ISO IDMP TF:
Reports from subgroups

EU ISO IDMP Task Force meeting
12 June 2015

Context

- Strategy proposal to address the ISO IDMP implementation challenges faced by regulators, the pharmaceutical industry and software vendors in the EU
- Proposal for the EU Operating Model to support ISO IDMP implementation

Compliance with the 2016 deadline

	Option 1	Option 2
Description	**Implement an EU-wide IDMP compatible SPOR data management system by 1 July 2016**	**Implement EU-wide IDMP compatible SPOR data management on a phased approach over a longer period of time**
PROS	• Compliance with PhV legislation - ISO IDMP implementation deadline 1.07.2016	• Phased and incremental approach provides more manageable workloads and reduces risk by delivering in smaller, well defined projects also allowing more agility in our delivery approach/reaction to changing circumstances • Timelines extended and budgets spread over longer periods & less pressure for urgent recruitment of expertise • Easier to manage change of systems and processes • Opportunity to improve on previous iteration experience • Agreed prioritisation of iteration scopes to meet NCA/EMA use cases • Managed change in-line with agreed use case requirements • Managed broadening of scope beyond Article 57
CONS	• Very high costs compressed into 2015 & early 2016 (Unaffordable) • Unreliable data migration/consolidation in EU repository • Data quality issues not resolved due to lack of time for data clean up • No time to request budgets within NCAs • Unavailability of competent resources • Too many uncertainties on the future operating model • Poor agreement between NCA / EMA / Vendors / Industry • Unclear implementation timelines for pharmaceutical regulatory systems software vendors	• ISO IDMP implementation after 1.07.2016 • Perceived lack of co-operation to legal mandate • Possible Impact on PhV implementation

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Referentials subgroup

Business cases

Data	Business cases
Consistent globally maintained terminologies	• Allows language independent, standardised data transfer i.e. facilitates interoperability • Enables exchange of Product, Substance and other relevant data ⇩ • Supports other use cases such as pharmacovigilance, inspections, prescription, etc • Allows automated analytics across larger data sets

•S&P subgroup is defining the use cases of the different product elements and implicitly for their CVs.
•S&P subgroup will define the scope of each iteration.

•R will focus on the CVs needed for each iteration and discuss the content of those prioritised CVs

- Whereas the main focus is to support ISO IDMP (11615 & 11238) **the same referentials** may also support **other use cases**.
- Referentials should be developed in **consensus with all interested parties** and eventually subsets or specific extensions may be required.

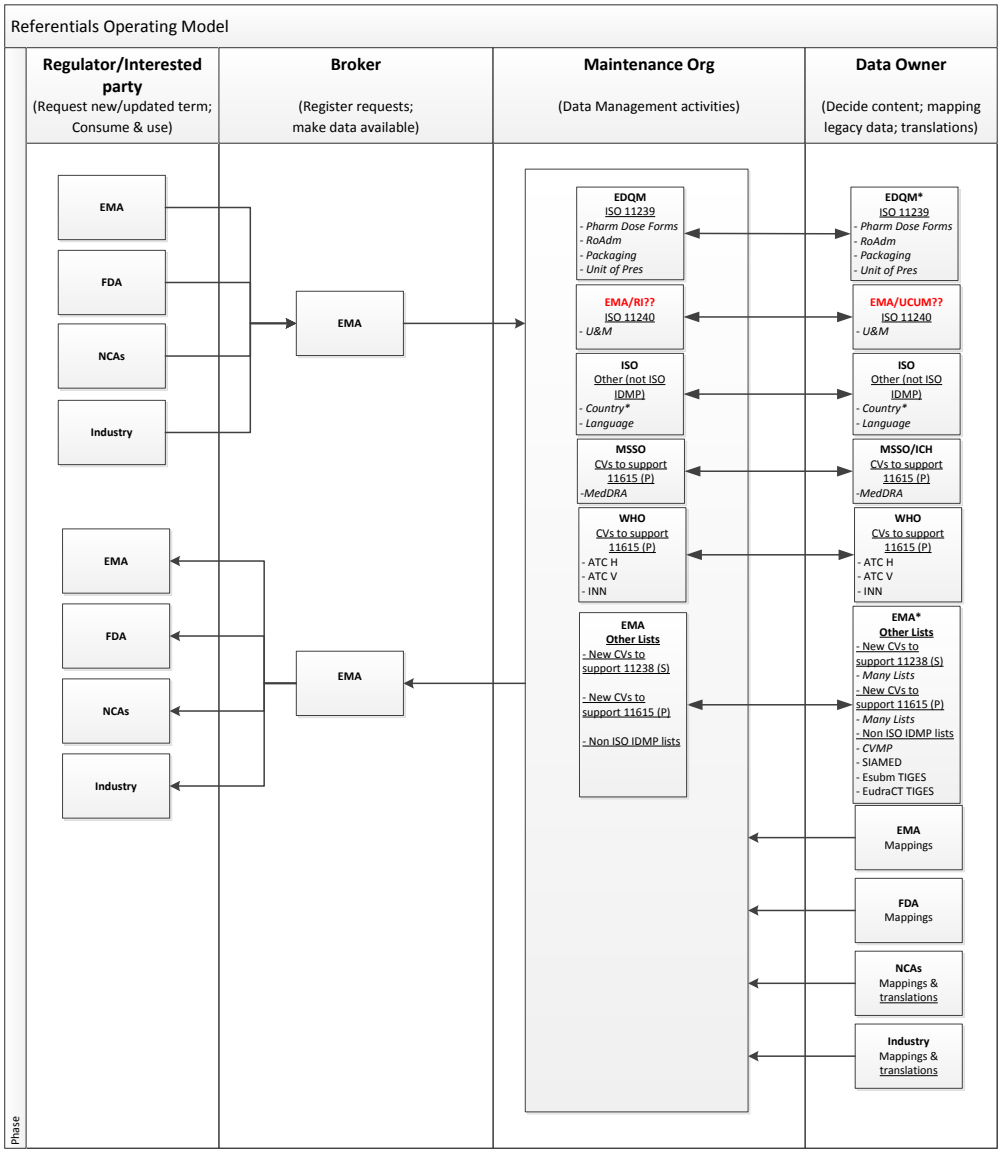
Problem Statement

Problem	Goals
• There is no **single source** of referentials and there are **multiple referentials** for similar purposes	• Implement a **single referential master** i.e. a common source to consume and request terms regardless of the different data owners
• Global federated service model needs **global scientific/regulatory knowledge** of existing and relevant terms and definitions to avoid inconsistencies	• Federated operating model with **multiple data owners specializing on different domains/expertise**
• There is **no clear process** to manage so many referentials across disparate maintenance organisations	• Each referential to have clear uses associated to it to ensure the right MO/DO, and when necessary to ensure the selection of the appropriate controlled terminology when multiple exist today
• IDMP is intended to be free to access but **licensing** of some referentials may be required	• Where no referentials exist define **global referentials for IDMP**
• Across SPOR: **cost of implementation**	• Across SPOR: Submitted once, used many times; streamline the regulatory process for all interested parties; **common operating model; common EU data model**

Operating Model - Options

	Option 1	Option 2	Option 3
Description	• Terms consumed directly from the different data owners. • Terms submitted to NCAs who registers in their systems. • Industry & NCAs may or may not subsequently register terms with EMA/data owner	• Terms consumed directly from EMA • Terms requested to EMA who registers/requests them to different data owners.	• Terms consumed directly from the different data owners. • Terms requested to EMA and data owners in advance.
PROS/ Benefits	• No need to change systems/processes (as-is) • Enhanced control by NCAs • No pre-registration needs • Consumption and mapping in place	• One common place to consume/request terms • Enhanced interoperability	• Increased data quality – all terms pre-approved • easier to handle external requests. • Enhanced control by NCAs,
CONS/ Restrictions	• Higher maintenance of several IT/healthcare systems • Need for maintaining mapping • extra complexity re eAF • limited interoperability • Resource demanding for NCAs	• May need initial mapping/adjustment to consume EUTCT/RMS; • Systems not using EUTCT/RMS referentials have to be maintained additionally • Resource demanding for EMA	• Higher maintenance of several IT/healthcare systems • Need for maintaining mapping • Complex to correct mistakes during a procedure due to multiple suppliers involved • Higher risk of errors, cost and delays • Resource demanding for Industry & NCAs

