

## Meeting report series

# Report of the 3<sup>rd</sup> ISC Working Group on Biobanks teleconference

20 October 2014

### Organization

Organized by: IRDiRC Scientific Secretariat

### Participants

Prof Hanns Lochmüller, Newcastle, UK (interim chair)

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### Apologies

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### Agenda

- ▶ Brief recap on previous teleconference
- ▶ Election of the chair
- ▶ Discussion on suggested biobanking-related issues and actionable points
- ▶ AOB

## REPORT

### Brief recap of previous teleconference

The roadmap is an ongoing discussion, where the Scientific Committees (SCs) and the Executive Committee (EC) hope to get input from all Working Groups (WGs). The EC has given its feedback to this WG, so the members should consider if there are points that should be revisited and changed in line with the comments given.

One of the major themes proposed by this WG relates to quality in biobanking. Industry frequently criticizes on unreliability of samples/data quality, but this may be addressed with the development of an appropriate scoring system and the improvement in cataloguing. There are some work being carried out by Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) and EuroBioBank (EBB) but these are European projects rather than something more overarching that could be applied to US/Australian biobanks. The problem related to quality system currently remains ineffectively managed, so one practical solution would be to certificate the governance of the network in order to improve the appropriateness of quality. However, with many researchers believing that their samples are of highest quality and in compliance with quality requirement, this may be difficult to implement.

Another approach may be to take a step back and ask the organizations what is already in place in terms of quality control and certifications. This would help the WG to formulate more specific action plan, or consider joint-effort with an organization such as BBMRI and extend their systems and approach to wider rare disease fields in IRDiRC.

- ⇒ Fact-finding, primarily with BBMRI and RD-HuB, perhaps ISBER (members restricted access), on their quality system and available questionnaire

BBMRI Sweden is considering starting a joint network with the Nordic countries and the patient organizations in these countries to investigate the number of sample collections related to rare diseases that are available, the quality of samples and the conditions for the consent, in order to have a comprehensible view of what is available and to improve the use of samples of research. This initiative could serve as an example for IRDiRC and may link with RD-Connect.

- ⇒ As this initiative also includes registries, any suggestion for a Nordic candidate to join the IRDiRC WG on Registries and Natural History is welcome.

### Election of Chair

Due to limited number of participant on this call, the election of a new Chair of the WG is postponed.

## **Discussion on suggested biobanking-related issues and actionable points**

The purpose of this teleconference was to appraise the suggestions coming from the WG members, and to agree on a list of things or issues, and possible solutions to report to the Interdisciplinary SC to connect to other WGS and to present to the Executive Committee.

### **Long-term financial stability (no one wishes to core fund them)**

It would be interesting to suggest step that IRDiRC needs to take to reach this goal of long-term stability. BBMRI-ERIC could be a possibility to solve this issue for states connected to it. For example, in Italy, biobanks are funded by institutions hosting them. Such institutions sent an application including a questionnaire to BBMRI-ERIC, which selected biobanks that fulfill the requirement to be considered a good biobanks. This recognition will assure funding from the government to the institution supporting the biobank.

For countries that are not part of the BBMRI-ERIC, another solution needs to be found.

### **Guidelines/legislation that are becoming increasingly difficult to work within and do not always appear to make sense. Add to this issue with cross jurisdictional incompatibilities or conflicts between guidelines when exchanging samples and/or information.**

This topic may concern the IRDiRC WG on Ethics and Governance.

It is necessary to know which guidelines/legislations are referred to in this comment for a more specific discussion.

Sample exchange is complicated by regulation but also by customs - samples stuck for weeks at custom when labeled DNA or biological material. What can be done? How to declare a parcel?

This issue is highly relevant to rare diseases where exchanging samples and shipping parcels across countries are necessary. A possible action item for this WG is to collect information, through a short questionnaire (4-5 questions) on difficulties and successes encountered by biobanks users, to then propose instructions and tips.

