5th EFSA Technical Group on Notification of Studies Database

29th June 2022

Trusted science for safe food

efsa
European Food Safety Authority

Today’s session is supported by…

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Welcome and Apologies for absences, adoption of agenda

(Bénédicte VAGENENDE)

Agenda

- Welcome and Apologies for absences, adoption of agenda
- Notification of Studies Database – Current Status
- New features on the list of intended studies for renewal
- Survey results on new functionalities and next features to be expected
- Have your say - TG members presentations (experience on the tool, future enhancements on tool and support)
- Training needs and material
- Group closure and discussion

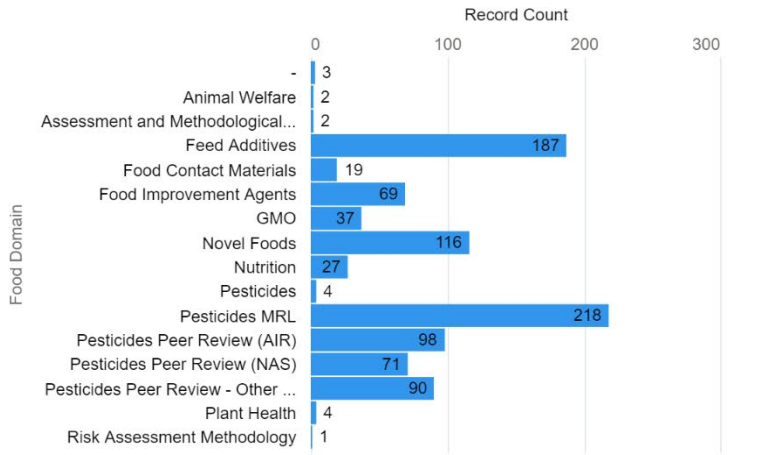
Notification of Studies Database – Current Status

(Stefano CAPPÈ)

NOS DB: New Applications

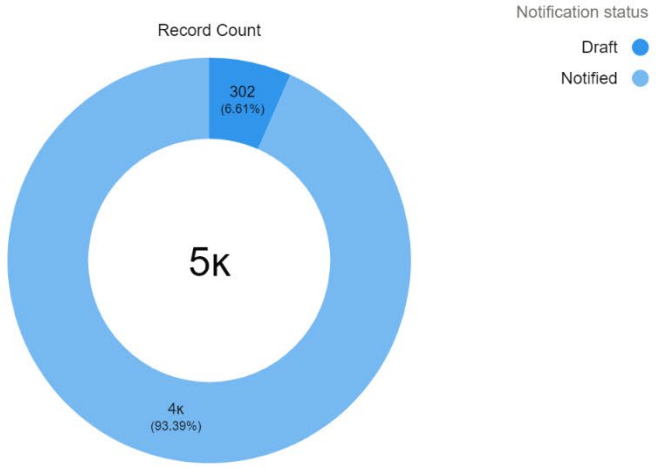
European Food Safety Authority

Pre-Application-Ids



View Report (New Applications -> Pre-Application-Id2)

Notifications of studies



View Report (New Applications -> Notifications)

Pre-Application-Ids

948

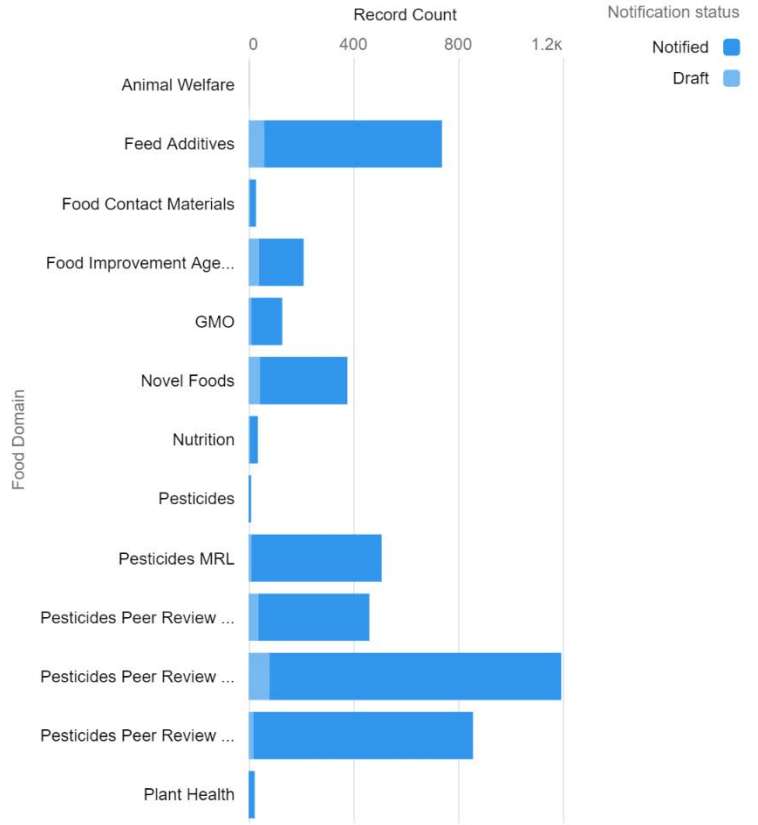
View Report (New Applications -> Pre-Application-Id2)

GPSAs

43

View Report (New Applications -> PSAs)

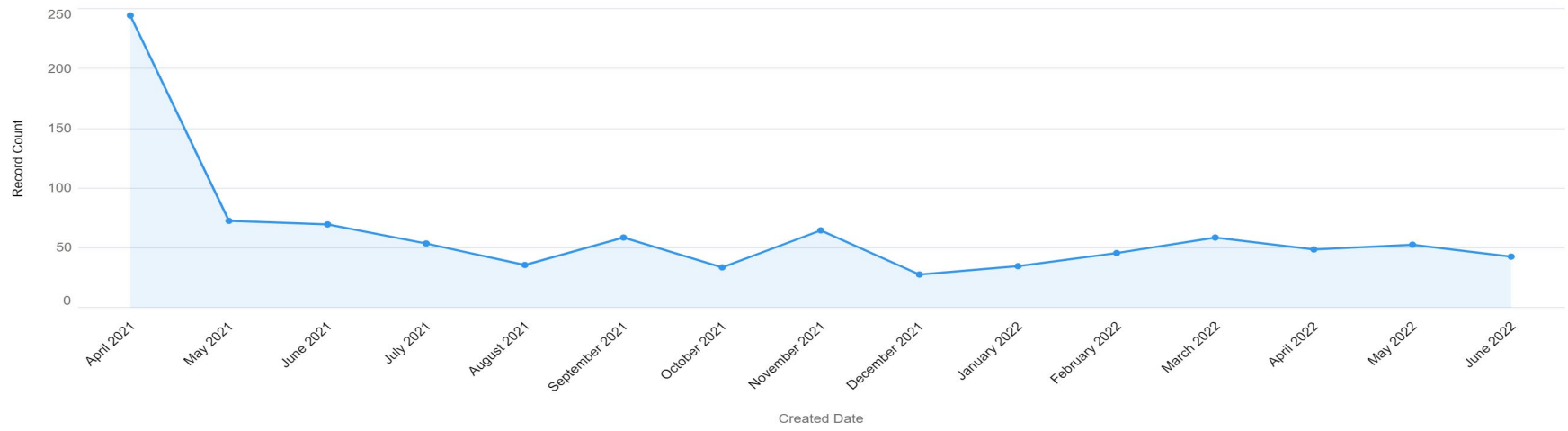
Notifications of studies by food domain



View Report (New Applications -> Notifications)

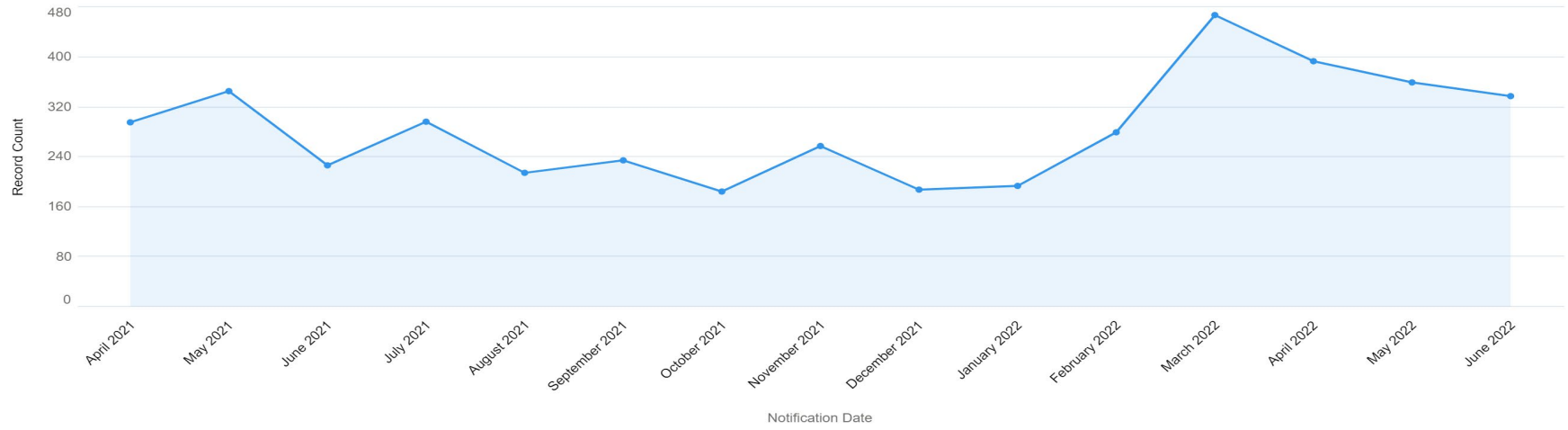
NOS DB: New Applications (over time)

PAIDs: New Applications



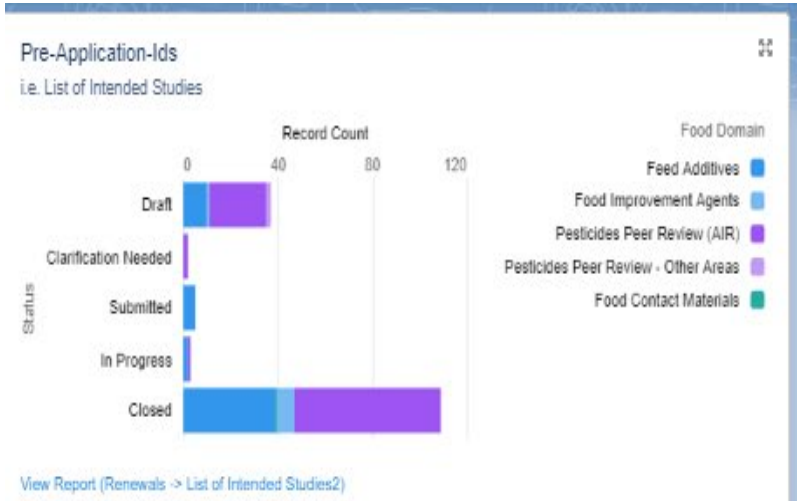
View Report (New Applications -> Pre-Application-Id2)

