

16 November 2020
Expert Group on General Food Law

Presentation of Notification of Studies Database

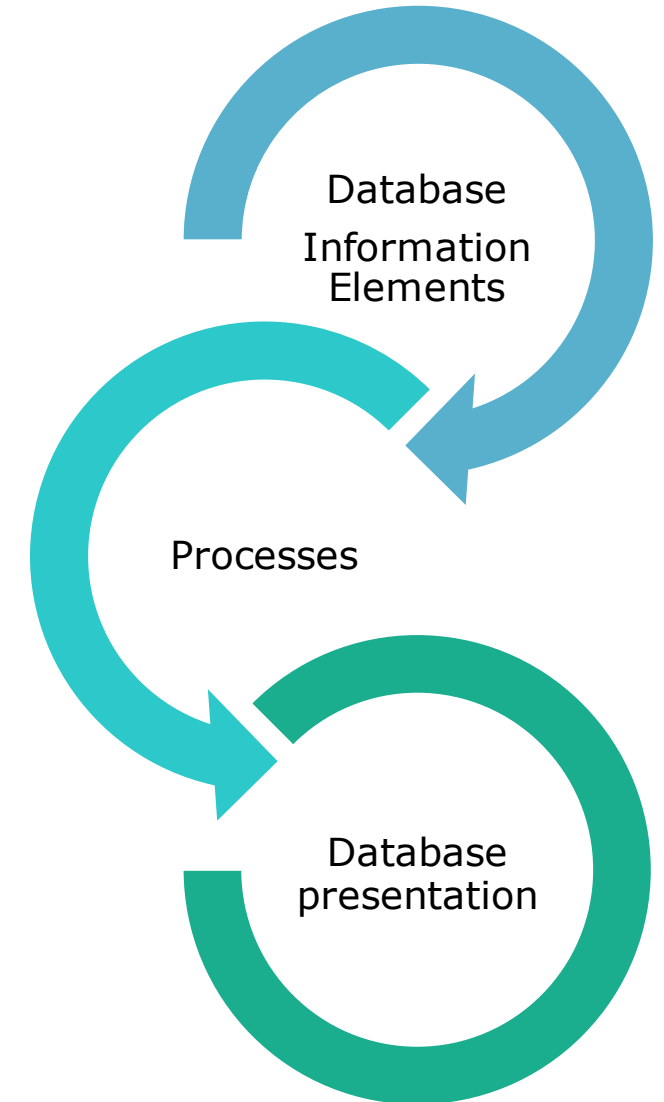
Stefano Cappè
Evidence Management Unit (DATA)
European Food Safety Authority

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

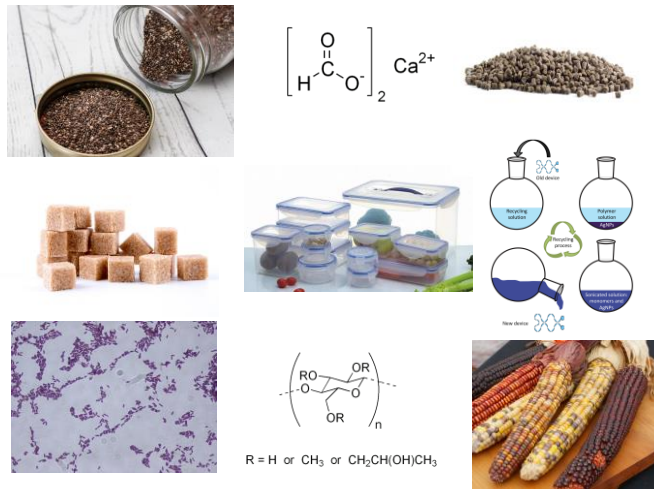
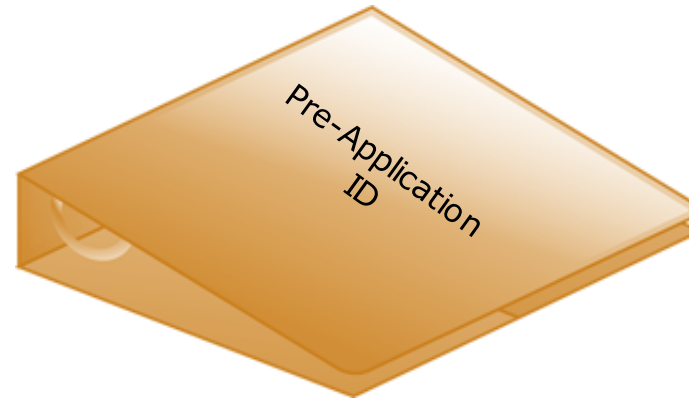
Business Operator



