efpia
European Federation of Pharmaceutical Industries and Associations

ebe
european biopharmaceutical enterprises

Vaccines Europe
An industry for healthy lives

EU IDMP Task Force 1st meeting

Industry Perspective

EMA, 31st March 2015

EGA

AESGP

EuropaBio™
The European Association for Bioindustries

Presentation Overview

- Strategic Objectives, and Requirements for Operational Excellence
- Industry Readiness – survey data
- Example Use Cases for IDMP
- Industry Analysis of IDMP
- Learning from XEVMPD
- Conclusions

Where do we stand today?

- Collaboration and clear strategic goals must come first
  - Industry values the **cross stakeholder engagements** including NCA's, vendors and EC
  - Industry is mobilising for IDMP but without **clear use cases** beyond XEVMPD this will remain slow
  - **Phased implementation** is necessary given breadth of potential uses and data elements

- 2016 deadline is acknowledged as unrealistic
  - EU IDMP Task Force must define a **clear scope** before assessing timeline

- Need to identify the appropriate activities through 2015 to deliver the IDMP roadmap this year

efpia

What is industry looking to achieve from the EU IDMP Task Force?

Slides shared at Jan EU TMB Meeting at EMA

European Federation of Pharmaceutical Industries and Associations
www.efpia.eu

Strategic Objectives

- Forward thinking / future proof: to collaboratively **develop and implement a comprehensive and sustainable IT strategy** that:
  - Supports the evolving and dynamic regulatory framework and science,
  - Adds value for European regulators network, industry and patients, and
  - Promotes and drives excellence with product information, specifically data standards, source, requirements, use, security and access.
- IT Strategy to be driven by Operational Excellence and close regulatory-industry cooperation

Strategic Objectives

- **Operational Excellence**: established through **close partnership** between regulators, and industry
  - Strong expertise: opportunity to gain from stakeholders' experience
  - Shared needs: information suppliers, users & consumers
- **Strategy**: advocate for early stakeholders' consultation at concept stage, and on strategic documents including Road Map (e.g. pending IDMP Road Map)
- **Execution**: enable through feedback and expertise regarding content, function and feasibility (e.g. Art. 57)

Requirements for Operational Excellence

- One time provision of data to agreed common standards “Capture once, use many”
- Quality controlled structured data* as part of the assessment process, when required
- International harmonisation and standards development
  - Ensure industry ability to maintain a global scientific understanding of a product and to consistently communicate
- Data security and integrity should be optimised to prevent unlawful breaches of the Database
  - Protection of PPD and CCI across the integrated system should be ensured since some of the incorporated data will be public while others will remain confidential

** ‘Structured data’: Information captured as individual fields and validated to a specified data model*

efpia

Current IT Environment Analysis

- Emphasis on stand alone and single systems (vs common data & information) leading to:
  - Repeated data capture by different authorities or bodies and multiple reporting of the same or overlapping product data
    - Ever increasing demand to submit structured data whilst industry is expected to maintain the same information in the dossier
    - National specificities
  - Poor data quality
- Regulatory processes and legislation typically oriented around documents (SmPC, protocol) whilst clinical operations have transitioned to structured data for operational/quality benefits
- Increased use in vendors providing business services and related systems

=> Data integration/master data technologies are breaking down system barriers but these take time and depend on appropriate data standards

How ready is industry for ISO IDMP?

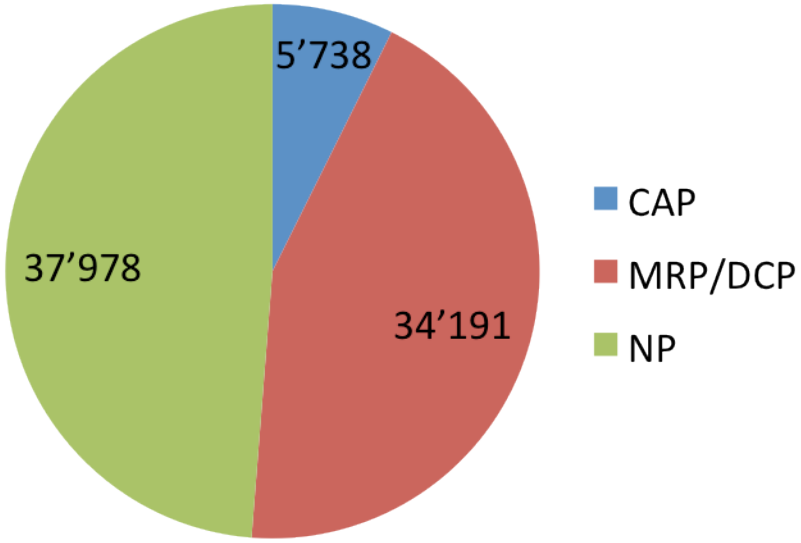
Survey Data

European Federation of Pharmaceutical Industries and Associations

www.efpia.eu

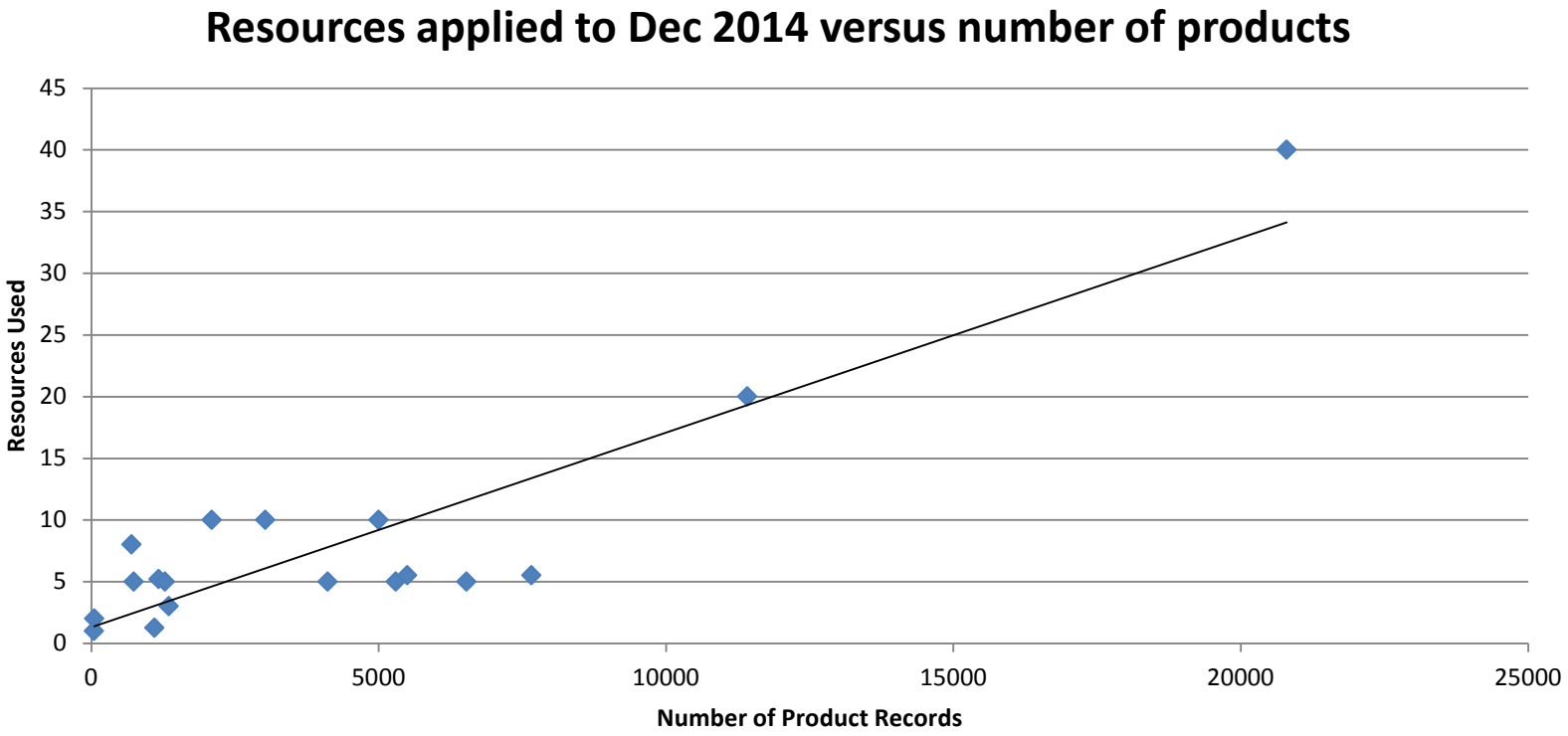
Key points from XEVMPD/IDMP survey*

- Run by IRISS in March 2015
- 18 mainly large Pharma companies replied
  - With a total number of products: 77’907



