



# **9th MDR Eudamed Actor Registration WG Meeting**

## **Implementation plan update for Actors**

29/01/2019

DG GROW

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# Meetings

- **29/01/2019 – Actor Registration WG**
- 07/02/2019 – CI/PS WG
- 13/02/2019 – Vigilance WG
- 21/02/2019 - NB & Certificates WG
- 14/03/2019 - UDI & Device WG
- 21/03/2019 - Data Exchange WG
- 28/03/2019 – Market Surveillance WG

# Project deliverables

- Eudamed information system
  - Restricted site
  - Public site
- Data exchange solutions
- User guide
- Technical documentation
- Training material
- Technical support
- Demos
- Playground

**NEW**

# Working documents

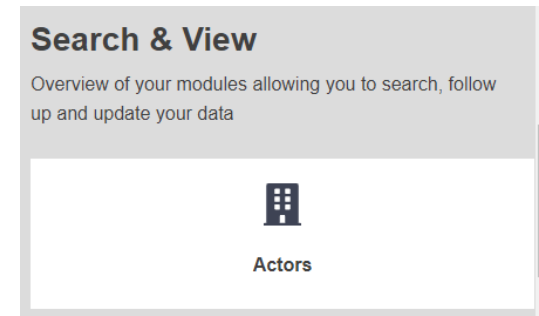
- Functional Specifications document contains:
  - Legal requirements
  - Functional specifications
  - Non-functional specifications
- Process overviews / use cases
- Data dictionary, Security matrix, Business rules
- Data models
- Wireframes / Mock-ups
- Implementation plan

# Implementation plan overview for 1st release

FS ID	Description	Status
FS-ACT-001	Economic Operator registration	Completed
FS-ACT-002	Economic Operator update	Ongoing
FS-ACT-003	Search and view actor details	Ongoing
FS-ACT-004	Machine to machine (M2M)	Ongoing
FS-ACT-005	Manage association (mandate) between non-EU MF and AR	Completed
FS-ACT-006	CA registration	Ongoing
FS-ACT-008	Upload and download for actor registration requests validation	Ongoing
FS-ACT-009	Search and view refused actor registration requests	Completed
FS-ACT-010	Importer link to non-EU manufacturer	Completed
FS-CRF-011	Provide NB actor and designation data	Not started
FS-CRF-012	Manage list of subsidiaries	Not started
FS-CRF-013	NB information, notifications for MDR/IVDR, and list of subsidiaries.	Not started
FS-EUD-004	Notification/Information email system	Ongoing
FS-EUD-006	User access management and User management	Completed
FS-EUD-008	Data protection	Completed
FS-PUB-ACT-001	Search and view actor details	Ongoing

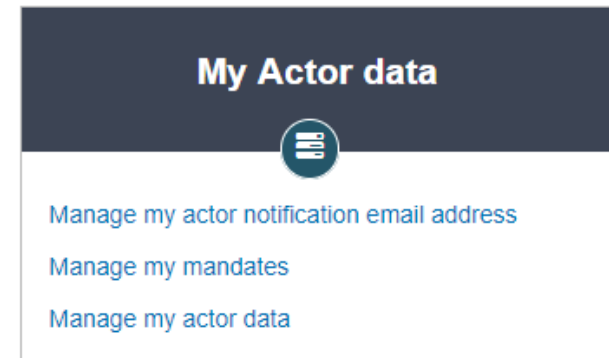
# State of play 1st release 1/5

- **FS-ACT-001 Economic Operator registration**
  - Completed: registration of MF, AR, Importer, SPPP.
- **FS-ACT-002 Economic Operator update**
  - Done: update of MF, AR, Importers, update mandate for non-EU MF.
  - Ongoing: SPPP update.
- **FS-ACT-003 Search and view actor details**
  - Done: search Actor details, dashboard for different Actor types.
  - Ongoing: view Actor's registered details.



# State of play 1st release 2/5

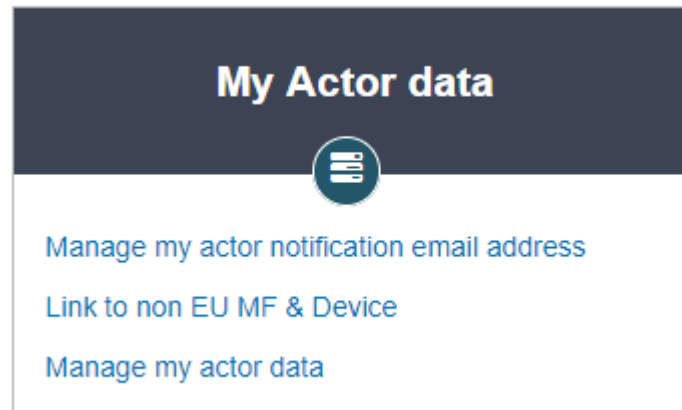
- FS-ACT-005 **Manage association (mandate)** between non-EU MF and AR
  - Completed: submit new mandate, update mandate, terminate mandate by MF, terminate mandate by AR, accept/reject mandate by AR.
- FS-ACT-006 **CA registration**
  - Solution for 1<sup>st</sup> release: registration will be performed by COM following MS information directly into Eudamed.
- FS-ACT-008 **Upload and download** for actor registration requests validation
  - Ongoing: download Actor registration request, upload assessment outcome of registration request.