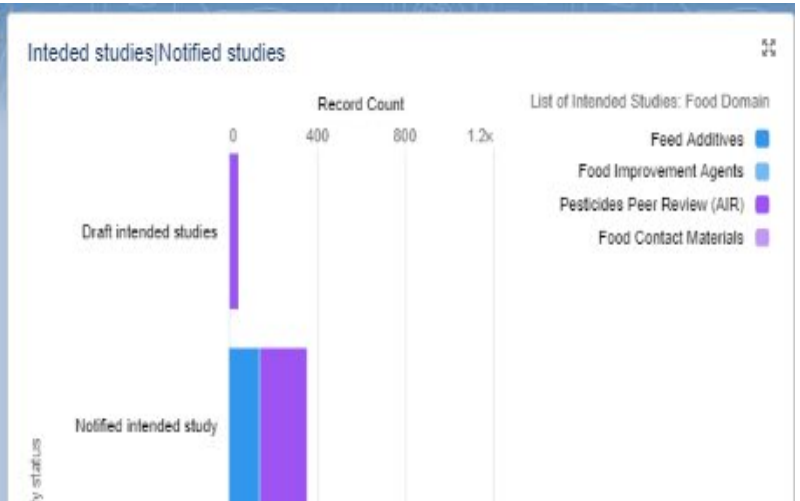
Notified studies

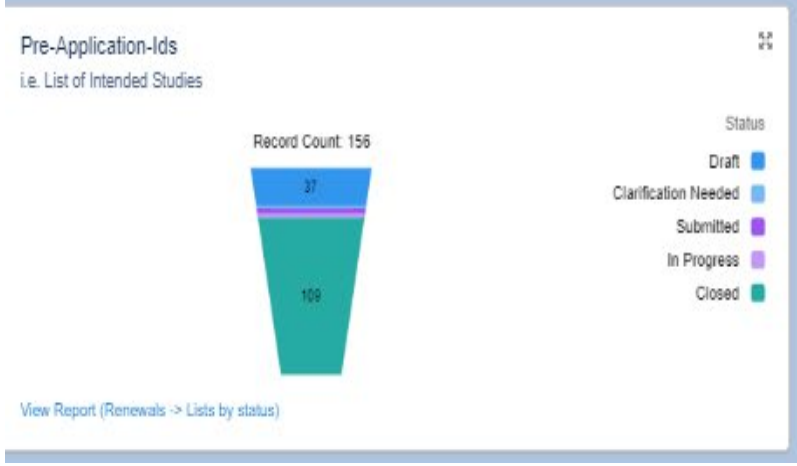


View Report (New Applications -> Notification TGM '22)

NOS DB: Renewals

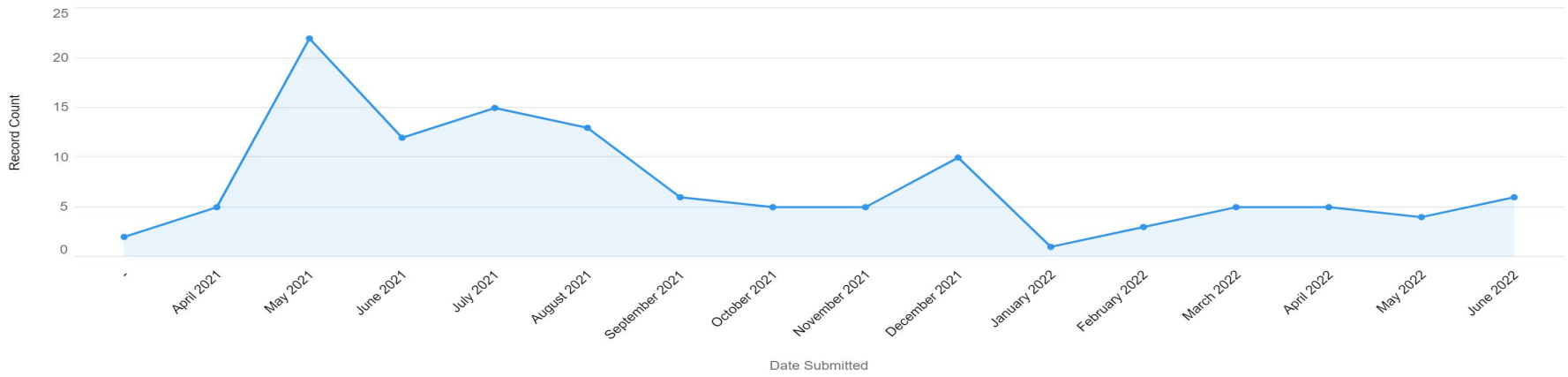






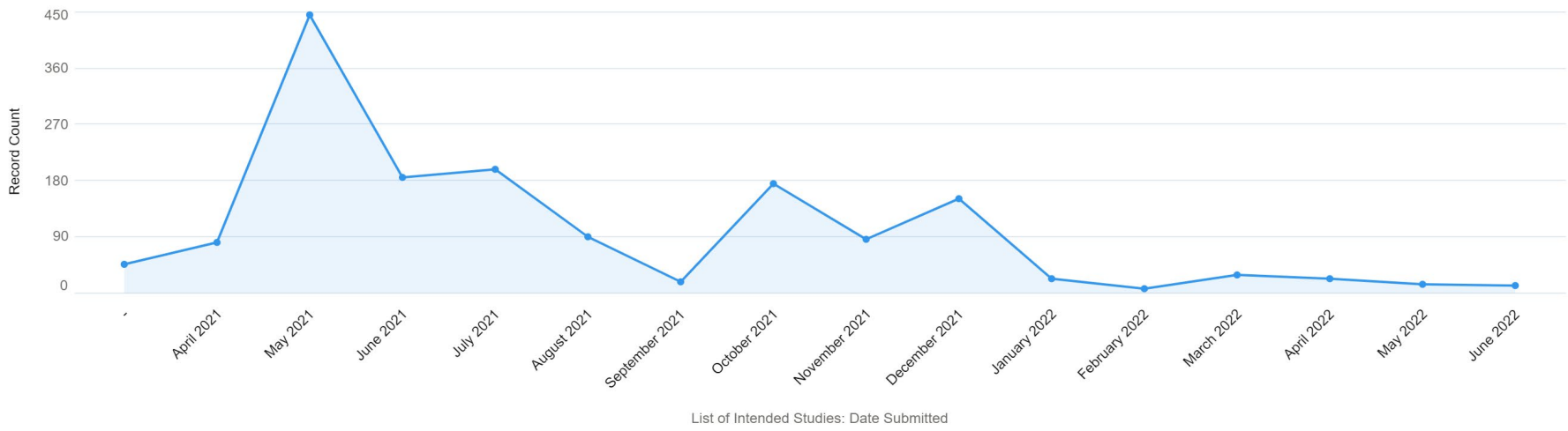
NOS DB: Renewals (over time)

PAIDs: Renewals



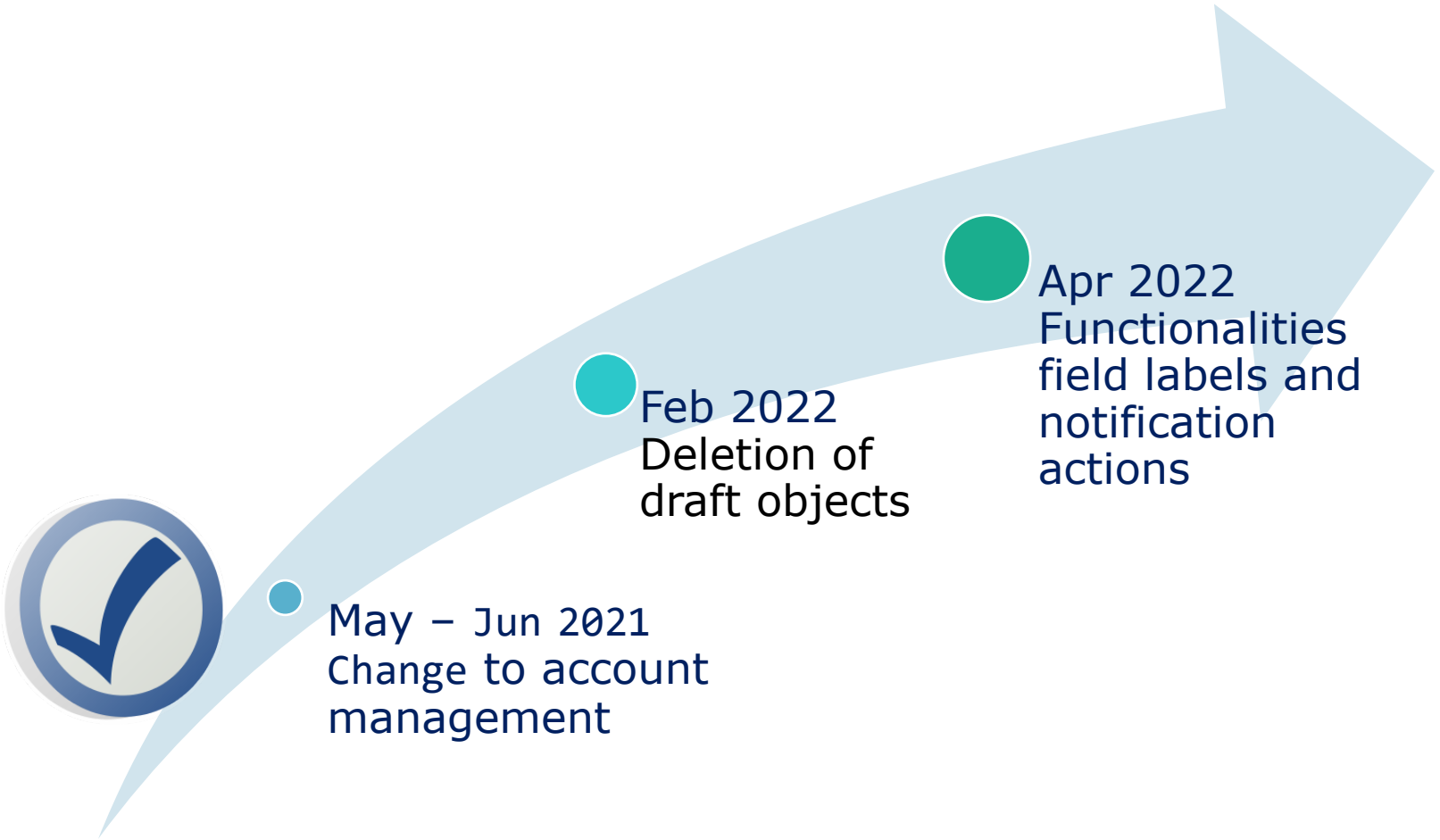
View Report (Renewals (c.date -> List of Intended)

Inteded studies



View Report (Renewals -> Inteded studies '22)

Releases after go-live



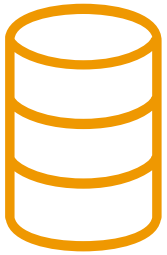
Change to account management

Authorisation of delegation to third parties

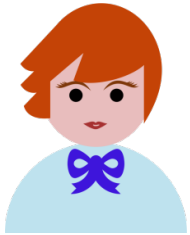
Martin

Third Parties

Martin send a notification on behalf of Sarah



Database of Study Notifications



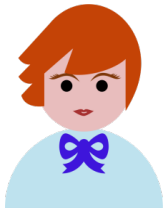
Sarah

Business Operators
Potential Applicants

Creates an account relationship

Change to account management

Organisations playing multiple roles



Sarah

Business Operators
Potential Applicants

John

Laboratories
Testing facilities

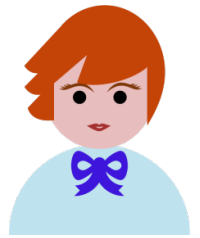
Martin

Third Parties

Business Operator

Laboratory

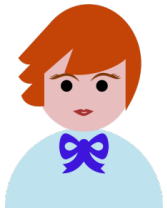
Third Party



Sarah

Change to account management

Two factor authentication



Sarah

Business Operators
Potential Applicants

John

Laboratories
Testing facilities

Martin

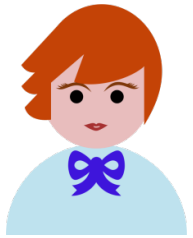
Third Parties

Introduced
June 2021

Releases after go-live

Deletion of draft objects

Deletion of ‘draft’ Pre-Application-ID



Sarah

Business Operators
Potential Applicants

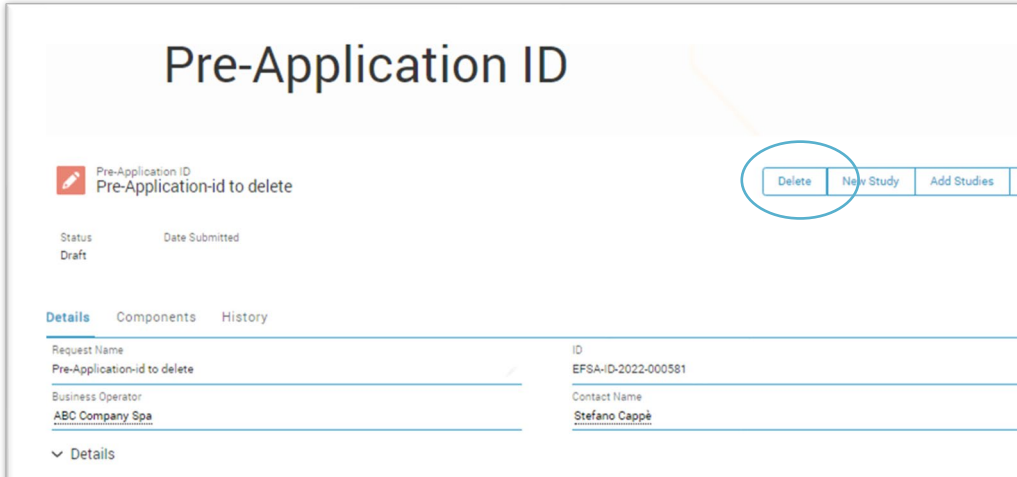
Is Pre-Application-Id empty (NOS, PSA)?

