SliceVault User Guides

The easy and compliant way to transfer medical images in clinical trials

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Preface

This manual is created for SliceVault v3.4.0

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Disclaimer

SliceVault provides a cloud-based service (the “platform” or “SliceVault”) to transfer, store, manage and share medical imaging data in clinical trials. No parts of the platform are categorized as a medical device by the FDA or EMA.

SliceVault comes with software systems for de-identification of medical imaging data. The responsibility for de-identification is in the hands of the person responsible for importing data to SliceVault.

SliceVault does not guarantee the correctness of data processed through its services.

Intended use/indications for use

SliceVault is intended to be used to transfer, store, manage and share medical imaging data in clinical trials.

SliceVault is intended to be used by trained professionals.

SliceVault is intended to be used in clinical trials, where the sponsor or other responsible party warrants that the clinical trial complies with applicable laws, rules, regulations, ICH guidelines for Good Clinical Practice, the Declaration of Helsinki, and study protocols and relevant permits related to the clinical trial are issued or approved by governments, regulatory authorities or ethics committees.

SliceVault key features

User authentication and authorization

- Closed system with restricted access

Data import

- Supports data in DICOM format and standard video and image formats
- Automatic de-identification of DICOM images
- Automatic redaction of images with burned in annotations

Data management

- Role based access to data and functionality
- Submit, manage and track data
- View imported data in the embedded DICOM viewer

- Querying functionality to open, resolve and close queries
- Role-based forms (case report forms, data transmittal forms, image quality control forms)
- Reader blinding

Auxiliary functions

- Secure audit logging
- Manage users and user groups

Software version numbering

SliceVault follows semantic versioning, where bug fixes will update the version number in the format 3.0.x., minor changes will update the version number in the format 3.x.0 and major changes will update the version number in the format x.0.0. This manual is valid for all future 3.x.x versions until a new manual is released.

Definitions

The table below defines the symbols used in this manual, their occurrence and meaning.

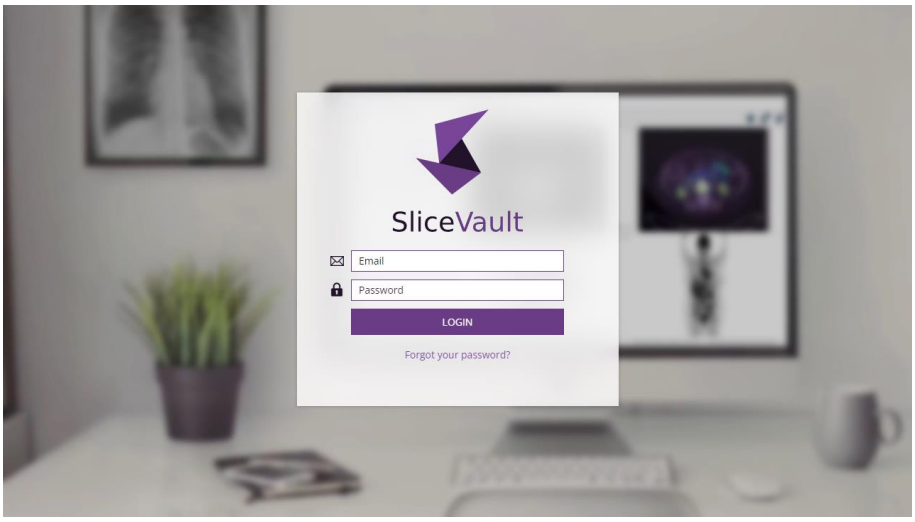
Symbol	Occurrence	Meaning
	In the user manual	Warning/caution. Is always clarified with an explanation.

Software errors and warnings

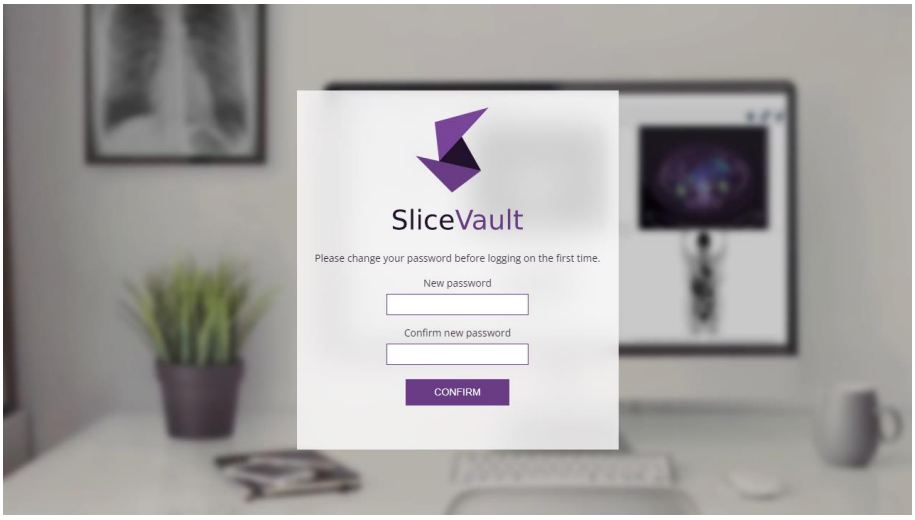
Unforeseen software errors and warning may appear in the browser, when users interact with the SliceVault. To help us prevent the error from happening in future versions SliceVault, you are requested to forward the error message to the SliceVault support team by sending an email to support@slicevault.com.

How to log in to your SliceVault account

1. Open a web browser.
2. Visit the login site written in the login email
   https://login.slicevault.com or
   https://company.slicevault.com
3. Enter your email address and password and click login.



Users logging in for the first time are requested to change password after login. Users are requested to change password at least every 3 months.

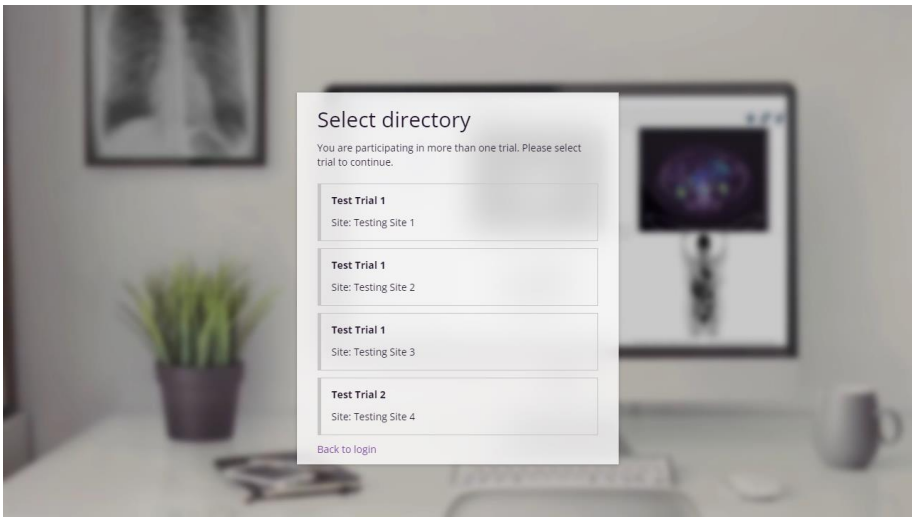


Users will see an error notification if the username or password is incorrect.

User accounts are suspended after five failed login attempts. Contact your trial administrator or SliceVault for support at support@slicevaut.com if your account is suspended.

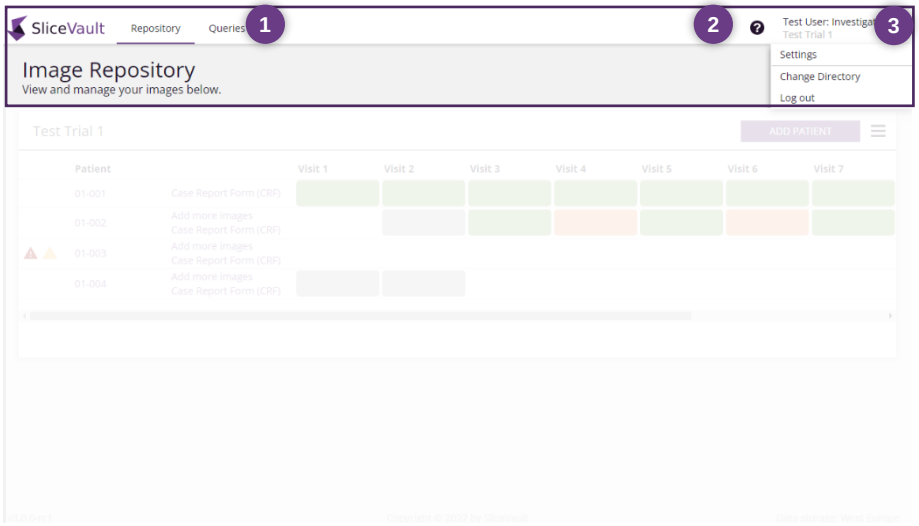
Users with access to only one trial are automatically redirected to their trial repository after log in.

Users with access to more than one trial must first select trial, after which the user is automatically redirected to their selected trial repository.



How to navigate SliceVault

The top navigation bar is the main navigation bar in SliceVault.

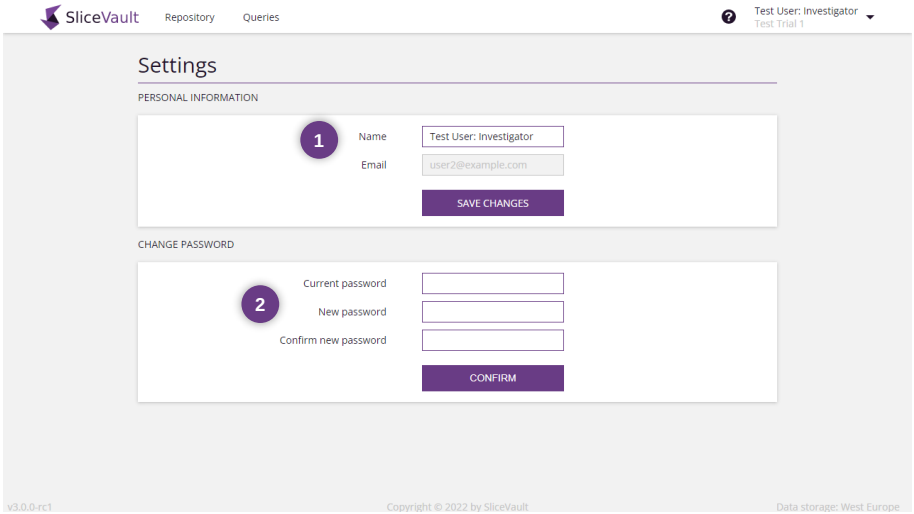


1. From the navigation bar you can access all your permitted sites.
2. A help section with step-by-step guides to all key functionalities is available to all users.
3. A dropdown menu with the user's name and trial name. From here the user can access and manage user settings, change directory (if the user has access to more trials) and log out.

Users are automatically logged out when the user is idle for more than 60 minutes. Users are recommended to log out of SliceVault and close their browser when SliceVault is not in use.

How to manage my user account

The user settings site is available via the dropdown menu in top navigation bar.



1. Users can change user name
2. Uses can change password. To change password users must type valid existing password, type new password and repeat new password.

Password must be at least 8 characters.
Password must have at least one digit.
Passwords must have at least one capital letter.
Password cannot replicate any of the three previous passwords used by the user.

A quick guide – step by step

This quick guide presumes that you have access to SliceVault and valid login credentials. It does not describe all functions of SliceVault, but aims to provide you with a quick overview of what you can do in SliceVault: how to access SliceVault, import and submit data. It is recommended that you read the whole manual before you start using SliceVault.

Log in to SliceVault

- Go to your login page and type in username and password, after which you will be redirected to the trial repository site.
- Select your desired trial if requested by the system.

Import data

- Click “add patient” to register a new patient or click “add more images” from the patient list to upload data to an already registered patient.
- Select the series to be imported and click next.
- Select visit name and image type for all series and click next, after which data is de-identified and uploaded to SliceVault.
- Select patient ID if requested by the system.

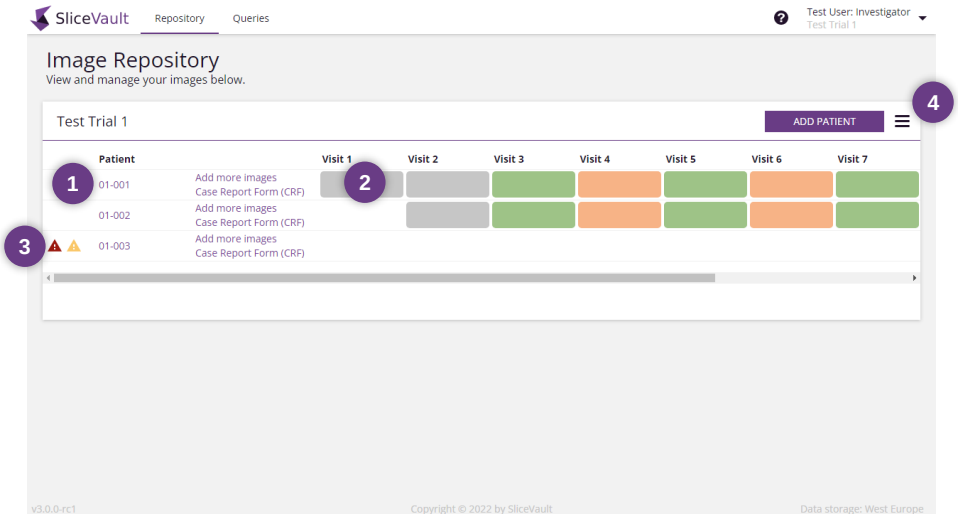
Submit data

- The patient list on the repository site contains all registered patients and provides an overview of all data imported to each patient.
- Click the coloured square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit.
- On the visit dashboard you can submit data by clicking “submit to QC”.

Understanding the main repository site

The repository site is the main site for most users. Here you can upload new data and see the patient list to submit and manage already uploaded data.

The patient list gives a complete overview of data uploaded to SliceVault from all users belonging to your user-group. The columns in the patient list will be customized to your clinical trial, and will not look exactly like the example below.



1. Click the Patient ID to change patient ID and trial enrollment status.
2. Click the colored square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit.
3. ⚠ This warning is displayed when an error has occurred during data upload and as a result SliceVault is not able to display the uploaded data correctly. Please contact SliceVault for support at contact@slicevault.com.
   ⚠ When this warning message is displayed, the patient is no longer enrolled in the trial. Please contact the Quality Control Manager for more information and to re-enroll the patient.
4. In a dropdown menu users have access to additional functionality. You can show/hide visit status.

The colors of the squares in the patient list refers to the status of the visit, where:

No data is uploaded to the visit

Data is uploaded but visit not yet submitted

Visit approved by QC 1, QC 2 and/or Readers

Visit rejected by QC 1, QC 2 and/or Readers

Visit approved by Readers in trial with special reader blinding

The colored squares can also be home to different icons, and these icons are visible when there is something in particular you should be aware of.

The query sign is shown when a visit has an open query

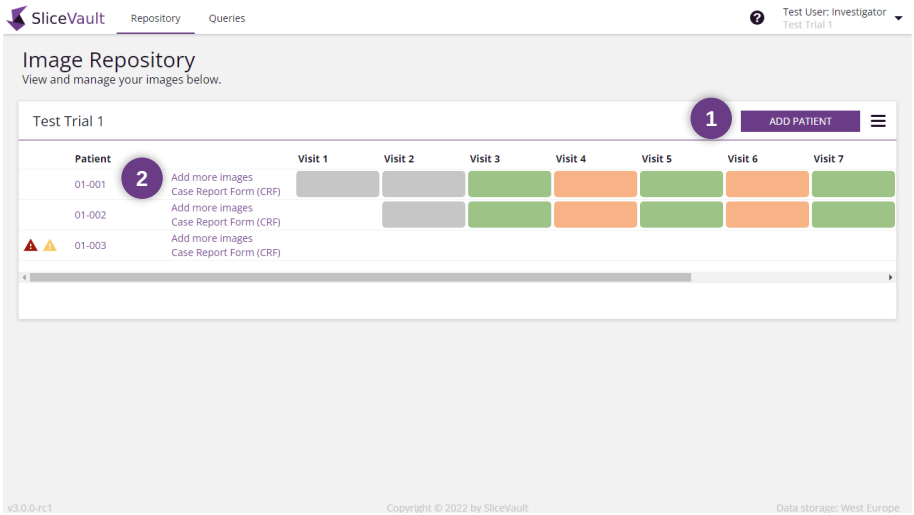
The checklist sign is shown when you have not yet completed your quality control checklist

How to upload data to SliceVault

Users are recommended to stay on the SliceVault website during upload. Switching to other applications or websites will significantly slow down the upload process. Closing the SliceVault website will cause fatal errors. The duration of upload depends on your internet connection and the amount of data you are uploading.

Start data import process

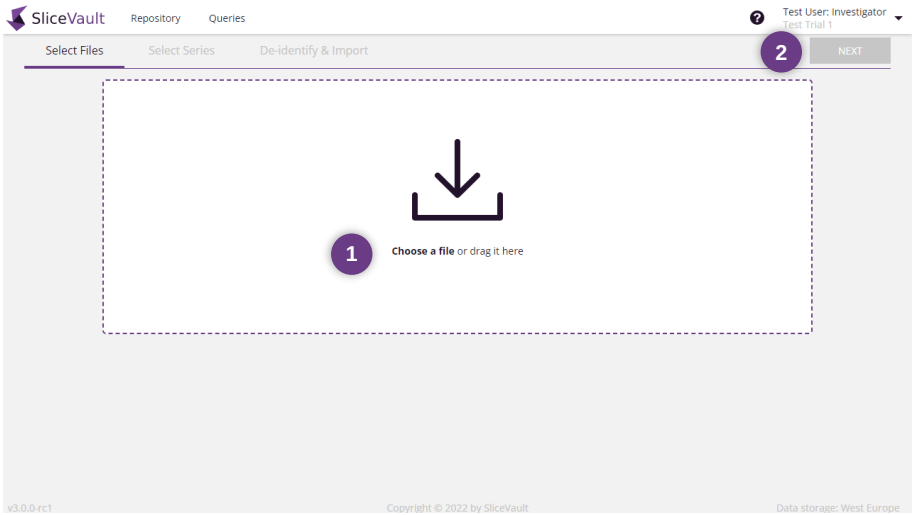
Users can start the data import process from the main repository site.



1. Click the “add patient” button to start the import process when adding data for a patient that is not yet registered on SliceVault.
2. Click the “add more images” link next to the patient with the right patient ID if you would like to add more data to an already registered patient.

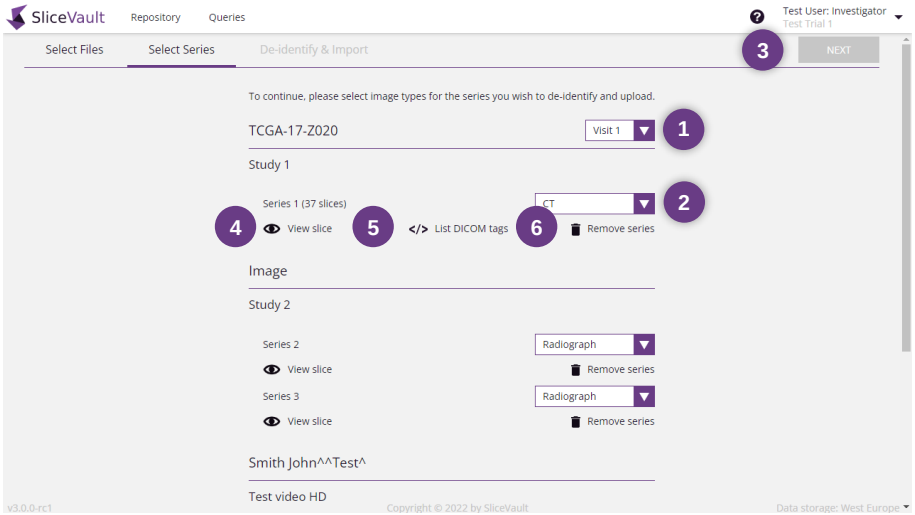
Step 1: Select files for import

SliceVault does not integrate into any picture archiving and communication systems (PACS). Users must export data from local PACS following local instructions before importing data to SliceVault. Please consult your local system administrator if you have difficulties exporting files.



