

EU-SRS PoC – Project update

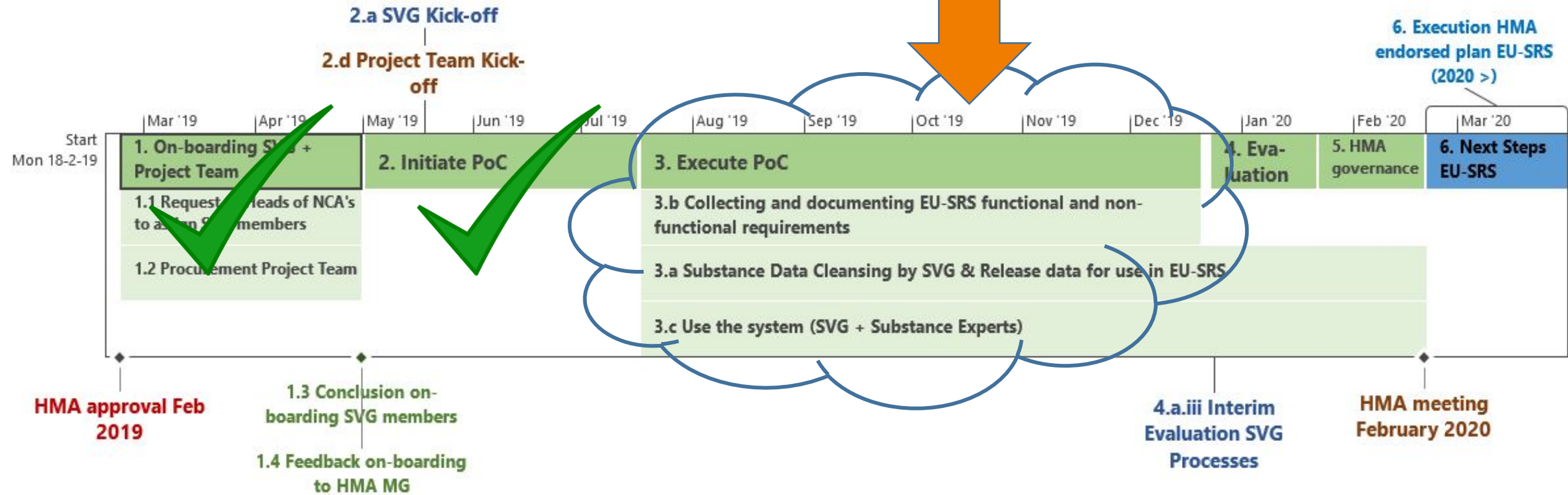
SPOR TF, EMA, October 16, 2019

GOOD
MEDICINES
USED
BETTER

- Project status
 - General status update
 - Status data cleansing
 - Status URS development
- Towards HMA
- Feedback from F2F S-group (15/Oct/2019)
 - Industry proposal on essential fields

Project Status: on schedule

$\frac{c}{M} \frac{B}{E} \frac{G}{B}$



On-boarding Substance Validation Group (SVG): Completed

$\frac{c \ B \ G}{M \ E \ B}$

Organizations joining the SVG

NoMA (Norway) – 1 SVG member

EMA – 2 SVG members

MPA (Sweden) – 2 SVG members

AEMPS (Spain) – 1 SVG member

MEB (Netherlands) – 3 SVG members

SUKL (Czech Republic) – 1 SVG member

BfArM (Germany) – 2 SVG members

Ages (Austria) – 2 SVG members

JAZMP (Slovenia) – 1 SVG member



Bundesinstitut
für Arzneimittel
und Medizinprodukte

$\frac{c \ B \ G}{M \ E \ B}$



Statens legemiddelverk
Norwegian Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



On-boarding Project Team: completed

$$\frac{C \ B \ G}{M \ E \ B}$$

Role	Name	Organization
Project Manager	Annet Rozema	MEB
SVG Coordinator	Inti van Eck	MEB
Business Analyst	Camiel Hoogendoorn	MEB
EMA IT Liaison	Gustavo Rodriguez	EMA
Subject Matter Expert	Herman Diederik	MEB
IT support*	Harald von Aschen	BfArM

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

Sporify selected for data cleansing

$\frac{C \ B \ G}{M \ E \ B}$

Discussions took place on data cleansing tools

- Sporify, a commercially available tool, is selected for data cleansing (prioritized over Excel).
- Decision taken to purchase 20 licenses of Sporify for the duration of 6 months (August 1 – January 31)
- A workshop was held (SVG, PT, Gary Wilson)

