EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Substance, Product, Organisation and Referential (SPOR) programme timelines

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Key SPOR milestones in 2017

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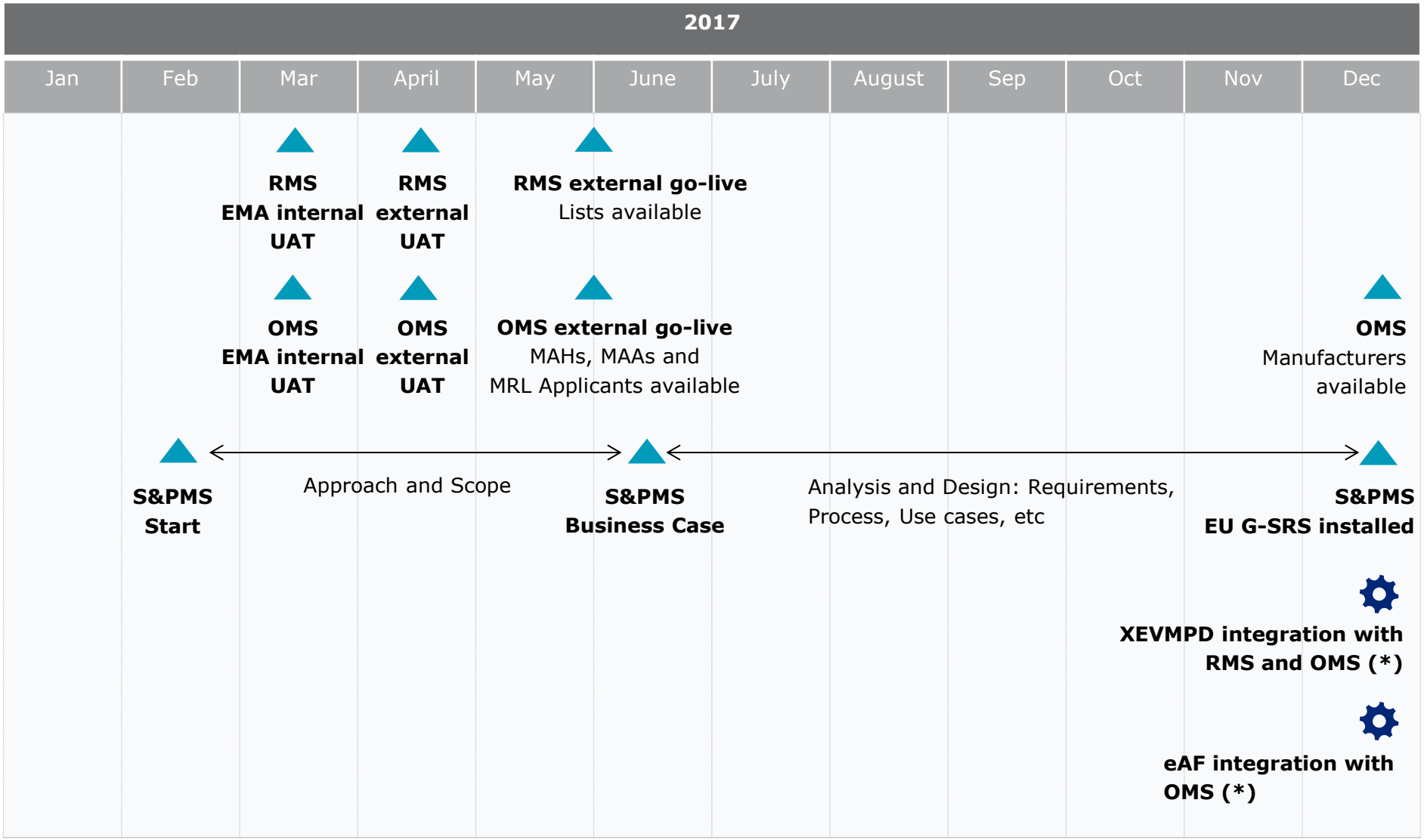

(*) – subject to XEVMPD and eAF planning

Impacts at go live of RMS and OMS

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- At RMS and OMS go-live, R & O data submission processes will continue as before - **no immediate process changes for stakeholders**
- Some changes in the current submission processes are being explored
  - consultation taking place with Art 57 IWG on Art 57 submission process (enforcement of R & O pre-registration)
- More information will be provided through SPOR Change Liaison Network to explain any applicable process changes and timings
- Any change requests submitted for R & O will be validated by EMA data stewards following the agreed process

