



MDR Eudamed (Actor) Registration WG 8th meeting

Planning - Roadmap

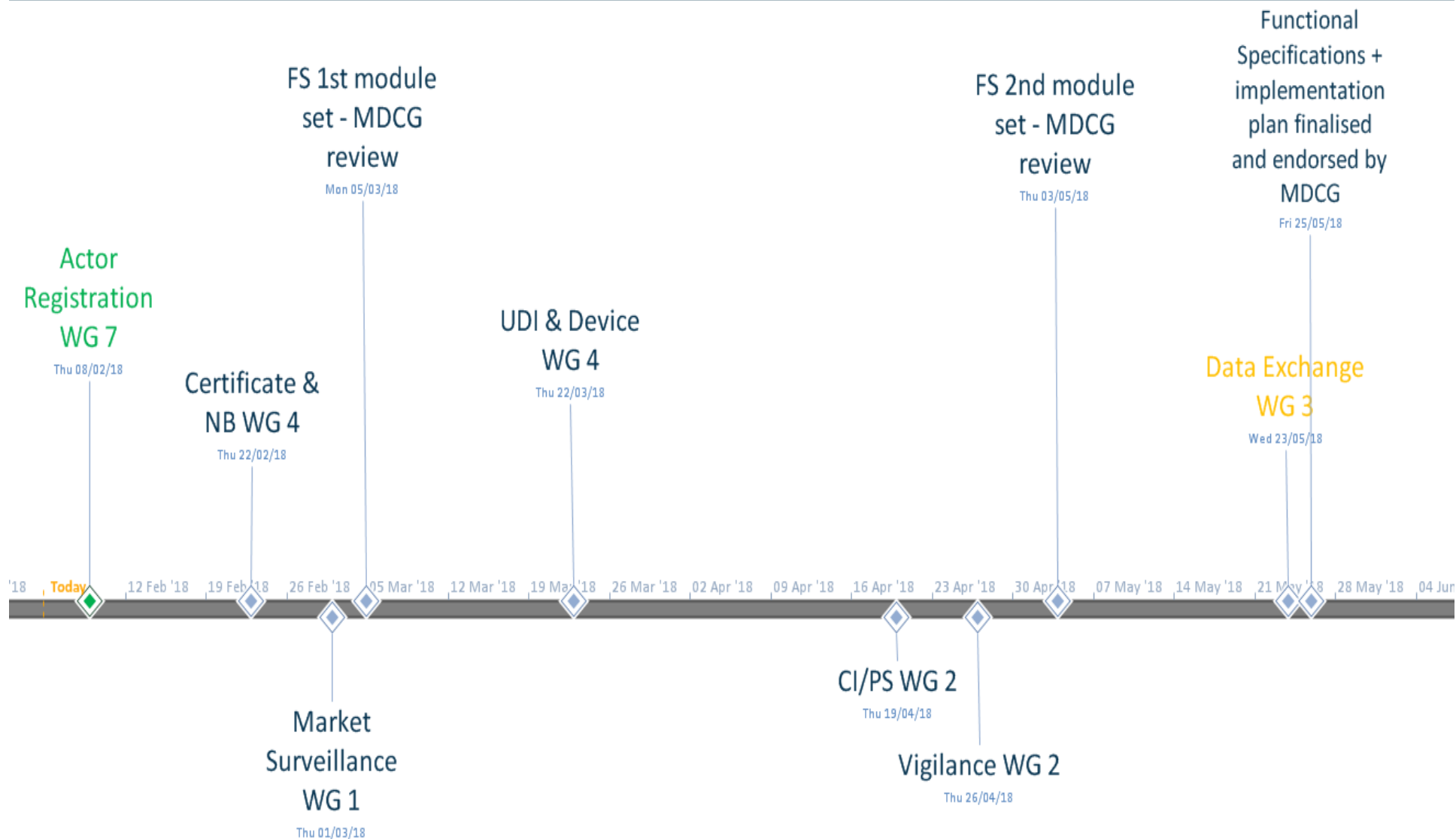
08/02/2018



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Planning

Slide 2

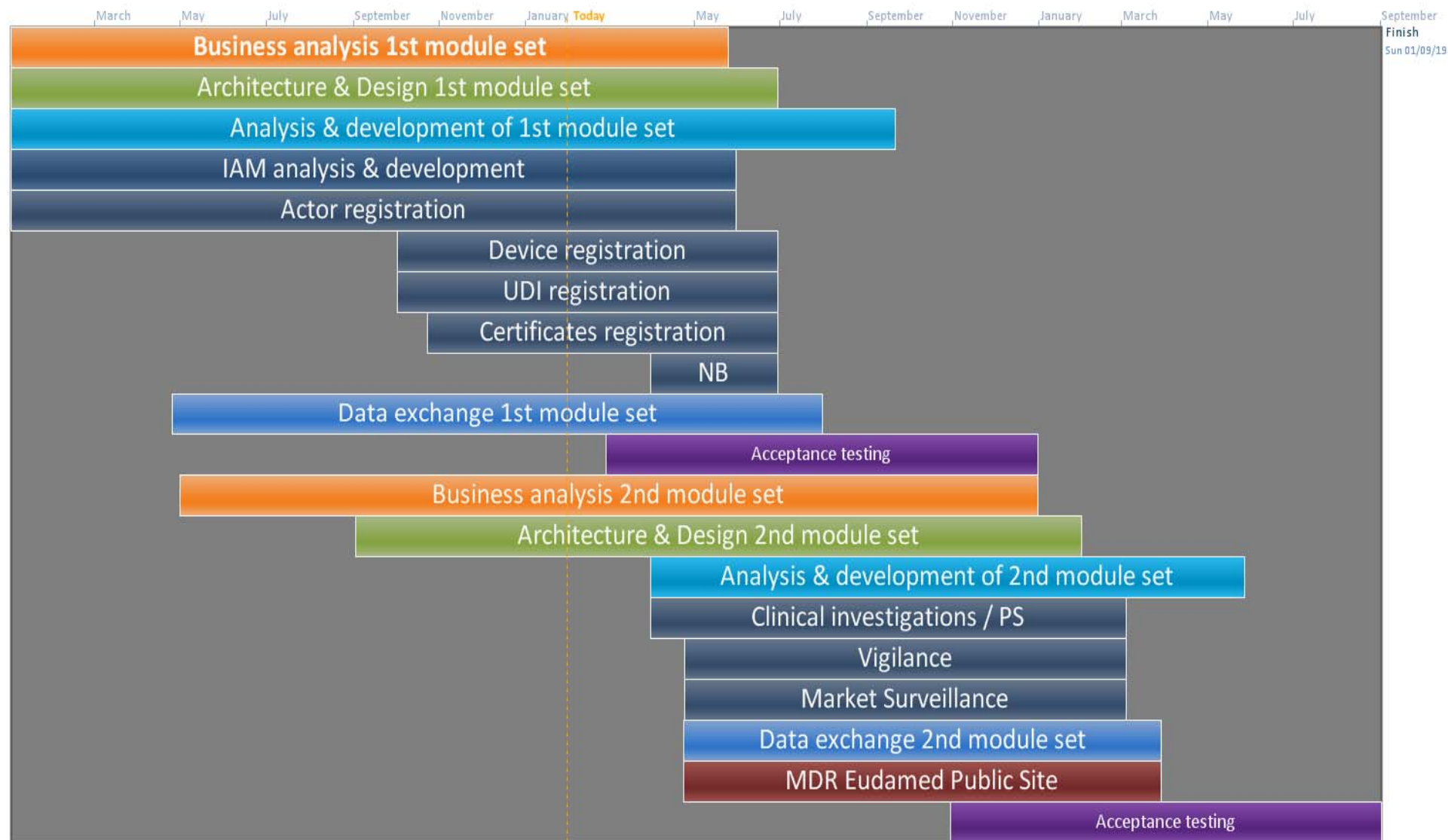




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Overall Roadmap

Slide 3





Acceptance process

- **Based on functional specifications**
- **Regular testing by WG members or delegates when functionality has been implemented**
 1. **Testing separate modules**
 2. **Testing integration between modules**
- **First time: on-site (DG GROW), in the future on-line**
- **Feedback will be done through wiki**
- **Feedback will be analysed and used to improve the system, in line with functional specifications**
- **Audit before Go-Live**



First Actor Registration test

- **Date: 12/04**
- **At DG Grow premises (GROW ROOM BREY 08/180 IT TRAINING (20P))**
- **Seats: 20**
- **EU login accounts for testing the system will be provided**
- **Morning session + beginning afternoon: based on test scenarios**
- **Afternoon session: free testing**
- **Attendees will receive access to wiki for feedback (personal EU Login account needed)**





Tests

- **What will be tested?: content and user interface for restricted site**
 - **Submit registration request of MF (EU, Non-EU), AR**
 - **Verification of registration request of non-EU MF by AR**
 - **Assessment of registration requests by CA**
 - **Assignment of SRN**
 - **Assistance for duplicate detection**
 - **List/Search registered Actors**
 - **Display Registered actor details**



- **Update Registered Actor data (MF, AR)**
