Date:	03/07/19	**Place:**	Brussels
Start:	9.00 AM CEST	**End:**	11.00 AM CEST

Topic: 1st AREB F2F MEETING

Invitees:

FGB: Viviana Giannuzzi, Annalisa Landi

INSERM: Daria Julkowska & EJP RD coordination team

AP-HP: Rima Nabbout, Bismpiki-Ganné Dimitra

BBMRI: Michaela Th. Mayrhofer

CVBF: Giovanni Migliaccio

DLR: Ralph Schuster, Sabrina Legies

EATRIS: Anton Ussi

ECRIN: Marta del Alamo

EMBL -DTL PROJECTS- ELIXIR/ELIXIR-NL: Rob Hooft

EURORDIS: Virginie Bros-Facer

FTELE: Stefano Benvenuti, Annamaria Merico, Barbara Sanavio

INSERM [Orpha]: Ana Rath

IOR: Luca Sangiorgi

RaDiCo: Sonia Gueguen, Daphné Jaoui

UKL-HD: Franz Schaefer

VUHSK: Laura Malinauskienė, Biruté Tumiene

ZonMw: Sonja van Weely

Participants:

FGB: Viviana Giannuzzi (TC), Annalisa Landi

INSERM: Daria Julkowska, Juliane Halftermeyer, Eleonora Passeri, Nguyen Catherine

AP-HP: Rima Nabbout

BBMRI: Michaela Th. Mayrhofer (TC)

CVBF: Giovanni Migliaccio

DLR: Ralph Schuster

ECRIN: Marta del Alamo

EMBL -DTL PROJECTS- ELIXIR/ELIXIR-NL: Rob Hooft

EURORDIS: Virginie Bros-Facer

INSERM [Orpha]: Ana Rath

VUHSK: Biruté Tumiene

ZonMw: Sonja van Weely

TOPIC DISCUSSED	DISCUSSION AND DECISIONS
1. AREB members and expertise	A. Landi started the discussion asking AREB members to introduce themselves. She reminded all that FGB will coordinate the AREB activities and that a mailing list "areb@ejprarediseases.org" has been set up by the coordination team to include AREB members (presentation annexed).
	A. Landi showed the declared expertise of AREB members as included in the draft of Deliverable 4.1 and classified according to the topics to be covered by the AREB.
	D. Julkowska asked clarifications on ECRIN expertise and A. Landi replied that ECRIN has been identified as part of AREB in the official GA. Accordingly, M. del Alamo (ECRIN) has been appointed as AREB member.
	M Th. Mayrhofer, representing BBMRI in the AREB, asked to add BBMRI expertise: informed consent and assent, personal data protection and privacy including secondary use, sharing and transfer and biosamples including secondary use, sharing and transfer.
	R. Hooft suggested to consider as topics to be covered by the AREB the Nagoya protocol issues and the personal data protection of researchers. A Landi replied that these topics deal with genetics and personal data protection and privacy issues already included in Deliverable 4.1.
	Finally, A. Rath suggested to foresee an interaction between AREB and **WP10 - User-driven strategic planning and transversal activities for Pillar 2 data ecosystem** on GDPR issues.
	Actions: • *To modify the Deliverable 4.1 accordingly (FGB)* • *To be in contact with Petr Holub (BBMRI)- Task 10.3 lead in order to discuss on how to collaborate on GDPR (FGB)*
2. AREB Operational work	A. Landi showed the key points of the operational work of the AREB including activities, queries management and timelines, the interaction with Ethics Advisor, WP21 activities and the operating group.
	With reference to the **activities**, according to the project, the AREB members are in charge of revising the ethical and regulatory aspects of documents and deliverables upon request by WP/Task Leaders;

managing queries on ethical and regulatory issues from WP/Task Leaders; joining 2-monthly teleconferences and annual face to-face meetings; preparing annual periodical reports.

B. Tumiene asked if the AREB will be in charge of managing only the requests coming from project partners. Rima Nabbout replied that, of course, the AREB will only handle requests concerning the project and the activity should not be considered like a helpdesk activity. All agreed.

