PMS Status Update

SPOR Task Force

22 June 2018

Topics

- PMS & SMS joint workshop summary
- PMS legacy data cleansing
- PMS Target Operating Model (TOM)
- NCA Data Pilot
- Iteration 1 data field review
- Project plan update and status check

PMS & SMS Joint Workshop Summary

- On 19-20 June, the SMS subteam joined with the PMS subteam in a workshop to work together on current key activities
  - Iteration 1
  - PMS Target Operating Model
  - Legacy Data Validation
  - NCA Data Pilot
  - Project plan update and status check
- These key components of the PMS program have progressed well since the last Task Force meeting
- The team provided important input into furthering activities and direction
- The following slides provide current overviews of each component as well as discussion of the workshop activities and next steps for each

Overall Summary

- Progress has been made on these key components of the PMS project since the last Task Force meeting
  - Legacy data validation/cleansing
  - Target Operating Model design
  - NCA data pilot
- The next priority is to define implementation plans for these and align them with the overall PMS implementation plan
  - Identify key design, approval and implementation milestones
  - Ensure the critical path across all components are aligned to support an overarching program timeline

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“PMS TOM” vs “Legacy Data Validation” - what is what?

Jeff Martin

PMS subgroup meeting 2018-06-19 20

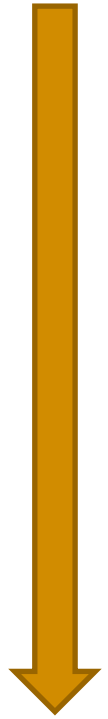
LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

2 Different Processes

- **PMS data cleansing – existing Art 57 data**
- **TOM – 2 flavours**
  - New Products
  - Variations/Changes

How will we use PMS data?

- **Different use cases for PMS data**
  - #1 Pharmacovigilance – mandated by law (Art 57)
  - Regulatory efficiency
  - Cross-border e-Health
    - Both human and veterinary



Increased need for good data quality & data standardisation

PMS Data Cleansing (1)

- **Cleaning existing PMS data**
- **Must be done in a series of data blocks**
  - DB1 – MA number
  - DB2 – essential product information
  - DB3 – active substance/ingredients
  - etc

approvals • authorisation • clinical trials • communication • competence • cosmtics • dialogue • directives • efficacy • environment • evaluation • guidelines • harmonisation • health economics • herbals • homeopathics • information • inspection laboratory analysis • market surveillance • medicinal products • medical devices • narcotics • public health • quality • registration • regulations • reliability • risk/benefit • safety • scientific • standardisation • transparency • vigilance • approvals • authorisation • clinical trials • communication • competence • cosmetics • dialogue • directives • efficacy • environment • evaluation • approvals • authorisation • clinical trials • communication • competence • cosmtics • dialogue • directives • efficacy • environment • evaluation • guidelines • harmonisation • health economics • herbals • homeopathics • information • inspection laboratory analysis • market surveillance • medicinal products • medical devices • narcotics • public health

PMS data cleansing (2)

- **When is the data in ”good shape”?**
- **How do we deal with NCAs that do not participate in the cleansing?**
- **Different Agencies will do the cleansing at different times**
  - How does this affect the use of PMS data?
- **Is there a need for Agencies to be IDMP internally?**

Why are we doing the cleansing?

- **Support for the three use cases**
  - #1 Pharmacovigilance – mandated by law
    - Is todays xEVMPD/Art 57 data quality sufficient for this?
    - When do we know it is sufficient?
  - Regulatory efficiency
    - xEVMPD/Art 57 Data quality insufficient today
  - e-Prescriptions Cross-border e-Health
    - xEVMPD/Art 57 Data quality insufficient today

Legacy Data Cleansing: Workshop Summary

- The team broke into small groups to brainstorm three key topics
  - ‘Data blocks’ for cleansing – use cases and other considerations to drive the fields to be included in each phased block of data for cleansing
  - Identifying challenges that the phased approach will bring in the living database and how to handle these
  - Requirements and recommendations for communication between NCAs and industry during the cleansing process

Legacy Data Cleansing: Key takeaways

- Breaking cleansing into data ‘blocks’ will help bring NCAs on board without being overwhelmed by a volume of work
- Key elements have been identified for Block 1 – these are elements owned by the NCAs (MA#, Authorization Status, Procedure Number)
- Data ownership for remaining elements still needs to be agreed
- Process for NCAs to communicate data cleansing issues/corrections is being defined. Progress has been made but work still to be done to complete this
- Reference document(s) for PMS data remains unresolved – SmPC or Module 3/Part 2?
- Next step is to establish milestones for data cleansing, in alignment with the other components of the SPOR PMS project. This will help define when resources are needed
- The critical component for PMS is that the data points required to support ID generation are reviewed and cleansed before PMS and the TOM go live

