One day meeting: Time-to-event and Recurrent Event Endpoints in Clinical Trials

Novartis Campus, Basel
8.30am – 4.30pm, 29th October 2019

Cox proportional hazard models and Kaplan-Meier curves often constitute the standard statistical analysis of clinical trials when the primary interest is in a single event such as progression-free survival, death, etc. However, there are event-driven trials in which the mentioned methods cannot capture the complexity of the primary event of interest. Examples include: (i) trials in which the occurrence of the primary event of interest is precluded by a different event, e.g. death precludes events such as hospitalizations; (ii) trials in which the primary event of interest is a recurrent event, i.e. an event that can occur multiple times for a single patient such as exacerbations in asthma.

This PSI one-day event provides the opportunity to hear from knowledgeable speakers from health authorities, academia, and pharma. The speakers will share their thoughts, ideas and experiences, including case studies, on a range of particular issues relating to planning, conduct, and analysis of event-driven trials. A variety of non-standard time-to-event and recurrent event models for clinical trials will be presented and their implications for the estimand framework will be discussed.

Agenda

Analysis of time-to-event data and safety events

Valentine Jehl (Novartis): *Quantitative assessment of adverse events in clinical trials - comparison of methods at an interim and the final analysis*
Qing Wang (Roche): *Comparison of time-to-first event and recurrent event methods in multiple sclerosis trials*
Filip De Ridder (Janssen): *Time to event model for early efficacy signal dose finding in epilepsy clinical trials*
Andrew Thomson (EMA): *Estimators and Estimands for safety events in time-to-event studies: a regulatory perspective*

Recurrent events with associated terminal events

Patrick Schlömer & Arno Fritsch (Bayer): *Estimands and estimators for recurrent events with an associated terminal event*
John Gregson (London School of Hygiene & Tropical Medicine): *Practical experience of modelling repeat events in the REDUCE-IT and COAPT trials*
Tobias Bluhmki (University of Ulm): *Simulating recurrent events with associated terminal events*
Rob Hemmings (Consilium): *Rejoinder*

Register at: http://psiweb.org/events/psi-events
Please contact david.lawrence@novartis.com and tobias.muetze@novartis.com if you have any queries.