EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR data services - update to SPOR TF

4 December 2018

Agenda

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Item	Preliminary draft agenda	Action	Who	Mins
1.	**Welcome** • Adoption of the draft agenda • Membership update	Adoption / Discussion	ICH	10
2.	**General updates** • HMA Nov • PMS TOM • Data Pilot • EU-SRS • NVR	Information	 GN GN JM/MH FS ACL	 20 20 20 20 20
3.	**Draft EU IG** • Structure overview	Information	IDS	10
4.	**S&PMS Progress update** • S&PMS 7 phases • Phase 1-2 progress update • Consultation update	Information	ICH	20
5.	**Programme updates** • OMS/RMS KUG • SPOR TF ToR	Information	ALA	10
6.	• **Other** • ISO /HL7 groups: status/progress & handbook • FHIR consultation & process	Information	PT	20
7.	**A.O.B** • Review of EU IDMP/SPOR TF actions log	Discussion	All	10

Agenda item 2. General updates

- HMA November meeting (GN)
- PMS TOM (GN)
- Data Pilot (JM/MH)
- EU-SRS (FS)
- NVR (ACL)

Agenda item 3. Draft EU IG

Draft EU IG: content of Version 1

- Introduction
- Chapter 1 – Pre-registration requirements
- Chapter 2 – Initial submission
- Chapter 3 – Maintenance (out of scope)
- Chapter 4 – Data quality assurance (out of scope)
- Chapter 5 – Data access/export (deprioritised/possibly to be removed)
- Chapter 6 – Technical specs on structure and Format
- Chapter 7 – migration guide
- Chapter 8 – examples (out of scope)

Draft EU IG

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Introduction

- **Description:** Introduction and document overview
- **Target audience:** all
- **No pages:** 1/2
- **Note**: introduction as is does not include legal basis of the submission and scope of the medicinal product as this is link to Network discussion and agreement

For information

Chapter 1: Pre-registration requirements

- **Description:** Guidance on how to get access to SPOR and what to do prior to submission
- **Target audience:** all
- **No pages:** 1/2
- **Note**: n/a

For information

Chapter 2: Initial Submission

- **Description:** Guidance on which medicinal product information (field and business rules) shall be submitted in the new format
- **Target audience:** Business (operations) and Technical profiles
- **No pages:** 120
- **Note**: this is described as process agnostic since the TOM is not finalised. Business process and requirements will be included in a later version of the IG.

For consultation

Chapter 6: API Technical Specifications

- **Description:** Technical specifications for the API, contains description of principles, security, resources, calls, end-points.
- **Target audience:** IT/ technical profiles
- **No pages:** 80

Separate consultation work stream

Chapter 7: PMS Migration Guide

- **Description:** migration rules between xEVMPD and PMS including backwards compatibility rules.
- **Target audience**: Art.57 stakeholders/ Business / IT/ technical profiles
- **No pages: 45**
- **Note**: n/a

For information

Agenda item 4. S&PMS Progress update

- S&PMS 7 phases
- Phase 1-2 progress update
- Consultation update

P&SMS Phased implementation plan

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We are here

Phase 1 | **Phase 2** | **Phase 3** | **Phase 4** | **Phase 5** | **Phase 6** | **Phase 7**

PMS

- Set up PMS data base as per the logical data model
- Migrate P data (subset of fields from Art.57 & EV Vet) into PMS
- PMS API* (to expose the data migrated to PMS)
- Veterinary (adaptation & extension if needed)
- H&V TOM (industry can start submitting data in the new format). *It is assumed that the UI to support TOM and allow to enter/update product data is CESP**.*
- Improvements to Human TOM
- Veterinary TOM (improvements & support to vet legislation)
- Art.57 enforcement of FHIR/TOM
- Reporting capabilities

SMS

- Set up SMS data base
- Migrate S data (from EUTCT & Art.57) into SMS
- Data management capabilities to create/update
- SMS API*
- SMS UI (portal similar to RMS & OMS portal)
- EU SRS synchronisation

**PMS API in Phase 2 is a "simple" API that supports search, create, update product. We have catered for standard patterns that are assumed to work with/without TOM, to support any needed transition.*
It is expected that such API will need improvements in subsequent phases of the project when the TOM requirements are more granular.