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Initial requirements

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Summary

- We need a concept which can be introduced short term without triggering big changes of regulatory processes
- We need a concept which can be implemented in the human AND veterinary domain
- The concept should support all procedure types (CP, MRP, DCP, NP)
- The concept should allow to share workload in the regulatory network and must consider specifics (like MRP/DCP/Worksharing, etc.)
- The concept should work with a minimum of pre-requisites for NCAs/EMA and applicants (keep it simple!
- The concept should be support the re-use of data for PMS and NCA/EMA databases
- Existing technology frameworks should be re-used for implementation

**** Find key principles in the annex***

TOM – Target Operating Model

Definition

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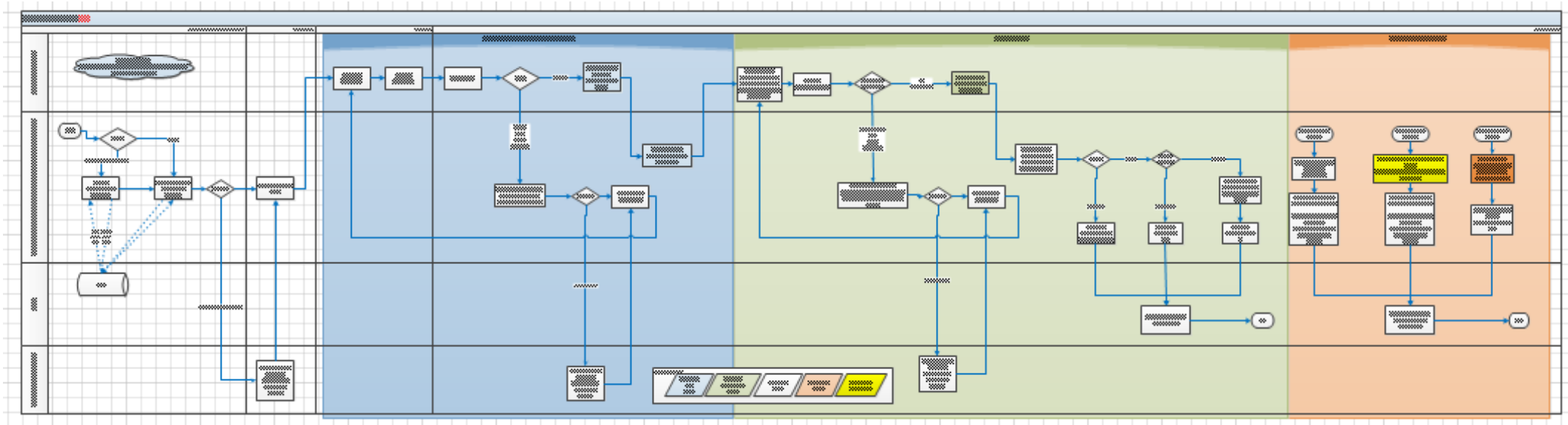
- TOM is a business process model to optimise the exchange of application data between regulators and applicants and within the regulatory network



Draft June 2018 (tbc)

TOM – Target Operating Model

Out of scope

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TOM isn’t a validation/cleansing/standardisation process for legacy data

Working on TOM includes

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- **Definition of a business process**
  - This process should be lean and simple **without adding additional burden** to applicants and regulators
- **Grouping of application data**
  - define responsibilities for creating and updating specific data elements
- **Utilising OMS; RMS; SMS; PMS**
- **Collaboration**
  - with regulatory bodies and stakeholders to agree on guidance and implementation plans

TOM - Data Groups

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1. **EU phase data group *(data which is the same for all concerned regulators)***
   a) Created by applicant, approved by RMS (e.g. active substance, dosage form, strength)

2. **National phase data group *(data which is different in member states)***
   a) national particulars, added by applicant, approved by RMS/CMS (e.g. name, legal basis for the supply)

3. **NCA data group *(contains approval information)***
   a) added by EMA/RMS/CMS (e.g. Date of approval, MA number)

4. **MAH data group (*contain post marketing data)***
   a) added by MAH after approval, no regulator validation (e.g. sales start, risk of shortage – Art 57 extra data)

5. **Additional data group (contains additional information)**
   a) added e.g. by EMA (e.g. EURD list)

