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SMS Update

EU SMS projects

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SMS implementation is shared as follows:

SMS "IDMP light"

- **Who:** Implemented by EMA
- **Data:** SMS data is the "simplified" PUBLIC substance data, that supports selection in regulatory processes and therefore enables you to distinguish two or more similar substances
- **Technology:** SMS solution covers:
  - Search, browse and export of PUBLIC substance data
  - Management of substance change requests
  - Translation management
- **Process/People:** EMA provides a broker service by managing substance requests, supporting translations and assuring data quality.

EU SRS ISO IDMP compliant

- **Who:** Implemented by MEB (NL)
- **Data:** EU SRS contains ISO IDMP substance data that supports scientific identification of substances. It includes PUBLIC and CONFIDENTIAL information subject to controlled access
- **Technology:** EU SRS solution covers only Substance data management
  - Software development/implementation led by NL in the short term in collaboration with EMA, under EU Telematics governance
  - Software maintenance to be transferred to EMA
- **Process/People:** This project is responsible to set up the EU Substance Validation Group (SVG) who will:
  - Prepare the EU substance list
  - Maintain the EU list by approving substance requests and managing substance data

(Draft) SMS Target Operating Model

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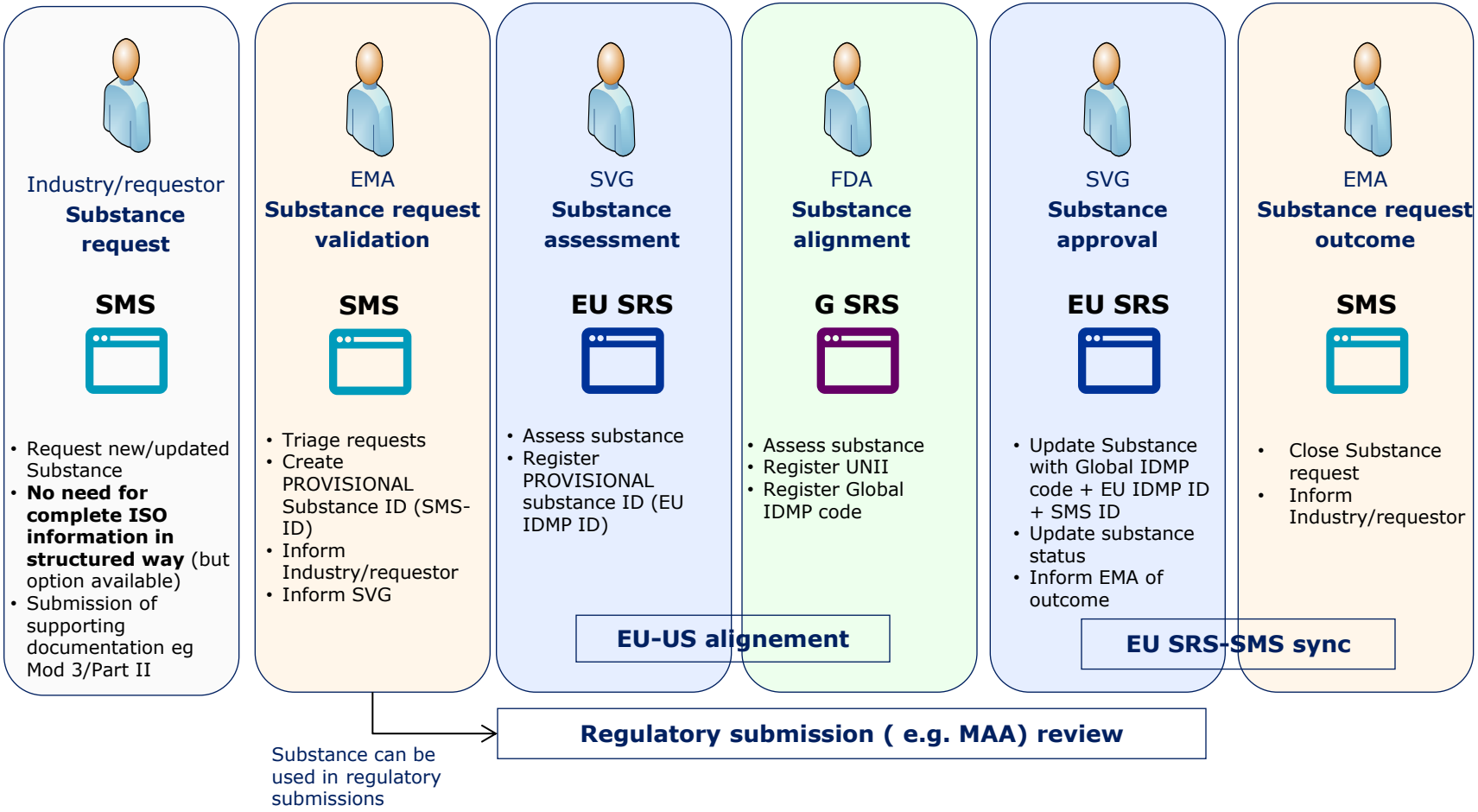
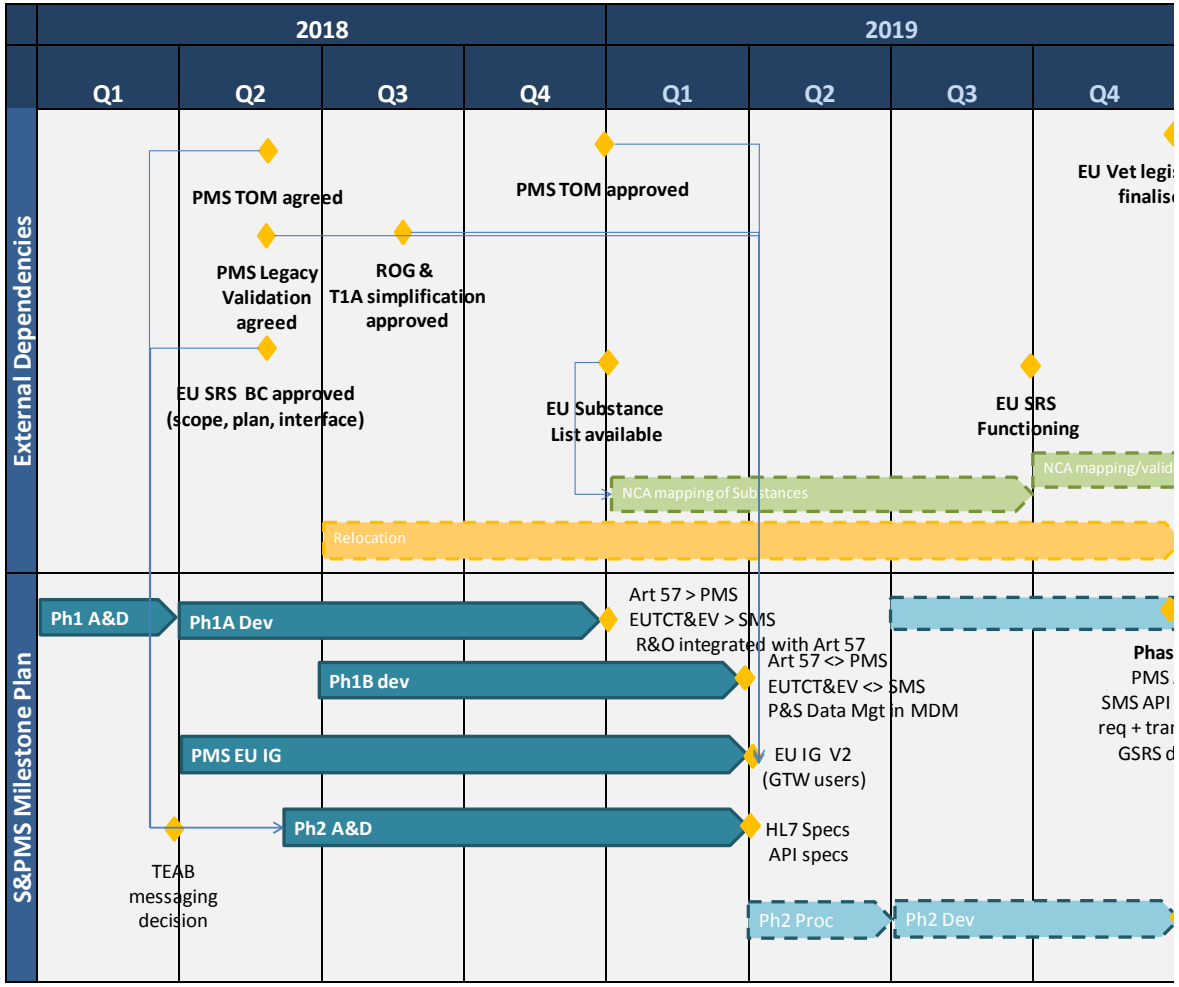


