

ePI update: roadmap and next steps

16th Industry Stakeholder Platform
on the Centralised Procedure

Presented by Elizabeth Scanlan, ePI Product Owner



ePI Pre-implementation work currently ongoing



Actions from pilot recommendations:

- Training material to be created
- Guidance to be created
- Business processes to be elaborated
- Stabilisation of new features at PLM portal



User Acceptance Testing in planning

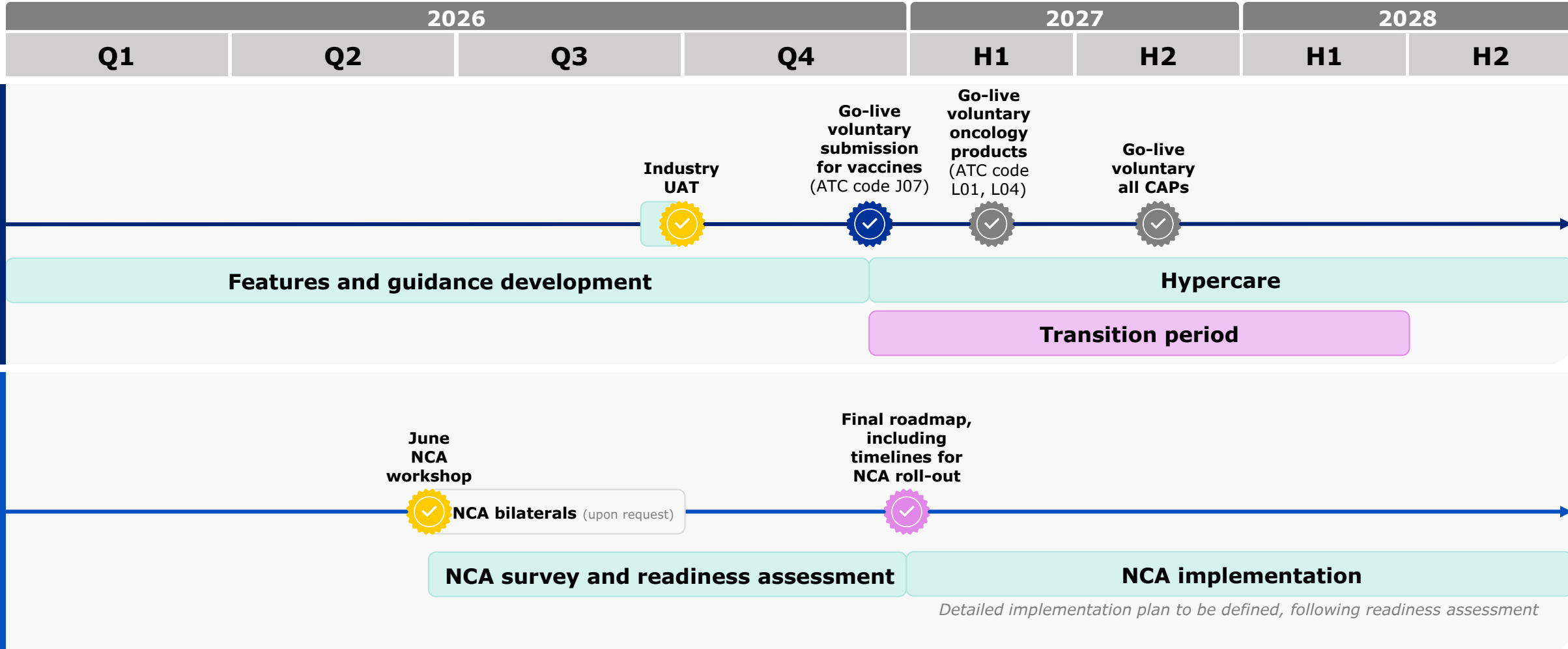


Road map published



Preparedness for new pharmaceutical legislation

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
-  Announcement

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**

UAT for industry prior to go live



Estimated end Q3 pending portal readiness: timing to ensure ePI team derive maximum benefit from testing



Participants from industry only, open call on EMA website/PLM portal



Goal: testing of core PLM portal functionality considered essential for go live to confirm go-no go for Q4 go live

Country-specific & paper-specific information

❖ **Reporting of suspected side effects**

Proposal to include URL linking to a website that includes reporting details for all EU countries

❖ **List of local representatives**

it is recommended to list all local representatives in ePI.

❖ **Dates**

Dates will not be in ePI at go live; ePI team to explore feasibility of other options with minimal disruption

❖ **Standard statement including name of Member State Agency**

It is recommended not to include this optional part of the standard statement in CAP ePI

❖ **Manufacturer responsible for batch release**

No update currently



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Thank you

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