Data Sharing and Embedded Research Guiding Principles

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Why?

- Public health
- Maximizing investment
- Accelerate learning
- Foster collaboration (pay it forward)

Ultimately…transparency, reproducibility, secondary use of medical research, are good for society

Recently …..

The New York Times
Biden Unveiling Public Database for Clinical Data on Cancer

FOX NEWS Health
Biden unveiling public database for clinical data on cancer

HealthData Management
NCI launches open access resource to spur cancer research

HOUSTON CHRONICLE
Biden unveils searchable government cancer database

SCIENTIFIC AMERICAN **REUTERS**
Biden Unveils Major Database to Advance Cancer Research

THE HUFFINGTON POST
Biden Announces Crucial Piece Of His Cancer Moonshot Initiative

The Washington Post
Biden unveils launch of major, open-access database to advance cancer research

FORTUNE
Joe Biden Just Announced a Huge New National Cancer Database

REUTERS
Biden announces U.S. project to promote cancer data sharing

CHICAGO SUN-TIMES
VP Joe Biden in Chicago to promote Moonshot Initiative vs. cancer

THE CANCER LETTER
Biden Designates NCI's Genomic Data Commons As Foundation of Cancer Moonshot

Daily Mail
New US data system to centralize cancer information

genomeweb
NCI Launches Genomic Data Commons for Cancer Data Sharing

HealthITAnalytics
NIH Launches Genomic Data Commons Supporting Cancer Moonshot

fedscoop
Biden launches data portal to back Cancer Moonshot

A Revival:
Gathering of Data Sharing *Evangelists*

SHARING CLINICAL TRIAL DATA

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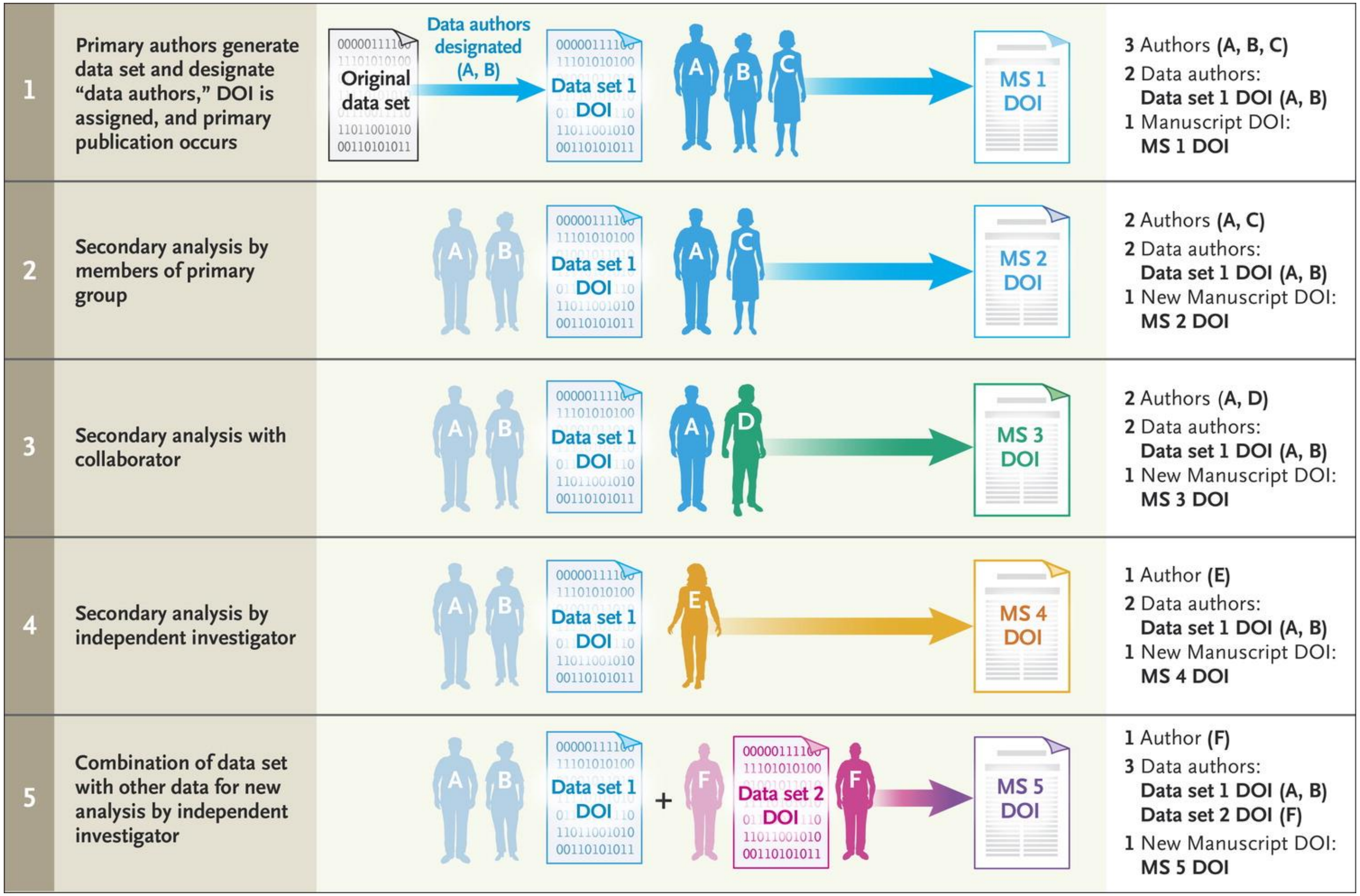
Carrots & Sticks: Author Incentives



