



NIH Collaboratory

Rethinking Clinical Trials®

Health Care Systems Research Collaboratory

HCS Research Collaboratory Data Sharing Requirements

Adrian F. Hernandez, MD, MHS



Data Sharing Mandate (2017 RFA)

“The HCS Research Collaboratory program encourages sharing of resources with broad availability of policies, practices, materials, and tools to facilitate collaboration, reuse, and replication. In addition, the HCS Research Collaboratory program requires sharing of study data from Demonstration Projects in a timely manner with appropriate privacy and confidentiality protections, in accordance with the Data Sharing Policy developed by the HCS Research Collaboratory.”

Why?

- Advancing public health
- Maximizing investment
- Accelerating learning
- Fostering collaboration (pay it forward)

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

Recently...



The NEW ENGLAND
JOURNAL of MEDICINE

EDITORIAL

Data Sharing Statements for Clinical Trials — A Requirement of the International Committee of Medical Journal Editors

Darren B. Taichman, M.D., Ph.D., Peush Sahni, M.B., B.S., M.S., Ph.D., Anja Pinborg, M.D., Larry Peiperl, M.D., Christine Laine, M.D., M.P.H., Astrid James, M.B., B.S., Sung-Tae Hong, M.D., Ph.D., Abraham Haileamlak, M.D., Laragh Collogly, M.D., M.P.H., Fiona Godlee, F.R.C.P., Frank A. Frizelle, M.B., Ch.B., F.R.A.C.S., Fernando Florenzano, M.D., et al.

thebmj

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Data sharing in medical research

BMJ 2018 ; 360 doi: <https://doi.org/10.1136/bmj.k510> (Published 14 February 2018)

Cite this as: BMJ 2018;360:k510

JAMA Network

September 2017

Sharing Clinical Research Data—Finding the Right Balance

Bernard Lo, MD¹; Steven N. Goodman, MD, PhD²

Annals of Internal Medicine

IDEAS AND OPINIONS

Data Sharing and Embedded Research

Gregory E. Simon, MD, MPH; Gloria Coronado, PhD; Lynn L. DeBar, PhD, MPH; Laura M. Dember, MD; Beverly B. Green, MD, MPH; Susan S. Huang, MD, MPH; Jeffrey G. Jarvik, MD, MPH; Vincent Mor, PhD; Joakim Ramsberg, PhD; Edward J. Septimus, MD; Karen L. Staman, MS; Miguel A. Vazquez, MD; William M. Vollmer, PhD; Douglas Zatzick, MD; Adrian F. Hernandez, MD, MHS; and Richard Platt MD, MS



Harlan Krumholz
@hmkyal

Following ▾

The answer is clearly: Yes!!! [Whose Data Are They Anyway? Can Patient Perspective Advance the Data-Sharing Debate?]

nejm.org/doi/pdf/10.105...

Whose Data Are They Anyway? Can a Patient Perspective Advance the Data-Sharing Debate?

Charlotte J. Haug, M.D., Ph.D.

Most patients haven't thought much about data sharing, according to Sara Riggare, but those who have "find the current disease — ways to use technology in monitoring and treating one-self. She is also a patient. Riggare had her first symptoms of Parkinson's disease at a summit on aligning incentives for data sharing want their data shared quickly, especially to ensure that other patients know



Data Sharing in Clinical Trials

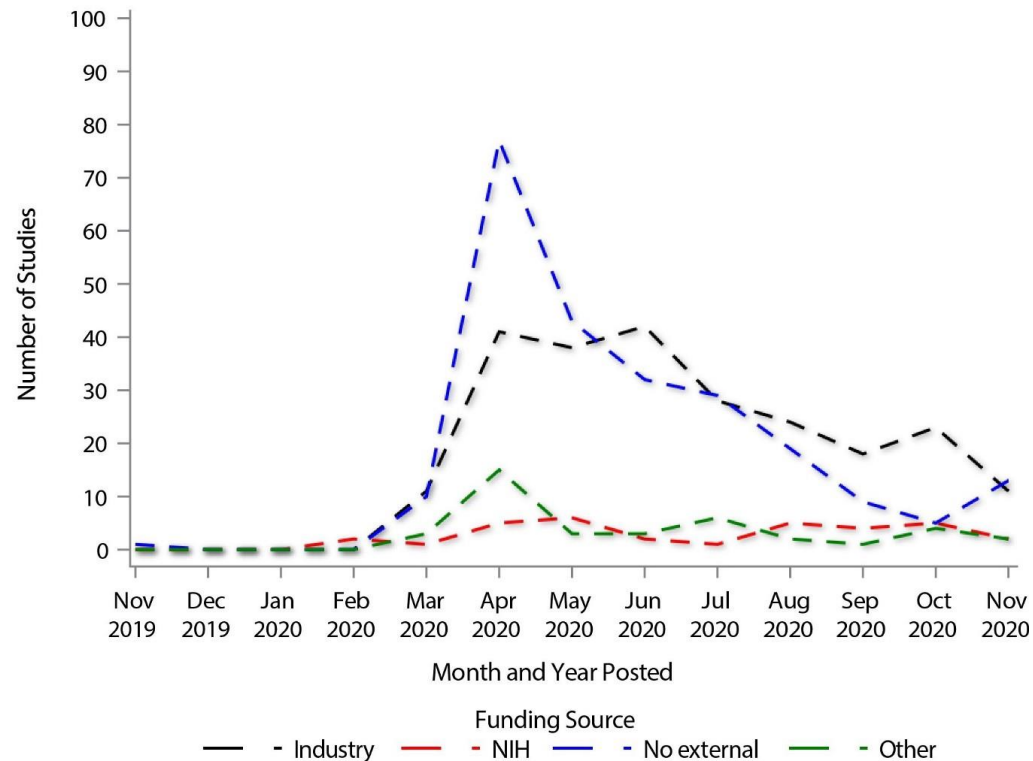


Jeffrey Drazen, MD – Editor-in-Chief of *The New England Journal of Medicine* –

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

And more recently...

The case of COVID and ton of small trials



RESEARCH

Open Access

COVID-19 trials: declarations of data sharing intentions at trial registration and at publication



Rebecca Li^{1,2*}, Megan von Isenburg³, Marcia Levenstein¹, Stan Neumann¹, Julie Wood¹ and Ida Sim^{1,4}

Table 2 Timing of intended data sharing

Reported timing of initial sharing	% that agreed to share in timeframe
Immediately	56 (38.6%)
1 to < 6 months	14 (9.6%)
6–12 months	22 (15.1%)
12–24 months	16 (11.0%)
No timing given	37 (25.5%)
Total number	145

Are you doing
trials for
public health?

Should we be
better than
the norm?

Data Sharing and Embedded Research

Gregory E. Simon, MD, MPH; Gloria Coronado, PhD; Lynn L. DeBar, PhD, MPH; Laura M. Dember, MD;
Beverly B. Green, MD, MPH; Susan S. Huang, MD, MPH; Jeffrey G. Jarvik, MD, MPH; Vincent Mor, PhD; Joakim Ramsberg, PhD;
Edward J. Septimus, MD; Karen L. Staman, MS; Miguel A. Vazquez, MD; William M. Vollmer, PhD; Douglas Zatzick, MD;
Adrian F. Hernandez, MD, MHS; and Richard Platt MD, MS

- The ethical responsibility to share data generated by publicly funded research must be balanced against the need to protect patient privacy and scientific integrity.
- Data sharing policies must not dissuade healthcare system participation.

NIH Data Sharing Policy and Implementation

- The privacy of participants should be safeguarded.
- Data should be made as widely and freely available as possible.
- Data should be shared no later than the acceptance for publication of the main study findings.
- Initial investigators may benefit from first and continuing use of data but not from prolonged exclusive use.

Expectations for Collaboratory Trials

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

For HEAL & PRISM...

- Can we take advantage of a common data repository?
- What will we learn across HEAL projects?

Summary

- Data sharing is a societal good
- Expectations are changing to increase data sharing
- Technologies are making data more available and useful
- Learning from data sharing remains a large opportunity
- Can the Collaboratory lead the way?

Thank You