GETTING STARTED GUIDE

Supervisor Role

GaelO

The Imaging Platform for Clinical Trials

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Introduction

What Is GaelO?

GaelO is a web platform for **imaging management in clinical trials**.

Each stakeholder can log in to the platform with their individual credentials. Depending on their role, they can upload, view, or download anonymized DICOM files, review images, or receive email alerts when an action is required on their part.

INFORMATION HIERARCHY

In GaelO, information is organized according to the following levels:

- **Clinical trial**: GaelO allows you to manage information from one or more clinical trials.
- **Patient**: Each clinical trial involves multiple patients.
- **Visit**: A visit in GaelO is the equivalent of a DICOM "study". It corresponds to a medical examination (for example, a thoraco-abdomino-pelvic scan). Each patient can undergo multiple visits during the trial.
- **Series**: Each visit can in turn contain one or more series (for example, thoracic series, abdomino-pelvic series, etc.).
- **Instance**: Within a series, each of the images produced corresponds to an instance.

Data processing workflow

The processing workflow for data entered into GaelO is as follows:

1. Patient creation (Supervisor role)
2. Visit creation (Investigator role)
3. Images upload + Form completion (Investigator role)
4. Quality control (Controller role)
5. Review (Reviewer role)

Supervisor role

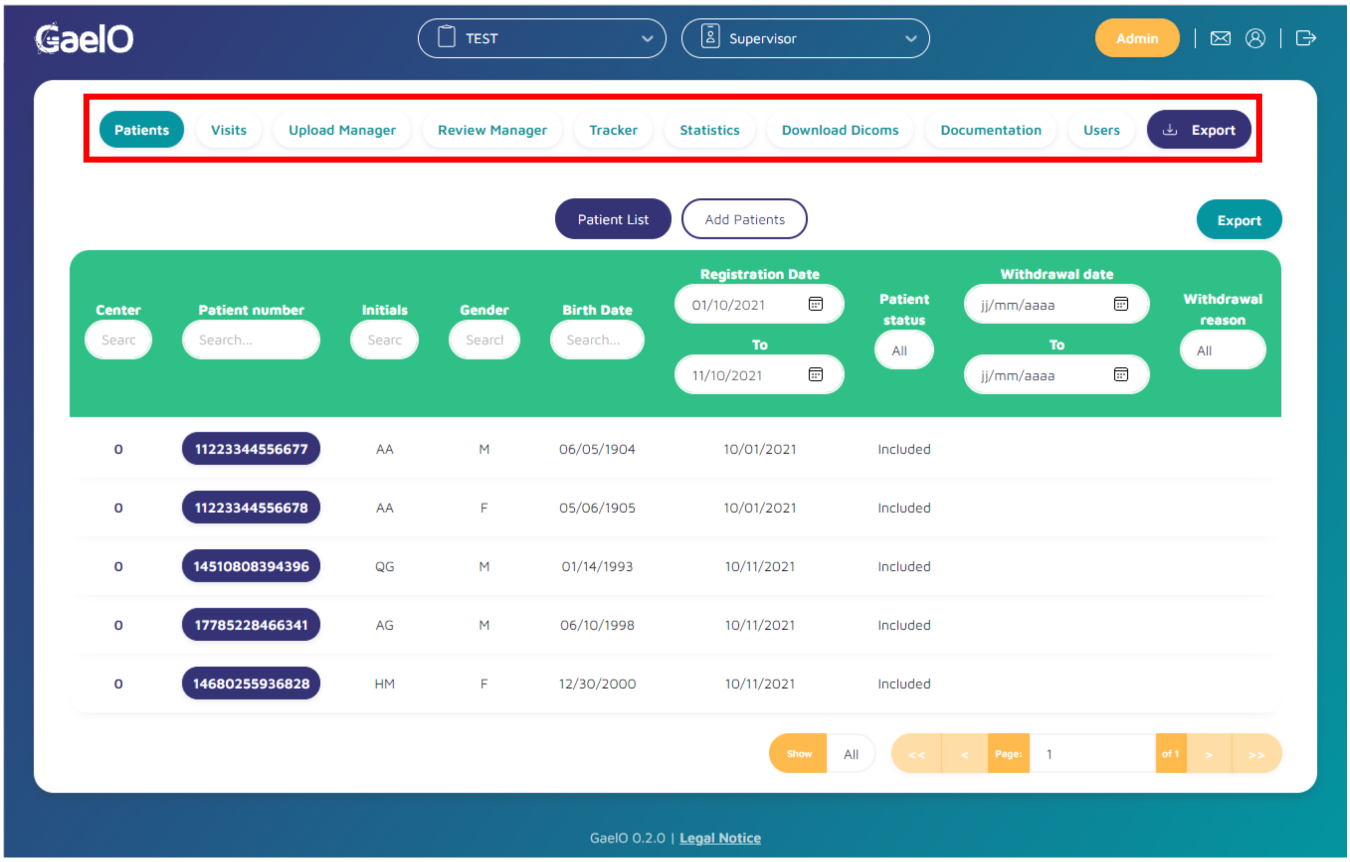
Supervisors are responsible for **managing the clinical study**. They enter the patients included in the trial, can **perform corrective actions** on the data they receive and have **direct access to the data** (images and forms).

