Data Repository

User Manual

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Table of Contents

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Data Repository 1.0 User Manual

The **Data Repository User Manual** provides instructions for using the Data Repository to organize and manage data and documents. Included in the manual are the following topics:

- Overview
- Concepts
- Using the Data Repository

The **Data Repository User Manual** provides a thorough description of how data and information are organized across the Data Repository, as well as how teams interact with the Data Repository.

Important information about the Data Repository might be provided in this guide using colored text boxes:

| Type of Information	Text Box Style
General Information	*Additional details about certain situations that may be helpful.*
Warnings	*Cautionary information and instructions.*
Tips	*Helpful tips and examples for specific cases.*

Overview

The Data Repository is a software module within the KIWI Cloud service used to facilitate the management and organization of data files used and produced during pharmacometric analyses throughout the drug development process.

This software module is a web application with a user interface which allows users to manage and browse files within a pre-defined directory structure stored in a version control system.

The system has a hierarchical structure to control organizational, team, and user access to shared data files. Users have assigned roles that enable specific actions unique to their roles and permissions.

The system gives the repository owner the ability to control user access to shared data files through the use of Teams and User Roles.
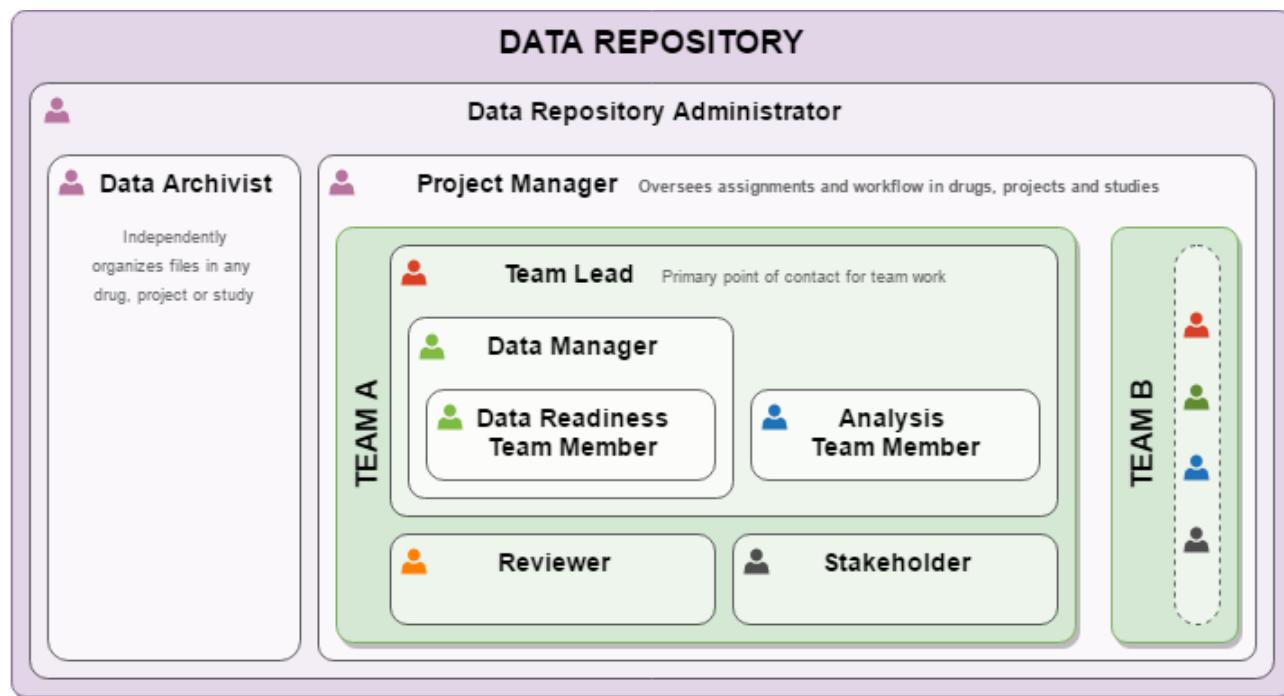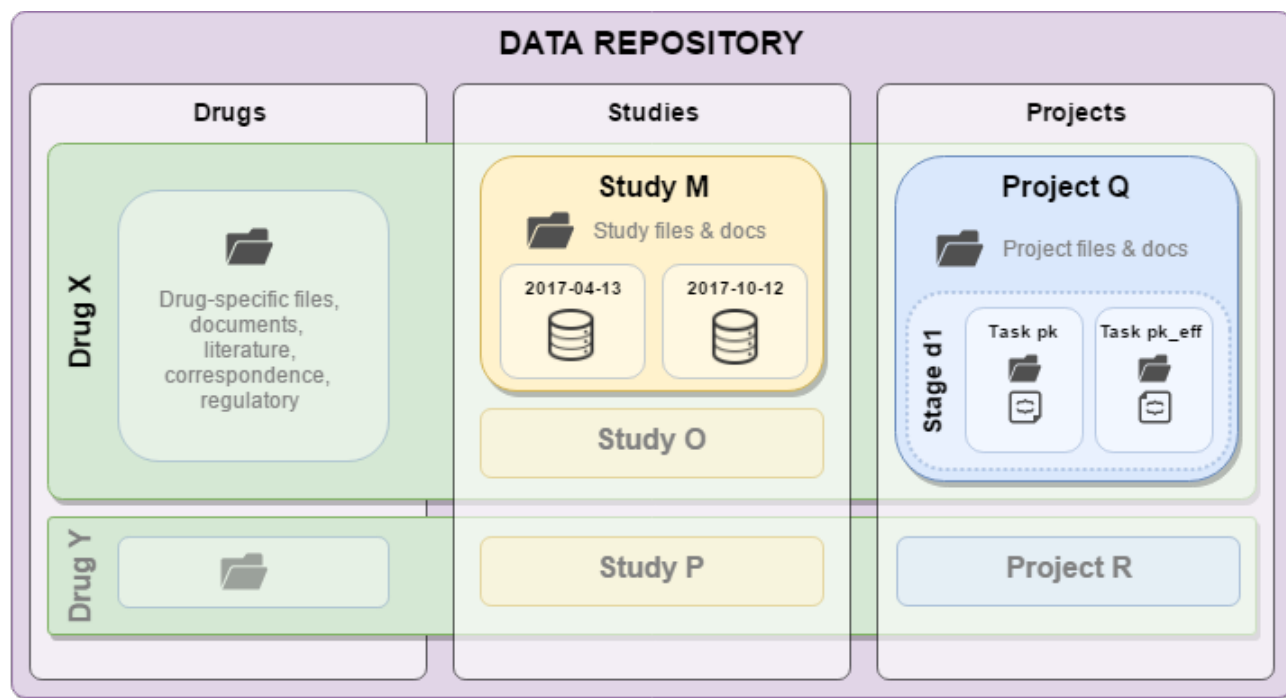
Each team consists of users from established partner organizations.
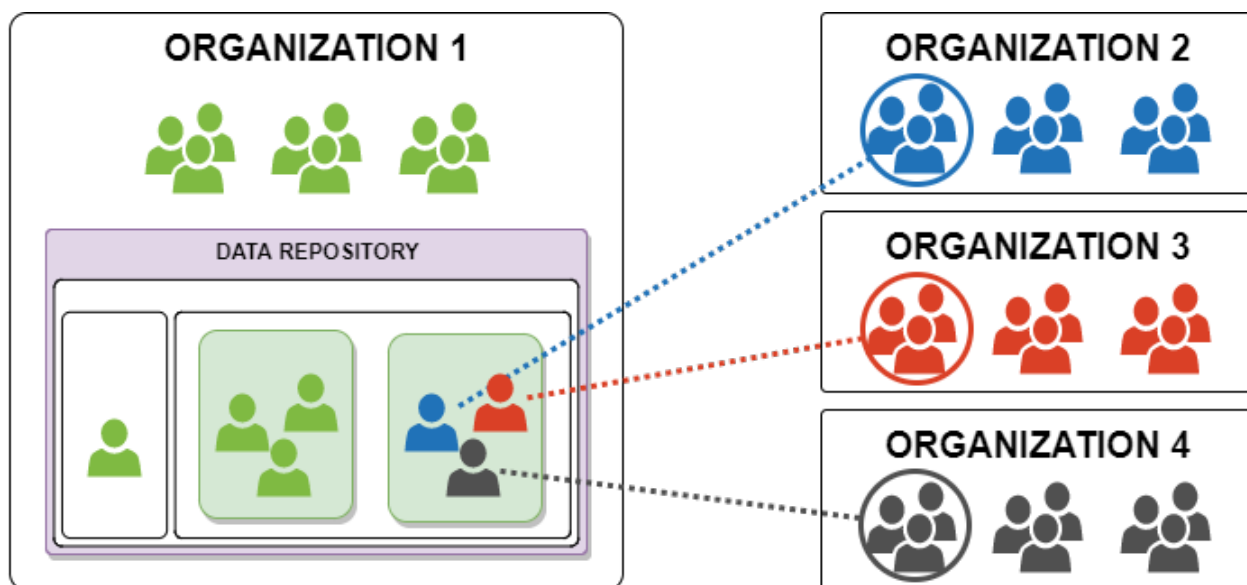
Teams are assigned to perform actions on data and documents for Drugs, Projects, and Studies.

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Concepts

Data Storage Components

Actions

Teams & Roles

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Data Storage Components

Types of Data Storage Components

Data Storage Components are logical units designed to organize and store data and documents, based on a template for the type of work the data and documents are associated with.

Three initial Data Storage Component types are defined for the initial version of the Data Repository application:

- Drug: This can be defined by the user as either a single chemical entity or a combination therapy.
- Study: This can be defined by the user as an experiment or trial.
- Project: This can be defined by the user as any work a team is assigned that corresponds to either a Drug or a Study.

The Data Repository hierarchy structure is such that, as a best practice, a Study or a Project should always be related to a Drug. Multiple Drugs and multiple Studies can be related to a single Project and vice versa.
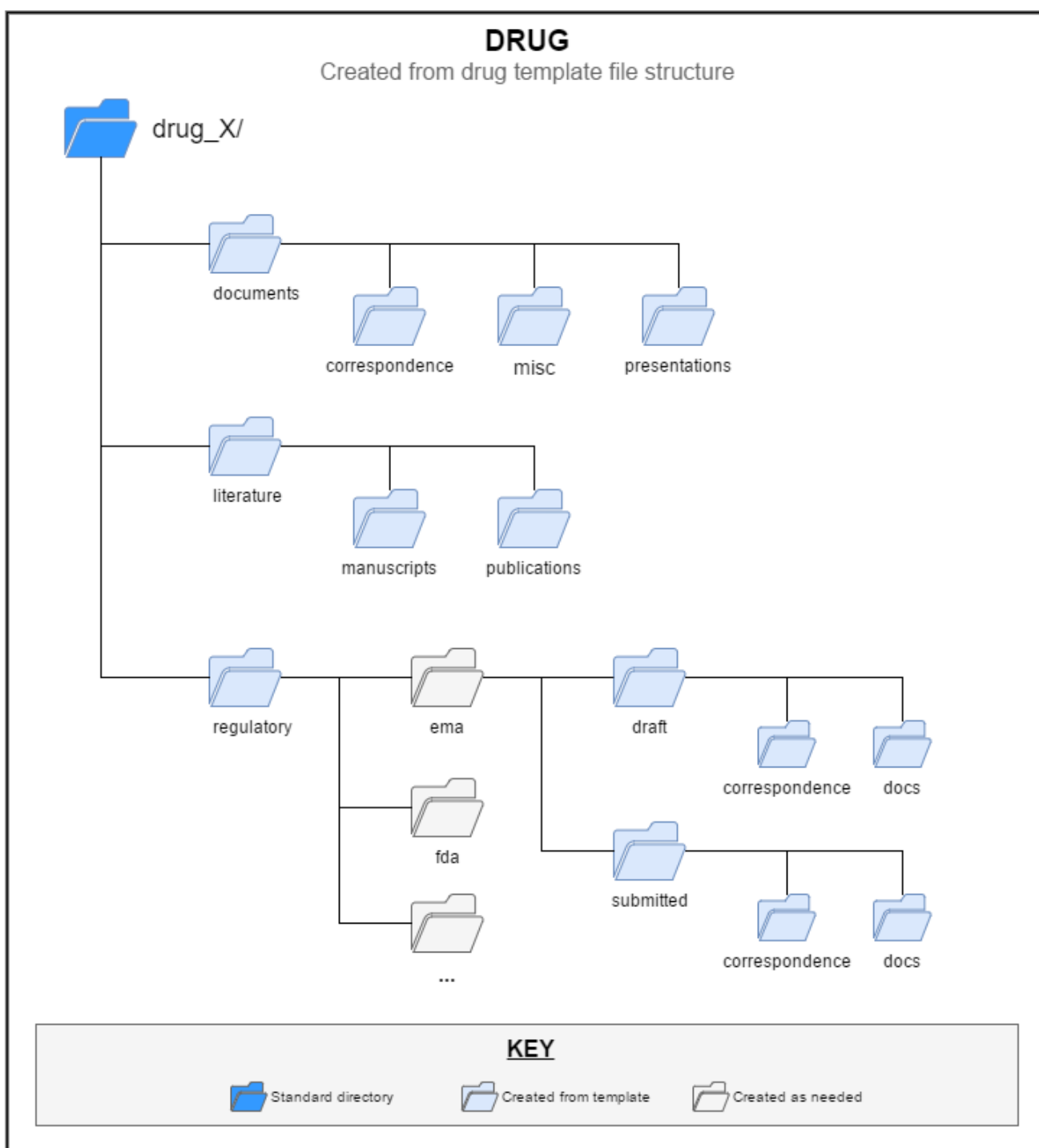
Additional diagram key descriptions for structure diagrams in the next sections:

Standard Directory		*Standard directory*	*This is the top-level root directory which houses all information within each Drug.*
Template Directory		*Created from template*	*Template directories are created automatically when a Drug is created and are located inside the Drug's root directory.*
Created as Needed		*Created as needed Program types, as needed*	*Directories can be added in special locations by users as needed. These directories can contain their own template directories. For example, when a Regulatory Agency directory is added, the sub-directories shown are automatically created at that time.*

Drug

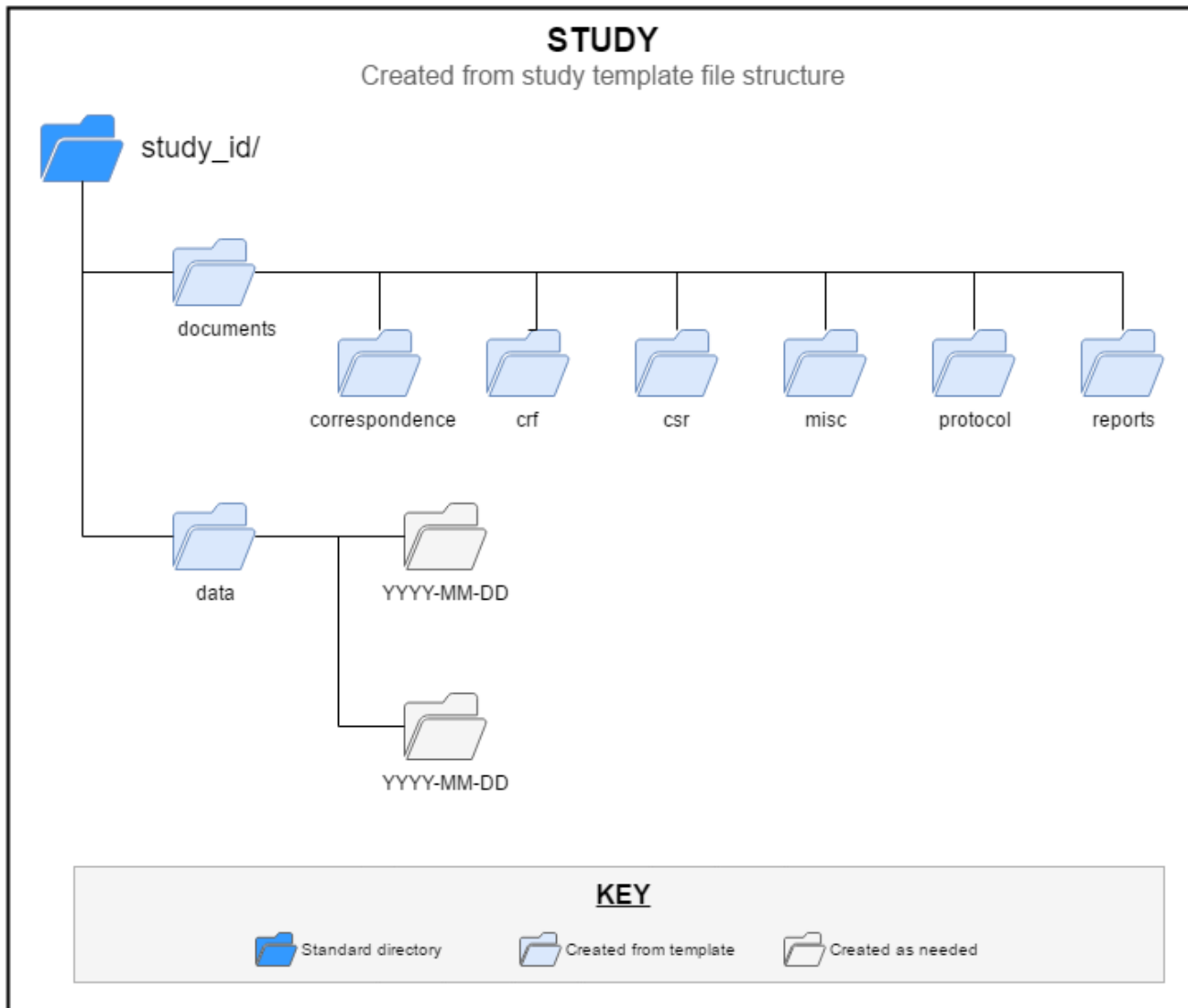The **Drug** component houses documents relative to the Drug itself.

DRUG
Created from drug template file structure

drug_X/
- documents
  - correspondence
  - misc
  - presentations
- literature
  - manuscripts
  - publications
- regulatory
  - ema
  - fda
  - ...
  - draft
    - correspondence
    - docs
  - submitted
    - correspondence
    - docs

KEY
Standard directory   Created from template   Created as needed

Drugs can have multiple Study components associated with them.

They can also have multiple Project components associated with them as well.

Study

The **Study** component contains data and documents that relate to individual Studies. Each Study should have its own protocol.

STUDY
Created from study template file structure

study_id/
- documents
  - correspondence
  - crf
  - csr
  - misc
  - protocol
  - reports
- data
  - YYYY-MM-DD
  - YYYY-MM-DD

KEY
Standard directory | Created from template | Created as needed

Data are further sub-divided into date-stamped sub-folders that correlate with the transfer date of the data. These data are used by Data Readiness team members to produce analysis-ready datasets for use in programs such as NONMEM.

Multiple Study components can be associated with a Drug component.

Project

The **Project** component is at the heart of all file sharing within the Data Repository.

PROJECT
Created from project template file structure

project_abc123/
- documents
  - analysis_plans
  - minutes
  - misc
  - proj_mgmt
  - proposals
  - reports
- stages
  - stage_001
    - tasks
      - task_001
      - task_002
      - task_003
        - assembly (R, sas, splus) — Data Readiness Related
        - datasets (modified, simulated)
        - programs (R, sas, splus)
        - analysis (nonmem, R) — Analysis Related
        - tables
        - graphs
  - stage_002
  - stage_003

KEY

Standard directory   Created from template   Created as needed   Program types, as needed

A Project can be associated with one or more Drug components. A Project can also be associated with multiple Study components.

Paths and Directories

Within the Data Repository, files are stored with a **template location path**. This path corresponds to a location in a storage hierarchy, or 'tree.'

There are three storage components, each having its own directory template structure: **Drug**, **Project**, and **Study**. In order to organize files to best correspond with these different components, each has a different structure. The diagram to the right demonstrates the path to a given location under Drug within the file tree.

In some cases, directories are added to the pre-defined structures on an as-needed basis.

