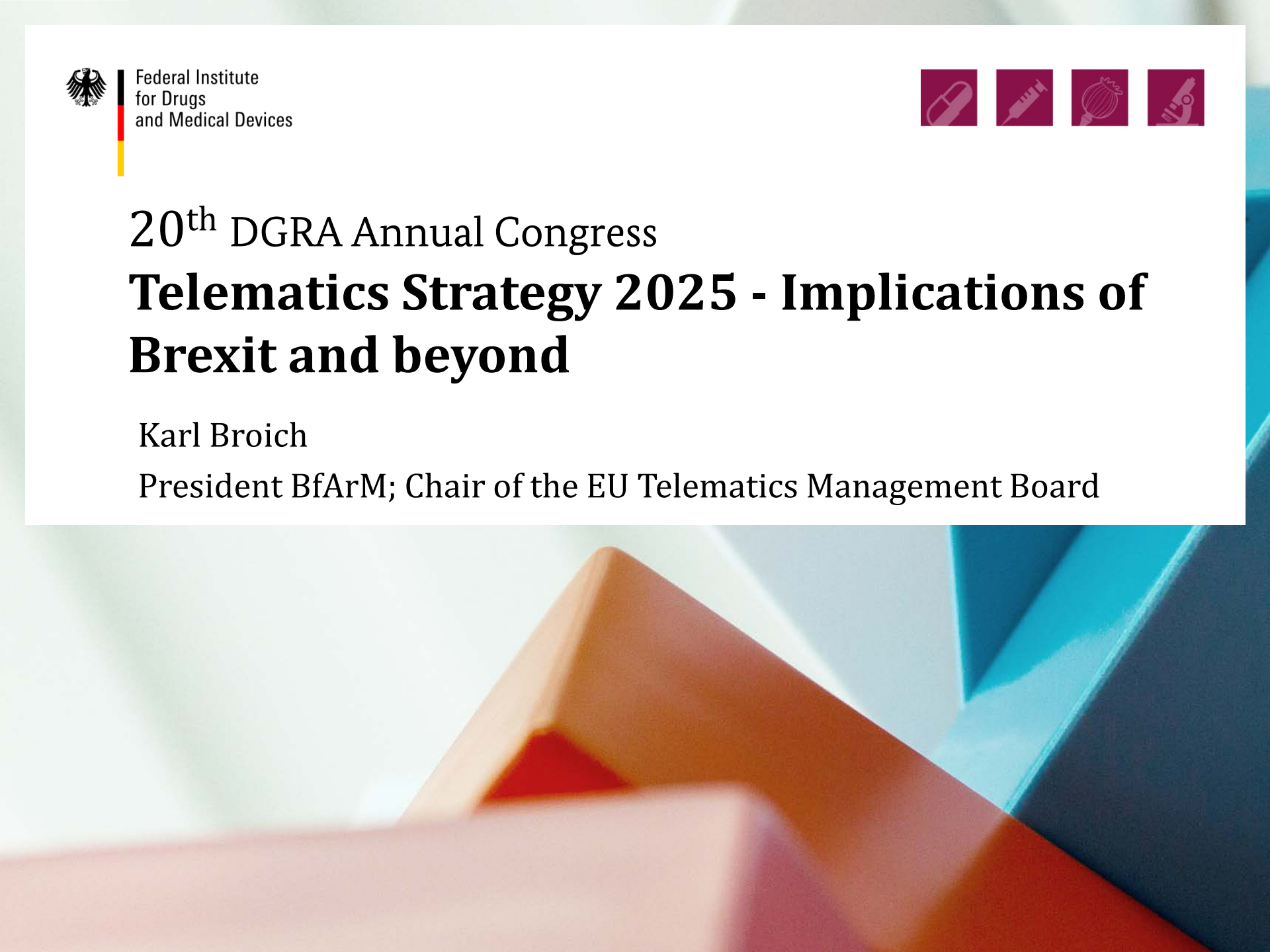
Federal Institute
for Drugs
and Medical Devices

20th DGRA Annual Congress

Telematics Strategy 2025 - Implications of Brexit and beyond

Karl Broich

President BfArM; Chair of the EU Telematics Management Board

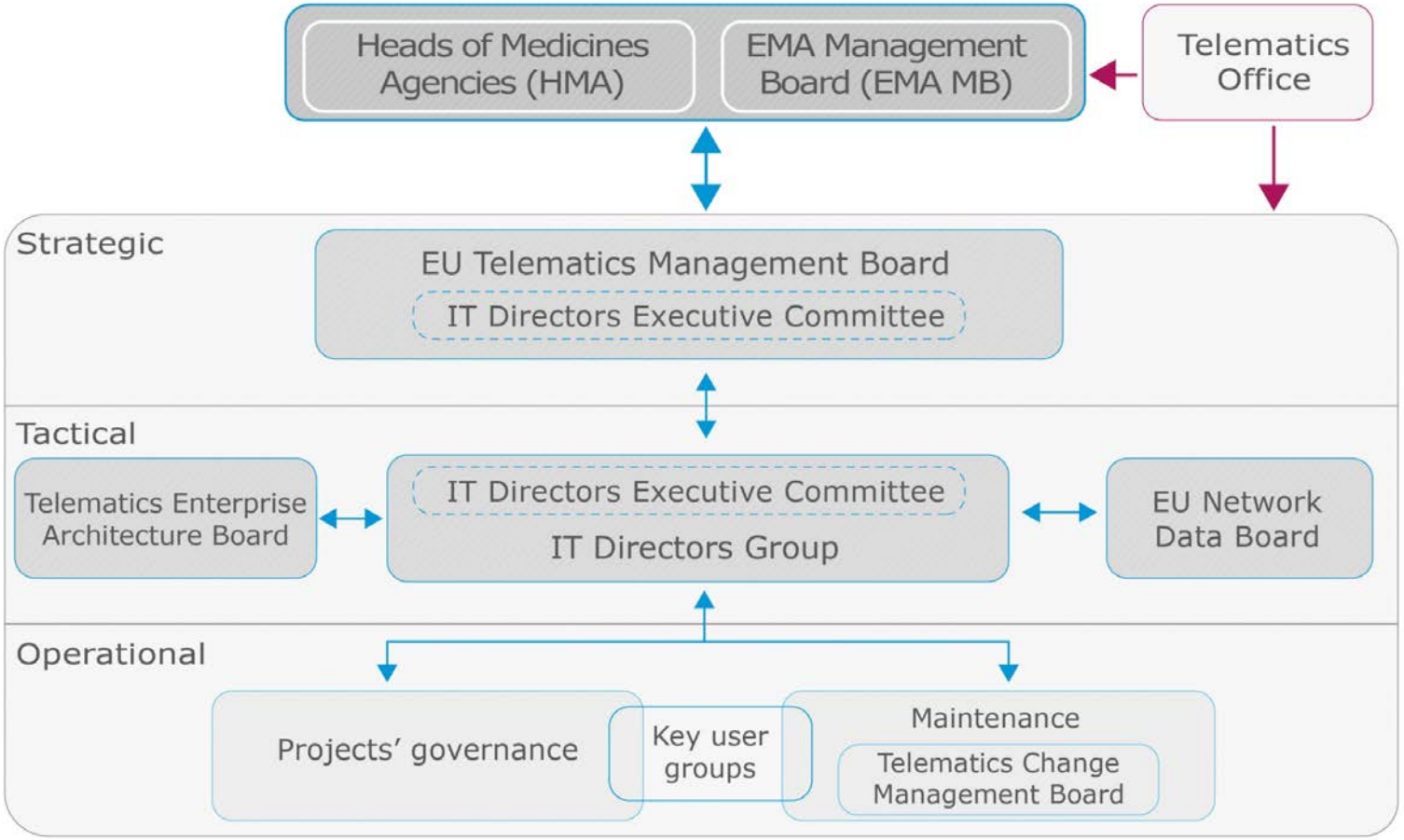


Agenda

- EU Telematics Governance Structure
- Current Telematics strategy
- Work on Strategy 2020 – 2025
- Telematics Projects
- Impact of Brexit / EMA Relocation on Telematics Projects
- Conclusions

EU Telematics Governance Structure

EU Telematics Governance Structure



Source: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/08/WC500148222.pdf

Full details of the Telematics governance structure are available here.

EU Telematics Management Board (TMB)

- The EU Telematics Management Board is the **strategic governance body** that operates on the behalf of the European Medicines Regulatory Network (EMA, the National Competent Authorities (NCAs) as represented by the Heads of Medicines Agencies (HMA) and the European Commission as represented by DG SANTE).
- **EU Telematics** is governed by the TMB.
- The TMB provides the **vision** for and **strategic oversight** of the **telematics program** and interacts with the EMA Management Board and the Heads of Medicines Agencies.
- The IT Directors Executive Committee is currently working on the concept paper for the new Telematics strategy.

