#GPRAS

Global Pharmaceutical Regulatory Affairs Summit

April 7

Berlin
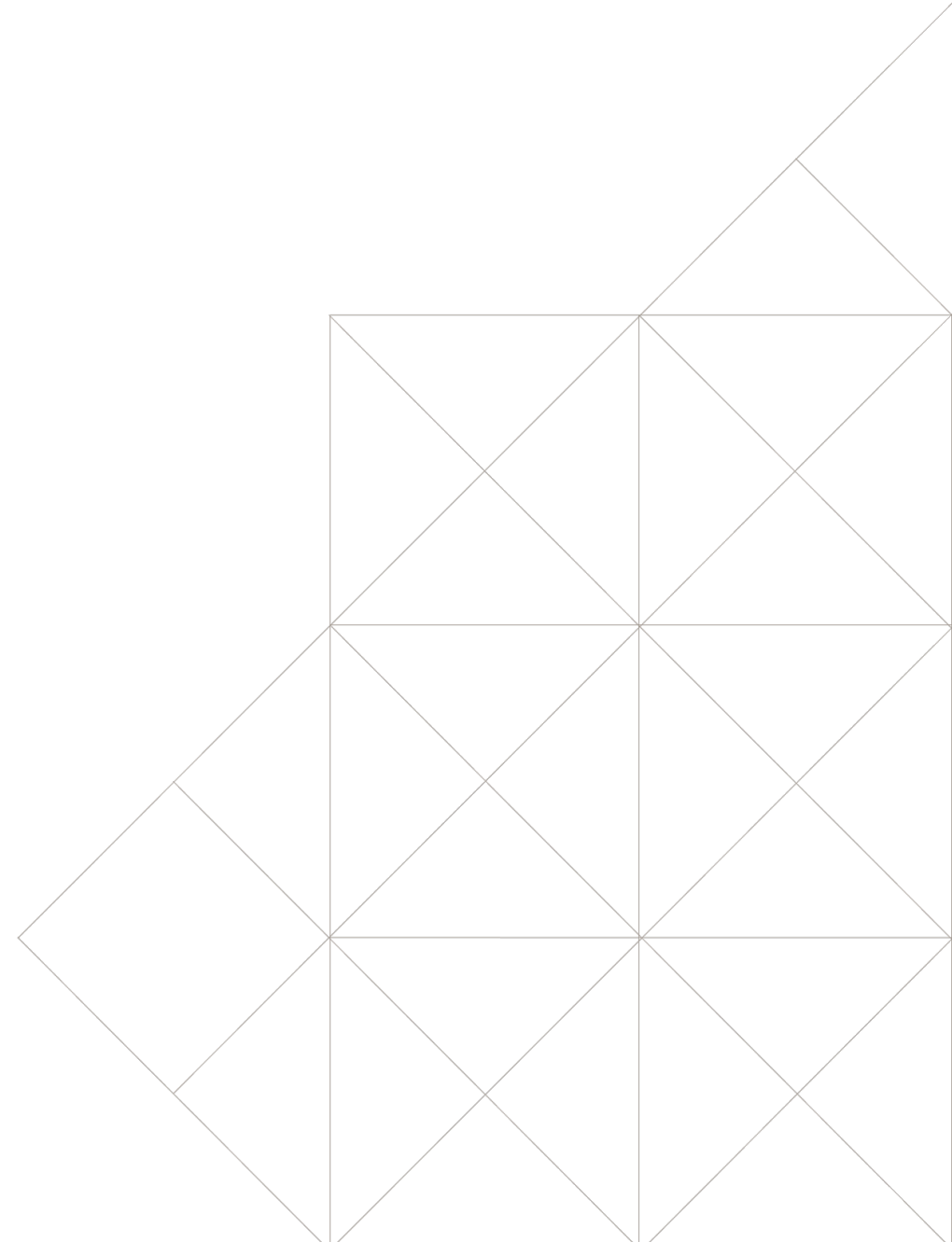
At Fonto, we make it easy for <u>everyone</u> to create, edit and review structured content.

- Founded in 2014
- Based in The Hague , The Netherlands
- Member of the RWS group of companies

An overview of the batches manufactured to date is provided in Table S.4.4-1, Table S.4.4-2, and Table S.4.4-3.

All PPQ batches were analyzed and evaluated according to the analytical procedures described in Section S.4.2 Analytical Procedures unless otherwise stated. An overview of analytical procedures used during development is provided in Section S.4.5.X Justification of Specification—Analytical Development.

> **GUIDANCE**
>
> In case some batches were analyzed using any previous analytical procedure, this should be briefly addressed here and the differences should be pointed out if applicable.

The batch analysis data are provided in Table S.4.4-4, Table S.4.4-5, and Table S.4.4-6.

The acceptance criteria indicated in the data tables are those that were in effect at the time of testing and release of each batch. If appliccable: Additional (i.e., not specified) tests have been included to provide the full analytical picture of these batches.

The assessment of the PPQ batches against the proposed commercial specification is provided in Table S.4.4-7.

2 Genealogy of Drug substance

The batch genealogies of MOLECULE-INN-DS-X drug substance are summarized in the following tables:–

Table S.4.4-1 Genealogy of Drug Substance PPQ/Commercial Batches

Today's talk

The Future of Documents is driven by changes in how information is **consumed**

"From Documents to Data", What is Structured Content ?

Maturity levels in the adoption of structured content

Expectation, changes and hurdles, how to overcome them

Forrester, December 2020: "The Future of Documents"

FORRESTER

- Human information consumption is evolving from paper to digital forms
- More and more information is interpreted by machines
- NLP/AI may be helpful but does not address the root-cause: the "semantic key-hole"

"The semantic key-hole"

Data-sources are rich in structure and semantics: MDMs, RIMs, LIMs, etc.

