ISO/IDMP Initiative: Maturing Structure and Standardization with the Healthcare Ecosystem

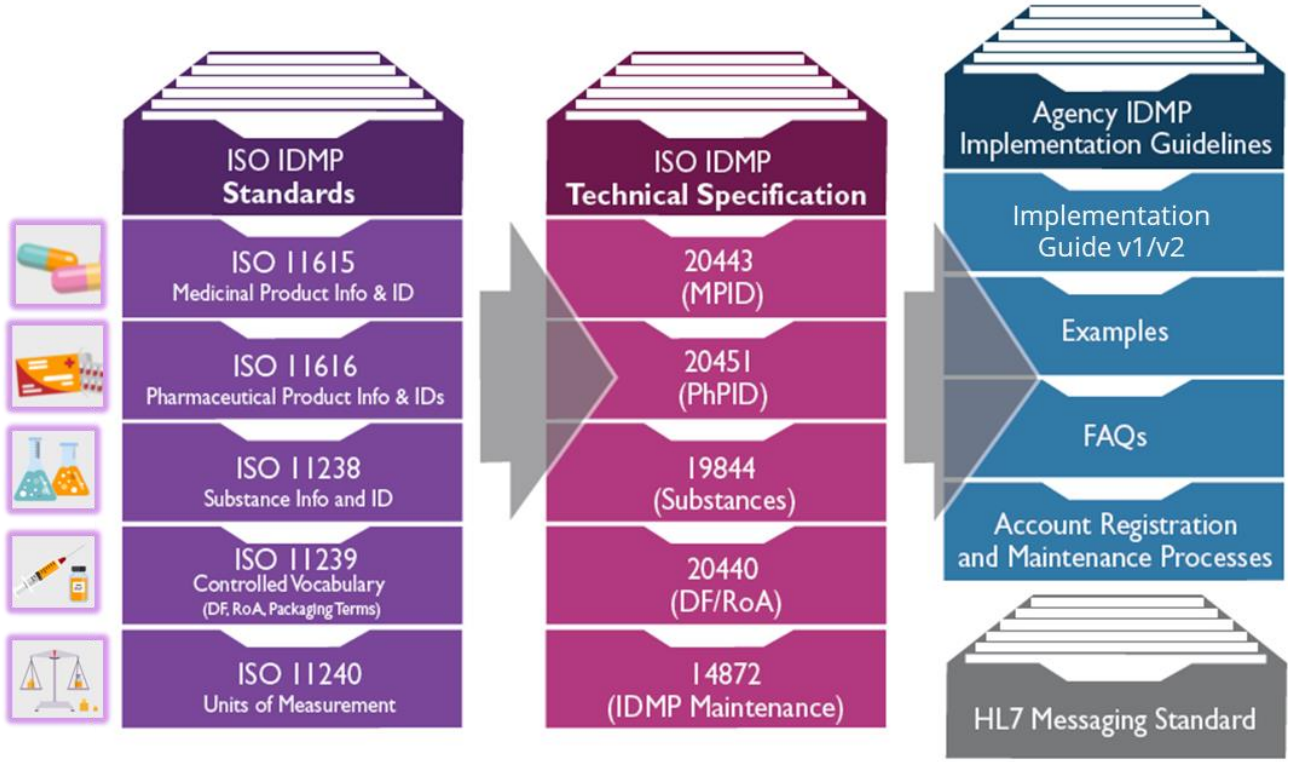
Brooke Casselberry

Associate Vice President, US R&D

ISO-IDMP Standards and Technical Specifications

Identification of Medicinal Products (IDMP)

Each Standard defines data elements and structures for unique identification and exchange of a certain aspect of a medicinal product



Implementing a global standard regionally

ICH harmonisation for better health

IDMP spins out of ICH to support improved patient safety to establish data foundation for ICSR

ISO

ISO assumes ownership of (ISO) IDMP and defines standards and implementation guidelines for the global implementation (2010-2018)

FDA

SPL, PQ/CMC

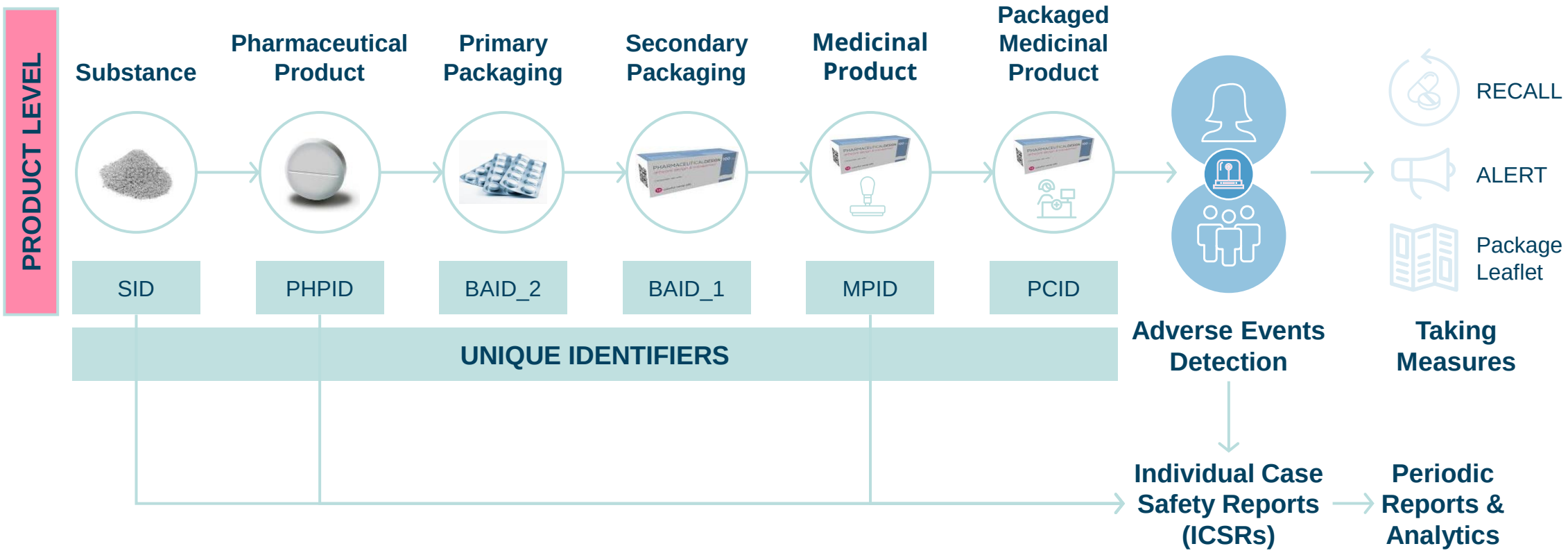
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR, xEVMPD, CESP