Yes

Delete Pre-Application-Id

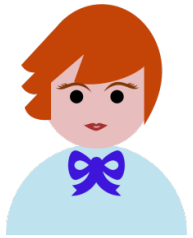
No

Delete draft Notification of studies, PSA



Deletion of draft objects

Deletion of ‘draft’ studies



Sarah

Business Operators
Potential Applicants

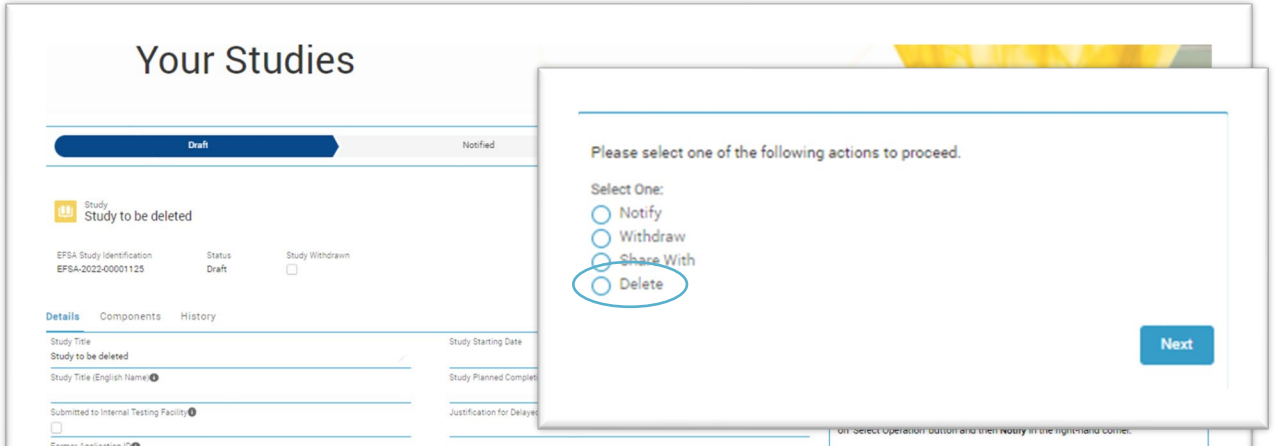
Is the study notified/co-notified?

Yes

The study cannot be deleted

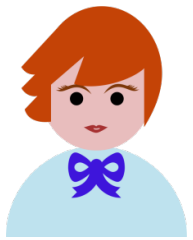
No

The study can be deleted



Deletion of draft objects

Deletion of 'draft' (G)PSA



Sarah

Business Operators
Potential Applicants

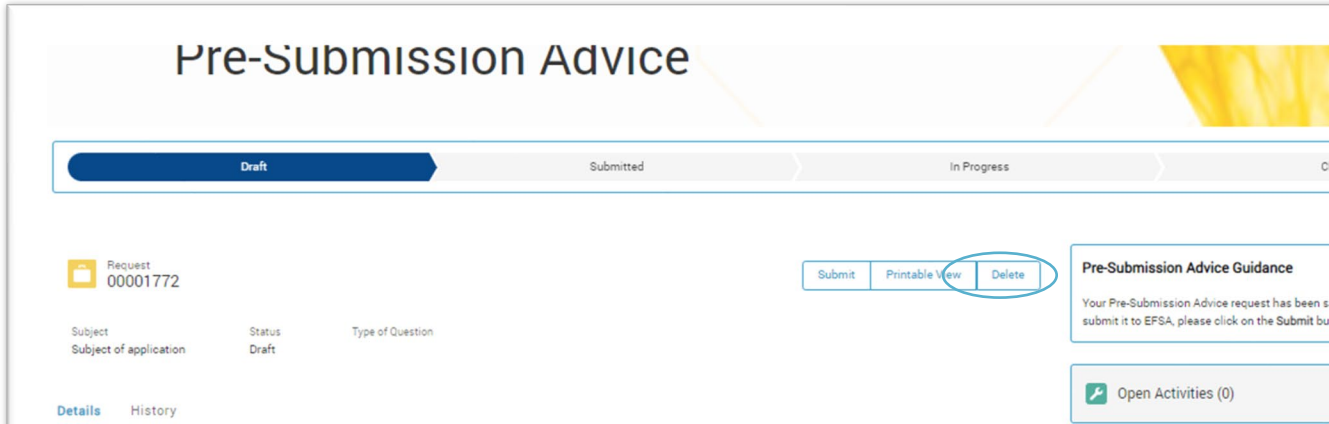
Is the (G)PSA request submitted?

Yes

The (G)PSA request cannot be deleted

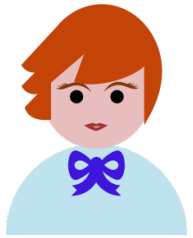
No

The (G)PSA request can be deleted



Deletion of draft objects

Deletion of ‘draft’ ‘my components’



Sarah

Business Operators
Potential Applicants

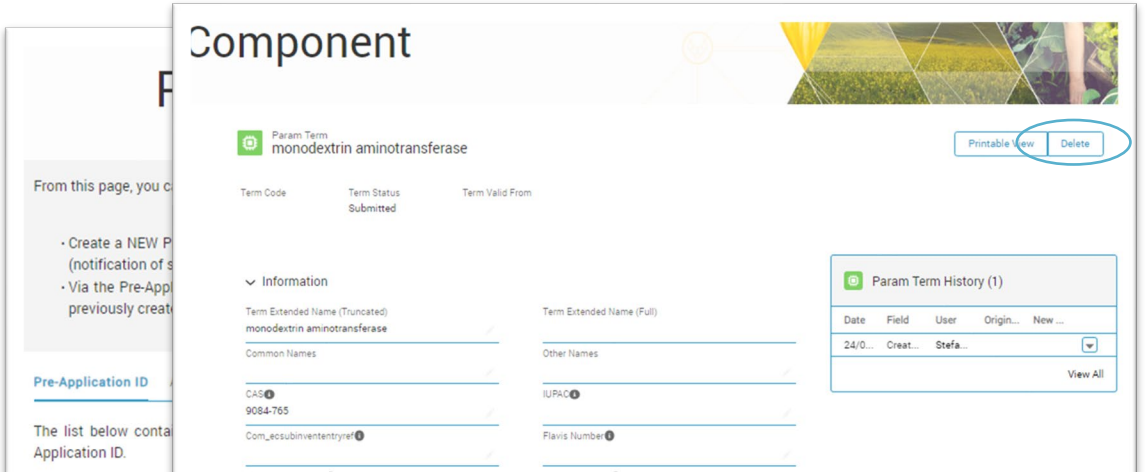
Has ‘my component’ been used in Pre-Application-Id or notification of studies?

