LiLi DICOM Viewer

User Manual

Elevate Imaging Inc.

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PREFACE

Thank you for using the LiLi DICOM Viewer, an application for medical image management and processing. Please keep this user manual in workplace so that users can access it conveniently.

This manual provides a detailed description of the design, functions, and operations of the LiLi DICOM Viewer software. Before using this software, please carefully read this user manual to ensure proper operations, and protect the safety of both the patients and the system's users. If you have any questions, please contact us.

The LiLi DICOM Viewer software is designed for the management, displaying, processing, annotation, transmission and archiving of DICOM medical images (DR, CR, CT, MR, Ultrasound, PET), as well as for the generating, editing and exporting of reports. This software features a user-friendly interface and is easy to use. It provides users with a variety of image processing tools to manipulate and measure medical images, and to generate and edit reports

Our service engineers use a USB flash drive provided with this product to install and deploy this software.

This software should be shipped in its original packaging. DO NOT open the original packaging during shipment. During transportation, extra caution must be taken to prevent rain, snow, and mechanical damage. This product in packaging should be stored indoors or in a warehouse with an ambient temperature of -10-50℃, a relative humidity of no more than 95%, no presence of corrosive gases, and with good ventilation.

The maintenance of this software is the responsibility of Elevate Imaging Inc., and our company's maintenance personnel have received professional training from the company. For the convenience of maintenance, this software will generate interface call logs and exception logs during operation. Without the permission of the manufacturer, any modification to this software is NOT allowed.

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Charpter 1 Product Overview

1.1 Product Description

Product Name: LiLi DICOM Viewer

Model: LiLi

Release Version: V1

Full Version: V1.0.0.001

The LiLi DICOM Viewer software is designed for the management, displaying, processing, annotation, transmission and archiving of DICOM medical images (DR, CR, CT, MR, Ultrasound, PET), as well as for the generating, editing and exporting of reports. Functions include users, projects, patients and image studies management, image reading, measurement and annotation, system configurations, and access control, etc.

LiLi DICOM Viewer adopts a B/S structure, and the client software runs on a browser. The software on client-side is available after connecting to the server through network. LiLi DICOM Viewer includes many image processing tools, categorized as follows:

1) Image Transform: change the size, position, and direction of images, and users can also rotate and reset the images.

2) Windowing: adjust the values of window width and level to better view images of different organs. Support preset templates, customized window width/level, and area window width/level.

3) Viewport Layout: display images in multi-viewports, making it convenient for readers to view more images of different body parts.

4) Image Annotation: annotate images with various annotation tools based on the need of reading, and annotated marks can be deleted selectively.

5) Measurement: measure objects with various measurement tools based on the need of reading, and the measurement records can be deleted selectively.

6) Screenshot of Images: capture the image and annotations of the current active viewport based on the need of reading.

7) Report: edit, save, submit and export imaging reports in batches based on the actual situation.

8) Image Sharing: share images and reports based on users' requirements, supporting online sharing and the download of images and reports.

1.2 Intended Use

LiLi DICOM Viewer is intended to be used as a medical image management and processing system for the displaying, processing, reading, measuring, communicating, distributing and archiving of medical images (DR, CR, CT, MR, Ultrasound, PET) in DICOM format, as well as for the generating, editing and exporting of reports.

1.3 Intended Users

Typical users of this system are trained healthcare professionals, including but not limited to radiologists, clinicians, nurses, medical technologists, and physician assistants.

1.4 Hardware and Software Requirements

The minimum hardware and software requirements of LiLi DICOM Viewer are as follows:

	Category	Parameter	Minimum Requirements
Server Side	Hardware	CPU	6 core 3.1GHz
		RAM	16GB
		Hard Disk	256GB SSD & 1024GB HDD
		Network Card	1000M
		Network Bandwidth	100M
	Software	Operating System	Windows Server 2016 64-bit
		Database	SQL Server 2016
		.NET Software Framework	.NET Core 6.0.0

		Software Tools	Nginx 1.20.2
Client Side	Hardware	CPU	4 core 1.6GHz
		RAM	16GB
		Hard Disk	512GB
		Network Card	1000M
		Network Bandwidth	100M
		Display	Resolution: 1920*1080
	Software	Operating System	Windows 10/11, MacOS 12.6
		Browser	Chrome 113+，Firefox 113+，Safari 16+，Microsoft Edge 113+

1.5 Access Control

Access to the LiLi DICOM Viewer software is password protected. To prevent security/confidentiality breaches, all users are required to set up usernames and passwords. Rules for usernames and passwords are as follows:

1) A username can only be consisted of letters, numbers, and underscores with a minimum length of 4 characters and a maximum of 16 characters.

2) System will generate a random password for a new account. When a user logs in for the first time, he/she is required to change this random password. The new password must contain:

    a. 8-32 characters;
    b. at least 1 number;
    c. at least 1 upper-case letter;
    d. at least 1 low-case letter;
    e. at least 1 special character.

To prevent unauthorized access to the system and patient data, the system takes the following measures:

1) The user interface will be automatically locked after 15 minutes of inactivity, and the user should enter the username and password to unlock it before resuming.

2) After 30 minutes of inactivity, the system will automatically log out and display the "Login" page. The user should enter the username and password to log in before resuming.

3) Users will log into the system from a web browser on client-side, and only one user is allowed to log into the system from the same browser at a time.

4) A user can only log into the system from one browser at a time.

1.6 Service Statement

The LiLi DICOM Viewer software must be installed by the service engineers from our company or by other authorized personnel.

For any modification to the hardware, network, or software configurations of an installed LiLi DICOM Viewer, please contact our engineers. Otherwise, you may lose the warranty.

We will be not responsible for any consequences caused by unauthorized modifications to the system. Should there be any issue related to the LiLi DICOM Viewer software, please contact us immediately.

1.7 Notice to Users

The intended users of the LiLi DICOM Viewer software are trained healthcare professionals, including but not limited to radiologists, clinicians, nurses, medical technologists, and physician assistants. To prevent mistakes, it is recommended that users read the *User Manual* to understand specific software information and/or contact our engineers for support and training. Qualified personnel are designated by a client's organization. Before using this software, users should have the correct version of the *User Manual* available for reference at any time. Please regularly review the operating procedures and safety precautions.

1.8 Symbol Description

For better understanding, this *User Manual* uses some special symbols to indicate different uses. Detailed descriptions are as follows:

Text / Symbol	Description
[ ]	[ ] is used to identify the following web components: • Human - Computer Interface • Data Table • Variables For example: [Add] popped window
< >	< > is used to identify the following web components: • Button Name • Interactive Web Page Elements For example: click < Confirm >button, click < Forgot Password > button

REMINDER

Help users to operate software more easily, and reduce erroneous operations.

CAUTION

Information that users should pay special attention to.

WARNING

Used to warn potential erroneous operations, which may cause losses if not avoided.

EXAMPLE

Use screenshots, case analysis or sample data to explain a concept or a specific step in detail.

1.9 Glossary

DICOM: Digital Imaging and Communications in Medicine

DR: Digital Radiography

CR: Computed Radiography

US: Ultrasound

CT: Computerized Tomography

MR: Magnetic Resonance

PET:	Positron Emission Tomography
HTTP:	Hyper Text Transfer Protocol
SUV:	Standardized Update Value
HU:	Hounsfield Unit
CPU:	Central Processing Unit
RAM:	Random Access Memory
SSD:	Solid State Drive
HDD:	Hard Disk Drive

Charpter 2 Software Installation

2.1 Software Installation and Authorization

The installation or upgrade of this software must comply with relevant laws and regulations, and must be done by our company's service engineers. Users are not supposed to install it by themselves.

Computers on which the software is installed should meet the requirements defined in Section 1.4 “Hardware and Software Requirements” and the minimum storage required for installation is 512MB.

During the installation process, insert the USB drive, run LiLi DICOM Viewer V1.exe, and start the installation program. The interface is as follows:

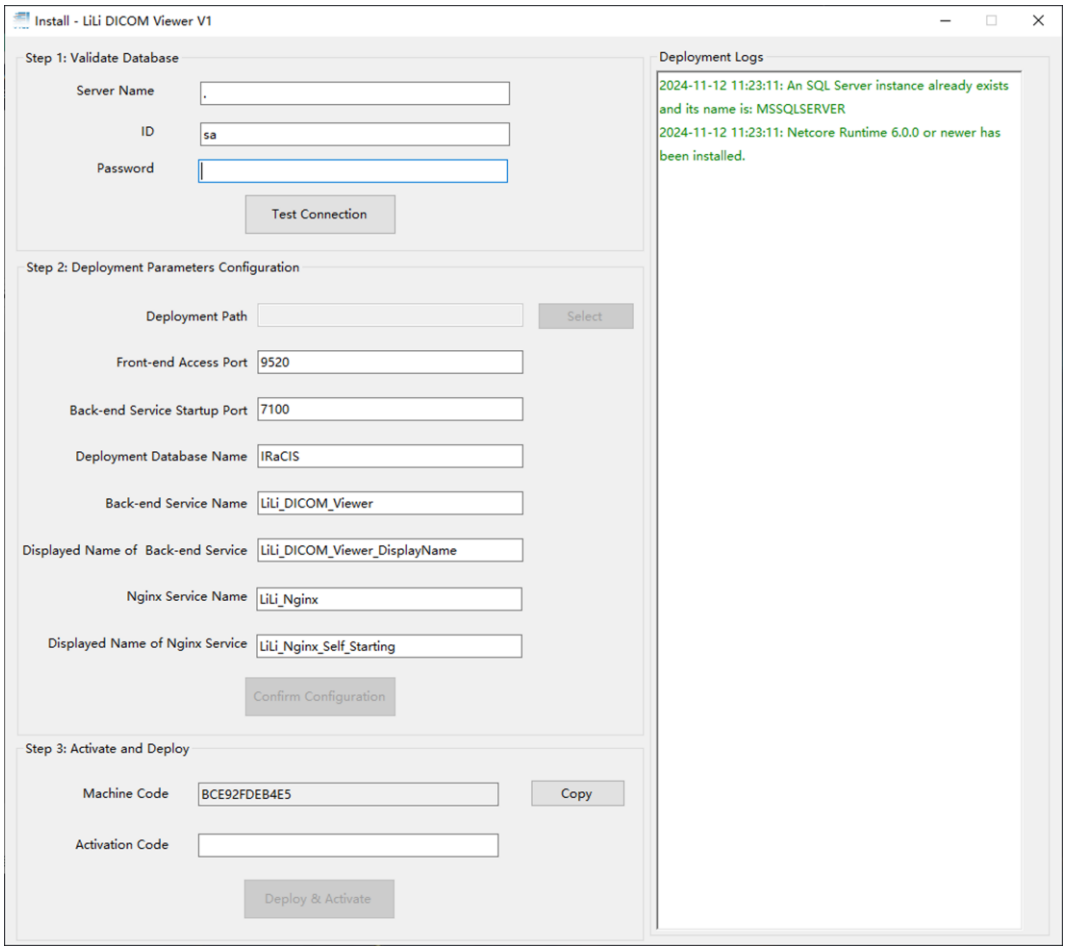

Fig. 1 Software Installation

The installation steps are as follows:

1) Verify the database: enter the database name, username and password, then clicking the <Test Connection> button. The verification result will be displayed in the logs window on the right.

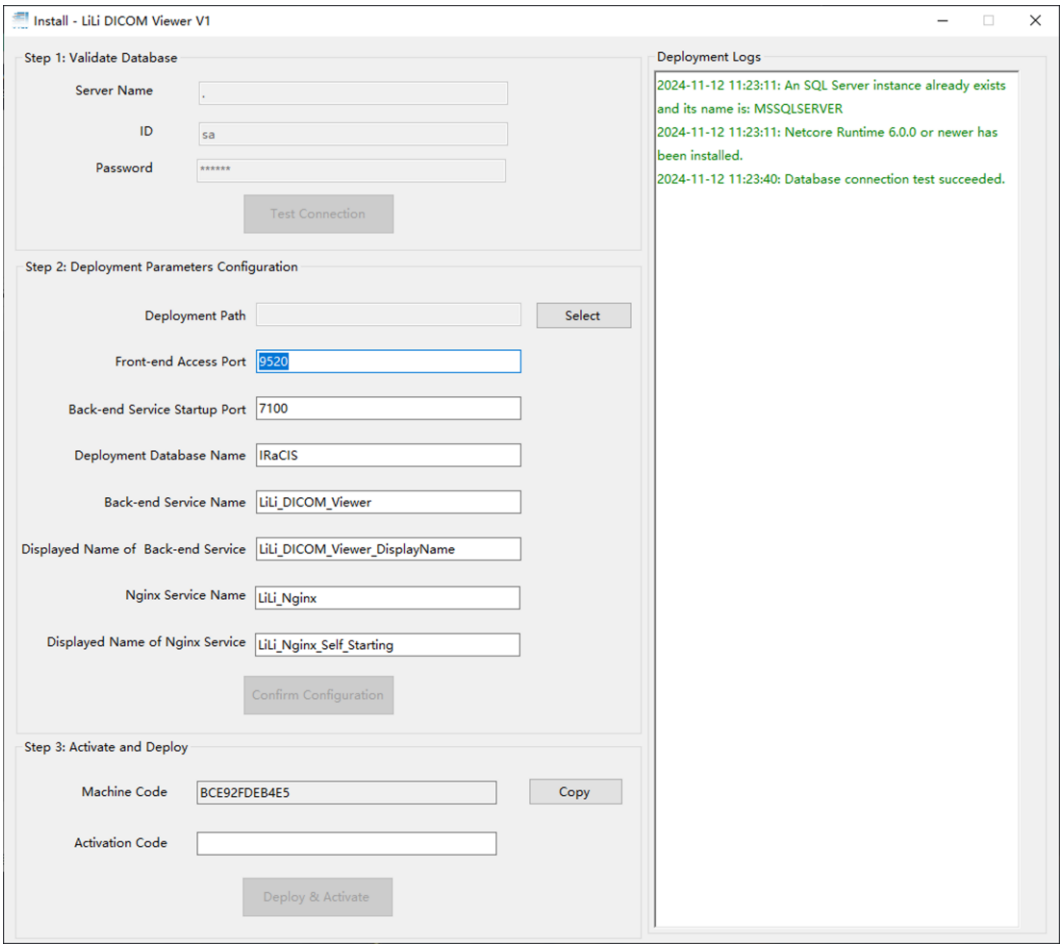

Fig. 2 Database Verification Passed

After the verification, proceed to step 2.

2) Configure the deployment parameters. Parameters for the back-end service are set as follows:
   a. Database Name: the name of the database which will be created during the deployment.
   b. Nginx Service Name: the name of the Nginx service, and the soft takes Nginx as the reverse proxy for the back-end service.
   c. Nginx Service Displayed Name: the displayed name of Nginx service
   d. Deployment Path: Service software installation path.
   e. Website Front-end Access Port: the server access port, which is the website's access port.

f. Website Back-end Service Startup Port: the server software back-end service listen port, which is the website front-end access back-end service port.

g. Website Back-end Service Name: name of server software back-end service.

h. Website Back-end Service Display Name: the displayed name of server software back-end service.

After completing the above configuration parameters, click the <Confirm Configuration> button. After confirmation, proceed to step 3.

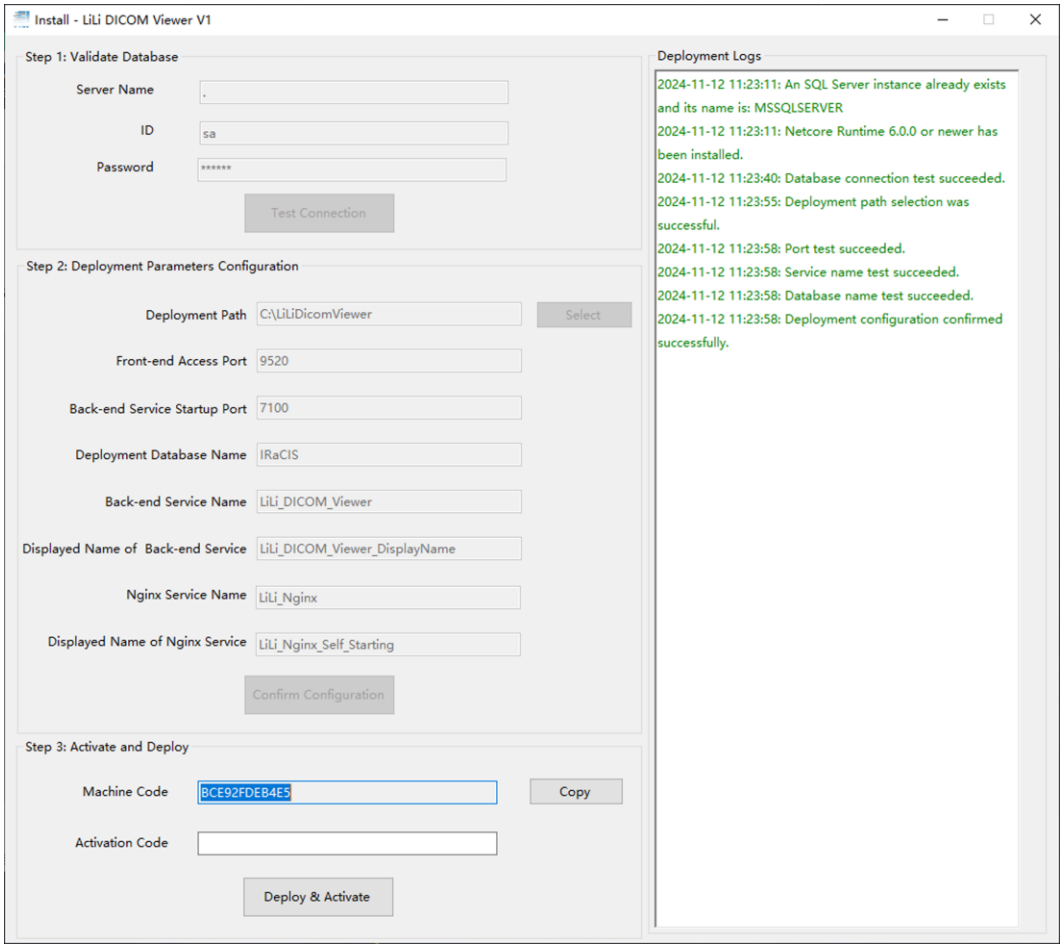

Fig. 3 Deployment Parameters Verification Passed

3) Activate & deploy: copy the machine code generated by the installation program and send it to the software license managers. Once receiving an activation code, the installation engineer enters it in the installation user interface to active and deploy.

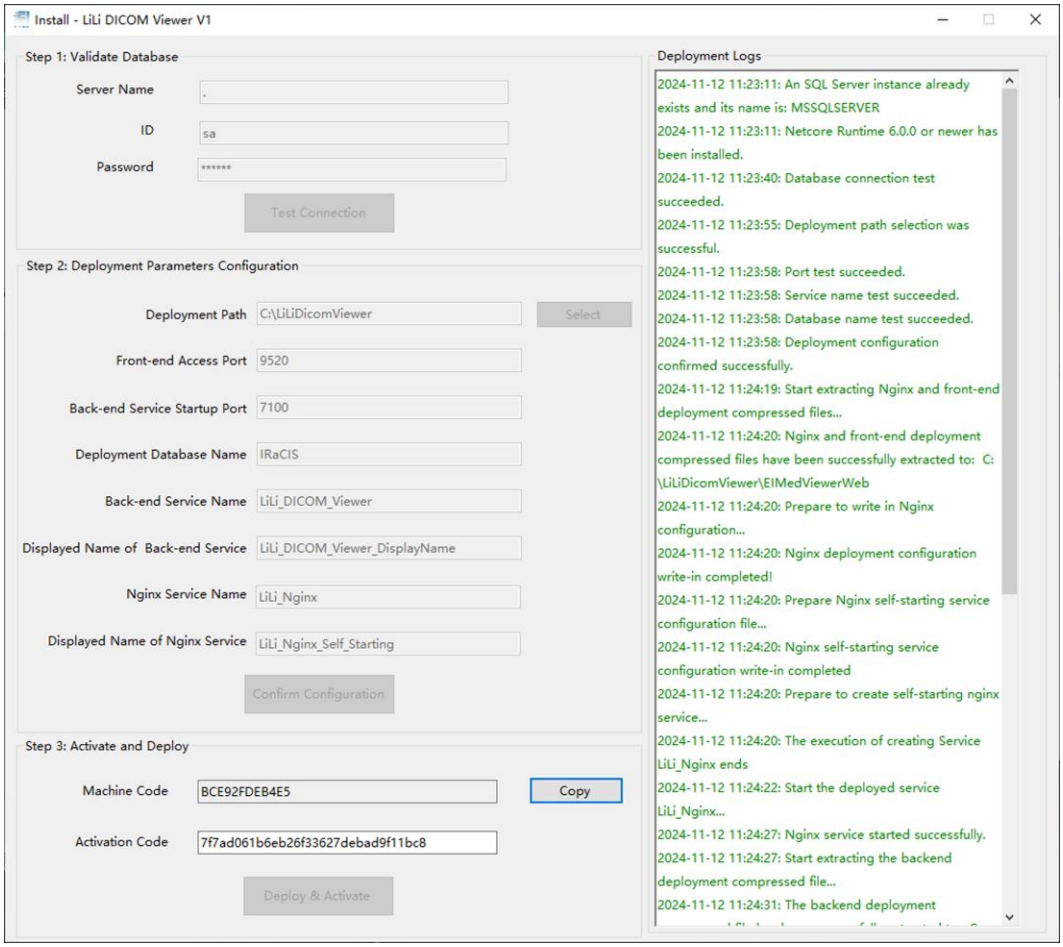

Fig. 4 Successfully Deployed & Activated

After the installation is completed, the server website will automatically start.

REMINDER

The domain name and SSL certificate deployed for the website will be configured in the Nginx program under the software installation path. After the configuration is completed, restart the Nginx service.

2.2 Software Uninstallation

Uninstalling software must be performed by our company's engineer or by other authorized personnel. Make sure to back up your data properly before software uninstallation.

When uninstalling, run Uninstall.exe in the installation path to start the uninstall program. After confirming on the uninstall interface, the software will be automatically uninstalled.

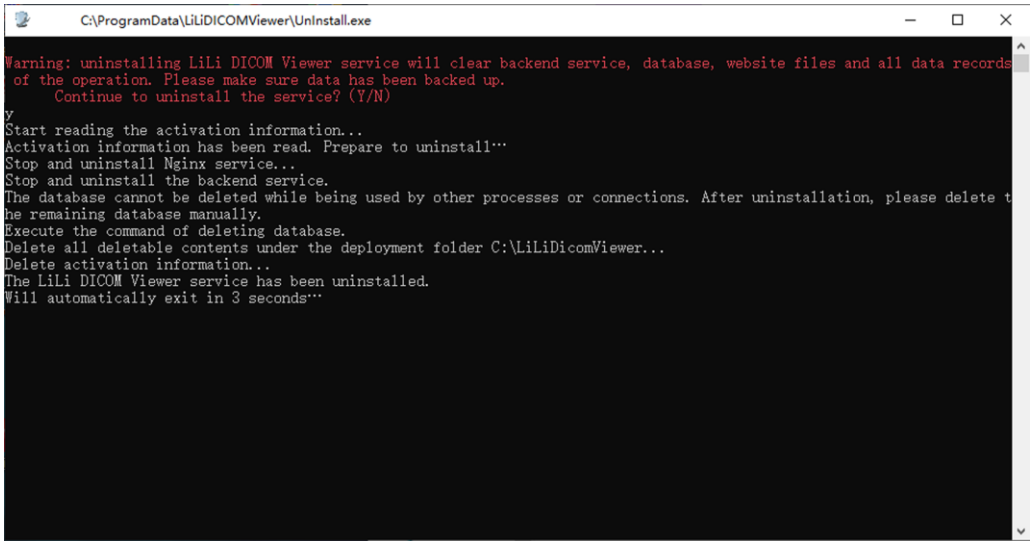

Fig. 5 Software Uninstall

WARNING

When uninstalling the software, all back-end services and databases will be deleted. Please back up the database and image data before uninstalling.

2.3 Software Upgrade

This software supports upgrade, and the upgrade steps are as follows:

1) The upgrade program package will be provided by our company.
2) Our service engineers select the original software installation path, and run the upgrade installation program with one click of a button.
3) During the upgrade process, only the software components are updated, and the existing configurations and data are not modified.

Charpter 3 Software Usage

3.1 User Interface and Workflow

3.1.1 User Interface

In our system, there are 4 top-level menu items in the user interface: User Management, Configurations, My Projects and My ID (displaying the current username and the role it is associated with).

There are also 4 major user roles in our system: Administrator, Project Manager (PM), Image Collector (IC) and Image Reviewer (IR). After logging in, users of different roles will see different menu items.

The description of each menu item is as follows:

1) User Management: manage and display user accounts and roles
2) Configurations: its sub-menu “Anonymization” manages DICOM image anonymization settings.
3) My Projects: include project list and project details. A project list is displayed for all non-administrator users. The detailed descriptions are as follows:
    a. Project details include four submenus: Patients, Study Batches, Reads, and Staff. Project Manager can access all submenus. Image Collector can only access the Patients and Study Batches submenus. Image Reviewer can only access the Reads submenu.
    b. The Reads tab in the second-level submenu includes four third-level submenus: Assignment, Tracking, Pending and Completed. Among them, Project Manager can access the Assignment and Tracking submenus, while Image Reviewer can access the Pending and Completed submenus.
4) My ID (displaying the current username and its role): it has two sub-menus: Profile and Sign Out. The “Profile” menu provides both the user account information and the password modification function.

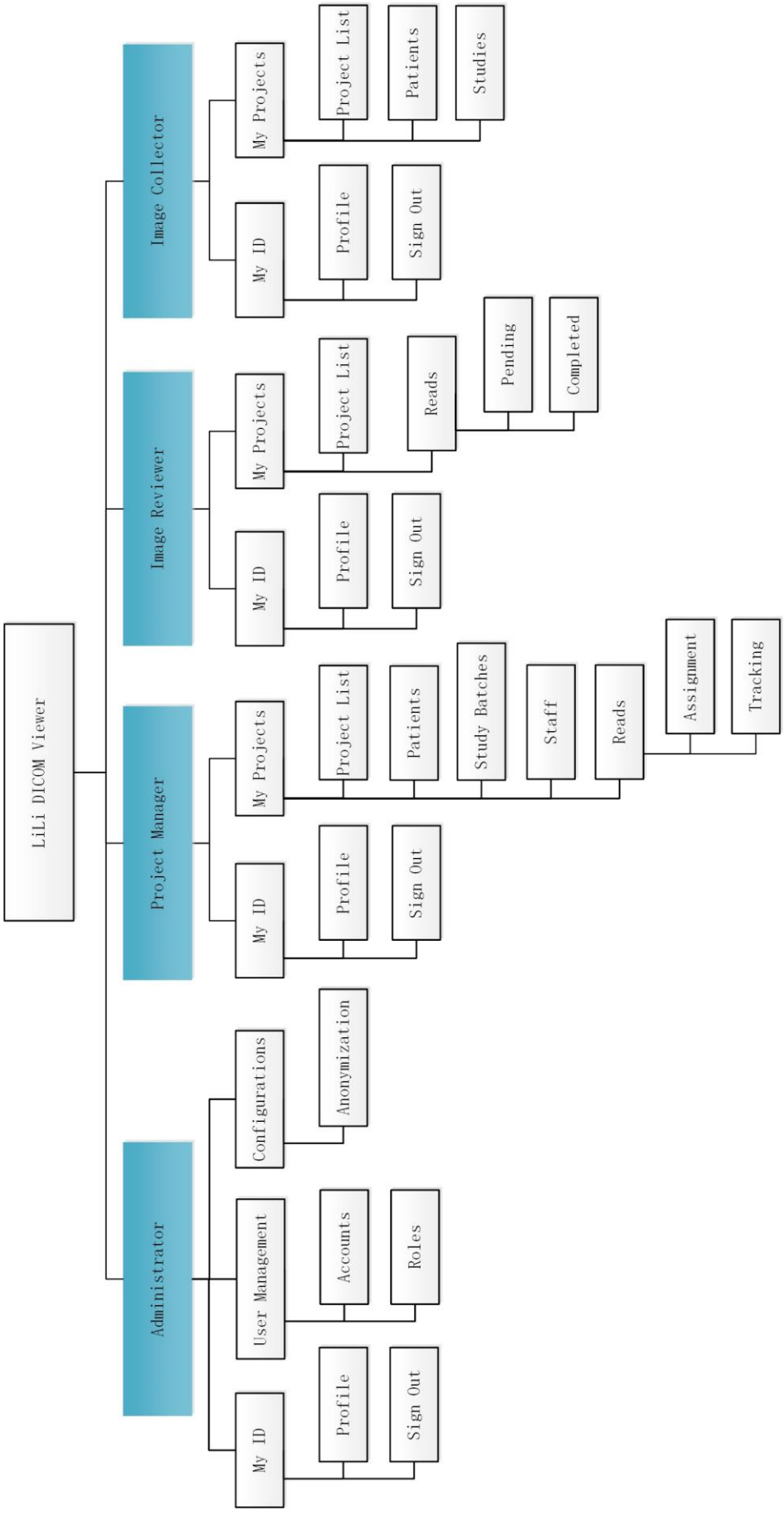

Fig. 6 LiLi DICOM Viewer User Interface Diagram

3.1.2 General Workflow

The LiLi DICOM Viewer software is designed for the management, displaying, processing, annotation, transmission and archiving of DICOM medical images (DR, CR, CT, MR, Ultrasound, PET), as well as for the generating, editing and exporting of reports.

A basic workflow of using this software includes the following steps:

1) Project Manager logs into the system. Please see Section **3.2 Login and Account Management** for details.
2) Project Manager creates a new project, enables it, and adds staff members to the project. Please see Section **3.3 Project Management** for details.
3) Image Collector adds patients and edits patient's information. Please see Section **3.4.1 Patient Management** for details.
4) Image Collector logs into the system and uploads DICOM images and edits the information of image studies. Please see Section **3.4.2 Study Management** for details.
5) Project Manager assigns reads to Image Reviewers. Please see Section **3.4.3 Reads Assignment** for details.
6) Image Reviewer reads, measures and annotates DICOM images. Please see Section **3.4.4 Image Reading** and **3.5 Image Reading** for details.
7) Image Reviewer edits, signs and submits the report. Please see Section **3.5.13 Edit Lesion Information** and **3.5.14 Report Management** for details.
8) Project Manager tracks the progress of image reading, and exports a summary of image review reports. Please see Section **3.4.5 Reads Tracking** for details.

3.1.3 Description of Generic Elements

3.1.3.1 Message

The LiLi DICOM Viewer software will generate informational and warning messages about the current status of the system. Some of these messages are related to information security, and users should pay attention to the messages and follow the instructions. Message types include Reminder, Confirmation, and Warning.

1) Reminder: information about the status of the system, and there is no need to confirm.

2) Confirmation: need to be confirmed before proceeding to the next step. A user clicks the <Confirm> button to proceed or the <Cancel> button to cancel the operation.
3) Warning: if there is a problem with a user's operation, a warning message will be displayed.

EXAMPLE

An example of a reminder message of data being successfully updated.

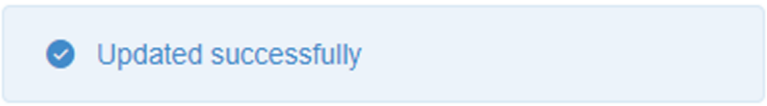

Fig. 7 A Reminder Message

EXAMPLE

An example of a confirmation message. On the Patients tab, when a patient is being deleted, the system will display a message for confirming the deletion.

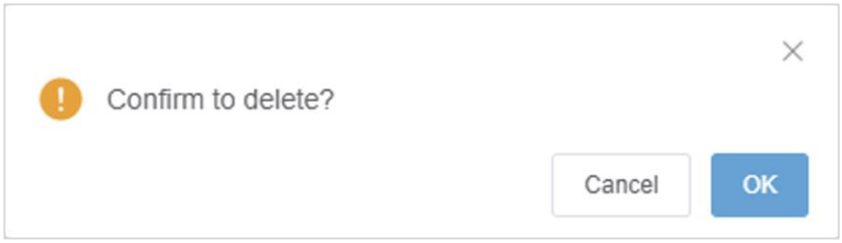

Fig. 8 A Confirmation Message

EXAMPLE

An example of a warning message. On the Profile page, when password is being changed, a warning message is displayed about the fact that the new password is the same as the latest old one.