*Taken from overall IRISS survey results provided by Andrew Marr

Key points from XEVMPD/IDMP survey*



* Average capital spent to Dec 2014: 250'000 Euros

*Taken from overall IRISS survey results provided by Andrew Marr

Key points from XEVMPD/IDMP survey*

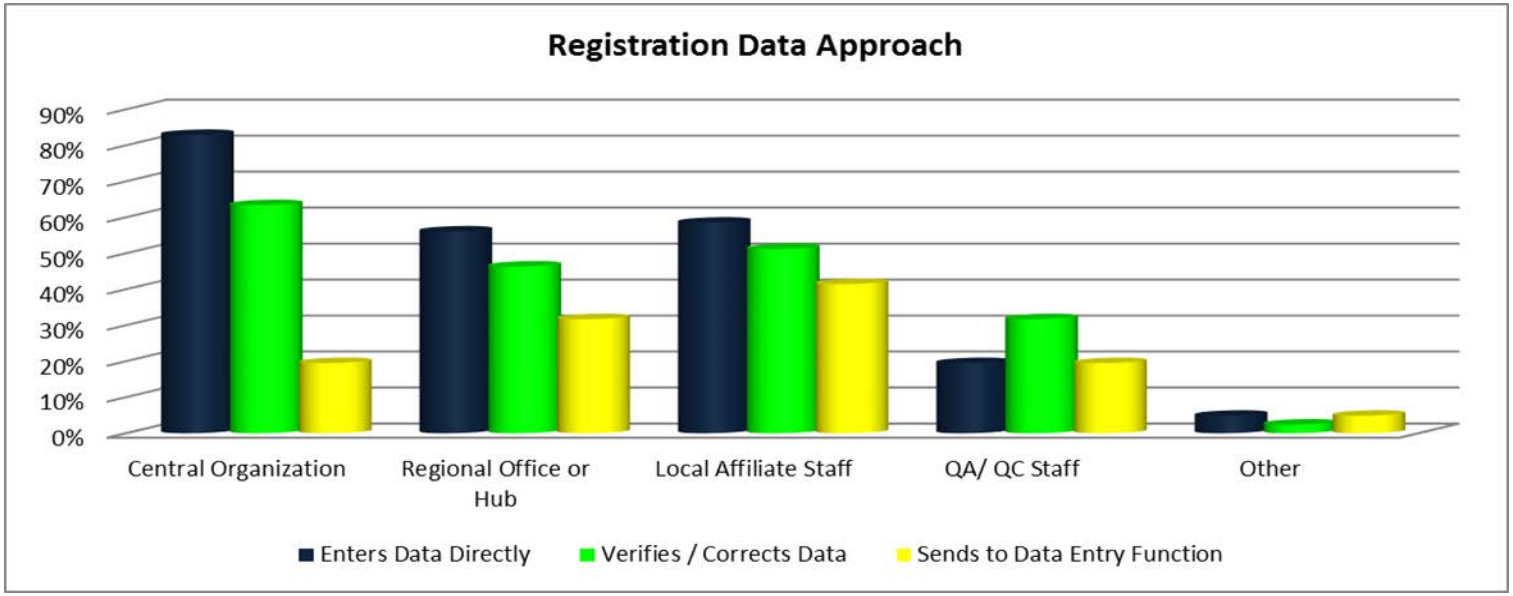
- Submission method: mainly EV Web (13/18 companies)
- Majority of companies is using 2 or 3 systems in XEVMPD
- 17/18 companies have or are forming IDMP project team
- Funding for mid-2016:
  - only 4/18 companies funded
  - 10 building the business case
  - 4 not in a position to progress at present
- Average expectation of IDMP project duration: 2-3 years
  - With the recent 'Phased implementation' signals from EMA we will adjust the project time line according to formal communication from EMA.

efpia

*Taken from overall IRISS survey results provided by Andrew Marr

Key points from survey analysis*

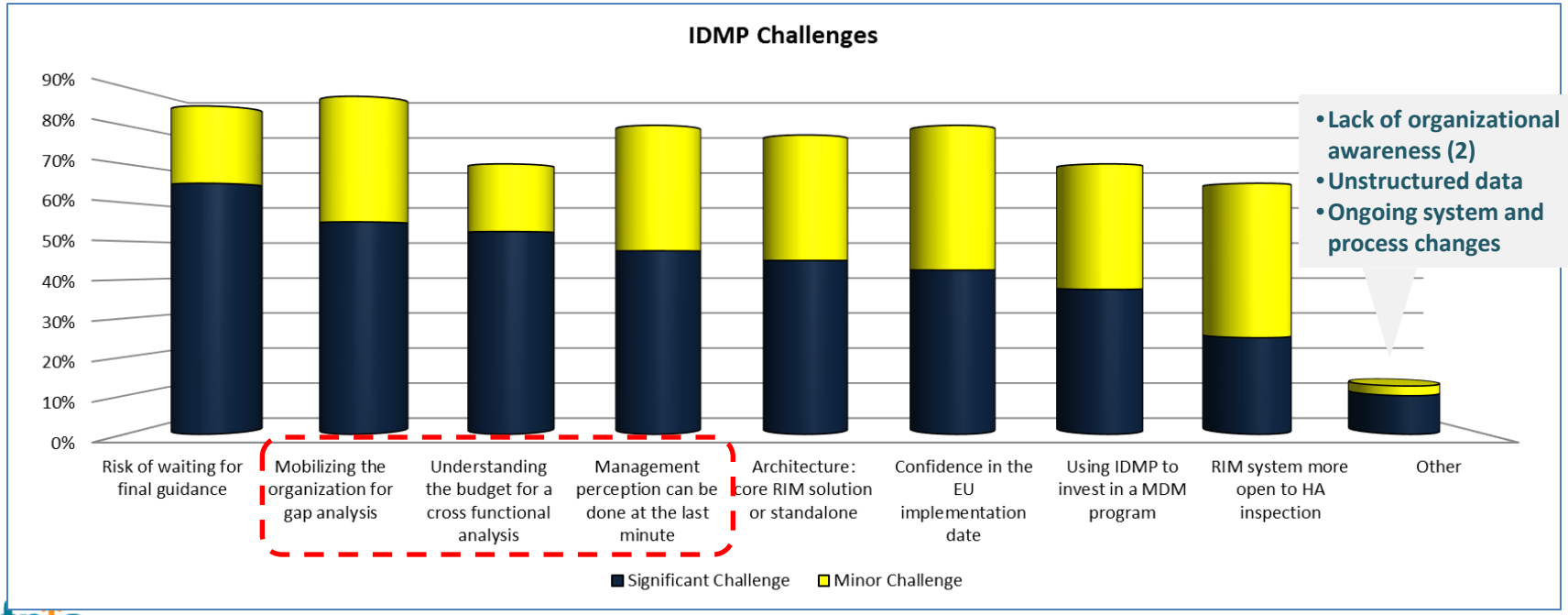
- 41 companies included in the report
  - 54% have products in 100 or more countries
- Organizational approach to product registration data entry and verification
  - Most companies have a hybrid data entry model with data entry occurring at more than one level e.g. Central + Regional + Local
  - 12 companies have a “Central only” model



*source: Report 2014 from Gens & Associates

Key points from survey analysis*

- Top IDMP challenges:
  - External challenges (HA guidance and commitment) are almost equal to the perceived internal challenges (mobilization, management perceptions and budget)
  - Internal challenges suggest an educational and awareness activity should be part of each company's IDMP strategy



*source: Report 2014 from Gens & Associates

What are the potential applications of ISO IDMP beyond todays XEVMPD?

European Federation of Pharmaceutical Industries and Associations
www.efpia.eu

Possible Use Cases for IDMP

These sample use cases are intended to reflect the variety of potential uses of IDMP. They are intended to illustrate the need to define intended use of the data to enable successful implementation.

IDMP is seen as a tool, the question these use cases seek to answer is where should the tool be applied first and to what intended effect?

Examples include:

- **PhV**
- **Product profiling**
- **Processes and efficiencies**

Pharmacovigilance Use Case

- The patient or HCP scans a product to report an adverse event and the app knows the exact product and the patient has access to the most current product information and aggregate safety data. Reports are passed to the regulator where by querying IDMP data they are forwarded automatically to the responsible MAH for processing

- Key product data used in the case management process is coded using IDMP (*Co-morbidity, Undesirable effects, Interactant, Contra-indication, Indication*). The case processing system is able to use the data to automate steps in the case assessment

- Surveillance scientists are able to use newly coded IDMP product data across all medicinal products to run systematic analysis across AE's to find new types of signals in the data e.g. … *what coded product data could be used and is not already available in SPL? Supply mfg site for a particular substance,…*

Product Profiling

- An HCP is prescribing product to a patient and the system uses granular data on the properties of a product to check for compatibility with the patients profile e.g.
  - Products without a particular ingredient e.g. lactose
  - Auto checking of contra-indications/co-morbidity
- A regulator approves changes to a product label, this information is automatically published to an electronic service (e.g DailyMed) so that is can be consumed immediately by any service provider as a trusted and authoritative source

Processes and efficiencies

- For specific changes to the profile of an approved medicine the updates are communicated via an IDMP message e.g. change in excipient supplier details, contact persons, therefore removing maintenance of this data from documents in the dossier

- Consistent identification of the legal status of supply for a product using IDMP can be joined together with actual supply chain data

