



# User Guide

## Notification of studies

Last update: 26 June 2024

# Note for the users

This user guide has been updated on 26 June 2024 to take into account the latest system enhancements.

- The layout and look & feel of the Connect.EFSA portal has been aligned with the other EFSA portals and websites, such as OpenEFSA and the EFSA website. Users find new colours and menus, redesigned sections and improved access to useful resources, frequently asked questions and to the Ask a question service.
- Business operators, laboratories and their third parties/consultants registered in Connect.EFSA find pre-application IDs and the notification of studies database in a new pre-submission activities main page, accessible simply by logging in. The new pre-submission activities main page is also available from any point of the Connect.EFSA by browsing to the top menu bar and selecting “More”.
- The pre-submission activities page has been enriched with help texts. Users are therefore guided to the correct section in case they need to create a new pre-application ID, manage existing ones or access the notification of studies database.

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

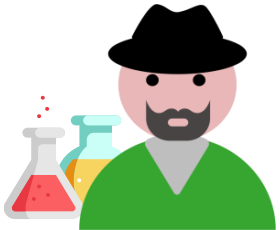
(green)

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.



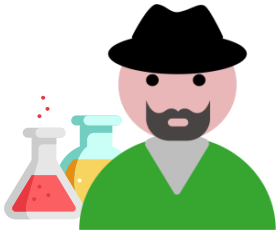
# 1.1 Account qualification

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

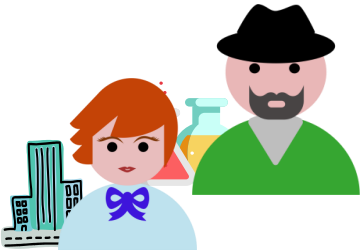
These qualifications are assigned by EFSA according to the needs of the users at the time of the registration.



**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.

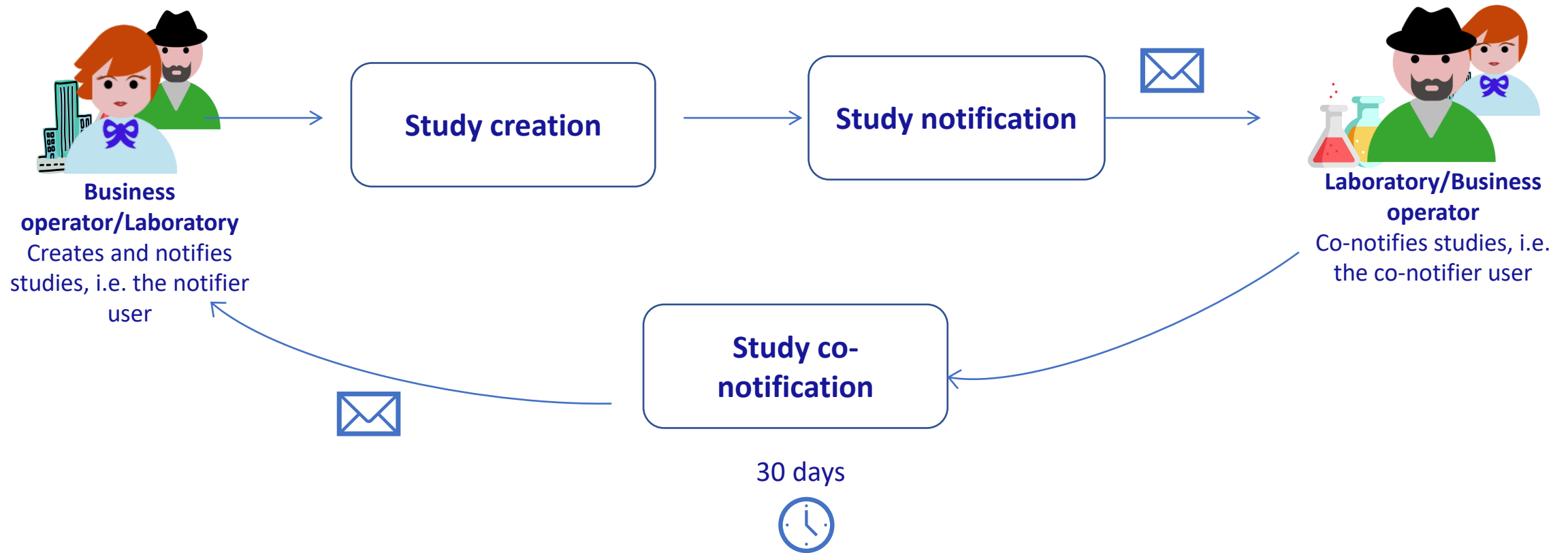


**Laboratory only:** organisations such as laboratories/external testing facilities. They act as laboratories conducting studies commissioned by business operators. These organisations can only create, notify and co-notify studies from the notification of studies database section. The same qualification 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).

# Accessing Connect.EFSA

#Connect.EFSA



## 2. Access the Connect.EFSA portal

Updated!

**Business operators** and **Laboratories**, and their third parties/consultants before starting to conduct pre-submission activities should [self-register an account](#) on behalf of their organisation by following the instructions available in the [Connect.EFSA registration user manual](#) and identifiable by a **pink banner** on the left-hand side of the slides.

**Registered users from Business operator** and/or **Laboratory** organisations can access Connect.EFSA portal from their `trusted` devices via the following link:

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



## 2.1 Accessing pre-submission activities

From the home page of Connect.EFSA users can access the **pre-submission activities page** in two ways:

1. before logging in, by clicking on 'More' and then selecting 'Pre-submission activities'
2. after logging in

The image shows two screenshots of the EFSA Connect website. The top screenshot shows the homepage with a 'More' dropdown menu open, highlighting 'Pre-submission activities'. The bottom screenshot shows the homepage after logging in, with a 'Pre-submission activities' button highlighted in the user's profile area.

**Way 1: Before logging in**

1. Click on 'More' in the top navigation bar.

2. Select 'Pre-submission activities' from the dropdown menu.

**Way 2: After logging in**

2. Click on the 'Pre-submission activities' button in the user's profile area.

**Open public consultations**

Public Consultation Number	Title
<a href="#">PC-0304</a>	Test 1906 single files
<a href="#">PC-0293</a>	CHG0035413 file & link

[View All](#)

**Ask a question**

EFSA is at your disposal to answer questions about EFSA's generic mandates, applications for regulated products, public access to documents, career opportunities and much more.

[Ask a question](#)

# 2.2 The pre-submission activities main page – Applicant view

New!

**efsa** CONNECT Home Consultations Ask a question More

## Pre-submission activities

[New pre-application ID](#) [Reports](#)

Quick buttons to create a new pre-application ID or access the report section.

Welcome John,

In this section you can manage pre-application IDs and study notifications, access reports related to your pre-submission activities and have an overview of all your submitted applications.

### Pre-application IDs

Create pre-application IDs, request general pre-submission advice, create and submit study notifications, and create and submit a list of intended studies for renewal applications.

[Access](#)

### Notifications of studies database

Access the lists of study notifications created by your organisation or shared with you by other organisations.

[Access](#)

### Current applications

View your submitted applications once they have been received by EFSA and assigned to an EFSA's question number.

[Access](#)

### Frequently asked questions

- [Does EFSA suggest consultancy companies for preparing and submitting an application?](#)
- [Where do I find the DAR \(Draft Assessment Reports\) application tool and related files?](#)
- [I have submitted an application for evaluation by EFSA. How can I check the status of my application?](#)

### Useful resources

- [Connect EFSA registration manual](#)
- [User guide on pre-application ID](#)
- [User guide on notification of studies](#)
- [EFSA's catalogue of services for applicants](#)

This page contains help texts and useful links to guide the user across the available functionalities.

## 2.3 The pre-submission activities main page – Laboratory view

New!

**efsa** CONNECT Home Consultations Ask a question More ▾

# Pre-submission activities

**Notification of studies database** ← Quick button to **access the notification of studies database section.**

Welcome John!

In this section you can manage study notifications related to studies commissioned to your organisation. You can access the list of study notifications requiring a co-notification by your organisation or directly notified by your organisation, and you can also notify a new study.

### Frequently asked questions

- Does EFSA suggest consultancy companies for preparing and submitting an application?
- Where do I find the DAR (Draft Assessment Reports) application tool and related files?
- I have submitted an application for evaluation by EFSA. How can I check the status of my application?
- Do I need to pay for EFSA's scientific evaluation and EFSA's pre-submission activities?
- Are the requirements the same for all feed additive applications?

[View all questions](#)

### Useful resources

- [ConnectEFSA registration manual](#)
- [User guide on pre-application ID](#)
- [User guide on notification of studies](#)
- [EFSA's catalogue of services for applicants](#)

This page contains **help texts** and **useful links** to guide the user across the available functionalities.

# Notification of studies

#Connect.EFSA





# 3 Study creation – Account type: Applicant

efsa CONNECT Home Consultations Ask a question More

**Pre-submission activities** **New!**

New pre-application ID Reports

Welcome John,

In this section you can manage pre-application IDs and study notifications, access reports related to your pre-submission and have an overview of all your submitted applications.

**Pre-application IDs**  
Create pre-application IDs, request general pre-submission advice, create and submit study notifications, and create and submit a list of intended studies for renewal applications.

**Notifications of studies database**  
Access the lists of study notifications created by your organisation or shared with you by other organisations.

Access Access

The user access this section **to create a new study notification from a pre-application ID.**

From this section the user can also **notify/manage studies** associated to already existing pre-application IDs.

**When needed**, in this section **the user may decide to create a new study notification not linked to a pre-application ID.**

**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 **notification of studies database** section:

- Notification of studies requested during admissibility/validity check in the cases where pre-submission activities where 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 where not conducted and therefore no pre-application ID was available.

# 3.1 Study creation (from *pre-application ID*) – Account type: Applicant

Updated!

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

**Pre-application ID**

Click this button to create a new pre-application ID.

New!

From every page, users can identify where they are within the portal through this bar.

In this page you can see the details of your pre-application ID, its related records and 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 all the pre-submission advice, i.e requests for general pre-submission advice and pre-submission advice on renewal
- Access and review all intended studies
- Access and review all lists of intended studies for renewal applications
- Access and review the components section

This box provides instructions to help the user to conduct pre-submission activities.

Pre-application ID   Pre-submission advice   Intended studies   List of intended Studies   Components

My Pre-Application IDs ▾

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

Search this list...


Request Name	ID	Food Domain	Application Type	Authorisation Type	Contact Name	Created Date
1 Renewal test RTYU	EFSA-ID-2024-000952	GMO	Application for renewal o...	Food and Feed - Regulati...	Betty Cook	10/06/2024 11:...

Click on the **request name of an existing pre-application ID** to access the corresponding page and view the study notifications associated, if any.

Here the user can search for a specific pre-application ID.

# 3.1 Study creation (from *pre-application ID*) – Account type: Applicant

Pre-submission activities / Pre-application ID / Pre-application ID detail page

 Pre-Application ID  
New application for FGH

ID  
EFSA-ID-2024-000951

**Edit** **New Study** **Add Studies** ▼

The user 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 pre-application ID.