When data is copied to a document, most of this semantics get lost.

At the receiving end, the data is interpreted, based on styling

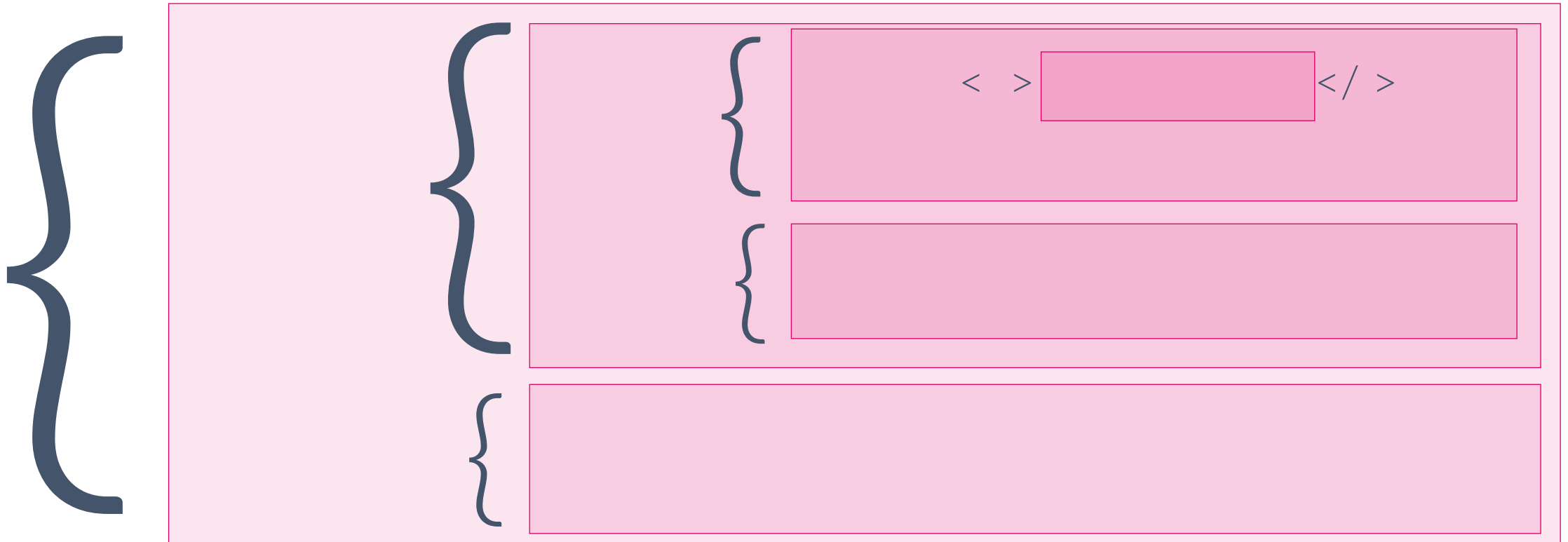**What exactly is structured content**

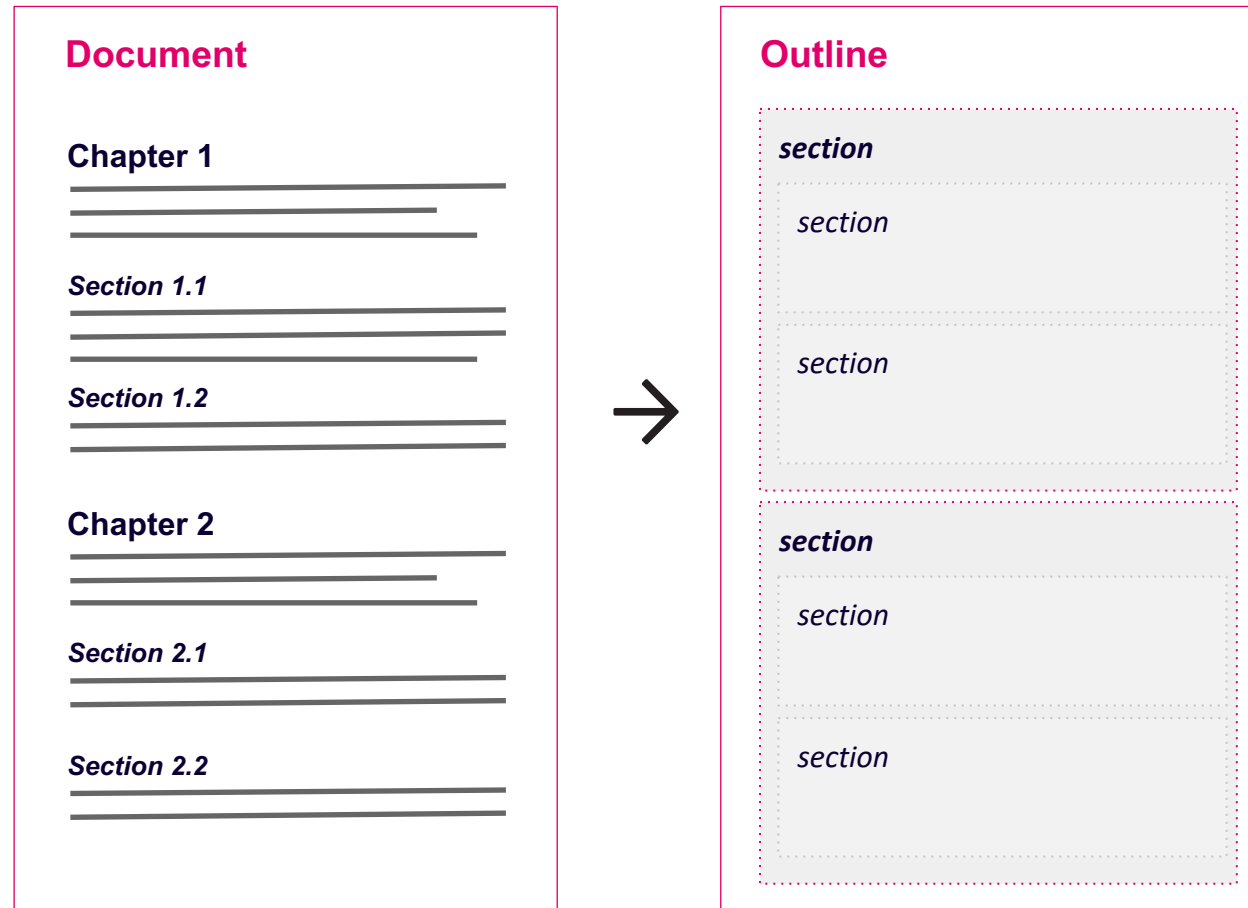|	
Structured Content is content stored in 'structured XML'	It is 'raw-material' to produce one, or multiple outputs
It is **not** styled	It is a collection of content-assets, rather than monolithic documents