Regional authorities implements in different initiatives based on legislation (2018 →)

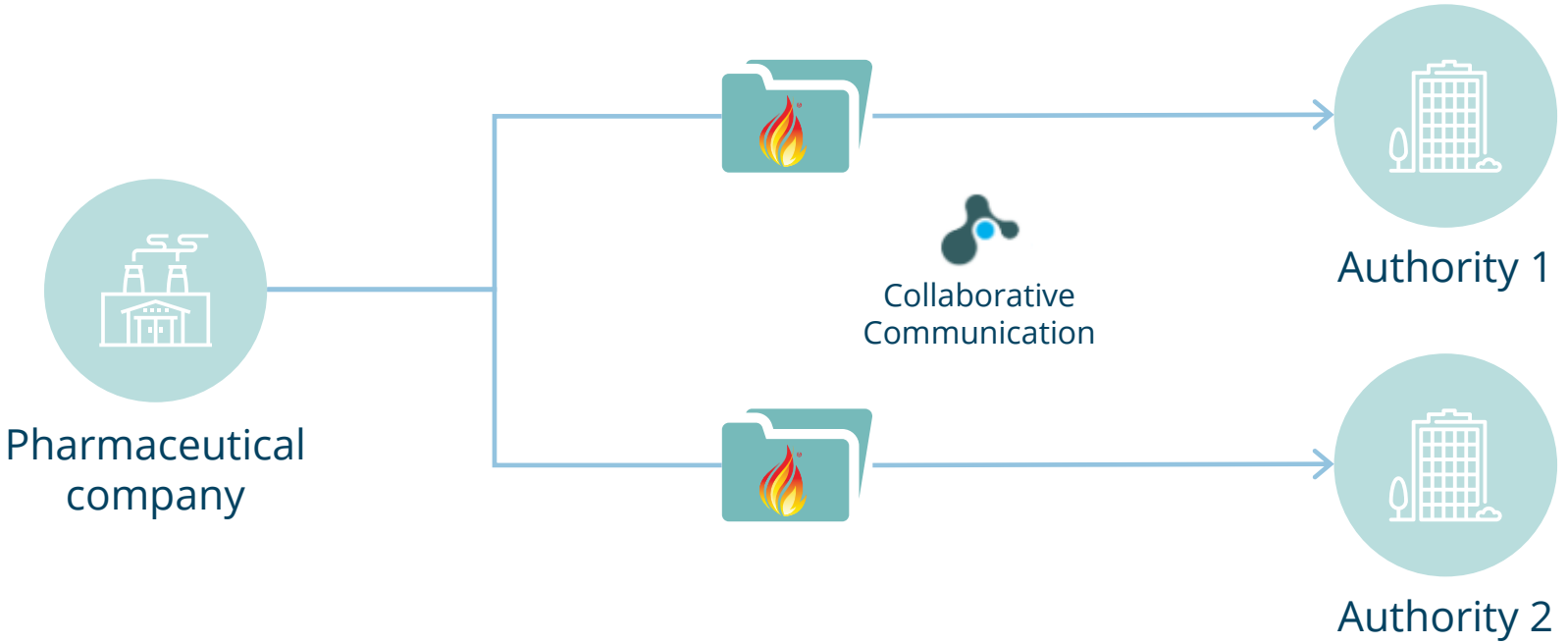
IDMP Drivers – Pharmacovigilance

Pharmacovigilance – Supported by the concept of Unique Identifiers



IDMP Drivers – Efficiency

Improve and unify the exchange of data between the pharma companies and authorities



HL7® FHIR®

Different authorities, same XML structure.
What eCTD is to documents, FHIR is to structured data!

