	2024 PSI ANNUAL CONFERENCE CONTRIBUTED **SESSION** SUBMISSION FORM Beurs Van Berlage, Amsterdam, Netherlands, 16th to 19th June 2024 Presentations may be any day from the 17th – 19th June.

Session Title:	Estimands for time-to-event outcomes: re-thinking old questions within the Estimand framework			
Session Lead Contact	Email:	Kaspar.rufibach@roche.com	Affiliation & Country:	Roche Switzerland

Duration of session (select preference)		90 minutes	
If you expressed a preference, would you also present for the other duration if required?	no		
Short text (50 words) for inclusion in the conference program telling the audience why they should attend this session	In this session you will learn how old questions regarding time-to-event outcomes, that we seemingly thought to understand well and were used to answer in certain ways, appear in a new light within the estimand framework.		
Optional: include a head & shoulders photo of the presenting authors to the abstract submission. Photos will be used for the conference website and promotion and will only be used if the session/presentation is accepted.			

If the session is selected speakers will receive a 10% discount code for use on the full 3-day conference price.

Please select the session(s) that best describe the theme of the session (max two).

Estimands: methods, theory and case studies		X
Analysis of ‘big’ data e.g. RWD, digital endpoints etc.		
Bayesian		
Data visualisation and animation		
Use of external data		
Health Technology Assessment		
Decentralized trials		
Innovative approaches		X
Complex trial designs including adaptive designs		
Use of R, Python etc.		
Analysis of Safety Data		
Master protocols and platform trials		
Non-technical topics e.g. leadership, influencing, soft skills		
Other		

Session Abstract (if applicable) (limit to 250 words):

This session organized by the Oncology Estimand SIG will discuss how old questions regarding time-to-event outcomes, that we seemingly thought to understand well and were used to answer in certain ways, appear in a new light within the estimand framework. The session will report on results of various task forces of the oncology estimand working group and beyond.

Please email your completed form to paul.terrill@ptstat.co.uk

Presentation / Presenter Details

(Copy pages for subsequent presenter details and abstracts to be included in the session, completing applicable information):

Title:	Looking back on our oncology estimand SIG working group journey			
Author(s):	Evgeny Degtyarev and Kaspar Rufibach			
Presenting / Contact Author:	Email:	Evgeny.degtyarev@novartis.com Kaspar.rufibach@roche.com	Affiliation & Country:	Novartis Roche Both Switzerland
Biography of presenting author: (max 250 words)				

Presentation Abstract (if applicable) (limit to 250 words):

The oncology estimand working group was founded in 2018 to address many open questions concerning estimands for oncology clinical trials which typically involve time-to-event outcomes. It soon became a SIG by PSI and EFSPI as well as ASA scientific working group and has evolved into a successful forum for scientific discussions among statisticians in industry, regulatory agencies, academia, and collaborative groups. In this talk we share some highlights of the group's work, identify factors that made this group an influential voice in the global scientific and regulatory dialogue and derive recommendations how to set up similar groups in the future.

Presentation / Presenter Details

(Copy pages for subsequent presenter details and abstracts to be included in the session, completing applicable information):

Title:	Re-Thinking treatment effect measure in clinical trials with time-to-event outcomes and competing risks			
Author(s):	Tobias Mütze and Stefan Englert			
Presenting / Contact Author:	Email:	tobias.muetze@novartis.com senglert@its.jnj.com	Affiliation & Country:	Novartis Switzerland Janssen Germany
Biography of presenting author: (max 250 words)				

Presentation Abstract (if applicable) (limit to 250 words):

In randomized clinical trials with a time to event outcome, the hazard ratio is still the most common effect measure. Post-randomization (i.e., intercurrent) events are often addressed through censoring without explicitly discussing or stating the underlying clinical question of interest. Alternative summary measures, especially on a probability scale or time scale, are rarely considered in clinical trials despite being seemingly easier to interpret and potentially more meaningful to patients and practitioners.
In this talk we will present the status of ongoing discussions on estimands for clinical trials with time-to-event outcomes and competing risks. In detail, we will discuss what key clinically meaningful questions of interest are when measuring the effect of an intervention through a time-to-event endpoint. We will reflect on the interpretation of various summary measures, the role of causality when defining an estimand in a clinical trial, and on how the choice of the estimand affects the design of a trial with a time-to-event endpoint. We will elaborate on the practicalities of summarizing the effect of treatment through a single number in a time to event setting and discuss separating testing and estimation. We will also propose a new approach to embed competing risks within the framework that we believe is helpful for describing estimands in a competing risk setting.

Presentation / Presenter Details

(Copy pages for subsequent presenter details and abstracts to be included in the session, completing applicable information):

Title:	Outcome and learnings from a recent survey on current practice in covariate adjustment and stratified analysis			
Author(s):	Sarwar I. Mozumder			
Presenting / Contact Author:	Email:	sarwar.mozumder@astrazeneca.com	Affiliation & Country:	AZ, UK
Biography of presenting author: (max 250 words)				

Presentation Abstract (if applicable) (limit to 250 words):

Careful consideration is required when adjusting for covariates in non-linear models for binary and time-to-event outcomes. Specifically, a decision must be made on the estimand we're most interested in - is it a marginal or conditional one? This is further highlighted by the recent release of the FDA guidance on covariate adjustment. Further questions arise out of this choice in estimand: what is the appropriate estimator for the target estimand? Do we really understand what estimand is being targeted when specifying a stratified or unstratified analysis? The conditional and marginal effects task force conducted a survey with the goal of identifying the current challenges associated with applying covariate adjustment, as well as understanding of the choice in estimand and impact on the associated analysis. We present these results along with learnings and some preliminary recommendations to progress towards establishing a consensus on covariate adjustment and stratified analysis best practices.

Presentation / Presenter Details

(Copy pages for subsequent presenter details and abstracts to be included in the session, completing applicable information):

Title:	Can we improve the analysis of safety events of special interest using the Estimand Framework?			
Author(s):	Pedro Lopez-Romero, Brenda Crowe, Philip He, Jonathan Siegel, Janet Wittes			
Presenting / Contact Author:	Email:	pedro-1.lopez_romero@novartis.com	Affiliation & Country:	Novartis Spain
Biography of presenting author: (max 250 words)				

Presentation Abstract (if applicable) (limit to 250 words):

In analyzing data from randomized clinical trials, the assessment of safety presents challenges different from those confronted when evaluating efficacy. Defining and quantifying treatment effects for safety outcomes requires special considerations due to the inherent complexity of evaluating safety outcomes. While there are typically many AEs, there are some AEs of scientific and medical concern specific to the sponsor's product or program, known as AEs of special interest (AESI), which require further investigation in order to fully characterize them. Usually, the interpretation of the effect of treatment on a specific AESI is complicated by the occurrence of intercurrent events (ICEs) such treatment discontinuations or initiation of rescue. To handle those ICEs the estimand framework (EF) considers several strategies, each of which targets different treatment effects. The understanding of these strategies will help study teams to define precise treatment effects for a given AESI, avoiding the use of a 'one size fits all approach that ultimately may lead to misleading and ambiguous results. Here, we address how the EF is useful in describing those AESIs, by helping study teams to formulate precise, unambiguous, and clinically meaningful treatment effects on AESIs. We illustrate the EF's practical use through a synthetic case study. We hope that the use of the EF can further advance the understanding of the safety profile of the investigational product, which in turn, can significantly impact the labeling claims and eventually can contribute to make better informed decisions in clinical practice.