

# Post-Doctoral Fellowship in Pediatric Real-World Evidence Research

at the Harvard-MIT Center for Regulatory Science

## ABOUT THE FELLOWSHIP PROGRAM

The Harvard-MIT Center for Regulatory Science is a partnership between Harvard, MIT and the FDA, focused on building innovative approaches for the development and evaluation of medical products. Working across academia, industry, and government institutions, the Center promotes regulatory science through research and education programs, uniting stakeholders under a common mission: to promote optimal patient health outcomes through biomedical innovation and the availability of safe and effective treatments.

Regulatory science brings together a range of scientific disciplines to assess the quality, safety, and effectiveness of therapeutics, helping to inform regulatory decision-making over the lifecycle of drugs, devices, and vaccines. The Regulatory Science [Fellowship Program](#) draws individuals with diverse expertise who are passionate about developing and applying novel methods in therapeutic science and contributing to the multi-disciplinary community of the Center.

## About the position

The Harvard-MIT Center for Regulatory Science, in close collaboration with the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Boston Children's Hospital, all at Harvard Medical School, is seeking a post-doctoral research fellow interested in the intersection of pediatric real-world evidence research with regulatory science. This includes pharmacoepidemiology research as it relates to the supplemental regulatory approval of medications for pediatric use. Up to 50% of medications in the outpatient setting and 80% in the inpatient setting are used off-label in pediatric patients. There is increasing interest in evaluating the suitability of real-world evidence studies to form the basis for supplemental regulatory approval of medications to be used in pediatric patients that were previously approved in adult patients. The fellow will conduct pediatric pharmacoepidemiology studies of medication safety and effectiveness using large claims and electronic health record data sources and studies how it impacts the regulation of medications in children.

The Division of Pharmacoepidemiology is internationally leading in training and research on the safety and effectiveness of medications applying advanced analytic methods to diverse large healthcare databases. It houses the FDA Sentinel Innovation Center and is working closely with FDA, EMA and NIH on a range of projects relevant to regulatory science. For this position, the fellow will work directly under the mentorship of Drs. Sebastian Schneeweiss and Tim Savage and with Dr. Florence Bourgeois, Co-Director of the Harvard-MIT Center for Regulatory Science. The fellow will be expected to participate in international conferences and publish conference and journal papers.

**Unique aspects of this fellowship program include:**

- Access to FDA scientists and collaborations on FDA projects
- Participation in an established multi-disciplinary community, enabling educational experiences and research activities outside of a single field of expertise
- Access to clinicians and investigators at multiple large healthcare centers, providing opportunities for research projects with direct medical applications

**BASIC QUALIFICATIONS**

- Individuals with doctoral degrees (MD, PhD, PharmD, or equivalent) and training or experience in healthcare data science, clinical pediatrics, clinical pharmacology, pharmacoepidemiology, epidemiology, or health services research

**APPLICATION PROCEDURE AND REQUIREMENTS**

Please include the following in the initial application:

- Curriculum vitae
- Cover letter
- Research statement describing the applicant's research interests, including a description of the relevance to regulatory science in pediatric populations
- Writing sample or up to three relevant publications

If selected to submit a full application, candidates will be interviewed and asked to provide:

- 3 letters of reference
- Project description (3 pages maximum) that includes justification for the work, specific research objectives, proposed methods, and the project's broader relevance and implications for regulatory science. The project description may be developed jointly with the mentor following submission of the initial application.

**POSITION DESCRIPTION**

Host Institution: Harvard Medical School

Appointing Department: Harvard Program in Therapeutic Science

Location: Boston, MA

Category: Research Fellow

Other responsibilities: no administrative or teaching obligations

Duration of fellowship: 2 years

## **EEO STATEMENT**

We are an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, gender identity, sexual orientation, pregnancy and pregnancy-related conditions or any other characteristic protected by law.

## **CONTACT**

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