1	Primary authors generate data set and designate "data authors," DOI is assigned, and primary publication occurs	3 Authors **(A, B, C)** 2 Data authors: **Data set 1 DOI (A, B)** 1 Manuscript DOI: **MS 1 DOI**
2	Secondary analysis by members of primary group	2 Authors **(A, C)** 2 Data authors: **Data set 1 DOI (A, B)** 1 New Manuscript DOI: **MS 2 DOI**
3	Secondary analysis with collaborator	2 Authors **(A, D)** 2 Data authors: **Data set 1 DOI (A, B)** 1 New Manuscript DOI: **MS 3 DOI**
4	Secondary analysis by independent investigator	1 Author **(E)** 2 Data authors: **Data set 1 DOI (A, B)** 1 New Manuscript DOI: **MS 4 DOI**
5	Combination of data set with other data for new analysis by independent investigator	1 Author **(F)** 3 Data authors: **Data set 1 DOI (A, B)** **Data set 2 DOI (F)** 1 New Manuscript DOI: **MS 5 DOI**

NIH Collaboratory *Rethinking Clinical Trials*®
Health Care Systems Research Collaboratory

BE Bierer, et al N Engl J Med 2017; 1684-1687

Carrots & Sticks:
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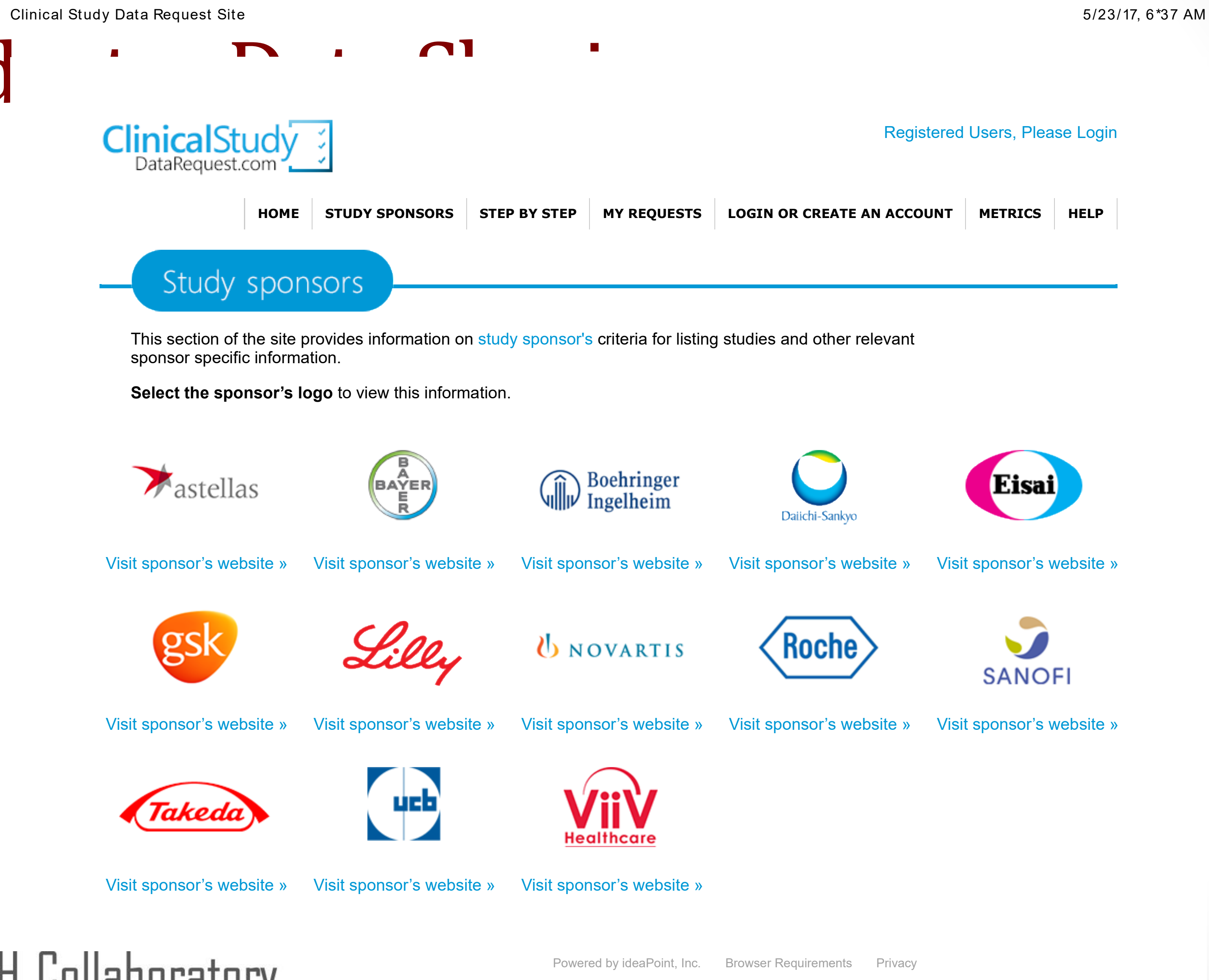

Clinical Study Data Request Site

5/23/17, 6*37 AM

ClinicalStudy DataRequest.com

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Contentious issues: data sharing…and comparisons

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Ethical Considerations

- The ethical responsibility to share data generated by publicly funded research must be balanced against the need to protect *patient privacy* and scientific *integrity*.

Principles

- Patient privacy: Essential obligation

Principles

- Patient privacy: Essential obligation
- Health system privacy: Sometimes necessary

The Balance of Benefits & Risks

Collaboratory Trials Policy

- Data sets will be structured to maximize future scientific value while protecting patient and health system privacy.
- Data should not include any of the 18 HIPAA-specified direct identifiers
- Investigators may make more detailed data available through a more "restrictive" data sharing option

Structures and tools (from least to most restrictive)

- Public archive – send data to any user
- Private archive – send data to approved users
  - For any purpose
  - For approved purposes only (e.g. governed by DUA)
- Public enclave – any user may send questions to data
- Private enclave – some users may send questions to data
  - Automatically executed
  - Moderated (either queries or results)

Summary

- Data sharing is a societal good
- Like healthcare, health systems are…. complex
- Collaboratory should lead the way

Thank You