Notice to applicant

Central Administration of Biological, Innovative products and Clinical Studies
General Administration of Clinical Trails

Companies User Manual for Clinical Trials Digital Platform

Year 2026

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Table of Contents

List of Abbreviations

- EDA: Egyptian Drug Authority
- BIOINN: Central Administration of Biological, Innovative products and Clinical Studies
- CT: Clinical Trails
- GCP: Good Clinical Practice
- CROs: Contract Research Organizations
- IMP: Investigational medicinal product

1 Introduction

1.1 Project Scope Overview

The Clinical Trials Project is a web portal that helps ease the process of applying for a Clinical Trials by the companies as it also facilitates tracking of application status without the need for continuous phone calls and frequent follow-ups with the Clinical Trials team.

The system will also manage the task distribution and streamline the workflows, enhancing the decision-making process and reducing unnecessary back-and-forth communication between both parties.

Clinical Trials Project web portal includes comprehensive functionalities that facilitate effective oversight, management, and transparency of clinical trials within the authority's jurisdiction. The portal centralizes trial registration and application management, secures essential trial documentation, and fosters communication among sponsors, investigators, ethics committees, and regulators. It offers real-time monitoring of trial progress, safety, and compliance, supports role-based access controls, integrates with international registries, and automates key regulatory workflows to ensure adherence to Good Clinical Practice and applicable laws, ultimately enhancing regulatory efficiency, data integrity, participant safety, and public transparency.

1.2 Intended Audience and Reading Suggestions

This document is intended for companies involved in clinical trials, such as sponsors and contract research organizations (CROs) that are going to be a user of this system, as well as users within the Egyptian Drug Authority (EDA) who manage, review, or oversee clinical trials through the system. It is recommended that all users read this manual before logging into the Clinical Trials Portal to ensure a smooth and efficient user experience.

1.3 Main Objectives of the Clinical Trials Project

The objectives of the Regulatory Authority's Clinical Trials Project web portal are to:

- Provide a centralized platform for the submission, management, and tracking of clinical trial applications and related regulatory documents.
- Facilitate efficient review and approval processes by regulatory staff, ensuring compliance with Good Clinical Practice (GCP) and applicable laws.
- Enhance transparency and accessibility to clinical trial data for stakeholders, while safeguarding participant confidentiality and data integrity.
- Support ongoing monitoring, safety reporting, and inspection activities through real-time data access and communication tools

- Enable collaboration and information exchange among sponsors, investigators, ethics committees, and regulatory bodies.
- Streamline regulatory oversight activities including protocol assessments, amendments, and site inspections.
- Ensure standardized, harmonized workflows aligned with relevant clinical trials laws and international regulatory requirements.
- Foster innovation and ethical conduct in clinical research by providing up-to-date guidance, notifications, and decision support within the portal environment.
- Promote public trust by making clinical trial information accessible through a secure, searchable interface.

These objectives collectively aim to strengthen regulatory oversight, safeguard participant well-being, and improve the quality and efficiency of the clinical trial regulatory lifecycle

2 Company Interface

2.1 First View + New Request

The main goal of this project is to enhance coordination between the clinical trials Team at EDA and the companies by improving workflow interactions and ensuring efficient and structured data exchange between both parties.

2.1.1 Login Page

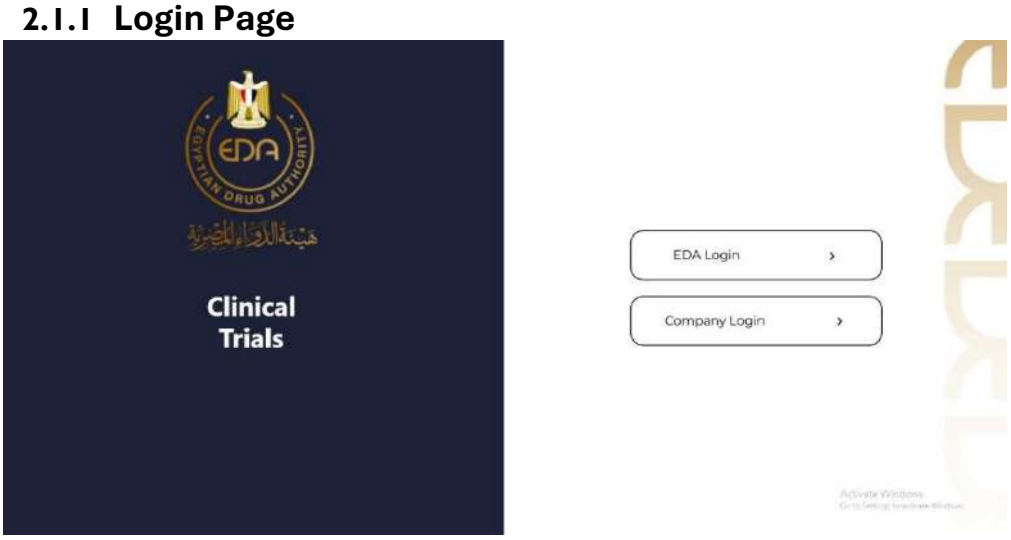

Figure 2.1: First Login page

This is the first page the user encounters once he opens the portal, all the applicants should choose to login as a company which will then direct them to the company login page

Figure 2.2: Second Login page

Companies can only login to the Portal from the Company Login page, Login will be through company account created in The Egyptian Drug Authority (EDA) company profile. The Egyptian Drug Authority (EDA) is responsible to provide each company a user name and a password for login.

2.1.2 Work-list

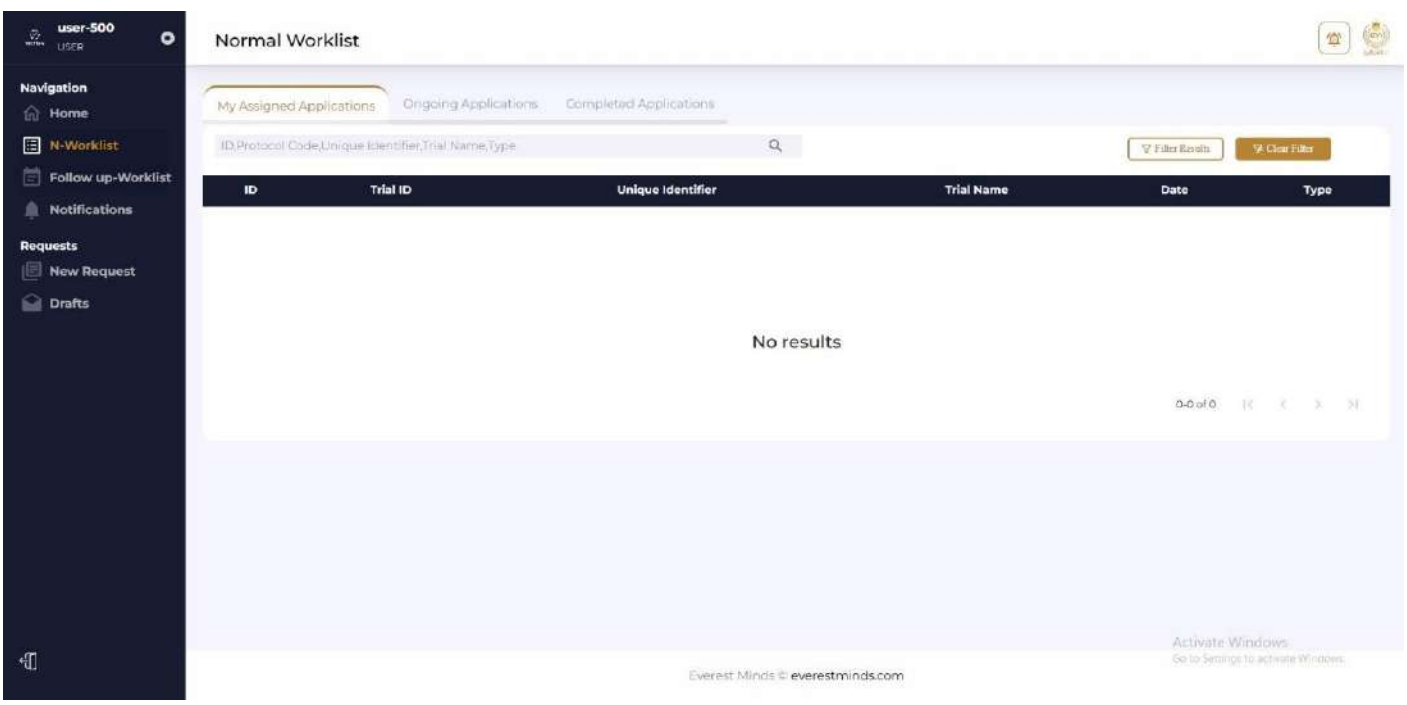

Figure 2.3: Work list

Once the user logs in he will land on this page “Work list” which is the main page for managing his work, user can find 3 different tabs to do so:

- My Assigned Applications: This tab contains all the submissions or tasks that the user must take an action upon.
- Ongoing Applications: This tab contains all the submissions or tasks the user has already worked on to be able to track the progress of his work and at this point the user can’t take any actions
  on the submission but just view them.
- Completed Applications: This tab shows only the finished submissions either the approved submissions or the rejected.

Additionally, a Follow-Up Worklist has been implemented on the side navigation bar on the left to improve tracking of all follow-up activities. This worklist contains two dedicated tabs:

- Available for follow-up tasks: displays all items available and pending follow-up tasks.
- In progress follow-up tasks: shows items currently in progress.

This structure ensures clearer visibility, better task organization, and more efficient monitoring of follow-up actions throughout the workflow.

