MDR Eudamed
6th Steering Committee Meeting

Planning - Roadmap

13/12/2018

Eudamed module sets

1st module set

- Actor registration
- UDI Device
- Certificates & Notified Bodies
- Data exchange for 1st module set

Eudamed module sets

2nd module set

- Vigilance – Post-Market Surveillance
- Clinical Investigations / Performance Studies
- Market Surveillance
- Data exchange for 2nd module set

Public Site

Planned Meetings

Planned Meetings:

- 13/12/18 – Steering Committee
- 29/01/19 – 9th Actor Registration WG
- 07/02/19 – 4th Clinical Investigations WG
- 13/02/19 – 4th Vigilance WG
- 21/02/19 – 6th NB & Certificates WG
- 14/03/19 – 6th UDI & Device WG
- 21/03/19 – 5th Data Exchange WG
- 28/03/19 – 3rd Market Surveillance WG

Working Documents

- Functional Specifications document contains
  - Legal requirements
  - Functional specifications
  - Non-functional specifications
- Process overviews / use cases
- Wireframes / Mock-ups
- Business rules
- Data models
- Implementation plan

Working Documents DTX

- Working Documents used for Data Exchange
  - Service / entity model
  - Service / entity models introduction XSD
  - Service entity models (zip file)
  - Service definition
  - Message Exchange Patterns
  - High level systems integration / security architecture

State of Play: 1. ACT

State of Play ACT

Deliverables

- Business Process Overview : (07/08/2018) - New Features to be added
- Business Rules: (10/08/2018) - New Features to be added;
- Entity Model : (14/08/2018) - New Features to be added;
- Use Case Registry : (29/10/2018) - New Features to be added;
- Security Matrix : New Features to be added;
- Wireframes : 80% finalized - New Features to be added;

Review and validation ongoing on all deliverables planned before next WG 01/2019

State of Play ACT

- FS-ACT-001 Economic Operator registration Required- High
  - Done: Registration of MF, AR, Importer
  - Ongoing: SPPP
  - To be done: Registration of Sponsors – Implementation planned for Q2 2019
- FS-ACT-002 Economic Operator and Sponsor details Update
  - Partially Done: Update of MF, AR, Importers
  - Ongoing: Mandate Update
  - To be done: Sponsors - Implementation planned for Q2 2019
- FS-ACT-003 Search and view actor details
  - Ongoing: Search and View, Actor detail, Dashboard for different actor types; implementation

State of Play ACT

- FS-ACT-005 Manage association (mandate) between non-EU manufacturer and AR
  - Ongoing: Update of mandate
- FS-ACT-006 CA registration
  - Registration will be performed by COM following MS information
  - Ongoing: Mock-ups showing screens for CA management
  - To be done: Implementation planned for Q3 2019

State of Play ACT

- FS-ACT-009 Search and view refused actor registration requests
  - Done for the CA
- FS-ACT-10 Importer to associate itself to non-EU manufacturer (and possibly their specific devices)
  - Done

State of Play ACT

- FS-CRF-011 Provide NB actor and designation data
  - Implementation for Q1 2019
  - Only NB actors details are in the scope of the Actors module in Eudamed
- FS-CRF-012 Manage list of subsidiaries
  - Implementation for Q1 2019
- FS-CRF-013, Enable to view NB information relating to its Actor information, notifications for MDR/IVDR Information and list of subsidiaries.
  - Implementation for Q2 2019 (Actor information and list of subsidiaries)

State of Play ACT

- FS-EUD-004 : Notification/Information email system
  - Done: engine to prepare and send emails, management of subscriptions for Actor
  - Ongoing : management of subscriptions for User
  - To be done: content of emails for the Actors module – Q2 2019
- FS-EUD-006 : User access management and User management
  - Done: Login to Eudamed using EU Login, LUA/LAA, identification of a user as subcontractor
  - To be done: see UAT conclusions concerning AR Verifier, access rights update according to updated security matrix, specific access rights for users of Sponsors - Q1 2019