### **Standardizations of associated clinical information including biospecimen and data quality**

Non-European members of the WG may not be aware that work on this topic is already ongoing in RD-Connect, BBMRI and EuroBioBank in Europe.

This topic can be either further discuss at a next teleconference or a private conversation.

### **Biobanking brought to the students: teaching biobanking in science classes should help normal people to understand both the impact of the new biomolecular technologies and the complexity of the issues related to donation of biological samples**

There is a great ignorance of what is biobanking for “normal people”. Teaching biobanking in school of medicine would increase the clinicians’ awareness of the important of biobanks that are not collections for themselves but also to assist people.

An educational package to be distributed to universities, schools, etc. would be useful. It is necessary to define who would be the actors, what would be the timeline, what sort of funding is required – to decide if seed money would be enough or if a grant would be necessary and thus that the topic should be included in call for application by an IRDiRC member.

⇒ This item could be included in the roadmap.

### **Development of biobanks of iPS: extremely demanding both economically and professionally**

From casual discussion, it appears that iPS biobanking is very important for research in the field of rare diseases.

In Europe there is a project called EBiSC (European Bank for induced pluripotent Stem Cells; <http://www.ebisc.org/>), a large European public-private partnership project supported jointly by the Innovative Medicines Initiative (IMI) and members of the European Federation of Pharmaceutical Industries and Associations (EFPIA), which aims at establishing the first European Bank for induced pluripotent Stem Cells.

However, this initiative may not solve all the demands for biobanking iPS cells. A map of the field is necessary and a screen of the projects funded by IRDiRC members to list the projects declaring doing iPS cells biobanking. These people will then be individually contacted to ask if they will contribute to the IRDiRC agenda, and specifically what the possibilities are for people with RD research interest to deposit the iPS cells that they may have generated themselves, and how to retrieve iPS cells from these facilities.

### **Promotion of collections of DNA from trios for NGS: this should facilitate detection of pathogenic variants**

Recommendations from the WG would be:

- ▶ To collect DNA from trios for NGS studies to facilitate the detection of pathogenic variants
- ▶ To encourage, in clinical trials and natural history studies, a change in approach to facilitate the re-use of samples

Samples collected in natural history studies or clinical trials, are usually only collected for a particular purpose, e.g. looking at effectiveness of drug A, and are thus lost to any further research. It would therefore be quite important - especially for IRDiRC members, many of them are pharma companies that run trials - to change their approach by constructing consent form and ethics in a different way to allow,

under certain conditions such as IP protection, the use of samples for other purposes. This will be difficult according to the experience of one of the WG members who worked with a pharma company.

- ⇒ Fact-finding on practice of pharma companies members of IRDiRC by asking them 2 questions in the purpose of understanding status quo on sample sharing in natural history study and clinical trials to make recommendations and contribute to the roadmap.
- 1) Do they collect samples from patient in their clinical trials?
  - 2) Did they make any sort of provision to share these samples or make available beyond the original research project?

### **Involve all RD in the upcoming BBMRI Catalogs, including well defined pre-analytical code for samples**

Members of the WG agreed that European biobanks should be participating in BBMRI catalogs. However, this is not applicable to North Americans or Australian biobanks.

For the moment, there is no plan to develop any BBMRI international relationships as setting up European memberships is already a substantial task.

### **Main deliverables**

- ▶ Fact-finding, primarily with BBMRI, RD-HuB, and ISBER on their quality system and available questionnaire.
- ▶ Send a suggestion for a Nordic candidate to join the IRDiRC WG on Registries and Natural History.
- ▶ Ask sender which guidelines/legislation he is referring to in his comment.
- ▶ Prepare a questionnaire on difficulties and successes to send samples across countries.
- ▶ Consider which funding mechanism is most appropriate for the development of an educational package on biobanking.
- ▶ Scan the list of projects funded by IRDiRC members to find which projects declare doing iPS cells biobanking.
- ▶ Fact-finding on practice of pharma companies members of IRDiRC to understand the status quo on sample sharing in natural history study and clinical trials.
- ▶ Provide more details on the comment on BBMRI catalogs.