

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"

"Extended Regulatory Grace Period"



Authors in this issue:

Vada Perkins, MSc, BSN, RN, Associated Partner, **LSCP**; **Prof. Peter Aiken**, Founder of **data blueprint**, Inc., a Strategic Partner & **Ruedi F. Blattmann**, Managing Partner; **Kathy Hagen**, Partner, CM SME, **LSCP**

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.

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

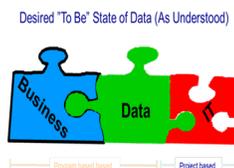
Mind shift: From Systems to Data



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”?

Collectively, we recommend:

Delays in implementation provide an opportunity for Industry to prepare and plan accordingly

Why we propose looking beyond ...

Independent of new EMA dates we strongly recommend to use the now

“Extended Regulatory Grace Period”

to organize **semantically enriched product data** (analyzing IDMP data element structures for re-use) from a **global perspective**, enterprise wide (**EDG**) in a way to

- reach *optimal agility*, regardless of what and when the forthcoming regulatory data requirements are going to be enforced and,
- to serve IDMP *data consumers* (Label, CMC, Market Access) in a most efficient way

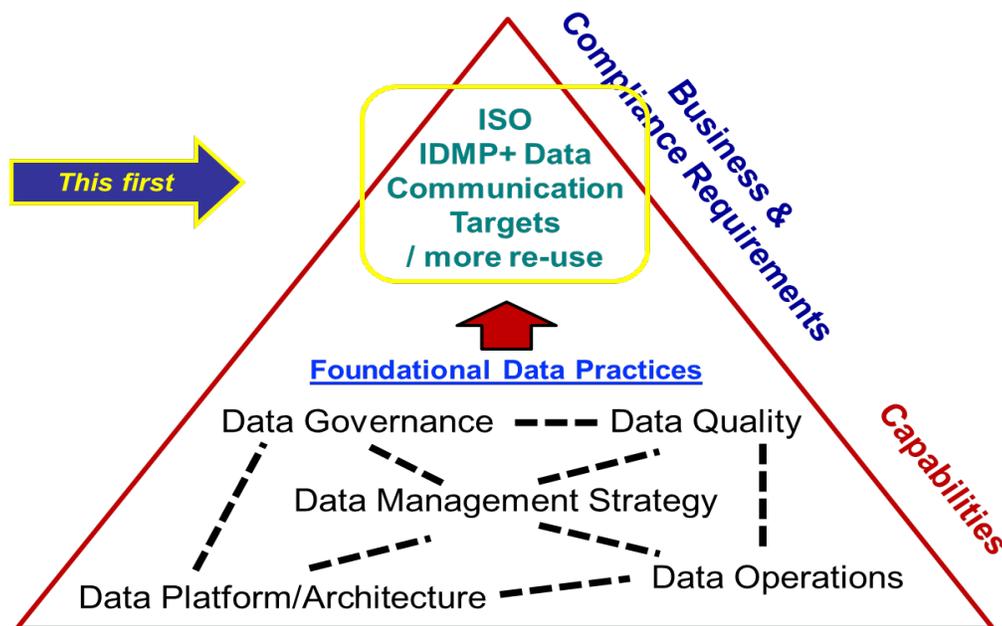
Option:

Looking beyond the “Regulatory Plate” - Content Creation, Management, In- & Output

At first, to recognize where data is going to be used (WHY) as well, a holistic view is a pre-requisite. By taking this route a company will avoid costly re-work in many aspects:

From “sectorial” selection for a *Proof-of-Value* (PoV) to a functional implementation of **EDG** in context of IDMP+ the Data Architect will have to consider ... Use Case (UC) Examples: Where can we identify priorities that create highest value as low hanging fruits?