*** For CESP to become the UI and support the PMS TOM a project is required. Discussion & prioritisation is ongoing in the Telematics strategy (EUTMB)*

Consultation plan Nov 2018 – Jun 2019

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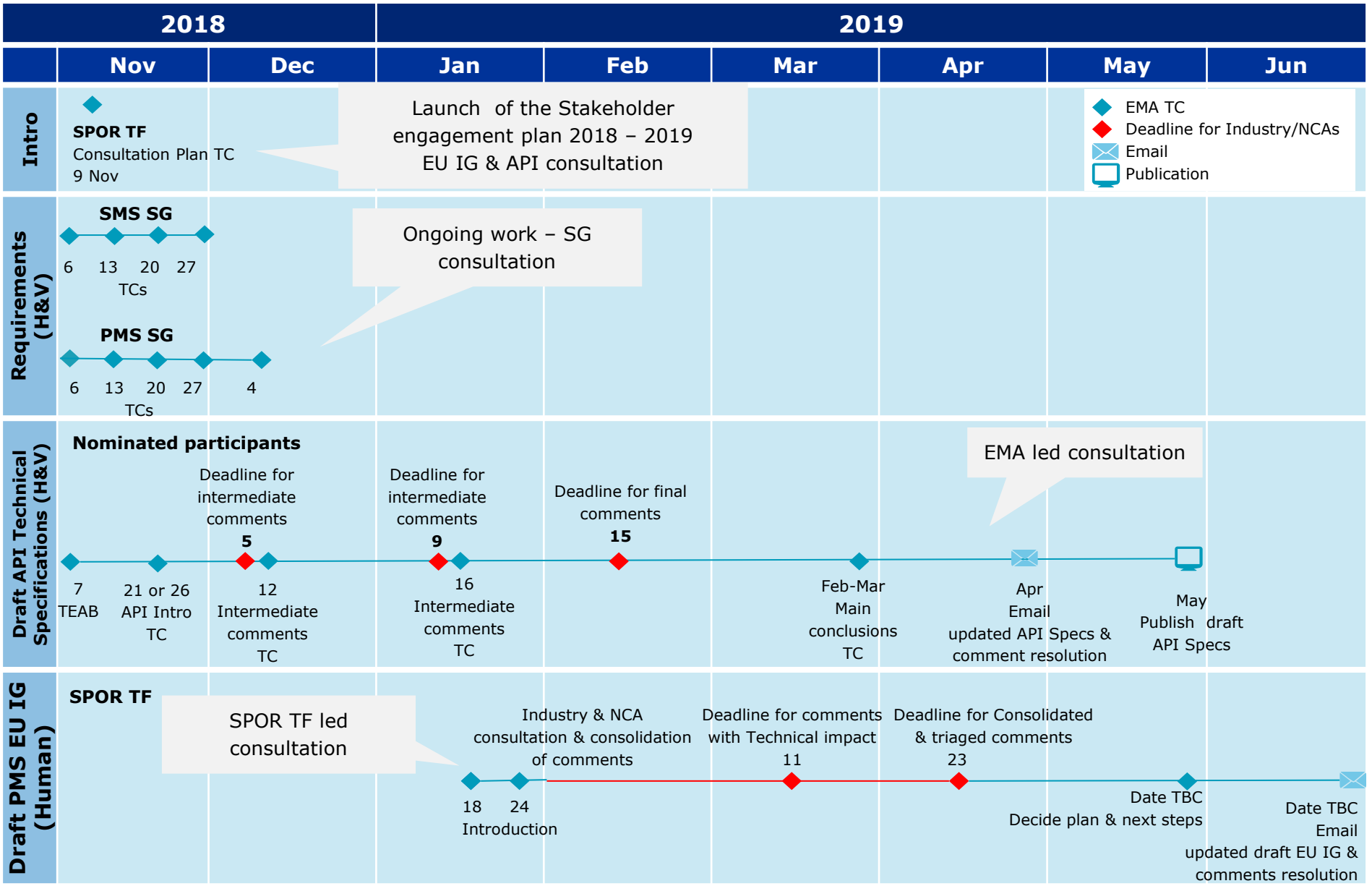

Artefacts for consultation

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PMS API Requirements (Human & Vet)
Ppts covering high-level requirements covering standard/basic CRUD functionality to support API implementation

Draft SPOR (P) API Technical specifications (Human & Vet)
Technical specifications for the Application Programing Interfaces, contains description of principles, security, resources, calls, end-points.

