



REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

ISOIDMP implementation – small agency's perspective

Estonian State Agency of Medicines

31.03.2015

About Estonian State Agency of Medicines (SAM)

SAM is one of the smallest NCAs in EU with 90 employees.

We cover marketing authorisations, clinical trials, pharmacovigilance, quality control and handling of the human and veterinary medicinal products.

Our IT staff is limited (2,5 specialists) and most of the services are outsourced.

Our annual IT budget is less than 0,5 millions euros.

Cooperation in the field of IT developments is very important for us and we are usually among the first users of the common solutions provided by the EMA or HMA.

Benefits of the ISO IDMP

Standardized master data and data exchange are mandatory for successful maintenance in all MSs and the whole network

- internationally agreed terminology, formats and standards
- data entered once, used multiple times and in several databases
- information is shared across the network of EU competent authorities and industry.

Risks for the small agencies

- Small agencies don't have enough human and financial resources and experienced experts for the implementation of ISO IDMP.
- Major changes needed in NCAs medicinal product, clinical trials and pharmacovigilance databases to implement ISO standards in very limited time.
- The roadmap of the implementation might not consider the capacities of the small NCAs and be unrealistic for us.
- As a joint agency for vet and human medicinal products we would like to have the same standards for the vet and human data.

Objectives

- Roadmap for IDMP implementation needs to be created and should be agreed by all parties including small agencies (taking into account both the size and the IT budget of the agencies).
- The exact roles and obligations needed for the implementation processes should be agreed between EMA and NCAs.
- Small agencies would like to rely on the experience and developments provided by EMA and to get support on the standardisation of data.
- More information and communication should be provided at the EU level.



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Thank you!

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