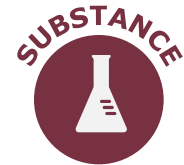




EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SMS - update to SPOR TF

SPOR Task Force meeting 24 May 2019



Presented by Jaume Gonzalez Noguerras on 24 May 2019
SMS Business Lead & SPOR Service Delivery Manager

An agency of the European Union




SMS plan Phase I-II (2019-2020)



Since mid 2018 EMA Service Desk portal is used by users such as MAHs and OD Applicants to request new S data or changes to existing S data. This is a temporary process until the SMS web portal is ready.

- SMS will replace EUTCT
- SMS CRs submitted through SMS portal
- NCAs and Industry will access S data through SPOR portal
- Users using S list from EUTCT will continue to have access through backward compatible API

 Sponsors of Clinical Trials will also need to use EMA Service Desk portal for development substances



Request Substance registration/updates via EMA Service Desk portal

Substance requests via SMS portal

2019

2020

2021

Phase I go live
- Data management capabilities to search/create/update data available to SPOR data stewards.

Phase II expected to be delivered in Q3 2020

- SMS web UI
- Additional capabilities: nullification/merge substances
- API

Phase III

- EU-SRS synchronisation (planned Q2 2021)



ETL

- UC5.1: Extract data from source systems
- UC5.2: Transform source data for loading into MDM
- UC5.3: Load source data into MDM
- UC5.6: Extract MDM data for feedback to source systems
- UC5.7: Transform product and substance data from MDM into source system model
- UC5.9: Load data into source systems

Create

- UC1.2: Create substance
- UC1.7: Bulk data entry

Update

- UC1.1: Update substance
- UC5.14: Automatic update

Other

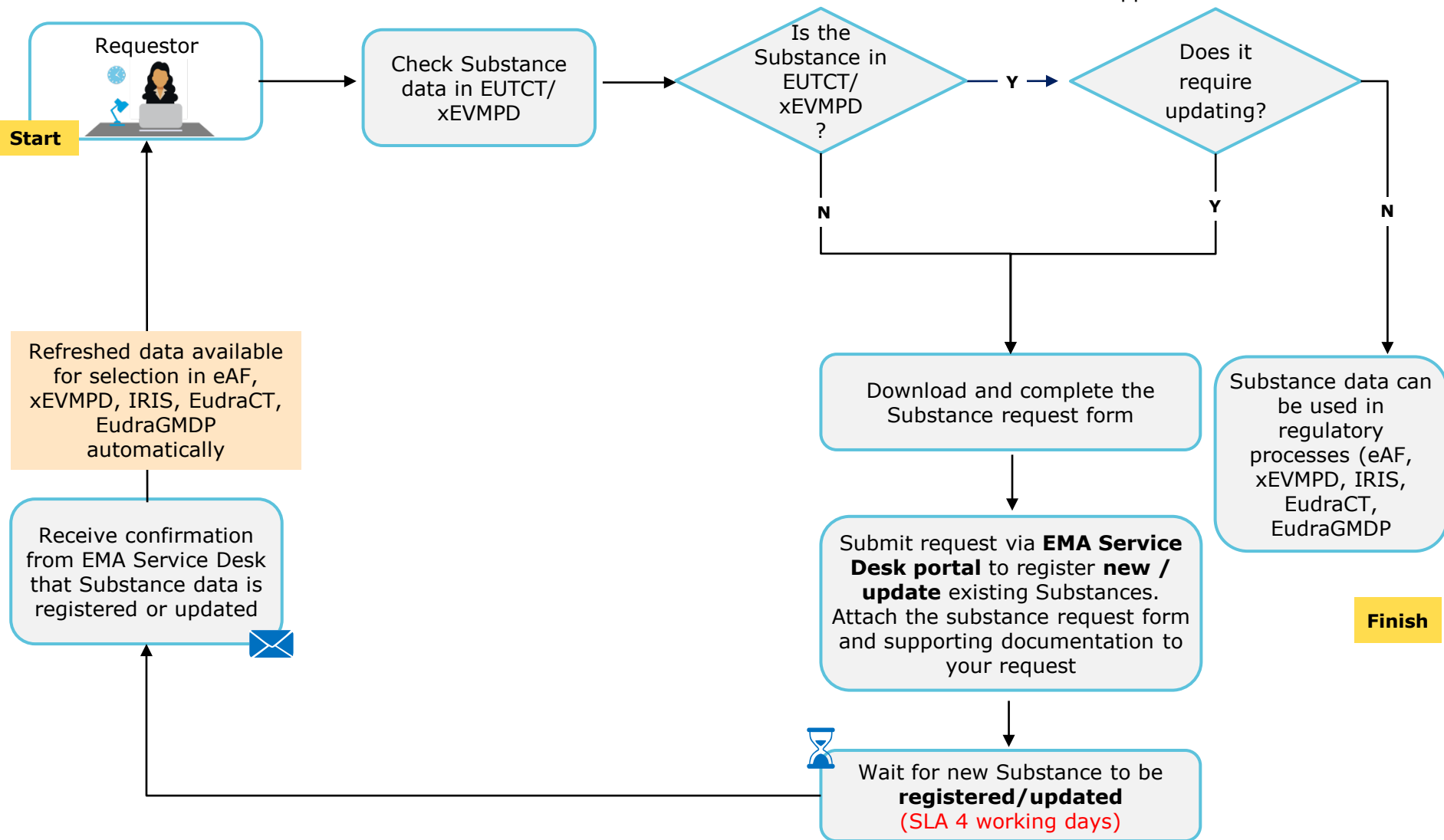
- UC10.1: IDD Login
- UC1.6: Search Substances in IDD
- UC5.11: Evaluate and action reference data change (S,O,R)

