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

09 October 2025, 11:00 – 12:00 (CEST)

Webinar: WebEx

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Welcome

Kristiina Puusaari, eAF Product Owner, EMA

Join at www.slido.com #EAFQA09

Agenda

1	**Welcome** **11:00 – 11:05**	**Kristiina Puusaari** *eAF Product Owner, EMA*
2	**Q&A Session** **11:05 – 11:55**	**Moderator:** **Pedon Isabella** *eAF Change Management Team*
3	**Next steps & Closing** **11:55 – 12:00**	**Kristiina Puusaari** *eAF Product Owner, EMA*

For Questions: www.slido.com code: #EAFQA09

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Q&A Session

Isabella Pedon, eAF Change Management Team

Join at www.slido.com #EAFQA09

Send your questions via Slido

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

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you choose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

Join at
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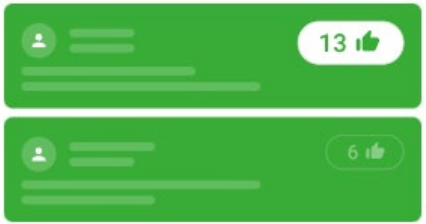
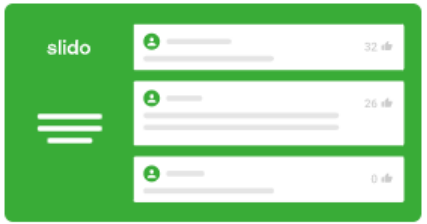
1. Join via the QR code or link



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 is now **Strongly Recommended use for all EU variations**

- 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 or data issues).*

The PLM Portal web-based variation form is replacing the interactive PDF variation form*, and it should be used in all case where the PDF was used, if possible.*

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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 next week:

- **Default search** will be updated from 10 products to **100 products**
- The **number of products shown/selected** will be displayed

Known limitation: multiselection using the high-level button is currently not available in ‘View selected products’ and ‘View added products’

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

- 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

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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/ IA_{IN} 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/ IA_{IN} variation notification.

In order to help MAHs ensuring that their Type IA/IA_{IN} 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/ IA_{IN} 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

Precise scope for change *

Segoe UI 16

Details of the changes

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

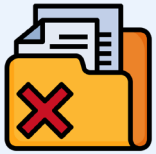
Segoe UI 16

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

For Questions: www.slido.com code: #EAFQA09

Upcoming features

Versioning to support the new variation classification



Organisation Deletion

Reference MAH Name (OMS Update)

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Next Steps & Closing

Kristiina Puusaari, eAF Product Owner, EMA

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eAF Q3-Q4 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 non -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

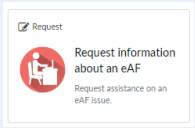
User Guidance on PLM Portal: Link

Q&A Document on PLM Portal: Link

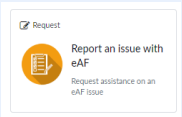
eAF News on PLM Portal: Link

PLM Newsletter: Subscribe Here

How can EMA be notified of eAF technical issues?



Ask a Question in EMA Service Desk



Report an Incident in EMA Service Desk

For issues related to organisational data from OMS, report an incident in EMA Service Desk

Ask a Question via email: plm.valuestream@ema.europa.eu

Consolidated NEW technical issues/new feature requests/questions on web-based eAF functionalities via email: plm.valuestream@ema.europa.eu

PMS data issue follow PMS guidance (either Service Desk or directly submitting corrections to xEVMPD

Note: Interactive pdf = the 'old' eAF from eSubmission website vs the PLM portal web-based eAF

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Thank you

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