GaelO also offers management tools, including features to communicate with investigators, send reminders when uploads are expected, display data graphically, etc.

Browsing GaelO

ACCESSING THE FEATURES

Once you have logged in to GaelO, after selecting a clinical trial and the Supervisor role if necessary, the GaelO screen looks like this:



By default, the patient list displays. The button bar at the top of the screen allows you to **navigate through the different features available**. Click on the links below for more details on each of them:

- Patients
- Visits
- Upload Manager
- Review Manager

- Tracker
- Statistics
- Download Dicoms
- Documentation
- Users
- Export

Filtering and sorting data

On each screen, you can **filter the list of data directly using the fields** at the top of the screen. Filtering is done dynamically as you enter information.

Click on the field **names** to sort the list according to the corresponding column. Click a second time to change the sort order.

Patient management

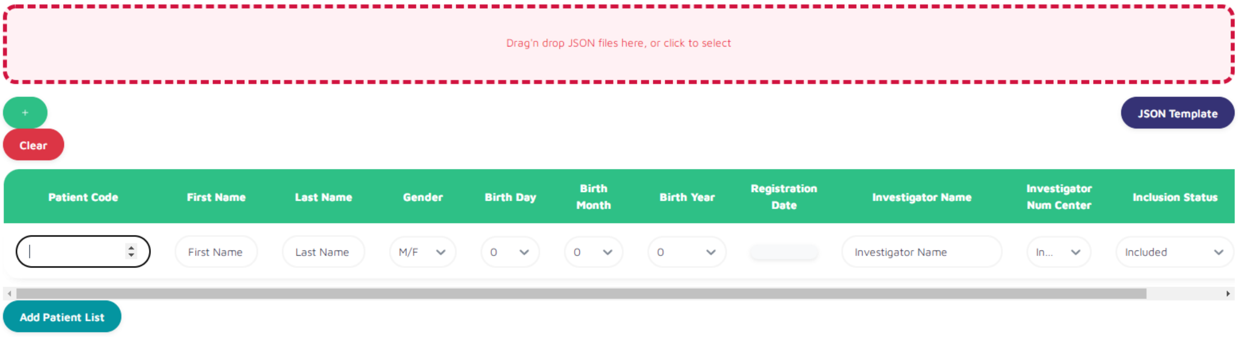
As a supervisor, you are in charge of **creating the patients** to which investigators will then attach visits. You will also be able to **view their details and edit them**. Note that it is however impossible to delete a patient.

Creating a patient

To create a patient:

1. If needed, click on the **Patients** button in the top bar.
2. Click on the **Add Patients** button.
3. Click on the + button.
   A line containing the fields to be completed displays.
4. Enter the required information.
   > A specific format may be required in the **Patient Code** field. See the clinical trial documentation for more information. Note that this field cannot be modified after creation.
   > For anonymization reasons, you can just enter the initial of the patient's first and last name, and leave the date of birth blank or incomplete.
5. If you want to add several patients at the same time, repeat steps 3 and 4 as many times as necessary.
6. Click on the **Add to Patient List** button.
   The new patient displays in the patient list.

Patients can also be batch created using a JSON file. The JSON template can be downloaded from the interface.

