

Developing a New Culture: NIH Policies in Data Management, Sharing & Access

JAIME M. GUIDRY AUVIL, PH.D.
Office of Data Sharing, NCI, NIH



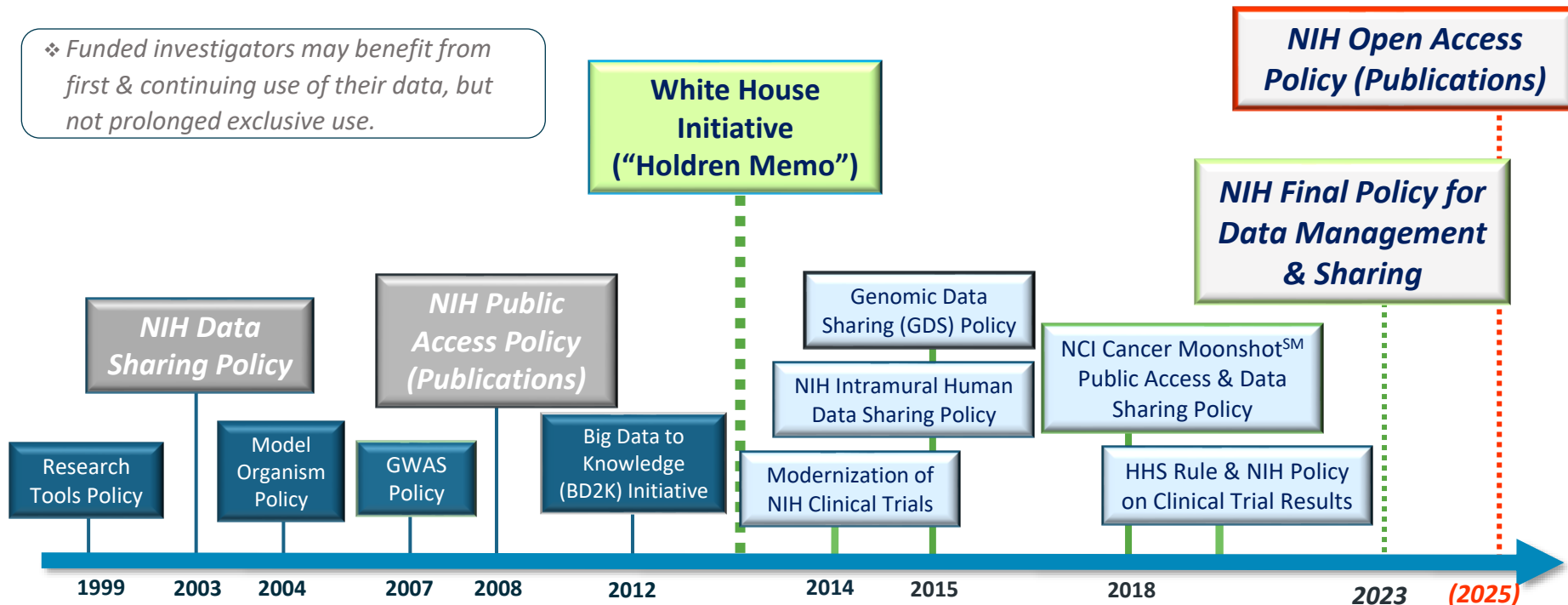
What is “Open Science”?

A “movement” to make scientific research (including *publications, DATA, physical samples, and software*) and dissemination accessible to all levels of society, amateur or professional.

- Open science is transparent and accessible knowledge that is shared and developed through **collaborative networks**.
- It encompasses practices such as:
 - publishing open research & campaigning for **open access**,
 - encouraging scientists to practice open-notebook science (such as **openly sharing data and code**),
 - broader dissemination and engagement in science, and
 - generally making it easier to publish, access and communicate scientific knowledge.
- Usage of the term varies substantially across disciplines, with a notable prevalence in the STEM disciplines.

NIH History of Data Sharing Policies

❖ *Funded investigators may benefit from first & continuing use of their data, but not prolonged exclusive use.*



Investigators must share any information necessary to understand, develop or reproduce published research (raw data, statistical methods, tools, source code)

Key Messages for Final NIH DMS Policy



Promote **open science**, stimulate new **discovery**, enable **rigor & reproducibility**, and provide **transparency**



Driving A Cultural Shift through planning for consistent, collaborative & impactful data management and sharing as a critical part of all research



NIH is taking a “**learning approach**” (i.e., phased and iterative implementation in the years to come).



Over time, thoughtful DMS plans will inform clear guidance on the highest value data types beyond genomics (repository, timelines, etc.)



