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SCIENCE MEDICINES HEALTH

SPOR impact on Veterinary stakeholders

Webinar with NCAs and Industry

20 February 2018, from 0900h to 1300h – EMA

Agenda

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#	Preliminary draft agenda	Action	Initials	Mins
1	**Welcome** • Adoption of draft agenda • Purpose and objectives of the meeting	Adoption	Chair, ALL	**10**
2	**SPOR** • Background and journey so far • Business case and opportunities for Veterinary sector	Information + Discussion	SPOR team EMA Veterinary	**15 + 15**
3	**What will SPOR deliver (Veterinary specific)** • S & O & R Operating Model (Human & Veterinary) • P Operating Model (Veterinary) • SPOR Operating Model (Veterinary) • SPOR Timelines & Outcomes	Information + Discussion	SPOR team	**30 + 30**
4	**Governance** • SPOR within the Telematics Governance • Opportunities for Veterinary stakeholders to engage • Draft communications/events plan 2018	Information + Discussion	EMA Veterinary	**10 + 10**
5	**What does it take to implement SPOR for an NCA and a company** • NCAs & Industry involvement through SPOR • Data Mapping & validation by NCAs	Information + Discussion	SPOR team	**20 + 20**
6	**Challenges and concerns implementing SPOR** Regulatory perspective an industry perspective: • Presentation from Veterinary NCA (France) • Presentation from Veterinary/Human NCA (Austria) • Presentation from Veterinary Industry	Information+ Discussion	TBC	**3x15**
7	**Closing remarks** • Wrap up final questions and concerns • Next steps for future engagement and follow up actions	Discussion	Chair	30

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1. Welcome

Objectives of the meeting

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- To have a common understanding of SPOR: What is SPOR? Why being involved?
- To provide a status update on main features of SPOR from the Veterinary domain point of view
- To listen to Veterinary stakeholders and list the concerns from NCAs and Industry side
- To agree next steps

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2. SPOR

Background and journey so far

SPOR TEAM

Why SPOR?

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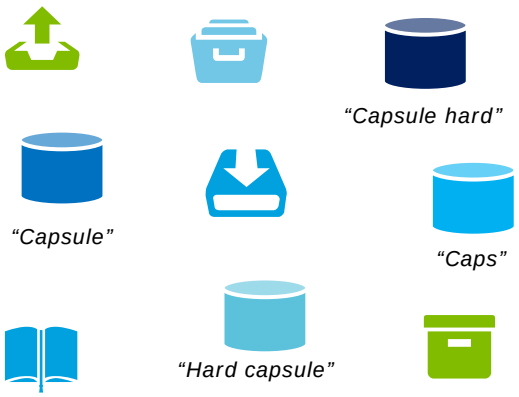
Data is submitted once



Lack of standardisation – data is not consistent & it cannot easily be reused

Data is standardised, validated and high quality

Centralised management of data in 4 domains of master data:

- **S**ubstance
- **P**roduct
- **O**rganisation
- **R**eferentials

Data is re-used many times

Other applications…

Integrate SPOR with business processes

What are SPOR data services?

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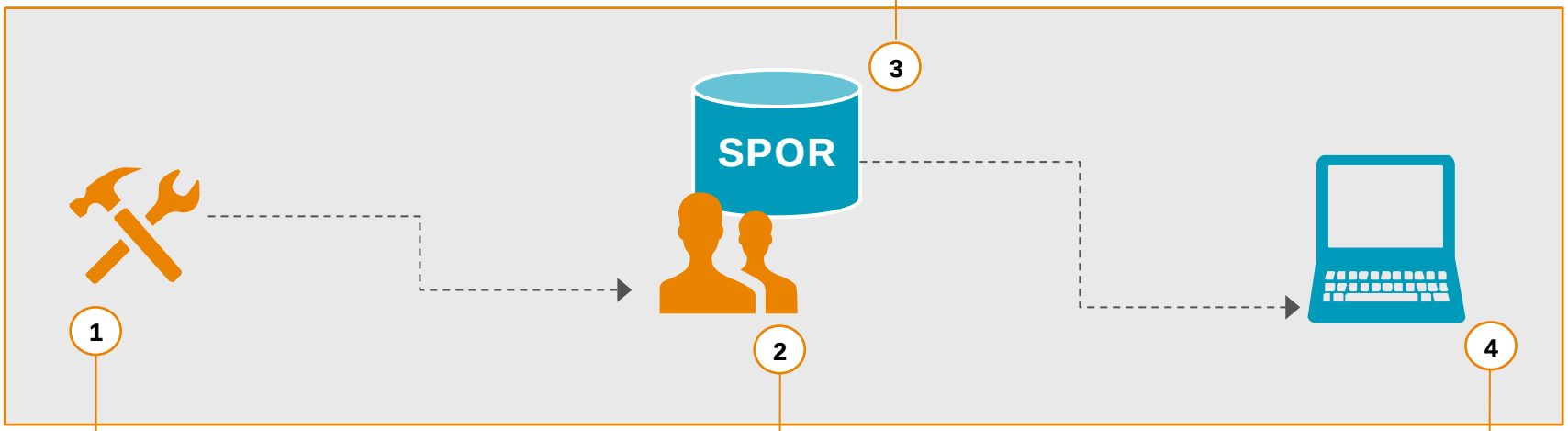
Data:
List of **organisations** (OMS dictionary), **Referentials Lists/Terms** and **Substances** for stakeholders to use in EU regulatory activities.
List of **authorised human & veterinary medicinal products**.

SPOR data services: People, Process, Data, Technology



Process:
New process for industry and NCAs to **pre-register/update SPOR data** before submitting regulatory applications.

People:
A specialised team of **EMA data stewards** to manage SPOR data and provide support to stakeholders.

Technology:
SPOR data is accessible via a **web User Interface** (UI) and programmatically via **SPOR APIs** (Application Programming Interface).

