



CRDSA

Clinical Research Data Sharing Alliance

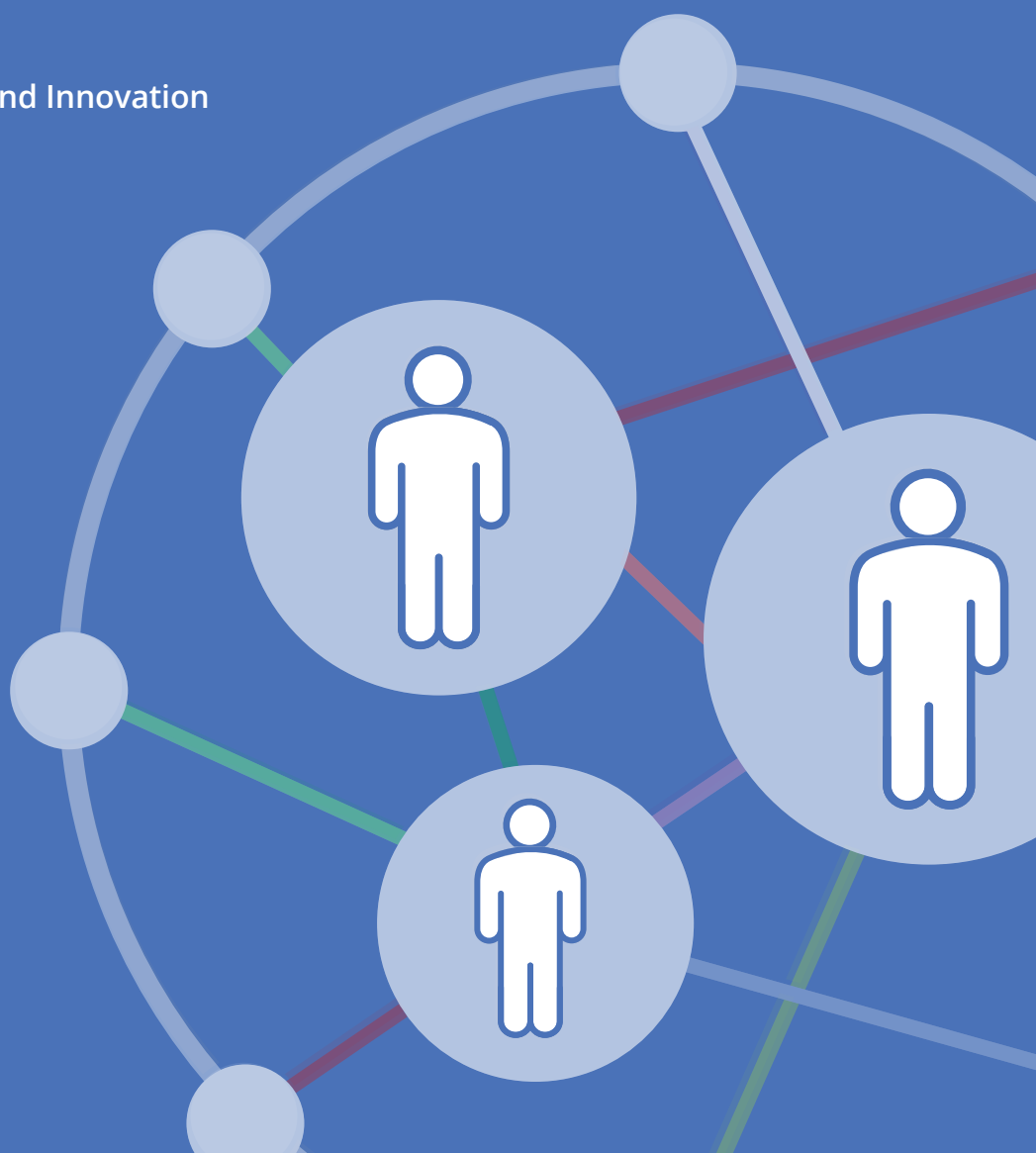
Data Sharing Technology Assessment Framework