NIH is providing resources, training, and guidance, to the extent possible, for initial rollout & will continue to develop these over time

Final NIH Policy for Data Management & Sharing (DMS)

Goal: Share scientific data supported by the NIH broadly and immediately



Scope

- **All NIH-supported research that generates scientific data**
 - Intramural & Extramural research
 - Grants, Contracts & OTAs
 - Human & non-human data; no budget threshold
- Submitted on/after **Jan. 25, 2023**
- **Complementary** to current data sharing policies (does not replace)



Expectations

- ✓ **Investigators must submit plans to manage & share data (research applications)**
- PIs should comply with applicable DMS Plans, and share data
 - In set repositories, to extent possible (**FAIR Principles**)
 - At publication or end of award, whichever sooner



Public Access

- Final manuscripts to PubMed Central w/i 12 months of acceptance

***Public Access policies to be updated asap (by Dec. 31, 2025) → agencies make publications & supporting data from federally funded research publicly accessible with no embargo on their free & broad release**

DMS Policy Applies to All **Scientific Data**

“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.”



Not Scientific Data Under the DMS Policy:

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

Responsibilities and Expectations: Investigators



Researchers to prospectively plan for how scientific data will be managed and shared through **submission of a DMS Plan** that considers any potential restrictions or limitations (no separate GDS Plans)



Researchers to maintain alignment with the approved DMS Plans by the NIH ICO (in the awards) and with the evolution of Plans during project period (through RPPR)

NIH DMS: Supplemental Guidance

Recommended Elements of a NIH DMS Plan



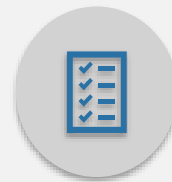
Data Types



Tools for Access/
Manipulation



Data Access/Reuse
Considerations



Data Standards



Sharing Oversight
Methods



Data Access &
Timelines

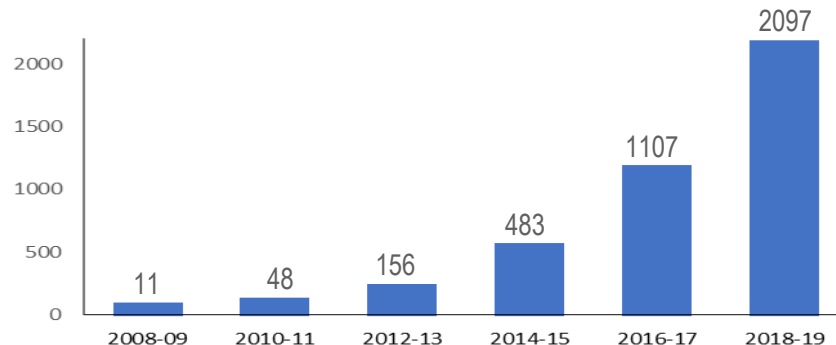
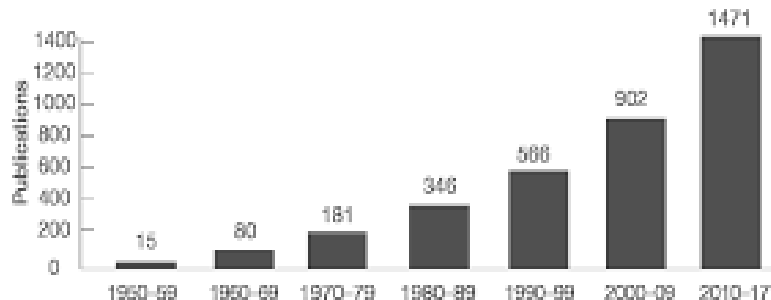


Guidance for
Selecting a Repository
for Data



Guidance for Allowable
Costs of Data
Management & Sharing

Driving Science through Publications, Data & Collaboration



	Framingham Heart Study	The Cancer Genome Atlas
<i>Study Length</i>	70 years	12 years
<i>Cases Studied</i>	15,144	11,429
<i>Publications</i>	3,698 (~38,000 PMC)	3,747 (~62,000 PMC)
<i>Controlled-access Data</i>	Consortia; HMB (+IRB/MDS, 2K=NPU)	Collaborative Teams & Public Use of Data; GRU
<i>Authorized Users</i>	715	3,335
<i>Open Data Use & Availability Timing</i>	Little Open Data; mostly available with publication	Some Open Data; All data immediately available to community

The Cancer Moonshot: Success in Mission-Driven Science

Cancer MoonshotSM:

Accelerate discovery, increase collaboration, and expand data sharing

In the Cancer Moonshot's first 4 years (2017-2021):



>2,000

Publications



49

Clinical Trials



>30

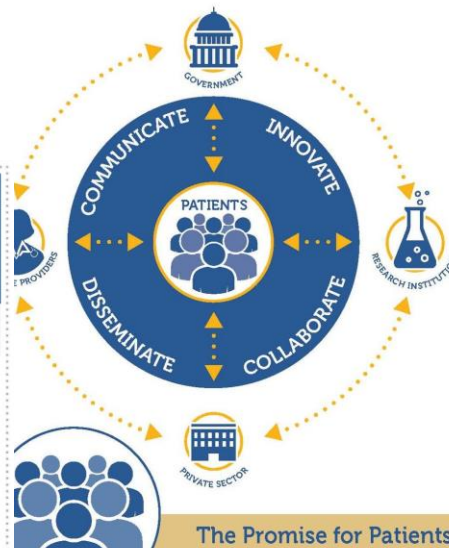
Patent Filings



INITIATIVES 2017-2022

OVER
70
CONSORTIUMS
OR PROGRAMS

OVER
240
RESEARCH
PROJECTS



MISSION

Dramatically accelerate efforts to prevent, diagnose, and treat cancer—to achieve a decade's worth of progress in 5 years

