



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Organisations

Presented by: Kepa Amutxastegi
Project Manager for OMS



1. Project status

2. Organisations Roll-out plan

3. OMS User Acceptance Testing (UAT)

Project Status

Amber

Key achievements since last EUNDB/Taskforce reporting (September 2015)

1. Business Case approved in December by EMA Executive Board
2. OMS subgroup tested the implementation of Phase I operating model based on real business scenarios
3. Work has begun to involve veterinary stakeholders in the SPOR activities (via EUNDB, ISO IDMP TF)
4. Change management / communication activities underway to support the SPOR projects

Key risks & issues:

1. EMA has limited resources for the project - Additional support required from the network (*Issue*)
2. Last minute registration requests before product iteration 1 enforcement – EMA won't cope with volumes (*Risk*)
3. IAM solution integration architecture is still uncertain (*Issue*)

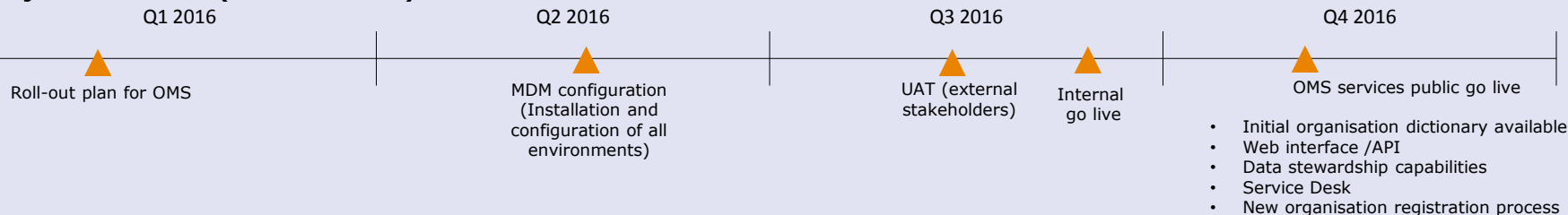
Activities since last f2f EUNDB/Taskforce (September 2015)

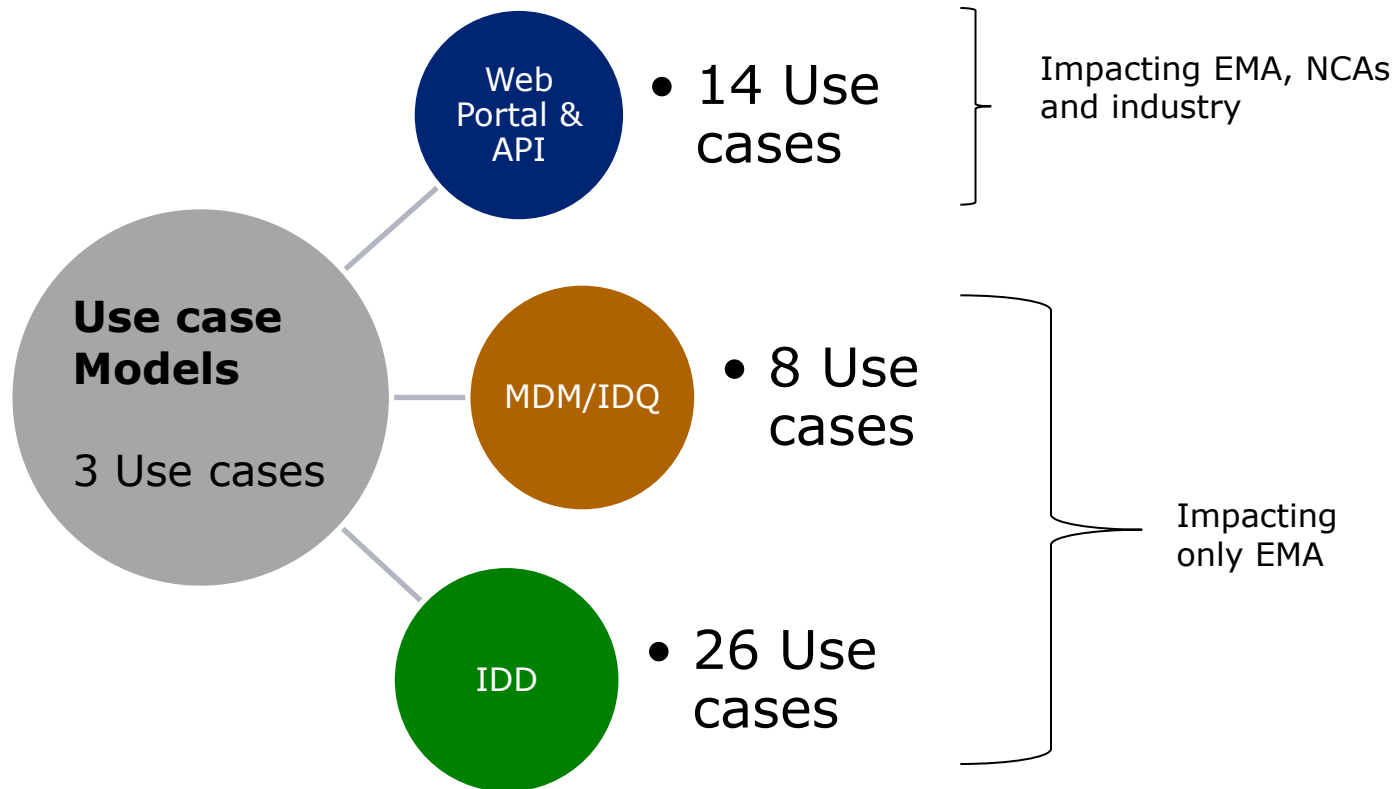
- Analysis and design phase almost complete
- Implementation phase started in January
- Roll-out plan for NCAs / Industry prepared with EUNDB, showing:
 - What organisational data requires mapping
 - Which use cases drive the mapping
 - When the activity should start
- OMS Subgroup conducted activities such as discussing, reviewing and endorsing the logical data model, requirements and solution in general

