User Guide

Notification of studies

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.

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

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

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Introduction

1. Actors of the Process

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

Business Operator/Consultant	(orange)
Laboratory /Consultant	(green)

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

1. Actors of the Process

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

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

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

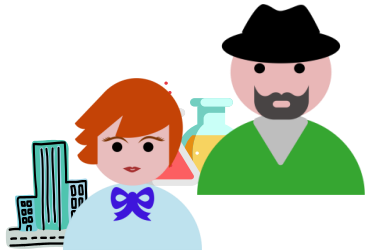
1.1 Account qualification

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

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

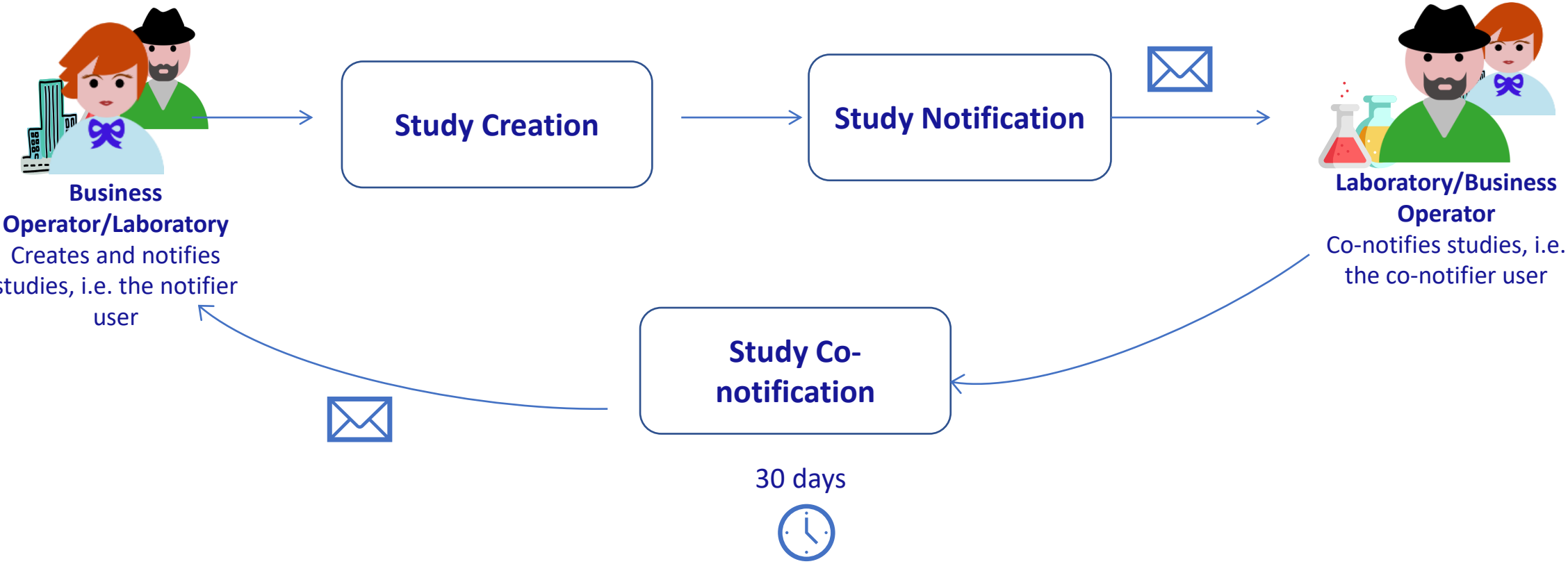
Applicant only: organisations such as business operators. They act as potential applicant conducting pre-submission activities linked to a future application for a regulated product in a specific regulated area. These organisations can create pre-application IDs, studies from a pre-application ID, notify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

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



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

1.2 Notification of Studies: Process Overview



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

Logging In

2. Log-in entry point

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

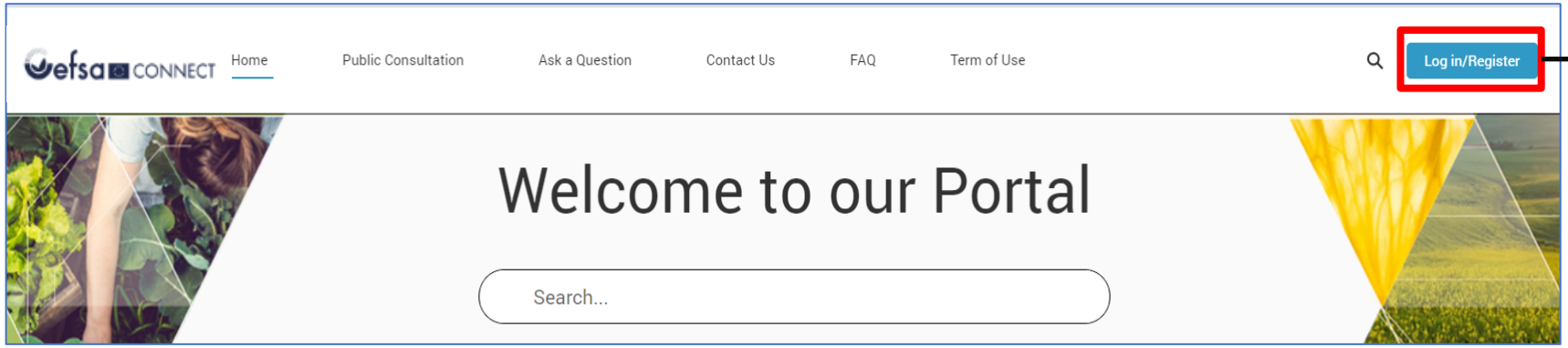
via the following link:

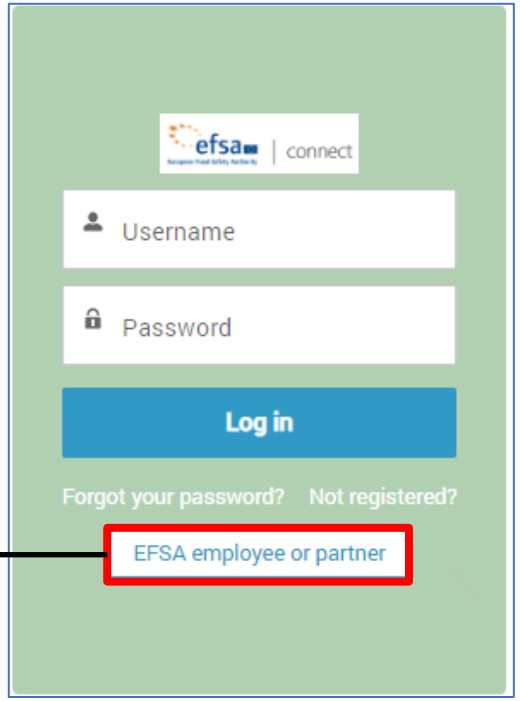
https://connect.efsa.europa.eu/RM

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)



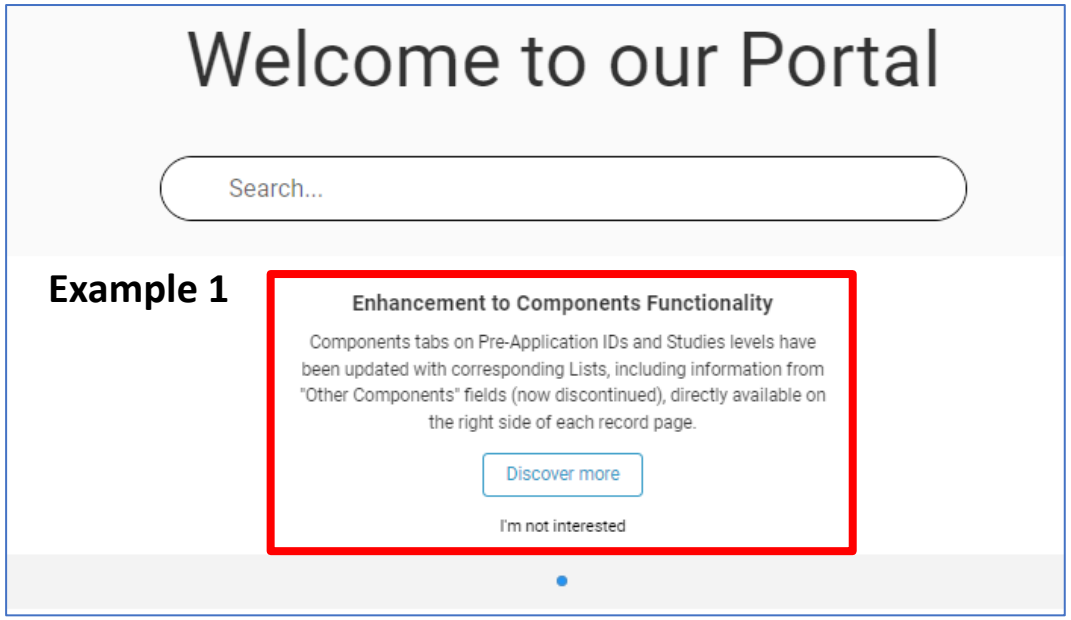


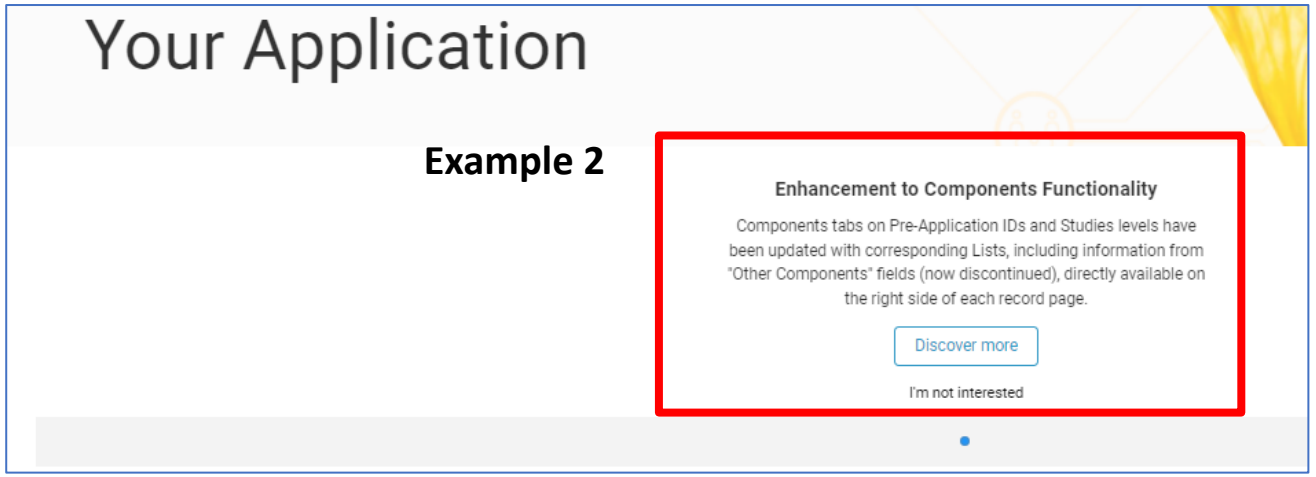
3. Click on this button to login. The system redirects the user to the **EFSA corporate login page where username and password will be requested.**

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).

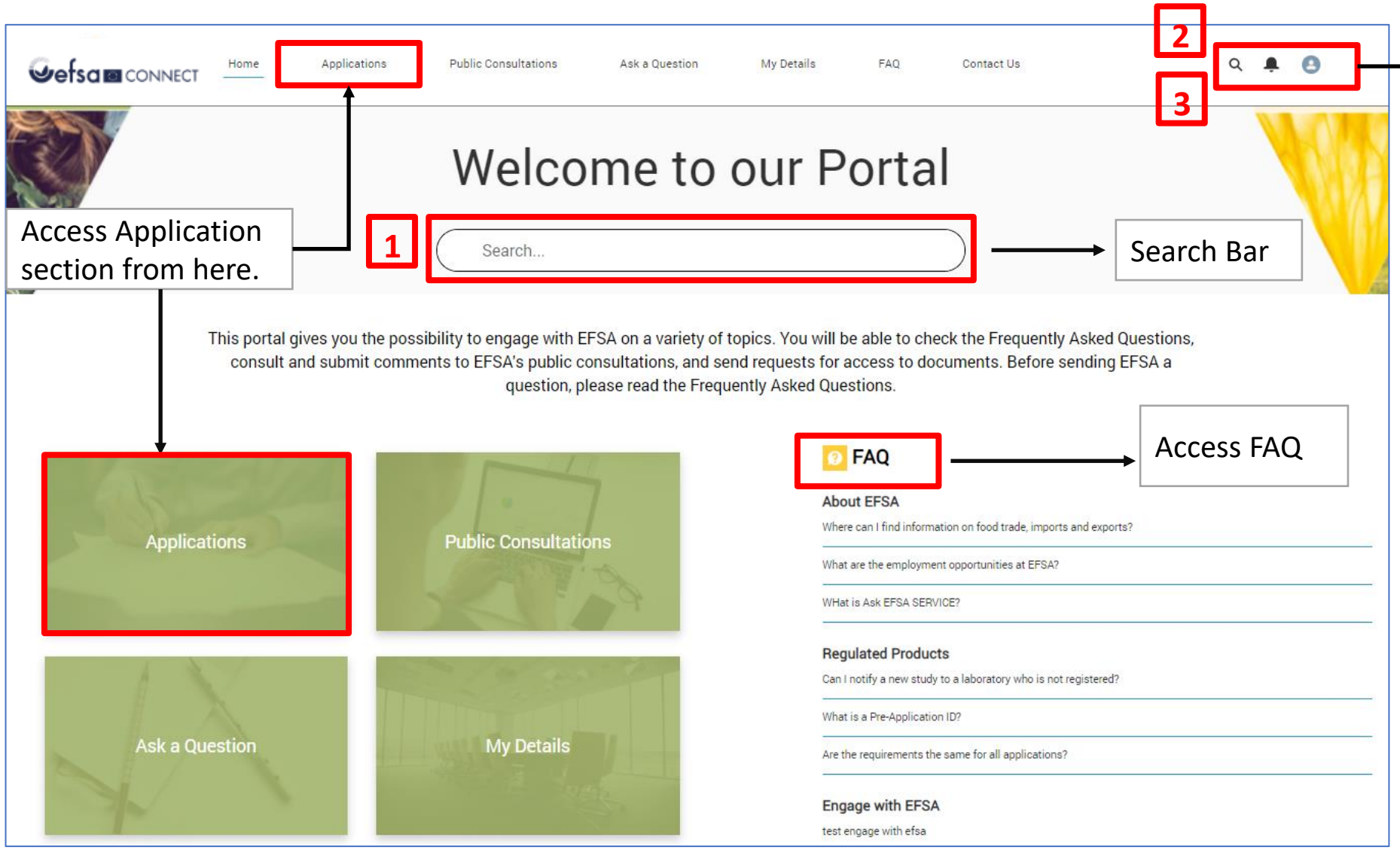




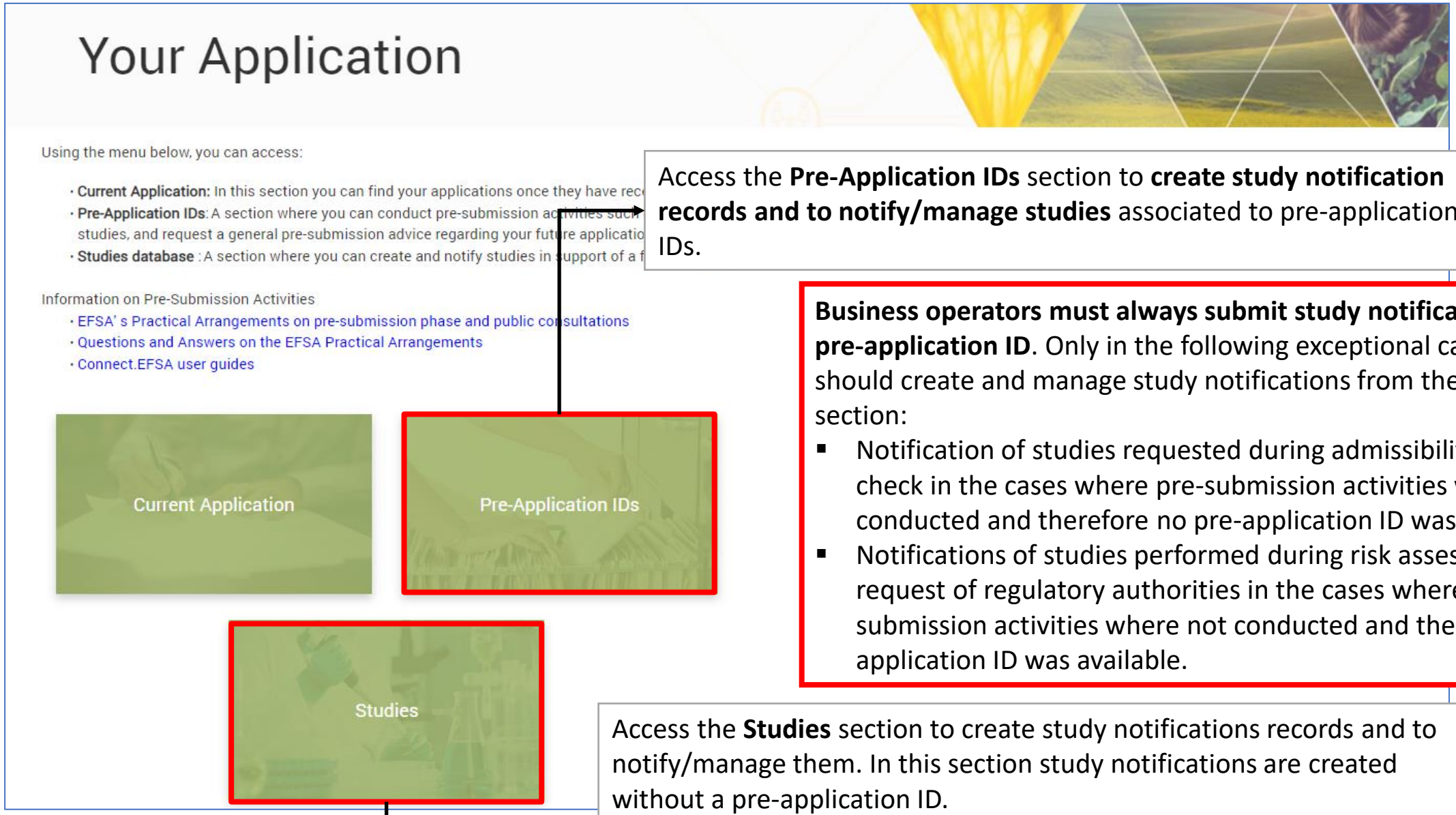
Notification of studies

3.1 Study creation – Applicant view

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



3.1 Study creation - Applicant view



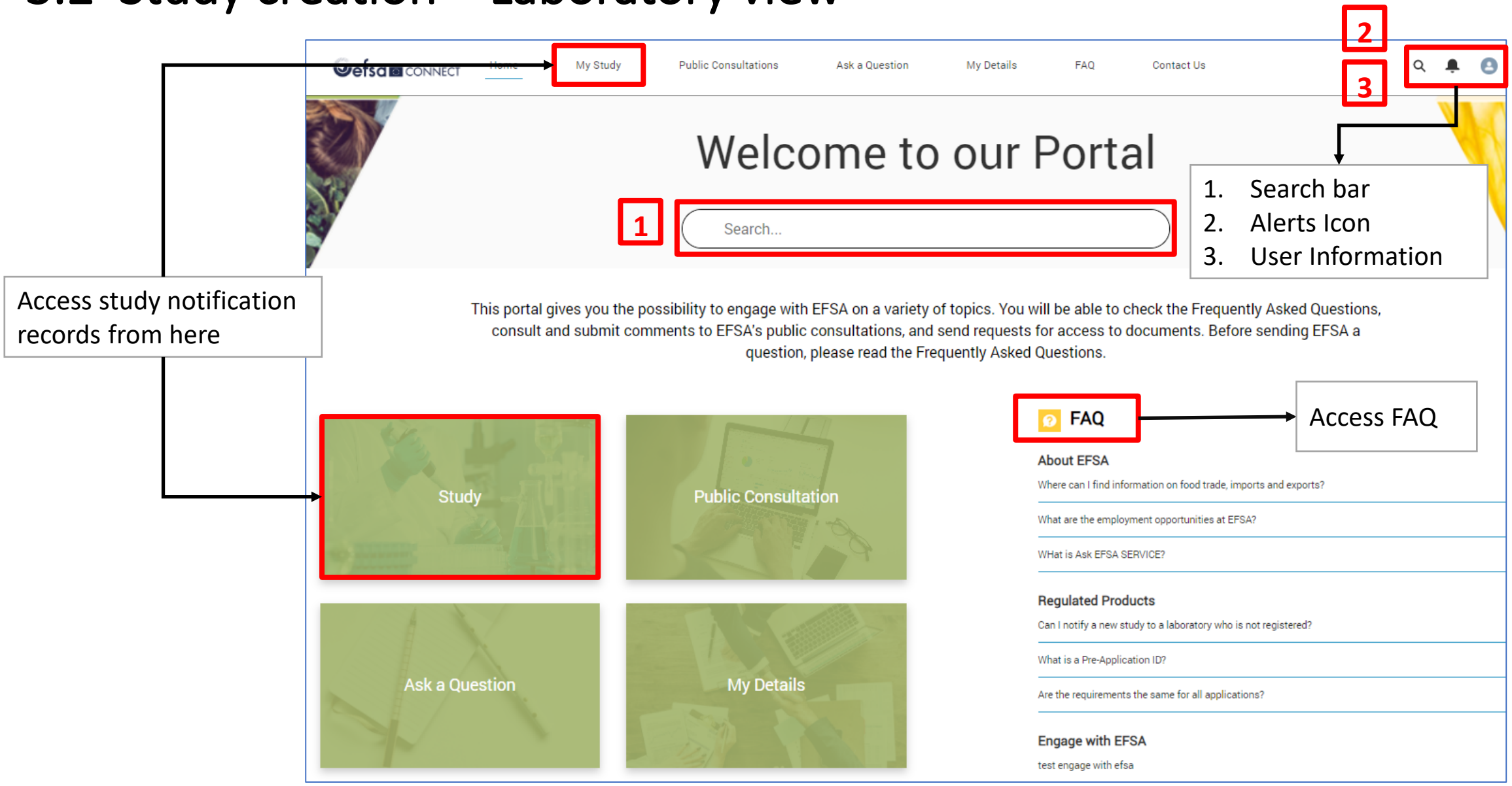
Access the **Pre-Application IDs** section to **create study notification records and to notify/manage studies** associated to pre-application IDs.

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

- Notification of studies requested during admissibility/validity check in the cases where pre-submission activities 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.

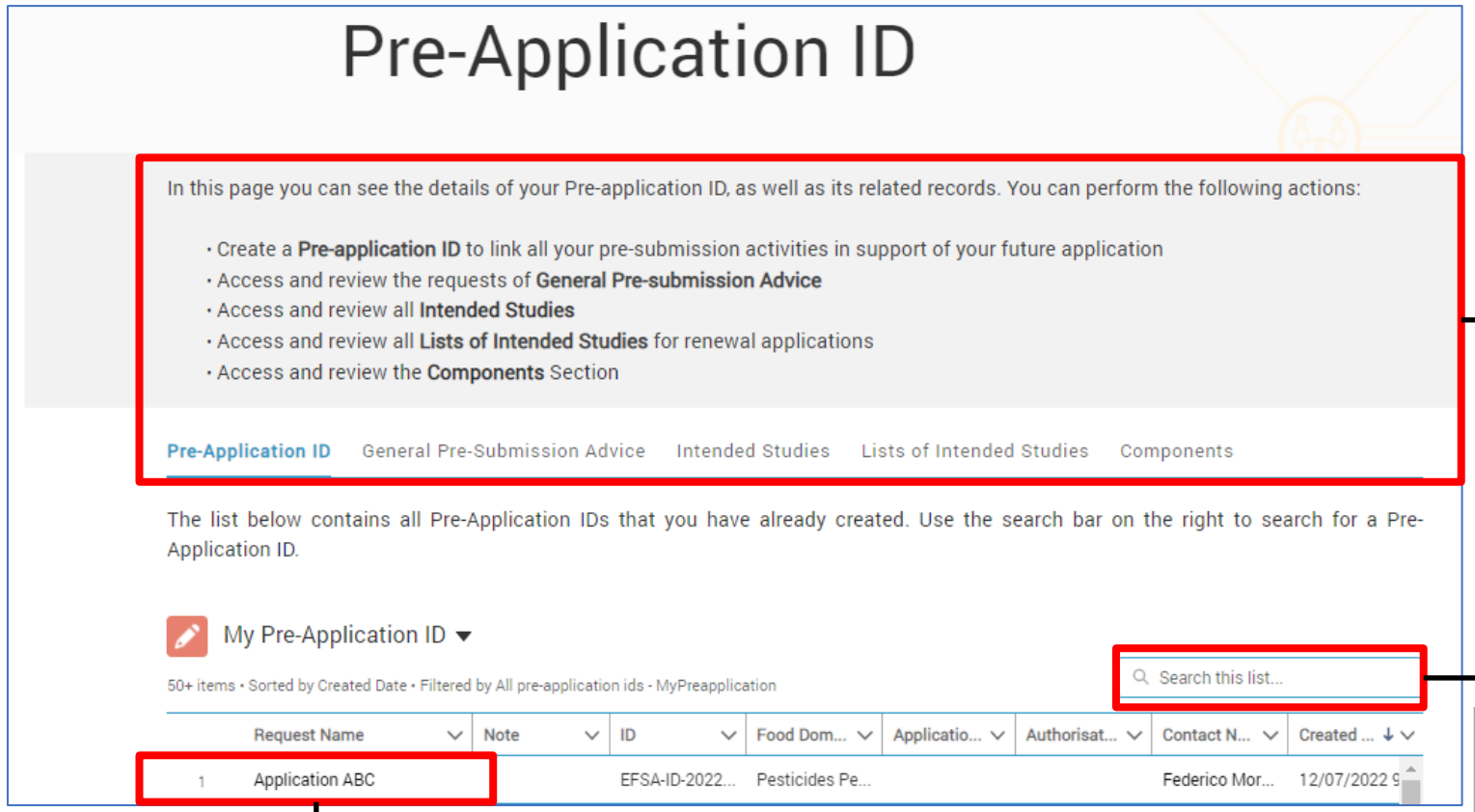
Access the **Studies** section to create study notifications records and to notify/manage them. In this section study notifications are created without a pre-application ID.

3.2 Study creation – Laboratory view



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

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

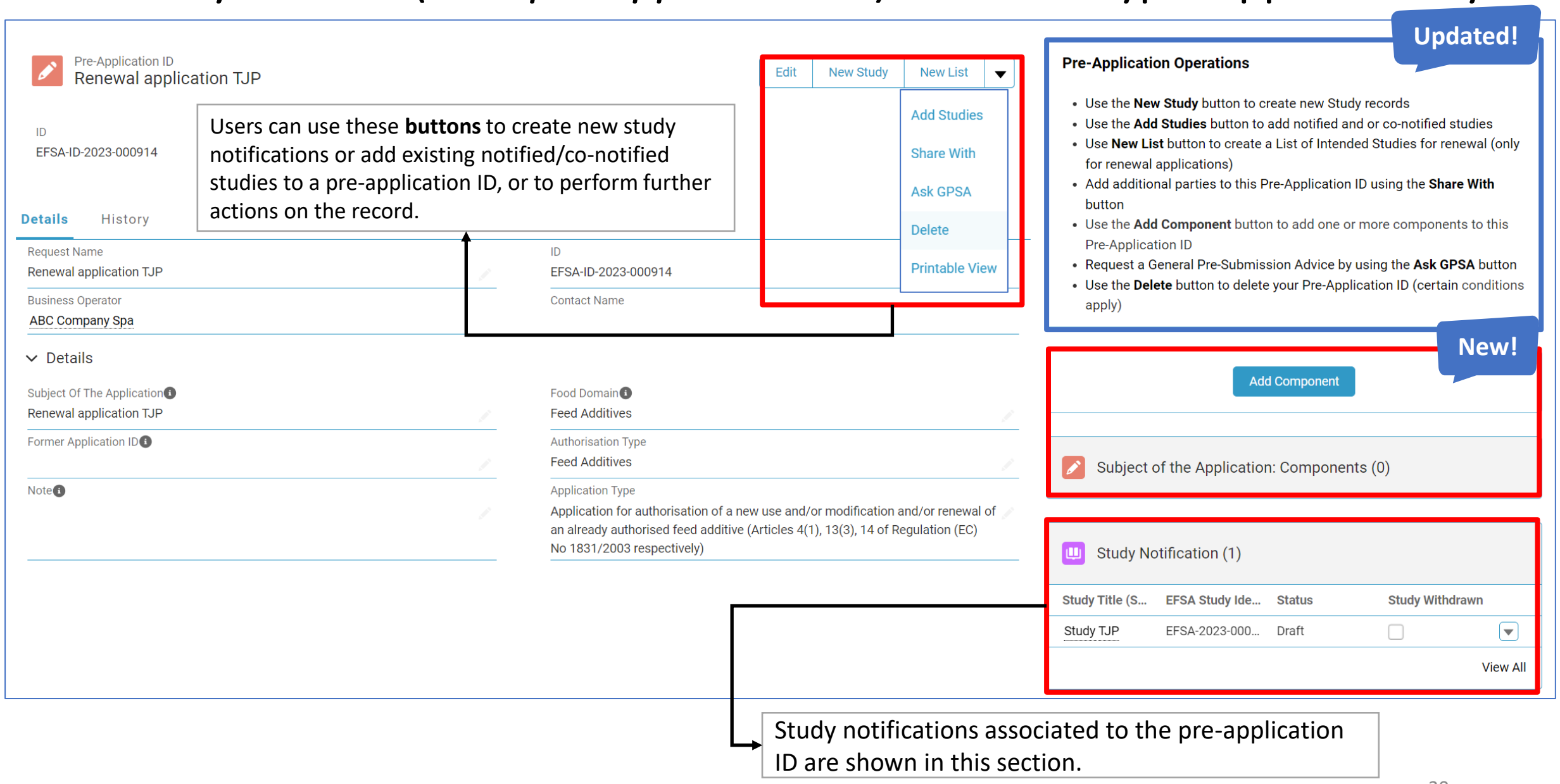


In this box, instructions to help the user to conduct pre-submission activities are provided.

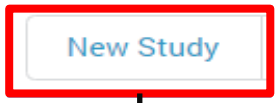
Here the user can perform a search according to values in the columns shown.

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

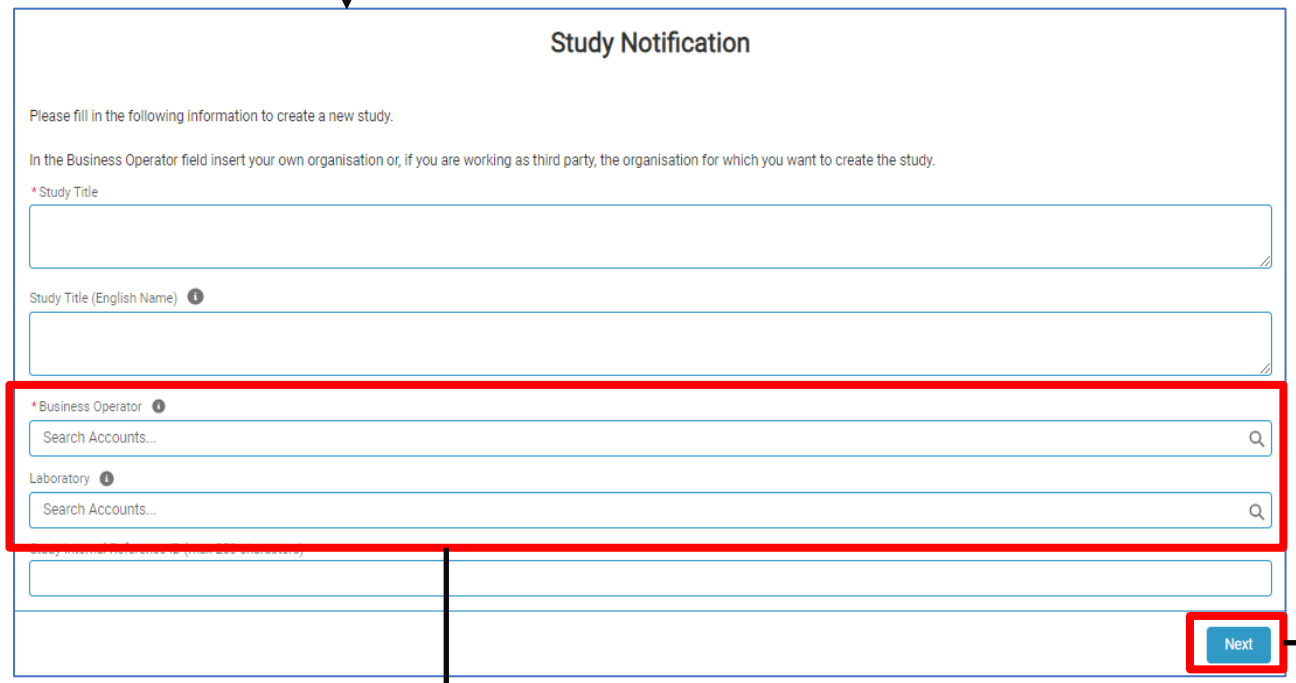
3.3 Study creation (from *pre-application ID*) – Account type: Applicant only

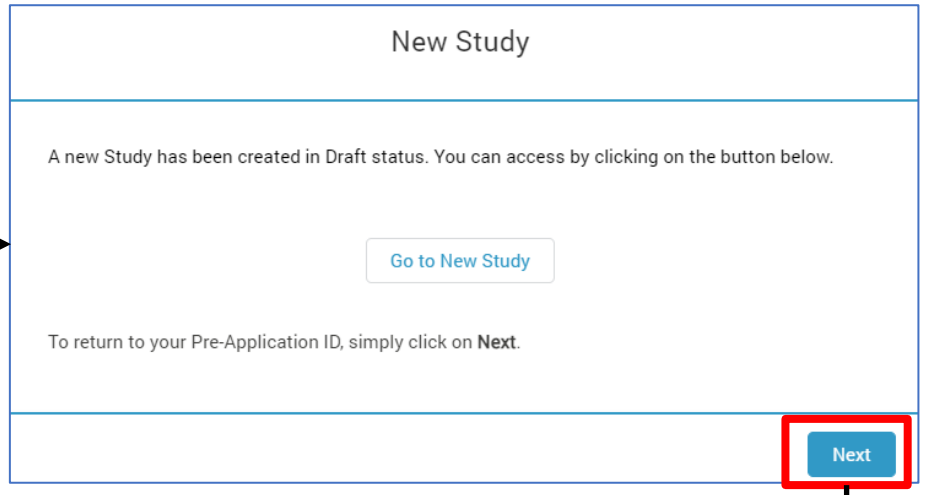


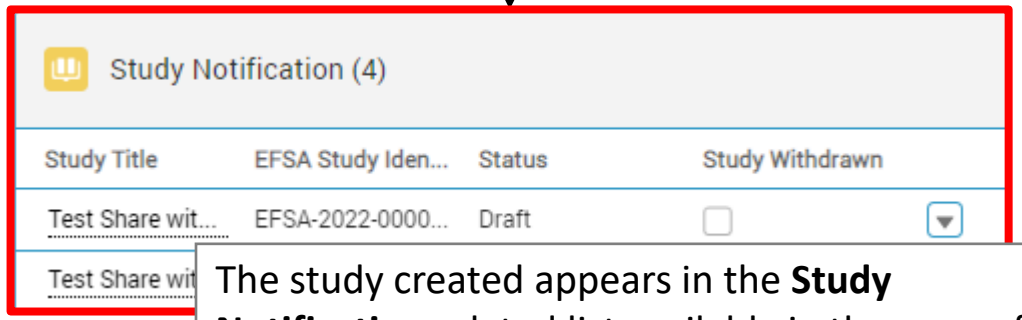
3.3 Study creation (from *pre-application ID*) – Account type: Applicant only



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





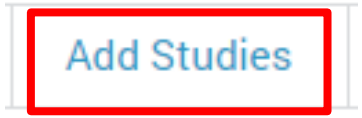


The study created appears in the **Study Notification** related list available in the page of the pre-application ID.

