

PHD STUDENTSHIP* IN BIOSTATISTICS

1. Introduction

Outline details of the studentship between UL and PAREXEL INT. are given below.

2. Main Objective.

2.1 The parties hereby agree that the main objective of the Research Project is to develop new statistical procedures for monitoring drug safety in Phase IV studies. Accordingly, this project is in the field of Pharmacovigilance. Current registry-based methods are expensive and the idea is to develop new methods, which are more economical, and to investigate their statistical properties in wide variety of practical population scenarios.

2.2 The Research Project requires the work of a PhD student (the “Researcher”) to develop the necessary statistical theory and to undertake the consequent simulations in order to demonstrate the potential cost advantages of the new designs

3. Research Project Outline

3.1 The Researcher will become familiar with the literature on case-control and case-cohort study methodology and the overall pharmacovigilance framework. In particular, he/she will absorb nested counter-matching methodology and become familiar with programming these statistical methods in R and SAS (IML).

3.2 The Researcher will develop simulation models mimicking Phase IV surveillance studies in which adverse events accrue according to pre-determined stochastic point process models and in which counter-matching designs have been implemented to attempt to identify the associated risk factors determining the adverse events.

3.3 The simulation scenarios will also cover most settings where on-going surveillance is considered feasible as well as in multi-centre trials settings post Phase III phase studies.

3.4 The objectives will be to understand how best to design effective Phase IV pharmacovigilance studies especially using prospective counter-matching strategies. This will include evaluation of effect size, sample size, recruitment strategies and data collection considerations especially as they impact on costs.

3.5 The ability of the proposed methods to cope with different generating mechanisms and unobserved confounders (for example by means of frailty) and time varying effects will also be evaluated. It will also be necessary to compare our new methods with alternative surveillance strategies and to evaluate their efficiency and quantify cost-savings, if any, under a wide range of scenarios.

3.6 It is anticipated that combination of theoretical model development and simulation will be required to assess the value of the proposal. It is likely that useful extensions of existing techniques will be uncovered and that completely new methods will be found.

3.7 The Research Project will be conducted in two major statistical paradigms: Classical & Bayesian. The latter will be useful when informative prior information is available.

3.8 The parties hereby agree that the main line of research shall be: using simulated data to work out main strengths and weaknesses of prospective case-cohort and the counter-matched nested case-control designs. Additional research topics shall be developed and agreed to by the Supervisors. Any changes to the Research Project outline set forth herein and/or to the main objective of the Research Project set forth in Section 2 above shall be agreed to by the parties.

4. Researcher & Supervision

The researcher will be supervised by Professors MacKenzie (UL) & Kiri (PAREXEL INT.) for the duration of the studentship.

5. Terms

The value of the studentship is c€25k per annum (see www.ircset.ie) . The student stipend is c€16k. The remainder covers fees up to EU level, limited travel and equipment.

*Further details including the IPR agreement between UL and PAREXEL, IRCSET terms & conditions and the full research agreement are available on application.