User Guide

Pre-application ID

Last update: 14 September 2023

EUROPEAN FOOD SAFETY AUTHORITY

Note for the users

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

- When adding a new component to a pre-application ID, business operators and/or their consultants are prompted with a new and more visible button as well as an enhanced layout.
- Associated components are showed in the related list “Subject of the Application: Components” on the right-hand side of the pre-application ID page. For easier identification of listed components, additional fields (e.g. Name, Type of Term, Origin) have been added.
- The “Other components” field in the pre-application ID page has been discontinued. Previously recorded information has been moved to the “Note” field.
- A time-limited notification box on the Application page (for business operators and/or their consultants) or Studies page (for laboratories) has been be introduced. This allows to notify users about newly introduced functionalities.

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

Index

Index

Index

Introduction

#Connect.EFSA

I - Scope of the pre-application ID

Pre-submission activities

- ✓ General pre-submission advice, Article 32a(1) of the GFL
- ✓ Notification of studies commissioned or carried out to support an application, Article 32b of the GFL
- ✓ Notification of intended studies for renewal application and renewal pre-submission advice, Article 32c(1) of the GFL

! After registration and prior to initiating any pre-submission activity, a potential applicant must create a pre-application ID, which links all pre-submission activities undertaken by a potential applicant to support a future application related to a specific regulated product in a given regulated product area.

1. Actors of the Process

The process for managing the pre-application ID might involve up to **two types of actors**:

Business operators	(orange)
Third parties/consultants	(blue)

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

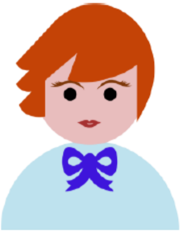
Business operators
Potential applicants

Business operators: these users create and manage their pre-application IDs in Connect.EFSA.

Third parties/ Consultants

Third parties/consultants: these users operate on behalf of business operators when authorised to represent one or more entities, shall also register-in (see the section on Account Relationship). They can create and manage pre-application IDs in Connect.EFSA.

1.1 Account qualification



Business operators
Potential applicants

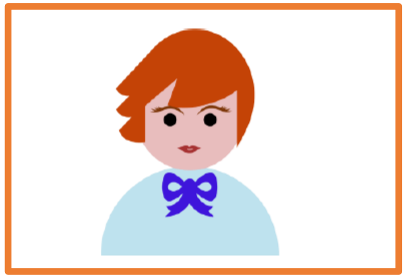
This guide applies to users qualified as applicant, i.e. organisations such as business operators. They act as potential applicant conducting pre-submission activities linked to a future application for a regulated product in a specific regulated area.

These organisations can create pre-application IDs.

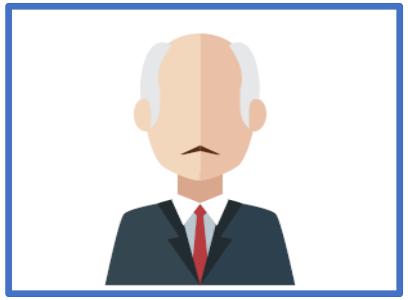
Third parties/
Consultants

The same qualification is assigned to consultants working on behalf of business operators.

1.2 Pre-application ID activities



Business operators
Potential applicants
Create and manage
pre-application IDs



Third parties/
Consultants
Can be authorised to manage
pre-application IDs

Add/create/delete study records

Add/create/delete component

Ask general pre-submission advice

Share/delete share with other business operators

1.3 List of intended studies for renewal: Process overview

Logging in

2. Log-in entry point

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

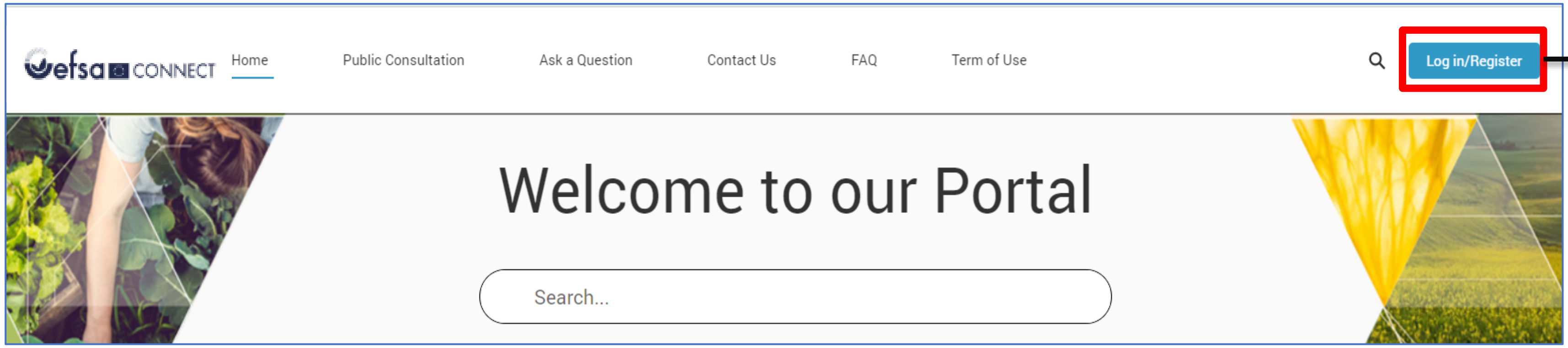
via the following link:

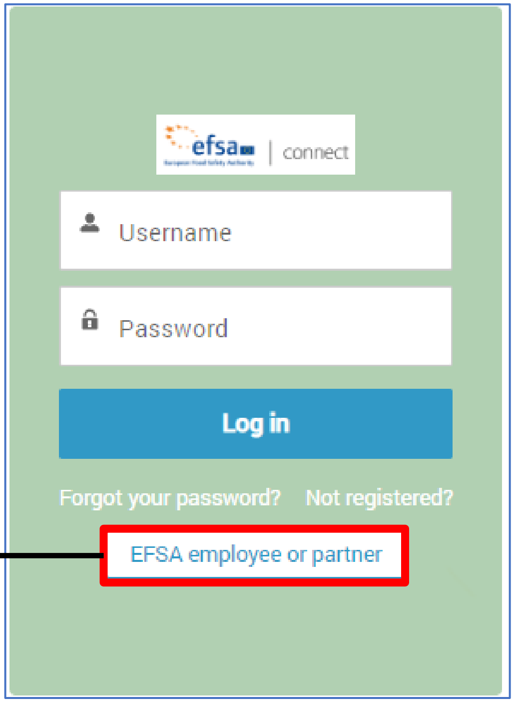
https://connect.efsa.europa.eu/RM

2.1 Users log in

To log into Connect.EFSA as Portal user:

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



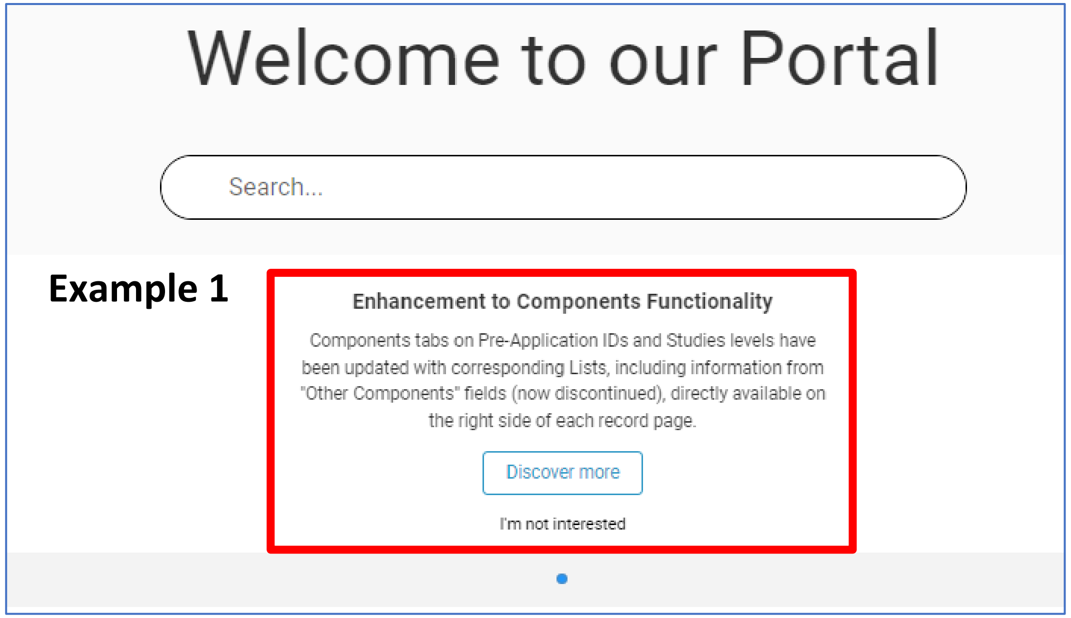


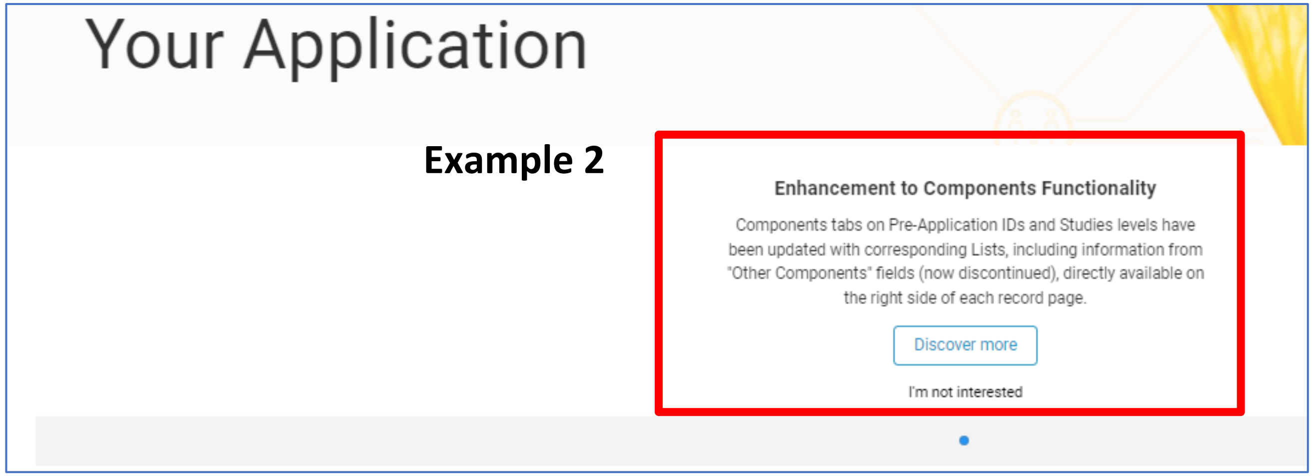
3. Click on this button to login. The system redirects the user to the **EFSA corporate login page where username and password will be requested.**

2.2 Time limited notification box

New!

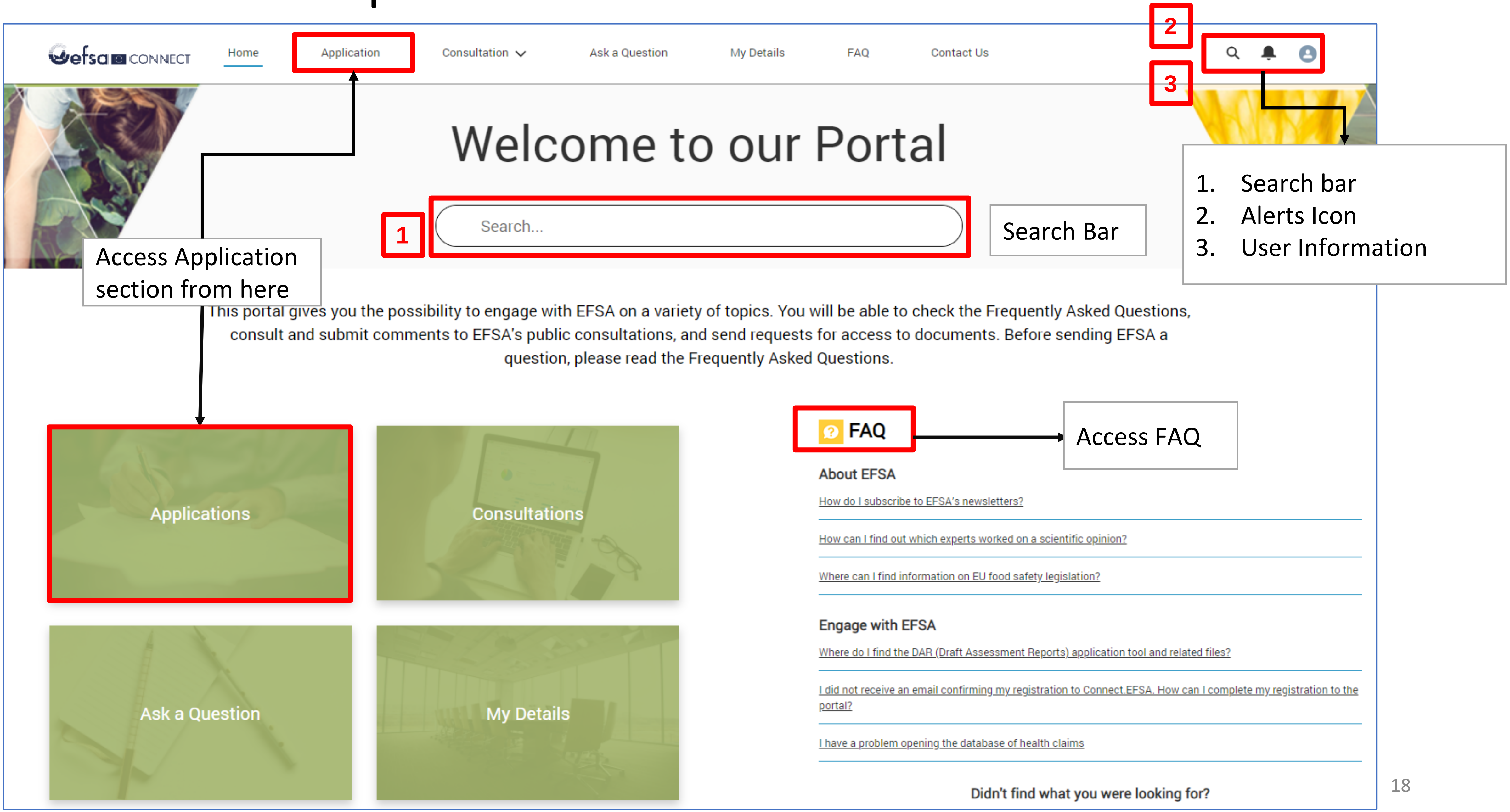
Users find information about newly introduced functionalities in the time limited notification boxes, which according to the relevance of the information for the various users (applicants or laboratories) may be showed in different pages of the Connect.EFSA portal. For instance, the main Portal page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



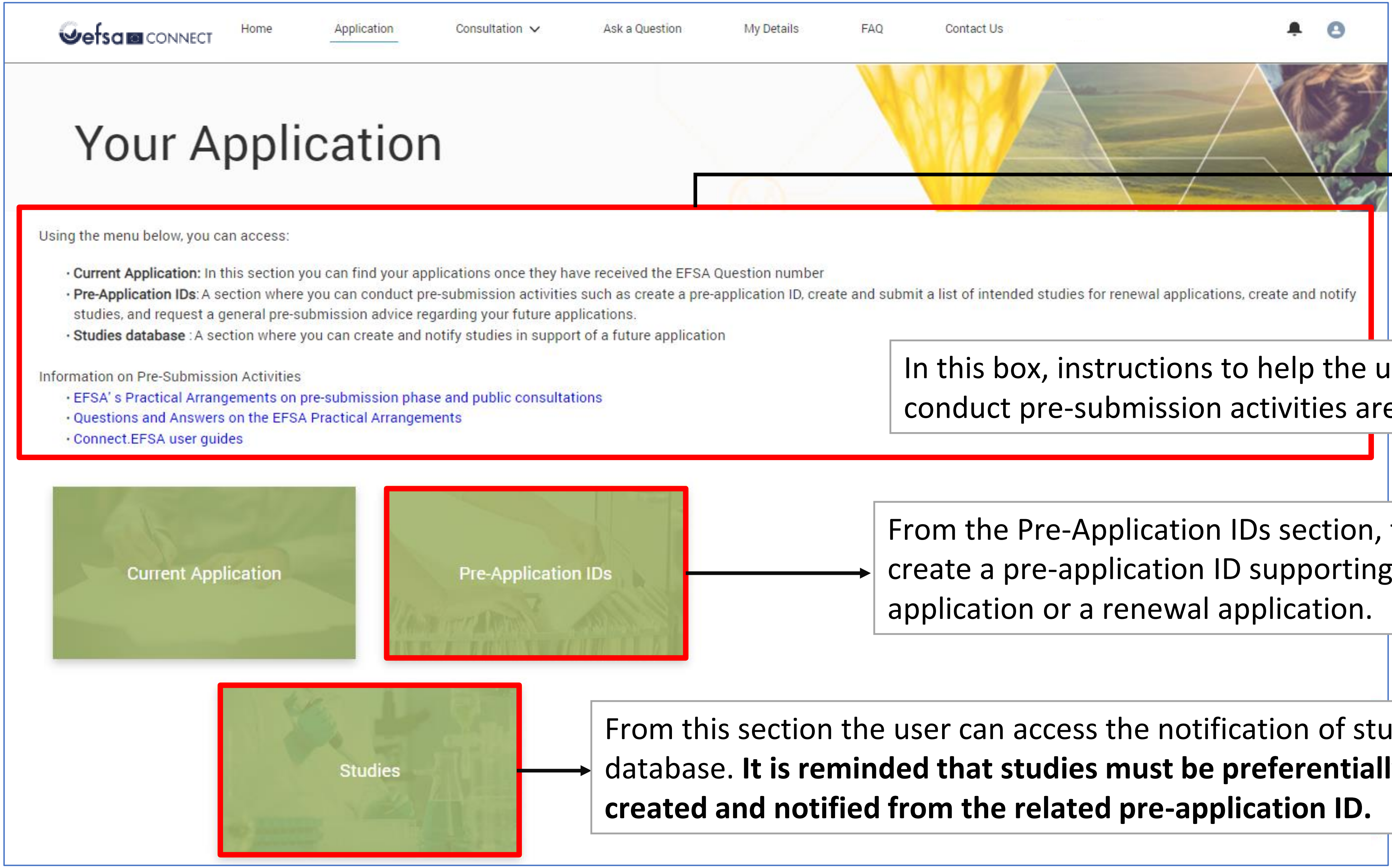


Pre-application ID

3. Connect.EFSA portal



3.1 Create a pre-application ID



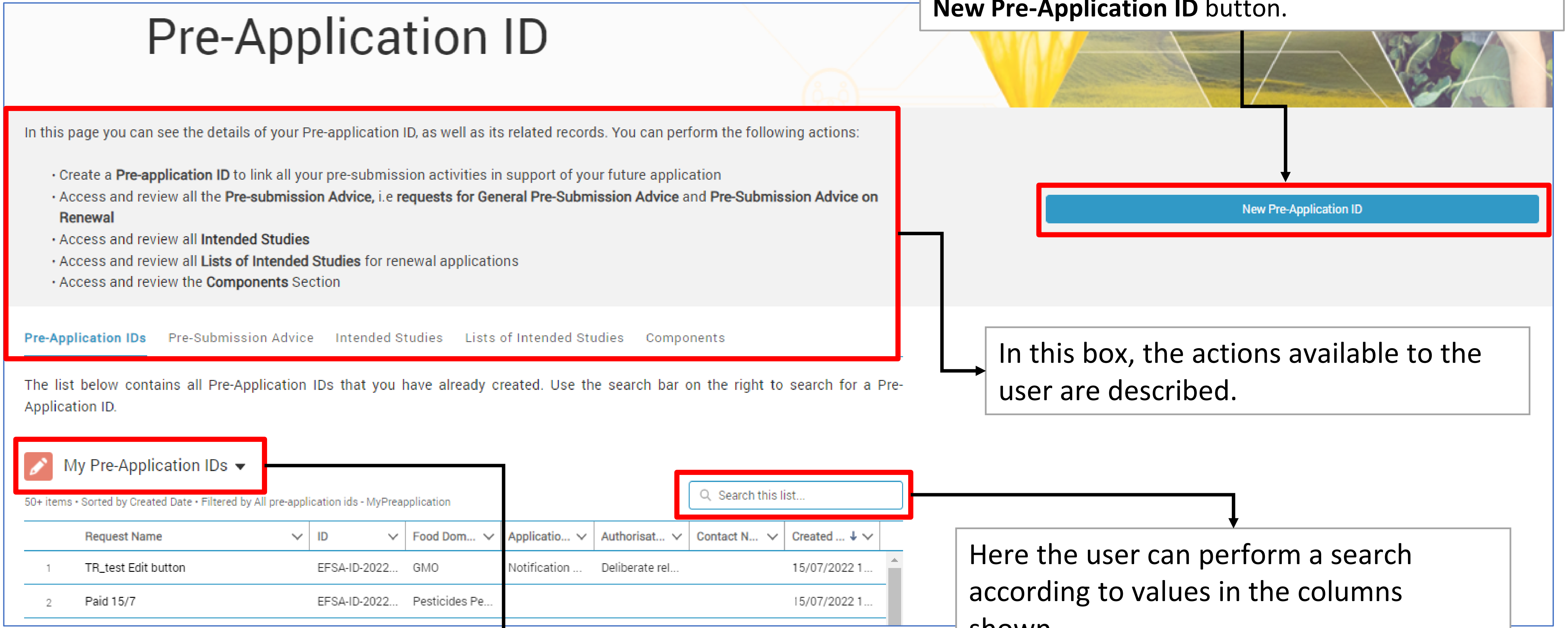
In this box, instructions to help the user to conduct pre-submission activities are provided.

From the Pre-Application IDs section, the user can create a pre-application ID supporting a new application or a renewal application.

From this section the user can access the notification of studies database. **It is reminded that studies must be preferentially created and notified from the related pre-application ID.**

3.1 Create a pre-application ID

To create a new pre-application ID the user selects the **New Pre-Application ID** button.



In this box, the actions available to the user are described.

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

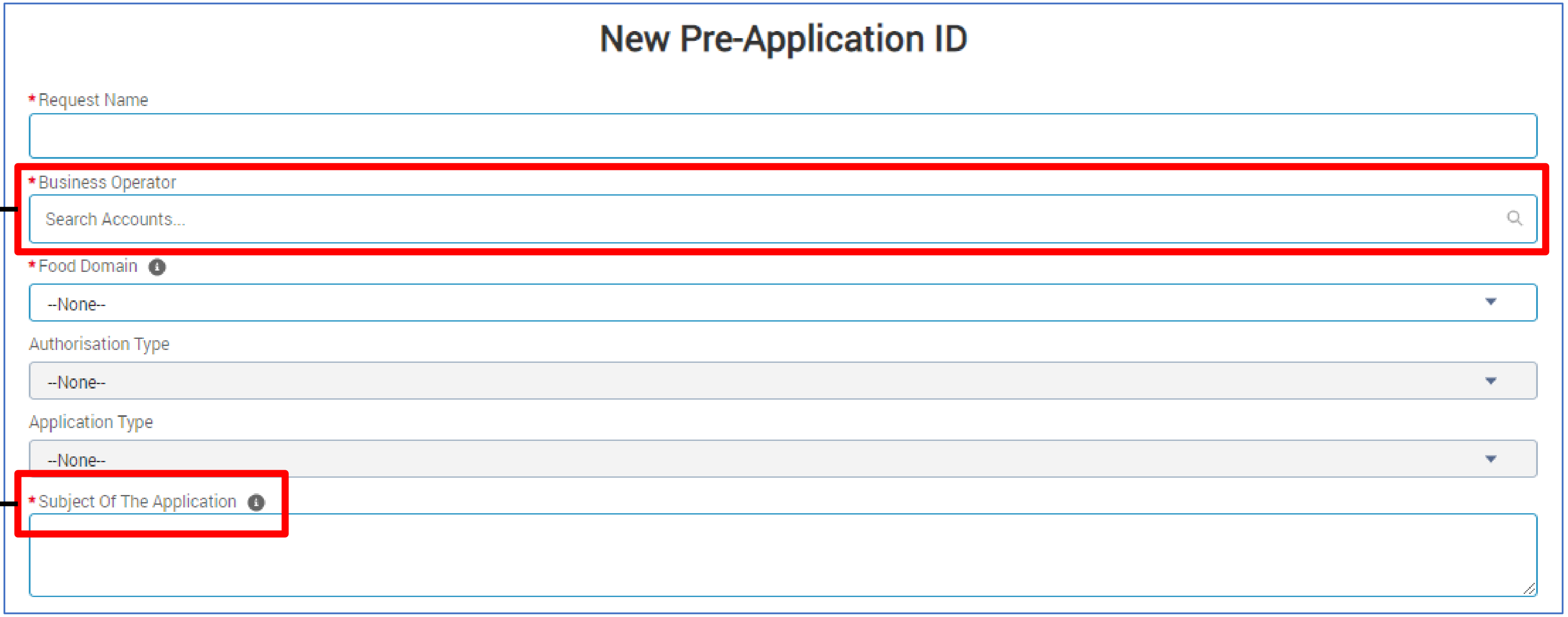
Use this dropdown menu to filter a search.

3.1 Create a pre-application ID

Step 1 – The user indicates the information required to create a new pre-application ID, such as the business operator name and the subject of the application.

The user can fill this field with:

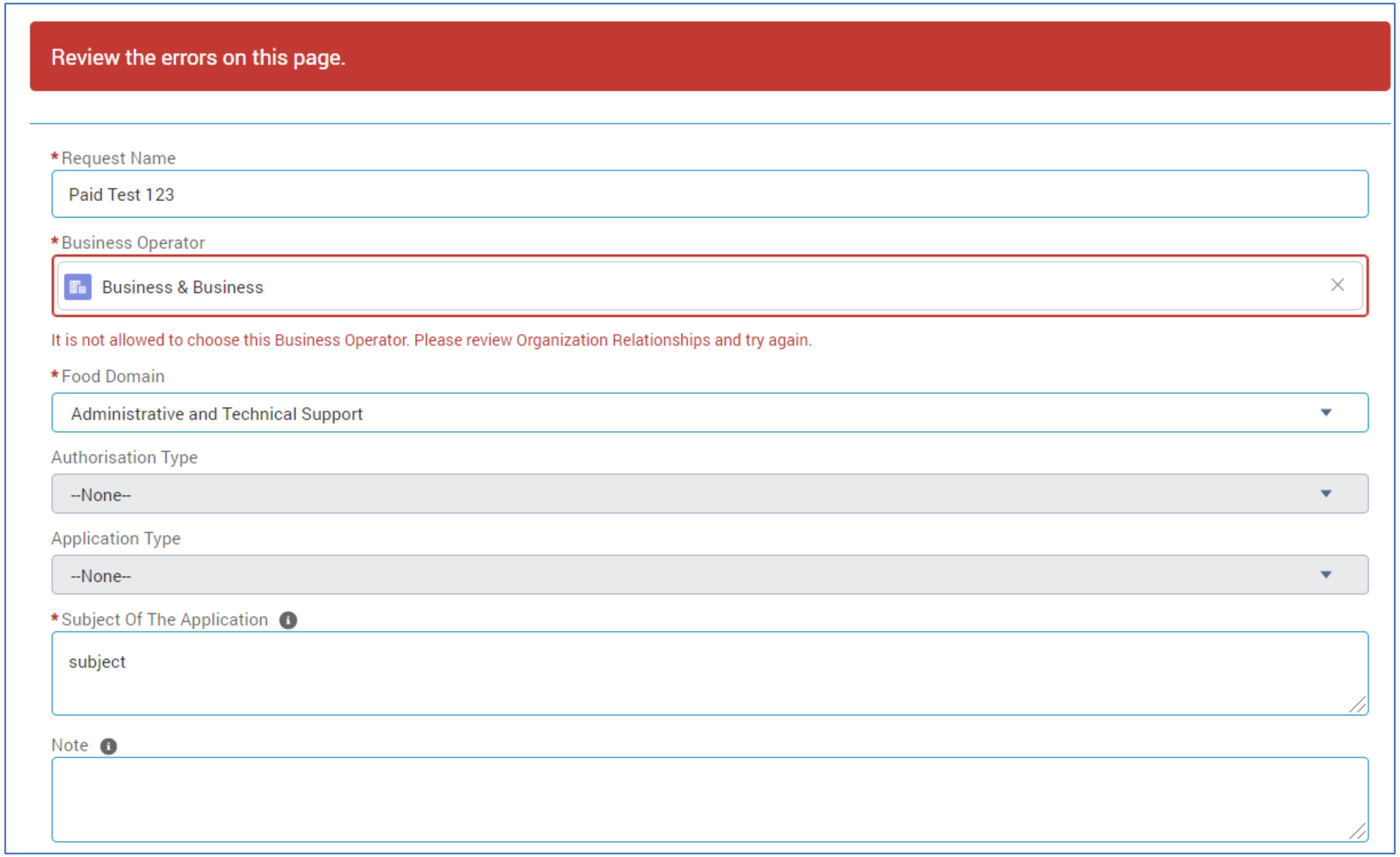
- Its own organisation name **(business operators)**
- The name of the business operator for which the **third party/consultant** is creating the pre-application ID "On behalf of".



- * this sign means that the field is **mandatory**
- this icon displays the **help text** for that field.

3.1 Create a pre-application ID

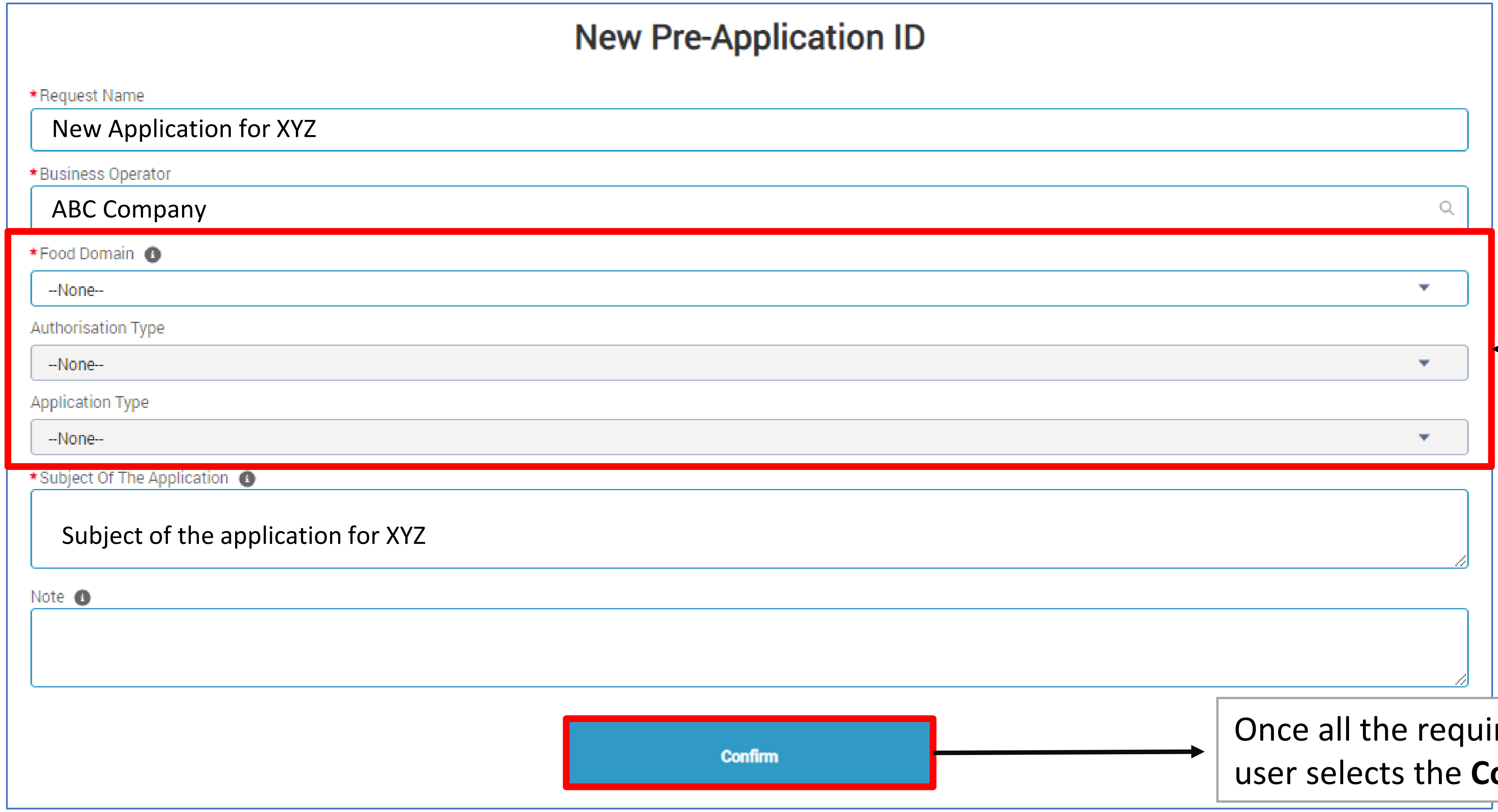
If a **business operator** or a **third party/consultant** tries to create a pre-application ID for another organisation, the system returns the following **error message**, unless a relationship between the two organisation has been previously established.



Look at the [Account Relationship section](#) to understand how to establish a relationship "On behalf of" and enable an organisation to work on behalf of the user's organisation.

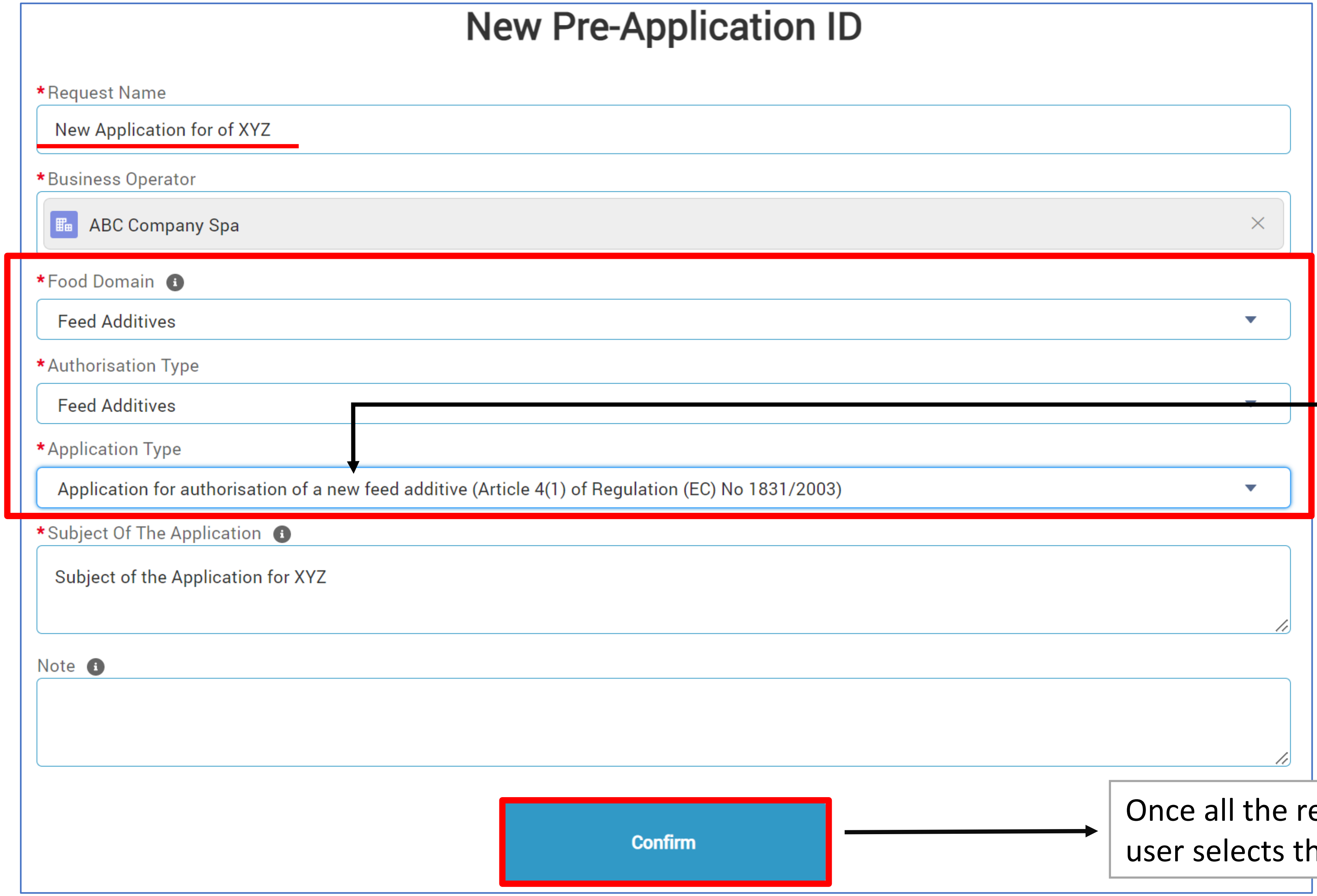
3.1 Create a pre-application ID

Step 2 - With a given combination of **Food Domain** and **Application Type**, the user can create a pre-application ID to link all pre-submission activities supporting a new application or a renewal application.



