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SCIENCE MEDICINES HEALTH

Product Management Services & Substance Management Services (P&SMS) Projects

Implementation of ISO IDMP standards through SPOR master data

Topics

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1.

Background

- SPOR vs IDMP
- What will SPOR deliver

2.

Implementation of IDMP through SPOR

- Past
- Next Steps
- EU Guidance
- Future
- Data Migration Strategy

3.

SPOR in the regulatory context

- SPOR in the regulatory context
- SPOR integration with eAF
- SPOR as an enabler of process changes

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1. Background

SPOR vs IDMP

- **ISO IDMP standards** (five standards) define the rules that uniquely identify medicinal product and the relevant elements to identify them
- Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) obliges European Union (EU) Member States, marketing authorisation holders and EMA to **make use of the ISO IDMP standards**.
- The **SPOR projects** implements the ISO IDMP standards as well as the processes to **manage** four domains of data (**master data**) in pharmaceutical / regulatory industry:
  - **S**ubstance Management Services (SMS) – ISO 11238
  - **P**roduct Management Services (PMS) – ISO 11615, 11616
  - **O**rganisation Management Services (OMS)
  - **R**eferentials Management Services (RMS) – ISO 11239, 11240
- **Delivery of SPOR is phased**
  - RMS and OMS services were delivered in June 2017
  - Delivery of PMS and SMS will follow
    - **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.
- **SPOR applies to both domains Human & Veterinary**

What will SPOR deliver?

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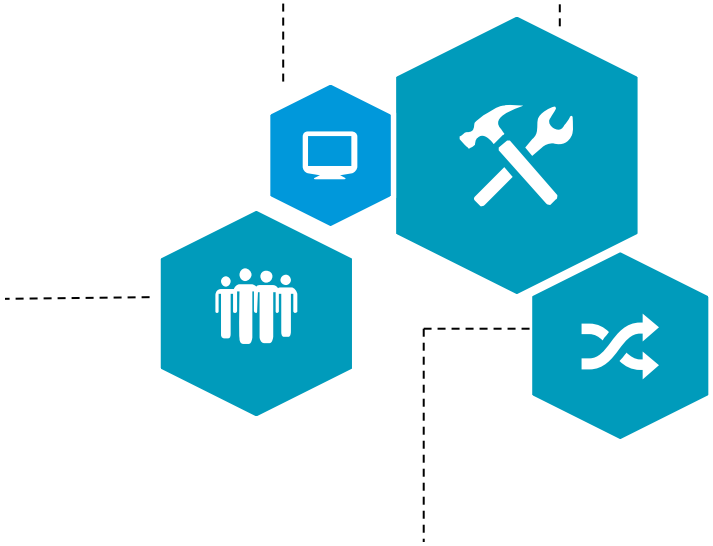
SPOR data is accessible via a web **User Interface** (UI) and **SPOR APIs*** (Application Programming Interface)

New process for industry and NCAs to **pre-register**/update SPOR data before submitting regulatory applications. Data is **entered once and reused** in different processes.

A specialised team of **EMA data stewards** will manage SPOR data and provide support to stakeholders



New **data management** approaches for industry, NCAs and the EMA:
- Data synchronisation on an ongoing basis
- Possible need for data transformation/enrichment

List of organisations (OMS dictionary), Referentials Lists/Terms and Substances for stakeholders to use in EU regulatory activities

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2. Implementation of IDMP through SPOR data management services

A. Past

The road behind (2015-2017) – SPOR Achievements

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Feb 2015: Selection of the technology to support SPOR implementation.

Mar 2015: SPOR Roadmap agreed.

Mar 2015: SPOR TF set up.

May 2015: RMS project started.

July 2015: Green light form HMA for RMS & OMS Target Operating Model (TOM) .

Jul 2015: Technology purchase.

Jul 2015: OMS project started.

Mar 2016: Change Liaison Network set up.

Jul 2016: Veterinary Stakeholders join the SPOR Task Force (TF).

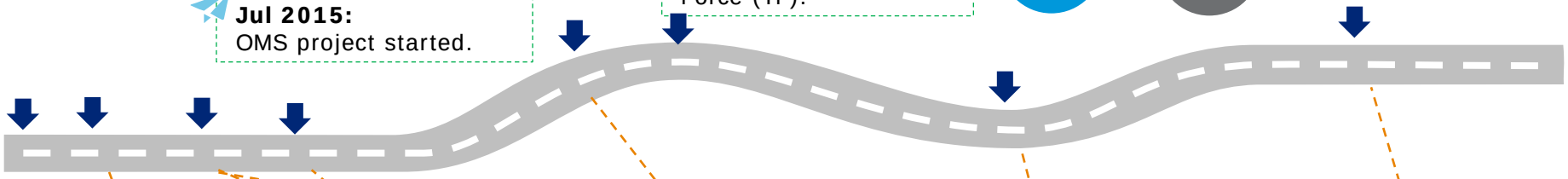
June 2017: RMS went live and **replaced EUTCT** as preferred source of regulatory referential data.

June 2017: OMS went live and manages regulatory organisation data. **NCA content** is available. Industry content expanded throughout 2017-2018.

June 2017: NCA users on-boarding **Dec 2017: Industry** user on-boarding.

Q1- Q2 2017: P&SMS project started.

June 2017: Initial schedule for P&SMS communicated to SPOR Task Force



Q1 2015: SPOR strategy and approach agreed with Industry, Regulators and EC.

Q2 2015: First two SPOR projects ongoing.

2015-2016: Engaging with Industry and regulators through SPOR TF and cascading communications through Change Liaison network.

June 2017: RMS implements **ISO11239** and **ISO11240 standards**; makes EMA **regulatory compliant.**

2017: Users start using SPOR Target Operating Model for **pre-registration of master data** to improve regulatory submissions.