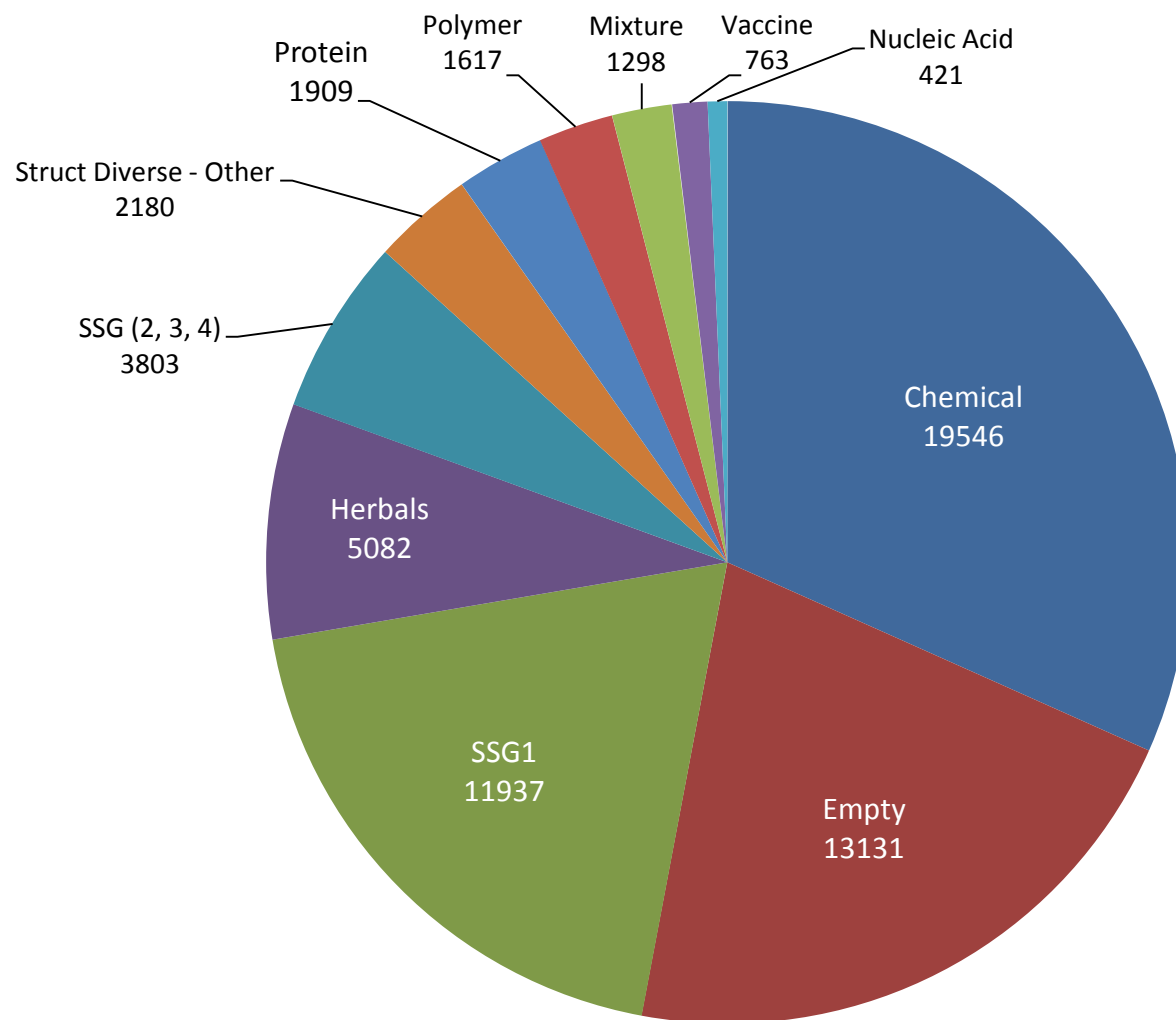
Data cleansing has started per **August 1, 2019!**

Data cleansing started!



