EU-SRS project update

4 December 2018

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Agenda

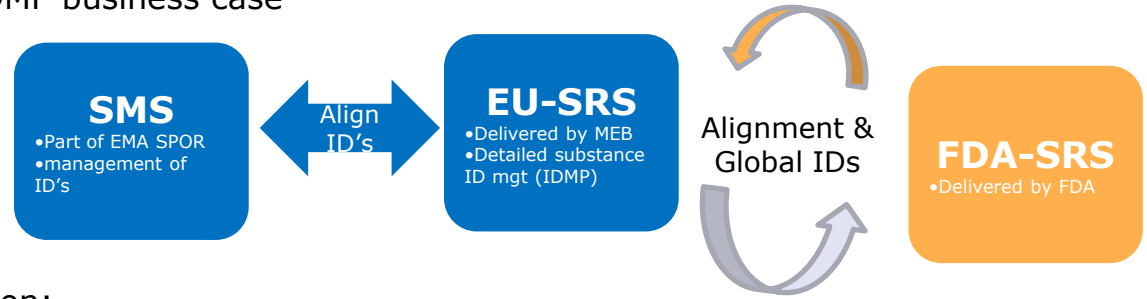
- Refresher of background
- Project status
- Next steps
- Q&A

- Appendix: background slides

What is EU-SRS

Precise substance identification supports unambiguous description of product composition as well as clinical safety and minimized toxicological risk

– as part of the IDMP business case



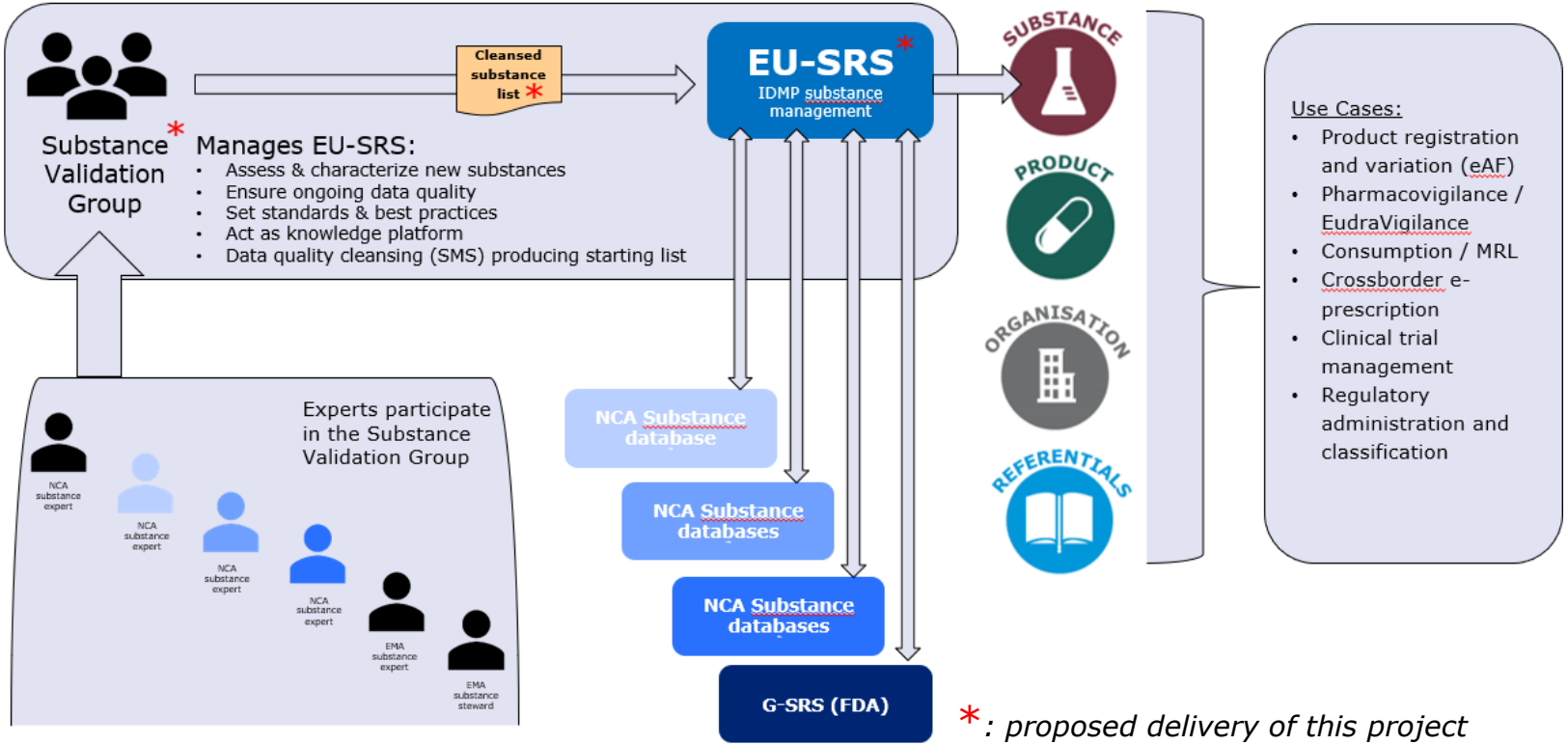
EU-SRS will focus on:

- Identification of complete chemical, protein, polymer, multi-substance material
- And structurally diverse substances in particular SMS is not equipped to capture the level of detail required for these classes:
  - Vaccines
  - Biologicals (e.g.monoclonal antibodies, plasma-derived substances)
  - Herbals
  - Homeopathics
  - Allergens

Benefits of substance management

- Acting as future proof knowledge platform for all substance experts in the network
- Increasing the cumulative substances knowledge for all agencies in the network – reducing duplicate efforts
- Reliable master data (substances) allows optimization and automation of processes and (semantic) interoperability (Telematics strategy, e.g. variations)
- Selection of substance / declaration of strength for product composition (in eAF) strongly improved, reducing rework
- Pharmacovigilance signal management – using high quality substance identifiers and hierarchy will improve side effect reporting and analysis capabilities
- Cross-border ingredient management – facilitating generic e-prescription
- European (and global) product supply chain traceability – control over ingredients in case of issues, Falsified Medicines

Outcomes of the project



*: *proposed delivery of this project*

Project status

- Extension of EU-SRS project team
  - EU-SRS Solution architect added through MEB (Pim Aarts)
  - Gustavo Rodriguez (EMA) joined as solution architect counterpart to ensure adequate hand-over (in due course)
  - Annet Rozema added to the team to support Project Management and preparation of the business case

Meeting BFARM, EMA and MEB

On November 25, BfArM hosted a meeting in Bonn between EMA, BfArM and MEB to align thougts on the substance management system

- BFARM decided to use GSRS as basis to start national substance system in Germany to replace legacy system
- Demonstration of DE-SRS was given
- GSRS acknowledged as good starting point for substance management
- This implementation is a good baseline for EU-SRS

Discussion was held on the way forward:

- Use the experience of BfArM as baseline for EU-SRS
- Expand the EU-SRS project team with BfArM expertise and input
- Ensure a stepwise approach

Next step:

- Senior management EMA, BfArM and MEB will meet to confirm this approach

EU-SRS day #2: December 11, 2018

Important meeting for EU-SRS project to align thoughts on:

- Strategy for EU-SRS
- EU-SRS proposed initial scope + roadmap
- Implementation plan including timelines
- Architectural approach
- SVG / Data cleansing – resources, processes and timelines

The feedback will be implemented in the project plan. This will be confirmed during the day #3 of EU-SRS in January 2019.

Next steps

- Agreement of EMA, BfArM and MEB on approach
- Align the materials on the (more) stepwise approach
- EU-SRS day(s)
- Continued work on the signature fields
- Joining all relevant Telematics meetings
- Communication for further collection of input via the S-Subgroup
- Preparation of HMA business case materials

Questions?