John

Laboratory/testing facility

Pre-Application Identification



Pre-Application Identification



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Preparing for new application

Notify Study 1

Notify Study 2

Notify Study 4

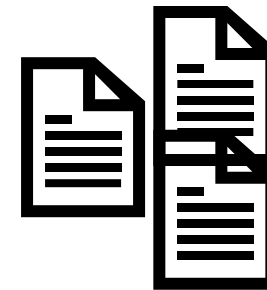


Notify Study 3

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

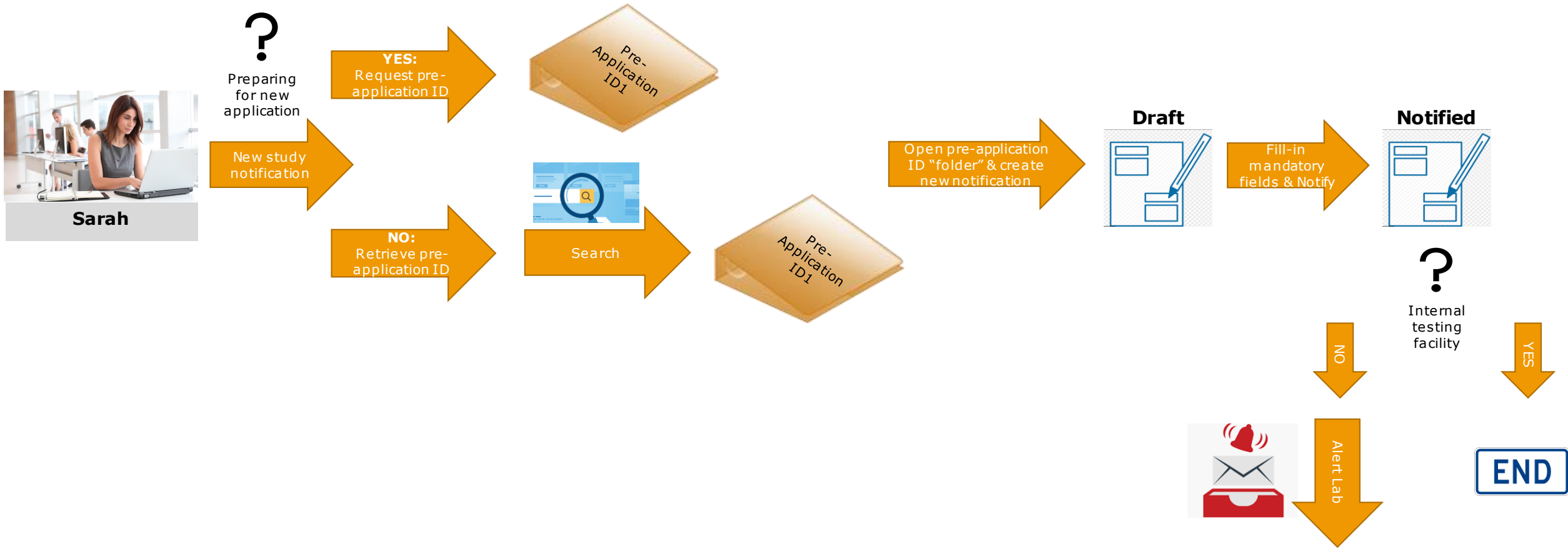
Study scope (G): Section composed of multiple elements. See next slide.