ISO IDMP Standards Data Elements – An Initial Industry Analysis

European Federation of Pharmaceutical Industries and Associations

www.efpia.eu

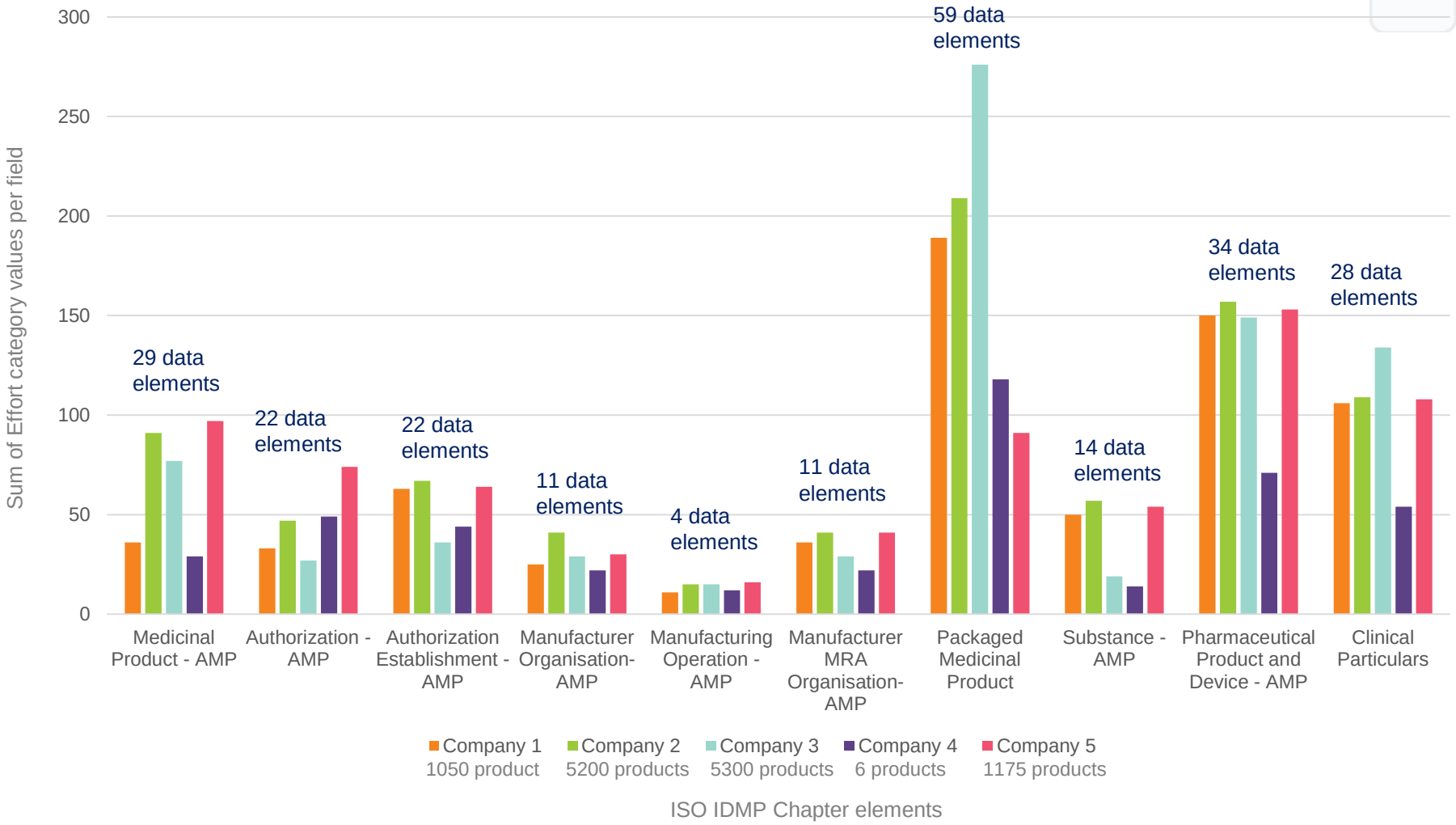
Method

- Analysis performed per data element from the ISO IDMP standards, by 5 Companies
  - To establish where the data has been located
  - To identify Industry's pain points

Effort level	Categorisation Rules
1	System (or excel) - Single Source which can be mapped to IDMP
2	System (or excel) - Single source which requires significant effort to format data for mapping to IDMP
3	System (or excel) - available in multiple systems requiring harmonisation, or with poor data quality
4	Unstructured Data (Documentation)
5	Location not found; substantial manual effort to retrieve information

efpia

Overview of Industry Effort Calculations



Effort calculatons averaged per field

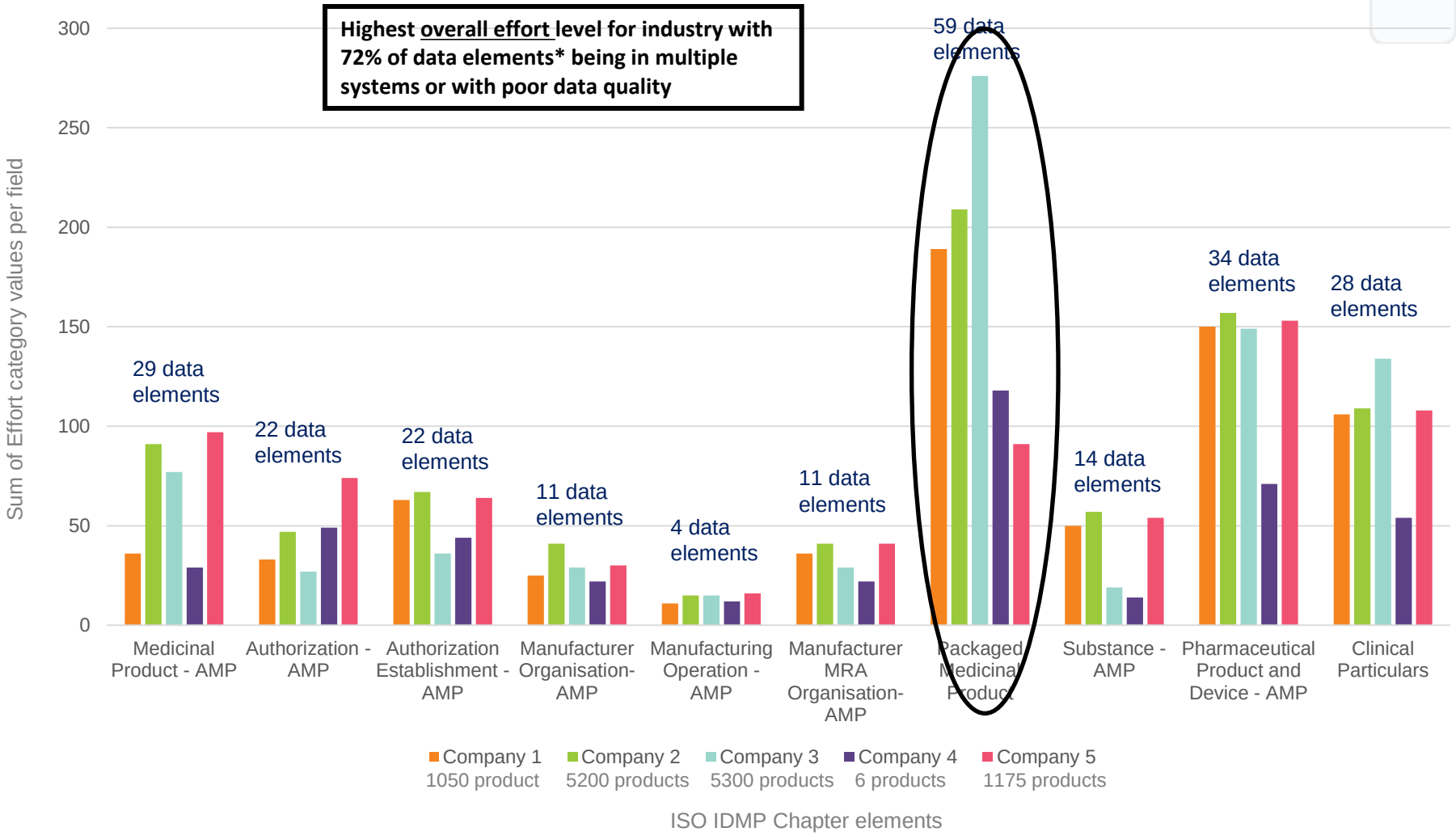
Average Calculations per fields*					
	Company 1 (1050 product registrations)	Company 2 (5200 product registrations)	Company 3 (5300 product registrations)	Company 4 (6 product registrations)	Company 5 (1175 product registrations)
Medicinal Product - AMP	1,2	3,1	2,7	1,0	3,3
Authorization - AMP	1,5	2,1	1,2	2,2	3,4
Authorization Establishment - AMP	2,9	3,0	1,6	2,0	2,9
Manufacturer Organisation- AMP	2,3	3,7	2,6	2,0	2,7
Manufacturing Operation - AMP	2,8	3,8	3,8	3,0	4,0
Manufacturer MRA Organisation- AMP	3,3	3,7	2,6	2,0	3,7
Packaged Medicinal Product	3,2	3,5	4,7	2,0	1,5
Substance - AMP	3,6	4,1	1,4	1,0	3,9
Pharmaceutical Product and Device - AMP	4,4	4,6	4,4	2,1	4,5
Clinical Particulars	3,8	3,9	4,8	1,9	3,9

