IDMP PMS TOM

16th October 2019

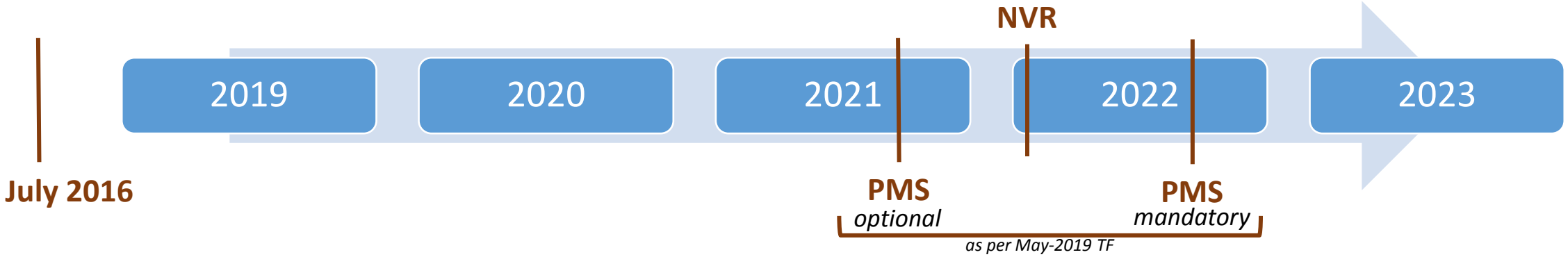
Industry Perspectives

Industry Concept Paper

- The Case for an Integrated Approach with SPOR
  - Developed by Industry Trade Associations *(endorsed by EFPIA, AESGP, MfE and EuropaBio)*
  - Sent to EMA and TMB end July – still awaiting a response
- Topics addressed
  - Need for **data quality** to serve **multiple use cases** (i.e. more than PV)
  - **Submit data once, assess by relevant CA**, store and reuse
  - Reinforce Industry support for **first TOM phase** starting at PMS go live
  - **No Industry support for current Article 57 process**
  - Promote an **end-to-end** program covering SPOR/IDMP, TOM and NVR

Setting the scene: IDMP Timelines

- Human Domain (IDMP/PMS)
  - Required in Regulation by: **July 2016**
  - IDMP/SPOR Task Force in May 2019:
    - Go Live (can submit to PMS): **Q3 2021**
    - Enforcement (must submit): **Q3 2022**
- Veterinary Domain (NVR/UPD)
  - Required in Regulation by: **January 2022**



Target Operating Model

- Current Article 57 process known to lead to data quality issues
  - Review of data post-approval, performed by EMA, based on labeling documents
- All willing to implement the TOM (EMA, NCAs, Industry)
  - Review of data during approval, performed by relevant CA, based on Module 3 (where relevant)

- Need **pragmatic** approach and **agreement** within Regulatory Network
  - Phased TOM approach
  - Limited process disruption from NCA perspective
  - Decision/endorsement by TMB before end 2019
  - TOM **Business Case** for TOM Phasing to present at **EU TMB** on **7-Nov-2019**

TOM Implementation – CESSP Approach

- CESSP Phases

Phase	Date	Dataset Module	Human	Vet
1	Q2 2020	▪ Initial MAA	▪ based on DES	▪ based on DES
2	Q4 2020	▪ Initial MAA ▪ Variation/Renewal	▪ based on DES ▪ -	▪ based on FHIR ▪ based on FHIR
3	Q3 2021	CESSP HA Extensions to support TOM		
4	Q1 2022	▪ Initial MAA ▪ Variation/Renewal	▪ based on FHIR ▪ based on FHIR	▪ based on FHIR ▪ based on FHIR
5	Q4 2022	CESSP Finalization H&V and HA Features		

  - Would bring IDMP PMS timelines to
    - Go Live (optional): **Q1 2023** at earliest
    - Enforcement (mandatory): **Q1 2024** at earliest

