



GETTING STARTED GUIDE

Controller Role



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.

CONTROLLER ROLE

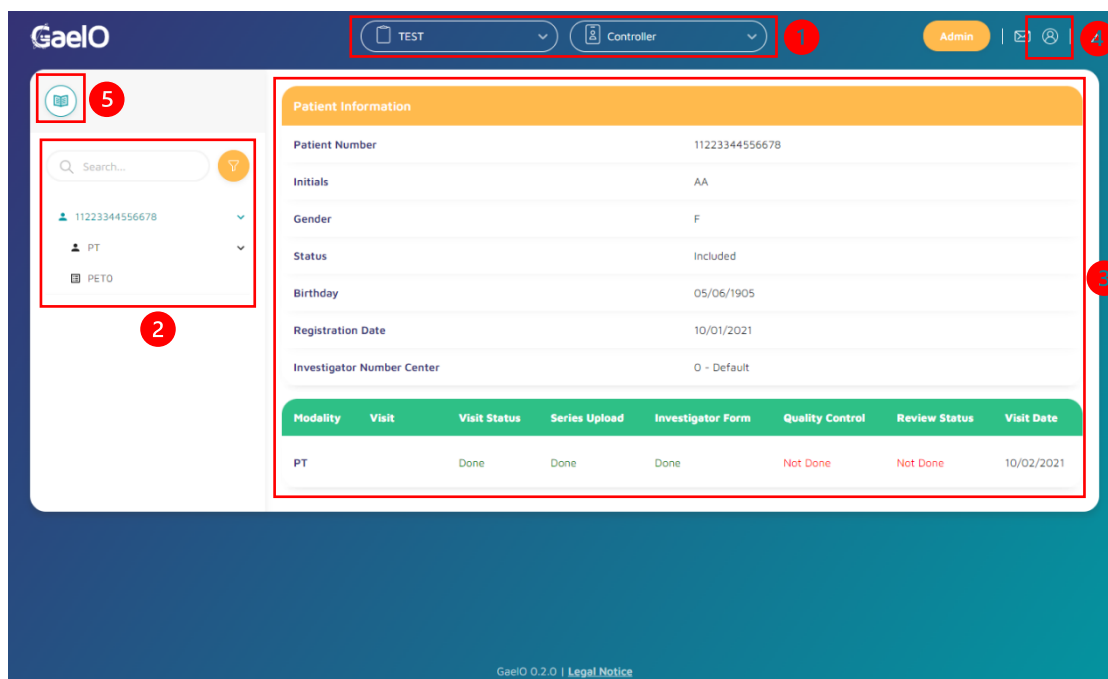
The controller carries out the **quality control for the data submitted by investigators**.

When images are uploaded into GaelO by an investigator, the controller receives a notification. Then, they need to view the images and data from the investigator form before deciding whether the submission's quality is sufficient: they can accept the submission, request a corrective action, or refuse the submission.

Browsing GaelO

MAIN SCREEN

Once you have logged in to GaelO, after selecting if necessary a clinical trial and the Controller role, then a patient, the main screen displays as follows:



See the next section for details on each available feature.

AVAILABLE FEATURES

1. Selecting a study and a role



If you have access to multiple clinical trials, **you can toggle between them at any time** using the **Study** drop-down list. Only patients corresponding to the selected clinical trial will be displayed in the tree view.

If you have access to different roles (for example, Supervisor or Controller), you can also switch from one to another using the **Role** drop-down list.

2. Browsing the tree structure


The left pane of the screen displays the **working list for the controller: all the visits requiring a quality control**.

Use the search field to retrieve a patient with **their inclusion number**.

3. Displaying the details of an item


The detail pane allows you to display the **information for the selected tree structure item** (patient or visit) and to perform the quality control for a visit.

4. Editing your personal information

Click the  icon at the top right of the main screen to view your personal information. You can edit **your last name, first name and phone number** on that screen.

To edit **your email address or password**, log out and go back to the login page. Follow the [Any requests or questions?](#) link to ask an administrator to change your email address or the [Forgot your password?](#) link to reset your password.

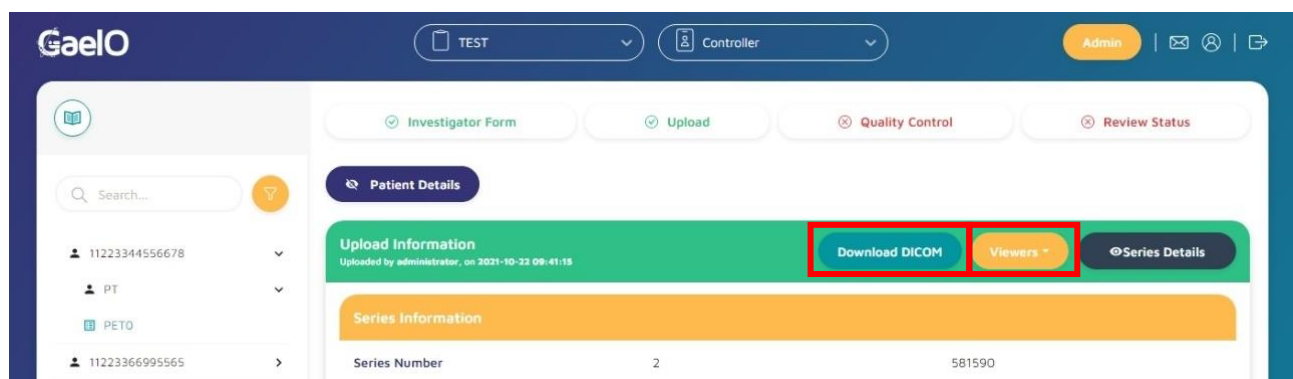
5. Displaying the documentation

Click the  button to display the different user guides available for the GaelO platform and for the clinical trial.

