

# „Analysis of adverse events in the context of estimands“

AG Therapeutische Forschung der GMDS

AG Pharmazeutische Forschung der IBS-DR

16<sup>th</sup> March 2020, Heidelberg

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gm<sup>d</sup>s

Deutsche Gesellschaft für  
Medizinische Informatik,  
Biometrie und  
Epidemiologie e.V.



**Venue and time:**

16<sup>th</sup> March 2020, 09:30 – 17:30

Marsilius-Arkaden, Turm Nord

Im Neuenheimer Feld 130.1, EG

69120 Heidelberg

**Participation fees:** free for members of gmds or IBS-DR; 100 Euro for non-members

**Obligatory registration at:**

<http://www.biometrie.uni-heidelberg.de/workshop>

**Program:**

09:30 – 09:45: Meinhard Kieser (University of Heidelberg), Frank Langer (Lilly, Bad Homburg), and Tim Friede (University Medical Center Göttingen): Welcome and program overview

09:45 – 10:15: Steffen Unkel (University Medical Center Göttingen): The ATF / APF Project Group: Safety analyses and estimands

10:15 – 11:15: Jan Beyersmann (University of Ulm) and Claudia Schmoor (Medical Center – University of Freiburg): Analyses of adverse events using time-to-event data techniques

**11:15 – 11:45: Coffee break**

11:45 – 12:30: Jan Beyersmann and Regina Stegherr (University of Ulm): Practicals in R

12:30 – 13:15: Regina Stegherr (University of Ulm): Some results from SAVVY, an empirical study

**13:15 – 14:00: Lunch break**

14:00 – 15:00: Burak Kürsad Günhan and Tim Friede (University Medical Center Göttingen): Meta-analyses of adverse events

15:00 – 15:30: Burak Kürsad Günhan and Tim Friede (University Medical Center Göttingen): Practicals in R

**15:30 – 16:00: Coffee break**

16:00 – 16:30: Norbert Benda (BfArM, Bonn): Safety analyses from a regulatory point of view

16:30 – 17:00: Ralf Bender (IQWiG, Köln): Safety analyses and HTA

17:00 – 17:30: Discussion