TOM - Concept of data groups

e.g. MRP/DCP n-NCAs concerned

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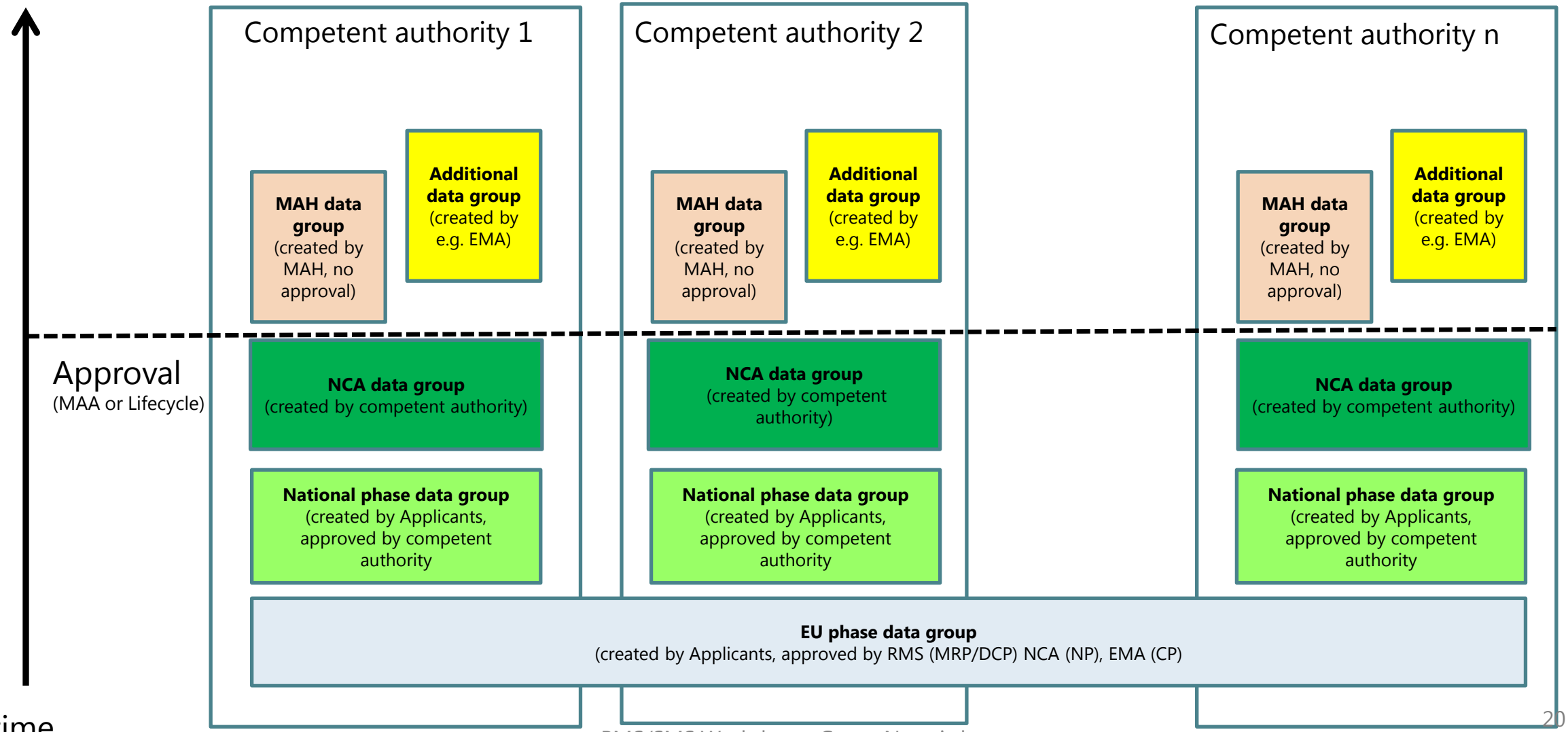

TOM – data cycle

Draft for NEW products – details in progress

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Create or update, submit a dataset

- Utilizes OMS, SMS, RMS and PMS
- could be supported by an extended CESP Dataset Management Module

Agree on *EU phase data group*

- Process as today
- **If needed an updated dataset has to be submitted**
- Approval of data group by the RMS (tbc)
- Lock data group

