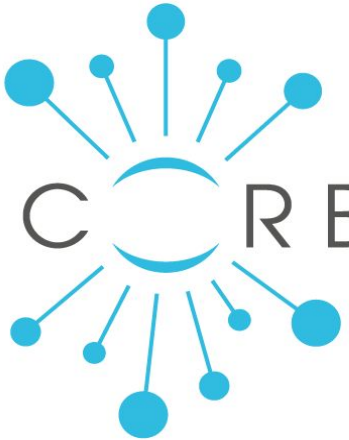


CORBEL shared services for life-science

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

4th and final AGM, 2.3.2020, Brussels

Christian Ohmann (ECRIN)

- Potential & issues
- Achievements so far
- Contribution by CORBEL/ECRIN
- Challenges

Patient-level data sharing

Potential*

**Thomas & Paarlberg, Medical Writing 2019; 28: 66*

September 5, 2012

Clinical Trial Data as a Public Good

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

» Author Affiliations

JAMA. 2012;308(9):871-872. doi:10.1001/jama.2012.9661

- 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

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

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

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 **WA**ste and **R**eward **D**iligence

http://researchwaste.net/

Efficiency of knowledge generation

Cochrane

Trusted evidence.
Informed decisions.
Better health.

Individual Participant Data Meta-analysis

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

Patient-level data sharing
Problems/concerns*

« 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*
https://figshare.com/articles/The_State_of_Open_Data_Report_2018/7195058

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 Trasparency 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

PERSPECTIVE OPEN

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

Marsha A. Wilcox[1], Adam J. Savitz[1], Anjené M. Addington[2], Gary S. Gray[3], Eva C. Guinan[4], John W. Jackson[5,6], Thomas Lehner[7], Sharon-Lise Normand[8], Hardeep Ranu[3], Geetha Senthil[7], Jake Spertus[8], Linda Valeri[9,10] and Joseph S. Ross[11,12,13]

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

Joanna Le Noury,[1] John M Nardo,[2] David Healy,[1] Jon Jureidini,[3] Melissa Raven,[3] Catalin Tufanaru,[4] Elia Abi-Jaoude[5]