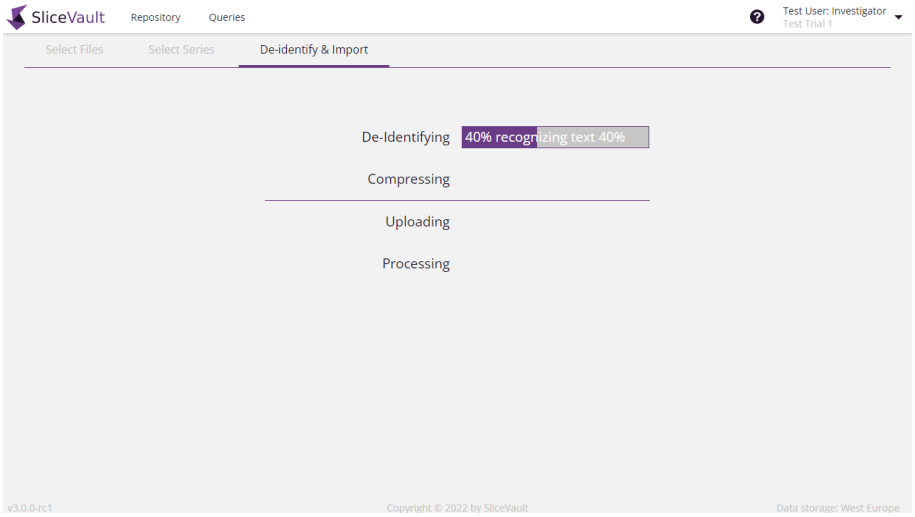
1. Drag and drop files to the drop zone or by clicking “choose a file” to select from file explorer.
2. The “next” button is enabled once you place files in the drop zone. Click “next” to proceed.

Step 2: Select series for import



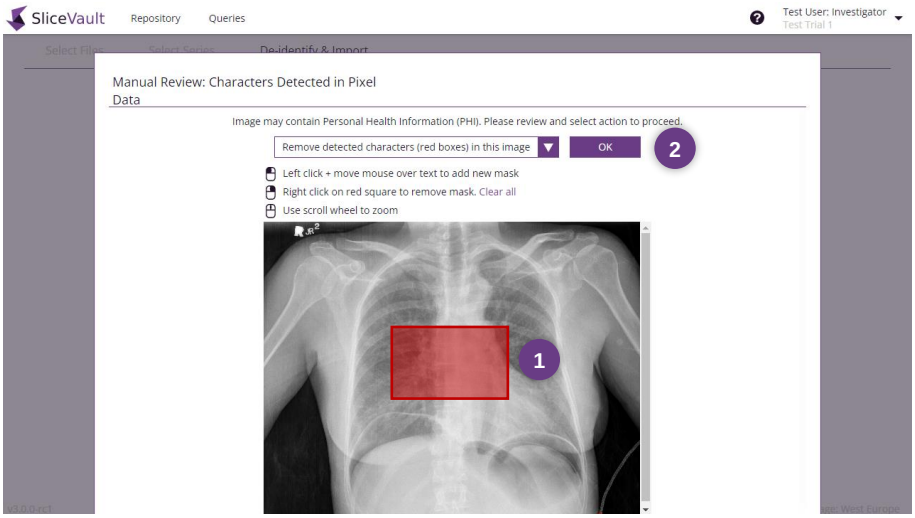
1. Select the visit to which the data belongs, to make sure data is labelled and analysed correctly. It is important that you select the right visit here, as you cannot change this later.
2. Files are sorted by patient and series. Select the correct data type from the dropdown to make sure data is labelled and displayed correctly.
3. When you have selected visit and data type for all series the “next” button is enabled. Click “next” to proceed.
4. Optional: You can view data in DICOM viewer to ensure you are about to upload correct data.
5. Optional: Click to see DICOM tags to compare tags before and after de-identification.
6. Optional: Click to remove series from upload.

Step 3: De-identification and upload



All data is de-identified locally before it is transferred to SliceVault. The de-identification procedure is rigorous and fully automated process executed in your browser, combining both DICOM tag redaction and optical character recognition.

- SliceVault provides a script for DICOM tag redaction in order to remove Personal Health Information (PHI) before data is uploaded to SliceVault. The script conforms to the requirement set forth in the current DICOM standard. No user input is required.
- After DICOM rag redaction, all files known to typically store PHI are scanned for burned in annotations, i.e., characters embedded directly in the pixels. SliceVault use optical character recognition to scan for characters, and user input is required if characters are detected.

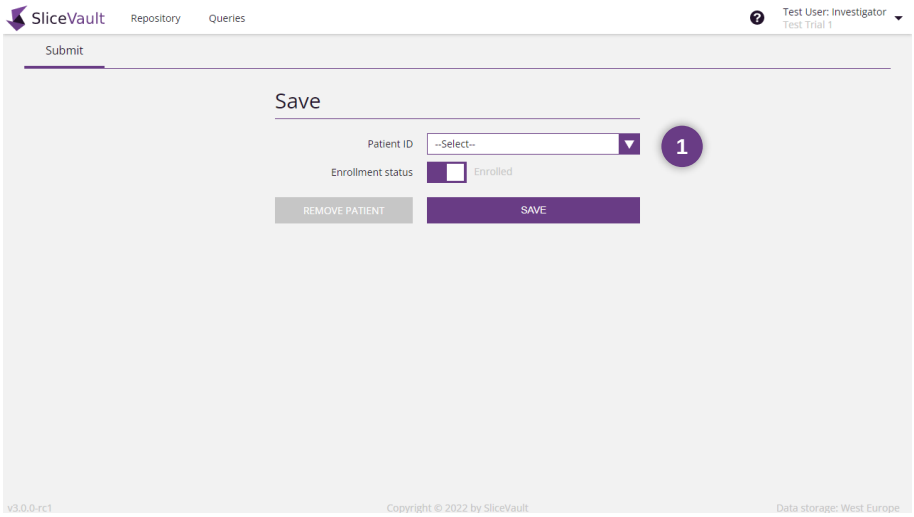


1. If characters are detected, use the mouse to mask areas containing PHI. Masks are replaced with black boxes and users can add multiple masks.
2. Select redaction action and click the “ok” button to continue the upload process.

When the de-identification process is complete, data is compressed and uploaded to SliceVault via secure and encrypted communication (SSL).

Step 4: Assign patient ID

After upload the user is redirected to this site, when adding data for a patient that is not yet registered on SliceVault. If the user is adding more data to an already registered patient the user is redirected to the repository site.

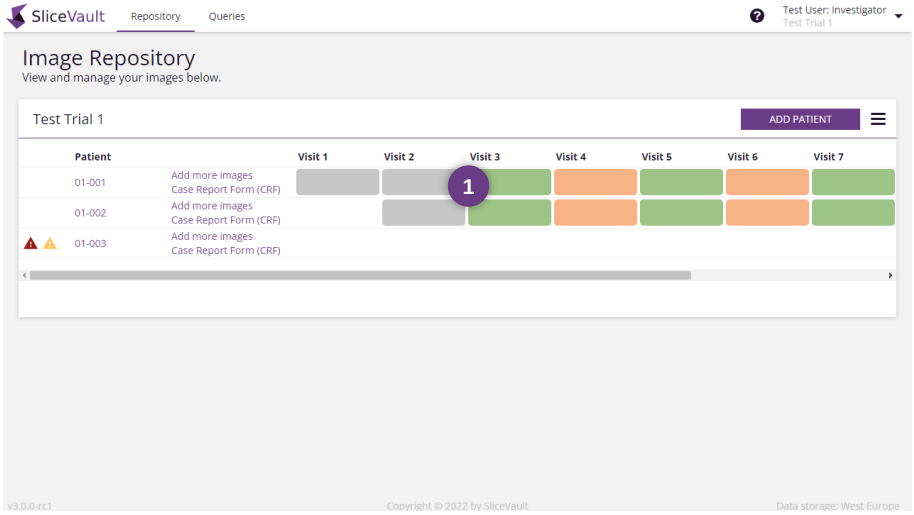


1 Users must select patient ID. Depending on trial setup, the user can either choose between pre-assigned patient IDs and/or specify patient ID themselves.

For compliance reasons users are advised not to specify patient IDs that can be used to re-identify patients (e.g., patient names or social security numbers).

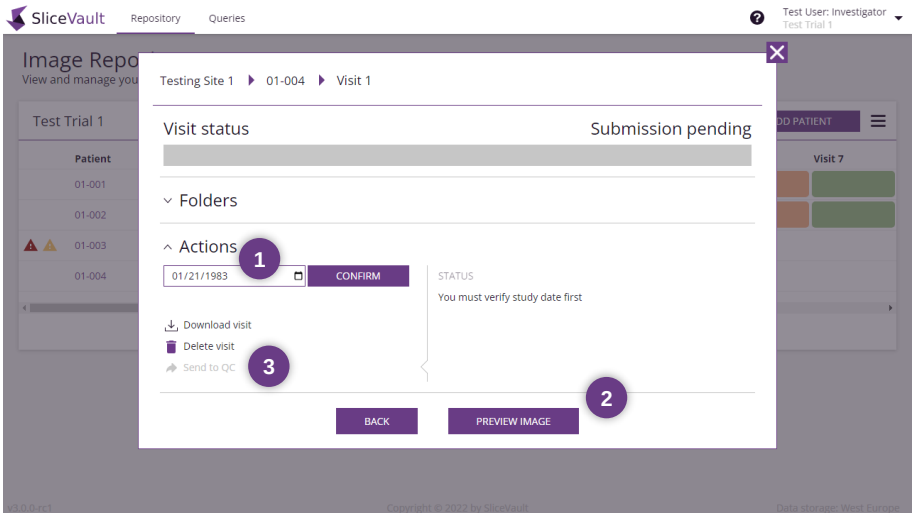
How to manage and view uploaded data

How to submit data



1 Open the visit dashboard to submit uploaded data. Locate the patient with the right patient ID in the patient list, and click on the square for the visit you would like to submit.

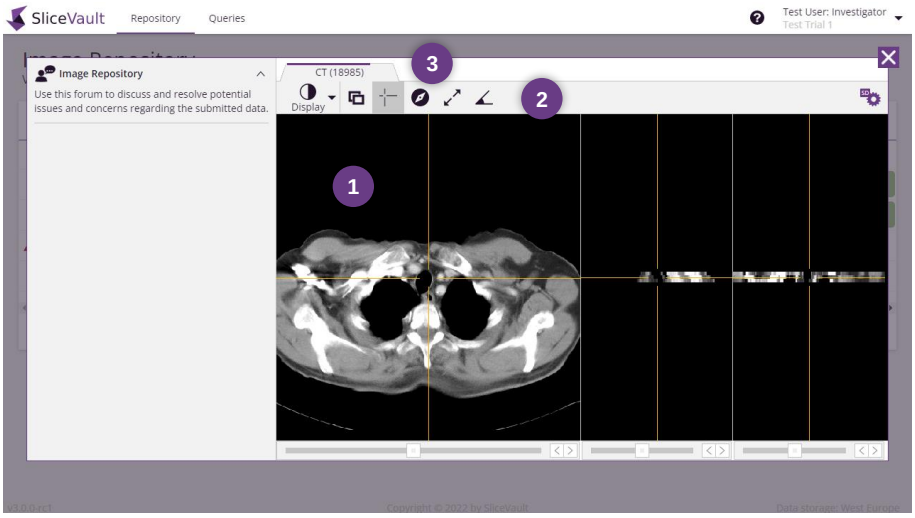
Current visit status is visible in the top section of the visit dashboard. All files uploaded to the visit folder is accessible from the middle section, where you can also view, download and delete individual files. In the bottom section you can view, download and delete the entire visit.



1. If required, you must confirm the study date before you can submit data.
2. If submitting a Data Transmittal Form (DTF) is a requirement in your trial, you must complete the DTF before you can submit data. Click the preview button to complete the form.
3. Click “send to QC”.

How to view data

Once you have opened the visit dashboard for your chosen visit, you can click the “preview image” button to view the image in the embedded DICOM viewer.

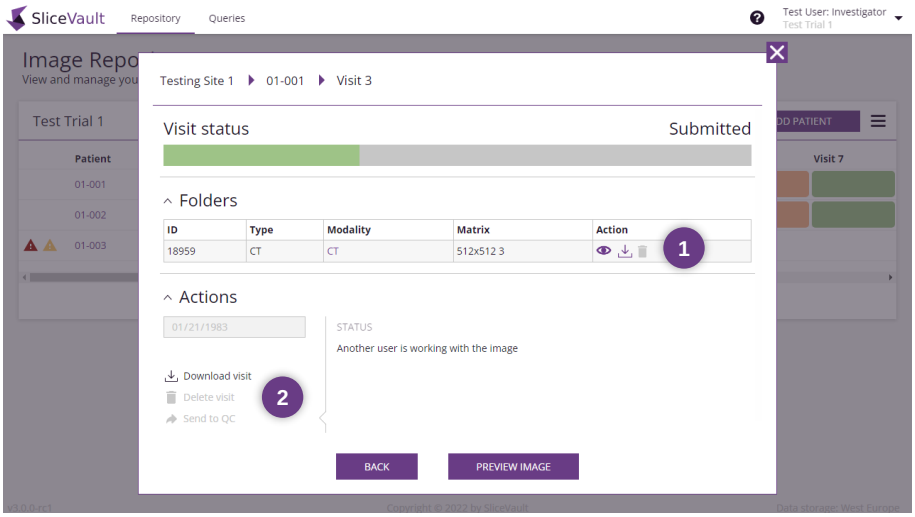


1. Images are displayed here. The default view depends on the selected image type.
2. Users can change display settings from the main control bar.

3 Users can switch between images by changing tab if the visit contains more than one image.

How to delete data

You can delete images or whole visits on the visit dashboard.



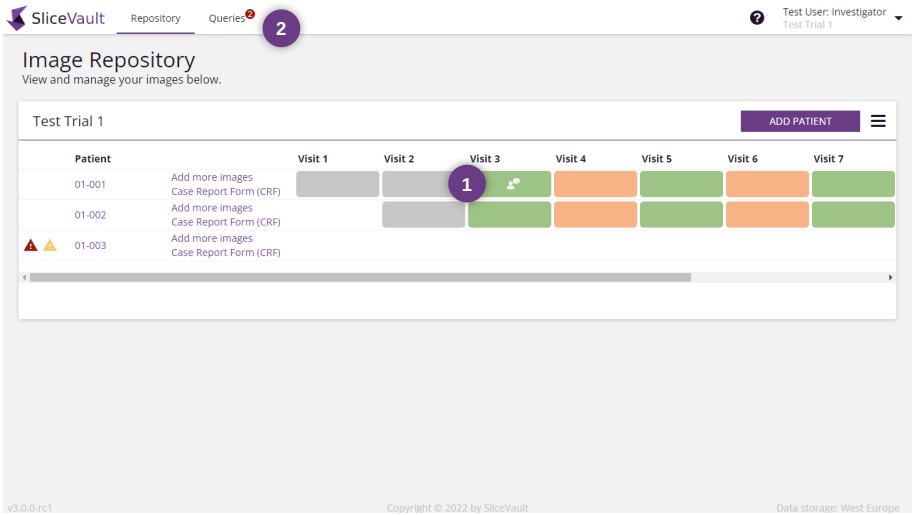
1 Open the “folder” section to delete images individually. Look for the trashcan icon.

2 Click the “delete visit” link to delete the visit including all data uploaded to the visit.

The delete functionality is enabled when a) the visit has not yet been submitted or b) is rejected by one of the Quality Control managers or Readers. At all other times, the delete functionality is disabled. In the screenshot above, for example, the delete functionality is disabled because the visit is submitted.

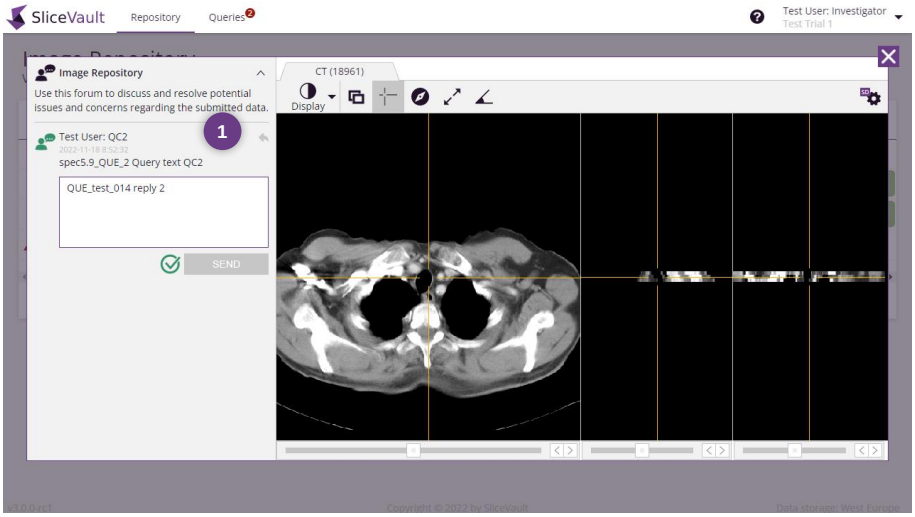
How to respond to queries

SliceVault querying module lets you respond to queries within the same system. You will be notified by email if a query is opened for you.



1. Users can see a querying icon on the visit dashboard if a query is open for the visit.
2. Users can see an overview of all queries on a separate query site.

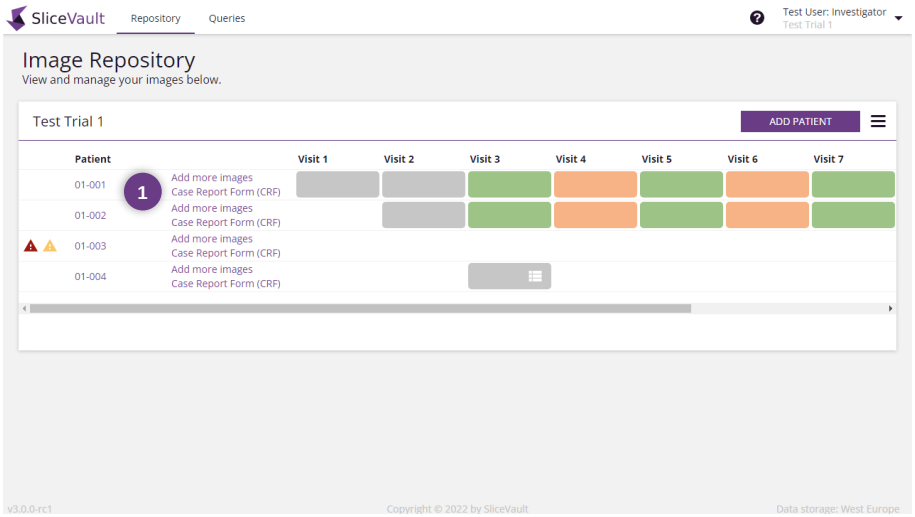
To respond to a query, you must first open the visit dashboard and click “preview image” as per section: How to manage and view uploaded data



1. Queries are listed in the left pane. To post a reply you must first click the reply icon (arrow) for the query to which you would like to reply (the list might contain more than one query). This opens a text field, where you can type your reply. When you are done you can click “send” to post your reply.

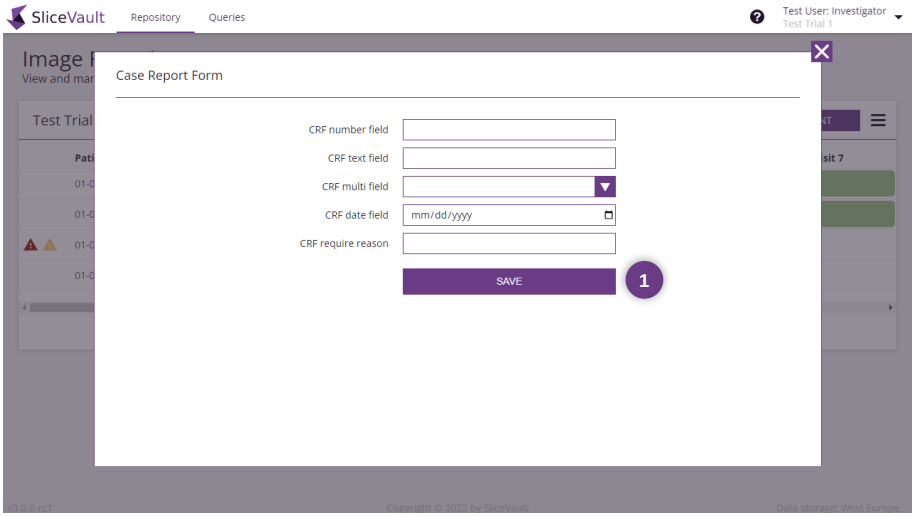
How to fill out a case report form

Depending on your trial, you might be required to submit a case report form per patient. Users can fill out case report forms directly from the repository site.



