Policy and Technology: Ensuring Ethics in the Submission and Access of Biomedical Research Data

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National Heart, Lung, and Blood Institute

The Benefits of Data Sharing

- **Preserves the scientific record**
  - Encourages better data management; not all results are published
- **Facilitates research integrity, transparency and trust**
  - Validates experiments and results
  - Engenders trust through transparency
- **Advances science and application**
  - Accelerates translation of results into practice
  - Suggests new hypotheses
  - Innovates through statistical methods, resources, and tools
- **Increases efficiency, fosters rigor and reproducibility**
  - Increases statistical power and value
  - Enables data generated from one study to be used by others to explore additional research questions
  - Decreases in spending on duplication of original studies

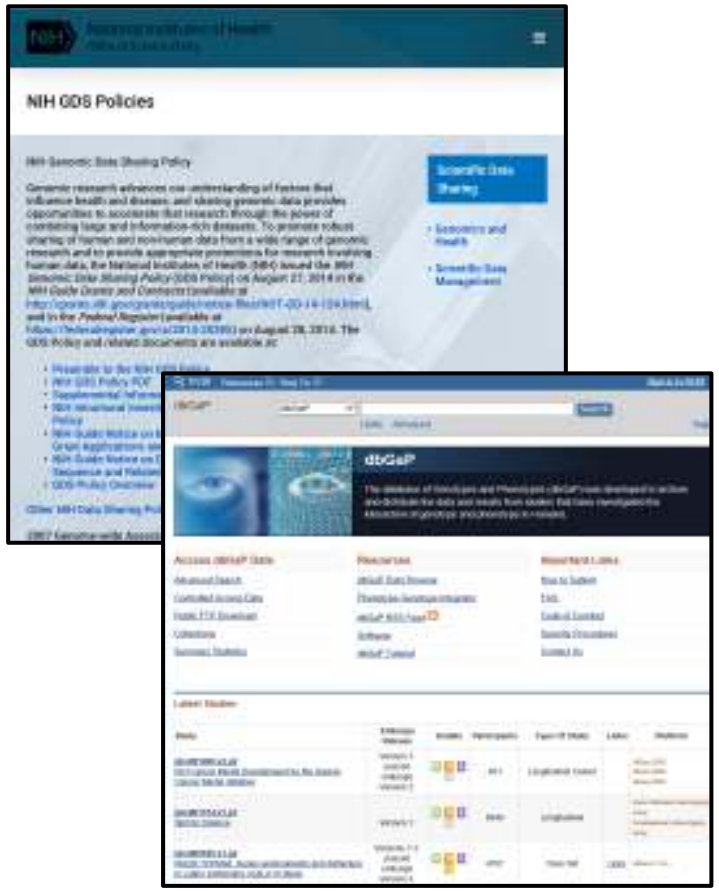
NIH has a longstanding commitment to data and resource sharing

Responsible Data Stewardship

Privacy and Trust are Key Components

- Participant protections and appropriate use of data
  - Health Insurance Portability and Accountability Act of 1996 (HIPAA)
  - Federal Policy for the Protection of Human Subjects (Common Rule – revised in 2018)
  - Certificates of Confidentiality
- Freedom of Information Act (FOIA)
- Privacy Act of 1974
- Genetic Information Nondiscrimination Act (GINA)
- Authentication and authorization of data users (e.g., for controlled-access data)

