



CRDSA

Clinical Research Data Sharing Alliance

Data Sharing Assessment App For Clinical Studies

17 September 2025

1. Overview

High-quality individual patient data (IPD) from clinical studies can support secondary research that verifies original findings, enables new analyses, and advances scientific understanding. These benefits, however, are only realized when IPD is shared in a manner that maximizes its research utility while safeguarding privacy and intellectual property.

The [CRDSA Standard for Sharing Clinical Study Data \(Std 1001\)](#), published in September 2024, was developed to address long-standing variability in what is shared, when, and in what form. The standard specifies the core components required for high-utility data sharing, including:

- **Datasets** in recognized formats (e.g., SDTM for raw data, ADaM for analysis-ready data).
- **Supporting documentation and metadata** sufficient for independent use and interpretation of the data.
- **Study-specific data transformation reports** detailing anonymization and other modifications.
- **Early provision of key documents** so that secondary researchers can determine potential relevance before requesting IPD.

While the standard provides a benchmark for good practice, organizations that fund, publish, or aggregate research (e.g., data platforms) require a practical way to evaluate the suitability of submitted data sharing plans and/or submissions of clinical study data. The Data Sharing Assessment App was created for this purpose. It translates the principles in Std 1001 into a short, structured instrument that can be applied consistently across data sharing use cases.



The assessment app is a 15-question scored rubric designed to objectively measure the completeness and quality of a proposed data sharing plan, commitment, or data contribution.

Access to the assessment is free, with no restrictions on frequency of use.

The Data Sharing Assessment App can be found here:

[Data Sharing Assessment](#)

2. Users and Use Cases

The assessment applies broadly to the sharing of clinical study data and can be used by research funders, data platforms, publishers, sponsors, and researchers. It is particularly valuable as a benchmark for evaluating the quality of a data sharing plan or a data contribution commitment.

Here are some example assessment use cases:

Research funders play a pivotal role in advancing data sharing practices. Many agencies and funders, including the US National Institutes of Health (NIH) and the UK National Institute for Health and Care Research (NIHR), mandate data sharing plans. However, clinical study data presents unique challenges related to privacy protection, metadata consistency, and data usability.

Use cases: Evaluate a data sharing plan submitted as part of a research proposal; ensure downstream (end-of-study) compliance with the submitted plan.

Scientific journals shape research practices through publication requirements and many already require sharing of underlying data. To enhance data transparency and methodological rigor, journals can require authors to state how shared data aligns with the CRDSA Data Sharing Standard. This will encourage researchers to include documentation and metadata that facilitates data reuse.

Use cases: Ensure published data meets the journal's standard for data access and data utility, reinforcing responsible data sharing practices and promoting reproducible research.

Data Platforms serve as intermediaries between data contributors and secondary researchers, making them the lynchpin of the shared data ecosystem. Recognizing that platform owners may not have full control over data contributor practices, adoption does provide an important benchmark for a study's potential research utility.

Use cases: Provide a benchmark for data contribution; portfolio evaluation assessing data utility across multiple studies; provide researchers (end-users) with an easy-to-use tool to evaluate a study's suitability for their research proposal.

Researchers and Academic Institutions are both producers and consumers of clinical study data. These institutions can support implementation of good data sharing practices by aligning internal data management policies with the CRDSA Data Sharing Standard. By embedding the practices into institutional workflows, universities and clinical research centers can ensure their investigators are equipped to meet the expectations of funders, platforms, and journals while promoting best practices in clinical research.

Use cases: Ensure data sharing plans will meet funding proposal or publication requirements; evaluate the suitability of secondary clinical study data to address specific research questions.

3. Extending and Customizing the Assessment

While the core 15-question assessment is fixed to preserve alignment with Std 1001, organizations may extend the tool for their own operational needs.

Portfolio Dashboard

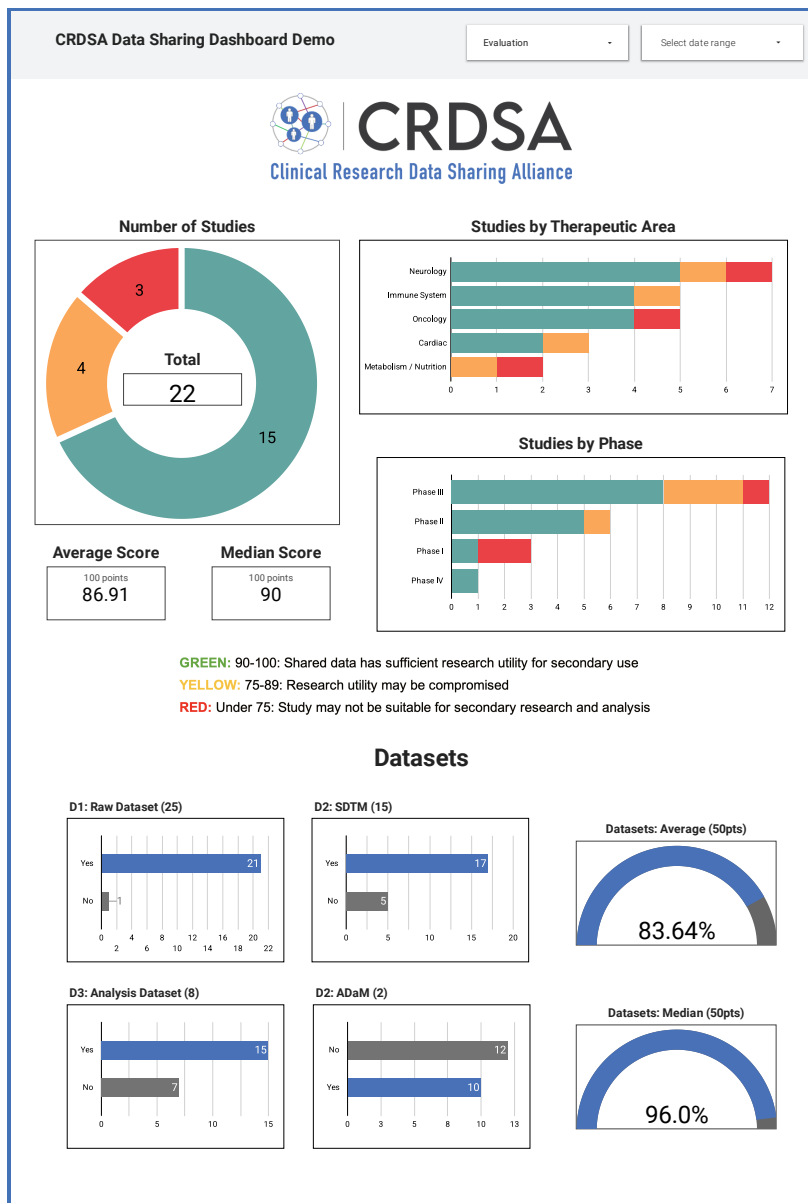
An organization specific dashboard provides a portfolio view of assessments across studies. It supports filtering and grouping by attributes such as sponsor type, funding mechanism, disease area, and study phase. The dashboard can be customized to meet specific operational or reporting needs.