Transition of Focus: EDG to IDMP+ Data Elements & Structures



Once we have created new capabilities, we then can select “best fit”, enabling technologies to meet your requirements



SME: Peter Aiken

Assisting to find an effective way to EDG



Managing Data with Guidance

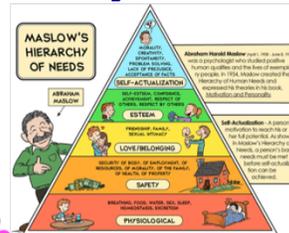
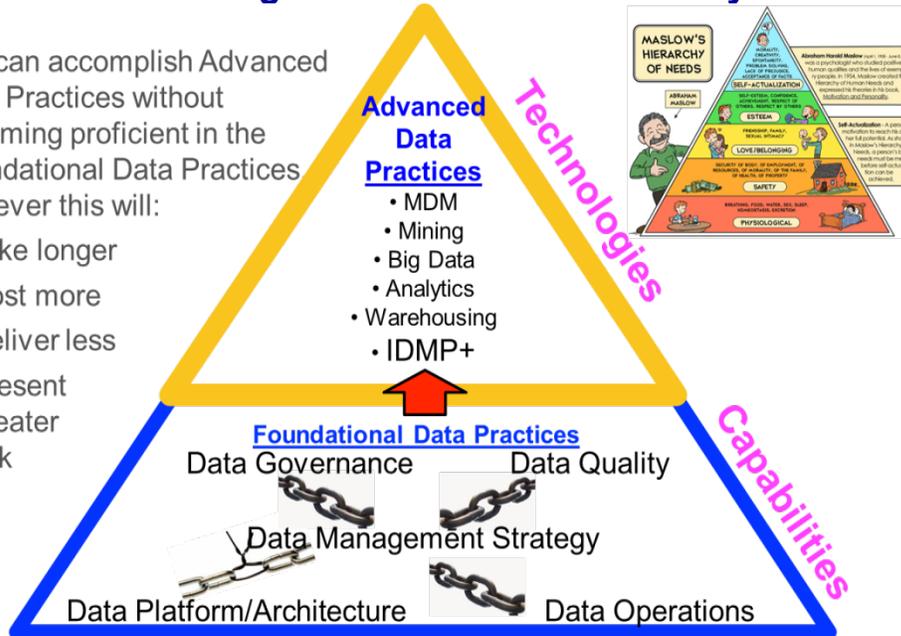
EDG is a PROCESS and not a project, getting processes data - not systems - driven!

It will not help to manage data like the industry did on “just” an application level as IDMP+ is cross functional and global with high level of content granularity: In our combined process you will take a decision on whether to manage millions of small documents and harmonize metadata (MDM vs NoSQL debate to take place), or move to managing information components to reach optimal agility:

Data Management Practices Hierarchy

You can accomplish Advanced Data Practices without becoming proficient in the Foundational Data Practices. However this will:

- Take longer
- Cost more
- Deliver less
- Present greater risk



Note:

Important here to recognize is that e.g. MDM is a technology, but can only perform desired results, if data capabilities are in place!

We would be happy to provide more information about Strategy development and implementation!



SME: Ruedi F. Blattmann

“Evolution of Search”

There will never be less data than right now –
Quality data (part of EDG) must enable you to make better and data documented decisions!

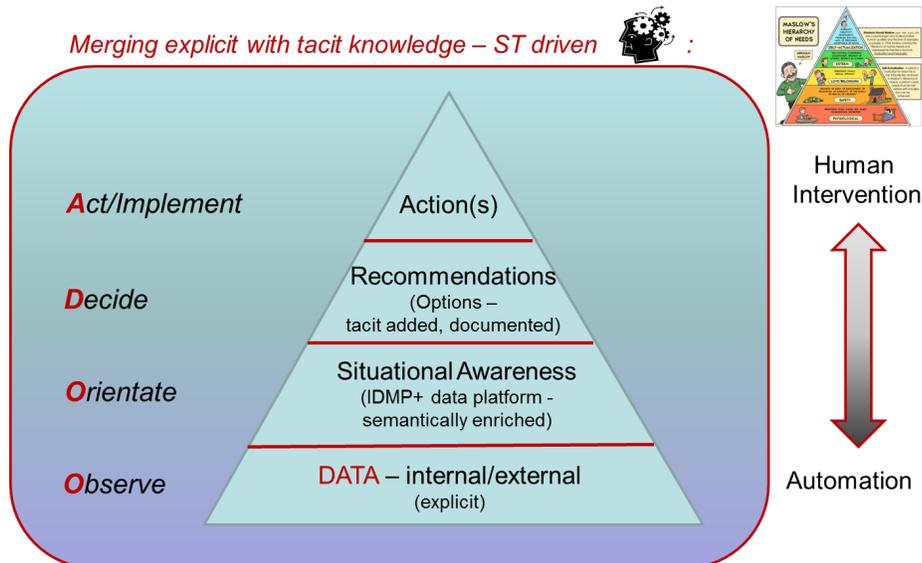
So the Challenge we face is how find relevant data effectively and in context:
The recommended path is to not just extract data from legacy documents, but to semantically enrich your content and build semantic data models.

