DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

PRIORITY CHARTER

PRIORITY 2: BEST PRACTICES
INITIATIVE 2B: MAPPING THE PATIENT JOURNEY

Deliverable

- Core Patient Journey Map for Decentralized Research with expanding call outs/ decision points, identify standards, points-of-burden, trends and best practice considerations to maximize patient inclusion, diversity and adoption of decentralized trial options

AT A GLANCE

High Level Description

- Graphic with expanding call outs/ decision points, Identify standards, trends and best practice considerations to maximize patient inclusion, diversity and adoption of decentralized trial options. Maximize patient engagement and retention.

Expected Timeline

- Short-Term
- Approx. Start: 2-August-2021
- Duration: 90 Days

External Spends

- Graphic Designer

Database Requirements

- Catalogue of case studies, metrics tracking for KPI's

KEY STAKEHOLDERS

Industry Experts

- FDA, EMEA, PDMA, IRB/EC

Organizations

- Patient Advocacy Groups; Medable; Patient Advisory Council, CTTi, C-Path PRO & ePRO Consortium, IMI Trials at Home

Other Influencers

- Clinicians, Nurses/Study Coordinators

VALUE TO ACHIEVE

- Optimized patient/participant experience as a result of having patient centered design and choices in DCT trial designs/solutions globally; adaptive journey based on nuances of trial/protocol
- Offsetting the burden of the clinical trial participation with patient preferred options (what would patients like to have, not have to have, meeting patients where they are)
- Making it easier for sponsors/CROs/vendors to consider the patient journey when developing and conducting their specific DCT, globally

CHALLENGES TO ADDRESS

- Identify any variations specific to patient demographics/therapeutic focus
- Improve inclusivity and diversity of patients opting for clinical trial participation
- Nomenclature standardization - Patients vs participants/subjects
- Define where it begins and ends- first interaction? Ad, Facebook, MD telemedicine visit, patient portal to deliver results back
- Identification of patients
- Consideration of Caregivers role
- Education(Clinical trial participation is not only for those that have the means to visit/travel to a prestigious academic center)

ACTIONS REQUIRED

- Start by stepping back and identify the simplest, best process possible rather than just swapping out all the existing steps (patient burden).
- Identify some DCT that have gone well and see how the patients progressed through.
- Interview patient advocacy groups/ identify patient leaders.
- Create an adaptive journey that segments patients into a few pathways where treatment areas have different needs.
- Survey where patients access/become aware of the study the study (advertising, referral, advocacy groups.
- Identify key decision points within the journey.
- Characterize the different ways in which patients could be supported/engaged in a DCT - e.g eConsent, eDiaries, Connected Devices, Home Health Nursing, local labs/POC tests, Televisits, ePRO's/COA's
- Catalogue of published case studies as references (focused on best practices, lessons learned and outcomes)
- Build a decision tree/ readiness checklist against study parameters- simple tool

POTENTIAL BARRIERS TO SUCCESS

- Variation between studies leading to too many "recommendations" to be beneficial.
- No real models of ideal patient journeys to learn from (theoretical)
- Inability to identify product that can display the graphic with the expanding sections
- Understanding how much burden and time is on the patient at various points within the journey