PMS TARGET OPERATING MODEL

Improved data quality

Automatized process

PMS

MAH
Submission of structured data supported by regulatory activity

Regulator
Assessment of structured data

EMA
Store approved data in EU-database

Patient
Access real-time approved data

4 May 2020 4PM CEST / 10AM ET

Workshop by Frits Stulp & Remco Munnik

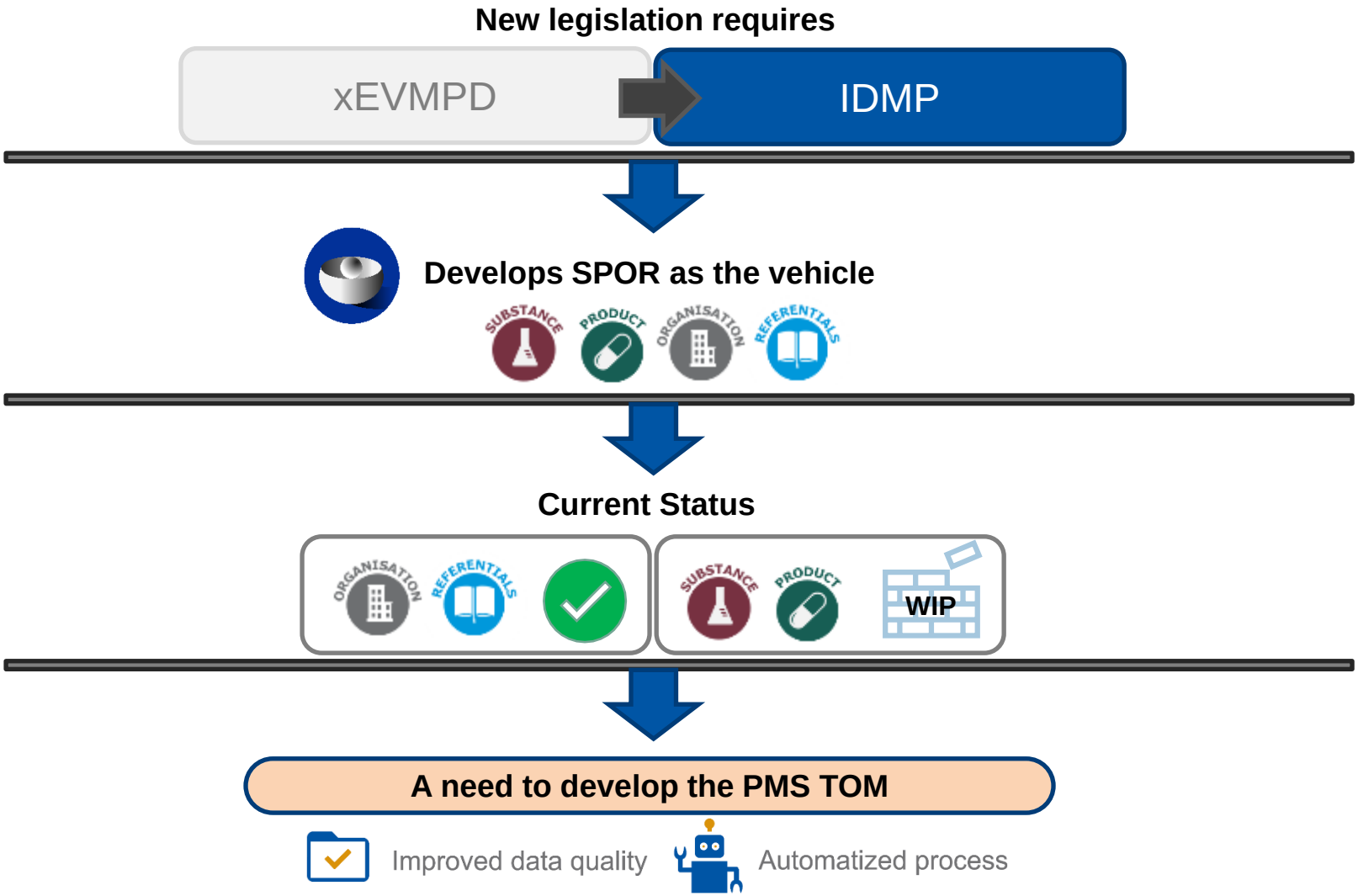
IPERION®

Agenda

- Introduction to TOM
- Impact of TOM
- Current milestones and deliverables
- Prioritization of activities
- Discussion of questionnaire results
- Planned roadmap vs reality
- Use cases
- Questions and Discussion

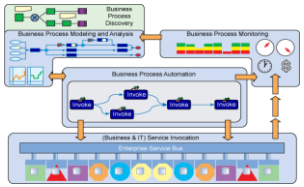
Introduction to TOM

Why are we here?



