2017 BBMRI-ERIC aims to increase the visibility of quality-graded biobanks by inviting the biobanks to complete and submit the self-assessment (Fig 1.) to BBMRI-ERIC. Biobanks that fulfill the criteria of the self-assessment survey will receive recognition by being flagged in the BBMRI-ERIC Directory. This will place the biobanks on the European map and makes the Directory a powerful tool enabling the researchers to find high-quality biobanks throughout Europe.

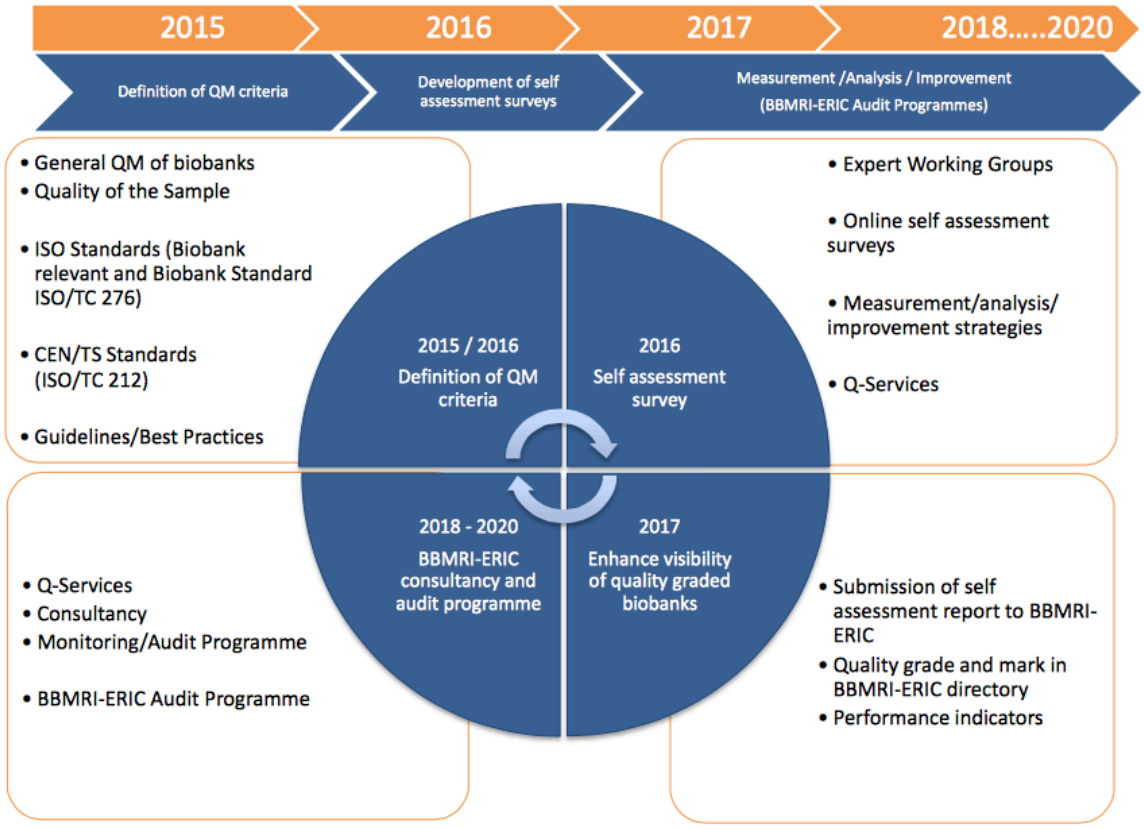

Fig 2. Quality Management Infrastructure developments from 2015 to 2020 (Source: BBMRI-ERIC Work Programme 2017)

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