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: The INSPIRE 3 Skin and Soft Tissue Infection Randomized Clinical Trial The INSPIRE 4 Abdominal Infection Cluster Randomized Clinical Trial
Checklist completed by: Shruti Gohil
Date: **5/21/25**
Link to ClinicalTrials.gov registration: ABD: https://clinicaltrials.gov/study/NCT05423743 SST: https://clinicaltrials.gov/study/NCT05423756
Link to trial website: https://www.ucihealth.org/healthcare-professionals/inspire

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	Abdominal infection trial: Not applicable. See Supplement 1 of the main outcome paper. Skin and soft tissue infection trial: Not applicable. See Supplement 1 of the main outcome paper.	
Link to main outcome papers	[Abdominal infection trial main outcome paper](#) [Skin and soft tissue infection trial main outcome paper](#)	
Link to other trial-related publications	[Accompanying editorial in *JAMA Network Open*](#) [Accompanying commentary in *JAMA Surgery*](#) [Secondary manuscript: Initial Antibiotic Selection and Subsequent Antibiotic Use.](#)	
Materials used to communicate overall trial results to participants (eg, lay summary)	HCA Healthcare System Leadership Call HCA Healthcare All-Hospitals INSPIRE Call Dissemination toolkit: https://www.ucihealth.org/healthcare-professionals/inspire	
Study tools		
Final version of the protocol, including summary of changes	Pending ClinicalTrials.gov approval and release	
Consent documents or consent process	Not applicable	Not applicable: HPHC IRB determined that informed consent was not required for these trials.
Tools for sites (eg, toolkits, checklists, instruction sheets, clinician-facing materials)	https://www.ucihealth.org/healthcare-professionals/inspire	

Participant-facing materials (eg, videos, flyers, handouts)	https://www.ucihealth.org/healthcare-professionals/inspire	
Computable phenotypes for outcome measures	Not applicable	Not applicable
Computable phenotypes for the inclusion/exclusion criteria	Not applicable	Not applicable
Code for generating variables in the analytic dataset from standard sources		No standard sources were used.
Datasets and documentation		
Annotated data collection forms	Not applicable	Not applicable: Automated data collection occurred through the electronic health record system at participating HCA Healthcare hospitals.
Link to public use dataset		There are both patient confidentiality and proprietary concerns with the release of this dataset. HCA will maintain the study's analysis datasets in a protected data enclave for three years from the date of publication. Requests to analyze the data will be evaluated by HCA and a technical team to determine whether the proposed use is consistent with the original aims of the trial and is technically appropriate. Approved requesters will create executable analysis programs that will be executed by HCA-affiliated analysts. Programs may only generate summary level, not patient-level, data. A data dictionary and request form will be provided upon request. A processing fee will apply. How to access data: Data sharing requests within three years of publication should be made to the first author at skgohil@hs.uci.edu for provision of the data dictionary and data request form.
Data dictionary (proc contents) for public use dataset		A data dictionary will be provided upon request. Data sharing requests within three years of publication should be made to the first author at skgohil@hs.uci.edu for provision of the data dictionary.

Other resources		