Human Variations electronic Application Form (eAF) – Key steps and milestones (December 2023)

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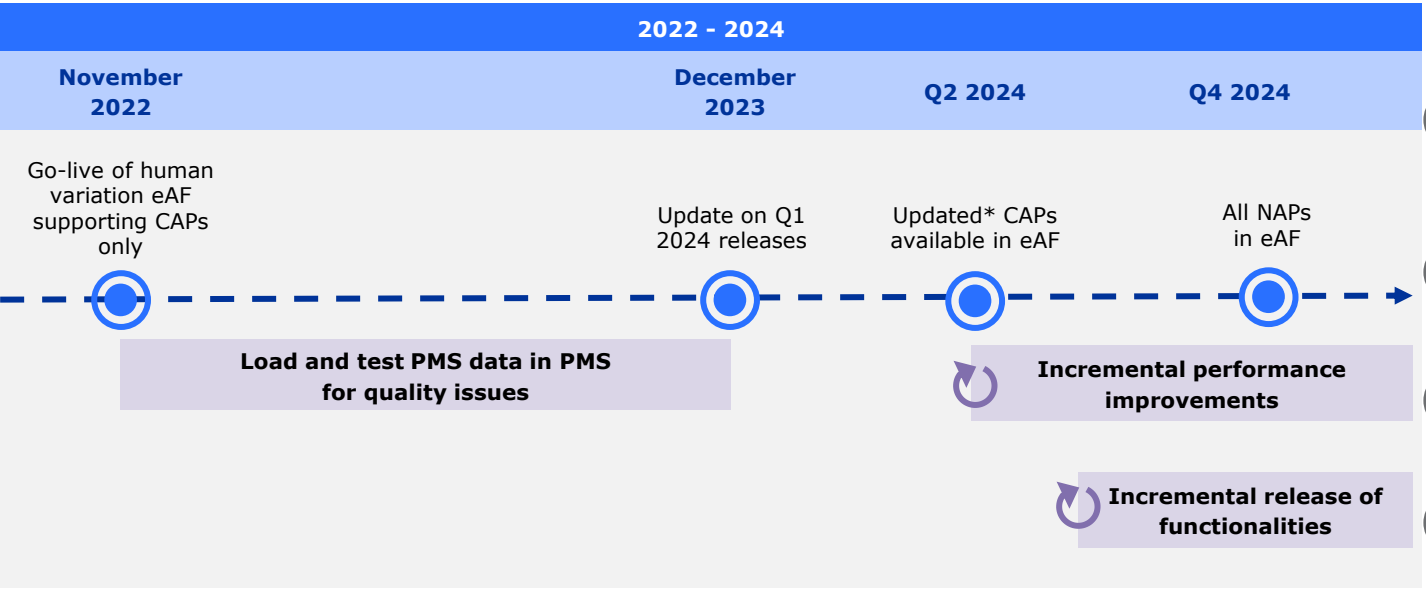

2025 & beyond	
UAT minus 2 months	UAT* announcement (*"Transition ready" form available)*
2 months after UAT	Confirmation of transition period start date
2 months after confirmation	Start of transition period
6 months after transition start	Use of variations web-form only

*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

*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 step/ Milestone

Dev activities for Human variations eAF

Recurring activity

Timeframes

eAF updated implementation timeline | Key points

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Background - Q4 2023 work

What we did:

- Load and test PMS data in PMS for quality issues
- Test PMS data in PLM Portal

What we found:

- Bugs in PMS related to match-merge* of CAPs
- Product UI data test (still ongoing)
- Technical issues preventing testing in eAF
- PLM Portal performance improvements required

2024 Plan

Q1 2024:

- Delivery of eAF features developed in Q4 2023
- Consolidation of development activities for PLM Portal product under one service provider

Q2 2024:

- ***Step 1:*** Release of all CAPs & NAPs in PMS database & updated* CAPs in eAF !
- ***Step 2:*** Delivery of PMS API (CAPs and NAPs view-only) and Product UI (CAPs view-only)

Q2 to Q4 2024:

Performance improvements and internal testing

Q4 2024:

NAPs release in eAF and Product UI, provided performance improvements are done

! In preparation of the updated CAPs load, 3-week period when recommended not submitting web-based eAFs in production to prevent validation issues.
The web-based eAF will remain accessible for familiarisation and training.

*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

Acronyms

API: Application Programming Interface
CAPs: Centrally Authorised Products
NAPs: Nationally Authorised Products
PMS: Product Management Service
PLM: Product Lifecycle Management
UI: User Interface