Patient-level data sharing in clinical research: a long story

4th and final AGM, 2.3.2020, Brussels

Christian Ohmann (ECRIN)
Patient-level data sharing
Aim of the presentation

- Potential & issues
- Achievements so far
- Contribution by CORBEL/ECRIN
- Challenges
Patient-level data sharing
Potential*

Sharing data from clinical trials benefits patients by pointing to new research questions that can lead to new discoveries. It also allows clinical trial results to be included in meta-analyses, which increases standards of evidence, and it allows published results to be confirmed, reducing bias.

*Thomas & Paarlberg, Medical Writing 2019; 28: 66
Patient-level data sharing
Public good and human right

September 5, 2012

Clinical Trial Data as a Public Good

Marc A. Rodwin, JD, PhD; John D. Abramson, MD, MS

Author Affiliations


- Publicly-funded research data are a public good, produced in the public interest
- Publicly-funded research data should be openly available to the maximum extent possible

Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency

Trudo Lemmens† & Candice Telfer††

American Journal of Law & Medicine, 38 (2012): 63-112
© 2012 American Society of Law, Medicine & Ethics
Boston University School of Law

Assess to meaningful information is a critical determinant in the right to highest attainable standard of health and requires a reliable system of knowledge production
Patient-level data sharing
Cultural change in research

Transparency/open science/FAIR

Moving Towards Transparency of Clinical Trials
Deborah A. Zarin* and Tony Tse
National Library of Medicine, National Institutes of Health, US Department of Health and Human Services, Bethesda, MD 20894 USA

RESEARCH & INNOVATION
Open Science

THE FAIR DATA PRINCIPLES

Waste in research

REWARD
REduce research WAste and Reward Diligence
http://researchwaste.net/

Reproducability crisis

1,500 scientists lift the lid on reproducibility
Survey sheds light on the ‘crisis’ rocking research.
Monya Baker
25 May 2016 | Corrected: 28 July 2016

Efficiency of knowledge generation

Cochrane

Individual Participant Data Meta-analysis
« What problems/concerns do you have with sharing datasets? »

- Concerns about misuse of my data
- Unsure about copyright and licensing
- Not receiving appropriate credit or acknowledgement
- Unsure I have the rights to share
- Organising data in a presentable and useful way
- Contains sensitive information

*Digital Science report 2018, Figshare
Patient-level data sharing
Principles and recommendations

- Principles for responsible clinical trial data sharing (PhMRA, EFPIA, 2014)
- Good practice principles for sharing individual participants data from publicly funded trials (MRC, UKCRC, CRUK, Wellcome, 2015)
- Transparency and registration in clinical research in the Nordic Countries (Nordic Trial Alliance Group on Transparency and Registration, 2015)
- Sharing clinical trial data: Maximizing benefits, minimizing risks (Institute Of Medicine, 2015)
- Data Sharing Statements for Clinical Trials (International Committee of Medical Journal Editors, 2017)
Patient-level data sharing

Outstanding examples

The Open Translational Science in Schizophrenia (OPTICS) project: an open-science project bringing together Janssen clinical trial and NIMH data

Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence

Use of the National Heart, Lung, and Blood Institute Data Repository
• Culture of openness improves steadily and sharing of research data increases

• High rates of intention of data sharing in surveys

• Several policies and recommendations for data sharing have been developed by different stakeholders (funders, publishers)

• Implementation of policies/recommendations lacks behind, availability of IPD from clinical trials and research output of secondary analysis need to be improved

• Access to IPD established for some disease-specific scientific networks but not generally implemented for academic trials

• Publication output of IPD sharing still limited
Patient-level data sharing
Contribution by CORBEL/ECRIN

Principles, recommendations

Quality criteria for repositories

Definition of processes

Training of researchers

Review the impact

Pilot repository

Toolbox

Ohmann et al., BMJ Open 2017

Ohmann et al., BMJ Open, submitted

Ohmann et al., F1000Research 2018

ECRIN, Data Workshop, 11/2018

Banzi et al., Trials 2019; 20: 169

Tilki et al., Methods Information Med, submitted

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*https://www.ecrin.org/sites/default/files/Data%20brochure/ECRIN%20data%20sharing%20brochure%202019.pdf
Patient-level data sharing
Principles & recommendations*

BMJ Open  Sharing and reuse of individual participant data from clinical trials: principles and recommendations

Christian Ohmann,1 Rita Banzi,2 Steve Canham,3 Serena Battaglia,4 Mihaela Matei,5 Christopher Arlyo,6 Lauren Becnel,7 Barbara Bierer,7 Sarah Bowers,5 Luca Clivio,2 Monica Dias,8 Christiane Drumli,10 Hélène Faure,11 Martin Fenner,19 Jose Galvez,15 Davina Gherzi,1,14 Christian Glueck,15 Trish Groves,16 Paul Houston,5 Ghassan Karam,17 Dipak Kalra,18 Rachel L. Knowles,19 Karmela Križa-Jeric,20 Christine Kubiak,1 Wolfgang Kuchinke,21 Rebecca Kush,22,23 Ari Lukkarinen,5 Pedro Silverio Marques,24 Andrew Newbigging,25,26 Jennifer O'Callaghan,29 Philippe Ravaud,28 Irene Schlünder,29,30 Daniel Shanahan,1,20 Helmut Sitter,21 Dylan Spalding,22 Catrin Tudor-Smith,23 Peter van Reusel,6 Evert-Ben van Veen,34,35 Gerben Rienk Visser,26 Julia Wilson,9 Jacques Demotes-Mainard9

ABSTRACT

Objectives  We examined major issues associated with sharing of individual clinical trial data and developed a consensus document on providing access to individual participant data from clinical trials, using a broad interdisciplinary approach.

