DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

PRIORITY CHARTER

PRIORITY 2: BEST PRACTICES
INITIATIVE 2C: TECHNOLOGY & DATA STRATEGY

Deliverable

- 'DCT Clinical Data Strategy' framework that outlines modern data requirements, data flow, data channels, data curation and insight generation to improve end-to-end data accessibility, reliability, integrity, and traceability across study phases

AT A GLANCE

High Level Description

- eStrategy Support - Data access, collection, handling, monitoring, data permissions and sharing. Ethical & legal frameworks.

Expected Timeline

- Long-Term
- Approx. Start: 21-June-2021
- Duration: 500 Days

External Spends

- Experienced technologists

Database Requirements

- Centralized repository within DTRA website

KEY STAKEHOLDERS

Industry Experts

- Clinical sites (HCP, clinicians, investigators etc), MCA and sponsors (Pharma companies)
- Regulatory Policy/Regulatory Affairs; Industry experts, TransCelerate; Platform and technology experts: Medidata

Organizations

- American Telemedicine Association, Health Authorities, Sponsors

Other Influencers

- Patient advocacy groups/ Clinical Trial Transparency (data provision back to the patients)

VALUE TO ACHIEVE

- Achieve improved end-to-end data accessibility, reliability, integrity, and traceability across the study phases through development of 'Clinical Digital Strategy' that outlines modern standards and frameworks in data entities, data requirements, data flow, data channels, data curation and insights generation.
- Video or infographic to provide guidance on how to abstract out data from the protocol concept phase to study execution and completion (what is the minimum data required to gather outcomes or insight). Consolidating the pandemic-driven accelerated adoption of DCT technology
- Increased patient access and engagement
- How can trust and transparency be achieved and value be communicated so that study participants are willing to share data.
- Include data related ethics and legal protection standards in the requirements with special attention to geographical differences in laws and regulations.
- Provide details on modern adaptive cloud based database architecture.

CHALLENGES TO ADDRESS

- Data handling, data protection, privacy, validation
- Access to data (study participants unwillingness to share data (lack of education, trust).
- Study participant's lack devices and tools to gather data leading to poor adoption of DCT.
- Continued adherence and compliance from the patient/caregiver/rater/eCRO due to lack of engagement
- Data volume/data cleaning/monitoring/generation of meaningful insights.
- Critical data elements to be collected. How to use and store additional nice to have exploratory data. How to capture the additional data (IRB concern on what using the data for). Map the path of how extra data is handled.
- Compliance unique to DCT
- The effect on personas
- Patient centricity in terms of technology familiarity
- Study buddy (with technology native knowledge) or training; BYOD - version generation, updates and compatibility

ACTIONS REQUIRED

- Understand all data flowing from source (patient/site) to storage (vendor/sponsor).
- Clarify compliance needs unique to DCT
- Identify core technologies, address data aggregation challenges and create templates for data requirements
- Ensure that DCT is compatible with and mapped to a decentralized healthcare model
- User flows & data flows should be separate

POTENTIAL BARRIERS TO SUCCESS

- Continuous proliferation of new devices in the market and continuous integration that is required to gather data
- Ensure the team has adequate experience