27 - 28 January 2021

NoS Technical Group Meeting

Case – Study 5: Pesticides renewals

Stefano Cappè

Evidence Management Unit

Trusted science for safe food

efsa
European Food Safety Authority

Potential Applicant

Sarah

Sara has to start an application for the renewal of the approval of the active substance X

Article 4(3) of DECISION LAYING DOWN THE PRACTICAL ARRANGEMENTS ON PRE-SUBMISSION PHASE AND PUBLIC CONSULTATIONS

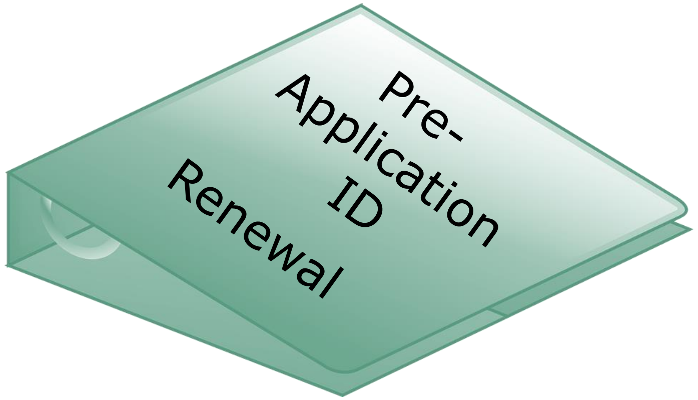
Where more than one potential applicant is planning to request renewal of the approval of the same active substance pursuant to the Commission Implementing Regulation (EU) 2020/1740 […] the Authority strongly recommends these potential applicants to request a preapplication ID jointly in accordance with paragraph 2.

Focus: notification with multiple potential applicants and control access to pre-application-ids and notifications

Pre-Application identification for renewal

Sarah

Request a pre-application ID for renewal

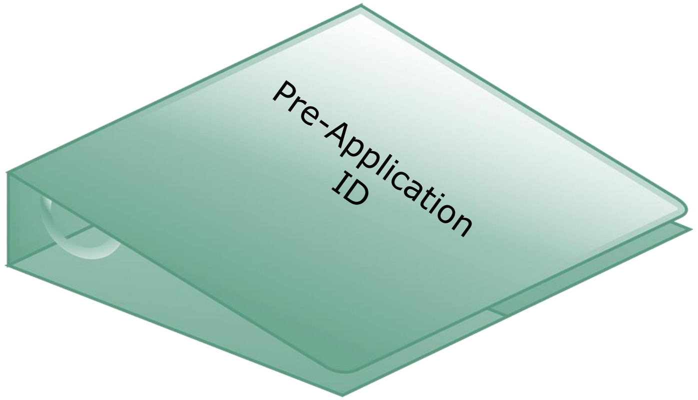

Pre-
Application
ID
Renewal

Pre-Application Identification for renewal

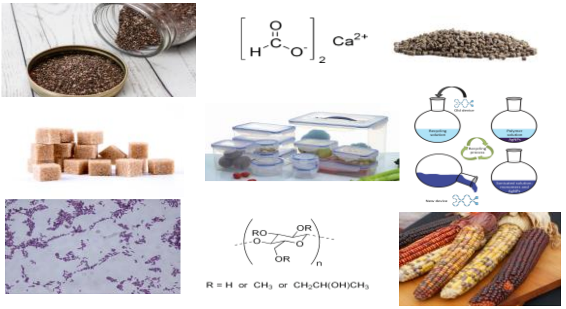
Request a pre-application ID for renewal

Sarah

All other Business Operators?


Pre-Application ID

Rapporteur MS

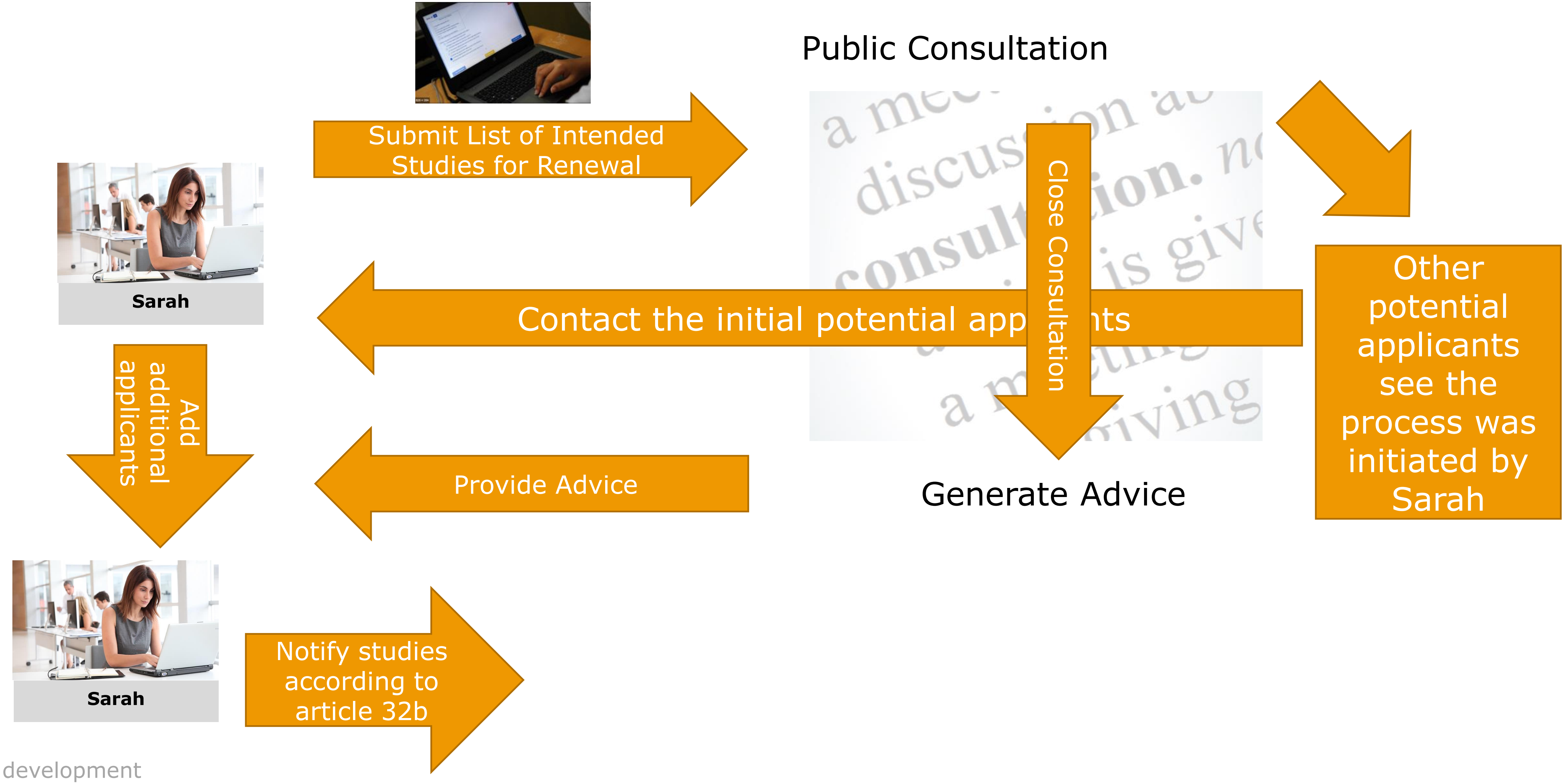

Ca2+
R = H or CH3 or CH2CH(OH)CH3

Subject of the application

Intended Area

Business Operator(s)