Upcoming activities

- Final sign-off of system use cases, logical data model, process models and detailed requirements underway
- Completion of draft API interface specification
- Endorsement of Phase I Operating Model by EUNDB / ISO IDMP TF in Feb
- Continue development of the UAT plan for OMS
- Presentation of the OMS Roll-out plan at the HMA in February
- Dedicated webinars to be delivered to IT Directors February / March to present the OMS roll-out plan and discuss mapping considerations

Project milestones (until end 2016)





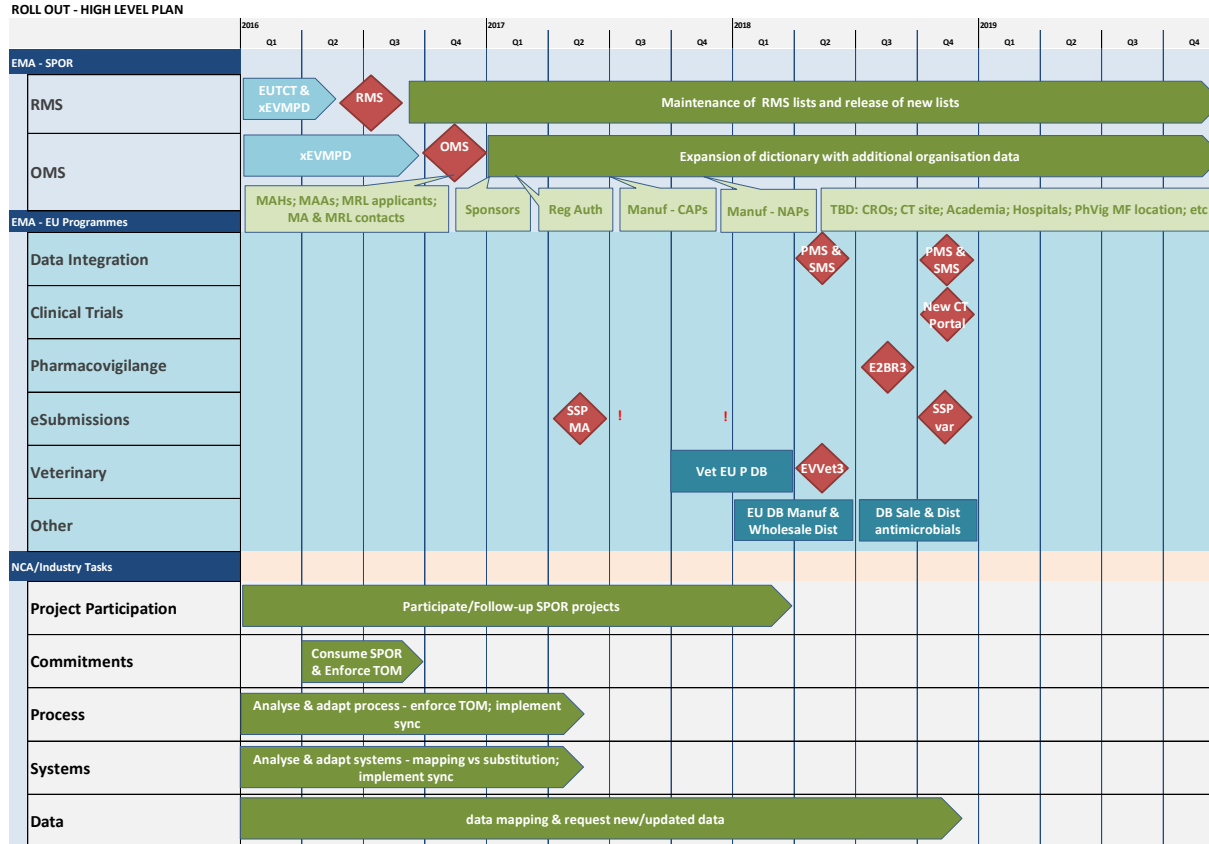


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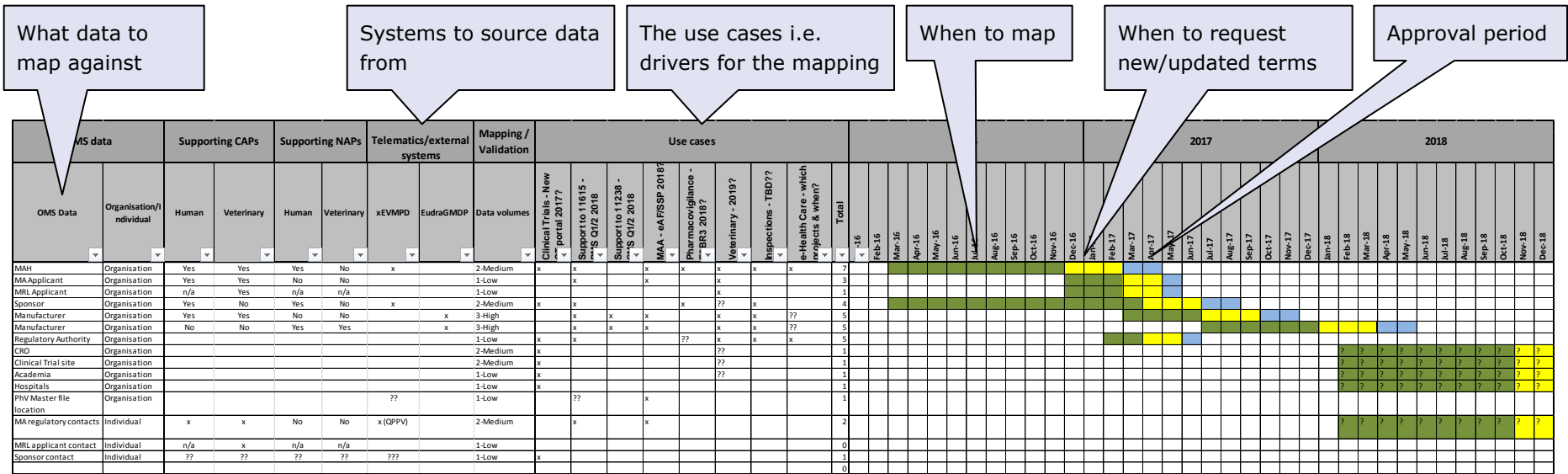
Organisations Roll-Out Plan



High Level Roll-out Plan



Organisations Data Roll-out Plan



- Mapping should start ASAP against xEVMPD for MAH and Sponsors
- Mapping of other organisations data can start only once it is available in the dictionary
- Mapping/requests need to complete ideally 3 months before implementation of intended Use case
- All major programmes have deliveries before 2019 -> to map all data work needs to start ASAP

