



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9th Industry Stakeholder Platform Meeting

Topic 5: Update on Type II validation team

24 November 2022



- ❖ The Type II validation centre was established in January 2022, with the following aims:
 - Increase consistency across submissions
 - Look at simplification of the process
 - Free up PL time for other activities
 - Handle pre-submission queries
 - Increase collaboration with industry

- ❖ The scope of the team excludes quality variations.

Validation Checklist

- Increase uptake of Validation Checklist
- Work on introducing changes to specifically address common issues

Chatbot Project

- Currently working on creating a chatbot for Q&As
- Will make navigation easier for companies

Communication with Industry

- Wrote an article on the most common issues
- Engage directly with industry representatives

Choosing the wrong Variation Classification

Submitting a Grouped application as a Single variation

Missing Present/Proposed Table in the Application Form

Missing or Incomplete (Non-)Clinical Expert Statement

Missing the 'Information relating to Clinical Trials' document

- On average the team handles 125 applications per quarter, spending an average of 2:30 hours on each.
- Validation Officers have reduced the variability across months and the amount of time spent per validation. Fewer changes to TTs are necessary.
- On average, it takes 7-10 days for a submission to be validated, which we consider a good standard.
- A Validation Checklist is now included in 50% of applications, and we expect that number to rise in the months ahead.
- The Chatbot Project is currently in progress in coordination with the Digital Transformation team to make it easier for companies to navigate the Q&A on our website.
- Interactions with industry representatives are planned in order to strengthen communication and share perspectives.
- There will be a review of the guidance on the EMA website as it is acknowledged to be complex and difficult to navigate

- From Jan 2022, MAHs were asked to raise pre-submission queries via the EMA Service Desk in analogy with the process that is already in place for type IA and IB variations
- Snapshot of queries received Jan-Jun 2022 (n=202) – also relayed by PLs



