



An investigator perspective

Data sharing in trials: Should all trials share all their data?

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Agenda

- Introduction to MRCT Center
- Extent of data sharing
- IPD
- Risks and benefits
- Considerations and planning
- Reducing administrative burden
- Credit for data sharing

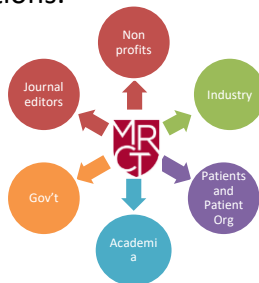


Investigator Perspective



Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

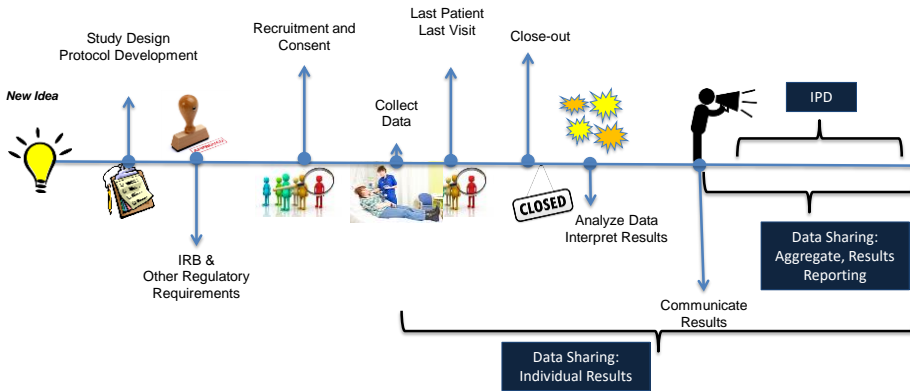


- Academic credibility
- Trusted collaborator
- Independent convener



Framework

Decision to share data, and considerations for data collection, begin at study concept and design, and requires planning:

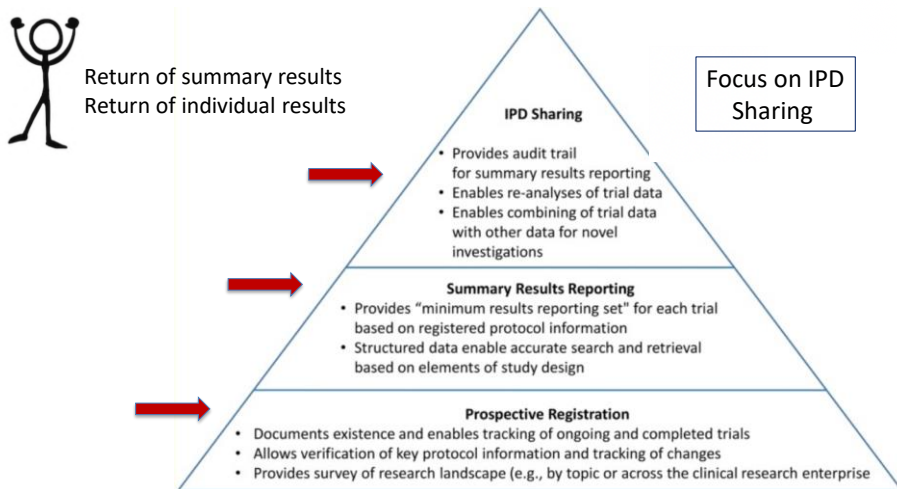


Privacy, Confidentiality, Security, Data Utility

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The value of IPD sharing: building on transparency



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4718525/>

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Purpose-driven Data Sharing Will Enhance Scientific Discovery And Public Trust: the Value Proposition

Benefits:

- Eliminate duplicative trials
- Enable new science discovery
- Enhance correlative and explanatory science
- Evaluate common AEs by compound class or subpopulation
- Identify surrogate endpoints
- Enhance public trust

Benefits only realized if:

- Risks are minimized, with attention to participant privacy
 - informed consent /respect for consent
 - Data anonymization
- Wide participation: including academia, biotech, government, etc.
- Data are interoperable and data sets can be pooled
 - Data standards are available, or alternative methodology
 - Metadata is shared
 - Real-time analytics are available
- State-of-the-art security is in place

FAIR Data:
Findable, Accessible, Interoperable, Reusable



Concerns of the PI

- “I believe in data sharing. But I spent 10 years collecting this data, and now I’m supposed to give it away for free?”
- “People won’t understand the data or the trial. People will do inappropriate analyses.”
- “I don’t have time to prepare that data; I’m working on another trial.”
- My post-doc is working on it. They need a project too.”
- “One more unfunded mandate.”



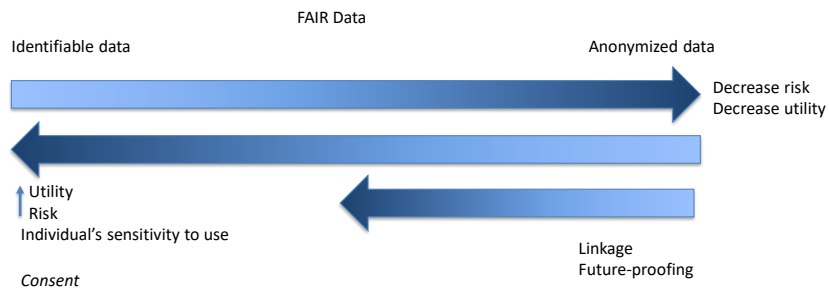
Framework: Data Sharing

- Consent
 - Data standards
 - Metadata
 - Data Source
 - Clinical trials (structured) data
 - Observational data (and source)
 - EHR
 - Imaging
 - Genetic
 - Mobile technology
 - Other
 - Data Origin
 - National (US)
 - EU (GDPR)
 - Other (China, Japan, Australia, etc.)
 - Data Storage and Security
 - Methods to share
 - Downloadable and freely accessible
 - Secure compute platform
 - Permission for specific use
 - Other
 - Administrative: DUA, DCA, etc.
- More sharing or better sharing?
- Incentives and barriers to data sharing

