Estimation of causal effects is a central goal of quantitative empirical analysis in many fields, including medicine, public health and social sciences. Partly motivated by the increasing availability of observational data from non-randomised studies, causal inference has attracted much renewed interest in the field of statistics, growing at a tremendous rate over the last decade. At the same time, a new awareness has emerged that ideas from the field of causal inference provide a useful framework for inference in randomized studies. For example the ICH E9 addendum on estimands uses the counterfactual viewpoint from causal inference to define treatment effects in clinical trials.

This course aims to empower you to think about causality in your own work, and provide you with a first exposure to the basic ideas of causal reasoning and to some of the tools of causal inference, including a formal language for the definition of causal effects on the basis of potential outcomes. We will also illustrate how it relates to questions and concepts encountered in randomized clinical trials (e.g., intent-to-treat, per-protocol analyses, covariate adjustments in regression analyses) and the strategies defined in the ICH E9 addendum on estimands. In addition, causal thinking in building external controls of single arm trials will be discussed. While the causal inference framework is in many aspects aligned with pharmaceutical statistics traditions, there are also areas where the framework sheds new light on established traditions, which we will outline in this training.

This event is the first in the BBS Training Series 2021 and is free of charge. However, if you wish to attend, we kindly ask you to fill out the online registration form. Participants will receive an online meeting invitation shortly before the event, and slides will be made available to participants after the event.

**Draft Program:**

14:00 – 14:05 Welcome: Marc Vandemeulebroecke, BBS board member

14:05 – 15:00 **Basic concepts, definitions and applications of causal thinking (1/2)**
Giusi Moffa, University of Basel, BBS Board member

15:00 – 15:10 Break

15:10 – 16:00 **Basic concepts, definitions and applications of causal thinking (2/2)**
Bjoern Bornkamp & Heinz Schmidli, Novartis

16:00 – 16:10 Break

16:10 – 16:45 **Practical application with implementation details**
Dominik Heinzmann, Roche, BBS board member

16:45 – 17:00 Final Q & A and closing: Marc Vandemeulebroecke, BBS board member

*We look forward to your participation!*