**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)

**Details** History

Request Name  
New application for FGH

Business Operator  
[ABC Company](#)

ID  
EFSA-ID-2024-000951

Contact Name  
[Betty Cook](#)

▼ Details

Subject Of The Application ⓘ  
New application for FGH


Note ⓘ


Food Domain ⓘ  
Novel Foods

Authorisation Type  
Novel Food Application

Application Type  
New Novel Food

**Add Component**

 Subject of the Application: Components (0)

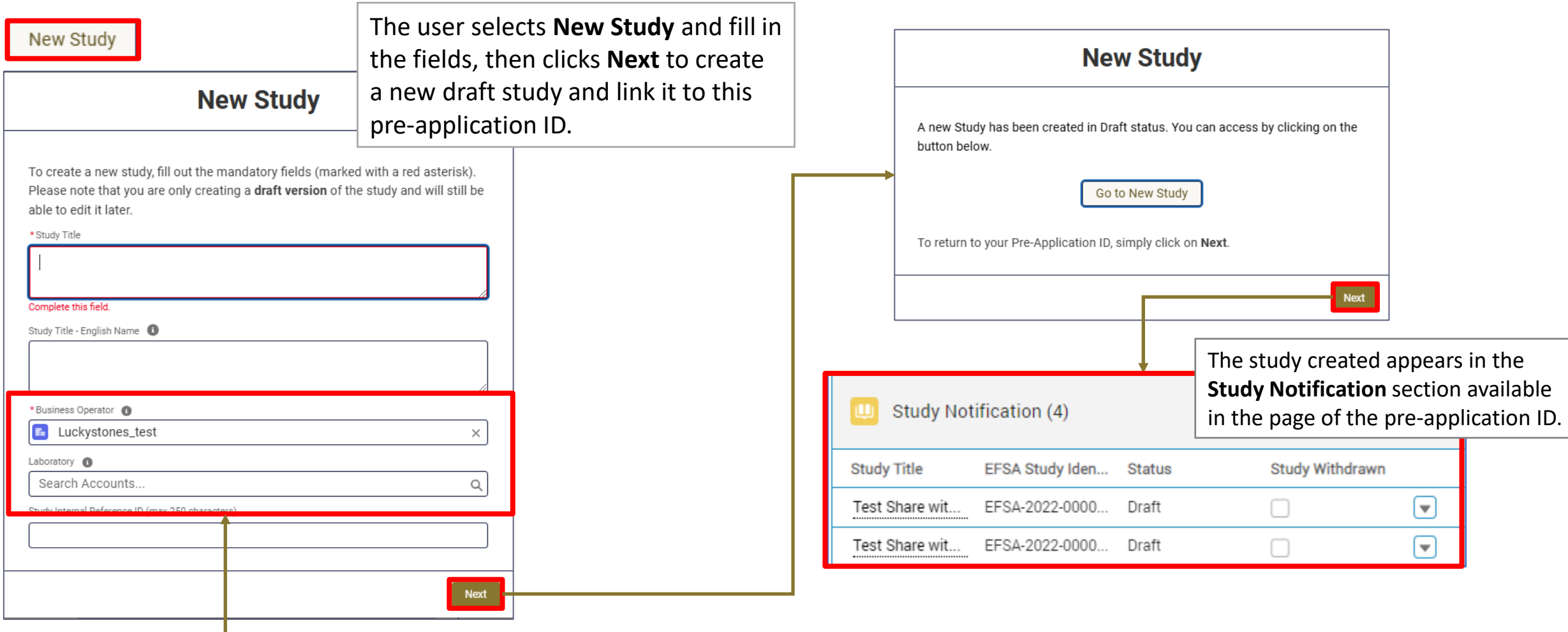
 Study Notification (0)

▼ Creation Details

Created Date

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

# 3.1 Study creation (from *pre-application ID*) – Account type: Applicant



**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 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.

# 3.1 Study creation (from *pre-application ID*) – Account type: Applicant

Add Studies

Click on **Add Studies** and use the search bar to find a study record. It is possible to select one or more study records the user would like to add to the pre-application ID. To continue click on **Next**.

Add Studies to Pre-Application ID

Search Studies...

**Selected Studies: 2**

EFSA-2023-00001617 x EFSA-2023-00001593 x

<input type="checkbox"/> Study Number	<input type="checkbox"/> Name	<input type="checkbox"/> Status	<input type="checkbox"/> Food Domain	<input type="checkbox"/> Created Date
<input type="checkbox"/> EFSA-2024-00001762	Study Title 98955191	Notified	Feed Additives	8-Feb-2024
<input checked="" type="checkbox"/> EFSA-2023-00001617	Study Title 78372026	Notified	Feed Additives	20-Mar-2023
<input checked="" type="checkbox"/> EFSA-2023-00001593	Study Title 24254589	Co-Notified	Animal Health	20-Mar-2023
<input type="checkbox"/> EFSA-2023-00001597	Study Title 89219473	Co-Notified	Animal Health	20-Mar-2023

**Next**

**Only notified and co-notified studies** can be added to the pre-application ID.

Added studies appear in the **Study Notification** section available in the page of the pre-application ID.

**Study Notification (3)**

Study Title	EFSA Study Iden...	Status	Study Withdrawn
TR_test2_Stud...	EFSA-2022-0000...	Notified	<input type="checkbox"/> <input type="checkbox"/>
Study 123	EFSA-2022-0000...	Notified	<input type="checkbox"/> <input type="checkbox"/>
Study to co-not...	EFSA-2022-0000...	Co-Notified	<input type="checkbox"/> <input type="checkbox"/>

[View All](#)

**Add to**

Selected Studies: 3

# 3.1 Study creation (from *pre-application ID*) – Account type: Applicant

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

The screenshot shows the 'Study TJP' notification page. At the top, there are buttons for 'Edit', 'Printable View', and 'Select operation'. The main content area is divided into a left sidebar with navigation links and a main content area. The sidebar includes 'Details' and 'History' tabs, and a list of sections: 'Study Title', 'Study Starting Date', 'Submitted to Internal Testing Facility', 'Business Operator & Laboratory Details', 'Study Scope', 'Study Design (Mandatory only for Renewal Request)', 'Study Notification Details', and 'Intended Study ID (if applicable)'. The main content area includes a 'Study Status Tracker' section with instructions and a 'Test Item: Components (0)' section. A table at the bottom shows 'Pre-Application ID(s) (1)' with columns for 'Request Name', 'Record Type', and 'Link to Study: Create...'. Two red boxes highlight the 'Test Item: Components (0)' section and the 'Pre-Application ID(s) (1)' table. Two text boxes provide annotations: 'This section is dedicated to components.' points to the 'Test Item: Components (0)' section, and 'This section shows the pre-application ID(s) to which the study is linked.' points to the 'Pre-Application ID(s) (1)' table.

**Study TJP**

EFSA Study Identification: EFSA-2023-00001727

Status: Draft

Study Withdrawn:

**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: ABC Company Spa

Business Operator Email: azocoo@atlantic-technologies.com

Laboratory: \_\_\_\_\_

Laboratory Email: \_\_\_\_\_

**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 (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.

## 3.2 Study creation (from *notification of studies database*) – Overview

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

### Notification of studies database

New!

Pre-submission activities / Notification of studies database

From this page, you can create a new study notification. Once you have created your new study, you can continue to edit it until you are ready to notify it to EFSA. Upon the notification, the indicated co-notifier will receive an email alert.

Create a new study

In draft   Notified   To correct co-notifier   Wrong co-notifier   To co-notify   Co-notified   Co-notified by me   Withdrawn   Shared with   On behalf of

My Drafts

50+ items • Sorted by EFSA Study Identification • Filtered by All studies - Status, Study Withdrawn, UserAccountid

Search this list...

	EFSA Study Identification ↑	Study Title (Short)	Business Operator	Created Date	Last Modified Date	
1	EFSA-2021-00000625	Study Title 53901459	ABC Company	22/06/2021 15.38	09/05/2024 15.12	⌵
2	EFSA-2021-00000626	Study Title 99314366	ABC Company	22/06/2021 15.39	09/05/2024 15.12	⌵
3	EFSA-2021-00000669	Study Title 11281382	ABC Company	26/06/2021 9.00	09/05/2024 15.12	⌵

- **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 co-notification.
- **Co-Notified:** all the studies co-notified by the co-notifier organisation.
- **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).

## 3.2.1 Study creation (from *notification of studies database*) – Account type: Applicant

From the section notification of studies database, 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.

**Notification of studies database**

From every page, users can identify where they are within the portal through this bar.

Pre-submission activities / Notification of studies database

From this page, you can create a new study notification. Once you have created your new study, you can continue to edit it until you are ready to notify it to EFSA. Upon the notification, the indicated co-notifier will receive an email alert.

Create a new study

Click here to create a new draft study notification.

In draft | Notified | To correct co-notifier | Wrong co-notifier | To co-notify | Co-notified | Co-notified by me | Withdrawn | Shared with | On behalf

My Drafts ▾

50+ items • Sorted by EFSA Study Identification • Filtered by All studies - Status, Study Withdrawn, UserAccountid

Search a record in this list.

Search this list...

	EFSA Study Identification ↑	Study Title (Short)	Business Operator	Created Date	Last Modified Date	
1	EFSA-2021-00000625	Study Title 53901459	ABC Company	22/06/2021 15.38	09/05/2024 15.12	▾
2	EFSA-2021-00000626	Study Title 99314366	ABC Company	22/06/2021 15.39	09/05/2024 15.12	▾
3	EFSA-2021-00000669	Study Title 11281382	ABC Company	26/06/2021 9.00	09/05/2024 15.12	▾



## 3.2.1 Study creation (from *notification of studies database*) – Account type: Applicant

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

Create a new study

Pre-submission activities / Notification of studies database / New study

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 ⓘ

Study Internal Reference ID (max 250 characters)

Save

- 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. ⓘ icon displays **help text** for that field.

Click here to create the study notification record.

### 3.2.2 Study creation (from *notification of studies database*) – Account type: Applicant and Laboratory

When the user's organisation is qualified both as Applicant and Laboratory, the user can decide between "[Create a new study as applicant](#)" or "[Create a new study as laboratory](#)".

**Notification of studies database**

From every page, users can identify where they are within the portal through this bar.

Pre-submission activities / Notification of studies database

From this page, you can create a new study notification. Once you have created your new study, you can continue to edit it until you are ready to notify it to EFSA. Upon the notification, the indicated co-notifier will receive an email alert.

Create a new study (applicant)

Create a new study (laboratory)

In draft   Notified   To correct co-notifier   Wrong co-notifier   To co-notify   Co-notified   Co-notified by me   Withdrawn   Shared with   On behalf of

My Drafts ▾

50+ items • Sorted by EFSA Study Identification • Filtered by All studies - Status, Study Withdrawn, UserAccount

	EFSA Study Identification ↑	Study Title (Short)	Business Operator			
1	EFSA-2021-00000625	Study Title 53901459	ABC Company	22/06/2021 15:38	09/05/2024 15.12	▾
2	EFSA-2021-00000626	Study Title 99314366	ABC Company	22/06/2021 15:39	09/05/2024 15.12	▾
3	EFSA-2021-00000669	Study Title 11281382	ABC Company	26/06/2021 9.00	09/05/2024 15.12	▾

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

**New!**

**Updated!**

### 3.2.3 Study creation as Applicant (from *notification of studies database*) – Account type: Applicant and Laboratory

Create a new study (applicant)

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

Pre-submission activities / Notification of studies database / New study

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 ⓘ

Study Internal Reference ID (max 250 characters)

Save

- 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. ⓘ icon displays **help text** for that field.