For example: **Drug X** has documentation that needs to be submitted to the **FDA**, but **Drug Y** is being studied in Europe, and, therefore, may need to be submitted to EMA. In this case, a different regulatory folder may be added.

In a similar fashion, one Project may have analytic source code written in **R**, while a different Project uses only **SAS**. Team Leads and administrators may add certain types of directories, as needed, depending on their specific requirements.

Another such example would be uploading Study dataset files, which are associated with a transfer date. Team Leads are able to add the appropriate dated directory in a pre-defined location, allowing for an organized structure with flexibility where needed.
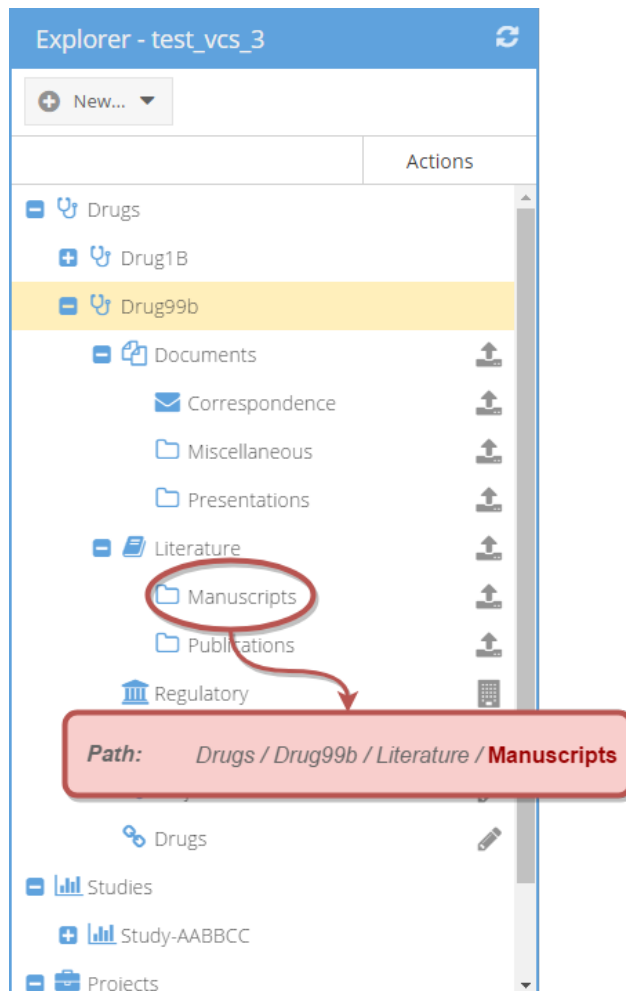
Relationships & Linking

In general, Drugs, Projects, and Studies are all treated as objects in the Data Repository. **Relationship Links** can be set up between these entities in any manner that makes sense to your organization.

RELATIONSHIPS BETWEEN STUDIES AND PROJECTS
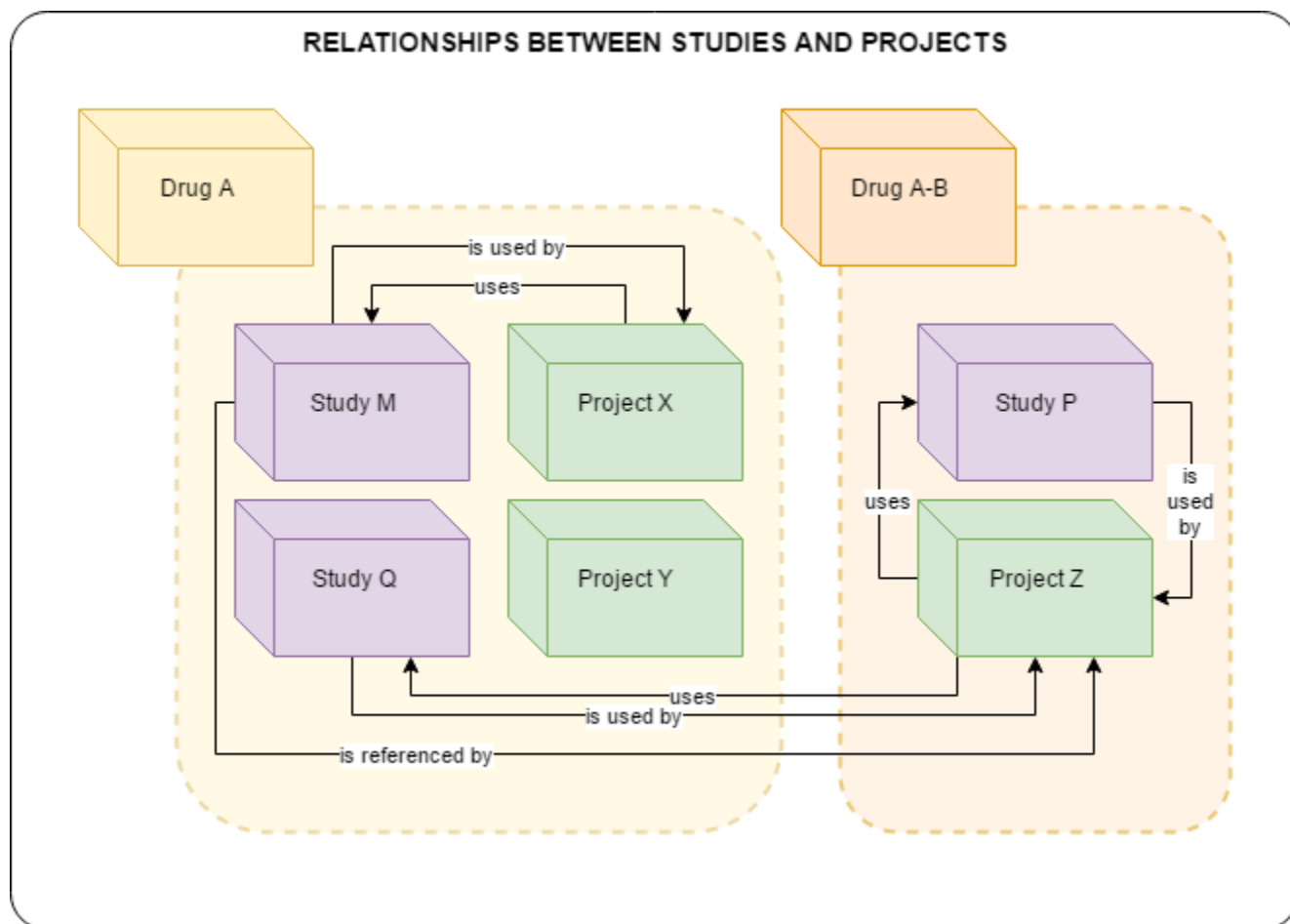
As a best practice, **Drugs** will be treated as the parent item in the hierarchy, since, typically, Studies and Projects each have a primary Drug association.

Within the Data Repository, **Relationship Links** can be set up between various Drugs, Projects, and Studies to help users identify relationships to guide navigation and access requests.

For example, if a user is on a team that has access to Drug A and Study M, but would like to learn what other Studies fall within Drug A's domain, (s)he would be able to see a list of Studies in Drug A's relationship link list. While this user would not be able to immediately gain access to Study Q, (s)he would see that it exists, and could request access or have further discussions with their Team Lead or Project Manager.

In another case, if a user is working on an analysis Project, Project Z, and (s)he wants to gather more information about the Studies used by Project Z, (s)he could examine the Project's relationship link list. If the relationship links had been configured as in the 'Relationships Between Studies and Projects' diagram, the user would see that Study P and Study Q are both used by Project Z, and could request additional access for exploratory analysis.

Types of Relationships

Any relationship can be assigned between any two data storage components that reside in the same Data Repository. Relationship links must be manually assigned by an authorized user.

The types of relationships are as follows, with **A** being the "source" component and **B** being the "destination":

- A **owns** B
- A **is owned by** B
- A **is related to** B
- A **is similar to** B
- A **uses** B
- A **is used by** B
- A **references** B

Relationships for a given component will be displayed under link icons within the component in the Explore Panel and are for informational purposes only.
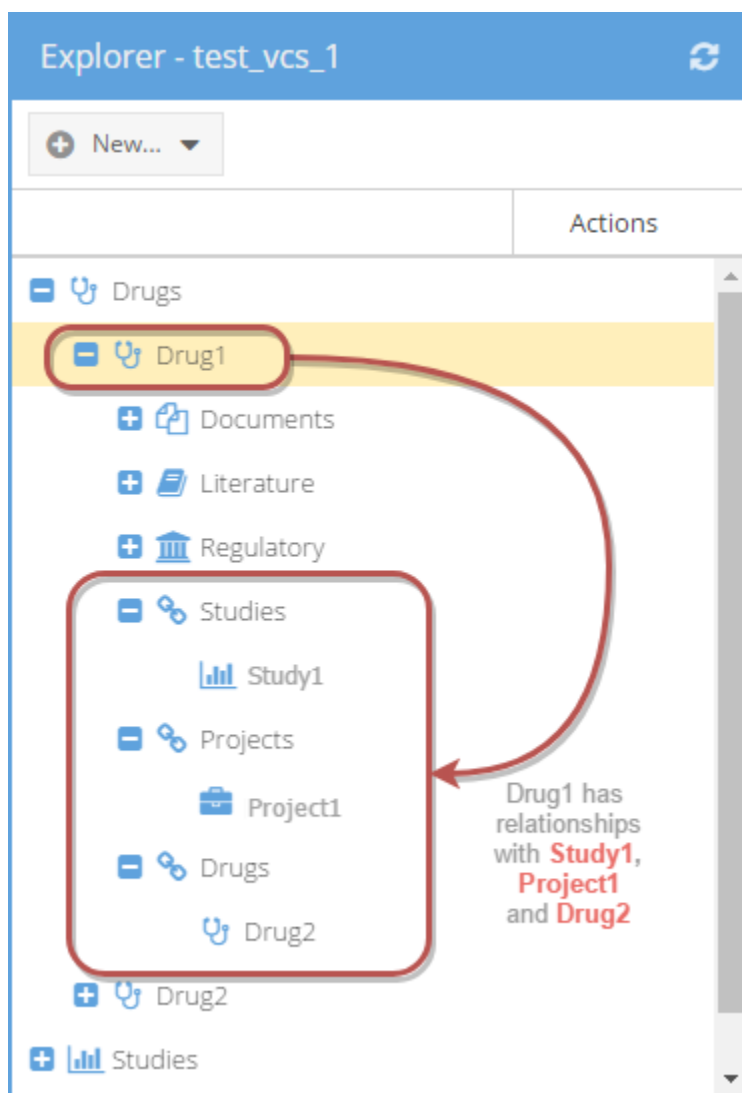
Actions

Actions can be described as functions that can be performed within the various Data Storage Components, as delineated in the table below. Each user role has a pre-defined set of these actions that can be used.

Action Name	Action Code	Icon	Applies to	Description
View	V	🛈	File	View file properties and metadata
Read	R	⬇	File	Read, download, and view file content
Comment	C	💬 comment 🚫 hide comment	File	Add comments, hide own comments
Write	W		File	Write, modify file properties and metadata (change file name, extension, description, etc.)
Upload File	U	⬆ upload	File	Upload file
Move File	O		File	Move files within a Drug/Project/Study
Import File	I	➦ import 🗑 delete unimported	File	Approve import of files to version control Delete files from staging area (unimported)
Make Subfolder	M	Varies based on type: 📗 reg agency 🗄 dataset ▤ stage ☑ task 📄 program	Drug, Project, Study	Make sub-folders (program folders, tasks, stages, etc.)
Create Drug, Project, Study	D	⊕	Drug, Project, Study	Create this type of object (Drug, Project, Study)
Link Drug, Project, Study	L	✏	Drug, Project, Study	Add/Modify links (applies only to Drug/Study/Project link directory nodes)
Delete Drug, Project, Study	X		Drug, Project, Study	Delete a Drug, Study, Project **Superusers only** - **API only**
Delete Repository System	B		Repository System	Delete Repository/VCS **Superusers only** - **API only**
Create Repository System	A		Repository System	Create Repository/VCS - **API only** DRAs and Superusers only
Manage Teams	T		Organization	Create/Delete/Modify teams - **API only**
Change Team Members	Z		Organization	Modify team membership - **API only**

Actions Not Yet Available

The following actions will be available in future releases.

Action Name	Action Code	Icon	Applies to	Description
Hide File	**H**	hide	File	Mark individual file items as hidden - **not yet available**
View All Comments	**Q**		File	View hidden comments from any user - **not yet available**
View All Files	**N**		File	View hidden files - **not yet available**
Hide Others Comments	**J**		File	Hide other users' comments - **not yet available**
Hide Drug, Project, Study	**S**	hide	Drug, Project, Study	Hide object - **not yet available**

Teams & Roles

Roles

System (Administrative) Roles

System Roles apply to the Data Repositories for an entire Organization. These roles allow administrators to manage the entire system and oversee teams, Data Storage Components, users, and assignments.

Role Name	Description
Data Repository Administrator	Responsible for the operational functionality of an entire Data Repository instance.
Data Archivist	Responsible for organizing files within a Data Repository. May move files that others have uploaded.
Project Manager	Responsible for creating Projects, managing teams, and administering permissions for each team/role.

Team Roles

Team Roles are assigned to users on a specific team. Team Roles allow users to perform specific actions within Drugs, Projects, and Studies that have been assigned to their teams.

Role Name	Description
Team Lead	Acts as the technical subject matter expert and central point of contact for a Project, Drug, or Study.
Data Manager	Creates/Manages the overall structure of a **Study or Project**. Responsible only for the Projects the user is assigned to, not for the entire Data Repository.
Data Readiness Team Member	Responsible for converting raw data collected from clinical trials into datasets of a uniform format with consistent data types based on requirements provided by the analyst.
Analysis Team Member	Responsible for analyzing and modeling data and providing dataset requirements.
Reviewer	Responsible for reviewing the content and quality of work products by other team members. Has minimal ability to change items within the system.
Stakeholder	Responsible for reviewing the high-level status of Projects, identifying risks, and providing direction for Team Leads. The user can not directly make changes within the system.

Role Interactions

Administrative roles are not assigned to teams. These users have the power to assign users and Data Storage Components to teams.

Typically, users with Team Lead roles should communicate with a Project Manager regarding the status and needs of their work. The Team Lead serves as the main point of contact for a team.

If a Data Archivist is assigned to a Repository, this user may need to communicate directly with Team Leads, Data Managers, and the Project Manager to ensure the correct data and files are organized properly.

A Team Lead would communicate with the Project Manager to request role and user additions/changes for their teams. Users may have multiple roles.
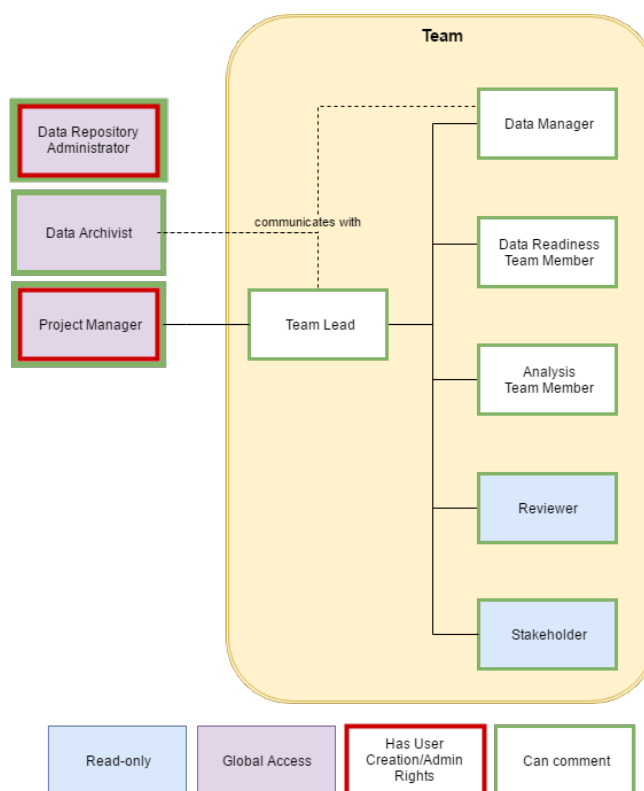
Key Item	Description
Read-only	Users with these roles are expected to view and give input as needed.
Global Access	These roles are not team-based, but apply to the entire Data Repository. These roles are administrative and users with these roles can view all Drugs, Projects, and Studies.
Has User Creation/Admin Rights	Roles with user creation and team administration rights can request new users or new teams to be added to the Data Repository. These users can also request changes in team assignments and user deactivation.
Can Comment	Users have the ability to add comments to the metadata of files (which they have access to), in order to communicate with other users.

Teams

Membership

Teams can include users from the same organization or disparate organizations (if access has been shared with another organization).
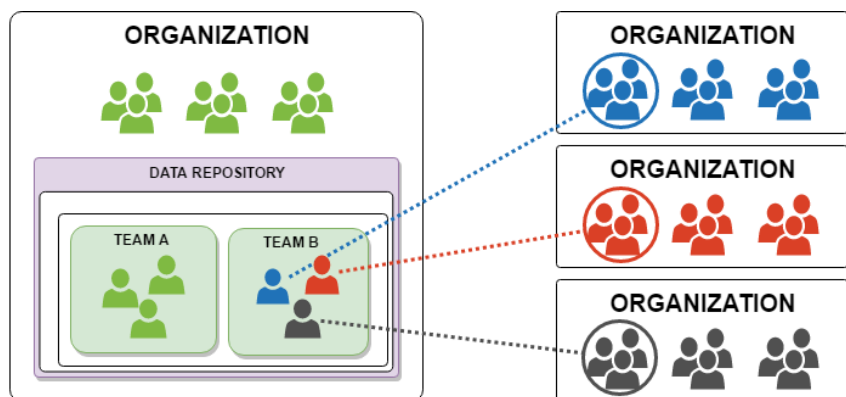
Assignments

Teams can be assigned to different Data Storage Components (Drugs, Projects, Studies). More than one team can be assigned to the same Data Storage Component. This allows different groups to collaborate on documents and data.
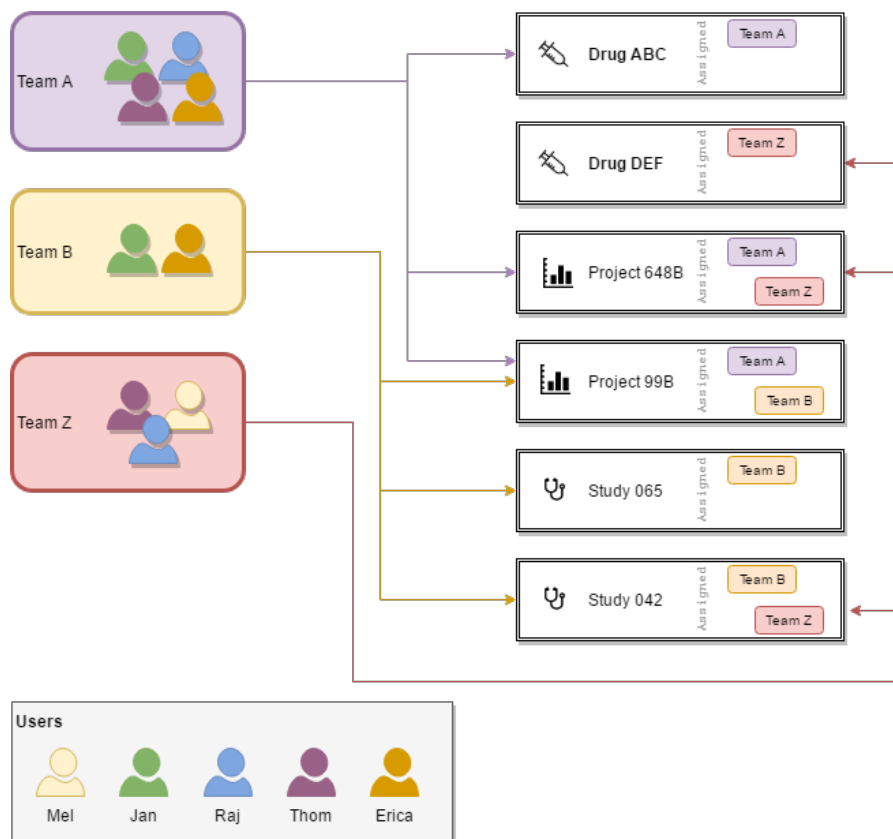
Workflow

