



Masterclass of Excellence on

Design and Implementation of Pharmacist-led Randomized Clinical Trials

Organized by the ESCP Research Committee

in co-operation with the Department of Clinical Pharmacology and
Pharmacoepidemiology, University of Heidelberg, Germany.

Sunday, 8 October 2017, 09:00-16.30
(the day before the Symposium)

“Achieving the highest evidence: How to run a RCT?”

Introduction

No doubt, randomization in clinical trials minimizes the risk of bias, especially selection bias. The different comparison groups allow the researchers to determine any effects of the treatment when compared with the no treatment/no intervention (often usual care = control) group, while other variables are kept constant. Hence, randomized clinical trials (RCTs) are considered the gold standard for a clinical trial to test the efficacy of an intervention providing the highest level of evidence. Consequently, evidence-based guidelines, systematic reviews including meta-analyses most often even do not consider other types of studies. However, RCTs are seldom conducted in pharmacist-led trials as they are in many aspects more challenging. This Masterclass of Excellence will provide an in-depth knowledge for current and future researchers in designing and performing pharmacist-led/pharmacy-based RCTs.

Program

09:00 - 09:45 **Why we need RCTs** – Levels of evidence and contemporary examples of successful RCTs

09:45 - 10:15 **No alternative!?** – Research questions where per patient RCTs are NOT first choice (eg cluster-randomized, before-/after, carry-/cross-over studies)

10:15 - 10:30 Coffee Break

11:00 - 12:00 **Designing a RCT** – trials and tribulations in outcomes research

12:00 - 13:00 Lunch

13:00 - 14:30 **Your choice!**

Group work **A**: Implementation and sustainability of RCTs – share your experiences including barriers, and facilitators or

Group work **B**: Case studies/research questions: Design your own RCT

14:30 - 15:00 **Practical issues** eg, recruitment, random allocation, motivation, monitoring, data gathering, blinded evaluation, role of committees and charters ...

15:00 - 16:00 **My next study will be a RCT** – presentations by the different groups and plenary discussion

16:00 - 16:30 Evaluation, final comments, and farewell: **Good luck with your next RCT!**

Your tutors

Marcel Bouvy, PharmD, PhD, FESCP, is Professor of Pharmaceutical Care and Research Manager at the SIR Institute for Pharmacy Practice and Policy in Leiden, in cooperation with Utrecht University, the Netherlands. He is the past president of the Scientific Section of Dutch Community Pharmacists (WSO), founding member of the European Society for Patient Adherence, Compliance and Persistence (ESPACOMP). His research focus on patient adherence, medication safety, including observational methods and evaluation of pharmacy interventions with a wide experience in RCTs. Marcel has attended ESCP conferences for >20 years and is a member of the ESCP Research Committee (ResCom).

Martin Schulz, RPh, PhD, FFIP, FESCP, is an Adjunct Professor at Goethe-University Frankfurt and Lecturer Department of Clinical Pharmacy, Freie Universitaet Berlin, Germany. He is the Director, Department of Medicine at ABDA and Chairman of the Drug Commission of German Pharmacists. His research focus on medication adherence and safety and evaluation of pharmacy-based interventions. Martin is a member of the ESCP ResCom and Co-Principal Investigator (PI) of the first pharmacy-based per patient RCT in Germany (PHARM-CHF, ClinicalTrials.gov identifier: NCT01692119).

Ross T. Tsuyuki, BSc(Pharm), PharmD, MSc, FCSHP, FACC, is a Professor of Medicine (Cardiology) and Director of the Epidemiology Coordinating and Research (EPICORE) Centre (a health research coordinating centre), Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Canada. His research interests include: improving public health through engaging community pharmacists as primary care providers (interventional pharmacy practice research). He is the PI of major randomized clinical trials studying pharmacists' interventions, such as RxING (BMJ Open 2013), RxACTION (Circulation 2015), and Rx EACH (JACC 2016). In addition, Ross is the Editor-in-Chief of the Canadian Pharmacists Journal (www.cpjournal.ca).

Venue

Heidelberg University Hospital, Im Neuenheimer Feld 410, 69120 Heidelberg, Germany.

Registration

<http://www.escpweb.org/Heidelberg>

Maximum number of participants

30 (first come – first serve)

Registrations fee (including lunch and refreshments)

Additional fee for registration if also registered with ESCP Symposium, ESCP member:	EURO 130
Additional fee for registration if also registered with ESCP Symposium, ESCP non-member:	EURO 150
Masterclass only, ESCP member:	EURO 160
Masterclass only, non-ESCP member:	EURO 200