Click here to create the study notification record.

### 3.2.3 Study creation as Applicant (from *notification of studies database*) – Account type: Applicant and Laboratory

The screenshot shows a web interface for creating a study. At the top, a progress bar indicates the status: 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 progress bar, the study details are shown. The study title is "Study RRR". The EFSA Study Identification is "EFSA-2023-00001728". The status is "Draft". A callout box points to the "Edit" and "Printable View" buttons, stating: "User can use these **buttons** to edit and get a printable view of the study."

The "Details" tab is active, showing fields for Study Title, Study RRR, Study Starting Date, Study Planned Completion Date, Submitted to Internal Testing Facility, and Justification for Delayed Notification. A callout box points to the "Business Operator & Laboratory Details" section, stating: "When the user select 'Notify the study as Applicant', the Business Operator fields will be filled in with information of the user's organisation."

On the right, the "Study Status Tracker" section provides instructions: "This Study has been saved as a **draft**. When ready, please click on 'Select Operation' button and then **Notify** in the right-hand corner." It lists required fields for notification: Main section (Study Title, Study Starting Date, Study Planned Completion Date) and Study Scope section (Study Type, Food Domain, Authorisation Type, Application Type, Study International Standard Certification, Study Objective, Study Test Item, Components). A callout box points to the "Related lists" section, stating: "Related lists: shows related records."

The "Related lists" section includes: "All Study Types", "All Study Guidelines", "Test Item: Components (0)", "Pre-Application ID(s) (0)", and "Share With (0)".

### 3.2.4 Study creation as Laboratory (from *notification of studies database*) – Account type: Applicant and Laboratory

By clicking on “**Notify a New Study as Laboratory**”, the user the user is asked to include the basic study information and the laboratory name.

Create a new study (laboratory)

Pre-submission activities / Notification of studies database / New study

#### 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 ?

Study Title - English Name ?

\* Laboratory ?

Business Operator ?

Study Internal Reference ID (max 250 characters)

? Save

- 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. ? icon displays help text for that field.

Click this button to create the study notification record.

### 3.2.4 Study creation as Laboratory (from *notification of studies database*) – Account type: Applicant and Laboratory

The screenshot shows a web interface for creating a study. At the top, a status bar indicates the current stage: **Draft** (highlighted in blue), **Notified**, and **Co-Notified**. A callout box on the right states: "The status bar shows the record progress."

Below the status bar, the study is identified as "Study as Lab" with EFSA ID "EFSA-2023-00001729". The status is "Draft" and "Study Withdrawn" is unchecked. A callout box notes: "User can use these **buttons** to edit and get a printable view of the study." The **Edit** and **Printable View** buttons are highlighted in red. A **Select operation** button is also visible.

The main form area includes fields for "Study Title" (Study as Lab), "Study Starting Date", "Study Planned Completion Date", "Submitted to Internal Testing Facility" (unchecked), and "Justification for Delayed Notification". A section for "Business Operator & Laboratory Details" is expanded, showing "Business Operator" (Pharma SPA) and "Laboratory Email". A callout box points to this section: "When the user select 'Notify the study as a laboratory', the Laboratory fields will be filled in with information of the user's organisation."

On the right, the "Study Status Tracker" provides instructions: "This Study has been saved as a **draft**. When ready, please click on 'Select Operation' button and then **Notify** in the right-hand corner." It lists required fields for notification: "Main section: Study Title - Study Starting Date - Study Planned Completion Date" and "Study Scope section: Study Type - Food Domain - Authorisation Type - Application Type - Study International Standard Certification - Study Objective - Study Test Item - Components (where applicable)". A note states: "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." Below this, a callout box says: "You can access the list of all available Study Types and Guidelines" with links for "All Study Types" and "All Study Guidelines". A separate callout box notes: "Related lists: shows related records."

At the bottom right, a "Test Item: Components (0)" section is highlighted in red, showing a refresh icon. Below it are sections for "Pre-Application ID(s) (0)" and "Share With (1)".

### 3.3 Study creation – Account type: Laboratory only

Users qualified as Laboratory only, manage study notifications from the notification of studies database section available from the pre-submission activities main page.

efsa CONNECT Home Consultations Ask a question More

## Pre-submission activities

**New!**

**Notification of studies database**

Click this button to access the notification of studies database.

Welcome John!

In this section you can manage study notifications related to studies commissioned to your organisation. You can access the list of study notifications requiring a co-notification by your organisation or directly notified by your organisation, and you can also notify a new study.

## Notification of studies database

**Updated!**

Pre-submission activities / Notification of studies database

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.

**New study**

**In draft** Notified To correct Co-Notifier Wrong Co-Notifier To Co-Notify Co-Notified Co-Notified by me Withdrawn Shared with On behalf of

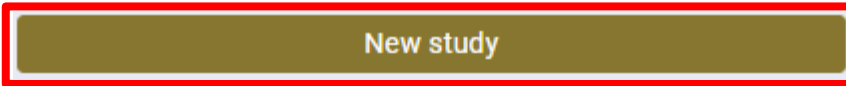
**New!**

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.

From every page, users can identify where they are within the portal through this bar.

## 3.3 Study creation – Account type: Laboratory only

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



Pre-submission activities / Notification of studies database / New study

### 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 ?

Study Title - English Name ?

\* Laboratory ?

Business Operator ?

Study Internal Reference ID (max 250 characters)

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

Click this button to create the study notification record.

- 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.



# 3.3 Study creation – Account type: Laboratory only

**Draft**      Notified      Co-Notified

Study as Lab      **Edit**      **Printable View**      **Select operation**

EFSA Study Identification: EFSA-2023-00001729      Status: Draft      Study Withdrawn

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

**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 (0)**  
**Pre-Application ID(s) (0)**  
**Share With (1)**

**Related lists: shows related records.**

**Business Operator & Laboratory Details**  
Business Operator:      Laboratory: **Pharma SPA**  
Business Operator Email:      Laboratory Email: **admin.efsa@atlantic-technologies.com**

**The user sees the business operator and laboratory information under the dedicated section.**

The status bar shows the record progress.

Related lists: shows related records.

# 3.4 Study notification form - all account types: 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 R

> Study Notification Details

> Intended Study ID (if applicable)

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

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

Details **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

## 3.5 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 titled 'Edit' and contains the following fields: 'Study Title' (Study XYZ), 'Study Title - English Name' (Study XYZ), 'Laboratory' (Pharma SPA), 'Study Starting Date', and 'Study Planned Completion Date'. The right form is also titled 'Edit' and contains: 'Study Title' (Study FGH), 'Study Title - English Name' (Study FGH), 'Business Operator' (Consultancy Spa), 'Study Starting Date', and 'Study Planned Completion Date'. A red box highlights the 'Laboratory' field in the left form and the 'Business Operator' field in the right form. Arrows from these boxes point to a central text box at the top.

Edit view if the notifier is a business operator.

Edit view if the notifier is a laboratory.

## 3.5 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.

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

Edit

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

\* Study Title

Study XYZ

Study Title - English Name ⓘ

Study XYZ

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.

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.

Click **Next** to save the changes.

## 3.5.1 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

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

Show All Results for "tox"

- Toxicity To Aquatic Invertebrates
- Toxigenicity And Pathogenicity
- Toxicity To Sediment Dwelling Orga...
- Extended One-Generation Reproduct...
- Fish Early Life Stage Toxicity Tes

Study Type

tox

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

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.

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

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

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
- Allergenicity

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.

## 3.6 Actions on a draft notification

Select operation

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

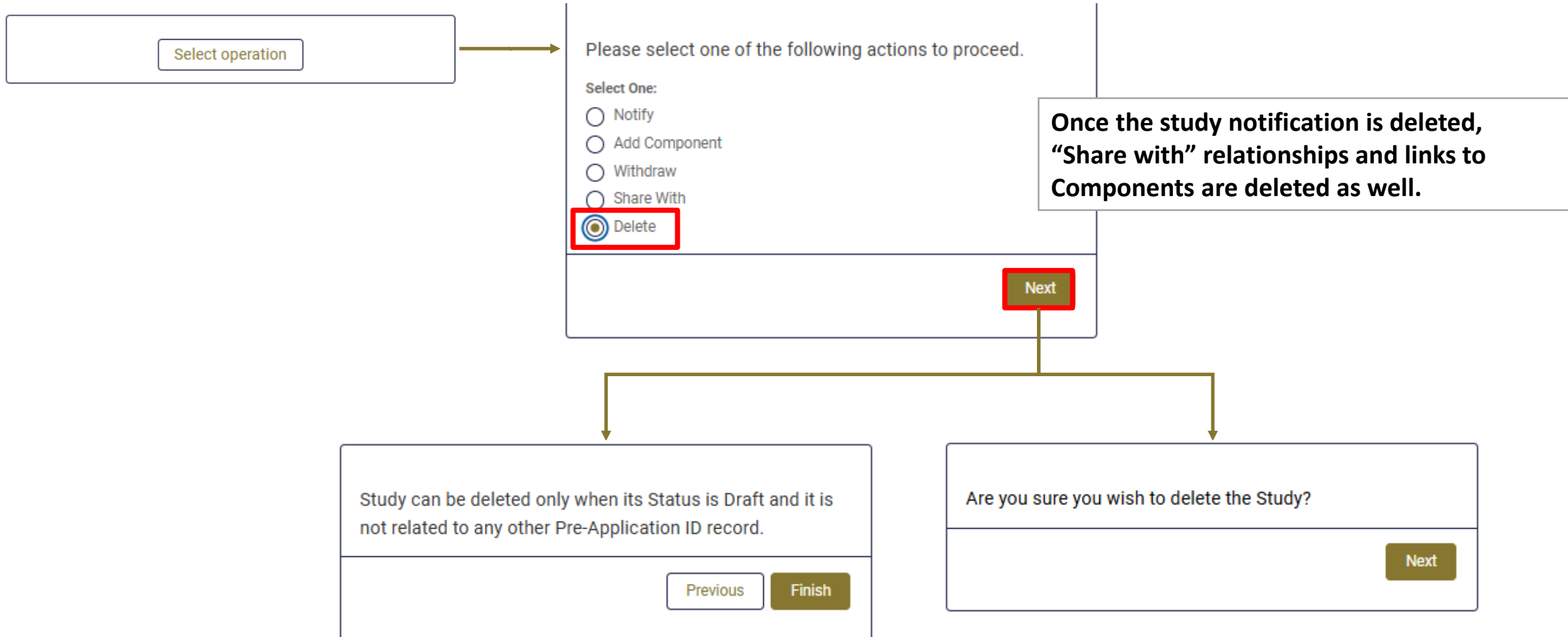
Next

1. **Notify** the study to EFSA indicating the co-notifier, i.e. a Business Operator or a Laboratory
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.

## 3.6.1 Delete a study notification

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**.



# Components

#Connect.EFSA





# 3.7 Component management - Add a component

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

Select operation

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

Check "Add Component" and click **Next**.

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

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.

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 ..."**.

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.

