

Date:	29/11/19	Place:	TC
Start:	4.00 PM CEST	End:	5.00 PM CEST
Topic: 2 nd AREB TC			
Participants:			
<p>FGB: Annalisa Landi</p> <p>EJP RD coordination team: Yanis Mimouni</p> <p>BBMRI: Michaela Th. Mayrhofer, Petr Holub</p> <p>EMBL -DTL PROJECTS- ELIXIR/ELIXIR-NL: Rob Hooff</p> <p>ZonMw: Sonja van Weely</p> <p>EATRIS: Ben Lydall</p>			
Apologizes:			
<u>Mandatory participation:</u>			
<ul style="list-style-type: none"> ➤ FGB: Viviana Giannuzzi ➤ RaDiCo: Sonia Gueguen ➤ ECRIN: Marta del Alamo ➤ CVBF: Giovanni Migliaccio 			
<u>Facultative participation:</u>			
<ul style="list-style-type: none"> ➤ EJP RD coordination team: Daria Julkowska ➤ INSERM [Orpha]: Ana Rath ➤ AP-HP: Rima Nabbout ➤ DLR: Ralph Schuster ➤ EATRIS: Anton Ussi ➤ EURORDIS: Virginie Bros-Facer ➤ REPRESENTATIVE OF THE ERN RESEARCH GROUP: Alberto M Pereira ➤ UKL-HD: Franz Schaefer ➤ VUHSK: Biruté Tumiene 			

TOPIC DISCUSSED	DISCUSSION AND DECISIONS
1. Ethics Advisors interviews	<p>A. Landi and Y. Mimouni gave an update on the interviews organised by the EJP RD coordination for the three shortlisted candidates who applied for the role of the EJP RD Ethics Advisor. Two candidates were identified, and their budget proposals were evaluated by the coordination.</p> <p><u>Post meeting update and decision:</u></p> <p>The financial resources needed to hire the best of the two candidates are equivalent to those needed for hiring the second one when considering the complementary expertise (including person-months</p>

	<p>additional allocation to AREB) that has to be sought in the latter case.</p> <p>A vote of the GA will be organized to finalize the decisions on the Ethic advisor recruitment and budget for Ethics activities (after sharing a document on the activities on Ethics that have to be run in the EJP RD based on the request on the EC and that were not initially planned in the work program/budget plan. Those Ethics activities concern the whole WP21 (15 deliverables on Ethics) and the recruitment of an Ethics Advisor.</p> <p>Action:</p> <ul style="list-style-type: none"> ➤ Coordination team to organise the vote of the GA to finalize the decisions on the Ethic advisor recruitment and budget for Ethics activities
<p>2. Meeting with the Ethics Advisor</p>	<p>A. Landi informed AREB members on the possibility to organise a meeting in person with the Ethics Advisor, once appointed, to be held in Brussels between January and February 2020.</p> <p>Action:</p> <ul style="list-style-type: none"> ➤ Coordination team to send a doodle poll to collect AREB members' preferences after the appointment of the Ethics Advisor
<p>3. Inclusion of a legal among AREB members</p>	<p>A. Landi notified AREB members on the future inclusion of a legal expert among them (besides the ones already part of the AREB) according to the suggestion of the candidates for the role of the Ethics Advisor. She added that it should be a member of the Consortium and asked TC participants to provide her and coordination team with suggestions on people that could be interested in taking on this role.</p> <p>Action:</p> <ul style="list-style-type: none"> ➤ All to provide FGB and Coordination team with names of possible candidates with legal expertise to be included in the AREB (by January 20th)
<p>4. Advancements, changes and news from the</p>	<p>A. Landi asked AREB members to provide her with any advancements, changes and news from the regulatory, ethical and legal framework in order to</p>

<p>regulatory, ethical and legal framework</p>	<p>share them with the Consortium. M. Th. Mayrhofer replied that she would give an update on a specific guideline next week. R. Hooft had no update. A. Landi informed them on the <i>Guidelines 3/2018 on the territorial scope of the GDPR (Article 3) Version 2.0</i> released in November 2019 after the public consultation. She reminded that all useful documents/links would be uploaded in a dedicated section on the EJP RD website. Y. Mimouni suggested to liaise with Eleonora Passeri for designing the AREB section (not implemented yet).</p> <p><u>Actions:</u></p> <ul style="list-style-type: none"> ➤ M. Th. Mayrhofer to update AREB members on the guideline ➤ AREB members to provide A. Landi with news from the regulatory, ethical and legal framework ➤ A. Landi to liaise with E. Passeri to create a dedicated section on the website
<p>6. KRIs</p>	<p>A. Landi showed the <i>Key Results Indicators</i> for WP4 activities as updated after the requests received from the coordination on behalf of Task 1.3 partners. She would like to share the draft with the AREB members to collect comments before sending it to the coordination. Y. Mimouni reminded that the final deadline would be December 10th.</p> <p>A. Landi and S. van Weely discussed the difficulties in understanding the information related to the indicators. S. van Weely clarified that the target/threshold (to represent the real-world completeness) are to be provided for the retrospective evaluation of the first year. Yanis added that these target/thresholds will be provided each year during the project and can be adapted and/or revised.</p> <p><u>Action:</u></p> <ul style="list-style-type: none"> ➤ A. Landi to share the file with AREB members to collect comments/suggestions and to send it to the coordination (by December 10th) <p><u>Post meeting information:</u></p> <p>The file was sent to the coordination.</p>