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

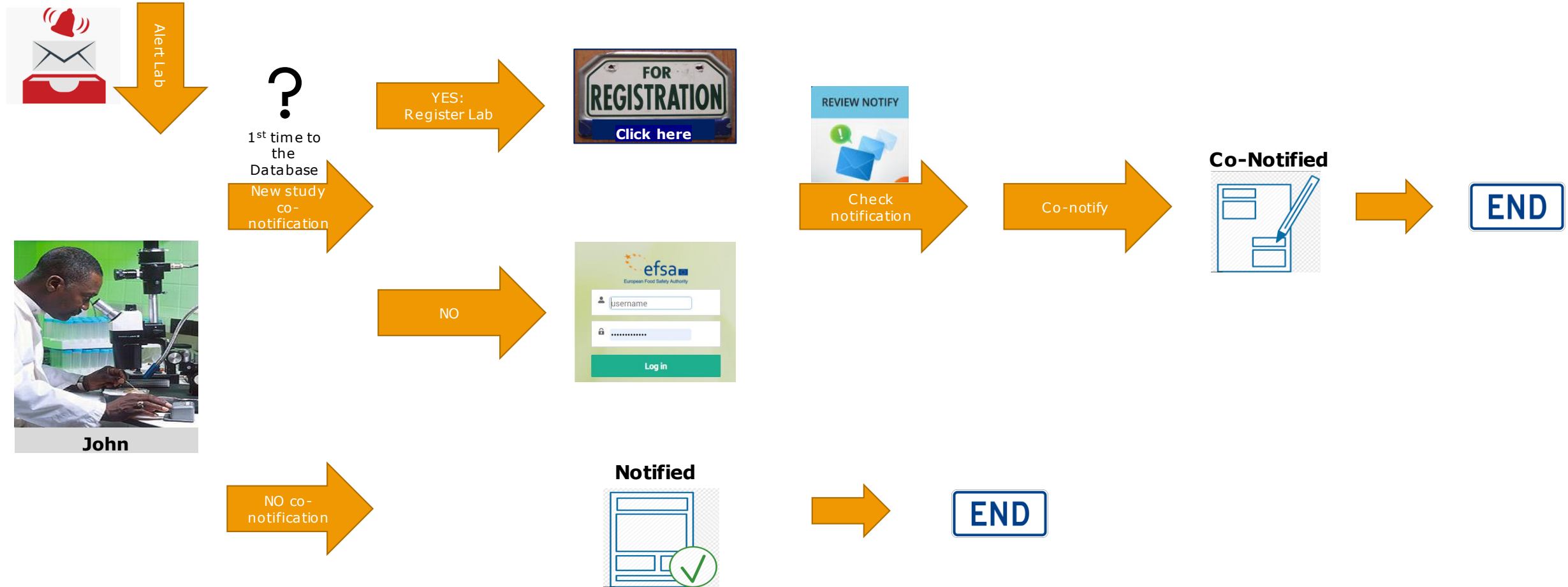
- **Study intended area (M) – Choose from list:** shall report the regulated product area of the future application that the study is meant to support
- **Study type (M) – Choose from list:** shall report the type of the study
- **Study international standard certification (M) – Choose from list:** shall 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

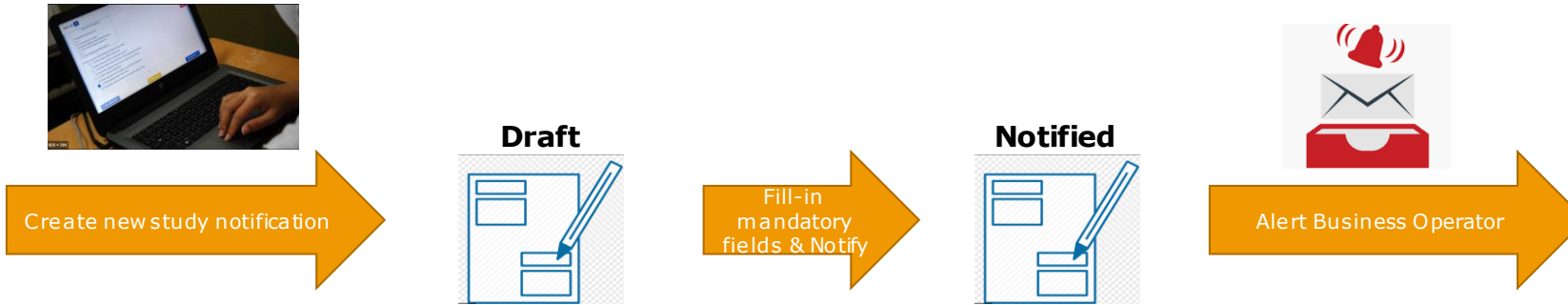
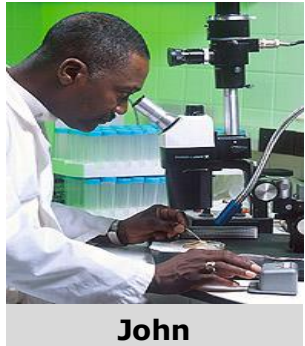
Notifying a Study as Business Operator



