EQIPD Summer School 2018 – draft program

Dates: September 10-14, 2018

@Radboud university medical center, Nijmegen, The Netherlands

Lecturers: Kim Wever, Thomas Steckler, Malcolm Macleod, Martin Michel, Anton Bespalov, Martien Kas, Lee Monk, Judith van Luijk

Day 1 (Monday September 10th) **EQIPD: Why are we here? (i.e. why do we need to address preclinical data quality?)**			
Time	Duration	Topic	Lecturer
9:00	15	Welcome, summer school objectives, program preview	Kim Wever
9:15	45	Introduction of participants and lecturers: Who are you? Why did you join this summer school? What have been your successes and challenges so far? What do you hope to learn?	Everyone
10:00	60	Lecture: "Origins of poor data robustness" • Robustness versus reproducibility • Poorly designed and powered studies • Positive predictive value • Poor control over experimental conditions • Poor generalizability of research findings	Thomas Steckler
11:00	*30*	*Break*	-
11:30	60	Lecture: rigor in preclinical research	Malcolm Macleod
12:30	30	Discussion: Stakeholders in research rigor: who is in the greatest need of higher research quality standards? E.g. industry, academia or CROs? Young scientists or mature researchers?	Thomas Steckler / Malcolm Macleod (/ Lee Monk)
13:00	*60*	*Lunch*	
14:00	60	Lecture: From pre-specified endpoints to data analysis: Common mistakes and how this affects data robustness	Martin Michel
15:00	60	Journal Club preparation: Study examples of papers illustrating the need for higher standards in research rigor #1: Paper with exploratory research where a confirmatory study design standards would be more appropriate #2: Paper with a data analysis example #3: Paper illustrating pre-specified endpoints	Martien Kas
16:00	*15*	*Break (flexible, during JC preparation)*	
16:15	30	Journal club: discuss our findings and possible solutions	Martien Kas
16:45 - 17:00	15	Closing remarks	Martien Kas
18:00		*Dinner*	

Day 2 (Tuesday September 11th) **Improving robustness of animal studies: design and execution**			
Time	**Duration**	**Topic**	**Lecturer**
9:00	30	Lecture and discussion: Exploratory versus confirmatory research, the importance of preregistration (e.g. to prevent HARKing)	Anton Bespalov

9:30	45	Lecture: Bias in primary research: what is it and how do we prevent it? Bias versus heterogeneity versus confounding Major types of bias part 1: Selection bias, performance bias, and detection bias	Kim Wever / Judith van Luijk
10:15	30	Practical: Formulating bias domains and measures to reduce the risk of selection bias, performance bias, and detection bias	Kim Wever / Judith van Luijk
10:45	*30*	*Break*	
11:15	25	Interactive discussion of practical session 3	Kim Wever / Judith van Luijk
11:40	20	Lecture: Major types of bias part 2: attrition bias and reporting bias	Kim Wever / Judith van Luijk
12:00	15	Practical: Formulating bias domains and measures to reduce the risk of attrition bias and reporting bias	Kim Wever / Judith van Luijk
12:15	15	Interactive discussion of practical session 7 (possible add-on: quiz on bias vs confounding vs heterogeneity)	Kim Wever / Judith van Luijk
12:30	*60*	*Lunch*	
13:30	45	Practical: hands-on randomisation and blinding	Kim Wever / Judith van Luijk
14:15	45	Study design (exploratory vs confirmatory research, randomization, blinding) – implementation challenges	Anton Bespalov
15:00	*15*	*Break*	
15:15	45	Beyond study design: Broad assessment of Risks of Bias (with reference to the first Open Discussion on Day 1)	Anton Bespalov
16:00	30	Open discussion: Use of lab journals – what they are and why are they important?	Anton Bespalov (/ Lee Monk)
16:30 - 16:45	15	Closing remarks	Anton Bespalov

Day 3 (Wednesday September 12th) **Improving robustness of animal studies: analysis and reporting**			
Time	**Duration**	**Topic**	**Lecturer**
9:00	4 hours	• Why statistics? When you need it and when not? • Importance of pre-specification • Pre- vs. post-hoc • P-hacking • P-values vs. False Discovery Rate	Martin Michel
~10:00	*15-30*	*Break*	
12:30	*60*	*Lunch*	
13:30	60	Publication standards: Presenting data in publications	Martin Michel
14:30	30	Introduction: Reporting guidelines	Kim Wever
15:00-16:00	60	Reporting of animal studies, assessing reporting quality according to the ARRIVE guidelines, using the IICARUS training	Kim Wever
16:00			

Day 4 (Thursday September 13th) **Hands-on training in systematic reviews of animal studies**			
Time	**Duration**	**Topic**	**Lecturer**
09:00	45	Lecture: Introduction to systematic reviews of animal studies	Kim Wever

09:45	15	Lecture: Comprehensive searching: identifying 'all' relevant studies	Judith van Luijk
10:00	60	Practical: Developing comprehensive search strategies	Kim Wever, Judith van Luijk
11:00	15	Practical: Screening and selecting studies (inclusion/exclusion)	Judith van Luijk
11:15	*15*	*Break*	-
11:30	30	Practical: External validity and extracting study characteristics	Kim Wever
12:00	30	Lecture: Assessing internal validity (risk of bias) in the context of SR, tools	Judith van Luijk
12:30	*60*	*Lunch*	
13:30	30	Practical: Performing a risk of bias assessment	Judith van Luijk
14:00	60	Lecture: Data extraction and meta-analysis	Kim Wever
15:00	*15*	*Break*	-
15:15	75	Practical: Meta-analysis	Kim Wever, Judith van Luijk
16:30 – 17:00	30	Closure and evaluation	Judith van Luijk

Day 5 (Friday September 14th) **Quality management systems and implementation of measures to improve research rigour**			
Time	**Duration**	**Topic**	**Lecturer**
9:00	09.45	Quality management systems • The relevance and benefits of having QMS for research • How much of what and when? (culture, systems and processes) • The impacts of the absence of a fit-for-purpose QMS.	Lee Monk
09.45	11.00	Interactive Workshop: QMS • (based on previous presentation)	
11:00	*15*	*Break*	
11:15	30	Open discussion: Exceptions when the standards discussed during this course cannot be implemented	Kim Wever, Lee Monk, Thomas Steckler, Judith van Luijk
11:45	30	Culture of tolerating negative results: from identifying key stakeholders to real-life examples and implications	Thomas Steckler
12:15	15	Guided Brainstorming: How to cope with the "negative" consequences of higher research quality standards (e.g. less positive data, lower chances to get published in a high IF journal, etc.)?	Kim Wever, Thomas Steckler, Lee Monk, Judith van Luijk
12:30	15	Closing remarks (what are take home messages that stuck with the participants?) & Adjourn	Everyone
12:45	60	(optional: lunch for those who do not have immediate travel arrangements)	Everyone