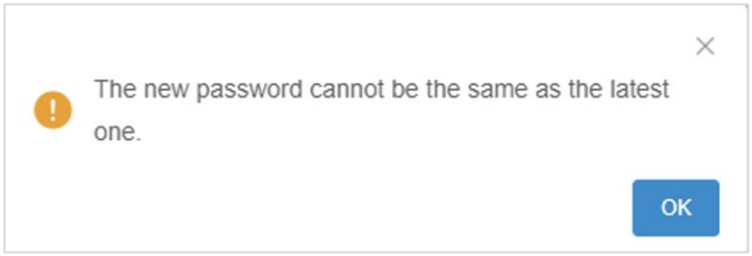

Fig. 9 A Warning Message

3.1.3.2 Search Function

Search function is available on all pages with lists. Search related elements are as follows:

1) Search Fields: input box, drop-down box, and time box. An input box supports entering texts to search. A drop-down box supports selecting a value to search. A time box supports selecting the time interval to search.
2) Interaction Buttons: <Search> button and <Reset> button. Click the <Search> button to search based on the search criteria. Click the <Reset> button to reset the search criteria.

EXAMPLE

1) An example of an input box: in the project list, search criteria such as Project ID, Project Name, Principal Investigator, Indications can be entered manually;
2) An example of a drop-down box: in the project list, a search parameter for Status can be selected in the drop-down box.

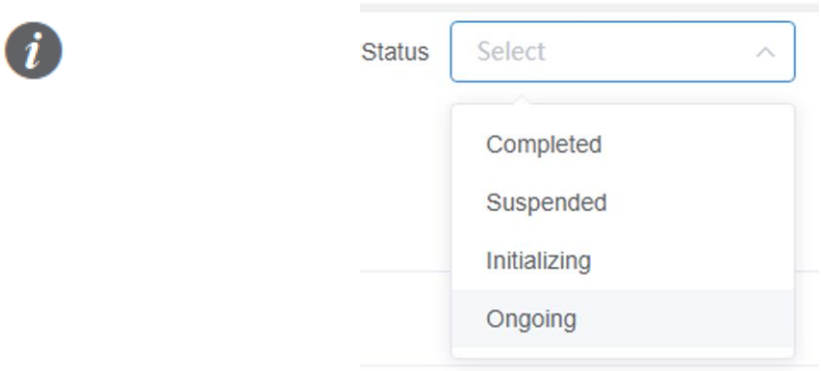

Fig. 10 Search with Input Box & Drop-Down Box

EXAMPLE

An example of a time box: in the project list, the search criteria of project created date can be selected from the time box.

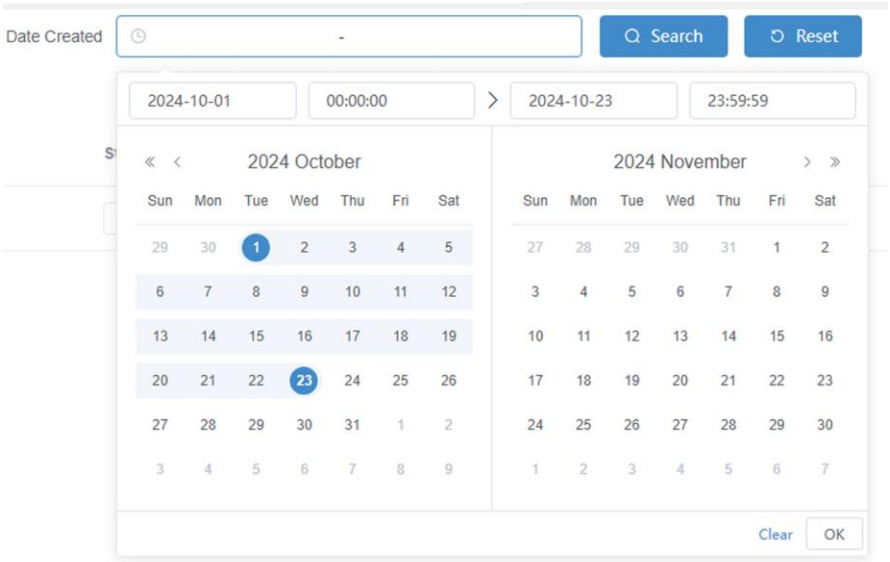

Fig. 11 Search with a Time Box

3.2 Login and Account Management

3.2.1 Login Interface

The user login page has functions of User Login, Password Reset and software information.

1) User Login:

Enter the username and password in this field and log into the system.

Fig. 12 Login Page

If the username or password is incorrect, a warning message will appear.

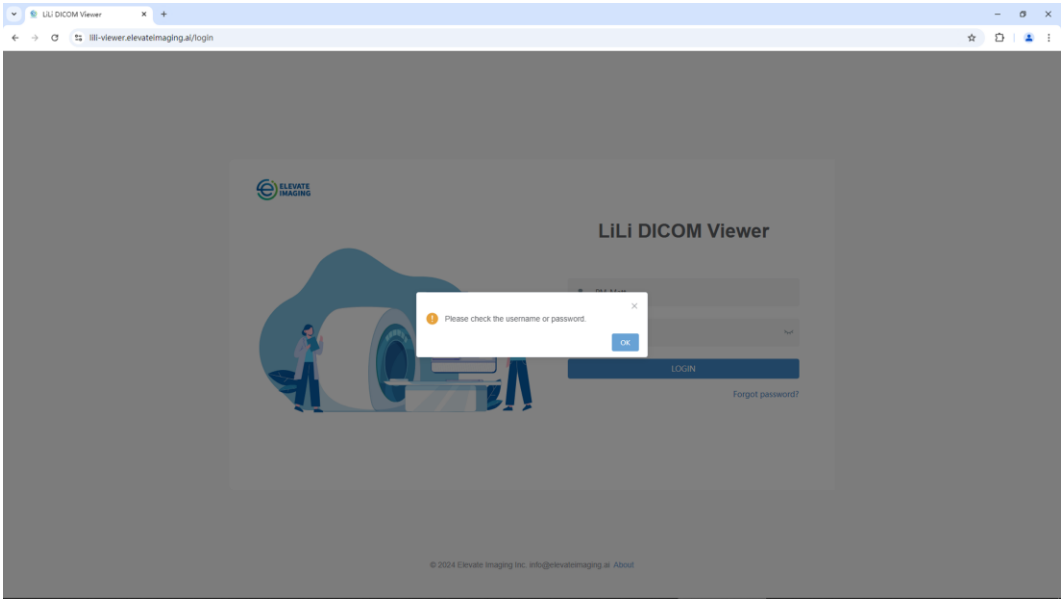

Fig. 13 A Warning of Incorrect Username or Password

2) Reset Password

If a user forgets the password, he/she can click the <Forgot Password> button on the login page to enter the [Reset Password] page and reset the password. The steps are as follows:

a. Enter the email address in the [Email] field, then click the <Verification Code> button to request for a verification code which will be delivered to the entered email address.

b. Enter the received verification code in the [Verification Code] field, and then click the <Verify> button. Once verified, the usernames linked to this email address will be displayed.

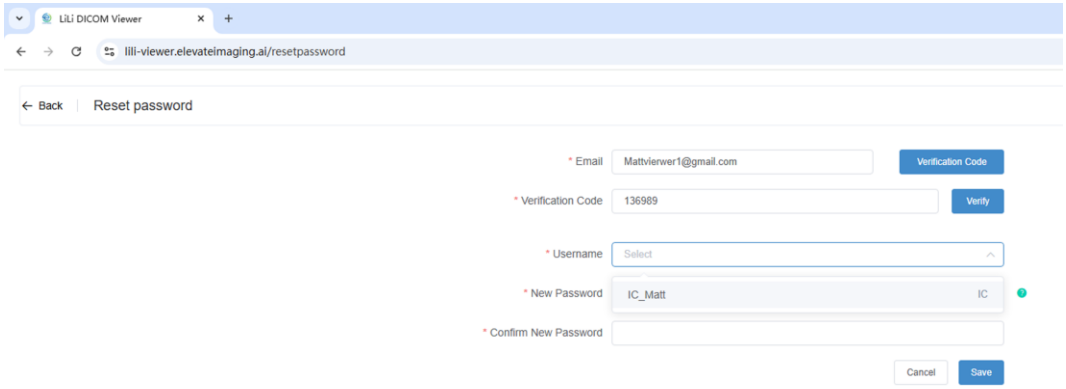

Fig. 14 Multiple Usernames Linked to an Email Address

c. Select the correct username in the drop-down menu, and enter the new password in the [New Password] field. The new password should comply with the system's password requirement rules; otherwise, a prompt will be displayed as follows:

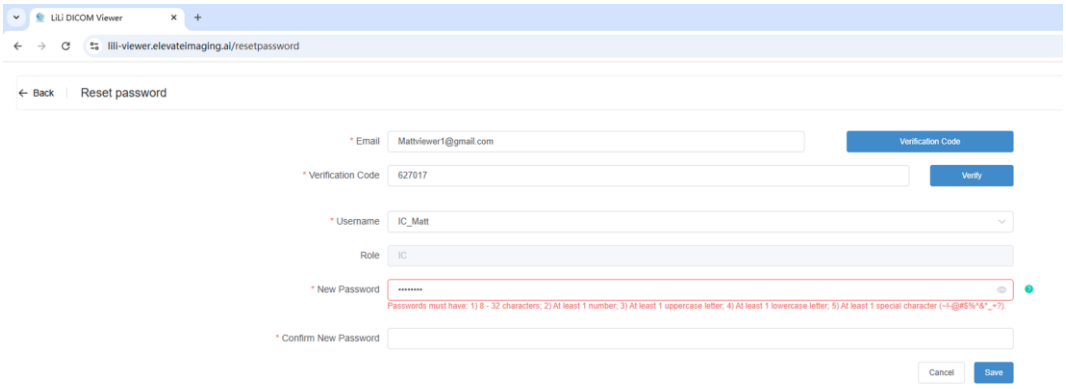

Fig. 15 A Reminder of Password Requirement Rules

d. Enter the new password again in the [Confirm New Password] field. If the re-entered new password doesn't match the original input, a prompt will be displayed as follows:

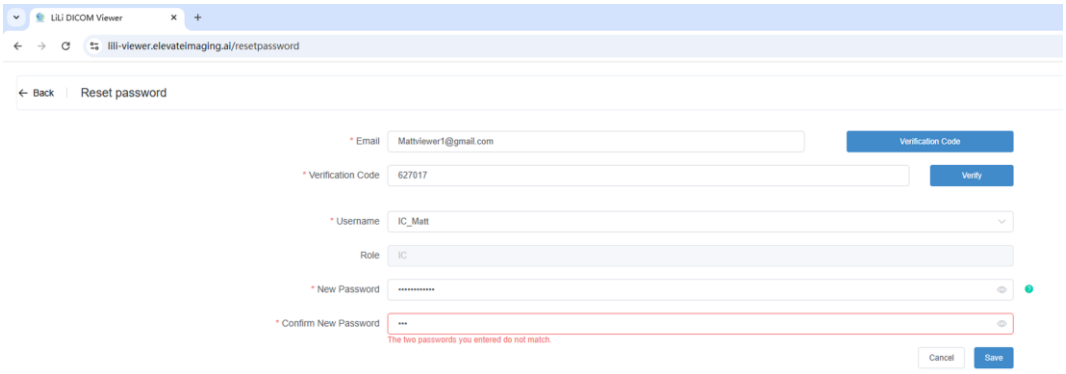

Fig. 16 A Reminder That the Re-entered New Password does not Match the Original.

CAUTION

A password must comply with the following rules:

a) 8-32 characters
b) At least 1 number
c) At least 1 upper-case letter
d) At least 1 lower-case letter
e) At least 1 special character

e. Click the <Save> button to reset the password.

3.2.2 Account Information Maintenance

After logging in, a user can manage account information through the Profile menu.

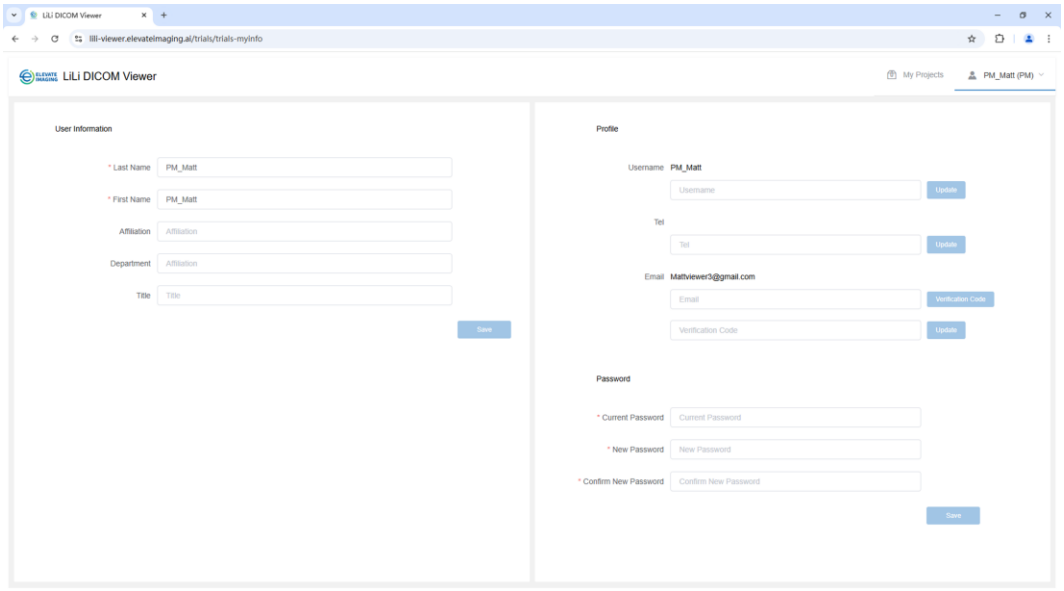

Fig. 17 Account Information Maintenance

1) Edit User Information

2) A user can edit information such as Last Name, First Name, Affiliation etc. here.

Edit Profile

A user can edit Username, Telephone Number, Email Address here.

CAUTION

1) A username can be consisted of letters, numbers and underscore with a minimum length of 4 characters and a maximum of 16.

2) To change the linked email address, a user needs to enter a new email address, clicking the <Verification Code> button, and a verification code will be sent to the new email address. Enter the received verification code, and the system will update the linked email address after verification.

3) Change Password

Users are allowed to change their passwords by themselves. When changing the password, a user must enter the old password and then the new password. The new password must be entered twice for verification purpose.

CAUTION

1) A password must comply with the following rules:

   a. 8-32 characters
   b. At least 1 number
   c. At least 1 upper-case letter
   d. At least 1 lower-case letter
   e. At least 1 special character

2）The new password cannot be the same as the latest old password.

If the verification fails, the system will display the following message:

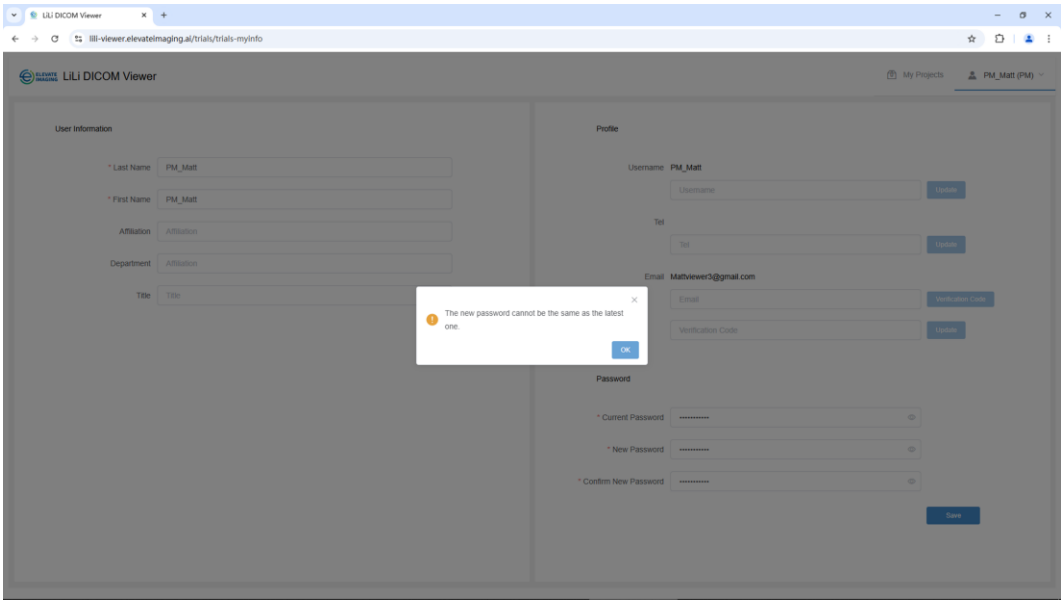

Fig. 18 A Warning of Password Verification

3.3 Project Management

3.3.1 Project Management

Project management module has the functions of creating new projects, editing basic project information, changing project status, deleting projects, and managing project details.

1) Add New Project

On [My Projects] page, clicking the <+ New> button will launch the [New] page. Project Manager then can create a new project by entering details such as project name, principal investigator, indication, and modality(ies).

Once all necessary information is entered, clicking the <Save> button will create a new project.

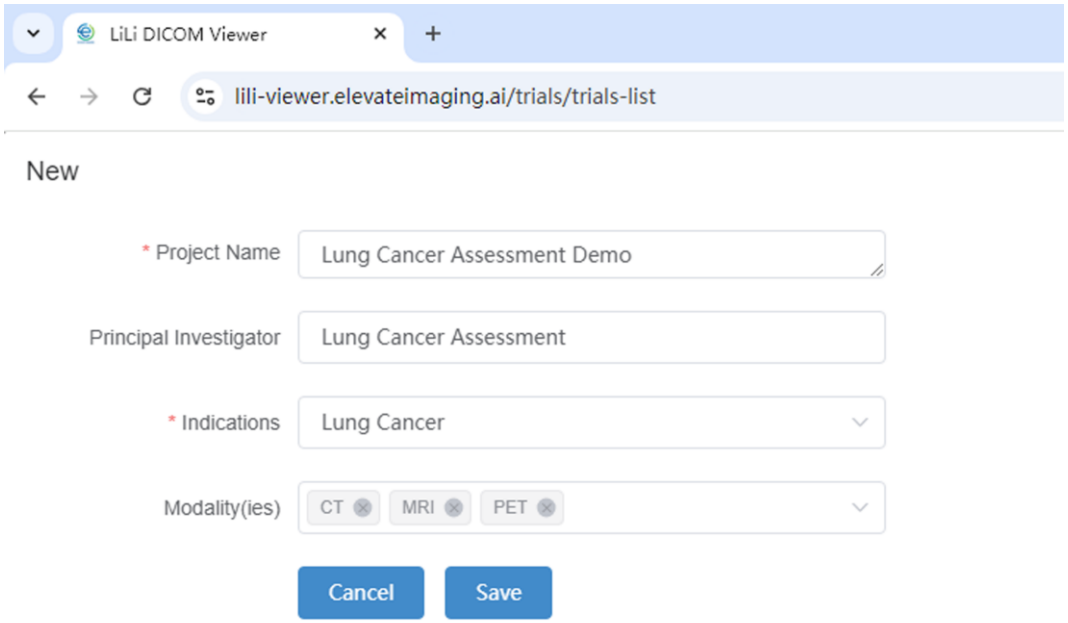

Fig. 19 Add a New Project

2) Edit Project Information

Clicking the <Edit> button in a project list launches the [Edit] page. Project Manager then can edit project information, such as project name, principal investigator, indication, and modality(ies) etc.

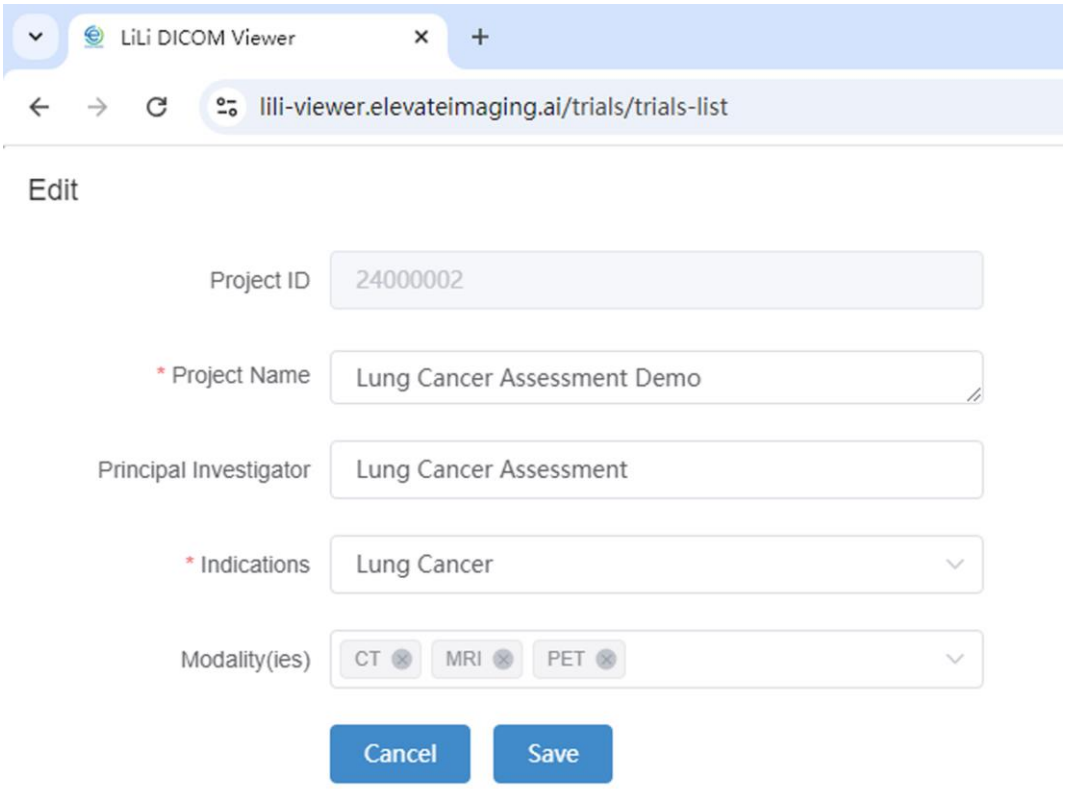

Fig. 20 Edit Project Information

3) Edit Project Status

Clicking the <Status> button in the list will bring up the [Project Status] window. Project Manager then can change the project status among Initializing, Ongoing, Suspended, and Completed.

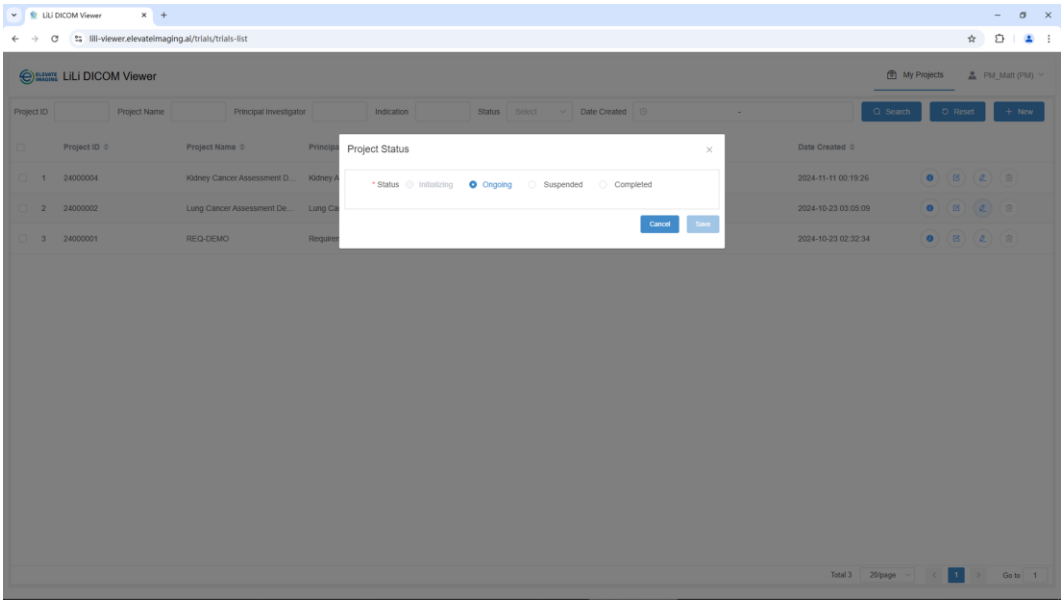

Fig. 21 Edit Project Status

Project Status shows the current status of a project:

a. Initializing: the initial status when a project is added;

b. Ongoing: a project is already in progress, and users can perform various operation in this project.

c. Suspended: a project has been temporarily suspended for certain reasons and can be resumed from this status. Users cannot modify data of a project if the status is “suspended”.

d. Completed: a project is completed normally. Project data cannot be changed anymore.

To complete the change of status, Project Manager needs to sign off.

CAUTION

The transitional relationship among project statuses is shown in the figure below. There is no need to provide a reason for the forward transition process of Initializing → Ongoing → Suspended/Completed. And a reason is required for the reverse transition process of Suspended/Completed → Ongoing.

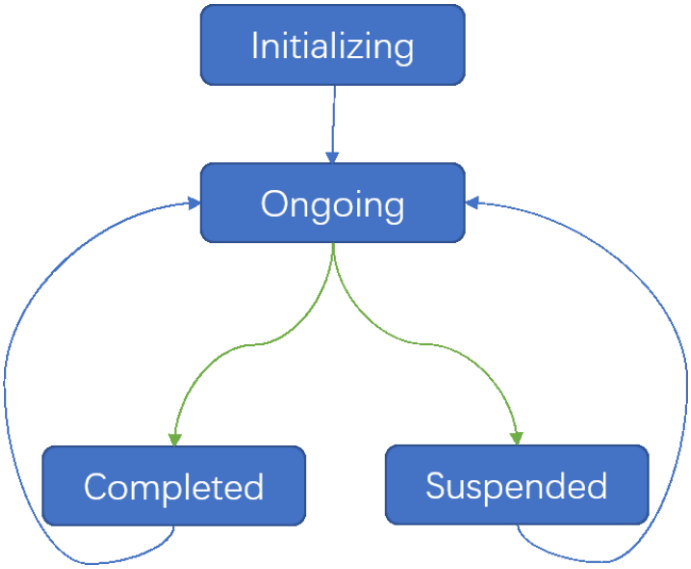

Fig. 22 Transitional Relationship among Project Statuses

4) Project Details

Clicking the <Details> button of a project list, you can view the details of a project through four tabs: [Patients], [Study Batches], [Reads] and [Staff].

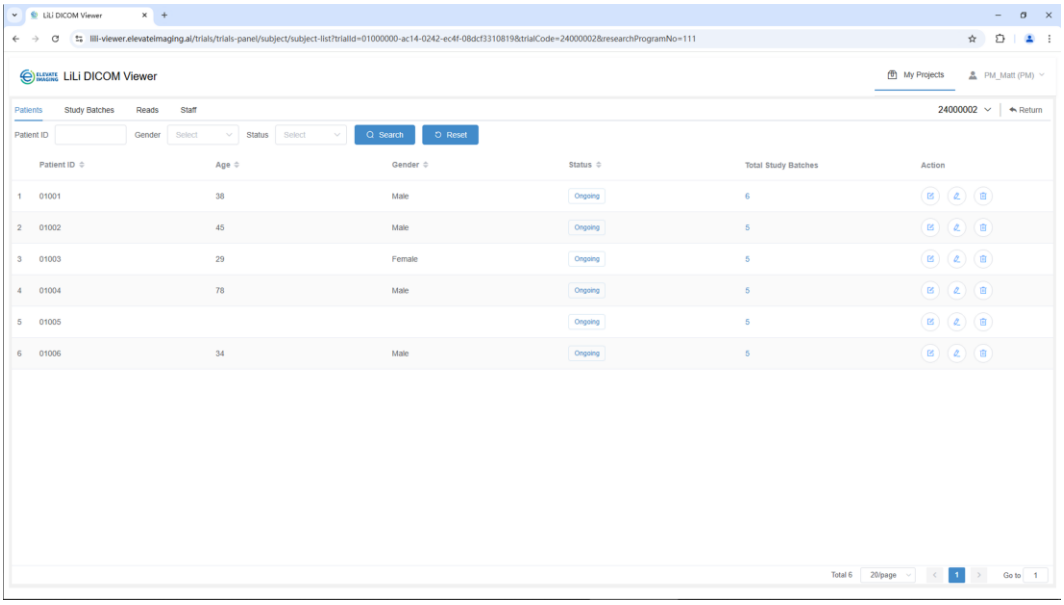

Fig. 23 Project Details

Clicking the Project ID on the upper right corner of the Project Details page, a drop-down list displays all projects the current user has participated in. Clicking any of the projects will switch the Project Detail page to that project.

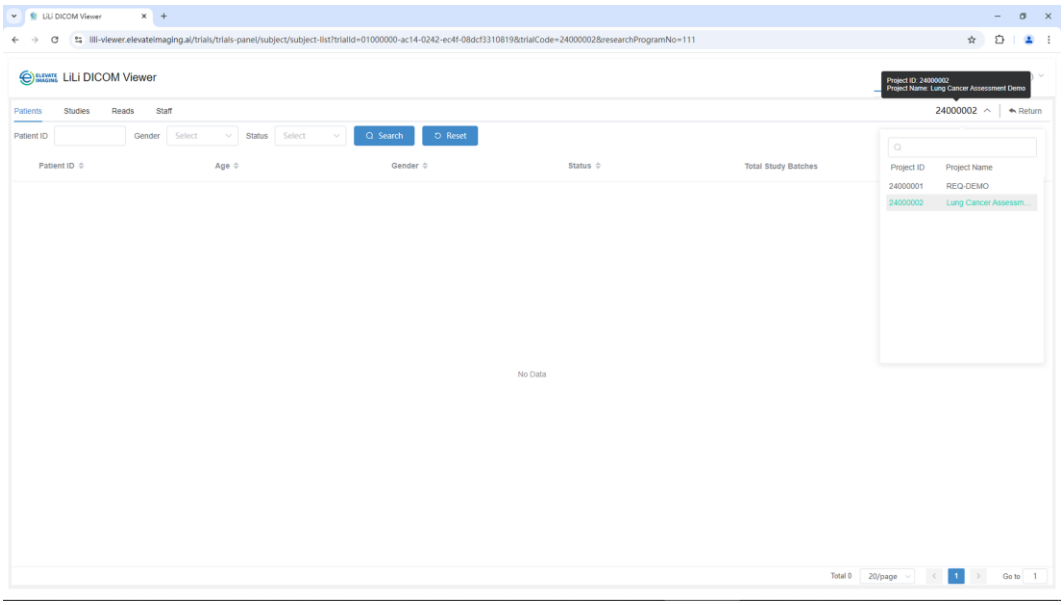

Fig. 24 Quick Switch between Projects

5) Delete Project

Clicking the <Delete> button in the list of a project, the system will display a confirmation window. This project will be deleted after the confirmation.

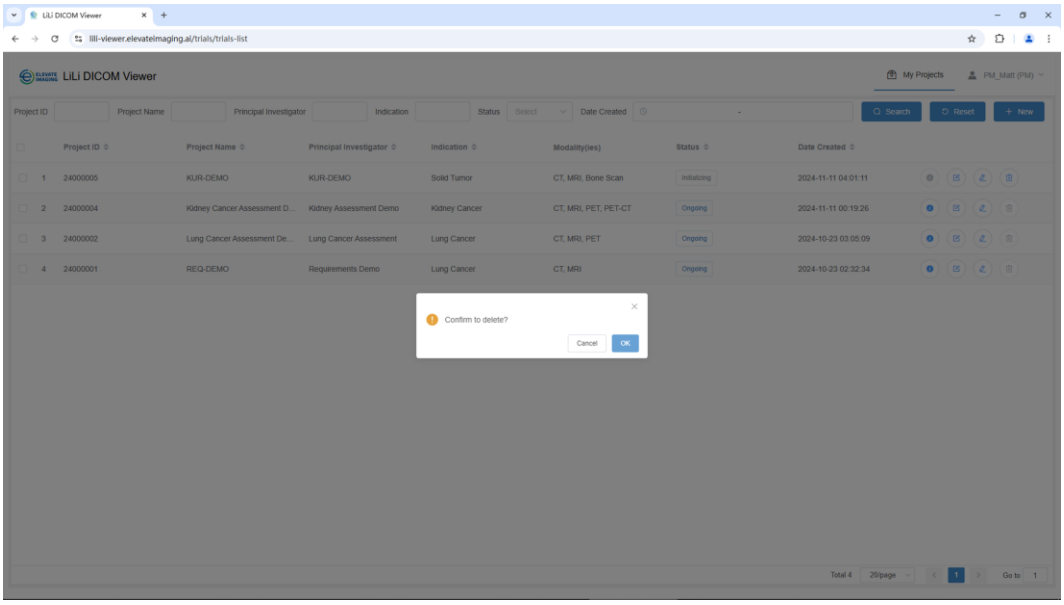

Fig. 25 Delete a Project

Reminder

The <delete> button is functional only when the project status is "Initializing".