DTX - State of Play

DTX FS – sorted by Priority

Actors

1. FS-ACT-004 : Machine to machine (M2M) Actors data Download – for CA only

   High – Analysis done – to do: collect reviews – close by 01/19

   High – Testing by 03/19

2. FS-ACT-008.01 / FS-ACT-008.02 : Enable a CA to download in a file submitted actor registration requests this CA has to validate / Enable a CA to upload from a file validation outcomes for submitted actor registration requests this CA has to validate

   High – Requirements collected XSD defined – to do: design of frontend – close by 01/19

   High – Testing by 04/19

ACT - State of Play

ACT Public FS

Analysis ongoing

FS-PUB-ACT-001 : Search and view actor details

Issues - ACT

- A complex legislation demands agreement on interpretation and harmonisation upon multiple members to define clear and stable requirements for a workable system; changes have more impact if they occur later in the project
- In order to define stable requirements multiple WG and TF are being held sometimes across modules
- New requirements from other modules, impacting the Actor and User module – SPPP, Sponsor registration, …
- Due to changes and additional requests for a base module reviews and tests are required to avoid regression, this has an impact on the deliverable date of other modules

State of Play: 2. UDI & Devices

State of Play UDI & Devices

Deliverables

- Business Process Overview : Updated after comments (version 2)- Final;
- Business Rules: Updated after comments (version 2)- Final ;
- Entity Model : Updated after comments (version 2)- Final ;
- Use Case Registry : version 1 submitted to WG members– Final;
- Security Matrix : comments implementation ongoing;
- Wireframes : 80% finalized;

State of Play UDI & Devices

1. FS-UDID-002.05, FS-UDID-002.08, FS-UDID-002.09 Priority - High

UDI registration for MF and non-EU MF (with prevention of duplicates) with exception of systems and procedure packs

- Done : Registration process and implementation of Business Rule is 90% done;
- To be done : Planned for January - Implementation of change requests in the registration process (Trade Name, Critical Warnings and Contra-Indications, adjustments based on the implementation of the new actor SPPP) and implementation;

2. FS-UDID-003.01 Priority - High

Device registration for MF and non-EU MF

- 80% done ;
- To be done : Register Device Data for existing UDI-DI;

State of Play UDI & Devices

3. FS-UDID-006.01, FS-UDID-006.02 Priority - High

Search and view UDI-DI and Device data

- Done : Analysis and Wireframes;
- Ongoing : Implementation of the functionalities – estimated time of delivery January 2019;

4. FS-UDID-002.06 Priority - High

UDI update

- Done : 50% Analysis and Wireframes;
- To be done –Implementation of the functionalities planned for the beginning of next year - Q1;

State of Play UDI & Devices

5. FS-UDID-003.02 Priority - High

Device update

- Done : 50% Detailed analysis deliverables and Wireframes;
- To be done –Implementation of the functionalities planned for the beginning of next year - Q1;

6. FS-UDID-002.01 Priority - High

Registration of Systems and procedure packs

- To be done : Detailed analysis deliverables and Wireframes; Implementation of the functionalities planned for the beginning of next year - Q1;

State of Play UDI & Devices

7. FS-UDID-002.02 Priority - High

Update System and procedure packs

- To be done : Detailed analysis deliverables and Wireframes; Implementation of the functionalities planned for Q2 2019;

8. FS-UDID-005.01 Priority - High

Enable NB to manage the information on certificate ID in device data (confirm, reject or enter/update)

- To be done : Detailed analysis deliverables and Wireframes; Implementation of the functionalities planned for Q2 2019;
- Dependency on the implementation on the Certificate Module;

State of Play UDI & Devices

9. FS-UDID-009 Priority - High

Enable NB to upload the SS(C)P and enter related meta-data to device data already provided by a manufacturer

- To be done : Detailed analysis deliverables and Wireframes; Implementation of the functionalities planned for Q2 2019;

10. Register specific device types requiring specific rules (Special Device types) (new, not in functional specification yet);

- To be done : Define requirements, detailed analysis and Wireframes;

State of Play UDI & Devices

11. FS-ACT-010.01 Priority - High

Enable Importers to associate their details to manufacturers (and possibly their specific devices) – implement through Actor Module

- Done

12. FS-UDID-001.01 Priority – High

Device Nomenclature data management (depending on decision for Device Nomenclature)

