

**Our Current Thinking: EDG & RWD/RWE ...**  
**LSCP “Format Free Initiative” (FFI) gets traction**

A solid **EDG Data Strategy** starts ...

**Executive Summary**

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Prof. Peter Aiken (data blueprint)

We have to get organized in a different way. Valuable data is extracted from your Digitalization processes. New data sources are being merged with legacy data. The amalgamation of data needs to make good business sense as well as regulatory sense. Regulators like FDA & EMA have recently published their views about what and how they would consider data to be relevant.

The proposal in this issue addresses some key factors to be considered in the context of making use of new data sources. It cannot be brushed off as just Big Data. We need a new approach to unify various data types and content in order to understand, interpret and act responsibly. We must avoid creating new data silos with “functional-only” approaches that do not recognize the existing dependencies between different views (e.g. Vocabularies, data types).

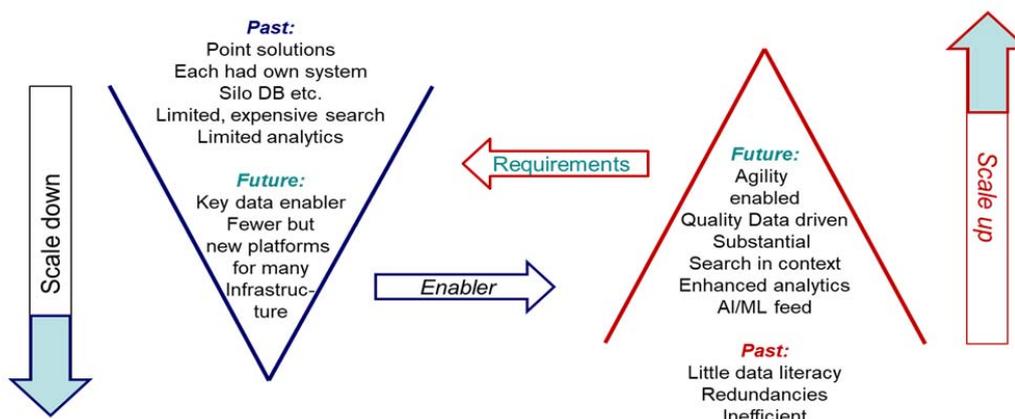
We have proposed, after a thorough conceptual and technical check, an approach to efficiently and effectively address the challenge within a company to unify legacy with new data sources.

**What comes first?**

Last year our colleagues at McKinsey recommended to “Shift Gears”. This is certainly appropriate in the digitally accelerating world. We also see a most important shift happening within companies that identifies how staff competencies and capabilities are changing and how this will impact a successful implementation with FFI. Peter can provide more narrative around this:

**Shifting Competencies & Capabilities**

*Leveraging Enterprise Data Assets – Business driven*



*Data-driven new Business Models mean also Part of Organizational Change!*

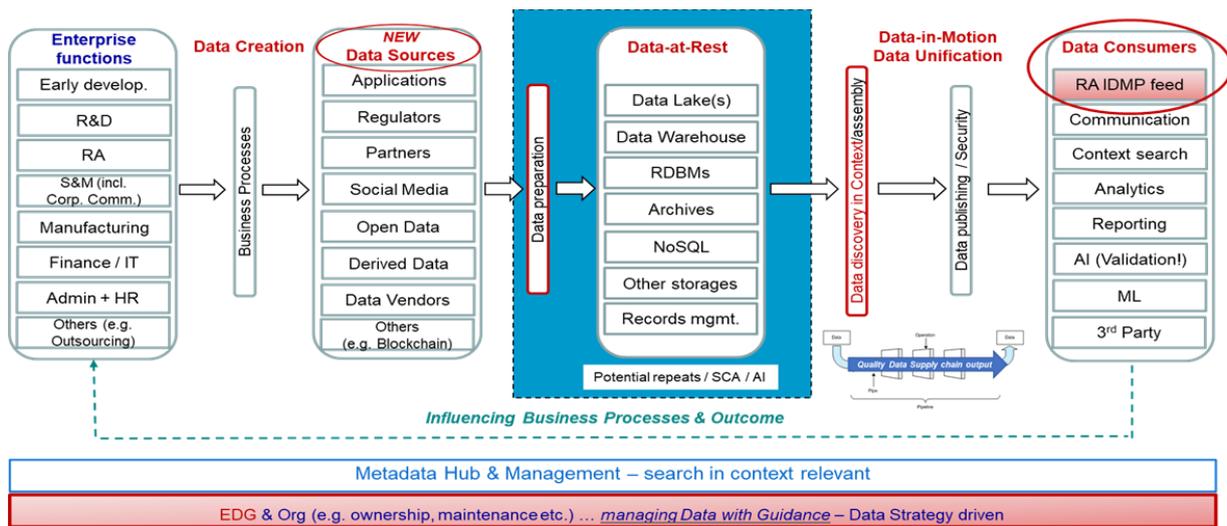
\* In our January 2019 edition of “Our Current Thinking”  
<http://www.lsc consultingpartners.com/wp-content/uploads/2019/01/LSCP-Our-Current-Thinking-012319-RWD-RWE-Format-Free-Initiative-final.pdf>

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**Organizational Change**

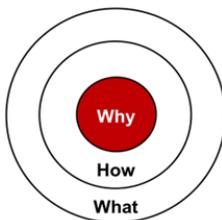
Data is being generated by various functions within R&D and beyond in the rest of the enterprise. Many data elements are being populated in place within the required structure for IDMP+. Mapping can produce many re-use opportunities and eliminate redundancy.

While discussing Enterprise Data Governance (EDG) and “data ownership”, we also need to address “data maintenance” overall and include compliance in particular.



We feel that it will be in your best interest to become aware of what assets Enterprise Data represent and whether traditional practices in Data Management (DM) will still be valid.

When you create – manipulate – assemble ...  
 Understanding Data is a pre-requisite to Meet recipient's EXPECTATIONS ON CONTENT VALUE



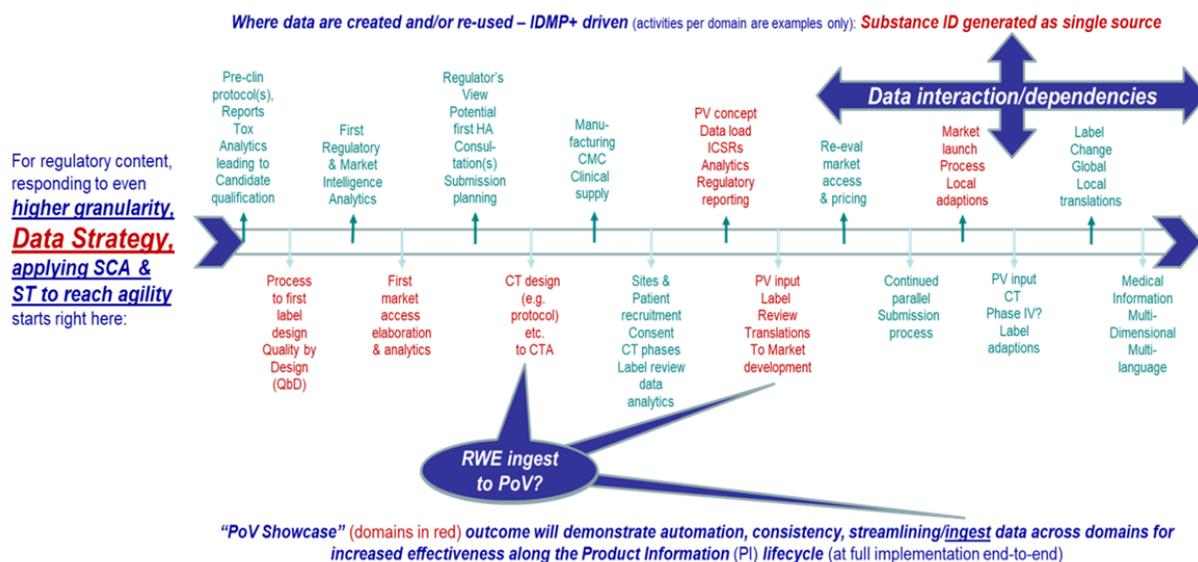
Govern your data holistically – including those from digitalization & new data sources – to grow your business while staying compliant, reducing costs and successfully mitigating risks.  
***Align and tune before accelerating***

It is important to ask the question – WHY?

Not only from a regulatory perspective, but we must also take into consideration the many scientific consultations with Authorities, in particular as to new data sources.

Our strong recommendation is to re-visit your Data Strategy. if we only take regulatory communications with the EMA, without label changes/new market access consultations, there are some 44 “authority decision points” that require a precise and harmonized data assembly to respond to the “WHY”. This will be best reached by creating a data strategy that enables agility.

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### Highlights of EMA/HMA RWD & RWE publication February 15, 2019 (complementing what we learned from FDA in December 2018)

#### Data standardisation

Core Recommendations:

- Promote use of global, harmonised and comprehensive standards to facilitate interoperability of data, with recent example of regulatory uptake and support of standards is provided by **ISO IDMP (LSCP marker)**
  - Tools to extract knowledge and insights from data in various forms both structured & unstructured

#### Regulatory acceptability of Big Data analyses

- Regulatory guidance is required on the acceptability of evidence derived from big data sources
  - Identify the best format to enhance the agility of guidance development and revision in this fast moving field
  - Exploration of novel analytics approaches such as NLP techniques to interrogate unstructured data

Source: 13/15 Feb 2019 EMA/105321/2019 HMA-EMA Joint Big Data Taskforce

#### A First Conclusion

Based on our experiences, together with data **blueprint** we are now able to present “**EDG/Data Strategy Best Practice**” in the above context – to include our 'prediction' that this type of scrutiny will increase success & learnings from other industries (e.g. banking):

**Let’s take a step back together, discuss and elaborate options**

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