DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

PRIORITY CHARTER

PRIORITY 1: DEFINITIONS
INITIATIVE 1C: CHANGING THE NORM

Deliverable

- The creation of a Decentralized Research Readiness Framework considerate of change management best practices for sponsors, CROs and sites.

AT A GLANCE

High Level Description

- Develop Industry best practices handbook to ease site burden and assist sites in adopting DCT
- Develop a criteria and a playbook to assess feasibility for a site, study (startup vs traditional startup)
- Create templates to assist sites and standardize process

Expected Timeline

- Long-Term
- Approx. Start: 21-June-2021
- Duration: 180 Days

External Spends

- Potentially around accessing platforms (survey)
- Graphic Designer

Database Requirements

- Repository for KPI/Metrics, Knowledge gathering and communication engine

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

- Assess the transformation journey for sites as they evolve their models into a DCT and/or hybrid model (survey) to include barriers and pain points.
- Enabling and assisting sites evolve their operating model into a hybrid/fully DCT format
- Minimize the burden on the sites as industry landscape is shifting
- Creating a playbook that includes a strategy and a methodology
- Create standardized templates, check list and communication guidelines
- Change management, well applied, bodes well for the successful implementation of change
- Engagement, transfer of knowledge
- Talent Pool
- PI advocacy (PI to bring in DCT, Trust, More participants in a study, more studies pr centers)
- Site for purpose (DCT for purpose) adopting this into a new ecosystem

CHALLENGES TO ADDRESS

- Sites are overwhelmed with studies (that require different technologies, multiple logins etc.)
- How adopting DCT changes the operating model for sites (including cost, material transfer, support and their interaction with sponsors, patients, HCP.)
- Perceptions about the DCT, think that the revenue reduces
- DCT and hybrid models. Understand inefficiencies in site operations
- Understand pain points and site interactions working with remote resources (contractors etc.,)
- Siteless and regulations (HIPPA compliance)
- AMCs vs smaller practices
- Cross state/geographies

ACTIONS REQUIRED

- Analysis of the sites pain points (survey)/Protocol (readiness framework)
- Guidance (playbook-living document) to DCT provider
- Templates to assist sites and standardize process and communication

POTENTIAL BARRIERS TO SUCCESS

- Variations in sites and study setups, subject/patient demography and trial requirements
- Look into site required submissions
- Cross state (contracts, patients etc.,) - (licensure-telehealth)