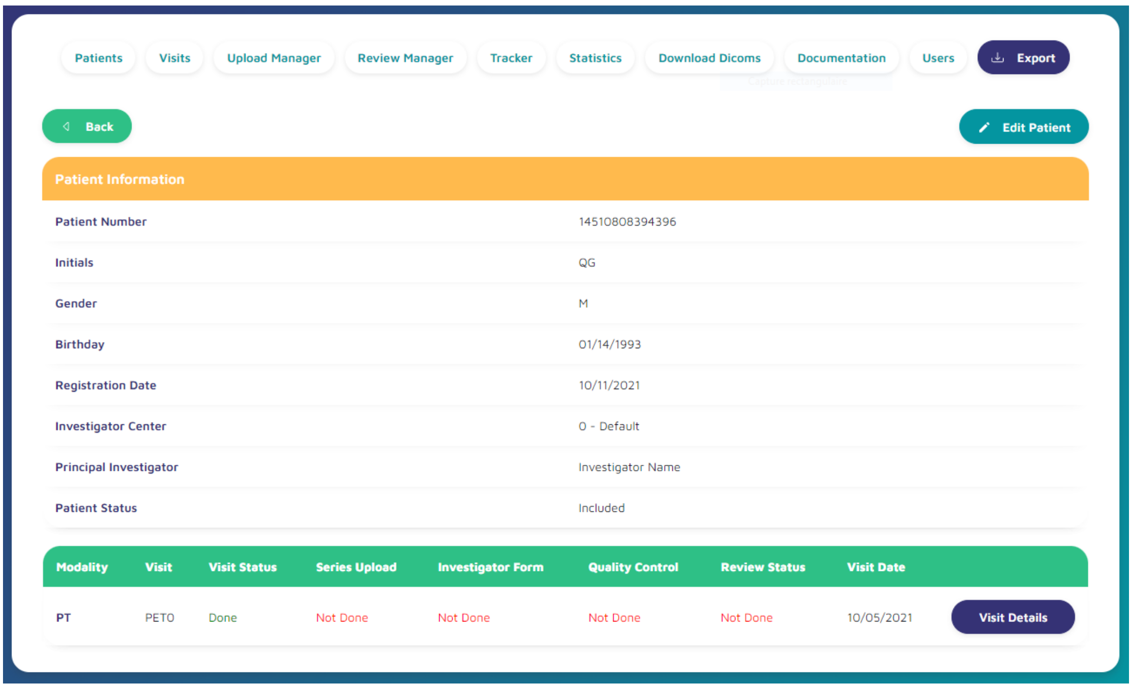


DISPLAYING AND EDITING A PATIENT

The patient interface allows you to **view the details of a patient, and to edit their information** (except for the patient number), in particular to declare a trial exit.

To edit a patient:

1. If needed, click on the **Patients** button in the top bar.
2. Click on the patient number of the patient you want to edit.
   - The patient details screen displays.



3. Click on the **Edit Patient** button located at the top right of the screen.
4. Edited the contents of the fields as you need.

The **Patient Status** is used to specify a patient left the trial. Once this is set, the platform will no longer allow the upload of new imaging for this patient.

5. Click on the **Apply Changes** button located at the top right of the screen.
   - A confirmation dialog displays.
6. Specify a reason for the change and click **Ok**.

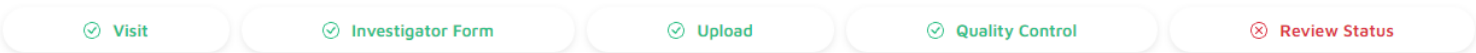
Visit management

As a supervisor, you can **access all information** about visits and their imaging, **change the acquisition date** of imaging, **reset quality controls**, and **delete visits**.

VIEWING THE DETAILS OF A VISIT

To view the details of a visit:

1. Click on the **Visits** button in the top bar.
2. Click on the button corresponding to the name of the visit (for example, "PET0").
3. The button bar at the top of the screen shows the workflow progress:



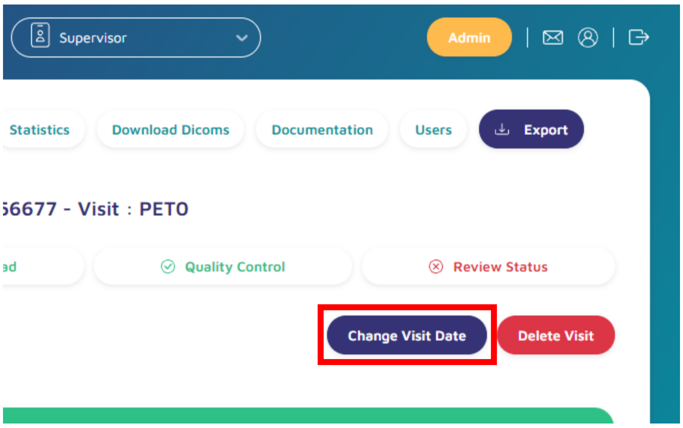
- **Visit**: visit creation and completion date
- **Investigator Form**: form filled in by the investigator
- **Upload**: imaging uploaded by the investigator (you can download the DICOM files or view them directly in GaelO)
- **Quality Control**: approbation status specified by the controller
- **Review Status**: review done by the reviewer

