Freie Universität Berlin

CLINICAL PHARMACY

The Department of Clinical Pharmacy and Biochemistry of the Institute of Pharmacy at the Freie Universitaet Berlin is currently looking for a:

Postdoctoral Research Fellow (m/v/d)

We are an interdisciplinary, international, research-oriented group applying high scientific standards and innovative methodologies with the ultimate aim to foster the rational use of medicines while empowering young scientists to perform clinically relevant research (http://www.clinical-pharmacy.eu/).

Our group is grounded on two research pillars: (1) Bioanalysis, microdialysis, cell culture, and (2) Pharmacometric (data) analysis. As key feature, the two pillars are bridged, as our pharmacometric projects are based on *in vivo* or *in vitro* data obtained by the experimental research pillar, while innovative dynamic in vitro systems utilise modelling and simulation approaches. In addition, many of our projects are realised as parts of clinical studies. Typically, our research is embedded in consortia at a national and international level (EU, global).

We are looking for a full-time postdoctoral fellow in the field of optimising drug therapy and drug development by applying innovative translational modelling and simulation techniques to join our research group for a period of at least 2 year; extension to 5 years is possible. To be eligible for the positions, a PhD and a strong record in the pharmacometric research area is needed. Additionally, experience in either or (i) evaluating pharmacokinetic, pharmacodynamic or systems pharmacology data and pharmacometric analysis with NONMEM, R or similar pharmacometric software, (ii) Bayesian analysis using STAN or similar platforms, or (iii) one of our experimental platforms (LC/MS-MS, microdialysis, bacterial infection models, in vitro metabolism) is required. The positions also offer supervision of PhD and Master/Diploma students.

Applications in English should include a letter of motivation along with a description of research interests and relevant qualifications for the position. In addition, a curriculum vitae including a list of publications and names/email addresses of 2-3 referees should be provided.

Please submit your application to: charlotte.kloft@fu-berlin.de

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Project summary

Currently, respiratory tract infections represent the third leading cause of death worldwide (about 3 million deaths per year). Bacterial pneumonia (either community- or hospital-acquired) is a leading cause of morbidity, quality-adjusted life year loss, and mortality in children, adults, and the elderly. In Europe, pneumonia costs €10 billion each year. Although antibiotics have transformed the management and treatment of bacterial pneumonia, their effectiveness is declining -because of antimicrobial resistance (AMR). The World Health Organization (WHO) estimates that bacterial infections due to AMR will outcompete any cause of death by 2050, meaning that it is crucial to develop new strategies to improve antibacterial treatment. In 2017, the WHO defined a priority list of bacteria for which new antibacterial therapies are urgently needed; it includes the major pneumonia-causing pathogens *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, and *Streptococcus pneumonia*.

The FAIR project (European grant H2020 -call SC1-BHC-14-2019) proposes a unique approach: aerosol delivery of an immunomodulatory protein (by nebulization), achieving direct release into the airways, prompting innate immunity activation in the lungs and preventing systemic immune activation. FAIR's objectives are to:

- develop nebulization modalities for optimal airway targeting and rapid action at the infection site
- demonstrate that nebulized flagellin strengthens the response to antibiotics in relevant preclinical models of antibiotic-resistant pneumonia
- identify host immune factors required for the gain of protection with systems biology
- implement pharmacokinetics/pharmacodynamics model-based design and simulation for clinical validation
- assess nebulized flagellin's safety in a Phase I clinical trial.
- analyze the acceptability and economic relevance of the therapy
- identify stratification markers that predict the course of pneumonia and treatment in antibiotic-treated cohorts.

The responsibility of work package 5 is to refine the preclinical experiments in cell-based and animal models (WP2, WP3, and WP4) by developing a PK/PD modelling and simulation, "ModSim" platform based on a combination of nonlinear mixed-effects (NLME) and physiologically-based (PB) modelling approaches (the 'middle-out' approach). This platform will be combined with a translational statistical model, in order to evaluate the dose-response relationship and enable dose-finding for the Phase I clinical trial (WP6) and the characterisation of the biologic's safety and PK profile in humans.

Please visit our website, https://www.clinical-pharmacy.eu for more information. The project is included in a research grant program "FAIR" (https://fair-flagellin.eu/) gathering European teams and coordinated by J.C Sirard, Inserm,Lille, France.

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Job profile

- Performance and publication of research projects in pharmacometric and translational modelling
- Contribution to EU project “FAIR” of the *Horizon 2020 initiative* (11 European partners from 6 different countries; Work package 5: Development of a translational modelling and simulation platform for flagellin PK/PD)
- Contribution to conception and realisation of new research ideas and collaborations
- General services in research (co-supervision of junior members; IT/Cluster contact) and research organisation

Qualification profile

Requirements:

- Graduation in Pharmaceutical or Life sciences or related field
- Qualified PhD thesis in Pharmacometrics, systems pharmacology or PBPK modelling, preferentially PK/PD modelling of therapeutic proteins

Assets:

1. Profound knowledge in pharmacometrics software: e.g. NONMEM/PsN, Berkeley-Madonna, Monolix, nlmxR or similar
2. Good knowledge in the software programs R, PKSim, STAN, Pirana or similar
3. In-depth experience in organisation and performance of research projects and in scientific publication in the area of pharmacometrics
4. Experience with or interest for *in vitro* work such as bacterial infection models, *in vitro* microdialysis or *in vitro* metabolism experiments.
5. High intrinsic motivation/high level of commitment
6. Excellent team player
7. Strong verbal/written communication skills
8. Language skills: English excellent