FerrArI – Screening Literature Review User Manual

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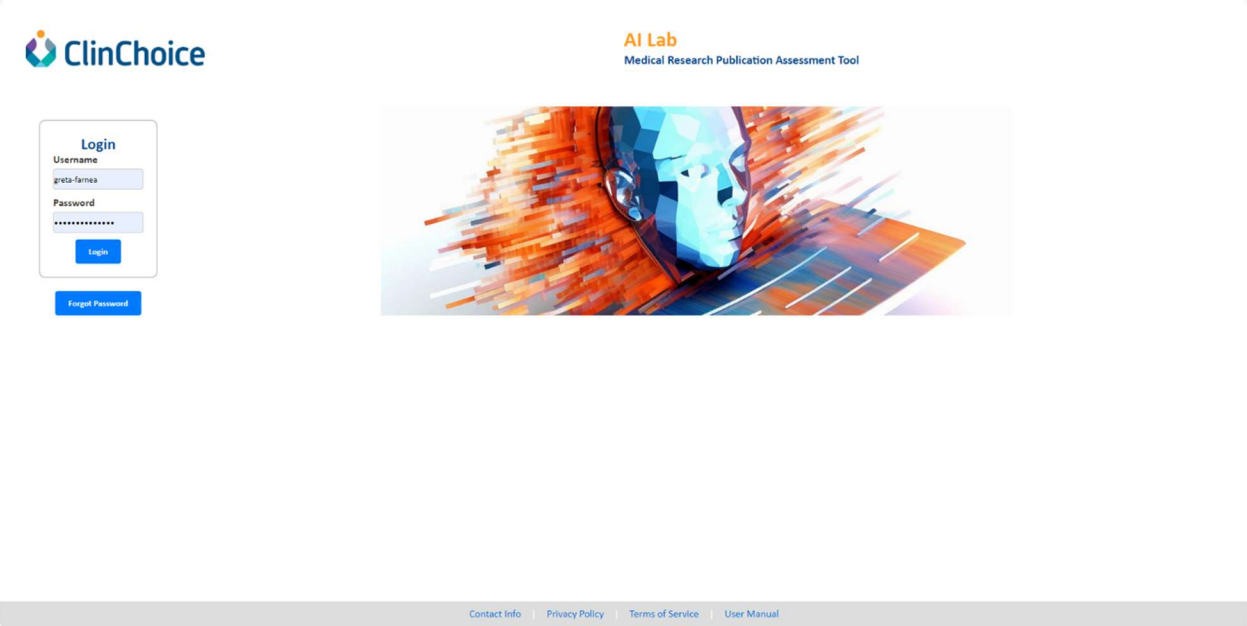
Introduction

This User Manual provides a full description and instructions of *FerrArI – Screening Literature Review* application, version 2.0.0.

Login Page

The user can navigate to the given URL and the login page will be displayed.

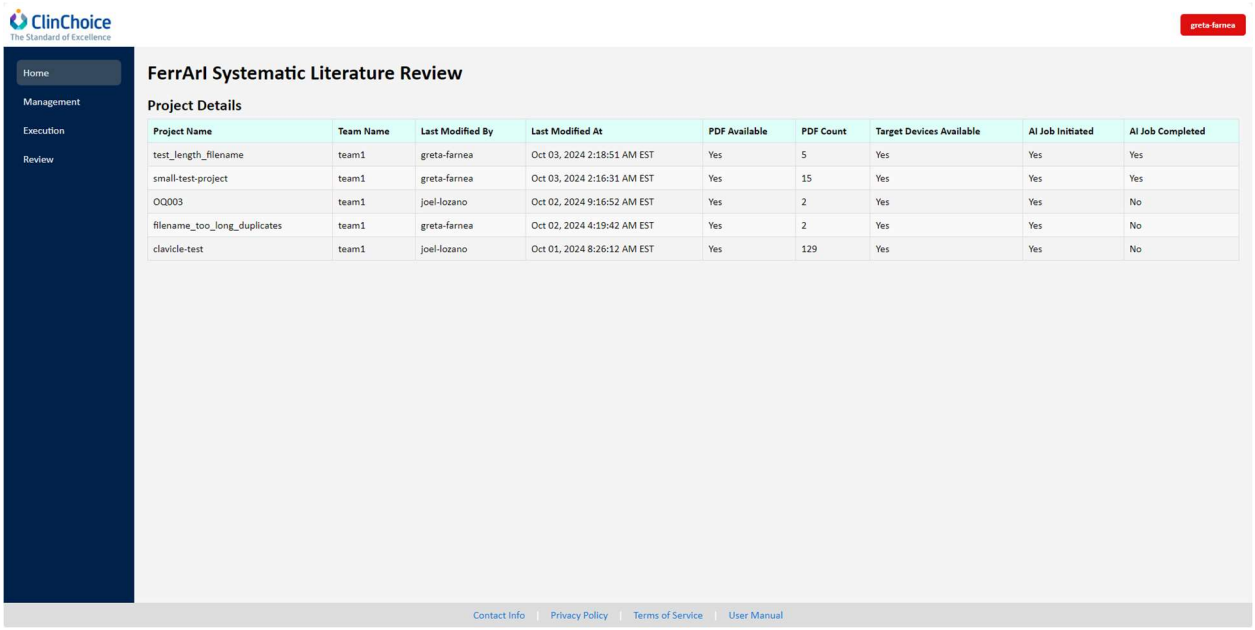
To enter the application, the user must have valid credentials (a username with an associated password) and must enter them in the form. When the Login button is clicked, the homepage of the application will be shown.



If the user does not remember their credentials, they can click on Forgot Password button. A form must be filled in with the username and the email address associated with the user, and once the validation is completed, the user can change their current password with a new one.

Once the user is logged in, the session will last **24 hours** at maximum. After that period, the user will be logged out of the application, and they need to insert their credentials again.

Homepage



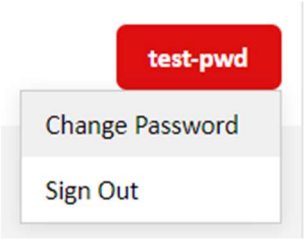
Once login process is successfully completed, the landing page appears.

The content of the page shows a list of 5 most recent projects that are associated with the user, along with some information about the overall status of the project.