Application Renewal Pre-submission Process



Submit List of Intended Studies for Renewal

Public Consultation

Sarah

Contact the initial potential applicants

Close Consultation

Other potential applicants see the process was initiated by Sarah

Add additional applicants

Provide Advice

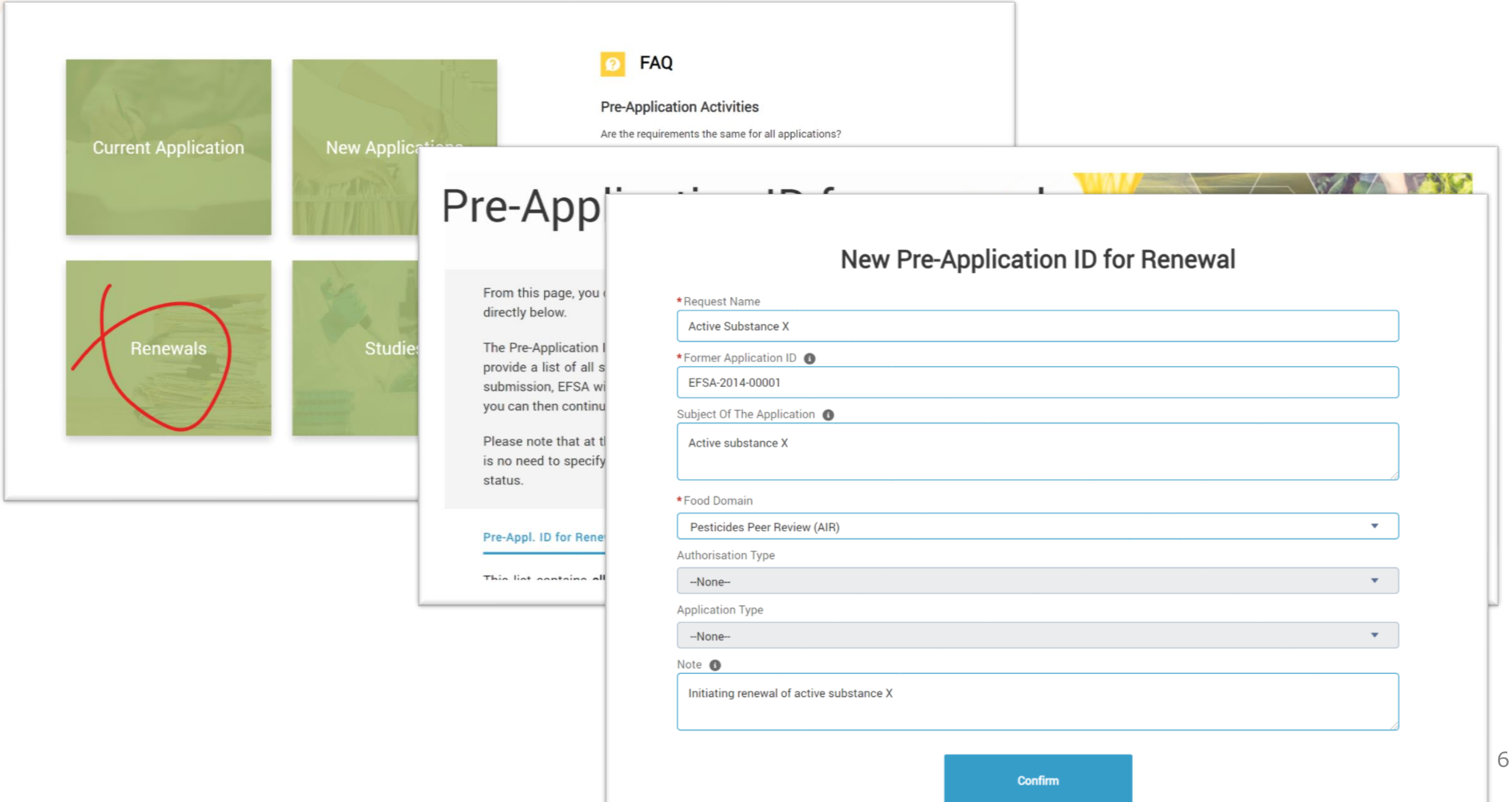
Generate Advice

Sarah

Notify studies according to article 32b

Under development

Pre-application-id for renewal


Current Application
New Applications
Renewals
Studies
FAQ
Pre-Appl. ID for Rene
Confirm

Pre-Application Activities

Are the requirements the same for all applications?

Pre-App

From this page, you
directly below.

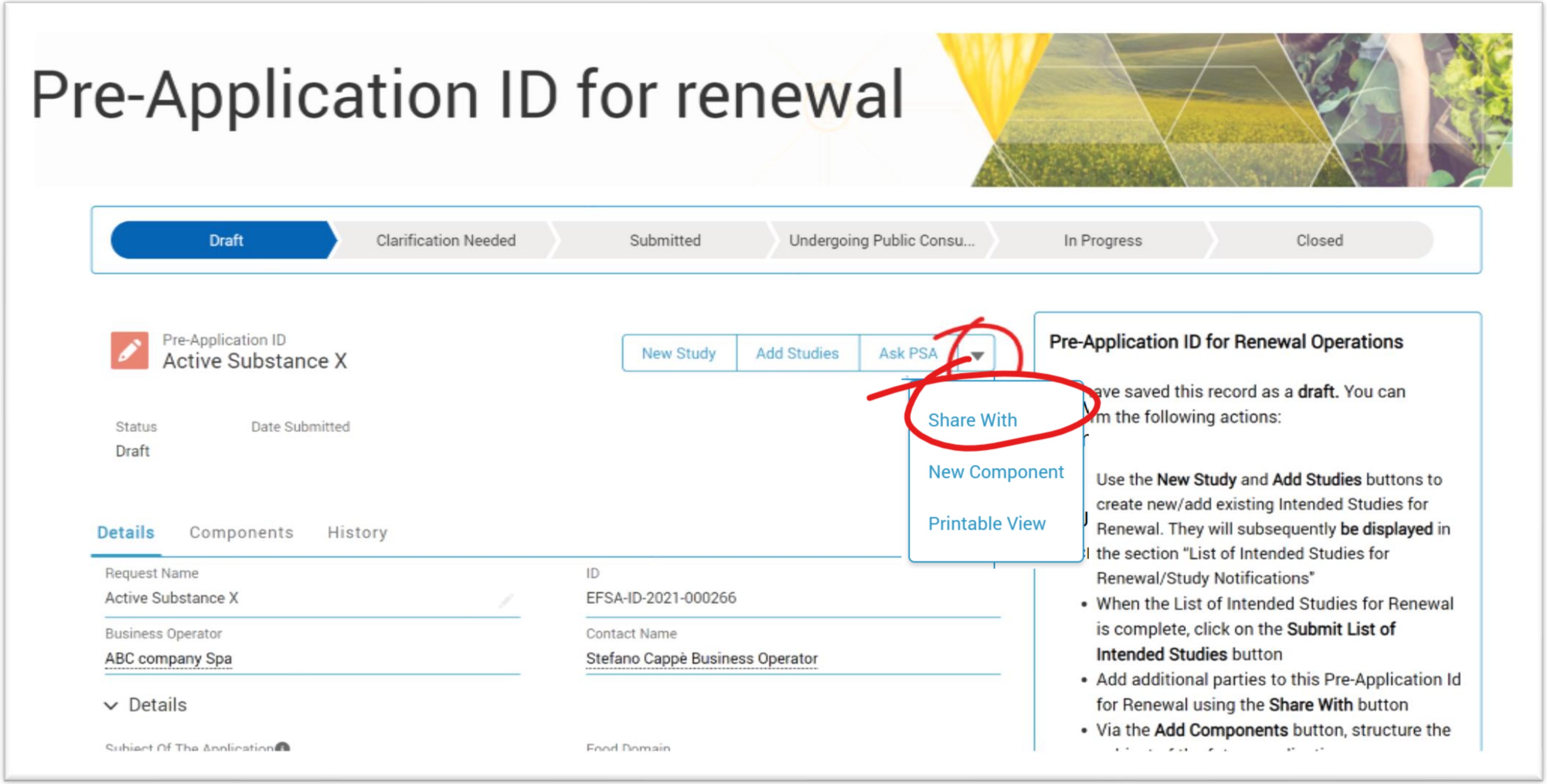
The Pre-Application I
provide a list of all s
submission, EFSA wi
you can then continu

Please note that at t
is no need to specify
status.

New Pre-Application ID for Renewal

*Request Name	Active Substance X
*Former Application ID	EFSA-2014-00001
Subject Of The Application	Active substance X
*Food Domain	Pesticides Peer Review (AIR)
Authorisation Type	--None--
Application Type	--None--
Note	Initiating renewal of active substance X

Pre-application-id for renewal: additional potential applicant


Pre-Application ID for renewal
Draft
Clarification Needed
Submitted
Undergoing Public Consu...
In Progress
Closed
New Study
Add Studies
Ask PSA
Share With
New Component
Printable View
Details
Components
History

