6th MDR Eudamed Clinical Investigation Performance Study WG meeting

Implementation plan update

19/09/2019
DG GROW

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Meetings

- **19/09/2019 – Clinical Investigations WG**
- 03/10/2019 – Data Exchange
- 24/10/2019 – NB & Certificates WG

Project deliverables

- Eudamed information system
  - Restricted site
  - Public site
- Data Exchange solutions

- User guide
- Technical documentation (for Data Exchange)
- Training material
- Application Support
- Playground

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Feature priority

Features	EUDAMED Priority
Serious Adverse Events	3rd Release (5/2021)
Application / notification Management	4th Release (5/2022)
End Report	4th Release (5/2022)
Coordinated Assessment Procedure	4th Release (5/2022)

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State of play 1/7

FS-CIPS-001: Manage application/notification for CI/PS

- Analysis and requirements to be finalised by June 2020

FS-CIPS-002: Withdraw application or notification for CI/PS or PMCF/PMPF

- Analysis and requirements to be finalised by November 2020

FS-CIPS-003 : Manage validation of application for CI/PS and setting of validation date

- Analysis and requirements to be finalised by June 2020

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State of play 2/7

FS-CIPS-004: Manage authorisation of CI/PS and setting of time limit for authorisation

- Analysis and requirements finalised by June 2020

FS-CIPS-015: Manage list of Ethics Committees

- Analysis requirements to be finalised by January 2021

FS-CIPS-005: Enter and communicate the start of the CI/PS or re-start after a suspension or temporary halt or start with substantial modification

- Analysis requirements to be finalised by January 2021

FS-CIPS-006: Manage substantial modifications to CI/PS after authorisation or PMCF/PMPF

- Analysis requirements to be finalised by January 2021

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State of play 3/7

FS-CIPS-007: Manage authorisation for substantial modifications to CI/PS or PMCF/PMPF

- Analysis and requirements finalised by January 2021

FS-CIPS-008: Manage recording and reporting of adverse events that occur during CI/PS

- Analysis and requirements finalised by June 2020

FS-CIPS-009: Manage information at the end of a CI/PS or PMCF/PMPF or in the event of a temporary halt or early termination

- Analysis and requirements finalised by January 2021

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State of play 4/7

FS-CIPS-010: Manage coordinated assessment procedure for CI/PS

- Analysis and requirements finalised by January 2021

FS-CIPS-011: Manage exchange of information and communication to all MS and the Commission on decisions and the grounds therefore related to CI/PS

- Analysis and requirements finalised by January 2021 (depending on FS-CIPS-003, FS-CIPS-004, FS-CIPS-007)

FS-CIPS-012: Search and view information on CIPS (only for SAE)

- SAE Analysis and requirements finalised by June 2020
- Remaining Analysis and requirements finalised by January 2021

State of play 5/7

FS-CIPS-013: Machine to machine (M2M) CI/PS information *upload*

- SAE Analysis and requirements finalised by June 2020
- Remaining Analysis and requirements finalised by January 2021

FS-CIPS-014: Machine to machine (M2M) CI/PS information *download*

- SAE Analysis and requirements finalised by June 2020
- Remaining Analysis and requirements finalised by January 2021

