



4th MDR Eudamed Vigilance WG Meeting

Implementation plan update

28/03/2019

DG GROW

Content

1. Meetings
2. Project deliverables
3. Features Priorities / Status of Templates
4. State of play FS level
5. Implementation plan update

Meetings

- 28/03/2019 – Vigilance WG
- 16/05/2019 – Clinical Investigations WG
- 23/05/2019 – Market Surveillance WG
- 21/06/2019 – NB & Certificates WG
- 29/08/2019 - 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
- Demos / Playground

Feature priority

| Features | EUDAMED Priority |
|--|------------------------|
| MIR - Manufacturer Incident Report | First Release (3/2020) |
| FSCA - Field Safety Corrective Action | First Release (3/2020) |
| FSN - Field Safety Notice | First Release (3/2020) |
| PSR Form (MPSR) and PSR Related MIR ("Light MIR") | Next Release |
| PSUR - Periodic Safety Update Report | Next Release |
| TR - Trend Report | Next Release |

Current Status of the Report Templates

| | Work group | | | | |
|--|--------------|------------------|-------------|----------------|-----------------------------|
| Features | Version Date | Version | Status Form | EUDAMED Status | Expected final version Date |
| MIR -Manufacturer Incident Report | 01/2019 | 7.1 | Final | Working | Finalised |
| FSN - Field Safety Notice | 06/2018 | 1.0 | Final | Working | Finalised |
| FSCA - Fields Safety Corrective Action | 03/2019 | 3.0 | Working | Working | end April 2019 |
| PSR Related MIR (“Light MIR”) | 12/2018 | N/A (MIR 7.0) | Working | Working | Q3 2019 |
| PSR Form (MPSR) | 01/2019 | 1.4 | Working | Working | Q3 2019 |
| PSUR – Periodic Safety Update Report | 02/2019 | 3.3 | Working | Working | Q3 2019 |
| TR - Trend Report | 04/2018 | V0.1 | Working | | Q4 2019 |

Status of Vigilance Analysis in EUDAMED

| Features | Status in Eudamed | | | | | |
|--|--|------------|-----------|---------|---------|-----------|
| | Analysis | Data Model | Processes | BR(s) | Mock-up | Use Cases |
| MIR -Manufacturer Incident Report | Version 2 (Business Process, Data Dictionary, etc.) | Working | Working | Working | Working | Working |
| FSN - Field Safety Notice | Detailed Req. Specification v2.0 (FSN) | Working | Working | Working | Working | Working |
| FSCA - Fields Safety Corrective Action | In progress | Working | Working | | | Working |
| PSR Related MIR (Light MIR) | In progress | Working | Working | | | Working |
| PSR Form (MPSR) | In progress | Working | Working | | | Working |
| PSUR – Periodic Safety Update Report | Detailed Req. Specification v2.0 (PSUR) | Working | Working | Working | | Working |
| TR - Trend Report | | | | | | |

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

- The Manufacturer Form is now finalised (at v7.1)
- CA Assessment details are not yet established
- Analysis ongoing – to be completed in Q2 2019
- Implementation to start in Q2

FS-VGL-005 : Manage FSCAs

- The Manufacturer Form is at v3.0, expecting the Final version by 04/2019
- CA Assessment details are not yet established
- Analysis started – awaiting Final version

FS-VGL-006 : Manage FSNs

- The Form is now finalised (at v1.0)
- Analysis ongoing

FS-VGL-003 : Manage PSRs

Required – Medium (2)

- The Form for “Light MIR” (To be complemented)
- The MPSR Form is at v1.4 (To finalize/ correct)
- Analysis started – awaiting Final version

FS-VGL-001 : Manage PSUR

Required – Medium (2)

- The Form is at v3.3, expecting the Final version by Q3/2019 (previously at Dec 18)
- Analysis started – awaiting Final version

FS-VGL-002 : Manage Trend Reports

Required – Medium (2)

- Trend Report is at early stages (not a priority)
- Analysis not started

FS-VGL-007 : Manage coordinated assessment procedure

Required – Medium (2)

- Analysis and Requirements to be defined by end of Q4 2019

FS-VGL-010 : Search and view post-market surveillance and vigilance information) analysis in parallel with respective Functional Specifications

