EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

25 October 2024, 10:00 – 10:30 (CEST)
Webinar: WebEx

Agenda

EUROPEAN MEDICINES AGENCY

1	**Welcome** **10:00 – 10:05**	**Kristiina Puusaari** *eAF Product Owner, EMA*
2	**Q&A Session** **10:05 – 10:25**	**Moderator:** **Isabella Pedon** *eAF Change Management Team*
	Next steps & Closing **10:25 – 10:30** We will **record** the session	**Kristiina Puusaari** *eAF Product Owner, EMA*

Send your questions via Slido

We will **record** the session

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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

Welcome

Kristiina Puusaari, *eAF Product Owner, EMA*

Q&A session

Moderator: Isabella Pedon, *eAF Change Management Team*

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Audience Q&A

ⓘ Start presenting to display the audience questions on this slide.

Next Steps & Closing

Kristiina Puusaari, *eAF Product Owner, EMA*

Next Steps

Webinar for NCAs on web-based eAF variation– 7 November 2024 (11:00 – 12:00 CET)
NCA event - registration available soon on EU-NTC

Training and Q&A Clinic Human Variation eAF - 8 November 2024 (10:00 – 11:00 CET)

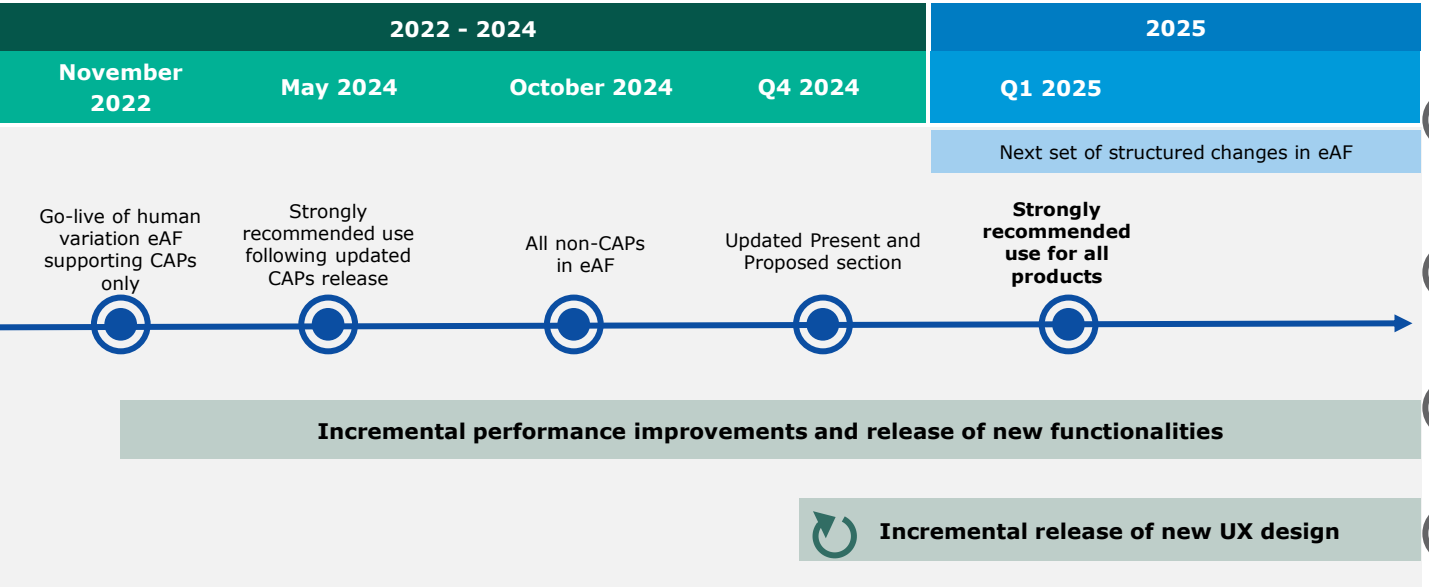
Q&A Clinic on eAF variations - 14 November 2024 (10:00 – 10:30 CET)

Public system demo: 12 December 2024

Join at slido.com #QANONCAPS

Human Variations electronic Application Form (eAF) – Key steps and milestones (October 2024)

OUTDATED



2025 & beyond	
UAT minus 2 months	UAT* announcement (*"Transition ready" form available)*
2 months after UAT	Confirmation of transition period start date
2 months after confirmation	Start of transition period
6 months after transition start	Use of variations web-form only

2026 & beyond	
Analysis & development of web forms	Marketing Authorisation Applications, Veterinary variations, Renewals

**2nd external UAT to confirm functionalities required for mandatory use

Note: CAPs and NAPs data in PMS is sourced from EMA's internal database and XEVMPD

Acronyms

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

XEVMPD: eXtended EudraVigilance Medicinal Product Dictionary

Legend

Key Milestone

Key Milestone

Dev activities for Human variations eAF

Recurring activity

Timeframes

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

eAF updated implementation timeline | Key points

OUTDATED

Background – Q2 and Q3 2024 work

What we did:

- Released updated CAPs in eAF*
- Strongly recommended the use of web eAF for CAPs
- Add Package feature
- **Released Performance Improvements**
- **Updated product search**

What we found:

- Data issues in PMS in CAPs and non-CAPs
- OMS issues affecting the PLM Portal, IRIS and UPD users
- Bugs in functionalities relating to non-CAPs in eAF
- Need for further performance improvements

Q4 2024 - H2 2025 Plan

Q4 2024:

- All non-CAPs in eAF. Recommended use for EMA led mixed CAP/non-CAP WS procedures
- Improved Present and Proposed section
- Further performance improvements

Q1 2025:

- **Recommended** use **for non-CAP procedures**
- Enhancements to non-CAP functionalities as requested by users
- Start development of the next set of structured changes (e.g. packages, manufacturers)

Q2 to Q4 2025:

- Further development and release of structured changes
- Incremental release of other features and fixes

Acronyms

API: Application Programming Interface
CAPs: Centrally Authorised Products
Non-CAPs: All nationally Authorised Products (incl. MRP/DCP/NP)
PMS: Product Management Service
PLM: Product Lifecycle Management
UI: User Interface

*including split & match-merge processes. The "Match-merge" process serves to include data from XEVMPD to products already released in PLM Portal. The "split" process serves to make released products ISO-IDMP compliant. Both processes are explained in detail in EU IG Chapter 7

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