



User Guide

Notification of studies

Last update: 14 September 2023

Note for the users

This user guide has been updated on 14 September 2023 to take into account the latest system enhancements.

- Business operators, their consultants and laboratories can add or create new components from the “Select Operations” button in the study notification page.
- Associated components are showed in the related list “Test Item: Components” on the right-hand side of the study notification page. For easier identification of listed components, additional fields (e.g. Name, Type of Term, Origin) have been added.
- The “Other components” field in the study notification page have been discontinued. Previously recorded information has been moved to a read-only “Other Components” box. Users can decide to leave the information there or create a new component with such information.
- A time-limited notification box on the Application page (for business operators and/or their consultants) or Studies page (for laboratories) has been be introduced. This allows to notify users about newly introduced functionalities.

Some editorial changes have been introduced to further clarify the existing content.



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Introduction

#Connect.EFSA



1. Actors of the Process

The process for managing the Notification of Studies process might involve up to **two types of actors**:

Business Operator/Consultant

(orange)

Laboratory /Consultant

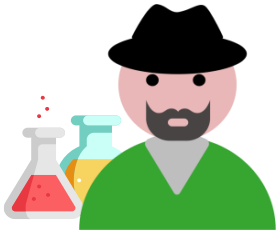
(green)

For ease of reference through this Guide, the two roles are visualised by the respective **colour stripe** on the left-hand side of slides.

1. Actors of the Process



Business operator, third party/consultant: these users belong to an organisation qualified as Applicant. They create and manage their studies in Connect.EFSA. Business operator, third party/consultant can both notify and co-notify studies. In order to perform these actions, they need to be registered as Applicant. Business operator can extend the power to complete such tasks to a **third party/consultant***.



Laboratory, third party/consultant: these users belong to an organisation qualified as Laboratory. They create and manage their studies in Connect.EFSA. Laboratories, third party/consultant can both notify and co-notify studies. In order to perform these actions, they need to be registered as Laboratory. Laboratories can extend the power to complete such tasks to a **third party/consultant**.

*When an organisation works as business operator and also as a laboratory or works on behalf of both business operators and laboratories, when performing the notification of studies process it can decide whether to act as an Applicant or as a Laboratory. This will be furtherly explained in the next slides.

1.1 Account qualification

Users registered on Connect.EFSA can be qualified to conduct pre-submission activities as **applicant** or as **laboratory** or **both**.

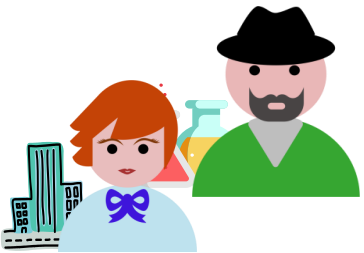
These qualifications are assigned by EFSA according to the needs of the users at the time of the registration.



Applicant only: organisations such as business operators. They act as potential applicant conducting pre-submission activities linked to a future application for a regulated product in a specific regulated area. These organisations can create pre-application IDs, studies from a pre-application ID, notify and co-notify studies. The same qualification is assigned to consultants working on their behalf.

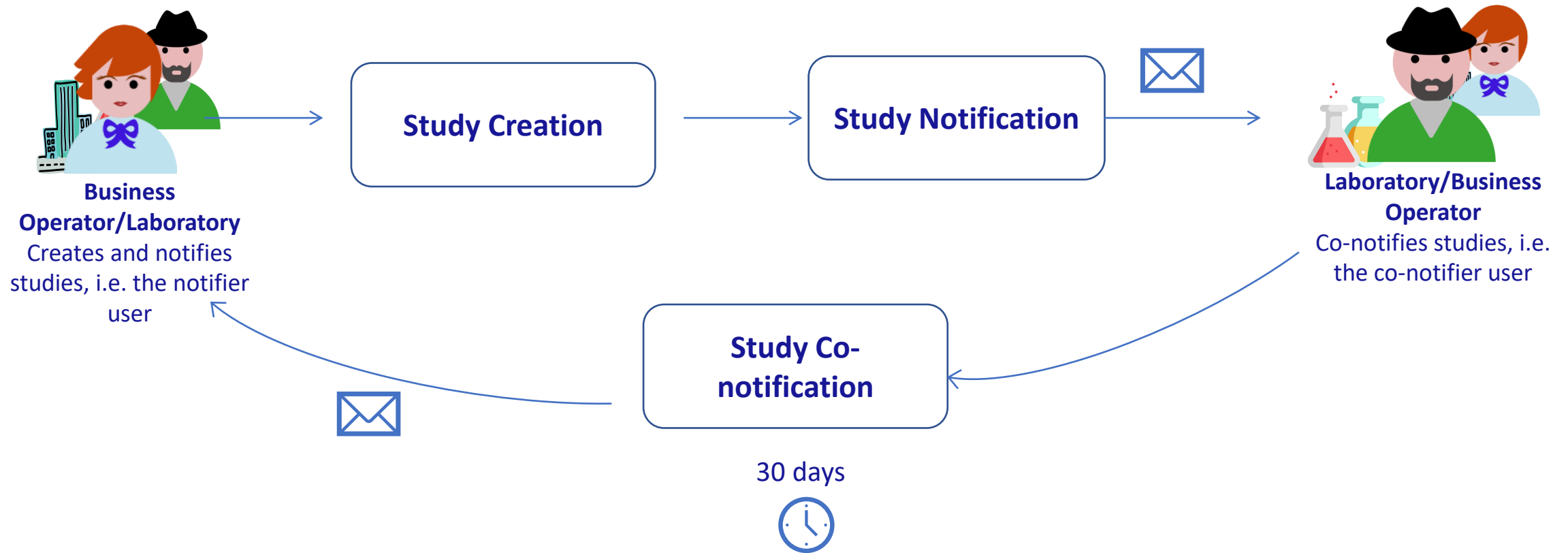


Laboratory only: organisations such as laboratories/external testing facilities. They act as laboratories conducting studies commissioned by business operators. These organisations can only create, notify and co-notify studies from the “Studies” section. The same qualification is assigned to consultants working on their behalf.



Applicant and Laboratory: organisations such as business operators, laboratories, and their consultants, which act in different roles depending on the pre-submission activity. This qualification combines the above. In this context, the system does not allow a business operator to operate as consultant for the laboratory to which it has commissioned the study.

1.2 Notification of Studies: Process Overview



The Notification of Studies process involves two main actors: **the notifier** (user who starts the process) and **the co-notifier**. The notifier can be either a Business Operator or a Laboratory and the co-notifier can be respectively either a Laboratory or a Business Operator (depending on who inserted the notification).

Logging In

#Connect.EFSA



2. Log-in entry point

Users can access Connect.EFSA portal from their `trusted` devices

via the following link:

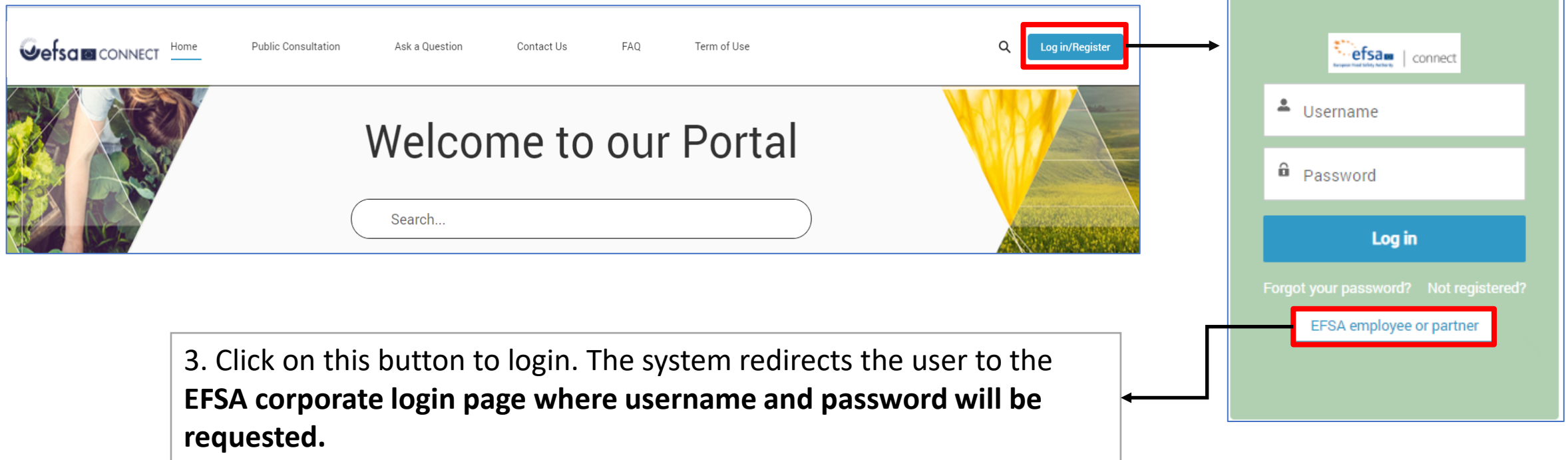
<https://connect.efsa.europa.eu/RM>



2.1 Users log in

To log into Connect.EFSA as Portal user:

1. Insert the following Url in the Browser: <https://connect.efsa.europa.eu/RM>
2. Click on the Log in/Register button (right upper corner)



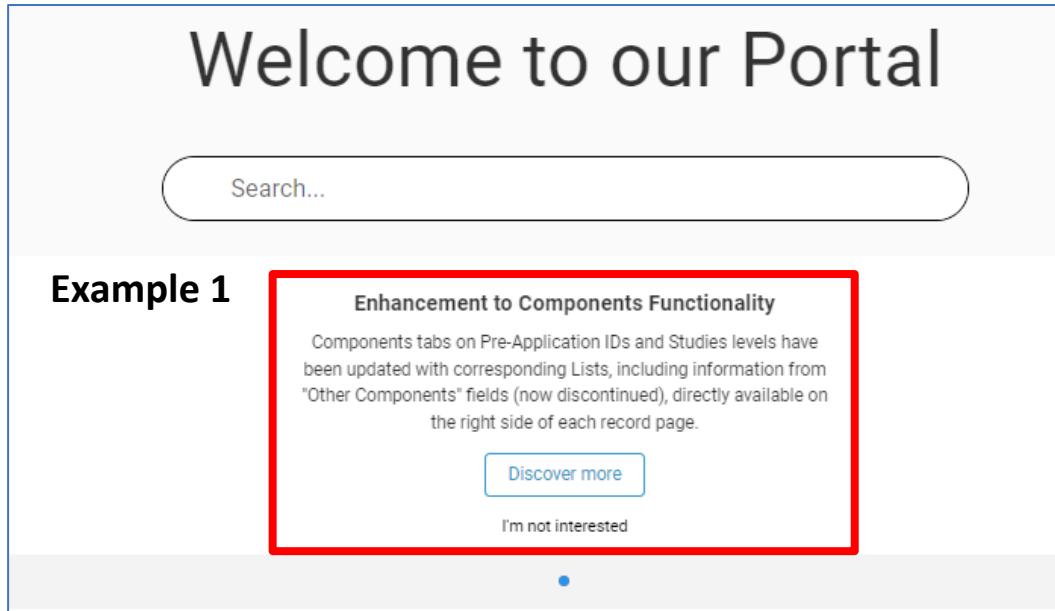
The image shows a screenshot of the EFSA Connect portal. The top navigation bar includes the EFSA logo, 'CONNECT', and links for 'Home', 'Public Consultation', 'Ask a Question', 'Contact Us', 'FAQ', and 'Term of Use'. A search icon and a 'Log in/Register' button (highlighted with a red box) are located in the top right corner. Below the navigation bar is a large banner with the text 'Welcome to our Portal' and a search bar. To the right of the banner is a login form with fields for 'Username' and 'Password', a 'Log in' button, and links for 'Forgot your password?' and 'Not registered?'. A red box highlights the 'EFSA employee or partner' link in the login form. Arrows indicate the flow from the 'Log in/Register' button to the login form and from the 'EFSA employee or partner' link to a text box.

3. Click on this button to login. The system redirects the user to the **EFSA corporate login page where username and password will be requested.**

2.2 Time limited notification box

New!

Users find information about newly introduced functionalities in the time limited notification boxes, which according to the relevance of the information for the various users (applicants or laboratories) may be showed in different pages of the Connect.EFSA portal. For instance, the main Portal page (example 1) or in the Application section (example 2).



Welcome to our Portal

Search...

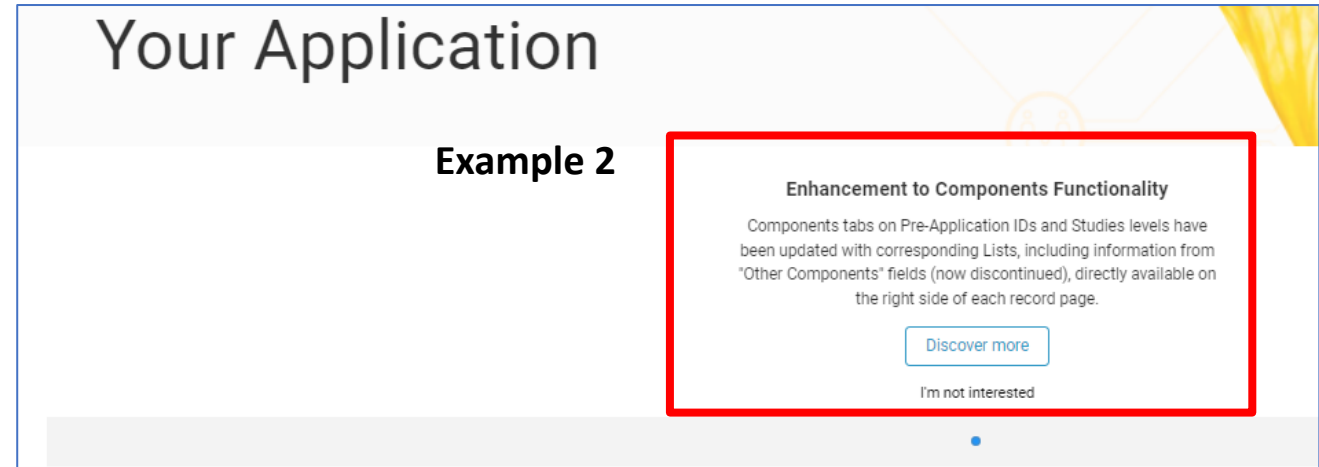
Example 1

Enhancement to Components Functionality

Components tabs on Pre-Application IDs and Studies levels have been updated with corresponding Lists, including information from "Other Components" fields (now discontinued), directly available on the right side of each record page.

[Discover more](#)

[I'm not interested](#)



Your Application

Example 2

Enhancement to Components Functionality

Components tabs on Pre-Application IDs and Studies levels have been updated with corresponding Lists, including information from "Other Components" fields (now discontinued), directly available on the right side of each record page.

[Discover more](#)

[I'm not interested](#)

Notification of studies

#Connect.EFSA



3.1 Study creation – Applicant view

- 1. Search bar
- 2. Alerts Icon
- 3. User Information

The screenshot shows the EFSA CONNECT portal interface. At the top, the navigation menu includes 'Home', 'Applications', 'Public Consultations', 'Ask a Question', 'My Details', 'FAQ', and 'Contact Us'. The 'Applications' link is highlighted with a red box and labeled '1'. Below the navigation, a large search bar is highlighted with a red box and labeled '1', with an arrow pointing to a 'Search Bar' label. In the top right corner, a search icon, a bell icon (Alerts), and a user profile icon are highlighted with red boxes labeled '2' and '3', with an arrow pointing to a legend box. The main content area features a 'Welcome to our Portal' heading and a paragraph: 'This portal gives you the possibility to engage with EFSA on a variety of topics. You will be able to check the Frequently Asked Questions, consult and submit comments to EFSA's public consultations, and send requests for access to documents. Before sending EFSA a question, please read the Frequently Asked Questions.' Below this, there are four green buttons: 'Applications' (highlighted with a red box), 'Public Consultations', 'Ask a Question', and 'My Details'. An arrow from the 'Applications' button points to a legend box labeled 'Access Application section from here.'. To the right, an 'FAQ' button (highlighted with a red box) has an arrow pointing to a legend box labeled 'Access FAQ'. The right side of the page displays the 'FAQ' section with sub-headers: 'About EFSA', 'Regulated Products', and 'Engage with EFSA'.