Thank you

Background information

Use cases for substance management

Backwards compatibility	Must	Should	Could	Won't (Read: later release)
Via EUTCT: • Clinical Trials: (EudraCT, new CT) • H Pre-submissions (Orphan, UPI, PedDRA) • H&V MAA & Var Regulatory submission (SIAMED, eAF, CESSP, CTS) • NCAs **Via Art 57:** • Pharmacovigilance: (EV H, PSUR rep.) • Referrals • Fees	• Pharmacovigilance (signal detection, analytics) – legal driver • Product (composition) registration (H&V) – PMS TOM • Consumption (Veterinary business case) – legal driver • MRL (veterinary use case) – legal driver • Cross Border ePrescription – EC/public health	• Evaluation of Risk of Shortages - EC/public health • Variations (manufacturer details change) – ROG • CEP Management – ROG • Toxicology use case (under investigation)	• GMDP Inspection Support	• ASMF Management • Batch Recall Support • Supply Chain Traceability

For Veterinary: although legal requirement for substance management is present, actual detailed requirements will vary. Therefore, consideration to do a more stepwise implementation for veterinary.

Next steps

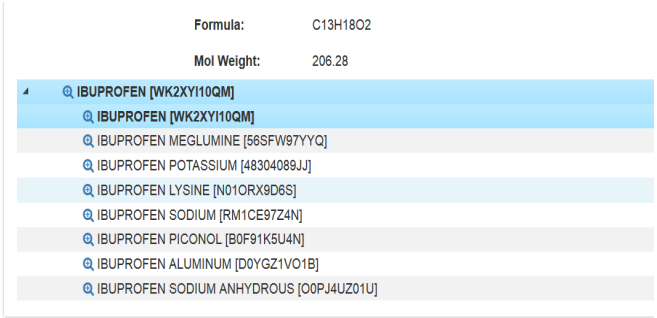
1. **Implementation of a European substances database (EU-SRS):**
   - with IDMP business logic for characterization of substances
   - Leading to a higher reliability of the list
   - Functionality to manage the more complex molecules such as biologicals, vaccines and herbals (known as structurally diverse)

2. **Introduction of the European Substances Validation Group (SVG):**
   - European (NCA/EMA) substance experts in virtual group
   - Governs the contents and enable European-wide use of substance information
   - Ensures high data quality and combines knowledge within EU Network

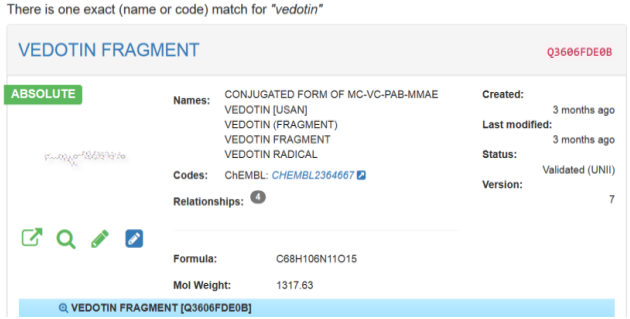
3. **Cleansing of the current substances list (EUTCT & EV):**
   - To level of quality that supports required processes (in SMS to SPOR, eAF, etc