Users upload and perform tasks on appropriate files on their assigned Drugs, Projects, and Studies. User actions are specific to their role and permissions.
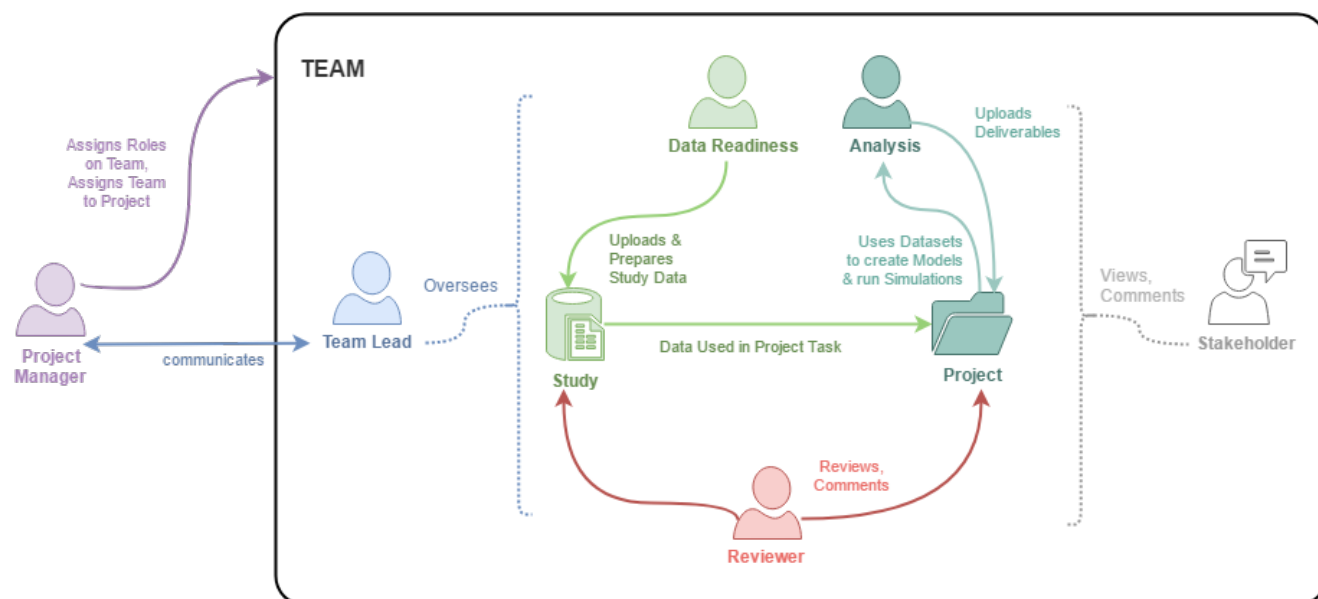
Data Repository Administrator Role

Type

Administrative Role

Role Description

The Data Repository Administrator (DRA) is responsible for the operational functionality of an entire Data Repository instance. This user is responsible for the technical aspects and infrastructure of the Data Repository.

The DRA does not have the ability to approve the import of files from the staging area to the Data Repository or move files because this user does not require that granular level of knowledge of the contents of the Data Repository.

A DRA must be assigned when the Data Repository System is initialized for an organization.

Abilities & Responsibilities

The Data Repository Administrator can create Drugs, Projects, and Studies. A DRA is not necessarily a Project Manager, however, the DRA has the ability to request new user creation and team creation/assignment, as needed.

The DRA can not approve files for import, as the DRA is not expected to have knowledge of the status of various workflows.

The DRA will be able to hide Drugs, Projects, and Studies, as well as view all comments (even hidden comments), and access action logs for the system.

Recommendations

> ⊘ **At least one user must be assigned to the Data Repository Administrator role.**
>
> *It is recommended that there are at least two DRAs responsible for each Repository System to ensure that the role will be covered if an absence occurs.*

Repository Actions

Action	Data Repository Administrator Can Perform
View	✔
Read, Download	✔
Comment	✔
Write, Edit Metadata	✔
Upload Files	✔
Move File	✘
Import	✘
Delete Unimported	✘
View All Files	✔
Make Sub-folders	✔
Create Storage Item	✔
Link Storage Items	✔

Administrative Actions	DRA Can Perform
Permanently Delete Storage Item	✘
Create Data Repository	✔
Manage Teams	✔
Modify Team Membership	✔

> ⓘ *Detailed permissions on an item-by-item basis are available in the DRA Role Permission Appendix.*

Project Manager Role

Type

Administrative Role

Role Description

The Project Manager (PM) oversees and assigns all Projects and Team Leads within the Data Repository. The PM keeps track of a portfolio of Projects at a high level and the Team Leads report to the PM.

Abilities & Responsibilities

The PM can request user and storage item team assignments. The PM is expected to manage user roles for team members for all Drugs, Projects and Studies.

The PM is not expected to be involved in managing file locations, but does have the ability to approve the import of files as a backup function in case Team Leads or a Data Archivist is not available.

> ✅ It is expected that the PM will send requests for user additions and team changes via the Admin Tools Panel (found in the Appendix: Data Repository Administration). In the future, the PM role will be able to manage users, teams, and role assignments directly.

Recommendations

> ⊘ **At least one user must be assigned to the Project Manager role.**
>
> It is recommended that there are at least two PMs responsible for each Repository System to ensure that the role will be covered if an absence occurs.

Repository Actions

Action	Project Manager Can Perform
View	✅
Read, Download	✅
Comment	✅
Write, Edit Metadata	✅
Upload Files	✅
Move File	✅
Import	✅
Delete Unimported	✅
View All Files	✅
Make Sub-folders	✅
Create Storage Item	✅
Link Storage Items	✅

Administrative Actions	PM Can Perform
Permanently Delete Storage Item	❌
Create Repository	❌
Manage Teams	✅
Modify Team Membership	✅

> ⓘ Detailed permissions on an item-by-item basis are available in the Project Manager Role Permission Appendix.

Data Archivist Role

Type

Administrative Role

Role Description

The Data Archivist (DA) role focuses on the organization of the contents of the Data Repository. The DA has the ability to approve the import of files from the staging area to the Data Repository and to move files. The DA is the librarian of the Data Repository. The DA is required to interact with users of teams for all Projects, Drugs, and Studies to ensure the data are uploaded at the right time to the right location.

Abilities and Responsibilities

Users assigned to a DA role may create Drugs, Projects, and Studies, as well as sub-directories that are relevant to each storage component. The DA can also move files within a storage item and approve importation of a file to version control. The DA may also add link relationships between storage items.

A DA cannot request team changes and is not expected to know the status of each storage item. A DA is expected to have a deep knowledge of where each type of file belongs within the file structure.

A DA is not expected to manage user addition requests nor manage team assignments.

Recommendations

It is **not required** that a Data Archivist be assigned for an organization. However, having a DA to examine, approve, and move files to their appropriate location is especially useful when many different users may not have knowledge of where information should be stored.

Repository-wide Actions

Action	Data Archivist Can Perform
View	✅
Read, Download	✅
Comment	✅
Write, Edit Metadata	✅
Upload Files	✅
Move File	✅
Import	✅
Delete Unimported	✅
View All Files	✅
Make Subfolders	✅
Create Storage Item	✅
Link Storage Items	❌

Administrative Actions	Archivist Can Perform
Permanently Delete Storage Item	❌
Create Repository	❌
Manage Teams	❌
Modify Team Membership	❌

ⓘ *Detailed permissions on an item-by-item basis are available in the Data Archivist Role Permission Appendix.*

Team Role - Lead

Type

Team Role

Role Description

The Team Lead role is expected to be the central point of contact regarding the Drugs, Projects, and Studies assigned to a given team. The Team Lead may have additional roles on the team, but should be able to communicate with all team members and monitor the upload and import of various files. The Team Lead normally belongs to the organization that owns the Data Repository System.

Abilities & Responsibilities

- Communicates with all team members to ascertain status of work products and file uploads.
- Approves import of files after reviewing the upload location and appropriateness of the uploaded documents.
- Communicates with Project Manager regarding the need to change team member assignments or the need to get access to other Drugs, Projects, and Studies.
- Communicates with the Project Manager to convey resource changes (addition or removal of users from the system or from a team).
- Communicates with Project Manager regarding status of work.
- Communicates with Data Archivist (if available) regarding file placement/location.
- Adds and manages associations (links) between the current Drug, Project, or Study and other related items.
- Corrects metadata and moves files, as appropriate.
- Creates sub-directories for data, program source files, and regulatory agency documents, as needed.

Recommendations

⚠ **Important: Each team should be assigned at least one Team Lead.**

General Actions

Action	Team Lead Can Perform
View	✅
Read, Download	✅
Comment	✅
Write, Edit Metadata	✅
Upload Files	✅
Move File	✅
Import	✅
Delete Unimported	✅
View All Files	✅
Make Sub-folders	✅
Link Storage Items	✅

Administrative Actions	PM Role Can Perform
Hide Storage Item	❌
Permanently Delete Storage Item	❌
Create Repository	❌
Manage Teams	❌
Modify Team Membership	❌

ⓘ *Detailed permissions on an item-by-item basis are available in the Team Lead Role Permission Appendix.*

Team Role - Data Manager

Type

Team Role

Role Description

The Data Manager is the knowledgeable expert regarding incoming data formats and accuracy, and acts as the primary point of contact regarding data readiness and assembly.

Abilities & Responsibilities

- Creates data directories within Studies for the upload of datasets.
- Communicates with other team Data Readiness users regarding data that must be uploaded.
- Corrects metadata for uploaded data file objects, as needed.
- Moves files within a given Study, as needed.

Recommendations

It is recommended that each Study have at least one Data Manager assigned, however, this is not required.

General Actions

Action	Data Manager Can Perform
View	✅
Read, Download	✅
Comment	✅
Write, Edit Metadata	✅
Upload Files	✅
Move File	Study only *
Import	❌
Delete Unimported	❌
View All Files	❌
Make Sub-folders	Some *
Link Storage Items	❌

Administrative Actions	Data Manager Can Perform
Permanently Delete Storage Item	❌
Create Repository	❌
Manage Teams	❌
Modify Team Membership	❌

ⓘ *Detailed permissions on an item-by-item basis are available in the Data Manager Role Permission Appendix.*
*A * symbol identifies actions with varying permissions depending on the directory path. The Appendix contains specific information regarding what can be performed in each directory.*

Team Role - Data Readiness

Type

Team Role

Role Description

The Data Readiness team member uploads datasets and related documents and files to Studies and Projects.

Abilities & Responsibilities

- Can create dated dataset folders, as well as upload to Study directories.
- Uploads items to certain sub-directories of Projects.
- Communicates with the team's Data Manager (if available) and/or the Data Archivist (if available) regarding data and file availability.
- Communicates with the Team Lead about work product status.

Recommendations

It is recommended, but not required, that Studies have a team with at least one assigned Data Readiness role or one Data Manager role.

General Actions

Action	Data Readiness Can Perform
View	✓
Read, Download	✓
Comment	✓
Write, Edit Metadata	Some *
Upload Files	✓
Move File	✕
Import	✕
Delete Unimported	✕
View All Files	✕
Make Sub-folders	Some *
Link Storage Items	✕

Administrative Actions	Data Readiness Team Member Can Perform
Permanently Delete Storage Item	✕
Create Repository	✕
Manage Teams	✕
Modify Team Membership	✕

ⓘ *Detailed permissions on an item-by-item basis are available in the Data Readiness Role Permission Appendix.*
*A * symbol identifies actions with varying permissions depending on the directory path. The Appendix contains specific information regarding what can be performed in each directory.*

Team Role - Analysis

Type

Team Role

Role Description

Analysis team members perform pharmacometric and/or statistical modeling and simulation work. Analysis team members have access to datasets and can produce documents, files, and additional datasets as a result of their workflows.

Abilities & Responsibilities

- Downloads datasets from Studies.
- Uploads modified and simulated datasets to assigned Projects.
- Uploads tables, reports, graphs, and other deliverable files to assigned Projects.
- Communicates with Team Lead regarding status and coordination of data.
- Communicates with Data Manager (if available) and/or Data Readiness team members regarding data issues.
- Can upload documents and other files to assigned Drugs, as appropriate.

Recommendations

While not required, it is recommended that each Project have at least one Analysis team member.

General Actions

Action	Analyst Can Perform
View	✓
Read, Download	✓
Comment	✓
Write, Edit Metadata	Some *
Upload Files	✓
Move File	✗
Import	✗
Delete Unimported	✗
View All Files	✗
Make Sub-folders	Some *
Link Storage Items	✗

Administrative Actions	Analysis Team Member Can Perform
Permanently Delete Storage Item	✗
Create Repository	✗
Manage Teams	✗
Modify Team Membership	✗

ⓘ *Detailed permissions on an item-by-item basis are available in the Analysis Role Permission Appendix.*

*A * symbol identifies actions with varying permissions depending on the directory path. The Appendix contains specific information regarding what can be performed in each directory.*

Team Role - Reviewer

Type

Team Role

Role Description

The Reviewer role applies to all Data Storage Component types (Drugs, Projects, and Studies). The Reviewer downloads, reads, examines, and, in some cases, uploads corrected versions of files and documents. The Reviewer is expected to communicate feedback on work products in the data repository. Currently, Reviewers can comment on files which they have permission to download.

The Reviewer has limited ability to upload some files, which is outlined in the Appendix.

Abilities & Responsibilities

- Communicates with the Team Lead and possibly the Project Manager regarding the need to review documents, data, and files.
- Downloads and reviews items, as needed.
- Comments on files to convey any issues to other team members.
- Uploads corrections to certain files in certain directories.

Recommendations

This role is not required. Each team or organization should determine when and whom to include as a Reviewer, based on their specific needs.

General Actions

Action	Reviewer Can Perform
View	✓
Read, Download	✓
Comment	✓
Write, Edit Metadata	✗
Upload Files	Some *
Move File	✗
Import	✗
Delete Unimported	✗
View All Files	✗
Make Sub-folders	✗
Link Storage Items	✗

Administrative Actions	Reviewer Can Perform
Permanently Delete Storage Item	✗
Create Repository	✗
Manage Teams	✗
Modify Team Membership	✗

ⓘ *Detailed permissions on an item-by-item basis are available in the Reviewer Role Permission Appendix.*
*A * symbol identifies actions with varying permissions depending on the directory path. The Appendix contains specific information regarding what can be performed in each directory.*

Team Role - Stakeholder

Type

Team Role

Role Description

Stakeholders are team members who are given access to a given Drug, Project, or Study, as needed. Stakeholders may be executives or financial parties that have an interest in or oversight role for a set of items. Stakeholders may not always be involved in the day-to-day work for a given item and may need to communicate with the Team Lead or Project Manager to obtain information on the status of the given work.

Abilities & Responsibilities

- Has limited ability to read and download files and data within assigned items.
- Has limited ability to upload documents to certain locations.
- Can comment on documents and files in certain locations.
- Can view the names of files that exist within items assigned to their teams.

Recommendations

This role is not required and should be used as needed. Each team or organization should determine when and whom to include as a Stakeholder based on their specific needs.

General Actions

Action	Stakeholder Can Perform
View	✅
Read, Download	Some *
Comment	Some *
Write, Edit Metadata	❌
Upload Files	Some *
Move File	❌
Import	❌
Delete Unimported	❌
View All Files	❌
Make Sub-folders	❌
Link Storage Items	❌

Administrative Actions	Stakeholder Can Perform
Permanently Delete Storage Item	❌
Create Repository	❌
Manage Teams	❌
Modify Team Membership	❌

ⓘ *Detailed permissions on an item-by-item basis are available in the Stakeholder Role Permission Appendix.*
*A * symbol identifies actions with varying permissions depending on the directory path. The Appendix contains specific information regarding what can be performed in each directory.*
If a Stakeholder requires different permissions, (s)he may request additional team roles from the Project Manager.

Project Structure & Workflow

Stages & Tasks

Due to the inherent complexity of pharmacometric analyses, the maintenance and utilization of a useful and universal Project directory structure is paramount.

Projects can be broken down into Stages, which can further be divided into Tasks, providing the ability to design, maintain, and communicate an accurate, comprehensive workflow. The decision on how and when to create new Stages and Tasks is the Data Repository Owner's preference. The examples below are provided to assist in data and file organization.

Example 1: PK and PD Analyses in Stages

Organization A receives a proposal for a population PK/PD analysis. The Project is named **Proj_A1B2**. The initial directory structure is set up to be Stage **d1** and the Task is named **pk_moddev**. The sponsor finds an assay calculation error which affects the reported plasma concentration values. The discovery of the assay error occurred after the pharmacometrician began model development. All of the work completed thus far needs to be retained and can not be overwritten.
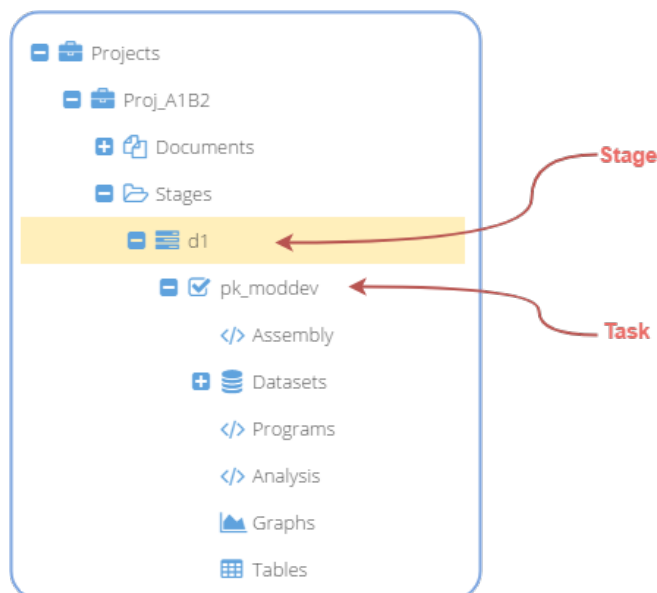
Therefore, a new Stage is created: **d2,** and a new Task: **pk_moddev**. The new Stage signifies a new Stage in the Project due to the receipt of the new plasma concentrations, which were corrected after the initial assay calculation error was discovered.

A new dataset is made and stored in this new Stage under Modified Datasets.
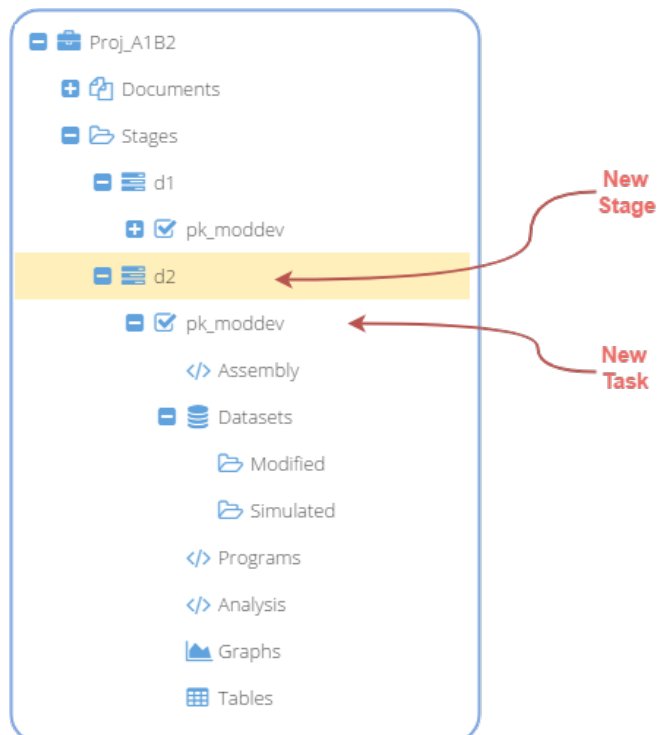
The pharmacometrician completes the PK analysis and the PK/PD model development begins. Two new Tasks are created, one for modeling the efficacy endpoint: **pd_eff** and one for modeling the safety endpoint: **pd_saf**.