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

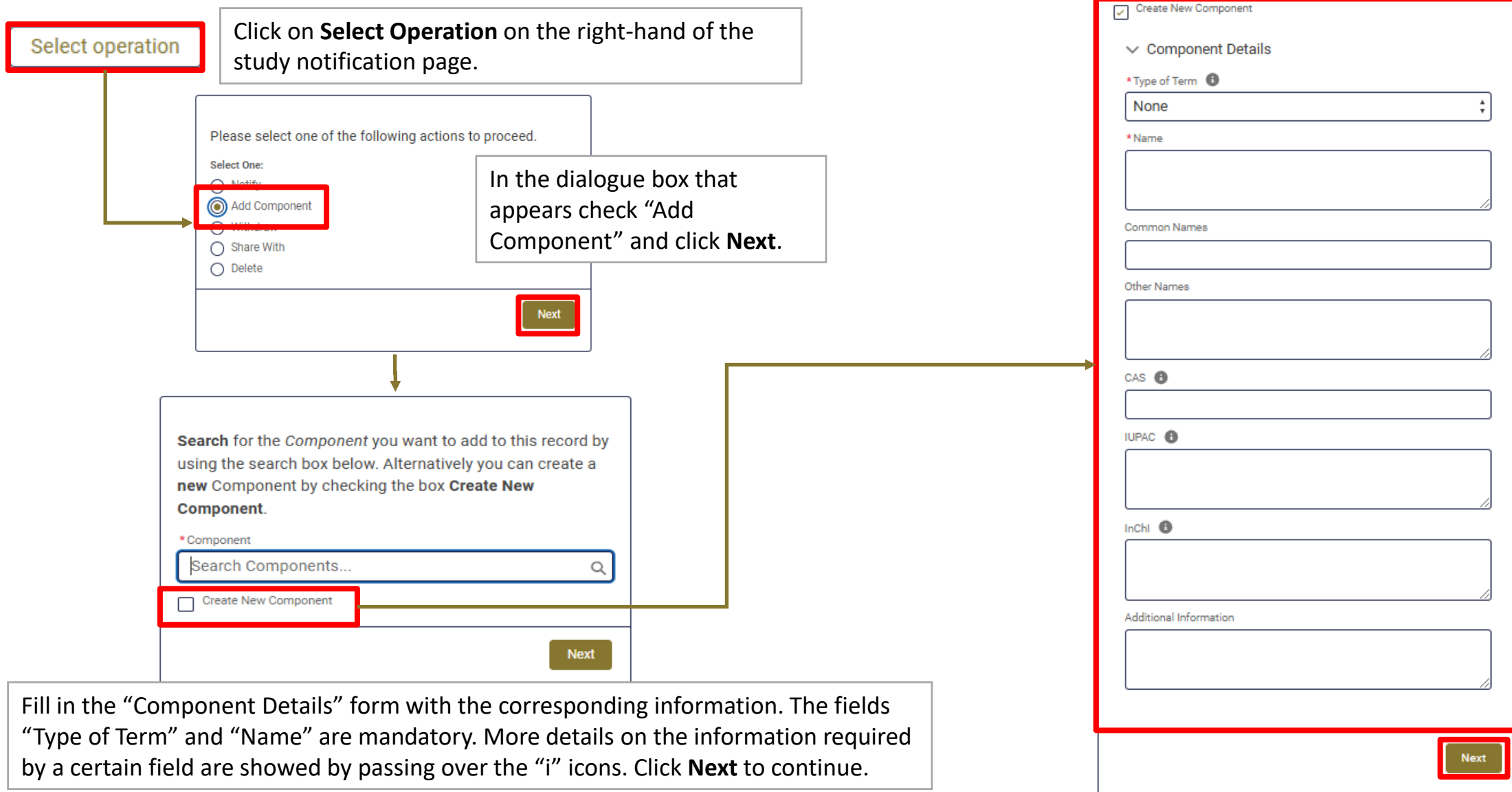
Baci

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** RT1477  
RF-00012001-PAR
- Bacillus thuringiensis**  
RF-00012002-PAR

# 3.7.1 Component management - Create component

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.



## 3.7.2 Component management - Related list “Test Item: Components”

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.

# 3.7.3 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**

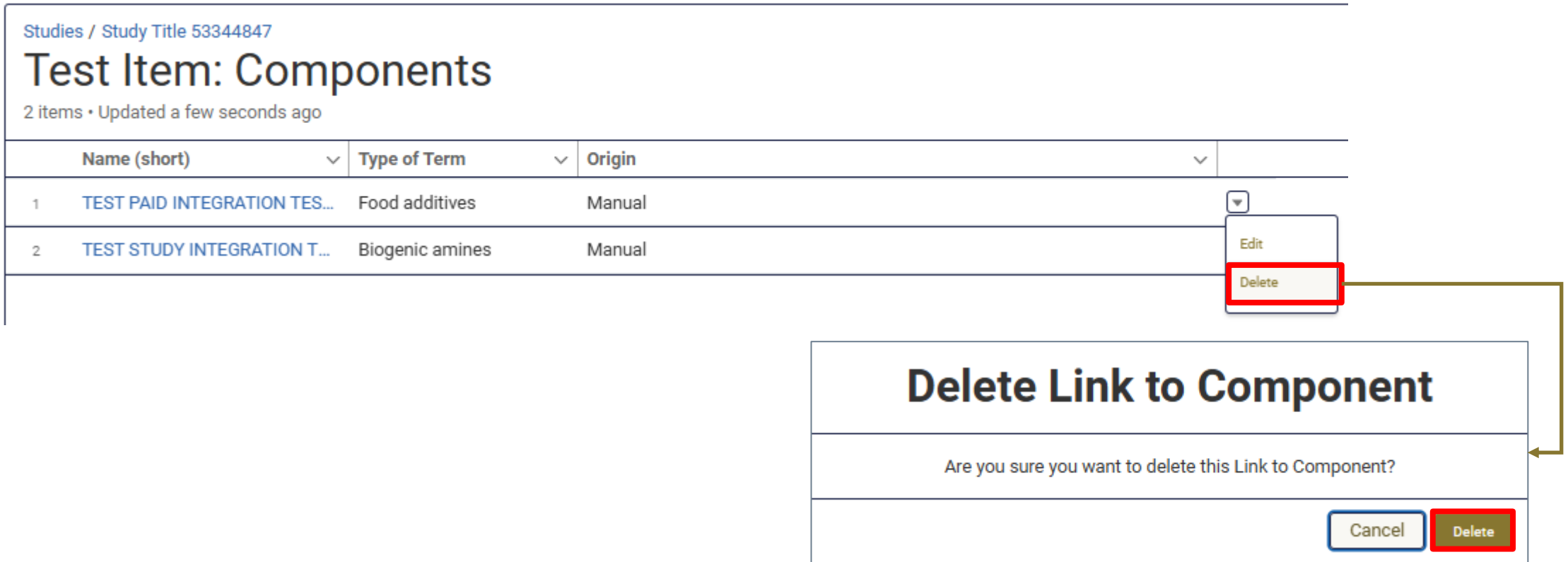
*This box displays (in read-only mode) previously recorded information from "Other Components" field, which has been discontinued. Any new entry should be recorded within "Test Item: Components" related list, via "Add Component" action under "Select Operation".*

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.

## 3.7.4 Component management - Delete link to components

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 says "Studies / Study Title 53344847" and "Test Item: Components" with "2 items • Updated a few seconds ago". Below this is a table with columns: "Name (short)", "Type of Term", and "Origin".

	Name (short)	Type of Term	Origin	
1	TEST PAID INTEGRATION TES...	Food additives	Manual	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
2	TEST STUDY INTEGRATION T...	Biogenic amines	Manual	

A confirmation dialog box is open, titled "Delete Link to Component". It asks "Are you sure you want to delete this Link to Component?" and has "Cancel" and "Delete" buttons. A red box highlights the "Delete" button in the dialog, and a red box highlights the "Delete" button in the table. A line connects the two boxes.

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

# 3.7.5 Component management - View Components

All Components created by the user are listed under the tab “**Components**” in the pre-application ID main page, and in the “My profile” page under “your organization information” section.

Pre-submission activities / Pre-application ID

In this page you can see the details of your pre-application ID, its related records and 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 all the pre-submission advice, i.e requests for general pre-submission advice and pre-
- 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   Pre-submission advice   Intended studies   List of Intended Studies   **Components**

My Components ▾

36 items • Sorted by Created Date • Filtered by All components - CreatedByMyAccount

	Name (short) ▾	Type of Term ▾	Common Names
1	test 12/09	Biogenic amines	
2	Bacillus RRR	Microorganisms	

**Updated!**

## Your organisation information

Account  
ABC Company

[+ Follow](#)   [New Contact](#)   [Manage Relationship](#)

English Name: ABC Company   Parent Account: [Luce Entertainment](#)

Related **My components**

**My Components** ▾

37 items • Sorted by Created Date • Filtered by All components - CreatedByMyAccount

	Name (s... ▾	Type of T... ▾	Common... ▾	Other Na... ▾	Create... ↓ ▾
1	Lactobacillu...	Microorgani...			07/06/2024... ▾

## 3.7.6 Component management - Details Page

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.

Component  
Bacillus RRR

Printable View Delete

Term Code Term Status Term Valid From  
Submitted

Information

Name  
Bacillus RRR

Common Names

CAS

EC Number

Molecular Formula

Zoo Label

InChi

Name (short)  
Bacillus RRR

Additional Information

Additional Information

Type of Term  
Microorganisms

Other Names

IUPAC

Flavis Number

Smiles Notation

Level of Details

Component History (1)

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

View All

PAIDs with this component (1)

ID	Request Name
EFSA-ID-2023-000914	Renewal application TJP

View All

Studies with this component (1)