NIH Genomic Data Sharing Policy

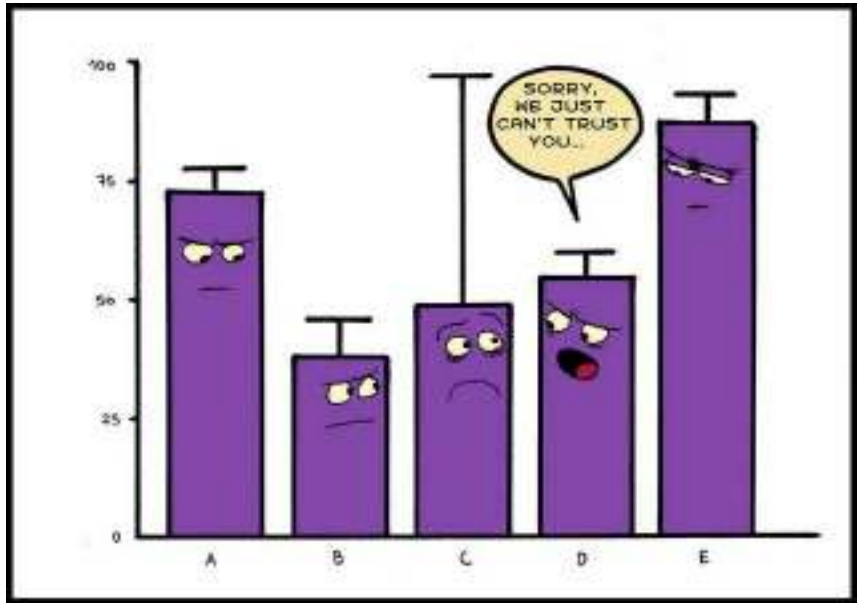


- Sets forth expectations and responsibilities to ensure the timely, broad, and responsible sharing and use of genomic data from NIH funded research
- Access to human data (de-identified) in **dbGaP** is tiered and based on informed consent of study participants
  - **Controlled-access**: individual-level genomic and phenotypic data (requires an application and approval by a Data Access Committee)
  - **Unrestricted-access**: Study descriptions; Genomic summary results (GSR, for most studies) under a new data management update
- Users, authenticated through eRA Commons, agree to terms of use and security practice
- **More than 1,200** studies available; **more than 57,000** Data Access Requests approved (cumulative)
- **More than 3,000** publications resulting from re-use of dbGaP data

dbGaP: database of Genotypes and Phenotypes

Access to “Genomic Summary Results (GSR)”

GSR Includes:
- Genotype counts
- Allele frequencies
- p-values
- Effect size estimates and standard errors



- GSR has been shared via “controlled-access” in dbGaP
  - Possibility of inferring group association of participants for some GSR