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SPOR Data Management Services portal

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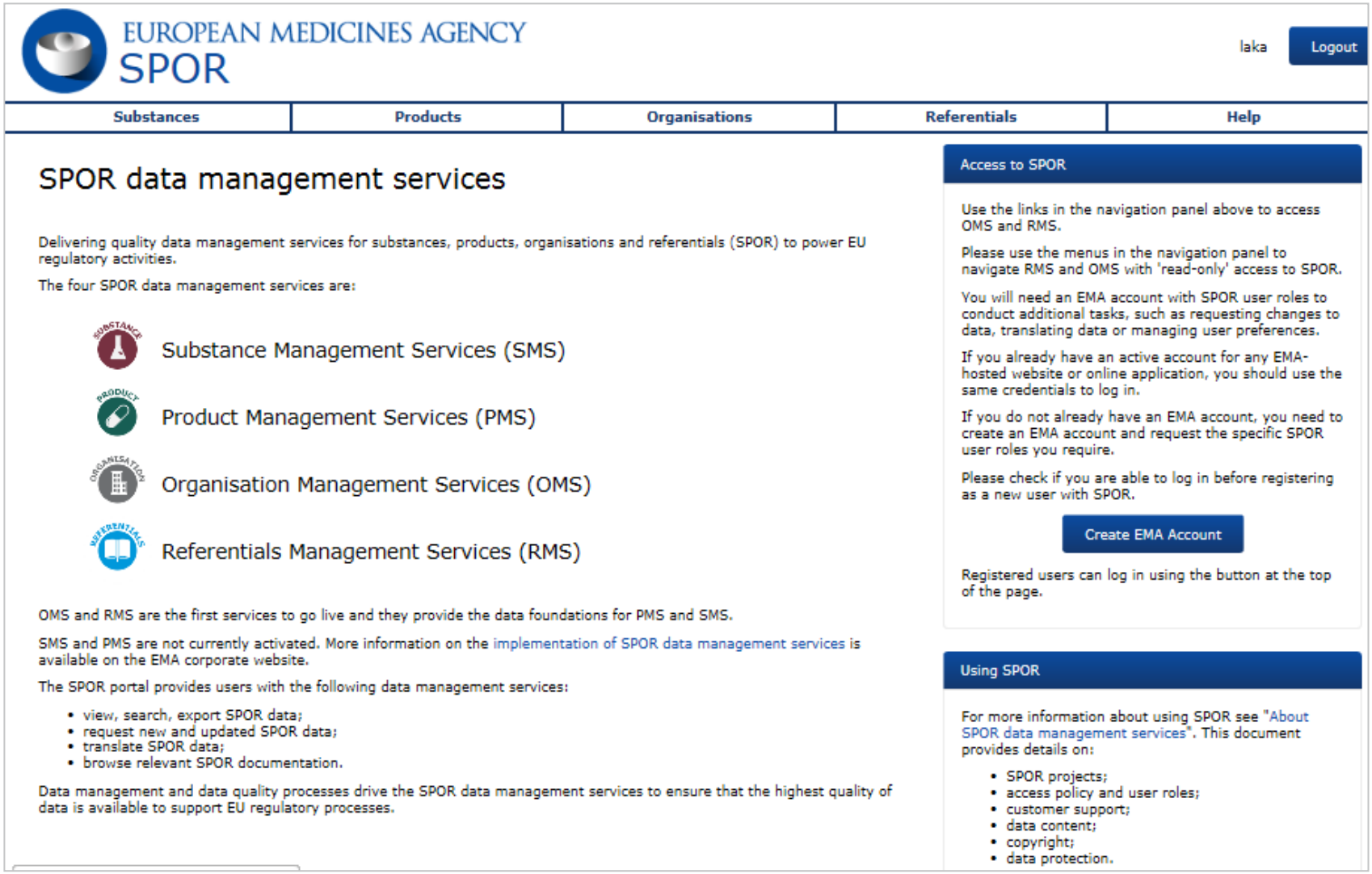
http://spor.ema.europa.eu/sporwi/



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

B. The next steps

The next steps (2017-2018) – SPOR Plans

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Q1 - Q2 2017: P&SMS project started.

Q4 2017: MAH content is available.

Q1 2018: Sponsor content is available.

Q3 2018: CAP & NAP Manufacturers are available.

Q4 2018: P&SMS It 1 Phase 1 delivers Art 57 Migration.

Q4 2017: Integrate OMS with ECD.

Q4 2018: Integrate RMS & OMS with CT Portal.

Q4 2018: Integrate RMS & OMS with Art 57/xEVMPD.

Q4 2017: Integrate OMS with eAF; RMS already integrated with eAF.

Q3/Q4 2018: Integrate RMS & OMS with CESSP (MAA).

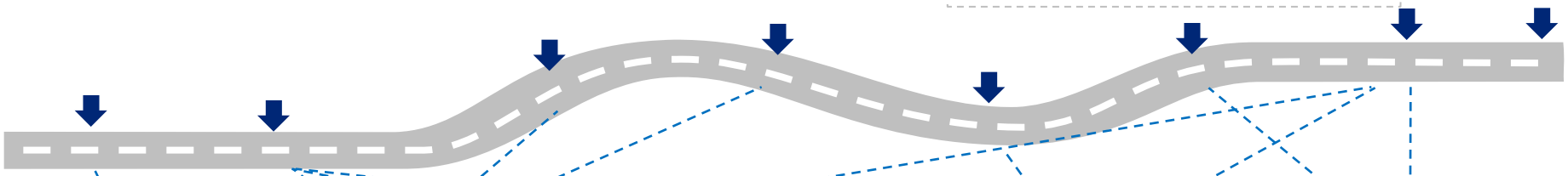
Q4 2018: (draft) API specs & User On-boarding strategy.

Q4 2017: TOM (draft) agreed.

Q1 2018: Messaging Format agreed.