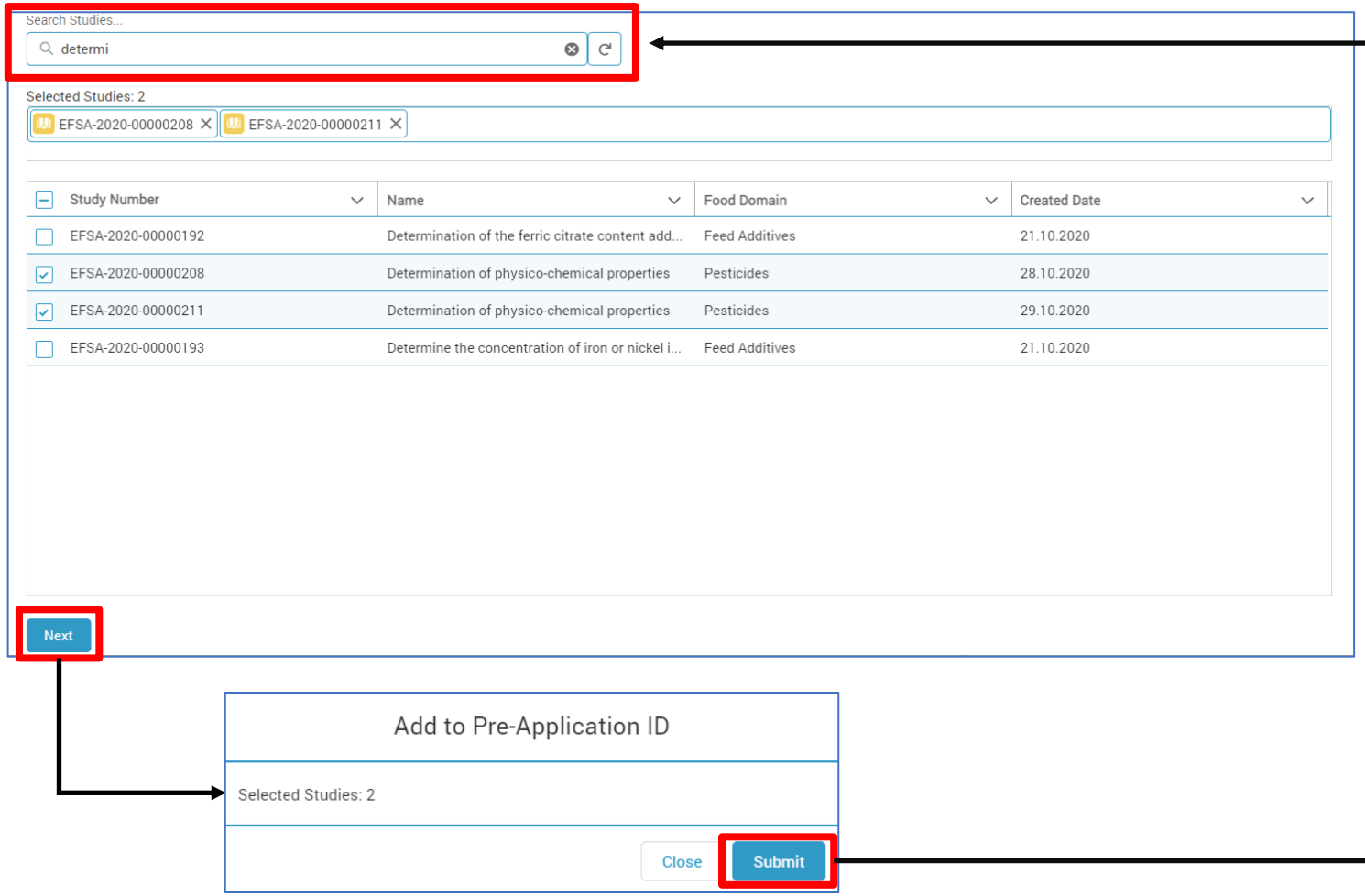
The user must indicate the business operator carrying out or commissioning the study. By default, it is the same user organisation as indicated in the pre-application ID. **When creating the study notification** (and **only** at that stage), it is possible to edit the "Business Operator" field and indicate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

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

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



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



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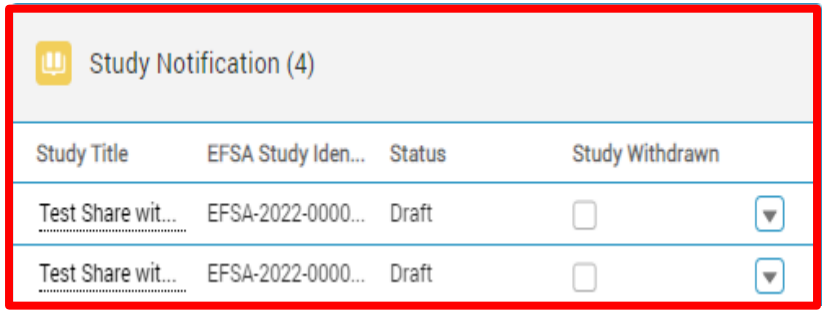
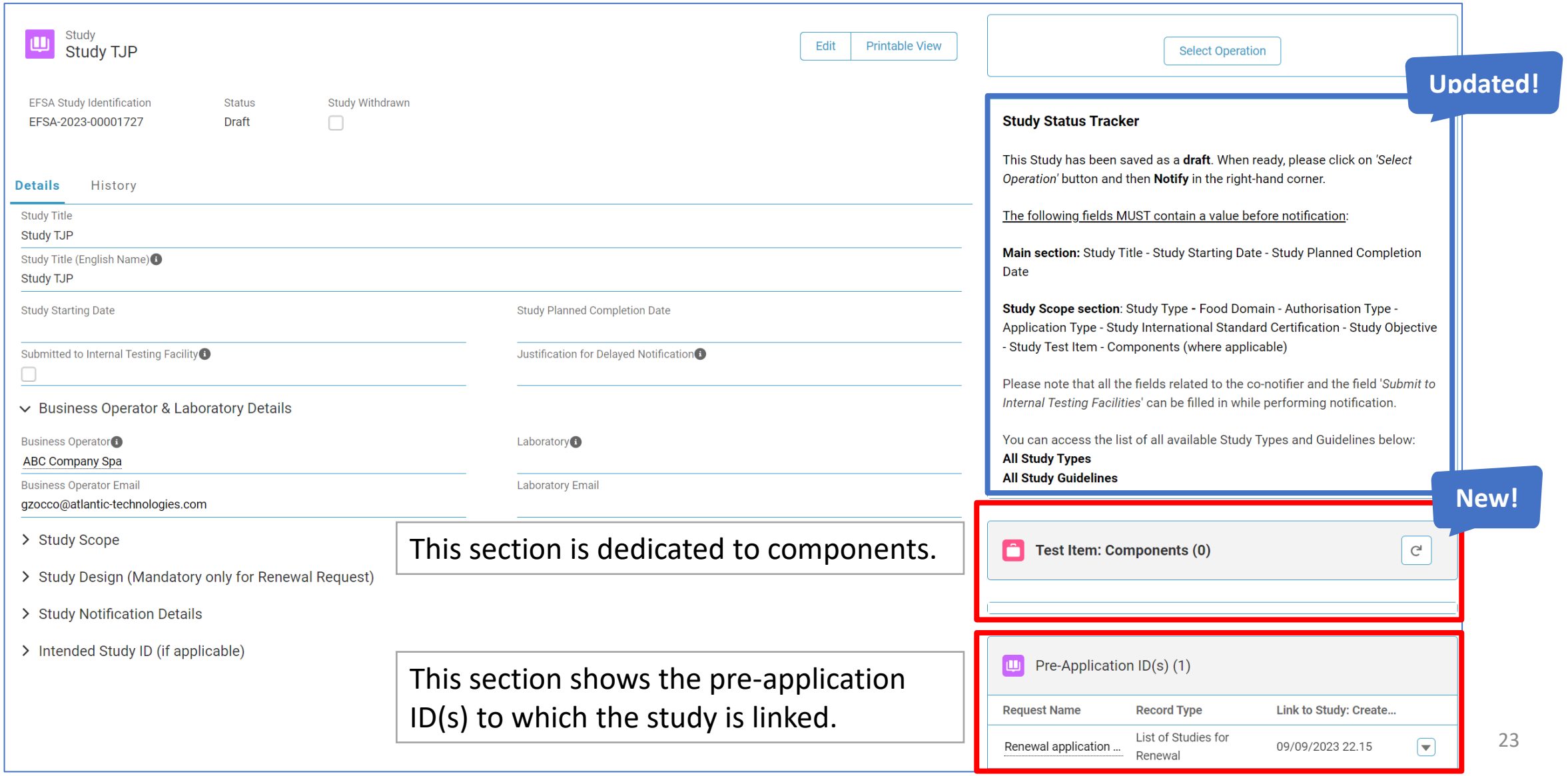


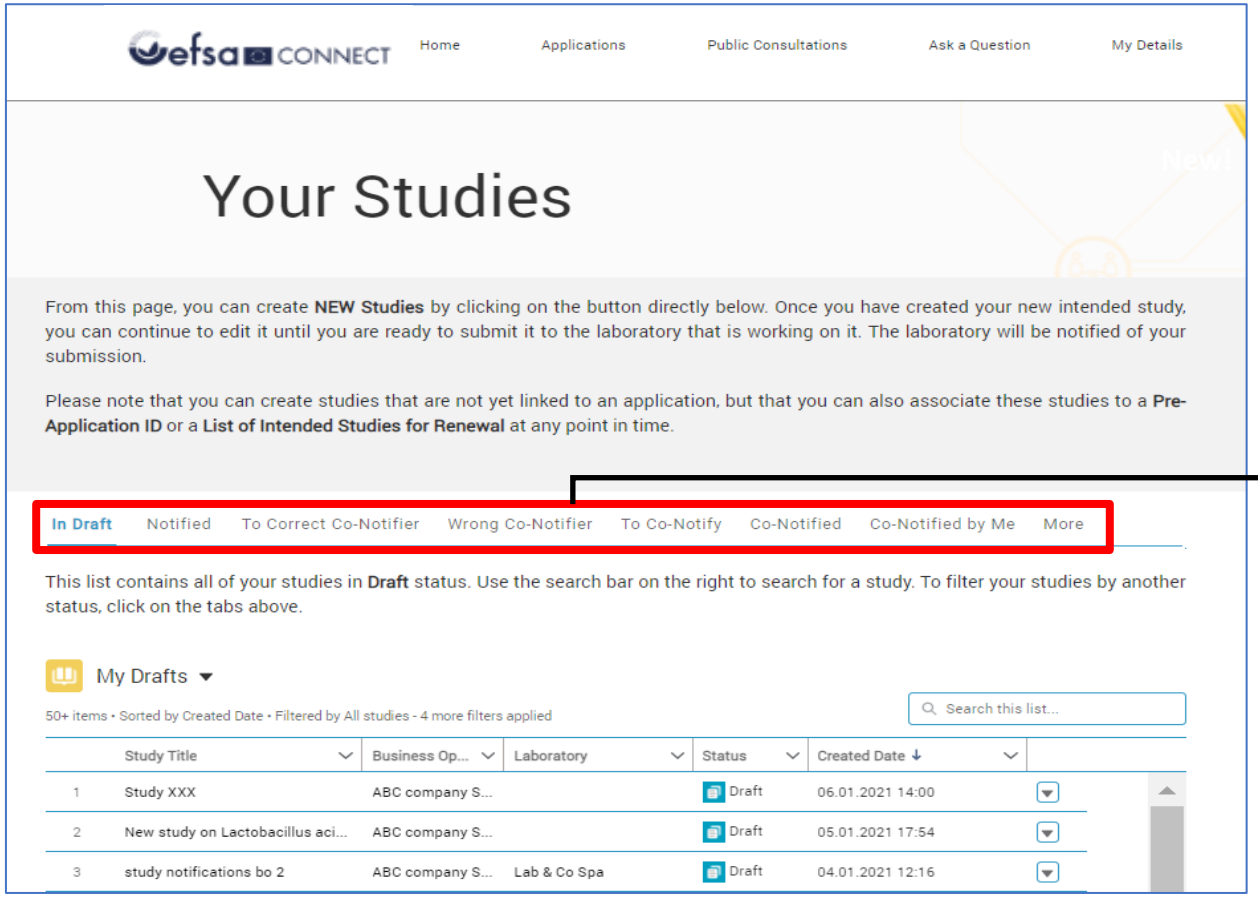
3.3 Study creation (from *pre-application ID*) – Account type: Applicant only

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



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

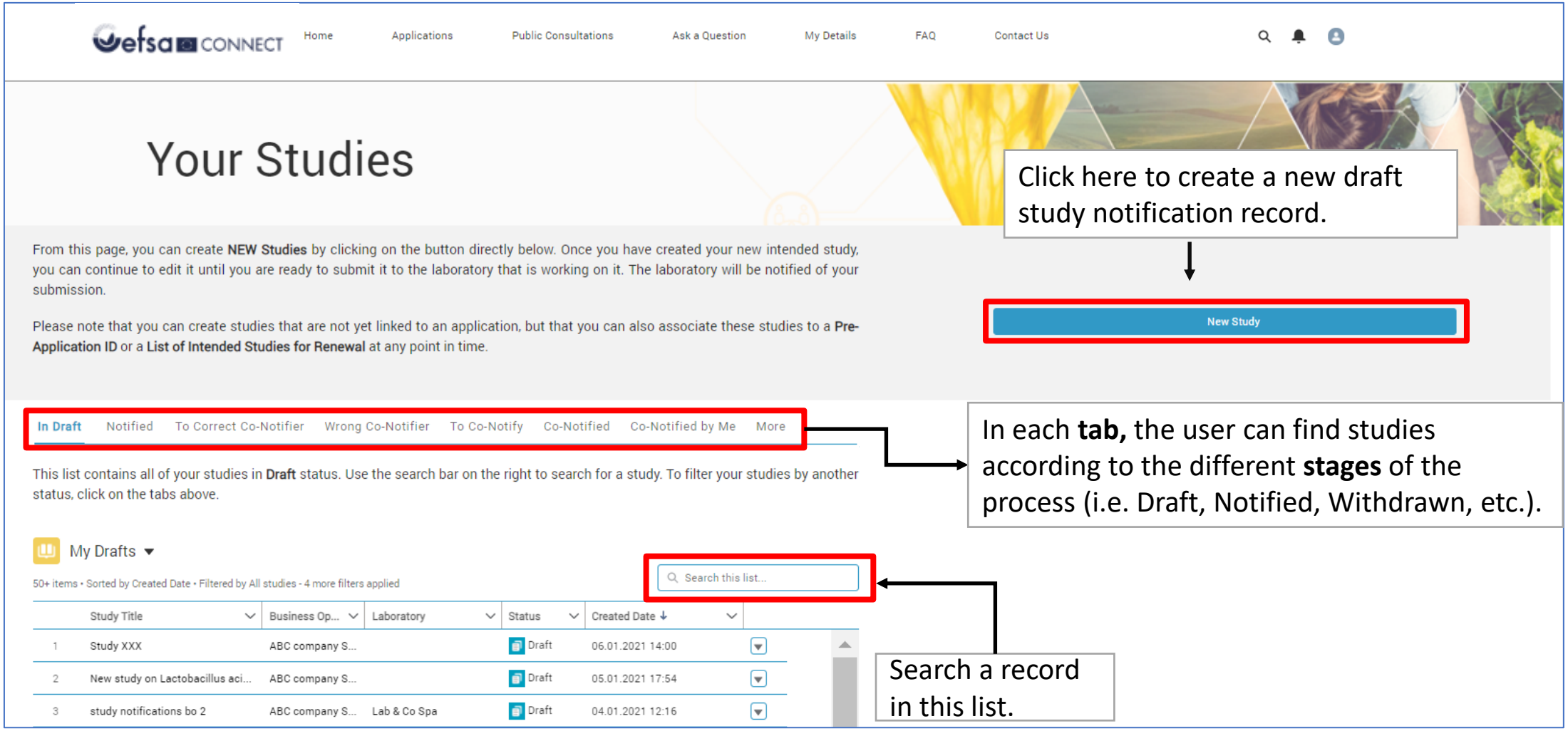
The list views presented in this slide are available in the Studies section and are the same for all the **Account qualifications**.



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

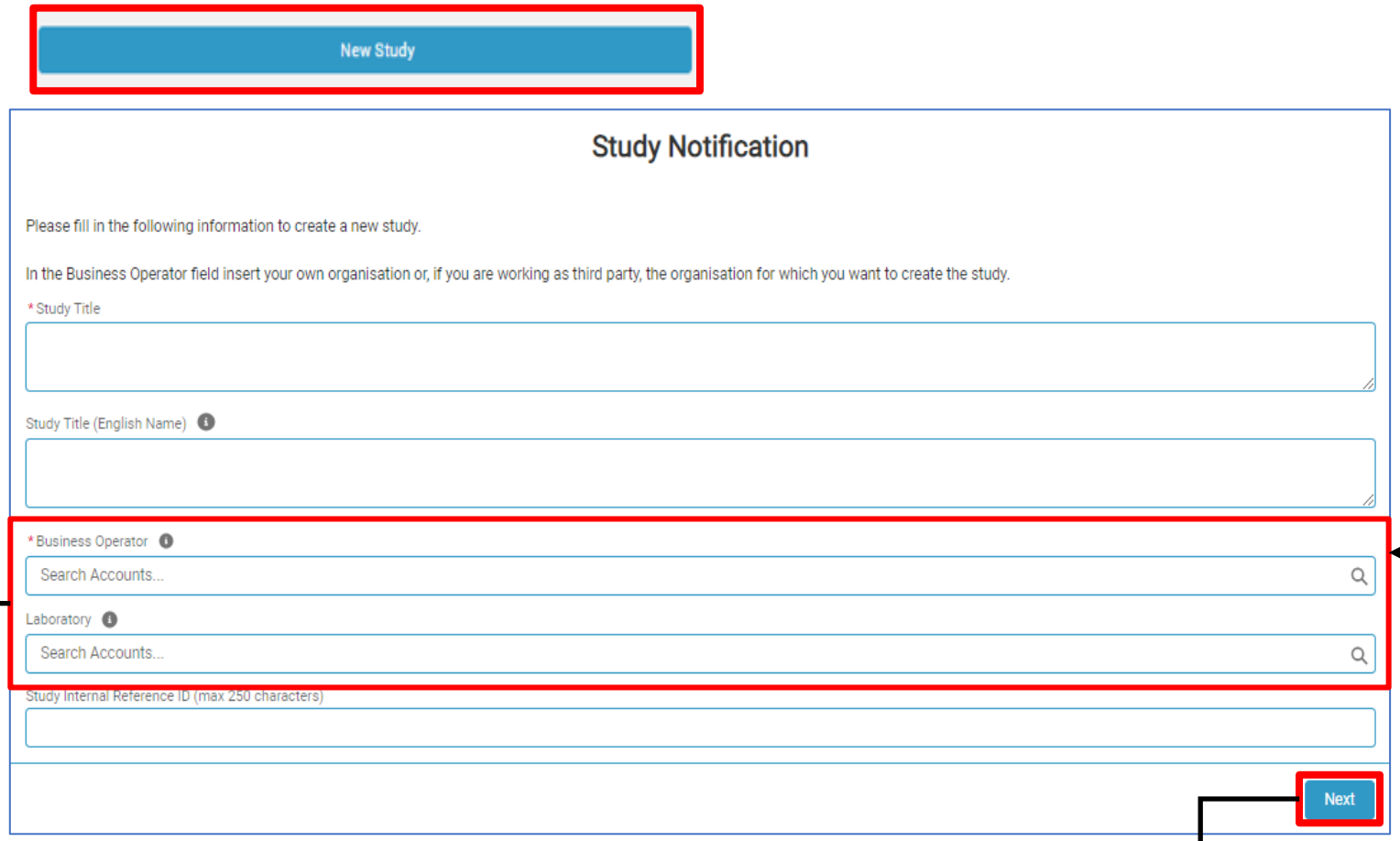
3.4 Study creation (from *Studies*) – Account type: Applicant only

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



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

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



- 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.

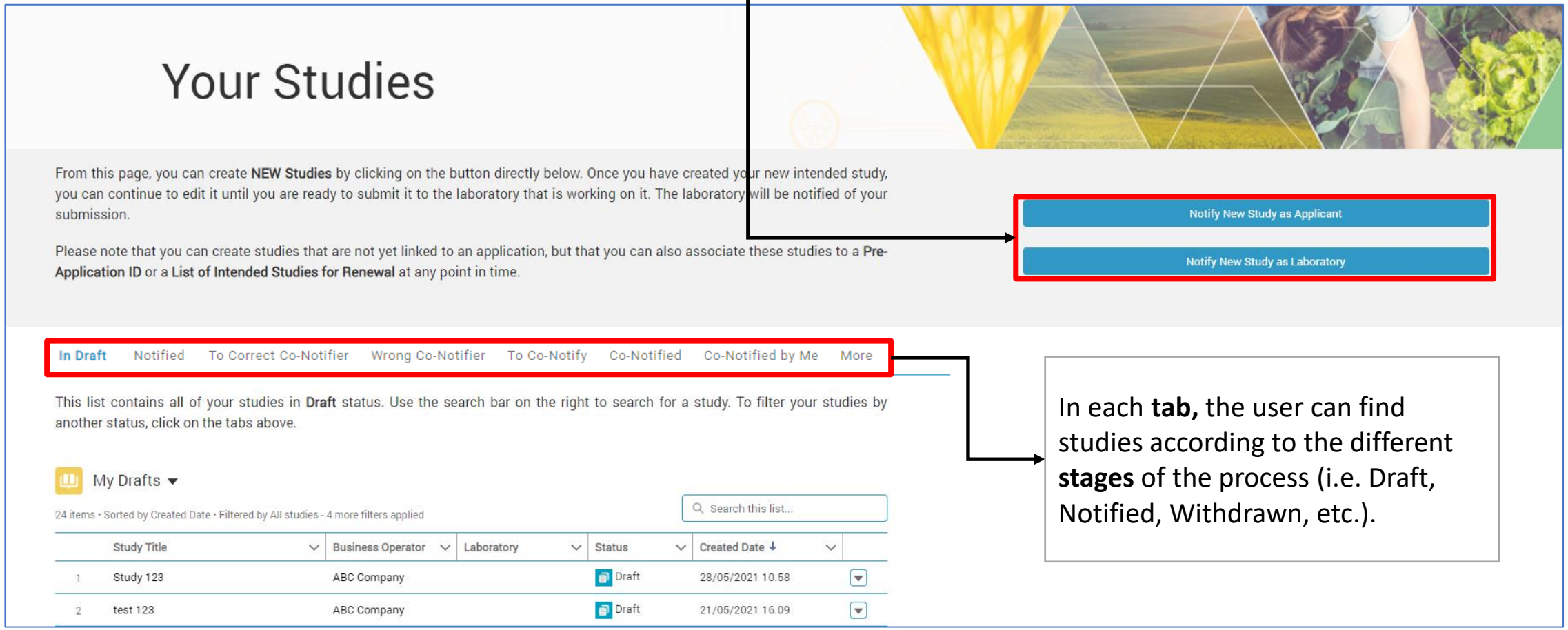
- **The user can also indicate the laboratory** commissioned to conduct the study. This information can be revised also at a later stage.

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

Click here to create the study notification record.

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

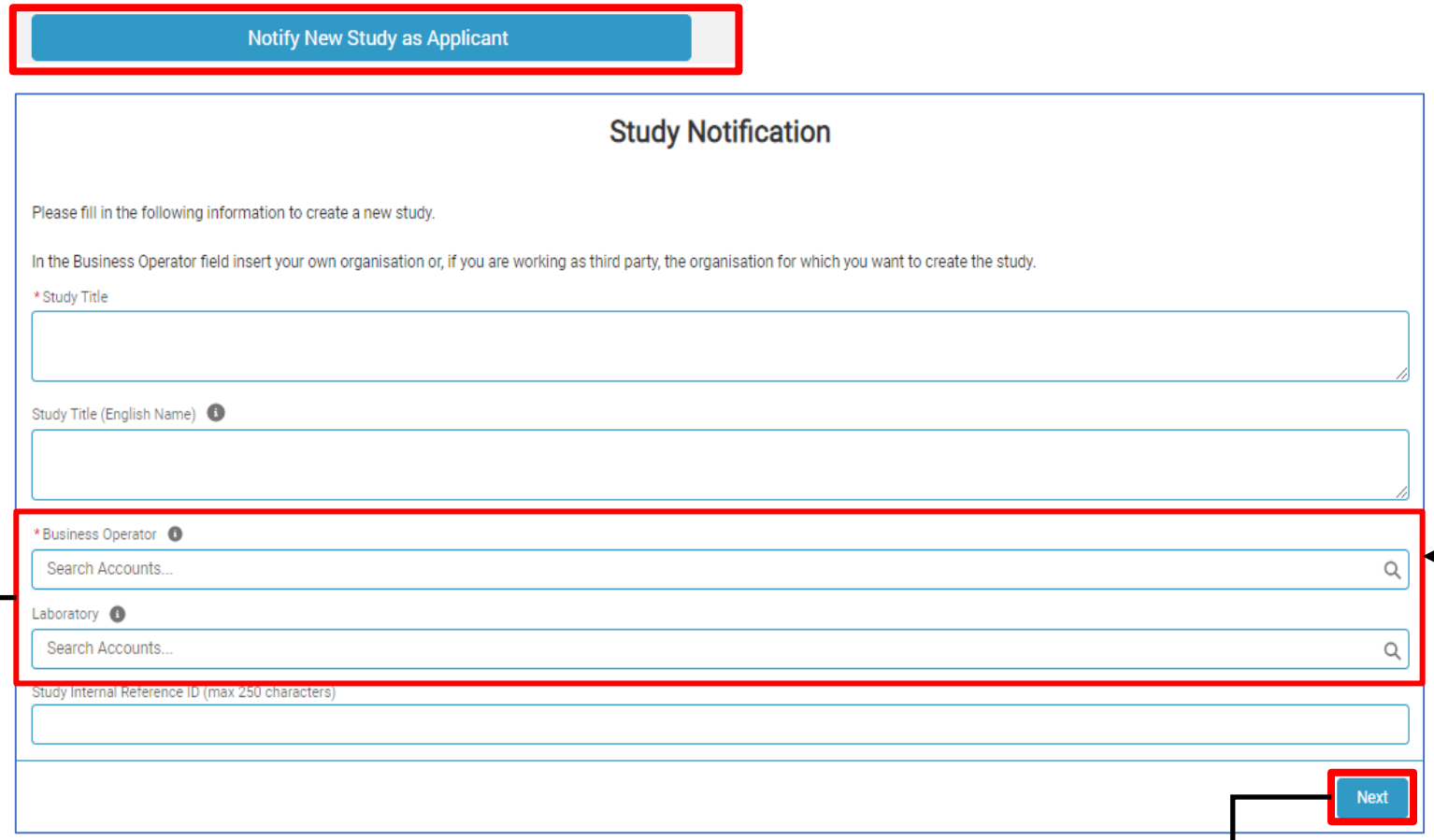
When the user's organisation is qualified both as Applicant and Laboratory, the user can decide between "**Notify a New Study as Applicant**" (see Section 3.5.1) or "**Notify a New Study as Laboratory**" (see Section 3.5.2).



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

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

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



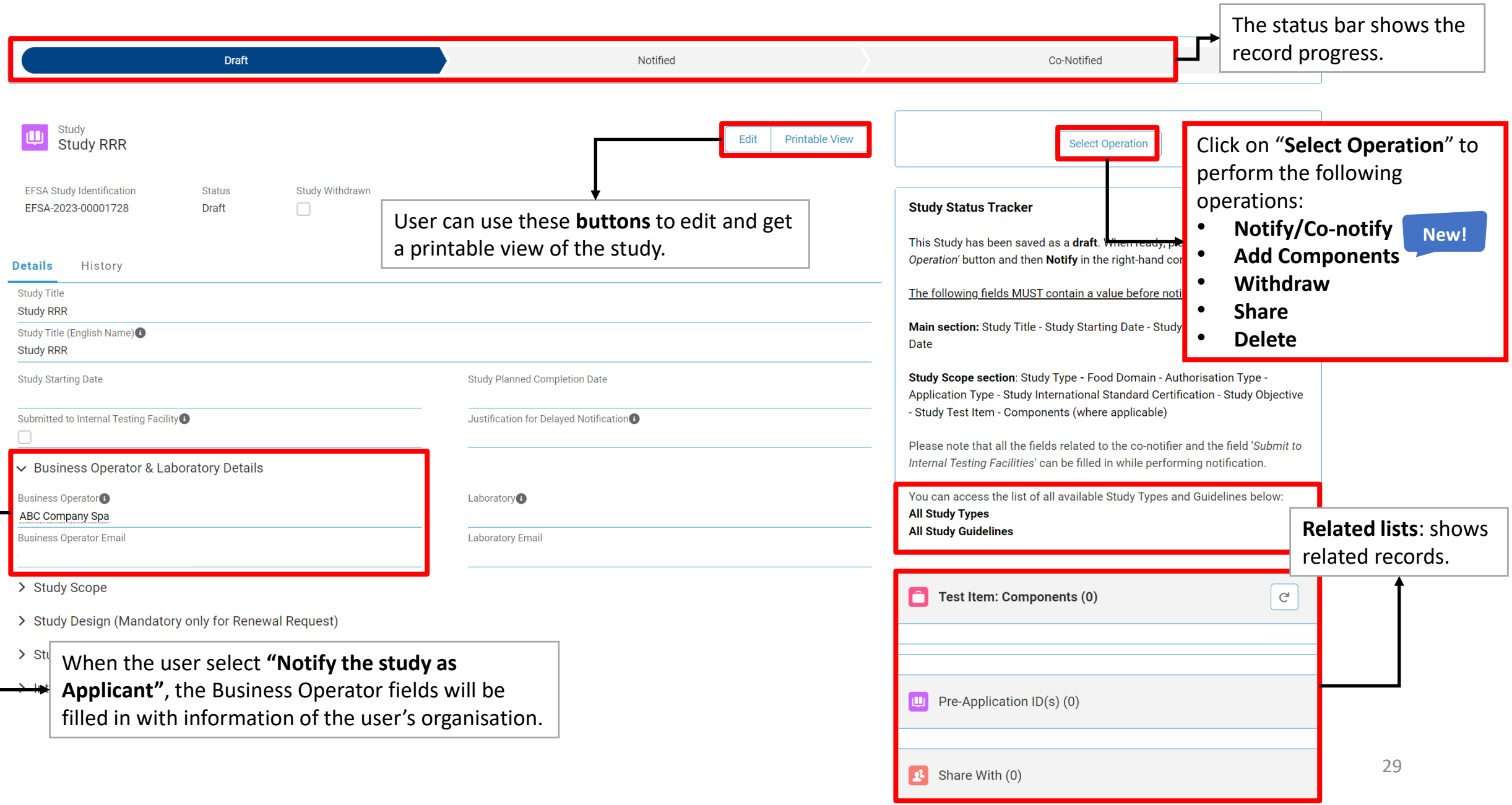
- Insert the user's organisation as **business operator.**
- If the notification is inserted by a consultant, the business operator for which the consultant is working 'On behalf of' should be inserted in the field 'Business Operator'. This relationship must be firstly established as explained in the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

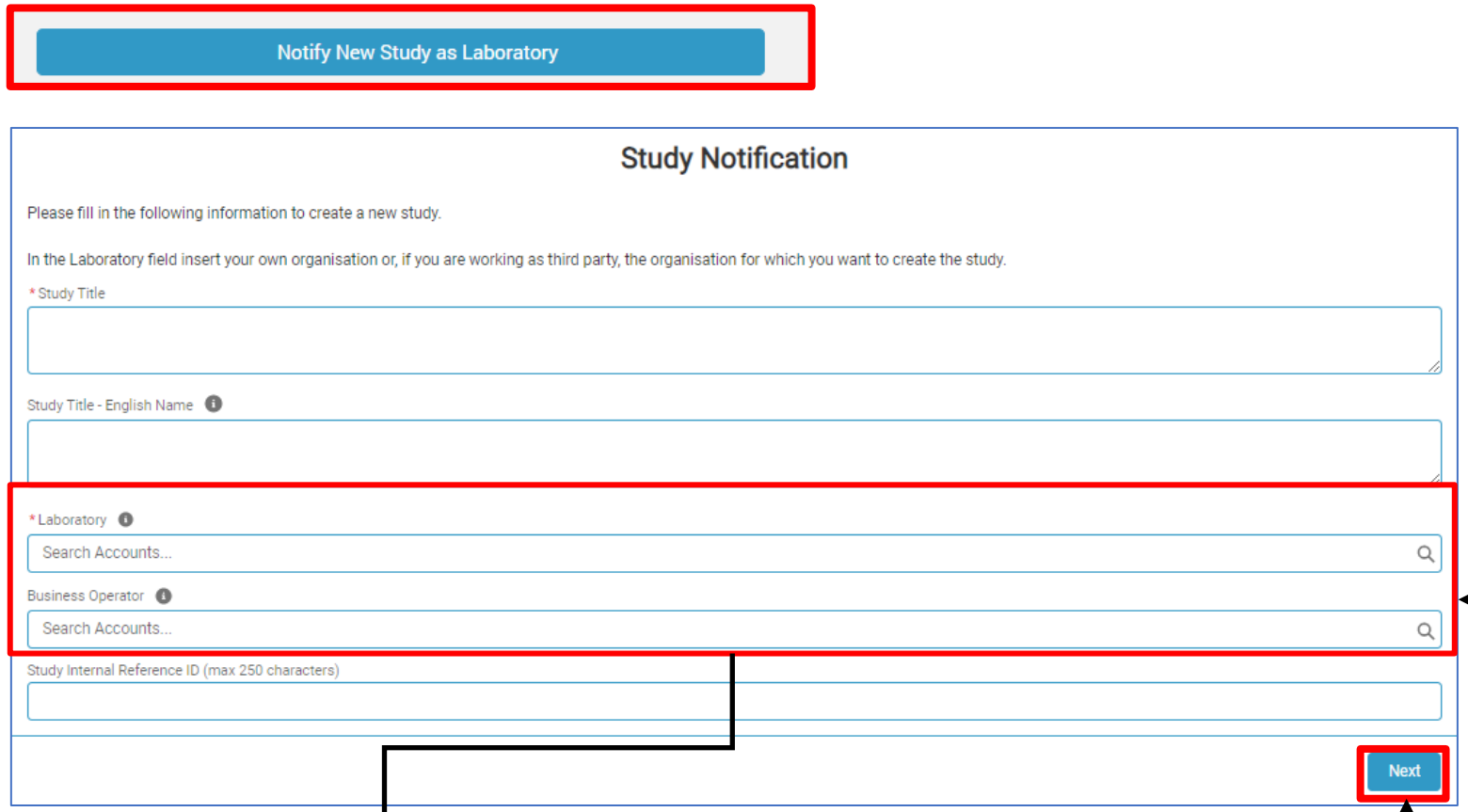
Click here to create the study notification record.

