Operator's Manual

Data Management Platform

Instructions for Use

CurveBeam AI

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Glossary of Symbols

Symbol	Symbol Title	Description
	Manufacturer	Indicates the medical device manufacturer.
	Country of manufacture	To identify the country of manufacture of products
	Caution	Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult instructions for use.	Indicates the need for the user to consult the instructions for use.
	Software number	Indicates the current version of the product.
	Terms of use	Is the icon and colour for the terms of use link.
	Instructions for Use	Is the icon and colour for Instruction for use link.
	Device Label	Is the icon and colour for device label link of the product.

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Symbol	Symbol Title	Description
	Uploader App Download	Is the icon and colour to download the Uploader application from the footer of the DMP application.

1. Device Description

1.1 Indications for Use/Intended Use

Data Management Platform (DMP) is a software application for imaging data management. It is intended to receive, transfer, store, and convert formats of medical imaging data. DMP is also intended to display medical imaging data to the intended users.

1.2 Intended Users

Healthcare professionals (e.g. radiologists, physicians, surgeons, machine operators).

DMP is only to be used by or under the supervision of qualified healthcare professionals, who have received training from CurveBeam AI Ltd. in the use of the software.

DMP allows following type of users to be created in the system

Role	Description
SuperAdmin	is a default application user that shall exist when the application starts
SysAdmin	are CurveBeam AI admin users, who shall manage the overall application
Administrators	are organization admin users, who shall manage the organization-related information in the application
Staff	are the organization users, that shall be created by the organization administrators to let them use the application to perform different actions
Service User	is a CurveBeam AI organization user, which shall exist by default in the system to allow the service pipeline to interact with the application

The DMP Application is not a medical device, therefore Intended Patient profile is not applicable.

1.3 Intended Operational Environment

- **Computer or laptop within the healthcare setting**

DMP is used by healthcare professionals on a desktop or laptop computer. The sources of distractions present in these environments, i.e., surrounding people or noise, mobile phone, or other sources of distractions, can affect the user's interaction with the device.

Bright light (natural or artificial) shining directly on the user's screen can affect the usage of DMP. Therefore, it is the user's responsibility to use DMP in an environment which has appropriate conditions including for lighting.

DMP is **NOT** intended to be used on mobile devices.

1.4 Warnings

Due to security reasons, after 15 minutes of inactivity, your session will be terminated, and you will be redirected to the login screen.

Before operating the software, all new users of DMP are required to read this User Manual in its entirety. Minor revisions may be made by CurveBeam AI at any time and without notice.

DMP is compatible with DICOM-compliant imaging data.

CurveBeam AI warrants the provision of patient data via the DMP application, which will be encrypted and decrypted through Amazon Web Services (AWS).

1.5 Cybersecurity Considerations

Report

- Report potential cyber security issues. Users should report to CurveBeam AI as soon as possible if the product appears to have been impacted by a cyber security issue.

Privacy

- Users should be aware of what content they share online, both in public and private forums, particularly relating to personal information.
- Users should log out of the DMP application when it is not in use on their computer/laptop.

Authentication

- Avoid re-using the same password across different services, especially if they are registered under the same email address.

- Never share your passphrases with anyone.
- Be aware of your surroundings when using login details in public.
- This device/application should only be used by authorized or registered users.
- In the event the user account is no longer needed, the account must be deactivated.

Network

- Only use trusted connections or a Virtual Private Network (VPN) when accessing an account, as using public Wi-Fi without the use of a VPN increases the risk that your information could become compromised.

Suspicious messaging

- DMP communicates to users via emails. Users should exercise caution and ensure that the email is trusted before acting on any information contained within it. If in doubt, contact CurveBeam AI, don't use the details or any links in the suspicious message, use contact details that you trust.

Operating system and web browser update

- Regularly updating the computer operating system and Chrome web browser that you use to access DMP is important because the most up-to-date software will generally be the most secure.

Antivirus and Firewall

- The cloud infrastructure that hosts the DMP website frontend and backend services have the firewall and antivirus software installed to protect against malware and malicious activity.
- Users shall have an antivirus software and firewall installed on the computer that is used to access DMP. It is recommended that the antivirus software and firewall be set up for auto-updates, so that these are updated automatically, such that the latest version is available for use.

1.6 Company Information

Company Name	CurveBeam AI Limited
Website	https://curvebeamai.com

US Office	**Australia Office**
CurveBeam LLC 2800 Bronze Dr. Suite 110 Hatfield, PA 19440, USA (Office) +1 267 483 8081 www.curvebeamai.com info@curvebeamai.com	Level 10, 10 Queen Street, Melbourne VIC 3000, Australia (Office) +61 3 9620 0250 www.curvebeamai.com info@curvebeamai.com

1.7 Customer Support

For any questions, issues, feedback or complaints, contact customer support via email:
techsupport@curvebeamai.com

For sales enquiries, please contact via email:
Sales
info@curvebeamai.com

1.8 IFU Location

The IFU document is available on the DMP application footer as an electronic IFU. Refer to section 4.3.8.8 Access IFU for steps to access the IFU.

Alternatively, the IFU is available on the CurveBeam AI company website. Navigate to “CUSTOMERS”. Register your account on the link. CurveBeam AI Ltd. will review the registration. Once the registration is accepted, the user can login using those credentials in the “CUSTOMERS” section in the CurveBeam AI website. Once logged in, the DMP IFU can be located in the Product Manuals section.

User can access the IFU on the company website after login with valid credentials.

1.9 Language

The IFU is written and available in the English language.

2. Product Label

Data Management Platform

CurveBeam AI Limited
Level 10,
10 Queen Street,
Melbourne,
Victoria 3000,
Australia.

V1.0.0

2024-06-04

3. System Requirements

3.1 Internet connection and a browser

An internet connection and a web browser are required to access the DMP Application.

DMP can be accessed via a browser. The following browser is recommended: Google Chrome

Chrome browser on Windows
To use Chrome browser, the user will need:

- **Windows 10 or later**
  An Intel Pentium 4 processor or later that's SSE3 capable.

- **Chrome browser on Mac**
  macOS 11 or later

- **Chrome browser on Linux**
  64-bit Ubuntu 20.04+, Debian 11+, openSUSE 15.4+, or Fedora Linux 36+
  An Intel Pentium 4 processor or later that's SSE3 capable.

The uploader application requires the following system specifications:

- Operating System: Windows 10 (64-bit) or later
- Memory (RAM): Minimum of 8 GB RAM, 16 GB or more recommended for better performance.

For optimal viewing of the DICOM scan in the Viewer, it is recommended to at least have 16 GB RAM installed on the operating machine.

3.2 Installation

DMP does not require installation by a user, only a supported web browser is required.

The upload application can be downloaded via the upload link in the DMP application footer. Refer to section 4.4.1 for uploader installation instructions.

To enable automatic scan uploading from the CurveBeam AI scanner to the DMP website, users should contact CurveBeam AI customer support to configure the uploading plugin on the scanner server.

3.3 Firewall

If the internet access of the user is behind a firewall, the DMP website domain will need to be whitelisted.

If the user cannot access the DMP website (e.g., firewall on user's device or network) the user will need to contact Customer Support.

3.4 Operational security options

There are no operational security options to be set at installation time.

3.5 Decommission and archival

For any new version of the DMP application that will be deployed, CurveBeam AI will inform users regarding the software update in advance. For decommission and archival of data, please contact CurveBeam AI Customer Support.

3.6 Error Handling

In cases where the user encounters errors with accessing DMP, consult the following list and follow the error resolution troubleshooting guidelines.

Error type	The DMP website on the user's device/system does not work temporarily.
Resolution	The user needs to close the tab/browser and re-open the DMP website. If the error persists, the user should contact Customer Support.

Error type	The user is unable to access the DMP website.
Resolution	Check internet connection and if internet is available and DMP website is still not accessible please contact Customer Support.

If the errors cannot be resolved as above or for any errors other than those stated above that prohibit the user from using DMP application, please contact CurveBeam AI Customer Support.

4. Data Management Platform (DMP) User Manual

4.1 General Aspects

4.1.1 Introduction

All new users of DMP are required to read this User Manual in its entirety. Improvements and changes to this user manual may be made by CurveBeam AI at any time. This manual is published by CurveBeam AI without any warranty.

4.1.2 Accessibility

The following items can be scaled using the zoom options of the browser and/or PDF viewer:

- The DMP Application website
- Product Label
- Instructions for Use

4.1.3 Information Security

CurveBeam AI warrants that the provision of image data via the online platform will occur via an encrypted connection. All the data kept in the object storage and the database are encrypted. All data transmission within the cloud infrastructure is protected through the private connection using VPC (virtual private cloud) endpoints. All other data transmissions are encrypted via the HTTPS protocol. The HTTPS protocol is secured by the SSL certificate.

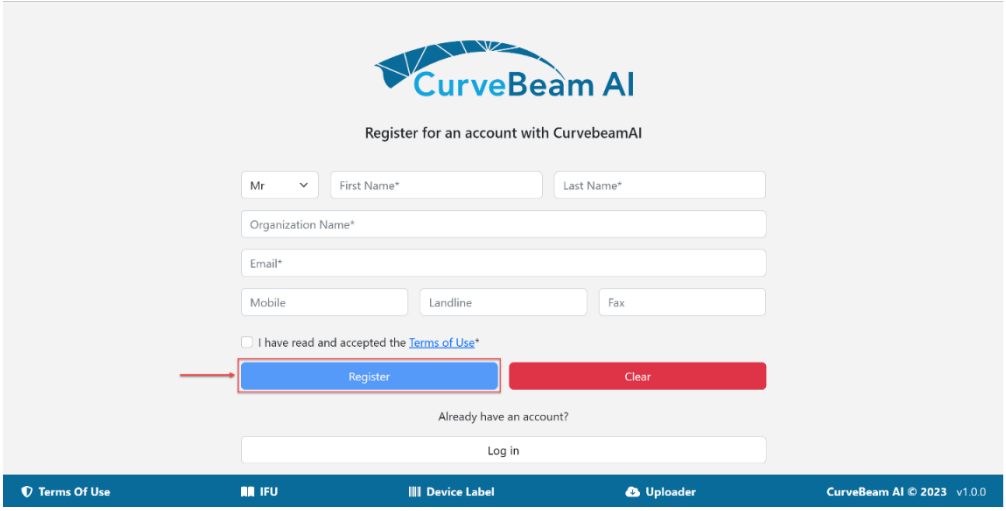
4.2 Major workflows

4.2.1 Account creation workflow

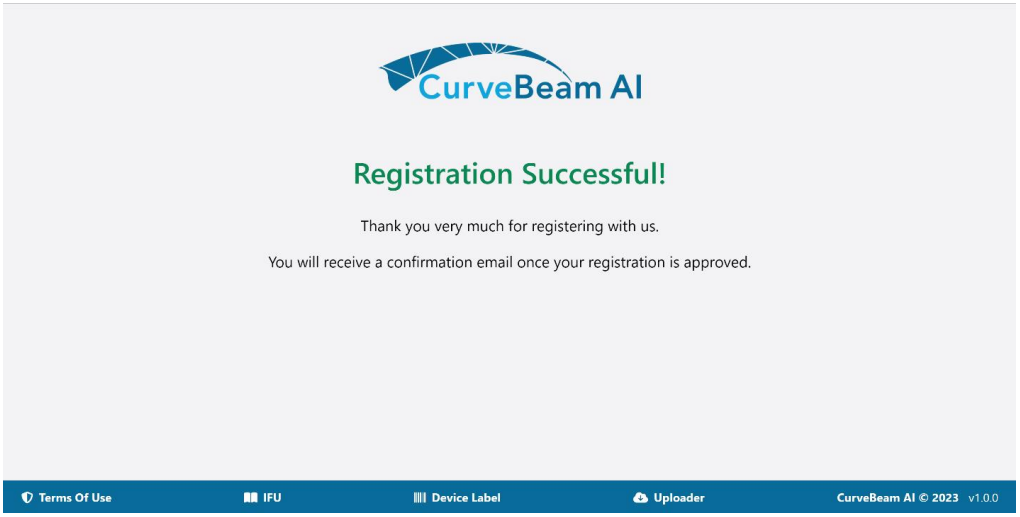
> This action can also be accessed from the login screen via clicking the `Create an account` button.

- Load the DMP application on the web browser and click on ‘Create an account’ button and perform the following steps:

1. Fill out the user and organization details.
2. Tick the checkbox confirming that you have read and accepted the Terms of Use
3. Click on the **Register** button.



- The `Registration Successful` message will be displayed. An automated email will be sent to you confirming the registration.



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- CurveBeam AI will validate and approve the registration. Once the registration is approved, your user account and organization will be created in the DMP system.
- CurveBeam AI will send you an email confirming the registration approval. This email also contains temporary login credentials - use these credentials to login for the first time and set your permanent password. Following this, you will be directed to the DMP dashboard.
- To create staff user for your organization, follow the steps provided in section 4.3.7.6
- Contact CurveBeam AI to setup cloud data store for your organization.
- Contact CurveBeam AI to setup Upload VM on scanner server.

4.2.2 Scans upload workflow using the Uploader application

Scan uploading can only occur if the organization cloud data store has been created.

These actions are available for organization admins and staff users

The steps to upload a scan via the uploader are detailed below -

- Open the application
  Unzip the application package and launch the application executable (refer to section 4.4.1)
- Login
  When the login UI appears, log into your account (refer to section 4.4.2)
- Select Folder
  Click the folder button and select the folder containing the scans (refer to section 4.4.3)
- Anonymization (Optional)
  Check/Uncheck the Anonymization check box based on requirement (refer to section 4.4.4)
  Check/Customize the anonymization options (refer to section 4.4.4)
- Tags (Optional)
  Add/Modify tags for the scans (refer to section 4.4.5)
- Upload
  Start the upload process by hitting the upload button (refer to section 4.4.7)

If the user interrupts the upload process, the upload application will roll back the process and not upload the scan(s) to the DMP website. Partial uploads will be abandoned. Users must re-upload CT images as needed.

If the upload process is interrupted unexpectedly, refer to Section 4.4.8 to report this issue to CurveBeam AI customer support.

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4.2.3 Scans upload workflow from the CT machine

Scan uploading can only occur if the organization cloud data store has been created.

These actions are available for organization admins and staff users

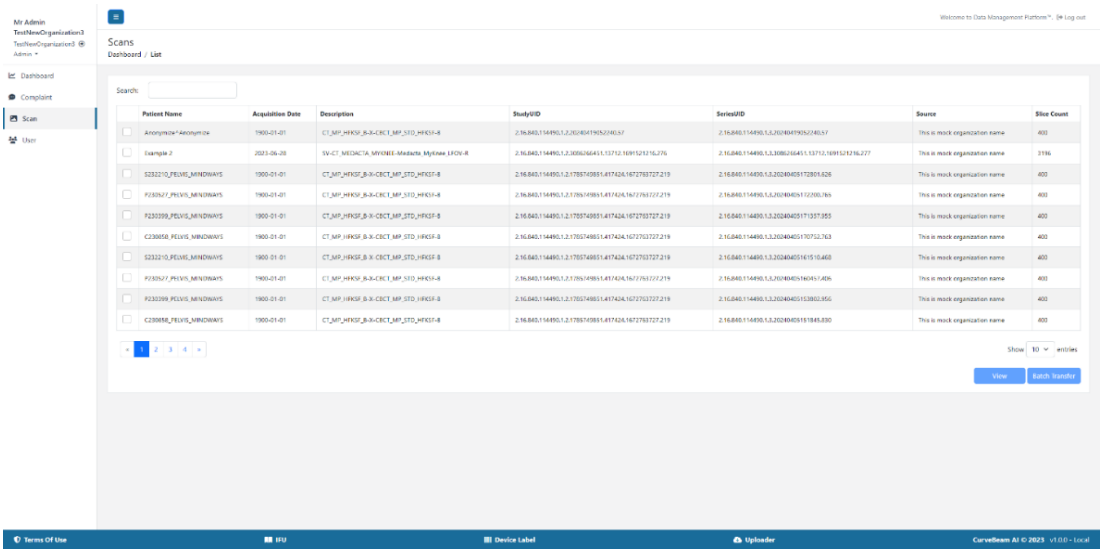
Alternatively, scans can be automatically uploaded once the uploader VM is installed on the CurveBeam AI scanner. Please refer to the CurveBeam AI scanner's IFU for guidance on scan acquisition and any risks associated to scan acquisition.

4.2.4 Scans transfer workflow

The DMP application allows an authenticated user to transfer an existing scan in their organization to another existing organization in the same or different region, if required.

This action can leak protected health information (PHI).

- Go to the scan list.



- Select scan/s for batch transfer by ticking the checkbox for each scan of interest.

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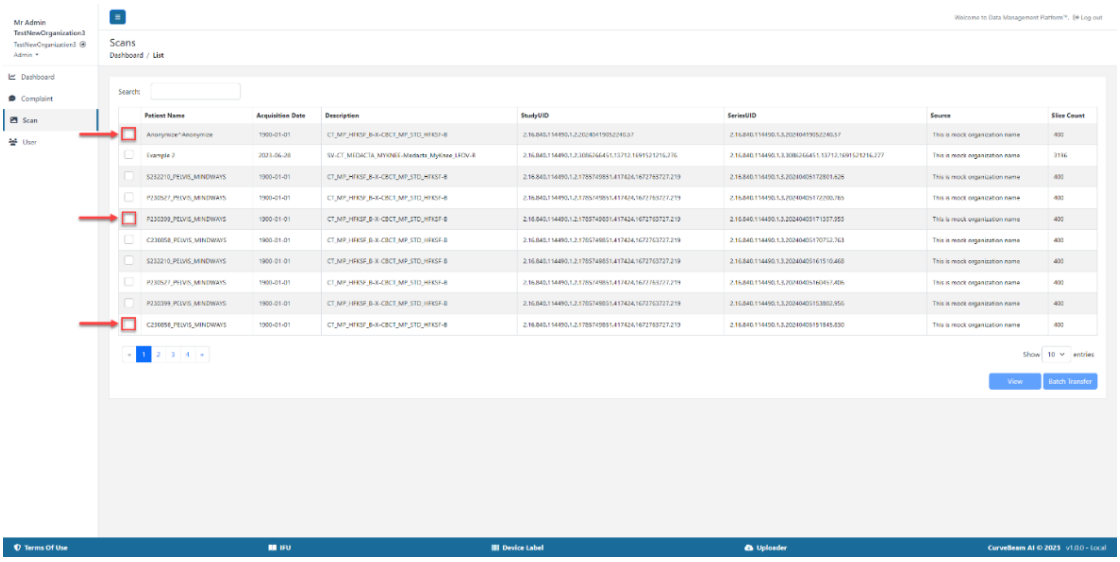
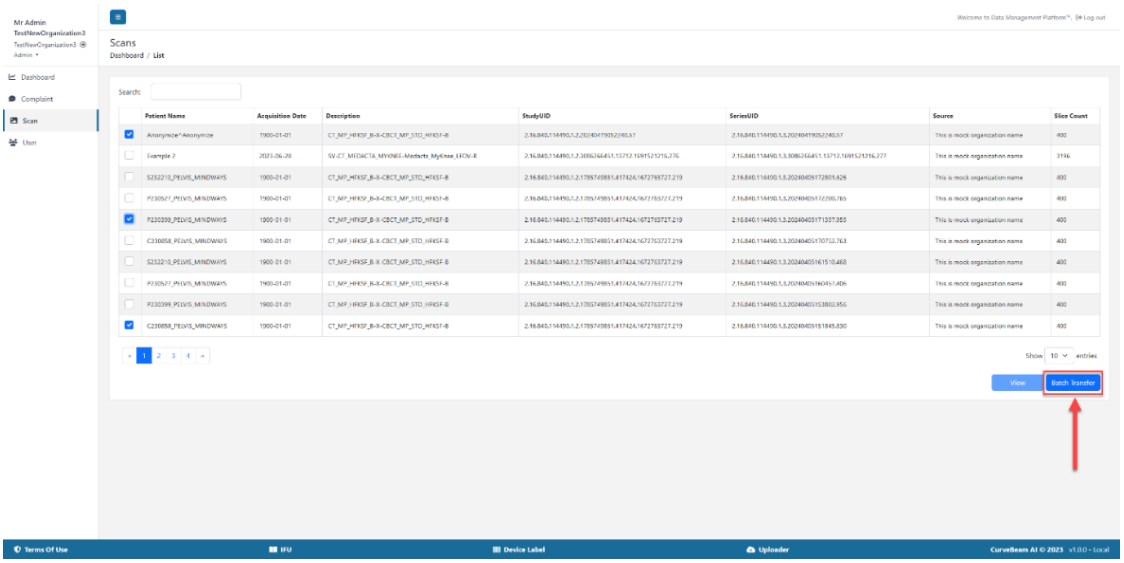
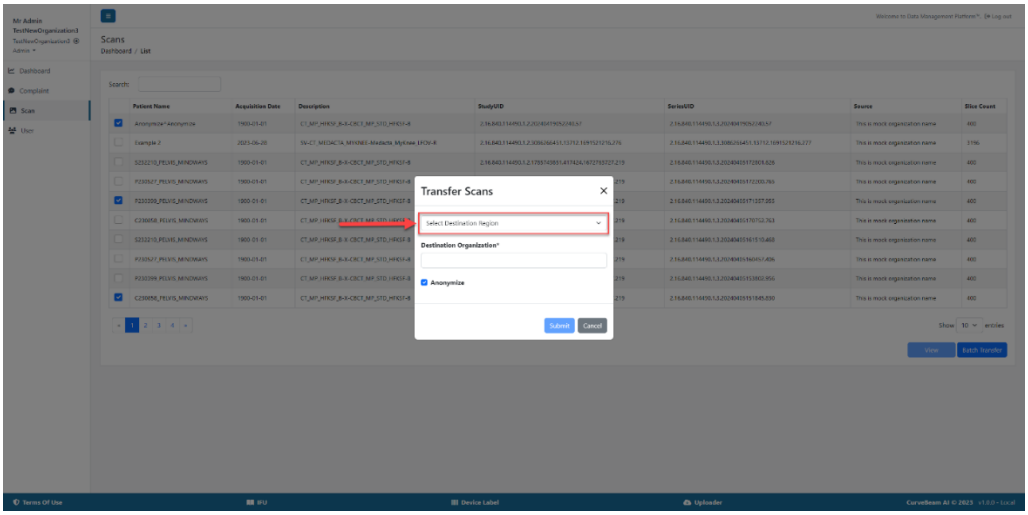
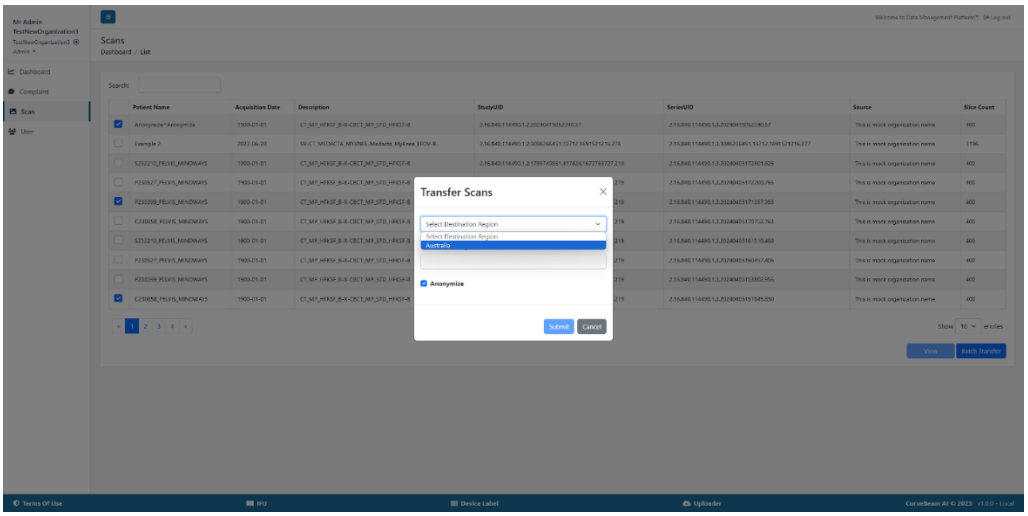


- Click on the **Batch Transfer** button.



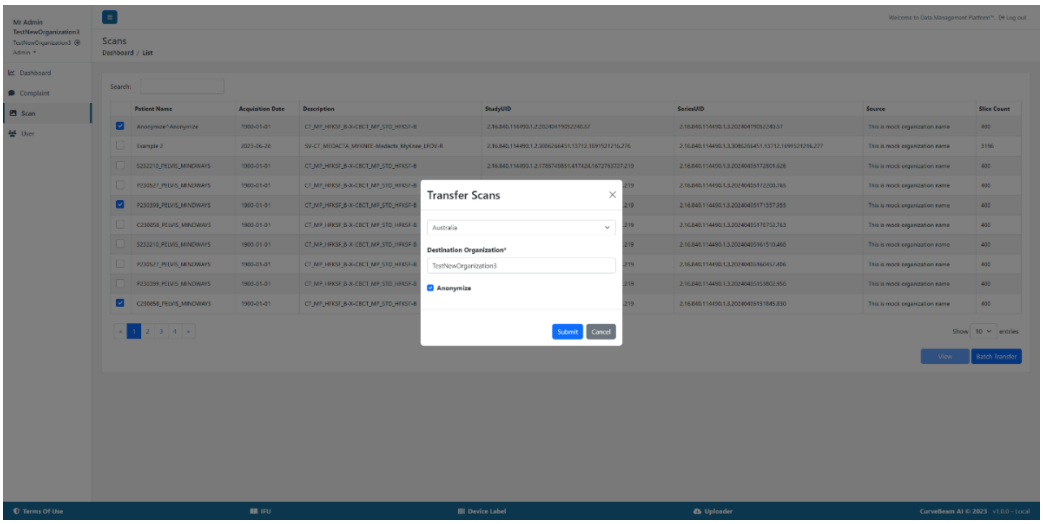
- The Batch Transfer form will pop up. Provide the following three details:
    - **Destination Region** – Click on **Select Destination Region** to display a dropdown list of regions. Choose the destination region of interest.





- **Destination Organization –** Fill in the associated textbox.

> Contact CurveBeam AI team immediately, if the scan is sent to the wrong organization.



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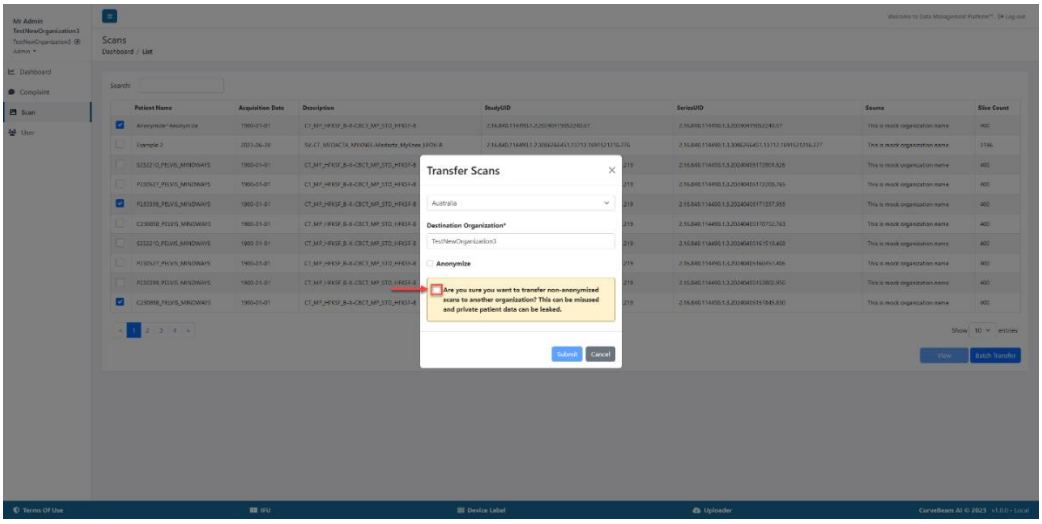
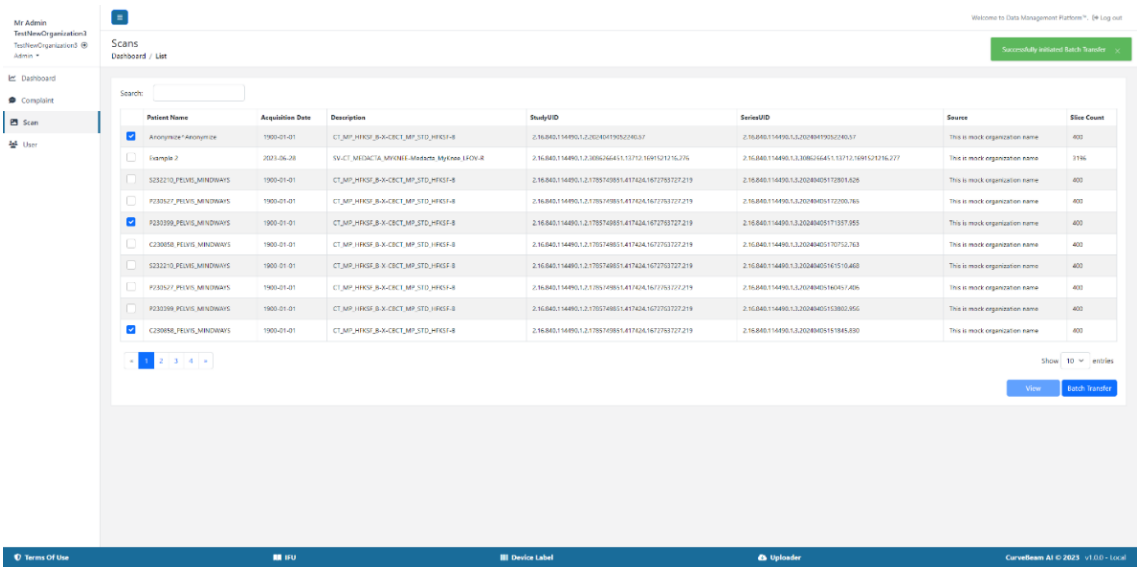
- **Anonymize** – Keep the checkbox ticked to anonymize the scan.

  If you don't wish to anonymize the transferred scans, then untick the checkbox. When you untick the anonymize checkbox, a warning message will be displayed informing on the PHI risk of transferring non-anonymized scans. You must tick the new checkbox that appears with this warning to confirm that you are aware of the PHI implications.



- Click the **Submit** button on the batch transfer form to initiate the batch transfer request.
- Once the batch transfer request has been initiated, a confirmatory notification will pop up.



- An automated email will be sent to the administrator users of both the source and destination organization notifying of the batch transfer request.
- Later when the batch transfer request has been processed, an automated email will be sent to the administrator users of both the source and destination organization notifying that the batch transfer request has been processed.

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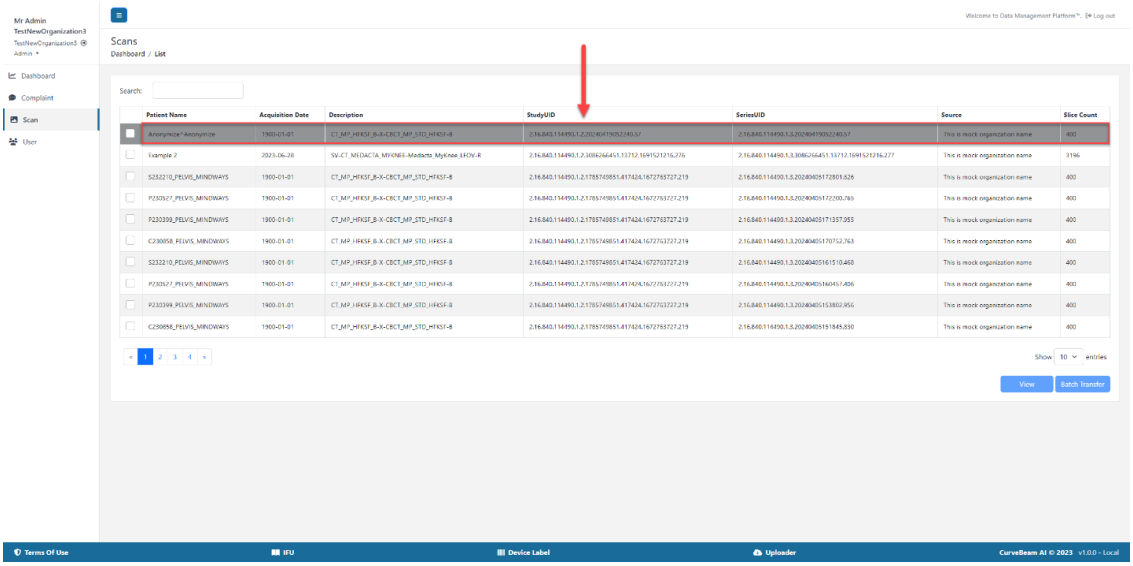
For complete information about scan management, refer to Section 4.3.5 Scans

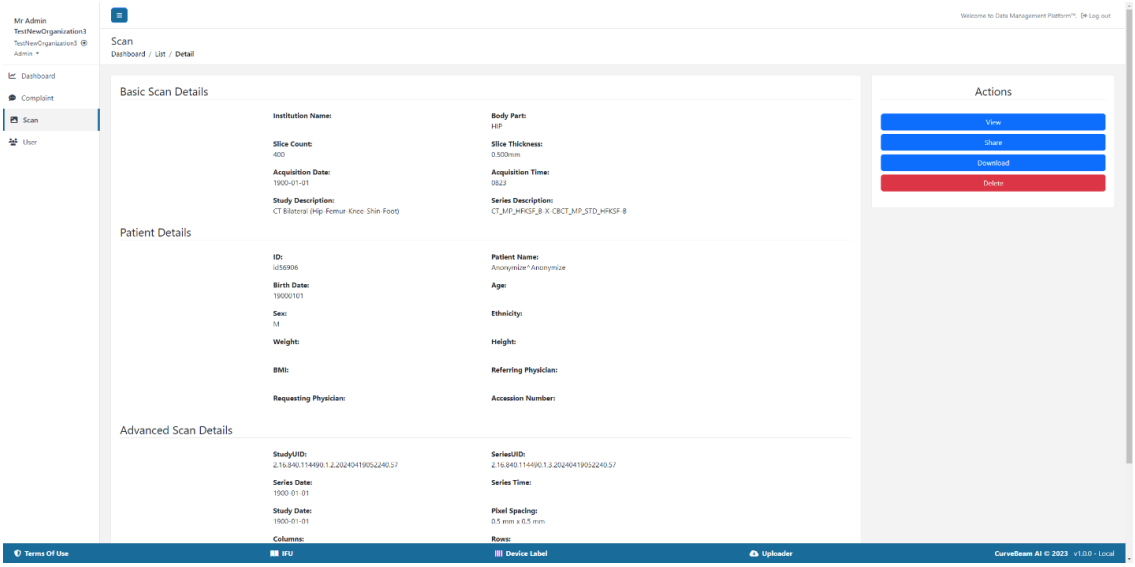
4.2.5 Scan view workflow

The application allows an authenticated user to view the details of the scans existing in their own organization.

- Go to the scan list and click on a scan of interest.



- The details of the selected scan will be displayed.



For complete information about scan management, refer to Section 4.3.5 Scans

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4.3 Web Modules

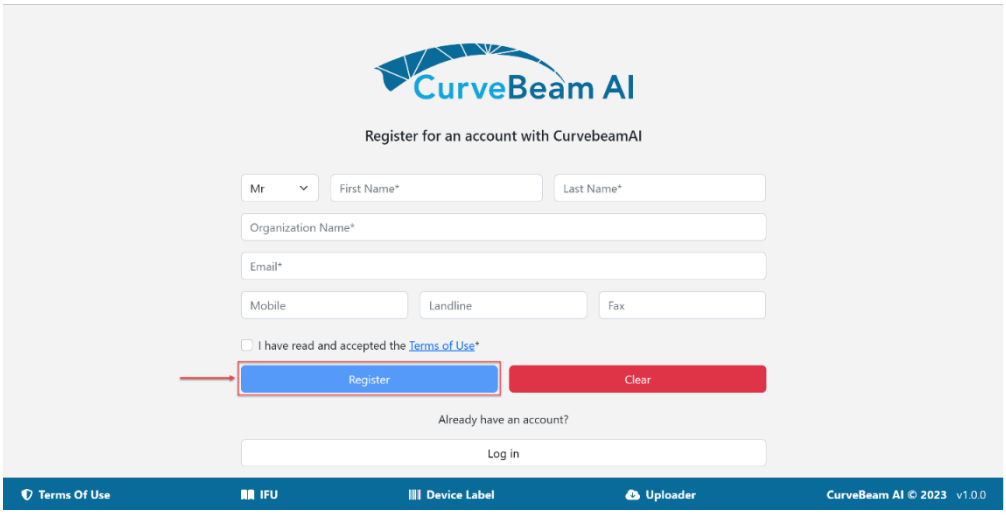
4.3.1 Registration

4.3.1.1 Create registration.

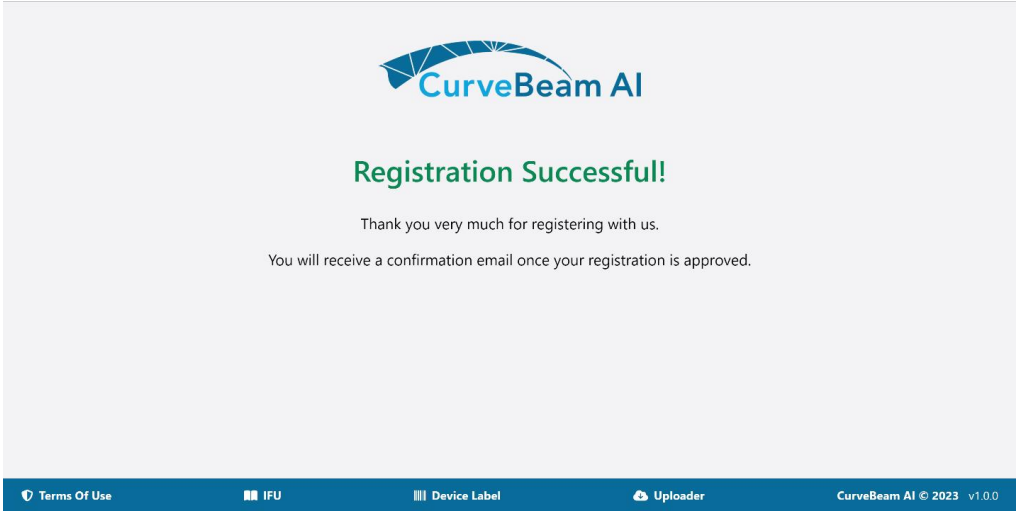
This action can also be accessed from the DMP login screen via clicking the `Create an account` button.

- Go to the registration form and perform the following steps:

1. Fill out the user and organization details.
2. Tick the checkbox confirming that you have read and accepted the Terms of Use
3. Click on the **Register** button.



- The `Registration Successful` message will be displayed. An automated email will be sent to you confirming the registration.

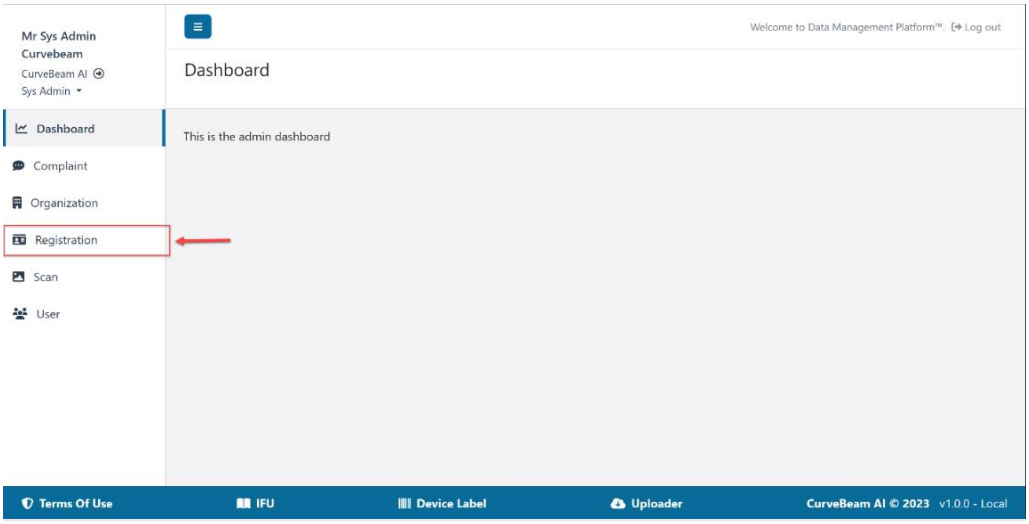


- CurveBeam AI will validate and approve the registration. Once the registration is approved, your user account and organization will be created in the DMP system.
- CurveBeam AI will send you an email confirming the registration approval. This email also contains temporary login credentials - use these credentials to login for the first time and update your password. Following this you will be directed to the DMP dashboard.

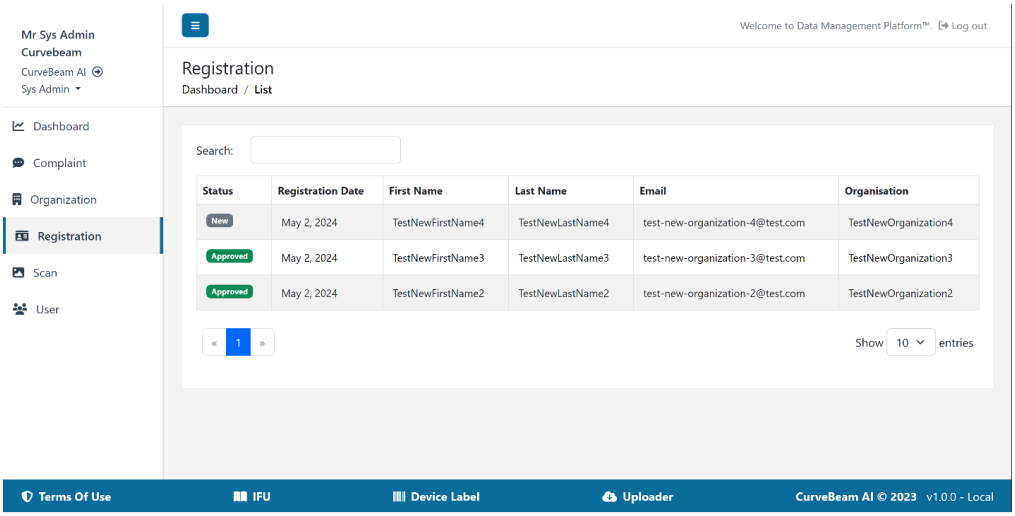
4.3.1.2 View registration list

> This action is only available for system administrators – CurveBeam AI

- To view the registration list, click on **Registration** on the side panel.



