efpia
European Federation of Pharmaceutical Industries and Associations

ebe
european biopharmaceutical enterprises

Vaccines Europe
An industry for healthy lives

IDMP IWG

SPOR benefits

June 2016

medicines for europe
better access. better health.

AESGP

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

EuropaBio™
The European Association for Bioindustries

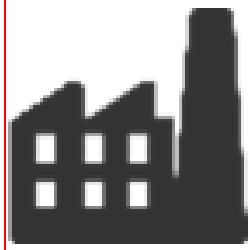
Key Messages

- Industry is committed to SPOR and IDMP
- Specific business cases bringing joint benefits to both Industry and NCAs will transform this commitment to action:

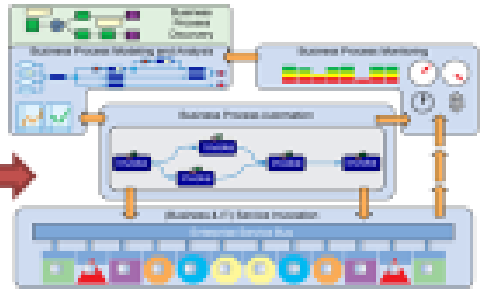
    1. Optimising Variations Process
    2. Pharmacovigilance (PSUR/ICSR)
    3. Falsified Medicines Directive
    4. Article 57 Database replacement

- All stakeholders need to continue to work together for IDMP/SPOR to be successful

Submission of regulatory data
ISO IhaveaDreaMP

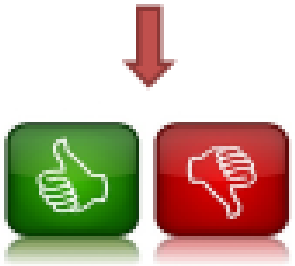


RA data
PcV data
Quality data
Clinical data



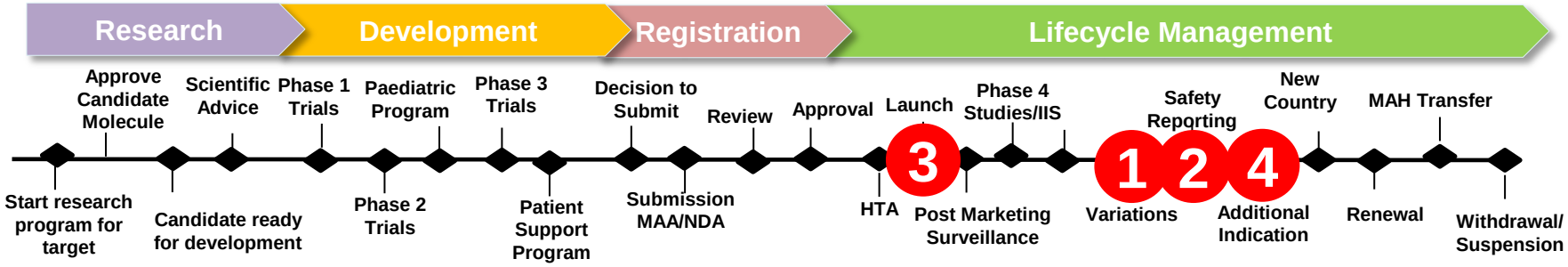
Data is captured and submitted only once

MAA,
variation,
Renewal,
ICSR,
CTA



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Four Specific Business Cases



1. Optimising Variations Process
2. Pharmacovigilance (PSUR/ICSR)
3. Falsified Medicines Directive
4. Article 57 Database replacement

1. Optimising Variations Process

- Certain Type IA Variations can be “Data Only” using SPOR/IMDP e.g. ‘organisations’

- This would save thousands of variation submissions a year in the EU and **greatly reduce the administrative burden** for NCAs and Industry

- There is already precedent for Regulatory Data changes outside the scope of the Common Technical Document e.g. QPPV Change in Art. 57 Database from 1st February 2016

Benefits of ‘Organisation’ Related changes as “Data Only”

Industry Benefits

- No need for variation submission preparation
- e.g. Cover Letter, eAF, Publishing, Submission through gateway

NCA Benefits

- No need for adminstrative processing of submission
- Notification of approval via system

Example: potential reduction of administrative burden

Change	Procedures affected	No. of MAs affected
Name change of a manufacturer	265 DCPs	4.402
MAH address change – affiliate Italy	230 DCPs	~ 2.000
MAH address change – EU Headquarters	591 DCPs + CPs	~ 1.340
Bulk manufacturer address change – street re-named	~ 280 DCPs	~ 3.000

Classifying “Data Only” Regulatory Changes and Type IA Variations for Optimisation