WHY NOW

New scientific understanding and vast amounts of rich data just waiting to be transformed into solutions

Immense science and technological capabilities positioning us for a quantum leap

A shared national commitment to harness the intellectual creativity and innovation of the American people

The Promise for Patients

New and improved treatment options



Better information for making medical decisions

More sensitive screening measures



Increased tools for community care providers

Improved use of effective prevention strategies



New ways to track and share health information

****Take Home Message: purposeful, broad, early access to data leads to much faster and impactful outcomes**

Together, we can end cancer as we know it.



NIH Resources to Support Investigators

<https://sharing.nih.gov>

- **A Central Data Sharing Website:** A one-stop-shop for information on NIH data sharing policies & related resources
 - *NIH Policy Notices & Supplemental Guidance*
 - *Relevant Forms & Templates*
 - *Frequently Asked Questions (FAQs)*
 - *Sample DMS Plans*
 - *Policy Decision Tool*
 - *Links to Individual NIH Institutes & Centers for program-specific references*
- **Other Resources and Tools** [e.g., DMPTool (<https://dmptool.org/>), Repositories]
- **NIH Training:** [News Events](#)
- **A Central Mailbox:** Help answer DMS questions (Sharing@nih.mail.gov).

U.S. Department of Health & Human Services | National Institutes of Health

NIH SCIENTIFIC DATA SHARING

DATA MANAGEMENT AND SHARING POLICY GENOMIC DATA SHARING POLICY OTHER SHARING POLICIES ACCESSING DATA ABOUT

Expediting the Translation of Research Results to Improve Human Health.

2-Part Webinar Series
Implementing the New NIH Data Management and Sharing Policy
REGISTER NOW

Explore the areas in which NIH has sharing policies.

Scientific Data Genomic Data Research Tools

Model Organisms Clinical Trials Research Publications

Not sure where to start?
Find which policies apply to you

Accessing Data



**NATIONAL
CANCER
INSTITUTE**

www.cancer.gov

www.cancer.gov/espanol

Additional Slides

Benefits of Broad Data Sharing

Collaborator Sharing

- Between investigator to investigator (e.g., sharing upon publication and request to the author)

Consortium Sharing

- Within large collaborative groups (e.g., sharing between investigators within a consortium/ network)

Broad Sharing

- Ensures fair and equitable access and secondary use of data by the wider research community (e.g., NIH's Genomic Data Sharing Policy)
- Has the most impact on *driving scientific innovation and discovery and ensuring replication of results*
- Broad sharing \neq Open access data



Framingham Study: Success in Data Collection Over Time

BY THE NUMBERS: Uncovering the Mysteries of the Heart

Years the Framingham Heart Study continues to break new ground on cardiovascular disease

70

By American Heart Association News

5,209

Initial volunteer participants

3

15,447

Participants over the past 70 years

Generations who have participated in the study

1960

Year the study pinned cigarette smoking as a risk factor for heart disease

3,698

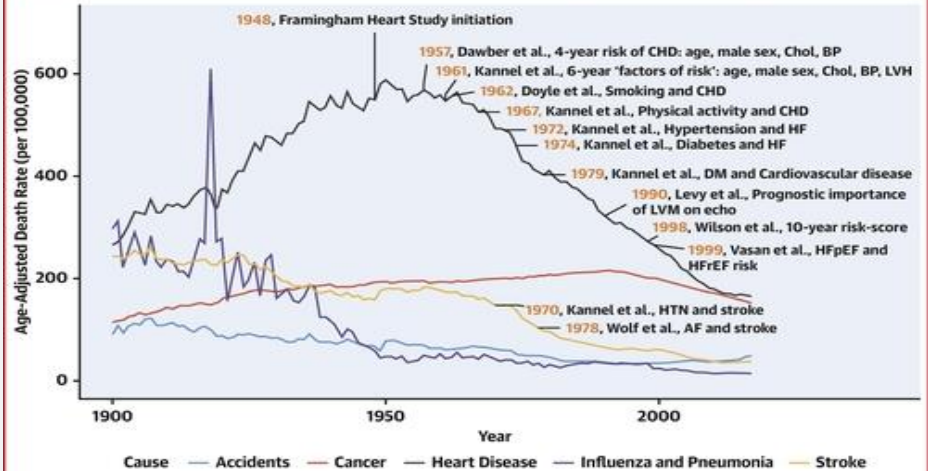
Published journal articles based on Framingham Heart Study data

