efpia
European Federation of Pharmaceutical Industries and Associations

ebe
european biopharmaceutical enterprises

Vaccines Europe
An industry for healthy lives

EU IDMP Task Force

Industry Perspective

EMA, 25th Sept 2015

EGA

AESGP

EuropaBio™
The European Association for Bioindustries

Alignment to Telematics Strategy

Industry review of the EU Telematics strategy is identifying gaps between IDMP and related programs incl….

- Iteration 2 & 4 need to align to the CT Portal & falsification of medicines respectively
- Gap in knowledge around IDMP requirements driven by E2B R3
- Need for inclusion of the Falsification of Medicines in the EU Telematics Strategy
- Need to acknowledge how longer term initiatives touch IDMP
  - Mobile applications as a medical products
- Need path forward to eLabelling/structured labelling (iteration 3)

Request – Joint development of a clear roadmap across EU telematics strategy including IDMP beyond 2017

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Industry requests from todays meeting

- Whilst expanding scope of iteration 1 could have value associated to it, this WILL slow implementation
  - Keep focused on minimum data to support identifiers in iteration 1
  - Scope iteration 3 (incl. eLabelling) now and prepare robust stakeholder model to ensure commitment and resource to deliver transformation
  - Collaboration in bridging gap between IDMP theory/XEVMPD issues and real world examples
- Alignment on process for development of EU IGs
  - Alignment on how EU IG will be developed in parallel with resolution of 188 pages of comments on ISO Guidance
  - Need to expand or compliment S&P group to create EU IG & FAQ
  - How to ensure stakeholder sign off for use that includes industry
- A clear path forward on public communication of near term MAH obligations

Key Questions on Iteration 1 Scope

- How to address a lack of collective understanding of what exactly is required to handle assignment of the required identifiers (PhPID, MPID, SID/SSID and PCID)
  - Intent to develop real life examples in order to finalise iteration 1 – ahead of next EU Task Force
- Need to keep iteration 1 scope aligned with our roadmap – XEVMPD & minimum required fields for identifiers
- Based on PhV needs industry recommends focusing on PhPID at the substance term level – example available to work with the S&P group – request for Joerg to join S&P
- Need for common understanding and alignment across regulators on data requirements including granularity of substances/indications

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