Pre-Application ID
Active Substance X

Status
Draft

Date Submitted

Request Name
Active Substance X

ID
EFSA-ID-2021-000266

Business Operator
ABC company Spa

Contact Name
Stefano Cappè Business Operator

Details

Subject Of The Application

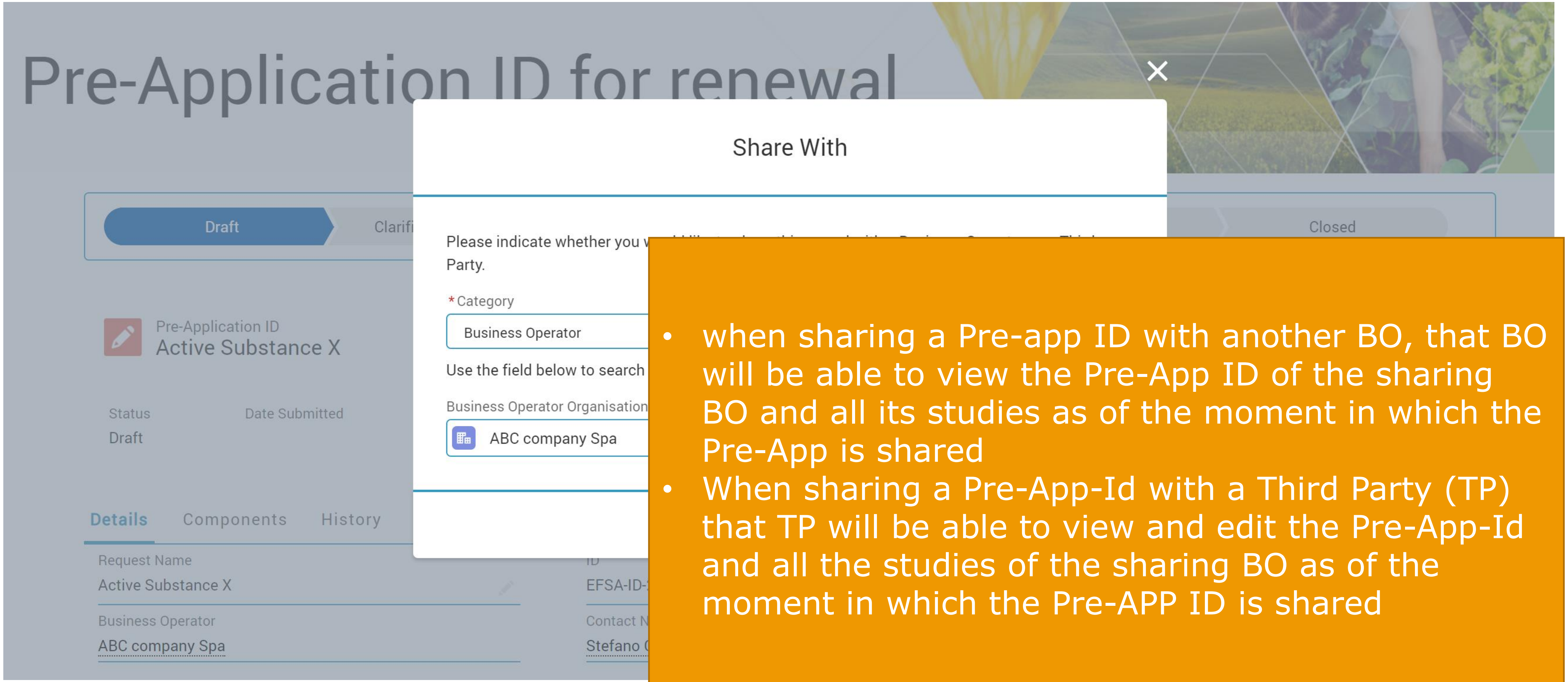
Food Domain

Pre-Application ID for Renewal Operations

ave saved this record as a **draft.** You can
m the following actions:

- Use the **New Study** and **Add Studies** buttons to create new/add existing Intended Studies for Renewal. They will subsequently **be displayed** in the section "List of Intended Studies for Renewal/Study Notifications"
- When the List of Intended Studies for Renewal is complete, click on the **Submit List of Intended Studies** button
- Add additional parties to this Pre-Application Id for Renewal using the **Share With** button
- Via the **Add Components** button, structure the

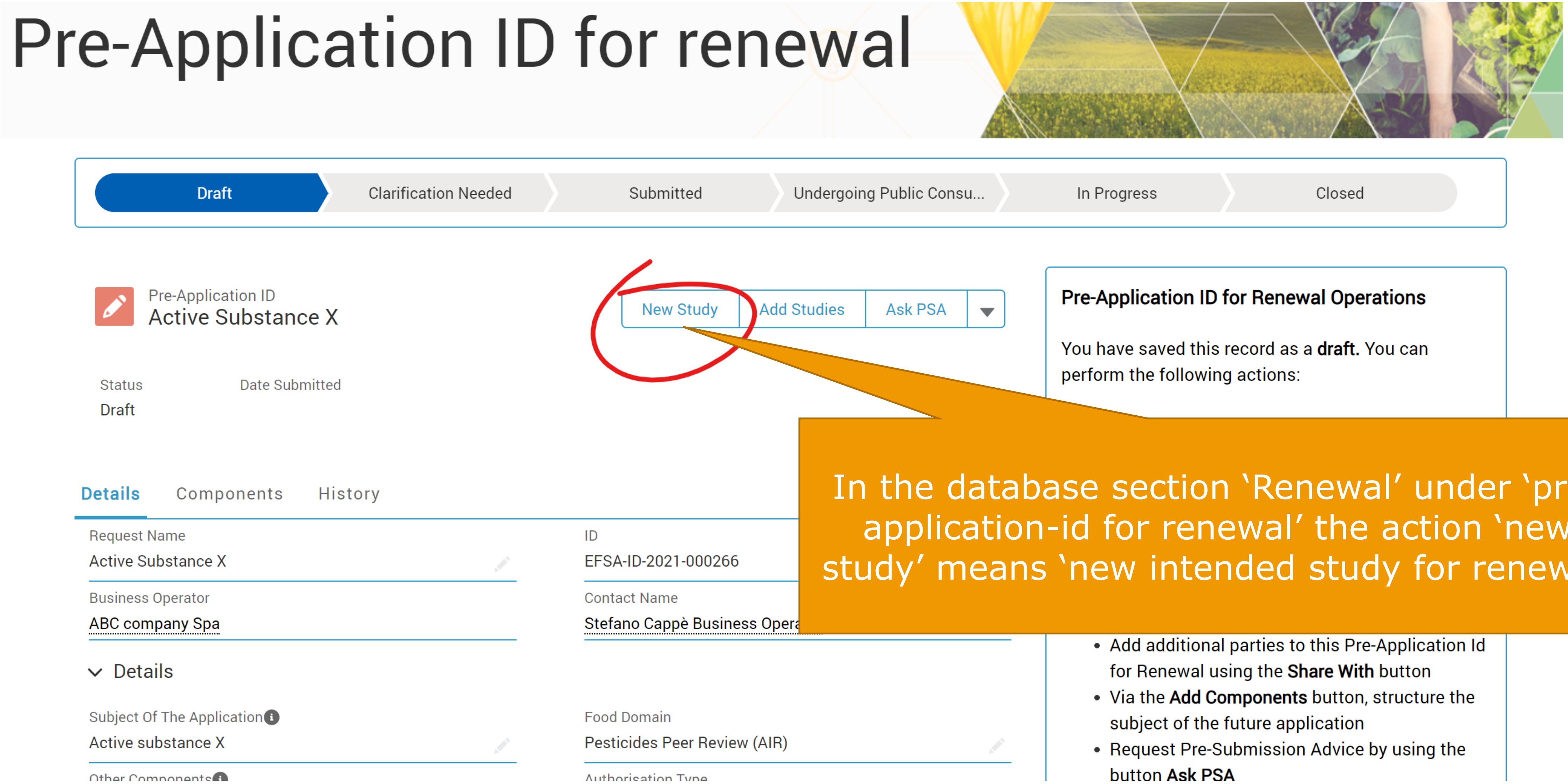
Pre-application-id for renewal: Additional business operators



Pre-Application ID for renewal
Draft
Clarifi
Closed
Share With
Please indicate whether you w
Party.
* Category
Business Operator
Use the field below to search
Business Operator Organisation
ABC company Spa
Pre-Application ID
Active Substance X
Status
Draft
Date Submitted
Details
Components
History
Request Name
Active Substance X
ID
EFSA-ID-
Business Operator
ABC company Spa
Contact N
Stefano

- when sharing a Pre-app ID with another BO, that BO will be able to view the Pre-App ID of the sharing BO and all its studies as of the moment in which the Pre-App is shared
- When sharing a Pre-App-Id with a Third Party (TP) that TP will be able to view and edit the Pre-App-Id and all the studies of the sharing BO as of the moment in which the Pre-APP ID is shared

Pre-application-id for renewal: New intended study for renewal


Draft
Clarification Needed
Submitted
Undergoing Public Consu...
In Progress
Closed
New Study
Add Studies
Ask PSA
Details
Components
History

Pre-Application ID for renewal

Pre-Application ID
Active Substance X

Status: Draft

Date Submitted:

Request Name: Active Substance X

ID: EFSA-ID-2021-000266

Business Operator: ABC company Spa

Contact Name: Stefano Cappè Business Opera

Details

Subject Of The Application: Active substance X

Food Domain: Pesticides Peer Review (AIR)