Assessment Range Customization

The ranges for the assessment (stoplight) scoring can be tailored to an organization's specific needs, users, and use cases.

Custom Sorting and Filtering

Organizations can include fields that support internal classification and reporting, for example geographic scope, budget band, or links to internal governance records. These fields improve search and enable targeted monitoring while leaving the standard score unchanged.



Additional Scoring Dimensions

Custom items can be added to reflect local policy requirements not covered in Std 1001 (e.g., repository or access requirements). Custom items are scored and reported separately from the standard score so that local priorities can be addressed without affecting comparability.

Tailored Visualizations and Reports

Reports can be configured for boards, review committees, or public transparency initiatives. Visual displays can show score distributions, common deficiencies, and portfolio-level trends.

The combination of a fixed core and optional extensions allows organizations to implement the assessment quickly, maintain comparability across studies and programs, and meet internal reporting needs without redefining the underlying standard.

Please email us at standards@crdsalliance.org to learn more about the portfolio dashboard and additional customizations.

4. Development of the Data Sharing Assessment App

The assessment is based on the foundational principles in [CRDSA's Standard for Sharing Clinical Study Data \(Std 1001\)](#). For more information on the development of the standard, please see Appendix A.

The assessment tool was created to answer a set of recurring questions faced by reviewers and decision-makers:

- Does the plan or contribution clearly describe what will be shared, in what format, and with what documentation?
- Will the shared data have sufficient utility for independent analysis?
- Are there gaps that must be addressed before the plan or contribution can be considered compliant?

Translating the standard into the consistent scoring rubric used in the assessment followed a rigorous development and iterative testing process:

- 1. Principle-to-question mapping:** Each question directly corresponds to one or more principles and criteria from the standard, stated in a manner that facilitates standard “yes/no/NA” answers. The 15 questions are divided into three sections: Datasets, Supporting Documentation and Metadata, and Data Transformation Report.
- 2. Weighting:** Each question was assigned a points value (out of a maximum of 100). The assigned values were determined by a multi-stakeholder work group including representatives from industry sponsors, data sharing platforms, and academic researchers. A core determinant of the value assigned to a question was the perceived research value of the element. These values were heavily informed by CRDSA's survey of industry and academic researchers (results in our 2023 publication [Establishing a Basis for Secondary Use Standards in Clinical Trials](#)).
- 3. Scoring:** The points score (out of 100) is evaluated using a stoplight scoring approach that communicates whether the plan is compliant, partially compliant, or non-compliant:
 - **Green (90-100):** The shared data has sufficient utility for secondary use.
 - **Yellow (75-89):** Research utility may be compromised.
 - **Red (<75):** Study may not be suitable for secondary research and analysis.

These ranges are based on an evaluation of research utility requirements, informed by reviews of industry sponsor data sharing governance policies and direct academic and non-profit hands-on data management experience.

While the research utility of data contributions has markedly advanced over the last five years, this is still an evolving area. We recognize that an existing portfolio of data sharing plans or data contributions will of necessity contain dated studies that may not reflect today's contribution policies or requirements. Please see section 4 (Extending and Customizing the Assessment) for organization-specific customization options.

4. **Testing and refinement:** The tool was piloted using sample data sharing plans or contributions from multiple sectors (industry, academic, nonprofit). This process identified ambiguous wording, refined the scoring logic, and ensured applicability across study designs and disease areas.
5. **Delivery:** The 15-question assessment is delivered via a secure, web-based form. Results are delivered via email and can be stored in an optional organization-specific portfolio dashboard that aggregates assessments over time. Access to the base assessment (delivered by email) is free, with no restrictions on frequency of use.

About CRDSA

CRDSA is a multi-stakeholder consortium that serves the clinical research data ecosystem.

Our mission is to accelerate the discovery and delivery of lifesaving and life-changing therapies to patients by expanding the research value of patient data from the clinical development process, academic research, and real-world settings. Broad access to these data has the power to transform the research process and improve human health. To find out more please visit crdsalliance.org.

Appendix A

The Clinical Study Data Sharing Standard and the Standard for Secondary Analysis followed CRDSA's approved [standards development process](#) and were informed by survey and systematic review data collected from clinical study sponsors, academic researchers, and industry experts.