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



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

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



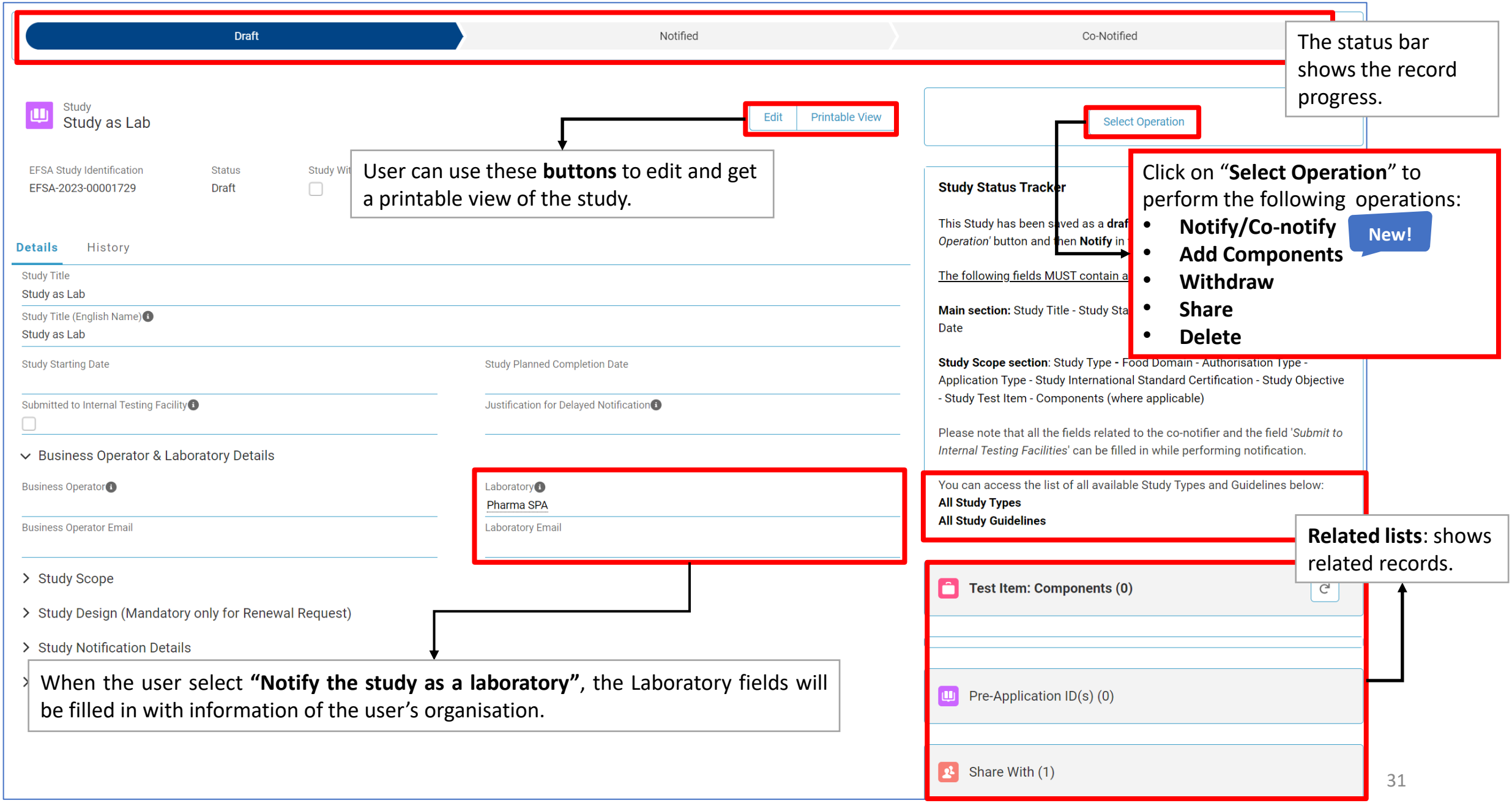
- Insert the user's organisation as **laboratory.**
- If the notification is inserted by a consultant, laboratory for which the consultant is working 'On behalf of' should be inserted in the field 'Laboratory'. This relationship must be firstly established as explained in the **Account relationship**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

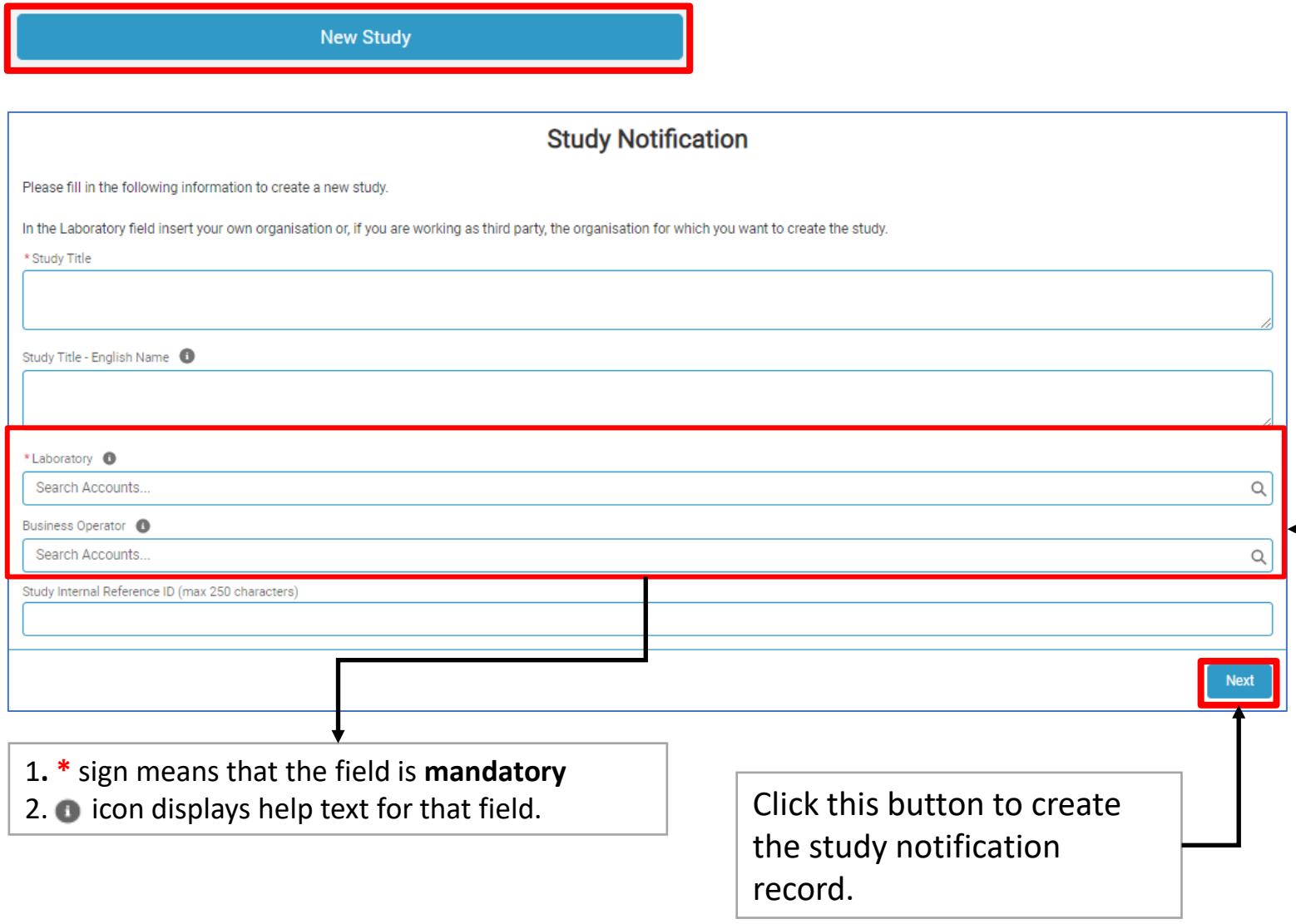
Click this button to create the study notification record.

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



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

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



- 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.

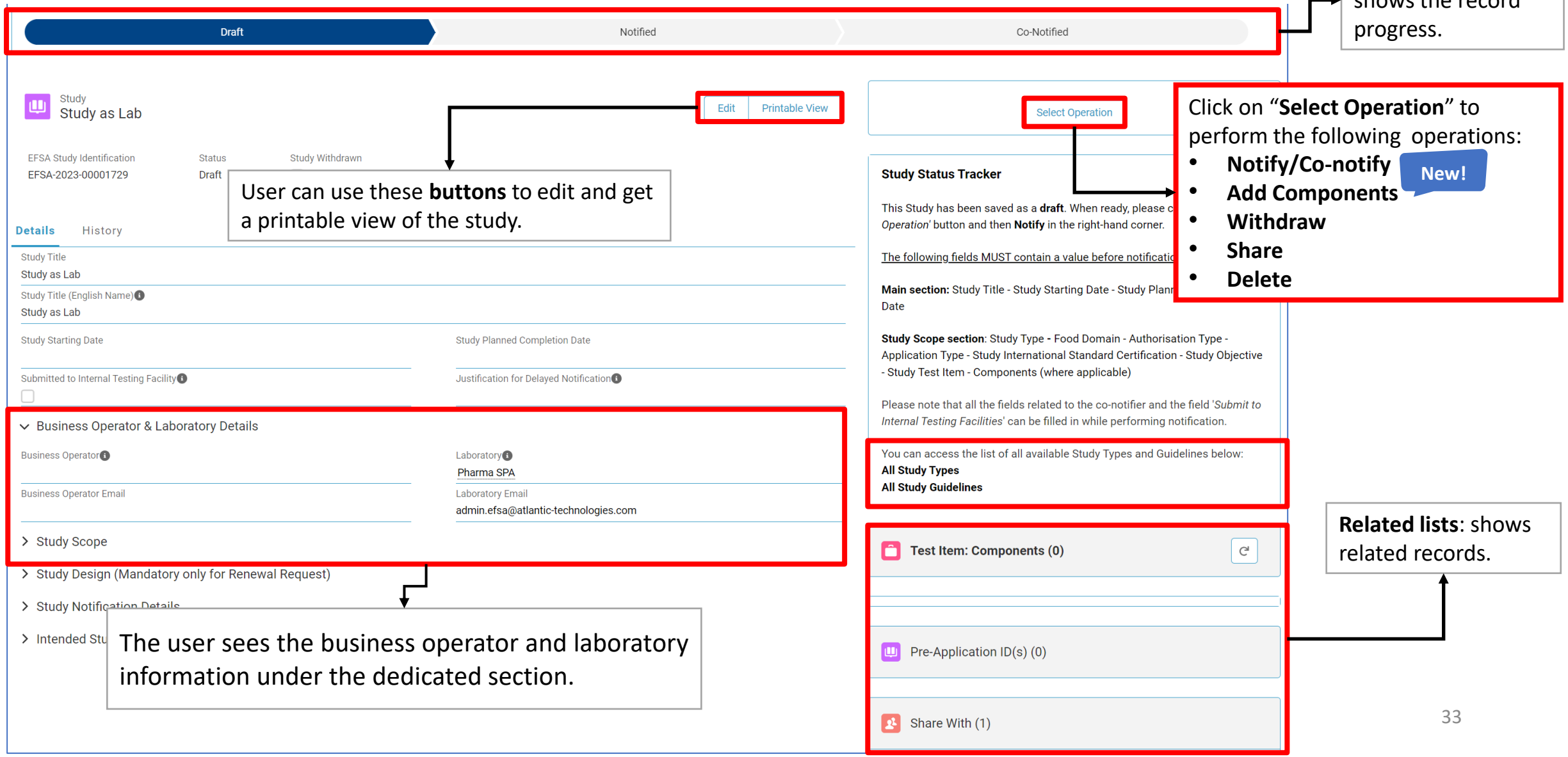
- **The user can also indicate the business operator** who commissioned the study. This information can be revised also at a later stage.

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

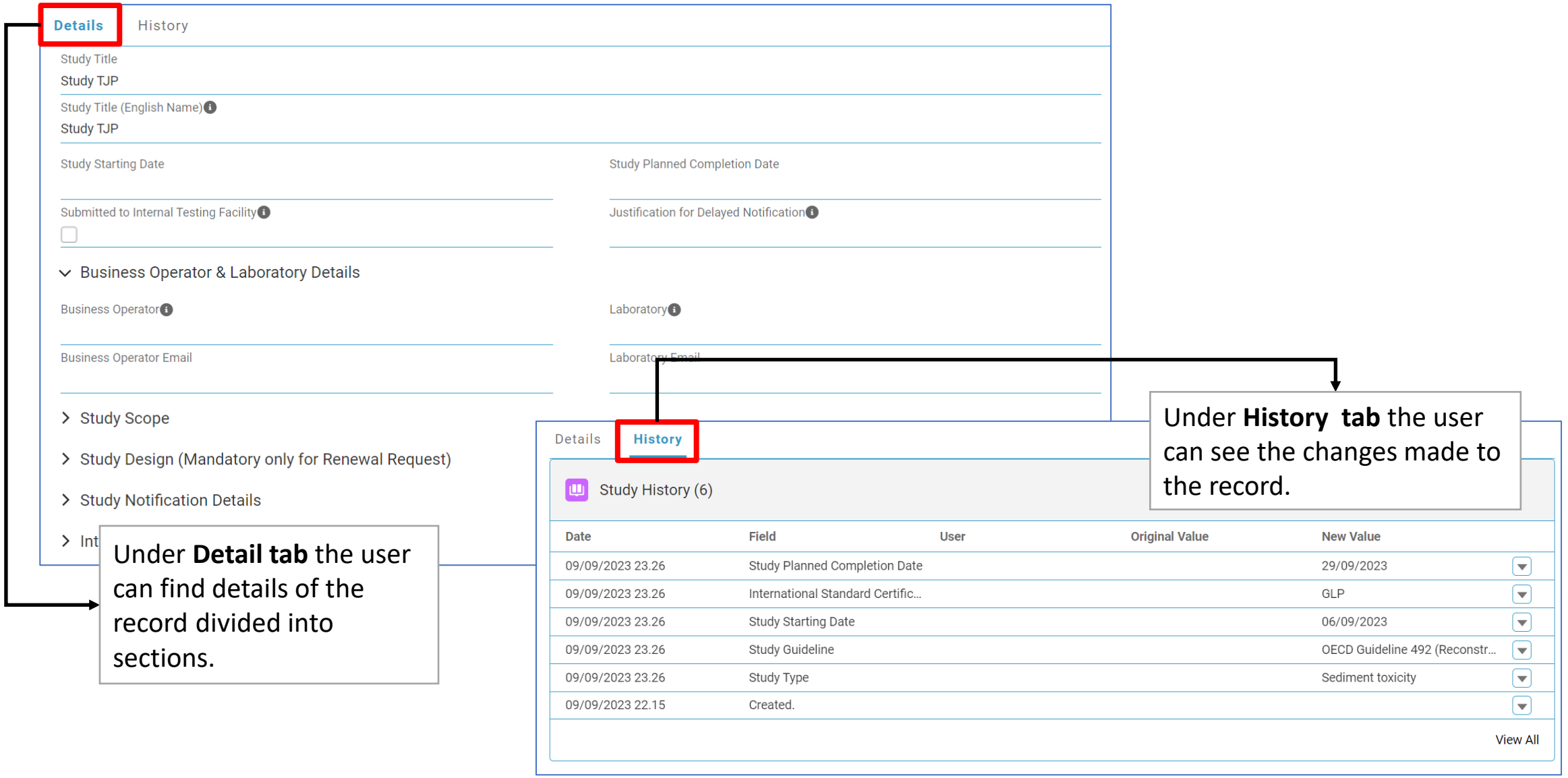
Click this button to create the study notification record.

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

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



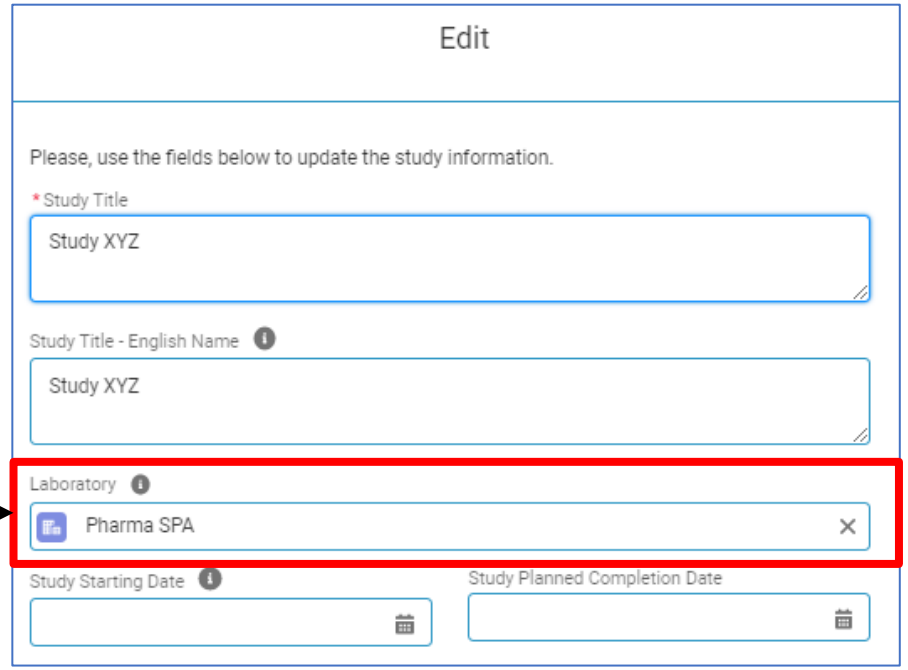
3.7 Study creation (from *Studies*) - Valid for all organisations -> Details and History tabs



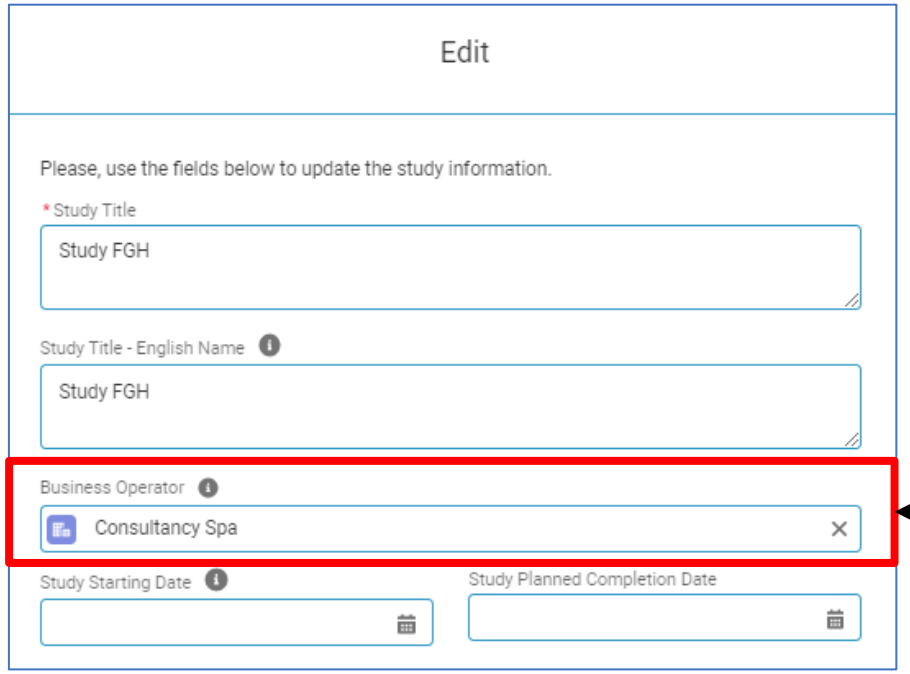
3.8 Edit a draft study

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

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



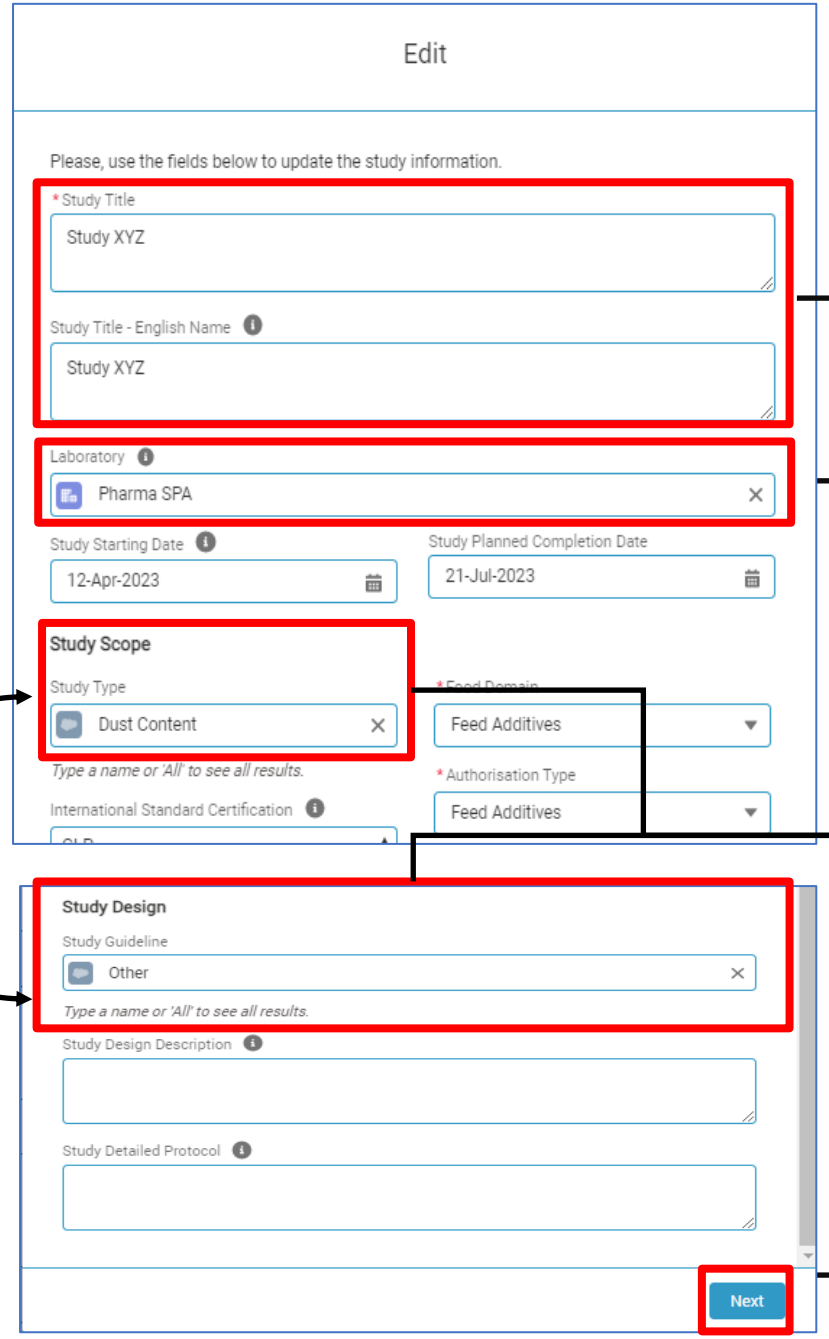
Edit view if the notifier is a business operator.



Edit view if the notifier is a laboratory.

3.8 Edit a draft study

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



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.

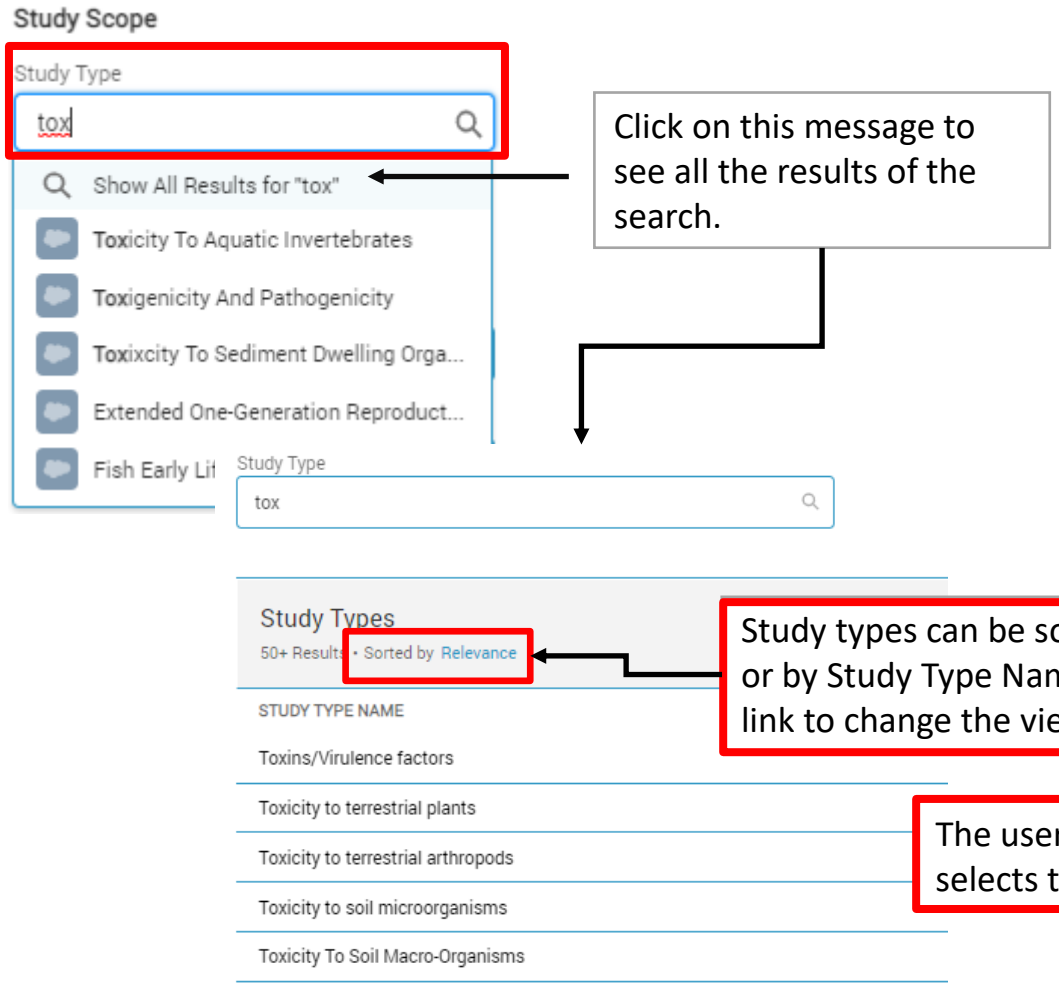
More details on the selection of a **Study Type** and **Study Guideline** are showed in the next slide.

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.

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

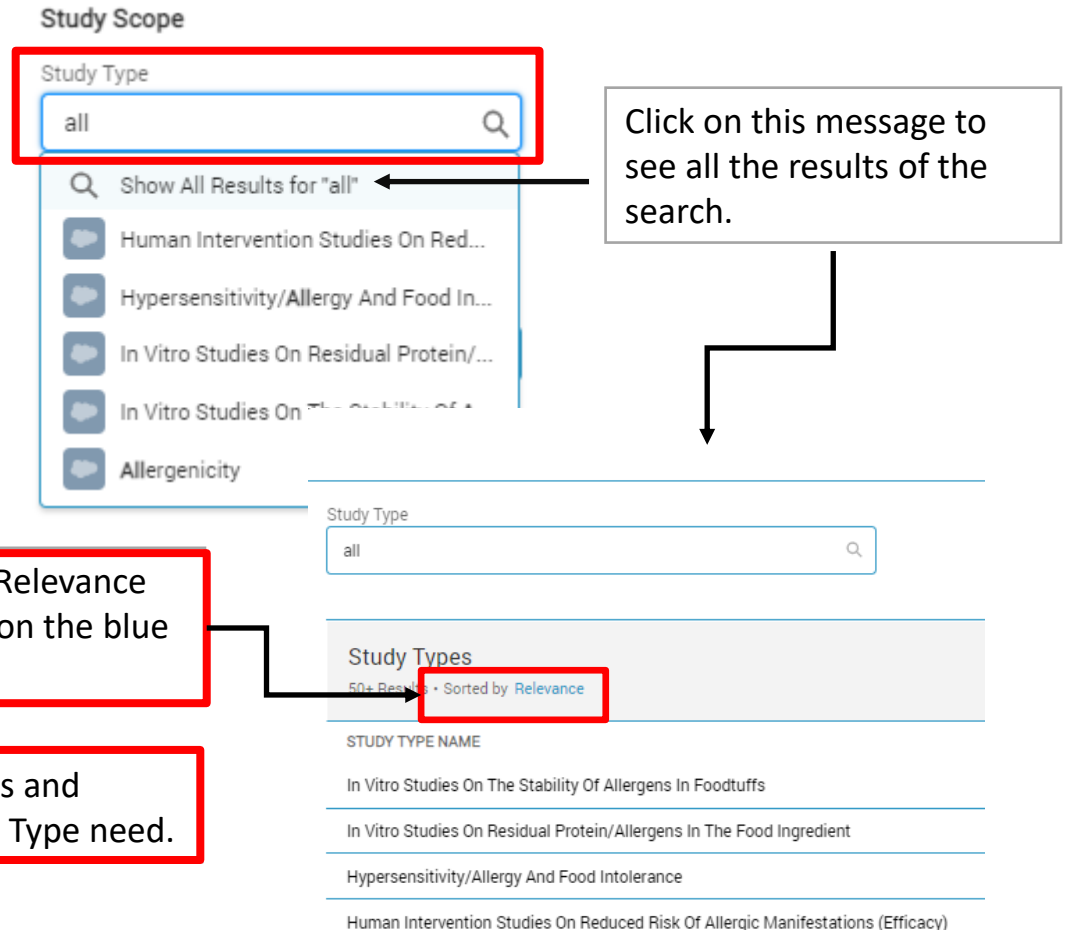
Users can search for a specific Study Type if known already.



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

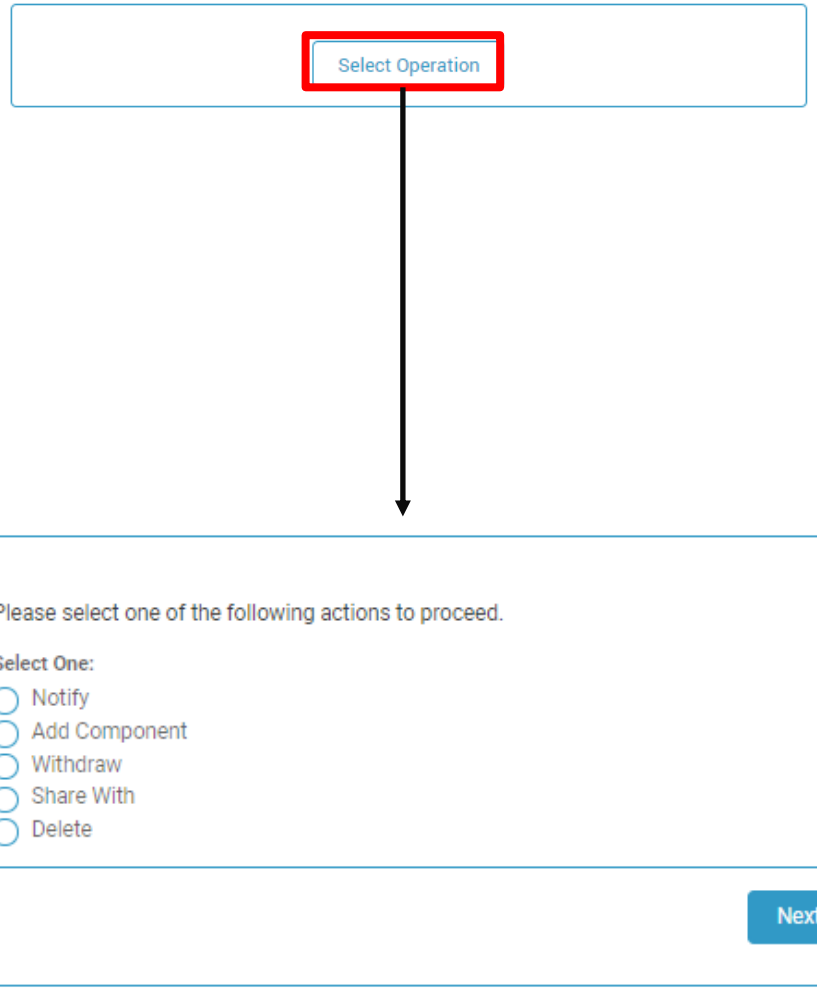
The user searches and selects the Study Type need.

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.**



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

3.9 Actions on a draft notification



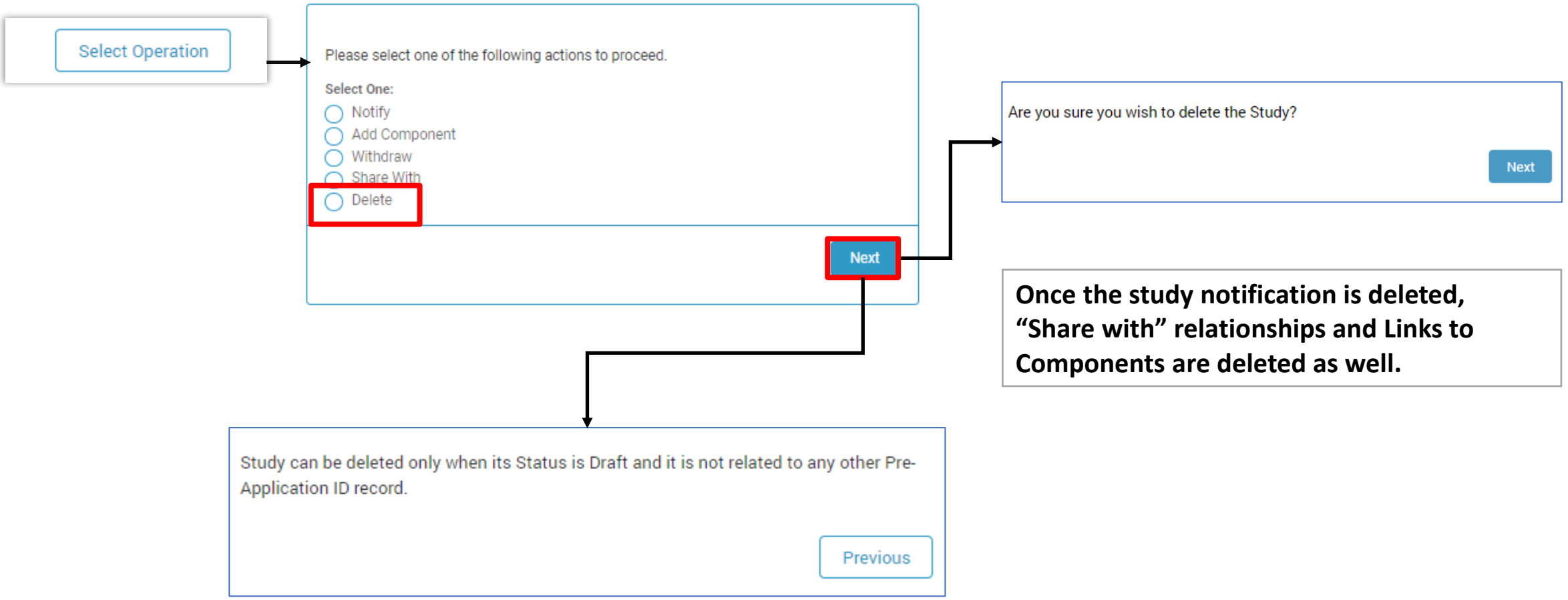
The notifier can perform several actions on the study notification record by clicking the function button **Select Operation** in the upper right corner of the page.

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

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

3.9.1 Delete study

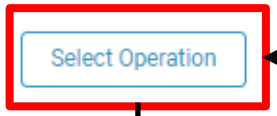
The notifier can delete a study notification record only when its **Status** is **Draft,** and it is **not related to** any other **pre-application ID**.



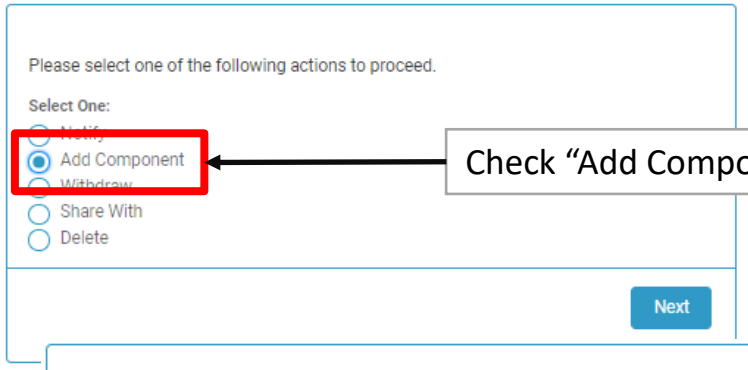
3.10 Component management - Add a component

New!

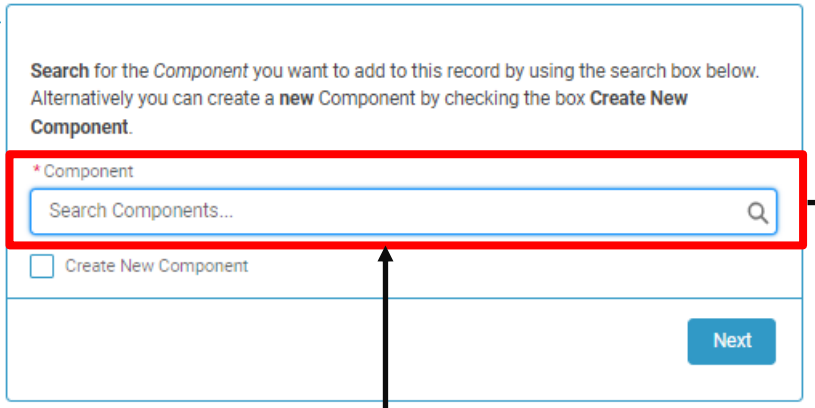
The notifier can add a component to give information on the test item of the study.



