EUROPEAN GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

ISO IDMP

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PATIENTS
Increasing patient access

QUALITY
Quality, safety and efficacy

VALUE
Investors in innovation

SUSTAINABILITY
160.000 jobs across Europe

PARTNERSHIP
Key partners for public health

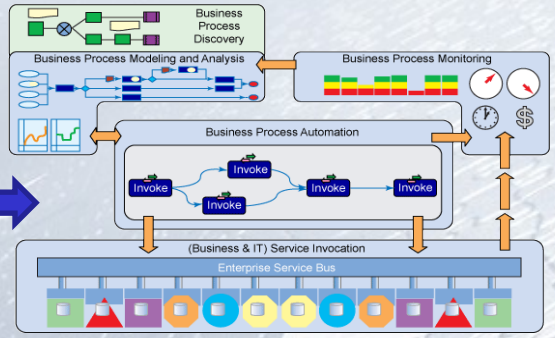


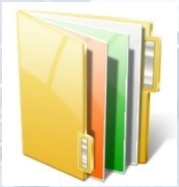


ISO IhaveaDreaMP

Making Medicines Affordable

Data is captured and submitted only once





Structured data for either RA, PcV, clinical, manufacturing information

MAA, variation, Renewal, ICSR, CTA

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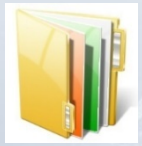
Future workflow

Application made by Industry:



- Product name
- MAH / Applicant
- Strength
- Dosage form
- ATC code
- Indications
- Packaging
- Composition
- Manufacturer
- CRO

Review by NCA/EMA

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Future workflow

- Applicant wants to submit a variation to add an additional API manufacturer
- Applicant prepares application by making reference to already registered product information. Based on unique ID of a product (ISO IDMP code), information of MAH, product name, MA-nr, procedure nr, active substance, etc. is populated
  - eAF/eCTD is populated by meta-data as registered
- Applicant adds new information by refering to structured data: ID of substance, ID of manufacturer
  - Application is submitted to ID´s of involved Agencies based on registrations in database
- Data is reviewed and approved by Authority
- Data is updated in Authority / EU database
- Data can be re-used by applicant for next application

Organisational point of view

- Terms of Reference / Scope
  - Alignment across projects:
    - *eCTD NMV*
    - *eAF*
    - *Gateway/CESP delivery*
    - *CTA*
    - *Structured labelling*
    - *xEVMPD*

Organisational point of view

- Roles and responsibilities / Stakeholders
  - Set-up, communication, responsibilities and structure of subgroups
- NCA and Vendor involvement in ISO IDMP
  - NCA´s to be involved in review and approval of regulatory data during regulatory review
- Change control process
  - To be implemented and followed

ISO IDMP implementation

- GAP analysis xEVMPD to ISO IDMP / Roadmap
  - Implementation date is July 2016 for EMA, NCA and Industry => need information on the next steps!
  - Phased approach for implementation
  - Reduced parallel activities (i.e. xEVMPD)
  - Migration of data
  - Re-use / restructure of data
  - Set-up of CV´s

- Substances *- Organisations*

- Prioritise work *- One system in EU / World*

ISO IDMP implementation

- Key learnings of xEVMPD
- Use cases of ISO IDMP
- Scope definition of individual data fields
- Detailed process description required
  - Validation of data
- Use of Telematics tools (Gateway / EVweb)
- Timelines for implementation / setting priorities together

Conclusion

- Industry needs information on what is to be expected from July 2016 and future
  - July 2016 is now
- All stakeholders (Agencies, Industry, Vendors) require sufficient time for implementation
- Scope of ISO IDMP implementation to be collaboratively agreed => agreed, realistic roadmap
- Define data requirements and data use
- Room for improvement for re-use of data in the complex EU process, which is benefit for Industry, NCA´s, EMA and patient