INTERNSHIP PROPOSAL

Institut de Recherches Internationales Servier (I.R.I.S),
Center of Expertise Methodology and Valorisation of Data (CentEx MVD),
Clinical Oncology Team

A Bayesian approach for event predictions in clinical trials with time-to-event outcomes

Context

In clinical trials with a time-to-event outcome as primary endpoint, the statistical power is based on the number of observed events, which drives the sample size calculation. The planned statistical analysis is conducted when a pre-specified number of events is reached. However, the calendar date of the last event and of the end of the study remains unknown. Statistical methods are developed to predict, at interim analyses, the date when the targeted number of events is reached, given the observed event rate.

The objective of the internship is to participate in the development of a new Bayesian method, taking into account the variability and specificities of enrollment of the newly recruited patients, time to event and time to censorship processes and significant covariates. The approach is based on Weibull models with MCMC algorithms and informative priors in a Bayesian framework.

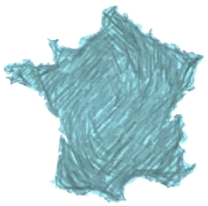
The predictive methodology proposed in this project was initially developed for application on an on-going oncology exploratory phase II trial to determine the additional time needed to achieve the target number of events to make the decision to start the phase III or not. The algorithm was used at different stages of the study to give to the clinicians a statistical tool allowing them to make informed decisions. Communications were conducted with the participation of a poster session during the international conference Statistical Methods in Biopharmacy (SMB) 2017.

Missions

- Literature review in order to identify existing approaches already published
- Validation of the method's performance using a simulation plan investigating many scenarios (study sample size, target number of events, enrollment processes, available information, …).
- Conduct a comparison of the proposed algorithm with existing approaches.
- Improvement, if needed, of the method's performance and flexibility.
- Application to real clinical trials.
- This work may result in the publication of an article in a statistical journal.

Master of Science (MSc) in Biostatistics equivalent.

R and SAS skills are required. Knowledge in Bayesian methodology would be appreciated.



Suresnes (92)

6 months (2019)

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