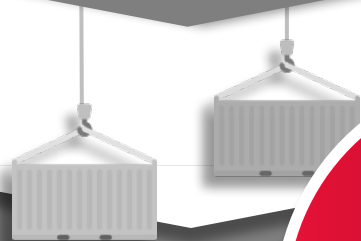


PROBLEM

Trapped, Unstructured Data



DATA MINING FOR REGULATORY

The path to digitization requires regulated life sciences organizations to identify solutions for information transformation.

- From Unstructured to Structured
- From Distributed to Single Storage

Creating a regulatory single source of truth will be required. Besides data gathering, the aspect of ongoing data maintenance needs to be planned for. The two data management options are:

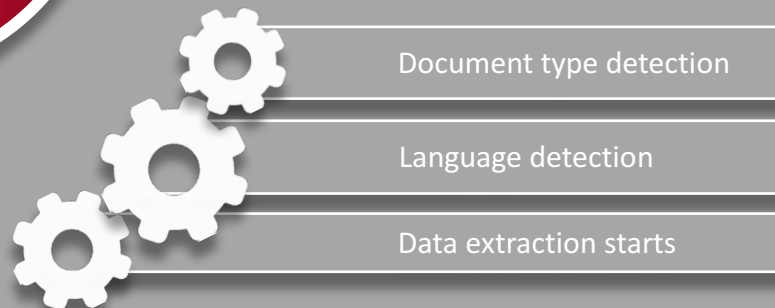
- Manual versus Automated

WHAT

Software Technology



Automated data mining is a sophisticated analytic process created to explore large amounts of data in order to find correlations, insights and patterns.



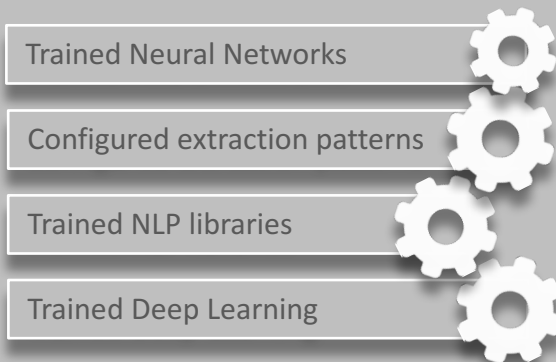
USE CASE IDMP: > 50% of the information needed for IDMP Iteration 1 resides in unstructured data sources such as SmPC's, eCTD 3.2.x and other documents. Data mining can be used to extract needed information in a smart, efficient and fast way. Here is how it works:

HOW

Deep Learning & NLP



Data mining software matured over the last 5 to 10 years and is able not just to convert text files but to understand what it is reading and to learn what we expect as a result.



RESULT

Save Costs and Time



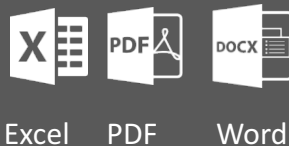
100% Quality

40% Cost

20% Time

automated
 manually

Step 1



Step 2

PHARMACEUTICAL FORM
Pink colour sugar coated tablets.

NAME OF THE MEDICINAL PRODUCT
Ibuprofen 400mg Tablets

Therapeutic indications

POM indications: DISPENSING PACK
Ibuprofen is indicated for its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies.

Step 3

Challenges Solved:

- Mixed languages in SmPC's
- Inconsistent data formats
- Horizontal vs vertical text
- SmPC template adherence

Step 4

Data Extraction Record

Section

- Medicinal Product Name
- Dosage Form
- Marketing Authorization
- Shelf Life
- Substances / Active Substance
- Substances / Excipients
- Clinical Particulars / Indications
- Clinical Particulars / Undesired Effects
- Packaged Items
- All Items