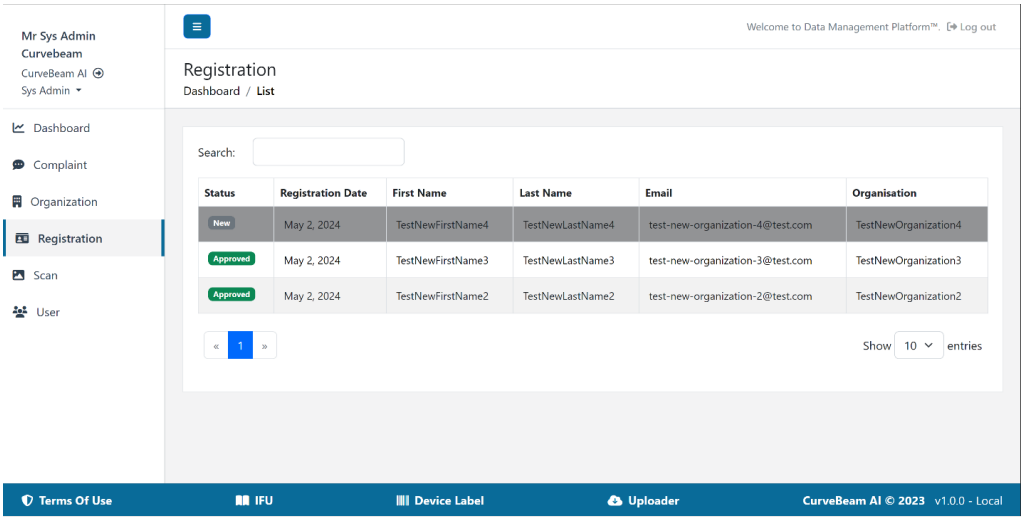
- The registration list will be displayed.



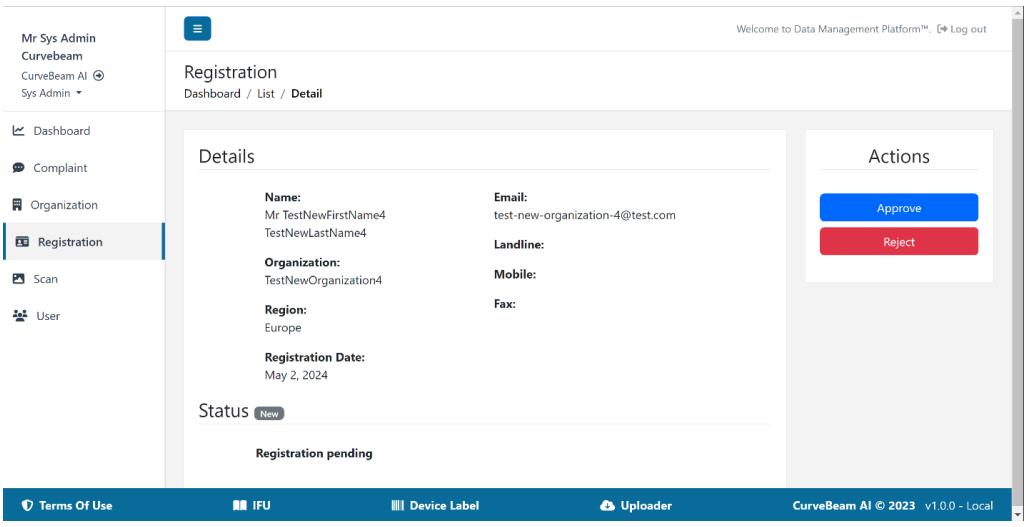
4.3.1.3 View registration details

This action is only available for system administrators – CurveBeam AI.

- Go to the registration list and click on a registration of interest.



- The details of the selected registration will be displayed.



4.3.1.4 Reject registration

This action is only available for system administrators – CurveBeam AI.

- Go to the registration list and click on a registration of interest with the ‘New’ status.

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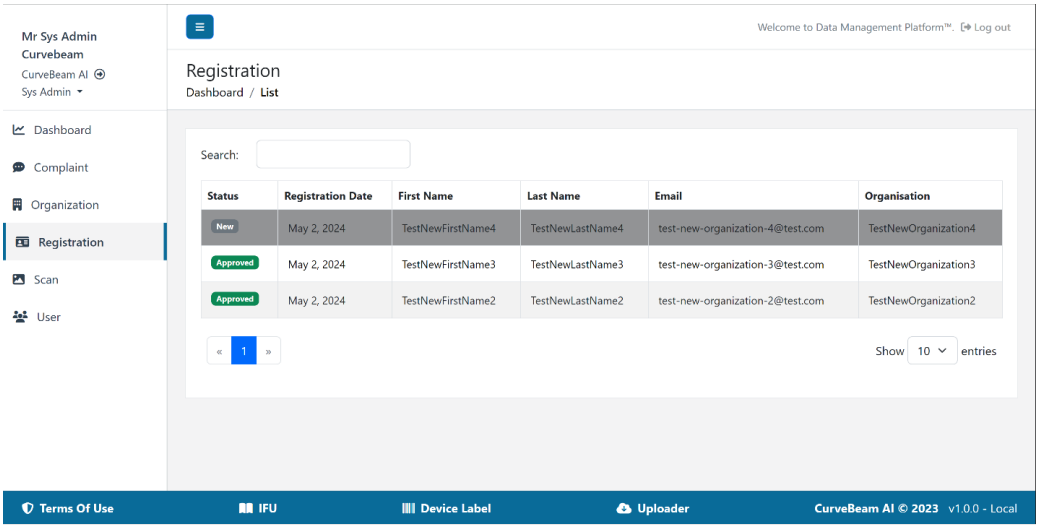
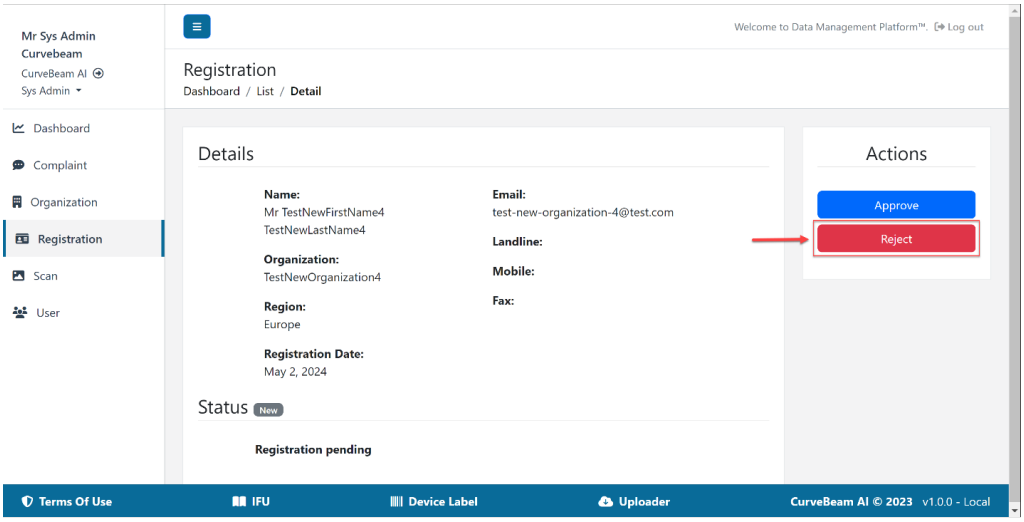
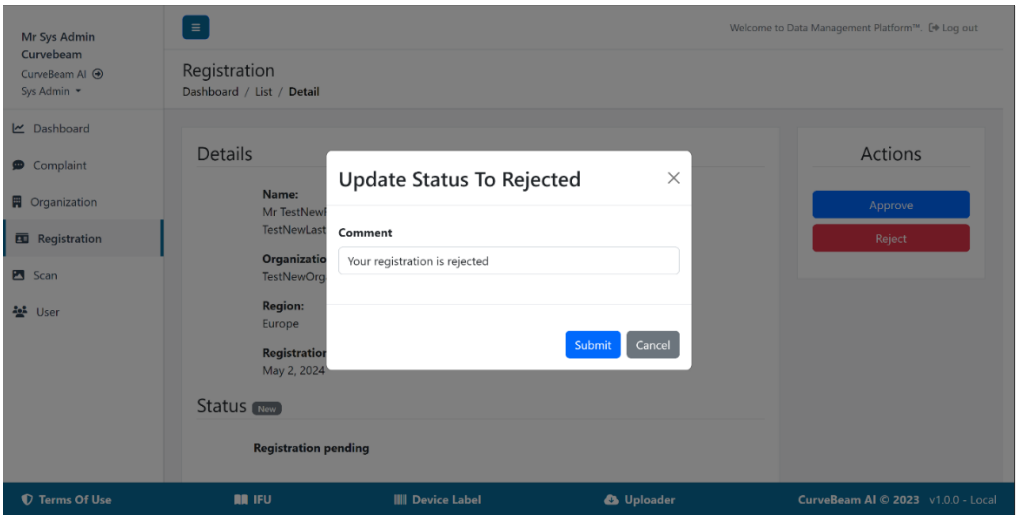


- On the registration detail page, click on the **Reject** button.



- A form will pop up prompting you for a comment. Type in a comment then click on the **Submit** button.



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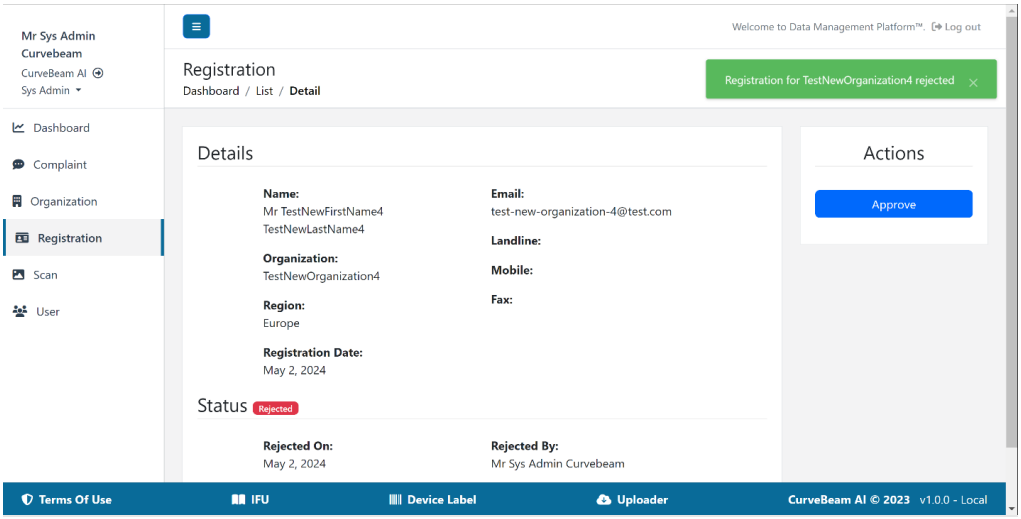
- Once the rejection has been processed, a confirmatory notification will pop up. The status section on the registration detail page will be updated accordingly.

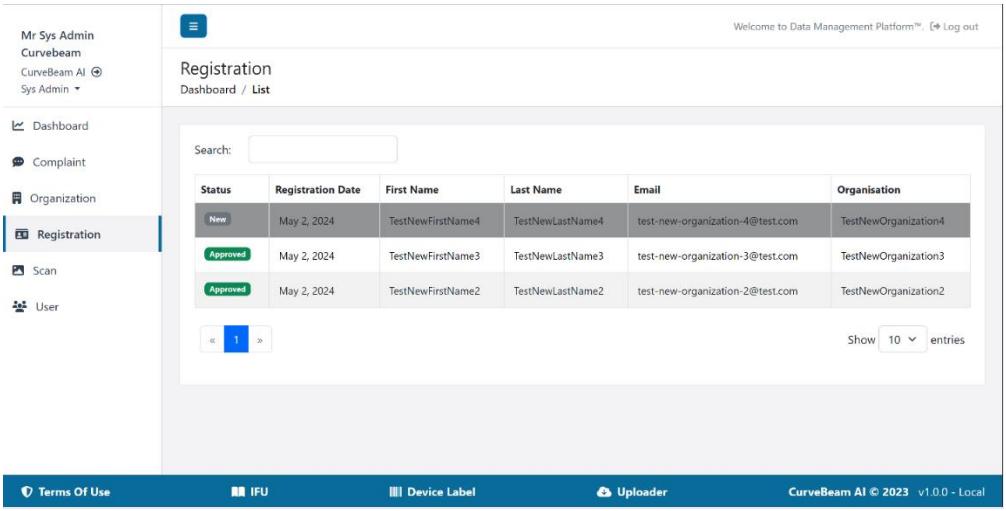


- An automated email will be sent to the registrant notifying of the rejection.

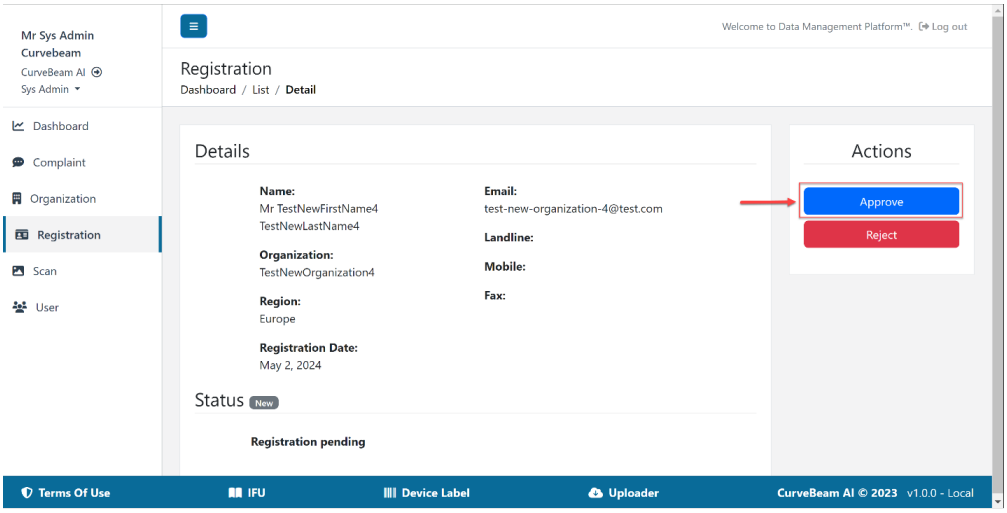
4.3.1.5 Approve registration.

> This action is only available for system administrators – CurveBeam AI

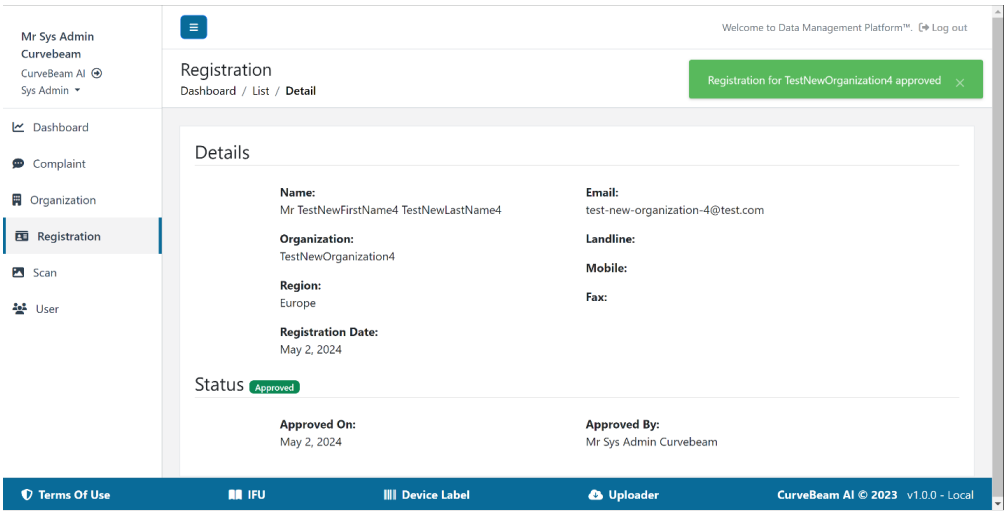
- Go to the registration list and click on a registration of interest with the `New` or `Rejected` status.



- On the registration detail page, click on the **Approve** button.



- Once the approval has been processed, a confirmatory notification will pop up. The status section of the registration detail page will be updated accordingly.

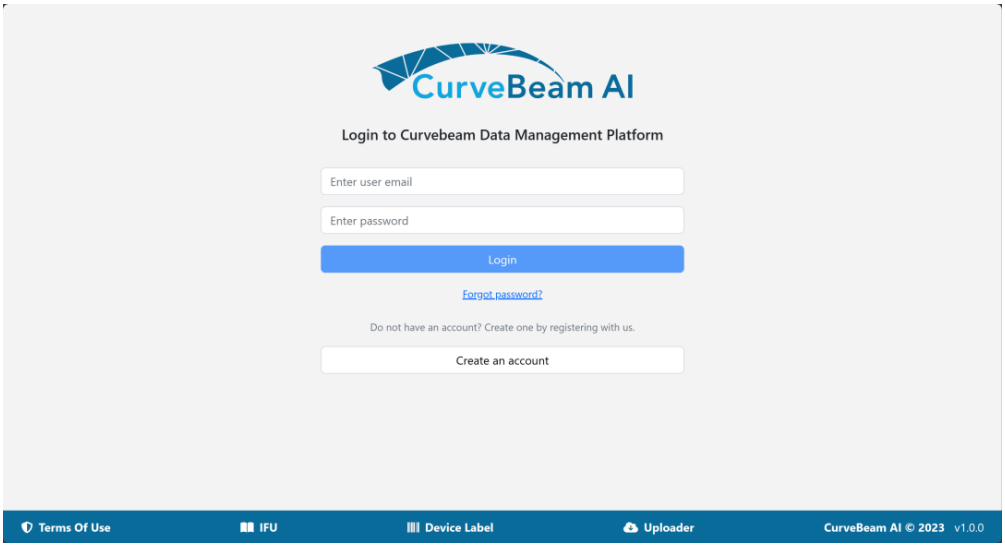


- An automated email will be sent to the registrant notifying of the approval. This email will also contain temporary login details for the newly created administrator user account.

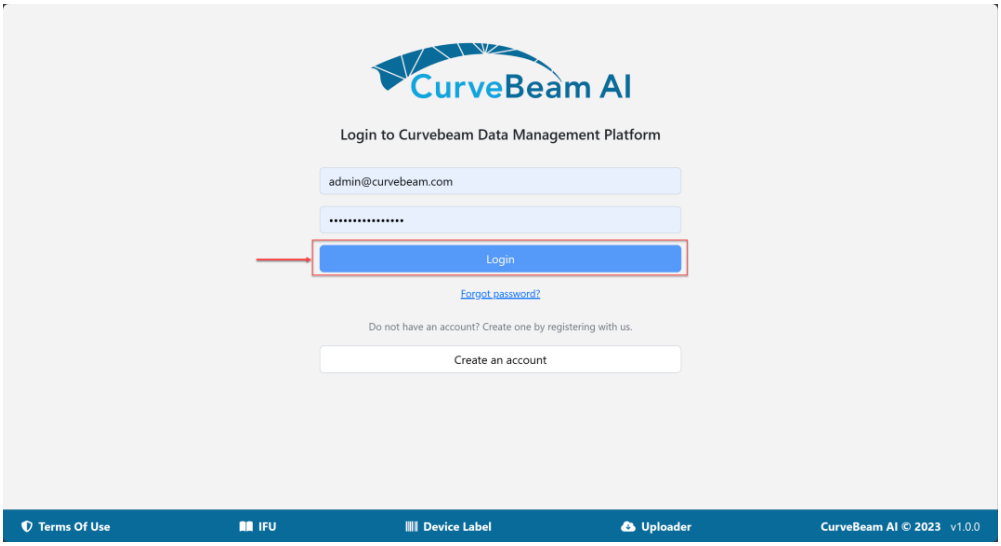
4.3.2 Login management

4.3.2.1 Initial login / Set new password.

- Go to the application login form.



- Fill in the email and temporary password provided in the account creation email and click **Login**. Please refer to 'Account creation' section for user account creation.



- The form to set a new password will be displayed.

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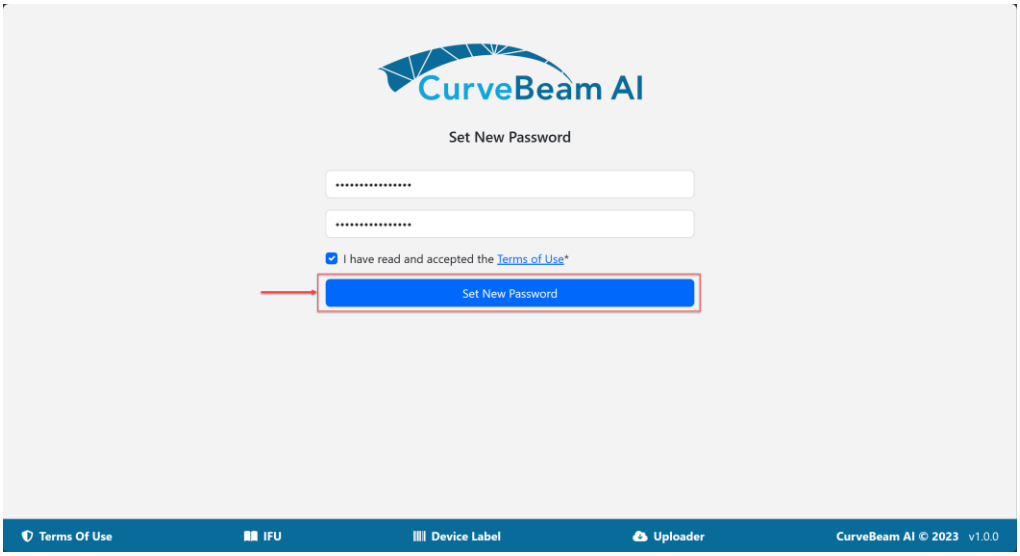
- Fill in the New Password, confirm new password field and accept the CurveBeam AI Terms of Use. Click on **Set New Password**.

Important

The password required must meet the following conditions.

- Should be at least 12 characters long.
- Have at least 1 lowercase character
- Have at least 1 uppercase character
- Have at least 1 number
- Have at least 1 special character



- You will be taken to the application dashboard.

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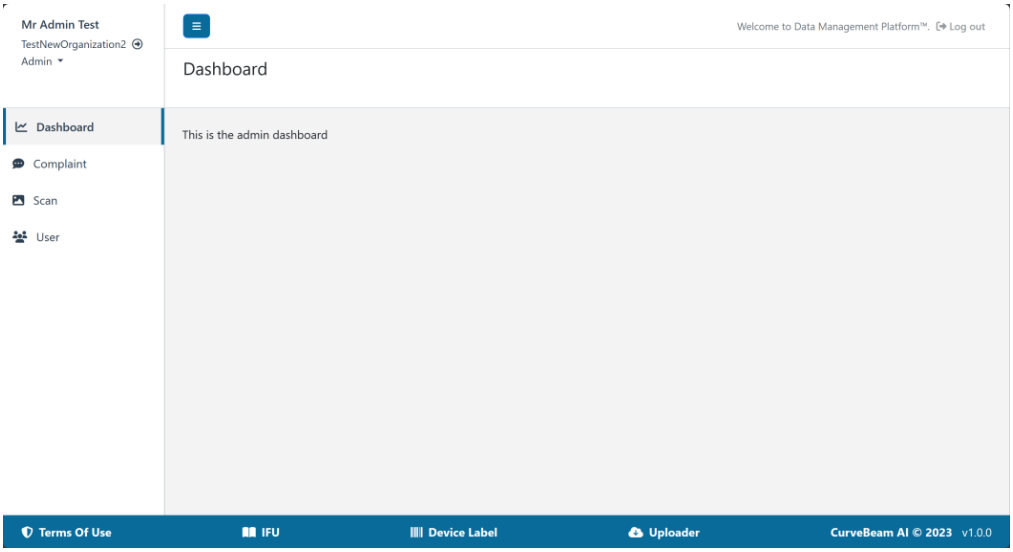
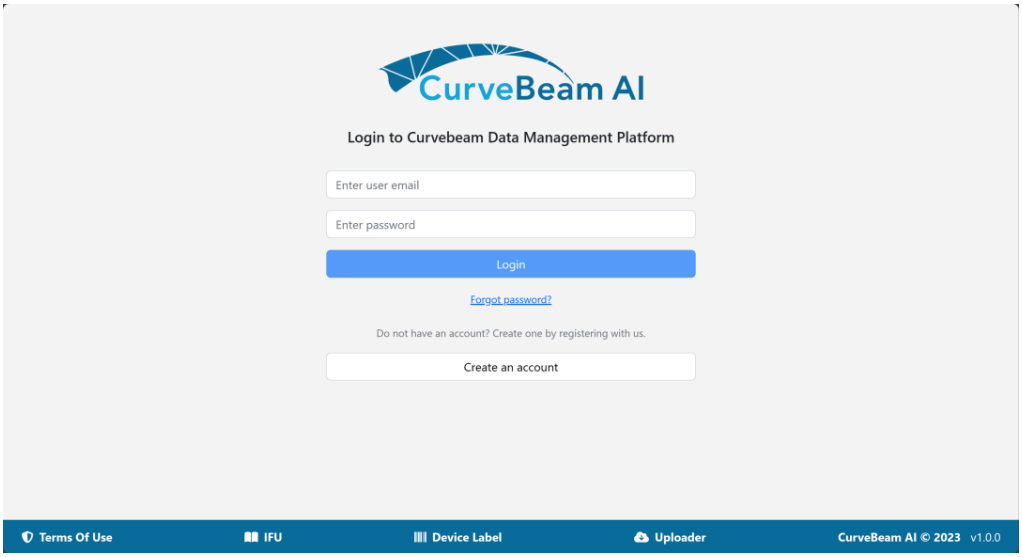


4.3.2.2 Login

- Open login form on the application.



- Fill in the email and password for your account and click on **Login**.

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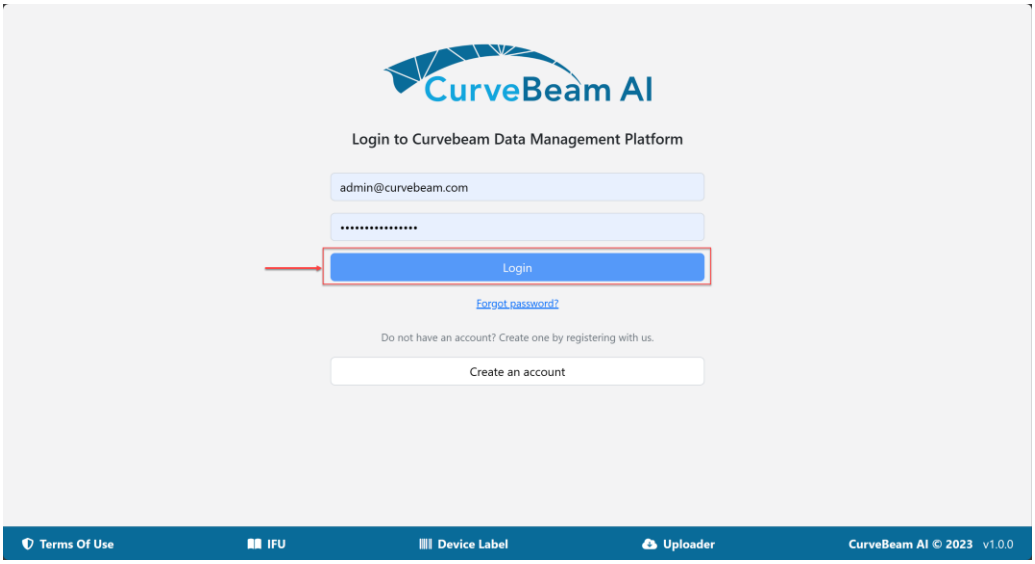
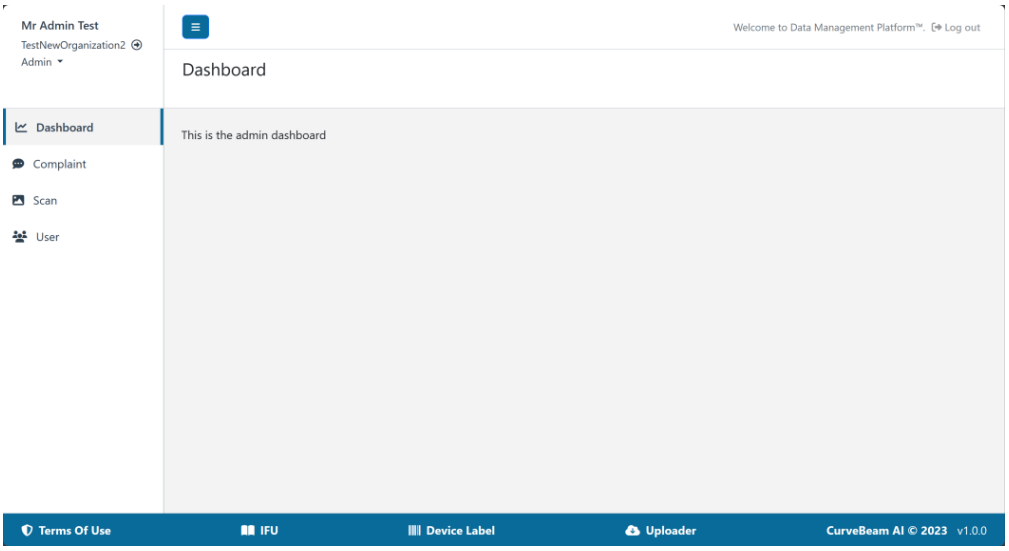


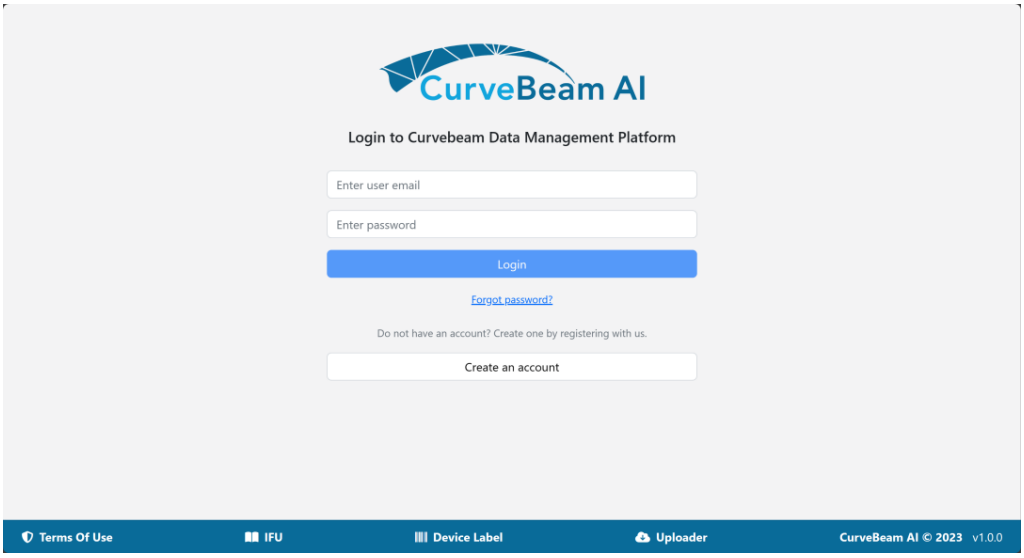
- You will be taken to the application dashboard.



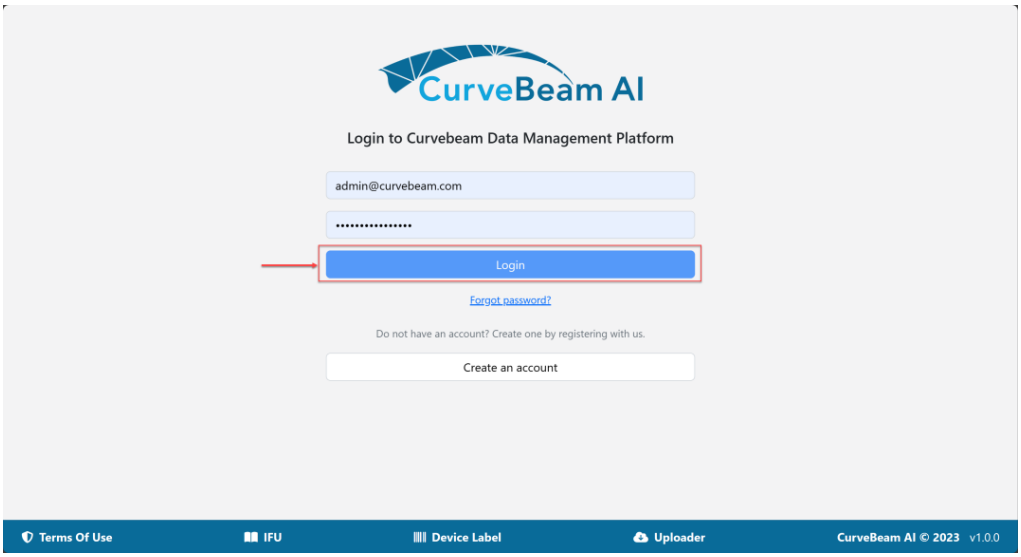
4.3.2.3 Login with multi-factor authentication

This workflow is only applicable to users who have enabled MFA in preferences.

- Go to the application login form.



- Fill in your email address and password and click on **Login**.



- An automated email will be sent to your registered email address containing a one-time code valid for 3 minutes.
- The form will be displayed prompting for a verification code.

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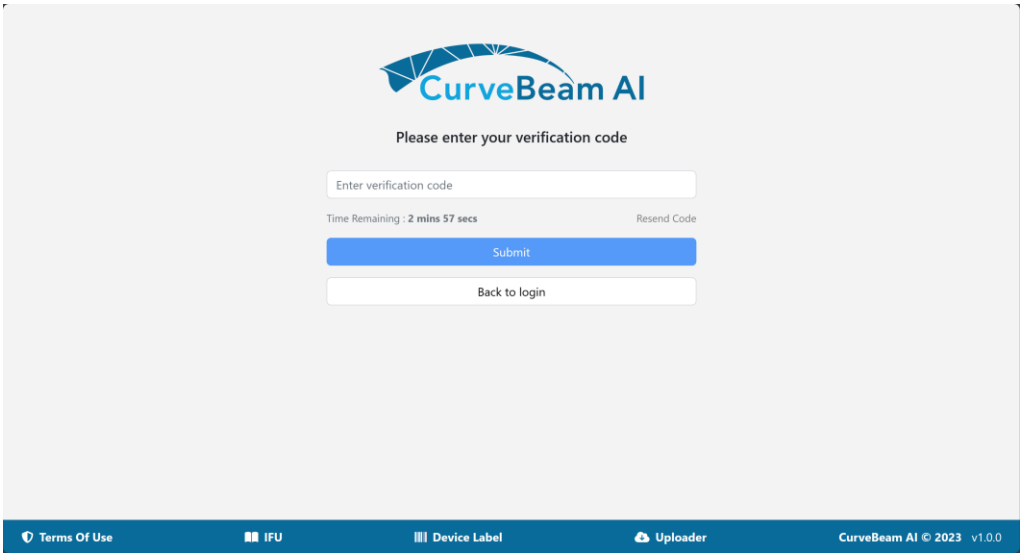
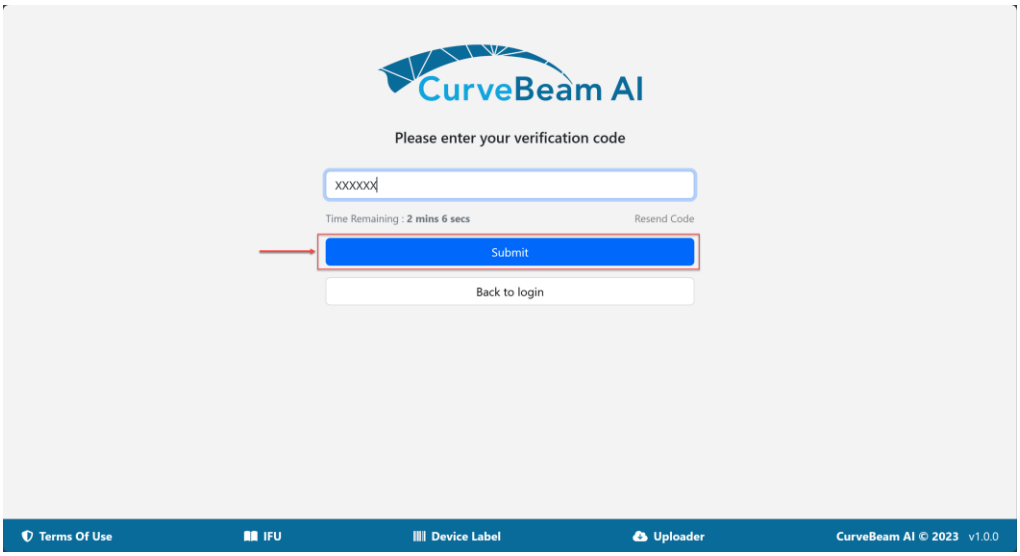


- Enter the code received in the email and click on **Submit**.



- If you have not received the code within 3 minutes, click on **Resend Code** to receive a new code in your email.

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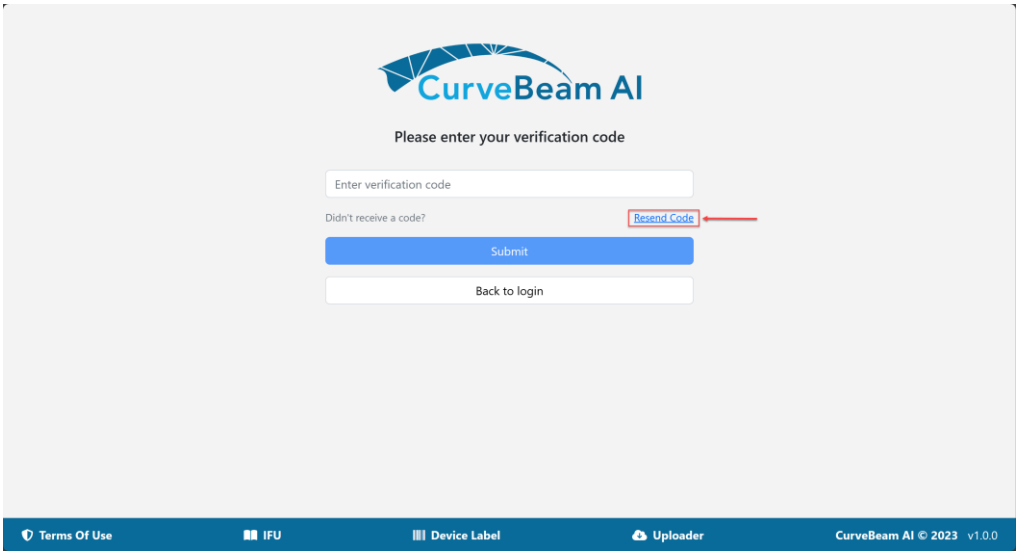
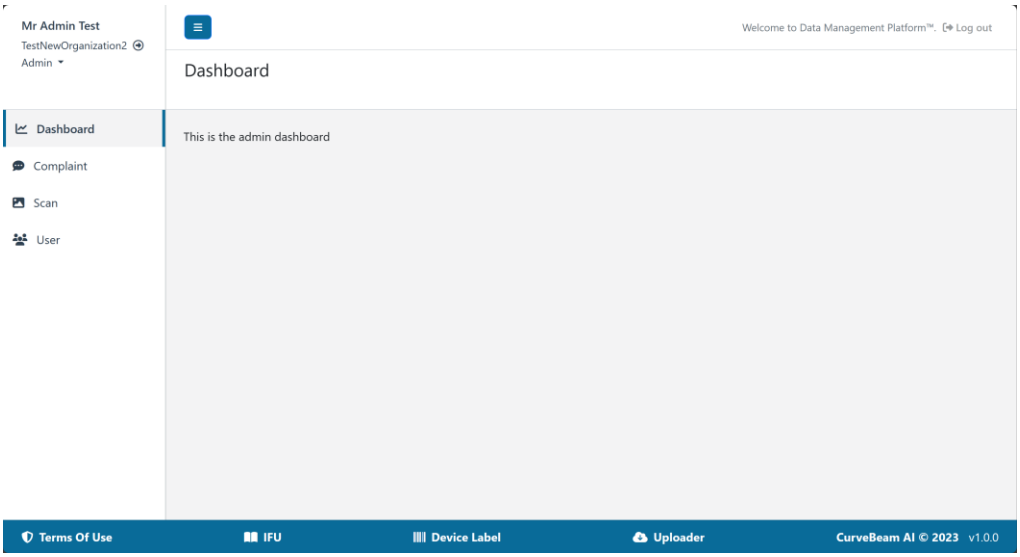
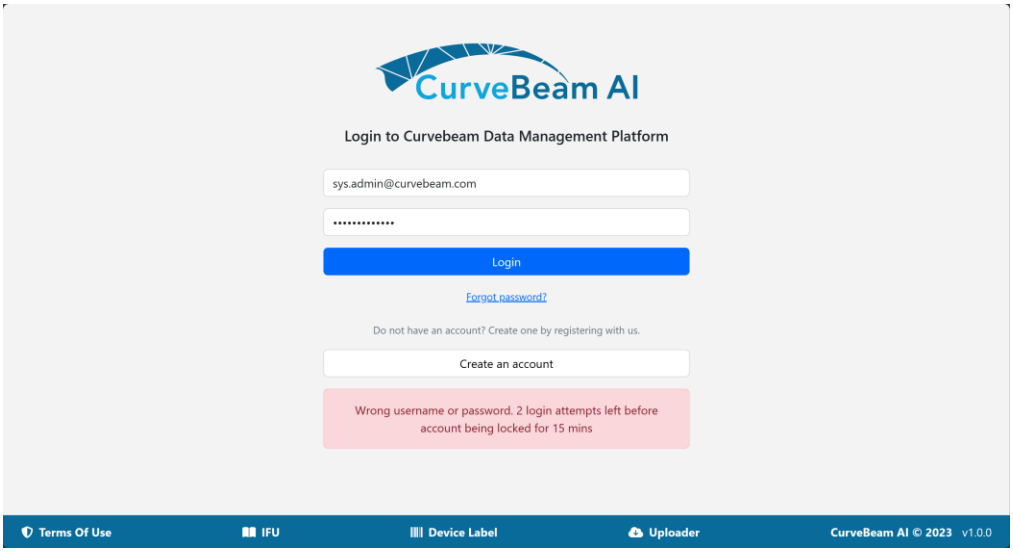


- Once you enter the verification code successfully, you will be taken to the application dashboard.

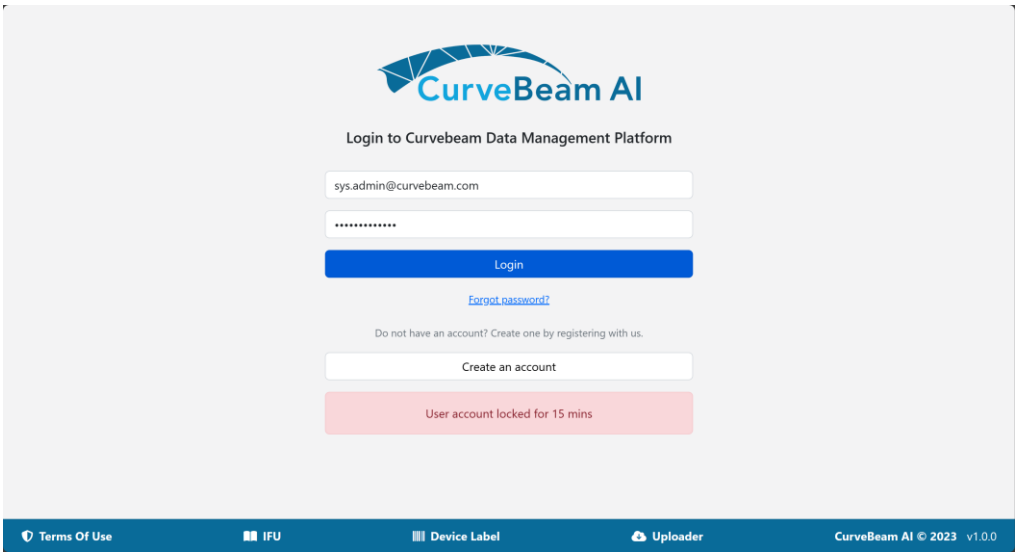


4.3.2.4 Account lockout

- The application allows a maximum of 3 continuous failed login attempts with incorrect password. Every failed login attempt with incorrect password will display an error message containing the number of attempts remaining.