At the left side of the page, a menu shows the four available sections of the application:

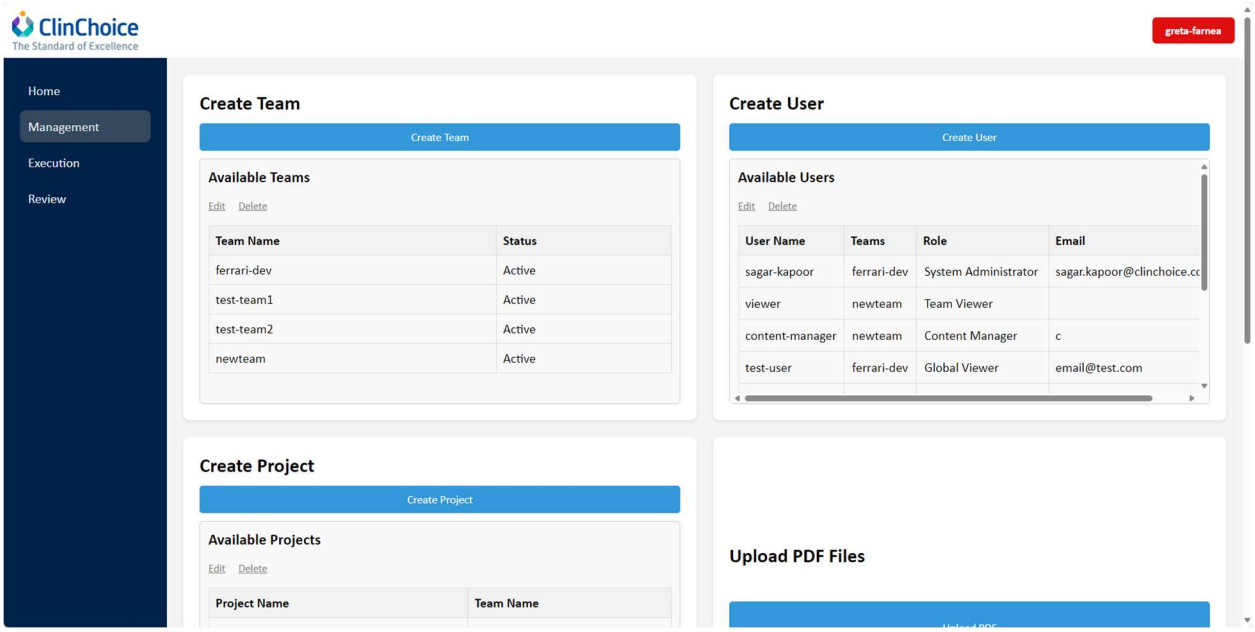
- **Home**: will show the Homepage;
- **Management**: user can create a project from start to end (create it, upload publication PDF files and add Target Device list), and admin user can manage any information about the users' access and teams' creation;
- **Execution**: the page is for starting the literature screening process for a project;
- **Review**: user can see the final classification of the project screening and can review the results.

At the top-right of the screen, a button with the username is displayed, and two options appear if it is clicked. The first option is the change password: the current user can update it by double-inserting a new string that follows the displayed rules.



The second option is a logout button, that allows the user to exit the application.

Management Page



Management Page displays five different forms that user can interact with.

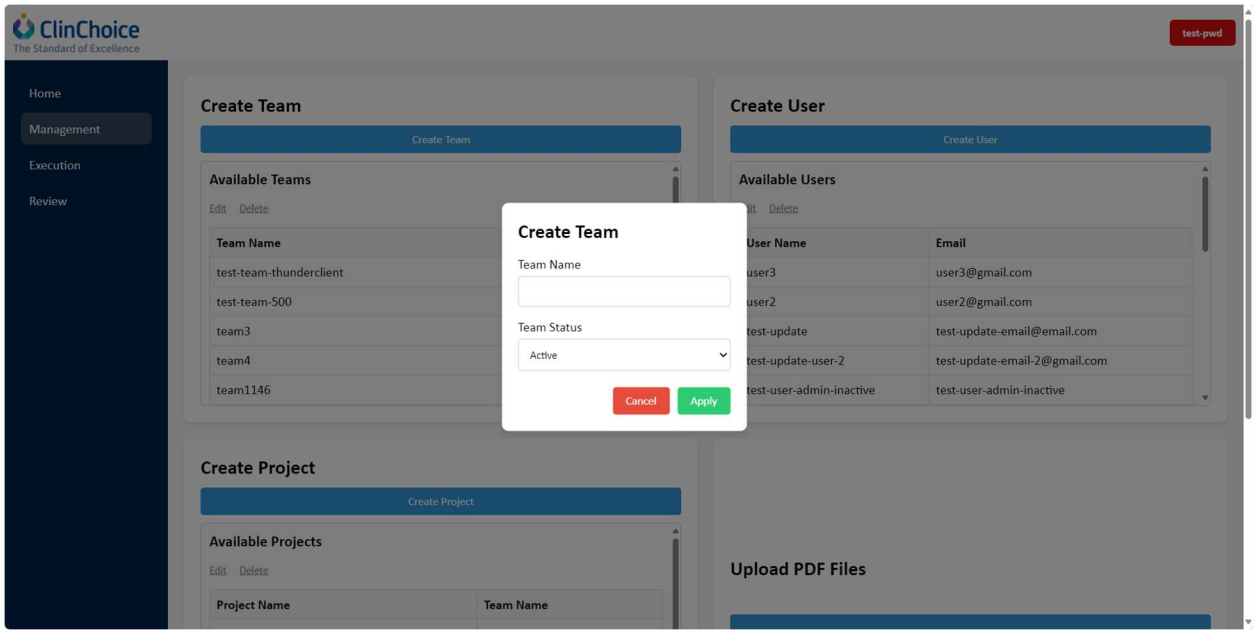
User Roles and Permissions

Operations are allowed or disabled according to the user's assigned roles. The current roles that are available are the followings, with their respective permissions:

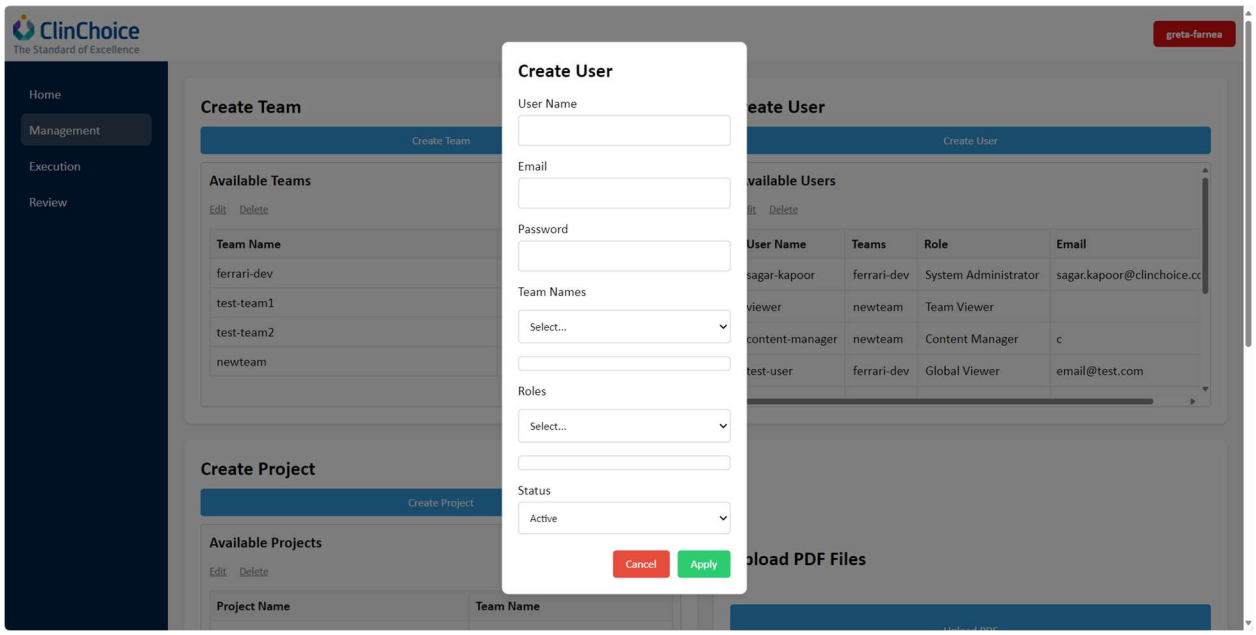
- **Team Viewer**: can view project-related information and team data without editing permissions;
- **Team Contributor**: role is focused on active participation within a specific team, allowing users to execute and review projects;
- **Global Viewer**: can access and view all user, team, project, and analytics data without making any changes;
- **Content Manager**: oversees the management of all projects and teams, with permissions to create, edit, and delete content across the platform;
- **System Administrator**: has comprehensive control over the system, with the ability to create, edit, and delete users, teams, and projects. This role can assign roles to users, manage all analytics, and oversee all aspects of the application. Administrators can also view and edit all content, ensuring the platform operates smoothly and securely.

Creation of new items

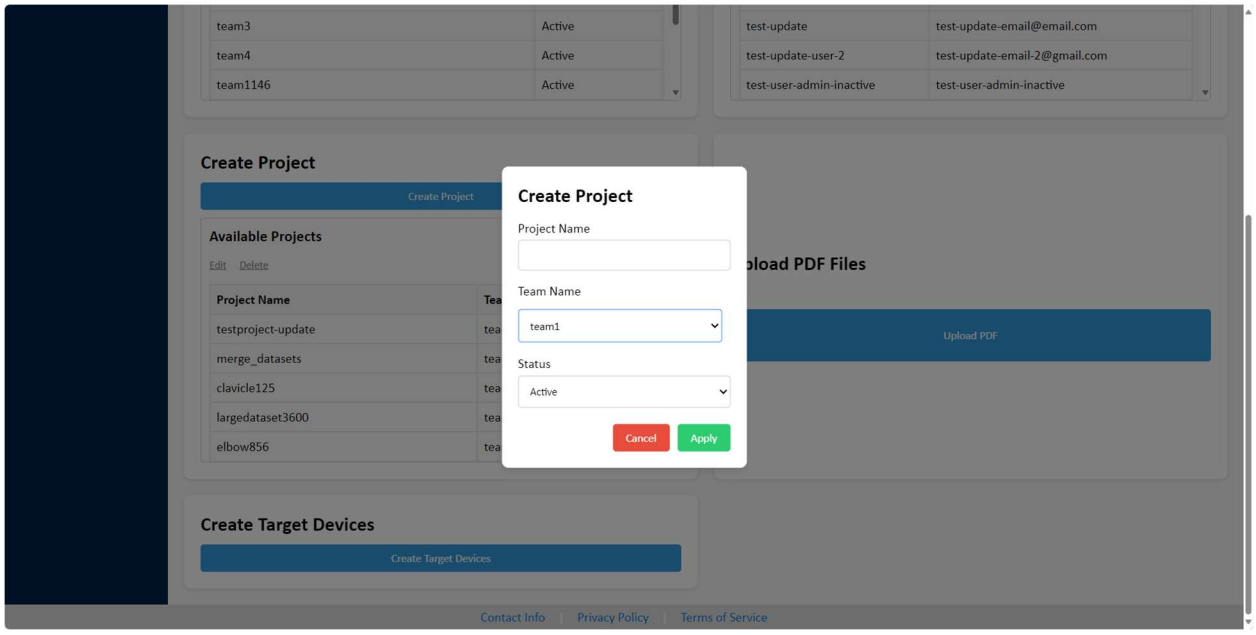
1. **Create Team**: user can create a team that will consist of users and with which a project can be associated.
   The name of the team must be unique, and the team status can be chosen from the dropdown menu between Active or Inactive.