6) Project List

The project list displays project information, including Project ID, Project Name, Principal Investigator, Indication, Modality(ies), Status, and Date Created.

Project Manager can search project by Project ID, Project Name, Principal Investigator, Indication, Status, and Date Created.

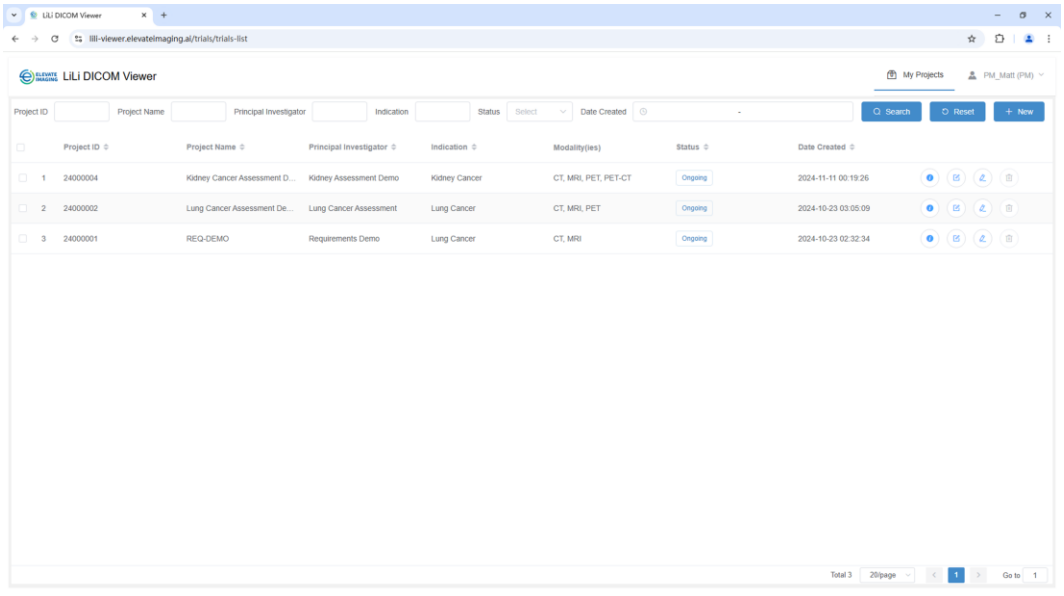

Fig. 26 Project List

3.3.2 Staff Management

Project Manager can add staff members and change the status of a staff member.

1) Add Project Staffs

Click the <+Add> button, and the [Add] page will pop up. Project Manager can then select and add a staff member to the project.

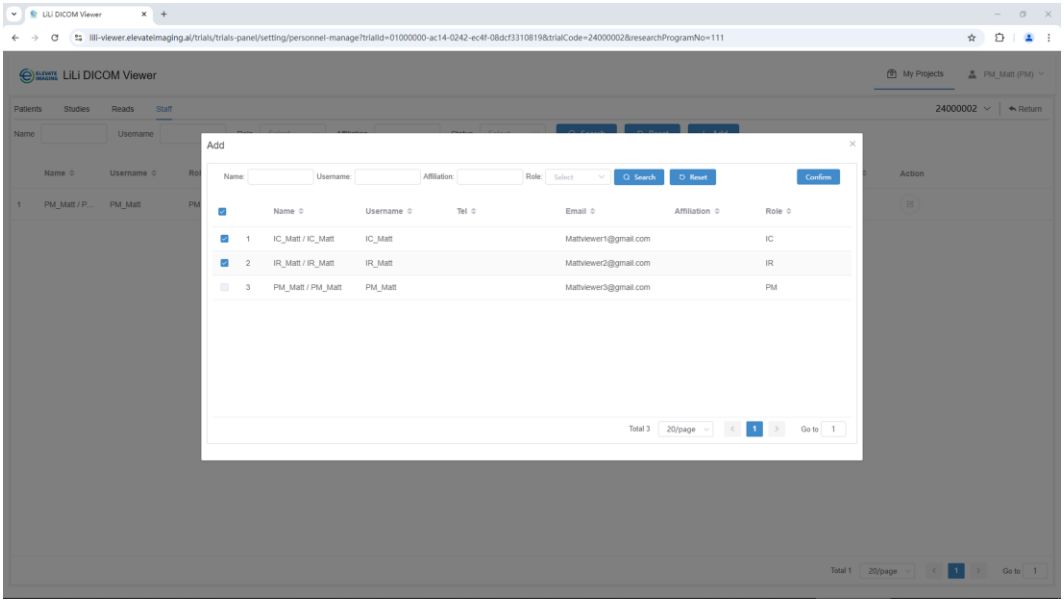

Fig. 27 Add a Staff Member

2) Edit the Status of a staff member

Project Manager can edit the status of a staff member. Statuses include Joined and Exited. A staff member with the status “Exited” cannot access any data of a project.

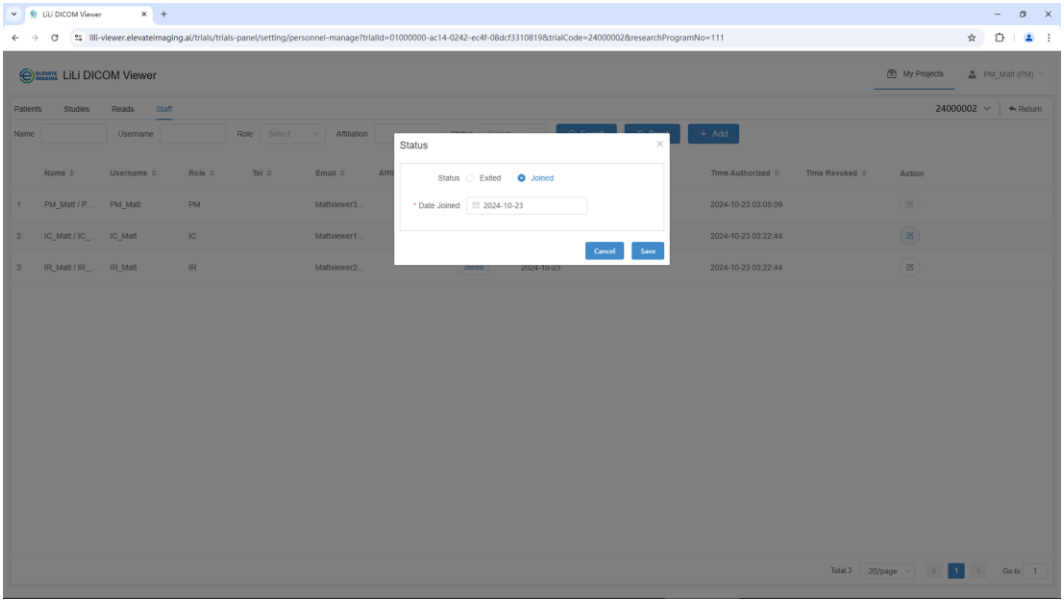

Fig. 28 Edit the Status of a Staff Member

3) Staff List displays information related to staff members who have joined a project, including Name, User Name, Role, Phone Number, Email Address, Affiliation, etc..

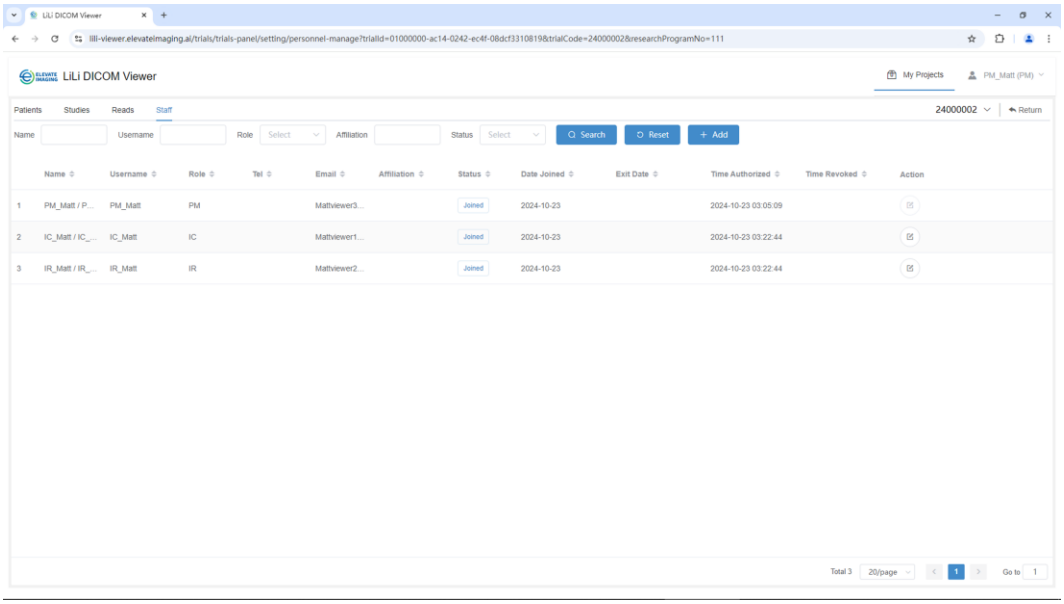

Fig. 29 Staff List

3.4 Image Data and Reading Management

In LiLi DICOM Viewer, image studies are archived in study batches. Before reading, it is necessary to associate patients, scan batches and imaging data. Relationship among patients, study batches, readers, reading assignments is shown as follows: a project can have multiple patients; a patient can have multiple study batches; a study batch can have multiple imaging studies. Each study batch will be assigned to a reader for reading, and each study batch is associated with a reading assignment, and each reading assignment is associated with a reader.

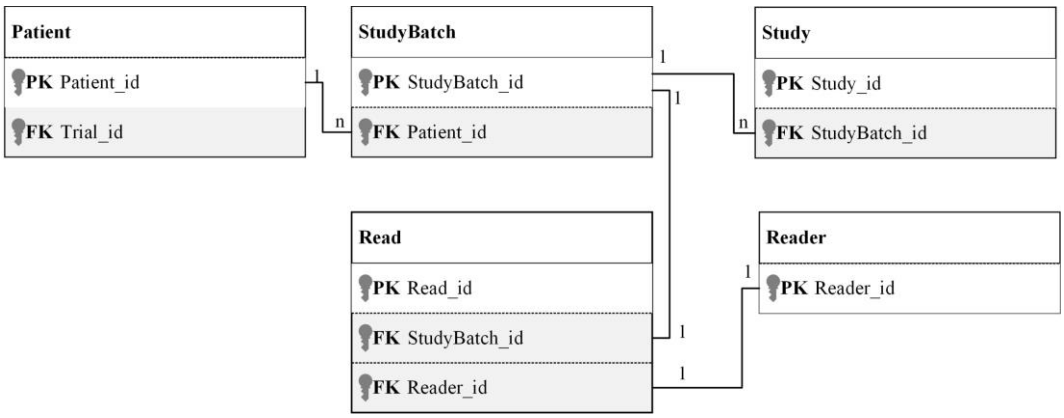

Fig. 30 Association among Patients, Study Batches, Reading Assignments and Studies.

3.4.1 Patient Management

The patient management module can be used to add patients, edit patient information, delete patients and search patients in patient list.1) Add Patients

Click the <+ New> button on the [Patients] page, you can enter the Patient ID, Gender and Age;

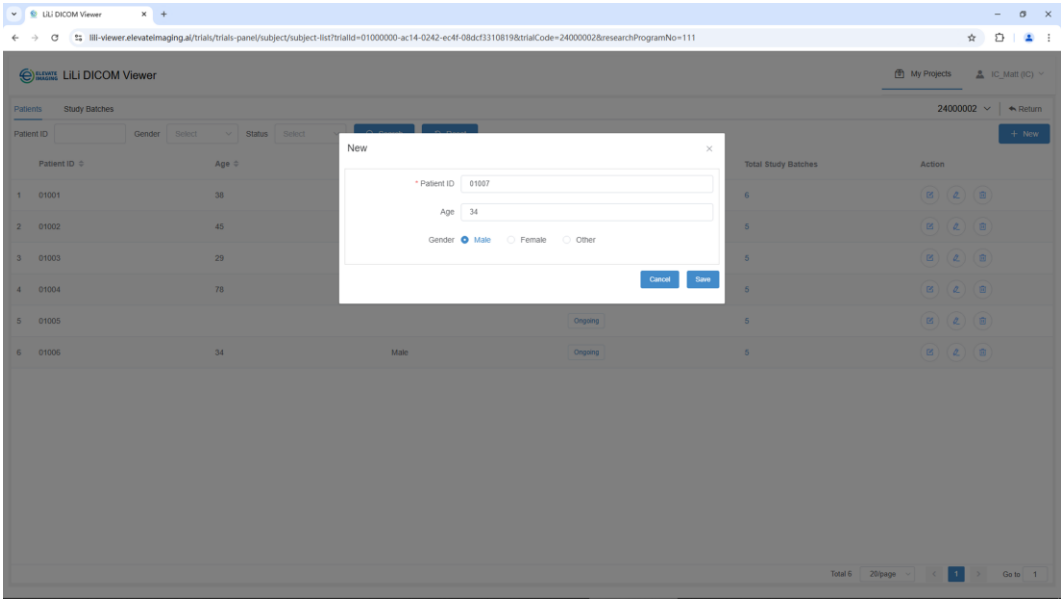

Fig. 31 Add a Patient

2) Edit Patients Information

In the patient list, click the <Edit> button to open the [Edit] page where you can edit patient ID, age, and gender.

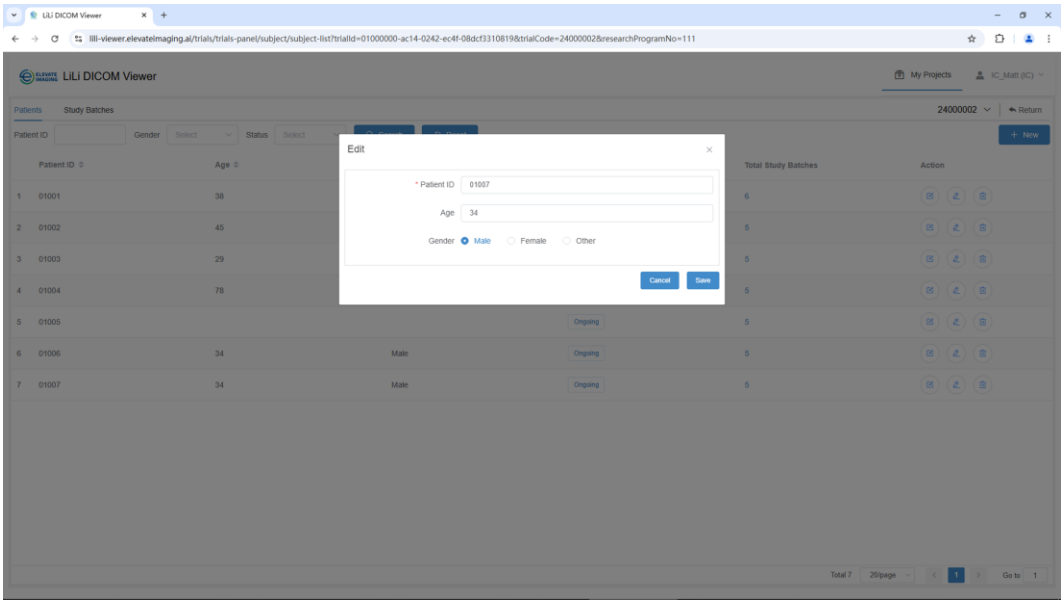

Fig. 32 Edit Patient Information

3) Edit the Status of Patients

In the patient list, click the <Status> button to open the [Status Change] page where you can change the status of a patient.

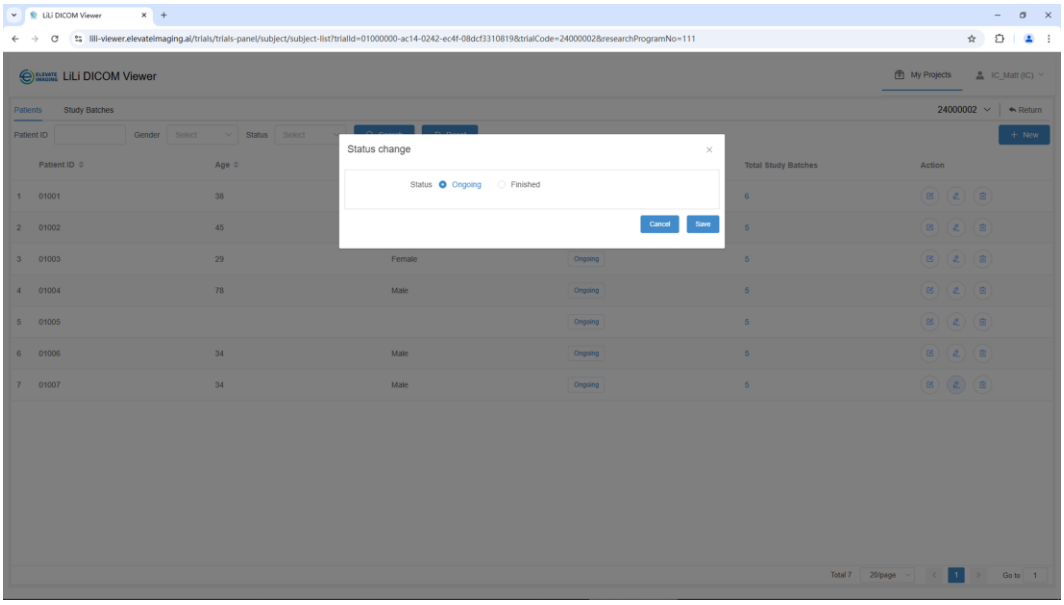

Fig. 33 Edit Status of a Patient

CAUTION

1) When the patient's status changes to Finished, a reason is required.
2) After the patient's status is set to Finished, images cannot be uploaded for the patient anymore.

4) Delete Patients

In the patient list, click the <Delete> button and the system will verify whether the patient can still be deleted.

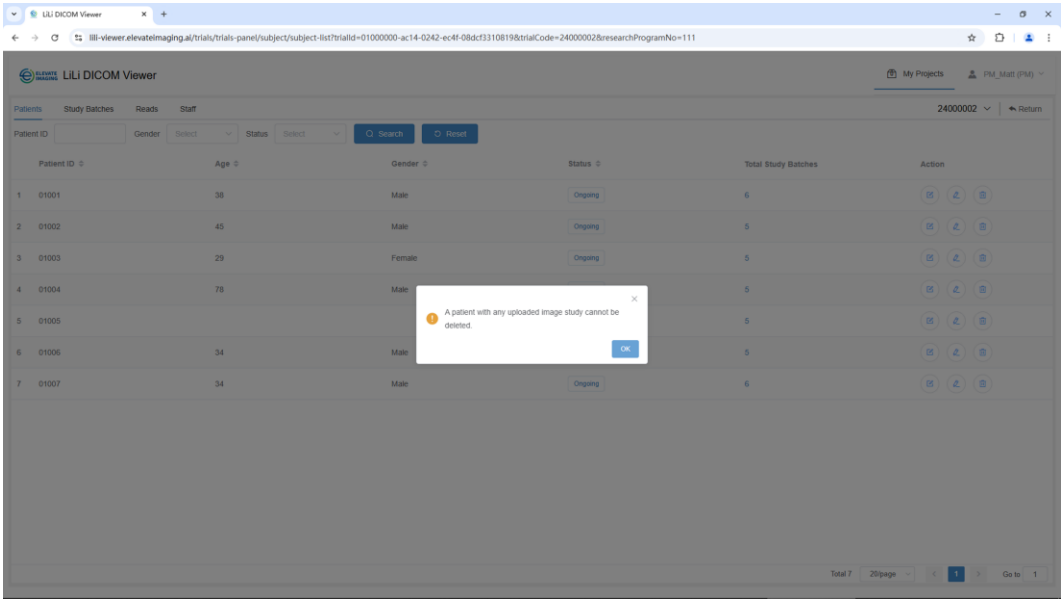

Fig. 34 Verification before Deleting a Patient

If a patient can still be deleted, a confirmation box will appear before this patient is deleted from the list.

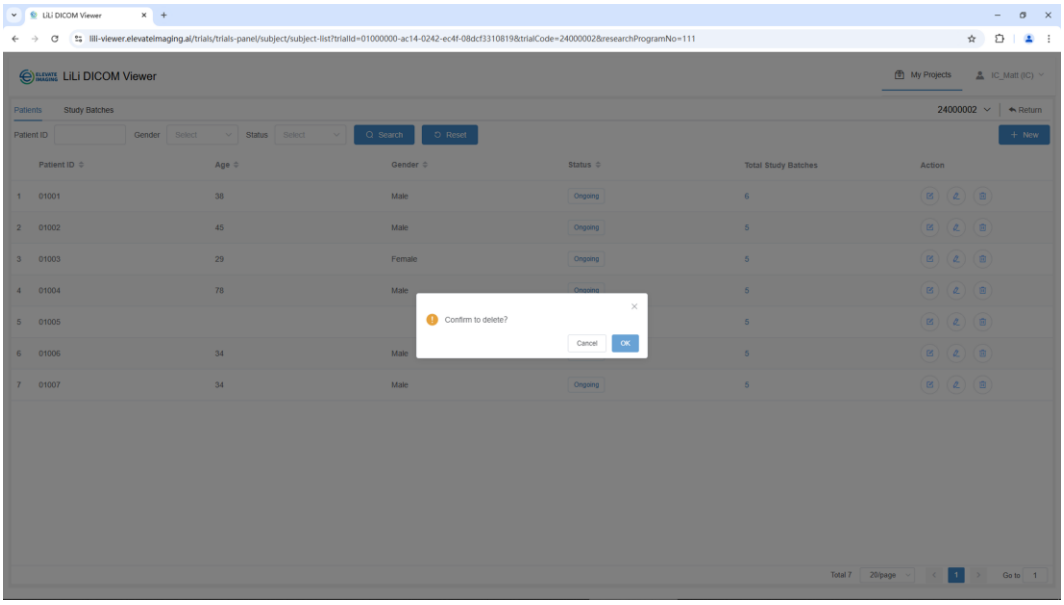

Fig. 35 Delete a Patient

Reminder

A patient can be deleted only before any image has not been uploaded for this patient.

5) Patient List

The patient list displays patient-related information, including Patient ID, Age, Gender, Status, and Total Studies. Clicking on the number in the Total Studies column will lead to the [Studies] page of the patient.

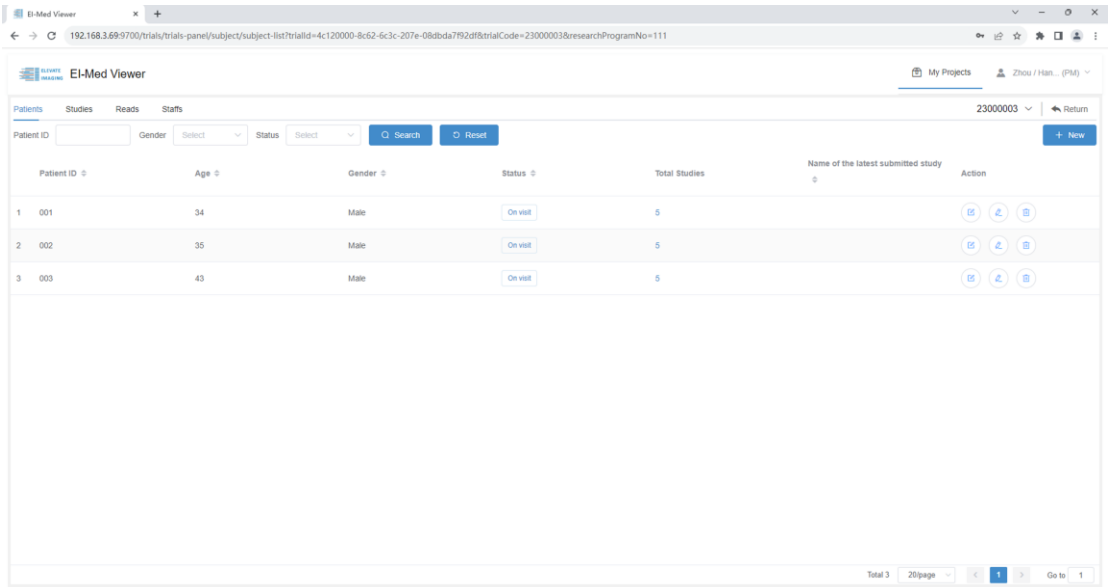

Fig. 36 Patient List

Users can search patients by Patient ID, Gender and Status.

3.4.2 Study Management

The study management module has the functions of adding study batches, uploading images, submitting images, deleting study batches, and checking studies.

1) Add New Study Batches

When adding a patient, the system automatically adds 5 study batches for the patient. Users can add additional study batches based on the actual need. Clicking the <+ New> button on the menu bar, and on the pop-up [Add New] page, users can add a new study batch by selecting Patient ID, inputting Study Batch name, and selecting Previous Study Batch.

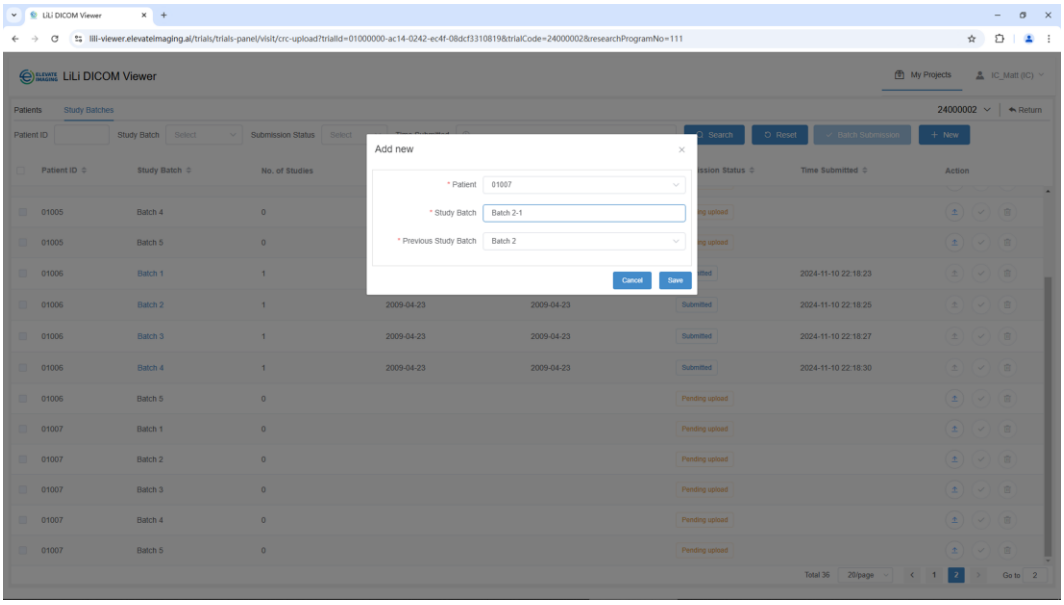

Fig. 37 Add a New Study Batch

Reminder

1) The name of a newly added study batch cannot be the same as that of an existing study batch of the same patient.
2) The new study batch will be inserted after the selected previous study batch.

2) Upload Images

The upload image module provides tools for selecting & uploading images from a computer, and for editing & deleting study information if necessary.

a. Select local images: In the study list, clicking the <Upload> button, and then clicking the <Select the Folder> button on the pop-up [DICOM Image

Upload] page. After selecting the local DICOM image folder, images inside this folder will be automatically archived and DICOM header information will be displayed.

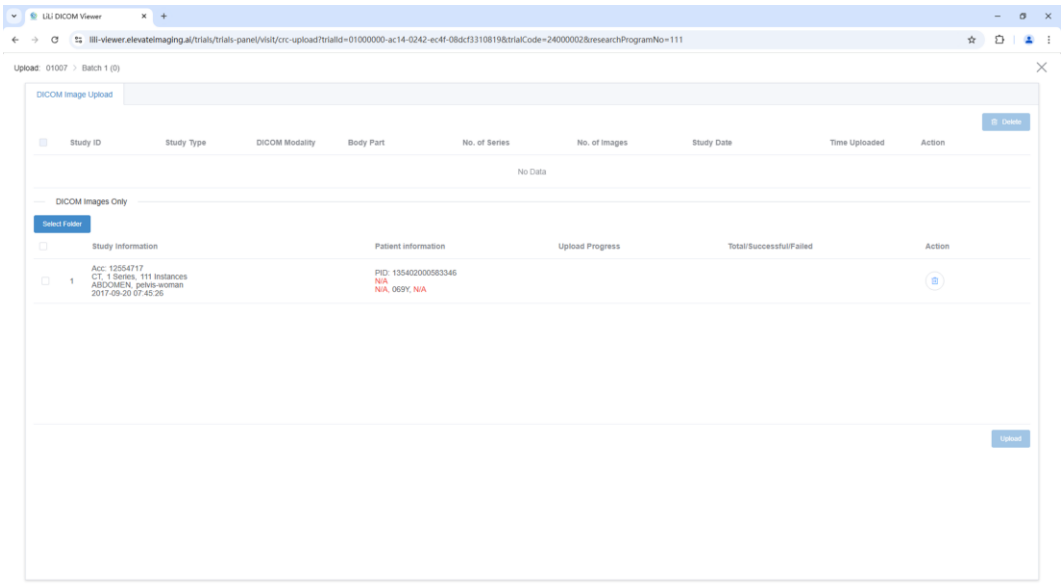

Fig. 38 Select a DICOM Image Folder

If the selected folder is incorrect, you can click the <Delete> button to delete it.

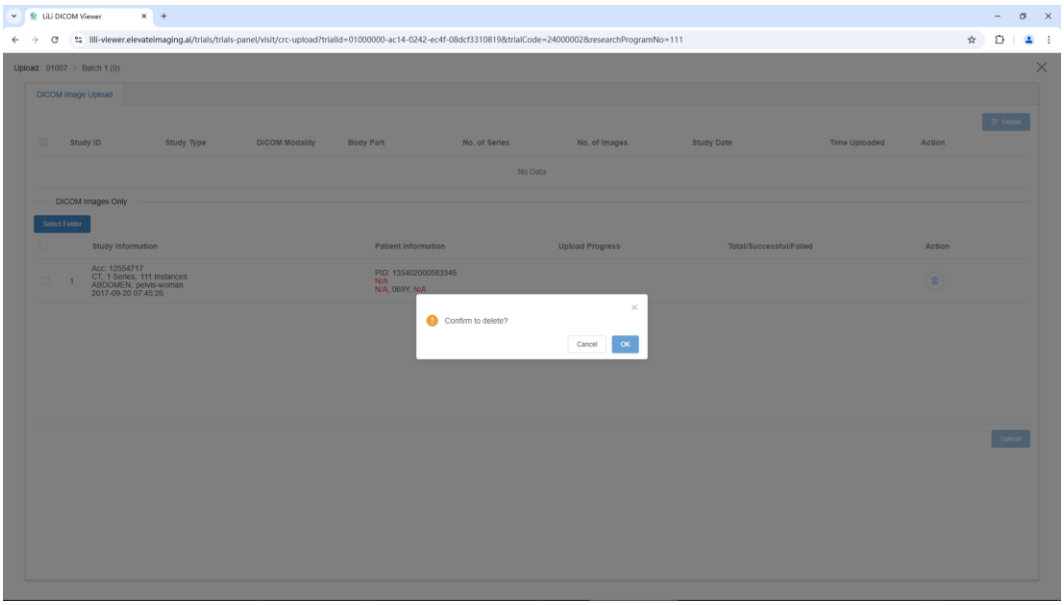

Fig. 39 Delete the Selected Folder

b. Upload Images: Select the image studies which need to be uploaded, and then click the <Upload> button. The progress of upload will be displayed.

