

How Do We Drive Change in the Incentive Structure to Promote Data Sharing?

Adrian Hernandez, MD

SC Meeting May 17, 2023



**NIH PRAGMATIC TRIALS
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Rethinking Clinical Trials®

Let's discuss...

- Incentives for data sharing
 - Researchers
 - Clinicians
 - Healthcare system leaders
- How to improve patient understanding of the importance of data sharing and encourage participation

Who influences research results?

- A. Sponsors
- B. Funders
- C. Investigators
- D. Technologies
- E. All of the above

Which funders may influence research results *the most* ?

- A. Private life science industry
- B. Public life science industry
- C. Government agencies
- D. Contract research organizations
- E. Data aggregators
- F. Research technology companies
- G. Social networks
- H. Any of the above

Case #1

- Its 2011 & a large clinical trial is completed
 - First of its kind
 - Largest ever
 - Published in NEJM
 - Sponsor interest is low or completely cool to continue funding any additional analyses
- Young faculty member is the coordinating center PI
 - *Friendly* advice from a colleague
 - “You should hold on to everything. That trial will make your career...”
- **Funding:** Multiple **future** mechanisms

Is there any potential risk for sponsor influence?

Sponsor influences?

- Are there **current** influences?
- \$0 current funding
- Are there **future** influences?
- \$XX future funding

Case #2

Novel trial being designed with new direct to participant methods that will harvest automatically electronic health records

Research technology: Promising platform that could solve the world's trial problems by allowing patients anywhere to enroll and get their data seamlessly

Trial plan:

- **Pilot phase:** Enroll 100 to evaluate feasibility
- **Full phase:** Enroll 10000 for a fully decentralized trial

Funding: Non-profit organization; Research technology company in-kind support/highly discounted

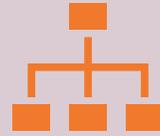
Future plans: Research technology company scaling up over next year with series of funding rounds...public offering

Is there any potential risk for research tech company influence?

Could research reproducibility crisis worsen?



Fierce competition (due to lower funding levels)



Structural problems and hierarchies



Higher future stakes



Complexity of science and data providence

Reasons to care:

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...

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 NEW ENGLAND JOURNAL of MEDICINE

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



Disseminating trial results: We can have both faster and better

Gregory E. Simon^{a,*}, Rachel L. Richesson^b, Adrian F. Hernandez^c



Editorials

Data sharing in medical research

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

JAMA Network

September 2017

Sharing Clinical Research Data—Finding the Right Balance

Bernard L. Lee, MD; Steven N. Goodman, MD, PhD²



Harlan Krumholz
@hrkumholz

Following

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

[nejm.org/doi/pdf/10.1055 ...](https://nejm.org/doi/pdf/10.1055)

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

David S. Hong, MD, PhD

More patients have thought about data sharing, according to Sara Aggarwal, but those who have "find the correct disease — use the technology in monitoring and testing, and tell the world about it. It's also a patient trigger for the symptoms of disease — or, signing incentives to data sharing, and their data shared quickly, especially to care that other patients receive