Feedback

- *Aggressive/Optimistic Timelines*
- *Industry Funding won't change Timelines*

TOM Implementation – EMA ‘fallback’ proposal
as we heard at the May Task Force

- **Phased** Approach
  - Start with **IDMP compliance through PMS only**, full TOM gets added later when CESSP is ready
    - IDMP go-live with PMS within announced timelines (2021-2022)
    - TOM-like assessment process is possible for CP only
  - No **project dependency** on CESSP (assuming TOM needs CESSP)
  - Assumption that TOM will be implemented #-years after (requires timeline **commitment**)
- **Initial phase details**
  - No full TOM, due to no extended CESSP
  - Partial TOM **for Centralized Procedure** (i.e. data assessment during procedure), enabled through procedure by the EMA within PMS
    - Source of truth for DQ assessment: Module 3 where applicable plus other documents incl. Labelling
  - Submit product data through PMS API (or PMS UI) directly to PMS database

Risks and benefits

	Benefits	Risks
CESSP/TOM Approach	▪ Data based on Module 3 and SmPC ▪ Assessment during Procedure for EMA ▪ Assessment during Procedure for NCAs ▪ **Full benefits of TOM at Go Live** ▪ Support additional use cases (Type IA variation simplification, ePI, FMD...)	▪ **Delay Go Live to after 2023** ▪ **Risk to disengage EMA/Industry** ▪ EU IG ready in 2020 – difficult to wait ▪ Keep XEVMPD for longer than expected ▪ Need to manage **dependencies** between PMS, NVR and CESSP, incl. governance and funding
EMA Fallback Approach	▪ Data based on Module 3 and SmPC ▪ Assessment during Procedure for EMA ▪ **Limited benefits of TOM at Go Live** ▪ Shortly abandon XEVMPD ▪ Rather **independent** start of PMS with regards to NVR and CESSP	▪ Assessment after Approval for NCAs ▪ Benefits of TOM in phased approach ▪ **Delay to implement CESSP** ▪ **Risk to disengage NCAs** ▪ **Risk to stay with Phase 1**