3.1 Study creation - Applicant view

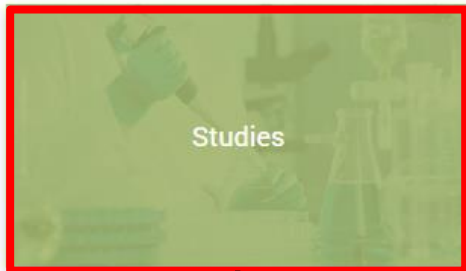
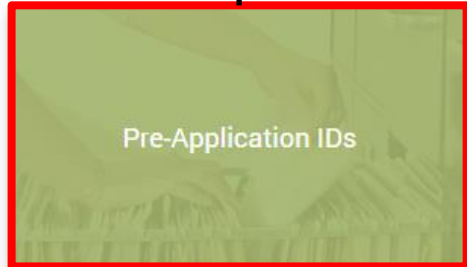
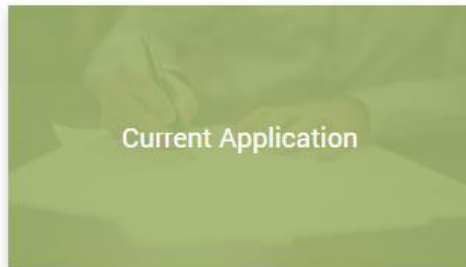
Your Application

Using the menu below, you can access:

- **Current Application:** In this section you can find your applications once they have received a decision.
- **Pre-Application IDs:** A section where you can conduct pre-submission activities such as studies, and request a general pre-submission advice regarding your future application.
- **Studies database:** A section where you can create and notify studies in support of a future application.

Information on Pre-Submission Activities

- [EFSA's Practical Arrangements on pre-submission phase and public consultations](#)
- [Questions and Answers on the EFSA Practical Arrangements](#)
- [Connect.EFSA user guides](#)



Access the **Pre-Application IDs** section to **create study notification records and to notify/manage studies** associated to pre-application IDs.

Business operators must always submit study notifications within a pre-application ID. Only in the following exceptional cases, users should create and manage study notifications from the **Studies** section:

- Notification of studies requested during admissibility/validity check in the cases where pre-submission activities were not conducted and therefore no pre-application ID was available.
- Notifications of studies performed during risk assessment on request of regulatory authorities in the cases where pre-submission activities were not conducted and therefore no pre-application ID was available.

Access the **Studies** section to create study notifications records and to notify/manage them. In this section study notifications are created without a pre-application ID.

3.2 Study creation – Laboratory view

The screenshot shows the EFSA CONNECT portal interface. The navigation bar includes 'Home', 'My Study', 'Public Consultations', 'Ask a Question', 'My Details', 'FAQ', and 'Contact Us'. The main heading is 'Welcome to our Portal'. A search bar is located below the heading, with a '1' annotation pointing to it. In the top right corner, there are icons for search, alerts, and user information, with '2' pointing to the alerts icon and '3' pointing to the user information icon. A list on the right side of the page contains the following items:

1. Search bar
2. Alerts Icon
3. User Information

Below the heading, there is a paragraph of text: 'This portal gives you the possibility to engage with EFSA on a variety of topics. You will be able to check the Frequently Asked Questions, consult and submit comments to EFSA's public consultations, and send requests for access to documents. Before sending EFSA a question, please read the Frequently Asked Questions.'

There are four main content tiles: 'Study', 'Public Consultation', 'Ask a Question', and 'My Details'. The 'Study' tile is highlighted with a red border. A callout box on the left side of the page points to the 'Study' tile and contains the text: 'Access study notification records from here'. On the right side, there is a 'FAQ' tile with a question mark icon, highlighted with a red border. An arrow points from this tile to a callout box containing the text: 'Access FAQ'. Below the 'FAQ' tile, there are sections for 'About EFSA', 'Regulated Products', and 'Engage with EFSA', each with a list of questions and answers.

3.3 Study creation (from *pre-application ID*) – Account type: Applicant only

In order to conduct pre-submission activities, including the notification of studies, potential applicant must firstly request a pre-application ID (see Article 4 of the [EFSA Practical Arrangements on pre-submission phase and public consultations](#)).

Pre-Application ID

In this page you can see the details of your Pre-application ID, as well as its related records. You can perform the following actions:

- Create a **Pre-application ID** to link all your pre-submission activities in support of your future application
- Access and review the requests of **General Pre-submission Advice**
- Access and review all **Intended Studies**
- Access and review all **Lists of Intended Studies** for renewal applications
- Access and review the **Components** Section

[Pre-Application ID](#) [General Pre-Submission Advice](#) [Intended Studies](#) [Lists of Intended Studies](#) [Components](#)

The list below contains all Pre-Application IDs that you have already created. Use the search bar on the right to search for a Pre-Application ID.

My Pre-Application ID ▼

50+ items • Sorted by Created Date • Filtered by All pre-application ids - MyPreapplication

Search this list...

Request Name	Note	ID	Food Dom...	Applicatio...	Authorisat...	Contact N...	Created ...
1 Application ABC		EFSA-ID-2022...	Pesticides Pe...			Federico Mor...	12/07/2022 9

In this box, instructions to help the user to conduct pre-submission activities are provided.

Here the user can perform a search according to values in the columns shown.

Click on the Request Name to access the record and the study notifications associated therein, if any.

3.3 Study creation (from *pre-application ID*) – Account type: Applicant only

Updated!

Pre-Application Operations

- Use the **New Study** button to create new Study records
- Use the **Add Studies** button to add notified and or co-notified studies
- Use **New List** button to create a List of Intended Studies for renewal (only for renewal applications)
- Add additional parties to this Pre-Application ID using the **Share With** button
- Use the **Add Component** button to add one or more components to this Pre-Application ID
- Request a General Pre-Submission Advice by using the **Ask GPSA** button
- Use the **Delete** button to delete your Pre-Application ID (certain conditions apply)

New!

Add Component

Subject of the Application: Components (0)

Study Notification (1)

Study Title (S...	EFSA Study Ide...	Status	Study Withdrawn
Study TJP	EFSA-2023-000...	Draft	<input type="checkbox"/> ▼

[View All](#)

Pre-Application ID
Renewal application TJP

ID
EFSA-ID-2023-000914

Details History

Request Name
Renewal application TJP

Business Operator
ABC Company Spa

ID
EFSA-ID-2023-000914

Contact Name

Details

Subject Of The Application ⓘ
Renewal application TJP

Former Application ID ⓘ

Note ⓘ

Food Domain ⓘ
Feed Additives

Authorisation Type
Feed Additives

Application Type
Application for authorisation of a new use and/or modification and/or renewal of an already authorised feed additive (Articles 4(1), 13(3), 14 of Regulation (EC) No 1831/2003 respectively)

Edit **New Study** **New List** ▼

- Add Studies
- Share With
- Ask GPSA
- Delete
- Printable View

Users can use these **buttons** to create new study notifications or add existing notified/co-notified studies to a pre-application ID, or to perform further actions on the record.

Study notifications associated to the pre-application ID are shown in this section.

3.3 Study creation (from *pre-application ID*) – Account type: Applicant only

New Study

The user selects **New Study** and fill in the fields, then clicks **Next** to create a new draft study notification record and link it to this pre-application ID.

Study Notification

Please fill in the following information to create a new study.

In the Business Operator field insert your own organisation or, if you are working as third party, the organisation for which you want to create the study.

* Study Title

Study Title (English Name) ⓘ

* Business Operator ⓘ

Laboratory ⓘ

Next

New Study

A new Study has been created in Draft status. You can access by clicking on the button below.

Go to New Study

To return to your Pre-Application ID, simply click on Next.

Next

Study Notification (4)

Study Title	EFSA Study Iden...	Status	Study Withdrawn
Test Share wit...	EFSA-2022-0000...	Draft	<input type="checkbox"/>
Test Share wit...			<input type="checkbox"/>

The study created appears in the **Study Notification** related list available in the page of the pre-application ID.

The user must indicate the business operator carrying out or commissioning the study. By default, it is the same user organisation as indicated in the pre-application ID. **When creating the study notification** (and **only** at that stage), it is possible to edit the “Business Operator” field and indicate the actual business operator for that specific study notification. To do so, this entity should establish a relationship “on behalf of” with the third party/consultant (see [Create an account relationship](#)).

The user can also indicate the laboratory commissioned to conduct the study. This information can be revised also at a later stage.

3.3 Study creation (from *pre-application ID*) – Account type: Applicant only

Add Studies

Search Studies...
Q determi

Selected Studies: 2
EFSA-2020-00000208 X EFSA-2020-00000211 X

<input type="checkbox"/>	Study Number	Name	Food Domain	Created Date
<input type="checkbox"/>	EFSA-2020-00000192	Determination of the ferric citrate content add...	Feed Additives	21.10.2020
<input checked="" type="checkbox"/>	EFSA-2020-00000208	Determination of physico-chemical properties	Pesticides	28.10.2020
<input checked="" type="checkbox"/>	EFSA-2020-00000211	Determination of physico-chemical properties	Pesticides	29.10.2020
<input type="checkbox"/>	EFSA-2020-00000193	Determine the concentration of iron or nickel i...	Feed Additives	21.10.2020

Next

Click on **Add Studies** and use the search bar to find studies **already notified and/or co-notified**. It is possible to select one or more studies the user would like to add to the pre-application ID. To continue click on **Next**.

The study created appears in the **Study Notification** related list available in the page of the pre-application ID.

Add to Pre-Application ID

Selected Studies: 2


Close Submit

Study Notification (4)

Study Title	EFSA Study Iden...	Status	Study Withdrawn
Test Share wit...	EFSA-2022-0000...	Draft	<input type="checkbox"/> ▼
Test Share wit...	EFSA-2022-0000...	Draft	<input type="checkbox"/> ▼

3.3 Study creation (from *pre-application ID*) – Account type: Applicant only

The **draft study notification record** appears as in the image below. From this point onwards, all the steps to manage and notify the study are the same whether the study has been created from a pre-application ID or from the Studies section.

 Study
Study TJP

EFSA Study Identification
EFSA-2023-00001727

Status
Draft

Study Withdrawn

[Edit](#) [Printable View](#) [Select Operation](#)

Updated!

Study Status Tracker

This Study has been saved as a **draft**. When ready, please click on 'Select Operation' button and then **Notify** in the right-hand corner.

The following fields **MUST** contain a value before notification:

Main section: Study Title - Study Starting Date - Study Planned Completion Date

Study Scope section: Study Type - Food Domain - Authorisation Type - Application Type - Study International Standard Certification - Study Objective - Study Test Item - Components (where applicable)

Please note that all the fields related to the co-notifier and the field 'Submit to Internal Testing Facilities' can be filled in while performing notification.

You can access the list of all available Study Types and Guidelines below:
All Study Types
All Study Guidelines

New!

Test Item: Components (0)

Pre-Application ID(s) (1)

Request Name	Record Type	Link to Study: Create...
Renewal application ...	List of Studies for Renewal	09/09/2023 22.15

This section is dedicated to components.

This section shows the pre-application ID(s) to which the study is linked.

3.4 Study creation (from *Studies*) – Account type: Applicant only

The list views presented in this slide are available in the Studies section and are the same for all the [Account qualifications](#).

From this page, you can create **NEW Studies** by clicking on the button directly below. Once you have created your new intended study, you can continue to edit it until you are ready to submit it to the laboratory that is working on it. The laboratory will be notified of your submission.

Please note that you can create studies that are not yet linked to an application, but that you can also associate these studies to a **Pre-Application ID** or a **List of Intended Studies for Renewal** at any point in time.

In Draft Notified To Correct Co-Notifier Wrong Co-Notifier To Co-Notify Co-Notified Co-Notified by Me More

This list contains all of your studies in **Draft** status. Use the search bar on the right to search for a study. To filter your studies by another status, click on the tabs above.

My Drafts ▼

50+ items • Sorted by Created Date • Filtered by All studies - 4 more filters applied

Study Title	Business Op...	Laboratory	Status	Created Date
1 Study XXX	ABC company S...		Draft	06.01.2021 14:00
2 New study on Lactobacillus aci...	ABC company S...		Draft	05.01.2021 17:54
3 study notifications bo 2	ABC company S...	Lab & Co Spa	Draft	04.01.2021 12:16

- **In Draft:** all your studies in Draft status.
- **Notified:** all studies that have been submitted to EFSA and pending co-notification by a laboratory.
- **To Correct Co-Notifier:** all notified studies for which a Co-notifier claimed to be wrongly selected and for which correction of Co-notifier entity is required by you.
- **Wrong Co-Notifier:** all notified studies for which the Co-notifier claimed to be wrongly selected and the Co-notifier entity cannot be further modified.
- **To Co-Notify:** all studies that are awaiting your co-notification.
- **Co-Notified:** all the studies co-notified by the co-notifier organization.
- **Co-Notified by me:** all studies have been co-notified by your organisation.
- **Withdrawn:** all studies that have been withdrawn.
- **Shared with me:** all the studies that have been shared with your organisation (read-only view)
- **On behalf of:** all the studies for which you have on behalf of access rights (read and edit).

3.4 Study creation (from *Studies*) – Account type: Applicant only

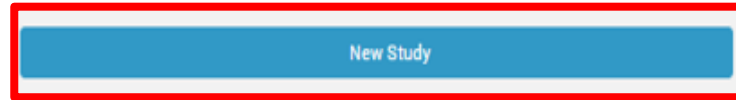
From the page “Studies” the user can create new studies and access those previously created or in which it is involved. **This is the normal view if the user has a business operator account qualified as Applicant.** Special views are presented in the next slides if the user’s business operator account is qualified both as Applicant and Laboratory.

The screenshot displays the 'Your Studies' interface. At the top, there is a navigation bar with the 'efsa CONNECT' logo and various menu items. Below the navigation bar, the main heading 'Your Studies' is prominently displayed. A callout box points to a blue 'New Study' button, with the text: 'Click here to create a new draft study notification record.' Below this, a paragraph explains that users can create new studies and edit them until submission. Another paragraph notes that studies can be associated with a Pre-Application ID or a List of Intended Studies for Renewal. A horizontal tab bar is visible, with 'In Draft' highlighted and circled in red. A callout box explains: 'In each **tab**, the user can find studies according to the different **stages** of the process (i.e. Draft, Notified, Withdrawn, etc.).' Below the tabs, there is a search bar and a table of studies. A callout box points to the search bar with the text: 'Search a record in this list.' The table has columns for Study Title, Business Op..., Laboratory, Status, and Created Date. Three draft studies are listed.

	Study Title	Business Op...	Laboratory	Status	Created Date
1	Study XXX	ABC company S...		Draft	06.01.2021 14:00
2	New study on Lactobacillus aci...	ABC company S...		Draft	05.01.2021 17:54
3	study notifications bo 2	ABC company S...	Lab & Co Spa	Draft	04.01.2021 12:16

3.4 Study creation (from *Studies*) – Account type: Applicant only

By clicking on **New Study**, the user will be asked by the system to include the **basic study information and the business operator name**.



Study Notification

Please fill in the following information to create a new study.

In the Business Operator field insert your own organisation or, if you are working as third party, the organisation for which you want to create the study.

* Study Title i

Study Title (English Name) i

* Business Operator i

Laboratory i

Study internal Reference ID (max 250 characters)

Next

- Insert the user's organisation as **business operator**.
- If the notification is inserted by a consultant, the business operator for which the consultant is working 'On behalf of' should be inserted in the field 'Business Operator'. This relationship must be firstly established as explained in the [Account relationship](#) section.