R Shiny Application Implementation Guide

Version: 2.0

Work Group: Technology and Innovation

Date: 25 October 2023



Data Sharing Technology Assessment Framework R Shiny Implementation Guide

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Abstract

The Clinical Research Data Sharing Alliance (CRDSA) Technology and Innovation Work Group has developed a data sharing technology assessment framework to support stakeholders in their evaluation of technologies and approaches that advance their data sharing initiatives, whether they are interested in technologies for external data sharing or to support an organization's internal data reuse. The framework is designed to assist stakeholders in determining the requirements and use cases important to their organization. The resulting assessment scores can be used to compare how well different technology approaches or project scopes meet organizational objectives.

Acknowledgments

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CRDSA Technology and Innovation Work Group:

Peter Mesenbrink (Work Group Chair, Novartis), Dave Alonso (The Michael J. Fox Foundation), Alain Njimoluh Anyouzoa (Takeda), Luk Arbuckle (Privacy Analytics), Srikanth Emmadi (GSK), Cathal Gallagher (D-Wise), Matt Harvey (AstraZeneca), Aaron Mann (CRDSA), Lucy Mosquera (Replica Analytics), Neil Postlethwaite (Health Data Research UK), Mai Tran (Roche), Ramona Walls (Critical Path Institute), Matthew Wien (Takeda), Julie Wood (Vivli), Shaoming Yin (Takeda).

Legal Disclaimer

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Introduction

Technology plays a central role in the data sharing ecosystem. New technology approaches can support innovative data governance approaches, advance patient-level data privacy, enhance data utility, improve infrastructure data protection, and enable more streamlined and safer access to data. With rapid advances in technical capabilities and access to a growing range of approaches to continuously improve the data sharing ecosystem, the “best” choice for an organization isn’t always clear.¹

The Clinical Research Data Sharing Alliance (CRDSA) Technology and Innovation Work Group has developed a data sharing technology assessment framework to support stakeholders in their evaluation of technologies and approaches that advance their data sharing initiatives, whether they are interested in technologies for external data sharing or to support an organization’s internal data reuse. The framework can also be used as a guide to ensure the maintenance of optimal solutions for effective data reuse.

The framework is designed to support stakeholders across the spectrum of organizational roles represented in the internal and external data sharing ecosystems:

- **Platform Owners:** The organizations or internal teams responsible for delivering the technical, legal, and governance infrastructure that enables data contributions and facilitates researcher access and use. These may encompass data sharing business process owners, technology and IT delivery teams, and data governance and data privacy subject matter experts. The platforms being delivered by the owners could be:
 - » **Internal Data Reuse Platforms:** facilitating an organization’s internal data reuse.
 - » **External Data Sharing Platforms:** serving as the conduit or connection between data contributors and end users/researchers (recognizing that organizations are often both contributors and end users of data).
- **Data Contributors:** Organizations providing data, whether internally for data reuse or when sharing externally.
- **Researchers:** Organizations or individuals (e.g., academic researchers) using shared data for a wide range of use cases that can include novel clinical trial design and enrichment strategies, predictive preclinical and clinical models, clinical trial simulation tools, biomarkers, clinical outcomes assessments, and more.²