Operating model – Preferred Option

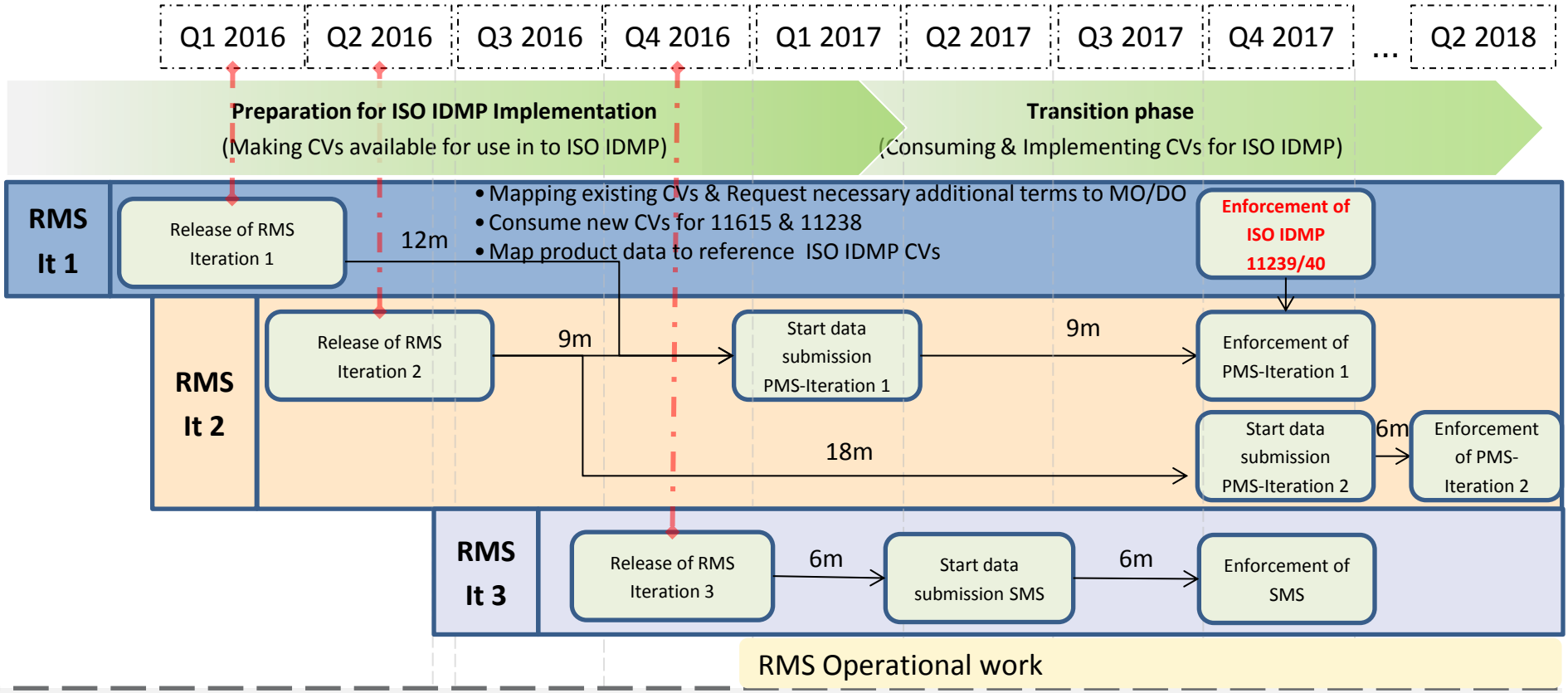


- **Global Operating model is critical!**
- EU (possibly Global) broker of requests and data
  - EMA
- Multiple Maintenance Organisations depending on the different lists
  - 11239 (Dose forms & Routes of administration): EDQM
  - 11240 (Units of Mesurements): Open issue to escalate
  - Existing CVs: ISO; WHO; MSSO; IHTSDO; etc
  - New CVs: EMA
- Multiple Data Owners depending on the different lists & data
  - 11239: EDQM or EDQM Consortium
  - 11240: Open issue to escalate
  - Existing CVs: ISO; WHO; MSSO; IHTSDO; etc
  - New CVs: EMA Consortium
  - Legacy & specific terms: All (EMA, NCAs, Industry)
    - Legacy terms - mapped only once
    - Specific extensions – in theory mapped only once and to be replaced gradually over time by approved terms, possible that there may be a transitional period
    - Local vs central mapping – Ongoing discussion
  - Translations: centralised if possible, possibly done by NCAs & Industry
- Global Data Governance
  - Setting up new CVs with Subject Matter Experts working groups
  - Overseeing operational global framework for maintenance
  - Strategic aspects

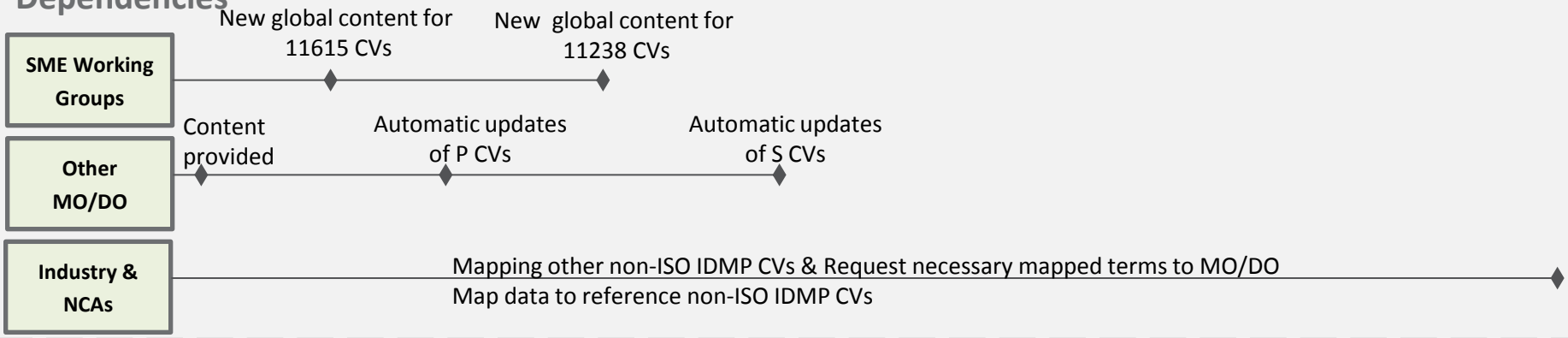
Iterations

Iteration #	Scope	Proposed timelines
I1	. Data: **Global ISO IDMP 11239 & 11240** compliant lists; migration of other EU non ISO IDMP 'static' lists . Process: list creation/publication, out-of-the-box data management	End Q1 2016
I2	. Data: **subset** of CVs required for ISO 11238/11615 iterations 1 & 2 of PMS/SMS (**CVs used in EU or adopted from other regions** + **new global CVs**); migration/consolidation of EUTCT/EV relevant lists . Process: addressing the list maintenance (e.g. automatic updates & sync with external providers)/stewardship process	End Q2 2016
I3	. Data: **subset** of CVs required for ISO 11238/11615 iterations 1 & 2 of PMS/SMS (**CVs used in EU or adopted from other regions** + **new global CVs**); migration/consolidation of EUTCT/EV relevant lists; migration of remaining EU non ISO IDMP from EUTCT (dynamic & complex) . Process: change request process; translation process; access to RMS; workflow; reporting; **. Decommissioning of EUTCT User Interface** (Rest interfaces to consume data are maintained and supported by new solution)	End Q4 2016
Operations	• *Harmonisation/globalisation of CVs used in EU and not adopted by other regions* • *Implementation of 11615 & 11238 CVs in support of subsequent iterations of PMS/SMS*	*From Q4 2016*

Implementation strategy



Dependencies



Key messages

Operating Model:

- Global Operating model based on a federated service delivery model is critical
- EDQM to act as Global Maintenance Organisation and Data owner (alone or in global consortium) for ISO 11239
- Uncertainty as to the Operating Model for ISO 11240
- EMA to act as EU (and possibly Global) broker for all CVs, Maintenance Organisation of new Global CVs (alone) and Data owner of new Global CVs (in global consortium)
- Mapping of legacy terms, specific extensions and translations done by all data owners (EMA, FDA, NCAs, Industry)
- Need to nominate/set up expert working group(s) to prepare content and data model/exchange standards – HMA to agree and possibly liaise with ICH/M5?