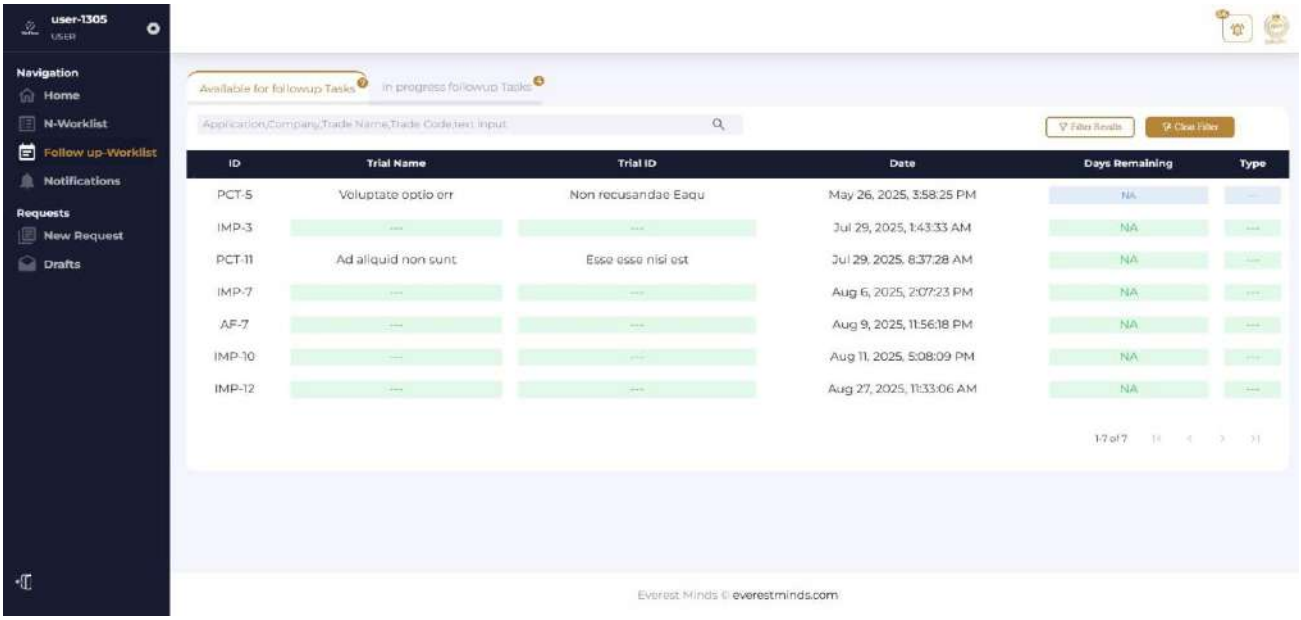

Figure 2.4: Follow-Up Worklis

2.1.3 Notifications

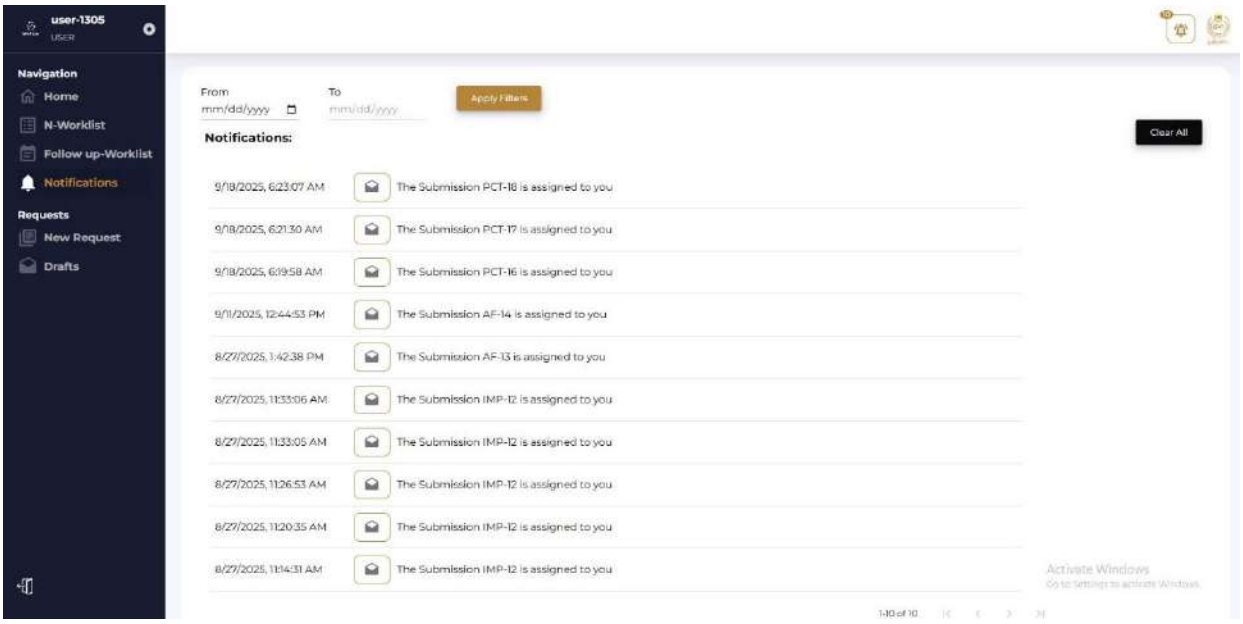

Figure 2.5: Notifications

From the side navigation bar you can access the notifications that are sent to you whenever an action regarding your application occurs or they can be accessed from the top right notification icon.

2.1.4 New Request

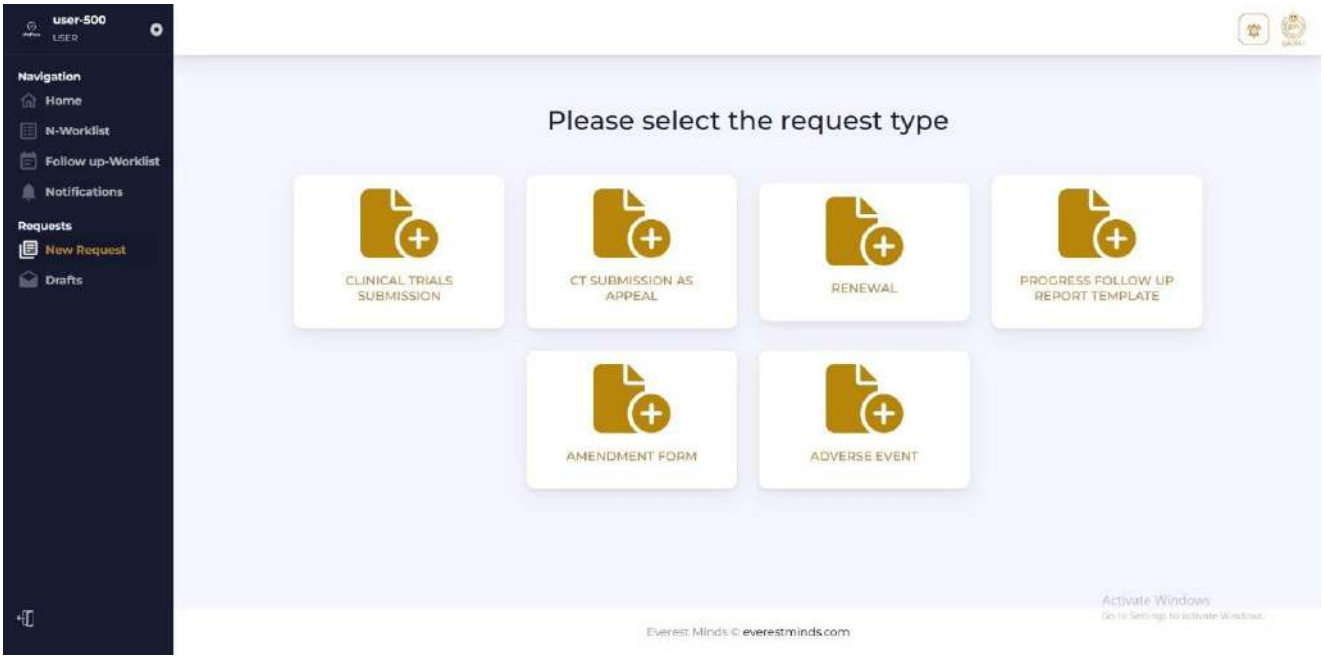

Figure 2.6: Selecting the request type

The company can start a new request from the New Request Tab in the side navigation bar, then they will be able to choose which type of request from the following:

- CT submission
- CT submission as an appeal
- Renewal
- Progress follow-up
- Amendment
- Adverse event

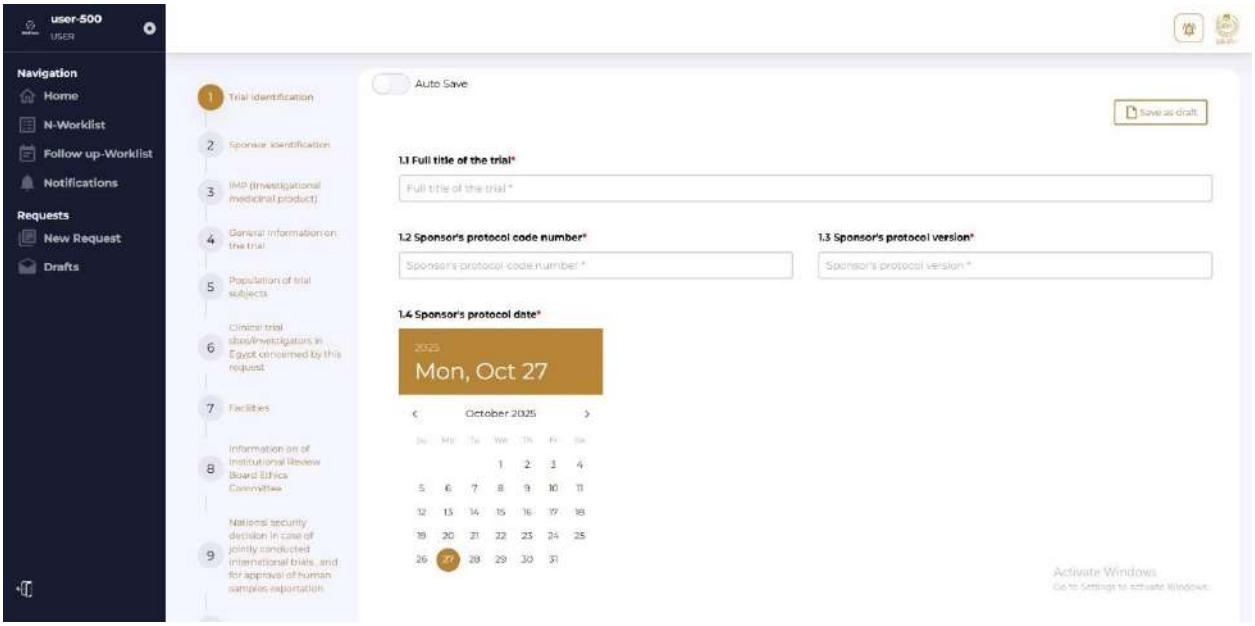

Figure 2.7: CT application form

To ensure data consistency and integrity, please note that certain fields within this section are automatically populated with information from EDA's central database.

These system-managed fields are displayed for your reference but are not editable directly within this form. Any updates to this underlying data must be performed through the appropriate administrative channels or system processes.

Summary of Field Types:

- Editable Fields: Clearly marked input areas where you can enter or modify information.
- System-Managed (Non-Editable) Fields: Clearly labeled fields whose values are sourced directly from the database and cannot be changed here.

This approach guarantees that you are always viewing the most accurate and up-to-date core information while preventing unintended changes to critical system data.

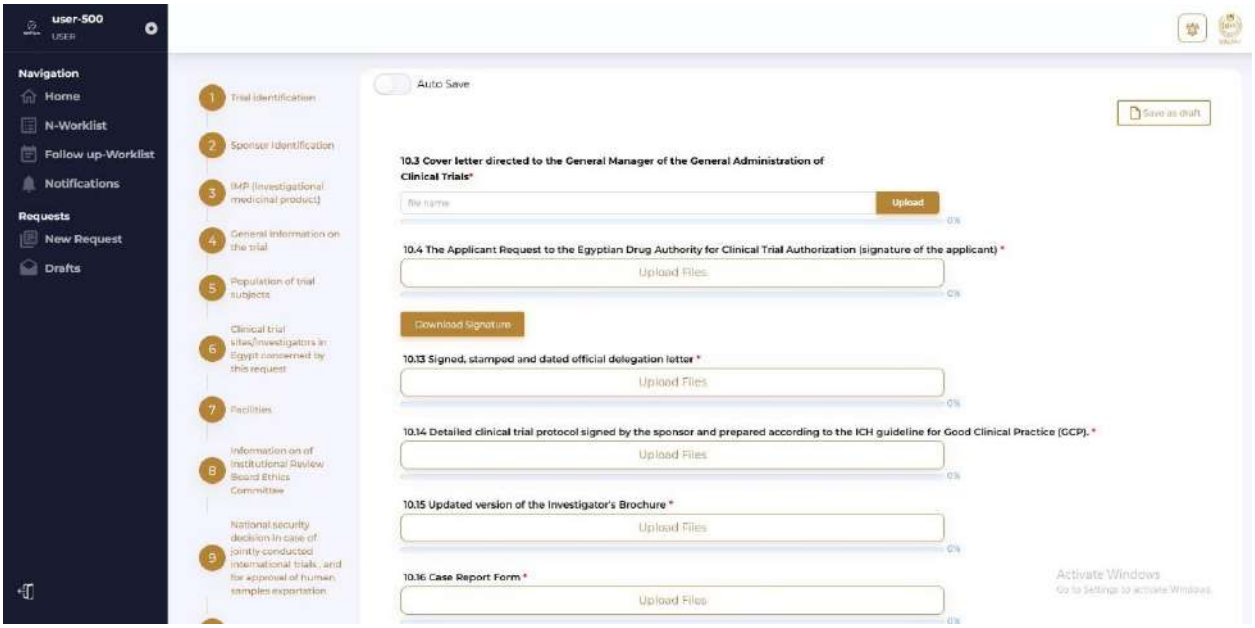

Figure 2.8: CT Checklist

After filling all the data in all 9 sections and pressing next the user will be asked to upload a list of files some of them are mandatory and some are optional as shown.