Co-notifying a Study as Laboratory



Notifying a Study as Laboratory



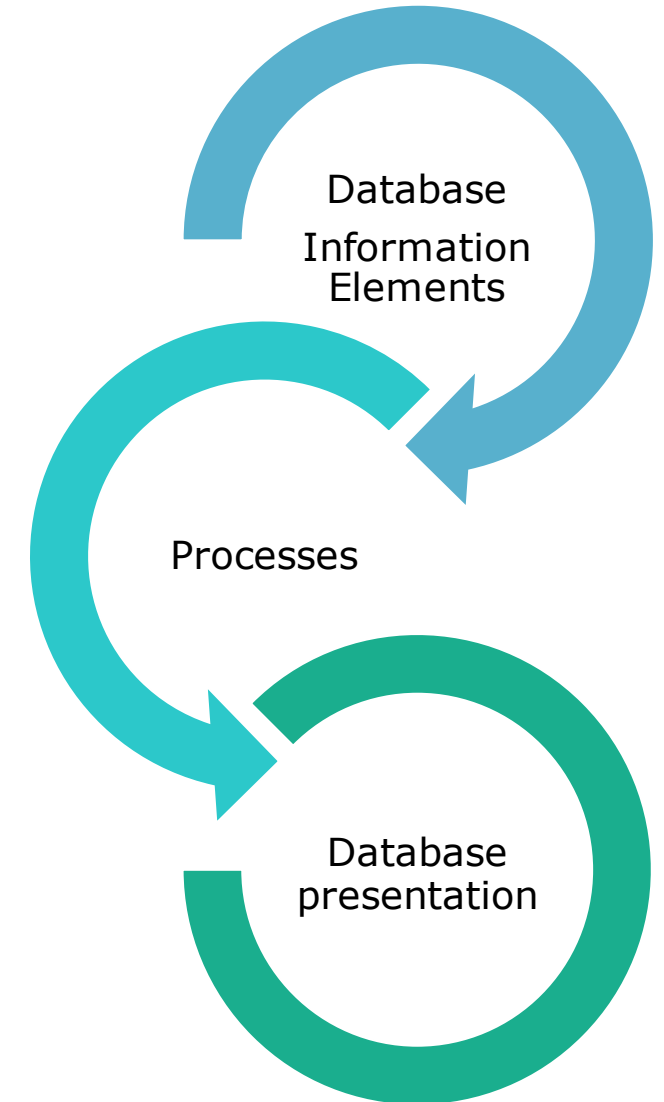
Co-notifying a Study as Business Operator