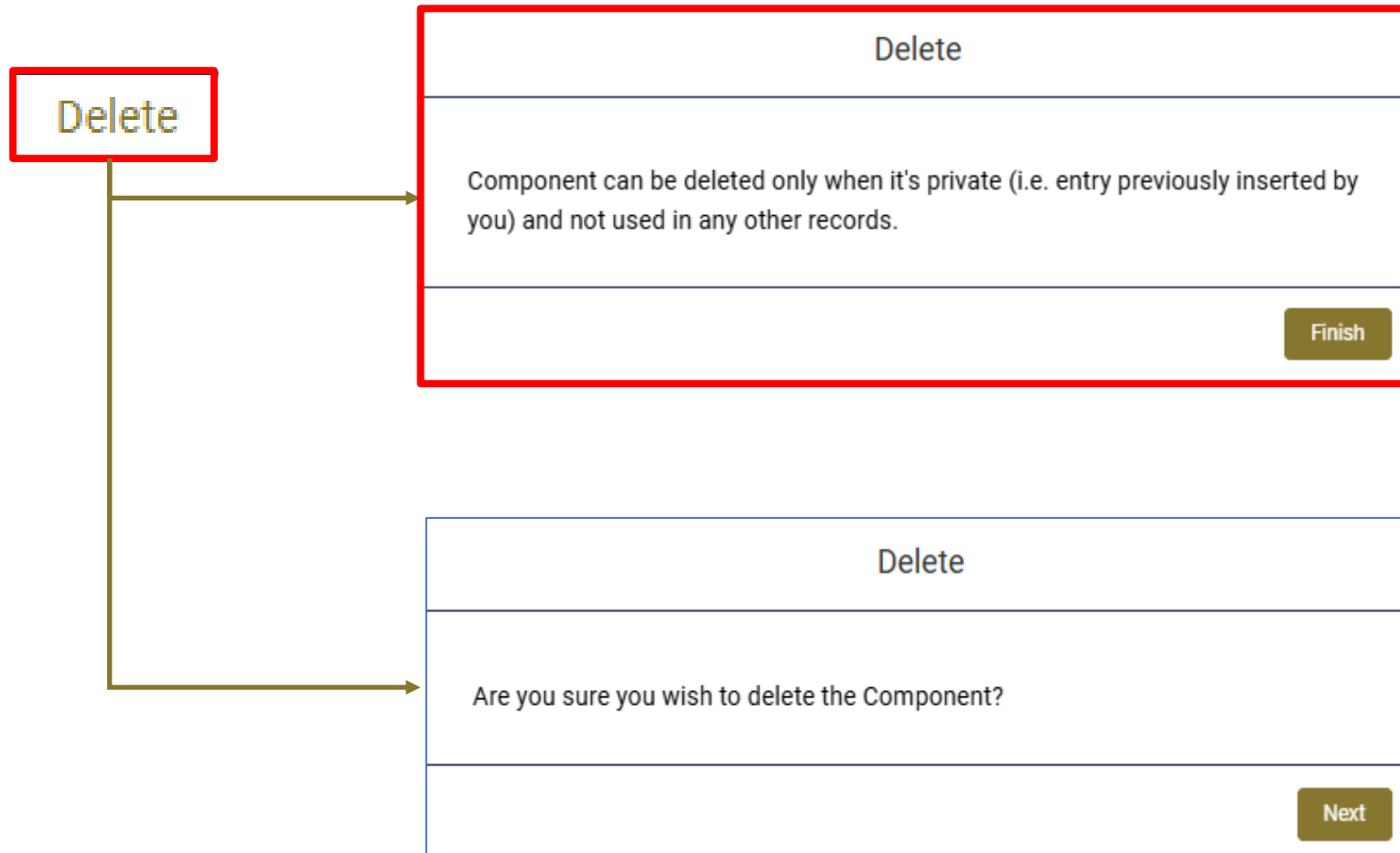
Study
Study RRR

View All

**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.

## 3.7.7 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, studies records).

To delete the component, the user must firstly remove all the existing links with the other records.



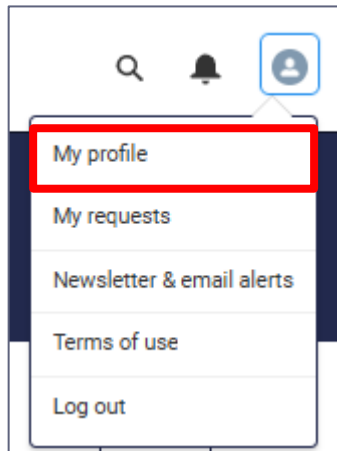
# Account relationships and sharing functions



## 3.8 Account relationship

Updated!

When a **business operator** or a **laboratory** wants to commission a third party/consultant to work on its behalf, the following relationship must be established at the account level from the **My profile** page under “**Your organization information**” section.



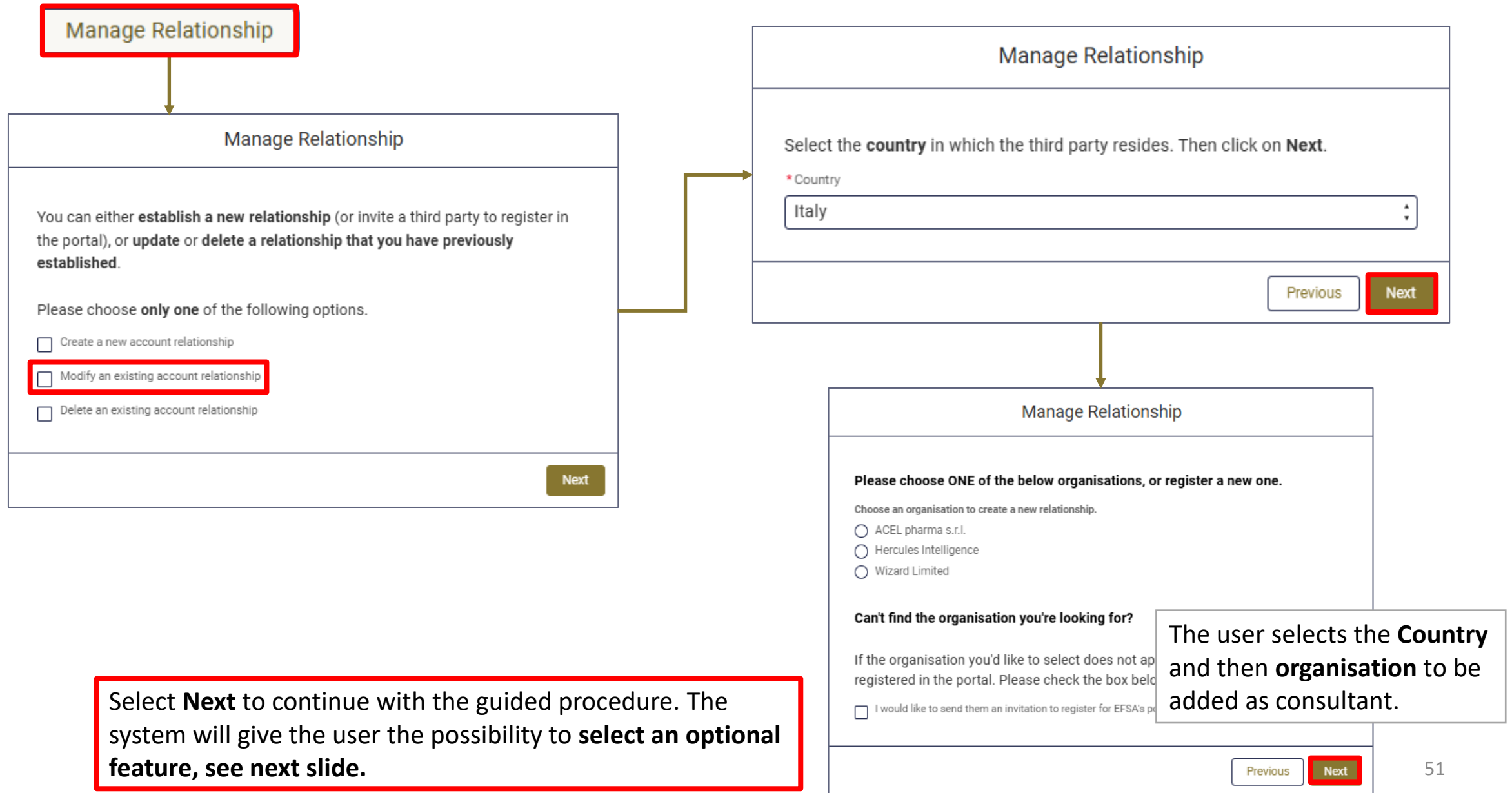
The main screenshot shows the 'Your organisation information' section. At the top, there's a header 'Your organisation information' (highlighted with a red box) and an 'Updated!' callout. Below it, the account details for 'ABC Company' are shown, including its English Name and Parent Account 'Luce Entertainment'. On the right, there are three buttons: '+ Follow', 'New Contact', and 'Manage Relationship' (highlighted with a red box). A text box explains that the 'Manage Relationship' button is used to create, modify, or delete relationships. Below this, the 'Related' tab (highlighted with a red box) is active, showing 'My components'. Under this tab, there are two sections: 'Contacts (6+)' which contains a table with columns 'Contact Name', 'Email', and 'Qualifications'; and 'Account Relationships' which has two sub-sections: 'Account Relationships: Account To (0)' and 'Account Relationships: Account From (0)'. A text box explains that 'Account To' is a list of organizations working on behalf of the user, and 'Account From' is a list of organizations the user is working on behalf of.

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

Under **Related** tab, the user can find the lists showing 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.

## 3.8.1 Create an account relationship



## 3.8.1 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 account relationship\(s\)](#) to know more details).

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

**Left Screenshot:** The form asks the user to "Please choose ONE of the below organisations, or register a new one." It lists three options: ACEL pharma s.r.l., Hercules Intelligence, and Wizard Limited (selected). Below this, it asks "Can't find the organisation you're looking for?" and provides an option to "I would like to send them an invitation to register for EFSA's portal." A "Next" button is highlighted in red.

**Right Screenshot:** This screen is reached after clicking "Next". It contains a red-bordered box with the following text: "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." Below this, there is a checkbox labeled "I want to enable this organisation to act as notifier and co-notifier." and a "Next" button highlighted in red.

A callout box at the bottom explains: "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.

## 3.8.1 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

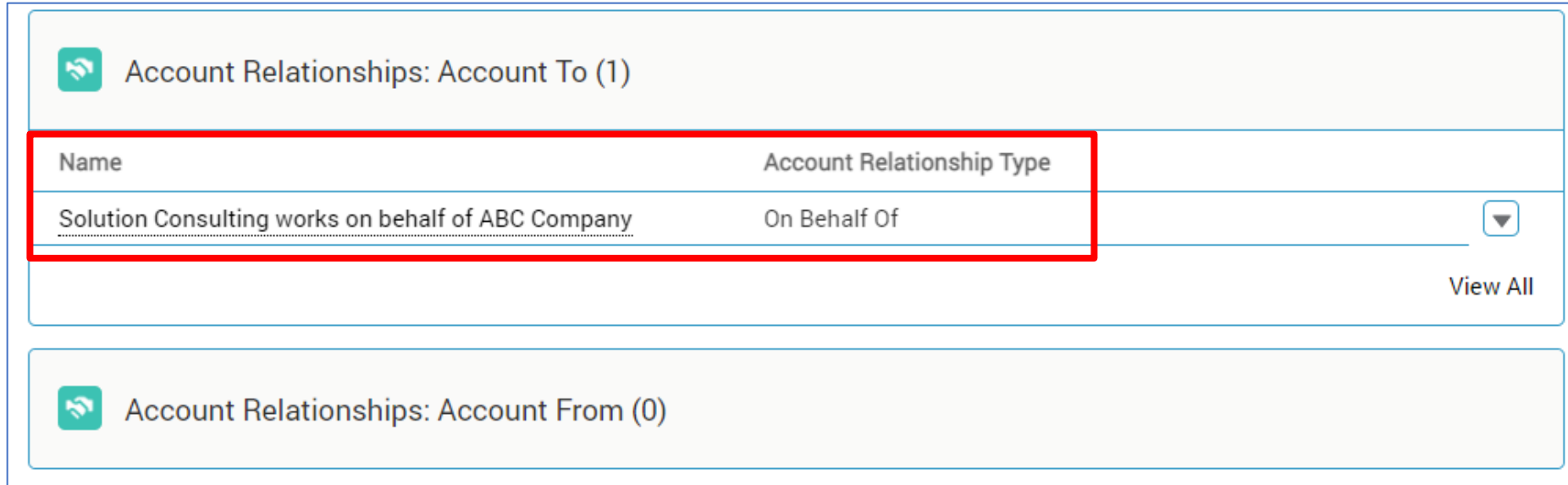
### How it works:

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 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.

