ADOPT BBMRI-ERIC
GRANT AGREEMENT NO. 676550

DELIVERABLE REPORT

Deliverable no	D6.5
Deliverable Title	Letter of interest of founding members of a Biomarker Expert Centre
Contractual delivery month	M36 (September 2018)
Responsible Partner	MUG (BBMRI.at)
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To coordinate efforts of existing and future Expert Centres towards biomarker research, and to include new Expert Centres early on, a meeting was prepared in Milano, Italy (locally organized by Marialuisa Lavitrano), on June 25, 2018. The Meeting agenda and minutes are enclosed. In this meeting, Expert Centre candidates and the existing Expert Centres declared their intention also to cooperate in an Expert Centre interest group. After the meeting, we received two letters of interest by OPBG and by CNAG (enclosed). On 27th of September 2018, CNAG-CRG sent the application to BBMRI-ERIC to become the next Expert Centre. After internal assessment the decision will be made at the Management Committee meeting 8th of October 2018.

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Timelines: Meeting on Biomarker Expert Centres Milano, 25 June, 2018
Letter of Interest OPBG, 19 July, 2018
Letter of Interest CNAG, 30 July, 2018

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 676550.

ADOPT BBMRI-ERIC gateway for health

Annexes

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Agenda Expert Centre Workshop

Milano June 25, 2018

University Milano Bicocca, Rodolfi Room, fourth floor building U6, piazza dell'Ateneo Nuovo, Milano.

The aim of the meeting is to promote interoperability of Expert Centres (ECs) regarding their output data. This means that data generated by one EC are generated from samples of highest quality, following European or International standards under consistent quality control. These data, obtained from different ECs can then be linked in larger studies, combining different types of analysis. One example would be linking molecular analysis data with Digital Pathology and imaging information.

As a use and test case we will plan a proficiency testing ring-trial, using reference material provided by the Medical University of Graz. Further, the meeting will initiate a strategy for designing an overarching QM system for ECs, and address the strengths of ECs in biomarker development, as well as future requirements.

To this meeting, representatives of ECs are invited (CBmed, ATMA, EXCEMET), from BBMRI-ERIC, the imaging community, as well as from an upcoming EC project, represented by the Barcelona Center of Genomics (CNAG/CRG).

11.00 Welcome and purpose of the meeting (Marialuisa Lavitrano)

11.10 Scope of ECs (Kurt Zatloukal)

11.30 Short presentation of ECs

CBmed (Sophie Narath)

ATMA (Giorgio Stanta, Marco Salvatore, Marco Salvatore, Marco Aiello)

EXCEMET (Claudio Luchinat)

Focus on paediatric biomarkers (Fabrizio de Benedetti)

13.00 Lunch

14.00 Discussion on interoperability (Chair: Kurt Zatloukal)

EC collaboration with SPIDIA4P

Requirements for a proficiency ring-trial

Reference material

Timelines

Data collation and evaluation of performance

Courses and Training in molecular analyses

15:00 Ideas for an overarching QM system for ECs (Chair: Marialuisa Lavitrano)

15:30 How can ECs support biomarker development? (Chair: Kurt Zatloukal)

16.00 End of the meeting

Minutes Expert Centre Workshop

Milano June 25, 2018

University Milano Bicocca, Rodolfi Room, fourth floor building U6, piazza dell'Ateneo Nuovo, Milano.

Attendance: Abuja (PMA), Aiello (MA), Canzonieri (VC), Cerrito (MGC), De Benedetti (FDB), Farina (LF), Franchin (TF), Grassilli (EG), Lavitrano (ML), Luchinat (CL), Narath (SN), Offenhaeuser (NO), Stanta (GS), Turano (PT), Zatloukal (KZ)

KZ explains briefly the concept and purpose of Expert Centres (ECs), namely boosting Open Science and Open Innovation, by (eventually) making high-quality data available in the public domain (e.g. EOSC). He points out one of the imminent problems ECs are facing, which is lack of funding. One of the goals in the near future should be therefore generating a continuous funding stream.

The presently existing ECs present themselves – CBmed, ATMA and EXCEMET (CBmed has already made their presentation available).

The discussion focuses on the items of increasing visibility, generating funding and showcasing the specific advantages ECs can offer to academia and industry. It is decided that some kind of 'branding' will be necessary that allows recognizing the ECs aim at producing reproducible, high-quality data and results, using European and international standards. Funding should be obtained through increased participation in EU funded projects, and from industry, by producing high-quality data, showcasing this in success stories. Another way of enhancing visibility would be the participation in quality-related ring trials, and also in education and training activities. An important part of the activities of ECs is, not only to adhere to the highest existing standards, wherever possible, but also to contribute to improving existing and establishing new standards.

Overarching QM systems need to take into account that quality requirements (pre-standardization) are defined by Learned Societies, and by Expert Centres as 'experts', together (i.e. standardization cannot be fully separated into design/definition and use). Contribution to CEN and ISO processes are also driven by ECs. Standards in different domains cannot be the same, but should be highest as defined in this domain, by agreement, if possible. Overarching/combined ´standards between ECs may be prerequisite for a possible CEN/ISO process.

