

# EU-SRS PoC – Project update

SPOR TF, EMA, May 24, 2019

GOOD  
MEDICINES  
USED  
BETTER

### A Proof of Concept EU-SRS project in 2019

- Reduced impact, limited costs, lowered ambitions
- Using GSRS software as-is; no adaptations
- EU-SRS PoC is hosted by BfArM
- In-kind contribution of NCA substance experts to the Substance Validation Group
- Data cleansed during the PoC project is delivered for use by EU Network
- Assessment from Proof of Concept reported to HMA by February 2020 indicating:
  - Suitability of EU-SRS for management of substances in EU
  - Enabling decision for next steps (e.g. use as-is, adapt)

HMA endorsed the proposal

### **The EU-SRS PoC will deliver the following:**

1. EU-SRS system for use in the PoC setting (hosted at BfArM)
2. An installed Substance Validation Group based on committed resources from NCA's
3. Cleansed substance data according to IDMP (for selected substance categories):
  - Human and Veterinary substances
  - Classes: Chemicals, Proteins, Polymers, Herbals, Vaccines (based on available SVG capacity)
4. Description of EU-SRS system: system documentation and user requirements
5. Assessment of system suitability for Europe and associated way forward
  - Evaluated SVG processes and supportive documents
  - EU-SRS system evaluation
  - Advice on next steps to HMA, February 2020

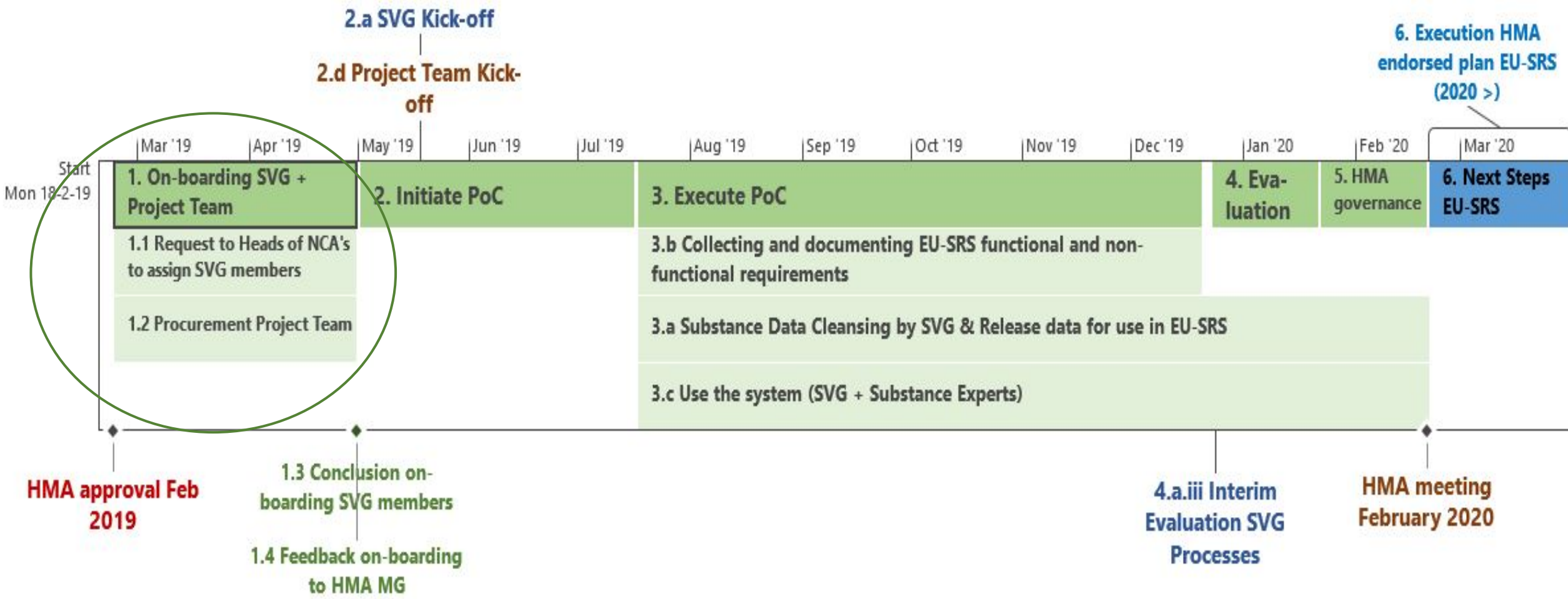
- Project status: what happened after HMA endorsement?
- Data cleansing
- Project execution
- Project governance