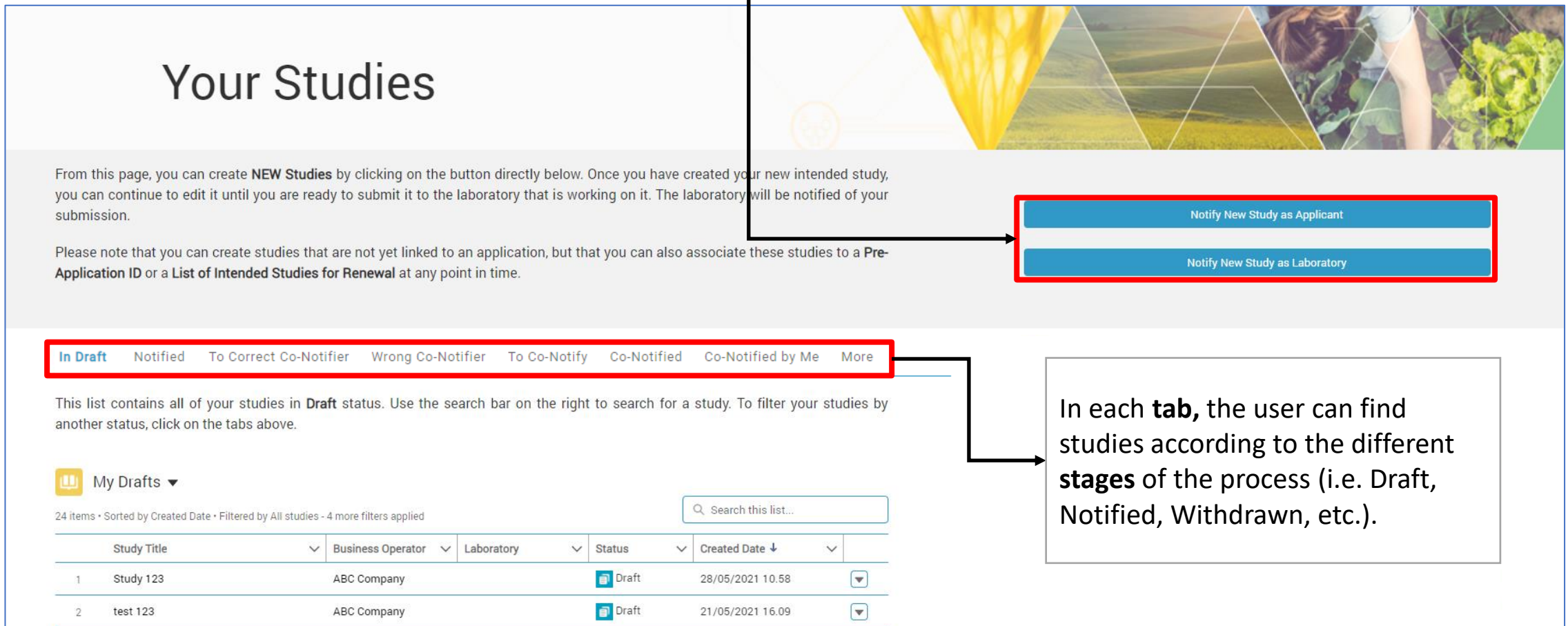
- **The user can also indicate the laboratory** commissioned to conduct the study. This information can be revised also at a later stage.

1. * sign means that the field is **mandatory**
2. i icon displays **help text** for that field.

Click here to create the study notification record.

3.5 Study creation (from *Studies*) – Account type: Applicant and Laboratory

When the user's organisation is qualified both as Applicant and Laboratory, the user can decide between “**Notify a New Study as Applicant**” (see Section 3.5.1) or “**Notify a New Study as Laboratory**” (see Section 3.5.2).



Your Studies

From this page, you can create **NEW Studies** by clicking on the button directly below. Once you have created your new intended study, you can continue to edit it until you are ready to submit it to the laboratory that is working on it. The laboratory will be notified of your submission.

Please note that you can create studies that are not yet linked to an application, but that you can also associate these studies to a **Pre-Application ID** or a **List of Intended Studies for Renewal** at any point in time.

Notify New Study as Applicant

Notify New Study as Laboratory

In Draft | Notified | To Correct Co-Notifier | Wrong Co-Notifier | To Co-Notify | Co-Notified | Co-Notified by Me | More

This list contains all of your studies in **Draft** status. Use the search bar on the right to search for a study. To filter your studies by another status, click on the tabs above.

My Drafts ▼

24 items • Sorted by Created Date • Filtered by All studies - 4 more filters applied

Search this list...

	Study Title	Business Operator	Laboratory	Status	Created Date	
1	Study 123	ABC Company		Draft	28/05/2021 10.58	▼
2	test 123	ABC Company		Draft	21/05/2021 16.09	▼

In each **tab**, the user can find studies according to the different **stages** of the process (i.e. Draft, Notified, Withdrawn, etc.).

3.5.1 Study creation as Applicant (from *Studies*) – Account type: Applicant and Laboratory

By clicking on “**Notify New Study as Applicant**” the user will be asked to include the basic study information and the business operator name.

Notify New Study as Applicant

Study Notification

Please fill in the following information to create a new study.

In the Business Operator field insert your own organisation or, if you are working as third party, the organisation for which you want to create the study.

* Study Title i

Study Title (English Name) i

* Business Operator i

Laboratory i

Study internal Reference ID (max 250 characters)

Next

- Insert the user’s organisation as **business operator**.
- If the notification is inserted by a consultant, the business operator for which the consultant is working ‘On behalf of’ should be inserted in the field ‘Business Operator’. This relationship must be firstly established as explained in the [Account relationship](#) section.

- **The user can also indicate the laboratory** commissioned to conduct the study. This information can be revised also at a later stage.

1. * sign means that the field is **mandatory**
2. i icon displays **help text** for that field.

Click here to create the study notification record.

3.5.1 Study creation as Applicant (from *Studies*) - Account type: Applicant and Laboratory

The screenshot shows a study creation interface with a progress bar at the top indicating stages: Draft (active), Notified, and Co-Notified. A callout box states: "The status bar shows the record progress." Below the progress bar, the study details for "Study RRR" are shown, including the EFSA Study Identification (EFSA-2023-00001728) and a status of "Draft". A callout box points to "Edit" and "Printable View" buttons, stating: "User can use these buttons to edit and get a printable view of the study." A "Select Operation" button is highlighted, with a callout box listing operations: "Notify/Co-notify", "Add Components", "Withdraw", "Share", and "Delete". A "New!" badge is next to "Notify/Co-notify". Below this, a "Study Status Tracker" section provides instructions on how to use the "Select Operation" button. A "Business Operator & Laboratory Details" section is highlighted, containing fields for Business Operator (ABC Company Spa) and Laboratory. A callout box explains: "When the user select 'Notify the study as Applicant', the Business Operator fields will be filled in with information of the user's organisation." At the bottom, a "Related lists" section shows "Test Item: Components (0)", "Pre-Application ID(s) (0)", and "Share With (0)". A callout box states: "Related lists: shows related records."

The status bar shows the record progress.

User can use these buttons to edit and get a printable view of the study.

Click on "Select Operation" to perform the following operations:

- **Notify/Co-notify** **New!**
- **Add Components**
- **Withdraw**
- **Share**
- **Delete**

Study Status Tracker

This Study has been saved as a **draft**. When ready, please click on the 'Select Operation' button and then **Notify** in the right-hand corner.

The following fields MUST contain a value before notification

Main section: Study Title - Study Starting Date - Study Planned Completion Date

Study Scope section: Study Type - Food Domain - Authorisation Type - Application Type - Study International Standard Certification - Study Objective - Study Test Item - Components (where applicable)

Please note that all the fields related to the co-notifier and the field 'Submit to Internal Testing Facilities' can be filled in while performing notification.

You can access the list of all available Study Types and Guidelines below:

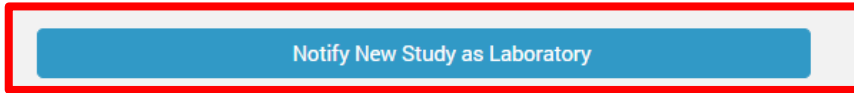
- All Study Types**
- All Study Guidelines**

Related lists: shows related records.

When the user select "Notify the study as Applicant", the Business Operator fields will be filled in with information of the user's organisation.

3.5.2 Study creation as Laboratory (from *Studies*) – Account type: Applicant and Laboratory

By clicking on “**Notify a New Study as Laboratory**”, the user sees and can fill in the following form



Study Notification

Please fill in the following information to create a new study.

In the Laboratory field insert your own organisation or, if you are working as third party, the organisation for which you want to create the study.

* Study Title i

Study Title - English Name i

* Laboratory i

Business Operator i

Study Internal Reference ID (max 250 characters)

Next

- Insert the user’s organisation as **laboratory**.
- If the notification is inserted by a consultant, laboratory for which the consultant is working ‘On behalf of’ should be inserted in the field ‘Laboratory’. This relationship must be firstly established as explained in the [Account relationship](#) section.

- **The user can also indicate the business operator** who commissioned the study. This information can be revised also at a later stage.

1. * sign means that the field is **mandatory**
2. i icon displays help text for that field.

Click this button to create the study notification record.

3.5.2 Study creation as laboratory (from *Studies*) – Account type: Applicant and Laboratory

The screenshot shows the 'Study as Lab' creation page. At the top, a status bar indicates the record's progress through 'Draft', 'Notified', and 'Co-Notified' stages. The main form includes fields for 'Study Title', 'Study Starting Date', and 'Business Operator & Laboratory Details'. A 'Select Operation' button is highlighted, leading to a list of actions: Notify/Co-notify, Add Components, Withdraw, Share, and Delete. A 'Related lists' section shows components, pre-application IDs, and share options. Annotations explain the status bar, edit/printable view buttons, the 'Select Operation' button's functions, and how the 'Notify the study as a laboratory' action populates laboratory fields.

The status bar shows the record progress.

User can use these buttons to edit and get a printable view of the study.

Click on "Select Operation" to perform the following operations:

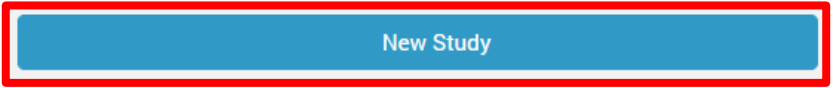
- **Notify/Co-notify** **New!**
- **Add Components**
- **Withdraw**
- **Share**
- **Delete**

Related lists: shows related records.

When the user select "Notify the study as a laboratory", the Laboratory fields will be filled in with information of the user's organisation.

3.6 Study creation as Laboratory (from Studies) – Account type: Laboratory only

By clicking on “**New Study**”, the user sees and can fill in the following form



Study Notification

Please fill in the following information to create a new study.

In the Laboratory field insert your own organisation or, if you are working as third party, the organisation for which you want to create the study.

* Study Title i

Study Title - English Name i

* Laboratory i

Business Operator i

Study Internal Reference ID (max 250 characters)

Next

- Insert the user’s organisation as **laboratory**.
- If the notification is inserted by a consultant, laboratory for which the consultant is working ‘On behalf of’ should be inserted in the field ‘Laboratory’. This relationship must be firstly established as explained in the [Account relationship](#) section.

- **The user can also indicate the business operator** who commissioned the study. This information can be revised also at a later stage.

1. * sign means that the field is **mandatory**
2. i icon displays help text for that field.

Click this button to create the study notification record.

3.6 Study creation as Laboratory (from *Studies*) – Account type: Laboratory only

Important note: from this point onwards the actions that can be performed by the laboratory and the business operator to edit, manage, notify or co-notify the study are the same.

The screenshot shows the 'Study as Lab' interface. At the top, a status bar indicates the current state: 'Draft' (highlighted in blue), 'Notified', and 'Co-Notified'. A callout box points to this bar, stating: 'The status bar shows the record progress.'

Below the status bar, the study details are shown. The status is 'Draft' and the study is 'Study Withdrawn'. There are 'Edit' and 'Printable View' buttons. A callout box points to these buttons: 'User can use these buttons to edit and get a printable view of the study.'

The 'Details' section includes fields for 'Study Title', 'Study Starting Date', 'Study Planned Completion Date', 'Submitted to Internal Testing Facility', and 'Justification for Delayed Notification'. A 'Select Operation' button is located in the top right of the details section. A callout box points to this button and lists the following operations: 'Notify/Co-notify' (with a 'New!' badge), 'Add Components', 'Withdraw', 'Share', and 'Delete'. Another callout box points to the 'Notify/Co-notify' option, stating: 'Click on "Select Operation" to perform the following operations: Notify/Co-notify, Add Components, Withdraw, Share, Delete.'

The 'Business Operator & Laboratory Details' section is expanded, showing information for 'Pharma SPA' (Laboratory) and 'admin.efsa@atlantic-technologies.com' (Laboratory Email). A callout box points to this section: 'The user sees the business operator and laboratory information under the dedicated section.'

At the bottom, there are sections for 'Test Item: Components (0)', 'Pre-Application ID(s) (0)', and 'Share With (1)'. A callout box points to these sections: 'Related lists: shows related records.'

3.7 Study creation (from *Studies*) - Valid for all organisations -> Details and History tabs

Details History

Study Title
Study TJP

Study Title (English Name) ⓘ
Study TJP

Study Starting Date Study Planned Completion Date

Submitted to Internal Testing Facility ⓘ

Justification for Delayed Notification ⓘ

Business Operator & Laboratory Details

Business Operator ⓘ Laboratory ⓘ

Business Operator Email Laboratory Email

> Study Scope

> Study Design (Mandatory only for Renewal Request)

> Study Notification Details

> Int

Under Detail tab the user can find details of the record divided into sections.

History

Study History (6)

Date	Field	User	Original Value	New Value	
09/09/2023 23.26	Study Planned Completion Date			29/09/2023	▼
09/09/2023 23.26	International Standard Certific...			GLP	▼
09/09/2023 23.26	Study Starting Date			06/09/2023	▼
09/09/2023 23.26	Study Guideline			OECD Guideline 492 (Reconstr...	▼
09/09/2023 23.26	Study Type			Sediment toxicity	▼
09/09/2023 22.15	Created.				▼

View All

Under History tab the user can see the changes made to the record.

3.8 Edit a draft study

The notifier (user who starts the notification process) can edit the **draft study notification** by clicking on the **Edit** button in the study page. By performing this action, the user can insert all the needed information to prepare the study for the following notification step.

At this stage, with the study still in draft status, **the user can revise and change, if needed, the information about the co-notifier (laboratory or business operator) from the co-notifier dedicated field.**

The image displays two side-by-side 'Edit' form screenshots. The left form is for a business operator notifier, showing 'Pharma SPA' in the 'Laboratory' field. The right form is for a laboratory notifier, showing 'Consultancy Spa' in the 'Business Operator' field. Both forms have 'Study Title' and 'Study Title - English Name' fields with 'Study XYZ' and 'Study FGH' respectively. At the bottom, there are 'Study Starting Date' and 'Study Planned Completion Date' fields with calendar icons. Red boxes highlight the 'Laboratory' and 'Business Operator' fields in their respective forms, with arrows pointing from the central text box to these fields.

Edit view if the notifier is a business operator.

Edit view if the notifier is a laboratory.

3.8 Edit a draft study

The notifier can edit the draft study to insert all the [information required for the notification](#) by clicking on the **Edit** button.

Edit

Please, use the fields below to update the study information.

* Study Title

Study Title

Study Title - English Name ⓘ

Laboratory ⓘ

Pharma SPA

Study Starting Date ⓘ 12-Apr-2023

Study Planned Completion Date 21-Jul-2023

Study Scope

Study Type

Dust Content

Feed Additives

Type a name or 'All' to see all results.

* Authorisation Type

Feed Additives

International Standard Certification ⓘ

Study Design

Study Guideline

Other

Type a name or 'All' to see all results.

Study Design Description ⓘ

Study Detailed Protocol ⓘ

Next

Notifier can use these fields to write a study title up to **300 characters long**.

Notifiers can edit this information from the edit box only when the study is in draft status. After the study is notified, this field disappears.

Notifiers can search for a **Study Type** and a **Study Guideline** by starting typing a name in the dedicated field and clicking on the message "Show all results for..." that appears below.

More details on the selection of a **Study Type** and **Study Guideline** are showed in the next slide.

Click **Next** to save the changes.

3.8.1 Edit a draft study – *Study Type and Study Guidelines*

Users can search for a specific Study Type if known already.

Study Scope

Study Type

tox



Show All Results for "tox"



Toxicity To Aquatic Invertebrates



Toxicogenicity And Pathogenicity



Toxicity To Sediment Dwelling Orga...



Extended One-Generation Reproduct...



Fish Early Lit

Study Type

tox



Click on this message to see all the results of the search.

Study Types

50+ Results • Sorted by [Relevance](#)

STUDY TYPE NAME

Toxins/Virulence factors

Toxicity to terrestrial plants

Toxicity to terrestrial arthropods

Toxicity to soil microorganisms

Toxicity To Soil Macro-Organisms

If users do not know exactly the Study Type name, it is possible to search for all the available values by typing "All" and press Enter.

Study Scope

Study Type

all



Show All Results for "all"



Human Intervention Studies On Red...



Hypersensitivity/Allergy And Food In...



In Vitro Studies On Residual Protein/...



In Vitro Studies On The Stability Of a



Allergenicity

Click on this message to see all the results of the search.

Study types can be sorted by Relevance or by Study Type Name. Click on the blue link to change the view.

The user searches and selects the Study Type need.