Data received from EMA for cleansing (27/Jul/2019)

$\frac{C \ B \ G}{M \ E \ B}$



- 60.000 records received from EMA
- 20.000 records concern Chemicals
- 13.000 records have missing subst class
- Data received contain Human data only

SVG will:

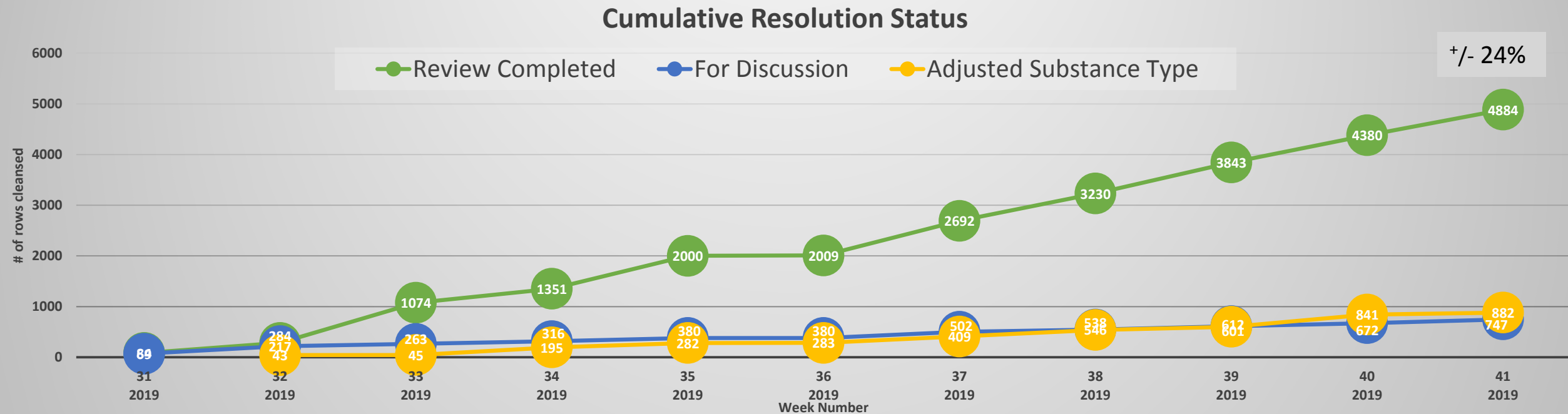
- Cleanse as many substance classes as possible
- Not be able to complete cleansing
- Focus on quality over quantity
- Estimate the efforts needed after the POC to complete data cleansing
- Use GSRS (US) data as basis for initial data cleansing

