Title: Innovative designs for early phase clinical trials

Position: 2 years postdoctoral fellowship, renewable 1 year (funding by the European Community)

Supervision: Sarah Zohar and Emmanuelle Comets

Location: Centre de Recherche des cordeliers, 15 rue de l'école de Médecine 75006 Paris

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We invite applications for a postdoctoral research position funded through a European project to work on "Innovative designs for early phase clinical trials", in the Centre de Recherches des Cordeliers at the University Paris 5. The post will be supervised by Dr Sarah Zohar and Dr Emmanuelle Comets. This is a 24 month fixed-term position, renewable for a further 12 months. The position is based in the center of Paris, and is available from June 1st, 2014. The project is part of a larger European initiative and offers ample opportunities for collaborative work with renowned experts in the field.

Early phase dose-finding studies are the first trials of a new medicinal product in humans and aim to obtain reliable information on an appropriate dose for use in further clinical trials. Sample sizes for such studies are typically small. Although efficient designs for dose-finding based on the minimum number of participants have been recently proposed, these methods generally relied primarily on observed safety data. There is a growing awareness of the need to use all the information gathered during these studies to better characterise the dose-concentration-effect relationship from an early stage to guide dose selection; in specific populations such as paediatrics, prior information may also be put to use.

The work will involve developing and evaluating methods taking into account safety, efficacy and pharmacokinetic/pharmacodynamic (PK/PD) measures. In a first step, the applicant will be expected to search for and compile relevant works from the literature, providing a landscape of current methods. Then, innovative model-based methods combining toxicity and safety measures with continuous or categorical PK/PD outcomes will be investigated. Simulations will play an intensive role in this work, and will be used to compare the methods in realistic settings. These novel design methods are expected to improve the estimation of the best dose level for further evaluation while ensuring the sample size for early phase trials is kept to a minimum.

The successful candidate will possess a completed or soon-to-be completed, doctorate in a relevant quantitative scientific discipline, such as biostatistics or statistics. Prior experience in pharmacokinetics and pharmacodynamics, basic to advanced knowledge of computer sciences and programming languages, an interest in the analysis of clinical trials, are essential. Prior knowledge and experience of pharmacometrics, including concepts of mixed-effect models and hands-on experience, is desirable.