Extended Telematics Implementation Roadmap 2018-2019

EMA Brexit preparedness Business Continuity Plan may affect programmes planning as a result of anticipated staff loss

2018: Q1, Q2, Q3, Q4
2019: Q1, Q2, Q3, Q4

Clinical Trials

CTIS (Clinical Trial Information System)

- Start of UAT7***
- Start of Audit***
- EMA MB decision on Audit***
- EC publication in OJ leading to go live in 2020***

*** Subject to re-planning adjustments due to EMA relocation related factors

eCollaboration

PSUR Rep.*
- Support for non-EU PSURs

eAF*
- NtA changes

Common Rep.*
- Mandatory use of Common Repository in CP for Veterinary products
- Mandatory use of Common Repository for EMA coordinated submissions for human products
- Support for ASMF, NAP SDA, EPITT, WS/NAP, PIMF, Ancillary
- Procedure involving NAPS

eCTD v.3.2*
- Mandatory use for all MRP submissions
- Mandatory use of eCTD for all new MAA
- Mandatory use of eCTD for all submissions in NP

eCTD v.4.0(on hold)
- Planning and preparation for the implementation

VNeeS
- Mandatory use of VNeeS for all new MAA in NP
- Mandatory use of VNeeS for all submissions in CP, DCP, MRP and NP

CESP Dataset Module & eAF (Single Submission Portal)
- Integration of H & V MAA eAFs into CESP Dataset Module (CESSP phase 1)

Data Integration

ISO IDMP Standards
- Publish ISO substance standard (11238) and ISO/TS 19844 for substances
- Normative edition of HL7V3 message (products & substances)
- HL7 FHIR IDMP design prototype

RMS*

OMS*
- MAHs (H+V) CAPs & NAPs (H); MAA (H+V) CAP; MRL applicants; Sponsors(H) CAP & NAPs
- EV organisations (supporting EV user management)
- OMS-CESP Data Set Module integration for MAA(vet/human)
- OMS Manufacturers (H+V) CAPs
- R&O integration with Art.57/xEVMPD
- OMS Manufacturers (H+V) NAPs
- Mandatory use of OMS-CESP Dataset Module for MAA (vet/human)

PMS & SMS**
- Build and test of incremental releases
- EUTCT&EV migration to SMS
- Art.57 migration to PMS
- Art 57 loop with PMS
- EUTCT&EV feedback with loop with SMS
- P&S Data Management in MDM
- EU IG Consultation
- HL7 & API Specifications

Veterinary

VMP database**
- Anticipated adoption of veterinary legislation

EV Vet3
- Design
- Planning for implementation & feasibility studies
- Build and test
- VICH messages via EV8 (subject to relocation)

Online

European medicines web portal (on hold)

Pharmacovigilance

PV-ADR*
- ADRII/EV8

PV-EVSM (on hold)

Key

- Publication of guides or legal requirement dates
- Pre-go live milestones
- System go live
- Project milestones
- Tentative milestones
- * Regular maintenance releases
- ** Original Veterinary product database project now fully under PMS and SMS scope