

# eAF – Q&A Clinic

09 March 2026, 11:00 – 12:00 (CEST)

Webinar: WebEx

# Agenda



1

**Introduction**  
11:00 – 11:10

**Kristiina Puusaari**  
*eAF Epic Owner, EMA*

2

**Q&A Session**  
11:10 – 11:55

**Moderator:**  
**Francesco Stella**  
*eAF Change Management Team*

3

**Next steps & Closing**  
11:55 – 12:00

**Kristiina Puusaari**  
*eAF Epic Owner, EMA*

For Questions: [www.slido.com](https://www.slido.com) code: #EAFQA0801



# Send your questions via Slido

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



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**#EAFQA0903**



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



# Introduction

Kristiina Puusaari, eAF Epic Owner,  
EMA

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# Human variations eAF – eAF List



## The eAF lists

(all tabs: Draft, Deactivated, Completed and All) will retain the **sorting order** and the column visibility **until the local cache is deleted.**

The settings are **saved for each separate tab.**

Electronic application forms list + New application

**Draft** Deactivated Completed All Column visibility Download Refresh

Application form ID	Friendly name	Reference MAH	Created on	Last modified by	Status	Actions
VAR/26/4167	test prod	European Medicines Agency	17/02/2026 09:55	Mihaela Pereteatcu	Draft	<a href="#">Check</a> <a href="#">Copy</a> <a href="#">More</a>
VAR/26/4154	test post deployment - NAPs	European Medicines Agency	17/02/2026 08:59	Mihaela Pereteatcu	Draft	<a href="#">Check</a> <a href="#">Copy</a> <a href="#">More</a>
VAR/26/4152	test post deployment	European Medicines Agency	17/02/2026 08:43	Mihaela Pereteatcu	Draft	<a href="#">Check</a> <a href="#">Copy</a> <a href="#">More</a>
VAR/26/4127	Test certificate - before	European Medicines Agency	16/02/2026 17:40	Mihaela Pereteatcu	Draft	<a href="#">Check</a> <a href="#">Copy</a> <a href="#">More</a>
VAR/26/4124	prep certificate test	European Medicines Agency	16/02/2026 17:28	Mihaela Pereteatcu	Draft	<a href="#">Check</a> <a href="#">Copy</a> <a href="#">More</a>

Showing 50 entries Load more

# Human variations eAF – Super grouping for NAPs




## Domain \*

Human use

## Type of application

Single Regulatory Activity

Including a line extension 

Worksharing 

Super-grouping 

## Procedure type

Variation Type IAIN



For the eAFs where:

- there are **1 or more products selected from the same country**, and
- **1 or more scopes of type IA/IAIN.**

The user can manually select the “**Super-grouping**” checkbox (to be used in case the health authority previously approved the use of “Super-grouping” for the specific scenario.

# Human variations eAF – Counter



In the product selection page, there is a **more complete counter** which details:

- products shown,
- products added,
- products selected in total

For example, if there were 4 products selected and the user adds a new one, the counter will show: 100 products shown, 1 added, 5 selected in total

<input checked="" type="checkbox"/>	✓	Abacavir/Lamivudină Terapia 600 mg/300 mg comprimate filmate	Film-coated tablet	Abacavir, Lamivudine
<input type="checkbox"/>	✓	Abacavir/Lamivudină Viartis 600 mg/300 mg comprimate filmate	Film-coated tablet	Abacavir, Lamivudine
<input checked="" type="checkbox"/>	✓	Abatixent 2,5 mg comprimate filmate	Film-coated tablet	Apixaban
<input type="checkbox"/>	✓	Abatixent 5 mg comprimate filmate	Film-coated tablet	Apixaban

100 products shown, 4 added, 5 selected in total



# Human variations eAF – New variation classification



- *The revised Variations Regulation applies since 1 January 2025 for variation applications implemented and submitted to the European Medicines Agency (EMA) from 1 January 2025.*
- A single cut-off date for the entry into application (i.e., **15 January 2026**) is set out in the **final** version of the **Variations Guidelines**.
- [Guidance on the application of the revised variations framework | European Medicines Agency \(EMA\)](#) and [Heads of Medicines Agencies: Revised Variations Framework](#)