802

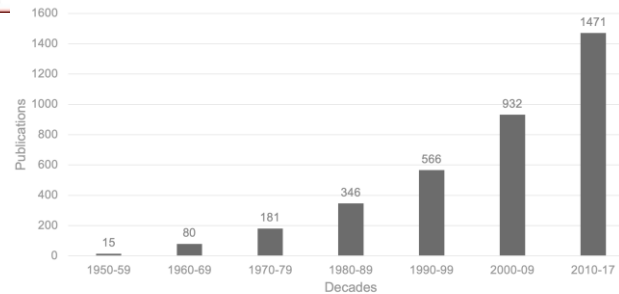
Participants who have donated or registered to donate their brain for further study

Sources: Framingham Heart Study, Boston University
Published Oct. 10, 2018

CENTRAL ILLUSTRATION: Age-Adjusted Death Rates for the Leading Causes of Death in the United States and the Framingham Heart Study



Andersson, C. et al. J Am Coll Cardiol. 2021;77(21):2680-92.



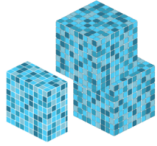
Total articles published through November 2017 = 3,561

The Cancer Genome Atlas: Success in Open Team Science

TCGA BY THE NUMBERS

TCGA produced over

2.5
PETABYTES
of data



To put this into perspective, **1 petabyte** of data is equal to

212,000
DVDs



TCGA data describes

33 DIFFERENT TUMOR TYPES



...including

10 RARE CANCERS

...based on paired tumor and normal tissue sets collected from

11,000 PATIENTS



...using

7 DIFFERENT DATA TYPES



TCGA RESULTS & FINDINGS



MOLECULAR BASIS OF CANCER

Improved our understanding of the genomic underpinnings of cancer

For example, a TCGA study found the basal-like subtype of breast cancer to be similar to the serous subtype of ovarian cancer on a molecular level, suggesting that despite arising from different tissues in the body, these subtypes may share a common path of development and respond to similar therapeutic strategies.



TUMOR SUBTYPES

Revolutionized how cancer is classified

TCGA revolutionized how cancer is classified by identifying tumor subtypes with distinct sets of genomic alterations.*



THERAPEUTIC TARGETS

Identified genomic characteristics of tumors that can be targeted with currently available therapies or used to help with drug development

TCGA's identification of targetable genomic alterations in lung squamous cell carcinoma led to NCI's Lung-MAP Trial, which will treat patients based on the specific genomic changes in their tumor.

THE TEAM



20

COLLABORATING INSTITUTIONS
across the United States and Canada

*TCGA's analysis of stomach cancer revealed that it is not a single disease, but a disease composed of four subtypes, including a new subtype characterized by infection with Epstein-Barr virus.

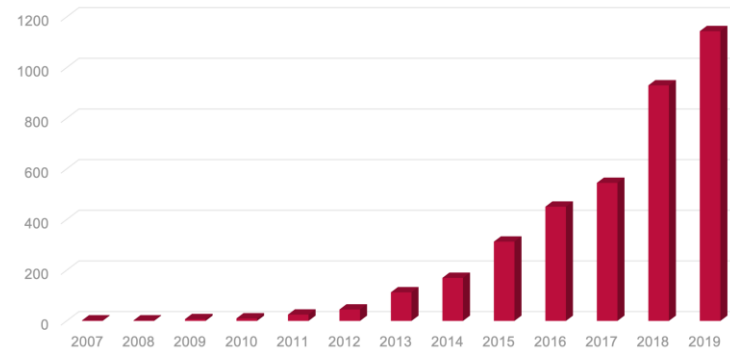
WHAT'S NEXT?

The Genomic Data Commons (GDC) houses TCGA and other NCI-generated data sets for scientists to access from anywhere. The GDC also has many expanded capabilities that will allow researchers to answer more clinically relevant questions with increased ease.

