



Offre n°2025-08764

Researcher in clinical evaluation and regulation of Digital Medical Devices

Type de contrat : Fixed-term contract

Contrat renouvelable : Oui

Niveau de diplôme exigé : Graduate degree or equivalent

Autre diplôme apprécié : Master's degree or PhD (preferred) in public health, epidemiology or biostatistics, health economics, pharmacy, medicine, sciences, or engineering.

Fonction : Tempary Research Position

Contexte et atouts du poste

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.

Mission confiée

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.

Principales activités

- 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.

Compétences

Technical skills and level required :

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

Languages :

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

Relational skills :

- Strong team collaboration skills.

Other valued appreciated :

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

Avantages

- 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

Informations générales

- **Thème/Domaine** : Optimization, machine learning and statistical methods
Statistics (Big data) (BAP E)
- **Ville** : Paris
- **Centre Inria** : [Centre Inria de Paris](#)
- **Date de prise de fonction souhaitée** : 2025-05-01
- **Durée de contrat** : 2 years
- **Date limite pour postuler** : 2025-05-31

Contacts

- **Équipe Inria :** [HEKA](#)
- **Recruteur :**
Boulet Sandrine / sandrine.boulet@inria.fr

A propos d'Inria

Inria est l'institut national de recherche dédié aux sciences et technologies du numérique. Il emploie 2600 personnes. Ses 215 équipes-projets agiles, en général communes avec des partenaires académiques, impliquent plus de 3900 scientifiques pour relever les défis du numérique, souvent à l'interface d'autres disciplines. L'institut fait appel à de nombreux talents dans plus d'une quarantaine de métiers différents. 900 personnels d'appui à la recherche et à l'innovation contribuent à faire émerger et grandir des projets scientifiques ou entrepreneuriaux qui impactent le monde. Inria travaille avec de nombreuses entreprises et a accompagné la création de plus de 200 start-up. L'institut s'efforce ainsi de répondre aux enjeux de la transformation numérique de la science, de la société et de l'économie.

L'essentiel pour réussir

- 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.

Attention: Les candidatures doivent être déposées en ligne sur le site Inria. Le traitement des candidatures adressées par d'autres canaux n'est pas garanti.

Consignes pour postuler

Sécurité défense :

Ce poste est susceptible d'être affecté dans une zone à régime restrictif (ZRR), telle que définie dans le décret n°2011-1425 relatif à la protection du potentiel scientifique et technique de la nation (PPST). L'autorisation d'accès à une zone est délivrée par le chef d'établissement, après avis ministériel favorable, tel que défini dans l'arrêté du 03 juillet 2012, relatif à la PPST. Un avis ministériel défavorable pour un poste affecté dans une ZRR aurait pour conséquence l'annulation du recrutement.

Politique de recrutement :

Dans le cadre de sa politique diversité, tous les postes Inria sont accessibles aux personnes en situation de handicap.