Application Form for E2E Design Lab
March 7th and 8th, 2018
Cambridge, MA

Introduction: The Design Lab (DL) will explore approaches to the design and implementation of integrated Efficacy to Effectiveness (E2E) clinical trials. Selected cases will be evaluated through this lens with a view to taking some candidate studies to an E2E pilot trial within the Trial Innovation Network. The DL session for each selected candidate will be organized according to the needs of the case being discussed. It may be a half or full day session and will consist of a case study presentation by the investigator and a robust multi-stakeholder discussion. Case studies will encompass 1) the traditional development and marketing plan/scenario with expected outcomes and metrics and 2) non-traditional scenarios with the same metrics and a comparison of expected outcomes between the scenarios.

The questions in this form are to facilitate the evaluation of the potential for the applications to serve as case studies in the context of the DL objectives.

Important Dates:

- Submission Form returned by September 15th,2017
- Case Selection Announcement on September 29th,2017
- Interactive Design Lab on March 7th and 8th, 2018

Please answer the following questions- (you may copy and paste these into your own letterhead) save your responses as a .pdf and submit them to Sheeona Gorman, PhD, Project Director, Tufts Medical Center via email (sgorman@tuftsmedicalcenter.org) no later than ***noon EDST on September 15th, 2017***

General Information

Investigator Name:

Investigator contact details for NEWDIGS Design Lab (e-mail and phone):

Project Title

Funding source (if current funding is available)

If not funded, please list the NIH IC you will submit to and proposed submission deadline

Proposed number of sites

Proposed number of subjects

Additional project-specific information

- Condition to be treated
- Description of unmet medical need- and degree of urgency
- Brief background to research leading 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 authorizations, at full authorization
    - Timelines
    - Length of course of treatment
- What does the competitive space for this research look like?
    - E.g. number of competitors currently, knowledge of pipeline for additional entrants
- What areas of additional expertise (outside of the NEWDIGS community and your company), would you like to have contribute to the discussion during your Scenario Design session? E.g. therapeutic area experts, patient advocacy groups, etc.?

Efficacy to Effectiveness (E2E)

- What is your rationale for pursuing an E2E approach?
    - Expected benefits to you?
    - Benefits/Costs for other key stakeholders (regulators, payers, providers, patients)
- Describe the challenges and opportunities that utilization of an E2E framework would create for your research.
- Describe how an E2E approach would integrate into your study development plan.
- What data from sources other than the actual trial would be useful/needed to support your efforts if selected?
- What types of data quality checks will be needed to assure the integrity of the data?

Queries regarding the completion of this form are welcome and should be directed to Sheeona Gorman, sgorman@tuftsmedicalcenter.org.