Implementation strategy:

- Delivery of required subset of CVs in line and enabling products timelines
- Delivery of a new solution and decommissioning of EUTCT system
- Subsequent Operational activities
  - Harmonisation/globalisation of CVs available in EU not adopted by other regions
  - Implementation of 11615 & 11238 CVs in support of subsequent iterations

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Substances & Products subgroup

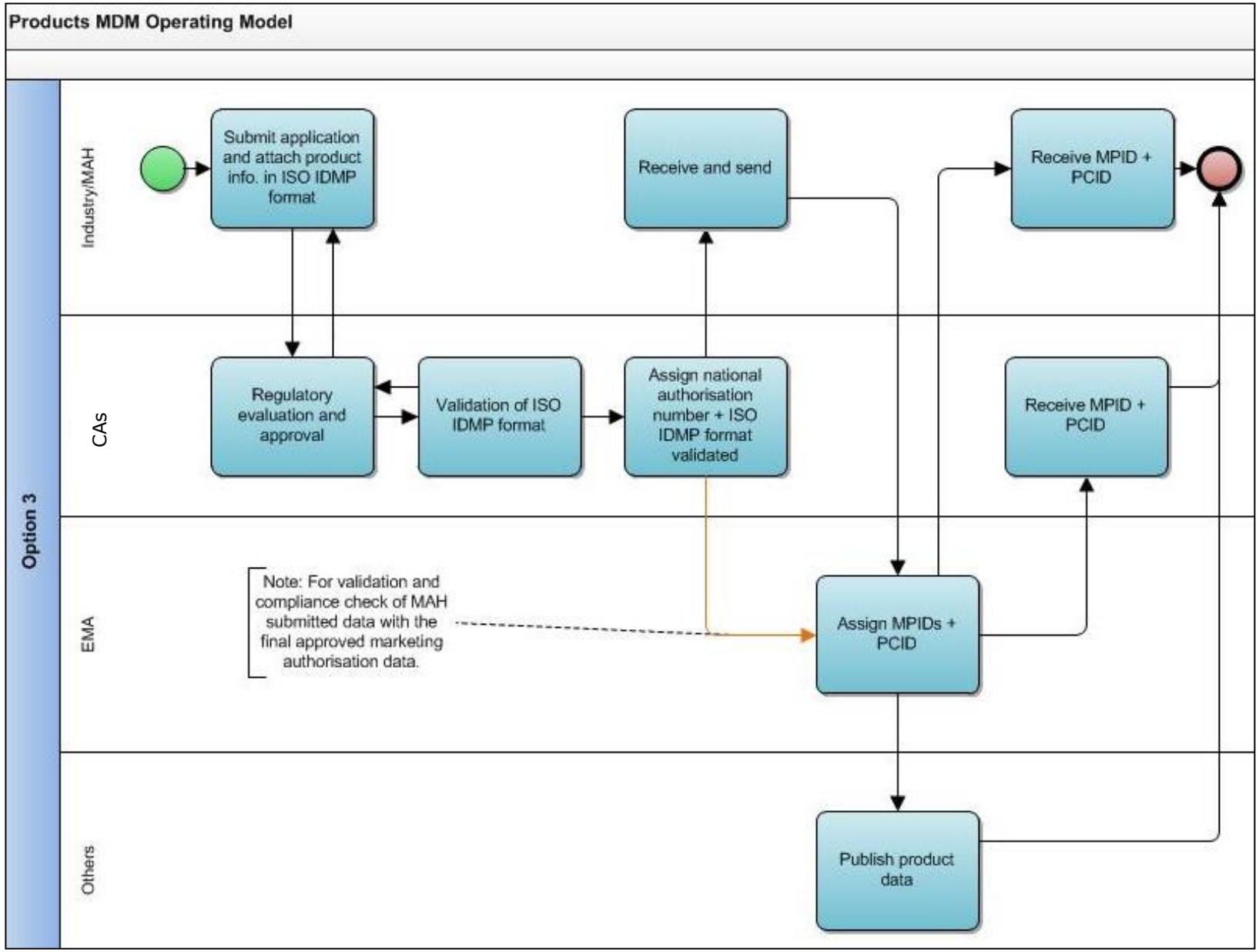
Problem Statement for S&P

Ultimate Goal: to build a **comprehensive list of medicines and substance in EU** with a **harmonised definition**, supported by an **standardised data exchange** model, available in an **easily accessible format** aimed to power business and regulatory processes in EU and at global level

Problem	Solution
A single implementation of the ISO IDMP standards on the July 2016 **legal deadline is unrealistic** due to dependencies on the availability of the ISO Implementation Guides, required technology changes and other external factors such as controlled vocabularies and interfaces with databases	• A **phased implementation** of ISO IDMP would mean more effective change management • It is expected a phased approach would result in **better adoption of the new operating model** and therefore achieve a sustained **higher quality of data** while also allowing for the **resources to be forecasted** appropriately

Analysis on Product

Operating Model – Preferred option



Operating model – Considerations

- In the **context of the product application** (i.e. initial MA or post-authorisation activities), the evaluation and validation of the (updated) substance information will be performed by the *Substance Advisory Board* established by the EU Network and EMA
  - The next phase of the project will be focused on defining technical implementation of the HL7/SPL message within relevant existing solutions (e.g. eCTD)

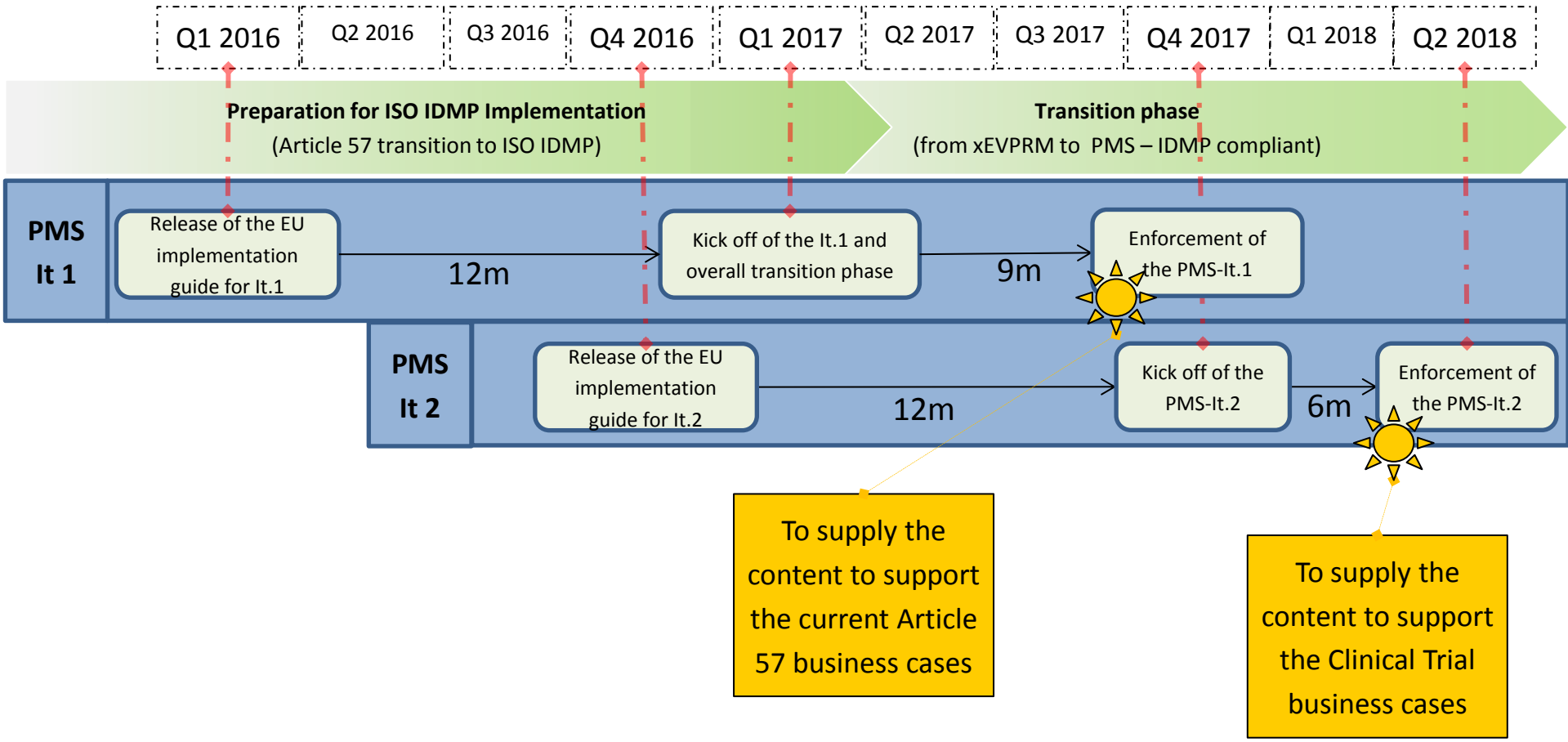
- The Product Management System will be **connected** and **integrated** to support the regulatory submission processes as defined in each iteration business cases to ensure **reduction of duplication of codification of product information** and **re-usability of data** across various domain (e.g. from pre to post-authorisation)