A glance in the possibilities of EU-SRS

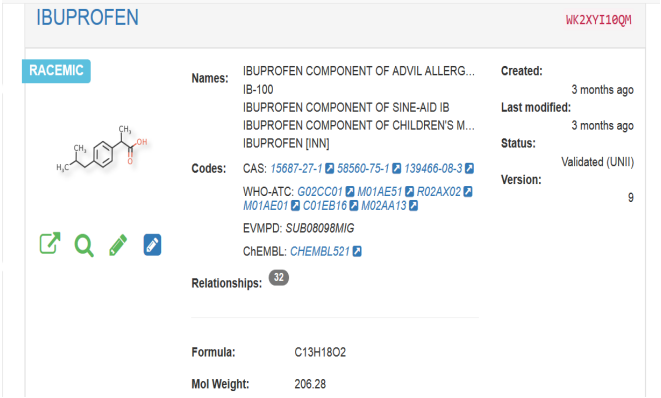
List of substances



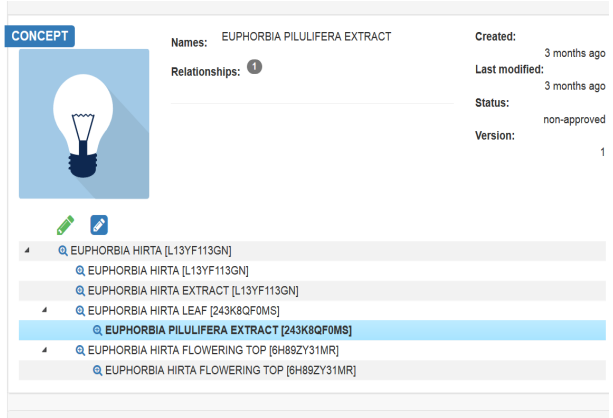
Details available



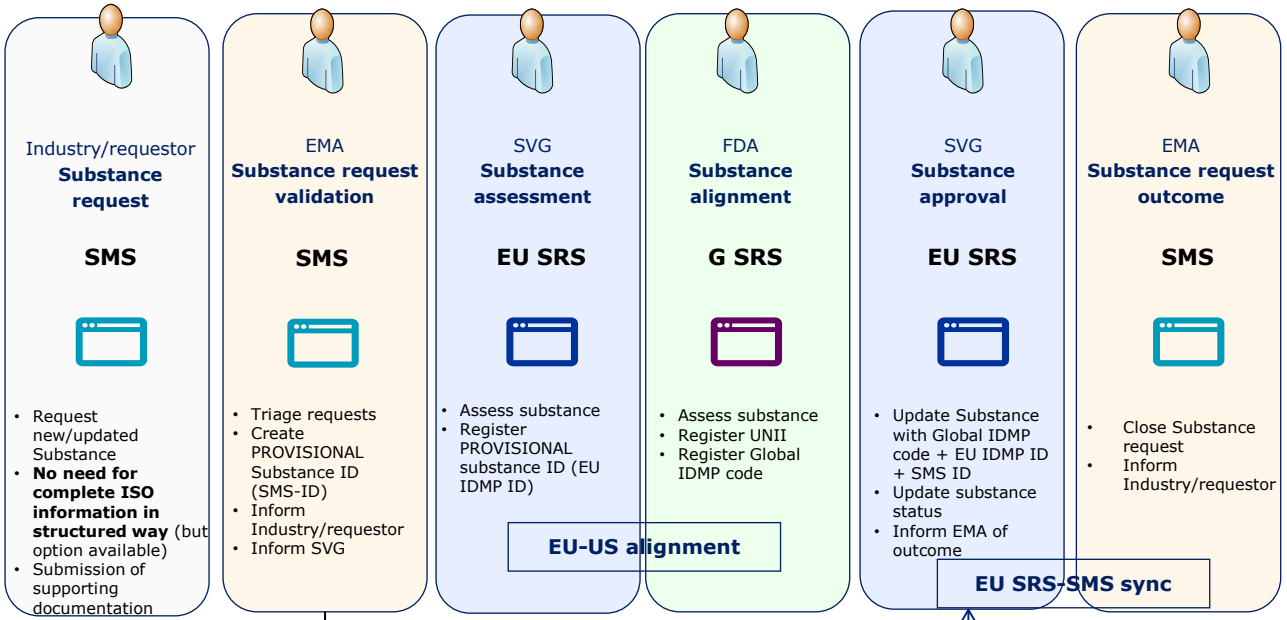
Links to sources and other codes



Hierarchy to related substances



Target Operating Model



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**