

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

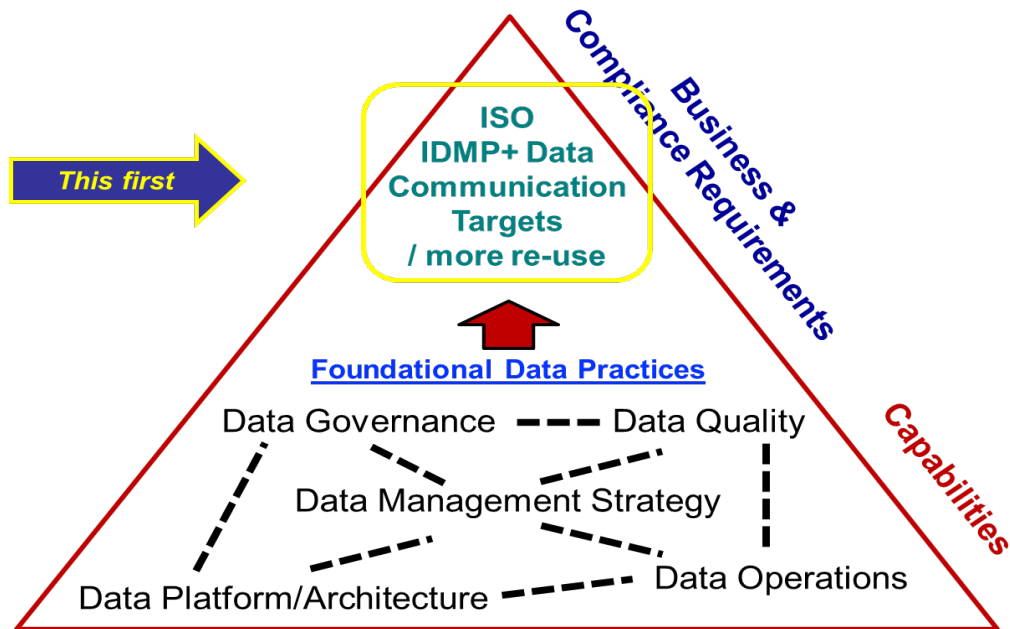
Option:

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

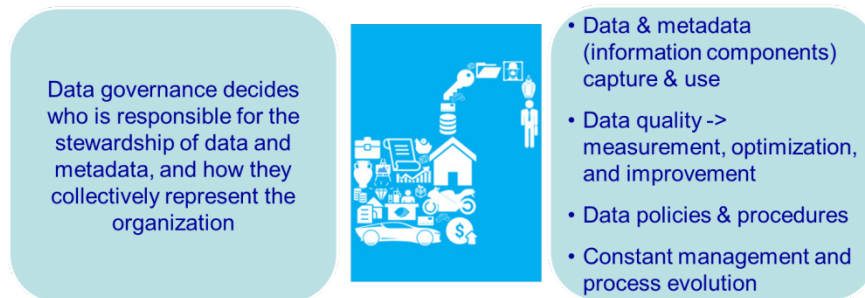


Once we have created new capabilities, we then can select “best fit”, enabling technologies to meet your requirements



SME: Peter Aiken

Assisting to find an effective way to EDG



Managing Data with Guidance

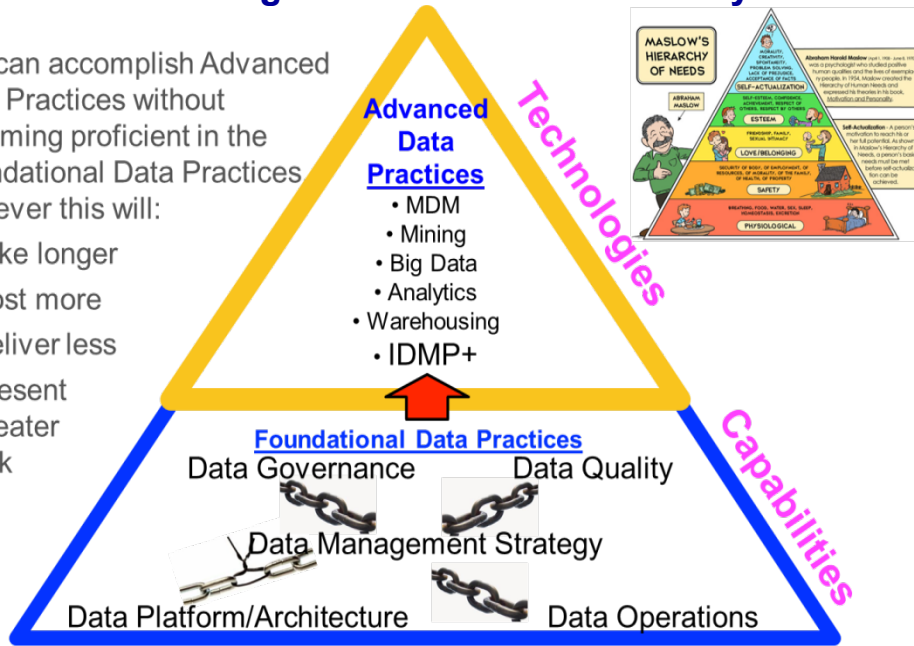
EDG is a **PROCESS** and not a project, getting processes **data** - not systems - **driven!**

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!