

## **Kolloquium „Statistische Methoden in der empirischen Forschung“**

Wann: 29. Januar 2019, 17:00 – 18:30 Uhr

Wo: Robert Koch-Institut | Nordufer 20 | 13353 Berlin (Wedding),  
S41, S42, U9 Westhafen | U9, Bus 142 Amrumer Str

### **Baldur Magnusson (Novartis Pharma AG)**

#### **Using principal stratification to address post-randomization events: A case study**

In a randomized controlled trial, occurrence of post-randomization events associated with treatment and the primary endpoint may complicate the interpretation of the overall treatment effect. In this presentation, we discuss how these events may be accounted for at the estimand and the estimator level in the context of a recent case study. We define a principal stratification estimand derived from the scientific question of interest. Consideration is given to identifying assumptions, model-based derivation of an estimator, handling of covariates and missing data. We also discuss the role of sensitivity analyses.