## 3.8.2 Manage account relationship(s)

Created relationship will appear in the related list **Account Relationships: Account To** as shown below.



The screenshot shows a user interface for managing account relationships. It features two main sections: 'Account Relationships: Account To (1)' and 'Account Relationships: Account From (0)'. The 'Account To' section contains a table with two columns: 'Name' and 'Account Relationship Type'. A red box highlights the first row of this table, which contains the text 'Solution Consulting works on behalf of ABC Company' under the 'Name' column and 'On Behalf Of' under the 'Account Relationship Type' column. To the right of the table is a dropdown arrow icon and a 'View All' link. The 'Account From' section is currently empty.

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

View All

Once relationship has been established at the account level:

1. The business operator can **share single records** with its third party/consultant (to know more see [Share a study "On behalf of"](#))
2. The third party/consultant can create pre-application IDs and perform all associated actions for the business operator.

## 3.8.2 Manage account relationship(s)

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](#)

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.

### 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

John Smith

Email

you@example.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](#)

### 3.8.3 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**

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

**Manage Relationship**

\* Choose an existing account relationship to edit.

- Consultancy Spa works on behalf of ABC Company Spa
- GiveAdvice works on behalf of ABC Company Spa
- ACEL pharma s.r.l. works on behalf of ABC Company Spa
- Solution Consulting works on behalf of ABC Company Spa**
- Business & Business works on behalf of ABC Company Spa
- Pharma SPA works on behalf of ABC Company Spa
- Honeyindustries works on behalf of ABC Company

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

**Previous** **Next**

Select the third party organisation name and click on **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**

**Previous** **Next**



## 3.8.4 Delete an 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.

- GiveAdvice works on behalf of ABC Company Spa
- ACEL pharma s.r.l. works on behalf of ABC Company Spa
- Solution Consulting works on behalf of ABC Company Spa
- Business & Business works on behalf of ABC Company Spa
- Pharma SPA works on behalf of ABC Company Spa
- Honeyindustries works on behalf of ABC Company
- Whirlwind Industries 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**

## 3.9 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
- Add Component
- Withdraw
- Share With
- Delete

Next

## 3.9.1 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 profile** 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

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

Previous Next

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

Share With (2)

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

View All

## 3.9.1 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 profile** 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 '**Shared 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 profile** in the navigation menu, click the button **Manage Relationship** and follow the instruction.

Finish

## 3.9.1 Share study “On behalf of”

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

### Notification of studies database

[Pre-submission activities](#) / Notification of studies database

From this page, you can create a new study notification. Once you have created your new study, you can continue to edit it until you are ready to notify it to EFSA. Upon the notification, the indicated co-notifier will receive an email alert.

Create a new study (applicant)

Create a new study (laboratory)

**In draft**   Notified   To correct co-notifier   Wrong co-notifier   To co-notify   Co-notified   Co-notified by me   Withdrawn   Shared with   **On behalf of**

 My Drafts ▾

50+ items • Sorted by EFSA Study Identification • Filtered by All studies - Status, Study Withdrawn, UserAccountId

🔍 Search this list...

	EFSA Study Identification ↑	Study Title (Short)	Business Operator	Created Date	Last Modified Date	
1	EFSA-2021-00000625	Study Title 53901459	ABC Company	22/06/2021 15.38	11/06/2024 17.49	⌵

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”).

## 3.9.2 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 profile** 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

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

Previous Next

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

Share With (1)	
Account Name	Relationship Type
Pharma SPA	Shared With

View All

## 3.9.2 Share study “Shared with”

### Notification of studies database


Pre-submission activities / Notification of studies database

From this page, you can create a new study notification. Once you have created your new study, you can continue to edit it until you are ready to notify it to EFSA. Upon the notification, the indicated co-notifier will receive an email alert.

Create a new study (applicant)

Create a new study (laboratory)

**In draft**   Notified   To correct co-notifier   Wrong co-notifier   To co-notify   Co-notified   Co-notified by me   Withdrawn → **Shared with**   On behalf of

 My Drafts ▾

50+ items • Sorted by EFSA Study Identification • Filtered by All studies - Status, Study Withdrawn, UserAccountId

🔍 Search this list...

	EFSA Study Identification ↑	Study Title (Short)	Business Operator	Created Date	Last Modified Date	
1	EFSA-2021-00000625	Study Title 53901459	ABC Company	22/06/2021 15.38	11/06/2024 17.49	▾

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.

### 3.9.3 Delete “Shared 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.

Share With (2)	
Account Name	Relationship Type
<a href="#">Pearl Lightning</a>	Shared With
<a href="#">Luckystones_test</a>	Shared With

▼

Edit

Delete

### 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.

Share With (0)	
----------------	--

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



## 3.10 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 test RTYU' (ID: EFSA-ID-2024-000952). The interface includes a 'Details' tab and a 'History' tab. The 'Details' section shows various fields such as Request Name, Business Operator, Subject Of The Application, and Food Domain. A 'Pre-Application Operations' section provides instructions on how to manage studies and components. Below this, there are sections for 'Subject of the Application: Components (0)' and 'Study Notification (1)'. The 'Study Notification' table shows a single entry with the status 'Draft'. A callout box points to the 'Delete' option in the table's context menu. Another callout box shows a confirmation dialog titled 'Delete Link to Study' with a 'Delete' button highlighted in red.

**Pre-Application ID**  
Renewal test RTYU

ID  
EFSA-ID-2024-000952

**Details** History

Request Name: Renewal test RTYU  
Business Operator: ABC Company  
Subject Of The Application: Renewal test RTYU  
Former Application ID: 555555  
Note

ID: EFSA-ID-2024-000952  
Contact Nar: Betty Cook  
Food Domain: GMO  
Authorisation Type: Food and Feed - Regulation (EC) No 1829/2003  
Application Type: Application for renewal of authorisation of genetically modified food and/or feed

**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)

Subject of the Application: Components (0)

Study Notification (1)

Study Ti...	EFSA Stu...	Status
<a href="#">Test for ...</a>	EFSA-202...	Draft

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 [Delete a study notification](#)).

**Delete Link to Study**

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

Cancel Delete

# 3.10 Delete a study from a pre-application ID

The screenshot shows the 'Pre-Application ID' interface for 'Renewal test RTYU'. At the top, there are buttons for 'Edit', 'New Study', and 'New List'. A green 'Add Component' button is also visible. The ID is 'EFSA-ID-2024-000952'. Below this, there are tabs for 'Details' and 'History'. The 'Details' section is expanded, showing fields for Request Name, Business Operator, Subject Of The Application, Former Application ID, Note, ID, Contact Name, Food Domain, Authorisation Type, and Application Type. To the right, the 'Pre-Application Operations' section lists instructions for using 'New Study', 'Add Studies', 'New List', 'Share With', 'Add Component', 'Ask GPSA', and 'Delete' buttons. Below this, there are sections for 'Subject of the Application: Components (0)' and 'Study Notification (1)'. The 'Study Notification' section contains a table with columns for 'Study Title', 'EFSA Study ID', 'Status', and 'Study ID'. A red box highlights a dropdown arrow in the 'Study ID' column, with a callout box pointing to it that says 'Click of the pointing down arrow and select **Delete**.' Below the table, a red box highlights the 'Delete' option in a dropdown menu.

Pre-Application ID  
Renewal test RTYU

ID  
EFSA-ID-2024-000952

Details History

Request Name: Renewal test RTYU

Business Operator: ABC Company

Subject Of The Application: Renewal test RTYU

Former Application ID: 555555

Note

ID: EFSA-ID-2024-000952

Contact Name: Betty Cook

Food Domain: GMO

Authorisation Type: Food and Feed - Regulation (EC) No 1829/2003

Application Type: Application for renewal of authorisation of genetically modified food and/or feed

**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)

Subject of the Application: Components (0)

Study Notification (1)

Study Ti...	EFSA Stu...	Status	Study
Study Tit...	EFSA-202...	Notified	

Click of the pointing down arrow and select **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

# Study notification and co-notification



# 3.11 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

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

**Edit**    Printable View

---

**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

**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.

### 3.11.1 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.**

**Edit**

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

\* Study Title  
study 456

Study Title - English Name ⓘ  
study 456

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

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

International Standard Certification ⓘ

\* Authorisation Type  
Feed Additives

**Study Design**

Study Guideline  
Other ×

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

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](#)

## 3.11.2 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

Search, Add Chart, Export

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)

Search, Add Chart, Export

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.

### 3.11.3 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 displays the EFSA study notification process. At the top, a progress bar shows 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 red-bordered button labeled "Select operation".

Metadata information includes: EFSA Study Identification (EFSA-2022-00001291), Status (Draft), and a "Study Withdrawn" checkbox.

A red-bordered box highlights the "Select operation" button, which leads to a selection menu. The menu asks the user to "Please select one of the following actions to proceed." and lists five options: **Notify** (selected with a radio button), Add Component, Withdraw, Share With, and Delete. A "Next" button is located at the bottom right of this menu.

Below the selection menu, a text box instructs the user: "Click **Next** to continue." A green arrow points from this instruction to the "Next" button in the selection menu.

On the left side, a text box provides instructions: "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." Below this text is a "Laboratory" search field containing "Pharma SPA" and a magnifying glass icon. A "Next" button is positioned below the search field.

A text box below the search field states: "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."

At the bottom right, another text box explains: "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." Below this text is a screenshot of the search field with "Ph" entered and a magnifying glass icon, with a "Show All Results for 'Ph'" button below it.

### 3.11.3 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 ⓘ

Pharma SPA X

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

example@email.com

\* Laboratory Email

example@email.com



### 3.11.3 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 screenshot displays the EFSA study notification interface. At the top, a notification box states: "Thank You! Your Study has been notified. Click on **Next** to view the changes you made on the Study page." with a "Next" button. Below this, a "Business Operator & Laboratory Details" section shows "Business Operator" as "ABC Company" and "Laboratory" as "Pharma Spa".

The main interface features a progress bar with three stages: "Draft", "Notified" (highlighted in blue), and "Co-Notified". The "Notified" stage is highlighted with a red border. Below the progress bar, the study details are shown:

- Study: Test selection laboratory
- EFSA Study Identification: EFSA-2021-00000625
- Status: Notified
- Study Withdrawn:

Buttons for "Edit", "Printable View", and "Select operation" are visible. A "Study Status Tracker" box contains the following text:

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: **2024-07-12**

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

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

Additional details include:

- Study Title: Test selection laboratory
- Study Title (English Name): Test selection laboratory
- Study Starting Date: 29/06/2024
- Study Planned Completion Date: 10/10/2030
- Submitted to Internal Testing Facility
- Justification for Delayed Notification

## 3.11.4 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**.

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

3

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

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

## 3.11.4 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.

Thank You! Your Study has been notified.  
Click on **Next** to view the changes you made on the Study page.

**Next**

Business operator information and laboratory details are automatically filled in.