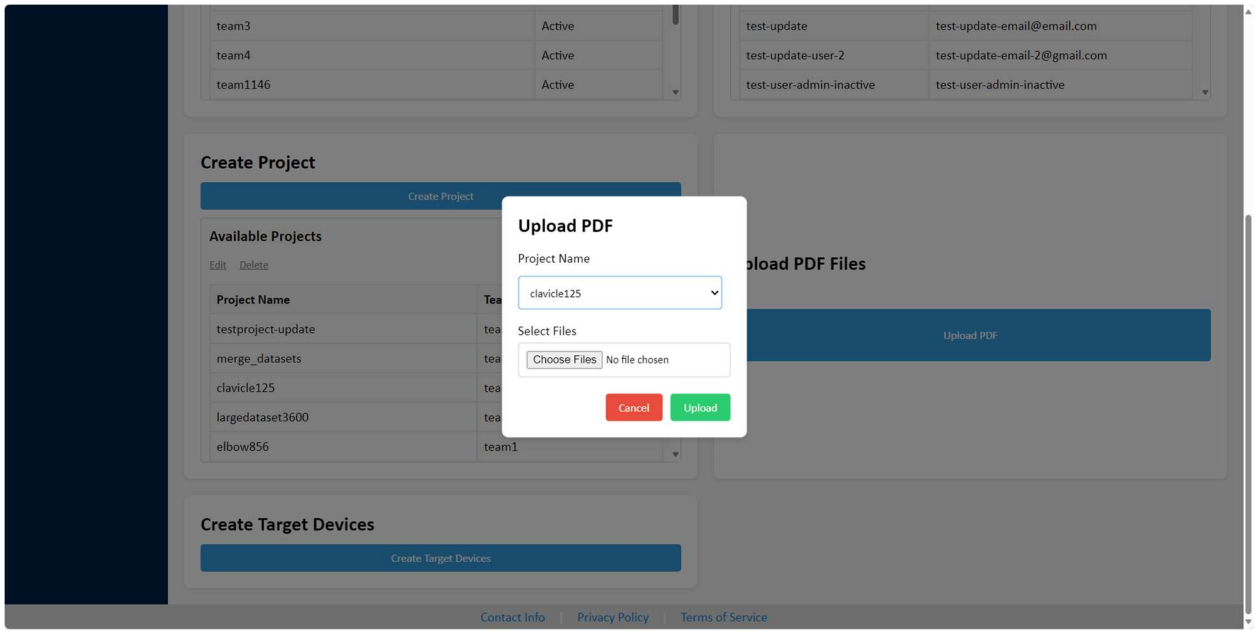
2. **Create User**: user can define new users: the Username must be unique and an email address is mandatory field. The password must follow some security rules. One or more teams and roles can be assigned to the user.



3. **Create Project**: user can define the name of a new project, that must be unique. A team must be associated with the project, meaning that the team members will have access to the project and can work on it. Any user that is not associated with that team will not have access to it.
   A project status can be chosen from a dropdown list between Active and Inactive, meaning that it can be executed and reviewed or not.



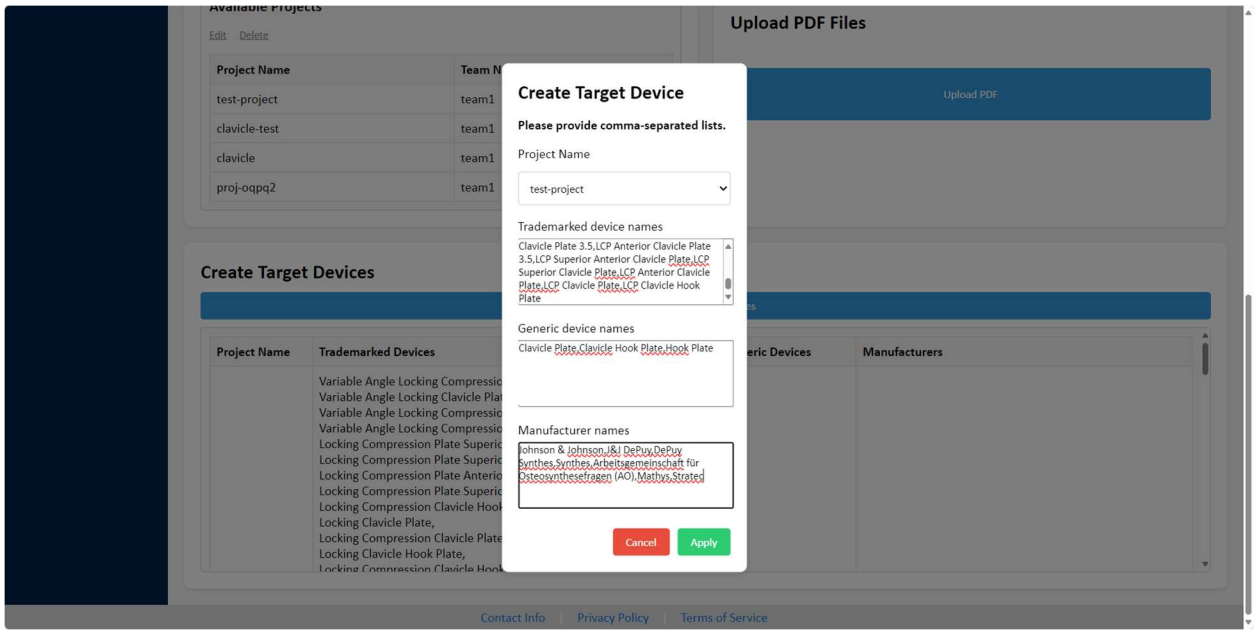
4. **Upload PDF Files**: user can select an existing project and can upload all the PDF files containing the publications and articles that must be screened. Choose File button must be clicked, and user can browse through their local folder system to search for the files, select and upload them to the application.
   File names must be a maximum of 256 characters long, otherwise an error pop-up will be displayed, and the user will be asked to rename those files with a name that is too long and upload them again.



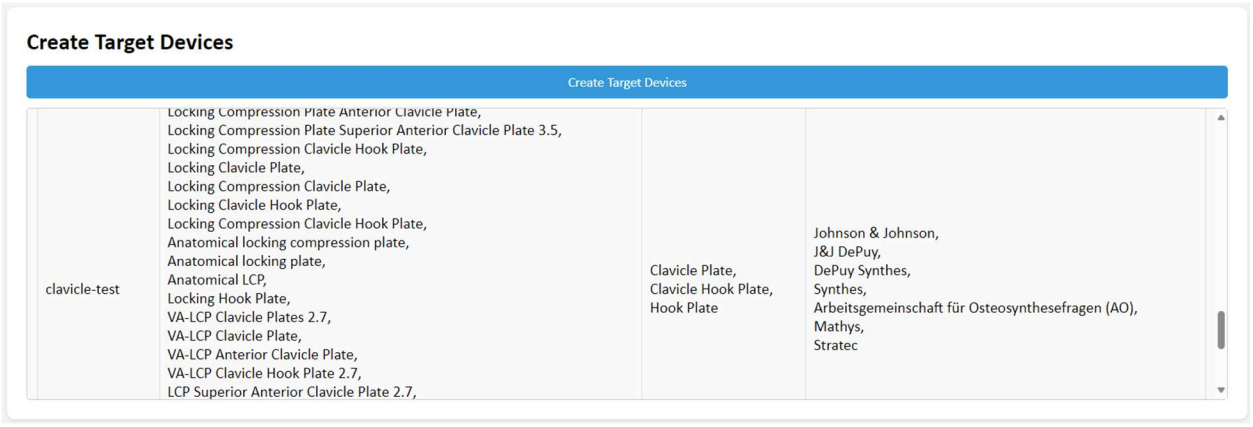
5. **Create Target Device**: user must associate the target devices of interest to each project before starting the screening process.
   The list must be provided in a comma-separated fashion in order to be correctly defined in

the application. Any device or manufacturer will have to be separated by a comma, *for example "Clavicle plate, Locking compression plate" or "Zimmer, Biomet".* User can refer to the Appendix to exactly follow the **Naming Conventions for Target Devices**.