Notification of studies database

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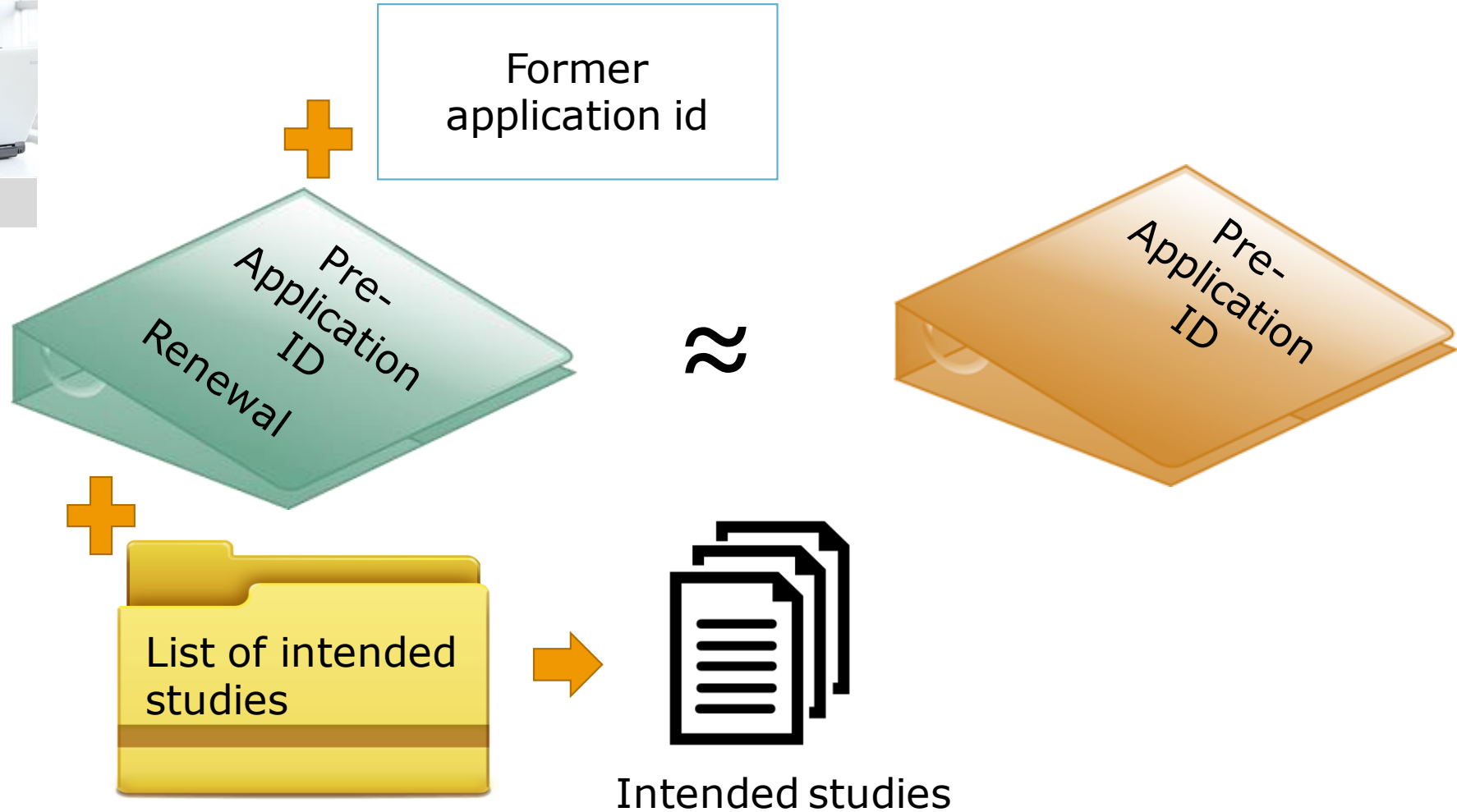


