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SCIENCE MEDICINES HEALTH

P&SMS Project Overview

P&SMS Drivers

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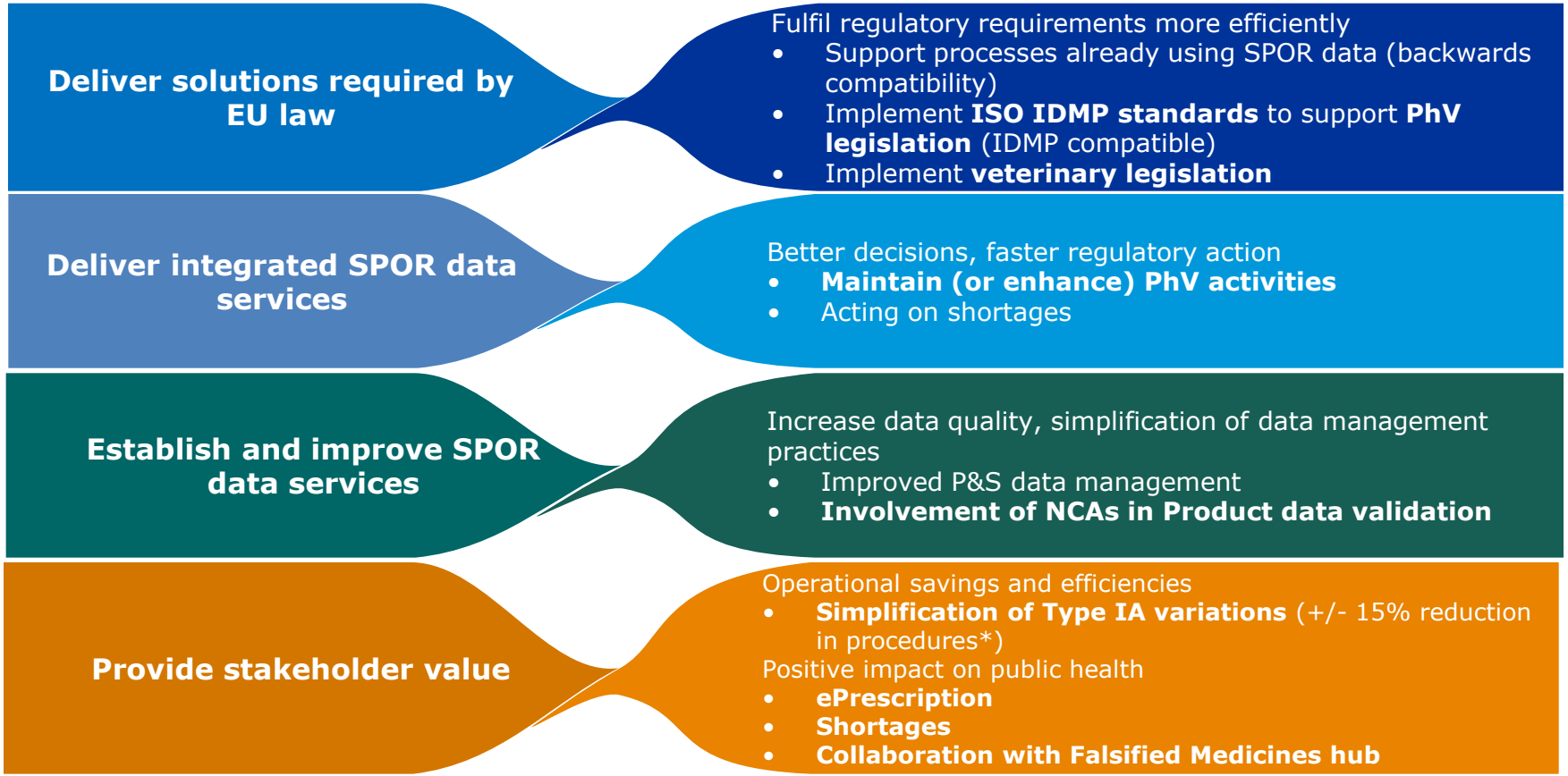

