

18 November 2020

**Ad Hoc Meeting of The Advisory Group On The Food Chain and Animal and Plant Health On The Implementation Of The Transparency Regulation**

**Presentation of Notification of Studies Database**

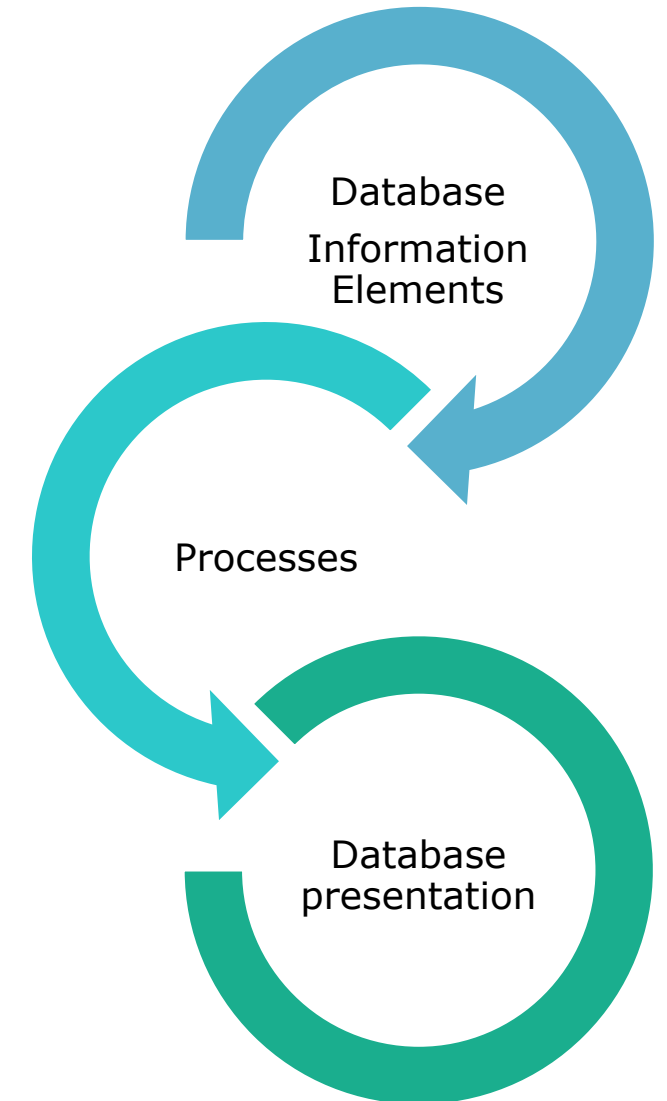
Stefano Cappè  
Evidence Management Unit (DATA)  
**European Food Safety Authority**

Trusted science for safe food

Notification of studies database

New applications – Article 32b

Renewals – Article 32c1

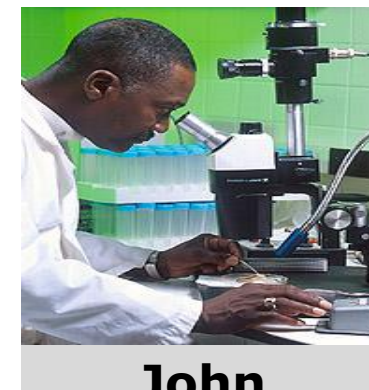


- Business operators, laboratories/testing facilities need to register before accessing the system and **initiate the notifications of studies**
- Laboratories/testing facilities need to register before accessing the system if they want **to perform co-notifications**
- Third parties acting on behalf of business operators, laboratories/testing facilities need to register before accessing the system and be delegated by their customers



**Sarah**

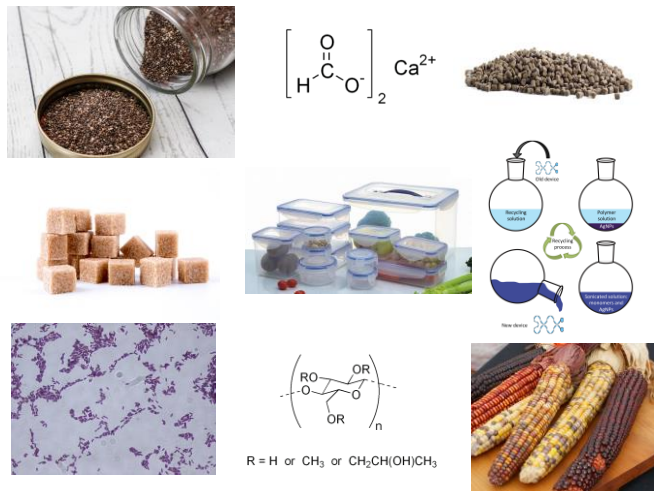
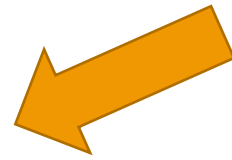
Business Operator



