

CAPs and Non-CAPs in web-based eAF - Q&A Clinic

30 September 2025, 15:00 – 16:00 (CEST)

Webinar: WebEx

Welcome

Kristiina Puusaari, eAF Product
Owner, EMA

Join at www.slido.com #EAFQA30



Agenda



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1

Welcome
15:00 – 15:05

Kristiina Puusaari
eAF Product Owner, EMA

2

Q&A Session
15:05 – 15:55

Moderator:
Pedon Isabella
eAF Change Management Team

3

Next steps & Closing
15:55 – 16:00

Kristiina Puusaari
eAF Product Owner, EMA

For Questions: www.slido.com code: #EAFQA30

Q&A Session

Isabella Pedon, eAF Change
Management Team

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Send your questions via Slido

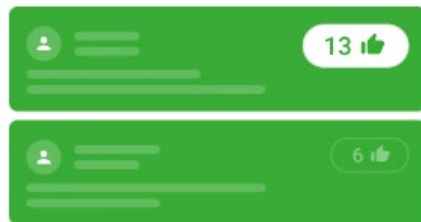
The session **is recorded** and will be shared



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1. Join via the QR code or link



2. Send or upvote the questions you want to hear answered



3. Questions will be shown on the screen and managed live in the Q&A session

Human variations eAF – **Strongly Recommended** use for all Variations



- The PLM Portal web-based variation form has been in **Strongly Recommended use for all CAP variations since May 2024.**
- Issues, concerns, bugs should be reported via the **EMA ServiceNow tool** – please pay attention to the correct category.

Note: **Strongly Recommended Use** = The **web-based eAF should be used in most cases.** The interactive **PDF** should **only** be used if **specific constraints** prevent the use of the web-based eAF (e.g., technical issues or missing features).

The PLM Portal web-based variation form will be **in Strongly Recommended use for all non-CAP variations** from Wednesday 29 September 2025.

Product selection – DEMO of the updated functionality



- When new form is created, the product selection page opens without a need to click to enter the product selection page
- Adding and deleting products is now easier and more intuitive

Further improvements coming 2 weeks time:

- Default search will be updated from 10 products to 50 products
- The number of products shown/selected will be displayed

Known limitation: multiselection using the highlevel button is currently not available in 'View selected products' and 'View added products'

Present and Proposed – reordering of sections now reflected in the pdf



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- When multiple sections are added in the pdf form, they can now be organised to reflect the order applicant wishes to display them on the pdf output following the deployment of the new FHIR and pdf versions on 25th September
- Other improvements are also now visible in the pdf export e.g.order or products is now based on the NCA country

Type IA Annual updates (annual notification)

4. How shall I present and submit my Type IA/IAIN Variation(s)? Rev. Jul 2025 ^

A Type IA/ IAIN variation notification should contain the elements listed in Annex IV of the Variations Regulation and should be presented in accordance with the appropriate headings and numbering of the EU-CTD format. The Commission '[Variations Guidelines](#)' further specifies which elements should be included in a Type IA/ IAIN variation notification.

In order to help MAHs ensuring that their Type IA/IAIN variations are complete and correct before submitting them to the Agency, it is strongly recommended to use the

[Pre-notification check for type IA/IAIN variations](#)

Also, in order to facilitate the completion of the application form, MAHs are advised to consult the [EMA/CMDh Explanatory Notes on Variation Application Form](#) and the

[European Medicines Agency practical guidance on the application form for centralised type IA and IB variations](#)

Type IA variations are intended to provide for a simple, rapid and efficient procedure for minor changes. The MAH should be aware that the submission of redundant information or a confusing dossier presentation will not facilitate such procedures. Similarly, deficient and missing documentation can lead to rejection of the variation. However, in **exceptional cases** the Agency may issue a single request for supplementary information, for which a response should be provided within 4 working days in the mandatory eCTD format for electronic submissions. Failure to provide the requested information, or submission of incomplete and/or unsatisfactory responses within 4 working days may lead to an unfavourable outcome.

The following elements should be included in a Type IA/ IAIN variation notification, as specified in the Variations Guidelines:

eSubmission delivery file

- In order to facilitate the registration of the submission, marketing authorisation holders are required to fill in all the submission attributes through the [eSubmission delivery file UI](#)
- Cover letter** (for groupings, include a short overview of the nature of the changes).
- Where a variation leads to or is the consequence of other regulatory procedure, a description of the relation between these procedures should be provided in the cover letter and a copy of the request should be annexed.
- For Type IA annual updates, the cover letter and eAF should clearly identify the submission as Type IA annual update.