* According to ROG workplan

P&SMS Risks

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Risk	Impact	Mitigation
• Future solution could become too complex	• Delayed delivery • Scope crunch	• Focus on minimal viable solution
• Low NCA engagement	• Product data not validated by NCAs • Benefits not materialised	• Invest on communication and change management • Sell the Business case (prove benefits e.g. process simplification) • Escalate in Telematics
• Low Industry engagement	• No regulatory compliance • Benefits not materialised	• Invest on communication and change management • Sell the Business case (prove benefits e.g. process simplification)

• Brexit	• Increased resource demands from the network to overcome UK loss
	• Project could be slowed/disrupted or even stopped…
		• Timebox project to 2019 at latest
		• Focus on Products
		  • Deliver efficiencies needed to overcome Brexit shortage of resources
		  • Support PhVig and Type I A variation simplification
		• Simplify/de-risk S implementation

• Project de-prioritisation at EMA	• Project could be slowed/disrupted or even stopped…	• Continue promoting Business case for SPOR

What is SPOR delivering with Iteration(s) 1?

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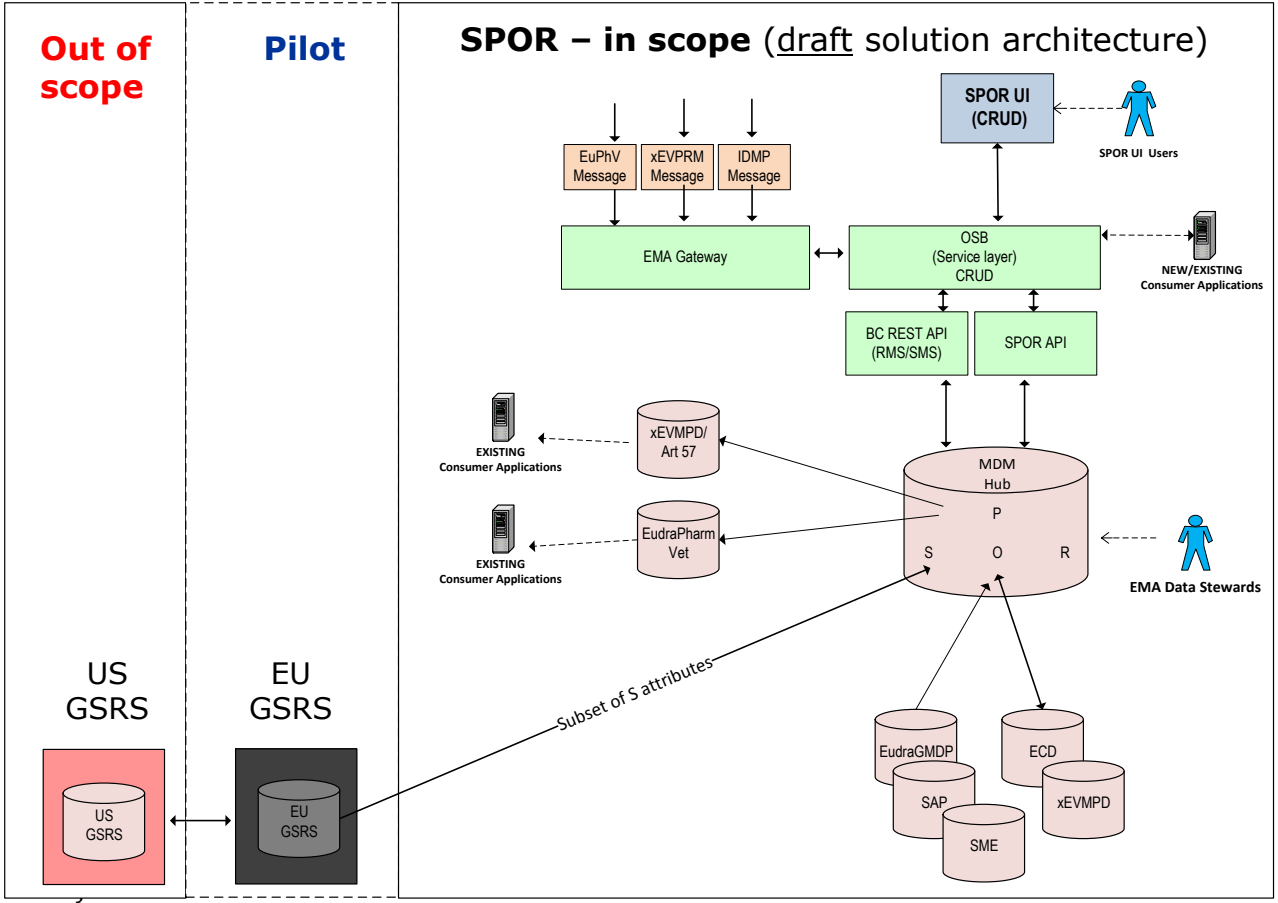