- Projects
  - Proj_A1B2
    - Documents
    - Stages
      - d1
        - pk_moddev
      - d2
        - pk_moddev
        - pd_eff
        - pd_saf

New Tasks
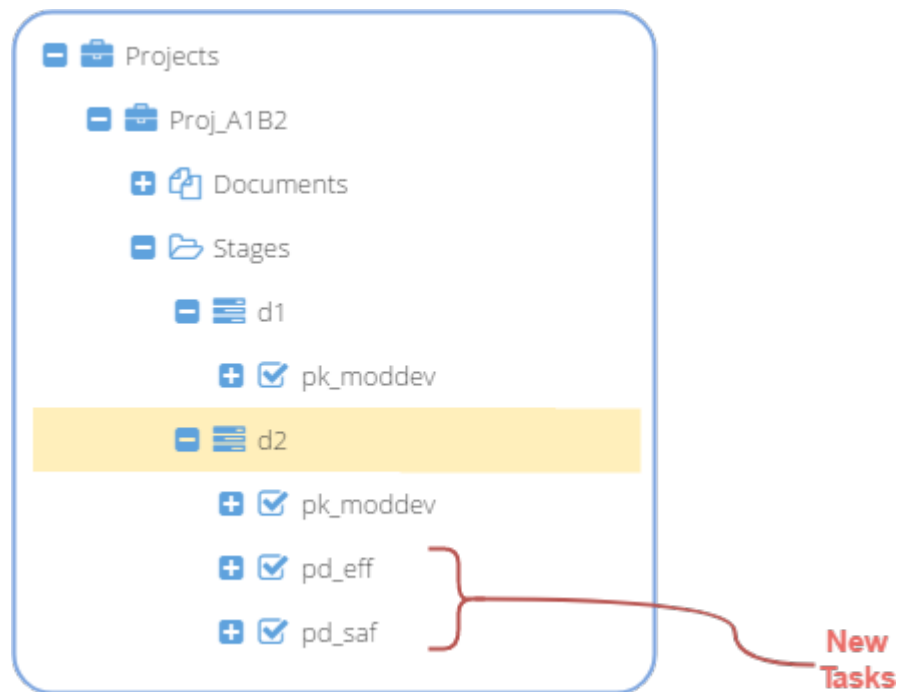
Example 2: Multiple modeling strategies

Organization 2 begins a population PK analysis for a Phase 2 clinical trial. The Sponsor encourages the use of a two-compartment model with linear absorption and linear elimination to start, as this model accurately characterized the first-in-human data. However, shortly into model development, secondary peaks are found in the dataset about eight hours postdose. The Team Lead determines subsequent model development must test the addition of including processes which describe enterohepatic recirculation.
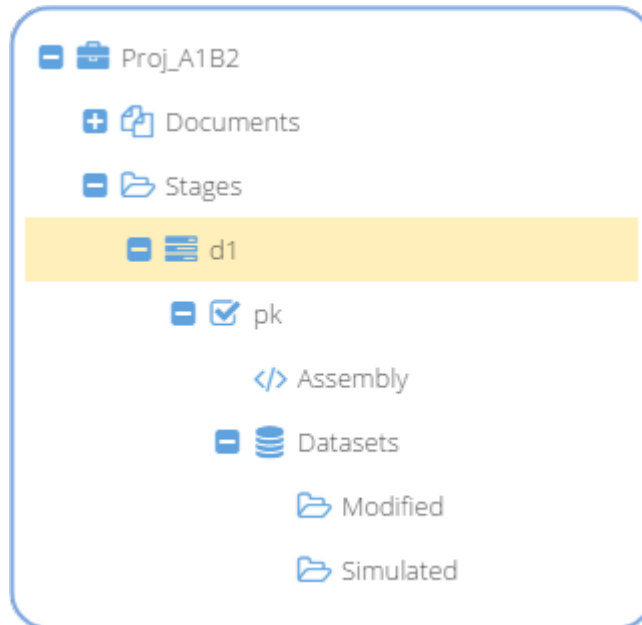
At this time, if a substantial amount of analyses (as determined by the Team Lead) has been conducted under the current Stage: **d1** in the Task: **pk,** a new Task could be created within Stage **d1** called **pk_peakEHC**.
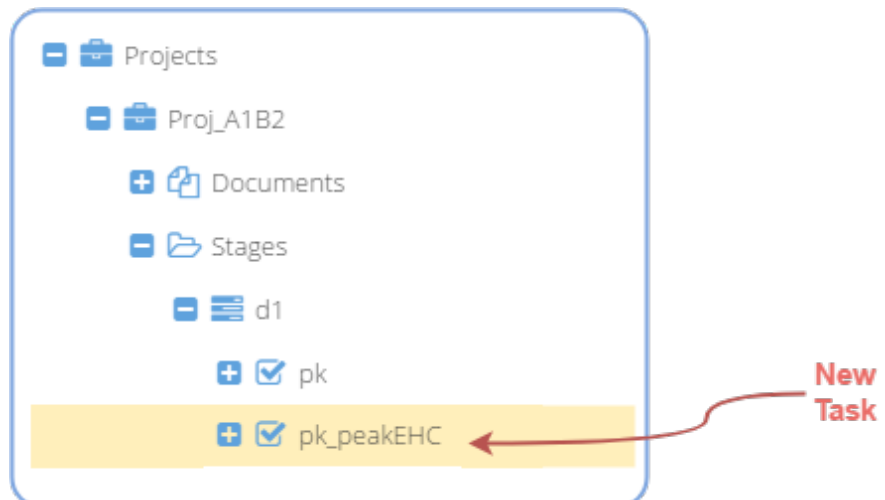
Using the Data Repository

The Dashboard

Browsing the Repository

Uploading Files

File Information

Approving File Import

Downloading Files

Creating Directories

Storage Component Links

Page intentionally blank

Using the Data Repository

Application Layout

The Data Repository window contains three panels:

- The **Top Menu Bar**, which has controls for Repository selection, User Role selection, Search, as well as Help.
- The **Side Menu**, which contains a menu that navigates between views in the Main Panel, and a Logout button.
- The **Main Panel**, which displays information relevant to the view that is selected in the Side Menu.

The Top Menu Bar

Selecting a Data Repository

| MMV: test_vcs_1 ▾ | Team Role ▾ | Search: Filename 🔍 | ❓ Help ▾ |

If the user has permissions to access multiple Data Repositories, the user can choose which system to use by selecting the appropriate name in the Repository drop-down menu. If the user only has access to a single Data Repository, this field will be automatically selected and the drop-down menu will be disabled.

Selecting a User Role

| MMV: test_vcs_1 ▾ | Team Role ▾ | Search: Filename 🔍 | ❓ Help ▾ |

This allows the user to select the role that (s)he will be assuming. When a user assumes an Administrator role, the top menu will change to the color orange. The color change is intended to help the user track the role they are currently assuming. When assuming an Administrator role, users will see additional controls and data items.

> ✅ *It is good practice to only use an elevated role when needed, and to use a team role for all other actions.*

Getting Help

| MMV: test_vcs_1 ▾ | Team Role ▾ | Search: Filename 🔍 | ❓ Help ▾ |

In the Help menu, users can find application information, as well as access a copy of the User Manual. Information includes copyright, citation, and contact details.

> ℹ️ *For requests and questions, users may also send an email to kiwisupport@cognigencorp.com. As much information as possible should be included.*

Searching

Searching for Filenames

| MMV: test_vcs_1 ▼ | Team Role ▼ | **Search:** | Filename 🔍 | ❓ Help ▼ |

The Search function allows a user to search the Data Repository for filenames containing a specific string of characters. The results of the Search are filtered according to the permission granted for the user performing the Search.

To use the Search function, enter a partial filename or file extension into the Search field and click the magnifying glass button (or hit the Enter key). A list of matching filenames will appear on a floating window.

ⓘ *The Search term can also be cleared by clicking the 'x' within the Search field.*

Search Results

Files with names containing the searched characters will appear in a list. A folder icon will appear in the Actions column. By clicking on this folder icon, the Browse panel will be activated and the Explorer panel will show the location of the file.

Search Results   ✖

Filename	Found In	Parent Type	Path	Actions
loremIpsum.txt	Drug1	drug	/test_vcs_1/Drugs/Drug1/Documents	📂
sampleGZIP.txt	project1	project	/test_vcs_1/Projects/project1/Documents/Ana...	📂
sampletar.txt	study1	study	/test_vcs_1/Studies/study1/Documents/Proto...	📂
loremIpsum.txt	Drug1	drug	/test_vcs_1/Drugs/Drug1/Documents/Miscella...	📂

Close

⚠ *Only files that a user's current role has permissions to view will be shown in the Search Results. A file that matches the Search term may exist in a Storage Item that the current user does not have permissions to view. When a user with an Administrative Role performs a search, all files containing the search term will appear.*

The Side Menu

Data Repository

- Dashboard
- Browse
- Admin Tools

User:
a1-dra@cognigencorp.com
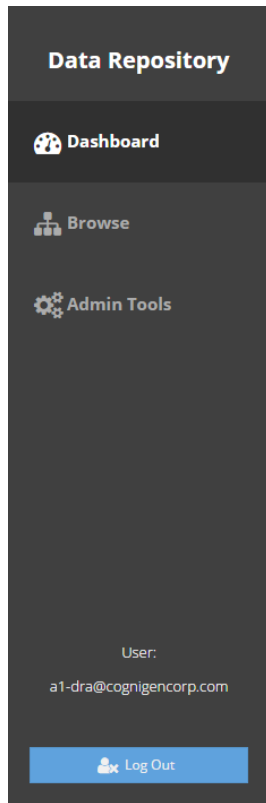
Log Out

Selecting a View

Select between the "Dashboard," "Browse," and "Admin Tools" Views.

> (i) *Users who do not hold an Administrative role will not see the Admin Tools menu item.*

Logging Out

Pressing the Log Out button will log you out, redirect you to the Login page, and clear your session.

> ✓ *It is good practice to Log Out when leaving a workstation unattended.*

The Dashboard

Screen Layout

The Dashboard View consists of the **Your Teams & Roles** component, and the **Drug**, **Study**, and **Project List** components.

ⓘ *Users that have Administrative roles may see additional button options in the Drug, Study, and Project List component headers, including the Add button.*

Your Teams & Roles

This panel displays all assigned teams and roles for the current user. These roles determine what actions a user can perform when operating in a Team Role mode. Team Role permissions are cumulative, meaning that the user has the ability to do any action that any of their assigned roles are permitted to perform.
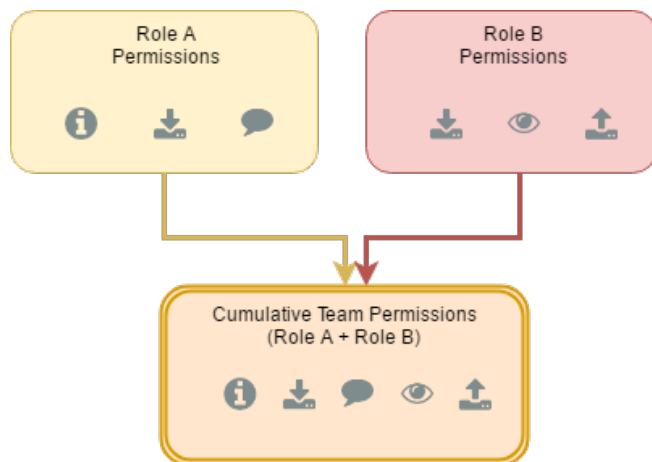
Team ↑	Your Role
Team ABC	Team Member - Lead
Team ABC	Team Member - Data Manager
Team XYZ	Team Member - Data Readiness

Drug List

This panel displays a list of the Drugs the user has access to. If the user has an Administrative Role, Drugs can be added to the list using the Add icon (plus sign). The Refresh icon (circular arrows) allows the user to see an updated list after Drugs are added.

Name ↑		Actions
A1		📂
Drug F		📂
Drug123		📂
RESS_Drug		📂

Study List

This panel displays a list of the Studies the user has access to. If the user has an Administrative Role, Studies can be added to the list using the Add icon. The Refresh icon allows the user to see an updated list after Studies are added.

Name ↑	Actions
Study022	📂

Project List

This panel displays a list of the Projects the user has access to. If the user has an Administrative Role, Projects can be added to the list using the Add icon. The Refresh icon allows the user to see an updated list after Projects are added.

💼 Project List	⊕ ⟳
Name ↑	Actions
ProjA1	📂

✅ 📂 *Use the **Jump to Location** icon to activate the Browse panel with the appropriate item selected/expanded. This icon appears in the Drug, Study, and Project list panels.*

⟳ *The **Refresh** icon can be used to display the latest information which exists in the panel of interest.*

⊕ *The **Add** icon can be used by Administrators to create a new Drug, Project, or Study.*

Browsing the Repository

The Browse Tab

Explorer

This panel provides the ability to navigate the directory trees under the Drugs, Projects, and Studies the user has access to.

Data Repository Administrators have the ability to use a drop-down menu above the tree that allows them to create a new Drug, Project, or Study folder.

Files

The File Panel shows all files associated with the location the user has navigated to which the user has permission to view. The status field will show if a file has been approved for inclusion into the Data Repository.

At the top of the Files Panel, there is a breadcrumb trail that will give the user a menu-based means of navigating the Explorer file tree.

> (i) *Files in the Staging Area, and not yet approved, will have a status of* **'staging - needs approval.'**

Staging Area

The Staging Area provides a list of all files that have been uploaded but have not yet been approved by a user with the authority to do so. Once a file is approved, the file will be removed from this area, and committed to the Data Repository in the designated location.

Uploading Files

Selecting a Location For File Upload
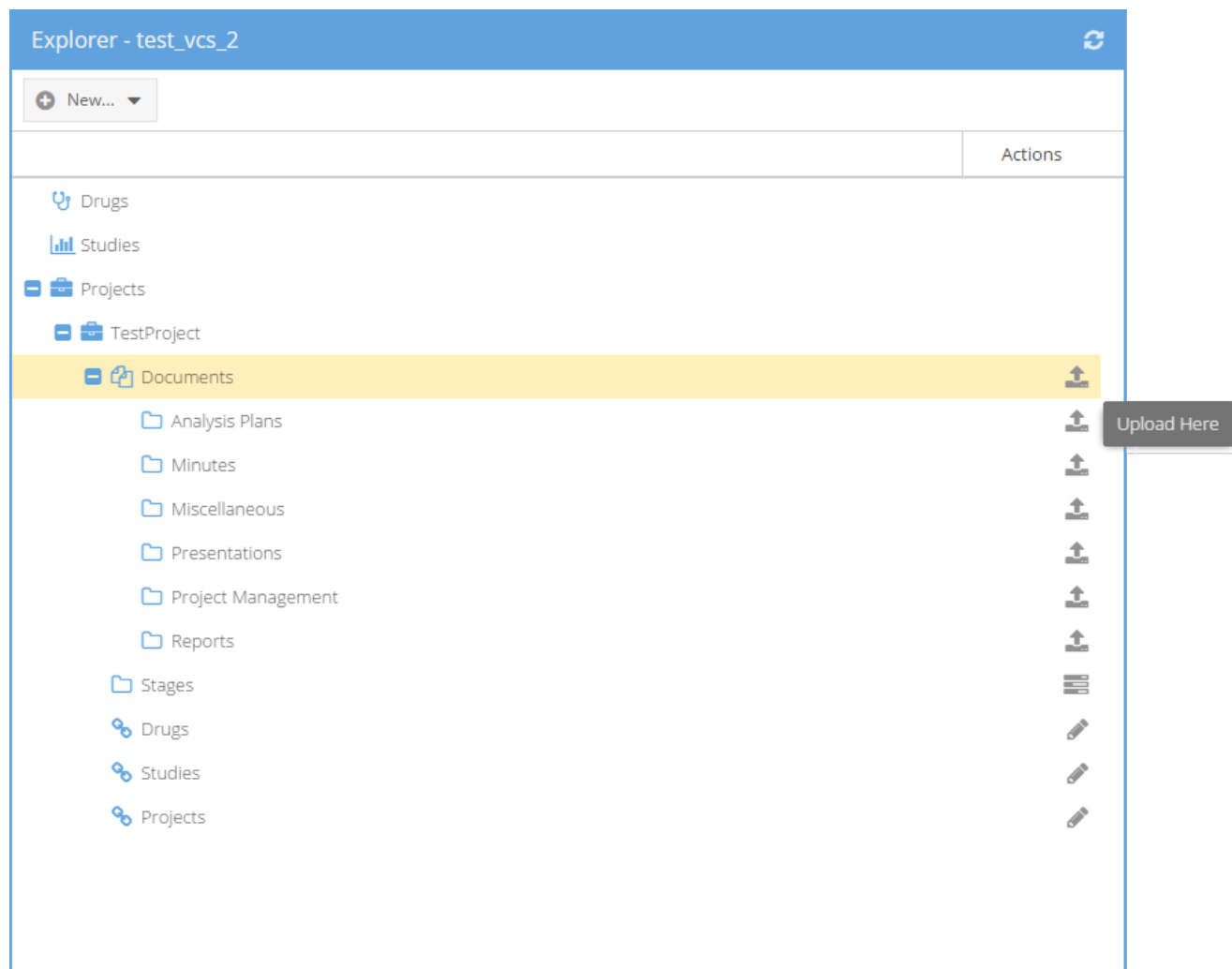
Navigate to the Browse Panel and use the Explorer component to show the location intended for the file upload. If the user has appropriate permission for the action, an Upload icon will appear in the Actions column to the right of the location name. Clicking this icon will display the Upload dialog.

Adding a Description

A file description is required. The description should be short, concise, and convey information regarding the purpose of the file in the Data Repository. The description will be uploaded with the file, and stored in the file's metadata.

> ✓ It is recommended that the description contains relevant keywords for potential future Search functionality.

Destination Path

The Destination Path field serves as a reminder of the intended upload location.

Upload to: ✖

File:

Book1.xlsx   Select File...

Description:

Spreadsheet with test data.

Destination Path:

/test_vcs_2/Projects/TestProject/Documents

Upload   Cancel

Selecting a File

Once the Upload dialog has opened, a file can be selected by clicking the Select File button. An operating system "Open" window will appear, allowing navigation on the local file system. After selecting a file, clicking the "Open" button will cause the file to be selected.

> ℹ️ **File Types**
> *Only approved file types may be selected. If a desired file does not appear in the "Open" window, the file may not be an approved type.*

> ✅ *Future versions of the Data Repository may support drag and drop for file upload. This is not supported in the current release.*
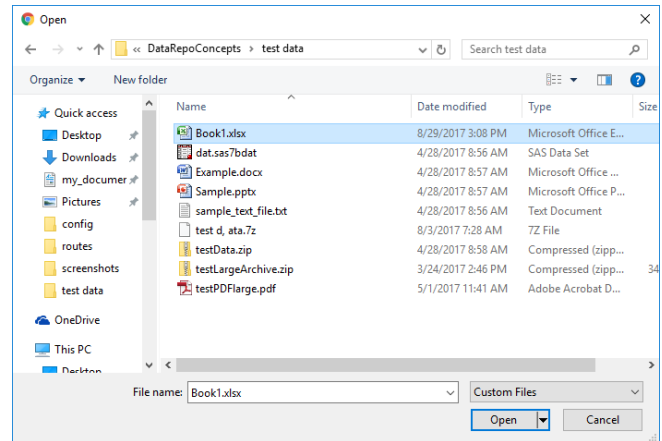
Uploading Process

After choosing a file and adding a description, clicking Upload will start the file transfer process. A notification window, with a progress bar showing upload status, will be displayed.