Mapping of Data IDMP to CMC – As Applicable

GUIDANCE DOCUMENT

Identification of Medicinal Products — Implementation and Use

MARCH 2023

Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Exchange; Request for Comments

Created by the **Food and Drug Administration**

"…the harmonization of global IDMP implementation is a process whereby regulatory recommendations across different countries or regions become aligned over time using international guidance documents, consensus standards, policies, and procedures." FDA Notice 2023-D-0266-0001

CANADA

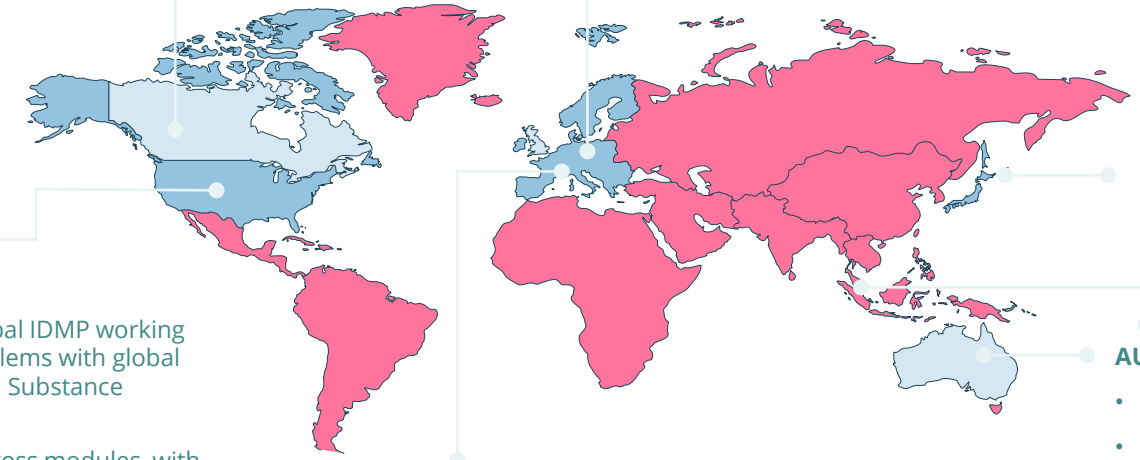
- Confirmed commitment to implement IDMP as appropriate in alignment with SPM and adoption of Controlled Vocabularies
- In June 2021, HC initiated Phase II: full production on voluntary basis for XML Structured Product Monographs (SPM). Timeline for mandatory transition under development. Following HL7 SPL and HC CVs

USA

- FDA is taking a Modular Approach
- FDA and EMA started a new GIDWG (Global IDMP working group) with WHO-UMC to tackle the problems with global implementation of IDMP – e.g. PhPID and Substance identification
- FDA testing Data Exchange Standards across modules, with alignment to ISO IDMP as appropriate: Module 3 PQ/CMC, Module 4 SEND, Module 5 ICSR E2B(R3), CeSHarP initiative using the Fast Healthcare Interoperability Resources (FHIR) messaging for exchange

EU

- EMA is taking an agile approach to IDMP implementation
- The eAF form approach will be aligned with SPOR databases, SIAMED, IRIS, and xEVMPD
- RMS and OMS rolled out and being used, SMS progressing, PMS UAT in progress



JAPAN

- Actively participating and the interest is also driven by the connection to the E2B(R3) standard in Pharmacovigilance
- Adoption of ICH Approach to Data Standards and Application

AUSTRALIA AND SINGAPORE

- Part of the ACSS consortium
- Following Switzerland and Canada

SWITZERLAND

- Swissmedic will follow EMA's approach closely, regarding both requirements and timelines

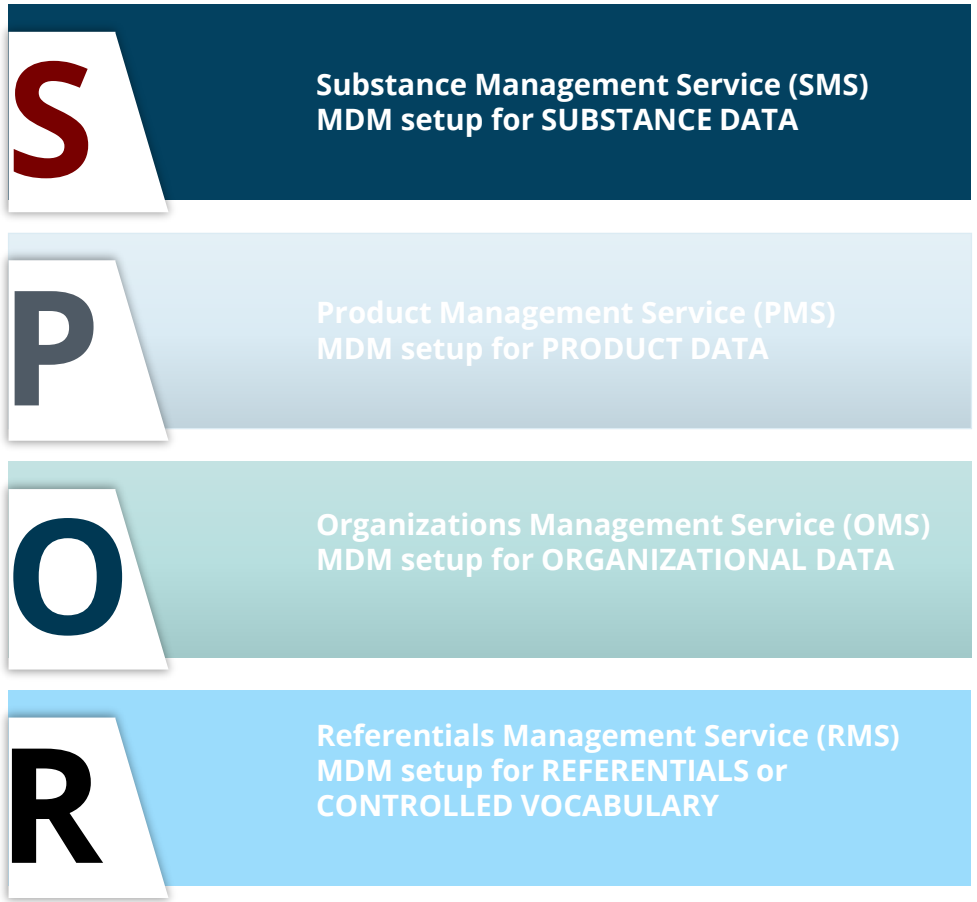
Key Elements

SPOR Controlled Vocabularies

IDMP is implemented by the EMA through SPOR.