IhaveaDreaMP

Structured data for either RA, PhV, QA, clinical, manufacturing information



Data is captured and submitted only once

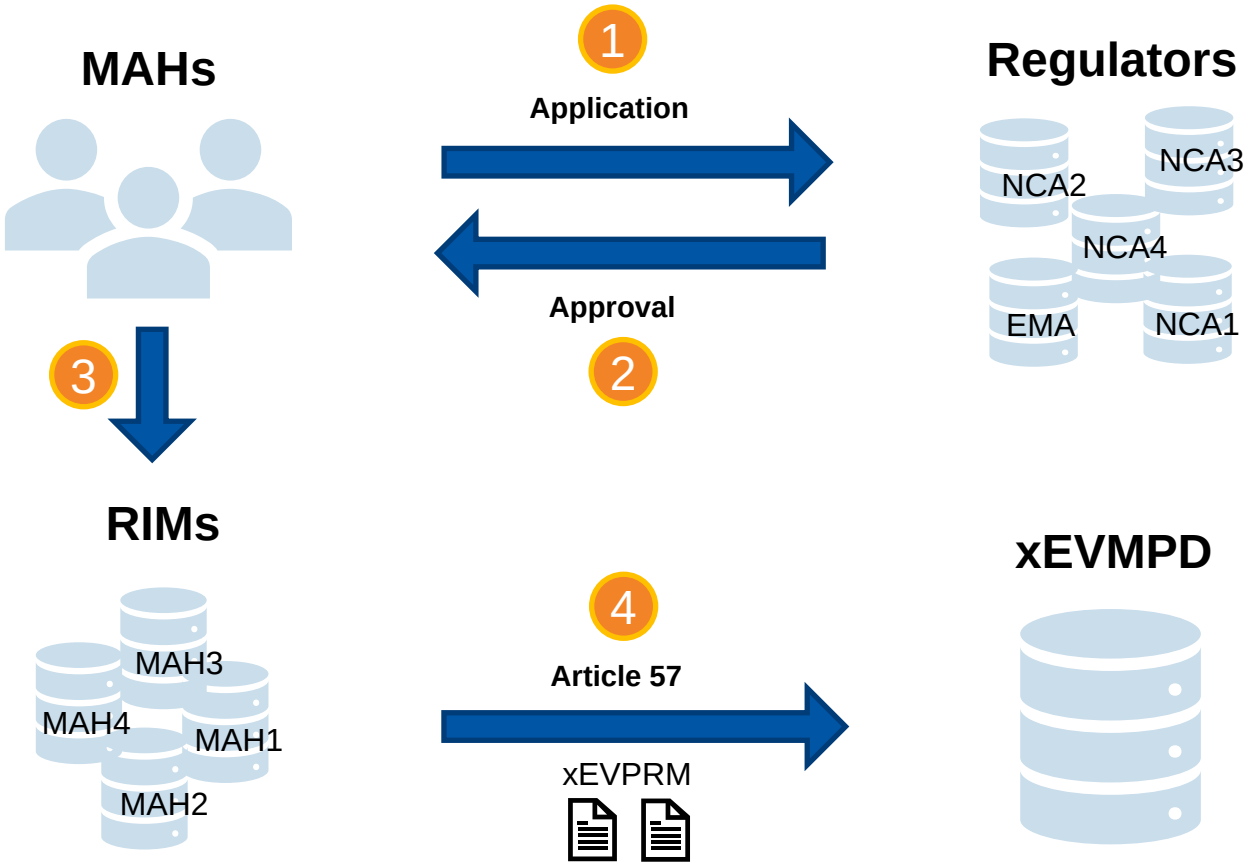
MAA,
variation, renewal,
ICSR,
CTA

How to achieve the dream→ work on Target Operating Model (TOM)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The need for common product data

