NIH Data Management and Sharing Policy: Compliance & Solutions

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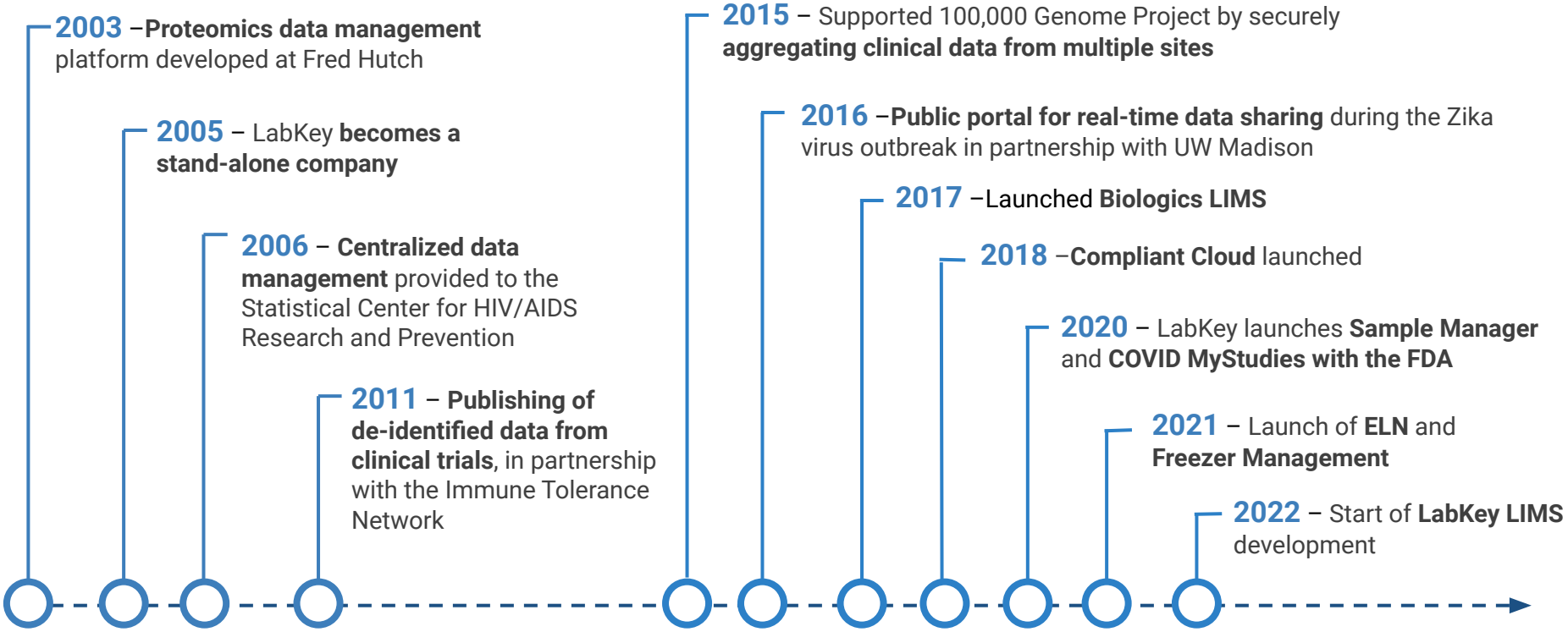