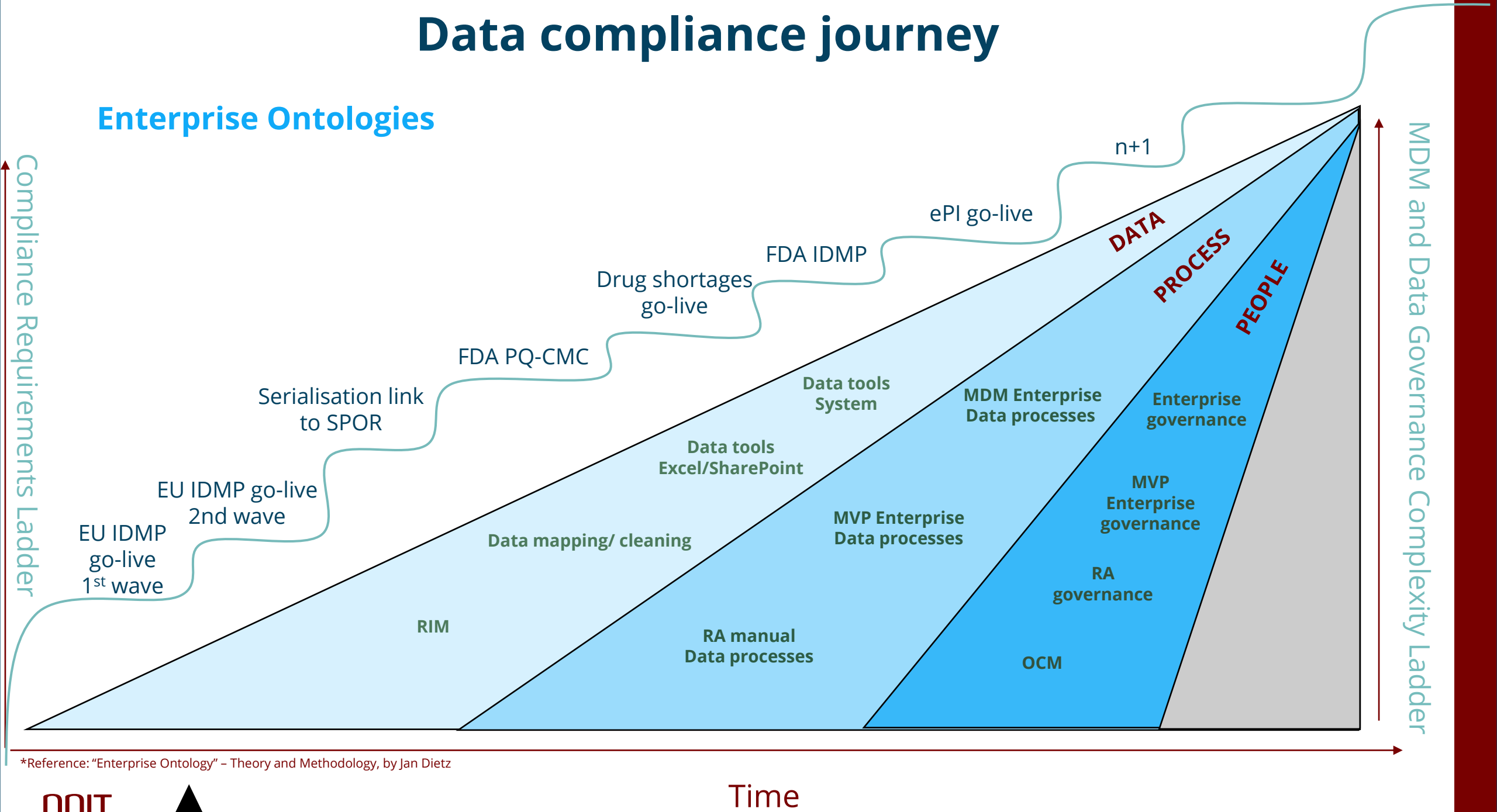
- The SPOR data management services will provide centralized management of master data and controlled vocabularies that comply with the ISO IDMP standards.
- Industry will use the SPOR services and processes for submitting and maintaining master data.

The standardized language for IDMP.