- Infrastructures will be made available to NCAs and Industry for the exchange and management of medicinal product information

Iterations

Iteration #	Scope	Business case
1	Content currently available in the **Article57** format and minimum required elements **to assign and maintain identifiers** for authorised medicinal products and support product **life cycle management** (MPIDs, PCIDs and PhPIDs)	• **Pharmacovigilance iteration 1** (i.e. to power the activities currently supported by Article 57) • **Regulatory submission Iteration 1** (i.e. MAA and post-authorisation submission) • GMP/Inspections Iteration 1 (current processes as supported by Article 57 database e.g. PhV inspections) • e-Prescription Iteration 1 (e.g. cross border identification of medicinal product in EU)
2	Additional data elements and ISO IDMP 11615 content to support the assignment and maintenance of the **Investigational Medicinal Product** IDs (i.e. development products)	• **Clinical Trial** and pre-authorisation regulatory activities iteration 1 (e.g. excluding scientific advice, orphan and paediatrics application) • Regulatory submission support Iteration 2 (e.g. include the Clinical Trial application)
3	Remaining EU requirements for the **Clinical Particulars** section	• **Pharmacovigilance iteration 2** • e-Prescription iteration 2
4	**Batch Identifiers** and remaining EU ISO 11615 and ISO TS 20443 compliant	• **GMP/Inspections** Iteration 2 (e.g. full traceability of medicinal products) • Scientific advice orphan/ paediatrics application • e-Prescription Iteration 2 • **Anti-falsified medicines**
5	Additional standards (TBC) to support **Veterinary** medicinal product	• **Veterinary products**

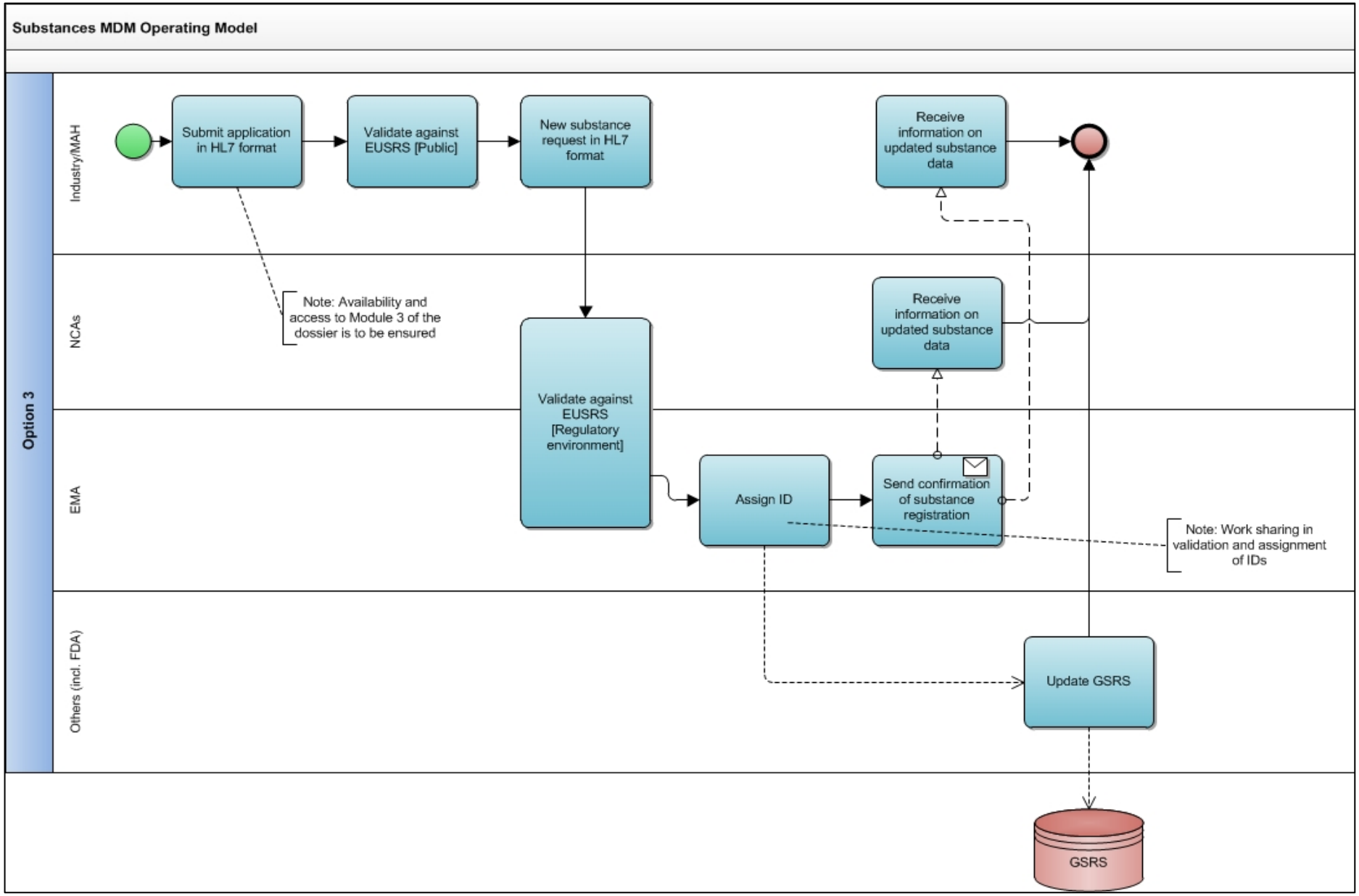
Implementation Timelines



NOTE: Further iterations will be implemented with a 12 + 6 months implementation cycle (Precise timelines to be defined in 2016)

