Bristol Myers Squibb™

Student Internship

Functional area : Biostatistics
Therapeutic Area : Cell Therapy
Prerequisites : A Ph.D. candidate or MSc candidate in Statistics. Experience in R (preferred) and/or SAS

Description of the project and work required (including references)

Late stage CAR T-cell trials often allow subject to switch treatment, usually from the control group to experimental group, when specific conditions are met. This is implemented in the trial design to safeguard the ethical principles of providing the best care for patients. However, the presence of treatment switching creates technical difficulties in estimate the true effectiveness of the experimental drug when long-term time-to-event endpoints are used – in fact, standard methods (i.e. ITT or the per-protocol approaches) would likely underestimate the experimental treatment effectiveness (i.e. loss in power). For this reason, more complex methodologies have been proposed to adjust for treatment switching[1]. These are the marginal structural models (MDS) using inverse probability of censoring weights (**IPCW**), the **two-stage adjustment** and the Rank preserving structural failure time models (**RPSFTM**) using g-estimation.

The candidate will be requested to become familiar with the concept of treatment switching, to understand the impact on the efficacy analyses and to deep-dive into IPCW, RPSFT and the 2-stage model to understand their features, pros and cons and their applicability to our studies.

The candidate will be required to perform literature review and generate simulation work as well as present her/his work at the end of the internship to the statistical department. Developing training slides will be generated for that too in order to provide guidance on the usability and implementation of IPCW, RPSFT and 2-stage model in our studies where treatment switching is allowed.

Skills/Knowledge Required (technical and soft skills)

Academic knowledge of statistical methodologies. Basic knowledge of clinical trial designs and drug development. Basic knowledge of statistical computing software (R preferred, or SAS). Good knowledge of Microsoft Office software. Ability to work in a team as well as independently. Good interpersonal, communication, writing and organizational skills

Anticipated/expected outcome of the project (how would you define a successful internship?)

The goal of this internship is to increase awareness around IPCW, RPSFT and 2-stage models as well to generate educational sessions and provide a set of tools for their implementation.

[1] NR Latimer, C Henshall, U Siebert and H Bell. Treatment Switching: Statistical and Decision-making Challenges and Approaches. Cambridge University Press Volume 32, Issue 3 2016 , pp. 160-166

Bristol Myers Squibb™

Benefits to the candidate

The candidate will become familiar with the drug development process, study designs, standard analysis methods as well the more complex methodologies to adjust for treatment switching. The candidate will also experience working in a global environment and for a pharma company.

Benefits to BMS

IPCW, RPSFT and 2-stage models are known methodologies that have however found little application in clinical development. This internship will create awareness about them (through educational sessions) but most importantly will provide a set of recommendations and tools for their implementation in our studies.

Other relevant items:

Depending on the development of the COVID-19 situation, the intern is to be office-based in Boudry.

Full-time internships are available and will last 4 to 6 months according to the university/school requirements and the study project. Part-time internship is possible when the student should continue to attend some courses during the internship period. This should be agreed with the intern supervisor. Starting and ending dates are flexible. Successful candidates will work closely with a senior-level statistician on statistical methodology and/or application topics related to the design and analysis of clinical trials and/or observational studies on a variety of therapeutic areas.

Successful candidates must have effective oral and written communication skills and good working knowledge of SAS and/or R and/or Python.

Additional Requirements:
Be authorized to work either in Switzerland.
Must not be employed at the time the internship starts.

To apply, send a résumé with a cover letter to the contact below.
Contact: Marie-Laure Casadebaig, Marie-Laure.Casadebaig@bms.com, +41 32 729 68 11