

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases	Policy Expanded Distribution of Clinical Research Endpoint Data	No.: DMID Policy-012 - NCRS 2.1 v 3
	Effective Date: 17-APR-2017	Version: 3.0

1.0 Purpose:

To describe the Division of Microbiology and Infectious Disease (DMID) policy on requirements for the distribution of clinical research endpoint data from the Data Coordinating Center (DCC).

2.0 Scope:

This policy applies to the release of clinical research endpoint data from DMID-supported contracts and other clinical research that use DMID-contracted DCCs.

3.0 Policy:

Clinical research endpoint data and analyses are only distributed by the DCC at the completion of the study unless data release is prospectively described in the protocol. The protocol, statistical analysis plan (SAP), and data release plan (DRP) should clearly delineate any staging of endpoint analysis and distribution. The DRP should identify recipients of the data. If the analysis and release are fully described in the protocol, endpoint data may be released by the DMID DCC.

For the purpose of this policy, study completion is defined as when all endpoint data have been collected; the query and quality assurance/quality control (QA/QC) processes have been completed; the data base has been locked; and the final datasets and/or analyses have been delivered to DMID.

Planned distribution of clinical research and endpoint datasets or analyses prior to the completion of the study must not affect the rest of the study nor the evaluation of other endpoints. For studies with masked/blinded data, the protocol, SAP, or DRP must cite measures to avoid compromising the masking/blinding procedure. In order to preserve the integrity of the study and data, endpoint datasets or analyses prepared while the study is ongoing may not be released prior to study completion, unless the query and QA/QC processes are completed, the datasets are “frozen,” and DMID approval has been confirmed.

Any deviation from this policy must be approved by the DMID Associate Director for Clinical Research. Approval for release will only be granted under special circumstances, such as a public health emergency.

The release of data to clinical trial partners and investigators must be in compliance with FDA regulations and guidances, HHS Human Subjects Protections regulations, ICH guidelines for good clinical practice and data management, and consistent with NIAID and DMID policies and SOPs.

4.0 Background:

In order to preserve the integrity of endpoint data generated from DMID-funded clinical research, the data should not be released until the planned enrollment and follow-up are reached, the data QA/QC processes completed, the data base is locked, and the final analyses or datasets have been delivered to DMID as described in the protocol, SAP, and DRP. Endpoint data distribution prior to completion of the study can lead to unblinding and/or misinterpretation of study results due to lack of QC procedures or not having the power to support the study’s endpoints.

DMID recognizes that in many studies there are advantages to release defined datasets prior to the end of the study. In order to consider this approach, DMID requires that the staging of release be

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prospectively described and reviewed by staff in order to ensure that processes are in place that protect the integrity of the on-going study.

Endpoint data compilation or analysis during the course of the study for clinical research oversight, or management is released only to DMID staff or DMID contractors responsible for these activities. The staff of the DMID-contracted DCC has access to the data. DMID staff and contractors responsible for clinical research management and monitoring of subject safety have limited access to endpoint data. Endpoint data and data summaries prepared for safety oversight committees remain confidential for DMID-designated committee members.

5.0 Definitions:

Clinical Research: NIAID human subjects term indicating research conducted on human subjects or on material of human origin that can be personally identified. Policy covers large and small-scale, exploratory, and observational studies. There are three types: Patient-oriented research (investigators directly interact with study participants); epidemiologic and behavioral studies; outcomes and health services research. This term applies to both clinical trials and clinical studies.

Data: A piece of information acquired by observation, measurement, or experiment and used as a basis for calculation or reference.

Data Coordinating Center: An entity dealing with tasks associated with the entry, transfer, and/or preparation of source data and derived items for entry into a clinical trial database. These activities may include database creation, data entry, review, coding, data editing, data QC, locking, or archiving.

Database Freeze: Action taken to obtain a “snapshot in time” of current data and archive them to ensure that an analysis, report or publication that uses the data can be reproduced at a later date. As multiple data freezes can be conducted over the course of the study for different reporting purposes, the database freeze does not imply that data are in their final state.

Database Lock: Action taken to prevent further changes to a clinical trial database. NOTE: Locking of a database is done after review, query resolution, and a determination has been made that the database is ready for analysis.

Dataset: A collection of structured data. Clinical data are typically stored in relational databases that contain multiple datasets or tables.

Endpoint: Variable that pertains to research evaluations such as safety, immunogenicity, pharmacokinetics, or efficacy.

Protocol Team: A group of individuals comprised of internal representatives from DMID and external members as appropriate, including investigators and other protocol support people, who are responsible for managing the development and review of a protocol. The team assesses the protocol design, data integrity, and the protection of human subjects, as well as ascertaining that the protocol execution follows good clinical practice (GCP), DMID’s current policies and requirements, and appropriate laws and regulations.

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Safety Oversight Committee (SOC): An SOC refers to a committee of experts, independent of the trial investigators, pharmaceutical sponsor (if any) and funding agency, that periodically reviews the conduct and results of the clinical trial. Following review they make recommendations to: continuation without change, continuation with change, or termination of the trial. SOC refers to either a Data and Safety Monitoring Board (DSMB) or a Safety Monitoring Committees (SMC).

6.0 Responsibilities:

Role	Responsibility
Clinical Project Manager	<ul style="list-style-type: none"> Determine whether any interim analysis proposed in the protocol meets the requirements of all relevant Standard Operating Procedures (SOPs) and policies Submit requests for interim analyses not included in the protocol to the Associate Director for Clinical Research on behalf of the protocol team
Contracting Officer's Representative(s) for Data Coordinating Center	<ul style="list-style-type: none"> Communicate approval of non-protocol-specified DAPs and DRPs to the DCC
DMID Associate Director for Clinical Research	<ul style="list-style-type: none"> Review and approve requests for distribution of datasets or analyses that are not described in the protocol, SAP, or DRP

7.0 References:

[U.S. Code of Federal Regulations 45 CFR 46: Protection of Human Subjects](#) (HHS)

[U.S. Code of Federal Regulations 21 CFR 312](#): - See 312.130

[U.S. Code of Federal Regulations 21 CFR 814](#): See 814.9

[Clinical Data Interchange Standards Consortium \(CDISC\) Clinical Research Glossary](#)

8.0 Inquiries:

Questions or comments regarding this policy may be directed to:

Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases (DMID)
NIH / NIAID
5601 Fisher Lane, Rm. 7E60
Bethesda, MD 20892
DMIDPolicyQuery@mail.nih.gov

9.0 Availability:

This policy is located electronically at:

<http://www.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch/Documents/datadistribution.pdf>

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10.0 Change Summary:

Version Number	Date of Revision: DD/MMM/YYYY	Replaces	Effective Date: DD/MMM/YYYY	Description of Revision/Retirement
1.0	N/A	N/A	01/FEB/2013	N/A
2.0	05/MAR/2015	1.0	01/APR/2015	Biennial review; Administrative edits
3.0	10/MAR/2017	2.0	17/APR/2017	Biennial review; Updated definition of DCC to match current definition