Date:	10/09/19	Place:	TC
Start:	3.00 PM CEST	End:	5.00 PM CEST

Topic: 1st AREB TC

Participants:

FGB: Annalisa Landi

EJP RD coordination team: Yanis Mimouni & Nadia Ibellaatti

CVBF: Giovanni Migliaccio

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

EATRIS: Ben Lydall

Apologizes:

Mandatory participation:

- ➤ FGB: Viviana Giannuzzi
- ➤ BBMRI: Michaela Th. Mayrhofer
- ➤ RaDiCo: Sonia Gueguen
- ➤ ECRIN: Marta del Alamo

Facultative participation:

- ➤ EJP RD coordination team: Daria Julkowska
- ➤ INSERM [Orpha]: Ana Rath
- ➤ AP-HP: Rima Nabbout
- ➤ DLR: Ralph Schuster
- ➤ EATRIS: Anton Ussi
- ➤ EURORDIS: Virginie Bros-Facer
- ➤ ZonMw: Sonja van Weely
- ➤ IOR: Luca Sangiorgi
- ➤ UKL-HD: Franz Schaefer
- ➤ VUHSK: Biruté Tumiene

TOPIC DISCUSSED	DISCUSSION AND DECISIONS
1. Ethics Advisor appointment	A. Landi asked Y. Mimouni news on the appointment of the Ethics Advisor. Y. Mimouni replied that many applications (CVs and motivation letters) have been received but the interviews to appoint the Ethics Advisor would be organised after the meeting in Gdansk. **Action:** ➤ **Coordination team to provide FGB and AREB members with the update on this topic by the end of October**

2. AREB requests management process	A. Landi showed the AREB request management process included in *D4.1 – First AREB report* and asked for additional comments and suggestions. R. Hooft and G. Migliaccio replied that they had no additional comments. R Hooft added that the process could be made public if all AREB members agree.
	A. Landi summarised the discussion that AREB members had during the AREB meeting in July on the implementation of an online tool for internal use (different from the existing helpdesk). She asked Y. Mimouni news on the online tool to be developed by coordination team to collect requests addressed to the AREB from the consortium. He replied that he would ask Juliane an update on the progress of the online system and, in the case of no progress, coordination team would plan to put the system in place quickly (within the year).
	In the meantime, Y. Mimouni suggested all the requests for AREB members would have been addressed to the existing helpdesk and forwarded by Juliane to A. Landi, the main contact of the AREB in charge of sharing the request with the other AREB members, until the online system would be implemented.
	Moreover, he suggested A. Landi submitting the deliverable and including additional details of the online tool in an update version of the deliverable. All agreed.
	Action: ➢ **Y. Mimouni to check with Juliane the progress of the online system to be developed for the AREB request management process and to provide FGB with an expected date for the implementation of the system** ➢ **A. Landi to describe the temporary AREB requests management process in the D4.1 and in the WP4 presentation** **POST NOTE TC: Additional details of the online system will be included in D4.2 – Second AREB report**
3. Finalisation of D4.1 - First AREB report	A. Landi informed AREB members that she would try to submit the Deliverable 4.1 before the meeting in Gdansk. No further comments on the Deliverable from AREB members in the teleconference.
	She asked Y. Mimouni if Sonia Gueguen could have been considered member of the AREB. Y. He replied that he would have been in contact with Daphnè

	JAOUI to provide A. Landi with a feedback. **Action:** ➢ **A. Landi to submit Deliverable 4.1** ➢ **Y. Mimouni to ask information on Sonia to Daphnè** **POST NOTE TC: Feedback received from Daphnè. Sonia provided A. Landi with her CV to be considered AREB member**
4. AREB presentation during the GA in Gdansk	A. Landi showed the first draft of the WP4 presentation she prepared for the meeting in Gdansk. She asked AREB members participating in the teleconference if they would like to share the presentation with her and Stefano Benvenuti. G. Migliaccio e R. Hooft replied that A. Landi would be welcome to present the slides on their behalf. Y. Mimouni asked if the update on regulatory, ethical and legal advancements have been included in the presentation as for Daria's suggestion during WP0-WP5 TC held in September. A. Landi replied that she included the update with focuses on particular topics (such as GDPR and new clinical trial regulation). G. Migliaccio and R. Hooft suggested her reducing the amount of information included for each topic and presenting a general overview of the regulatory and ethical landscape without entering details. R. Hooft proposed A. Landi providing a general regulatory and ethical landscape by referring to the responsibilities of people in the audience (e.g. PIs, researchers). G. Migliaccio recommended focusing more on the AREB request process and on how consortium members could consult the applicable laws and guideline for each topic. Y. Mimouni asked A. Landi if the revision of the orphan drug regulation would be presented by WP4. A. Landi confirmed that Stefano would continue the presentation introducing this topic. Finally, all agreed on the inclusion of an example of the AREB management process in the presentation to inform the community on the process (e.g. last request on GDPR issues). **Actions:** ➢ **A. Landi to ask all AREB members if they want to**

	share the presentation with her and Stefano during the GA ➢ **A. Landi to review the presentation according to the suggestions she received during the teleconference and to agree them with Stefano**
5. List of documents to be presented during the GA	A. Landi asked all to provide her with additional documents to be presented during the GA to inform on the advancements, changes and news from the regulatory, ethical and legal framework besides those she already included in *Deliverable 4.1* and in the WP4 draft presentation. **Action:** ➢ **All to provide A. Landi with missing documents to be included in D4.1 and in WP4 presentation (if any)**
6. KRIs	A. Landi showed the *Key results indicators* for WP4 she prepared with Stefano and sent to the coordination team. She added that the document would be finalised after the validation of the AREB request management process. Y. Mimouni commented that WP3 was encountering difficulties in reviewing KRIs sent from the different WP leaders because often KRIs were confused with KPIs. G. Migliaccio commented that WP4 KRIs seemed more KPIs and suggested A. Landi considering as KRIs milestones reached and documents submitted. Y. Mimouni informed them that a short discussion on KRIs would be held in Gdansk. All agreed that the file would have been reviewed and re-submitted after the meeting. **Action:** ➢ **A. Landi to share the file with AREB members to collect comments/suggestions and to review the file after the meeting in Gdansk**