Performing a quality control

VIEWING IMAGES

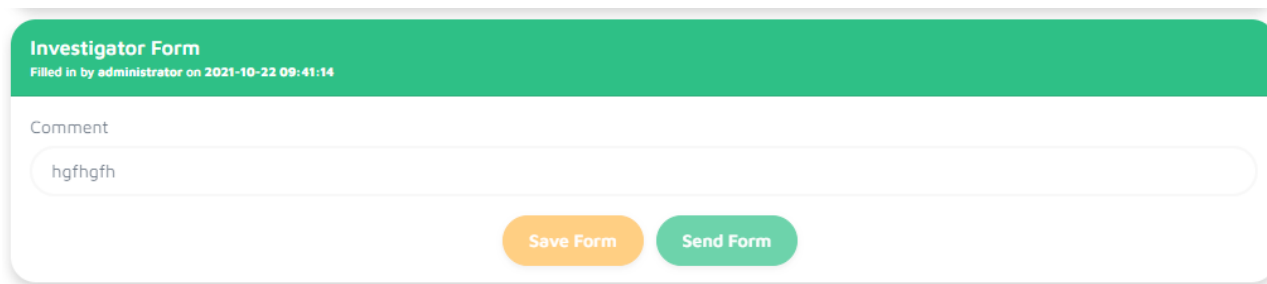
The **Download DICOM** and **Viewers** buttons located at the top right of the screen allow you to view the DICOM images uploaded by investigators into GaelO:



Images can be viewed directly inside GaelO with two online viewers or downloaded and opened in a third-party tool, so the controller can check their quality and completeness.

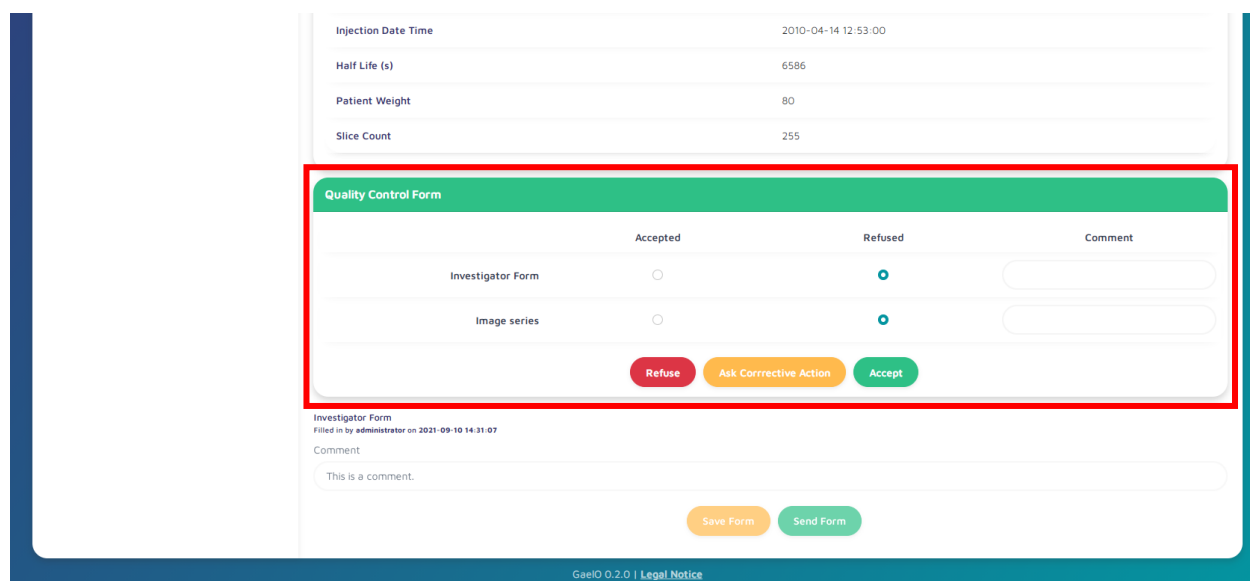
VIEWING THE INVESTIGATOR FORM

The investigator form filled in by the investigator can be viewed on the interface so that you can check its consistency.



SUBMITTING THE QUALITY CONTROL DECISION

The form **located at the bottom right of the detail screen** allows you to submit your quality control comments:



A quality control decision must be made for:

- The **images**
- The **investigator form**

Each item must be accepted or rejected. If an item is rejected, you need to provide an explanation in the **Comment** field.

If one of the two items is **Refused**, the final decision can be:

- **Ask Corrective Action:** If the controller considers that the submission can be corrected to be usable, the visit is forwarded back to the investigator who will see the controller's comments and correct his submission. Then, the data will go back to quality control after being re-submitted.
- **Refuse:** The submission is entirely rejected. You consider that the visit cannot be used or corrected. There will be no medical review for this visit.

If both items are **Accepted**, then the final decision must be **Accept**. The visit will be instantly forwarded to medical experts who will be notified by email that images are available to be interpreted.