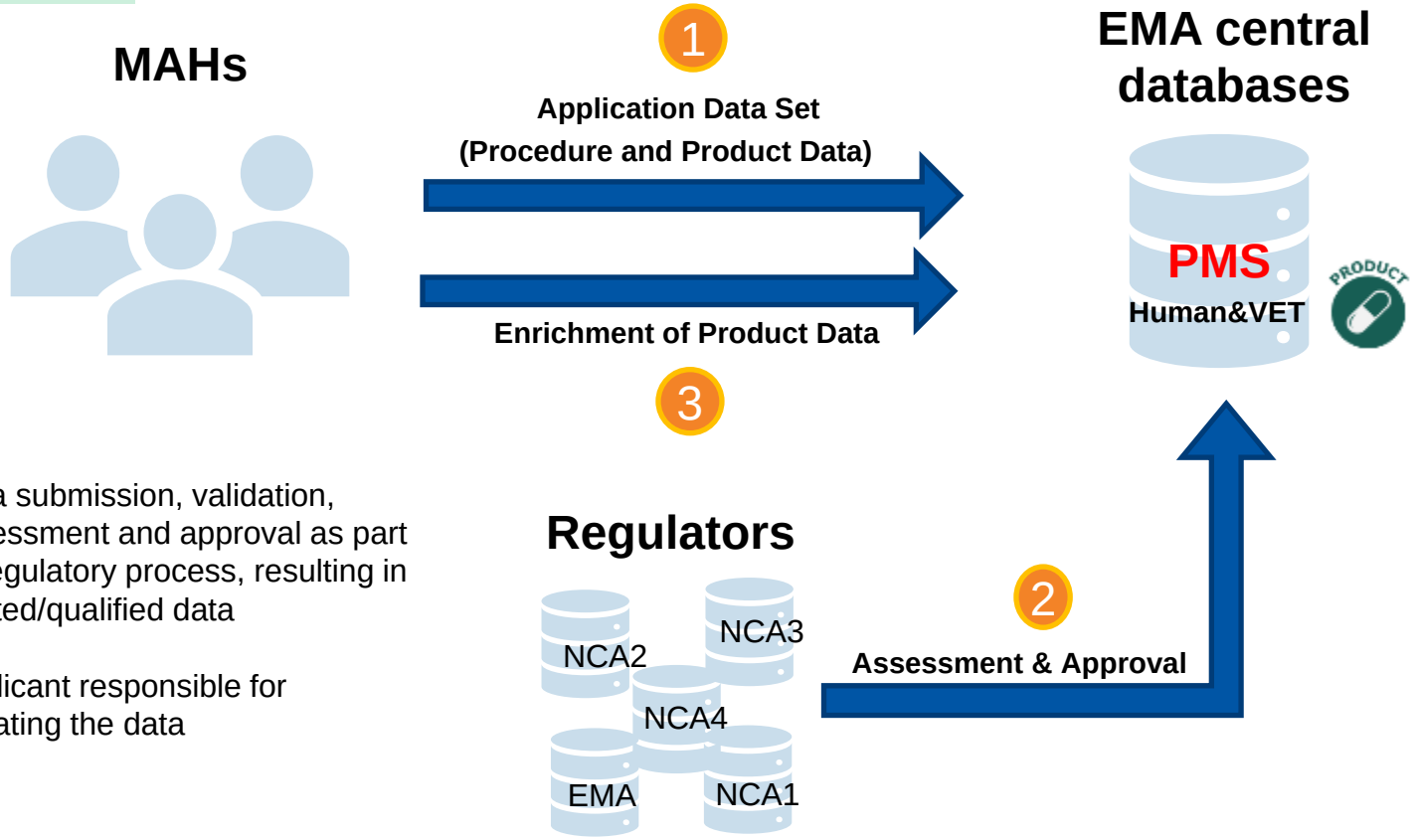
NOW:



No single source of truth & No involvement of the relevant NCA during xEVMPD submission

Future Single EU database

Future:



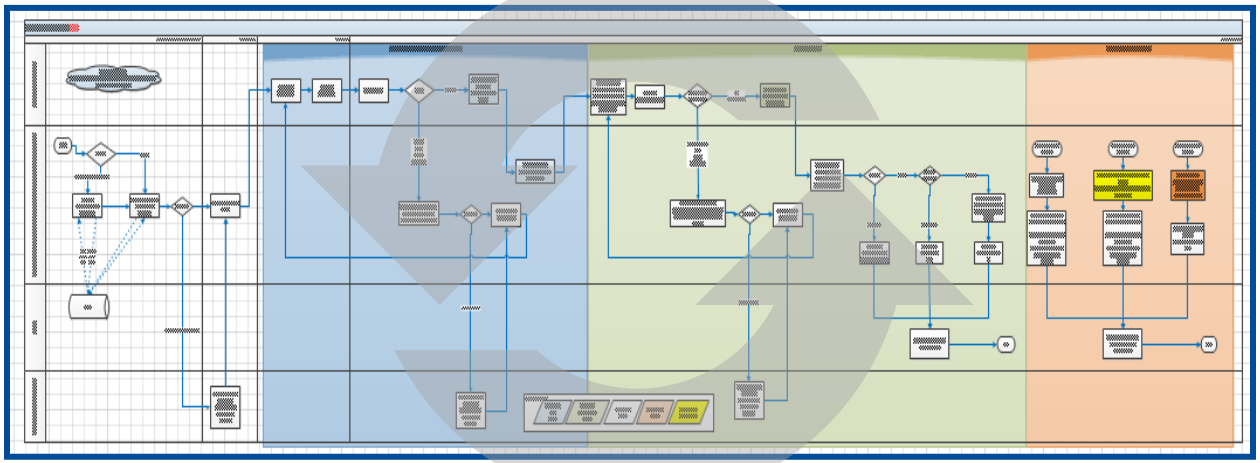
- ✓ Data submission, validation, assessment and approval as part of regulatory process, resulting in trusted/qualified data
- ✓ Applicant responsible for updating the data