Product Profiling & PHV use cases

Processes and Efficiency

* Sum of Effort category values per field divided by number of fields to acquire the average

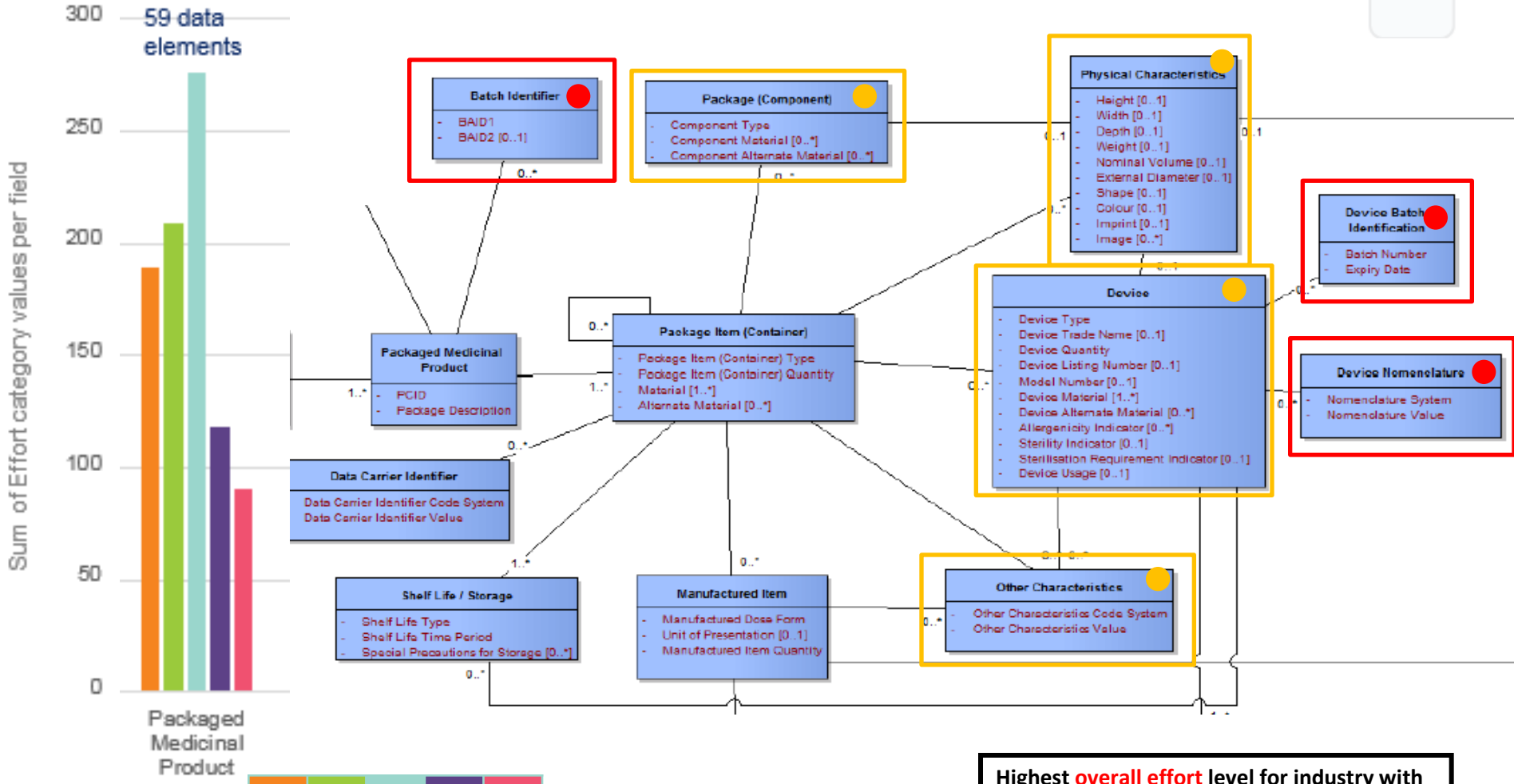
Overview of Industry Effort Calculations



** average score across the 5 companies*

Effort for Packaged Medicinal Products

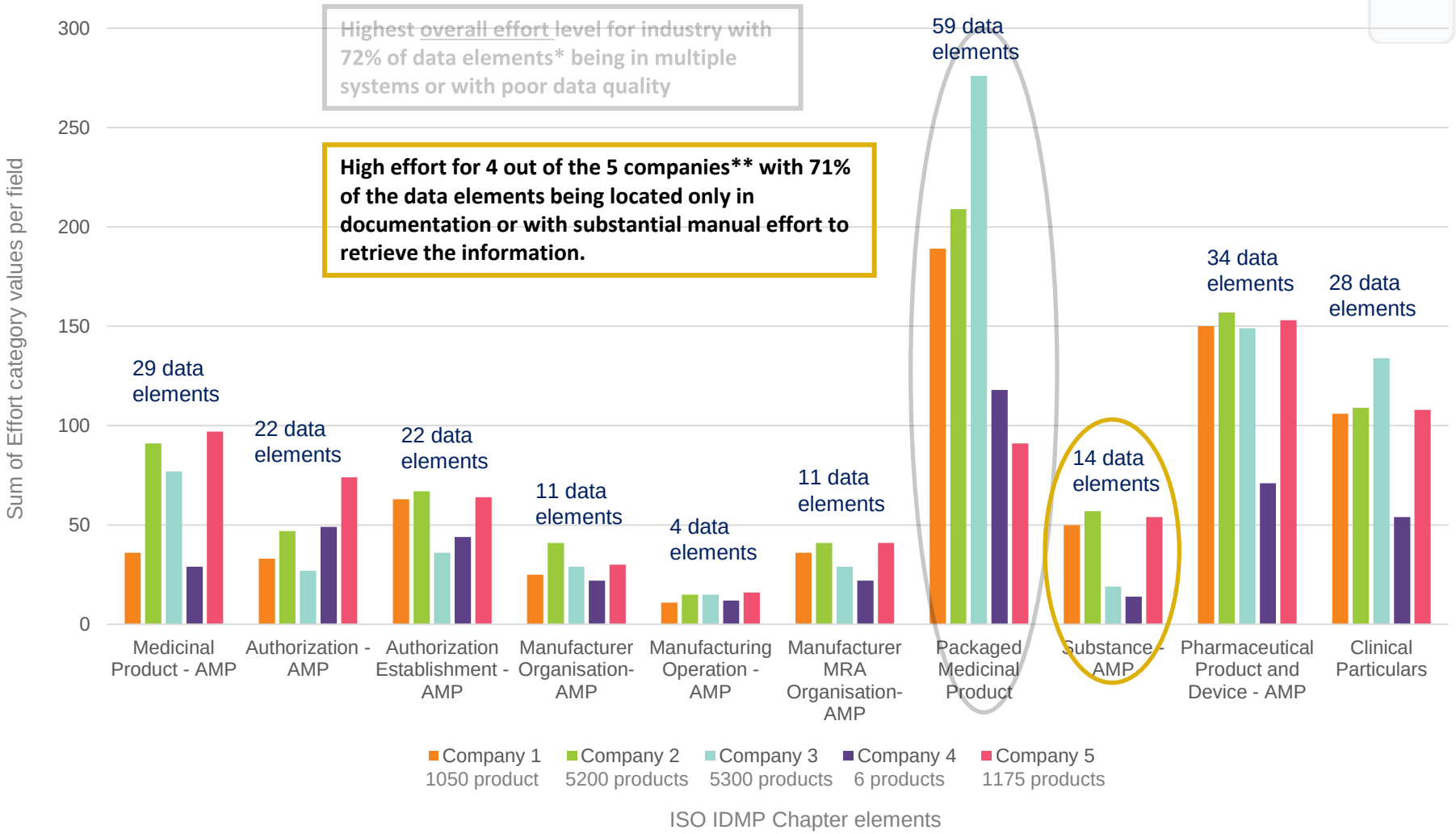
- Average Effort score 3.0 to 3.5
- Average Effort score 3.5 or more



1	2	3	4	5	Company
3.2	3.5	4.7	2.0	1.5	Average effort level of the data elements

Highest overall effort level for industry with 72% of data elements* being in multiple systems or with poor data quality