Phased delivery of SPOR

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SPOR Programme Phases

Referentials Management Services **(RMS)**

Organisations Management Services **(OMS)**

Substance Management Services **(SMS)**

Product Management Services **(PMS)**

P&SMS is divided into iterations:

- P&SMS Iteration 1 covers authorised **Human & Veterinary medicinal products**
- P&SMS Iteration 2 covers Investigational medicinal products
- P&SMS Iteration 3 covers Clinical Particulars

- **RMS & OMS** were **delivered** in June 2017
- **Delivery of PMS** & **SMS** will follow and it will be **iterative**
- **SPOR applies to Human & Veterinary domains**
- **Benefits** will be **visible incrementally** as all phases of SPOR are delivered and **SPOR data is reused**

Summary of RMS milestones & impacts on veterinary stakeholders (NCAs & Industry)

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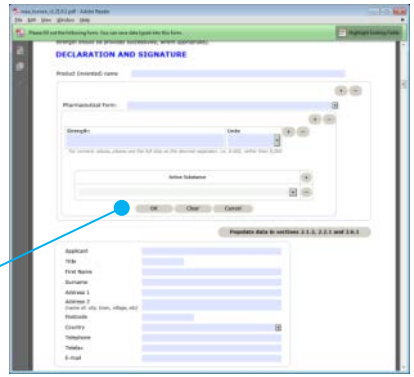
- **RMS services live** in June 2017.
- **RMS replaced EUTCT** for all lists except for the substance lists which remain in the EUTCT until SMS is delivered.
- **NCAs invited to start registering their SPOR users & start using RMS services.**
- No impact on regulatory submissions at go live.

Industry use mdms@ema.europa.eu to request new / updated terms

2017 | **2018**



RMS supplying master data to eAF

15 Dec 2017 **Industry stakeholders invited to start registering their SPOR users & start requesting new / updated terms via new RMS portal.**

1 July 2018 - requesting new / updated terms via RMS portal is mandated.
Requests via mdms@ are no longer accepted.

Summary of OMS milestones & impacts on veterinary stakeholders (NCAs & Industry)

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No standardisation of organisation data.

June 2017 new OMS data services are live.
Organisation data is validated, standardised and can be re-used.
NCAs are invited to start registering their SPOR users. Use of OMS services as of 15 Dec 2017.
No impact on regulatory submissions at go live.

15 Dec 2017 **Industry stakeholders are invited to start registering their SPOR users & start using OMS services.**

No standardisation | **OMS dictionary expanded with additional data sets**

2017 | **2018**

Q3/Q4 plan to mandate the use of OMS in eAF (aligned with CESSP MA go-live) (*)

Dec 2017 OMS starts supplying organisation master data to the eAF.
Use of OMS in eAF initially optional.
Stakeholders can start requesting new orgs & updates via OMS portal *(OMS change requests).*

(*) – subject to planning

Summary of OMS content & impacts on veterinary stakeholders (NCAs & Industry)

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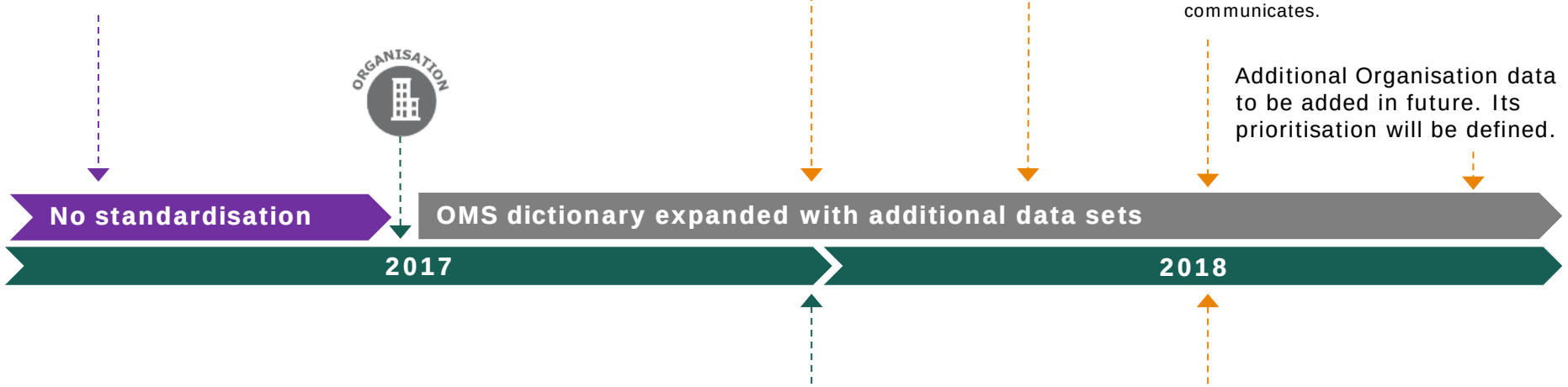
The initial content of the OMS dictionary originates from the Telematics systems, *i.e.* xEVMPD – Art.57, EudraGMDP, and other EMA corporate systems. **MAHs** for **Veterinary CAPs** were mainly sourced from an **EMA corporate repository** that is used for the management of **centralised procedure. The data was not loaded from EudraPharm Veterinary.**
The data was taken from these systems in Q4 2016.

Jan 2018 data set 1 includes:
- **MAHs:** (H+**V**) CAPs & (H) NAPs
- **MAAs:** (H+**V**) CAPs

Q1/Q2 2018
Manufacturers: (H+V) CAPs
Do not submit OMS change requests for Manufacturers CAPs until EMA communicates.

End of Q3 2018
Manufacturers: (H+V) NAPs
Do not submit OMS change requests for Manufacturers NAPs until EMA communicates.

Additional Organisation data to be added in future. Its prioritisation will be defined.



Registered SPOR users can start submitting OMS change requests (**CRs**) for the above data set 1 to request changes or additions to the organisation data:
- **Add Organisation**
- **Update Organisation**
- **Add Location**
- **Update Location**
- **Update Organisation & Location**

Agreed Approach:

OMS dictionary will be expanded with **Veterinary MAH for non CAPs** via OMS change request (**CRs**) process.
Timing to be announced in 2018.

Business case and opportunities for Veterinary sector

EMA VETERINARY

Business case for the Veterinary Sector

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Goal of SPOR is to centralise the management of pharmaceutical/regulatory master data for **R**eferentials, **O**rganisations, **P**roducts and **S**ubstances **(SPOR) & re-use data to support** multiple business cases, eg:

- **E-submissions:** Users can use SPOR structured and quality controlled data as input in their initial MA, extensions, variation or renewal applications submitted via eAF as well as CESSP. Regulators perform fewer checks on the data received
- **Variations:** The administrative variations could be submitted directly as structured data into the product database and therefore reducing the manual effort for all parties involved (Industry, NCAs and EMA), while improving the quality and re-usability of data
- **MRLs:** Users can use SPOR structured and quality controlled data as input in their MRL application. Regulators perform fewer checks on the data received

Business case for the Veterinary Sector

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- **Consumption:** Users use standardised data on product and their intended animal species. Using the same standardised data to also collect information on antimicrobial medicines used in animals across the European Union (EU) enables better data collection (data can be re-used) and better data analysis
- **Pharmacovigilance:** Systems will be using the products and substance database as unique EU source to:
    - Identify the products used in adverse event reporting
    - To allow signal detection across all products authorised
    - To allow organisation of workshare for PhV inspections at EU level (via the Master file identifiers)
    - To make information available in line with the access policy
    - Long-term: integration with e.g. product data from FDA will allow to immediately identify similar products. (e.g. third country reporting)