Design and methods  This was a consensus-building process among the members of a multiscale stakeholder task force, involving a wide range of experts (researchers, patient representatives, methodologists, information technology experts, and representatives from funders, regulatory authorities, funders, and commercial companies).

Strengths and limitations of this study

- An effective and formal consensus-building process among a large group of very experienced researchers and others involved in clinical trials.
- A unique perspective (Europe-wide, non-commercial), with a focus on the particular needs of researchers.
- A large number of practical recommendations set against an overarching framework of principles.
- The recommendations now need to be implemented and tested in practice, and feasibility and usability.

*doi:10.1136/bmjopen-2017-018647
Patient-level data sharing
Workflow modelling*

Main processes in sharing of IPD from clinical trials

1. Preparation for data sharing (in general)
2. Plan for data sharing
3. Preparation of data sharing (after data collection or data update)
4. Transforming data ontology to external repository
5. Repository data and access management
6. 2.6 Data access arranged
6.2.6 Access to IPD and associated data objects
7. Discovering the data
8. Carry out secondary analysis
9. Monitoring data sharing

The following symbols from BPMN (http://www.bpmn.org) were applied:
- Lane
- Start event (process trigger)
- Stop event (process trigger)
- Activity
- Group
- Gateway (forking / merging of paths)
- Sequence Flow (order of activities)
- Optional collaboration between data requester and data generator

### Suitability of the repository for hosting clinical study data

<table>
<thead>
<tr>
<th>Repository</th>
<th>Guidelines for upload and storage</th>
<th>De-identification</th>
<th>Data quality control</th>
<th>Contract for upload and storage</th>
<th>Application of metadata</th>
<th>Application of identifiers</th>
<th>Flexibility of Access</th>
<th>Long term Preservation</th>
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*Banzi et al. Trials 2019; 20:169
# Patient-level data sharing

Assessment of a Dspace pilot*

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Result</th>
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<tr>
<td>1a. The repository should support a range of file types and metadata schema</td>
<td>Demonstrated</td>
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<td>1b. The repository should provide mechanisms for the upload of files, including instructions</td>
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<tr>
<td>2a. The repository should be able to provide links to de-identification tools and requirements</td>
<td>Partially demonstrated</td>
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<tr>
<td>2b. The repository should implement de-identification tools</td>
<td>Not demonstrated</td>
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<td>3a. The repository should support quality control in its workflow</td>
<td>Partially demonstrated</td>
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<td>4a. The repository should incorporate a data transfer agreement in system workflow</td>
<td>Partially demonstrated</td>
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<td>5a. The repository should use a consistent metadata schema to describe its content</td>
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<td>5b. The repository should allow a customised metadata schema to be applied</td>
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<td>5c. The repository should provide tools to help data generators to complete metadata fields</td>
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<td>5d. The repository should make metadata openly (public) available</td>
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<td>6a. The repository should be able to apply a primary persistent identifier system</td>
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<td>6b. The repository should be able to use other persistent identifiers as appropriate</td>
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<td>7a. The repository should allow open access to material, with an optional embargo period</td>
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<td>7b. The repository should allow open access after web-based self-attestation of the user</td>
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<td>7c. The repository should offer managed access through group membership</td>
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<td>7d. The repository should offer managed access through application on a case by case basis</td>
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<td>7e. The repository should support granular access to different parts of datasets collections</td>
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<td>8a. The repository should support long-term preservation of data and metadata</td>
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<td>8b. The repository should make use of sustainable software systems</td>
<td>Demonstrated</td>
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* Tilki et al., Submitted to Methods of Information in Medicine, 2019
Scoping review
Status of sharing of Individual Participant Data from clinical trials, use of shared data and impact of research outputs of sharing data: a scoping review protocol

* Ohmann, Naudet, Moher, OSF home, 2018, https://osf.io/pb8cj/
Patient-level data sharing
Status and impact of data sharing*

* Ohmann et al. BMJ Open - submitted
Patient-level data sharing
Current work

CORBEL WP3.3: Providing access to patient-level clinical trials data (lead: ECRIN)

Deliverable 3.8: report on implementation, including economic model and solutions for sustainability

3 scenarios are considered and explored:

a) Best practice illustrative example

b) Operational repository

c) Repository support service (Figshare)
« Although evidence documenting tangible benefits of data sharing has not emerged, optimism about the potential clinical and scientific benefits is considerable »

* Miller et al. BMJ 2019; 366:14127
Data should become first class research product

• Validated
• Preserved
• Cited
• Credited

* Kratz J, Strasser C: Data publication consensus and controversies
  F1000 Research 2014; 3:94
Patient-level data sharing
Challenges

• User-friendly data sharing tools & services incorporated into the data sharing workflow (« data sharing toolbox »)

• Training of researchers in data sharing and education of data scientists to support of data sharing

• Improvement of platforms/repositories (e.g. quality assessment – certification, interoperability, business model, fragmentation)

• Harmonisation of data sharing processes (e.g. data transfer agreements, data access boards, data use agreements)

• Exploration and application of reliable measures of true impact of data sharing
In the EU H2020-funded project XDC a demonstrator for a **metadata repository (MDR)** for clinical research has been implemented under the coordination of **ECRIN** with the following functionality:

- Identification of clinical research studies *(e.g. via clinical trial registries)*
- Display and selection of data objects related to a specific clinical study
- Display of metadata of a data object, including nature of the object *(e.g. name, type, provenance)* and the mode of access *(public, restricted, private)*.
- Link to the data object *(if possible)*

Within EOSC-Life the demonstrator will be extended, completed and qualified and finally published as FAIR data source in the EOSC.
ACKNOWLEDGMENTS

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Serena Battaglia
Steve Canham
Mihaela Matei
Jacques Demotes

IRFMN
Rita Banzi