

2020-05-19

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| <b>Date:</b>   | 19/05/20     | <b>Place:</b> | TC           |
| <b>Start:</b>  | 4.30 PM CEST | <b>End:</b>   | 5.30 PM CEST |
| <b>Topic:</b> 5th AREB TC  |              |               |              |
| <b>Participants:</b><br>FGB: Annalisa Landi, Viviana Giannuzzi<br>EJP RD coordination team: Yanis Mimouni<br>ECRIN: Marta del Álamo<br>RaDiCo: Sonia Gueguen<br>EATRIS: Ben Lydall<br>DLR: Ralph Schuster<br>EMBL -DTL PROJECTS- ELIXIR/ELIXIR-NL: Rob Hooff<br>ZonMw: Sonja van Weely<br>BBMRI: Michaela Th. Mayrhofer  |              |               |              |
| <b>Apologizes:</b><br><u>Mandatory participation:</u><br>➤ CVBF: Giovanni Migliaccio<br><br><u>Facultative participation:</u><br>➤ INSERM [Orpha]: Ana Rath<br>➤ EURORDIS: Virginie Bros-Facer<br>➤ REPRESENTATIVE OF THE ERN RESEARCH GROUP: Alberto M Pereira<br>➤ EATRIS: Anton Ussi<br>➤ AP-HP: Rima Nabbout<br>➤ DLR: Katarzyna Saedler, Michaela Fersh<br>➤ VUHSK: Biruté Tumiene<br>➤ UKL-HD: Franz Schaefer<br>➤ BBMRI: Petr Holub |              |               |              |

| TOPIC                                    | DISCUSSION AND DECISIONS   |
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| 1. First Periodic AREB report – CONTENTS | <p>V. Giannuzzi introduces the topic: Deliverable 4.2, the first AREB report and the deadline at M19 (July 2020).</p> <p>The idea is to prepare a detailed report on the activities performed by the AREB during the first year of the project, considering the period from July 2019 to June 2020. However, before starting the draft of the deliverable, V. Giannuzzi would like to know which is the opinion of the AREB members as well as the one of the EJP RD Coordination team on the structure and on the contents they would like to include. In particular, she asked AREB members how to differentiate this Deliverable as report of the activities from the technical report. Y. Mimouni says that that the deliverable will be part of the technical report and M. Del Alamo adds that the deliverable should be more detailed than the technical report and with more scientific content and relevant expertise. Any templates produced could be added as attachments. R. Hooff suggests to not exceed 30 pages in length. All agree.</p> <p>She reminds that AREB members have to update the list of key ethical and regulatory documents useful for consultation that was included in Deliverable 4.1.</p> <p>A first draft of the report will be circulated during the first week of June in order to retrieve preliminary comments and revisions from the AREB members.</p> |

