NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Data and Resource Sharing Checklist

Background

All NIH Collaboratory Trials will be expected to review this checklist as part of the onboarding process so they understand what will be expected. They will complete the checklist at closeout.

As part of the NIH Pragmatic Trials Collaboratory's commitment to sharing, all of its 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), on a repository (eg, GitHub), or on a study website. We will link to the materials from the Living Textbook on each trial's webpage and through a separate Data and Resource Sharing section. 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 NIH Collaboratory Trials.

Data and Resource Sharing Checklist for Plan Development – Part 1

Data and Resource Sharing Checklist
1. Trial information
Trial name and acronym: Primary Palliative Care for Emergency Medicine (PRIM-ER)
Checklist completed by: Nina Siman
Date: 2/11/2025
Link to ClinicalTrials.gov registration: https://clinicaltrials.gov/study/NCT03424109
Link to trial website: N/A

Data and Resource Sharing Checklist for Plan Development – Part 2

Data and Resource Sharing Checklist		
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	https://bmjopen.bmj.com/content/9/7/e030099.long	
Link to main outcome paper	https://jamanetwork.com/journals/jama/article-abstract/2829286	
Link to other trial-related publications	PRIM-ER publications	
Materials used to communicate overall trial results to participants (eg, lay summary)		See study snapshot.
Study tools		
Final version of the protocol, including summary of changes	Included in our protocol paper: https://bmjopen.bmj.com/content/9/7/e030099.long	
Consent documents or consent process		CMS claims of patients 66 years and older with serious, life-limiting illness who made a visit to any of our EDs during the study period will be used to measure outcomes in our patient cohort. We will seek a waiver of Health Insurance Portability and Accountability Act authorization for ED patients as this study presents no more than minimal risk and cannot be practicably conducted without the waiver given the study's geographic breadth and sheer number of participants (>300 000 eligible patients). Obtaining informed consent for participation and use of Medicare claims from all patients in this study is not feasible and will interfere with the conduct of this study.
Tools for sites (eg, toolkits, checklists, instruction sheets, clinician-facing materials)	See Data and Resource Sharing folder in the Knowledge Repository	
Participant-facing materials (eg, videos, flyers, handouts)	See Data and Resource Sharing folder in the Knowledge Repository	

Computable phenotypes for outcome measures	Included in our main outcome paper: https://jamanetwork.com/journals/jama/article-abstract/2829286	
Computable phenotypes for the inclusion/exclusion criteria	Included in our main outcome paper: https://jamanetwork.com/journals/jama/article-abstract/2829286	
Code for generating variables in the analytic dataset from standard sources	PRIMER-main-outcomes_v009.sas	
Datasets and documentation		
Annotated data collection forms		We used the Centers for Medicare & Medicaid Services (CMS) patient-level database
Link to public use dataset		Our study utilized Medicare claims data, which contains PHI. Given our data use agreement with the CMS, we are unable to publicly share individual-level claims data
Data dictionary (proc contents) for public use dataset		Our study utilized Medicare claims data, which contains PHI. Given our data use agreement with the CMS, we are unable to publicly share individual-level claims data
Other resources		