The 2024 CRDSA Summit

The Patient Data Revolution: From Promise to Realization

February 29, 2024

Session 2:
Standards for Secondary Use Research and Data Contribution

This session opens the public comment period for CRDSA's new draft standards and will provide an overview of the contents and scope of each document.

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Data Collaboration Center
Critical Path Institute (C-Path)

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Senior Advisor
Clinical Research Data Sharing Alliance

CRDSA
Clinical Research Data Sharing Alliance

www.crdsalliance.org

Presentation Outline

CRDSA

- The need for standards
- Scope, structure and content overview
- Adoption
- How you can provide comments

The need for standards

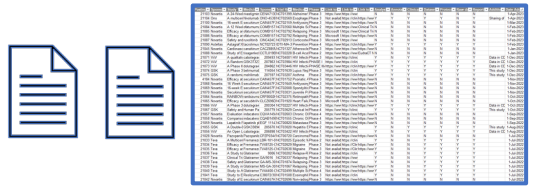
Why are standards needed?

Researchers

- Need to be able to conduct accurate and reproducible analyses
- Need consistent and comprehensive data and meta-data

Data Contributors

- Want to ensure their data is used appropriately
- Benefit from a consistent approach and referenceable benchmarks



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CRDSA

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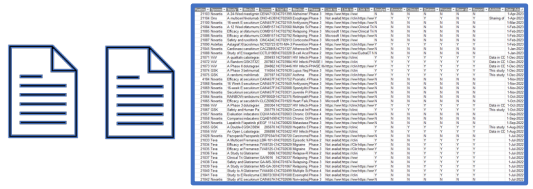
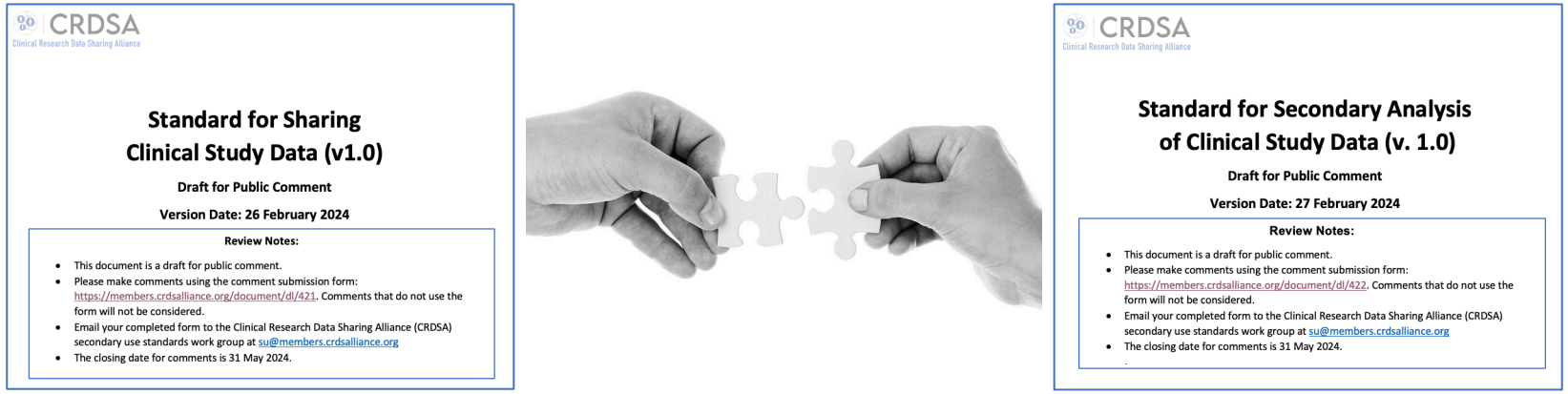


Current State

- Data sharing and research planning may be time-consuming
- Analyses may be found not to be feasible after data is provided
- Analysis errors can be made

Why are standards needed?