13. FS-UDID-007 Priority- High

Search and view Device Nomenclature data

- To be done : Decision on the Nomenclature is required ; Detailed requirements, analysis and Wireframes ;

State of Play UDI & Devices

14. FS-UDID-004 Priority – High

Enable an AR to indicate its disagreement with information related to a Basic UDI-DI / UDI / Device information referencing this AR

- Will be implemented in a future release

DTX - State of Play

UDI & Devices

3. FS-UDID-008.03: Enable downloading (M2M) the registered (Basic) UDI-DI data and Device data or to extract in an electronic format a search result list - (SSCP included)

   High – Analysis done – to do: collect reviews – close by 01/19

   High – limited to CA - Testing by 05/19

4. FS-UDID-008.01: Enable manufacturers to submit through upload (M2M or XML file) the required information (new and update) on Basic UDI-DI, UDI-DI and device data (with bulk upload providing multiple records possibility).

   High – Analysis done – to do: collect reviews – close by 01/19

   High – Testing by 06/19

DTX - State of Play

UDI & Devices

5. FS-UDID-008.02: Enable System/Procedure pack Producer to submit through upload (M2M or XML file) the required information on (new and update) on Basic UDI-DI and UDI-DI

   High – Analysis done – to do: collect reviews – close by 01/19

   High – Testing by 06/19

State of Play UDI & Devices

UDI & Devices Public FS

Analysis ongoing

FS-PUB-UDID-001 : Search and view UDI-DI and Device data (including SS(C)P)

Issues - UDI & Devices

- Time for getting stable requirements due to new UDI guidance rules and features that impact the already implemented functionalities as:
  - Trade Name
  - Critical Warnings and Contra-Indications
  - Adjustments based on the implementation of new actor type (SPPP)

Issues - UDI & Devices

- Requirements that need clarifications or decisions in order to define the final form of the implementation:
  - Device Nomenclature structure and were the information regarding the Nomenclature Code will be stored for the Device (Basic UDI-DI, UDI- DI, if several nomenclature codes and updates will be allowed);
  - Registration of Directive (legacy) Devices in EUDAMED (if it is mandatory / optional or non-applicable). How Regulation Devices could be registered in case the equivalent Directive (legacy) Device would already be (same (Basic) UDI-DI, update or new registration?);
  - Managing the Device Status and related scope for FSCA initiated and Recall from Vigilance data (FSN) associated to those devices;
  - Device data (Annex VI Part A Section 2) under Basic UDI-DI or UDI-DI

State of Play: 3. CRF

State of Play CRF

Deliverables

- Business Process Overview : Version 1 submitted to the WG. Awaiting comments from WG to update and submit an update (version 2).
- Business Rules: Received comments from WG (version 1, only certificates). New version to be submitted before next WG (version 2, full coverage)
- Entity Model : Received comments from WG (version 1, only certificates). New version to be submitted before next WG (version 2, full coverage)
- Use Case Registry : Version 1 to be submitted before next WG.
- Security Matrix : Version 1 to be submitted before next WG.
- Wireframes : 50% prepared (mainly issued/refused certificates, applications, CECP).

State of Play CRF

FS-CRF-005.01 Priority - High

Issued certificate registration

- Done : 80% Detailed analysis and Wireframes;
- To be done – Implementation of the functionalities planned to start in Q1 next year; Start with normal devices and progressively include CMDs, SPPs and scrutiny mechanism.

FS-CRF-008.01 Priority - High

Search and view issued and refused certificates

- To be done : Analysis; Implementation of the functionalities planned to start in Q1 next year.

State of Play CRF

FS-CRF-006.01 Priority - High

Management of certificate versions

- Done : 60% Analysis (expected feedback from/agreement in the next WG);
- To be done : Detailed analysis deliverables and Wireframes; Implementation of the functionalities planned to start in Q2 next year.

FS-CRF-007.01 Priority - High

Management of refused certificates (close similarities with registration of issued certificate)

- Done : 70% Analysis and Wireframes;
- To be done – Detailed analysis deliverables; Implementation of the functionalities planned to start in Q2 next year.