Telematics Change Management Board (CMB)

- The objective in establishing the CMB is to provide more transparency and increase consensus in the decision-making process for change requests, as well as strengthening the shared ownership model between EMA and the Member States of the Telematics initiative taking into account the big picture.
- Telematics CMB main role: review the prioritisation of business change requests across Telematics systems.
- Old eSubmission CMB and its maintenance groups/harmonisation groups become “key user groups”.
- **Industry representatives** from European Federation of Pharmaceutical Industries and Associations (EFPIA), EuropaBio and European Generic Medicines Association (EGA) are members of these key user groups.

Overview of current strategies

Current Telematics Strategy

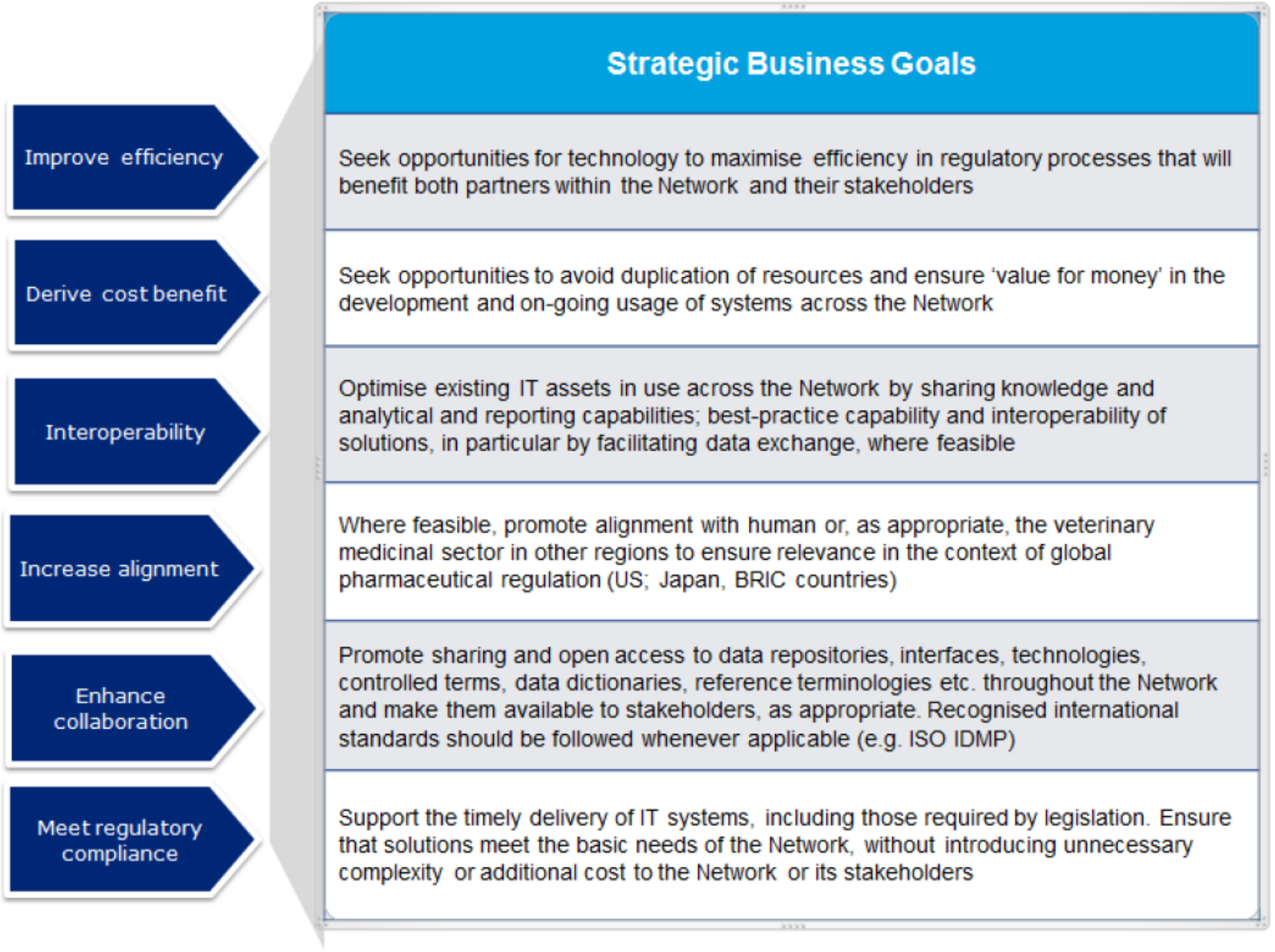
Vision for EU Telematics:

"A European IT collaboration that will deliver a broad range of cost-effective, efficient and interoperable services to the European Medicines Regulatory Network and its stakeholders, ultimately improving the quality and effectiveness of their business activities."

Source: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/08/WC500191875.pdf

Current (Telematics) Strategy Documents

- (EMA/HMA, public consultations): EU Medicines Agencies Network Strategy to 2020
- (HMA): Multi Annual Work Plan (MAWP), updated to 3rd version to 2020
- (EMA/HMA): EU Telematics Strategy 2014 – 2016
- (EMA/HMA, consultation with NCAs/industry): EU Telematics strategy and implementation roadmap 2015 -2017
- (EMA/HMA): eSubmission Roadmap (v 2.1, 28/02/18) to (about) 2020/2021 (regularly updated)
- (EMA): multi-annual work program 2018 – 2020 (version 19/03/18)



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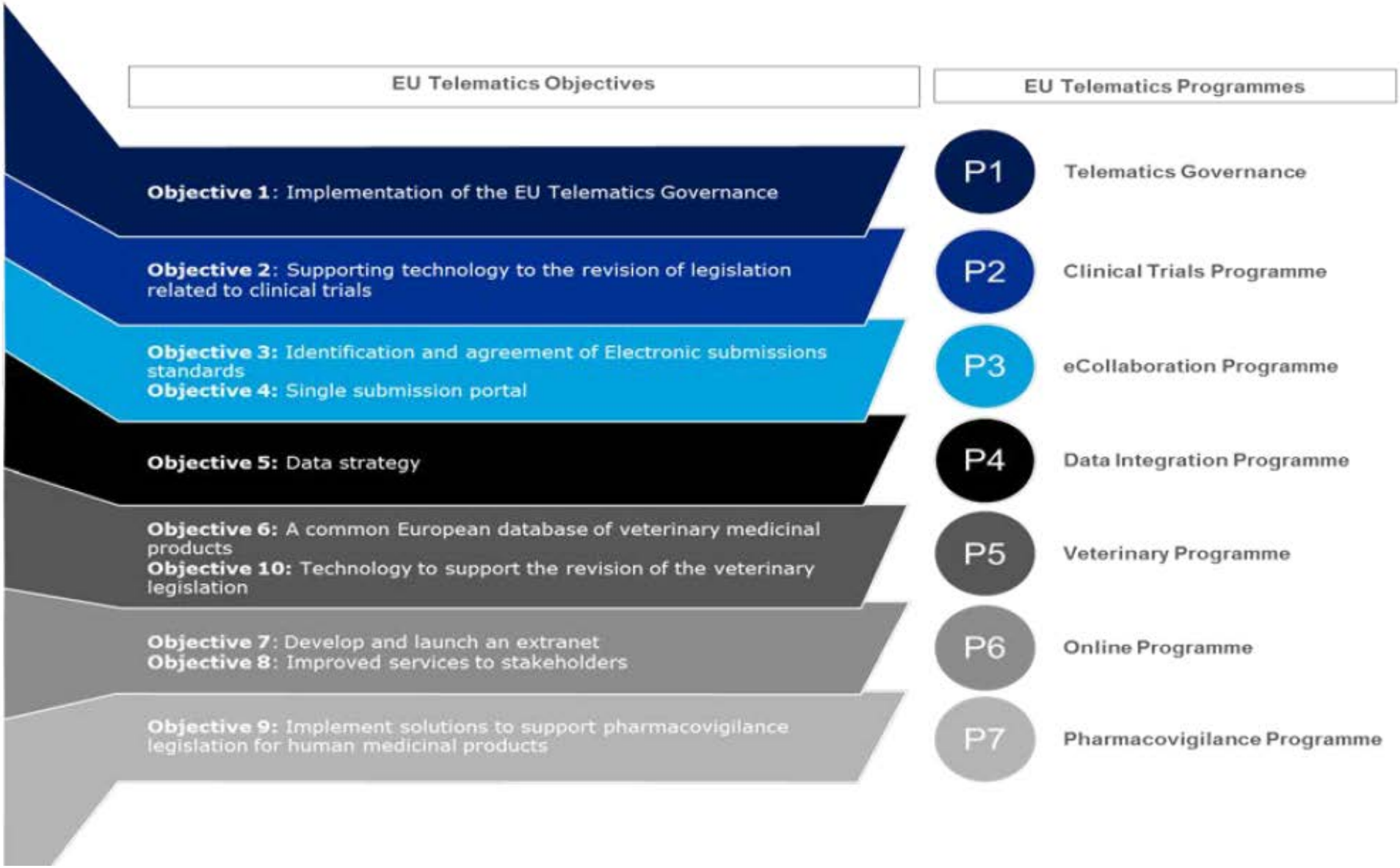