Business case for the Veterinary Sector

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Goal of SPOR is to centralise the management of pharmaceutical/regulatory master data for **R**eferentials, **O**rganisations, **P**roducts and **S**ubstances **(SPOR) & re-use data to support** multiple business cases, eg:

- **Cascade use:** The products and substance database should become the go to EU reference database for veterinarians in search for potential treatment options under the cascade ruling
- **Referral cases:** The SPOR system will allow to quickly identify the veterinary medicinal products falling within the scope of a potential referral
- When integrated with the **EudraGMDP** database it will become possible to cross identify e.g. medicinal products that are potentially involved in case of GMP issues identified at a certain site

Opportunities for the Veterinary Sector

- Solutions **adapted to the vet sector**

- Data scope:
  - **Minimum data entry**; what is really needed
  - **Veterinary specificities** taken into account
    - Species
    - MRL/withdrawal time
    - Sales data
  - While the same data model will be used across human & veterinary domains it is recognised that **not all fields/ rules will be applicable** to the veterinary domain (*Use case analysis finalised 2016*)

- Possibility to contribute and benefit from the project by being involved in different groups

- Preparedness: **Targeted communication and training**

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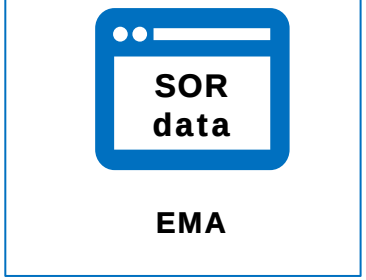
3. What will SPOR deliver

Operating model

S & O & R Operating Model (Human & Veterinary)



- Use SOR data for regulatory applications
- Requests for new/updated SOR data

EMA providing SOR data services to the EU network

- One stop shop for data required in regulatory submissions
- Hosts Referential Lists from different Maintenance Organisations in a structured format
- Maintains Organisation data
- Hosts Simplified Substance list
- Processes requests for new/updated SOR data
- Supports Master data translation process
- Specialised EMA Data Stewards

- Decide how each SOR and how it will be approved/ published

P Operating Model (Veterinary)

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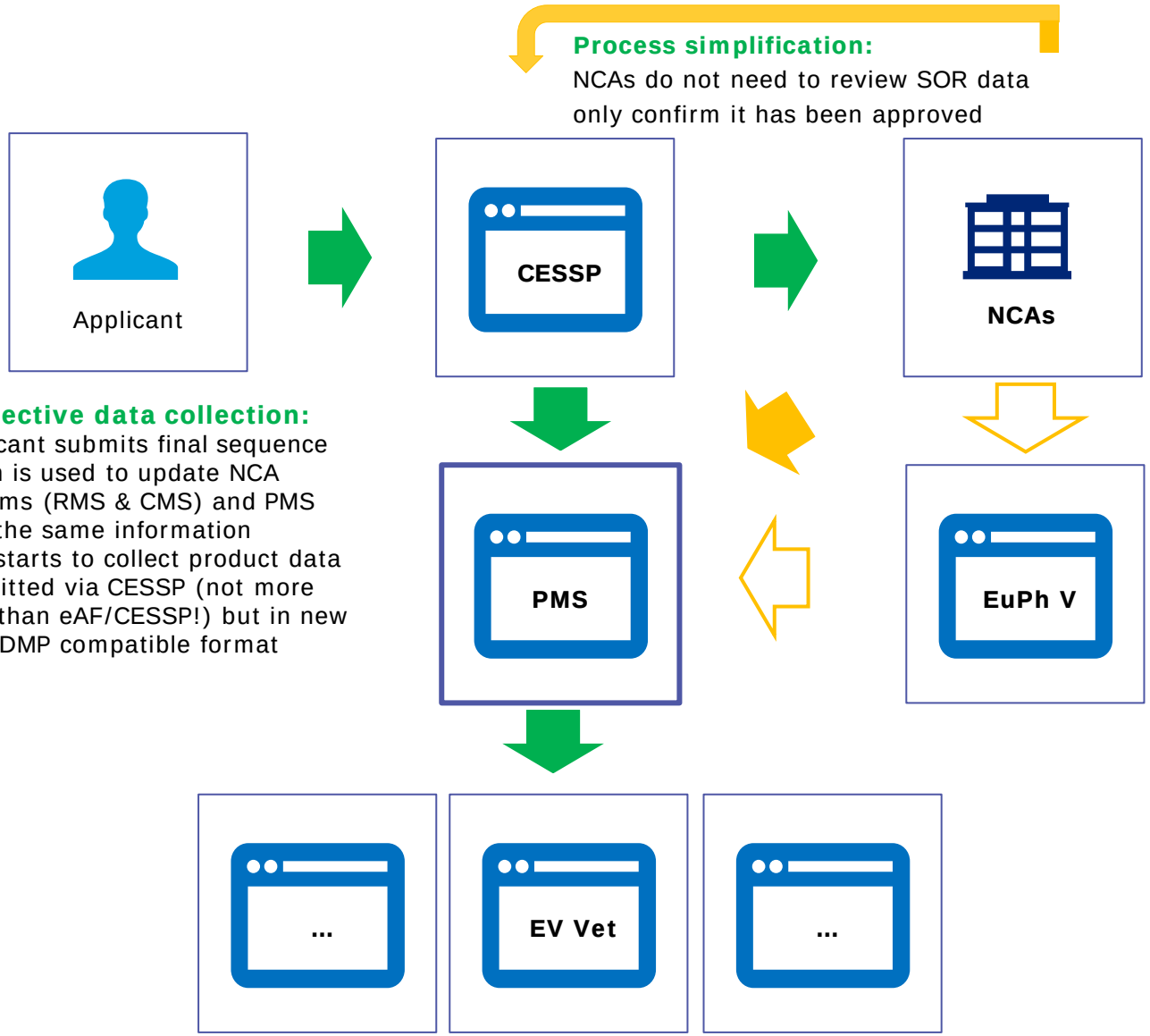

Prospective data collection:

- Applicant submits final sequence which is used to update NCA systems (RMS & CMS) and PMS with the same information
- PMS starts to collect product data submitted via CESSP (not more data than eAF/CESSP!) but in new ISO IDMP compatible format

Retrospective data collection:

- Legacy data will be transmitted **by NCAs**
- It has not been decided if legacy data will be submitted to EudraPharm and migrated to PMS or directly to PMS
- Legacy data can be submitted to PMS using the PMS API or via CESSP.
- The data scope (number of fields) that needs to be submitted has not been agreed.