SPOR high level timelines 2017 - 2019

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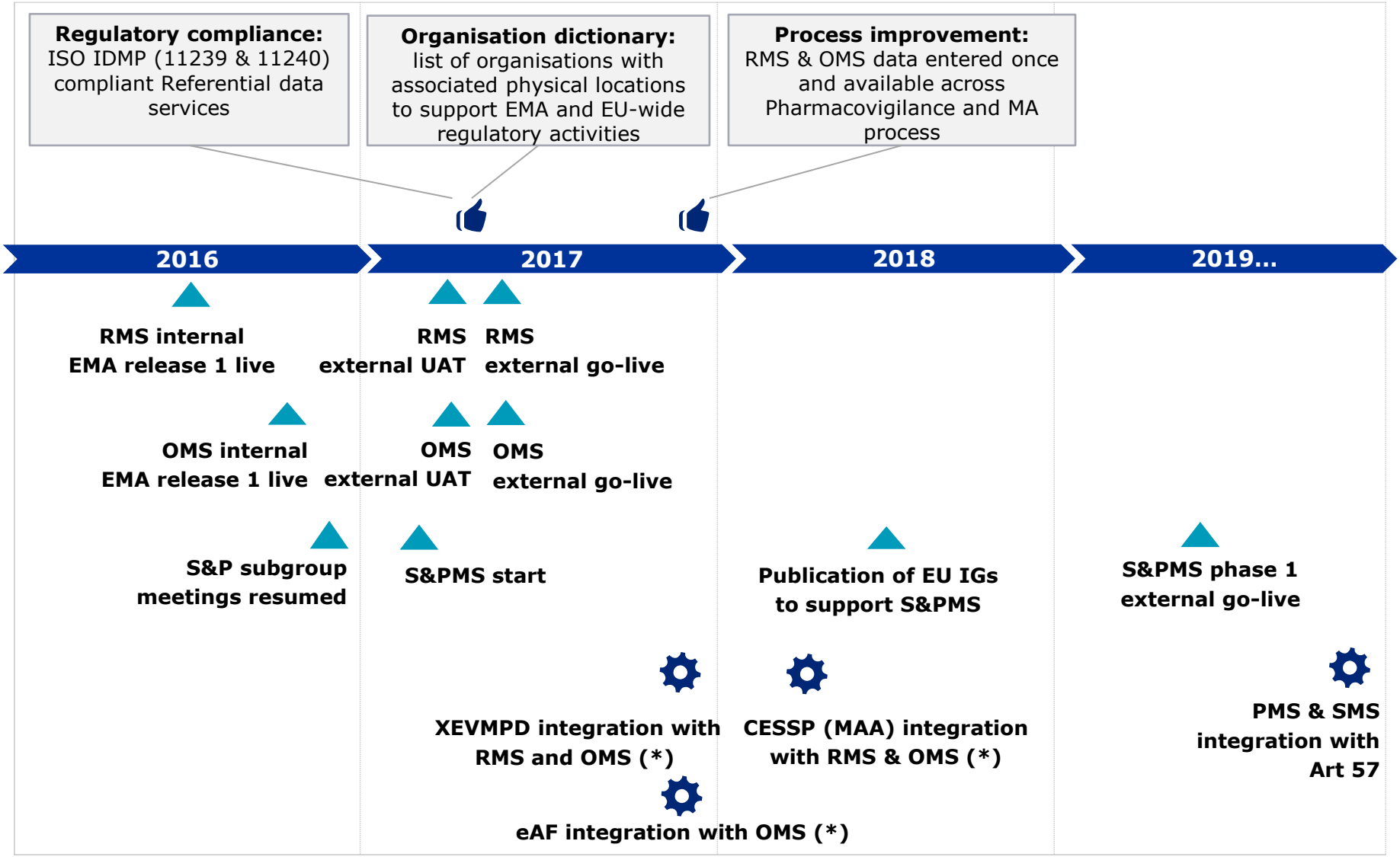
Benefits will be realised incrementally through each iteration within SPOR and through integration with other EU Telematics programmes. First benefits are expected in 2017



(*) – subject to XEVMPD, eAF, CESSP planning

NCAs and Industry involvement throughout SPOR

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