1. Locate the row containing the patient ID, for which you would like to fill out a case report form, and click the “case report form (CRF)” link to open access the form.

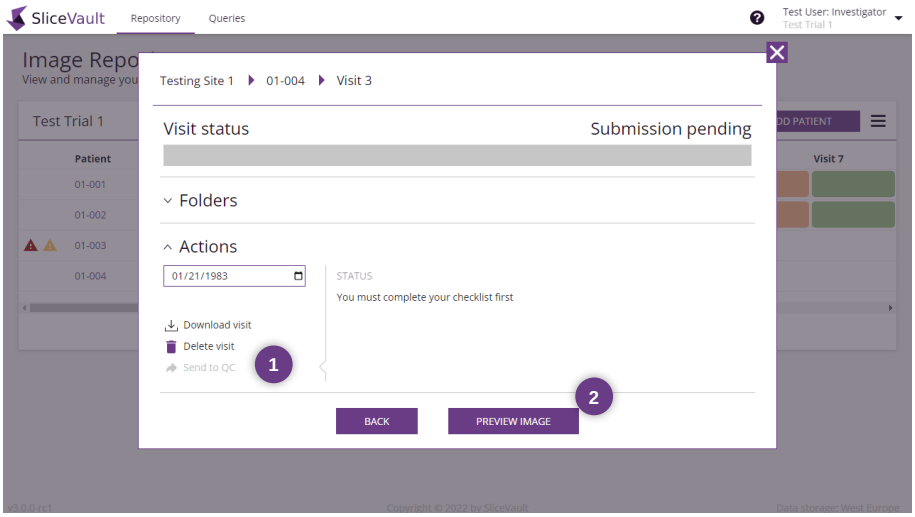
Please note, the “case report form (CRF)” link is hidden if such forms are not required for your trial in SliceVault.



1 Fill out the fields and click the “save” button to save your form.

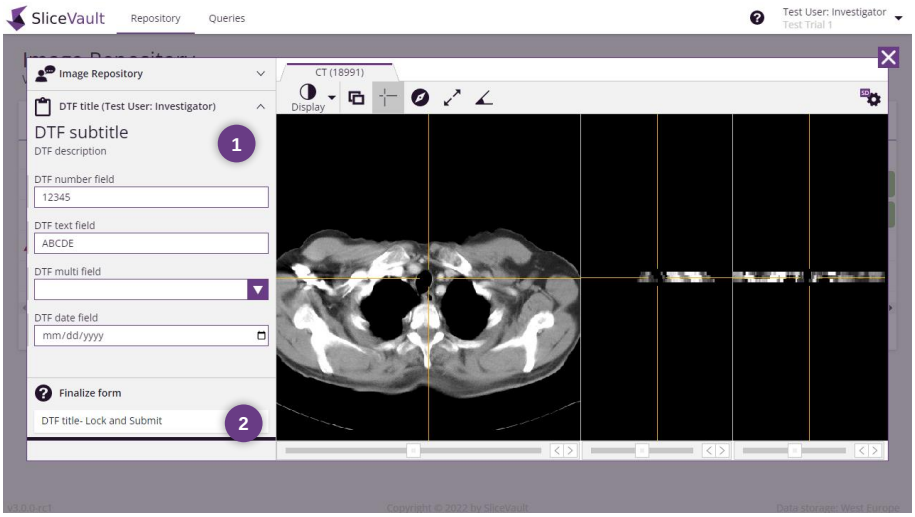
How to complete a data transmittal form

Depending on your trial, you might be required to submit data transmittal forms as part of your data submission. You will be notified on the visit dashboard, if you are required to submit a data transmittal form. Data transmittal forms can be different from visit to visit.



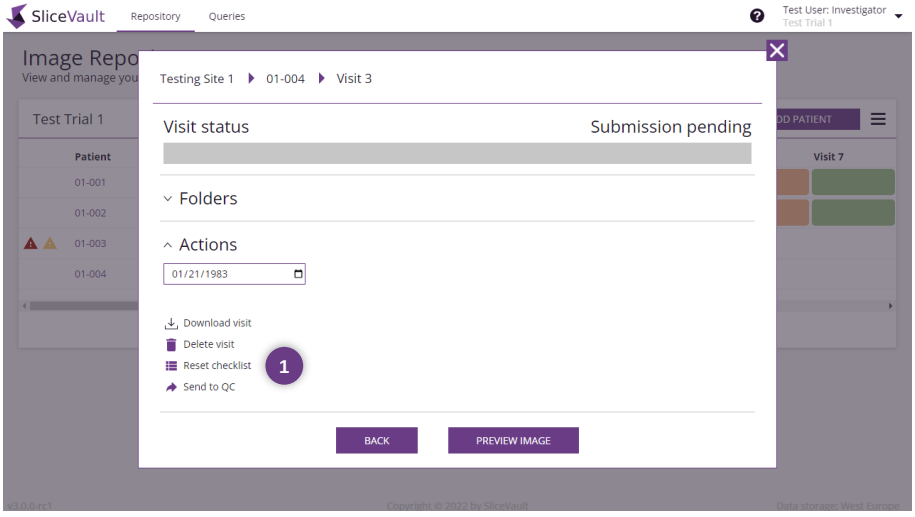
1 You must submit the data transmittal form before you can submit data.

2 The data transmittal form is accessible in the image viewer. Click the “preview image” button.



1. The data transmittal form is visible next to the DICOM viewer.
2. Fill out all required fields and click the “lock and submit” button to submit the form, after which the form becomes read-only.

If you discover a mistake in a locked form, you can reset the form from the visit dashboard.

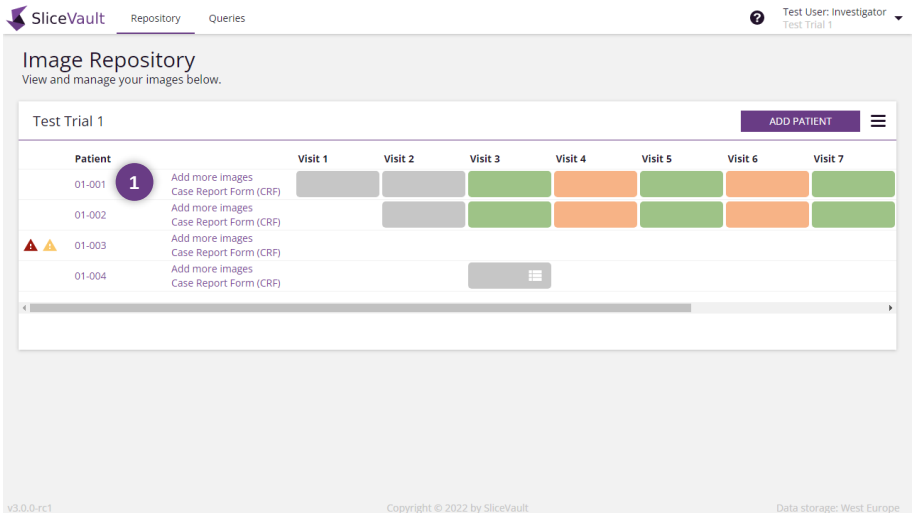


1. Click the “reset checklist” link to reset a form. Please note, all form fields will be emptied.

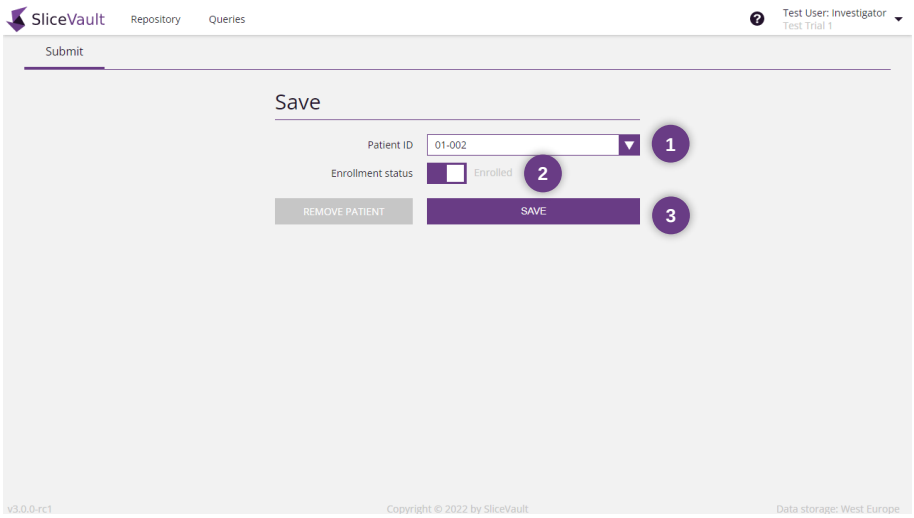
When the form is locked, the “send to QC” link is enabled.

How to change patient ID or trial enrollment status

You can access functionality to change patient ID and trial enrollment status on the patient list.



1. Locate the row containing the patient ID you would like to change. Click the “patient ID” link (e.g., 01-002).



1. Depending on trial setup, the user can either choose between pre-assigned patient IDs and/or specify patient ID themselves.
2. Users can change status from enrolled to not enrolled.
3. Click save to save changes. Please note, you might be asked to provide a reason for the change.

Once you have changed trial enrolment status to “not enrolled” you cannot re-enroll the patient again. Please contact your Quality Control Manager or SliceVault Support at support@slicevault.com to re-enroll a patient.

Frequently asked questions

How to re-upload data in case of rejection

There are two ways to do this, but the way choose depends on the situation.

If the image has been rejected during QC (by one of the Quality Control Managers), you must first delete the visit as per section: How to delete data. When the visit is deleted, you can follow the steps in section: 'How to upload data to SliceVault' to upload new data.

If the image has been rejected by the Reader, you cannot delete the visit. Instead, you must upload supplementary images to the already submitted visit. Visits that get rejected by Reader is "opened" again to the Investigators, and you can add supplementary images by following the steps in section: 'How to upload data to SliceVault'.

How do I submit data when 'submit to QC' is disabled?

The 'submit to QC' link can be disabled for many reasons. Follow the steps below to troubleshoot:

- Make sure you have confirmed the study date on the visit dashboard
- Make sure to fill out and click "lock and submit" on any required data transmittal form
- Wait for the data import process to finalize

How do I add more data when the "add more data" link is hidden?

The option to add more data to an existing patient is disabled for patients where all visits are submitted. Please contact your Trial Administrator or SliceVault Support via support@slicevault.com to re-open an already submitted visit.

How do I add a new patient when the "add patient" button is disabled?

The option to add patients can be disabled for many reasons. Follow the steps below to troubleshoot:

- You user-role does not permit you to add data
- There are no more vacant Patient IDs assigned to your site

Please contact your Trial Administrator or SliceVault Support via support@slicevault.com to resolve the issue.

SliceVault for Quality Control Managers

A quick guide – step by step

This quick guide presumes that you have access to SliceVault and valid login credentials. It does not describe all functions of SliceVault, but aims to provide you with a quick overview of what you can do in SliceVault: how to access SliceVault, fill out quality control checklists, open and close queries and change visit status. It is recommended that you read the whole manual before you start using SliceVault.

Log in to SliceVault

- Go to your login page and type in username and password, after which you will be redirected to the trial repository site.
- Select your desired trial if requested by the system.

Fill out quality control checklists

- The patient list on the repository site contains all registered patients and provides an overview of all data imported to each patient.
- Click the coloured square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit.
- Click “preview image” to open the embedded DICOM viewer. Next to the image is the quality control checklist. Fill it out and hit the “lock and submit” button.

Open and close queries

- Click “preview image” on the visit dashboard. Locate the query field next to the viewer to open and post a new query. Investigators will be notified automatically.
- When a query is resolved, you can close it by clicking on the tick mark icon in the query section of the DICOM viewer.

Change visit status

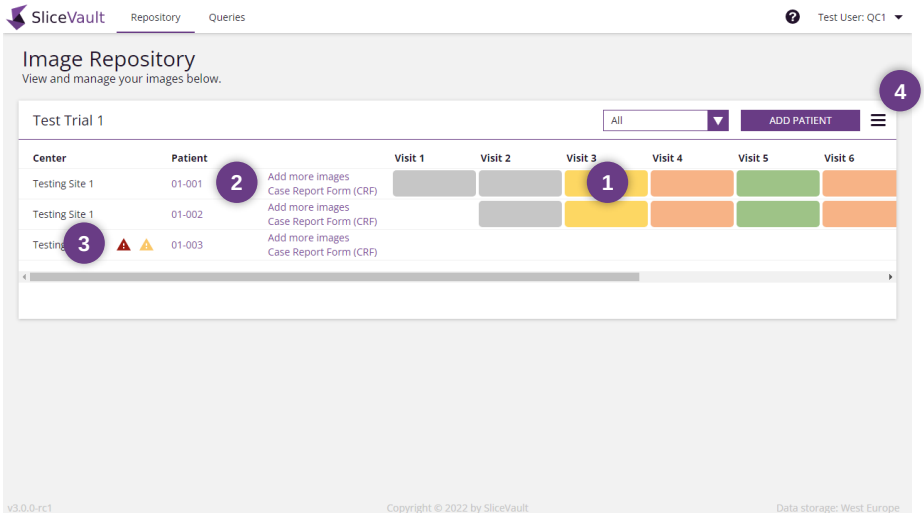
- Locate the status dropdown on the visit dashboard to change visit status. If the dropdown is disabled, look for the reason given to you on the visit dashboard, and follow the steps to enable the functionality.

Understanding the main repository site

Quality Control Managers can view and download submitted data, fill out quality control checklists, open and close queries, change visit status, download a variety of project reports, import data on behalf of investigators and more.

Quality Control Managers can have access to data from all sites or have restricted access to a subset of sites depending on your trial configuration. As such, one or more Quality Control Managers can share the workload.

The patient list gives a complete overview of data uploaded to SliceVault that is available to you. The columns in the patient list will be customized to your clinical trial, and will not look exactly like the example below.



1. Click the colored square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit and it is from here, you can complete your quality control checklist.
2. Click the Patient ID to change patient ID and trial enrollment status.
3. ⚠ This warning is displayed when an error has occurred during data upload and as a result SliceVault is not able to display the uploaded data correctly. Please contact SliceVault for support at contact@slicevault.com.

   ⚠ When this warning message is displayed, the patient is no longer enrolled in the trial. Please contact the Quality Control Manager for more information and to re-enroll the patient.
4. In a dropdown menu users have access to additional functionality. For example, you can download several study reports depending on your trial configuration.

The colors of the squares in the patient list refers to the status of the visit, where:

No data is uploaded to the visit

Data is uploaded but visit is not yet available to you

Visit is ready for you and pending your input

Visit approved and might be pending input from another user

Visit rejected and pending input from another user

Visit approved by Readers in trial with special reader blinding

The colored squares can also be home to different icons, and these icons are visible when there is something in particular you should be aware of.

The query sign is shown when a visit has an open query

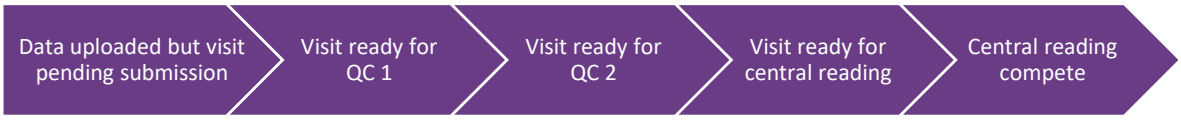
The checklist sign is shown when you have not yet completed your quality control checklist

The warning sign is shown when the deadline has passed for completing your quality control checklist. Depending on the trial you will typically have a given number of days to perform you QC assessment.

Understanding visit status

Here we will go through all key functionalities available to Quality Control Managers, but before we get started, let us take a look at the general structure of image management in SliceVault, and how that relates to the you as Quality Control Manager. This is important in order to understand when your input is required and why you do not have access to data and functionality at all times.

The overall data processing workflow in SliceVault consists of consecutive steps:



When an investigator uploads data to SliceVault, the data will remain accessible to users belonging to the investigator site only. Users at the investigator sites have full control over the data, and can view, download, delete and submit the visit to QC.

After submission to QC, the image is ready for QC 1. Now, users belonging to the investigator site can no longer make change to the data, as control is handed over to QC 1. QC 1 can complete their quality control checklist, view, download and delete the visit, and change the visit status. If QC 1 rejects the visit, the visit and control is returned to the users belonging to the investigator site (step 1). If QC 2 approves the visit, the visit and control is sent forward to QC 2 (step 3).

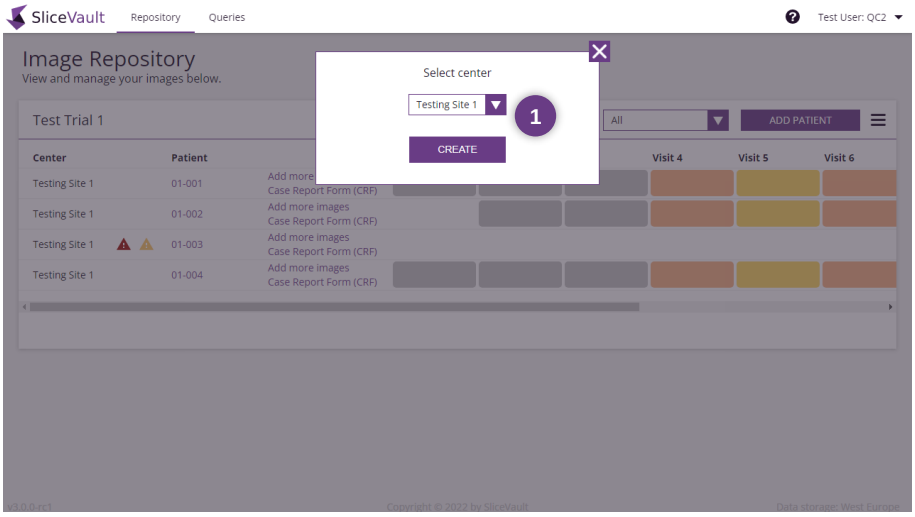
When QC 2 can access and have control over the visit, they can complete their quality control checklist, view, download and delete the visit, and change the visit status. If QC 2 rejects the visit, the visit and control is returned to the users belonging to the investigator site (step 1). If QC 2 approves the visit, QC 2 can forward the data forward to central reading (step 4).

Readers can now view and download the visit to complete reader assessments. Readers can reject the visit (send visit and control back to QC 1 and QC 2) or approve the visit with no further steps required (step 5).

As such, access to functionality and data depends on both visit status and user role. Even though the tasks at hand seem similar for both Quality Control Managers, their input is required at different stages of the overall data processing workflow.

How to upload data to SliceVault on behalf of investigators

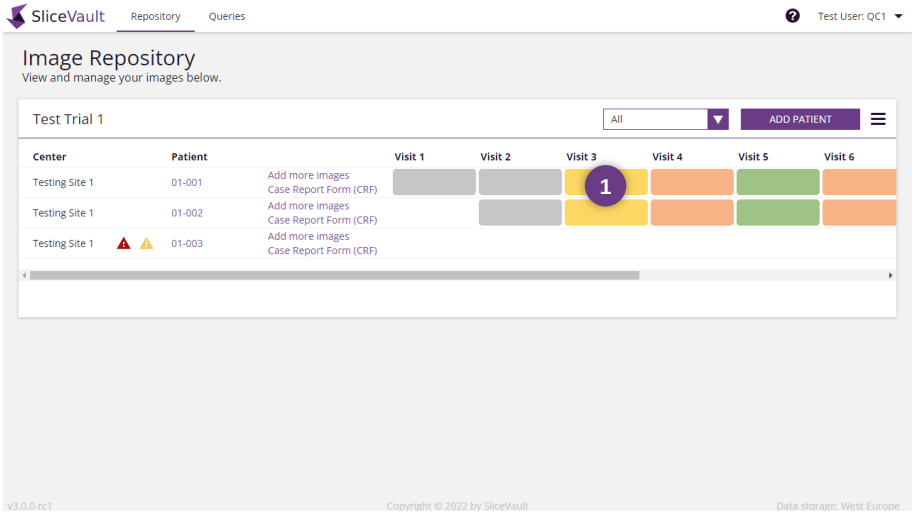
Quality Control Managers can upload data to SliceVault on behalf of Investigators. The process follows the steps in section: 'How to upload data to SliceVault'. However, Quality Control Managers are required to select Investigator site, to specify data ownership, when adding data for a patient that is not yet registered on SliceVault. Please see step below before proceeding to section: 'How to upload data to SliceVault'.



