NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Closeout Data and Resource Sharing Checklist

Purpose

As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all Collaboratory trials are expected to share data and resources, such as protocols, phenotypes, videos, training materials, consent documents, and recruitment materials. We recommend that elements of a final data sharing package include the items listed in the checklist below. If an element will not be included in the data sharing package, please provide a brief explanation for the omission. Resources can be housed in the NIH Collaboratory Knowledge Repository (KR), in a repository (i.e., GitHub), or on a study website. We will link to the materials from the Living Textbook. To request posting of materials to the KR, contact nih-collaboratory@dm.duke.edu.

Note: There will **not** be a dedicated space on the NIH Collaboratory website for posting analytic datasets; rather, we will post a hyperlink to the data sharing repository chosen by each trial. In the Data Sharing Information Document, the EHR Core provides a partial list of existing data sharing platforms. The accompanying Data Sharing Information Document also contains information on data sharing requirements for the NIH Pragmatic Trials Collaboratory, NIH, and medical journals; information on data sharing mechanisms and platforms; and examples from Collaboratory Trials.

Data and Resource Sharing Checklist

All NIH Pragmatic Trials Collaboratory Trials are expected to complete this checklist at closeout. The information provided in the checklist will be published in the Living Textbook on each Collaboratory Trial's page and on a Data and Resource Sharing page.

Data and Resource Sharing Checklist		
1. Trial information		
Trial name and acronym:		
Checklist completed by:		
Date:		
Link to ClinicalTrials.gov registration:		
Link to trial website:		
2. Resource location		
Item	**Provide hyperlink or indicate if item will be stored in the KR**	**If item will not be shared, please provide a brief explanation for the omission**
Publications/Dissemination		
Link to protocol paper		
Link to main outcome paper		
Link to other trial-related publications		
Materials used to communicate overall trial results to participants (eg, lay summary)		
Study tools		
Final version of the protocol, including summary of changes		
Consent documents or consent process		
Tools for sites (eg, toolkits, checklists, instruction sheets, clinician-facing materials)		
Participant-facing materials (eg, videos, flyers, handouts)		
Computable phenotypes for outcome measures		
Computable phenotypes for the inclusion/exclusion criteria		
Code for generating variables in the analytic dataset from standard sources		

Datasets and documentation		
Annotated data collection forms		
Link to public use dataset		
Data dictionary (proc contents) for public use dataset		
Other resources		