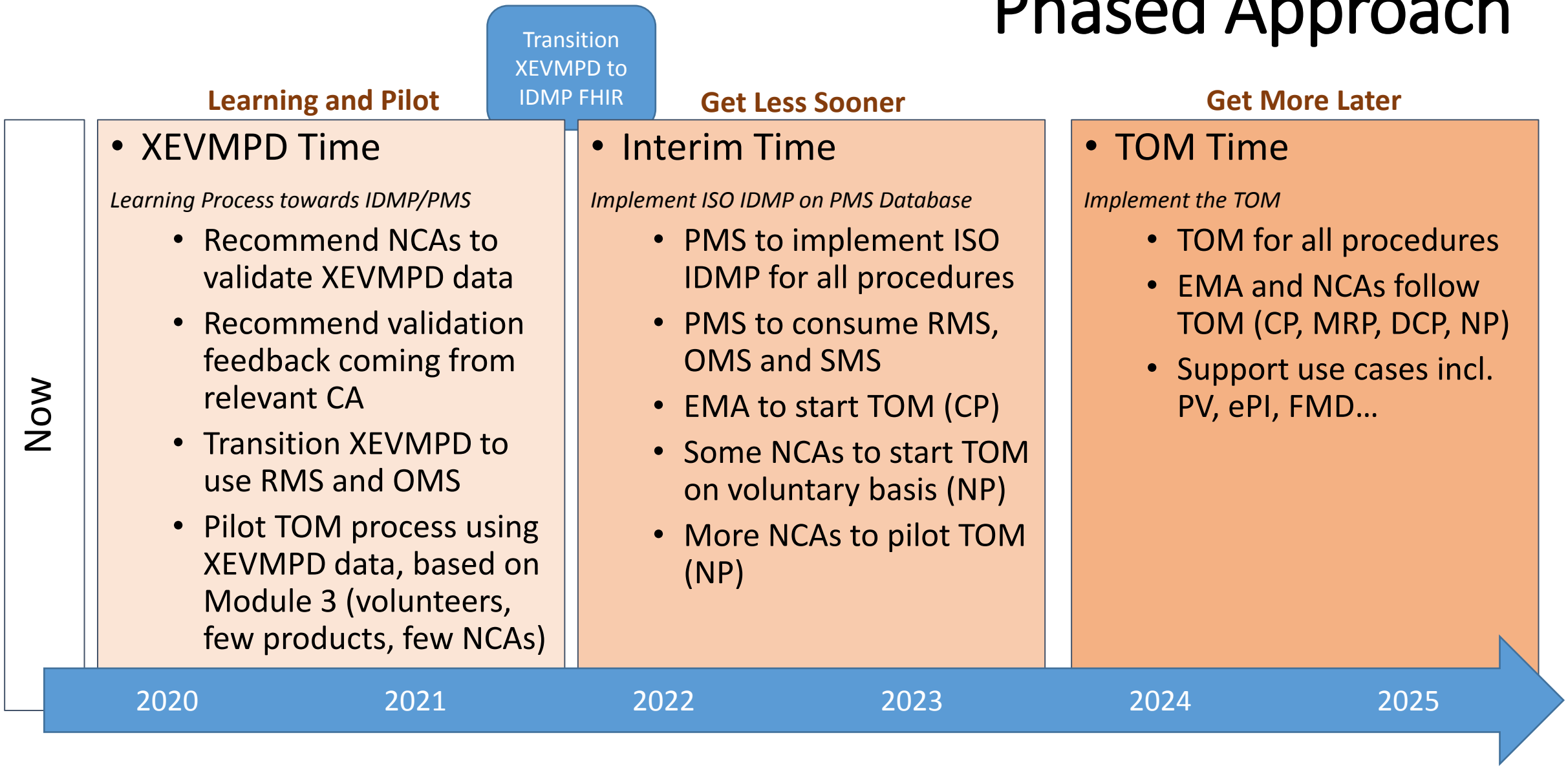
Industry Proposed Option Forward 1/2

- Pre-requisites/quick wins
  - Connect OMS with EudraGMDP for Manufacturers – needed to replace Type IA variations
- **ALL Procedure Types** (single process for Industry)
  - Industry to submit product data to PMS during procedure time
- **Centralized Procedure**
  - EMA/NCAs to review PMS data during procedure (TOM) based on PMS database
    - Start with to review PMS data and the Dossier under CP
    - Pilot data-only changes to the Dossier under CP (to replace Type IA variations)
    - Likely to require to submit and check baseline before supporting replacement of Type IA variations
- **MRP/DCP/NP**
  - Data is already in PMS at the time of submission, but will be reviewed by EMA only post-approval (to support PV use case)
  - Simplification of Type IA variations to be an incentive for NCAs to join TOM

Industry Proposed Option Forward 2/2

- Requirements/Expectations
  - Need HMA approval on the option forward
  - Need commitment from NCAs to join TOM for MRP/DCP/NP within defined timelines
- Expected Benefits
  - Better quality for PMS data (under CP at first)
  - Single process for CP/MRP/DCP/NP (at procedure time) – whatever the review process
  - As today for MRP/DCP/NP with more data
    - Including possibility for NCAs to pilot TOM
  - All progress on PMS will strengthen RMS, OMS and SMS
    - In addition to Industry willing to lead KUG efforts
  - Despite the strong & idealistic Industry Concept Paper position statements, **Industry members also want to be pragmatic and are ready to defend** the adoption of a first phase of PMS & TOM for CP only as a step towards full TOM implementation, **under certain conditions**
    - Use cases beyond PV...
    - Commitment to enable full TOM within defined timeframe

Phased Approach

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