



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# ISO IDMP Implementation: Benefits, Impacts, Risks

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EMA's perspective – EU ISO IDMP Task Force meeting - 31 March 2015



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# Benefits

- Normalisation of the definition of product and substance facilitating the identification and exchange of such information in EU
- Improvement of Data Integrity enabling:
  - Reliability of data
  - Re-usability of data within the Agency and across the network
  - Avoidance of duplication of data and services
- Optimisation and simplification of data operating model and data management practices reducing silos and improving interoperability across EU systems
- Streamline, optimise and simplify regulatory processes to fulfil regulatory requirements more efficiently
- Speed up decision-making and improve communication with our stakeholders through easily accessible and highly reliable data



# Impacts

- Remapping and integration of existing systems and business processes (e.g. PhV)
- Prepare for a smooth change management within the EMA and with stakeholders
- Transfer knowledge and training to internal EMA staff and external stakeholders (e.g. communication plan to be developed within the Agency and for external stakeholders)
- Financial and resource implications



# Risks

- Engagement and commitment from all stakeholders in implementing ISO IDMP
- Lack of EU/global governance models and agreed EU operating model for SPOR data management that may not make possible a 'single' EU ISO IDMP implementation
- Delays in deliverables from International activities (e.g. developing the EU Technical specification guides for ISO IDMP)
- Difficulties in gathering information to enrich substance and product data to make it ISO IDMP compliant
- Disruption in current business during the transition period and up to when ISO IDMP/SPOR will be fully functional (e.g. business continuity)
- Inadequate resourcing to oversee and execute all SPOR projects in parallel



**Thank you**

**Question?**