

PRIORITY 4: REMOVING BARRIERS

INITIATIVE 4A: GLOBAL CONDUCT INSIGHTS MAP



Deliverable

- Create a Central Library of regulatory, legal, privacy, and culture information that contains dynamic links to relevant regulatory sites.

AT A GLANCE

High Level Description

- Summarize currently available information – key points
- Provide links to regulatory information/materials/documents that embodies global regulatory agencies
- Crowdsourcing to engage the community (digi-pedia)

Expected Timeline

- Short-Term
- Approx. Start: 21-June-2021
- Duration: 90 Days

External Spends

- Potential Research Consultants
- Digi-pedia Platform Funding and Updates

Database Requirements

- Can DTRA provide resources needed to maintain platform?

KEY STAKEHOLDERS

Industry Experts

- Regulatory experts, DCT vendors, Central IRB/IECs, DTRA members

Organizations

- Government/Regulatory agencies - FDA, EMEA, etc. IMI

Other Influencers

- Large industry organizations - PhRMA

VALUE TO ACHIEVE

- Easier for anyone looking for Regulatory Information/Regulations related to DCT
- All key information located in one place
- Provide a table for people with links that can help interested parties understand regulations related to DCT

CHALLENGES TO ADDRESS

- Could be significant amount of information to review / collect
- The regulations are rapidly changing; the outcome should be dynamic and easily updated
- Regulatory guidelines have been changed (not updated) have the links changed, as well?
- Regulatory agencies will not give you a break because you clicked the wrong link
- If we use crowdsourcing is the information that is provided accurate? DCT Experts can help?
- May not be a clear definition of DCT (link with Team #1)

ACTIONS REQUIRED

- Research what information is available
- Understand what resources already exist, leverage them
- Determine the scope of the project, for example:
- In-Scope: Large regulatory agencies in US, Europe, Asia, Japan, China, Africa
- Out of Scope: Local regulatory agencies – i.e. Cities, states,

POTENTIAL BARRIERS TO SUCCESS

- Amount of Information to research and collect.
- Repository of information.