Process to register / update S data via EMA Service Desk portal




Note: Temporary process to be discontinued once the SMS web portal goes live. At that point all substance requests will be submitted via the SMS portal.

Note: Request S data before the application submission



Substance request form – part of Service Desk request process (until SMS portal goes live)



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REQUEST FOR REGISTRATION OF A NEW SUBSTANCE			
Please provide at least one preferred term in English and as many aliases as known. Copy the table below if multiple substances are being requested.			
Please adjust the privacy settings of each name if your substance is still in development. Public names will be published in EUTCT.			
Note: proposed INN and company code are not acceptable for Orphan Designation, Opinions on Paediatric Investigation Plans/waivers, and Marketing Authorisations			
Name type	Name	Privacy setting	Comments
Recommended INN		Public	
Proposed INN		Public	
Chemical name		Public	
Scientific name		Public	
Common name		Public	
Company code		Public	
Other (specify)		Public	
Molecular formula		Public	
CAS number		Public	

Substance request excel form

- Requestors must complete Request for registration of a new Substance or an update to existing Substance + supporting documents (SmPC or Investigator’s Brochure).
- In the form:
 - Company codes can be set as the substance preferred term
 - Privacy settings can be adjusted for all additional names and molecular formula
- Substance form will have to be attached to Service Desk request

The form will be available:

- as a knowledge article in EMA Service Desk portal
- on the Orphan Designation section of the EMA website
- in EudraCT



- The distinction between “approved substance” and “development substance” does not exist in ISO 11238.
- The purpose is to use the same substance ID across the whole lifecycle of medicinal product: orphan designation (if applicable), clinical trials, marketing authorisation and pharmacovigilance.
- No more development substances will be created in SMS.
- All new substances created in SMS will be synchronised to XEVMPD as “approved substances” (including substances for clinical trials).
- If an update is requested to a “development substance”, a new approved substance will be created instead.
- Privacy settings will be in place in SMS to prevent the publication of confidential information (e.g. chemical names or molecular formula) in XEVMPD/EudraCT.



- After SMS Phase I goes live, instead of creating development substances directly in xEVMPD, Sponsors of CT will need to request them in advance if they want to submit a clinical trial application or an Investigational Medicinal Product.
- Requests will need to be made through the **EMA Service Desk portal**
- In the requests users must attach:
 - Completed Substance request form (excel template)
 - **supporting documentation** for the substance (e.g. SmPC or Investigators' Brochure).
- This process is not new, it is being extended to registration of development substances
- **4 w/d SLA to process the request**
- Users need to take the SLA into consideration when planning the submission of their applications
- In Q3 2020 EUTCT will be replaced by SMS service and at that point substance registration and updates will be directly requested through the SMS portal.



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Thank you for your attention

Further information

Please send any queries to:

Jaume.gonzalez@ema.europa.eu

European Medicines Agency

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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