Overview of Industry Effort Calculations

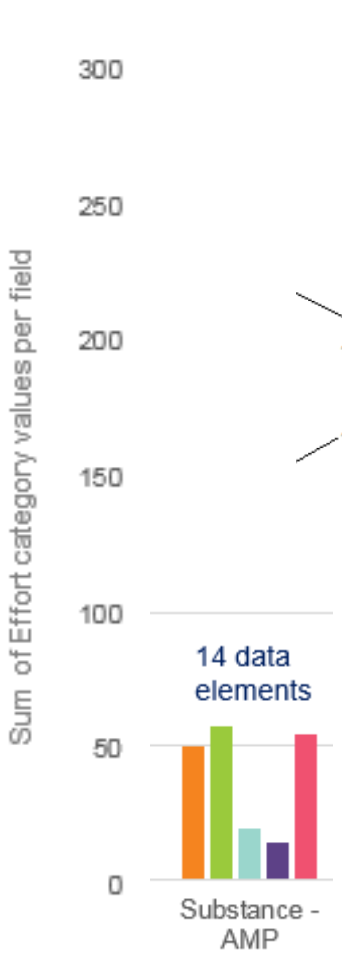


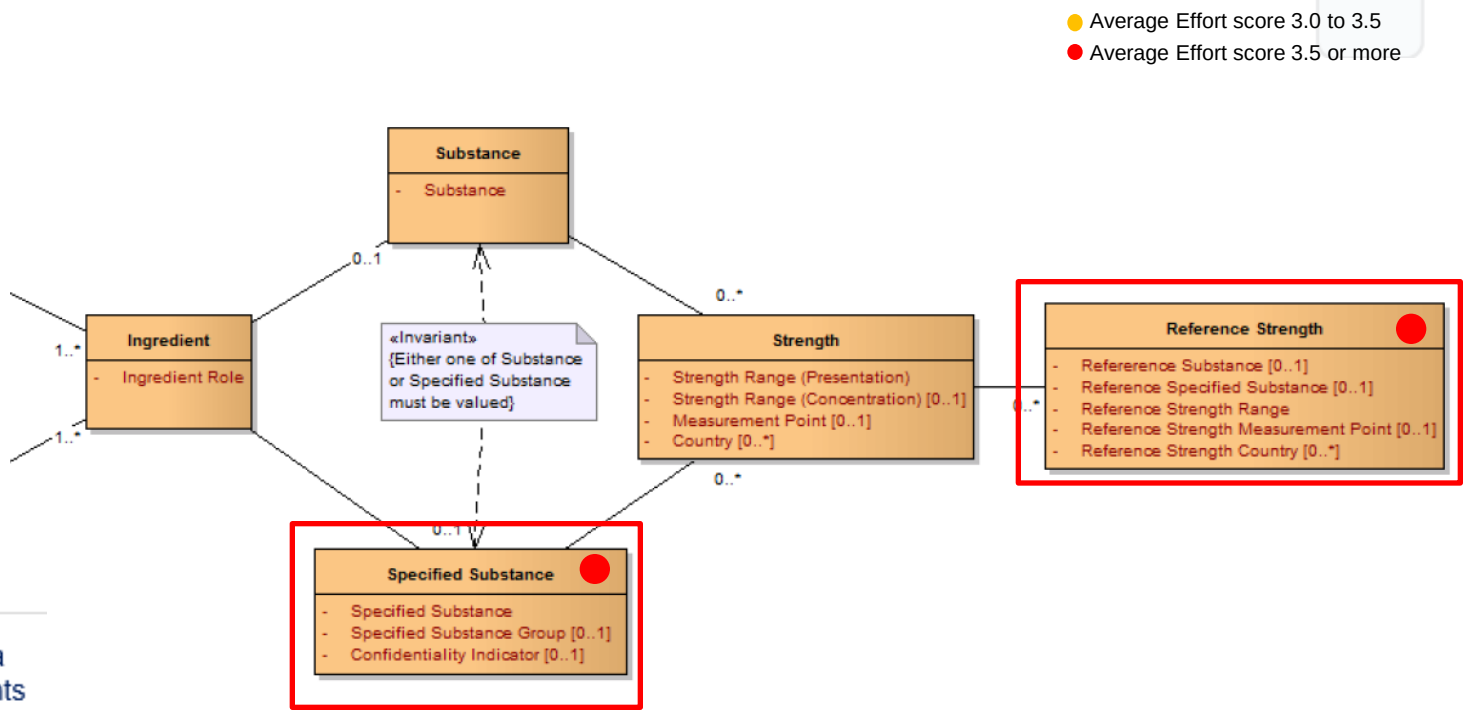
efpia

** average score across the 5 companies*

*** Company 4 has all Substance data fields available in a system ready for IDMP submission*

Effort for Substances



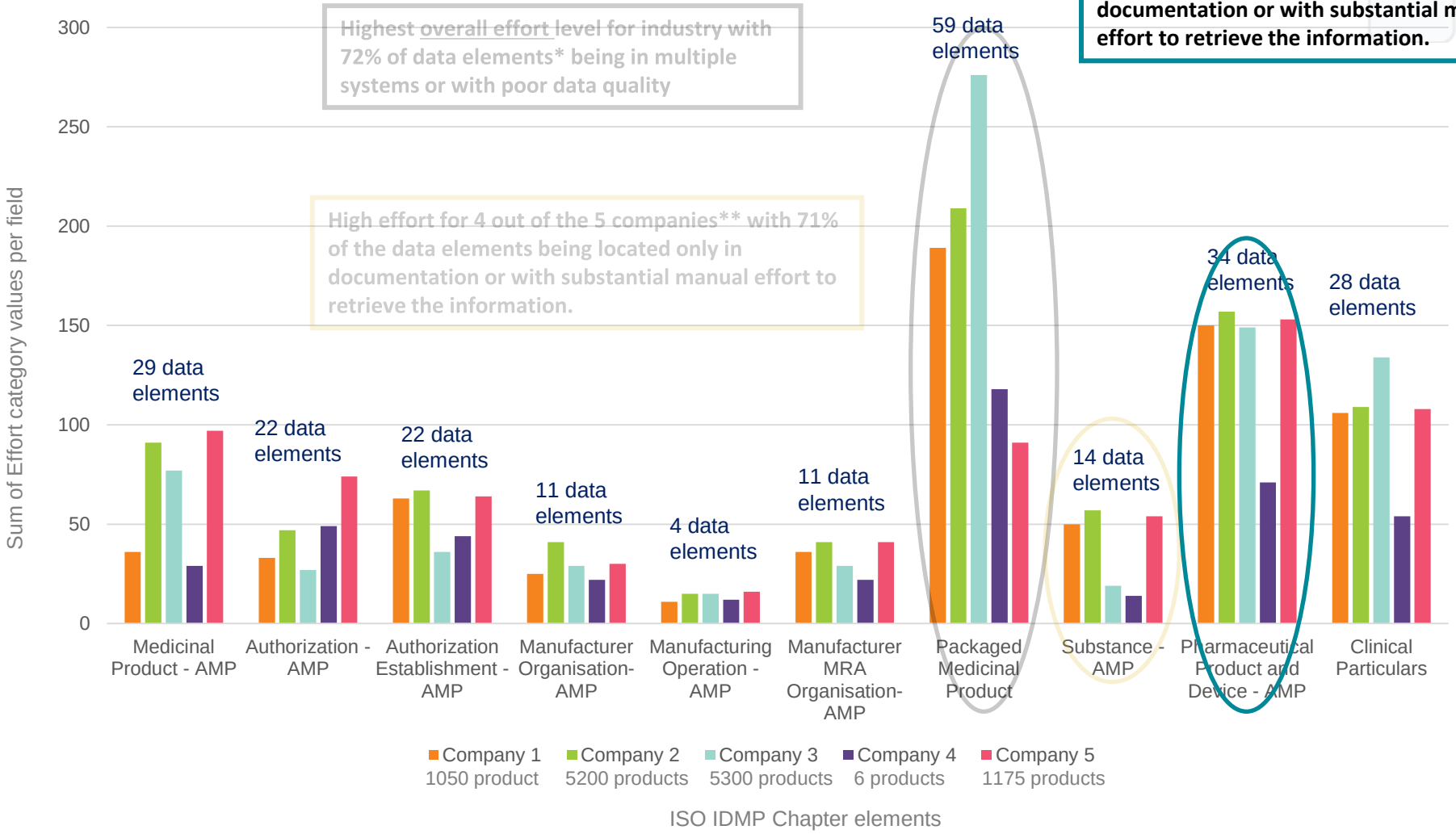


High effort for 4 out of the 5 companies with 71% of the data elements being located only in documentation or with substantial manual effort to retrieve the information.**

1	2	3	4	5	Company
3.6	4.1	1.4	1.0	3.9	Average effort level of the data elements

Overview of Industry Effort Calculations

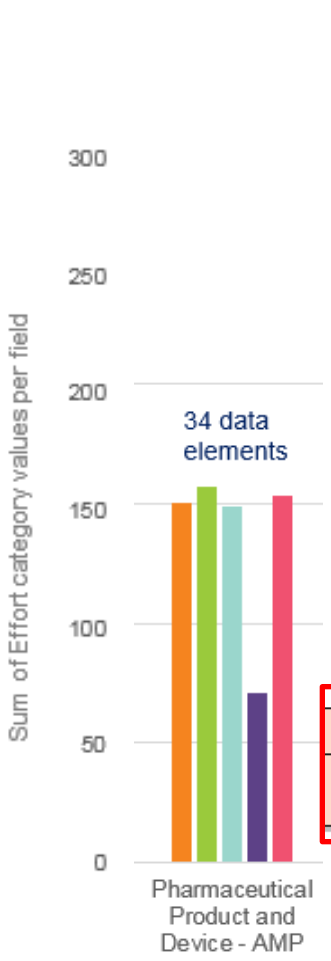
High effort per data element with 85% of the data elements* being located only in documentation or with substantial manual effort to retrieve the information.