Study Type

all



Study Types

50+ Results • Sorted by [Relevance](#)

STUDY TYPE NAME

In Vitro Studies On The Stability Of Allergens In Foodtuffs

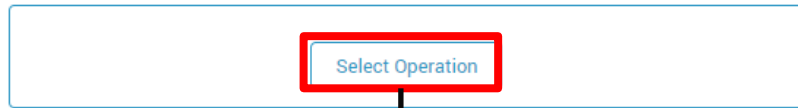
In Vitro Studies On Residual Protein/Allergens In The Food Ingredient

Hypersensitivity/Allergy And Food Intolerance

Human Intervention Studies On Reduced Risk Of Allergic Manifestations (Efficacy)

The same option is also available for the Study Guidelines field.

3.9 Actions on a draft notification



The notifier can perform several actions on the study notification record by clicking the function button **Select Operation** in the upper right corner of the page.



Please select one of the following actions to proceed.

Select One:

- Notify
- Add Component
- Withdraw
- Share With
- Delete

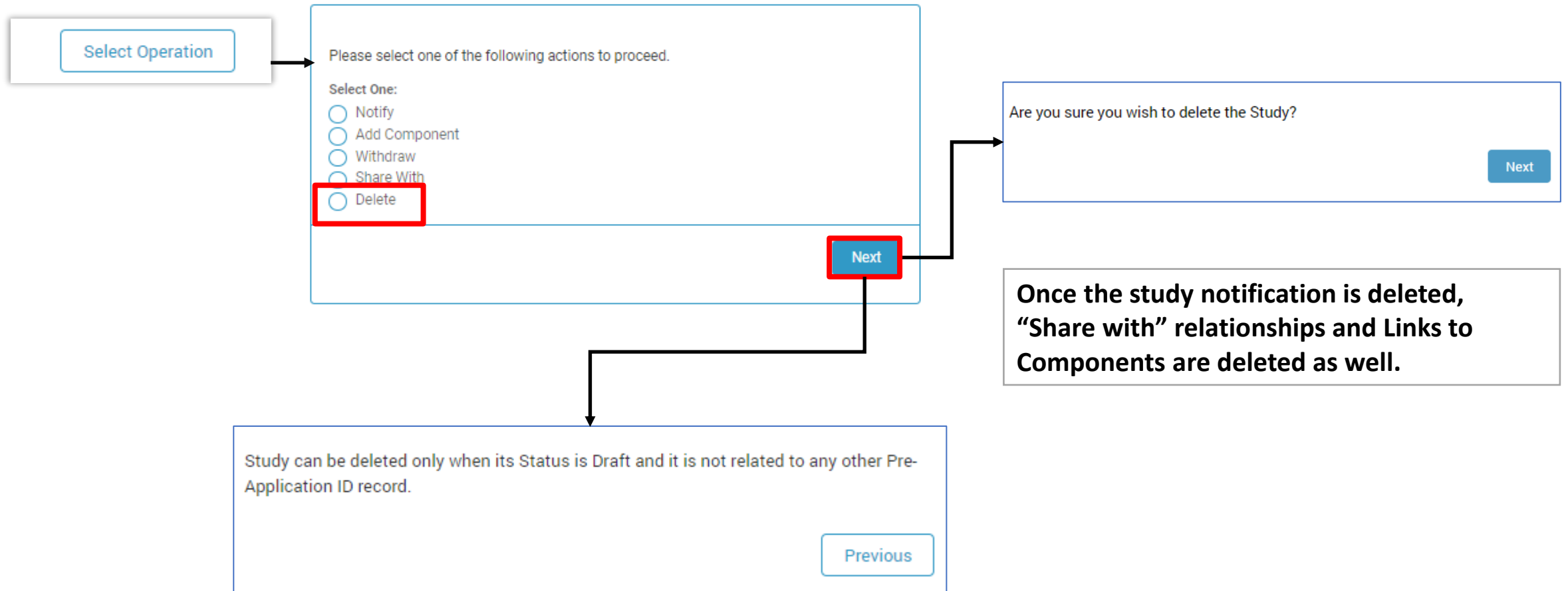
Next

1. **Notify** the study to EFSA indicating the co-notifier, i.e. a Business Operator or a Laboratory New!
2. **Add** existing or new **components**
3. **Share** the study notification with another organisation
4. **Delete** the **draft** study notification

The notifier should not use the **withdrawn** function for **Draft study notifications**, as they can simply be deleted.

3.9.1 Delete study

The notifier can delete a study notification record only when its **Status** is **Draft**, and it is **not related to** any other **pre-application ID**.



3.10 Component management - Add a component

New!

The notifier can add a component to give information on the test item of the study.

Click on **Select Operation** on the right-hand of the study notification page.

Please select one of the following actions to proceed.

Select One:

- Notify
- Add Component
- Withdraw
- Share With
- Delete

Next

Search for the *Component* you want to add to this record by using the search box below. Alternatively you can create a **new** Component by checking the box **Create New Component**.

* Component

Search Components...

Create New Component

Next

Type at least three letters of the component name to find all the related results. To expand the search results click on "Show All Results for ...".

Search for the *Component* you want to add to this record by using the search box below. Alternatively you can create a **new** Component by checking the box **Create New Component**.

* Component

Baci

- Show All Results for "Baci"
- Bacillus licheniformis** FMCH001 RF-00011997-PAR
- Bacillus subtilis** FMCH002 RF-00011999-PAR
- Bacillus subtilis** IAB/BS03 RF-00012000-PAR
- Bacillus subtilis** RTI477 RF-00012001-PAR
- Bacillus thuringiensis** RF-00012002-PAR

Select one of the results and click on **Next** to continue. The added component appears in the related list **Test item: Components** in the study notification page.

It is possible to **search for existing components in the EFSA catalogue (PARAM)**. The search includes also the components already created by the user. See **"View Component"** section for details.

3.10.1 Component management - Create component

New!

If a component is not retrievable using the search function, the notifier checks the box “Create New Component” in the “Add Component” dialogue box. The newly created component appears in the related list **Test Item: Components** in the study notification page.

Click on **Select Operation** on the right-hand of the study notification page.

Please select one of the following actions to proceed.

Select One:

- Notify
- Add Component
- Withdraw
- Share With
- Delete

Next

Search for the Component you want to add to this record by using the search box below. Alternatively you can create a new Component by checking the box **Create New Component**.

Create New Component

Next

Fill in the “Component Details” form with the corresponding information. The fields “Type of Term” and “Name” are mandatory. More details on the information required by a certain field are showed by passing over the **i** icons. Click **Next** to continue.

Add Component

Search for the Component you want to add to this record by using the search box below. Alternatively you can create a new Component by checking the box **Create New Component**.

Create New Component

Component Details

- * Type of Term **i**
None
- * Name
[Text Field]
- Common Names
[Text Field]
- Other Names
[Text Field]
- CAS **i**
[Text Field]
- IUPAC **i**
[Text Field]
- InChI **i**
[Text Field]
- Additional Information
[Text Field]

Next

3.10.2 Component management - Related list “Test Item: Components”

New!

Users find the components associated to a study in the related list “**Test Item: Components**”. For easier identification of the listed components, additional fields (e.g. Name, Type of Term, Origin) are available.

Name (short)	Type of Term	Origin	
Bacillus RRR	Microorganisms	Manual	▼

View All

Click on pointing down arrow to Edit or Delete the component from the list. More information in the Section dedicated to [Delete link to components](#).

Click on the name of the component to open the corresponding details page. More information in the Section dedicated to the [Components details page](#).

The related list shows a limited number of entries, users can click on “View All” to expand the related list box and view all the associated components.

3.10.3 Component management – Other components box

Study
TEST STUDY INTEGRATION TESTS

EFSA Study Identification: EFSA-2023-00001713 | Status: Draft | Study Withdrawn:

[Edit](#) [Printable View](#) [Select Operation](#)

Study Status Tracker

This Study has been saved as a **draft**. When ready, please click on 'Select Operation' button and then **Notify** in the right-hand corner.

The following fields **MUST** contain a value before notification:

Main section: Study Title - Study Starting Date - Study Planned Completion Date

Study Scope section: Study Type - Food Domain - Authorisation Type - Application Type - Study International Standard Certification - Study Objective - Study Test Item - Components (where applicable)

Please note that all the fields related to the co-notifier and the field 'Submit to Internal Testing Facilities' can be filled in while performing notification.

You can access the list of all available Study Types and Guidelines below:
All Study Types
All Study Guidelines

Test Item: Components (2)

Name	Origin
TEST STUDY INTEGRATION TESTS 00	Manual
TEST PAID INTEGRATION TESTS Component	Manual

[View All](#)

Other components

This box displays (in read-only mode) previously recorded information from "Other Components" field, which has been discontinued. Any new entry should be recorded within "Test Item: Components" related list, via "Add Component" action under "Select Operation".

component 1 and component 2
bia biab bla

The field “Other Components” has been discontinued, users find the information corresponding to this field in the Other components box under the Test Item: Components related list. This information is read-only.

New!

3.10.4 Component management - Delete link to components

Updated!

The notifier can **always** remove components from the study notification record. By performing this action, the notifier will delete only the link between the study notification and the component, **not the component itself**.

The screenshot shows a web interface for managing components. At the top, it displays 'Studies > Study RRR' and 'Test Item: Components' with '3 items · Updated a minute ago'. Below this is a table with columns: 'Name (short)', 'Type of Term', and 'Origin'. The table contains three rows:

	Name (short)	Type of Term	Origin	
1	Bacillus RRR	Microorganisms	Manual	▼
2	Water		ParamTerm	Edit
3	4-(p-Tolyl)butan-2-one		ParamTerm	Delete

The 'Delete' button for the third row is highlighted with a red box. An arrow points from this button to a confirmation dialog box titled 'Delete Link to Component'. The dialog asks 'Are you sure you want to delete this Link to Component?' and has 'Cancel' and 'Delete' buttons. The 'Delete' button in the dialog is also highlighted with a red box.

As a result, **the component is removed from the related list** “Test item: Components” on the study notification page.

3.10.5 Component management - View Components


All components created by the notifier are listed under the tab “My Components” in the Pre-Application ID, and in the “My Details” page.

Pre-Application ID

From this page, you can:

- Create a NEW Pre-Application ID clicking the button below. The Pre-Application ID is necessary to group pre-submission activities (notification of studies and pre-submission advice) to a future application
- Via the Pre-Application ID, you can create new notifications of studies, search for and associate notifications of studies that you previously created, and submit Pre-Submission Advice


Pre-Application ID Additional Involvement On Behalf Of **My Components**

 My Components ▾

17 items • Sorted by Last Modified Date • Filtered by All param terms - CreatedByMyAccount


	Term Extended Na...	Term Exten...	Te...	Term...	CAS	Te...	Te...	Last Modif...	
1	component 14/1 14.32			Submitt...	44			14/01/2022 14...	▾
2	Component by Chiara			Submitt...	dd			12/01/2022 11...	▾

My Details

 Account
ABC Company

English Name Billing Address
Milan
Italy

Details Related **My Components**

 My Components ▾

17 items • Sorted by Last Modified Date • Filtered by All param terms - CreatedByMyAccount

	Term Extended Nam...	Term Extende...	Term...	Term St...	CAS	Term...	Term...	Last Modifie...	
1	component 14/1 14.32			Submitted	44			14/01/2022 14.33	▾
2	Component by Chiara			Submitted	dd			12/01/2022 11.57	▾

3.10.6 Component management - Details Page

Updated!

The detail page of the component appears as in the image below. Information on the component can be added/modified directly from this page only for components created by the user.

The screenshot shows the 'Component Details' page for 'Bacillus RRR'. At the top right, there are 'Printable View' and 'Delete' buttons. Below them is a box labeled 'Available operations'. The main content area is divided into two columns of input fields for various identifiers and properties. On the right side, there is a 'Component History (1)' section with a table showing a single entry for 'Created' by 'Federico Mo...'. Below this are sections for 'PAIDs with this component (0)' and 'Studies with this component (1)', with the latter showing a 'Study RRR' entry. A red box highlights the 'Component History' and 'Studies' sections. Arrows point from the 'Available operations' box to the 'Component History' section and from the 'Component History' section to a text box at the bottom.

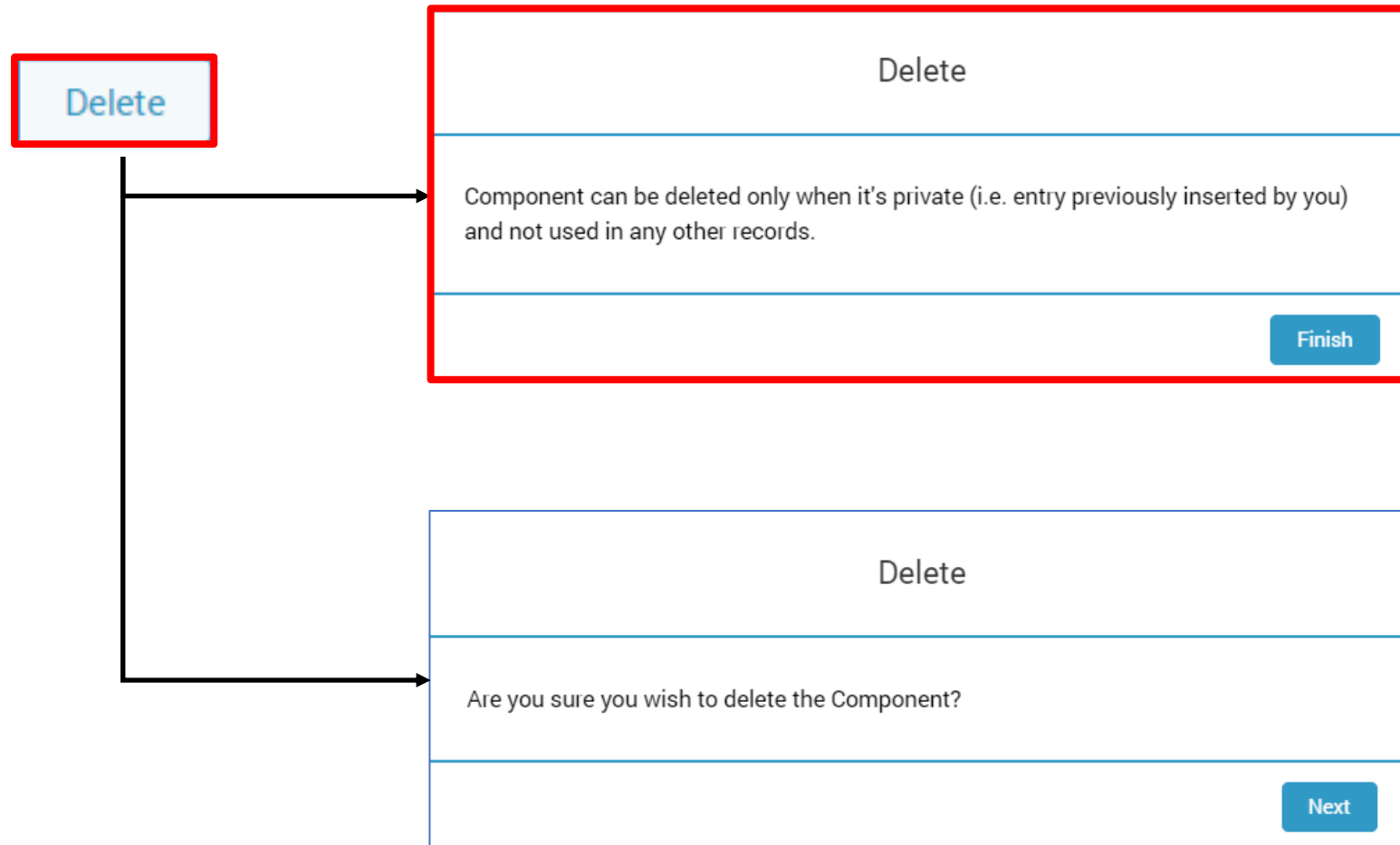
Date	Field	User	Original Value	New Value
12/09/202...	Created.	Federico Mo...		

Study
Study RRR

Related lists of the component page: inform the user about the history of the component record (e.g. creation, editing actions), and whether the component is associated to a pre-application ID or other study notifications.

3.10.7 Component management - Delete Components

From the detail page My Components the user can delete a component record by using the **Delete** function button.



This **error message** appears if the component is used in any other record (i.e. pre-application IDs, study notification records).

To delete the component, the notifier must firstly remove all the existing links with the other records as explained in the previous slides.

3.11 Account Relationship

When a **business operator/laboratory** wants to commission a third party/consultant to work on its behalf, the following relationship must be established in the page **My Details**.

