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

**Acronyms**
- **CAPs**: Centrally Authorised Products
- **NAPs**: Nationally Authorised Products
- **XEVMPD**: eXtended EudraVigilance Medicinal Product Dictionary

### Key steps and milestones (December 2023)

- **November 2022**: Go-live of human variation eAF supporting CAPs only

### 2022 - 2024

- **December 2023**: Update on Q1 2024 releases
- **Q2 2024**: Updated* CAPs available in eAF
- **Q4 2024**: All NAPs in eAF

### Incremental performance improvements

### Load and test PMS data in PMS for quality issues

### 2025 & beyond

- **2022 - 2024**
  - **Q4 2024**: Incremental release of functionalities

- **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

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

*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.

*Including split & match-merge processes.
eAF updated implementation timeline | Key points

**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

*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](#).

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**Acronyms**

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

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.