Data compliance journey

Enterprise Ontologies



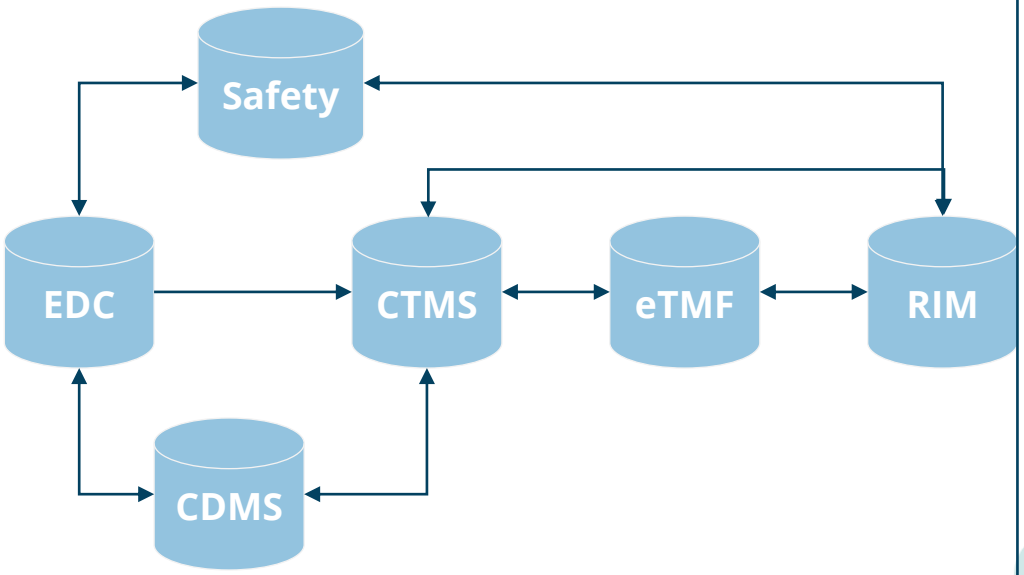
*Reference: "Enterprise Ontology" – Theory and Methodology, by Jan Dietz

NNIT

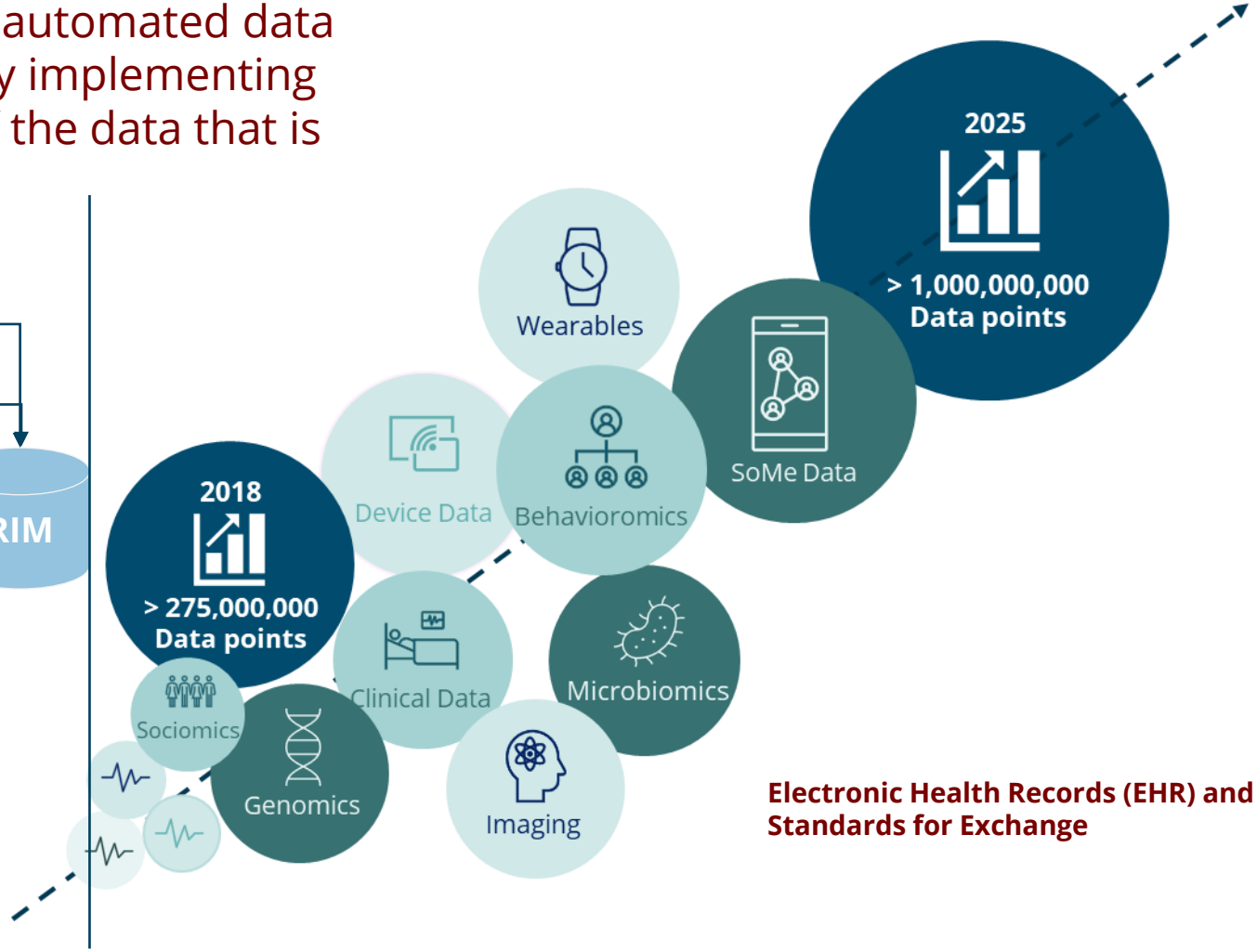
Explosion in collected datapoints but inefficient use

The drug development landscape is subject to rapid change, introducing an increasing amount of data sources.