Yes

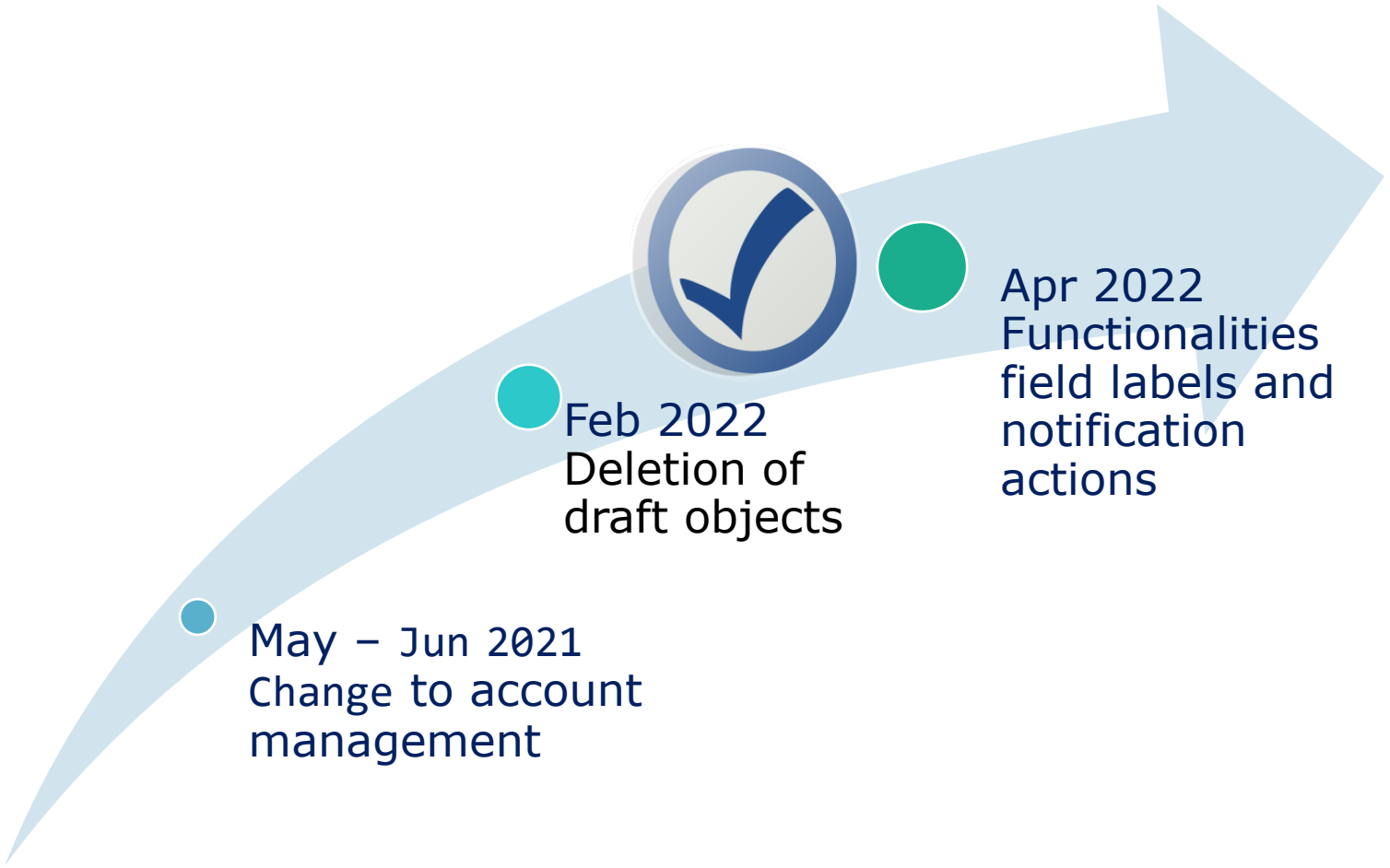
‘my component’ cannot be deleted

No

‘my component’ can be deleted

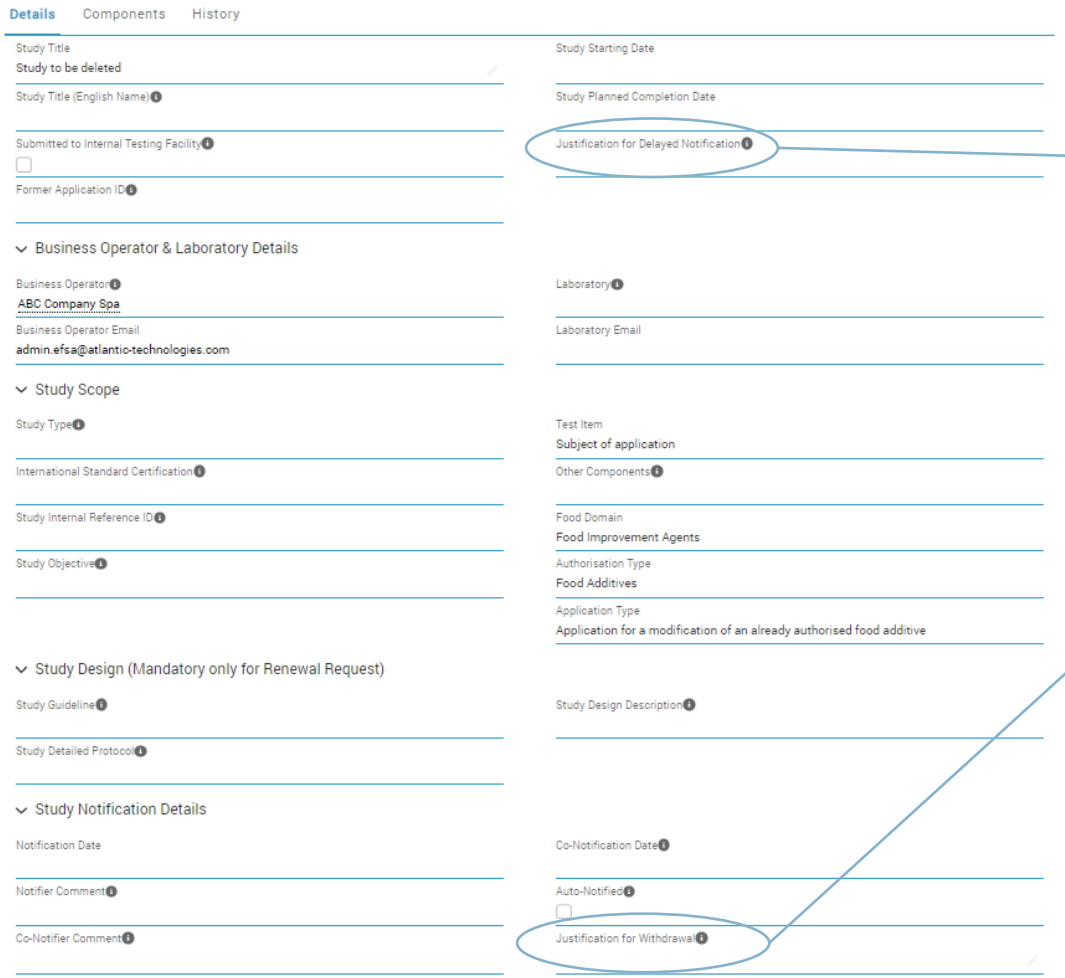


Releases after go-live



Functionalities of field labels

Fields and label amended



Justification for Delayed Notification

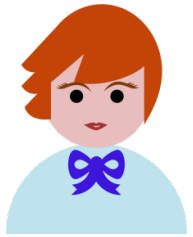
Extended to 2000 characters
Can be edited after (co-)notification

Justification for Withdrawal

Extended to 2000 characters
Can be edited (co-)notification

Notification actions

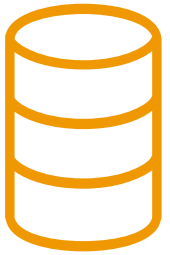
Cannot notify and co-notify the same study notification



Sarah

Business Operators
Potential Applicants
Third Party of Lab

Sara send a notification indicating LAB as laboratory



Database of Study Notifications

Sara tries to co-notify for LAB

Sara is also third party of LAB

Bug fixes (examples)

- Sep 21
  - Laboratory had issue to notify studies due to wrong address
  - Fix impossibility to send long lists of intended studies
- Oct 21
  - Some users were unable to perform co-notification
- Nov 21
  - Same intended study could be added several times to the list of intended study for renewal

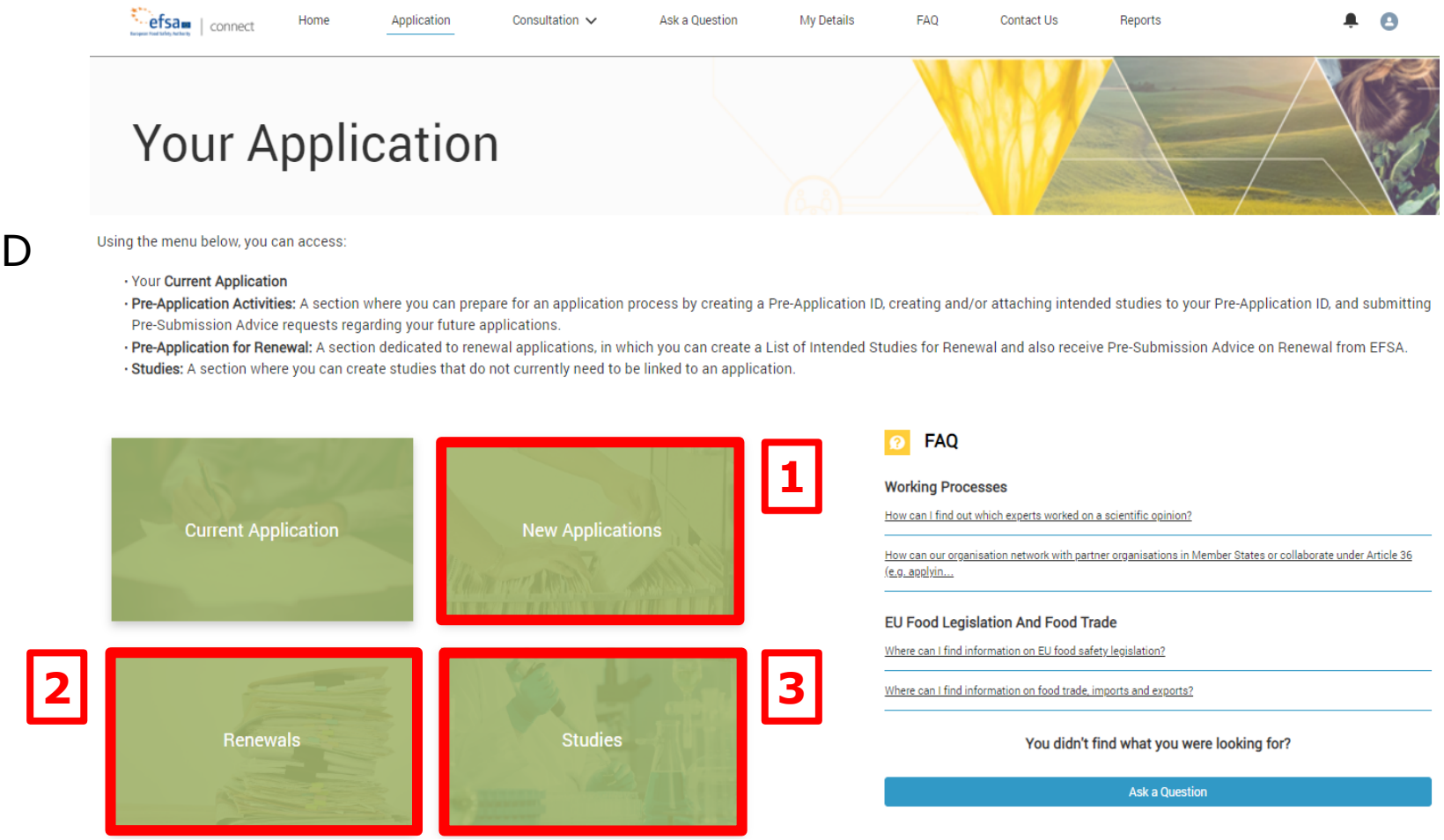
New features on the list of intended studies for renewal

(Federico MORREALE, Chiara Selene FACCHINI)

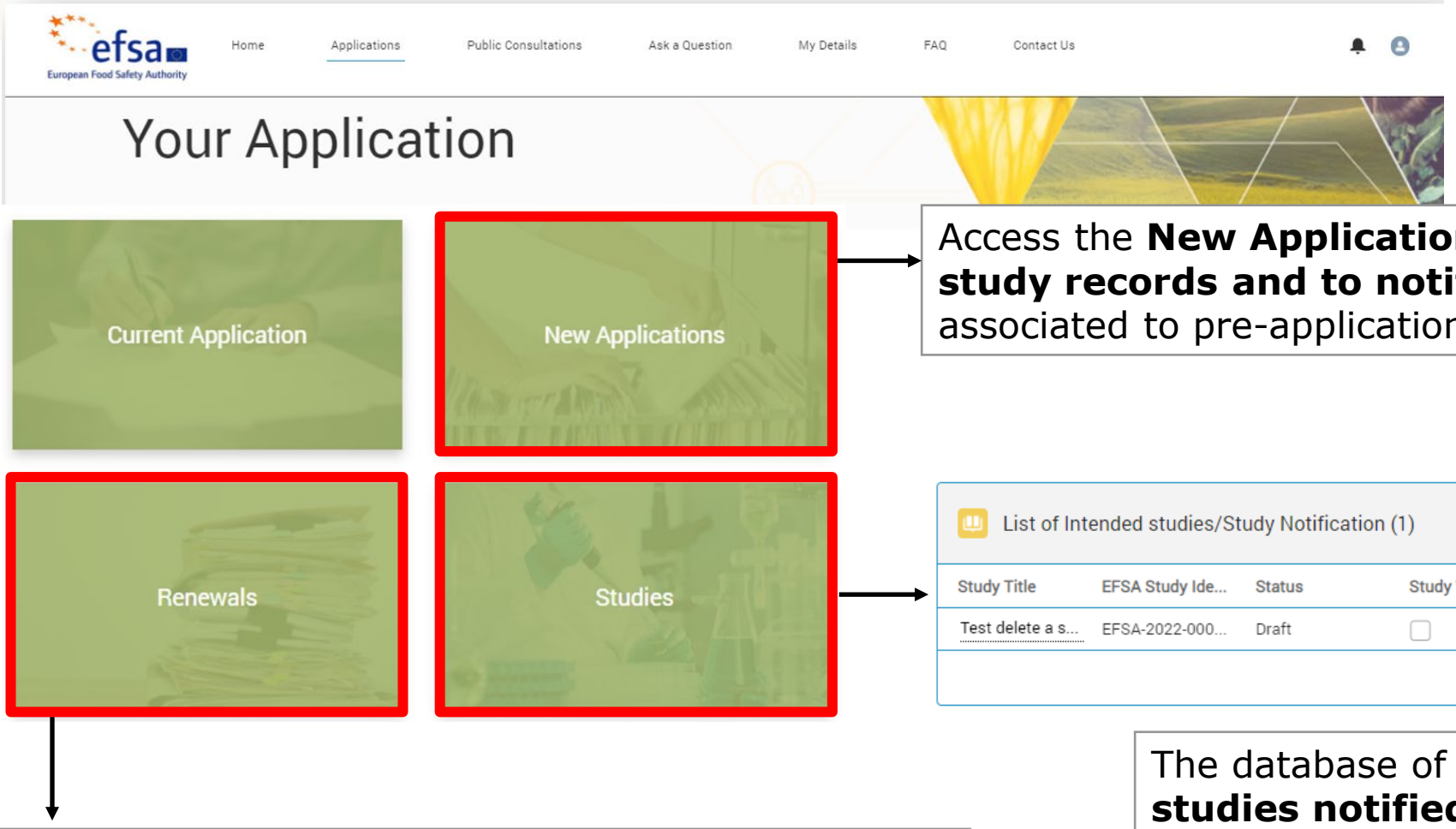
Current set up of Connect.EFSA

Connect.EFSA currently has three different sections dedicated to pre-submission activities:

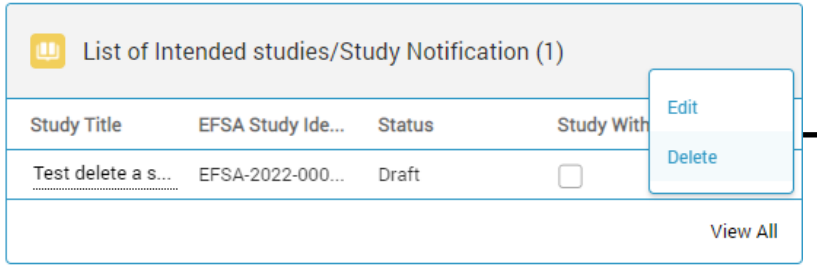
1. For new applications
2. For renewal applications
3. For notification of studies outside the pre-application ID