One time exchange & Single source of truth

TOM – Targeting Operating Model

TOM is needed to optimise the exchange of application data between regulators and applicants, and within the regulatory network to ensure **data quality**.

Product Data



Qualified Product Data

Defined processes in which data is submitted, validated, assessed and approved

Defined way of working between regulators and industry

Defined message exchange format

Expectations of TOM

Support

- All procedure types (CP, MRP, DCP, NP), discussion to start with CP
- The re-use of data for PMS and NCA/EMA databases
- The re-use of existing technology frameworks for implementation

Enables

- The sharing of workload in the regulatory network and must consider specifics (such as MRP/DCP/Worksharing, etc.)

Can be

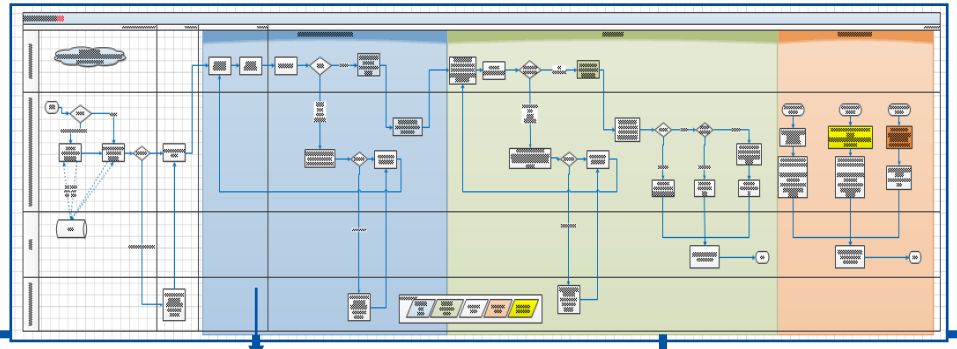
- Introduced in the short term without triggering big changes in the regulatory processes
- Used in both human and veterinary domains

Require

- Minimum requirements for NCAs/EMA and applicants (keep it simple!)
- Commitment to develop and implement the TOM
- The network to start using SPOR data

Impact of TOM

Impact of TOM



P Process

Current process in which data is managed and exchanged will change

O Organization

Increased responsibility and collaboration for product data management

T Technology

The messaging format in which product data is exchanged will change

I Information

The way information is captured and used will change

How does that look like?

Product data submission goes from post-approval to pre-approval

P Process

- New process to facilitate the preparation of procedure and/or product data for submission
- New process to facilitate interactions between regulators and industry

O Organization

- New process owners
- New roles and responsibilities assigned
- Governance in place (i.e. data, processes, systems)

T Technology

- Relevant product data sourced from relevant systems
- The message exchange format embedded