Organisations Roll-out plan

What	When	Details
<ul style="list-style-type: none"> Participate/Follow-up OMS project 	<ul style="list-style-type: none"> Throughout 2016 	<ul style="list-style-type: none"> OMS Subgroup will need to continue work throughout 2016 and at lesser intensity through 2017 to support product and substance iteration 1 implementation
<ul style="list-style-type: none"> Commitments <ul style="list-style-type: none"> Consume Organisation data & enforce operating model Contact Points (EMA, NCAs and industry) 	<ul style="list-style-type: none"> By end February 	<ul style="list-style-type: none"> Each NCA to nominate a contact point for SPOR (to be provided to IT Directors in preparation of the Telematics Forum)
<ul style="list-style-type: none"> Adapt systems & processes 	<ul style="list-style-type: none"> From 2016 	<ul style="list-style-type: none"> Analyse impact on existing processes to support: <ul style="list-style-type: none"> Implementation of the operating model including pre-registration of organisations data Transformation / enrichment / mapping of data locally Data consumption / synchronisation with OMS Choose implementation approach: continuous mapping between own system & SPOR vs substitution of own data by new SPOR references
<ul style="list-style-type: none"> Map / Validate data 	<ul style="list-style-type: none"> Start ASAP vs xEVMPD 	<ul style="list-style-type: none"> From now until Nov 2016 map: Mapping / validation of MAH and Sponsors (<i>xEVMPD</i>) From Dec 2016 – Mar 2018: Mapping / validation of content of dictionary: <ul style="list-style-type: none"> MAHs full list (<i>in OMS dictionary</i>) Sponsors, Regulatory Authorities, Manufacturers, etc. (added in the dictionary during Dec-2016 and Dec-2017) (<i>in OMS dictionary</i>)
<ul style="list-style-type: none"> New process to create new/update organisation data 	<ul style="list-style-type: none"> From November 2016 	<ul style="list-style-type: none"> From Dec 2016 - Feb 2017 request data for: MAH (NAPs/CAPs) + MA applicant (CAPs), MRL Applicant From Apr 2017 – Jun 2017 request data for: Sponsor & Regulatory Authority From Jul 2017 – Sep 2017 request data for: Manufacturers (CAPs) From Jan 2018 – Mar 2018 request data for: Manufacturers (NAPs) Others.... TBC (CROs, CT sites, PhV Master file location, Academia, Hospitals, etc.)



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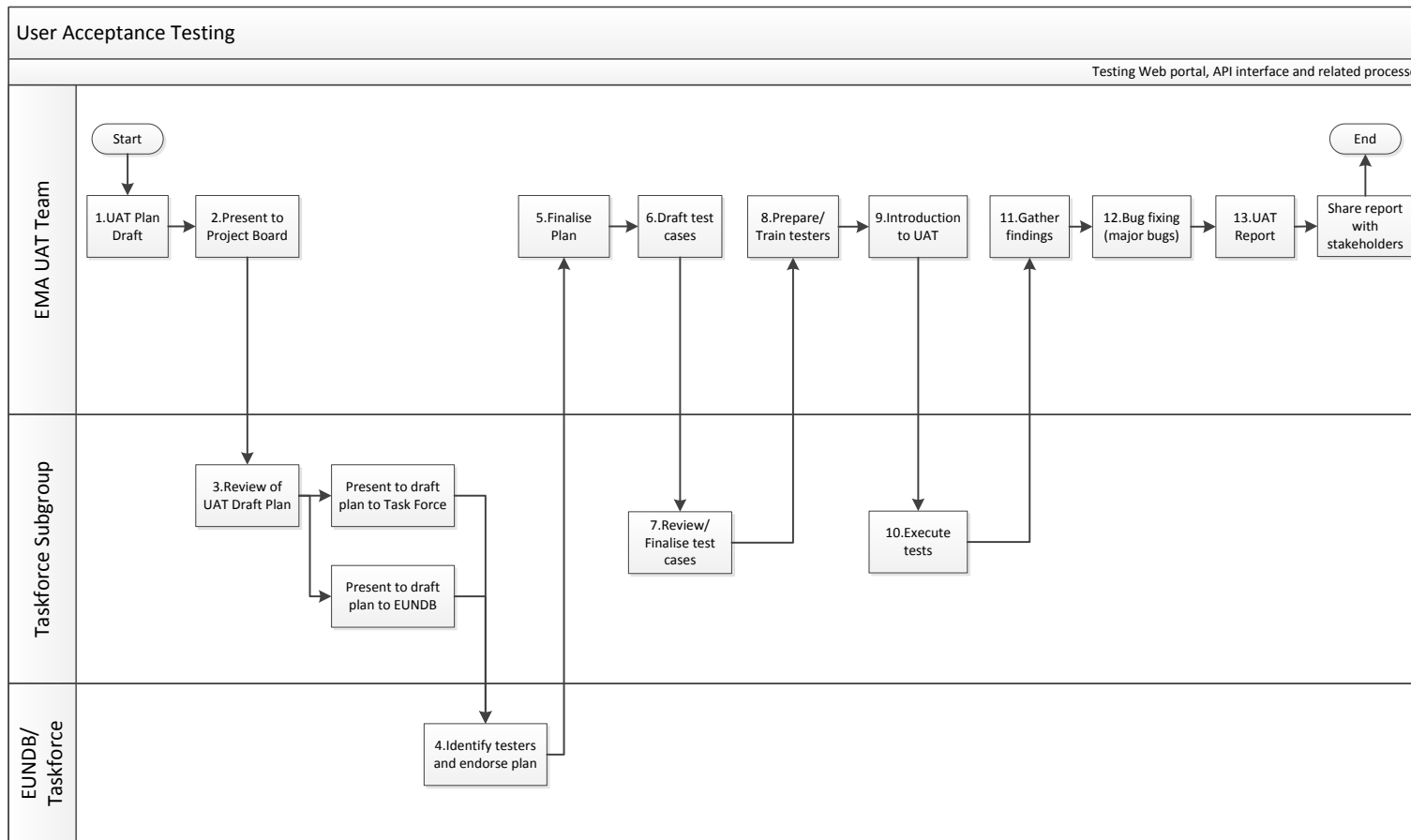
OMS UAT