Q3-Q4 2018: (draft) Data scope; Migration & Validation strategy; Business processes (Ph1) are available.

Agency Relocation



Q2 2017: Remaining SPOR projects ongoing.

2017-2018: Organisation data is incrementally available.

2017: Users start using SPOR Target Operating Model for pre-registration of **R & O** data to improve regulatory submissions.

2018: RMS & OMS master data is integrated with business processes i.e it is entered once and reused across different business processes.

2018: Guidance is available to support Industry and regulators implementing SPOR.

P&SMS projects

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- P&SMS project was initiated early 2017

- Considering:
  - Project vision and scope
  - Available capabilities and skill set
  - Brexit and other constraints

- The approach the EU network is taking:
  - PMS implementation is led and undertaken by EMA
  - SMS implementation is shared as follows:
    - SMS - IDMP light – implemented by EMA
    - EU SRS - ISO IDMP compliant – implemented by MEB (NL)

PMS

- **PMS Iteration 1** will be the first iteration of ISO IDMP 11615 and 11616 compatible data management solution for **authorised human & veterinary products**. It will support **generation and maintenance of MPID, PhPID & PCID**
  - To fully address the implementation of IDMP 11238 further projects will be required
- PMS Iteration 1 has been divided into multiple phases. Phase 1, before relocation, is an EMA internal delivery comprising:
  - A new ISO IDMP compliant Master Data Managemnet (MDM) hub (also covering Veterinary and other needs)
  - Two way synchronisation of medicinal product information (including S, R and O) between Art.57 database and the new MDM solution
  - Data Quality (DQ) assurance/data entry of human medicinal Product information by EMA and possibly by some NCAs

EU SMS projects

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SMS implementation is shared as follows:

SMS "IDMP light"

- **Who:** Implemented by EMA
- **Data:** SMS data is the "simplified" PUBLIC substance data, that supports selection in regulatory processes and therefore enables you to distinguish two or more similar substances
- **Technology:** SMS solution covers:
  - Search, browse and export of PUBLIC substance data
  - Management of substance change requests
  - Translation management
- **Process/People:** EMA provides a broker service by managing substance requests, supporting translations and assuring data quality.

EU SRS ISO IDMP compliant

- **Who:** Implemented by MEB (NL)
- **Data:** EU SRS contains ISO IDMP substance data that supports scientific identification of substances. It includes PUBLIC and CONFIDENTIAL information subject to controlled access
- **Technology:** EU SRS solution covers only Substance data management
  - Software development/implementation led by NL in the short term in collaboration with EMA, under EU Telematics governance
  - Software maintenance to be transferred to EMA
- **Process/People:** This project is responsible to set up the EU Substance Validation Group (SVG) who will:
  - Prepare the EU substance list
  - Maintain the EU list by approving substance requests and managing substance data

SMS

- **SMS Iteration 1** will be the will be the first iteration towards ISO IDMP 11238 compatible data management solution for substances
  - To fully address the implementation of IDMP 11238 further projects will be required
- SMS Iteration 1 has been divided into two phases. Phase 1, before relocation, is an EMA internal delivery comprising :
  - New MDM hub for the substnace management service
  - Migration of substance data from multiple EMA sources (EV H, EUTCT H, EUTCT V, EV V) to MDM hub, which support future consolidation and synchronisation
    - *This data is not yet mapped to other external sources such as G-SRS*
  - Management of substance data as per current process/DQ standards

EU SRS

- In parallel to SMS Phase 1, EU SRS project led by MEB (NL) will:
  - Set up SVG
  - Set up initial EU list by consolidation of FDA + NCA + EMA lists in English and with some translations
  - Prepare EU SRS implementation

C. EU Guidance

EU Guidance Process

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Draft EU IG

2018:
Several sections of EU IG available:
- ***(Draft)*** *API specs*
- ***(Draft)*** *Data fields & business rules;*
- *User on-boarding strategy;*
- *User registration process;*
- *Data Migration strategy;*
- *Data Validation/DQ assurance strategy*
- ***(Draft)*** *TOM*

Develop/Test /UAT API

Not before 2019:
PMS API UAT:
- *Minor changes/improvements are expected as result of API development and testing*

Finalise EU IG

Not before 2019:
(Final) EU IG is available:
- ***API specs***
- ***Data fields & business rules;***
- *User onboarding strategy;*
- *User registration process;*
- *Data Migration strategy;*
- *Data Validation/DQ assurance strategy*
- ***TOM***
- ***Submission/Registration process***

Start Transition

Not before 2020:
Industry can start to submit product information using new IDMP compatible format to comply with Art 57
- *EU IG + 12 months*

Enforcement

Not before 2021:
Enforcement: Industry can only submit product information using new IDMP compatible format to comply with Art 57
- *Transition + 12 months*

EU Guidance and Relevant milestones for Human Industry

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2017:
High-level principles agreed:
- *Data scope;*
- *Migration & Validation strategy;*
- *Business processes (Ph1)*

2017:
(Draft) TOM

2018:
Several sections of EU IG available:
- *(Draft) API specs*
- *(Draft) Data fields & business rules;*
- *User onboarding strategy;*
- *User registration process;*
- *Data Migration strategy;*
- *Data Validation/DQ assurance strategy*

2018:
Messaging Format agreed

2018-2019:
Revised plans published

Not before 2019:
Several sections of EU IG available:
- *TOM*
- *Submission/Registration process*

