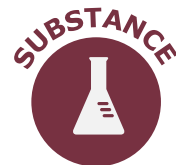




EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

S&PMS Plan & Progress - update to SPOR TF

16 October 2019





Overall approach:

- S&PMS project has been split in 7 phases
 - 2019-2023
- Every phase takes 6-9 months and consists of several work package that go live during that period.
- A UAT will be organised for every work package if impact on NCA or Industry (systems, business processes, ...)



Overview objectives of all S&PMS phases:

- **Phase 1:**
 - Limited Human prod data from Art 57 available in PMS – Phase 1A ✓
 - Product and substance data from Siamed II (CAP mgt system) available in S&PMS Ongoing
 - Substance data from EV H and EUTCT H&V available in SMS ✓
 - Functionality to manage substance data in SMS by EMA ✓
 - Functionality to feed back data from SMS to EV H and EUTCT ✓
 - API to provide access to the data in S&PMS for EMA-internal systems Ongoing
- **Phase 2⁽²⁾:**
 - Vet prod data from EudraVigilance Vet available in PMS: Delivery of the UPD DB and API components
 - API to provide access to the product (and substance) data in UPD (S&PMS) to NCAs, CESP and other consumers
- **Phase 3:**
 - Functionality to manage product data in PMS by EMA (and NCA if so desired)
 - Remaining Human prod data from Art 57 available in PMS
 - Either: SMS web portal (UI) to provide access to substance data in SMS to NCAs, CESP and other consumers
Or: Integration with EU-SRS
- **Phase 4:**
 - Provision of human & vet product data into PMS via the FHIR message by MAHs & NCAs
 - Either: SMS web portal (UI) to provide access to substance data in S&PMS to NCAs, CESP and other consumers
Or: Integration with EU-SRS
- **Phase 5:**
 - PMS UI for Industry/NCAs (optional)
- **Phase 6:**
 - (TBD: Implementation for Vet legislation and improvements for vet TOM)
- **Phase 7:**
 - Provision of product-related data to DWH, Doc repository, SAS,...

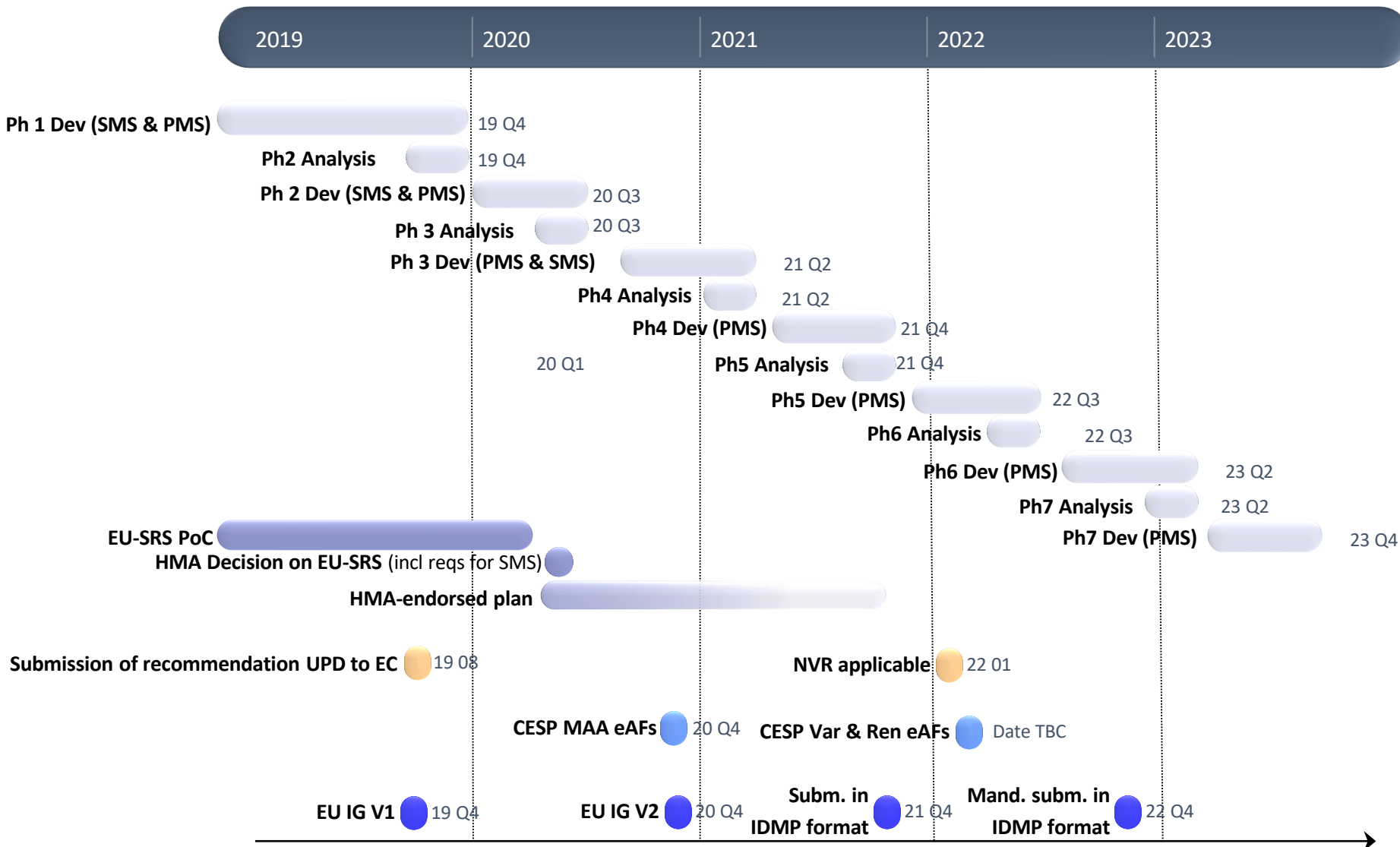
Note:

(1): Phase 1 has been approved and funded; subsequent phases are not yet approved and could still be further discussed.

(2): Assuming confirmation EMA budget by MB and NVR UPD Project Group selects PMS and its API as the UPD DB component and API component, PMS phases 2 and 3 will be switched to accommodate the UPD project and SMS phase 3 will move to phase 4.



Timeline 7 phases S&PMS:





Overview objectives of S&PMS phase work packages:

- **Package E:**
 - Substance data from EV H and EUTCT H&V available in SMS
 - Functionality to manage substance data in SMS by EMA
 - Functionality to feed back data from SMS to EV and EUTCT
- **Package D:**
 - Product and substance data from Siamed II (CAP mgt system) available in S&PMS
- **Package G:**
 - API to provide access to the data in S&PMS for EMA-internal systems



Timeline S&PMS Phase 1:

2019

Jan-May

Jun

Jul

Aug

Sep

Oct

Nov

Dec

Analysis Phase 2

Package C: Analyse Siamed data

Package D: Deliver ETL for Product and Substance Data from Siamed II to S&PMS

Package E: Deliver SMS Phase 1b

Package G: Deliver the API

Questions?



EUROPEAN MEDICINES AGENCY





Thank you for your attention

Further information

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