Presented by: David Scanlon (AstraZeneca)



Phase	Objective	Who	Dates
UAT nominations	<ul style="list-style-type: none"> • NCAs = 4 H + 2 V (across L/M/S NCAs) • Industry = 4-6 H + 2 V • Software vendors = 2 • EMA = 4 	All	February 2016
UAT Preparation	<p>Test cases for:</p> <ul style="list-style-type: none"> • Agree on UAT plan • User registration • API interface • Web interface <ul style="list-style-type: none"> • Viewing & searching for organisation data • Create and view requests for new / updates of organisation/location • Exporting Organisation dictionary • MDM data stewardship <p>Data Preparation</p>	OMS subgroup	February– May 2016
Review	<ul style="list-style-type: none"> • Review UAT plan and Test Cases 	OMS subgroup & UAT testers	February - June 2016
Perform UAT	<ul style="list-style-type: none"> • Introduction & Training • Execution of UAT Test scripts, report any feedback 	UAT testers	11 July – 30 August 2016
Bug fixes & UAT completion report	<ul style="list-style-type: none"> • Ensure the UAT feedback has been appropriately documented, consolidated and classified • Draft and review UAT report 	EMA	26 July – 6 September 2016

OMS UAT Plan – Proposed process



OMS UAT Plan – Areas to test

Use Case	Activity/System Role	EMA Admin	Data Steward	NCA Super User	NCA user	Industry super user	Industry user	Unaffiliated user	Guest user
001, 004, 005, 001, 002, 046	View and search dictionary content	YES	YES	YES	YES	YES	YES	YES	YES
001, 002, 046	Open and view help document	YES	YES	YES	YES	YES	YES	YES	YES
001, 047	Upload help document	YES	YES						
004, 005, 007	Export dictionary & search results	YES	YES	YES	YES	YES	YES		
004, 005, 006, 008	Create & view Requests	YES	YES	YES	YES	YES	YES		
022, 023, 024, 025, 027	Accept/Reject requests	YES	YES						
026	Send notifications to requestor	YES	YES						
024, 025,	Implement data change in MDM	YES	YES						
N/a	Self register with IAM	YES	YES	YES	YES	YES	YES	YES	
N/a	Validate super user (NCA/Industry) access request	YES	YES						
N/a	Validate Industry/NCA user access request	YES	YES	YES		YES			
009	API: View and search dictionary	YES	YES	YES	YES	YES	YES	YES	
009	API: Export dictionary & search results	YES	YES	YES	YES	YES	YES		
003	API: Create & view Requests	YES	YES	YES	YES	YES	YES		
101	Log into the SPOR secure site	YES	YES	YES	YES	YES			
ALL except 009 & 003	Performance of the SPOR portal	YES	YES	YES	YES	YES	YES	YES	YES
003, 009	Performance via the API interface	YES	YES	YES	YES	YES	YES	YES	

This list is not exhaustive

Thank you