- **Allow users to switch between Actors**
- **Submission of new user access requests**
- **Assessment of new user access requests**





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Test Scenarios

Slide 8

FRs Area:		ACTORS REGISTRATION			
Module:		EUDAMED- ACTOR REGISTRATION			
Test Summary					
Test ID:		EU.ACT.MF-A04/A12		REQUIREMENT TRACEABILITY:A04/ A12	
Scenario:		A Requesting User can log onto EUDAMED Application and submit registration as a Manufacturer			
Test Objective:		The Manufacturers register their identification data in EUDAMED and receive a Single Registration Number, after validation by a Competent Authority. As soon as the Actor is registered the system assigns the Local Actor administrator profile to the requesting user, so that he/she may manage additional users of this Actor.		Pre-Requisites:	1. The Requesting User has an EU Login account, has opened session in EUDAMED. 2. A user acting on behalf of the Competent Authority responsible for Actor registration has an account in EUDAMED with the profile "Validator"
Base Test Data					
User Profile - Requesting User with EU LOGIN Account					
Step ID	Step Details	Test Data	Expected Result	Passed Y/N	Comments/ Actual Result
ACT.EC 01.01	Log into EUDAMED Web application		EUDAMED Home Page (User and Actor Registration Page) is displayed		
ACT.EC 01.02	Select the link to ACTOR REGISTRATION in the EUDAMED Home Page		Actors Registration Disclaimer Page is displayed		
ACT.EC 01.03	Click on the Check Box for - (have read the disclaimer and click on Next button at the bottom of the page		Actors Registration Registration Page is displayed		
ACT.EC 01.04	...				



Questions?