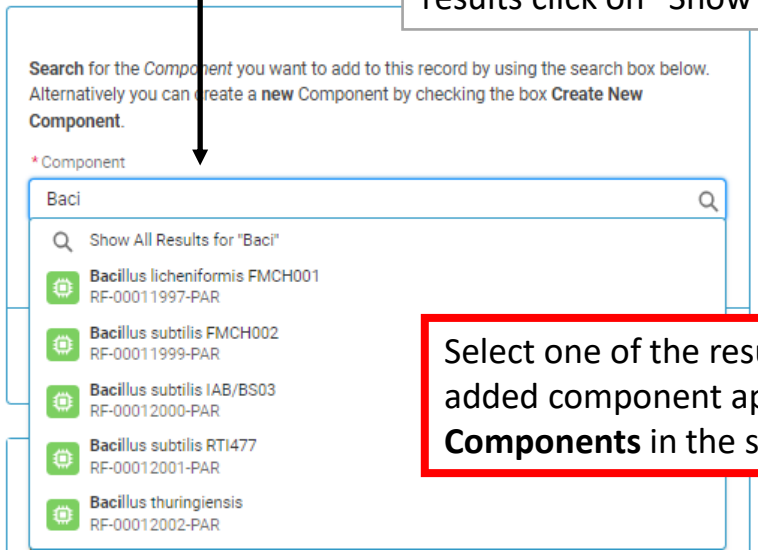
Click on **Select Operation** on the right-hand of the study notification page.



Check “Add Component” and click **Next**.



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



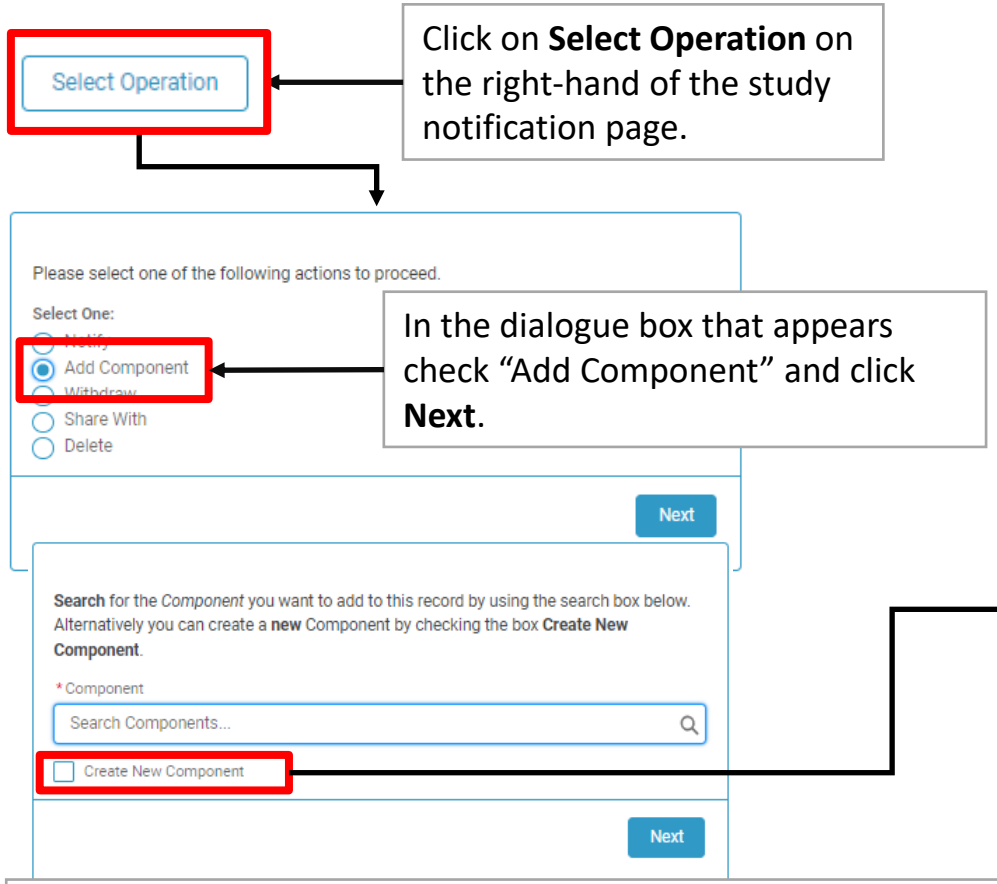
Select one of the results and click on **Next** to continue. The added component appears in the related list **Test item: Components** in the study notification page**.**

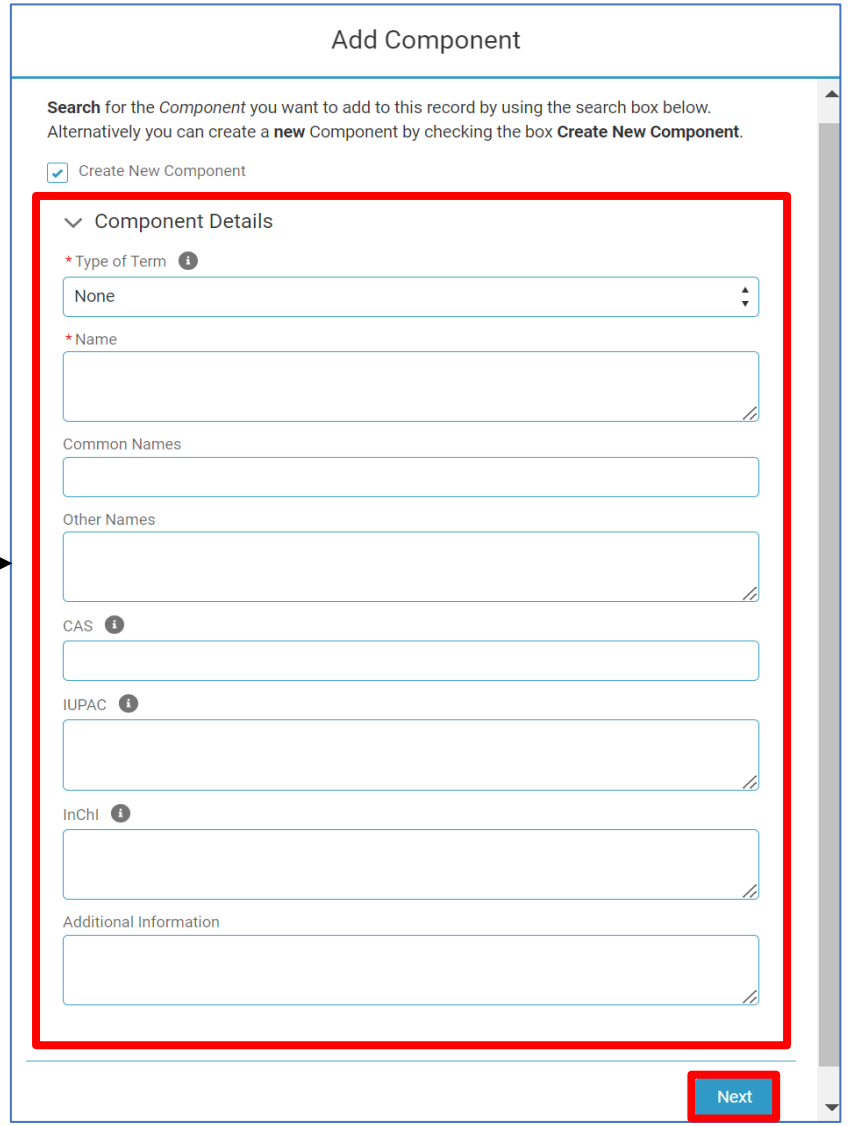
It is possible to **search for existing components in the EFSA catalogue (PARAM)**. The search includes also the components already created by the user. See **“View Component”** section for details.

3.10.1 Component management - Create component

New!

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



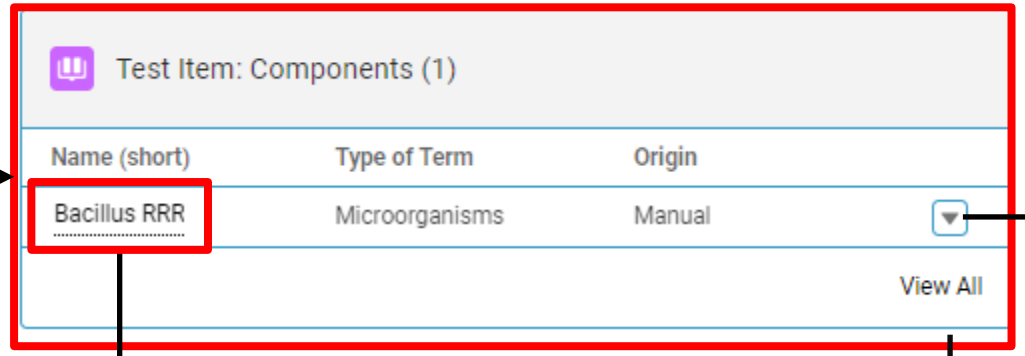


Fill in the “Component Details” form with the corresponding information. The fields “Type of Term” and “Name” are mandatory. More details on the information required by a certain field are showed by passing over the ⓘ icons. Click **Next** to continue.

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

New!

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

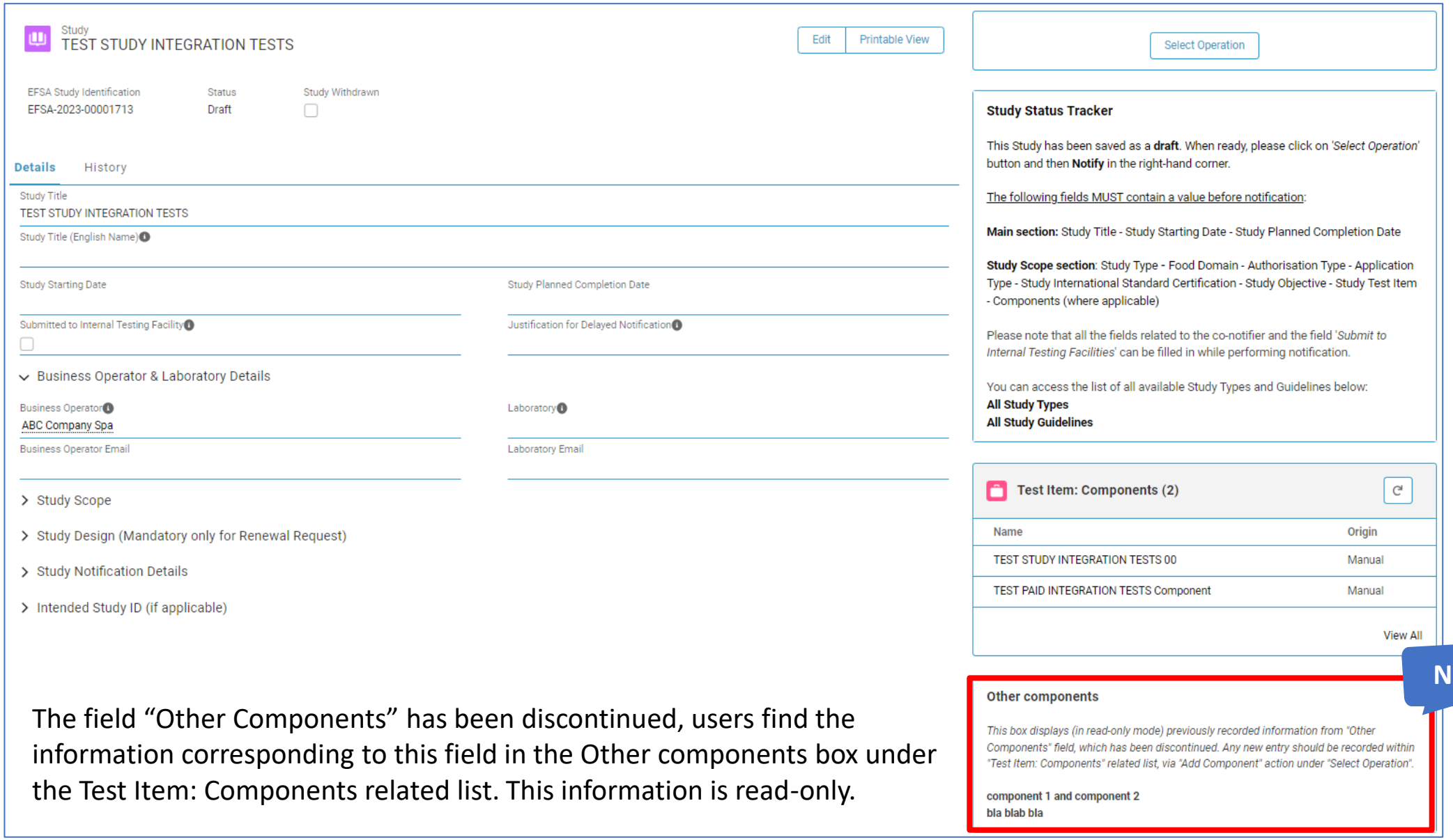


Click on pointing down arrow to Edit or Delete the component from the list. More information in the Section dedicated to **Delete link to components**.

Click on the name of the component to open the corresponding details page. More information in the Section dedicated to the **Components details page**.

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

3.10.3 Component management – Other components box

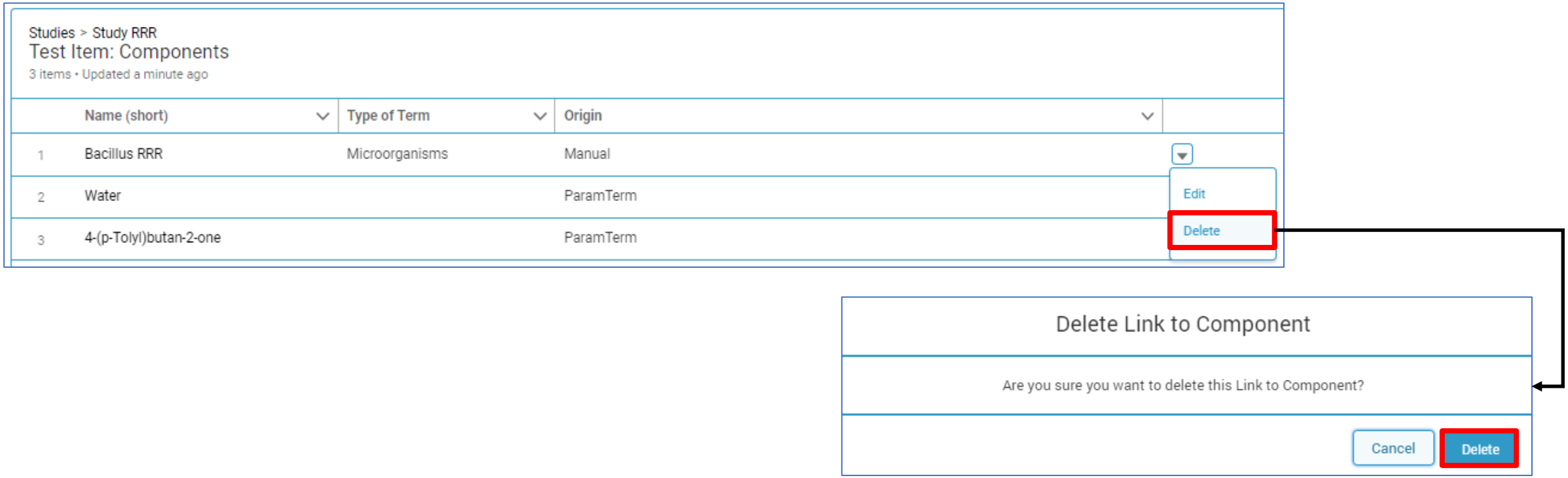


The field “Other Components” has been discontinued, users find the information corresponding to this field in the Other components box under the Test Item: Components related list. This information is read-only.

3.10.4 Component management - Delete link to components

Updated!

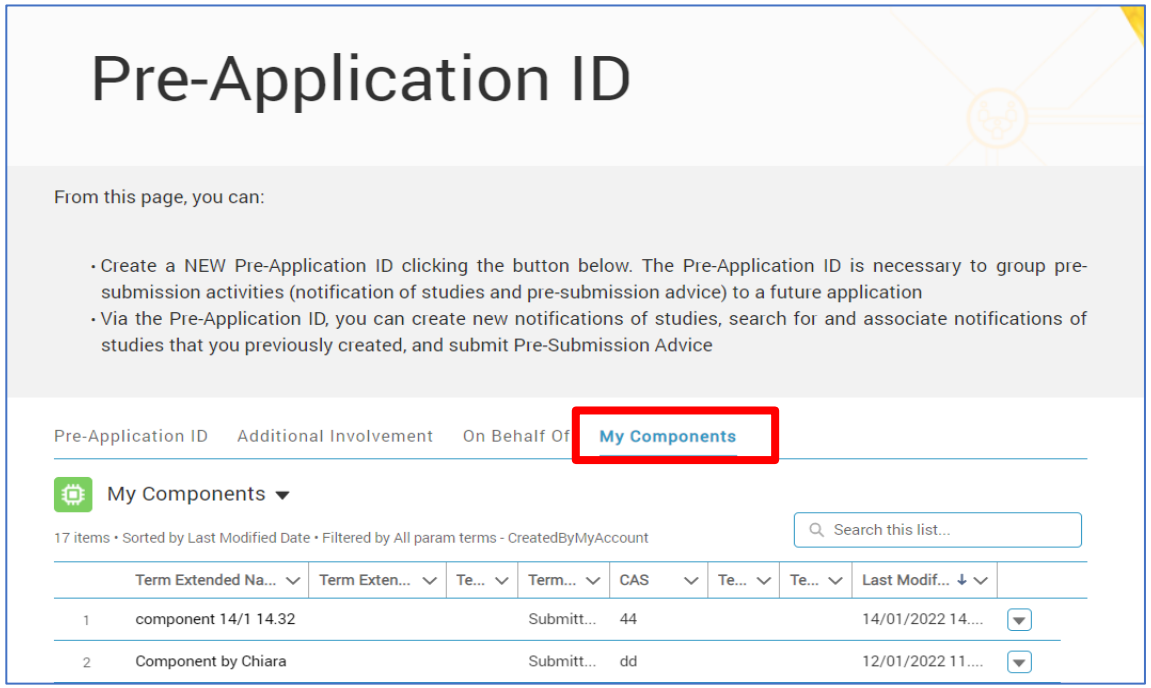
The notifier can **always** remove components from the study notification record. By performing this action, the notifier will delete only the link between the study notification and the component, **not the component itself**.

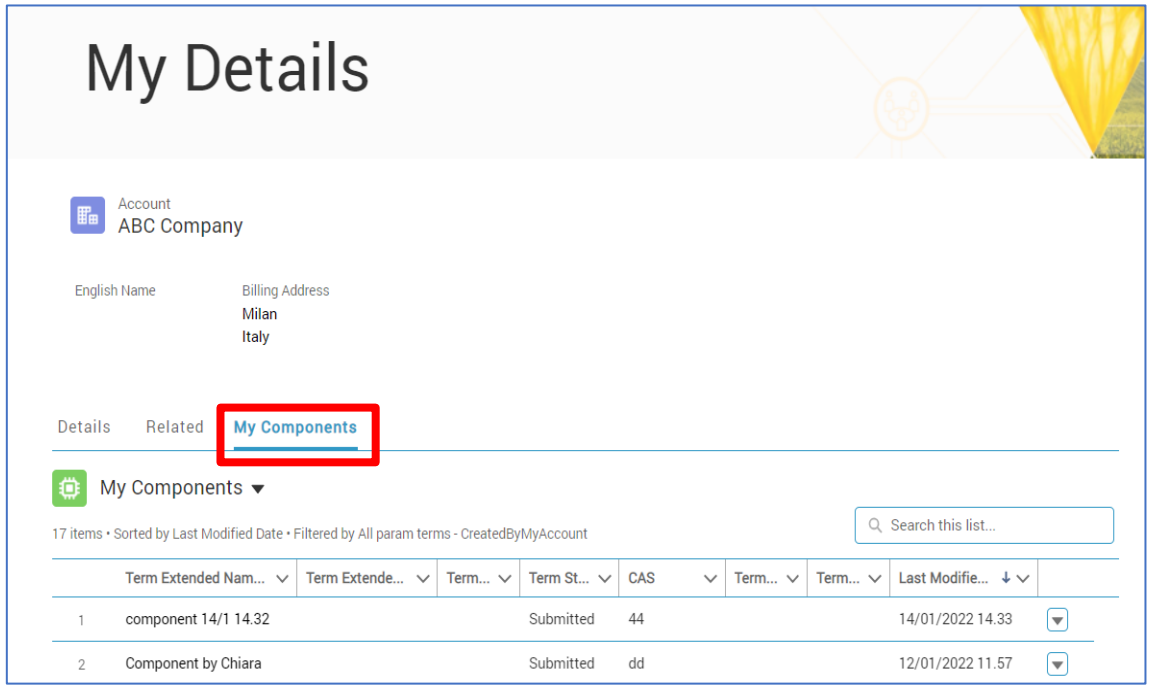


As a result, **the component is removed from the related list** "Test item: Components" on the study notification page.

3.10.5 Component management - View Components

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

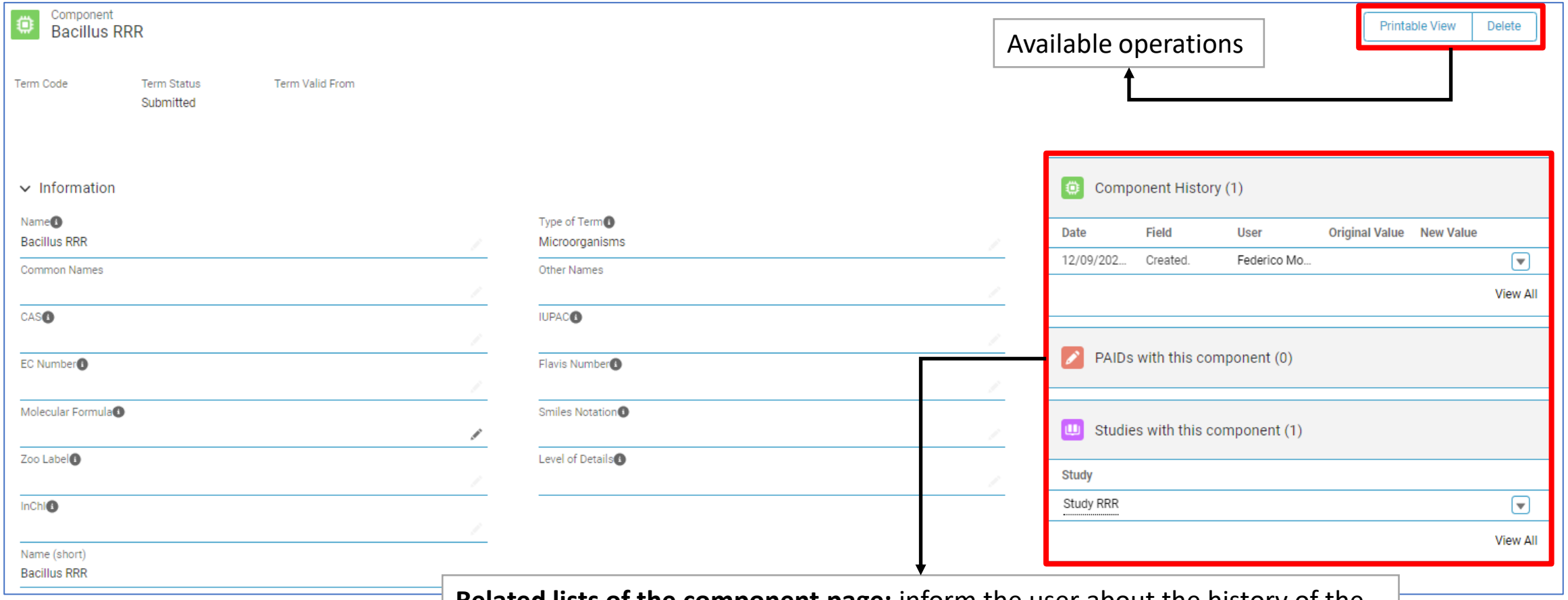




3.10.6 Component management - Details Page

Updated!

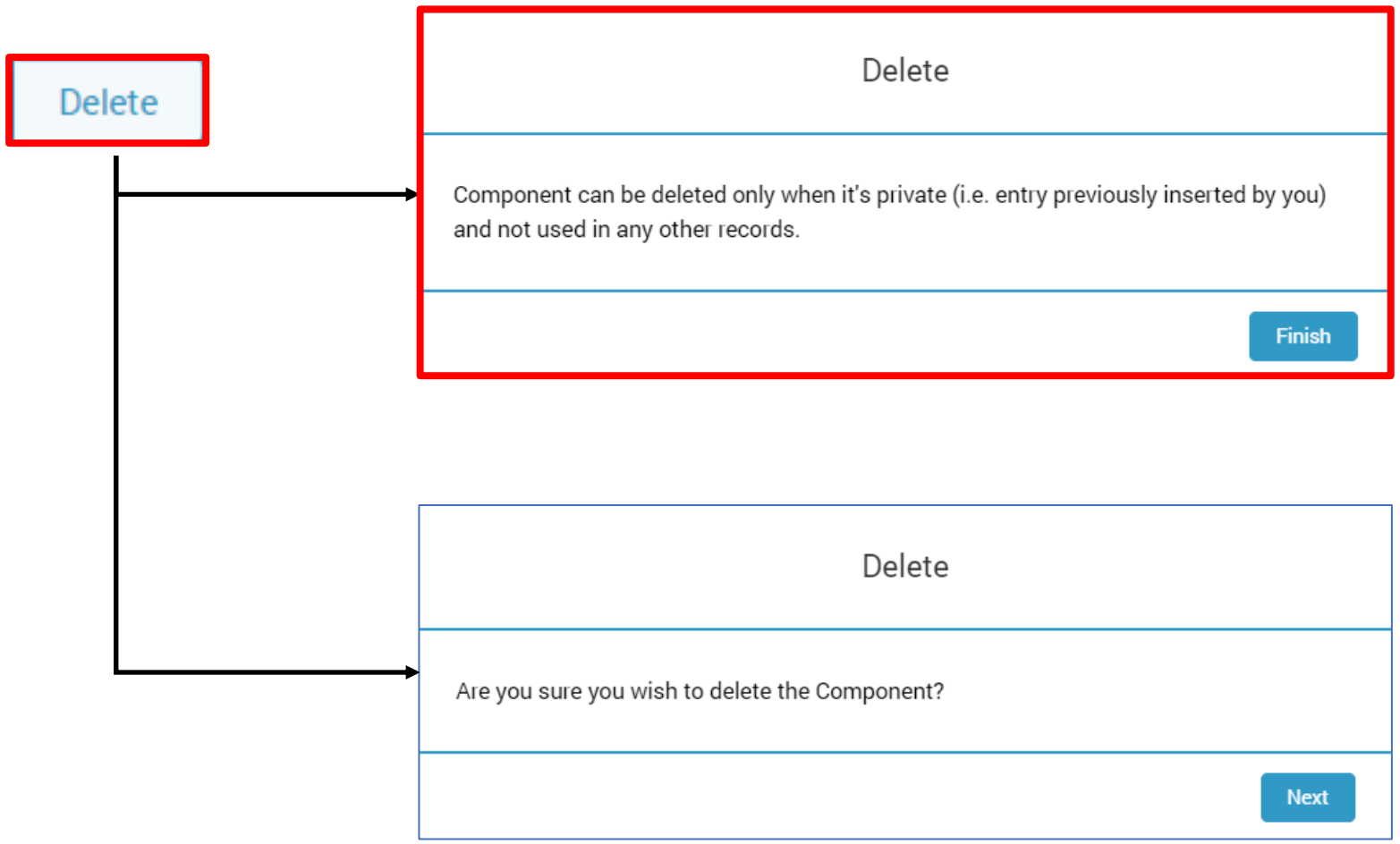
The detail page of the component appears as in the image below. Information on the component can be added/modified directly from this page only for components created by the user.



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

3.10.7 Component management - Delete Components

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

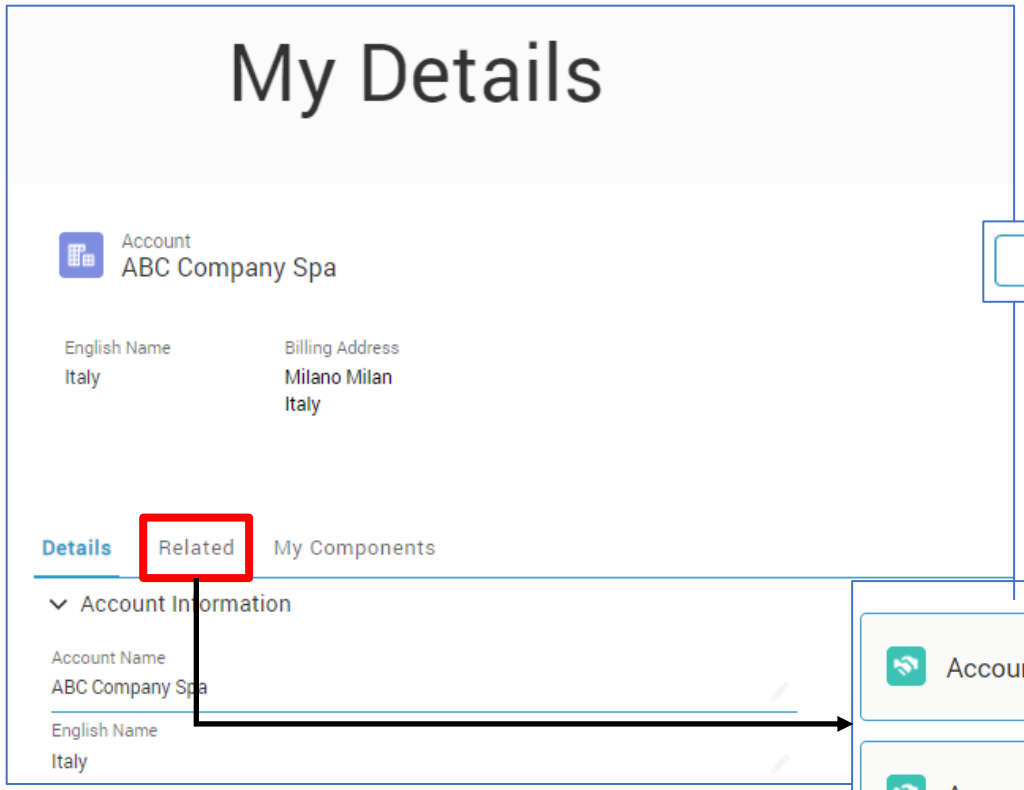


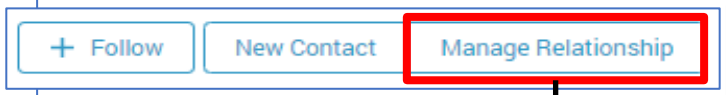
This **error message** appears if the component is used in any other record (i.e. pre-application IDs, study notification records).

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

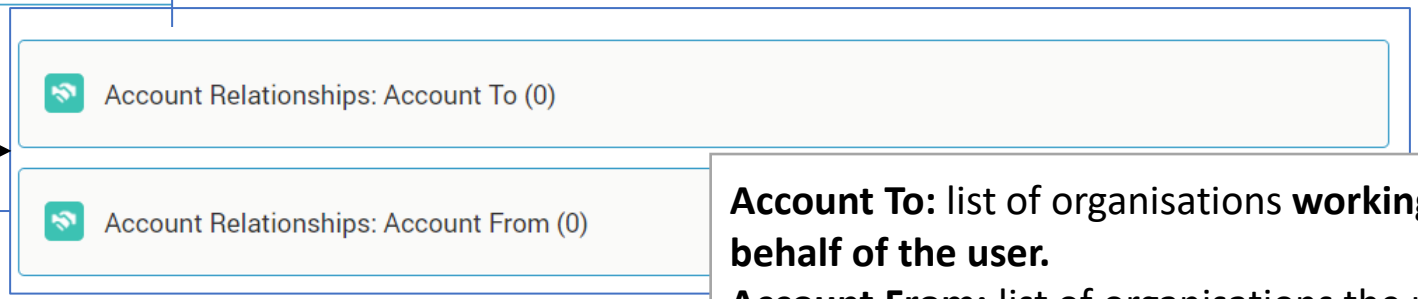
3.11 Account Relationship

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





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

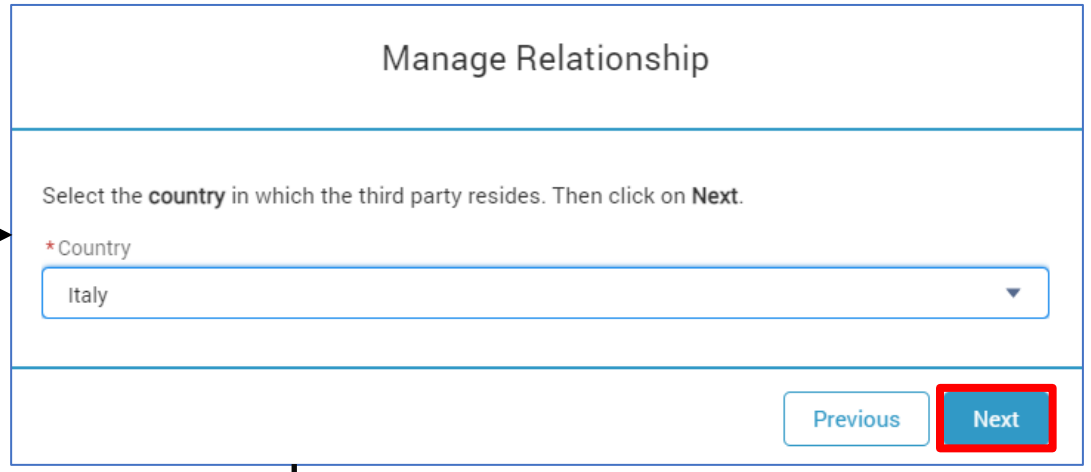


User can find under the tab **Related** the lists showing the existing relationships.

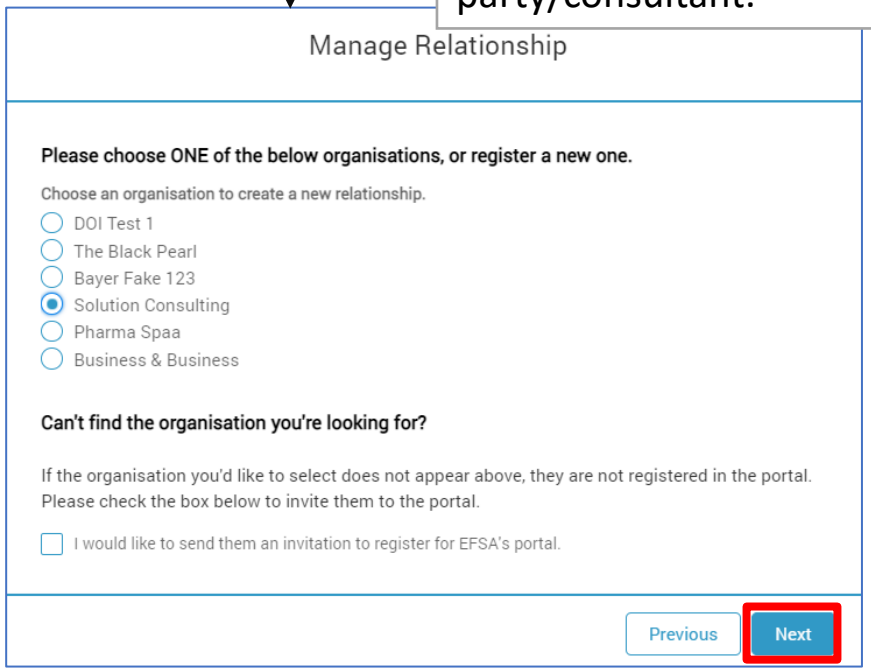
Account To: list of organisations **working on behalf of the user.**
Account From: list of organisations the user **is working on behalf of.**

3.11.1 Create an account relationship

Manage Relationship



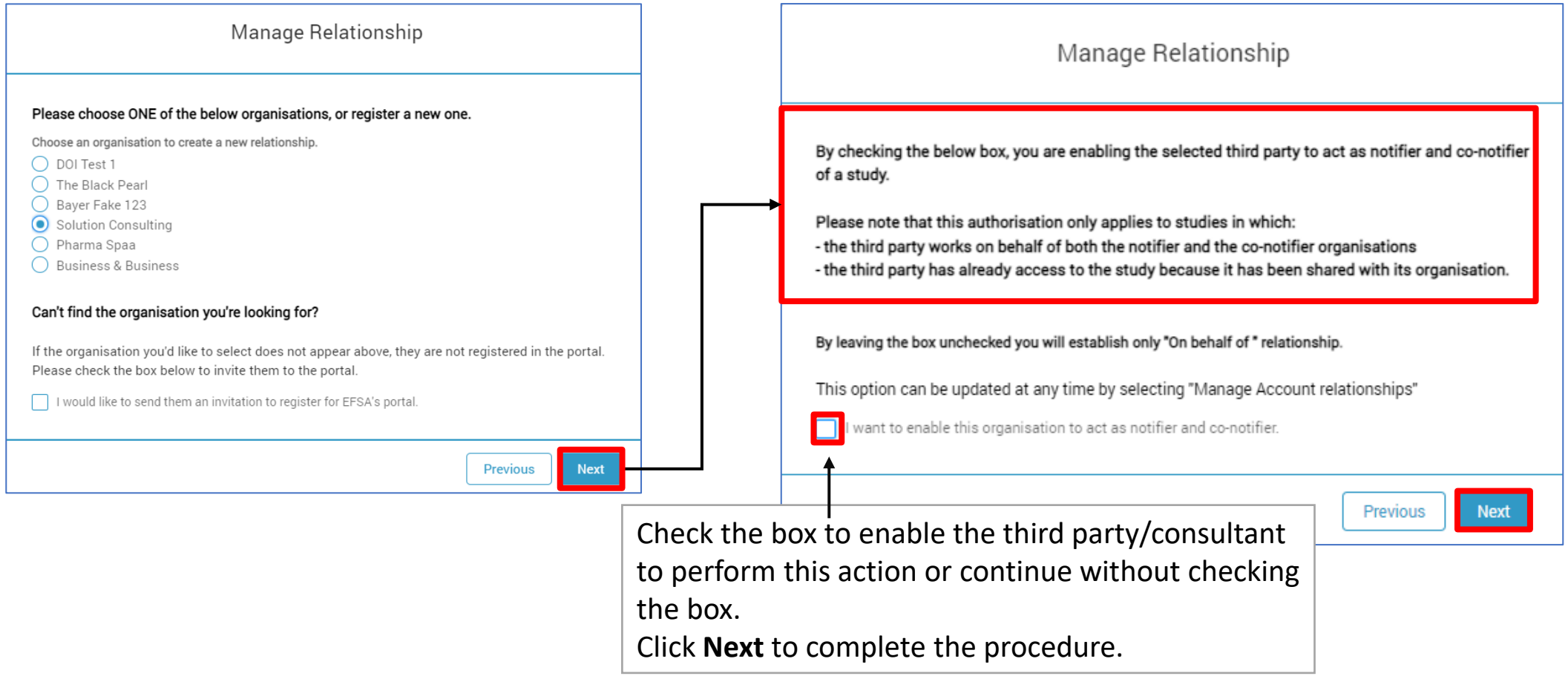
Select the **Country** and then the **organisation** to be added as third party/consultant.



