



8th MDR Eudamed Actor Registration ad hoc WG Meeting

**Implementation plan update for
Actors**

23/08/2018

Planned Meetings:

- 23/08/18 – 8th Actor Registration WG
- 13/09/18 – 5th NB & Certificates WG
- 27/09/18 – 5th UDI & Device WG
- 04/10/18 – 3rd Vigilance CI/PS WG
- 18/10/18 – 3rd CI/PS Vigilance WG
- 25/10/18 – 2nd Market Surveillance WG
- ~~21~~29/11/18 – 4th Data Exchange WG
- 13/12/18 – Steering Committee
- 29/01/19 – 9th Actor Registration WG

Implementation plan

Project deliverables

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



Implementation plan

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





ACT - State of Play

- Functional Specifications document
 - a new version following last MDCG meeting, discussions and feedback received from Member States & stakeholders will be sent for review by end of next week to MDCG and WGs
- Implementation plan
 - Update will be sent after inclusion of the new version of the functional specifications
- Documents provided for review for Actor Registration (ACT) and for Identity & Access Management (IAM)
 - Business Processes (ACT + IAM)
 - Use Cases (ACT + IAM)
 - Business Rules (ACT + IAM)
 - Entity Model (ACT)
 - Security Matrix
 - UAT conclusions



ACT - State of Play

- Soon to be provided for review
 - Wireframes / Mock-ups for user navigation and dashboards
- Have review iterations on these documents with the aim to finalise in October 2018



State of Play

- FS-ACT-001 Economic Operator registration
 - Done: Registration of MF, AR
 - To be done: Registration of Sponsors (until 17/12), Importers (until 28/09), remove Generic device groups, SPPP
- FS-ACT-002 Economic Operator and Sponsor details Update
 - Partially Done: Update of MF, AR
 - To be done: Sponsors, Importers, mandate update
- FS-ACT-003 Search and view actor details
 - Done: filtering and view
 - To be done: simple search (search criteria to define), dashboards for different actor types





State of Play

- FS-ACT-004 Machine to machine (M2M) Actors data Download
 - Service definition (for review by DTX WG)
 - Simplified version ready for testing by CA in November
- FS-ACT-005 Manage association (mandate) between non-EU manufacturer and AR
 - Planned for development in September
- FS-ACT-006 CA registration
 - Registration will be performed by COM following MS information
 - Mock-ups will be provided in September showing screens for CA



State of Play

- FS-ACT-008 Download/Upload for actor registration requests validation
 - Download expected to be tested in November
 - Upload expected to be tested in January 2019
- FS-ACT-009 Search and view refused actor registration requests
 - Planned until 28/09
- FS-ACT-10 Importer to associate itself to non-EU manufacturer (and possibly their specific devices)
 - To be done (November)





State of Play

- FS-CRF-011 Provide NB actor and designation data
 - Planned for December
 - Dependent on Nando update
 - Only NB actors details are in the scope of the Actors module in Eudamed
- FS-CRF-012 Manage list of subsidiaries
 - Planned for December
- FS-CRF-013.01 Enable to view NB information relating to its Actor information, notifications for MDR/IVDR Information and list of subsidiaries.
 - Planned for December is NB information relating to its Actor information and list of subsidiaries.



State of Play

- FS-EUD-004 : Notification/Information email system
 - Done: engine to prepare and send emails
 - To be done: management of subscriptions (will be managed in the Actor module for all modules) and content of emails for the Actors module
- 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





Acceptance testing

- Next acceptance testing for actors module in January 2018



Questions?