EDITING THE DATE OF A VISIT

You can choose to **edit the imaging acquisition date** specified by the investigator. To do this:

1. Click on the **Visits** button in the top bar.
2. Click on the button corresponding to the name of the visit (for example, "PET0").
   - By default, you're taken to the **Visit** step of the workflow.

3. Click on the **Change Visit Date** button located at the top right of the screen:

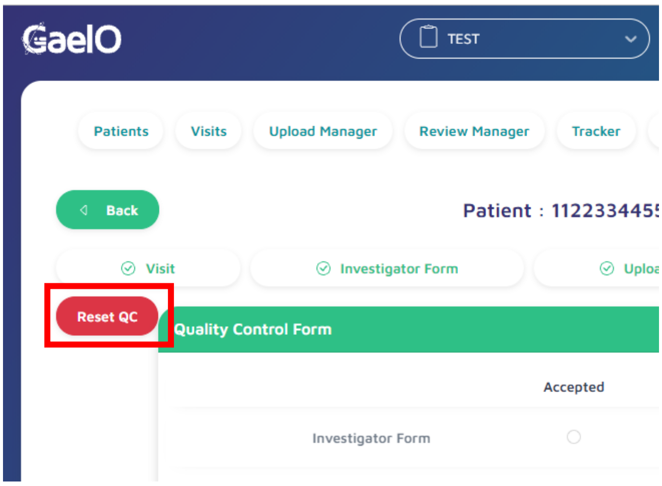


4. Select a date and click **Validate**.

Resetting the Quality Control of a Visit

Once the quality control has been performed by a controller, you can choose to **reset it so that this step is performed again**. To do this:

1. Click on the **Visits** button in the top bar.
2. Click on the button corresponding to the name of the visit (for example, "PET0").
   - ✔ By default, you're taken to the **Visit** step of the workflow.
3. In the button bar, select the **Quality Control** step. (It has to display in green, showing that the step has been completed.)
4. Click on the **Reset QC** button located at the top left of the screen:



   - ✔ A confirmation dialog displays.
5. Specify a reason for the reset and click **Ok**.
   - ✔ The quality control step returns to the incomplete status and displays in

red. The visit becomes available again for controllers, who need to **perform the quality control again**.

INVALIDATING OR DELETING A FORM

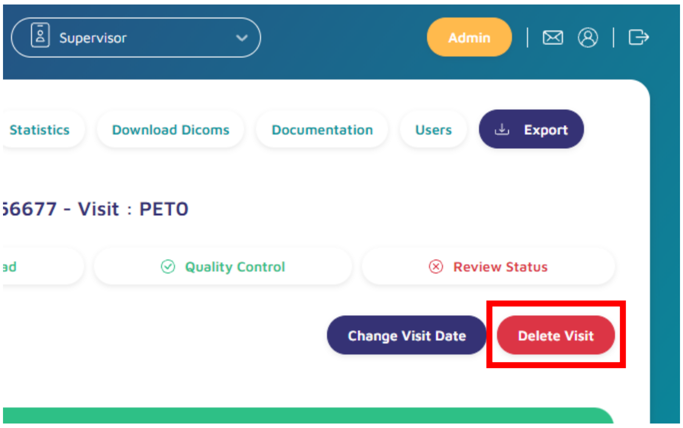
The **Investigator Form** and **Review Status** steps contain the data filled in by an investigator and a reviewer in the corresponding forms. For each form you can perform:

- **Invalidation**: The data remains stored in memory, but the form becomes editable by its author again.
- **Deletion**: The data is marked as deleted. The investigator or reviewer can submit new data from a blank form.