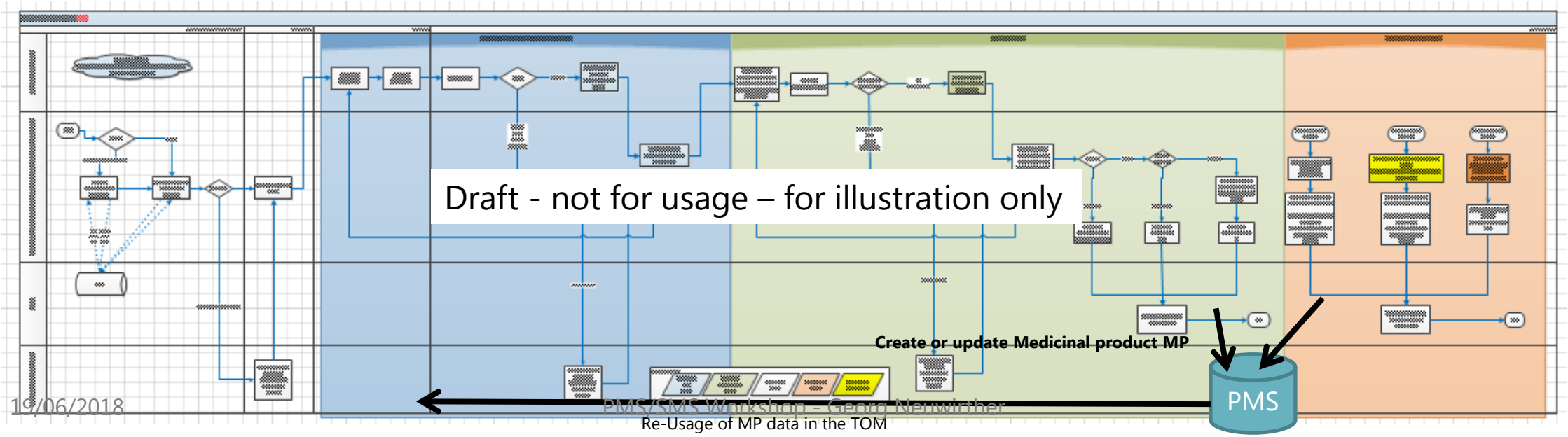
Agree on *National phase data group*

- Pattern like before
- Approval by the relevant NCAs
- Lock data group

Create *NCA data Group*

Create *MAH data group*

Create *additional data group(s)*



The five elements of TOM

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Summary

- Ensure **data consistency** in a regulatory activity
  - Applicants and regulators work on the same application data basis during the process
- Ensure that data is **up-to-date**
  - Agree a process flow that ensures that all parties in the network receive updates on application data
- Support **sharing of workload** in the network
  - Define data blocks and responsibilities to support a collaborative working model
- Ensure **data integrity**
  - Once data elements are approved regulators can rely that subsequent activities are based on these approvals
- Ensure **readability and automatisation**
  - People and IT can read and consume the data,
  - establish messaging of data which can be used for regulatory tasks as well as for populating databases

Next steps

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1. Continue working on the process
2. Liaise with CMDh, CMDv, NtA, and others to clarify open topics
3. Liaise with the telematics governance structure
4. Document high level requirements
5. Draft technical solution scenarios
6. Go for approvals (HMA / EMA, ..)
7. Setup implementation

- **Challenges:**
  - Ensure funding and resources for further steps!
  - “Digitalise” regulatory guidance (softly but effectively)!

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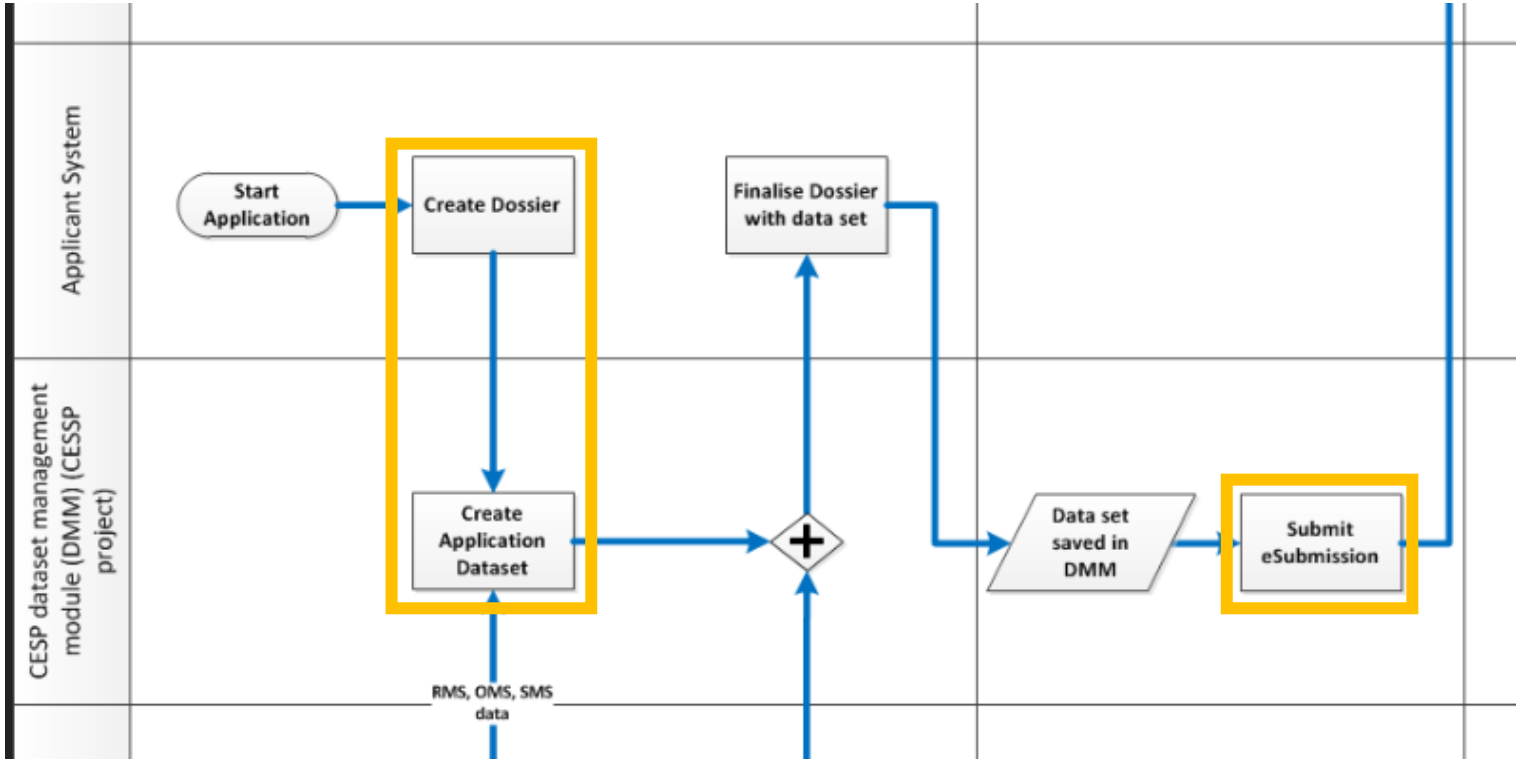
“Meat doesn’t originate from the supermarket” Additional considerations for TOM architecture