Upon completion of the upload, a Success message will appear. If an error has occurred during upload, the details of the error encountered will display instead of the Success message. The Success message will disappear after a few moments and the Upload form will close.
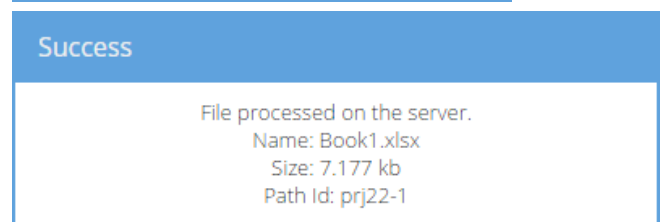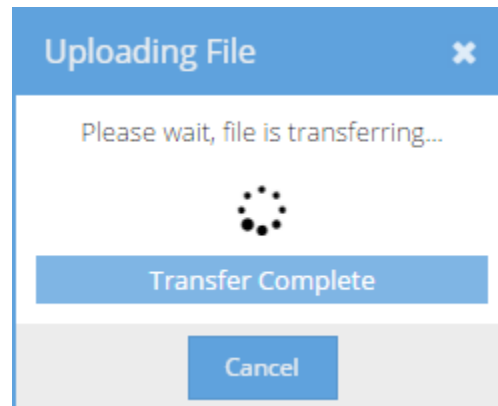
Supported File Types

The system currently supports the files types listed to the right. Files must be named with the appropriate extension. Extensions may be lowercase or uppercase.

File Type	Description	Extensions
7zip	Archive file creating using the 7zip compressor	.7z
Bitmap	Image file	.bmp
CSV	Comma-separated values (spreadsheet)	.csv
CTL	Control file (Kiwi)	.ctl
DOC	Microsoft Word document	.doc .docx
Email	Email export file	.eml
GIF	Image file	.gif
Gzip	Archive file using tar/gzip compression	.gz .gzip
JPG	Image file	.jpg .jpeg
NMDAT	NONMEM data file	.nmdat
PDF	Adobe Acrobat document	.pdf
PowerPoint	Microsoft PowerPoint file	.ppt .pptx
PNG	Image file	.png
PUB	Adobe Publisher document	.pub
R	Source code in the R language	.r
RPT	Report text file	.rpt
RTF	Rich text document	.rtf
SAS	SAS programming source document	.sas
SAS7BDAT	SAS data format file	.sas7bdat
TIFF	Image file	.tif .tiff
TXT	Plain text file	.txt
XLS	Microsoft Excel spreadsheet	.xls .xlsx
XPT	SAS transport file (dataset formatted for sharing)	.xpt

File Information

The View Metadata (Info Icon) Action

When viewing the Browse tab, the Files and Staging Area display lists of files. If permissions allow, clicking the **Info Icon** in the Actions column next to a filename will display the Metadata Window.

The Metadata Window

The Metadata Window consists of three tabs. Depending on the user's permissions, these tabs may be active or disabled.

The Metadata Window tabs are: View, Comments, and Edit Metadata.

The name of the file currently being viewed is always displayed in the upper left header. In the examples, the filename is **SampleZip.zip**.

Users without permission to view all of the metadata tabs will view metadata tabs which are greyed-out, disabled, and can not be activated.

Viewing Metadata

The View Metadata Tab

The View tab of the Metadata Window has three sections containing information about a file.

General Information

The General Information section displays information such as filename, extension, file size, description, and status.

History

The History section displays information about the user who originally uploaded the file, the date it was uploaded, import date (if available), and last modified date.

Commits

The Commits section contains information for files that have been imported into version control. Once approved for import, any changes to a file's metadata will be recorded and tracked. Each change event will have an associated "hash identifier."

General

The General Panel shows file metadata such as name, extension, unique ID, size in kilobytes, destination path, status, and description.

The description corresponds with the file itself and can be edited within the Metadata tab by users with the correct permissions.

History

The History Panel displays information about the date of the original upload and the user who originally added the file to the system.

Commits

Commits

After import, information about historical changes can be viewed below.

	Hash & Message	Date ↑	Time
⊟	ba90606	10/18/2017	13:22:39 GM...
	Full Message Text: User- test@cognigencorp.com , Message- changed filename		
⊞	a1811d4	10/18/2017	13:22:39 GM...
⊞	84e1f38	10/18/2017	13:22:28 GM...
⊞	69ef476	8/23/2017	09:09:11 GM...
⊞	57d15bb	8/23/2017	09:09:11 GM...

Commit Hash: Identifier for the change. Can be used for troubleshooting with administrators and support.

Use the expand/collapse button to reveal additional information about the change event.

Once a file has been imported and is being version controlled, any change event that takes place is referenced by a 'commit hash.' This is a unique identifier associated with the change that was performed and contains information such as the date, user, and a brief message about what kind of change occurred.

Commenting on Files

The Comments Tab

The Comments tab of the Metadata Window displays any existing comments that have been added to the current file, and allows permitted users to add new comments.

Comment List

The Comment List displays the date and user associated with a comment, and the details of the comment can be viewed by expanding the Comment row by clicking the Expander button.

Add Comment Form

Entering comment text and clicking the "Save Comment" button will record a new comment associated with the current file, as well as the date/time and the user that created the comment.

A Success message will be shown and the Comment List updated after a comment has been added.

Comments can not be deleted or hidden at this time. A confirmation dialog will appear when adding comments to ensure that the comment is relevant and that it is permanent in nature.

Editing Metadata

The Edit Metadata Tab

This tab within the Metadata Window allows permitted users to change filenames, extensions, descriptions, and target paths (locations) for a selected file. Upon changing any form and clicking "Update," a message will appear after the update is complete.

Not all users are permitted to edit metadata. A grayed-out (disabled) tab indicates that the role does not allow this action.
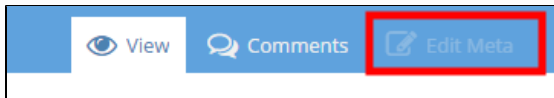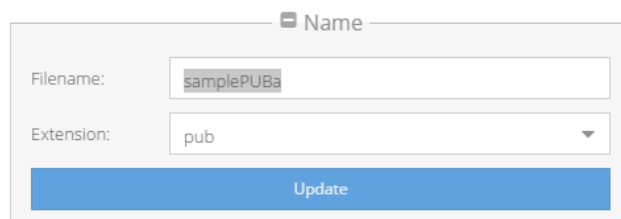
After clicking 'Update' in any of the Edit Metadata forms, a 'Success' notification will be visible when the action has been completed.

Editing Metadata: Change Name Form

This form can be used to change a filename or extension. Simply change the name in the Filename field or choose a different Extension from the drop-down menu. Once the appropriate field(s) has been changed, clicking the "Update" button will save the changes.
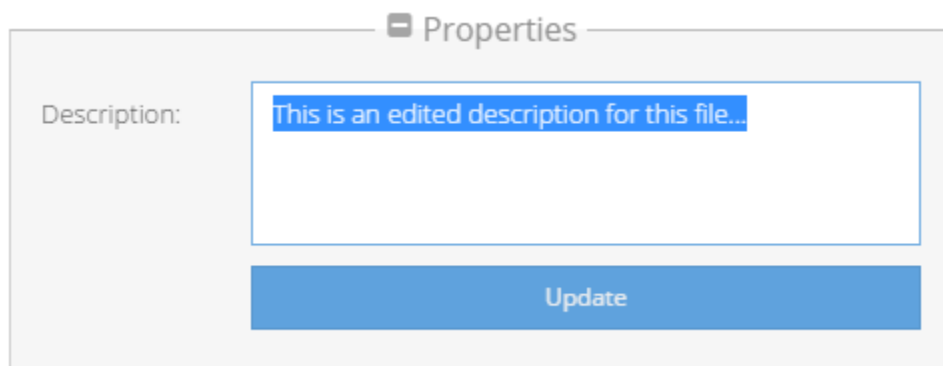
⊟ Name

Filename: samplePUBa

Extension: pub ▾

Update

⊘ *Choosing a different extension will not cause a file to be converted to another format.*

Editing Metadata: Change Properties Form

⊟ Properties

Description: This is an edited description for this file...

Update

The File Description may be edited by altering the text in the Description field and then clicking the "Update" button.

Editing Metadata: Destination Path Chooser
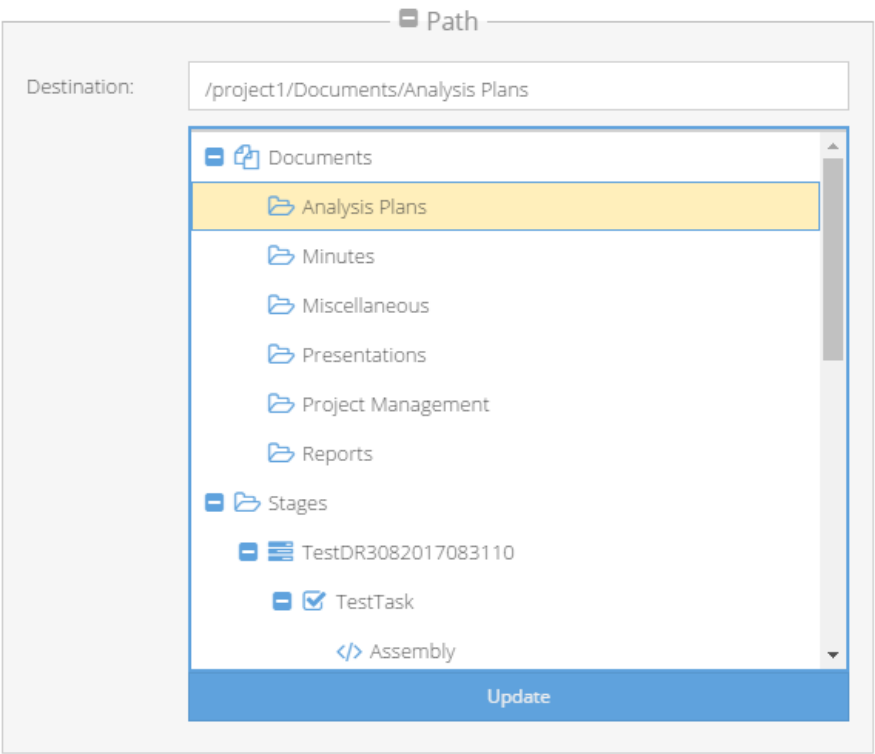
The current file's location will automatically appear selected in the Destination Path Chooser panel. To update the current file's location, simply click on a different folder and then click the "Update" button in the same panel.

> *If a file cannot be moved to a given location, the clicked location will not become highlighted and the Destination Path text will not change.*

> *Not all roles are allowed to move files. A message will be displayed if the user's role(s) does not include permissions to change file locations.*
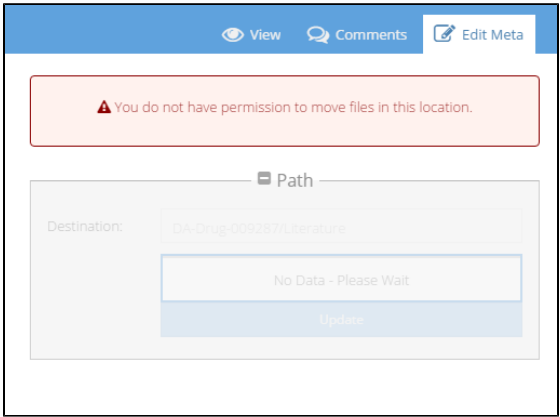
Approving File Import

Files in the Staging Area Panel

Files that appear in the Staging Area Panel for a Data Storage Component have a status of 'staging - needs approval.'

This allows the Team Lead and other users to review the intended directory and the file itself before allowing other users to access it.

Files that have been uploaded to the wrong directory can be moved, and inappropriate or incorrect files can be deleted.

> ⓘ *Not all users are allowed to Approve Import. If a green arrow icon is not visible in the Actions column of the Staging Area Panel, this action is not permitted.*

Importing a File

If a user holds a Team Lead role on a team that has access to a given Data Storage Component, or if a user is acting as an Administrative Role (e.g. Project Manager), that user will see a green arrow icon next to each file in the Staging Area.

Approve Import icon

The green arrow icon is the 'Approve Import' icon, and when clicked will cause the Data Repository to import and process the file and begin using version control on that file.

Once the import operation is complete, an informational Success message will be displayed for a few moments. If an error occurs, a dialog box with details about the error will be displayed.

If import was successful, the file that was imported will disappear from the Staging Area Panel. It will also change status - this can be viewed by navigating to the appropriate sub-directory. Imported files have a status of "imported" and are displayed in bold, dark grey text in the Files Panel, whereas unimported files are displayed in light grey, italicized thin text.

> (i) *Once imported, a file **can not be deleted**. In the future, users will be able to archive or hide old files, but they will remain in the system within version control. Files, however, can be moved within their containing Data Storage Objects and renamed.*

Are you sure you want to import this file?

(?) This file will be imported and version control will begin. The file will be associated with the current project/drug/study.

[Yes] [No]

Success

File import successful.
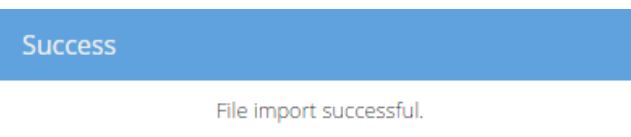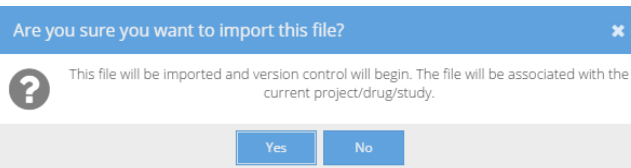
Files (in selected Explorer location)

Sebastians Rep > Studies > Study022 > Documents >

Filename	Status	Actions
LinkExplorer1abc.png	*staging - needs approval*	Unimported File
testData.zip	**imported**	Imported Files
TestDoc.txt	**imported**	

Deleting an Unimported File

If a user has uploaded a file into an incorrect Drug, Project, or Study, a Team Lead user (or appropriate Administrative user) should delete the file from the Staging Area.

To delete a file from the Staging Area, click on the Trash Icon that appears in the Actions area in that file's row in the Staging Area Panel.

Delete Unimported File icon

A Confirmation dialog will appear, and if 'Yes' is clicked, the file will be permanently deleted and a message will be stored in the system log.

> (!) *File deletion in the Staging Area Panel is permanent and can not be undone.*

Are you sure you want to delete this file?

(?) Deletion of files in the upload area cannot be undone. Are you certain you wish to delete this file?

[Yes] [No]
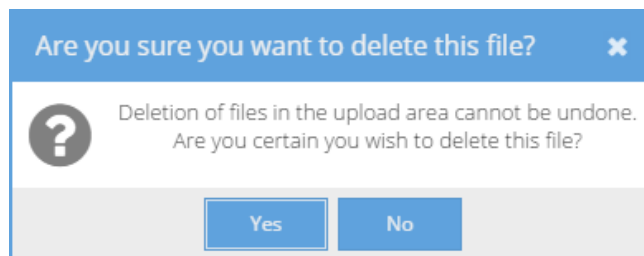
Downloading Files

Files can be downloaded from the Files Panel after selecting a folder location in the Explorer Panel.

If a user has uploaded a file, but the file has not yet been approved for import, then the user who uploaded the file will be able to download and review the file.

Other users whose roles do not allow the approval of importing a file will not be able to download the file from the Staging Area.

Downloaded files will open in a new tab or appear in your browser's "Download" area. In Chrome, this is a small bar at the bottom of the window; other browsers may vary.

Creating Directories

Depending on the structure of the Data Storage Panel you are working with, it may be necessary to add certain types of directories. Certain user roles are allowed to create these directories based on permissions (see the Permissions Appendices for more information).

Regulatory Agencies (Within Drugs)
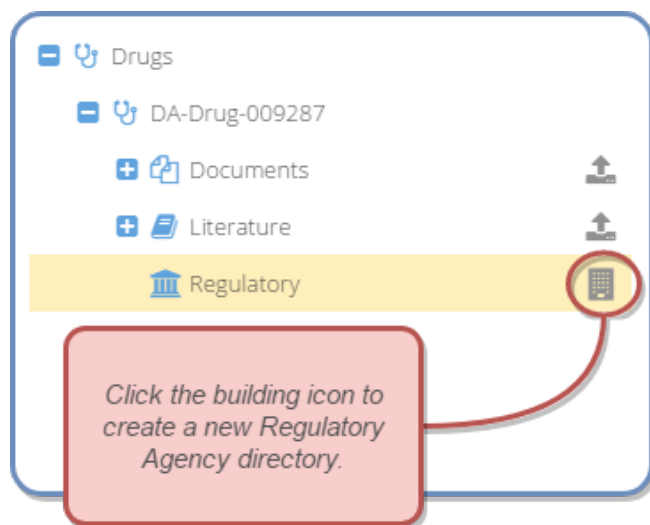
In the Explorer Panel, located in the Browse View of the main application, there are icons in the Actions column of the Explorer tree grid.

If the appropriate role and permissions have been assigned, a New Agency icon (building) will reside next to the Regulatory node within a Drug.

To create a new Regulatory Agency directory, click on the building icon.

In the prompt window, enter the desired name of the Agency.

Duplicate names are not allowed, nor are names containing spaces or special characters.

Dated Transfer Directories (Within Studies)
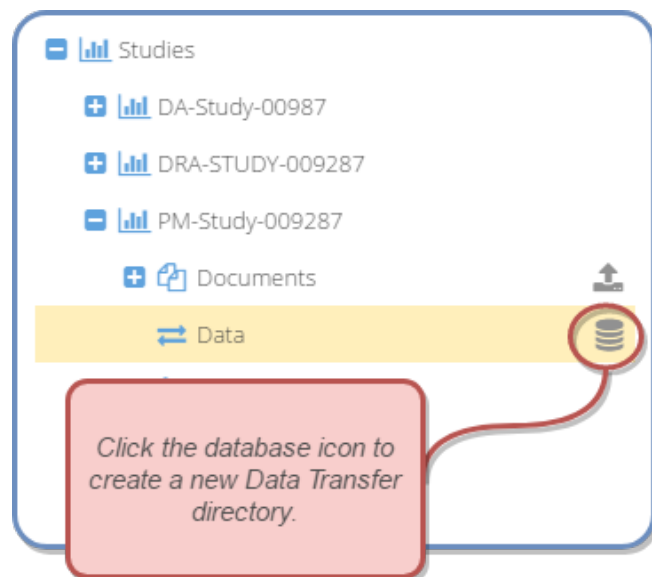
In the Explorer Panel, located in the Browse View of the main application, there are icons in the Actions column of the Explorer tree grid.

If the appropriate role and permissions have been assigned, a Database icon will appear next to the Data directory within a Study.

To create a new Data Transfer directory, click on the database icon.

Studies

⊞ DA-Study-00987

⊞ DRA-STUDY-009287

⊟ PM-Study-009287

⊞ Documents

⇄ Data

Click the database icon to create a new Data Transfer directory.

In the prompt window, select the relevant data transfer date.

Duplicate dates are not allowed within a Study. Once a date directory has been chosen/created, another with the same date can not be created.

Dates in the past or future may be selected to account for historical data and planned transfers.

✓ *If multiple data transfer events occur on the same day, simply rename your files with a timestamp or other indicator.*

Create new data transfer directory

Please choose a date to associate this dataset with. The date should correspond to the transfer date or collection date of the data, as appropriate for your workflow.

The timezone is assumed to be UTC (GMT), which is 4 hours ahead of the local timezone. Please keep this in mind when choosing a date.

Selected Date: 2017-10-18

«		October 2017 ⌄				»
S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	1	2	3	4
5	6	7	8	9	10	11

Today

Create   Cancel

Stages and Tasks (Within Projects)

Creating Stages

In the Explorer Panel, located in the Browse View of the main application, there are icons in the Actions column of the Explorer tree grid.

If the appropriate role and permissions have been assigned, a Stage icon (stacked rectangles) will appear next to the Stages directory within a Project.

To create a new Project Stage, click on the Stage icon.

In the prompt window, type the desired Stage name.

Duplicate Stage names in the same Project are not allowed.

Spaces and special characters are not permitted in Stage names.

