5th MDR Eudamed Vigilance WG Meeting

Implementation plan update

29/08/2019
DG GROW

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Meetings

- **29/08/2019 – Vigilance WG**
- 19/09/2019 – Clinical Investigations WG
- 03/10/2019 – Data Exchange
- 24/10/2019 – NB & Certificates WG
- End January 2020 (TBC) – Vigilance 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

Feature priority

Features	EUDAMED Priority
MIR - Manufacturer Incident Report	2nd Release (11/2020)
FSCA - Field Safety Corrective Action	2nd Release (11/2020)
FSN - Field Safety Notice	2nd Release (11/2020)
PSR Form (MPSR) and PSR Related MIR ("Light MIR")	3rd Release (5/2021)
PSUR - Periodic Safety Update Report	3rd Release (5/2021)
TR - Trend Report	4th Release (5/2022)
Coordinated Assessment	4th Release (5/2022)

Status of Report Templates

	Work group				
Features	**Version Date**	**Version**	**Status Form**	**EUDAMED Status**	**Expected final version Date of Templates**
MIR -Manufacturer Incident Report	01/2019	7.1	Final	Under finalisation	Finalised
FSN - Field Safety Notice	06/2018	1.0	Final	Under finalisation	Finalised
FSCA - Fields Safety Corrective Action	03/2019	3.0	Final	Under finalisation	Finalised
PSR Related MIR ("Light MIR")	12/2018	N/A (MIR 7.0)	Final	Stand By	Finalised
PSR Form (MPSR)	01/2019	1.4	Final	Stand By	Finalised
PSUR – Periodic Safety Update Report	02/2019	3.3	Working	Stand By	Q1 2020
TR - Trend Report	04/2018	V0.1	To start	Stand By	Q3 2020

State of play 1/6

FS-VGL-004 : Manage serious incidents reports (MIR)

- The Manufacturer Form is now finalised (at v7.1)
- Analysis ongoing – to be completed in Q3 2019
- Development to start in Q1 2020

FS-VGL-005 : Manage FSCAs

- The FSCA Form is under finalisation (v3.0)
- Analysis ongoing – to be completed in Q3 2019
- Analysis ongoing – data dictionary, Use Case register, and wireframes ready

State of play 2/6

FS-VGL-006 : Manage FSNs

- The FSN Template is finalised (at v1.0)
- Analysis ongoing – to be completed in Q3 2019
- Analysis ongoing - data dictionary, Use Case register, and wireframes ready

FS-VGL-003 : Manage PSRs

- The “Light MIR” Template is finalised
- The MPSR Template is finalised
- Analysis started

State of play 3/6

FS-VGL-001 : Manage PSUR

- The Form is at v3.3, expecting the Final version by Q1/2020
- Analysis started – awaiting Final version

FS-VGL-002 : Manage Trend Reports

- Trend Report not started, expecting the Final version by Q3/2020
- Analysis not started

FS-VGL-007 : Manage coordinated assessment procedure

- Analysis and Requirements to be defined by end of 2020

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State of play 4/6

FS-VGL-010 : Search and view post-market surveillance and vigilance information

- Analysis follows respective FS of each Form

FS-VGL-011 : Grant CAs of third countries or International organisations, appropriate access level to Eudamed

- For future release (after release 4)

FS-VGL-012 : Analysis of vigilance data assessment

- Analysis not started – to be done in collaboration with JRC (to see what will be possible for release 4)

State of play 5/6

FS-VGL-008 : Machine to Machine (M2M) vigilance and post-market surveillance information *upload*

- Implementation will be done in parallel of the corresponding Functional Specifications
- Analysis at early stages

FS-VGL-009 : Machine to Machine (M2M) vigilance and post-market surveillance information *download*

- Implementation will be done in parallel of the corresponding Functional Specifications
- Analysis at early stages