State of Play CRF

6. FS-CRF-009.01 Priority - High

Management of notifications for refused/withdrawn applications for conformity assessment (close similarities with registration of issued certificate)

- Done : 70% Analysis and Wireframes;
- To be done – Detailed analysis deliverables; Implementation of the functionalities planned to start in Q2 next year.

8. FS-CRF-010.01 Priority - High

Search & view notifications of refusal/withdrawal of applications for conformity assessment

- To be done : Analysis; Implementation of the functionalities planned to start in Q2 next year.

State of Play CRF

FS-CRF-002.01, FS-CRF-003.01 Priority - High

Manage and view list of nominated Experts

- Done : 90% Analysis;
- To be done : Detailed analysis deliverables and Wireframes; Implementation of the functionalities planned to start in Q2 2019.

State of Play CRF

13. FS-CRF-017.01, FS-CRF-017.02 Priority - High

Manage requests for suspension/withdrawal of certificates and notify CA of manufacturer

- Done : 50% Analysis and Wireframes;
- To be done – Detailed analysis deliverables; Implementation of the functionalities planned to start in Q2 next year.

14. FS-CRF-017.03 Priority - High

Search & view DA requests for suspension/withdrawal of certificates

- Done : 50% Analysis and Wireframes;
- To be done – Detailed analysis deliverables; Implementation of the functionalities planned to start in Q2 next year.

State of Play CRF

FS-CRF-001.01, FS-CRF-004.01 Priority - High

Manage and view MS Summary Reports

- Done : 90% Analysis;
- To be done : Detailed analysis deliverables and Wireframes; Implementation of the functionalities planned to start in Q3 next year.

FS-CRF-014 Priority - High

CECP management/submission of information (from various actors)

- Done : 60% Analysis (processes, data model, business rules) and Wireframes;
- To be done – Complete analysis taking in account the CEAR. Implementation planned to start in Q3 next year.

State of Play CRF

FS-CRF-016.01 Priority - High

Search & view CECPs

- Done : 20% Analysis and Wireframes;
- To be done – Detailed analysis deliverables; Implementation of the functionalities planned to start in Q3 next year.

State of Play CRF

FS-CRF-015.01 Priority - Medium

Workflow control for CECP (reminders)

- Done : 40% Analysis (processes, data model, business rules) and Wireframes;
- To be done – Complete analysis;

FS-CRF-021.01, FS-CRF-022.01 Priority – Medium (2)

Manage list of Expert Panels, View list of expert panels

- Done : 90% Analysis and Wireframes;
- To be done – Detailed analysis deliverables;

DTX - State of Play

Certificates & NB

15. FS-CRF-019.01: Import using a M2M web service certificates NB own information from their database to Eudamed for submission of issued, updates, renewal and refused certificates (upload from NB to Eudamed)

    High – Analysis done – to do: collect reviews – close by 02/19

    High – Testing by 06/19

16. FS-CRF-020.02: 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 - only CA/DA

    High – Analysis done – to do: collect reviews – close by 02/19

    High – Testing by 06/19

Issues CRF

- WG difficulties/delays to agree on fundamental definitions of business rules for certificate registration and updates (certificate number, status, issue date, validity date) – Under finalisation

- Gaps in CECP dossier management process and content that should be managed through Eudamed (and Expert panels management) – Under finalisation

State of Play: 4. VGL

State of Play VGL

Deliverables

- Business Process Overview : First version submitted to WG members;
- Business Rules:20% - BR(s) for MIR form submitted to WG members;
- Entity Model : First version- not submitted to WG members;
- Wireframes : 15% finalized;

VGL Reports - State of Play

Features	EUDAMED Priority
MIR - Manufacturer Incident Report	1
FSCA - Field Safety Corrective Action	2
FSN - Field Safety Notice	3
PSR Related MIR	4
PSR Form	5
PSUR - Periodic Safety Update Report	6
TR - Trend Report	7