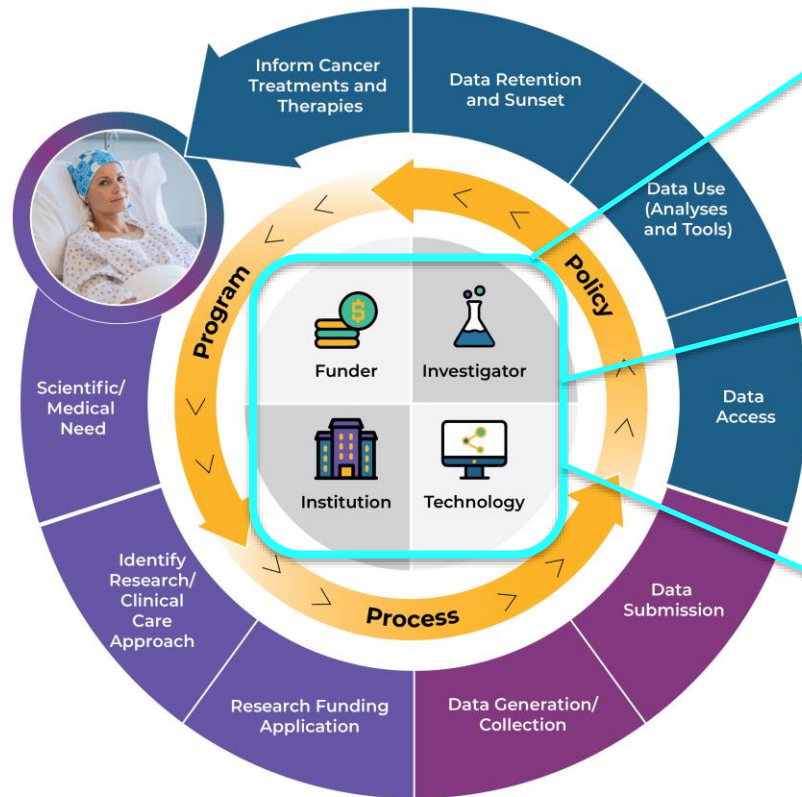


www.cancer.gov/ccg

Number of Publications Using TCGA Data



Scientific Data Lifecycle: Keys to Impactful Discovery



Critical Questions to Answer

Programs that define therapeutic needs and essential scientific gaps to be filled using structured datasets.

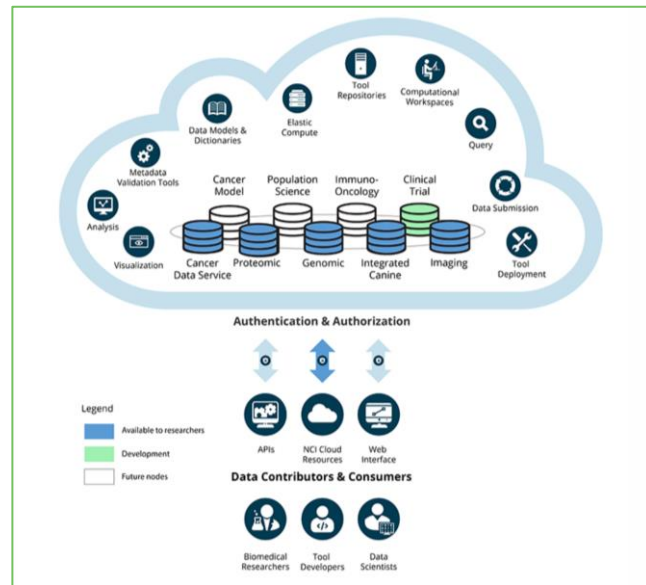
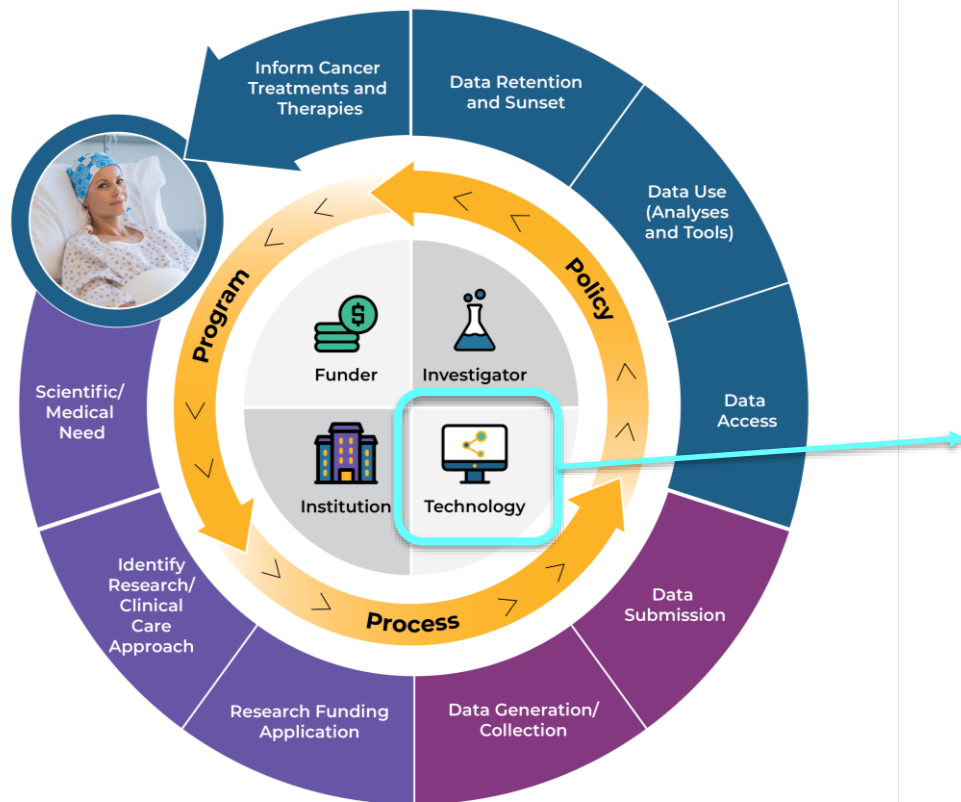
Policies to Promote Broad Use

Implementation of aggressive data management, sharing and access policies that ensure rapid, free and immediate access to all types of data.