**John**

Laboratory/testing facility

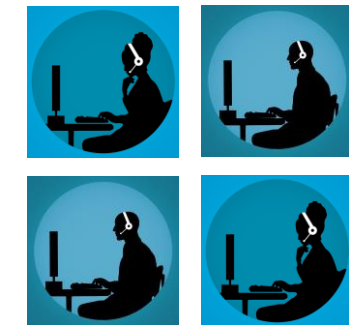
# Pre-Application Identification



**Subject of the application**



**Intended Area**



**Business Operator(s)**

# Pre-Application Identification



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Preparing for new application

Notify Study 1

Notify Study 2

Notify Study 4



Notify Study 3

Notify Study 5

⋮

Notify Study N



**Study Title (M) – Free text:** title of the study

**Study Title (O) – Free text:** (English name) title of the study in English language

**Study starting date (M) - Date:** the experimental starting date

**Study planned completion date (M) - Date:** the date on which the study report is expected to be signed

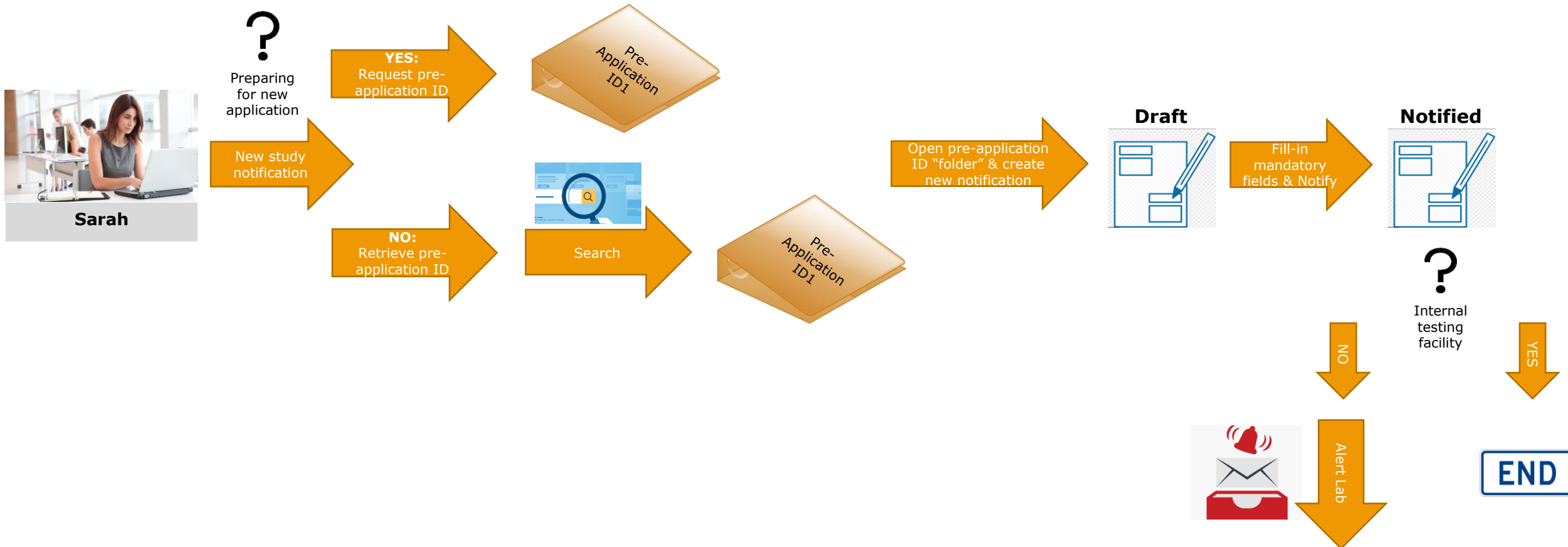
**Study scope (G):** Section composed of multiple elements. See next slide.