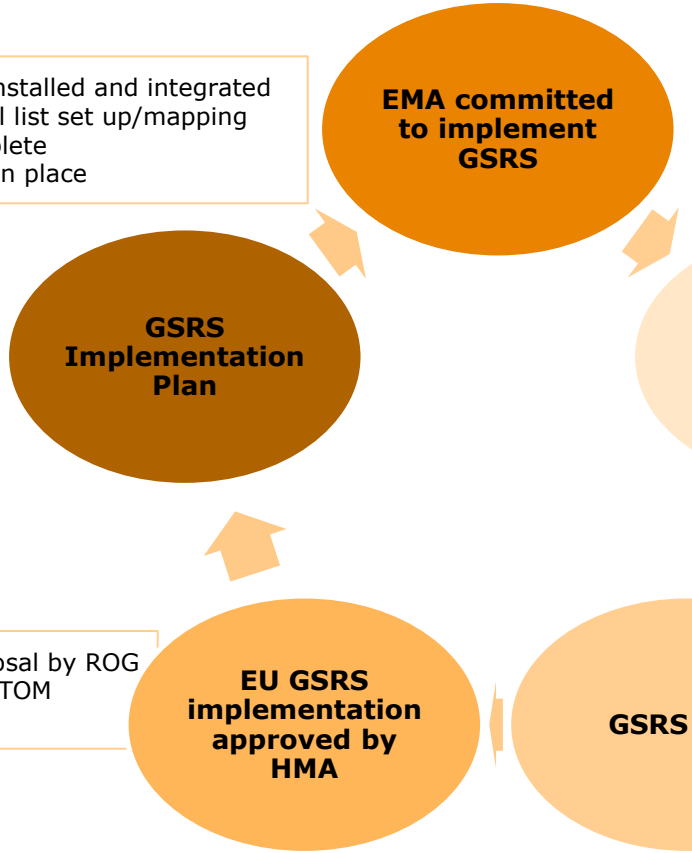
Referentials:
- ISO IDMP 11239 & 11240
- Data from EUTCT, xEVMPD
- Support Backwards Compatibility for systems consuming from EUTCT API

Organisations:
- Data from Internal and Telematics systems (EudraGMDP, SAP and SME)
- Feedback to Internal and Telematics systems (ECD and xEVMPD)

Products:
- Data from xEVMPD/Art 57 and EudraPharm Vet (+/- 60 fields)
- New data as per ISO 11615 and 11616 to support specific Business Cases (up to +/- 80 fields)
- Support processing of new messaging IDMP compatible/compliant (format TBC)
- Support Backwards Compatibility to xEVMPD/Art 57 and EudraPharm Vet
- Support NCA involvement in data validation
- Support O related type IA variation simplification

Substances:
- Consolidated data from EUTCT H, EUTCT V, xEVMPD, EudraPharm Vet
- Simple list to support Backwards Compatibility
- ***IDMP/GSRS implementation?***

SMS & GSRS Implementation



- SW installed and integrated
- Initial list set up/mapping complete
- SAB in place

- EMA is fully committed to building a more comprehensive S able to support extensive regulatory and public health use cases
- EMA must strive for a robust, feasible and pragmatic plan taking into account EMA and Network resource capabilities

- Software: implementation and maintenance
- Initial list set up: effort, resources, duration
- List maintenance: effort, resources (number and skills)

