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Student Internship

Functional area : Biostatistics
Therapeutic Area : Hematology
Cell Therapy
ICF(Immunology/Cardiovacular/Fibrosis)
Medical and Market Access
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)

Pediatric studies and small sample size

In recent times, the needs for new drugs to be tested within the pediatric setting has increased to now being an integral requirement of the regulatory process, with legislation surrounding pediatric drug testing undergoing many changes in recent time; more recently the FDA Reauthorization Act (FDARA 504), enacted August 2018 and took effect August 2020. The new ICH E11 (R1) outlines the need for developing "additional statistical and pharmacokinetic methods" that integrate and leverage existing knowledge, as well as extrapolation of information from other populations (adults or pediatric subgroups).

With the ever-increasing needs for pediatric studies and the requirements surrounding then, so too has the need to increase clinical trial methodologies in terms of when to plan and developed, clinical trial design and how to maximize data use.

Most pediatric studies in hematology/oncology inherently rely on the availability of subjects from a very small population, resulting in unique challengers impacting study design and leveraging the most from the available study data. In a setting where subject availability is low and the clinical trial landscape competitive with ever increasing robust results requires, and where the regulatory reward can be lucrative to BMS, there is high value for the advancement of statistical methodologies as outlined.

BMS is in the process of developing a Pediatric Centre of Excellence, creating a knowledge center which will bring people from across all functions with a focus to advancing pediatric drug development. Having an intern that may in some part be able to help shape future thinking will be a welcome addition. The Pediatric Center of Excellence Mission: To fulfill regulatory requirements and exclusivity needs and advance the development of medicines that help pediatric patients prevail over disease.

Exploring various clinical trial designs using small sample sizes in various phase 2 settings, and the best use of a control arm will be integral parts to this internship. Using completed Celgene pediatric studies to work off of, simulation techniques should be applied to help understand and identify the most appropriate type(s) of study designs and how best to incorporate a comparison of the experimental arm to a control, be it a form of randomized arm, historical control arm, or a simulated arm based on literature reviews. In short; how to optimize the available study population and the data it has to offer as well as data readily available in the literature or in the academic world. Where to better use Bayesian methods and designs is fully part of the internship for optimizing the information provided by adult studies.

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Resampling methods (i.e. bootstrapping, jackknifing, and hot-decking) may also be considered, to further identify the most appropriate methodology under various simulations, in the phase 2 study setting when considering different types of endpoints and how the endpoints are analyzed.

Skills/Knowledge Required (technical and soft skills)

Master student in Statistics (ideally Medical Statistics / Biostatistics) with good understanding of basic methodology of clinical research. Good working knowledge of using SAS (and/or R) and MS Office products (Word, PowerPoint).
Be able to work well in a team and independently. Good organization and communication skill.

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

The student will have to deliver an internship report, in alignment with requirements from his/her university. For BMS internal use, the student will develop a PowerPoint presentation of his/her work and findings, and a possible guidance document. Their work will go towards possible changes to the way BMS design/consider pediatric and other small sample size studies.

Benefits to the candidate

The candidate will become more familiar with the drug development process with regards to study designs and the topics included in this proposal, as well as regulatory requirements.
Internship should be considered part of the student education and the work contribute partly/fully to their MSc thesis.

Internship outcomes may lead to publications and further researches.

Additional benefits for the chosen student is they would develop a good footing for a future career within the pharmaceutical industry, and learning and understanding requirements of them and of the industry as well as a sense of achievement, pride, responsibility gained and working within a global company both in a team and independently.

Benefits to BMS

1. The BMS statistical team will gain experience in best use of control data for small sample size studies.
2. Results of applying the approaches may be used for future study designs and comparisons with control data.
3. Broaden the pool of candidates for future potential job openings in the BMS Biostatistics department.
4. Having an intern will be the start of developing a pediatric statistical research group to complement the Pediatric Center of Excellence, providing crucial statistical knowledge to the group.

Other relevant items:

Offer opened only to University students as part of their studies.
Internship is tripartite agreement/commitment between BMS, the student and the university.

This will provide BMS the opportunity to demonstrate its citizenship engagement and inclusion in its local socio-economic environment and to develop BMS homegrown talent.

Location: Boudry, Switzerland / Uxbridge, UK.
Internship period: According to the School/University rules.

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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