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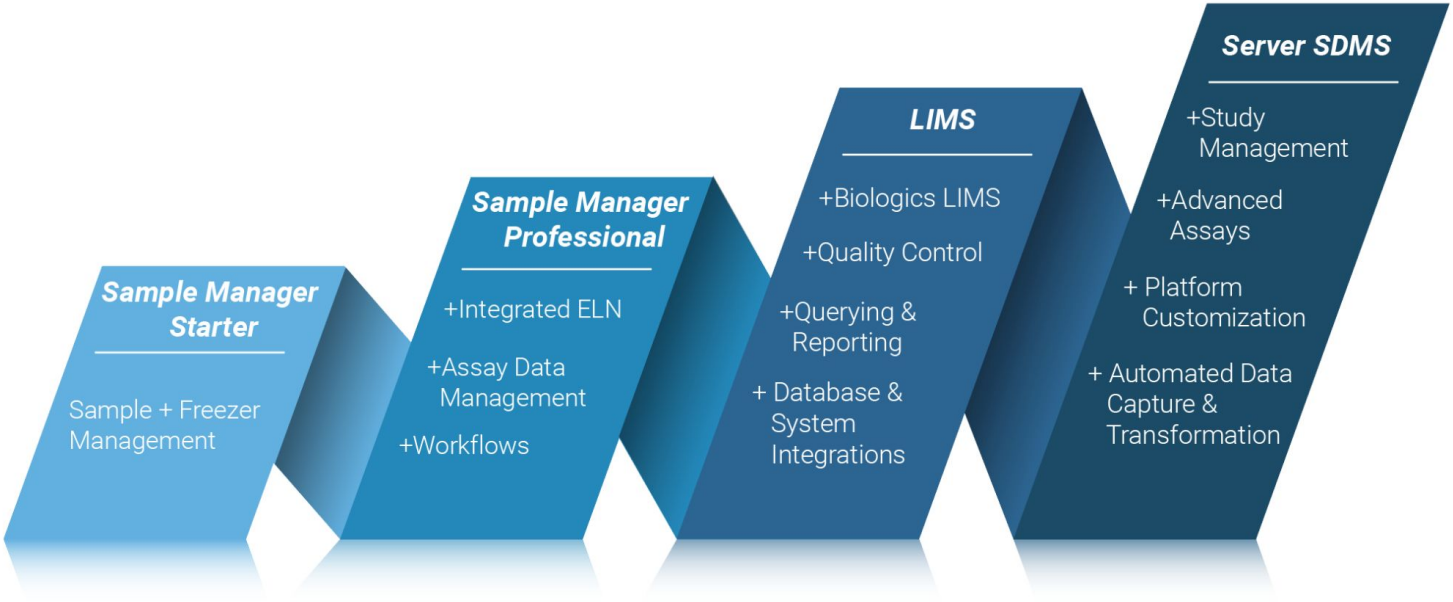
LabKey Data Management Solutions



The NIH Data Management and Sharing (DMS) Policy creates a consistent minimum expectation for all research supported by the agency.

Under the DMS policy, NIH expects that new funding applications or renewals after Jan 25th 2023 will:

- Plan and budget for the managing and sharing of data
- Submit a DMS plan for review when applying for funding
- Comply with the approved DMS plan

NIH SCIENTIFIC DATA SHARING

Scope: Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of “scientific data”.

- Research Projects
- Certain Career Development Awards (Ks)
- Small Business SBIR/STTR
- Research Centers

"Scientific data" is defined as:

"the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."

Length of Time to Maintain Data:

- Grantee institutions are required to keep the data for 3 years following closeout of a grant or contract agreement. Contracts may specify different time periods.
- Grantee institutions may have additional policies and procedures regarding the custody, distribution, and required retention period for data produced under research awards.

Scientific data does not include:

- Data not necessary for or of sufficient quality to validate and replicate research findings
- Laboratory notebooks
- Preliminary analyses
- Completed case report forms
- Drafts of scientific papers
- Plans for future research
- Peer reviews
- Communications with colleagues
- Physical objects, (e.g., laboratory specimens)

Justifiable reason for limiting sharing include:

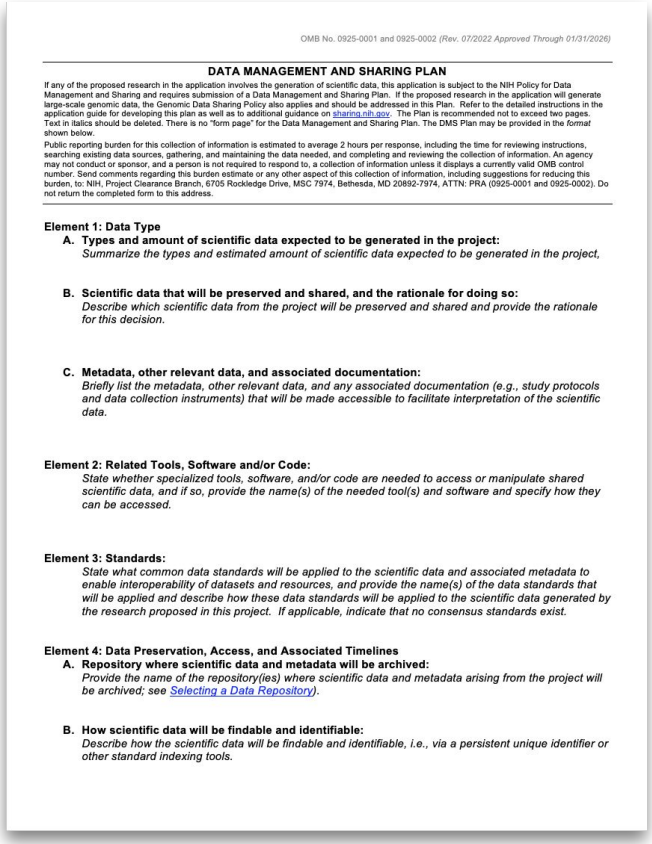
- Informed consent will not permit or limits scope of sharing or use
- Privacy or safety of research participants would be compromised and available protections insufficient
- Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
- Restrictions imposed by existing or anticipated agreements with other parties

Reasons NOT generally justifiable to limit data sharing:

- Data are considered too small
- Researchers anticipate data will not be widely used
- Data are not thought to have a suitable repository

Creating a DMS Plan

- Target length is two pages
- Almost all NIH-provided samples are three pages
- No specific format required
- NIH-provided template is available
  - Twelve prompts/sections
  - *Public reporting burden for this collection of information is estimated to average 2 hours per response*
- Many repositories and other resources are providing sample responses



OMB No. 0925-0001 and 0925-0002 *(Rev. 07/2022 Approved Through 01/31/2026)*

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing.nih.gov. The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:
Summarize the types and estimated amount of scientific data expected to be generated in the project,

B. Scientific data that will be preserved and shared, and the rationale for doing so:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

C. Metadata, other relevant data, and associated documentation:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Element 2: Related Tools, Software and/or Code:
State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Element 3: Standards:
State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:
Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see Selecting a Data Repository).

B. How scientific data will be findable and identifiable:
Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

Elements of a DMS Plan

Data Type:

- Summarize the types and amount of scientific data to be generated and/or used in the research. Descriptions may include the data modality, level of aggregation, and/or the degree of data processing.

- Describe which scientific data from the project will be preserved and shared. Researchers should decide which scientific data to preserve and share based on ethical, legal, and technical factors. The plan should provide the reasoning for these decisions.

- A brief listing of the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data

Elements of a DMS Plan

Related Tools, Software and/or Code:

Indicate whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and name(s) of the needed tool(s) and software. If applicable, specify how needed tools can be accessed.

Standards:

Describe what standards, if any, will be applied to the scientific data and associated metadata (i.e., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation).

Elements of a DMS Plan

Data Preservation, Access and Associated Timelines:

Give plans and timelines for data preservation and access, including:

- The name of the repository(ies) where scientific data and metadata arising from the project will be archived.
- How the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.
- When the scientific data will be made available to other users and for how long. Identify any differences in timelines for different subsets of scientific data to be shared.

Elements of a DMS Plan

Access, Distribution, or Reuse Considerations:

Applicable factors affecting access, distribution, or reuse of scientific data.

- Informed consent
- Privacy and confidentiality protections consistent with applicable federal, Tribal, state, and local laws, regulations, and policies
- Whether access to scientific data derived from humans will be controlled
- Any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements
- Any other considerations that may limit the extent of data sharing.
- Any potential limitations on subsequent data use should be communicated to the individuals or entities (for example, data repository managers) that will preserve and share the scientific data.

