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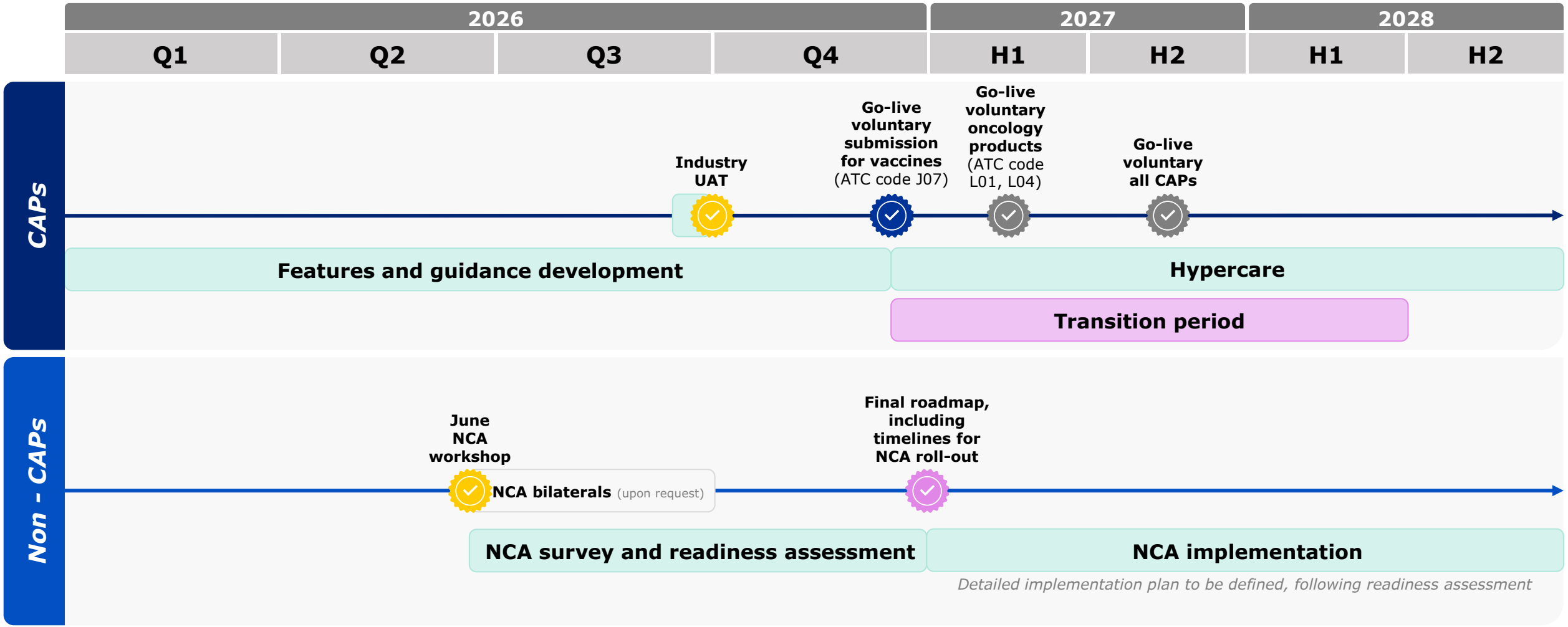
ePI update: roadmap and go live for CAP vaccines

17th Industry Standing Group (ISG) meeting

Presented by Amparo Revuelta,
ePI Implementation Lead, Human Medicines Division

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

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ePI pre-implementation work ongoing

- Training material creation
- Guidance creation
- Business processes to be published
- Stabilisation of new features at PLM portal

NCA readiness assessment: open day, bilaterals, survey

Preparation for end Q3 User Acceptance Testing: you are invited!

Q4: ePI roles available in EMA Account Management

Go-live: ePI can be submitted for CAP vaccines (ATC J07)

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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

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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 when new legislation in application**

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Practical guidance

Available now

✓ **Registration Guide**: how to get your ePI role

✓ **User guide for applicants**: know your way around the PLM portal

For importing FHIR:

✓ **Implementation guide**: technical blueprint for the EU ePI Common Standard

✓ **Style guide**: what styling to include and what not to include in your ePI

✓ **QRD template lists**: codes and rules needed for creating your ePI

Coming soon

➲ **Training on use of PLM portal** for applicants: interactive, user-friendly, self-paced training on working in the PLM portal as an applicant

➲ **Guide for ePI in regulatory procedures**: when ePI should be submitted in the business process

➲ **Guide for translators**: how should translators work with FHIR XML

➲ **Guide for non-compliant PI**: what to do if PI is not compliant (e.g., mandatory sections missing or split/combined etc)

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