Not before 2019:
PMS API UAT

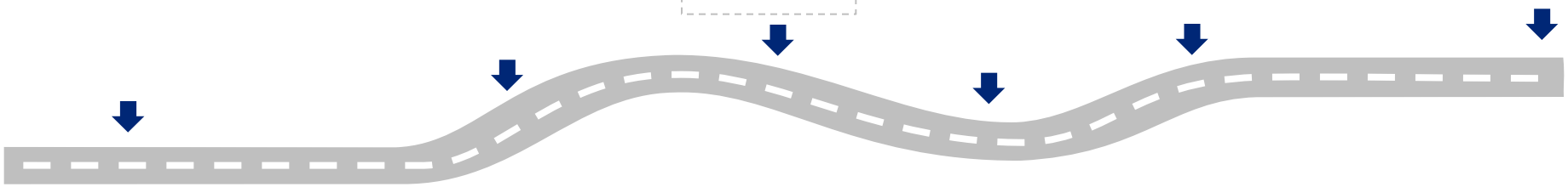
Not before 2019:
(Final) EU IG is available

Agency Relocation

Not before 2020:
Start Transition: Industry can start to submit product information using new IDMP compatible format to comply with Art 57

Not before 2021:
Enforcement: Industry can only submit product information using new IDMP compatible format to comply with Art 57

Not before 2020:
P&SMS It 1 Phase 4 delivers the Human Products Target Operating Model:
- *PMS collects (new/updated) product data submitted by Industry via eAF/CESSP to support all regulatory processes including Art. 57*



(Draft) Sections of EU IG enable to plan in 2018 and start some preparatory work 2019

12 months available for **preparatory work** since (final) EU IG is published to start of Transition

Transition period extended to 12 months

EU Guidance and Relevant milestones for Vet Industry

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2017:
High-level principles agreed:
- *Data scope;*
- *Validation strategy;*
- *Business processes (Ph1)*

2017:
(Draft) TOM

2018:
Several sections of EU IG available:
- *(Draft) API specs*
- *(Draft) Data fields & business rules;*
- *User onboarding strategy;*
- *User registration process;*
- *Data Validation/DQ assurance strategy*

2018:
Messaging Format agreed

2018-2019:
Revised plans published

Not before 2019:
Several sections of EU IG available:
- *TOM*
- *Submission/Registration process*

Not before 2019:
PMS API UAT

Not before 2019:
(Final) EU IG is available

Agency Relocation

Not before 2020:
Legacy data will be transmitted by NCAs to Eudrapharm/PMS (NVR Art 51)

Not before 2020:
P&SMS It 1 Phase 4 delivers the Vet Products Target Operating Model:
- *PMS collects (new/updated) product data submitted by Industry via eAF/CESSP (not more data than eAF!)*
- *Assessment/validation of that product data is solely the responsibility of NCAs*
- *EMA acts as custodian*

P&SMS TOM ensures data is validated by NCAs so only **trusted substance and product data** is available for use in regulatory processes

Documentation produced enables vet Industry to be aware of developments and prepare for future process

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)

EU Guidance and Relevant milestones for NCAs

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2017:
High-level principles agreed:
- *Data scope;*
- *Validation strategy;*
- *Business processes (Ph1)*

2017:
(Draft) TOM

2018:
OMS content is expanded: MAH> CAP Manufacturers> NAP Manufacturers

2018:
Several sections of EU IG available:
- *(Draft) API specs*
- *(Draft) Data fields & business rules;*
- *Data Validation/DQ assurance strategy – Validation of legacydata*

2018:
Messaging Format agreed

2018-2019:
Revised plans published

Agency Relocation

Not before 2019:
EU Substance list is available

Not before 2019:
Several sections of EU IG available:
- *TOM*
- *Submission/Registration process*

Not before 2019:
PMS API UAT

Not before 2019:
(Final) EU IG is available

Not before 2020:
A core set of product data is validated by NCAs and available for use in regulatory products

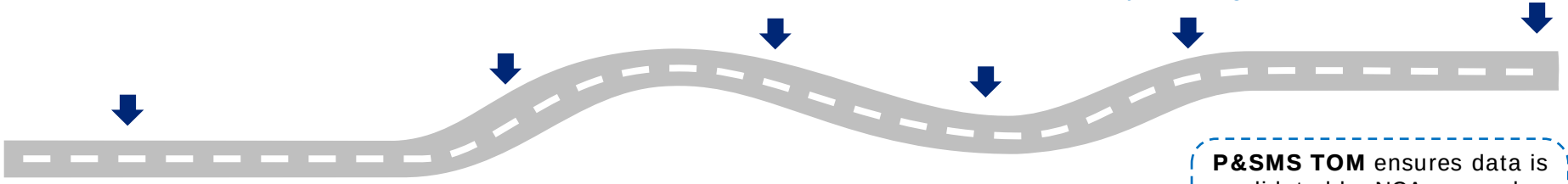
Not before 2020:
P&SMS It 1 Phase 4 delivers the Human Products Target Operating Model

2016-2018: NCAs to map the referentials in their systems against RMS

2018-2019: NCAs to map the Organisations in their systems against OMS

2019-2020: NCAs to map the Substances in their systems against SMS

2020: Human NCAs check product data in their systems against PMS
Vet NCAs send a core set of product data to EudraPharm/PMS



P&SMS TOM ensures data is validated by NCAs so only **trusted substance and product data** is available for use in regulatory processes

D. Future

The journey ahead (2019 +) – SPOR Roadmap

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EU Implementation Guides are available

P&SMS It 1 Phase 2 delivers PMS API & SMS ISO 11238 Compliant data

P&SMS It 1 Phase 3 delivers Migration of Vet products

P&SMS It 1 Phase 4 delivers the Human Products Target Operating Model

Start Transition: Industry can start to submit product information using new IDMP compatible format

Agency Relocation

P&SMS It 1 Phase 5 delivers PMS User Interface

P&SMS It 1 Phase 6 delivers the Veterinary Products Target Operating Model

Enforcement: Industry can only submit product information using new IDMP compatible format