Current set up of Connect.EFSA



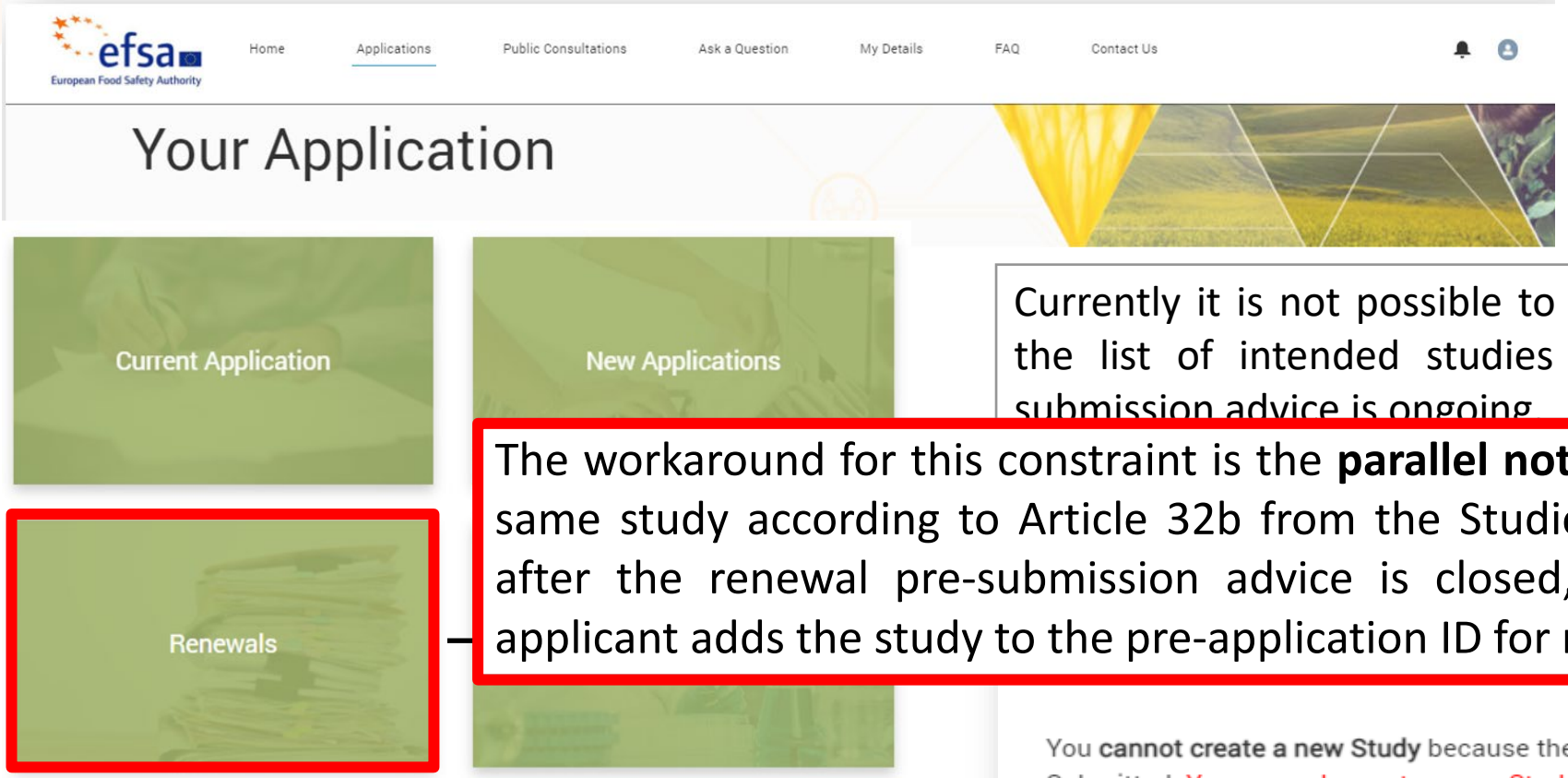
Access the **New Applications** section to **create study records and to notify/manage studies** associated to pre-application IDs.



Access the **Renewal** section to **create intended studies and to notify/manage studies** associated to pre-application IDs for renewal.

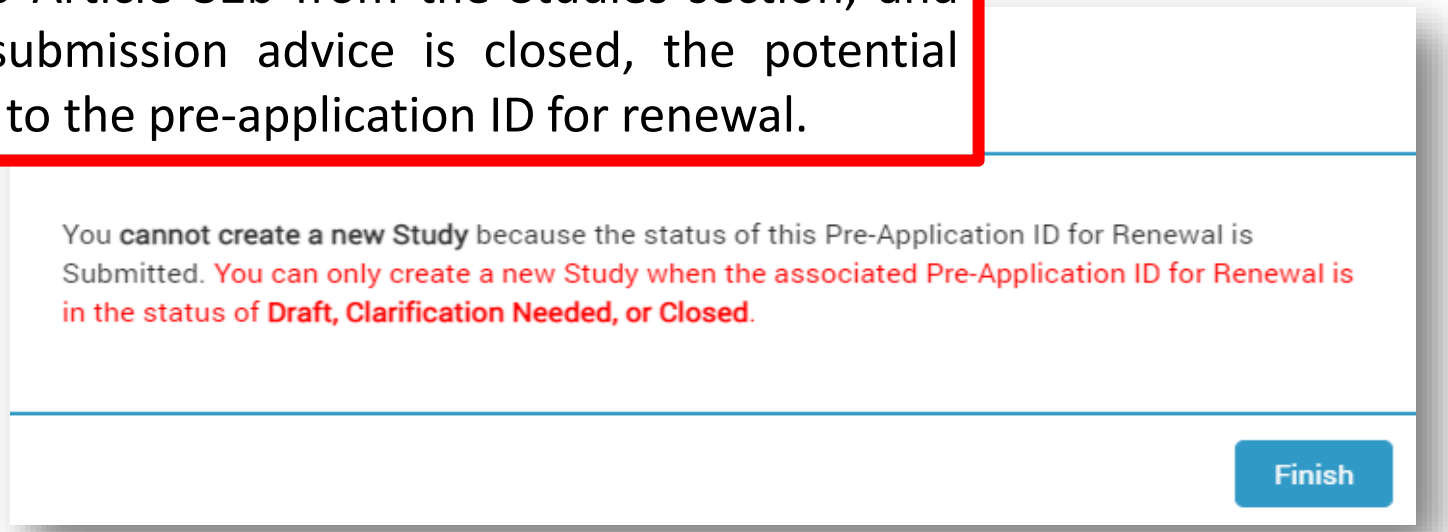
The database of study notification shows together **studies notified according to Article 32b** and **intended studies for renewal (Article 31c(1)).**

Current set up of Connect.EFSA



Currently it is not possible to submit a new study notification when the list of intended studies is submitted, and the renewal pre-submission advice is ongoing.

The workaround for this constraint is the **parallel notification** of the same study according to Article 32b from the Studies section, and after the renewal pre-submission advice is closed, the potential applicant adds the study to the pre-application ID for renewal.

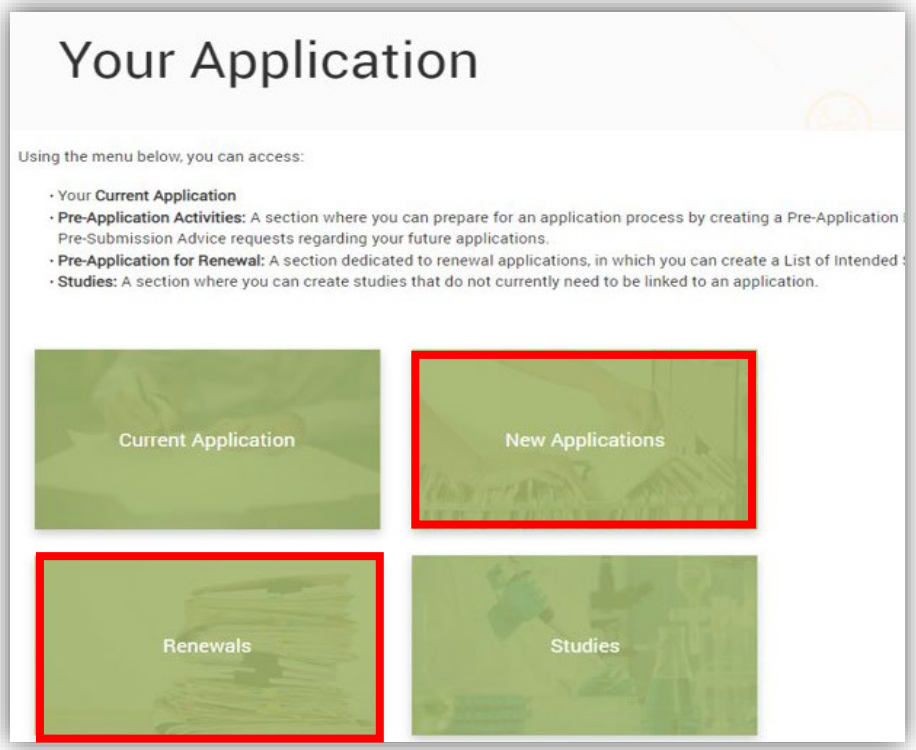


Towards a new Connect.EFSA layout

Our attention was focused on improving the experience of users that are working on their pre-submission activities.

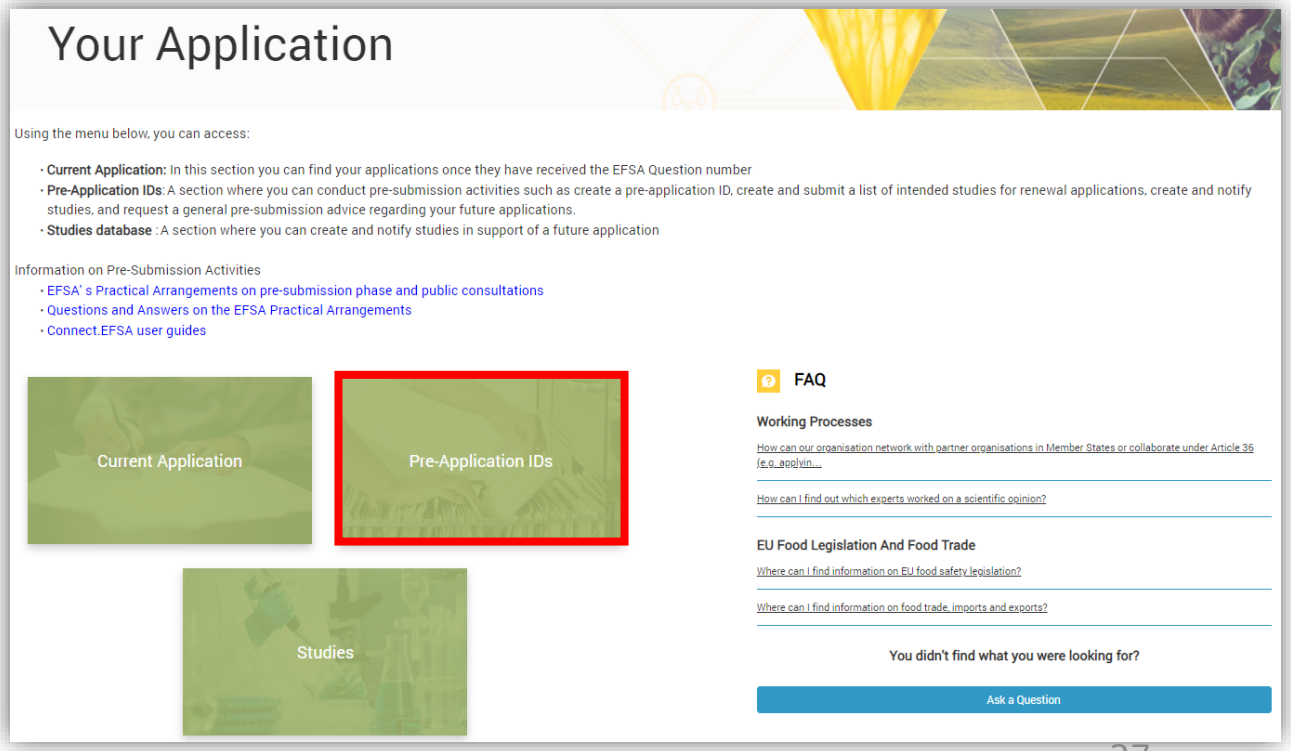
We designed a **single access point** for potential applicants who are creating pre-application IDs

Old layout of Application section



New layout of Application section

New!



