

"It's All About the Data"

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

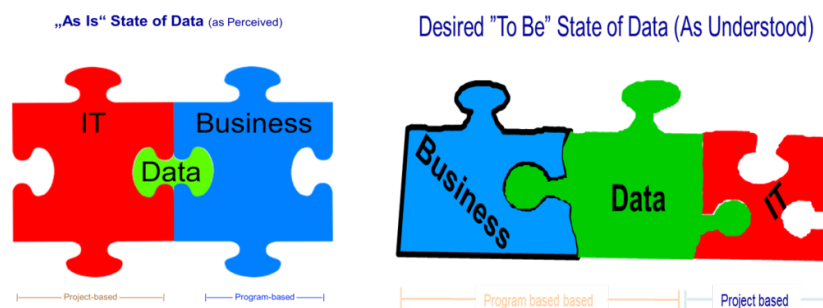
Addressing the strategic concept: Publish data to any format when time is right

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.

This will allow stakeholders to "free" themselves from technology solutions - re-think the future ...

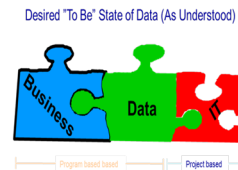
Mind shift: From Systems to Data



Data – not systems – will drive process outcome!

A well-structured workshop will launch an intense dialogue in the process of the above shift:

**Goal must be shared Business/IT understanding –
No disagreements = insufficient communication!**



Re-scoping & re-planning the “shift” from the beginning thereof calls for Leaders

And here are some thoughts around **EDG**

- 1) Abstracting the problem up to a higher level will permit a focus shift away from tools towards capabilities (away from 'repository' and towards 'remembering') - this effort would produce the outline of a 'capable architecture' that should produce lower implementation costs and higher efficiencies
- 2) Leverage existing good efforts by using the three perspectives as an architectural component that can unlock significant business value when extended to include process reengineering - this effort would likely be unique (as they are ahead of the competition)
- 3) Good opportunity to evaluate the potential that their Structured Content Authoring (SCA) efforts can contribute
- 4) What does it mean to the Enterprise? Identify the priorities and low hanging fruits in such transformation process – measured step-be-step - taking advantage of the “extended Regulatory Grace Period”! Start with an “example” (PoV experimental), learn, adapt, pilot, learn, deploy
- 5) New data formats will be considered: Real World Data (RWD), Image, Voice ...

One of Vada’s comments: As to IDMP+ they don’t know that they don’t know! So what can we, in a simplified way show/visualize that they “learn to acquire knowledge”?