The screenshot displays the 'My Details' page for 'ABC Company Spa'. The page includes account information such as 'English Name: Italy' and 'Billing Address: Milano Milan Italy'. It features three tabs: 'Details', 'Related', and 'My Components', with 'Related' highlighted. A 'Manage Relationship' button is visible in the top right, along with 'Follow' and 'New Contact' buttons. Below the tabs, there is a section for 'Account Information' and two relationship lists: 'Account Relationships: Account To (0)' and 'Account Relationships: Account From (0)'. Arrows indicate the flow from the 'Manage Relationship' button to the relationship lists and from the 'Related' tab to the 'Account Information' section.

User can click on the button **Manage Relationship** to **create, modify or delete** a relationship with an organisation that works on its behalf.

User can find under the tab **Related** the lists showing the existing relationships.

Account To: list of organisations **working on behalf of the user.**
Account From: list of organisations the user **is working on behalf of.**

3.11.1 Create an account relationship

Manage Relationship

Manage Relationship

You can either **establish a new relationship** (or invite a third party to register in the portal), or **update** or **delete a relationship** that you have previously established.

Please choose **only one** of the following options.

- Create a new account relationship
- Modify an existing account relationship
- Delete an existing account relationship

Next

Select **Next** to continue with the guided procedure. The system will give the user the possibility to **select an optional feature, see next slide.**

Manage Relationship

Select the **country** in which the third party resides. Then click on **Next**.

* Country

Italy

Previous Next

Select the **Country** and then the **organisation** to be added as third party/consultant.

Manage Relationship

Please choose **ONE** of the below organisations, or register a new one.

Choose an organisation to create a new relationship.

- DOI Test 1
- The Black Pearl
- Bayer Fake 123
- Solution Consulting
- Pharma Spaa
- Business & Business

Can't find the organisation you're looking for?

If the organisation you'd like to select does not appear above, they are not registered in the portal. Please check the box below to invite them to the portal.

I would like to send them an invitation to register for EFSA's portal.

Previous Next

3.11.1 Create an account relationship

OPTIONAL FEATURE - During the creation of an account relationship, **business operators and laboratories can agree on enabling a selected third party/consultant to act as Notifier and Co-notifier**, at the same time, of one or more studies. It is possible to modify this choice at any time (see [Modify an account relationship](#) to know more details).

The image shows two sequential screenshots of a web form titled "Manage Relationship".

Left Screenshot:

- Section: "Please choose ONE of the below organisations, or register a new one."
- Text: "Choose an organisation to create a new relationship."
- Radio buttons for: DOI Test 1, The Black Pearl, Bayer Fake 123, **Solution Consulting** (selected), Pharma Spaa, Business & Business.
- Section: "Can't find the organisation you're looking for?"
- Text: "If the organisation you'd like to select does not appear above, they are not registered in the portal. Please check the box below to invite them to the portal."
- Form element: I would like to send them an invitation to register for EFSA's portal.
- Buttons: "Previous" and "Next" (highlighted in red).

Right Screenshot:

- Section: "By checking the below box, you are enabling the selected third party to act as notifier and co-notifier of a study."
- Text: "Please note that this authorisation only applies to studies in which:"
- List:
 - the third party works on behalf of both the notifier and the co-notifier organisations
 - the third party has already access to the study because it has been shared with its organisation.
- Text: "By leaving the box unchecked you will establish only 'On behalf of ' relationship."
- Text: "This option can be updated at any time by selecting 'Manage Account relationships'"
- Form element: want to enable this organisation to act as notifier and co-notifier. (The checkbox is highlighted in red)
- Buttons: "Previous" and "Next" (highlighted in red).

Callout Box:

Check the box to enable the third party/consultant to perform this action or continue without checking the box.
Click **Next** to complete the procedure.

Note: a practical example of how this feature works is given in the next slide.

3.11.1 Create an account relationship

Actors of the process:

- A business operator, e.g. "Business Operator"
- A laboratory, e.g. "Laboratory"
- A third party/consultant, e.g. "Consultant"

Scenario: "Business Operator" commissions a study to "Laboratory". **The two parties decide to delegate to "Consultant" part or the entire process of notification of studies.**

Manage Relationship

By checking the below box, you are enabling the selected third party to act as notifier and co-notifier of a study.

Please note that this authorisation only applies to studies in which:

- the third party works on behalf of both the notifier and the co-notifier organisations
- the third party has already access to the study because it has been shared with its organisation.

By leaving the box unchecked you will establish only "On behalf of" relationship.

This option can be updated at any time by selecting "Manage Account relationships"

I want to enable this organisation to act as notifier and co-notifier.

[Previous](#) [Next](#)

How it works:

1. "Business Operator" and "Laboratory" **create an account relationship with "Consultant"**, and both **enable this organisation to act as notifier and co-notifier.**
2. "Consultant" creates and notifies a new study notification record on behalf of "Business Operator".
3. "Consultant" co-notifies the study on behalf of "Laboratory".

The process works also if "Laboratory" starts the notification process.

3.11.1 Create an account relationship

The relationship created will appear as follows in the related list **Account Relationships: Account To**.

Name	Account Relationship Type
Solution Consulting works on behalf of ABC Company	On Behalf Of

View All

Once the relationship has been established at the account level:

1. The user can **share single records** with its third party/consultant (to know more see [Share Study “On behalf of”](#)).
2. The third party/consultant can manage study notifications for the business operator and the laboratory.

3.11.1 Create an account relationship

If the organisation that the user wants to create a relationship with is not registered in the system, it is possible to send an invitation to register by following these steps.

Manage Relationship

Please choose ONE of the below organisations, or register a new one.
Choose an organisation to create a new relationship.

Can't find the organisation you're looking for?

If the organisation you'd like to select does not appear above, they are not registered in the portal.
Please check the box below to invite them to the portal.

I would like to send them an invitation to register for EFSA's portal.

Previous Next

Manage Relationship

Fill in the information and click **Next**.

Please enter a name and an email address for the organisation you'd like to register in the portal.
They will subsequently receive an email notification with a registration link.

Fill in the fields

First Name
Mario Rossi

Email
mariorossi@test.com

Previous Next

Manage Relationship

Success! You have sent the organisation an invitation to register for EFSA's portal.

IMPORTANT: Please note that the relationship to your organisation will NOT be automatically created when it has registered. Instead, you will need to manually add this relationship via the **Manage Relationship** button (the third party will be available in the list of organisations after they have registered).

Finish

Please note that the relationship with this organisation is not automatically created upon its registration. The user needs to create the relationship once the organisation is registered.

3.11.2 Modify an account relationship

Business operators and Laboratories can modify the option that enables a selected third party/consultant to act as Notifier and Co-notifier at any time.

Manage Relationship

You can either **establish a new relationship** (or invite a third party to register in the portal), or **update** or **delete a relationship** that you have previously established.

Please choose **only one** of the following options.

- Create a new account relationship
- Modify an existing account relationship**
- Delete an existing account relationship

Next

Manage Relationship

*Choose an existing account relationship to edit.

- GiveAdvice works on behalf of ABC Company Spa
- ACEL pharma s.r.l. works on behalf of ABC Company Spa**
- Pharma works on behalf of ABC Company Spa
- Business & Business works on behalf of ABC Company Spa
- Consultancy Spa works on behalf of ABC Company Spa
- Valagro S.p.A. works on behalf of ABC Company Spa
- Solution Consulting works on behalf of ABC Company Spa
- Mulino Bianco works on behalf of ABC Company Spa

NB: If no account relationships appear, you have not created any account relationships yet.

Next

Manage Relationship

By checking (unchecking) this box, you are enabling (preventing) the selected third party to act as notifier and co-notifier of a study.

Please note that this authorisation only applies to studies in which:

- the third party works on behalf of both the notifier and the co-notifier organisations
- the third party has already access to the study because it has been shared with its organisation.

I want to enable this organisation to act as co-notifier

Next

It is possible to grant or revoke this permission by checking or unchecking this box. Click on **Next** to continue.

Select the third party/consultant name and click on **Next**.

3.11.3 Delete account relationship

To **delete** an existing relationship with an organisation, follow these steps.

Manage Relationship

Manage Relationship

You can either **establish a new relationship** (or invite a third party to register in the portal), or **update** or **delete a relationship** that you have previously established.

Please choose **only one** of the following options.

- Create a new account relationship
- Modify an existing account relationship
- Delete an existing account relationship

Next

Manage Relationship

Select the relationship to delete and click **Next**.

*Choose an existing account relationship to delete.

- Solution Consulting works on behalf of ABC Company

NB: If no account relationships appear, you have not created any account relationships yet.

Previous Next

Manage Relationship

You have **successfully deleted** the relationship.

This organisation has been notified by email.

Click on **Finish** and refresh the page to return to your company details and view your changes.

Finish

3.12 Share study

Business Operators and Laboratories can share single records with other organisations using the button **“Share With”**.

The study notification record can be shared in two different ways:

- Relationship type: **“On behalf of”**. In this case the business operator/laboratory provides to the other organisation the possibility to **view, edit, notify and/or co-notify** the shared study notification record. In order to be able to perform this type of sharing, the user must establish an **account relationship** with this organisation beforehand (see [Create an account relationship](#))
- Relationship type: **“Shared with”**. In this case the business operator/laboratory involves another organisation in the notification process and provides **read-only access** to the shared record. No previous actions are required to perform this sharing.

Please select one of the following actions to proceed.

Select One:

Notify

Withdraw

Share With

Delete

Next

3.12.1 Share study “On Behalf of”

Choose the Relationship Type “**On Behalf of**” to enable the other organisation to **see and perform actions** on the study notification record. The user searches and selects the organisation to share the record with.

Share With

Please indicate the type of relationship you want to establish with another organisation (e.g. On behalf of or Share With).

- If you choose **On Behalf of**, you'll enable another organisation see and perform actions on this study record.

*NB: In order to be able to perform this action it is necessary to establish the relationship with your third party at organisation level. To do so, click on **My Details** and use the button **Manage Relationship**.*

- If you choose **Shared With**, you'll enable another organisation to see this study record.

You can only create one relationship at the time.

* Relationship Type
On Behalf Of

Use the field below to search for the organisation's name.

* Organisation
Solution Consulting

Next

Share With

You have successfully shared this study with another organisation. You can view your changes in the **Shared With** related list on the study page.

Previous **Next**

The organisation is added to the related list **Shared With** and can now see and perform actions on the study notification record.

Account Name	Relationship Type
Pharma SPA	Shared With
Solution Consulting	On Behalf Of

View All

3.12.1 Share study “On Behalf of”

If the Account Relationship with the third party/consultant has not been established beforehand, the system returns an **error message** when the user tries to share a record with the relationship type “On behalf of”.

Share With

Please indicate the type of relationship you want to establish with another organisation (e.g. On behalf of or Share With).

- If you choose **On Behalf of**, you'll enable another organisation see and perform actions on this study record.

*NB: In order to be able to perform this action it is necessary to establish the relationship with your third party at organisation level. To do so, click on **My Details** and use the button **Manage Relationship**.*

- If you choose **Shared With**, you'll enable another organisation to see this study record.

You can only create one relationship at the time.

* Relationship Type
On Behalf Of

Use the field below to search for the organisation's name.

* Organisation
Solution Consulting

Next

Share With

You cannot do the sharing "on behalf of" with this organisation, because you did not establish a relationship with it.

Please, either select:

- relationship type '**Share With**' (in this way the organisation selected will be able to only view, but not edit the record), or
- Enable a relationship with a third party. To do so click on **My Detail** in the navigation menu, click the button **Manage Relationship** and follow the instruction

Finish

3.12.1 Share study “On Behalf of”

Your Studies

From this page, you can create **NEW Studies** by clicking on the button directly below. Once you have created your new intended study, you can continue to edit it until you are ready to submit it to the laboratory that is working on it. The laboratory will be notified of your submission.

Please note that you can create studies that are not yet linked to an application, but that you can also associate these with an **Application ID** or a **List of Intended Studies for Renewal** at any point in time.

The third party/consultant can find the studies shared with its organisation under the **On behalf of** tab.

The screenshot shows the 'Your Studies' interface. At the top, there is a navigation bar with tabs: 'In Draft', 'Notified', 'To Correct Co-Notifier', 'Wrong Co-Notifier', 'To Co-Notify', 'Co-Notified', 'Co-Notified by Me', and 'More'. The 'In Draft' tab is highlighted with a red box. Below the navigation bar, there is a search bar and a dropdown menu. The dropdown menu is open, showing options: 'Withdrawn', 'Shared with', and 'On Behalf Of'. The 'On Behalf Of' option is highlighted with a red box. Below the dropdown menu, there is a table with columns: 'EFSA Study Ident...', 'Study Title', 'Business Ope...', 'Created Da...', and 'Last Modifie...'. The table is filtered by 'All studies - Status, Study Withdrawn, UserAccountId'.

The **organisation** (consultant) can:

1. **Read and edit** the study information
2. **Notify and/or co-notify** the study
3. **View and add components**
4. **Share the study with other business operators and laboratories** (only with relationship type “shared with”).

3.12.2 Share study “Shared with”

Choose the Relationship Type “**Shared with**” to enable the other organisation to **only see** the study ID record. Then, the user searches and selects the organisation to share the record with.

Share With

Please indicate the type of relationship you want to establish with another organisation (e.g. On behalf of or Share With).

- If you choose **On Behalf of**, you'll enable another organisation see and perform actions on this study record.

*NB: In order to be able to perform this action it is necessary to establish the relationship with your third party at organisation level. To do so, click on **My Details** and use the button **Manage Relationship**.*

- If you choose **Shared With**, you'll enable another organisation to see this study record.

You can only create one relationship at the time.

* Relationship Type
Shared With

Use the field below to search for the organisation's name.

* Organisation
Pharma

Next

Share With

You have successfully shared this study with another organisation. You can view your changes in the **Shared With** related list on the study page.

Previous Next

The organisation is added to the related list **Shared With** and can now see the study notification record.

Share With (1)

Account Name	Relationship Type
Pharma SPA	Shared With

View All

3.12.2 Share study “Shared with”

Your Studies

From this page, you can create **NEW Studies** by clicking on the button directly below. Once you have created your new intended study, you can continue to edit it until you are ready to submit it to the laboratory that is working on it. The laboratory will be notified of your submission.

Please note that you can create studies that are not yet linked to an application, but that you can also associate these studies to a **Pre-Application ID** or a **List of Intended Studies for Renewal** at any point in time.

This list contains all of your studies in **Draft** status. Use the search bar on the right to search for a study by another status, click on the tabs above.

In Draft Notified To Correct Co-Notifier Wrong Co-Notifier To Co-Notify Co-Notified Co-Notified by Me **More**

Withdrawn
Shared with
On Behalf Of

My Drafts ▼

50+ items • Sorted by Created Date • Filtered by All studies - Status, Study Withdrawn, UserAccountId

Q Search this list...

EFSA Study Ident... ▼	Study Title ▼	Business Ope... ▼	Created Da... ↓ ▼	Last Modifie... ▼
-----------------------	---------------	-------------------	-------------------	-------------------

The **organisation** can:

1. Find the studies shared with them under the **Shared with** tab.
2. Read the study information.
3. View components added to the study.

3.12.3 Delete “Share with”/”On behalf of” relationships

Important note: The Notifier can remove “Shared With” relationships only if **the status of the shared study** is equal to **Draft**. Conversely, it is **always possible** to remove “On behalf of” relationships.

Account Name	Relationship Type	
Business & Business	Shared With	Edit
Solution Consulting	On Behalf Of	Delete

View All

Delete Link to Organisation

Are you sure you want to delete this Link to Organisation?

Cancel Delete

The user clicks on the pointing down arrow next to the organisation to remove the existing relation from the study notification record.

As a result, the organisation is removed from the “Share With” list and it cannot see anymore the study notification record. This action will not delete the organisation account, but only the rights to access the study notification record.

“Shared with” Relationship can be removed only if Studies have Status equal to Draft

Share With (0)

3.13 Delete a study from a pre-application ID

Users with applicant qualification can remove studies from a pre-application ID only if the **status** of such studies is equal to **Draft**. It is not possible to remove a study when it is notified.