The company should only upload PDF files, other types of files will be rejected by the portal and this message should appear "please check files extensions". Also, encrypted PDF files won't be accepted.

The company can use the multiple uploads feature. This means the company can upload more than one file under each attachment request. There is a difference between the multiple upload feature and the single upload feature. Multiple uploads feature does not have a load bar, while the single upload feature has a load bar. Moreover, the button for multiple upload feature says "Upload Files", while the single upload feature says "Upload".

Please note that the red asterisk means that this file is mandatory which means that you could not submit unless you upload all the mandatory files.

The checklist changes according to the type chosen while filling the application information data

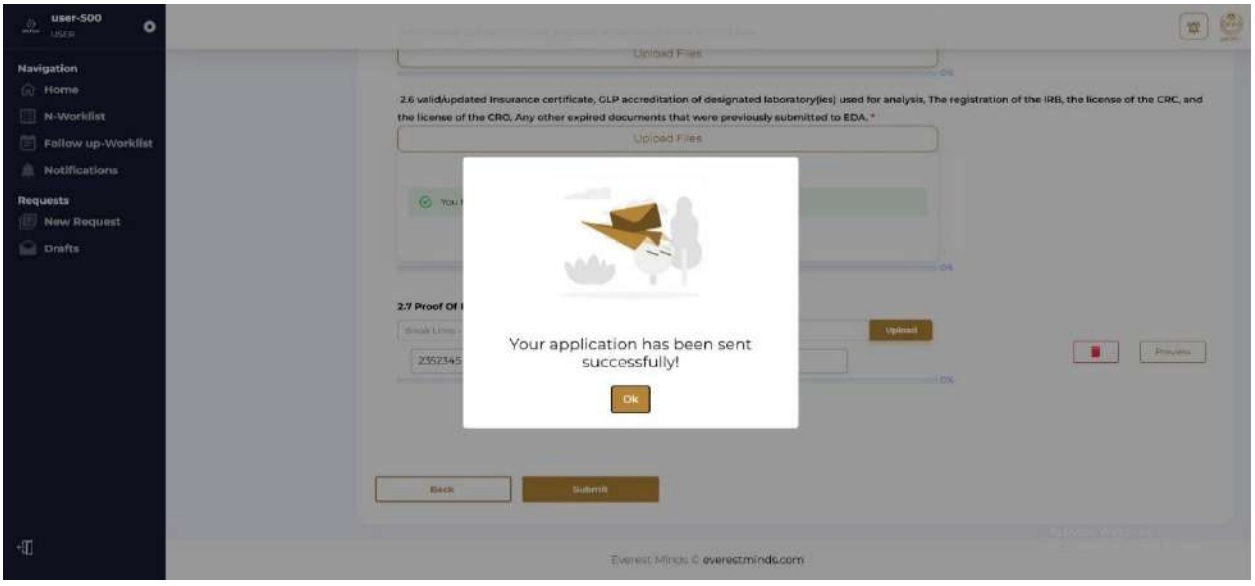

Figure 2.9: Successful submission

Once the application is filled successfully and all the mandatory fields are filled the user can then submit his application and he will then get the following message notifying him that the application is now submitted as shown.
The application features an intelligent Auto-Save function designed to safeguard your work continuously. This system automatically captures and securely stores all data entered into the form fields at regular intervals and upon any detected change. You can proceed with confidence, knowing that your progress is preserved in real-time, effectively eliminating the risk of data loss due to unexpected interruptions such as browser closures, power outages, or connectivity issues. Your information will be promptly restored upon your return, allowing you to resume your work seamlessly from the last saved stat

2.1.5 Draft

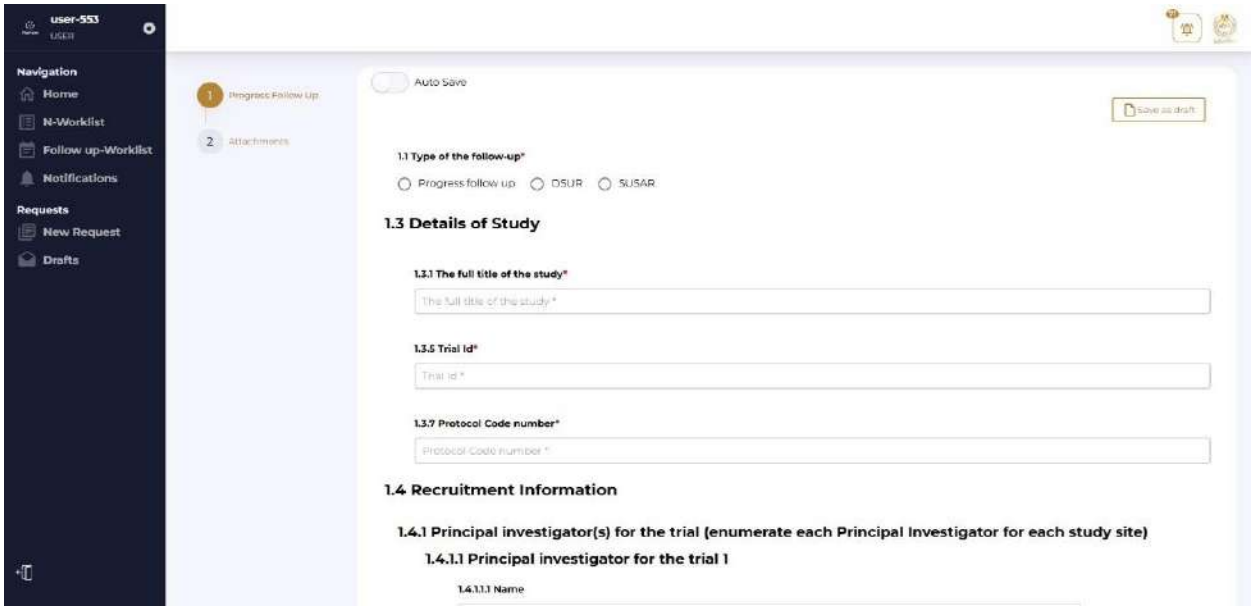

Figure 2.10: Draft

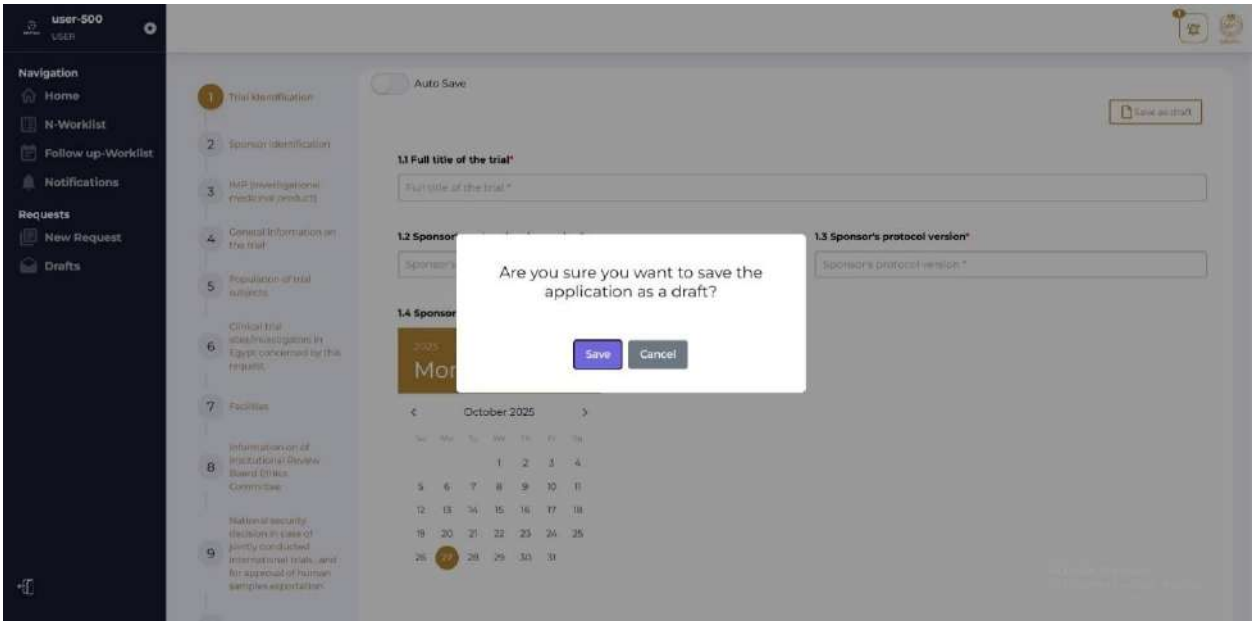

Figure 2.11: Draft 1

While filling the application the user will have the ability to save the application as a draft from the button at the top right corner “Save As Draft”, the user will then be asked to confirm his choice and press save as shown.

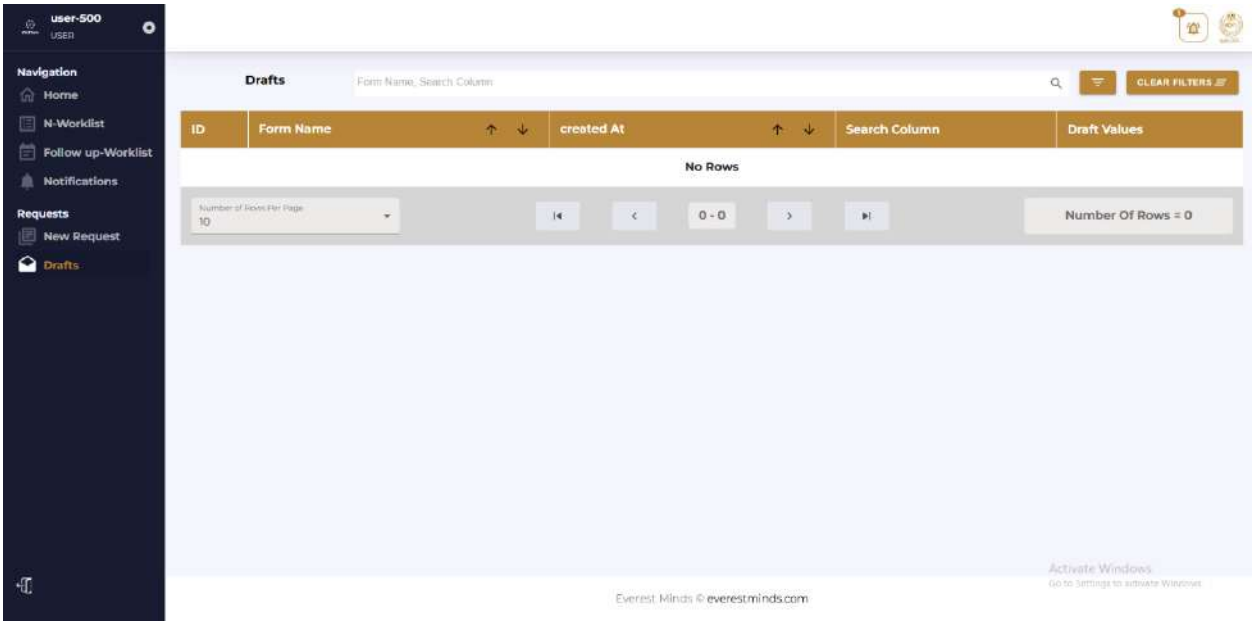

Figure 2.12: Draft 2

The user will then be able to find all his drafted applications on the tab named “Draft” in the side navigation bar, he will also be able to find his drafts as shown.