Design Philosophy and Scope

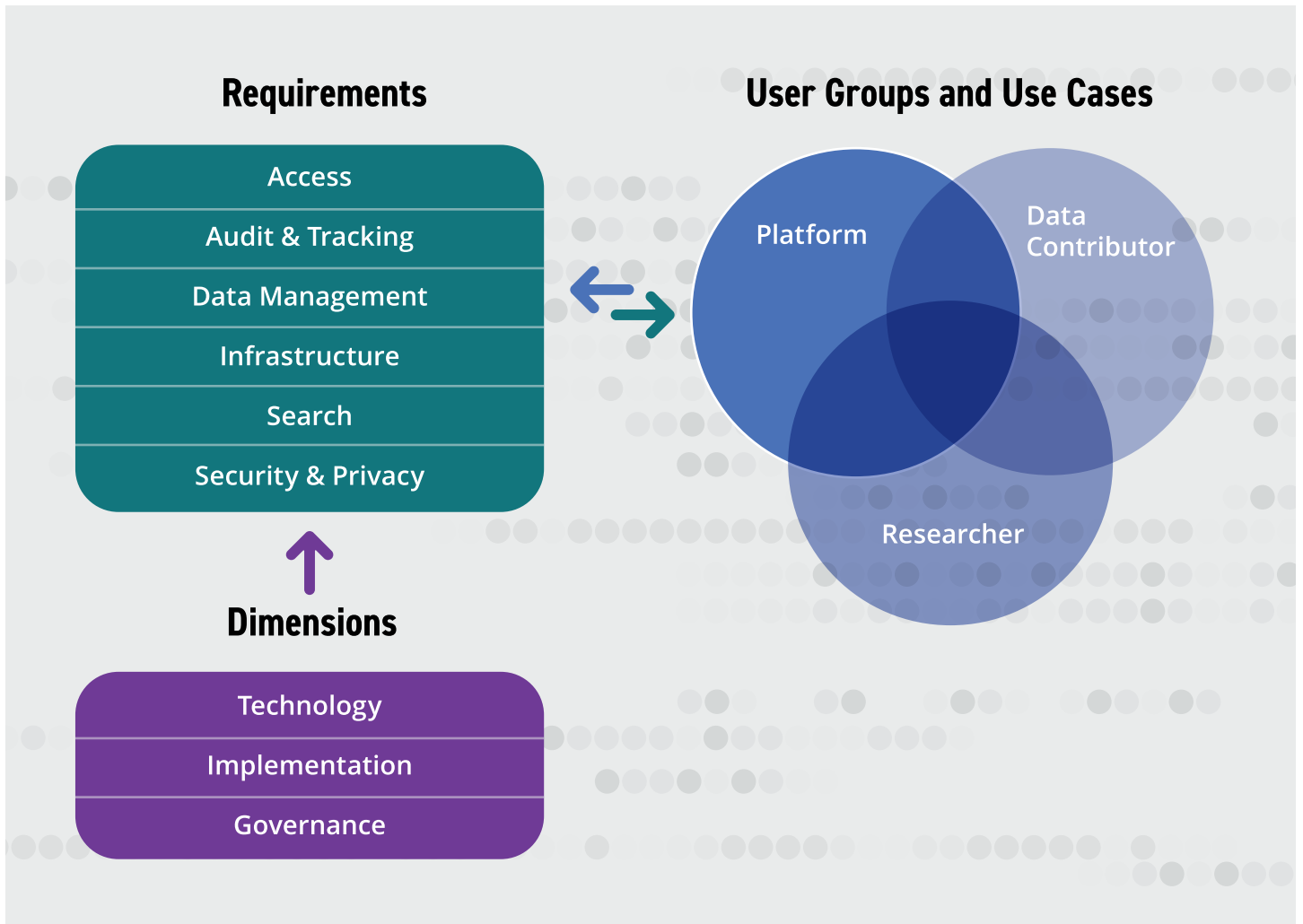
Fundamental to the Assessment Framework is the idea that there is no universal “best” or “one size fits all” technology. Rather than attempt to give an overall score, the technology being assessed by the framework is evaluated against specific use cases.

This framework is intended to be used for project scoping rather than as a vendor-selection tool. Considerations that may be paramount in an RFI/RFP process are expressly out of scope. However, users may find the framework helpful in determining the project scope for a subsequent RFI/RFP process. The framework is designed to assist stakeholders in determining the requirements and the use cases that are important in their application.