1 Select investigator site in the dropdown and click create. Data will be uploaded to the chosen investigator site and the visit will automatically receive status "submitted to QC" and control handed over to QC 1.

How to perform quality control check

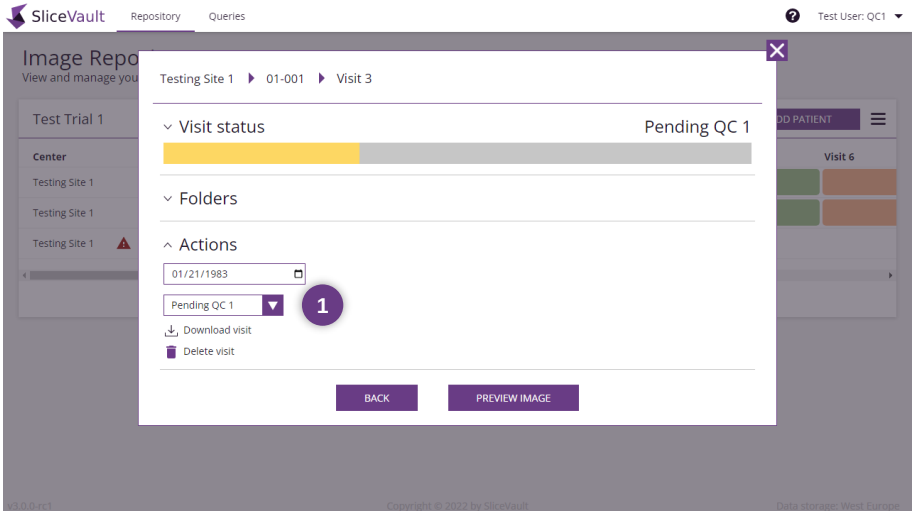
It is time for your quality control check when you see a yellow-colored square. This indicates that the visit is ready for you and your input is required to progress the visit in the overall data processing workflow.



1 The visit dashboard is home to all the functionality you need in order to perform your quality control check. Locate the patient with the right patient ID in the patient list and click on the yellow square to open the visit dashboard.

How to change visit status

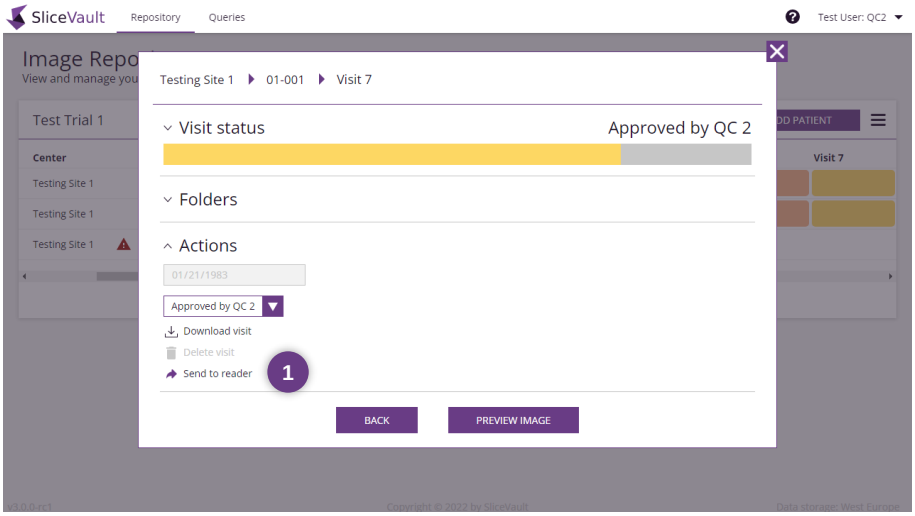
Current visit status is visible in the top section of the visit dashboard. All files uploaded to the visit folder is accessible from the middle section, where you can also view, download and delete individual files. In the bottom section you can view, download and delete the entire visit.



1 Use this dropdown to select visit status.
QC 1 can select: pending QC 1, approved by QC 1 and rejected by QC 1.
QC 2 can select: approved by QC 1, approved by QC 2 and rejected by QC 2.

How to forward visits to central reading

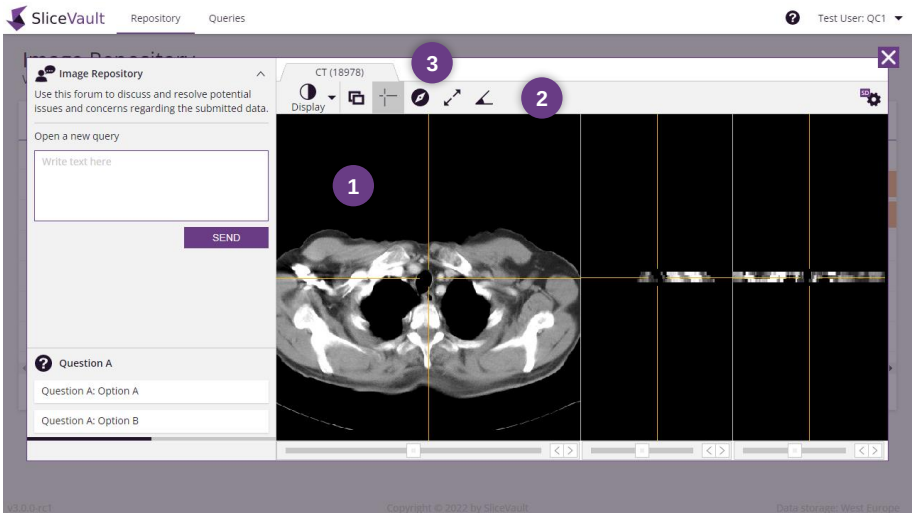
Quality Control Manager 2 can forward visit to central reading on the visit dashboard, provided that the visit has been approved by QC 2.



1 Click “send to reader” which will make the visit available to all Readers in your trial.

How to view data

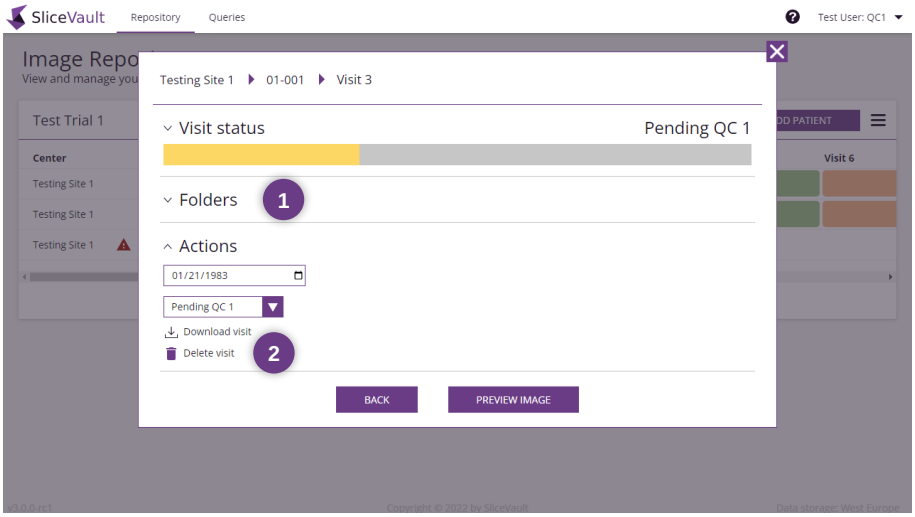
Once you have opened the visit dashboard for your chosen visit, you can click the “preview image” button to view the image in the embedded DICOM viewer.



1. Images are displayed here. The default view depends on the selected image type.
2. Users can change display settings from the main control bar.
3. Users can switch between images by changing tab if the visit contains more than one image.

How to delete data

You can delete images individually or whole visits on the visit dashboard.

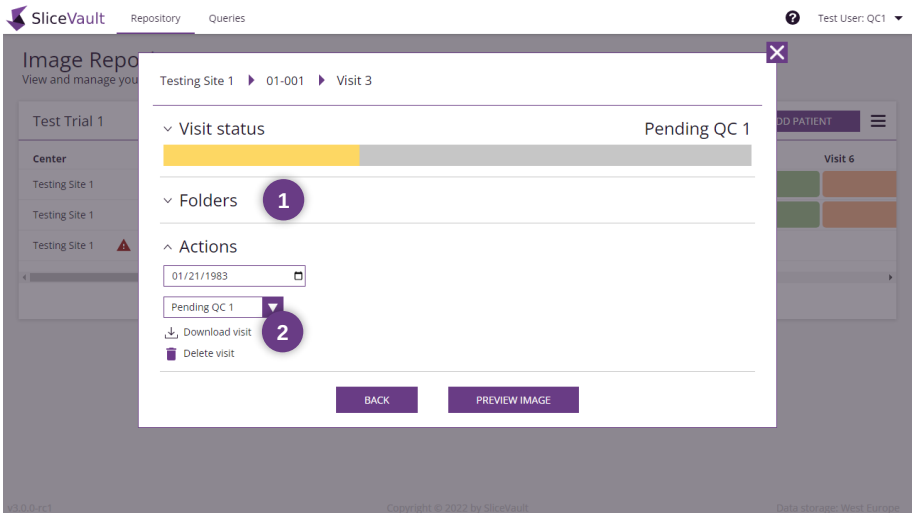


1. Open the “folder” section to delete images individually. Look for the trashcan icon in each row.
2. Click the “delete visit” link to delete the visit including all data uploaded to the visit.

When you approve a visit (either approved by QC 1 or approved by QC 2) the delete functionality is disabled.

How to download data

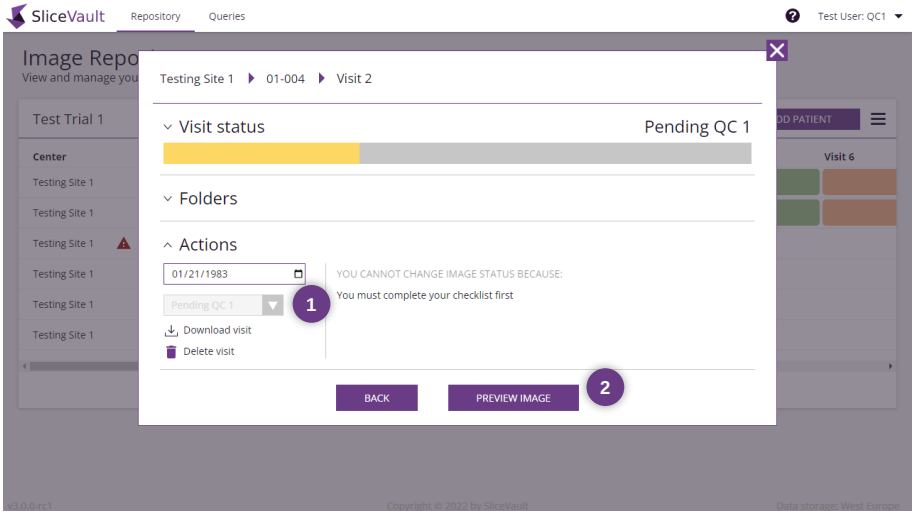
You can download images individually or whole visits on the visit dashboard.



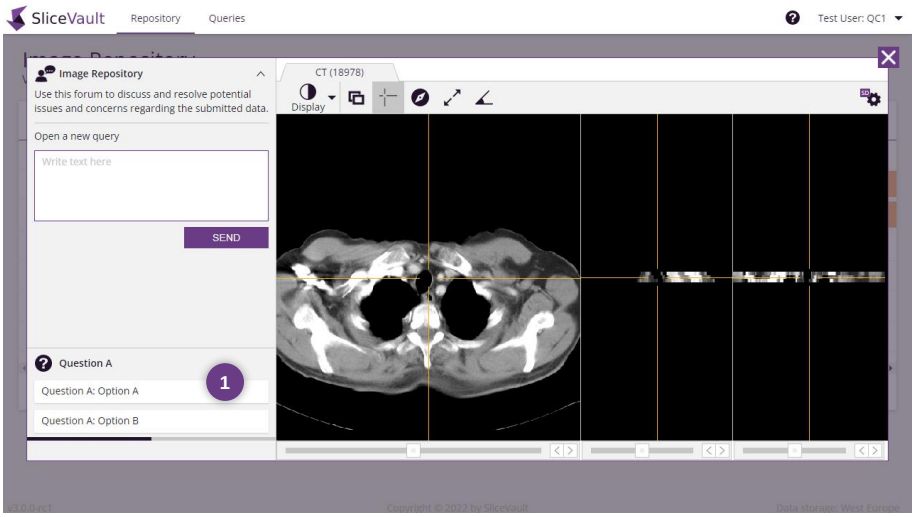
1. Open the “folder” section to download images individually. Look for the download icon in each row.
2. Click the “download visit” link to download the visit including all data uploaded to the visit.

How to complete a quality control checklist

Depending on your trial, you might be required to complete a quality control checklist before you can change visit status. You will be notified on the visit dashboard, if you are required to complete a quality control checklist. Quality control checklists can be different from visit to visit.

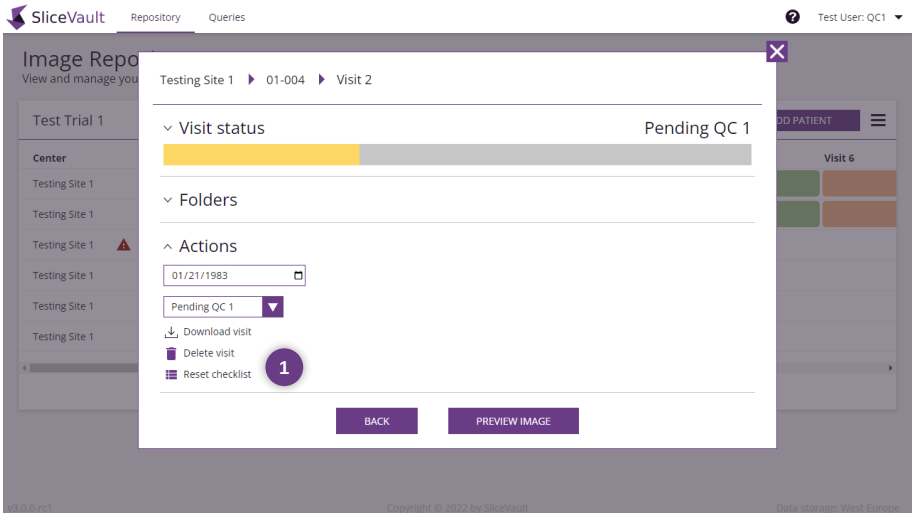


1. You must complete the quality control checklists before you can change visit status.
2. The quality control checklist is accessible in the image viewer. Click the “preview image” button.



1 The quality control checklist consists of one or more multiple choice questions that is visible next to the DICOM viewer. Click on option to select answer.

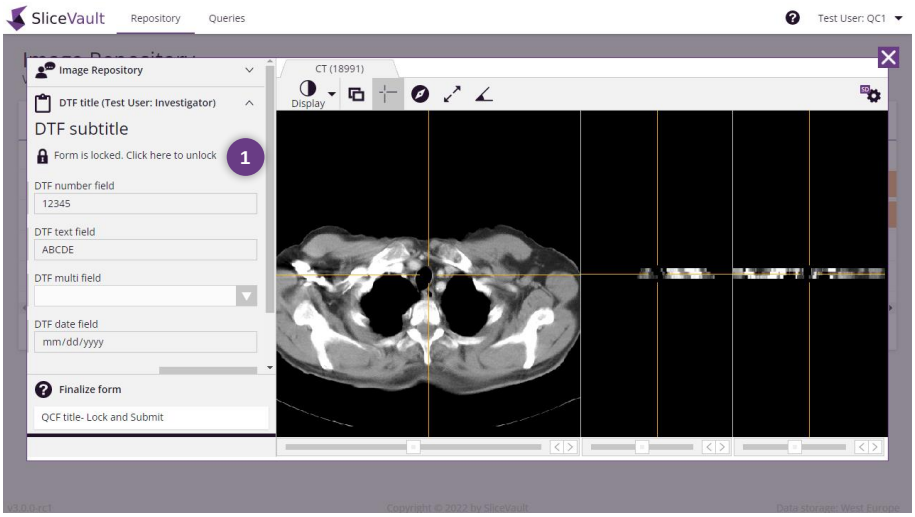
If you discover a mistake in one of the answers to a quality control checklist, you can reset the checklist from the visit dashboard.



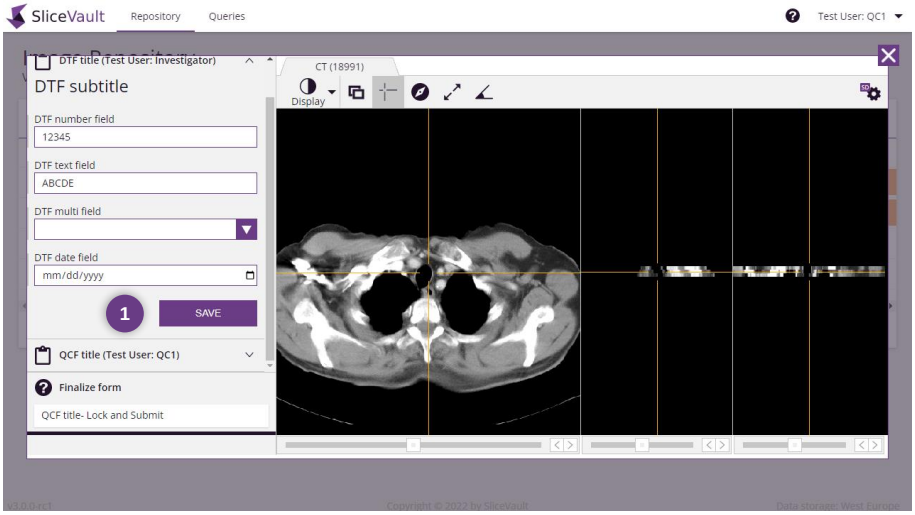
1 Click the “reset checklist” link to reset the checklist. Please note, all answers will be emptied.

How to see data transmittal forms

Depending on your trial, you might be able to view or edit data transmittal forms submitted by Investigators. Once you have opened the visit dashboard for your chosen visit, you can click the “preview image” button to access the data transmittal form.



1 The data transmittal form is locked by default. If you editor permission, you can click the link to unlock the form.

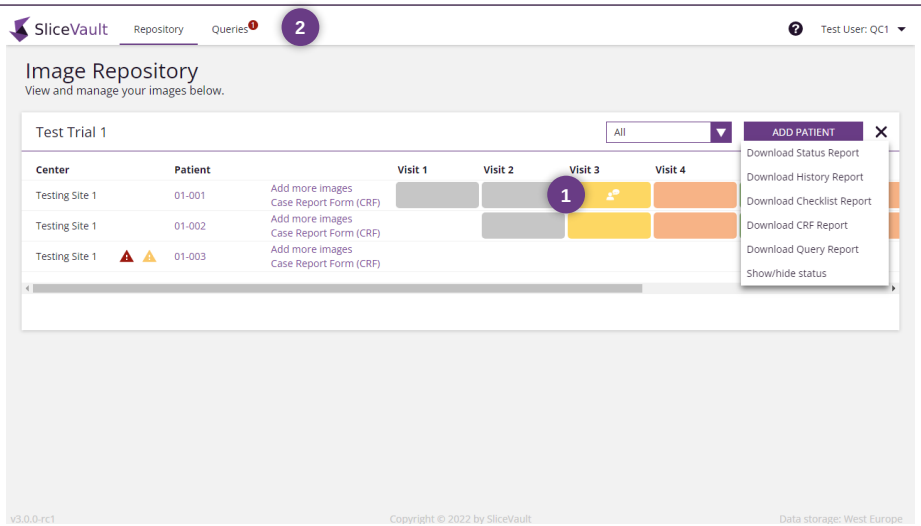


1 When the form is unlocked you can make changes to the form. Click save to save changes, after which the form becomes read-only.

