8ᵗʰ MDR Eudamed NB & Certificates ad hoc WG Meeting

Implementation Plan Update for NB & Certificates

24/10/2019

DG GROW

Content

- Meetings
- Project deliverables
- Working documents
- Playground deliverables
- State of play
- Public site - state of play
- Implementation Plan

Upcoming WG Meetings

Before 2019, 31 WG meetings done and 6 Steering Committee meetings (since 2016)

During 2019, more than 10 WG meetings done.

- 29/08/2019 – 5th Vigilance WG

- 19/09/2019 – 6th CI/PS WG

- 03/10/2019 – 6th Data Exchange WG

- 24/10/2019 – 8th NB and Certificates WG

- Q1 2020 – 6th Vigilance WG

- Q1 2020 – 9th NB and Certificates WG

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Project deliverables

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

- Technical documentation
- Technical support
- Playground

Working documents

- Functional Specifications document contains:
  - Legal requirements
  - Functional specifications
  - Non-functional specifications
- Process overviews / use cases
- Data dictionary, Security matrix, Business rules
- Wireframes / Mock-ups
- Implementation plan for Playground and go-live

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Playground deliverables

Playground (February 2020) – 4th Version

- Registration of a Certificate (Basic flow without CECP and SSCP)
- Search and view Certificates
- Search and view Notified Body data from NANDO

Playground (April 2020) - 5th Version

- Registration of a CECP
- CECP management
- Registration of a Certificate (including CECP and SSCP)
- Management of refused certificates

Playground (Jun 2020) - 6th Version

- Update Certificates
- Management of certificate corrections
- Notification of refusal of withdrawal of applications for Conformity Assessment

Playground (March 2021) - 7th Version

- Management of Summary reports
- Management of Nominated Expert list
- Management of request for withdrawal/suspension of certificate(s)
- Management of Expert panels

State of play I

FS-CRF-005 : **Issued certificates registration**

- Analysis – FINALISATION / Development Started

FS-CRF-006 : **Registration of new certificate version**

- Analysis - FINALISATION

FS-CRF-007 : **Registration of refused certificates**

- Analysis - FINALISATION

FS-CRF-008 : **Search and view certificates and refused certificates**

- Analysis on-going

FS-CRF-011 : **Provide NB actor and designation data**

- Analysis COMPLETED

FS-CRF-012 : **Manage list of subsidiaries**

- Analysis COMPLETED

FS-CRF-013 : **View information related to NB**

- Analysis on-going

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State of play II

FS-CRF-014 : **Clinical evaluation consultation procedure (CECP) for CECP devices**

- Analysis on-going

FS-CRF-015 **Workflow control for CECP**

- On complete implementation

FS-CRF-016 : **Search and view information on CECP**

- Analysis on-going

FS-CRF-019 : **Machine to machine (M2M) Certificate information upload**

- Analysis on-going

FS-CRF-020: **Machine to machine (M2M) conformity and certificate information download**

Export using a M2M web service information submitted for a conformity assessment or a certificate by NB together with related information in Eudamed to the national MS database of that CA

- Analysis on-going

State of Play III

FS-CRF-009 : **Notification of refusal or withdrawal of applications for conformity assessment**

- Analysis on-going

FS-CRF-010 : **Search and view notifications of refusal or withdrawal of applications for conformity assessment**

- Analysis on-going

FS-CRF-018 : **Grant access to the first Local NB Actor Administrator**

Enable the designating authority of a NB to validate the access requests of the first Local NB Actor Administrator

- Analysis on-going

State of Play IV

FS-CRF-002 : **View list of nominated experts**

- Analysis to be started

FS-CRF-003 : **Manage list of nominated experts**

- Analysis to be started

FS-CRF-004 : **Manage MS Summary Report**

- Analysis to be started

FS-CRF-001 : **View MS Summary Report on monitoring and on-site assessment activities regarding NBs**

- Analysis to be started

FS-CRF-020: **Machine to machine (M2M) conformity and certificate information download**

- Export using a M2M web service NB own information submitted for a certificate by that NB in Eudamed to that NB database

State of Play V

FS-CRF-021: **Manage list of expert panels**

- Analysis to be started

FS-CRF-022: **View list of expert panels**

- Analysis to be started

FS-CRF-017 : **Requested withdrawal/suspension of certificates**

- Analysis to be started

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Public site : Playground (March 2020)

FS-PUB-CRF-001 : **View information about NBs**
- Analysis on-going

FS-PUB-CRF-003 : **Search and view certificates**
- Analysis on-going

FS-PUB-CRF-005 : **View both the expert panel opinion and the justification of the NB**
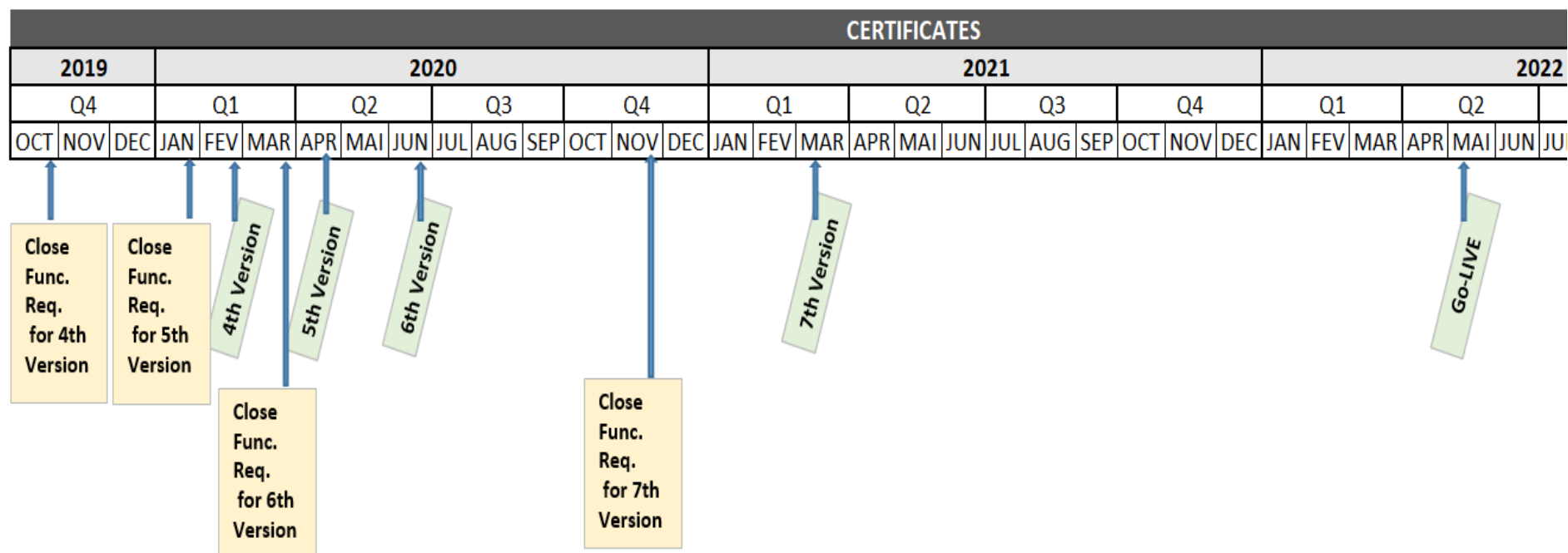- Analysis to be started

Public Site : (March 2021)

FS-PUB-CRF-004 : **View MS's Summary Reports on NBs**
- Analysis to be started

Implementation Plan

Thank-you for your collaboration !

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