

**PRIORITY 4: REMOVING BARRIERS**  
**INITIATIVE 4B: COLLABORATE ON**  
**REGULATORY GAPS**

**Deliverable**

- Gap analysis of where current regulations are not addressing DCT with outreach/engagement with Regulatory Authorities as appropriate



**AT A GLANCE**

**High Level Description**

- Conduct a gap analysis of where current regulations are not addressing DCT
- Work with agencies or with large organizations (PhRMA) to drive awareness with agencies of the gaps and offer solutions

**Expected Timeline**

- Long-Term
- Approx. Start: 20-August-2021
- Duration: 400 Days
- 1- 2 years; after initial Gap Analysis leveraging existing standards to move this initiative forward more quickly

**External Spends**

- TBD

**Database Requirements**

- TBD

**KEY STAKEHOLDERS**

**Industry Experts**

- DCT Vendors, Central IRB/IECs, Engaging with regulatory agencies to understand their needs

**Organizations**

- Regulatory Agencies, DTRA, PhRMA, Trial Nation (Denmark), health authorities, Japanese Pharmaceutical Manufacturers Association (DCT Task Force), lobbying groups

**Other Influencers**

- Large Sponsors, CROs

**VALUE TO ACHIEVE**

- Determine what is missing in the current regulations related to DCT
- Drive awareness to fill the GAPS/inconsistencies; understand the regulatory agencies needs related to DCT by providing a proposal to guide the conversation

**CHALLENGES TO ADDRESS**

- May not know what is required
- Lack of influence to drive change in regulations
- Which agency is responsible in which country? (Is it the gov. Alternative organizations?)
- Need a clear definition of DCT (Team #1)

**ACTIONS REQUIRED**

- Collect current regulations related to DCT
- Determine gaps between current and required
- Identify how to drive awareness in regulatory agencies
- Generate a list for sponsors of which regulators are in charge in which country
- Create a proposal to guide health authorities with the process flow around DCT
- Next Steps: Illustrate the findings in a position to inform regulators, pharma, etc.

**POTENTIAL BARRIERS TO SUCCESS**

- Not having the leverage to influence regulatory agencies