- Internal processes within industry complicate this picture
- Understanding the industry subprocesses is important for defining the technology requirements for implementation

Industry Recommendations for next steps

- Further elaborate the industry process to support definition of solution requirements (industry)
- Define ownership for technology requirements for each portion of the high-level TOM process:
  - Industry for the portions up to submission & for variation/inquiry response submissions
  - NCAs for portion related to readability of submitted data and review/approval process
  - EMA for the portion related to data storage and usability in SPOR applications
- Review of requirements across combined team to make sure no handoffs or complications are missed (make sure the train tracks meet up)

Target Operating Model – Workshop Summary

- Workshop presentation included a review and discussion of the current version of the TOM swimlane process diagram
- The team broke into small groups to begin looking at solution requirements for
  - Initial preparation of the application
  - Tracking, locking data, worksharing across NCAs
  - Issue resolution how would errors found in the submitted dataset be resolved at the different points in the process?
- These initial requirements will be further elaborated as part of the TOM workstream

Target Operating Model – Key takeaways

- The TOM and the overall architecture concepts have continued to mature through the work of the NCA team
- The consultation with the team in the workshop was positive and there is overall agreement with what has been designed, enabling work to move forward
- This design is seen to meet the objectives as stated and will result in high quality of PMS data with minimal impact on NCA resources
- Incorporating industry process steps in the requirements analysis has had positive results
- Next step is to establish plan and milestones for approval of this model through the relevant governing bodies (CMDh, HMA) in alignment with the other components of the SPOR PMS project
  - Goal is approval by year end as this is a critical component for the EU Implementation Guide authoring which begins at the end of 2018

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Deliverables

- Products in an Excel sheet
- A short report describing issues and resolutions
- A list of issues that could not be resolved
- Presentations to PMS sub-group, EUNDB, SPOR taskforce. Maybe ISO?
- Publically available information

Participants - NCAs

- **Led by NoMA (Martha Schei Hynne) and SE MPA (Jeff Martin)**
- **FR – ANMV (vet), EE, AT, ES, DE – BfArM, DE – PEI, NL, EMA**
- **Consultations with industry**

What have we done so far?

