Offer #2025-08764

Researcher in clinical evaluation and regulation of Digital Medical Devices

Contract type : Fixed-term contract

Renewable contract : Yes

Level of qualifications required : Graduate degree or equivalent

Other valued qualifications : Master's degree or PhD (preferred) in public health, epidemiology or biostatistics, health economics, pharmacy, medicine, sciences, or engineering.

Fonction : Tempary Research Position

Context

HeKA (https://team.inria.fr/heka/) is a multidisciplinary research team specializing in biomedical informatics, biostatistics, and applied mathematics for digital health. The team focuses on developing learning health systems that leverage multimodal health data (e.g., electronic health records, clinical trials) to improve precision medicine and healthcare quality. HeKA collaborates with leading institutions across Europe to advance digital innovations in healthcare.

The HeKA team at Inria, Inserm, and University Paris Cité is seeking a motivated researcher to join the SMATCH (Statistical and AI based Methods for Advanced Clinical Trials CHallenges in Digital Health) project, which is part of the PEPR (“ *Programme et Equipements Prioritaires de Recherche”* - Priority Research Programs and Equipment) *Santé Numérique* (Digital Health). The objective of the SMATCH project is to develop and apply statistical and AI- based methods with the ultimate goal of accelerating the development of medical interventions (drugs and DMDs) during their evaluation in clinical trials. The consortium is made up of 16 teams, mainly from Inria and Inserm Centers recognized in this field, bringing a

unique and complementary expertise in data sciences and AI applied to health problems and specifically to clinical trials.

AI-based computational models can be used by health care professionals or patients within DMD (using the definition of EU regulation 2017/745) aiming at preventing, diagnosis, monitoring, treating or alleviating disease. These devices impact the health outcome of individuals as any other treatment, but they present many methodological challenges in their clinical evaluation. Further, regulators, are struggling in approving and labelling these DMDs as the clinical evidence provided by stakeholder is heterogeneous. This position will contribute to the development of a framework and guidelines for trials or study designs that could be used to evaluate DMDs. This work will be done with the collaboration of the Digital Health department of the HAS.

Assignment

The recruited researcher will focus on the following key tasks:

- Coordinate the scientific work with all collaborators involved in the task led by Inserm.
- Assess existing designs concerning artificial intelligence (AI) based Digital Medical Devices (DMDs) and interoperable devices.
- Analyze, based on the clinical evidence and clinical studies (as clinical trials or real-world data – RWD - analysis), the DMDs that got reimbursement agreement from the French Health Technology Assessment (HTA) body HAS ("*Haute Autorité de Santé*") and those that did not.
- Identify the needs concerning DMD designs that did not meet the "evidence threshold" and HAS requirements, i.e., published methodological guidelines by HAS.
- Study existing requirements for DMDs in various European Union (EU) Member States (e.g., France, Germany, Belgium).
- Develop a framework and guidelines of trial or study designs that could be used to evaluate DMDs according to each subtype, i.e., therapeutics, diagnostics, monitoring, disease management using either hardware with software or software alone, in EU.
- Collaborate with HAS to cross-validate findings.

Main activities

- Evaluate the methodological needs in innovative designs for accelerating access of innovation to patients.
- Conduct literature reviews on DMD clinical evaluation and reimbursement frameworks.
- Design and implement methodologies for evaluating DMDs.
- Write scientific articles and present findings at conferences.
- Organize regular meetings with project collaborators.

Skills

Technical skills and level required :

- Proficiency in statistical software or programming languages like R or Python.

Languages :

- Fluent in French and English (B2 lever or higher).

Relational skills :

- Strong team collaboration skills.

Other valued appreciated :

- Ability to work independently while contributing to a multidisciplinary team.

Benefits package

- Subsidized meals
- Partial reimbursement of public transport costs
- Leave: 7 weeks of annual leave + 10 extra days off due to RTT (statutory reduction in working hours) + possibility of exceptional leave (sick children, moving home, etc.)
- Possibility of teleworking (after 6 months of employment) and flexible organization of working hours
- Professional equipment available (videoconferencing, loan of computer equipment, etc.)
- Social, cultural and sports events and activities
- Access to vocational training
- Social security coverage

General Information

- **Theme/Domain :** Optimization, machine learning and statistical methods Statistics (Big data) (BAP E)
- **Town/city :** Paris
- **Inria Center :** Centre Inria de Paris
- **Starting date :** 2025-05-01
- **Duration of contract :** 2 years
- **Deadline to apply :** 2025-05-31

Contacts

- **Inria Team :** HEKA
- **Recruiter :**
  Boulet Sandrine / sandrine.boulet@inria.fr

About Inria

Inria is the French national research institute dedicated to digital science and technology. It employs 2,600 people. Its 200 agile project teams, generally run jointly with academic partners, include more than 3,500 scientists and engineers working to meet the challenges of digital technology, often at the interface with other disciplines. The Institute also employs numerous talents in over forty different professions. 900 research support staff contribute to the preparation and development of scientific and entrepreneurial projects that have a worldwide impact.

The keys to success

- Expertise in public health (epidemiology or biostatistics) or Health Economics and Outcomes Research (HEOR).
- Training/expertise in the digital field.
- Knowledge of DMDs.
- Familiarity with EU regulations such as HTAR, MDR, AIA, and EHDS.

Warning : you must enter your e-mail address in order to save your application to Inria. Applications must be submitted online on the Inria website. Processing of applications sent from other channels is not guaranteed.

Instruction to apply

Defence Security :
This position is likely to be situated in a restricted area (ZRR), as defined in Decree No. 2011-1425 relating to the protection of national scientific and technical potential (PPST).Authorisation to enter an area is granted by the director of the unit, following a favourable Ministerial decision, as defined in the decree of 3 July 2012 relating to the PPST. An unfavourable Ministerial decision in respect of a position situated in a ZRR would result in the cancellation of the appointment.

Recruitment Policy :
As part of its diversity policy, all Inria positions are accessible to people with disabilities.