All relevant documents and information will be made available and regularly updated on the project website.

A. Rath asked if AREB will be in charge of drafting guidelines to cover all the project activities. V. Giannuzzi replied that, according to the project, it is not expected that the AREB will produce guidelines or documentation other than the annual reports. D. Julkowska added that any drafting of guidelines will be under the responsibility of the Ethics Advisor and the AREB contribution will be expected.

G. Migliaccio asked information on the AREB activity concerning the update of documents/ regulations. D. Julkowska replied that the AREB is in charge of updating partners on the ethical and regulatory news during the annual meetings. A. Landi added that AREB members will also provide update in AREB annual reports. V. Giannuzzi underlined that AREB should timely update (through the newsletters, the website, etc.) project partners on important changes that could be applied to the research.

Queries management and timelines

A. Landi explained FGB proposal regarding the management of queries and provided the example of S. van Weely's request on the need for ethical evaluation in WP7 calls. FGB proposed that all the questions could be communicated to areb@ejprarediseases.org (that includes all AREB members) and according to the issue (consent, data protection, secondary uses, sharing and transfer, etc), AREB members declaring expertise in the field, should provide a feedback to FGB and other AREB members by 1 week. Finally, FGB should forward the agreed feedback to questions copying areb@ejprarediseases.org.

AREB members should be made aware of the requests and members declaring expertise on the topic under discussion should be able to reply to the request.

AREB members considered email messages not suitable to manage queries and proposed to set up a simple online tool. In fact, an online system should be able to track the questions and answers process. Furthermore, this tool would allow to assign the request to one AREB member while the other members would be "observers".

All requests should be managed according to the level of complexity. Simple questions may be addressed to one AREB member. All agreed that FGB will be in charge of assigning the request according to the expertise declared.

B. Tumiene added to also take into account the nationality of the requestor when assigning the request to a specific AREB member, given the national nature of many ethical issues.

With regards to the *timelines*, all the participants agreed that one week is ambitious and that the request should be classified according to the level of complexity (e.g. 1 week for simple questions, 3 weeks for complex issues). Ad hoc TCs should be foreseen for the most difficult requests.

G. Migliaccio proposed to draft an operational flowchart on the queries management process declaring the timelines, the people in charge and the classification of the issues. All agreed and V. Giannuzzi proposed to include the flowchart in D4.1.

Considering that the timeline for answering the requests will be a performance indicator of the project, an online tool would result also useful to measure the performances related with AREB activities.

V. Giannuzzi asked if D1.18 on key performance indicators could be amended according to the decision taken on the AREB activities and timelines. G. Migliaccio replied that the deliverable will be amended according to the agreed decisions on this process.

M. del Alamo explained that ECRIN has developed a tool called CAMPUS, a database that includes country-specific information on regulatory and ethical requirements in clinical research across Europe, that could be used for the project. G. Migliaccio replied that it would be useful to share the link with the project partners.

A. Landi suggested to include all the useful links and documents in the section of the project websites dedicated to AREB activities. V. Giannuzzi added that AREB members can start sharing documents listed in D4.1. She also proposed to draft a FAQ list in the database containing the uncovered issues and remembered the AREB members on the possible interaction with the EMA.

Actions:

- *To develop a tool for the management of requests (INSERM)*
- *To define the queries management process and to prepare an operational flowchart to be included in D4.1 (FGB to propose it and all AREB to agree)*
- *To provide project partners with regulatory and ethical updates during the whole project duration (AREB members)*

Operating group

A. Landi asked members of the operating group collaborating with the AREB, to introduce themselves. They will inform the AREB about what is going on in the project and therefore create a link between the AREB and the project activities to ensure that the AREB is properly and timely informed on what is going on in every pillar, including possible ethical and regulatory issues arisen by EJP RD partners.

A. Landi asked if the operating group should use the same online tool to address ethical and regulatory queries or the above mentioned AREB email address. D. Julkowska replied that the same system should be used but members of the operating groups can also ask queries during project TCs and meetings.