State of play 6/6

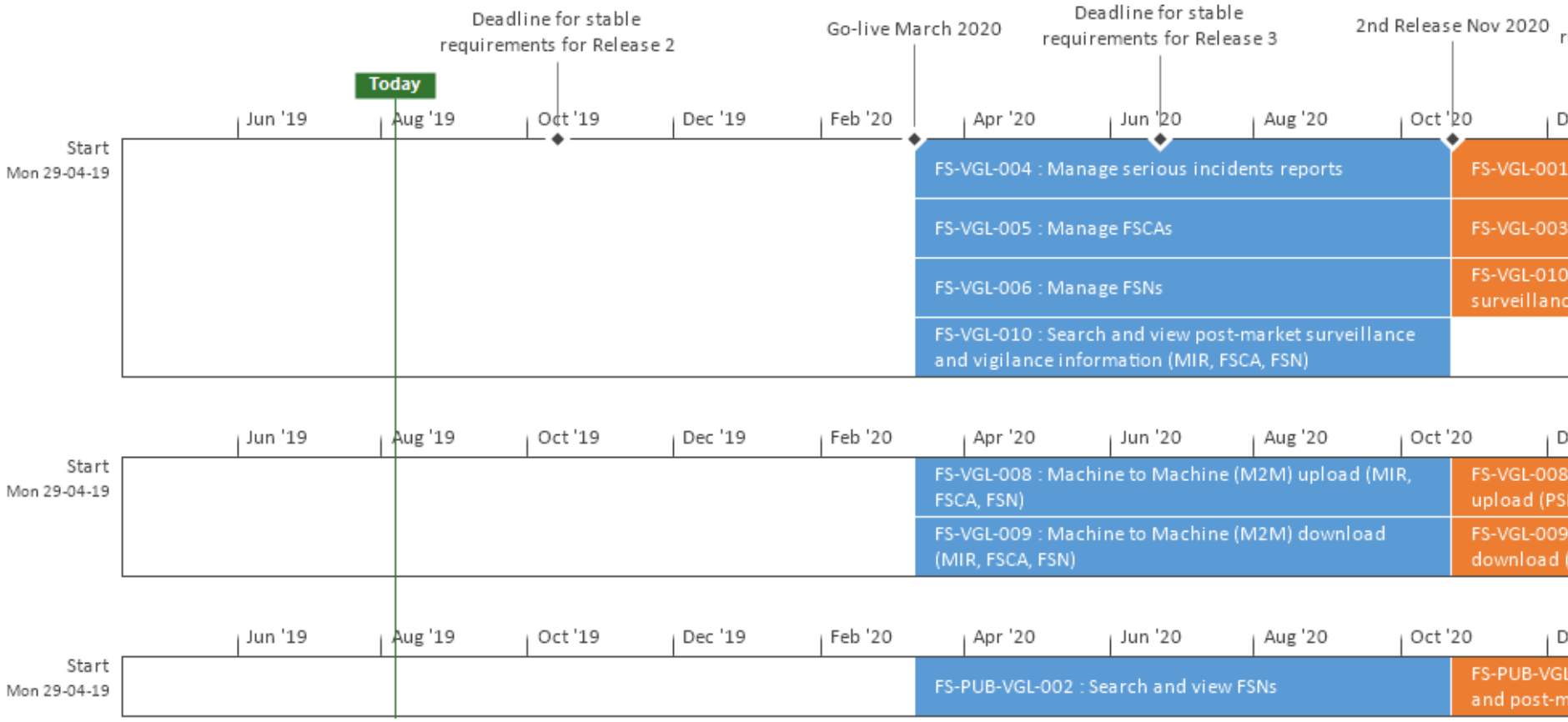
FS for public site - specifications will follow after the specifications for the restricted site

- **FS-PUB-VGL-002**: Search and view FSNs
  - Analysis started
- **FS-PUB-VGL-001**: Search and view vigilance and post-market surveillance information
  - Analysis not started yet (waiting for outcome of Transparency TF – MIR)

Playground

- The Eudamed First Playground on Vigilance (with MIR or FSCA) will be available in Q2 2020 (for Second Release). Exact date will be communicated.