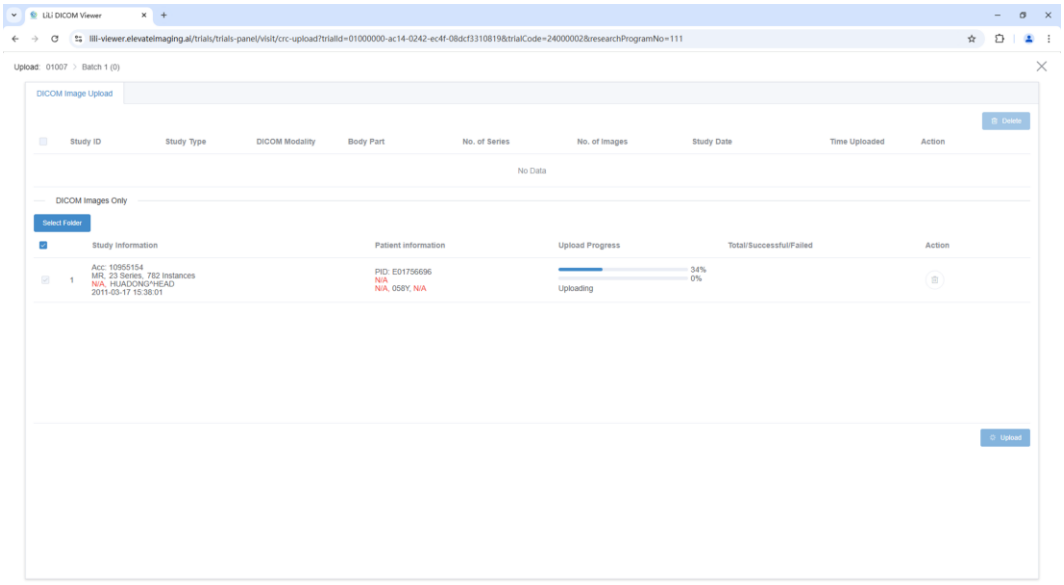

Fig. 40 Upload Images

After the image uploading is completed, a list of uploaded studies will appear on the page.

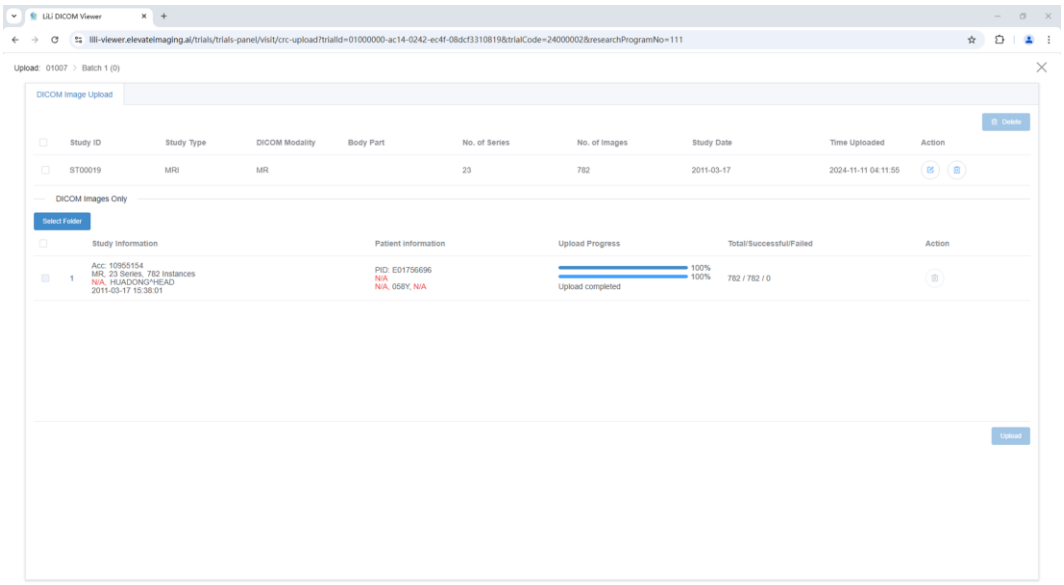

Fig. 41 List of Image Studies Uploaded

During the image upload process, multiple image studies can be uploaded for one study batch. Different series of the same image study can also be uploaded separately. After uploading, images of the same study will be archived together.

CAUTION

Before image uploading, the system will verify the image data. Rules include:

1) In the same project, the same image study cannot be uploaded to different patients, and cannot be uploaded to different study batches of the same patient.

2) For the same patient, the scan date of a study of a later study batch cannot be earlier than that of any study of a previous study batch.

c. Edit information of an uploaded study: clicking the <Edit> button at the right of the study list, users can edit the study information in the pop-up [Edit] box.

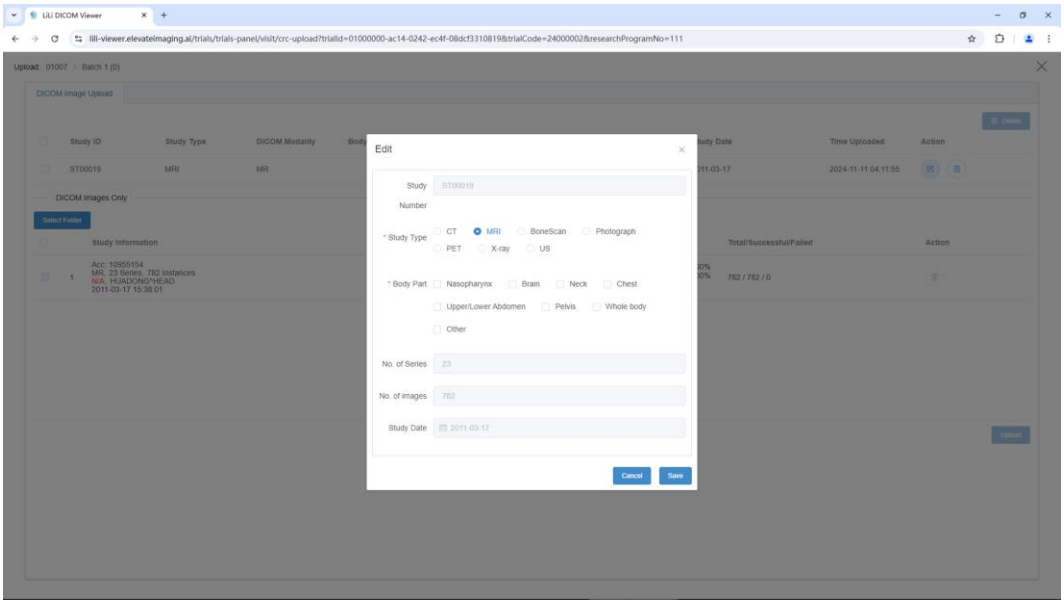

Fig. 42 Edit Information of an Uploaded Study

REMINDER

1) Study Type: study type can be selected by users.

2) Modality: modality is acquired from DICOM header and cannot be changed.

d. Delete an uploaded study: click the <Delete> button in the study list, and then click the <Confirm> button in the pop-up confirmation box to delete a study. Users can also check the selection boxes in front of lists and then click the <Delete> button on the upper right corner to delete multiple studies simultaneously.

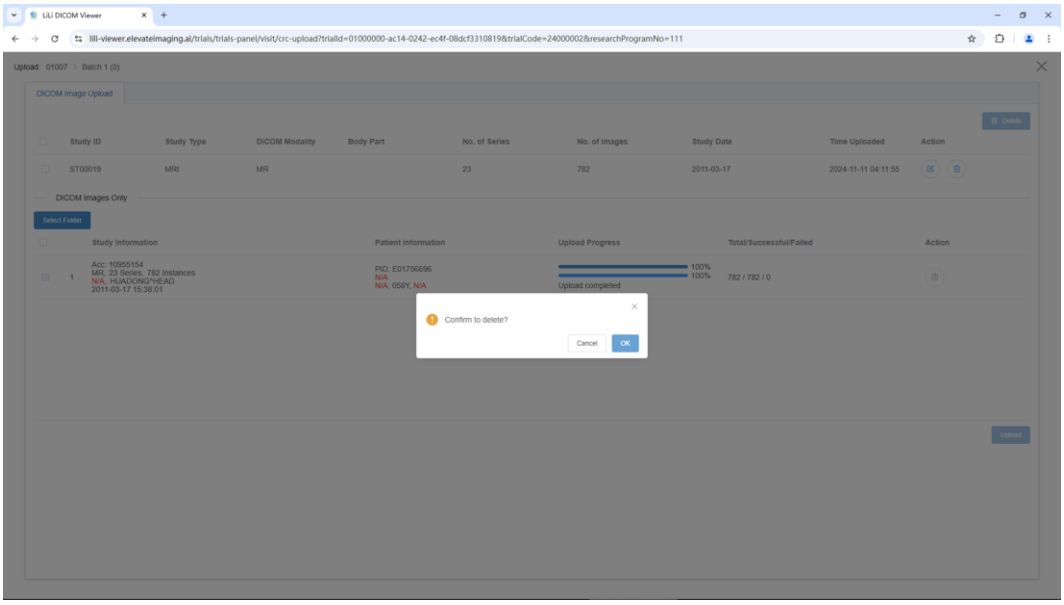

Fig. 43 Delete an Uploaded Study

3) Image Study Submission

LiLi DICOM viewer supports the submission of single or multiple image study batches.

a. Single Batch Submission: click the <Submit> button at the right of a study batch record, and then click the <Confirm> button in the pop-up box to submit a study.

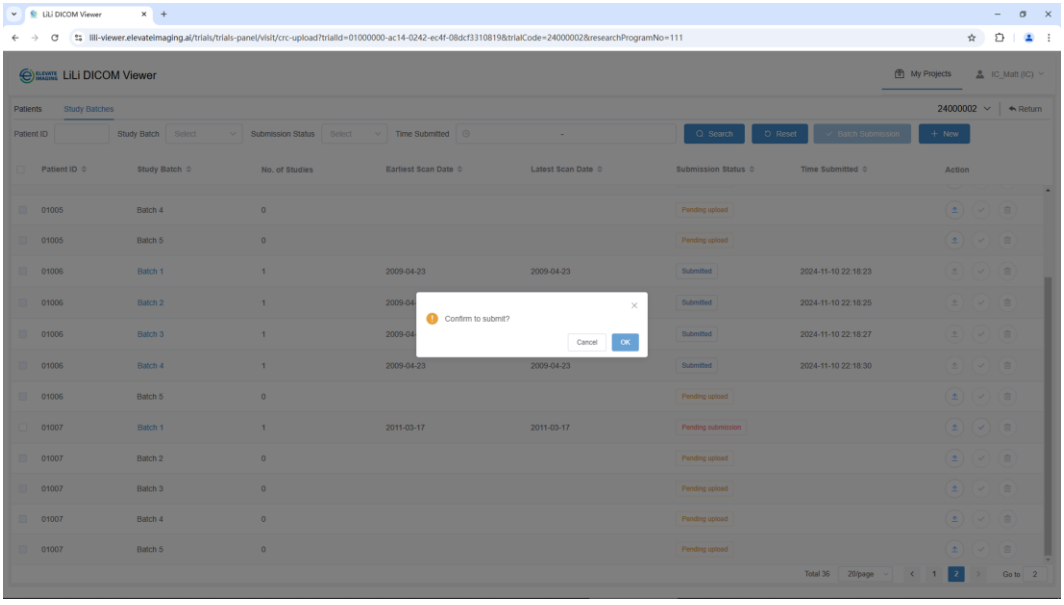

Fig. 44 Submit an Image Study Batch

If a subsequent image batch is submitted first, the user will be prompted to submit earlier study batches as soon as possible.

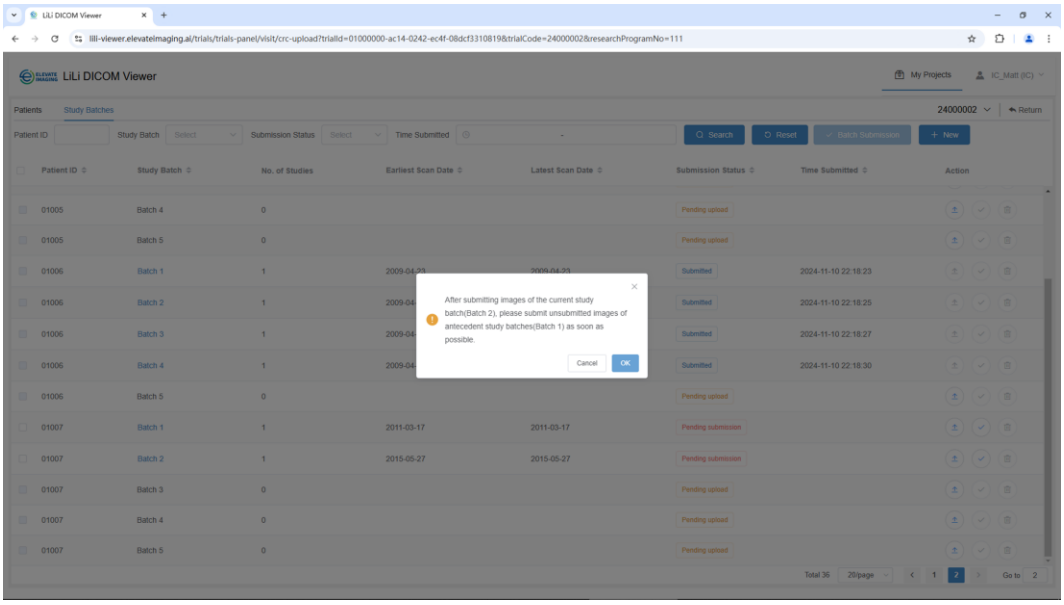

Fig. 45 A Reminder to Submit Earlier Image Batches

b. Multiple Batches Submission: select the study batches pending submission, and then click the <Batch Submission> button and the <Confirm> button in the pop-up box.

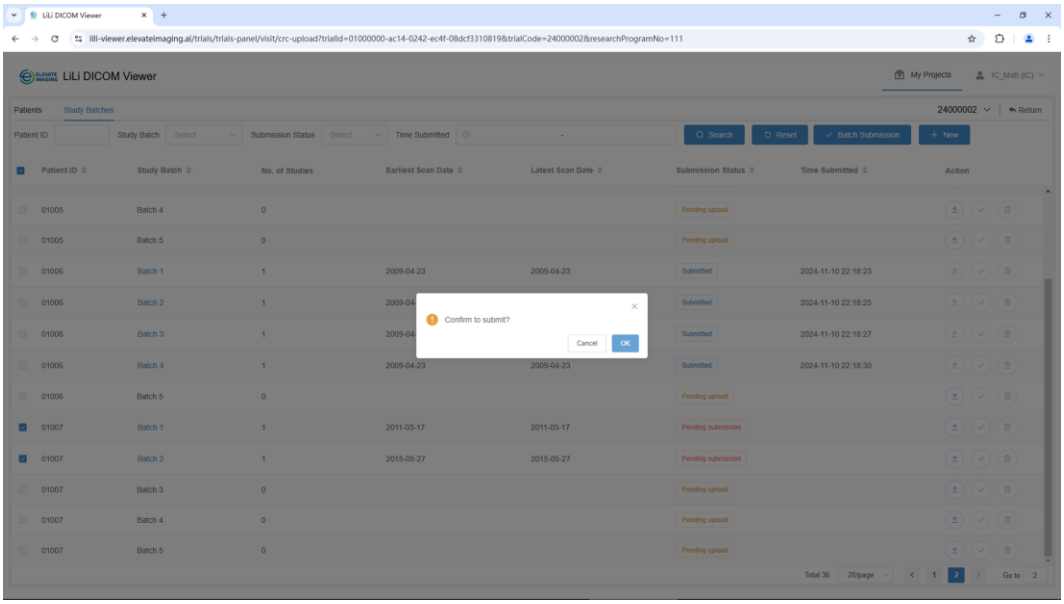

Fig. 46 Submission of Multiple Study Batches

4) Delete a study batch which is manually added

Click the <delete> button at the right of a study batch record which is manually added, and then click the <Confirm> button in the pop-up box.

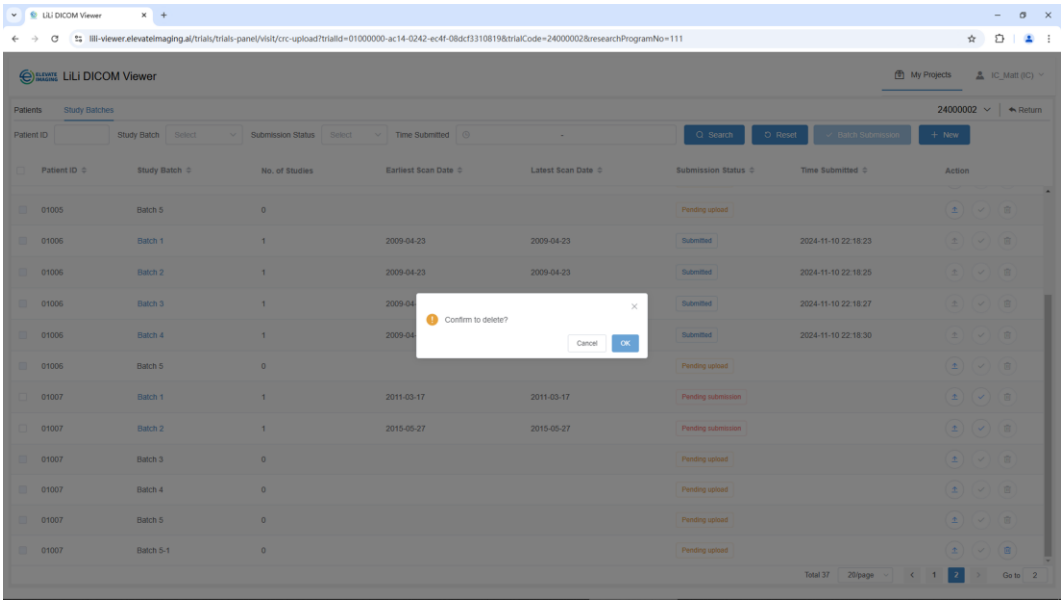

Fig. 47 Delete a Manually Added Study Batch

REMINDER

1） A study batch which is generated by the system automatically after adding a patient cannot be deleted.

2） A manually added study batch cannot be deleted after any images have been uploaded. And a manually added study batch can be deleted again only after all uploaded images are deleted.

5) List of Study Batches

List of study batches displays information, including Patient ID, Study Batch Name, Number of Studies, Earliest Scan Date, Latest Scan Date, Submission Status, and Time Submitted.

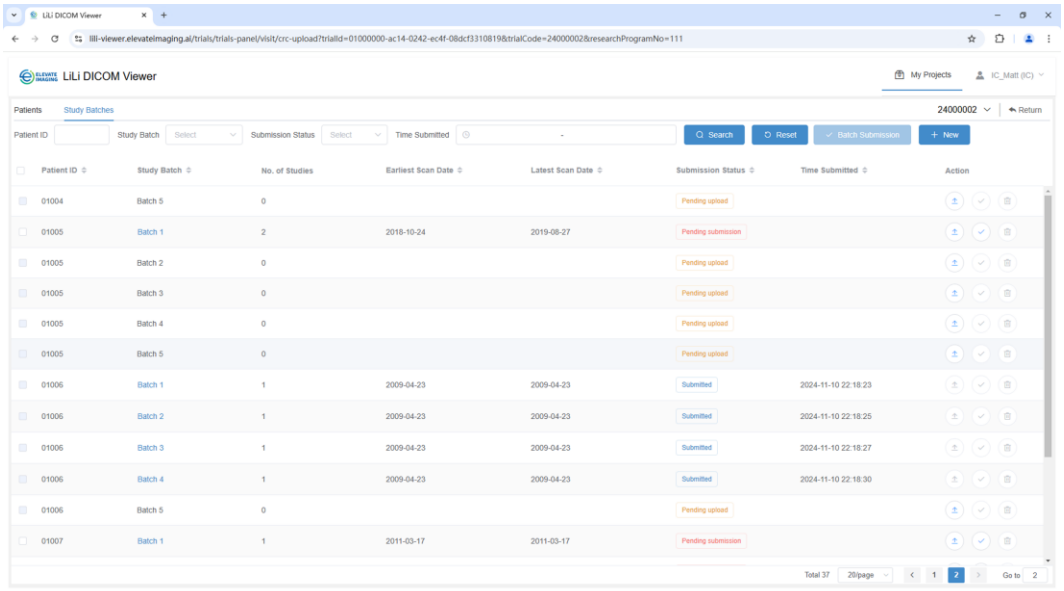

Fig. 48 List of Study Batches

If a user clicks a clickable Study Batch name in the list, the uploaded image studies of this study batch will be displayed.

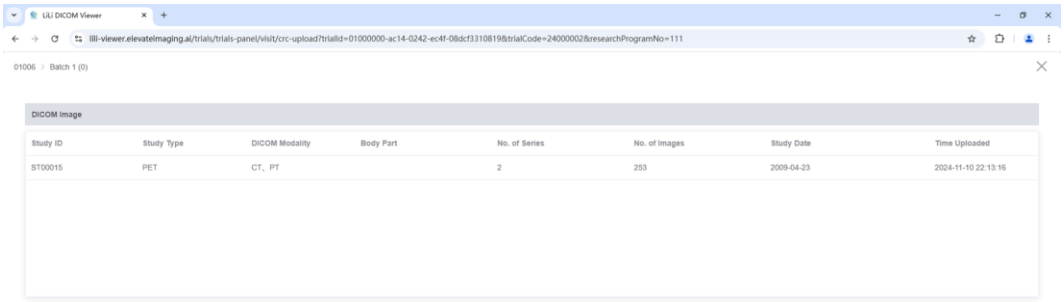

Fig. 49 Uploaded image studies of a study batch

A user can search a specific study batch based on Patient ID, Study Batch Name, Submission Status and Time Submitted.

3.4.3 Reads Assignment

The reads assignment module has the functions of assigning reads to image reviewers, and remove assigned reads from image reviewers.

1) Assign Reviewer

On the [Reads] -- [Assignment] tab, assign image reads of a patient to reviewers. Click the <Assign Reviewer> button in the action list and select the reader in the <Assign Reviewer> pop-up window.

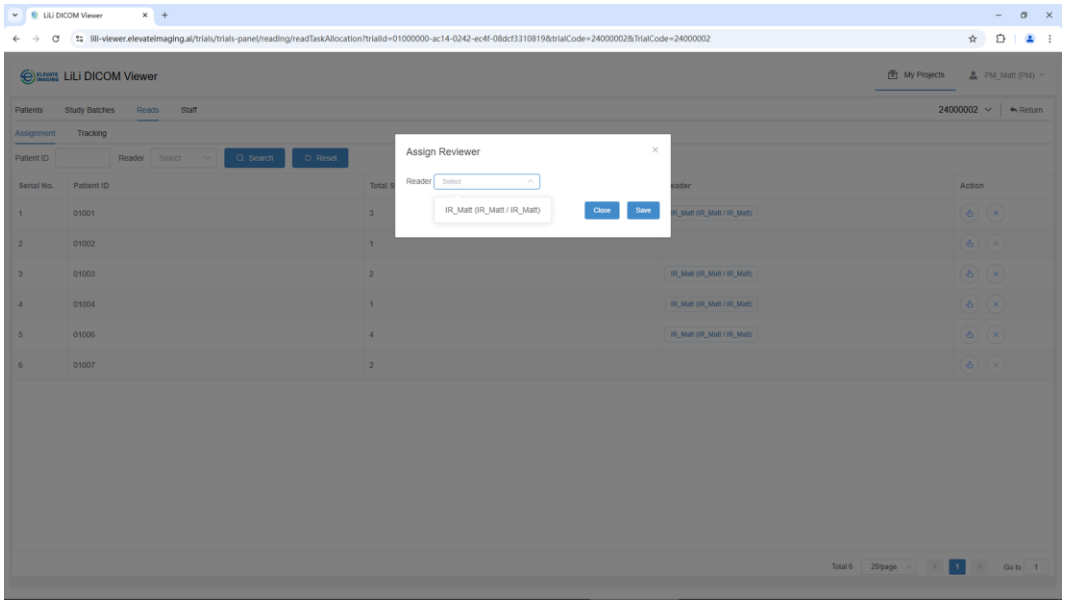

Fig. 50 Assign Reviewer

2) Unassign Reviewer

Click the <Unassign Reader> button, and then select and unassign the Reviewer in the pop-up window.

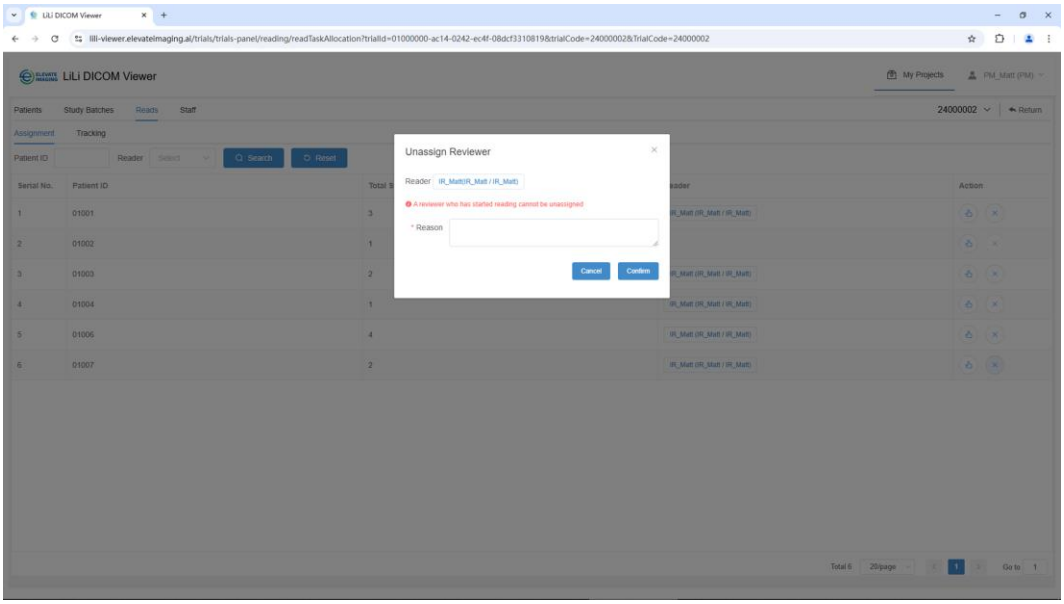

Fig. 51 Unassign Reviewer

CAUTION

If reading has already started, a reader cannot be unassigned anymore.

3) Reads Assignment List

Information such as patient ID, Total Studies and Reader are displayed on the Read Assignment List. A user can search assignments based on Patient ID and Reader.

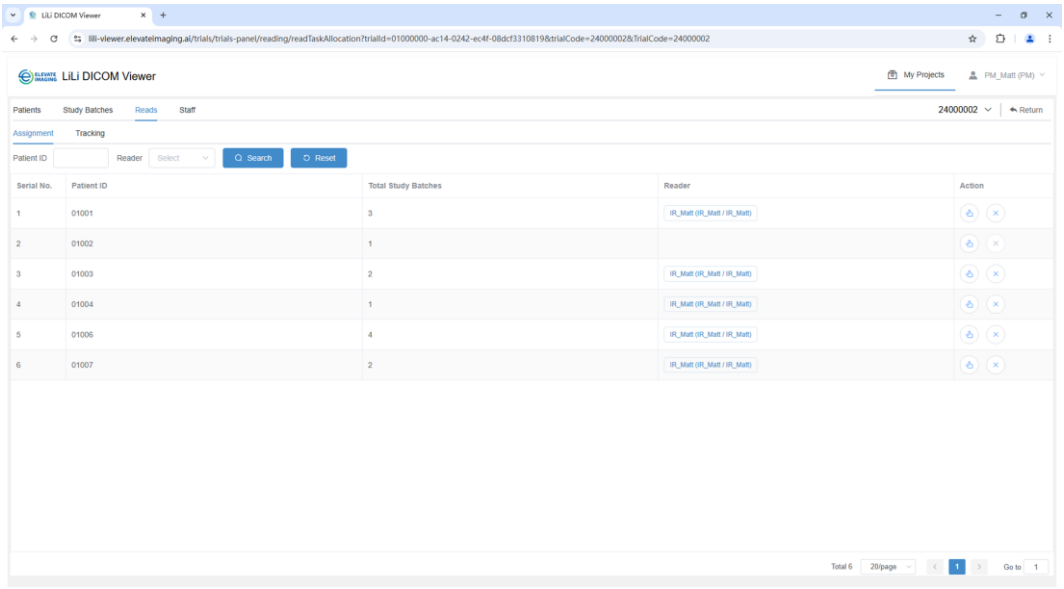

Fig. 52 Reads Assignment List

3.4.4 Image Reading

Image reading is performed by an image reviewer who can view and manage pending and completed reads on the [Read s] page.

1) Pending Reads

On the [Reads] page-- [Pending] tab, Patient ID, Remaining Reads, and Suggested Finish Time are displayed. An image reviewer can search reads based Patient ID.

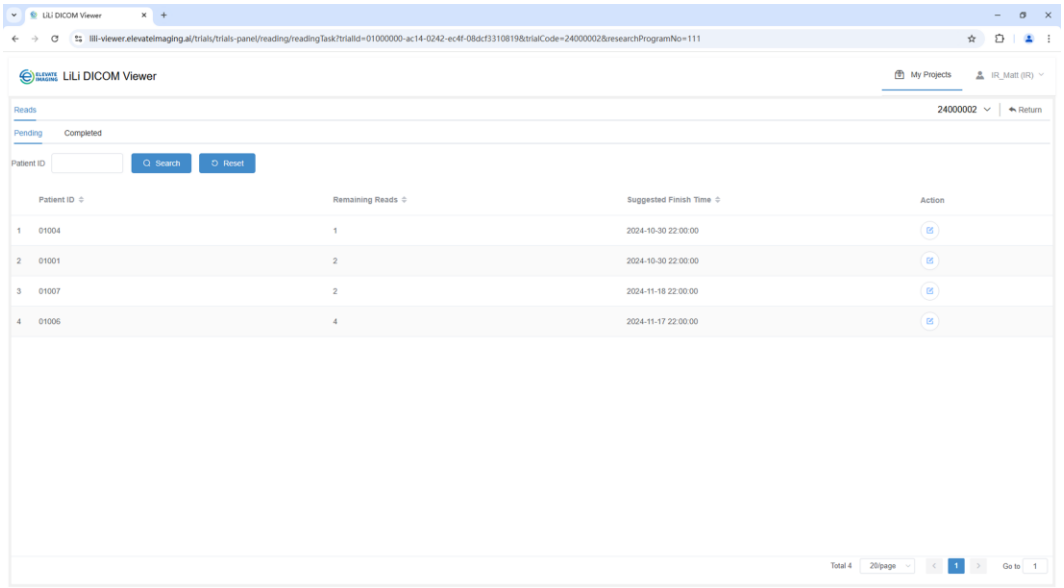

Fig. 53 Pending Reads

REMINDER

1) Reads are sorted based on Patient ID, and an image reviewer reads pending studies sequentially.

2) The suggested finish time is a recommendation by the system, not mandatory.

2) Image Reading

On the [Pending] tab, click the <Reading> button to enter the image reading interface which has two tabs: [Reading] and [Report]. An image reviewer can read images, and edit the report on the tabs. Please refer to **Section 3.5 Image Reading** for details.

3) Completed Reads

On the [Reads] -- [Completed] tab, Read No., Patient ID, Study Batch and Time Signed are displayed.

Image reviewer can search reads based on Patient ID.