Infrastructure to Support FAIR Principles

Technology platforms and tools that employ standards to make data findable, accessible, interoperable and reusable.

Sharing Data Openly through a Cancer Data Ecosystem



Cancer Research Data Ecosystem

How to “Plan” for NIH Data Management & Sharing

Data Collection

What data types will be generated in your research project?

~Align w/ Specific Aims in application (e.g. omics, clinical, imaging, flow cytometry)

Data Management

How will those data be managed?

~Outline plan to maintain data throughout project (e.g. lab, Institute data core, DCC, hard drive/ cloud)

Data Sharing

Which data files are most useful for broad uses in research community?

~Determine data needed for new research projects to avoid duplication or supplement experiments

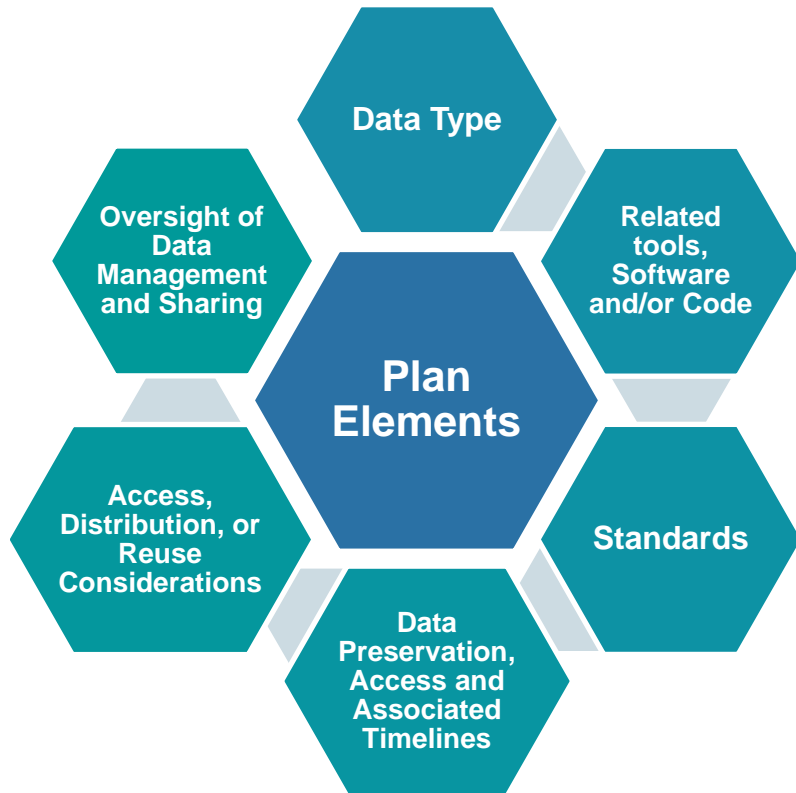
Plan Writing

Are all DMS Plan elements addressed (data, repositories, costs)?

~Submit all costs in Budget Justification (e.g. data formatting, curation)