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

3.11.1 Create an account relationship

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



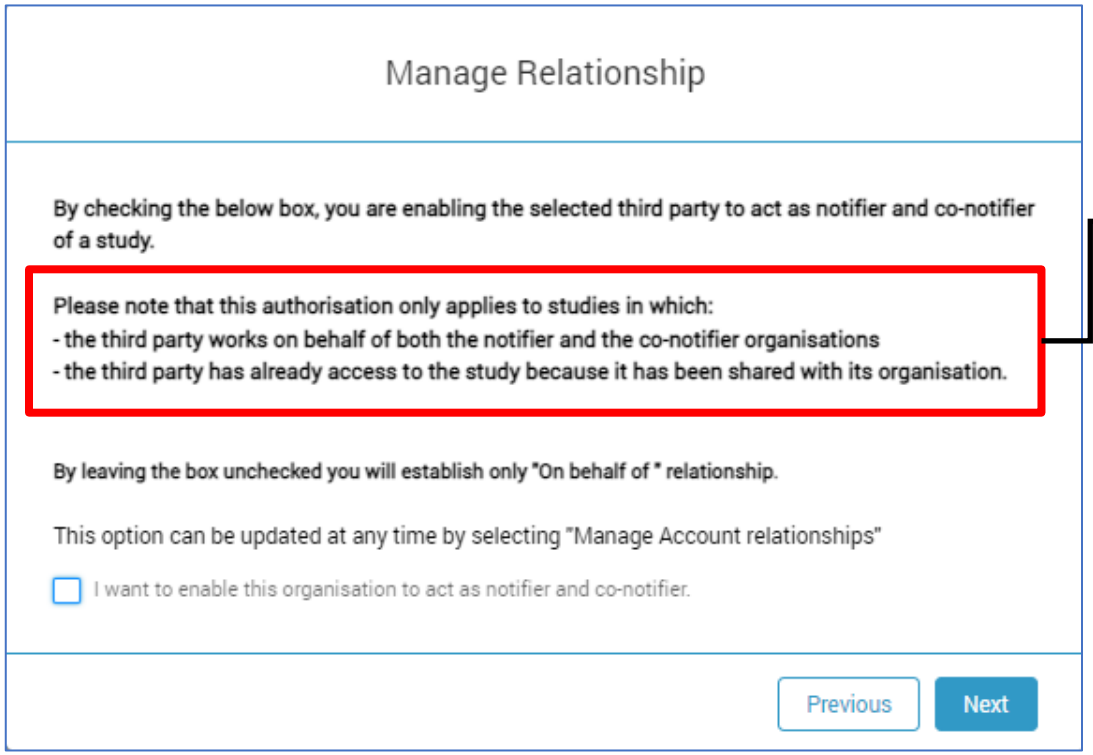
Check the box to enable the third party/consultant to perform this action or continue without checking the box.
Click **Next** to complete the procedure.

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

3.11.1 Create an account relationship

Actors of the process:
- **A business operator**, e.g. “Business Operator”
- **A laboratory**, e.g. “Laboratory”
- **A third party/consultant**, e.g. “Consultant”

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

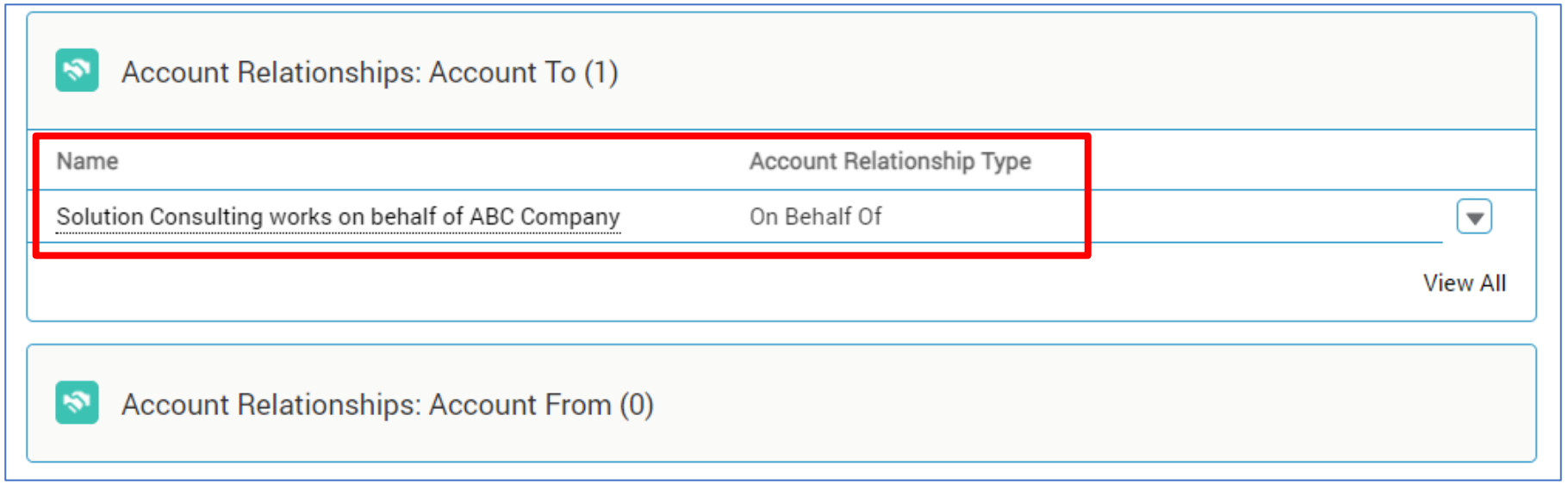


How it works:
1. “Business Operator” and “Laboratory” **create an account relationship with “Consultant”,** and both **enable this organisation to act as notifier and co-notifier.**
2. “Consultant” creates and notifies a new study notification record on behalf of “Business Operator”.
3. “Consultant”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

The process works also if “Laboratory” starts the notification process.

3.11.1 Create an account relationship

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

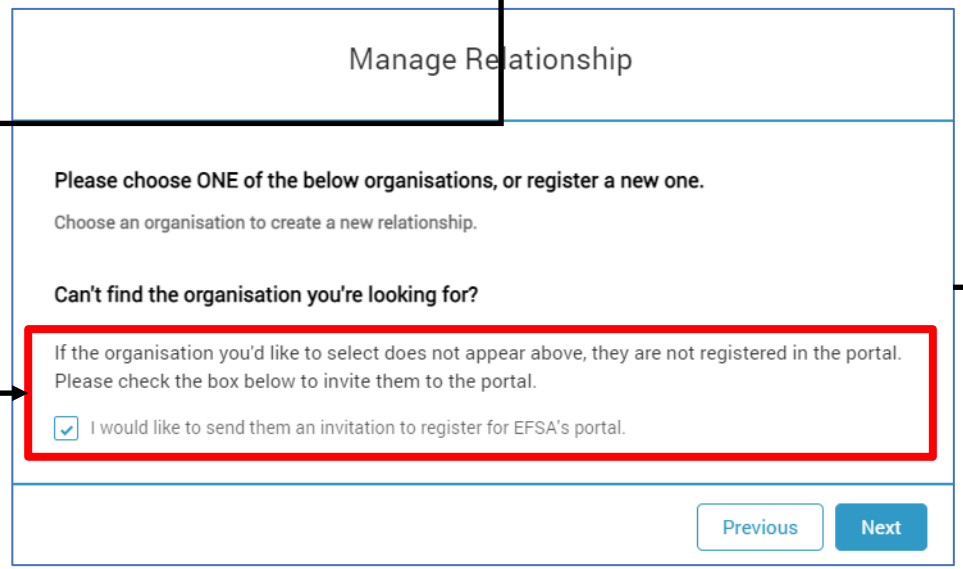


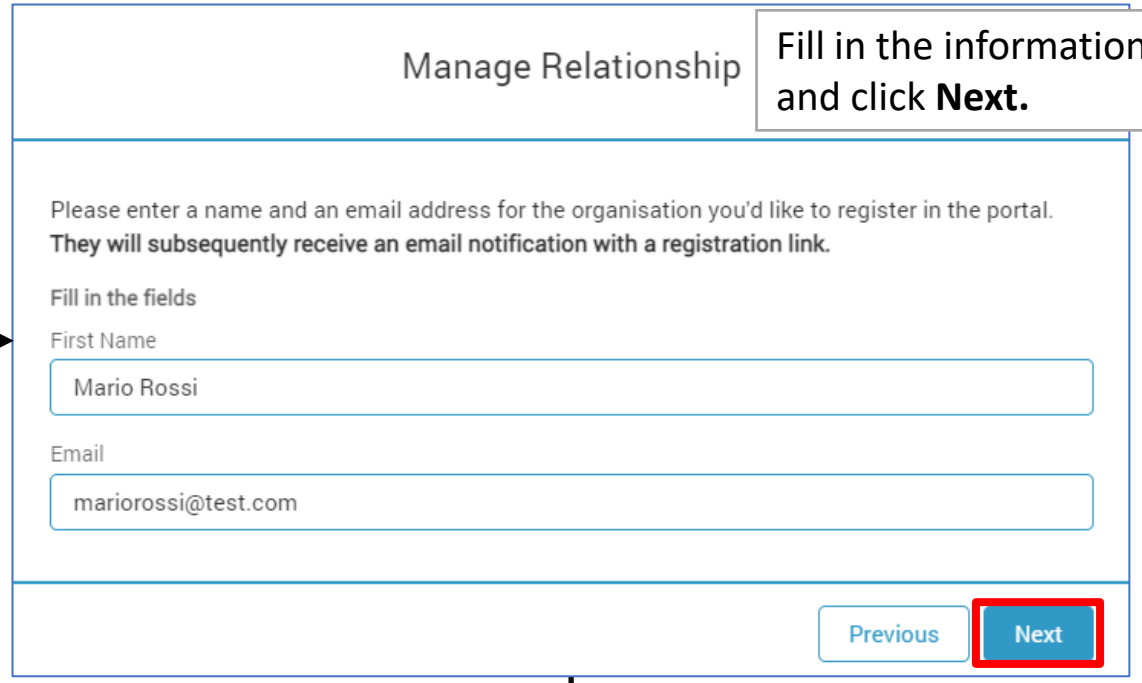
Once the relationship has been established at the account level:

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

3.11.1 Create an account relationship

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



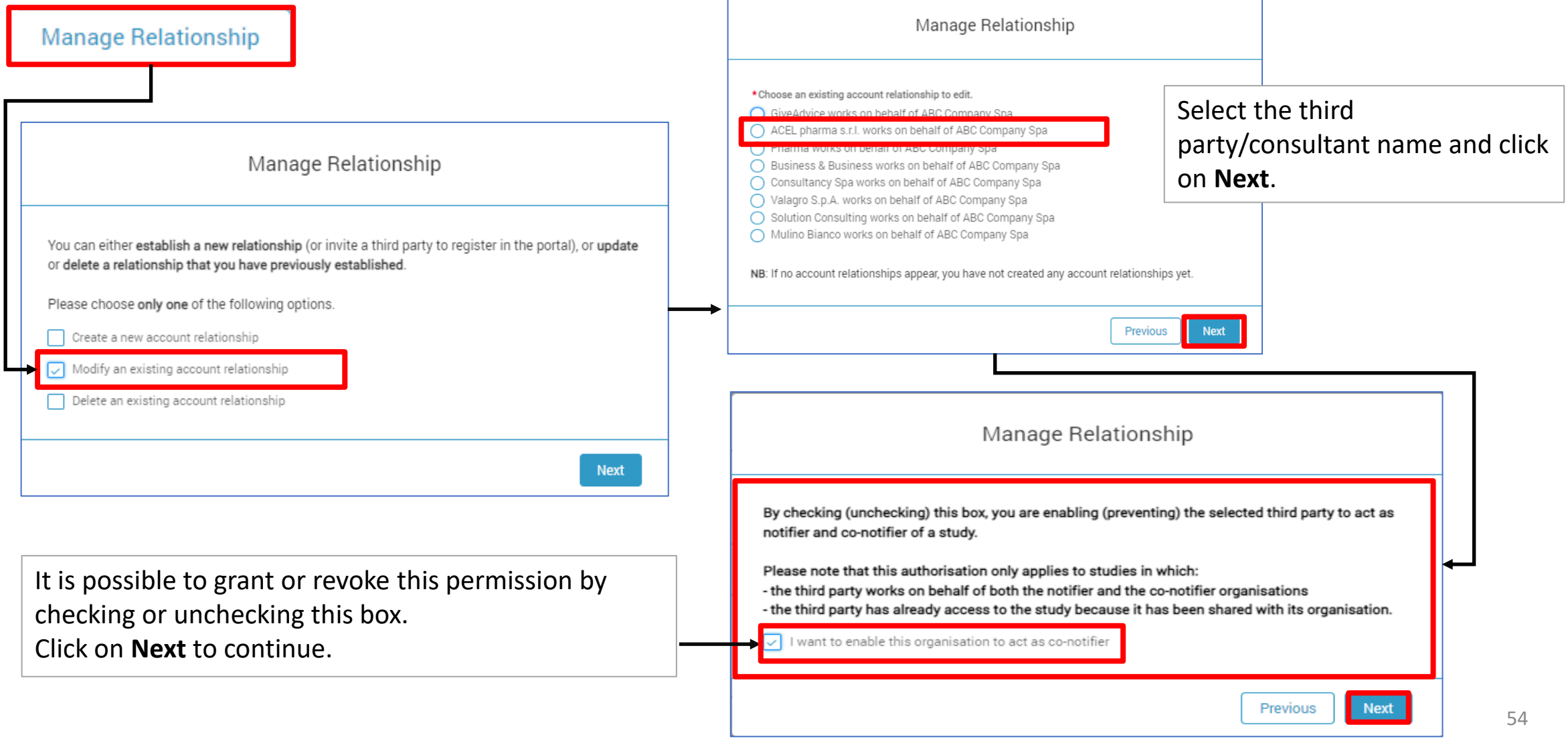


Fill in the information and click **Next.**

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.

3.11.2 Modify an account relationship

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



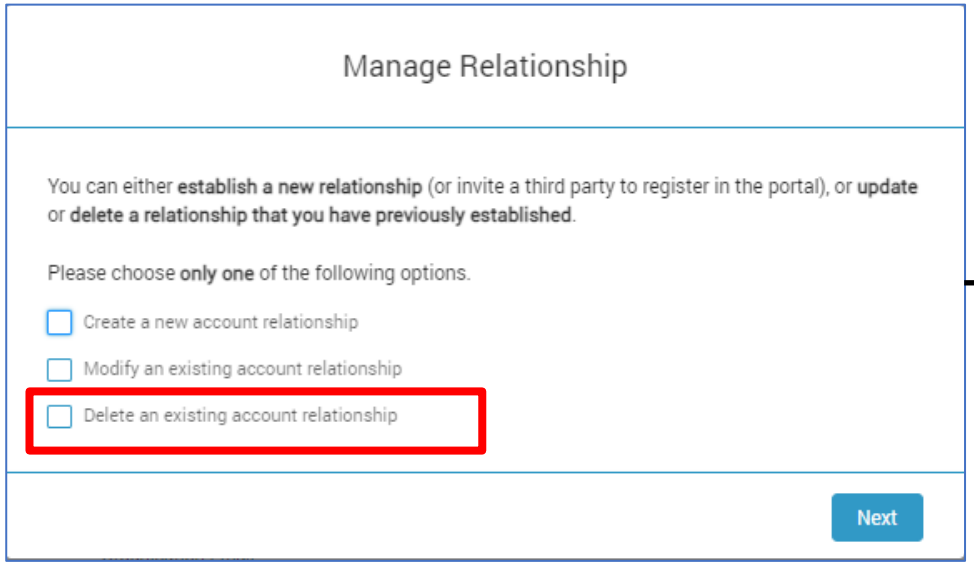
Select the third party/consultant name and click on **Next**.

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

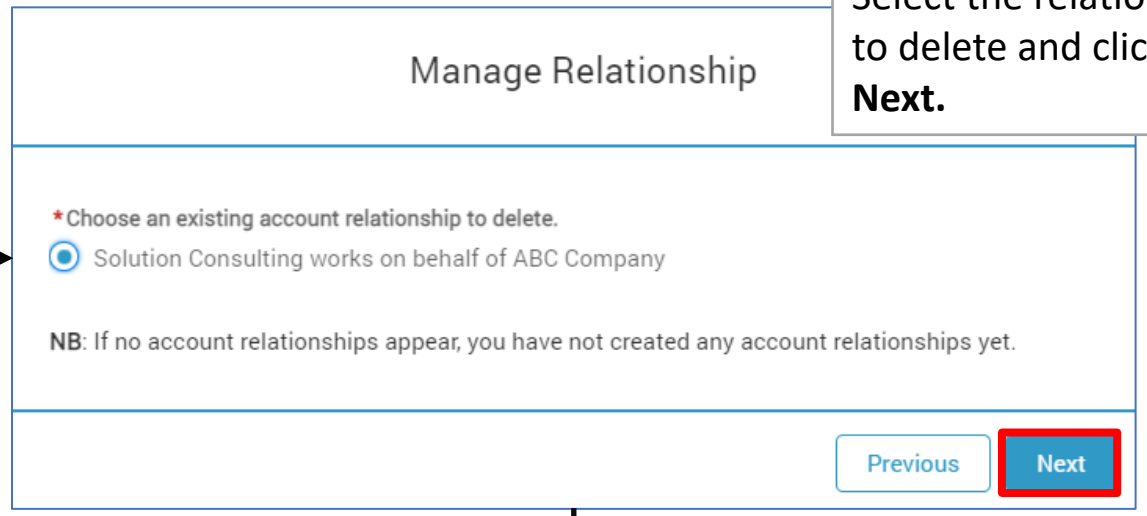
3.11.3 Delete account relationship

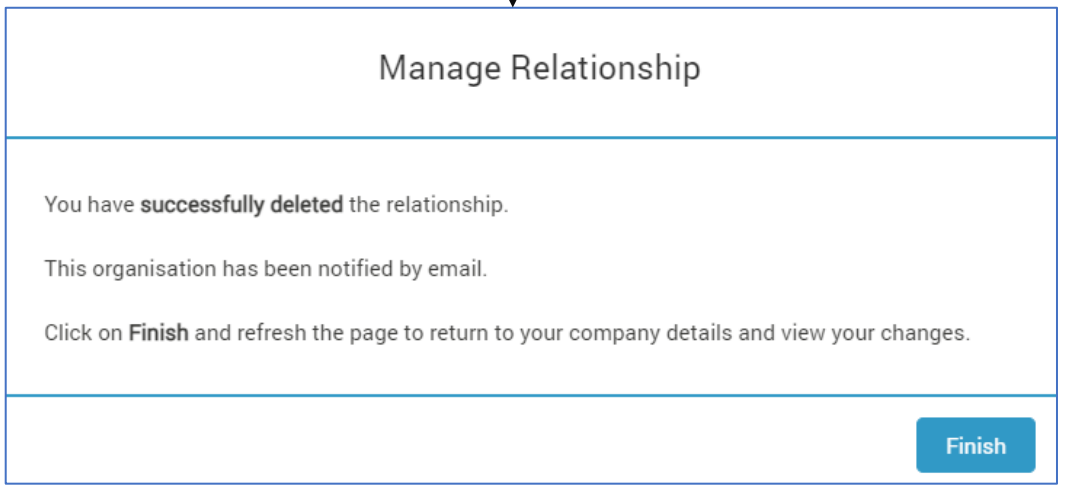
To delete an existing relationship with an organisation, follow these steps.

Manage Relationship



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



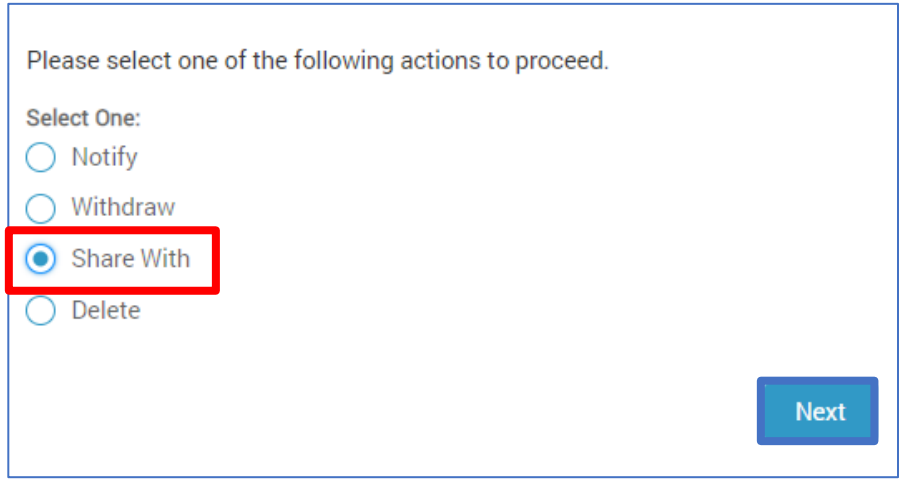


3.12 Share study

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

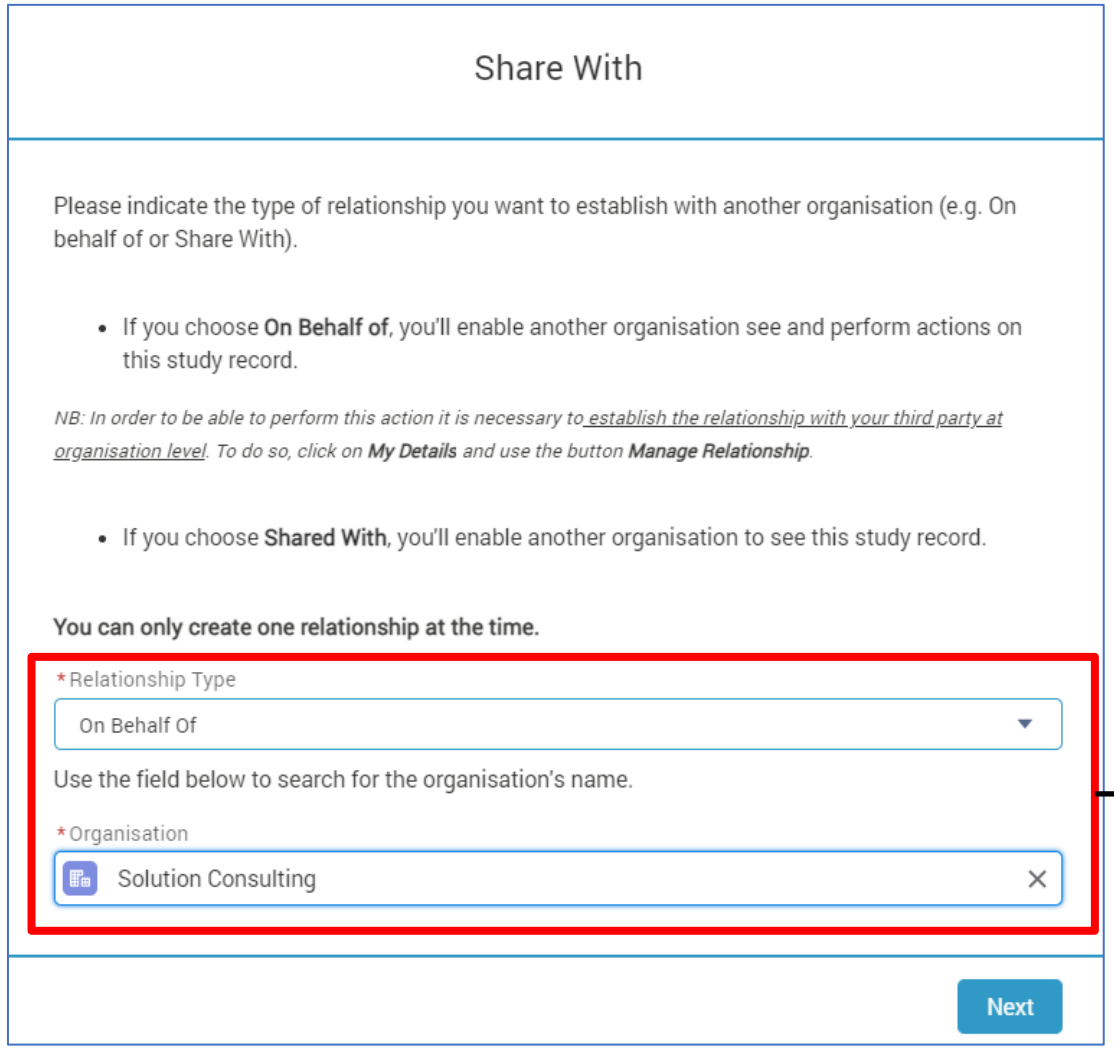
The study notification record can be shared in two different ways:

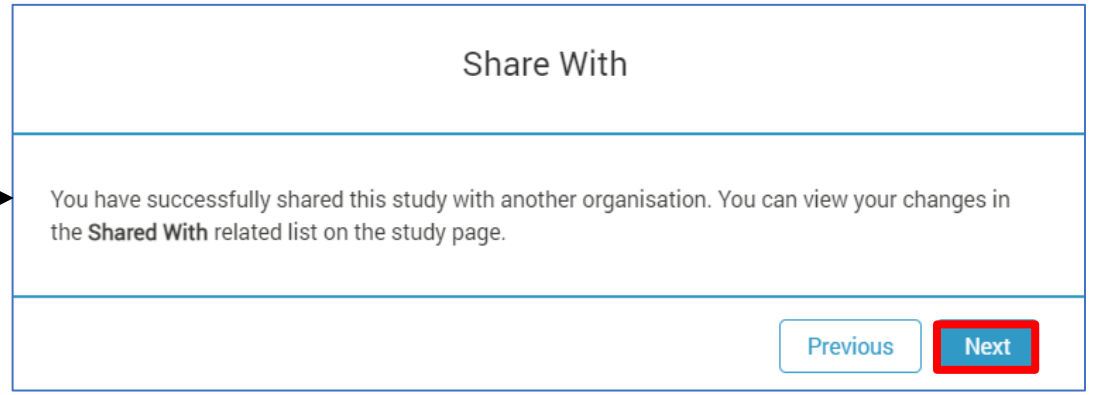
- Relationship type: **“On behalf of”**. In this case the business operator/laboratory provides to the other organisation the possibility to **view, edit, notify and/or co-notify** the shared study notification record. In order to be able to perform this type of sharing, the user must establish an **account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

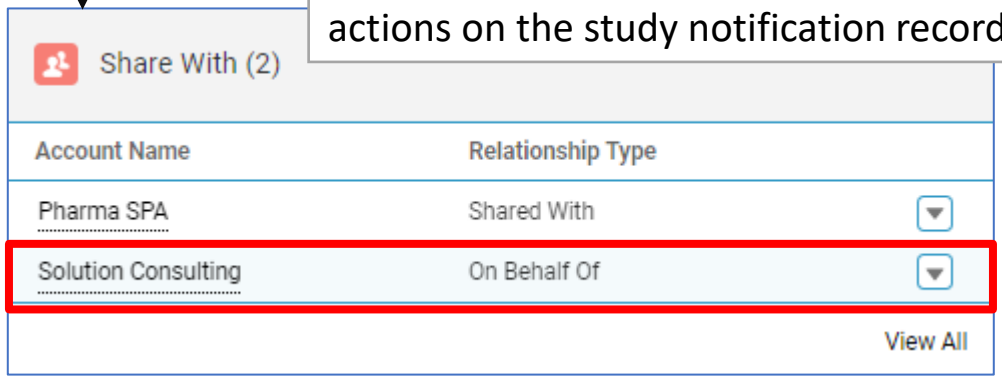


3.12.1 Share study “On Behalf of”

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



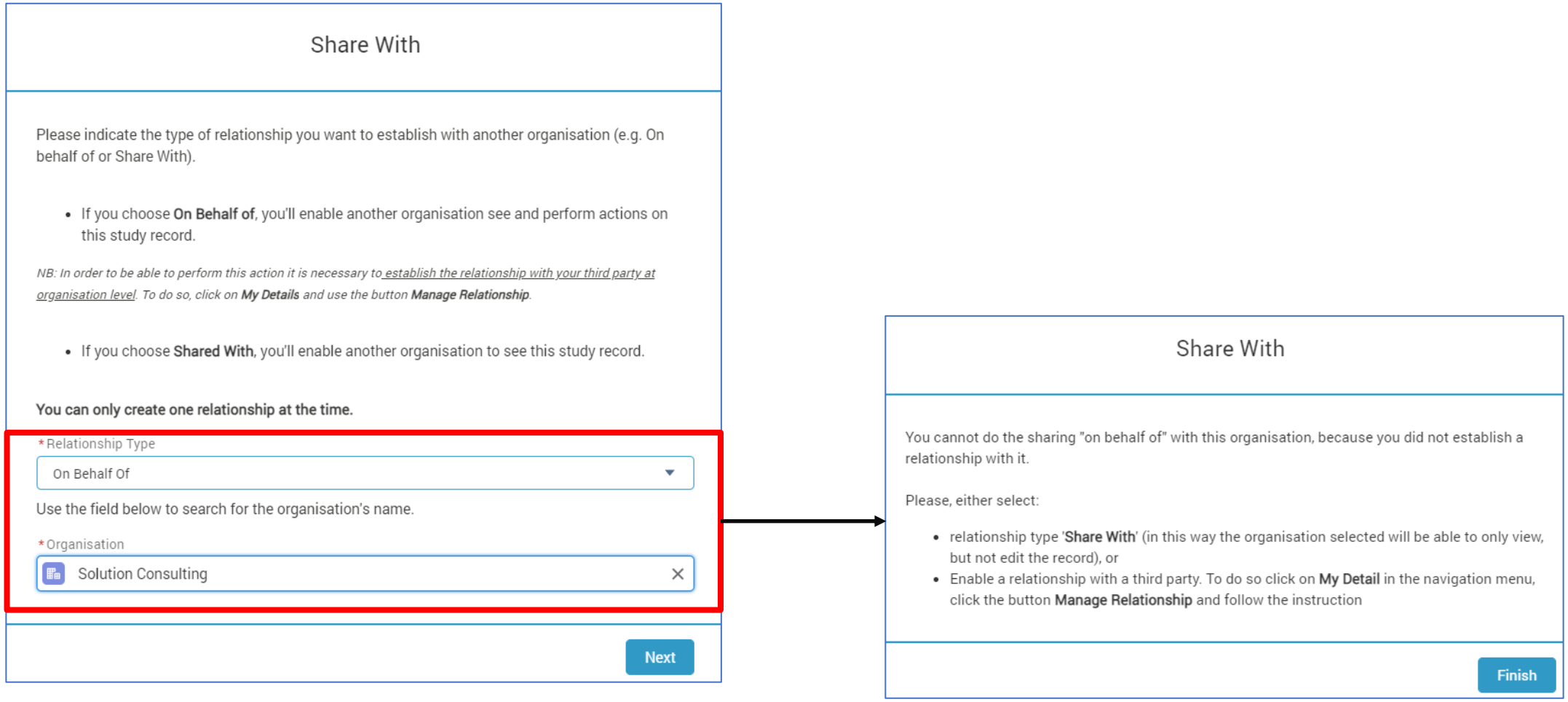




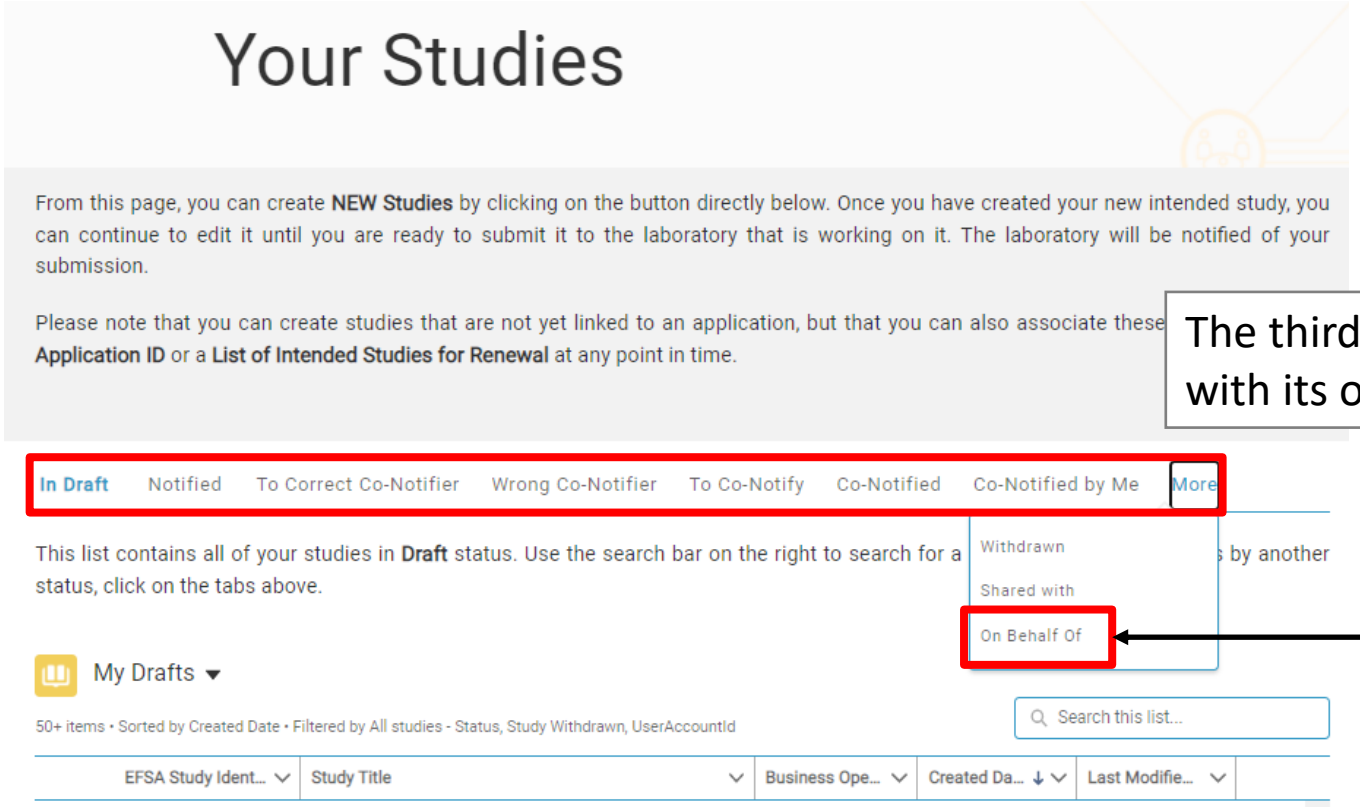
The organisation is added to the related list **Shared With** and can now see and perform actions on the study notification record.

