AstraZeneca

Roadmap for eCTD v4.0

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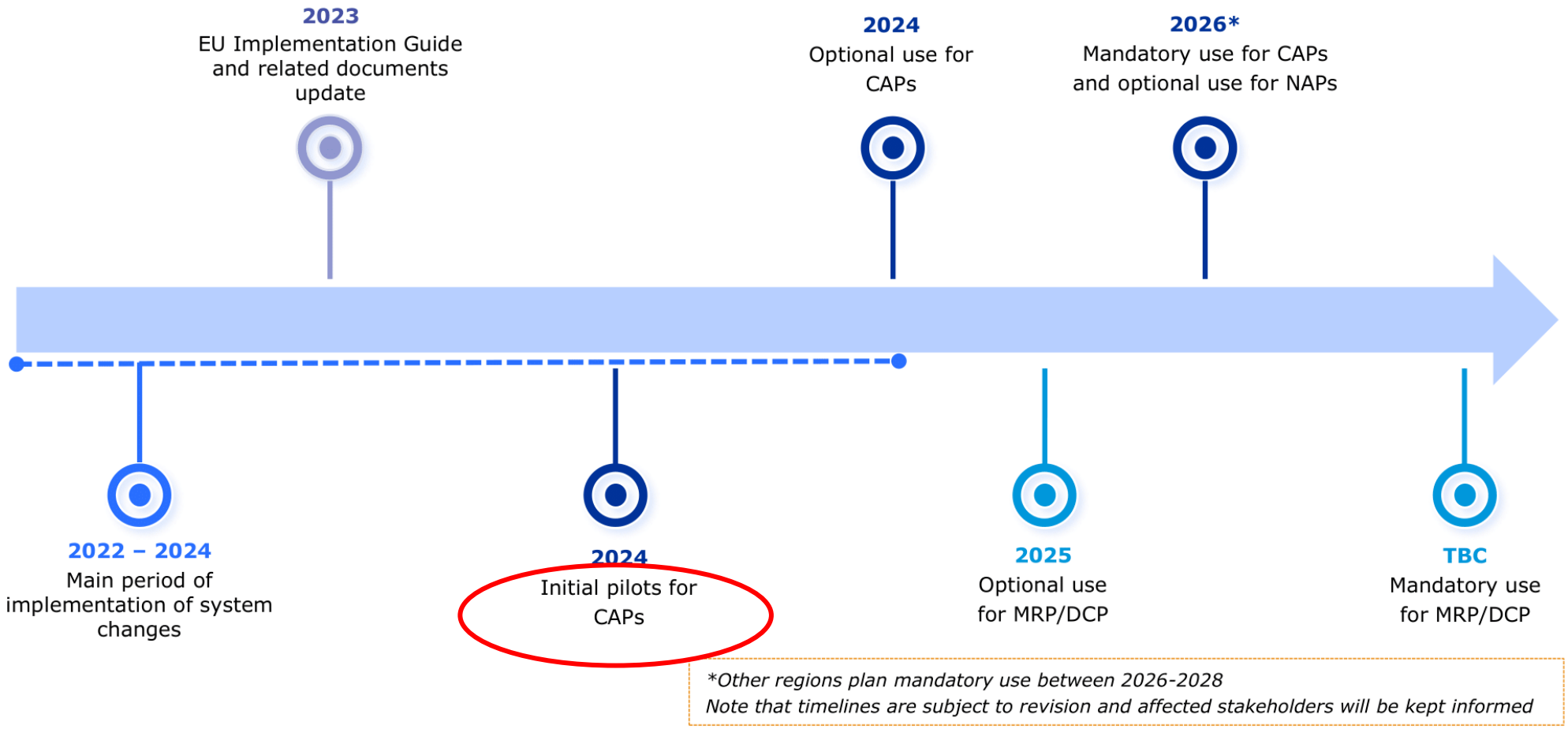
ICH eCTD v4.0 Timelines – Next Update Planned July 2023

https://ich.org/page/ich-electronic-common-technical-document-ectd-v40

Region	Technical Pilot[1]	Implementation Dates[2]	Implementation Documents
ANVISA, Brazil	2Q 2023 (Planned)	3Q 2023 (Production Pilot) 2023 (Voluntary)	TBD
EC, Europe	2024 CAPs (Planned)	2024 (Voluntary for CAPs) 2025 (Voluntary for MRP/DCP) 2026 (Voluntary for NAPs) 2026 (Mandatory for CAPs) TBC (Mandatory for MRP/DCP)	EC, Europe regional implementation page
FDA, United States	2022 - IQ 2023	2023 (Voluntary) 2028 (Mandatory)	FDA, United States regional implementation page
Health Canada, Canada	2023 (Planned)	2024 (Voluntary) 2027 (Mandatory)	Health Canada, Canada regional implementation page
MHLW/PMDA, Japan	2Q 2021 (Completed)	2022 (Voluntary) 2026 (Mandatory)	MHLW/PMDA, Japan regional implementation page
Swissmedic, Switzerland	2024 (Planned)	2024 (Voluntary) 2028 (Mandatory)	Swissmedic, Switzerland regional implementation page
TGA, Australia	TBD	2023 (Voluntary)	2023 (Planned)

EMA eCTD v4.0 Proposed Timeline

eCTD v4.0 Timeline



Considerations for: Road Map for Implementation 1

- Plans for elimination of paper, e-paper in the transition to eCTD
- Strategic Decisions
  - Data driven TOC* (vs. browser) makes it easier to transition from paper.
    - Documents vs. Folders (3.2) make the transition easier for ANVISA
    - Every Document gets a unique ID
    - Context of use Objects
    - Impact of Authoring Changes to metadata and granularity needs to be assessed by sponsors and HA's for endorsing content granularity.
  - Assess ICH M4 and SPQS Implications on eCTD 4.0 Structure
  - Strategy for using and lifecycling metadata that was not used previously.
  - Strategy for maintenance of lifecycle is needed

Considerations for: Road Map for Implementation 2

- Use FHIR (Fast Healthcare Interoperability Resources) to link eCTD with IDMP (Identification of Medicinal Products)
  - FHIR endorsed as basis for API for PMS : The Carrier, Transport Mechanism
  - Strategy for dealing with this: FHIR HL7 will not support RPS
  - HL7 incorporating ISO IDMP Standards into FHIR Specifications; but some terminology between IDMP and eCTD 4.0 is different and needs reconciliation
    - Module 1: Application Forms – DADI (starting October 2022 for variations)
    - Module 2+3: Quality Data – PQ/CMC (FDA Guideline from March 2022)
    - Module 2: Art 57 Data / ICSR – (June 2022 deadline) for IDMP
    - Module 1: ePI – structured labelling (ongoing; roadmap announced)
- Next Generation eCTD ?

THANK YOU