

**Undergraduate Student Research Project**

**MIT Center for Biomedical Innovation – NEWDIGS Program**

**Project Title:** A global lifecycle data map for pharmaceuticals

**Project Description:**

A number of pathways have been established in recent years to offer patients earlier access to new treatments under certain conditions. In addition, the European Medicines Agency (EMA) has recently launched pilots for Adaptive Licensing (AL) in an effort to improve timely access to new drugs for patients. The EMA AL pilot builds on work conducted at MIT's Center for Biomedical Innovation (CBI) within the NEWDIGS program.

Critical to these early access pathways is the need to collect and analyze data on the safety and effectiveness of new medicines in order to reduce uncertainty related to their use over time. In turn, this information supports decisions to be made on the drug by various stakeholders including physicians, patients, regulators, HTA bodies, payers and industry sponsors.

Multiple countries and organizations collect various types of data on diseases and on the use of medications, including electronic health records, claims data and clinical trial results. The goal of this project is to create a global map of the different data sources available along with a brief description of the type(s) of data collected, scope of the database (for example, number of patients included, disease-focused or not, limited to a geographic region or not, etc.) and administrative characteristics (data ownership, funding, etc.). This global lifecycle data map will then be used to support activities of the NEWDIGS Program related to the facilitation of cross-system and cross-jurisdiction sharing of data to support the ongoing monitoring of medicines once they become available on the market.

**Responsibilities:** Working with the project manager, the student will create a system to evaluate and characterize the databases. He/she will then use a systematic approach to identify and describe the relevant data sources available in the United States and major European countries. Possible project expansions include the addition of mid- and low-income countries and/or the mapping of stakeholder decisions to the appropriate data sources.

**Commitment:** 15-20 hours per week during the summer with possibility to continue during the Fall semester (hours may be adjusted as needed). The rate for this position is \$15/hour.

**To Apply:** Please e-mail your resume, unofficial transcript and a brief summary of your interest in the position to Sophie Desbiens at [sophied@mit.edu](mailto:sophied@mit.edu).