Once all the required fields are filled in, the user selects the **Confirm** button to proceed.

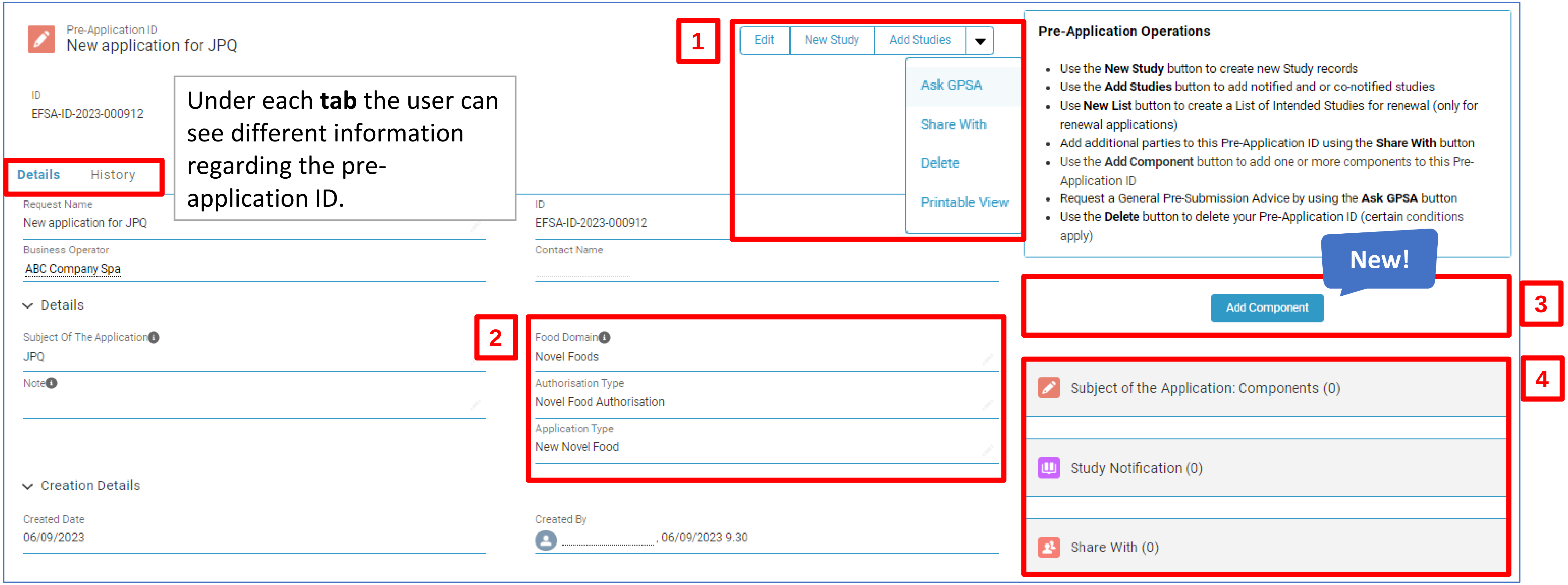
3.1.1 Pre-application ID - Applications



In this case, the user creates a **pre-application ID** to link pre-submission activities **supporting an application**.

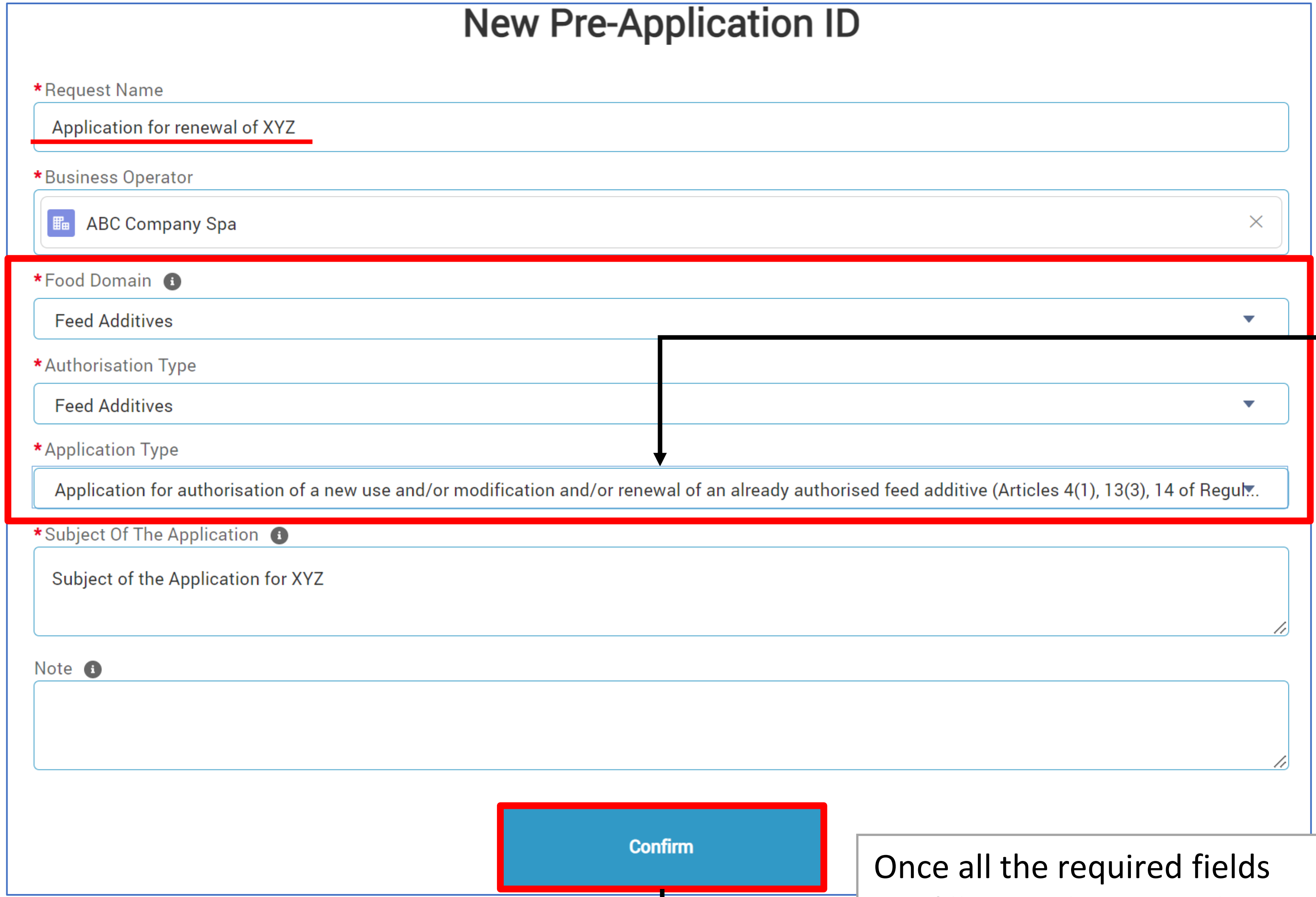
Once all the required fields are filled in, the user selects the **Confirm** button to proceed.

3.1.1 Pre-application ID - Applications



1. Use these buttons to create a new draft study or add a notified study, request a GPSA or delete the pre-application ID.
2. Values in these fields can be modified only when there are no submitted objects associated to the pre-application ID.
3. Use the Add Component button to add/create one or more components and link them to the pre-application ID.
4. This section lists all the associated objects and the sharing relationships.

3.1.2 Pre-application ID - Renewal applications



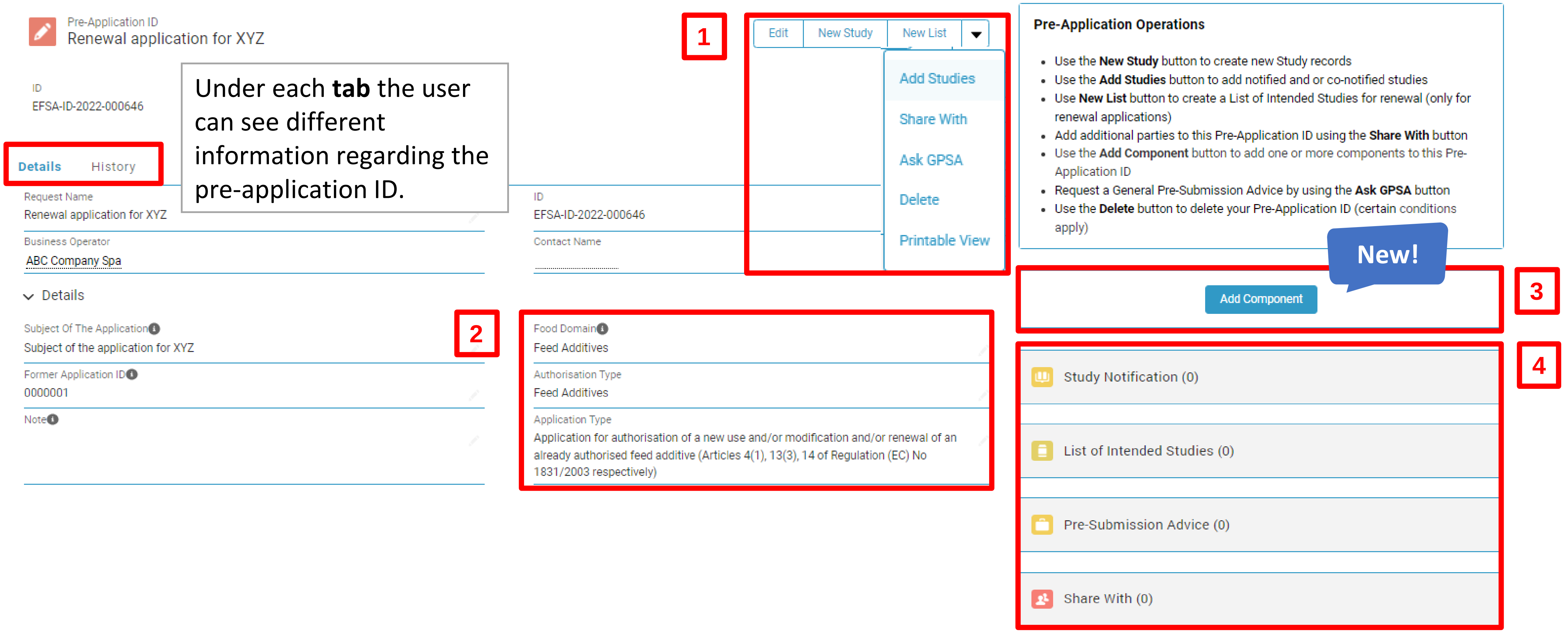
Suggested video tutorial: [pre-application ID and list of intended studies](#).

In this case, the user creates **a pre-application ID** to link pre-submission activities **supporting a renewal application**.

The system allows the creation and submission of a list of intended studies.

Once all the required fields are filled in, the user selects the **Confirm** button to proceed.

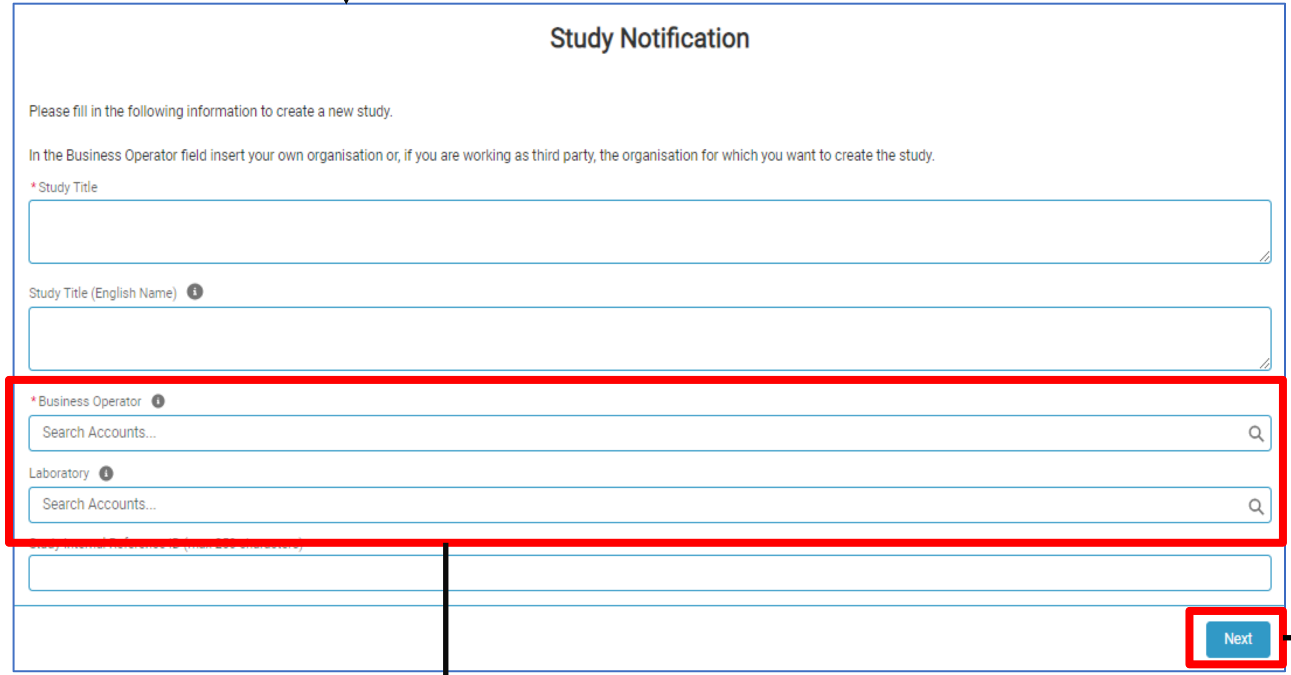
3.1.2 Pre-application ID - Renewal applications

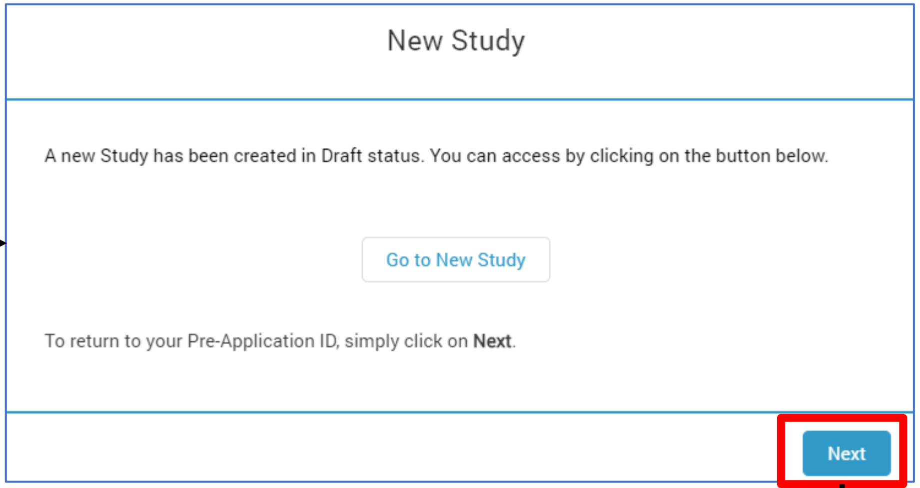


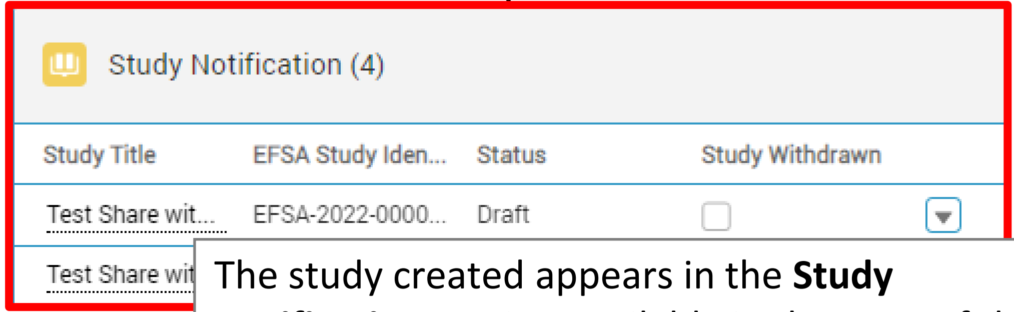
1. Use these buttons to create a new draft study or add a notified study, request a GPSA, create and submit a list of intended studies or delete the pre-application ID.
2. Values in these fields can be modified only when there are not submitted objects associated to the pre-application ID.
3. Use the Add Component button to add/create one or more components and link them to the pre-application ID.
4. This section lists all the associated objects and the sharing relationships.

3.2 Create a new study

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







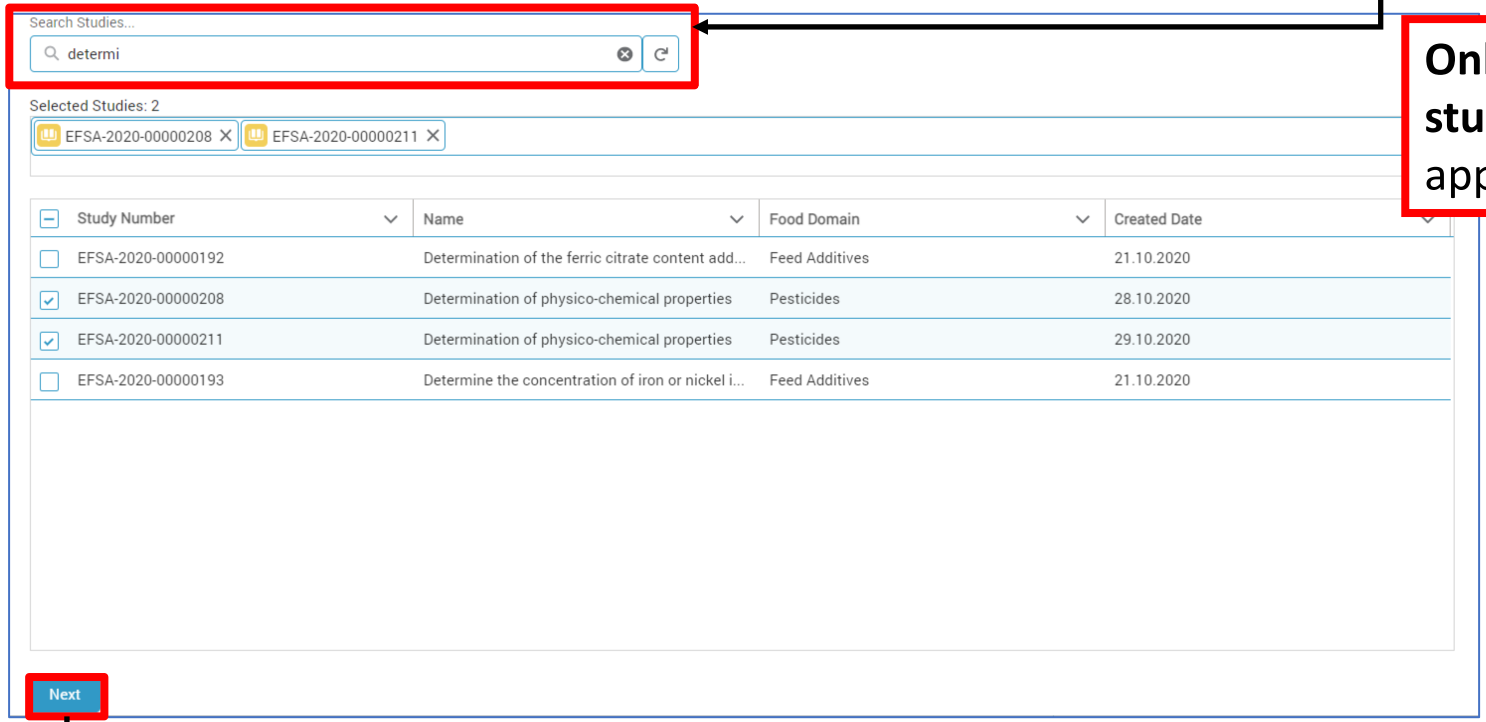
The study created appears in the **Study Notification** section available in the page of the pre-application ID.

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

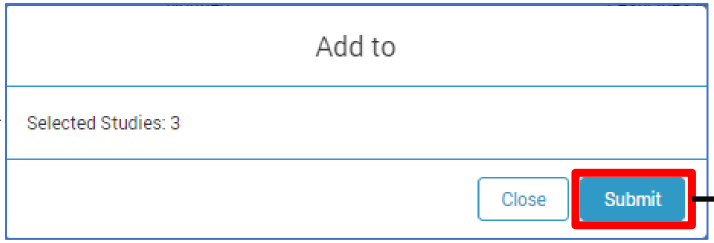
The user can also indicate the laboratory commissioned to conduct the study. This information can be revised also at a later stage.

3.3 Add a study to the pre-application ID

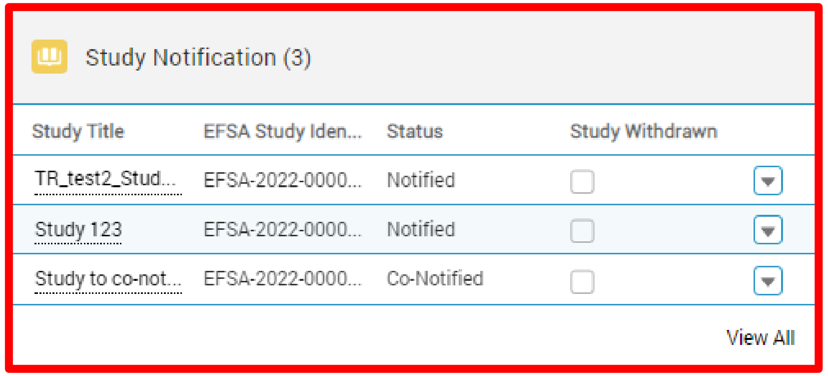
Click on **Add Studies** and use the search bar to search a study record. It is possible to select one or more study records the user would like to add to the pre-application ID. To continue click on **Next.**



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



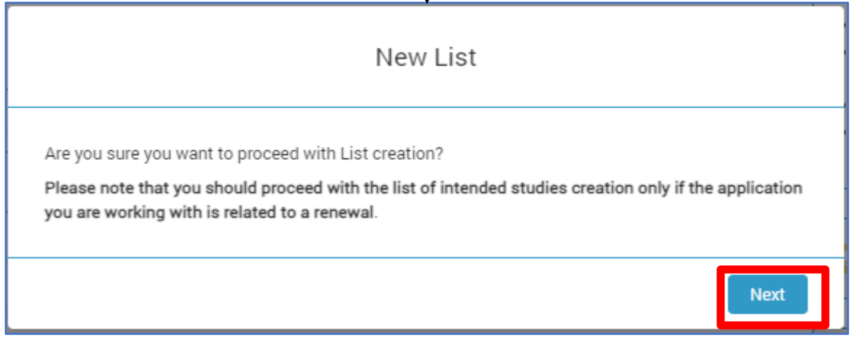
Added studies appear in the **Study Notification** section available in the page of the pre-application ID.

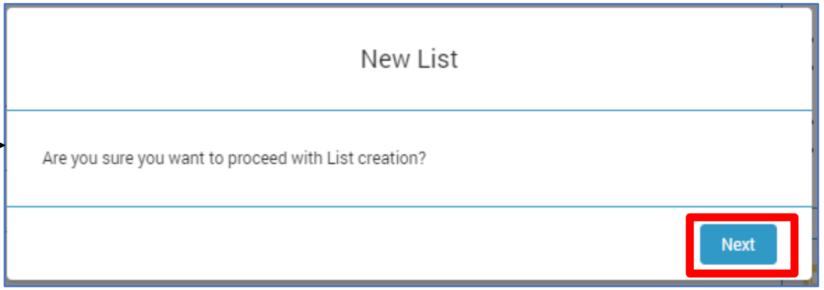


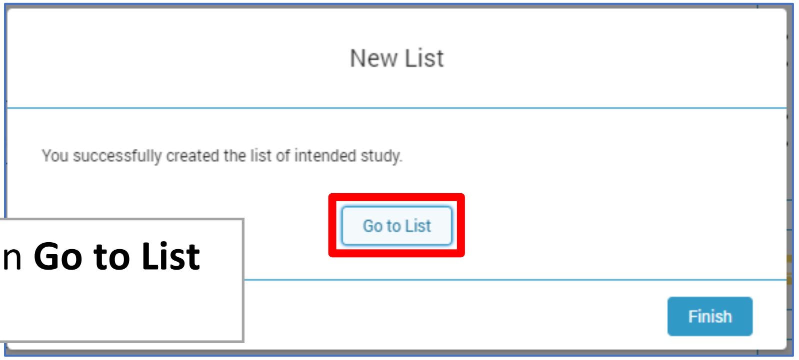
3.4 Create a list of intended studies for renewal

From the page of a pre-application ID supporting a renewal application the user can **create a new list of intended studies** by clicking on **New List**.

If the selected Food Domain is Feed Additives the message below is shown (it is only a warning message that does not block the process). For all the other Food Domains, a simple alert appears.



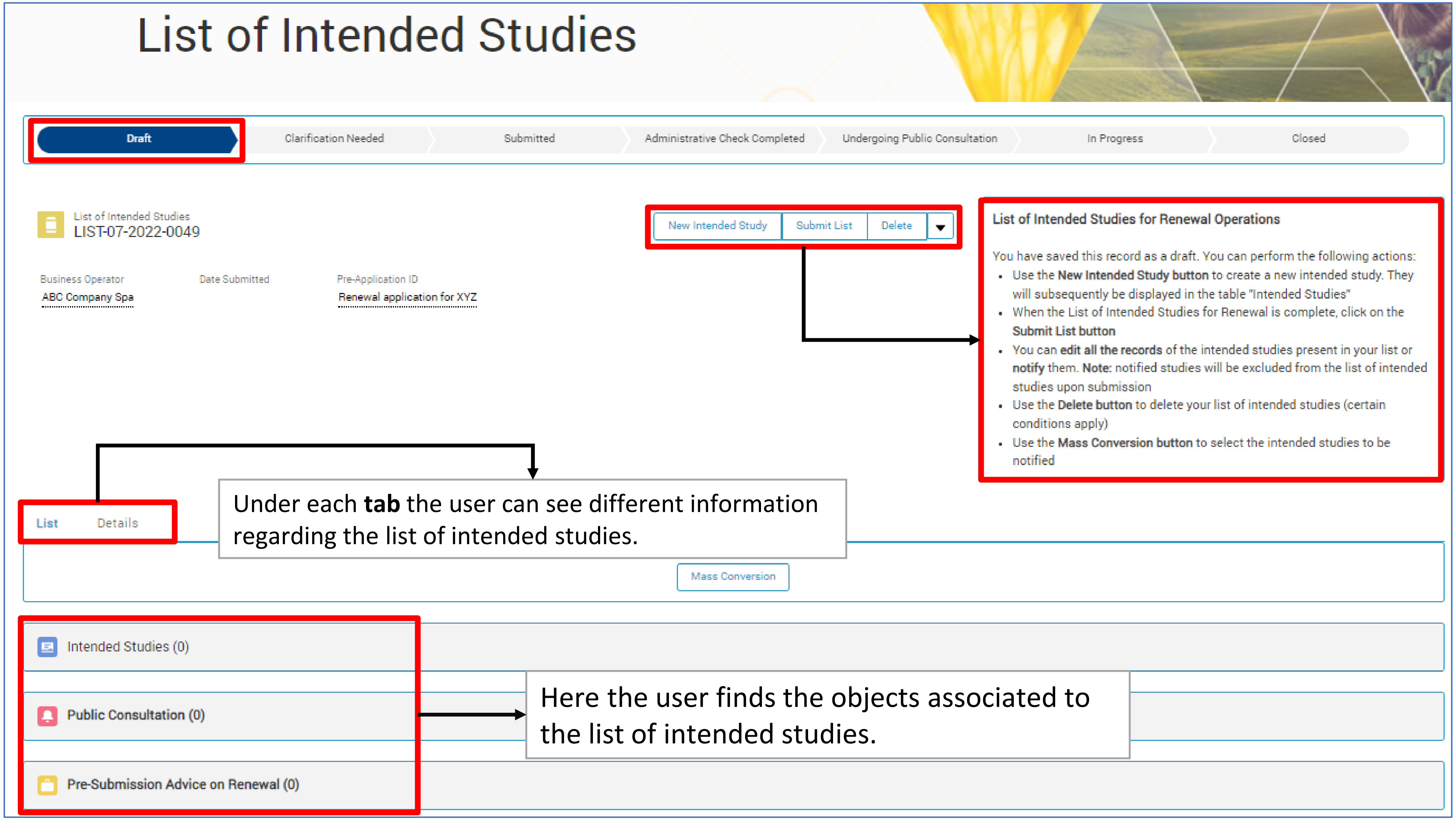




In both cases click **Next**, then **Go to List** to proceed.

3.4 Create a list of intended studies for renewal

Upon creation, the status of the list of intended studies is set as **Draft.**



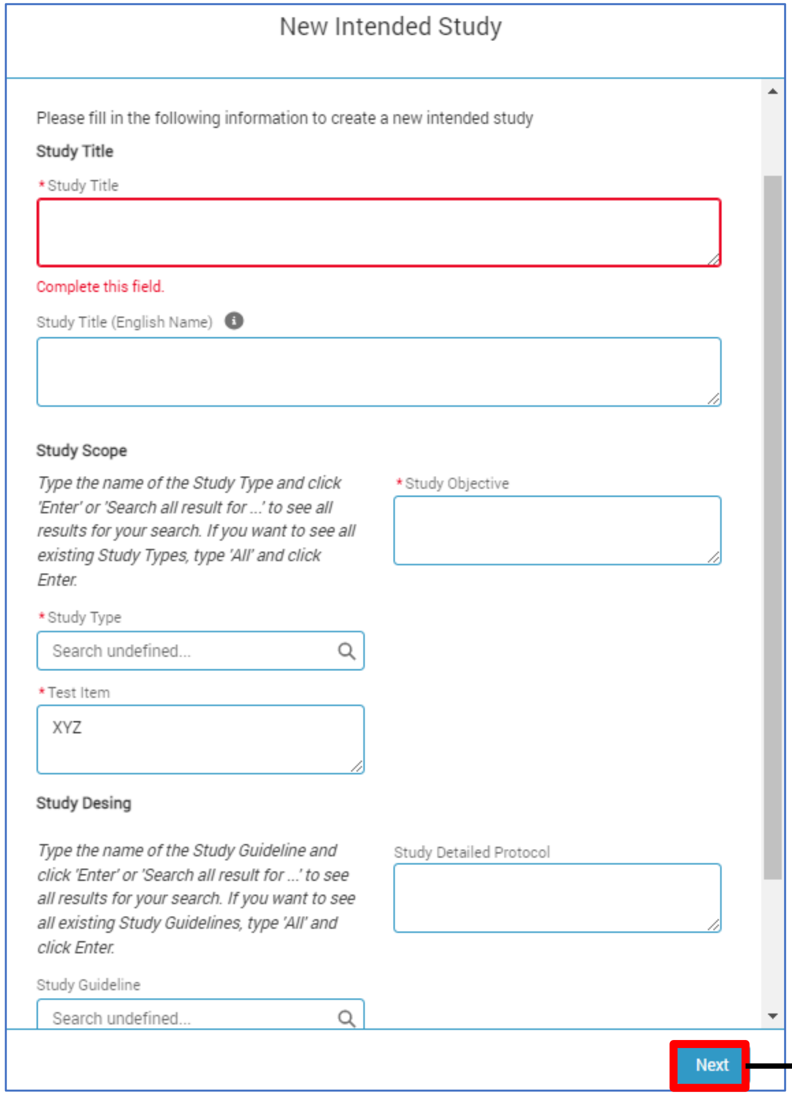
In this box, the actions available to the user on the list of intended studies are described.

3.4.1 Create an intended study

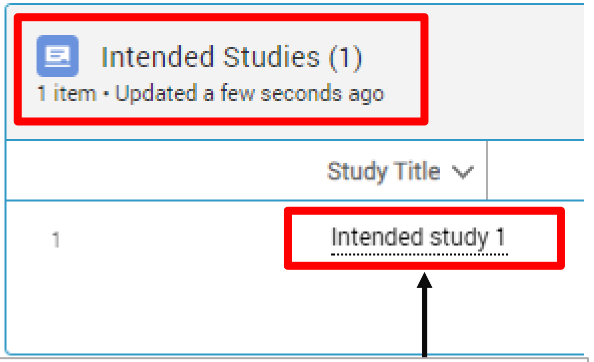
Users can create **new intended studies** that will be part of the list according to the provisions of Article 32c(1) of the General Food Law and Article 12 of the [EFSA Practical Arrangements on pre-submission phase and public consultations].

The New Intended Study form must be completed indicating all the mandatory information. Then the user clicks **Next**.

If needed, it is possible to **edit** the information of the new intended study in a second moment before the submission of the list.



Upon creation, the intended study is shown in the **Intended Studies section** of the list.

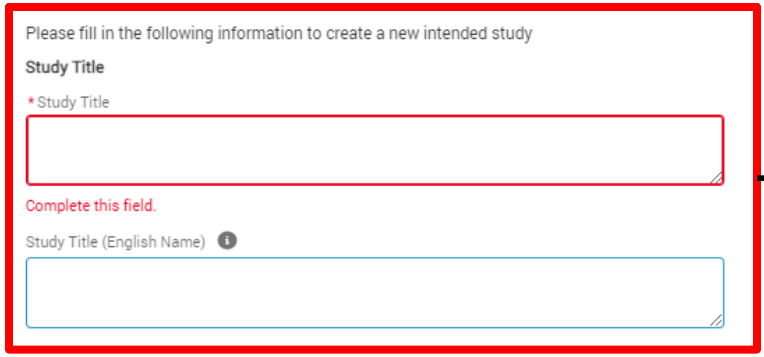


Click on the study title to access it.

Suggested read: [Question and Answer on the EFSA Practical arrangements], section **Intended applications for renewal**.

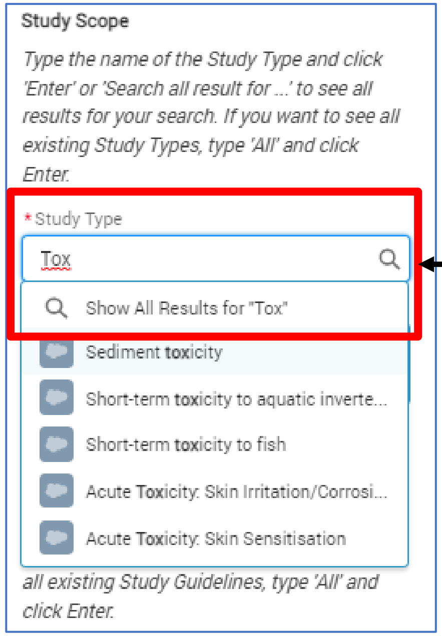
3.4.1 Create an intended study

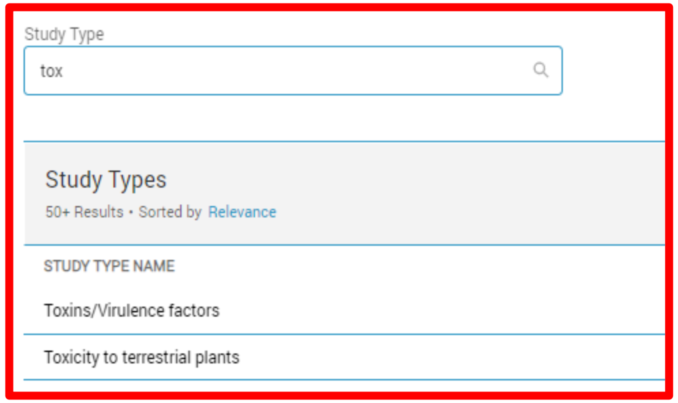
The form for the intended study allows to indicate a study title up to 300 characters long and to search more easily among values of Study Type and Study Guidelines and select the most relevant.

