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Practicum Opportunity Site

Johns Hopkins School of Public Health

**Name of Organization/Agency:**

Food and Drug Administration/CBER/Office of Biostatistics and Epidemiology

Purpose or Mission of Organization/Agency:

Protect and enhance public health through promoting the development and licensure of effective and safe drugs and biologics.

Practicum Title:

Development of epidemiological model to evaluate the benefit-risk of biologics and drugs for prevention and treatment of COVID-19

Brief Practicum Description & Proposed Approach:

There are many models being developed for forecasting COVID-19 related infections, deaths, and medical resource utilization associated with a variety of operational risk mitigations such as community closure and social distancing etc. However, no model has been constructed to incorporate the potential effects of vaccines and drugs on prevention and treatment of the disease and assess their impact on disease dynamics. The effects of vaccines and drugs will become important aspects of the model as we anticipate some of these products will be available in the foreseeable future. We propose to extend the quantitative frameworks from established SIR-type models and develop a model that can provide a tool for benefit-risk assessments of CBER-regulated products assisting the review process at the agency. Also, the proposed framework will be instrumental in performing epidemiological forecasting that can support policy-making decisions. The modeling framework will be able to assess multiple products individually and/or together, stratified by important risk factors.

Practicum Goals:

To develop a quantitative epidemiological model to assess the benefits/risks of potential therapeutic interventions and their impact on the epidemiology of COVID-19

Examples of work the intern could accomplish during the placement:

1. Modify an established SIR model and identify data sources needed for assessment of benefits-risks of vaccines and drugs and benefit-risk profiles for different populations.
2. Assess model performance through goodness-of-fit, model validation, uncertainty analysis.
3. Create a user manual of the tool
4. Contribute to writing up a manuscript about the tool for eventual submission to a peer-reviewed journal

All work will be completed in collaboration with experienced statistical modelers in the Office of Biostatistics and Epidemiology. The student may have additional opportunities to gain exposure to the work of the Office as well as the FDA more broadly - details to be worked out between the student and preceptor depending on student experience, interests, and start date.

Practice Activities:

Analyze Data (Primary or Secondary)
Attend and Participate in Inter and/or Intra Agency Meetings
Review Literature
Write Report
Other - Develop epidemiological model

Skills needed by the student to complete the practicum:

Required: High proficiency in R/Python programming languages, MS Office (Excel, Word). Ability to apply working knowledge of statistics/probability theory, ODEs, and other relevant mathematical concepts to model disease epidemiology.

Preferred: Working knowledge of GitHub a plus.

Number of students requested for this practicum:

1

Anticipated time commitment needed for one student (hours per week):

10

Anticipated Total Practicum Hours:

100

Expected START DATE for practicum:

Expected END DATE for practicum:

5/1/2021

Location and Travel

Practicum Area:

Street:

City:

State:

Zip:

Country: UNITED STATES

Primary Location:

Remote Work Acceptable

Routes that can be used to access the organization:

Compensation?:

No

Additional details from preceptor:

Start date is flexible, but we are looking for a student to start as soon as possible. Total hours may exceed 100 depending on student's level of experience with this work.

All work can be completed virtually/remotely.

Application Procedure:

Please provide a cover letter and resume highlighting all relevant programming and/or modeling experience to: Hong.Yang@fda.hhs.gov.

NOTE: This position has **Restricted Student Eligibility**: Completion of a successful background investigation by the Office of Personnel Management (OPM) is required for an applicant to be on-boarded at FDA. **OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.**

You must currently be residing in the US and meet all criteria above to be able to apply. Unfortunately international applicants are not eligible.

Organization URL:

<https://www.fda.gov/home>

Deadline to submit application materials:

Application will remain open until filled. Note: You may want to check the status of the project with the preceptor before submitting your application materials.