P&SMS It 1 Phase 7 delivers reporting & document management

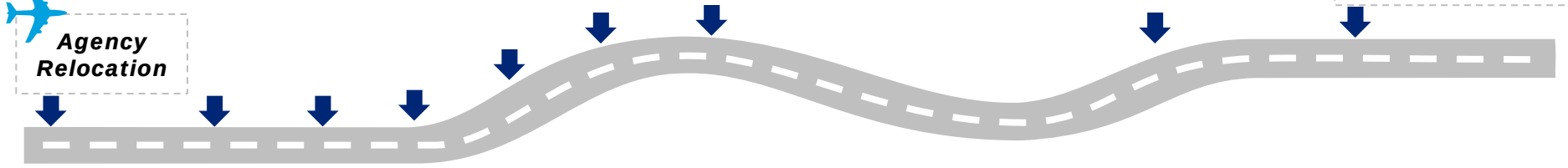
Integrate P&SMS with Regulatory processes

Integrate P&SMS with CT processes

Integrate P&SMS with PhVig processes

P&SMS Iteration 2 *opportunity to expand scope, eg* ***Investigational Medicinal Products***

P&SMS Iteration 3 *further opportunity to expand scope e.g.* ***Clinical Particulars***



SMS implements **ISO11238**; makes EMA **regulatory compliant.**

PMS implements **ISO11615** and **ISO11616 standards**; makes EMA **regulatory compliant.**

P&SMS TOM ensures data is validated by NCAs so only **trusted substance and product data** is available for use in regulatory processes.

SPOR master data is integrated with business processes i.e it is entered once and reused across different business processes.

P&SMS Iteration 1 covers authorised human & veterinary medicinal products.

PMS

- PMS Iteration 1 has been divided into multiple phases. After relocation PMS will deliver:
  - Authorised human & veterinary medicinal products accessible via a web User Interface (UI) and SPOR Application Programming Interface (APIs)
  - New ISO IDMP compliant message
  - **Products Target Operating Model**
    - No changes to regulatory processes (including timelines as well as roles and responsibilities)
    - Simultaneous submission of product information to NCAs as part of regulatory procedures and registration in PMS to support multiple use cases
    - New ways to assess information electronically

(Draft) PMS Target Operating Model

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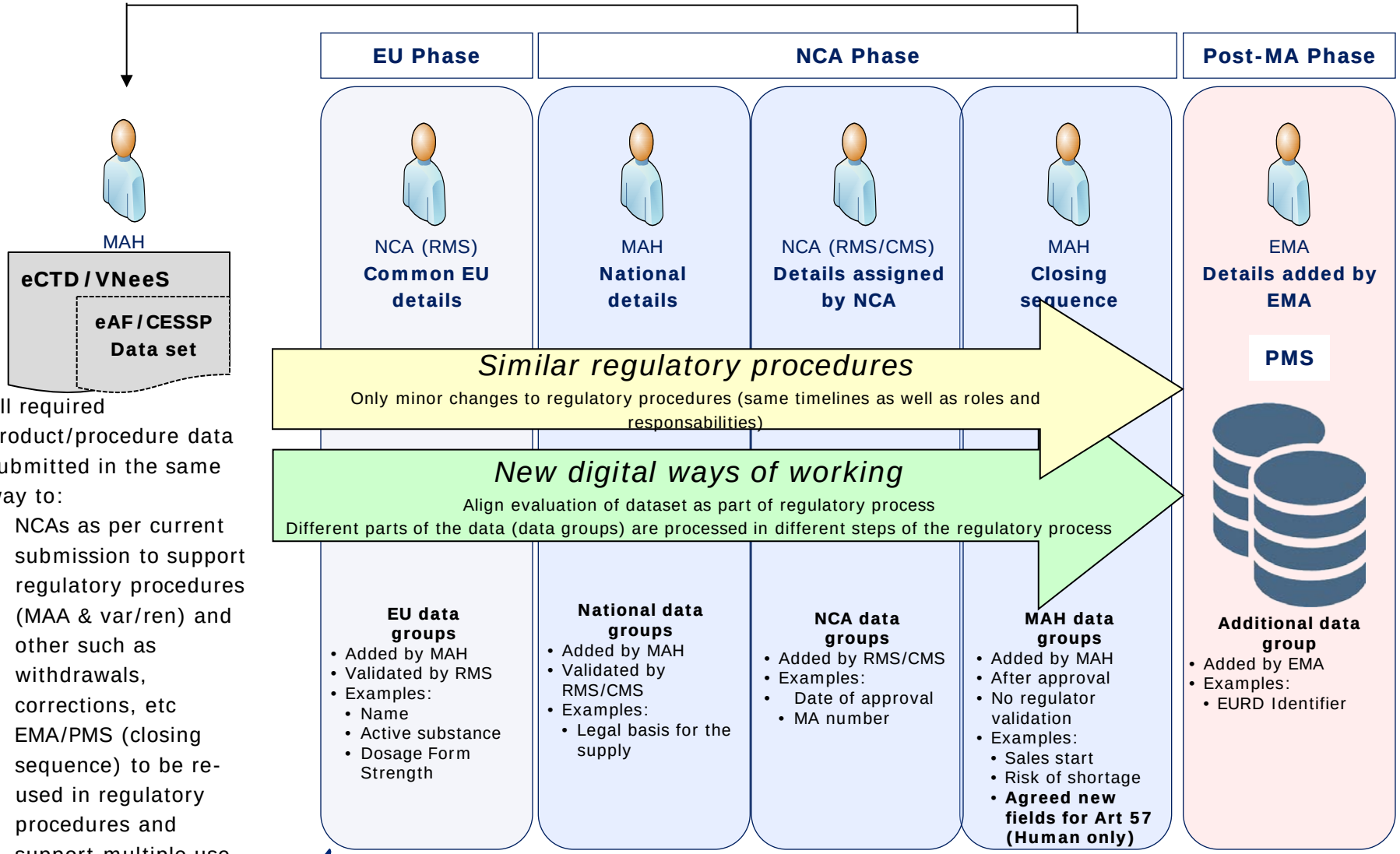

