Innovation unleashed:
The Crucial Role of Collaboration in Advancing Drug Development

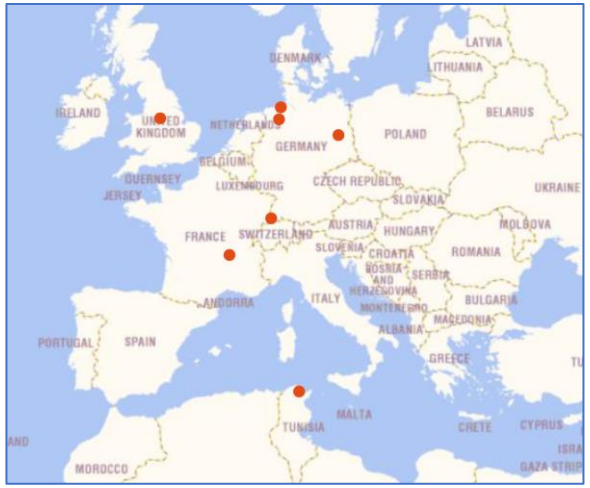
Mouna Akacha (Novartis Pharma AG)
BBS Next Generation Seminar
Basel - June 21st, 2023

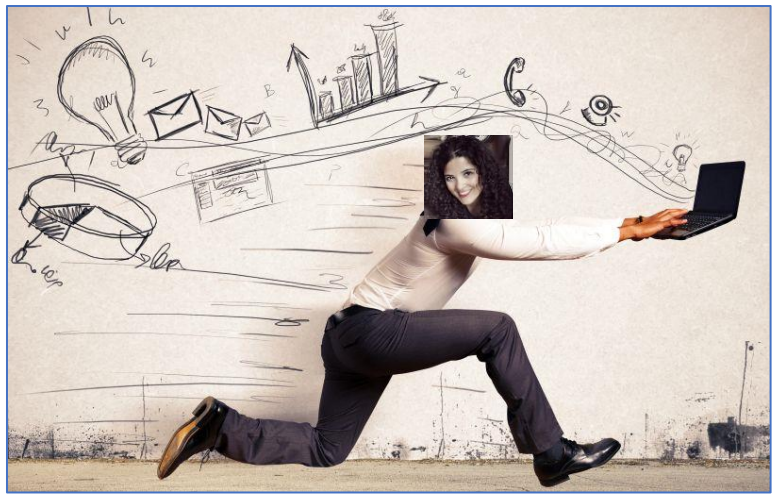
About me…

CARL VON OSSIETZKY universität OLDENBURG

THE UNIVERSITY OF WARWICK

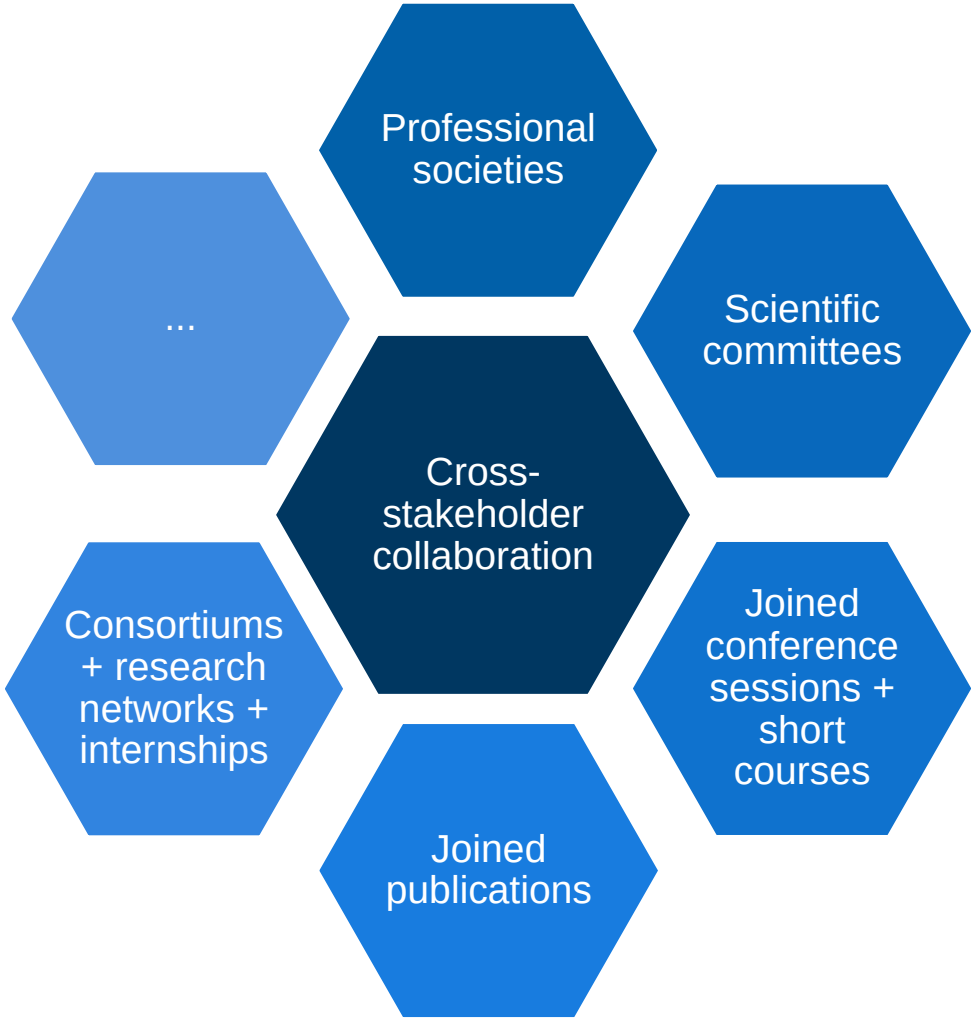
NOVARTIS





Why is collaboration crucial?

- Drug development faces scientific complexity and rigorous regulatory framework
- “Innovation = Invention * Commercialization” cannot be achieved in isolation!
- Diversity and inclusion of different perspectives ultimately serves patients



PSI

ASA Biopharmaceutical Section

ISCB International Society for Clinical Biostatistics

BBS Basler Biometric Section

MEDIASRES

ICH harmonisation for better he

IDEAS Improving drug development

EU-PEARL EU PATIENT-CENTRIC CLINICAL TRIAL PLATFORMS

Assessing Treatment Effects That Capture Disease Burden in Serious Chronic Diseases

Mouna Akacha PhD, Bruce Binkowitz PhD, Brian Claggett PhD, H. M. James Hung PhD, Guenther Mueller-Velten MS & Norman Stockbridge MD, PhD

Therapeutic Innovation & Regulatory Science **53**, 387–397 (2019) | Cite this article

Statistics in Medicine

Featured Article | Full Access

Estimands in clinical trials – broadening the perspective

Mouna Akacha, Frank Bretz, Stephen Ruberg

Pharm Stat. 2020 Jul;19(4):370-387. doi: 10.1002/pst.1986. Epub 2020 Jan 9.

What matters most? Different stakeholder perspectives on estimands for an invented case study in COPD