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| <p>2. 2nd Annual AREB meeting – ORGANISATION AND CONTENTS</p>            | <p><input type="checkbox"/> @FBG to circulate the first draft of D4.2 by <u>June 8th</u></p> <p>A. Landi informs AREB members that FGB asked for Daria's advice on the second AREB meeting organisation. The proposal was to move the meeting in September and Daria suggested to leave the meeting in July (before or after the Policy Board and ExCom meeting) since some key project documents are expected to be ready in September (annual report, update on relevant ethical and regulatory aspects) and be reported during the General Assembly.</p> <p>Thus, the meeting will be held online in July and A. Landi asks Yanis if the AREB can choose the timeslot or if the coordination should assign us a dedicated time and room. A. Landi reminds that the meeting should last 2-3 hours and that it could be useful to let the Ethics Advisor participating in order to start with a brief presentation of her, to update her on the activities performed in the first year and to decide how to collaborate in the future.</p> <p><input type="checkbox"/> <b>Doodle to select a date for the 2nd annual AREB meeting "Online" (After Policy Board + ExCom meeting):</b> <a href="https://doodle.com/poll/nzxprxt6rh5nyz9y">https://doodle.com/poll/nzxprxt6rh5nyz9y</a><br/><b>Please answer before 30/05/2020</b></p> <p><input type="checkbox"/> @Yanis to schedule the AREB annual meeting</p>  |
| <p>3. EJP RD JTC 2019 projects: ethics monitoring – update</p>           | <p>A. Landi gives an update on the ethics monitoring of the JTCs 2019.</p> <p>Eight of the 9 JTCs, considered by the ethics assessors as proposals having urgent requirements to be addressed before the grant agreement/signature, required additional explanation and confirmation besides those already provided by the applicants to the Pillar 1 leaders, according to the AREB revisions and considerations.</p> <p>At the end of March 2020, A. Landi and V. Giannuzzi reached by email the ethics contact points of each of the 8 proposals with the AREB comments and through the email account dedicated to the monitoring of the JTCs (jtc-ethics-monitoring@ejprarediseases.org).</p> <p>To date, only 4 of the 9 proposals have the ethics requirements fully fulfilled at this stage.</p> <p>FGB is expecting the feedback from the other 5 proposals in order to finalise this preliminary check. The new deadline is the end of May 2020. No feedback received from two proposals: IDOLS-G and LQTS-NEXT. The other 3 proposals did not fulfil all the requirements yet (some approvals are still pending due to the COVID-19 situation).</p> <p>Moreover, A. Landi informs all that the <a href="#">Excel file</a> containing the <b>overview of the ethics monitoring process</b> is regularly updated by her in order to be consulted by people in the JTCs MS Teams channel.</p> <p>The last update is included in the column "Feedback provided to AREB comments." She asks R. Schuster how to proceed with the ones with no feedback received and when the ethics monitoring is expected again. R. Schuster asks A.Landi to provide him with a reminder by mail for the two projects IDOLS-G and LQTS-NEXT and that the next monitoring is expected during summer.</p> <p><input checked="" type="checkbox"/> @A.Landi to provide R.Schuster with a reminder on the two projects IDOLS-G and LQTS-NEXT</p> |
| <p>4. Pillar 2 Use Case on informed consent – update of the activity</p> | <p>A. Landi gives an update on the activity in which some AREB members are involved in (A. Landi, V. Giannuzzi, M. Del Alamo and M. Th. Mayrhofer).</p> <p>The group joined two teleconferences yet and the Pillar 2 Annual Retreat meeting while the third teleconference is expected to be held the last week of May.</p> <p>In particular, Esther van Enckevort and A. Landi gathered interests to work together and feedback on specific request from people working in the biobanks. The request for info was addressed to Mariapia Iermito, Maria del Carmen Sanchez Gonzalez and Michaela Th. Mayrhofer to investigate the current status of informed consent procedure in the involved biobanks and what they would like to change and how the Virtual Platform can help them in simplifying and improving consent related procedures.</p> <p>The parallel session on informed consent held during the Pillar 2 Annual Retreat focused</p>   |

more on technical aspects. The proposal is to update the existing ADA-M, developed by GA4GH, in version 2.0.

The involvement of patient representatives as well as people working in biobanks was deemed relevant, so these people have been asked to join the group.

The discussion in the parallel session on informed consent brought to different conclusions, among which the following:

- an online application integrated with the registry/biobank is preferred (easy to use),
- the use case will be piloted involving some biobanks and registries
- the inclusion of patient representatives in the group is relevant to investigate their perspectives.

**Volunteers in join the group are welcome and may contact A. Landi**

## 5. Various updates

### • **Ethics Advisor appointment**

- The hiring procedure is undergoing. **The Ethics Advisor will start her role in EJP RD on 01/06/2020.**

◦ **The Ethics Advisor is expecting to have a meeting with the AREB dedicated to the organisation of the collaborative work. This meeting should take place before the next AREB meeting on July 2020**

◦ **AREB can propose some availabilities in June 2020**

### • **ERN VASCERN REQUEST**

Operational work is ongoing on the VASCA registry (for Vascular Anomalies) with a focus on Common Data Element (CDE) data model that describes the set of common data elements and their interrelationships in a machine readable way with existing standard ontologies.

The model makes the data elements interoperable to enable federated queries and analysis across registries.

