



# **6<sup>th</sup> MDR Eudamed DTX ad hoc WG Meeting**

## **DTX – Planning - Roadmap**

03/10/2019

DG GROW

# Content

- Meetings
- Working documents
- State of play
- Implementation plan overview
- DTX Playground Planning

# 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 – 6<sup>th</sup> Data Exchange WG
- 24/10/2019 – 8<sup>th</sup> NB and Certificates WG

# Working documents: done

- Data modelling - XSDs + description of the models
  - Actors /Actor registration
  - UDID
  - CRF
- Service definitions:
  - Actors / Actor registration
  - UDID registration & updates
  - CRF
- Architecture overview
- Documentation support for playground
- Service / entity model
- Service / entity models introduction XSD
- Service entity models (zip file)
- Service definition
- Message Exchange Patterns

# Working documents: on going

- High level systems integration / security architecture
- Service / entity model Legacy Devices
- Certificates

# Implementation plan overview

## DTX Service

## Status

FS-ACT-004	Machine to machine (M2M) Actors data Download	Machine to machine (M2M) Actors data Download	CA	
<b>ACTOR: GET</b>				<b>Playground</b>
FS-ACT-008.01	Enable a CA to download in a file submitted actor registration requests this CA has to validate	Enable a CA to download in a file submitted actor registration requests this CA has to validate	CA	
<b>ACTOR_REGISTRATION: GET (Bulk Upload - GUI)</b>				<b>On Going</b>
FS-ACT-008.02	Enable a CA to upload from a file validation outcomes for 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	CA	
<b>ACTOR_REGISTRATION: POST (Bulk Upload - GUI)</b>				<b>On Going</b>
FS-UDID-008.01 (MF) FS-UDID-008.02 (PR)	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).	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).	MF	
<b>DEVICE: POST</b>				<b>Playground</b>
<b>Legacy DEVICE: POST</b>				3th Version PG
<b>UDI_DI: POST</b>				<b>On Going</b>
<b>Legacy EU_DI DATA: POST</b>				3th Version PG
<b>BASIC_UDI: PATCH</b>				3th Version PG
<b>Legacy EU_DI: PATCH</b>				3th Version PG
<b>UDI_DI: PATCH</b>				3th Version PG
<b>Legacy EU_DI DATA: PATCH</b>				3th Version PG
<b>MARKET_INFO: POST</b>				3th Version PG
<b>SSCP: POST</b>				3th Version PG
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	Enable downloading (M2M) the registered (Basic) UDI-DI data and Device data or to extract in an electronic format a search result list	EC, CA, NB, MF, PR, AR, Importer	
<b>DEVICE: GET</b>				<b>Playground</b>
<b>Legacy DEVICE: GET</b>				3th Version PG
<b>SSCP: GET</b>				3th Version PG
<b>Legacy SSCP: GET</b>				3th Version PG

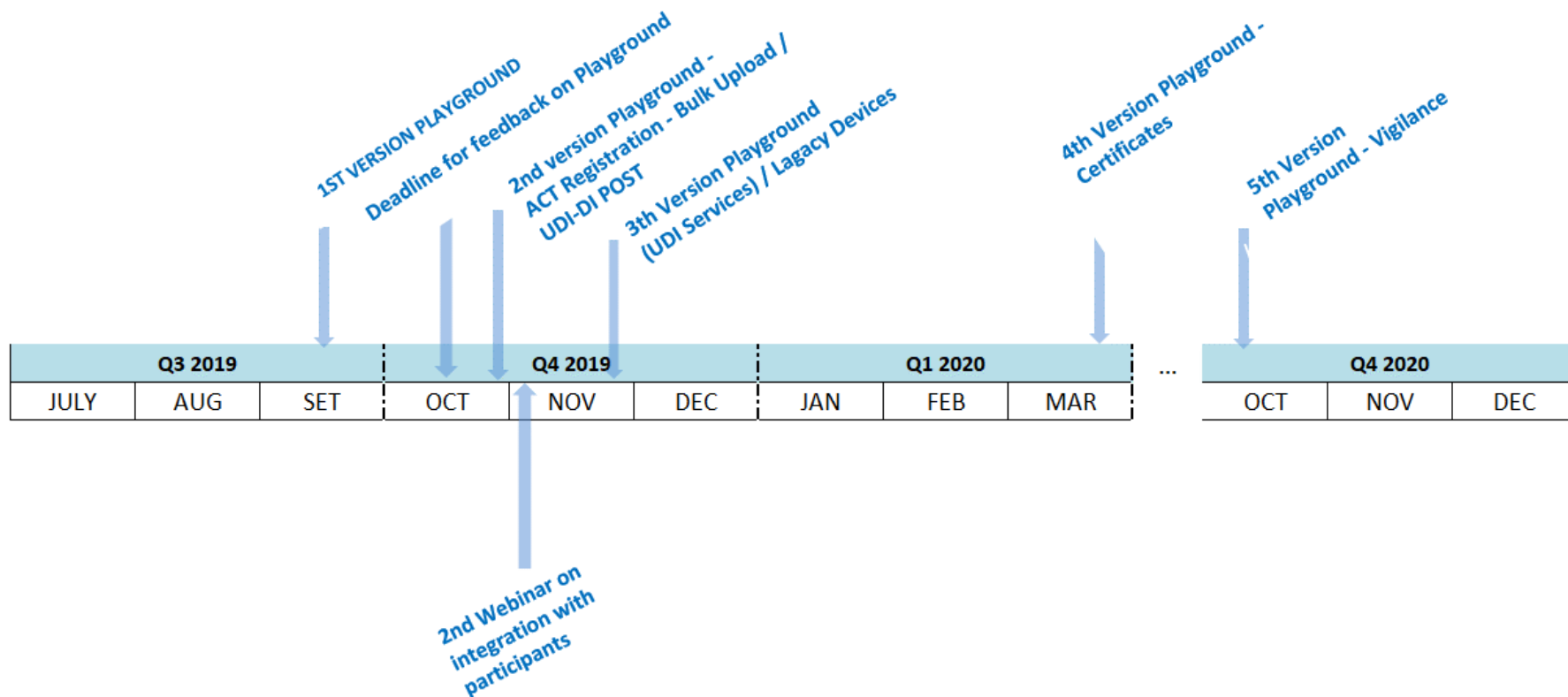
**2nd Version of Playground  
(31st October)**

# Implementation plan overview

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	Import using a M2M web service certificates NB own information from their database to Eudamed for submission of issued, updates, renewal and refused certificates	NB	
ISSUED_CERTIFICATE: POST				4th Version PG
ISSUED_CERTIFICATE: PATCH				4th Version PG
REFUSED_CERTIFICATE: POST				4th Version PG
ISSUED_DECISION_CERTIFICATE_STATUS: POST				4th Version PG
FS-CRF-020.01	Export using a M2M web service NB own information submitted for a certificate by that NB in Eudamed to that NB database.)	Export using a M2M web service NB own information submitted for a certificate by that NB in Eudamed to that NB database.)	NB	
ISSUED_CERTIFICATE: GET				4th Version PG
REFUSED_CERTIFICATE: GET				4th Version PG
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	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	CA	
CECP: GET				4th Version PG

**3th Version of Playground  
(March 2020)**

# DTX Playground Planning 2019/2020



# Next WG meeting

**Date:** April 2020 (date will be communicated in due time)

# Thanks for your attention

## Questions?