Creating Tasks Within a Stage
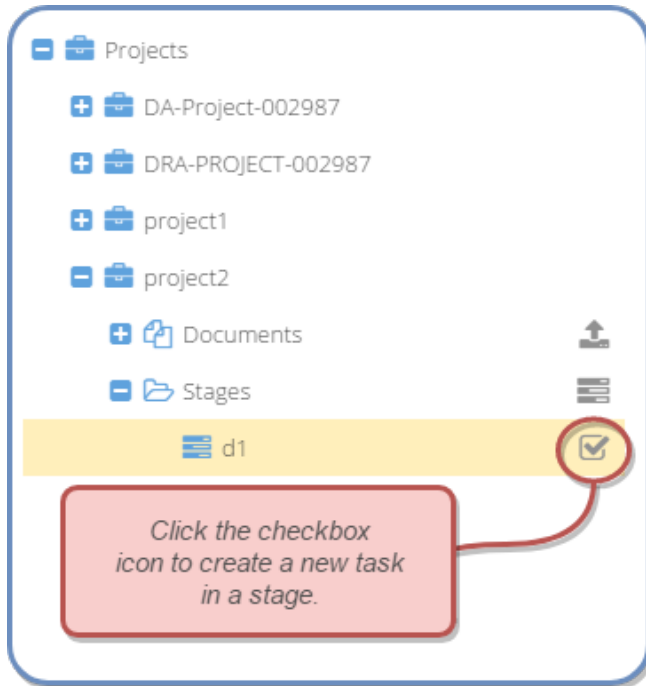
Click the checkbox icon to create a new task in a stage.

In the Explorer Panel, located in the Browse View of the main application, there are icons in the Actions column of the Explorer tree grid.

If the appropriate role and permissions have been assigned, a Task icon (a checked box) will appear next to a named Stage directory within a Project.

In the example, **d1** is a Stage within **project2**.

To create a new Task within a Project Stage, click on the checkbox icon.

In the prompt window, type the desired Task name.

Duplicate Task names in the same Stage are not allowed.

Spaces and special characters are not permitted in Task names.

Programming Language Directories (Within Project Tasks)
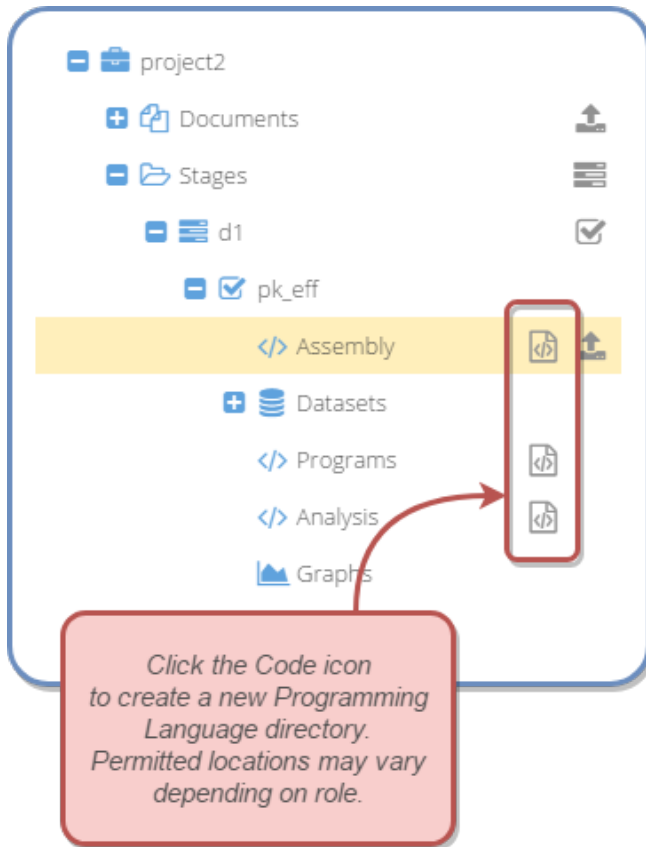
In the Explorer Panel, located in the Browse View of the main application, there are icons in the Actions column of the Explorer tree grid.

If the appropriate role and permissions have been assigned, a Programming Language icon will appear next to a sub-directory within a Project Task.

In the example, directories may be created within the **Assembly**, **Programs**, and **Analysis** sub-directories of Task: **pk_eff** within Stage: **d1** in Project: **project2**.

To create a new Programming Language directory within a Task sub-directory, click on the Programming Language icon.

> project2
> Documents
> Stages
> d1
> pk_eff
> Assembly
> Datasets
> Programs
> Analysis
> Graphs

Click the Code icon to create a new Programming Language directory. Permitted locations may vary depending on role.

In the prompt window, type the desired Programming Language directory name.

Duplicate Programming Language directory names in the same parent directory are not allowed.

Spaces and special characters are not permitted in Programming Language directory names.

Create new program directory ✖

Please enter a unique programming language name. This cannot be a duplicate of an existing program directory name.

Name: [Desired name]

[Create] [Cancel]

Storage Component Links

Data Storage Components (Drugs, Projects, and Studies) can have a variety of relationships between each other, added by users as needed. The intention of these relationship links is to inform various team members about other storage components that may be relevant to the Drug, Project, or Study currently being viewed.

It is recommended that Studies and Projects are linked to at least one Drug.

There is no limit to how or when links are used. A Drug that has some type of similarity to another Drug or a Project that may be of interest to team members, may be linked for any reason that a user finds useful. Administrators should guide users if any policies or guidelines apply to the usage of storage item links.

Link Display
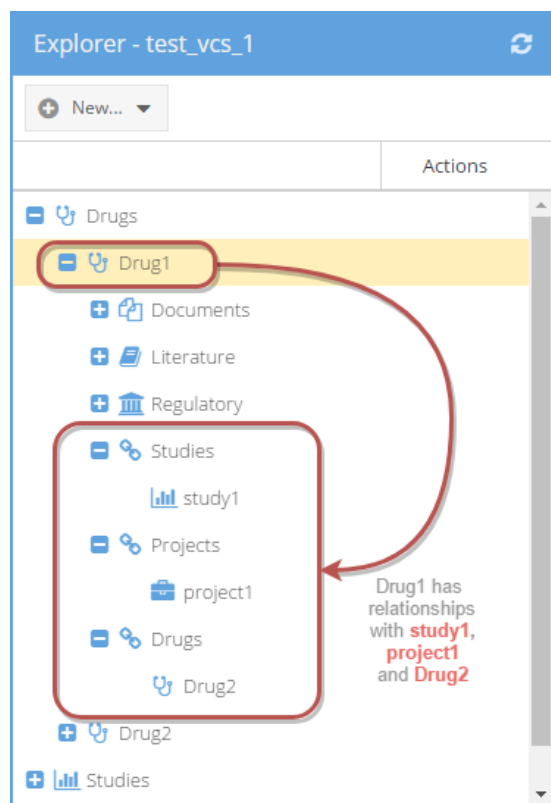
Each Storage Component, when viewed in the Explorer Panel, displays a list of links. This list will be empty for new items.

The list of links is divided by types, so that Drugs, Projects, and Studies are displayed in separate link categories.

Currently, linking is for display and informational purposes only. In the future, users will be able to view the type of relationship and perform additional actions.

Creating and Managing Links

The **links** of Drug1B can be added or managed by clicking any of the pencil icons
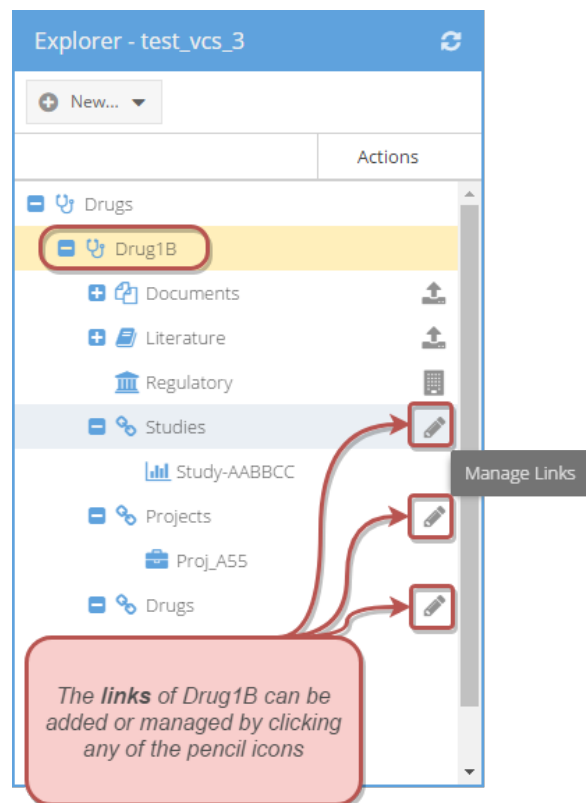
Users who hold a role with permissions to manage links will view the Manage Links icon (pencil) in the Actions column of the Explorer Panel.

To add or edit links, click on the pencil icon.

Link Relationships include:

- A owns B
- A is owned by B
- A is related to B
- A is similar to B
- A uses B
- A is used by B
- A references B

Manage Links Dialog

The Manage Links Window shows a list of existing links.

The current Storage Component (in this example, a Drug named DRA-DRUG-009287) can either be the "source" or "destination" of the link relationship.

The Type column lists the target of the link. The target is the "other side" of the relationship, that is, the Storage Component to which the current one is linked.

Links can be deleted by clicking the Delete Link icon (garbage can icon).

Links can be added by expanding the Add a Link form and choosing a link relationship type and a target from the drop-down menus.

Since the current Storage Component can be either the Source or Destination of a link, caution is advised that the correct type of relationship is chosen.

When adding a link, the current Storage Component (in this case, DRA-DRUG-009287) must be selected either on the left side or on the right.

Identical links are not allowed to be duplicated. For example, if a link exists such that DRA-DRUG-009287 is similar to Drug B, if a user tries to add the same relationship again, an error message will be displayed.
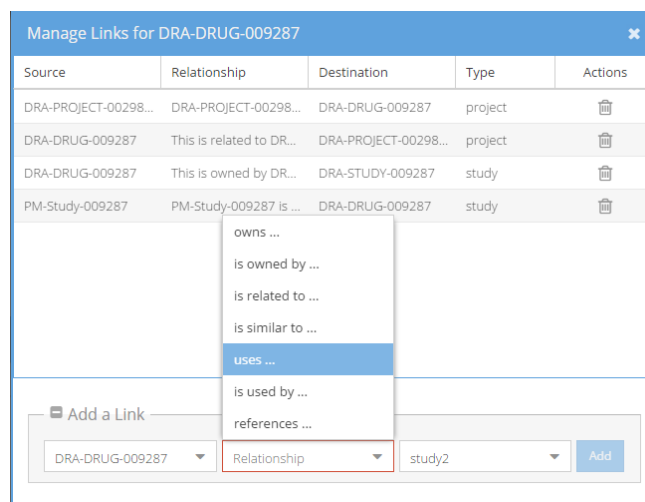
Appendices

Data Repository Administration

Admin Tools

Creating Data Storage Components

Supported Environments

Permissions By Role

Data Repository Administrator

Project Manager

Data Archivist

Team Roles

Page intentionally blank

Data Repository Administration

Admin Tools

Admin Tools Panel Layout

The Admin Tools View is available to Administrative users who have selected their role with the Role Selector drop-down menu.

The Admin Tools View contains a **right column** that displays all of the Drugs, Projects, and Studies in the current Data Repository System for easy reference and navigation.

> ✅ *Clicking on the Folder icon next to a Drug, Project, or Study name in this panel will activate the Browse View and display the selected item in the Explorer Panel.*

The Admin Tools View also contains **five accordion panels** with useful data displays and forms:

- User List
- User/Team Request Forms
- Team Assignments
- Unassigned Items List
- Action Log Records

The User List

The User List displays information about all of the users who currently have access to the Data Repository System that the user is logged into.

Users in test_vcs_1				
Last Name ↑	First Name ↑	Email / User ID	Team Assignments	Team Roles
Testuser1	Teamuser	a1-dra@cognigencorp.com	Bills	DRVCS_T_Stakeholder on team Bills
Testuser11	Teamuser	u11-tl@cognigencorp.com	Jets	DRVCS_T_Lead on team Jets
Testuser12	Teamuser	u12-multi@cognigencorp.com	Jets	DRVCS_T_Analysis on team Jets DRVCS_T_DataReadiness on team Jets
Testuser13	Teamuser	u13-multi@cognigencorp.com	Bills Jets	DRVCS_T_Lead on team Jets DRVCS_T_Stakeholder on team Bills
Testuser14	Teamuser	u14-multi@cognigencorp.com	Pats	DRVCS_T_Lead on team Pats
Testuser15	Teamuser	u15-sh@cognigencorp.com	Pats	DRVCS_T_Stakeholder on team Pats
Testuser4	Teamuser	u4-tl@cognigencorp.com	Bills	DRVCS_T_Lead on team Bills
Testuser5	Teamuser	u5-dm@cognigencorp.com	Bills	DRVCS_T_DataManager on team Bills
Testuser6	Teamuser	u6-dm@cognigencorp.com	Bills	DRVCS_T_DataReadiness on team Bills
Testuser7	Teamuser	u7-a@cognigencorp.com	Bills	DRVCS_T_Analysis on team Bills
Testuser8	Teamuser	u8-r@cognigencorp.com	Bills	DRVCS_T_Reviewer on team Bills

The list can be sorted according to first and last names as well as email addresses.

The Team Assignments column displays the different teams that the given user is assigned to, and the Team Roles column displays the role name(s) that the user holds on those teams.

User/Team Requests

Forms that can be used to submit requests regarding users and team assignments can be found here.

The New User Request form can be used to submit requests for user additions and changes. See Managing User Access for additional details.

The Team Request form can be used to request team creation, assignment, and membership changes. See Requesting Team Assignments for additional details.

Team Assignments

The area entitled Items Assigned to Teams displays information about the Data Storage Components within the system. This area displays which items are assigned to various teams.

Users in test_vcs_1				+
User / Team Requests				+
Items Assigned to Teams				−

Team Name ↑	ID	Assigned Drugs	Assigned Projects	Assigned Studies
Bills	7	DeleteMe-DR714-Drug Test-Deleteme PM-Drug-009287 DA-Drug-009287 DRA-DRUG-009287 Drug2 Drug1	DA-Project-002987 DRA-PROJECT-002987 project2 project1	PM-Study-009287 DA-Study-00987 DRA-STUDY-009287 TempStudy-DR3205 study1
Jets	8	None	None	TempStudy-DR320 study2
Pats	10	PM-Drug-009287 DA-Drug-009287 DRA-DRUG-009287 Drug2	DA-Project-002987 DRA-PROJECT-002987 project1	PM-Study-009287 DA-Study-00987 DRA-STUDY-009287 study1

Unassigned Items				+
Action Log				+

The list can be sorted by clicking on any of the column headers.

⊘ *When a team is not assigned to a particular item type (such as Drugs), the background of the cell will appear dark grey.*

Unassigned Items

When new Data Storage Components are created, they are initially not assigned to any Drugs, Projects, or Studies. The Unassigned Items list shows any Data Storage Component that is not assigned to a team and, therefore, not visible to any user.

Users in test_vcs_1   +

User / Team Requests   +

Items Assigned to Teams   +

Unassigned Items   —

These drugs, projects and studies are not currently assigned to any teams, and will not be visible to team users.

Item Name ↑	Type ↑	ID
DeleteMeDDR611-Garbage	drug	29
test-drug-deleteme	drug	40

Action Log   +

Action Logs

The Action Logs list can be used to retrieve and display a history of actions performed within the Data Repository System.

To view the Action history, click the 'Get Logs Now' button. After a few moments, the Action history table will load.

Users in test_vcs_1	+
User / Team Requests	+
Items Assigned to Teams	+
Unassigned Items	+
Action Log	−

⊞ Get Logs Now

Date ↓	Time ↓	Level	Message
2017-10-30	16:56:41	INFO	File Download
2017-10-30	16:48:52	INFO	File Download
2017-10-30	16:48:47	INFO	A file has been successfully created
2017-10-30	16:48:47	INFO	A file has been successfully uploaded
2017-10-30	16:40:00	INFO	File Download
2017-10-30	16:37:28	INFO	File Download
2017-10-30	16:37:10	INFO	File Download
2017-10-30	16:36:51	INFO	File Download
2017-10-30	16:35:38	INFO	File Download
2017-10-30	16:29:50	INFO	File Download
2017-10-30	16:29:21	INFO	File Download
2017-10-30	16:28:43	INFO	A file has been successfully created

ⓘ *The Action Log shows basic information about events that have occurred. If your organization needs more detailed records, please contact kiwisupport@cognigencorp.com and the Kiwi Support team will provide the required details in a format that works best for your needs.*

Managing User Access

Requesting User Changes

At this time, the addition or modification to a user's role assignment must be requested via KiwiSupport. For a user with Administrative roles, the Admin Tools Panel contains a User Request form.

Click on the User/Team Requests to open the accordion panel.

Use this form when requesting new users, when users should have access disabled, or if any user changes are required.

The Access field is required. After the required fields have been edited, the 'Send Request' button will allow you to submit the request to Cognigen's Kiwi Support team. A reply will be emailed to the email on file with your user account.

✓ *You may also email* *kiwisupport@cognigencorp.com* *if you have a User Access request and can not use this form.*

New User Request

___ User Info ___

Email:

[Email Address]

Update existing:

☐ Yes

___ User Information ___

First Name:

[First Name]

Last Name:

[Last Name]

Company / Org:

[ ]

Access:

[Please describe the teams and roles this user needs, or should be removed from.]

[Send Request]

Requesting Team Assignments

Administrative users can submit Team Requests by navigating to the Admin Tools panel and opening the User/Team Requests accordion.

The Create/Update Team Request form can be used to request:

- New team creation
- Users be assigned to team(s)
- Changes (additions, subtractions) in team roles for users
- Assignment of teams to various Drugs, Projects, and Studies

The Request New Team button will become enabled when the required fields have been filled out. Clicking this button will submit the team change request to the KiwiSupport team and a reply will be sent to the email address on file with your account.

> ✅ *Administrative users may also contact Kiwi Support at kiwisupport@cognigencorp.com to request team and user assignment changes. Please provide as much information as possible.*

> ⓘ *A self-service Team Management Module will be released in the near future. Users will be notified when this feature is available, and instructions will be added to the online User Manual at that time.*

Create / Update Team Request

Team Info

Team Name:

[Team Name]

Update existing:

☐ Yes

Assignment Information

Assign Drugs:

[Should this team have access to any existing drugs? List drug names here.]

Assign Projects:

[Should this team have access to any existing projects? List project names here.]

Assign Studies:

[Should this team have access to any existing studies? List study names here.]

Request New Team

Creating Data Storage Components

Creating Items From the Dashboard

Create Item Buttons
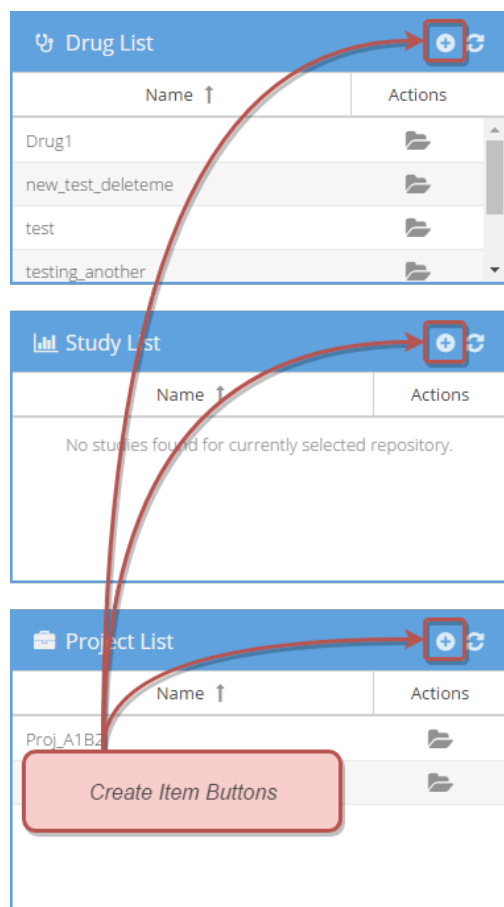
To create a new Data Storage Component from the Dashboard View, click the plus button that appears in the header of each component list.