****Not all managed data need to be shared for secondary use***

Six Elements of A DMS Plan

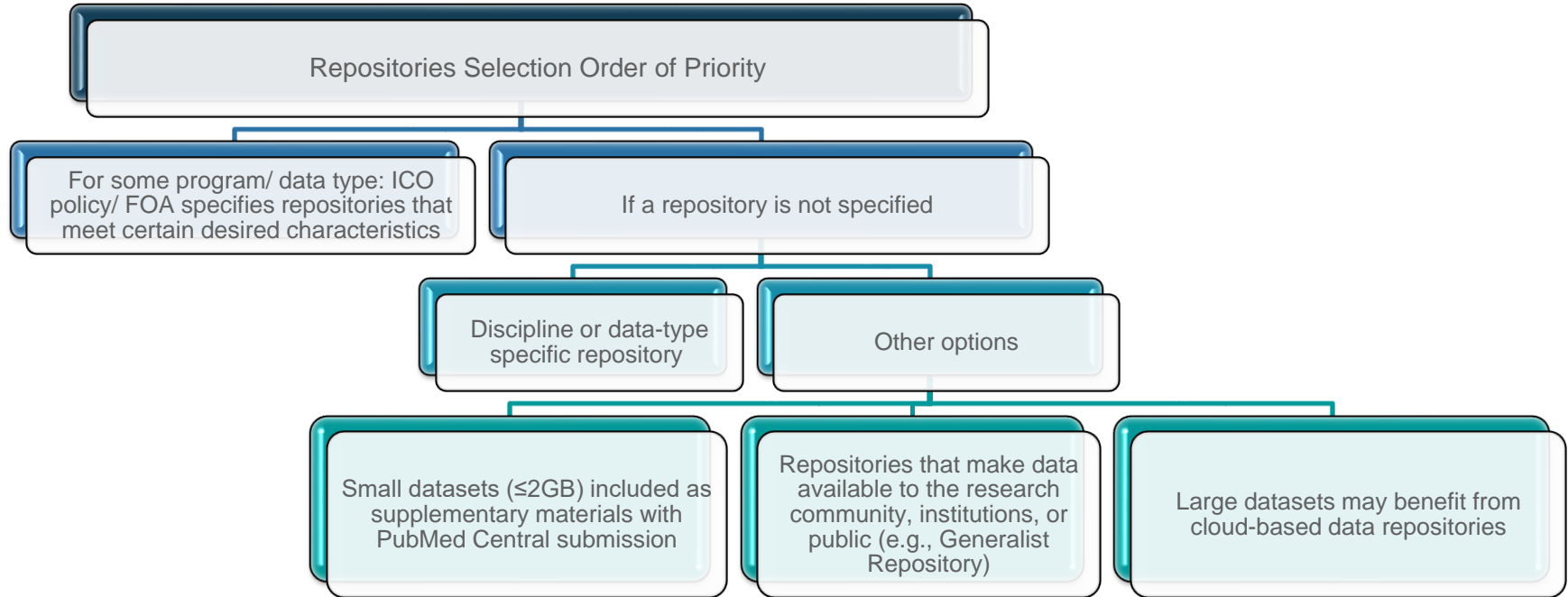


- **Data type**
 - Identifying data to be preserved and shared and listing metadata
- **Standards**
 - Standards to be applied to scientific data and metadata (i.e., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation)
- **Data preservation, access, timelines**
 - Repository to be used, persistent unique identifier, and when/ how long data will be available
- **Access, distribution, reuse considerations**
 - Description of factors for data access, distribution, or reuse
- **Related tools, software, code**
 - Tools and software needed to access and manipulate data
- **Oversight of data management and sharing**
 - Indicates how compliance with the DMS plan will be monitored and managed

See [Writing a Data Management & Sharing Plan](#) for details

Selecting A Data Repository

Promoting the use of established data repositories to improve FAIRness of data



What is not a Repository? Supplemental material in a journal or Lab website

NIH Resources to Guide Repository Selection

NIH-Supported Repositories

- Filterable list of 75+ [NIH Repositories](#) that are open to taking in data of various types & formats
- PubMed holds up to 2Gb of data (as supplemental information to manuscripts)

Institute or Center	Repository Name	Repository Description
NCI		Keyword Filter

NCI	Cancer Nanotechnology Laboratory (caNanoLab)	caNanoLab is a data sharing portal designed to facilitate sharing in the biomedical nanotechnology research community. It expedite and validate the use of nanotechnology in laboratory research. caNanoLab provides support for the annotation of nanotechnology characterizations resulting from physico-chemical, in vitro assays and the sharing of these characterizations and associated data.
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Other Repository Resources

- [Generalist repositories](#) (9 listed by NIH as part of GREI)
- [Nature's Data Repository Guidance](#)
- [Registry of Research Data Repositories](#)



See [Repositories for Sharing Scientific Data](#)

Data Management and Sharing Costs

ALLOWABLE COSTS

- Curating data/developing supporting documentation
- Preserving/sharing data through repositories
- Local data management considerations
- **IMPORTANT:** Must be incurred during the performance period

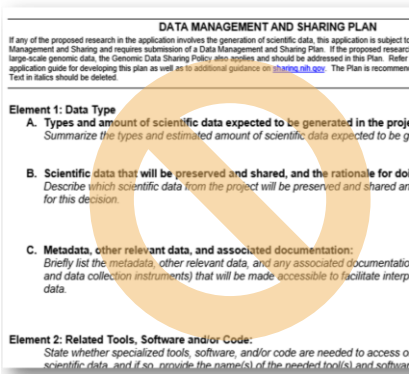
UNALLOWABLE COSTS

- Infrastructure costs typically included in indirect costs
- Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)
- **Additional Example:** Data storage costs in NIH/ NCI-supported data repositories

See [Budgeting for Data Management & Sharing](#) for details

Responsibilities and Expectations: Peer Reviewers

- Peer Review Will NOT assess DMS Plans*
- DMS Plan assessment is an administrative issue, reviewers assess only scientific merit of applications
- Peer Review Will NOT see full Plan or be providing comments on Plans*
- DMS Plan will be excluded from the application image shown to peer reviewers
- Peer Review will NOT factor DMS Plans into their impact scores*



**Exceptions for FOAs where data sharing is core to the science, e.g., FOAs for data dissemination centers)*

What Should a DMS Plan Look Like (OER)?