Business Operator & Laboratory Details

Business Operator ⓘ  
ABC Company

Business Operator Email

Laboratory ⓘ

Laboratory Name ⓘ  
Laboratory XXX

Laboratory Email  
test@test.com

Country  
Italy

City  
Milan

Reference Person

Draft **Notified** Co-Notified

Study  
Test selection laboratory

Edit Printable View

Select operation

EFSA Study Identification  
EFSA-2021-00000625

Status  
Notified

Study Withdrawn

Details History

Study Title  
Test selection laboratory

Study Title (English Name) ⓘ

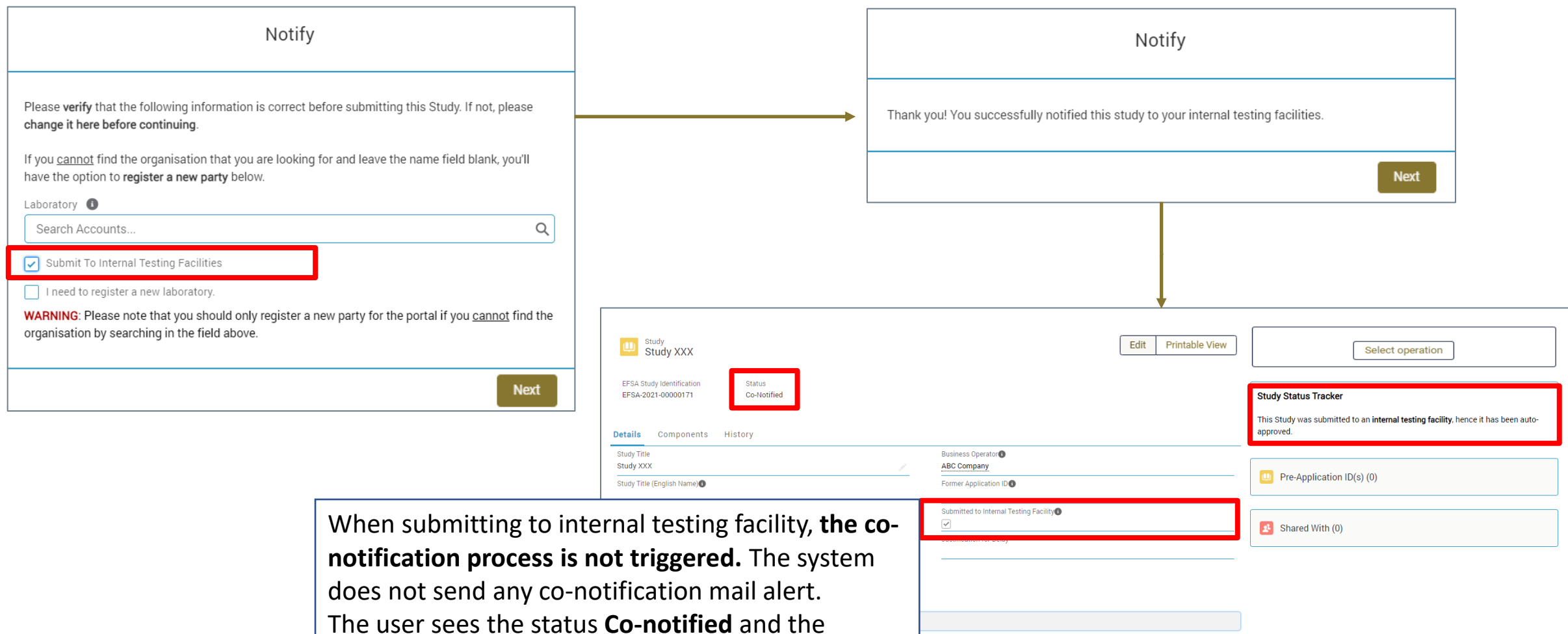
**Study Status Tracker**

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: **2024-07-12**

## 3.11.5 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”**.



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.

## 3.11.6 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.

## 3.12 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).

### Notification of studies database

Pre-submission activities / Notification of studies database

From this page, you can create a new study notification. Once you have created your new study, you can edit it until you are ready to notify it to EFSA. Upon the notification, the indicated co-notifier will receive an

In draft   Notified   To correct co-notifier   Wrong co-notifier   **To co-notify**   Co-notified

**To Co-Notify** ▼

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

	EFSA Study Identification ↑	Study Title (Short)	Business Operator
1	EFSA-2021-00000607	Study Title 35735593	Pearl Lightning

**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

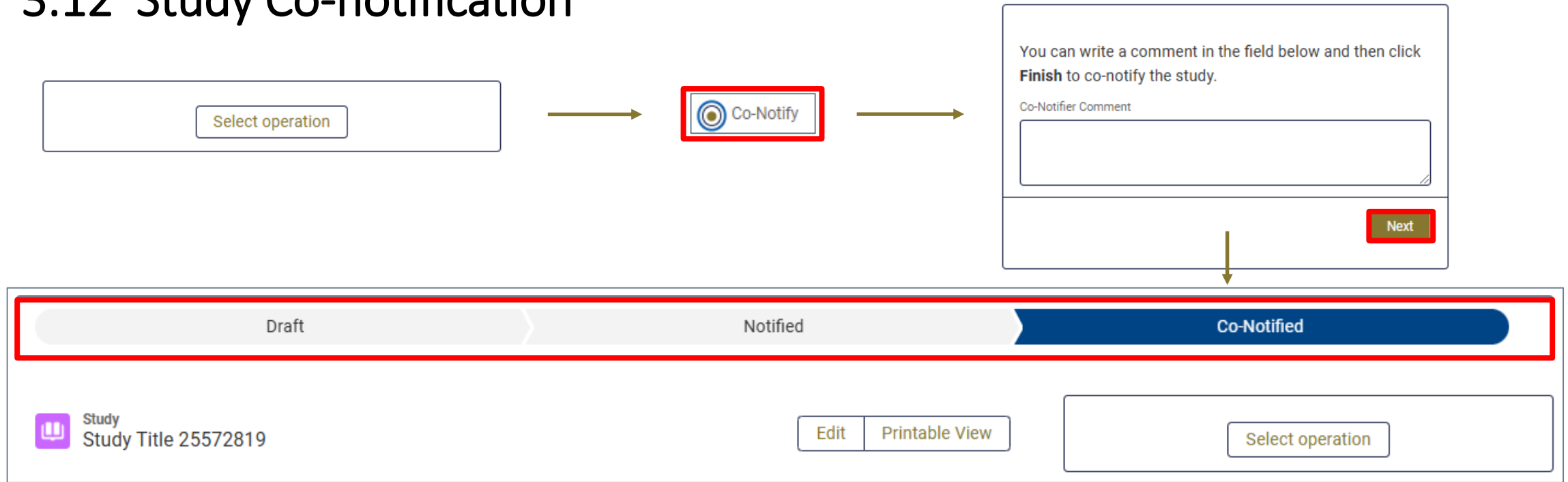
Wrong Co-Notifier

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.

## 3.12 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

## 3.12.1 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**.

Draft **Notified** Co-Notified

Study  
Study Title 95678232

EFSA Study Identification  
EFSA-2021-00000599

Status  
Notified

Study Withdrawn

Edit Printable View

Please select one of the following actions to proceed.

Select One:

Co-Notify

Wrong Co-Notifier

Manage Notification Alerts

Next

**Study Status Tracker**

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.

**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: **2022-09-02**

Details History

Study Title

Study Title (English Name) ⓘ

Study Starting Date

Study Planned Completion Date  
08/09/2022

Submitted to Internal Testing Facility ⓘ

Justification for Delayed Notification ⓘ

Business Operator & Laboratory Details

Business Operator ⓘ  
[ABC Company](#)

Laboratory ⓘ  
[Elecoms](#)

Business Operator Email  
[jasonwashington@sfdc.co.a0g1q000002lcjqaa2](mailto:jasonwashington@sfdc.co.a0g1q000002lcjqaa2)

Laboratory Email  
[frankgriffin@sfdc.co.a0g1q000002lcjqaa2](mailto:frankgriffin@sfdc.co.a0g1q000002lcjqaa2)

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



## 3.12.2 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
- Add Component
- Withdraw
- Share With
- Delete

Next

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

Next

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

More information in the next slide.

## 3.12.2 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.

### 3.12.3 Study Co-notification – “auto-notified” studies

#### Notification of studies database

Pre-submission activities / Notification of studies database

From this page, you can create a new study notification. Once you have created your new study, you can edit it until you are ready to notify it to EFSA. Upon the notification, the indicated co-notifier will receive an

In draft   Notified   To correct co-notifier   Wrong co-notifier   **To co-notify**   Co-notified

**To Co-Notify** ▼

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

	EFSA Study Identification ↑	Study Title (Short)	Business Operator
1	EFSA-2021-00000607	Study Title 35735593	Pearl Lightning

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 the notification of studies database section.

## 3.12.4 Study Co-notification – *Manage Study Notification*

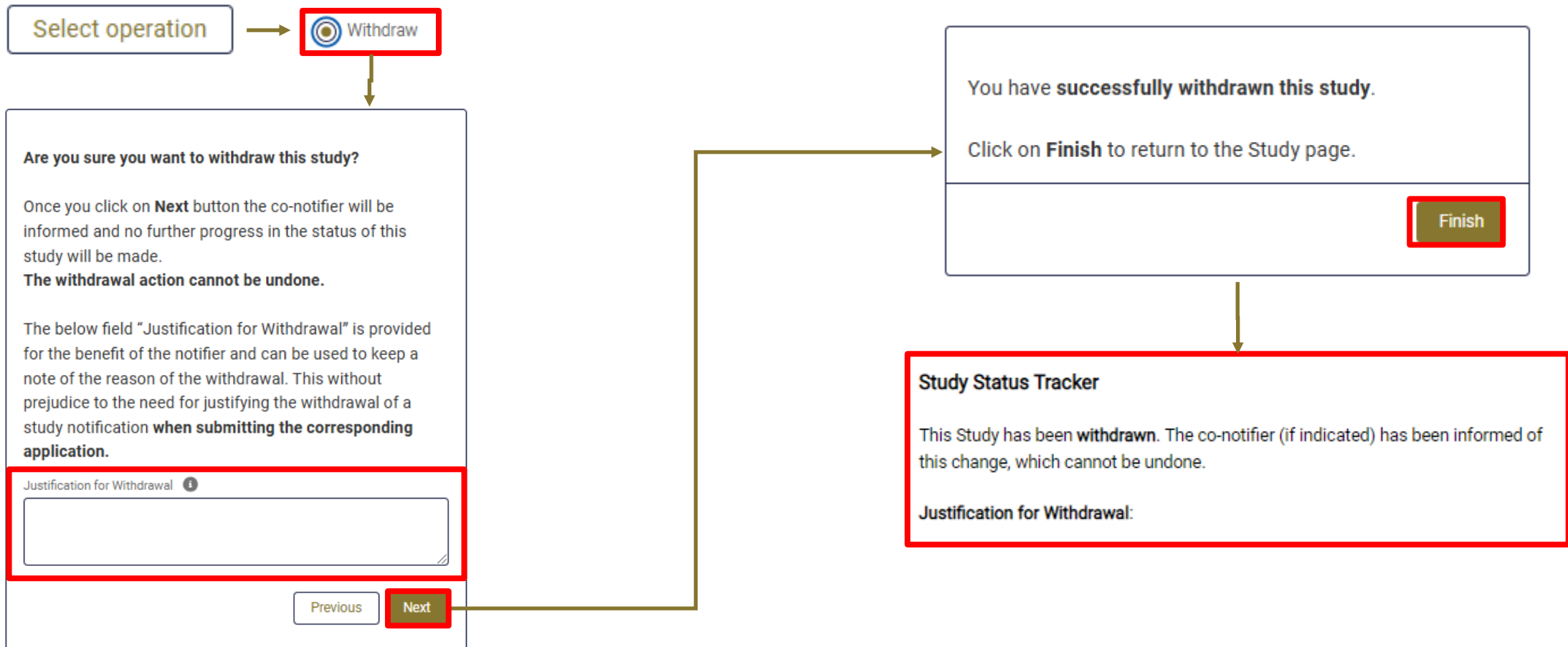
By default, the co-notifier receives an **email alert** every time the notifier edits the study notification record.  
To change this setting the co-notifier can click on the button **Select Operation** and then **Manage Study Notification** to deactivate them.