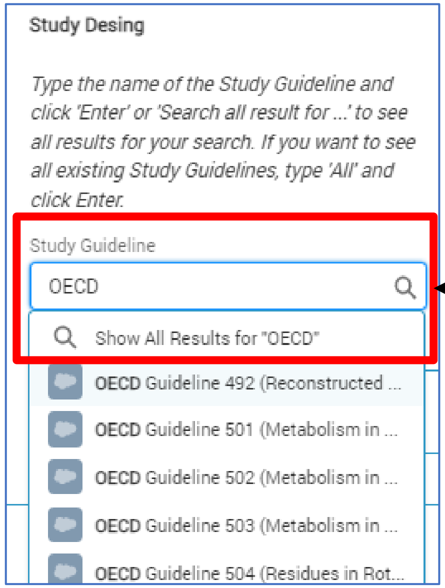


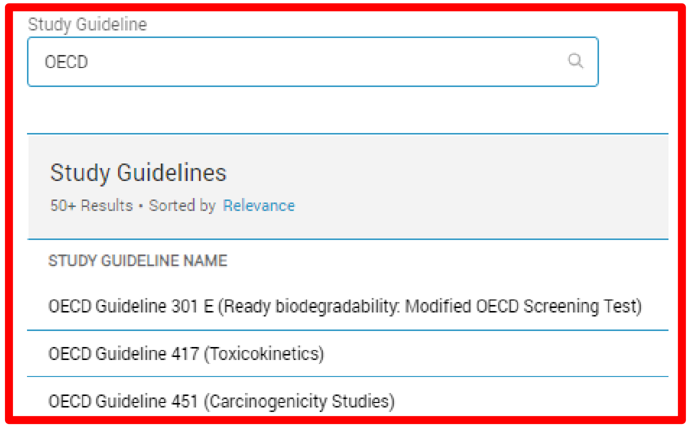
Up to 300 characters long.

This field can be used to **search and select a specific Study Type or Guideline**. Click on the below message "Show All Results for…" to see the search results. **Type "All"** and press **Enter** to see the full list.



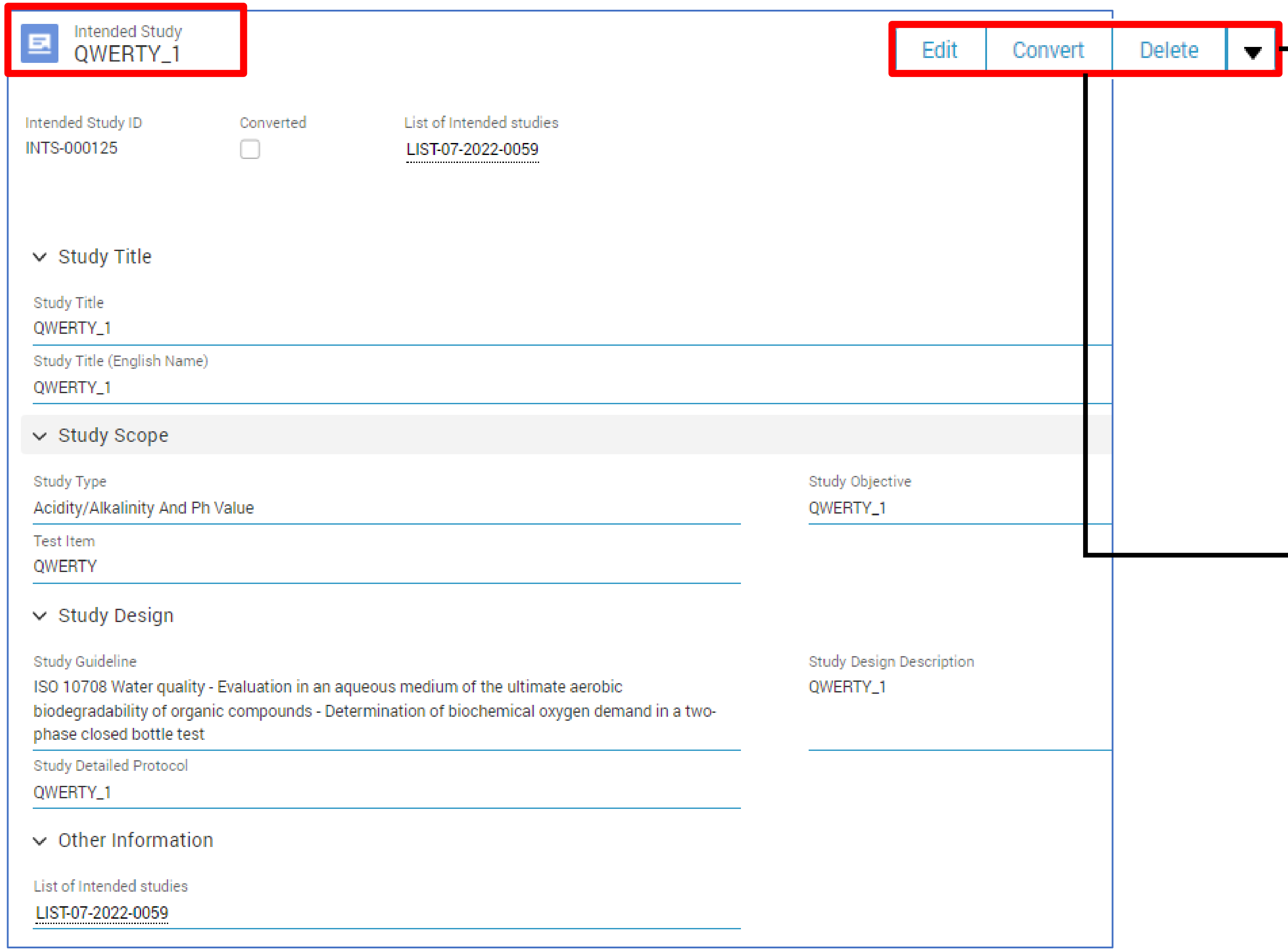






3.4.1 Create an intended study

In the intended study page, the user can revise the information provided and perform further actions on the intended study record.



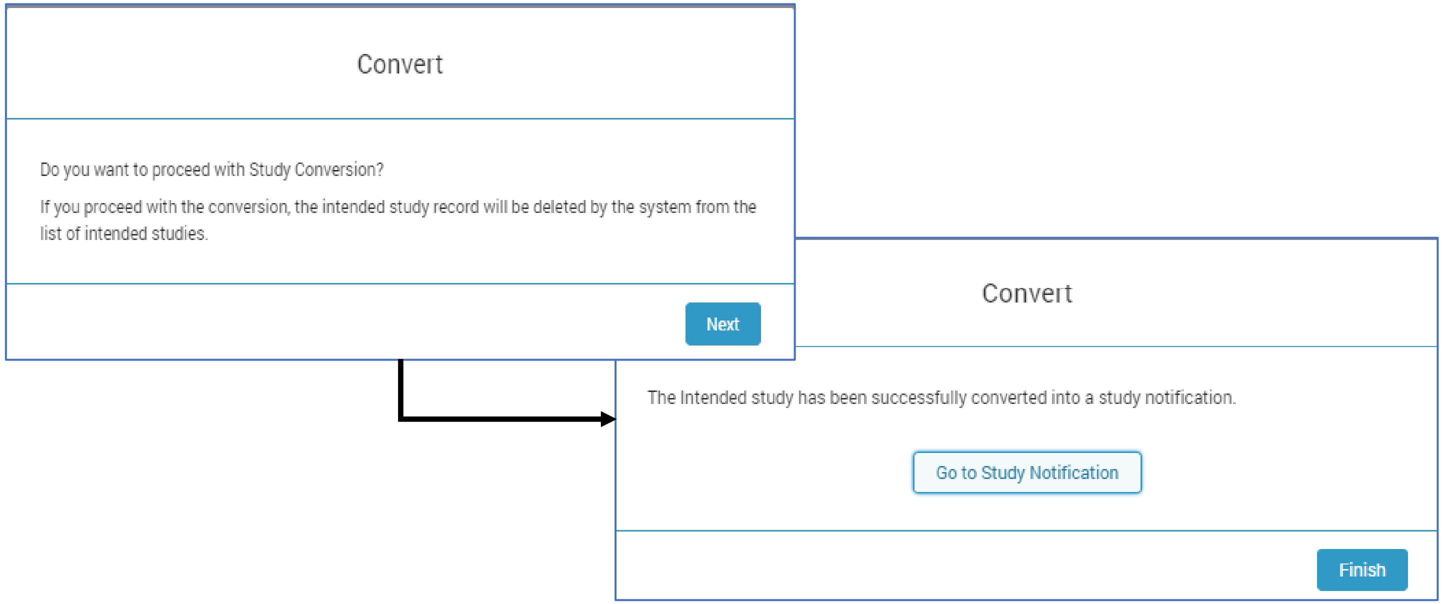
Intended studies can be **edited** or **deleted** only if the status of the list of intended studies is equal to “Draft” or “Clarification Needed”.

Intended studies can be **converted into notifiable draft studies (for notifications according to Article 32b of the General Food Law)** only if the status of the list of intended studies is “Draft”, “Clarification Needed” or “Closed”.

3.4.2 Convert single intended studies

Single intended studies that are going to be commissioned can be converted into notifiable draft studies (for notifications according to Article 32b of the General Food Law) **only** when the status of the list is **“Draft”**, **“Clarification Needed”** or **“Closed”**.

The user clicks **Convert** from the intended study record page. **If the status of the list is “Draft”** or **“Clarification Needed”**, a warning message appears, clarifying that the converted notifiable study will not be subject to public consultation (as such, study can no longer be considered as ‘intended’).



If the user decides to **convert an intended study when the status of the list is “Closed”** the original copy of the intended study will remain in the Intended Studies section of the list as record history and **marked as converted**.

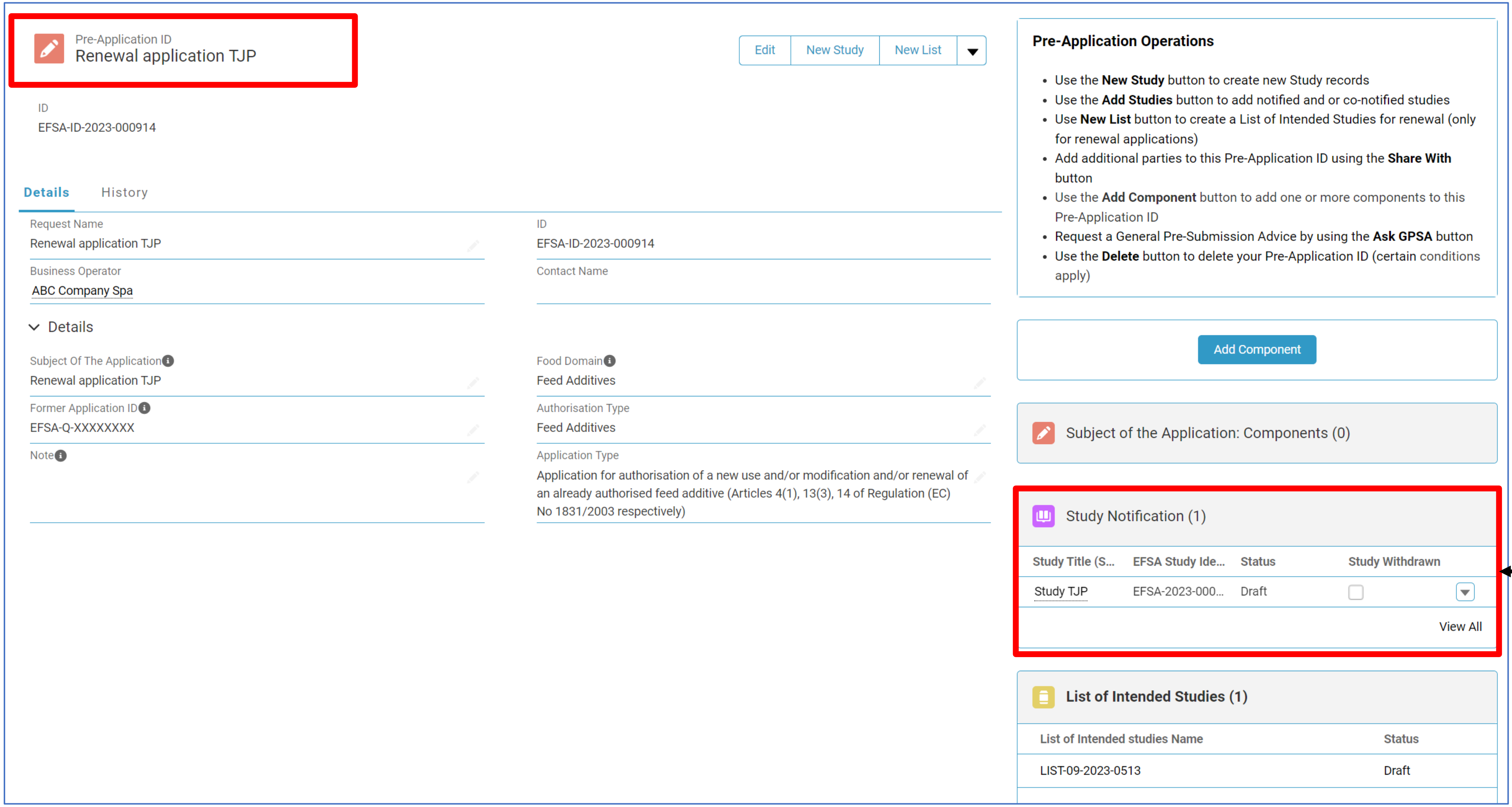
Intended Studies (4)
4 items • Updated a few seconds ago

	Study Title	Study Type	Study Objective	Study Guideline	Test Item	Study Design Descr...	Study Detailed Prot...	Converted
1	test uat 6	Acute Toxicity To Bees	test uat 6	ISO 10253 (Water qual...		test uat 6	test uat 6	☑
2	test uat 5	Pre-Clinical Data: In Vit...	test uat 5	OECD Guideline 433 dr...		test uat 5	test uat 5	☐
3	test uat 4	Repeated dose toxicity...	test uat 4	OECD Guideline 438 (I...		test uat 4	test uat 4	☑
4	test uat 7	Acute toxicity: other ro...	test uat 7	Other		test uat 7	test uat 7	☑

3.4.2 Convert single intended studies

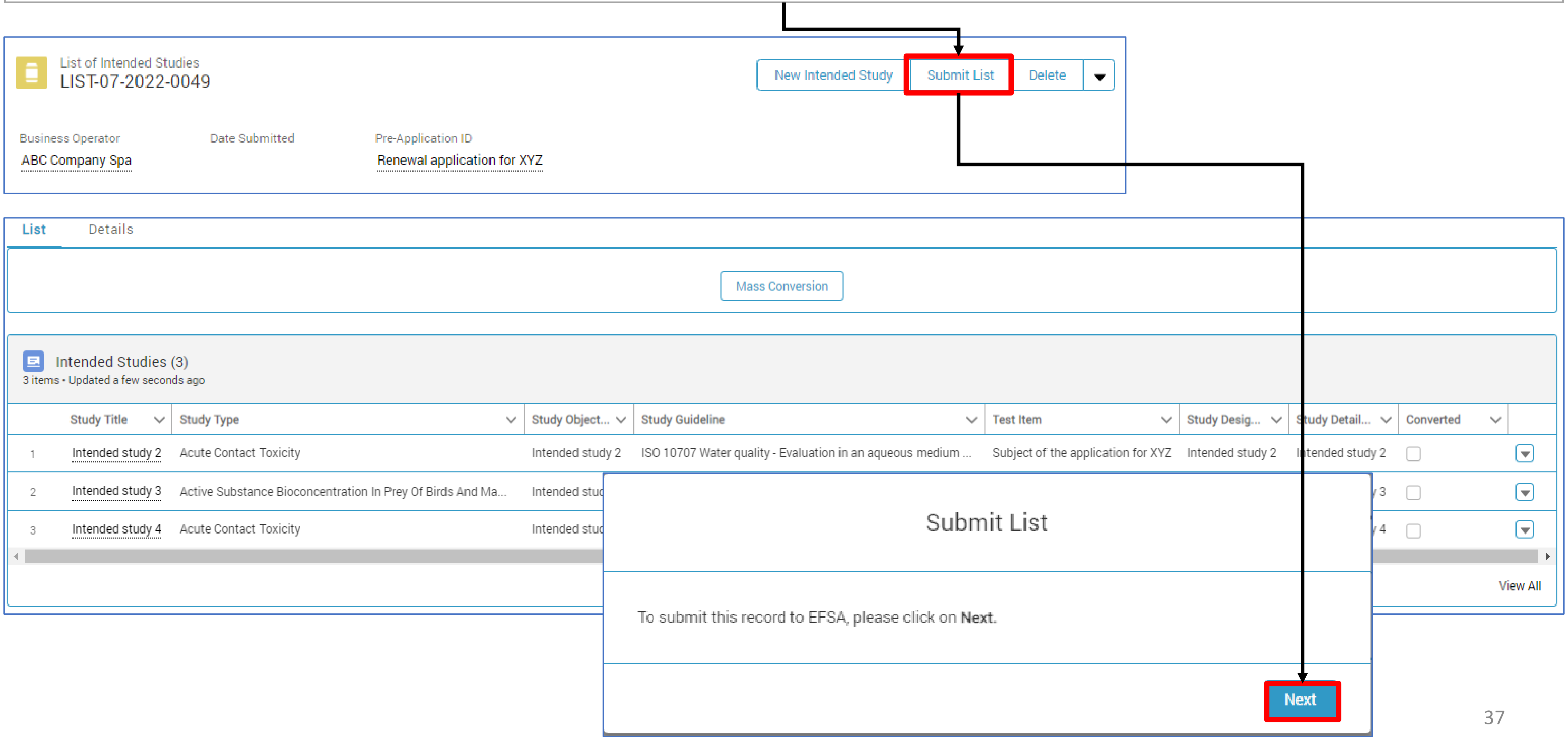
Updated!

Following the conversion, **an intended study is transformed into a draft notifiable study** (for notifications according to Article 32b of the General Food Law). The **draft study record** is moved into the “Study Notification” section of the related pre-application ID. The user can access the draft study and edit it before the notification.



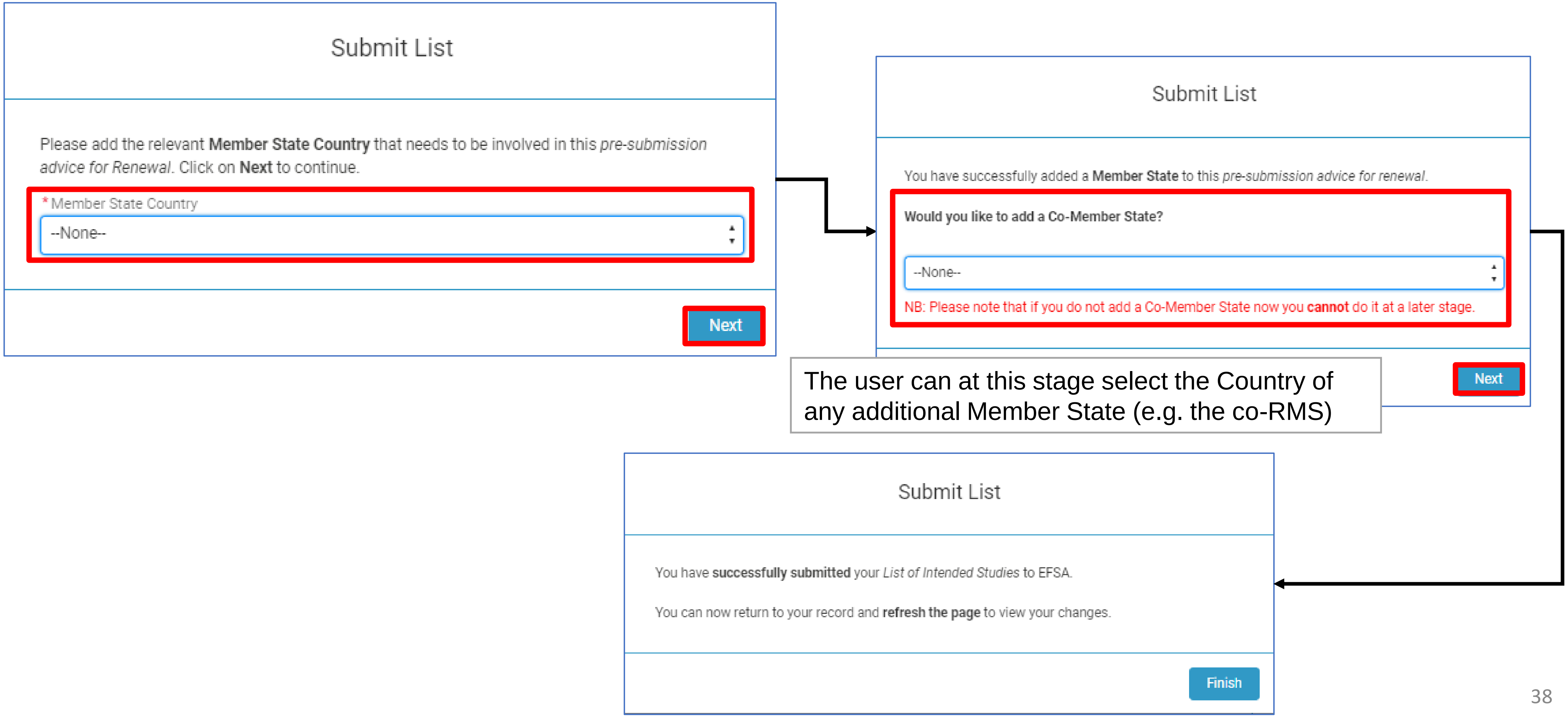
3.4.3 Submit a list of intended studies

When the list of intended studies is ready, the user can submit it to EFSA by using the function button **Submit List** and then **Next.**



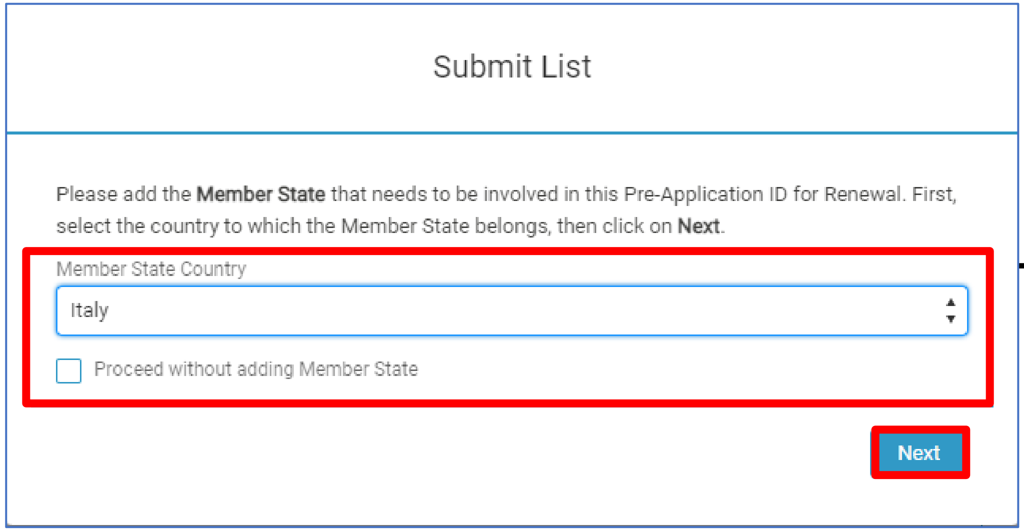
3.4.3.1 Submit a list of intended studies - Pesticides

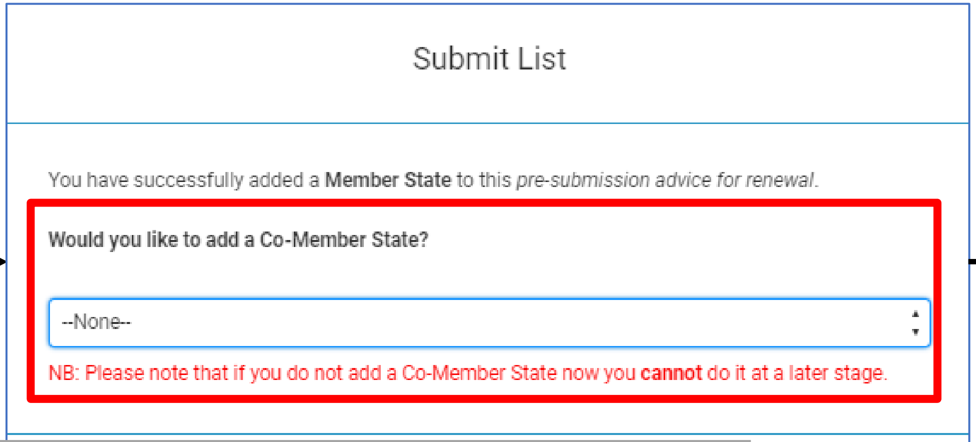
When the pre-application ID for the renewal is related to the Food Domain **Pesticides (AIR)**, the user **must** select the **Member State Country** corresponding to the relevant Competent Authority in the rapporteur Member State/Co-rapporteur Member State for that renewal application.



3.4.3.2 Submit a list of intended studies - GMO Directive 2001/18/EC

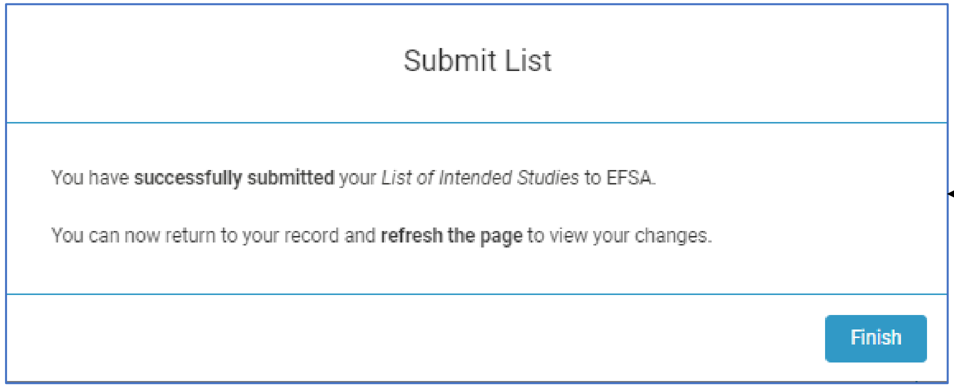
When the pre-application ID for the renewal is related to **GMO Directive 2001/18/EC**, the user is asked to select the **Member State Country** corresponding to the relevant Competent Authority in the Member State for that renewal notification.





The user can select an additional Member State, if needed, or continue without adding it.

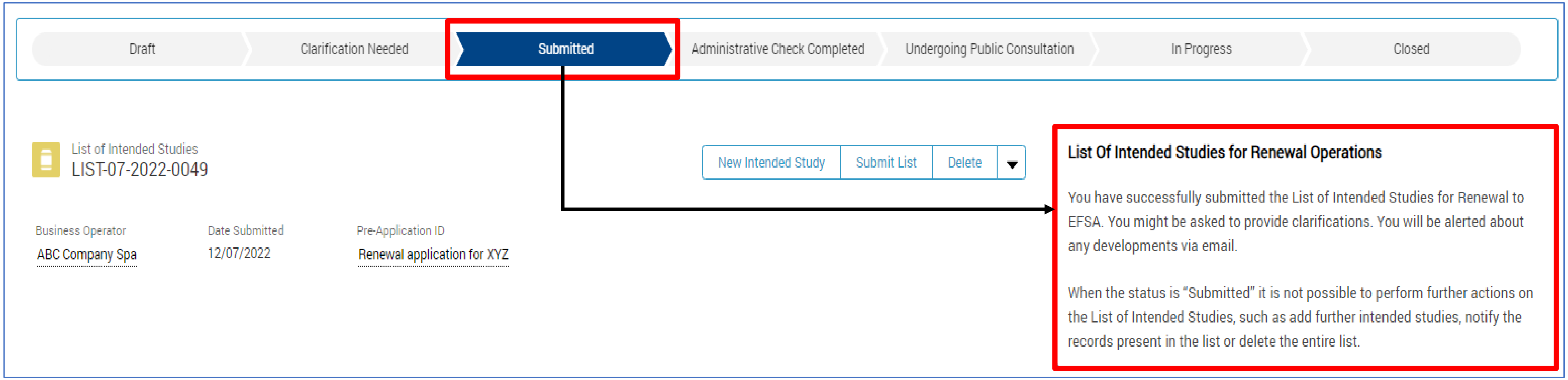
If the Member State is not known, the user can tick the box 'Proceed without adding Member State'. Further information might be requested by EFSA during the Administrative Check.

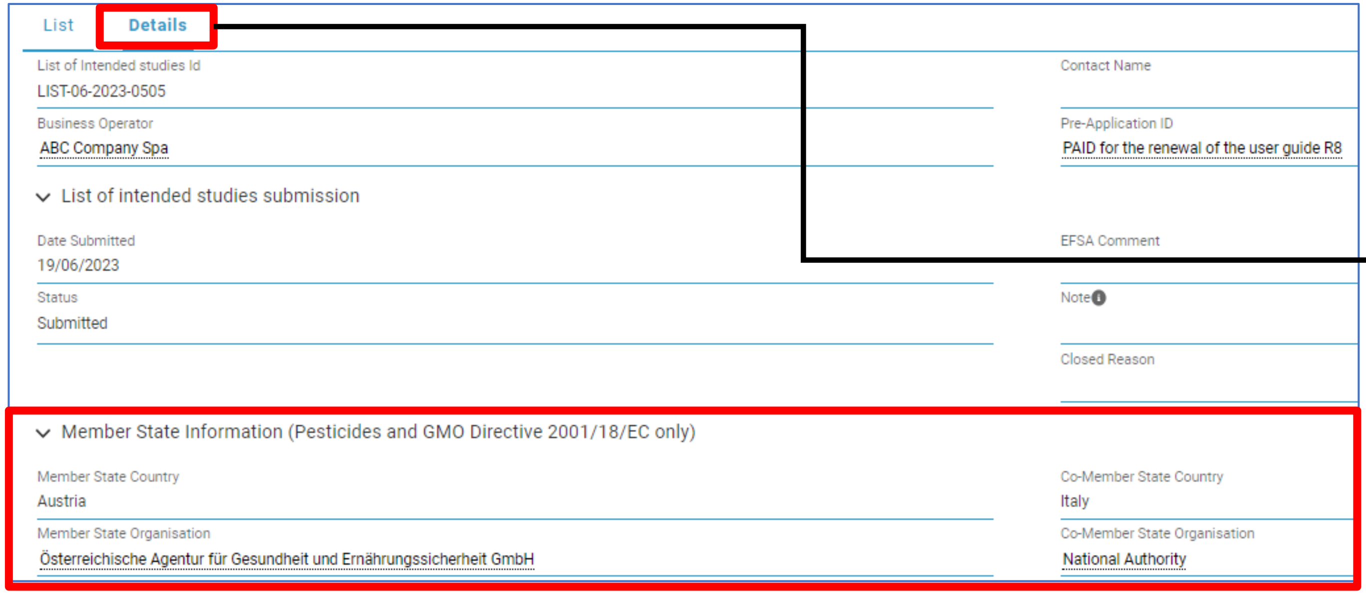


Suggested read: [Commission Notice on the submission of notifications under Articles 13 and 17 of Directive 2001/18/EC]

3.4.3 Submit a list of intended studies

Upon the submission of the list of intended studies its status turns into **Submitted**.





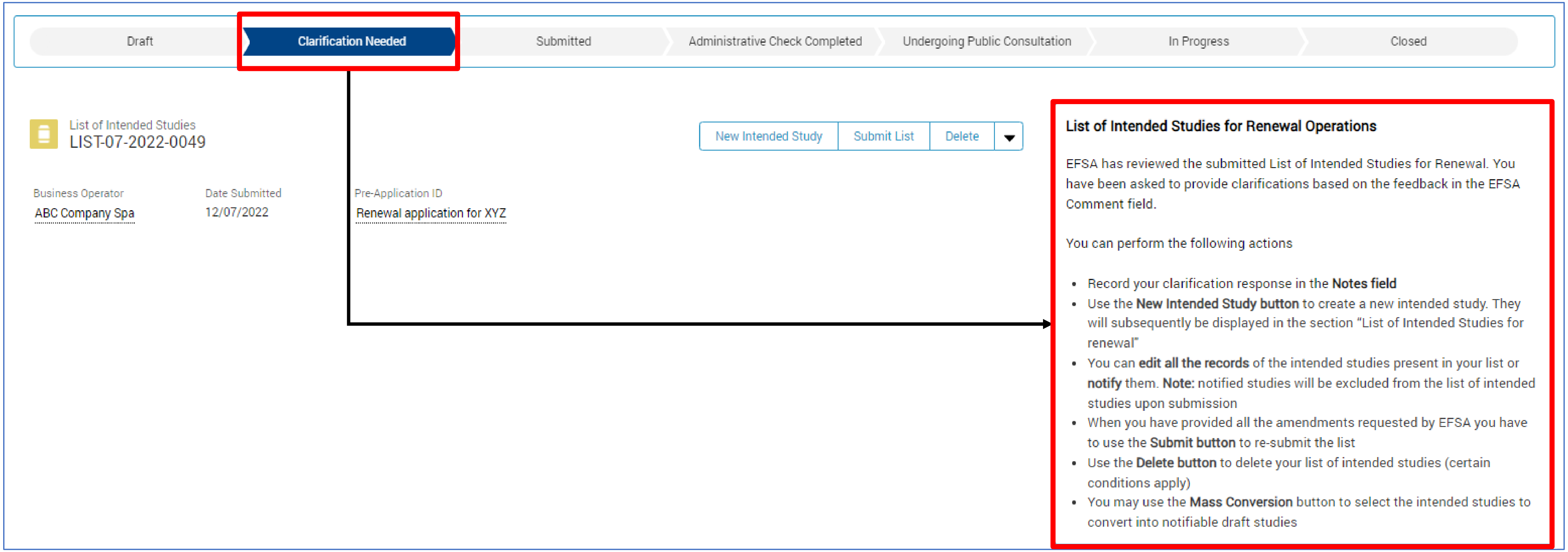
Upon submission and after each step, the record information reported in the **Details tab** is automatically updated.

In the **Details tab** the user finds also the selected Member State(s) information, if required by the type of application for renewal.

3.4.4 List of intended studies - Clarification Needed

During the administrative check performed by EFSA, there might be the need for clarification on the information submitted with the list. EFSA will set the status of the list to **Clarification Needed**.

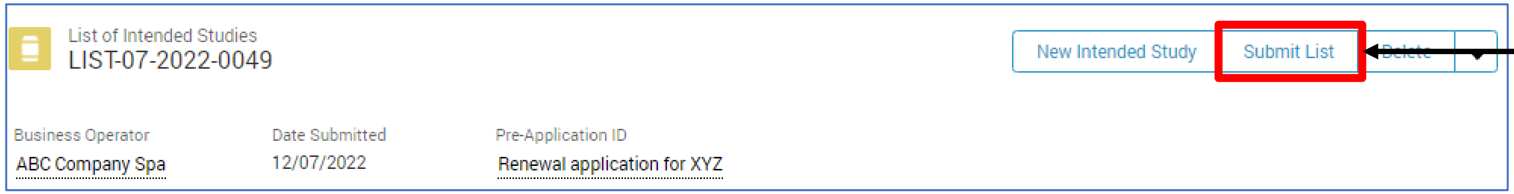
To reply to the clarification request, users can **edit** the pre-application ID and the list record. It is also possible to **add, delete or convert** intended studies into notifiable draft studies by using the specific buttons.