# State of play 1st release 3/5

- FS-ACT-009 Search and view **refused actor registration requests**
  - Completed: view refused Actor registration requests.
- FS-ACT-010 **Importer link to non-EU manufacturer**
  - Completed.



# State of play 1st release 4/5


- FS-CRF-011 **Provide NB actor and designation data**
  - Only NB actors details are in the scope of the Actors module in Eudamed
  - Implementation for Q1 2019
- 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 1st release 5/5

- 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: define content of emails for the Actors module – Q2 2019
- FS-EUD-006 : **User access management** and User management
  - Completed: login to Eudamed using EU Login, LUA/LAA, identification of a user as subcontractor, submit account request, assessment of submission, terminate account
- FS-EUD-008 : **Data protection**
  - Completed: Acknowledgment method to inform users about personal data policies

## Tasks

Easy and quick access to your main tasks

<b>My Actor data</b>	<b>User management</b>
	Assess User access requests
Manage my actor notification email address	Manage your users
Manage my mandates	
Manage my actor data	

# Public site for 1st release: state of play

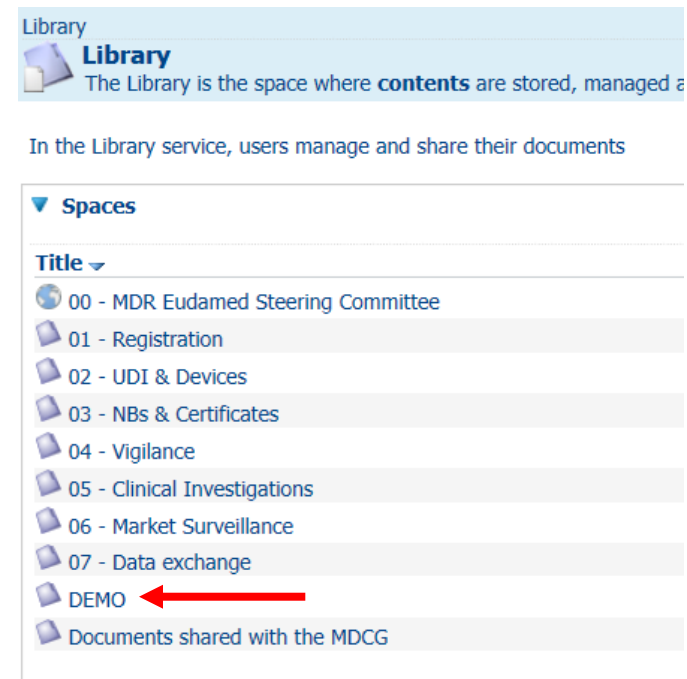
- FS-PUB-ACT-001 **Search and view actor details**
  - Ongoing: analysis
  - Done: draft sitemap is created

# Data exchange

- FS-ACT-004 **Machine to machine** (M2M) CAs can download Actors data
  - Ongoing: collect reviews
  - Testing on March 2019
- FS-ACT-008.01 / FS-ACT-008.02 Enable CAs to **download a file** with all submitted actor registration requests / Enable a CA to **upload a file** with the validation outcomes for those requests
  - Done: requirements collected, and XSD definition of fields ready
  - Ongoing: design of User Interface
  - Testing on April 2019

# Playground and demos

- The Eudamed playground will be available on the 11<sup>th</sup> of February.
  - **Deadline for feedback** on the playground is the 21<sup>st</sup> of February.
- Please note that no real information should be encoded in the playground, only dummy data for verification of the implemented functionality.
- A functional mailbox for questions and comments will also be communicated.
- Videos/demos will be available from CIRCABC on the [DEMO library](#) on the 4th of February.