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In General



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Consent for data sharing (US)

- To advance science, medicine, and public health, we might share information about you from this research study with other researchers, but only after personal information that may identify you has been removed. Your information may be combined with other people's data and/or placed in a repository for future research. Some repositories are freely available to anyone. Other repositories may only be accessed by scientists who have permission. We protect your privacy by removing any identifiers, but despite our best efforts, there is still a very small chance that you could be re-identified. In the unlikely event that we learn of a breach of confidentiality, someone from the research team will contact you with additional information. If, at any point during or after this study, you think that you may have been re-identified, please contact us and let us know.

Reviewed by IRBs, institutional officials, patients and patient advocates

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More data or better data

- Better data before more data (...and then more data)
 - Demonstration of utility important
 - Resource intensive
- Data scientists are generally not the clinical trialists
- Data scientists: all data all the time all freely accessible forever
- Clinical trialists: challenging
 - Incentives for sharing data
 - Academic credit for data sharing
 - Funder expectations, appreciation, and ability to track portfolio
- Reuse important to understand value, risk (?), benefit (!)



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The potential down-side of data sharing

- Resource implications for data generators
- Ability of original data generator to publish secondary analyses
- Unfair commercial use
- (Unlawful) patient re-identification
- Unjustified health scares
- Other?

Not yet



However, data generators are not currently rewarded

- Academic system incentivizes researchers to conduct subsequent analyses of their own data.
- No way for researchers who share their data to receive proper academic credit for doing so.
- Efforts to and contributions of data sharing are not generally rewarded in grant reviews or applications reviewed by government and non-profit funders

Credit for Data Sharing: Vision, Scope, and Potential



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Data Authorship as an Incentive to Data Sharing

Barbara E. Bierer, M.D., Mercè Crosas, Ph.D., and Heather H. Pierce, J.D., M.P.H.



Envisioning a solution

- Both to incentivize data sharing and promote fairness, those who gathered, curated, and made available data for secondary use should receive appropriate and standardized credit. A system to ensure credit is necessary.
- Such a system should:
 - Reward good data management and curation.
 - Build on and leverage current data citation efforts.
 - Be an end-to-end solution that is machine-readable and accessible
 - Permit tracking of data re-use, applicable to contributor
 - Be an anticipated and routinized part of journal submission and publication
 - Be recognized for academic advancement
 - Permit tracking of data for funders for value assessment



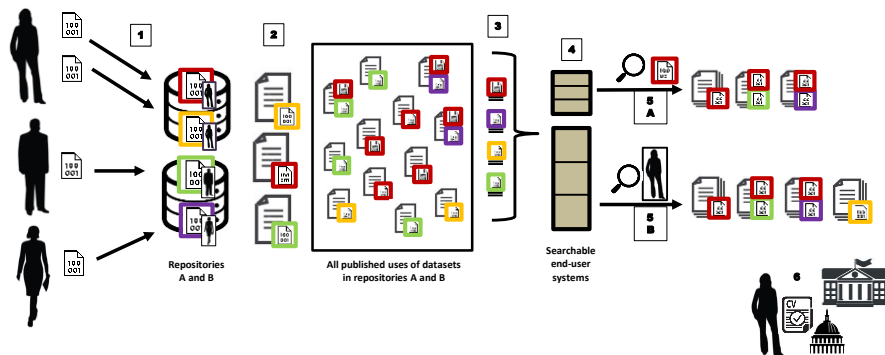
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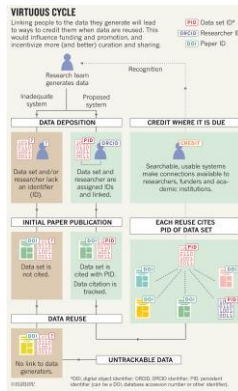
Credit for Data Sharing: End-to-End Process



1. A dataset is deposited in a repository, assigned a persistent identifier (PID), and linked to one or more ORCID IDs.
2. A dataset underlying any primary and secondary publications is cited using its PID and the appropriate metadata.
3. The publisher submits dataset citation/metadata to a central system (e.g. Crossref).
4. Organizations use the aggregated citation information to create searchable end-user systems.
5. Individuals, funders or institutions can search for dataset citations by (A) PID and/or (B) ORCID ID.
6. Individuals and entities are able to utilize information and metrics on shared datasets.



Credit for Data Sharing: Making the Case for Data Impact



Aligns with increasing mandates for sharing and requirements for researchers to deposit data and obtain an ORCID ID

Relies on the consistent adoption of unique identifiers for both data sets and investigators

Individuals and organizations can use citation information and metrics to assess the impact of shared data

Pierce, H.H., Dev, A., Statham, E., Bierer, B.E. Credit Data Generators for Data Reuse. *Nature*. 2019 Jun;570(7759):30-32.



Policy and Practice Changes: Stakeholder-specific Recommendations

- **Journals and Publishers**
 - Required submission information
 - Data policies
 - Culture change
 - Resources
- **Funders**
 - Data Management Plans
 - Application processes
 - Progress reports and post-award requirements
 - General funding considerations
- **Academic Institutions**
 - Institutional policies and incentives
 - Infrastructure
 - Researcher education





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