

Application Form for Clinical Trial Design Lab

June 29th and 30th, 2020

Boston, MA

Call: The JHU-Tufts Trial Innovation Center is looking for investigators who are interested in pursuing innovative clinical trial designs to participate in a Design Lab. The Design Lab, jointly run by the Tufts Institute for Clinical Research and Health Policy Studies and the MIT Center for Biomedical Innovation, will explore innovations in clinical trial design in the context of the full treatment development pathway, with a particular focus on innovative clinical effectiveness trial design. Two examples of innovative designs explored in recent Design Labs include efficacy-to-effectiveness (E2E) trials and efficacy and effectiveness too (EE2) trials, as outlined below.

Efficacy-to-Effectiveness (E2E) Trials

Innovative trials that begin with an *efficacy* trial, which tests how a treatment works under ideal conditions, and then seamlessly transitions to an *effectiveness* trial, which tests how the treatment works in usual care settings, by expanding eligibility and endpoints while the drug is under regulatory review.

Efficacy and Effectiveness Too (EE2) Trials

Innovative trials that incorporate both *efficacy* and *effectiveness* trials into a single trial, with a study sample that includes a cohort to address efficacy as well as a wider range of patients.

The Design Lab: The purpose of the Design Lab is to explore approaches to clinical effectiveness evidence development, with a focus on different stakeholders, including patients, payers, regulators, healthcare providers and others. The Design Labs are organized according to the needs of the project being discussed. The Lab may be a half or full day session that involves a presentation by the investigator and team, and a robust discussion by a diverse multi-stakeholder group of participants.

Presentations: Investigators will develop a briefing book that outlines their proposed project, with input from Tufts and MIT. The book will be distributed to Design Lab attendees, under confidentiality agreements if required. They should include:

1. the traditional development and marketing plan with expected outcomes and metrics, as well as
2. a non-traditional scenario with the same metrics and a comparison of expected outcomes between the two scenarios.

Important Dates:

- Application form returned by January 30th, 2020
- Selection on February 6th, 2020
- Design Lab on June 29th and 30th, 2020

Application: Please answer the questions on the following page, limiting your response to two pages (excluding appendices), save your responses as a .pdf, and submit them to Marisha Palm at mpalm@tuftsmedicalcenter.org no later than 5pm EST on January 30th, 2020.

General Information

Investigator Name:

Investigator contact details (e-mail and phone):

Project Specific Information

Project Title:

Funding source or intended funder and submission deadline:

Proposed number of sites:

Proposed number of subjects:

Condition to be treated:

Description of unmet medical need:

Brief background to the proposed trial, including regulatory status:

- Development phase
- Mechanism of action
- Recommended dosage & frequency

Target indication and treatment population:

Definition of the target population:

At initial authorization, interim authorization, full authorization:

- Timelines
- Length / course of treatment

Areas of expertise you would like to have contribute to the discussion at your Design Lab:

Rationale for pursuing an innovative approach to including effectiveness:

- Expected benefits for you
- Benefits/Costs for other key stakeholders (regulators, payers, providers, patients)

Describe the challenges and opportunities that this approach would create for your research:

Questions

Queries regarding the completion of this form are welcome and should be directed to Marisha Palm, mpalm@tuftsmedicalcenter.org