2.1.6 Submission Details page

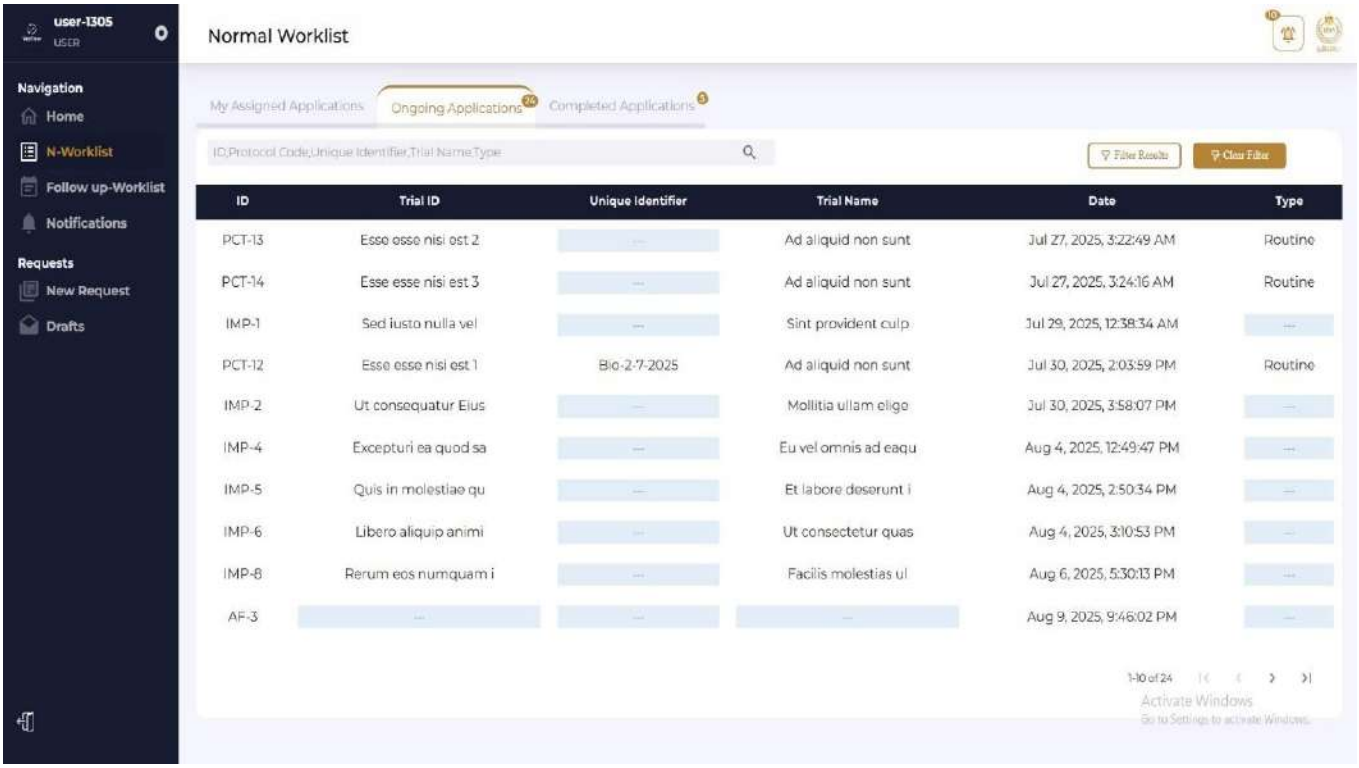

Figure 2.13: Submission details page

Once the user submits his application, he can then find it inside the ongoing tab, and he can press on it to open the submission details page.

The submission details page will contain more than one tab each containing different types of data regarding the application. These tabs are as follows:

- Clinical Trials Application form
  - Trialidentification
  - SponsorIdentification
  - IMP (Investigational medicinal product)
  - General Information on the trial
  - General Information on the trial
  - CT sites
  - Facilities
  - Information on of Institutional Review Board Ethics Committee
  - National security decision in case of jointly conducted international trials, and for approval of human samples exportation
  - Checklist
- Labs [Quality Labs] (Concerned Labs)
- Company Attachments
- Generated Files

1 Submission Details

The Submission Details page contains all the submission details

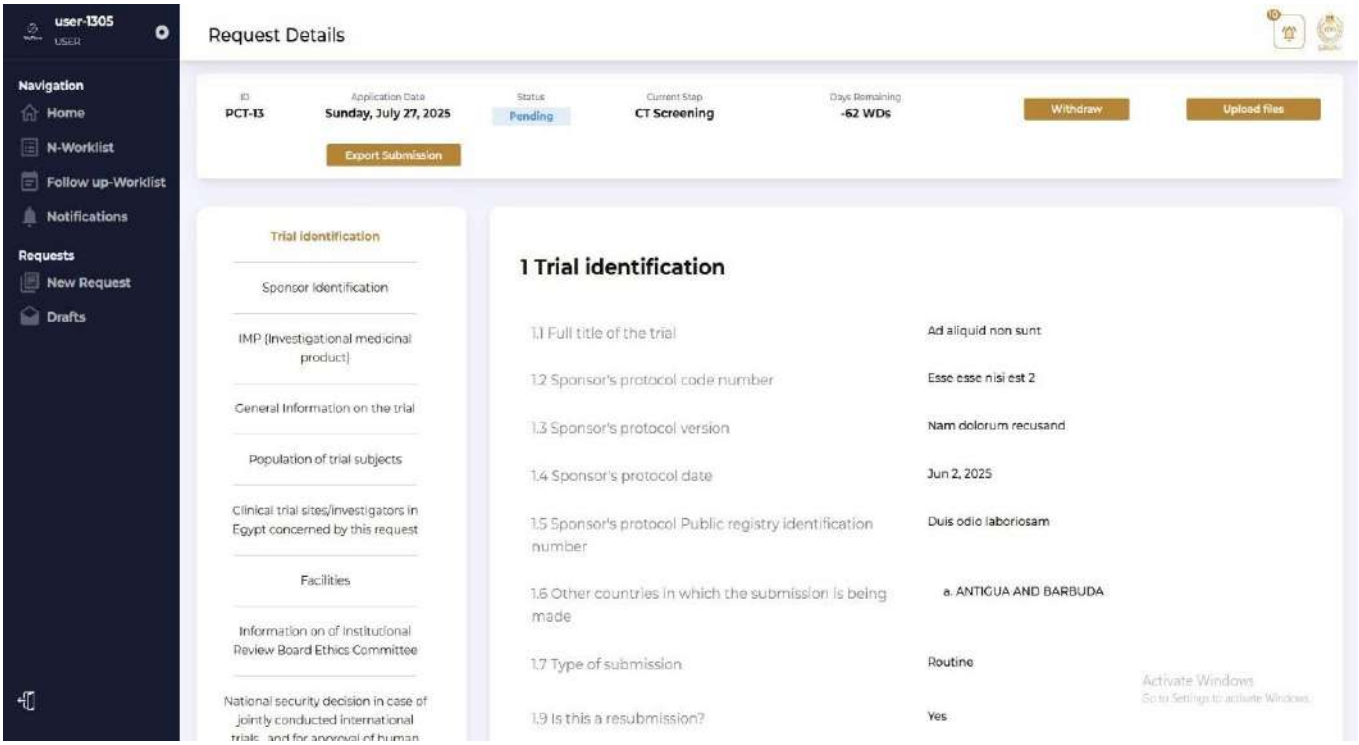

Figure 2.14: Submission details page

2 Screening Checklist

Screening Checklist contains the documents uploaded by the company

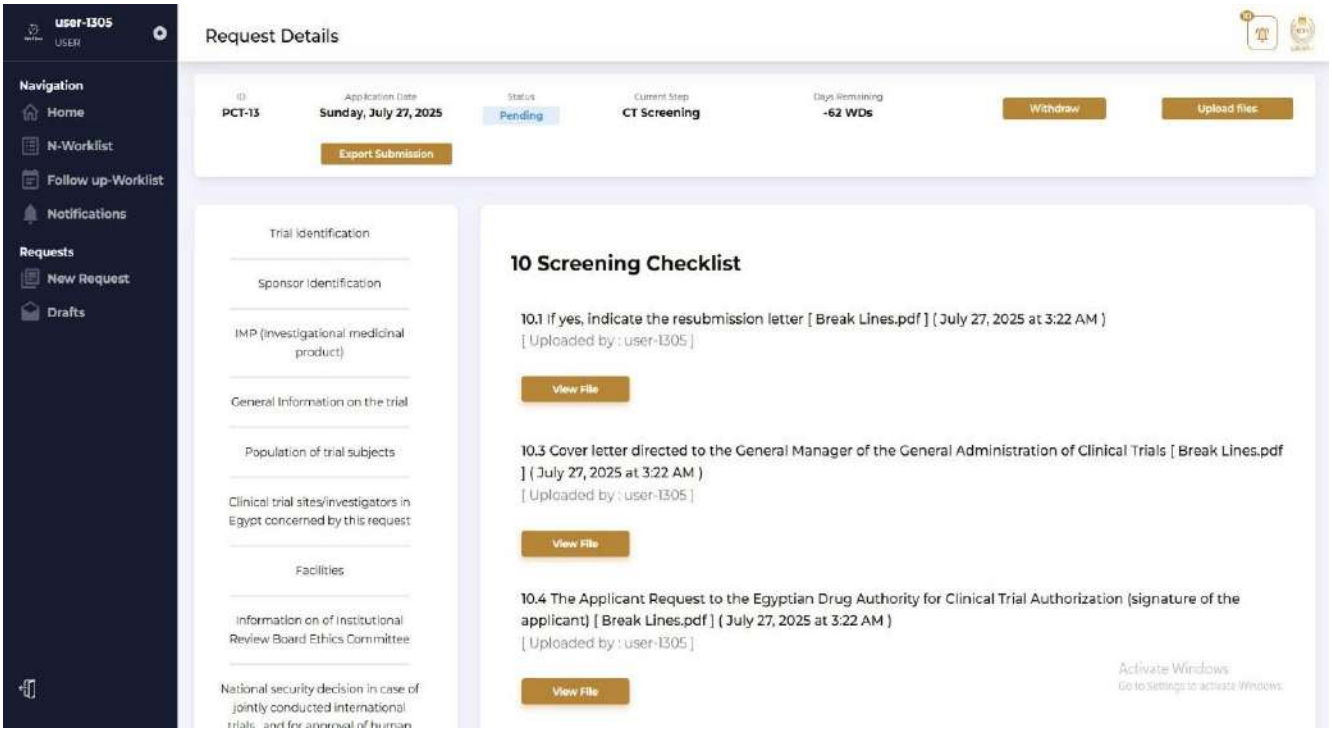

Figure 2.15: Screening checklist

3 Company attachments

The Company Attachments section serves as a centralized and easily accessible repository for all PDF documents uploaded by the company to the portal.