Enabling Semantic Technologies (ST) for the Knowledge Space will be – also for those (multi-multi directional, but consistent and transparent) Communication Targets:

- Indexing and Search of unstructured content
- - Natural Language Processing and Linguistics
- - - Text Analytics (to include sentiments from Social Media)
- - - - Entity Extraction, and ultimately
- - - - - Fact Extraction,

leading to the description of the progression” ... “strings to things” – **discovering in context**

ST Objective: Actionable Data - fact-based decisions!

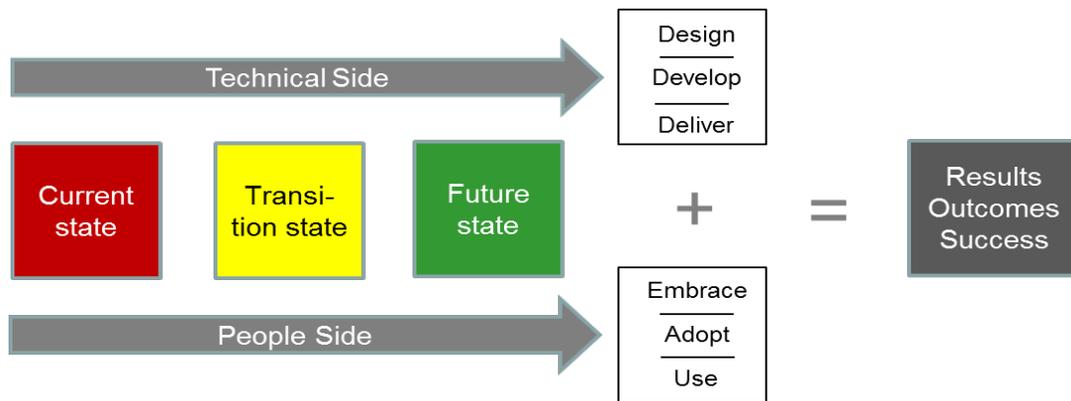


And once you have defined your new holistic PI Framework, you should think of this:

CHANGE MANAGEMENT (CM – SME Kathy Hagen)

The People Part of a Project:

The transition to implementing IDMP+ and EDG requires that everyone involved is aware of, accepts and acts on the change. Without people engagement, the work will achieve limited value.



Source: Prosci

LSCP has a deep understanding of CM and all of the critical aspects including Communication, Organizational/Cultural Change, Effective/Targeted Training and Leadership Alignment

Our CM process and tools are integrated throughout the project and our communication planning will be integral at every step of the way. We will partner with you to create a Change and Communication Strategy to ensure sustainable success of this crucial work

CM Enhances Sustainable Success and is crucial as you transitions to an Enterprise Data Platform



The CM Process ensures the people side of the return on investment is achieved.

LSCP believes CM is integral to project success: Therefore, the CM process is integrated in every step of the project and the CM Lead is part of the **LSCP** Leadership Team. Our team has implemented successful Change and Communication Strategies for numerous large scale initiatives and we will apply that expertise to assist you in engaging the various stakeholder groups to implement and adapt to the changes required, as well as receive the business benefits presented.

In a first phase of your project we will focus on the partnership with stakeholders (CM, Communications, Training, HR and Talent Management) on the first two steps; to assess the culture, organizational change readiness and impact, communications channels, and training environment to create a targeted, effective overall CM concept, strategy and CM Roadmap.

To close,

Our Contribution/Objective

- We do understand that your company is, as to IDMP already “in full swing”! Is your initiative holistically under way, including SPL & ICSR, referencing the ISO IG?
- **LSCP** is probably one of the few Service Providers in this space with a **HOLISTIC** approach to **IDMP+** in conjunction with **Enterprise Data Governance (EDG)** and the application of **Semantic Technologies (ST)** – aiming to **leverage** your current/past **investments** in the topic or part of it
- We would like to **COMPLEMENT** existing initiatives (integrate with current providers – non-disruptive!) and **not to replace them!**
- *Thanks for considering this message from this perspective*

AND ...