Other Components

Authorisation Type

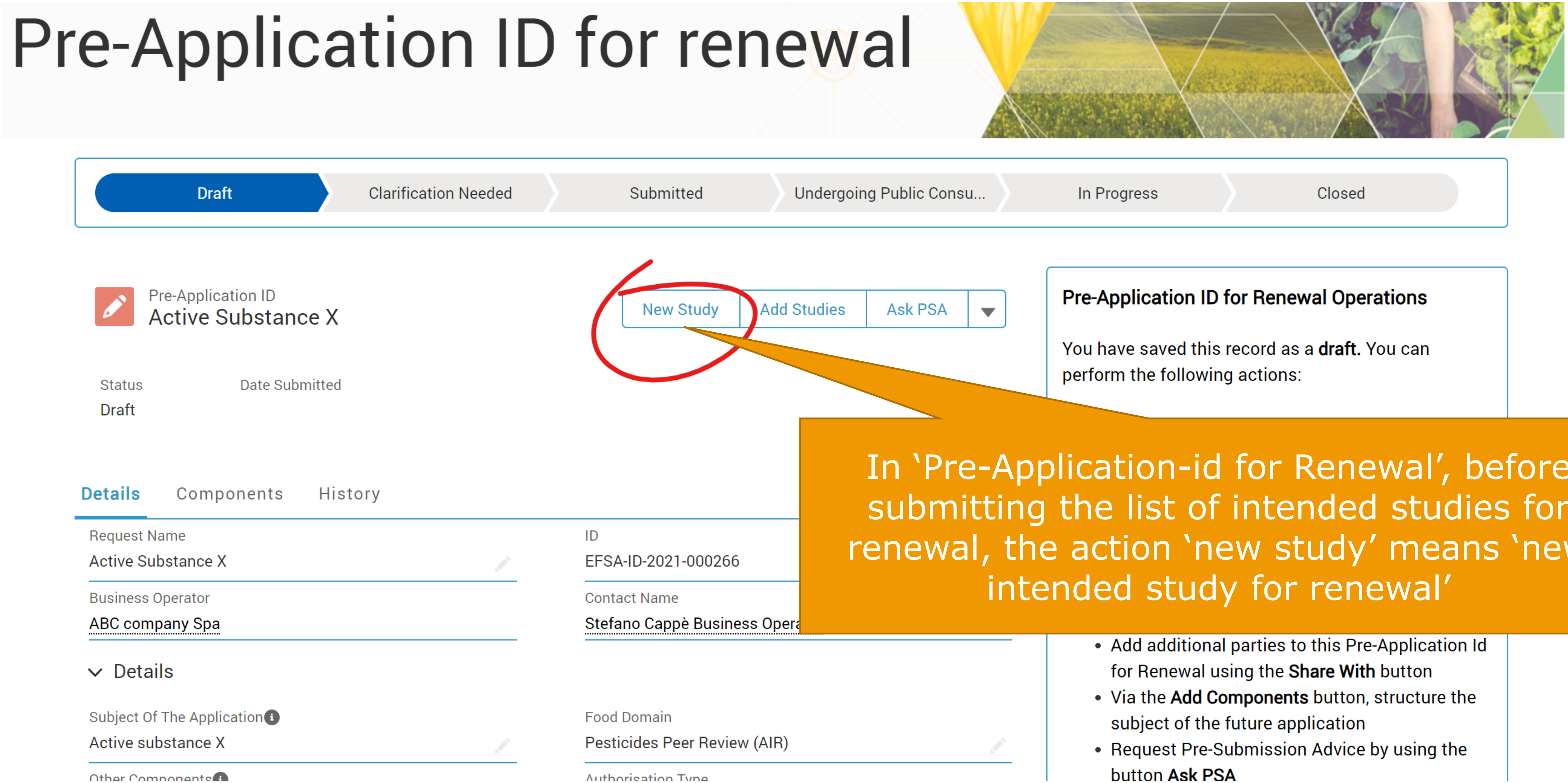
Pre-Application ID for Renewal Operations

You have saved this record as a **draft.** You can perform the following actions:

- Add additional parties to this Pre-Application Id for Renewal using the **Share With** button
- Via the **Add Components** button, structure the subject of the future application
- Request Pre-Submission Advice by using the button **Ask PSA**

In the database section ‘Renewal’ under ‘pre-application-id for renewal’ the action ‘new study’ means ‘new intended study for renewal’

Pre-application-id for renewal: Add intended studies



Pre-Application ID for renewal

Draft
Clarification Needed
Submitted
Undergoing Public Consu...
In Progress
Closed

Pre-Application ID
Active Substance X

New Study
Add Studies
Ask PSA

Status
Draft

Date Submitted

Details
Components
History

Request Name
Active Substance X

ID
EFSA-ID-2021-000266

Business Operator
ABC company Spa

Contact Name
Stefano Cappè Business Opera

Details

Subject Of The Application
Active substance X

Food Domain
Pesticides Peer Review (AIR)

Other Components

Authorisation Type

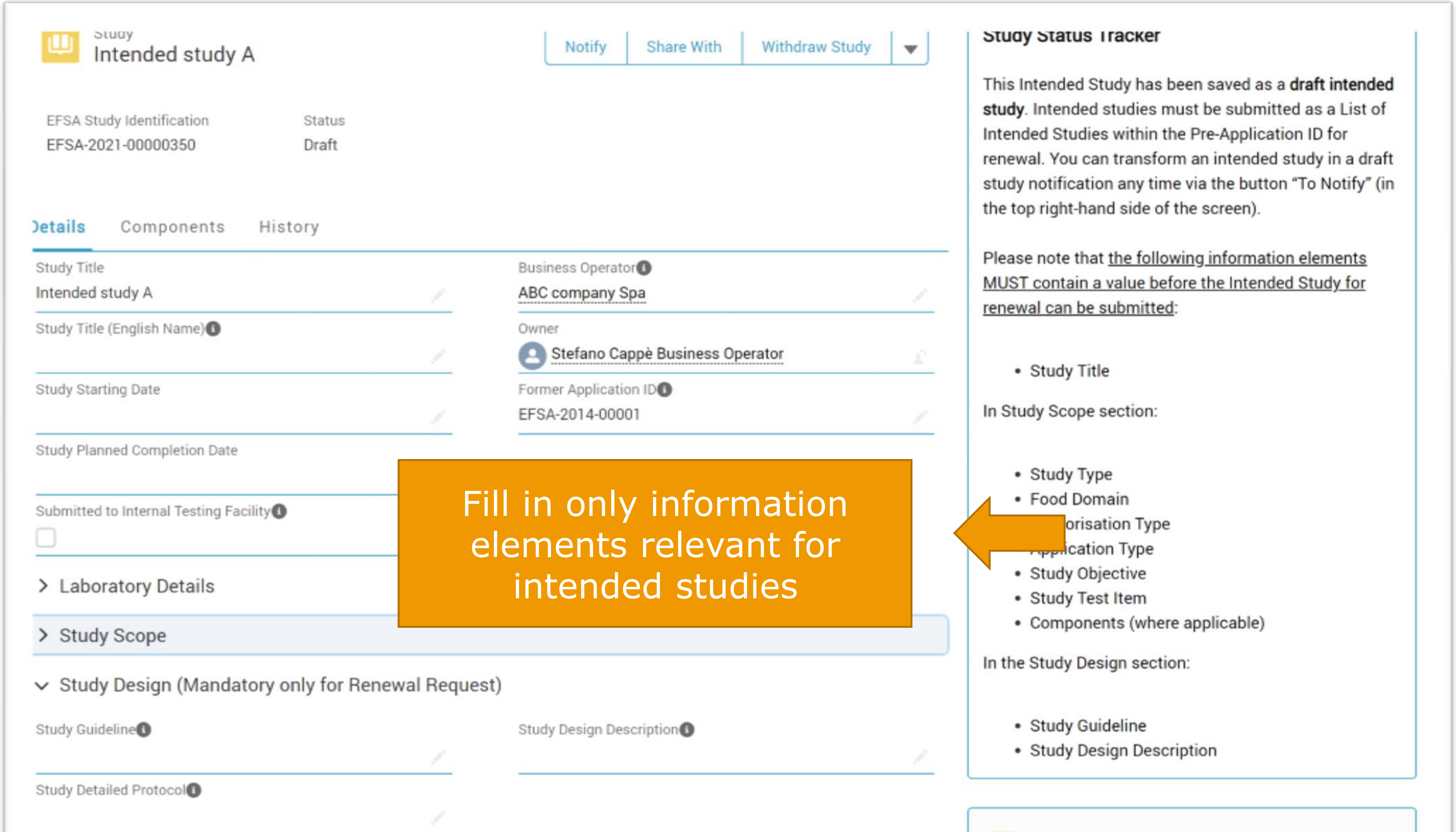
Pre-Application ID for Renewal Operations

You have saved this record as a **draft.** You can perform the following actions:

- Add additional parties to this Pre-Application Id for Renewal using the **Share With** button
- Via the **Add Components** button, structure the subject of the future application
- Request Pre-Submission Advice by using the button **Ask PSA**

In ‘Pre-Application-id for Renewal’, before submitting the list of intended studies for renewal, the action ‘new study’ means ‘new intended study for renewal’

Pre-application-id for renewal: fill in intended study information



Study
Intended study A

EFSA Study Identification: EFSA-2021-00000350
Status: Draft

Study Title Intended study A	Business Operator ABC company Spa
Study Title (English Name)	Owner Stefano Cappè Business Operator
Study Starting Date	Former Application ID EFSA-2014-00001
Study Planned Completion Date	
Submitted to Internal Testing Facility ☐	

- Laboratory Details
- Study Scope
- Study Design (Mandatory only for Renewal Request)

Study Guideline	Study Design Description
Study Detailed Protocol	

Study Status Tracker

This Intended Study has been saved as a **draft intended study**. Intended studies must be submitted as a List of Intended Studies within the Pre-Application ID for renewal. You can transform an intended study in a draft study notification any time via the button "To Notify" (in the top right-hand side of the screen).

