Background
The International Conference on Harmonisation (ICH) has published a series of recommendations and guidelines for clinical trials, including ICH E6 'Good Clinical Practice' and ICH E9 'Statistical Principles for Clinical Trials'.

In 2019, an addendum on estimands and sensitivity analysis in clinical trials to ICH E9 has been published and since adopted by all major regulatory agencies. The addendum defines an estimand as "a precise description of the treatment effect reflecting the clinical question posed by the trial objective". Estimands are of particular importance in confirmatory clinical trials; their study protocols now overwhelmingly define primary estimands. However, discussing and defining an estimand for a non-confirmatory clinical trial can also add value. In some cases, the implementation of the estimands concept is explicitly requested in funding proposals.

Aim of this workshop
In this workshop, participants will learn about the estimand concept and how to implement it. The workshop is split into two parts.

The **first part** provides a general introduction to the estimand framework, including how to reflect post-randomization events in the clinical question of interest, and how to implement estimands in a study protocol.
The **second part** focuses on aligning the analysis of a clinical trial with the estimand. Each part includes class-room style presentations followed by practical exercises.

Target audience
- Part 1: Clinical scientists, biostatisticians and other professions working in the field of clinical trials with an interest in learning about estimands and their implementation in study protocols.
- Part 2: Biostatisticians and interested other professions working on data analysis in clinical trials.

Wednesday, 30.07.2025

Day 1

13:30 – 15:00
- Introduction to estimands

15:00 – 15:30
- Coffee break

15:30 – 17:30
- Case study and interactive group work on defining estimands

17:30 – 18:00
- Coffee break

18:00 – 19:00
- Implementation of estimands in study protocols

→ Afterwards get-together at dinner time (location will be communicated in advance, dinner à la carte on one's own expense)

Thursday, 31.07.2025

Day 2

09:00 – 11:00
- Estimand-aligned analysis for treatment policy estimands

11:00 – 11:30
- Coffee break

11:30 – 13:30
- Estimand-aligned analysis for hypothetical estimands

13:30 – 14:00
- Discussion & Q&A

For the practical exercises on Day 2, please **bring a laptop with R v4.1 or newer** as well as the **R packages tidyverse** and **rbmi** already installed.

Venue:

Center of Drug Absorption and Transport (C_DAT)
University Medicine Greifswald
Felix-Hausdorff-Str. 3
17487 Greifswald

Lecturer:

Prof. Tim Friede
University Medicine Göttingen, Germany
Professor of Biostatistics
Dept. of Medical Statistics
DZHK - German Centre for Cardiovascular Research

Dr. Tobias Mütze
Director Statistical Methodology
Novartis Campus, Basel, Switzerland

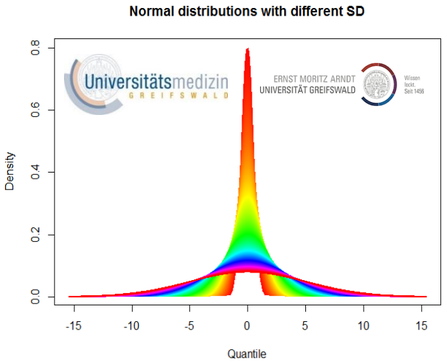
Mandatory registration until 30.04.2025 at:
https://terminplaner6.dfn.de/b/80282673a66f0d4316262027fb21576a-1054718

Participation is possible independent from DZHK membership.

Participants who are members of the YOUNG-DZHK can reimburse their travel costs via their local DZHK partner site.

Maximum no. of participants: 30

DZHK
Deutsches Zentrum für Herz-Kreislauf-Forschung



Workshop – Estimands in Clinical Trials

"Introduction to estimands and estimand-aligned estimation: Clinical considerations and statistical methods"

organized by the DZHK

30. – 31. July 2025
Greifswald