Regulatory Information
Future trends and vision

RESEARCH SEMINAR – an update of ongoing regulatory science projects

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One Global “Research” Project
Regulatory Affairs 1.0
Regulatory Affairs 2.0

GPS

Electric Engine

Automatic Software Upgrades

Wireless
Meet the Patient
Patients are becoming more than just passive recipients of therapies...
Meet the Stakeholders
Pharmaceutical or IT Company?

Pharmaceutical Company

- RIMS
- Labelling Mgmt
- eSubmission
- EDMS

Business systems

- ERP
- Safety
- Change Control
- CTMS

EMA

<table>
<thead>
<tr>
<th>System</th>
<th>Manage (create, update, store)</th>
<th>Volumes of records (&quot;000s)</th>
<th>Human / Vet</th>
</tr>
</thead>
<tbody>
<tr>
<td>EudraVigilance 7</td>
<td>* * * *</td>
<td>39</td>
<td>5.4</td>
</tr>
<tr>
<td>EudraCT B</td>
<td>* * * *</td>
<td>51</td>
<td>484</td>
</tr>
<tr>
<td>SARPED</td>
<td>* * * *</td>
<td>&gt;0.8</td>
<td>&gt;3.6</td>
</tr>
<tr>
<td>ECO</td>
<td>* * * *</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>SAP</td>
<td>* * * *</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>EU/CT</td>
<td>* * * *</td>
<td>29</td>
<td>N/A</td>
</tr>
<tr>
<td>ESVAC</td>
<td>* * * *</td>
<td>10.5</td>
<td>8.7</td>
</tr>
<tr>
<td>EudraVigilance (Vet)</td>
<td>* * * *</td>
<td>29</td>
<td>11</td>
</tr>
<tr>
<td>EudraSMP</td>
<td>* * * *</td>
<td>&gt;18</td>
<td>N/A</td>
</tr>
<tr>
<td>Orphan Drugs</td>
<td>* * * *</td>
<td>&gt;4.3</td>
<td>&gt;2.7</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>* * * *</td>
<td>19</td>
<td>0.4</td>
</tr>
<tr>
<td>Scientific Advice</td>
<td>* * * *</td>
<td>&gt;4.9</td>
<td>&gt;4.9</td>
</tr>
<tr>
<td>All Other Systems</td>
<td></td>
<td>Over 40 applications</td>
<td>N/A</td>
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</tbody>
</table>

52 applications!
The bulk of regulated information is still found in unstructured format... Is the operating model viable?
And we still can’t agree on standardisation initiatives

Classification of clinical particulars: Amoebic dysentery (100000016648)

Classification of medicinal product: Mepenzolate (A03AB12)

Classification of clinical particulars: Amoebic dysentery (387754006)

Classification of medicinal product: Mepenzolate (25990-43-6)
Maybe we need to go digital
Navigating the Regulatory Ecosystem requires firm corporate strategy with direct input from Regulatory Affairs....


- **Goal 1:** Supporting Regulatory Operations
  - Electronic Submission Gateway (ESG)

- **Goal 2:** Electronic Regulatory Submissions
  - eCTD enforcement

- **Goal 3:** Data Standards
  - CDISC, IDMP, ICH E2B(R3)

Increasing regulatory requirements have fostered a silo based application landscape. This landscape doesn’t support true end-to-end regulatory and safety activities and the changes within the regulatory environment (e.g., transparency)

A growing demand for data sharing (across applications) and oversight (internal & external) suggests a revision of the Regulatory Architecture.
ISO, EMA and the FDA are pushing for Digital Regulatory Information....

The regulators strategies point toward a full standardized and integrated data environment.

Business cases are many but among others to:

• Improve pharmacovigilance
• Ensure the possibility of trending across the different submission, as well as between the regulators
• Minimise the duplication of data entry
• Ensure standardised ways of reporting and working
“The electric light did not come from the continuous improvement of candles”
ISO IDMP Supports Promotes

Data standardisation

Health Authority Interoperability
Promoting interoperability – removing ambiguity

Organizational data e.g. 2.3.S.2, 3.2.S.2.1

EMA IDMP Initiative SPOR

xEVMPD + CTD information(e.g. 3.2.P.7)
### 3.2.P.1 Description and Composition of the Drug Product (name, dosage form)

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount pr. unit</th>
<th>Function</th>
<th>Quality Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>200 mg</td>
<td>Drug Substance</td>
<td>Ph.Eur, USP-NF</td>
</tr>
</tbody>
</table>

**ISO 11615**
- Substance ID
  - Specified Substance 3 ID

**Specified Substance**
- Grade: 
  - Grade Type: CD
  - Grade Name: ST
  - Grade Reference Source: ST

**Strength**
- Strength Range (Presentation): R(T)D=0,5-25)
- Strength Range Concentration: R(T)C=0,3-25%
- Measurement Form: ST [5, 11]
- Density: CD [8, 7]
Type IA variations as “Data Only”

- Once the Article 57 database is considered functional, marketing-authorisation holders may notify EMA of administrative changes concerning the **qualified person for pharmacovigilance** (QPPV) and location of the **pharmacovigilance system master file** (PSMF) through the Article 57 database only, without the need to submit a type IA\textsubscript{IN} variation to vary the marketing authorisation.

Data Driven variations may drive overall cost down both for industry and regulators.....
Transition to Tesla

The PSUR Repository is mandatory as of 13 June 2016
Regulatory focus areas beyond 2017....

1. Regulatory IT spending may increase due to additional requirements for data driven submissions & standardisation. Opportunities for operational efficiency at the respective agencies & pharmaceutical companies may however “absorb” this cost (i.e. variation fee structure may change).

2. Through “innovative” Regulatory Strategies push the boundaries for inclusion of additional data to support new or existing products

3. Ensure active participation in relevant Regulatory communities (IRISS, ISO, ICH etc.) to drive and support global Regulatory initiatives. Proactively shape the future of regulatory affairs.
Thank You!

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