# Project Status

*What happened after HMA endorsement*

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# EU-SRS PoC Project Planning



# On-boarding Substance Validation Group (SVG): Completed

Name	Organization
Bjørg Overby	NoMA (Norway)
Pedro Batista	EMA
Katerina Deli	EMA
Lotta Wiik Knut Almgren	MPA (Sweden)
Isabel Perez	AEMPS (Spain)
Ciska Matai	MEB (Netherlands)
Edita Moravcová	SUKL (Czech Republic)
Aylin Mende	BfArM (Germany)
Alexander Knieps Fabian Boehnel	Ages (Austria)
Luka Kosec	JAZMP (Slovenia)

## Total SVG FTEs assigned:

2,7 FTE confirmed for SVG membership  
(12 members) = 13,5 man days per week

## Good to know:

SVG members have indicated that they are able & willing to include colleagues in specific discussions (e.g. on vaccines, veterinary substances)

## Successful onboarding SVG:

- Sufficient # of substance experts join SVG
  - Combined expertise NCAs & EMA
- HMA MG is informed of this result; the project is ready to initiate

Role	Name	Organization
Project Manager*	Annet Rozema	MEB
SVG Coordinator*	Annet Rozema, a.i.	MEB
Business Analyst*	<i>vacancy</i>	MEB
EMA IT Liaison	Gustavo Rodriguez	EMA
Subject Matter Expert	Herman Diederik	MEB
IT support**	Harald von Aschen	BfArM

\*MEB was awaiting funding by the Ministry of Health. This is now confirmed, recruitment is about to start

\*\*Harald von Aschen is supported by IT contractor, funded by BfArM



## At the SVG Kick-off (May 13-15):

- SVG members trained in IDMP principles
- First time to access the EU-SRS TST system
- SVG charter discussed
- Planning of (data cleansing) activities
- Conclude on preferred data sources for cleansing & cleansing approach

## IT Preparations

- Install and setup EU-SRS PoC and TST environment at BfArM (done)
  - EU-SRS TST – 100k records from NCATS loaded for training and testing purposes
  - EU-SRS POC – Cleansed data will be loaded here.

- Create users in EU-SRS
  - EU-SRS TST – SVG users with write access (done)
  - EU-SRS POC – SVG users with write access, NCA read-only users



# Data Cleansing

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### **Prioritization of EMA data for cleansing:**