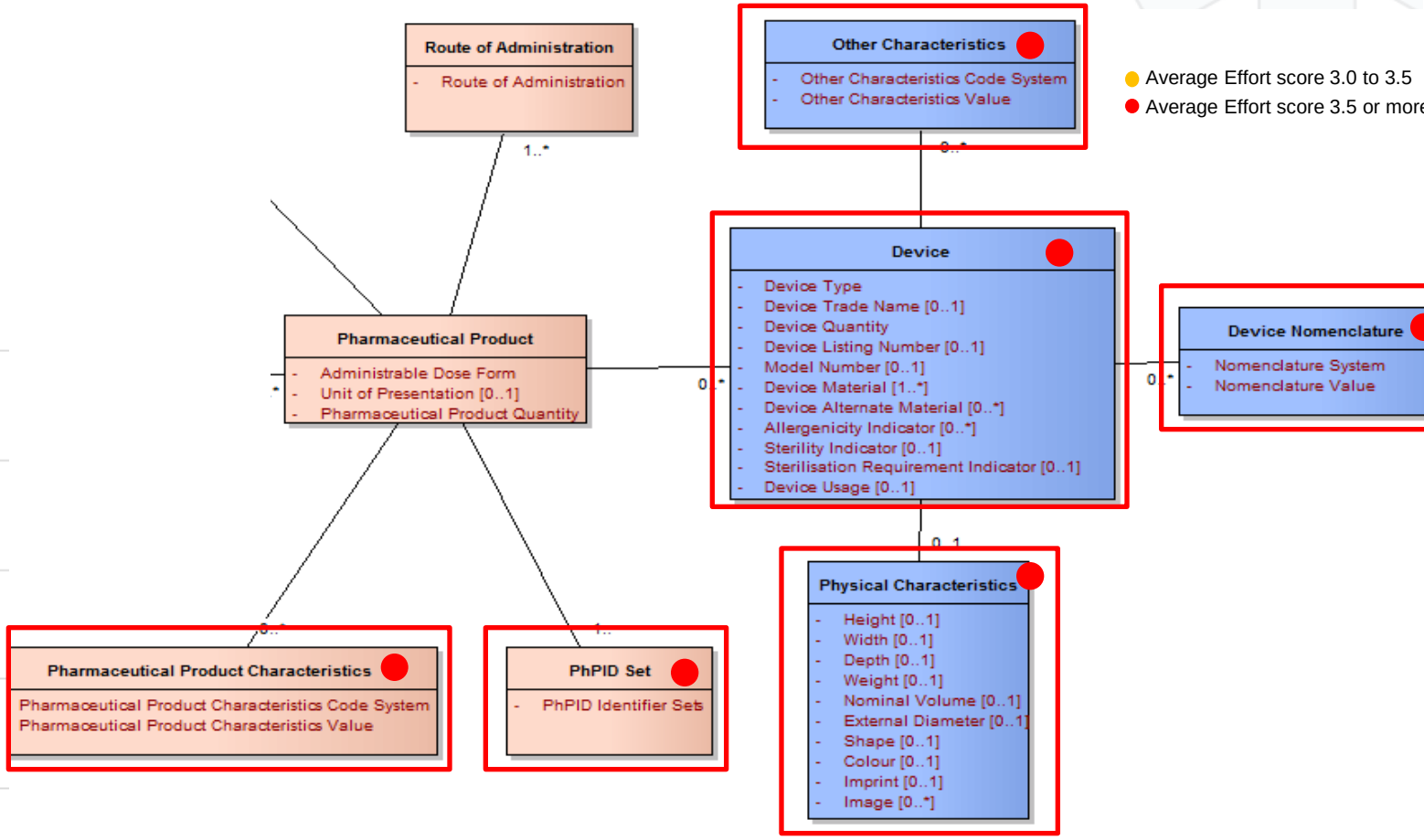


** average score across the 5 companies*

*** Company 4 has all Substance data fields available in a system ready for IDMP submission*

Effort for Pharmaceutical Product & Device



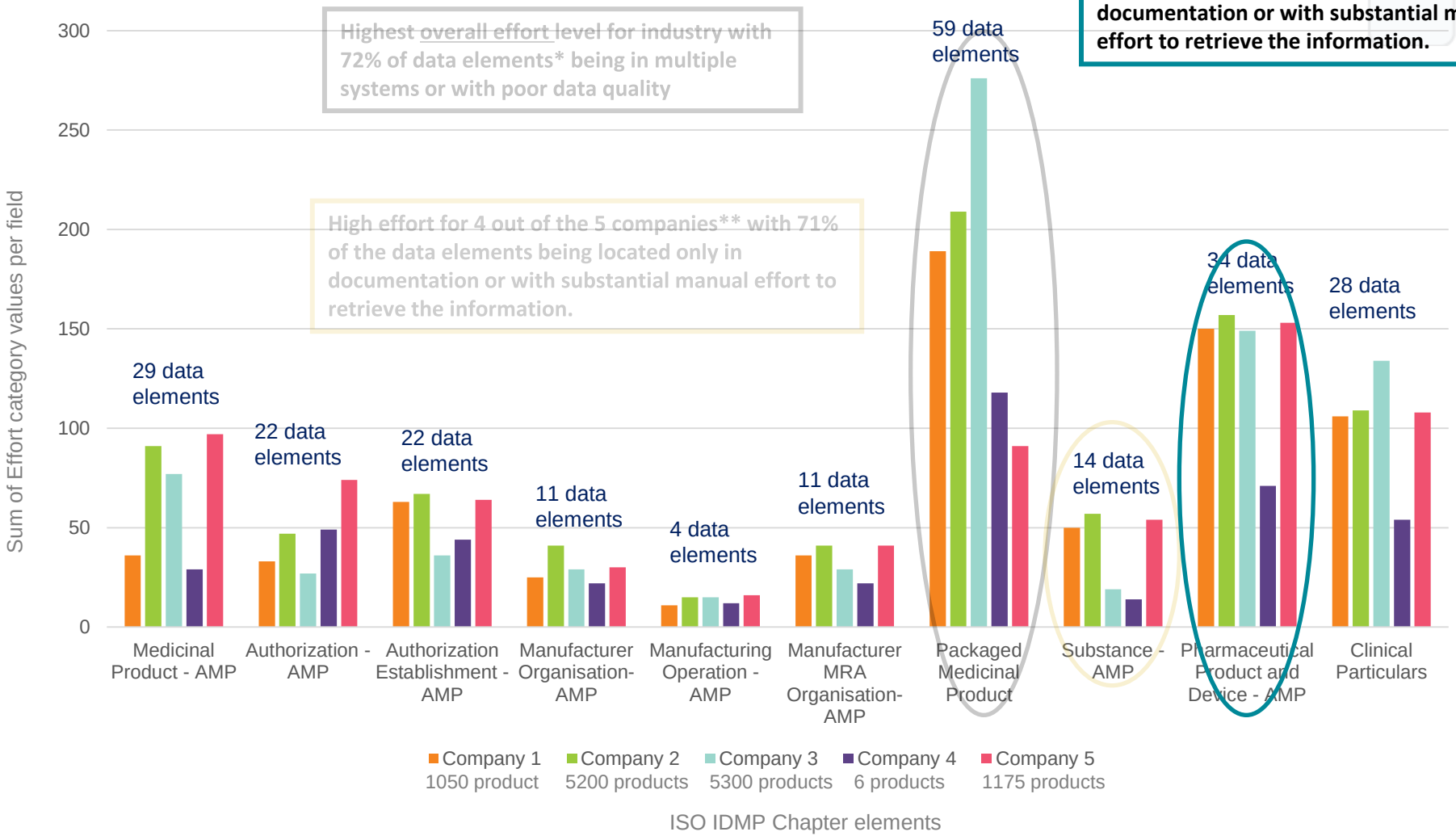


1	2	3	4	5	Company
4.4	4.6	4.4	2.1	4.5	Average effort level of the data elements

High effort per data element with 85% of the data elements* being located only in documentation or with substantial manual effort to retrieve the information.