SMS TOM ensures:

- Regulatory processes can start as soon as substance is Provisionally registered
- EU-US alignment
- Data is approved by SVG before conclusion of regulatory processes i.e **only trusted data is used in regulatory processes**

SMS Plan & Dependencies



- **Phase 1A**
  - SMS ISO compatible/simplified hub
  - EUTCT&EV (H&V) migration into SMS
- **Phase 1B**
  - S data management in MDM (CRUD)
  - SMS feedback loop into EUTCT & EV – Backwards compatibility
  - Possible data load?
- **Phase 2 A&D**
  - TOM, Business process - syncronisation
  - Use cases
  - HL7 & API specifications
- **Phase 2 Dev**
  - SMS API
  - SMS UI (Change Requests & translations)
  - EU SRS synchronisation
  - EUTCT decommissioning

- Dependencies already in 2018
- Mitigation involves monitoring and exploring options
- If materialised may imply delays or a re-plan

SMS Dependencies

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Area	Dependency/Impact	Deadline	Mitigation/Options

EU SRS	• SMS Phase 2 Analysis and Design (A&D) cannot start without agreement on:
	  • Scope
	  • Interface
		• Q2 2018	• Work closely with EU-SRS team in Mar-Apr to get an outline of the scope of EU-SRS, requirements we can expect to be fulfilled by EU-SRS and the timing thereof
			• Monitor GSRS Business Case (June)
			• **Decision point in June.** If needed identify options and chose way forward:
			  • Delay Phase 2 A&D and as a result also delay the implementation of Phase 2
			  • Phase 2 with new scope (no EU SRS deltas)
			  • Add SMS Phase 3 (EU SRS deltas & improvements)
			• Re-plan

Relocation	• Changes to EMA systems cannot be deployed as there is a freeze and unavailablity of environments and deployments during defined periods in Q3-Q4 2018	• Q3-Q4 2018	• Plan around this
EU SRS	• NCA mapping/ product validation cannot start if a Substance list is not available	• Q4 2018	• Discuss with NCAs options & impacts