3.12.1 Share study “On Behalf of”

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



3.12.1 Share study “On Behalf of”



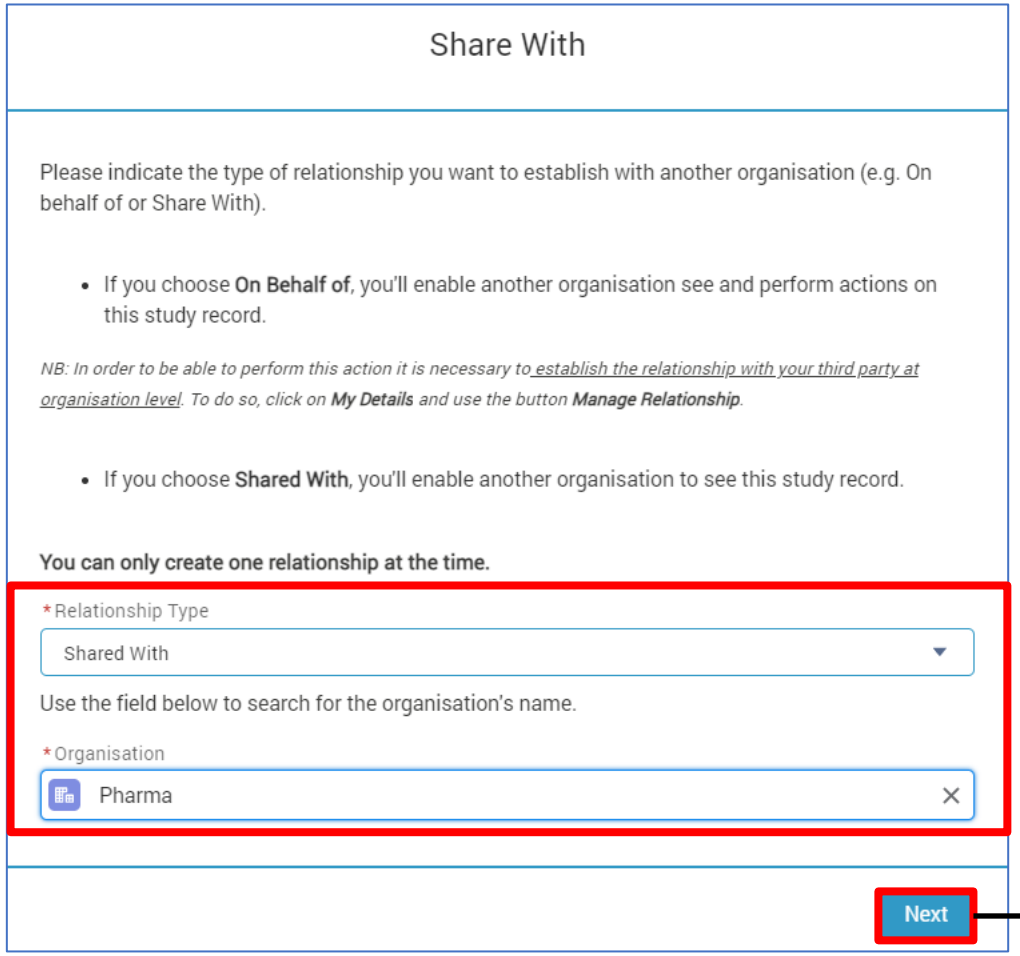
The third party/consultant can find the studies shared with its organisation under the **On behalf of** tab.

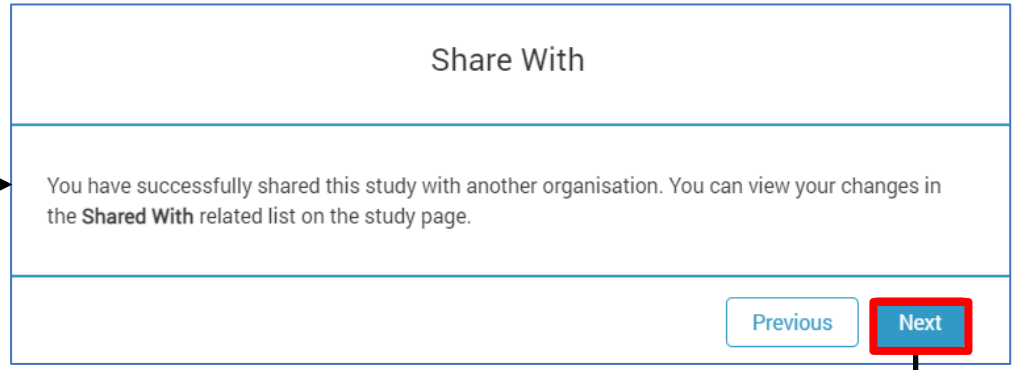
The **organisation** (consultant) can:

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

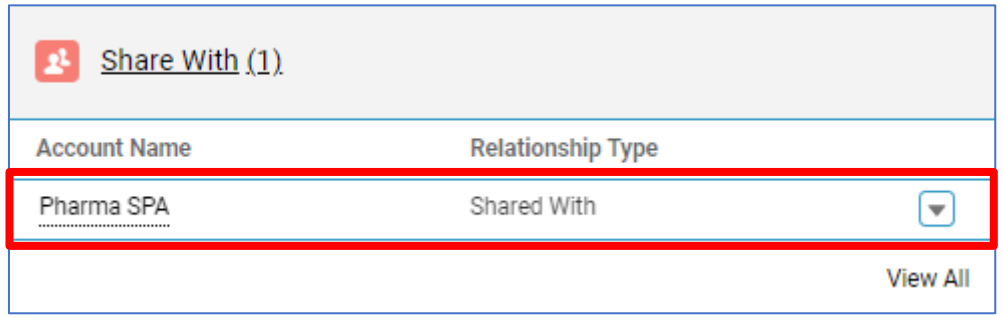
3.12.2 Share study “Shared with”

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

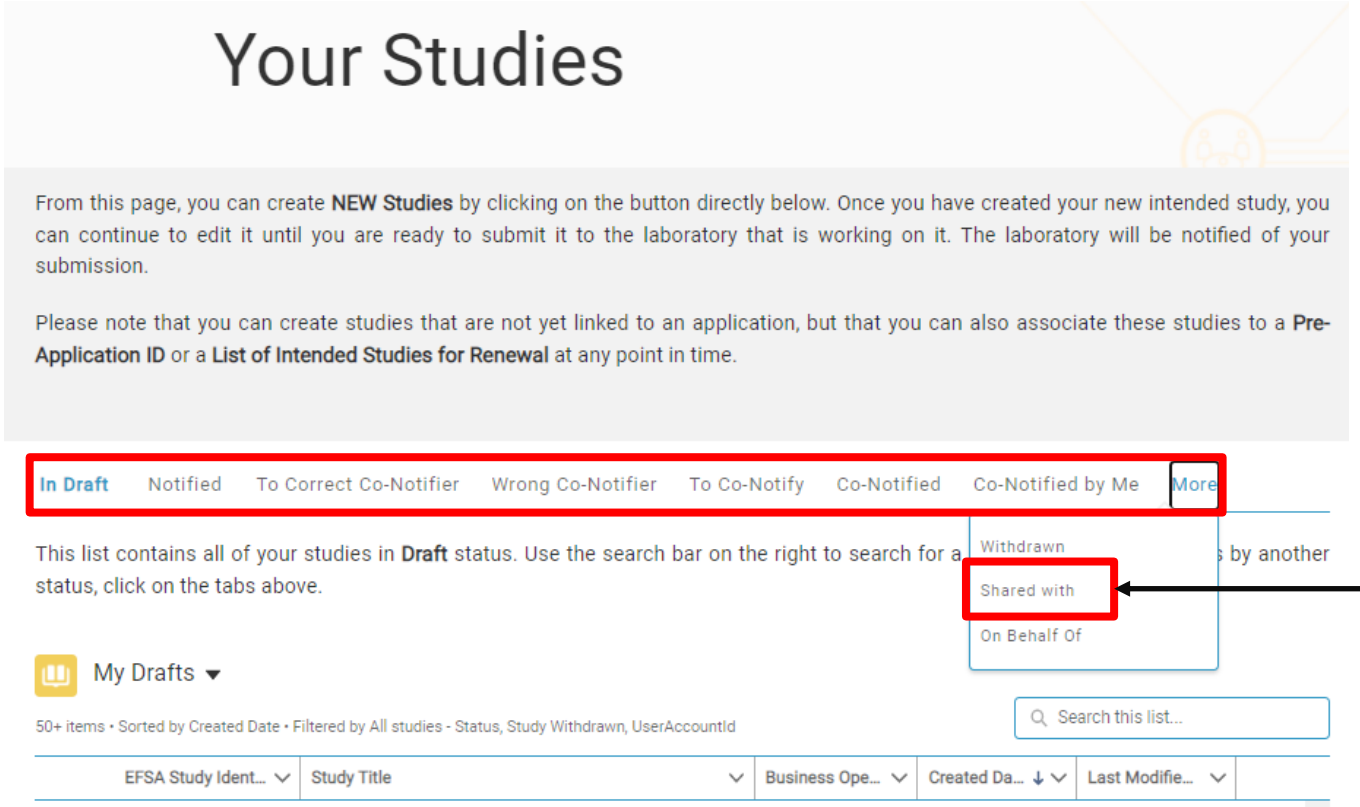




The organisation is added to the related list **Shared With** and can now see the study notification record.



3.12.2 Share study “Shared with”

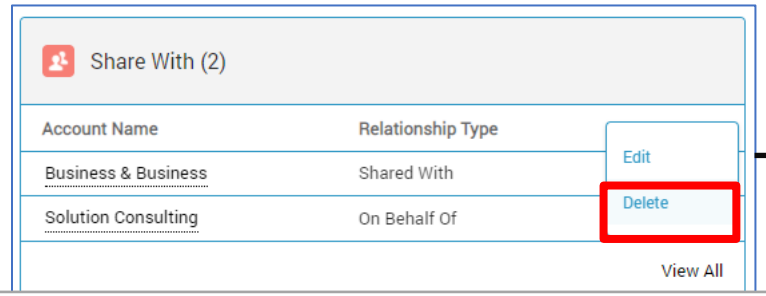


The **organisation** can:

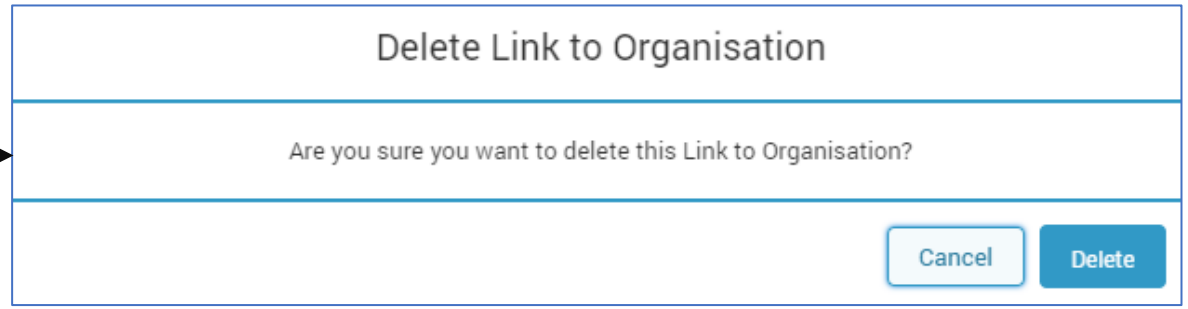
1. Find the studies shared with them under the **Shared with** tab.
2. Read the study information.
3. View components added to the study.

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

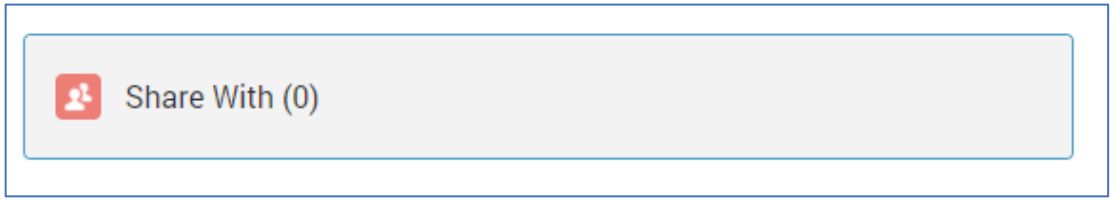
Important note: The Notifier can remove “**Shared With**” relationships only if **the status of the shared study** is equal to **Draft.** Conversely, it is **always possible** to remove “**On behalf of**” relationships.



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

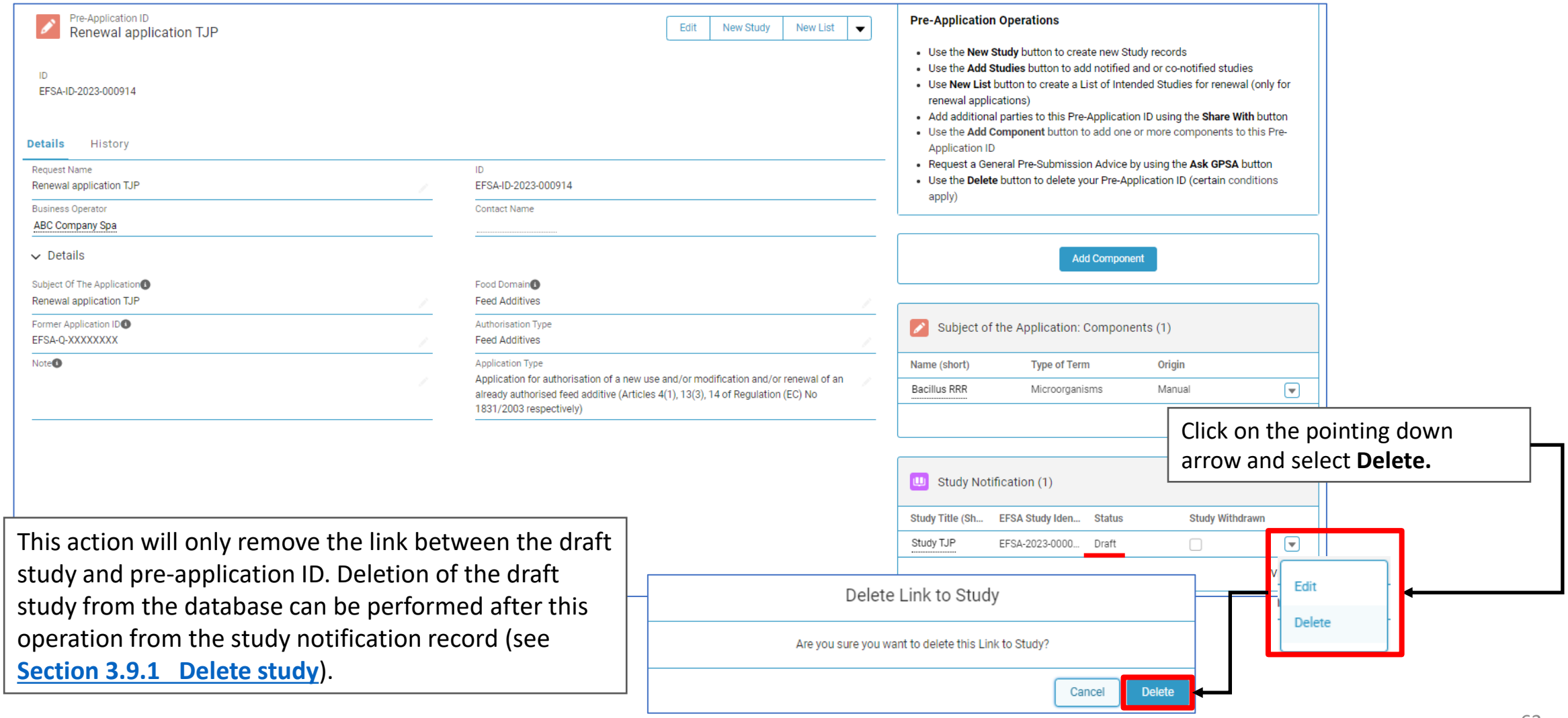


As a result, the organisation is removed from the “Share With” list and it cannot see anymore the study notification record.
This action will not delete the organisation account, but only the rights to access the study notification record.



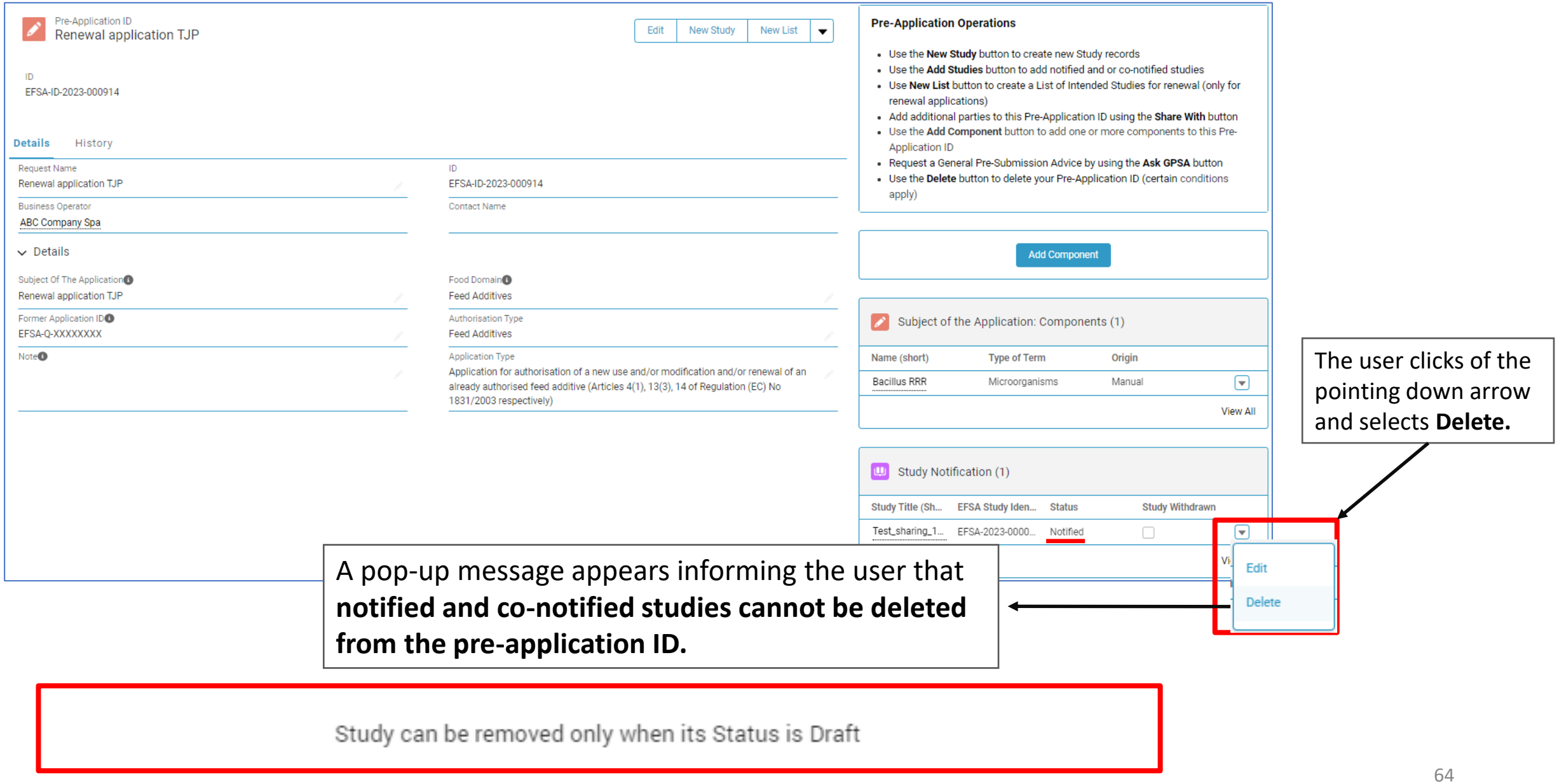
3.13 Delete a study from a pre-application ID

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



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

3.13 Delete a study from a pre-application ID



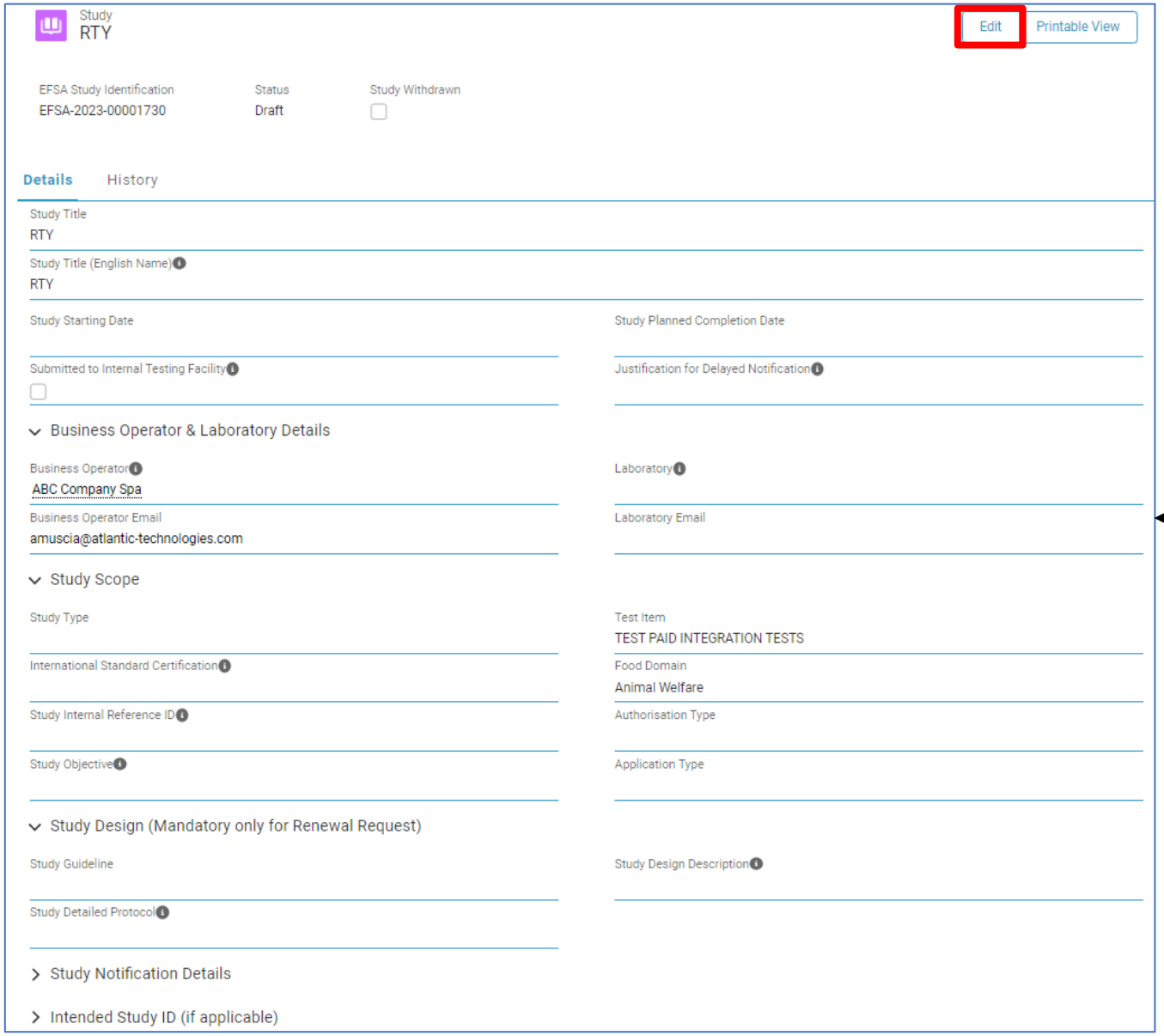
The user clicks of the pointing down arrow and selects **Delete.**

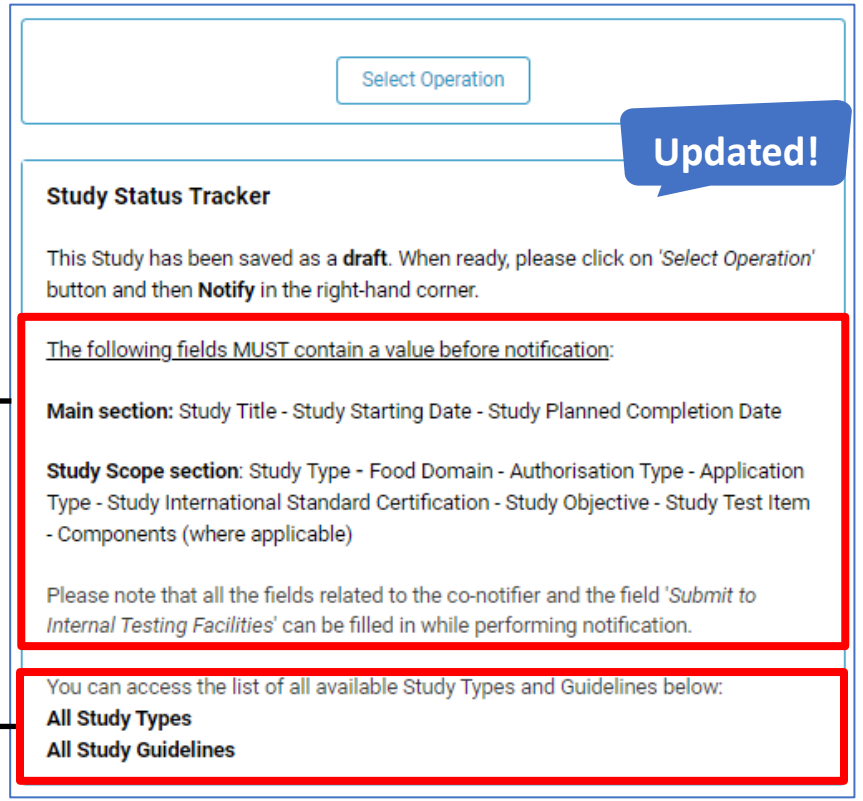
A pop-up message appears informing the user that **notified and co-notified studies cannot be deleted from the pre-application ID.**

Study can be removed only when its Status is Draft

3.14 Study Notification

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



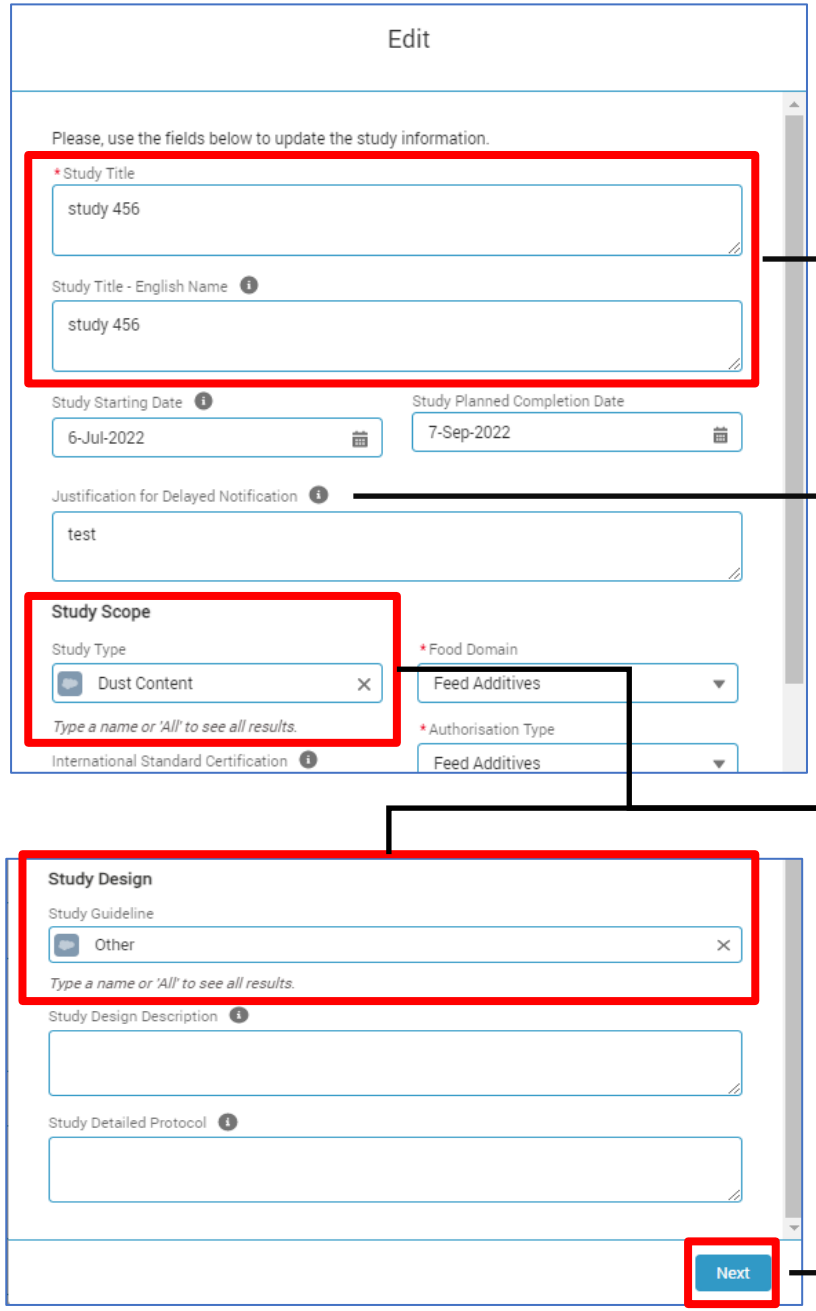


Click on these links to see all the available values for **Study Types** and **Study Guidelines** picklist.

3.14.1 Study Notification – *Edit function*

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

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



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

This field appears only if the "notification date" is later than the "study starting date". For more details, see the section **Justification for Delayed Notification**.

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

Click Next to save the changes.

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

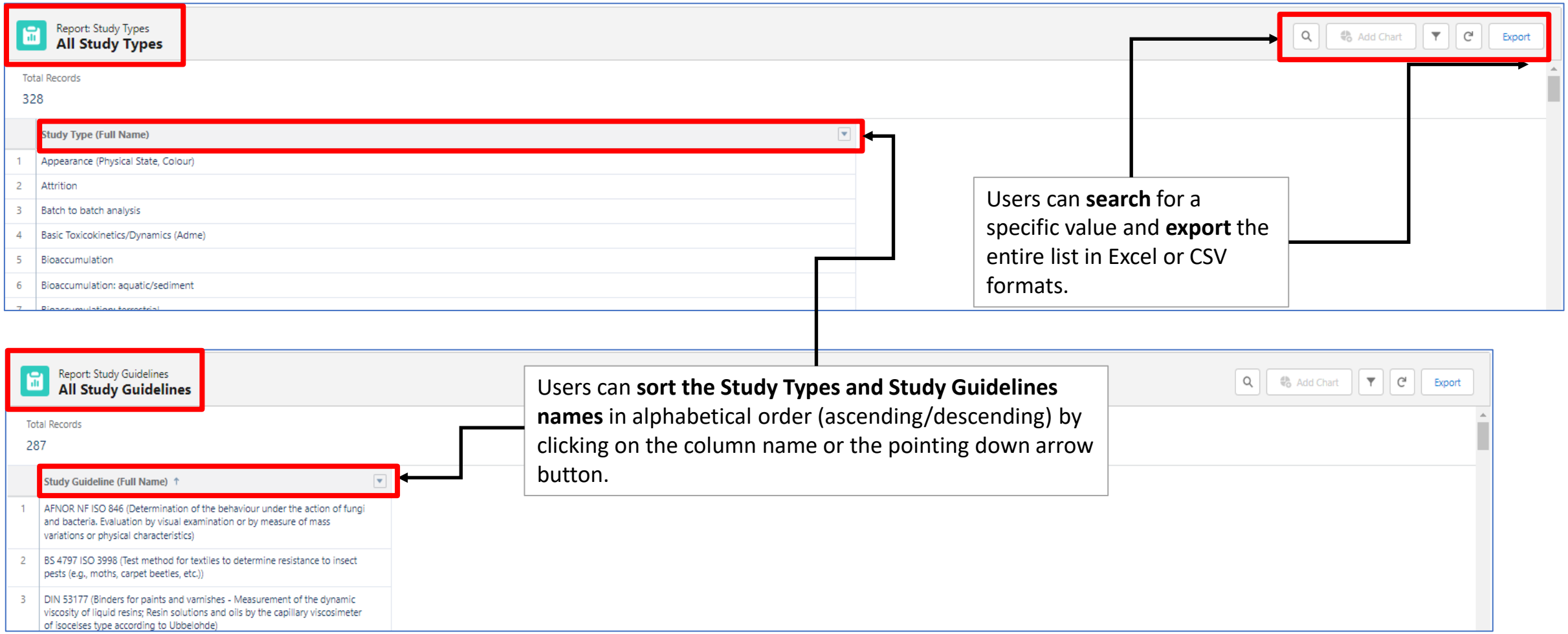
3.14.2 Study Notification – *Study Types and Study Guidelines*

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

All Study Types

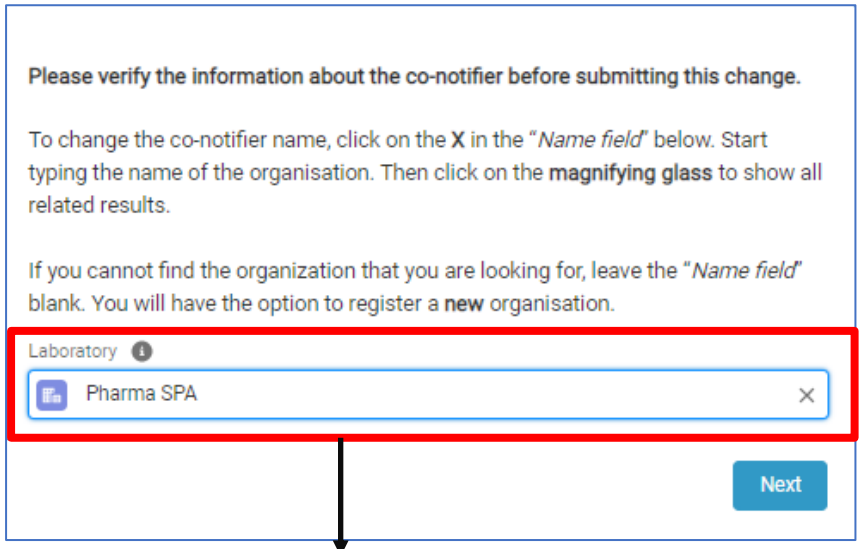
All Study Guidelines

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



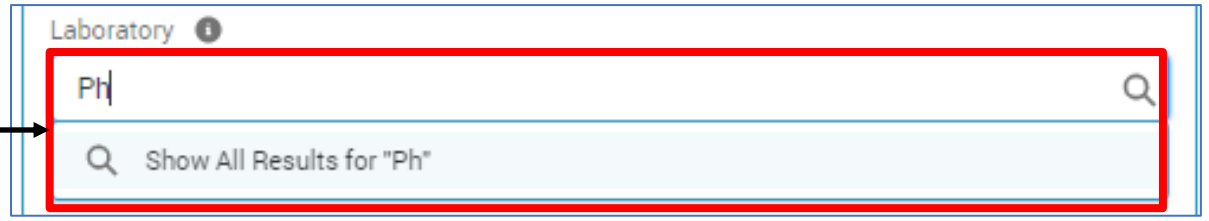
3.14.3 Study Notification – *To registered laboratory*

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

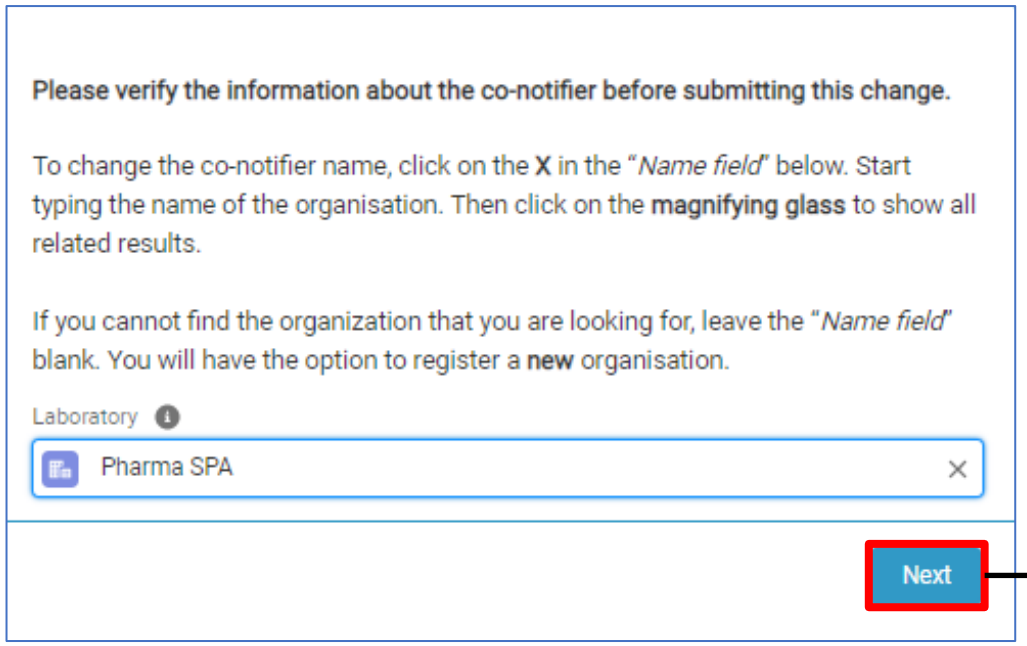


If the user has indicated the laboratory when creating the study notification record, this information is displayed here and can be revised at this stage, if needed.

