DTRA
DECENTRALIZED TRIALS
&
RESEARCH ALLIANCE

PRIORITY 4: REMOVING BARRIERS
INITIATIVE 4C: DATA CONNECTIVITY
Deliverable

- Defined norms for data collection and adoption, collaborate towards necessary standards.

4C

AT A GLANCE

High Level Description

- Establishing standards regardless of data collection method, that will ensure the data collected will match the standards for endpoint readout in the clinical trial design.
- Meeting certain thresholds and standards would reduce barriers related to collection method/type. This could also help ease the burden of ethics/regulatory agencies.

Expected Timeline

- Mid- to Long-Term
- Approx. Start: 19-Sept-2021
- Duration: 90 Days

External Spends

- TBD

Database Requirements

- TBD

KEY STAKEHOLDERS

Industry Experts

- TBD

Organizations

- Vendor Organization (CTTI)

Other Influencers

- TBD

VALUE TO ACHIEVE

- Establishing standards regardless of data collection method, that will ensure the data collected will match the standards for endpoint readout in the clinical trial design.
- Meeting certain thresholds and standards would reduce barriers related to collection method/type. This could also help ease the burden of ethics/regulatory agencies.

CHALLENGES TO ADDRESS

- Any time we collect data remotely, we have to do verification, validation, justification, usability. The challenge is to create standards that provide for these four things.
- Despite many attempts at interfacing patient EMR with clinical trial databases, most sponsors have not succeeded in linking patient medical records with clinical databases
- Using language like "accreditation"

ACTIONS REQUIRED

- Define the different remote data collection methods (needs to be dynamic as technology continues to evolve) and establish criteria for these technologies to be adapted.
- Identify a third party to help regulate the data collection processes related to DCT (lead standard)

POTENTIAL BARRIERS TO SUCCESS

- Evolving technologies
- There are no existing standards- we will be building this from the ground up
- Adoption - The vendors providing the data collection tools must sign on to these standards