DELETING A VISIT

You can choose to **delete a visit entirely**. All steps of the workflow will be canceled. To do this:

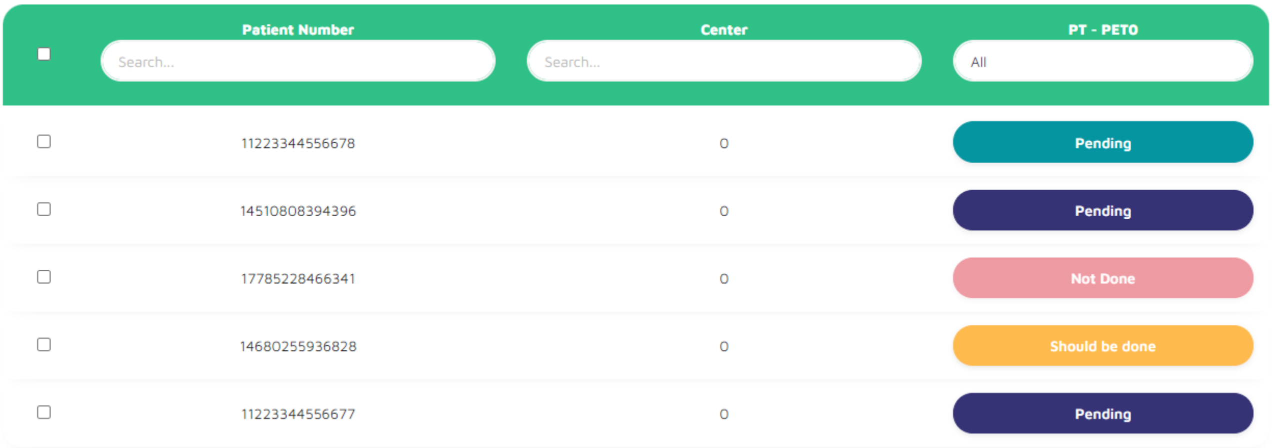
1. Click on the **Visits** button in the top bar.
2. Click on the button corresponding to the name of the visit (for example, "PET0").
   ✔ By default, you're taken to the **Visit** step of the workflow.
3. Click on the **Delete Visit** button located at the top right of the screen:



   ✔ A confirmation dialog displays.
4. Specify a reason for the deletion and click **Ok**.

Upload management

The "Upload Manager" section provides an overview of **the data upload progress**, for each patient or visit:



A visit can have the following status:

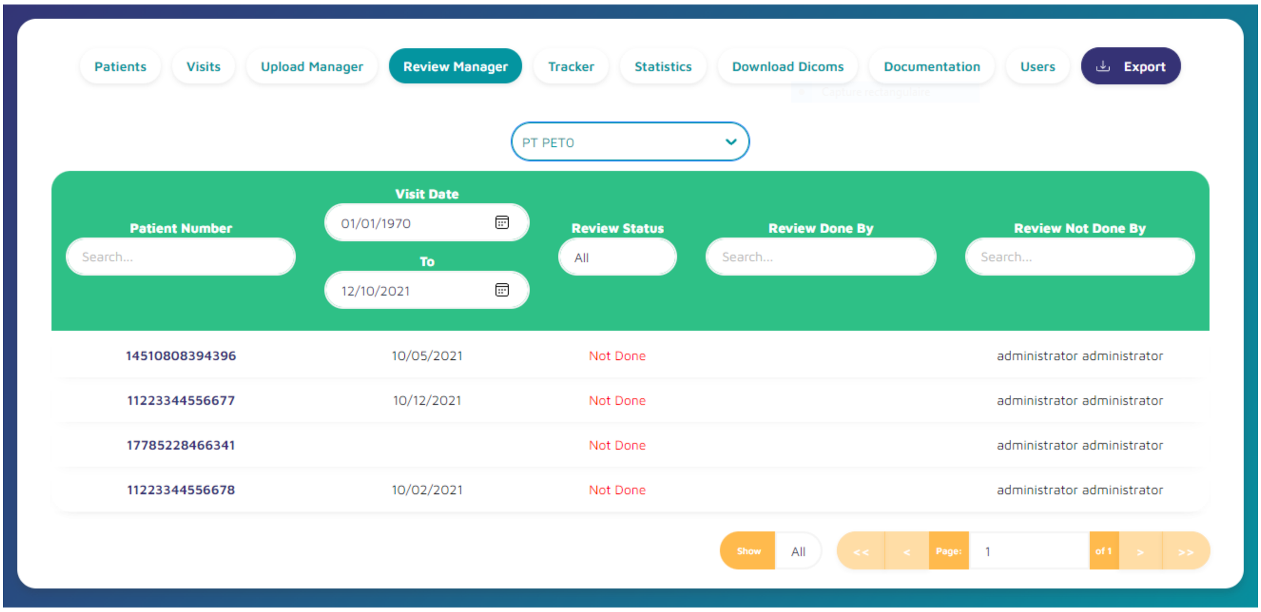
- **Not Done**: The visit will not be carried out (a reason was provided by the investigator when creating the visit) or the visit is scheduled on a later date.
- **Pending**: The visit has not been done, and its deadline has not expired yet.
- **Should Have Been Done**: The visit has not been done, and its deadline has expired.
- **Done**: The visit has been done.

