DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

PRIORITY CHARTER

PRIORITY 2: BEST PRACTICES
INITIATIVE 2A: BEST PRACTICES HANDBOOK

Deliverable

- A dynamic, wiki-style "Decentralized Research Best Practices Handbook" including core guiding principles related to patient safety, data integrity, protocol design, and other key barriers of adoption

AT A GLANCE

High Level Description

- Living document with ability for any member to contribute and process for consensus - Wiki format with a process to confirm "What is a best practice?"

Expected Timeline

- Mid-to Long-Term Initiative
- 3 months for initial version with expectation for revisions
- 1 year for final product
- Approx. Start: 27-June-2021
- Duration: 300 Days

External Spends

- Knowledge gathering & communication engine development & hosting; getting the message out

Database Requirements

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

KEY STAKEHOLDERS

Industry Experts

- Regulators(RA/EC/IRB), Physicians/Nurses (sites and Sponsors - medical), Biometrics, Technology, Quality

Organizations

- Sponsors, CROs & other service providers, Sites, Regulators (RA/EC/IRB)

Other Influencers

- Patients, Patient Advocacy Groups

VALUE TO ACHIEVE

- Allowing for early, strategic thinking/planning of DCTs that ensure patient safety, data integrity and adoption
- Resource for stakeholders - Bridging knowledge gaps to allow consideration and adoption (primer)
- Continuous improvement & evolution

CHALLENGES TO ADDRESS

- How do you measure success?
- Allow for flexibility, hybrid- Crowdsourcing (need to monitor this)
- Need to address quickly but lots of stakeholders - blueprint for other initiatives
- Consensus - any gaps (potential outreach beyond DTRA team?)
- Adoption and getting the message out

ADDITIONAL HIGH LEVEL DESCRIPTION

- Core guiding principles - patient safety, data integrity, protocol design (define requirements)
- Breakdown by life-cycle of drug development
- How to identify if protocol is suitable for DCT - questions to ask (akin to TransCelerate RBQM), requirements checklist (e.g. route of IMP, type of EPs), work from EPs backwards
- How to implement - tools/systems/best practices/therapeutic area considerations
- Matrix of R/R based on where in life-cycle - each player best practice (patient, point of care providers, CRO, Sponsor)
- Flexibility, proactive planning/strategy, hybrid design
- Resource/bandwidth requirements - tech, people, consider geography
- Measuring success - feedback loop - timeline and quality KPIs (recruitment, retention, diversity) - need to define most important

ACTIONS REQUIRED

- Determine who is the target audience? Sponsor/CRO/academic/owner of the study w/reference to site/patient pieces developed separately?
- Identify inter and intra dependencies within/amongst working groups - work closely with definitions pillar
- Define what we are not going to do with this Handbook, what it is not intended to cover
- List of industry standard KPIs to measure success
- Develop Wiki format and process (knowledge gathering and communication engine) in addition to content
- Patient focus/feedback - work closely with "Map the Patient Journey" initiative

POTENTIAL BARRIERS TO SUCCESS

- Recruitment challenges – do patients really want DCTs?
- Lack of consensus and/or adoption
- Regulatory authority & IRB/EC buy-in