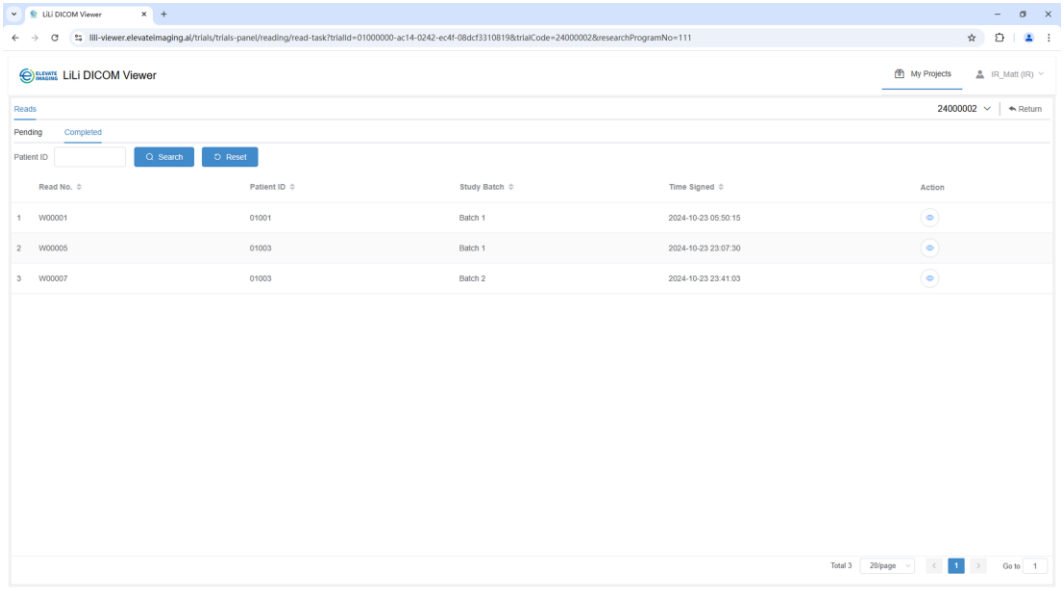

Fig. 54 Completed Reads

3.4.5 Reads Tracking

On the [Reads]--[Tracking] tab, Project Manager can track the status of reads.

1) Reads Tracking List

The reads tracking list displays Read No., Patient ID, Read Name, Time Created, Reader, Time Assigned, Suggested Finish Time, Read Status, and Time Completed.

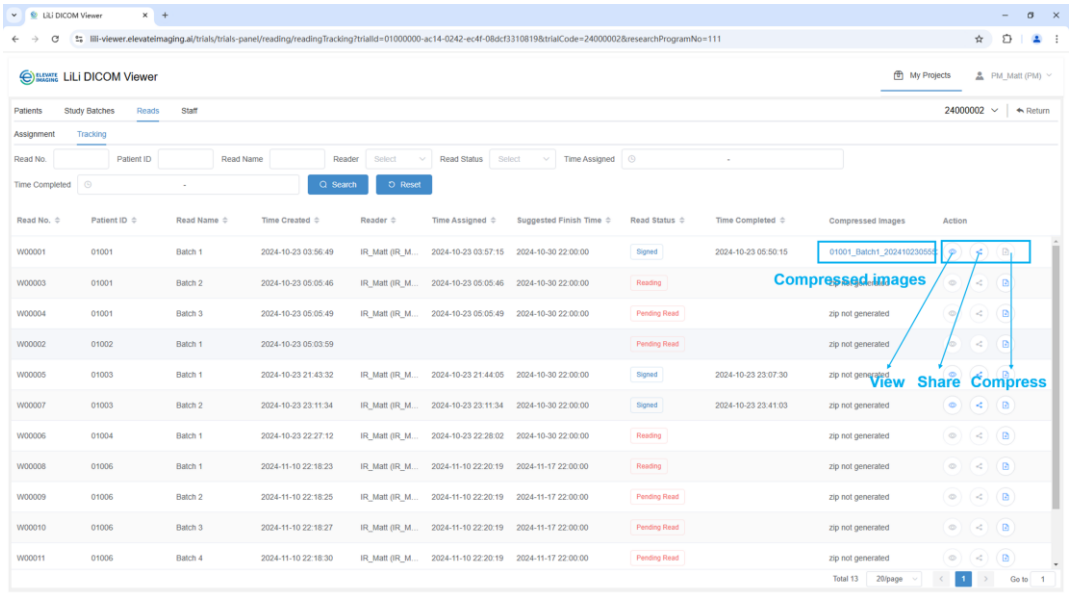

Fig. 55 Reads Tracking

Project Manager can search reads based on Read No., Patient ID, Read Name, Reader, Read Status, Time Assigned and Time Completed.

2) View Reading Results

On the page of [Reads]--[Tracking], click the <View > button to view the images & reports of completed reads. A user can only review images & reports and cannot change or edit anything. Please refer to **Section 3.5 Image Reading** for details.

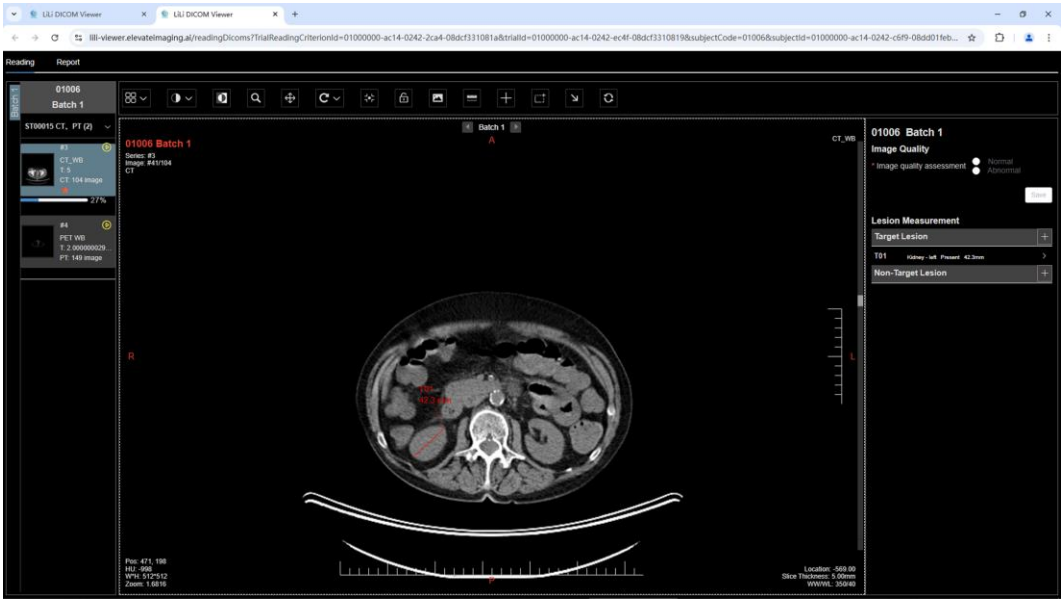

Fig. 56 View Reading Results

3) Share Reading Results

On the page of [Reads]--[Tracking], click the <Share> button, and a user can copy the sharing link & verification code.

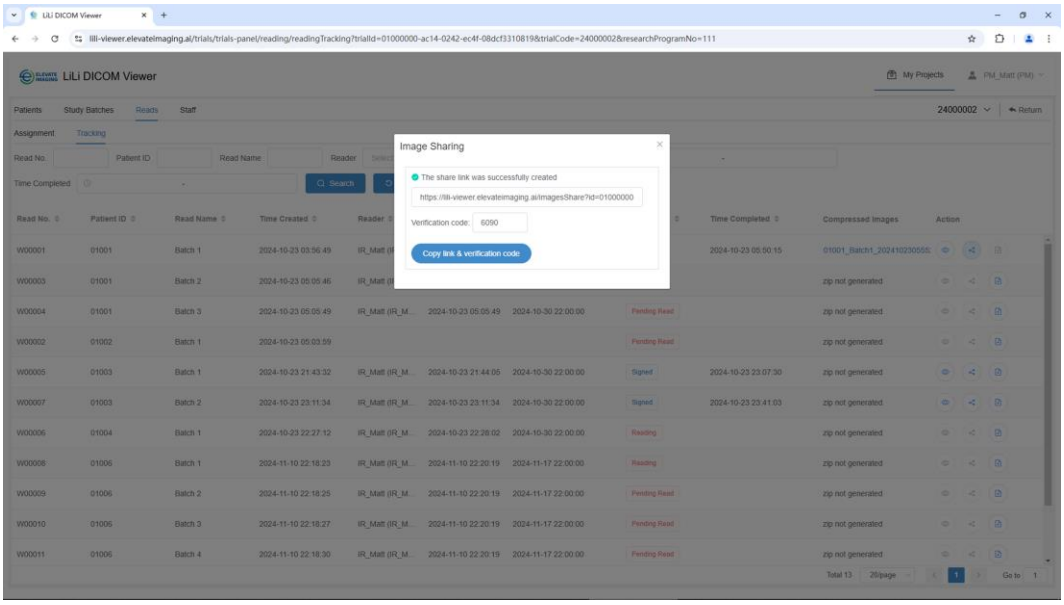

Fig. 57 Image Sharing Link & Verification Code

The recipient of the link and verification code can access a website, and view the images and reports.

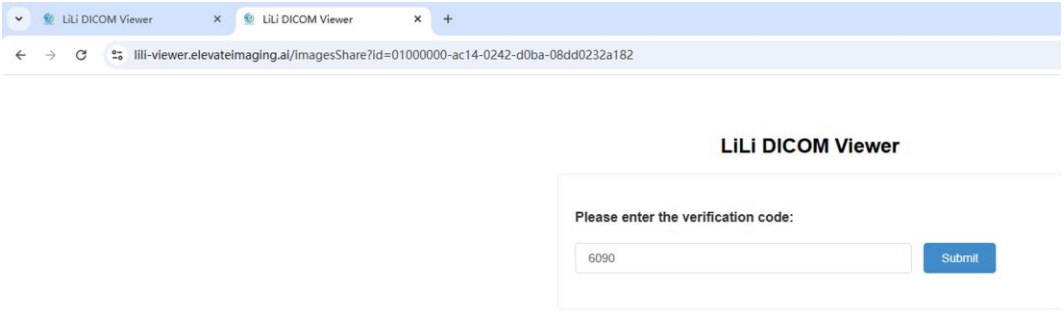

Fig. 58 Website Providing Reading Results Sharing

4) Download Images

On the tab of [Reads]--[Tracking], click the <Compress> button to compress images of a read. After the compression is completed, click the zip file to download it.

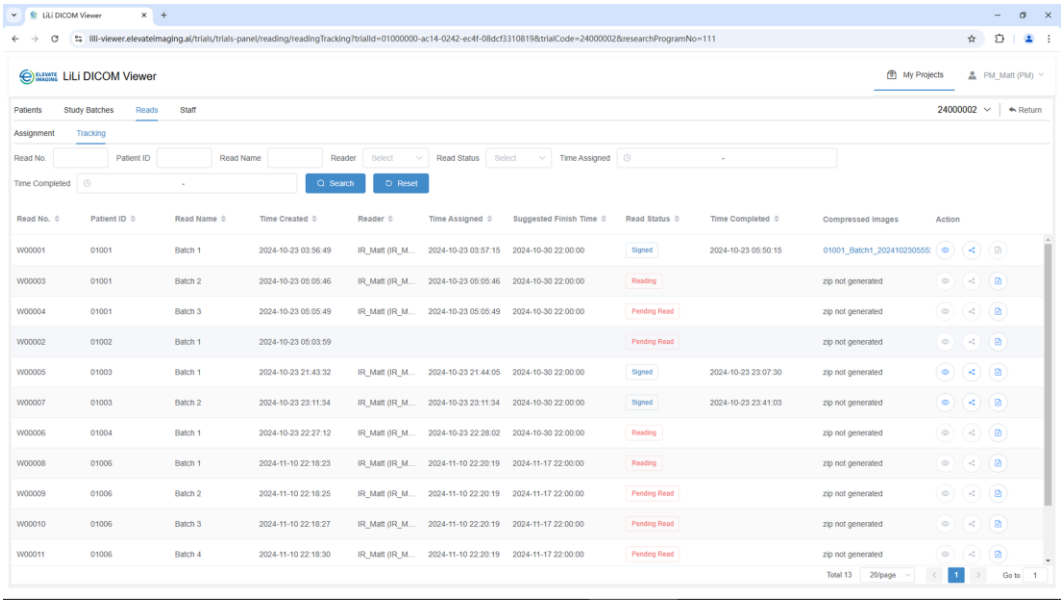

Fig. 59 Compress & Download Images

3.5 Image Reading

3.5.1 Image Reading Page

Image Reviewer logs into the system, and a list of projects is displayed. Then Image Reviewer clicks on the [details] button, and the [Reads] page is displayed, The [Reads] page has two tabs: [Pending] and [Completed]. Image Reviewer then clicks on the [Reading] button, launching a new page with two tabs: [Reading] and [Report]. The [Reading] tab mainly displays images and annotation tools. Description of each zone of this page is as follows:

Zone 1: tab navigation bar which is used to switch between [Reading] & [Report] tabs.

Zone 2: image navigation bar which displays the study batches, studies, series description and series thumbnails. An image reviewer can click on the thumbnail to display an image series.

Zone 3: toolbar which has all the annotation tools.

Zone 4: display the selected image series. This zone can be further divided into several viewports. As shown in the figure below, the current reading area is divided into 2 viewports: 4-1 & 4-2.

Zone 5: lesion list which displays details of the annotated lesion.

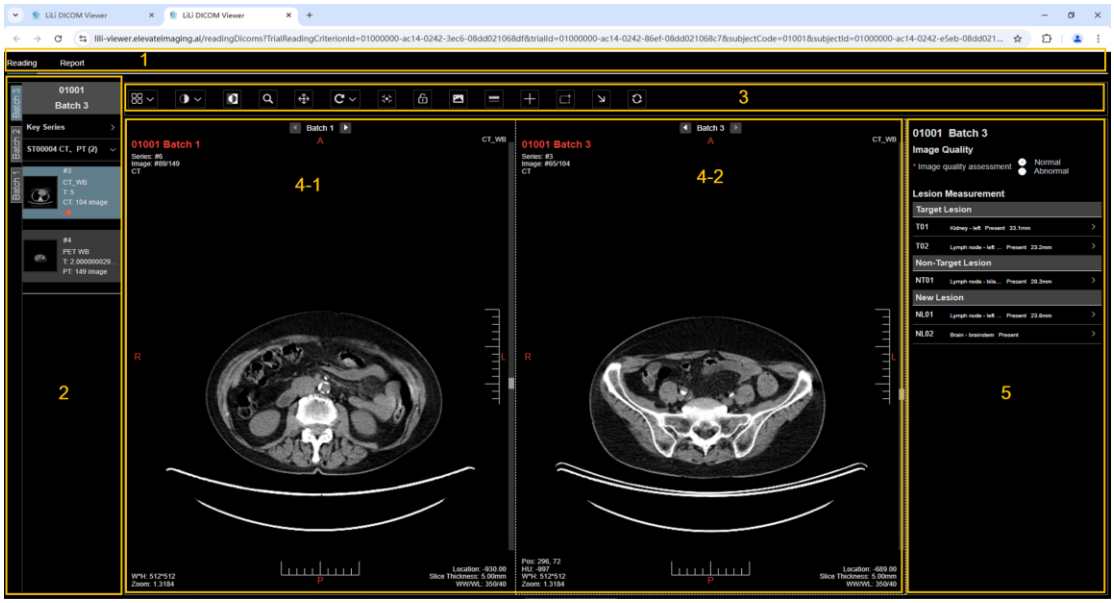

Fig. 60 Reading Tab

The [Report] tab displays the reading report which can be edited, saved, and submitted. The [Report] tab is shown in the figure below, and the descriptions of different zones are as follows:

Zone 1: page navigation bar which is used to switch between the [Reading] & [Report] tabs.

Zone 2: toolbar which has all the action button.

Zone 3: report area which displays report data of all study batches.

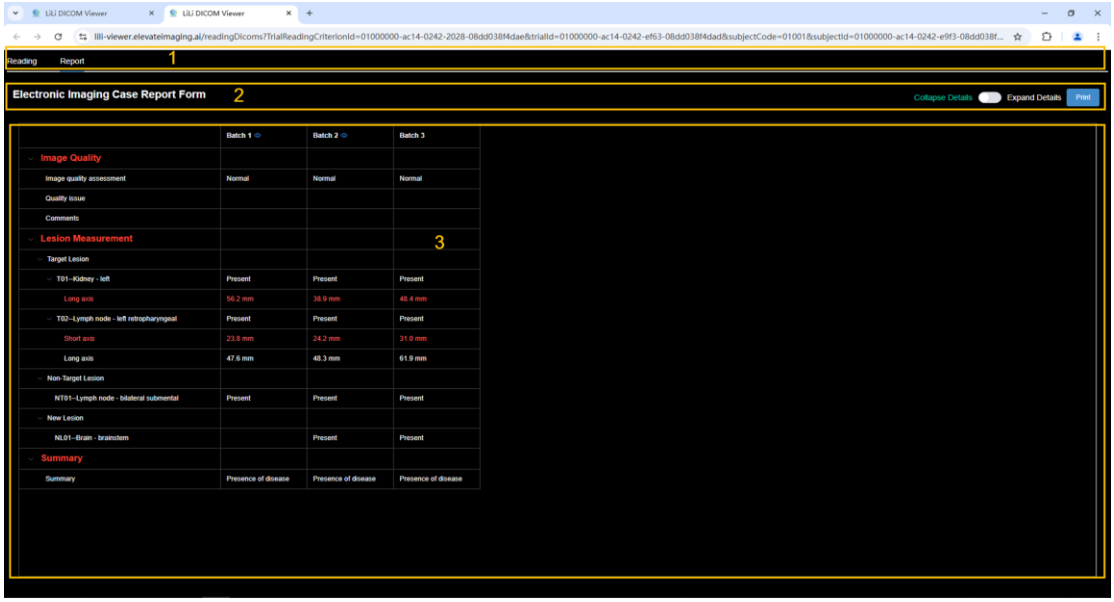

Fig. 61 Report Tab

3.5.1.1 Image Navigation Pane

The image navigation pane displays patient ID, study batch name, study ID, series ID and series description related to the current read. Descriptions of all sub-areas are as follows:

Zone 1: patient ID and study batch name.

Zone 2: tabs of all study batches.

Zone 3: study information which can be expanded or collapsed.

Zone 4: series information, including series number, series description, status of each series, thumbnails and etc.

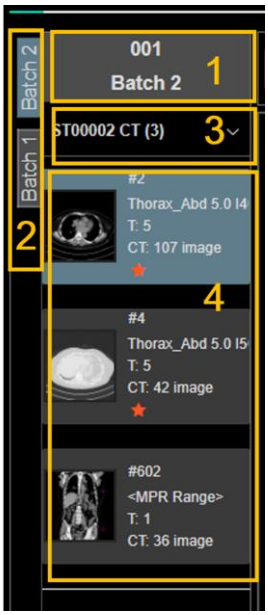

Fig. 62 Image Navigation Pane

The status of each series includes: image download status, annotation status, and display status. Descriptions of series status are as follows:

1) Image download status: when there is a <download> button on the upper right corner of the series information area, images of this series have not been downloaded; when there is a <pause> button and a progress bar in the series information area, download of images is in progress; when there are no such buttons, images of this series have been fully downloaded.

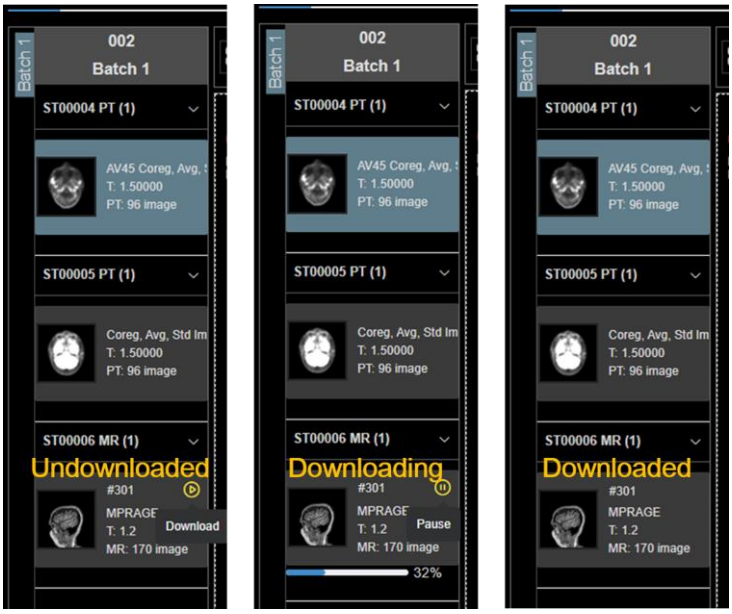

Fig. 63 Image Download Status

REMINDER

The system will automatically download images of series with fewer than 100 images and a slice thickness of 5mm.

2) Annotation status: if a series contains any annotated images, a red pentagram will be added to the series information area.

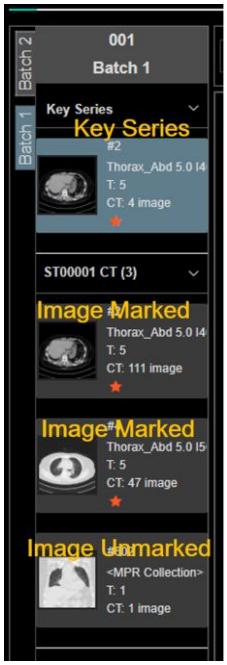

Fig. 64 Series with Annotated Images

3) Current series status: a blue background of the series information area indicates that this series is the current image series displayed in the active viewport.

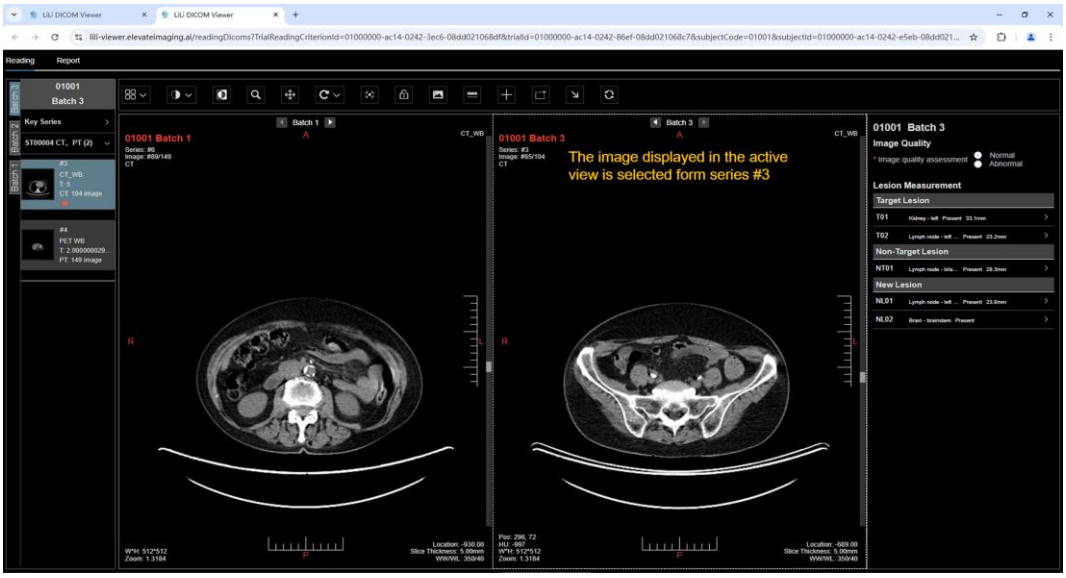

Fig. 65 Current Series Displayed in the Active Viewport

3.5.1.2 Toolbar

The toolbar displays interactive tools for image annotation, as shown in the figure below. Some of the toolbar buttons, e.g. the windowing tool, have dropdown menus.

Fig. 66 Image Annotation Toolbar

Statuses of tools include: active, inactive, and disabled, as shown in the figure blow. When an image reviewer clicks a tool button, it will be activated. At a given time, only one tool can be active. When images are in certain states, certain tools will be in the “disabled” state.

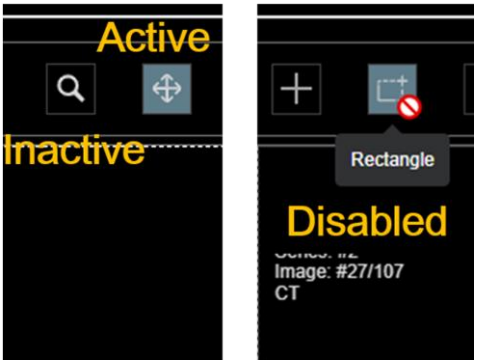

Fig. 67 Status of a Tool

EXAMPLE

An example of a tool in the “disabled” state: all annotation tools are disabled when reviewing a finished and submitted read.

3.5.1.3 Image Viewing Area

The image viewing area is the main interface for reviewing and annotating images, as shown in the figure below:

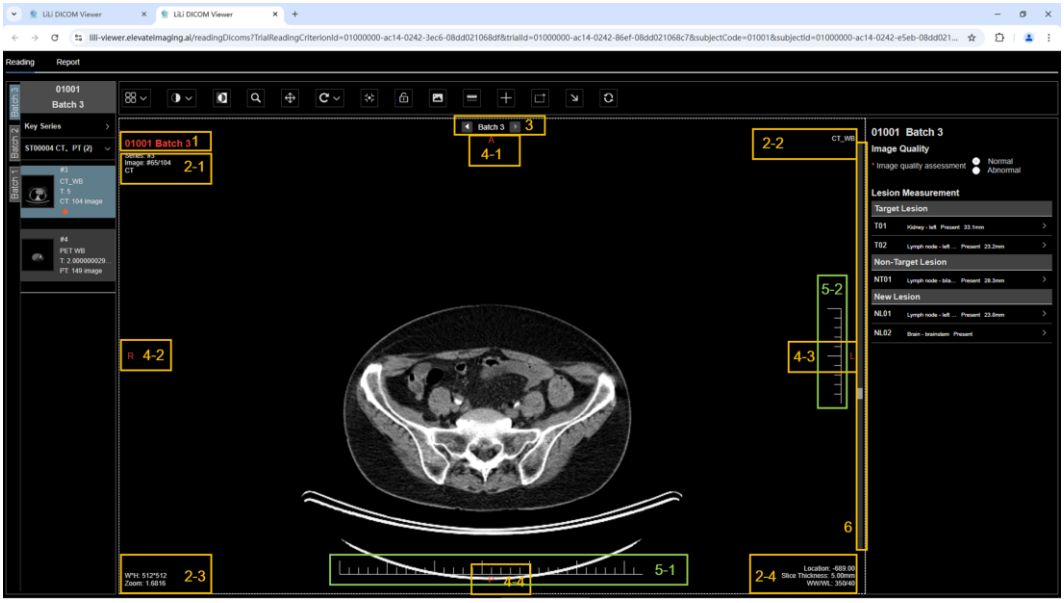

Fig. 68 Image Viewing Area

The image viewing area can be further divided into several viewports, as shown in Chapter 3.5.3 Viewport Settings. Beside images and annotations, each viewport also includes the following zone:

1) Zone 1: patient ID and the name of the study batch.
2) Zone 2: image information including:

   2-1: Series No., No. of current image/Total number of images, Modality

   2-2: Series Description

   2-3: Pixel Position, Pixel Value, Image Resolution, Scale Factor

   2-4: Location, Slice Thickness, Window Width/Level

REMINDER

1) Pixel value and coordinate are displayed only when a cursor hovers over the image.
2) Pixel value is determined by the type of the modality. For CT images, the unit is HU; for PET images, the unit is SUV; for other modalities, the unit is the grayscale value of the pixel.

3) Zone 3: Study Batch Switch Button
4) Zone 4: Image Direction Information
5) Zone 5: Image Size Scale, 1 cm for each unit
6) Zone 6: Scroll Bar

There are active viewport and inactive viewport in the image viewing area, and the active viewport is identified by dashed borders. All operations can only be carried out in the active viewport.

3.5.1.4 Lesion List

To add lesions and edit lesions information in the lesion list is shown in the figure below:

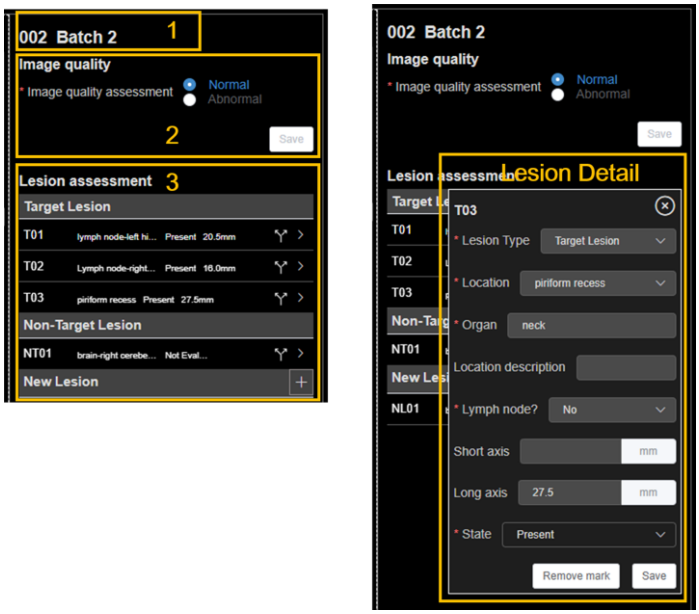

Fig. 69 Lesion List

The major areas of the lesion list are as follows:

Zone 1: Patient ID & the Name of the Study Batch

Zone 2: Image Quality Evaluation

Zone 3: Lesion Evaluation Area, including 3 tables: Target Lesion, Non-Target Lesion, & New Lesion. Please refer to Section 3.5.14 Lesion Annotation for details.

3.5.1.5 Report Tab

The [Report] tab displays the reading results of a patient's different study batches, and can be used to edit the reading results of the current study batch.

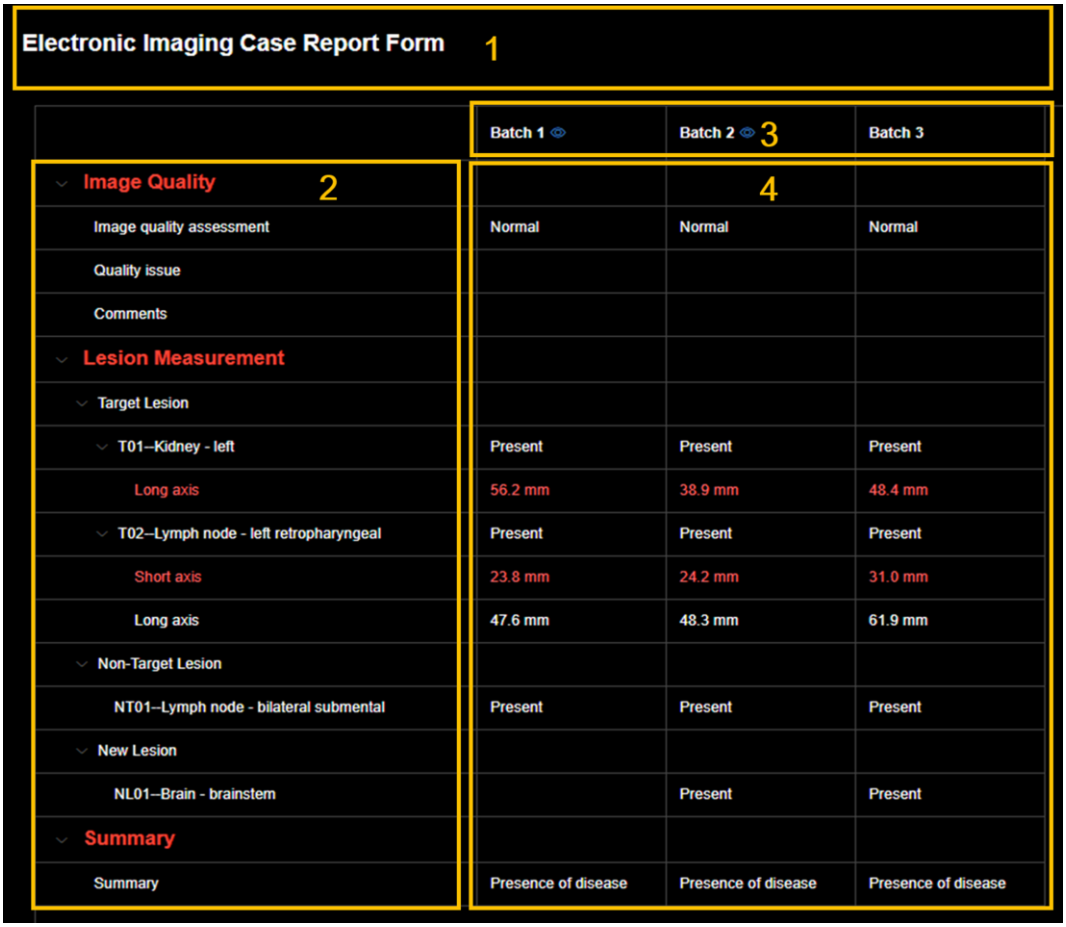

Fig. 70 Report Tab

The report tab includes the following zones:

Zone 1: Title of the report.