Overview of Industry Effort Calculations

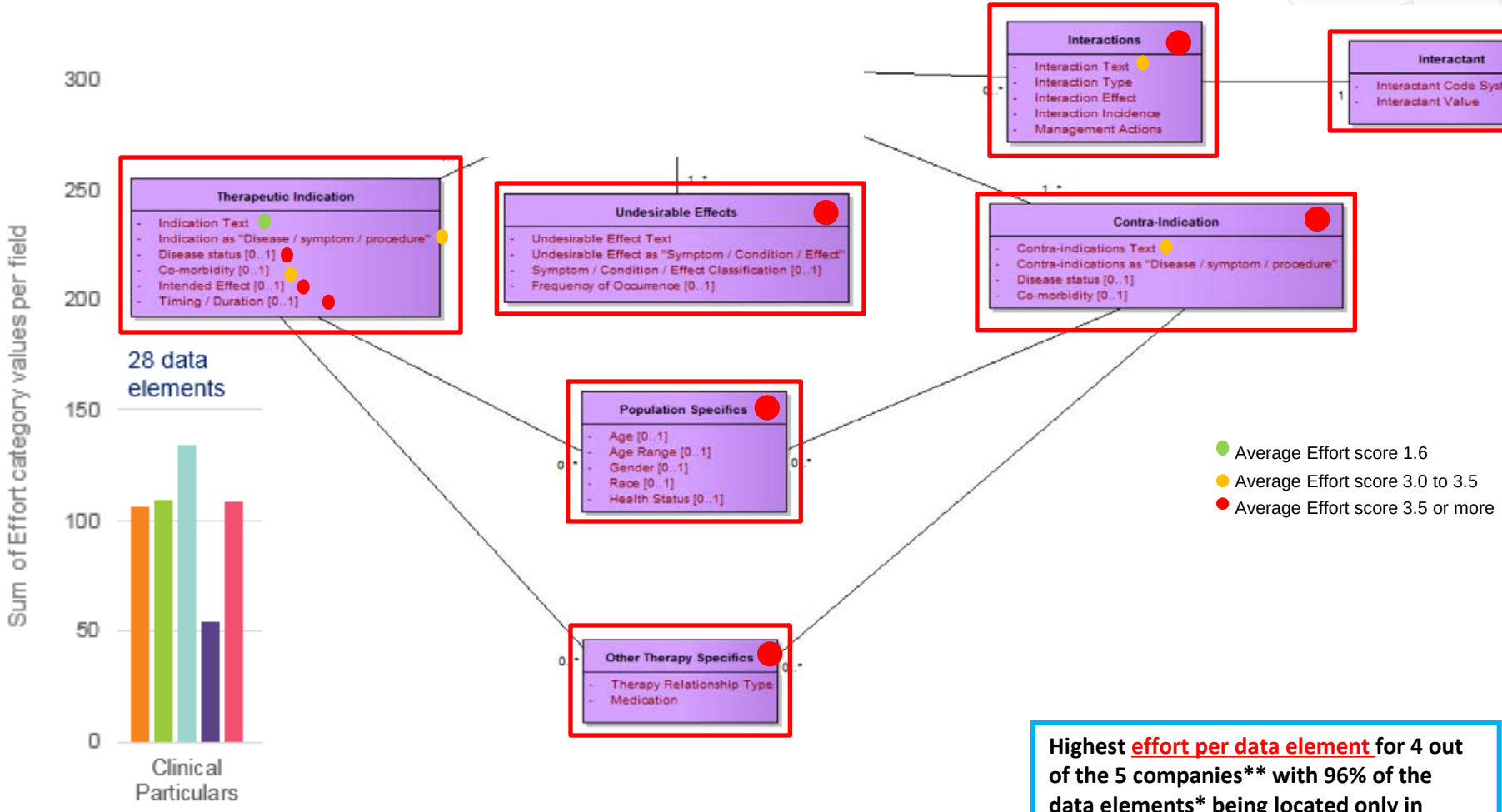
High effort per data element with 85% of the data elements* being located only in documentation or with substantial manual effort to retrieve the information.



** average score across the 5 companies*

*** Company 4 has all Substance data fields available in a system ready for IDMP submission*

Effort for Clinical Particulars



1	2	3	4	5	Company
3.8	3.9	4.8	1.9	3.9	Average effort level of the data elements

Highest effort per data element for 4 out of the 5 companies with 96% of the data elements* being located only in documentation or with substantial manual effort to retrieve the information.**

Conclusions from Initial Industry analysis

- The transition of **XEVMPD data** elements to IDMP may be attainable depending on the availability and content of the implementation guidance, although still with considerable work effort from Industry which should not be underestimated

- **Medicinal Products** and **Authorisation** data fields are captured within systems by industry, but require mapping to IDMP

- **Clinical particulars** require a high work effort from Industry as this information is captured (mostly) in unstructured format, however we recognise the concrete benefits for this data to be available in a structured format as per the use cases

- The data elements for **Packaged Medicinal Products** and **Substances** require a high work effort from Industry and we would like to understand the proposal for how these data elements would be used

What can we learn from the XEVMPD project?

XEVMPD Slides shared at Jan EU TMB Meeting at EMA with minor updates

European Federation of Pharmaceutical Industries and Associations
www.efpia.eu

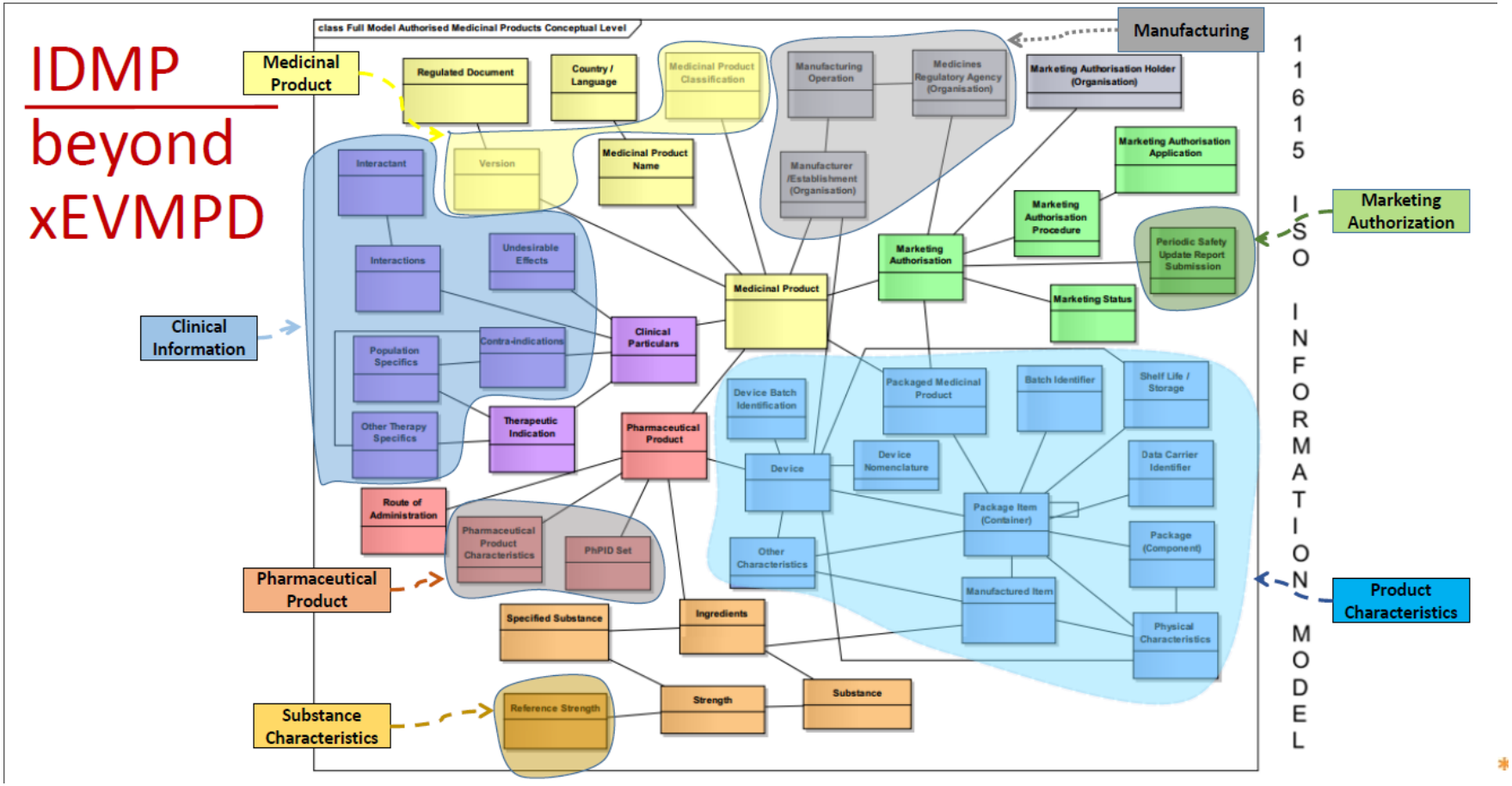
xEVMPD story - Benefit of close collaboration