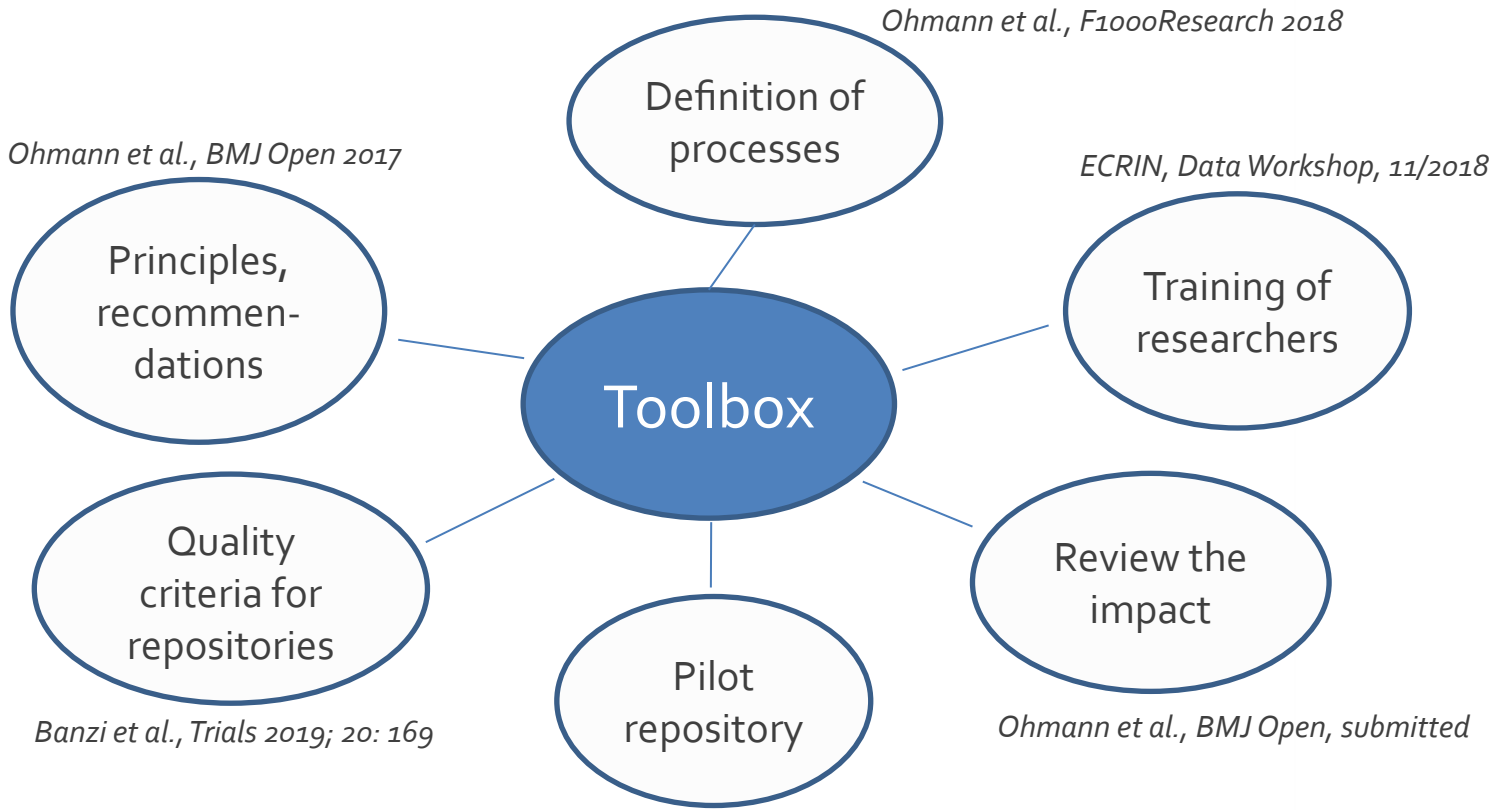
SPECIAL ARTICLE

Use of the National Heart, Lung, and Blood Institute Data Repository

Sean A. Coady, M.S., M.A., George A. Mensah, M.D., Elizabeth L. Wagner, M.P.H., Miriam E. Goldfarb, B.S., A.S.N., Denise M. Hitchcock, B.S., and Carol A. Giffen, D.V.M.

- 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



*https://www.ecrin.org/sites/default/files/Data%20brochure/ECRIN%20data%20sharing%20brochure%202019.pdf

Patient-level data sharing
Principles & recommendations*

Open Access Research

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,[4] Christopher Ariyo,[5] Lauren Becnel,[6] Barbara Bierer,[7] Sarion Bowers,[8] Luca Clivio,[2] Monica Dias,[9] Christiane Druml,[10] Hélène Faure,[11] Martin Fenner,[12] Jose Galvez,[13] Davina Ghersi,[14] Christian Gluud,[15] Trish Groves,[16] Paul Houston,[6] Ghassan Karam,[17] Dipak Kalra,[18] Rachel L Knowles,[19] Karmela Krleža-Jerić,[20] Christine Kubiak,[4] Wolfgang Kuchinke,[21] Rebecca Kush,[22,23] Ari Lukkarinen,[5] Pedro Silverio Marques,[24] Andrew Newbigging,[25,26] Jennifer O'Callaghan,[27] Philippe Ravaud,[28] Irene Schlünder,[29] Daniel Shanahan,[11,30] Helmut Sitter,[31] Dylan Spalding,[32] Catrin Tudur-Smith,[33] Peter van Reusel,[6] Evert-Ben van Veen,[34,35] Gerben Rienk Visser,[36] Julia Wilson,[8] Jacques Demotes-Mainard[4]

To cite: Ohmann C, Banzi R, Canham S, *et al*. Sharing and reuse of individual participant data from clinical trials: principles and recommendations. *BMJ Open* 2017;**7**:e018647. doi:10.1136/bmjopen-2017-018647

► Prepublication history and additional material for this paper are available online. To view these files, please visit

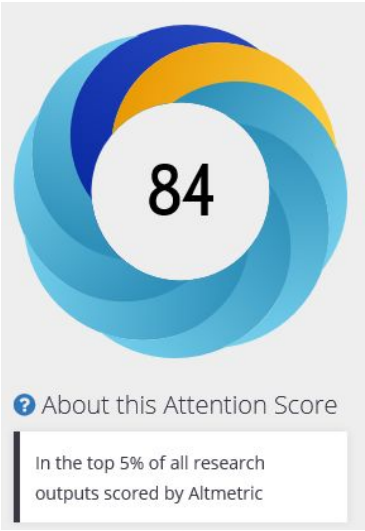
ABSTRACT

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 multistakeholder task force, involving a wide range of experts (researchers, patient representatives, methodologists, information technology experts, and representatives from funders,