- Product data can be re-used in multiple regulatory procedures and use cases

SPOR Operating Model (Veterinary)

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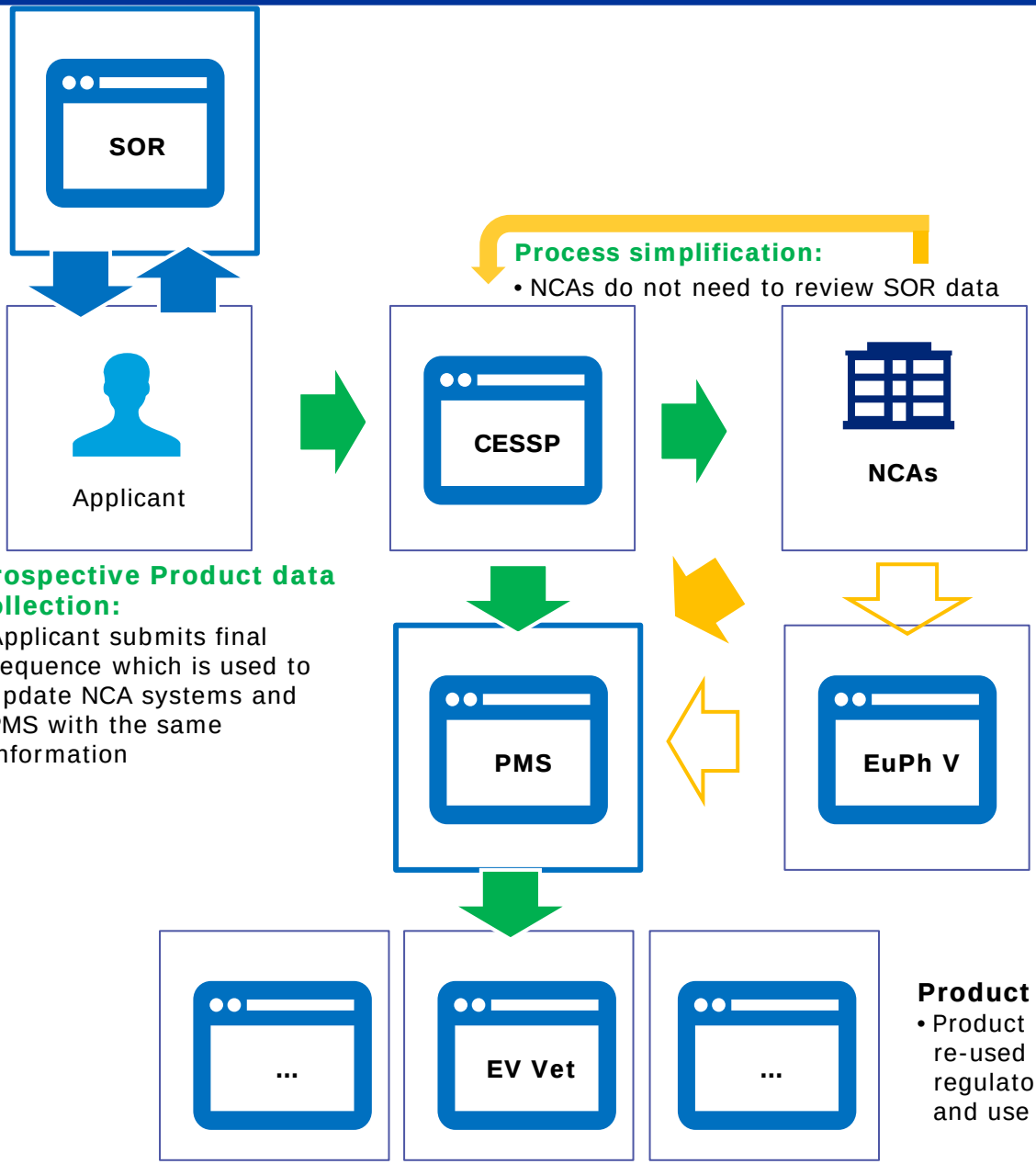
SOR pre-registration:
- Applicant requests new/updated SOR data before regulatory applications



Prospective Product data collection:
- Applicant submits final sequence which is used to update NCA systems and PMS with the same information

Retrospective Product data collection:
- Legacy data will be transmitted **by NCAs**

Product data re-use
- Product data can be re-used in multiple regulatory procedures and use cases

SPOR Timelines & Outcomes

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2017

- **Q2:** P&SMS project started
- **Q2:** RMS & OMS live
- **Q2:** RMS & OMS Target Operating Model (TOM)
- **Q4:** Integrate OMS with eAF; RMS already integrated with eAF

2018

- **Q3:** CAP & NAP Manufacturers
- **Q3:** Integrate RMS & OMS with CESSP (MAA)
- **Q4: (**Draft) EU IG available

> 2019

- EU Substance list is available
- Substances TOM
- PMS API UAT
- (Final) EU IG is available

> 2020-2021

- **H&V Products (TOM):**
  - PMS starts to collect product data submitted via eAF/CESSP (not more data than eAF!) – ISO IDMP compatible format
  - Assessment/validation solely the responsibility of NCAs
  - EMA acts as custodian

> 2020-2021

- Legacy data will be transmitted by NCAs to Eudrapharm/PMS (NVR Art 51)?

> 2021-2022

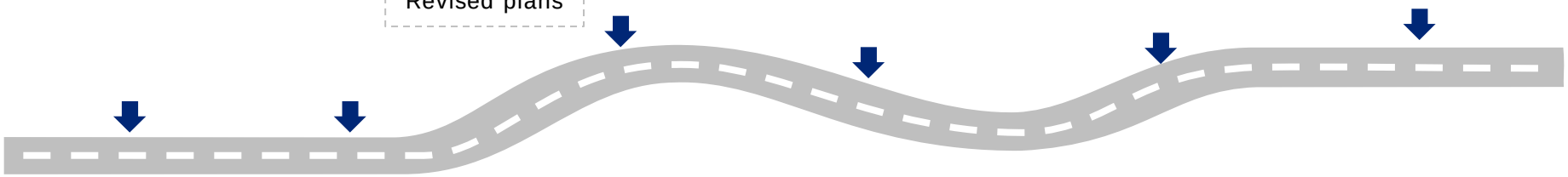
- Human Products TOM Enforcement

TBD

Veterinary Products Target Operating Model Enforcement ???

