Harmonized Governance Tools for Data Sharing

AIM

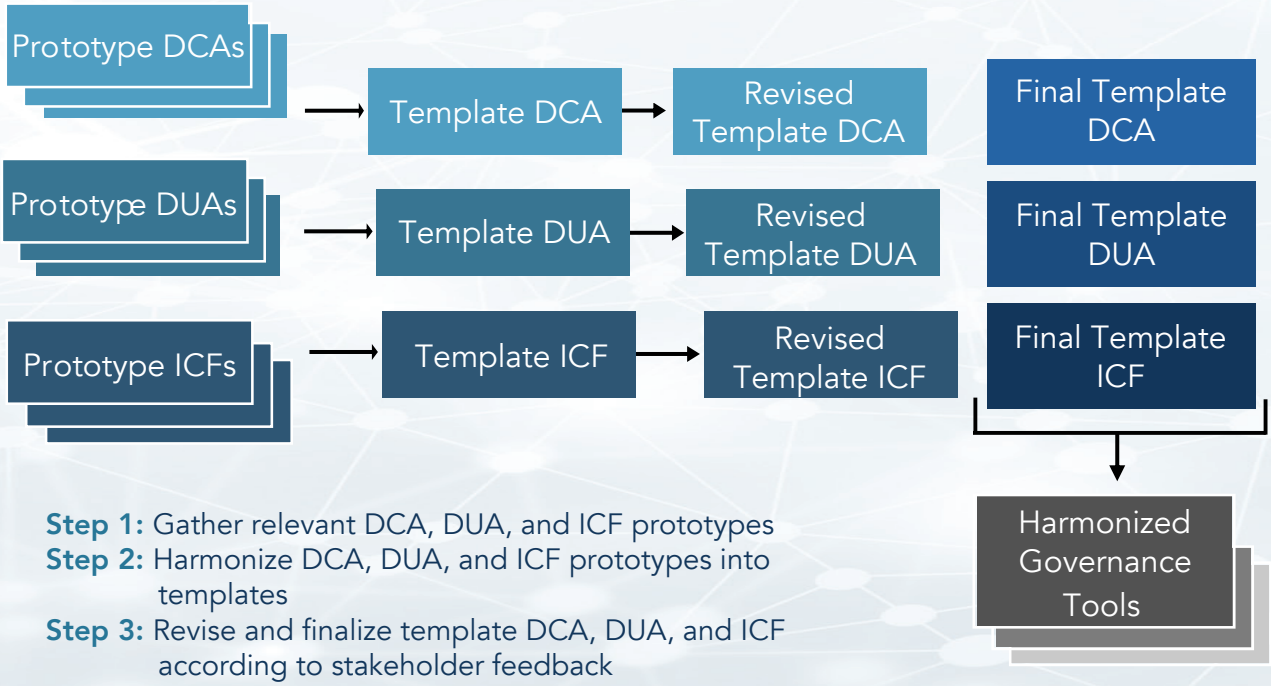
To plan, develop, demonstrate, and disseminate 3 harmonized governance tools for data sharing with support from the Patient-Centered Outcomes Research Institute (PCORI):

1. **Template Data Contributor Agreement (DCA):** clarifies data contributor responsibilities and requirements for deposition of data in repository
2. **Template Data Use Agreement (DUA):** delineates responsibilities and requirements for requesters or data from data repositories
3. **Data Sharing Section of Informed Consent Form (ICF):** enables research participants to understand secondary use of collected data elements for open science

OBJECTIVES

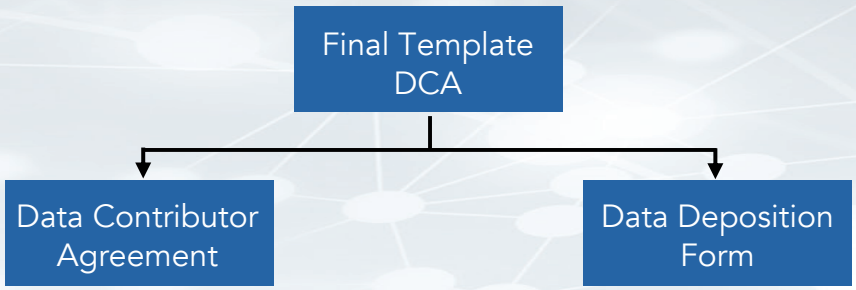
1. Reduce contractual barriers and administrative burden(s) of data sharing
2. Facilitate new discovery by enabling interoperability of anonymized datasets
3. Respect interests of data generators, data users, funders, and research participants
4. Ease the implementation of data sharing mandates among organizations that fund clinical research

Harmonized Governance Tools Development Process



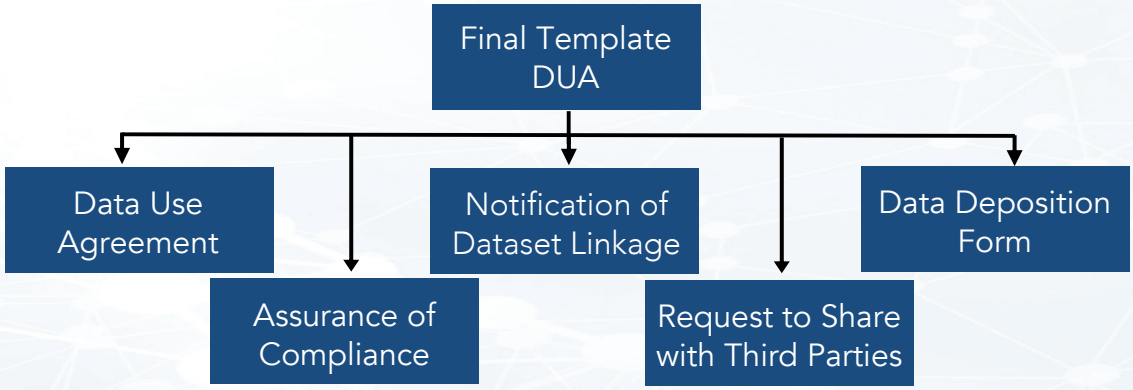
Step 1: Gather relevant DCA, DUA, and ICF prototypes
Step 2: Harmonize DCA, DUA, and ICF prototypes into templates
Step 3: Revise and finalize template DCA, DUA, and ICF according to stakeholder feedback
Step 4: Submit harmonized DCA, DUA, and ICF to PCORI for dissemination to grant awardees

Key Elements of Final Template DCA



- Agreement to deposit data package in repository
- Description of data package requirements
- Description of repository's hosting services and responsibilities
- Description of data contributor responsibilities
- Anonymization/ de-identification requirements
- Statement regarding data ownership
- Permission to host data for intended re-use
- Permission to disseminate data for approved purposes

Key Elements of Final Template DUA



- Definition of terms, parties, and relationship between parties
- Description of repository's hosting services and responsibilities
- Description of requester's responsibilities
  - Use of dataset for proposed research only
  - Commitment to not attempt to re-identify participants
  - Agreement to not re-distribute to data to unapproved third parties
- Expectations for data citation, publication, submission of secondary analyses, and registration on ClinicalTrials.gov
- Breach notification responsibilities and processes
- Liability provisions
- Duration of agreement and procedures for violation

Access the harmonized governance tools for data sharing at www.mrctcenter.org/news/template-data-sharing-governance-tools-released