Draft PMS EU IG – HL7 specifications only (Human only)
Outlines the HL7 format that will be used for the exchange of product information and comprises the description of all fields and business rules.
This version of the EU IG (human only) is intended to be process agnostic and does not yet comprise elements on the to-be process i.e. TOM (Target Operating Model)

SMS Portal requirements & screen walk through (Human & Vet)
Ppts covering detailed requirements and screen mock-ups to support the implementation of the SMS Portal/User Interface (UI)

Draft SPOR (S) API Technical specifications (Human & Vet)
Technical specifications for the Application Programing Interfaces, contains description of principles, security, resources, calls, end-points.

SPOR API uses

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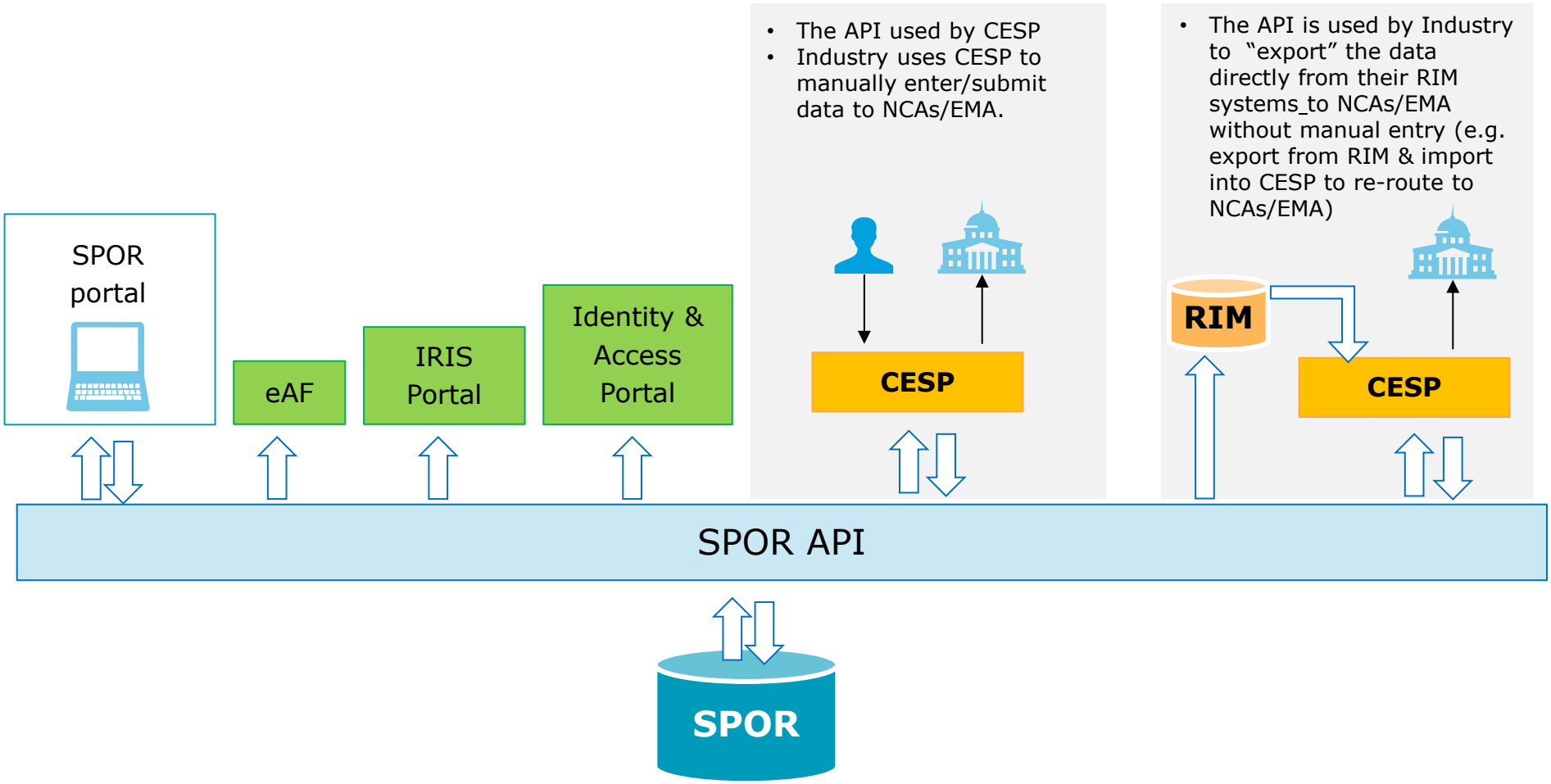