Plus: It is semantically rich !

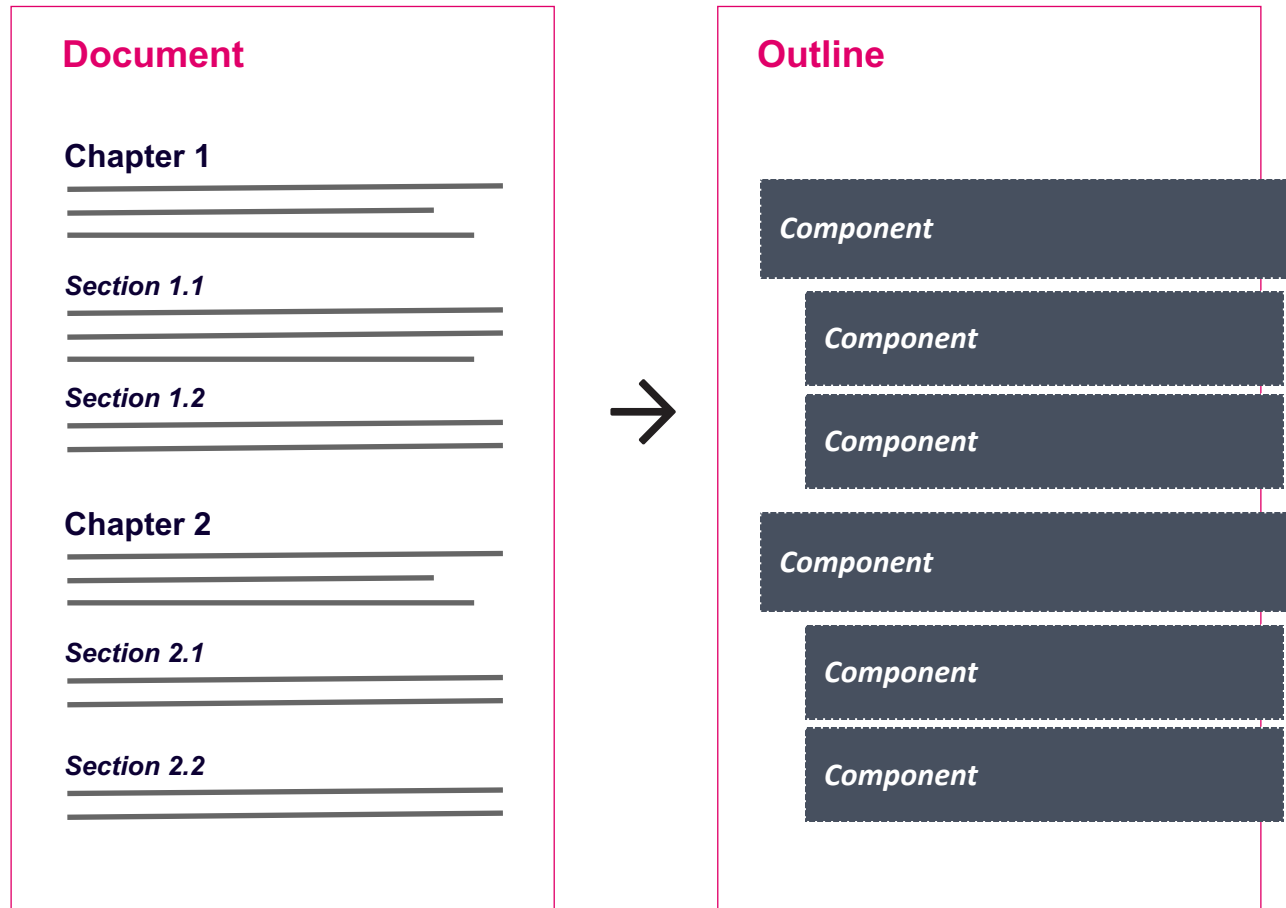# Content architecture: structures and components

Content architecture: Granularity (1/2)

Document

Chapter 1

Section 1.1

Section 1.2

Chapter 2

Section 2.1

Section 2.2

→

Outline

section

section

section

section

section

section

- The document is a single file

- Closely resembles the way of working with Word

- *Granularity: "coarse"*

Content architecture: Granularity (2/2)