**M: Mandatory**   **O: Optional**   **G: Group of elements**

- **Study intended area (M) – Choose from list:** shall report the regulated product area of the future application that the study is meant to support
- **Study type (M) – Choose from list:** shall report the type of the study
- **Study international standard certification (M) – Choose from list:** shall report the standard certification of the study
- **Study objective (M) – Free text:** shall report the narrative describing the objective of the study
- **Study internal reference id (O) – Free text:** shall report the identifier of the study as assigned by the business operator/laboratory or testing facility
- **Test item (M) – Free text:** shall report the identification of study test item. Depending on the type of test item, information on the test item **components** (for chemical productions substances and metabolites, microorganisms, GMOs) shall also be provided
- **Components (M) – if applicable:** shall report the identification of substances, micro-organisms, GMO Names: (GMO Unique identifier, Protein name). It is possible to select from pick lists or report free text.

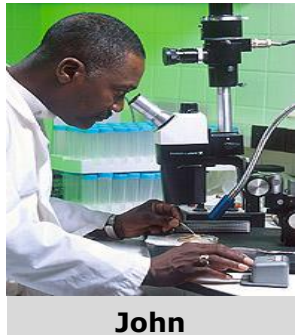
M: Mandatory O: Optional

# Notifying a Study as Business Operator

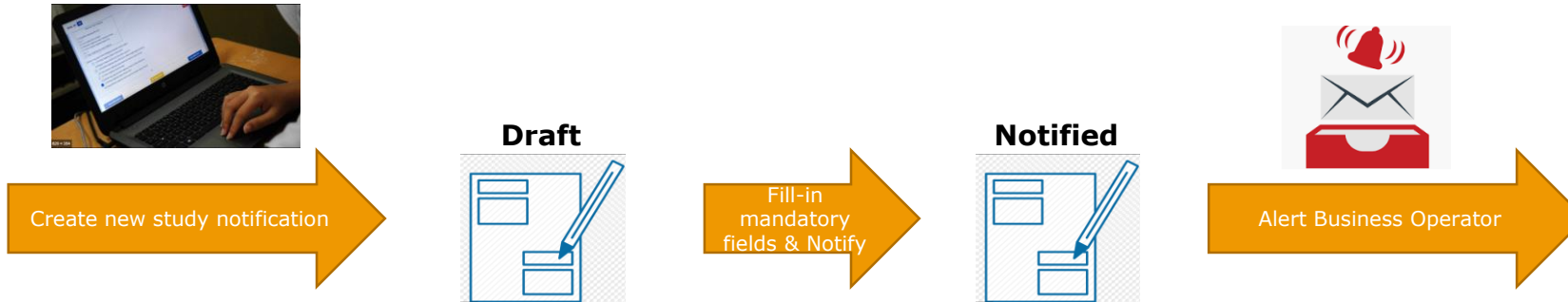




# Co-notifying a Study as Laboratory



# Notifying a Study as Laboratory



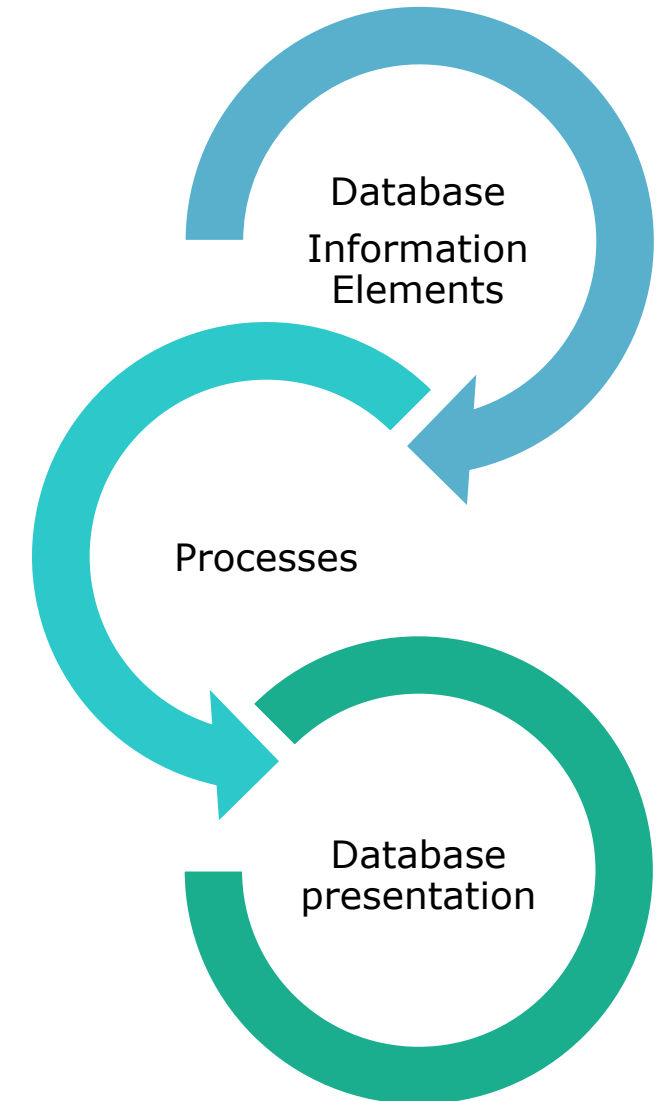
# Co-notifying a Study as Business Operator