For example: to create a new Study, click the plus button at the top of the Study List.

Creating Items From the Browse View

New Data Storage Components can also be created when using the Browse View. To do so, click the **New** drop-down menu at the top left corner of the Explorer Panel.

Choose the type of item you would like to create, and the appropriate form will display.
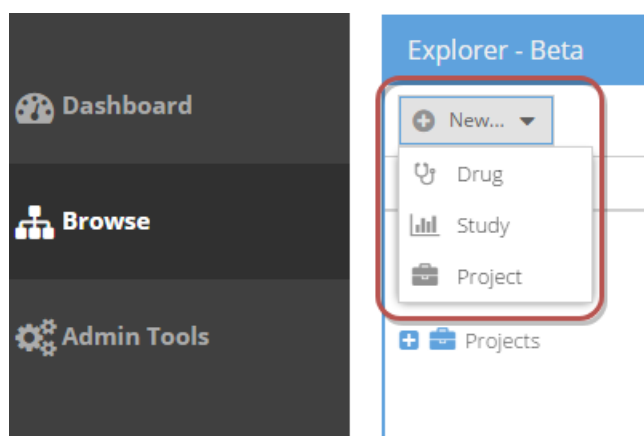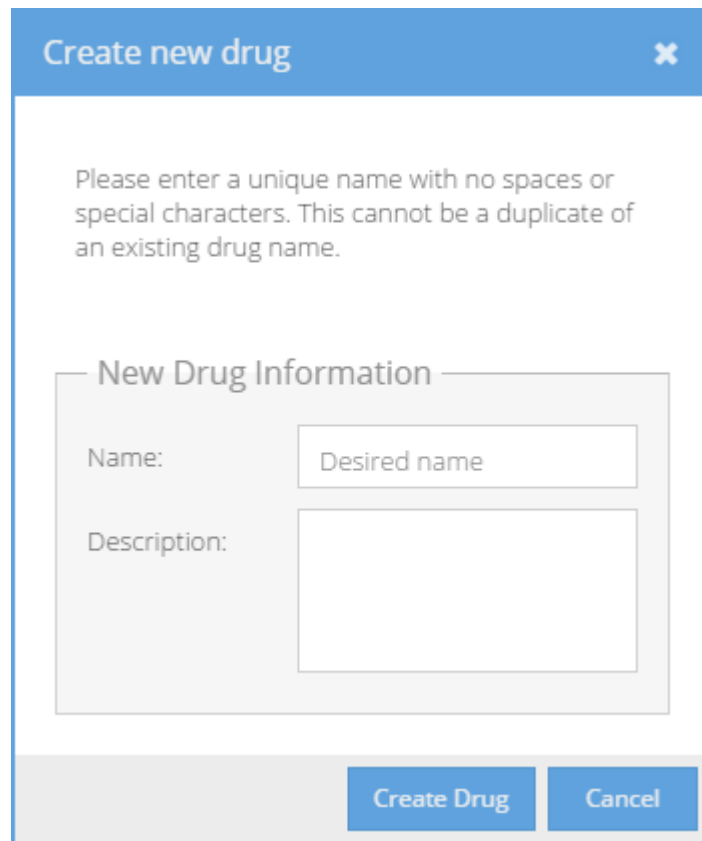
The Create Item Forms

Create Drug Form
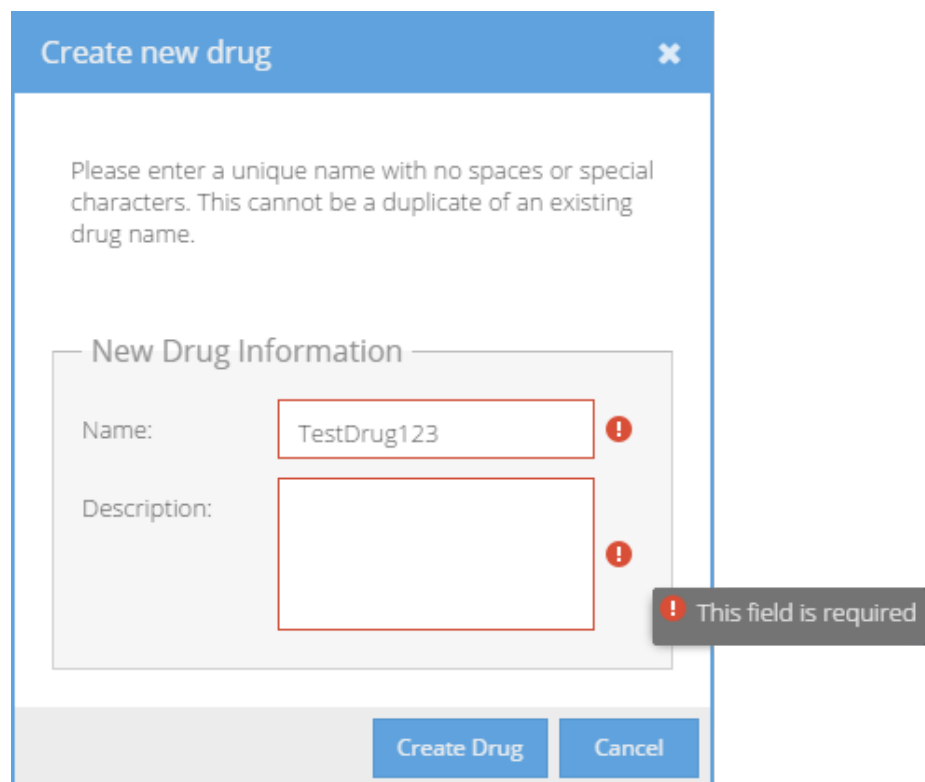
The forms used to create new Data Storage Components are very similar.

Choose a name for the new Drug and type it into the Name field. Names can not contain spaces or special (non alpha-numeric) characters. Duplicate names are also not allowed (two drugs with the same name can not be created in the same Data Repository).

Create new drug ✖

Please enter a unique name with no spaces or special characters. This cannot be a duplicate of an existing drug name.

New Drug Information

Name: Desired name

Description:

Create Drug   Cancel

If required information is missing, errors will be displayed on the form. These errors must be resolved prior to form submission.

Create new drug ✖

Please enter a unique name with no spaces or special characters. This cannot be a duplicate of an existing drug name.

New Drug Information

Name: TestDrug123 ❗

Description: ❗

❗ This field is required

Create Drug   Cancel

Create Study Form

Choose a name for the new Study and type it into the Name field. Names can not contain spaces or special (non alpha-numeric) characters. Duplicate names are also not allowed (two studies with the same name can not be created in the same Data Repository).

If required information is missing, errors will be displayed on the form. These errors must be resolved prior to form submission.
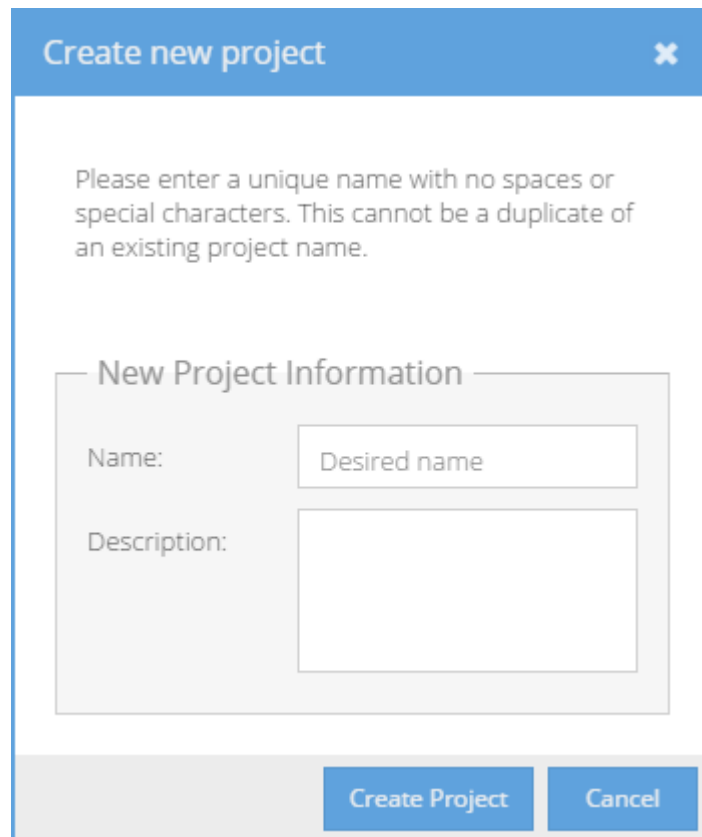
Create new study

Please enter a unique name with no spaces or special characters. This cannot be a duplicate of an existing study name.

— New Study Information —

Name: [Desired name]

Description: [ ]

[Create Study] [Cancel]

Create Project Form

Choose a name for the new Project and type it into the Name field. Names can not contain spaces or special (non alpha-numeric) characters. Duplicate names are also not allowed (two projects with the same name cannot be created in the same Data Repository).

If required information is missing, errors will be displayed on the form. These errors must be resolved prior to form submission.

Create new project

Please enter a unique name with no spaces or special characters. This cannot be a duplicate of an existing project name.

— New Project Information —

Name: [Desired name]

Description: [ ]

[Create Project] [Cancel]

Supported Environments

Browsers

The following internet browsing applications are supported as of this writing (*****: **preferred**):

- **Google Chrome 17 (or higher) ***
- **FireFox 10 (or higher) ***
- Microsoft Internet Explorer 11 (or higher)
- Microsoft Edge 12 (or higher)

Internet Availability

To use this application, an internet connection with access to the Data Repository URL is required. Extremely slow connections or latency will result in poor performance.

Permissions By Role

The legend below can be used in the following sections.

- Data Repository Administrator (DRA)
- Project Manager
- Data Archivist
- Team - Lead
- Team - Data Manager
- Team - Data Readiness
- Team - Analysis
- Team - Reviewer
- Team - Stakeholder

Key	Meaning
Red/Bold Text	Item is added by users with permission, and **Name** is chosen by user upon creation. There may be more than one of this type of item.
Gray Background / Blank Cell	Not applicable to this location.
✔	This user role has permission to perform the action in the top header, in the folder path shown in the left header.
✖	User explicitly does NOT have this permission.
⭐ Create	User can create an item of the specified type, which may be any of the following. The word which replaces "Create" under or next to the stars in the table are noted in the parentheses below for each item creation. - Drug, Project, Study (Drug, Project, Study) - regulatory agency (Agency) - dated dataset directory (Data Dir) - stage, task (Stage, Task) - programming language directory (Dir) - links to related Drugs, Projects, and Studies (Link)
DL	DL is short-hand for download.

Data Repository Administrator (DRA)

Drugs - DRA

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
🩺 **DrugName**	⭐ Drug							
📑 documents		✅	✅	✅	✅	✅	❌	❌
✉ correspondence		✅	✅	✅	✅	✅	❌	❌
📂 miscellaneous		✅	✅	✅	✅	✅	❌	❌
📂 presentations		✅	✅	✅	✅	✅	❌	❌
📕 literature		✅	✅	✅	✅	✅	❌	❌
📂 manuscripts		✅	✅	✅	✅	✅	❌	❌
📂 publications		✅	✅	✅	✅	✅	❌	❌
🏛 regulatory	⭐ Agency	✅						
🏢 **AgencyName**		✅						
✏ draft		✅	✅	✅	✅	✅	❌	❌
📑 documents		✅	✅	✅	✅	✅	❌	❌
✉ correspondence		✅	✅	✅	✅	✅	❌	❌
🔗 submitted		✅	✅	✅	✅	✅	❌	❌
📑 documents		✅	✅	✅	✅	✅	❌	❌
✉ correspondence		✅	✅	✅	✅	✅	❌	❌
🔗 drugs	⭐ Link	✅						
🔗 projects	⭐ Link	✅						
🔗 studies	⭐ Link	✅						

Studies - DRA

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	⭐ Study							
🗂 documents		✅	✅	✅	✅	✅	❌	❌
✉ correspondence		✅	✅	✅	✅	✅	❌	❌
📂 crf		✅	✅	✅	✅	✅	❌	❌
📂 csr		✅	✅	✅	✅	✅	❌	❌
📂 miscellaneous		✅	✅	✅	✅	✅	❌	❌
📂 protocol		✅	✅	✅	✅	✅	❌	❌
📂 reports		✅	✅	✅	✅	✅	❌	❌
⇄ data	⭐ Date Dir	✅						
🗄 **YYYY-MM-DD (dated transfer directory)**		✅	✅	✅	✅	✅	❌	❌
🔗 drugs	⭐ Link	✅						
🔗 projects	⭐ Link	✅						
🔗 studies	⭐ Link	✅						

Projects - DRA

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	⭐ Project							
🗐 documents		✓	✓	✓	✓	✓	✗	✗
📂 analysis plans		✓	✓	✓	✓	✓	✗	✗
📂 minutes		✓	✓	✓	✓	✓	✗	✗
📂 miscellaneous		✓	✓	✓	✓	✓	✗	✗
📂 presentations		✓	✓	✓	✓	✓	✗	✗
📂 project management		✓	✓	✓	✓	✓	✗	✗
📂 reports		✓	✓	✓	✓	✓	✗	✗
📂 stages	⭐ Stage	✓						
🎚 **StageName**	⭐ Task	✓						
☑ **TaskName**		✓						
</> assembly	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
🗋 **Name**		✓	✓	✓	✓	✓	✗	✗
🗄 datasets		✓	✓	✓	✓	✓	✗	✗
📂 modified		✓	✓	✓	✓	✓	✗	✗
📂 simulated		✓	✓	✓	✓	✓	✗	✗
</> programs	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
🗋 **Name**		✓	✓	✓	✓	✓	✗	✗
</> analysis	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
🗋 **Name**		✓	✓	✓	✓	✓	✗	✗
📈 graphs		✓	✓	✓	✓	✓	✗	✗
▦ tables		✓	✓	✓	✓	✓	✗	✗
🔗 drugs	⭐ Link	✓						
🔗 projects	⭐ Link	✓						
🔗 studies	⭐ Link	✓						

Project Manager

Drugs - PM

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
🩺 **DrugName**	⭐ Drug							
🗐 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
🗁 miscellaneous		✅	✅	✅	✅	✅	✅	✅
🗁 presentations		✅	✅	✅	✅	✅	✅	✅
📕 literature		✅	✅	✅	✅	✅	✅	✅
🗁 manuscripts		✅	✅	✅	✅	✅	✅	✅
🗁 publications		✅	✅	✅	✅	✅	✅	✅
🏛 regulatory	⭐ Agency	✅						
🏢 **AgencyName**		✅						
✏ draft		✅	✅	✅	✅	✅	✅	✅
🗐 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
🔗 submitted		✅	✅	✅	✅	✅	✅	✅
🗐 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	⭐ Link	✅						
🔗 projects	⭐ Link	✅						
🔗 studies	⭐ Link	✅						

Studies - PM

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	⭐ Study							
🗐 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
📂 crf		✅	✅	✅	✅	✅	✅	✅
📂 csr		✅	✅	✅	✅	✅	✅	✅
📂 miscellaneous		✅	✅	✅	✅	✅	✅	✅
📂 protocol		✅	✅	✅	✅	✅	✅	✅
📂 reports		✅	✅	✅	✅	✅	✅	✅
⇄ data	⭐ Date Dir	✅						
🗄 **YYYY-MM-DD (dated transfer directory)**		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	⭐ Link	✅						
🔗 projects	⭐ Link	✅						
🔗 studies	⭐ Link	✅						

Projects - PM

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	⭐ Project							
🗂 documents		✅	✅	✅	✅	✅	✅	✅
📂 analysis plans		✅	✅	✅	✅	✅	✅	✅
📂 minutes		✅	✅	✅	✅	✅	✅	✅
📂 miscellaneous		✅	✅	✅	✅	✅	✅	✅
📂 presentations		✅	✅	✅	✅	✅	✅	✅
📂 project management		✅	✅	✅	✅	✅	✅	✅
📂 reports		✅	✅	✅	✅	✅	✅	✅
📂 stages	⭐ Stage	✅						
☰ **StageName**	⭐ Task	✅						
☑ **TaskName**		✅						
</> assembly	⭐ Dir	✅	✅	✅	✅	✅	✅	✅
📄 **Name**		✅	✅	✅	✅	✅	✅	✅
🗄 datasets		✅	✅	✅	✅	✅	✅	✅
📂 modified		✅	✅	✅	✅	✅	✅	✅
📂 simulated		✅	✅	✅	✅	✅	✅	✅
</> programs	⭐ Dir	✅	✅	✅	✅	✅	✅	✅
📄 **Name**		✅	✅	✅	✅	✅	✅	✅
</> analysis	⭐ Dir	✅	✅	✅	✅	✅	✅	✅
📄 **Name**		✅	✅	✅	✅	✅	✅	✅
📈 graphs		✅	✅	✅	✅	✅	✅	✅
⊞ tables		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	⭐ Link	✅						
🔗 projects	⭐ Link	✅						
🔗 studies	⭐ Link	✅						

Data Archivist

Drugs - Data Archivist

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
🩺 **DrugName**	⭐ Drug							
📑 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
📂 miscellaneous		✅	✅	✅	✅	✅	✅	✅
📂 presentations		✅	✅	✅	✅	✅	✅	✅
📕 literature		✅	✅	✅	✅	✅	✅	✅
📂 manuscripts		✅	✅	✅	✅	✅	✅	✅
📂 publications		✅	✅	✅	✅	✅	✅	✅
🏛 regulatory	⭐ Agency	✅						
🏢 **AgencyName**		✅						
✏ draft		✅	✅	✅	✅	✅	✅	✅
📑 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
🔃 submitted		✅	✅	✅	✅	✅	✅	✅
📑 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	❌	✅						
🔗 projects	❌	✅						
🔗 studies	❌	✅						

Studies - Data Archivist

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	⭐ Study							
🗐 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
📂 crf		✅	✅	✅	✅	✅	✅	✅
📂 csr		✅	✅	✅	✅	✅	✅	✅
📂 miscellaneous		✅	✅	✅	✅	✅	✅	✅
📂 protocol		✅	✅	✅	✅	✅	✅	✅
📂 reports		✅	✅	✅	✅	✅	✅	✅
⇄ data	⭐ Date Dir	✅						
🗄 **YYYY-MM-DD (dated transfer directory)**		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	❌	✅						
🔗 projects	❌	✅						
🔗 studies	❌	✅						

Projects - Data Archivist

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	⭐ Project							
🗐 documents		✓	✓	✓	✓	✓	✓	✓
📂 analysis plans		✓	✓	✓	✓	✓	✓	✓
📂 minutes		✓	✓	✓	✓	✓	✓	✓
📂 miscellaneous		✓	✓	✓	✓	✓	✓	✓
📂 presentations		✓	✓	✓	✓	✓	✓	✓
📂 project management		✓	✓	✓	✓	✓	✓	✓
📂 reports		✓	✓	✓	✓	✓	✓	✓
📂 stages	⭐ Stage	✓						
🗏 **StageName**	⭐ Task	✓						
☑ **TaskName**		✓						
</> assembly	⭐ Dir	✓	✓	✓	✓	✓	✓	✓
🗎 **Name**		✓	✓	✓	✓	✓	✓	✓
🗄 datasets		✓	✓	✓	✓	✓	✓	✓
📂 modified		✓	✓	✓	✓	✓	✓	✓
📂 simulated		✓	✓	✓	✓	✓	✓	✓
</> programs	⭐ Dir	✓	✓	✓	✓	✓	✓	✓
🗎 **Name**		✓	✓	✓	✓	✓	✓	✓
</> analysis	⭐ Dir	✓	✓	✓	✓	✓	✓	✓
🗎 **Name**		✓	✓	✓	✓	✓	✓	✓
📈 graphs		✓	✓	✓	✓	✓	✓	✓
🔢 tables		✓	✓	✓	✓	✓	✓	✓
🔗 drugs	❌	✓						
🔗 projects	❌	✓						
🔗 studies	❌	✓						