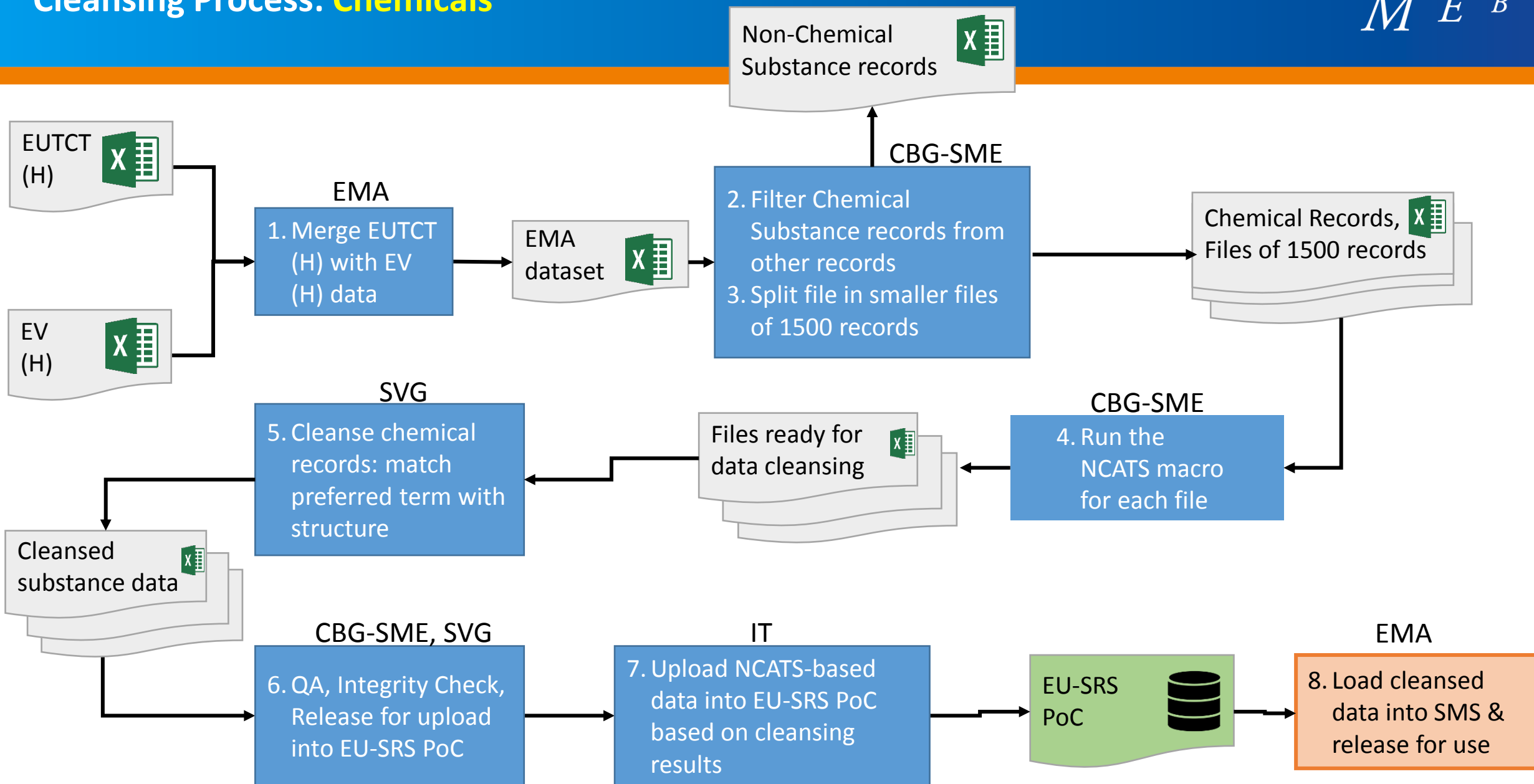
- Authorized substances only, development/investigational substances are out of scope
- Preferred names and synonyms, translations are out of scope
- Substances used in Human products; veterinary-only records are out of scope
- Substances used in medicinal products

### **Data cleansing will be done class-by-class: SVG consensus to start with Chemicals**

- Use NCATS dataset as reference dataset for initial data cleansing of chemicals
- **Match the Preferred Name with the Structure**
- The cleansed chemical substance records will be loaded in EU-SRS, enriched with NCATS data
- All substance IDs will be retained; UNII code will be loaded as reference, EUSUB-ID is new key