Source: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/08/WC500191875.pdf

Current Situation about Telematics Strategy

- The current Telematics Strategy & Roadmap came to an end in 2017
- The EU Medicines Agencies Network strategy that provides guidance on the European Medicines Regulatory Network's (Network) strategic business priorities covers the period from 2016 to 2020
- As a result and taking into account planning and budget cycles, the Network is in need to **start developing** a new Telematics strategy beyond 2019 to **ensure** that the vision for information management and technology is clearly described and appropriately represents Network's business needs

Aims of Telematics Think Tank

- To prepare a meaningful Telematics strategy, we need to clarify the business requirements of the Network
- Network IT Strategy approved until 2020:

  For new IT investments after 2020, we require the Telematics strategy at the latest by spring 2019.
- **Think tank workshop hosted by BfArM** on 8 November 2017 in Berlin
  - Goal: brainstorm on what might be the key business strategies which the new Telematics strategy should enable
  - Participants: EUTMB + Chair of EMA Management Board

Discussions at the Think Tank Workshop

- Lessons learned from execution of the current Telematics strategy (2015-2017)
- Identified 3 business objectives:
  1. Better and more efficient regulatory decision making
  2. Build “empowered” patient/animal owner
  3. Facilitate research and development
- Business and IT capabilities to be developed to achieve the identified objectives
- Key strategic risks and mitigation measures for the identified objectives

Working on the new Strategy: Telematics Strategy Concept Paper

- A concept paper is currently developed
- Purpose of this paper:
  - Outlines the direction that the development of Telematics Strategy 2020 – 2025 should take;
  - Assures, early on, that there is adequate top-down strategic direction for business changes that the Network will have to make over the period of time to inform information management changes; and
  - Once approved by HMA and the EMA Management Board, will serve as direction for bottom-up consultation and as a foundation for developing the Telematics strategy 2020-2025.
- **Outcome:** Three business objectives have been identified:
  - Better and more effective regulatory decision making in the Network
  - Facilitate research and development (R&D) in Europe
  - Build trust in medicines by empowering patients, animal owners and healthcare professionals

Planning for the upcoming Telematics Strategy and Implementation Roadmap

- As for the previous strategy consultation is planned to take into account all stakeholders (also industry).
- It is planned to have the Telematics strategy and the implementation presented more comprehensibly.

  The implementation roadmap will be aligned more clearly to the strategy.
- The impact on all stakeholders should be worked out and clearly represented.
- For further implementation roadmaps it is planned to have more reliable timelines for project milestones.

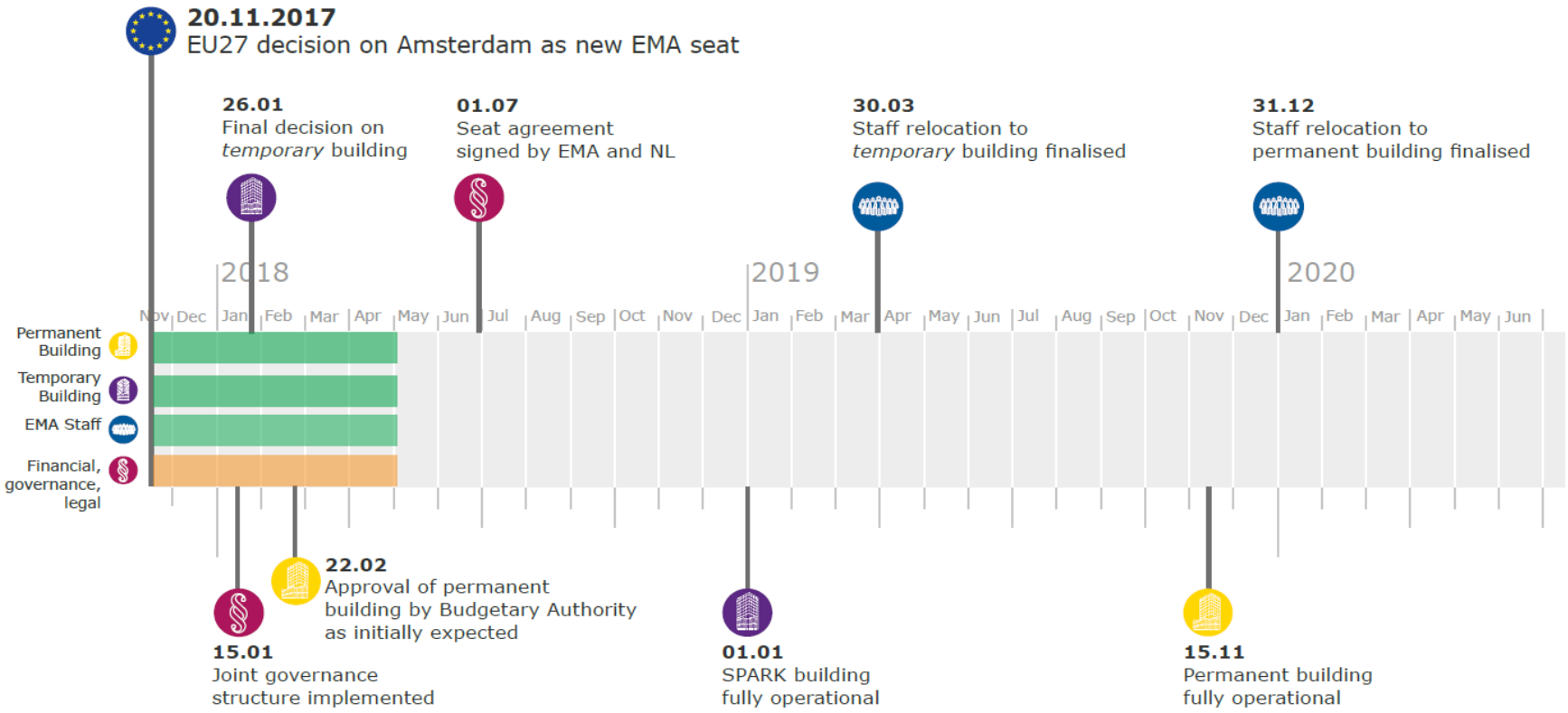
➔**Timeline for the next steps will be currently reviewed**

(final cycle of acceptance and endorsement planned for Q 2-3 2019).

➔ **Work might be delayed due to Brexit and relocation.**

Impact of Brexit/EMA Relocation on Telematics Projects

EMA tracking tool: relocation to Amsterdam
Main milestones



Please click on the icons to be directed to the related work streams.
EMA stands for European Medicines Agency and NL stands for the Netherlands.

last updated on 30 April 2018

progress on track
progress delayed but overall still on track
progress at risk

Source: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/03/WC500244941.pdf

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Where to get informed about workload due to Brexit/EMA Relocation?

❖Because the British NCA MHRA will no longer be able to engage in centralized regulatory procedures and DCP/MRP, this workload has to be distributed.

- Information from EMA
- Information from HMA: CMD*h* and CMD*v*

EMA has provided two different documents with more information:

- EMA Brexit Preparedness Business Continuity Plan (13/10/17)
- EMA final programming document 2018 – 2020 as the multi annual working plan.

Business Continuity EMA

- EMA has to be prepared for
  - Relocation preparedness
  - Operational and financial preparedness
  - Human resource-related matters (e.g. anticipated staff loss and loss of the UK expertise)
  - Communication activities
- Many activities will be affected.

➔ **The actual effects can only be estimated in advance.**

Impact on Telematics Projects 2018/2019 (1)

- **High Priority:**
  - EU Clinical Trials Portal & Database for new regulation.
  - SPOR (substances, products, organizations and referentials) as master data approach for implementing ISO IDMP in Europe).

