Basel Biometrics Section
Basel, 2021

BBS Workshop: Analysis of Risk and Safety Data in Clinical Development

Date: Tuesday 4th and Wednesday 5th May 2021,
14:00 – 17:00 CET
Venue: Virtual event

Safety evaluation is a key aspect of any medical product development. The aim of this workshop is to give insights about structuring, analyzing and interpreting safety data from clinical trials. We will review statistical methods for the analysis of adverse events; methods for quantifying the risk of false discoveries, discuss conclusions drawn which can be drawn from the safety analyses and possible consequences.

In the past years, companies have increased their focus on the oversight and prevention of potential risks impacting individual clinical studies or the overarching clinical program success by means of subject well-being and protection, data quality and site performance as well as accuracy and correctness of final study results.

Quantifying the risk-benefit profile of drugs, i.e. characterizing its efficacy and safety, is the ultimate goal of any drug development program. While statistical inference is routinely used for the efficacy assessments, safety assessments are often confined to descriptions and frequency counts. This imbalance in the handling of efficacy and safety should be changed.

Part 1 May 4th: Adverse event types and signal detection
Lecturer: Ekkehard Glimm, Novartis Pharma

Part 2 May 5th: Time-to-event analyses and competing risks for safety data
Lecturer: Prof. Jan Beyersmann, University of Ulm

The seminar is free of charge. However, if you wish to attend, we kindly ask you to fill out the registration form by 30th April 2021, for organisational reasons. Attendance / log-in details will be shared in the first days of May.

Please follow this link for the registration: link. In case of issues with the registration tool, please send an email to laurence.guillier@roche.com.

Slides will be made available after the event on the BBS webpage, pending speaker approval.