Post-doc position: Design and analysis of clinical trials for advanced therapy medicinal products at Hôpital Saint Louis, Paris, France

In the context of small clinical trials due to rare disease or patient subsets (targeted by the drug) or ethical concerns notably in frail populations (children, advanced diseases in refractory/relapsing patients, etc), the standard clinical evaluation process for advanced therapy medicinal products (ATMPs) such as cell therapy has been shown inefficient. To accelerate the process while ensuring patients safety, we need efficient, innovative and robust clinical trial designs.

So far, two main approaches have been used. The first one is to depart from the randomized control paradigm, avoiding randomization and switching to single-arm trials completed by an external indirect comparison, possibly from real-world data (RWD). The other is to propose adaptive designs, that allow flexibility over time while data accumulate along and outside the trial, and possibility combining sequential phases of drug development (phase I/II, II/III, etc). However, all innovative designs should not undermine the validity and integrity of the trial. This requires the use of biostatistical methods to carefully address the statistical issues of selection bias, multiple testing, post-hoc examinations, that possibly result in false decisions.

The post-doc will be based within the Department of Biostatistics of Saint Louis hospital in Paris, France (https://www.sbim-stlouis.org/) and work closely with both the Clinical Research Unit (Unité de Recherche Clinique, URC) of the hospital and the biostatistics research team ECSTRRA (Epidemiology and Clinical Statistics for Tumor, Respiratory, and Resuscitation, INSERM U1123) where they will benefit from real-life experience working with specialists on clinical trials, including ATMPs trials, early phase trials and causal inference. The objectives of the initial short-term proposal are to:

(a) Review existing literature of the design and analysis approaches of ATMP trials, including all phases and medical fields.

(b) Evaluate statistical properties and operating characteristics of selected trial designs and analysis strategies in a simulation study, representing the most commonly used approaches.

At least 1 peer reviewed publication is anticipated in a methodological/clinical trial journal, from the first part of the project.

This initial project is part of the Horizon Europe JOIN4ATMP consortium "*Map, join and drive European activities for advanced therapy medicinal product development and implementation for the benefit of patients and society*" (https://join4atmp.eu/). The supervisory team includes trial design expert methodologists Prof Sylvie Chevret, head of the Department and research team, and Dr Lucie Biard; The project will include consulting with other members of the JOIN4ATMP group to design and plan the study.

The initial proposal is for a 9-month post-doctoral contract with Assistance Publique – Hôpitaux de Paris, within the JOIN4ATMP consortium. The contract may be renewable to pursue further research projects in the team on statistical methods for the evaluation of ATMPs.

Requirements: PhD level in biostatistics, clinical epidemiology, with experience and proficiency in R programming.
Start date: As soon as possible, depending on administrative recruitment deadlines.
Duration: 9 months, with the possibility of extension.
Salary: Postdoctoral level; Assistance Publique – Hôpitaux de Paris salary scale.

HOW TO APPLY

For further inquiries, and to apply, please send your CV and cover letter to sylvie.chevret@u-paris.fr and lucie.biard@u-paris.fr .