5th MDR Eudamed Clinical Investigation / Performance Study WG Meeting

Implementation Plan update

16/05/2019
DG GROW

Content

1. Meetings
2. Project deliverables
3. Working documents
4. State of play FS level
5. Implementation plan update

European Commission

Upcoming WG Meetings

➢ **16/05/2019 –** Clinical Investigation

➢ 23/05/2019 – Market Surveillance

➢ 21/06/2019 - NB & Certificates

➢ 29/08/2019 – Vigilance

➢ 19/09/2019 – Clinical Investigation

➢ 03/10/2019 – Data Exchange

➢ 17/10/2019 – Market Surveillance

European Commission

Project deliverables

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

- User guide
- Technical documentation
- Training material
- Technical support
- Demos / Playground

European Commission

Working documents

1. Functional Specifications document 4.1 (which contains):
   - Legal requirements
   - Functional specifications
2. Business Process Overview 2.0
3. Use Cases / Use Case diagram
4. Data dictionary, Security matrix, Business rules
5. Data models
6. Wireframes / Mock-ups

European Commission

State of Play

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

- Analysis and requirements to be finalised by June '19

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

- Analysis and requirements to be finalised by June '19

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

- Analysis and requirements to be finalised by Q3/19

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

- Analysis and requirements finalised by Q3/19

FS-CIPS-015: Manage list of Ethics Committees

- Analysis requirements to be finalised by Q3/19

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 and requirements to be finalised by Q3/19

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

- Analysis and requirements to be finalised by Q4/19

European Commission

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

- Analysis and requirements finalised by Q3/19

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

- Analysis and requirements finalised by Q4/19

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 Q4/19

European Commission

State of Play

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

- Analysis and requirements finalised by Q1/20

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

- Analysis and requirements finalised by Q1/20 (dependency on FS-CIPS-003, FS-CIPS-004, FS-CIPS-007)

FS-CIPS-012: Search and view information on CI/PS

- Analysis and requirements finalised by Q1/20

European Commission

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

Analysis and requirements finalised by Q2/20

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

Analysis and requirements finalised by Q2/20

European Commission

FS for Public site - will follow after the specifications for the restricted site reach advanced/complete status (*tbd*)

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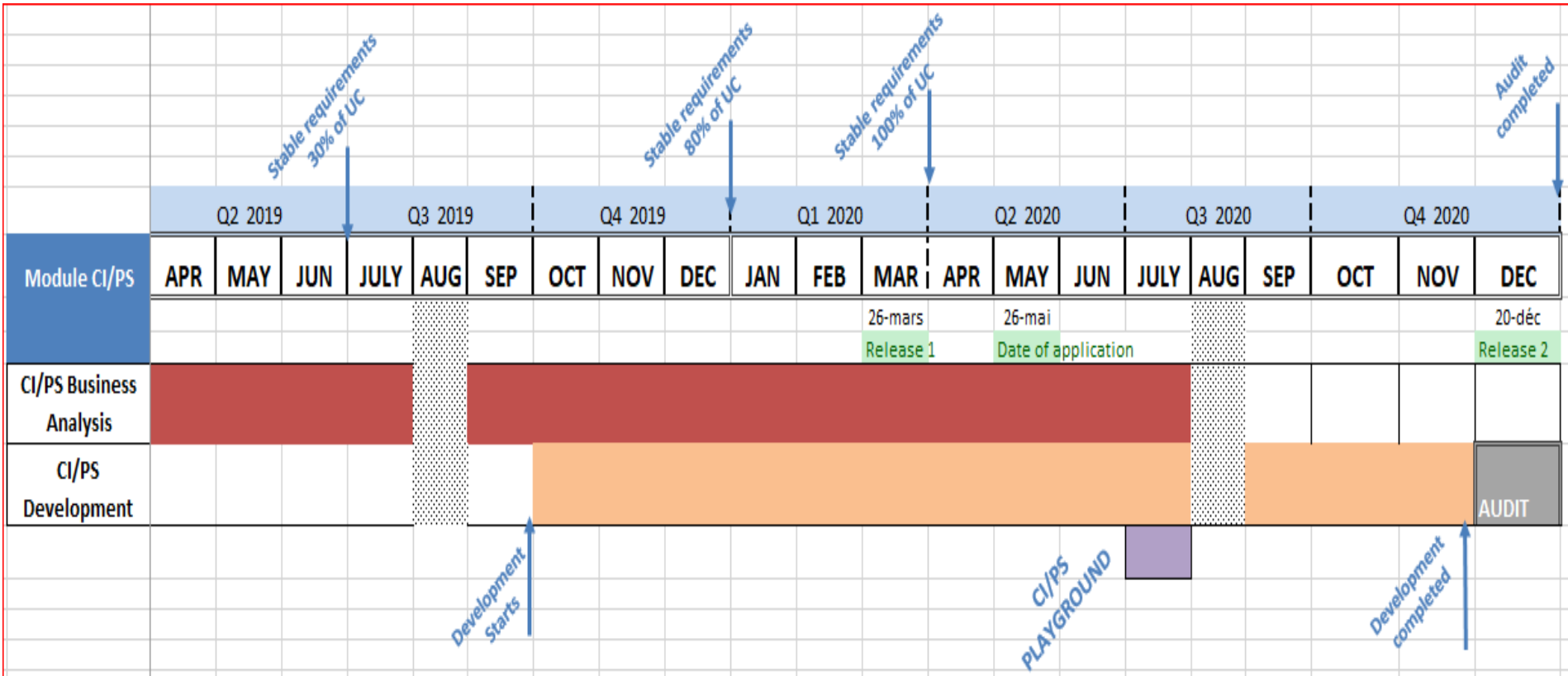
- **FS-PUB-CIPS-004** : Protect subjects data

FS Horizontal features - will follow after the specifications for the restricted site reach advanced/complete status

- **FS-EUD-006.04** Enable a LAA/LUA of a <u>sponsor</u> or a CA to grant/remove access to users for a specific CI/PS of this sponsor/associated to this CA.

  Analysis and requirements expected finalised by **Q3/19**

European Commission

Playground for CI/PS

- A Playground environment is planned to be provided towards Q3/2020 with purpose to solicitate additional feedback and provide user experience

- It will be complimented by Quick Guides

- Please note that no real information should be encoded in the playground, only dummy data for verification of the implemented functionality.

- A functional mailbox for questions and comments will also be communicated in due time

European Commission

Implementation Plan update

Q & A

Thank-you for your collaboration !

European Commission