The Technology Assessment Framework

The Assessment Framework is designed to allow consistent evaluation of the technology capabilities based on common use cases and requirements. The framework has three major components: Use Cases, Requirements, and Dimensions.



These components work together to provide a consistent framework that can be applied across a range of approaches, including data lakes and federated models.



Use Cases

The use cases represent the diverse range of data sharing stakeholder groups and, within those groups, outline scenarios typically relevant to or considered by stakeholders. The use cases are the essential “lens” for assessment, allowing framework users to determine which requirements apply to each use case and then serving as the basis for assessment scoring. The framework allows users to select which requirements apply to each use case based on their specific needs.

Use cases are defined across 3 user groups:

- **Platform:** The platform use case encompasses the technical and infrastructure considerations enabling data contributions, facilitating research use, and ensuring compliance with regulatory and organizational policies.
- **Data Contributor:** Contributor requirements typically include many of the same privacy, security, IT, and compliance needs as are applicable at the platform level. Two data governance use cases are included in the framework:
 - » **Restricted Access:** Researcher downloads are not allowed, and dataset-level on-platform access may be limited or prohibited. Data may only be analyzed on or through the data sharing platform (DSP).
 - » **Controlled Access:** The researcher may access and download data via the data platform.³
- **Researcher:** The research use cases represent a range of allowed researcher access privileges. Applicable use cases will depend on the specific research use or question being addressed.
 - » **Remote Data Interrogation:** The researcher can query but not view or otherwise access the underlying datasets. The analysis is “taken to the data.”⁴
 - » **Locked Box:** The researcher will access and analyze data on-platform, including access to the individual patient data (IPD).
 - » **Data Released to the Researcher:** Allows the researcher to use their analytics platform.
 - » **Regulatory Use:** Data is released to the researcher and will or may be used in a regulatory setting. This is considered distinct from the preceding use case because regulatory use often carries additional data provenance considerations. These considerations may necessitate the application of additional requirements, particularly around audit and data management.

These use cases can be in partial or direct conflict with each other. For example, a data contributor may require access to underlying datasets to be restricted to the platform. Conversely, end-user researchers may want the ability to interrogate the underlying data in their own computing environment (for example, to facilitate the pooling of external and internal data or access to organization-specific analytics tools). Therefore, the assessment does not render an overall score; instead, each use case is evaluated based on the requirements specific to that use case.

Requirements

The 39 requirements described in the framework are a collection of functional and technology needs representing a balanced range of data sharing platform considerations. The framework requirements are classified into 6 categories:

- **Access:** Defining and controlling end-user permissions, restrictions, and available on-platform research tool capabilities.
- **Audit & Tracking:** Includes mechanisms to enable compliance oversight and capabilities to track and retrieve changes to data, information, and system-generated or transactional events.
- **Data Management:** The activities involved in collecting, organizing, keeping, storing, and using data securely and efficiently.
- **Infrastructure:** Requirements relating to the combined components, such as hardware, software, facilities, etc., required to operate and manage the IT solutions.
- **Search:** Capabilities that enable users to find data and information effectively.
- **Security & Privacy:** Ensuring that data are safeguarded and protected per applicable regulatory and organizational requirements.

The categories highlight important general capability areas, allowing users to understand areas of strength and identify gaps quickly.

Dimensions

Dimensions are not used in assessment scoring; rather, they are provided as helpful context to understand why a particular requirement was or wasn't met. Requirements may rest on technical functionality (i.e., does the technology provide for the requirement?), but they are often also scope choices made at the platform level (i.e., does the platform implement or allow the requirement?). Three dimensions are provided:

- **Technology:** Does the technology approach being assessed have the underlying capability to meet the requirement? For example, a solution delivered only on-premises does not meet a requirement for cloud delivery.
- **Implementation:** Is meeting the requirement related to whether a specific functionality is (or is intended to be) implemented in the platform?
- **Governance:** In operationalizing the solution, does the legal and governance structure support (or is it intended to support) a specific functionality?

