A vacancy in our Biostatistics Section is available for a

**Biostatistician (m/f/d)**

**The Paul-Ehrlich-Institut**
We are a senior federal authority responsible for vaccines and biomedicines that performs scientific research in the field of life sciences. Our institute networks with national and international players which makes it a competent partner for the general public, science, medicine, politics, and economics.

**About the Biostatistics Section**
Responsibilities of this section include the evaluation of applications for clinical trials, marketing authorisation applications for national and European marketing authorisations of medicines, and the participation in scientific advice of pharmaceutical companies and researchers. Besides, it supports our in-house working groups in performing and evaluating experiments and conducts in-house statistic and methodological research with focus on regulatory affairs.

**About the project**
The vacancy is available for an international EU-funded IMI project ([https://www.imi.europa.eu](https://www.imi.europa.eu)). The task of the IMI project EU-PEARL ([http://eu-pearl.eu](http://eu-pearl.eu)) is the exemplary development of adaptive integrated master protocols of four clinical indications (*Major Depressive Disorder*, MDD, *Tuberculosis*, TB, *Non-Alcoholic Steatohepatitis*, NASH, and *Neurofibromatosis*, NF) and to master methodological, operational, and regulatory challenges. The project is carried out in close co-operation with European universities and research centres, the European pharmaceutical industry ([European Federation of Pharmaceutical Industries and Associations](https://www.efpia.eu), EFPIA), small and medium-sized enterprises (SMEs), patient advocacy organisations and regulatory authorities.

**Your responsibilities**
- Development and evaluation of study designs for integrated platform studies
- Methodological (further) developments of group sequential and adaptive trial designs (e.g. error control and bias)
- Assessment of regulatory and operational aspects (e.g. Informed Consent, Protocol Amendments)
- Representation of the PEI as regulatory partner within and outside the project
- Supervising PhD students would be desirable

**Our requirements**
• Academic degree in statistics, biostatistics or mathematics with focus on statistics or equivalent academic degree
• Successful PhD or comparable experience in research in a relevant subject area
• Relevant experience in the field of group sequential and adaptive designs is required
• Practical experience in Bayesian clinical trials would be an advantage
• Experience in the implementation of a broad spectrum of methods of statistical analysis procedures
• Experience in the statistical advice during the planning and evaluation of clinical studies
• Practical experience with statistical data analysis systems (preferably R)
• Thorough understanding of medical and biological relations
• Special interest in regulatory issues
• Excellent team-playing and communication skills
• Interest in contributing to interdisciplinary and international teams
• Able to work without supervision, care and conscientiously
• Enjoy regular business travels within Europe
• Excellent English language skills, written and spoken (and basic knowledge of German) are a must

Please note that at the time of entering into an employment contract, a Declaration of Interest must be made with the EMA as well as a declaration pursuant to Section 77a AMG (German Medicines Act).

Our offer
A versatile challenging workplace in the centre of the Rhine-Main area with good communications (motorways, airport, commuter train). Being an employer in the public sector, we offer the usual social benefits of such an employer including annual bonus, retirement pension-scheme of the public sector, and employer-based savings schemes.

The successful candidate will be employed on a 2-year fixed-term contract with the possibility of an extension. Part-time working is possible in principle. In this case, an appropriately extended term of the contract (up to 30 April 2023 maximum) could be agreed. The payband is E 14 TVöD (Tarifvertrag für den öffentlichen Dienst, Collective Bargaining Agreement for the Public Service), Part III No. 12 of Annex 1 of TVEntgO Bund (Tarifvertrag über die Entgeltordnung des Bundes, Collective Bargaining Agreement for the Pay System of the Federal German Public Service). The assignment to a payband is made based on the consideration of your individual professional experience. Disabled candidates will be given preference if their skills and qualifications are equivalent to those of non-disabled candidates. The Paul-Ehrlich-Institut encourages gender equality and life-work balance, especially in respect to the family. For this purpose, we have various employment models to offer including flexible working hours (different forms of part-time work, flexible working from home, teleworking, no core time), child care facilities, and various opportunities for further professional training.

Please send your application containing your job related education and skills to our job application portal (blue button) by 30 August 2020 indicating JobID 477.

For questions related to the job profile please contact the head of the Biostatistics Section PD Dr Benjamin Hofner (email: benjamin.hofner@pei.de, phone: +49 6103/77-3722). For questions related to the job application procedure, please contact Ms Melanie Peters (email: karriere@pei.de, phone: +49 6103/77-1143).

We look forward to your job application.

Please note that the German Federal Ministry of Health will in some cases (if required) be authorised to inspect your application documents (Section 6 (1), No. C, General Data Protection Regulation (GDPR) in connection with Section 2 (1) Gemeinsame Geschäftsordnung der Bundesministerien (joint rules of procedure of the federal ministries), and Article 65 of the German Constitution (Grundgesetz, Fundamental Law) to ensure a staff selection which fulfils its purpose and is in the interest of all parties involved. Your data will be erased immediately after the application procedure has been completed.