Note: Other business applications can use SPOR API in future

API consultation update

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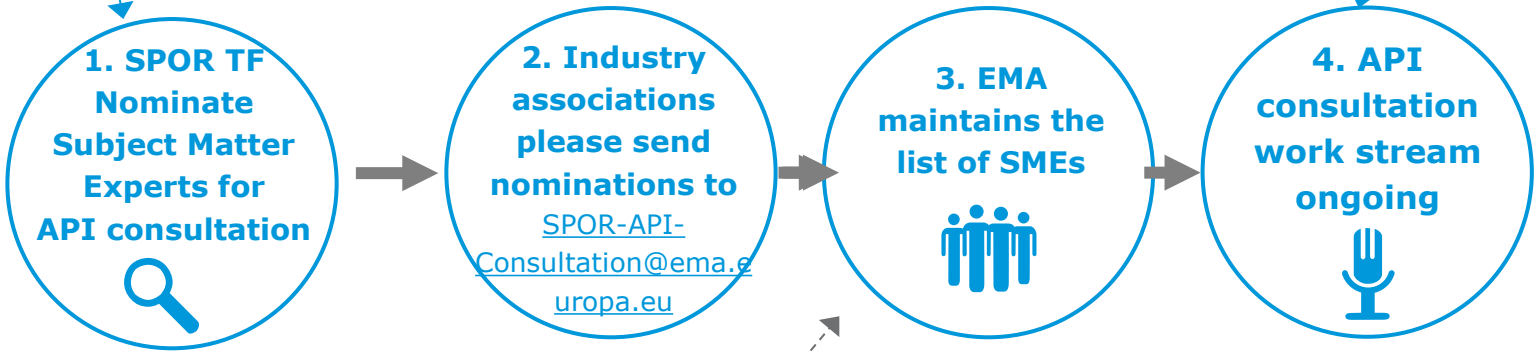
Software Vendors must contact Industry associations for their nominations

Software Vendors must contact Industry associations for their comments



13 NCAs nominated their SME

- 7 Human & Veterinary NCAs (Austria, Estonia, Denmark, Sweden, Spain, Belgium, Finland)
- 4 Human NCAs (France, UK, Germany, Italy)
- 2 Veterinary NCAs (France, Germany)

Industry stakeholders

- 36 SMEs
- 24 organisations
- Industry associations (ECI-EEIG, Medicines for Europe, AESGP, EFPIA)

Draft PMS EU IG (Human)

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Audience	Expected feedback/ Follow-up	Date	Content
SPOR TF	• Feedback on relationships, cardinality, business rules. • Comments submitted in appropriate template here • 1 consolidated set of comments/ Industry association and NCA • Software Vendors must contact Industry associations for their comments • Comments sent to PMS-EU-IG-Consultation@ema.europa.eu	18/01	• Intro part 1
		24/01	• *TBC - Intro part 2 or duplicate webinar of 18/01*
		11/03	• **Deadline for comments with Technical impact**
		23/04	• **Deadline for consolidated & triaged comments**
		May	• Agree plan & next steps
		TBC	• Email with new version of the draft EU IG and resolution of every individual comment

IMPORTANT

The EU IG is a **working document** and while the consultation is ongoing the document or parts of it should be considered **CONFIDENTIAL.**

Industry Associations/NCAs can **consult their members** but should **NOT** report on the findings of these discussions or share the content of the documentation in public events, blogs, websites, etc.