- EMA cannot plan a reliable IDMP/GSRS implementation
- There needs to be a Pilot to address the unknown and bring further light into IDMP/GSRS implementation in EU

- MEB/EMA/Industry Pilot
- Clarity on Software, initial List set up and TOM
- Propose Plan/Resources

- Proposal by ROG
- SMS TOM
- SAB

SMS Iteration 1 Scope

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In scope:

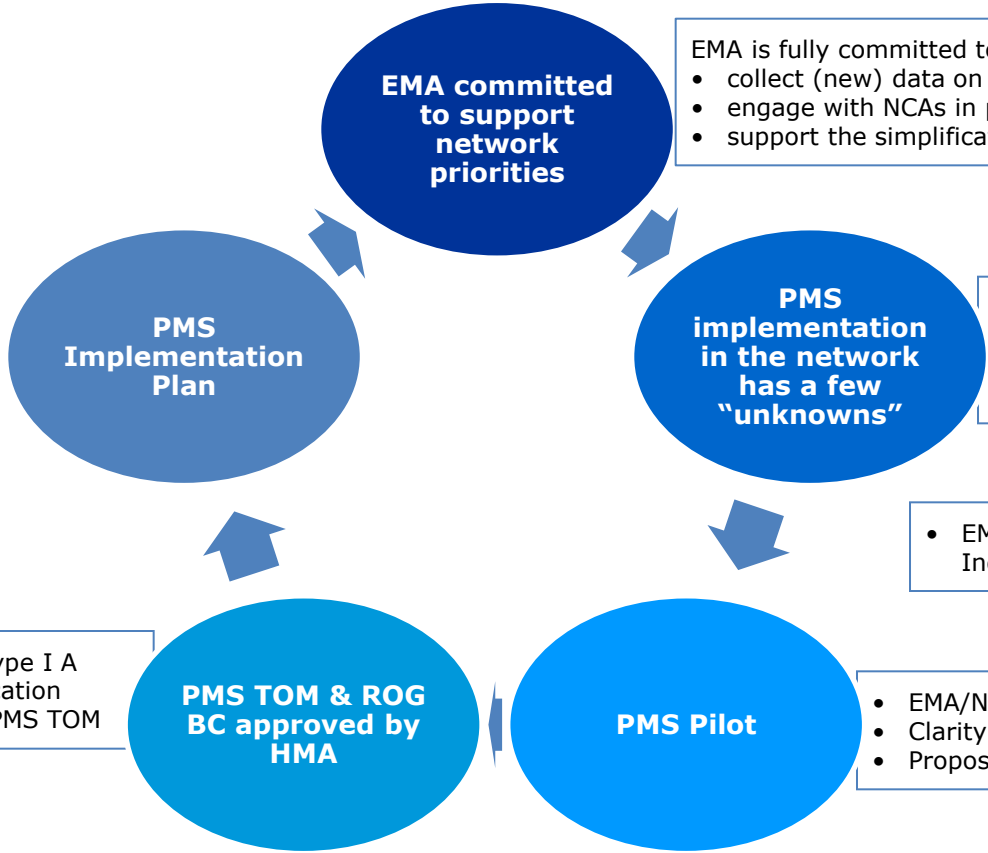
"Simple" list to support regulatory process across EU network

- Migrated data from EUTCT Human S, EUTCT Vet S, EV Human, EudraPharm Vet
- A consolidated Human and vet list
- Capabilities to Support substance data management – creation and updates, change requests, translations, subscriptions/notifications, etc
- Capability to get updates (deltas) from external source (e.g. GSRS) – * if updates available the list will be ISO IDMP compatible as IDs/records will be uniquely generates according to ISO 11238 specifications

Out of scope – subject to Pilot:

- SPOR integration with GSRS
- Initial mapping/set up of the EU substance list together with NCAs
- Set up of Target Operating Model with Substance Advisory Board
- *ISO IDMP compliant/compatible**
- EU-US consolidated list

PMS & Suppport to network priorities



EMA is fully committed to:
- collect (new) data on products including manufacturers;
- engage with NCAs in product data validation (PMS TOM) and
- support the simplification of Type IA variations through data submissions.