Agency Relocation

2018-2019: Revised plans



2018: RMS & OMS integrated with business processes

2018-2019: Documentation produced enables vet Industry to be aware of developments and prepare for future process

2020: P&SMS TOM ensures only **trusted data** is available for use in reg processes

The current plan **does not require Industry to backfill details on already approved products** (the provisions of pharmacovigilance Art.57 do not apply to veterinary medicines~~)~~

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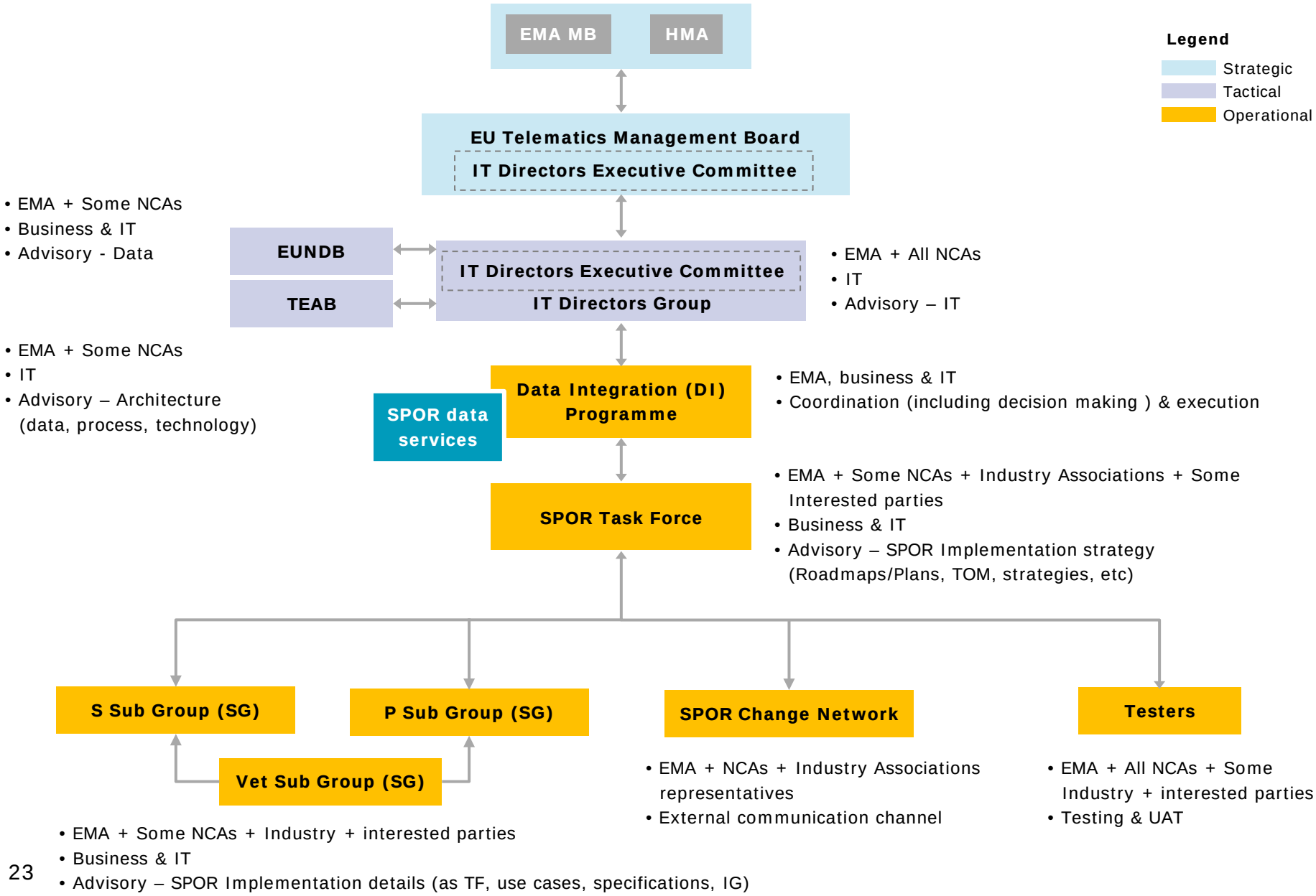
4. Governance

SPOR within the Telematics Governance



Veterinary sub-group

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- Advisory role
- Provide dedicated forum to discuss and advise on veterinary specific topics related to both PMS and SMS from the point of view of both veterinary & human and veterinary only Agencies
- Take into account the proposals of the draft New Veterinary Regulation which will affect PMS and SMS
- Prepare and review proposals regarding aspects related to SPOR projects implementation
  - **IN**: review veterinary specific recommendations for Roadmap/Plans, EU Implementation Guide, Target Operating Model, Data Migration & enrichment strategy, Data Models and migration mappings, Operating models and business processes, Business requirements, system use cases, screen mock-up run through, API specifications
  - **OUT: Communication, demos (live system), testing & UAT**
- The Vet SG holds ad-hoc meetings via conference calls/webinars on specific topics identified

SPOR Change Liaisons

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Change network across NCAs & Industry (SPOR change liaisons) established to broaden the reach of SPOR.

Its role:

- cascade information to stakeholders who need to be aware of SPOR and who will be impacted by SPOR
- stay up-to-date on implementation of SPOR and how it is impacting their organisation in terms of systems, processes and roles & responsibilities;
- maintain an overview of progress and issues relating to implementation, provide feedback where relevant
- promote visibility of training material
- act as an advocate, promoting the changes brought about by SPOR
- share knowledge between each other/individuals within their organisations to support them in best practice for undertaking SPOR implementation

SPOR Change Liaisons

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NCAs with nominated SPOR Change Liaison		Veterinary Industry Associations
Veterinary NCAs: • Bulgaria • Cyprus • Czech Republic • France • Germany • Hungary • Italy • Latvia • Lithuania • Portugal • Romania • Slovak Republic • UK • Malta	**Veterinary / Human NCAs:** • Austria • Belgium • Denmark • Estonia • Finland • Germany • Iceland • Ireland • Liechtenstein • Luxembourg • Netherlands • Norway • Poland • Slovenia • Spain • Sweden	• EGGVP • Animal Health Europe

- If you would like to find out who is your SPOR contact please email SPOR-Change-Liaisons@ema.europa.eu
- SPOR change liaisons please inform your colleagues about your role

Testers

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- Testing role
- Involved in solution demos & User Acceptance Testing (UAT)
  - The documentation discussed and circulated to this group (test scripts, mock-ups, screenshots, planning details, etc.) is ALL CONFIDENTIAL and cannot be shared/published outside of the group!
  - OUT: comms, recommendations (improvements/changes decided by PB upon review of feedback)
- Future calls for expressions of interest to be published soon
  - Nomination process to follow if interested in participating in UATs
  - Organisations (not individuals) selected are appointed for the duration of the P&S project
  - Even if Vet data will be taken into account in Phase 3, need to already register interest to be on reserve list of testers

