



1st AREB F2F MEETING

Brussels, 3 July 2019

AGENDA

-  AREB members
-  AREB Operational work
-  AREB forthcoming Milestones & Deliverables
-  AOB & uncovered issues

AREB members

-  **Marta del Alamo** (ECRIN)
-  **Viviana Giannuzzi** (FGB)
-  **Michaela Th. Mayrhofer** (BBMRI)
-  **Rob Hooft** (EMBL-DTL PROJECTS-ELIXIR/ELIXIR-NL)
-  **Giovanni Migliaccio** (CVBF)
-  **Sonia Gueguen** (RaDiCo-Inserm)

areb@ejprarediseases.org

FGB will coordinate AREB activities!

AREB expertise

REGULATORY/ETHICAL ISSUE	EXPERTISE COVERED
informed consent and assent	FGB; ECRIN; RaDiCo; CVBF
personal data protection and privacy including secondary use, sharing and transfer	ELIXIR; FGB; RaDiCo
biosamples including secondary use, sharing and transfer	FGB; ECRIN
paediatrics	FGB
clinical trials	ECRIN; CVBF; FGB; RaDiCo
clinical studies	FGB; ECRIN; RaDiCo; CVBF
animal welfare	CVBF
genetics, use of ATMPs	CVBF; FGB
regulatory procedures (biomarker qualification, ODD, ATMPs, PIP, etc)	FGB; RaDiCo; CVBF

Operating group members collaborating with AREB

-  Daria Julkowska (INSERM)
-  Rima Nababout (AP-HP)
-  Ralph Schuster (DLR)
-  Anton Ussi (EATRIS)
-  Virginie Bros-Facer (EURORDIS)
-  Luca Sangiorgi (IOR)
-  Franz Schaefer (UKL-HD)
-  Biruté Tumiene (VUHRSK)
-  Sonja van Weely (ZonMw)
-  Ana Rath (INSERM-Orpha)

Operational work of the AREB

ACTIVITIES

TIMELINES

INTERACTION WITH
ETHICS ADVISOR –
WP21 ACTIVITIES

QUERIES
MANAGEMENT

INTERACTION WITH
THE OPERATING
GROUP

Operational work of the AREB

ACTIVITIES

- ✿ Revision of documents and deliverables with reference to ethical and regulatory aspects upon request by WP/Task Leaders
- ✿ Management of queries on ethical and regulatory issues from WP/Task Leaders

AREB activities, all relevant documents and information will be made available and regularly updated on the project website!

Operational work of the AREB

ACTIVITIES

- 🌐 2-monthly teleconferences
- 🌐 annual face to-face meetings
- 🌐 annual periodical reports



Operational work of the AREB

How to manage requests from EJP partners?

QUERIES
MANAGEMENT

PROPOSAL

- 🌟 Questions communicated to areb@ejprarediseases.org
- 🌟 According to the issue (consent, data protection, secondary uses, sharing and transfer, paediatrics, clinical trials, clinical studies, animal welfare, genetics, ATMPs, regulatory procedures, etc), AREB members declaring expertise in the field in charge of discussing and providing a feedback to FGB and other AREB members by 1 week
- 🌟 FGB to forward the agreed feedback to questions copying areb@ejprarediseases.org

Operational work of the AREB

QUERIES
MANAGEMENT

Example:

- Request from Sonja van Weely on the need for ethical evaluation in WP7 calls on 28 June 2019 ⇒ *to be sent to areb@ejprarediseases.org*
- ELIXIR, FGB, RaDiCo: AREB members declaring expertise on data protection ⇒ discuss and agree on the feedback
- FGB to forward the feedback by 1 week copying EA

Operational work of the AREB

The AREB will strictly collaborate with the operating group by creating a well-established link between the AREB and the Pillars 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

INTERACTION WITH
THE OPERATING
GROUP

PROPOSAL

The operating group will

- 🌟 be invited to join AREB TCs and meetings
- 🌟 inform the AREB of any ethical and regulatory issue arising in the project emailing to areb@ejprarediseases.org

Operational work of the AREB

The Ethics Advisor

- is in charge of 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
- supervises AREB actions
- participates in AREB meetings and TCs

INTERACTION WITH
ETHICS ADVISOR –
WP21 ACTIVITIES

PROPOSAL

AREB will

- forward to the EA any document or report produced by AREB
- copy EA while providing feedback to the EJP partner on the arisen issues

Operational work of the AREB

WP21 to provide:

- 🌈 general guidance on Directive 2010/63/EU (welfare of animals)
- 🌈 Details on procedures and criteria used to identify/recruit research participants, informed consent & templates, processing personal data, authorisations for personal data processing

INTERACTION WITH
ETHICS ADVISOR –
WP21 ACTIVITIES

*Which
involvement of
AREB in WP21
activities?*



Forthcoming MILESTONES & DELIVERABLES

MILESTONES

- 🌟 **MS10** - 1st Annual AREB meeting held (M6) ✓
- 🌟 **MS11** - 2nd Annual AREB meeting held (M18 – June 2019)

DELIVERABLES

- 🌟 **D4.1** First AREB report (M6) ✓
- 🌟 **D4.2** First Periodic AREB report (M19)

Sonia Gueguen
CV missing!



CONCLUSION & DECISIONS TO ISSUE

- *Coordination team to provide EJP partners with the AREB email address to forward specific ethical and regulatory queries*
- *Coordination team to inform EJP partners on the decisions taken during the AREB meetings (queries management and requests for support)*
- *FGB to draft meeting minutes and finalise D4.1*

.....**TO BE CONTINUED!**

AOB & uncovered issues

- 🌍 R. Schuster: Ethics review procedure for the first call for proposals JTC 2019 (AREB members cannot act as ethics reviewers)
- 🌍 Any other?