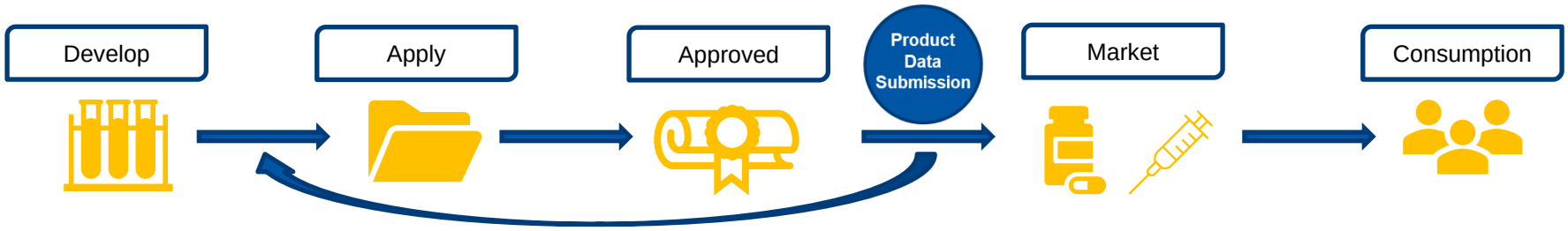
HL7® FHIR®

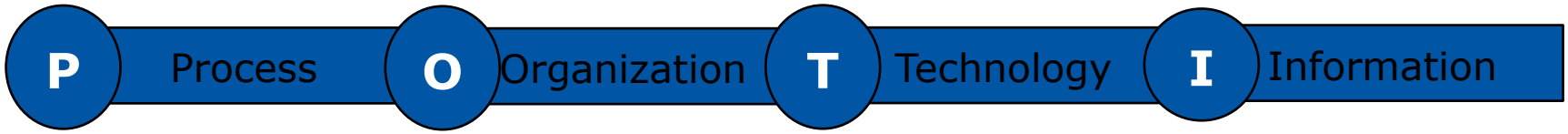
I Information

Procedure and Product data ready for submission

- Organizations, Referentials and Substances data ready in SPOR
- Product data structured in accordance to EU IG

What are the concrete changes?





- Data needs to be collected earlier
- Establish data governance
- Pre-register and align with SPOR
- Systems integration
- Write new SOPs

Employees need to be trained:

- New SOPs
- SPOR usage
- IDMP
- New Tools

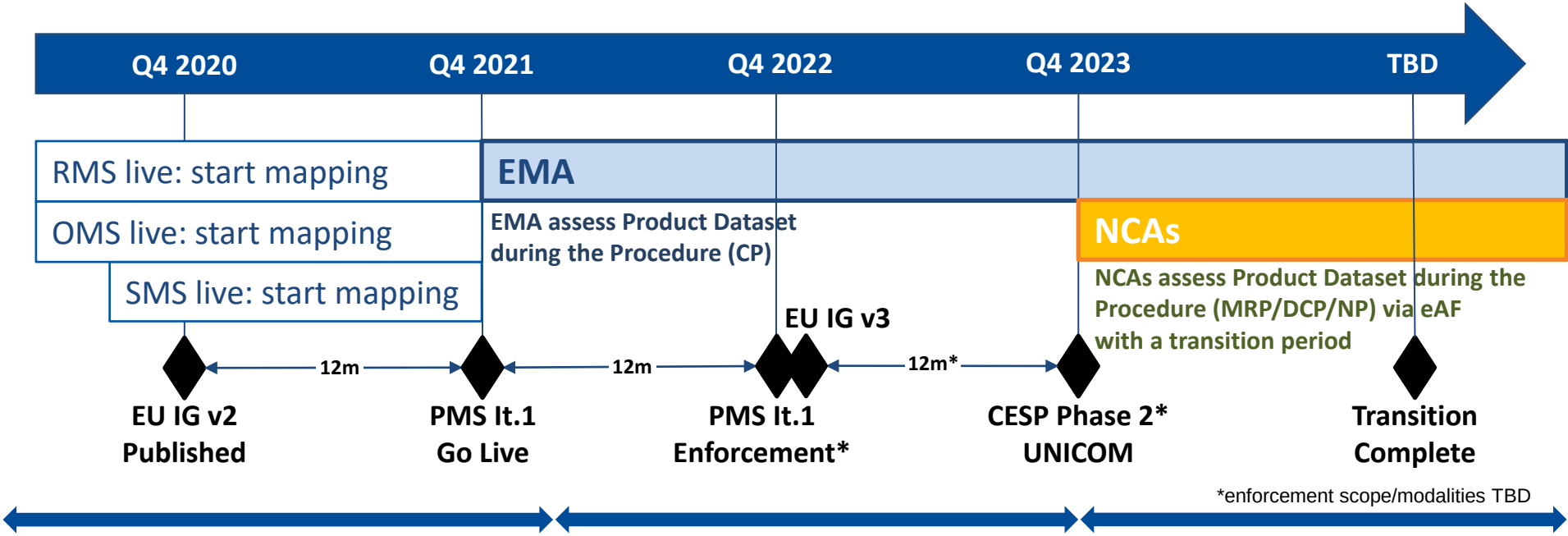
- Integrate new tools for collecting and managing data
- Develop interfaces for system integration
- Implement messaging formats for data exchange

Data needs to be:

- Collected
- Mapped
- Cleansed
- Structured
- Stored

Current Milestones and Deliverables

Planned Milestones and Deliverables



XEVPRM

- Submission of product data post-approval
- Assessment by EMA

STEP 1

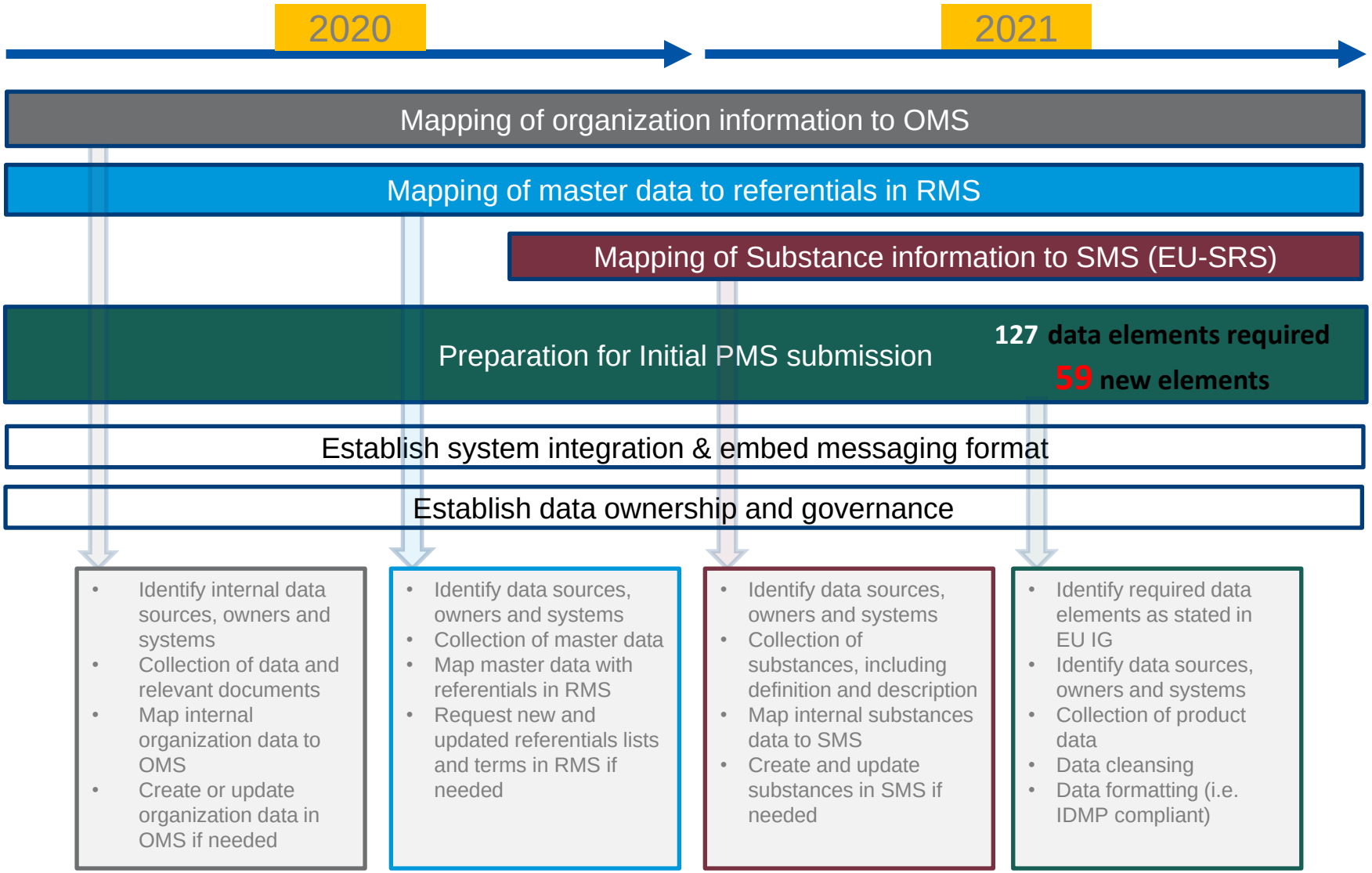
- Submission of product data in procedure for CP
- Submission of product data post approval for non-CP
- Assessment by EMA

STEP 2

- Submission of product data in procedure for all procedures
- Assessment by NCAs