Communications / events 2018 (draft)

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2018

	Q1	Q2	Q3	Q4
SPOR related Milestones	Increase awareness / adoption of SPOR services amongst Veterinary stakeholders ◆ Expansion of OMS dictionary: MAHs (V) CAPs, MAAs: (V) CAPs	◆ Expansion of OMS dictionary: Manufacturers: (H+**V**) CAPs	◆ Mandate use of RMS portal for industry to request new/updated terms	◆ Expansion of OMS dictionary: Manufacturers: (H+**V**) NAPs ◆ Vet MAH for non CAPs via OMS change request ◆ Use of OMS in eAF mandated (aligned with CESSP MA go-live) (*)
Comms/ events	SPOR Veterinary webinar 20 Feb SPOR OMS mapping Webinar with NCAs 27 Feb	◆ Announce expansion of the OMS dictionary (web update) SPOR OMS mapping Webinar with industry 5 April	◆ Announce mandating of RMS portal (web update) ◆ Announce inclusion of Vet MAH for non CAPs via CR (web)	◆ Announce expansion of the OMS dictionary (web publication) ◆ Announce mandating of OMS via eAF (web)
	Email updates to SPOR Change Network			

(*) – subject to planning

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5. What does it take to implement SPOR for an NCA and a company

NCAs & Industry involvement through SPOR

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2018:				2019				...
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	...

RMS & OMS use

RMS & OMS integration with CESSP MA (*)

- **Industry & NCAs** – keep registering your SPOR users
- **Industry -** start requesting new/updated terms via RMS portal prior to regulatory submission *(user registration is required)*
- **Industry -** start requesting new/updated data via OMS prior to regulatory submission *(user registration is required)*
- **NCAs -** request new/updated terms via RMS portal *(user registration is required)*
- **NCAs** - start requesting new/updated data via OMS *(user registration is required)*

Programme participation

- **NCAs & Industry -** SPOR Programme participation & Engagement via SPOR Change Liaisons
- **NCAs & Industry -** Analyse / adapt process to keep data synchronised (**)
- **NCAs & Industry -** Analyse / adapt systems to support process changes (**)
- **NCAs -** Synchronise local data with SPOR (**)
- **NCAs -** continue mapping Referentials (in preparation for PMS)
- **NCAs -** OMS mapping (in preparation for PMS)
- **Industry -** map against new Referential Lists (**)
- **Industry** - OMS mapping (**)

* Subject to planning

** Only if using/planning to use automated integration with eAF/CESSP

Stakeholders involvement through SPOR

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- At the RMS & OMS go-live there were **no immediate changes** to submission processes
- The process for **industry** to **pre-register** referential data **before submitting eAF in regulatory applications** was already in place. Pre-registration of Organisations before eAF submission process was implemented in **2017.** There could be some **changes in the processing of eAF by NCAs** due to eAF integration with OMS.
- **CESSP MAA** is also expected to integrate with OMS & RMS & SMS and use the same process
- There are currently **no other envisaged process changes** with regards to Product submission by Industry
  - Any changes arising from the ongoing P&SMS projects are **not due before Agency relocation**. Detailed plans/impacts will be communicated to veterinary stakeholders after relocation

- NCAs have been requested to **continue with the mapping of Referentials** in support to PMS implementation. As NCAs complete their mapping they can send **change requests** for their unmapped terms to RMS**.**

Data Mapping & validation by NCAs

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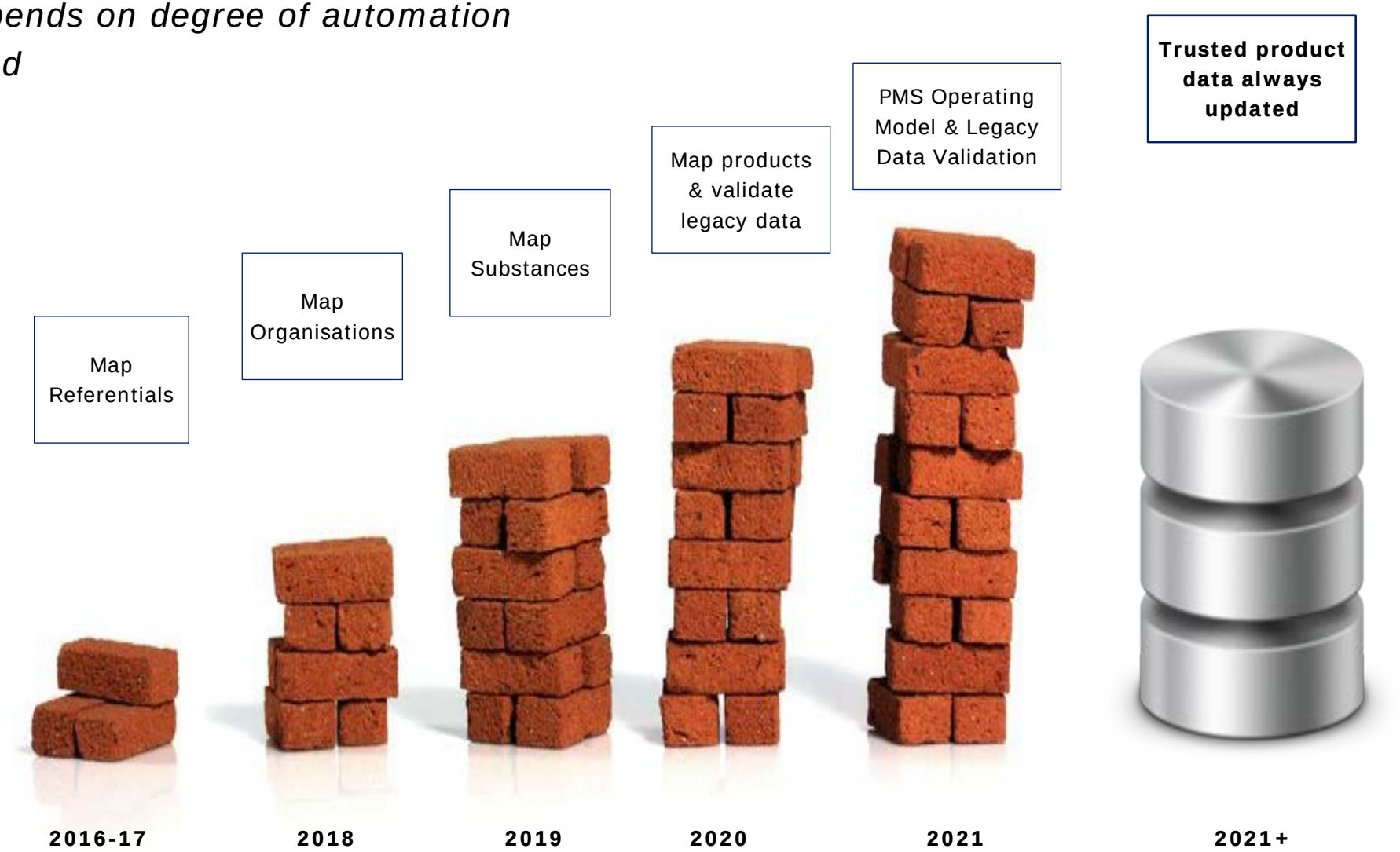
Need to map/integrate for Industry depends on degree of automation used