*If you find an incomplete scope (missing conditions, missing documentation, or different content/name for the details of a scope), please raise a Service Desk ticket with the RMS team ([Request RMS Service - Employee Center](#) )*

## Q&A Session

Kristiina Puusaari  
eAF Epic Owner, EMA

Francesco Stella  
eAF Change Management Team

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# Closing remarks

Kristiina Puusaari

eAF Epic Owner, EMA

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# eAF Useful Resources



**PLM Portal: [Link](#)**

**[eSubmission Website: Link](#)**

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

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

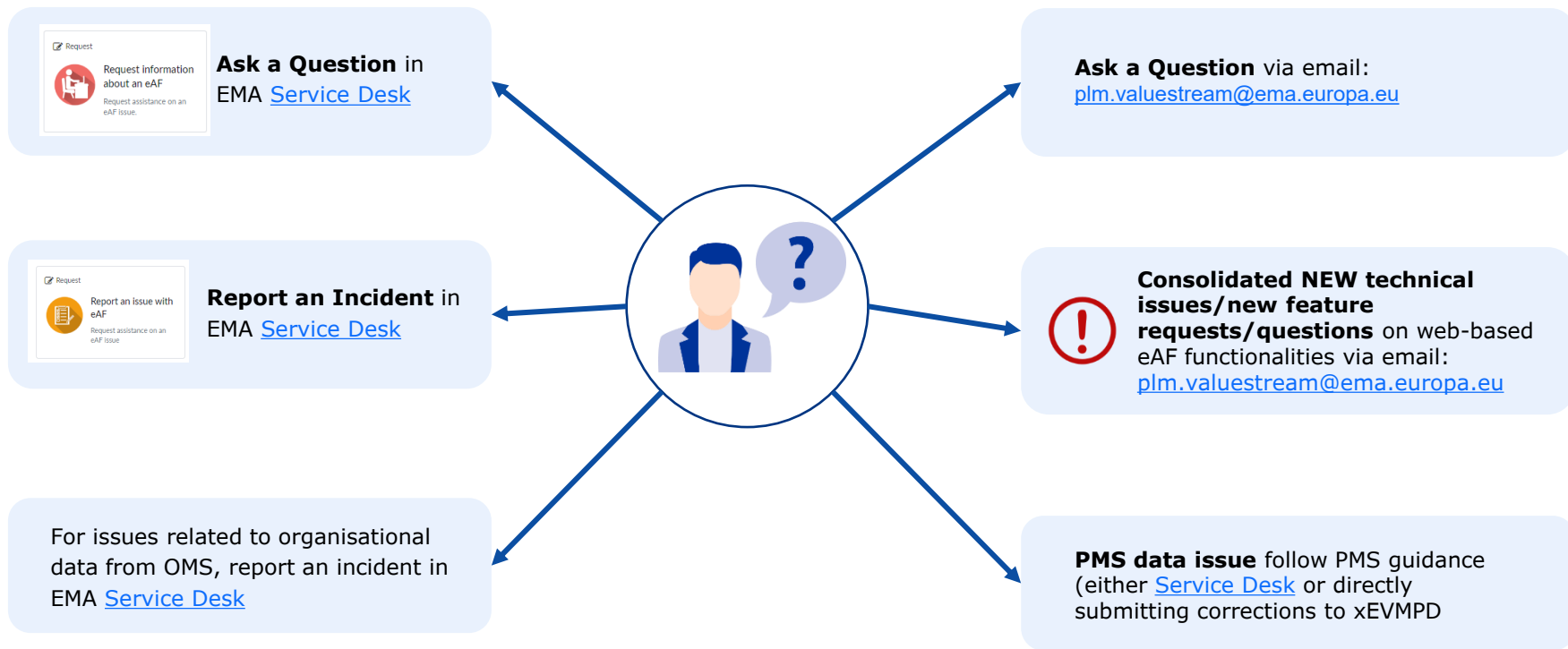
**[Q&A Document on PLM Portal: Link](#)**

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

**[PLM Newsletter: Subscribe Here](#)**



# How can EMA be notified of eAF technical issues?





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