Prioritization of Activities

Industry Activities 2020-2021 to realize the plan

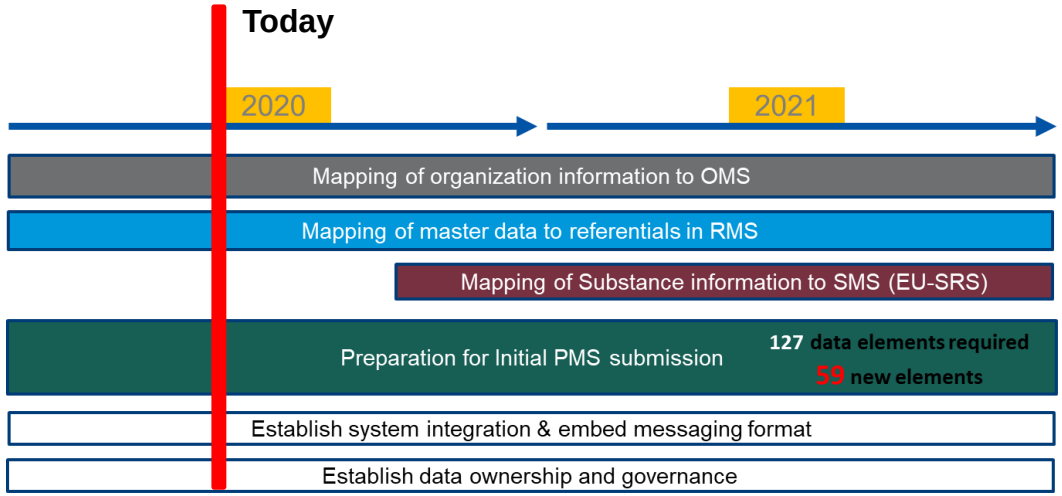


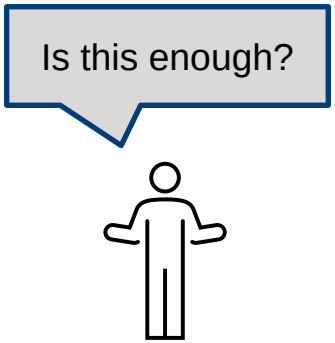
Discussion of Questionnaire Results

Planned Roadmap vs Reality

Proposed Roadmap vs Reality

Proposed:





Use Cases

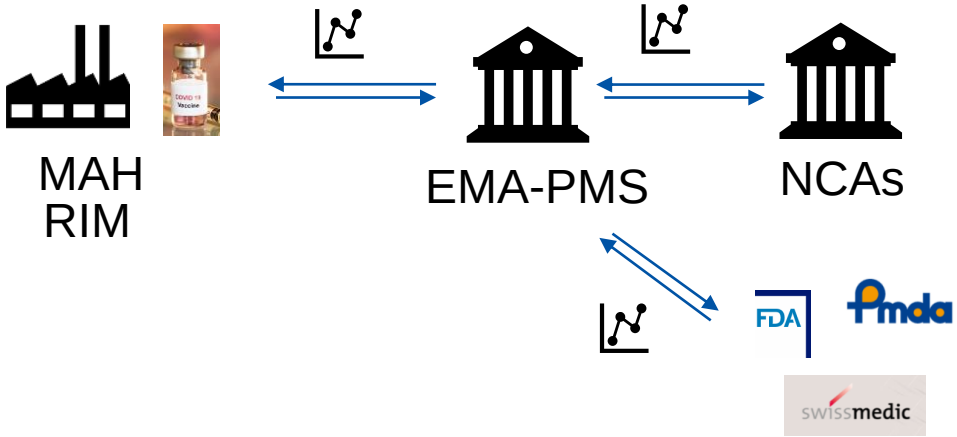
TOM – Covid-19 new drugs

There are currently **no authorised vaccines or treatments** in the EU to prevent or treat COVID-19. However, there are ongoing clinical trials evaluating new potential treatments.

There is need for a faster approval process and international coordination in case of extraordinary events like a pandemic

With **TOM** implementation

- Faster submission and communications thanks to electronic notification (via SPOR)
- Linked system accelerates procedural efficiency
- Telematics allows data exchange internationally



Potential faster approvals!

TOM – Covid-19 existing drugs: Off label use

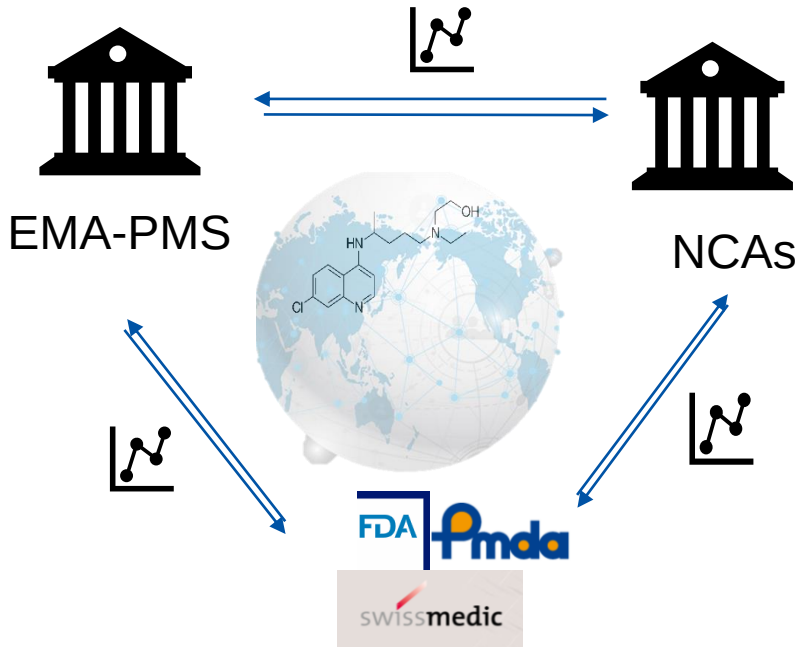
Currently different existing medicinal products are tested as off label use for Covid-19. E.g. Hydroxychloroquine

