Common Protocol Template

Create a common template for clinical protocols to ease interpretation and use as well as enable downstream automation of many clinical processes

Value for Stakeholders

- Alignment with FDA / NIH has led to increased industry adoption and Regulatory acceptance
  - “Harmonizing our templates worked out well for both sides. Developing a template with FDA & NIH alone, there is no way that we would have found traction with industry” - Regulator
- Improved ability for Sites to access information: protocols streamlined and organized with an investigator focus
- Improved communication between Patients and Sites due to increased protocol consistency
- Increased operational efficiencies for Sponsors; automation of downstream processes and improved reuse of content
- Improved conduct of the study and quality of data collected
- Enables therapeutic area standards implementation
  - Reduced complexity of regulatory reviews: enables ease of data interpretation and ability to compare protocols, facilitating regulatory input on protocol design
- Enabling end-to-end use of metadata and traceability
- Improved Patient access to protocol information and efficiency in clinical development

Initiative Status

Last Update: September 2018

Explore Design Deliver Maintain

Deliverables:
All deliverables are available for public use on the TransCelerate CPT Assets website, including the following:


Upcoming Milestones:
- Content reuse capability from the CPT to the SAP and CSR
- Establish a governance model to manage the annual update release and ensure sustainability of this suite of templates