Document

Chapter 1

Section 1.1

Section 1.2

Chapter 2

Section 2.1

Section 2.2

→

Outline

Component

Component

Component

Component

Component
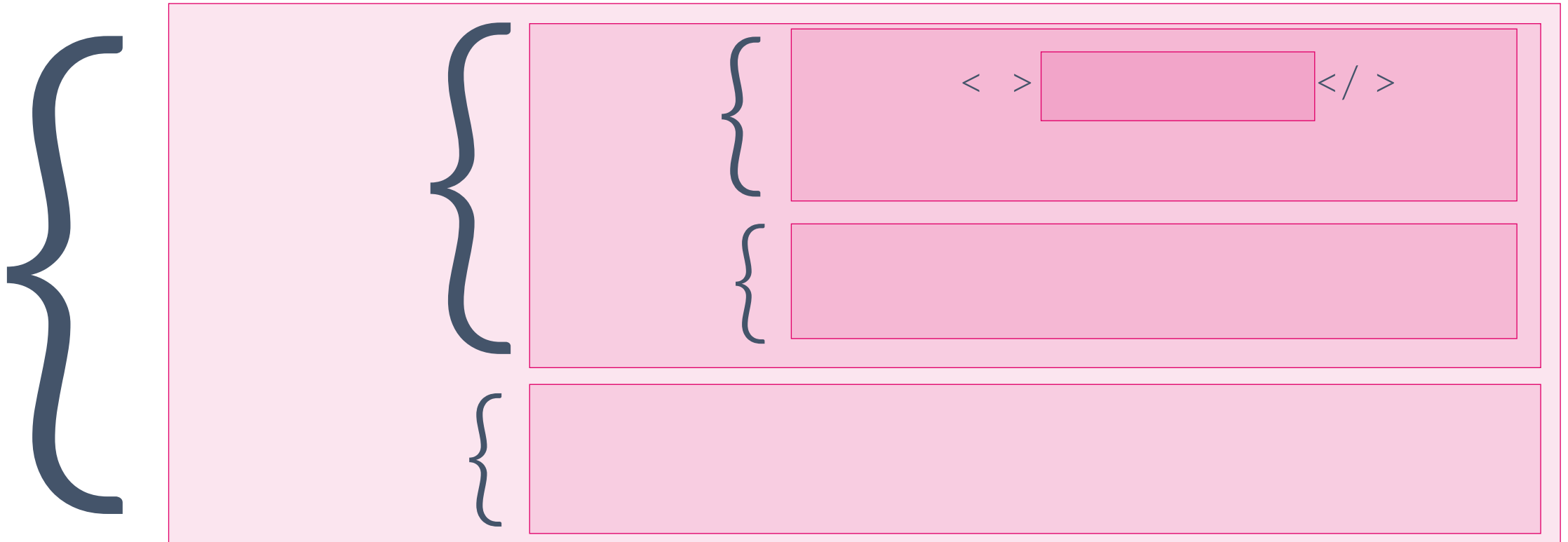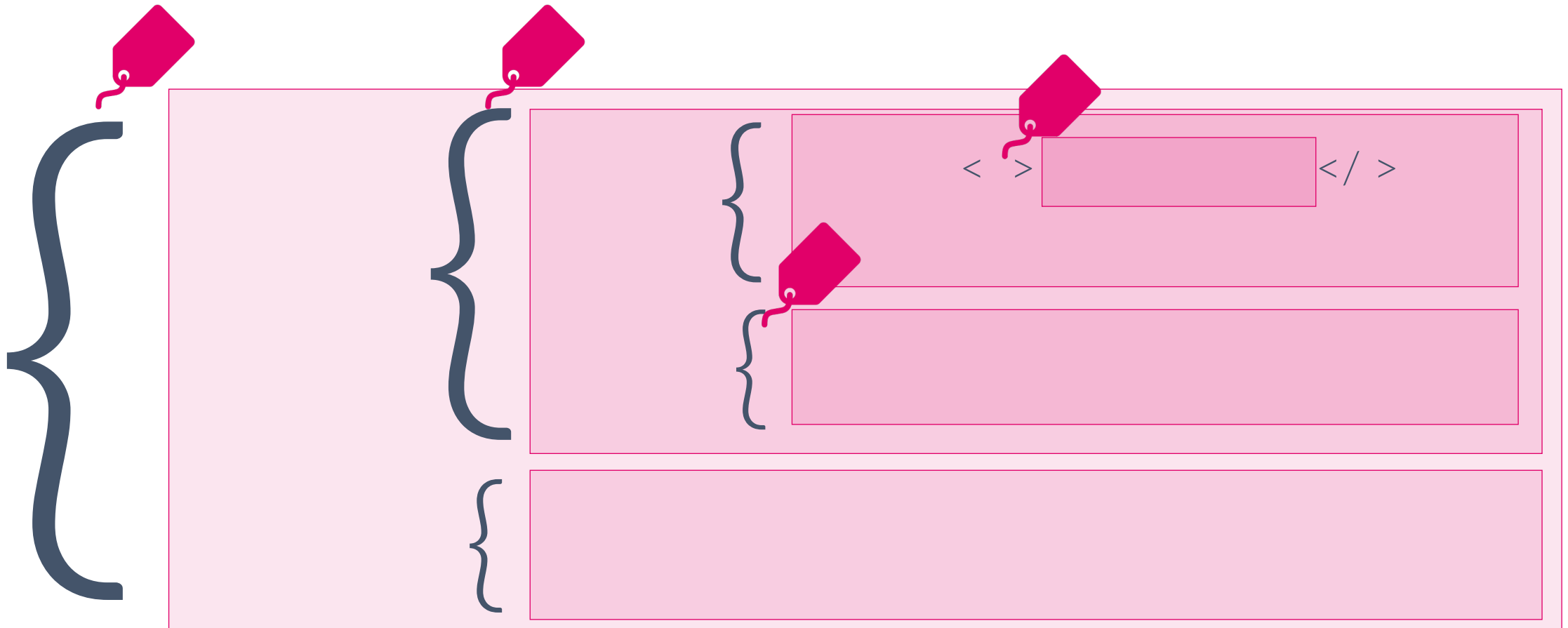
Component