EU IG (Human) consultation – Ground Rules

Participation on EMA hosted TCs

- By invitation only to SPOR TF , please do not forward invitations
- Attendance of a minimum representation per Industry Association/NCA is advisable

Consultation

- Industry Association/NCA are expected to consult their members, explain and collect input to the EU IG (Human)

Do's:

- Set up dedicated events/TCs to:
  1. provide context of the document
  2. explain document content
  3. explain the consultation approach and its context/plan
  4. clarify how the information can/cannot be used
- Distribute the documents to members and provide information on the points 1-4 above

Don'ts:

- Report on the findings of these discussions beyond the SPOR TF
- Share the content of the documentation in public events, blogs, websites, etc.

WHY SPOR TF?

- First draft only, working doc
- Skill/resources available within SPOR TF
- As there was no open call for consultation – content discussion stays with SPOR TF
- At this stage still 1st consultation. There will be a second and wider consultation in second half 2019

Consolidation of comments

- Industry associations/NCAs consolidate comments in appropriate template
  - Software Vendors must contact Industry associations for their comments
- Industry associations/NCAs triage the comments by:
  - Categorising them into clarification/editorial comment/technical comment
  - identifying duplicate/similar comments

Second consultation in 2019 (to be planned)

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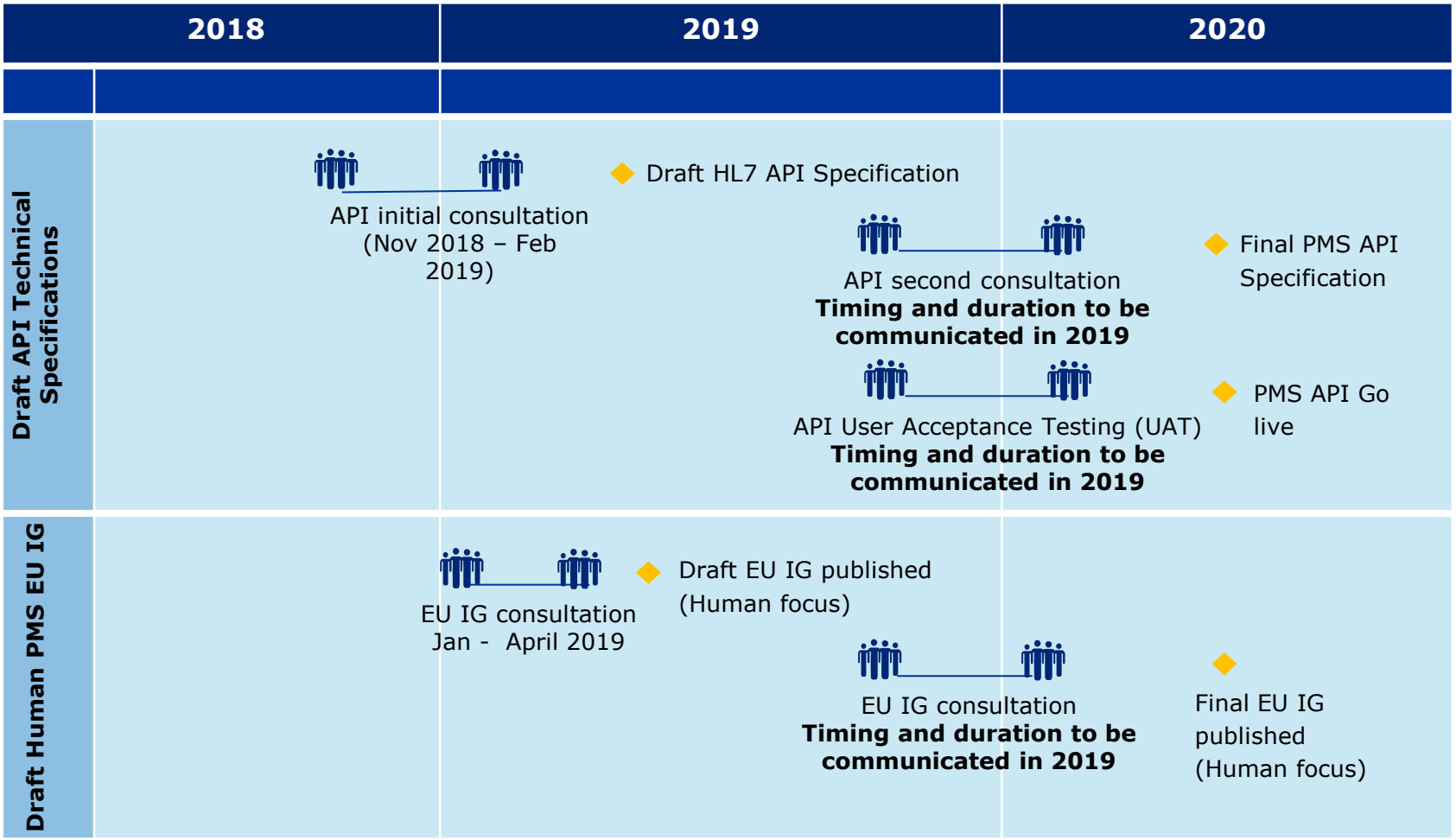