Data Sharing and Secondary Analysis Standards work together to enable good science

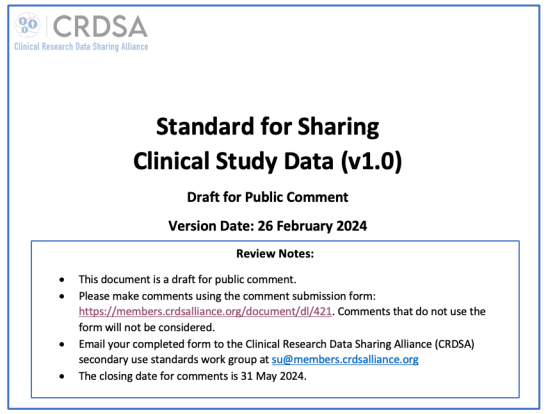


How to share individual patient data (IPD) from clinical studies

How to use contributed IPD in secondary research

Scope, structure, and content overview

Data Sharing Standard - Scope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Standard for Sharing Clinical Study Data (v1.0)

Draft for Public Comment

Version Date: 26 February 2024

Review Notes:

- This document is a draft for public comment.
- Please make comments using the comment submission form: https://members.crdsalliance.org/document/dl/421. Comments that do not use the form will not be considered.
- Email your completed form to the Clinical Research Data Sharing Alliance (CRDSA) secondary use standards work group at su@members.crdsalliance.org
- The closing date for comments is 31 May 2024.

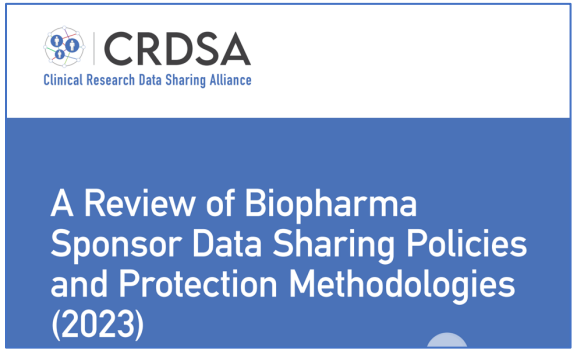
- Includes sharing individual patient data from interventional clinical studies conducted in patients and non-interventional clinical studies using patient data
- Focus is on the data and meta-data to be provided
- This version of the standard does not include:
  - What studies are to be shared
  - When studies are to be shared
  - How access is to be provided
- Based on CRDSA expertise and CRDSA research – for example:

Establishing a Basis for Secondary Use Standards for Clinical Trials

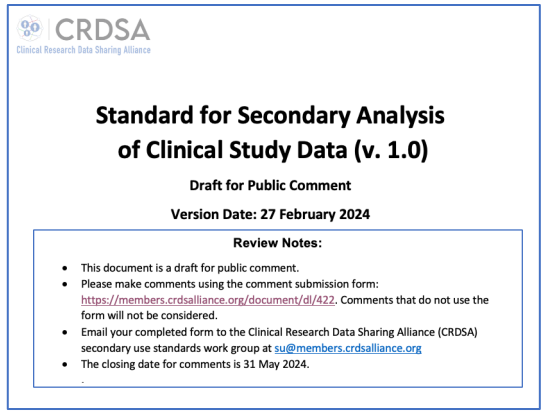
Published on: March 8, 2023

Ernest Odame, Tracy Burgess, Luk Arbuckle, Andrei Belcin, Gwenyth Jones, Peter Mesenbrink, Ramona Walls, Aaron Mann

Study seeks to understand how different forms of data meet the needs of researchers.



Secondary Analysis Standard - Scope


CRDSA
Clinical Research Data Sharing Alliance

Standard for Secondary Analysis of Clinical Study Data (v. 1.0)

Draft for Public Comment

Version Date: 27 February 2024

Review Notes:

- This document is a draft for public comment.
- Please make comments using the comment submission form: https://members.crdsalliance.org/document/dl/422. Comments that do not use the form will not be considered.
- Email your completed form to the Clinical Research Data Sharing Alliance (CRDSA) secondary use standards work group at su@members.crdsalliance.org
- The closing date for comments is 31 May 2024.