VGL Reports - State of Play

	Work group				
Features	**Version Date**	**Version**	**Status Form**	**Status Documentation**	**Expected final version Date**
MIR -Manufacturer Incident Report	22/10/2018	6.2	Final	Working	Awaiting final validation
FSN - Field Safety Notice	28/06/2018	Rev 1	Working	Working	END November 2018
FSCA - Fields Safety Corrective Action	April 2018	V1.2	Working		END November 2018
PSR Related MIR	12/10/2018	V0.1	Working	Working	Mid December 2018
PSR Form	12/10/2018	0.3	Working	Working	Mid December 2018
TR - Trend Report	April 2018	V0.1	Working		END February 2019
PSUR – Periodic Safety Update Report	24/09/2018	3.3	Working		Mid December 2018

VGL - State of Play

	Status in Eudamed						
Features	**Analysis**	**Mapping**	**Data Model**	**Processes**	**Business Rules**	**Mock-up**	**Use Cases**
MIR -Manufacturer Incident Report	In Progress	Version 0.7 for 19/10/2018	Working	Working	Working	Working	
FSN - Field Safety Notice	In Progress		Working	Working			
FSCA - Fields Safety Corrective Action	In Progress		Working	Working			
PSR Related MIR	In Progress		Working				
PSR Form	In Progress		Working				
TR - Trend Report							
PSUR – Periodic Safety Update Report	In Progress						

State of Play VGL

1. FS-VGL-004 : Manage serious incidents reports
    - Final version of the Form is expected (deadline was the End of November);
    - Done: 60% Analysis and Wireframes
    - Implementation can start in the beginning of Q2

2. FS-VGL-005 : Manage FSCAs

    Form, Deadline Final version TF: **11/18**
    - Final version of the Form is expected - estimated deadline for receiving the final version February 2019;
    - Analysis and Requirements should be defined by end of Q2 2019

State of Play VGL

3. FS-VGL-006 : Manage FSNs

Document, Deadline Final version TF: **11/18**

- Analysis – 25% (Entity Model, Requirements and Metadata);
- Analysis and Wireframes should be defined by end of Q2 2019;

4. FS-VGL-003 : Manage PSRs

Form, Deadline Final version TF: **12/18**

- Process close to be clarified (still in discussion);
- Final version of the Form is expected;
- Analysis and Requirements should be defined by end of Q2 2019

State of Play VGL

Vigilance Private FS – sorted by Priority

5. FS-VGL-001 : Manage PSUR

Document, Deadline Final version TF: **12/18**

- First meeting of the Task Force in December;
- Final version of the Form is expected;
- Analysis and Requirements should be defined by end of Q2 2019

6. FS-VGL-002 : Manage Trend Reports

Form, Deadline Final version TF: **02/19**

- Will be implemented as a form upload with few metadata associated;
- Analysis and Requirements should be defined by end of Q2 2019

State of Play VGL

Vigilance FS for restricted site

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

- Analysis and Requirements should be defined by end of Q2 2019

8. FS-VGL-007 : Manage coordinated assessment procedure

- Analysis and Requirements should be defined by end of Q2 2019

State of Play VGL

Vigilance FS for restricted site

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

For future release

10. FS-VGL-012 : Analysis of vigilance data assessment

For future release

State of Play VGL

In parallel with implementation of other FS –

- FS-VGL-008 : Machine to Machine (M2M) vigilance and post-market surveillance information upload
  - Priority: MIR and PSR
  - To do: Define services and priorities
- FS-VGL-009 : Machine to Machine (M2M) vigilance and post-market surveillance information download
  - Priority: MIR and PSR
  - To do: Define services and priorities
- FS-EUD-004 : Notification/Information email system
  - Done: engine to prepare and send emails
  - To do: management of subscriptions (will be managed in the Actor module for all modules) and content of emails for the VGL module

State of Play VGL

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

- FS-PUB-VGL-002: Search and view FSNs
- FS-PUB-VGL-001: Search and view vigilance and post-market surveillance information
  - **For future release if needed (except FSN FS-PUB-VGL-002)**

Issues Vigilance

- Lack of details on requirements for content from MDR/IVDR increasing the time taken for clarifying and getting harmonised agreements on the different forms delaying the development;
- Differences between the different forms/ procedures needed to be implemented in EUDAMED increase the complexity and time needed to standardise and clarify the details, causing time delays in the project;
- MDD Devices handling issue (not determined yet)
- Number of functional specifications for DTX to be reviewed (Priority will be given to serious incident reporting (MIR, light MIR, FSN, FSCA)
- For public site, to determine which data beside the FSN (still ongoing)?
- Search criteria and therefore meta-data for FSN to be determined with possibly healthcare professional not represented in Eudamed WG

