DTRA
DECENTRALIZED TRIALS & RESEARCH ALLIANCE

PRIORITY CHARTER

PRIORITY 1: DEFINITIONS
INITIATIVE 1A: GLOSSARY

Deliverable

- A comprehensive Decentralized Research Glossary that is easily accessible to relevant stakeholders.

AT A GLANCE

High Level Description

- DCT industry glossary

Expected Timeline

- Short-Term
- Approx. Start: 21-June-2021
- Duration: 40 Days

External Spends

- None

Database Requirements

- None

KEY STAKEHOLDERS

Industry Experts

- Dr. Isaac Rodriguez-Chavez, PhRMA

Organizations

- PRA, FDA, PhRMA's Digital Health Lexicon (look to the endnotes referencing FDA definitions), International Regulatory Agencies, CTTI, IMI

Other Influencers

- TransCelerate, DiME, eClinical Forum (Trial of the Future),

VALUE TO ACHIEVE

- Establish common nomenclature, definitions, archetypes to make communication more meaningful - Learn from the regulatory glossary but do not stop there
- Common set of terms from which metrics can be derived

CHALLENGES TO ADDRESS

- The complexity of communication
- Consider the lexicon of other countries (including virtual, hybrid, remote, etc)
- "Decentralized" (Regulatory) vs. "Virtual" – regulatory vocabulary contradicts
- A lot of stakeholders doing the same thing
- Not one-size-fits-all, may be a spectrum
- Defining interoperability
- Scoping – scope could be too broad
- Educate clinical staff on new definitions/new concepts, etc.
- Fill in the white space around defining archetypes & KPIs

ACTIONS REQUIRED

- Capture the work that has already been done (can include links from other resources)
- Collaborate w/ Education workstream on distribution of / access to the glossary
- Gap assessment

POTENTIAL BARRIERS TO SUCCESS

- Risk of multiple industry standard groups publishing core definitions that contradict each other simultaneously (and companies with glossaries that fit their own culture / teams)
- Understanding if FDA, EMA, other agencies that have created lexicons already – we need to not veer too far from them
- Adoption of the definitions