- ✓ Plans should be no more than 2 pages in length
- ✓ Applications subject to both DMS and GDS Policies submit a single Plan
- ✓ Optional format page available
- ✓ Exploring structured form in future (*NCI & NICHD have each developed forms; possible pilot*)

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](https://www.nih.gov/data-management/data-sharing). The Plan is recommended not to exceed two pages. Text in italics should be deleted.

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

DMS Plan format page will be added to list of [Format Pages](#) and incorporated into FORMS-H application instructions by Fall 2022

A Decision Support Tool to Guide Plan Assessment

- Optional tool to guide POs through DMS Plan assessment
- Stepwise list of considerations for each element
- Additional ICO or program-specific guidance may also apply



ELEMENT	PROPOSED ASSESSMENT CRITERIA
Element 1, Data Type	<ul style="list-style-type: none">• <input type="checkbox"/>Y <input type="checkbox"/> N - Does the Plan identify the types and estimated amounts of scientific data to be generated and/or used in the research (e.g., 256-channel EEG data and fMRI images from ~50 research participants)?• <input type="checkbox"/>Y <input type="checkbox"/> N - Does the Plan identify which scientific data will be preserved and shared with the scientific community?• <input type="checkbox"/>Y <input type="checkbox"/> N - Has a rationale been provided justifying the decision of which scientific data will be preserved and shared, based on ethical, legal, and technical factors?• <input type="checkbox"/>Y <input type="checkbox"/> N - Does the Plan 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? <p>For research subject to the GDS policy:</p> <ul style="list-style-type: none">• <input type="checkbox"/>Y <input type="checkbox"/> N - Does the Plan describe whether the proposed research involves human data, non-human data, or both.• <input type="checkbox"/>Y <input type="checkbox"/> N - Does the Plan list the type(s) and amounts of genomic data that will be shared (e.g., sequence, transcriptomic, epigenomic, and/or gene expression data) and whether it is individual-level data, aggregate-level data, or both)? <p>If the answer is “no” for ANY of the questions above, more information is needed from the applicant to accurately assess the Plan</p>

Harmonization of DMS and Genomic Data Sharing Plans

Investigators	Program Staff
<ul style="list-style-type: none">• One Plan: Genomic data sharing considerations to be addressed in DMS Plans using the expected DMS Plan elements.• Timeline: At the time of application or Just-in-Time.• <i>For human data subject to GDS:</i> Applicants should complete the DMS Plan anticipating sharing according to the criteria in the <u>Institutional Certification (IC)</u>.	<ul style="list-style-type: none">▪ IC or provisional certification must be submitted and accepted before issuing the award. Investigators should state in the DMS Plan what data can be shared and how if IC criteria cannot be met.▪ Plans will be reviewed by Program Staff. Peer reviewers will no longer comment on the Plans but rather on the reasonableness of the DMS budget.▪ Submission timelines for non-human and human data subject to GDS will remain unchanged.▪ Compliance and enforcement terms for awards subject to GDS will be handled in accordance with that under DMS (i.e., “end of the performance period” is the <i>latest</i> opportunity to submit data).

Notice Number: [NOT-OD-22-198](#)

How Do the DMS and Genomics Data Policies Compare?

	2015 NIH GDS Policy	2023 NIH DMS (New Policy)
Effective Dates	<ul style="list-style-type: none"> ▪ New applications: received on/after January 25, 2015 	<ul style="list-style-type: none"> ▪ New applications & Competitive renewals (Type 2, previously funded awards): For submission on/after January 25, 2023
Scope	<ul style="list-style-type: none"> ▪ Large-scale genomics data & some smaller studies (<i>programmatically priority, rare diseases</i>) ▪ Thresholds & assay types defined 	<ul style="list-style-type: none"> ▪ All NIH-supported research that generates scientific data ▪ Not applicable to other activities (e.g. training, infrastructure development) ▪ No detailed expectations defined outside of GDS, CT or programs
	<ul style="list-style-type: none"> ▪ Intramural & Extramural research mechanism (grants, cooperative agreements, contracts, other transactions) <ul style="list-style-type: none"> ▪ Human and non-human data; no budget threshold 	
NIH Expects (for PIs)	<ul style="list-style-type: none"> ▪ Submit & release data through NIH repositories ▪ Use guidelines for standard formats, levels of data 	<ul style="list-style-type: none"> ▪ Prospectively plan how to preserve & share scientific data ▪ Outline in Data Management & Sharing (DMS) Plan (w/ applications), and ▪ Report data sharing progress in annual submission of RPPR
	<p><i>*Only one plan will be submitted;</i> DMS plans will include genomics elements along with other data types (i.e. no separate GDS plan submitted after January 25, 2023)</p>	
Timelines	<ul style="list-style-type: none"> ▪ Lower-level primary data: released by 9 months (full, QC dataset generation) ▪ Summary analyses at publication 	<ul style="list-style-type: none"> ▪ Shared scientific data: as soon as possible → <u>by time of associated publication, or end of performance period</u> (whichever comes first)