Zone 2: Content of evaluation, including Image Quality, Lesion Measurement, and Summary

Zone 3: Name of the study batch

Zone 4: Values

In the [Report] tab, the evaluation results of all study batches can be viewed and compared, but only the values of the current study batch can be edited.

3.5.2 Image Scrolling and Synchronization

Users can browse images in the image viewport in two ways:

1) Scroll independently: in the active viewport, drug the scroll bar or scroll the mouse wheel.
2) Synchronized scroll after click the “Synchronized Scroll” button, drugging the scroll bar or scrolling the mouse wheel in the active viewport will scroll images in all viewports in synchronization.

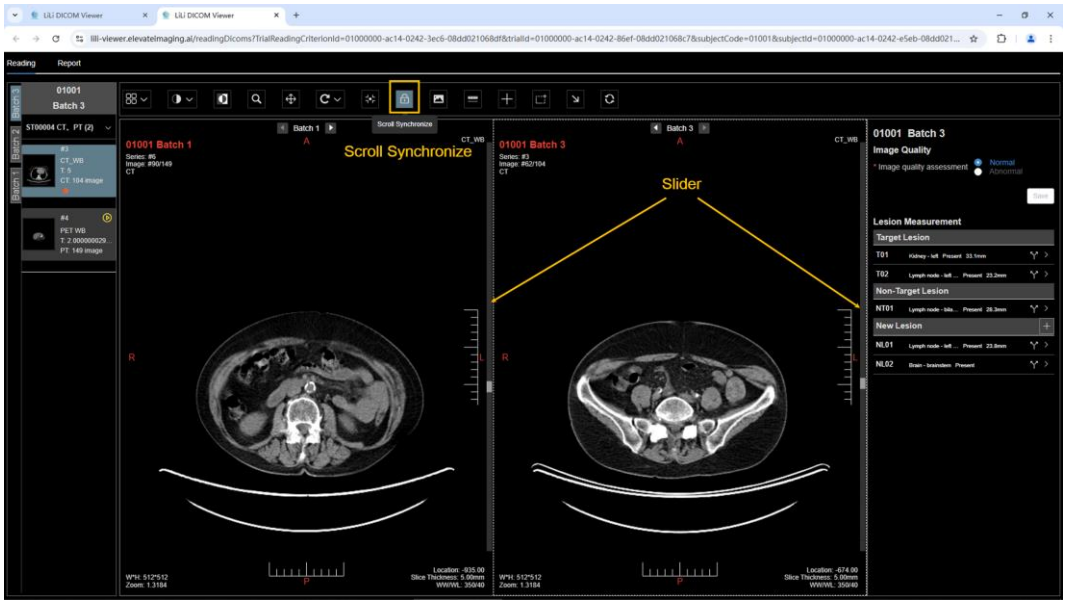

Fig. 71 Image Scrolling

3.5.3 Viewport Setting

Users can use the viewport setting tool to set different viewports layout based on their actual needs. Currently, the system supports 1x1, 1x2, & 2x2 layouts. Among them, 1x2 supports two modes: A | A and A | B. Here A | A refers to two viewports displaying images of the same study batch, and A | B refers to two viewports displaying images of different study batches.

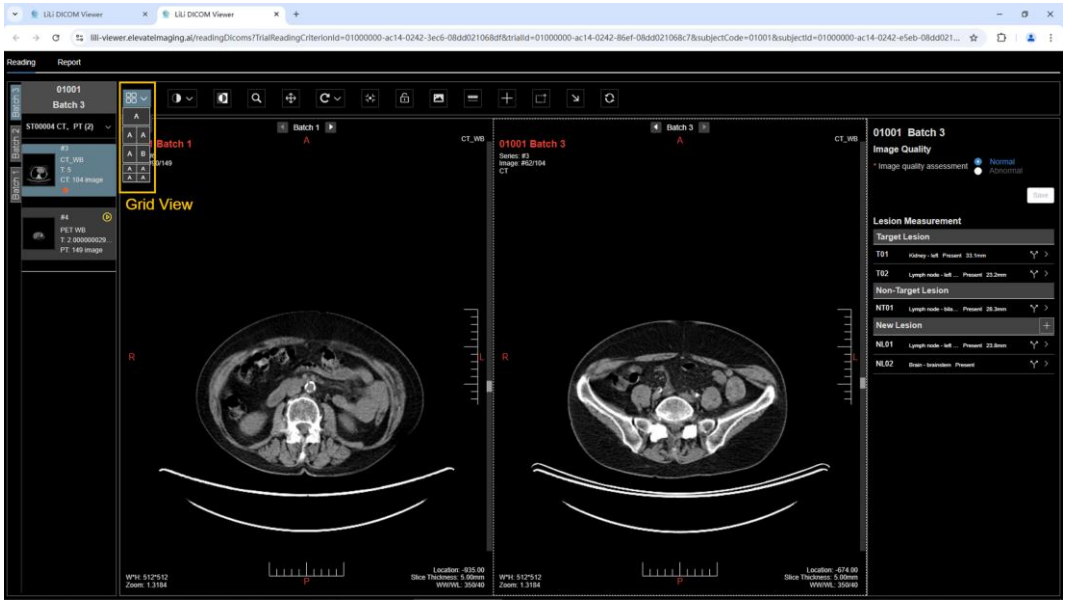

Fig. 72 Viewport Setting

In the multiple viewport layout, double-click the active viewport to make it to occupy the entire reading area, and double-click it again to restore it to the original viewport layout.

3.5.4 Window Width/Level Adjustment Tool

Users can set the window width and window level through the window width/level adjustment tool. Currently, it supports full dynamic windowing, default windowing, customized windowing, area windowing, preset windowing.

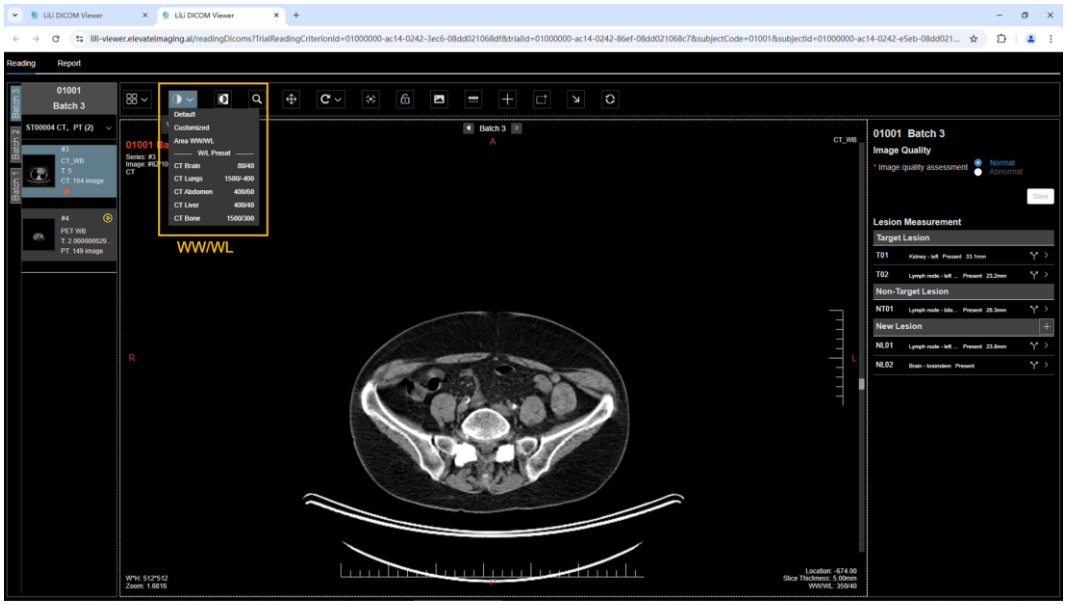

Fig. 73 Window Width/Level Adjustment Tool

1) Full dynamic windowing: after clicking the <Windowing> button, place the mouse in the active viewport, hold down the left mouse button, move the cursor up and down to adjust the window level, and move the cursor left and right to adjust the window width. When adjusting the window level, moving the cursor down increases it and moving the cursor up decreases it; when adjusting the window width, moving the cursor right increases it and moving the cursor left decreases it.
2) Default windowing: after clicking the <Default> button in the drop-down menu of the <Windowing> tool, the image in the current active viewport will be restored to the defaulted window width and level.
3) Customized windowing: after clicking the <Customized> button in the drop-down menu of the <Windowing> tool, enter the values for window width and level in the pop-up window of [Customized Windowing] and then click the<Save>button. The customized values will be applied to the image in the current active window.

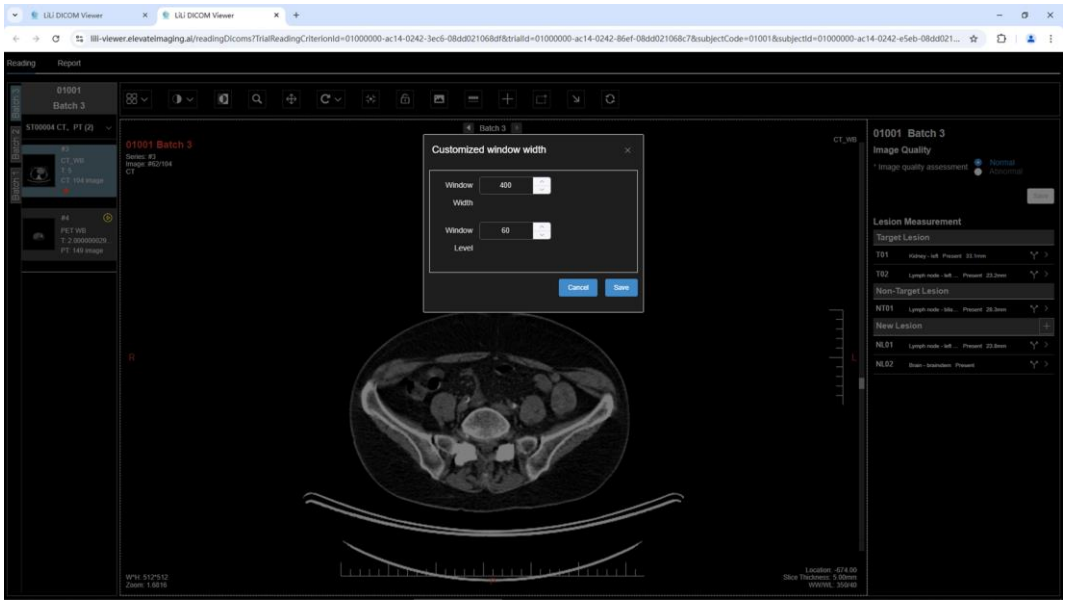

Fig. 74 Customized Windowing

CAUTION

Values of window width/window level can only be integers.

4) Area windowing: after clicking the <Area WW/WL> button in the drop-down menu of the <Windowing> tool, draw a rectangle in the active viewport, and then the window width and window level values will be calculated based on the pixel values within the rectangle and applied to the entire image of the current active image viewport.

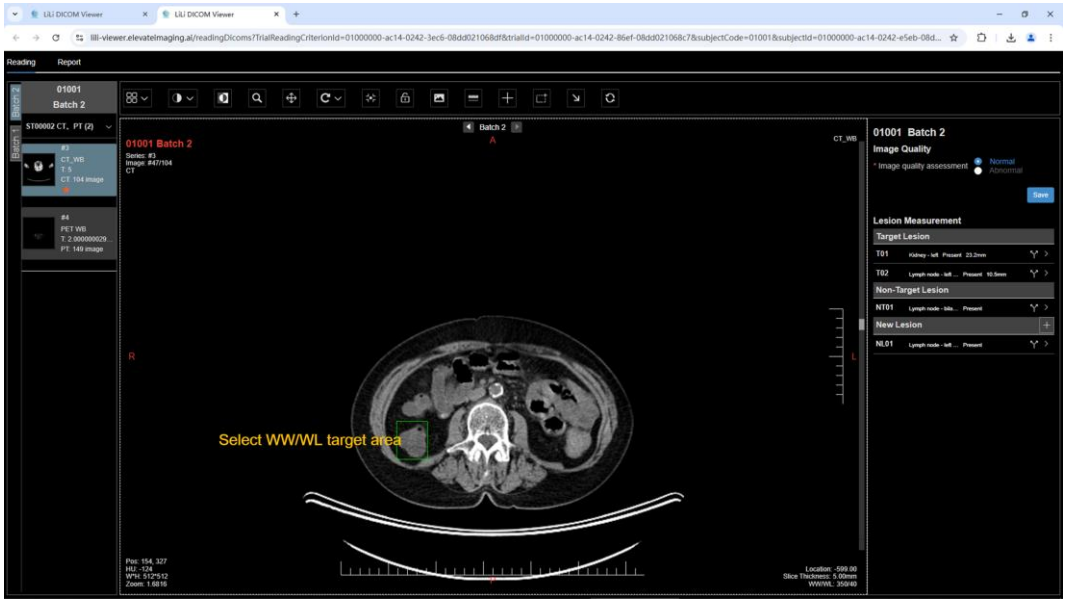

Fig. 75 Area Windowing

5) Preset windowing: several preset window width/level templates are listed in the <Windowing> tool's drop-down menu, and the selected template will be applied the image of the current active viewport.

3.5.5 Inverse Color

Clicking the <Inverse Color> button will invert the color of the image in the active viewport.

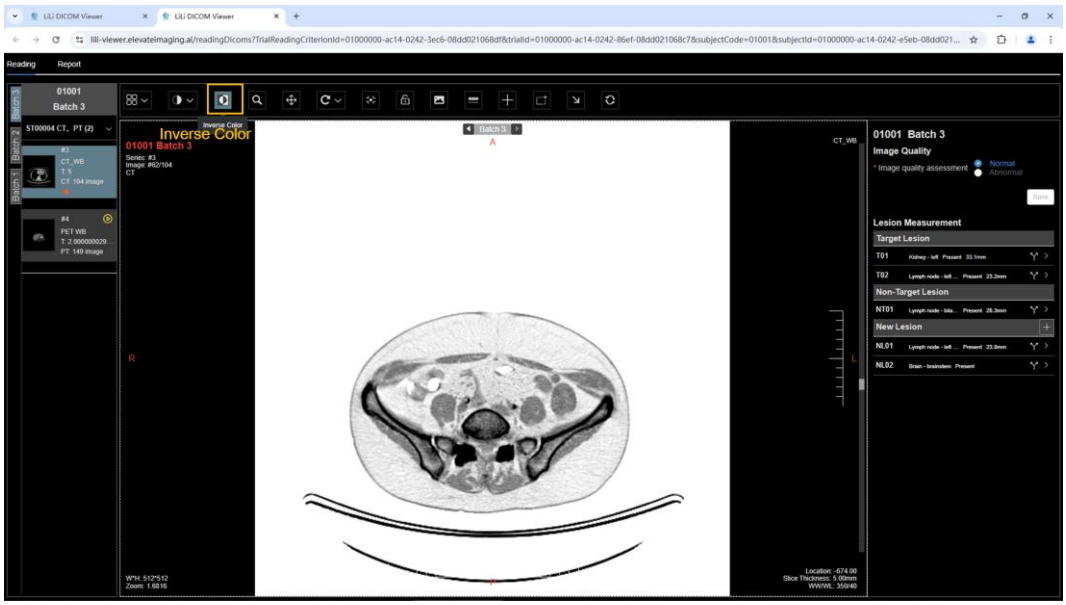

Fig. 76 Invert Image Color

3.5.6 Image Scaling

Users can change the size of the image in the active viewport through the zoom tool and the image size self-adaptation functions.

1) Zoom: click the <Zoom> tool, hold down the left mouse button and move the cursor down to zoom in, and move the cursor up to zoom out.

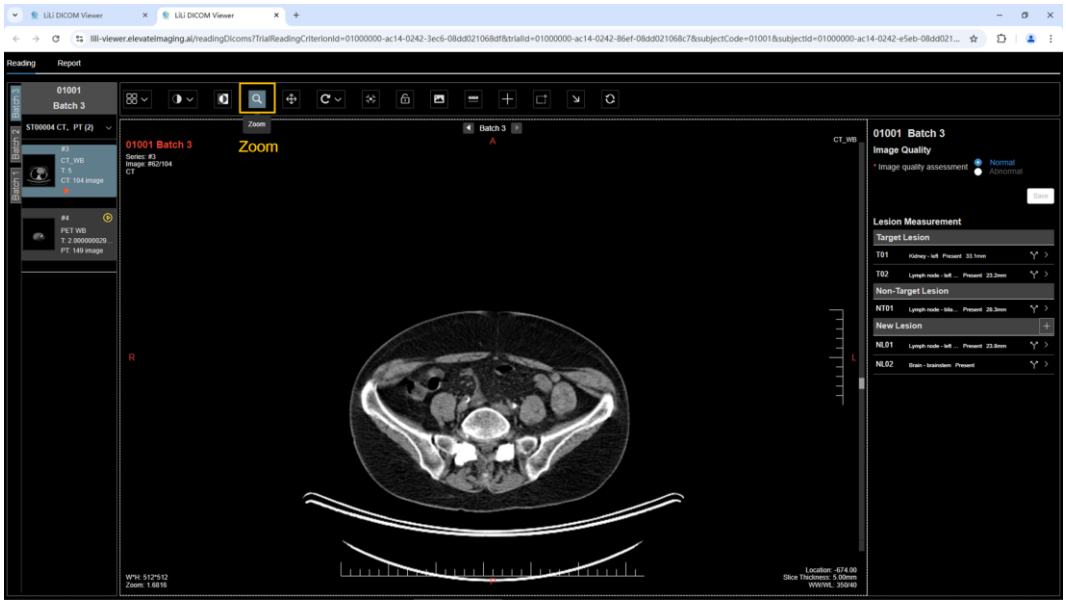

Fig. 77 Image Zoon In/Out

2) Fit to Viewport: click the <Fit to Viewport> button, the size of the image in the active viewport will be automatically adapted to the size of the viewport.
3) Fit to Image: click the <Fit to Image> button, the image in the active viewport will be displayed in its original size.

The <Fit to Viewport> button and the <Fit to Image> button are located at the same position of the menu.

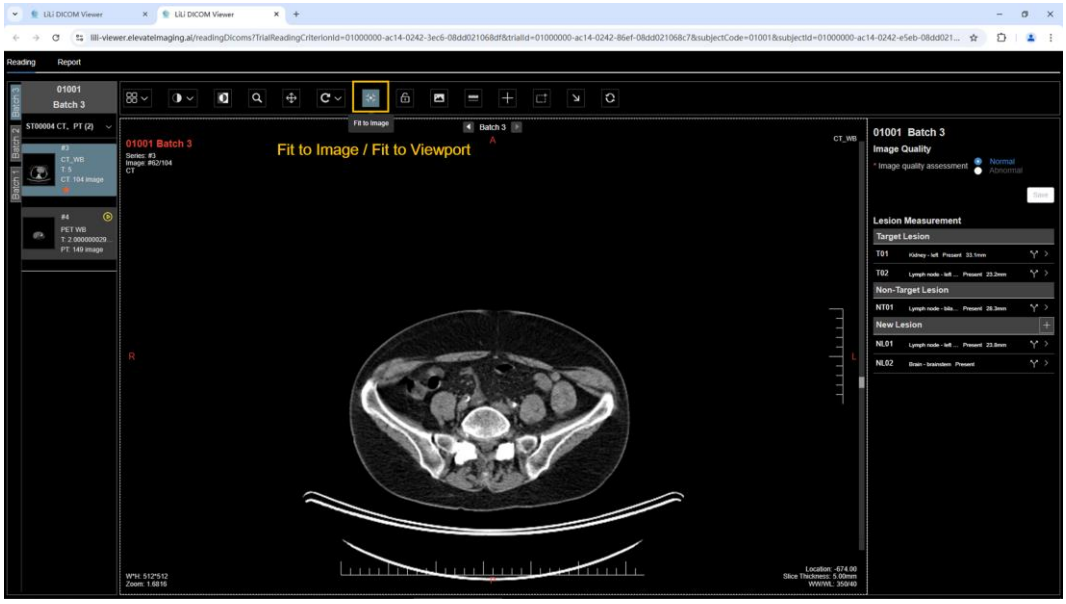

Fig. 78 Fit to Viewport and Fit to Image Buttons

3.5.7 Image Moving

Users can move image with the move tool.

After clicking the <Move> button, place the mouse in the active viewport and hold down the left mouse button to move the image in any direction.

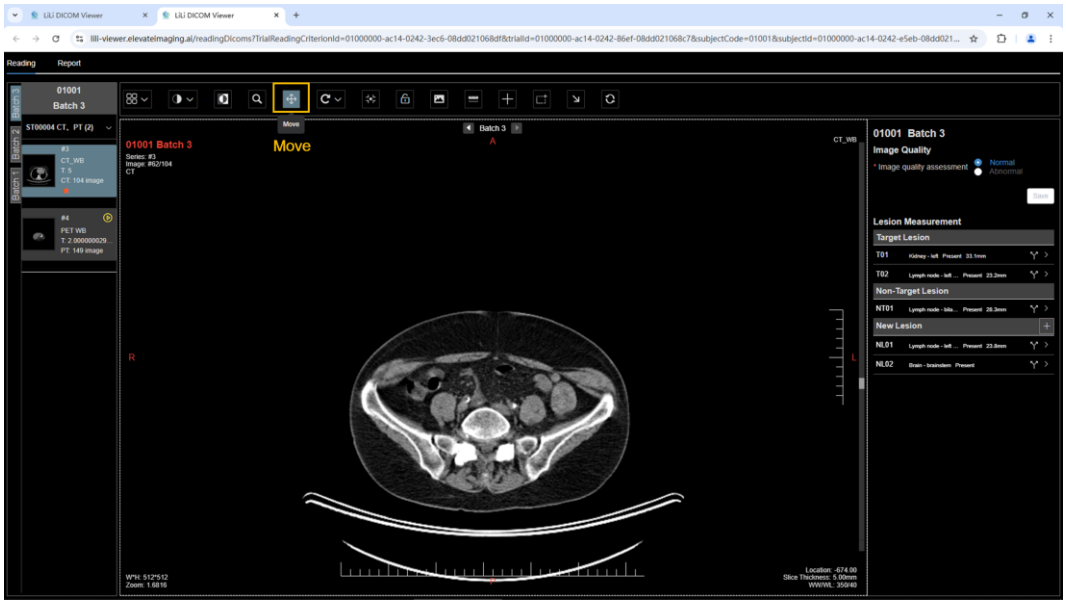

Fig. 79 Image Moving

3.5.8 Image Rotating

Users can use image rotating and flipping tools to rotate and flip the image in the active viewport. After clicking the <rotate> tool, a pull-down menu will appear. The operations are as follows:

1) Default: restore the image in the active viewport to the default orientation.

2) Vertical Flip: the image will turn upside-down. The left/right orientation will stay the same.

3) Horizontal Flip: the image will turn side-to-side, as in a mirror. The up/down orientation will stay the same.

4) Rotate Left: the image will turn 90 degrees; the top of the image will rotate to the left.

5) Rotate Right: the image will turn 90 degrees; the top of the image will rotate to the right.

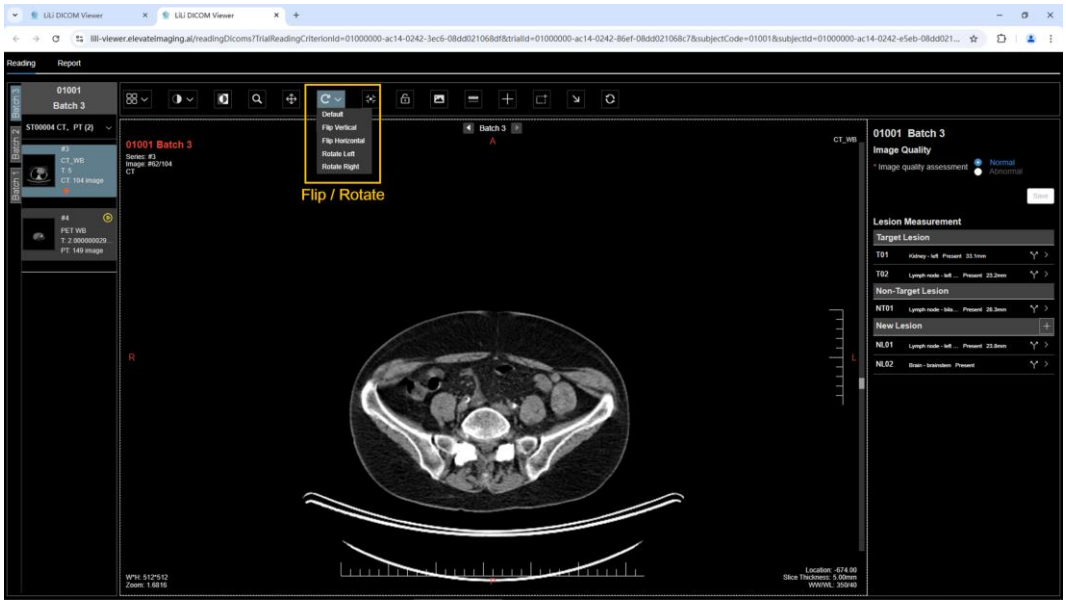

Fig. 80 Image Rotate & Flip

3.5.9 Image Screenshot

Users can use the screenshot tool to save the image and annotations in the active viewport. After clicking the <Screenshot> button, the system saves the image and annotations in the active viewport to a PNG format image, and then automatically download it through the browser.

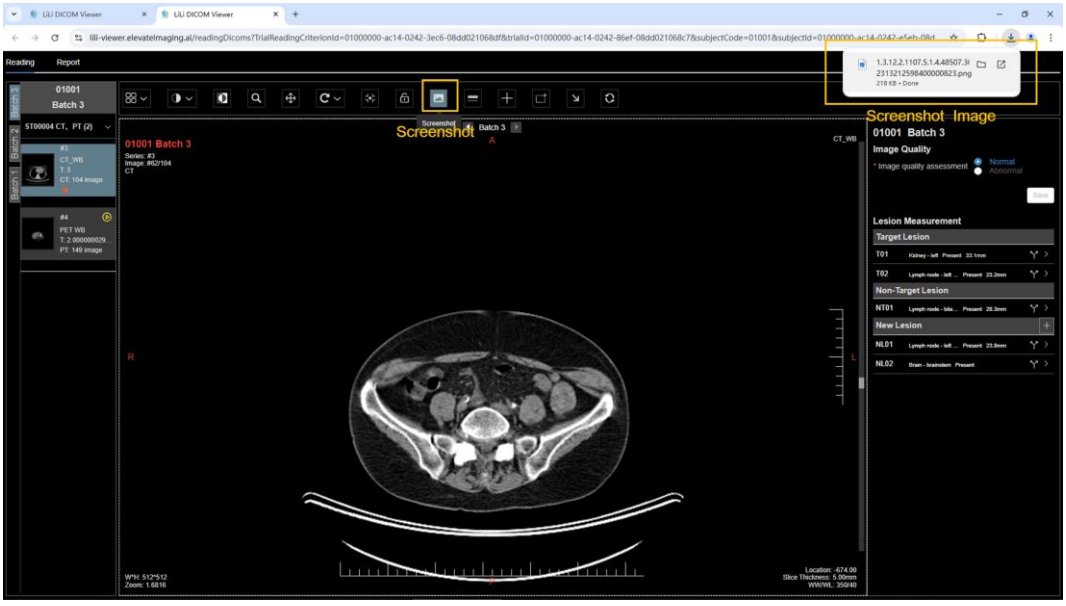

Fig. 81 Image Screenshot

3.5.10 Measurement and Annotation

Users can use measurement and annotation tools to measure certain values and annotate images. Functions currently supported include single point measurement, unidirectional measurement, bidirectional measurement, rectangular measurement, and arrow annotation.

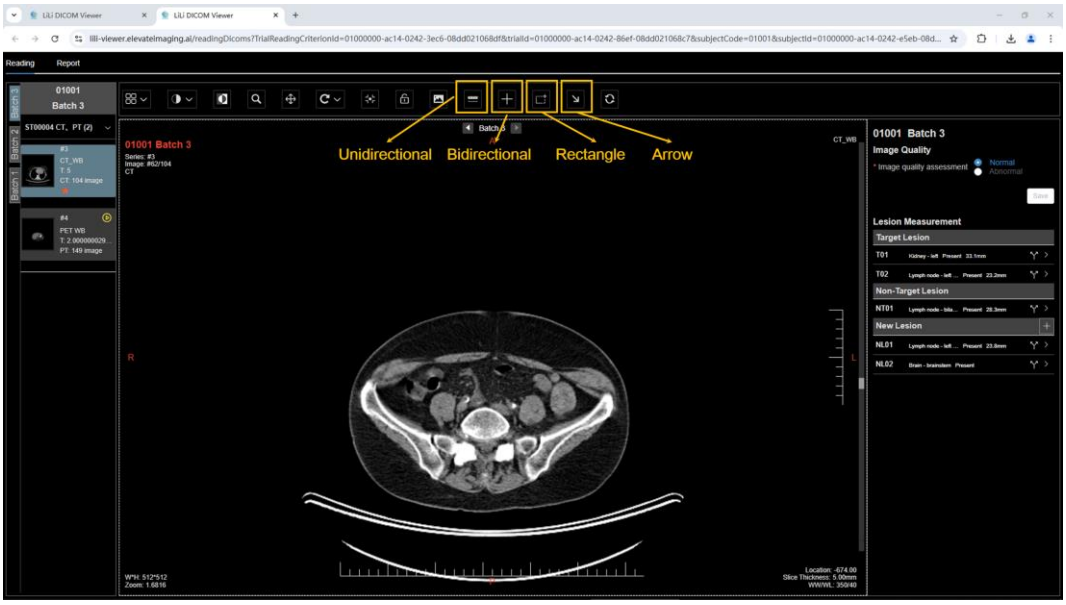

Fig. 82 Measurement and Annotation

a. 1) Single point measurement: certain values of the current cursor position will be automatically measured and displayed based on the type of image modality. CT images: single point HU measurement.

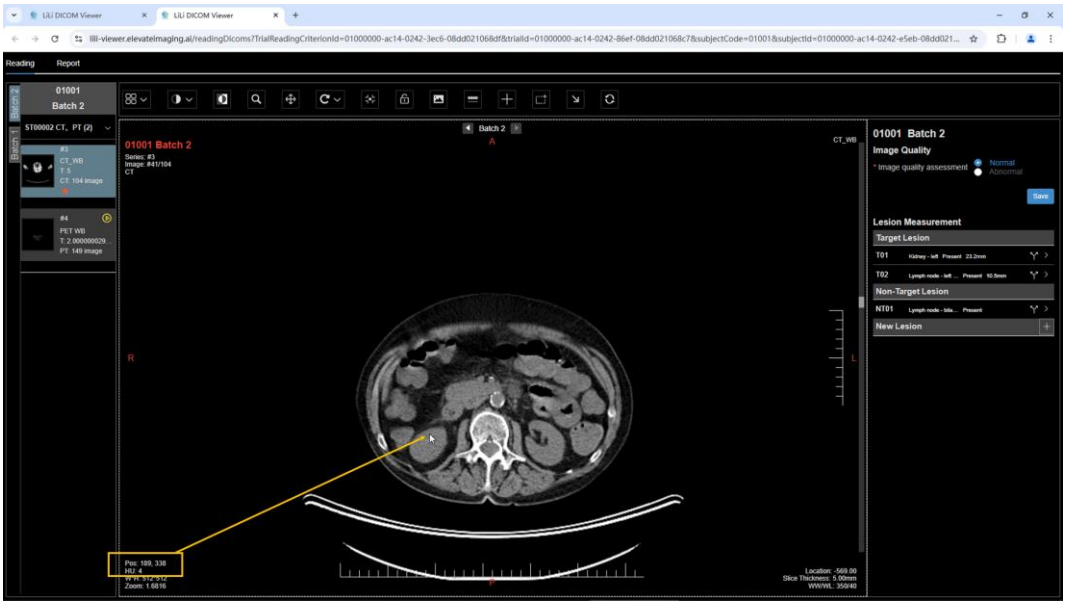

Fig. 83 Single Point Measurement for CT Image

b. PET images: single point SUV measurement.