- Community to NIH - benefits of moving GSR to unrestricted-access outweigh potential risks
- GSR management update has been released!!!

Protections and Safeguards for dbGaP Data Access and Use

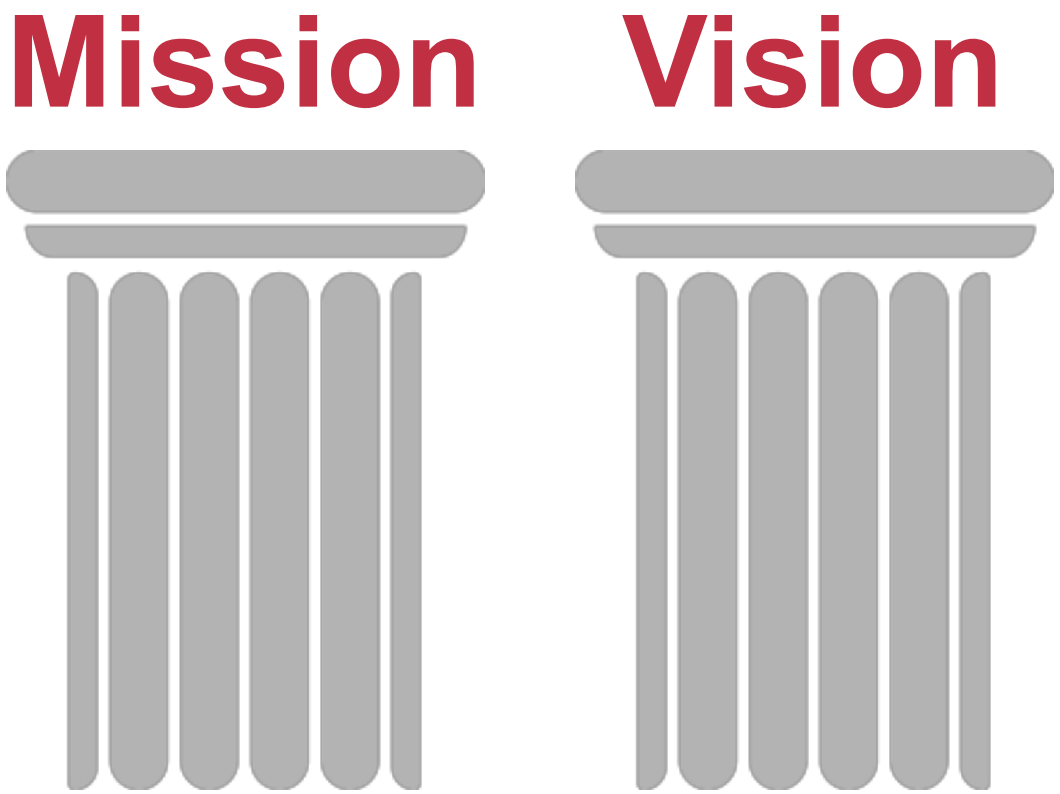
- **Protections:**
  - Institutional Certification for data submitters
    - Appropriateness of access level
    - Informed consent and any exceptions for data submission
    - Awareness of and respect for cultural and/or community-based concerns
    - Institutional certification and IRB determinations of consent applicability & data protection
  - Data Use Certification for data users
  - NIH Data Access Committees review of Data Access Request
  - Certificate of Confidentiality protects "identifiable, sensitive information"
- **Safeguards:**
  - Prevent identification of individual participants without appropriate approvals
  - Only authorized individuals can gain access to data
  - Use requested datasets solely in connection with project approved for data use
  - Approved investigators follow guidance on security best practices
  - Report any inadvertent data release, breach of data security, or other data management incidents