The screenshot displays the 'Pre-Application ID' interface for 'Renewal application TJP' (ID: EFSA-ID-2023-000914). The 'Details' tab is active, showing application information. On the right, the 'Pre-Application Operations' section lists actions like 'New Study', 'Add Studies', and 'Delete'. Below this is a table of 'Subject of the Application: Components (1)' with one entry: 'Bacillus RRR' (Microorganisms, Manual). A 'Study Notification (1)' table below shows a 'Draft' status study. A red box highlights a dropdown menu with 'Delete' selected. A callout box points to this dropdown with the text: 'Click on the pointing down arrow and select **Delete**.' Below the table, a 'Delete Link to Study' dialog box asks 'Are you sure you want to delete this Link to Study?' with 'Cancel' and 'Delete' buttons. A second callout box points to the 'Delete' button in the dialog with the text: 'This action will only remove the link between the draft study and pre-application ID. Deletion of the draft study from the database can be performed after this operation from the study notification record (see [Section 3.9.1 Delete study](#)).'

Pre-Application ID
Renewal application TJP

ID
EFSA-ID-2023-000914

Details History

Request Name
Renewal application TJP

Business Operator
ABC Company Spa

Details

Subject Of The Application
Renewal application TJP

Former Application ID
EFSA-Q-XXXXXXX

Note

ID
EFSA-ID-2023-000914

Contact Name

Food Domain
Feed Additives

Authorisation Type
Feed Additives

Application Type
Application for authorisation of a new use and/or modification and/or renewal of an already authorised feed additive (Articles 4(1), 13(3), 14 of Regulation (EC) No 1831/2003 respectively)

Pre-Application Operations

- Use the **New Study** button to create new Study records
- Use the **Add Studies** button to add notified and or co-notified studies
- Use **New List** button to create a List of Intended Studies for renewal (only for renewal applications)
- Add additional parties to this Pre-Application ID using the **Share With** button
- Use the **Add Component** button to add one or more components to this Pre-Application ID
- Request a General Pre-Submission Advice by using the **Ask GPSA** button
- Use the **Delete** button to delete your Pre-Application ID (certain conditions apply)

Add Component

Subject of the Application: Components (1)

Name (short)	Type of Term	Origin
Bacillus RRR	Microorganisms	Manual

Study Notification (1)

Study Title (Sh...	EFSA Study Iden...	Status	Study Withdrawn
Study TJP	EFSA-2023-0000...	Draft	<input type="checkbox"/>

Delete Link to Study

Are you sure you want to delete this Link to Study?

Cancel Delete

Click on the pointing down arrow and select **Delete**.

This action will only remove the link between the draft study and pre-application ID. Deletion of the draft study from the database can be performed after this operation from the study notification record (see [Section 3.9.1 Delete study](#)).

3.13 Delete a study from a pre-application ID

Pre-Application ID
Renewal application TJP

Edit New Study New List

ID
EFSA-ID-2023-000914

Details History

Request Name Renewal application TJP	ID EFSA-ID-2023-000914
Business Operator ABC Company Spa	Contact Name
Subject Of The Application Renewal application TJP	Food Domain Feed Additives
Former Application ID EFSA-Q-XXXXXXXX	Authorisation Type Feed Additives
Note	Application Type Application for authorisation of a new use and/or modification and/or renewal of an already authorised feed additive (Articles 4(1), 13(3), 14 of Regulation (EC) No 1831/2003 respectively)

Pre-Application Operations

- Use the **New Study** button to create new Study records
- Use the **Add Studies** button to add notified and or co-notified studies
- Use **New List** button to create a List of Intended Studies for renewal (only for renewal applications)
- Add additional parties to this Pre-Application ID using the **Share With** button
- Use the **Add Component** button to add one or more components to this Pre-Application ID
- Request a General Pre-Submission Advice by using the **Ask GPSA** button
- Use the **Delete** button to delete your Pre-Application ID (certain conditions apply)

Add Component

Subject of the Application: Components (1)

Name (short)	Type of Term	Origin
Bacillus RRR	Microorganisms	Manual

View All

Study Notification (1)

Study Title (Sh...	EFSA Study Iden...	Status	Study Withdrawn
Test_sharing_1...	EFSA-2023-0000...	Notified	<input type="checkbox"/>

The user clicks of the pointing down arrow and selects **Delete**.

A pop-up message appears informing the user that notified and co-notified studies cannot be deleted from the pre-application ID.

Study can be removed only when its Status is Draft

3.14 Study Notification

To notify a study, all the mandatory fields must be filled in. The user clicks on **Edit** to insert the required information.

Study RTY Edit Printable View

EFSA Study Identification: EFSA-2023-00001730 Status: Draft Study Withdrawn:

Details History

Study Title: RTY

Study Title (English Name): RTY

Study Starting Date: _____ Study Planned Completion Date: _____

Submitted to Internal Testing Facility: Justification for Delayed Notification: _____

Business Operator & Laboratory Details

Business Operator: ABC Company Spa Laboratory: _____

Business Operator Email: amuscia@atlantic-technologies.com Laboratory Email: _____

Study Scope

Study Type: _____ Test Item: TEST PAID INTEGRATION TESTS

International Standard Certification: _____ Food Domain: Animal Welfare

Study Internal Reference ID: _____ Authorisation Type: _____

Study Objective: _____ Application Type: _____

Study Design (Mandatory only for Renewal Request)

Study Guideline: _____ Study Design Description: _____

Study Detailed Protocol: _____

> Study Notification Details

> Intended Study ID (if applicable)

Select Operation

Updated!

Study Status Tracker

This Study has been saved as a **draft**. When ready, please click on 'Select Operation' button and then **Notify** in the right-hand corner.

The following fields MUST contain a value before notification:

Main section: Study Title - Study Starting Date - Study Planned Completion Date

Study Scope section: Study Type - Food Domain - Authorisation Type - Application Type - Study International Standard Certification - Study Objective - Study Test Item - Components (where applicable)

Please note that all the fields related to the co-notifier and the field 'Submit to Internal Testing Facilities' can be filled in while performing notification.

You can access the list of all available Study Types and Guidelines below:

All Study Types

All Study Guidelines

Click on these links to see all the available values for [Study Types](#) and [Study Guidelines](#) picklist.

3.14.1 Study Notification – *Edit function*

It is possible to complete/update the information provided in the studynotification record by editing the form.

The information can be edited at any time before the study planned completion date.

Study Title (300 characters limit)

Study Title - English Name

Study Starting Date: 6-Jul-2022 | Study Planned Completion Date: 7-Sep-2022

Justification for Delayed Notification: test

Study Scope

Study Type: Dust Content

Food Domain: Feed Additives

Authorisation Type: Feed Additives

Study Design

Study Guideline: Other

Study Design Description

Study Detailed Protocol

Next

Users can use these fields to write a study title up to **300 characters long**.

This field appears only if the “notification date” is later than the “study starting date”. For more details, see the section [Justification for Delayed Notification](#).

Users can search for a **Study Type** and a **Study Guideline** by starting typing a name in the dedicated field and clicking on the message “Show all results for...” that appears below, as showed in the [Study Type](#) and a [Study Guideline](#) dedicated section.

Click Next to save the changes.

Suggested read: Article 20(3) of the [EFSA Practical Arrangements on pre-submission phase and public consultations](#)

3.14.2 Study Notification – *Study Types and Study Guidelines*

You can access the list of all available Study Types and Guidelines below:

[All Study Types](#)
[All Study Guidelines](#)

Users click on these links to view a report of all the available values for Study Types and Study Guidelines picklist.

Report: Study Types
All Study Types

Total Records
328

Study Type (Full Name)
1 Appearance (Physical State, Colour)
2 Attrition
3 Batch to batch analysis
4 Basic Toxicokinetics/Dynamics (Adme)
5 Bioaccumulation
6 Bioaccumulation: aquatic/sediment
7 Bioaccumulation: terrestrial

Users can search for a specific value and export the entire list in Excel or CSV formats.

Report: Study Guidelines
All Study Guidelines

Total Records
287

Study Guideline (Full Name) ↓
1 AFNOR NF ISO 846 (Determination of the behaviour under the action of fungi and bacteria. Evaluation by visual examination or by measure of mass variations or physical characteristics)
2 BS 4797 ISO 3998 (Test method for textiles to determine resistance to insect pests (e.g., moths, carpet beetles, etc.))
3 DIN 53177 (Binders for paints and varnishes - Measurement of the dynamic viscosity of liquid resins; Resin solutions and oils by the capillary viscosimeter of Isocelses type according to Ubbelohde)

Users can sort the Study Types and Study Guidelines names in alphabetical order (ascending/descending) by clicking on the column name or the pointing down arrow button.

3.14.3 Study Notification – *To registered laboratory*

To notify a draft study the user needs to click on **Select Operation** and then on the picklist value **Notify**. The following instructions are valid also in case the laboratory starts the notification process.

The screenshot shows a progress bar at the top with four stages: **Draft** (highlighted in blue), **Notified**, **Co-Notified with Remarks**, and **Co-Notified**. Below the progress bar, the page title is "Study Test laboratory selection". There are buttons for "Edit" and "Printable View", and a highlighted "Select Operation" button. The main content area shows study details: "EFSA Study Identification: EFSA-2022-00001291", "Status: Draft", and "Study Withdrawn" (with an unchecked checkbox). A red box highlights a "Select One:" menu with options: "Notify", "Add Component", "Withdraw", "Share With", and "Delete". Below this menu is a "Click Next to continue." instruction and a "Next" button. A text box on the left explains that users should verify co-notifier information and provides instructions on how to search for or add a new organization. A red box highlights a search field containing "Pharma SPA" and a "Next" button. A text box on the right explains that if the field is empty, users should type the name and click the magnifying glass to see search results. A final screenshot shows the search results for "Ph" with a "Show All Results for 'Ph'" button.

Please verify the information about the co-notifier before submitting this change.

To change the co-notifier name, click on the X in the "Name field" below. Start typing the name of the organisation. Then click on the magnifying glass to show all related results.

If you cannot find the organization that you are looking for, leave the "Name field" blank. You will have the option to register a new organisation.

Laboratory

Next

If the user has indicated the laboratory when creating the study notification record, this information is displayed here and can be revised at this stage, if needed.

Please select one of the following actions to proceed.

Select One:

- Notify
- Add Component
- Withdraw
- Share With
- Delete

Click **Next** to continue.

If the field is empty, the user starts typing the name of the laboratory and click on the magnifying glass to show all related results, including address details, in order to identify the correct legal entity.

Laboratory

3.14.3 Study Notification – *To registered laboratory*

Please verify the information about the co-notifier before submitting this change.

To change the co-notifier name, click on the **X** in the "Name field" below. Start typing the name of the organisation. Then click on the **magnifying glass** to show all related results.

If you cannot find the organization that you are looking for, leave the "Name field" blank. You will have the option to register a **new** organisation.

Laboratory ⓘ

 ✕

Next

After having carefully checked that the laboratory selected is the correct legal entity to which the study has been commissioned, click on **Next**.

Write a comment in this text area, if needed.

Review the contact emails. It is possible to indicate an address different from the default one (i.e. organisation email), if needed.

If you would like to add any comments for the Reviewer before submitting this Study, please add them using the field below.

Please also double check that the business operator and laboratory emails below are correct. If not, the relevant people may not be notified of your study.

Comments

* Business Operator Email

* Laboratory Email

3.14.3 Study Notification – *To registered laboratory*

Once the study has been notified the status turns into **Notified**, the contact person of the **laboratory receives an email alert on the email address indicated at the moment of the notification action.**

The image illustrates the study notification process. It features three main components:

- Confirmation Message:** A box on the left containing the text "Thank You! Your Study has been notified." and "Click on **Next** to view the changes you made on the Study page." with a blue "Next" button.
- Business Operator & Laboratory Details Form:** A form on the right with a dropdown arrow and the title "Business Operator & Laboratory Details". It contains two columns of input fields: "Business Operator" (with "ABC Company" entered) and "Business Operator Email", and "Laboratory" (with "Pharma Spa" entered) and "Laboratory Email".
- Study Status Tracker:** A large interface at the bottom showing the study's progress. A red box highlights a progress bar with three stages: "Draft", "Notified" (the current stage, highlighted in blue), and "Co-Notified". Below the bar, the study is identified as "Study 123" with an EFSA Study Identification of "EFSA-2022-00001437". The status is "Notified" and the "Study Withdrawn" checkbox is unchecked. A "Study Status Tracker" box on the right provides a summary: "The study has been successfully **Notified**. The co-notifier will proceed with the co-notification and might decide to leave comments. An email will inform you about the progress." and "The co-notification due date is: **2022-11-04**". It also includes links for "All Study Types" and "All Study Guidelines".

3.14.4 Study Notification – *To a new laboratory*

Notify

Please **verify** that the following information is correct before submitting this Study. If not, please **change it here before continuing**.

If you **cannot** find the organisation that you are looking for and leave the name field blank, you'll have the option to **register a new party** below.

Laboratory ⓘ

Search Accounts...

I need to register a new laboratory.

WARNING: Please note that you should only register a new party for the portal if you **cannot** find the organisation by searching in the field above.

Next

1

Check this box to notify the study to a laboratory that is not yet registered. **NOTE: the user needs to select this option also if the laboratory is non-EU and is not going to register.**

Laboratory ⓘ

Search Accounts...

Submit To Internal Testing Facilities

I need to invite the laboratory to register in the system

WARNING: Please note that you should invite a new organisation to register to the portal, only if you **cannot** find the organisation by searching in the field above.

* Laboratory Name (max. 250 characters)

Email

you@example.com

* Country

Afghanistan

Please be aware that if the Organisation you are inviting is not located in the EU or in a third country with an agreement or arrangement within the meaning of Article 32b(3), second paragraph, of the General Food Law, there is **no obligation** for the laboratory to register and co-notify the study.

City (max. 100 characters)

Reference Person (max. 250 characters) ⓘ

Next

2

Fill in with the laboratory information and click **Next**.

3

Write a comment on the text area (if needed), double check the email addresses and click **Next**.

If you would like to add any comments for the Reviewer before submitting this Study, please add them using the field below.

Please also double check that the business operator and laboratory emails below are correct. If not, the relevant people may not be notified of your study.

Comments

* Business Operator Email

costuni@atlantic-technologies.com

* Laboratory Email

test@test.com

Next

The system sends an email alert to the laboratory with the invitation to register and co-notify the study.

3.14.4 Study Notification – *To a new laboratory*

Once the study has been notified, the status turns into **Notified**. The new laboratory receives **an email alert** with the invitation to register for the portal, review the information of the study and proceed with the co-notification.

The screenshot displays a user interface for a study notification. At the top, a message box states: "Thank You! Your Study has been notified. Click on **Next** to view the changes you made on the Study page." A blue "Next" button is visible. Below this, a section titled "Business Operator & Laboratory Details" contains two forms. The "Business Operator" form is pre-filled with "ABC Company" and has a "Business Operator Email" field. The "Laboratory" form is pre-filled with "Laboratory XXX", "Laboratory Email: test@test.com", "Country: Italy", and "City: Milan". A callout box points to these forms, stating: "Business operator information and laboratory details are automatically filled in." Below the forms is a progress bar with three stages: "Draft", "Notified" (highlighted in blue), and "Co-Notified". The main content area shows study details for "Study 123", including the EFSA Study Identification (EFSA-2022-00001437), Status (Notified), and a "Study Withdrawn" checkbox. A "Study Status Tracker" section provides information: "The study has been successfully **Notified**. The co-notifier will proceed with the co-notification and might decide to leave comments. An email will inform you about the progress. The co-notification due date is: **2022-11-04**. You can access the list of all available Study Types and Guidelines below: **All Study Types** and **All Study Guidelines**." The bottom of the page shows the Study Starting Date (06/10/2022) and Study Planned Completion Date (06/11/2022).

3.14.5 Study Notification – *To internal testing facilities*

To notify the study to an internal testing facility the user needs to click on Select Operation, **Notify** option and then check the box **“Submitted to Internal testing facility”**.

Notify

Please **verify** that the following information is correct before submitting this Study. If not, please **change it here before continuing**.

If you **cannot** find the organisation that you are looking for and leave the name field blank, you'll have the option to **register a new party** below.

Laboratory ⓘ

Search Accounts... 🔍

Submit To Internal Testing Facilities

I need to register a new laboratory.

WARNING: Please note that you should only register a new party for the portal if you **cannot** find the organisation by searching in the field above.

Next

Notify

Thank you! You successfully notified this study to your internal testing facilities.

Next

Study XXX [Edit] [Printable View] [Select Operation]

EFSA Study Identification: EFSA-2021-00000171 [Status: **Co-Notified**]

Study Status Tracker
This Study was submitted to an **internal testing facility**, hence it has been auto-approved.

