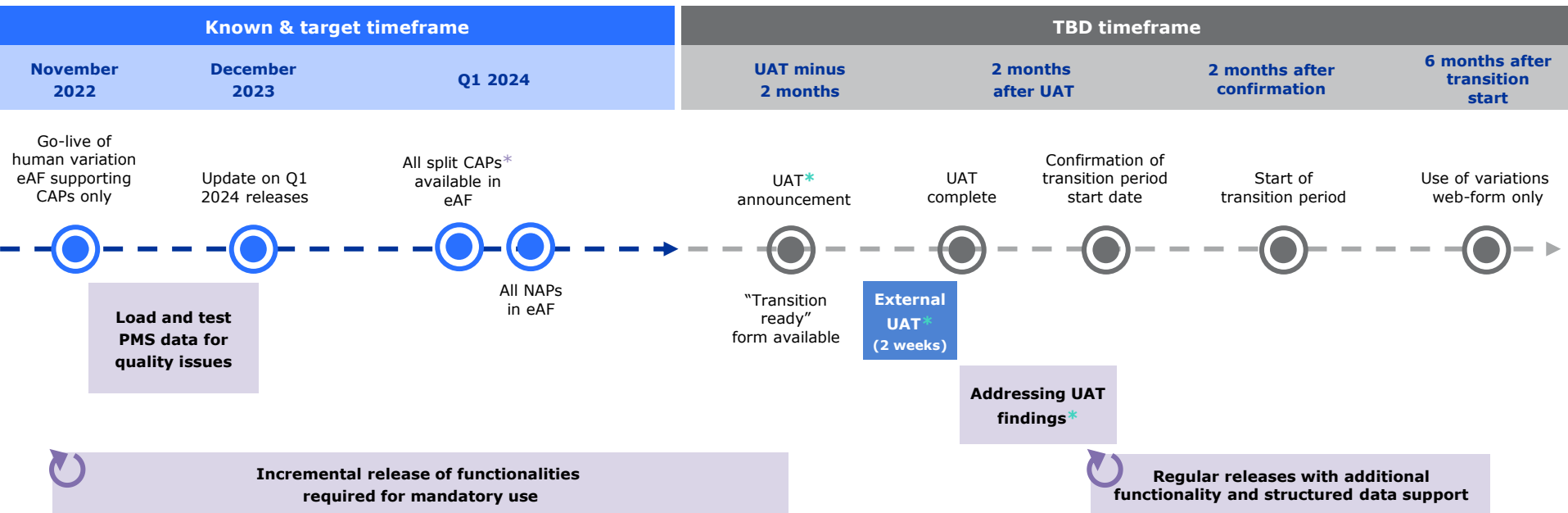


Human Variations electronic Application Form (eAF) – Key steps and milestones (October 2023)



EUROPEAN MEDICINES AGENCY



*CAPs migrated from SIAMED not following ISO IDMP structure. For this reason, they have undergone a further step in the data migration to PMS in addition to the match and merge protocol.

*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



User Acceptance
Testing (UAT)



Recurring
activity

Timeframes