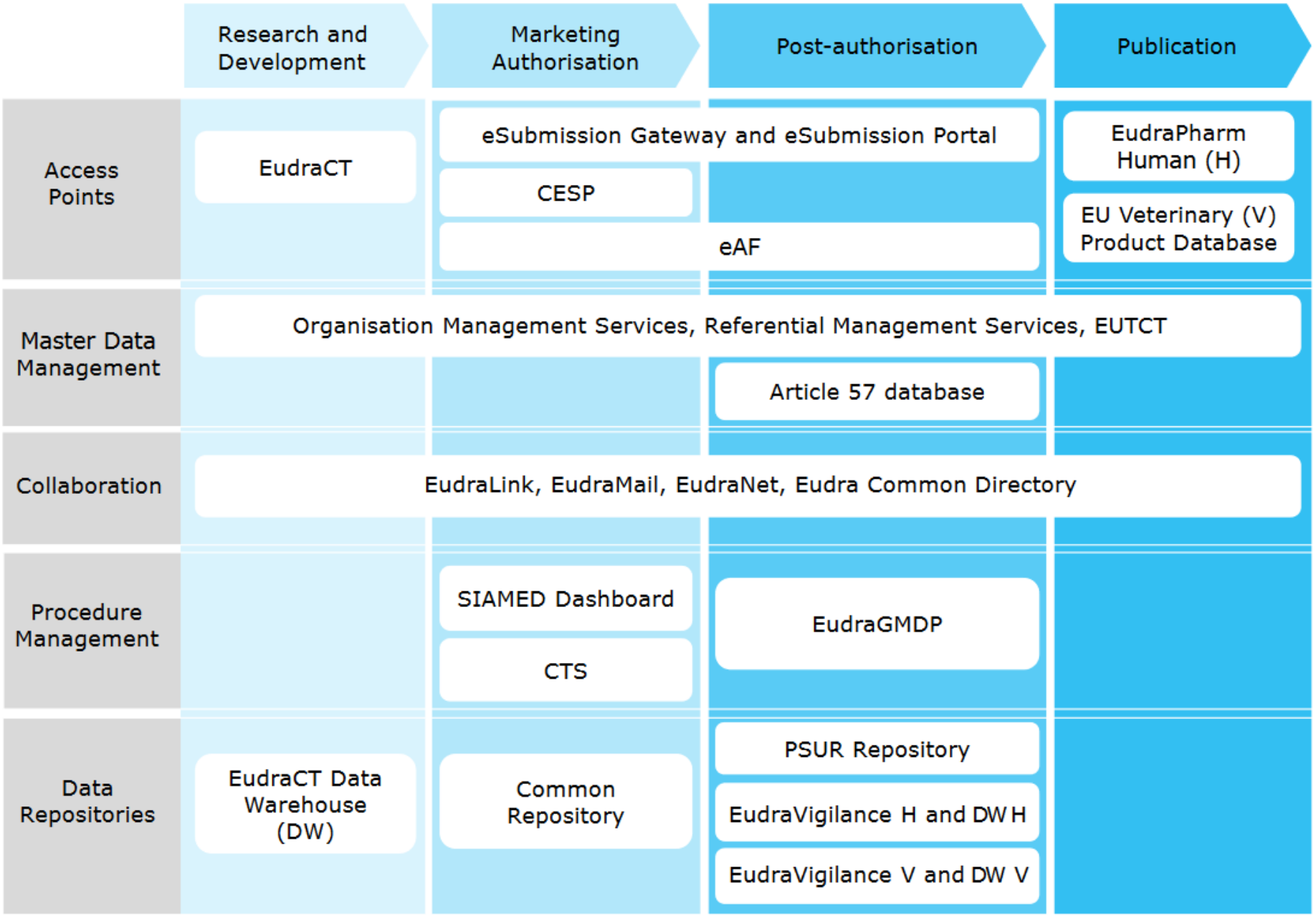
- **Reduced activities:**
  - Gap analysis and impact assessment of new veterinary regulation on existing procedures and technical requirements.
  - Reduction in business change requests to established and running Telematics applications and systems in 2018/2019.

Impact on Telematics Projects 2018/2019 (2)

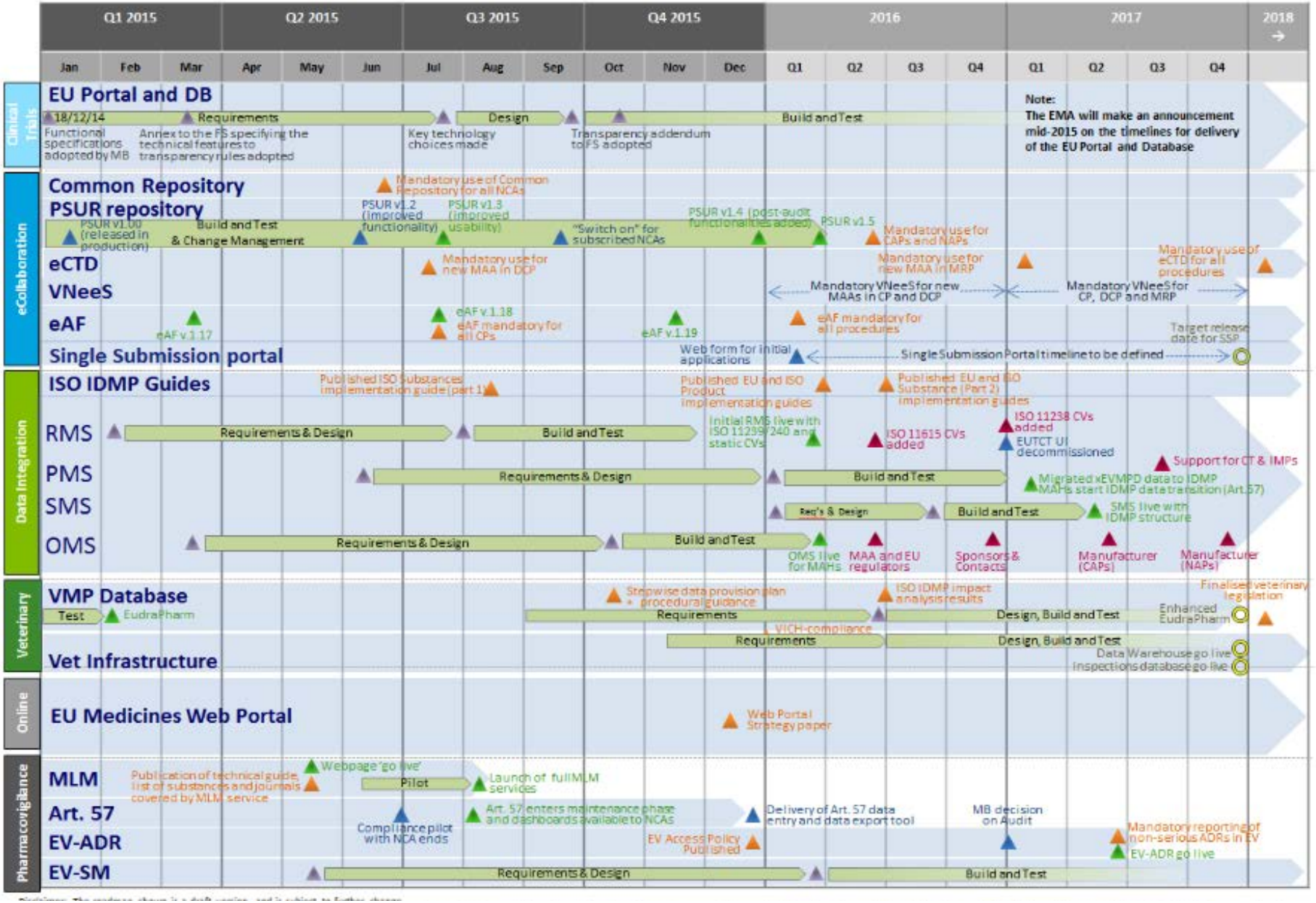
- **Postponed activities:**
  - Optional use of eCTD v 4.0 has been further postponed to 2020 Q3 TBC for centralized procedures (human domain) in the eSubmission Roadmap. **EMA has currently suspended the implementation of eCTD v4.0 as of 03/07/2017.**
  - Use of CESP (Common European Submission Platform) with the dataset module for new marketing authorization applications for human and vet domain has shifted to optional use in 2018 Q4 and mandatory use in 2019 Q2.
  - Use of CESP dataset module for variation and renewal application forms has shifted to optional use in 2020 Q1 and mandatory use in 2020 Q3.

- **Suspended activities:**
  - European Medicines Web Portal work temporarily suspended as of 03/07/2017.