Proposed changes

Scope and background for change ①

Precise scope for change *

Rich text editor toolbar with options for font face (Segoe UI), size (16), bold (B), italic (I), underline (U), text color, background color, bulleted list, numbered list, decrease indent, increase indent, link, unlink, insert image, print, and other standard editing tools.

Details of the changes

Background for change and **justification for grouping**, worksharing and classification *

Rich text editor toolbar with options for font face (Segoe UI), size (16), bold (B), italic (I), underline (U), text color, background color, bulleted list, numbered list, decrease indent, increase indent, link, unlink, insert image, print, and other standard editing tools.

For Type IA annual updates, the cover letter and eAF should clearly identify the submission as Type IA annual update.

Upcoming features



Versioning to support the new variation classification



Organisation Deletion



Reference MAH Name (OMS Update)

Next Steps & Closing

Kristiina Puusaari, eAF Product
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eAF Q3 events



Training session on Human variations web-based electronic Application Form (eAF) for non-CAPs 01 July 2025 ([Link to the Event Page](#))



Q&A clinic on web-based electronic Application Form (eAF) functionalities
08 July 2025 ([Link to the Event Page](#))



eAF Training on web-based electronic application form functionalities for CAPs
10 September 2025 ([Link to the Event Page](#))



eAF Training on web-based electronic application form functionalities for CAPs
15 September 2025 ([Link to the Event Page](#))



Quarterly System Demo – Q3 2025
17 September 2025 ([Link to the Event Page](#))



Q&A Clinic on web-based electronic application form functionalities
30 September 2025 ([Link to the Event Page](#))



Q&A Clinic on web-based electronic application form functionalities
09 October 2025 ([Link to the Event Page](#))

eAF Useful Resources



PLM Portal: [Link](#)

[eSubmission Website: Link](#)

[Training Videos on PLM Portal: Link](#)

[User Guidance on PLM Portal: Link](#)

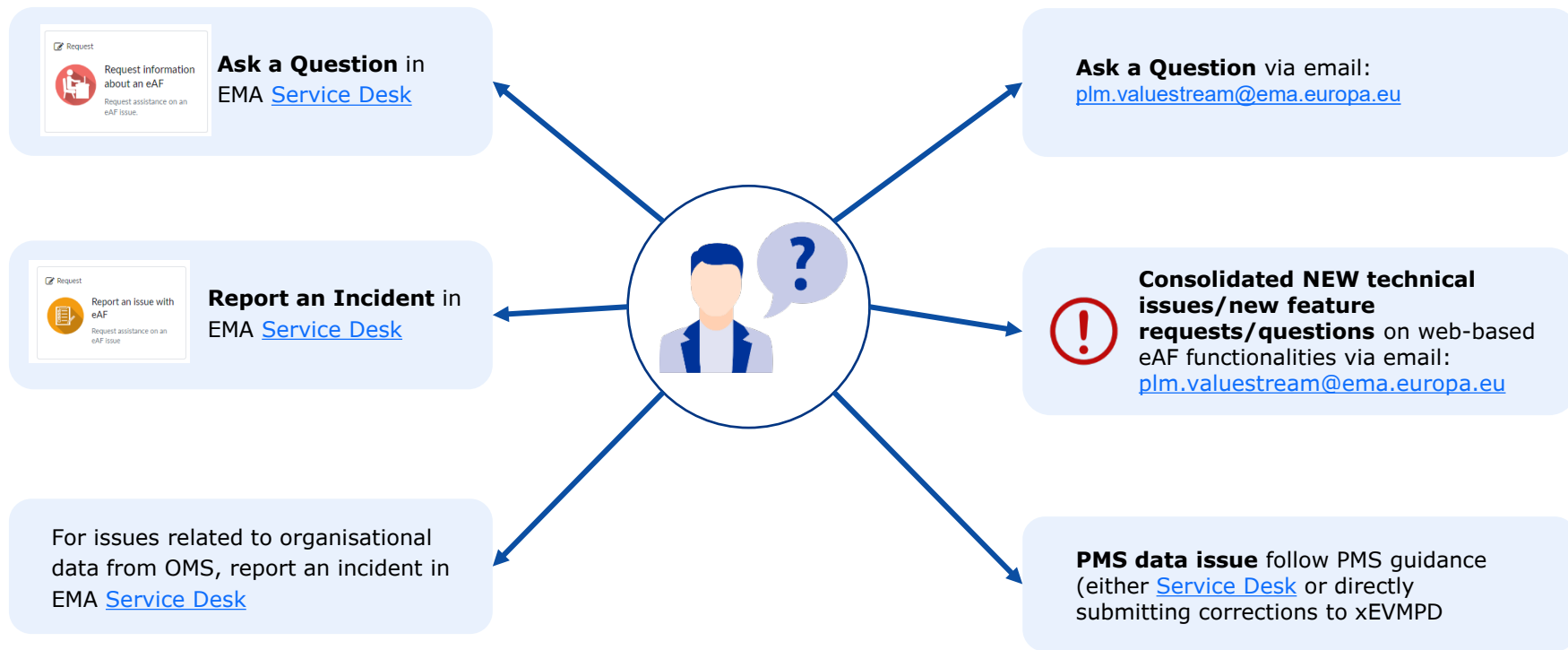
[Q&A Document on PLM Portal: Link](#)