**SVG will first start with data cleansing of Chemicals; other substance classes will follow later**

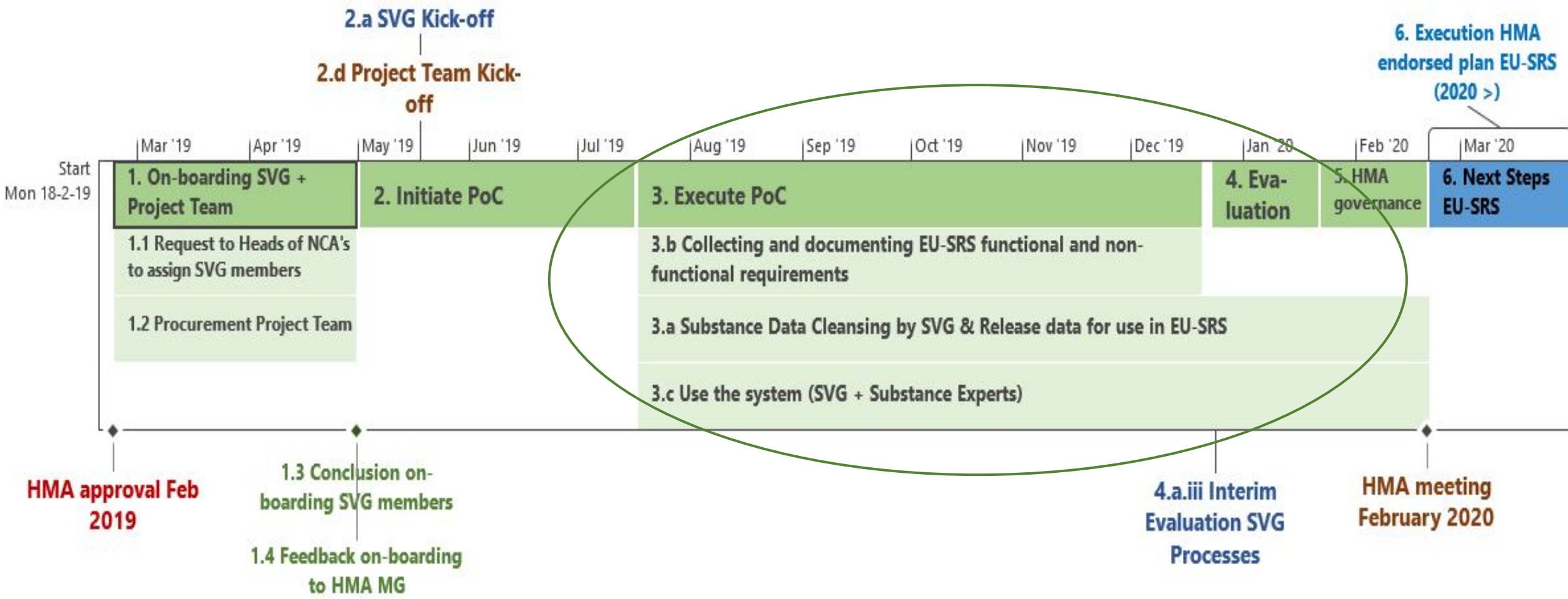
# Cleansing Process: Chemicals



# Project Execution

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# EU-SRS PoC Project Planning



Complete sourcing project team members

Finalize detailed description of data cleansing plan for chemicals

- Explanation on data cleansing rules / approach for SVG members (cleansing manual)
- Dry run of the full process with a small dataset

Estimated start data cleansing of chemicals: **June 10**

Regular meetings with SVG members to:

- Discuss difficult data cleansing cases
- Document consensus on cleansing matters
- Build knowledge base of best practices

Next F2F meeting to discuss next steps: **September 2-4**

- Data cleansing of other substance classes
- User requirements EU-SRS
- Approach to gain feedback on use of EU-SRS system

# Governance

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# EU-SRS PoC – communication with stakeholders / governance

Stakeholder	Governance role	Details	Known dates
EU-SRS PoC SC	T.b.d.	Discussion ongoing (conclusion expected early June)	
Telematics Office	Oversight	Monthly project status report to Telematics office (timelines, progress, issues)	By email
Telematics MB	Information sharing	On request, EU-SRS PoC will be an agenda item, where a status update will be provided. One already scheduled for end of May. (for decision: data source for cleansing)	Sept 2019
EUTAB	Information sharing	In preparation for HMA	Jan 2020
EUNDB	Information sharing	In preparation for HMA	Jan 2020
ITDEC / IT Directors	Information sharing	Verbal update during IT Directors meeting ITDEC on request, and in preparation of the HMA	On request & Jan 2020
EU-SRS community	Sounding board - EU-SRS day #4 - EU-SRS day #5	2 days to be scheduled during the PoC Day 4: discuss SVG processes & user feedback on EU-SRS Day 5: confirm conclusions from EU-SRS PoC	w/c 15 Oct 2019 w/c 13 Jan 2020
HMA	Endorsement of conclusions	Update HMA Endorse conclusions on way forward EU-SRS Feb 2020	June 2019 Feb 2020

Stakeholder	Governance role	Details	Known dates
FDA/NCATS	Information sharing	Where possible, global alignment. Align Controlled Vocabulary where possible NCATS Support with data load in EU-SRS PoC Provide feedback to FDA/NCATS on functionality* Support FDA/NCATS with testing*	w/c 17 June 2019 Regular TC's
SPOR taskforce	Information sharing and discussion		24 May 2019
S-group	Sounding board, including industry	Standing agenda item, every first Tuesday each month	04 June 2019
Industry	Knowledge sharing & gaining feedback	Industry SRS day	To be planned
IRISS Forum	Information sharing	Regulators, Industry and Software vendors Meets once per month, standing agenda item	2nd Thu / month

\*CBG support to FDA/NCATS, outside the scope of EU-SRS PoC



Let's make it happen!  
Together, we can make it work.

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