- Article 57(2) demonstrates shared needs, value and strength of close collaboration between EMA & Industry
- Article 57 IWG has achieved the longer term vision, i.e. a database of all human medicinal products registered in the EU
- **Execution**: original scope not feasible and EMA and Industry found a pragmatic solution over time
  - However, timelines were very tight for industry to comply with
  - National specificities put a stretch on the system – case by case finding of mitigation solutions needed => Involvement from NCAs highly desirable
  - Vendors' involvement would have been beneficial also
- **Data Quality:** missing validation criteria => onus put on industry to revalidate data
  - Improved only once dialogue opened to understand respective needs and processes
- Close collaboration drives better business decisions and solutions
  - Industry believes that the IWG could have delivered at less cost (expense/resource) and with greater quality data from an earlier stage (less remedial work)
  - All parties are information and data suppliers and users – common needs
  - Lessons learnt from regulators and industry to inform the way forward

xEVMPD vs. IDMP

Gap Analysis

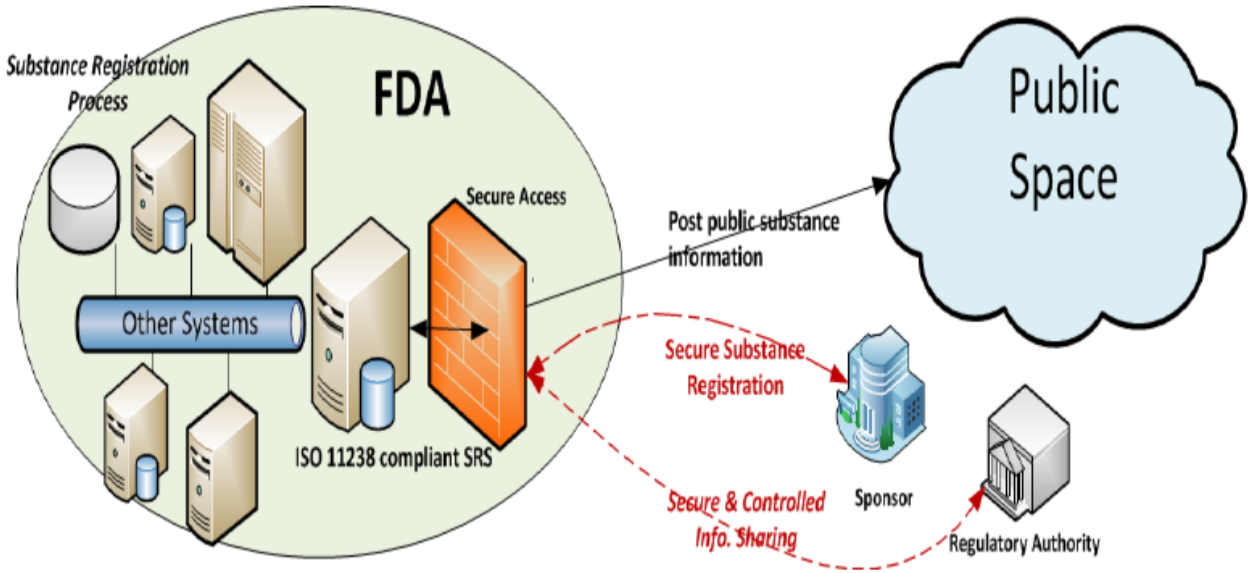
- IDMP standard covers more data elements than xEVMPD
- SPL R7 as Exchange Standard, Global Organisations for IDs and CVs



IDMP Implementation

- **Concerns – IDMP Level**
  - ISO Standards to be finalised by end-2015
  - SPL Release 7 expected by mid-2015
  - EU Implementation Guide expected by end 2015
  - Maintenance Organizations processes still to be put in place
    - E.g. GInAS for Substances
    - Migration aspects still to be looked at

Late Compared to July 2016 Deadline

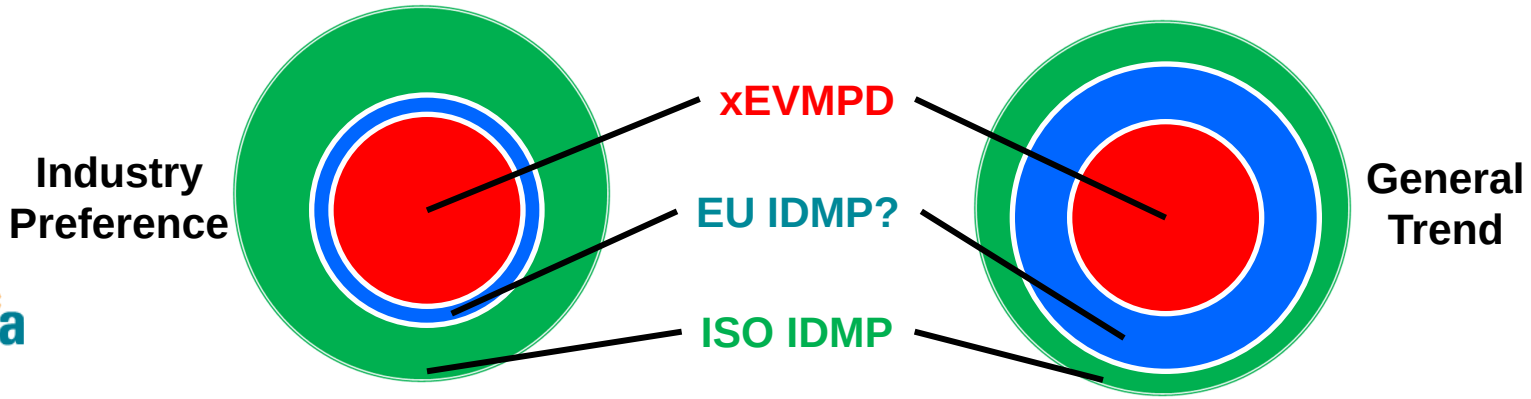


efpia

IDMP Implementation

Concerns – EU Level

- Clear Road Map for common understanding of the overall vision and scope of IDMP implementation is missing
  - 2-way discussion platform is needed
  - Implementation within industry (with software vendors) to be organised also
- Staggered/phased implementation as part of the Road Map is critical
- Reasonable timelines needed knowing that software solutions and new processes take time to go through development/testing/implementation life cycles
- EU SPOR initiative in consideration as part of IDMP implementation
  - EU approach for the data management of key concepts across all NCAs
    - Substances, Products, Organizations, References
- EU Implementation Guide will be late to allow smooth industry transition
  - Unclear what data elements will be required by July 2016



Conclusions for success

Conclusions

- Collaboration and clear strategic goals must come first
  - Industry values the **cross stakeholder engagements** including NCA's, vendors and EC
  - Industry is mobilising for IDMP but without **clear use cases** beyond XEVMPD this will remain slow
  - **Phased implementation** is necessary given breadth of potential uses and data elements
- 2016 deadline is acknowledged as unrealistic
  - EU IDMP Task Force must define a **clear scope** before assessing timeline
- Need to identify the appropriate activities through 2015 to deliver the IDMP roadmap this year

efpia

Playing in tune…and in time together!


grazzi
tanan
dakujem
efcharisto
obrigada
havala
dekuji
paldies
spasibo
obrigado
ThankYou
kiitos
grazie
blagodarya
tack
Merci
dekui
gracias
dzieki
multumesc
Danke
dank
koszi

Back up slides

Summary of Initial Industry Analysis

ISO IDMP Chapter	Effort level	XEVMPD	Mandatory fields*	Use cases
Medicinal Product - AMP	*	23	1	
Authorization - AMP	*	13	15	
Authorization Establishment - AMP	*	0	10	
Manufacturer Organisation- AMP	*	0	8	Processes & Efficiency
Manufacturing Operation - AMP	* * *	0	3	Processes & Efficiency
Manufacturer MRA Organisation- AMP	* *	4	8	Processes & Efficiency
Packaged Medicinal Product	* * * *	4	16	Processes & Efficiency
Substance - AMP	* * * *	4	4	
Pharmaceutical Product and Device - AMP	* * * * *	6	6	
Clinical Particulars - AMP	* * * *	4	12	Product Profiling & Pharmacovigilance

** in addition to XEVMPD fields, includes „Conditional" fields*

Occurence vs Effort values – Company 1

Occurrence categorisation

Occurrence High: Updated information multiple times per year (more than 2x)	**6**	3	4	0	0	0
Occurrence Relatively frequent: Updated information once or twice per year	**5**	6	0	0	4	2
Occurrence Infrequent: Updated information once every 2-5 years	**4**	1	6	2	17	0
Occurrence Low: Updated information less than once in 5 years	**3**	13	3	10	19	6
Occurrence Unlikley: Information unlikely to require update but it could happen	**2**	1	10	0	55	23
Occurrence onetime only: Occurs only once within the lifecycle	**1**	14	1	1	0	2
		1	**2**	**3**	**4**	**5**
		System (or excel) - Single Source which can be mapped to IDMP	System (or excel) - Single source which requires significant effort to format data for mapping to IDMP	System (or excel) - available in multiple systems requiring harmonisation, or with poor data quality	Unstructured Data (Documentation)	Location not found; substantial manual effort to retrieve information

- An assessment is currently being conducted to establish (per ISO IDMP data field) what the frequency of occurrence is
- An initial analysis on the data received from Company 1 reveals that alot of the data which is unsturctured or not yet located is estimated to have a low occurrence rate
  - This is good news with regards to maintenance... However,
  - The question remains: what is the purpose of this data, what will it be used for?

23 data fields, 2 of which are mandatory. The remainder: 20 pharmaceutical product, 1 medicinal product

55 data fields, 11 of which are mandatory, 26 of which are included in XEVMPD. The remainder: 36 packaged medicinal product, 12 substances, 2 manufacturer establishment, 1 clinical particulars.

Effort categorisation