*What is your **CONCLUSION** here ...?*

LSCP would like encouraging you to get in touch with us at your earliest convenience:

We suggest to mutually discussing with your IDMP+ Stakeholders and our leading functional SMEs: Design and potentially execution of a Workshop to elaborate together an optimal, pragmatic approach defining about how to create and manage your **data assets** in the future. Benefit from the given synergies of the three key and crucial domains outlined above - high level to start with!

Collectively, we thank you for your attention ... and action!

IDMP+ Status Reflections



• **Vada Perkins (US) MSc, BSN, RN** is a recognized international expert for the suite of ISO Identification of Medicinal Products (IDMP) standards as he is the topic leader in this initiative within ISO Technical Committee 215/Working Group 6-Health Informatics: Medicines and Pharmacy Business. During his tenure at the U.S. FDA, Vada worked closely with senior leadership on a broad range of regulatory and policy issues in the development, interpretation, and implementation of guidance, regulations, and international data standards (e.g., ISO IDMP, HL7 SPL, eCTD/RPS, ICSR, UDI) to support the comprehensive review of drugs, biologics, and devices throughout the product lifecycle. Vada brings along **EDG** experience within a major Health Authority. He is also a Managing Principle at IDENTIFICA, LLC.



• **Peter Aiken, (US) PhD, EDG** lead. Peter Aiken is acknowledged to be a top data management (DM) authority. As a practicing data consultant, author and researcher, he has been actively performing and studying DM for more than 30 years. His expertise has been sought by some of the world's most important organizations and his achievements have been recognized internationally. He has held leadership positions, consulted with more than 75 organizations in 21 countries across numerous industries, incl. defense, banking, healthcare, telecommunications & manufacturing. Sought-after keynote speaker and author of multiple publications, incl. his latest the "Case for the CDO" & "Monetizing Data Management". He hosts the longest running and most successful webinar dedicated to DM (hosted by Dataversity.net). Peter is the Founding Director of Data Blueprint, a consulting firm that helps organizations leverage data for competitive advantage & operational efficiencies. He is also Associate Professor of Information Systems at Virginia Commonwealth University (VCU), past President of the International Data Management Association (DAMA-I) and Associate Director of the MIT International Society of Chief Data Officers.



• **Ruedi F. Blattmann, (CH)**, Managing Partner of the **LSCP** global network, Ruedi is recognized for thought leadership on implications of eCTD, ISO IDMP & ISCR(R3) in a *Holistic Vision & Strategy (V&S) from an EDG perspective*: Focusing on flow of information in collaboration and process outcome, optimal transparency, consistent content re-use opportunities, developing business benefits while maintaining compliance, e.g. in Pharmacovigilance (PV); Knowledge Management (KM) – semantically enriched/enabled concepts for “discovery in context” in the LS market space and beyond, focusing on Enterprise Structured Content Authoring & -Management, Change Management (CM), Compliance dimensions, RM. An active member in the Swiss eHealth scene with all stakeholders, incl. Health Insurer.



• **Kathy L. Hagen, (US)** Partner, SME CM/KM. Extensive Academic & Industry experience. Organizations are experiencing large scale risk from worker retirements, globalization, multi-generations in the workforce, mergers and acquisitions and regulatory/legislative changes. Kathy Hagen is an expert in Critical Knowledge Transfer and Change Management (CM) programs, helping clients reduce risk, retain business critical knowledge and ensure employee and leadership engagement in all types of transitions. The KM Strategies, Knowledge Transfer methodologies and CM/Change Leadership programs developed by Ms. Hagen have been successfully implemented in companies around the world, used extensively by organizations facing the challenges of a transitioning workforce, those needing to quickly and effectively transfer business critical knowledge to a diverse workforce

Vada.perkins@lsconsultingpartners.com

paiken@datablueprint.com

ruedi.blattmann@lsconsultingpartners.com

kathy.hagen@lsconsultingpartners.com