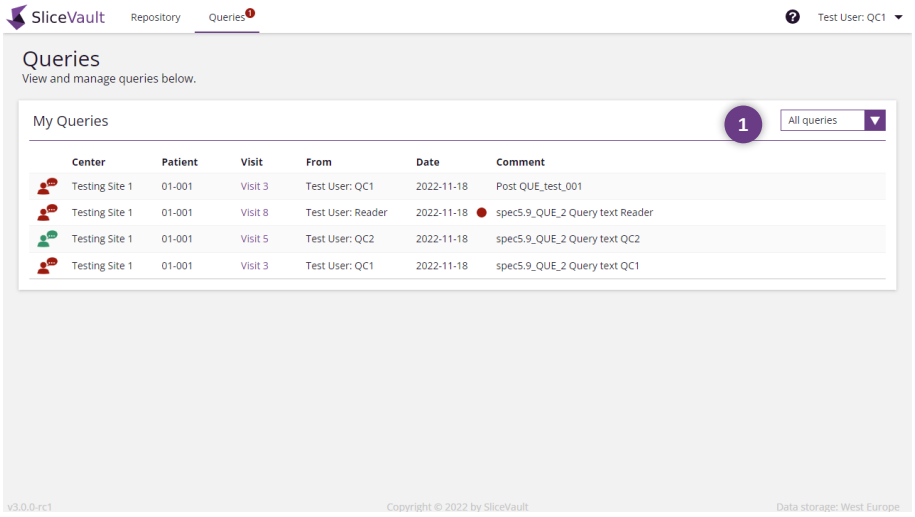
How to open and close queries

SliceVault querying module lets you open, respond and close queries within the same system. Relevant users are automatically notified when queries are opened, responses are posted and queries are closed. The querying offers two separate lines of communication:

1. Queries opened by Quality Control Managers are visible to Investigators. Responses posted by Investigators to queries opened by Quality Control Managers are visible to Quality Control Managers.
2. Queries opened by Readers are visible to Quality Control Managers. Responses posted by Quality Control Managers to queries opened by Readers are visible to Readers.

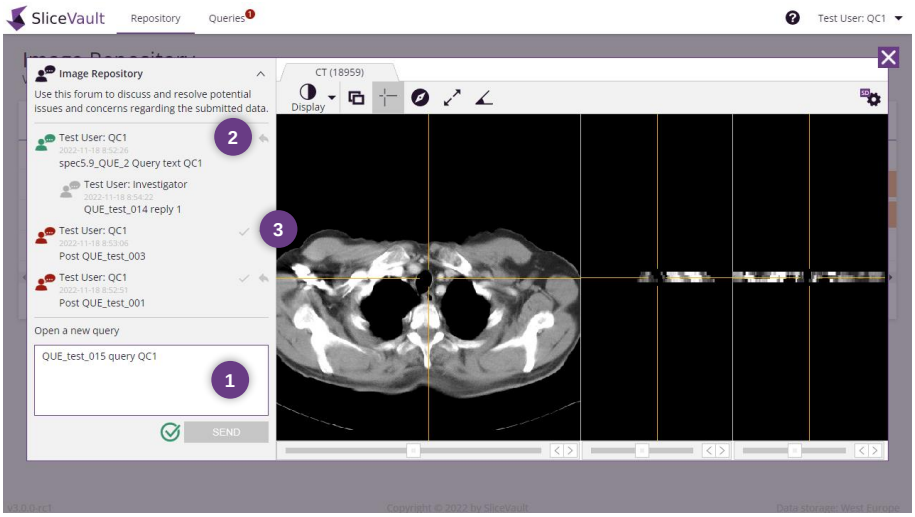


1. Users can see a querying icon on the visit dashboard if a query is open for the visit.
2. Users can see an overview of all queries on a separate queries site.



1. On the queries site, users can see all queries and filter queries by status.

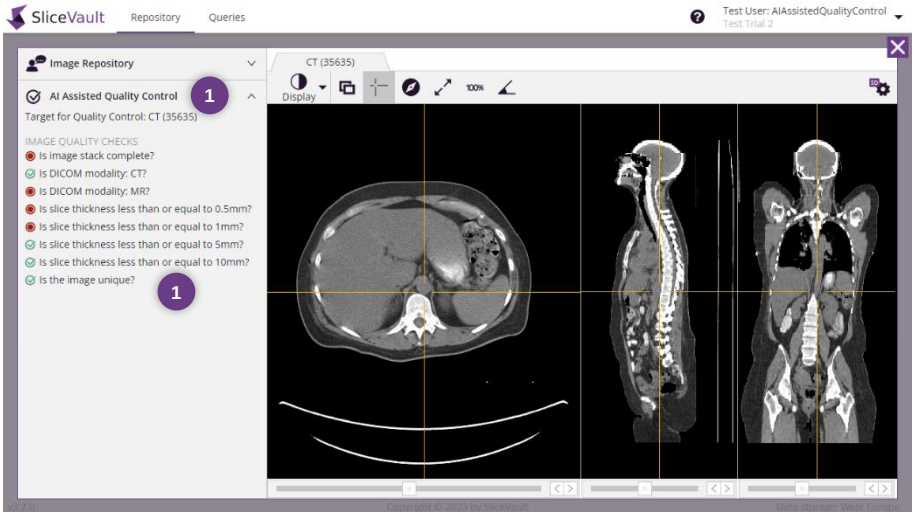
To open a query, to see query responses and to close queries, you must first open the visit dashboard and click “preview image”.



1. Queries are listed in the left pane. Type your query in the text field to open a new query. When you are done you can click “send” to post your reply.
2. To post a reply you must first click the reply icon (arrow) for the query to which you would like to reply (the list might contain more than one query). This opens a text field, where you can type your reply. When you are done you can click “send” to post your reply.
3. To close a query, you must click the tick mark icon for the query you would like to close.

AI assisted quality control

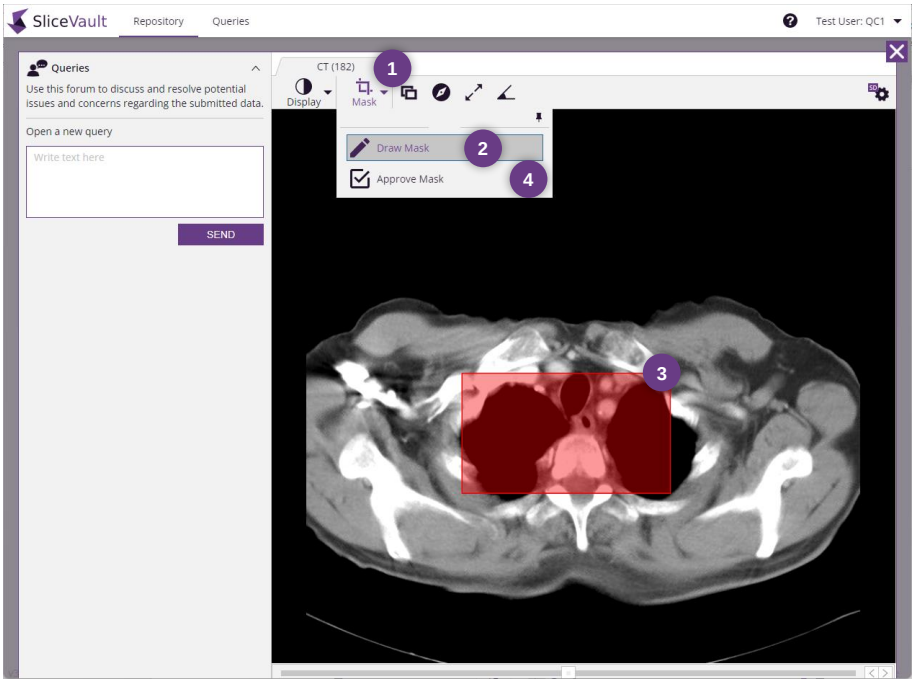
SliceVault uses artificial intelligences (AI) and an intelligent rule system to analyze all submitted studies and flag images that does not comply with study specifications. The AI assisted quality control functionality is intended as a decision support tool for QC managers.



1. Quality checks are listed in the left pane. Click the header to expand the section.
2. Checks can be customized to each trial. Click a check for detailed information.

Image masking of burned-in annotations

Users with permission can mask images to remove burned in annotations with sensitive Personal Health Information (PHI). Masks are applied to all frames in multi frame images such as CT.



1. Hover on the “Mask” icon in the toolbar to show the menu
2. Click “Draw Mask” to begin masking
3. Use the mouse (left click followed by mouse movement) to mask areas containing PHI. Right click to delete masks.
4. Click “approve mask” to update image. Once you click “approve mask” the operation cannot be undone.

Frequently asked questions

An investigator site is missing from the list when adding a new patient

The list only includes investigator sites that have vacant patient IDs or enabled the functionality to create patient IDs using free text. If a site is missing, please contact your Trial Administrator or SliceVault Support via support@slicevault.com to create more patient IDs for the missing site.

How to change visit status when dropdown is disabled

The dropdown can be disabled for several reasons. Follow the steps below to troubleshoot:

- Another user is currently working with the visit and it is not yet ready for your input.
- You cannot change visit statis if you have not completed your required quality control checklist. Please complete your quality control checklist to change visit status.

- You cannot change visit status if there is an open query. Please close the query to change visit status.

Send to reader button not visible

The functionality to send visits to reader is only available to Quality Control Manager 2. To enable the button, you must first change visit status to "approved by QC 2".

What does it mean when dashboard says “another user is working with the image”?

The visit is not yet ready for your input. Please wait for other users to complete their work. When they are done the visit will be open to you.

How to I enable buttons on the visit dashboard

You have restricted access to the preview image button, download button and the delete button. You have access to these buttons at various stages of the overall data processing workflow.

If the preview button is disabled, it is because the visit is not yet ready for you, and you have to check back at another time.

If the download button or the delete button is disabled it is because the current visit status does not allow you to download or delete the images.

How to re-open a visit to the Investigators if it is rejected by Reader?

Click the “notify investigator” link on the visit dashboard to re-open the visit for the Investigators. The link is only available when the current visit status is “rejected by reader”. After clicking the “notify investigator” link the Investigators can upload additional data to the visit and re-submit the visit to QC.

SliceVault for Readers

A quick guide – step by step

This quick guide presumes that you have access to SliceVault and valid login credentials. It does not describe all functions of SliceVault, but aims to provide you with a quick overview of what you can do in SliceVault: how to access SliceVault, view and download data, complete reader assessments and change visit status. It is recommended that you read the whole manual before you start using SliceVault.

Log in to SliceVault

- Go to your login page and type in username and password, after which you will be redirected to the trial repository site.
- Select your desired trial if requested by the system.

View and download data

- The patient list on the repository site contains all registered patients and provides an overview of all data imported to each patient.
- Click the coloured square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit.
- Click the “download visit” link to download all data uploaded to the visit or click “preview image” to open the embedded DICOM viewer.

Complete reader assessments

- Click “preview image” on the visit dashboard to open the DICOM viewer. The reader assessment form is located to the right of the image. Fill it out and hit the “lock and submit” button to submit your assessment, or
- Click “preview image” on the visit dashboard to complete your annotations/assessment.

Change visit status

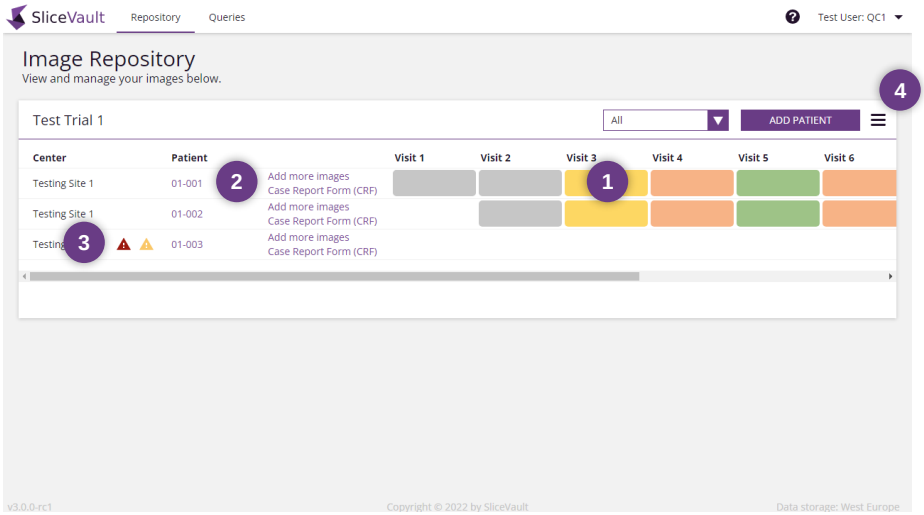
- Locate the status dropdown on the visit dashboard to change visit status. If the dropdown is disabled, look for the reason given to you on the visit dashboard, and follow the steps to enable the functionality.

Understanding the main repository site

SliceVault supports unblinded and blinded Reader workflows. For both workflows, Readers can view and download submitted data, complete reader assessments, open and close queries, and change visit status.

A trial can have one or more Readers, and each Reader can have access to data from all sites or have restricted access to a subset of sites depending on trial configuration.

The patient list gives a complete overview of data uploaded to SliceVault that is available to you. The columns in the patient list will be customized to your clinical trial, and will not look exactly like the example below.



1. Click the colored square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit and it is from here, you can complete your quality control checklist.
2. Click the Patient ID to change patient ID and trial enrollment status.
3. ⚠ This warning is displayed when an error has occurred during data upload and as a result SliceVault is not able to display the uploaded data correctly. Please contact SliceVault for support at contact@slicevault.com.

   ⚠ When this warning message is displayed, the patient is no longer enrolled in the trial. Please contact the Quality Control Manager for more information and to re-enroll the patient.
4. In a dropdown menu users have access to additional functionality. For example, you can download several study reports depending on your trial configuration.

The colors of the squares in the patient list refers to the status of the visit, where:

No data is uploaded to the visit

Data is uploaded but visit is not yet available to you

Visit is ready for you and pending your input

Visit approved by you

Visit rejected by you

The colored squares can also be home to different icons, and these icons are visible when there is something in particular you should be aware of.

The query sign is shown when a visit has an open query

The checklist sign is shown when you have not yet completed your reader assessment

The warning sign is shown when the deadline has passed for completing your reader assessment. Depending on the trial you will typically have a given number of days to complete your reader assessment.

Understanding visit status

Here we will go through all key functionalities available to Readers, but before we get started, let us take a look at the general structure of image management in SliceVault, and how that relates to the you as Reader. This is important in order to understand when your input is required and why you do not have access to data and functionality at all times.

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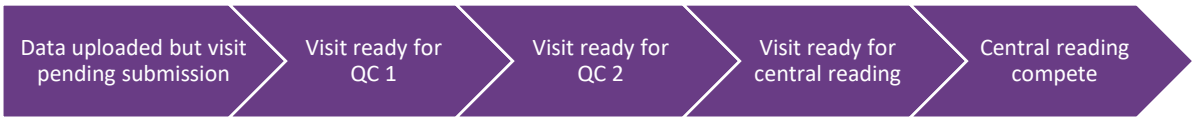


When an investigator uploads data to SliceVault, the data will remain accessible to users belonging to the investigator site only. Users at the investigator sites have full control over the data, and can view, download, delete and submit the visit to QC.

After submission to QC, the image is ready for QC 1. Now, users belonging to the investigator site can no longer make change to the data, as control is handed over to QC 1. QC 1 can complete their quality control checklist, view, download and delete the visit, and change the visit status. If QC 1 rejects the visit, the visit and control is returned to the users belonging to the investigator site (step 1). If QC 2 approves the visit, the visit and control is sent forward to QC 2 (step 3).

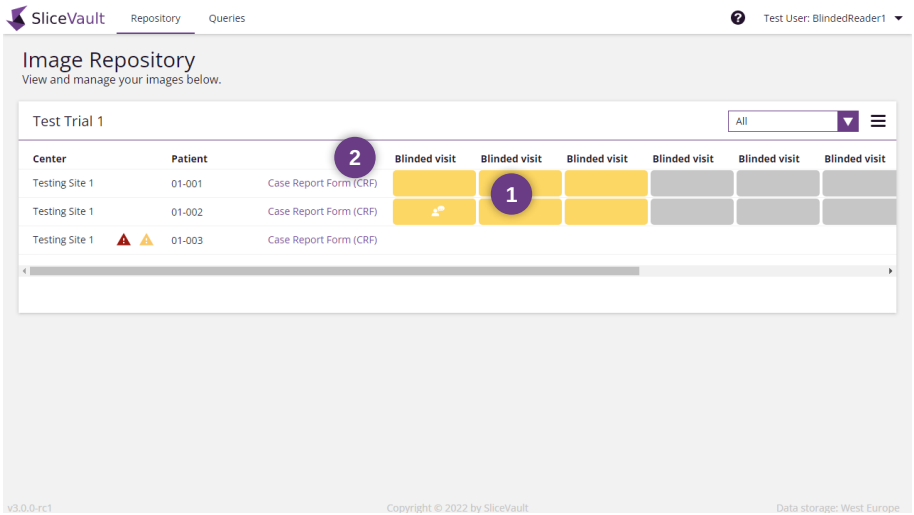
When QC 2 can access and have control over the visit, they can complete their quality control checklist, view, download and delete the visit, and change the visit status. If QC 2 rejects the visit, the visit and control is returned to the users belonging to the investigator site (step 1). If QC 2 approves the visit, QC 2 can forward the data forward to central reading (step 4).

Readers can now view and download the visit to complete reader assessments. Readers can reject the visit (send visit and control back to QC 1 and QC 2) or approve the visit with no further steps required (step 5).

As such, access to functionality and data depends on both visit status and user role. As Reader your input is required towards the end of the overall data processing workflow.

How to perform and submit reader assessments

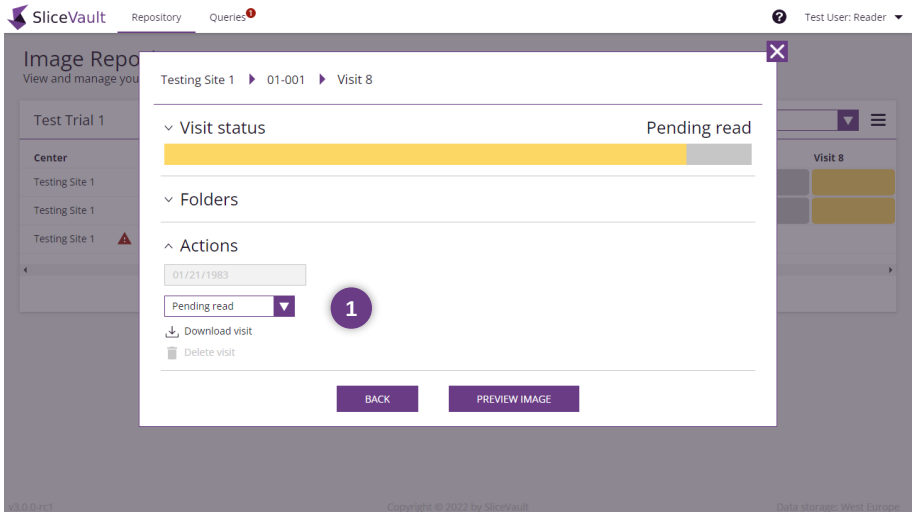
Your input is required when you see a yellow-colored square in the patient list.



1. The visit dashboard is home to all the functionality you need in order to complete your reader assessment. Locate the patient with the right patient ID in the patient list and click on the yellow square to open the visit dashboard.
2. Depending on your trial, the visit names might be blinded (unblinded visit names are replaced by “Blinded visit”) on the patient list, visit dashboard, reports and more.

How to change visit status

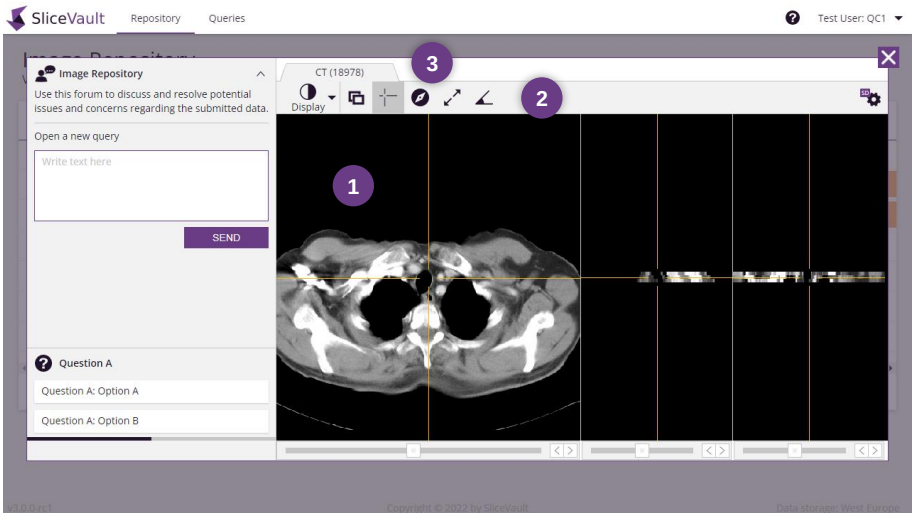
You must change the visit status to indicate that you have completed your reader assessment. Current visit status is always visible in the top section of the visit dashboard. All files uploaded to the visit folder is accessible from the middle section, where you can also view, download and delete individual files. In the bottom section you can view, download and delete the entire visit.