It is important to understand the difference between the documents here and those in the main Checklist:

- Checklist Attachments: These are mandatory documents required to fulfill specific application. They are directly tied to the checklist and are critical for the evaluation process.
- Company Attachments (This Section): This area contains voluntary, supplementary documents provided by the company. These are extra materials not linked to a specific checklist item but are made available to offer additional context, support, or information to authorized users.

This dedicated section ensures that all supplementary documents uploaded by the company are readily available in a single location. By consolidating these materials, the feature streamlines access to critical information, eliminating the need to search through disparate emails or announcements and ensuring you are always referencing the most current versions of company-provided documents.

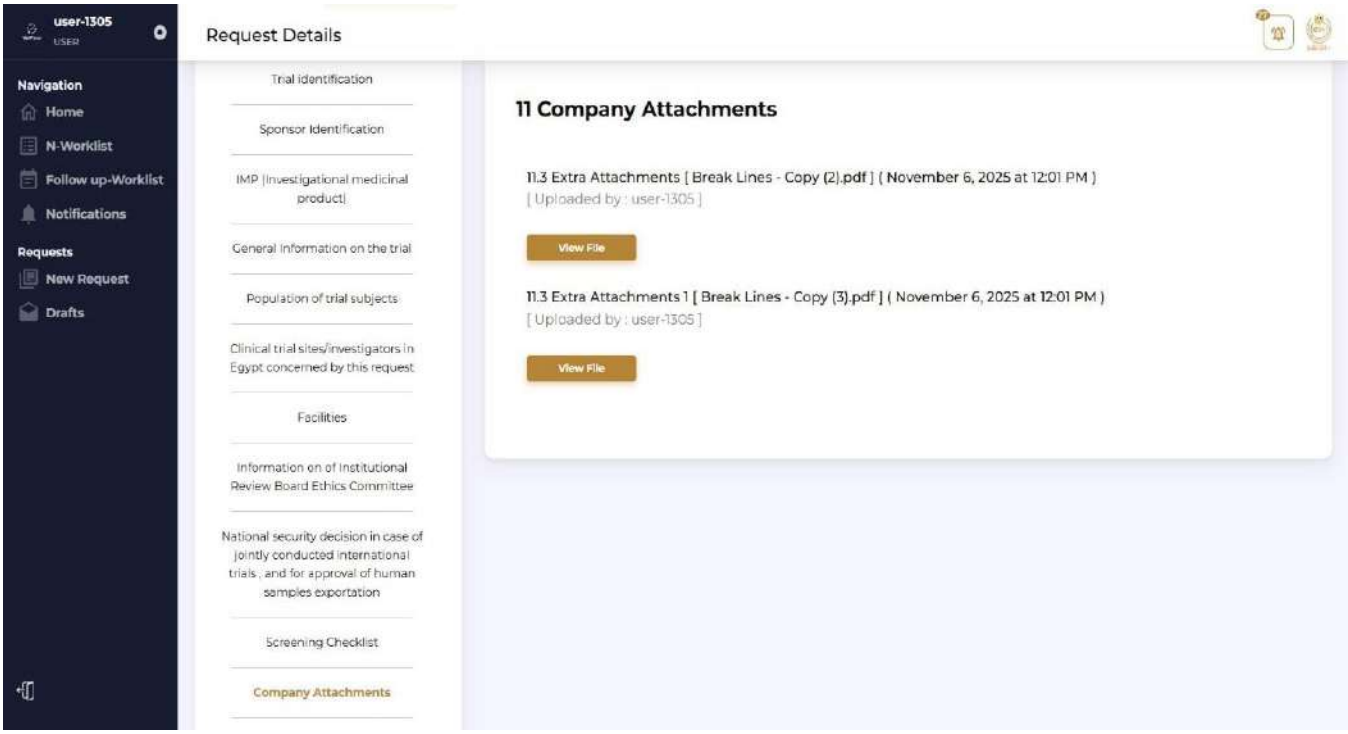

Figure 2.16: Company attachments

4 Upload Attachments Feature

The portal provides a persistent Upload Attachments feature, granting your company unrestricted access to submit necessary documents at any time. This always-available functionality ensures you can promptly add new files directly without delay to your profile other than the main screening checklist. The feature supports the submission of PDF types only as mentioned earlier.

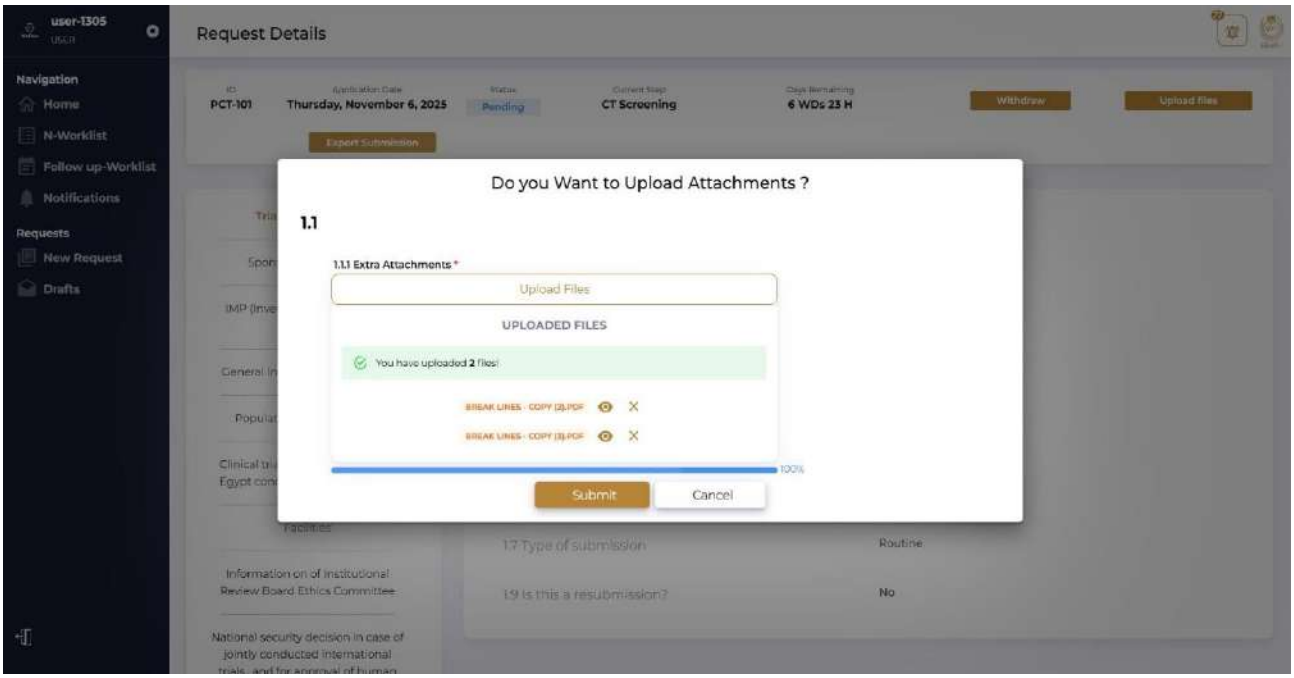

Figure 2.17: Upload Attachments Feature

5 Generated Files Section

The Generated Files section serves as a dedicated repository for all documents automatically produced by the system. This centralized location contains essential files generated from the EDA process, including reports, Letters of Requirements, and official approval or rejection letters. All documents are systematically organized within this section, providing a complete and easily accessible audit trail of all system-generated communications and outputs. This ensures that users have immediate access to critical information for review, download, and record-keeping purposes.

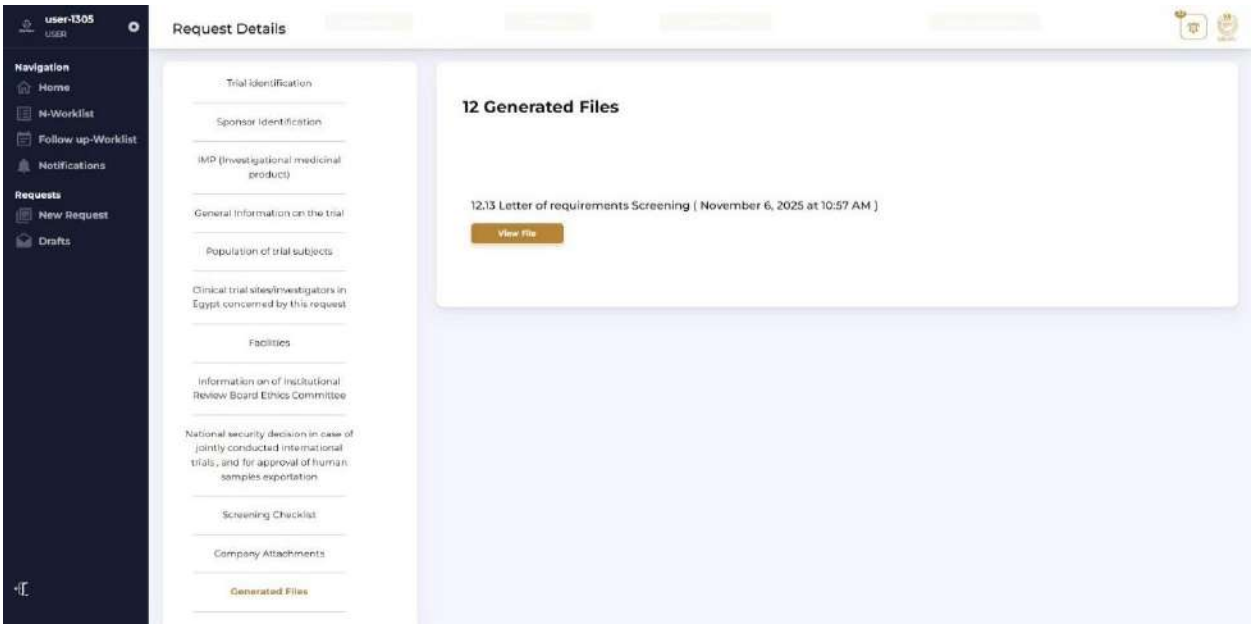

Figure 2.18: Generated Files Section

6 Export Submission Feature

The portal includes an Export Submission feature, enabling you to generate a comprehensive and consolidated record of your entire application. With a single click, this function produces a single PDF document that captures all data, entered information, and details from the current submission page. This provides a complete and portable snapshot of your submission for offline archiving, internal record-keeping, or official review processes, ensuring you have a formal and permanent record readily available.

