PRECLINICAL DATA FORUM / EQIPD
Training Workshop "How to Make Preclinical Research Robust"

Outline

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

This training is held as a videoconference over four days, other formats possible

EQIPD volume on Good Research Practice in Non-Clinical Pharmacology and Biomedicine (all chapters in open access):
https://link.springer.com/book/10.1007/978-3-030-33656-1

AGENDA FOR THE INITIAL TRAINING

DAY 1 – Why are we talking about research rigor?

Time	Topic
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
09.15 – 10.00	Evidence for lacking rigor in research - Meta-research - PPV and the Ioannidis paper - Surveys of current practices - "Reproducibility" discussion
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]
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
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)
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)
11.10 – 11.25	Coffee break & Networking[2]
11.25 – 12.10	Systematic Reviews: a tool to identify factors important for research quality
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)
12.55 – 13.00	Challenge Question[3]

DAY 2 – What do we need to do to enhance research rigor? (Part 1 – Rigor in study design)

Time	Topic
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
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)*
10.00 – 10.15	Open discussion: Should these standards apply to in vitro research? To the same extent as to in vivo?
10.15 - 10.45	Pre-specification

[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

	- Researcher's degrees of freedom - Inclusion & exclusion criteria - Preregistration
10.45 – 11.00	Open discussion: Use of lab journals – what they are and why are they important?
11.00 – 11.15	Coffee break & Networking
11.15 – 12.00	Blinding & randomization - Practical aspects - Challenges and exceptions
12.00 – 12.15	Open discussion: When and how can the research rigor measures be harmful?
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
12.55 – 13.00	Challenge Question

DAY 3 – What do we need to do to enhance research rigor? (Part 2 – Data integrity and analysis)

Time	Topic
Pre-read	- Motulsky 2014
9.00 – 9.15	Feedback & discussion on the Challenge Question from the last session
9.15 – 9.45	Effect size estimation: - Practical aspects (do's and donot's)
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?
10.00 – 11.00	From pre-specified endpoints to data analysis: Common mistakes and how this affects data robustness
11.00 - 11.15	Coffee break & Networking
11.15 – 11.30	Open discussion: Why do we need to keep raw data?
11.30 – 12.10	Data integrity - Raw data - ALCOA principles - FAIR
12.10 – 12.25	Hands-on (interactive discussion): - How to set-up unique study IDs? - How to trace back published data to raw data? - How to archive data?
12.25 – 12.35	Open discussion: Why quality matters for you (referring to the EQIPD slide deck)?
12.35 – 12.40	Challenge Question

DAY 4 – How do we introduce the changes needed to enhance research rigor?

Time	Topic
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 – 9.20	Impact of lacking rigor in research - Ethics (incl. RAW), Patients, Reputation of individual scientists, Monetary (society, funders, scientists), IP - Boundary between GRP and RI
9.20 – 9.35	Feedback & discussion on the Challenge Question from the last session
9.35 – 10.05	Publication standards: - ARRIVE guidelines - Minimum information reporting standards *(one-question poll "have you heard about ARRIVE?")*
10.05 – 10.50	Publication standards: - Presenting data in publications (bar graphs, approaches to inference, etc.)
10.50 – 11.05	Open discussion: What if the editor or reviewers request data to be presented in a "conventional way"?
11.05 – 11.35	Negative results: What are they and what do we do with them? *(two-question poll about publishing of negative results)*
11.35 – 11.50	Coffee break & Networking
11.50– 12.20	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
12.20 – 12.30	Closing remarks / discussion