2024 Design Labs

FACT SHEET

What is a Clinical Trial Design Lab?

A Clinical Trial Design Lab is a method to support investigators who want to develop innovative approaches to clinical effectiveness trial design. It begins with an expert consultation to prepare investigators for a multi-stakeholder event that includes participants from across the treatment development pathway. The event is typically a full day and involves clinicians, patients, researchers, funders, industry experts, policy experts, regulatory experts, and payers.

Who is part of the expert consultation?

The investigator and their team are invited to a series of expert consultation meetings prior to the Design Lab event. These meetings include clinical trialists and clinicians, as well as statistical, regulatory, and stakeholder engagement experts. They prepare investigators for the event by supporting the mapping of relevant stakeholders and the development of a briefing book. They also help investigators to consider innovative design options and hone questions to ask the multi-stakeholder group.

Who is invited to a Clinical Trial Design Lab event?

Design Lab events are by invitation only. The consultation team works with the investigator team to understand who the study stakeholders are and to invite expert participants who have a variety of different perspectives and expertise. Participants are carefully selected, provided with a briefing book ahead of the event, and sent a write-up report after the event.

What does the Design Lab event involve?

The Design Lab event begins with an overview and framework, then the investigator team provides an introduction to their clinical trial, and there is facilitated time for questions before structured break out group discussions and synthesis. The event operates under the Chatham House Rule, which means that Design Lab participants are free to share themes from the discussion but asked not to attribute them to any individual or affiliated organization.

If my proposal is successful, what can I expect?

If your proposal is successful, we will set up a kick off call to discuss your project. You will be invited to a total of three calls with the entire expert consultation team and other ad hoc meetings with sub-groups as needed. You will receive structured templates and support to develop your project briefing book and questions for the event.

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Questions? **Contact Ellaina Reed, ellaina.reed@tuftsmedicine.org**

How would I maintain confidentiality and/or protect my intellectual property?

We ask all expert participants not to disclose the specifics of the clinical trials that are discussed at the Design Lab. The briefing books and follow-up reports are sent as confidential and we ask people not to circulate them to those who were not at the event. If you would prefer to have participants sign a Confidential Disclosure Agreement, our team can facilitate this process.

What are examples of innovative clinical effectiveness trial design?

There are several innovative clinical effectiveness trial designs, including but not limited to: effectiveness-implementation hybrid trial design, registry-based randomized trials, decentralized trials, micro-randomized trials, multi-stage randomized trials (i.e. SMART trials), point-of-care clinical trials, and adaptive trials. Three trial designs that we have used in previous Design Labs are explained below.

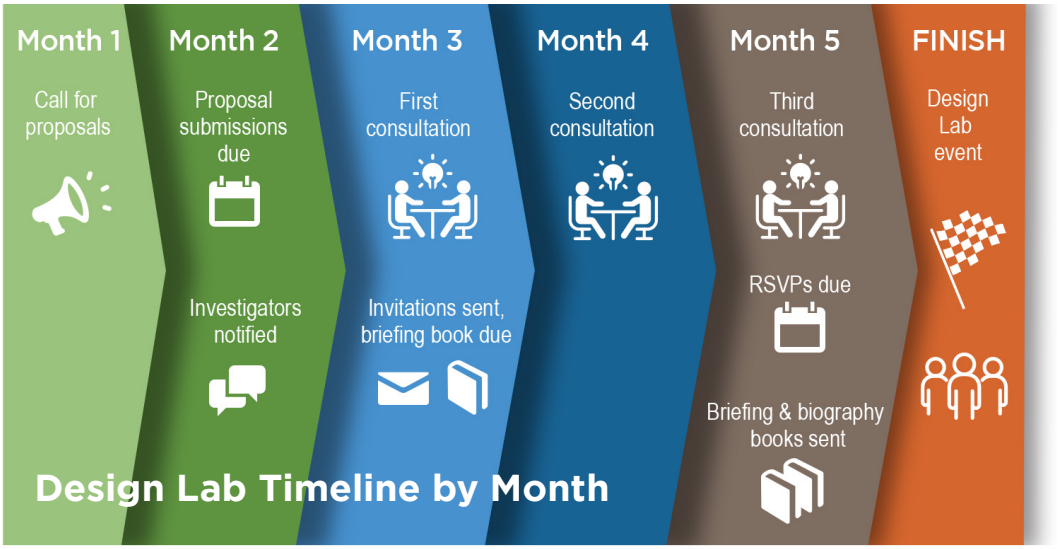
Efficacy-to-Effectiveness (E2E) Trials • Innovative trials that begin with an *efficacy* trial, which tests how a treatment works under ideal conditions, and then seamlessly transitions to an *effectiveness* trial, which tests how the treatment works in usual care settings, by expanding eligibility and 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.

N-of-1 Trials • 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.

What is the timeline for a Clinical Trial Design Lab?

The timeline, starting with the call for proposals, followed by a series of consultations, event preparation, and then the Design Lab event, is approximately 6 months. We have created a graphic that highlights the activities that occur by month.



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