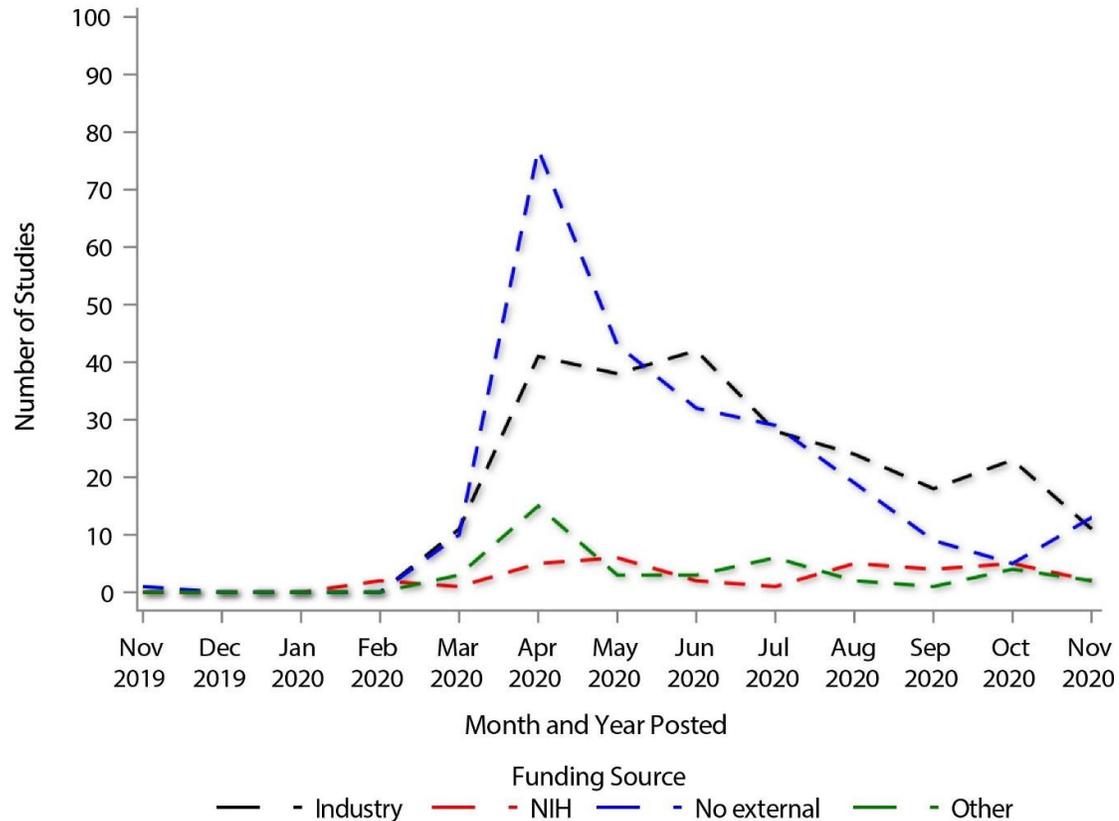
Data Sharing in Clinical Trials



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

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

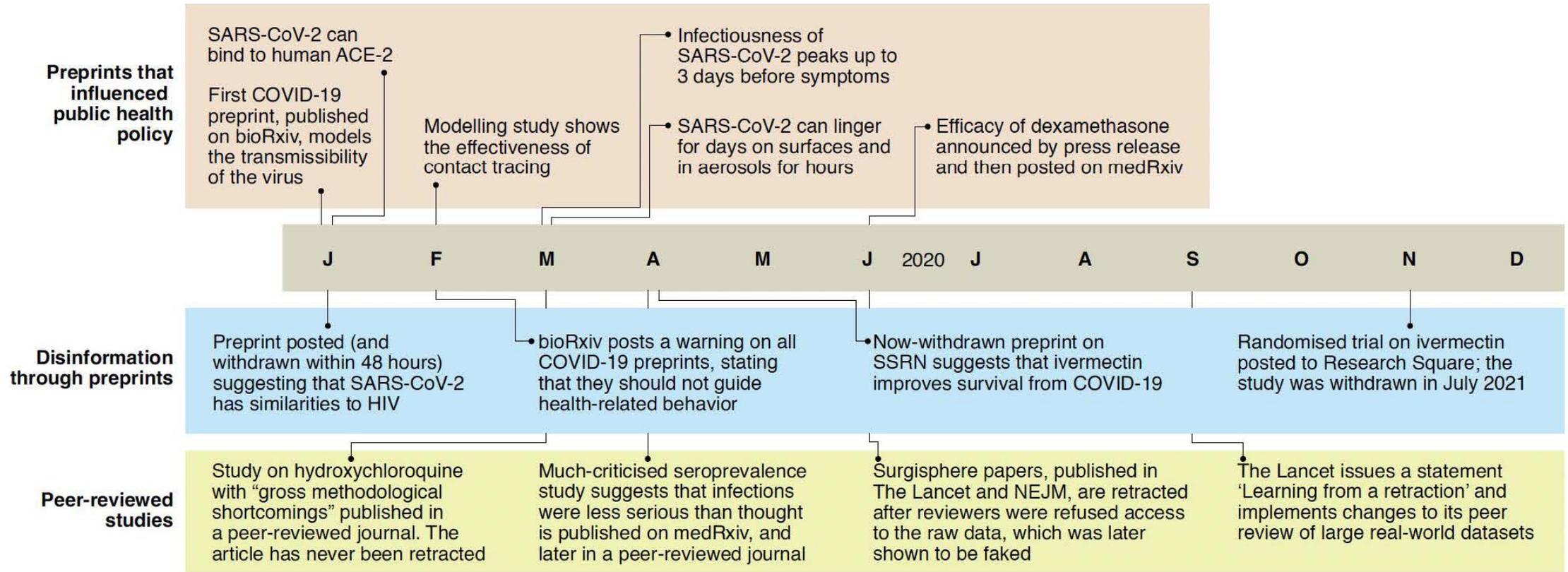
Surgisphere.....