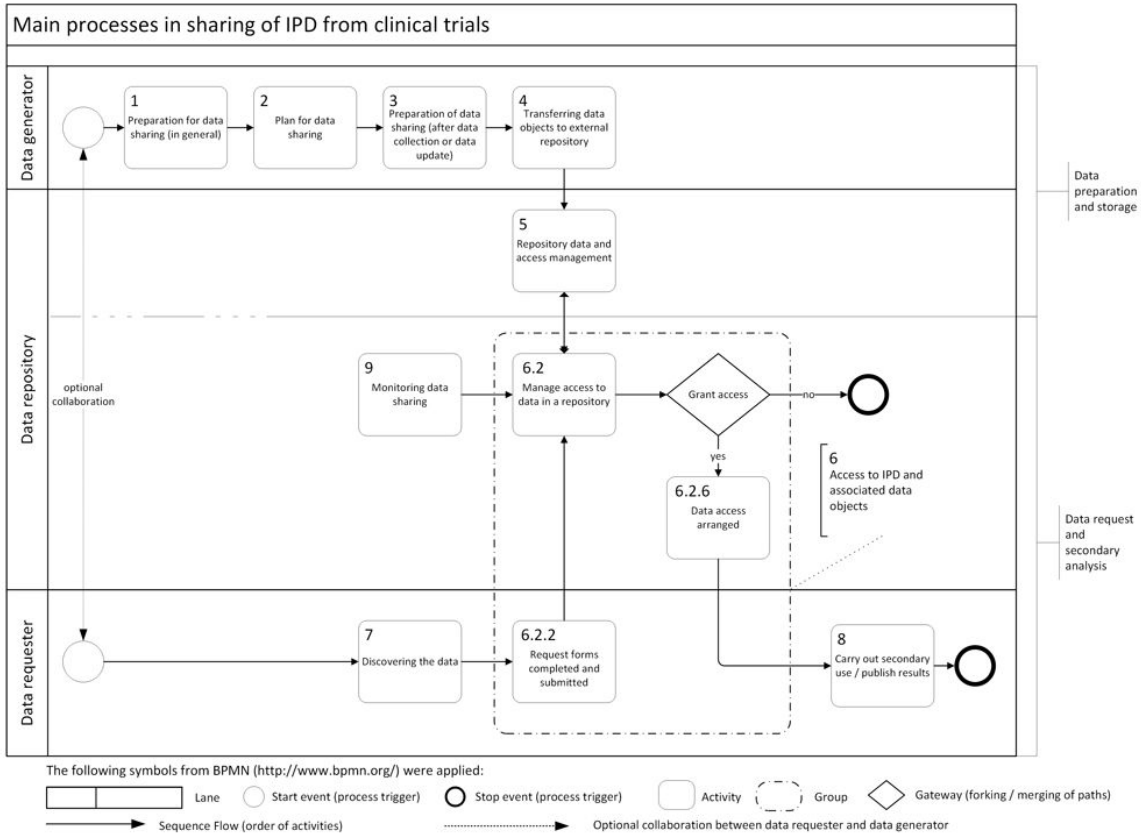
Strengths and limitations of this study

- ► 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*



** Ohmann C et al., F1000Research 2018, 7:138*

Patient-level data sharing
Evaluation of repositories*

Suitability of the repository for hosting clinical study data

	Guidelines for upload and storage	De-identification	Data quality control	Contract for upload and storage	Application of metadata	Application of identifiers	Flexibility of Access	Long term Preservation
Dryad	■	■	■	■	■	■	▒	■
Swedish National Data Service	■	◢	■	■	■	■	■	■
Drum	■	■	■	■	■	■	▒	▒
EASY	▒	■	▒	■	■	■	■	■
FigShare	▒	■	■		■	■	■	▒
ICPSR	■		■	■	■	■	■	▒
NDCT NIMH	■	■	■	■	■	■		◢
NDACAN (Child Abuse)	■	■	■	▒	■	■		◢
NIH BioLINCC	■	■	■	▒	■	◢		◢
Edinburgh DataShare	■	◢	▒	▒	■	■	■	■
Vivli	■	■	◢	■	◢	◢	▒	◢
B2Share	▒			◢	■	■	▒	▒
Open Science Framework	◢	◢	◢	◢	◢	■	■	▒
Project Datasphere	■	■	◢	■				◢
Zenodo					▒	■	■	■
NIDDK	■	■	▒	■				◢
ITN Trialshare	■◢	■	◢	◢	▒	◢		◢
CancerData.Org	◢	◢		◢	■	■		◢
WWARN	■	▒	■	▒			▒	◢
Melanoma MMP	▒	◢	■	◢	◢	◢		◢
ProAct	■	■	▒	◢	▒	◢		◢
FreeBird	▒	▒	◢	◢				◢
EBCTCG		◢	■	◢	▒			◢
UMIN	▒			◢	◢	◢		◢
TBI-IMPACT				◢	◢			