- If the last login attempt fails, an error message will be displayed to show that the account has been locked for 15 minutes.



- During the account lockout period the application cannot be accessed. You can try to login using correct credentials after 15 minutes have lapsed.
- If a login attempt is made with the wrong password after the lockout period is finished, the user account will be locked for a further 15 minutes.

4.3.2.5 Forgot Password

- Go to the application login page and click on **Forgot Password**.

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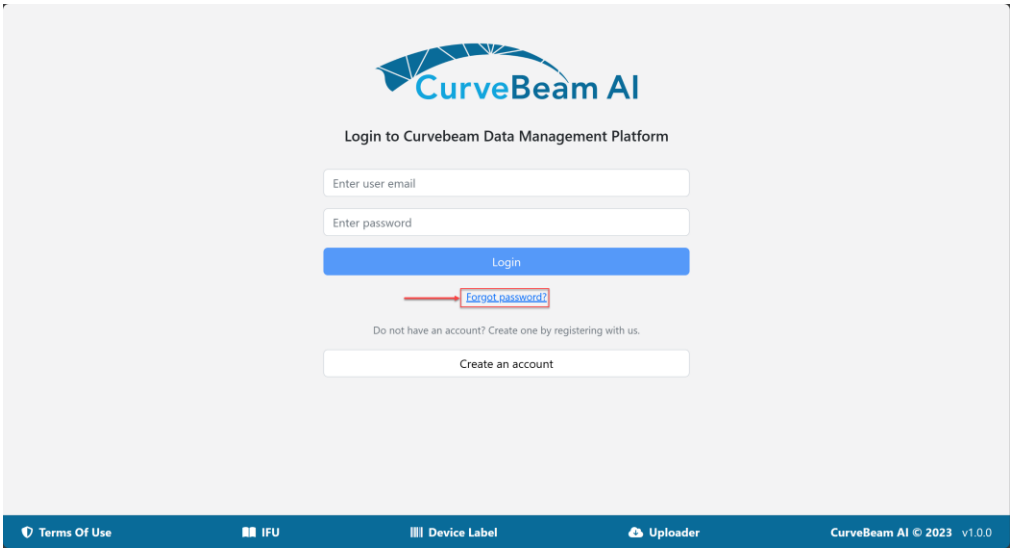
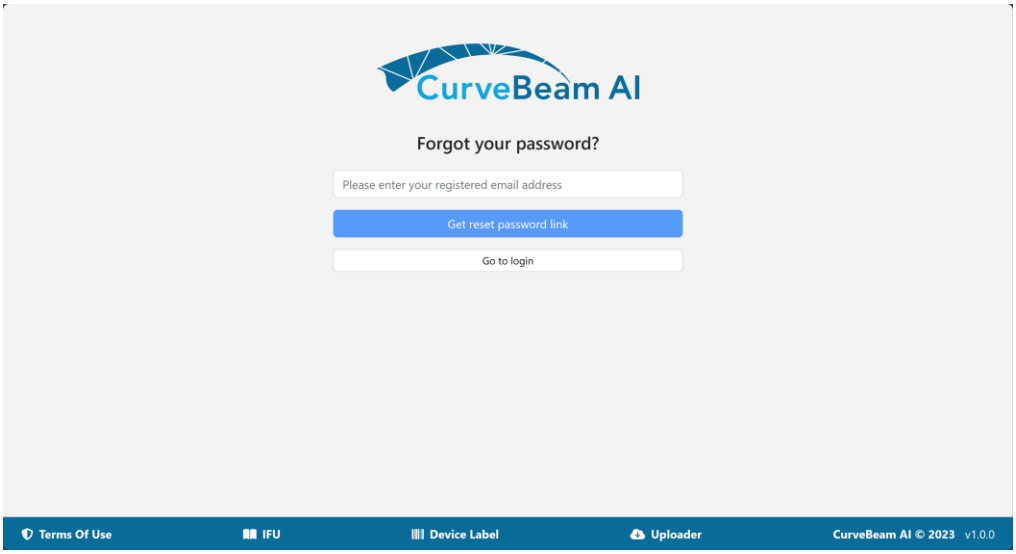


- The form will be displayed to enter your email address.



- Fill in the registered email address for your account and click on **Get reset password link**.

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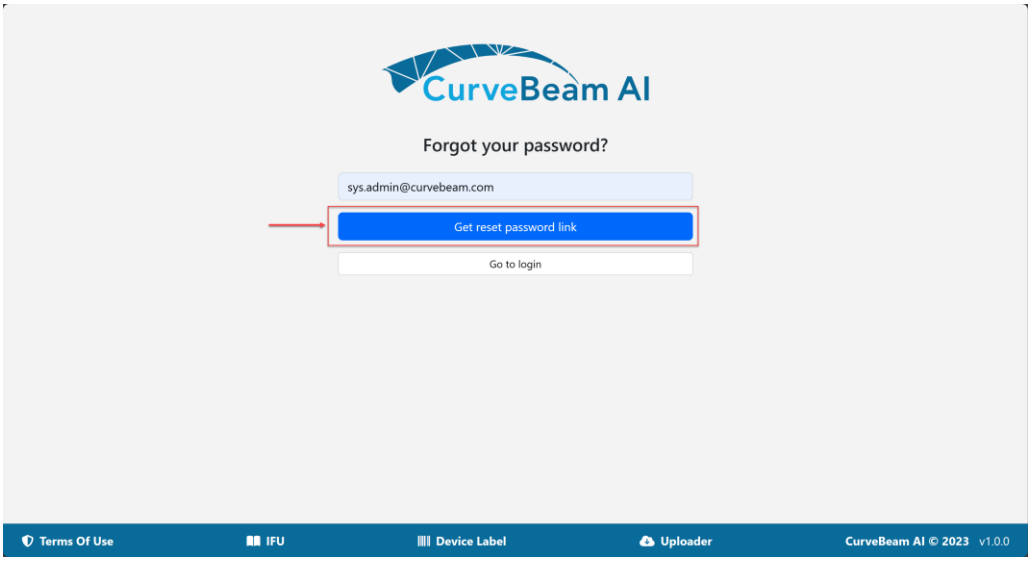
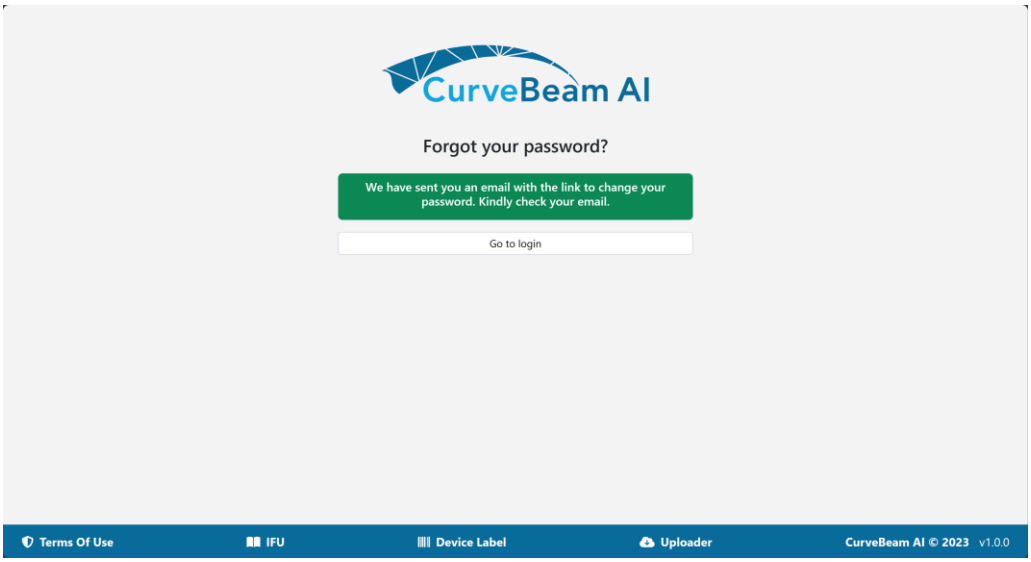


- A confirmatory message is displayed, and an automated email will be sent to your registered email address, containing a link to reset the password.



- Go to the reset password link received in the email. You will be directed to the form to reset the password.

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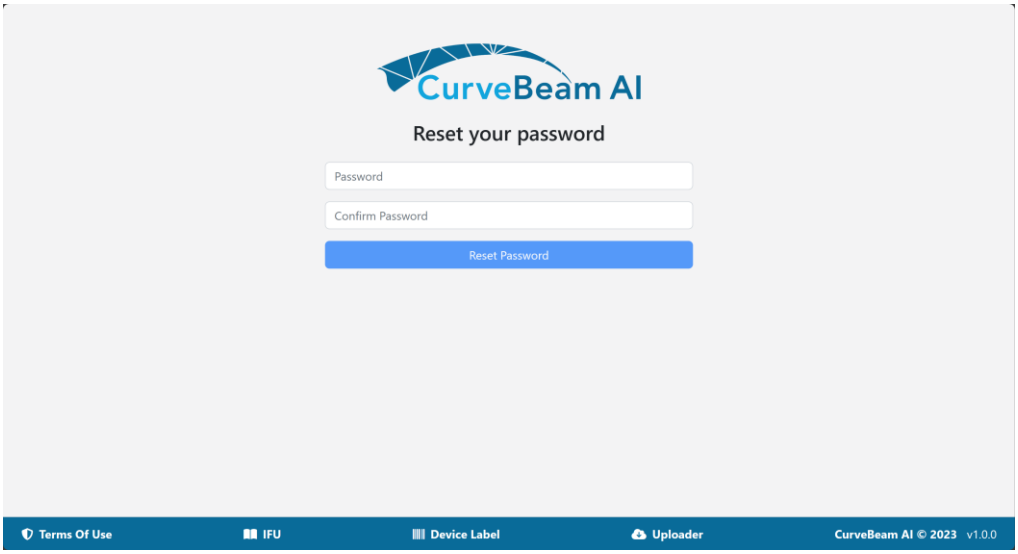
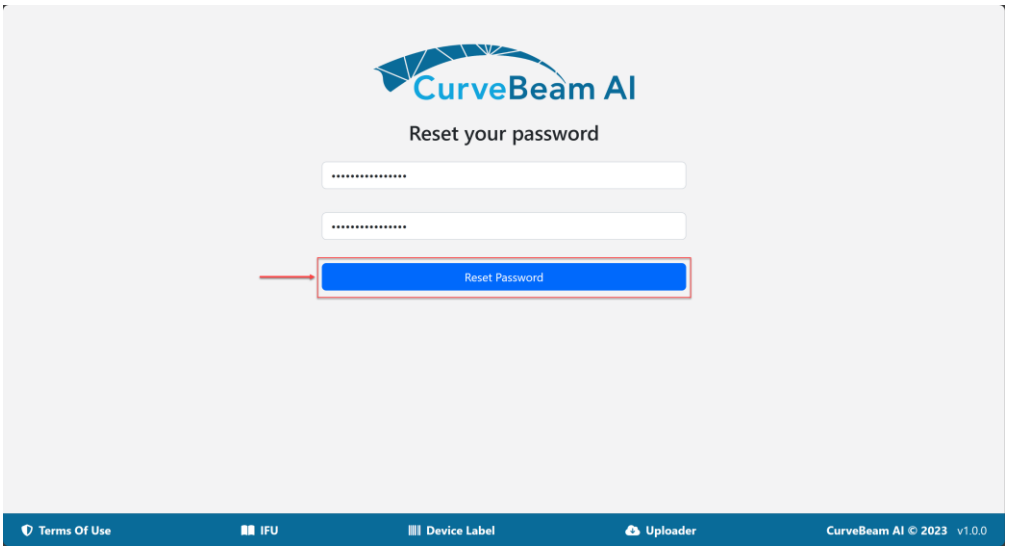


- Fill in the password and confirm password fields. Click on **Reset Password**.

Important

The password required must meet the following conditions.

- Should be at least 12 characters long.
- Have at least 1 lowercase character
- Have at least 1 uppercase character
- Have at least 1 number
- Have at least 1 special character



- Once the update has been processed, a confirmatory notification will pop up and the user will be taken to the login screen.

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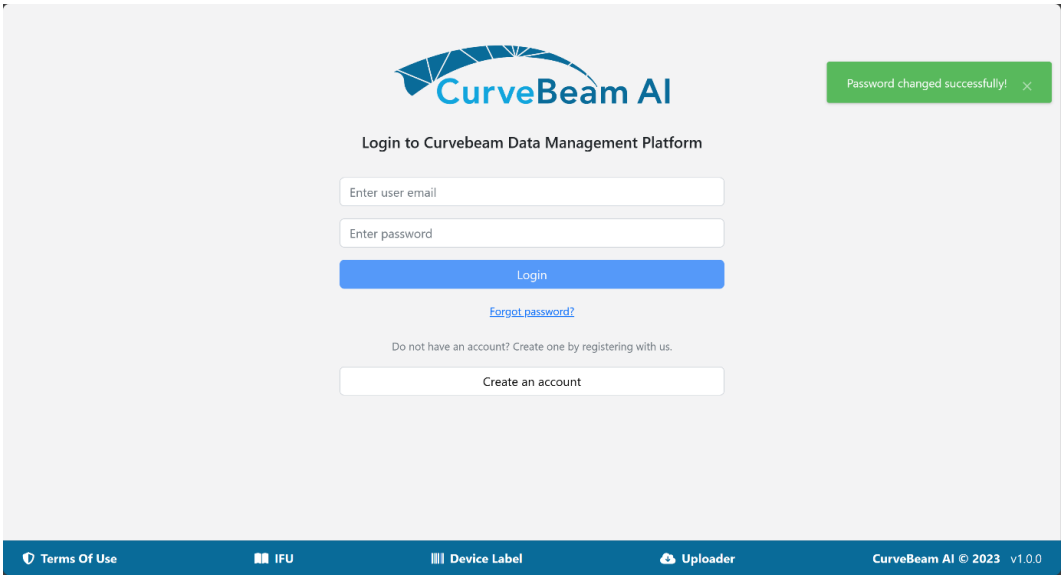
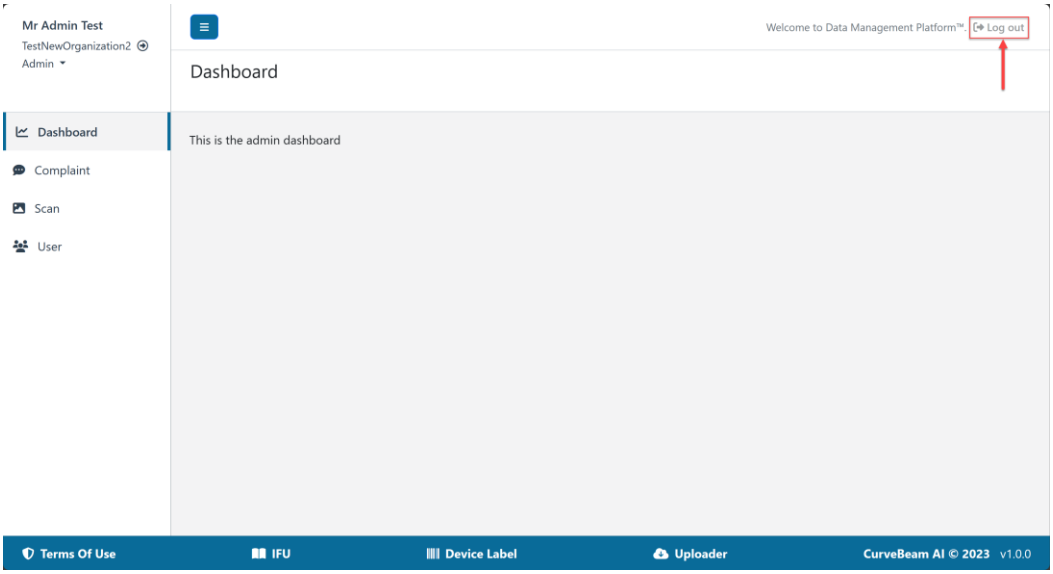


- An automated email will be sent to you notifying that your password has been changed.

4.3.2.6 Logout

- To end your session in the application, click on **Logout** in the DMP application.



- You will be taken to the login screen.

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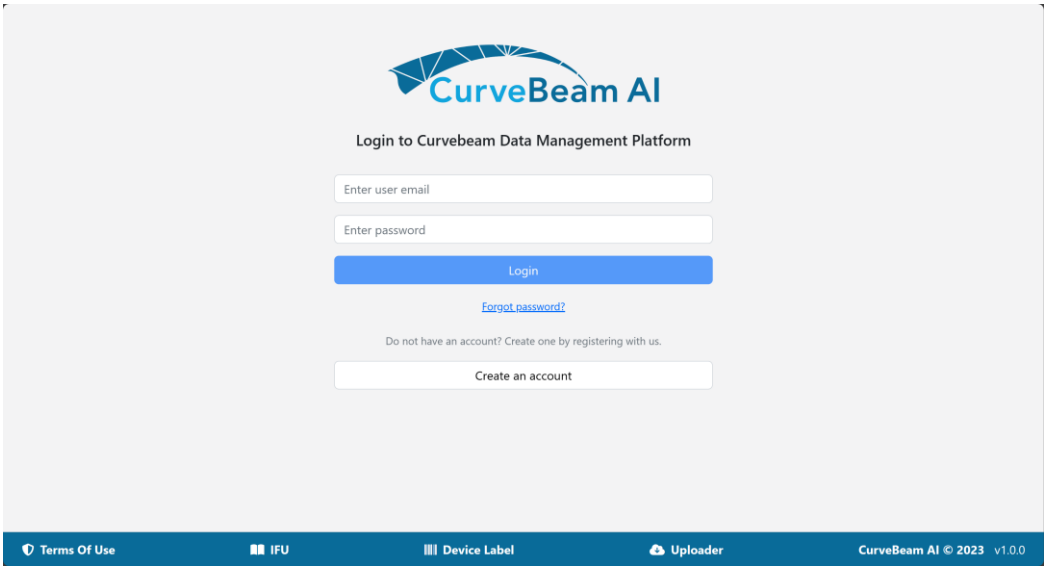
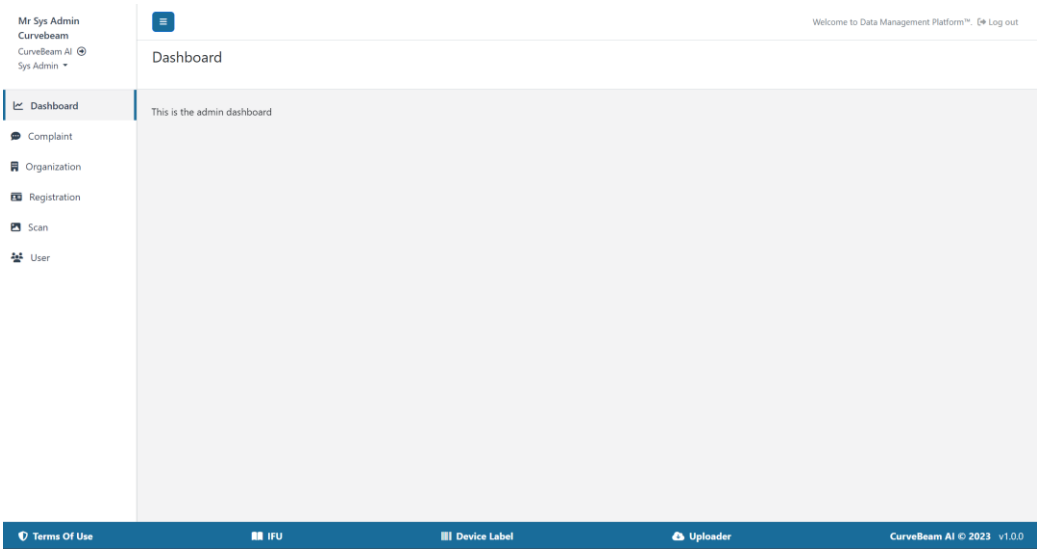


4.3.3 Dashboard

4.3.3.1 View dashboard

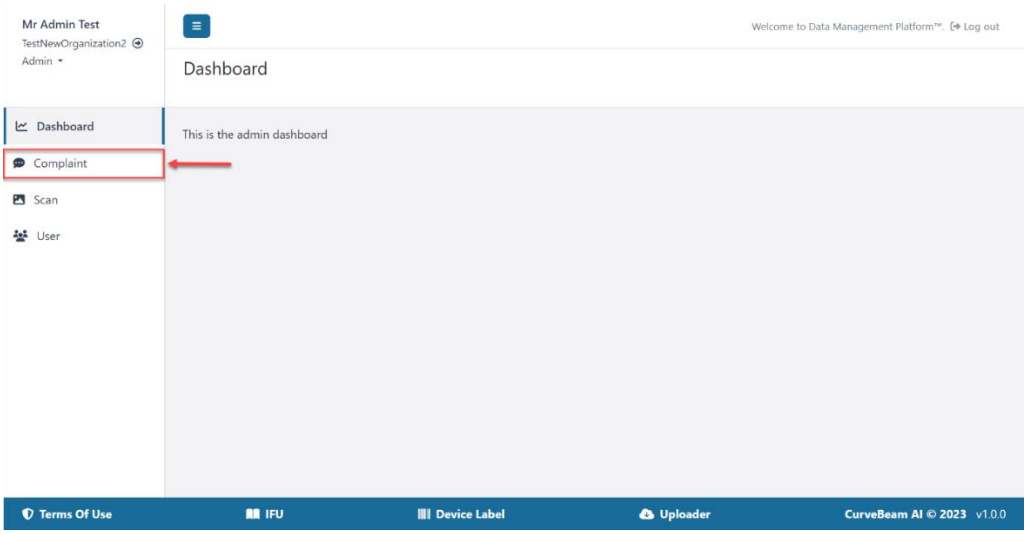
- After successful login, you will be redirected to the dashboard page.



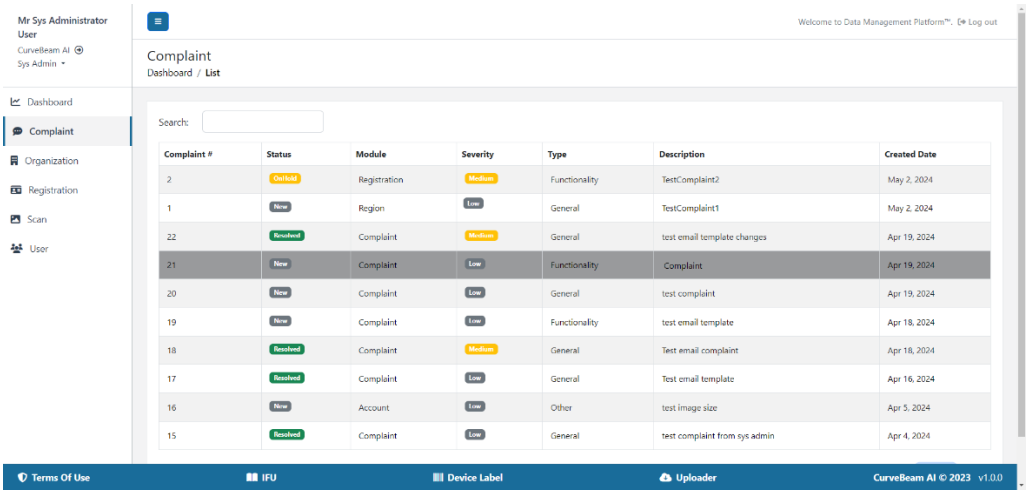
4.3.4 Complaint

4.3.4.1 View complaint list

- To view the list of complaints, click on **Complaint** on the side panel. CurveBeam AI Sys administrators can see all complaints raised in the application.
- Organization Admins can see all complaints raised for their organization in the application.
- Staff user can see all complaints raised by them in the application.

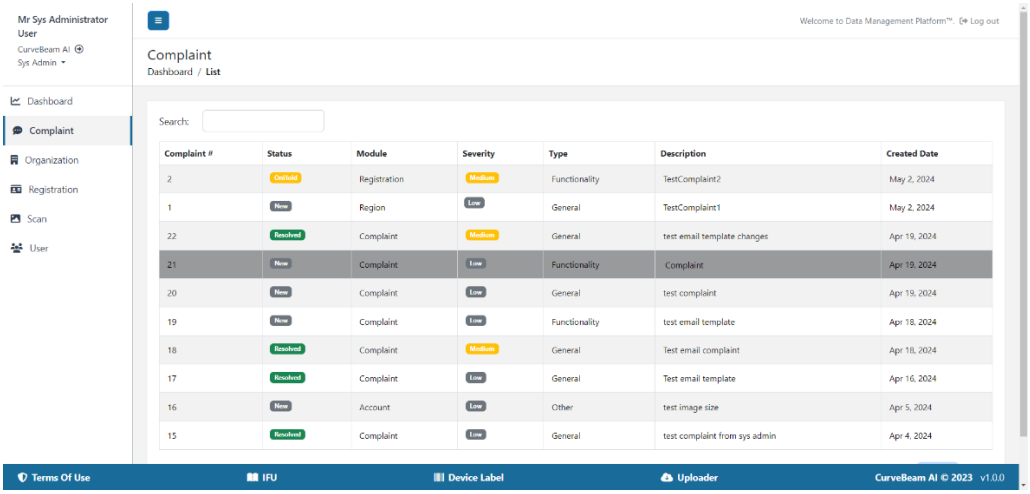


- The complaint list will be displayed.



4.3.4.2 View complaint details

- Go to the complaint list and click on a complaint of interest.



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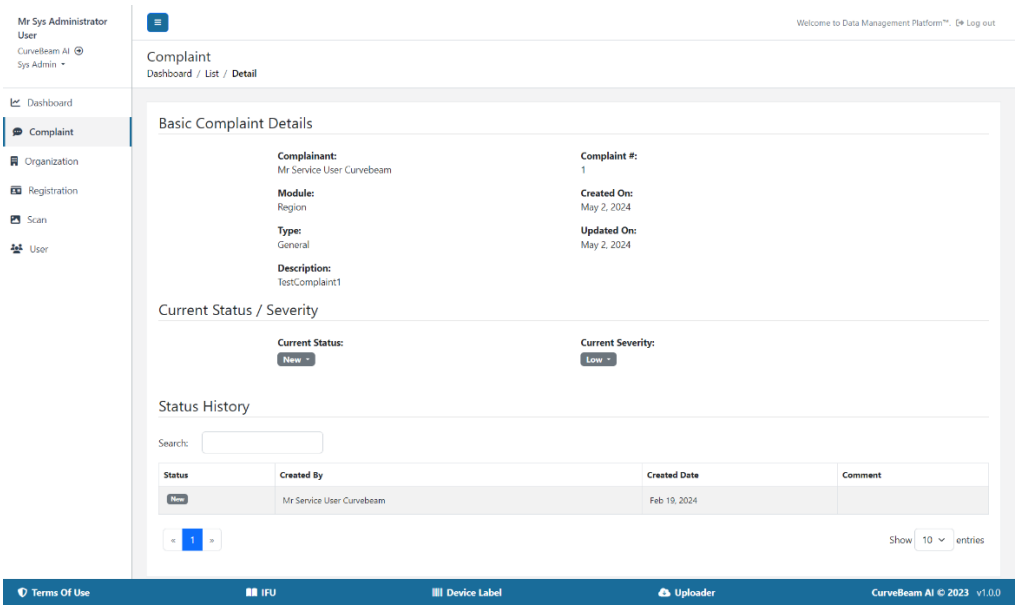
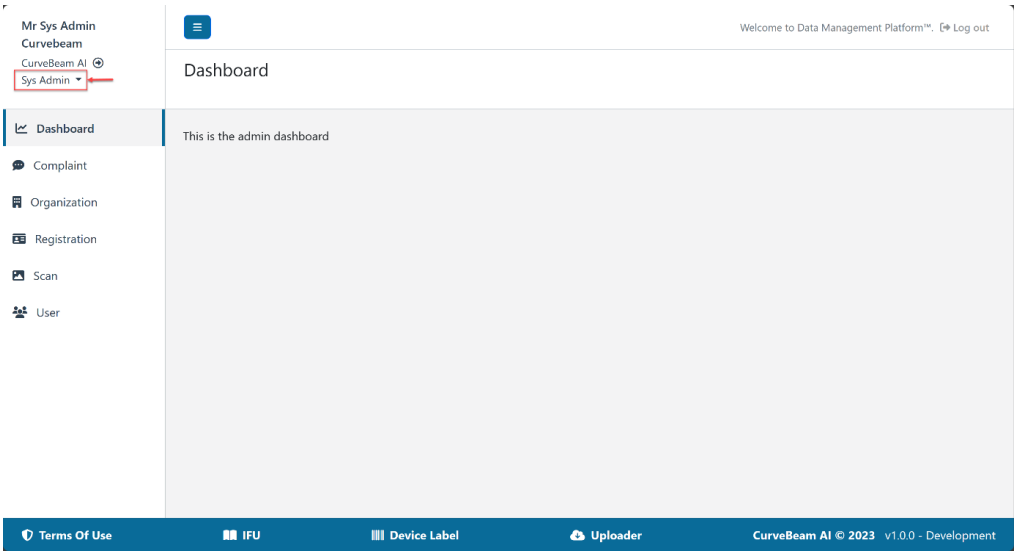
- The details of the selected complaint will be displayed.



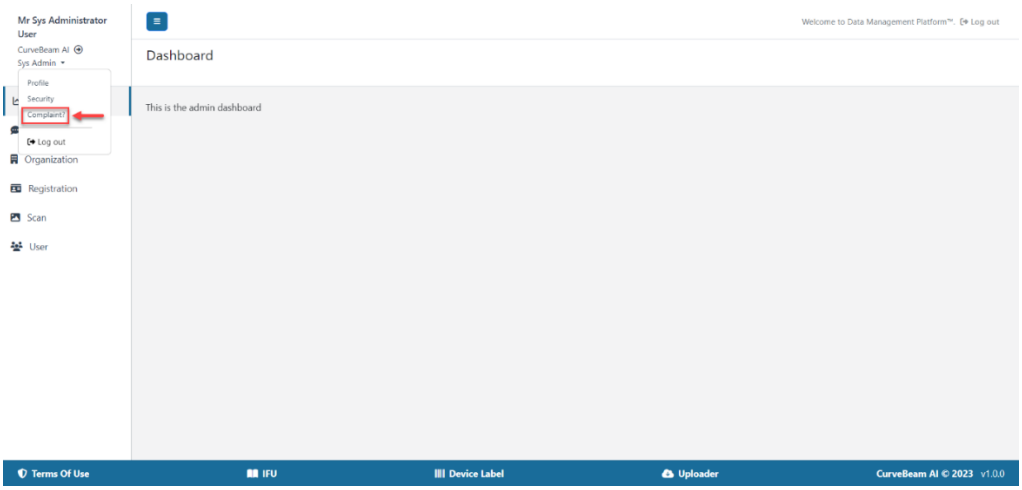
4.3.4.3 Add complaints.

The attachment image size must be less than 2 MB.

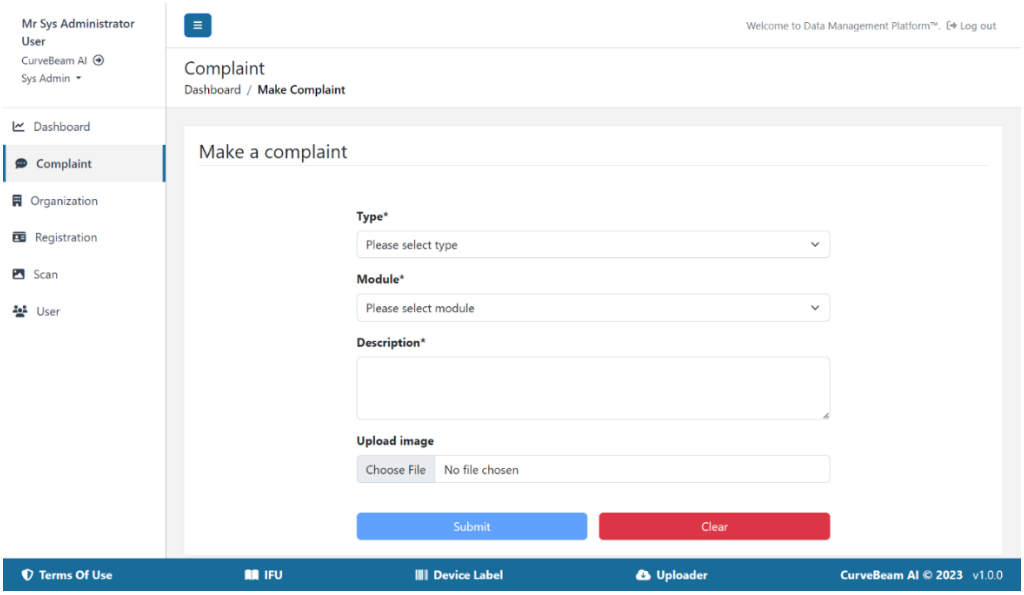
- Click on user role on the side panel.



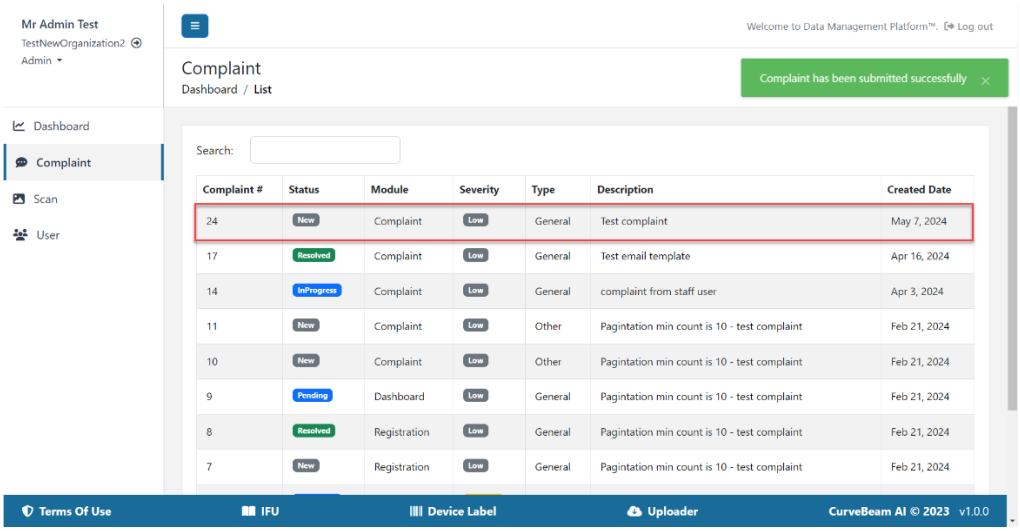
- A dropdown menu will be displayed, click on **Complaint?** option.



- **Make Complaint** form will be displayed.



- Fill in the required details and click on **Submit**.
- Once the complaint is submitted, a confirmatory notification will pop up on the screen and you will be redirected to the complaint list page.

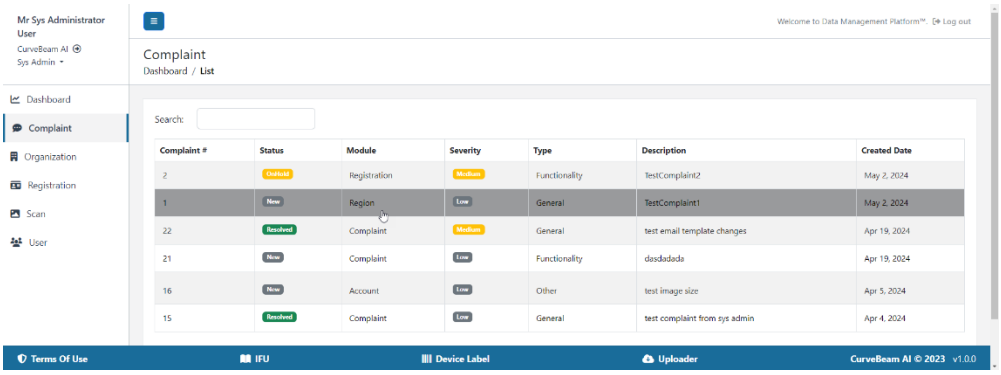


- An automated email will be sent to the system administrator and the complainant notifying the new complaint.

4.3.4.4 Change complaint severity

This action is only available for system administrators.

- Go to complaint list and click on the complaint of interest.



- On the complaint details page, under ‘Current Status/Severity’ section, click on the **Current Severity** dropdown button. Choose the required level from the dropdown list to set the new severity level for the complaint.

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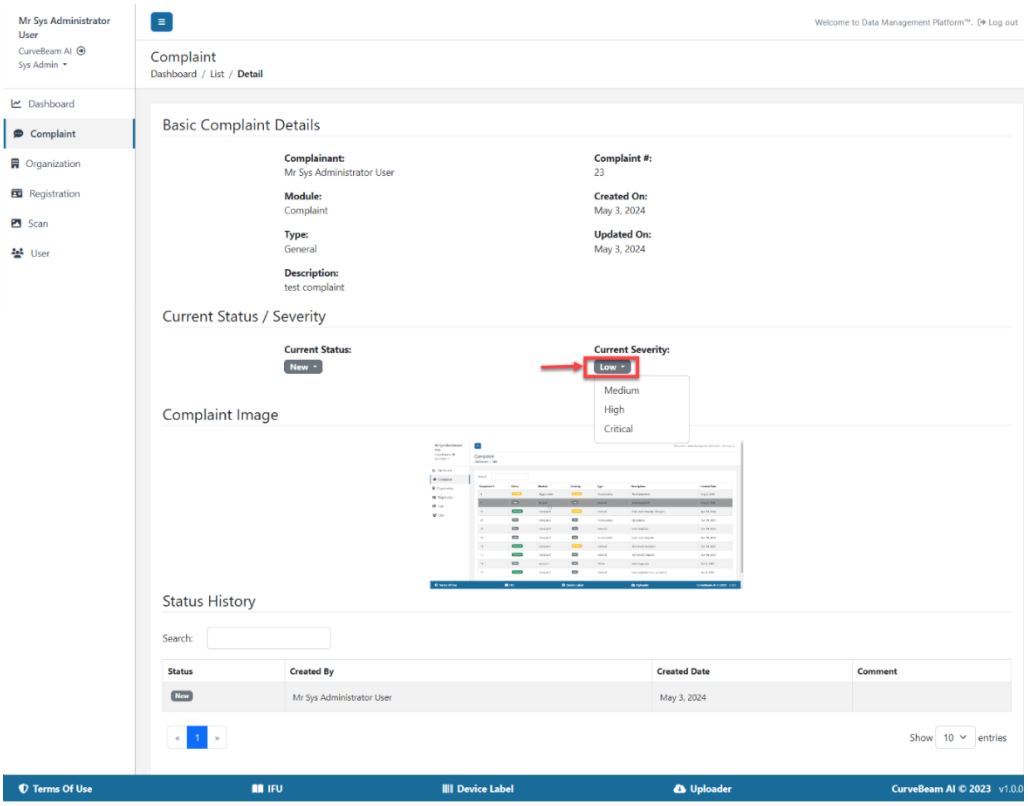
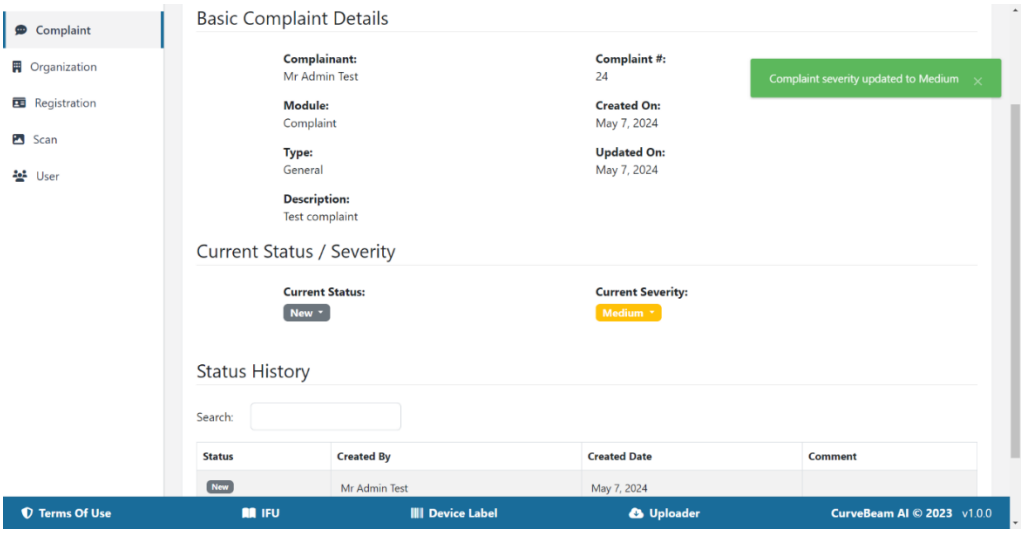


- The confirmatory message will pop up and the new status will be reflected on the details page under ‘Current Status / Severity’ section.



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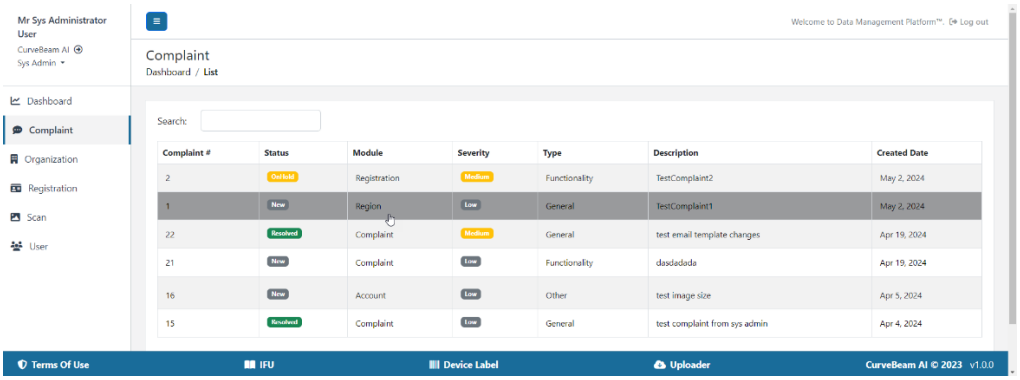
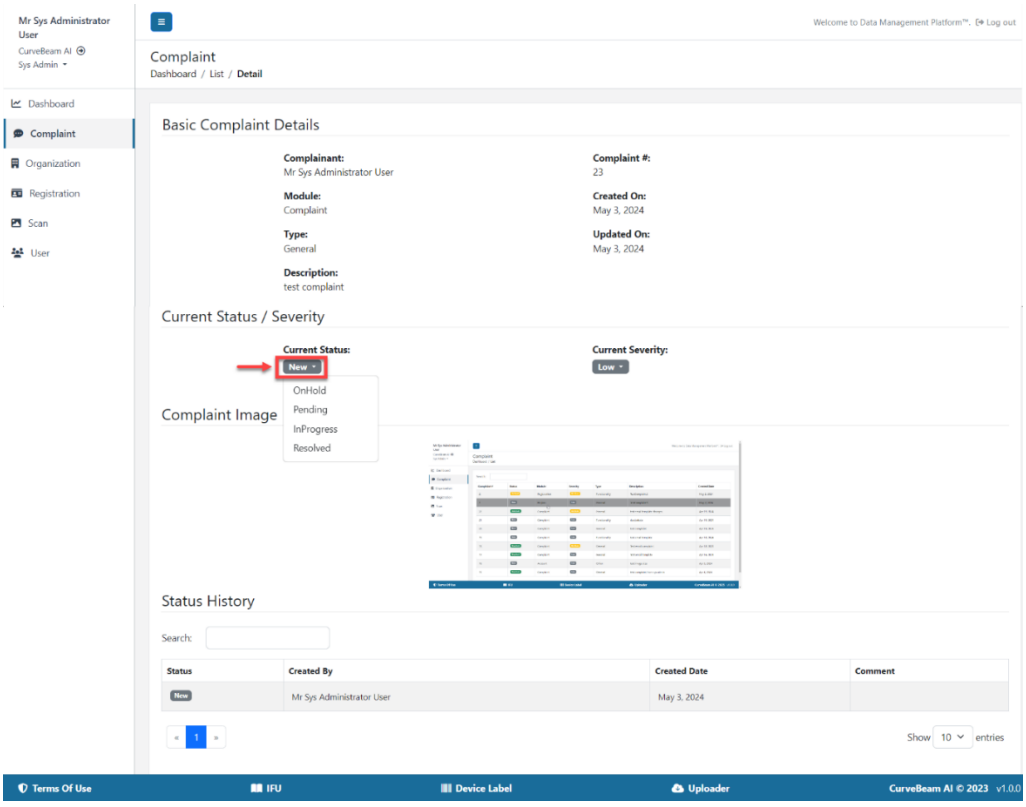
4.3.4.5 Change complaint status

This action is only available for system administrators.