- The document is 'chunked'

- Every Component and can be reused in multiple contexts

- *Granularity: 'fine grained'*

Content architecture: structures

Content architecture: Semantics

Semantic tagging: text turned into data

```
<warning>Wear a medical face mask</warning>

<product>Aspirin</product>
```

```
<warning ref=ISO22609:2004>Wear a medical face

mask</warning>

<product FDA-NDA=016039>Aspirin</product>
```

The outcome of content-architecture: "Schema"

Which **Structures** are allowed in the content

Which **Semantics** are present

Standardized schemas are the **basis for digital data-exchange**

Structured and Component based authoring: 3 stages

STAGE 3

The organization can publish not only documents but also data-sets, in an integrated manner. Data and content are integrated
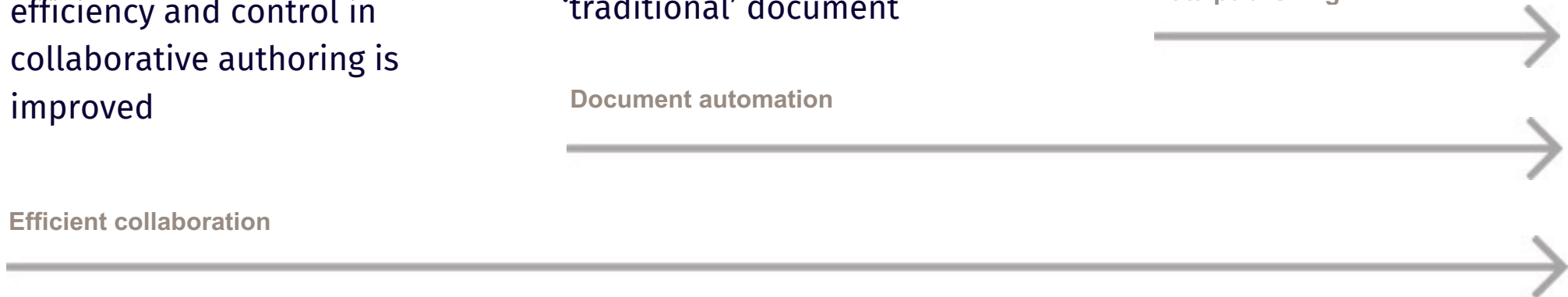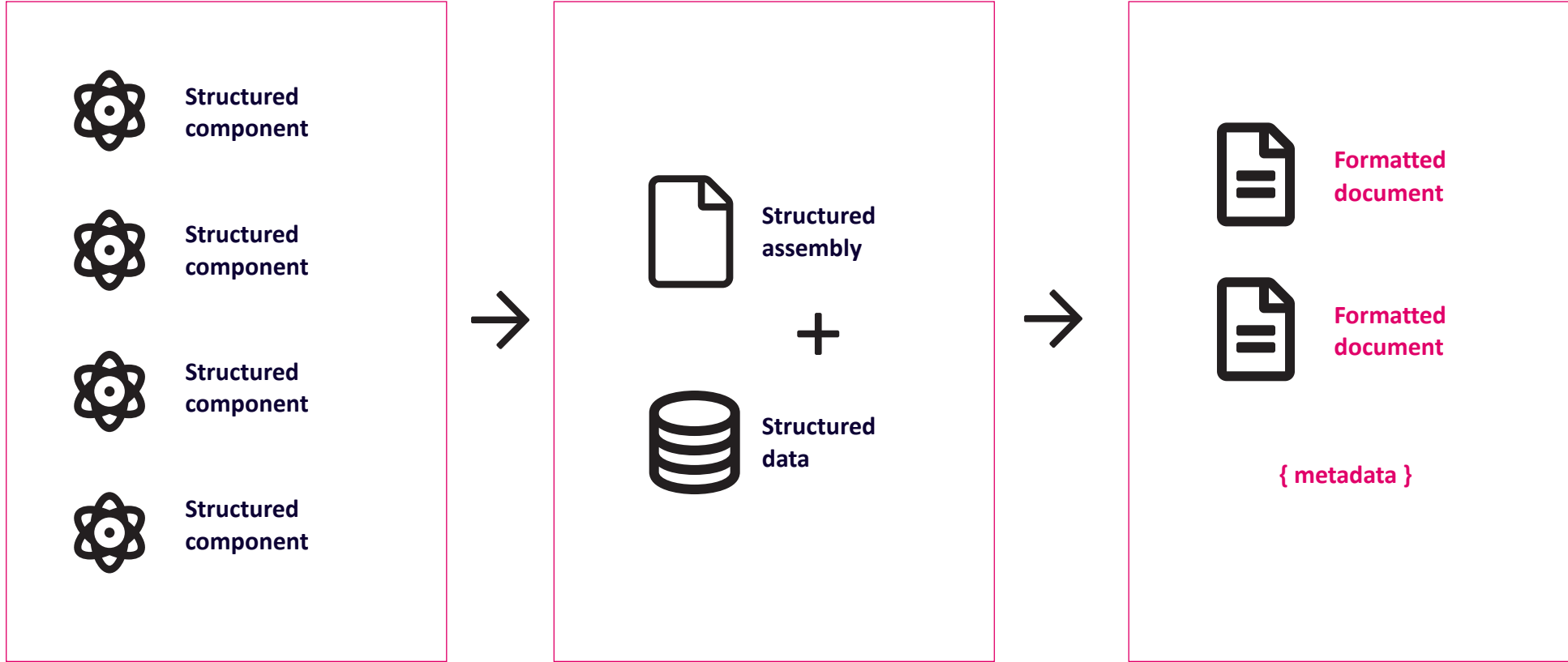
STAGE 2