Pre-Application Identification for Renewal



is notifying for Potential Applicant A

Requests a
Pre-Application-Id
for Renewal



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

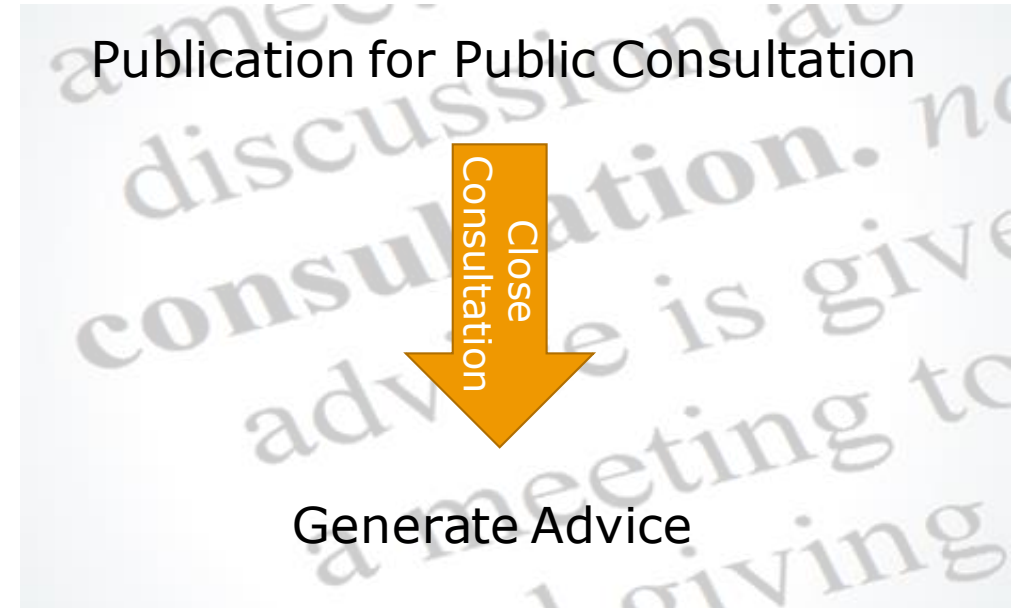
OR

- **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