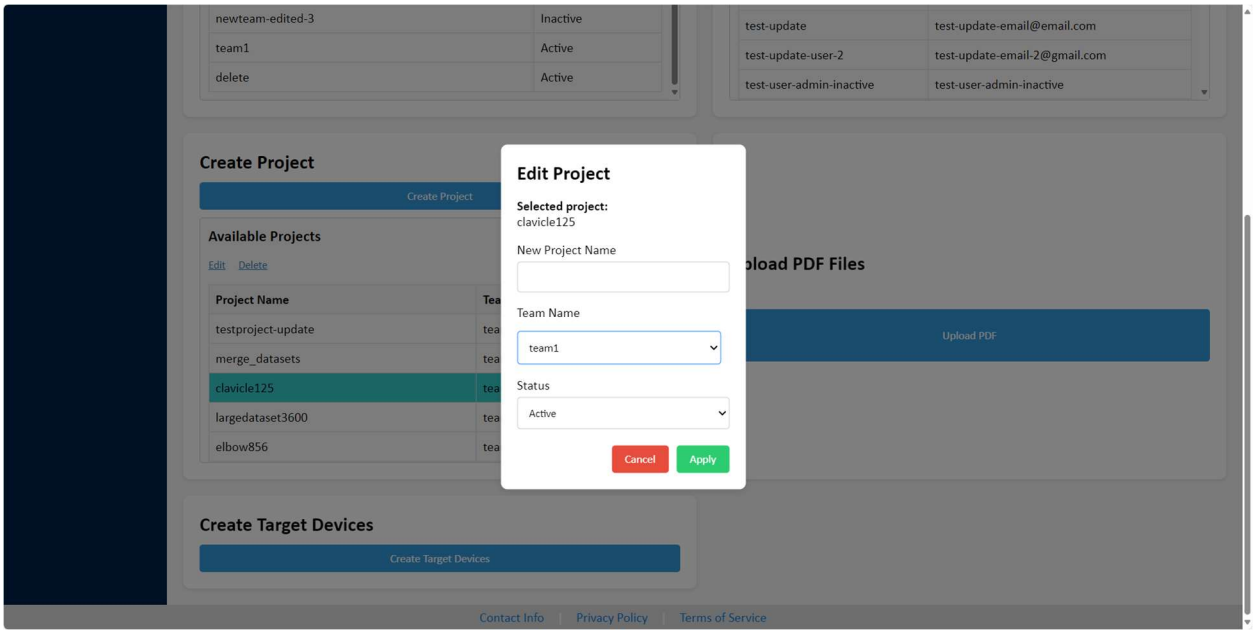
a. **Project Name**: user must select an existing project with which the devices will be associated;
b. **Trademarked Devices Name**: user must insert any device that will not require to be followed by a manufacturer;
c. **Generic Devices Name**: user must insert any device that is generic and will have to come along with a Manufacturer name in the publication to be identified;
d. **Manufacturers Name**: user must insert any Manufacturer name of interest that must appear in the publication next to a generic device.



When target devices are saved, they can be reviewed in a tabular format for that project:

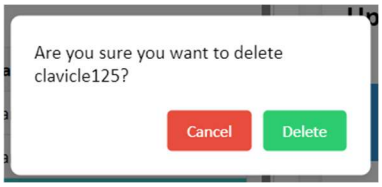


Edit and delete existing items

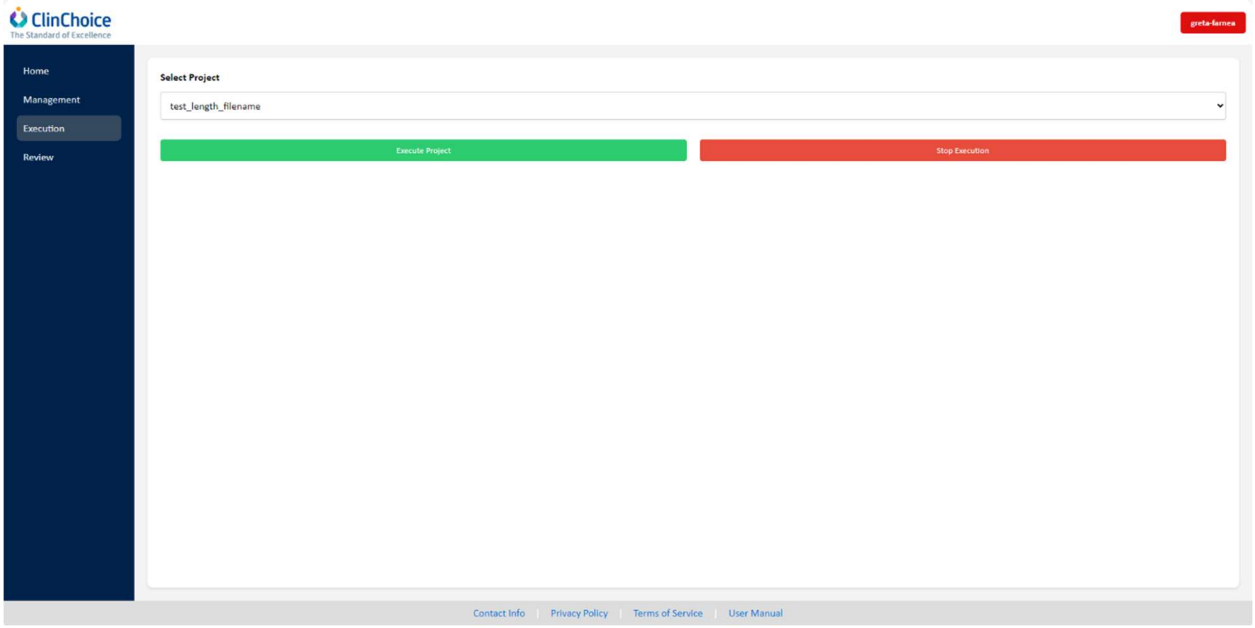


The user can edit teams, users, projects information and target devices list. The item must be selected from the list and the Edit link will be enabled. The user can click it and a form is open with the fields that can be modified.