All required product/procedure data submitted in the same way to:

- NCAs as per current submission to support regulatory procedures (MAA & var/ren) and other such as withdrawals, corrections, etc
- EMA/PMS (closing sequence) to be re-used in regulatory procedures and support multiple use cases

PMS TOM ensures:

- Clearer governance and **ownership of data**
- Data is validated by NCAs so only **trusted product data** is available for use in regulatory processes

- SMS Iteration 1 has been divided into two phases. After relocation SMS will deliver:
  - Substances accessible via a web User Interface (UI) and SPOR Application Programming Interface (APIs)
  - Synchronisation with EU SRS
  - **Substances Target Operating Model**
    - New process for industry and NCAs to pre-register/update Substance data before submitting regulatory applications
    - EU-US alignment
    - Substance data is assessed in parallel with MA review
    - Substance data is approved before conclusion of regulatory processes

(Draft) SMS Target Operating Model

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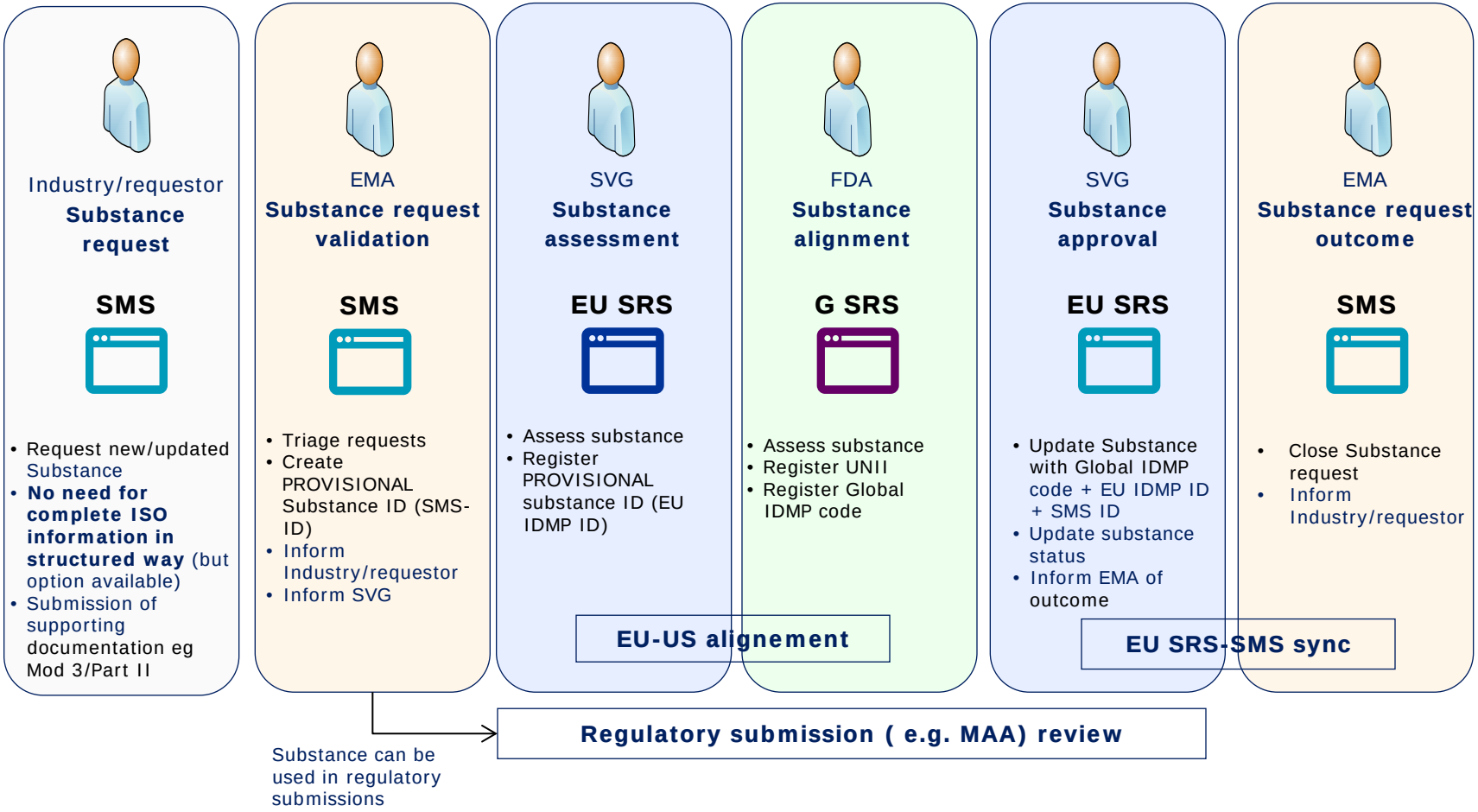

SMS TOM ensures:

- Regulatory processes can start as soon as substance is Provisionally registered
- EU-US alignment
- Data is approved by SVG before conclusion of regulatory processes i.e **only trusted data is used in regulatory processes**

E. Data Migration Strategy

Migration Strategy

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EMA migration

2018:
EMA Migration:
- *EMA migrates xEVMPD data into PMS*
- *PMS has same data content as xEVMPD*
- *PMS data is transformed into a new ISO compatible format (as possible)*

PMS API

Not before 2019:
PMS API:
- *Industry solutions (RIM) can import/pull Product data from PMS API (ISO message)*

Industry enrichment

Not before 2019:
Industry is expected to validate the data migrated/ transformed from Art 57 and enrich/transform the data as per specifications in the EU IG:
- *Industry can perform validation/enrich ment via own RIM solution*

TOM (Start Transition)

Not before 2020:
Industry can start to submit product information using new IDMP compatible format to:
- *comply with Art 57 and/or*
- *support any regulatory procedure (TOM)*

Industry can also use the PMS UI to:
- *Export product data – ISO message, xls*
- *Perform their own validation/enrichment*