Each requirement is assigned one or more dimensions. These dimensions can also be helpful when using the framework to construct a solution scope.



Using the Framework R Shiny Application

The Framework is publicly available as an R Shiny application (<https://nvs-apps.shinyapps.io/data-sharing-technology-assessment-framework>). CRDSA member organizations can access an editable Excel version (and Excel-specific implementation guide) through the [CRDSA member portal](#).

Completing an Assessment

There are two steps in completing the assessment. These steps can be done in either order or be separated between teams — for example, an IT team could assess requirements separately from a team looking at which requirements apply to each use case. As a general recommendation, completing the use cases first may surface some requirements that aren't used by any use cases relevant to your organization, which would then not need to be evaluated.

Matching Requirements to Use Cases

In this step, select relevant requirements for each stakeholder use case by checking the appropriate boxes.

DATA SHARING TECHNOLOGY ASSESSMENT FRAMEWORK

The Clinical Research Data Sharing Alliance (CRDSA) Technology and Innovation Work Group has developed this data-sharing technology assessment framework to support stakeholders in their evaluation of technologies and approaches that advance their data-sharing initiatives. The framework provides baseline requirements organized in 6 categories (Access, Audit & Tracking, Data Management, Infrastructure, Search, Security & Privacy). The framework allows for selection of specific requirements applicable to 7 Use Cases defined for three primary user groups (Platform, Data Contributor, and Researcher).

Assessment

Category

All

| | Category | Dimension | Requirement | Met | PLATFORM Technical and Infrastructure Considerations | DATA CONTRIBUTOR Data limited to on-platform tools or remote interrogation | DATA CONTRIBUTOR Researchers can access and download datasets | RESEARCHER Remote Data Interrogation | RESEARCHER Locked Box | RESEARCHER Data Released to Researcher | RESEARCHER Regulatory Use |
|-----|----------|-----------|---|-----|--|--|---|---|--------------------------|---|------------------------------|
| R1 | Access | I | Gated User Access | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R2 | Access | O | Open User Access | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R3 | Access | I | Trusted and controlled research environment | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R4 | Access | O | Researcher access can be restricted to the Research Environment (no downloads allowed) | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R5 | Access | I | Research environment has or allows for robust on-platform analysis tools (SAS, Python, etc.) | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R6 | Access | IG | Allows or facilitates Researcher to access multiple datasets (e.g. for cohort building) through the Research Platform | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R7 | Access | I | Allows or facilitates on-platform Researcher use of their own licensed tools | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R8 | Access | IG | Access to view Individual Patient Data (IPD) On-Platform | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R9 | Access | IG | Access to view and work with (e.g., derive new variables) IPD On-Platform | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R10 | Access | O | Allows for Download of Source Data (Data can be taken off platform for analysis) | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R11 | Access | IG | Allows for the enforcement of access constraints on derived data | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| R12 | Access | IG | Facilitates or enables third-party access | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Summary



Assessing the Requirements

In this step, determine whether the requirement is met by the technology approach being assessed. Requirements may be skipped if they don't apply to any use cases in your assessment. In this example, the requirement R3 is met:

DATA SHARING TECHNOLOGY ASSESSMENT FRAMEWORK

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|------------|----------|----------|-----------|-------------|---|---|---|--|---|--------------------------|---|------------------------------|
| | All | R1 | Access | I | Gated User Access | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | R2 | Access | O | Open User Access | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | R3 | Access | I | Trusted and controlled research environment | YES | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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Summary

PRO TIP

REFINING REQUIREMENTS

The assessment is designed to aid in developing a project or program scope; therefore, requirements are either “met” or “not met.” Your organization may wish to append specifics to requirements that define minimum satisfaction criteria.