V. Bros-Facer asked if the operating group should join all the AREB TCs and meetings. While D. Julkowska considered useful their participation in all the AREB activities, R. Nabbout proposed the group to join the TCs based on the topics in the agenda. D. Julkowska concluded that AREB TCs and meetings should be mandatory only for the AREB members and facultative for the operating group. All agreed.

A. Landi added that each member of the operating group could ask in advance to include topics to be discussed in the agendas of forthcoming TCs/meetings

	and therefore should participate depending on the topics included. A calendar with specific dates of AREB TCs has not been decided yet. **Action:** • *To ask FGB for including specific topics to be discussed in TCs and meetings agendas (Operating group)*
3. AREB forthcoming Milestones & Deliverables	A. Landi introduced the topic of forthcoming milestones and deliverables. V. Giannuzzi specified that we have not received the CV from Sonia Gueguen yet. D. Julkowska asked if RaDiCo has contributed to WP4 activities and V. Giannuzzi replied that we have not received any input from them. D. Julkowska continued that she will ask them if they want to be part of the AREB and then communicate the decision to the AREB members. G. Migliaccio asked for clarification on the AREB member nomination procedure and on a form of recognition. V. Giannuzzi replied that all the EJP partners involved in WP4 indicated a member to be included in the AREB according to their expertise. D. Julkowska confirmed that, according to the project, AREB members are partners of the project while the Ethics advisor is external. V. Giannuzzi concluded that the AREB members nomination procedure together with the duration of the role will be included in D4.1 **Actions:** • *To provide AREB members with a feedback on RaDiCo's involvement in the AREB (INSERM)* • *AREB members nomination process to be included in D4.1 (FGB)*

4. Interaction with ethics advisor – wp21 activities	A. Landi introduced the activities to be performed by the Ethics Advisor according to the project: advising on and monitoring ethical/legal/regulatory issues of the EJP RD (including the Data Management Plan and the projects funded within EJP RD) to ensure that the ethics management of the projects are carried out within the H2020 framework, supervising AREB actions and participating in AREB meetings and TCs. In particular, the AREB will forward to the Ethics Advisor any document or report produced by AREB. The Ethics Advisor has not been appointed. With reference to WP21 activities and according to the project, WP21 will provide general guidance on Directive 2010/63/EU (welfare of animals) and details on procedures and criteria used to identify/recruit research participants, informed consent & templates, processing personal data, authorisations for personal data processing. V. Giannuzzi added that it is not foreseen that the AREB should provide guidance or templates but they should be provided by WP21. A. Landi underlined that the involvement of the AREB in WP21 activities has not been clarified. G. Migliaccio asked how many hours should be dedicated to WP21 activities. D. Julkowska replied that there are fixed deliverables imposed by the European Commission under the responsibility of INSERM and will be prepared by the Ethics Advisor. There is not additional budget for AREB members if performing WP21 activities. However, the help from the AREB would be useful. G. Migliaccio suggested to consider the AREB only for the final approval of the documentation/guidelines set up within WP21. **<u>Action:</u>** • *To inform AREB members on the appointment of the Ethics Advisor (INSERM)*
5. AOB & uncovered issues	A. Landi concluded that the coordination team should provide EJP partners with the AREB email address and inform EJP partners on the decisions taken during the AREB meetings (queries management and requests for support) while FGB will draft meeting minutes and finalise D4.1.

	D. Julkowska confirmed that the decision taken will be disseminated to the project partners after the finalisation of the procedures.
	R. Schuster updated the AREB members on the topic that he had already discussed during the first WP4 TC when asked AREB members to provide him with suggestions of ethical experts to review joint transnational projects funded within Pillar 1 from the ethical points of view. FTELE provided some names.
	R. Schuster underlined that the AREB is not allowed to review the proposal, and he wanted to ask advice for experts outside the project.
	Action: • *To provide EJP partners with the AREB email address and with the queries management procedure when finalized (INSERM)* • *To draft meeting minutes and finalise D4.1 (FGB)* • *To provide R. Schuster with contacts of possible experts to perform the ethical evaluation of projects funded within Pillar 1 (ALL)*