Agenda item 5. Programme updates

- OMS/RMS KUG
- SPOR TF ToR

RMS & OMS usage and integration

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User on-boarding

- 719 Industry Super Users & 395 Users registered
- 18 access requests to SPOR API (NCAs & Industry)

Usage

- Over 2200 OMS CRs received since 15 December 2017:
  - 67% - Approved
  - 33% - Rejected (e.g. lack of supporting documents to validate the CR)
- eAF using RMS & OMS data
  - OMS Loc ID used in 54% of eAF applications (CP procedure) information based on the sample of data
- **EV user registration** process using OMS data
- **IRIS** portal using RMS & OMS
- In future other applications such as CESP, CT, EudraGMDP, xEVMPD are expected to use SPOR data

Setting up the OMS/RMS KUG

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We are here

KUG Terms of Reference (ToR) being drafted
- Dec 2018 /Jan 2019

Webinar with the SPOR TF (OMS SG?)
- **Feb 2019**
- Start discussing OMS DQ issues

KUG TOR signed off
- > Q2 2019

Call for expression of interest / nominations for the KUG
- > Q2 2019

KUG kick off meeting / on-boarding
- > Q2 2019

Data Quality issue log maintained by OMS data stewards
Based on experience with the validation of the OMS CRs.

Data Issue #	Date of Issue	OMS data area	Issue title	Issue Description	Add - Country	For Decision	Standard to be applied
OMS-DI001	01/02/2018	AD address verification	Unwanted data enrichment	AD enriches address with District name which the user wants to remove.	DE	Option 1) We enrich the address as provided by AD Option 2) We Ignore AD and manually remove it every time Option 3) Reconfigure AD to ignore district names from the address reference data in all cases	
OMS-DI002	01/02/2018	AD address verification	Unwanted data enrichment	AD enriches address with State name which the user wants to remove.	DE	Option 1) We enrich the State as provided by AD Option 2) We Ignore AD and manually remove it every time Option 3) Reconfigure AD to ignore district names from the State reference data in all cases	
OMS-DI003	06/02/2018	AD address verification	FR characters in address	Postal service provider has removed some of the non EN characters from their addresses e.g. inverted commas on vowels, umlauts, etc. Informatica's address verification follows this approach. For more information click here.	FR	Option 1) We accept the data as verified by AD Option 2) We manually insert the non EN French characters	

SPOR TF – Terms of Reference (ToR)

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- There are **no changes** to the SPOR TF Terms of Reference envisaged in 2019

- SPOR TF face to face meetings in 2019
  - 24 May 2019 - SPARK building in Amsterdam
  - 4 October 2019 - SPARK building in Amsterdam