Please note that the following information elements MUST contain a value before the Intended Study for renewal can be submitted:

- Study Title

In Study Scope section:

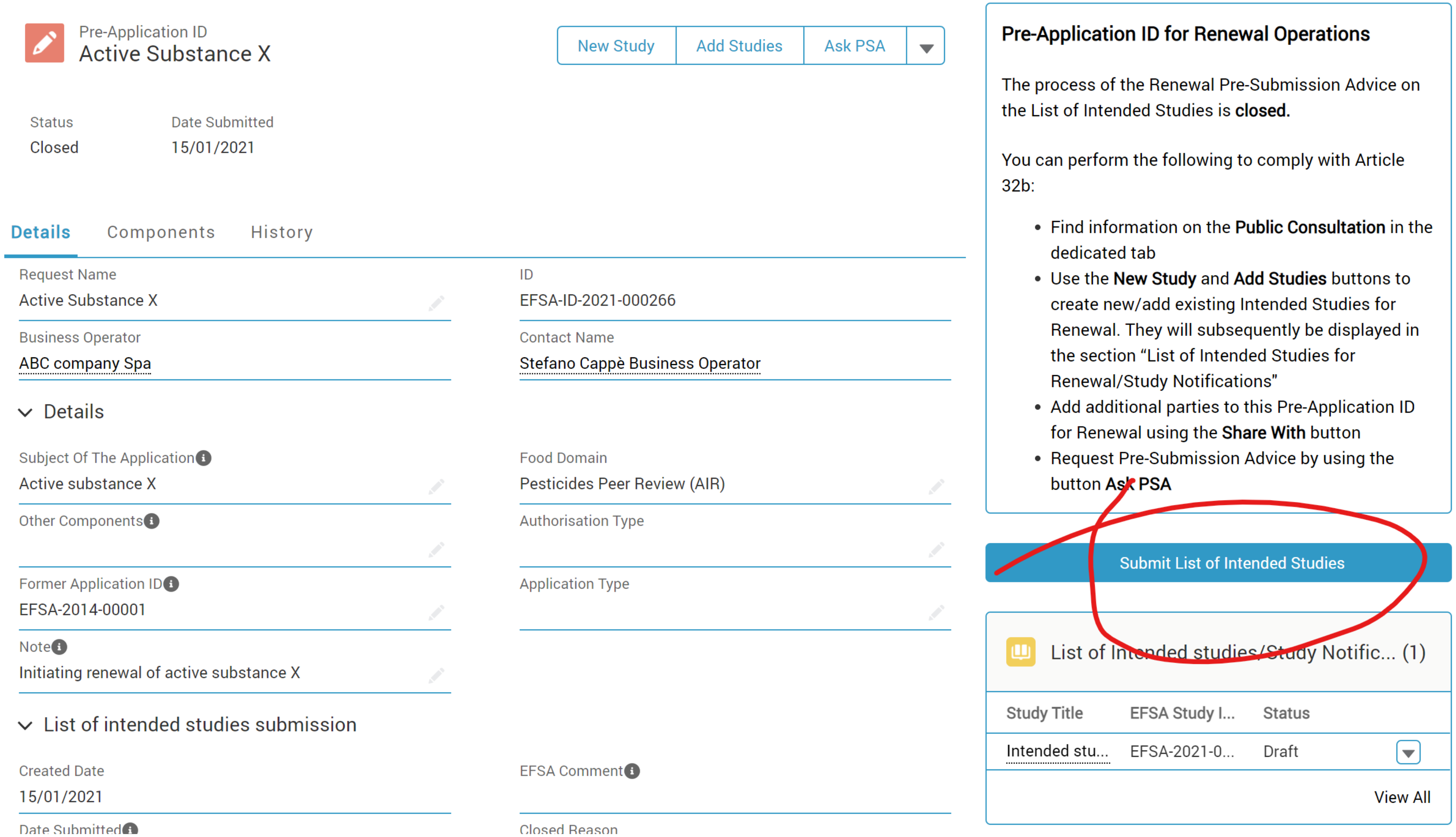
- Study Type
- Food Domain
- orisation Type
- ication Type
- Study Objective
- Study Test Item
- Components (where applicable)

In the Study Design section:

- Study Guideline
- Study Design Description

Fill in only information elements relevant for intended studies

Pre-application-id for renewal: submit list of intended studies



Pre-Application ID
Active Substance X

Status: Closed
Date Submitted: 15/01/2021

Request Name: Active Substance X
ID: EFSA-ID-2021-000266
Business Operator: ABC company Spa
Contact Name: Stefano Cappè Business Operator

Details

Subject Of The Application: Active substance X
Food Domain: Pesticides Peer Review (AIR)
Other Components:
Authorisation Type:
Former Application ID: EFSA-2014-00001
Application Type:
Note: Initiating renewal of active substance X

List of intended studies submission

Created Date: 15/01/2021
EFSA Comment:
Date Submitted:
Closed Reason:

Pre-Application ID for Renewal Operations

The process of the Renewal Pre-Submission Advice on the List of Intended Studies is **closed.**

You can perform the following to comply with Article 32b:

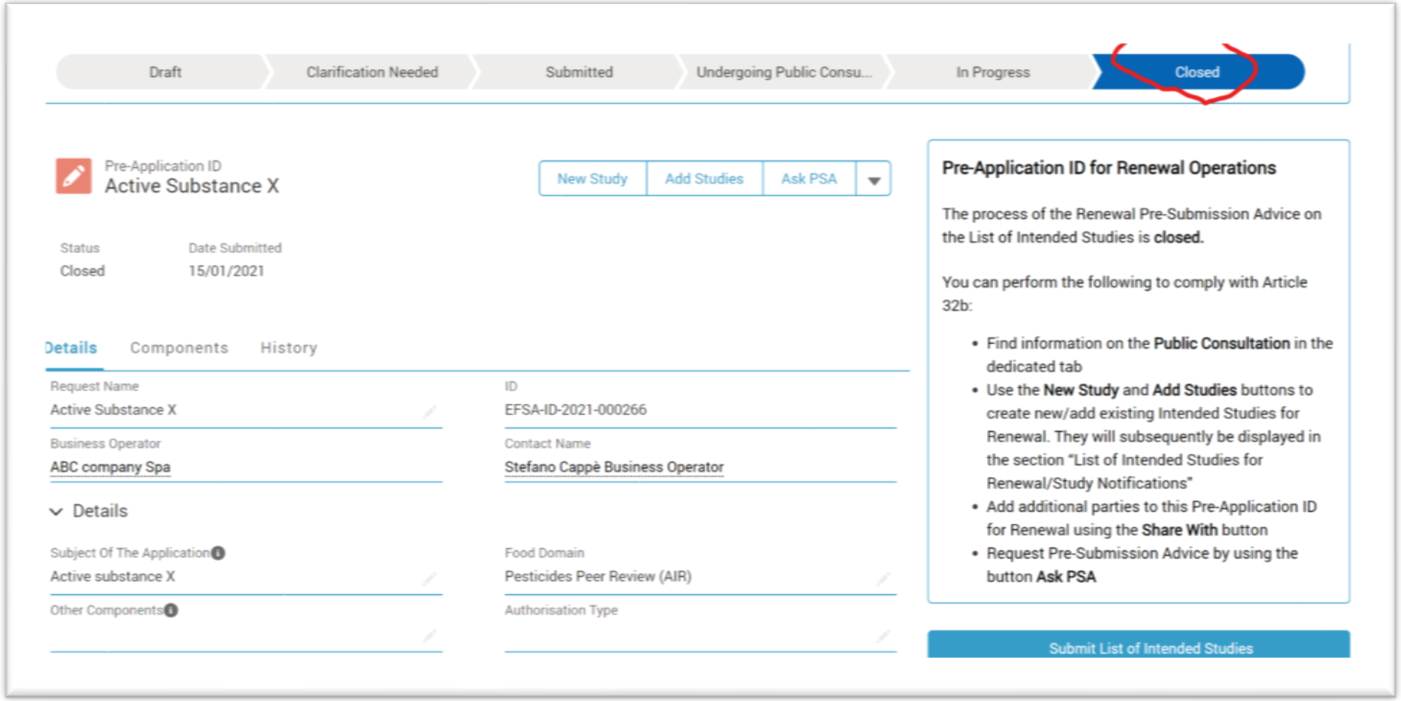
- Find information on the **Public Consultation** in the dedicated tab
- Use the **New Study** and **Add Studies** buttons to create new/add existing Intended Studies for Renewal. They will subsequently be displayed in the section “List of Intended Studies for Renewal/Study Notifications”
- Add additional parties to this Pre-Application ID for Renewal using the **Share With** button
- Request Pre-Submission Advice by using the button **Ask PSA**