	Data only	Data & Document	Document Only
1. Non-regulated information	e.g. Marketing status		e.g. Package dimensions
2. Regulated information with no scientific review	e.g. QPPV	e.g. Marketing Authorisation Holder	e.g. Manufacturer name Change
3. Regulated information with scientific review		e.g. Therapeutic Indication change	
	Future state for certain data attributes **e.g. IDMP/SPOR only**	**Future state submission with IDMP process** **e.g. eCTD with IDMP Data**	**Current state submissions** **e.g. eCTD/NeES only**

A draft process map and data flow was developed during the IDMP Process Workshop

Iteration 1 Manufacturer Information

Industry willing to provide following information about manufacturing sites under the assumption that future administrative variations (e.g. name and address change) can be handled in the SPOR database (as per QPPV change):

- Active Substance manufacturer
- Bulk manufacturer
- Primary packager
- Secondary packager
- Testing site
- Batch release site
- Establish link to EudraGMDP

2. Pharmacovigilance (PSUR/ICSR)

- Clear pharmacovigilance business cases could not be identified for breaking down the medicinal product name, certain clinical particulars, risk of shortage of supply and packaging component materials

- However, we do see potential value in the following fields:
  - Paediatric Indication
  - MA :Date of First Authorization
  - Marketing Information: Marketing Status/Start and Stop Dates
  - Excipients
- Indication case also needs to be considered closely from a pharmacovigilance business case perspective

- To conclude this conversation we propose a joint “workshop style” meeting of Industry/NCA IDMP and Pharmacovigilance Colleagues

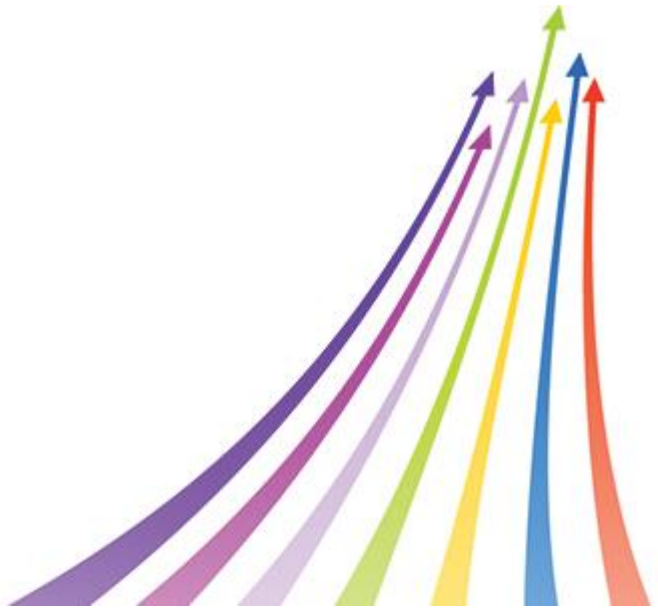
3. Falsified Medicines Directive

- Integration of SPOR with the EMVS system is an excellent example of leveraging master data and avoiding duplication
- Reinforces SPOR as the authoritative source for registered product information
- Implementation approach can support quality and completeness of Product data (further discussion on this during FMD update)
- Great example of industry and agency working together to find the right solution to a complex problem
- Potential future business cases supported by this integration
  - Leverage FMD data to understand marketed status of products
  - PV: ability for patients/HCPs to provide barcode information to link adverse event reports to specific pack
  - eLabeling

4. Replacement of Article 57 Database with SPOR

- The Regulator's business case for replacing Article 57 with the SPOR system is well understood
- Many companies are undergoing similar transitions to prepare for SPOR with activities including:
  - Mapping, translation and maintenance of Referentials and Organizations in internal databases such as SAP, RIM, PV, CT, MDM
  - Setting up cross-functional data governance structures including data stewardship
  - Process re-engineering to ensure high data quality with maximum efficiency
  - Significant Data Collection and Remediation Effort
  - Potential large technology investments (upgrades of existing systems or MDM)

Way Forward



A New Approach to the EU IDMP TF: Same Energy, Faster Progress

- Organize a face to face meeting with small group of Industry and Regulators to finalize process and data detailed requirements
- Focused sessions of small teams working on specific topics will accelerate our transition to IDMP/SPOR
- Open communication of project risks, mitigations and decisions to be resolved together
- Establish SMART collective objectives with dedicated resources e.g. Finalise Iteration 1 Scope in a workshop, identifying quick wins and mapping to business cases
- Taskforce should be used only for status reporting in conjunction with Communications Team
- Fewer weekly TCs with more objective-focused communication