1. Use this dropdown to select visit status. You can select: pending read, approved by reader or rejected by reader

How to view data

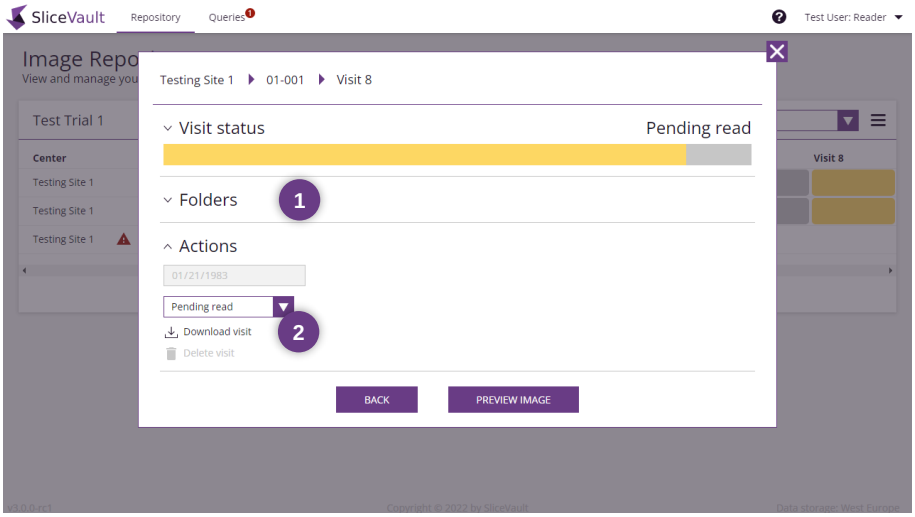
Once you have opened the visit dashboard for your chosen visit, you can click the “preview image” to view the image in the embedded DICOM viewer.



1. Images are displayed here. The default view depends on the selected image type.
2. Users can change display settings from the main control bar.
3. Users can switch between images by changing tab if the visit contains more than one image.

How to download data

You can download images individually or whole visits on the visit dashboard.



1. Open the “folder” section to download images individually. Look for the download icon in each row.
2. Click the “download visit” link to download the visit including all data uploaded to the visit.

How to complete your reader assessment

Depending on your trial, you might be required to complete a reader assessment in SliceVault before you can change visit status. SliceVault offers a diverse range of reader assessment options to cater to various needs. Broadly, we categorize these into two types, each following a distinct workflow.

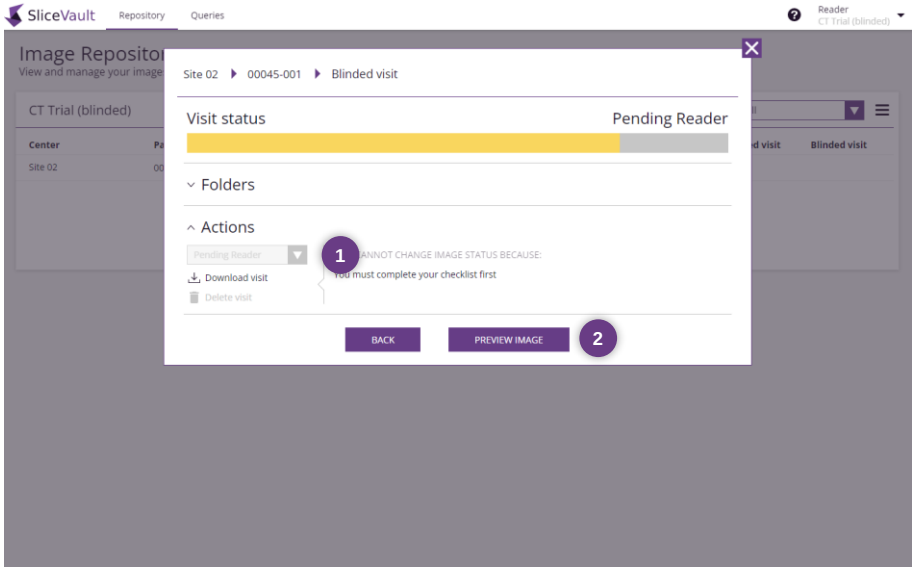
General Reader Assessment: This type involves utilizing a pre-defined assessment template that readers are required to complete. The focus here is on capturing essential information efficiently.

Advanced Assessment: For this type, readers are engaged in more intricate tasks. They might be asked to perform segmentations or annotations, and in some cases, fill out custom forms tailored to each assessment. This approach accommodates more complex and specific evaluation scenarios.

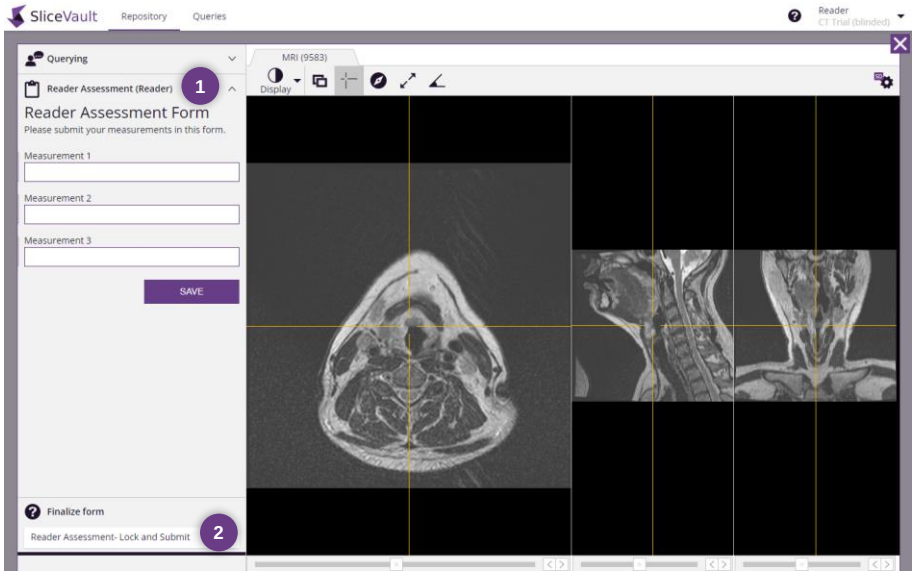
By distinguishing between these assessment types, SliceVault ensures an appropriate workflow for different assessment objectives.

Workflow for General Reader Assessment:

Depending on your trial, you might be required to complete a general reader assessment in SliceVault before you can change visit status. You will be notified on the visit dashboard, if you are required to complete a reader assessment. Reader assessments can be different from visit to visit.

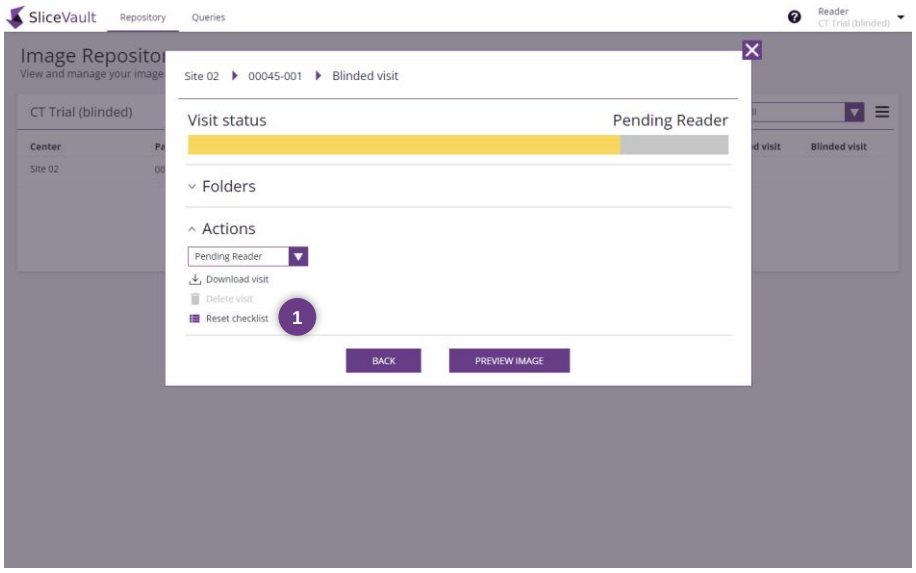


1. You must complete the reader assessment before you can change visit status.
2. The reader assessment form is accessible in the image viewer. Click the “preview image” button.



1. The reader assessment form is visible next to the DICOM viewer. The form consists of one or more input fields depending on your trial and might require you to perform certain measurements directly in the image.
2. Click the “lock and submit” button to submit your reader assessment form.

If you discover a mistake in a submitted reader assessment form you can reset the form from the visit dashboard.

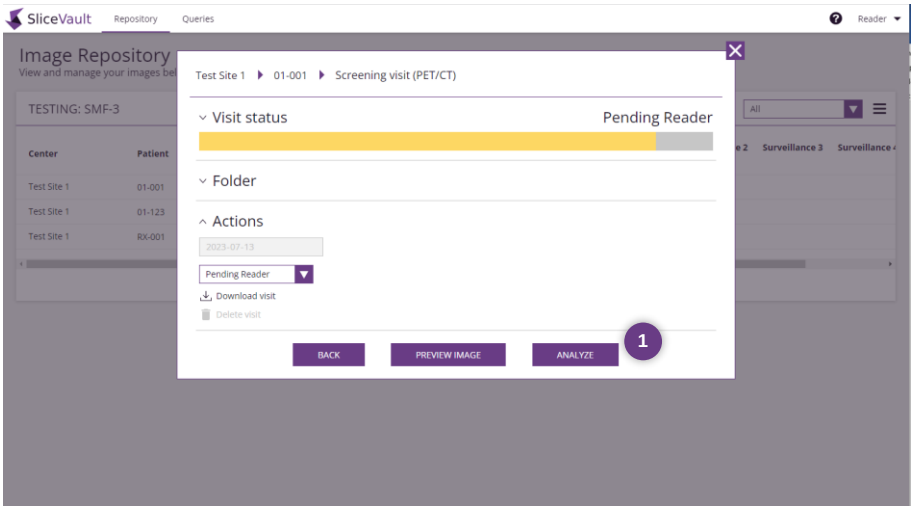


1. Click the “reset checklist” link to reset the form. Please note, all answers will be emptied.

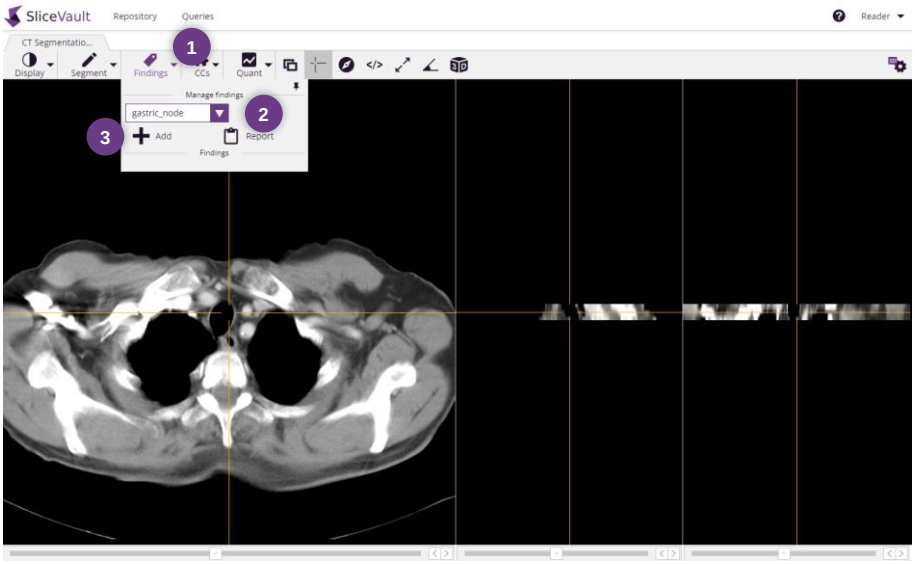
<u>Workflow for Advanced Assessment:</u>

If your assessment entails advanced tasks like conducting segmentations or annotations, and possibly completing customized forms designed for each assessment, you'll discover a dedicated

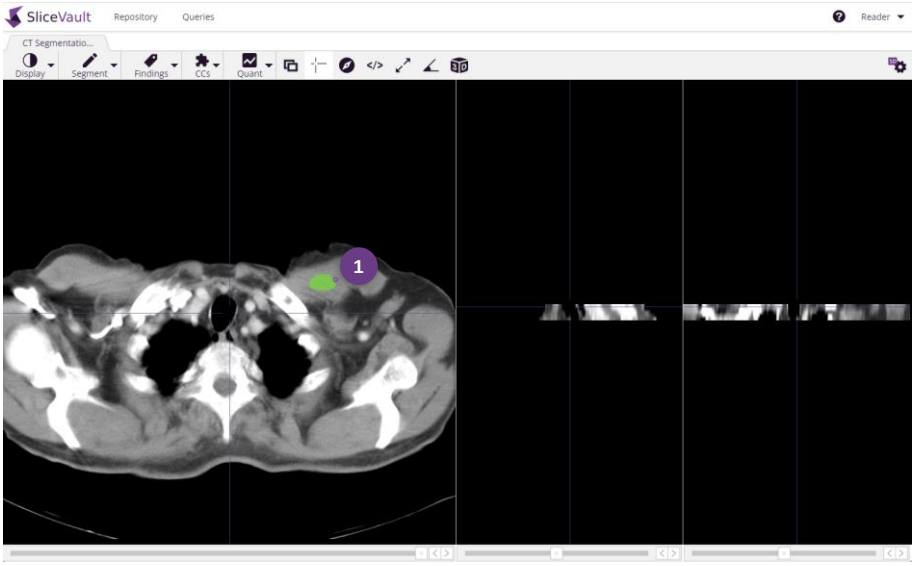
analysis module available for your use. To start the process, all you need to do is click the "analysis" button and begin.



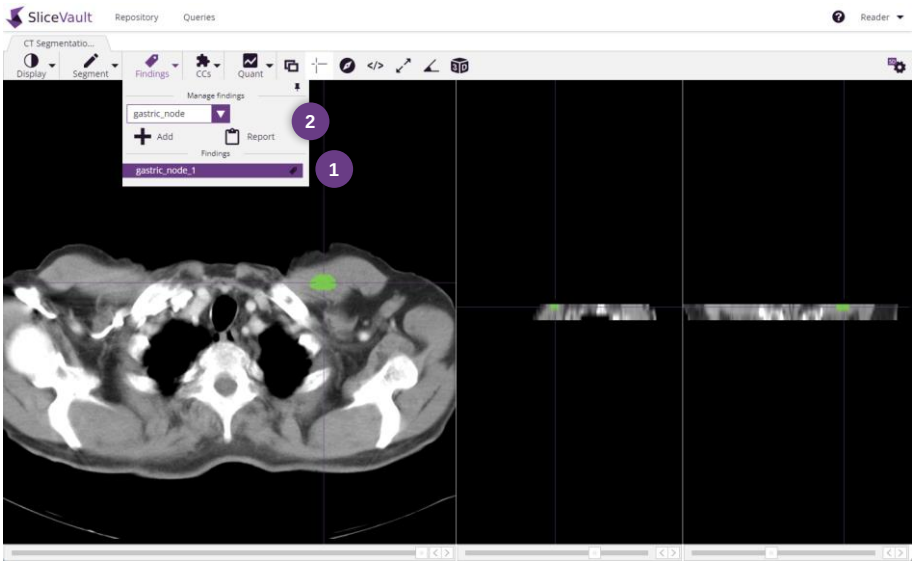
1. Click “analysis” to open the advanced DICOM viewer to perform your assessment. The image opens in a new browser tab.



1. Open the “findings” menu
2. If you have access to multiple labels, such as "gastrointestinal lymph nodes" and "esophageal lymph nodes," please ensure that you first select the appropriate segmentation label before proceeding.
3. Click “add” to start segmenting

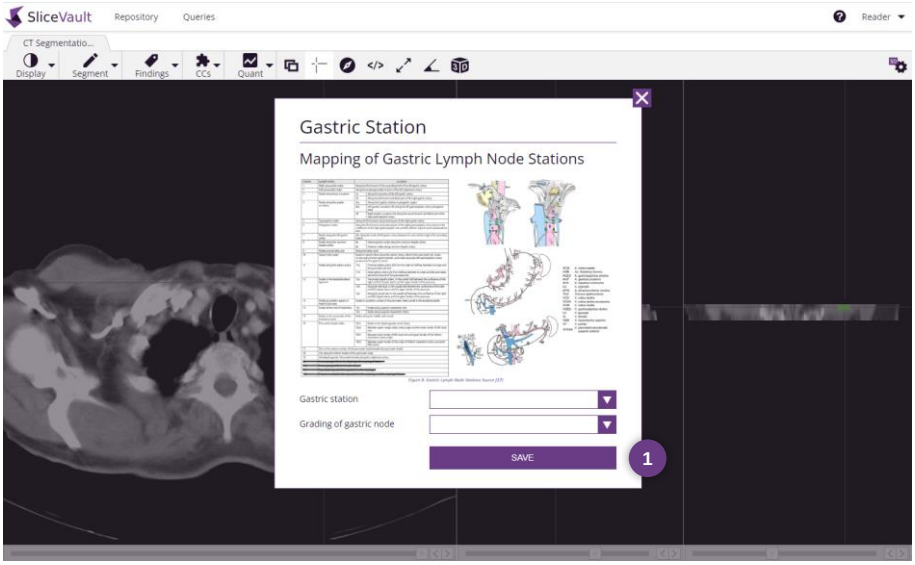


1 Use your mouse to draw your segmentation. Feel free to draw across one or more slices as needed. If you need, you can open the segmentation menu to change brush size, etc.



1 Once your segmentation is finalized, you'll notice a distinct purple row in the “findings” menu. To proceed, simply click on the label icon ( ), which will open the corresponding form for you to complete.

2	Optional: To view a comprehensive list of all segmentation labels and their associated form values, navigate to the "findings" menu and click on "report".

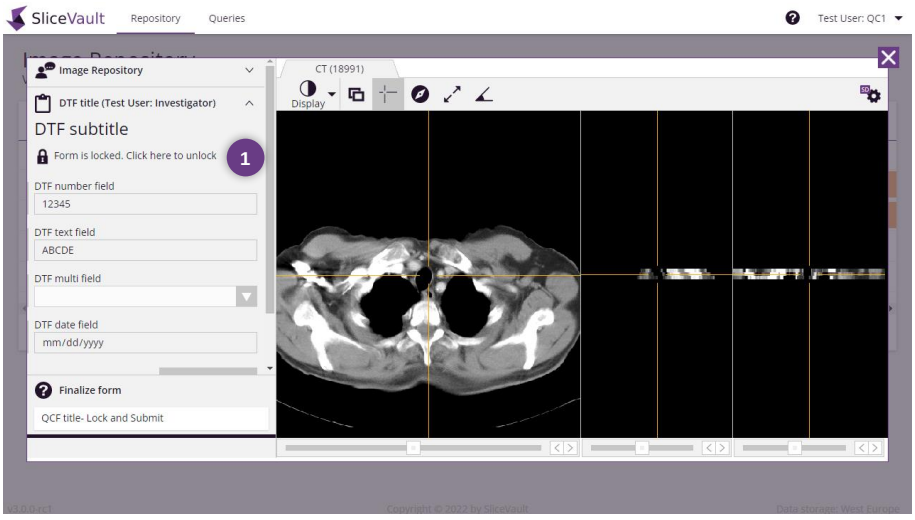


1 Fill out the form and click “save”.

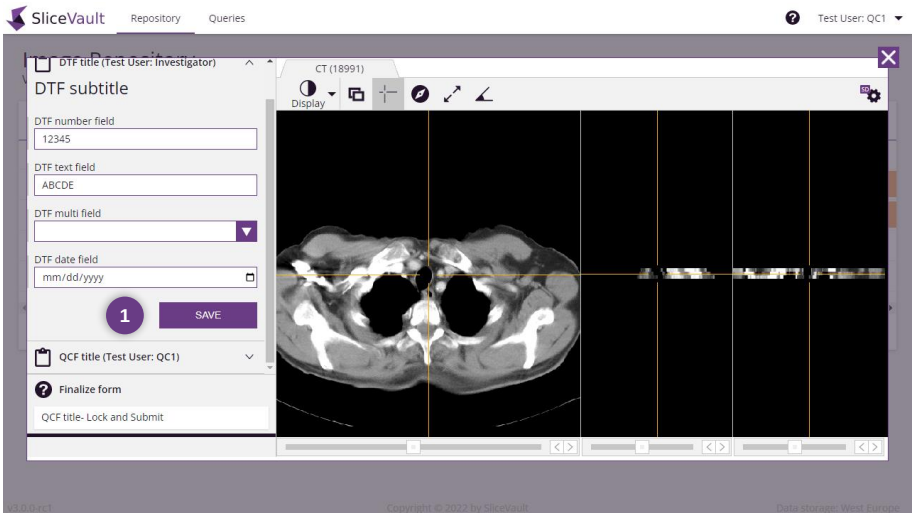
Repeat this procedure for all necessary labels. Once your assessment is finished, kindly navigate back to the visit dashboard. Then, follow the guidelines outlined in the "How to change visit status" section to update the visit status to "approved by reader".