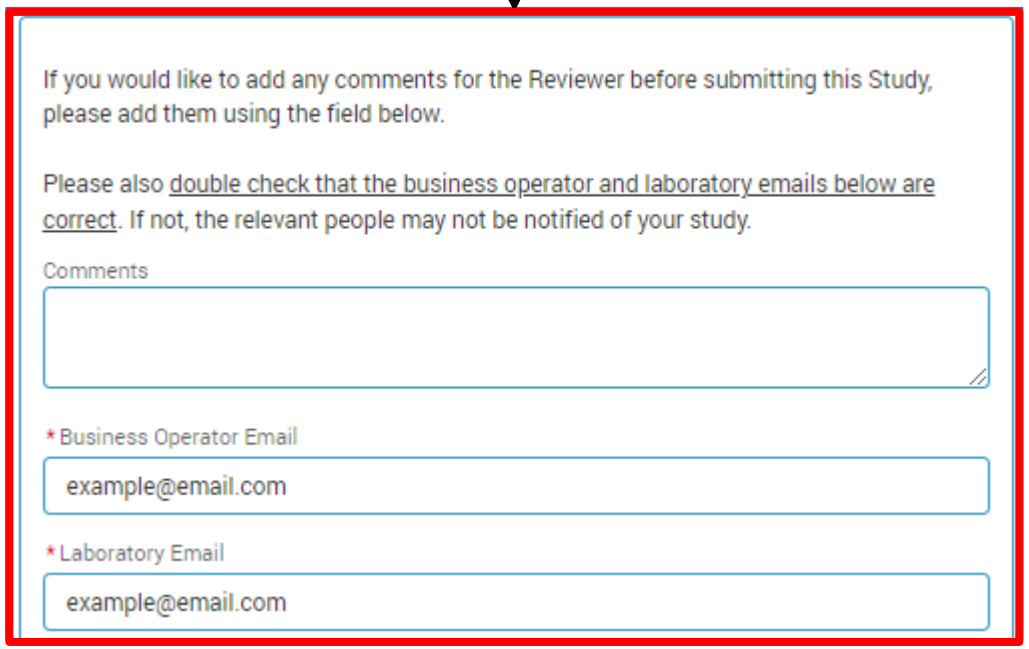
If the field is empty, the user **starts typing the name of the laboratory and click on the magnifying glass** to show all related results, including address details, in order to identify the correct legal entity.



3.14.3 Study Notification – *To registered laboratory*



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

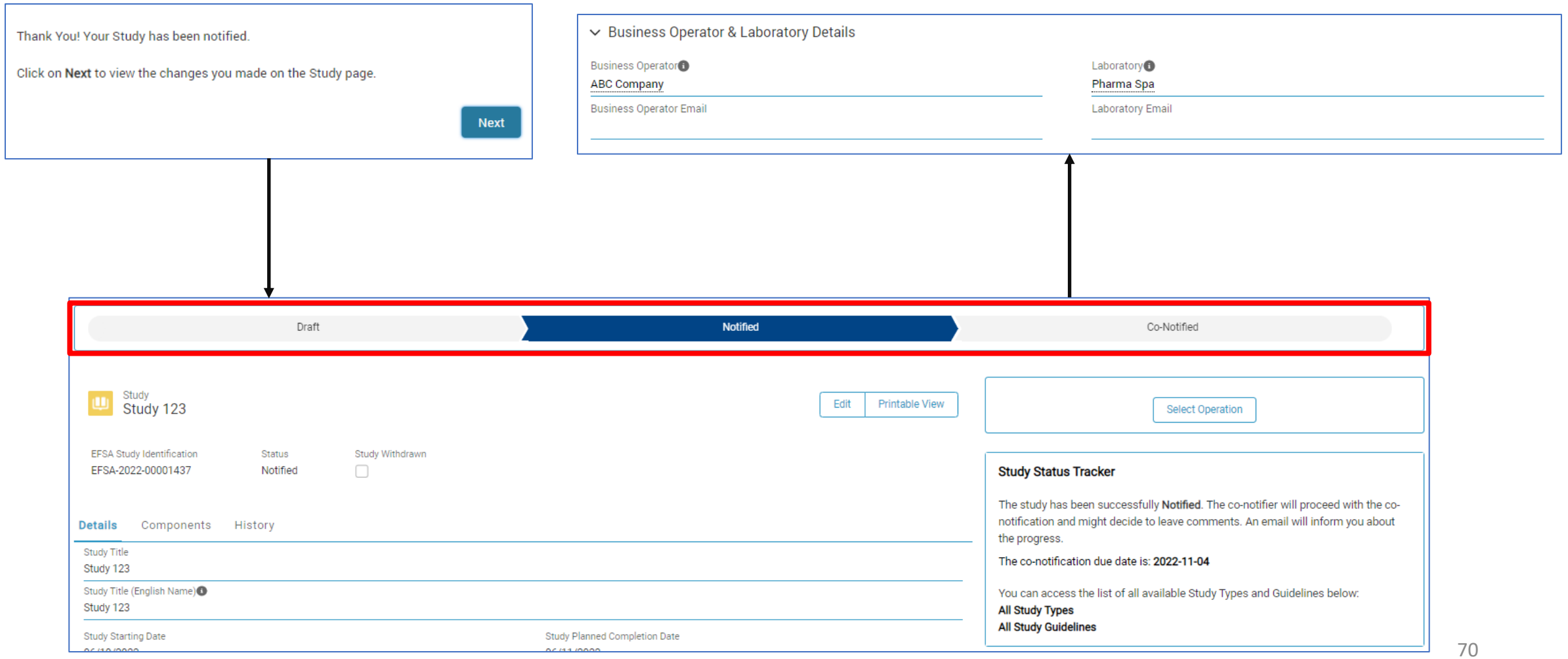


Write a comment in this text area, if needed.

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

3.14.3 Study Notification – *To registered laboratory*

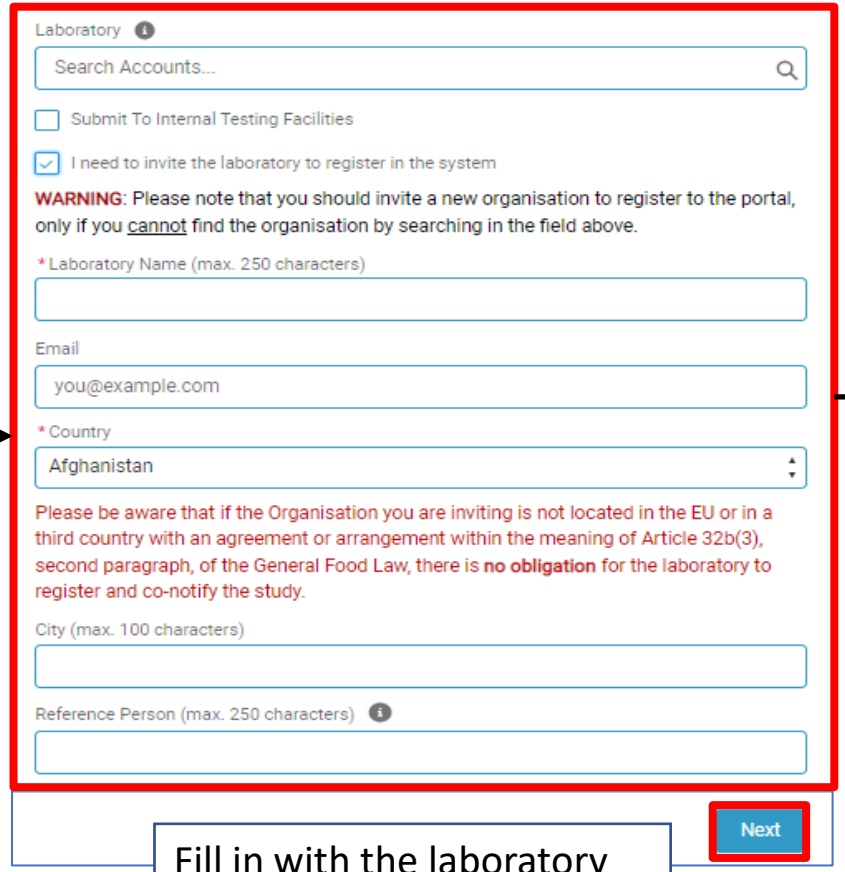
Once the study has been notified the status turns into **Notified,** the contact person of the **laboratory receives an email alert on the email address indicated at the moment of the notification action**.



3.14.4 Study Notification – *To a new laboratory*

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.

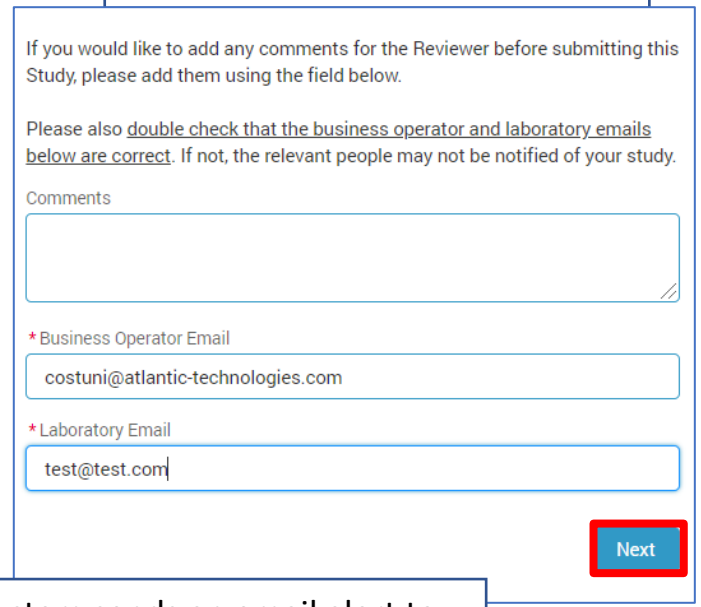


Fill in with the laboratory information and click **Next.**

2

3

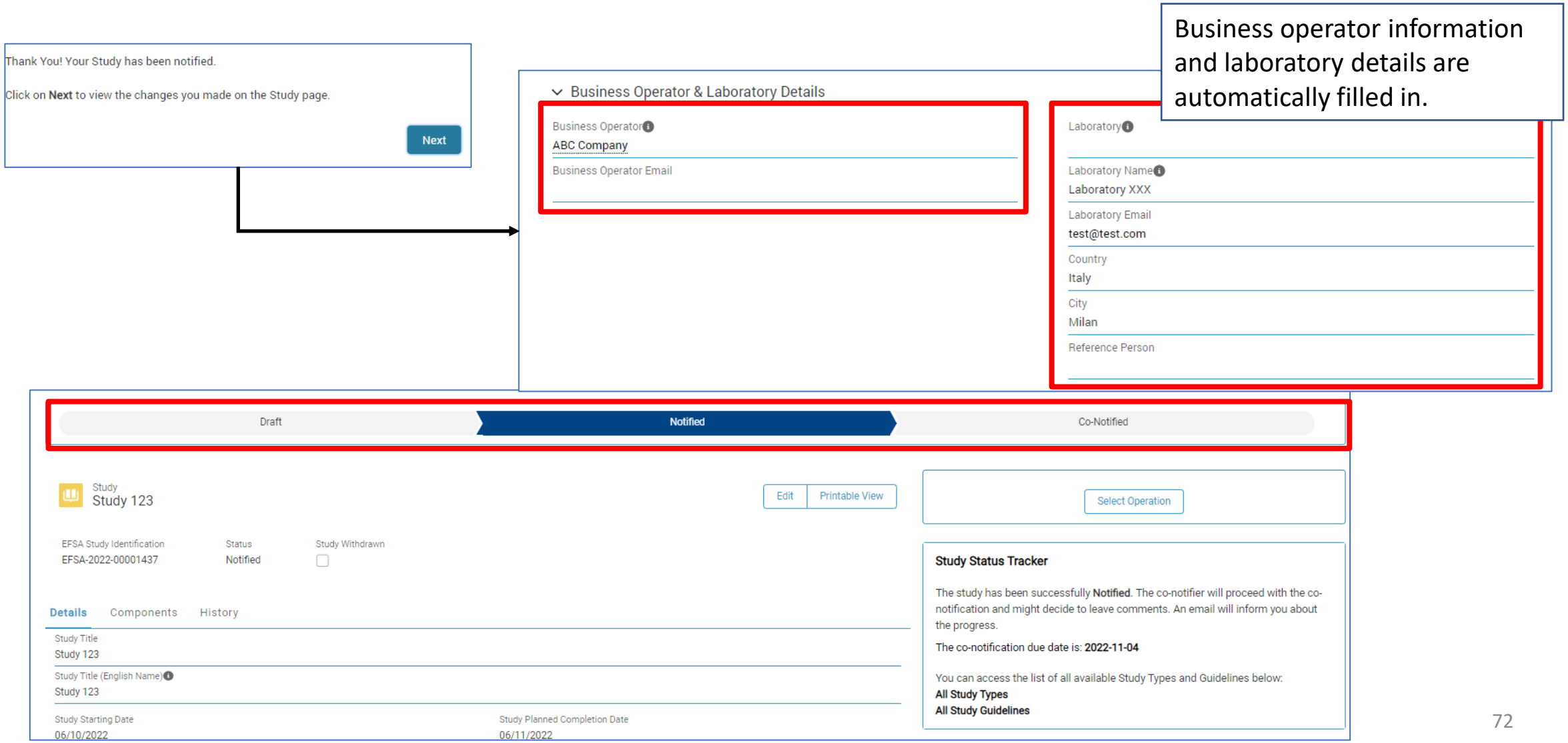
Write a comment on the text area (if needed), double check the email addresses and click **Next.**



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

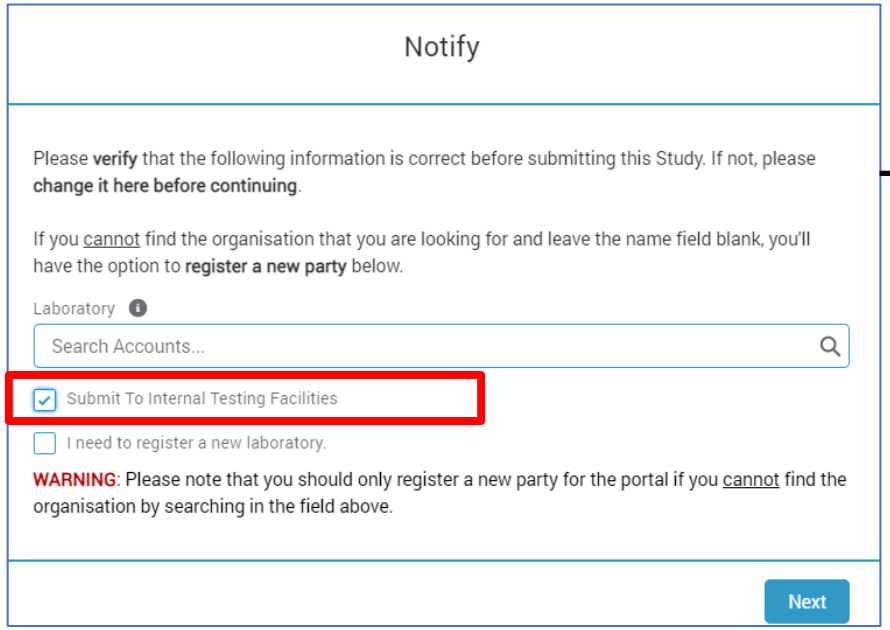
3.14.4 Study Notification – *To a new laboratory*

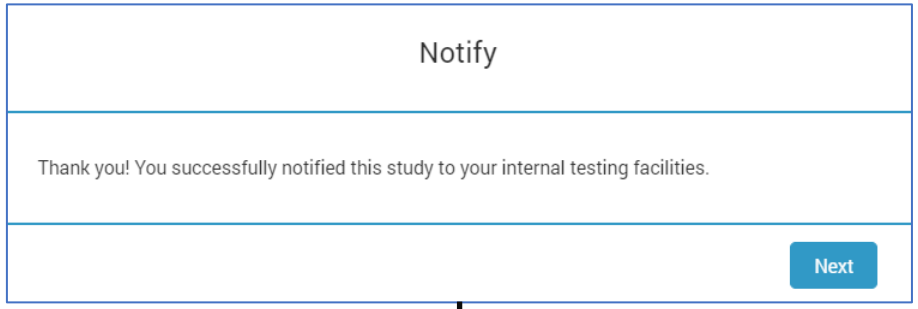
Once the study has been notified, the status turns into **Notified.** The new laboratory receives **an email alert** with the invitation to register for the portal, review the information of the study and proceed with the co-notification.

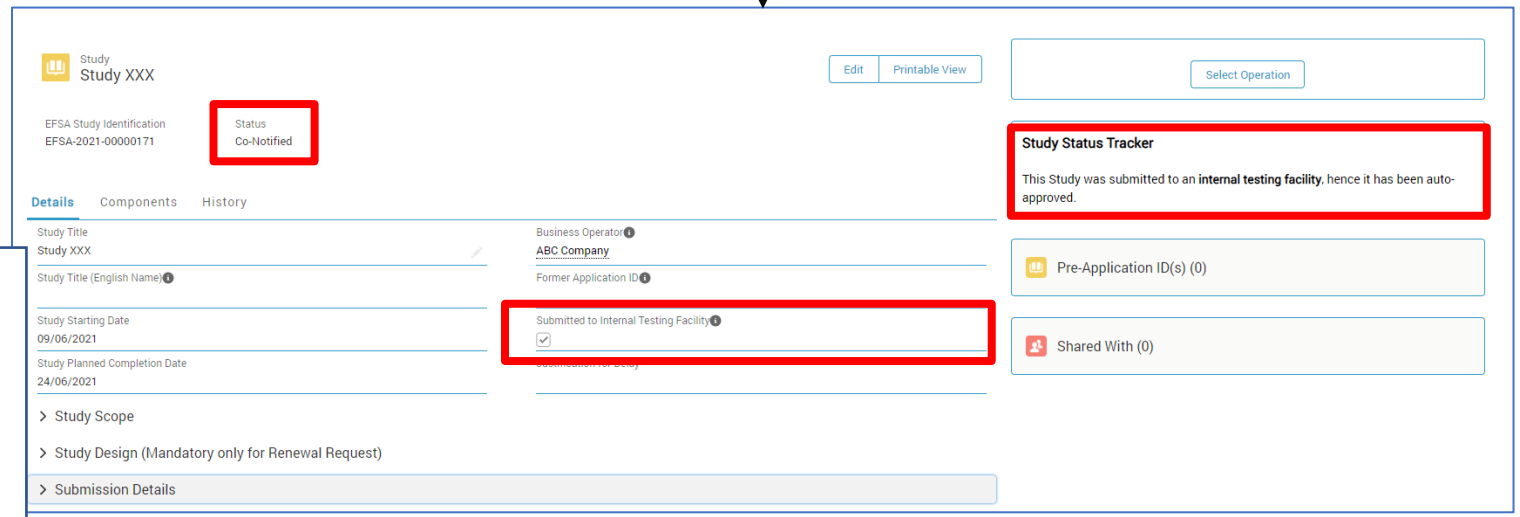


3.14.5 Study Notification – *To internal testing facilities*

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



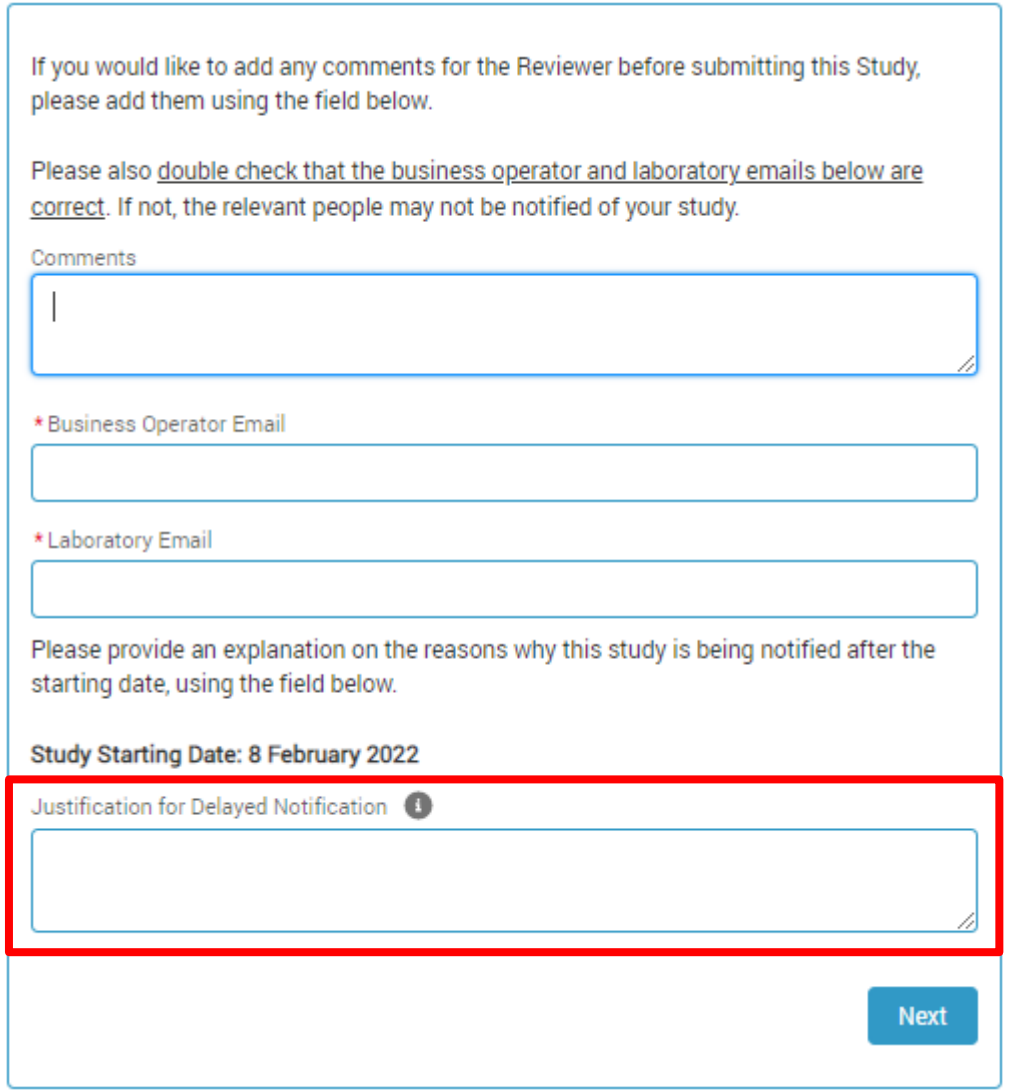




When submitting to internal testing facility, **the co-notification process is not triggered.** The system does not send any co-notification mail alert.
The user sees the status **Co-notified** and the checkbox **Submitted to internal testing facilities** is automatically checked.

3.14.6 Study Notification – *Justification for delayed notification*

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

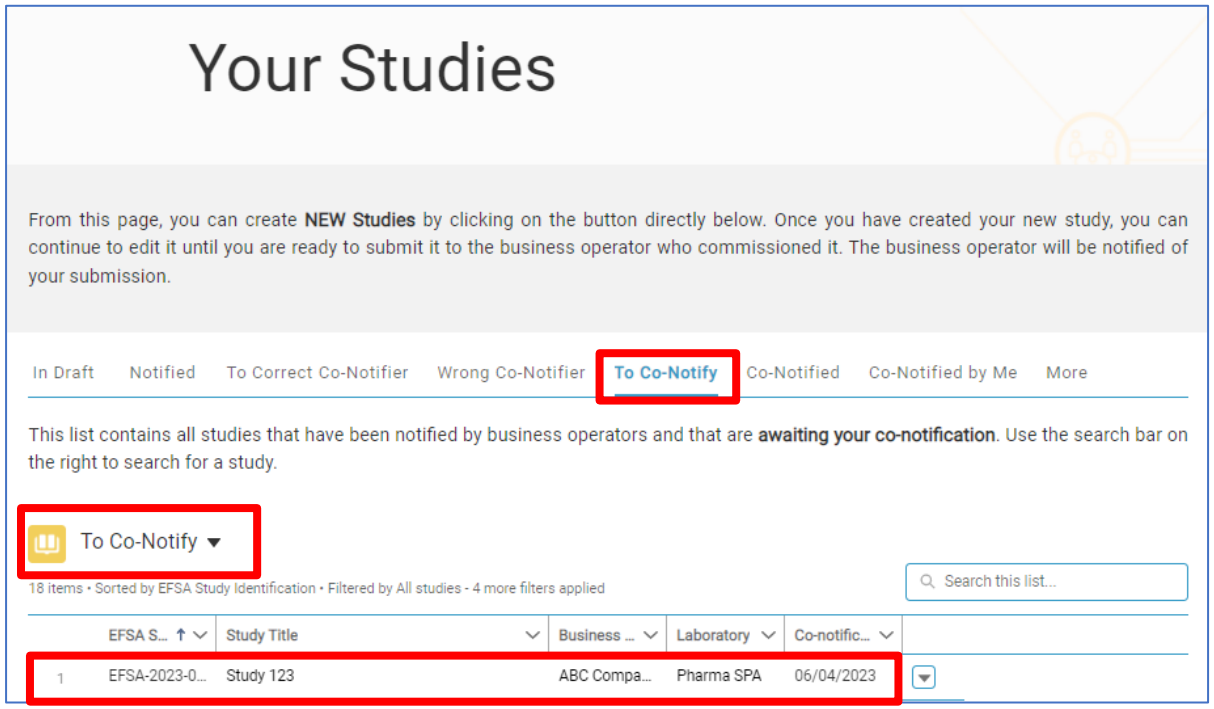


The field "Justification for Delayed Notification" is provided for the benefit of the notifier and can be used to keep a note of the reason of the delayed notification.
This without prejudice to the need for justifying the delayed notification **when submitting the corresponding application** as outlined in Article 19(4) of the EFSA Practical Arrangements on pre-submission phase and public consultations.

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

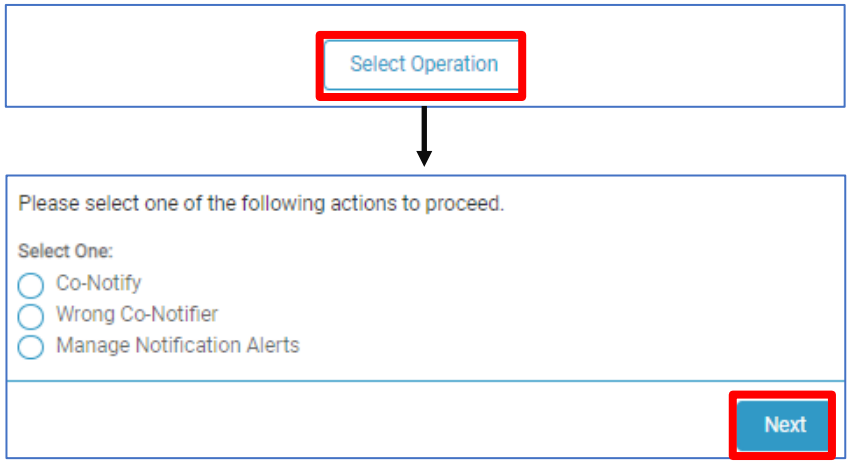
3.15 Study Co-notification

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



Follow the below steps to co-notify

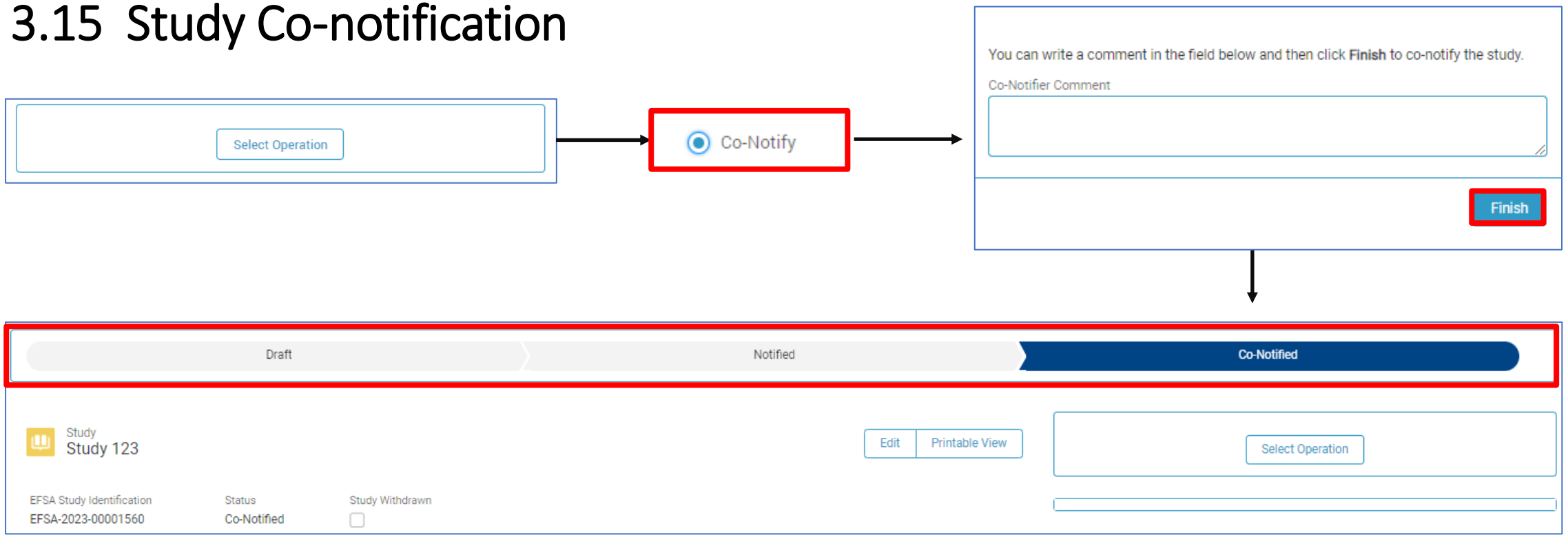
1. The user can find the studies to co-notify under the tab **To Co-Notify**.
2. The user **selects the study to be co-notified and revises the information** showed in the study page.
3. From the upper right corner of the study page the user clicks on **Select Operation.**



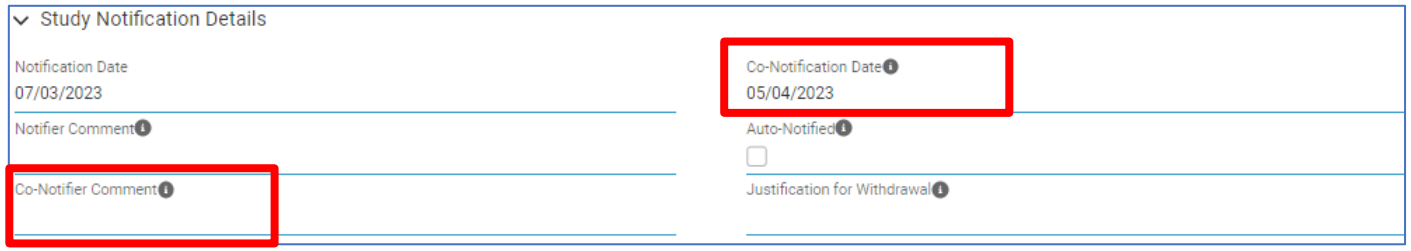
- To co-notify the study, the user selects "**Co-Notify**", then clicks on **Next**.
- If the user notices that its own organisation has been wrongly selected as co-notifier, checks the "**Wrong Co-Notifier**" box then clicks on Next.

More details about this new function in the dedicated section "Wrong Co-Notifier".

3.15 Study Co-notification

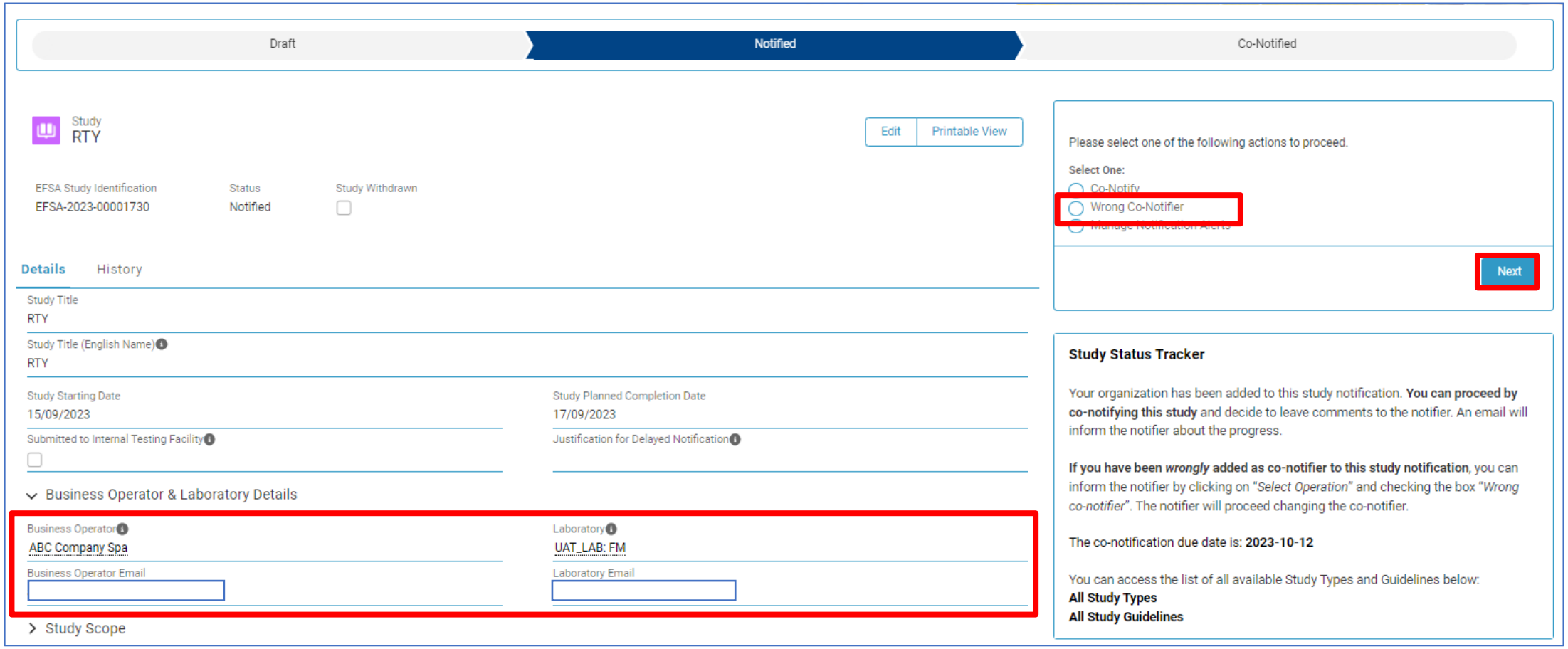


The status turns into **Co-Notified.**
Comments and co-notification date are available in the “Study Notification Details” section.
The notifier receives an email alert upon co-notification.