State of Play: 6. CIPS

State of Play CIPS

Deliverable:

- CIPS Business Process Overview

Schedule for delivery:

- Overall CIPS process overview – final version
- Application management – To be finalised (TBF) by Q1/19 (excluding coordinated assessment- TBF by Q4)
- CIPS conduct – TBF by Q2/19 (excluding coordinated assessment of substantial modifications - TBF by Q4)
- Submit outcome report – TBF by Q2/19 (excluding coordinated assessment of substantial modifications - TBF by Q4)

State of Play CIPS

Deliverables:

- Detailed requirements
- Entity Model
- Business Rules
- Use Case Model
- Security Matrix
- Wireframes

Schedule for delivery:

- Application management – TBF by Q1/19 (excluding coordinated assessment- TBF by Q4)
- CIPS conduct – TBF by Q2/19 (excluding coordinated assessment of substantial modifications - TBF by Q4)
- Submit outcome report – TBF by Q2/19 (excluding coordinated assessment of substantial modifications - TBF by Q4)

State of Play CIPS

1. **FS-CIPS-001** Priority - High

Manage application/notification for CI/PS

- Application Form: Updated form expected from TF 15/12/2019.
- TBD: Collect requirements for resubmission and PMCF investigation. Analysis and requirements to be finalised by Q1/19

2. **FS-CIPS-002** Priority – High

Withdraw application or notification for CI/PS or PMCF/PMPF

- TBD: Analysis and requirements finalised by Q1/19

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

- Analysis ongoing
- TBD: Collect requirements. Analysis and requirements finalised by Q1/19

State of Play CIPS

4. **FS-CIPS-004** Priority - High

Manage authorisation of CI/PS and setting of time limit for authorisation

- Analysis ongoing
- TBD: Collect requirements. Analysis and requirements finalised by Q1/19

5. **FS-CIPS-005** Priority - High

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

- TBD: Collect requirements. Analysis and requirements finalised by Q2/19

6. **FS-CIPS-006** Priority - High

Manage substantial modifications to CI/PS after authorisation or PMCF/PMPF

- TBD: Collect requirements. Analysis and requirements finalised by Q2/19

State of Play CIPS

7. **FS-CIPS-007** Priority - High

Manage authorisation for substantial modifications to CI/PS or PMCF/PMPF

- TBD: Reuse as much as possible analysis and design for FS-CIPS-004. Analysis and requirements finalised by Q2/19

8. **FS-CIPS-008** Priority - High

Manage recording and reporting of adverse events that occur during CI/PS

- TBD: Form: Reuse as much as possible analysis and design for MIR form. Analysis and requirements finalised by Q2/19 (dependency on progress of VIG - FS-VGL-004)

9. **FS-CIPS-009** Priority - High

Manage information at the end of a CI/PS or PMCF/PMPF or in the event of a temporary halt or early termination

- TBD: Collect requirements. Analysis and requirements finalised by Q2/19

State of Play CIPS

10. **FS-CIPS-010** Priority - High

Manage coordinated assessment procedure for CI/PS

- TBD: Reuse as much as possible analysis and design for FS-CIPS-003 & FS-CIPS-004. Collect requirements. Analysis and requirements finalised by Q4/19

11. **FS-CIPS-011** Priority - High

Manage exchange of information and communication to all MS and the Commission on decisions and the grounds therefor related to CI/PS

- TBD: Collect requirements. Analysis and requirements finalised by Q3/19 (dependency on FS-CIPS-003, FS-CIPS-004, FS-CIPS-007)

12. **FS-CIPS-012** Priority - High

Search and view information on CI/PS

- TBD: Collect requirements. Analysis and requirements finalised by Q3/19

State of Play CIPS

13. **FS-CIPS-013**

Machine to machine (M2M) CI/PS information upload

Priority - Low (for Sponsor) implementation in subsequent release.

Priority - High (for CA) Collect requirements/services.