Elements of a DMS Plan

Oversight of Data Management and Sharing:

Indicate how compliance with the DMS Plan will be monitored and managed, the frequency of oversight, and by whom (e.g., title, roles).

This element refers to oversight by the funded institution, rather than by NIH. The DMS Policy does not create any expectations about who will be responsible for Plan oversight at the institution.

Data Management Implications

Proper data management helps ensure that researchers and collaborators are using data consistently and accurately.

- Carefully storing and documenting data allows more people to use the data in the future, potentially leading to more discoveries beyond the initial research.
- NIH emphasizes the importance of good data management practices and encourages data management to be reflective of practices within specific research communities.
- NIH encourages data management and sharing practices to be consistent with the **FAIR** (Findable, Accessible, Interoperable, and Reusable) data principles.

HOW LABKEY HELPS:

- Encourage data management throughout the research process
- Well-established tools, support, and recommendations

Metadata and Other Associated Documentation

Metadata and other documentation associated with a dataset allow users to understand how the data was collected and how to interpret the data. Importantly, this ensures that others can use the dataset and prevents misuse, misinterpretation, and confusion.

Examples of metadata or other information that may be included with research data:

- Methodology and procedures used to collect the data
- Data labels
- Definitions of variables
- Any other information necessary to reproduce and understand the data

HOW LABKEY HELPS:

- Capture structured metadata about samples, assays, subjects, etc
- Use standard or custom ontologies and simple value lists

Data Management Implications

Naming Conventions

Within a project team, agreement on naming conventions for multiple objects or files—or multiple versions of files—could be useful before embarking on a project that generates large amounts of data that need names or unique identifiers.

HOW LABKEY HELPS:

- Add data validation and quality control flagging
- Automatically route data based on file names and other conventions
- Assign sample, subject, and other identifiers

Data Management Implications

Common Data Elements

Common data elements (CDEs) are pieces of data common to multiple datasets across different studies. NIH encourages researchers to use CDEs, which helps improve accuracy, consistency, and interoperability among datasets within various areas of health and disease research.

HOW LABKEY HELPS:

- Integrate disparate data sources
- Connect to existing systems like REDCap, OpenEMPI, and relational databases

Data Management Implications

Data Storage Format

There are many storage formats for different types and sizes of datasets. For instance, small and simple datasets can be managed in spreadsheets while more complicated or larger datasets may need to be managed in a database. Remember that some types of data storage incur costs, which may be part of the project budget.

HOW LABKEY HELPS:

- Capture spreadsheets and other simple tabular data
- Import specialized file formats in a database
- Audit log history and security controls
- Consistently analyze data via R scripts, Jupyter notebooks, SQL queries, and other coding tools

NIH encourages use of established repositories.

Depositing data in a quality repository generally improves the FAIRness of data – Findable, Accessible, Interoperable, Reusable

- For data generated from research for which no data repository is specified by NIH, researchers are encouraged to select a data repository that is appropriate for the data generated from the research project.

- Primary consideration should be given to data repositories that are discipline or data-type specific to support effective data discovery and reuse.

Data Repository Selection

- NIH isn't endorsing specific repositories, but does have a list of examples
- Consider whether to select one or multiple
- Leverage ones you're already using (due to journal requirements, etc)
- Think about where you look for public datasets
- Don't plan to establish your own repository without a good reason

HOW LABKEY HELPS:

PanoramaWeb — Targeted mass spectrometry repository for Skyline users

Immune Tolerance Network TrialShare Clinical Trials Research Portal — Clinical trial results from Immune Tolerance Network

IMMUNESPACE — Data management and analysis of human immunological data

LabKey Open Research Portal — Real-time Zika and Covid data sharing

Key Takeaways

- Applies to all new NIH funding application and renewals
- Plan and budget for the managing and sharing of data using FAIR standards
- Create and submit a DMS plan for review when applying for funding
- Ensure you have the systems and resources in place to comply with your plan

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LabKey has helped researchers and institutions manage scientific data for more than 20 years.

Get in touch to see how our solutions can help you!

Q&A

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