List of Intended studies/Study Notific... (1)

Study Title	EFSA Study I...	Status
Intended stu...	EFSA-2021-0...	Draft

Then the system will ask to indicate the rapporteur MSs

Pre-application-id for renewal:
Renewal pre-submission advice received


Draft
Clarification Needed
Submitted
Undergoing Public Consu...
In Progress
Closed
New Study
Add Studies
Ask PSA
Details
Components
History
Submit List of Intended Studies

Pre-Application ID
Active Substance X

Status: Closed
Date Submitted: 15/01/2021

Request Name: Active Substance X
ID: EFSA-ID-2021-000266
Business Operator: ABC company Spa
Contact Name: Stefano Cappè Business Operator

Details

Subject Of The Application: Active substance X
Food Domain: Pesticides Peer Review (AIR)
Other Components:
Authorisation Type:

Pre-Application ID for Renewal Operations

The process of the Renewal Pre-Submission Advice on the List of Intended Studies is **closed.**

You can perform the following to comply with Article 32b:

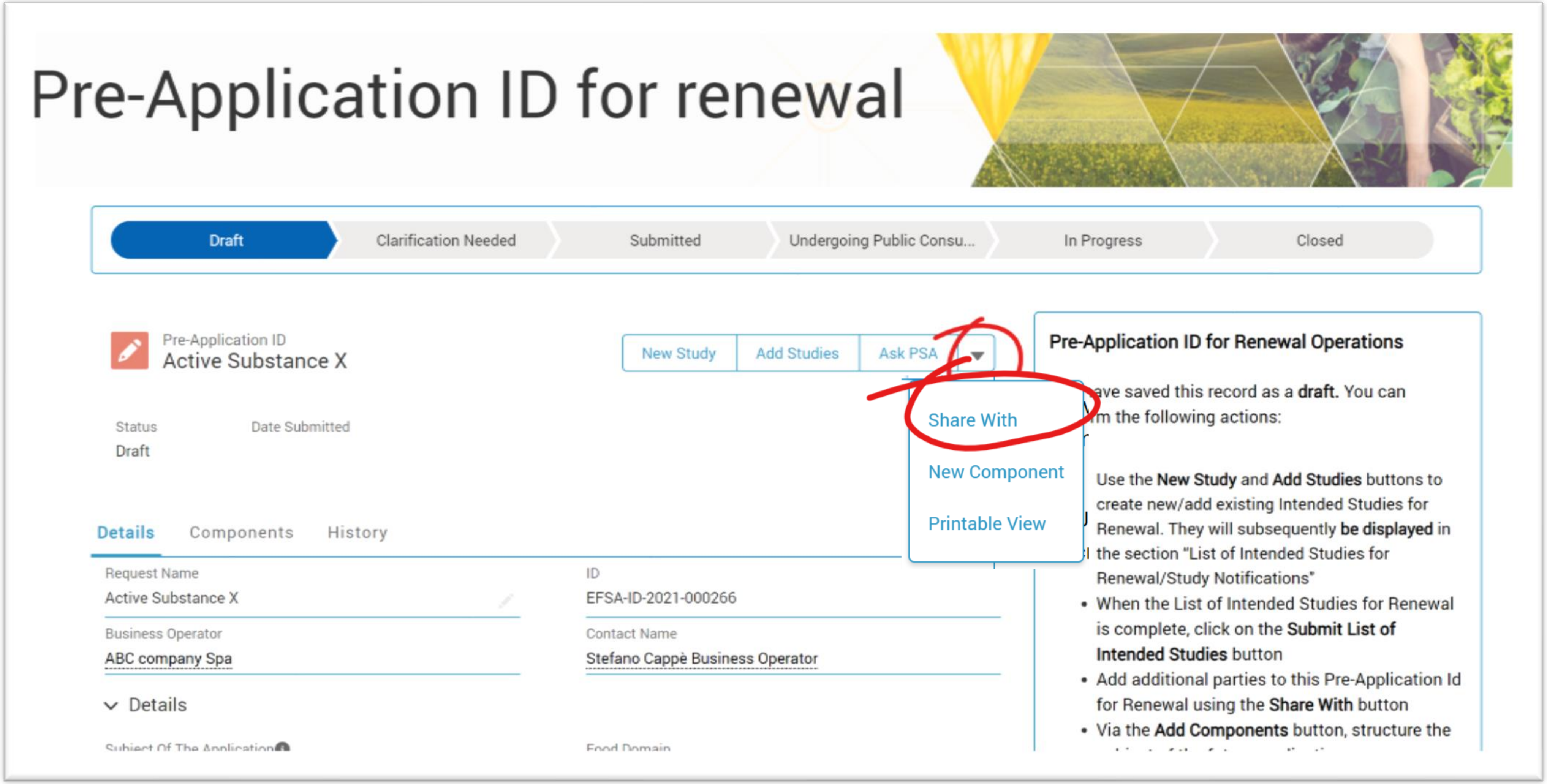
- Find information on the **Public Consultation** in the dedicated tab
- Use the **New Study** and **Add Studies** buttons to create new/add existing Intended Studies for Renewal. They will subsequently be displayed in the section "List of Intended Studies for Renewal/Study Notifications"
- Add additional parties to this Pre-Application ID for Renewal using the **Share With** button
- Request Pre-Submission Advice by using the button **Ask PSA**

Process Renewal Pre-Submission Advice Completed and advice received from potential applicant

Insert additional potential applicants

Notify studies according to article 32b

Pre-application-id for renewal: additional potential applicants can be added


Pre-Application ID for renewal
Draft
Clarification Needed
Submitted
Undergoing Public Consu...
In Progress
Closed
New Study
Add Studies
Ask PSA
Share With
New Component
Printable View
Details
Components
History

Pre-Application ID
Active Substance X

Status
Draft

Date Submitted

Request Name
Active Substance X

ID
EFSA-ID-2021-000266

Business Operator
ABC company Spa

Contact Name
Stefano Cappè Business Operator

Details

Subject Of The Application

Food Domain

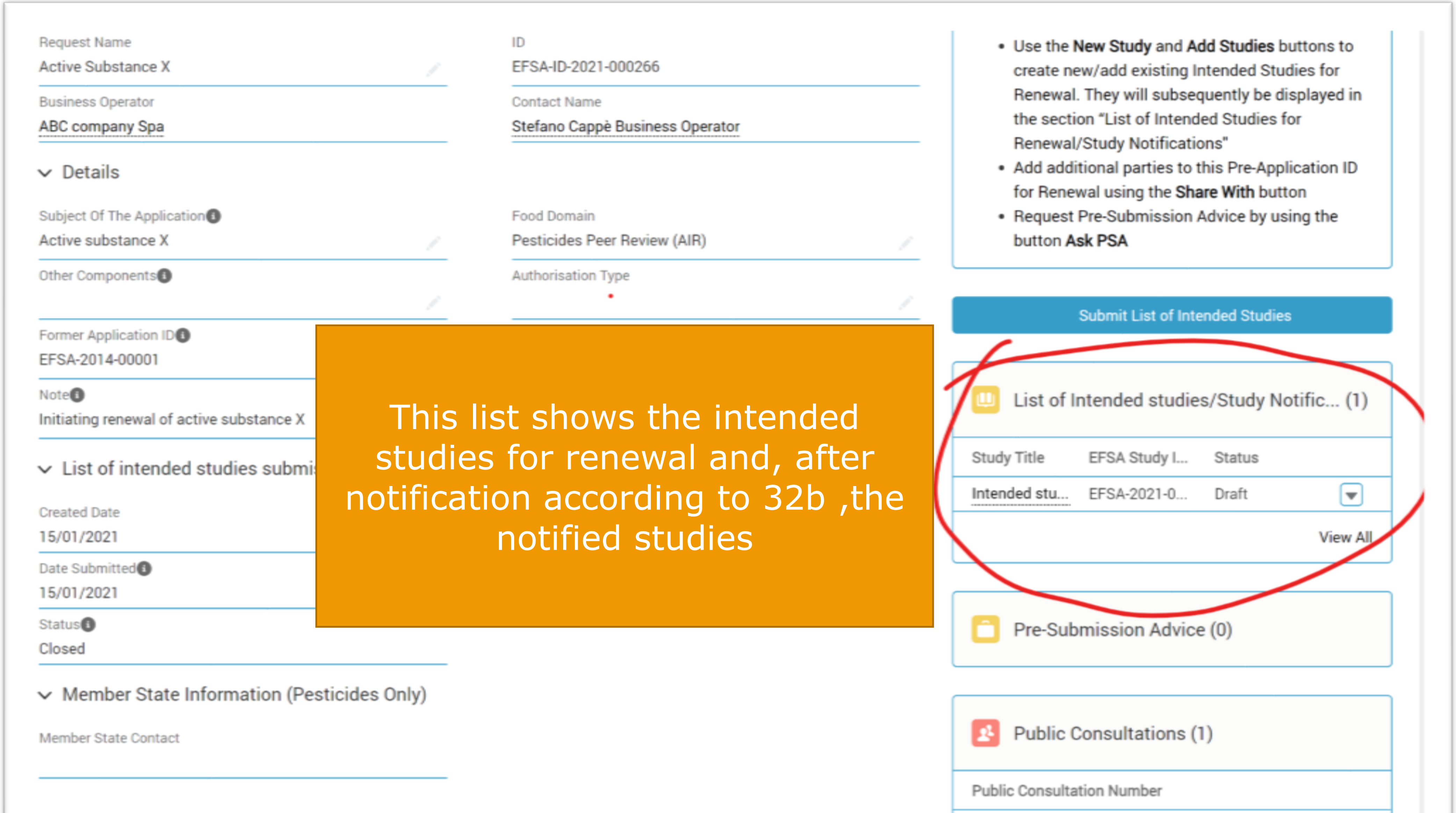
Pre-Application ID for Renewal Operations

