PRECLINICAL DATA FORUM / EQIPD

Training Workshop "How to Make Preclinical Research Robust"

Online version

Customized for projects where EQIPD provides support to research teams in a package including:

- A series of training seminars (i.e., the workshop below)
- Review of current practices and improvement recommendations
- Support in developing rigorous study plans

January 18-25, 2020

IMI PainCare

Zoom videoconference and dial-in details:

Sent by Dr. Paulina Nunez-Badinez (Bayer)

Lecturers / moderators:

Dr. Thomas Steckler (Janssen Pharmaceutica)
Dr. Kim Wever (Radboud University)
Prof. Malcolm Macleod (Edinburgh University)
Prof. Martin Michel (Mainz University / PAASP Heidelberg)
Anton Bespalov (PAASP Heidelberg)

IMPORTANT NOTE TO ALL PARTICIPANTS:

- All presentations (but not the discussions) will be recorded and may later be made publicly available via the websites of EQIPD and/or Preclinical Data Forum
- Please be advised that if you raise a question ***during*** the presentation, it will be recorded
- During the presentations, all participants other than the speaker are asked to mute the microphones and to switch off the cameras.

DAY 1 – January 18, 2021 (Monday) - Why are we talking about research rigor?

Time	Topic	Lecturer/ Discussant
Pre-read	- Ioannidis 2005 - Nuzzo 2015 - SYRCLE RoB tool - Currie et al 2019 - Macleod et al 2020	
09.00 – 09.15	Introductions, Agenda, Workshop objectives	AB
09.15 – 10.00	Evidence for lacking rigor in research - Meta-research - PPV and the Ioannidis paper - Surveys of current practices - "Reproducibility" discussion	TS
10.00 – 10.20	Origins of lacking rigor in research - Competition; Pressure to publish; Lack of tolerance to negative data; Risks of bias; Lack of training; Dichotomous decision making *(one-question poll on which of the above is the most relevant for the students)*[1]	TS
10.20 – 10.40	Impact of lacking rigor in research - Ethics (incl. RAW), Patients, Reputation of individual scientists, Monetary (society, funders, scientists), IP - Boundary between GRP and RI	TS
10.40 – 11.05	Open discussion: Who is in the greatest need of higher research quality standards – industry, academia, CROs, young scientists or mature researchers? (i.e., who should not wait until tomorrow)	AB
11.05 – 11.10	Homework: Ask to find whether student's institution has a RI policy and whether it covers "questionable research practices" such as those in ALLEA (no feedback expected)	AB
11.10 – 11.25	Coffee break & Networking[2]	
11.25 – 12.10	Systematic Reviews: a tool to identify factors important for research quality	KW
12.10 - 12.55	Identifying sources of bias, and assessing internal validity and risks of bias in primary studies (using SYRCLE's risk of bias tool)	KW
12.55 – 13.00	Challenge Question[3]	AB

[1] to be administered in such a way that the speaker does not get distracted and the results are shared with the audience at the end

[2] at least one course instructor stays online to answer questions or facilitate the discussion during the breaks

[3] These are questions that participants are asked to think about and will be discussed during the next session

DAY 2 – January 20, 2021 (Wednesday) - What do we need to do to enhance research rigor?
(Part 1 – Rigor in study design)

Time	Topic	Lecturer/ Discussant
Pre-read	- Dirnagl 2020 - Bert et al 2019 - Lefevre and Balice-Gordon 2020	
9.00 – 9.15	Feedback & discussion on the Challenge Question from the last session	MMich
9.15 – 10.00	Knowledge-claiming research: What this is? - Exploratory vs confirmatory - Hypothesis-generating vs hypothesis testing - Decision support / enablement - Lessons learned from EBM - Attributes of knowledge-claiming research (*must* and *should*) - Factors that prevent implementation of maximal possible rigor *(one-question poll on which factors and conditions are the most interfering with application of greater rigor)*	MMich
10.00 – 10.15	Open discussion: Should these standards apply to in vitro research? To the same extent as to in vivo?	MMich
10.15 - 10.45	Pre-specification - Researcher's degrees of freedom - Inclusion & exclusion criteria - Preregistration	AB
10.45 – 11.00	Open discussion: Use of lab journals – what they are and why are they important?	AB
11.00 – 11.15	Coffee break & Networking	
11.15 – 12.00	Blinding & randomization - Practical aspects - Challenges and exceptions	AB
12.00 – 12.15	Open discussion: When and how can the research rigor measures be harmful?	AB
12.15 – 13.00	Concept of statistical power - Prevalence of underpowered studies - Why power is important - When power becomes critical - Biological vs experimental units, technical vs biological replicates	MMich
12.55 – 13.00	Challenge Question	MMich

DAY 3 – January 22, 2021 (Friday) - **What** do we need to do to enhance research rigor?
(Part 2 – Data integrity and analysis)

Time	Topic	Lecturer/ Discussant
Pre-read	- Motulsky 2014	
9.00 – 9.15	Feedback & discussion on the Challenge Question from the last session	MMich
9.15 – 9.45	Effect size estimation: - Practical aspects (do's and donot's)	MMich
9.45 – 10.00	Open discussion: How do you deal with effect size estimation if no prior studies, if physiological or therapeutic relevance of any specific effect size is not known?	MMich
10.00 – 11.00	From pre-specified endpoints to data analysis: Common mistakes and how this affects data robustness	MMich
11.00 - 11.15	Coffee break & Networking	
11.15 – 11.30	Open discussion: Why do we need to keep raw data?	MMich
11.30 – 12.20	Data integrity - Raw data - ALCOA principles - FAIR	MMich
12.20 – 12.55	Hands-on (interactive discussion): - How to set-up unique study IDs? - How to trace back published data to raw data? - How to archive data?	AB
12.55 – 13.00	Challenge Question	AB

DAY 4 – January 25, 2021 (Monday) - How do we introduce the changes needed to enhance research rigor?

Time	Topic	Lecturer/ Discussant
Pre-read	ARRIVE 2.0 guidelines with explanations (separate file) Videos introducing EQIPD Quality System: Why (Part 1), What (Part 2), and How (Part 3)	
9.00 – 9.15	Feedback & discussion on the Challenge Question from the last session	TS
9.15 – 9.45	Publication standards: - ARRIVE guidelines - Minimum information reporting standards *(one-question poll "have you heard about ARRIVE?")*	TS
9.45 – 10.30	Publication standards: - Presenting data in publications (bar graphs, approaches to inference, etc.)	MMacL
10.30 – 10.45	Open discussion: What if the editor or reviewers request data to be presented in a "conventional way"?	MMacL
10.45 – 11.15	Negative results: What are they and what do we do with them? *(two-question poll about publishing of negative results)*	TS
11.15 – 11.30	Coffee break & Networking	
11.30– 12.00	EQIPD Quality System (assuming that everyone watched the videos and basics do not need to be re-introduced) - Introduction using a series of examples - Implementation options	AB
12.00 – 12.15	Open discussion: Why quality matters for you (referring to the EQIPD slide deck)?	AB
12.15 – 12.30	Closing remarks / discussion	AB