The **Compliance** field indicates whether the date on which the visit was carried out meets the deadline after inclusion date set for the clinical trial.

Review management

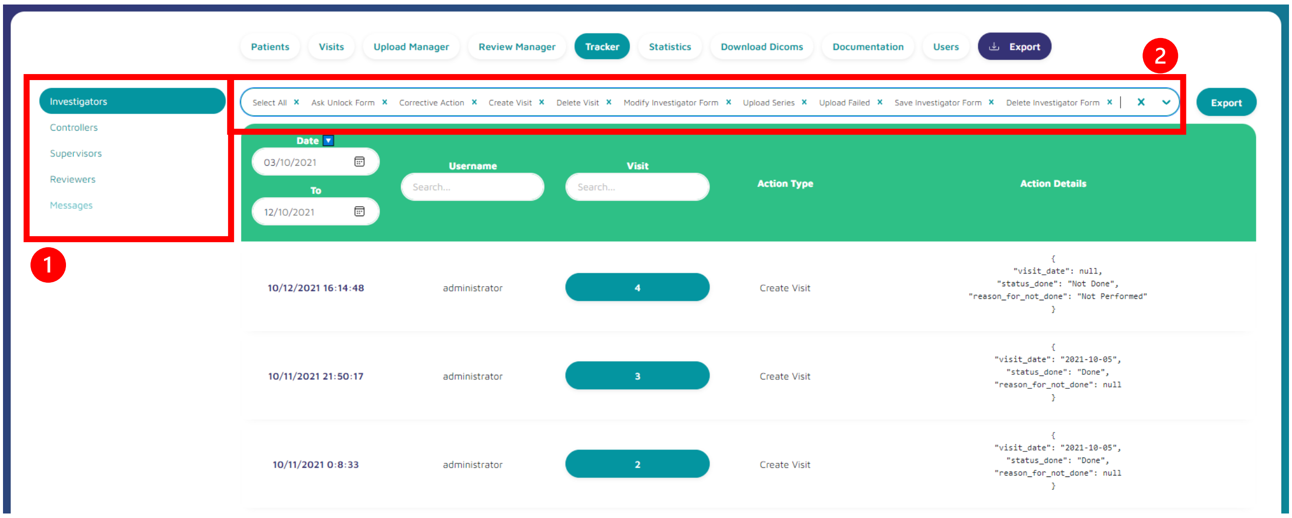
The "Review Manager" section lists the review forms status, centralized for each visit.

Select the type of visit you want to analyze. For each visit created, this menu lists the **reviews already carried out and the visits still awaiting review**.



User action audit

The “Tracker” section is a tool for tracking user actions. Each action performed in GaelO is timestamped, identified, and recorded, making it possible to trace the actions of users step by step.



Actions are organized:

- By role (1)
- By type (2)

Select a role and the type of actions you want to display.

The table lists the actions corresponding to your selections, with the user ID, the date and time of the action, the visit concerned and the related details.