Deletion of items is available only to Admin users. When the item is selected, the Delete link will be enabled. Once clicked, the user needs to confirm the deletion through the pop-up that appears.



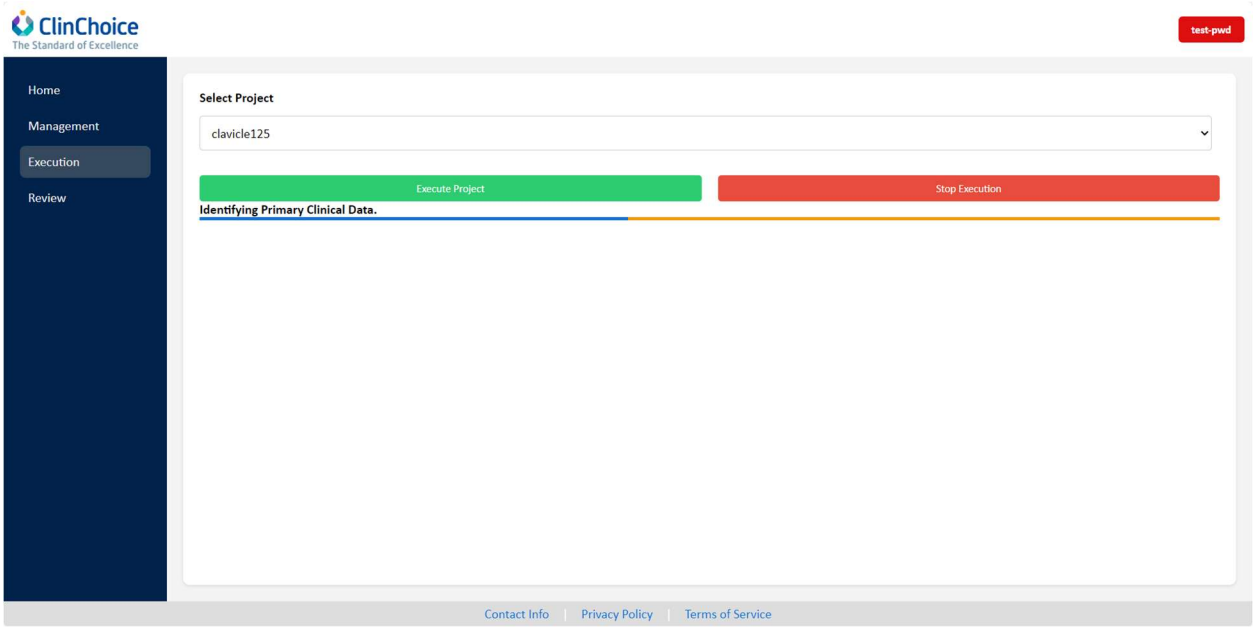
Execution Page



Execution Page allows the user to select a project from a dropdown menu and, by clicking Execute Project button, the screening literature review starts. If the user wants to stop the execution, they just need to click on the Stop Execution button.

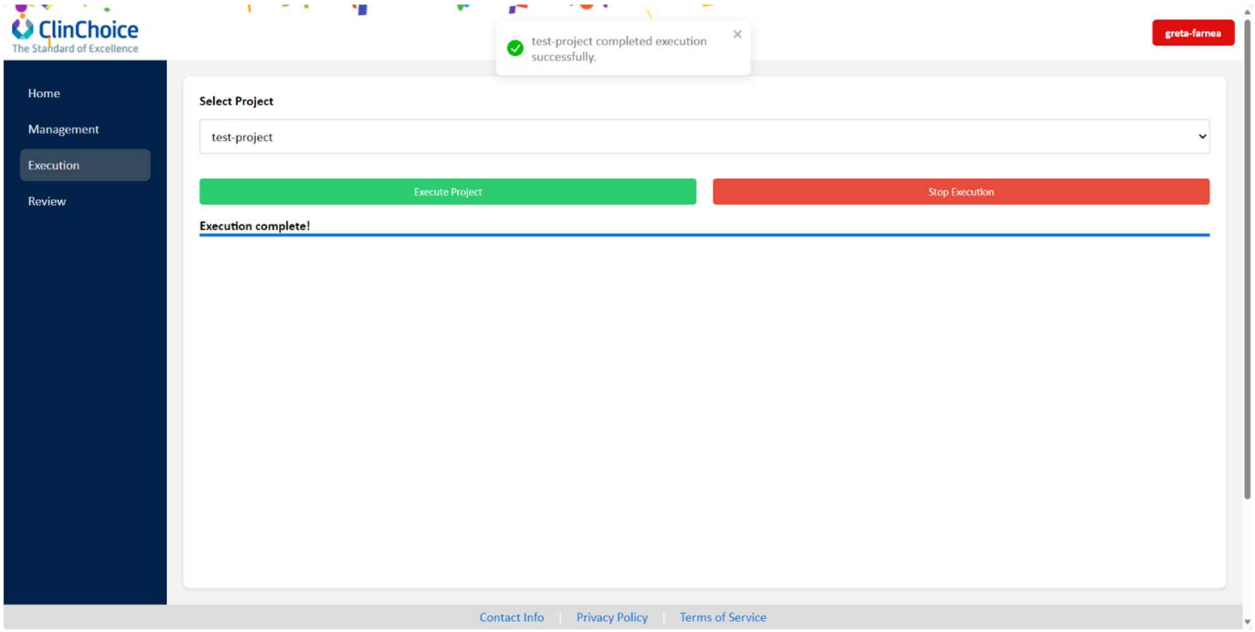
Note: Execution jobs run in a serial way. To get the best performance from the application, please execute each project individually.

As the process goes on and each criterion is executing, a progress bar will be displayed and will visualize the step that the system is processing at the current time.



Once the screening process is completed, a successful message will be displayed, and the results will be available in the Review section.