[eAF News on PLM Portal: Link](#)

[PLM Newsletter: Subscribe Here](#)

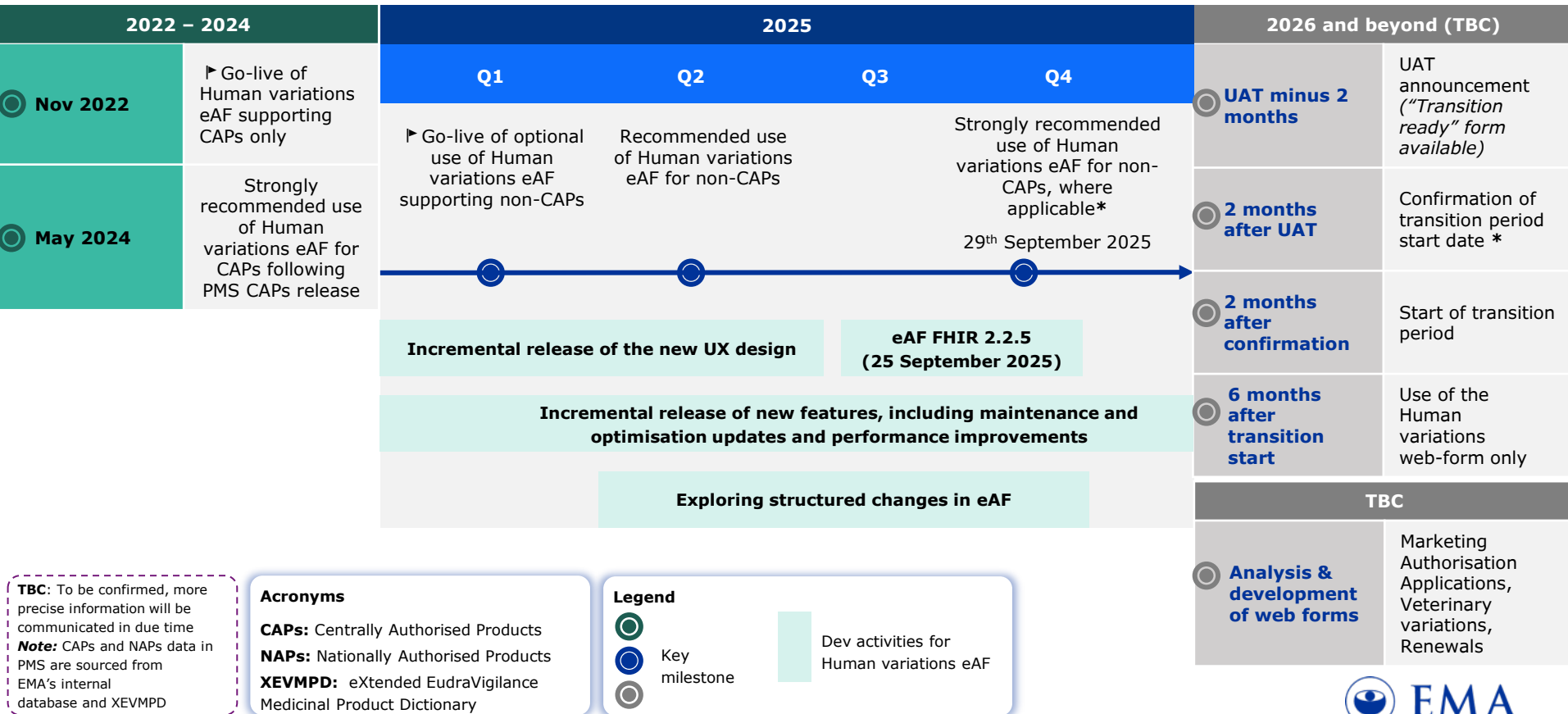


How can EMA be notified of eAF technical issues?



Human variations eAF – Key steps and milestones

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* on the condition that no major issues are identified