EU Telematics Systems in operation



Annex 1 – EU Telematics Implementation Roadmap 2015 – 2017



Source: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/08/WC500191875.pdf

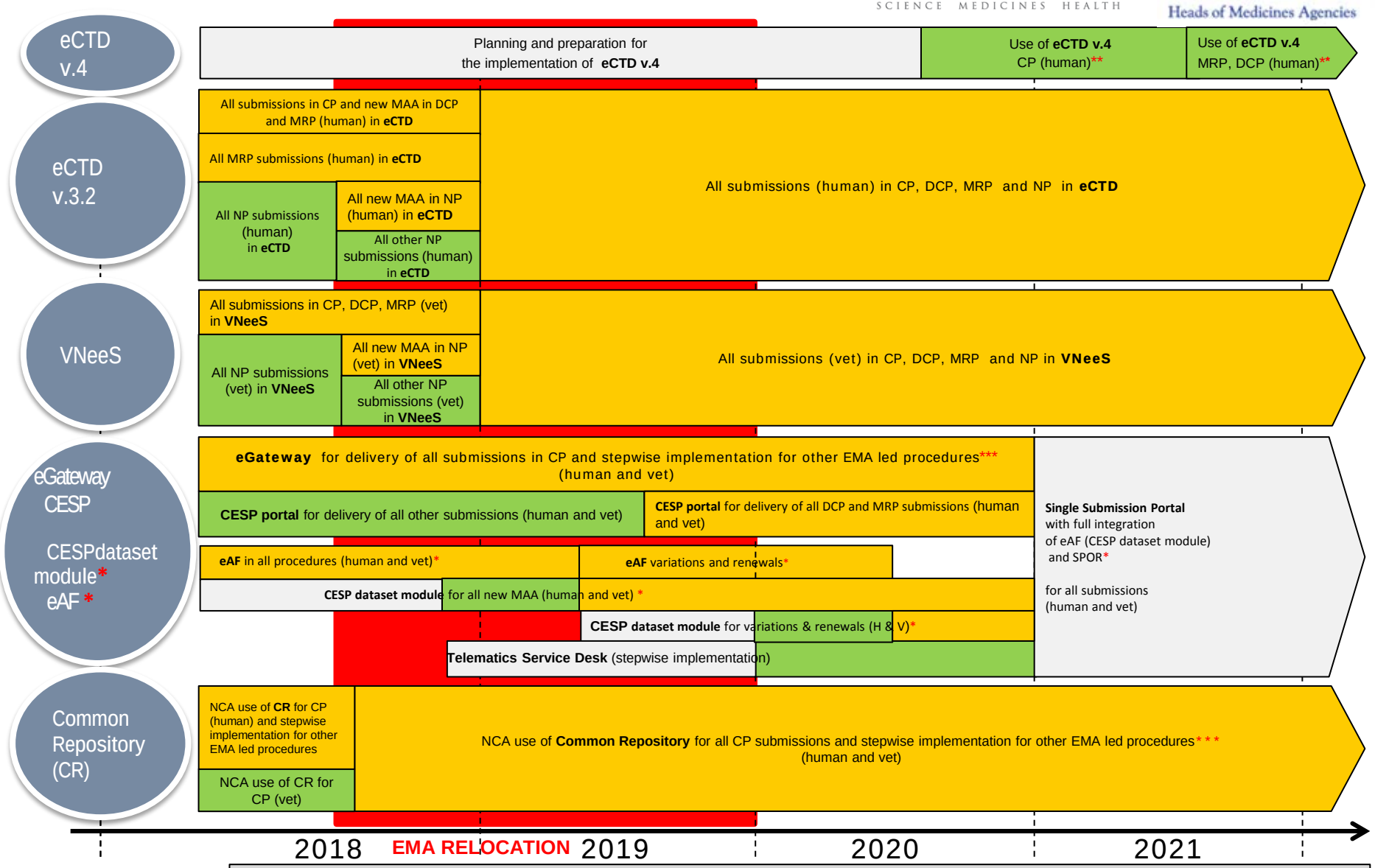
eSubmission-Roadmap version 2.1

eSubmission Roadmap - timelines

(reflecting version 2.1 dated 28 February 2018)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies



Planning in progress
Ongoing or optional
Mandatory

*) The SPOR project will stepwise (see specific Roadmap) deliver master data services (RMS, OMS, SMS, PMS) to be integrated with the eAF and CESP dataset module. Currently, the mandatory use of OMS is planned for Q4 2018, subject to outcomes of further planning exercise.

) Timelines subject to planning *) Some procedure types are excluded

Main updates compared to version 2.0

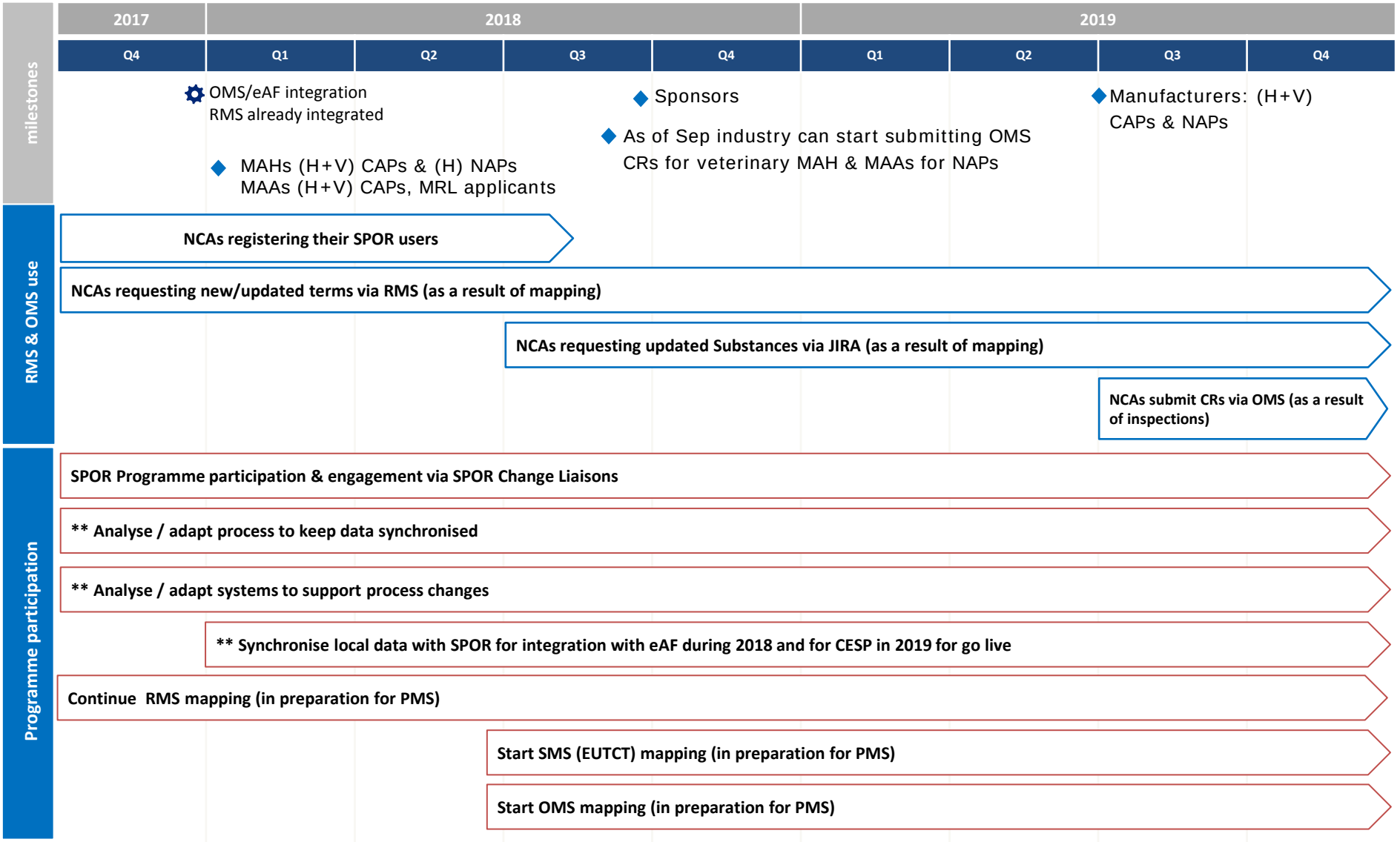
eCTD v4.0	The timeline has been further postponed, now proposing **optional use of eCTD v.4.0** from Q3 of 2020 for CP submissions.
eCTD v.3.2 (current version)	No change
VNeeS	No change
eGateway, CESP, eAF, Single Submission Portal	The stepwise deliveries towards the mandatory, fully integrated, single submission portal have been updated and more details have been included. **CESP dataset module** (formerly called CESSP) to be used for new MAA by Q4 2018 and **mandatory** use by Q2 2019. CESP dataset module for other applications by Q1 2020 and mandatory use by Q3 2020 *(CESSP phase 2 TBD).* The date for preparation of mandatory use of an **EU single submission portal** is set to Q1 2021 which will also include a stepwise implementation of a common telematics service desk. **Mandatory use of current CESP for delivery** of all DCP and MRP (human and vet) submissions has been included and set to Q3 2019.
Common Repository	Stepwise implementation for **mandatory use of the Common Repository (CR) for all other EMA led procedures** than just Centralised Procedures, e.g. Referrals, ASMF worksharing procedures and PMF. Timeline for veterinary submissions in centralised procedure in the CR has been slightly postponed (delivered Q4 2017 and mandatory in Q2 2018).
Other updates	The document has been updated to reflect the already achieved milestones (Done) and a few editorial changes have been made.