To unlock the full potential of data and automated data flow, it is vital to ensure “data health” by implementing measures that preserve the integrity of the data that is collected.



Simplified representation of data flow through disparate R&D systems.



Electronic Health Records (EHR) and FHIR Standards for Exchange

Industry Vision: Documents to Data – Structured Content

Current Data Flow vs Future Data Flow

Data generated / received

Data captured and updated in multiple documents

Data stored in various systems

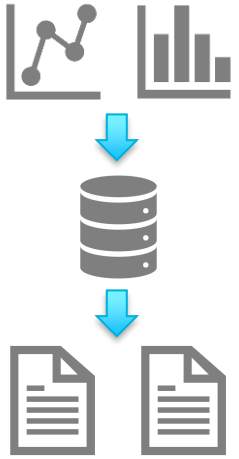
Outcome: a high percentage of data elements remains in documents.

Data generated / received

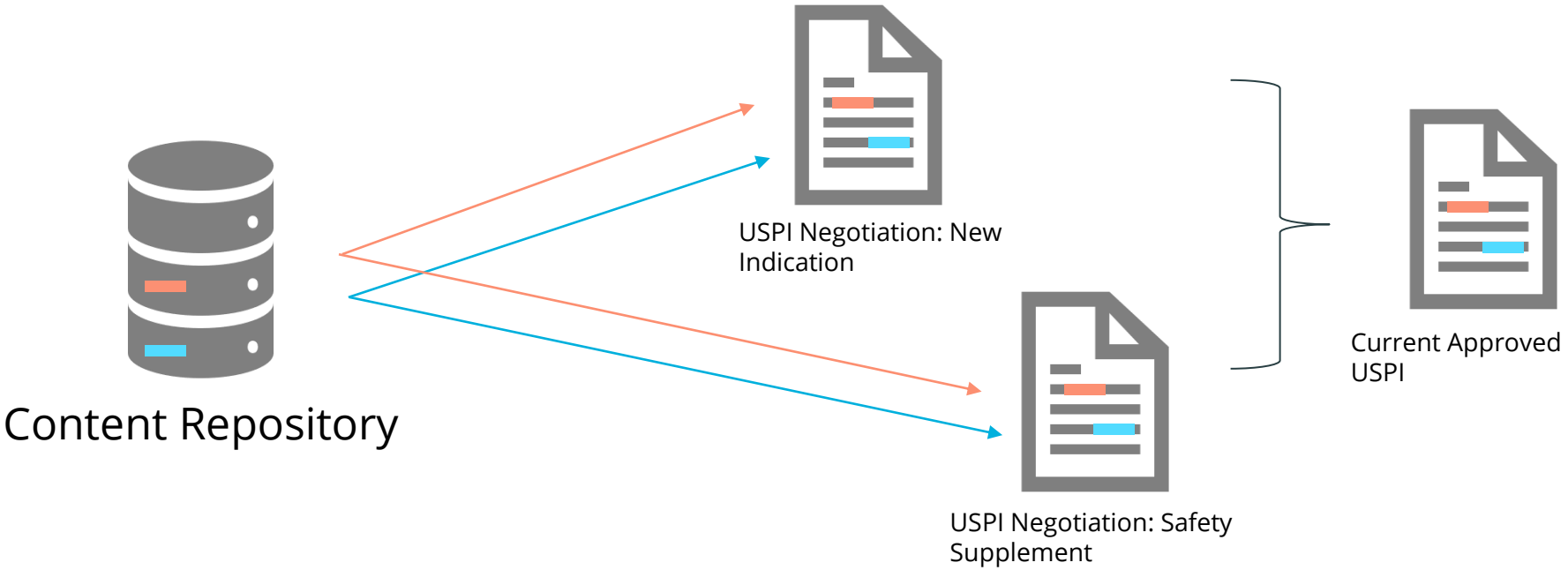
Data captured in databases

Documents are populated from data

Outcome: data centric processes enhance data quality and provide a foundation for large scale analytics and content reuse.