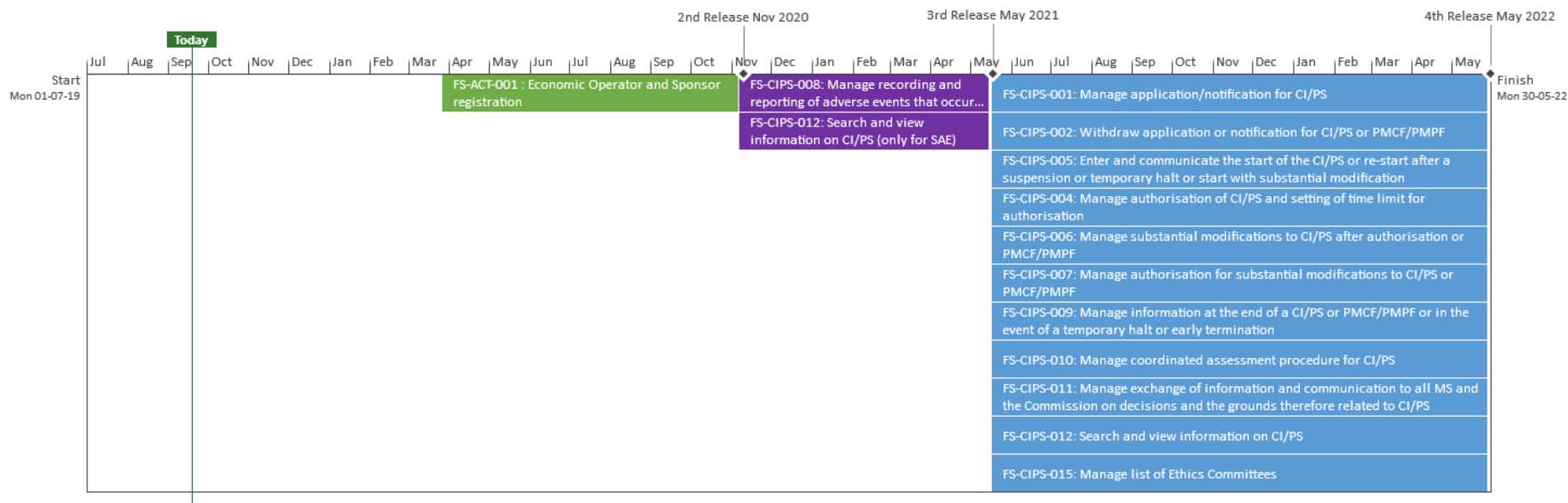European Commission

State of play 6/7

FS for public site - specifications will follow after the specifications for the restricted site (to follow in parallel)

- **FS-PUB-CIPS-001 :** Search and view CI/PS (application/notification) information and related updates for related information made publicly available

- **FS-PUB-CIPS-002 :** Search and view CI/PS reports and summaries made publicly available

- **FS-PUB-CIPS-003 :** Search and view reported adverse events and device deficiencies and related updates for related information made publicly available (tbd)

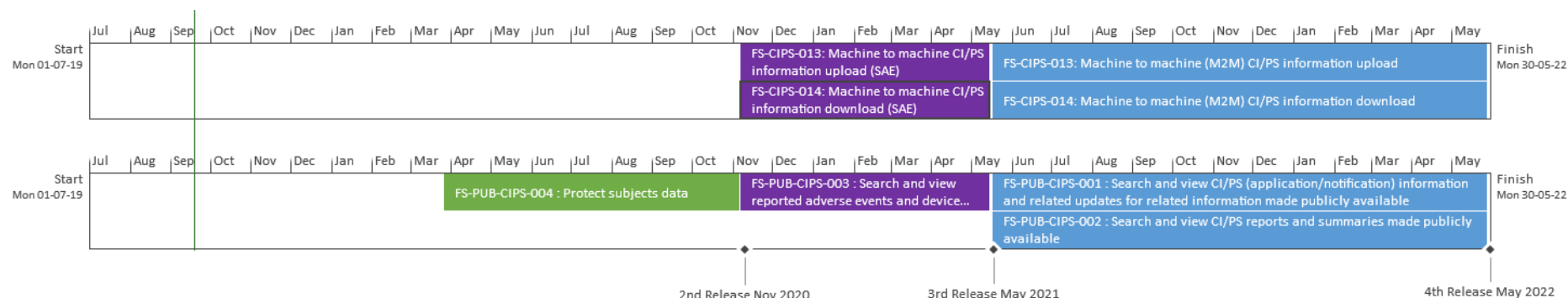- **FS-PUB-CIPS-004 :** Protect subjects data

Playground

- The Eudamed First Playground on CIPS (with SAE) will be available around Q1 2021 (for Third Release).

Implementation Plan 1/2

Implementation Plan 2/2

Q & A

Thank-you for your collaboration !

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