Documents are automatically produced, built from reused components and automatically populated with data. Output is still 'traditional' document

STAGE 1

By organizing authoring, review and approval on the level of components, efficiency and control in collaborative authoring is improved

Data publishing →

Document automation →

Efficient collaboration →

Document Automation: still the 'old paradigm', but already valuable

Structured component

Structured component

Structured component

Structured component

→

Structured assembly

+

Structured data

→

Formatted document

Formatted document

{ metadata }

Content reuse
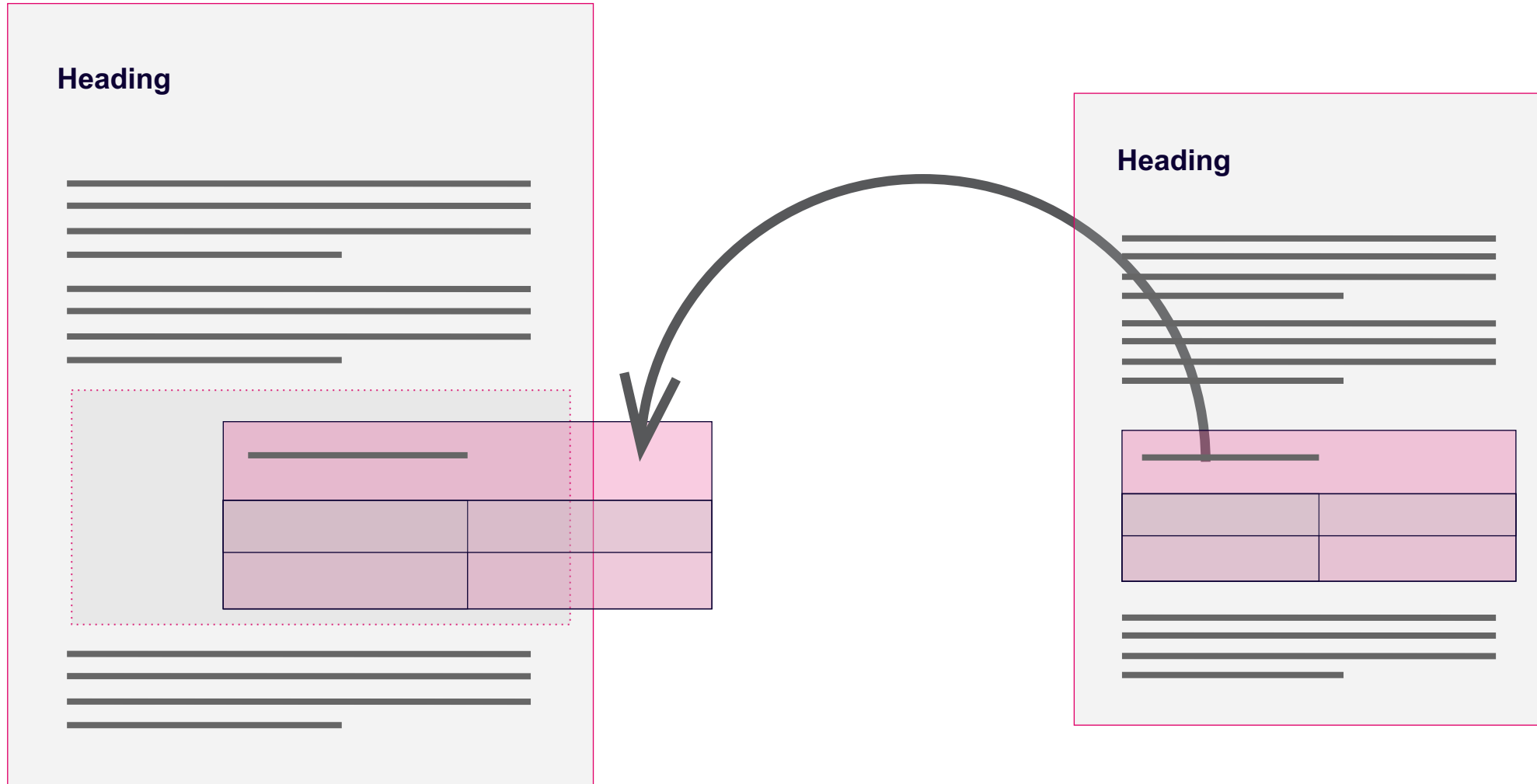
Data Source Inclusion

New roles in authoring

Model document → Working document → Generated document()