Analysis on Substance

Operating Model – Preferred option



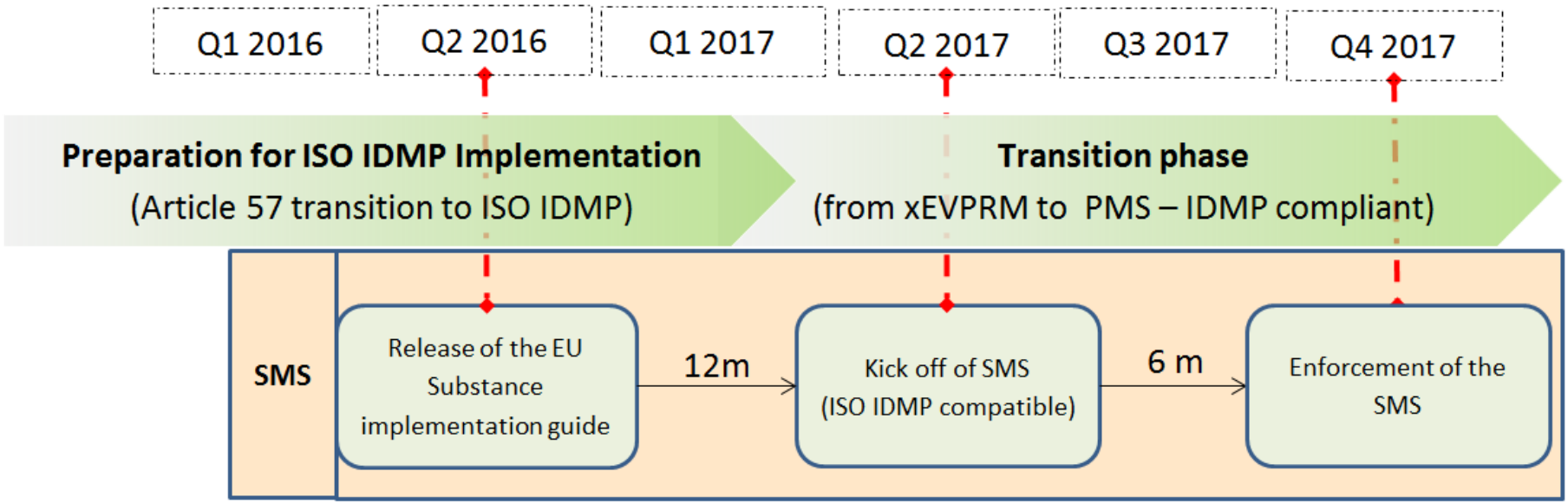
Operating model – Considerations

- The validation and assessment of substance information will be performed by a ***Substance Advisory Board*** established by the substance experts within the EU Network and coordinated by the EMA
  - The next phase of the project will define technical implementation of the HL7/SPL message within relevant existing solutions ensuring access to the substance information submitted in module 3 of the dossier to support the scientific validation and evaluation (e.g. eCTD)
- The Substance Management System will be **connected** and **integrated** to support the regulatory submission processes as defined in each iteration business cases to ensure **reduction of duplication of en-codification of substance information** and **re-usability of these data** across various domain (from pre to post authorisation activities)
- Necessary infrastructures will be made available to NCAs and Industry for the exchange and management of substance information
- Data **synchronisation with the US/global substance database(s)** will be ensured

Iterations

Iteration #	Scope	Business case
1	Implementation of the minimum required mandatory elements as defined in **ISO Technical Specification 19844** • EU mandatory elements based on the EU requirements (TBC if any differences apply based on the further development of the ISO 19844 TS – differences will be minimised)	• **Pharmacovigilance** activities currently supported by Article 57 (e.g. Signal management, PhV fee) • **GMP/Inspections/ Falsified medicines** • **Clinical Trials** • **Regulatory submission** support (e.g. marketing authorization application, CT application, e-Application Form)
2	Additional phase(s) to implement additional requirements outlined in the ISO TS 19844 in **alignment with US**	Better **global oversight** of medicines Global efficiencies
3	Additional standards (TBC) to support **Veterinary** medicinal product	Identification of **veterinary substance**

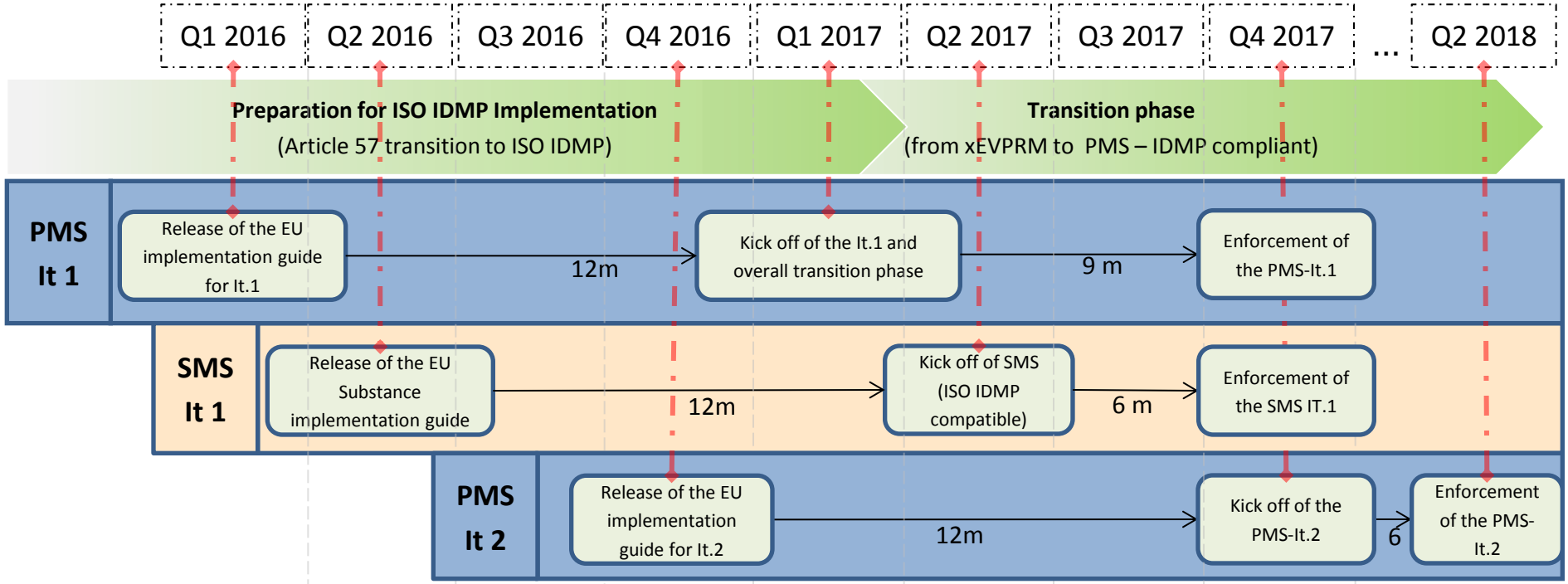
Implementation strategy



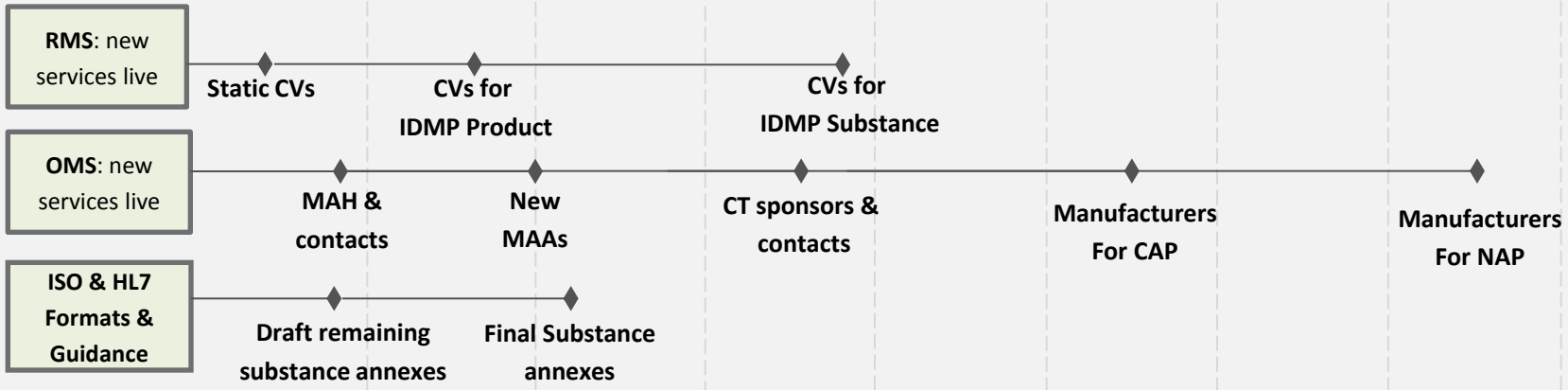
NOTE: Further iterations of SMS will be implemented with a 12 + 6 months implementation cycle (timelines and content TBC in future)