Source: http://esubmission.ema.europa.eu/tiges/docs/eSubmission%20Roadmap_v.2.1%20final%20adopted%20HMA%2028.02.18.pptx

SPOR

*S*ubstances
*P*roducts
*O*rganisations
*R*eferentials

NCAs involvement through SPOR 2018-2019

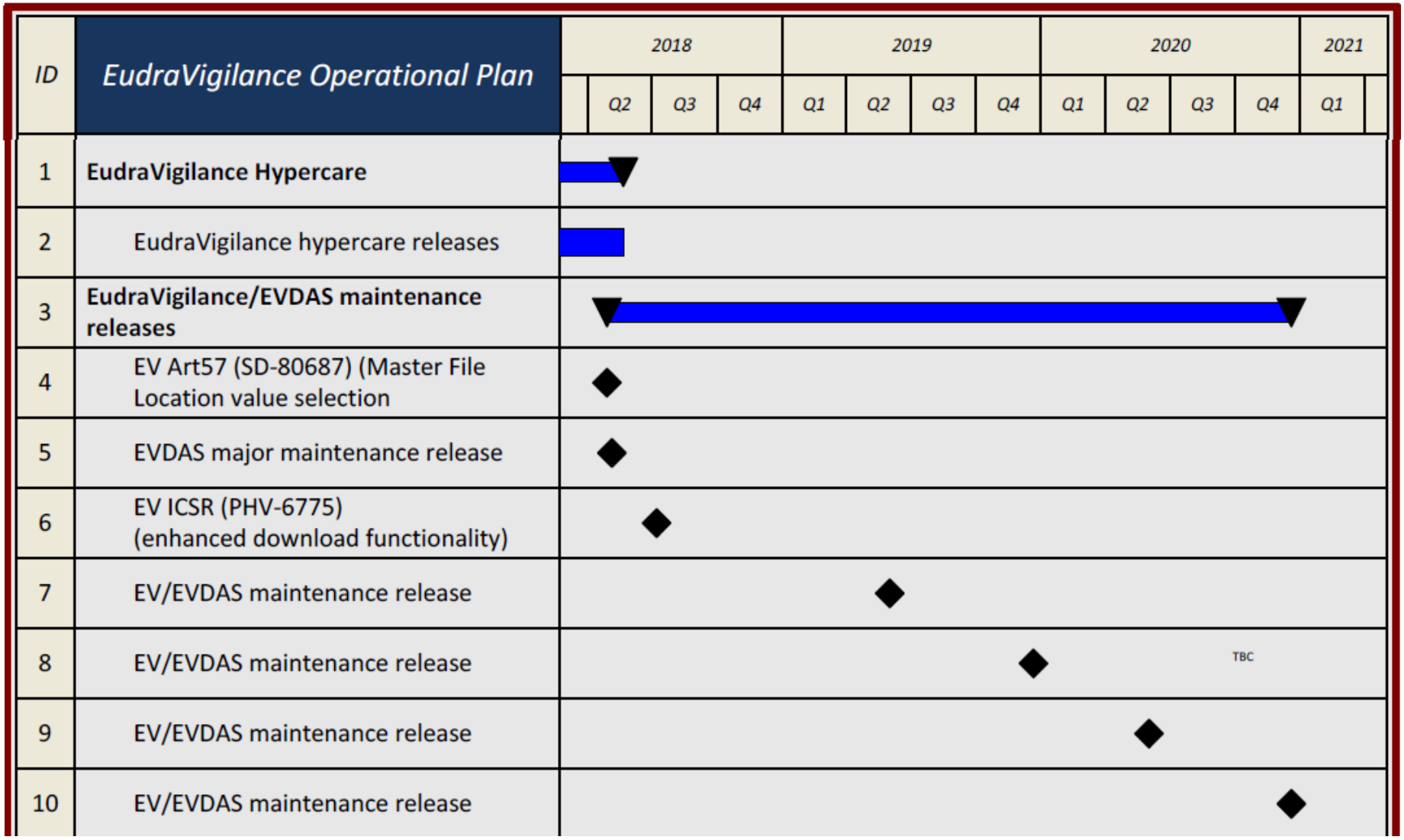


** Only if using/planning to use automated integration with eAF/CESP

EudraVigilance

EudraVigilance 2018 – 2020

- EudraVigilance is the system for **managing** and **analyzing** information on **suspected adverse reactions** to medicines authorized or being studied in clinical trials in the European Economic Area (EEA). EMA operates the system on behalf of the European Union medicines regulatory network (EMA/NCAs via HMA, European Commission).
- The new EudraVigilance (human) system was launched in November 2017.
- **PRAC (**EMA's Pharmacovigilance Risk Assessment Committee) has adopted the EudraVigilance operational plan from 2018 to 2020.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EudraVigilance Operational Plan
2018
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Q4
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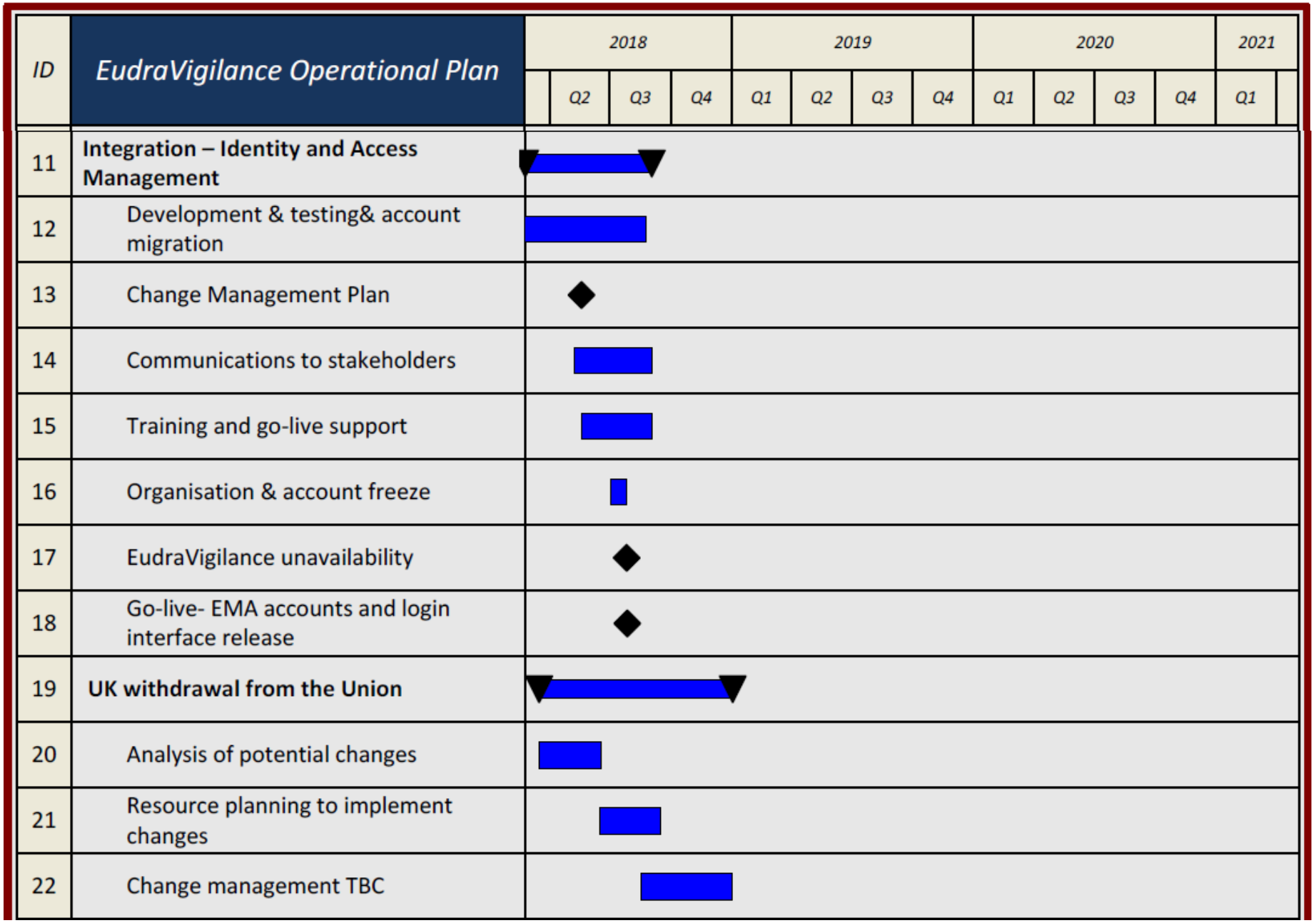
1 EudraVigilance Hypercare
2 EudraVigilance hypercare releases
3 EudraVigilance/EVDAS maintenance releases
4 EV Art57 (SD-80687) (Master File Location value selection
5 EVDAS major maintenance release
6 EV ICSR (PHV-6775) (enhanced download functionality)
7 EV/EVDAS maintenance release
8 EV/EVDAS maintenance release
TBC
9 EV/EVDAS maintenance release
10 EV/EVDAS maintenance release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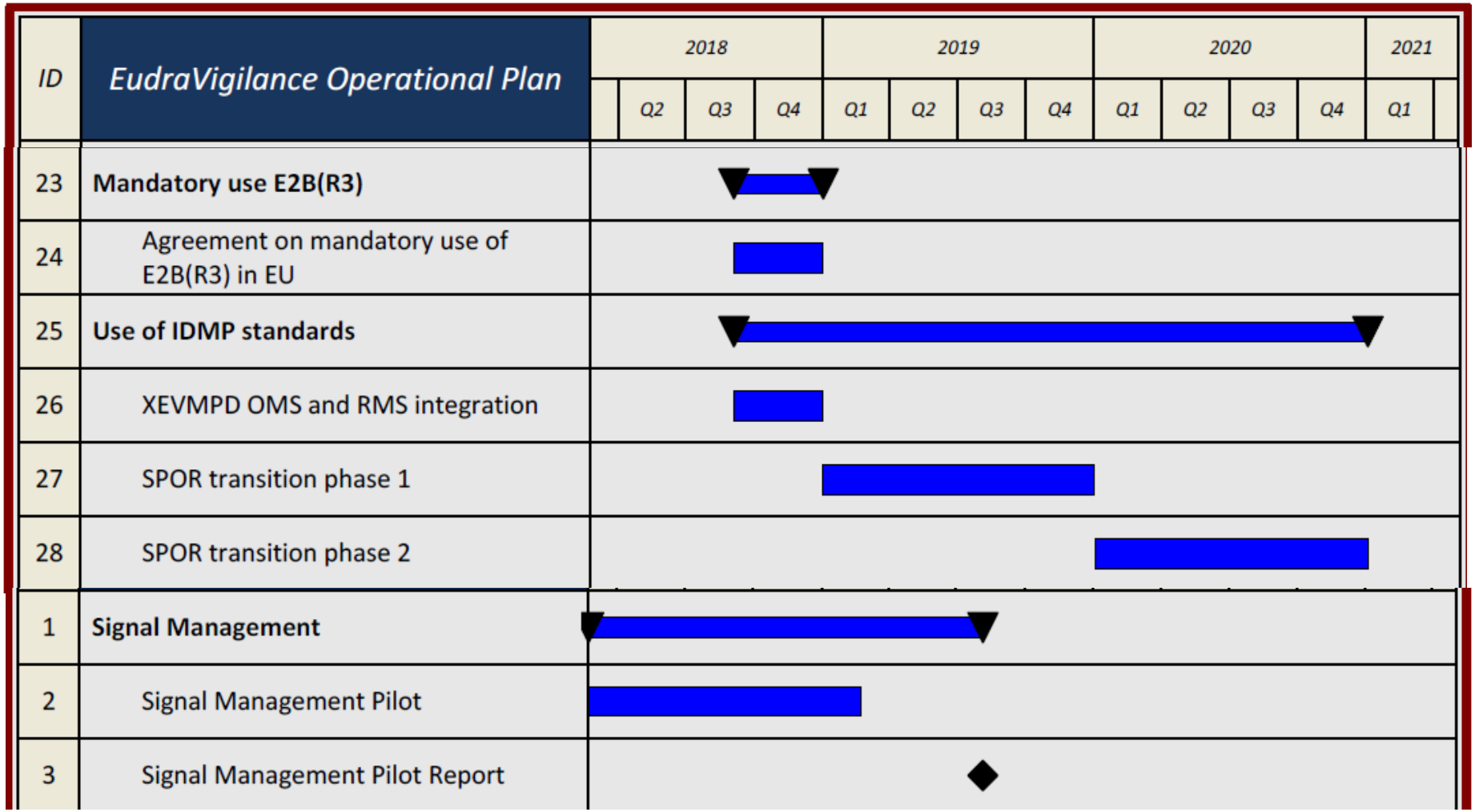
Q4
Q1
11
Integration – Identity and Access Management
12
Development & testing& account migration
13
Change Management Plan
14
Communications to stakeholders
15
Training and go-live support