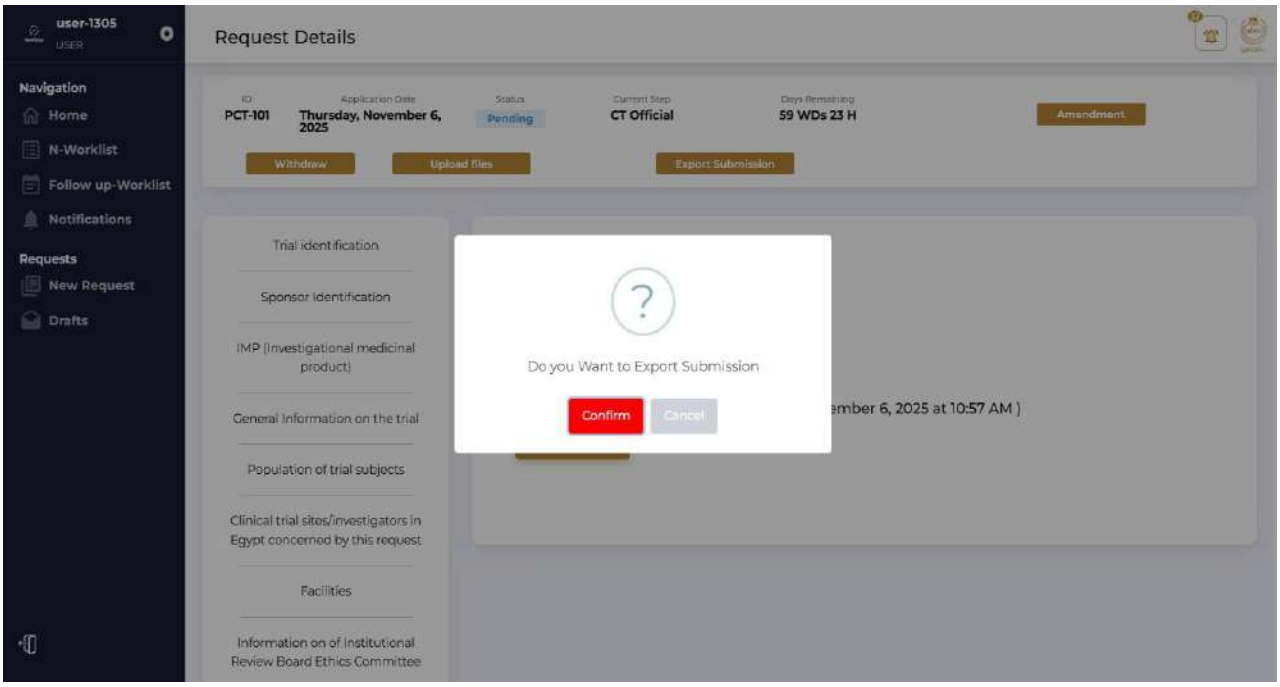

Figure 2.19: Export Submission Feature

2.1.7 Comments section

In this section the company can find all the back-and-forth communication between them and the Egyptian Drug Authority (EDA).

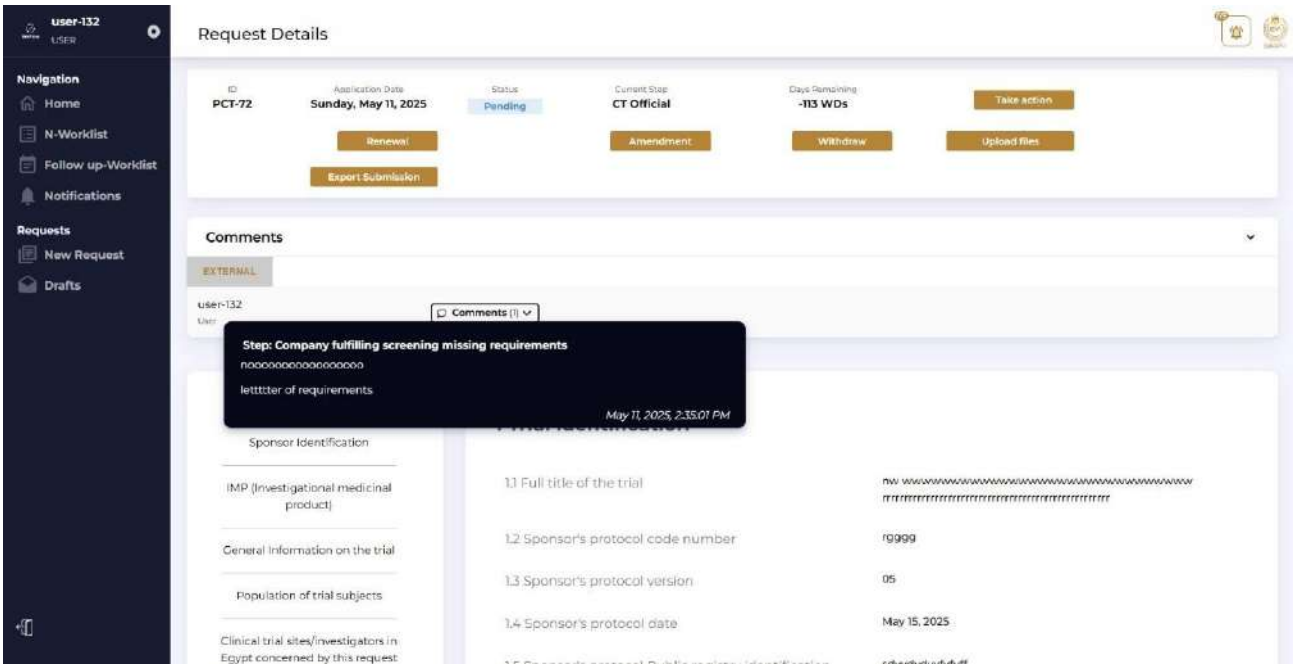

Figure 2.20: Comments sections

The company can find the comments sent to them in the comments section showing the date of the

2.2 Re-uploading rejected files

At any time during the process the submission can be sent back to the company to re-upload the unaccepted documents

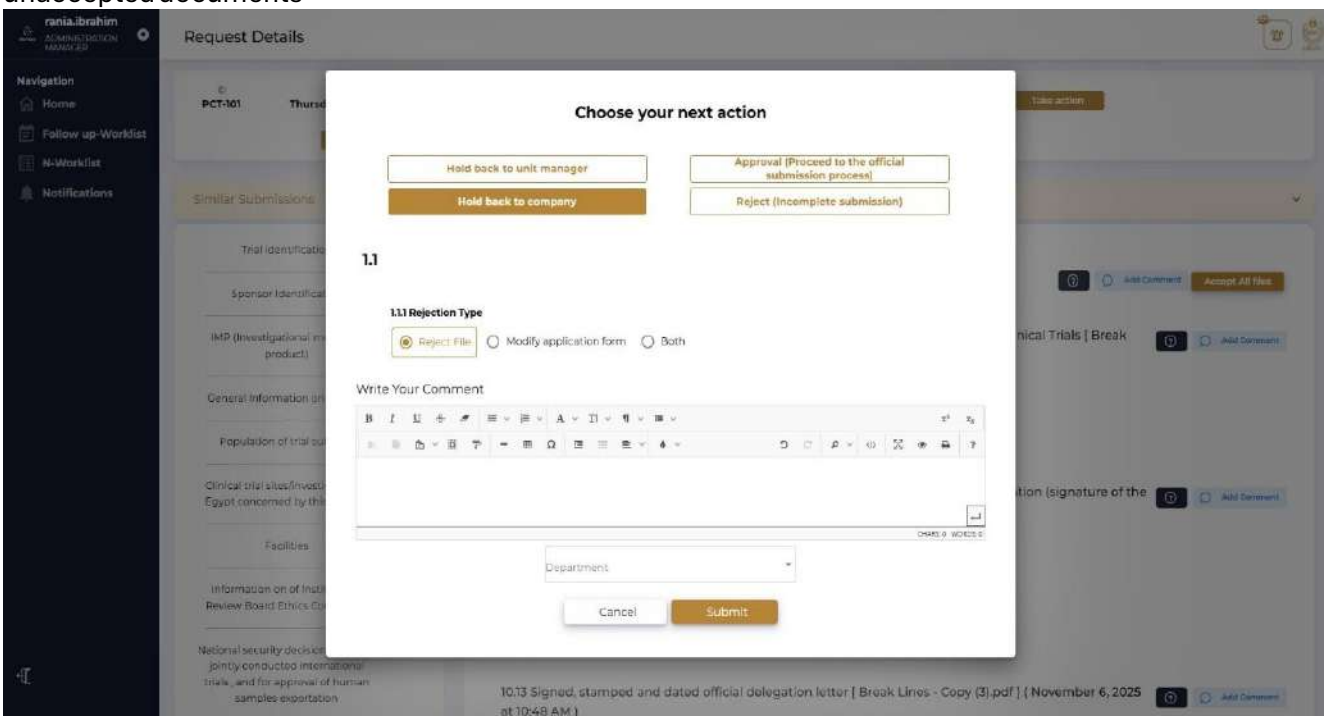

Figure 2.21: Re-uploading rejected file

The company will be able to open the submission from their work list “My Assigned Applications Tab” or from the notification they received to open the submission details page from which they will be able to access all their submission details and re-upload the required documents.
The company will then have to re-upload the required documents by opening the Checklist Tab on the left navigation bar inside the details page and start re uploading all the documents.
Please note: Any previously uploaded documents will be automatically archived as a historical record. These old documents will not be visible for the re-upload process but can still be viewed by EDA users for tracking and compliance purposes.

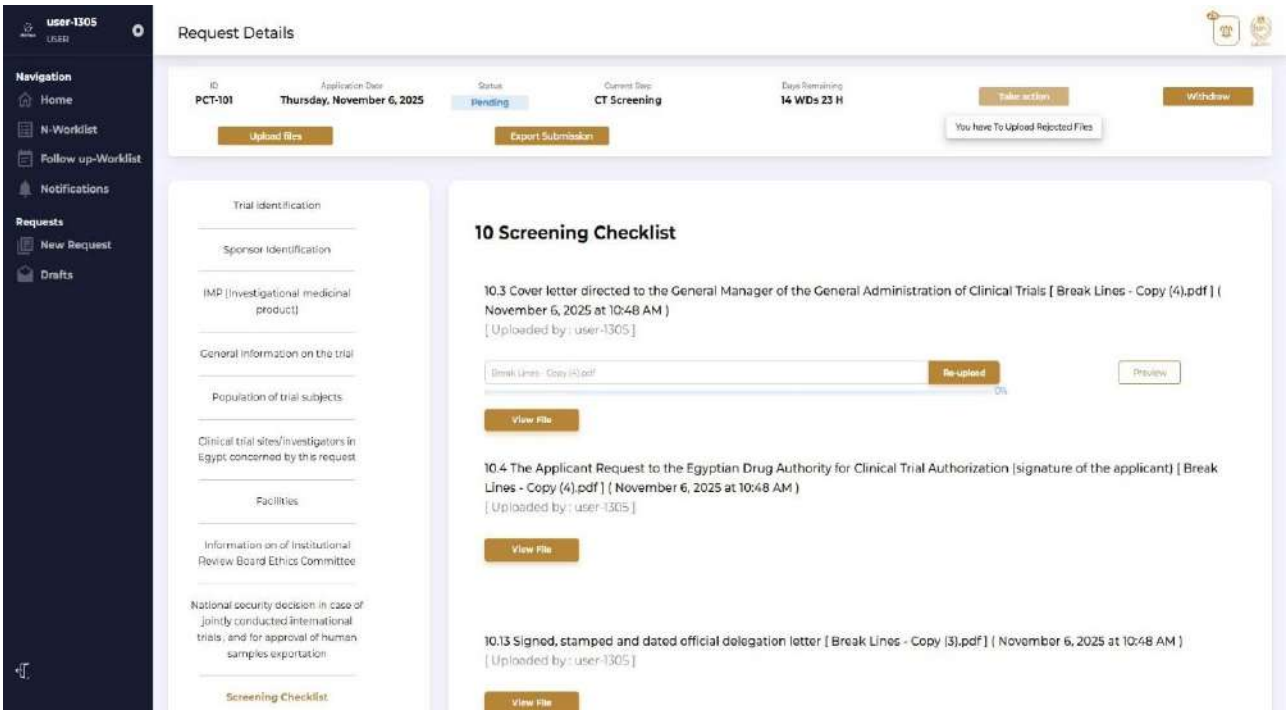

Figure 2.22: Take action

After re-uploading all the documents, the user should make sure to press on the save button on the top right to confirm his new uploads.