Agenda item 6. Other

- ISO/TC 215 WG6
- HL7

ISO/TC 215 WG6 - Pharmacy and medicines business

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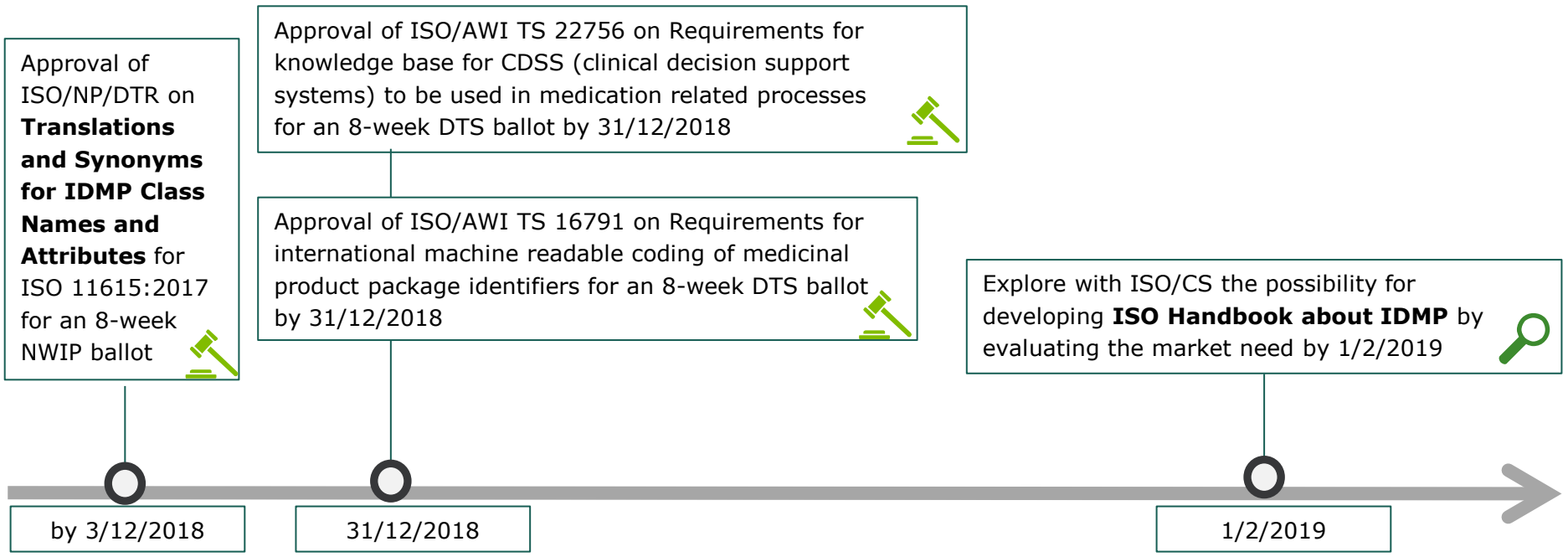

IDMP vs FHIR vs SPOR API

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IDMP Standard

A
B
C
D
E
F
G
H
I

- Full IDMP Conceptual Model

SPOR API Tech. Specif.

FHIR Core

- REST api, formats (XML, JSON), shared data types, common infrastructure

FHIR Resources

A
B
C
C1
D
E
F
F1
G
H
I

- Physical Implementation of the **full IDMP model**
- FHIR resources are granular and **roughly correspond to IDMP subject areas**
- Contains FHIR/PMS extensions

Draft EU IG

- Reference/copies of full FHIR resources
- A number of FHIR profiles are provided with details on the Fields/business rules in scope of Iteration 1

FHIR Profiles

C1
D
F
F1
G'
I

- **Simpler view, subset of the IDMP model in scope for Iteration 1 and their business rules e.g.** these profiles classify classes and attributes as mandatory, conditional, optional or never
- ***Not all Profiles available yet:*** *some require Implementation Guide & previous consultations*

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SPOR API (implemented)