- TBD: Analysis and requirements finalised by Q3/19 (dependency on data model - FS-CIPS-001 to FS-CIPS-011)

14. **FS-CIPS-014**

Machine to machine (M2M) CI/PS information download

Priority - Low (for Sponsor) implementation in subsequent release.

Priority - High (for CA) Collect requirements/services.

- TBD: Analysis and requirements finalised by Q3/19 (dependency on data model - FS-CIPS-001 to FS-CIPS-009 and FS-CIPS-015)

15. **FS-CIPS-015** Priority - High

Manage list of Ethics Committees

- TBD: Collect requirements. Analysis and requirements finalised by Q1/19

State of Play CIPS

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

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

State of Play CIPS

FS horizontal features - specifications will follow after the specifications for the restricted site

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

  Analysis and requirements finalised by Q3/19

Issues CIPS

- Most complex module because a complex application form associated to a complex process for validation and assessment that requires harmonisation for having common rules defined ensuring as well the workability of the system
- Takes much time to define an acceptable and workable solution with a limited number of WG meetings and resources available (on both side EC and MS)
- Determine data identifying in a unique way a CI/PS that cannot change for the same CI/PS beside the Single Identification Number
- Application structure, identification rules and content in the context of CI/PS taking place in several Member States with coordinated procedure or not
- What application data should be considered as common to all Member States (global data set), or specific to a Member State (national data set) or even at site level.

State of Play: 5. MSU

State of Play MSU

Deliverables

- Detailed Requirements : First Version submitted to WG

Detailed Requirements document contains the following items for all functional specifications:

- Business Processes
- Entity Model
- Data Dictionary
- Detailed Requirements

State of Play MSU

MSU Restricted FS – sorted by Priority

1. FS-MSU-002 : Manage the final inspection reports of the MS

   High – Collect Requirements – Define Template – 11/18

2. FS-MSU-008 : Search and view information on market surveillance

   High – Collect Requirements - 3/19 (Functionality added for each FS)

3. FS-MSU-005 : Manage notification and exchange information on devices presenting an unacceptable risk to health and safety

   High – Collect Requirements – 1/19

State of Play MSU

MSU Restricted FS – sorted by Priority

4. FS-MSU-006 : Manage information on measures taken for a non-compliant device not presenting an unacceptable risk to health or safety or other aspects of the protection of public health

   High – Collect Requirements – 1/19

5. FS-MSU-007 : Manage notification on preventive health protection measures

   High – Collect Requirements – 1/19

State of Play MSU

MSU Restricted FS – Further release

6. FS-MSU-001 : Manage the annual summaries of the results of the surveillance activities of the MS

   Medium– Collect Requirements – Define Template – Further Release

7. FS-MSU-003 : Manage the summaries of the results of the reviews and assessment of the market surveillance activities of the MS

   Medium– Collect Requirements – Define Template – Further release

State of Play MSU

MSU Restricted FS – Further release

8. FS-MSU-004 : Communicate results of the review and assessment by the MS of the functioning of its market surveillance activities

   Medium– Collect Requirements – Define Template – Further release

9. FS-MSU-011 : Platform for cooperation and collaboration between MS and between MS and the Commission

   Medium – Collect Requirements – Further release

State of Play MSU

MSU Machine to Machine FS – sorted by Priority

1. FS-MSU-009 : Machine to machine (M2M) market surveillance data Download

   High – Collect Requirements / Services – 2/19

2. FS-MSU-010 : Machine to machine (M2M) market surveillance data Upload

   High – Collect Requirements / Services – 3/19

State of Play MSU

MSU Public FS

FS-PUB-MSU-001 : Search and view a summary of the results of the reviews and assessments of the market surveillance activities of a MS

Medium – Collect Requirements / Services – Further Release

Issues MSU

- COEN Eudamed Market surveillance task force is being set up very late and with limited availability to provide feedback in a short time. Communication channel was lacking for long time
- Lack of details on content from MDR/IVDR → No common templates exist for the moment, therefore the EC formulates proposals to speed up the requirements gathering process
- Lack of resources in Member States with necessary knowledge for providing input on what should be the requirements and content in Eudamed, seems to be a low priority

Questions?

European Commission