

Meeting report series

Report of the 2nd ISC WG on Ethics and Governance teleconference

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Organization

Organized by: IRDiRC Scientific Secretariat
Teleconference

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Agenda

1. Welcome
2. Review of the report of the 1st teleconference
3. Further discussion on gaps and hurdles from an ethics and governance point of view
4. Other topics

REPORT

Review of the report of the 1st teleconference

The members of the WG validated the report of the previous teleconference. Updates were provided for topics previously discussed as summarized below.

Attribution of scientific input/publication guidelines from other consortia/alliance

Members of the WG started searching how other consortia approach the problem of attribution of scientific input and equitable distribution for samples and data sharing. However, this topic is set aside for the moment as the chair of the ISC think that the IRDiRC policies and guidelines are sufficient for the time being.

Global Alliance

The aim of the Global Alliance, gathering 91 institutions over 47 countries, is to put together infrastructures and funding to create an international distributed/federated cloud system for genomic and clinical data sharing. A transitional scientific committee is now meeting weekly to prepare by December a roadmap to be presented to Global Alliance's members as a MOU. There are three areas of interest: cancer, rare diseases and infectious diseases.

European Data Protection Directive

Will there be an exemption for research? The exact terms of this exemption are unknown, in particular what would be the consensus for consent and re-consent. Epirare is lobbying the parliament about the research exempt. A summary of the possibilities for the Parliament to vote on will be circulated to the WG members following the next meeting of the Parliament to be held on September 26th.

Discussions on data sharing and consent are also ongoing in the USA and Australia.

Gaps and hurdles from an ethics and governance point of view

Four possible actions emerged from the discussion on the necessity of developing a controlled-access database specific to samples and data of the RD community.

Creation of a questionnaire to capture the sensitivity, aspirations and hopes of the RD patients and families about data sharing

The right of privacy of information to be shared is an important problem for all type of databases (biobanks, registries, etc.). Perceptions and attitudes of the general public toward biobanks and the right of privacy have been studied through surveys (Eurobarometer published by the European Commission). However, the perception of patients with rare diseases might be different from the

ones with common diseases as the former may be more willing to share data if it would help the discovery of therapies.

It would thus be interesting to create a short survey, based on questions previously asked to the general public, to capture the sensitivity, aspirations and hopes of the RD patients and their families through the Patient advocacy groups members of IRDiRC.

As another source of information, eMerge Network is developing a large survey including biobanks. As the project is in the development stage, it may be possible to insert questions about international data sharing in the survey.

Minimal consensus on standards, policies and guidelines among IRDiRC members for data sharing

Cross continental data sharing necessitates a minimal consensus about standards, guidelines and policies among countries or funders. Laws regulating data sharing are different from one country to another. For example, it is difficult in France to export data and samples as the law regarding biobanks is very restrictive, more restrictive than the European agreement. In Canada, there is no harmonization between the laws of the different regions of the country.

An analysis of the standards, policies and guidelines from the funders to find a minimal consensus on data sharing would facilitate international collaboration for data sharing and shared funding mechanisms.

P³G is creating IPAC (International Policy interoperability and data Access Clearinghouse), an office working on the harmonization of data sharing laws around the world and also a separate project to create an Ethic Safe Harbour to recognize ethics equivalency between countries/regions. P³G and IRDiRC could work together for the internationalization of data sharing.

Oversight committee

It would be necessary to fund an oversight committee or advisory board across jurisdiction to set up and monitor all the guidelines and assure the sustainability of databases by encouraging their integration to health structures. The first step would be to enquire about the monitoring mechanisms of funders that have some oversight on compliance issues.

Analysis of the organization of biobanks/registries databases

To facilitate the discovery of new therapies, the biobanks/registries databases should be organized in such a way that pharmaceutical companies/biotech could find the information they need to run a clinical trial. The first step would thus be to analyze and compare the organization of the existing databases.

Other topics

The RD-Connect member responsible for the Ethics work package should be invited to join the WG.

Main deliverables

- ▶ Provide a summary on the possibilities for the parliament to vote on regarding a research exemption for the EU directive
- ▶ Provide the Scientific Secretariat with sources of surveys, etc. for analysis and circulation to the WG
- ▶ Provide the Scientific Secretariat with the article to be published by the European Journal of Health Law mentioning rules for data sharing in 8 countries, once peer-reviewed, for circulation to the WG members
- ▶ Send a doodle to organize the next teleconference to be held beginning of November