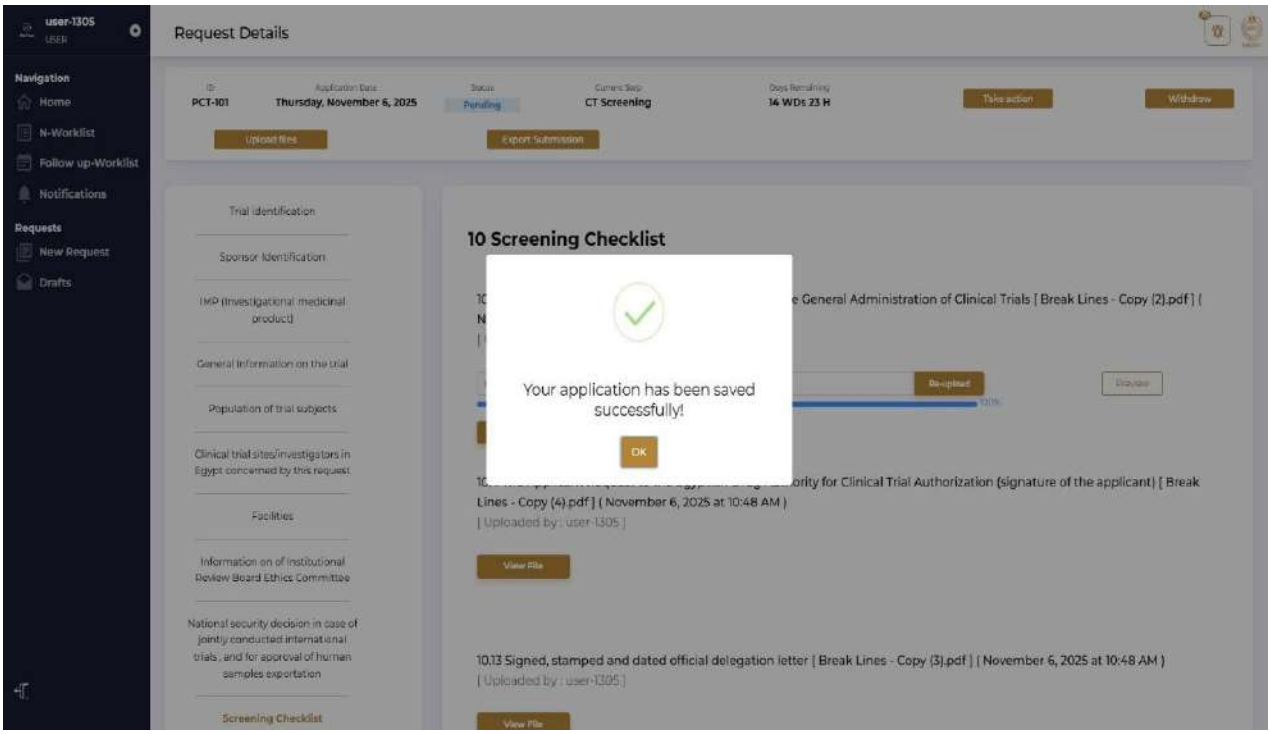

Figure 2.23: Save

The take action button on the top corner inside the details page will now be enabled.

The company is now able to press on the “Take Action Button” to Re-forward their submission again to the Egyptian Drug Authority (EDA); they will also be given an option to send a comment if needed.

By pressing submit the application will be sent once again to the Egyptian Drug Authority (EDA) to continue assessment.

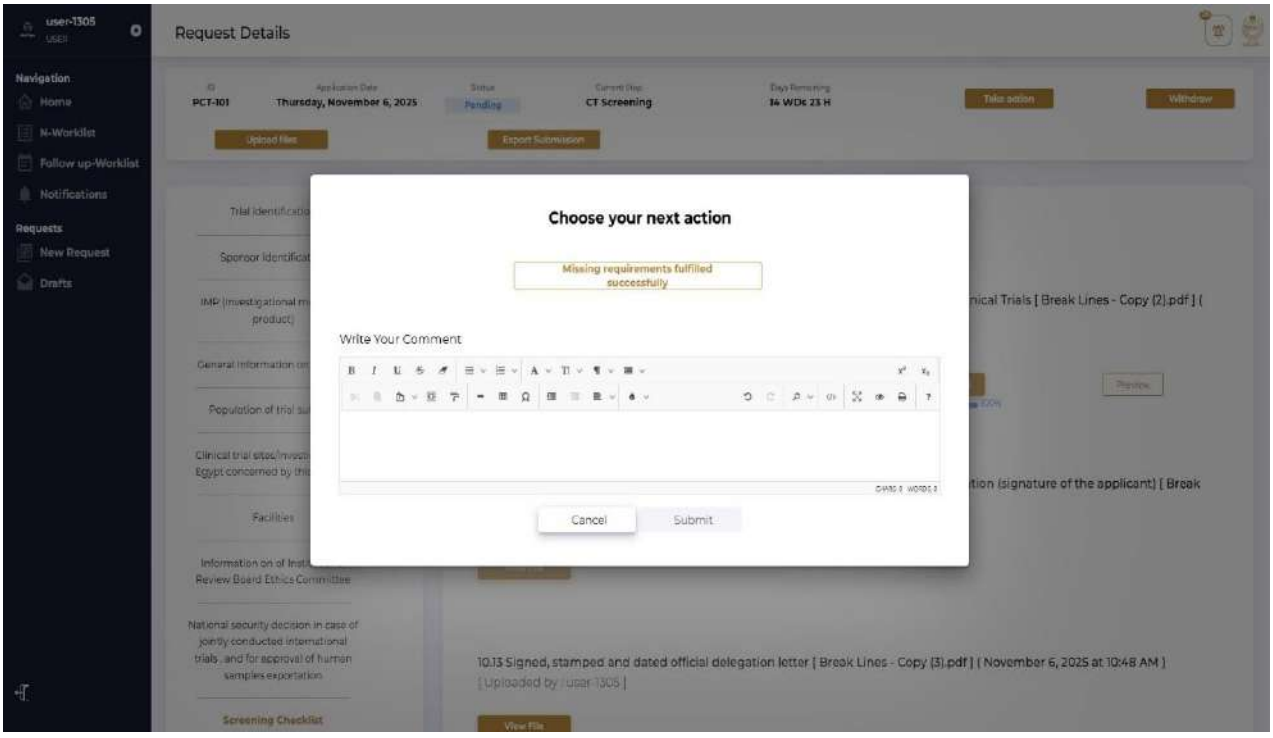

Figure 2.24: Save

2.3 Modify application form

We've mentioned the scenario where a file can be rejected by the Egyptian Drug Authority (EDA) and accordingly the submission is sent back to the company in order to re-upload the rejected file. Moreover, the application form can be the only rejected section. This will lead us to the "Edit" scenario. The EDA can either reject a file or reject the application form or reject the whole submission

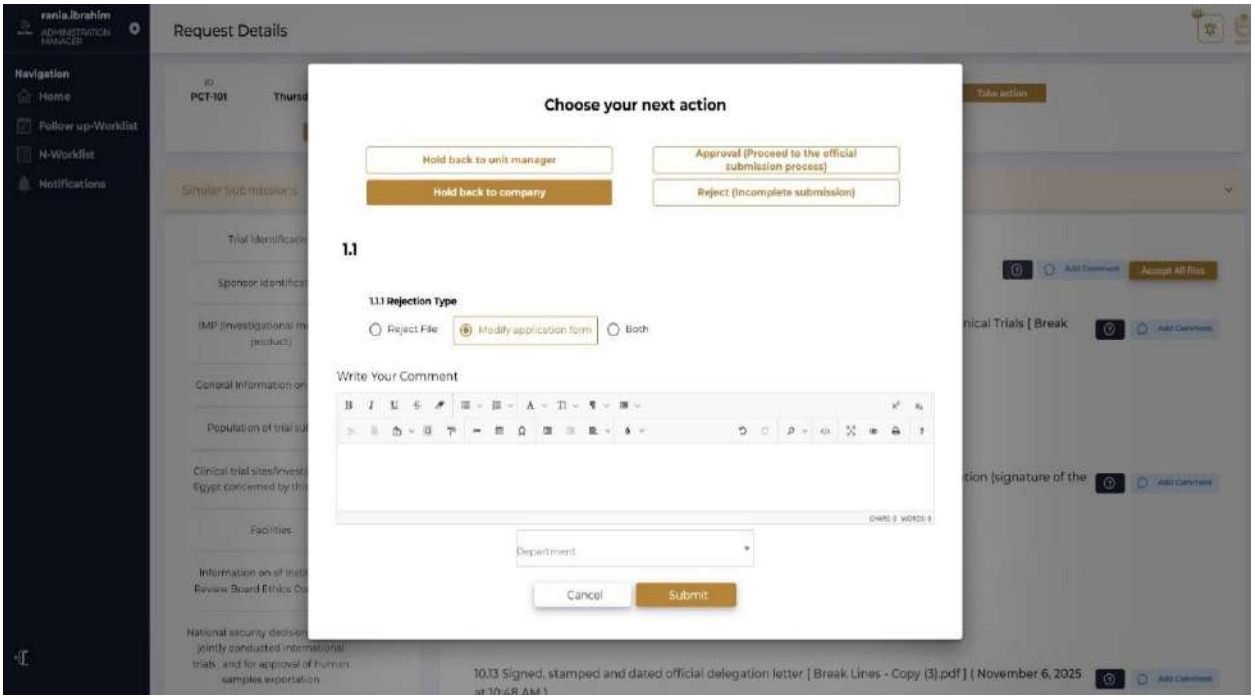

Figure 2.25: Modify application form

Therefore, the submission will be sent to the company in order to edit the submission application

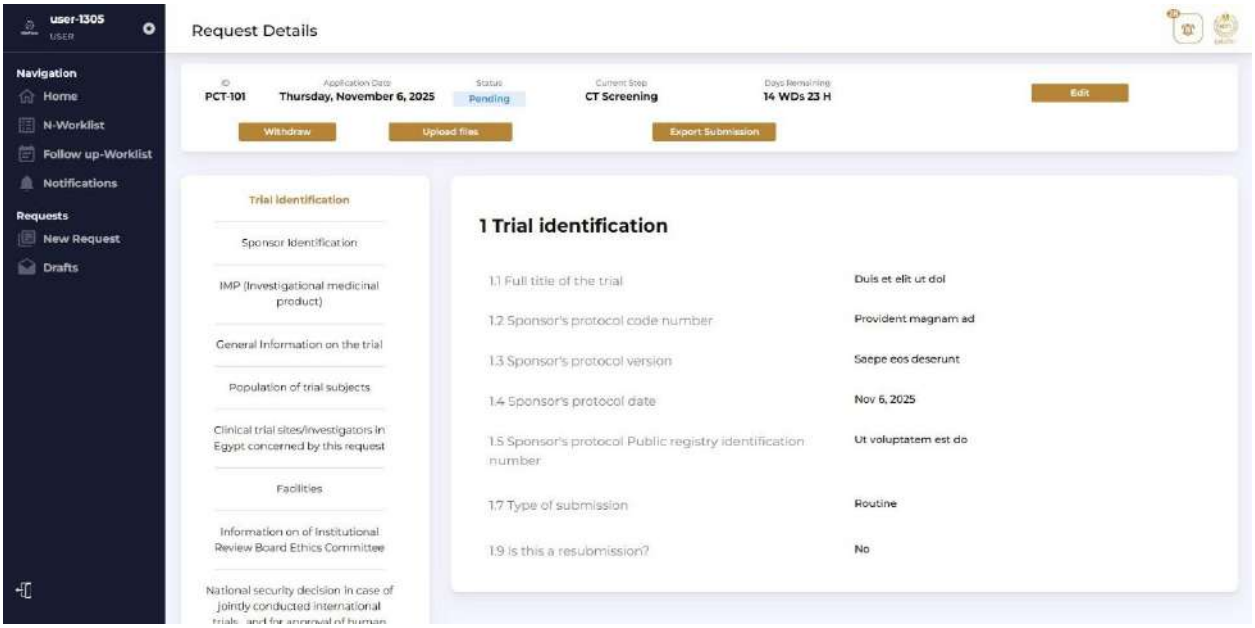

Figure 2.26: Edit

The company is now able to press on the “Edit” button to modify and change any necessary data regarding their submission again and sent it again to the Egyptian Drug Authority (EDA)

By pressing "Submit" the application will be sent once again to the Egyptian Drug Authority (EDA) to continue assessment.