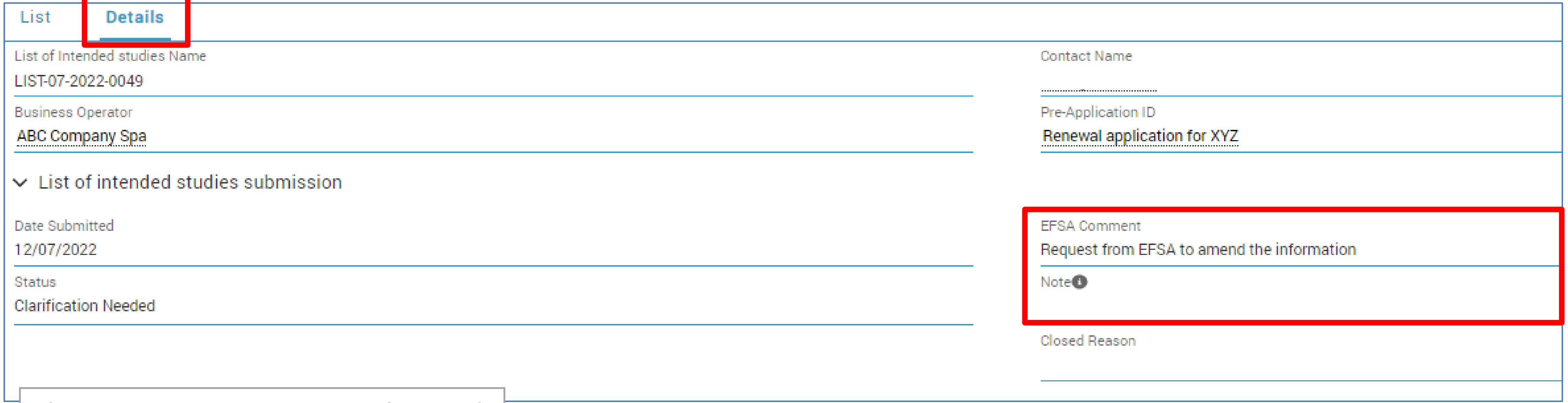


Suggested reads: Article 13 of the [EFSA Practical Arrangements on pre-submission phase and public consultations](#)
Questions 22.B and 24.B of the [EFSA Q&A on Practical Arrangements](#).

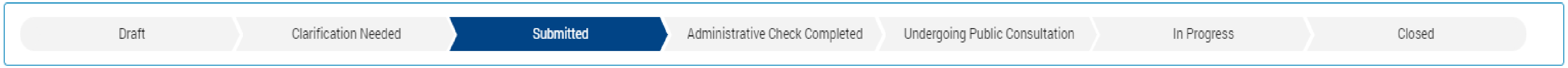
3.4.4 List of intended studies - Clarification Needed

Under the **Details tab** of the list the user finds the section **EFSA comments** containing the request(s) of clarification. A reply can be submitted by the user using the **Note section**.
After the required amendments have been done and the list is ready, the user must **Submit** the **list** again.





The status turns again into **Submitted**.



3.4.5 List of intended studies – Administrative Check Completed and Public Consultation

When EFSA has completed the administrative check, the status turns into **Administrative Check Completed.**

Draft | Clarification Needed | Submitted | **Administrative Check Completed** | Undergoing Public Consultation | In Progress | Closed

List of Intended Studies
LIST-07-2022-0049

New Intended Study | Submit List | Delete

Business Operator	Date Submitted	Pre-Application ID
ABC Company Spa	12/07/2022	Renewal application for XYZ

List Of Intended Studies for Renewal Operations

EFSA completed the administrative check on the information submitted with your list of intended studies.

When the status is "Administrative check completed" it is not possible to perform further actions on the List of Intended Studies, suach as add further intended studies, notify the records present in the list or delete the entire list.

Draft | Clarification Needed | Submitted | Administrative Check Completed | **Undergoing Public Consultation** | In Progress | Closed

List of Intended Studies
LIST-07-2022-0049

New Intended Study | Submit List | Delete

Business Operator	Date Submitted	Pre-Application ID
ABC Company Spa	12/07/2022	Renewal application for XYZ

List Of Intended Studies for Renewal Operations

A public consultation on the list of intended studies for renewal is ongoing.

Public Consultation End Date: 30 July 2022

When the status is "Undergoing Public Consultation" it is not possible to perform further actions on the List of Intended Studies, such as add further intended studies, notify the records present in the list or delete the entire list.

The day the public consultation is **planned** by EFSA, the status of the list turns into **Undergoing Public Consultation** and the user can access the public record of the public consultation from a dedicated section in the list page.

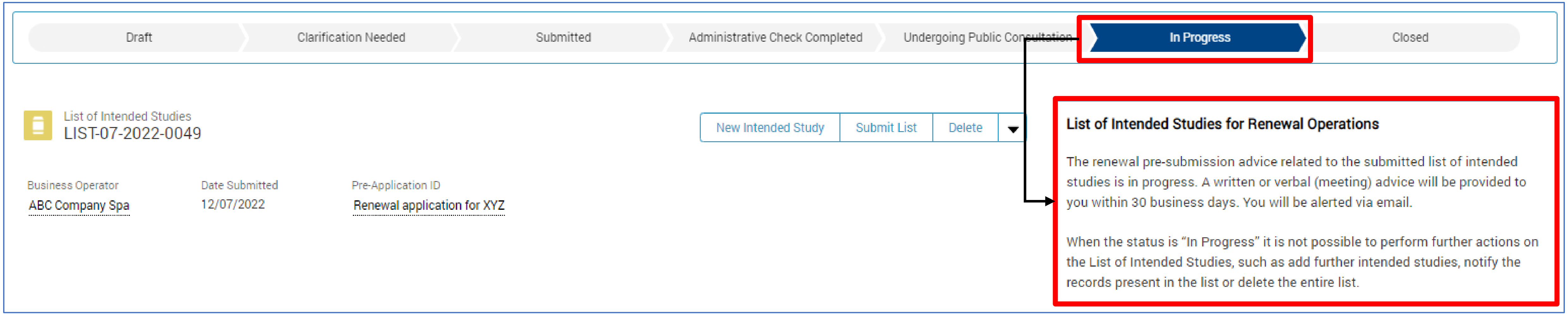
Public Consultation (1)

Public Consultation Number
PC-0172

View All

3.4.6 List of intended studies – In Progress

After the end of the public consultation the status of the list turns into **In Progress**. This means that EFSA is considering the comments received during the public consultation and will provide the user with the renewal pre-submission advice in 30 working days.

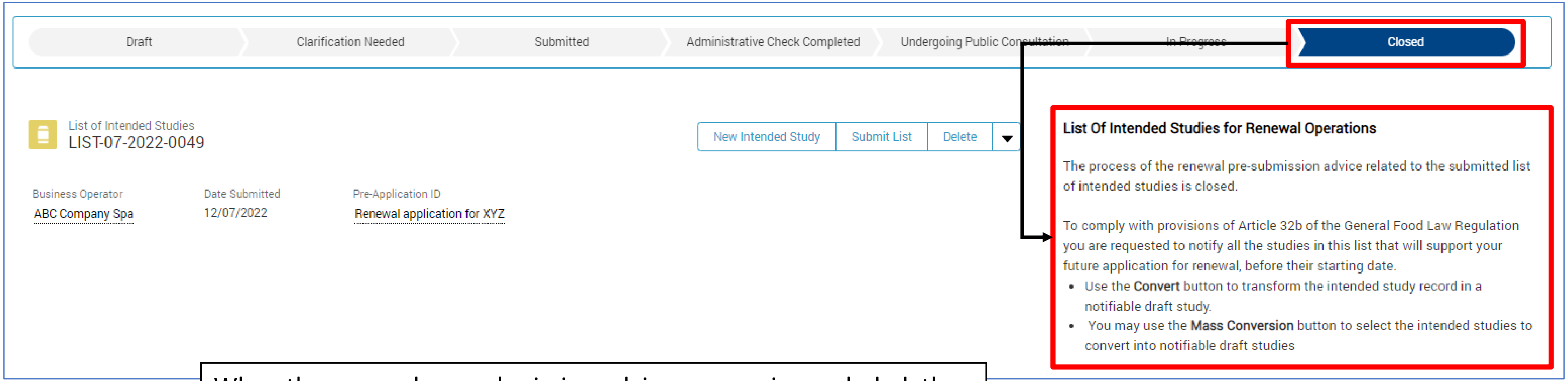


!

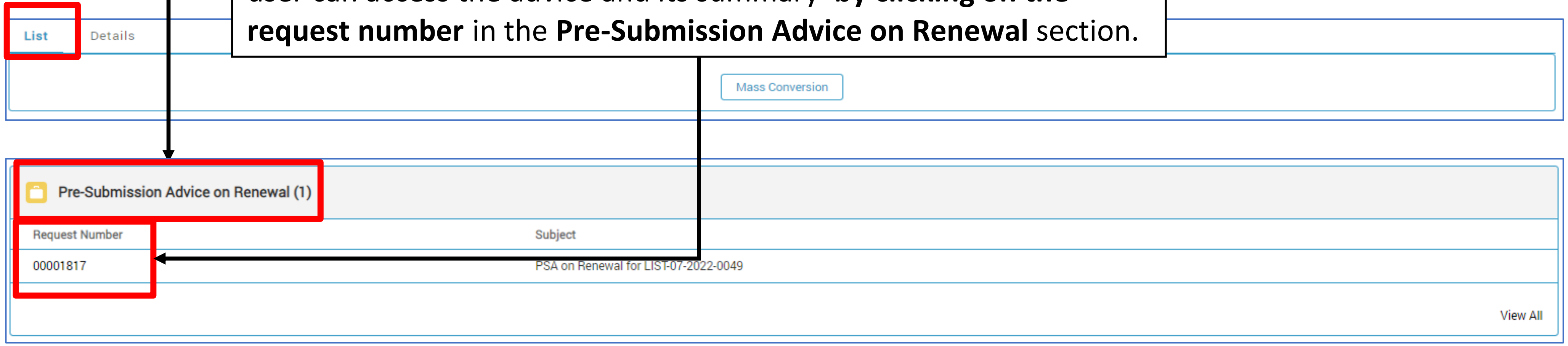
Note: when the status of the List is "Submitted", "Administrative Check Completed", "Undergoing Public Consultation" or "In Progress" it is not possible to perform further actions on the List.
However, it is always possible to create and notify studies or add already notified studies by using the function buttons (i.e. New Study, Add studies) in the related pre-application ID page.

3.4.7 List of intended studies – Closed

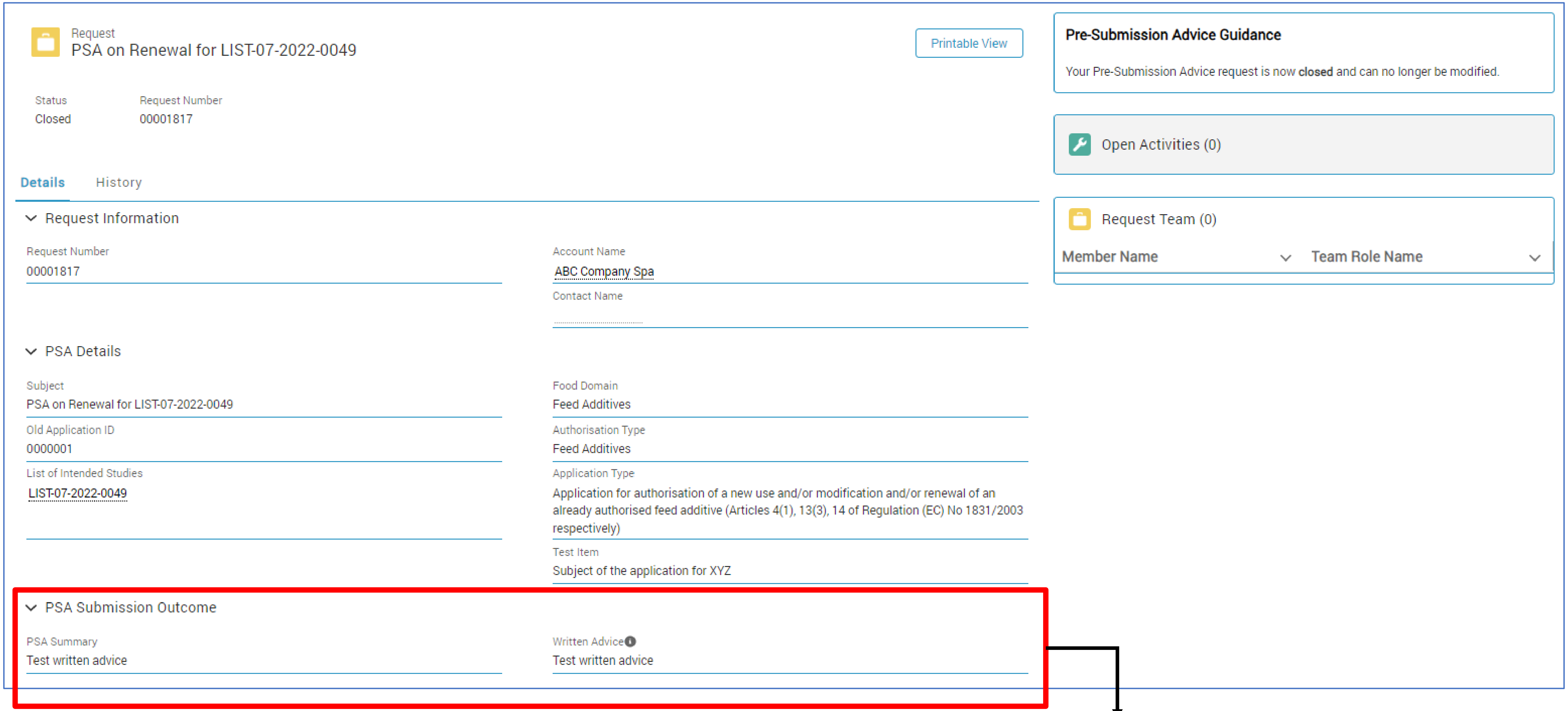
When the renewal pre-submission advice is sent to the potential applicant, the status of the list turns into **Closed**.



When the renewal pre-submission advice process is concluded, the user can access the advice and its summary **by clicking on the request number** in the **Pre-Submission Advice on Renewal** section.



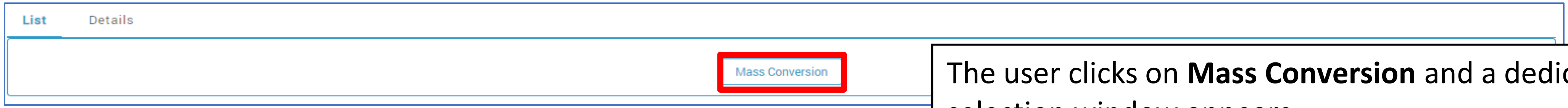
3.5 Renewal pre-submission advice and summary of the advice



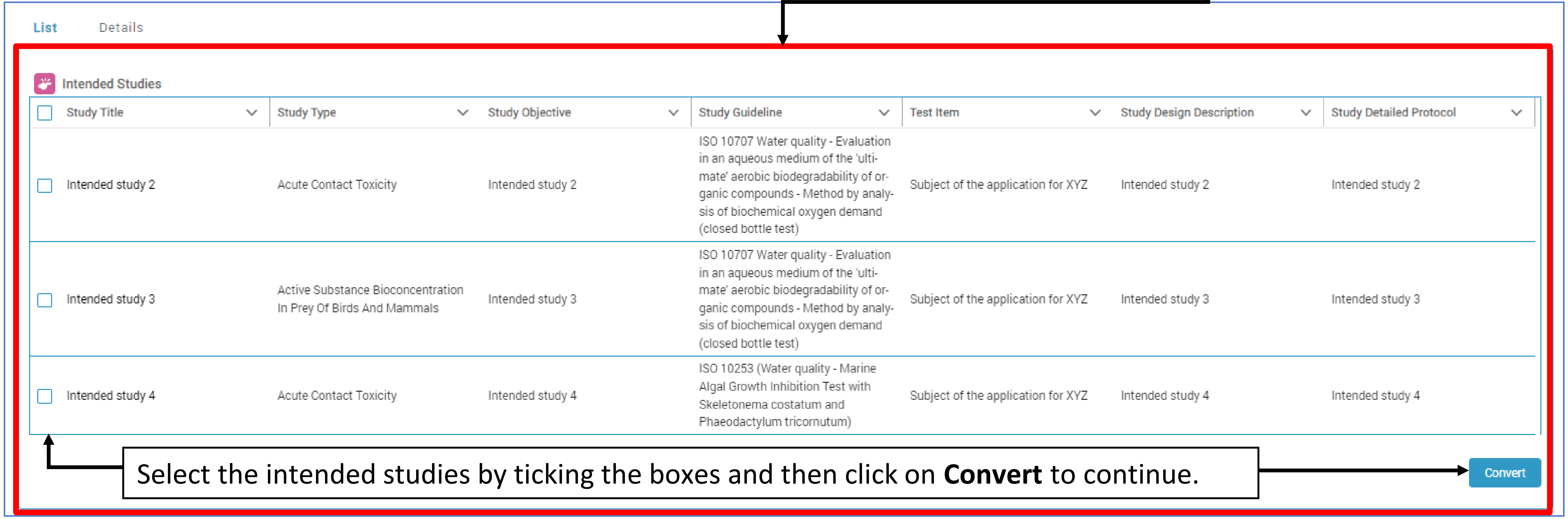
The advice and its summary can be found in the **PSA Submission Outcome** section.

3.6 Mass conversion of intended studies

Intended studies that are going to be commissioned can be converted into draft notifiable studies (for notifications according to Article 32b of the General Food Law) when the status of the list is “Draft”, “Clarification Needed” and “Closed”. Users can use the **Mass Conversion** button from the List tab to select which studies need to be converted. The same rules of the [conversion of single intended studies]apply.



The user clicks on **Mass Conversion** and a dedicated selection window appears.



Study Title	Study Type	Study Objective	Study Guideline	Test Item	Study Design Description	Study Detailed Protocol
Intended study 2	Acute Contact Toxicity	Intended study 2	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)	Subject of the application for XYZ	Intended study 2	Intended study 2
Intended study 3	Active Substance Bioconcentration In Prey Of Birds And Mammals	Intended study 3	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)	Subject of the application for XYZ	Intended study 3	Intended study 3
Intended study 4	Acute Contact Toxicity	Intended study 4	ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum)	Subject of the application for XYZ	Intended study 4	Intended study 4

Select the intended studies by ticking the boxes and then click on **Convert** to continue.

3.6 Mass conversion of intended studies

Convert

Once the users clicks on Convert, a message appears.

List | Details

Do you want to proceed with Study Conversion?

Click again on **Convert** to continue or **Cancel** to go back.

Cancel | Convert

Pre-Application ID
Renewal application for XYZ

Edit | New Study | New List

ID
EFSA-ID-2022-000646

Details | History

Request Name
Renewal application for XYZ

ID
EFSA-ID-2022-000646

Business Operator
ABC Company Spa

Contact Name

Details

Subject Of The Application
Subject of the application for XYZ

Food Domain
Feed Additives

Former Application ID
0000001

Authorisation Type
Feed Additives

Note

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

Converted studies (in draft) can be found in the **Study Notification** section of the pre-application ID page.
Click on **View All** for a complete view.

Study Notification (3)

Study Title	EFSA Study Iden...	Status	Study Withdrawn
Intended study 1	EFSA-2022-0000...	Draft	
Intended study 2	EFSA-2022-0000...	Draft	
Intended study 3	EFSA-2022-0000...	Draft	

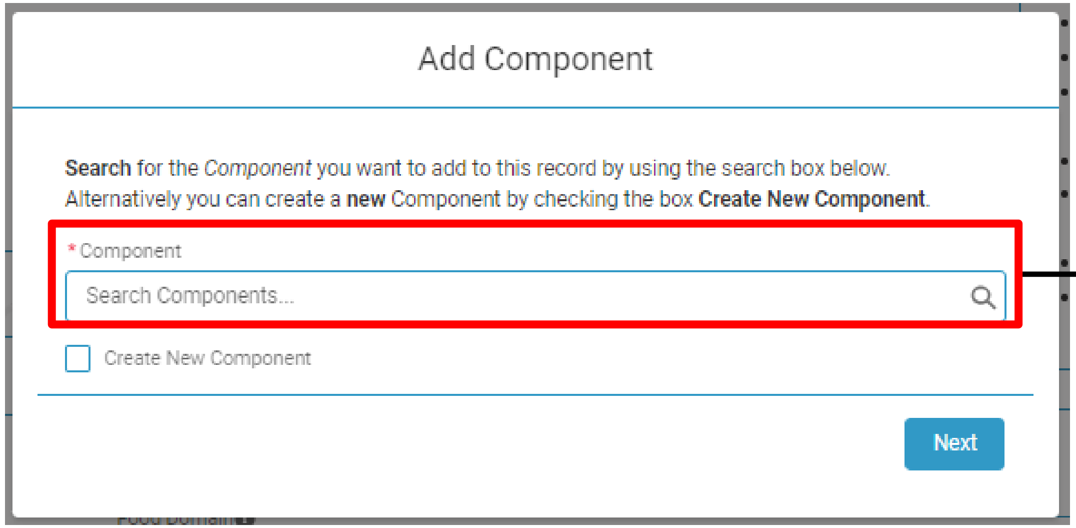
View All

3.7 Add a component

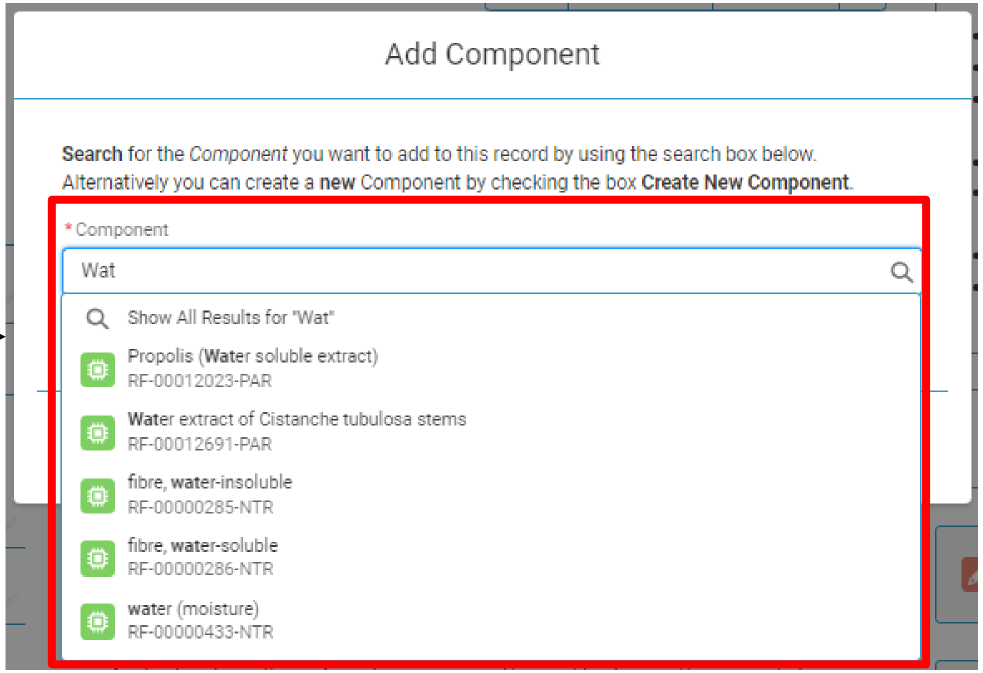
New!

Component(s) can be added to a pre-application ID to give more information about the subject of the application.

The user clicks on the **“Add Component”** button right-hand side of the pre-application ID page.



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

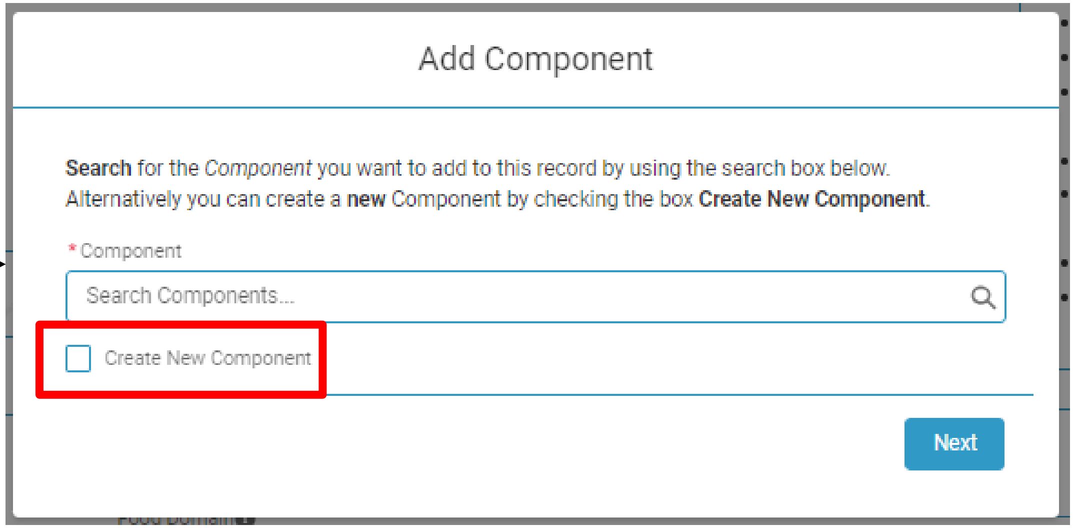


Type at least three letters of the component name to find all the related results. To expand the search results click on “Show All Results for …”.

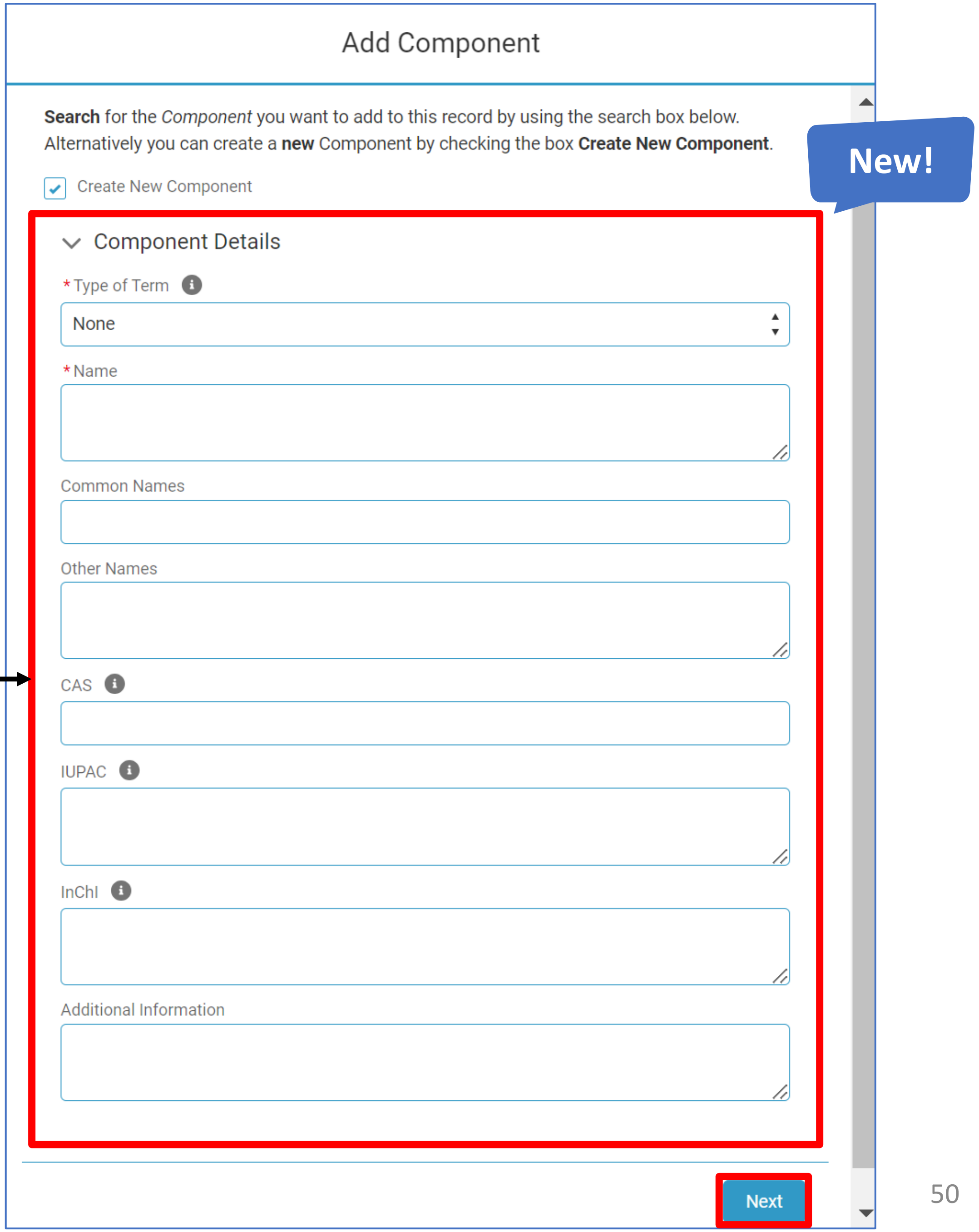
Select one of the results and click on **Next** to continue. The added component appears in the related list **Subject of the application: Components** in the pre-application ID page**.**

3.7.1 Create a new component

If a component is not retrievable using the search function, the user checks the box “Create New Component” in the “Add Component” pop-up window.



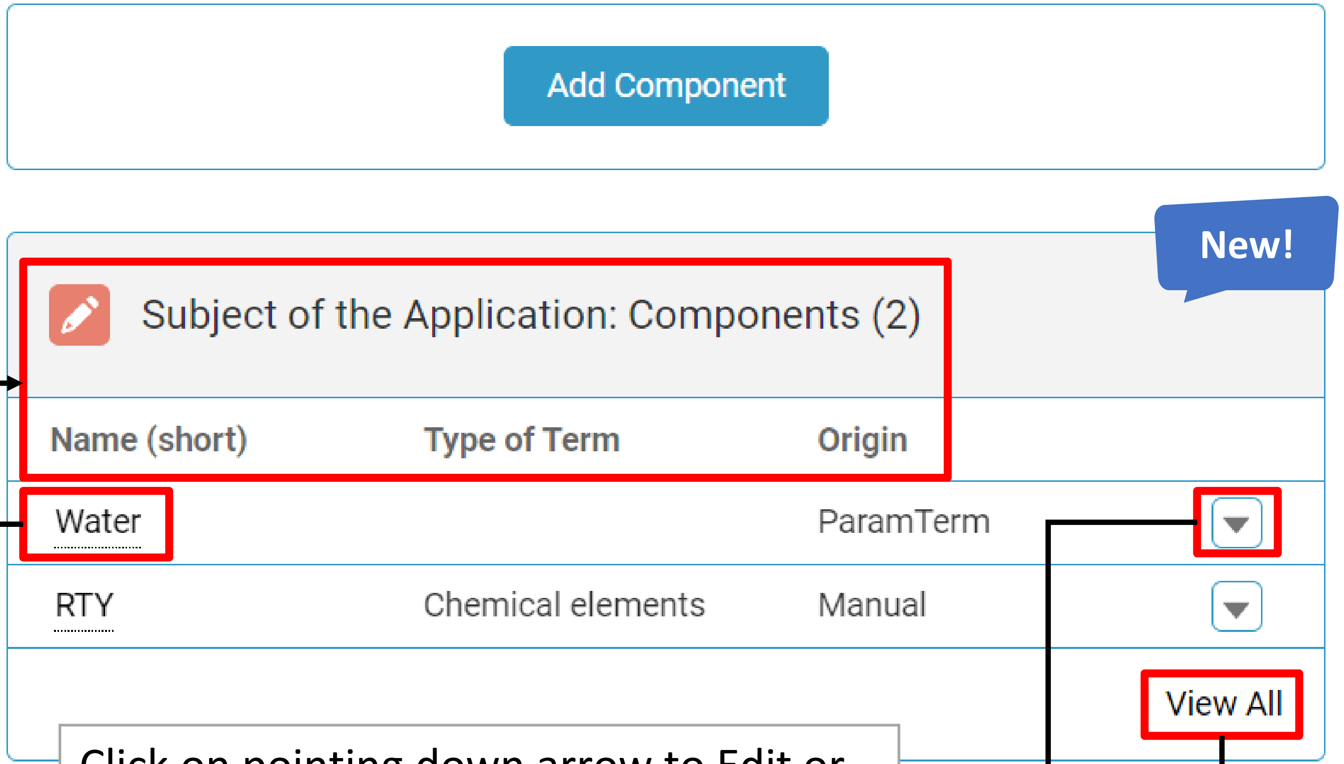
Fill in the “Component Details” form with the corresponding information. The fields “Type of Term” and “Name” are mandatory. More details on the information required by a certain field are showed by passing over the ⓘ icons. Click **Next** to continue.



The newly created component appears in the related list **Subject of the application: Components** in the pre-application ID page.

3.7.2 Related list “Subject of the Application: Components”

Users find the components associated to a pre-application ID in the related list **“Subject of the Application: Components”**. For easier identification of the listed components, additional fields (e.g. Name, Type of Term, Origin) are available.



Click on the name of the component to open the corresponding **details page**.

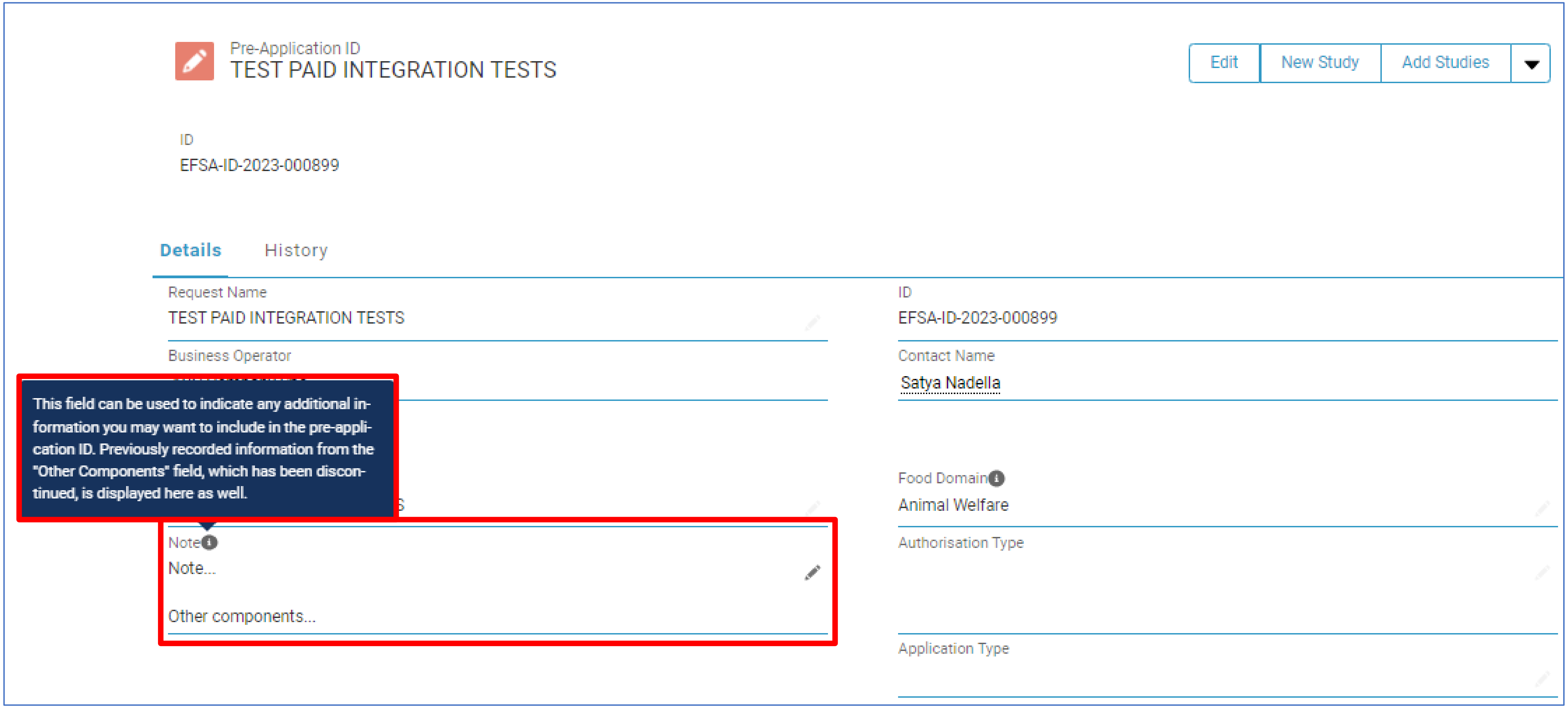
Click on pointing down arrow to Edit or **Delete** the component from the list.

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 Note field and Other Components

New!

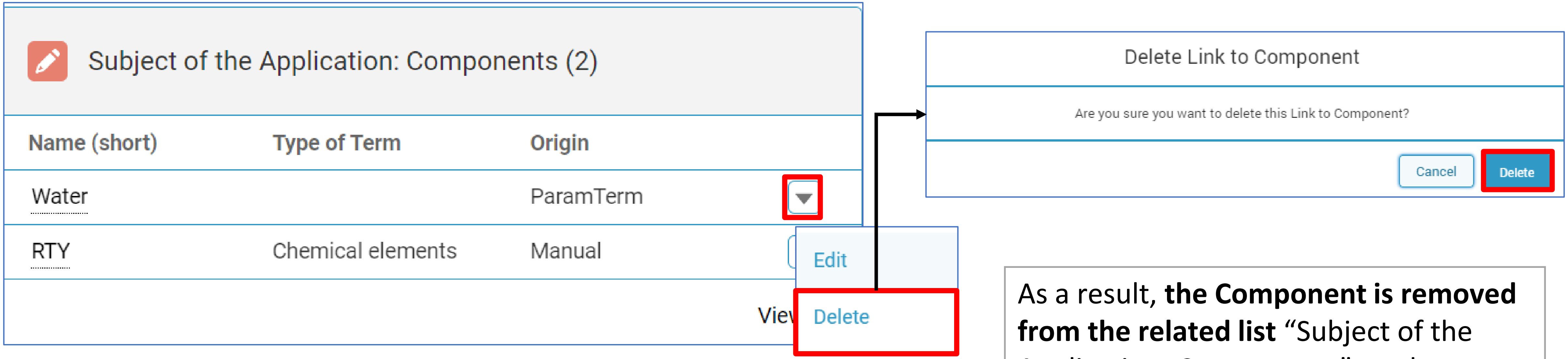
The “Other Components” field was discontinued, the data previously contained, if any, is now available in the “Note” field. Users can modify such data or decide to [create a component]() to be linked to the pre-application ID.



3.7.4 Delete link to components

Updated!

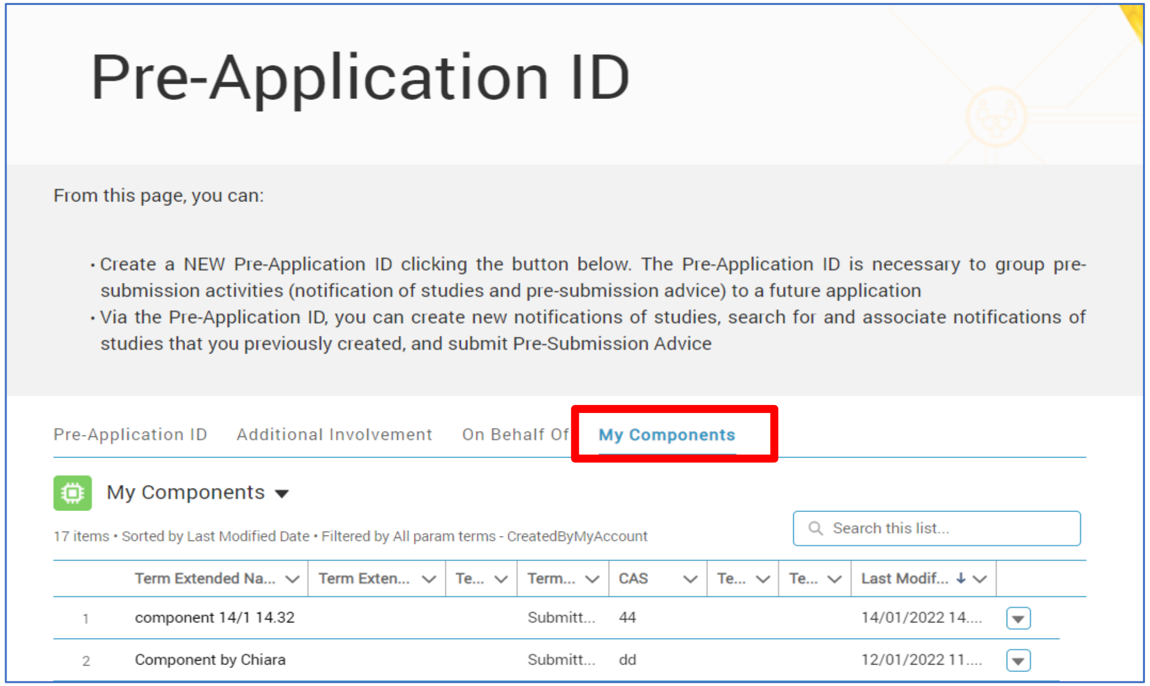
The user can **always** remove Components from the pre-application ID. By performing this action, the user will delete only the link between the pre-application ID and the Component, **not the Component itself.**

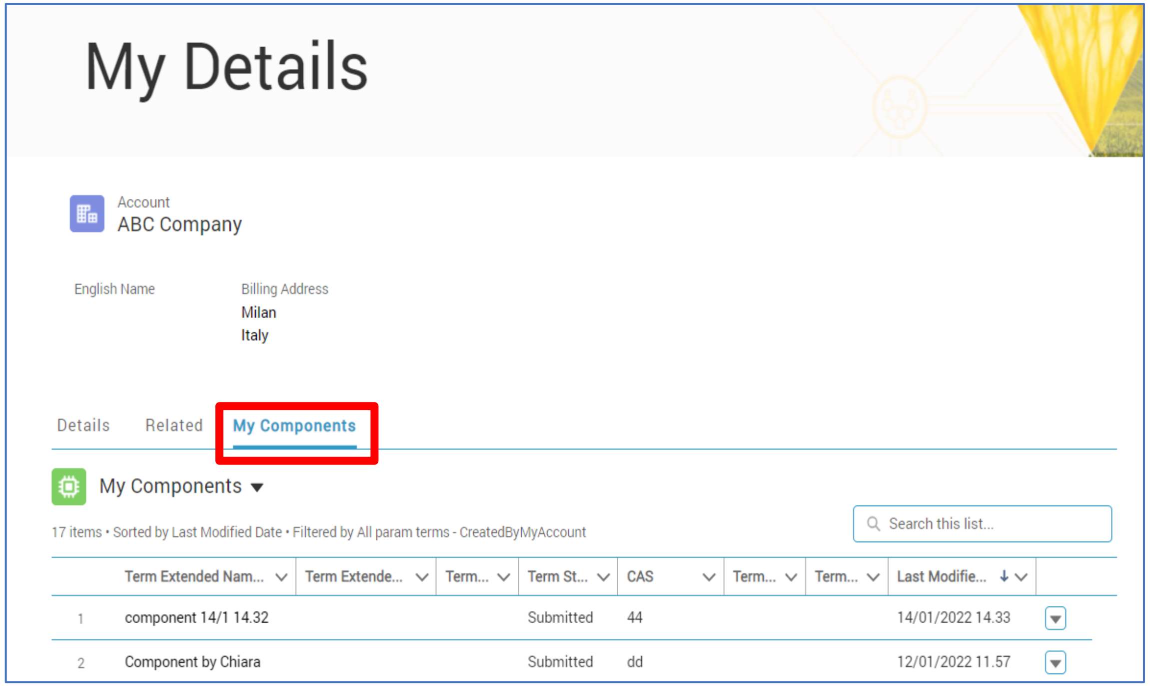


As a result, **the Component is removed from the related list** “Subject of the Application: Components” on the pre-application ID page.

3.7.5 View Components

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

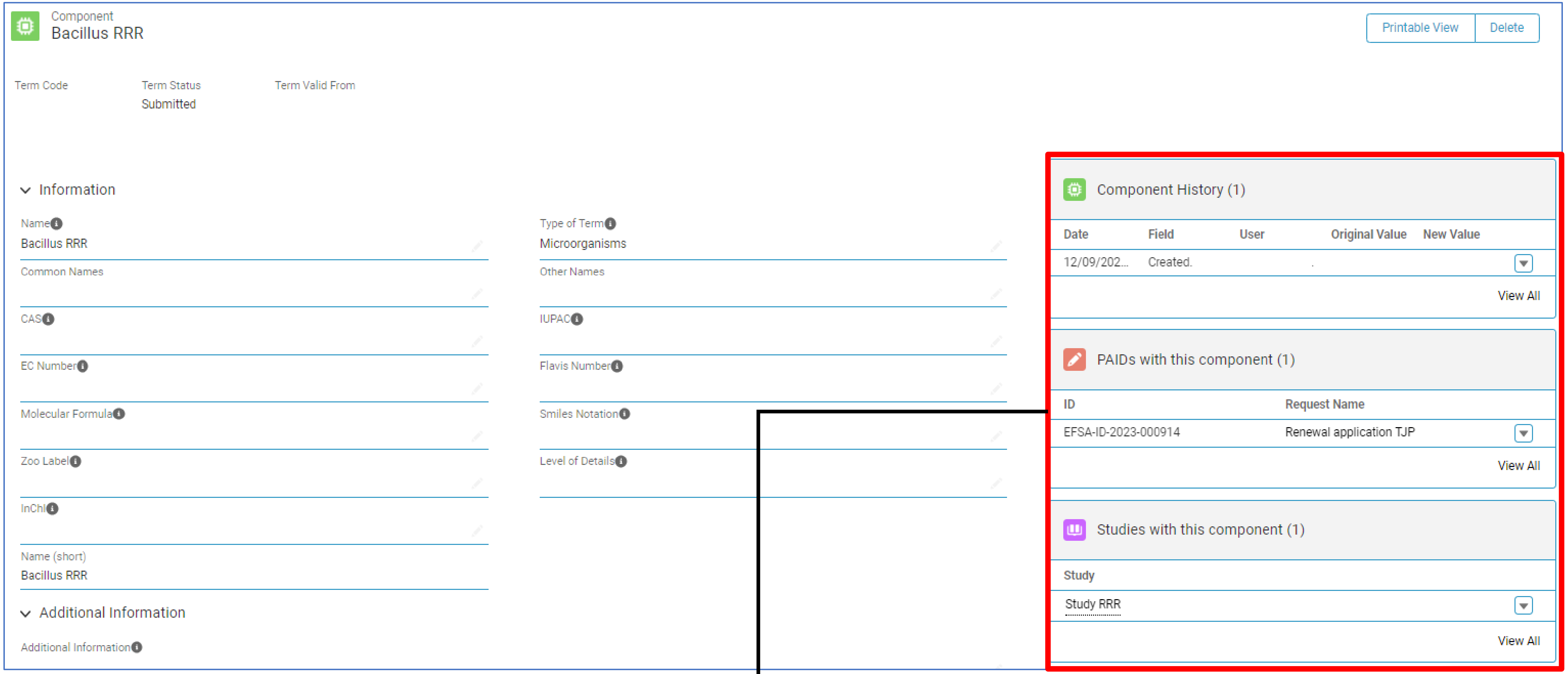




3.7.6 Component details page

Updated!

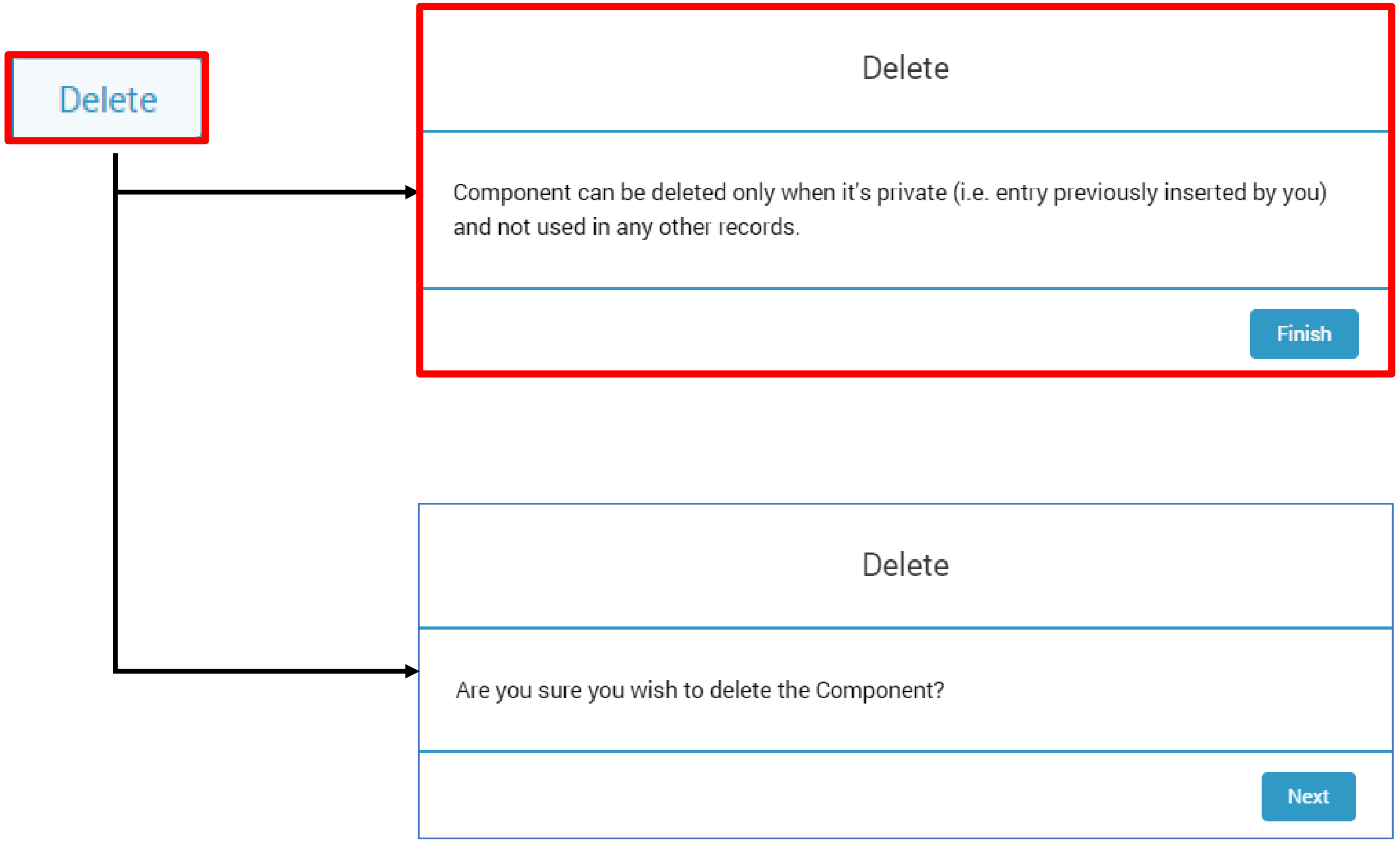
The detail page of the component appears as in the image below. Information on the component can be added/modified directly from this page only for components created by the user.



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 Delete Components

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

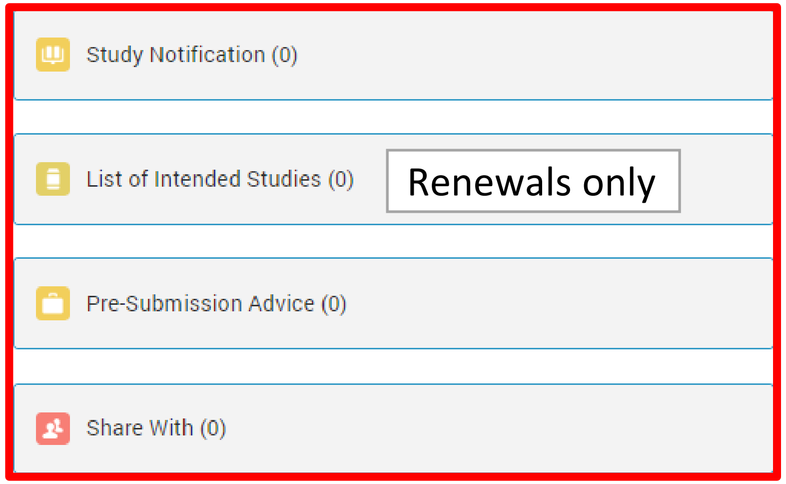


This **error message** appears if the component is used in any other record (i.e. Pre-Application IDs, Studies records).

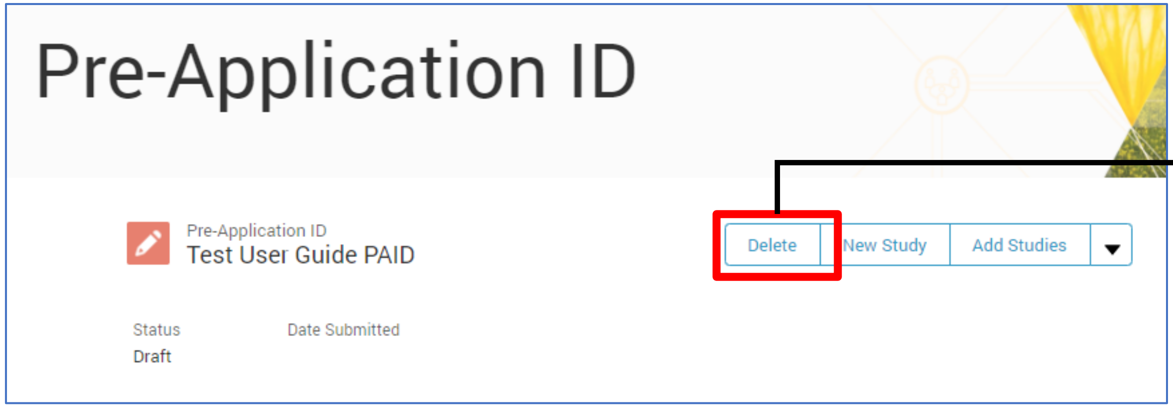
To delete the component, the user must firstly remove all the existing links with the other records as explained in the previous slides.

3.8 Delete a pre-application ID

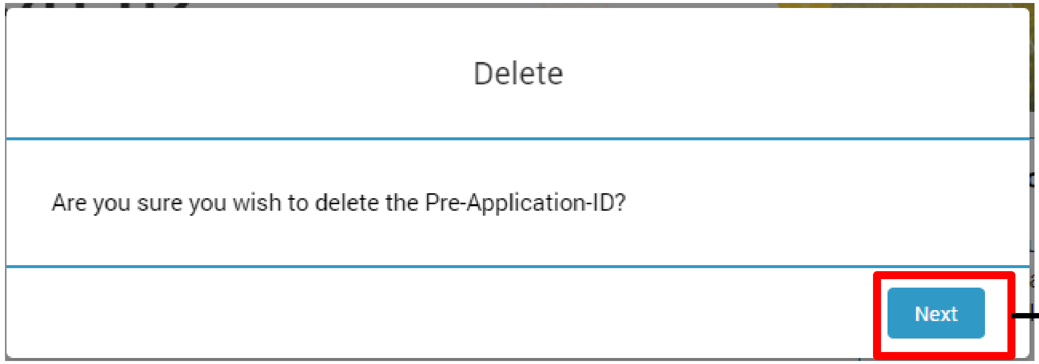
Users can delete a pre-application ID only when there are no records associated, such as notified studies, list of intended studies or general pre-submission advice.



If the above conditions are not fulfilled, the system will return an **error message**.



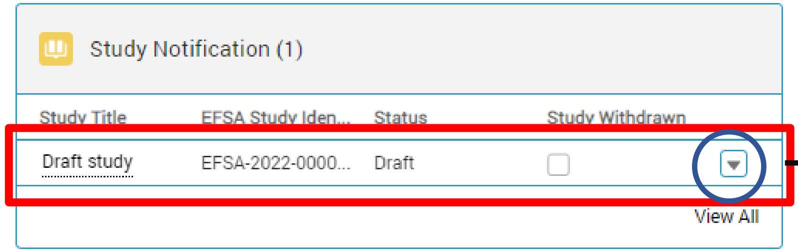
In the pre-application ID page, click on the function button **Delete.**

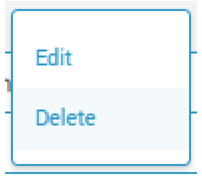


Users must click on **Next** to confirm the deletion.

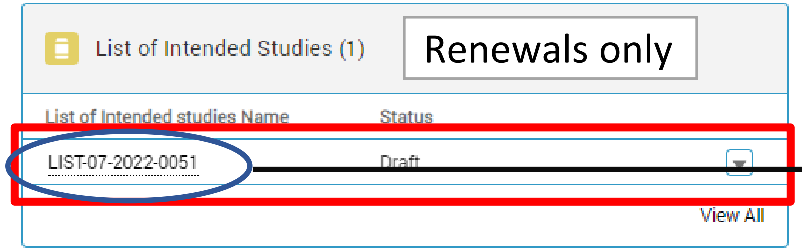
3.8.1 Delete a pre-application ID and/or remove relationships and draft objects

If a pre-application ID is associated with **draft objects,** such as **studies or general pre-submission advice** request(s), the user must first remove all the associations to be able to delete the pre-application ID record.

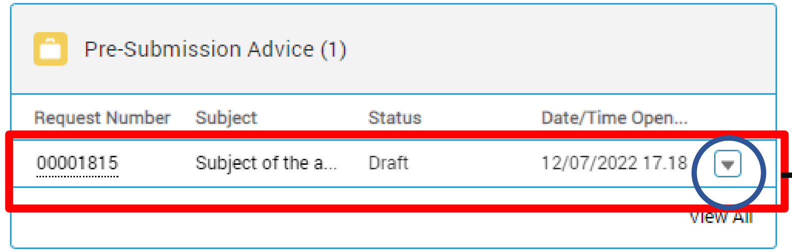


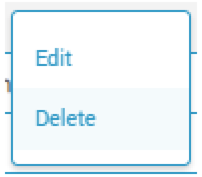


Select **Delete** to remove the draft study from the pre-application ID. This action will not delete the study itself.
Notified and co-notified studies cannot be removed.

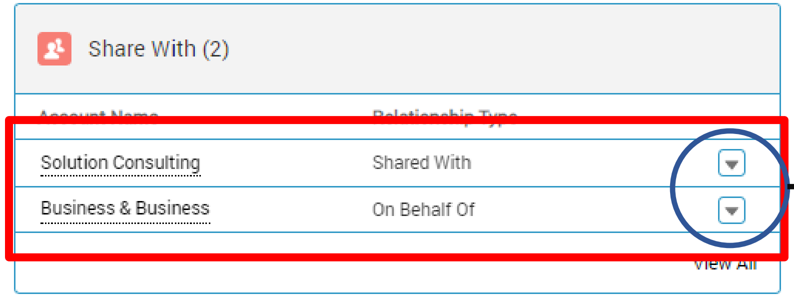


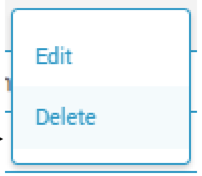
Click on the list name to open the list of intended studies page. **Only empty list of intended studies can be deleted.** Intended studies associated with the list **can be deleted only** when the status corresponds to “**Draft**” or “**Clarification Needed**“.





Select **Delete** to remove the draft general pre-submission advice. Submitted general pre-submission advice will prevent deletion of the pre-application ID.

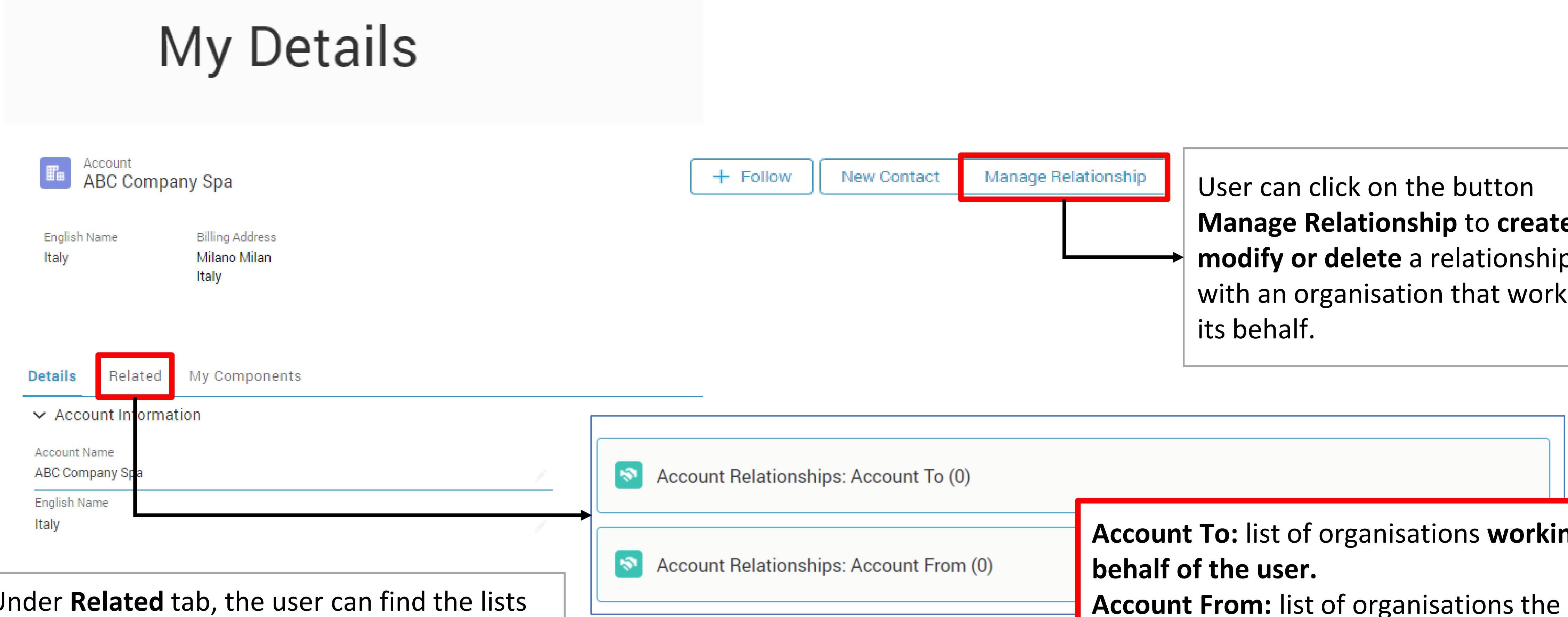




Select **Delete** to remove the relationship(s). If there are submitted records associated to the pre-application ID, **“Shared with” relationship cannot be removed.** “On behalf of” relationships can be always removed.

3.9 Account relationship(s)

When a business operator wants to commission a third-party/consultant to work on its behalf, a relationship “on behalf of” must be established at the account level in the page **My Details**.

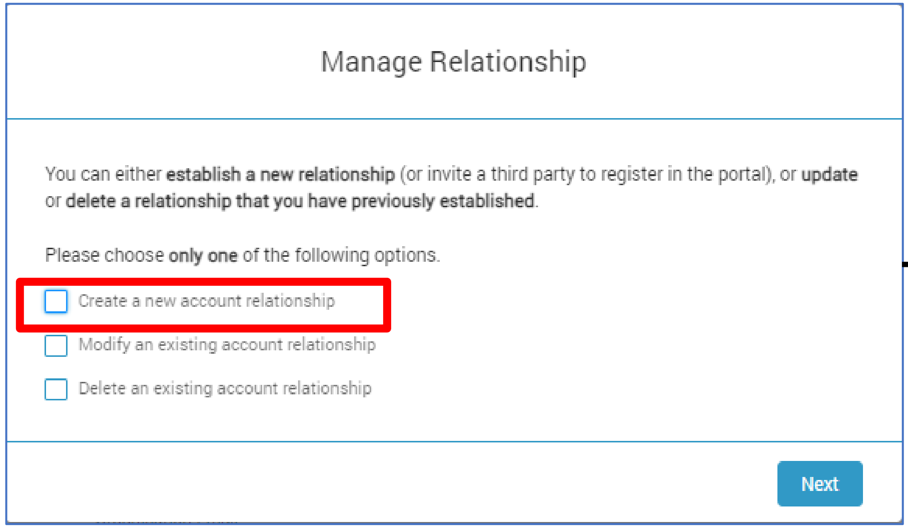


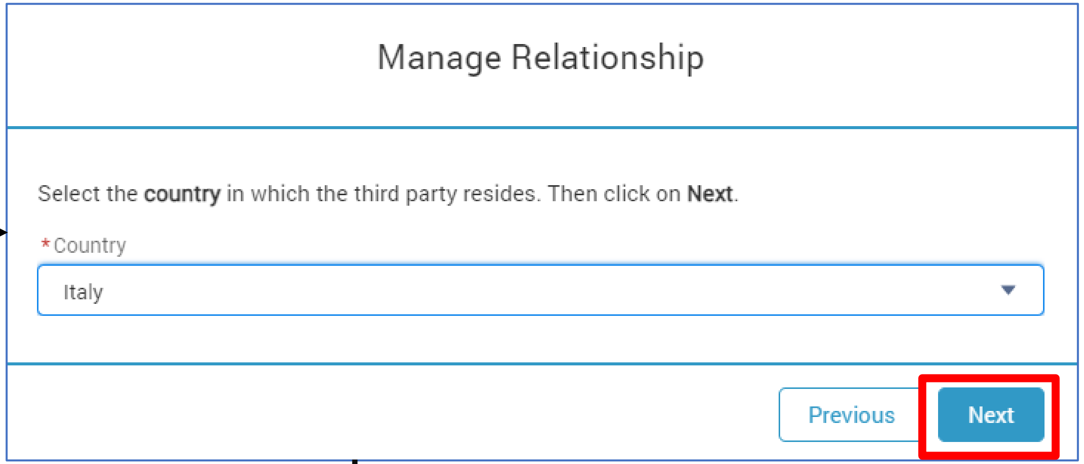
User can click on the button **Manage Relationship** to **create, modify or delete** a relationship with an organisation that works on its behalf.

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

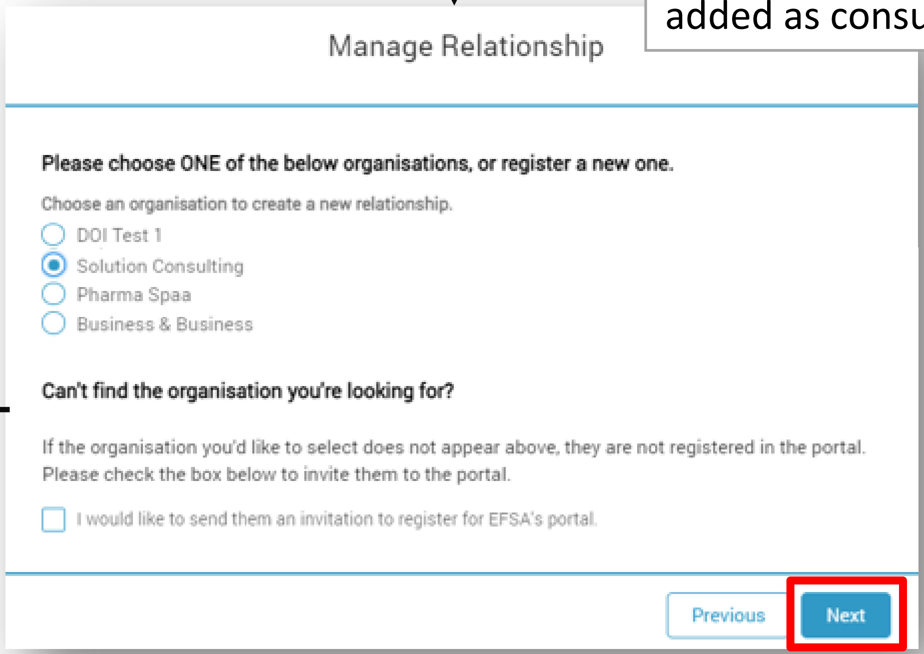
Account To: list of organisations **working on behalf of the user.**
Account From: list of organisations the user **is working on behalf of.**

3.9.1 Create an account relationship





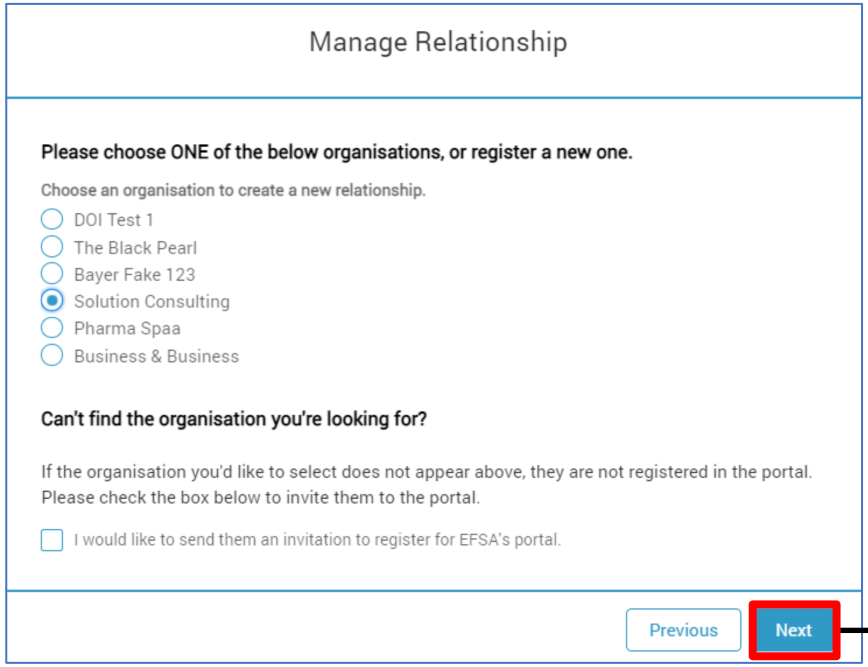
The user selects the **Country** and then **organisation** to be added as consultant.

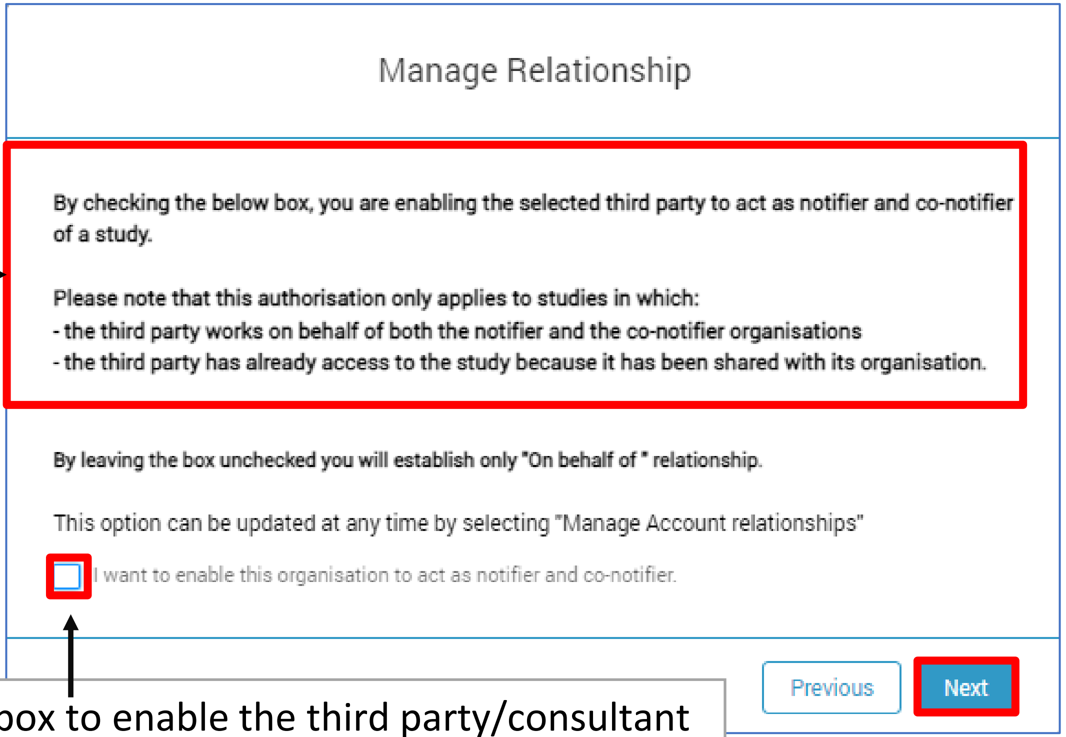


Select **Next** to continue with the guided procedure. The system will give the user the possibility to **select an optional feature, see next slide.**

3.9.1 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 Manage account relationship(s) to know more details).





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.

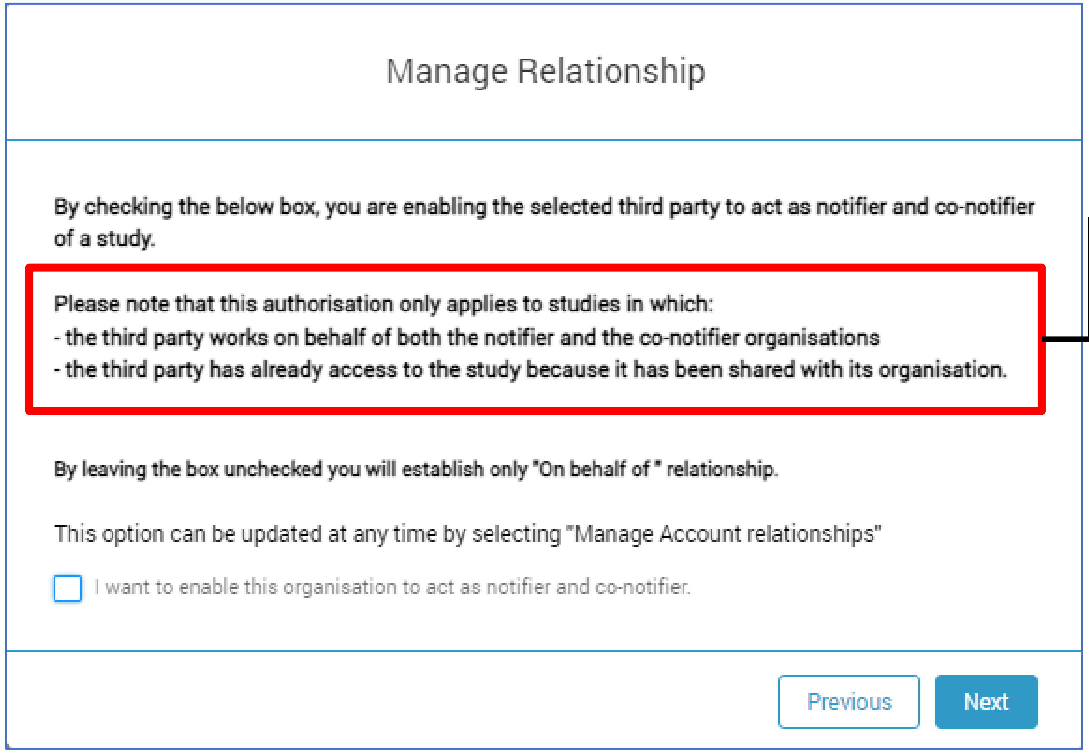
Note: a practical example of how this feature works is given in the next slide.

3.9.1 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

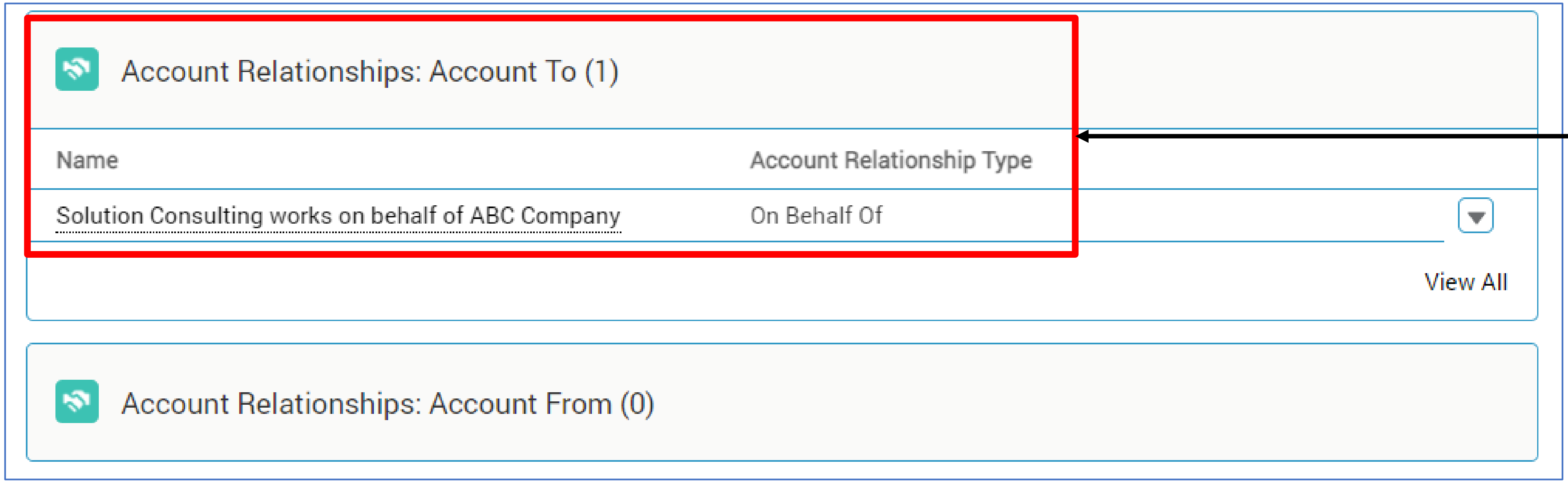
How it works:

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.

3.9.2 Manage account relationship(s)

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

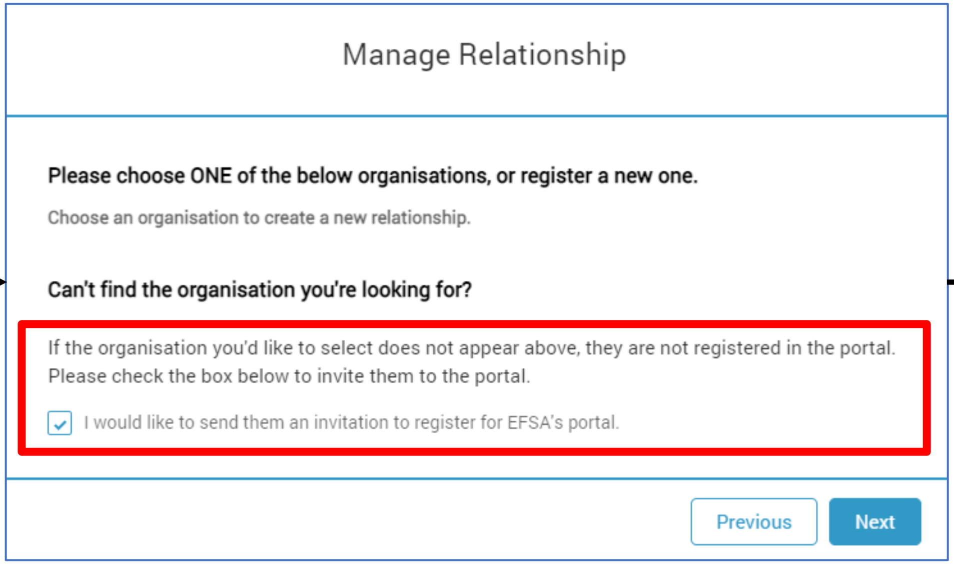


Once relationship has been established at the account level:

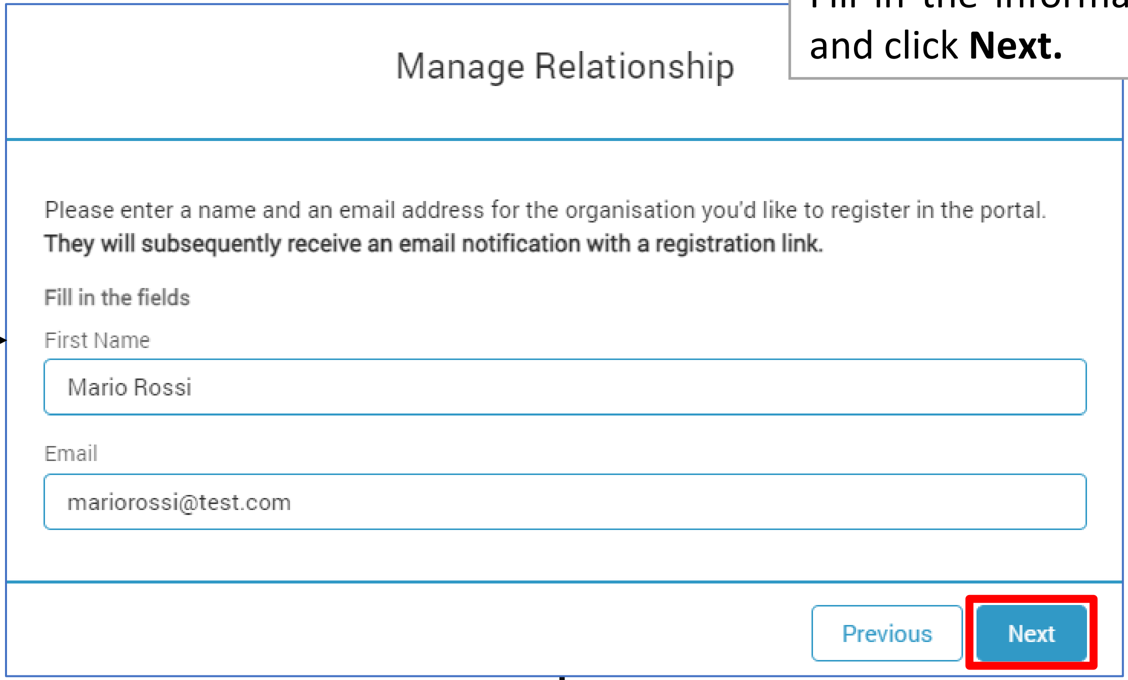
1. The business operator can **share single records** with its third party/consultant (to know more see Share pre-application ID "On behalf of")
2. The third party/consultant can create pre-application IDs and perform all associated actions for the business operator.

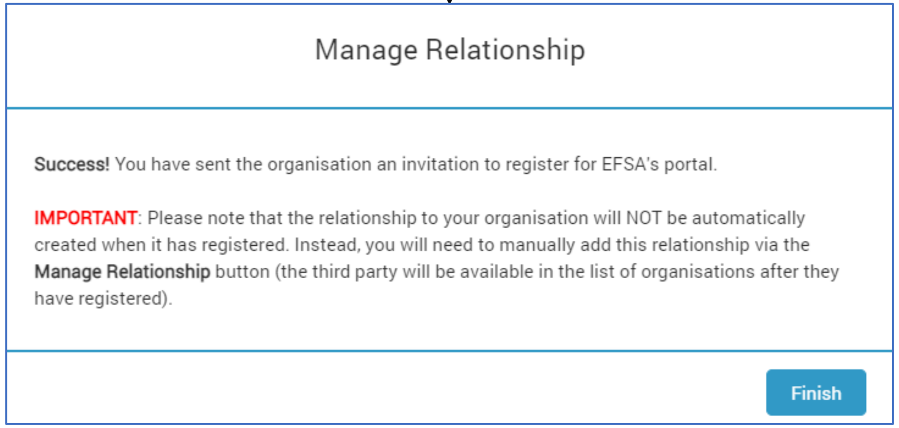
3.9.2 Manage account relationship(s)

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.



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

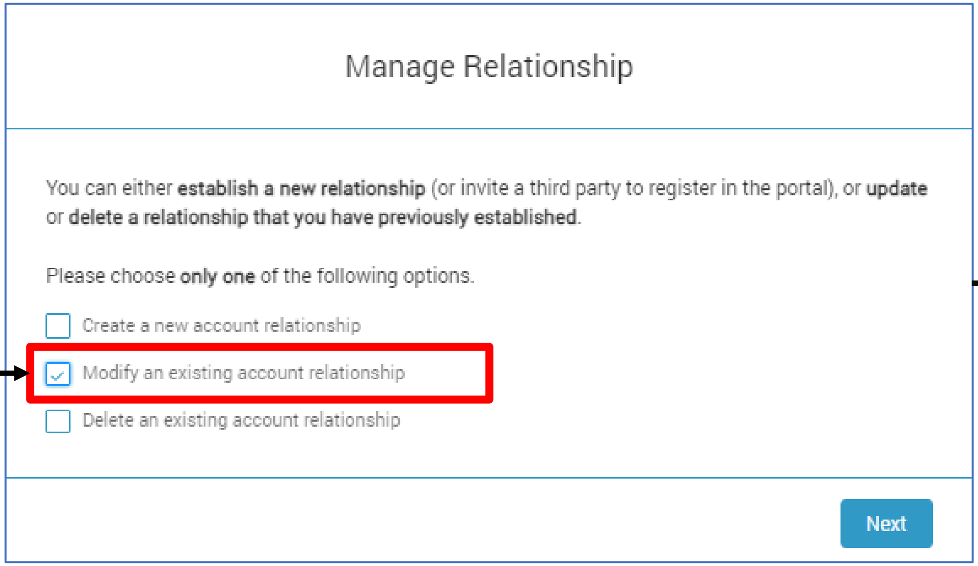




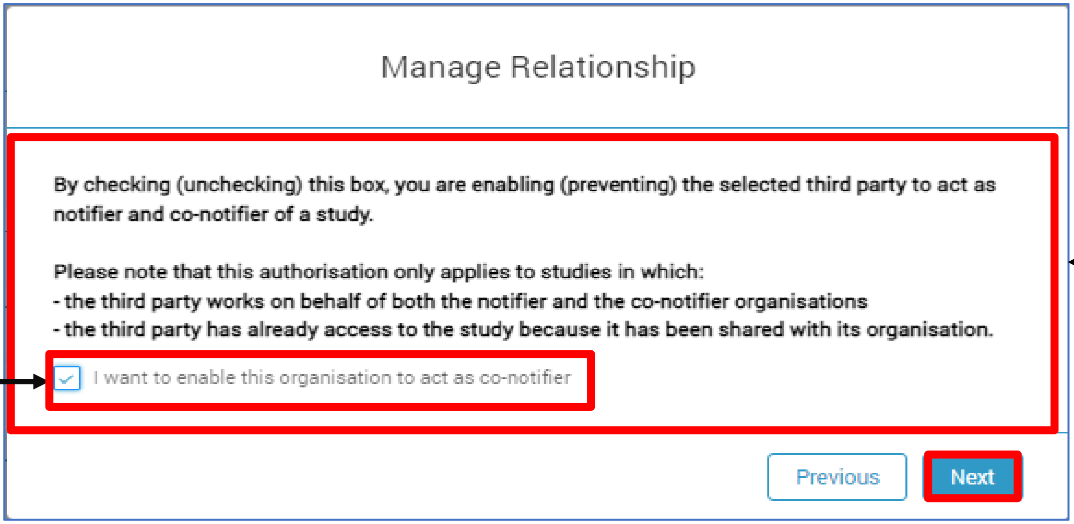
Please note that the relationship with this organisation is not automatically created upon its registration. The user needs to create the relationship once the organisation is registered.

3.9.3 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.



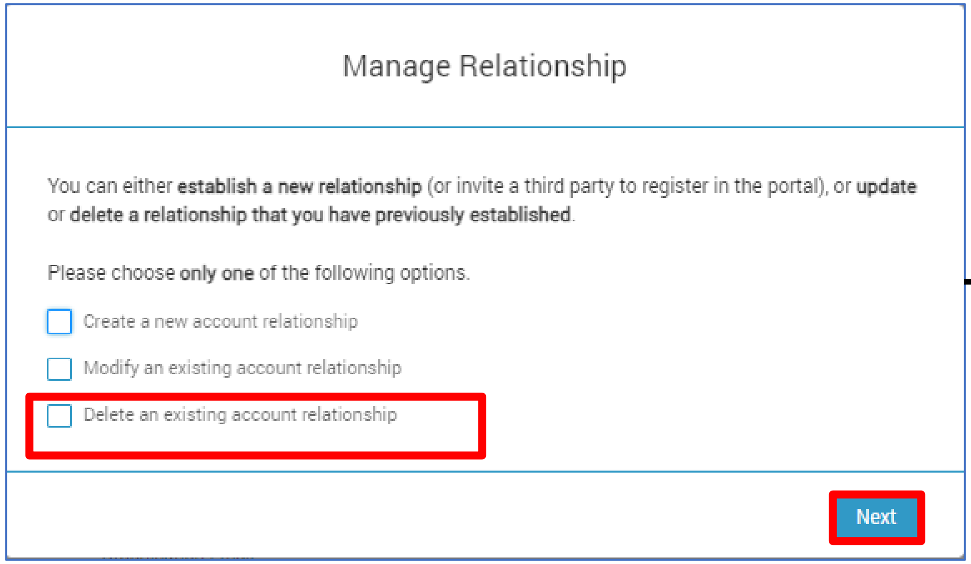
Select the third party organisation name and click on **Next**.



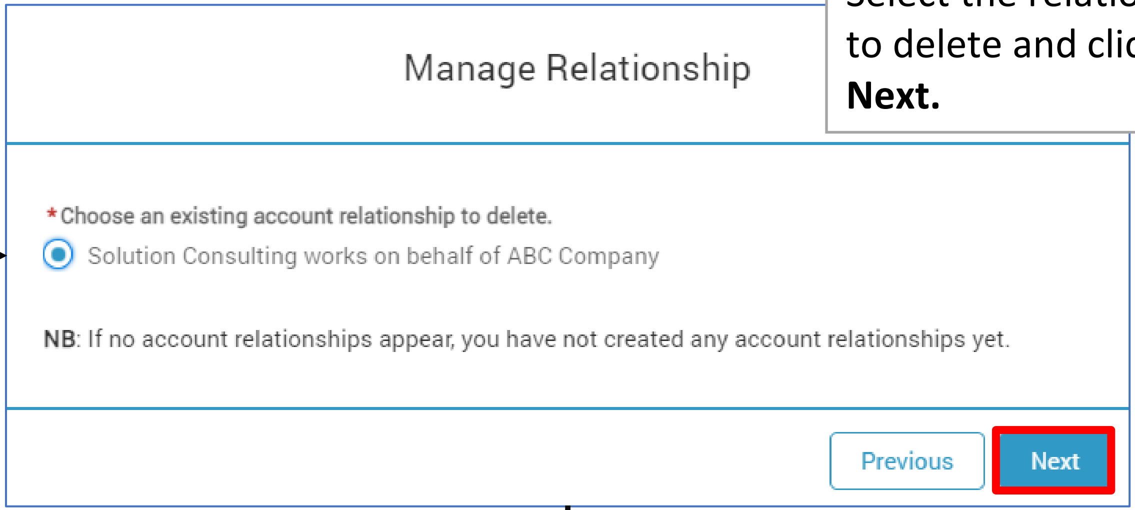
It is possible to grant or revoke this permission by checking or unchecking this box.
Click on **Next** to continue.

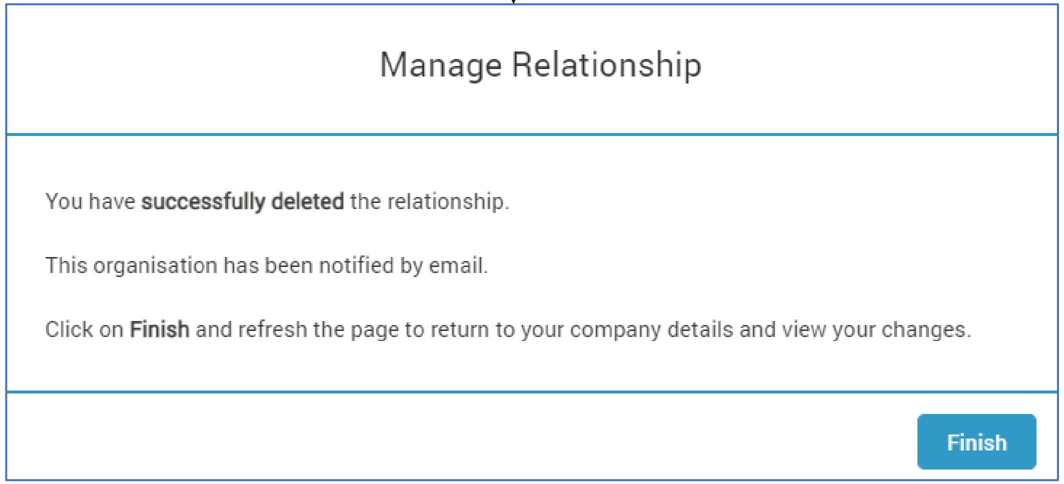
3.9.4 Delete an account relationship

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



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



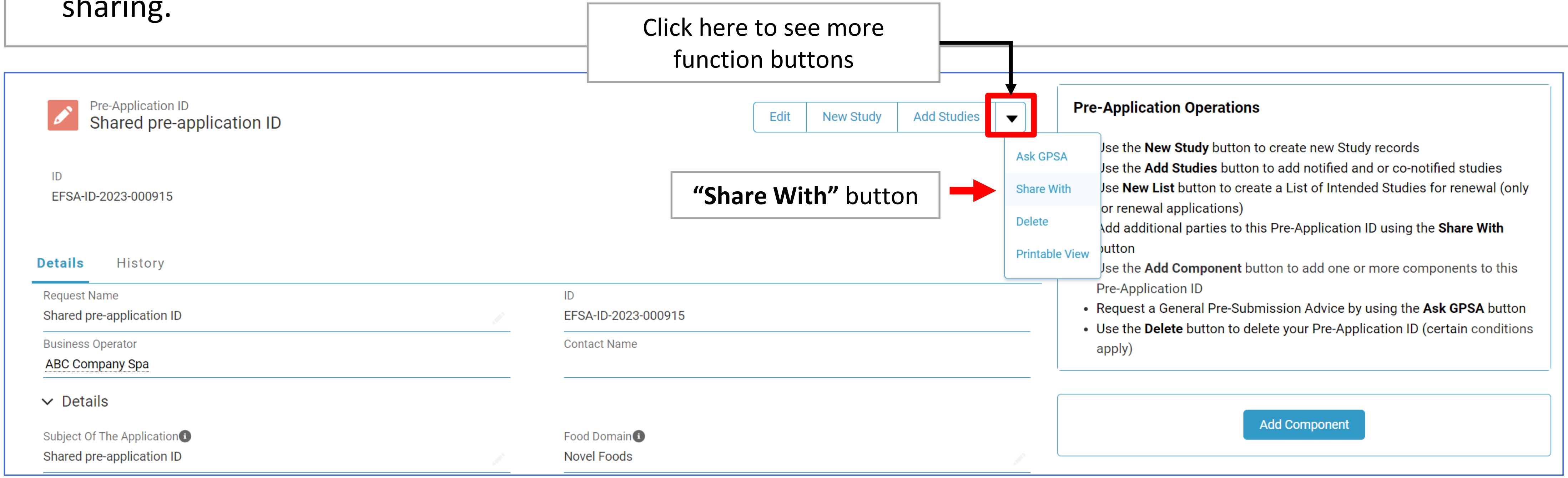


3.10 Share a pre-application ID

Business operators or **third parties/consultants** can share pre-application ID(s) with other organisations using the button **"Share With"**.

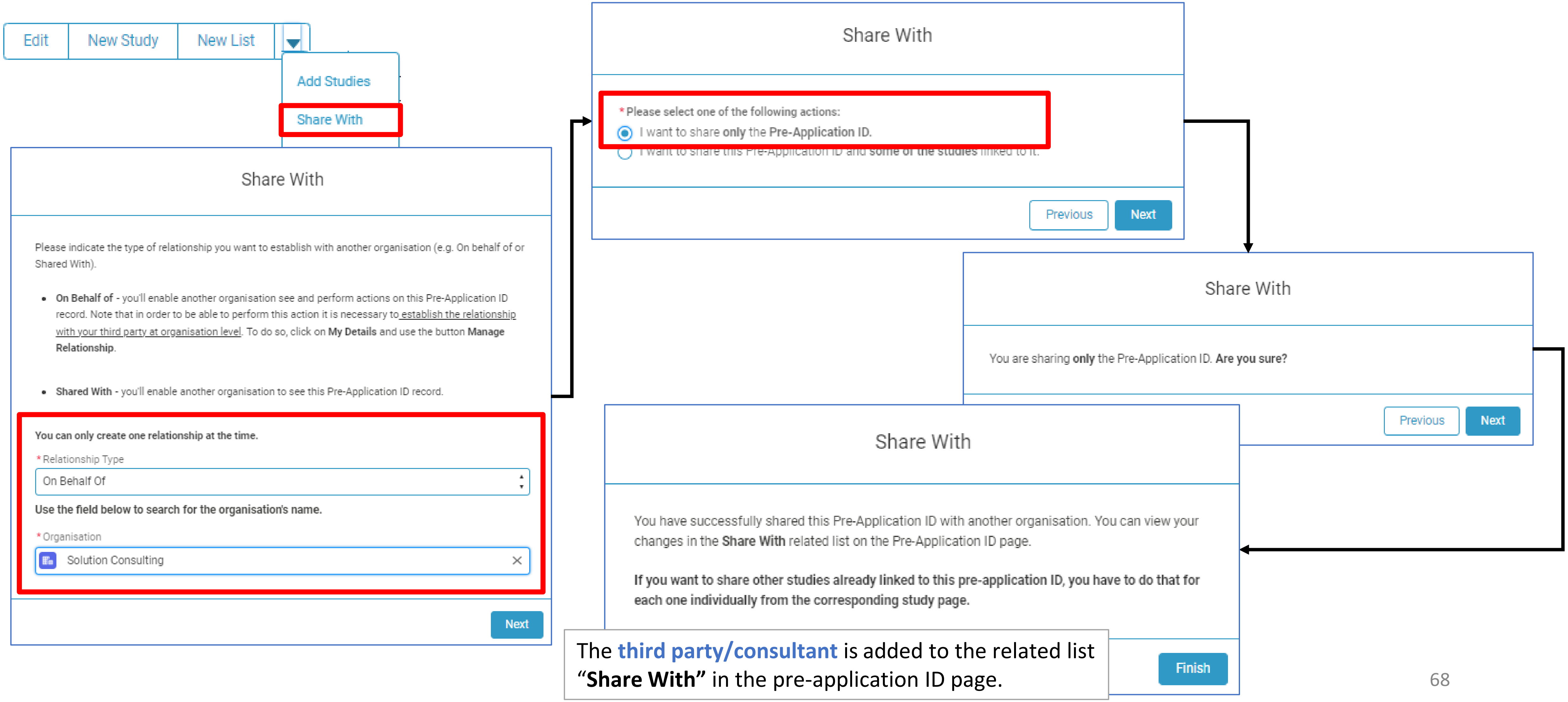
The pre-application ID(s) can be shared in two different ways:

- Relationship type: **"On behalf of"**. With the sharing type "On behalf of" users can decide to share with **third parties/consultants** only the pre-application ID or the pre-application ID along with some/all the study records already linked to it. In order to be able to perform this type of sharing, the user must establish an **account relationship** with this organisation beforehand (see Account Relationship).
- Relationship type: **"Shared with"**. In this case the user involves another organisation in the pre-submission activities and provides **read-only access** to the shared pre-application ID. No previous actions are required to perform this sharing.



3.10.1a Share a pre-application ID "On behalf of" – *without studies*

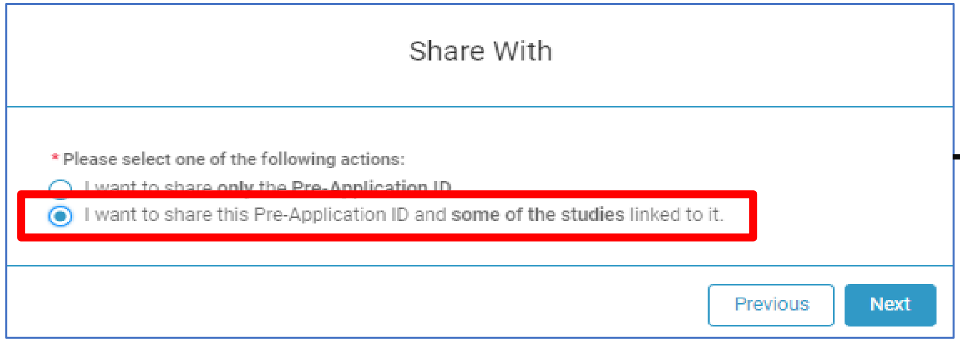
To share only the pre-application ID (without any of the linked studies), the user chooses the sharing type "On behalf of" and the name of the **third party/consultant**, then checks the box corresponding to "**I want to share only the pre-application ID**".

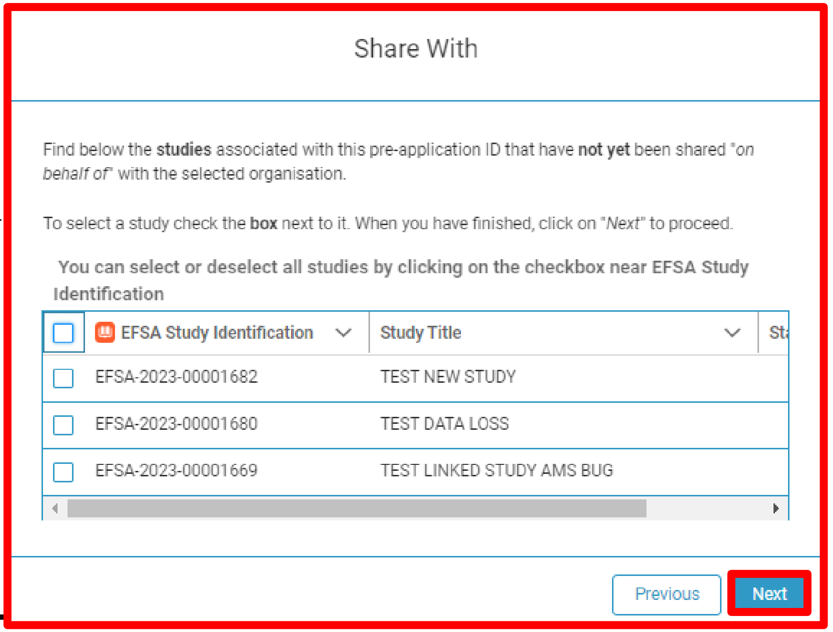


The **third party/consultant** is added to the related list "**Share With**" in the pre-application ID page.

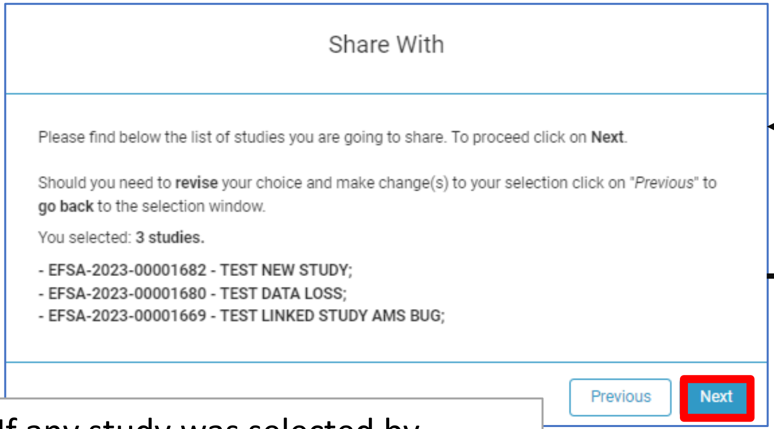
3.10.1b Share a pre-application ID "On behalf of" – *with studies*

To share both **pre-application ID and also some/all the studies already linked to it**, the user chooses the sharing type "On behalf of" and the name of the **third party/consultant**, as showed in the previous slide, then checks the box corresponding to "**I want to share this pre-application ID and some of the studies linked to it**".

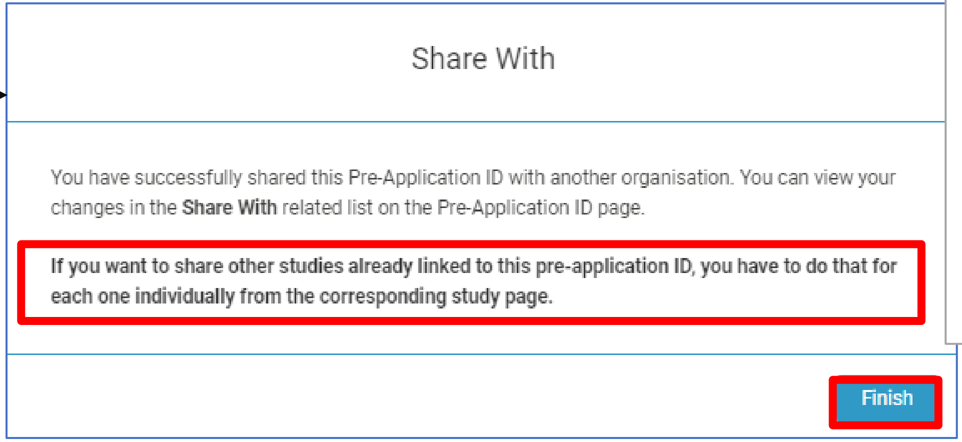




The system displays only the studies that have not been shared yet with the selected third party/consultant.



If any study was selected by mistake, click on **Previous** to edit the selection.



The **third party/consultant** is added to the related list "**Share With**" in the pre-application ID page.

Note: The user cannot repeat the sharing procedure by selecting the same **third party/consultant** to share additional studies.

3.10.1 Share a pre-application ID "On behalf of"

Share With

Share With

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

- **On Behalf of** - you'll enable another organisation see and perform actions on this Pre-Application ID record. Note that in order to be able to perform this action it is necessary to establish the relationship with your third party at organisation level. To do so, click on **My Details** and use the button **Manage Relationship**.
- **Shared With** - you'll enable another organisation to see this Pre-Application ID 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

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

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 Detail** in the navigation menu, click the button **Manage Relationship** and follow the instruction

Finish

3.10.1 Share a pre-application ID "On behalf of"

Actions allowed to business operator or a third party/consultant for a pre-application ID shared using the relationship type **"On behalf of":**

1. View and edit the pre-application ID information*
2. Create new studies or add already existing studies to the pre-application ID
3. View and edit the studies that have been shared with the pre-application ID**
4. Create, edit and submit a list of intended studies (for renewals only)
5. Manage the intended studies associated to a list (for renewals only)
6. View and add components
7. Share the pre-application ID with other business operators

*if the pre-application ID contains already a list of intended studies, this will also be shared and editable by the consultant who will be able to submit it as well.

**studies previously created/added need to be shared following the procedure described in Section 3.10.1b.

3.10.2 Share a pre-application ID "Shared with"

Share With

The user chooses the relationship type **"Shared with"** to enable another organisation to **only view** the pre-application ID.

Share With

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

- **On Behalf of** - you'll enable another organisation see and perform actions on this Pre-Application ID record. Note that in order to be able to perform this action it is necessary to establish the relationship with your third party at organisation level. To do so, click on **My Details** and use the button **Manage Relationship**.
- **Shared With** - you'll enable another organisation to see this Pre-Application ID 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

Business & Business

Next

The user searches and selects the organisation name to share the pre-application ID with and clicks **Next**.

Share With

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

If you want to share other studies already linked to this pre-application ID, you have to do that for each one individually from the corresponding study page.

Finish

The organisation is added to the related list **Share With** in the pre-application ID page.

Share With (2)

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

View All

3.10.2 Share a pre-application ID “Shared with”

Actions allowed to **business operator** or a **third party/consultant** for a pre-application ID shared using the relationship type **“Shared with”**:

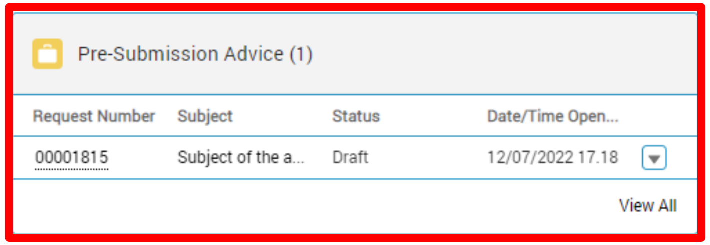
1. See the pre-application ID information
2. View the list of intended studies and all the information contained in its page (renewals only)
3. View components added to the pre-application ID
4. View **only** studies created/added after the record was shared*

*studies previously created/added need to be shared one by one.

3.11 General pre-submission advice (GPSA)

Users can request a general pre-submission advice from the pre-application ID by using the dedicated button **Ask GPSA**, **at any moment** prior the submission of the application. **This action is the same for new and renewal applications.**

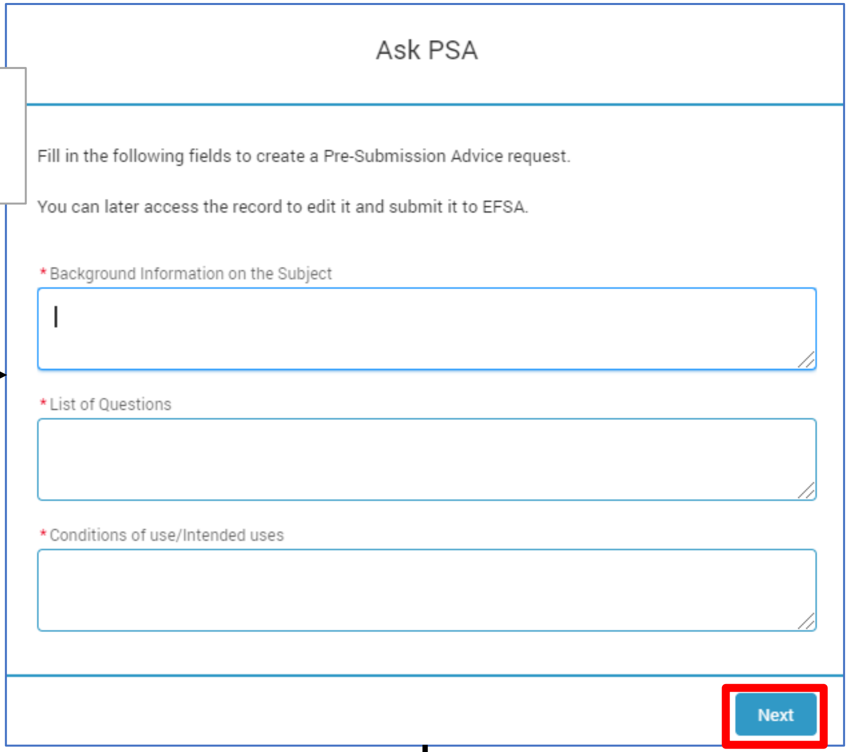
The user can access the GPSA request(s) at any time from the dedicated section in the pre-application ID page.



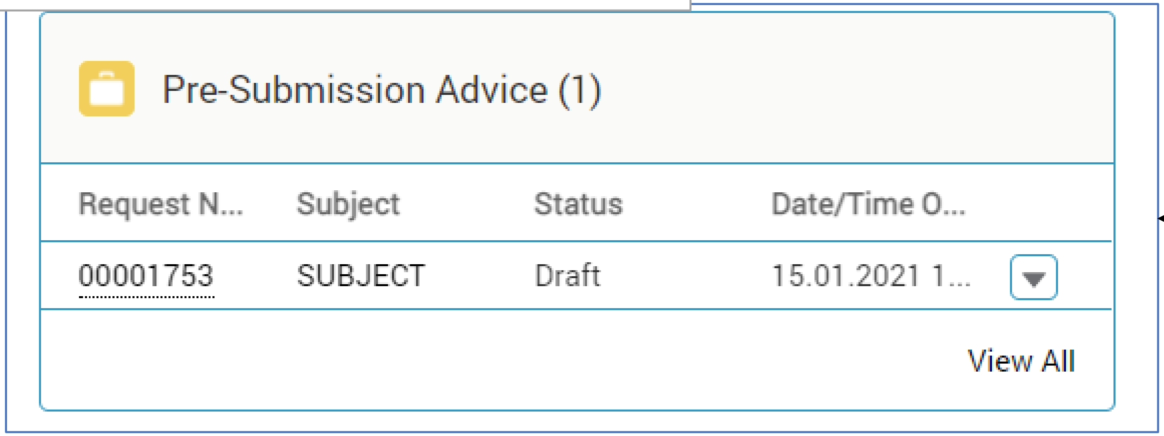
Suggested video tutorial: request general pre-submission advice

3.11.1 Request a GPSA

Fill in the information and click **Next** to create the GPSA request in draft status.



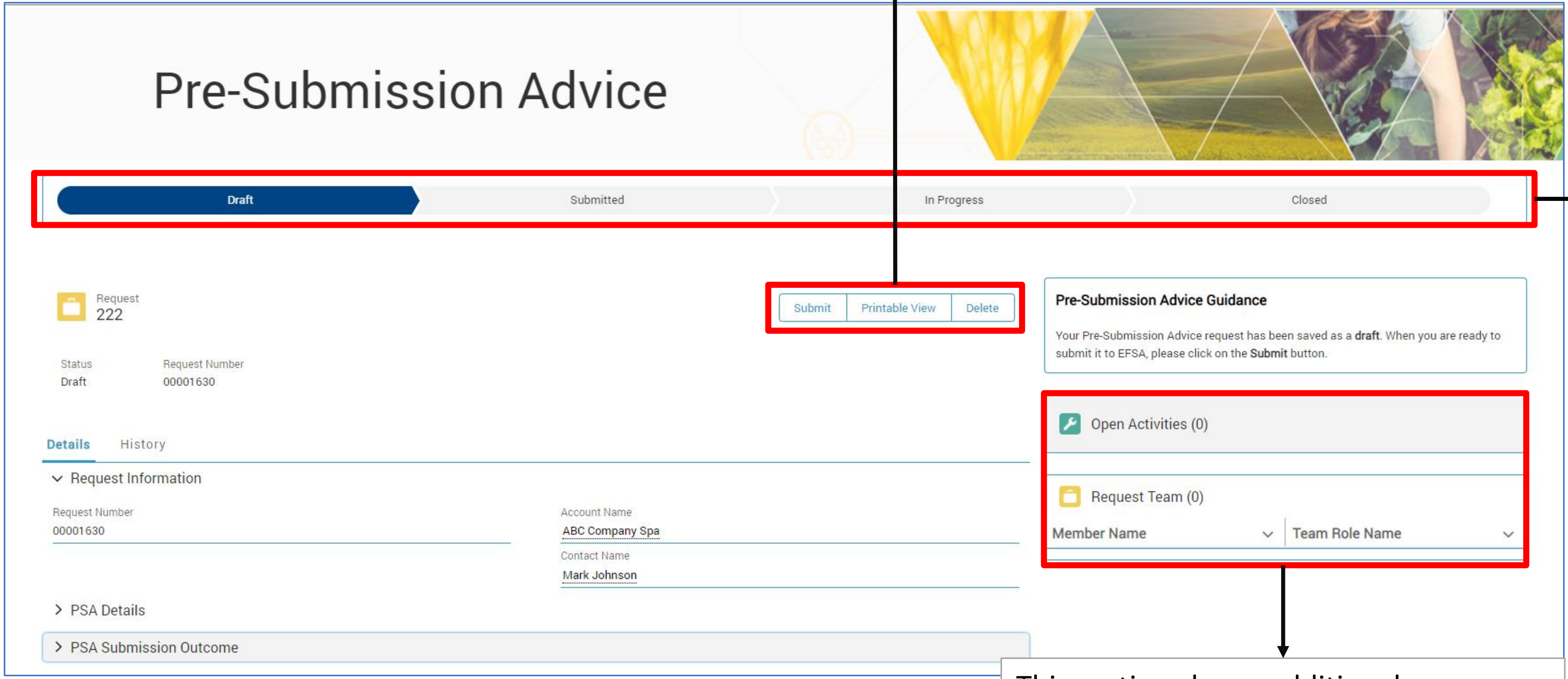
The GPSA request will appear and be accessible from the related list **pre-submission advice** on the pre-application ID.



3.11.1 Request a GPSA

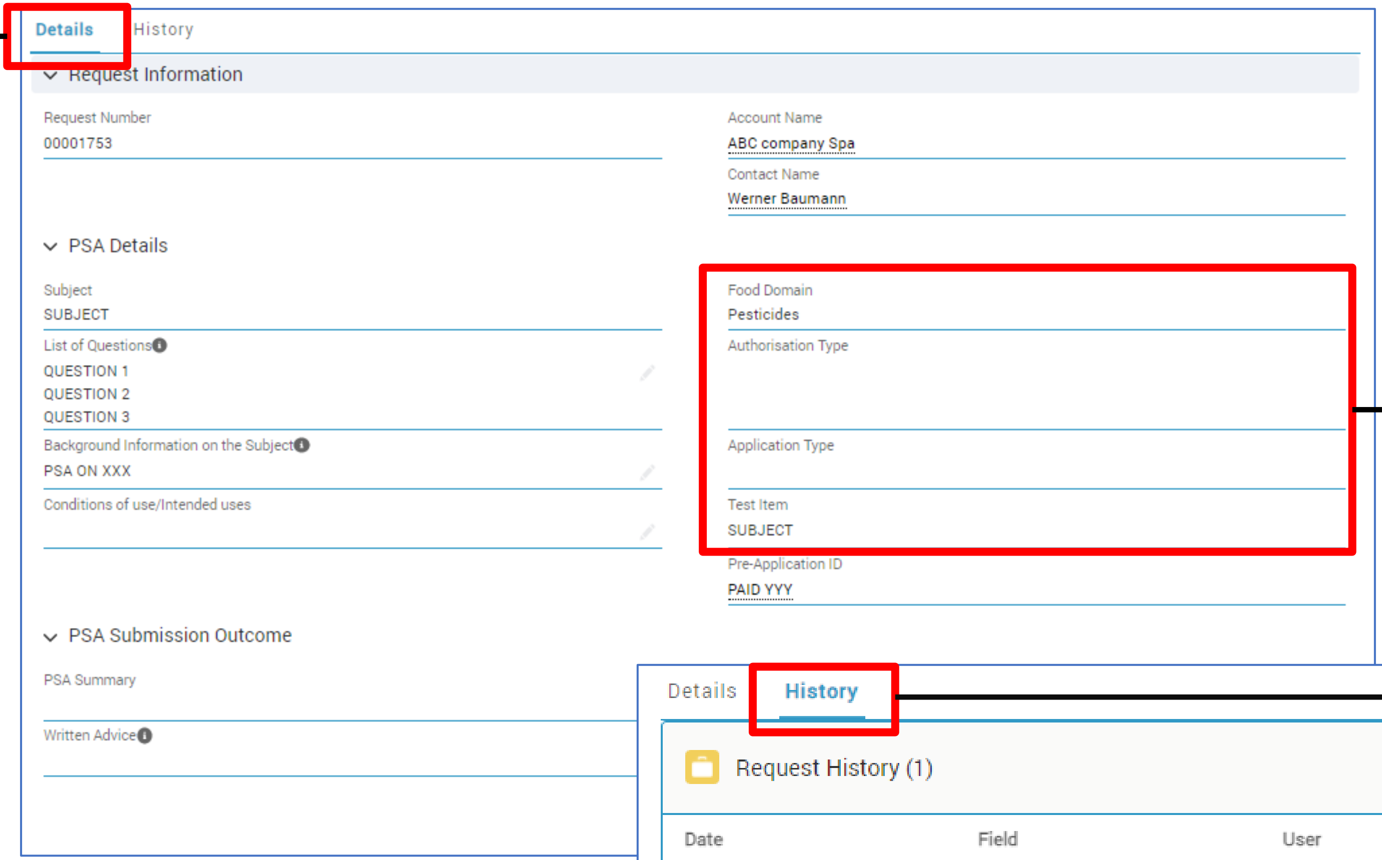
Use these function **buttons** to perform actions on the record.

The status bar shows the record progress.
When the status is **Draft** the user can still edit the record.



This section shows additional information on the GPSA request.

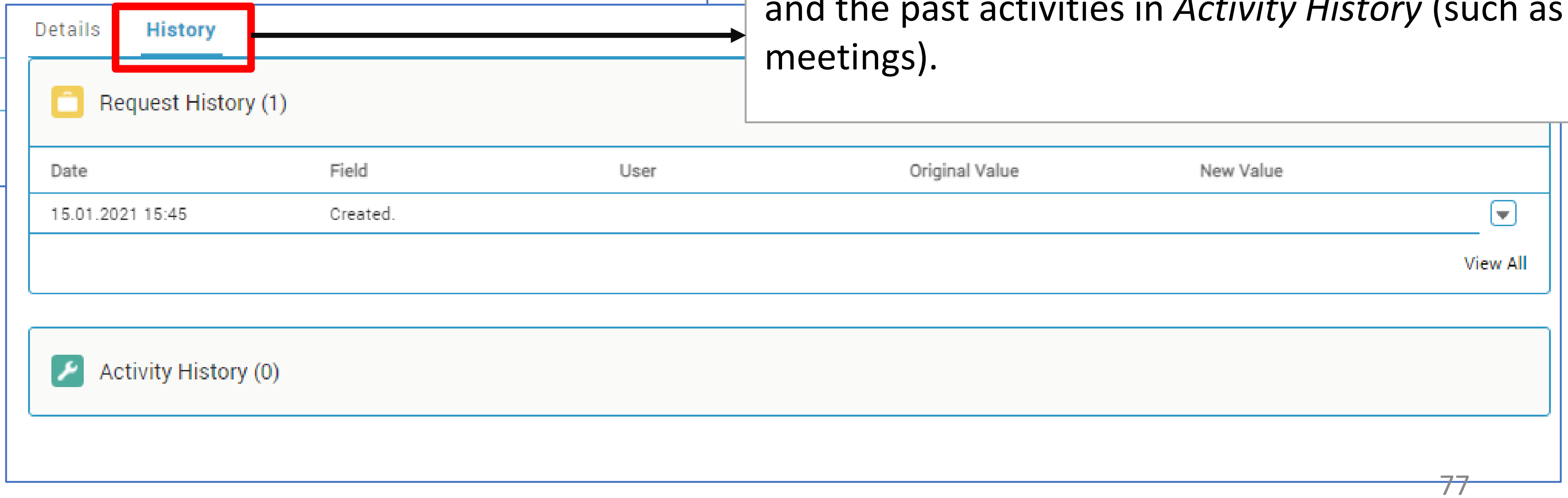
3.11.1 Request a GPSA



The following fields are automatically copied from the pre-application ID information:

- Food Domain
- Authorisation Type
- Application Type
- Test Item

These fields cannot be edited.

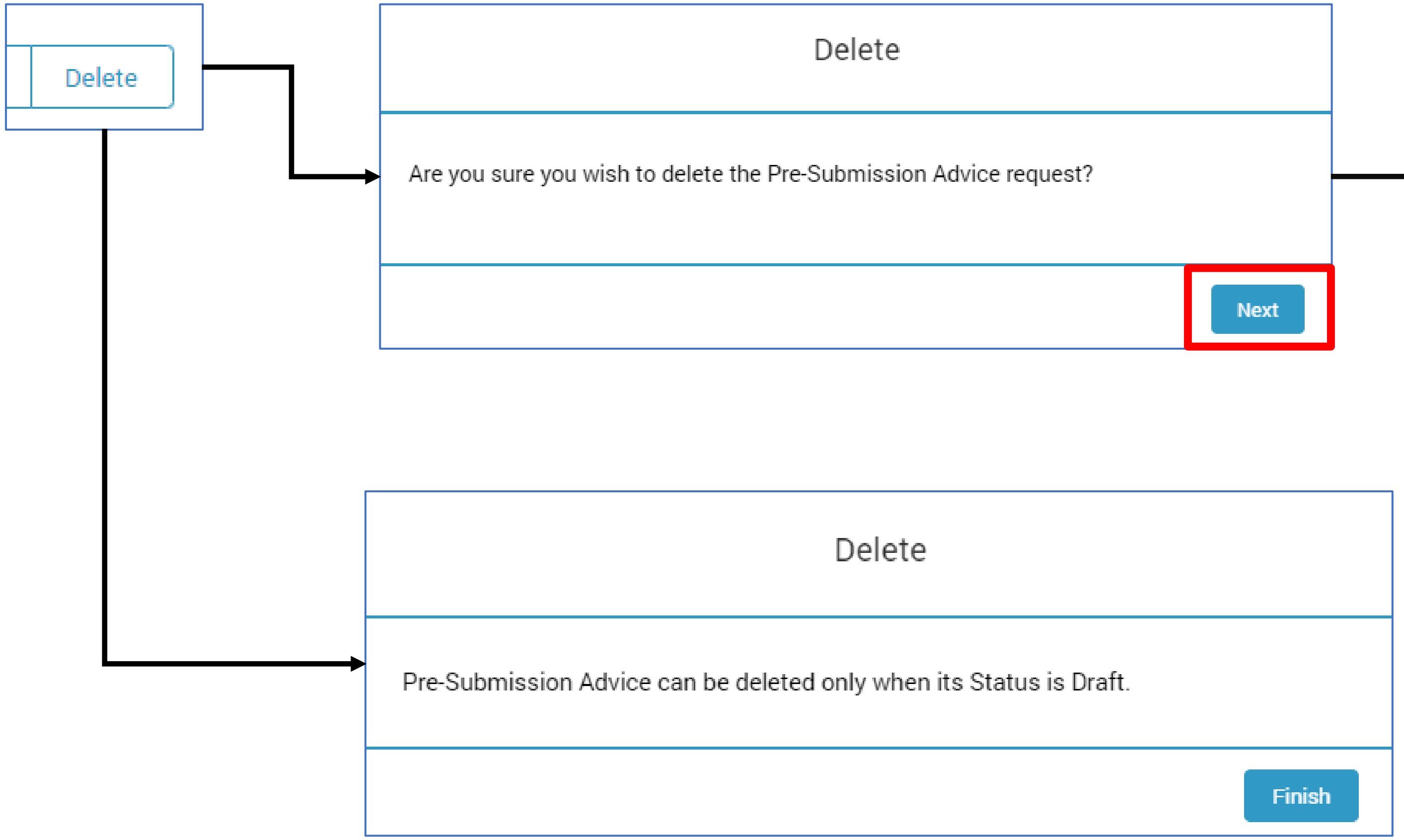


Under the **History tab** the user can see the changes made to the record on *Request History* and the past activities in *Activity History* (such as meetings).

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

3.11.2 Deletion of a request for GPSA

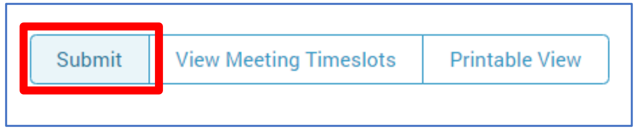
It is possible to delete the GPSA request **only when its status is equal to Draft**, otherwise an **error message** will appear.



The user is redirected to the pre-application ID page.

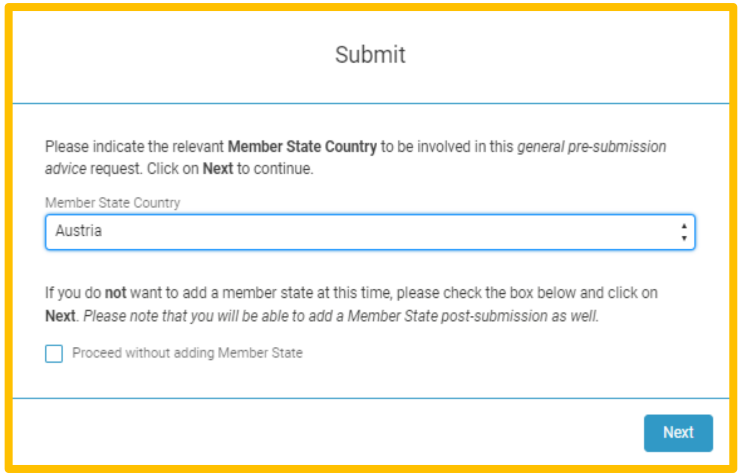
3.11.3 Submission of a request for GPSA – Pesticides

When submitting a GPSA requests linked to future applications with Food Domain: **Pesticides Peer Review (NAS), Pesticides MRL, Pesticides Peer Review (AIR) and Pesticides Peer Review - Other Areas**, the user is requested to indicate **the country** of the Rapporteur Member State (RMS) and the Co-Rapporteur Member State (Co-RMS).

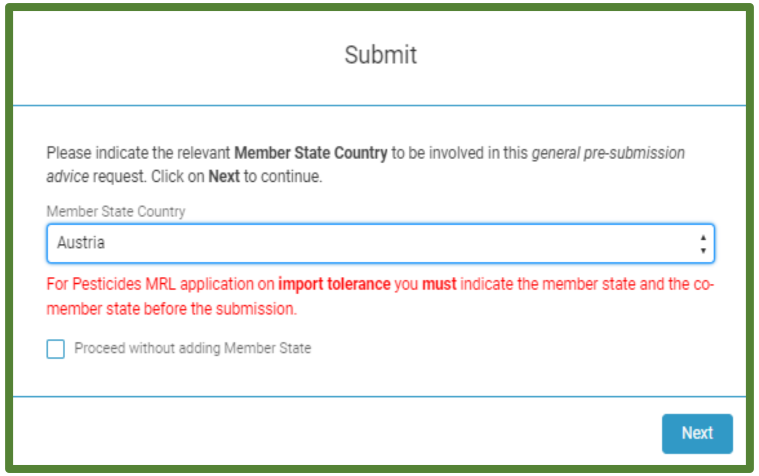


Depending on the Food Domain, the system will display a different window for the selection of the Member State(s), to clarify when the selection of the RMS and co-RMS is mandatory.

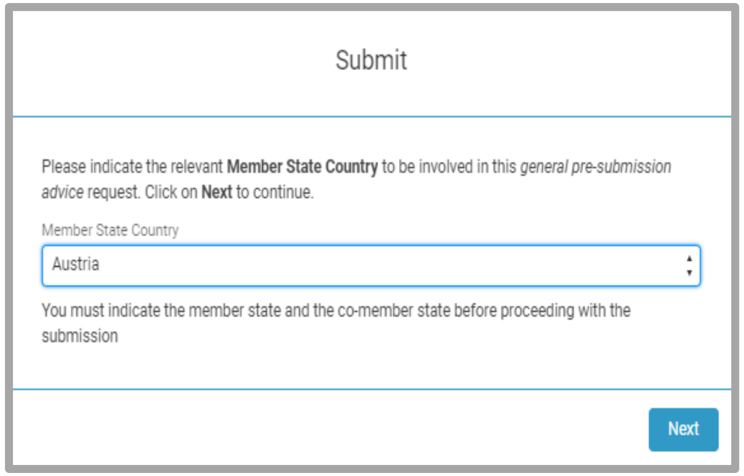
Pesticides Peer Review (NAS) & Other Areas



Pesticides MRL

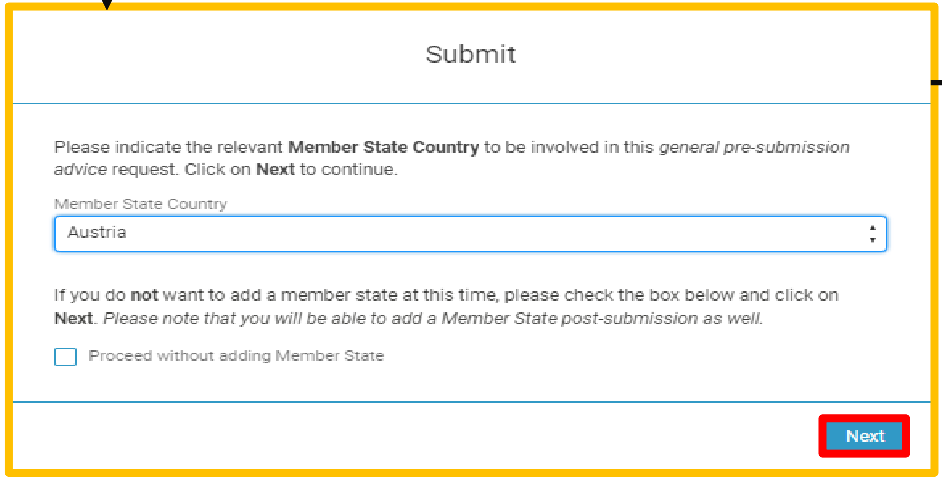


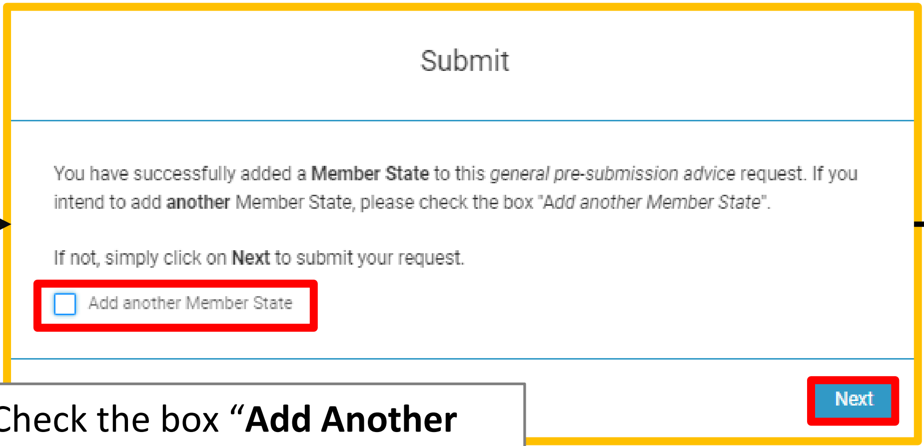
Pesticides Peer Review (AIR)



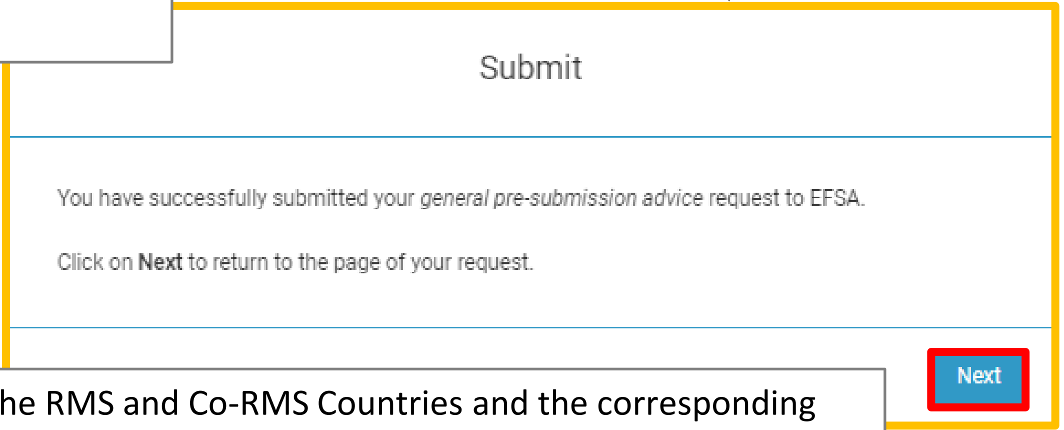
Note: more details on the submission workflow of a GPSA request for each Pesticides Food Domain are presented in the next slides.

3.11.3.1 Submission of a request for GPSA – Pesticides Peer Review (NAS) & Other Areas





Check the box "**Add Another Member State**" to add the Co-RMS, if relevant.



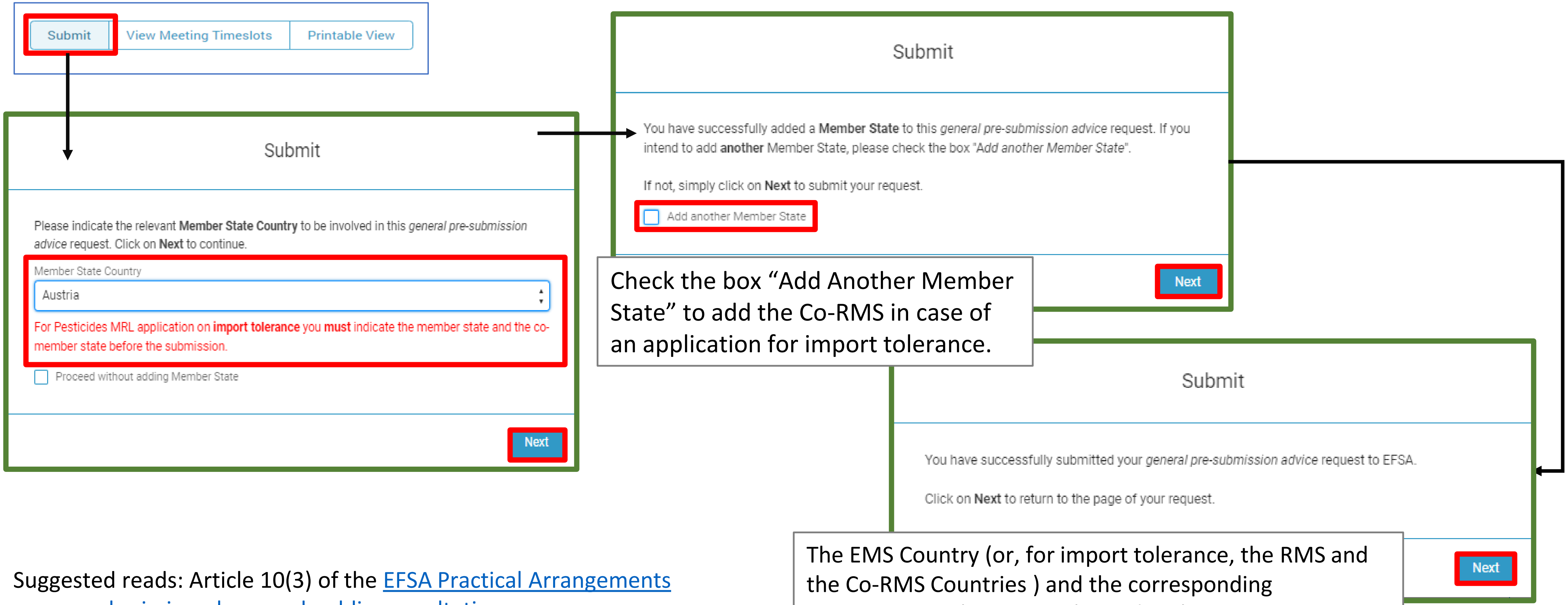
In case of **Pesticides Peer Review (NAS) & Pesticides Peer Review Other Areas** the user must indicate the RMS and where relevant the Co-RMS. If not known yet, the user can tick the box 'Proceed without adding Member State'.

The RMS and Co-RMS Countries and the corresponding Competent Authorities are showed in the Request Team section of the GPSA page.

Suggested reads: Article 10(3) of the EFSA Practical Arrangements on pre-submission phase and public consultations
Questions 20.B of the EFSA Q&A on Practical Arrangements.

3.11.3.2 Submission of a request for GPSA – Pesticides MRL

In case of Pesticides MRL, the user must indicate the evaluating Member State (EMS). If not known yet, the user can tick the box ‘Proceed without adding Member State’. For **Pesticide MRL applications on import tolerance**, the information on **RMS and Co-RMS is mandatory**, therefore the box must not be ticked.



Check the box “Add Another Member State” to add the Co-RMS in case of an application for import tolerance.

The EMS Country (or, for import tolerance, the RMS and the Co-RMS Countries) and the corresponding Competent Authority are showed in the Request Team section of the GPSA page.

Suggested reads: Article 10(3) of the EFSA Practical Arrangements on pre-submission phase and public consultations
Questions 20.B of the EFSA Q&A on Practical Arrangements.

3.11.3.3 Submission of a request for GPSA – Pesticides Peer Review (AIR)

Submit | View Meeting Timeslots | Printable View

Submit

Please indicate the relevant **Member State Country** to be involved in this *general pre-submission advice* request. Click on **Next** to continue.

Member State Country

Austria

You must indicate the member state and the co-member state before proceeding with the submission

Next

Submit

You have successfully added a **Member State** to this *general pre-submission advice* request. If you intend to add **another** Member State, please check the box "*Add another Member State*".

If not, simply click on **Next** to submit your request.

Add another Member State

Next

Check the box “Add Another Member State” to add the Co-RMS.

Submit

Please indicate the relevant **Member State Country** to be involved in this *general pre-submission advice* request. Click on **Next** to continue.

Member State Country

Italy

You must indicate the member state and the co-member state before proceeding with the submission

Previous | Next

Submit

You have successfully submitted your *general pre-submission advice* request to EFSA.

Click on **Next** to return to the page of your request.

Next

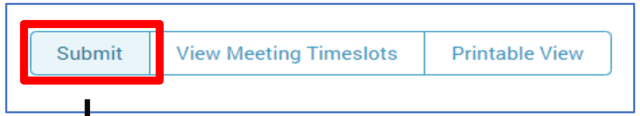
In case of Pesticides Peer Review (AIR), the information on **RMS and co-RMS is mandatory.**

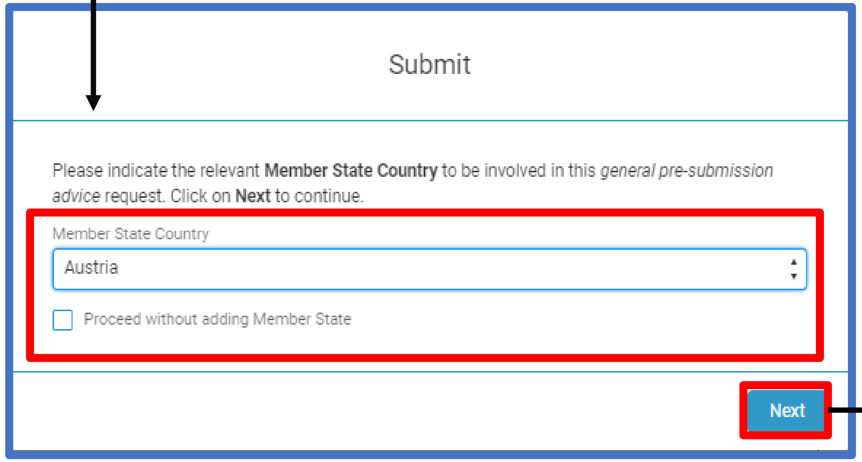
The RMS and Co-RMS Countries and the corresponding Competent Authorities are showed in the Request Team section of the GPSA page.

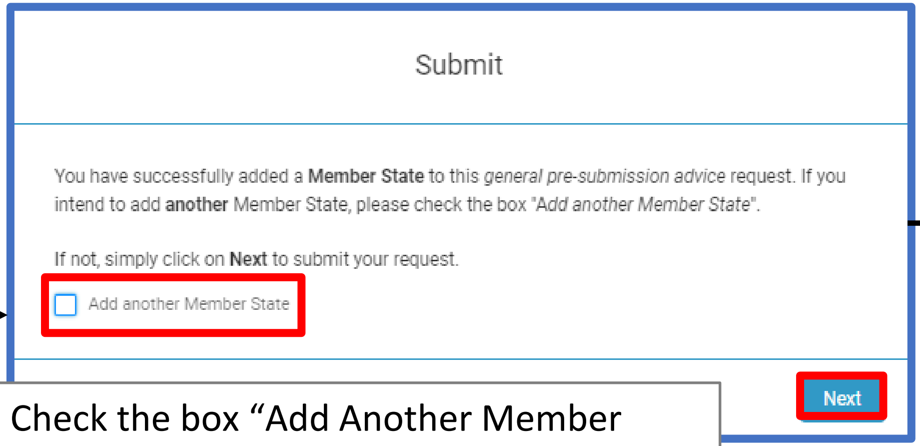
Suggested reads: Article 10(3) of the EFSA Practical Arrangements on pre-submission phase and public consultations
Questions 20.B of the EFSA Q&A on Practical Arrangements.

3.11.4 Submission of a request for GPSA – GMO Directive

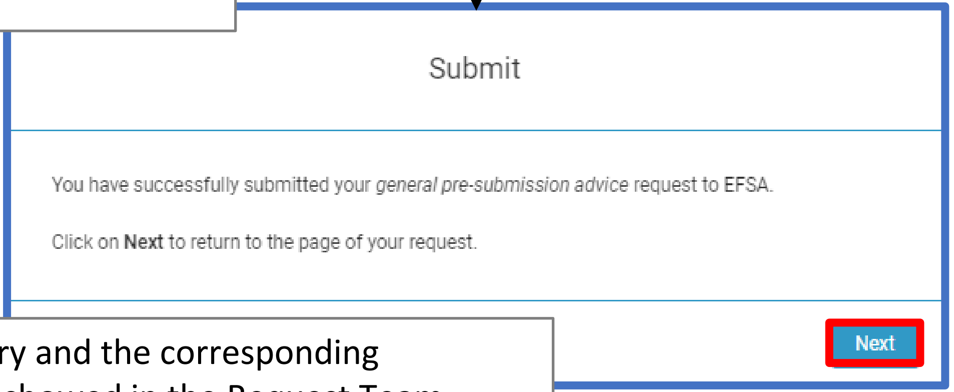
When submitting a GPSA requests linked to future notification under Articles 13 and 17 of Directive 2001/18/EC, the user is requested to indicate the **Country of the Member State** that will be notified.







Check the box "Add Another Member State" to add an additional Member State, if needed.

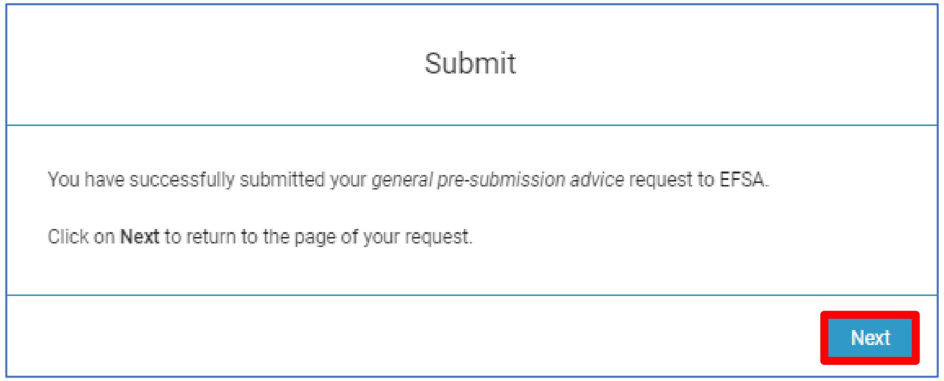


If the Member State is not known yet, the user can tick the box 'Proceed without adding Member State'.

The Member State Country and the corresponding Competent Authority are showed in the Request Team section of the GPSA page.

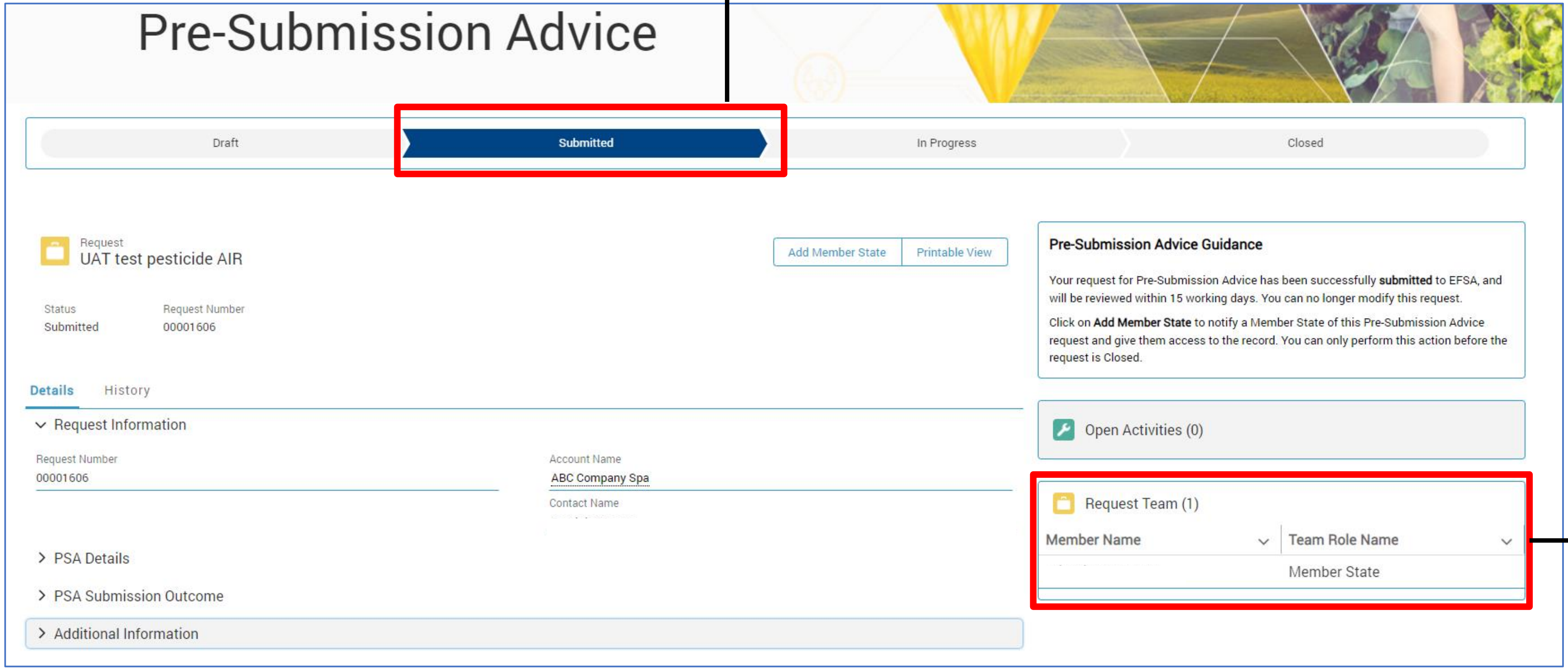
Suggested read: [Commission Notice on the submission of notifications under Articles 13 and 17 of Directive 2001/18/EC]

3.11.5 Submitted request for GPSA – Pesticides and GMO Directive



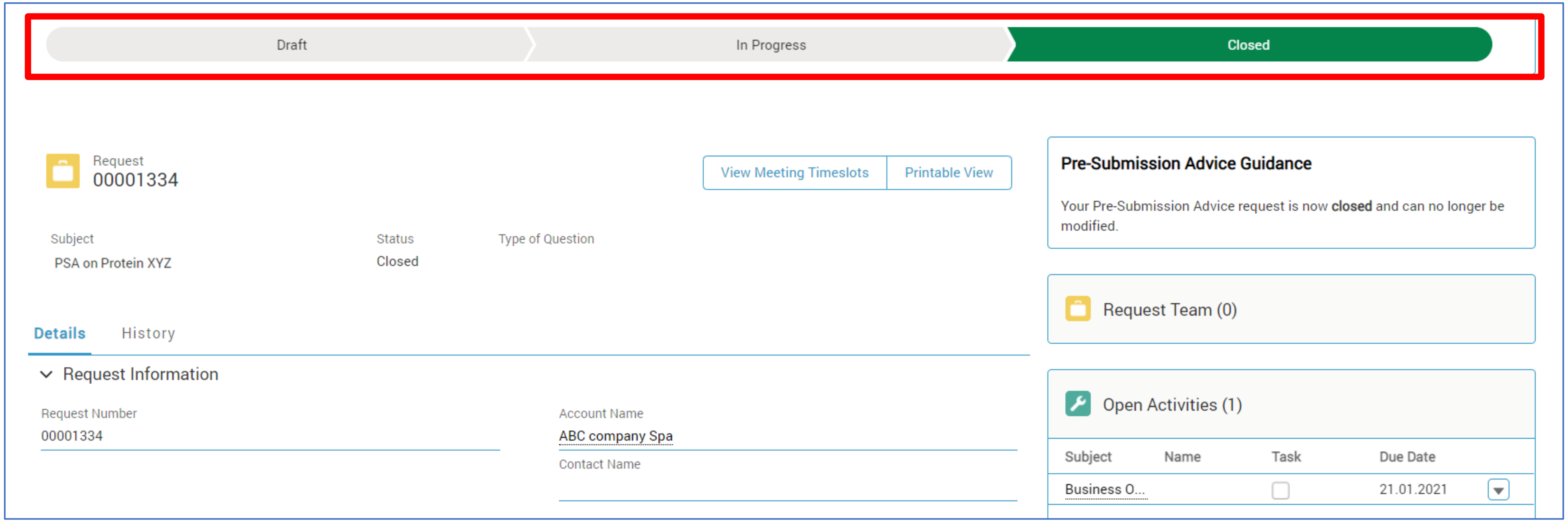
The Status turns into **Submitted** and the Member State contact is added to the **Request Team** related list.

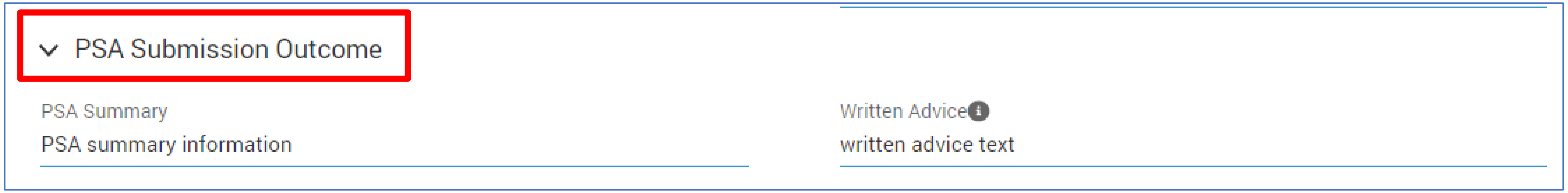
The Member State contact will be alerted by email and will be able to see and read the GPSA request.



3.11.6 Receiving a written GPSA

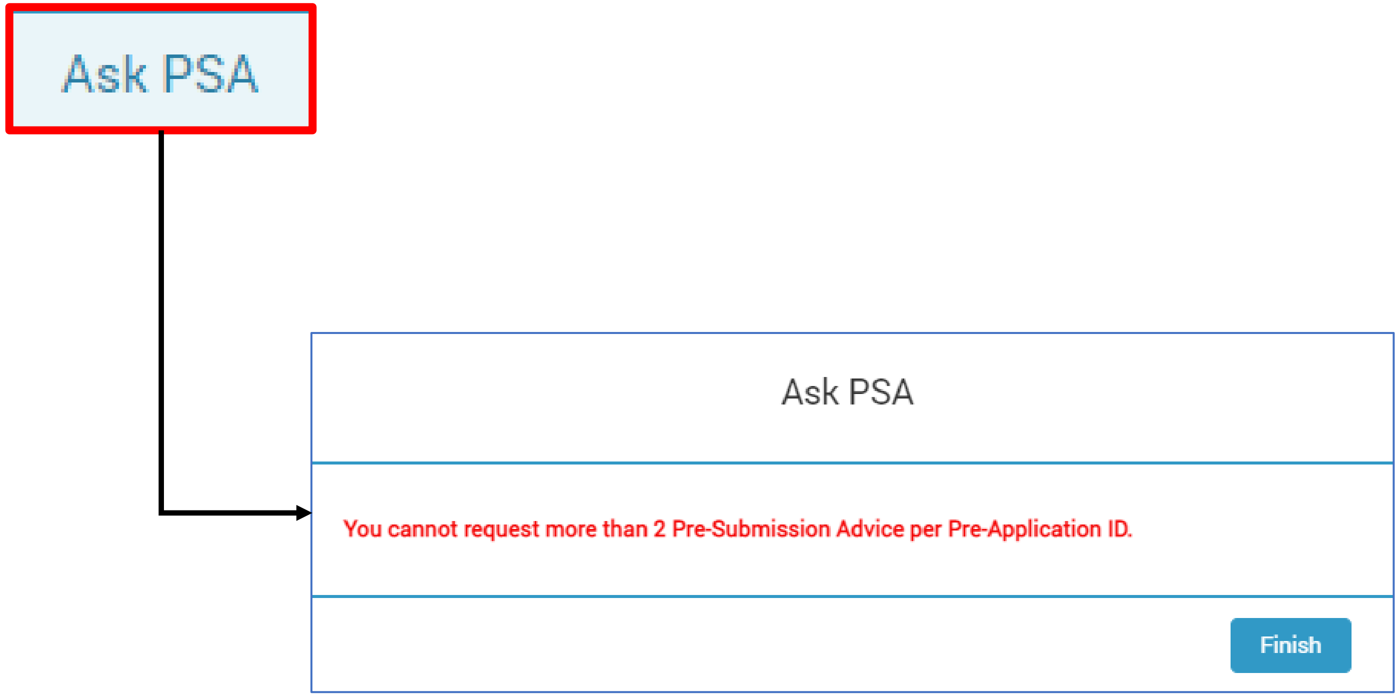
The user sees the record in Closed status and can read the written advice and the GPSA summary under the **PSA Submission Outcome** section.





3.11.7 Limit number of GPSA requests

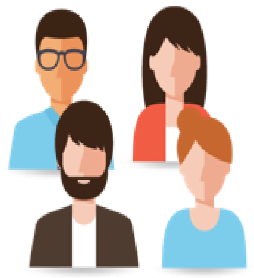
Each registered **business operator** or **third party/consultant** can submit **up to two GPSA requests** per pre-application ID.



When the user tries to submit more than two GPSA requests for the same pre-application ID, the system returns an **error message**.

Task force scenario

4.1 Task force scenario – no third party/consultant involved



Business operators task force

The business operator representing the task force (i.e. the main potential applicant) creates the pre-application ID

The main potential applicant shares the pre-application ID with all the business operators

Share the pre-application ID before creating the studies

Option 1*

Option 2**

All companies composing the task force are mentioned in the notifications

By default, the main potential applicant appears in the field ‘Business Operator’ of the pre-application ID and of all the studies linked therein.

*Option 1 - Pre-application ID shared with relationship type “Share With”: the companies composing the taskforce, other than the main potential applicant, can only view the studies created and notified that are linked to the pre-application ID.

Option 2 – Pre-application ID shared with relationship type “On behalf of”: **when creating the notification (and **only** at that stage), the Business Operator may be changed to reflect the actual organisation in the task force commissioning the study/ies, as showed in Section 3.2. To do so, the main potential applicant should establish an additional relationship “on behalf of” with such organisation(s).

Both options are adequate to describe a task force scenario. Potential applicants can choose according to their needs.

4.2 Task force scenario – with a third party/consultant involved

Business operators task force

→ The business operator representing the task force (i.e. the main potential applicant) needs to establish a relationship "on behalf of" with the third party

→ The third party/consultant creates the pre-application ID

The main potential applicant must be indicated in the field "Business operator" of the pre-application ID.

→ The third party/consultant shares the pre-application ID with all the business operators

Share the pre-application ID before creating the studies

Option 1*
Option 2**

→ All companies composing the task force are mentioned in the notifications

By default, the main potential applicant appears in the field 'Business Operator' of the pre-application ID and of all the studies linked therein.

*Option 1 - Pre-application ID shared with relationship type "Share With": the companies composing the taskforce, other than the main potential applicant, can only view the studies created and notified that are linked to the pre-application ID.

Option 2 – Pre-application ID shared with relationship type "On behalf of": **when creating the notification (and **only** at that stage), the Business Operator field may be changed to reflect the actual organisation in the task force commissioning the study/ies, as showed in Section 3.2. To do so, this entity should establish a relationship "on behalf of" with the third party/consultant.

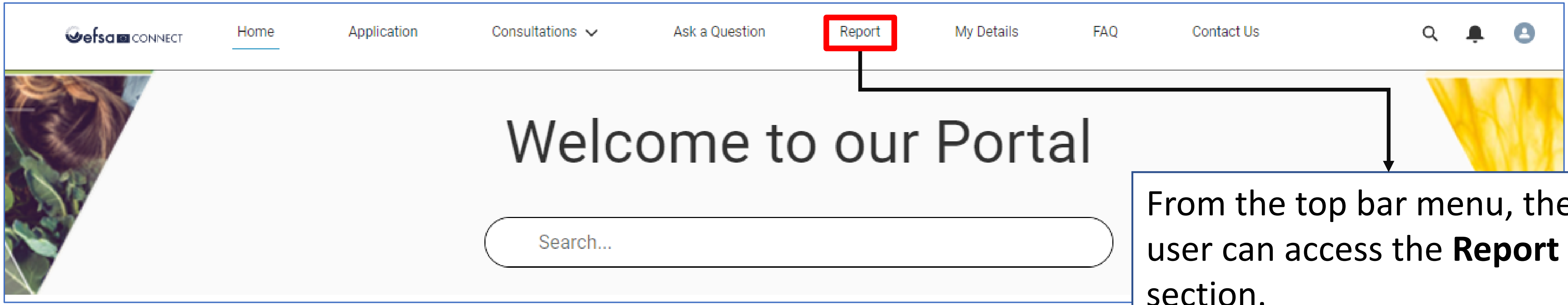
Both options are adequate to describe a task force scenario. Potential applicants can choose according to their needs.

4.3 Highlights of the task force scenario

- The main potential applicant must be indicated in the field "Business operator" of the pre-application ID.
- If a third party/consultant is involved, the main potential applicant must establish firstly an account relationship "on behalf of" with this organisation.
- The pre-application ID may be shared with relationship type "share with" or "on behalf of" with the other companies composing the task force.
- It is possible to include, at a later stage, additional potential applicants under an already created pre-application ID by creating a relationship before sharing the pre-application ID with them.
- Should one of the joint potential applicants wish to seek general pre-submission advice separately or notify studies without sharing them with the other potential applicants of the task force (to avoid sharing confidential issues), they could request an additional individual pre-application ID. When the joint application will be submitted, all the pre-application IDs need to be reported.

Reporting features

5. Reporting features



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

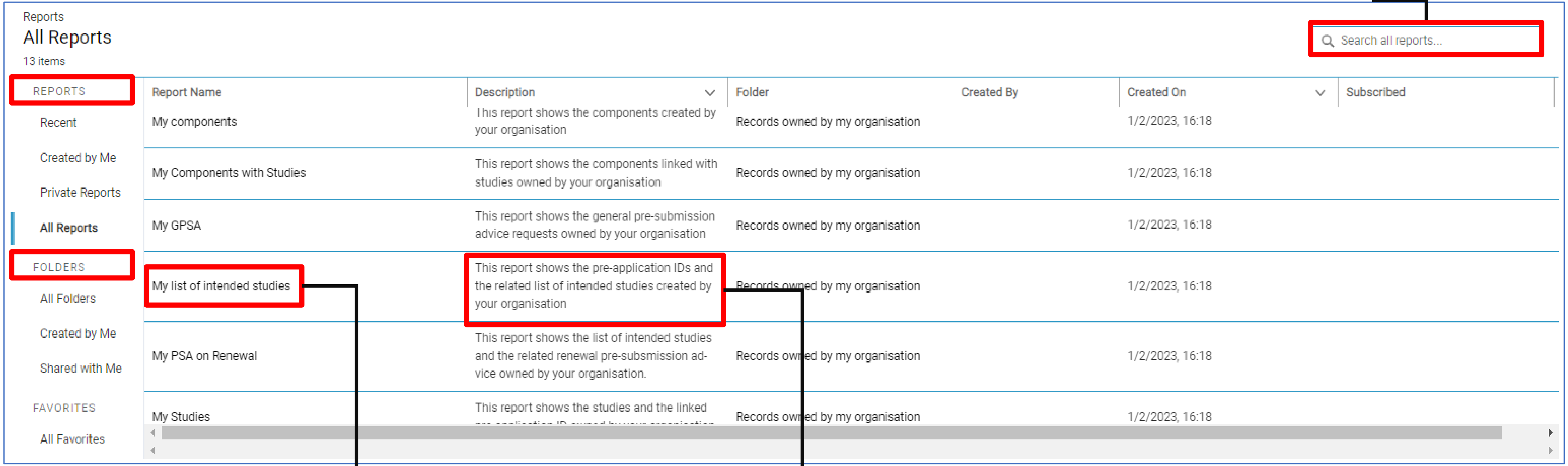
Important notes about reports:

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

5.1 Reporting features – Overview

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

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

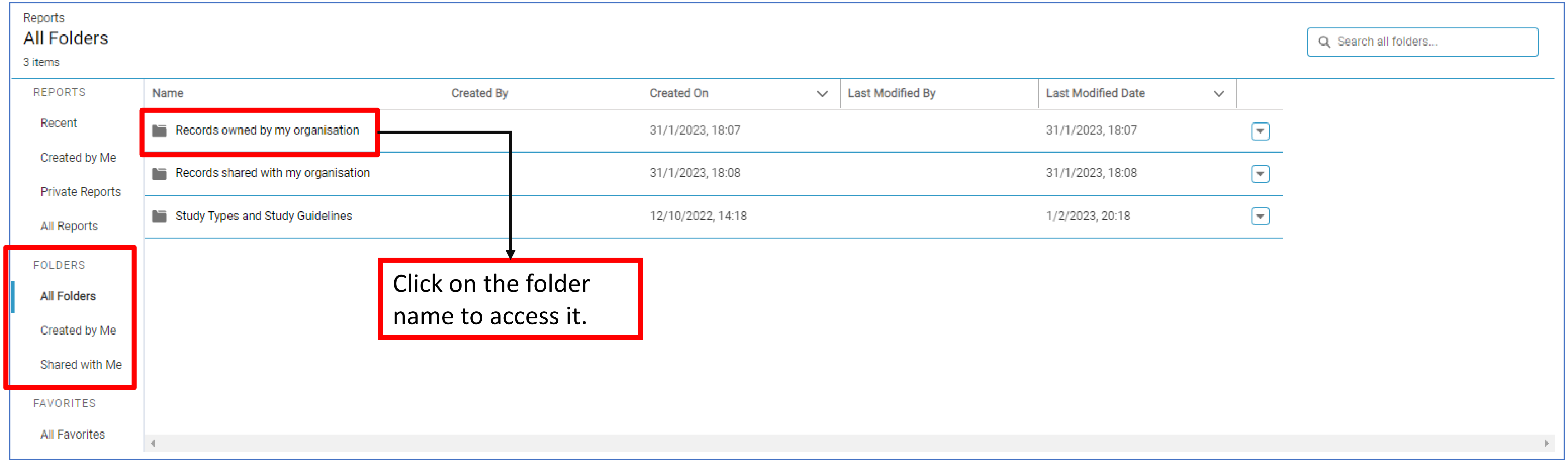


Click on the report name to access it.

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

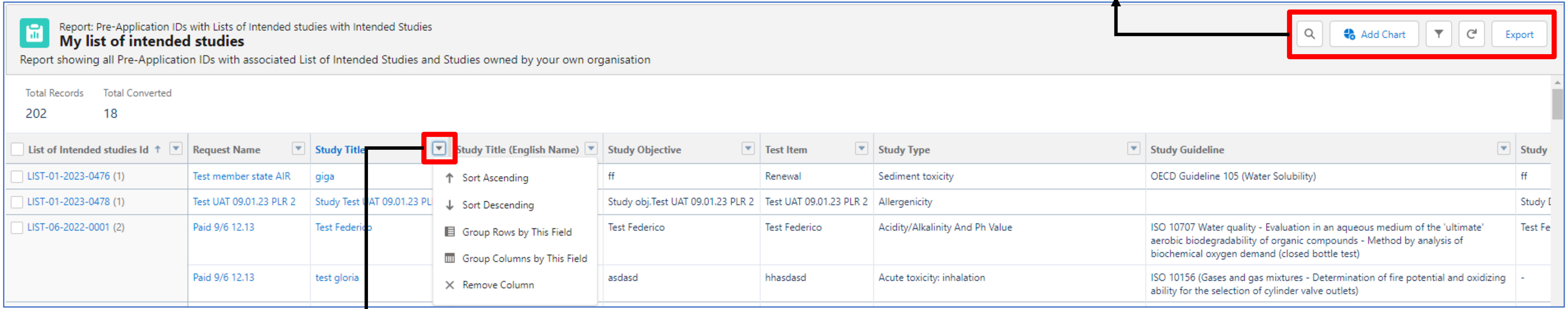
5.2 Reporting features - Folders

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



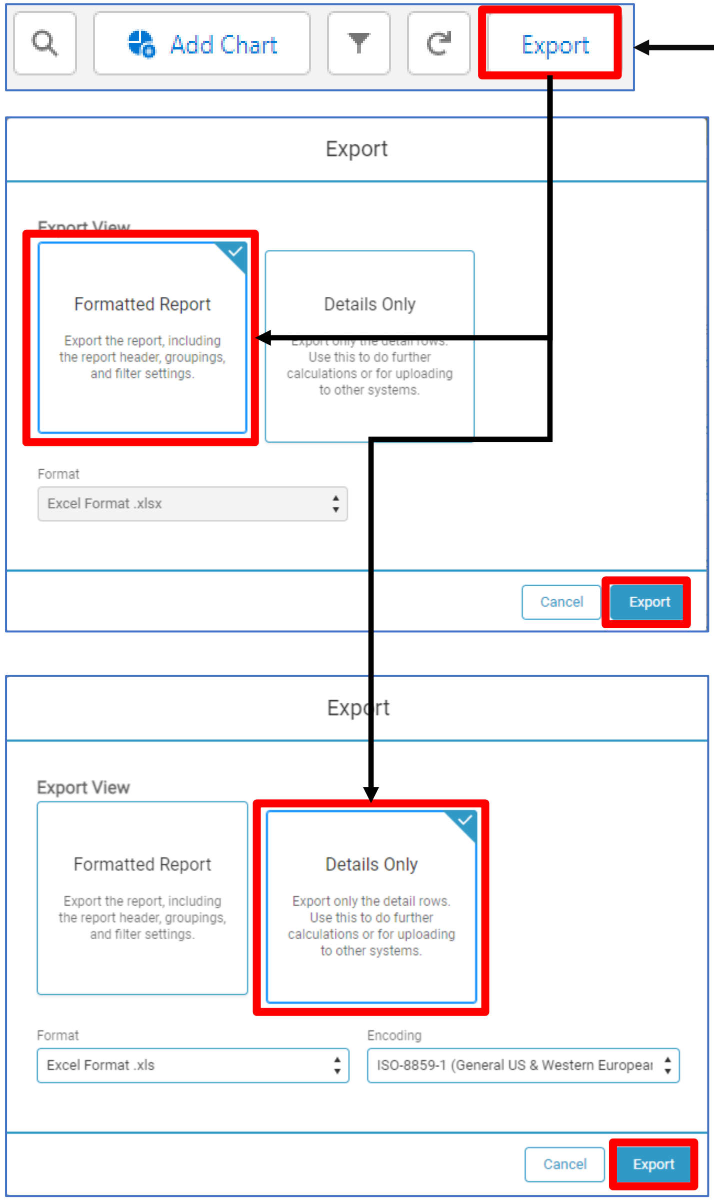
5.4 Reporting features – Actions allowed on a report

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



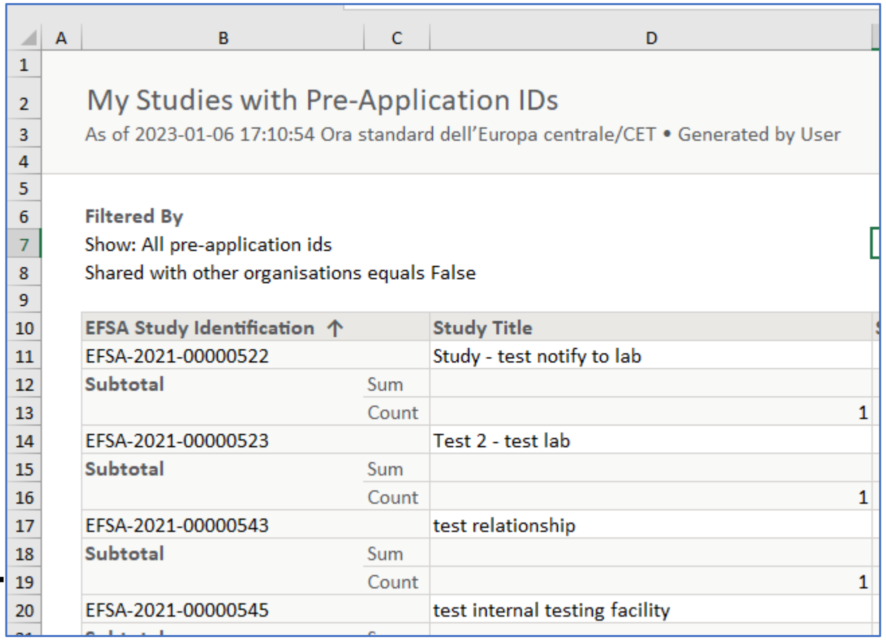
Click on one of the pointing down arrows to perform actions on the report table.
The user can:
- **sort the values**
- **group/ungroup values**
- **remove columns**

5.5 Reporting features – Export a report

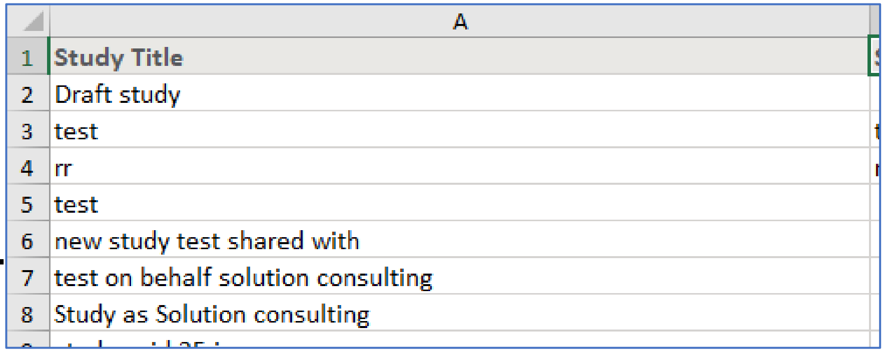


Click on **Export** button and select the preferred format.

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.

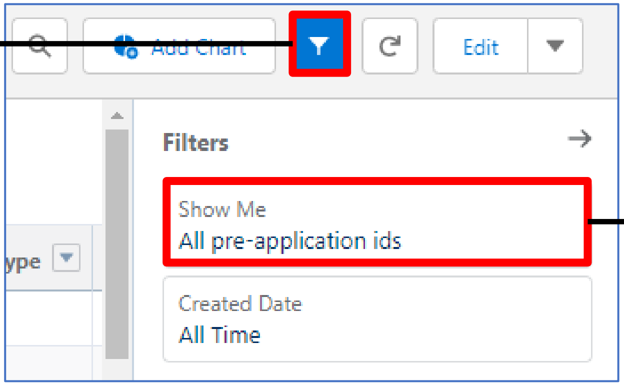


Details Only
Reports can be exported as Excel or CSV file showing only the detail rows.

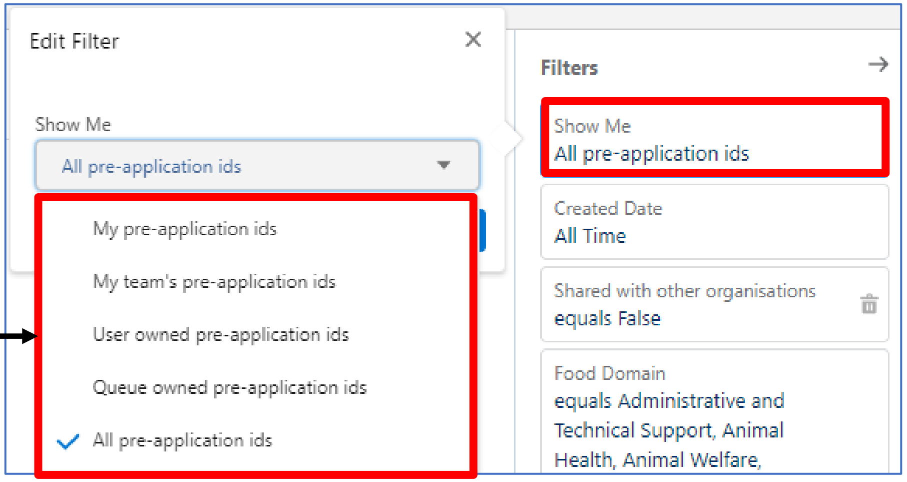


5.6 Reporting features – Filters functionality

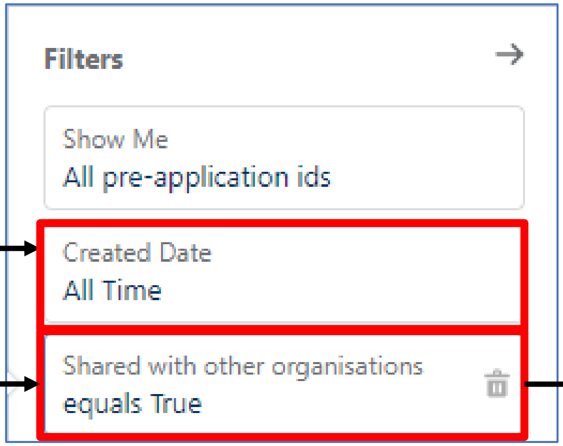
Depending on the type of data showed in the report, predefined filters are available. Once the user refreshes the page the default filtering rules set by EFSA will be restored.

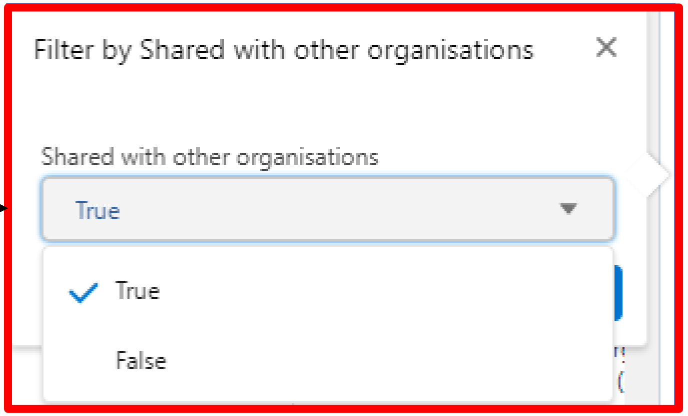


Click on the Filters icon and select the filter to apply.

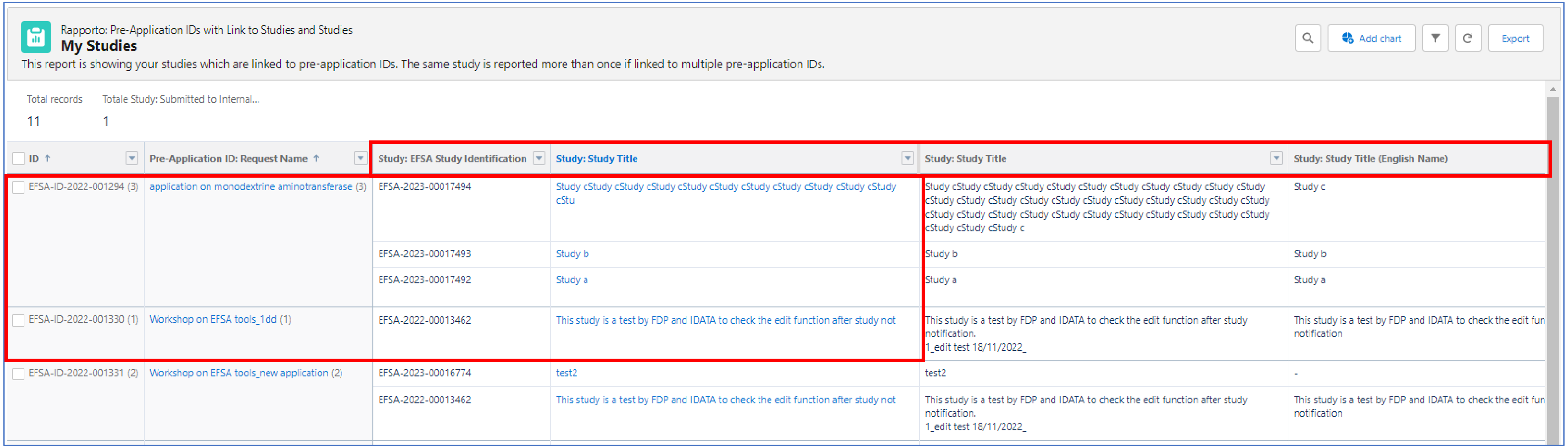


Some filters will allow to restrict the view to records on the basis of their **creation date**, while others allow to view only the records **shared with the user's organisation**.





5.6 Reporting features – My studies report


Rapporto: Pre-Application IDs with Link to Studies and Studies
My Studies
This report is showing your studies which are linked to pre-application IDs. The same study is reported more than once if linked to multiple pre-application IDs.

Add chart
Export

Total records 11
Totale Study: Submitted to Internal... 1

ID ↑	Pre-Application ID: Request Name ↑	Study: EFSA Study Identification	Study: Study Title	Study: Study Title	Study: Study Title (English Name)
EFSA-ID-2022-001294 (3)	application on monodextrine aminotransferase (3)	EFSA-2023-00017494	Study cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStu	Study c	Study c
		EFSA-2023-00017493	Study b	Study b	Study b
		EFSA-2023-00017492	Study a	Study a	Study a
EFSA-ID-2022-001330 (1)	Workshop on EFSA tools_1dd (1)	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. 1_edit test 18/11/2022_	This study is a test by FDP and IDATA to check the edit fun notification
EFSA-ID-2022-001331 (2)	Workshop on EFSA tools_new application (2)	EFSA-2023-00016774	test2	test2	-
		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. 1_edit test 18/11/2022_	This study is a test by FDP and IDATA to check the edit fun notification

This report shows all the studies owned by the users organisation which are linked to pre-application IDs. The user finds:

1. The **ID** and the **Request Name of the pre-application ID** and **all the studies linked therein**.
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.

5.7 Reporting features – All my Studies reports

Rapporto: Studies

All my Studies

This Report shows all your studies regardless of a link to one or several Pre-Application IDs.

Add chart | Export

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