There is need for structured and quick exchange of information on off label use of drugs already on the market

In the TOM era

PMS-TOM as database and processes to collect and exchange structured data on medicinal products

Information on off label use of existing medicinal products will be retrieved faster in case of extraordinary events like the Covid-19 pandemic



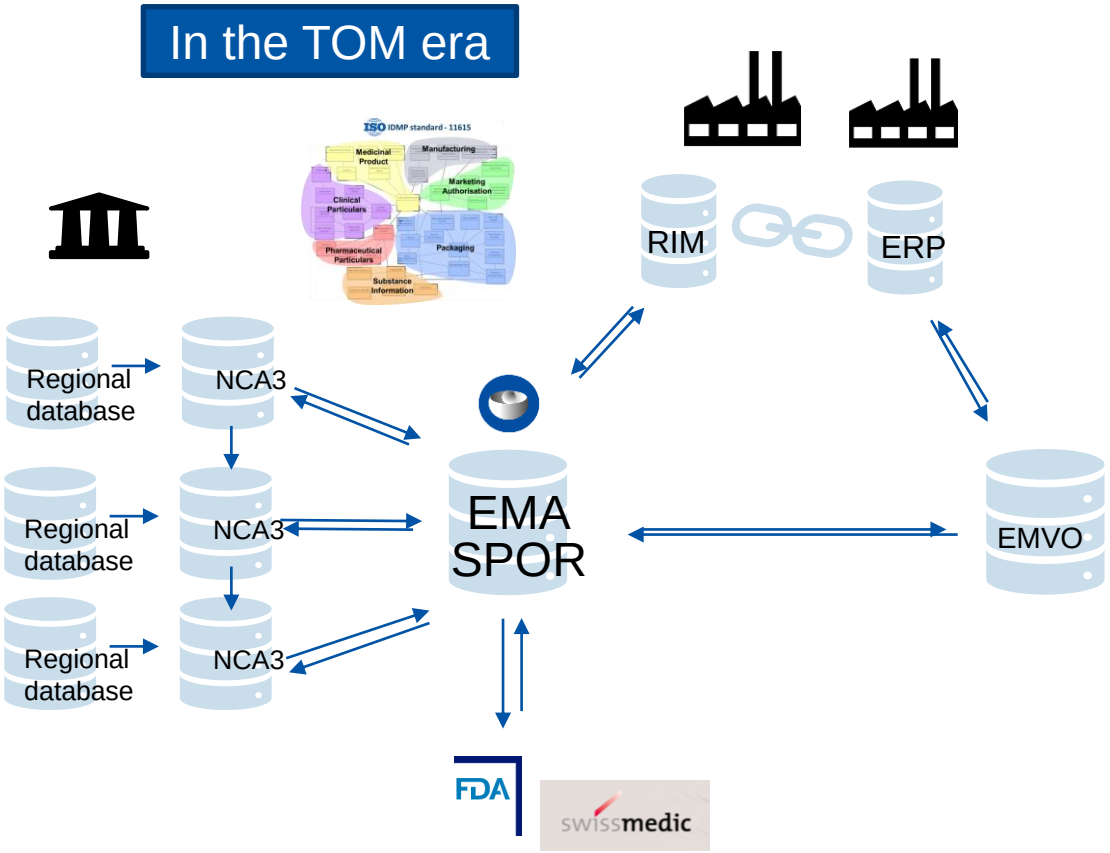
TOM – Covid-19 existing drugs: availability

Currently different countries are experiencing drug shortages due to the Covid-19 pandemic and the effect of lockdowns on manufactures. Moreover, episodes of shortages on OTC drugs have been registered due to higher demands from the public.

There is a need to prevent and act fast on drug shortages

IDMP and TOM implementation will help in connecting silos and the international networks

Fast response in case of drug shortages!



Questions and Discussion

General agreements of the planned milestones