- **Excel template is ready**
- **Instructions for use are ready**
- **EMA are hosting a Confluence document sharing site – just starting up**
- **AT, NO, SE, ES, DE-PEI, EE, FR – ANMV (vet) have delivered a few products each, others are working on them**

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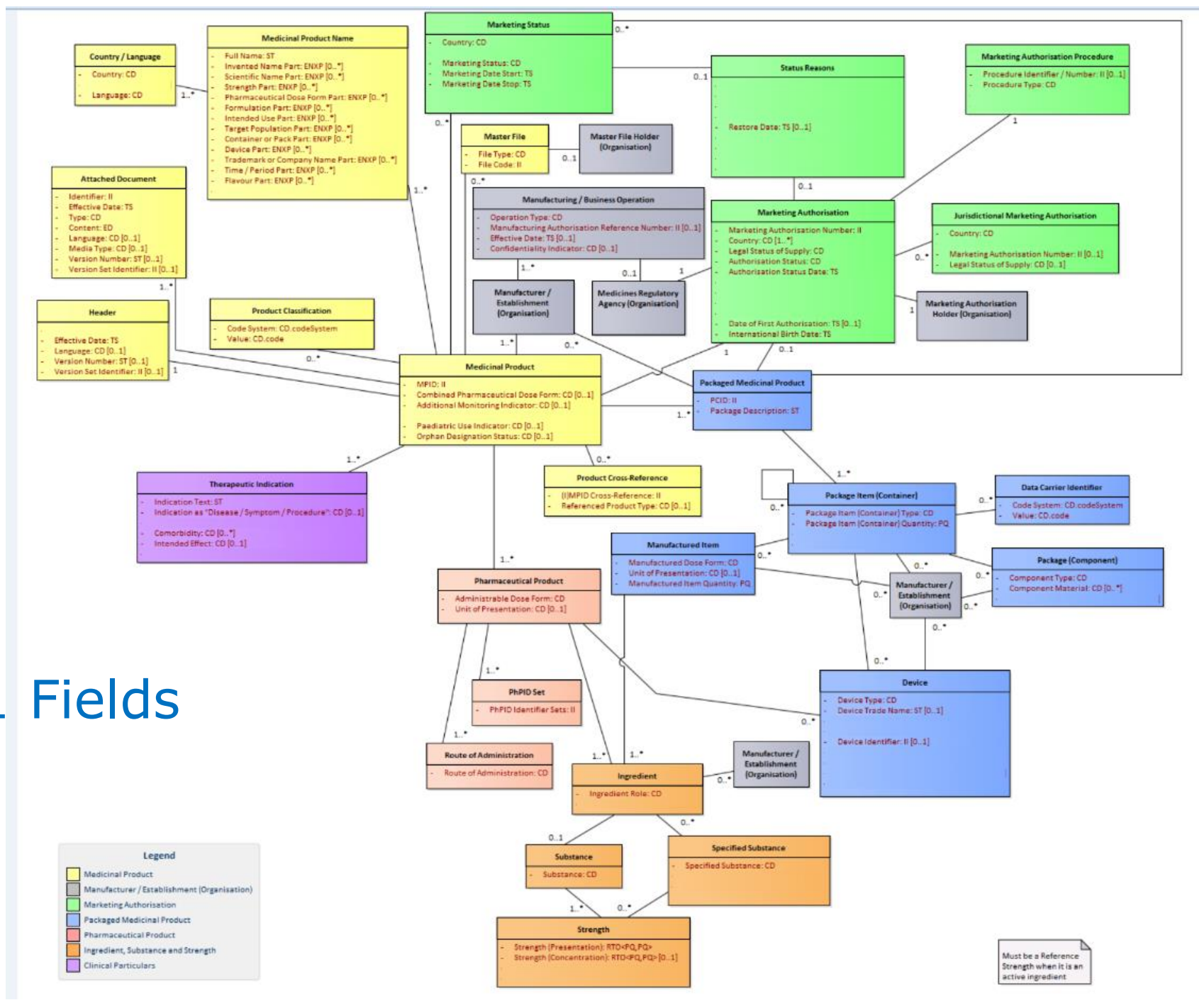
Iteration 1 fields recap

- EMA gave a brief business overview of the current Iteration 1 fields in the context of the IDMP data model
- The presentation provided an analysis of critical data for legacy validation as input into the breakout team work