7. AOB

✓ **EJP RD JTC 2019 projects: Procedure for ethics monitoring**

S. van Weely introduced the topic on behalf of Ralph Schuster, the other Pillar 1 co-leader. They would inform the AREB on the recommendations received from the ethics experts performing the review (according to Horizon 2020 standards) of the projects recommended for funding. In particular, the experts recommended that all ethical concerns involved in the research projects funded under EJP RD JTC 2019 would be monitored by AREB and the external Ethics Advisor. She added that the 22 projects received conditional approvals and annual ethics reports would be sent to the AREB for review from March 2021.

M. Th. Mayrhofer asked if the duties of the Ethics Advisor were decided by Pillar 1 or by the European Commission. S. van Weely replied that it was decided by the European Commission.

Actions:

- **A. Landi to share the file sent by Ralph with AREB members**
- **S. van Weely and R. Schuster to update the AREB on this topic**

Post meeting information:

A teleconference will be scheduled in January to discuss the topic.

✓ **ERN VASCERN REQUEST**

A. Landi introduced the request coming from the ERN VASCERN to the EJP RD helpdesk and consisting of two parts: multinational registries and clinical studies. Considering that the same request was also submitted to the ECRIN helpdesk, A. Landi, M. del Alamo and the coordination team already agreed on leaving the support on clinical studies to ECRIN and asking AREB members support on the questions related to the multinational registries with particular reference to GDPR and informed consent issues.

Y. Mimouni clarified that VASCERN was already part of EJP RD beneficiaries, it applied to the call launched by the EC, outside from the scope of EJP RD, notwithstanding data transfer concerns. People from Pillar 2 were already involved in addressing the issues related to the FAIRification, interoperability

and to the metadata transfer, but VASCERN needed help/general recommendations from the AREB on the issue of data transfer. VASCERN is planning to make 5 registries for 5 different pathologies, gathering pseudonymized clinical data (using the tool provided by EU) from 11 countries. Ethical, regulatory and legal issues were raised by sending data from one country to another, and by addressing the necessary rules of the different involved countries for this regard. M. Th. Mayrhofer asked if data would be shared outside the EU. Y. Mimouni replied that data would be shared only within the EU.

Post meeting information:

Even if VASCERN has responded to a call that is independent from EJP RD, the coordination would like to consider helping them. Coordination suggests:

- For the technical part involving “the model of registry they plan to put in place (centralized/federated)” and “the pseudonymization tooling (provided by the EU RD Platform at JRC)” to liaise VASCERN with the contact persons of the pillar 2 Work Foci “use cases” and “interoperability for ERN registries”
- For the part on “data consent and control” to liaise VASCERN with both the aforementioned contact persons and the AREB
- Regarding the “legal arrangements”, since this call is independent from EJPRD and the AREB does not have yet a legal member, propose to work together with VASERN to identify the relevant persons at the JRC and the commission (and check if any legal support is provided by JRC as part of their offer to ERNs registries).

Annalisa agreed on following the above-mentioned suggestion.

Actions:

- **After agreement of Ana Rath (Pillar 2 co-leader), coordination will send through the EJP RD central helpdesk a reply to VASCERN coordinator implementing the actions described in the abovementioned suggestion**

➤ **A. Landi to liaise with AREB members for follow-up**

✓ **Update on Data Transfer Agreement being generated for WP13 work**

Yanis informed the AREB on a Data Transfer Agreement (DTA) that is being generated (and reviewed by Inserm-Transfert partner) to address the need of the task 13.2 in WP13. The DTA template provided as an attachment in the EJPRD Framework Consortium Agreement (FCA) was used. It was completed by Inserm-Toulouse (France), as data provider, and the EJPRD partner RUMC (PI Peter-Bram t'Hoen) as the Data recipient. A data transfer on the Embassy Cloud is planned.

P. Holub added a consideration on the Embassy Cloud to be used for the EJP RD activities that is an international organisation not in the EU jurisdiction. All agreed that GDPR compliance is mandatory for the processing of EU data. Y. Mimouni replied that the coordination is investigating the presence of any contract describing the provisions for the use of the Embassy Cloud.

The completed DTA with the necessary clarifications regarding the use of Embassy Cloud will be shared with the AREB members for comments.

Post meeting information:

A TC will be held on 09/01/2020 to discuss (subject to change):

- the use of the embassy cloud by Pillar2 (including WP13)
- the policy for sensitive data transfers into Embassy tenancies
- the data recipient designation

It will gather:

- The leaders of the task 11.3 (from EMBL-EBI) "*Data deposition and access to data infrastructures for RD research*"
- The leaders of the task 11.4 "*Provision of RD analysis and data sharing capabilities through online resources*"
- The current Embassy cloud tenant (Morris Swertz from UMCG) and the PI who will process the data (Peter-Bram t'Hoen from RUMC)

	<p>Action:</p> <ul style="list-style-type: none">➤ Y. Mimouni to share the DTA with AREB members to collect comments/suggestions
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