

Creating a Holistic View on Actionable, Regulated Data Assets

Executive Summary

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Have you ever explored content value of data assets that Regulatory Affairs governs in one way or another? Is the process of current data/information exchange “seamless” between

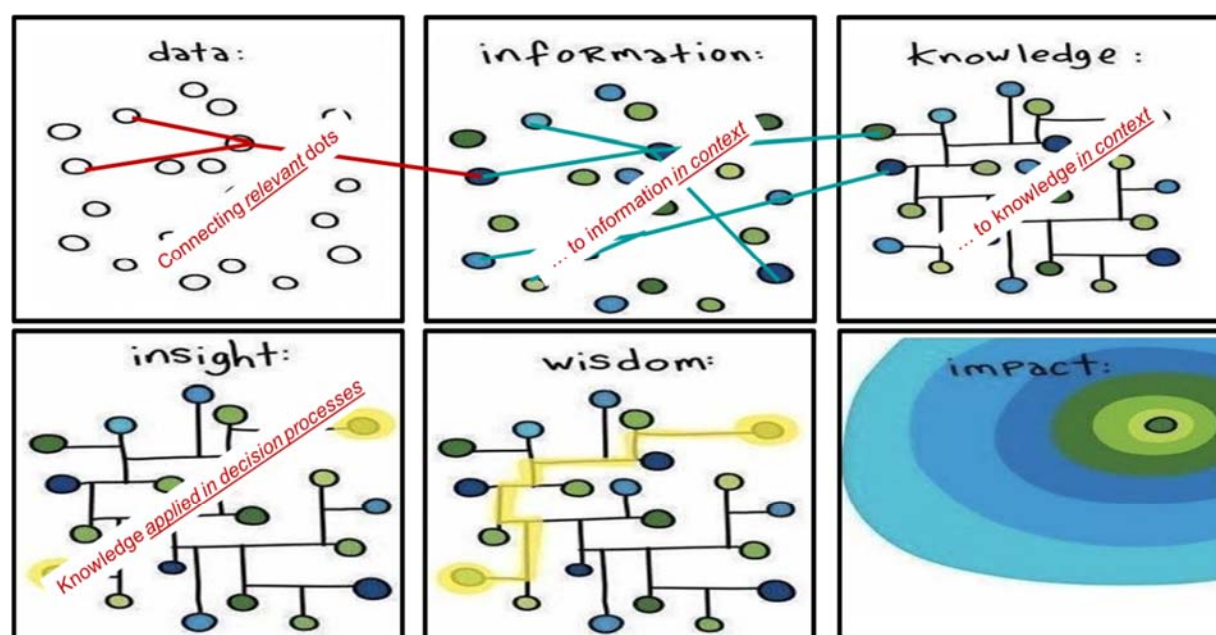
Market Access >> Medical Information (Affairs)
>> Regulatory Affairs >> Health Authorities <> Others?

The outcome goes right to the bottom line and enhances the value chain on multiple levels

Following “Our Current Thinking” January & February 2019 editions (links at end of this document), we shift from document and system to data. Here below what it means:

Data Evolution ... Stakeholders to Understand & “Execute”

(Any Data Type and its contents vs. Information, represented always in context!)



To reach agile delivery for personalized content:
Extract data, components (SCA - data strategy based!) from regulatory documents

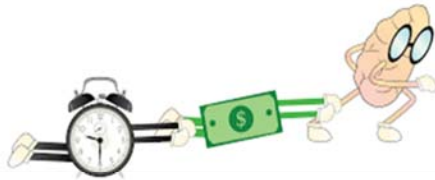
Source: unknown via LinkedIn adapted

Our Format Free Initiative (FFI) as a key enabler – a *novel approach*:

Data are captured/stored in a “format free container” (e.g. Docuvera’s Topic), semantically enriched (e.g. Smartlogic’s Semaphore), including metadata (IDMP+ harmonized) and managed on adequate platforms, creating value:

Our Current Thinking: Internal/external Data Consumers

Comprehension by others is critical!



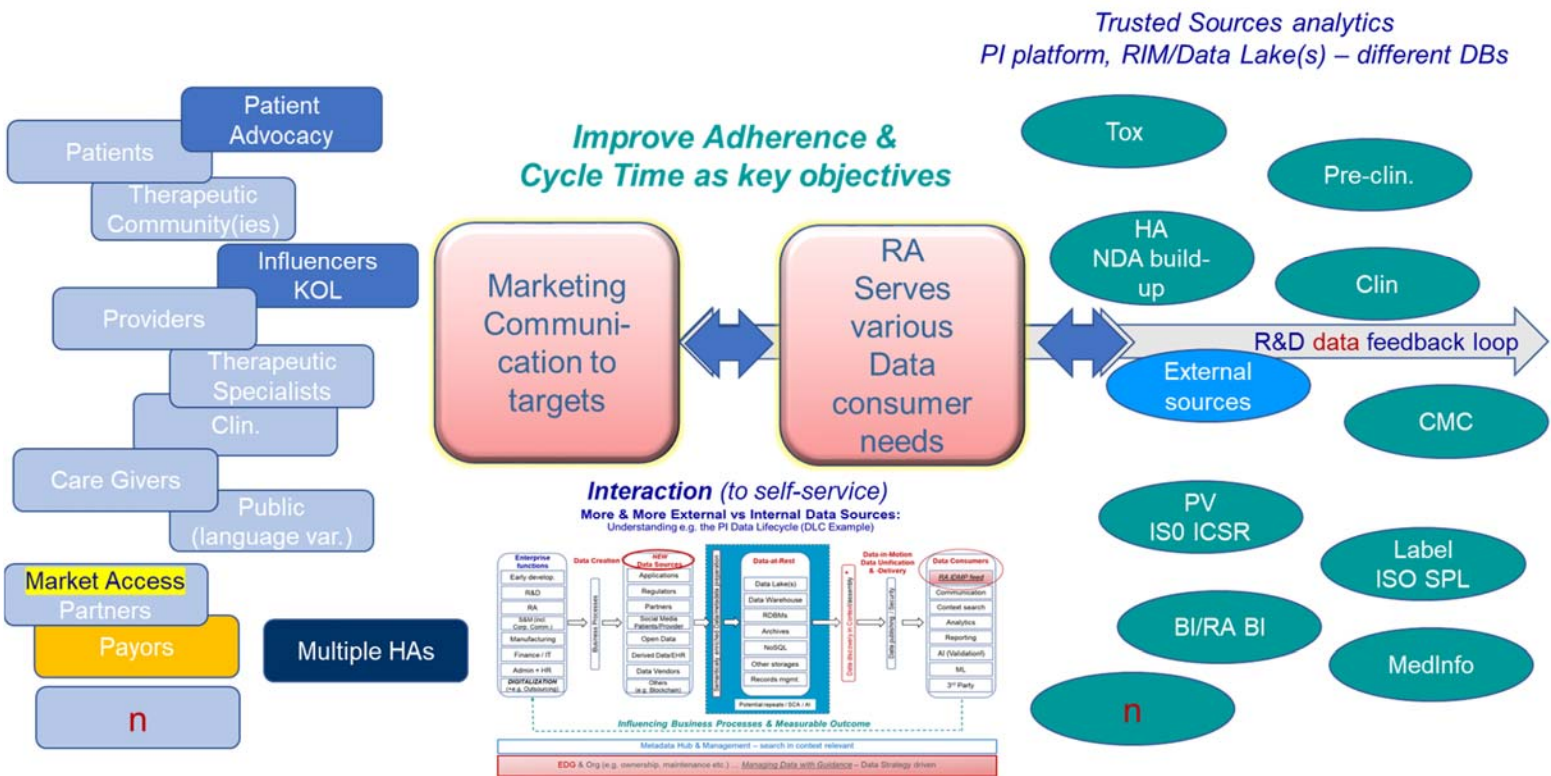
- If others do not understand what you do, then you are perceived with a **cost** bias



- If others understand what you do, then you can be perceived with a **value** bias for e.g. communication targets

Architecting and building the starting ramp to exchange data/information for assembling components as needed for trusted, personalized communication:

... visualized Overview – Source – Target - Source



Looking at content, granularity today can help achieve agility in the organization, and will extend the benefit to many, enabling personalized communication for above needs

All these considerations should lead stakeholders creating a Vision & Strategy (V&S) effort to help understand two very important elements of change: Structured Component Authoring (SCA) and advanced Semantic Technology (ST). These two components will support agility in how to capture, analyze and merge any type of content (data) and how Enterprise Data Governance (EDG) can provide the better framework:

Our Current Thinking: Internal/external Data Consumers

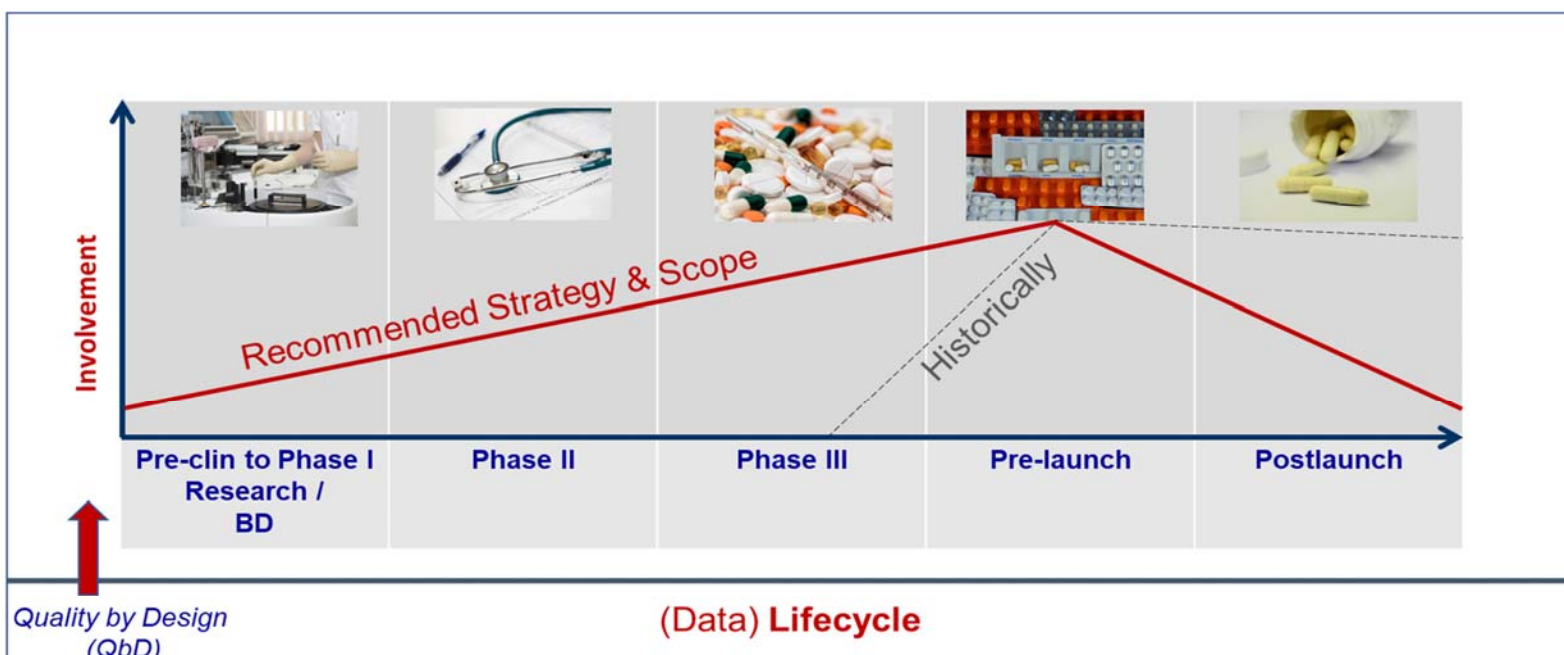
ISO Identification of Medicinal Product (IDMP+ to include SPL & ICSR) with the advances in FDA ISO Structured Product Labeling and EMA's Iteration 1 draft Implementation Guide to be available early 2020 are "just" the regulatory drivers!

LSCP current Opinion

Our Dr. Beat Widler (Core Team Member & CT SME) comments:

The business perspective counts and IT will enable!

Early Market Access/Others: Pay-off for Strategic Change in HA communication ...



Such data driven process has many content component re-use (mapping) opportunity
How easy can RA, Market Access & Medical Affairs/Information exchange data?

End-to-End Data Strategy to Reach Agility along the Product Information (PI) Pike

As we know, innovation needs trusted quality data – internal & external, a prerequisite worth looking at

- Within the Data Lifecycle, **who interacts with whom under what circumstances?**
- What is the **process from external data capturing** (Patients/Providers, Social Media etc.) up to a **meaningful data integration >>> to interact?**
- Do **media breaks** cause manual work?
- Are **data** and their **dependencies mutually understood** across functions to **leverage** such assets?
- Can we just be **satisfied** when **successfully reached a study's endpoint** and neglect enhanced performance to **expedite harmonized data exchange at high-quality** levels?
- Do **Market Access > Medical Information/Affairs > RA interact and viseversa** in a seamless manner to appropriately **feed patient/provider** battleground in a **credible way?**
- ...

Accelerating management of Regulated Content:

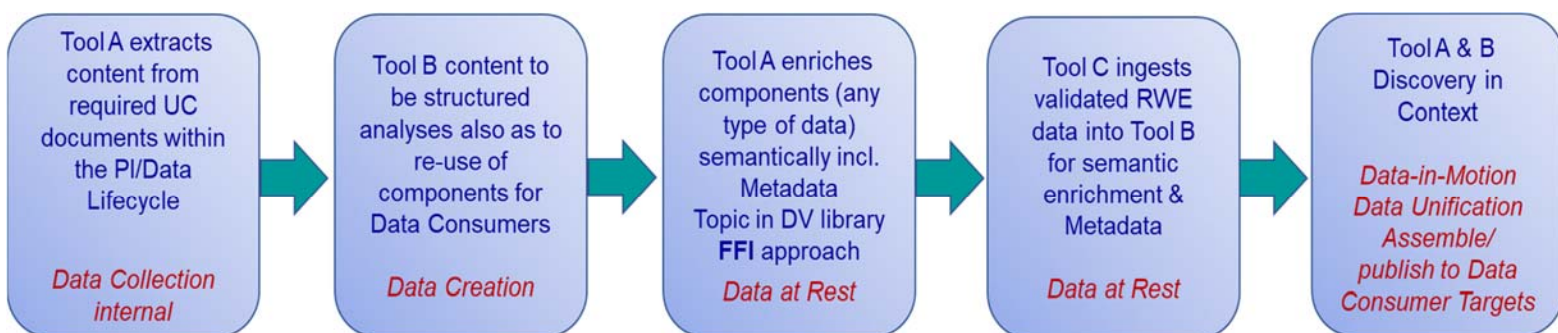
Our Current Thinking: Internal/external Data Consumers

A simple example will illustrate how a section of the SmPC could be structured as data topic to expedite re-use and change in multiple documents – communication internal & external

Get started step-by-step: Concept/Process for Proof-of-Value (PoV) enriched by your input

The following visual is on the conceptual level: By identifying Use Cases (UCs) we will populate it in a Docuvera Topic (“container”) with real data! The Format Free Initiative (**FFI**) allows utmost agility to serve the big variety of targets (personalization). A scalable Data Strategy framework will be developed

Example only: The aim is to pragmatically deliver measurable process outcome for a solid “Marketing” Business Case (BC). Via the selected UCs documents from what relevant functions will be part of the project objective



Tool providers below have a proven record as to data in the Life Science Industry

- Tool A : Smartlogic’s Semaphore for extraction, harmonization, metadata hub and discovery in context
- Tool B : Author-it’ Docuvera Structured Component Authoring and – Management
- Tool C : Big Data RWD to RWE Analytics (customer tool)

The PoV will:

- Deliver new data/metadata that it is currently too difficult or too expensive to produce – because it requires extensive human efforts
- A first phase to a scalable/evolutionary Data Strategy Framework
- Improve decision making based on more and higher quality data in context
- Enable higher levels of efficiency and agility through easy re-use/re-purposing of data to support personalization in a compliant manner

AND

If we closely look at SCA with its inherit opportunities and benefits in order to develop a comprehensive and holistic Enterprise Data Strategy, we urge you to assume the highest level of content granularity and to manage these newly-defined data elements through **EDG** on a platform that is focused on the business needs of tomorrow, enabling increased agility!

Let’s discuss, identify and elaborate options (Happy to provide Author/Contributor’s CV)

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