Oliver N Keene [1], Stephen Ruberg [2], Alexander Schacht [3], Mouna Akacha [4], Rachael Lawrance [5], Anna Berglind [6], David Wright [7]

Estimating time-varying effects for overdispersed recurrent events data with treatment switching

Qingxia Chen, Donglin Zeng, Joseph G. Ibrahim, Mouna Akacha, Heinz Schmidli

Biometrika, Volume 100, Issue 2, June 2013, Pages 339–354,

Request for CHMP Qualification Opinion

Clinically interpretable treatment effect measures based on recurrent event endpoints that allow for efficient statistical analyses

Mouna Akacha, Bruce Binkowitz, Frank Bretz, Arno Fritsch, Philip Hougaard, Antje Jahn, Franco Mendolia, Henrik Ravn, James Roger, Patrick Schlömer, Heinz Schmidli, Jiawei Wei

Tutorial 2: Recurrent Event Data Analysis in Clinical Trials

Instructors:

Mouna Akacha, PhD
Statistical Methodologist
Novartis Pharma AG, Switzerland

H. M. James Hung, PhD
Director, Division of Biometrics I, Office of Biostatistics, Office of Translational Science
CDER, FDA

CS3 The Analysis of Recurrent Event Data in Clinical Trials

Sunday 9th July - 10.00-13.30 h. - Room: Sala Mar 4
Mouna Akacha, *Novartis Pharma AG, Switzerland*
Richard Cook, *University of Waterloo, Canada*

Session 1: New Scientific and Regulatory Environment ICH E9 Addendum

Thursday 13th July - 09.30-13.30 h.
Moderator: R. Lamarca

ICH E9 addendum on 'Estimands and Sensitivity Analysis'

Rob Hemmings, *Medicines and Healthcare products Regulatory Agency, United Kingdom*
Mouna Akacha, *Novartis Pharma AG, Switzerland*