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SCIENCE MEDICINES HEALTH

PMS – Target Operating Model (TOM) Next Steps

SPOR Taskforce meeting 24 May 2019

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PMS Business lead

PMS and TOM

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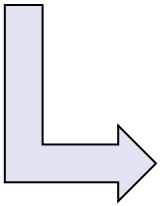
There is a legal obligation to make use of the terminologies defined in ISO IDMP standards: Regulation (EU) No 520/12012 (art. 25 & 26)

Scope of SPOR/PMS is determined by Business Case Implementation of IDMP standards

IDMP standards are all about master data

Key elements to support a TOM which links product data submission and validation within regulatory procedures are beyond master data



- Dates
- Procedure Types
- Assessment phases
- User access / Functionalities marked by step of procedures

PMS needs of parallel IT solution that can manage these aspects

Submission of product data - Human

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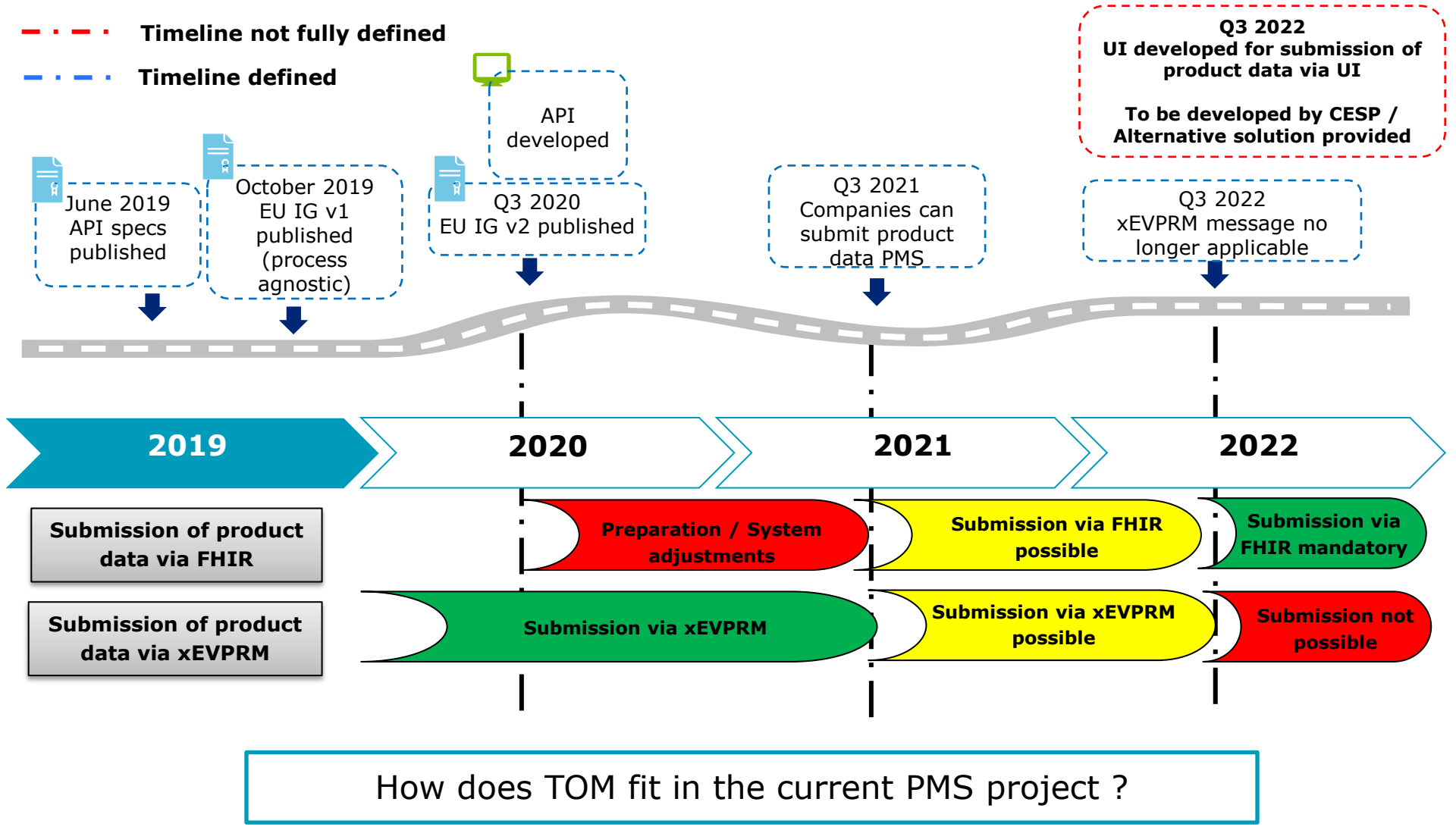
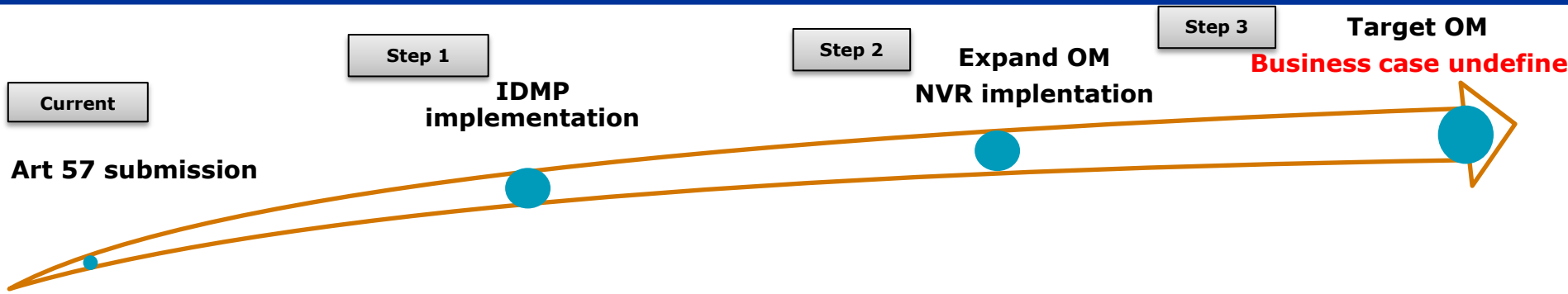


How does TOM fit in the current PMS project ?

How these factors fit into a TOM phase implementation?



Current – Art 57. submission	Step 1- IDMP implementation	Step 2 – Expand OM implementation	Step 3 – Target OM
Product data de-coupled from regulatory procedure - after procedure is finalised	Product data submission at possible at any time of the procedure – optional, likely for CAPs	Submission of Product data linked to regulatory submission	Submission of Product data linked to regulatory submission – full integration
Quality assurance of Product Data by EMA	Quality assurance of Product Data by EMA after regulatory procedure (Validation during procedure for CAPs can be explored)	Validation of product data during regulatory procedure by NCAs for NAPs and EMA for CAPs	Validation of product data during regulatory procedure by NCAs for NAPs and EMA for CAPs
Use of SmPC	**Use of Mod 3/SmPC**	**Use of Mod 3/SmPC**	**Use of Mod 3/SmPC**
Submission via xEVPRM	Submission via FHIR	Submission via FHIR	Submission via FHIR
xEVPRM database	Availability of API/EU IG/MDM hub	Basic technology solution (UI) to View/Edit/Create products	Needs of use case to support the change and development
	Business case available	**HMA/MB approval**	**HMA/MB approval**

Any questions?

Further information

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