Notification of studies database

New applications – Article 32b

Renewals – Article 32c1



# Pre-Application Identification for Renewal



is notifying for Potential Applicant A

Former application id



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Requests a Pre-Application-Id for Renewal



Intended studies

**Study Title (M) – Free text:** title of the study

**Study Title (O) – Free text:** (English name) title of the study in English language

**Former application id (M)– Free text:** shall contain the identifier of the application to be renewed (e.g. former EFSA question number)

**Study scope (G):** Section composed of multiple elements. See next slide

M: Mandatory   O: Optional   G: Group of elements

- **Study intended area (M) – Choose from list:** shall report the regulated product area of the future application that the study is meant to support
- **Study type (M) – Choose from list:** shall report the type of the study
- **Study objective (M) – Free text:** shall report the narrative describing the objective of the study
- **Test item (M) – Free text:** shall report the identification of study test item. Depending on the type of test item, information on the test item **components** (for chemical productions substances and metabolites, microorganisms, GMOs) shall also be provided
- **Components (M) – if applicable:** shall report the identification of substances, micro-organisms, GMO Names: (GMO Unique identifier, Protein name). It is possible to select from pick lists or report free text.

M: Mandatory O: Optional

## ■ Study design

- **Study guideline (M) – Choose from list:** shall report the guideline or guidance document to be followed by the study

**OR**

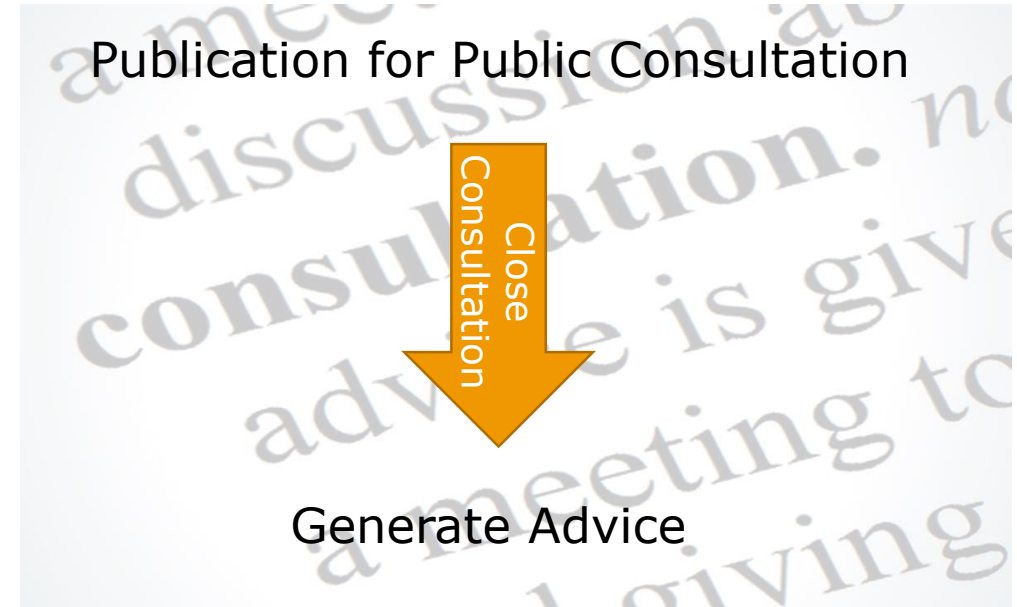
- **Study design description (M) – Free text:** shall contain the description of the design of study including the hypothesis

- **Study detailed protocol (O) – Free text:** shall contain more detailed information and further elaborating methodology, statistical considerations, and organization of a study. The protocol usually gives the background and rationale for the study.