Pre-Application IDs section

New!

Pre-Application ID

Potential applicants find a revised **pre-application ID section** to work on their pre-submission activities.

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

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

New Pre-Application ID

Pre-Application ID | General Pre-Submission Advice | Intended Studies | Lists of Intended Studies | Components

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

My Pre-Application ID

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

Search this list...

	Request Name	Note	ID	Food Do...	Applicati...	Authoris...	Contact Name	C
1	Paid test Solution		EFSA-ID-2022-000610	Feed Additiv...	Application ...	Feed Additiv...	Werner Baumann	
2	New System TGM		EFSA-ID-2022-000609	Feed Additiv...	Application ...	Feed Additiv...	Sorina Puiu	
3	test		EFSA-ID-2022-000608	Feed Additiv...	Application ...	Feed Additiv...	Sorina Puiu	
4	Gloria Test 6		EFSA-ID-2022-000606	Pesticides P...			Werner Baumann	
5	Gloria Test 5		EFSA-ID-2022-000605	Feed Additiv...	Application ...	Feed Additiv...	Werner Baumann	

FAQ

Working Processes

How can our organisation network with partner organisations in Member States or collaborate under Article 36 (e.g. applyin...

How can I find out which experts worked on a scientific opinion?

EU Food Legislation And Food Trade

Where can I find information on EU food safety legislation?

Where can I find information on food trade, imports and exports?

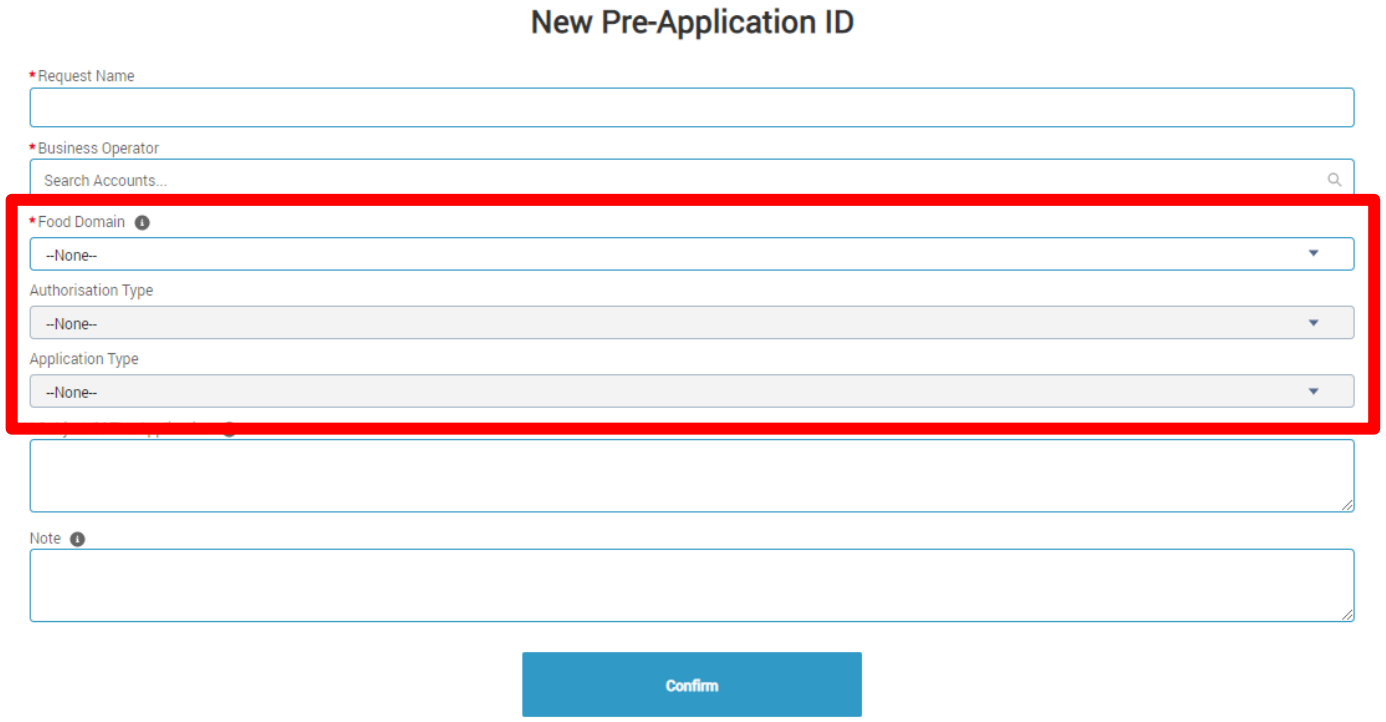
You didn't find what you were looking for?

Ask a Question

Creation of a Pre-Application ID

One of the major changes in the layout of Connect.EFSA was made on the creation process of a new pre-application ID, which was unified by merging new and renewal pre-application IDs.

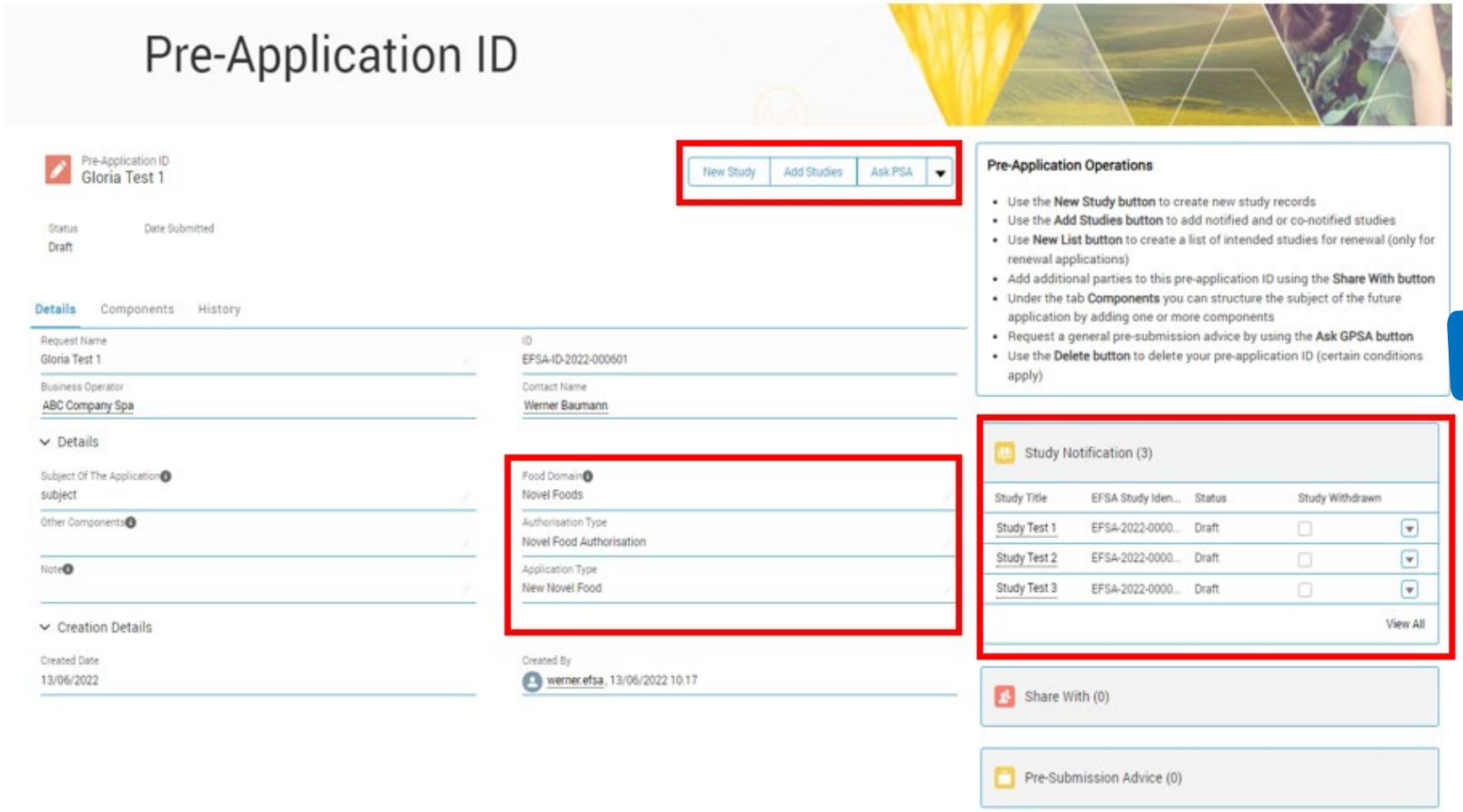
Potential applicants will no longer need to choose between two types of pre-application ID (i.e. new applications *versus* renewal applications).



The system uses the information provided in the field "Food Domain", "Authorisation Type" and "Application Type" to activate dedicated functions of the pre-application ID, such as the creation of a list of intended studies for renewal.

Pre-Application ID – Case 1

In the following case the potential applicant wants to conduct pre-submission activities to support **a new application** for a new Novel Food.

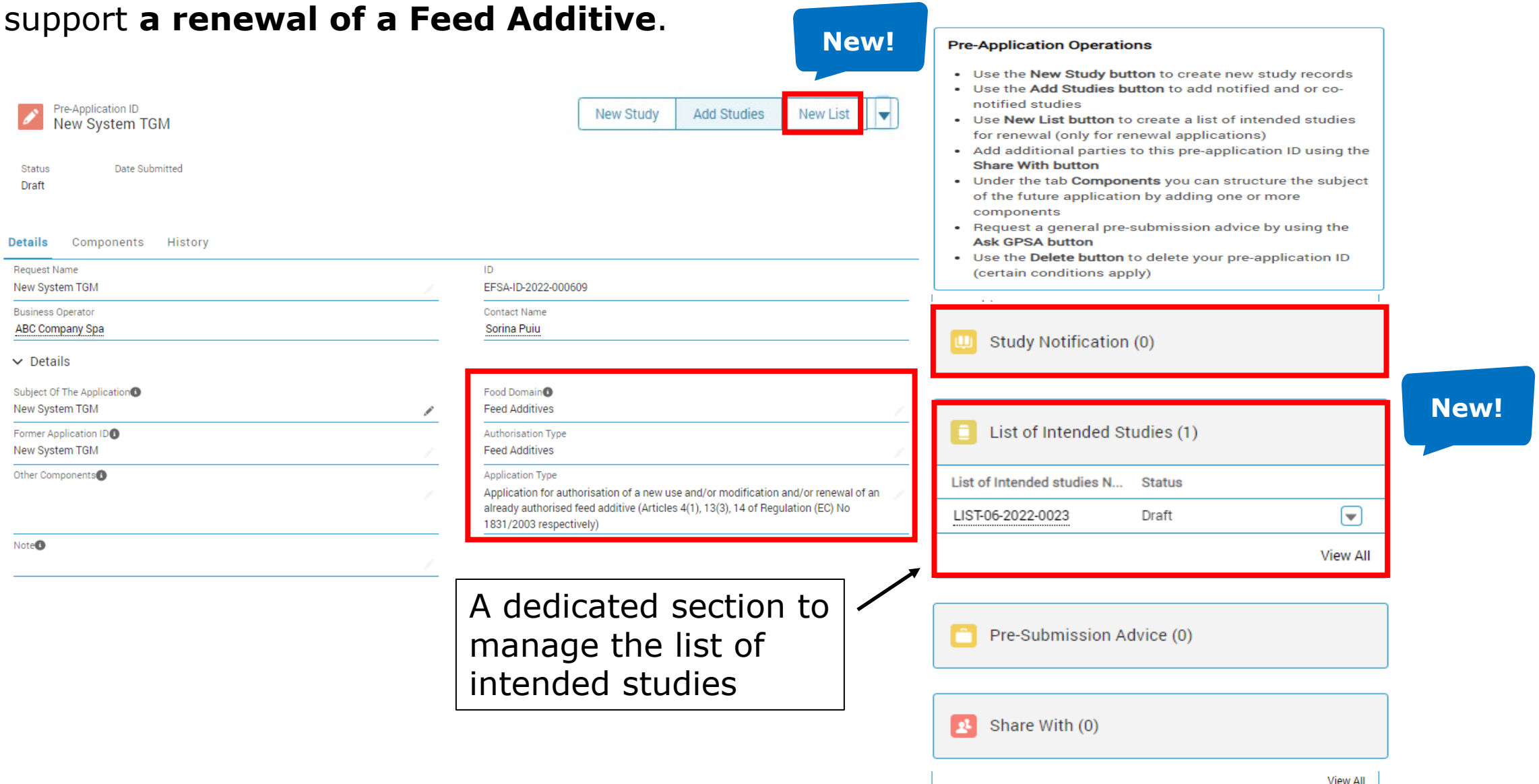


New!