- Data collection: What data? Where from?
- Data validation: How? Against what? For how long? Resources (skills/numbers)?
- Type IA simplification: Dependencies? When? How?

- EMA also recommends a Pilot to understand the implications to Industry and NCAs

- EMA/NCAs/Industry Pilot
- Clarity on data collection and data validation: process, resources
- Propose Plan/Resources

- ROG: Type I A simplification
- SPOR: PMS TOM

PMS Iteration 1 Scope

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In scope:

- Migration data from Art57 and EudraPharm Vet
- Inclusion of the new data fields agreed in scope for PMS iteration 1
- Deliver EU Implementation Guide
- Art57 business processes and functionality revised in line with the new technology, new data fields, new message(s), additional variation types ("O" type 1A variations)
- Support processing of new messaging ISOIDMP compatible (format TBC)
- Capabilities to support product data management and data quality assurance & control framework(s)
- Capability to receive and manage updates from NCAs in the context of the data quality control framework

Out of scope – subject to Pilot:

- Integration with CESSP (to feed PMS in a single step)

P&SMS Project Timeframes

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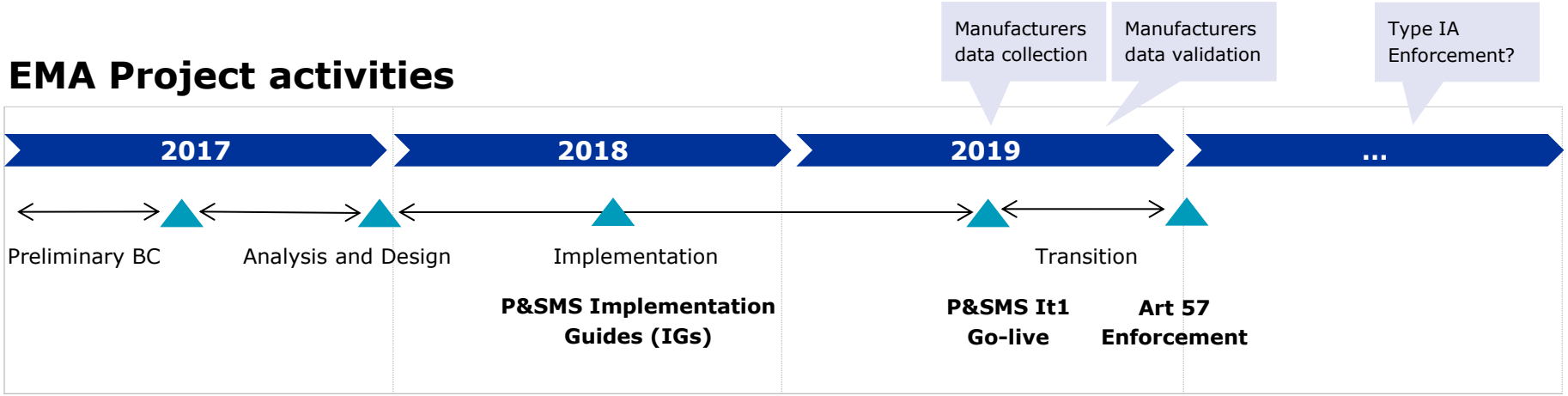
EMA Project activities



- Stages/milestones are **indicative** and reflect an estimated **timeboxed** plan based on external drivers/constraints.
- It requires adjustment of scope vs time so further details will be communicated at a later stage.

Telematics Governance involvement

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2017

- Engagement at Operational level (P&S SG, SPOR TF and Change Liaisons) to ensure requirements are captured and will be met
- Raise awareness mostly at Tactical level (EUNDB, IT Directors, IT DEC) of:
  - SPOR Business case
  - NCA activities and R&O mapping
  - P&SM plans & approach
- Support ROG Work Plan

2018

- Approvals at Strategic level (EUTMB/HMA) of:
  - P: EU IG (including fields, business process and NCA involvement in data validation)
  - S: Pilot results, EU IG (including fields, business process and NCA (SAB) involvement in data maintenance)
- Mobilisation of resources at Tactical level (IT Directors)

Thank you!