How to see data transmittal forms

Depending on your trial, you might be able to view or edit data transmittal forms submitted by Investigators. Once you have opened the visit dashboard for your chosen visit, you can click the “preview image” button to access the data transmittal form.



1 The data transmittal form is locked by default. If you editor permission, you can click the link to unlock the form.

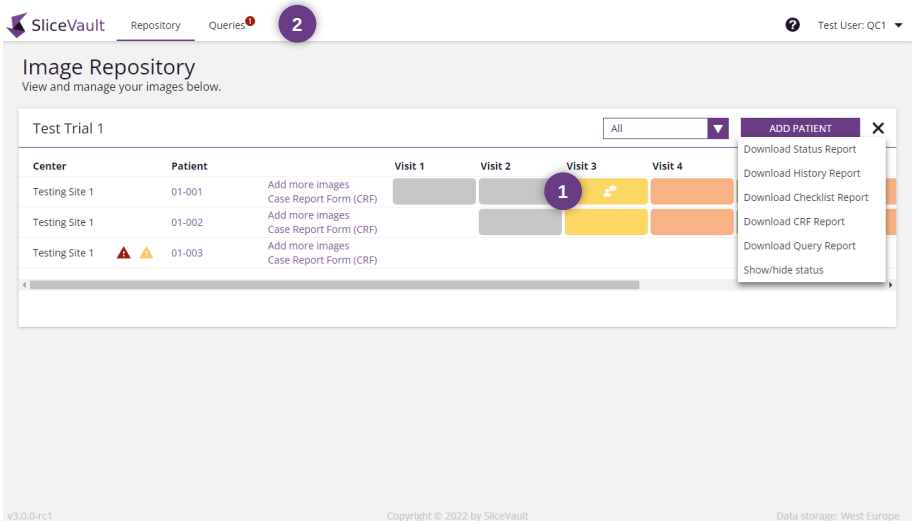


1 When the form is unlocked you can make changes to the form. Click save to save changes, after which the form becomes read-only.

How to open and close queries

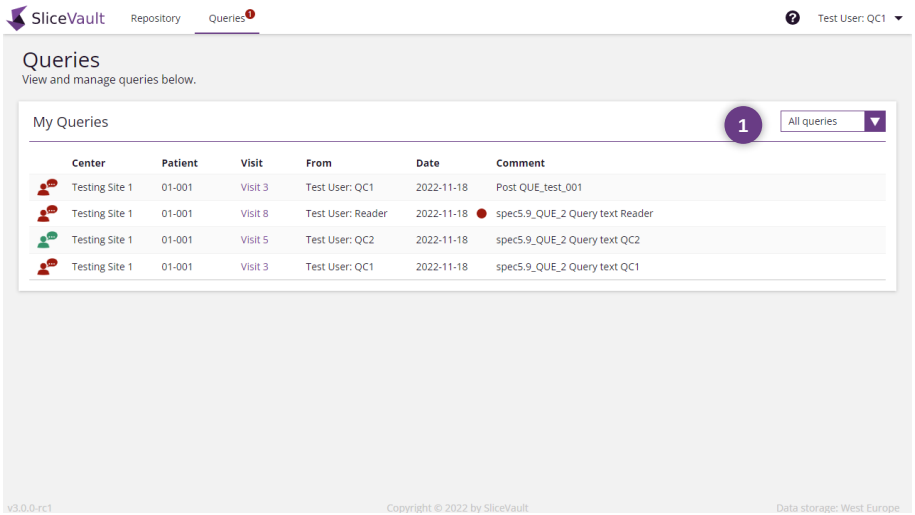
SliceVault querying module lets you open, respond and close queries within the same system. Relevant users are automatically notified when queries are opened, responses are posted and queries are closed.

Queries opened by Readers are visible to Quality Control Managers. Responses posted by Quality Control Managers to queries opened by Readers are visible to Readers.



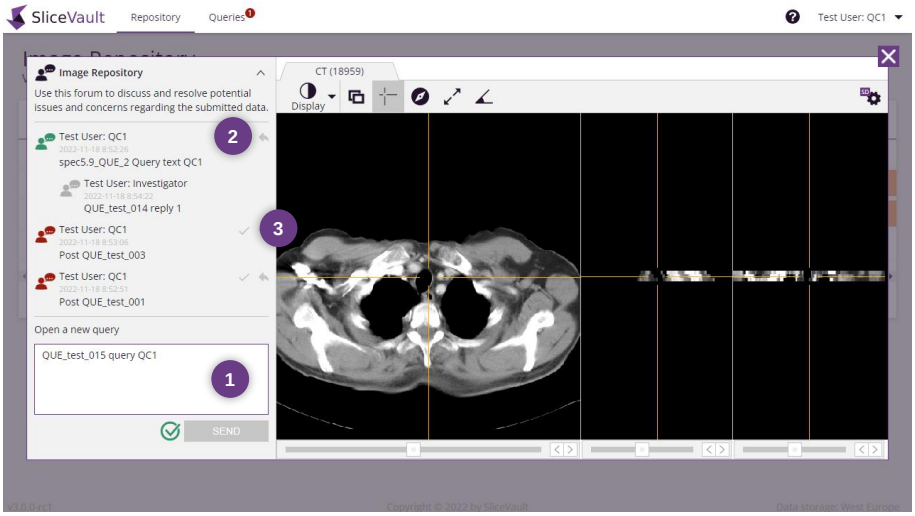
1 Users can see a querying icon on the visit dashboard if a query is open for the visit.

2 Users can see an overview of all queries on a separate queries site.



1. On the queries site, users can see all queries and filter queries by status.

To open a query, to see query responses and to close queries, you must first open the visit dashboard and click “preview image”.



1. Queries are listed in the left pane. Type your query in the text field to open a new query. When you are done you can click “send” to post your reply.
2. To post a reply you must first click the reply icon (arrow) for the query to which you would like to reply (the list might contain more than one query). This opens a text field, where you can type your reply. When you are done you can click “send” to post your reply.
3. To close a query, you must click the tick mark icon for the query you would like to close.

Frequently asked questions

How to indicate that my assessment is complete when the visit status dropdown is disabled

The dropdown can be disabled for several reasons. Follow the steps below to troubleshoot:

- Another user is currently working with the visit and it is not yet ready for your input.
- You cannot change visit statis if you have not filled out your reader assessment form. Please make sure to click the “lock and submit” button to change visit status.
- You cannot change visit status if there is an open query. Please close the query to change visit status.

What does it mean when dashboard says “another user is working with the image”?

The visit is not yet ready for your input. Please wait for other users to complete their work. When they are done the visit will be open to you.

How to I enable buttons on the visit dashboard

You have restricted access to the preview image button, download button and the delete button. You have access to these buttons at various stages of the overall data processing workflow.

If the preview button is disabled, it is because the visit is not yet ready for you, and you have to check back at another time.

If the download button or the delete button is disabled it is because the current visit status does not allow you to download or delete the images.

SliceVault for Monitors

A quick guide – step by step

This quick guide presumes that you have access to SliceVault and valid login credentials. It does not describe all functions of SliceVault, but aims to provide you with a quick overview of what you can do in SliceVault: how to access SliceVault and how to view and download data. It is recommended that you read the whole manual before you start using SliceVault.

Log in to SliceVault

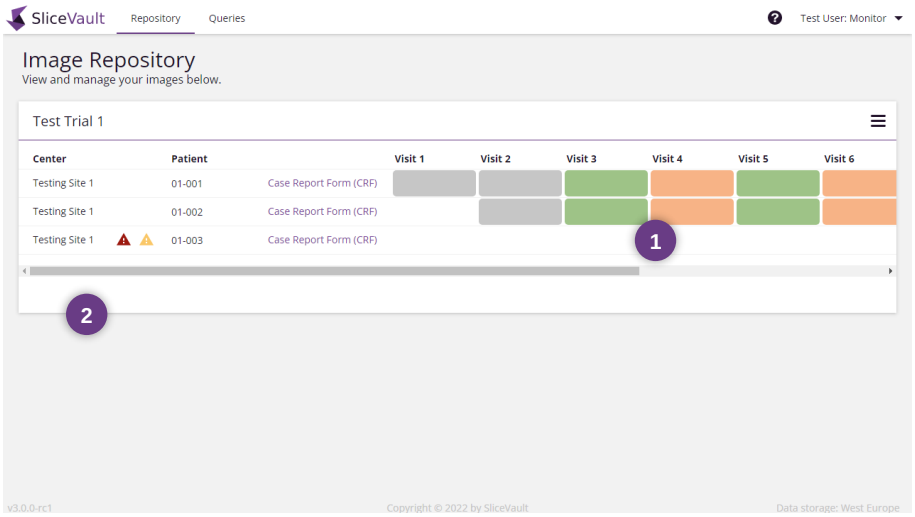
- Go to your login page and type in username and password, after which you will be redirected to the trial repository site.
- Select your desired trial if requested by the system.

View and download data

- The patient list on the repository site contains all registered patients and provides an overview of all data imported to each patient.
- Click the coloured square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit.
- Click the “download visit” link to download all data uploaded to the visit or click “preview image” to open the embedded DICOM viewer.

Understanding the main repository site

The patient list gives a complete overview of data uploaded to SliceVault that is available to you. The columns in the patient list will be customized to your clinical trial, and will not look exactly like the example below.



1. Click the colored square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit.

2. ⚠ This warning is displayed when an error has occurred during data upload and as a result SliceVault is not able to display the uploaded data correctly. Please contact SliceVault for support at contact@slicevault.com.

3. ⚠ When this warning message is displayed, the patient is no longer enrolled in the trial. Please contact the Quality Control Manager for more information and to re-enroll the patient.

The colors of the squares in the patient list refers to the status of the visit, where:

No data is uploaded to the visit

Data is uploaded but visit is not yet available to you

Visit approved by QC 1, QC 2 and/or Readers

Visit rejected by QC 1, QC 2 and/or Readers

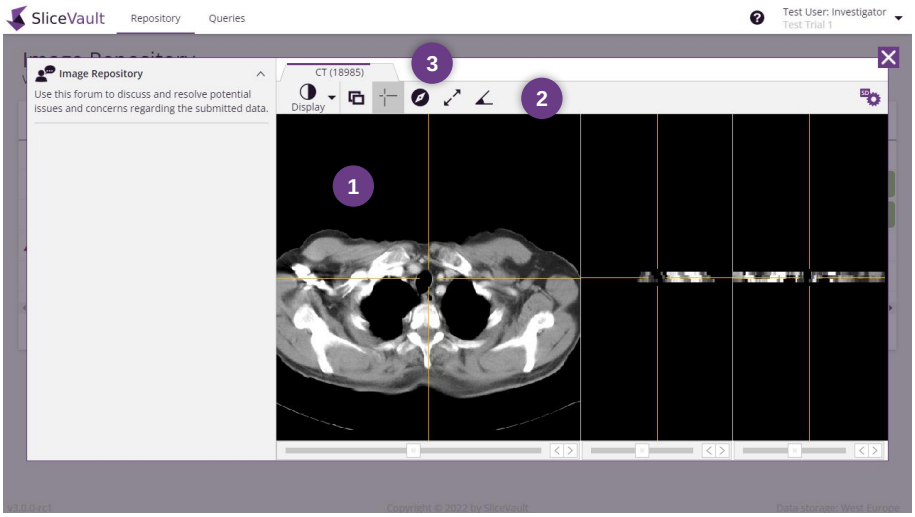
Visit approved by Readers in trial with special reader blinding

The colored squares can also be home to different icons, and these icons are visible when there is something in particular you should be aware of.

The query sign is shown when a visit has an open query

How to view submitted data

Once you have opened the visit dashboard for your chosen visit, you can click the “preview image” button to view the image in the embedded DICOM viewer.



1. Images are displayed here. The default view depends on the selected image type.
2. Users can change display settings from the main control bar.
3. Users can switch between images by changing tab if the visit contains more than one image.

SliceVault for Project Managers

A quick guide – step by step

This quick guide presumes that you have access to SliceVault and valid login credentials. It does not describe all functions of SliceVault, but aims to provide you with a quick overview of what you can do in SliceVault: how to access SliceVault, view and download data, see key performance indicators. It is recommended that you read the whole manual before you start using SliceVault.

Log in to SliceVault

- Go to your login page and type in username and password, after which you will be redirected to the trial repository site.
- Select your desired trial if requested by the system.

View and download data

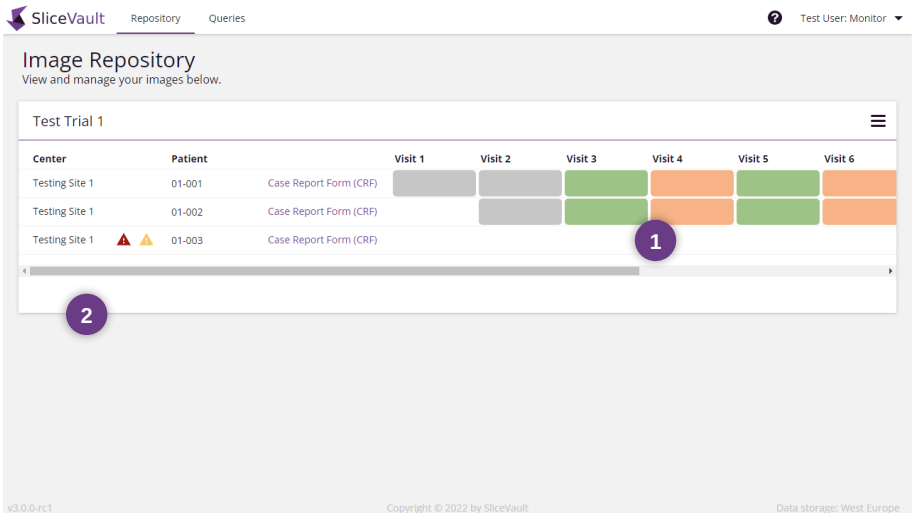
- The patient list on the repository site contains all registered patients and provides an overview of all data imported to each patient.
- Click the coloured square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit.
- Click the “download visit” link to download all data uploaded to the visit or click “preview image” to open the embedded DICOM viewer.

Key performance indicators

- Click “statistics” in the top navigation bar to access the KPI site. Here you can monitor key performance indicators on an aggregated level and drill down to each site.

Understanding the main repository site

The patient list gives a complete overview of data uploaded to SliceVault that is available to you. The columns in the patient list will be customized to your clinical trial, and will not look exactly like the example below.



1. Click the colored square in the intersection between patient ID and visit name to open the visit dashboard. The visit dashboard contains information for the selected patient and visit.

2. ⚠ This warning is displayed when an error has occurred during data upload and as a result SliceVault is not able to display the uploaded data correctly. Please contact SliceVault for support at contact@slicevault.com.

3. ⚠ When this warning message is displayed, the patient is no longer enrolled in the trial. Please contact the Quality Control Manager for more information and to re-enroll the patient.

The colors of the squares in the patient list refers to the status of the visit, where:

No data is uploaded to the visit

Data is uploaded but visit is not yet available to you

Visit approved by QC 1, QC 2 and/or Readers

Visit rejected by QC 1, QC 2 and/or Readers

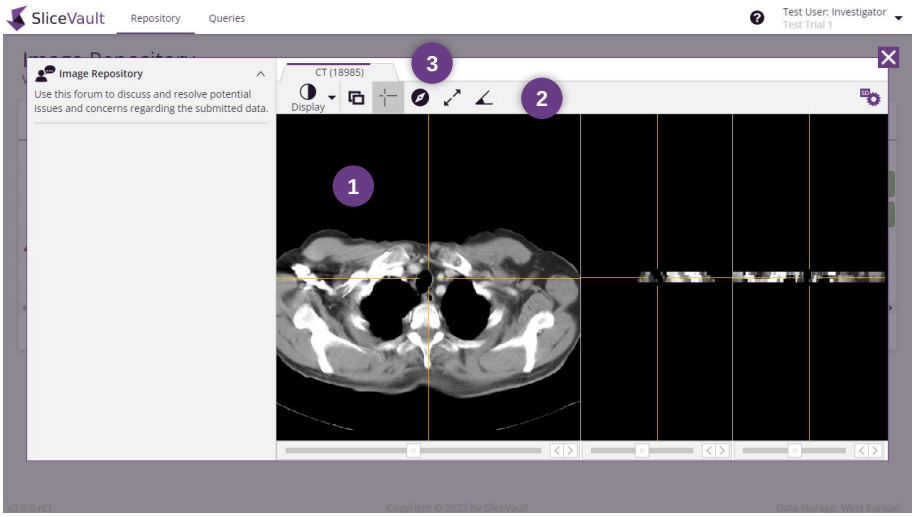
Visit approved by Readers in trial with special reader blinding

The colored squares can also be home to different icons, and these icons are visible when there is something in particular you should be aware of.

The query sign is shown when a visit has an open query

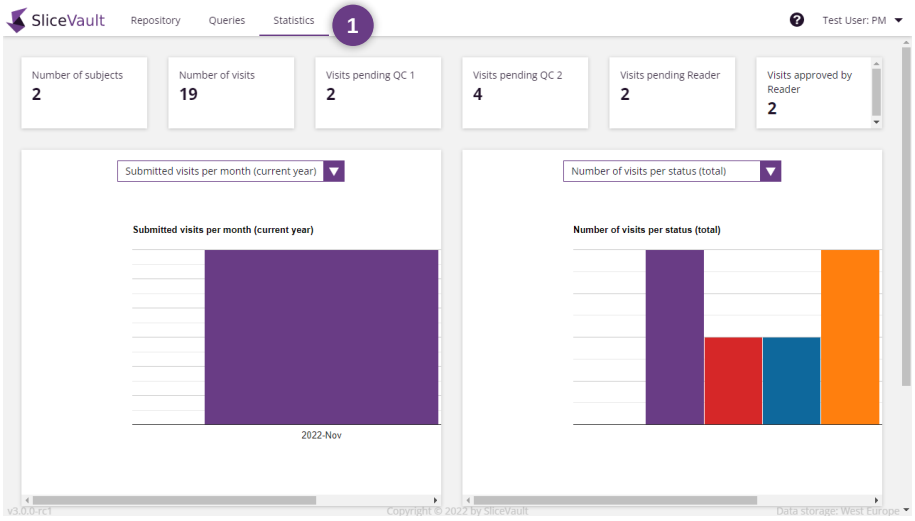
How to view submitted data

Once you have opened the visit dashboard for your chosen visit, you can click the “preview image” button to view the image in the embedded DICOM viewer.



1. Images are displayed here. The default view depends on the selected image type.
2. Users can change display settings from the main control bar.
3. Users can switch between images by changing tab if the visit contains more than one image.

How to see key performance indicators



1. Click “statistics” in the top navigation bar to access the KPI site. Here you can monitor key performance indicators on an aggregated level and drill down to each site.

SliceVault for Trial Administrators

A quick guide – step by step

This quick guide presumes that you have access to SliceVault and valid login credentials. It does not describe all functions of SliceVault, but aims to provide you with a quick overview of what you can do in SliceVault: how to create sites, manage sites and users and access the audit log. It is recommended that you read the whole manual before you start using SliceVault.

Log in to SliceVault

- Go to your login page and type in username and password, after which you will be redirected to the trial repository site.
- Select your desired trial if requested by the system.

Create sites

- Click the “add new centre” button to add a new site and fill in all the required information.