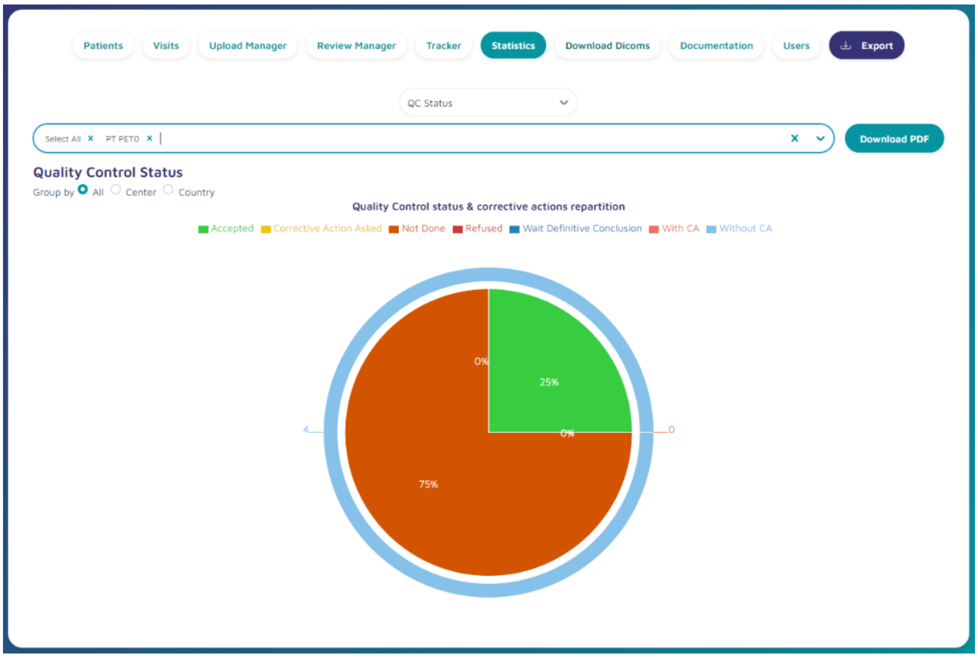
Statistics visualization

The "Statistics" section allows you to **display the data graphically**, for descriptive analysis.

These charts are generated in real time (when you are viewing them).

They include:

- Data about the clinical trial progress
  - The number of visits available/pending/overdue
  - The number of reviews carried out
  - The number of visits concluded and the conclusion deadlines
  - Statistics on quality control answers and deadlines
- Descriptive visualization of the data
  - Data from investigator forms
  - Data from centralized review forms

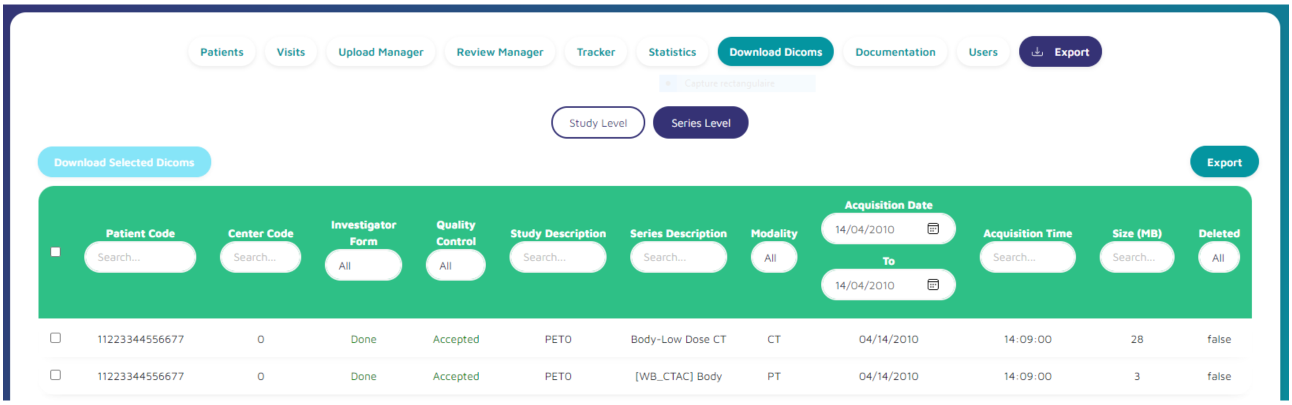


DICOM files download

The "Download DICOM" section allows you to download the images at any time.

DICOM files can be listed either by visits or by series. The filtering tools in the table header allow you to display the DICOMs of your choice.

Select the DICOMs that you want to download, and click on **Download Selected Dicoms**:



The DICOM download is done via your browser in the form of a ZIP file.