Forming an Expert Centre interest group is agreed on, to work on implementing the suggestions made above.

Bambino Gesù
OSPEDALE PEDIATRICO

The Scientific Director

Rome, July 19, 2018
Prot. 375

Prof.ssa Maria Luisa Lavritrano

Biobanking and biomolecular resources research infrastructure of Italy (BBMRI.it)

Dear Prof. Lavitrano,

I am pleased to submit the Bambino Gesù Children Hospital's application as hub expert centre within BBMRI for the control and validation of paediatric biomarkers.

With my warmest regards

Prof. Bruno Dallapiccola

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cnag
centre nacional d'anàlisi genòmica
centro nacional de análisis genómico

CRG
Centre for Genomic Regulation

Barcelona, 30th July 2018

RE: Letter of interest to be part of the BBMRI-ERIC associated Expert Centres network

To whom it may concern,

This letter serves to confirm that Centro Nacional de Análisis Genómico (CNAG-CRG), one of the largest European genome sequencing operations, is strongly interested in becoming part of the "BBMRI-ERIC associated Expert Centres trusted partners".

The Centro Nacional de Análisis Genómico (CNAG-CRG) is a non-profit organization funded by the Spanish Ministry of Science, Innovation and Universities and the Catalan Government through the Economy and Knowledge Department and the Health Department. Competitive grants and contractual research with the private sector provide additional funds. The centre was set up in late 2009 and since the 1st July 2015 it is integrated with the Centre for Genomic Regulation (CRG).

The CNAG-CRG's mission is to carry out projects in DNA sequencing and analysis in collaboration with researchers from Catalonia, Spain and from the international research community in order to ensure the competiveness of our country in the strategic area of genomics.

The CNAG-CRG takes part in genome sequencing and analysis projects in areas such as cancer genetics, rare disorders, host-pathogen interactions, the preservation of endangered species, evolutionary studies and improvement of species of agricultural interest, in collaboration with universities, hospitals, research centres and companies in the sector of biotechnology and pharma. The CNAG-CRG, is led by Dr. Ivo Gut and has a headcount of 80 staff. The centre is organized in two production-oriented groups for Sequencing and Bioinformatics Analysis that secure seamless operation, and cover a range of capabilities including whole genome, de novo sequencing, whole genome re-sequencing, targeted re-sequencing, profiling of mRNAs, epigenome sequencing, single cell sequencing and Genotyping-by-Sequencing.

Our expertise is guaranteed by professionals with extensive experience in sequencing, data analysis, data banking and data serving. The Centre has a highly qualified staff, 50% of which holds a PhD degree. The bioinformatics team together with an outstanding computing infrastructure (7.6 petabyte of data storage and 3472 cores of computing) places CNAG-CRG as a centre of excellence in data analysis.

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CNAG-CRG has always been committed to the highest possible level of quality under internationally standardized conditions.

Since December 2014, CNAG-CRG is certified on the most established international quality framework, ISO 9001 "Quality management systems – Requirements", for the following activities: "Management and performance of high throughput sequencing and genomic analysis projects and services." This certification has already been renewed once.

In 2016, CNAG-CRG obtained the international recognition of its competence with the accreditation on ISO 17025 "General requirements for the competence of testing and calibration laboratories", for the "DNA / RNA analysis by high throughput sequencing (Next Generation Sequencing)" activities. This standard specifies the general requirements for the competence of laboratories to carry out tests and/or calibrations, including sampling.

CNAG-CRG ensures the expected sequencing data quality monitoring its performance by comparison with results of other laboratories. Over the last four years CNAG-CRG has participated in seven different interlaboratory comparison projects (ILC), and has always been assessed for all processes of its workflow with very satisfactory results/score.

Interlaboratory programmes were organized by:

- ✓ The College of American Pathologists (CAP).
- ✓ Integrated BioBank of Luxemburg.
- ✓ United Kingdom National External Quality Assessment Service (UKNEQAS)
- ✓ SPIDIA4P project funded by the European Union FP7 programme.
- ✓ ICRNA (Interlaboratory Comparison of RNA samples); involves 5 European sequencing centres coordinated by CNAG

Based on the continuous improvement of its processes, CNAG-CRG works not only on the maintenance of its already established quality management system but also to incorporate the procedures and controls defined in UNE-EN ISO/IEC 27001:2013 "Information technology - Security techniques - Information security management systems – Requirements" and to obtain the accreditation on ISO 15189:2012 "Medical laboratories – Requirements for quality and competence".

For all previously exposed we consider that CNAG-CRG strongly fulfils the requirements and definition of an Expert Centre: "key intermediary between public and private sectors performing the analysis of biological samples under internationally standardized conditions", and we are convinced that CNAG-CRG expertise and technology can contribute to the important work developed by "BBMRI-ERIC associated Expert Centres trusted partners".

Best wishes,

Ivo Gut
Director of the Centro Nacional de Análisis Genómico (CNAG-CRG)