Data submitted by Industry overwrites previous versions in PMS
Data submitted by Industry is DQ assured by NCAs (also creates a new version)

Enforcement

Not before 2021:
Enforcement:
(Using RIM or PMS capabilities)
Industry can only submit product information using new IDMP compatible format to:
- *comply with Art 57 and/or*
- *support any regulatory procedure (TOM)*

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3. SPOR in the Regulatory context

R & O (& S) in the Regulatory context

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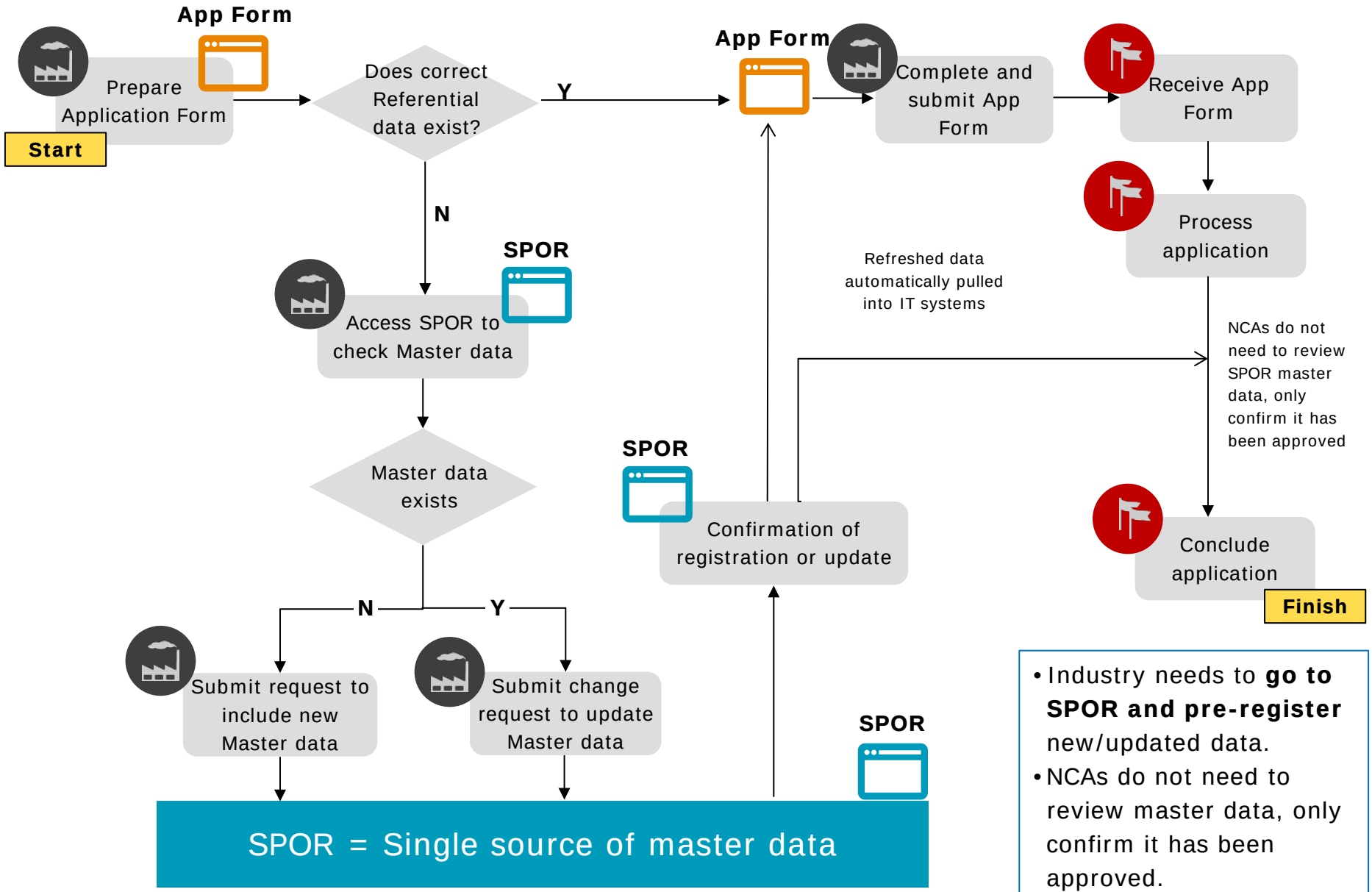
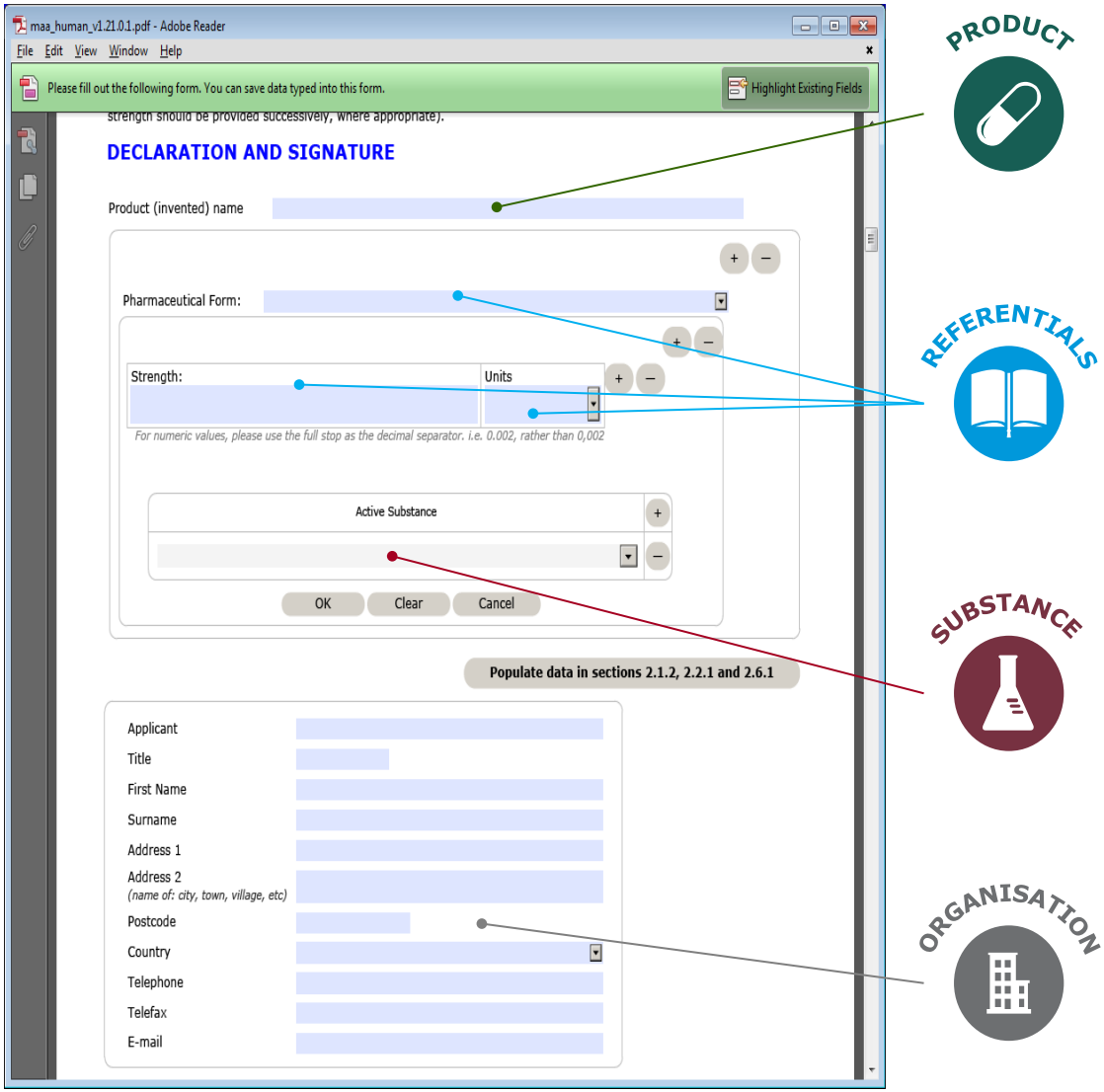