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Key messages

Veterinary specific considerations

S&O&R:

- **One stop shop** for data required in regulatory submissions
- Not more structured information than required today
- **Process simplification:** NCAs do not need to review SOR data

Products:

- **Same DM used across human & veterinary** domains to bring regulatory efficiencies
  - not all fields/ rules will be applicable to the veterinary domain (Use case analysis finalised 2016)
- **Legacy data** will be transmitted by **NCAs**
- Applicant submits **final sequence** which is used to **update NCA systems (RMS & CMS) and PMS with the same information**

- **Solution still being defined!** This is the moment to **adapt it to veterinary needs**

Thank you for your attention

Further information

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

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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Annex

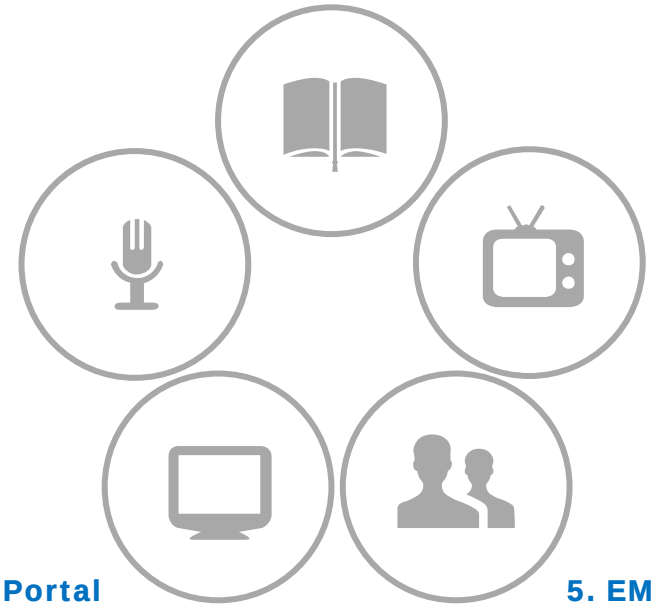
OMS support / guidance

1. Reference documents provide detailed guidance for the RMS. Accessible via the SPOR portal.

- OMS web user manual
- SPOR user registration manual
- SPOR affiliation template (to register the first industry super user)
- Change Request Validation in OMS
- Organisation data quality standards in OMS
- SPOR SLAs

3. Material from SPOR webinars

Topic related content available on the SPOR portal (under documents section) and EMA public website. For example “Industry on-boarding to SPOR”, “Using RMS data in eAF”



2. Training videos

OMS training videos available to view on-demand by SPOR users on the @emainfo channel

4. EMA Account Management Portal

To create a new EMA account in order to obtain access to EMA systems (including SPOR). To request SPOR user role.

Account Management Portal.

5. EMA Service Desk Portal

Service requests, issues, requests for technical support shall be submitted through the Service Desk Portal.

RMS support / guidance

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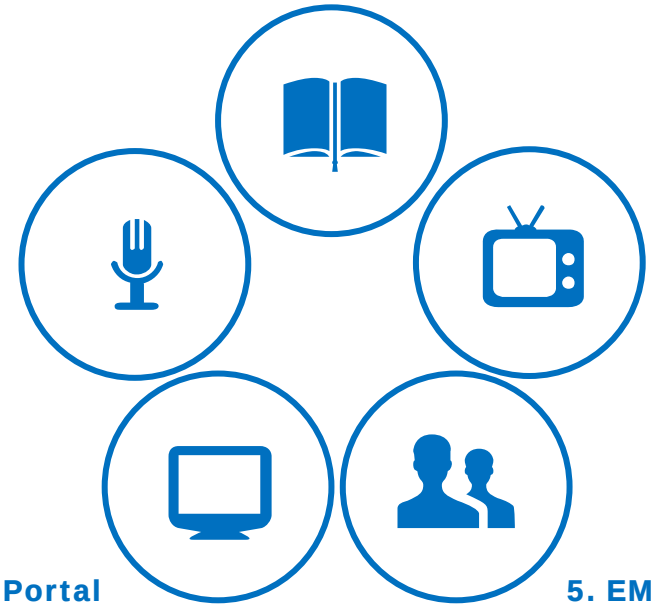
1. User manuals & reference documents

Provide detailed guidance for the RMS. Accessible via the SPOR portal.

- RMS web user manual
- SPOR user registration manual
- SPOR SLAs



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SPOR Data Management Services portal