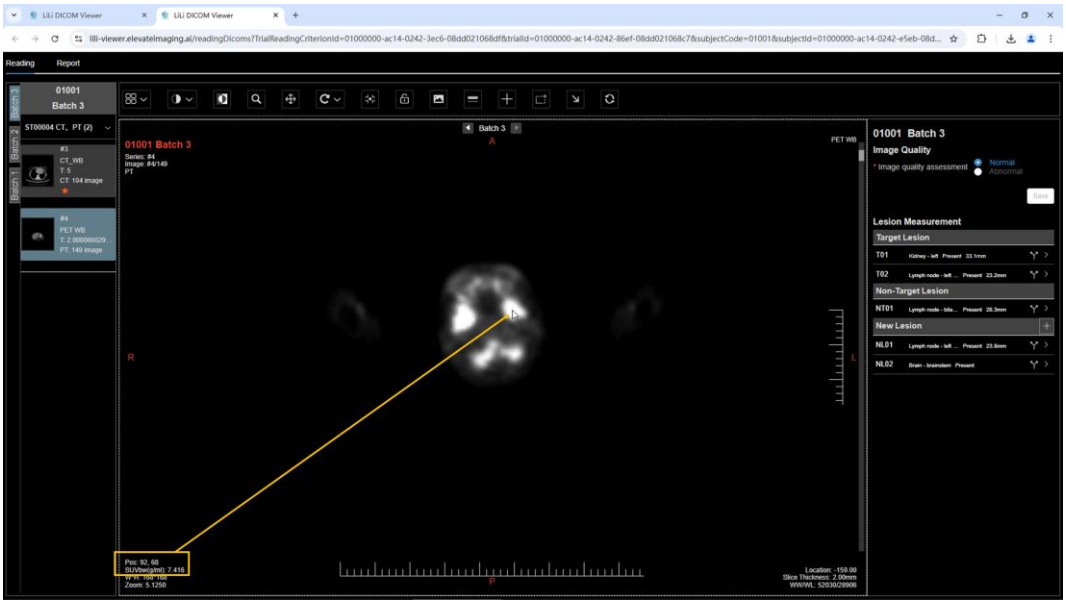

Fig. 84 Single Point Measurement for PET Image

c. MR images: single point pixel value measurement.

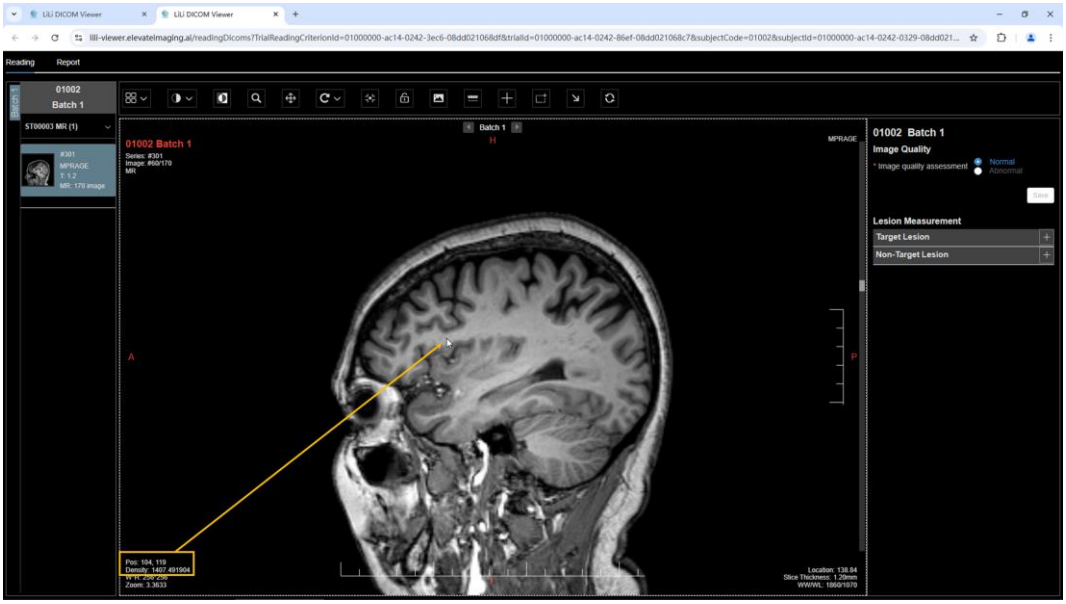

Fig. 85 Single Point Measurement for MR Image

2) Unidirectional measurement: after clicking the <Unidirectional> button, hold down the left mouse button to draw a line in the active viewport, and then after releasing the left mouse button, the measurement value will be displayed along the line segment.

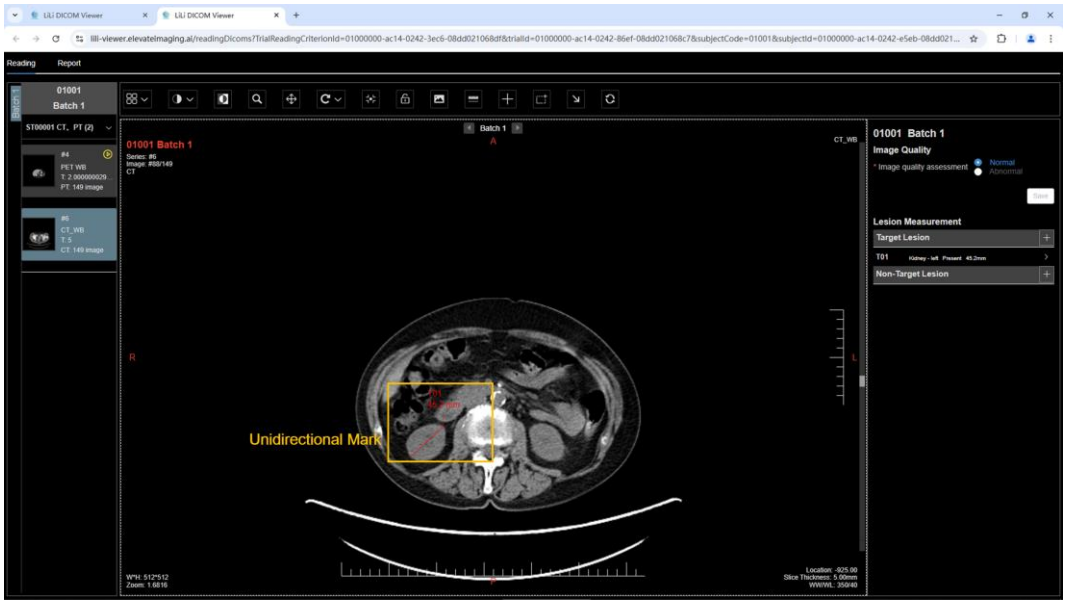

Fig. 86 Unidirectional Measurement

Both the length and the location of the line segment of the unidirectional measurement can be modified before submitting the report. Move the mouse cursor to a location near the line segment, and the line segment will turn green and into the editable mode. There are two ways to edit:

a. Move the mouse cursor to either end of the line segment, when a circular control point appears, the length of the line segment can be modified by dragging the circular control point.

b. Select the entire line segment, and move it around to change its position.

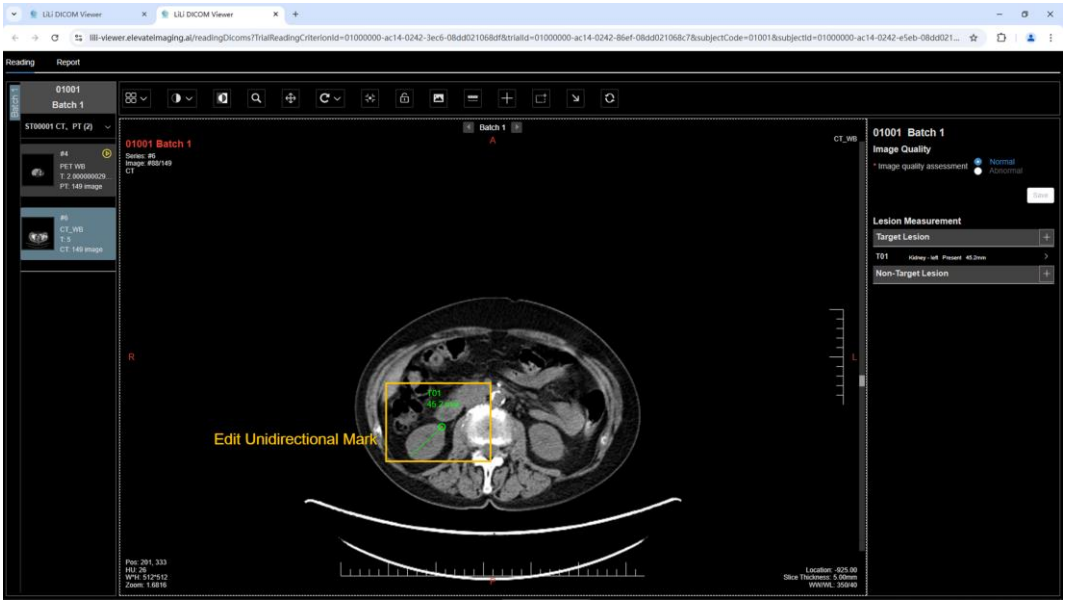

Fig. 87 Edit Unidirectional Measurement

3) Bidirectional diameter measurement: after clicking the <Bidirectional> button, hold the left mouse button to draw a crosshair in the active viewport, and then after

releasing the left mouse button, the measurement values will be displayed along the crosshair.

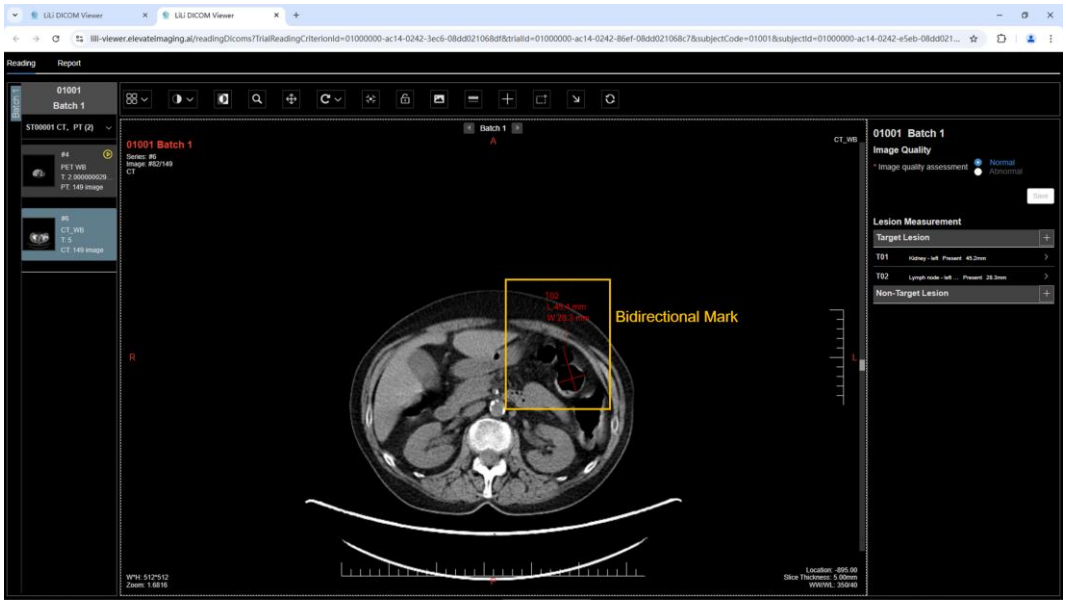

Fig. 88 Bidirectional Measurement

Both the length values and the location of the crosshair can be modified before submitting the report. Move the mouse cursor to a location near the crosshair, and the crosshair will turn green and into the editable mode. There are two ways to edit:

a. Move the mouse cursor to either end of one of the two line segments, when a circular control point appears, the length of this line segment can be modified by dragging the circular control point.

b. Select the entire crosshair, and move it around to change its position.

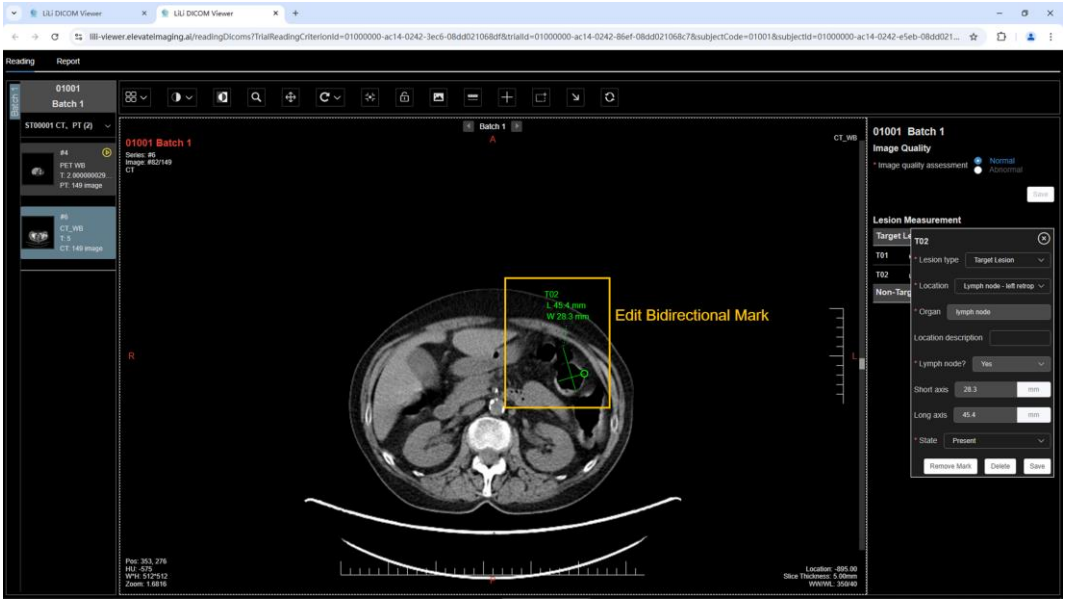

Fig. 89 Edit the Bidirectional Measurement

4) Rectangle measurement: after clicking the <Rectangle> button, hold down the left mouse button to draw a rectangle in the active viewport, and then after releasing the left mouse button, measurement values will be displayed alongside the rectangle.

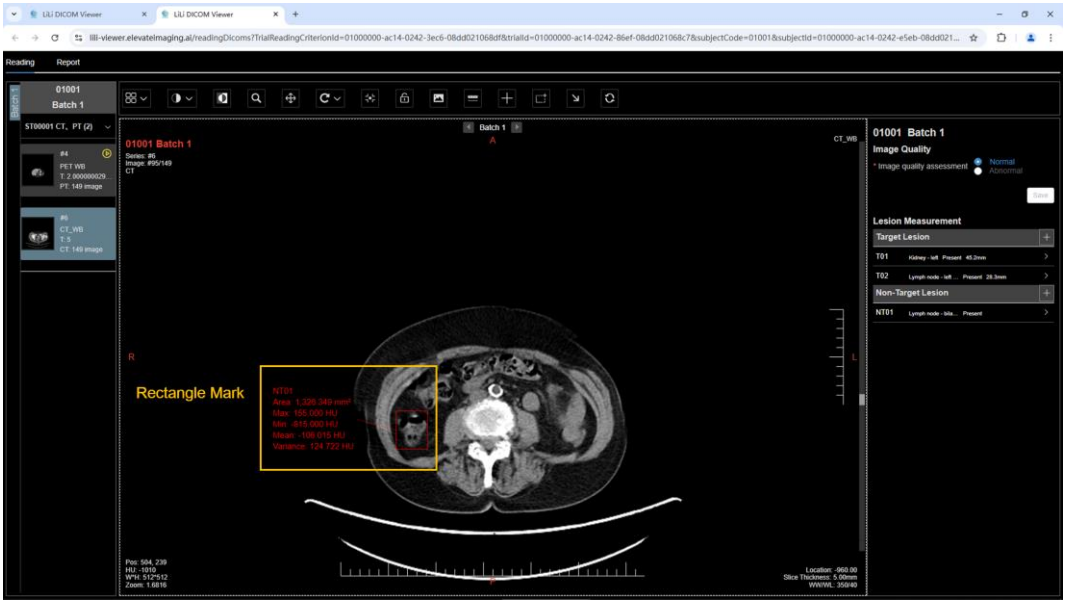

Fig. 90 Rectangle Measurement

The rectangle measurement can be modified before submitting the report. Move the mouse cursor to a location near the rectangle, and the rectangle will turn green and into the editable mode. There are two ways to edit:

a. Move the mouse cursor to either upper left or lower right corner of the rectangle, when a circular control point appears, the dimensions of the rectangle can be modified by dragging the circular control point.

b. Select the entire rectangle, and move it around to change its position.

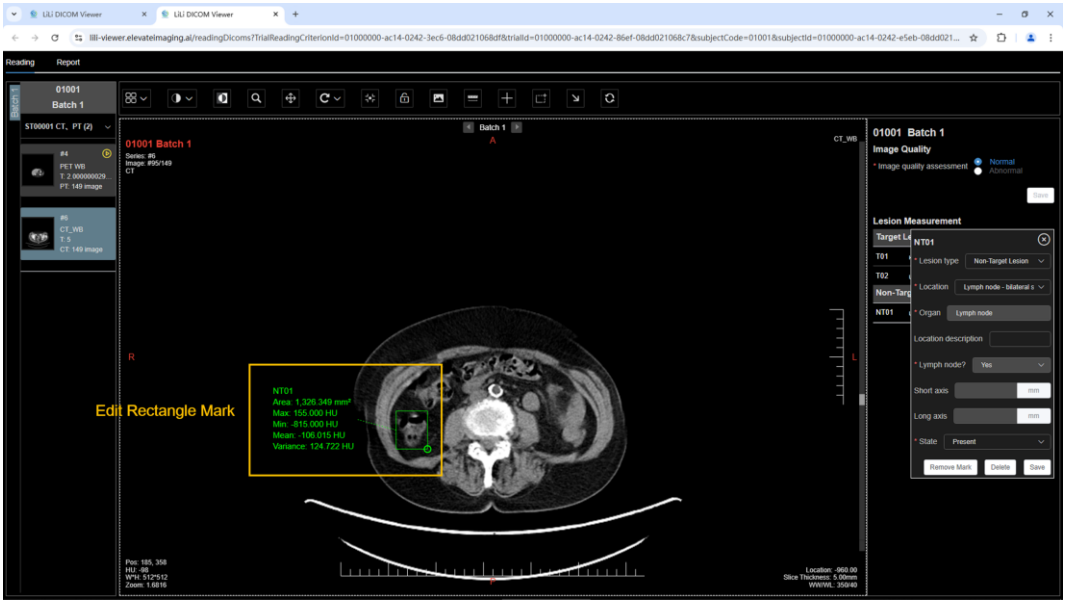

Fig. 91 Edit the Rectangle Measurement

Values of rectangle measurement vary depending on the image modality. For CT images, the rectangle's area, maximum/minimum/mean/variance of HU values are displayed. For PET images, the rectangle's area, maximum/minimum/mean/variance of SUV values are displayed. For images of other modalities, the rectangle's area, maximum/minimum/mean/variance of pixel values are displayed.

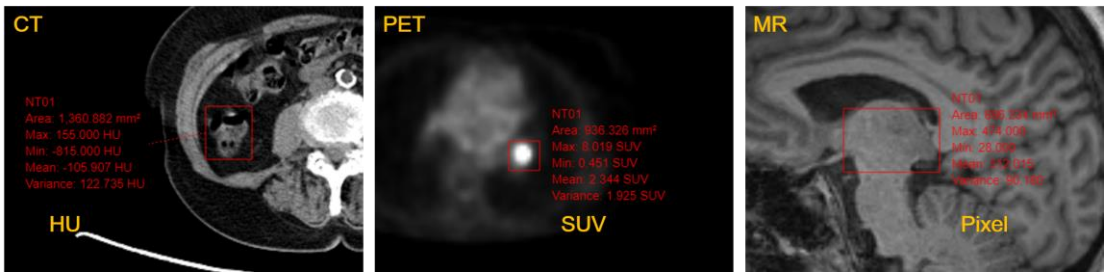

Fig. 92 Rectangle Measurement for CT/PET/MR Images

5) Arrow Annotation: after clicking the <Arrow> button, hold down the left mouse button to draw an arrow in the active viewport, and then after releasing the left mouse button, an arrow annotation will be placed.

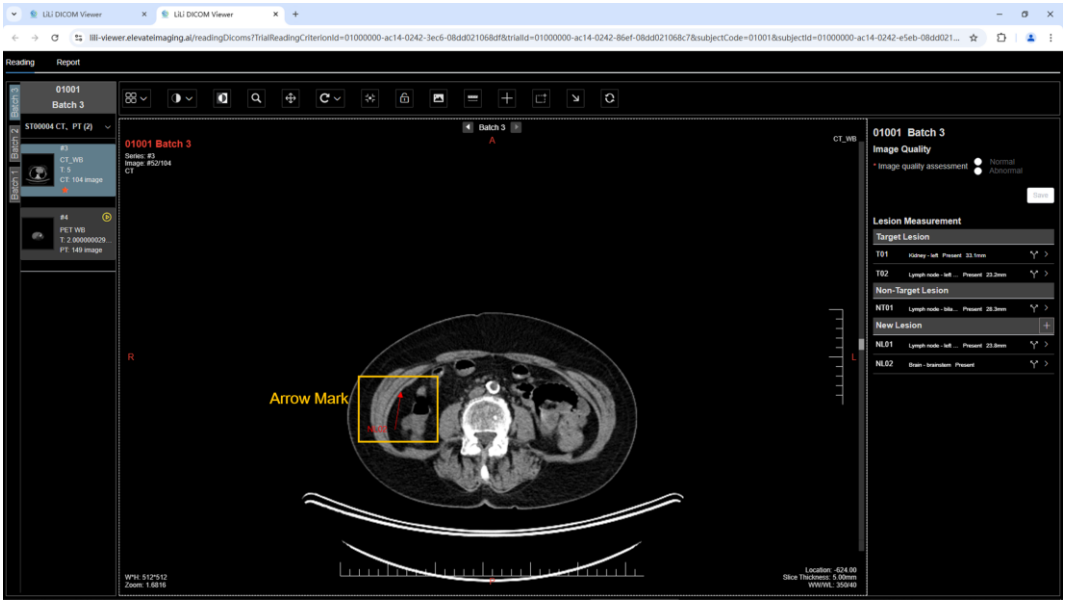

Fig. 93 Arrow Annotation

The rectangle measurement can be modified before submitting the report. Move the mouse cursor to a location near the arrow, and the arrow will turn green and into the editable mode. There are two ways to edit:

a. Move the mouse cursor to the tail end of the arrow, when a circular control point appears, the length of the arrow can be modified by dragging the circular control point.

b. Select the arrow, and move it around to change its position.

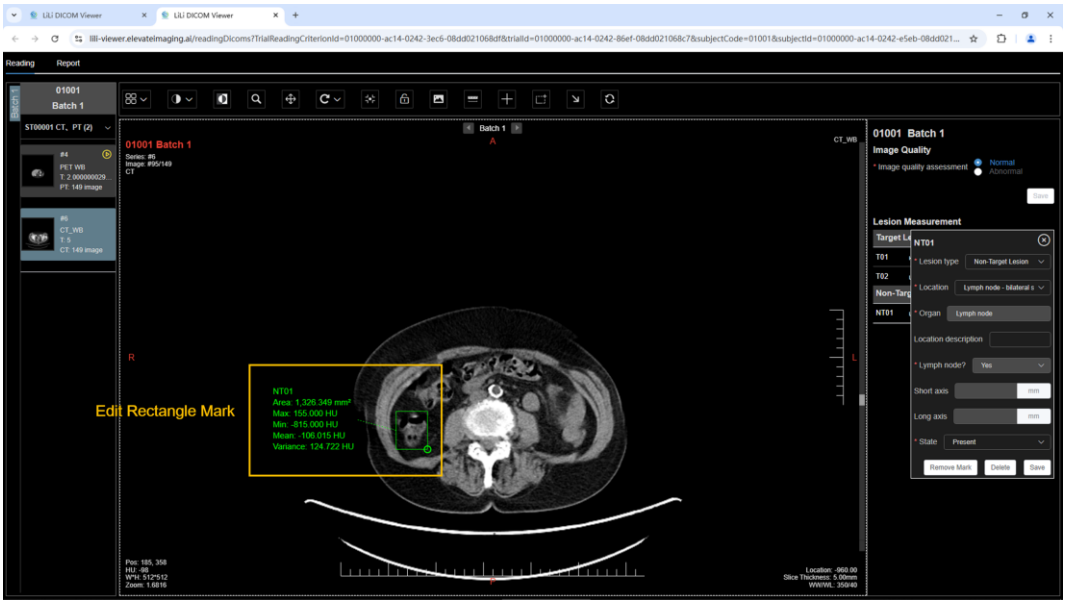

Fig. 94 Edit Arrow Annotation

3.5.11 Reset Image

After clicking the <Reset> tool, the image in the active viewport will return to its original status.

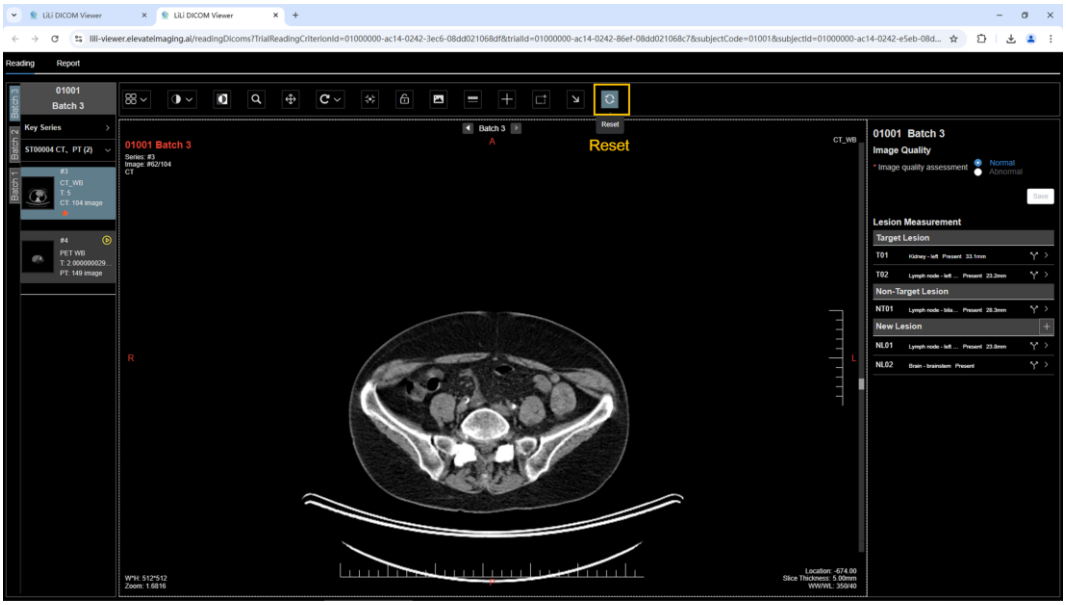

Fig. 95 Reset Image

3.5.12 Edit Lesion Information

Users can add lesions, edit lesions information, & delete lesions. Lesions can be divided into target lesions, non-target lesions, and new lesions.

CAUTION

1) Target lesions and non-target lesions can be added and deleted only in the first study batch, and can only be edited only in subsequent study batches.

2) New lesions can only be added in subsequent study batches. The new lesions added in the previous study batch can only be edited and cannot be deleted in the current study batch.

Information of lesion includes: lesion No., lesion type, location, organ, location description, lymph node status, short axis, long axis, and state.

CAUTION

1) A lesion's location, organ, and lymph node status are related and users only need to select its location, and then other values will be automatically filled in based on the association.

2) Short axis and long axis will be calculated and filled automatically based on lesion's marking.

The process of adding, deleting, and editing lesions is as follows:

1) Add a lesion: on the [Reading] tab, a lesion can be added in two ways:
   a. Use a measurement or annotation tool. After a successful measurement or annotation, a lesion will be automatically added, and its type (target or non-target) will be decided based on the type of the measurement or annotation tool.

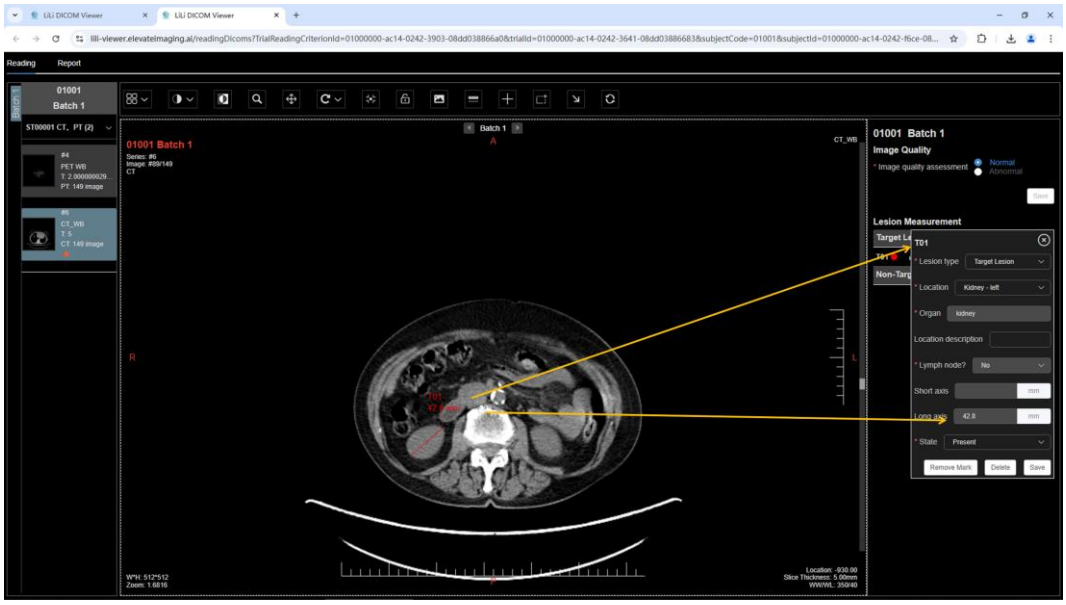

Fig. 96 Add a Lesion Through Measurement or Annotation

b. Click the [+] button in the lesion list to add a lesion. Once the lesion information window appears, a successful measurement or annotation will automatically add a lesion, and its type (target or non-target) will be decided based on the type of the measurement or annotation tool.

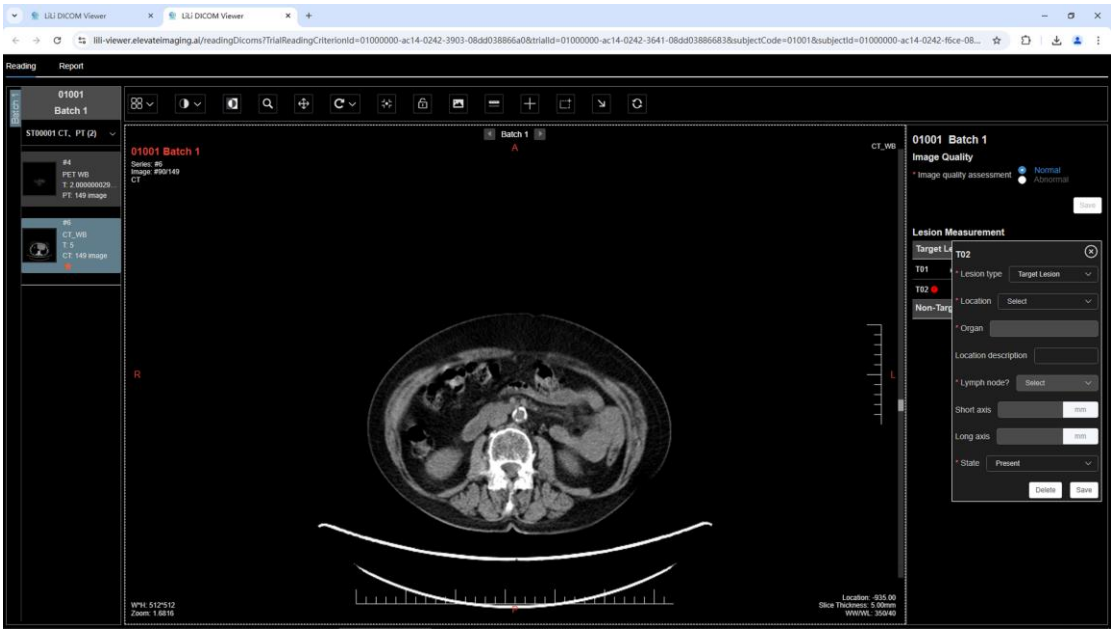

Fig. 97 Add Lesion Through Lesion List's [+] Button

3.5.13 Report Management

Users can view, edit, save and submit a report in the [Report] tab.