- Industry needs to **go to SPOR and pre-register** new/updated data.
- NCAs do not need to review master data, only confirm it has been approved.

SPOR integration with eAF



SPOR as an enabler for process changes (1/2)

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Handling variations Type 1, where there is administrative change (12% of total variations)

As Is today

Manufacturer name change	Manufacturer informs each MAH (contractual obligation)	MAH update the product information (*) (*) - several products belonging to the same MAH can be impacted	Each MAH informs the relevant NCA (legal obligation - variation)	NCAs
Manufacturer		MAH 1 — Product A in Germany MAH 2 — Product B in Germany MAH 3 — Product C in Germany		

SPOR as an enabler for process changes (2/2)

Handling variations Type 1, where there is administrative change (12% of total variations)

How SPOR can improve the process and how it could work with ROG

Pre-requisite: there is a regulatory change (process, communication)

SPOR

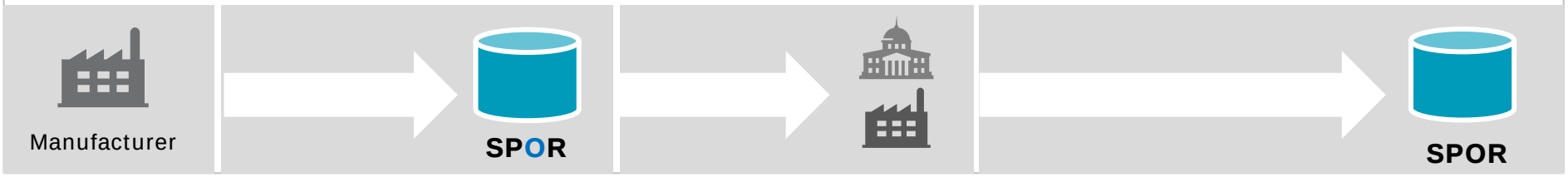
ROG

Manufacturer name change

Data entered by MAH or Manufacturer

NCA & MAH are automatically informed

All products automatically updated or flagged for updating



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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Glossary

Backward compatibility	Capability of a new solution to successfully interface/work with previous versions of software/hardware.
CESSP	The Common European Single Submission Portal (CESSP) is an ongoing Telematics programme that aims to integrate the electronic Application Form (eAF) data sets in to CESP. CESP is the current submission channel for all procedures (not technically integrated with eAF).
Controlled vocabularies	(aka Referentials) are lists of terms that refer to attributes of medicinal and pharmaceutical products e.g. dosage form, route of administration, unit of measurement.
CT Portal	(aka EU Portal and Database) will be the upgraded version of Eudra CT enabling a single entry point for submission and assessment of clinical trial applications at an EU level.
eAF	The eAF is a collection of Application Forms that facilitate electronic submission of data relating to Renewals, Variations, Marketing Authorisation Applications (Human & Vet).
Eudra CT	The existing platform for submitting and viewing information relating to regulatory activities relating to Clinical Trials.
EUTCT	A repository and provider of controlled terms (or controlled vocabularies) in multiple languages. It is the predecessor of RMS. RMS will replace EUTCT with regards to management of controlled vocabularies. EUTCT can only be fully replaced after SMS implementation as it also contains substances.
Unique identifiers	The ISO IDMP standards outline a set of attributes/data elements that make up a **unique identifier** . This enables the creation of a unique record for each medicinal product, packaged product, pharmaceutical product, substance and referential.