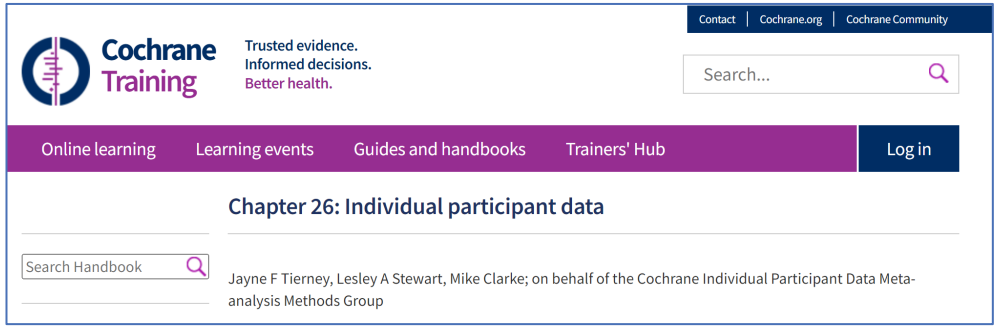
- Includes secondary analyses of interventional clinical trials conducted in patients and non-interventional clinical studies using patient data
- Includes planning, conducting and reporting secondary analyses
- Does not include details of statistical methods and analyses
- Based on CRDSA expertise and external publications – for example:


DOI: 10.1186/s12874-016-0171-x • Corpus ID: 35794000

EFSPI/PSI working group on data sharing: accessing and working with pharmaceutical clinical trial patient level datasets – a primer for academic researchers

R. Sudlow, J. Branson, T. Friede, D. Morgan, C. Whately-Smith less •

Published in BMC Medical Research... 8 July 2016 • Medicine, Business


Contact | Cochrane.org | Cochrane Community

Cochrane Training

Trusted evidence.
Informed decisions.
Better health.

Search...

Online learning | Learning events | Guides and handbooks | Trainers' Hub | Log in

Chapter 26: Individual participant data

Search Handbook

Jayne F Tierney, Lesley A Stewart, Mike Clarke; on behalf of the Cochrane Individual Participant Data Meta-analysis Methods Group

Structure of the Standards

Principles (requirements)

PLAN

2.1 RESEARCH QUESTION

PRINCIPLE: THERE IS TO BE A DOCUMENTED AND WELL-DEFINED RESEARCH QUESTION OR HYPOTHESIS THAT IS TESTABLE BY ANALYSIS OF CLINICAL STUDY DATA

Having a documented and well-defined research question and/or hypothesis helps ensure that the analysis is focused and meaningful. A clear research question is also important when using data mining techniques to identify patterns and relationships in the data so that valid inferences can be made from the results. In addition to having a research question/hypothesis to show the validity of the research, how this question/hypotheses can be tested using clinical study data that may be available is to be shown.

Best Practices

- Published literature and information available on data sharing platforms/study registries about ongoing studies and analyses should be reviewed to identify gaps in knowledge or areas where further investigation is needed. The research questions that have been addressed in previous studies and the limitations of these studies should be considered. Areas where there may be conflicting or inconclusive findings, or where further investigation is needed to confirm or extend previous findings, should be identified.
- Key variables should be identified to help clarify and refine the research question. By considering which variables are most relevant to the research question, a more focused and specific research question can be developed.
- For meta-analyses, the value of IPD analysis compared with the traditional aggregate approach should be considered [3].

The Standards provide principles CRDSA considers to be mandatory. Principles may be supplemented with criteria to be followed to meet the principle

Non-mandatory recommendations are provided as best practices

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Non-mandatory recommendations are provided as best practices

Checklist
(for case-by-case exceptions)

The principles and criteria may not be applicable for every study that is shared or every analysis that is conducted- a checklist is provided where any deviations or exceptions from the principles/criteria for a shared study or analysis can be explained

PLAN

		Yes/No/NA	NA Explanation
RESEARCH QUESTION	Is there a documented and well-defined research question and/or hypothesis that is testable using clinical trial data?		
STUDIES	Have studies that include the required data been objectively identified and assessed using predefined criteria?		
TEAM	Does the team have statistical expertise and experience in clinical trial data analysis as shown by statistical qualifications and previous analyses of clinical study data?		
	Does the team include the expertise and skill sets needed to navigate clinical study documents and fully understand the relationship of study designs to the intended analysis as shown by formal training and/or previous research?		
	Does the team include expertise to manage the types of datasets being accessed and use the relevant software as shown by formal training and/or previous research?		
	Does the team include specific expertise relevant for the analysis (e.g., MedDRA expertise for analysis of safety) as evidenced by formal training and/or previous research?		
SAP	Is there a prespecified statistical analysis plan (SAP) dated before the analysis was conducted?		
	Does the SAP include all of the following? - The questions and hypotheses being addressed - Effect measure of interest (e.g., for inferential studies: odds ratio, risk or rate ratio, risk or rate difference, absolute difference) - The populations and variables to be analyzed, including details of any subjects and data that will be included and excluded		