Manage sites and users

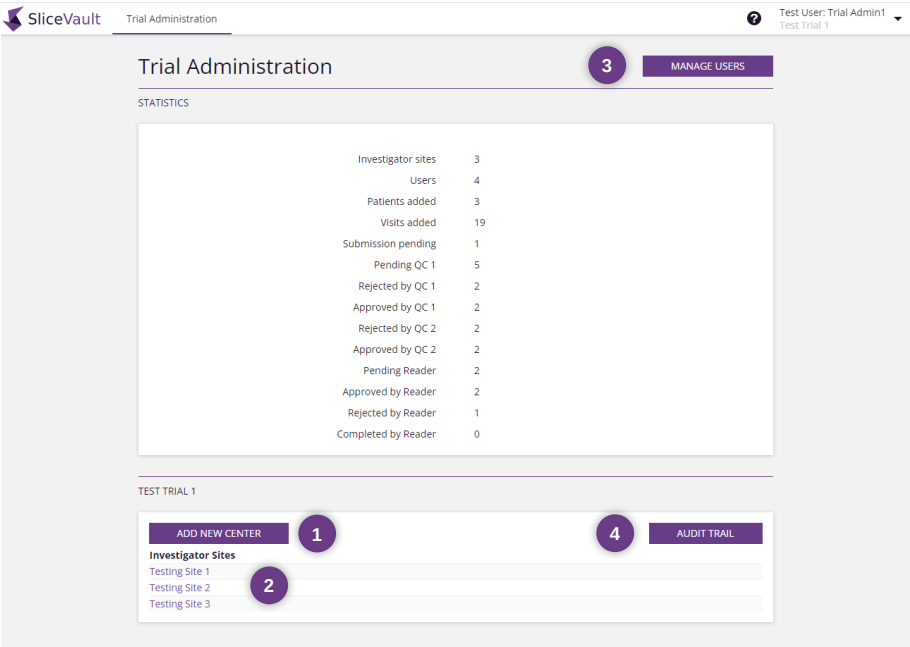
- Locate the desired site in the site list and click site name to open the site editor. From here you can manage patient ID, manage site users, manage SliceVault access and more.
- You can assign patient IDs to the site that investigators can select when uploading data. You can even allow Investigators to create patient IDs themselves using free text.
- You can invite users to the site and grant editor or reader user role for each user.

Access audit log

- Click the “audit trail” button to access the audit log. Here you can view all change events for the trial.

Understanding the main trial administration site

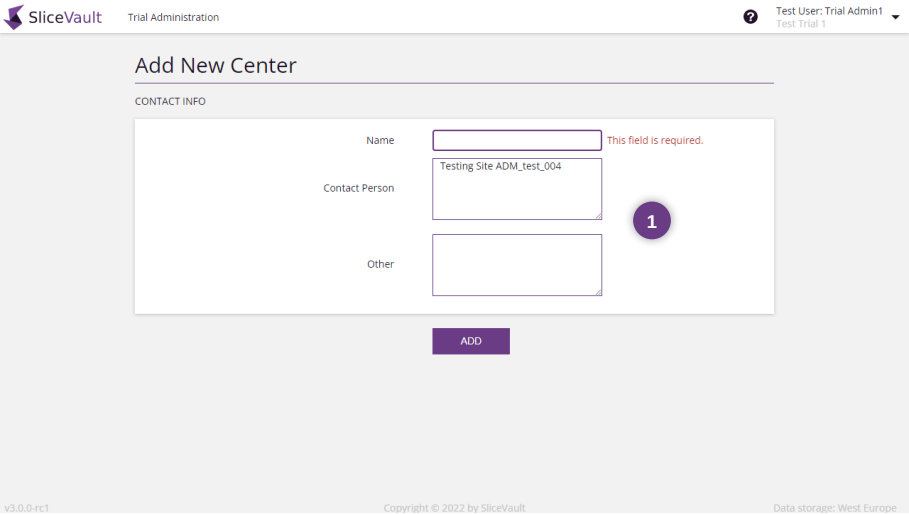
Trial Administrators can manage users and sites and access other functionality via the main trial administration site.



1. Click “add new center” to add new investigator site.
2. Click on site name to edit existing investigator site.
3. Click “manage users” to see and manage all users including users like Quality Control Managers and Readers.
4. Click “audit trail” to view audit trail.

How to add new investigator site

After clicking “add new center” from the main trial administration site you see this screen:



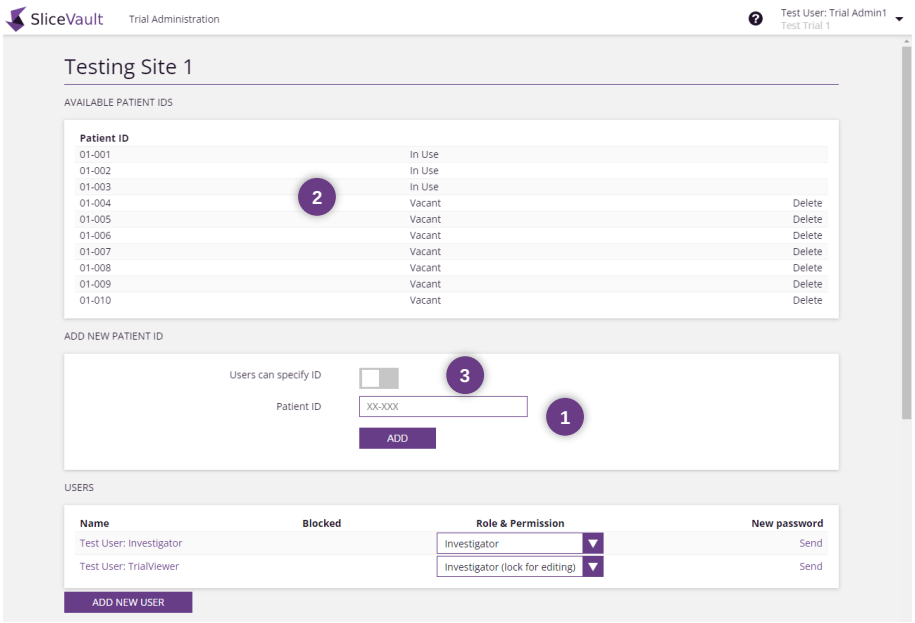
1. You are required to fill in site name and contact person. Click the “add” button to create site, after which you are redirected to the site editor for further site configuration.

How to manage investigator sites

You can manage existing investigator sites by clicking on site name in the site list on the main trial administration site.

How to manage patient IDs

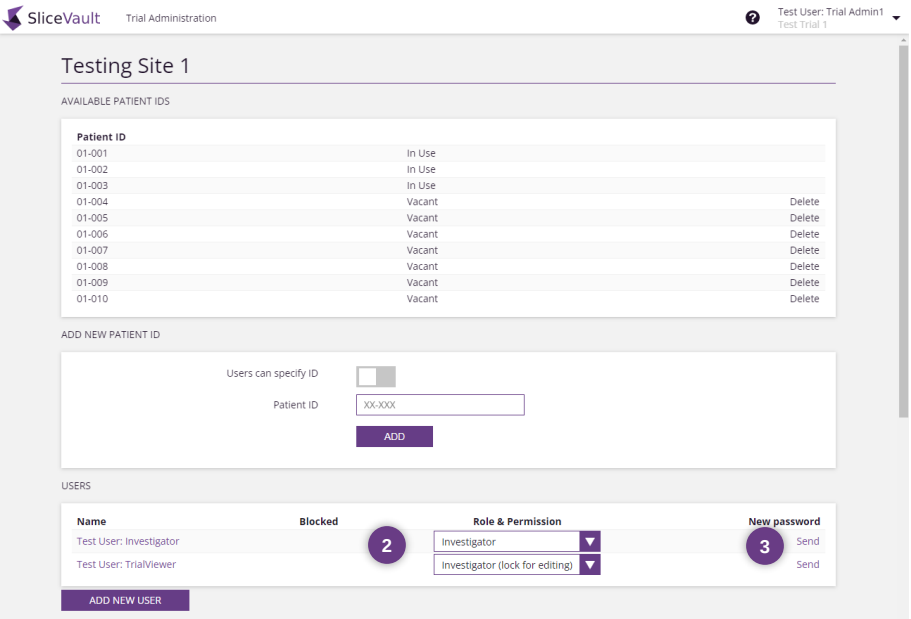
Investigators must specify patient ID when adding data for a patient that is not yet registered on SliceVault. Trial Administrators can restrict the patient IDs that Investigators can select.



1. Type patient ID and click the “add” button to assign the new patient ID to the site. The syntax of the patient ID can be restricted depending on your trial.
2. A list of patient IDs for the site is available. You can delete vacant patient IDs from the list.
3. By enabling the “users can specify ID” slider you allow Investigators to create patient IDs themselves using free text. The syntax of the patient ID can be restricted depending on your trial.

How to manage investigator users

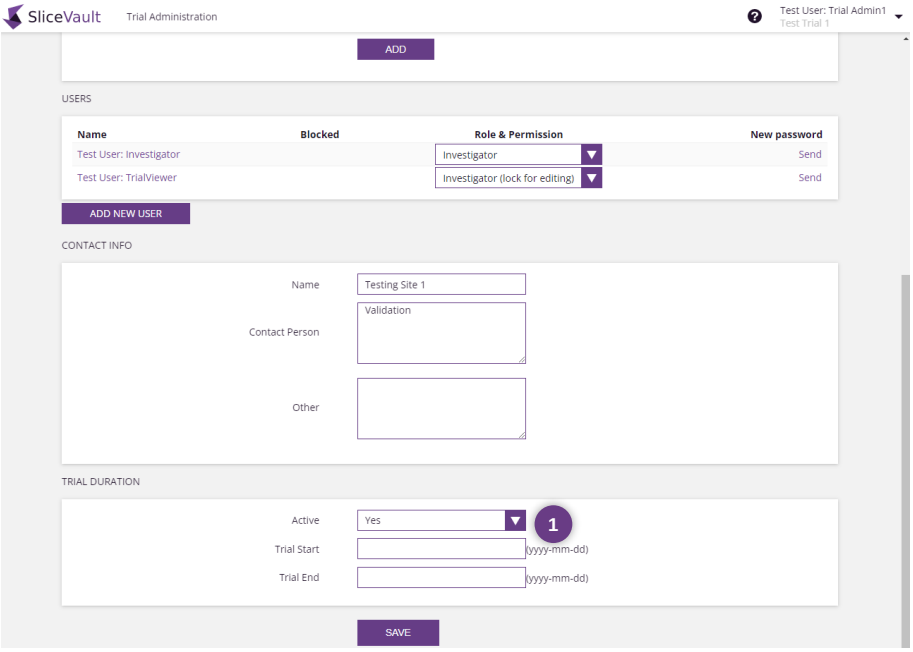
In the site editor, you can invite new Investigator users and manage existing users.



1. Click “add new user” to create a new user. You must fill in username and email. An email with login credentials is automatically sent to the user’s email.
2. You can restrict investigators by changing their user role from “Investigator” to “Investigator (lock for editing)”, which will prevent the investigators from uploading and managing data.
3. You can issue new password by clicking the “send” link. An email with new login credentials is automatically sent.

How to manage group access

You can manage group access, which will impact all users belonging to the site.



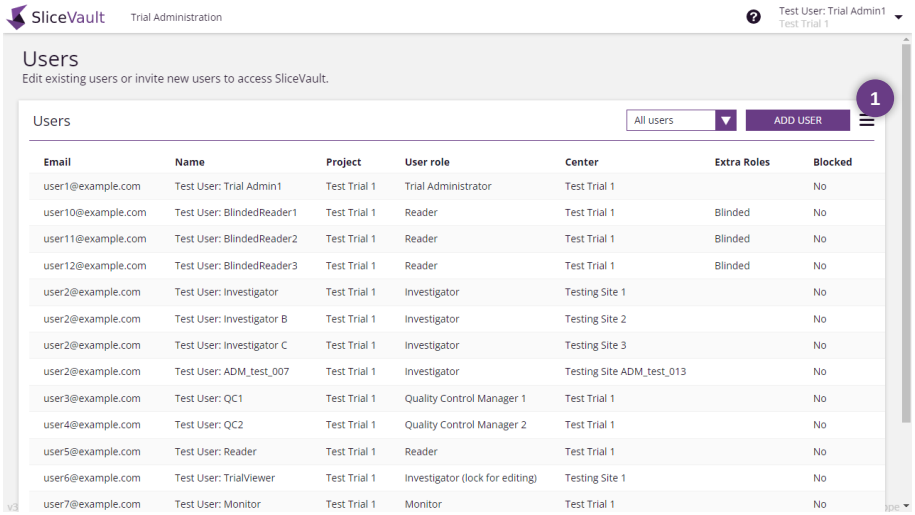
1. Site must have active status YES for site users to login to SliceVault.

By changing status to NO, all users belonging to the site (even though they have valid login credentials) will not be permitted to login to SliceVault.

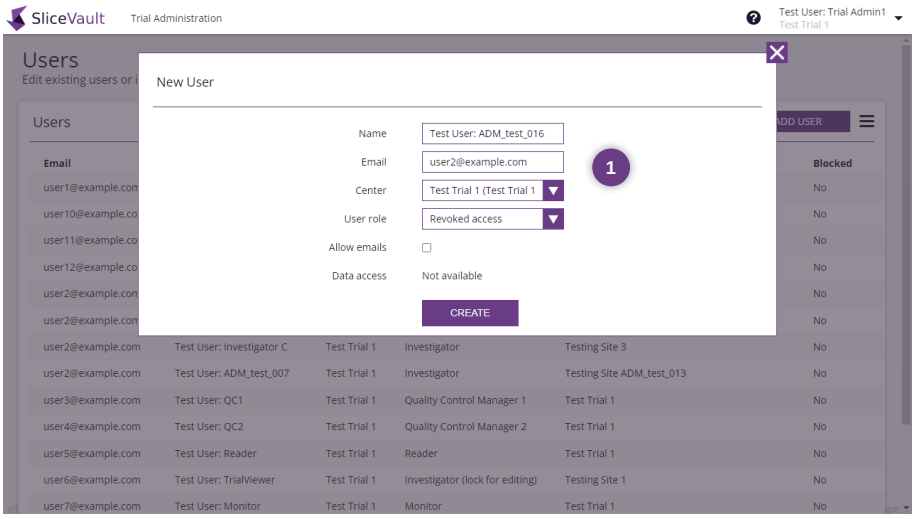
You can specify an access window, in which site users are permitted to access SliceVault.

How to view and manage all trial users

Trial administrators can manage all trial users, including users like Quality Control Managers and Readers, by clicking the “manage users” button from the main trial administration site.



1 Click the “add user” button to create a new user.



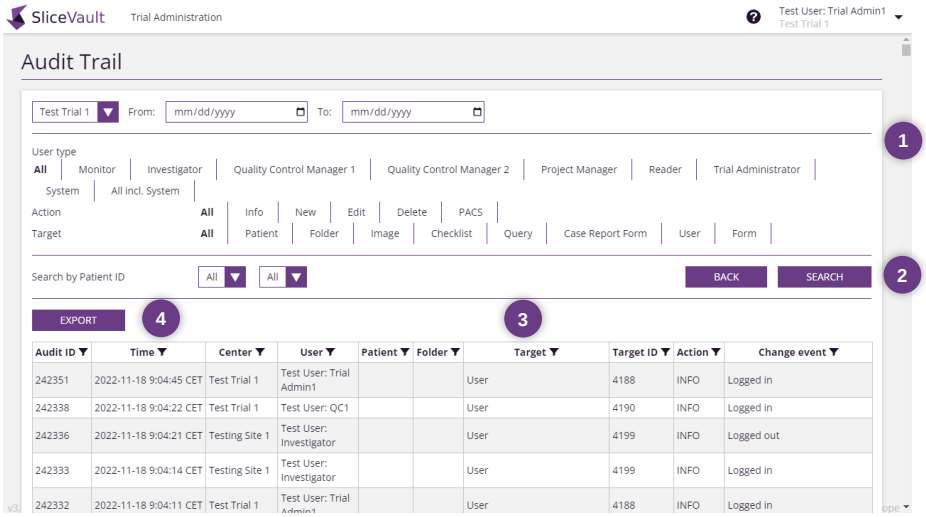
Fill in the required information to add the new user. Please note that you cannot change email or center after the user is created.

1

Depending on your trial and choice of user role, you might be able to assign extra roles, such as “blinded” for users with user role Reader, or restrict access to data by site.

How to view the audit log

The audit log is accessible from the main trial administration site.



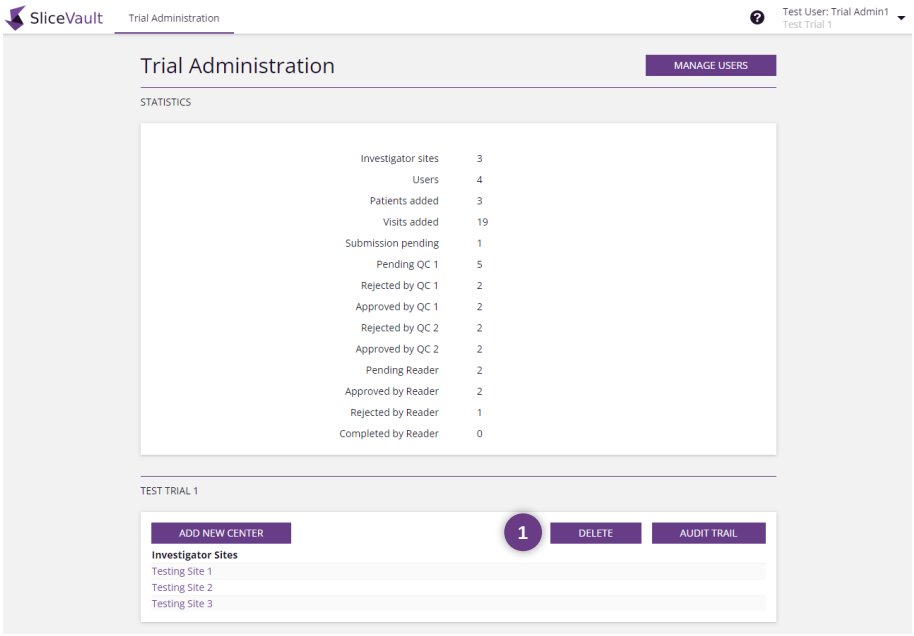
1. You can apply filters to the audit log such as date intervals, event type, event target or user. This makes it easier to track specific change events.
2. You can search for change events by user group or patient ID. Click the “search” button to retrieve the audit log based on selected filters.
3. Audit log is displayed in a read-only format.
4. You can export the audit log to standard file formats.

How to permanently delete trials including all data

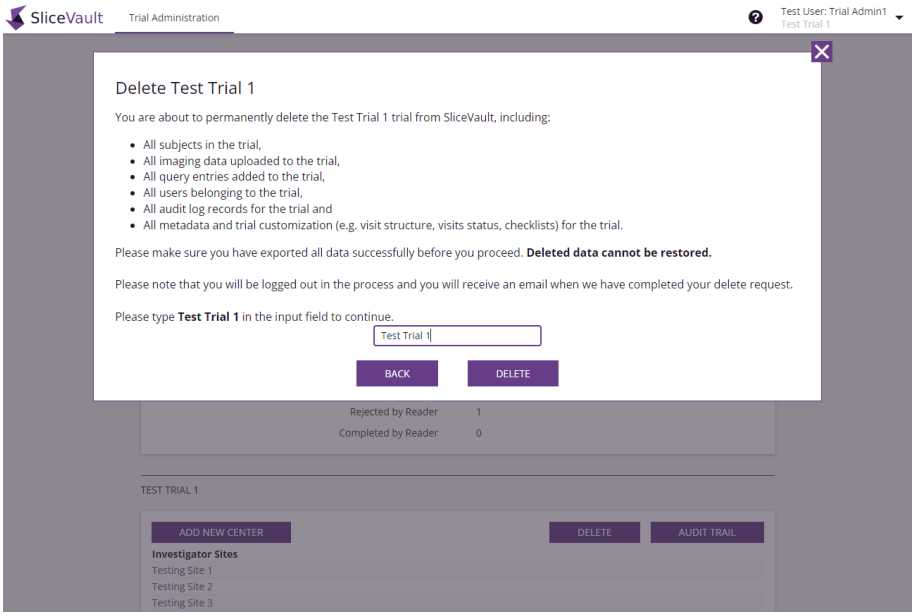
Trial Administrators have the option to permanently delete a trial, when a trial is complete and it is time to permanently delete all data from SliceVault.

The functionality is disabled for Trial Administrators by default. Please contact SliceVault Support at support@slicevault.com to enable the delete trial functionality.

A “delete trial” button is visible on the main trial administration site when the when the functionality is enabled.



1 Click delete trial to start.



1 To avoid accidental deletion, you are requested to type in the trial name in the input field to enable the “delete” button.

Deleting a trial is an irreversible action and will permanently delete all data pertaining to the trial from SliceVault servers (including all uploaded data, all metadata, all users registered to the trial, all audit log entries, etc.).