Legend

■ Demonstrated
Not demonstrated
▒ Partially demonstrated
◢ Missing or partial information available

*Banzi et al. Trials 2019; 20:169

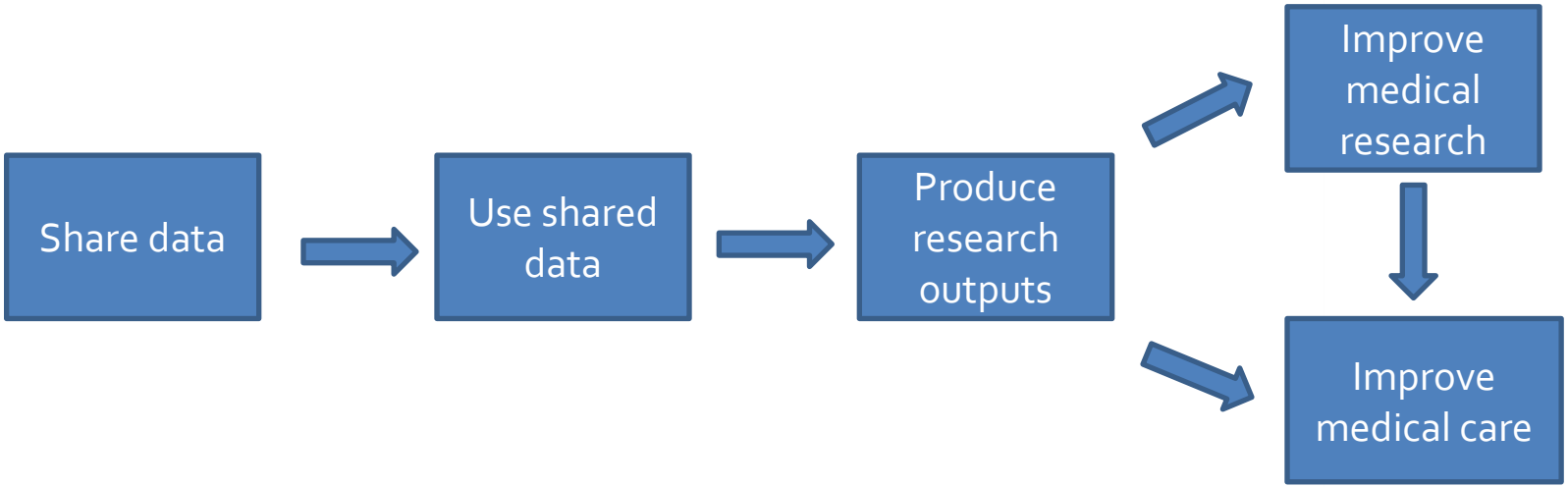
Patient-level data sharing
Assessment of a Dspace pilot*

Requirement	Result
1a. The repository should support a range of file types and metadata schema	Demonstrated
1b. The repository should provide mechanisms for the upload of files, including instructions	Demonstrated
2a. The repository should be able to provide links to de-identification tools and requirements	Partially demonstrated
2b. The repository should implement de-identification tools	Not demonstrated
3a. The repository should support quality control in its workflow	Partially demonstrated
4a. The repository should incorporate a data transfer agreement in system workflow	Partially demonstrated
5a. The repository should use a consistent metadata schema to describe its content	Demonstrated
5b. The repository should allow a customised metadata schema to be applied	Demonstrated
5c. The repository should provide tools to help data generators to complete metadata fields	Demonstrated
5d. The repository should make metadata openly (public) available	Demonstrated
6a. The repository should be able to apply a primary persistent identifier system	Demonstrated
6b. The repository should be able to use other persistent identifiers as appropriate	Demonstrated
7a. The repository should allow open access to material, with an optional embargo period	Demonstrated
7b. The repository should allow open access after web-based self-attestation of the user	Not demonstrated
7c. The repository should offer managed access through group membership	Demonstrated
7d. The repository should offer managed access through application on a case by case basis	Demonstrated
7e. The repository should support granular access to different parts of datasets collections	Demonstrated
8a. The repository should support long-term preservation of data and metadata	Demonstrated
8b. The repository should make use of sustainable software systems	Demonstrated