1) Edit Report Summary: Lesion information in the [Reading] tab will be automatically populated into the Electronic Imaging Case Report Form in the [Report] tab, and users only need to input or edit the summary of the report.

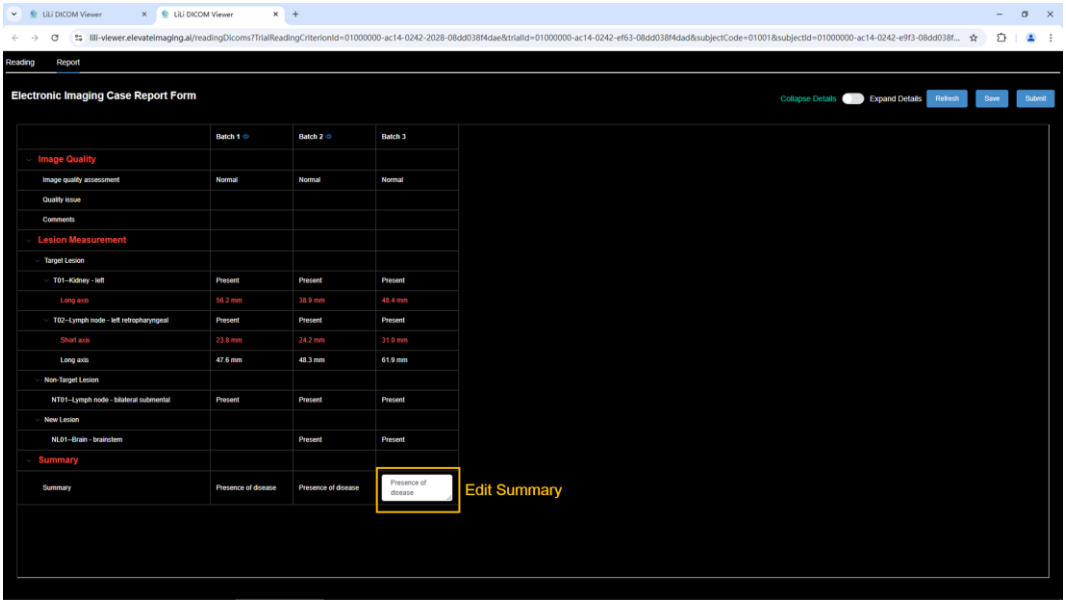

Fig. 98 Edit Report Summary

2) Save Report: click the <Save> button to save the report.

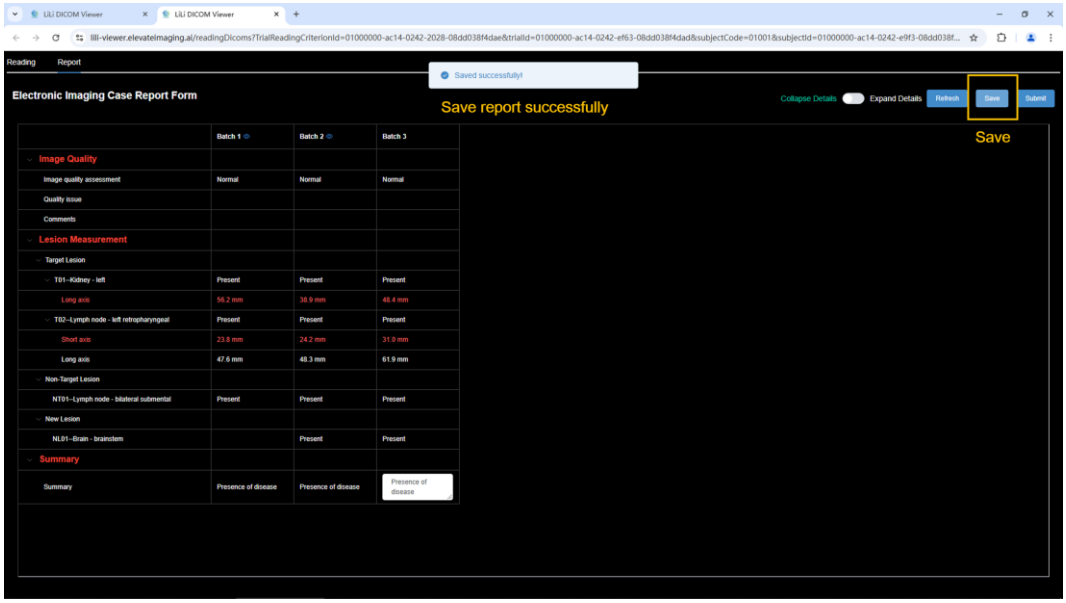

Fig. 99 Save Report

3) Submit Report: After the <Submit> button being clicked, the system will verify the lesion information. If there is any nonconformity, an alert message box will pop up.

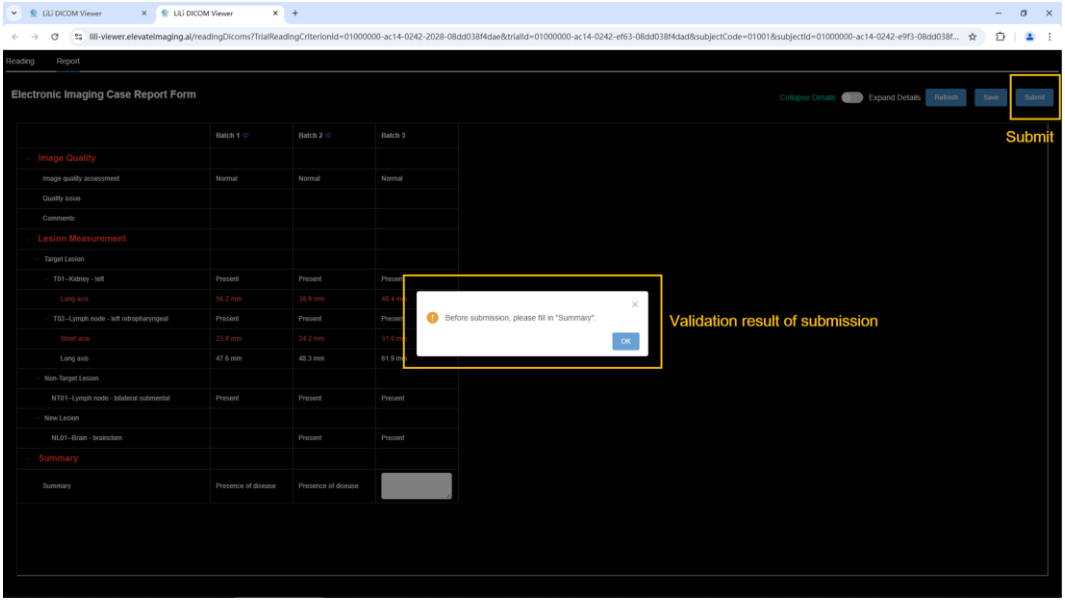

Fig. 100 An Alert for Nonconformity in Report

Once the verification process is done, the report will be submitted successfully.

4) Print Report: a report can be printed after it's submitted. Click the <Print> button in the submitted report tab, a preview page for the printed report will pop up.

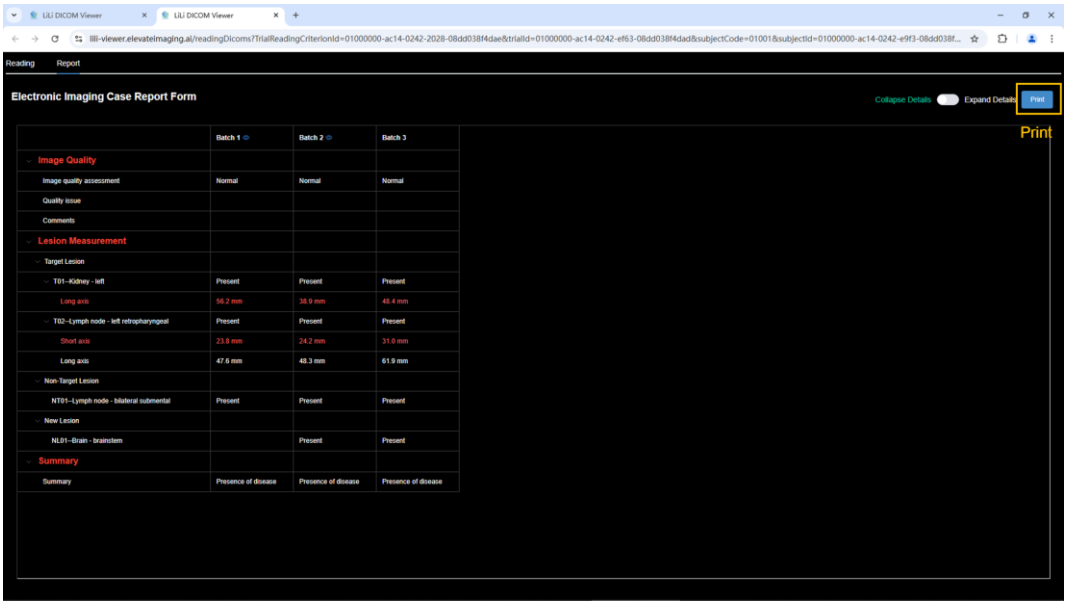

Fig. 101 Print Report

If everything of the report in preview page is correct, the user can click the <Print> button at the lower right corner to print it.

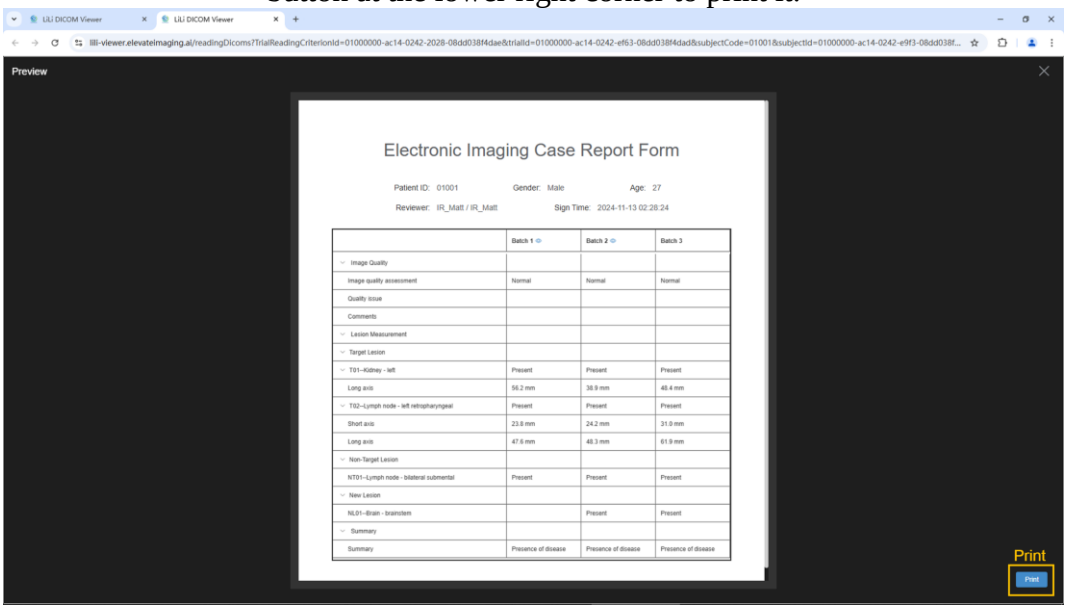

Fig. 102 Preview Page for the Printed Report

3.6 System Management

3.6.1 User Management

The user management module can be used to add/delete users, edit user information, and view roles' information.

1) Add User

On the [Accounts] page of the user management module, click the [New] button to add a new user. Information to be entered includes: username, last name, first name, email, phone number, role, affiliation, department, and position.

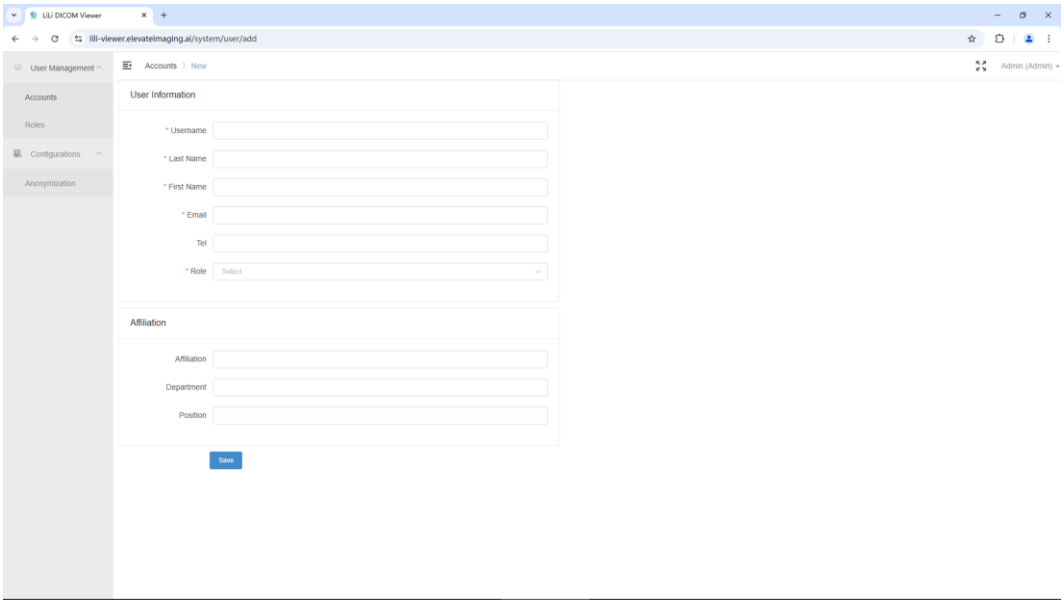

Fig. 103 Add a User

CAUTION

1） A username can be consisted of letters, numbers and underscores with the minimum length of 4 characters and the maximum length of 16 characters.

2） In this system, an email address can only be associated with one user account of a certain role.

2) Edit User Information

Click the <Edit> button in the user list, and an administrator can edit the user information on the [User Information] page. The editable information includes: username, last and first name, email address, phone number, status, role, and affiliation information.

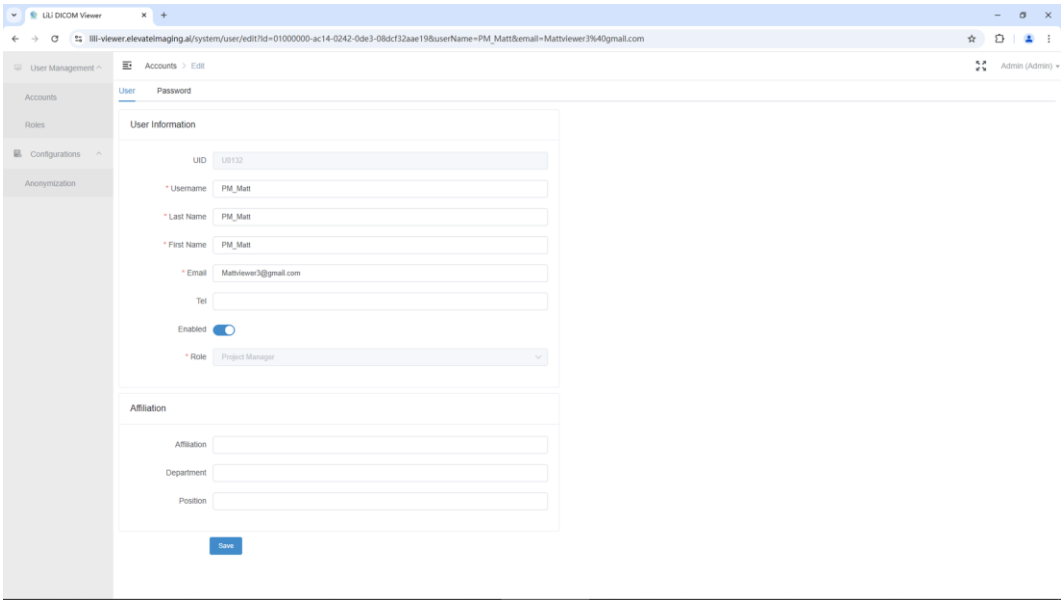

Fig. 104 Edit User Information

A user can reset his/her password on the [Password] tab by clicking the [Reset Password] button, and a confirmation message box will pop up. After a user clicks the [OK] button, a new password randomly generated will be sent to this user through email.

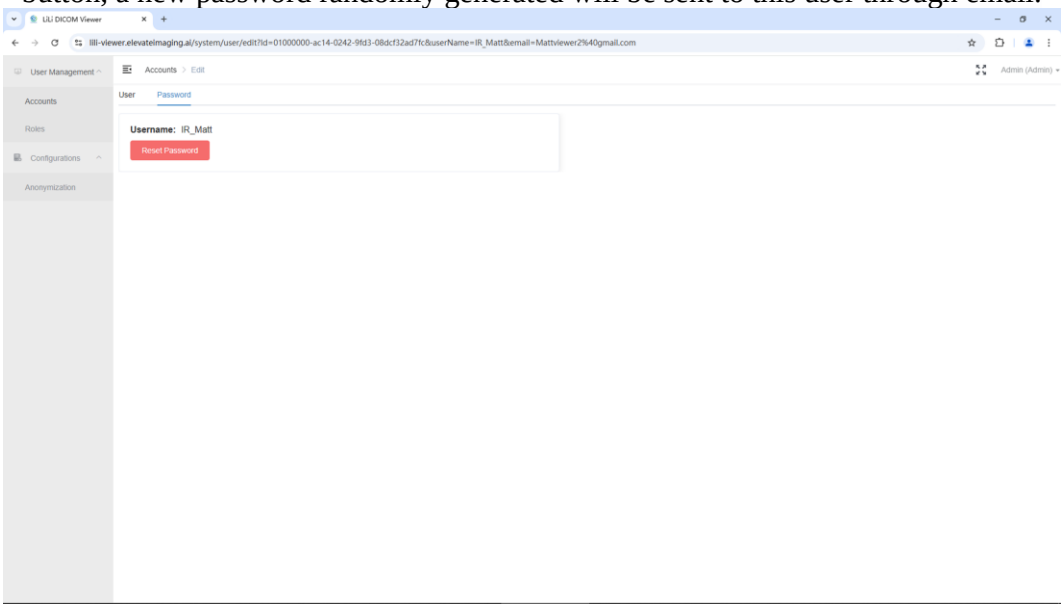

Fig. 105 Reset Password

3) Delete a User Account

Click the <Delete> button in the user list, and a user account will be deleted after confirmation.

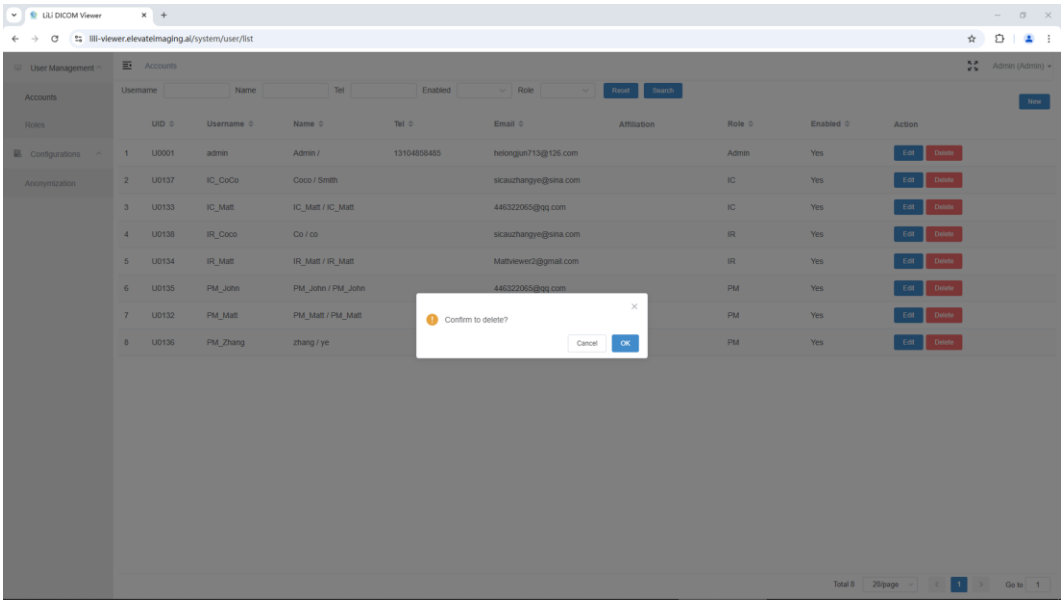

Fig. 106 Delete a User Account

4) View Roles

On the [Roles] page of the user management module, each role and its shortname and description can be viewed.

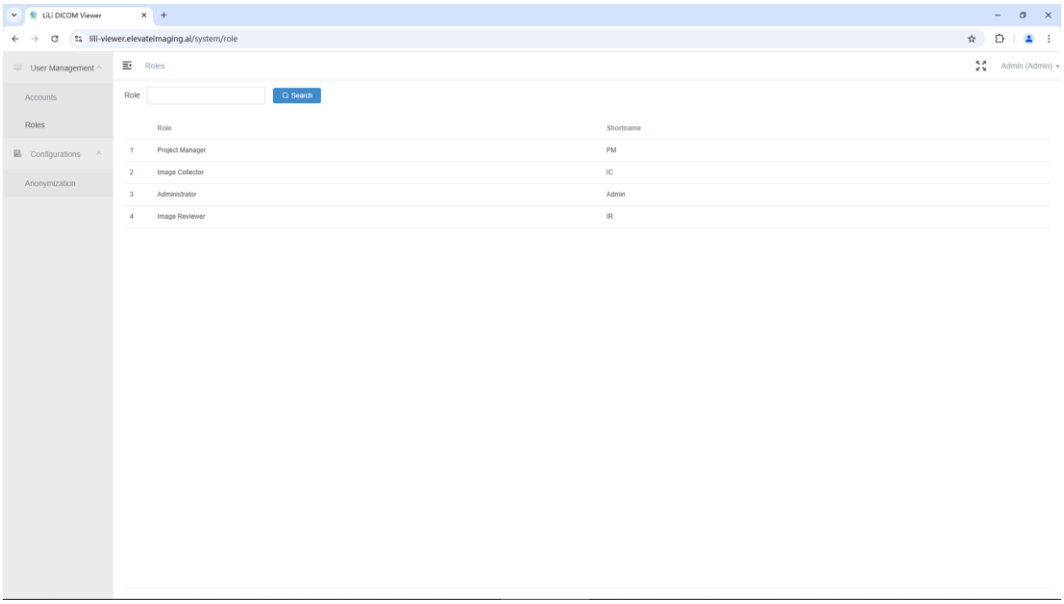

Fig. 107 List of Roles

3.6.2 Anonymization Configuration

DICOM anonymization configuration is available if a user is logged in as a system administrator.

1) Add DICOM tag for anonymization

On the [Anonymization] page, users can click the [New] button to add a DICOM tag which needs to be anonymized.

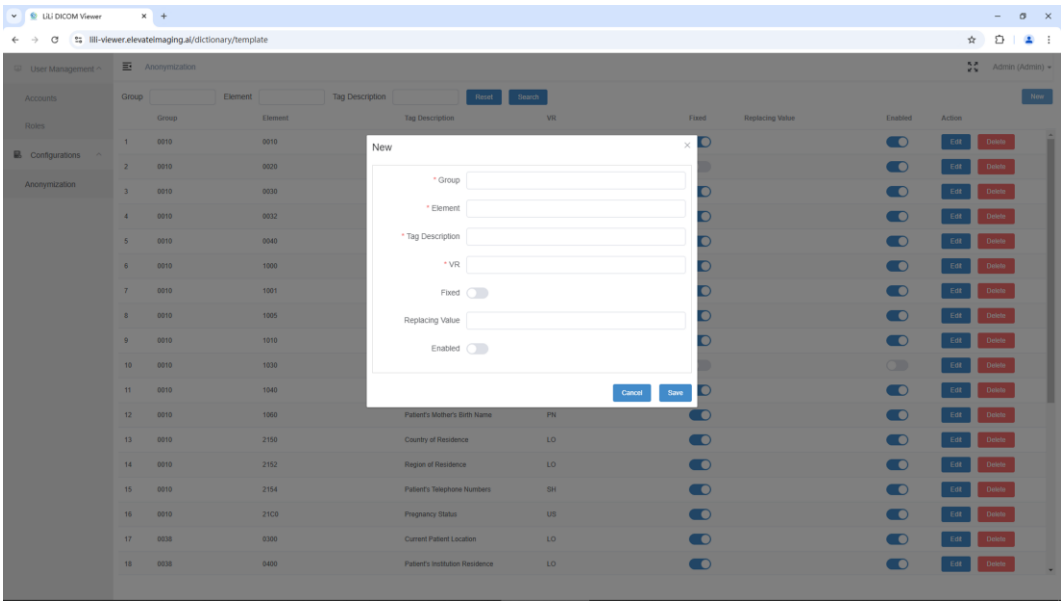

Fig. 108 Add a DICOM Tag for Anonymization

2) Edit DICOM anonymization configuration

After clicking the [Edit] button at the right of a DICOM tag record, an administrator can view and edit the detailed information of the DICOM tag that needs to be anonymized.

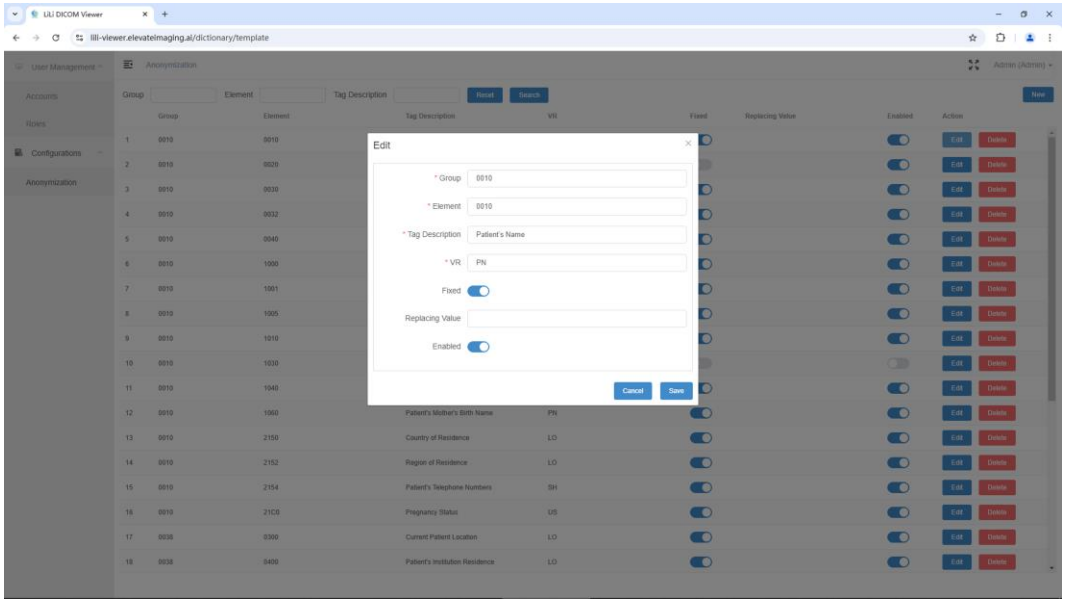

Fig. 109 Edit DICOM Anonymization Configuration

3) Delete DICOM Anonymization Configuration

Click the [Delete] button at the right of a DICOM tag record to delete it.

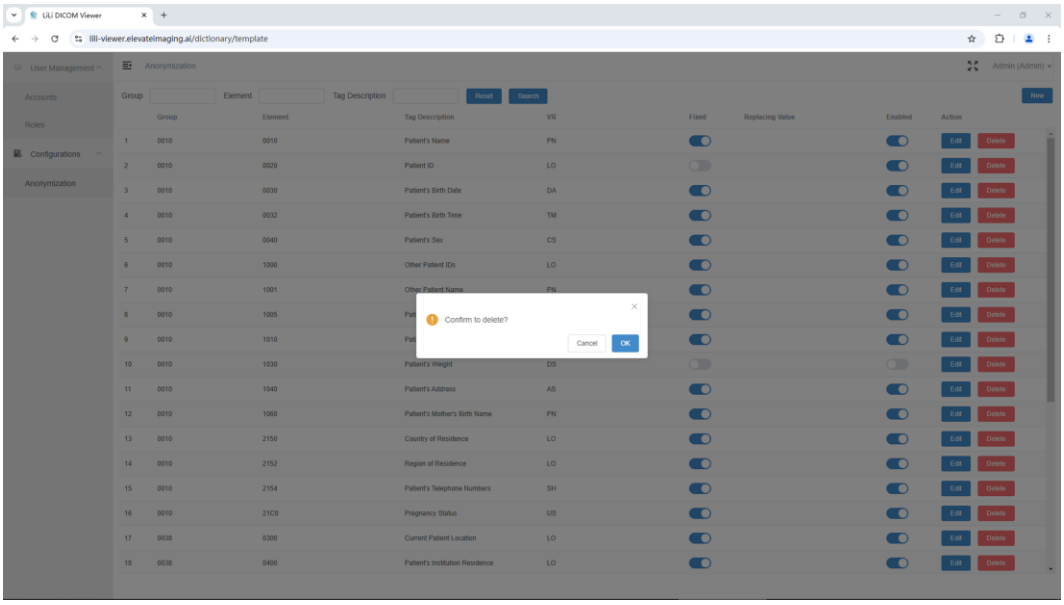

Fig. 110 Delete a DICOM Anonymization Configuration

Charpter 4 System Maintenance

4.1 Data Backup and Recovery

In order to minimize the loss of data in the event of a system failure, it is necessary to regularly backup the system data during the operation of the software. The backup data can be used for system recovery. The backup and recovery of the system data can be configured and carried out based on clients' need.

4.1.1 Data Backup

Data includes the software application and its configurations, databases, and business data (including images, reports, templates, etc.). Different backup schemes are required for different types of data.

1）Software application and its configurations: file backup is used, and its schedule is based on the actual business need.

2）Business data: file backup is used and its schedule is based on the actual business need, usually on a daily basis.

3）Database: this system uses a SQL Server database which can be backed up with SQL Server's backup tools. The backup schedule is based on the actual business need, usually on a daily basis.

4.1.2 Data Recovery

In the event of a system operation problem, the backup data can be used for recovery. The recovery operations vary for different types of data:

1) System application and configurations: Redeploy the system and modify the system configurations based on the backup files.
2) Business data: Restore the business data to the specified directory and modify the corresponding path in the system configuration.
3) Database: Import the backup database file into the SQL Server database and modify the corresponding database connection configuration in the system configuration.

4.2 Maintenance Plan

To ensure the effective operation of the equipment, scheduled maintenance procedures should be performed at defined intervals. Scheduled maintenance shall be performed by a

service representative or similarly qualified and trained personnel in accordance with the requirements set forth in the table below. The following table lists the preventive maintenance tasks.

Maintenance Task	Time Interval
Verify the integrity of server-side external cable connections to peripherals, including network connections	12 months
Test the available network bandwidth on the server side	12 months
Verify the usage of server-side computing resources	12 month
Check server-side storage usage and available storage space	1 months
Check server database usage	3 month
Check the data backup status on the server	1 month
Back up server-side software configurations	1 month
Review server-side system run logs	1 month
Check the compatibility of applications installed on the server side	3 months
Check the number of client connections	1 month

4.3 Troubleshooting

Defect Classification	Defect Description	Precautions or Solutions
Network Failure	When a user encounters problems such as unable to connect to the network or the network is unstable, the system will remind the user to check whether the network connection is normal.	Check the network environment, check the network problems, and wait for the network environment to be repaired before using the software.
Interface Request Error	During the use of the product, users may encounter interface request errors, such as data request errors, and a prompt message will appear.	1. Carefully check the prompt questions fed back by the system, check the input data, or the operation path, and modify it to the correct data before operation; 2. A problem cannot be resolved by yourself, please contact the system maintenance personnel for help.

4.4 Personal Data Breach If there is a personal data breach, including a cybersecurity incident, please notify Elevate Imaging immediately (no later than 24 hours after the breach occurs). Use the following contact information to reach the Data Protection Officer:

Name: Derek Kung

Tel:202-421-1155

Mail:kung.derek@gmail.com

4.5 Serious Incidents Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (via email:kung.derek@gmail.com) and the competent authority of the Member State in which the user and/or patient is established.

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