C1
D
F
F1
G'
I

- Physical Implementation of the PMS Iteration 1

HL7 & SPOR

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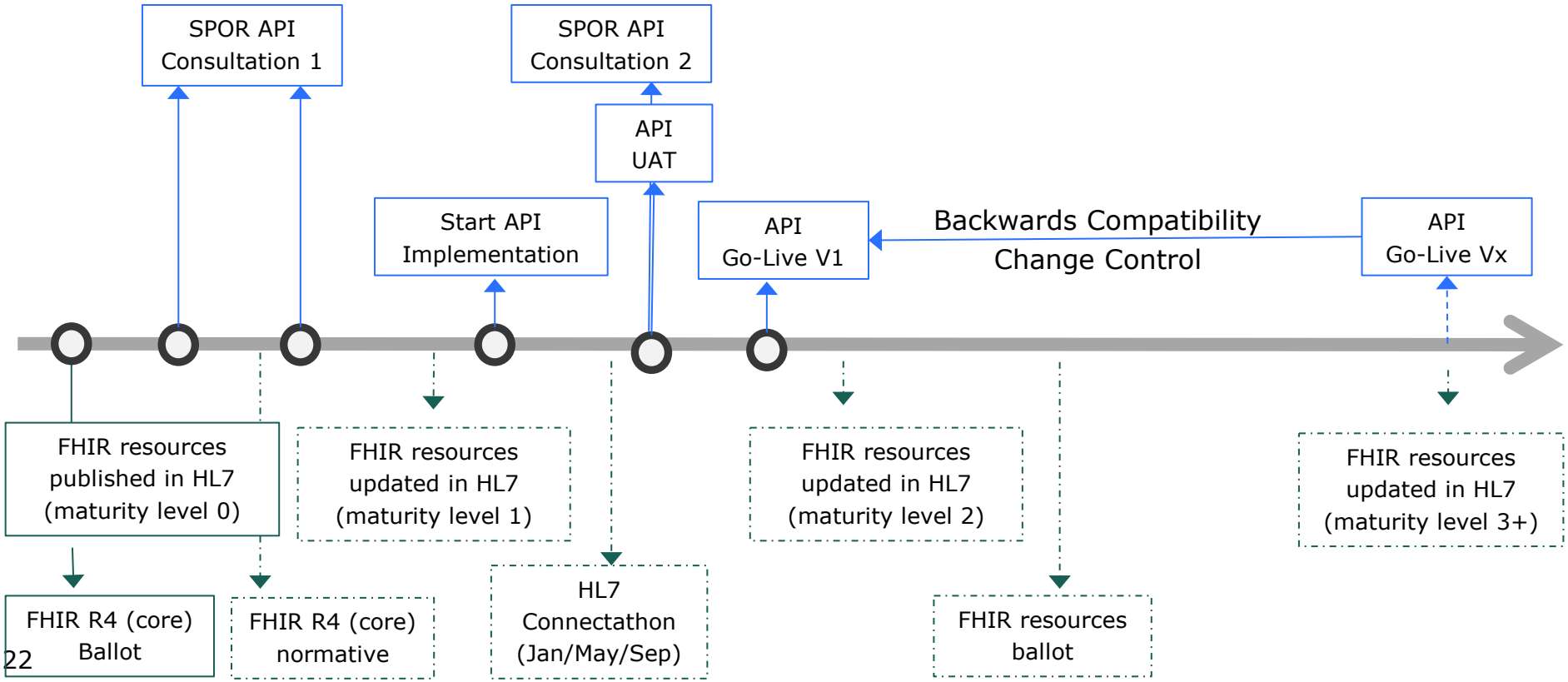
- **Draft FHIR resources** (maturity level 0) have been created for both products and substances
  - **We cannot wait for FHIR maturity before implementing. We create FHIR maturity by implementing.**
- The **FHIR resources are subject to review/changes** by EUMRN but also by the international FHIR community
  - The core methods of FHIR will not change. This is the bulk of any implementation.
  - Changes in resources are typically things getting renamed or moved around. Sometimes from one resource to another.
- There is no obligation to "keep up" with FHIR i.e. **EU but does not have to implement all changes adopted by FHIR community**
- **Changes to PMS FHIR resources** are also subject to change control and **will ensure backwards compatibility**



Thank you for your attention

Further information

Please send any queries regarding the IDMP/SPOR to:
SPOR-Change-Liaisons@ema.europa.eu

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