

After the repeated EMA IDMP delays out to 2021:

Content relevant Standards: eCTD 4.0; RPS; IDMP; SPL; ICSR ...

"It's All About the Data"

How important are Product Information (PI) Assets to you?

Updates and Recommendations:

Again, with the new EMA timelines have been communicated that strengthen our approach to have a closer, holistic view on **IDMP**, SPL(R7), ICSR(R3) – we call it collectively IDMP+, Enterprise Data Governance (**EDG**), driven by the fact of increased content granularity and last but not least to dramatically increase matured discovery in context by applying **Semantic Technologies** (ST) to make data assets become actionable:

You have (substantially) invested in all 3 ISO IDMP+ areas, so the driver here is recommended to be: Preserve investments, prevent knowledge drain and motivation – bring all into a new focus where everyone that engaged so far can continue to contribute

What about eCTD V4 & RPS in the above context?

*As **Corporate Data Assets** (unstructured [80%]; structured [20%]) drive the business, especially in context of IDMP+ (compliant data, many more opportunities “outside” regulatory affairs), Industry has an ideal momentum to **leverage** those **assets** by Managing Data with Corporate Guidance:*

No innovation without Information – Time is Right digging deeper for more value!

PI are one so important group of Corporate Data Assets to diligently take care of:

Product, document, creating and maintaining DATA LIFECYCLE ...

A Claim from our IDMP+ Leader

Regulatory data deficiencies (i.e., incorrect, improper, missing data) **are costly and adversely impacts regulatory decision making thus affecting your authorization to market. A solid solution must be built upon sound data governance principles ensures compliance and strengthens your competitiveness from strategy to execution, allowing you to have command and control of your data.**

Vada Perkins, 2017

Impact:

Data lifecycle management, moving from “simple” document level to more sophisticated structured content to enable improved agility

- Data Models, Data elements and their structure(s) – what elements for use where
- Content (not document) re-use

Over time: Building a Solid Data Foundation via EDG*

Architecture to enable future steps down to IDMP+ Data Elements and their detailed structure to optimize re-use – for business and regulatory purposes

Addressing the strategic concept: Publish data to any format when time is right

When we think “**data**”, want to organize them, understand their relationship we recommend to take the latest **ISO IDMP/SPL/ICSR (IDMP+) Implementation Guides (IG)** as a “**benchmark**”, representing the compliance part of the data requirements – to drive the business ones!

IDMP Strategy – re-scope: Process output is/must be to provide a strategic, holistic framework for all functions about how data (from a business perspective) will be created – manipulated and managed – stored – search/discover in context and apply (WHY to what target as a business/compliance requirement) – re-plan.