Conclusions on S&P

S&P Implementation Timelines



Dependencies



Analysis of implementation strategy

	Single Implementation of ISO IDMP Standards on 1 July 2016	Phased Implementation as per proposed timelines
Advantages	• Meets deadline of 1 July 2016	• Effective change management given current unavailability of key dependencies for implementation (i.e. ISO implementation guides) • Opportunity to align use of IDMP data with other EU regulatory requirements • Additional time will promote effective transition to a single, harmonized Operating Model across product lifecycle and product types • Phased implementation and alignment with current technologies and standards; consequently reduces duplication of effort • Scalable implementation with robust testing and development of each iteration prior to future iterations (i.e. from system and resource perspectives) • Resource forecasting in line with annual budget cycles • Validated technology changes implemented in an appropriate timeframe • Realistic timelines for communication, roll out of training and data migration • Allows focus on individual aspects of the IDMP implementation minimising risks and improving data quality within each iteration • Provides more agility and risk management considering the deliverables and dependencies for the implementation of IDMP (e.g. RMS, OMS and international activities)
Disadvantages	• High likelihood of failure to deliver leading to incomplete and inaccurate data unable to support business cases • No testing of Operating Model before full use disrupting ongoing and new Regulatory Procedures • High cost in short time • Unavailability of technology will lead to unsustainable manual codification • Unable to align with other projects to reduce redundant activities meaning duplication of efforts in data submissions • Very limited time for knowledge transfer and communication leading to very poor data quality	• Does not fully meet deadline of 1 July 2016 • The availability of full EU ISO IDMP compliant data will be delayed • May impact other EU projects (To be confirmed)

S&P implementation - Key messages

Operating Model:

- Proposed operating models integrated with the regulatory process for the assessment and evaluation of the substance and product information delivering an agile and high quality content solution with greater efficiency

Implementation strategy:

- A phased implementation of ISO IDMP would mean more effective change management and would result in better adoption of the new operating models allowing for appropriate resource allocation and training in a realistic timeframe
  - Change management strategy to transition into the 'TO BE' processes will be defined from July 2015

Identified dependencies:

- Dependencies on international and other (MDM) project deliverables will be closely monitored and current plan will be adapted as necessary

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Organisations subgroup

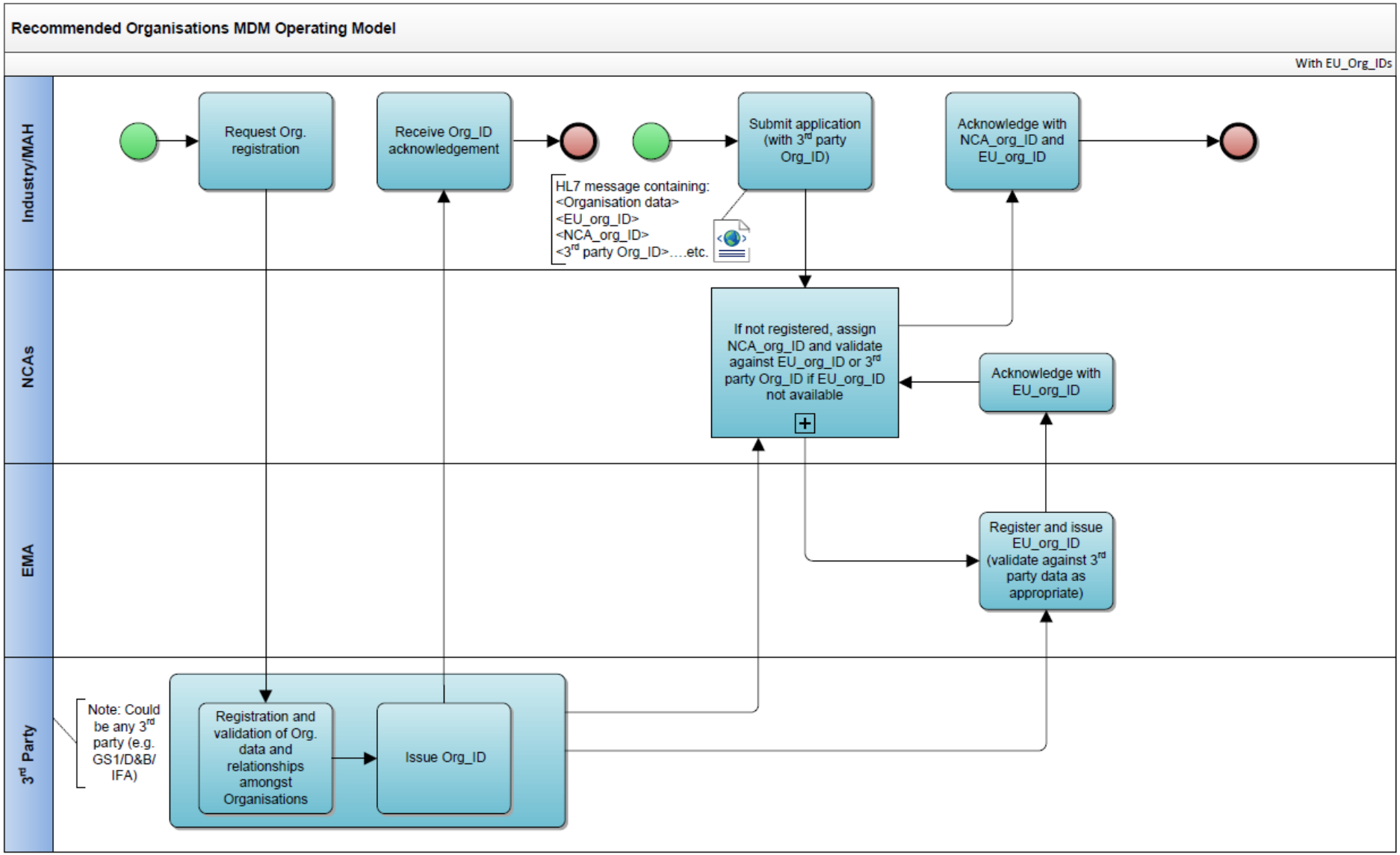
Problem Statement

Problem	Goals
Lack of standardisation on organisation data management across EU reduces effectiveness & efficiency in data exchange and sharing.	An EU wide operating model to manage organisation data based on a single data model and format.
Poor data quality on organisation data with operational and financial impacts e.g. incorrect invoicing, failed inspections, etc.	Provision of a high quality organisation data.
Not a single reference to organisation data within the EU.	Provision of a single dictionary of organisations to support all regulatory activities within the EU.

Operating Model - Options

	Option 1	Option 2	Option 3
Description	• Industry registers and maintains organisation data as a 'self service'. • Regulators (NCAs/EMA) establish and maintain the linkage between the organisations and products/substances.	• Introduction of a third party to issue unique organisation IDs. • Third party provides validated quality data on the organisation to the regulator. • Pre-registration of organisation with third party would be sought before regulatory submissions. • Regulators would use the third party organisation data for validating regulatory submission data. • NCAs and EMA would manage organisation data locally (no EU wide allocation of IDs and data management).	• EU wide data repository for Organisations and EU_ID for all organisations supporting EU regulatory activities. • New organisations registered at NCA would also need to be registered at EU db.
PROS/ Benefits	• MAH in control of data creation and maintenance. • Quick creation of ID for MAH.	• Independent third party responsible for creation of ID´s.	• Independent third party responsible for creation of ID´s. • Company specific ID can be used for national agency databases. • One single of EU database of organisations. • Can support the provision of an EU wide organisation dictionary more efficiently.
CONS/ Restrictions	• Limited control of creation of registrations for organisation, risk of duplication by MAH. • Time consuming for Agencies to maintain the link in case of updates of organisations.	• No EU single database of ID´s. • Time consuming for Agencies to maintain the link in case of updates of organisations. • Pre-registration of company at third party supplier.	• Workload to assign EU ID for agencies. • Pre-registration of company at third party supplier.

