Celgene International, Boudry, Switzerland
Biostat 3-month internship

Proposal 1:

SPONSOR	Alessandro Previtali
SUPERVISOR	Alessandro Previtali
DEPARTMENT	Biostatistics, Global Clinical Development
PREREQUISITES	A Ph.D. candidate or MSc candidate in Statistics. Experience in SAS and/or R

Description of the project and work required (including references)

In August 2017 the addendum on estimands and sensitivity analysis in clinical trials (ICH E9 addendum) was released for public consultation[1]; consultation ended in February 2018 with the working group receiving more than 1000 comments. Findings were discussed and addressed in the final version of the document which will be available this year in June.

The candidate will be requested to become familiar with the concept of estimand, to understand the difference between the proposed framework and the current one and to apply the new methodology. Application might be implemented theoretically or in the context of a Celgene study, as an alternative to the original approach (for example re-visiting the analysis section of a CAR T study in order to propose an alternative in the estimand framework).

The candidate will be required to perform literature review 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. Optionally, the candidate may be requested to present this topic to other functions (for their awareness) as well as producing a publication.

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 (SAS or R). 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 the internship is to increase awareness and visibility around the concept of estimand. In addition, the analysis of its impact on the current clinical development practice will be shared within statistics as well as cross-functionally (clinical, regulatory, etc…). Building a group of experts as well as improve familiarity on this topic will be considered as having achieved a successful internship.

Benefits to the candidate

The candidate will become familiar with the drug development process, study designs, standard analysis methods as well as with the concept of estimand. The candidate will also experience working in a global environment and for a biotech company. The candidate may also be co-author of a publication on estimand.

Other relevant items

Intern to be office-based in Boudry.

[1] https://www.ema.europa.eu/documents/scientific-guideline/draft-ich-e9-r1-addendum-estimands-sensitivity-analysis-clinical-trials-guideline-statistical_en.pdf

Proposal 2:

SPONSOR	Roland MARION-GALLOIS
SUPERVISOR	Jixian (Jason) WANG
DEPARTMENT	Biostat, MAMA & Pediatrics, Boudry
PREREQUISITES	MSc or Ph.D Student in Statistics. Trained in R (best to have, in SAS)

Description of the project and work required (including references)

Provide a framework for deciding which Propensity Score Matching method is the most appropriate given the context.

In absence of a study with a direct comparison, it is usual to consider an indirect comparison between the experimental cohort and an observational retrospective one. Use of Propensity Score Matching (PSM) became a standard for creating comparative subgroups within the cohorts before performing matched or adjusted analyses.

Several methods for have been developed, with pros and cons depending on, not only their intrinsic characteristics, but also the context in which they are applied. The properties of the matching methods are also affected by the context. When comparing enasidenib data with 2 historical cohorts, it has been observed that the quality of the matching was highly influenced by the cohort characteristics despite same protocol, same methodology and same statistical analysis plan.

The choice of the method is important in practice, hence the proposed work will examine how to make the right balance between the representativeness and the homogeneity of matched population, while also taking the estimand into consideration.

Skills/Knowledge Required (technical and soft skills)

Master or PhD student in Statistics (ideally Bio-Statistics) with good understanding of basic methodology of clinical research. Excellent programming skills and autonomy in using R.
Previous experiences on using R matching packages is a plus, so is the programming in SAS and knowledge of MS Office products (Word, PowerPoint).
Team player. 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 Celgene internal use, the student will have to deliver a guidance document and PowerPoint presentation.

Benefits to the candidate

Internship should be considered part of the student education.
The intern will gain working experience of applying PSM in the context of pharmaceutical industry.
Internship outcomes may lead to publications and further researches.

Other relevant items

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

Location: Boudry, Switzerland.

Internship period: According to the School/University rules.

Duration: 3 months minimum. According to School/University rules.

Proposal 3:

SPONSOR	Roland MARION-GALLOIS
SUPERVISOR	Roland MARION-GALLOIS / Jixian (Jason) WANG
DEPARTMENT	Biostat, MAMA & Pediatrics, Boudry
PREREQUISITES	MSc or Ph.D Student in Statistics. Trained in R and SAS

Description of the project and work required (including references)

Developing a synthetic representation of the multivariate effect of a treatment including primary and secondary efficacy endpoints, symptom assessments, quality of life, and health economics outcomes.

Clinical trials generally focus on primary efficacy endpoint. However, treatment may have effect on many health dimensions including efficacy, safety, quality of life, co-medication, health related cost… And within these dimensions, the effect may appear to several outcomes, sometime complementary, sometime in competition. Therefore, it is useful to develop a synthetic representation of the multidimensional effect for comparative benefit-risk assessment.

It could be interesting to map different products, or diverse group of patients under the same products, in a synthetic representation expressing the multivariate treatment effect.

The purpose of the internship work will be to explore and adapt multivariate analysis methods for providing a synthetic representation of the multidimensional treatment effect.

Skills/Knowledge Required (technical and soft skills)

Master or PhD student in Statistics (ideally Bio-Statistics) with good understanding of basic methodology of clinical research.
Excellent programming skills and autonomy in using R and SAS. Previous experiences on using R packages dedicated to factorial analyses are welcomed, so is the knowledge of factorial analysis softwares (like Coheris SPAD, XLSTAT…).
Knowledge of MS Office products (Word, Excel, PowerPoint) is expected.
Team player. 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 Celgene internal use, the student will have to deliver a guidance document and PowerPoint presentation.

Benefits to the candidate

Internship should be considered part of the student education.
The intern will gain working experience of applying PSM in the context of pharmaceutical industry.
Internship outcomes may lead to publications and further researches.

Other relevant items

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

Location: Boudry, Switzerland.

Internship period: According to the School/University rules.

Duration: 3 months minimum. According to School/University rules.