Pre-Application ID(s) (0)

Shared With (0)

Submitted to Internal Testing Facility

Study Title: Study XXX

Business Operator: ABC Company

Former Application ID: [redacted]

Study Starting Date: 09/06/2021

Study Planned Completion Date: 24/06/2021

> Study Scope

> Study Design (Mandatory only for Renewal Request)

> Submission Details

When submitting to internal testing facility, **the co-notification process is not triggered**. The system does not send any co-notification mail alert. The user sees the status **Co-notified** and the checkbox **Submitted to internal testing facilities** is automatically checked.

3.14.6 Study Notification – *Justification for delayed notification*

When a study is notified after the starting date, the notifier must provide a **justification for the delay**.

If you would like to add any comments for the Reviewer before submitting this Study, please add them using the field below.

Please also double check that the business operator and laboratory emails below are correct. If not, the relevant people may not be notified of your study.

Comments

* Business Operator Email

* Laboratory Email

Please provide an explanation on the reasons why this study is being notified after the starting date, using the field below.

Study Starting Date: 8 February 2022

Justification for Delayed Notification ⓘ

Next

The field “Justification for Delayed Notification” is provided for the benefit of the notifier and can be used to keep a note of the reason of the delayed notification.

This without prejudice to the need for justifying the delayed notification **when submitting the corresponding application** as outlined in Article 19(4) of the EFSA Practical Arrangements on pre-submission phase and public consultations.

The field “Justification for delay” can be updated by the notifier at any time after the study notification by clicking on **Edit** button. If left empty, the notification will not be blocked.

3.15 Study Co-notification

It is recommended to revise the study information ideally within 30 calendar days from the receipt of the email with the invitation to co-notify (i.e. the notification date).

Your Studies

From this page, you can create **NEW Studies** by clicking on the button directly below. Once you have created your new study, you can continue to edit it until you are ready to submit it to the business operator who commissioned it. The business operator will be notified of your submission.

In Draft Notified To Correct Co-Notifier Wrong Co-Notifier **To Co-Notify** Co-Notified Co-Notified by Me More

This list contains all studies that have been notified by business operators and that are **awaiting your co-notification**. Use the search bar on the right to search for a study.

To Co-Notify ▼

18 items • Sorted by EFSA Study Identification • Filtered by All studies • 4 more filters applied

Search this list...

EFSA S...	Study Title	Business ...	Laboratory	Co-notific...		
1	EFSA-2023-0...	Study 123	ABC Compa...	Pharma SPA	06/04/2023	▼

More details about this new function in the dedicated section [“Wrong Co-Notifier”](#).

Follow the below steps to co-notify

1. The user can find the studies to co-notify under the tab **To Co-Notify**.
2. The user **selects the study to be co-notified and revises the information** showed in the study page.
3. From the upper right corner of the study page the user clicks on **Select Operation**.

Select Operation

Please select one of the following actions to proceed.

Select One:

Co-Notify

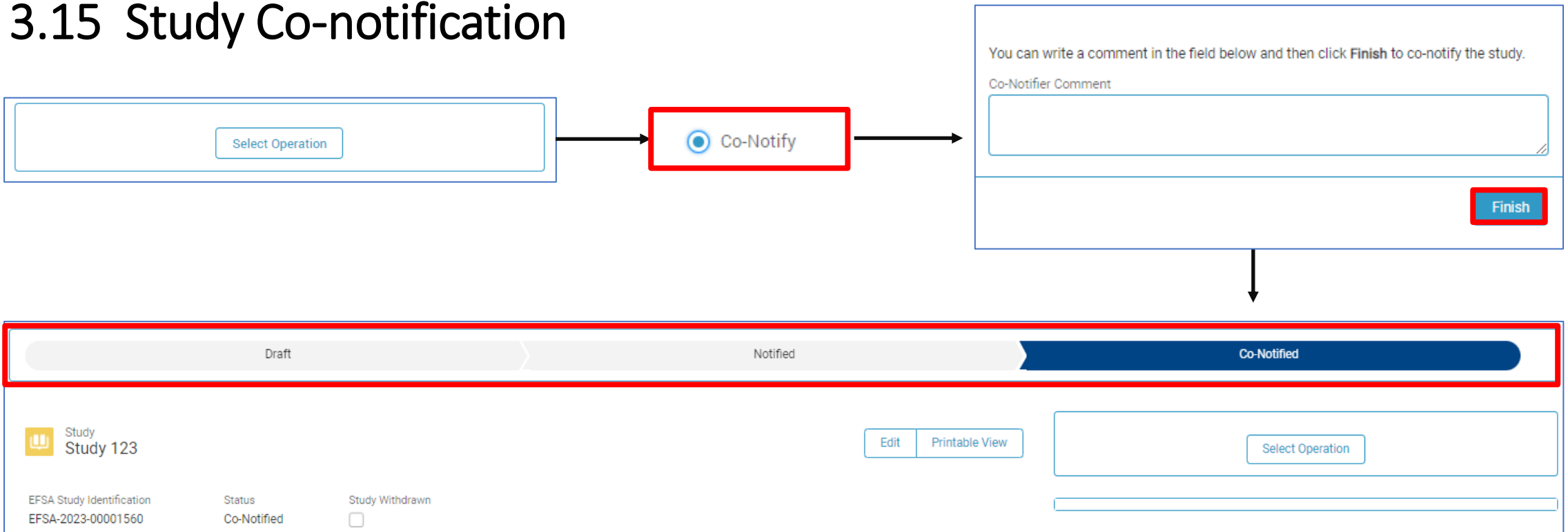
Wrong Co-Notifier

Manage Notification Alerts

Next

- To co-notify the study, the user selects **“Co-Notify”**, then clicks on **Next**.
- If the user notices that its own organisation has been wrongly selected as co-notifier, checks the **“Wrong Co-Notifier”** box then clicks on Next.

3.15 Study Co-notification



The status turns into **Co-Notified**. Comments and co-notification date are available in the “Study Notification Details” section. The notifier receives an email alert upon co-notification.

Study Notification Details	
Notification Date 07/03/2023	Co-Notification Date 05/04/2023
Notifier Comment	Auto-Notified <input type="checkbox"/>
Co-Notifier Comment	Justification for Withdrawal

3.15.1 Study Co-notification – “Wrong Co-Notifier” (co-notifier side)

An organisation (business operator or laboratory) that has been **wrongly selected as co-notifier** for a study should promptly **inform the notifier** about the mistake. The notifier has **30 calendar days** from the receipt of the Wrong-Co-Notifier alert email to amend the information. From the **Select Operation** menu the user checks the box “**Wrong Co-Notifier**” then clicks **Next**.

The screenshot shows a web interface for a study notification. At the top, a progress bar indicates the current stage is 'Notified', with 'Draft' and 'Co-Notified' as previous and subsequent stages. The main content area is divided into several sections:

- Study Information:** Displays 'Study RTY' with 'EFSA Study Identification' EFSA-2023-00001730, 'Status' as 'Notified', and 'Study Withdrawn' as an unchecked checkbox. There are 'Edit' and 'Printable View' buttons.
- Action Selection:** A section titled 'Please select one of the following actions to proceed.' with 'Select One:' and three radio button options: 'Co-Notify', 'Wrong Co-Notifier' (highlighted with a red box), and 'Manage Notification Alerts'. A 'Next' button is located at the bottom right of this section.
- Study Status Tracker:** A section providing instructions: 'Your organization has been added to this study notification. You can proceed by co-notifying this study and decide to leave comments to the notifier. An email will inform the notifier about the progress.' It also states: 'If you have been wrongly added as co-notifier to this study notification, you can inform the notifier by clicking on "Select Operation" and checking the box "Wrong co-notifier". The notifier will proceed changing the co-notifier.' The co-notification due date is '2023-10-12'. Links for 'All Study Types' and 'All Study Guidelines' are provided.
- Business Operator & Laboratory Details:** A section containing fields for 'Business Operator' (ABC Company Spa), 'Business Operator Email', 'Laboratory' (UAT_LAB: FM), and 'Laboratory Email'. This entire section is highlighted with a red box.
- Navigation:** 'Details' and 'History' tabs are visible at the top left of the main content area. A 'Study Scope' link is at the bottom left.

When the wrong co-notifier clicks on Next, the study notification record is no longer accessible. **This action cannot be undone.**

3.15.2 Study Co-notification – *Wrong Co-Notifier (notifier side)*

If the co-notifier informs the notifier to have been wrongly assigned to a study notification, the notifier receives an email alert.

Wrong Co-Notifier email message

The organisation you selected to co-notify the study *EFSA-YYYY-NNNNNNNN* reported that you have wrongly selected them as co-notifier. Please, revise the information about the co-notifier within **30 days**.

The deadline to change co-notifier is **DD Month YYYY**

To view the study please use the following link:

Once this timeframe has passed it will **no longer possible** to perform this action. If you wish to correct this study notification, you should **withdraw** it and proceed with a new study notification. More details on the user guide available on the [EFSA Toolkit page](#).

Follow the below steps to change the co-notifier

1. The user clicks on the link and enters into the study page, from the **Select Operation** menu checks “**Notify**” to start the procedure.
2. The user follows the indications reported in the dialogue box and changes the co-notifier organisation name. Click on **Next** to continue.

Please select one of the following actions to proceed.

- Select One:
- Notify
 - Withdraw
 - Share With
 - Delete

Please verify the information about the co-notifier before submitting this change.

To change the co-notifier name, click on the **X** in the “*Name field*” below. Start typing the name of the organisation. Then click on the **magnifying glass** to show all related results.

If you cannot find the organization that you are looking for, leave the “*Name field*” blank. You will have the option to register a **new** organisation.

Laboratory ⓘ

Pharma SPA X

Next

3. The following steps are similar to the study notification process.

More information in the next slide.

3.15.2 Study Co-notification – *Wrong Co-Notifier (notifier side)*

NOTE

- The process is triggered **only** by the co-notifier action.
- The possibility to change the co-notifier is not a new study notification. **The original study notification date will not change.**
- The co-notifier can be changed **within 30 days from the moment co-notifier informs the notifier to have been wrongly assigned to a study notification.**
- The revision and change of the co-notifier information can be done **only once.**

In following two circumstances the user cannot amend the co-notifier information of an existing study notification:

1. The information about the wrong co-notifier is not revised within 30 days from the receipt of the “Wrong Co-Notifier” email alert
2. The user selects a wrong co-notifier organisation for the second time.

If the users wishes to correct the information of a study notification, it should withdraw the study and proceed with a new study notification.

Follow the below steps to withdraw the current study and proceed with a new study notification

1. The user creates and [submits](#) a new study notification.
2. In case **the new notification is inserted with delay**, the user indicates in the [justification for the delay](#) that this new study notification is related to a wrong study notification (**include the Study ID**), which was withdrawn because the information about the co-notifier was not correct.
3. The user proceeds with the **withdrawal of the wrong study notification**. In the [justification for the withdrawal](#), the user specifies that the study notification is withdrawn because the information about the co-notifier is not correct and indicates the study ID related to the newly inserted study notification.

3.15.3 Study Co-notification – “auto-notified” studies

The screenshot shows the 'Your Studies' page with a navigation bar containing tabs: 'In Draft', 'Notified', 'To Correct Co-Notifier', 'Wrong Co-Notifier', 'To Co-Notify', 'Co-Notified', 'Co-Notified by Me', and 'More'. The 'To Co-Notify' tab is highlighted with a red box. Below the navigation bar, a text block explains that the list contains studies notified by business operators awaiting co-notification. A search bar is present. A table below shows 18 items, sorted by EFSA Study Identification. The first row is highlighted with a red box and contains the following data:

EFSA S...	Study Title	Business ...	Laboratory	Co-notific...		
1	EFSA-2023-0...	Study 123	ABC Compa...	Pharma SPA	06/04/2023	

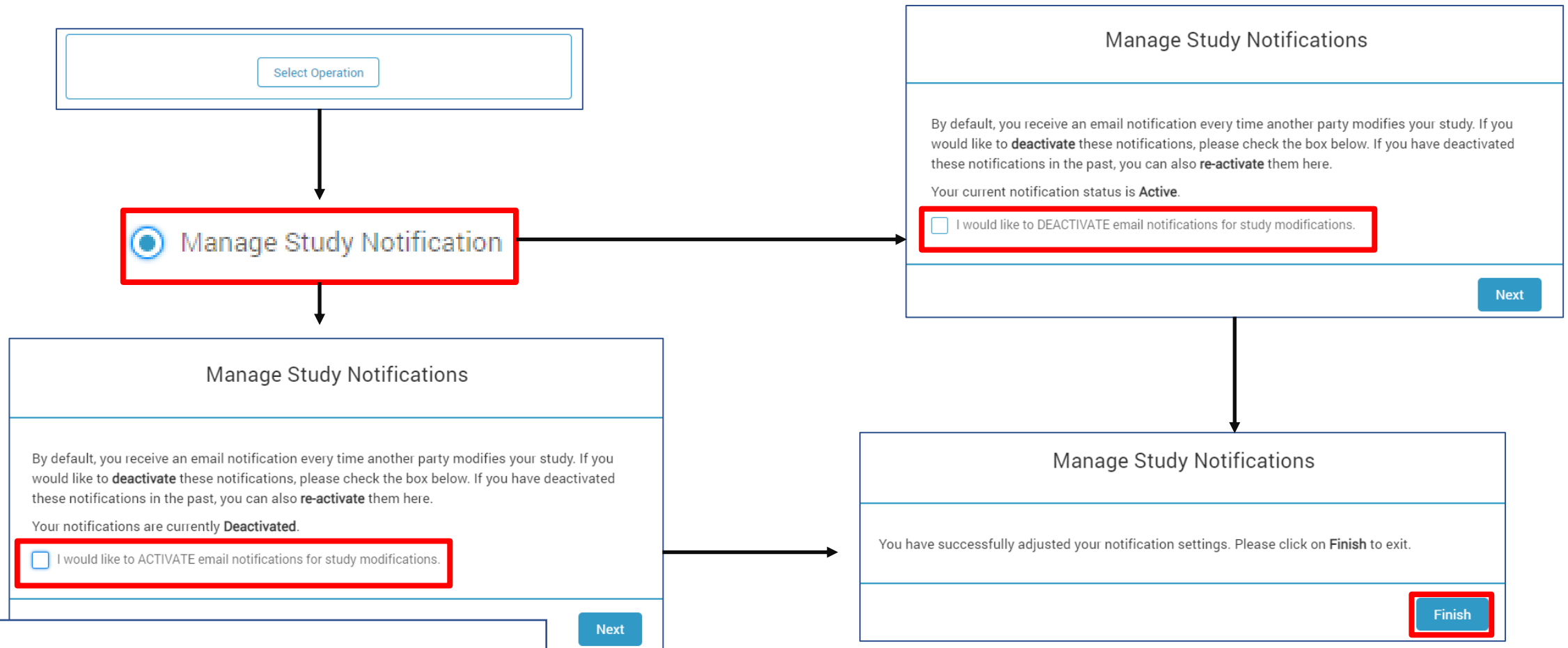
After the timeframe of 30 days for the notification has passed, the system marks the study as “auto-notified”.

An auto-notified study is not yet co-notified. The co-notifier should still complete the notification process by co-notifying such study. The co-notifier can inform the notifier to have been wrongly selected as co-notifier.

Studies marked as “auto-notified” are available in the To Co-Notify tab of “Your Studies” section.