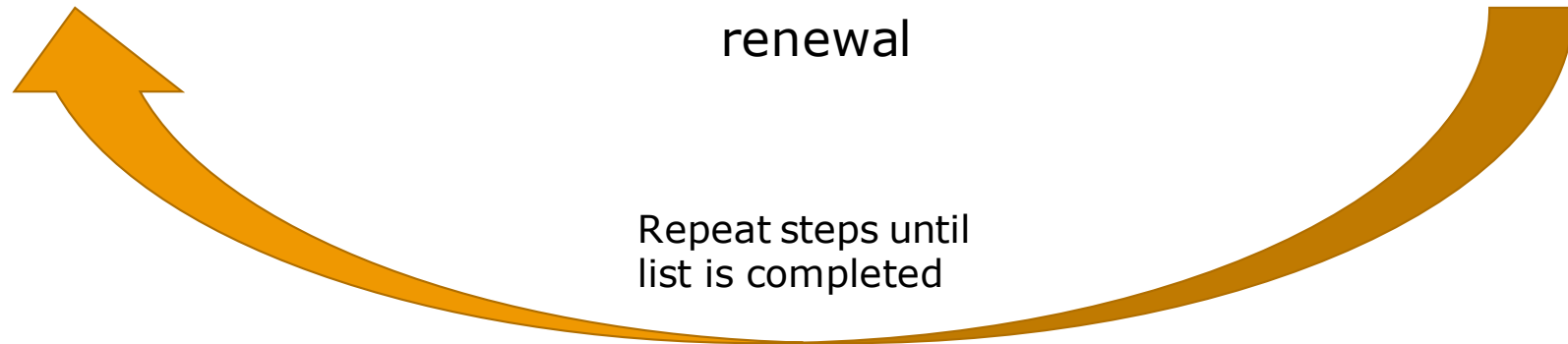


Intended studies

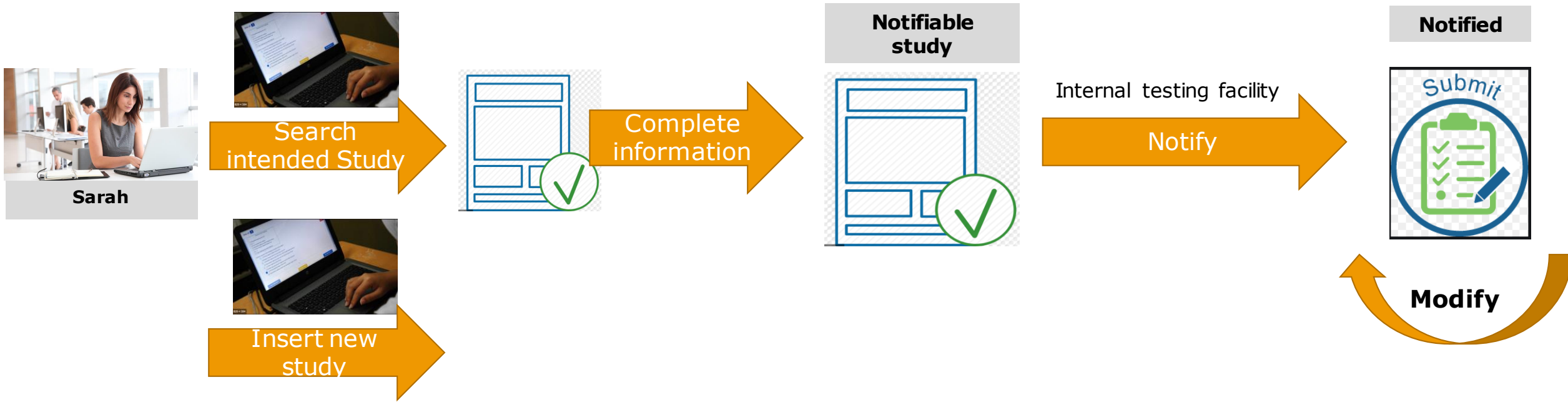
Complete List



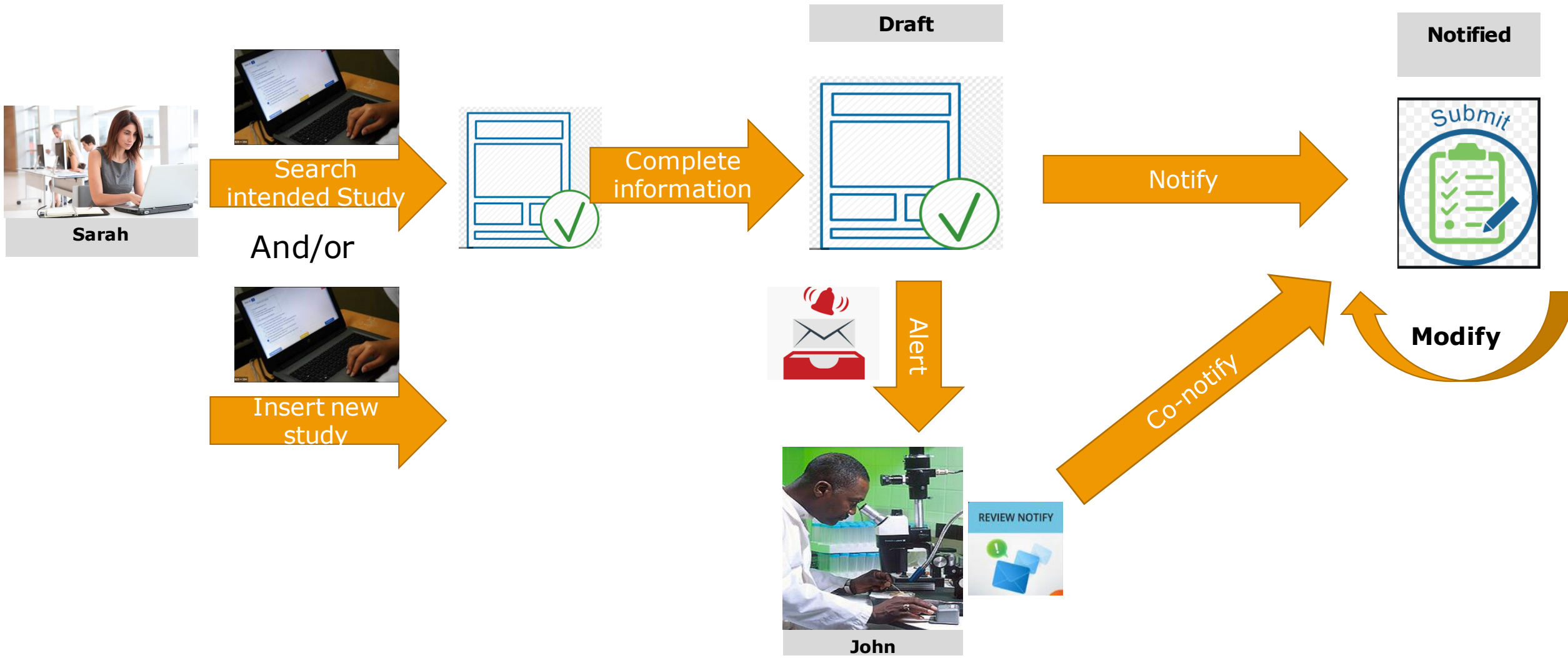
Submit



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 + trainings

Questions?

