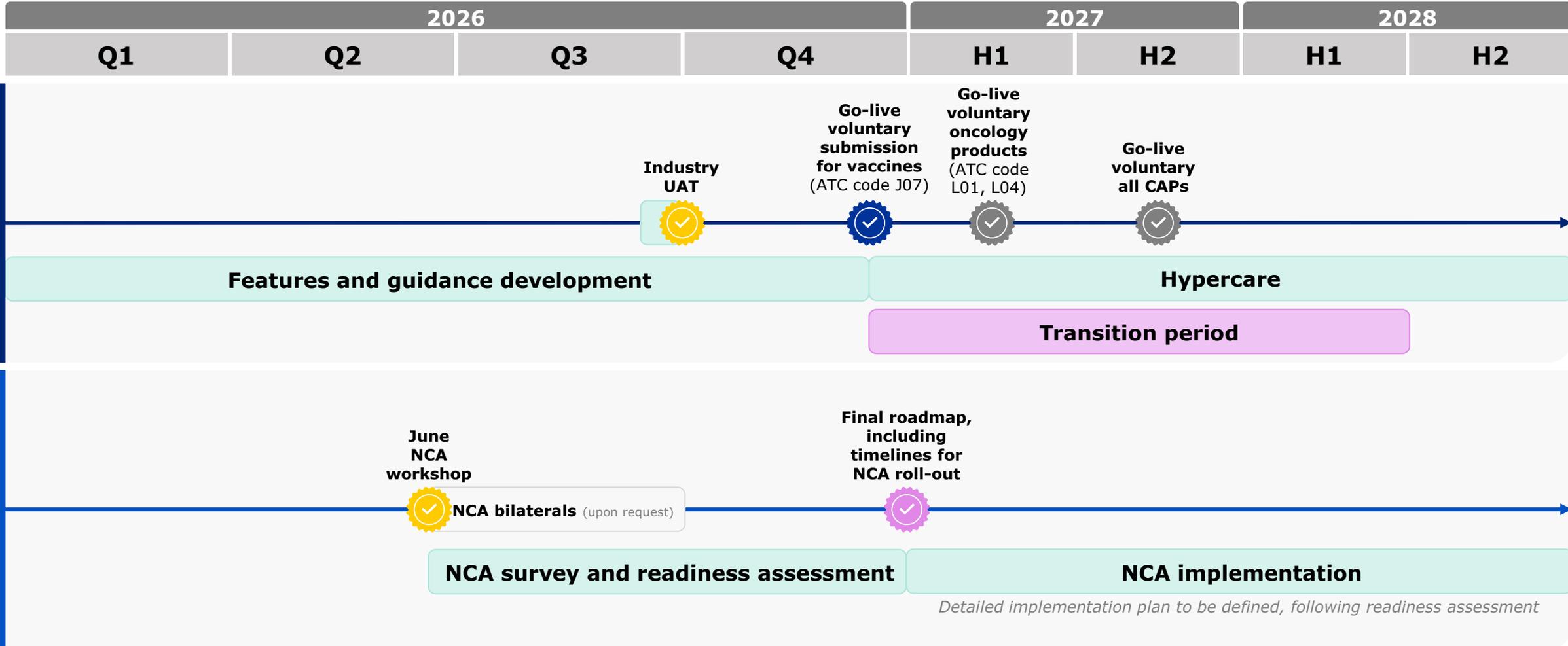


ePI implementation roadmap [DRAFT]



Acronyms

CAP: Centrally Authorised Product
Non-CAP: Non-Centrally Authorised Product
HMA: Heads of Medicines Agencies

NCA: National Competent Authority
TBC: To be confirmed
ATC: Anatomical Therapeutic Chemical
UAT: User Acceptance Testing

Legend

 Go-live
  Milestone
  Go-live TBC
 Dev. activities
  Annoucement

Features in development 2026



Developing and adapting **business process** for CAPs and NAPs



Guidance development



Stabilisation and **performance** optimisation



User Acceptance Testing



Additional **PLM portal development**



IRIS-eSubmission integration

Phased CAPs go live (from Q4 2026)

CAP progressive voluntary implementation by therapeutic area:



Vaccines



Oncology



Other therapeutic areas or progress to **all CAPs**

Kick-off implementation



Initial implementation **will not interfere** with the assessment



Applicants will be requested to **author / upload ePI** at the **PLM portal** through an extra step in process (alongside current Word/PDF submission)



Future vision: ePI integrated in a fully digitalised assessment



Once a product's PI is available in electronic format, it will **remain electronic in all subsequent variations**



CAPs: Initial ePI implementation for **English**, with all languages optional – **fully multilingual at a later stage**

NCA implementation



ePI central **repository proposed in NPL (new pharmaceutical legislation)** – model tested during the pilot



NCAs implementation may require:



Each NCA to do pre-implementation development work to adapt national systems as well as **NCA**s procedure change management



Additional development may be needed by EMA/NCA to support full interoperability of each NCA



Joint EMA/HMA Road Map for implementation will support orderly, well managed & timely go live

ePI public interface



ePI to be displayed on the **European Medicines Web Portal (EMWP)** for all EU medicines (multilingual) once developed



For CAPs, in the interim period until EMWP is available, it will be displayed on **EMA website** (on **EPAR page** of each medicine)



For **NAPs**, in addition to the **EMWP**, **NCA**s may decide to also display **ePI in their own national websites**.



ePI will be **publicly available** for any other third-party use