Team - Lead

Drugs - Team Lead

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
🩺 **DrugName**	❌							
🗐 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
📂 miscellaneous		✅	✅	✅	✅	✅	✅	✅
📂 presentations		✅	✅	✅	✅	✅	✅	✅
📕 literature		✅	✅	✅	✅	✅	✅	✅
📂 manuscripts		✅	✅	✅	✅	✅	✅	✅
📂 publications		✅	✅	✅	✅	✅	✅	✅
🏛 regulatory	⭐ Agency	✅						
▦ **AgencyName**		✅						
✎ draft		✅	✅	✅	✅	✅	✅	✅
🗐 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
↪ submitted		✅	✅	✅	✅	✅	✅	✅
🗐 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	⭐ Link	✅						
🔗 projects	⭐ Link	✅						
🔗 studies	⭐ Link	✅						

Studies - Team Lead

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	❌							
🗂 documents		✅	✅	✅	✅	✅	✅	✅
✉ correspondence		✅	✅	✅	✅	✅	✅	✅
📂 crf		✅	✅	✅	✅	✅	✅	✅
📂 csr		✅	✅	✅	✅	✅	✅	✅
📂 miscellaneous		✅	✅	✅	✅	✅	✅	✅
📂 protocol		✅	✅	✅	✅	✅	✅	✅
📂 reports		✅	✅	✅	✅	✅	✅	✅
⇄ data	⭐ Date Dir	✅						
🗄 **YYYY-MM-DD (dated transfer directory)**		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	⭐ Link	✅						
🔗 projects	⭐ Link	✅						
🔗 studies	⭐ Link	✅						

Projects - Team Lead

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	❌							
🗂 documents		✅	✅	✅	✅	✅	✅	✅
📂 analysis plans		✅	✅	✅	✅	✅	✅	✅
📂 minutes		✅	✅	✅	✅	✅	✅	✅
📂 miscellaneous		✅	✅	✅	✅	✅	✅	✅
📂 presentations		✅	✅	✅	✅	✅	✅	✅
📂 project management		✅	✅	✅	✅	✅	✅	✅
📂 reports		✅	✅	✅	✅	✅	✅	✅
📂 stages	⭐ Stage	✅						
☰ **StageName**	⭐ Task	✅						
☑ **TaskName**		✅						
</> assembly	⭐ Dir	✅	✅	✅	✅	✅	✅	✅
📄 **Name**		✅	✅	✅	✅	✅	✅	✅
🗄 datasets		✅	✅	✅	✅	✅	✅	✅
📂 modified		✅	✅	✅	✅	✅	✅	✅
📂 simulated		✅	✅	✅	✅	✅	✅	✅
</> programs	⭐ Dir	✅	✅	✅	✅	✅	✅	✅
📄 **Name**		✅	✅	✅	✅	✅	✅	✅
</> analysis	⭐ Dir	✅	✅	✅	✅	✅	✅	✅
📄 **Name**		✅	✅	✅	✅	✅	✅	✅
📈 graphs		✅	✅	✅	✅	✅	✅	✅
⊞ tables		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	⭐ Link	✅						
🔗 projects	⭐ Link	✅						
🔗 studies	⭐ Link	✅						

Team - Data Manager

Drugs - Data Manager

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
🩺 **DrugName**	✗							
📑 documents		✓	✓	✗	✓	✓	✗	✗
✉ correspondence		✓	✓	✗	✓	✓	✗	✗
📂 miscellaneous		✓	✓	✗	✓	✓	✗	✗
📂 presentations		✓	✓	✗	✓	✓	✗	✗
📖 literature		✓	✓	✗	✗	✓	✗	✗
📂 manuscripts		✓	✓	✗	✗	✓	✗	✗
📂 publications		✓	✓	✗	✗	✓	✗	✗
🏛 regulatory	✗	✓						
🏢 **AgencyName**		✓						
✏ draft		✓	✓	✗	✗	✓	✗	✗
📑 documents		✓	✓	✗	✗	✓	✗	✗
✉ correspondence		✓	✓	✗	✗	✓	✗	✗
↪ submitted		✓	✓	✗	✗	✓	✗	✗
📑 documents		✓	✓	✗	✗	✓	✗	✗
✉ correspondence		✓	✓	✗	✗	✓	✗	✗
🔗 drugs	✗	✓						
🔗 projects	✗	✓						
🔗 studies	✗	✓						

Studies - Data Manager

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	❌							
🗂 documents		✅	✅	✅	✅	✅	❌	✅
✉ correspondence		✅	✅	✅	✅	✅	❌	✅
📂 crf		✅	✅	✅	✅	✅	❌	✅
📂 csr		✅	✅	✅	✅	✅	❌	✅
📂 miscellaneous		✅	✅	✅	✅	✅	❌	✅
📂 protocol		✅	✅	✅	✅	✅	❌	✅
📂 reports		✅	✅	✅	✅	✅	❌	✅
⇄ data	⭐ Date Dir	✅						
🗄 **YYYY-MM-DD (dated transfer directory)**		✅	✅	✅	✅	✅	✅	✅
🔗 drugs	❌	✅						
🔗 projects	❌	✅						
🔗 studies	❌	✅						

Projects - Data Manager

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	✗							
🗂 documents		✓	✓	✗	✓	✓	✗	✗
📂 analysis plans		✓	✓	✓	✓	✓	✗	✗
📂 minutes		✓	✓	✗	✓	✓	✗	✗
📂 miscellaneous		✓	✓	✗	✓	✓	✗	✗
📂 presentations		✓	✓	✗	✓	✓	✗	✗
📂 project management		✓	✓	✗	✓	✓	✗	✗
📂 reports		✓	✓	✗	✓	✓	✗	✗
📂 stages	✗	✓						
▤ **StageName**	✗	✓						
☑ **TaskName**		✓						
</> assembly	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
📄 **Name**		✓	✓	✓	✓	✓	✗	✗
🛢 datasets		✓	✓	✓	✓	✓	✗	✗
📂 modified		✓	✓	✓	✓	✓	✗	✗
📂 simulated		✓	✓	✓	✓	✓	✗	✗
</> programs	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
📄 **Name**		✓	✓	✓	✓	✓	✗	✗
</> analysis	✗	✓	✓	✗	✗	✓	✗	✗
📄 **Name**		✓	✓	✗	✗	✓	✗	✗
📈 graphs		✓	✓	✗	✗	✓	✗	✗
▦ tables		✓	✓	✗	✗	✓	✗	✗
🔗 drugs	✗	✓						
🔗 projects	✗	✓						
🔗 studies	✗	✓						

Team - Data Readiness

Drugs - Data Readiness

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
🩺 **DrugName**	✗							
📑 documents		✓	✓	✗	✓	✓	✗	✗
✉ correspondence		✓	✓	✗	✓	✓	✗	✗
📁 miscellaneous		✓	✓	✗	✓	✓	✗	✗
📁 presentations		✓	✓	✗	✓	✓	✗	✗
📖 literature		✓	✓	✗	✗	✓	✗	✗
📁 manuscripts		✓	✓	✗	✗	✓	✗	✗
📁 publications		✓	✓	✗	✗	✓	✗	✗
🏛 regulatory	✗	✓						
🏢 **AgencyName**		✓						
✏ draft		✓	✓	✗	✗	✓	✗	✗
📑 documents		✓	✓	✗	✗	✓	✗	✗
✉ correspondence		✓	✓	✗	✗	✓	✗	✗
🔗 submitted		✓	✓	✗	✗	✓	✗	✗
📑 documents		✓	✓	✗	✗	✓	✗	✗
✉ correspondence		✓	✓	✗	✗	✓	✗	✗
🔗 drugs	✗	✓						
🔗 projects	✗	✓						
🔗 studies	✗	✓						

Studies - Data Readiness

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	❌							
🗐 documents		✅	✅	❌	✅	✅	❌	❌
✉ correspondence		✅	✅	❌	✅	✅	❌	❌
📂 crf		✅	✅	❌	✅	✅	❌	❌
📂 csr		✅	✅	❌	✅	✅	❌	❌
📂 miscellaneous		✅	✅	❌	✅	✅	❌	❌
📂 protocol		✅	✅	❌	✅	✅	❌	❌
📂 reports		✅	✅	❌	✅	✅	❌	❌
⇄ data	⭐ Date Dir	✅						
🗄 **YYYY-MM-DD (dated transfer directory)**		✅	✅	❌	✅	✅	❌	❌
🔗 drugs	❌	✅						
🔗 projects	❌	✅						
🔗 studies	❌	✅						

Projects - Data Readiness

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	✗							
🗐 documents		✓	✓	✗	✓	✓	✗	✗
📂 analysis plans		✓	✓	✓	✓	✓	✗	✗
📂 minutes		✓	✓	✗	✓	✓	✗	✗
📂 miscellaneous		✓	✓	✗	✓	✓	✗	✗
📂 presentations		✓	✓	✗	✓	✓	✗	✗
📂 project management		✓	✓	✗	✓	✓	✗	✗
📂 reports		✓	✓	✗	✓	✓	✗	✗
📂 stages	✗	✓						
▤ **StageName**	✗	✓						
☑ **TaskName**		✓						
</> assembly	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
📄 **Name**		✓	✓	✓	✓	✓	✗	✗
🛢 datasets		✓	✓	✓	✓	✓	✗	✗
📂 modified		✓	✓	✓	✓	✓	✗	✗
📂 simulated		✓	✓	✓	✓	✓	✗	✗
</> programs	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
📄 **Name**		✓	✓	✓	✓	✓	✗	✗
</> analysis	✗	✓	✓	✗	✗	✓	✗	✗
📄 **Name**		✓	✓	✗	✗	✓	✗	✗
📈 graphs		✓	✓	✗	✗	✓	✗	✗
▦ tables		✓	✓	✗	✗	✓	✗	✗
🔗 drugs	✗	✓						
🔗 projects	✗	✓						
🔗 studies	✗	✓						

Team - Analysis

Drugs - Analysis

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
DrugName	✗							
documents		✓	✓	✗	✓	✓	✗	✗
correspondence		✓	✓	✗	✓	✓	✗	✗
miscellaneous		✓	✓	✗	✓	✓	✗	✗
presentations		✓	✓	✗	✓	✓	✗	✗
literature		✓	✓	✗	✗	✓	✗	✗
manuscripts		✓	✓	✗	✗	✓	✗	✗
publications		✓	✓	✗	✗	✓	✗	✗
regulatory	✗	✓						
AgencyName		✓						
draft		✓	✓	✗	✗	✓	✗	✗
documents		✓	✓	✗	✗	✓	✗	✗
correspondence		✓	✓	✗	✗	✓	✗	✗
submitted		✓	✓	✗	✗	✓	✗	✗
documents		✓	✓	✗	✗	✓	✗	✗
correspondence		✓	✓	✗	✗	✓	✗	✗
drugs	✗	✓						
projects	✗	✓						
studies	✗	✓						

Studies - Analysis

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	✗							
🗐 documents		✓	✓	✗	✓	✓	✗	✗
✉ correspondence		✓	✓	✗	✓	✓	✗	✗
📂 crf		✓	✓	✗	✓	✓	✗	✗
📂 csr		✓	✓	✗	✓	✓	✗	✗
📂 miscellaneous		✓	✓	✗	✓	✓	✗	✗
📂 protocol		✓	✓	✗	✓	✓	✗	✗
📂 reports		✓	✓	✗	✓	✓	✗	✗
⇄ data	✗	✓						
🗄 **YYYY-MM-DD (dated transfer directory)**		✓	✓	✗	✗	✓	✗	✗
🔗 drugs	✗	✓						
🔗 projects	✗	✓						
🔗 studies	✗	✓						

Projects - Analysis

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	✗							
🗎 documents		✓	✓	✗	✓	✓	✗	✗
📂 analysis plans		✓	✓	✓	✓	✓	✗	✗
📂 minutes		✓	✓	✗	✓	✓	✗	✗
📂 miscellaneous		✓	✓	✗	✓	✓	✗	✗
📂 presentations		✓	✓	✗	✓	✓	✗	✗
📂 project management		✓	✓	✗	✓	✓	✗	✗
📂 reports		✓	✓	✗	✓	✓	✗	✗
📂 stages	✗	✓						
▤ **StageName**	✗	✓						
☑ **TaskName**		✓						
</> assembly	✗	✓	✓	✗	✗	✓	✗	✗
🗎 **Name**		✓	✓	✗	✗	✓	✗	✗
🗄 datasets		✓	✓	✗	✗	✓	✗	✗
📂 modified		✓	✓	✗	✗	✓	✗	✗
📂 simulated		✓	✓	✗	✗	✓	✗	✗
</> programs	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
🗎 **Name**		✓	✓	✓	✓	✓	✗	✗
</> analysis	⭐ Dir	✓	✓	✓	✓	✓	✗	✗
🗎 **Name**		✓	✓	✓	✓	✓	✗	✗
📈 graphs		✓	✓	✓	✓	✓	✗	✗
▦ tables		✓	✓	✓	✓	✓	✗	✗
🔗 drugs	✗	✓						
🔗 projects	✗	✓						
🔗 studies	✗	✓						

Team - Reviewer

Drugs - Reviewer

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
🩺 **DrugName**	❌							
🗐 documents		✅	❌	❌	✅	✅	❌	❌
✉ correspondence		✅	❌	❌	✅	✅	❌	❌
📂 miscellaneous		✅	❌	❌	✅	✅	❌	❌
📂 presentations		✅	❌	❌	✅	✅	❌	❌
📖 literature		✅	✅	❌	✅	✅	❌	❌
📂 manuscripts		✅	✅	❌	✅	✅	❌	❌
📂 publications		✅	✅	❌	✅	✅	❌	❌
🏛 regulatory	❌	✅						
🏢 **AgencyName**		✅						
✏ draft		✅	✅	❌	✅	✅	❌	❌
🗐 documents		✅	✅	❌	✅	✅	❌	❌
✉ correspondence		✅	✅	❌	✅	✅	❌	❌
↪ submitted		✅	✅	❌	✅	✅	❌	❌
🗐 documents		✅	✅	❌	✅	✅	❌	❌
✉ correspondence		✅	✅	❌	✅	✅	❌	❌
🔗 drugs	❌	✅						
🔗 projects	❌	✅						
🔗 studies	❌	✅						

Studies - Reviewer

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	✗							
🗐 documents		✓	✓	✗	✓	✓	✗	✗
✉ correspondence		✓	✓	✗	✓	✓	✗	✗
📂 crf		✓	✓	✗	✓	✓	✗	✗
📂 csr		✓	✓	✗	✓	✓	✗	✗
📂 miscellaneous		✓	✓	✗	✓	✓	✗	✗
📂 protocol		✓	✓	✗	✓	✓	✗	✗
📂 reports		✓	✓	✗	✓	✓	✗	✗
⇄ data	✗	✓						
🛢 **YYYY-MM-DD (dated transfer directory)**		✓	✓	✗	✗	✓	✗	✗
🔗 drugs	✗	✓						
🔗 projects	✗	✓						
🔗 studies	✗	✓						

Projects - Reviewer

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	❌							
🗐 documents		✅	✅	❌	✅	✅	❌	❌
📂 analysis plans		✅	✅	❌	✅	✅	❌	❌
📂 minutes		✅	✅	❌	✅	✅	❌	❌
📂 miscellaneous		✅	✅	❌	✅	✅	❌	❌
📂 presentations		✅	✅	❌	✅	✅	❌	❌
📂 project management		✅	✅	❌	✅	✅	❌	❌
📂 reports		✅	✅	❌	✅	✅	❌	❌
📂 stages	❌	✅						
▤ **StageName**	❌	✅						
☑ **TaskName**		✅						
</> assembly	❌	✅	✅	❌	❌	✅	❌	❌
📄 **Name**		✅	✅	❌	❌	✅	❌	❌
🛢 datasets		✅	✅	❌	❌	✅	❌	❌
📂 modified		✅	✅	❌	❌	✅	❌	❌
📂 simulated		✅	✅	❌	❌	✅	❌	❌
</> programs	❌	✅	✅	❌	❌	✅	❌	❌
📄 **Name**		✅	✅	❌	❌	✅	❌	❌
</> analysis	❌	✅	✅	❌	❌	✅	❌	❌
📄 **Name**		✅	✅	❌	❌	✅	❌	❌
📈 graphs		✅	✅	❌	❌	✅	❌	❌
▦ tables		✅	✅	❌	❌	✅	❌	❌
🔗 drugs	❌	✅						
🔗 projects	❌	✅						
🔗 studies	❌	✅						

Team - Stakeholder

Drugs - Stakeholder

Template Path	Create	View	Read & DL	Change Metadata	Upload Files	Comment on Files	Approve Import	Move Files
🩺 **DrugName**	❌							
📑 documents		✅	❌	❌	✅	✅	❌	❌
✉ correspondence		✅	❌	❌	✅	✅	❌	❌
📁 miscellaneous		✅	❌	❌	✅	✅	❌	❌
📁 presentations		✅	❌	❌	✅	✅	❌	❌
📖 literature		✅	✅	❌	❌	✅	❌	❌
📁 manuscripts		✅	✅	❌	❌	✅	❌	❌
📁 publications		✅	✅	❌	❌	✅	❌	❌
🏛 regulatory	❌	✅						
🏢 **AgencyName**		✅						
✏ draft		✅	✅	❌	❌	✅	❌	❌
📑 documents		✅	✅	❌	❌	✅	❌	❌
✉ correspondence		✅	✅	❌	❌	✅	❌	❌
🔗 submitted		✅	✅	❌	❌	✅	❌	❌
📑 documents		✅	✅	❌	❌	✅	❌	❌
✉ correspondence		✅	✅	❌	❌	✅	❌	❌
🔗 drugs	❌	✅						
🔗 projects	❌	✅						
🔗 studies	❌	✅						

Studies - Stakeholder

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
📊 **StudyName**	❌							
🗐 documents		✅	✅	❌	✅	✅	❌	❌
✉ correspondence		✅	✅	❌	✅	✅	❌	❌
📂 crf		✅	✅	❌	✅	✅	❌	❌
📂 csr		✅	✅	❌	✅	✅	❌	❌
📂 miscellaneous		✅	✅	❌	✅	✅	❌	❌
📂 protocol		✅	✅	❌	✅	✅	❌	❌
📂 reports		✅	✅	❌	✅	✅	❌	❌
⇄ data	❌	✅						
🗄 **YYYY-MM-DD (dated transfer directory)**		❌	❌	❌	❌	❌	❌	❌
🔗 drugs	❌	✅						
🔗 projects	❌	✅						
🔗 studies	❌	✅						

Projects - Stakeholder

Template Path	Can Create	View	Read & DL	Change Meta	Upload Files	Comment on Files	Approve Import	Move Files
💼 **ProjectName**	✗							
🗐 documents		✓	✓	✗	✓	✓	✗	✗
📂 analysis plans		✓	✓	✗	✓	✓	✗	✗
📂 minutes		✓	✓	✗	✓	✓	✗	✗
📂 miscellaneous		✓	✓	✗	✓	✓	✗	✗
📂 presentations		✓	✓	✗	✓	✓	✗	✗
📂 project management		✓	✓	✗	✓	✓	✗	✗
📂 reports		✓	✓	✗	✓	✓	✗	✗
📂 stages	✗	✓						
☰ **StageName**	✗	✓						
☑ **TaskName**		✓						
</> assembly	✗	✓	✗	✗	✗	✗	✗	✗
📄 **Name**		✓	✗	✗	✗	✗	✗	✗
🛢 datasets		✓	✗	✗	✗	✗	✗	✗
📂 modified		✓	✗	✗	✗	✗	✗	✗
📂 simulated		✓	✗	✗	✗	✗	✗	✗
</> programs	✗	✓	✗	✗	✗	✗	✗	✗
📄 **Name**		✓	✗	✗	✗	✗	✗	✗
</> analysis	✗	✓	✗	✗	✗	✗	✗	✗
📄 **Name**		✓	✗	✗	✗	✗	✗	✗
📈 graphs		✓	✗	✗	✗	✗	✗	✗
▦ tables		✓	✗	✗	✗	✗	✗	✗
🔗 drugs	✗	✓						
🔗 projects	✗	✓						
🔗 studies	✗	✓						