Connecting NIH Data Systems and Resources

- Align dbGaP access management with standardized NIH research commons Identity and Access Management specifications

- Develop a framework for resource management within cloud environments
  - Modeling of authority and the permissions required to access resources in order to support cooperative computing amongst the internal NIH ICOs and future federated partners
  - Allows for a federated login for researchers

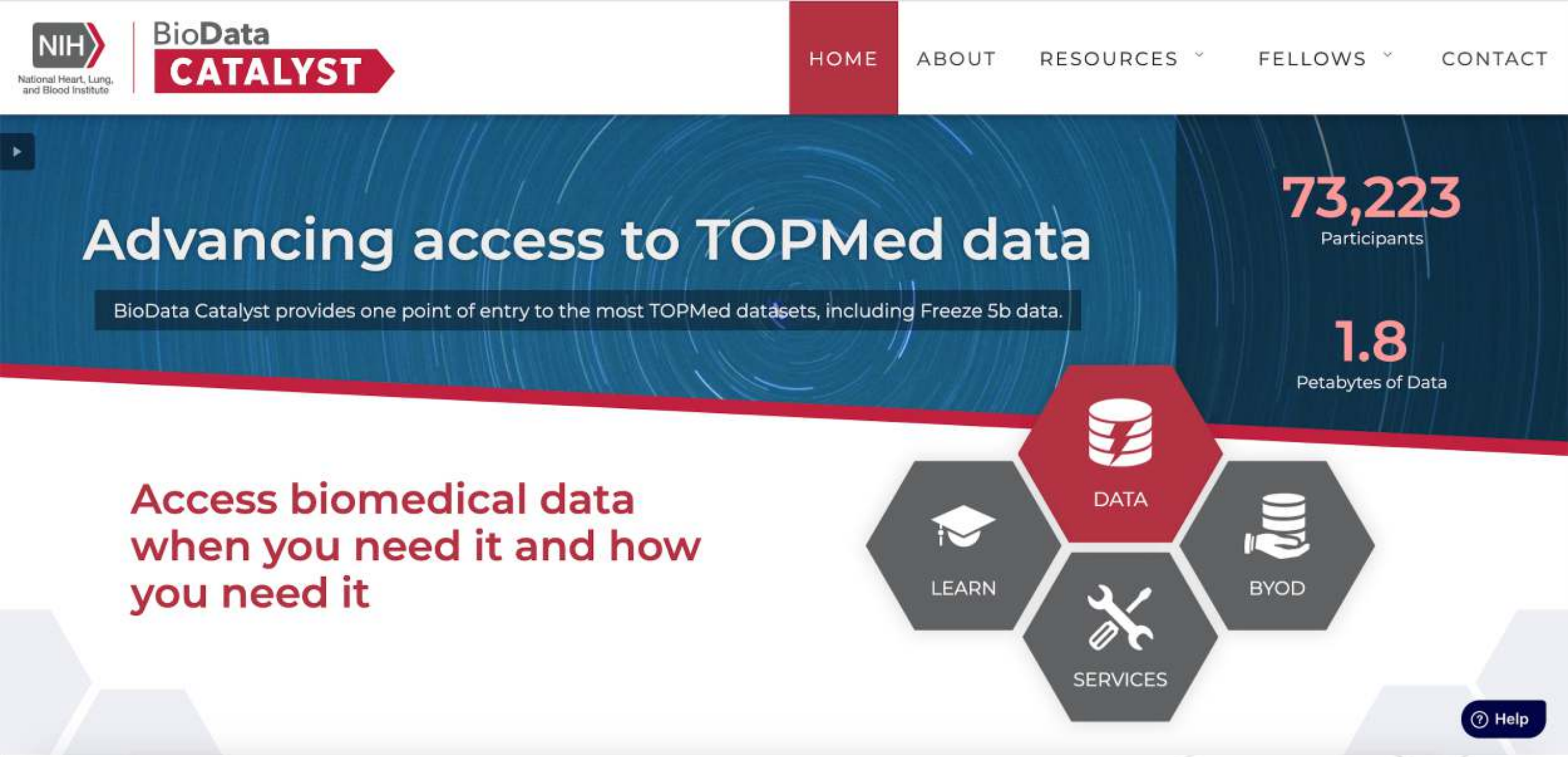
NHLBI BioData Catalyst



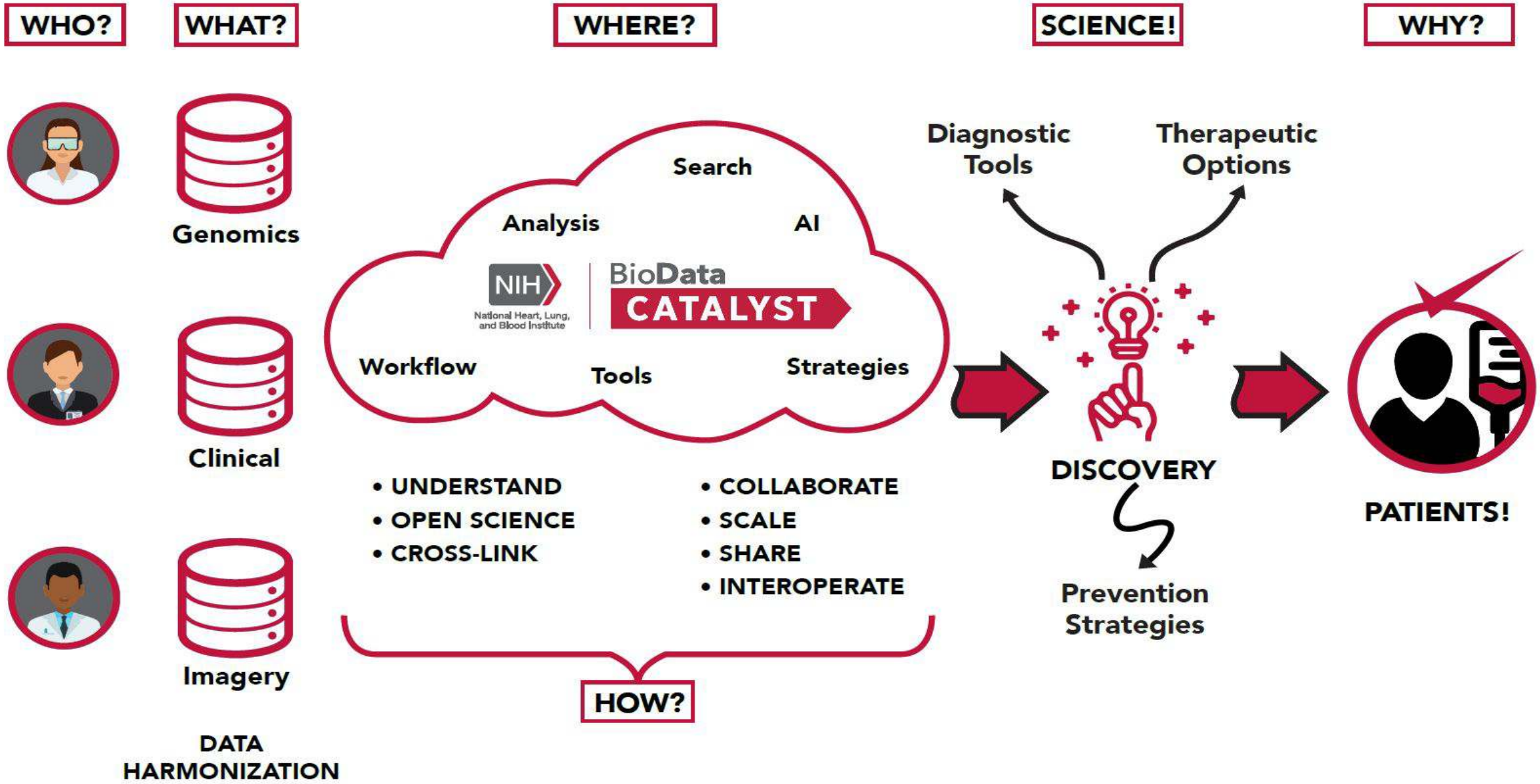
The ***mission*** is to develop and integrate advanced cyberinfrastructure, leading edge tools, and FAIR data to support the NHLBI research community.