CRDSA

Moving across the R3 row, you can quickly see where R3 has been applied:

DATA SHARING TECHNOLOGY ASSESSMENT FRAMEWORK

More

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Assessment 1

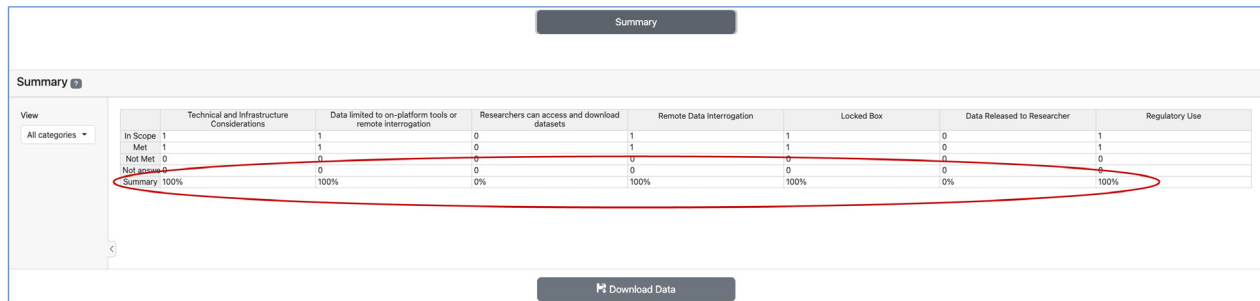
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|----------|----------|-----------|-------------|---|--|--|---|---|-------------------------------------|---|-------------------------------------|
| All | R1 | Access | I | Gated User Access | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | R2 | Access | O | Open User Access | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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| | R5 | Access | I | Research environment has or allows for robust on-platform analysis tools (SAS, Python, etc.) | Y/N | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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Summary



Understanding the Results

The complete results can be found on the summary field panel at the bottom of the window. The summary panel provides aggregated information for each use case and details on the requirements categories. It is intended to aid the determination of the areas of strength and weakness of the technology and to help inform technology selection decisions. The percentages in the summary row indicate which use cases are best supported by the technology being assessed.



| View | Technical and Infrastructure Considerations | Data limited to on-platform tools or remote interrogation | Researchers can access and download datasets | Remote Data Interrogation | Locked Box | Data Released to Researcher | Regulatory Use |
|--------------|---|---|--|---------------------------|------------|-----------------------------|----------------|
| In Scope | 1 | 1 | 0 | 1 | 1 | 0 | 1 |
| Met | 1 | 1 | 0 | 1 | 1 | 0 | 1 |
| Not Met | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Not assessed | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Summary | 100% | 100% | 0% | 100% | 100% | 0% | 100% |

For each use case, the summary shows the percentage of requirements met and the total number in-scope/met/not-met.

PRO TIP

LIMIT USE CASE REQUIREMENTS

It is best to limit the number of “in scope” requirements for each use case. For example, including “nice to have” requirements can affect the score by obscuring the negative impact of a critical “need to have” requirement that isn’t met. Focus on the requirements you deem critical to success.

One then has the option to download the Assessment and/or the summary of the assessment in an Excel file:

Download Options

File Name:

[Download Assessment](#) [Download Summary](#)



Summary

The Technology and Innovation Work Group built this framework to support a project assessing several technologies matched to “best fit” use cases. The framework is intended as a starting point for Work Group use and as an asset for the broader data sharing community. While the framework is provided “as is,” we welcome suggestions and feedback to inform future refinements. You can reach us at framework@crdsalliance.org.refinements.

About CRDSA

CRDSA is a multi-stakeholder alliance that serves the clinical data sharing ecosystem. Our mission is to accelerate the discovery and delivery of life-saving and life-changing therapies to patients by expanding the research value of secondary use data. Broad access to these data has the power to transform the research process, improve trial design and delivery, and benefit the patients who donate their time and their data as part of the clinical development process. To find out more please visit crdsalliance.org.



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