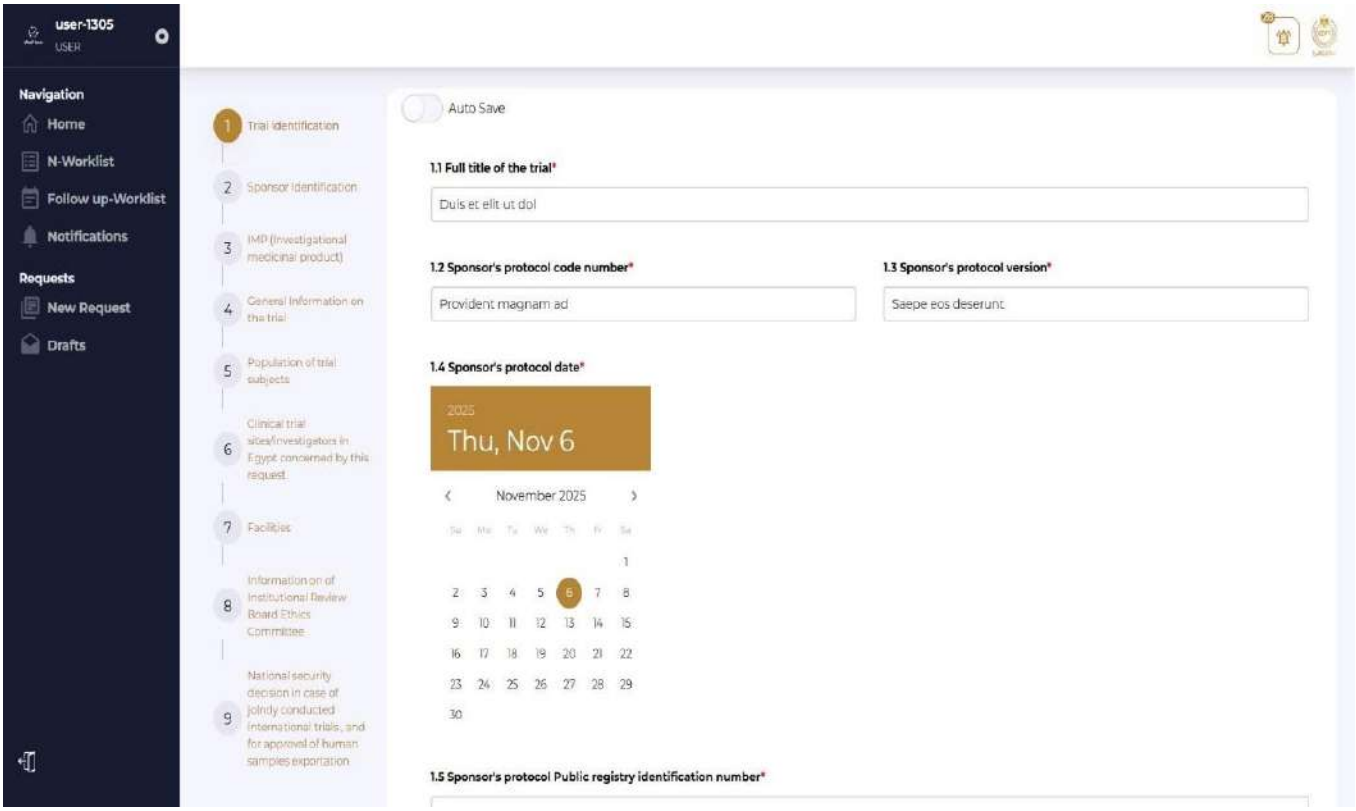

Figure 2.27: Modify application form

2.4 Both

The platform facilitates a structured resubmission process in the event that the Egyptian Drug Authority (EDA) requires changes to a submission. The EDA may reject a specific file, the application form itself, or the entire submission. In all cases, the submission is returned to the company for corrective action. To manage this efficiently, the system provides a guided workflow. For instances involving both rejected files and a rejected application form, the company must first address all file-related rejections by re-uploading the corrected documents. Once this mandatory step is complete, the "Edit" button for the application form becomes enabled, allowing the necessary modifications to the protocol details and other data. After all required corrections are made, clicking "Submit" sends the revised and complete application back to the EDA for reassessment, ensuring a clear and sequential path to compliance.

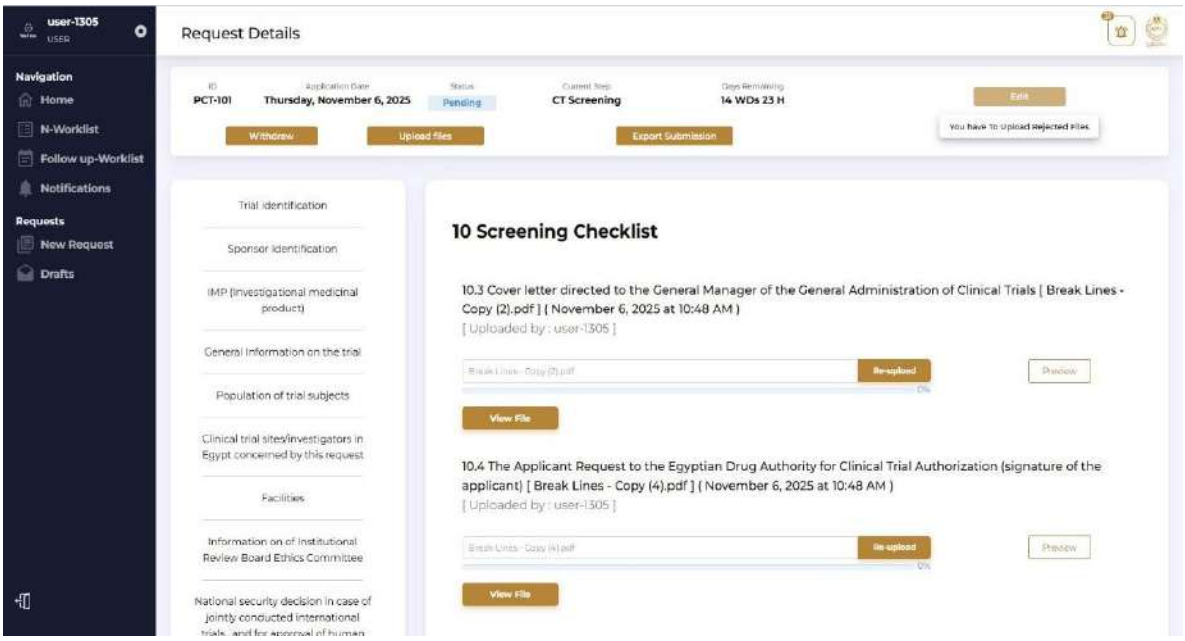

Figure 2.28: Both

2.5 Proof of payment

To complete the proof of payment process, the company must follow a specific sequence of actions to ensure accurate and valid payment registration. First, a PDF copy of the official payment receipt must be uploaded to the platform. Following a successful upload, the company is then required to manually enter the corresponding unique receipt number and the specific receipt number for the service into the designated data fields. It is critical to note that the platform's validation system does not permit duplicate entries; each payment receipt number can be associated with only a single transaction and must be unique across the entire system. This ensures the integrity of all financial records and prevents any potential processing errors.

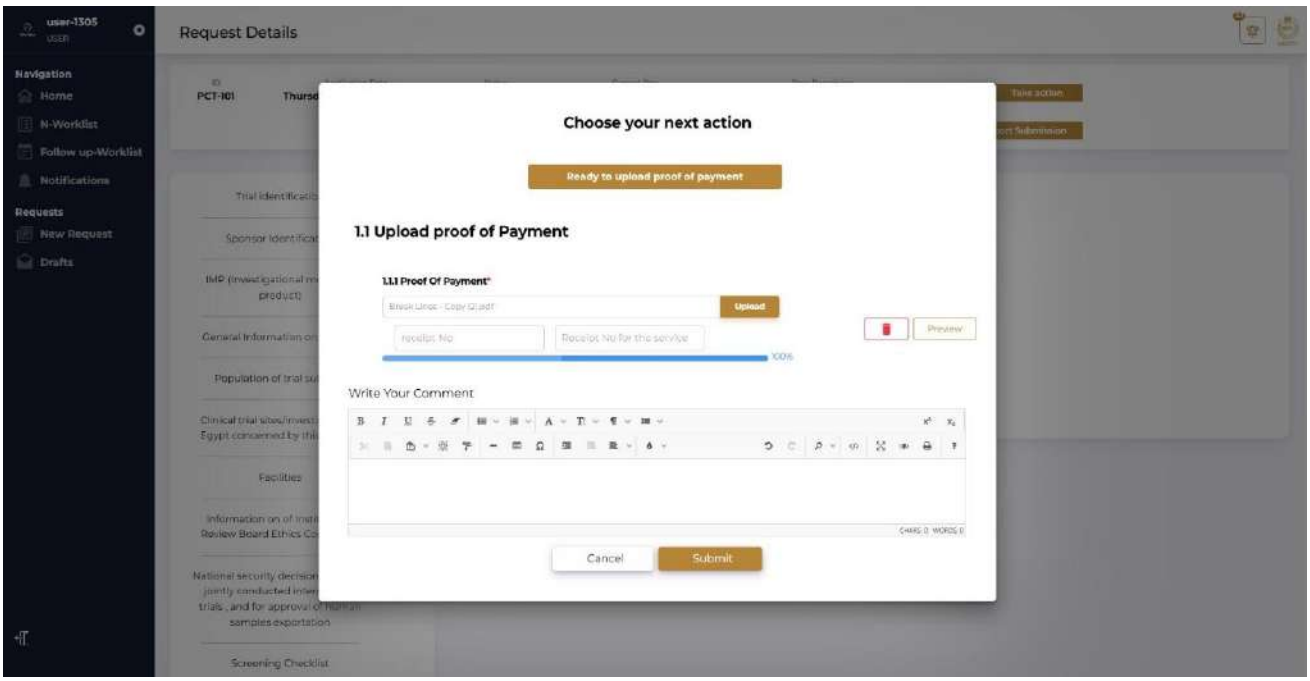

Figure 2.29: Proof of payment

History Table

Version No.	Issue date	Summary of Changes