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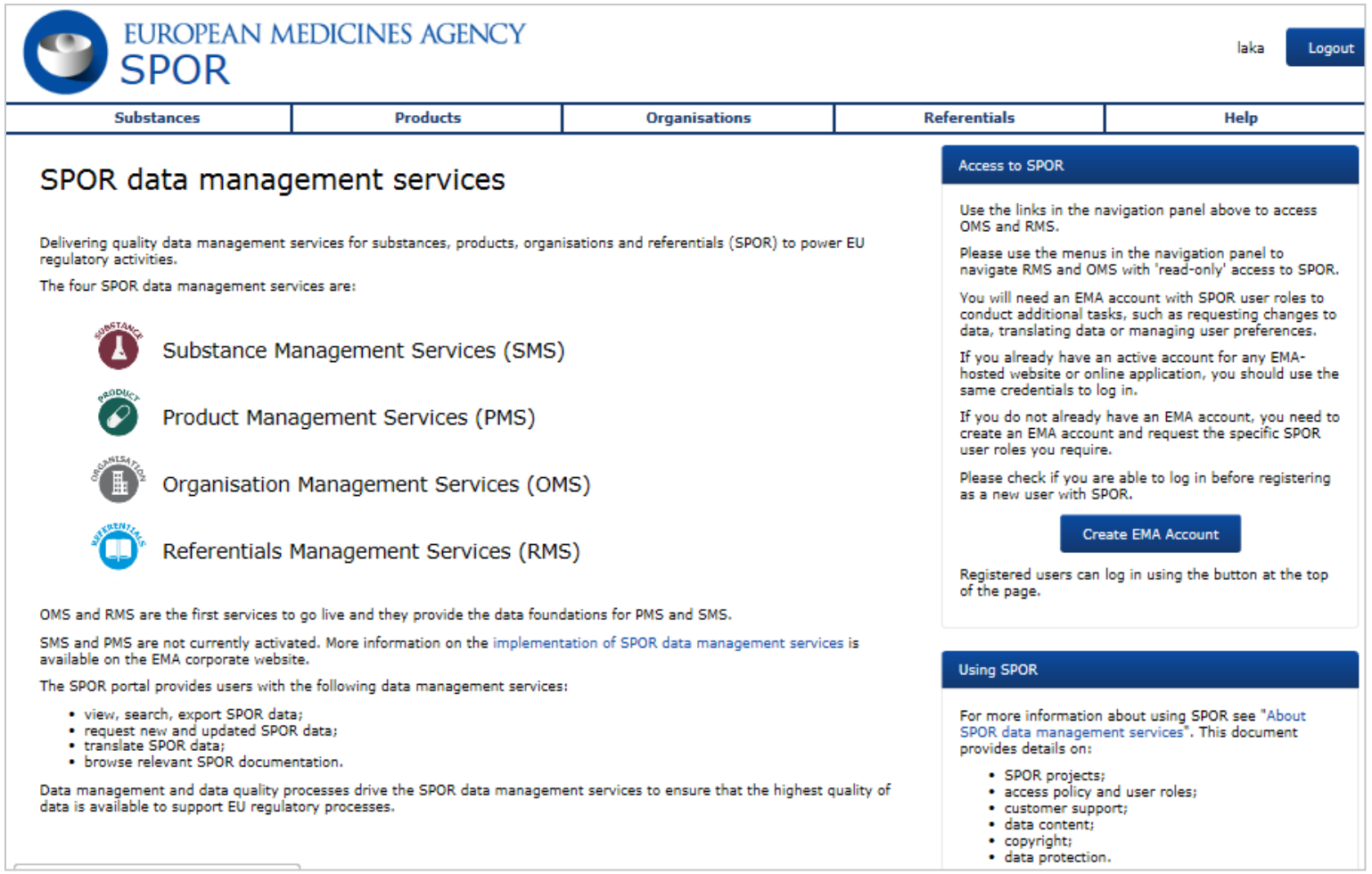
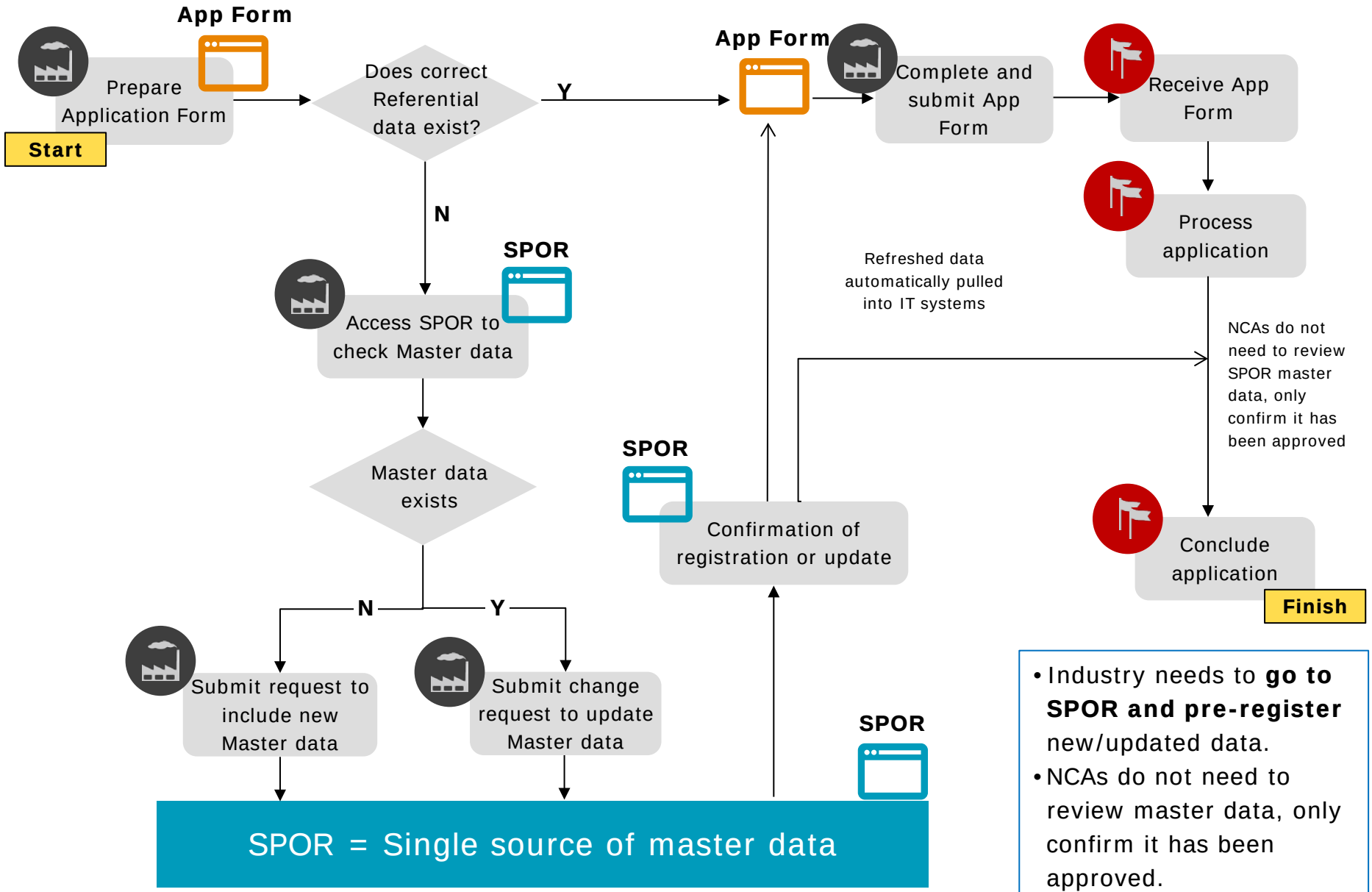
http://spor.ema.europa.eu/sporwi/



SPOR portal is compatible with web browsers Internet Explorer (version 10 and above) and Chrome (version 58 and above)

R & O (& S) in the Regulatory context



- Industry needs to **go to SPOR and pre-register** new/updated data.
- NCAs do not need to review master data, only confirm it has been approved.

Disclaimer