



CropLife Europe's inputs to the 3rd Meeting of EFSA Tools Technical Group

Key messages

- ☛ **CLE sees the system developing positively with continuous improvements being made**
 - ☛ EFSA staff responsiveness is much appreciated.
- ☛ **We see opportunities for improvement in order to increase efficiency and accuracy of the system and data**
- ☛ **Opportunities for exchange and continuous dialogue are very much appreciated**

■ New Reporting Functionality

- Will customized reporting be available to end users?
- A report on all registered Contract Research Organizations (i.e. Labs) would be very useful. Suggest to create that report
- Status withdrawn not visible, studies indicated as draft, which is very relevant difference with respect to follow-up actions
- Is the reporting function accessible to Member States? What is the timing of the report generation ahead of the dossier submission?

■ 'Add Studies to Pre-Application ID'

- Unresponsive wait times when performing any action within window
- Searching for studies to add to pre-app ID

■ In the future, an import functionality allowing for validation would increase efficiency of the notification process.

Losing visibility of notified studies

- Applicant lost visibility of 39 notified studies, some of which were needed to support imminent IUCLID submissions. After contacting the EFSA service desk, they were informed that the 'sharing settings' on the 39 identified notifications were lost due to changes in their system, which was the cause of the inability to see their own notifications. EFSA worked with their external vendor to restore the sharing settings of those we identified were 'missing', but it required several back and forth checking to get visibility on all 39 notifications restored. There is still concern that we don't understand exactly why the visibility was lost and whether it may happen again in future.

User accounts

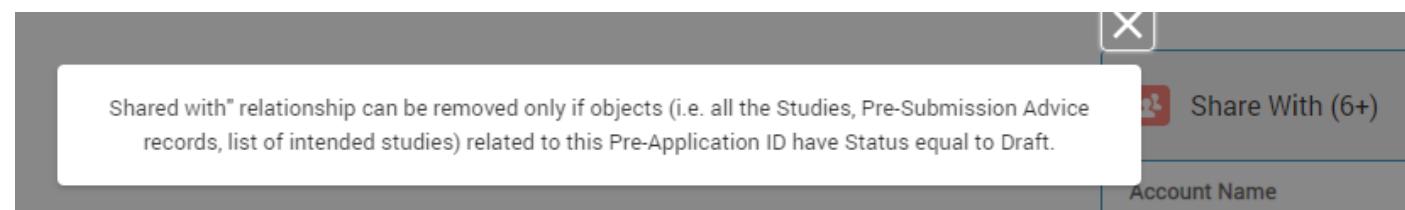
- Anyone can sign up (potentially in error) and "use" one of our restricted number of logins. There is no approval process by the admin of a registered company entity to approve user account requests within that legal entity.
- When deactivating a user account within a legal entity, the user still appears in the system list of users with no indication from our side that they are now inactive.

Editing Sharing settings

- It is currently only possible to remove 'shared with' relationships on 'draft' status notifications or pre-app IDs where ALL objects are in 'Draft' status. It must be possible to modify the 'shared with' relationship on notified studies and pre-app IDs, in case a Task force membership changes, or a study ownership is divested to another company, after a study is notified, or the pre-app ID has been submitted for the R-PSA process.

Case Study

- Renewal Pre-App ID for active substance created by leading applicant of Task Force
- Pre-app ID 'Shared with' 6 other task force members
- Submitted list of intended studies for R-PSA process
- 6 months later, two members of the Task Force decided to leave the Task Force. Contractually, the exiting members no longer have permission to access study information related to the Task Force
- **However, the leading applicant of the Task Force is unable to remove exiting Task Force member from pre-app ID and study notifications, due to system restrictions**



- Consequence of system restrictions: Confidential information in the EFSA database is now transparent to non-contractually obligated industry competitors