16
Organisation & account freeze
17
EudraVigilance unavailability
18
Go-live- EMA accounts and login interface release
19
UK withdrawal from the Union
20
Analysis of potential changes
21
Resource planning to implement changes
22
Change management TBC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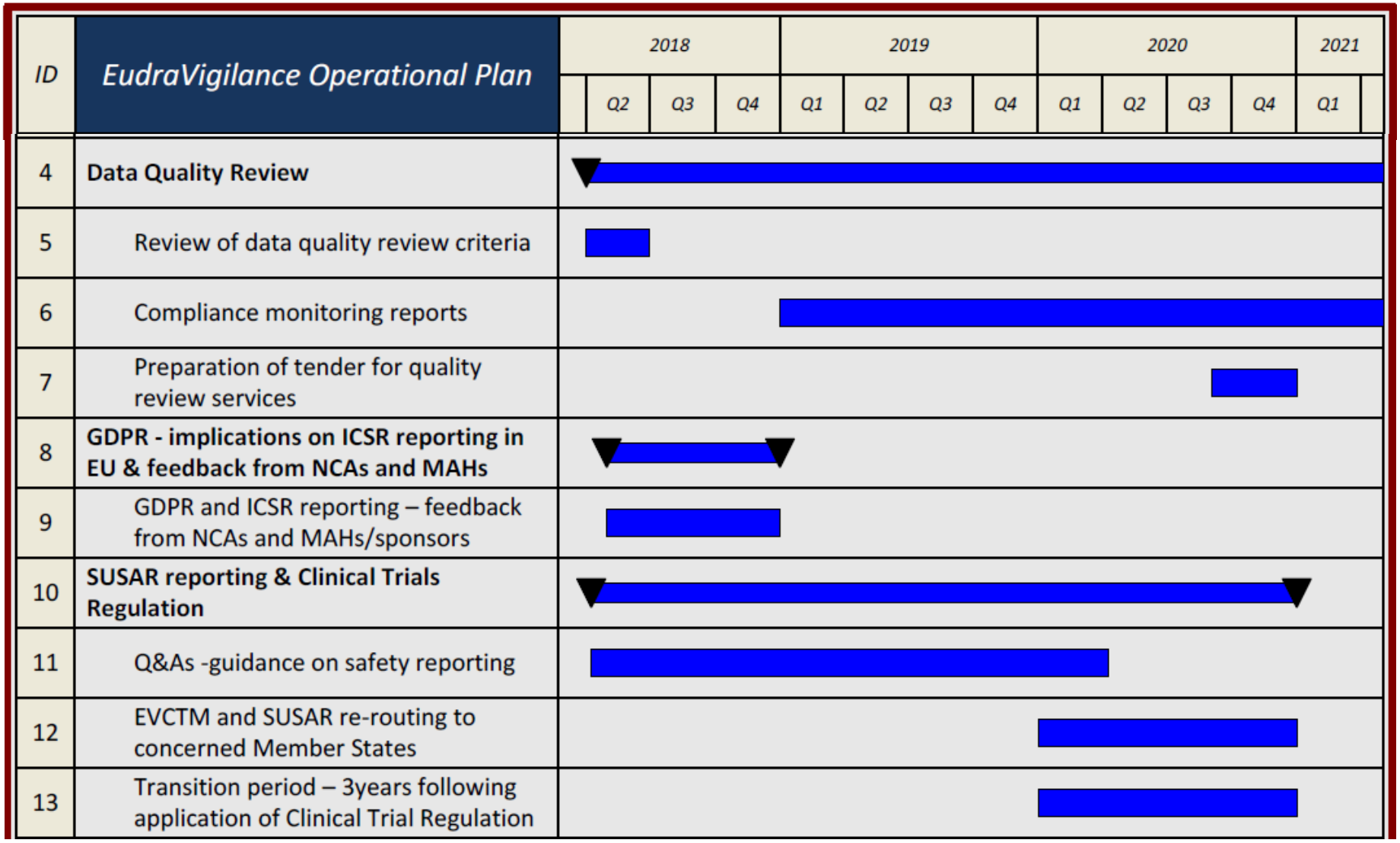
Q4
Q1
23 Mandatory use E2B(R3)
24 Agreement on mandatory use of E2B(R3) in EU
25 Use of IDMP standards
26 XEVMPD OMS and RMS integration
27 SPOR transition phase 1
28 SPOR transition phase 2
1 Signal Management
2 Signal Management Pilot
3 Signal Management Pilot Report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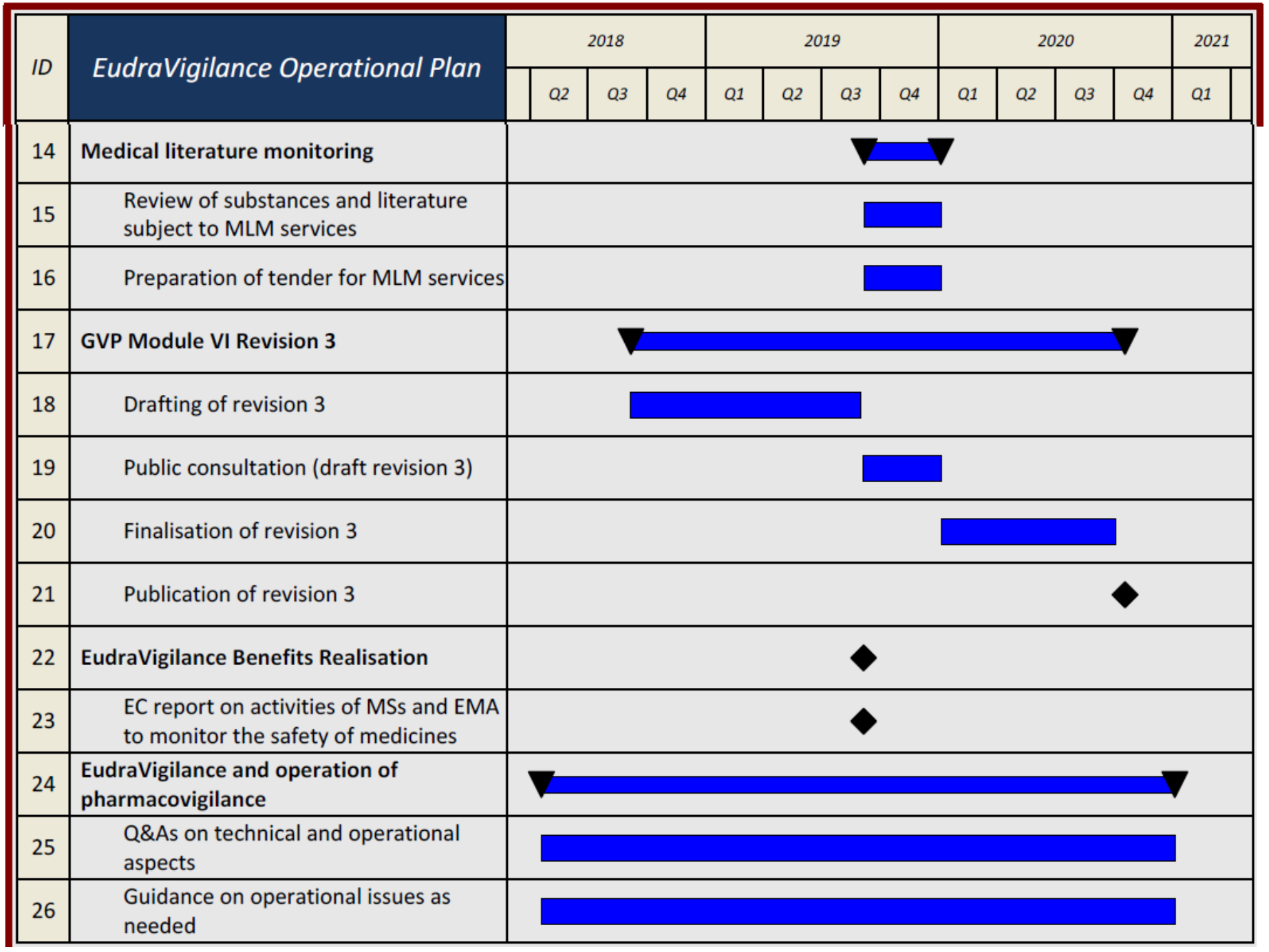
4 Data Quality Review
5 Review of data quality review criteria
6 Compliance monitoring reports
7 Preparation of tender for quality review services
8 GDPR - implications on ICSR reporting in EU & feedback from NCAs and MAHs
9 GDPR and ICSR reporting – feedback from NCAs and MAHs/sponsors
10 SUSAR reporting & Clinical Trials Regulation
11 Q&As -guidance on safety reporting
12 EVCTM and SUSAR re-routing to concerned Member States
13 Transition period – 3years following application of Clinical Trial Regulation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14 Medical literature monitoring
15 Review of substances and literature subject to MLM services
16 Preparation of tender for MLM services
17 GVP Module VI Revision 3
18 Drafting of revision 3
19 Public consultation (draft revision 3)
20 Finalisation of revision 3
21 Publication of revision 3
22 EudraVigilance Benefits Realisation
23 EC report on activities of MSs and EMA to monitor the safety of medicines
24 EudraVigilance and operation of pharmacovigilance
25 Q&As on technical and operational aspects
26 Guidance on operational issues as needed