VASCERN has chosen to focus on the "CDE interoperability" and will introduce the results of other people's data consent work later.

A Hackathon is planned for 23&25/06/2020 on how ERNs can implement the CDE data model, with different EDC software providers participation, where the VASCA use case will be used.

Y. Mimouni asked Pillar 2 persons mainly involved with the current VASCERN registry development for more feedback on the sub-part on "data consent and control"

**Y. Mimouni to update on the "data consent and control" planned activity**

### • **Update on Data Transfer Agreement being generated for WP13 work**

- The "**Terms and Conditions for use of the EJP RD Work Package 13 Digital Research Environment (DRE)**" was prepared  
(by Jumamurat R. Bayjanov, Peter A. C. 't Hoen and revised by Lennart Johansson, Koen ten Hove, Franz Schaefer, Annalisa Landi, Petr Holub, Daria Julkowska, Barbara Sanavio, Yanis Mimouni, Irene Schlünder and Tamara Carapina).

- The EJP RD Operating Group (OG) validated the document (the OG trusted all the expertise put into contribution to develop this document).

◦ **This document lists the terms and conditions that apply to the use of the EJP RD Digital Research Environment (DRE) for the analysis of data belonging to the showcases selected for WP13.**

- The Host of the DRE is the anDREa consortium, hosting the GDPR-compliant, Microsoft Azure cloud based workspace (<https://www.andrea-consortium.org/about-andrea/>). It is a secure platform to work with pseudonymized research data

- This DRE is a temporary, secure compute environment / private 'cloud' for storage of data as well as tailored and de novo bioinformatics analysis in EJP RD WP13. It is controlled by the system administrators employed by the Tenant (who is the EJP

RD beneficiary Radboudumc, acting as a system administrator) and the Data Producer (they are the joint 'workspace owners')

- The EJP RD DRE workspace will cease to exist after the analysis in the EJP RD project has been finalized, that is at the latest two years after the end of the project

- Link to the document: [EJPRD Terms and Conditions of Access to DRE final](#)

- This document has to be signed by all EJP RD DRE workspace users and sent to the Tenant (Radboudumc) before access to the EJP RD DRE workspace is authorized.

- The document contains

- some key definitions,

- a reminder on the contractual basis that mentions that the data transfer agreement is signed by the Data Producer/Data Controller and the Tenant, the latter as representative for EJP RD authorised DRE users.

- The list of the terms and conditions

- The general research objectives defined for WP13 (see Annex 1) and the specific research objectives defined in the showcase descriptions.

- **Inclusion of a legal member among AREB members – survey**

- The survey was prepared and shared with the whole EJP RD consortium on 15/05/2020. It was prepared with the help of Yanis and shared following the approval of Daria and Juliane.

- The deadline is the end of May and we are seeking to include in the AREB a member with Legal Expertise. This member shall be part of the EJP RD Consortium.

- We also included additional information (on AREB Description & Operational work) in the first page of this survey.

- Up to date (19/05/2020 - 15:00 CET), two persons were proposed

- @All to suggest members of their institutions through the survey: [Legal Advisor proposal \(for EJP RD - AREB\)](#)**

- **GA4GH consultations:**

- A. Landi informs the AREB that Viviana, Eva Bermejo and her are participating in the REWS of the GA4GH and would like to share with the AREB important consultations to which they can contribute, if they wish.

- [Machine Readable Consent Clauses](#) DEADLINE: June 5th, 2020.

- Please submit your comments on the policies directly on the documents or by contacting [Adrian Thorogood](#).

- [Model Genomic Consent Clauses for Research](#) DEADLINE PASSED: May 12nd, 2020

- Please submit your comments on the policies directly on the documents or by contacting [Kristina Kekesi-Lafrance](#).

- [Ethics Review Recognition Policy](#) DEADLINE: May 22nd, 2020

- Note that this policy is open for comments with minor updates and will be on the agenda for consent approval.

- Please submit your comments on the policies directly on the documents or by contacting [Adrian Thorogood](#).

- @AREB members interested to provide contribution to the survey are welcome**