Operating model – Preferred Option



Operating model – Considerations

- Introduction of a 3rd party to issue unique organisation IDs.
- Third party provides validated quality data on the organisation to the regulator.
- Pre-registration of organisation with third party would be sought before regulatory submissions.
- Regulators would use the third party organisation data for validating regulatory submission data.
- EU wide data repository for Organisations and EU_Org_ID for all organisations supporting EU regulatory activities.
- New organisations registered at NCA would also need to be registered at EU db.

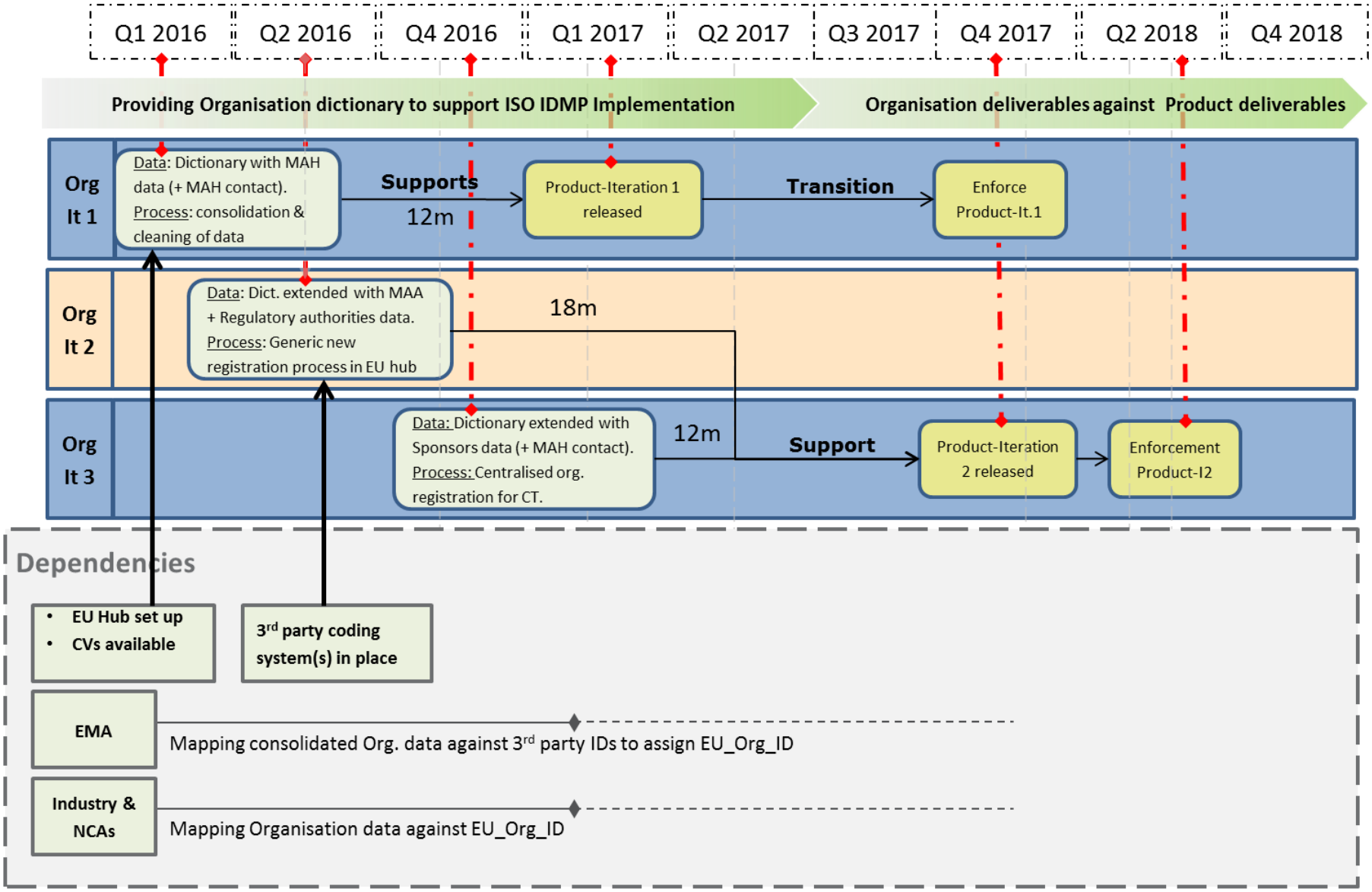
Business cases

Data	Business cases
MA Holder	• Start with existing data for ease of implementation. • ISO IDMP compliance • Support for: Fees/Billing, Post authorisation regulatory submissions, Inspections, PhV monitoring.
Sponsor	• Start with existing data for ease of implementation (EV – Not EudraCT). • ISO IDMP compliance • Support for: Clinical Trials, Inspections, PhV monitoring.
MA Applicant	• Start with existing data for ease of implementation. • ISO IDMP compliance • Support for: Fees/Billing, Initial MA regulatory submissions, Inspections.
Data submitters on behalf of Sponsor/MAA/MAH	• Support for: MA regulatory submissions
Manufacturers	• Start with existing data for ease of implementation. • ISO IDMP compliance. • Support for: MA regulatory submissions, Inspections.
Contract Research Organisation (CRO)	• Support for: Clinical Trials, MA regulatory submissions, Inspections
Regulatory Authority	• Start with existing data for ease of implementation. • ISO IDMP compliance. • Support for: Clinical Trials, MA regulatory submissions, Inspections, other.
Clinical Trial site	• Support for: Clinical Trials.
Person/Individual (contacts) -MA official contact persons (Initial MA app) -Single Sponsor/MAA/MAH contact person	• ISO IDMP compliance. • Support for: MA regulatory activities, Clinical Trials, PhV activities.
Academia…etc.	