It 1 Fields


Country / Language
Country: CD
Language: CD
Medicinal Product Name
Full Name: ST
Invented Name Part: ENXP [0..*]
Scientific Name Part: ENXP [0..*]
Strength Part: ENXP [0..*]
Pharmaceutical Dose Form Part: ENXP [0..*]
Formulation Part: ENXP [0..*]
Intended Use Part: ENXP [0..*]
Target Population Part: ENXP [0..*]
Container or Pack Part: ENXP [0..*]
Device Part: ENXP [0..*]
Trademark or Company Name Part: ENXP [0..*]
Time / Period Part: ENXP [0..*]
Flavour Part: ENXP [0..*]
Marketing Status
Country: CD
Marketing Status: CD
Marketing Date Start: TS
Marketing Date Stop: TS
Status Reasons
Restore Date: TS [0..1]
Marketing Authorisation Procedure
Procedure Identifier / Number: II [0..1]
Procedure Type: CD
Master File
File Type: CD
File Code: II
Master File Holder (Organisation)
Attached Document
Identifier: II
Effective Date: TS
Type: CD
Content: ED
Language: CD [0..1]
Media Type: CD [0..1]
Version Number: ST [0..1]
Version Set Identifier: II [0..1]
Manufacturing / Business Operation
Operation Type: CD
Manufacturing Authorisation Reference Number: II [0..1]
Effective Date: TS [0..1]
Confidentiality Indicator: CD [0..1]
Marketing Authorisation
Marketing Authorisation Number: II
Country: CD [1..*]
Legal Status of Supply: CD
Authorisation Status: CD
Authorisation Status Date: TS
Date of First Authorisation: TS [0..1]
International Birth Date: TS
Jurisdictional Marketing Authorisation
Country: CD
Marketing Authorisation Number: II [0..1]
Legal Status of Supply: CD [0..1]
Header
Effective Date: TS
Language: CD [0..1]
Version Number: ST [0..1]
Version Set Identifier: II [0..1]
Product Classification
Code System: CD.codeSystem
Value: CD.code
Manufacturer / Establishment (Organisation)
Medicines Regulatory Agency (Organisation)
Marketing Authorisation Holder (Organisation)
Medicinal Product
MPID: II
Combined Pharmaceutical Dose Form: CD [0..1]
Additional Monitoring Indicator: CD [0..1]
Paediatric Use Indicator: CD [0..1]
Orphan Designation Status: CD [0..1]
Packaged Medicinal Product
PCID: II
Package Description: ST
Therapeutic Indication
Indication Text: ST
Indication as "Disease / Symptom / Procedure": CD [0..1]
Comorbidity: CD [0..*]
Intended Effect: CD [0..1]
Product Cross-Reference
(I)MPID Cross-Reference: II
Referenced Product Type: CD [0..1]
Package Item (Container)
Package Item (Container) Type: CD
Package Item (Container) Quantity: PQ
Data Carrier Identifier
Code System: CD.codeSystem
Value: CD.code
Manufactured Item
Manufactured Dose Form: CD
Unit of Presentation: CD [0..1]
Manufactured Item Quantity: PQ
Package (Component)
Component Type: CD
Component Material: CD [0..*]
Pharmaceutical Product
Administrable Dose Form: CD
Unit of Presentation: CD [0..1]
Manufacturer / Establishment (Organisation)
PhPID Set
PhPID Identifier Sets: II
Device
Device Type: CD
Device Trade Name: ST [0..1]
Device Identifier: II [0..1]
Route of Administration
Route of Administration: CD
Ingredient
Ingredient Role: CD
Manufacturer / Establishment (Organisation)
Substance
Substance: CD
Specified Substance
Specified Substance: CD
Strength
Strength (Presentation): RTO<PQ,PQ>
Strength (Concentration): RTO<PQ,PQ> [0..1]
Must be a Reference Strength when it is an active ingredient
Legend
Medicinal Product
Manufacturer / Establishment (Organisation)
Marketing Authorisation
Packaged Medicinal Product
Pharmaceutical Product
Ingredient, Substance and Strength
Clinical Particulars

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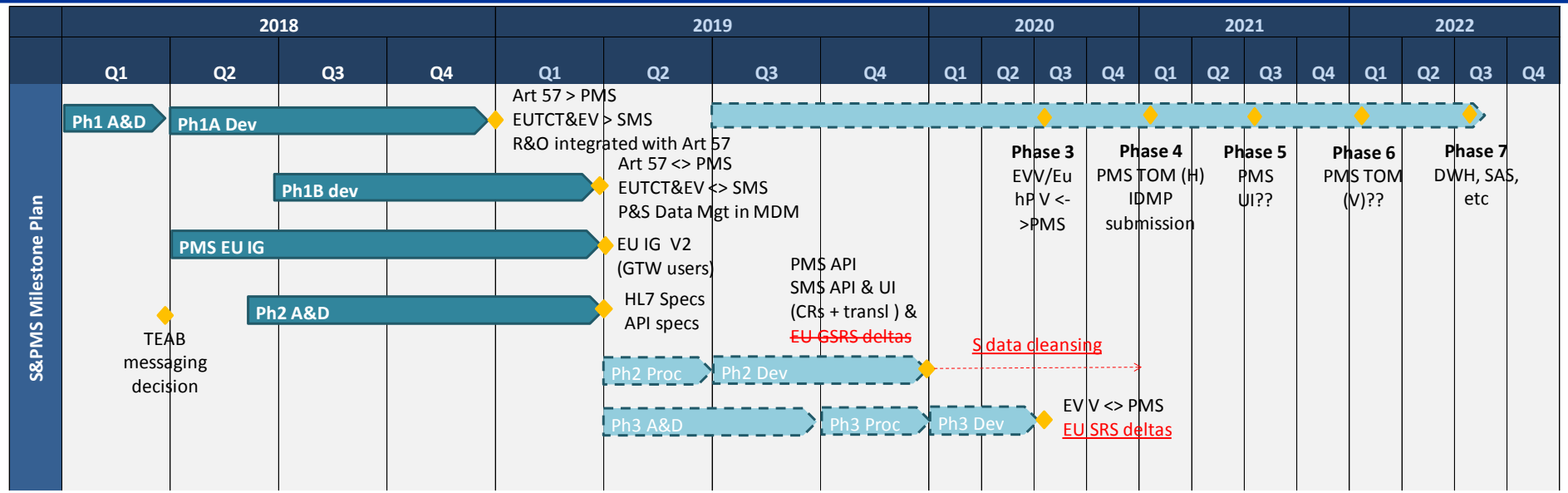
P&SMS Plan



