



AIFA and the ISO IDMP implementation

EU NDB March 31th, 2015

AIFA roadmap to ISO IDMP

- AIFA is currently following the internal IT roadmap in terms of meeting the 2016 deadline.
- Early March 2015 AIFA sent to EMA the database BDUF (medicinal products DB), and is currently collaborating with Ana Cochino in order to perform a detailed analysis of the data dictionary.
- AIFA performed a gap analysis regarding its actual data infrastructure versus the ISO IDMP Standard.
- This analysis and the currently approved IT roadmap will allow AIFA to respect the 2016 deadline.

Considerations

- AIFA is a regulatory Agency that, in addition to the scientific aspects, is in charge also of the medicines' price negotiation.
- Price information is not provided and not included in the ISO IDMP standard.
- AIFA will provide independently to manage information on prices, in parallel to the ISO IDMP compliance.

Thank you