Documentation management

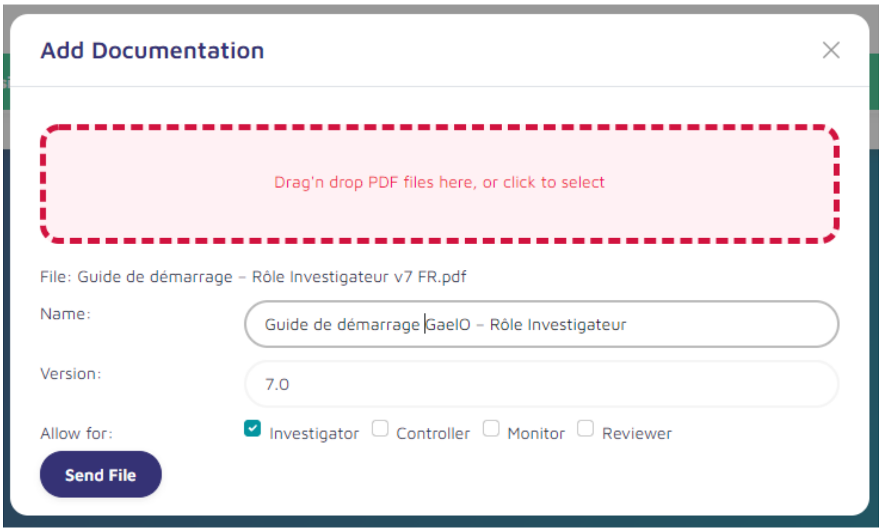
The "Documentation" section allows you to **manage the PDF files that will be available to users** with the Investigator, Controller, Monitor and Reviewer roles when they click on the button in their interface.

ADDING A DOCUMENTATION

To add a documentation:

1. Click on the **Documentation** button in the top bar.
2. Click on the button.
   - A drag-and-drop dialog displays.
3. Drop the PDF file of your choice into the red frame.

- New fields appear:



4. Specify the name and version of the documentation, as well as the roles it is intended for.
5. Click on the **Send File** button.

   - Documentation becomes available to the selected users. You can change the roles with access to the documentation at any time.

Deleting a documentation

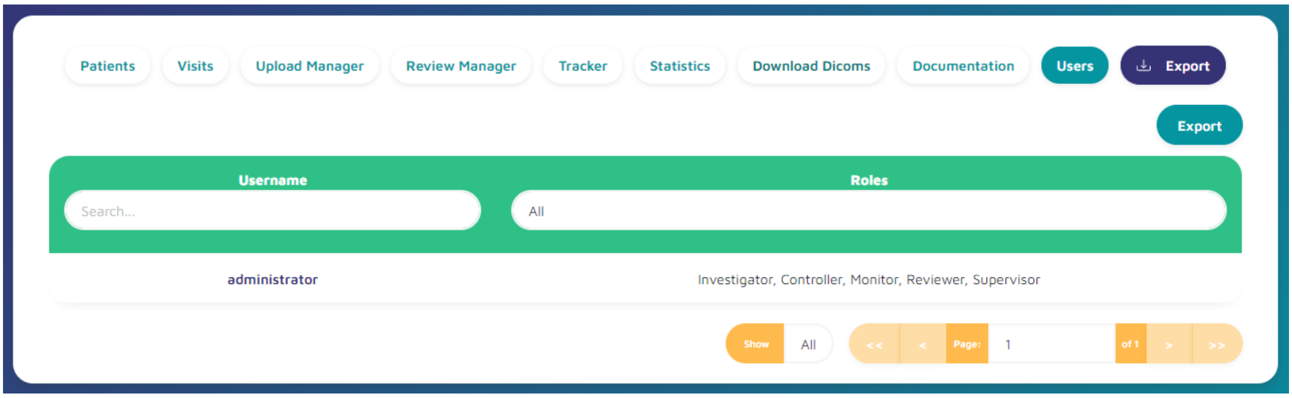
To delete a documentation:

1. Click on the **Documentation** button in the top bar.
2. Click on the  button.
   - A confirmation dialog displays.
3. Click on the **Yes** button.
   - The documentation remains available in the list for possible reactivation, but disappears from the users' interface.

User list display

The "Users" section lists the users with a role in the clinical trial.

Role assignment is carried out by the administrator of GaelO. Contact the administrator to add/remove a user in the clinical trial and assign them a role.



Data export

As a supervisor, you can use the **Export** button at the top of the screen to **trigger the download of clinical trial data**, excluding DICOM files.

This data is exported in a ZIP file which contains several files:

- CSV and XLSX spreadsheets containing lists of DICOM files, data from investigator and reviewer forms, status of visits…
- The files connected to the forms (if any).