3.15.4 Study Co-notification – Manage Study Notification

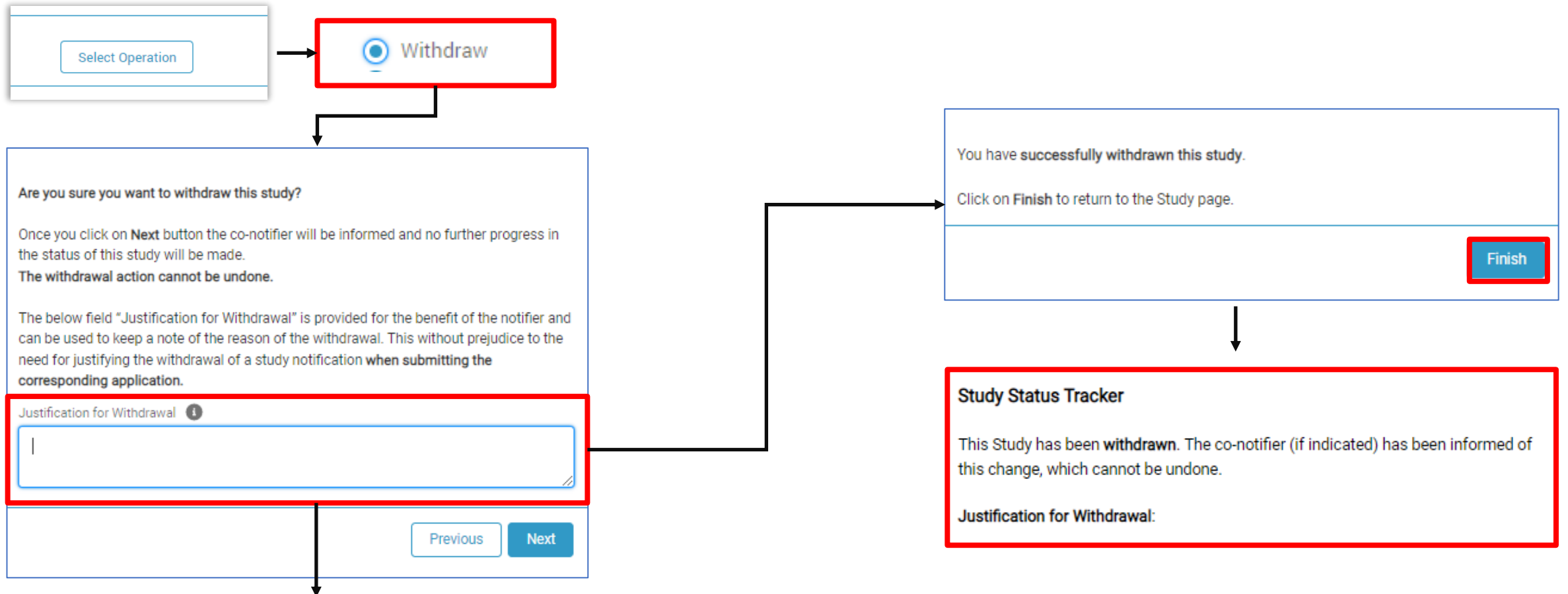
By default, the co-notifier receives an **email alert** every time the notifier edits the study notification record. To change this setting the co-notifier can click on the button **Select Operation** and then **Manage Study Notification** to deactivate them.



The co-notifier can at any moment **re-activate** the email alert by using the same button.

3.16 Study Withdrawal

The Notifier can withdraw a study before its planned completion date by clicking on the button **Select Operation** and then selecting **Withdraw**. The field “Justification for Withdrawal” is provided for the benefit of the notifier and can be used to keep a note of the reason of the withdrawal. This without prejudice to the need for justifying the withdrawal of a study notification **when submitting the corresponding application** as outlined in Article 20(4) of the EFSA Practical Arrangements on pre-submission phase and public consultations.



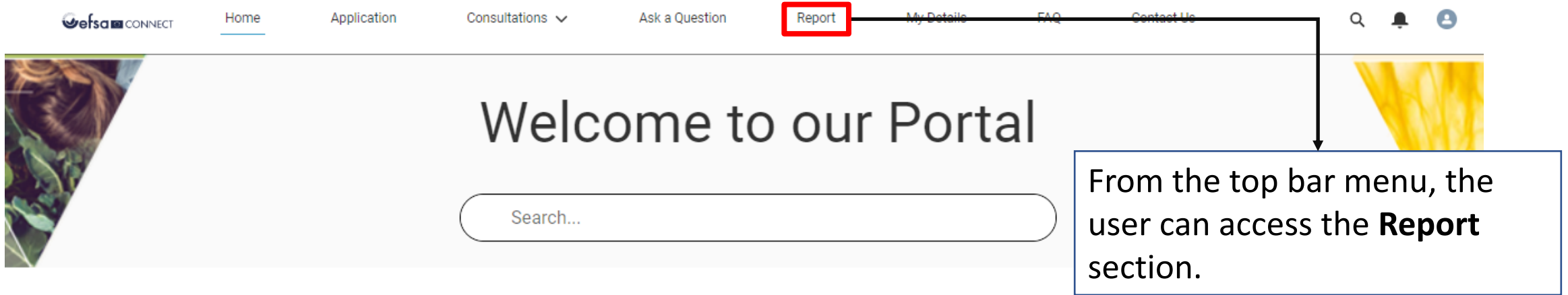
The field “Justification for Withdrawal” can be edited by clicking the “Edit” button also after the study is withdrawn.

Reporting features

#Connect.EFSA



4. Reporting features



From the top bar menu, the user can access the **Report** section.

Important notes about reports:

- The user entering the Report section finds an overview of all the **Reports** available.
- Reports are collected in two main folders: “Records owned by my organisation”, “Records shared with my organisation”. Hence it is not possible to see records belonging to another organisation unless they have been shared. An additional folder “Study Types and Study Guidelines” contains the already available reports on study type and study guidelines.
- All reports and folders available on the portal are predefined by EFSA and in **read-only mode**. This means that changes done by the user will not be saved. When the page is refreshed, the system will restore the original version of the report. The user cannot create new folders.
- It is possible to (temporarily) apply some changes to the online reports. They can also be **exported in an editable Excel or CSV file**.



4.1 Reporting features – Overview

The user can access the reports from the **REPORTS** (All Reports) view, or from the **FOLDERS** (All Folders) view.

From this search bar it is possible to search for a specific report.

Reports
All Reports
13 items

REPORTS	Report Name	Description	Folder	Created By	Created On	Subscribed
Recent	My components	This report shows the components created by your organisation	Records owned by my organisation		1/2/2023, 16:18	
Created by Me	My Components with Studies	This report shows the components linked with studies owned by your organisation	Records owned by my organisation		1/2/2023, 16:18	
Private Reports	My GPSA	This report shows the general pre-submission advice requests owned by your organisation	Records owned by my organisation		1/2/2023, 16:18	
All Reports	My list of intended studies	This report shows the pre-application IDs and the related list of intended studies created by your organisation	Records owned by my organisation		1/2/2023, 16:18	
FOLDERS	My PSA on Renewal	This report shows the list of intended studies and the related renewal pre-submission advice owned by your organisation.	Records owned by my organisation		1/2/2023, 16:18	
All Folders	My Studies	This report shows the studies and the linked pre-application IDs owned by your organisation	Records owned by my organisation		1/2/2023, 16:18	
Created by Me						
Shared with Me						
FAVORITES						
All Favorites						

Click on the report name to access it.

A short description of the content of the report is provided.

4.2 Reporting features - Folders

All the reports available to the user are saved in **three distinct folders**.

Reports
All Folders
3 items

Search all folders...

REPORTS	Name	Created By	Created On	Last Modified By	Last Modified Date
Recent	Records owned by my organisation		31/1/2023, 18:07		31/1/2023, 18:07
Created by Me	Records shared with my organisation		31/1/2023, 18:08		31/1/2023, 18:08
Private Reports					
All Reports	Study Types and Study Guidelines		12/10/2022, 14:18		1/2/2023, 20:18

FOLDERS

- All Folders
- Created by Me
- Shared with Me

FAVORITES

- All Favorites

Click on the folder name to access it.

4.3 Reporting features – Actions allowed on a report

The user can perform actions on the report using these buttons. It is possible to:

- **search for a specific value** in the table
- **add a chart**
- **apply filters**
- **refresh the values in table**
- **export the report** in Excel or CSV formats

Report: Pre-Application IDs with Lists of Intended studies with Intended Studies
My list of intended studies
Report showing all Pre-Application IDs with associated List of Intended Studies and Studies owned by your own organisation

Total Records: 202 Total Converted: 18

List of Intended studies ID	Request Name	Study Title	Study Title (English Name)	Study Objective	Test Item	Study Type	Study Guideline	Study
<input type="checkbox"/> LIST-01-2023-0476 (1)	Test member state AIR	giga	↑ Sort Ascending	ff	Renewal	Sediment toxicity	OECD Guideline 105 (Water Solubility)	ff
<input type="checkbox"/> LIST-01-2023-0478 (1)	Test UAT 09.01.23 PLR 2	Study Test UAT 09.01.23 PLR 2	↓ Sort Descending	Study obj:Test UAT 09.01.23 PLR 2	Test UAT 09.01.23 PLR 2	Allergenicity		Study I
<input type="checkbox"/> LIST-06-2023-0001 (2)	Paid 9/6 12.13	Test Federico	≡ Group Rows by This Field	Test Federico	Test Federico	Acidity/Alkalinity And Ph Value	ISO 10707 Water quality - Evaluation in an aqueous medium of the 'ultimate' aerobic biodegradability of organic compounds - Method by analysis of biochemical oxygen demand (closed bottle test)	Test Fe
	Paid 9/6 12.13	test gloria	≡ Group Columns by This Field	asdasd	hhasdasd	Acute toxicity: inhalation	ISO 10156 (Gases and gas mixtures - Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets)	-
			✕ Remove Column					

Click on one of the pointing down arrows to perform actions on the report table.

The user can:

- **sort the values**
- **group/ungroup values**
- **remove columns**

4.4 Reporting features – Export a report

Click on **Export** button and select the preferred format.

Formatted Report

Export the report, including the report header, groupings, and filter settings.

Details Only

Export only the detail rows. Use this to do further calculations or for uploading to other systems.

Format: Excel Format .xlsx

Cancel Export

Formatted Report
 Reports can be exported in a format similar to the online version, e.g., keeping the grouping and the other settings. This option exports the report as Excel file only.

A	B	C	D
1	My Studies with Pre-Application IDs		
2	As of 2023-01-06 17:10:54 Ora standard dell'Europa centrale/CET • Generated by User		
3	Filtered By		
4	Show: All pre-application ids		
5	Shared with other organisations equals False		
6	EFSA Study Identification ↑		
7	EFSA-2021-00000522		Study Title
8	Subtotal		Sum
9			Count
10			1
11	EFSA-2021-00000523		Test 2 - test lab
12	Subtotal		Sum
13			Count
14			1
15	EFSA-2021-00000543		test relationship
16	Subtotal		Sum
17			Count
18			1
19	EFSA-2021-00000545		test internal testing facility

Details Only

Export only the detail rows. Use this to do further calculations or for uploading to other systems.

Format: Excel Format .xls

Encoding: ISO-8859-1 (General US & Western European)

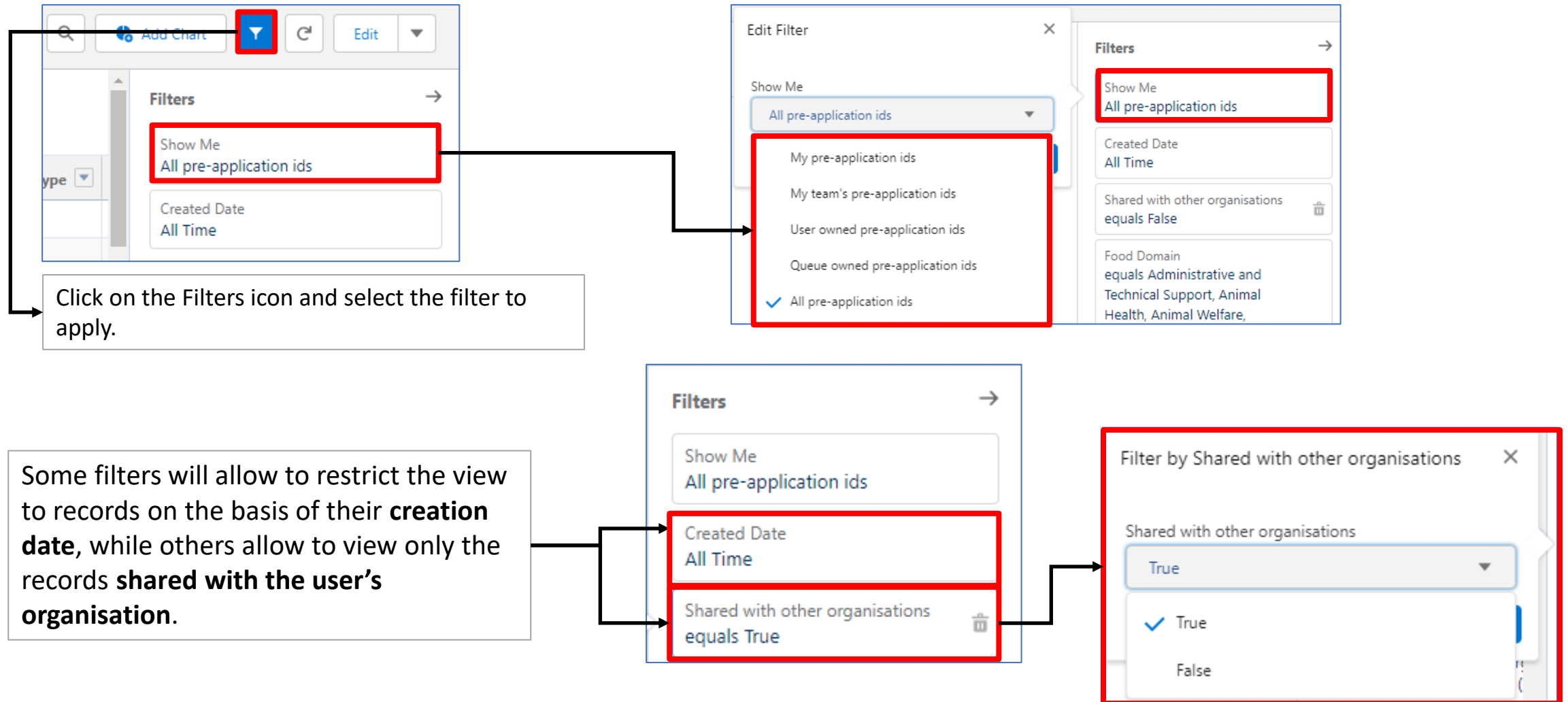
Cancel Export

Details Only
 Reports can be exported as Excel or CSV file showing only the detail rows.

A
1 Study Title
2 Draft study
3 test
4 rr
5 test
6 new study test shared with
7 test on behalf solution consulting
8 Study as Solution consulting

4.5 Reporting features – Filters functionality

Depending on the type of data showed in the report, predefined filters are available. Once the user refreshes the page the default filtering rules set by EFSA will be restored.



4.7 Reporting features – All my Studies reports

Rapporto: Studies
All my Studies
This Report shows all your studies regardless of a link to one or several Pre-Application IDs.

Record totali: 13 Totale Submitted to Internal Testin...: 1

	EFSA Study Identification	Study: Study Title	Study Title	Study Title (English Name)	Status	Study Objective	Business Operator
1	EFSA-2022-00014929	Test_studyType_duplicates	Test_studyType_duplicates	-	Draft	test	FDP Team Advice B
2	EFSA-2022-00015871	Test study typeff	Test study typeff	Test study type	Draft	test	FDP Team Advice B
3	EFSA-2023-00016774	test2	test2	-	Draft	-	FDP Team Advice B
4	EFSA-2023-00017492	Study a	Study a	Study a	Draft	dd	FDP Team Advice B
5	EFSA-2023-00017493	Study b	Study b	Study b	Draft	-	FDP Team Advice B
6	EFSA-2023-00017494	Study cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStu	Study c	Study c	Draft	-	FDP Team Advice B
7	EFSA-2023-00018347	Study XYZ	Study XYZ	-	Draft	-	FDP Team Advice B
8	EFSA-2023-00018348	Study ABC	Study ABC	-	Draft	-	FDP Team Advice B
9	EFSA-2023-00018349	Study CBD	Study CBD	-	Draft	-	FDP Team Advice B
10	EFSA-2023-00018350	Study FGI	Study FGI	-	Draft	-	FDP Team Advice B
11	EFSA-2023-00018351	Study EPO	Study EPO	-	Draft	-	FDP Team Advice B
12	EFSA-2022-00013462	This study is a test by FDP and IDATA to check the edit function after study not	This study is a test by FDP and IDATA to check the edit function after study notification	This study is a test by FDP and IDATA to check the edit function after study notification	Co-Notified	investigate acute tox	FDP Team Advice B

This report shows all the studies owned by the user organisation, regardless they are linked or not to a pre-application ID. The user finds:

1. The **EFSA Study IDs**.
2. The **Study Title information** comprehensive of “Study Title” with direct link to the study notification record page, “Study Title” (i.e. the full length version) and “Study Title (English Name)”.
3. Other available information includes: Status, Study Objective, Business Operator name and email, Laboratory name and email, etc.

Recommended documents and links

Applicants Toolkit

<https://www.efsa.europa.eu/en/applications/toolkit>

Transparency Regulation

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1381>

Practical Arrangements

<https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

Q&A on Practical arrangements

<https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements>