- 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

FS-VGL-012 : Analysis of vigilance data assessment

- For future release

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

- Priority on MIR, FSCA and FSN
- Analysis at early stages

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

- Priority on MIR, FSCA and FSN for CA and NB
- Analysis at early stages

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

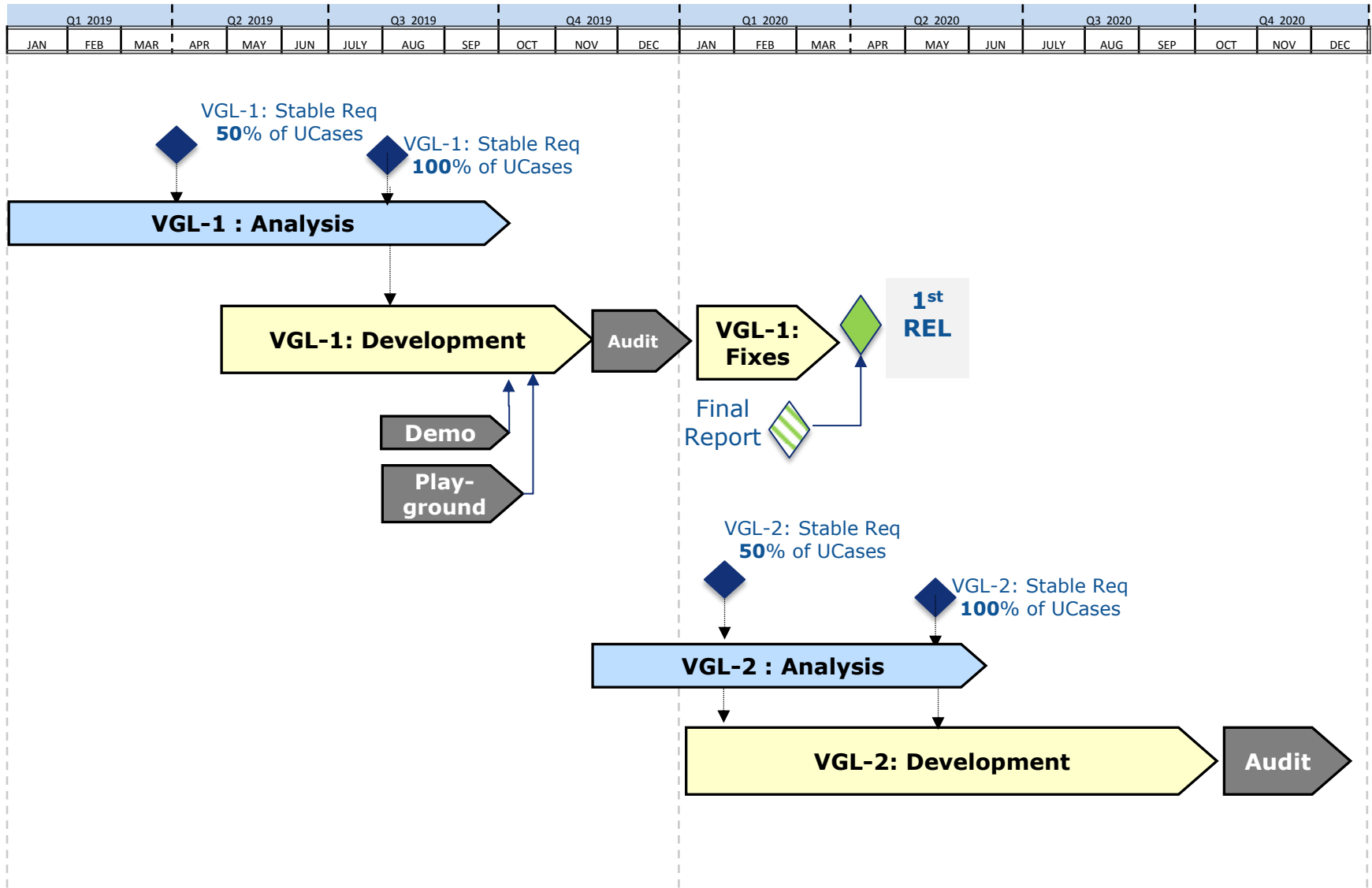
- **FS-PUB-VGL-002:** Search and view FSNs – Required High (1)
 - Analysis started
- **FS-PUB-VGL-001:** Search and view vigilance and post-market surveillance information Required Medium (2)
 - For future release following an agreement
 - Yet to determine what information will be available to the public

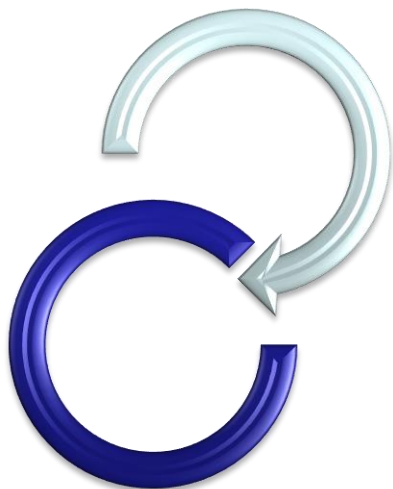
Playground and demos

- The Eudamed playground on Vigilance will be available at the end of Q3 2019 (for First Release). Exact date will be communicated.
- Videos/demos will also be available in Q3 2019 from CIRCABC on the [DEMO library](#)



Implementation Plan update





Thank-you for your
collaboration !