

Call for Applications:

2021 Design Labs in Clinical Effectiveness Trial

Are you a clinical investigator looking to design and run an innovative clinical trial that will inform real-world practice?

Are you pursuing an innovative clinical trial design and would like expert and stakeholder feedback to advance your design and trial?

If so, consider applying to take part in our 2021 Innovations in Clinical Effectiveness Trial Design Lab!

Application Deadline:
May 7, 2021

The **Johns Hopkins University-Tufts Medical Center Trial Innovation Center (JHU-Tufts TIC)** is looking for clinical investigators who are interested in pursuing innovative clinical trial designs to participate in its annual Design Lab workshops.

The Innovations in Clinical Effectiveness Trial Design Labs, jointly run by the Tufts Medical Center Institute for Clinical Research and Health Policy Studies and the MIT Center for Biomedical Innovation, explore innovations in clinical trial design in the context of the full development pathway for drugs and new treatments, with a particular focus on innovative clinical effectiveness trial design.

Please review the following pages for more information and how to apply.



Application Form for Clinical Trial Design Lab

2021

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. Three examples of innovative designs are outlined below efficacy-to-effectiveness (E2E) trials, efficacy and effectiveness too (EE2) trials, and N-of-1 trials.

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.

N-of-1 Trials

An N-of-1 trial is a clinical trial done in a single patient using multiple crossover trials, usually randomized and often blinded. Multiple N-of-1 trials can be combined to effectively constitute a cross-over design clinical trial.

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 May 7th 2021
- Design Lab to be held in Fall 2021

Application: Please answer the questions on the next 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 May 7th 2021.

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
- of subjects

Condition to be treated:

Description of unmet medical need:

Brief background to the proposed trial, including regulatory status:

Target indication and treatment population:

Length/course of treatment (if applicable):

Definition of the target population:

Project Timeline:

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