A dedicated section only to manage study notifications in line with Article 32b

Pre-Application ID – Case 2

In the following case the potential applicant wants to conduct pre-submission activities to support **a renewal of a Feed Additive**.



A dedicated section to manage the list of intended studies

Pre-Application ID – Case 2

List of Intended Studies

New!

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

List of Intended Studies
LIST-06-2022-0012

New Intended Study | Submit List | Delete

Business Operator: ABC Company Spa
Date Submitted:
Pre-Application ID: New System TGM

List of Intended Studies for Renewal Operations

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

- Use the **New Intended Study button** to create a new intended study. They will subsequently be displayed in the table "Intended Studies"
- When the List of Intended Studies for Renewal is complete, click on the **Submit List button**
- You can **edit all the records** of the intended studies present in your list or **notify** them. **Note:** notified studies will be excluded from the list of intended studies upon submission
- Use the **Delete button** to delete your list of intended studies (certain conditions apply)
- Use the **Mass Conversion button** to select the intended studies to be notified

List | Details

Mass Conversion

Intended Studies (1)
1 item • Updated a few seconds ago

	Study Title	Study Type	Study Objective	Study Guideline	Test Item	Study Design D...	Study Detailed ...	Converted
1	Test New system 2	Acute toxicity: inhalation	Test New system 2	EU Method C.4-B (Determination of the 'Ready' Biodegradability - Modified OECD Screening Test)	New System TGM	Test New system 2	Test New system 2	☐

View All

Public Consultation (0)

Pre-Submission Advice on Renewal (0)

A dedicated page for potential applicants to prepare and manage a **list of intended studies** and follow the life-cycle of a **renewal pre-submission advice**.

Intended study for renewal layout

Intended Study

Intended Study
Test New system 3

Converted

List of Intended studies
LIST-06-2022-0012

New!

Convert | Delete | Printable View

Convert button allows to transform an intended study in a notifiable draft study.

Study Title

Study Title
Test New system 3

Study Title (English Name)

List of Intended studies
LIST-06-2022-0012

Study Scope

Study Type
Residues

Study Objective
Test New system 3

Test Item
New System TGM

Study Design

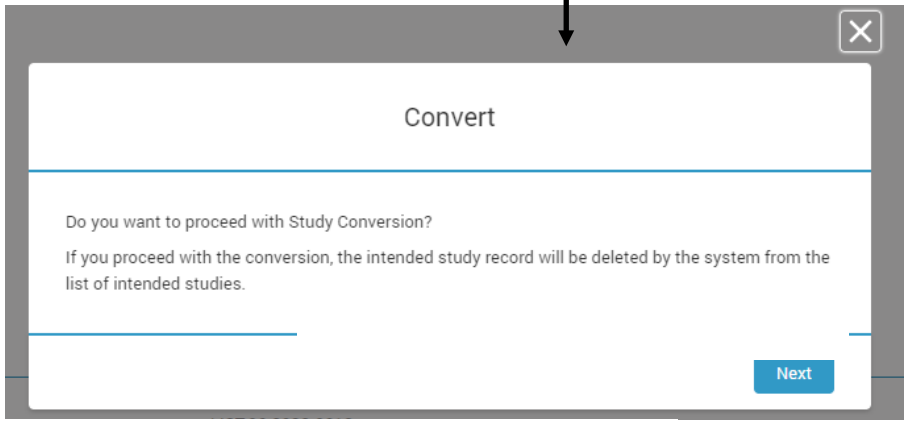
Study Guideline
ISO 10156 (Gases and gas mixtures - Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets)

Study Design Description
Test New system 3

Study Detailed Protocol
Test New system 3

Other Information

Converted



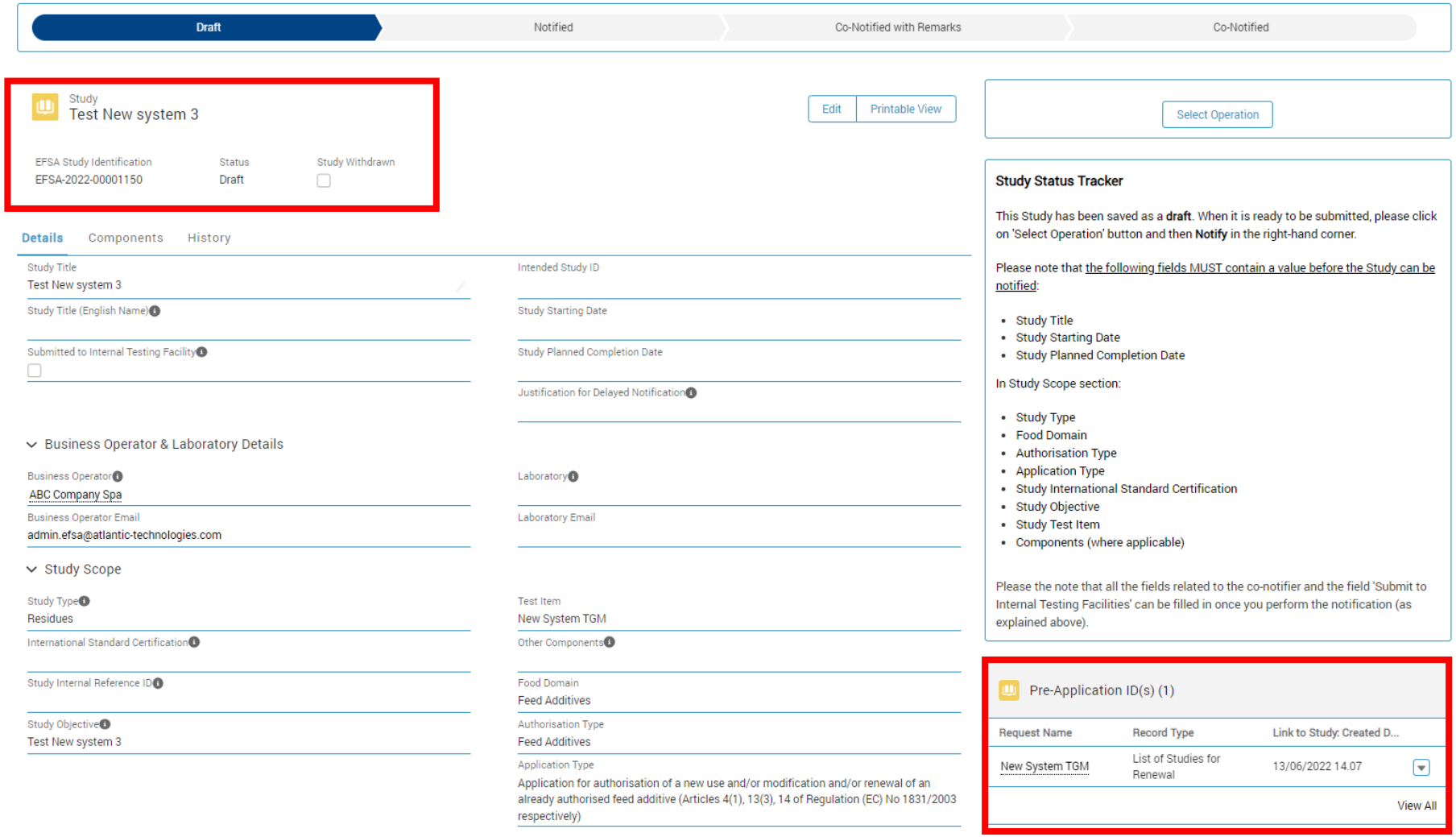
Study Notification (2)

Study Title	EFSA Study Iden...	Status	Study Withdrawn
Test New syste...	EFSA-2022-0000...	Draft	
Test New syste...	EFSA-2022-0000...	Draft	

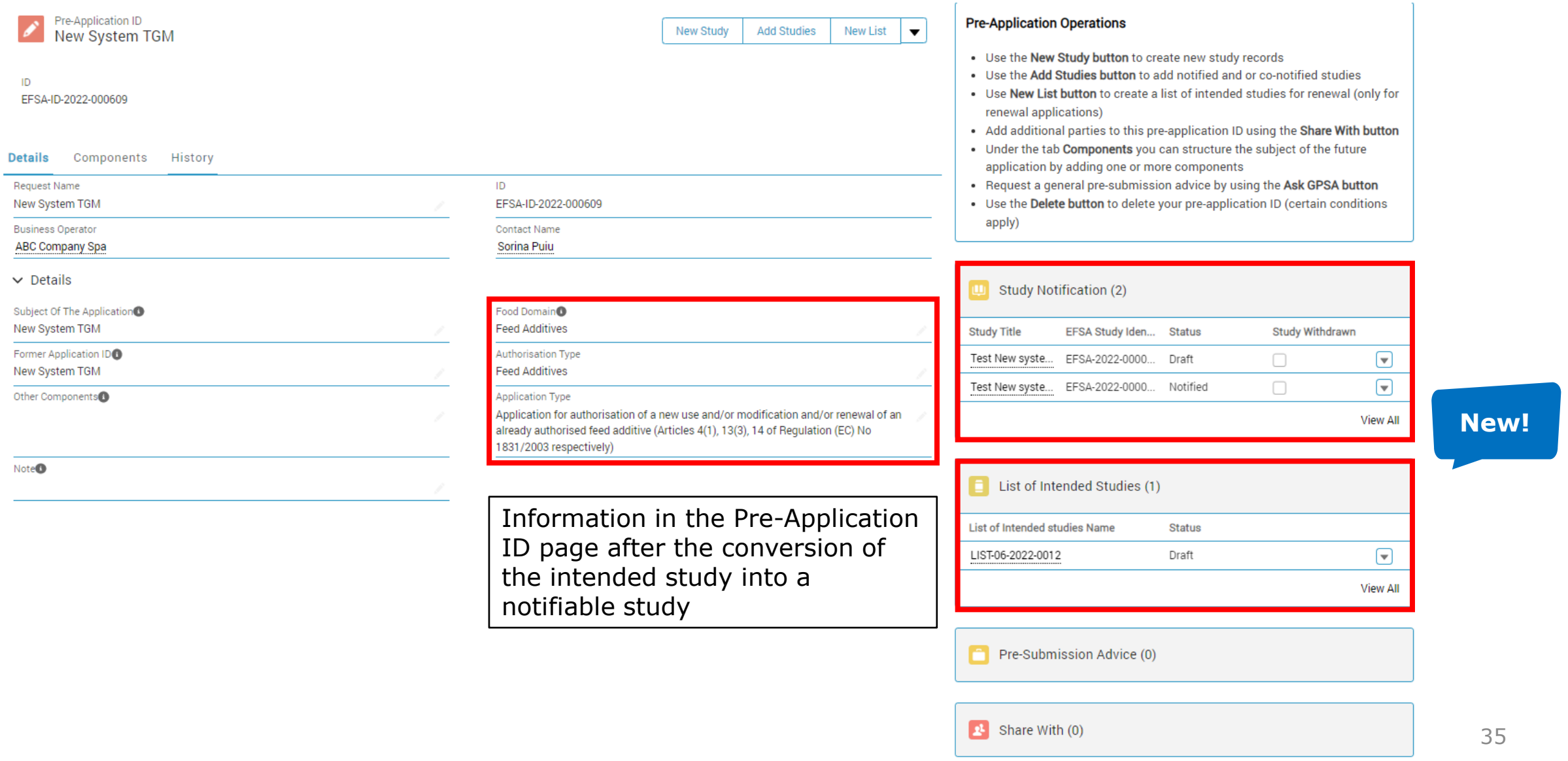
View All

Conversion example

In this example the former intended study "Test New system 3" was converted into a **notifiable draft study.** Potential applicants will find the usual layout for the study notification.