Structures, semantics, data → Formatting (automated)
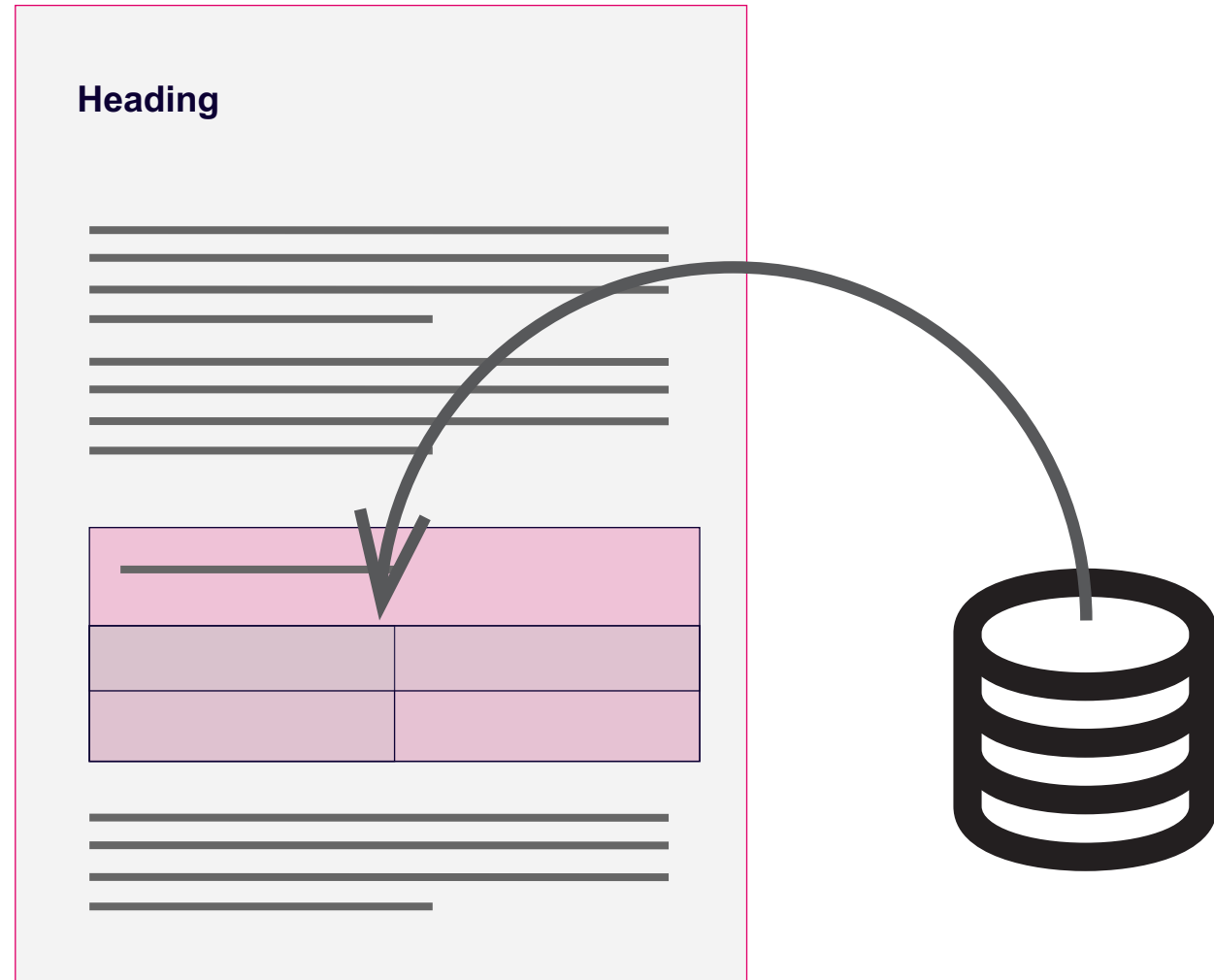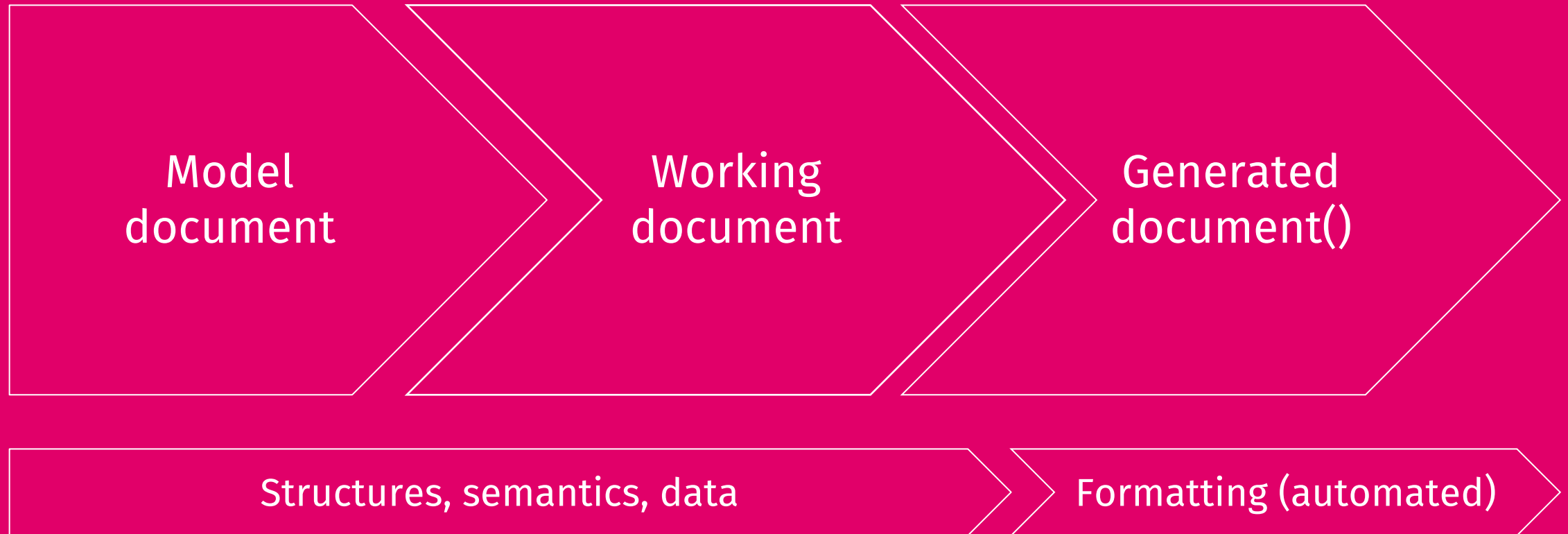
From Content-assets to 'classic' documents: semantics to styling