PMS EU IG

- Mapping Art57-PMS work started and ongoing, completion planed for >Q3
- EU IG fields/business rules (word doc) planned for consultation starting in Q4

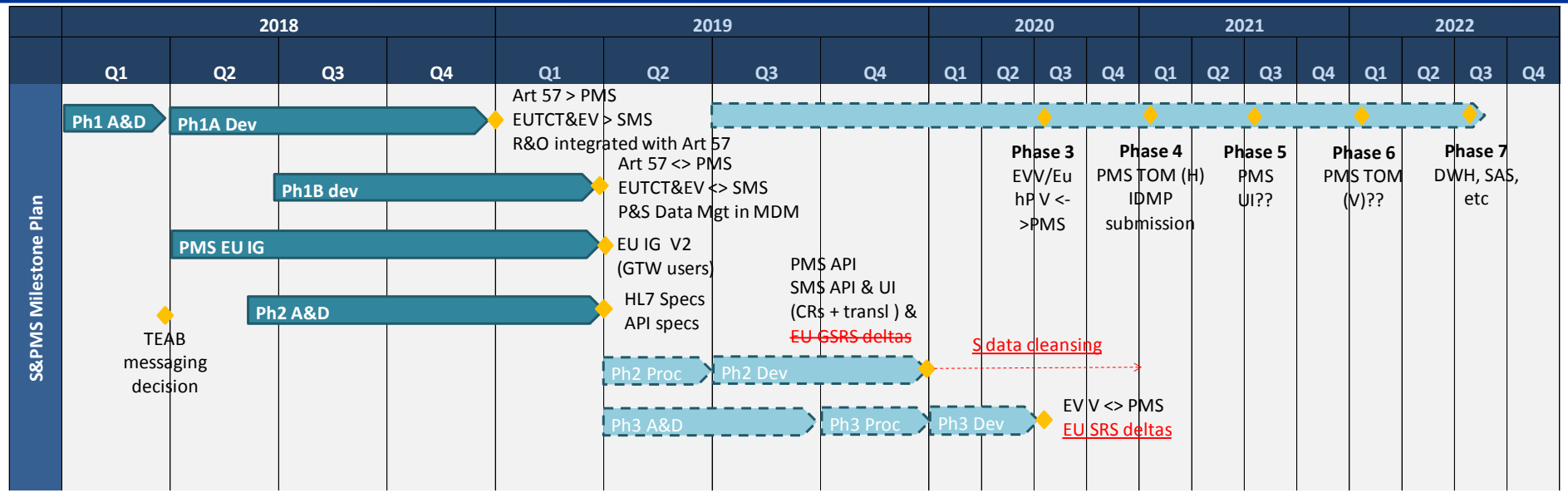
Phase 1

- Ph1 A&D (ETLs and Data mgt functionality) complete
- Ph1A (migration) design work started
- Ph1B procurement underway and work (Data mgt functionality and feedback to EV) planed to start in Q3
- So far progress as per plan but increased risk profile due to EMA BCP/relocation

Phase 2

- Ph2 A&D (API specification) started, planned to complete end Q3 and feed into EU IG, consultation planned for Q1 2019
- Ph2 Procurement planned for EMA relocation period

P&SMS Plan



Iteration 1

- No visibility of EMA relocation impact in the long term (after Ph1) plan yet.
- SMS changes: Agreement with EU SRS that full sync not possible by Ph2 and therefore to be moved to a new Ph3. In the meantime manual periodic sync
- PMS phases are placeholders that represent an agreed strategy and an indicative scope/effort. There is some flexibility to adjust scope providing effort is equivalent
- PMS plan comprises activities currently under EMA/SPOR team control. Activities such as NCA validation, TOM implementation and EU SRS implementation need to be detailed and considered alongside those of PMS.