M: Mandatory   O: Optional



# Renewal Pre-Submission Advice Process



# Linking Intended Studies for renewal to the List



New/find list of Intended Studies



List of intended studies for renewal

Add Intended Studies to List

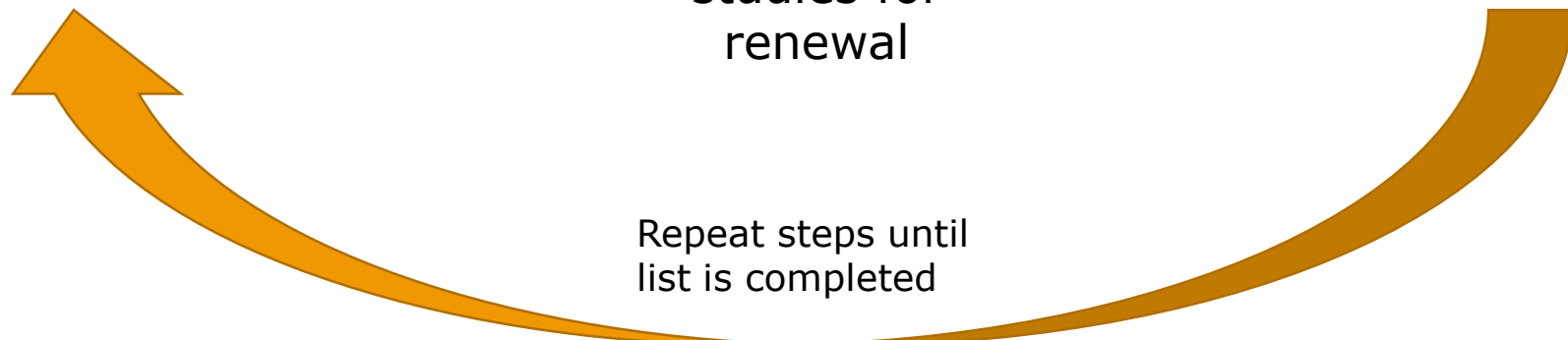


Intended studies

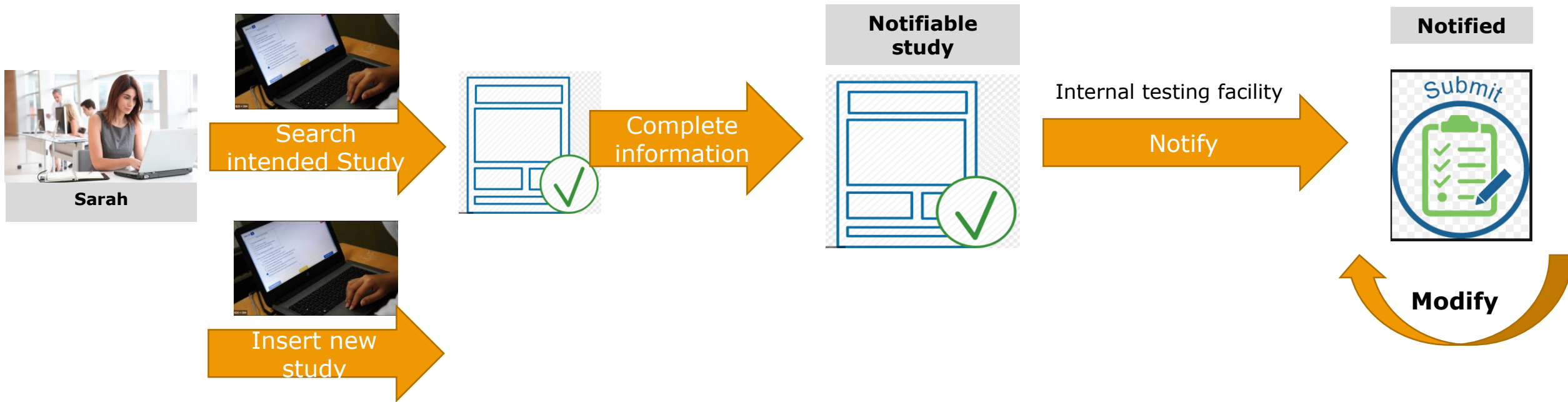
Complete List



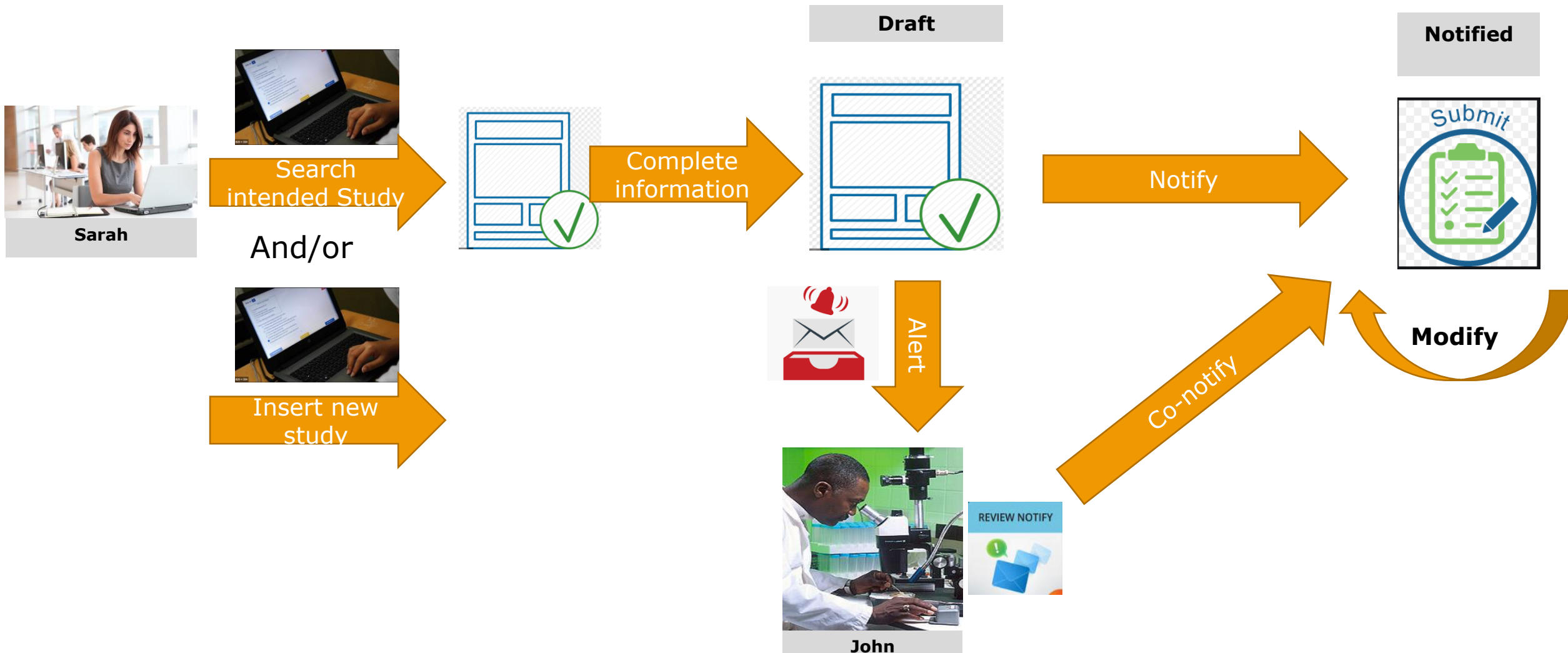
Submit



# Business Operator Notifies Intended Study under 32b



# Business Operator Notifies Intended Study under 32b



## TG Notification of Studies Database

- Composition: new members from laboratories/facilities
- Member States (x3), ECHA, EC (SANTE, JRC), industry stakeholders (x6), laboratories/facilities (4), other interested stakeholder groups (x3)

## Meetings

- 2 core meetings ([February 2020](#), [October 2020](#))
- Regular virtual meetings to allow continuation of discussions
- Good progress and discussions; updated presentation to laboratories/facilities, process for new studies, for renewal studies, update process for multiple actors, basic information concept, testing database.
- January 2021 - next TG core meeting
- Feb – March 2021 – Training and progressive opening of the systems<sub>2,1</sub>

# Questions?