Cleansing Summary Chemicals

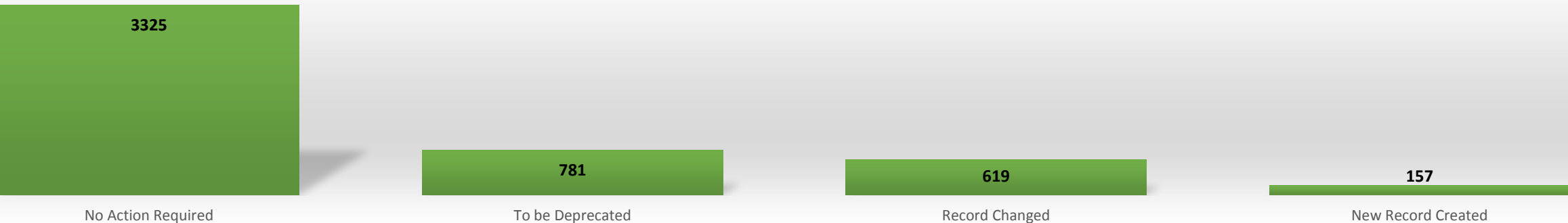
Note: Data from
Thursday 10/10/2019

Review Completed
4884

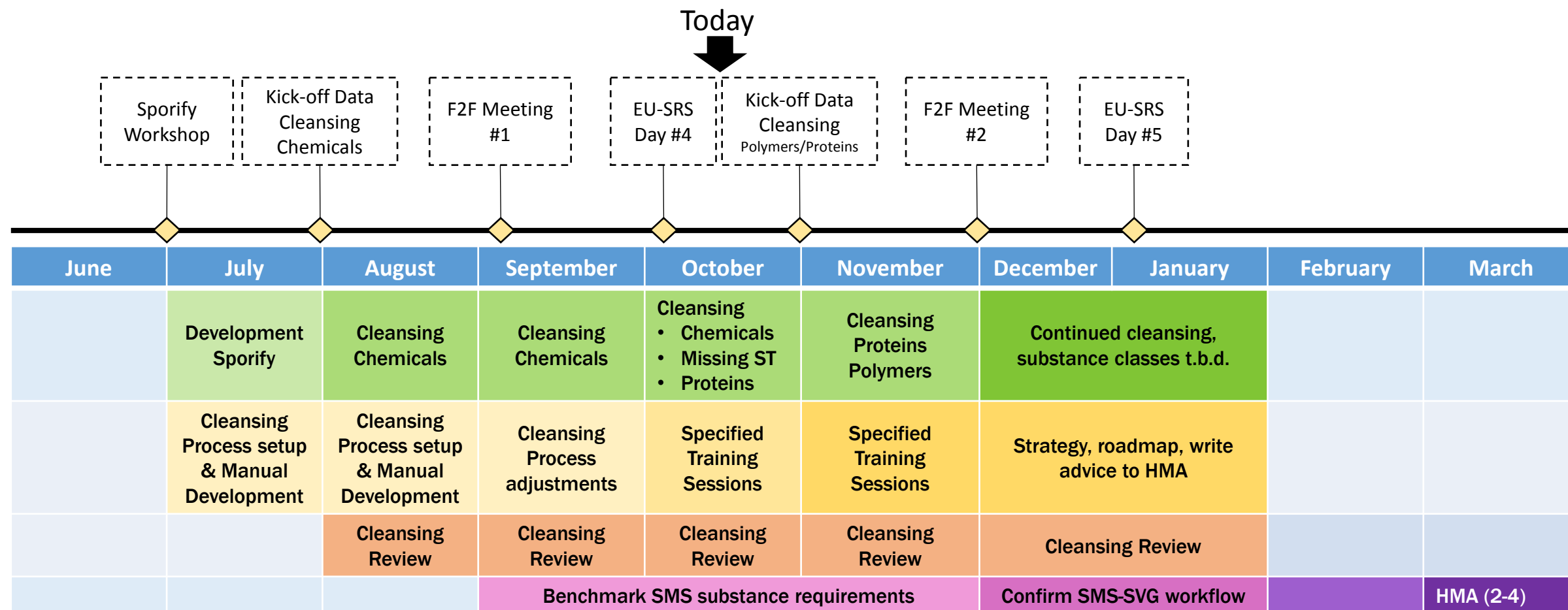
Adjusted Substance Type
882



Totals Cleansing Outcome for Resolutions Status "Review Completed" (Total 4882)



Timeline data cleansing



User Requirements are one of the key deliverables of the EU-SRS PoC:

- What should the EU-SRS be able to do in order to facilitate the regulatory network in EU.
- The user requirements must be set-up with the future business process in mind, such as:
 - Entry and maintenance of substances information
 - Interaction between SMS – EU-SRS
 - NCA access to detailed substance information
 - Extracting substance data (API)

User requirements will be used as a basis to perform the gap analysis of GSRS software:

- Confirm if the GSRS software is fit for purpose, the minimal viable product
- Identify possible gaps, and discuss & analyse the gaps with FDA/NCATS
- Draft a plan for required software development (if any)

User Requirements: status by requirements category

$\frac{c \ B \ G}{M \ E \ B}$

- Header 
- Navigation Bar 
- Home Buttons 
- Filters 
- Record view 
- Record Navigation 
- Record Detail 
- Search 
- Structure Search 
- Security 
- Users 
- Database 
- Audit Trail 

- Workflow 
- Substance Specific Requirements
 - o Chemical 
 - o Protein 
 - o Polymer 
 - o Nucleic Acid 
 - o Structurally Diverse 
 - o Mixture 
 - o Concept 
 - o Specified Substance Group 1 
 - o Specified Substance Group 2 
 - o Specified Substance Group 3 
 - o Specified Substance Group 4 

Advice to HMA will cover a summary of the deliverables, and the advised way forward with EU-SRS.