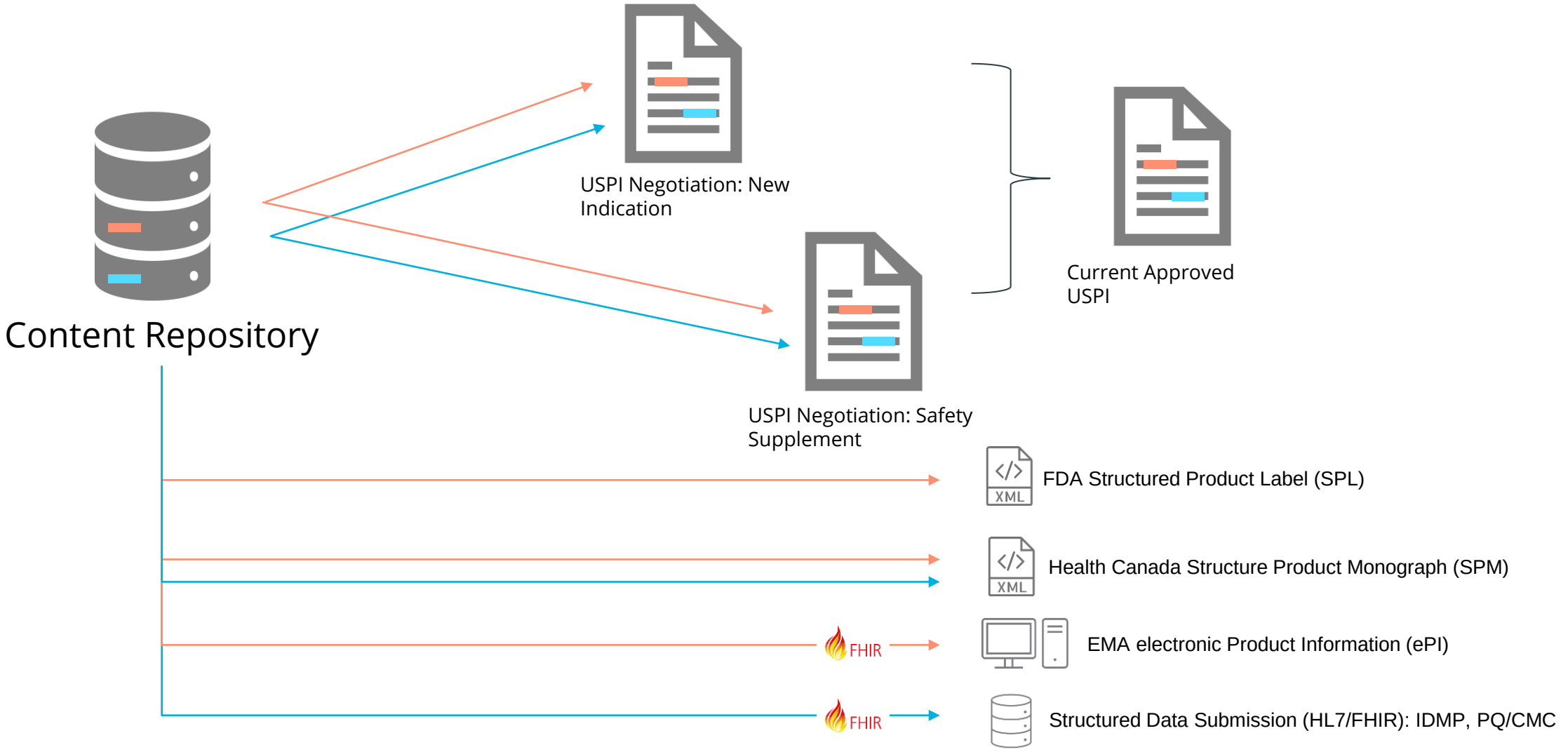


Example Use Cases for Content Reuse



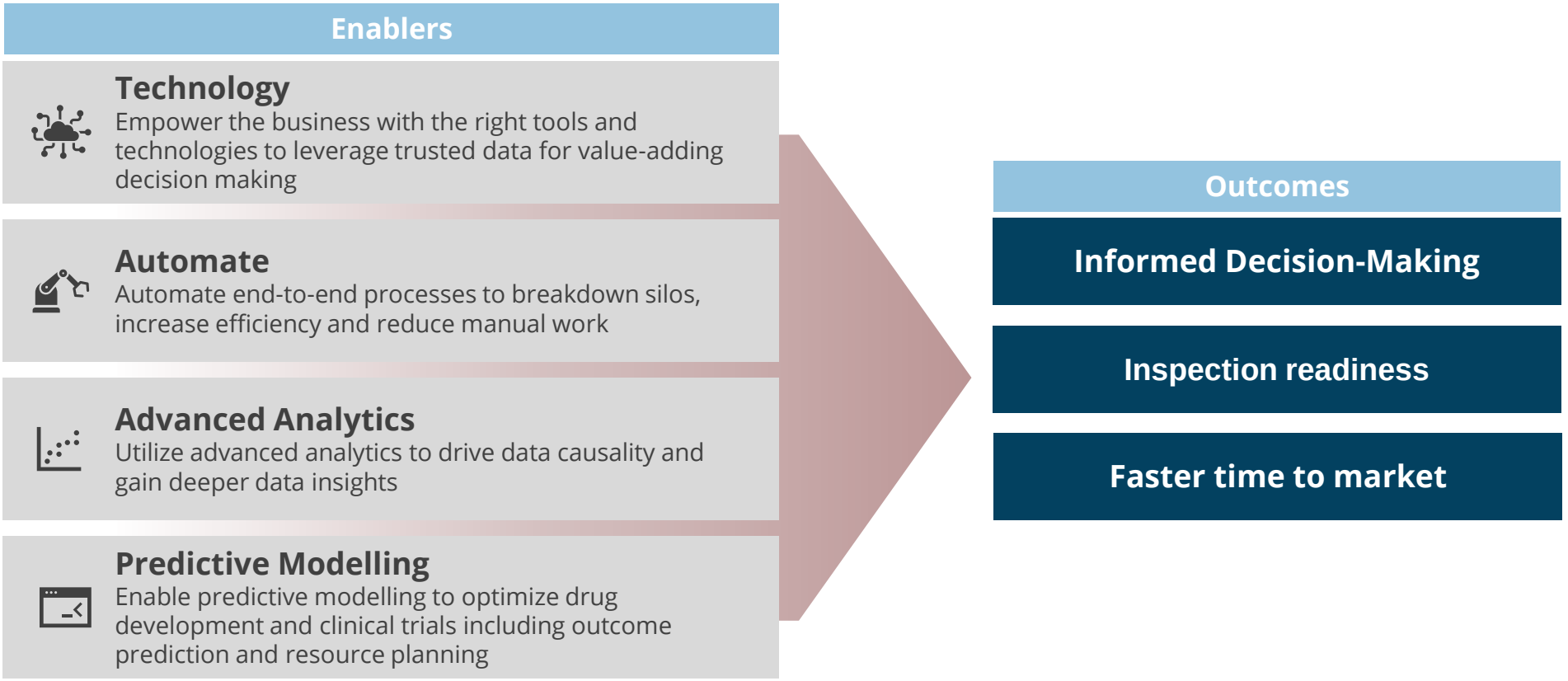
- Components are reused across different projects and document types
- Components can be edited collaborated on prior to approval
- Change history captures the lifecycle of the component
- Traceability reports are generated to determine “where used” impact across the Content Repository