Conversion example



Information in the Pre-Application ID page after the conversion of the intended study into a notifiable study

New!

Benefits for the users

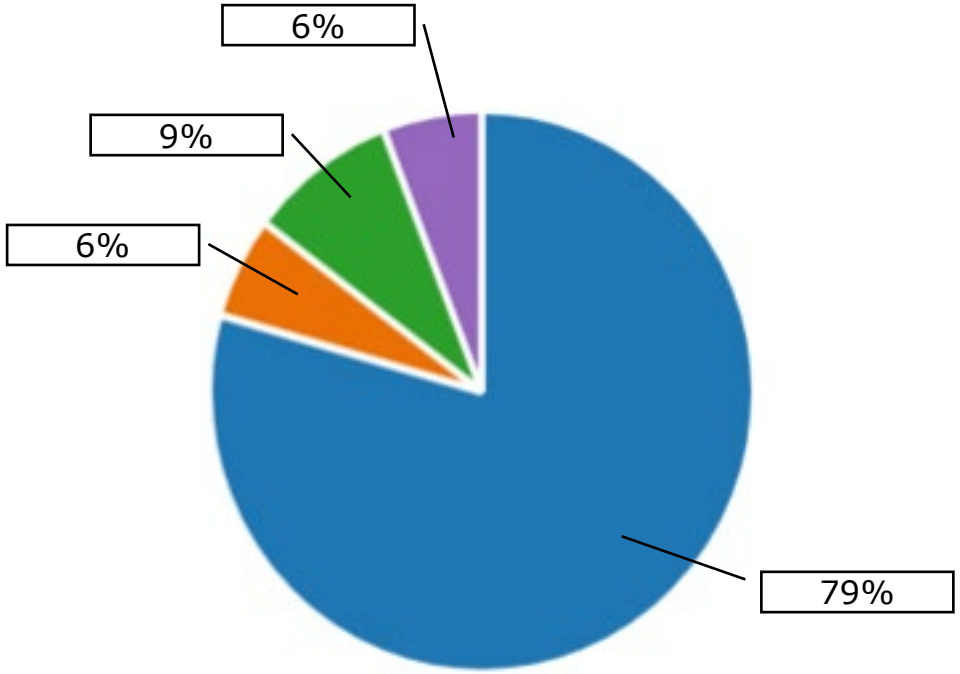
- Creation and management of pre-application IDs from a single access point.
- Dedicated section only for the list of intended studies and the renewal pre-submission advice.
- Two separate paths for intended studies for renewal (Article 32c(1)) and notified studies (Article 32b).
- Possibility to submit a list of intended studies to receive a renewal pre-submission advice and contemporarily create and notify other studies supporting such renewal from the same pre-application ID.
- More flexibility in managing studies supporting a future application for renewal. For instance, it will be possible to notify an intended study when this can no longer be considered as intended, if the status of the list of intended studies is “draft”, “clarification needed” or “closed”.
- Overcoming the parallel notification currently in place to allow notification of studies due to time constraints related to renewal process.

Survey results on new functionalities and next features to be expected

(Tomas ROVESTI)

Survey Results: participation

Business Operator	27
Laboratory	2
3rd Party operating on behalf of business operators	3
3rd Party operating on behalf of laboratories	0
National competent authority (MS)	2



Anonymous survey
Total participants: 32 (incl. 2 respondents with more than one role)
Last year participants: 9

Survey Results: Most Appreciated Aspects of NOS

Quick login

Web interface

Quality control Transparency

Quick support Fit-for-purpose

Search Functionality

Clear structure

Pre-populated fields **Performance**

Continuous improvement

Ease of use

Survey Results: Less Appreciated Aspects of NOS and Suggestions for Enhancements

Areas of improvement	Detail	Status
Field length limitations	• Study Internal Reference ID (10 chars) to be increased to 250 chars • Study Title (80 chars) to be increased to 300 chars by introducing field "*Study Title (full length)*"	July '22 release Autumn '22 release
Ability to change laboratory	• The name of the laboratory commissioned to conduct a study is an information specific for each study notification. If the laboratory changes a new study notification is required	n/a
Laboratory selection	• Display more information to clearly identify laboratory prior to submission of notification	To priorities (2022)
Study Type	• Study Type – remove duplicated values • Food Domain – remove nonrelevant values • Study Type and Study Guidelines - improve searchability • Harmonized terminology for scientific research (Zenodo)	Autumn '22 release
Notification messages	• Enhancement to content, relevance and frequency	To consider (2023)

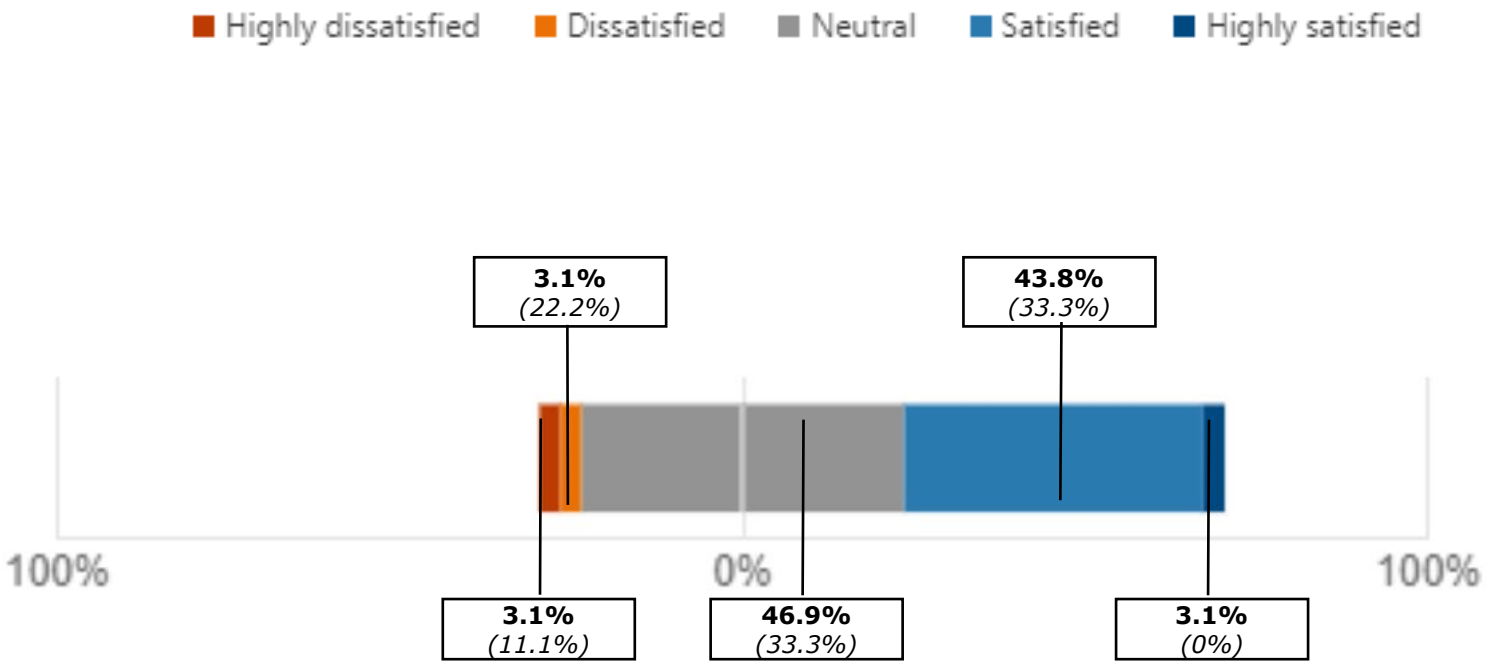
Survey Results: Less Appreciated Aspects of NOS and Suggestions for Enhancements

Areas of improvement	Detail	Status
Mandatory fields	• Mandatory fields to be highlighted before notifying study (need to enforce at creation of record to implement)	n/a
Integration with application portal	• NOS to integrate with ESFC/IUCLID to reduce double entry	To consider (2023)
Export functionality	• Ability to export study and pre-application IDs records (.xlsx, .csv)	Winter '22 release
Reporting	• Possibility to sort, group and filter lists with study and pre-application IDs	Winter '22 release
Import functionality	• Ability to import study records in bulk	To consider (2023)
Search improvements on study lists	• Search list views by other columns than Study Title	To consider (2023)

Survey Results: Less Appreciated Aspects of NOS and Suggestions for Enhancements

Areas of improvement	Detail	Status
Login experience	• Six user accounts per organisation • Supported browsers: Google Chrome, MS Edge, Mozilla Firefox, Apple Safari. (latest stable versions) • Link: https://connect.efsa.europa.eu	n/a
Move of studies between PAIDs	• Studies (draft or notified) cannot be moved between PAIDs. Study designed to support application to which also the pre-application ID is linked. • Adding notified studies (in bulk) to multiple pre-application IDs possible via Add Studies function to add notified studies to multiple pre-application IDs (consistent information).	n/a

Satisfaction Level for the Support



Anonymous survey
Total participants: 32

This year results
(last year results)

Survey Results: Opportunities for Improving the Support

Areas of improvement	Detail	Status
System enhancements	Consider queries related to procedural aspects on NoS as well as the technical issues for future system enhancements	Currently considered during the analysis of new system enhancements
System enhancements news	Enhance communication with users informing about any improvement, error correction or new functionality.	News are regularly published on the EFSA Toolkit page and in the supporting channel for applicants on LinkedIn.
User manuals and help sentences	More short, specific tutorials, included directly in the platform while filling in the fields.	Help and guidance sentences on the platform have been revised and are constantly improved. User Guides are updated in line with releases and will be accompanied by tutorial in case of major changes in tool.

Survey Results: Opportunities for Improving the Support

Areas of improvement	Detail	Status
Communication, email alerts	Communication between the system and external users, emails should be sent not only to the organisation email	It is already possible to indicate an email address different than the organization email for NoS, webqueries and PSA
Ask a Question service	Direct contact with EFSA in case of need, time to deliver a reply for a request is rather long.	Replies on NoS related questions via Ask a Question are generally given in less than 15 WDs. Monitoring system in place to ensure urgent questions on NoS are replied in the shortest time possible. FAQ to be revised to include recurrent questions on PAID.
Supporting activities	General request of supporting activities such as dedicated conferences, meeting or clarification calls. support during the application process	Webinars, roundtable and other meeting occasion with stakeholders are organized regularly (next webinar on NoS scheduled for 14/9). Support during the application process -> GPSA. See also

Have your say - TG members presentations

(experience on the tool, future enhancements on tool and support)

Training needs and material

User Guides and additional activities

- User Guide – Pre-application ID (New Applications/ Renewals)
- User Guide – Notification of Studies

Upcoming next:

- User Guides update (end July) and Info session on the Notification of Studies (mid September)
- Supporting channel for applicants on LinkedIn (EFSA support to applicants)
- Monitor Application Toolkit page for latest news

Group closure and discussion

What comes next?

- Creation of **new** "EFSA Technical Group on the tools related to the implementation of the Transparency Regulation"
- **Objectives**: to enhance interaction and communication, exchange views and collect feedback on usability and possible further improvements and, where relevant, for EFSA to present enhancements of the tools before their implementation.
- Call for expression of interest will be launched soon, first meeting planned for September 2022

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