ID	EudraVigilance Operational Plan	2018				2019				2020				2021
		Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	
1	**Training and support**													
2	Face-to-face training offerings (as per training calendar)													
3	Training videos (update or new videos)													
4	EVDAS training for NCA users													
5	EV and EVDAS support webinars (as per webinar calendar)													
6	**Stakeholder engagement and communication**													
7	Industry platform meetings on the operation of EU pharmacovigilance													
8	Annual Stakeholders forum on the pharmacovigilance legislation													
9	EV/Signal Management Information Days (as per EMA event calendar)													
10	Pharmacovigilance Newsletter (bi-annually)													

Source: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/06/WC500250477.pdf

Clinical Trials

Clinical Trials (1)

- Update at EMA MB March/June 2018:

  Development of the **auditable version is nearing completion** and is in an **intensive phase of testing**.

  - development resource will be adjusted as necessary to ensure quality
  - progress is in line with the current project plan
  - **Board agreed refinements** to the **governance, reporting and user engagement to support** the **project through the vital phases of its development**

Source: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp

Clinical Trials (2)

- To account for EMA's relocation to Amsterdam, some further **planning adjustments** may be required. These include timing of:
  - user acceptance testing of the auditable version (planned for Nov. 2018), to allow for completion of the relocation of the development data centre beforehand;
  - the audit, due to start in early 2019, will need to accommodate relocation of staff in early March 2019.
- Adjustments for these events are not currently expected to have a major impact on overall timing for the project, but will require careful management. EMA is monitoring further impact of the relocation and putting in place mitigation measures where possible, in particular in the event of loss of key EMA/developer staff.
- Clinical trial system continues to be a **priority** in EMA's Brexit preparedness business continuity plan.

Source: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp

Take-Home Message

Take-Home

- Brexit and EMA relocation will delay projects and have impact on the current workload (*check provided documents*).

- Work on Telematics Strategy 2020 – 2025 has started but might be delayed.
  Timeline for the next steps is currently reviewed.
  Industry will be consulted via the pharmaceutical industry trade groups.

- Current EU implementation roadmap will be updated for 2018 and 2019 reflecting any delay.
  Industry can contribute via their representatives in the Maintenance Groups of the Change Management Board.

Thank you very much for your attention!

Contact

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