Implementation Plan 1/2



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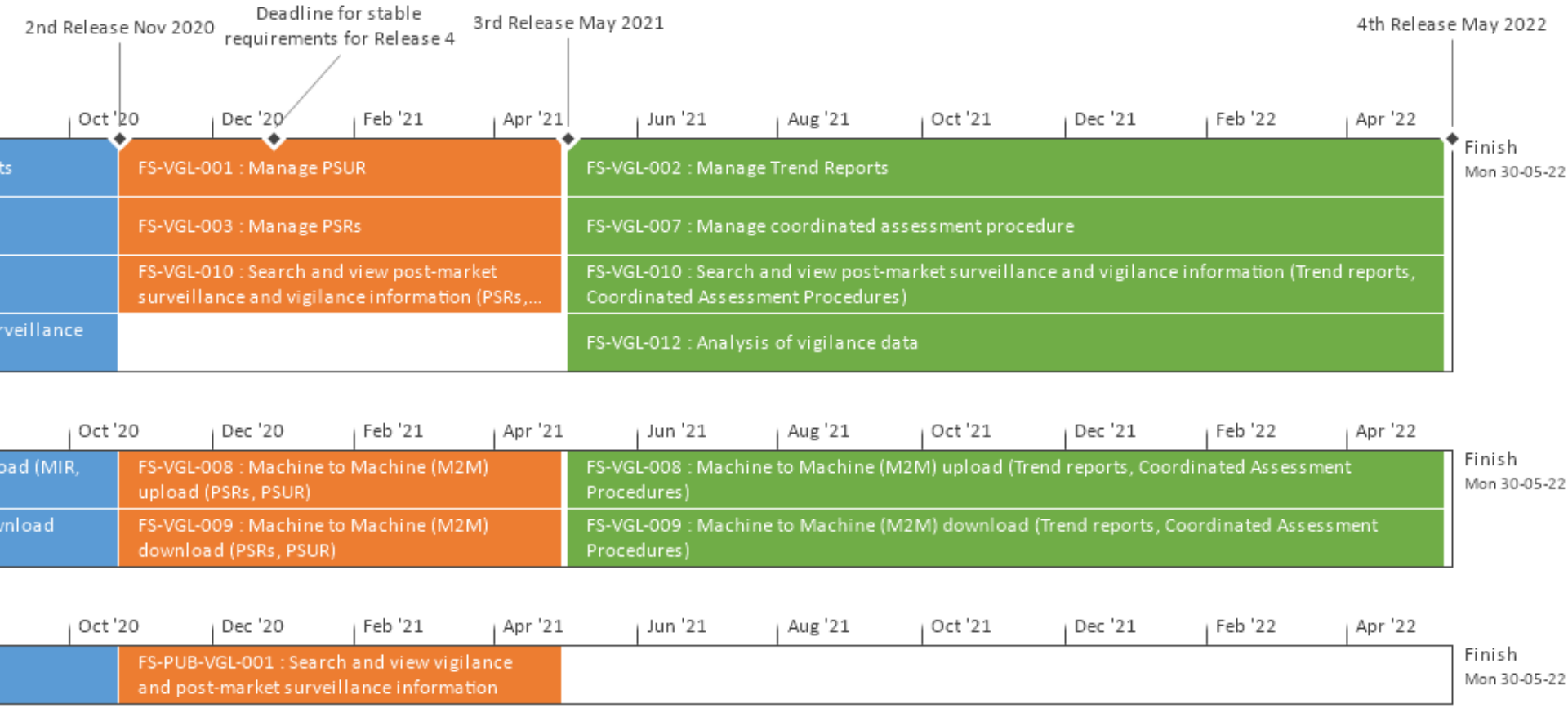
Implementation Plan 2/2



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Q & A

Thank-you for your collaboration !

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