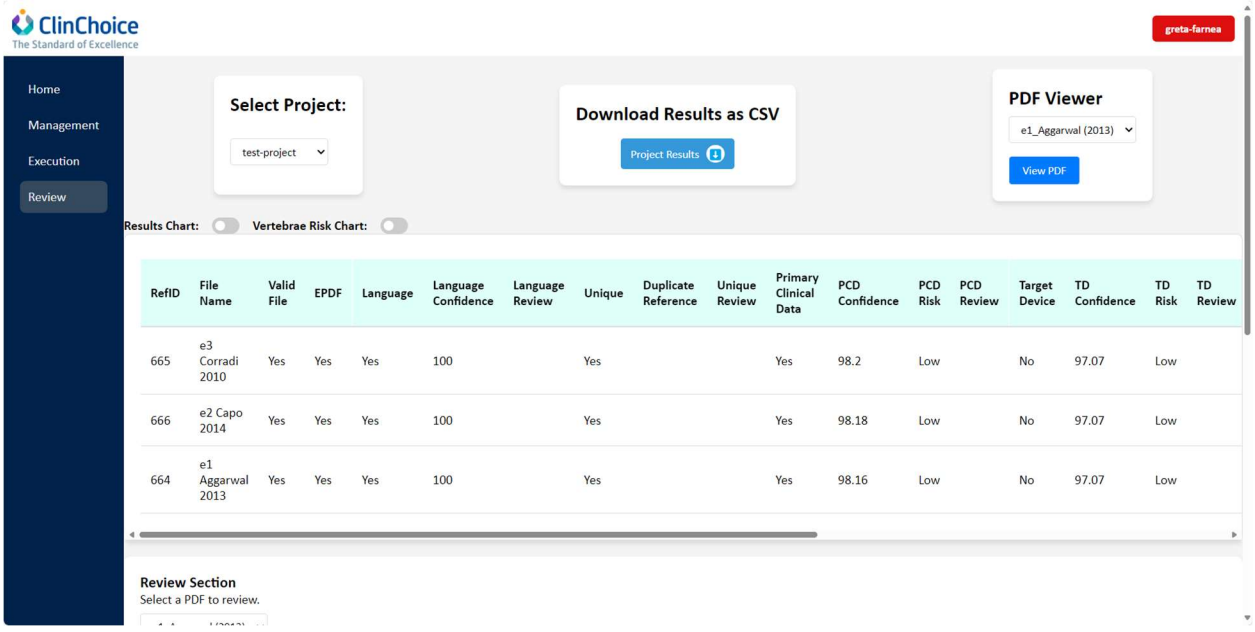
Moreover, if the user is navigating in other sections of the application, the completion pop-up will be displayed as well, so the user is notified about the successful execution.



Review Page

This page is divided into two main sections. In the first half of the page, the Results section displays the screening results for a project. In the second half of the page, there is a section dedicated to Review by the user whenever a classification of an article needs to be corrected.

Results section



Once a project is completely executed (in Execution Page), its result will be available in the Review Page. The user can select the project from a dropdown menu and the table will be updated.

To read and review a specific article, the user can select that from the dropdown menu and click on View PDF to open it. Then, if the user wants to download the results into a CSV format, they can click on e "Project Results" button and the file will be automatically downloaded.

Note: *if Excel local application is not set properly, the file might result non-human readable since it is a CSV. In order to properly visualize it, the user can execute the following steps:*

1. *Open the CSV file with Excel;*
2. *Select the whole first column A;*
3. *From the menu, go to "**Data**" and then "**Text to Columns**";*
4. *On the second panel of the modal, select the "**Comma**" checkbox and click on Finish.*

Two toggles for graphical visualizations can be clicked and, at the bottom of the page, two bar charts will be shown. The first one visualizes the numbers of included and excluded publications overall and by criteria as well. The second one shows the distribution of the risks (Low, Medium, High) by vertebra.

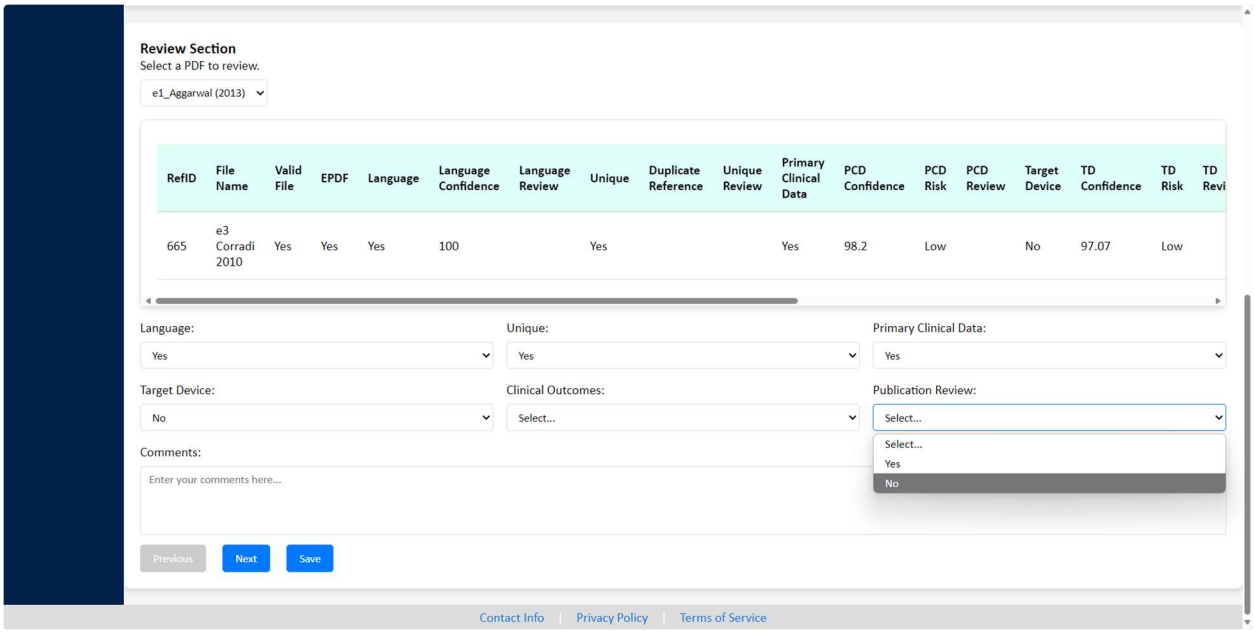
Regarding the results table, each publication classification will be displayed by row, and the columns will be the following:

1. **RefID**: the identifier of the article;
2. **File name**: the name of the PDF file that has been uploaded, usually composed of author and year of publication;
3. **Valid File**: Yes if the application can read the file, No otherwise;
4. **EPDF**: Yes if the file is electronic pdf, No otherwise;
5. **Language**: Yes if the application determines the text is in English, No if another foreign language is detected;
6. **Language Confidence**: the score that reflects the confidence with which the model has identified the language. It is displayed in percentage format, where 0 represents the lowest confidence and 100 the highest confidence;
7. **Language Review**: classification that is manually inserted by the user;
8. **Unique**: Yes if the publication is unique and there is no duplication, No if it is a duplicate of a previous article;
9. **Duplicate Reference**: if the article is detected as a duplicate, this column shows the RefID of the original article;
10. **Unique Review:** classification that is manually inserted by the user;
11. **Primary Clinical Data**: Yes if the publication is about a study on Primary Clinical Data, No if Secondary Clinical Data or no mention to the type of data are identified;
12. **PCD Confidence**: the score that reflects the confidence with which the model has detected the presence of Primary Clinical Data or not. It is displayed in percentage format, where 0 represents the lowest confidence and 100 the highest confidence;
13. **PCD Risk**: based on the PCD Confidence, a risk label is associated with the classification (HIGH, MEDIUM and LOW labels);
14. **PCD Review:** classification that is manually inserted by the user;
15. **Target Device**: Yes if the article contains any mention to a device that has been associated with the project (from the Management Page), No if no device of interest has been detected;

16. **TD Confidence**: the score that reflects the confidence with which the model has detected the presence of Target Devices or not. It is displayed in percentage format, where 0 represents the lowest confidence and 100 the highest confidence;
17. **TD Risk**: based on the TD Confidence, a risk label is associated with the classification (HIGH, MEDIUM and LOW labels);
18. **TD Review:** classification that is manually inserted by the user;
19. **Clinical Outcomes**: Yes if the publication contains any mention to a medical outcome, No if no clinical result is detected;
20. **CO Confidence**: the score that reflects the confidence with which the model has detected the presence of Clinical Outcomes or not. It is displayed in percentage format, where 0 represents the lowest confidence and 100 the highest confidence;
21. **CO Risk**: based on the CO Confidence, a risk label is associated with the classification (HIGH, MEDIUM and LOW labels);
22. **CO Review:** classification that is manually inserted by the user;
23. **Publication Included**: Yes if all the criteria have been classified as Yes, meaning that the article can be included, No if the publication has failed on criteria, meaning that the publication must be excluded from the project;
24. **Publication Confidence**: the score that reflects the confidence with which the final classification has been defined. It is an average between all the scores of the individual criteria. It is displayed in percentage format, where 0 represents the lowest confidence and 100 the highest confidence;
25. **Publication Risk**: based on the Publication Confidence, a risk label is associated with the classification. HIGH, MEDIUM and LOW labels allow the user to detect the publications that must be reviewed (for example, the ones labeled with HIGH risk);
26. **Publication Review:** classification that is manually inserted by the user;
27. **Comments**: it displays the comments that the user has written for that article, if any.

The columns header can be clicked, and the result table will be ordered following the alphabetical order, that will switch between ascending or descending as the user chooses.

Review section



As mentioned in the above section, each publication will have a risk label that is assigned based on the confidence score of the models. Since this application relies on Artificial Intelligence models, the latter may sometimes predict the result of a criteria with a low confidence score. This can end up with a HIGH-risk classification for some medical articles. In this final phase, the user is of utmost importance, as they can review and correct any results if necessary.

The Review Section is composed of several elements. The user can select a specific publication to review using the available dropdown menu. When clicked, the row with the classification results for that publication is displayed, so that the user can review each criterion separately. Below that, user can modify the classification of a criterion by choosing the correct label (Yes, No) from a dropdown menu. User can also add a comment in the corresponding textbox if some notes must be added to the correction.

Any changes are saved when the Save button is clicked, otherwise they are automatically saved if the user clicks on Next button.

By clicking Previous or Next buttons, the user navigates through the following articles to be reviewed.

Appendix – Target Devices Naming Convention

These rules will be provided to the user as a guide to properly provide the target device names for the optimal functioning of our Target Device Identification Algorithm. Not adhering to these guidelines may decrease performance, leading to target devices being missed or returned when there are none.

1. When providing the list of trademarked or generic devices, make sure to give as many acceptable variations/synonyms for each target device. Acceptable variations of a target device are different names that could possibly be found in various articles, all referring to the same device.

2. If any abbreviations are present in the target device name, wrap them in parenthesis ("(LCP) Elbow Plate"), and make sure to provide the same device with the full form of the abbreviation as well. The case convention for the target device names is flexible, but it is recommended to keep abbreviations uppercase as that's how they're usually found. Here are some synonyms of "Locking Compression Clavicle Plate" based on the above rules:
    a. "(LCP) clavicle plate"
    b. "locking compression clavicle plate"
    c. "clavicle locking compression plate"
    d. "clavicle locking plate"
    e. "locking clavicle plate"

3. While providing the list of generic device names, mention any devices which can be considered as an appropriate target device, if manufactured by a company from the target manufacturers list. An example list for a dataset could be:
    a. "clavicle plate"
    b. "clavicular plate"
    c. "clavicle hook plate"
    d. "clavicular hook plate"
    e. "hook plate"

4. If any generic devices are given, a list of target manufacturer names must be provided to determine whether the generic device found is a target device or not. Make sure commercial brand names are capitalized.

Appendix – Essential Cookies Usage

Cookies

Our website uses cookies to manage and maintain your session while you interact with our services. This document explains how and why we use these cookies and the choices available to you regarding their use.

What Are Cookies?

Cookies are small text files that are placed on your device when you visit a website. They allow the website to recognize your device and store certain information about your preferences or past actions.

How We Use Cookies

We use cookies to manage user sessions through a mechanism called **Iron Session**. These cookies are essential for the operation of our website and are used for the following purposes:

1. **Session Management**: Iron Session cookies allow us to securely manage your session, keep you logged in, and remember your preferences as you navigate our website.
2. **Security**: These cookies help protect your account by enabling security features and detecting malicious activity.

Types of Cookies We Use

- **Essential Cookies**: These are the cookies set by Iron Session. They are necessary for the proper functioning of our website. Without these cookies, certain features and services may not be available. The type of cookies you see are **encrypted session cookies** containing application-specific data that is not readable or alterable by the client.

Your Choices Regarding Cookies

Since Iron Session cookies are essential for the functionality of our website, they cannot be disabled without affecting your experience on our site. However, you can manage your cookie settings through your browser, where you have the option to block or delete cookies.

Please note that blocking essential cookies may result in the inability to access certain features of our website.

Changes to This Policy

We may update this privacy policy to reflect changes to our practices or for other operational, legal, or regulatory reasons. Please revisit this page periodically to stay informed of any updates.