3.15.1 Study Co-notification – *"Wrong Co-Notifier" (co-notifier side)*

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



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

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

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

Wrong Co-Notifier email message

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

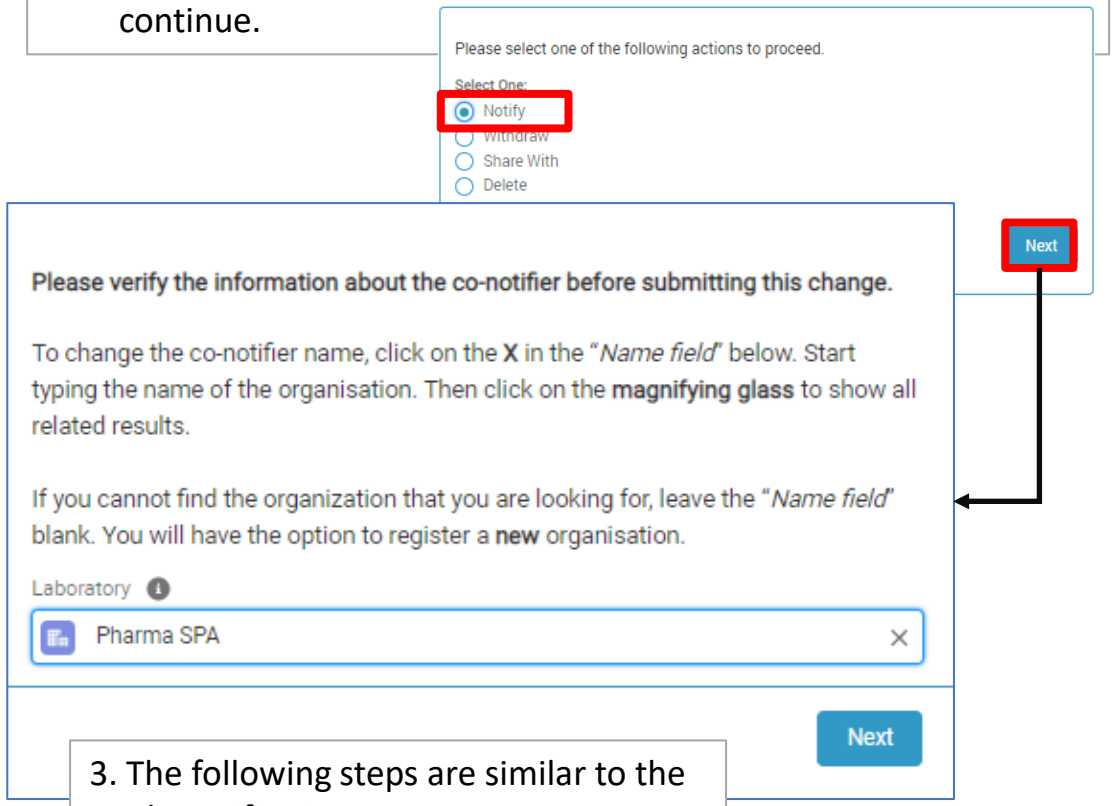
The deadline to change co-notifier is **DD Month YYYY**

To view the study please use the following link:

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

Follow the below steps to change the co-notifier

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



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

More information in the next slide.

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

NOTE

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

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

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

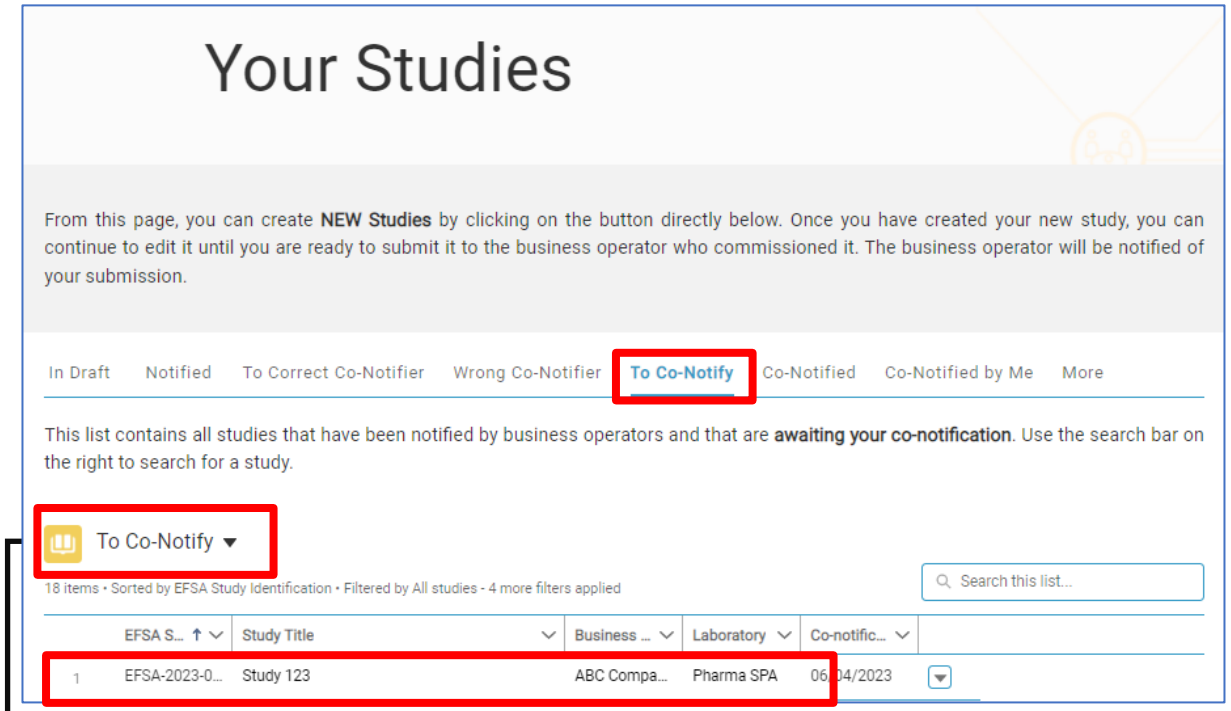
If the users wishes to correct the information of a study notification, it should withdraw the study and proceed with a new study notification.

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

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

Suggested read: Article 20(4) and 21 of the EFSA Practical Arrangements on pre-submission phase and public consultations.

3.15.3 Study Co-notification – *"auto-notified" studies*



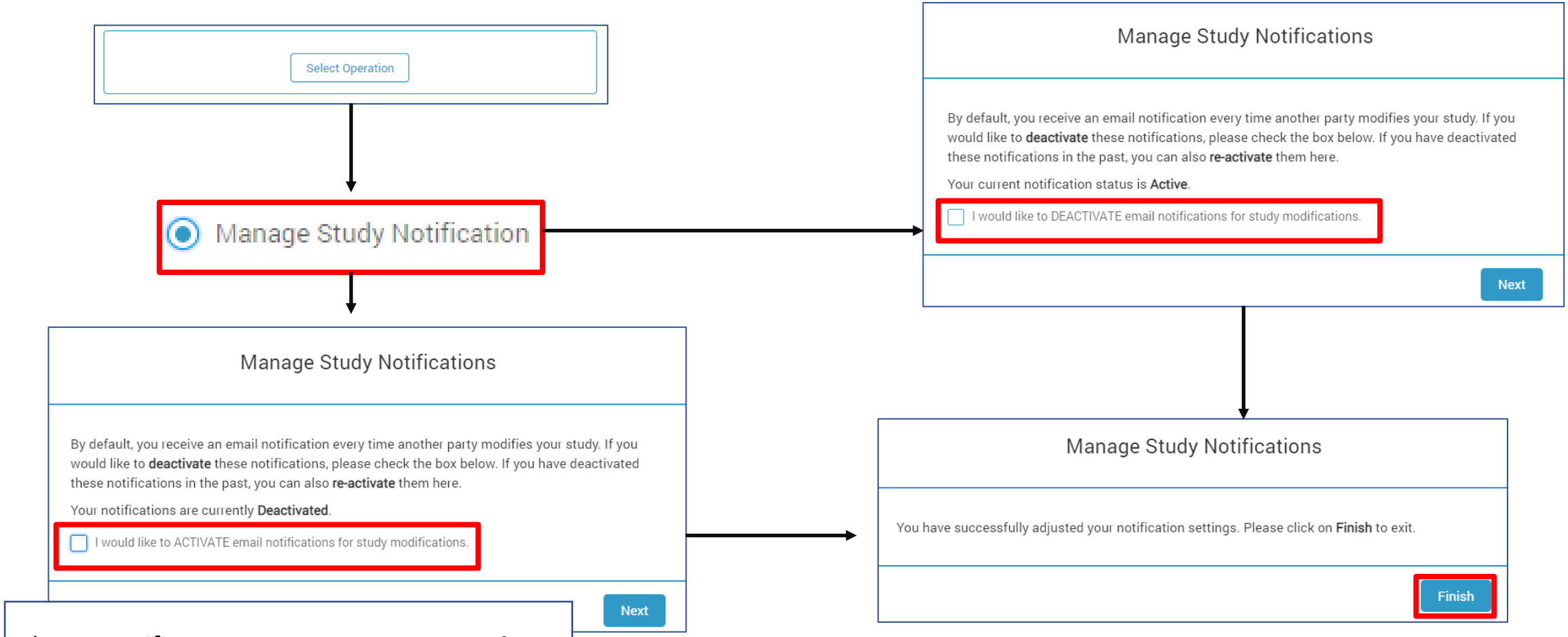
After the timeframe of 30 days for the notification has passed, the system marks the study as "auto-notified".

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

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

3.15.4 Study Co-notification – *Manage Study Notification*

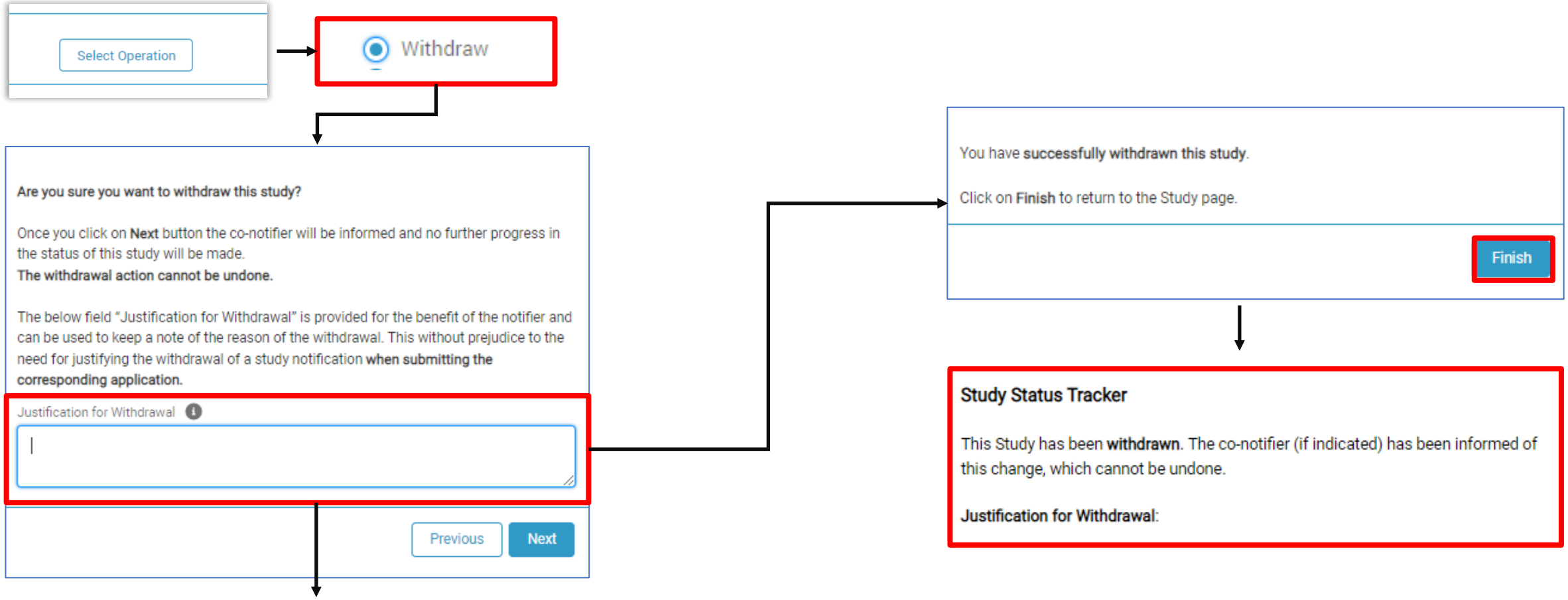
By default, the co-notifier receives an **email alert** every time the notifier edits the study notification record.
To change this setting the co-notifier can click on the button **Select Operation** and then **Manage Study Notification** to deactivate them.



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

3.16 Study Withdrawal

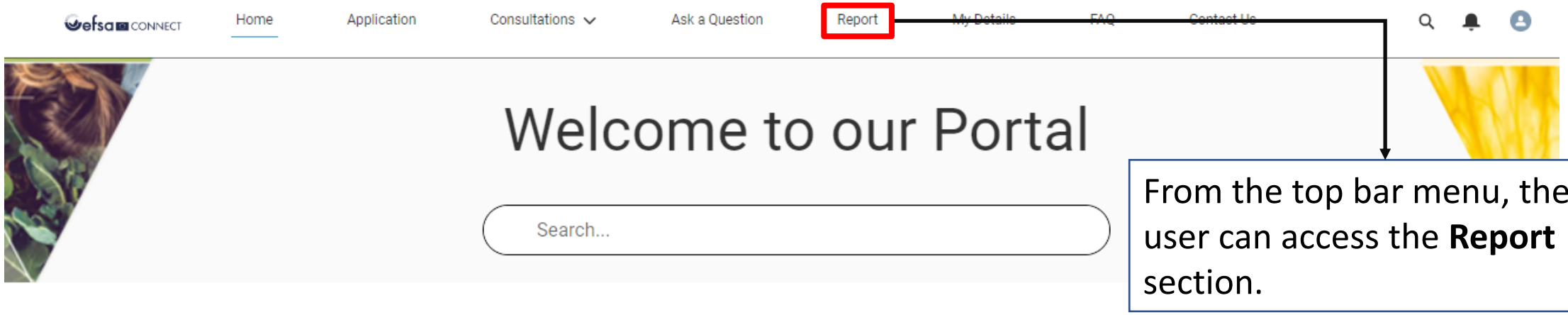
The Notifier can withdraw a study before its planned completion date by clicking on the button **Select Operation** and then selecting **Withdraw**. The field "Justification for Withdrawal" is provided for the benefit of the notifier and can be used to keep a note of the reason of the withdrawal. This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



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

Reporting features

4. Reporting features



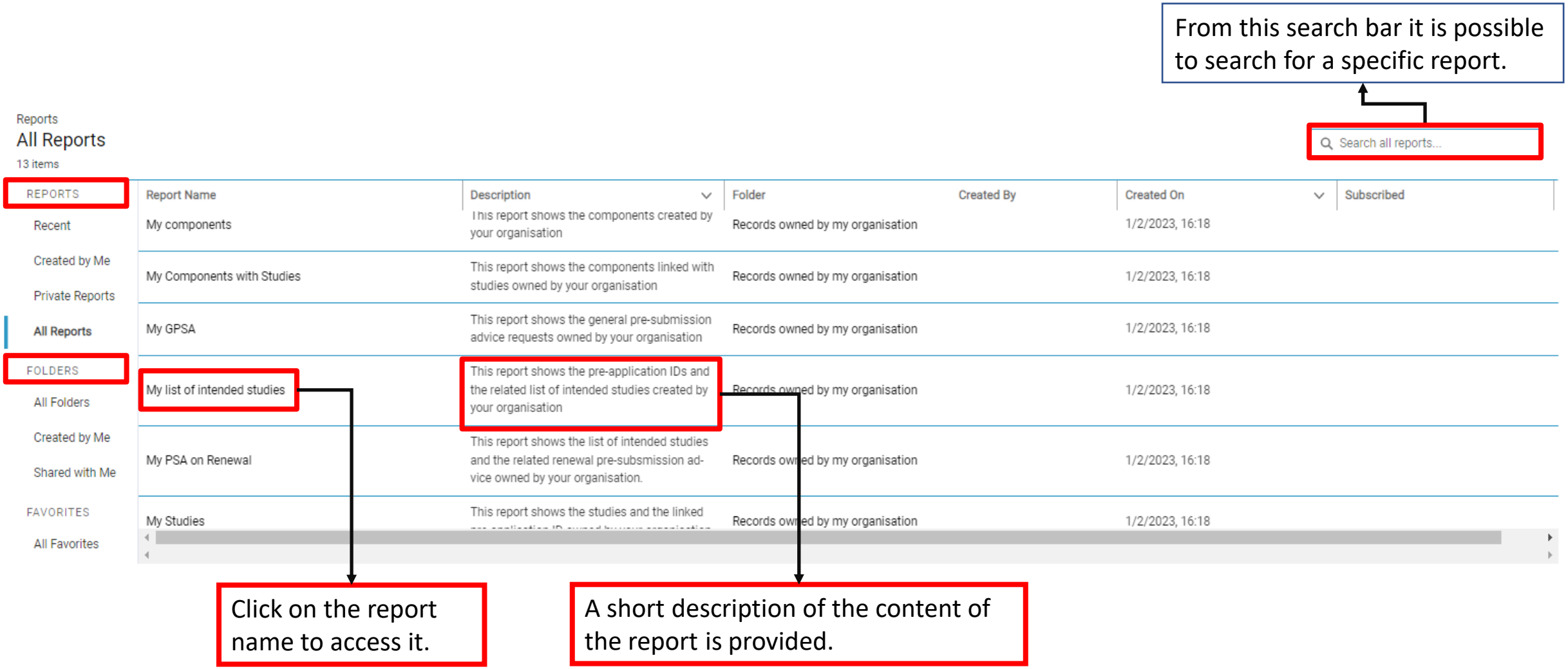
Important notes about reports:

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

4.1 Reporting features – Overview

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

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

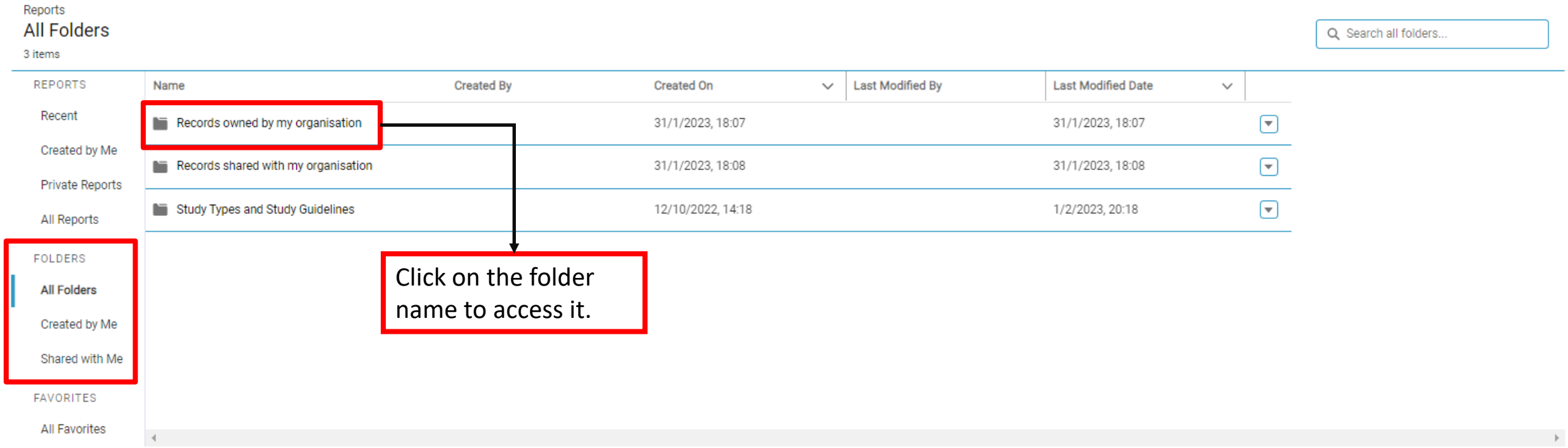


Click on the report name to access it.

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

4.2 Reporting features - Folders

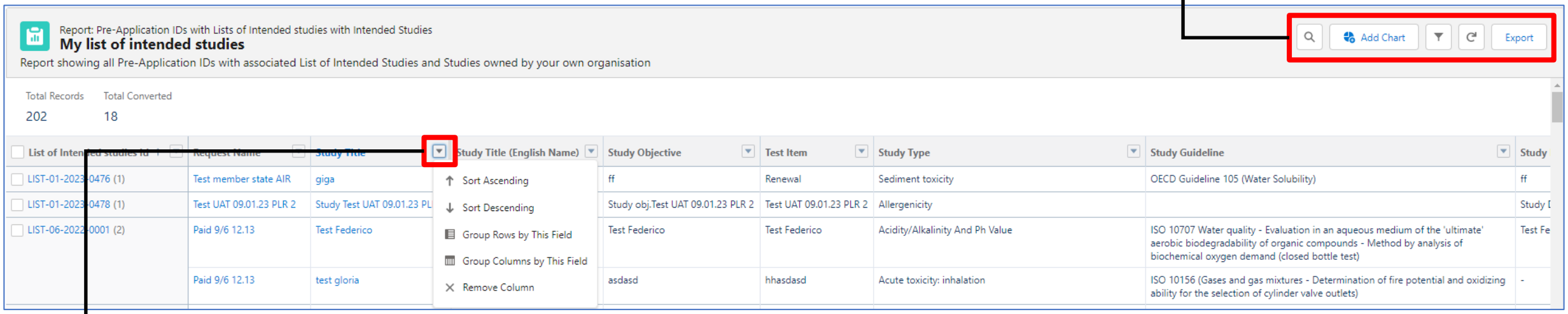
All the reports available to the user are saved in **three distinct folders**.



4.3 Reporting features – Actions allowed on a report

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

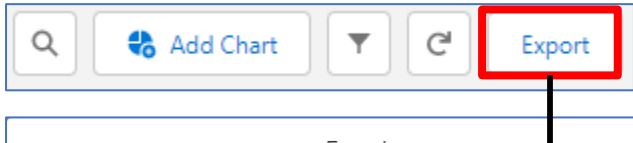
- **search for a specific value** in the table
- **add a chart**
- **apply filters**
- **refresh the values in table**
- **export the report** in Excel or CSV formats



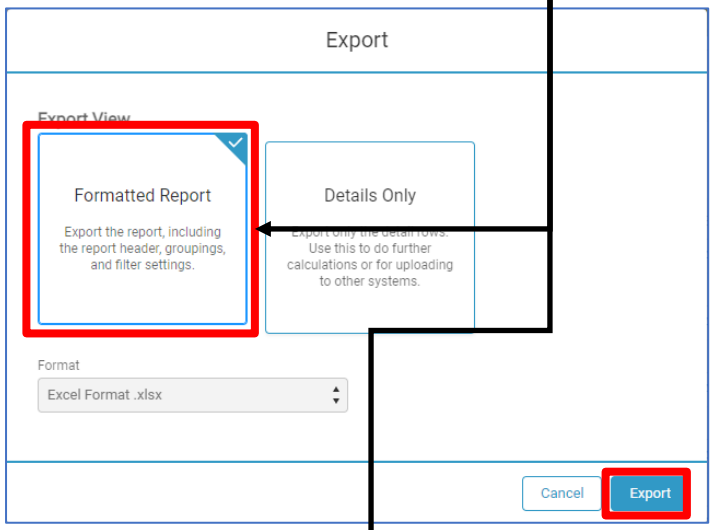
Click on one of the pointing down arrows to perform actions on the report table.
The user can:

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

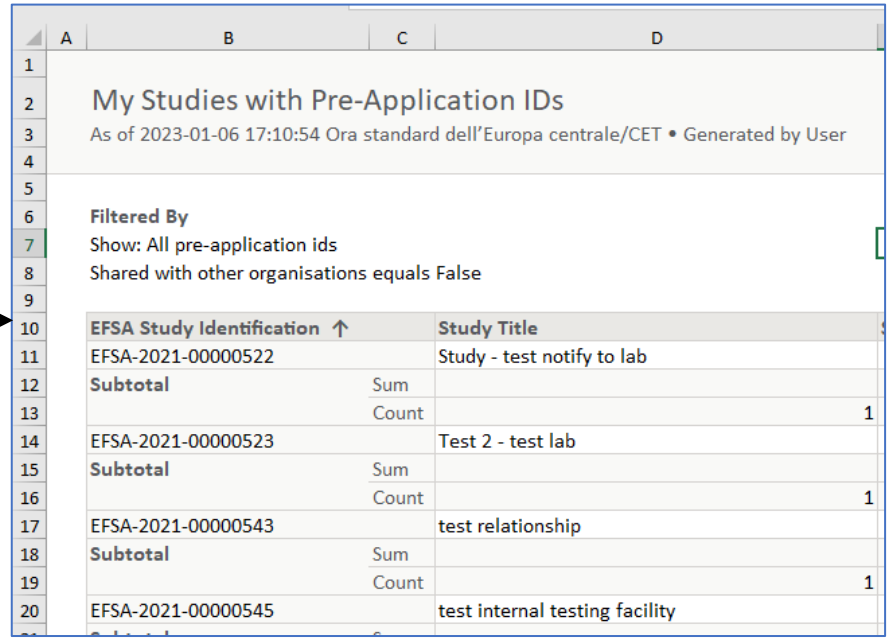
4.4 Reporting features – Export a report

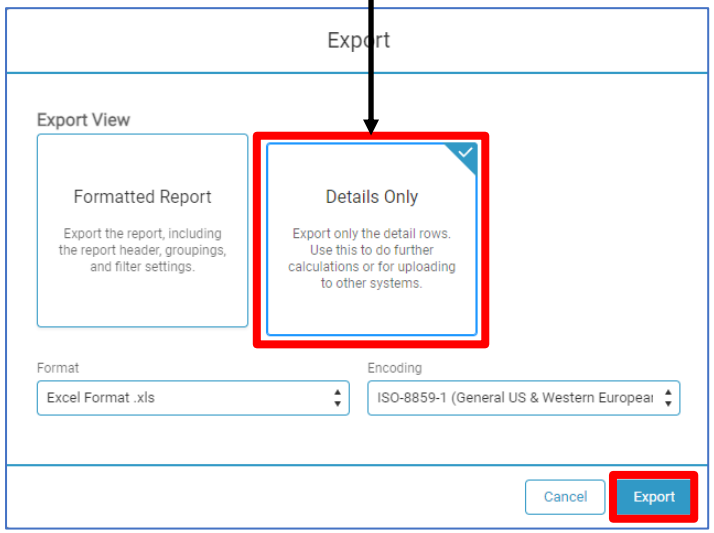


Click on **Export** button and select the preferred format.

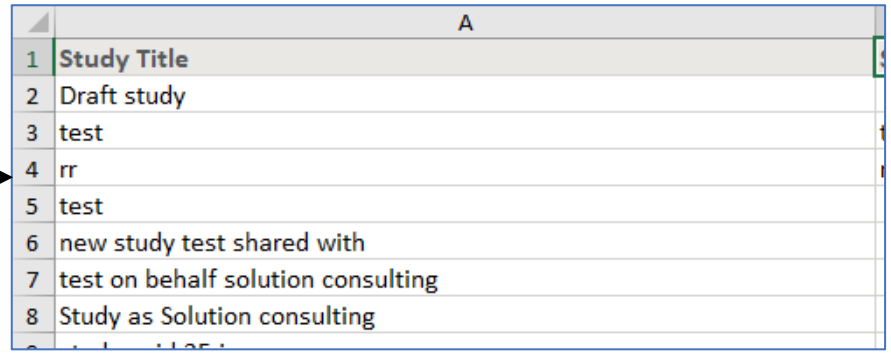


Formatted Report
Reports can be exported in a format similar to the online version, e.g., keeping the grouping and the other settings. This option exports the report as Excel file only.



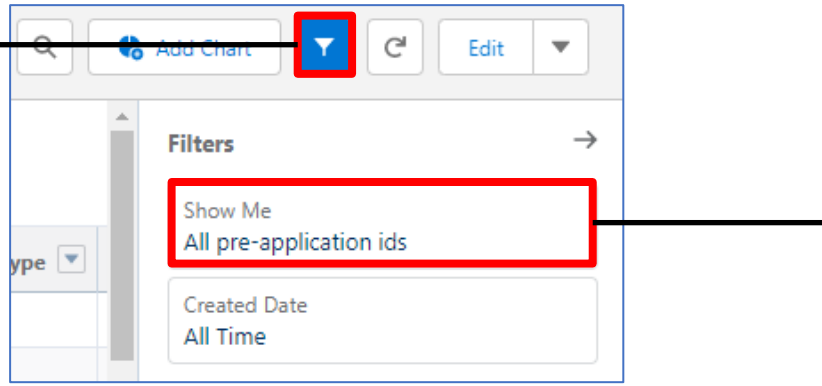


Details Only
Reports can be exported as Excel or CSV file showing only the detail rows.

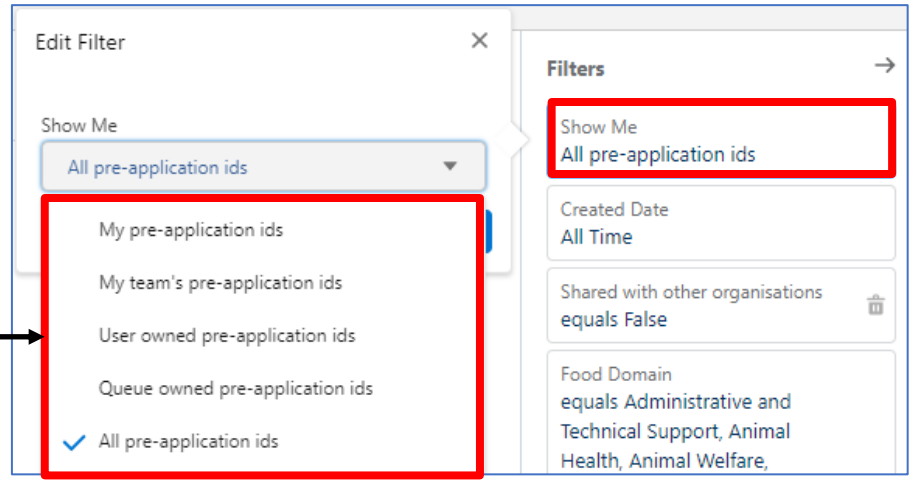


4.5 Reporting features – Filters functionality

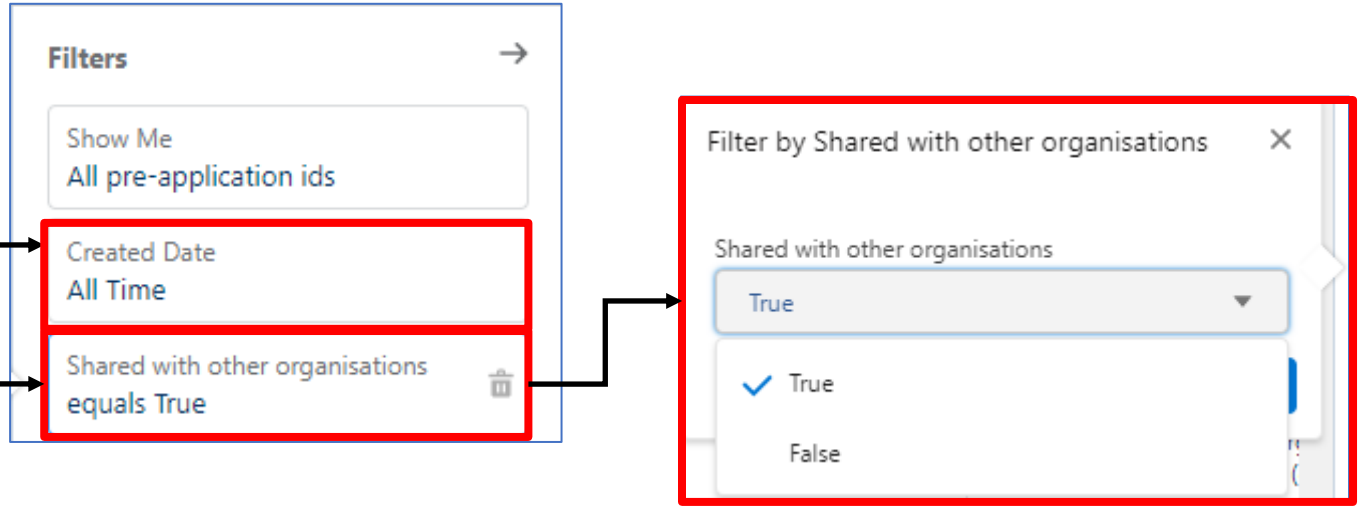
Depending on the type of data showed in the report, predefined filters are available. Once the user refreshes the page the default filtering rules set by EFSA will be restored.



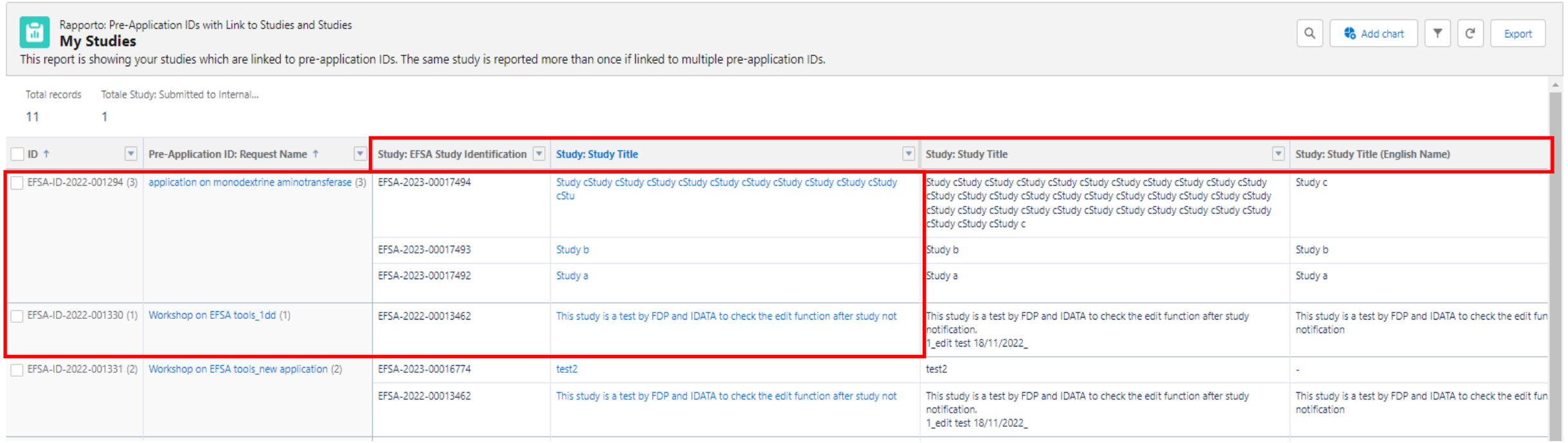
Click on the Filters icon and select the filter to apply.



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**.



4.6 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	Totale Study: Submitted to Internal...
11	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 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 notification record page, “Study Title” (i.e. the full length version) and “Study Title (English Name)”.
3. Other available information includes: Status, Study Objective, Business Operator name and email, Laboratory name and email, etc.

4.7 Reporting features – All my Studies reports

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

Add chart | Export

Record totali	Totale Submitted to Internal Testin...
13	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 cStu	Study c	Study c	Draft	-	FDP Team Advice B
7	EFSA-2023-00018347	Study XYZ	Study XYZ	-	Draft	-	FDP Team Advice B
8	EFSA-2023-00018348	Study ABC	Study ABC	-	Draft	-	FDP Team Advice B
9	EFSA-2023-00018349	Study CBD	Study CBD	-	Draft	-	FDP Team Advice B
10	EFSA-2023-00018350	Study FGI	Study FGI	-	Draft	-	FDP Team Advice B
11	EFSA-2023-00018351	Study EPO	Study EPO	-	Draft	-	FDP Team Advice B
12	EFSA-2022-00013462	This study is a test by FDP and IDATA to check the edit function after study not	This study is a test by FDP and IDATA to check the edit function after study notification	This study is a test by FDP and IDATA to check the edit function after study notification	Co-Notified	investigate acute tox	FDP Team Advice B

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

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

Recommended documents and links

Applicants Toolkit	https://www.efsa.europa.eu/en/applications/toolkit
Transparency Regulation	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1381
Practical Arrangements	https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements
Q&A on Practical arrangements	https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements