Stakeholder perspective - Pharmaceutical industry – Medicines for Europe

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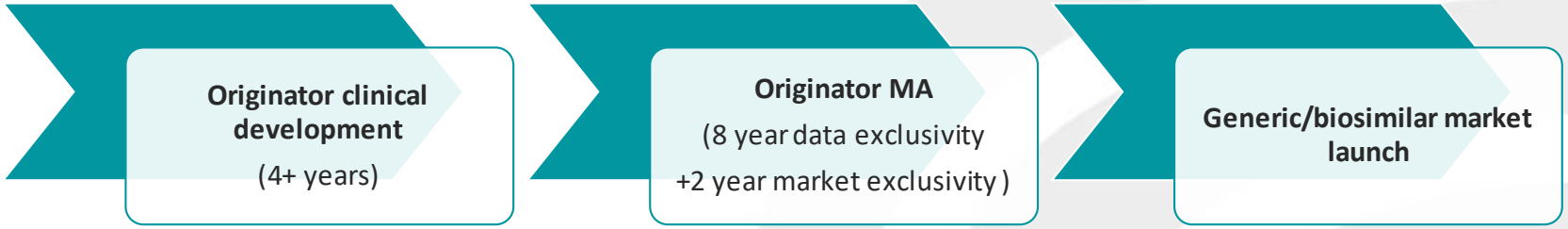
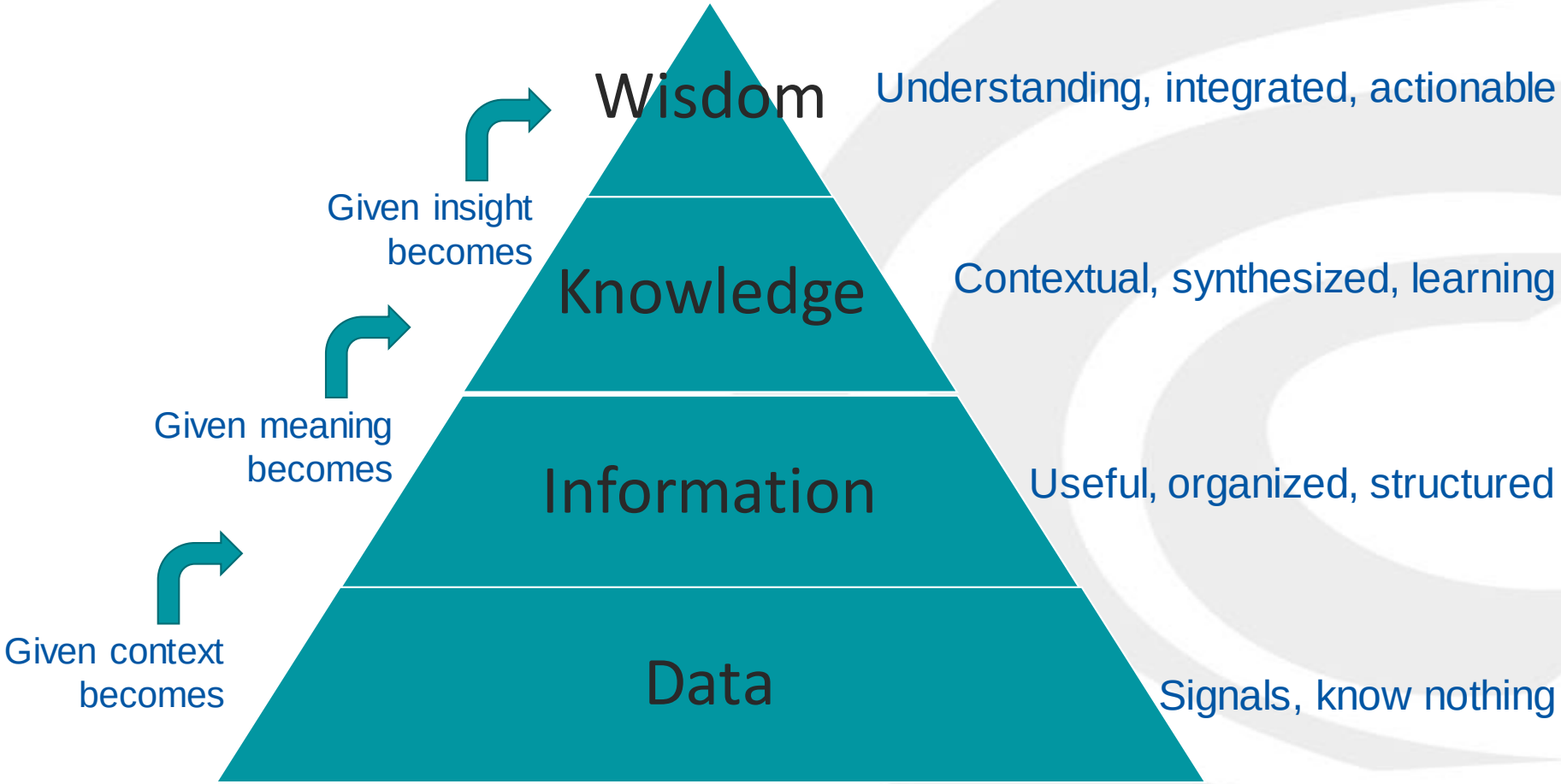
Context of off patent products



By the time the off patent product is launched, there is already very long clinical experience with it

DIKW pyramid



Adapted from Gajzler, Marcin. (2016). Usefulness of Mining Methods in Knowledge Source Analysis in the Construction Industry. Archives of Civil Engineering. 62. 10.1515/ace-2015-0056.

Underlying questions

Data is not intrinsically a good thing:
too much data = noise

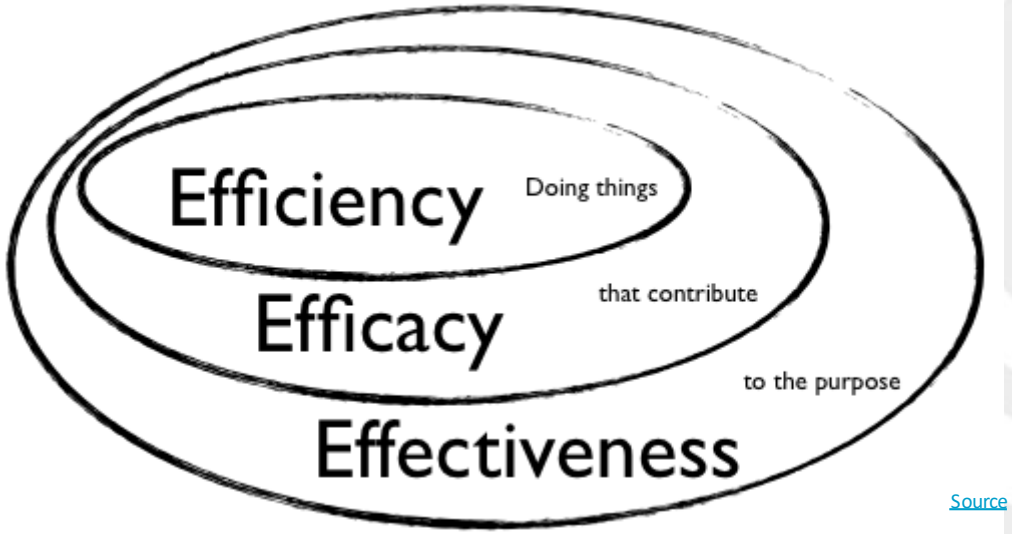
Source

1. Why do we need the data?
WHAT IS THE GOAL/PURPOSE?

2. What do we intend to do with the data?
HOW WILL WE ANALYZE IT?

Case study

- **Example: signal detection in pharmacovigilance**
- Data is collected in Eudravigilance
- Data is downloaded and analyzed in parallel by ALL MAHs (multi-source environment) – massive resources
- There is very little added benefit for patient safety: very small number of valid signals from the pilot phase



Source

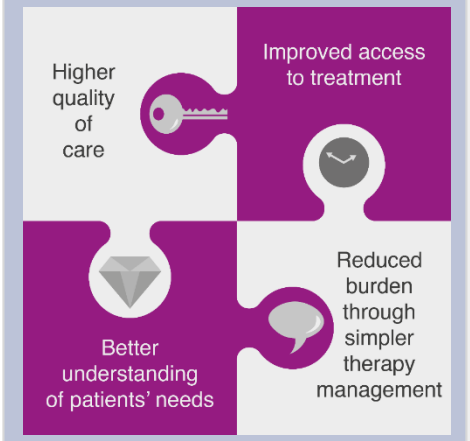
Opportunities and risks

- Repurposing of drugs
- Assessing adherence and patient preferences
- Access to anonymized patient data from registries to leverage repurposing
- Patient recruitment in clinical trials
- Data reuse – highlighting the need for systems interoperability
- Reusability by third parties and public benefit from data

DRUG REPOSITIONING
Finding new indications

DRUG REFORMULATION
New delivery system

COMPLEX COMBINATION
New regimens
or adding technology



Opportunities for future pragmatic evidence generation on added therapeutic benefit of innovation on well-established substances - Value Added Medicines:

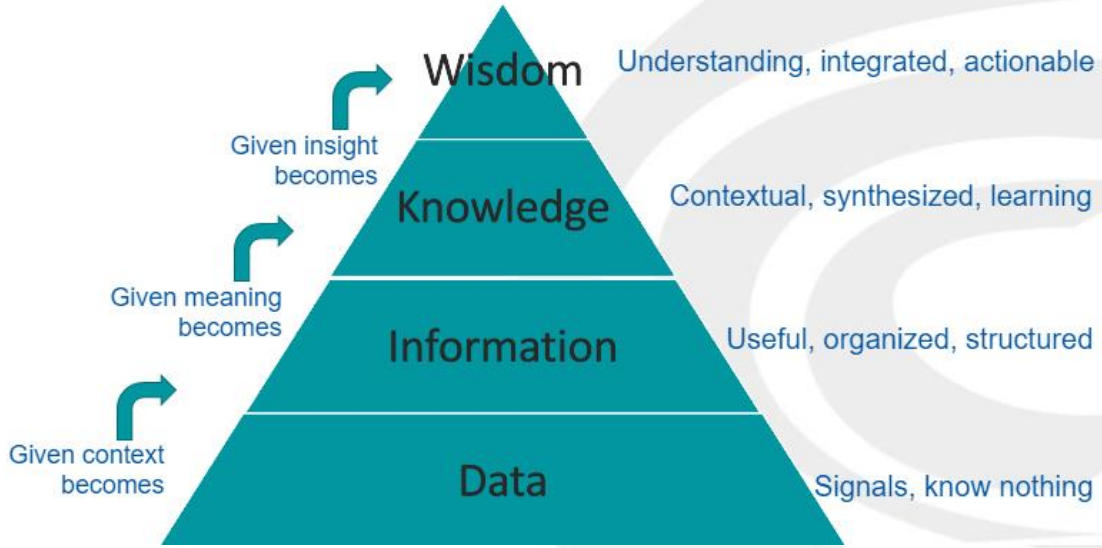
- ✓ Repurposing
- ✓ Integrating patient preference in the design of formulation
- ✓ Improved adherence
- ✓ Tailoring to individual needs

Priorities in the off-patent context

- By the time generic medicines/biosimilar medicines enter the market, the product profiles are already very well characterized
- Additional efforts to collect data that go beyond the current fit for purpose approaches should be well balanced:
  - There must be a clear purpose in all data collection efforts
  - Efficient data collection and efficient data analysis are critical

Areas for collaboration/engagement

- Medicines for Europe and its members across its sector groups are open to collaborating and further engaging on these potential topics



medicines for europe
better access. better health.

Thank you!