ave saved this record as a **draft.** You can
m the following actions:

Use the **New Study** and **Add Studies** buttons to create new/add existing Intended Studies for Renewal. They will subsequently **be displayed** in the section "List of Intended Studies for Renewal/Study Notifications"

- When the List of Intended Studies for Renewal is complete, click on the **Submit List of Intended Studies** button
- Add additional parties to this Pre-Application Id for Renewal using the **Share With** button
- Via the **Add Components** button, structure the

Pre-application-id for renewal:
Select studies to notify according to 32b



Request Name
Active Substance X

ID
EFSA-ID-2021-000266

Business Operator
ABC company Spa

Contact Name
Stefano Cappè Business Operator

Details

Subject Of The Application
Active substance X

Food Domain
Pesticides Peer Review (AIR)

Other Components

Authorisation Type

Former Application ID
EFSA-2014-00001

Note
Initiating renewal of active substance X

List of intended studies submi

Created Date
15/01/2021

Date Submitted
15/01/2021

Status
Closed

Member State Information (Pesticides Only)

Member State Contact

- Use the **New Study** and **Add Studies** buttons to create new/add existing Intended Studies for Renewal. They will subsequently be displayed in the section "List of Intended Studies for Renewal/Study Notifications"
- Add additional parties to this Pre-Application ID for Renewal using the **Share With** button
- Request Pre-Submission Advice by using the button **Ask PSA**

List of Intended studies/Study Notific... (1)

Study Title	EFSA Study I...	Status
Intended stu...	EFSA-2021-0...	Draft

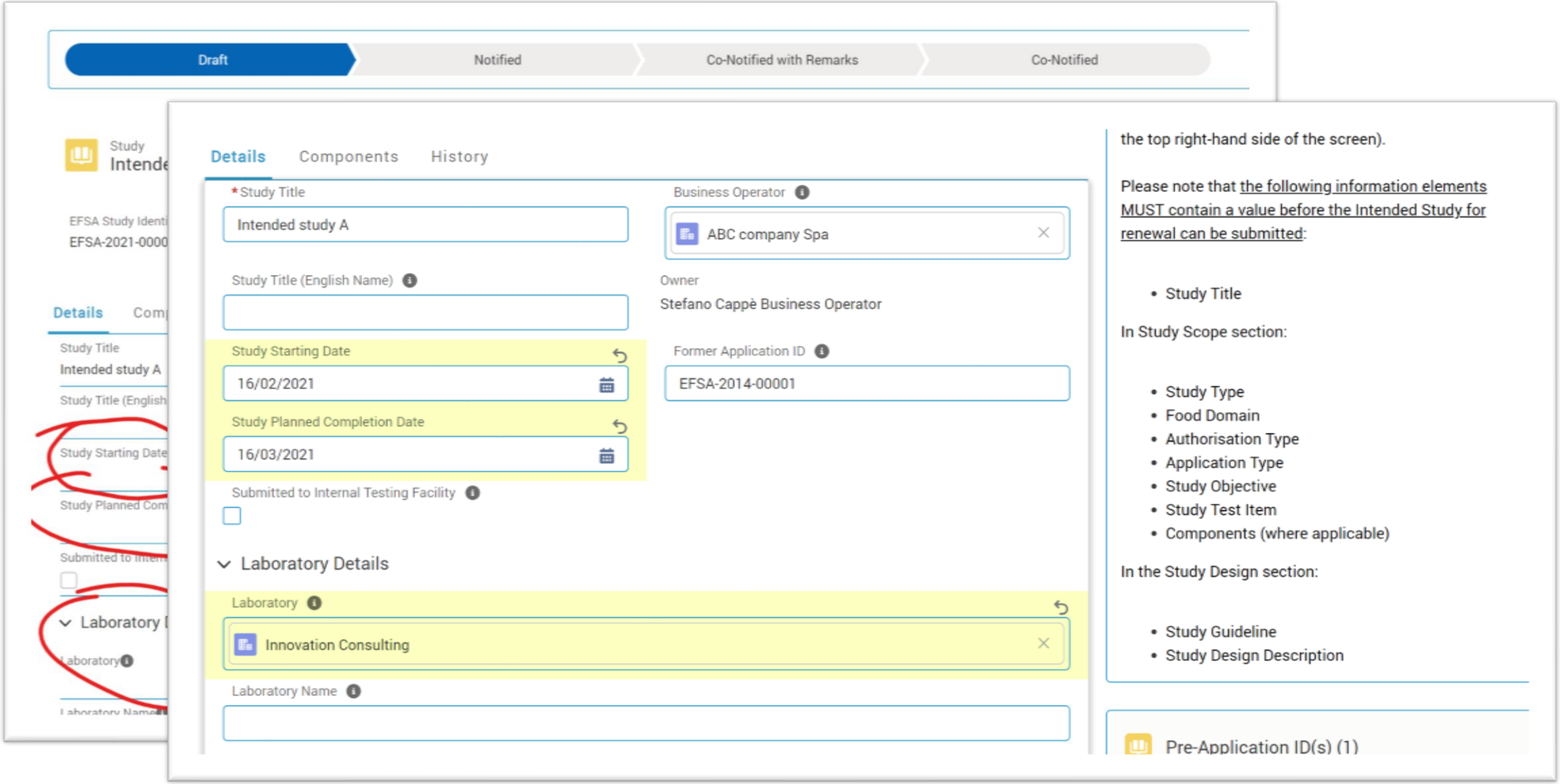
Pre-Submission Advice (0)

Public Consultations (1)

Public Consultation Number

This list shows the intended studies for renewal and, after notification according to 32b ,the notified studies

Pre-application-id for renewal: Complete study notification information


Draft
Notified
Co-Notified with Remarks
Co-Notified
Study
Intende
Details
Com
Components
History
Laboratory Details

EFSA Study Identi

EFSA-2021-0000

Study Title

Intended study A

Study Title (English

Study Starting Date

Study Planned Com

Submitted to Intern

☐

Laboratory

Laboratory Name

* Study Title

Intended study A

Business Operator

ABC company Spa

Study Title (English Name)

Owner

Stefano Cappè Business Operator

Study Starting Date

16/02/2021

Former Application ID

EFSA-2014-00001

Study Planned Completion Date

16/03/2021

Submitted to Internal Testing Facility

☐

Laboratory

Innovation Consulting

Laboratory Name

the top right-hand side of the screen).