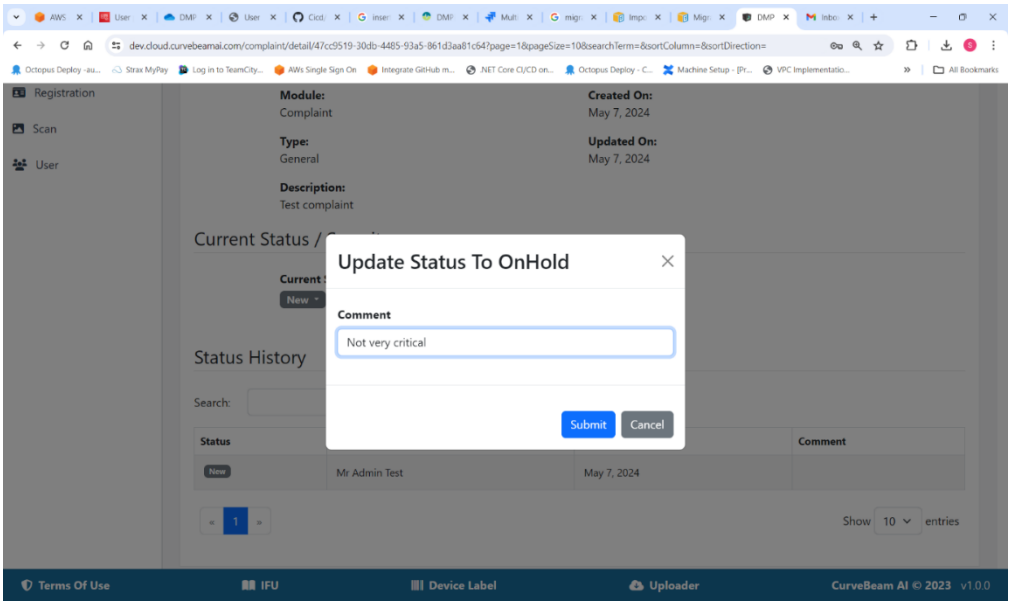
- Go to complaint list and click on the complaint of interest.



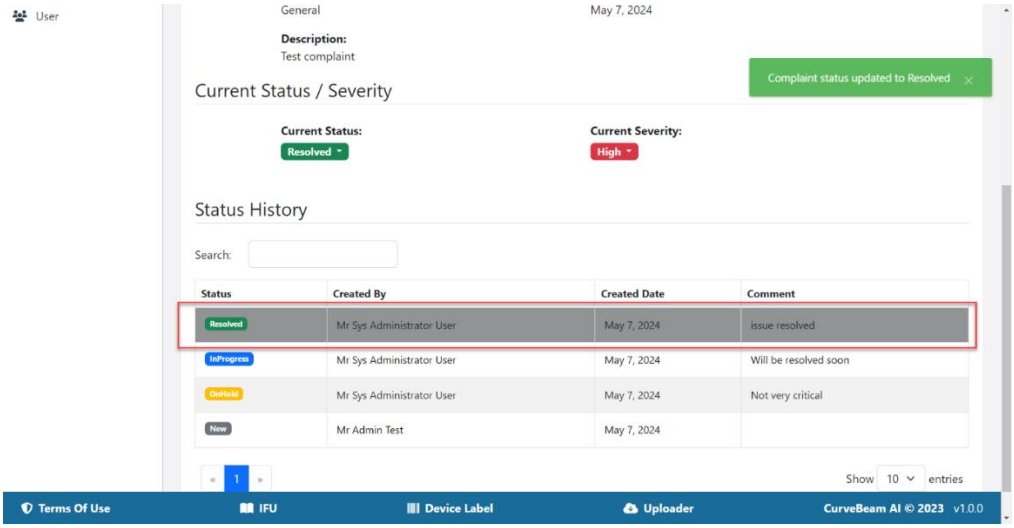
- On the complaint details page, under 'Current Status/Severity' section, click on the **Current Status** dropdown button. Choose the required status from the dropdown list to set the new status for the complaint.



- A form will pop up prompting for a comment. Type in a comment and click on **Submit** button.



- The confirmatory message will pop up and the new complaint status will be reflected on the details page. Also, the status history table will be updated.



- When the status is set to ‘InProgress’ or ‘Resolved’, an automated email will be sent to the complainant to notify about the complaint status update.

4.3.5 Scans

4.3.5.1 View Scan list of a selected organization

This action is only available for system administrators and service users.

- To view the scan list, click on **Scan** on the side panel.

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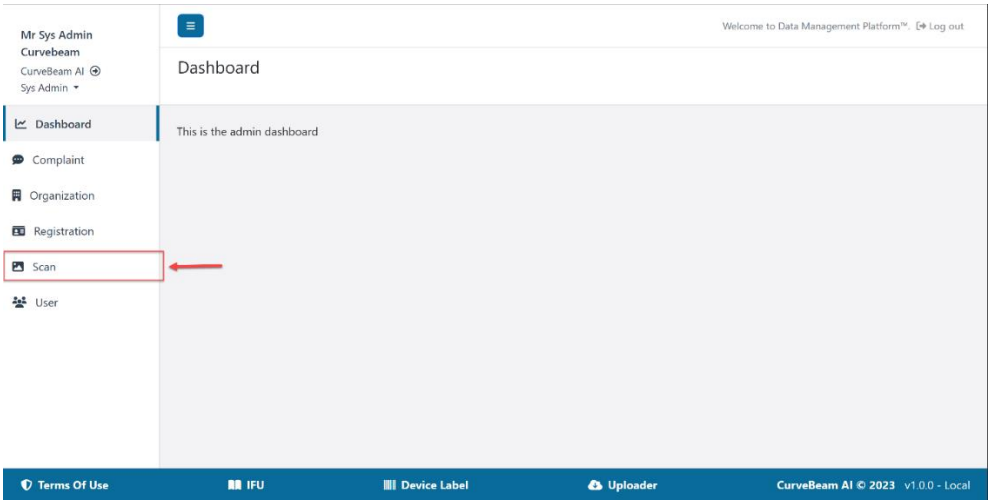
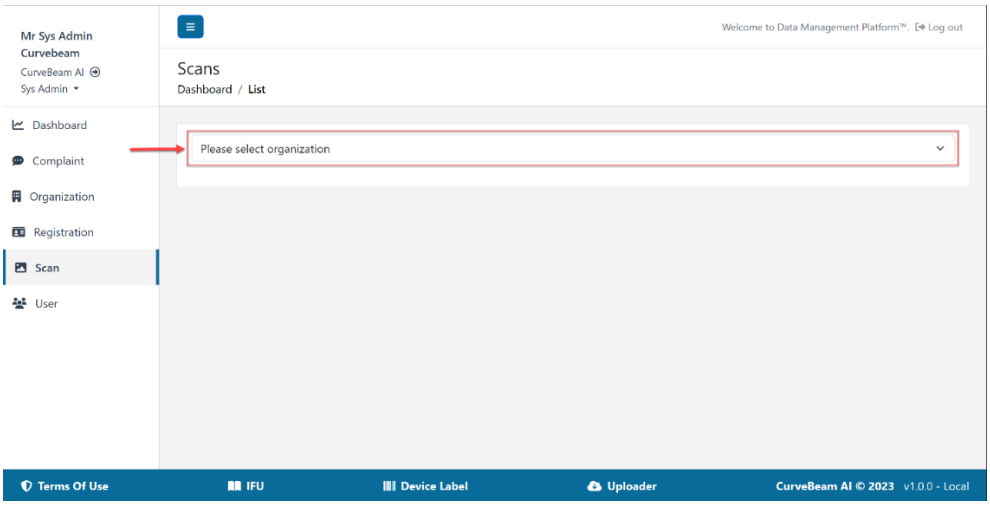
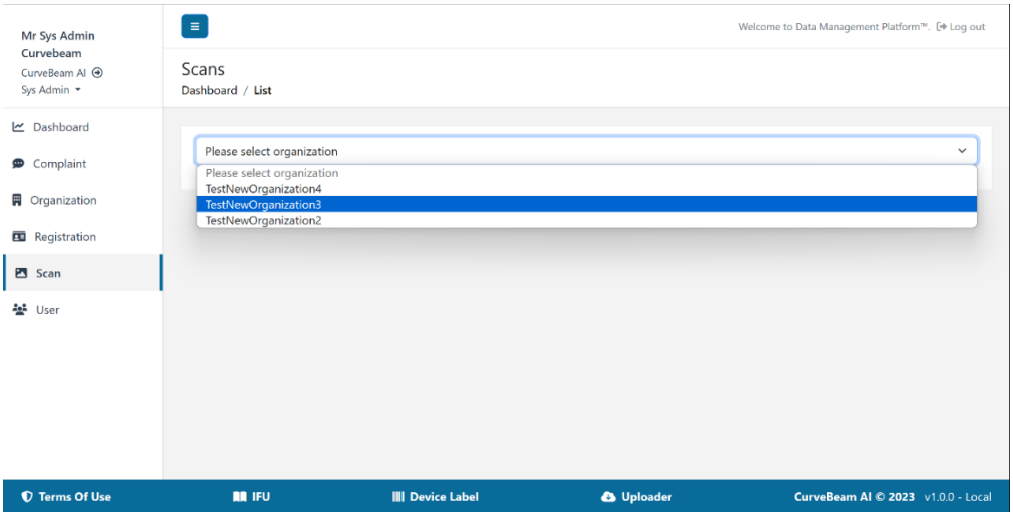


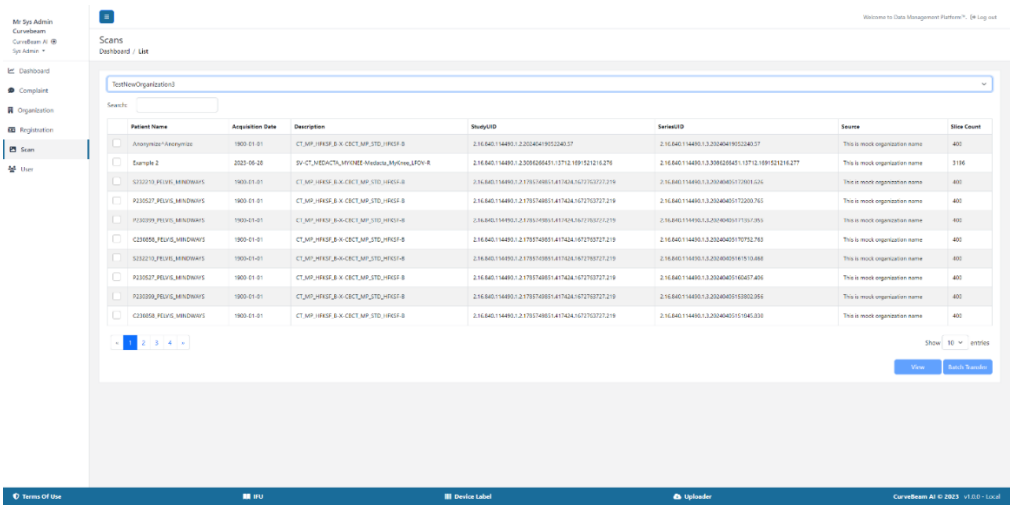
- An organization dropdown menu will be displayed. Click on **Please select organization** to display a dropdown list of organizations.



- From the dropdown list of organizations, click on an organization of interest.



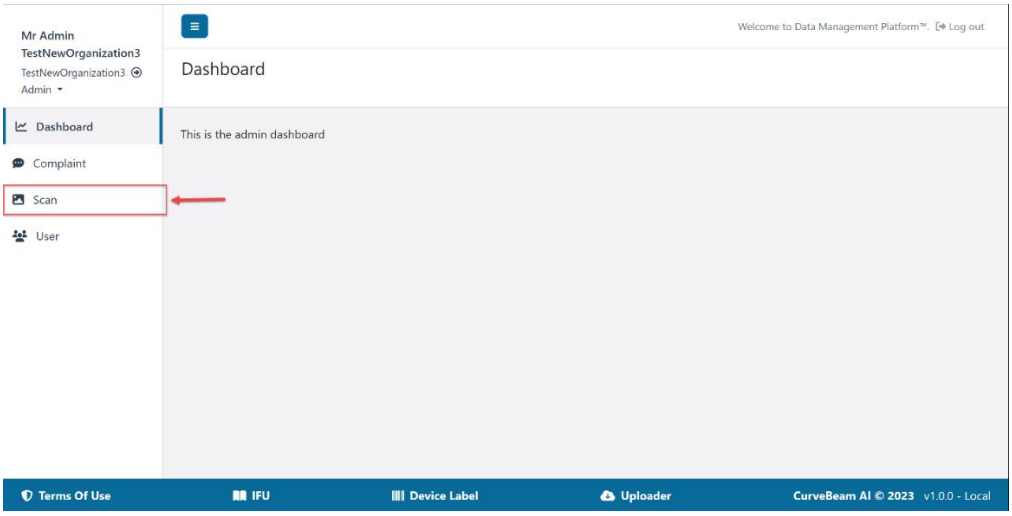
- The scan list of the selected organization will be displayed.



4.3.5.2 View Scan list of your own organization

> This action is only available for administrators and staff users.

- To view the scan list, click on **Scan** on the side panel.



- The scan list of your organization will be displayed.

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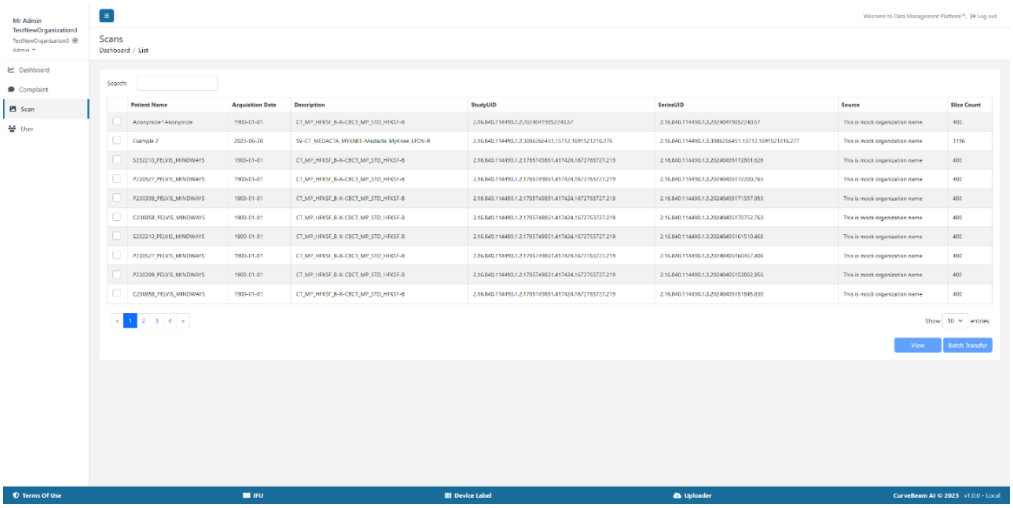
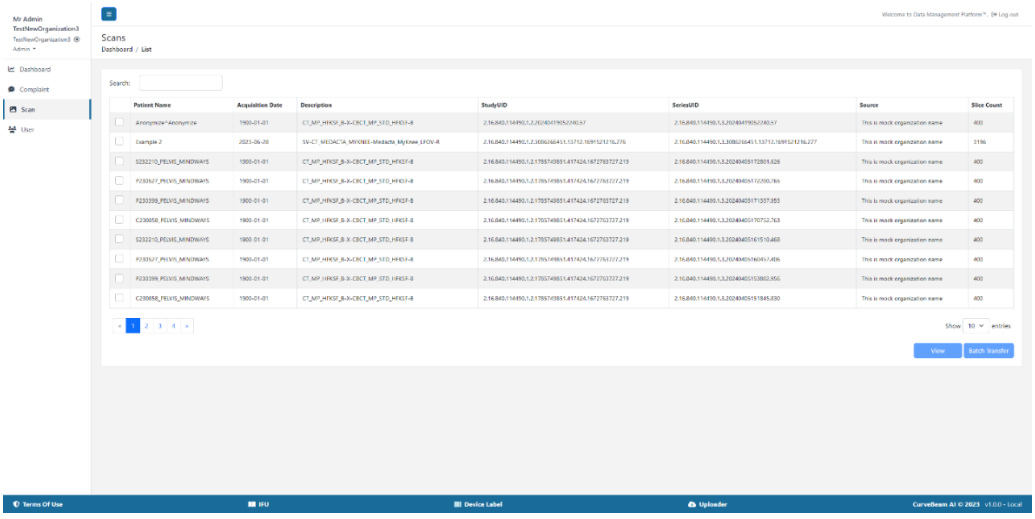


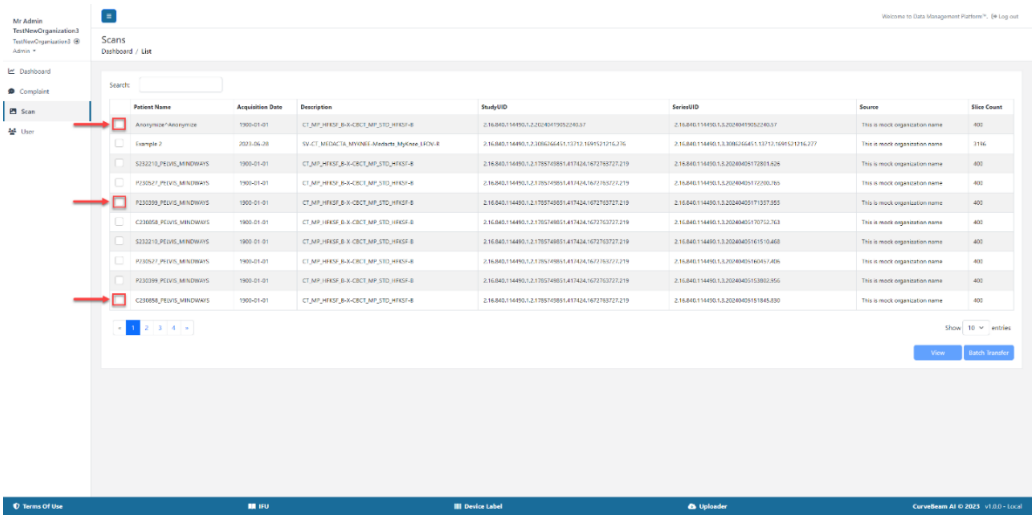
4.3.5.3 Batch transfer scans to another organization

> This action can leak protected health information (PHI).

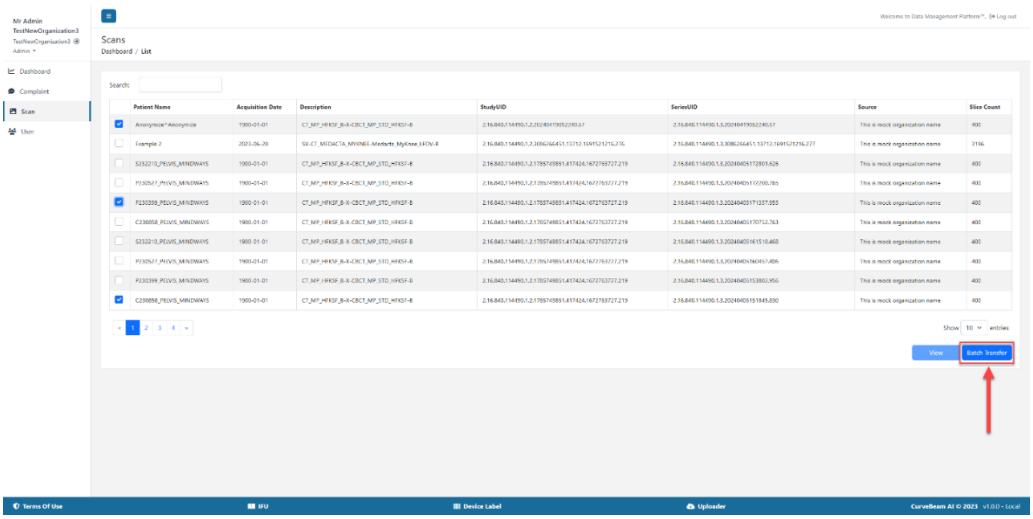
- Go to the scan list.



- Select scan/s for batch transfer by ticking the checkbox for each scan of interest.



- Click on the **Batch Transfer** button.



- The Batch Transfer form will pop up. Provide the following three details:
  - **Destination Region** – Click on **Select Destination Region** to display a dropdown list of regions. Choose the destination region of interest.

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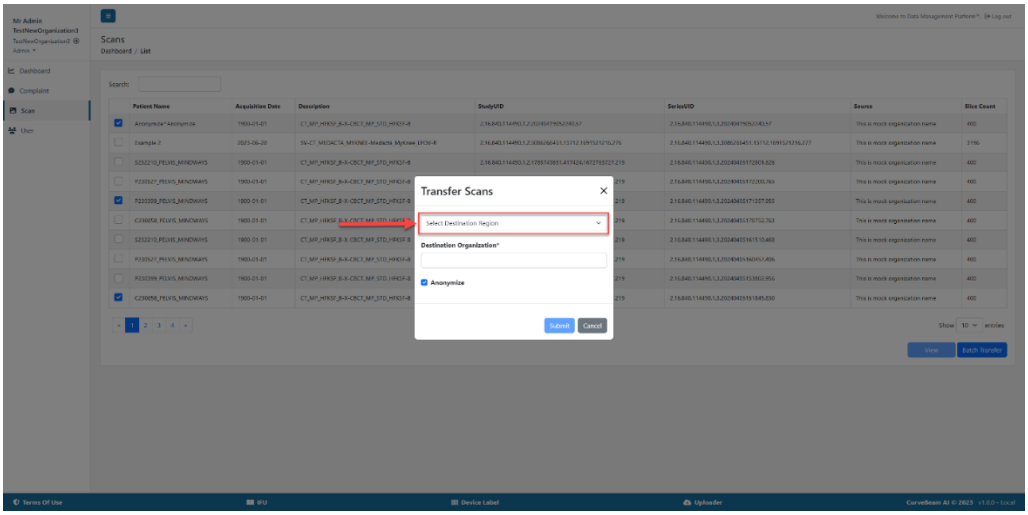
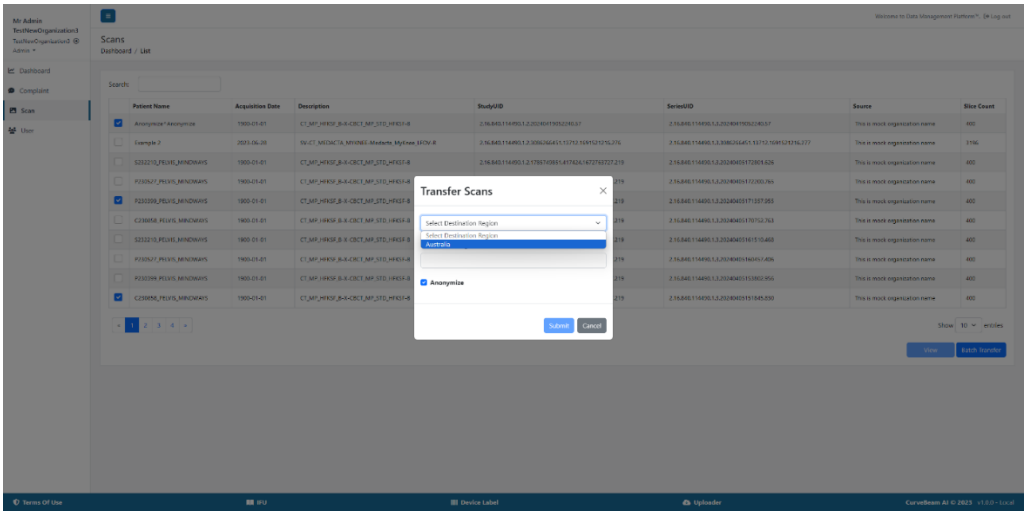
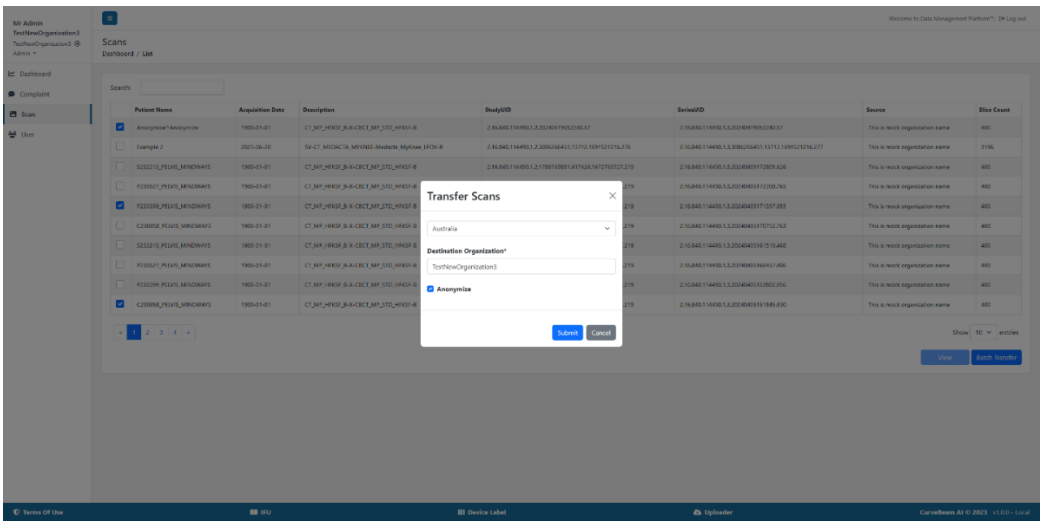




- **Destination Organization –** Fill in the associated textbox.

Contact CurveBeam AI team immediately, if the scan is sent to the wrong organization.



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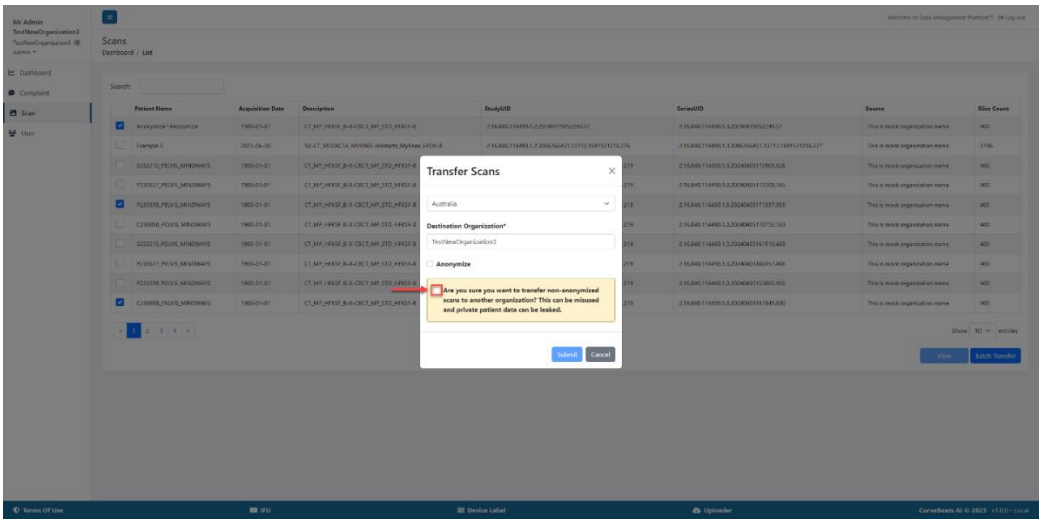
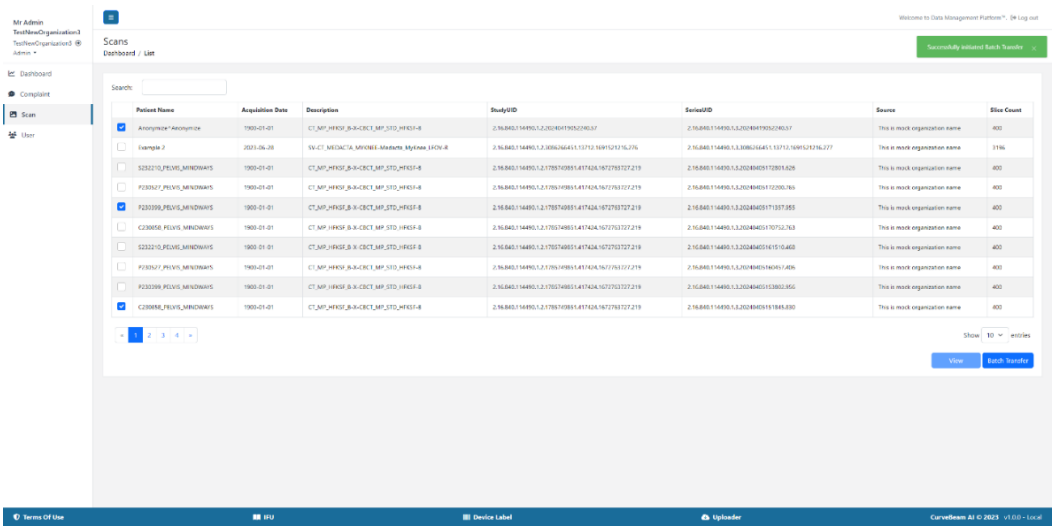
- **Anonymize** – Keep the checkbox ticked to anonymize the scan.

If you don't wish to anonymize the transferred scans, then untick the checkbox. When you untick the anonymize checkbox, a warning message will be displayed informing on the PHI risk of transferring non-anonymized scans. You must tick the new checkbox that appears with this warning to confirm that you are aware of the PHI implications.



- Click the **Submit** button on the batch transfer form to initiate the batch transfer request.
- Once the batch transfer request has been initiated, a confirmatory notification will pop up.

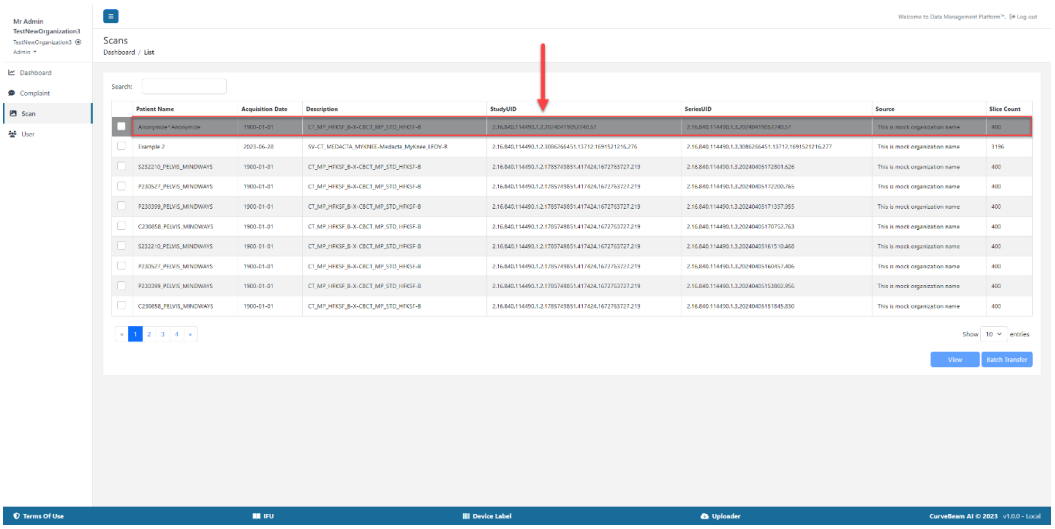


- An automated email will be sent to the administrator users of both the source and destination organization notifying of the batch transfer request.
- Later when the batch transfer request has been processed, an automated email will be sent to the administrator users of both the source and

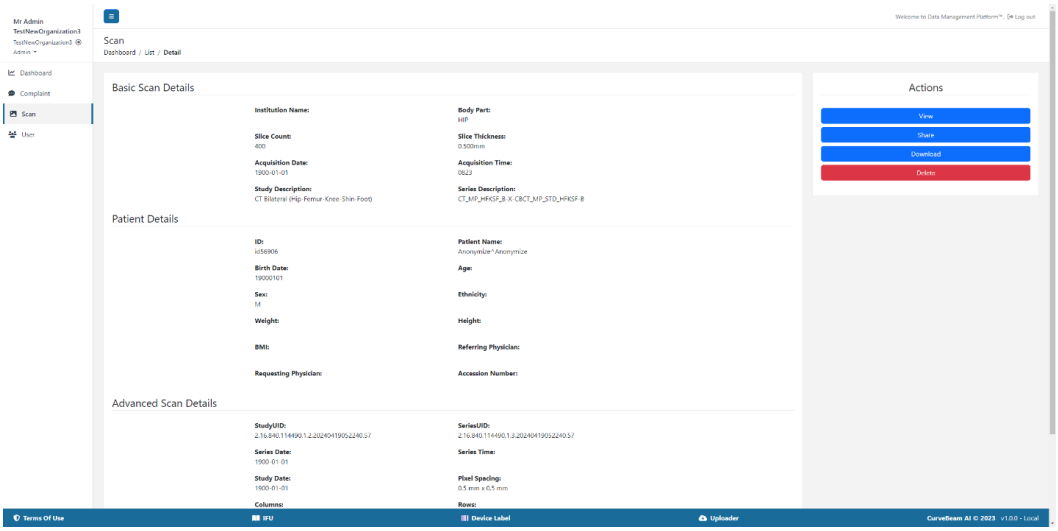
destination organization notifying that the batch transfer request has been processed.

4.3.5.4 View scan details

- Go to the scan list and click on a scan of interest.



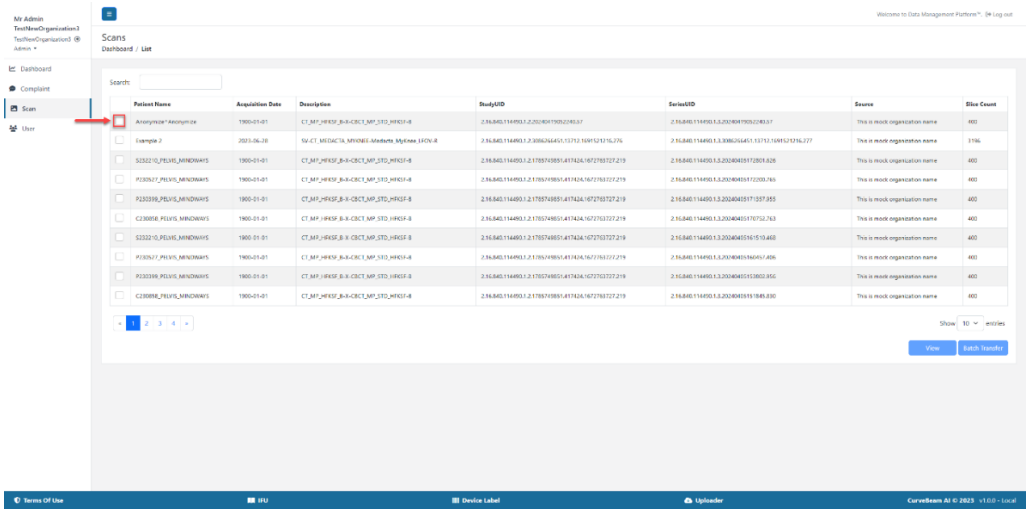
- The details of the selected scan will be displayed.



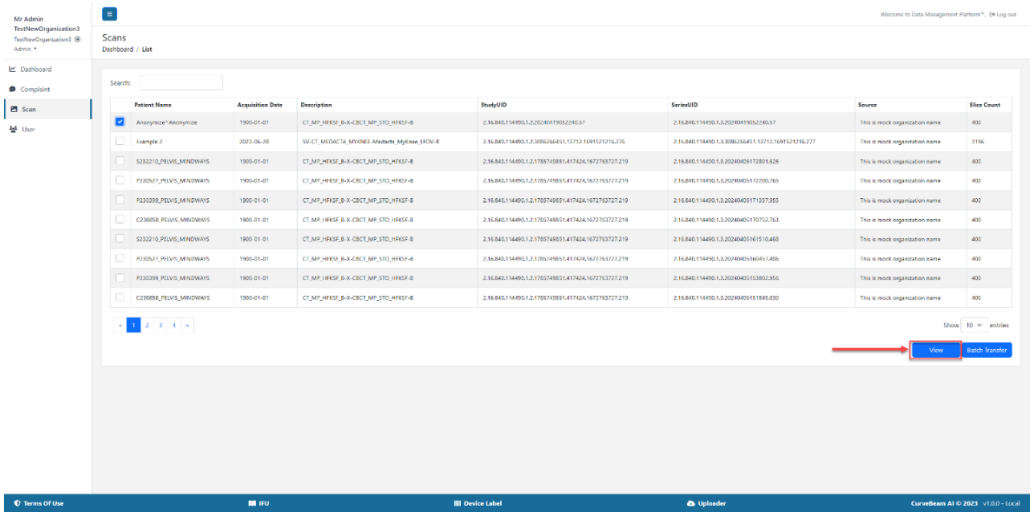
4.3.5.5 View scan in medical image viewer

4.3.5.5.1 View scan in medical image viewer (from scan list)

- Go to the scan list and select a single scan of interest by ticking the associated checkbox.



- Click on the **View** button.



- The CurveBeam AI medical image viewer application will open in another tab.

> Scan images displayed on the image viewer are not in the original resolution. They have been adapted to fit the image viewer specifications.

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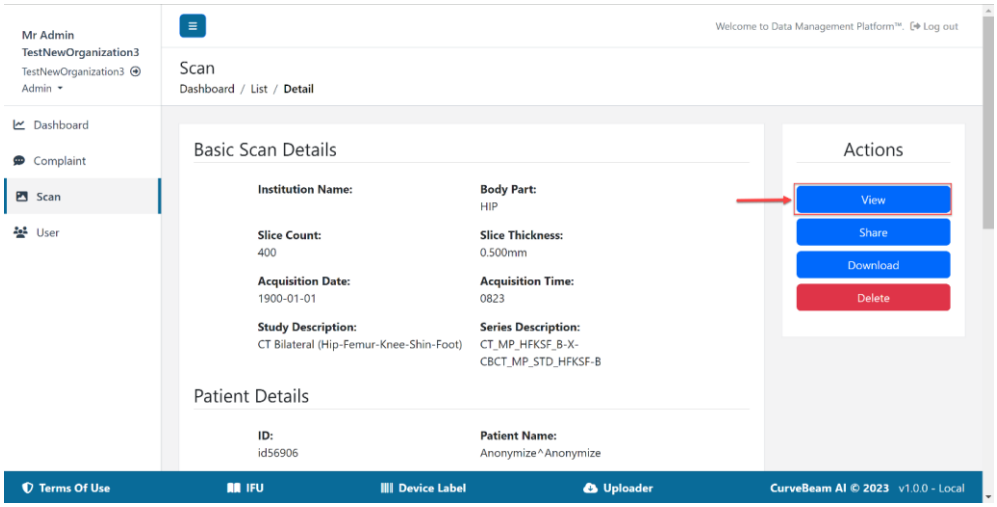
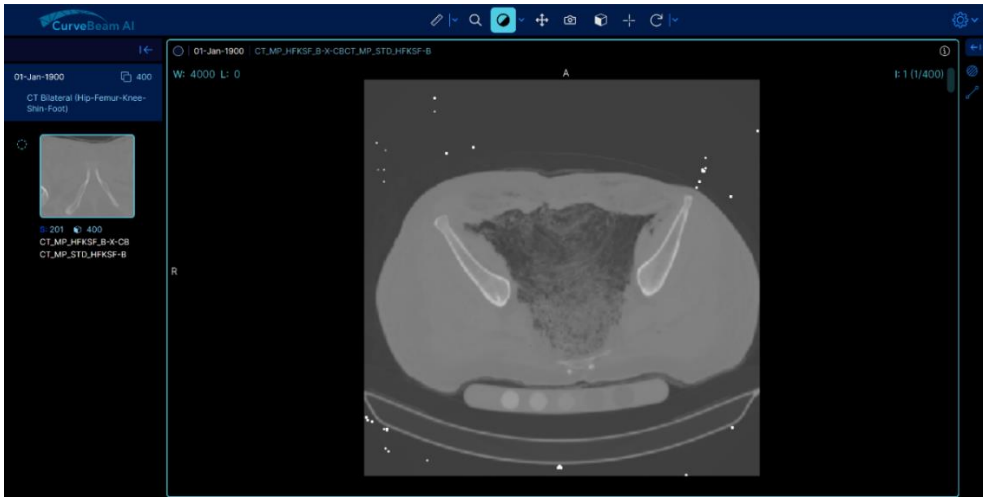
4.3.5.5.2 View scan in medical image viewer (from scan detail)

- Go to the scan detail page for a scan of interest. Click on the **View** button.



- The CurveBeam AI medical image viewer application will open in another tab.

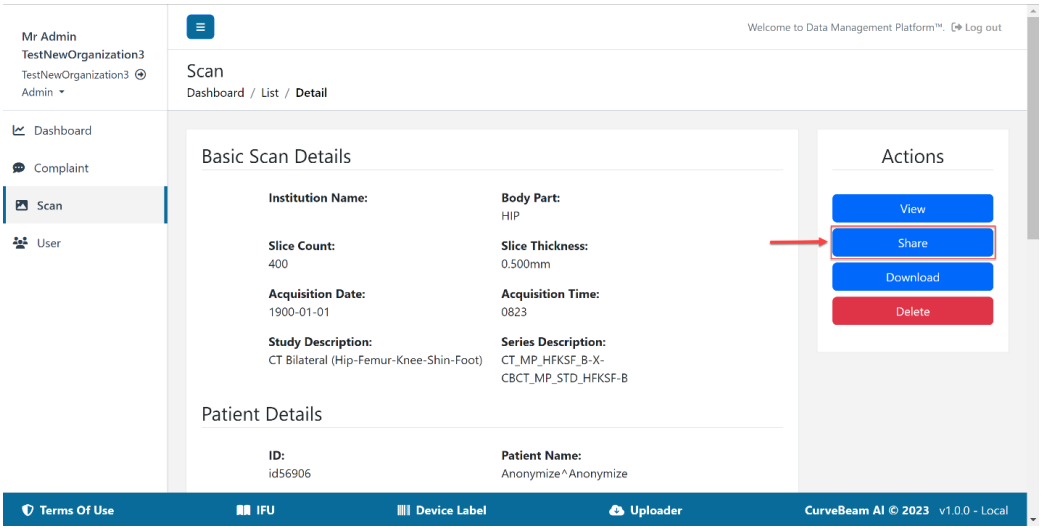
> Scan images displayed on the image viewer are not in the original resolution. They have been adapted to fit the image viewer specifications.



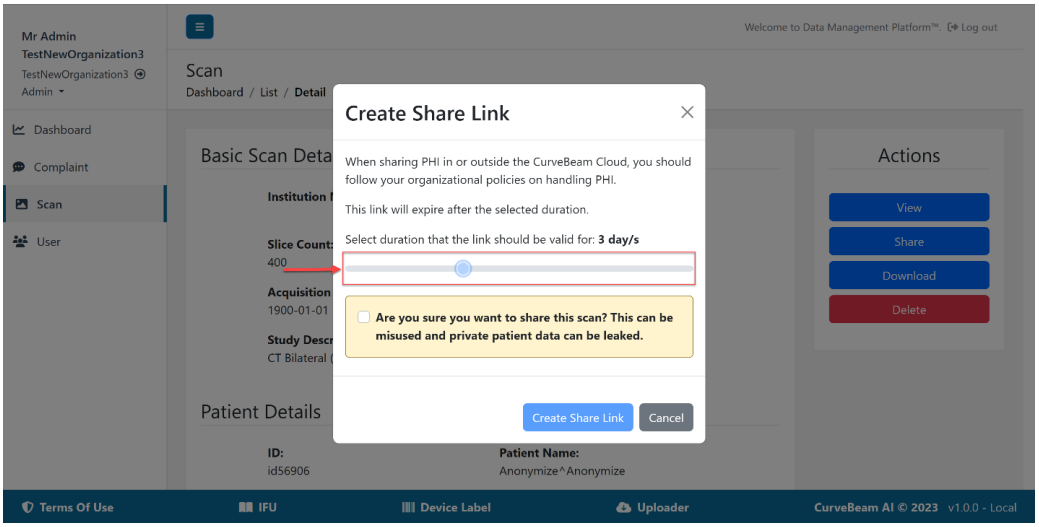
4.3.5.6 Generate shareable link for scan.

> This action can leak protected health information (PHI).
> Follow your organization's patient data privacy protocols.

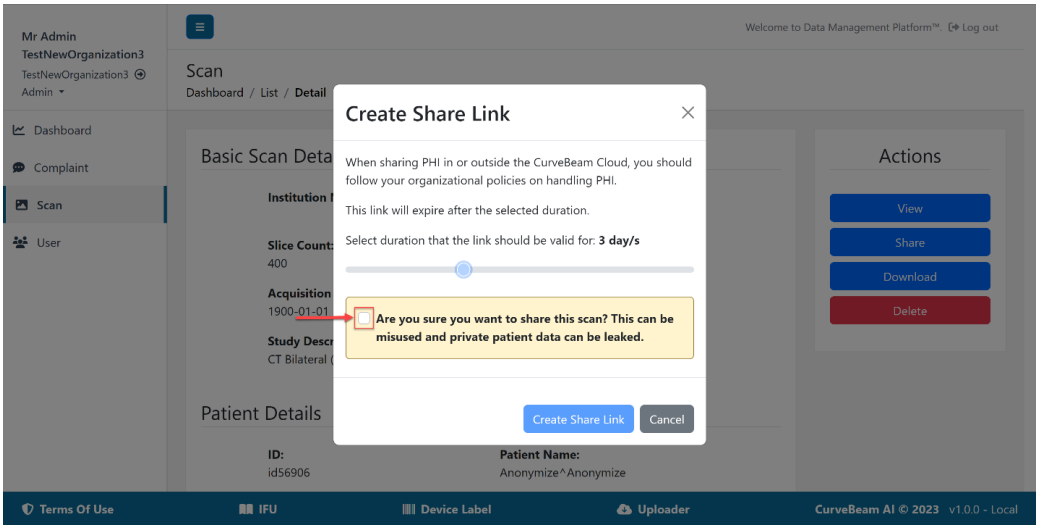
- Go to the scan detail page for a scan of interest. Click on the **Share** button.



- The Create Share Link form will pop up. Provide the following detail:
  - **Share link validity duration –** Drag the slider to select the number of day/s you would like the share scan link to be valid for. The minimum allowed value is 1 day, and the maximum allowed value is 7 days.



- You must also tick the warning message checkbox to confirm you are aware of the PHI implications of creating a scan share link.



- Click on the **Create Share Link** button.
- Once the share link is created, the Create Share Link form will display a success message with the newly created scan share link.

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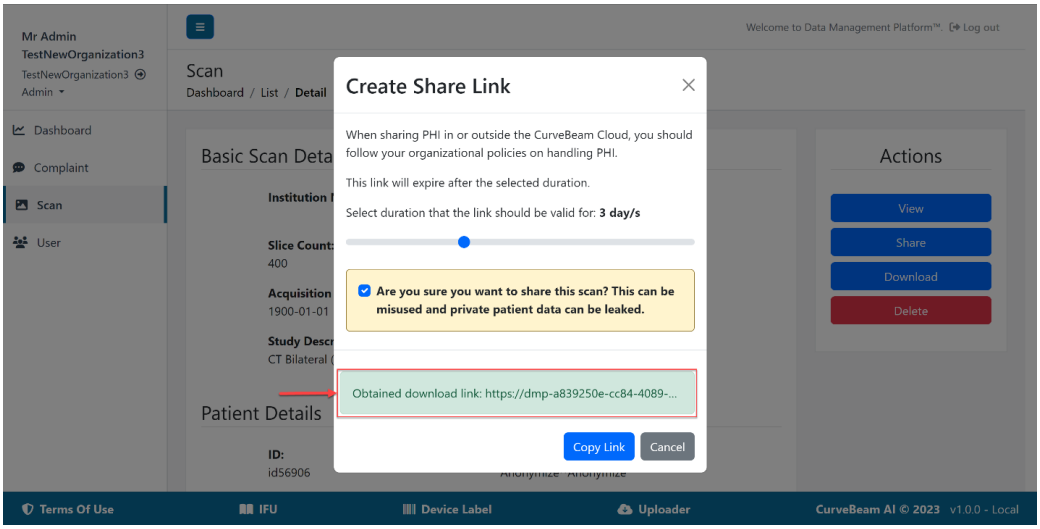
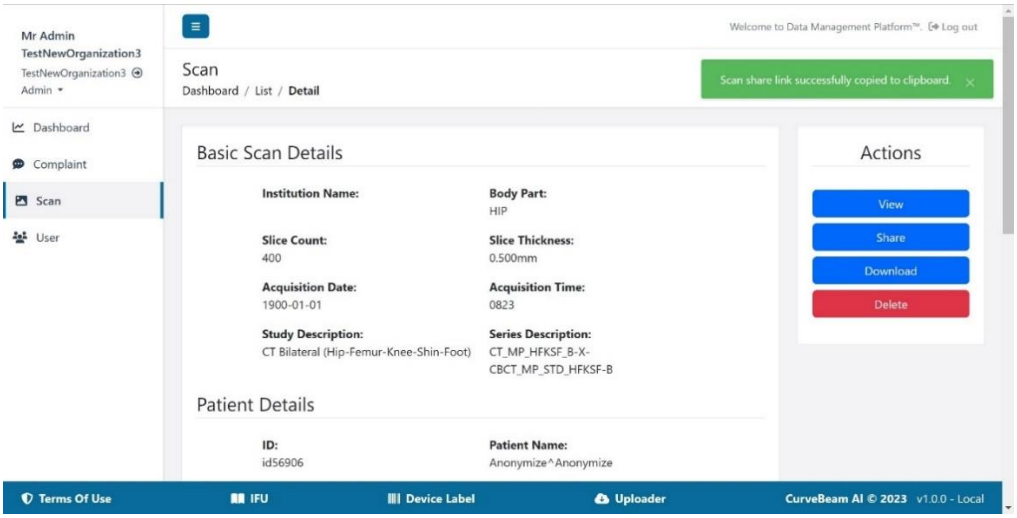


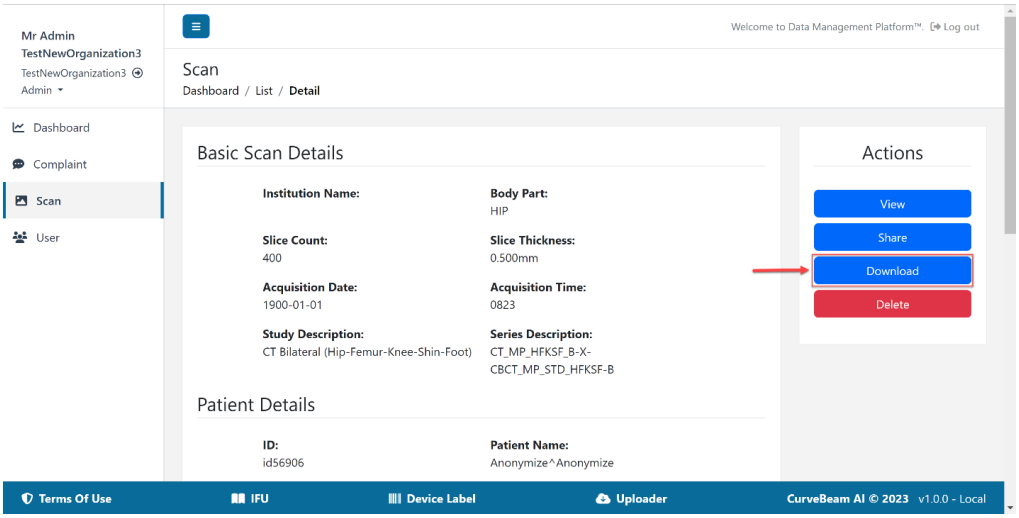
- Click on the **Copy Link** button, the scan share link will be copied to your clipboard and the Create Share Link form will disappear. A confirmatory notification will pop up.



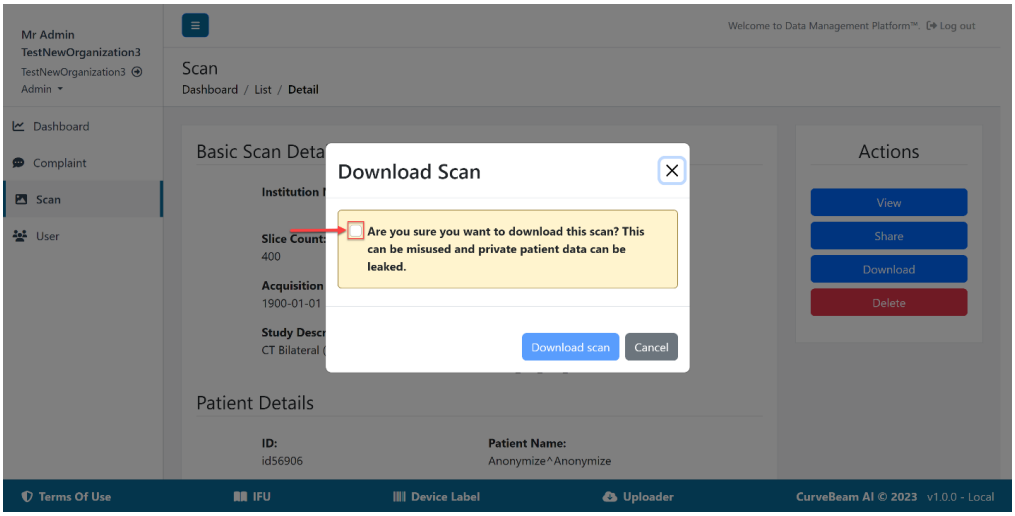
4.3.5.6 Download scans

This action can leak protected health information (PHI). Follow your organization's patient data privacy protocols.

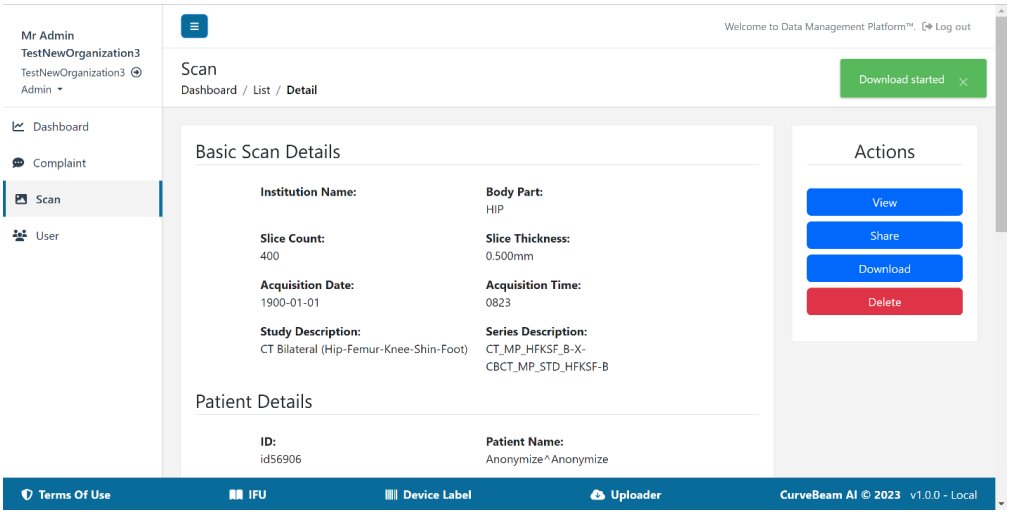
- Go to the scan detail page for a scan of interest. Click on the **Download** button.



- A form will pop up with a warning message informing in the PHI risk of downloading scan/s. You must tick the checkbox to confirm that you are aware of the PHI implications.



- Click on the **Download scan** button.
- The scan will be downloaded to your computer, and a confirmatory notification will pop up.

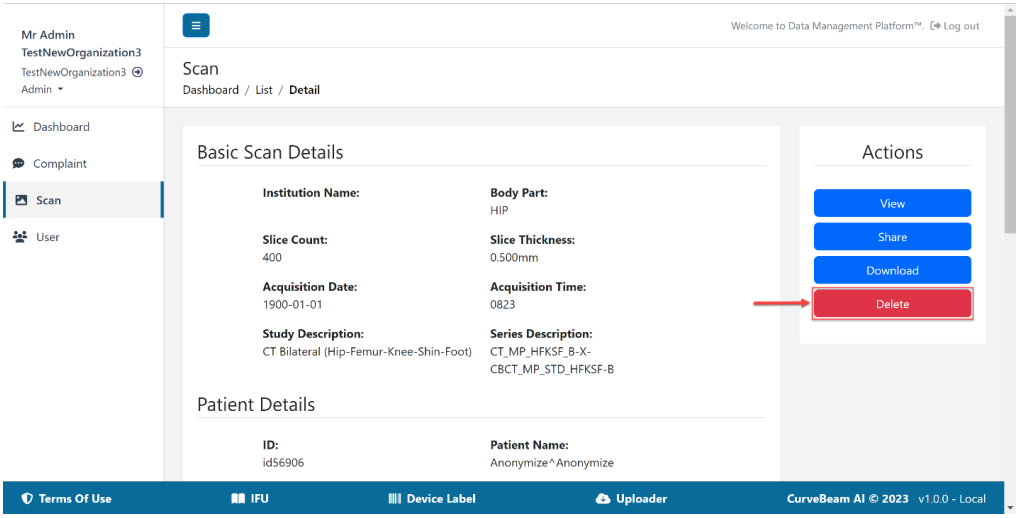


4.3.5.7 Delete scans.

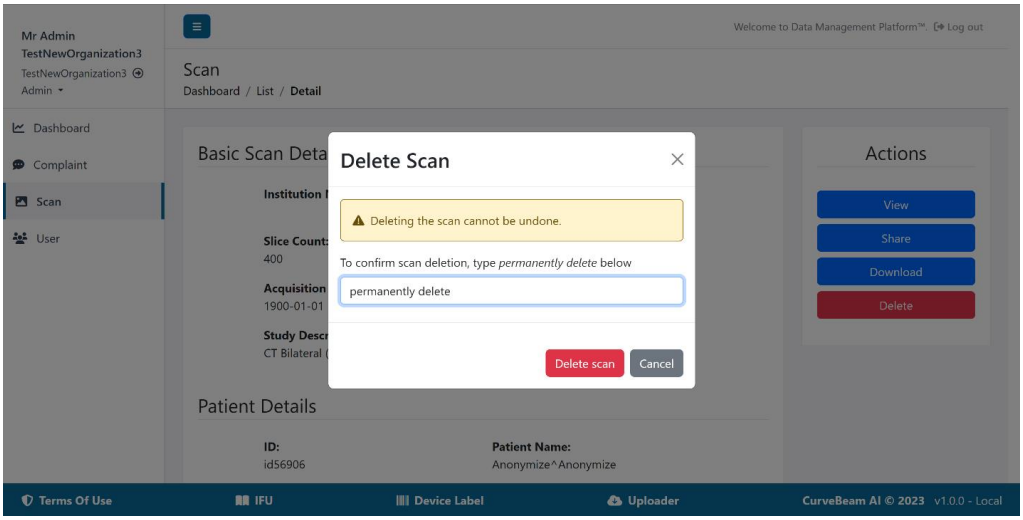
Contact CurveBeam AI to restore a deleted scan from the backup data. To delete the backup data, send an email to the CurveBeam AI customer support email address. Please note that the delete action is irreversible.

This action is only available for organization administrators.

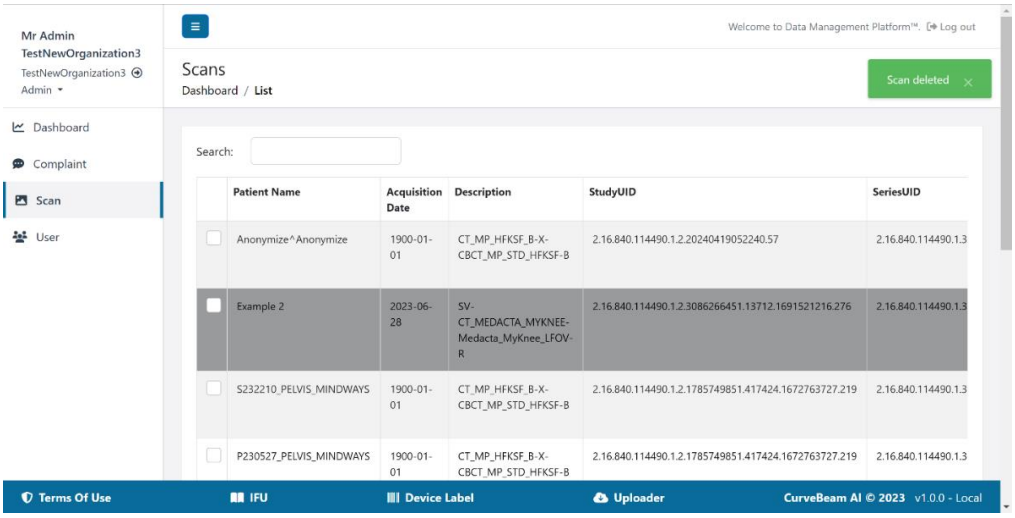
- Go to the scan detail page for a scan of interest. Click on the **Delete** button.



- The Delete Scan form will pop up with a warning message. Type ‘permanently delete’ into the textbox to confirm that you would like to delete the scan.



- Click on the **Delete Scan** button.
- Once the delete has been processed, you will be redirected to an updated scan list and a confirmatory notification will pop up.



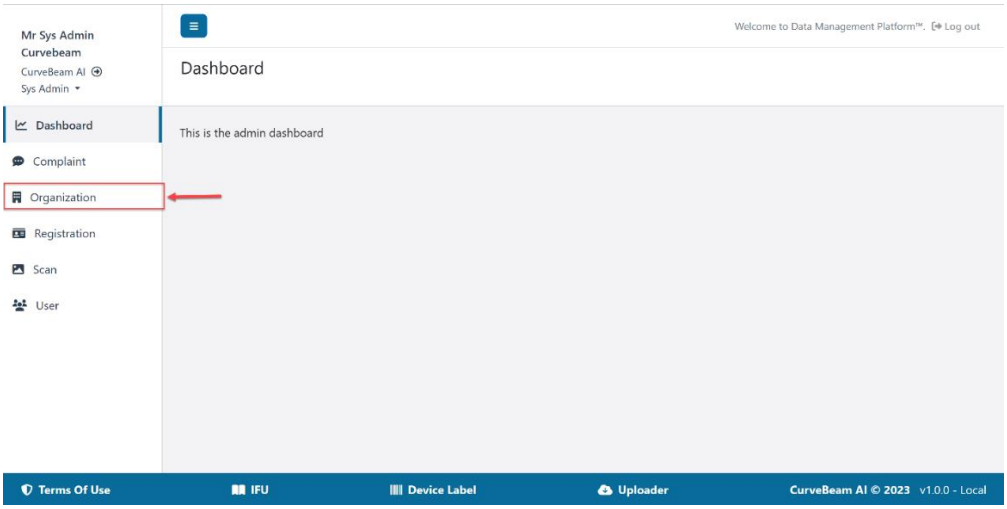
- An automated email will be sent to the administrator users in your organization notifying that the scan has been deleted.

4.3.6 Organization

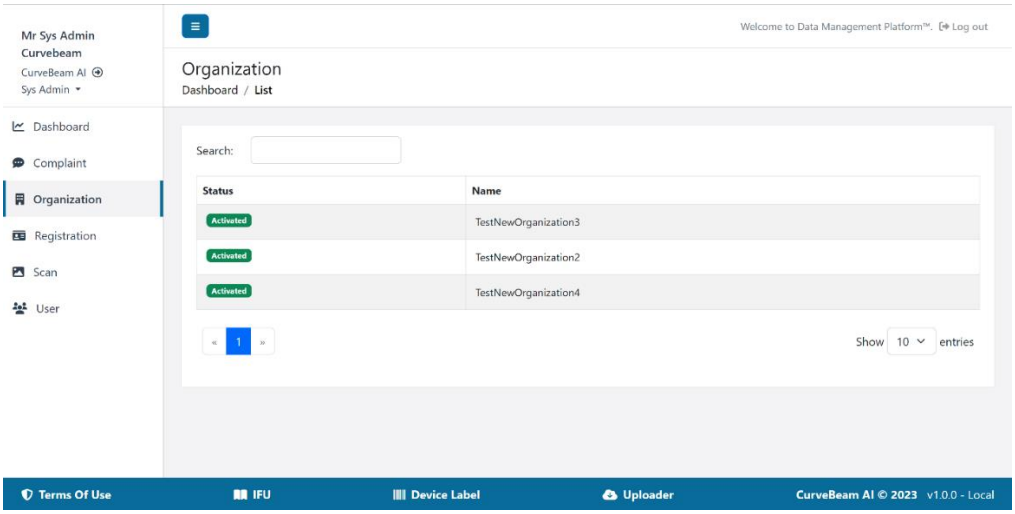
4.3.6.1 View organization list

> This action is only available for system administrators – CurveBeam AI.

- To view the organization list, click on **Organization** on the side panel.



- The organization list will be displayed.



4.3.6.2 View organization details

> This action is only available for system administrators – CurveBeam AI.

- Go to the organization list and click on an organization of interest.

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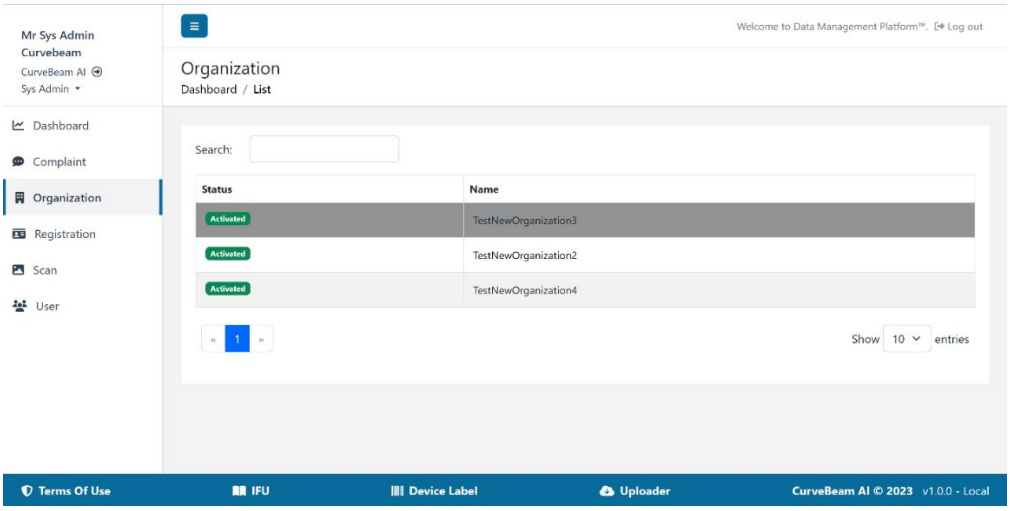
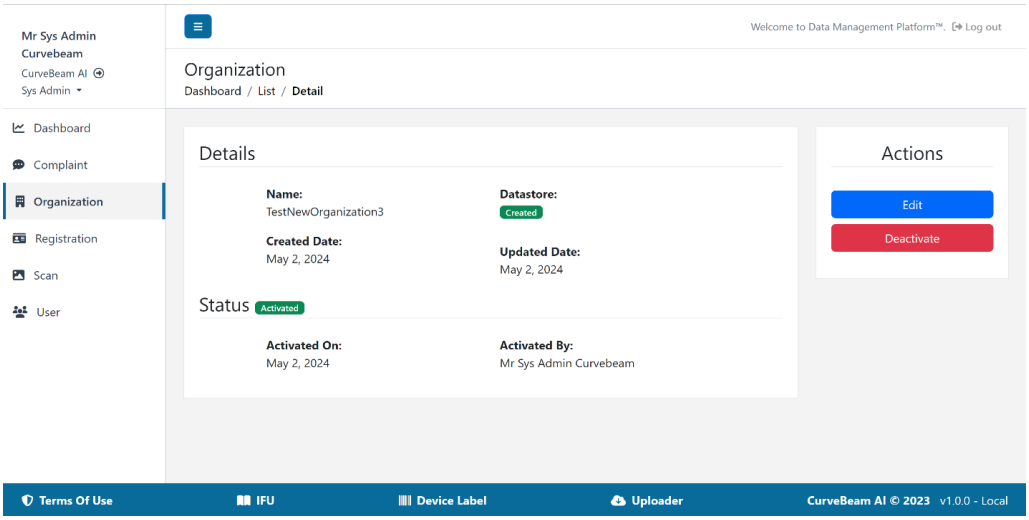


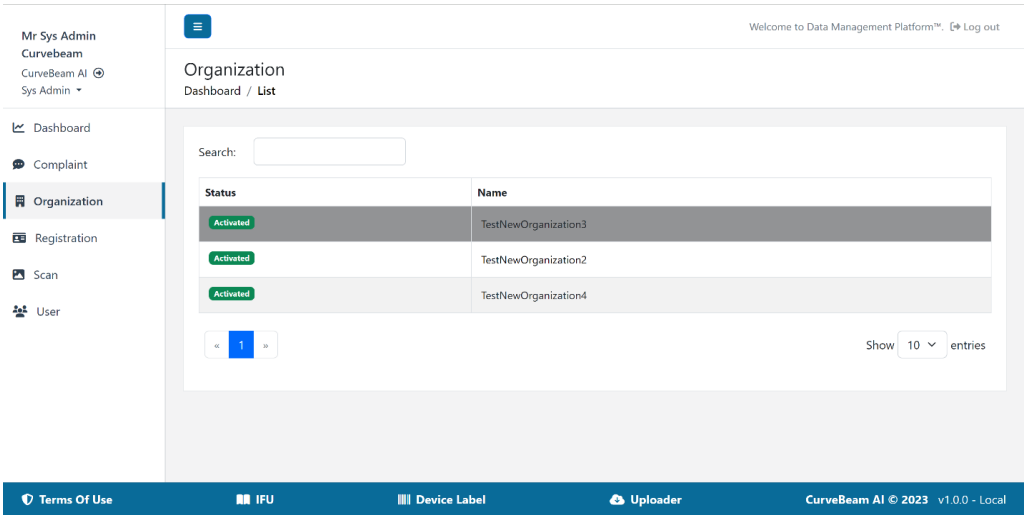
- The details of the selected organization will be displayed.



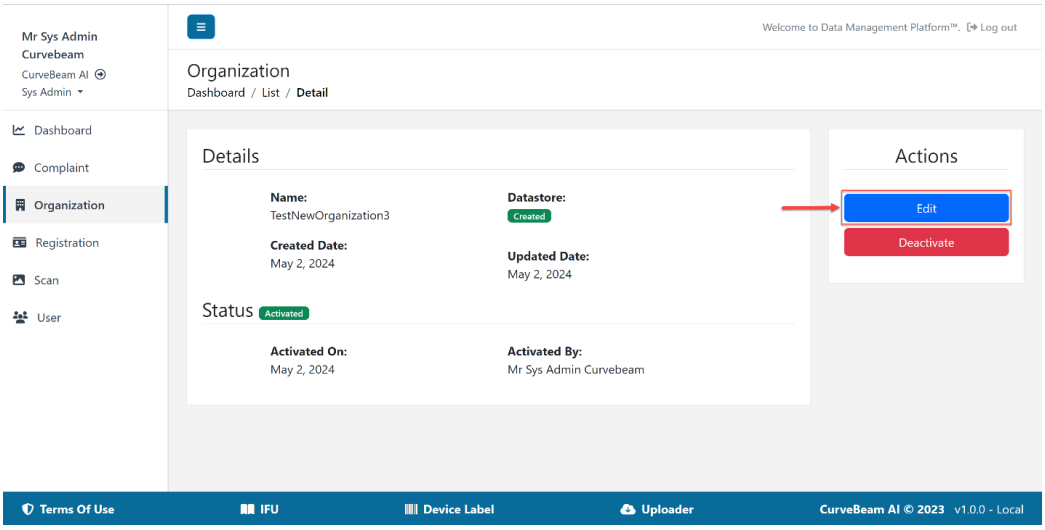
4.3.6.3 Edit organization details.

This action is only available for system administrators – CurveBeam AI

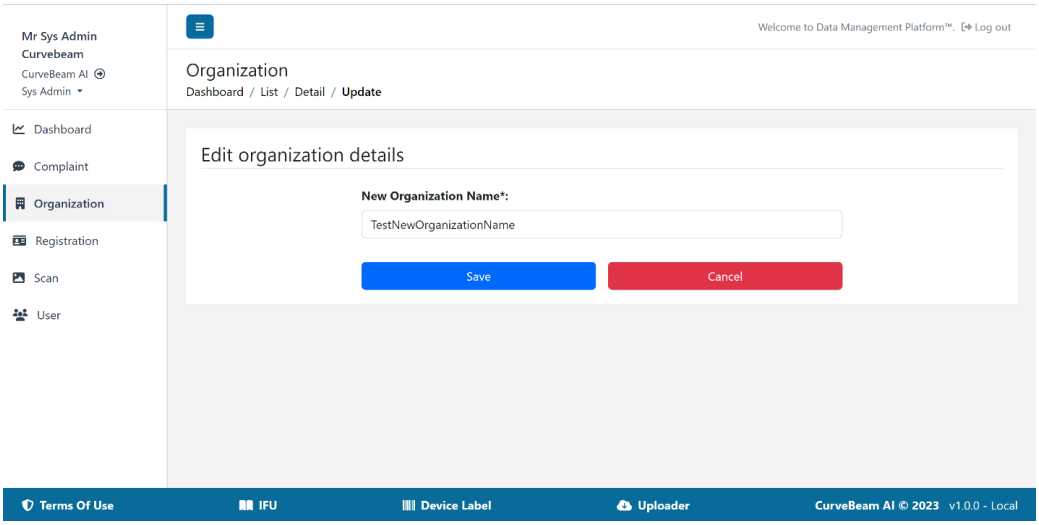
- Go to the organization list and click on an organization of interest.



- On the organization detail page, click on the **Edit** button.



- The edit organizations detail form will be displayed. Provide the following detail:
    - **New Organization Name –** Fill in the associated textbox.



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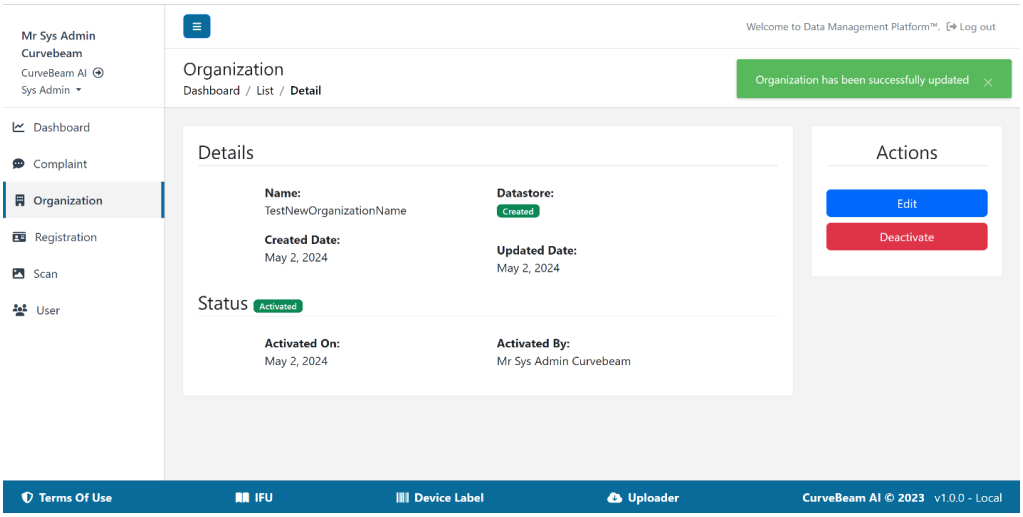
- Click on the **Save** button.
- An updated organization detail page will be displayed, and a confirmatory notification will pop up.

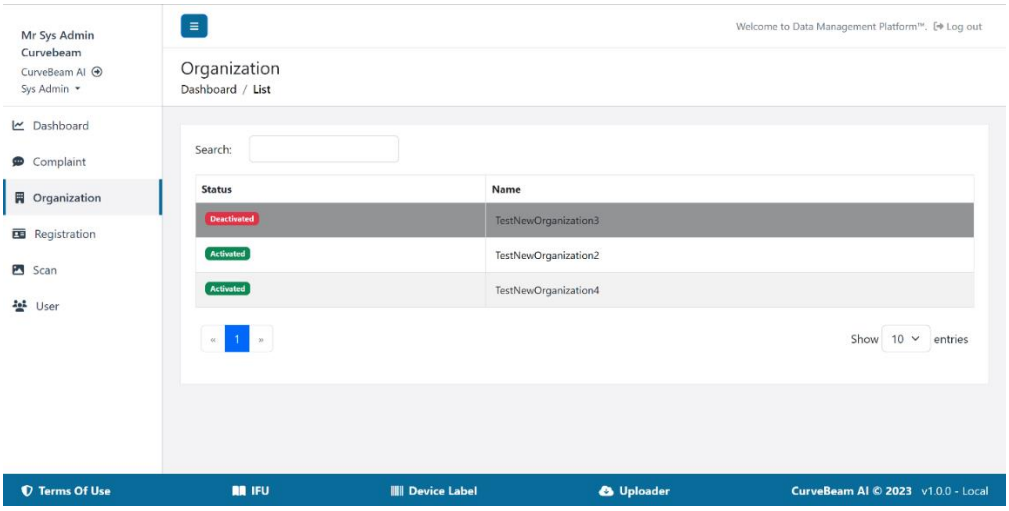


- An automated email will be sent to organization users notifying of the edited details.

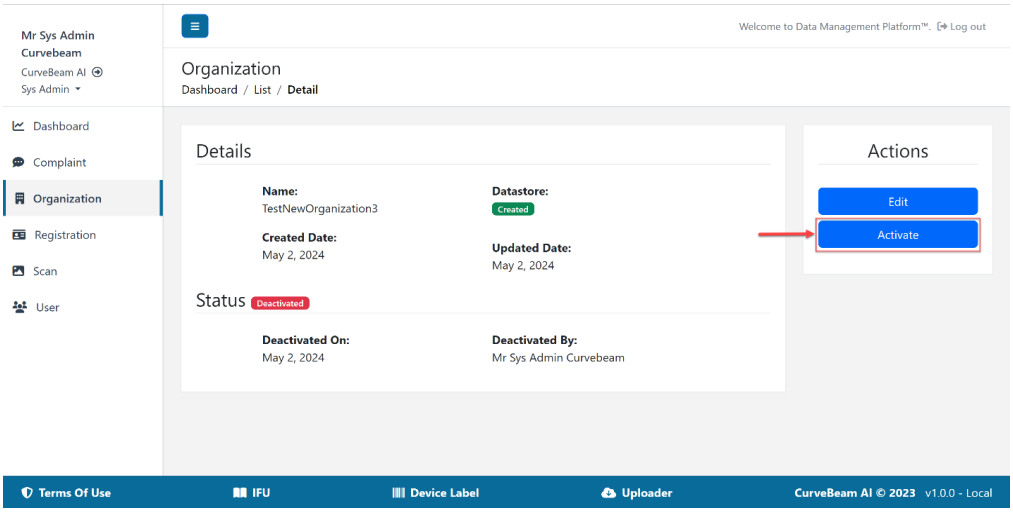
4.3.6.4 Activate organization

This action is only available for system administrators – CurveBeam AI.

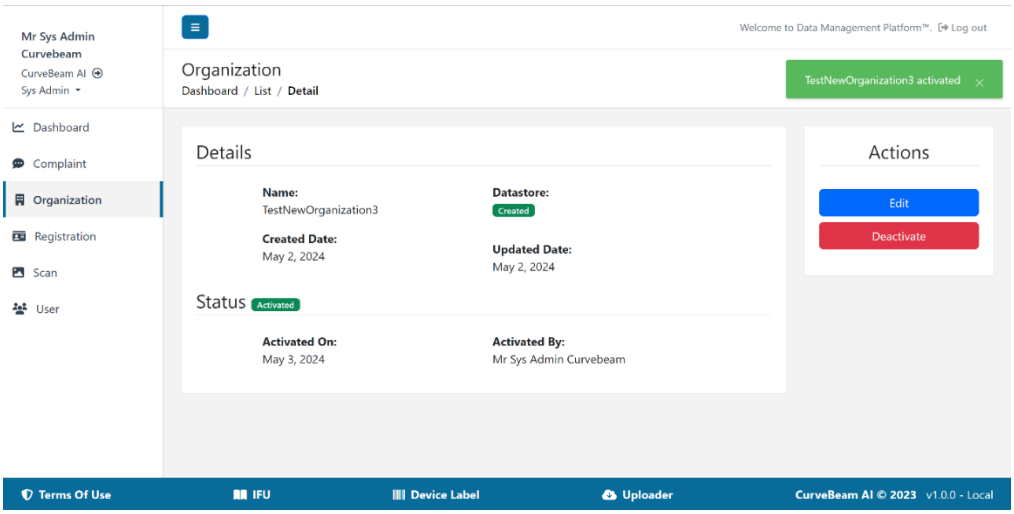
- Go to the organization list and click on an organization of interest with `Deactivated` status.



- On the organization detail page, click on the **Activate** button.



- Once the activation has been processed, a confirmatory notification will pop up. The status section of the organization detail page will be updated accordingly.

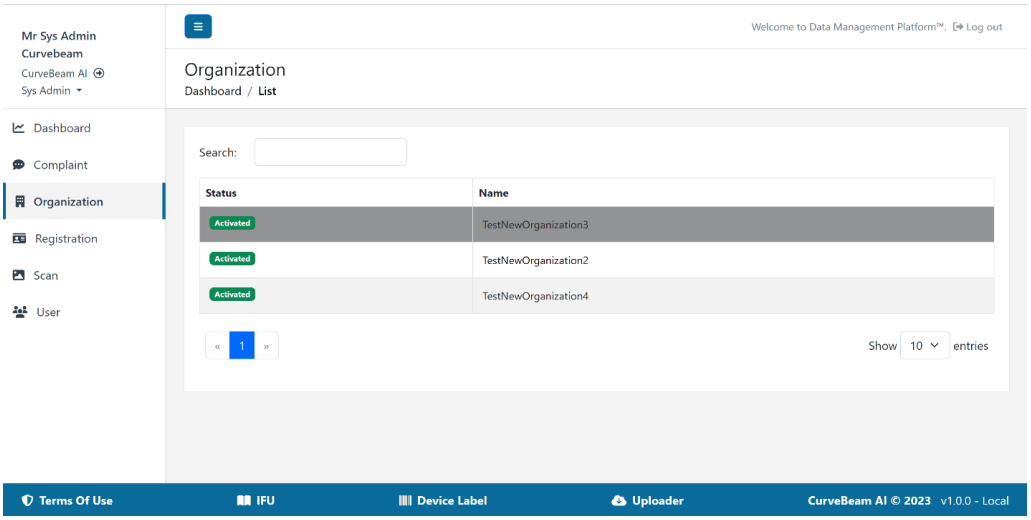


- An automated email will be sent to organization users notifying of the activation.

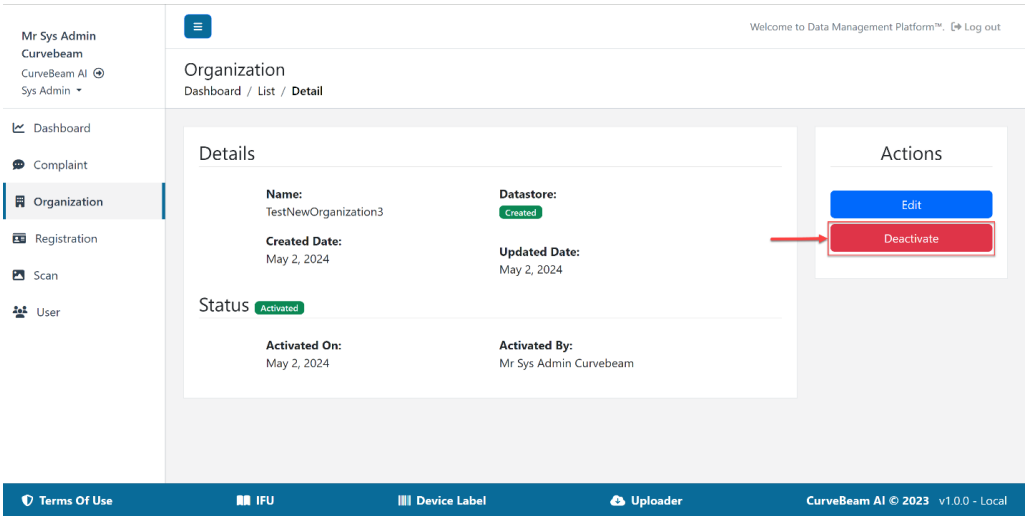
4.3.6.5 Deactivate organization.

This action is only available for system administrators – CurveBeam AI.

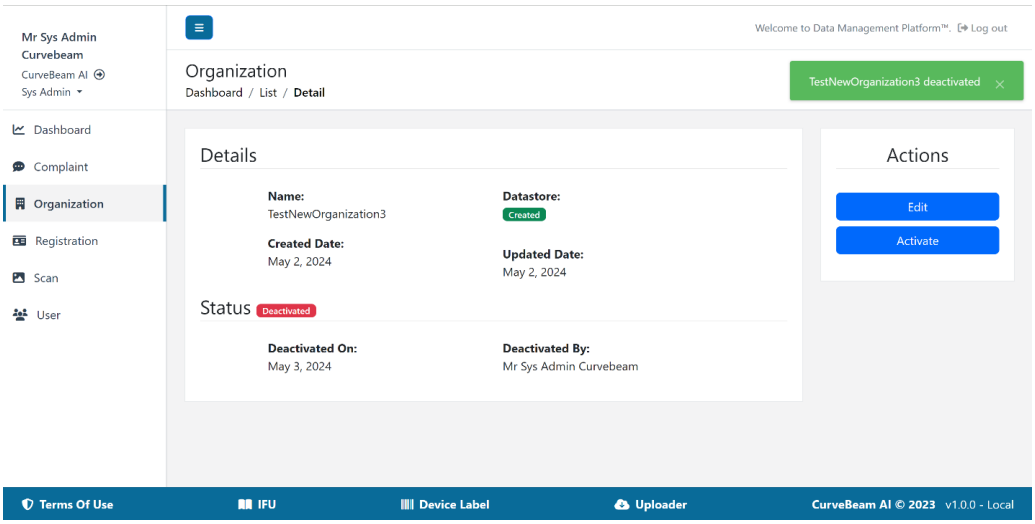
- Go to the organization list and click on an organization of interest with the `Activated` status.



- On the organization detail page, click on the **Deactivate** button.



- Once the deactivation has been processed, a confirmatory notification will pop up. The status section of the organization detail page will be updated accordingly.



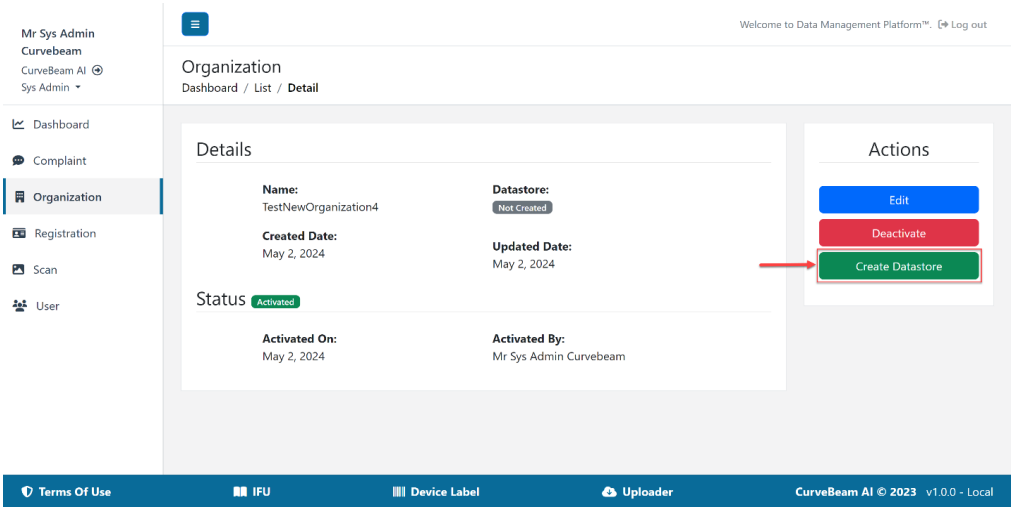
- An automated email will be sent to organization users notifying of the deactivation.
- Users in the deactivated organization will not be able to log into the DMP.

4.3.6.6 Create cloud DICOM datastore for organization.

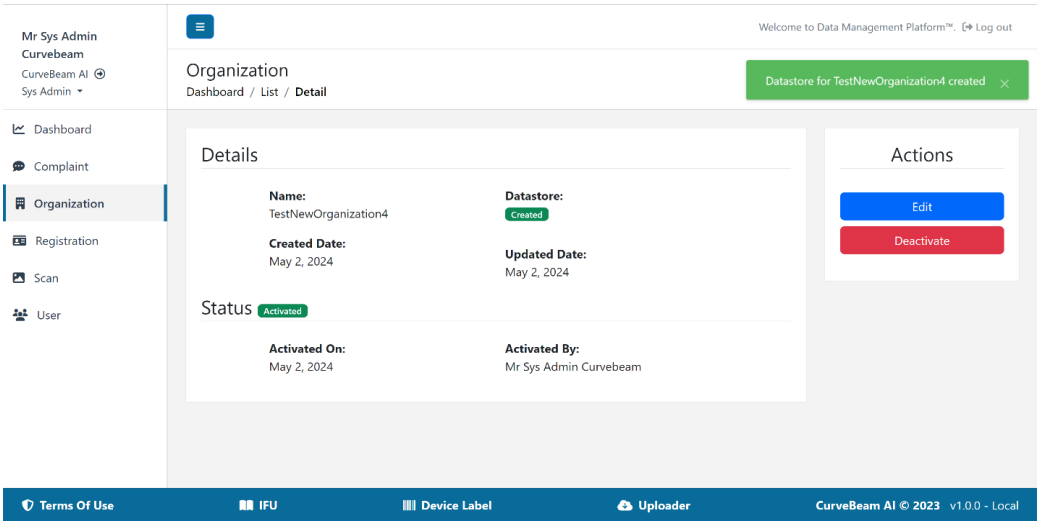
This action is only available for system administrators and organization administrators.

This action is only available if the cloud DICOM datastore has not been previously created.

- Go to the organization detail page for the organization of interest and click the **Create Datastore** button.



- Once the cloud DICOM datastore creation has been processed, a confirmatory notification will pop up. The Datastore status field of the organization detail page will be updated accordingly.



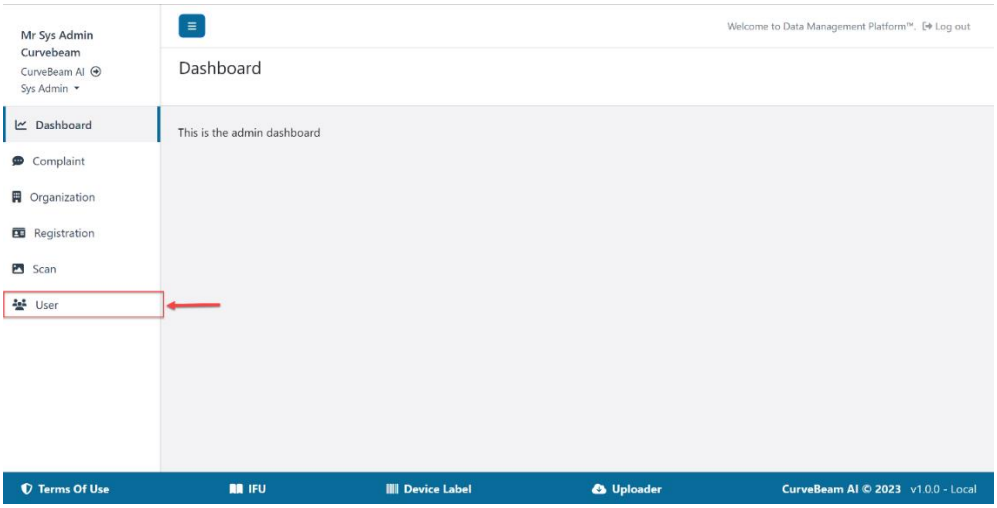
- An automated email will be sent to organization users notifying of the datastore creation.

4.3.7 User

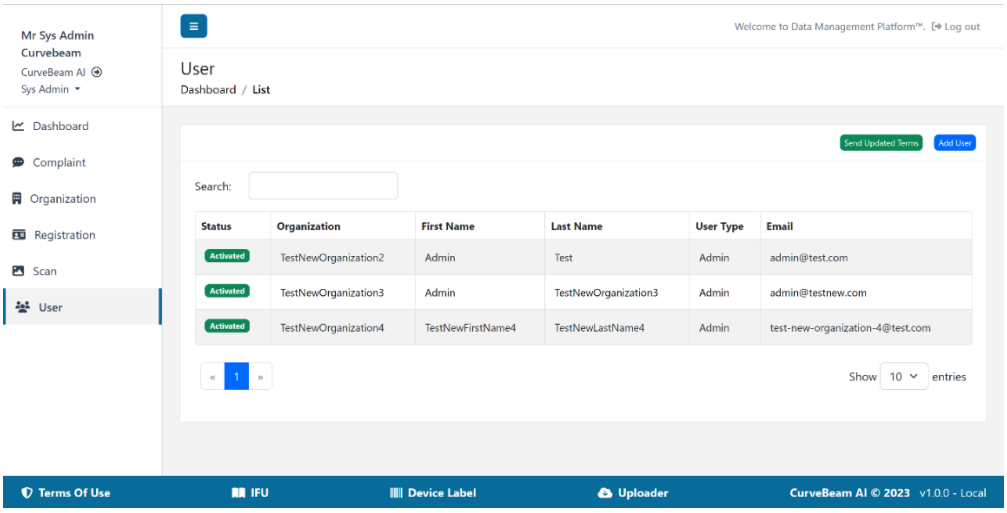
4.3.7.1 View user list

> This action is only available for super admin, system administrators and organization administrator.

- To view the user list, click on **User** on the side panel.



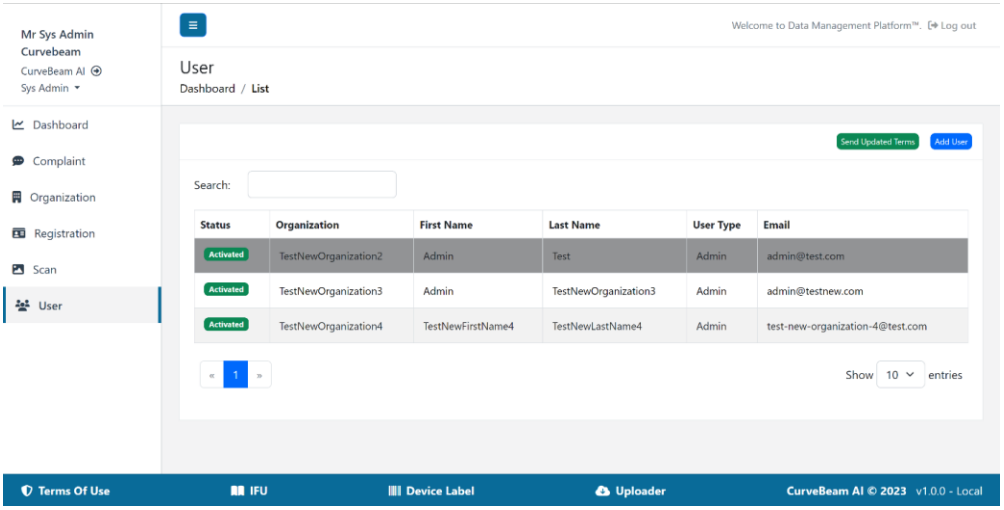
- The user list will be displayed.



4.3.7.2 View user details

This action is only available for super admin, system administrators and organization administrator.

- Go to the user list and click on a user of interest.



- The details of the selected user will be displayed.

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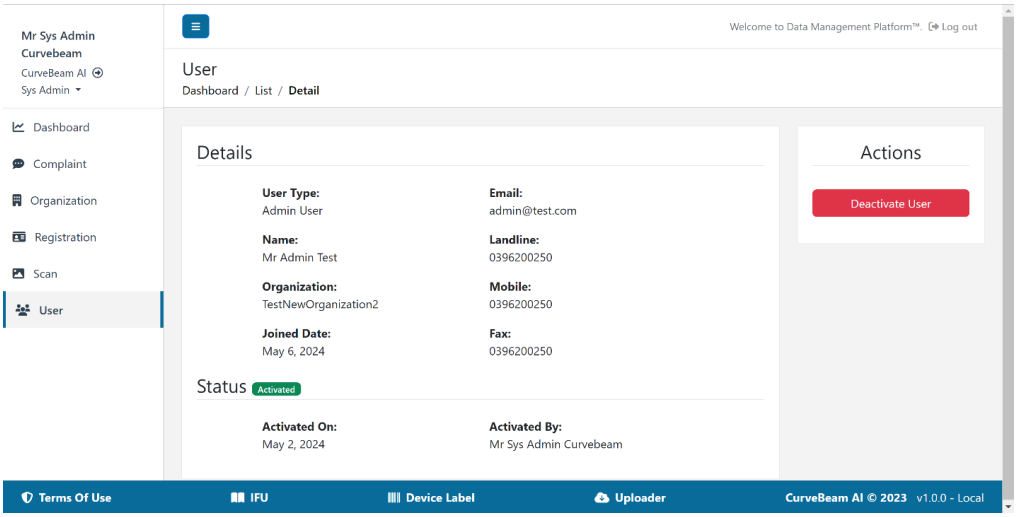
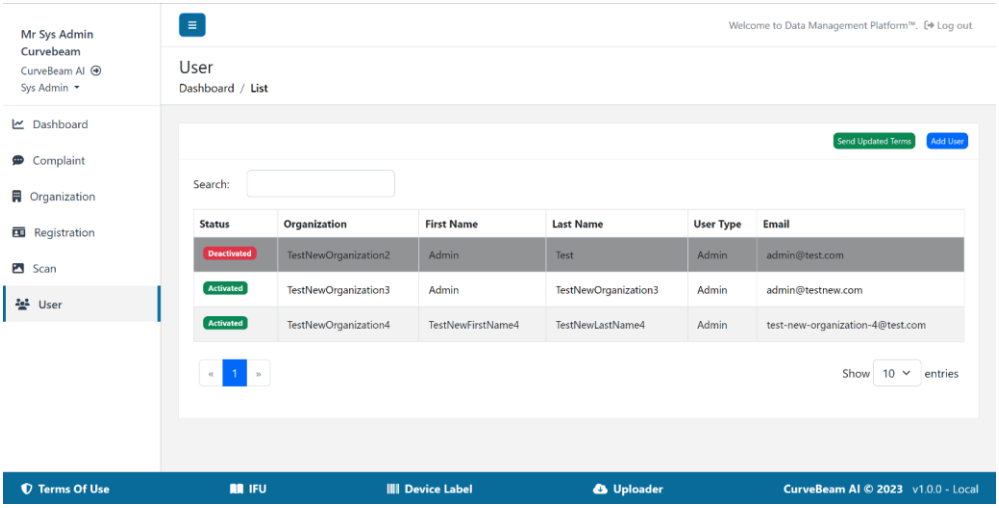


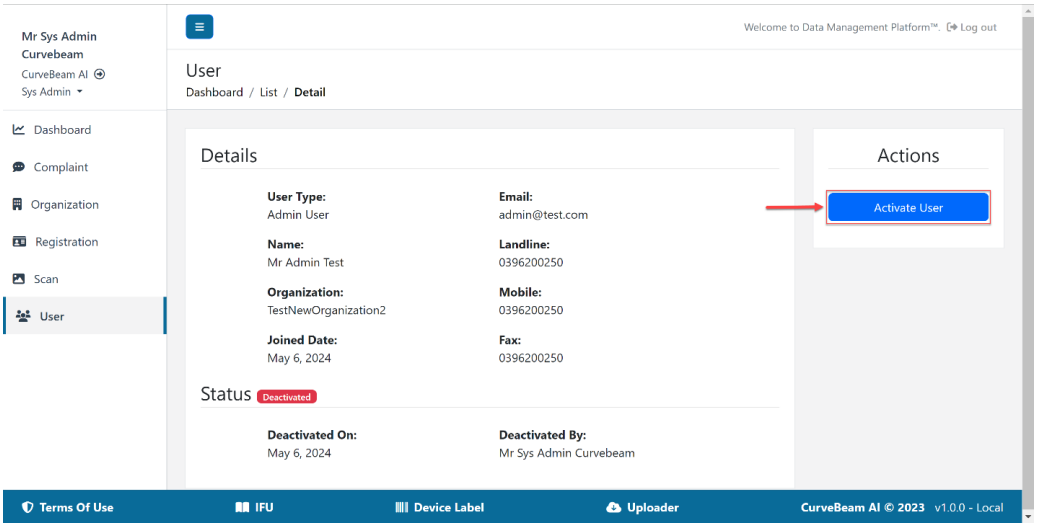
4.3.7.3 Activate users.

This action is only available for super admin, system administrators and organization administrator.

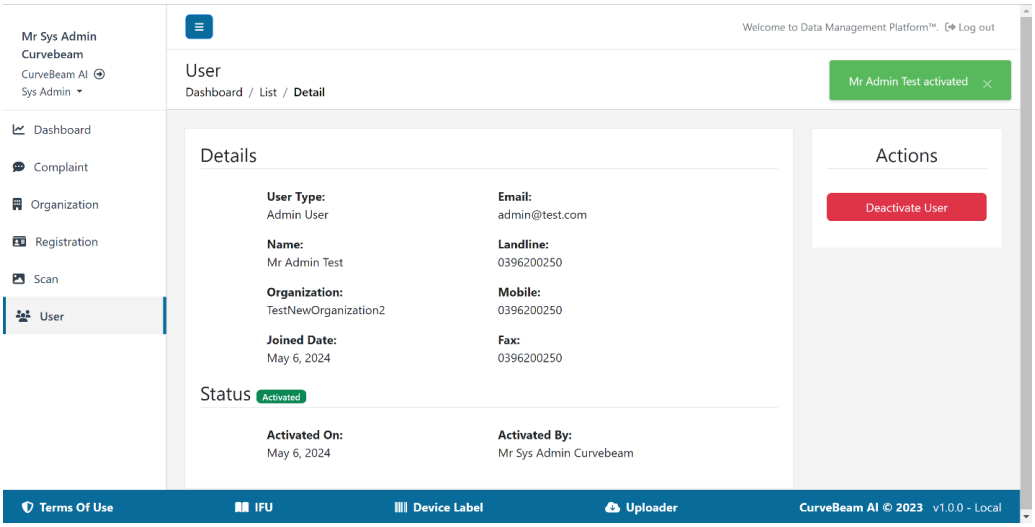
- Go to the user list and click on a user of interest with the `Deactivated` status.



- On the user detail page, click on the **Activate User** button.



- Once the activation has been processed, a confirmatory notification will pop up. The status section of the user detail page will be updated accordingly.

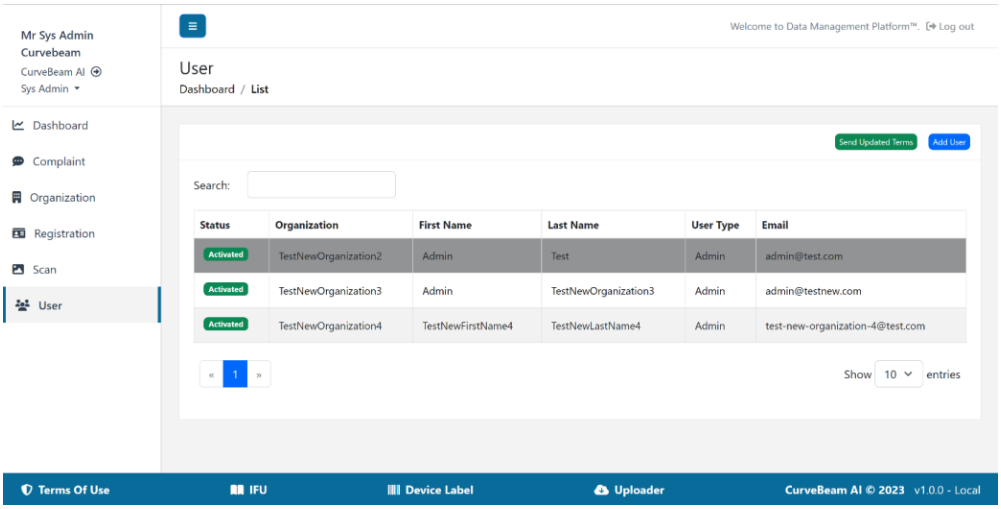


- An automated email will be sent to the user notifying of the activation.

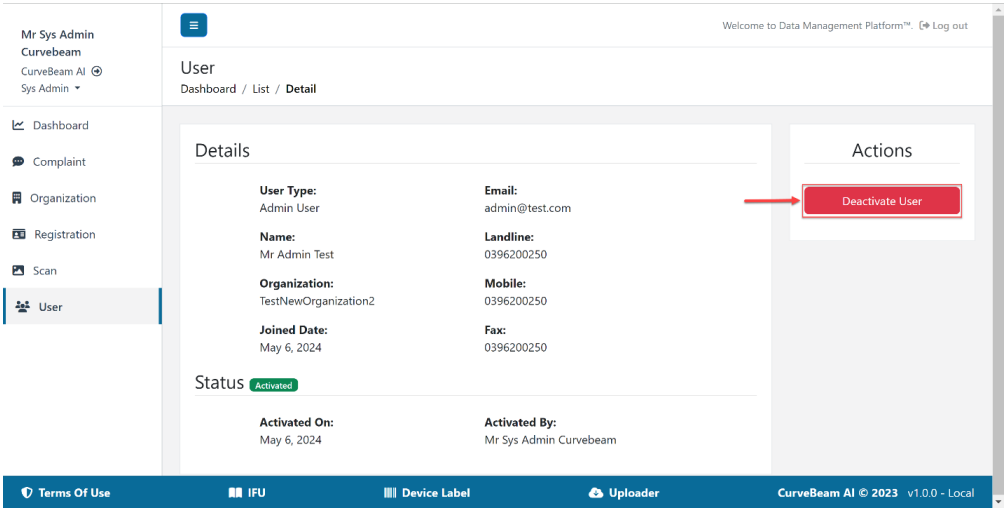
4.3.7.4 Deactivate user.

This action is only available for super admin, system administrators and organization administrator.

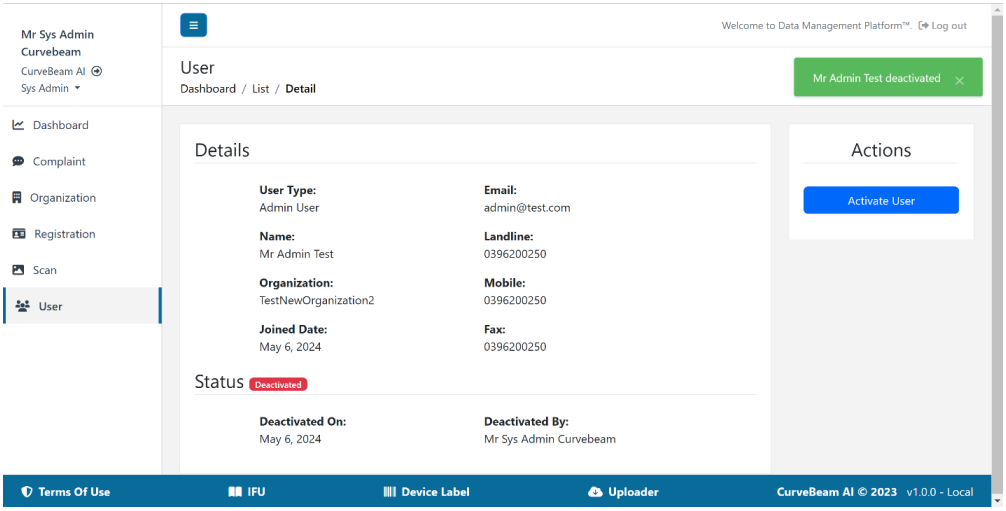
- Go to the user list and click on a user of interest with the `Activated` status.



- On the user detail page, click on the **Deactivate User** button.



- Once the deactivation has been processed, a confirmatory notification will pop up. The status section of the user detail page will be updated accordingly.



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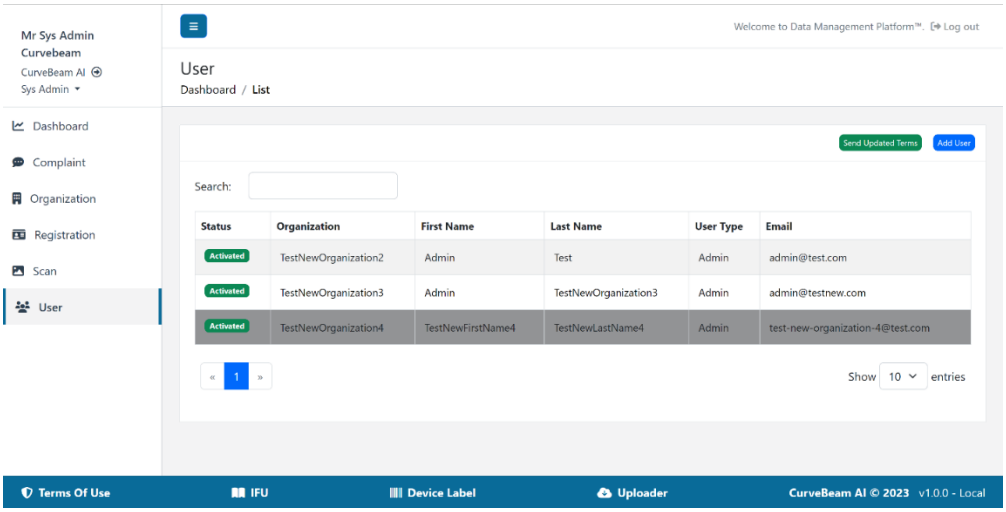
- An automated email will be sent to the user notifying of the deactivation.
- The deactivated user will not be able to log into the DMP.

4.3.7.5 Reset temporary password for user.

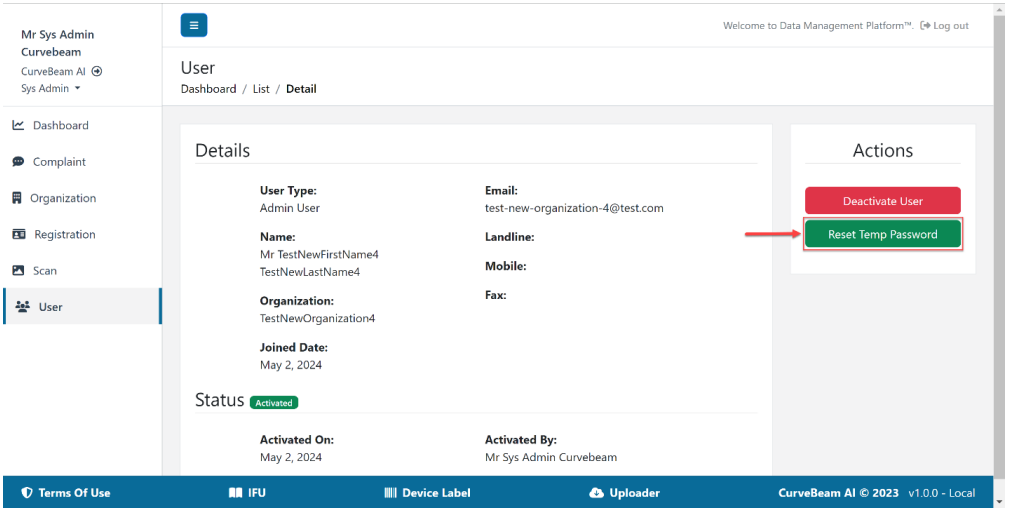
> This action is only available for super admin, system administrators and organization administrator.

> This action is only available if the user of interest has not previously set a permanent password.

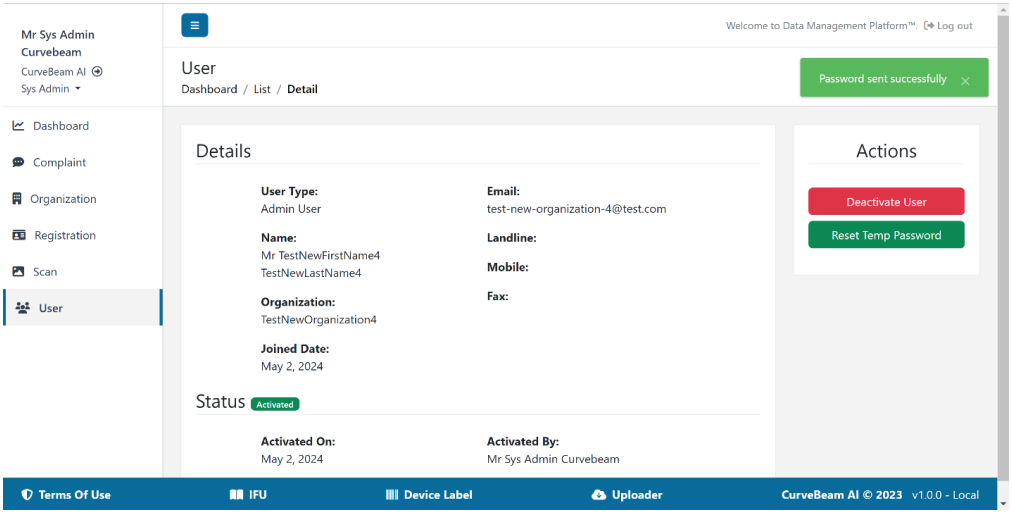
- Go to the user list and click on a user of interest.



- On the user detail page, click on the **Reset Temp Password** button.



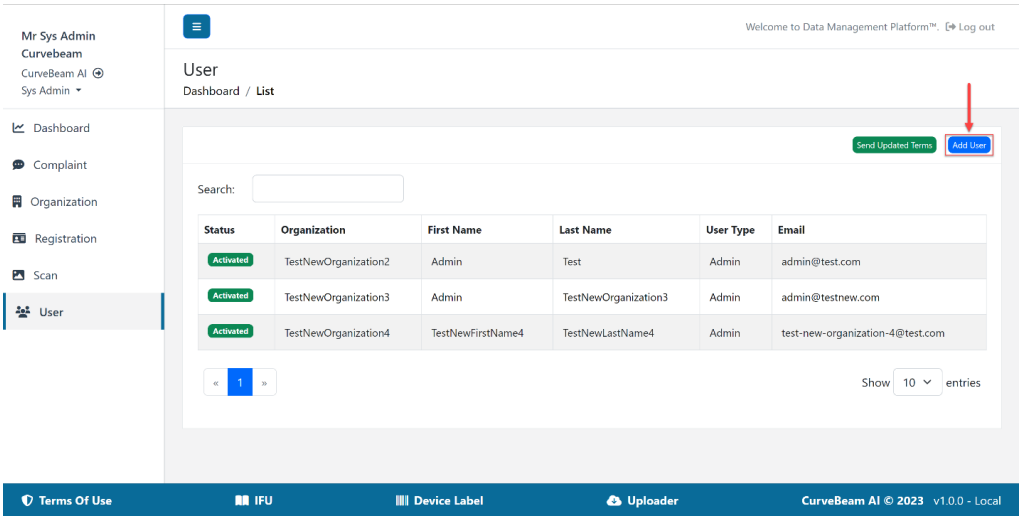
- Once the reset temporary password request has been processed, a confirmatory notification will pop up. An automated email will be sent to the user notifying of their new temporary password.



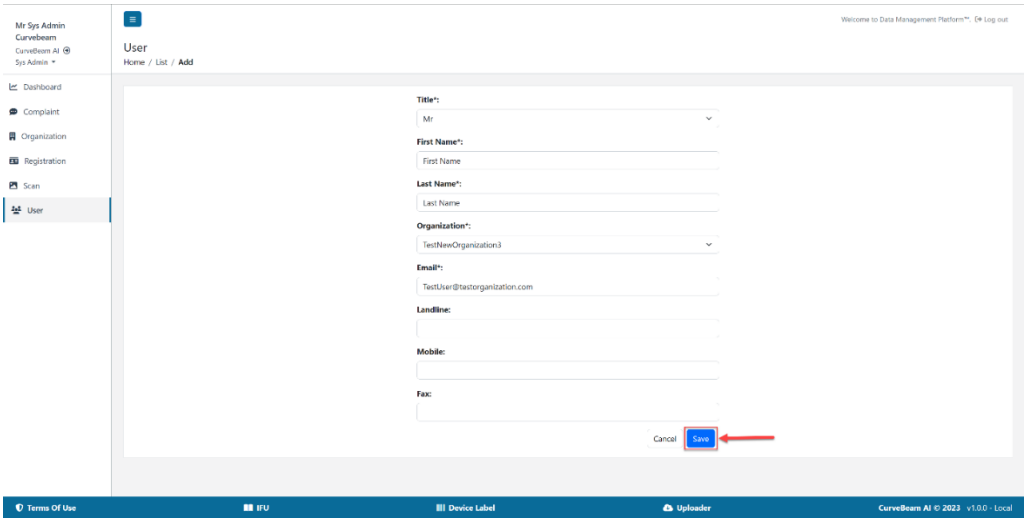
4.3.7.6 Add user.

This action is only available for super admin, system administrators and organization administrator.

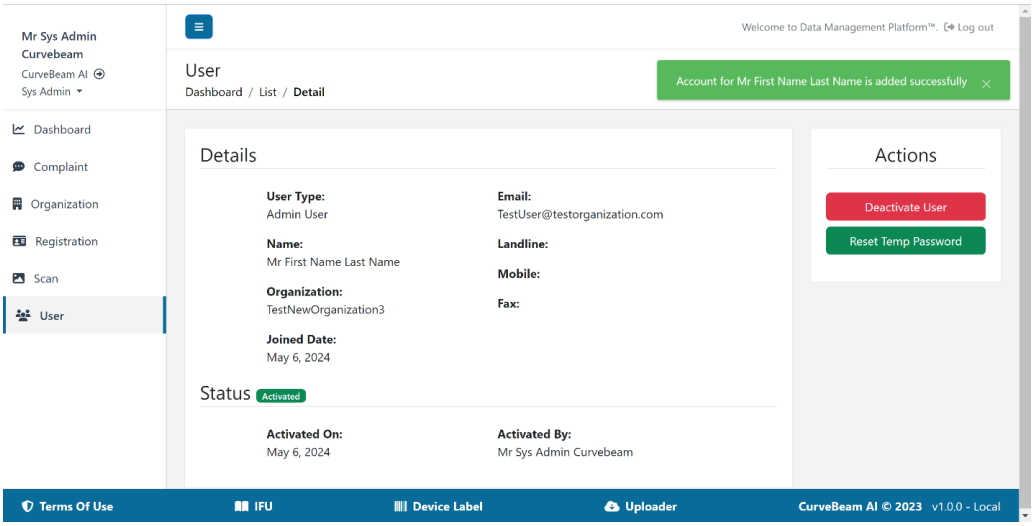
- Go the user list and click on the **Add User** button.



- In the form that appears, fill out the new user details. Once finished, click the **Save** button.



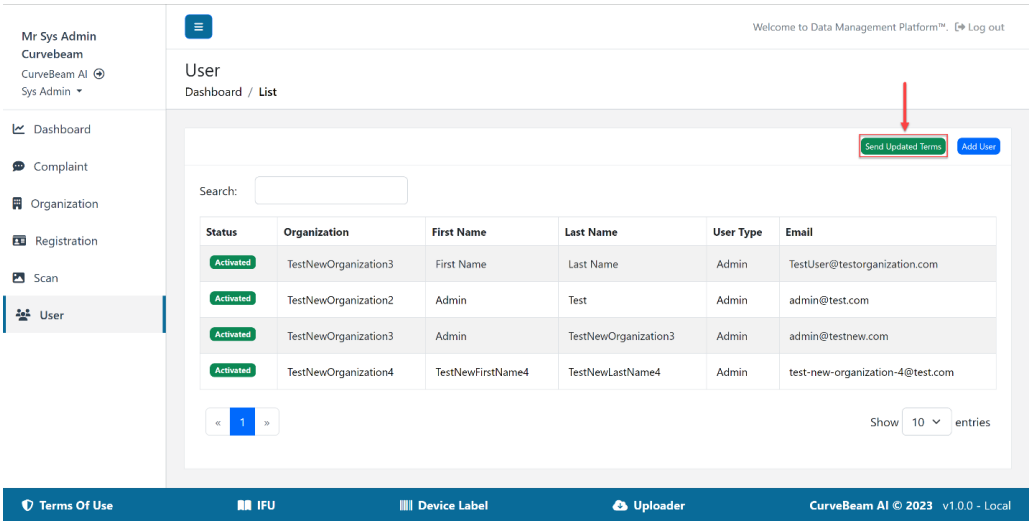
- Once the add user request has been processed, the new user details will appear, and a confirmatory notification will pop up. An automated email will be sent to the new user notifying of their temporary login credentials.



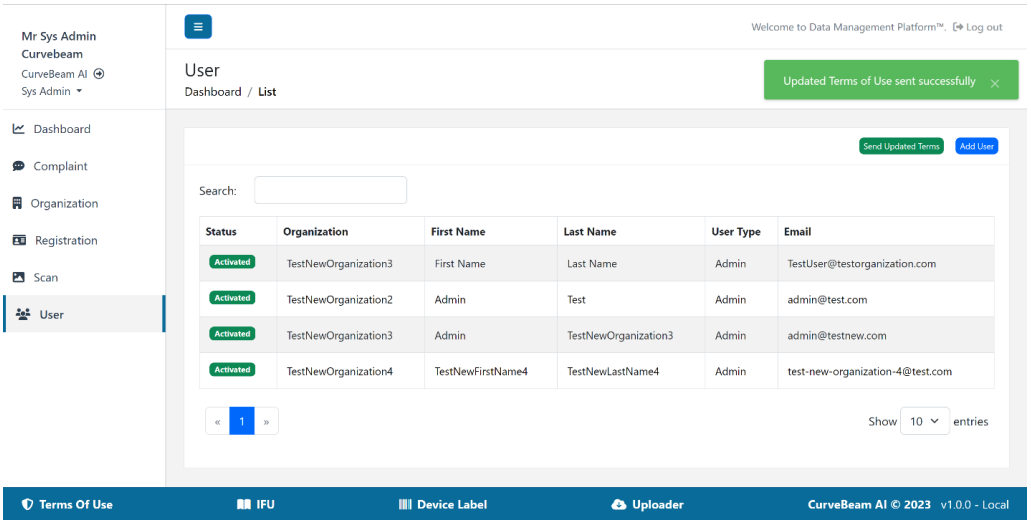
4.3.7.7 Send updated terms of use

This action is only available for system administrators.
This feature is used when terms of use are updated, and this information needs to be shared with all the users.

- Go the user list and click on the **Send Updated Terms** button.



- Once the send updated terms request has been processed, a confirmatory notification will pop up.



4.3.8 Account

4.3.8.1 View profile information

- Click on user role on the side panel.

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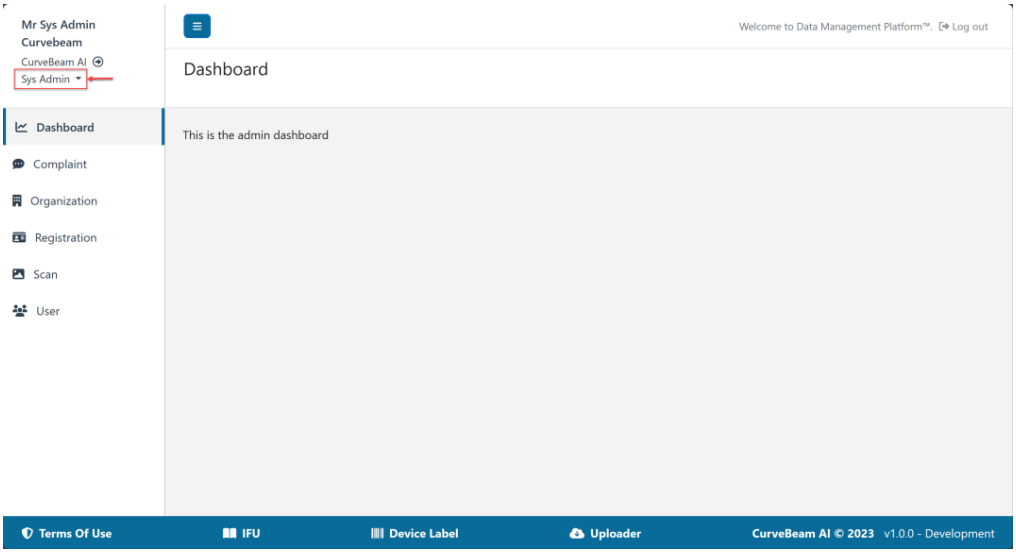
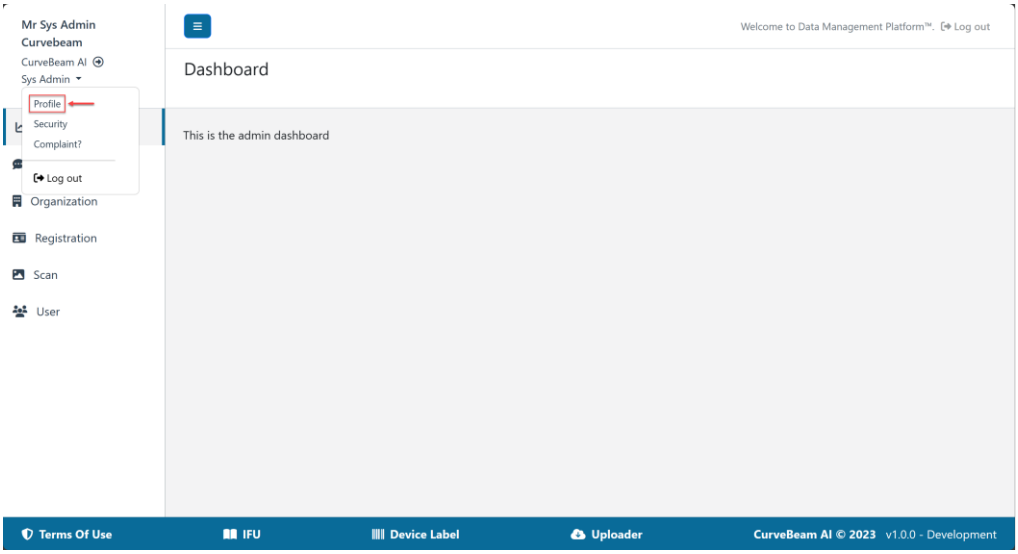


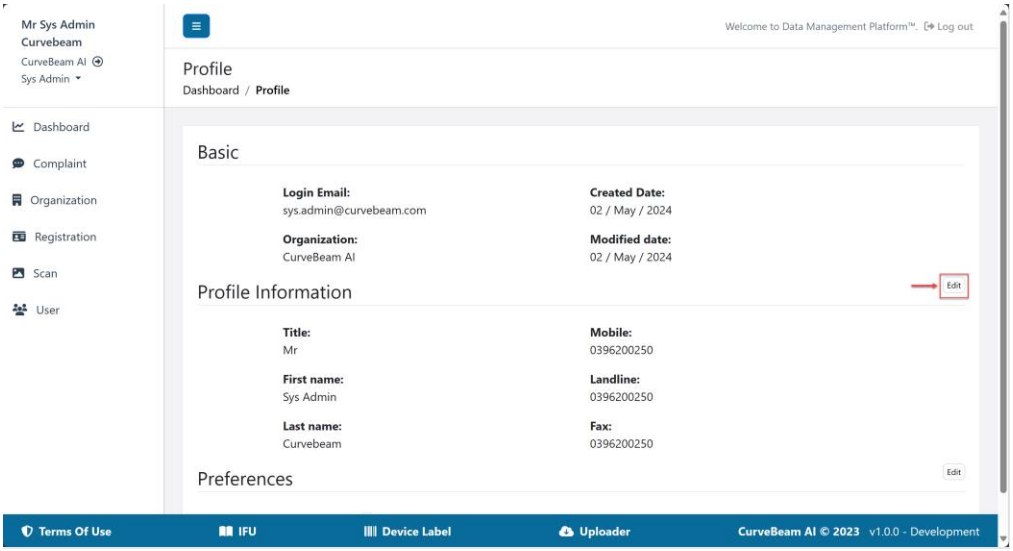
- A dropdown menu will be displayed, click on **Profile**.



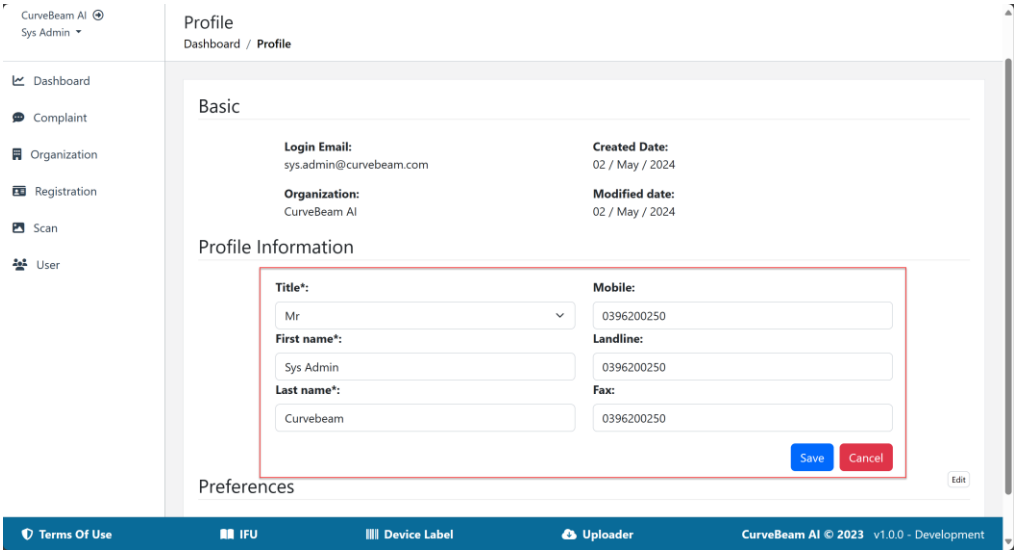
- The profile information will be displayed.

4.3.8.2 Update profile information

- Go to profile information page. In the profile information section, click on **Edit**.



- A form will be displayed with current field values.



- Update the field of interest and click on **Save**.

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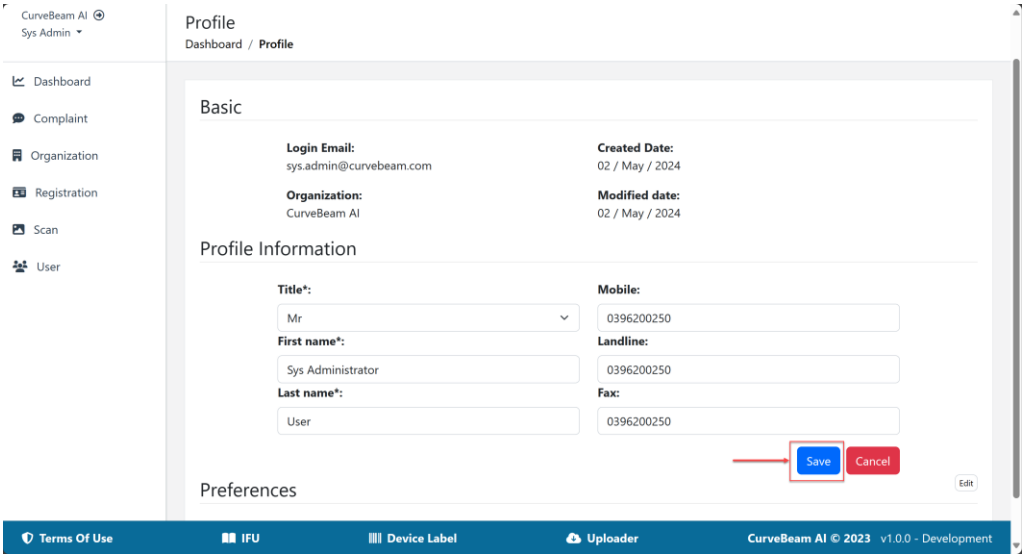
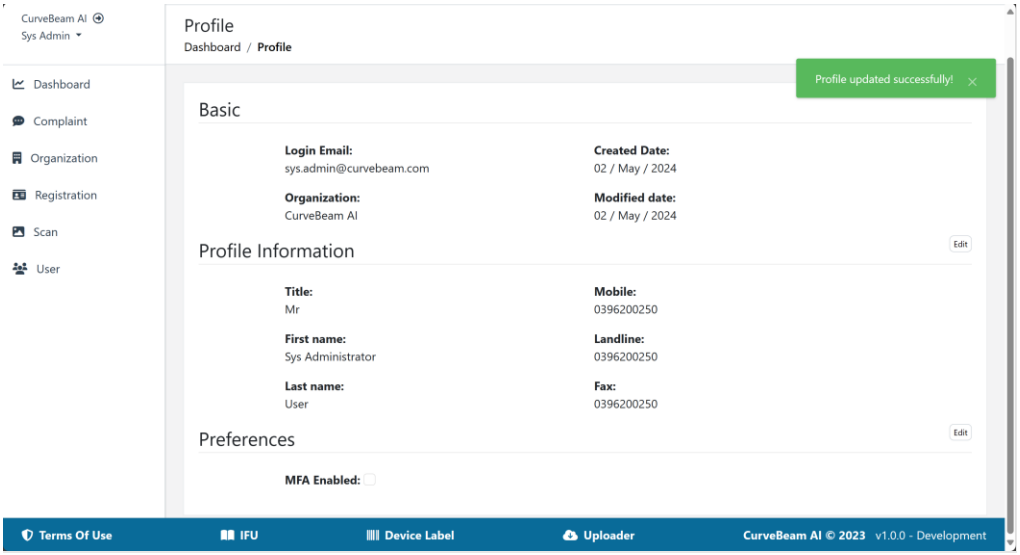
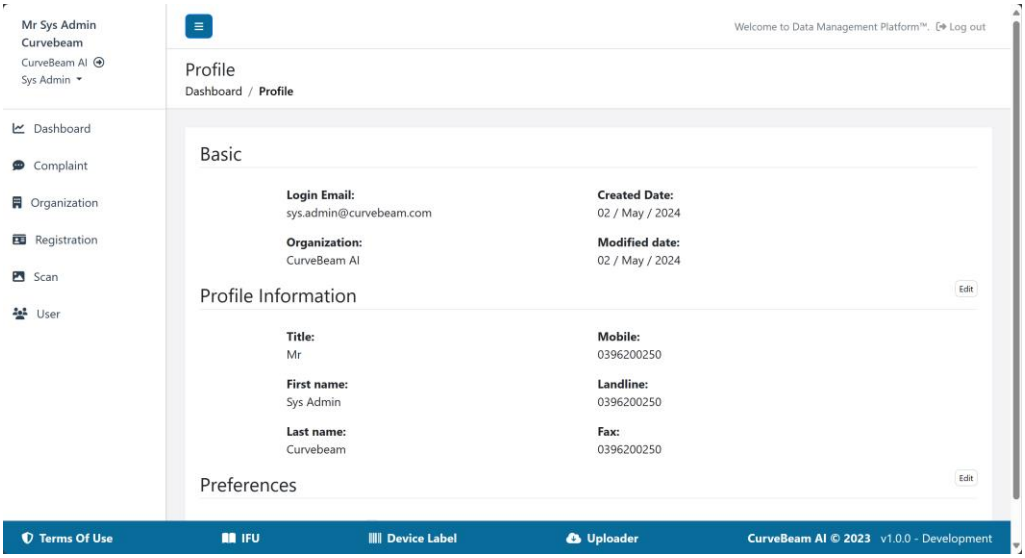


- Once the update has been processed, a confirmatory notification will pop up. The profile information section will be updated accordingly.

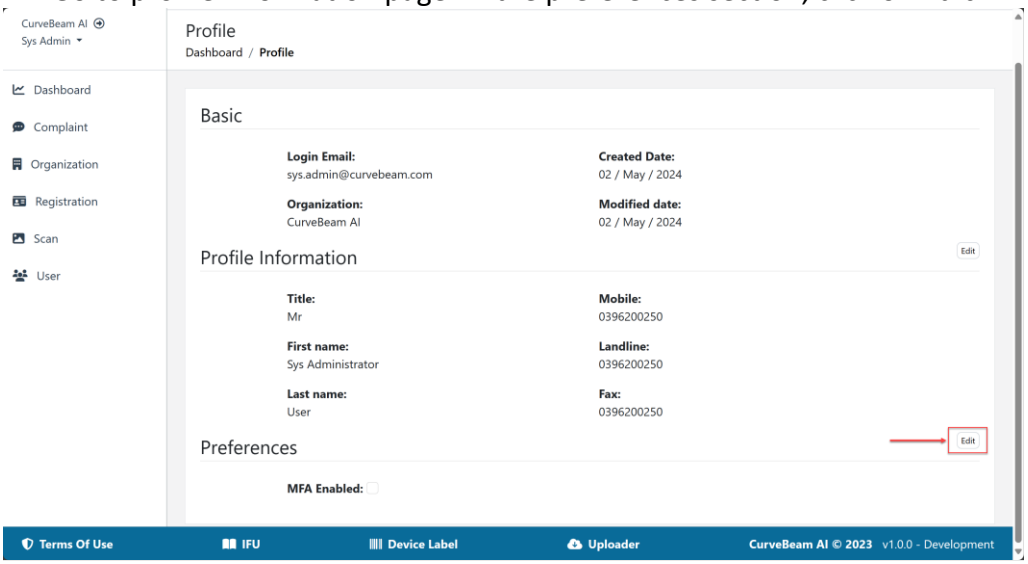


- An automated email will be sent to the user notifying that their profile information has been updated.

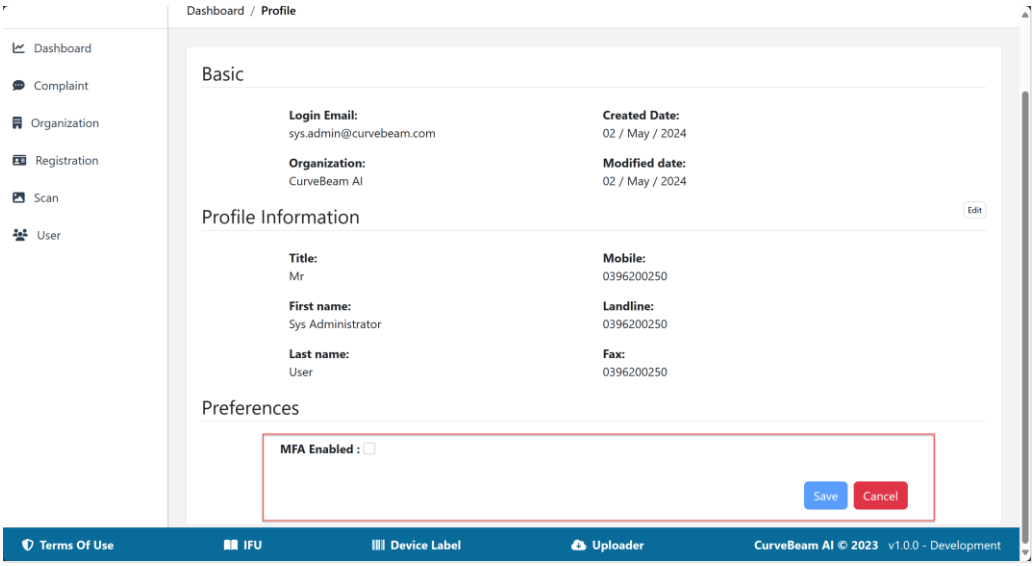


4.3.8.3 Update Multi-Factor Authentication (MFA) preference

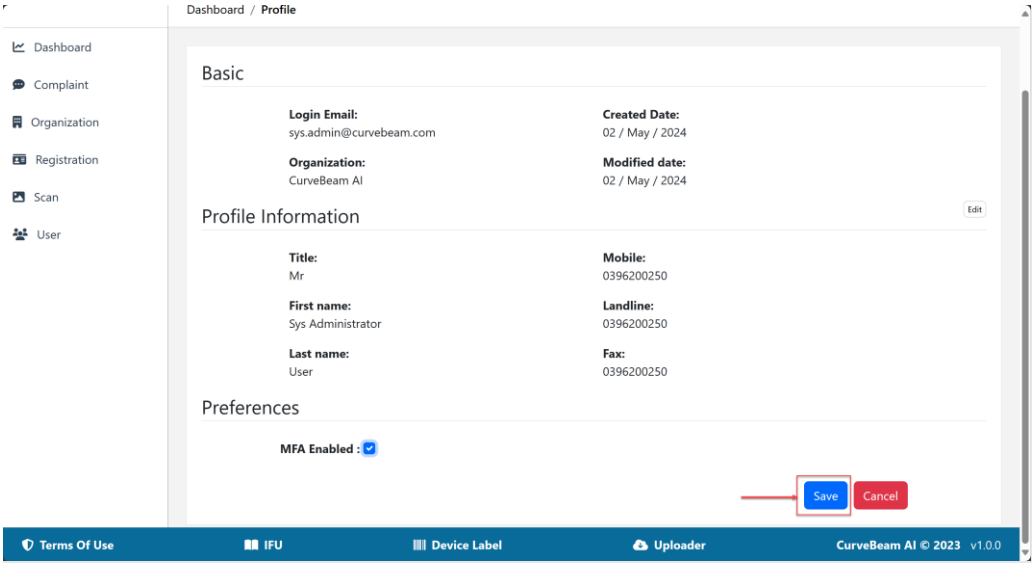
- Go to profile information page. In the preferences section, click on **Edit**.



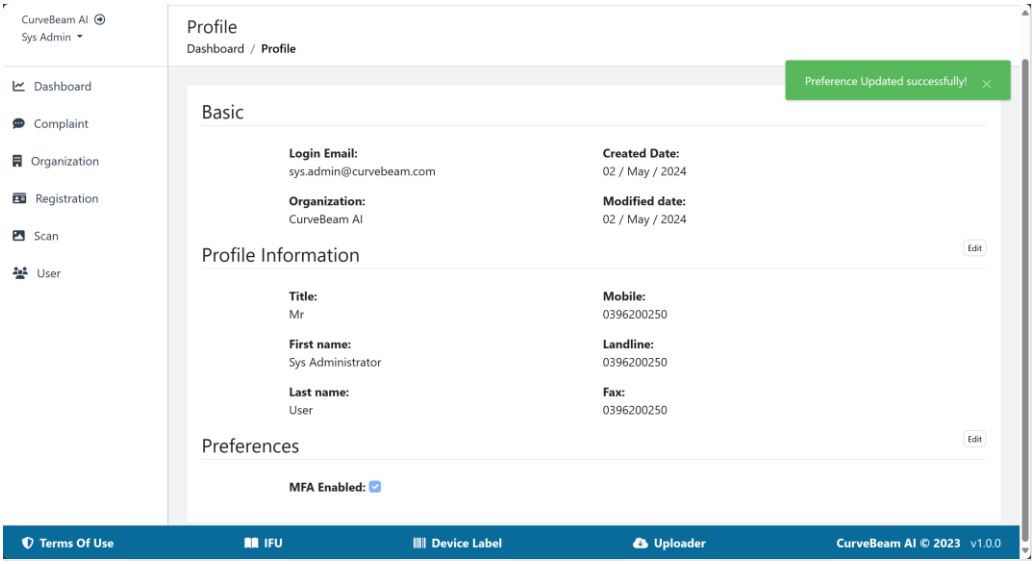
- A form will be displayed with the current MFA Enabled value.



- Update the field and click on **Save**.

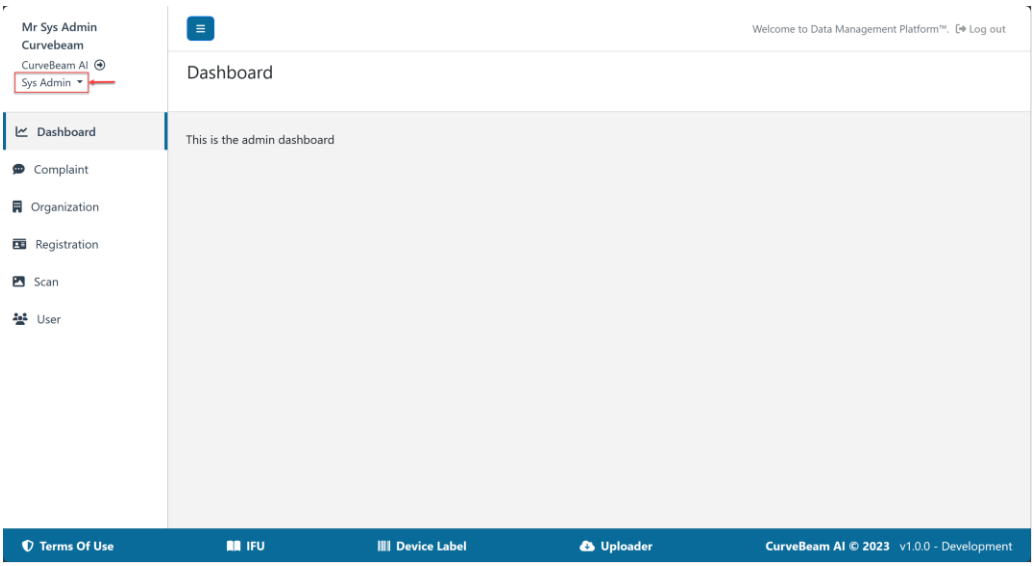


- Once the update has been processed, a confirmatory notification will pop up. The preferences section will be updated accordingly.

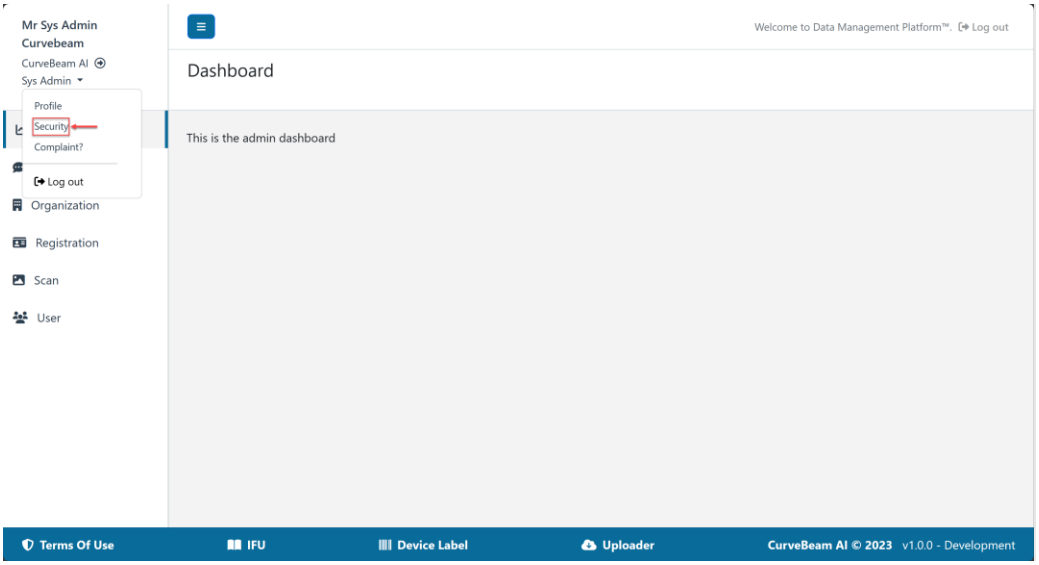


4.3.8.4 Change password

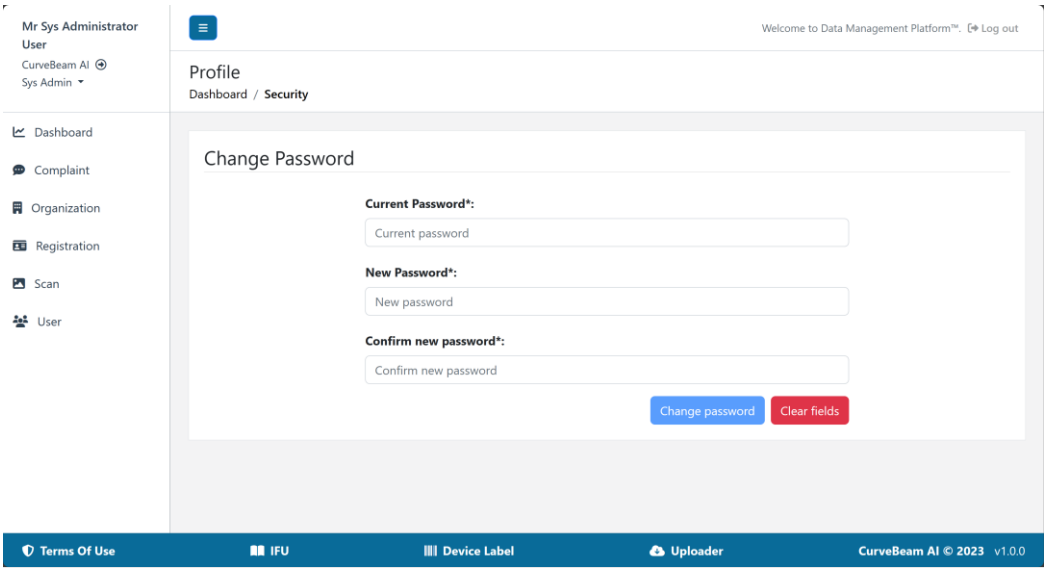
- Click on user role on the side panel.



- A dropdown menu will be displayed, click on **Security**.



- A change password form is displayed.



- Fill in the current password, new password and confirm password fields and click on **Change password**.

Important

The password required must meet the following conditions.

- Should be at least 12 characters long.
- Have at least 1 lowercase character
- Have at least 1 uppercase character
- Have at least 1 number
- Have at least 1 special character

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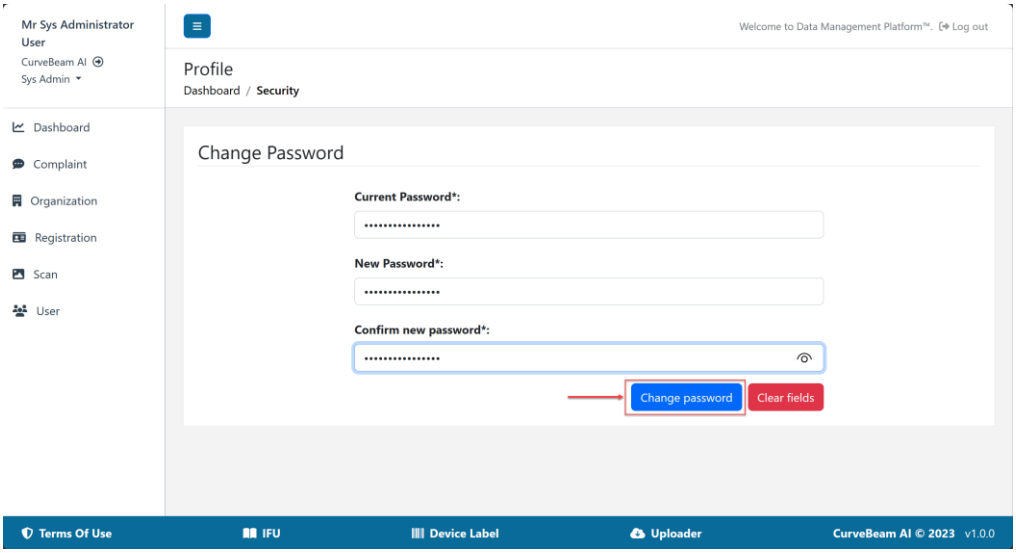
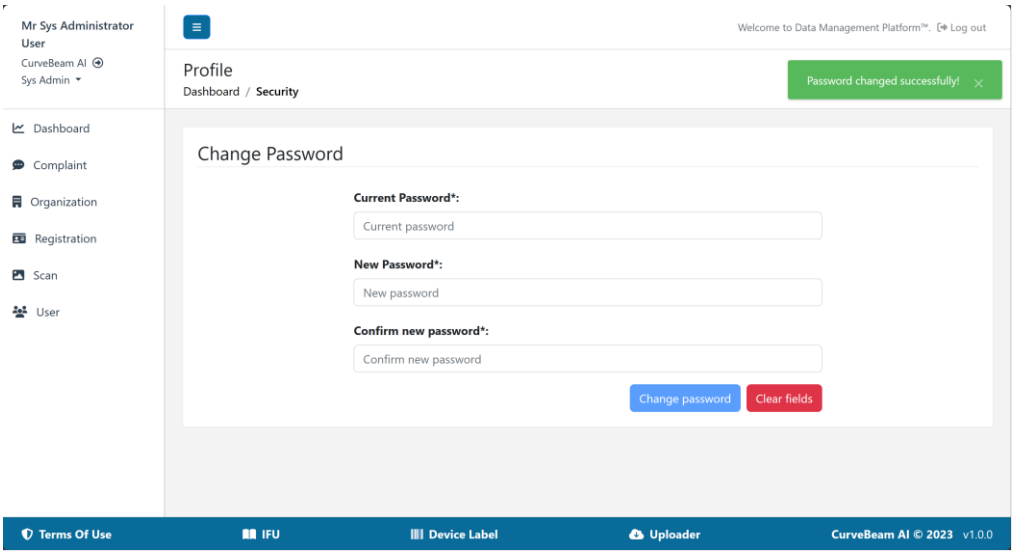


- Once the update has been processed, a confirmatory notification will pop up.

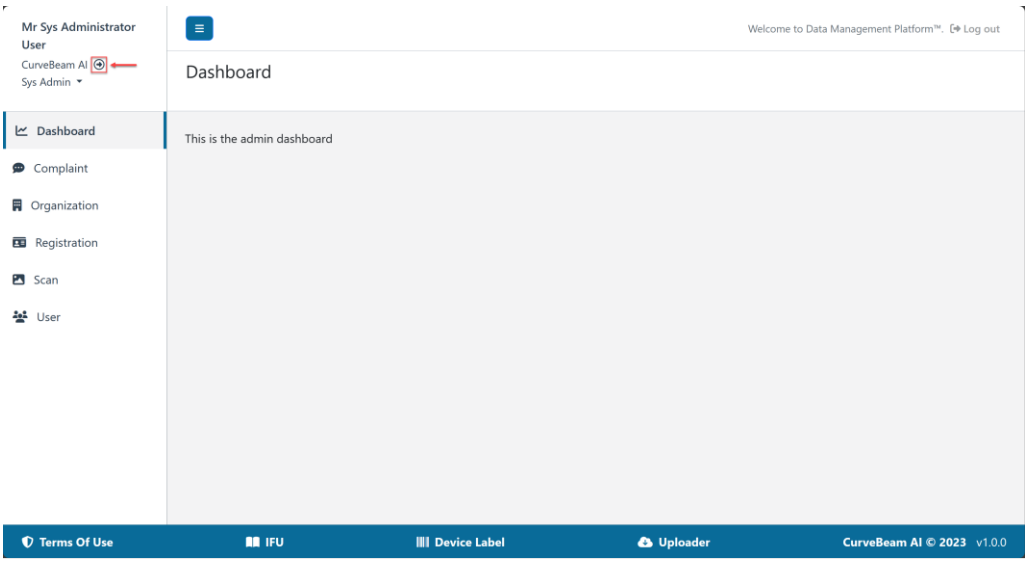


- An automated email will be sent to the user notifying that their password has been updated.

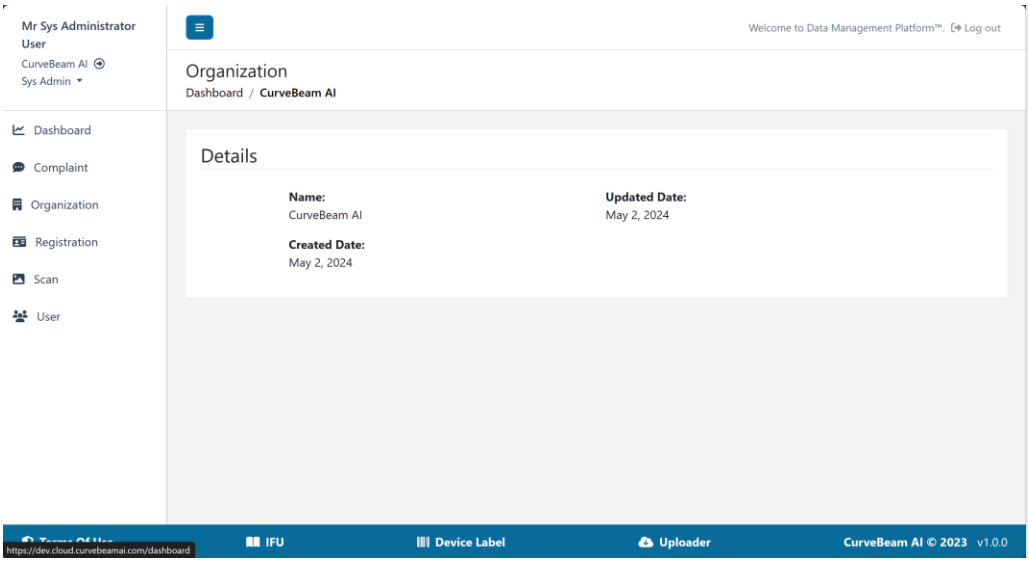
4.3.8.5 View own organization details

> This action is only available for organization administrators and staff users.

- Click on the arrow next to the Organization name.



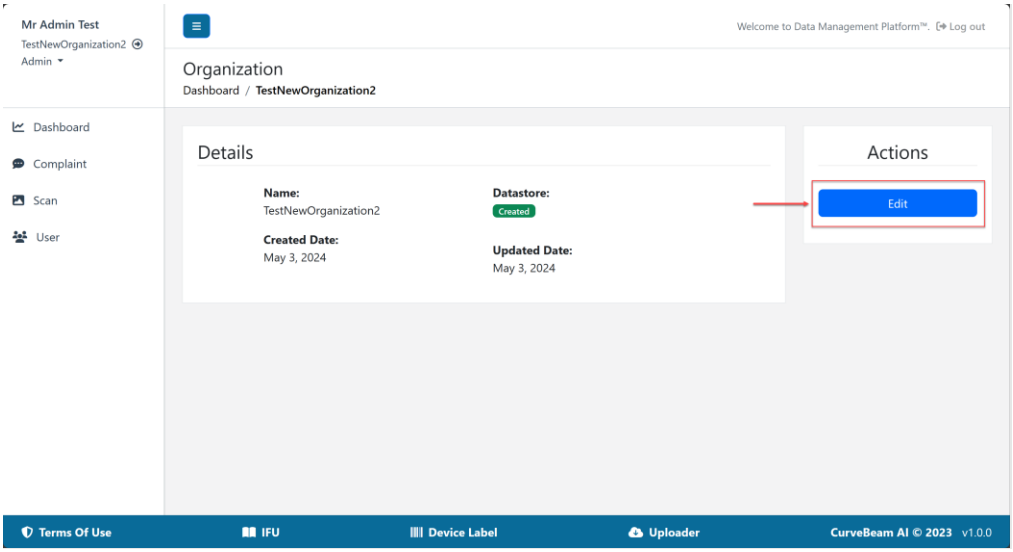
- The details of the organization will be displayed.



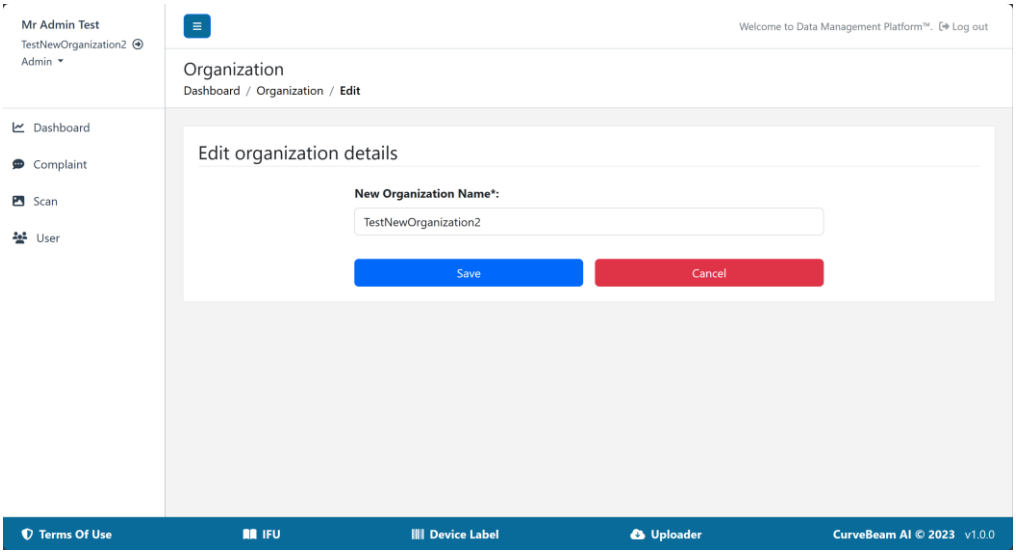
4.3.8.6 Update own organization details

This action is only available for Organization Administrators.

- Go to your own organization details and click on **Edit**.



- A form is displayed with current organization name.



- Update the organization name and click on **Save**.

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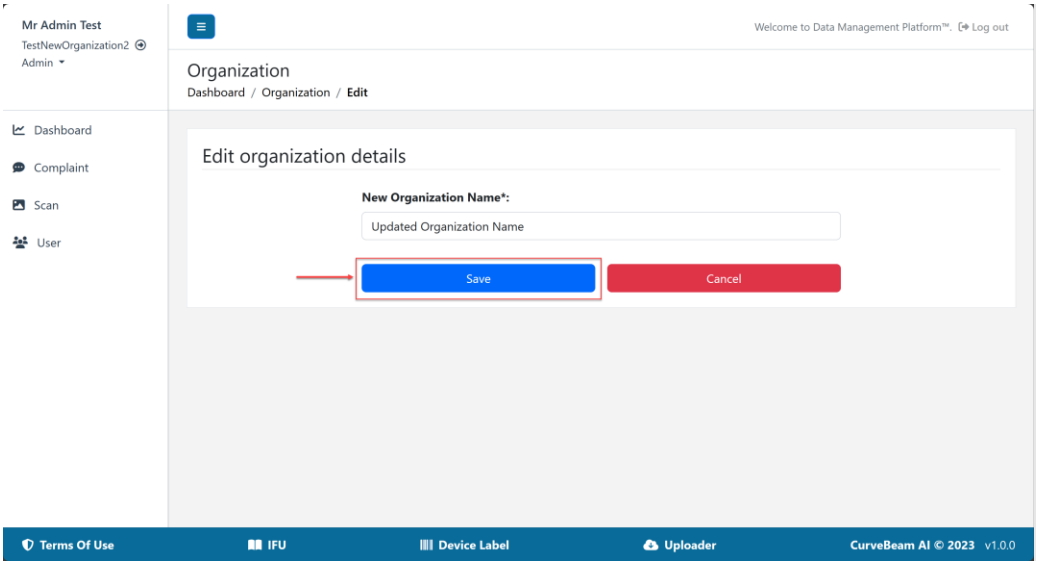
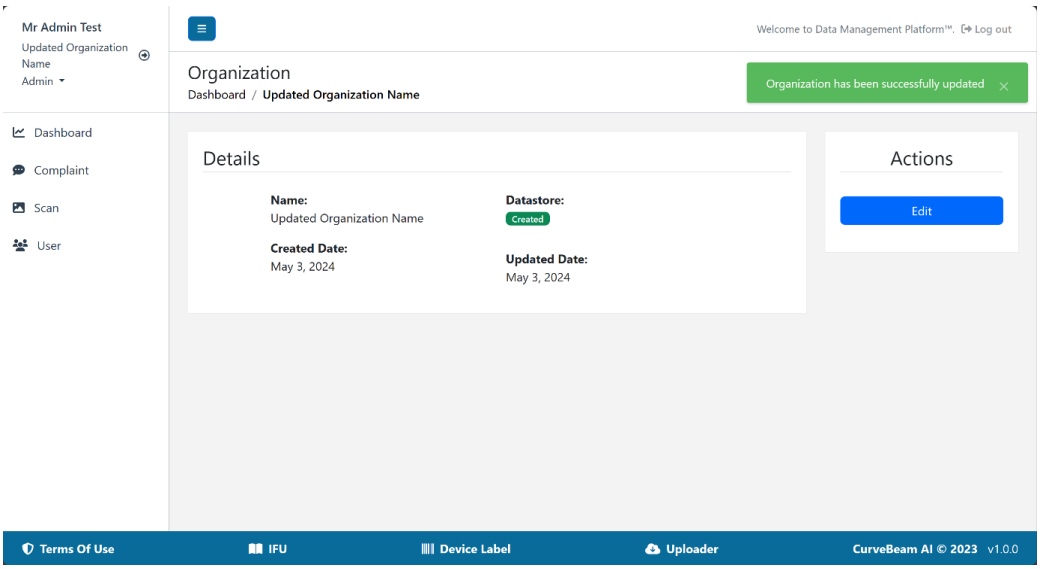


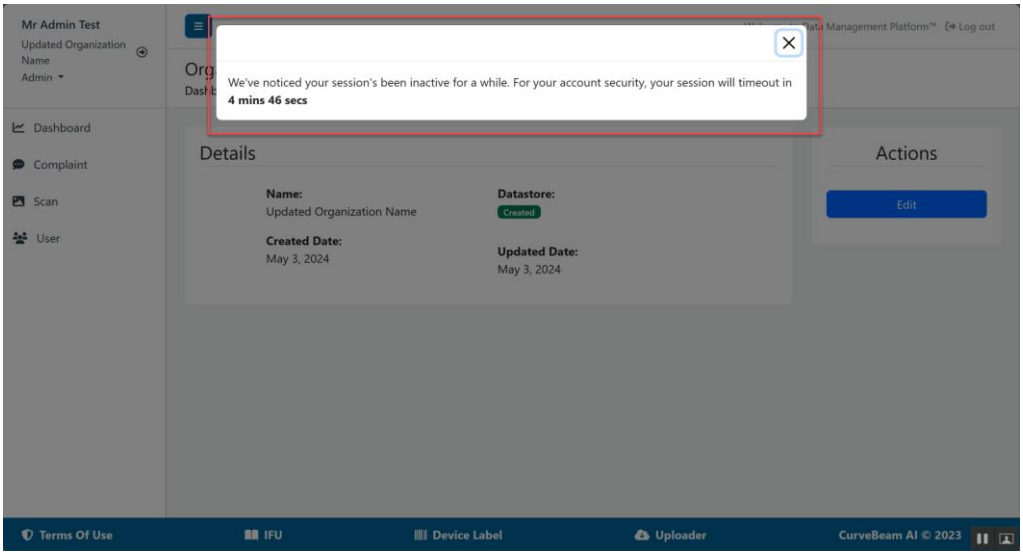
- Once the update has been processed, a confirmatory notification will pop up. The organization details page will be updated accordingly.



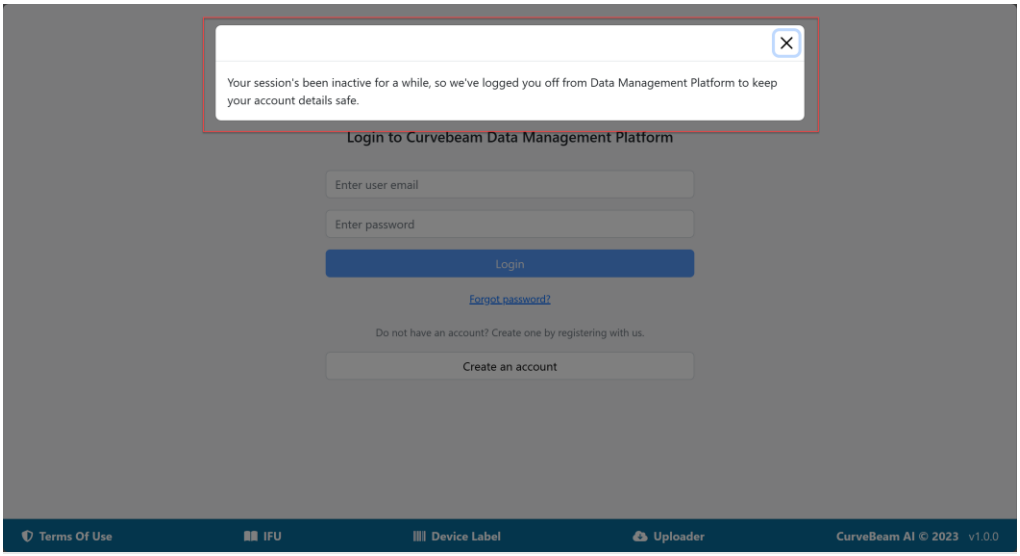
- An automated email will be sent to all the users of the organization notifying that their organization information has been updated.

4.3.8.7 Auto logout

- If you are not actively interacting with the application for more than 10 minutes, a modal will pop up displaying a warning message with a 5-minute countdown.

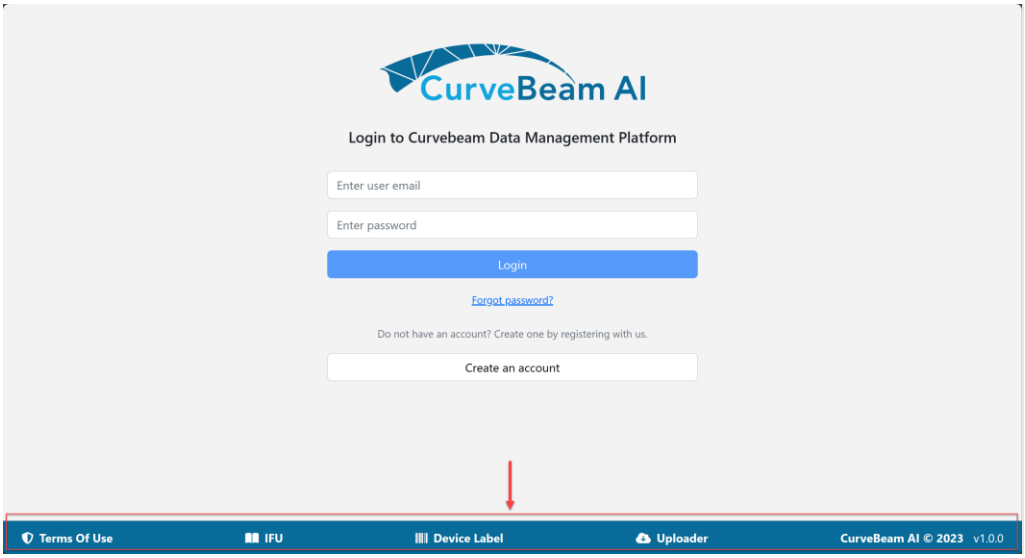


- If you do not interact with the application in the given 5-minute countdown, you'll be logged out and taken to the login screen. The modal pop up will display an appropriate message.

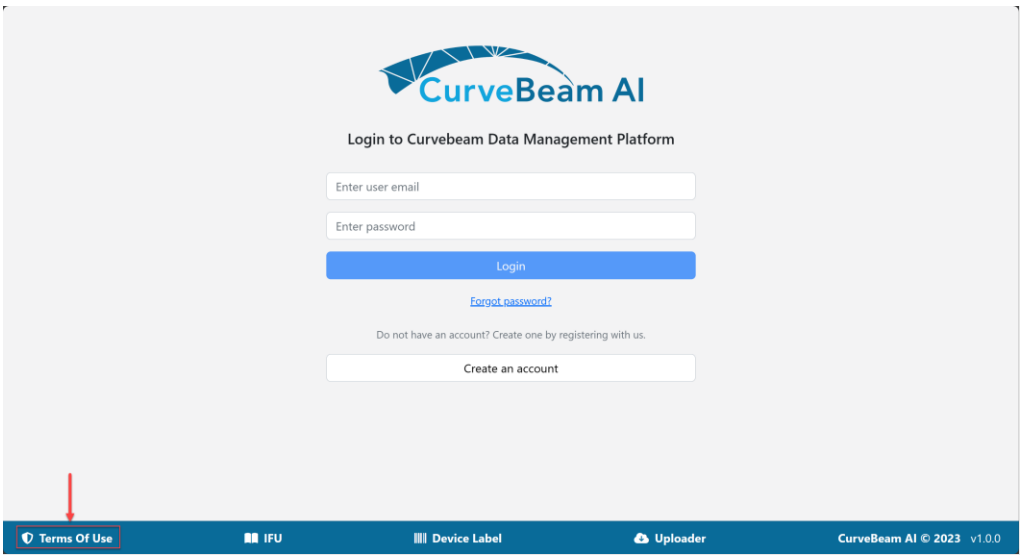


4.3.8.8 Access to Terms of Use

- The Terms of Use are available on the application footer. To view the Terms of Use, click on the option – Terms of Use.



- On footer of the application, Click on **Terms of Use**.



- You will be taken to the CurveBeam AI - Terms of Use page.

4.3.8.9 Access IFU

The IFU is available on the DMP application footer. To view the IFU click on the option highlighted below.

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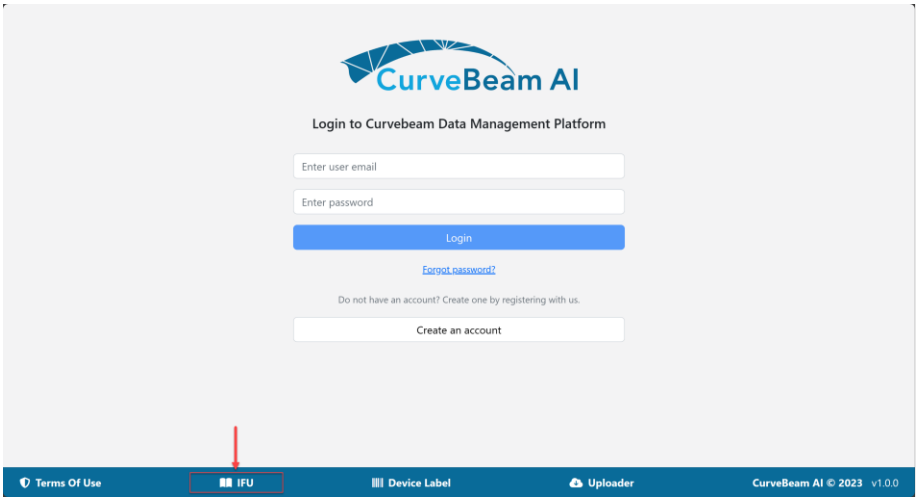
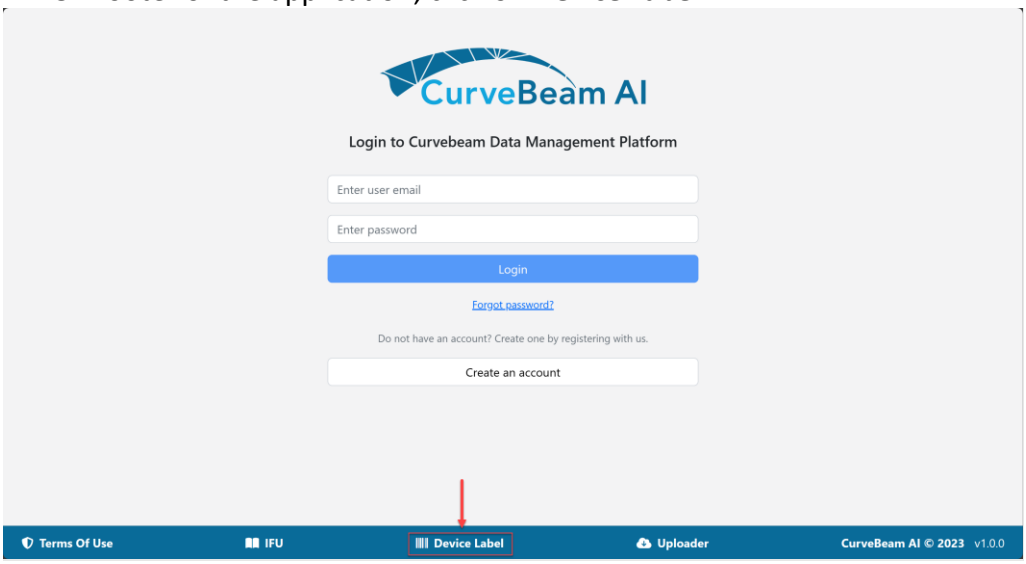


- You will be taken to CurveBeam AI IFU page.

4.3.8.10 Access device label

The Device Label is available on the DMP application footer. To view the Device Label, click on the option.

- On footer of the application, click on **Device Label**.

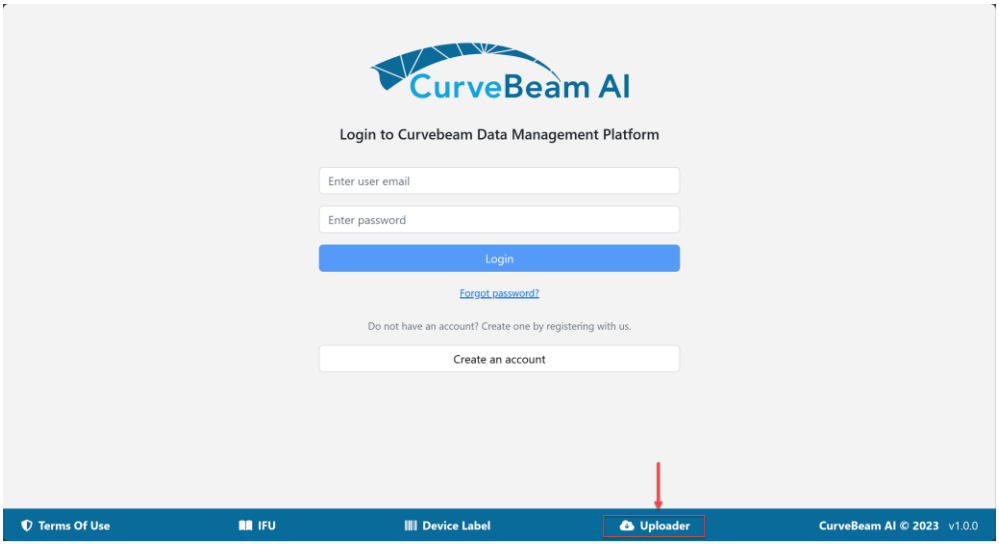


- A modal will pop-up displaying the device label.

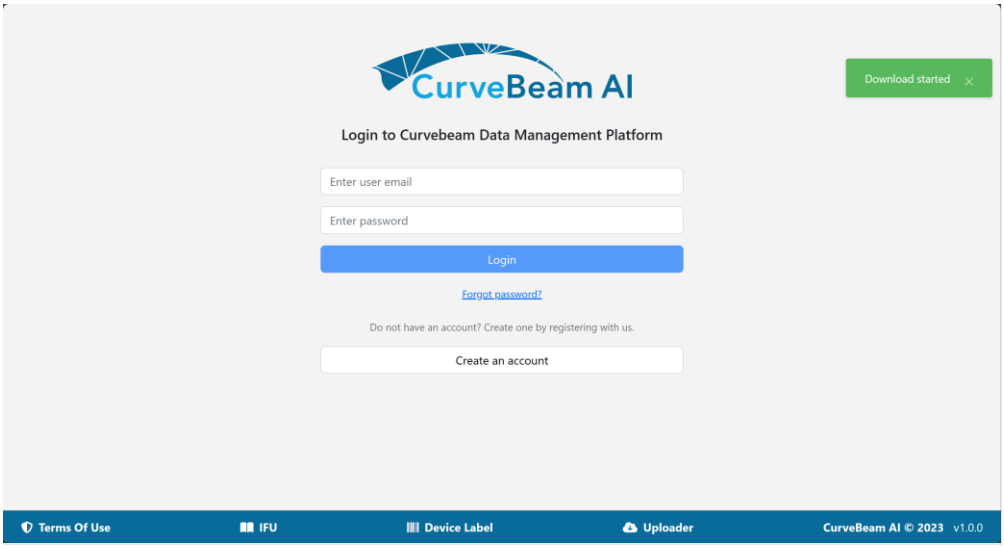
4.3.8.11 Download the uploader app.

The option to download the uploader app is available on the application footer. To download, click on the option.

- On footer of the application, click on **Uploader**.



- A confirmatory notification will pop-up and the download will start.



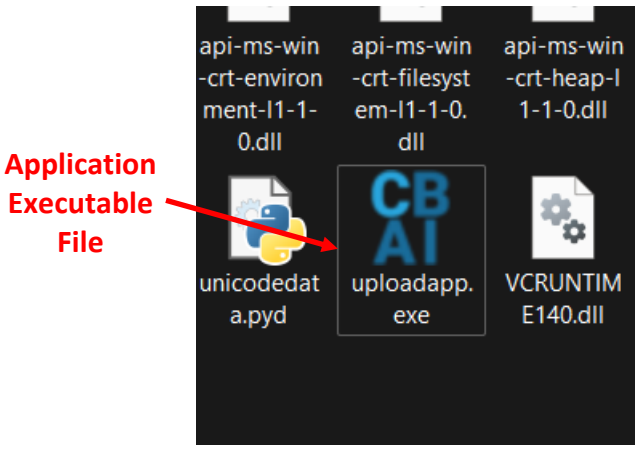
4.4 Uploader Application

4.4.1 Launching the Application

The application for uploading files will be provided in the form of a zip file.

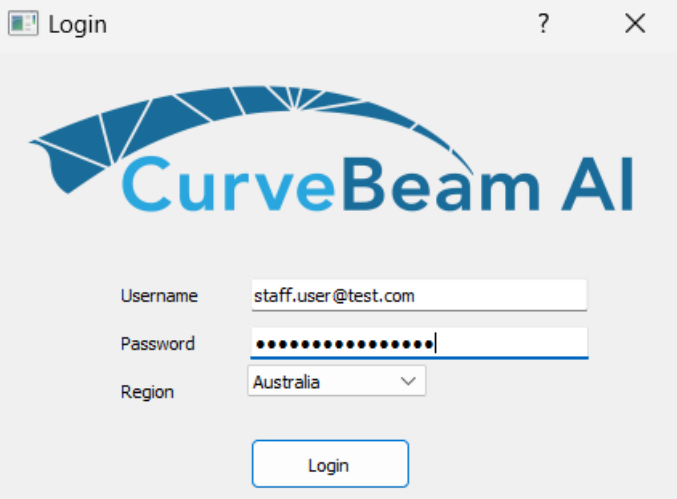
Steps to launch the application:

- Extract the contents of the zip file (**uploadapp.zip**) to a designated location.
- Upon extraction, a new folder with identical name as the zip file (**uploadapp**)
- will be generated.
- Navigate into this folder and locate the executable file named **uploadapp.exe**.



4.4.2 Login UI

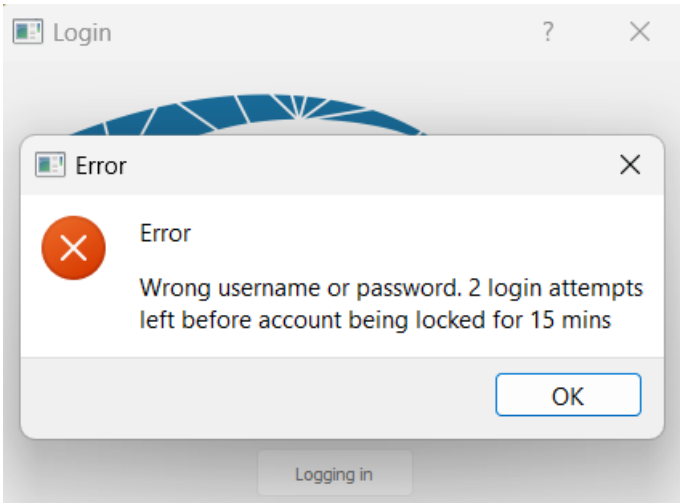
When the user opens the upload application, the initial window one encounters is the **login UI, as** shown below.



To log in, follow these steps:

- Select the region from the drop-down menu.
- Enter the username and password.
- Click the Login button.

If an incorrect password is entered, the application will allow the user two additional attempts before locking the account for 15 minutes.

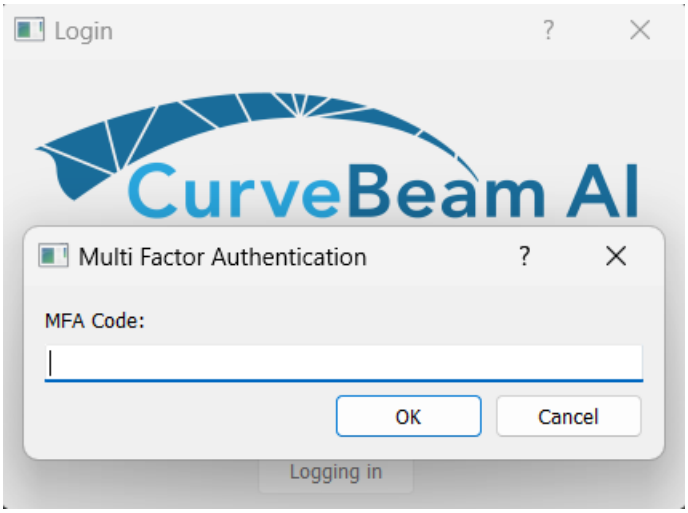


4.4.2.1 MFA Disabled

If the user has disabled the Multi-Factor Authentication (MFA), they will be able to log into the main window for uploading.

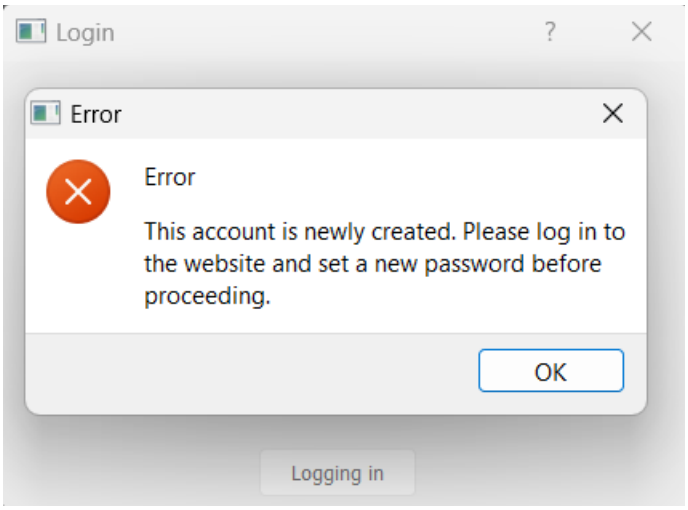
4.4.2.2 MFA Enabled

If MFA is enabled on the user account, the application will prompt the user for the MFA window during login. The MFA code will be sent to the email address provided when the account was created.



4.4.2.3 New User Login

When a new account is created, a default password will be assigned and sent to the email address. If the user tries to log into the application using this password, the following error will be displayed.



4.4.3 Main UI Window

The main window includes the following features, each of which will be elaborated on in subsequent sections:

- **Folder Selection** – This feature enables users to select the folder containing DICOM slices and upload them to the cloud using the **Folder** and **Upload** buttons.
- **Selection Window** – Users can view a list of scans to be uploaded along with details such as **series ID**, **upload status**, and **slice count**.
- **Anonymization Toggle** – Users can activate or deactivate the anonymization function using the **checkbox**. The **custom button** allows for the customization of anonymization settings.
- **Tag Section** – In this section, users can view the tags that will be added to the scan post-upload. Tags can be edited using the **Modify button**.

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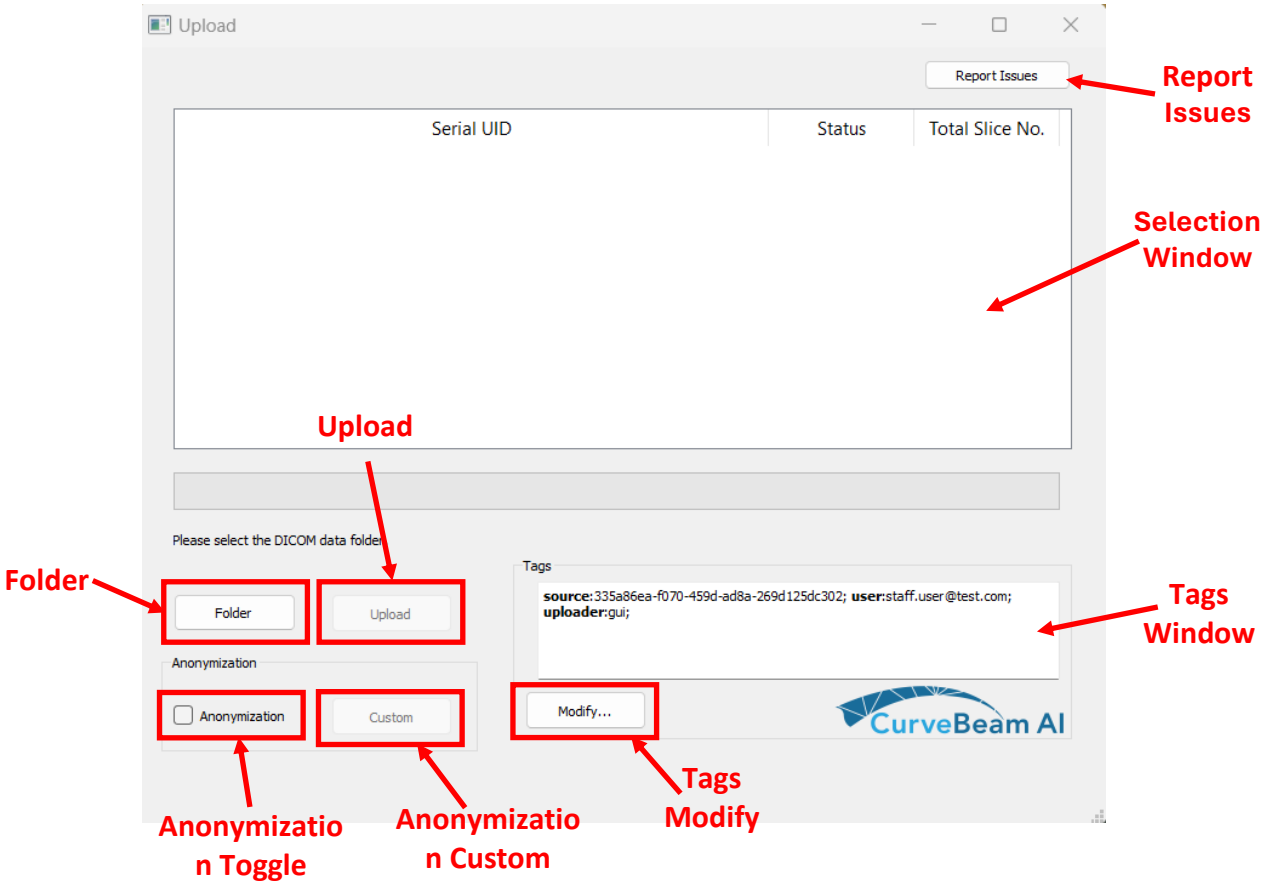
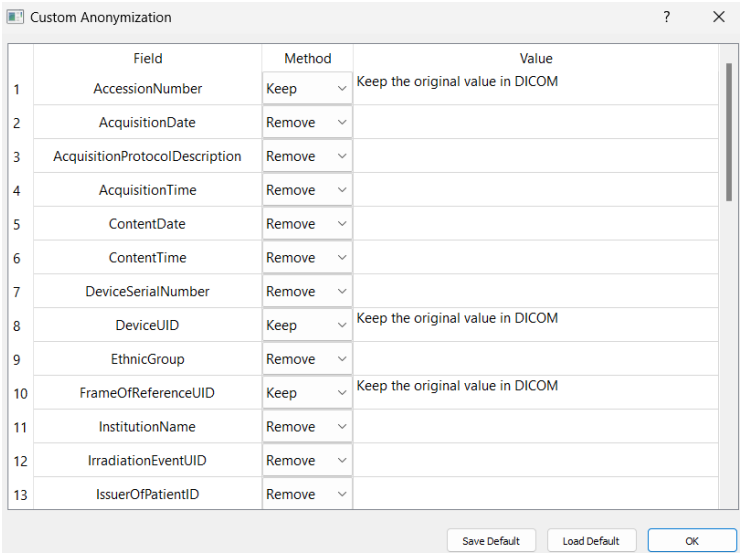
- **Report Issue** – The **Report Issue button** facilitates the uploading of log files to the cloud for reporting errors.



4.4.4 Scan anonymization

4.4.4.1 Anonymization Customization

To customize the anonymization options, users can click the **'Custom'** button on the main window, which will open the Anonymization window. This window presents a table with three columns: Field, Method, and Value, as shown below.

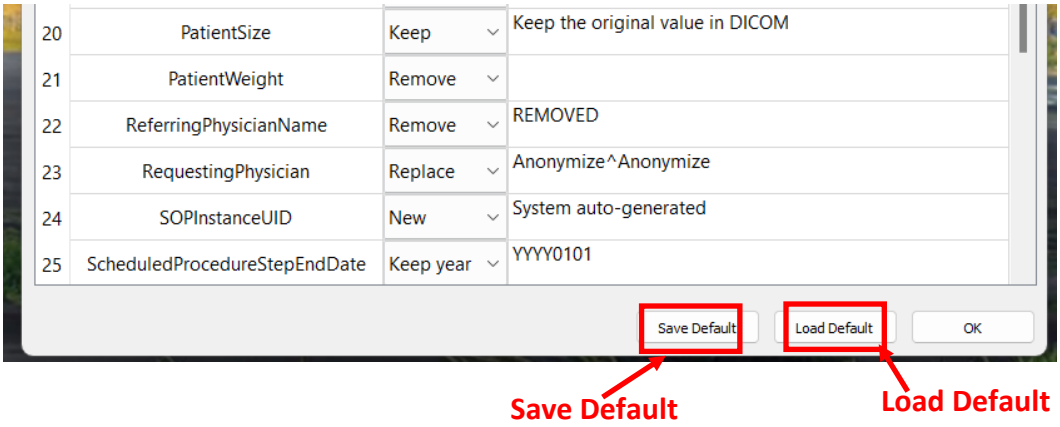


The **'Field'** column displays the different DICOM tags the application can modify within the DICOM metadata (e.g., Accession Number, Patient ID, etc.).

The **'Method'** column specifies the anonymization behaviour, offering four options: Keep, Keep Year, Replace, Remove, and New:

- **Keep** – The value in the dicom metadata will not be modified.
- **Keep Year** – This is applicable for date values where only the year is kept.
- **Replace** – The value is replaced with a default or user-entered value.
- **Remove** – The value in the metadata is removed.
- **New** – The value is replaced by an auto-generated value.

The **Value column** is useful when the **Replace method** is selected. It can be edited by the user to input the replacement value.



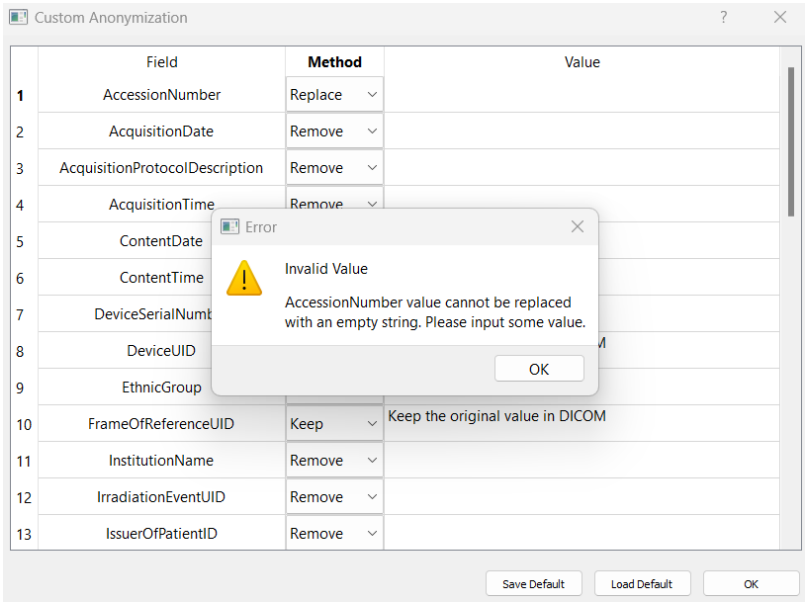
4.4.4.2 Save Default

This button will retrieve the current anonymization settings from the table and upload them to the default anonymization setting stored in the cloud.

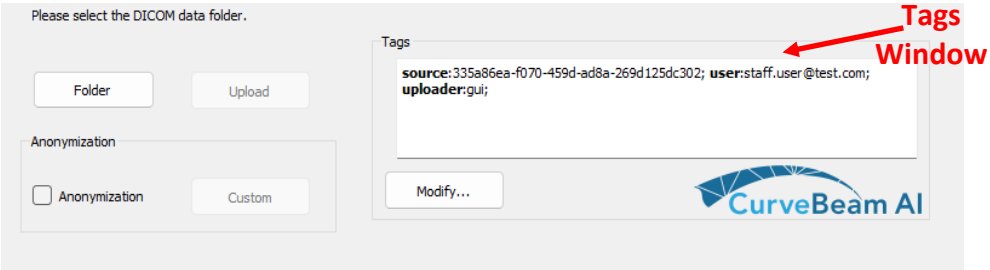
Any modifications made to the settings will overwrite the existing default settings in the cloud.

4.4.4.3 Load Default

This button loads the default anonymization settings from the cloud. If there are any invalid entries in the default anonymization settings, such as replacing a mandatory field with an empty value, the application will prompt a warning to the user and prevent them from saving the changes.



4.4.5 Tags



The Tags window displays the tags that will be added to the scan during upload. To modify, add, or remove tags, users can click the **'Modify'** button on the main UI, which will open the Tags Modification window, as depicted below."

Editing or Removing tags

- A tag can be removed using **the remove button.**
- **Source**, **user,** and **uploader** are system-generated tags and cannot be removed.

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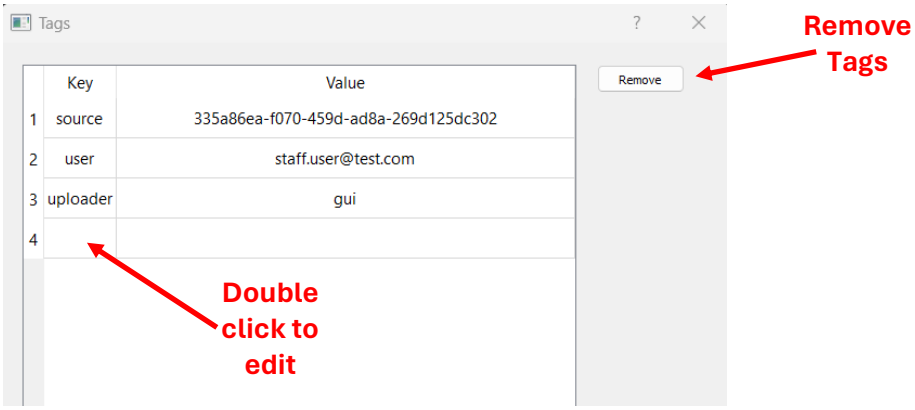


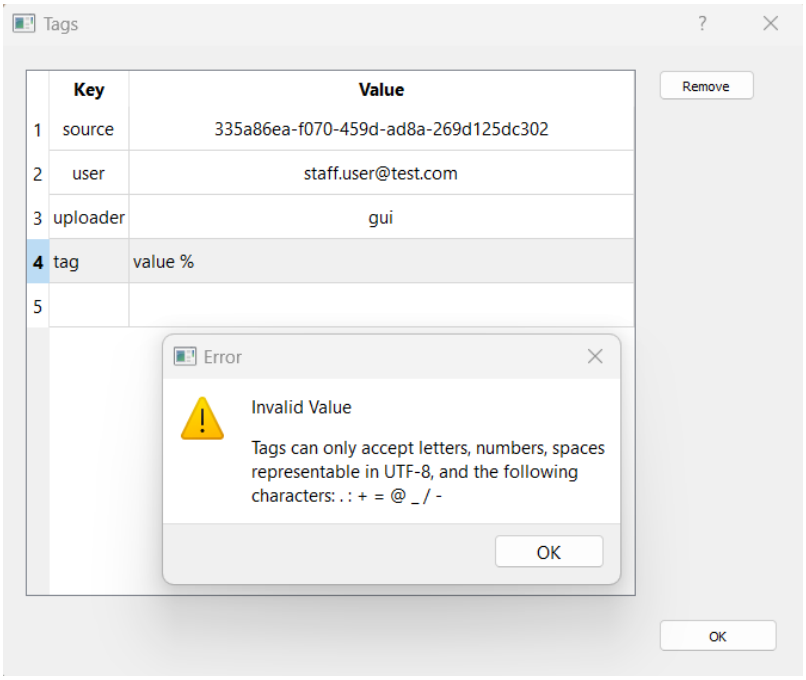
Note: Every tag must have a **key** and **value**. If either of the fields is empty, the tag will not be saved.

Adding invalid tags

The following basic naming and format requirements apply to tags:

- Each scan shall have a maximum of 5 user-created tags.
- The tags shall not begin with aws: prefix.
- Each tag key shall be unique, and each tag key can have only one value.
- The tag key shall be a minimum of 1 and a maximum of 64 Unicode characters in UTF-8.
- The tag value shall be a minimum of 1 and a maximum of 64 Unicode characters in UTF-8.
- The allowed characters shall be letters, numbers, spaces representable in UTF-8, and the following characters: _ . : / = + - @.
- Tag keys and values shall be case-insensitive.

If invalid tags are entered, the window will display an error message containing detailed information about why the tag is invalid, as illustrated below.



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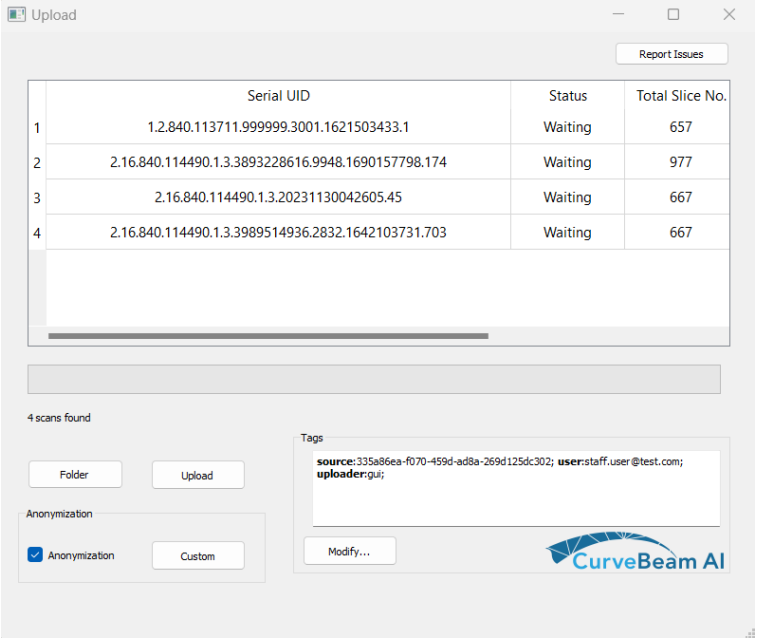
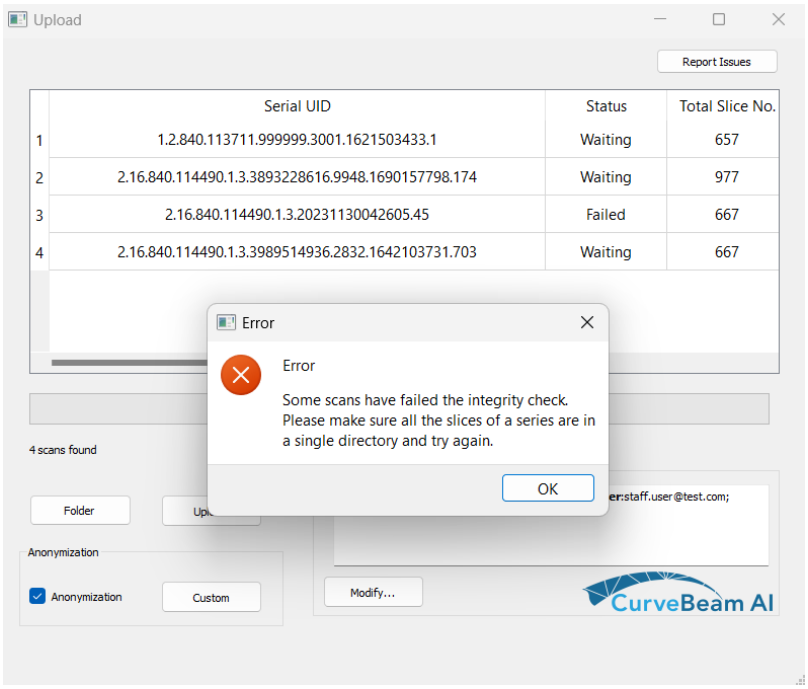
4.4.6 Folder Select

When the user selects a folder, the application analyses all the files within it, and the identified scans are presented in the window alongside their respective **series ID** and **slice count**. The status column indicates the upload status of each scan. The status will be' **Waiting**' before clicking the '**Upload**' button.



When a folder is selected, the application conducts an integrity check on its contents. This ensures that all scans belonging to a series are located within the same folder path. If slices from the same series are found in multiple folders, the application will display an error message, as depicted below.



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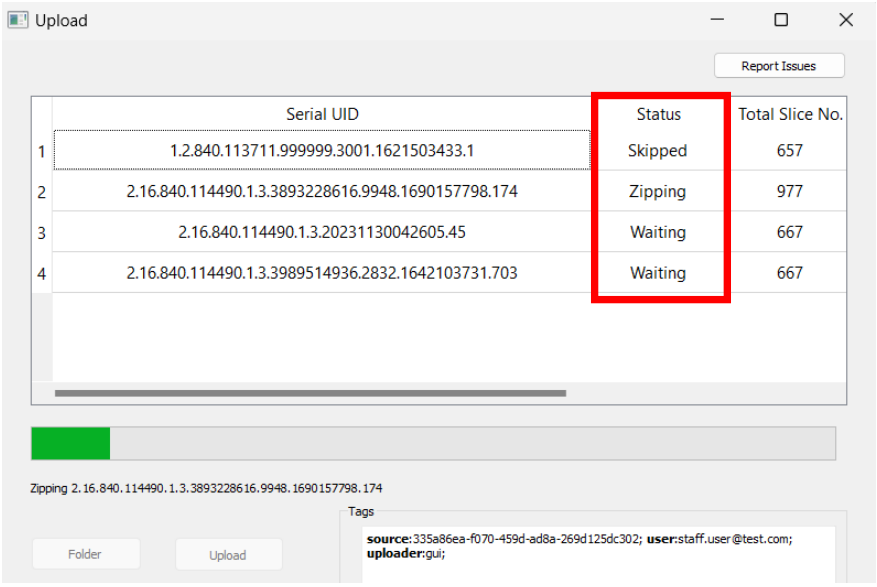
4.4.7 Upload Process

4.4.7.1 Upload Status

When the upload process begins, the status is dynamically updated to reflect the current stage of processing for each scan. The statuses include Waiting, Anonymizing, Zipping, Uploading, Skipped, Importing, Finished, and Failed.



4.4.7.2 On Upload Complete

The upload application will notify users once all scan slices are successfully imported to the DMP website. If users do not receive this notification, refer to section 4.4.8 to report the issue to CurveBeam AI support.

After the uploads are completed, the application displays a summary of all the successful and failed scans.

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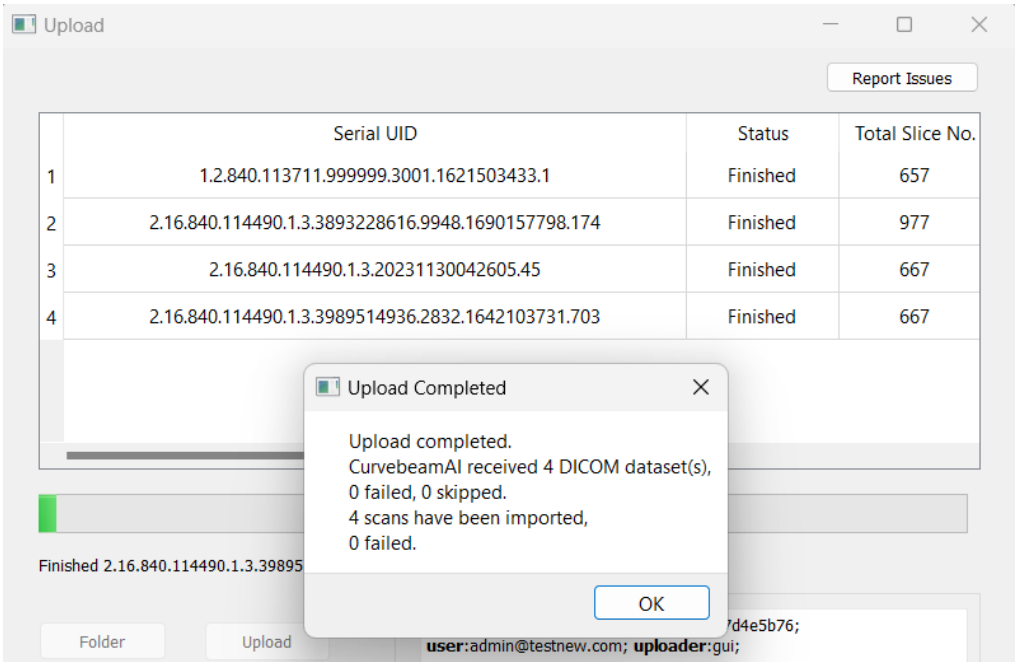
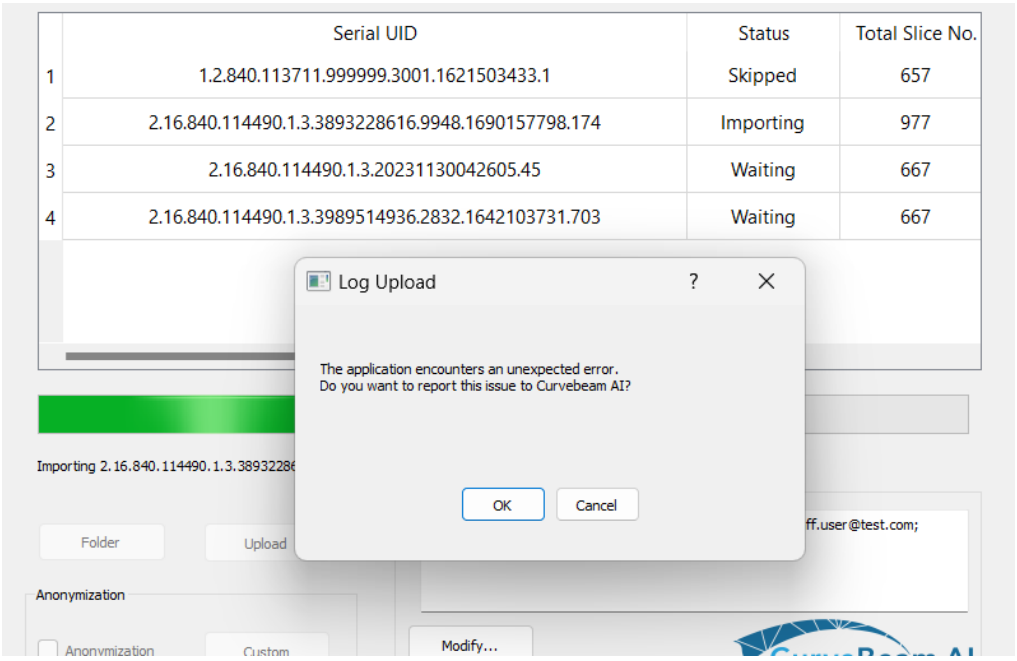


4.4.8 Reporting issues

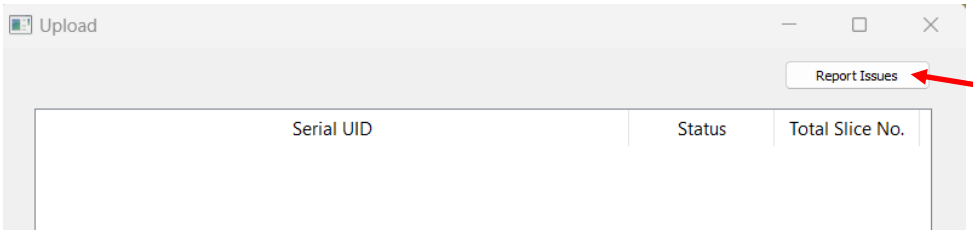
Issues during the upload

If an unexpected error occurs during the upload process, the application will prompt the user to decide whether they wish to report the issue.

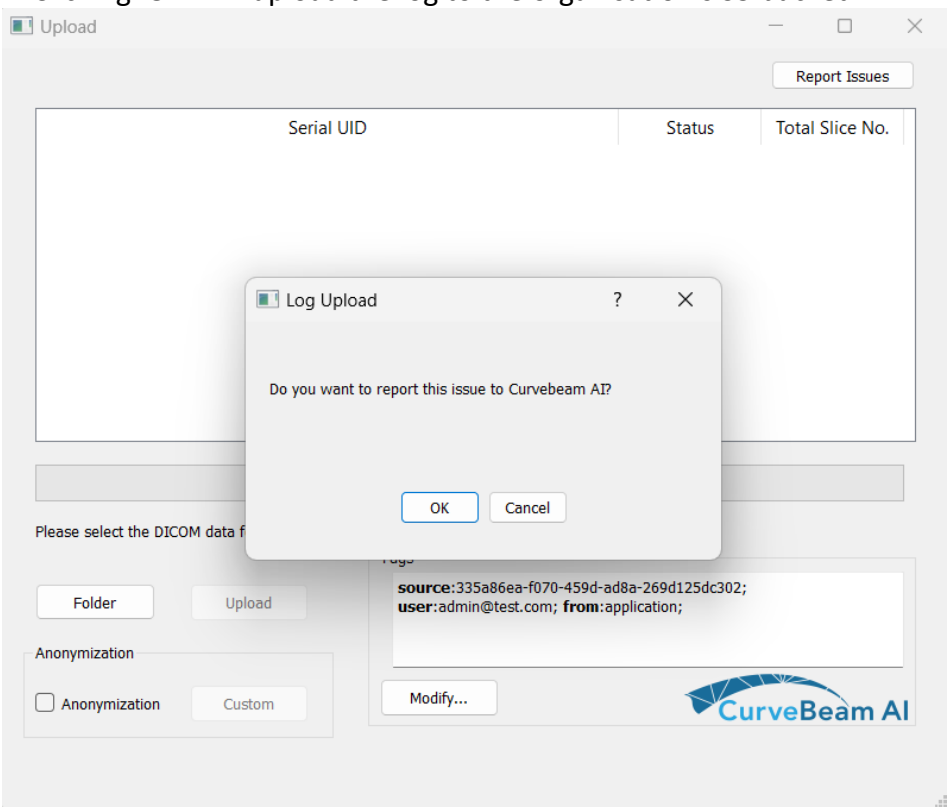


User Reporting Issue

Users can manually report issues by utilizing the "**Report Issues**" button on the main user interface.



Clicking the ‘Report Issues’ button will bring up the log upload confirmation dialog box. Clicking ‘OK’ will upload the log to the organisation’s S3 bucket.



Revision History

Revision	Release Date	Change Description
1	04/Jun/2024	Initial release