Example Use Cases for Content Reuse



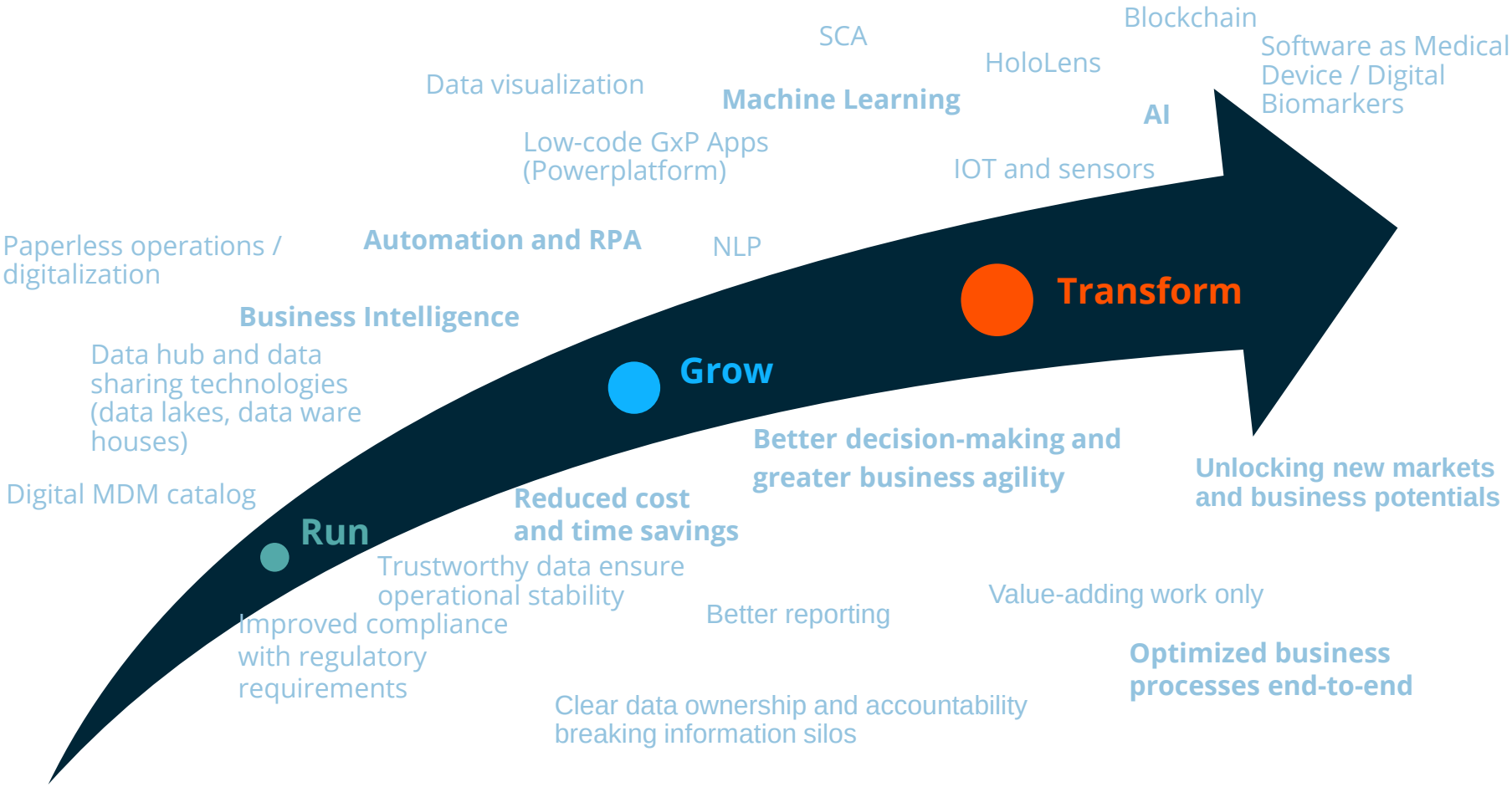
Data enablement – Empower those who change lives

Enable your R&D data and achieve real business outcomes



Unlock the business benefits of data and accelerate the use of emerging technologies

The business benefits can be categorized into three categories; **run** the business, **grow** the business and **transform** the business.



Recap


Global Collaboration
Product Identification and Safety
Data and Enterprise Ontologies
Data from Content within Context
Easier Adoption of Technology Advancements.

Thank You

Brooke Casselberry

Associate Vice President

US R&D Advisory and Consulting

NNIT, Inc.

BRCY@NNIT.com

Slide Credits:

Excellis, an NNIT Group Company

Katherine Novak