Please note that the following information elements MUST contain a value before the Intended Study for renewal can be submitted:

- Study Title

In Study Scope section:

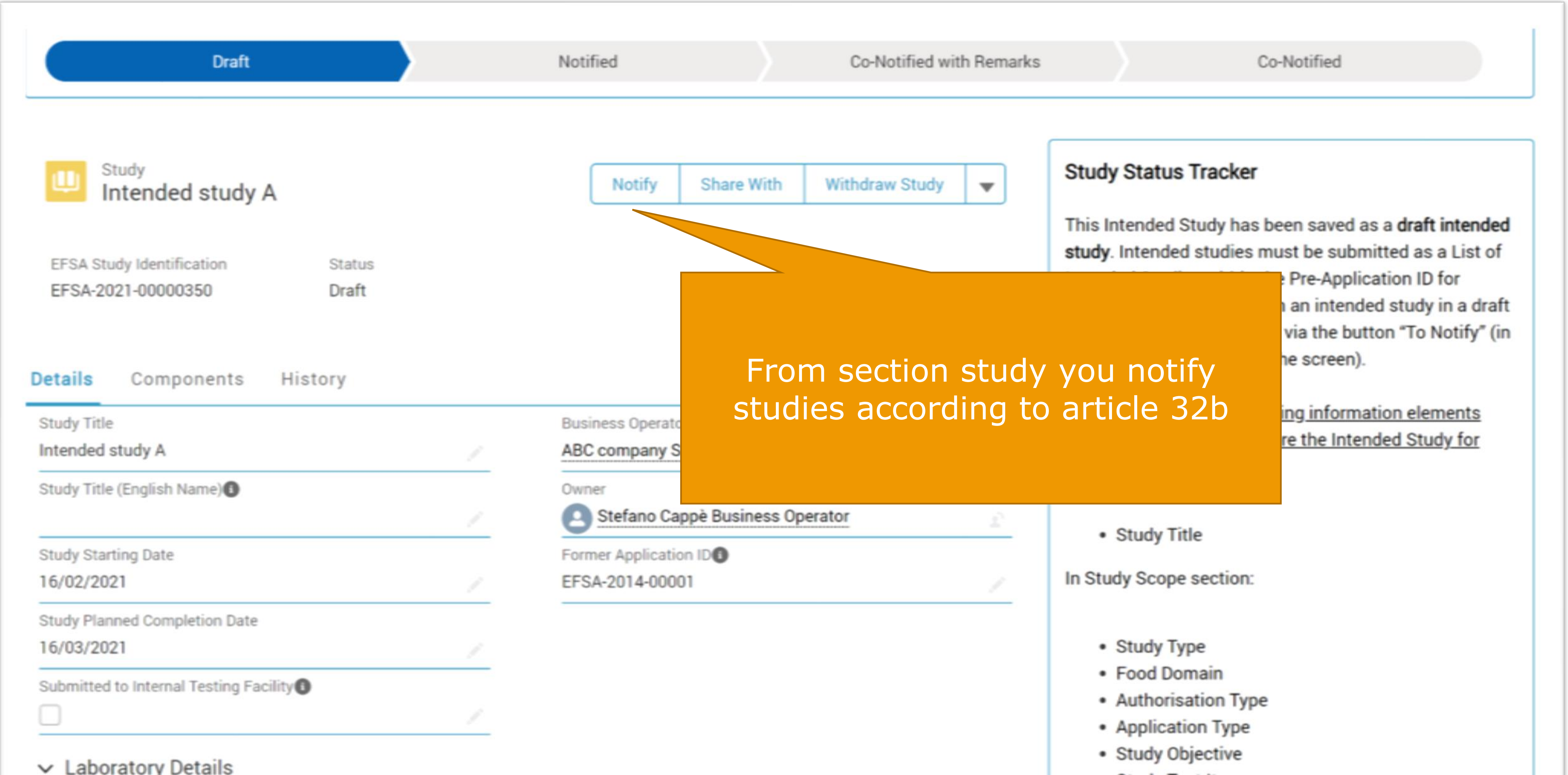
- Study Type
- Food Domain
- Authorisation Type
- Application Type
- Study Objective
- Study Test Item
- Components (where applicable)

In the Study Design section:

- Study Guideline
- Study Design Description

Pre-Application ID(s) (1)

Pre-application-id for renewal:
Complete study notification information


Draft
Notified
Co-Notified with Remarks
Co-Notified
Notify
Share With
Withdraw Study
Details
Components
History

Study
Intended study A

EFSA Study Identification
EFSA-2021-00000350

Status
Draft

Study Title
Intended study A

Study Title (English Name)

Study Starting Date
16/02/2021

Study Planned Completion Date
16/03/2021

Submitted to Internal Testing Facility
☐

Laboratory Details

Business Operat
ABC company S

Owner
Stefano Cappè Business Operator

Former Application ID
EFSA-2014-00001

Study Status Tracker

This Intended Study has been saved as a **draft intended study**. Intended studies must be submitted as a List of
e Pre-Application ID for
an intended study in a draft
via the button "To Notify" (in
he screen).

ing information elements
re the Intended Study for

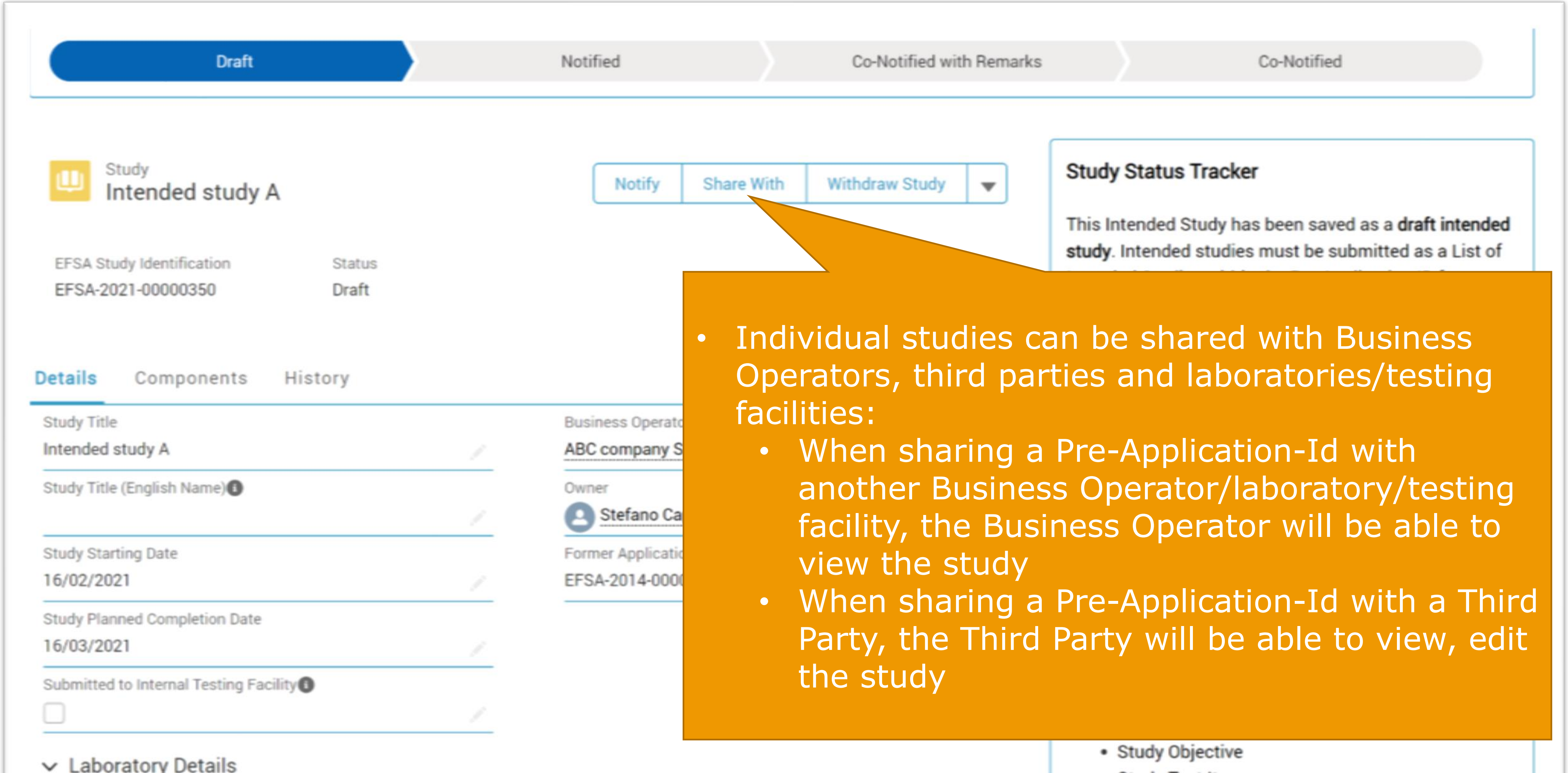
- Study Title

In Study Scope section:

- Study Type
- Food Domain
- Authorisation Type
- Application Type
- Study Objective

From section study you notify studies according to article 32b

Pre-application-id for renewal: Sharing individual studies


Draft
Notified
Co-Notified with Remarks
Co-Notified
Notify
Share With
Withdraw Study
Details
Components
History
Laboratory Details

Study
Intended study A

EFSA Study Identification
EFSA-2021-00000350

Status
Draft

Study Status Tracker

This Intended Study has been saved as a **draft intended study**. Intended studies must be submitted as a List of

- Study Objective

Study Title
Intended study A

Study Title (English Name)

Study Starting Date
16/02/2021

Study Planned Completion Date
16/03/2021

Submitted to Internal Testing Facility
☐

Business Operat
ABC company S

Owner
Stefano Ca

Former Applicati
EFSA-2014-000

- Individual studies can be shared with Business Operators, third parties and laboratories/testing facilities:
  - When sharing a Pre-Application-Id with another Business Operator/laboratory/testing facility, the Business Operator will be able to view the study
  - When sharing a Pre-Application-Id with a Third Party, the Third Party will be able to view, edit the study

Time for
Questions