Protecting Quality: Peer Review vs. Preprint vs. Data Sharing?

Preprints, press releases, and policy

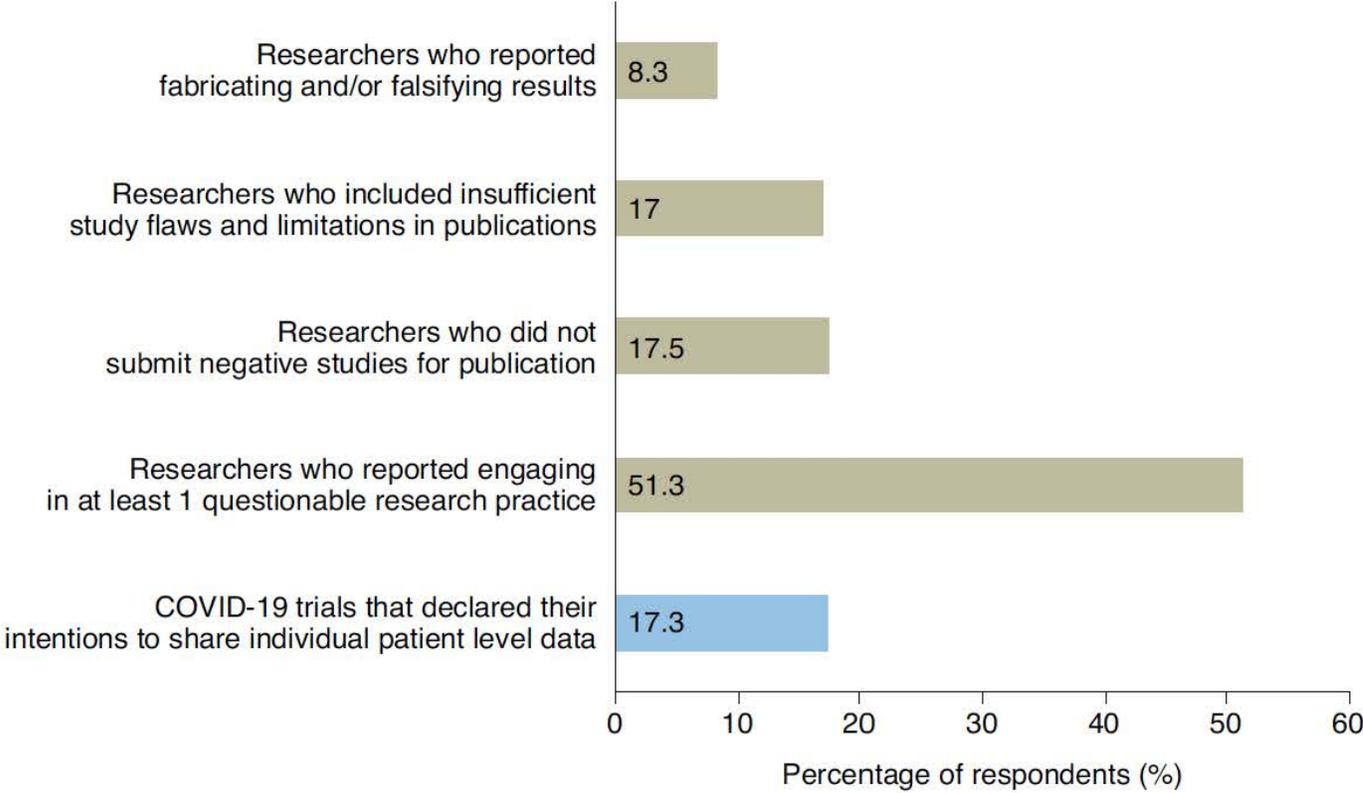
Preprints influenced public health policy, but others spread disinformation, with some peer-reviewed articles also criticized and retracted.



Watson, C. (2022). Rise of the preprint: How rapid data sharing during COVID-19 has changed science forever. <https://doi.org/10.1038/s41591-021-01654-6>

Best practices for research during COVID?

A survey of 6813 researchers at Dutch institutes found that many admitted to engaging in questionable research practices, as did data sharing statements from 924 registered COVID-19 trials.



Sources: G. Gopalakrishna et al. MetaArXiv, 6 July 2021; R. Li et al. Trials 22, 153 (2021)

NIH viewpoint

- Initial investigators may benefit from first and continuing use of data but not from prolonged exclusive use.



Data Sharing and Embedded Research

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- 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.*

Annals of Internal Medicine®

Ideas and Opinions | March 2023

Moving From Idealism to Realism With Data Sharing

Keith A. Marsolo, PhD  , Kevin P. Weinfurt, PhD , Karen L. Staman, MS , and Bradley G. Hammill, DrPH 

- Different resources needed for:
 - new generative science
 - transparency and reproducibility
- Data sharing should be more than just a box checking exercise to meet a mandate

How do you solve the riddle?

Easy...

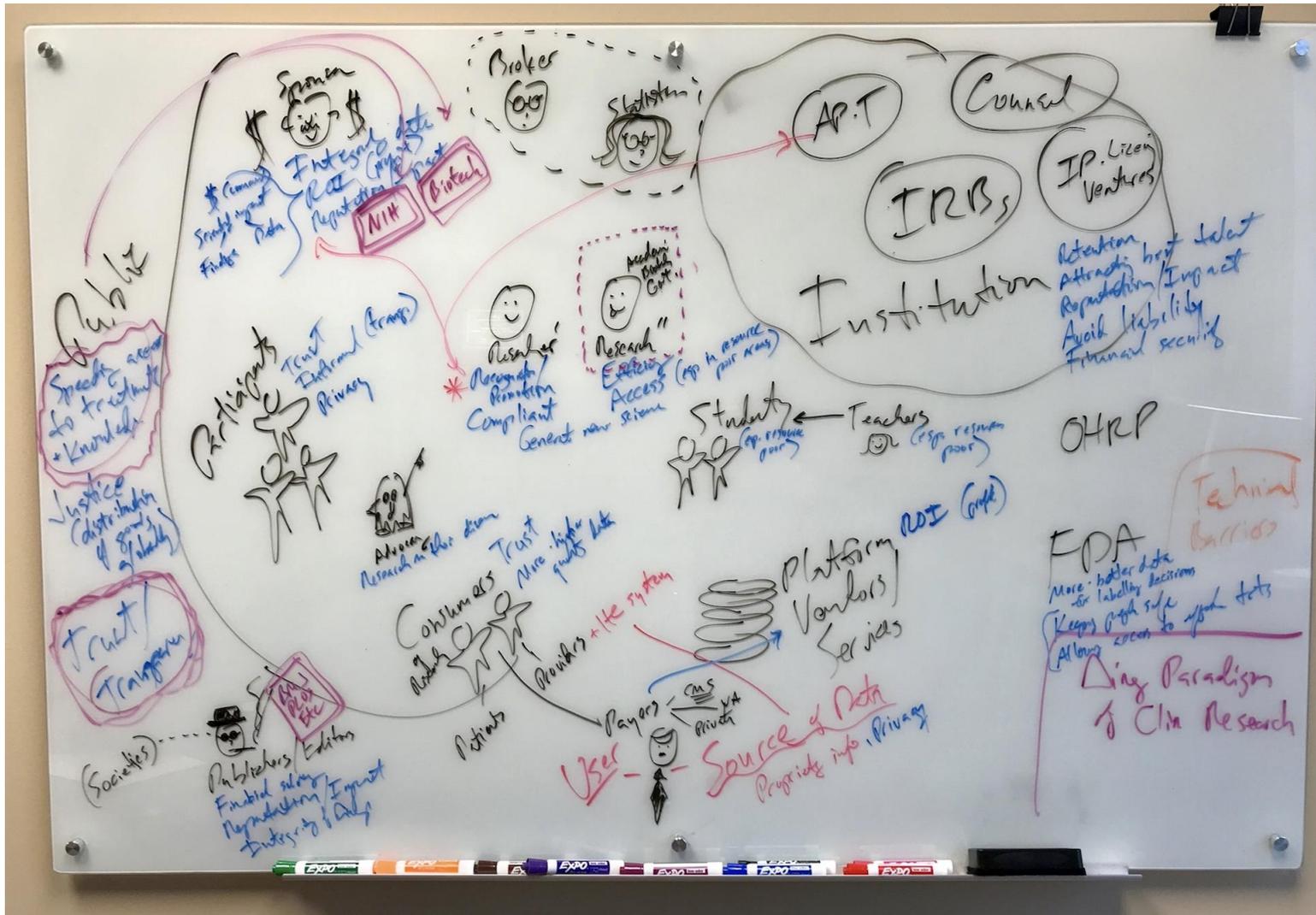
Just ask Kevin

Weinfurt to think about
something

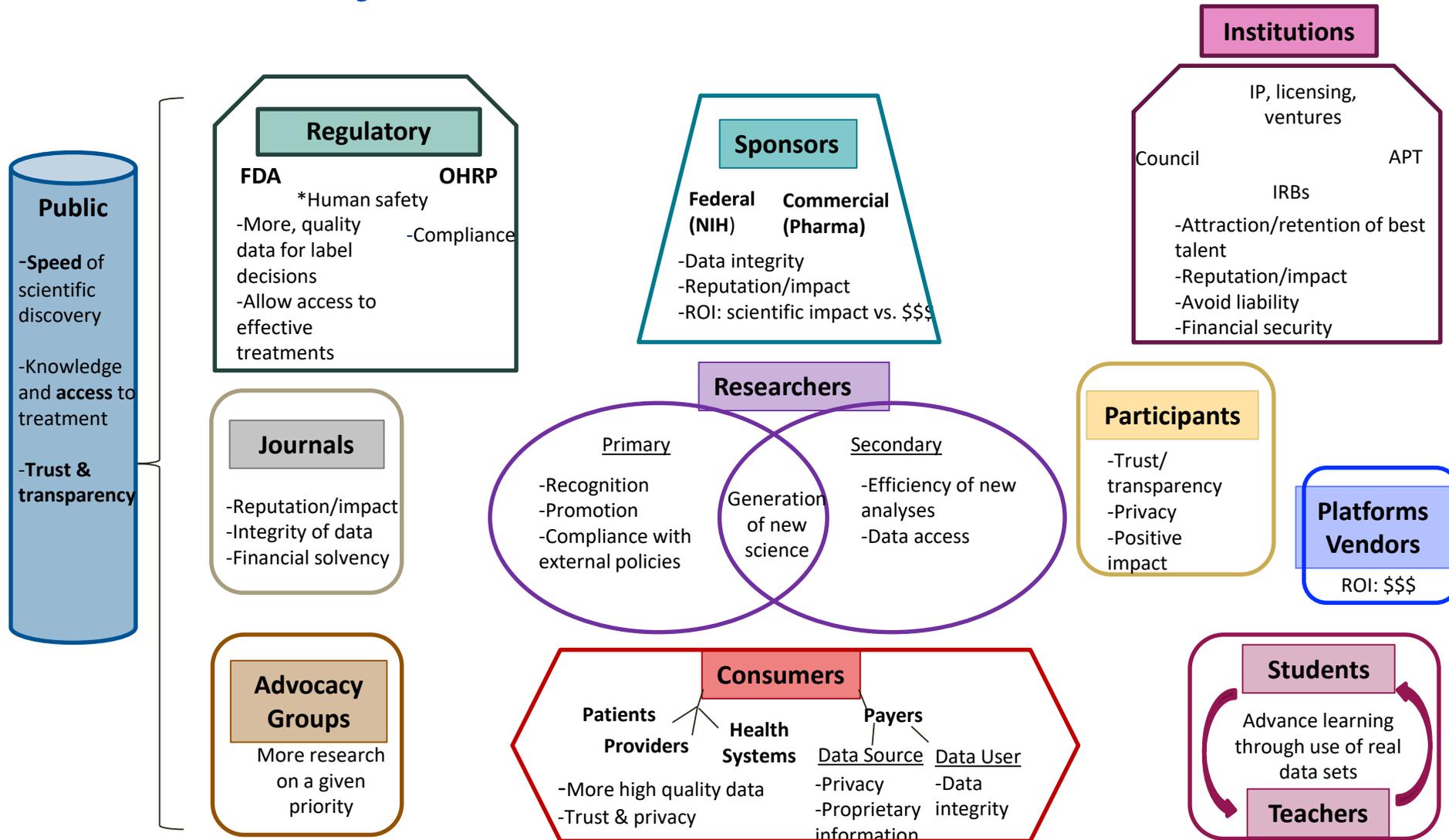


RIALS

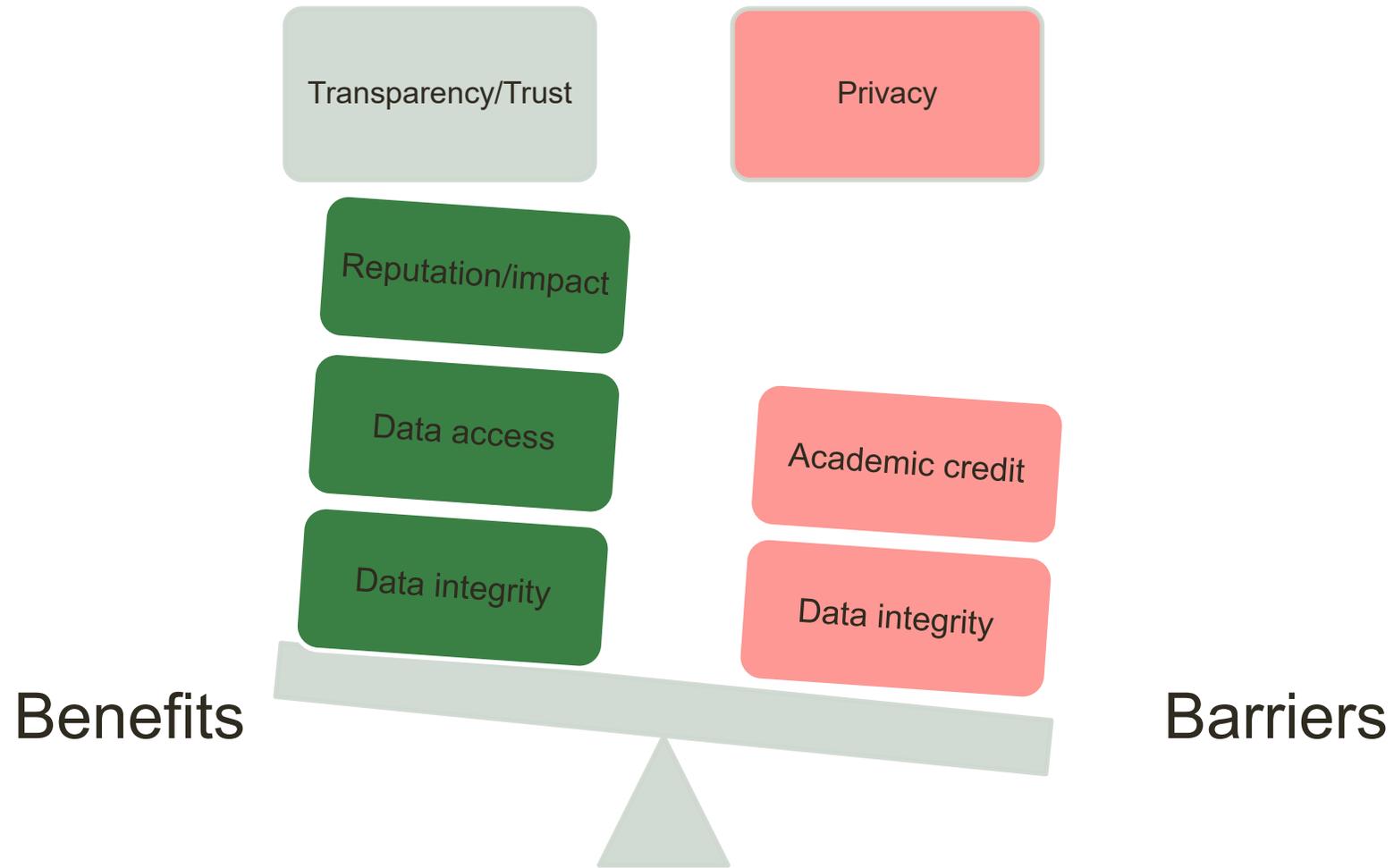
Incentomap



Research Ecosystem: Influencers and Stakeholders



Opposing Values



Incentives?

Researchers and Clinicians

- Ability to cite data sets, DOIs
- Link to promotion and tenure
- Altimetrics?
- NIH Popularity?

Healthcare system leaders

- Carrots/Reputation
- Tie to quality
- Public reporting (best practices)?
 - US News Report?
- Sticks/Federal penalties?

Summary

- Data sharing is a societal good
- Pandemic changed expectations to increase data sharing
- Technologies are making data more available and “useful”
- Opportunity >>>> Current practices
- However.....
 - We need to strengthen incentives for all

Thank You!



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