When generating a document, semantics are converted to a 'style':

`<warning>` → Box with a frame and an
`<product>` → Small Caps and bold

Semantics can include conditions, such as **countries**, or **audiences**. This allows multiple outputs from a single source

Observations

Structured content is often understood as forms, templates, ToCs or standardized sections. But is means a **schema** and **structured** XML

To date, a lot of projects are 'Document Automation". While there is value in that, the real leverage will come when organizations (have to) 'publish' digital data

The technology is ready and proven in other markets. Authors and habits will change.
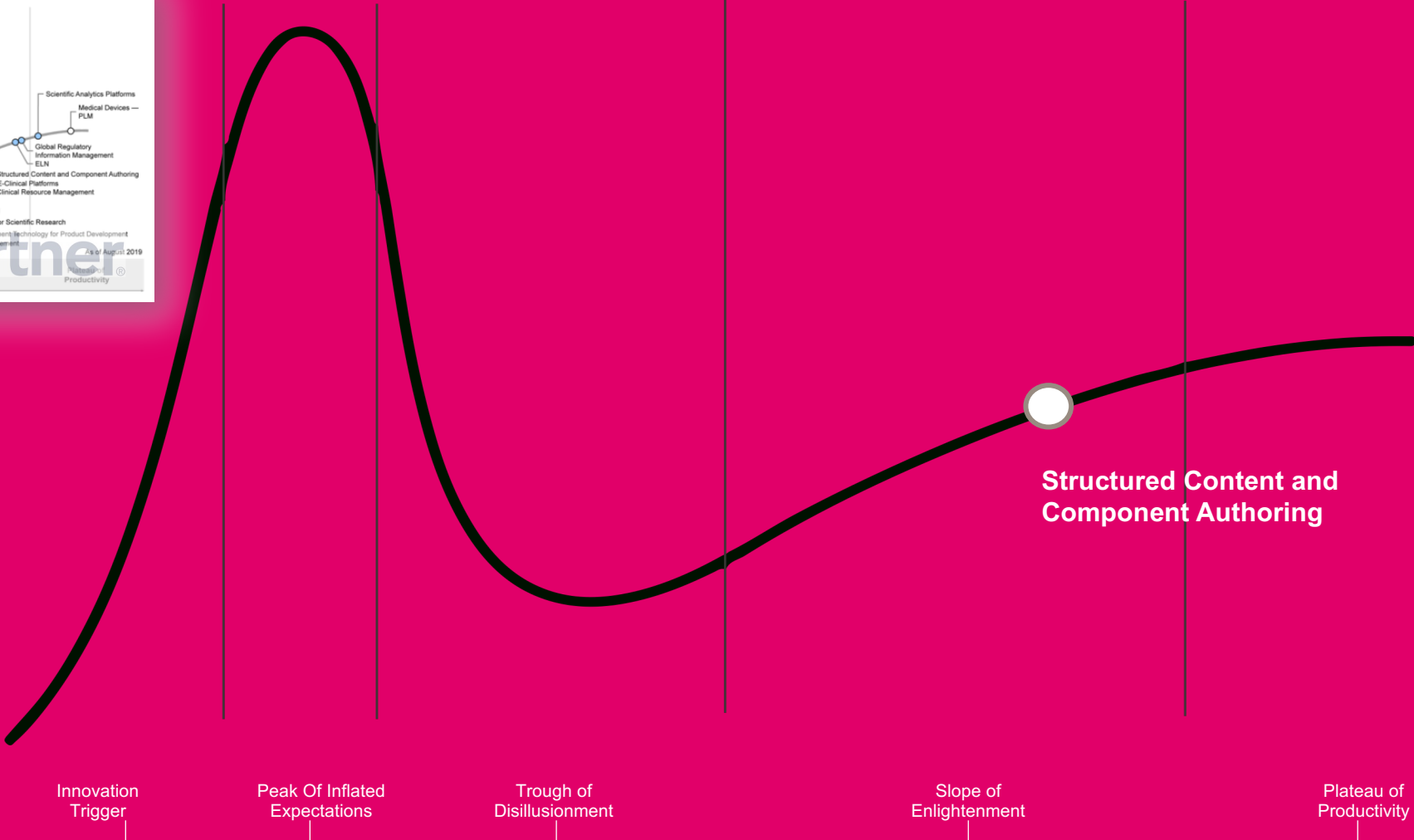
Expectations

Hype Cycle for Life Science Research and Development, 2019

Structured Content and Component Authoring

Expectations

Innovation Trigger

Peak Of Inflated Expectations

Trough of Disillusionment

Slope of Enlightenment

Plateau of Productivity

Time

Forrester, December 2020: "The Future of Documents"

- "Documents are ready for their own digital disruption"
- By 2027, a main-stream paradigm shift will have taken place in how documents are consumed and produced

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