** Tilki et al., Submitted to Methods of Information in Medicine, 2019*

Scoping review

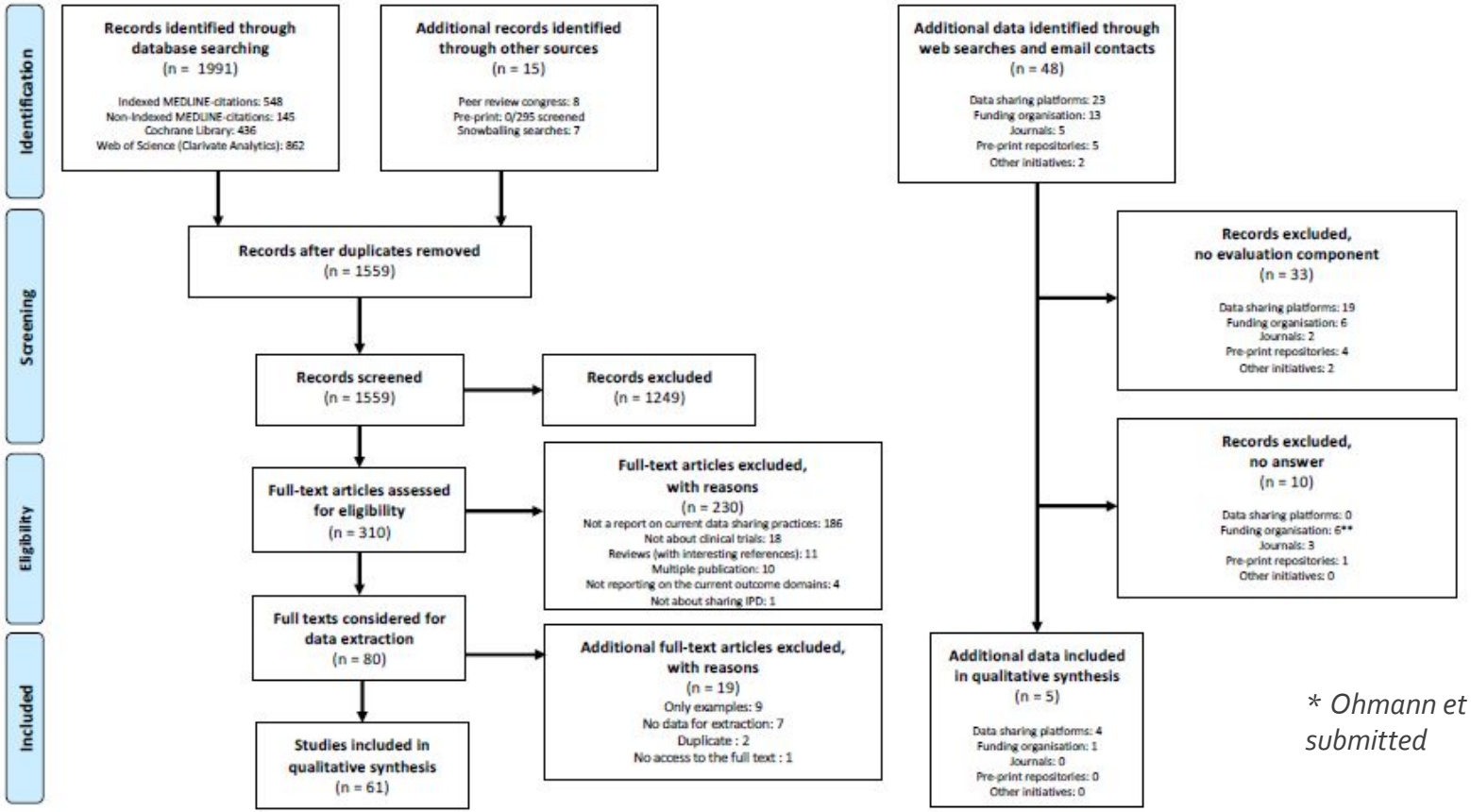
Status of sharing of Individual Participant Data from clinical trials, use of shared data and impact of research outputs of sharing data: a scoping review protocol



** 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*

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 ; 36614127*

Data should become first class research product

- Validated
- Preserved
- Cited
- Credited

** Kratz J, Strasser C: Data publication consensus and contoversies 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

ECRIN
Serena Battaglia
Steve Canham
Mihaela Matei
Jacques Demotes

IRFMN
Rita Banzi

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 654248.