- **System-related advice:**
 - System landscape
 - Implementation strategy & Roadmap
 - Costs, planning
- **SVG-related advice:**
 - Conclusion on feasibility of SVG
 - Prerequisites: man-power, expertise, # people
 - Documented SVG processes (SMS-SVG)
- **Path forward regarding data cleansing:**
 - Estimated efforts to complete cleansing of substance data

Cleansed data delivered to EMA

Proposal on essential fields per substance class from industry

GOOD
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Contributors – Based on documents received

[illegible]

- Consolidation of feedback from selected industry members on substance signature fields was shared in the S-group
 - Per substance class, the agreement per field was clarified
 - For a selection of fields full consensus from industry was already reached, for others conditional comments were provided
- The project team deemed the proposal very acceptable and follow-up will now be planned
- **Next steps:**
 - Confirm the acceptance of the proposal in detail in the S-group (with EMA, NCA and industry representation) and address any open issues / comments

Chemicals

Example : Trometamol

Consolidation	Approved	12
	Approved with comment(s)	2
	Against	0
	Abstain	1

4 - Companies

Proposals

Comment(s)

– Name

Substance Name

Substance Name Type

(Common Name, Official Name, Scientific Name...)

Official Name Type

– Structure

Structural Representation

Structural Representation Type

(ex: InChI, MOLFILE, CDX,...)

Stereochemistry

– Molecular Formula

Molecular Formula

– Molecular Weight

Molecular weight method

Amount Type

Amount

Unit

– Code

Code

Code System

UNII, CAS, XEVMPD... should be considered

Which ones are to be considered

XEVMPPD should not be part of this list, as not available prior to declaration

– Source Material

Source Material Class

Source Material Type

Source Material State

Organism Name

Intraspecific Type

Intraspecific Description

Part

Fraction Name

Fraction Material Type

Proteins

Example : Corynebacterium Diphtheria CRM197 protein

Consolidation	Approved	7
	Approved with comment(s)	4
	Against	0
	Abstain	5

4 - Companies

Proposals

Comment(s)

- | | | | | | | | | |
|---|-------------------------------|--|--|----------------------|---------------------------|-------------------------------|-------------------|---------------|
| – | Name | Substance Name | | Substance Name Type | | Official Name Type | | |
| – | Code | Code | | Code System | | | | |
| – | Sequence | Sequence type | | Number of Subunit | | Sequence | Length | |
| – | Molecular Weight | Molecular weight method | | Amount type | | Average
Low and High Limit | Unit | |
| – | Modification | If applicable See slide (?) | | | | | | |
| (See slide « Modifications » to see the fields for each modification type, not all modifications being depicted here) | | | | | | | | |
| – | Substance Relationship | Relationship
(ex: protein to protein) | Relationship type
(ex: covalent link) | | Related
Substance Name | Amount
type | Amount
Unit | |
| – | Source Material | Source Material Class | | Source Material Type | | Source Material State | | Organism Name |
| | | Intraspecific Type | Intraspecific Description | | Part | Fraction Name | Fraction Material | |

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Multiplied according to
relevant nbr of names

new

If confirmed that CAS #
is required for INN
request **(To check)**

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Source Mat State not to be used for storage condition.

Do Recomb. Proteins need Source Material?



Re-used from SSG1:

- | – Constituent | n/a | n/a | – Physical Form | n/a | n/a |
|---------------|-------------------------|-------------------------|-----------------|-----------------------|----------------------------|
| | <i>Constituent name</i> | <i>Constituent name</i> | | <i>Physical State</i> | <i>Physical State Form</i> |

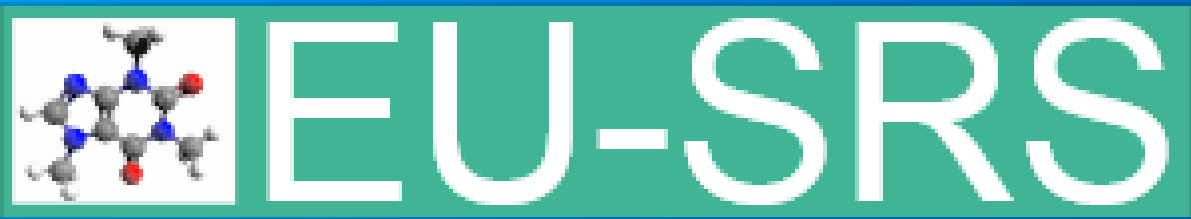
The EU-SRS project strongly appreciates this pro-active input and will incorporate this in the materials to be presented to the HMA

How to arrange feedback

- Industry can collect input through consultation in trade associations (a.o.)
- EMA and NCA feedback will be collected within the EU-SRS PoC project

Use S-group working sessions per substance class:

- Walk-through GSRS software / example record
- Agree on substance-class-specific Required fields
- User requirements



Questions?

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