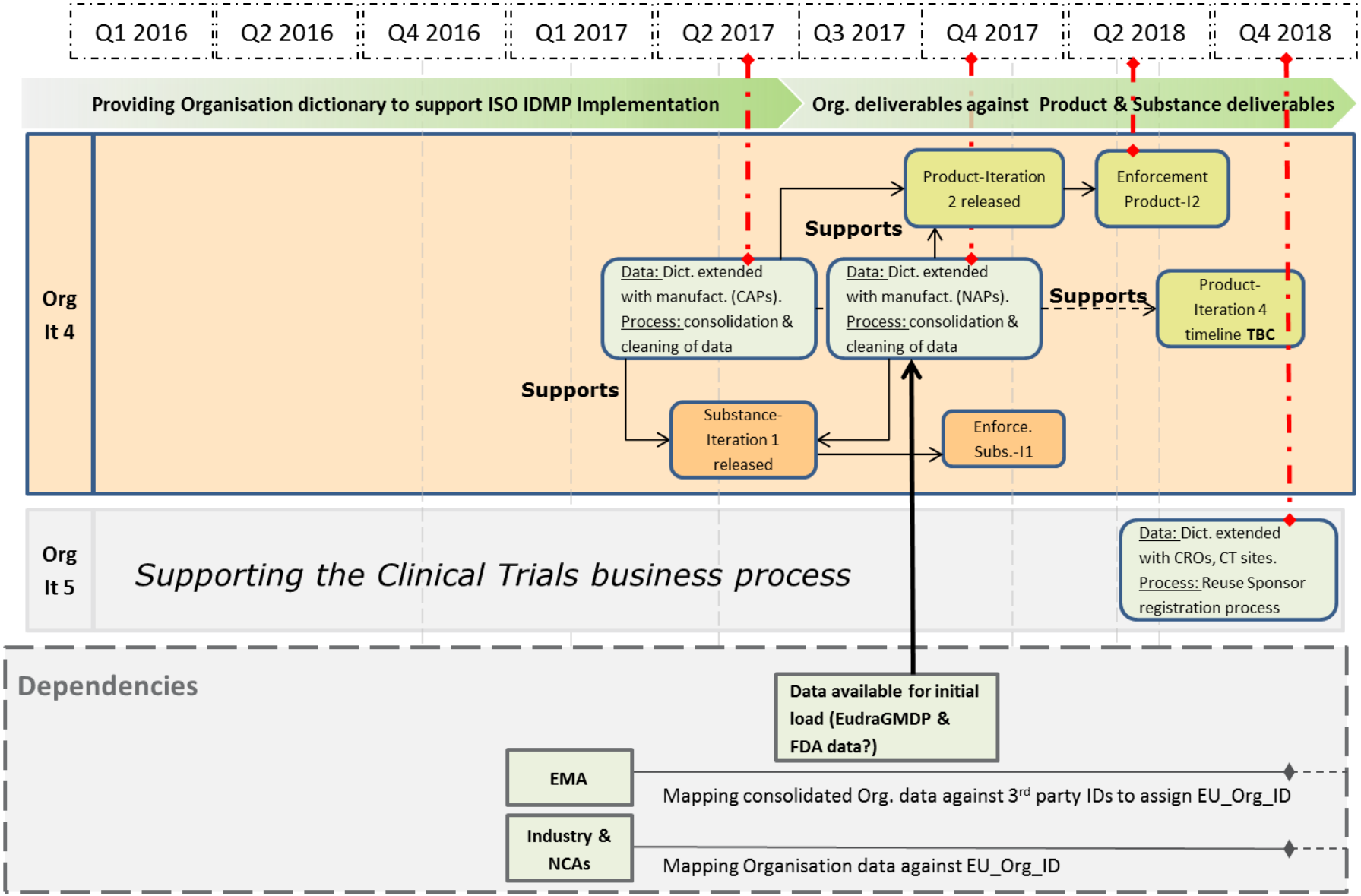
Iterations

Iteration #	Scope	Proposed timelines
I1	MA Holders + unique (MA) contact (persons) [process for unique admin contact to be put in place] Process: Consolidation/cleaning/provision of dictionary	End Q1 2016
I2	MA Applicants + Regulatory Authorities Process: New process to register/update/access Org. data	End Q2 2016
I3	Sponsors + contact Process: New centralised data authoring process.	End Q4 2016
I4	Manufacturers (supporting CAPs & NAPs) Process: Missing manufacturers data from EudraGMDP to be submitted separately.	End Q4 2017
I5	CROs + Clinical Trials sites + (Data submitters on behalf of Sponsor/MAA/MAH ??) Process: Reuse of Sponsor reg. process.	End Q4 2018

Implementation strategy (1/2)



Implementation strategy (2/2)



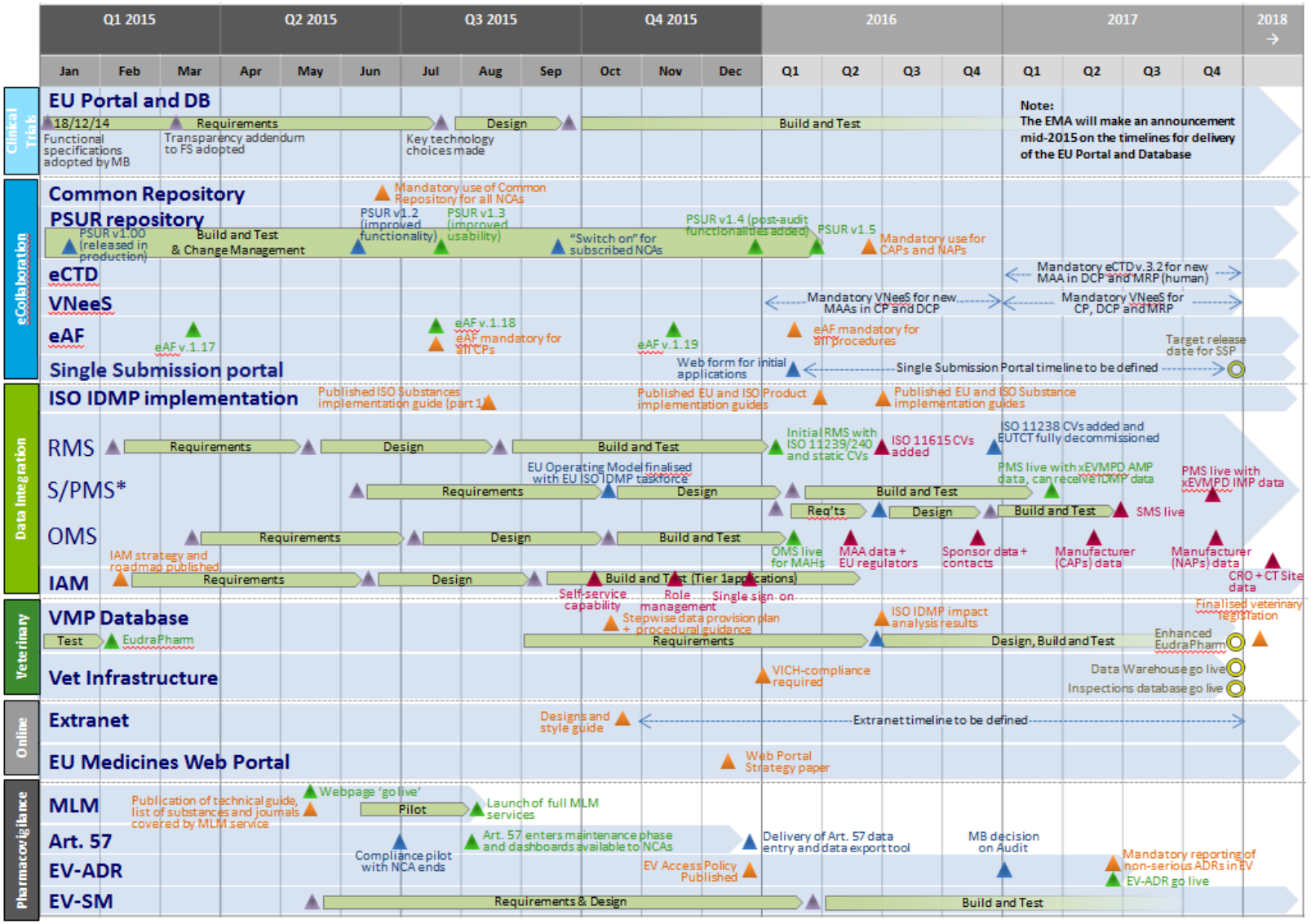
Key messages

- Legal basis to enforce 'O' data submission is required
  - Can we use the PhV legislation on ISO IDMP to enforce use of DUNS/GS1 without extra legislation/regulation - No current legal basis to enforce the pre-registration of organisation before submission (with EU regulator, DUNS, GS1, etc.)
  - We can concentrate on one area or try to take a broad perspective
  - How shall we handle areas that the NCAs cover that EMA does not?
  - Can enforcement be done with regulation Europe-wide or nationally/NCA-level? (Notice to Applicants, other areas individually or together?)
- Data model and processes implemented should support any type of organisation data and should be resilient to change when supporting new business processes.
- Implementation should be in stages in a prioritised approach. Multiple phases will be needed for full implementation.
- EMA proposed to be the maintenance organisation.
- Considerable training on data stewardship and new processes.

HMA meeting preparation

For discussion

SPOR & ISO IDMP in EU context



Disclaimer: The roadmap shown is a draft version, and is subject to further change

** The timelines for the S&P project are indicative at this stage because they are based on a preliminary analysis; they will be revised during the approval process for the S&P project and they will be influenced by both the development of the ISO IDMP technical specifications in the ISO international arena and the outcome of the ISO IDMP Taskforce discussions. Deviations are considered likely.*

Glossary

Acronym	Description
11238	ISO Substances (Substance ID) standard
11239	ISO Pharmaceutical dose forms, units of presentation, routes of administration and packaging standard
11240	ISO Units of measurement (UCUM) standard
11615	ISO Medicinal product information (MPID/PCID) standard
11616	ISO Pharmaceutical product information (PHPID) standard
CVs	ISO Controlled Vocabularies; controlled terminologies; Dictionaries; Lists A list of structured and maintained information
MSSO	Maintenance and Support Service Organisation (MSSO) Manages MedDRA
IHTSDO	International Health Terminology Standards Development Organisation Manages Snomed CT
EDQM	European Directorate for the Quality of Medicines and Healthcare Manages the standard terms for Dosage Forms; Routes of Administration; Containers
WHO	World Health Organization Manages the INN; ATC/DDD and ATCvet Controlled Term Lists
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