Senior Advisor, Regulatory Affairs

The International Digital Health & AI Research Collaborative (I-DAIR)
Deadline for submissions: 23 December 2020

Background

The International Digital Health & AI Research Collaborative (I-DAIR) is a Geneva-based non-profit initiative for the inclusive, responsible and innovative use of data and digital technologies for global health. We are currently funded by some of the leading foundations in the area of health and innovation, and our partners are pursuing exciting and cutting-edge work in digital and artificial intelligence (AI) - based applications for health across the globe.

The goal of the initiative is to co-create a neutral trusted platform for enabling global research collaborations on digital health and AI for health, and for convening stakeholders to develop and share global public goods as well as solve problems for the inclusive, equitable and responsible deployment of data and AI for health. We are a small but fast-growing and highly diverse team, currently working in a hybrid format (remotely and at our HQ in Geneva, Switzerland).

A series of pathfinder projects in areas such as a global research map, real time epidemiology and dashboards, data architectures and data interoperability, bridging research and practice communities through micro-narratives, experience sharing and capacity-building, and governance for AI and data for health are currently being developed and implemented. These projects serve as a prelude to further development of the platform, which is currently incubated within the Global Health Centre (GHC) at the Graduate Institute, Geneva, and its formal launch in 2022.

I-DAIR is currently looking for a Senior Advisor, Regulatory Affairs to lead its engagement with regulators bodies and standards setting agencies. This position will be full-time, and the location is flexible, though preference will be given to candidates based in Geneva, Switzerland. The expected start date is February 2021 (negotiable).

Job Description

The primary role of the Senior Advisor, Regulatory Affairs will be to lead the I-DAIR engagement with national, regional and international regulatory bodies and standards setting agencies of relevance for digital health and AI for health. The purpose of the engagement is to ensure key stakeholders and decision makers are informed of the I-DAIR work and initiatives, and to convene them regularly with a view to promote and build the case for a new generation of human-centered governance and benchmarking frameworks and tools co-created by I-DAIR, its partners and co-conveners. The Senior Advisor will work alongside the I-DAIR’s Senior Advisors on Science Engagement and Business Development, as well as the Engagement and Governance Leads, to ensure alignment of efforts. Key duties include:
- Map the regulatory landscape globally with a focus on geographies hosting I-DAIR’s hubs; maintain up-to-date knowledge of global regulatory landscape, including requirements, precedents, new regulations and laws that may affect digital health and AI for health; create and maintain regulatory dossiers (for select countries) including information relevant to I-DAIR pathfinder projects;
- Define the regulatory affairs engagement strategy for assigned pathfinder projects and ensure implementation – first priority being engagement strategy with regulators on benchmarking; provide advice to I-DAIR leadership on regulatory discussions/negotiations with the competent authorities on regulatory issues related to I-DAIR pathfinder projects;
- Engage, convene and help create consensus among regulators and other key stakeholders such as the WHO on the next generation of regulatory and benchmarking standards for digital health;
- Develop, maintain and deepen effective relationships with regulatory bodies (IMDRF, FDA, EMA, and others from priority countries) to ensure key stakeholders and decision makers are informed of relevant I-DAIR work in digital health and AI for health; and consider I-DAIR’s work as a credible source of insights and input into their policy work;
- Build and fortify key relationships with other priority stakeholders in the digital/AI governance and regulatory landscape (for instance WSC (ISO, ITU AND IEC), IEEE, OECD, GPAI), seeking to develop and execute scientific, regulatory policy and other collaborative initiatives with them that advance digital health and AI for health.

Experience

- Minimum 8 years of progressively responsible and significant experience working in public health regulatory affairs and/or public policy with significant cross-country and cross-cultural exposure;
- Significant experience working in public health, experience in digital health and AI for health strongly preferred;
- Excellent working knowledge of relevant regulatory bodies at national, regional and international level and their requirements; practical experience with EU/European and US regulatory requirements (EMA, FDA) and their implementation strongly preferred;
- Existing networks and successful experience in engaging global leaders from the public sector;
- Demonstrated experience working within or interacting with government policy and regulatory bodies on scientific and regulatory policy topics, understanding of decision-making and regulatory processes;
- Demonstrated experience in successfully managing regulatory challenges and/or complex development programs;
Experience building up new partnerships, particularly related to start up / pilot projects strongly preferred;

Proven ability to identify opportunities and influence outcomes;

Significant cross-country and cross-cultural exposure.

Education/Qualifications

- Master’s degree in a scientific discipline, public health, politics, law or other relevant field;
- Strong knowledge and substantial understanding of current operational and policy trends in public health, digital health, data and AI;
- Strong knowledge of regulatory environments for health and digital technologies;
- Excellent knowledge of English, with fluency in other languages an added advantage (especially French, Spanish, Mandarin, Russian or Arabic).

Personal skills and competencies

- Demonstrated success at developing collaborative and effective relationships;
- Self-motivated and proactive with a sense of urgency, with proven ability to prioritize and focus on key objectives;
- Solution-oriented and innovative; can identify creative options for resolving issues that respond to multiple stakeholder interests and needs;
- Excellent networking and diplomatic skills;
- Excellent verbal, representational and written communication skills;
- Demonstrated cultural sensitivity and interpersonal skill;
- Passion for learning and a «start-up mindset».

How to apply

Applications should be submitted in English and by email only. The following set of documents is required:

- A cover letter explaining your suitability to fulfil this assignment (2-page limit);
- A personal CV detailing relevant past experiences, as well as indicating the current location and nationality / work permit for Switzerland (if applicable).

Complete applications should be sent to the Project Manager, Ms. Anna Brezhneva (anna.brezhneva@graduateinstitute.ch) with the subject “Application: Senior Advisor, Regulatory Affairs”. Please include the required attachments merged into one PDF.

Deadline for submissions: 23/12/2020 (midnight, CET). Please note that incomplete or late applications will not be accepted.
Due to the large number of applications, we are only able to inform the successful candidates about the outcome or status of the selection process.