

BBS Seminar: Graphics for decision-making in biomedical research and drug development

Date: Monday, 8th March 2021, 14:00 – 17:00 CET **Venue:** Virtual event

Decision making is a challenging task in biomedical and pharmaceutical research and development. Difficult situations where we need decisions fast and under uncertainty are common.

Integrating and synthetizing the information from complex data is a critical step in the process enabling optimal evidence-based decisions. In this context, statistical graphics may be a very effective tool to capture and communicate the most relevant aspects of any available data.

The objective of this BBS seminar is to discuss the principles of fit for purpose statistical graphics which aim to support decision making. Various examples from real case studies will illustrate applications informing decisions at the time of drug development milestones and in biomedical research.

The event will feature talks from experts in communication with graphics from industry and academia. The organizing committee of this event are Marc Vandemeulebroecke (Novartis), Dominik Heinzmann (Roche) and Giusi Moffa (University of Basel).

The seminar is free of charge. However, if you wish to attend, we kindly ask you to fill out the registration form by 28.2.2021, for organisational reasons. Attendance / log-in details will be shared in the first week of March.

Registration: https://forms.qle/SjJnqB8MtmLQP4uV9

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

Program:

- 14:00 14:10 Dominik Heinzmann (Roche and BBS board member): Welcome
- 14:10 15:40 Hannah Diehl and Tamara Broderick (MIT), Andy Stein and Niladri Roy Chowdhury (Novartis): The "See"-Value App: Visual Decision Making for Drug Development
- 14:40 15:10 Neil McQuarrie (Flatiron): Better understanding and reacting on impact of COVID-19 on RWD collection by combining statistics with visualization
- 15:10 15:25 Break
- 15:25 15:55 Tadeusz Lewandowski (Roche): Interactive clinical study visualisation in enabling the faster decision making
- 15:55 16:25 Markus Lange (Novartis): Unraveling a single number using graphics to explain Probability of Success
- 16:25 16:55 Anne-Marie Meyer (Roche): Population Level Analytics for pandemic response: Predicting vaccine uptake and vaccine hesitancy
- 16:55 17:00 Giusi Moffa (University of Basel and BBS board member): Closure

Abstracts are included below. We look forward to your participation!

Abstracts:

Hannah Diehl and Tamara Broderick (MIT), Andy Stein and Niladri Roy Chowdhury (Novartis): The "See"-Value App: Visual Decision Making for Drug Development

Humans are notorious at seeing patterns in plots even when there are none, especially when there is some incentive (e.g. financial) to do so. To avoid these pitfalls, the lineup protocol (Buja et al. 2009) calls for generating a number of simulated ("null") plots and asking a user to try to pick out the real data from the rest. We created an R-shiny App that allows the user to generate these lineups by using preloaded examples or by uploading their own data. Any number of users can then select the plot that they each think has the real data and individually check if their choice was correct. If enough users choose correctly (before seeing the real answer), the evidence suggests the real plot is significantly (and substantively) different from the null plots. To make this intuition precise, our app calculates a "see"-value, which can be used to decide statistical significance. Our app supports different types of analysis using continuous, binary, or time-to-event responses --- and continuous or categorical predictors.

Neil McQuarrie (Flatiron): Better understanding and reacting on impact of COVID-19 by combining statistics with visualization

Utilizing a large, multi-dimensional data source of electronic health records to make decisions can require a blend of creativity and science in its own right. When an external shock such as COVID-19 affects how that data is merely collected -- and in initially unknown ways -- the creative element in that mix may need to be expanded upon and built out even further. Learn about what we have done at Flatiron Health in the face of such a challenge to use statistical data visualization to track and if needed to adjust data collection and processing.

Tadeusz Lewandowski (Roche): Interactive clinical study visualisation in enabling the faster decision making

In the process of the clinical trial evaluation the flexibility of the results exploration is key, in particular in the biomarker exploratory analyses after the database lock. The presentation will focus on the unique capability in visualising the study results of the primary endpoints and the flexibility in exploring the different baseline biomarker candidates in order to generate insights in the decision making process in timely manner: from the bias selection process, correlations, univariate/bivariate analyses and biomarker selection based on the efficacy outcomes.

Markus Lange (Novartis): Unraveling a single number – using graphics to explain Probability of Success

Probability of success (PoS) is an important metric that is used by Novartis governance boards to inform decisions about which development programs to prioritize, and by teams to optimize their development strategies. To improve the accuracy, transparency and consistency of our PoS estimates, we have developed and implemented a quantitative Bayesian approach for calculating the probability of success before the planning of any pivotal trials. This approach integrates internal

clinical data generated to date, together with cross-industry success rates, and the outcome is a probability.

It needs a lot to understand a single number, and visualizations are key to inform how this number came to be. In this talk, we will discuss how the use of graphics can increase the acceptance of this metric. In particular, we will demonstrate how graphics allow us to gain deeper knowledge (e.g. by identifying bottlenecks and by contextualizing information) and as a result improve decision-making.

Anne-Marie Meyer (Roche): Population Level Analytics for pandemic response: Predicting vaccine uptake and vaccine hesitancy

The COVID-19 pandemic has highlighted the tension between inferences we can make from a single study, and it's generalizability to a larger population. In COVID-19 we need to understand variables like test positivity or genetic variation in disease regionally and temporally. While individual cohort studies are still a predominant lens to study real-world diseases, we need to be able to place these studies into a population contest. For this purpose, Roche has developed a COVID-19 platform at the population level in partnership with several stakeholders. The platform includes visual tools, including geospatial analyses (such as measures like Morans I), enabling selection of COVID trajectories on areas of interest, and compare locations over time. Users can then identify population phenotypes or highlight important subgroups relative to disease risks and outcomes. For example, vaccine uptake or hesitancy is a critical topic. By looking at correlations between key population variables and past vaccination acceptance rates in the United States, regional phenotypes emerge that indicate a more complicated path to vaccine acceptance. Understanding unique regional phenotypes and their underlying causes of vaccine hesitancy can be used to create regionally tailored vaccine messaging strategies that promote COVID-19 vaccine acceptance that will in turn help end the pandemic