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

## 3.13 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.



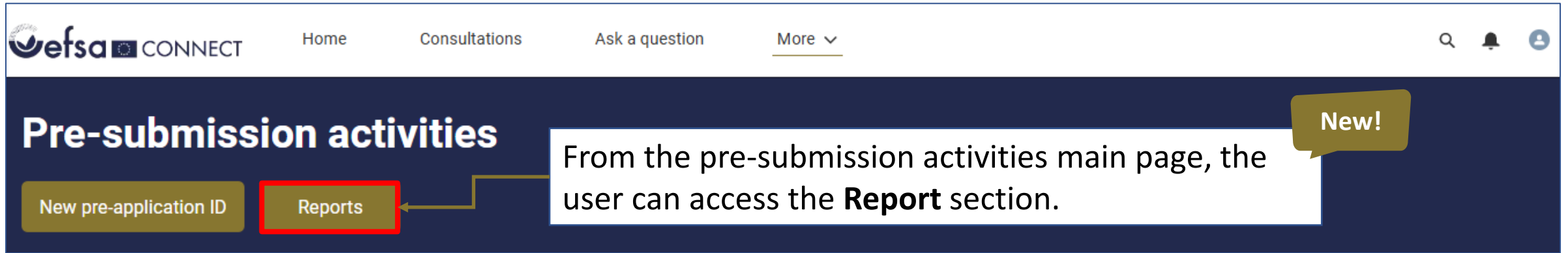
The field “Justification for Withdrawal” can be edited by clicking the “Edit” button also after the study is withdrawn.

# Reporting features

#Connect.EFSA



## 4. Reporting features



The screenshot shows the EFSA CONNECT portal interface. At the top, there is a navigation bar with the EFSA logo and 'CONNECT' text, followed by links for 'Home', 'Consultations', 'Ask a question', and 'More'. On the right side of the navigation bar are icons for search, notifications, and user profile. Below the navigation bar, the main content area is titled 'Pre-submission activities'. There are two buttons: 'New pre-application ID' and 'Reports'. The 'Reports' button is highlighted with a red border. A callout box with a 'New!' badge points to the 'Reports' button, containing the text: 'From the pre-submission activities main page, 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.

**Home / Reports**

**From every page, users can identify where they are within the portal through this bar.**

**New!**

**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	
<b>FOLDERS</b> 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	
All Folders Created by Me Shared with Me 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	
FAVORITES 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	
All Favorites					

**Click on the report name to access it.**

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

Search all reports...



## 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

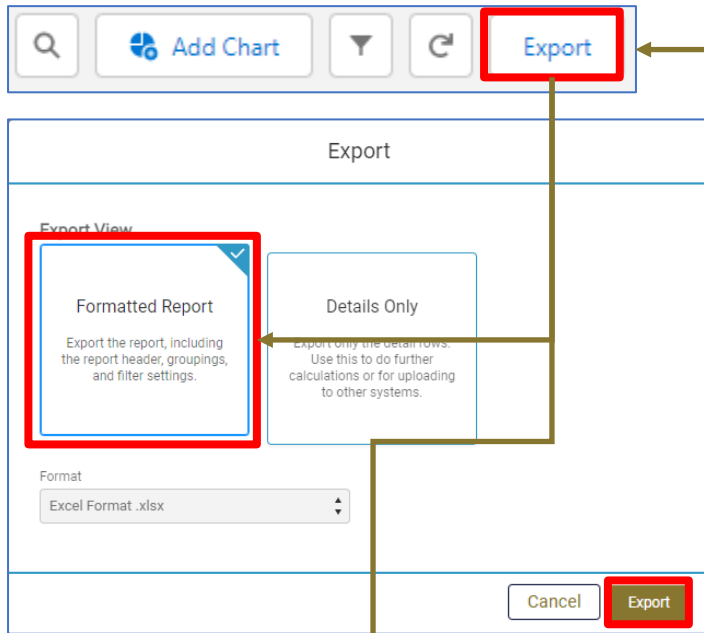
<input type="checkbox"/> List of Intended studies Id ↑	Request Name	Study Title	Study Title (English Name)	Study Objective	Test Item	Study Type	Study Guideline	Study
<input type="checkbox"/> LIST-01-2023-0476 (1)	Test member state AIR	giga	↑ Sort Ascending	ff	Renewal	Sediment toxicity	OECD Guideline 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-06-2022-0001 (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:

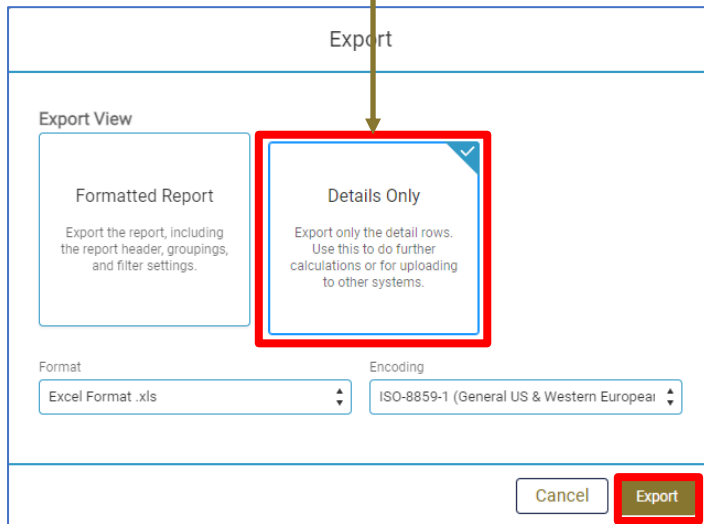
- **sort the values**
- **group/ungroup values**
- **remove columns**

# 4.4 Reporting features – Export a report



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

**Formatted Report**  
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.



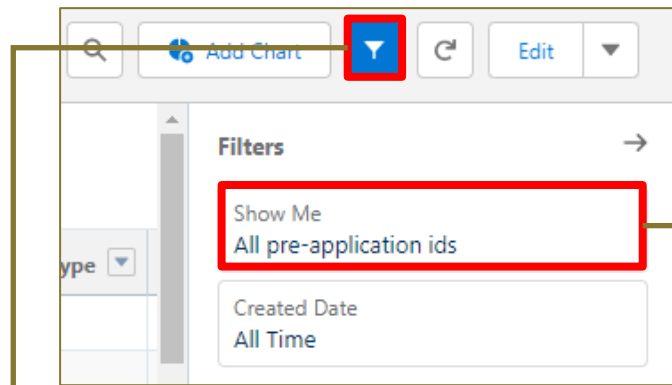
**Details Only**  
Reports can be exported as Excel or CSV file showing only the detail rows.

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

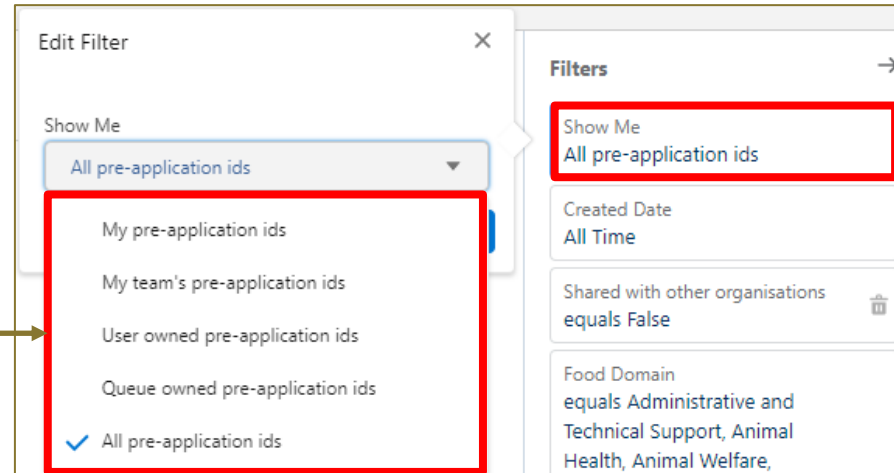
	A
1	<b>Study Title</b>
2	Draft study
3	test
4	rr
5	test
6	new study test shared with
7	test on behalf solution consulting
8	Study as Solution consulting

## 4.5 Reporting features – Filters functionality

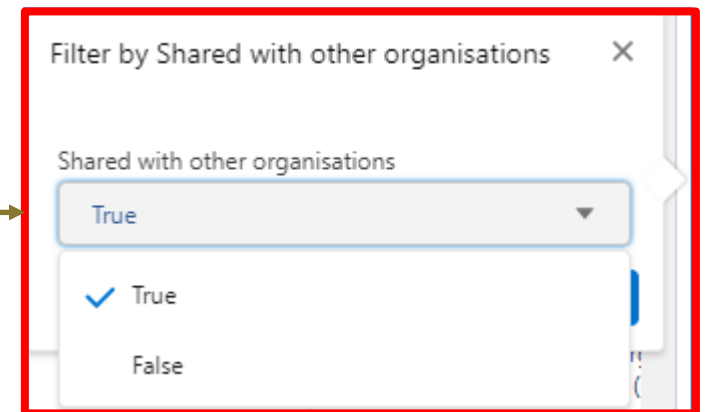
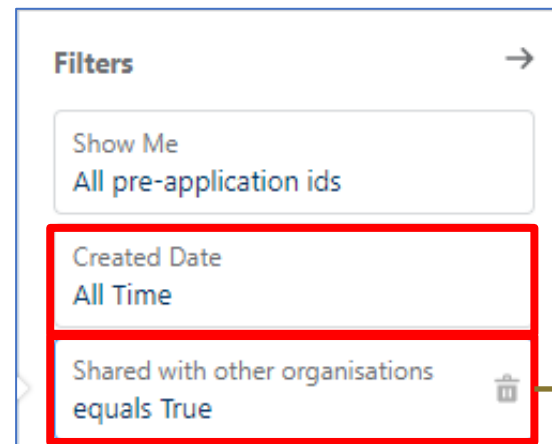
Depending on the type of data showed in the report, predefined filters are available. Once the user refreshes the page the default filtering rules set by EFSA will be restored.



Click on the Filters icon and select the filter to apply.



Some filters will allow to restrict the view to records on the basis of their **creation date**, while others allow to view only the records **shared with the user's organisation**.





## 5.6 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 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>