# Scope of 2nd release 1/2

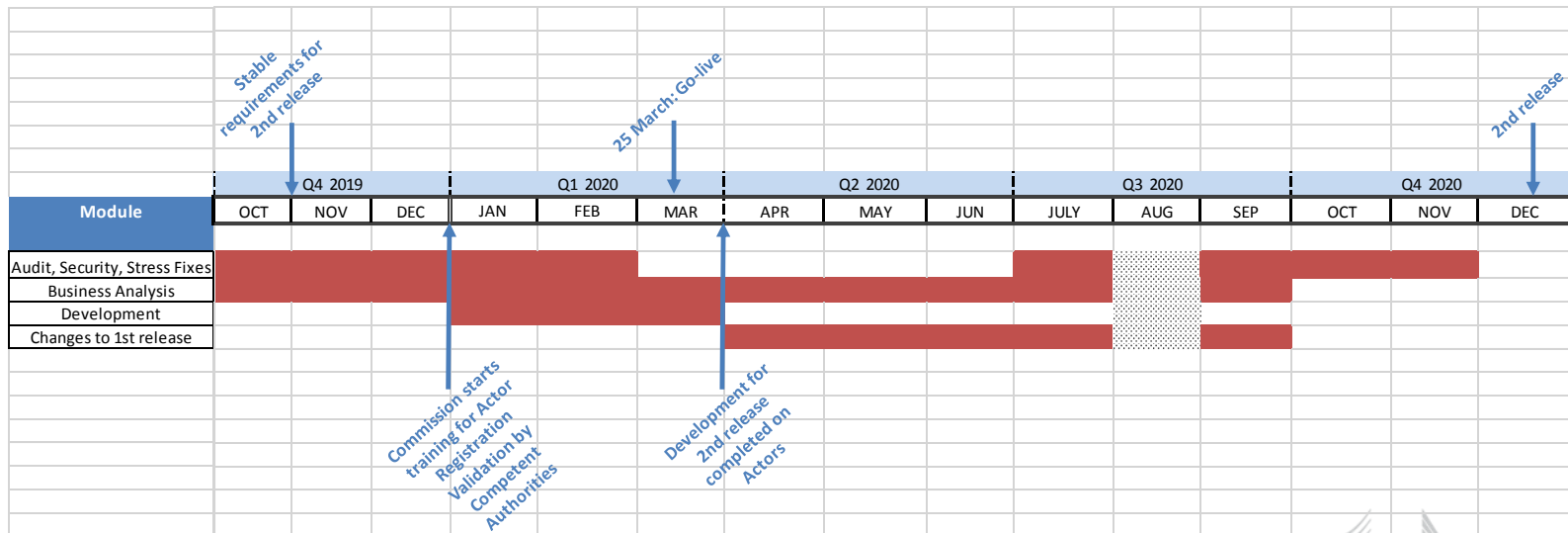
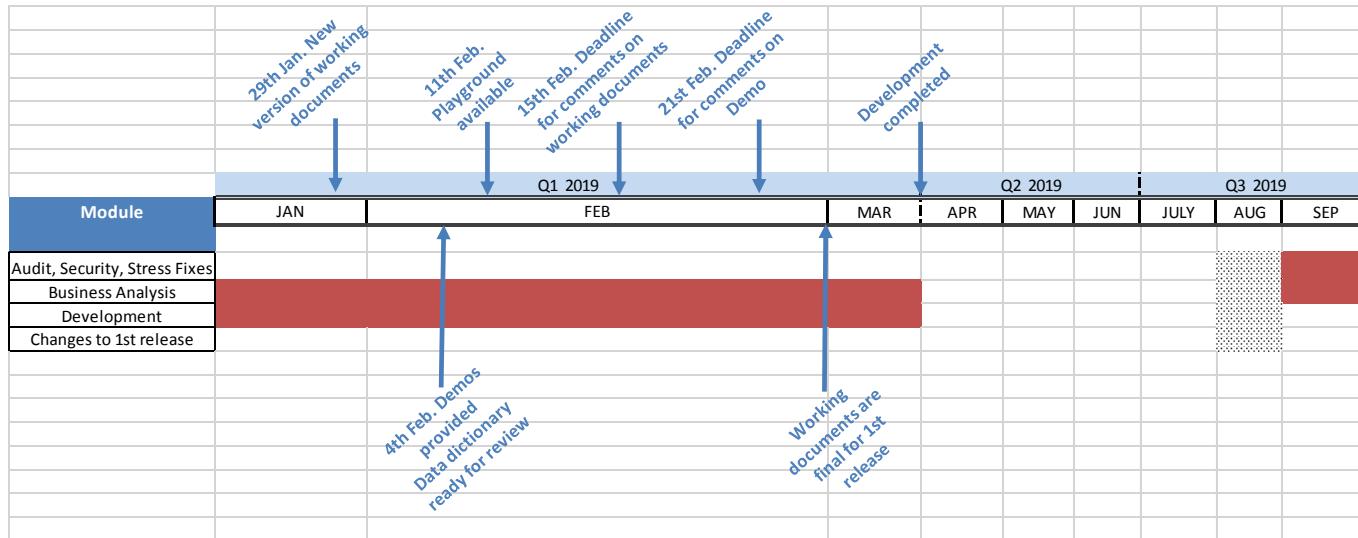
- Show terminated accounts on My Account(s) page
- Delete long running draft Actor Registration Requests
- Reactivate an actor
- Confirm periodically Economic operator data accuracy
- Deactivate Economic Operator or Sponsor
- Deactivate own Actor
- Register third countries' Organisations
- Register a Competent Authority
- Deactivate Competent Authority
- Create a new version of Competent Authority details
- Make relationships between actors other than importer/non-EU manufacturer ones

# Scope of 2nd release 2/2

- Suspend my account
- Suspend an account
- Resume my account
- Terminate my account
- Resume an account
- Reactivate an account
- Terminate all my accounts
- Suspend all my accounts
- Resume all my accounts



# Implementation plan update



# Thanks for your attention

- Questions?