Feedback on EFSA Notification of studies database

4th Meeting EFSA Technical Group on Notification of Studies Data

8th June 2021

- It is recognized the work of EFSA staff in responding/solving the immediate blocking issues in timely manner.

- Applicants are gaining experience, so the processes are becoming smoother

- Several technical bugs are still hindering the processes.

- A clear development roadmap and changelog for the IT tools from EFSA would be beneficial

- The lack of flexibility for the DRAFTING phase, does not allow for testing, doing trials and errors while in draft mode.

Identified issues and suggestions for improvements

- **The limited number of accounts (users) remains a difficulty for several companies**
  - For companies with various entities the overall visibility is extremely challenging (also lack of an export function).
  - Requests for additional accounts (users) are not timely processed, while the legal entity was validated.

- **Difficulties for Task Forces management**
  - "share with" and "on behalf of" options are inconsistent, some users can see the shared PAIDs, others not.
  - Can a cloud based system be explored ?

- **Character limits in many fields are a challenge (do not allow accurate data entry):**
  - Internal study identification limited to 10 characters
  - Study title field / Study design description field
  - When raising scientific questions for pre submission requests (no attachment possible)

Identified issues and suggestions for improvements

- **Study notification**
  - Study type and test guidelines lists are incomplete
  - Test guideline 'other' does not open another box allowing to provide the test guideline
  - Sharing can occur by using share with or on behalf. The functionality on behalf was installed later in the program. It does not work properly. Despite full access rights have been granted, only shared with functionality is available (read only mode).
  - Some studies and PAIDs which do not appear in the respective list of renewals/studies list of a user can be found via the search bar. All studies available for a user should be listed accordingly.
  - No option for multiple Business Operators/Task Forces in case of shared ownership of a study
  - Study disappears from list after notification if notification performed "on behalf of" for another Business Operator, although correctly shared "on behalf of". The study can reappear in list after shared once more via "on behalf of" by original Business Operator
  - Menu "Your Studies" should also contain a sheet/column "shared with/on behalf of" or "Task Force" to be able to sort and see studies, where BO is involved but which the BO has not submitted by himself
  - In case study was linked to a wrong Pre Application ID, there is no option to correct it.