The ***vision*** is to be a community-driven ecosystem implementing data science solutions to democratize data and computational access to advance Heart, Lung, Blood, and Sleep science.

FAIR – findable, accessible, interoperable, reusable



[To view a video-only demonstration, click here.]


WHO?
WHAT?
WHERE?
SCIENCE!
WHY?
Genomics
Clinical
Imagery
DATA HARMONIZATION
Search
Analysis
AI
NIH
National Heart, Lung, and Blood Institute
BioData CATALYST
Workflow
Tools
Strategies
• UNDERSTAND
• OPEN SCIENCE
• CROSS-LINK
• COLLABORATE
• SCALE
• SHARE
• INTEROPERATE
HOW?
Diagnostic Tools
Therapeutic Options
DISCOVERY
Prevention Strategies
PATIENTS!

Using Deep Learning with the BDCatalyst Ecosystem

What are the **key features** of subjects that makes them **more likely** to develop **severe symptoms of COVID-19?**

BDCatalyst User Community

1. Researcher enters the NHLBI BDCatalyst portal
2. Researcher authenticates with Gen3.
3. Data search and cohort creation occurs with PIC-SURE
4. Data is exported to a workspace for analysis

Gen3 Data Commons

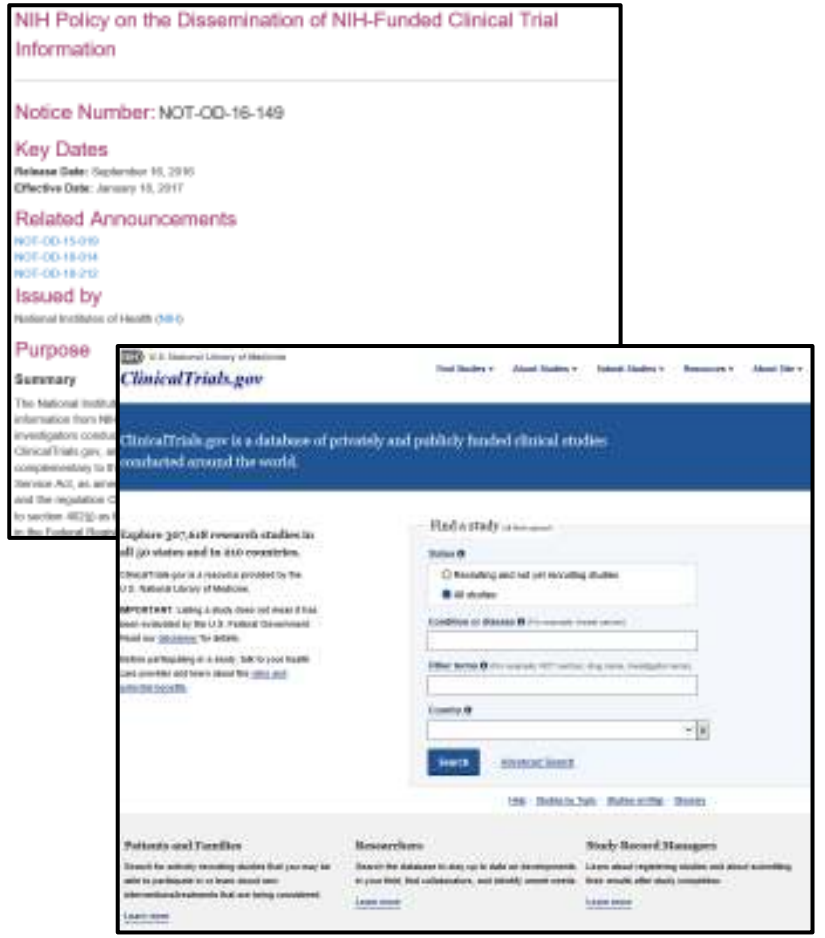
PIC-SURE

SevenBridges

Terra

Safeguards for Clinical Trial Data: Dissemination of Results

- Enhance transparency into NIH-funded and other clinical trials
- Registration of study objectives, design, etc. at **ClinicalTrials.gov**
- Summary results of clinical trial and participant characteristics
- **No** participant level data
- Linked to related information – possibly participant level data
- Full study protocol
- **More than 350,000** registered studies; **more than 39,000** summary results; **more than 115,000** users/ day



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NIH Data Management and Sharing Policy Development

Released for Public Comment: Proposed Policy Provisions for a Draft NIH Data Management and Sharing Policy (**October 2018**)

Analysis of public comments, and considerations for Policy Guidance and Implementation for:

- **Data Management and Sharing Plans** (elements, costs, collecting and evaluating, ensuring compliance)
- **Infrastructure** (e.g., NIH Figshare Pilot program, characteristics of repositories)
- **Timing** of Policy implementation
- **NIH Policy** that is **reasonable** and **achievable** for NIH-funded research

Released for public comment: draft NIH Data Management and Sharing Policy and supplemental guidance (**November 2019**)

Release final NIH Policy

Image from: http://www.whistlercentre.ca/2010/03/draft-icsp-framework-nearing-completion-for-williams-lake/people-working-together-small/

Application of Novel Tools and Technologies: Future Considerations

For approaches such as artificial intelligence (AI):

- Purpose, type of data, source of data
- Ethics and security
  - Governance
  - Risk and responsibility
  - Potential biases
- Future use and unintended use
- Transparency, validation, trust

AI is integrated into numerous technologies that people use every day. *Credit: iStock-metamorworks*

Lessons Learned and Take-away Messages

- **Considerable value** from enhancing access to (biomedical) data
  - Accelerates and improves **science**
  - Builds **trust** in the research enterprise
- **Sharing not binary (yes/no) – Effective models exist** for sharing data while providing necessary protections, e.g.,
  - Summary statistics from clinical trials, genomics research
  - Controlled access to deidentified participant level data
- **Consistency with informed consent** of great importance
- **Approaches**
  - Conservative initially
  - Listen to the community
  - Risk/benefit analysis
  - Balanced approach with solution that accommodates sensitive studies/populations
- **Technology and policy** go hand-in-hand

THANK YOU!

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