Contents

Data Sharing Standard

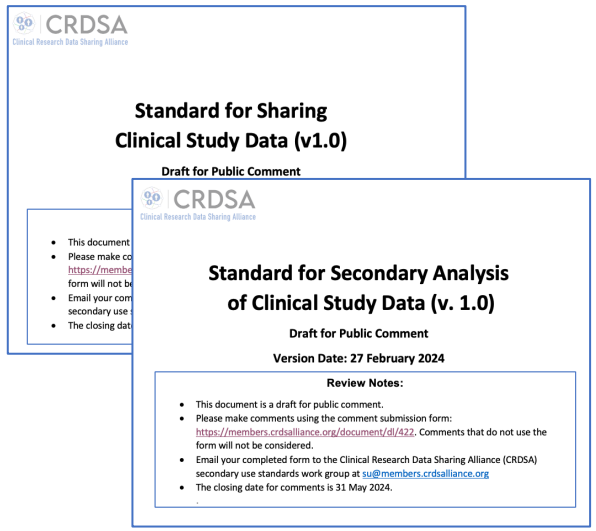
- Datasets to be shared
- Supporting documentation and meta-data to be shared
- Data transformation report
- When supporting documentation is to be shared

Secondary Analysis Standard

- Plan
- Conduct
- Report

Adoption

Adoption



The standards can be adopted by data sharing platforms, funders, research institutions, and scientific journals.

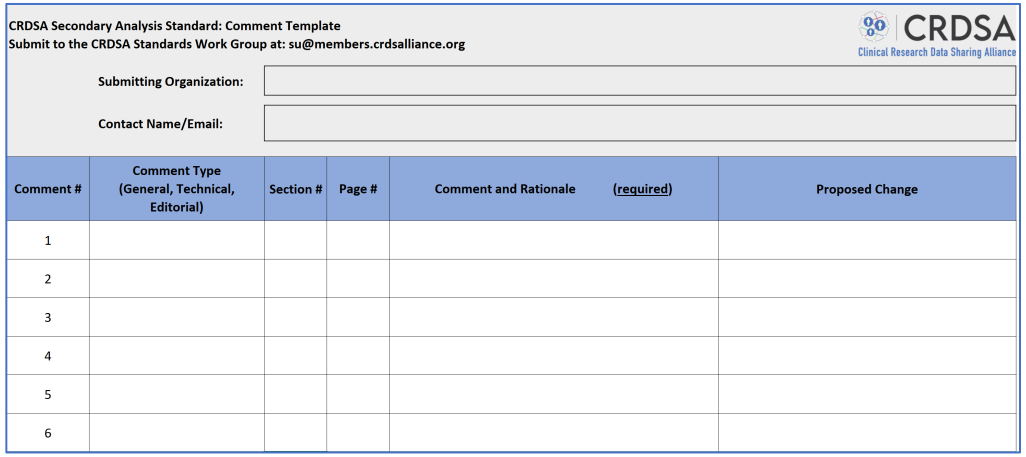
When adopting a CRDSA standard, the organization incorporates the principles into their policy (the organization governs compliance with the policy), for example:

"Organization X adopts the CRDSA Standard and requires data contributors/researchers to follow the principles and complete the checklist in the CRDSA Standard"

How to provide comments

How you can provide comments

- The draft standards will be available for public comment at: https://crdsalliance.org/resources/#sus
- Webinars to discuss the contents in more detail have been scheduled. Register through the links provided in the summit resources or by going to https://crdsalliance.org/news-events/
- Please make comments using the comment submission form (linked in the draft documents)



CRDSA Secondary Analysis Standard: Comment Template
Submit to the CRDSA Standards Work Group at: su@members.crdsalliance.org

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Submitting Organization:

Contact Name/Email:

Comment #	Comment Type (General, Technical, Editorial)	Section #	Page #	Comment and Rationale (required)	Proposed Change
1					
2					
3					
4					
5					
6					

- Email your completed form to the CRDSA secondary use standards work group at su@members.crdsalliance.org
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Q&A

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Thank you!

For additional resources and information, please visit:

https://crdsalliance.org/resources