Building a bridge from regulatory data to patients

The Global Labeling process leveraging Structured Component Authoring

Dr. Niklas Jänich, MDRA
Boehringer Ingelheim

- Head of Global Labeling Operations & Digitization at Boehringer Ingelheim
- Certified pharmacist, PhD in medicinal chemistry, Master of Drug Regulatory Affairs
- 10+ years experience in the pharmaceutical industry
- Responsible for Labeling process, systems, compliance and digitization
- Drives the implementation of structured content management & ePI in the GxP-regulated Labeling process

Agenda

- How it all started – Thinking data, not documents
- The Labeling process & ecosystem in the new world
- The why - Business benefits in perspective
- Bridge to the patients – unseen potential

How it all started…

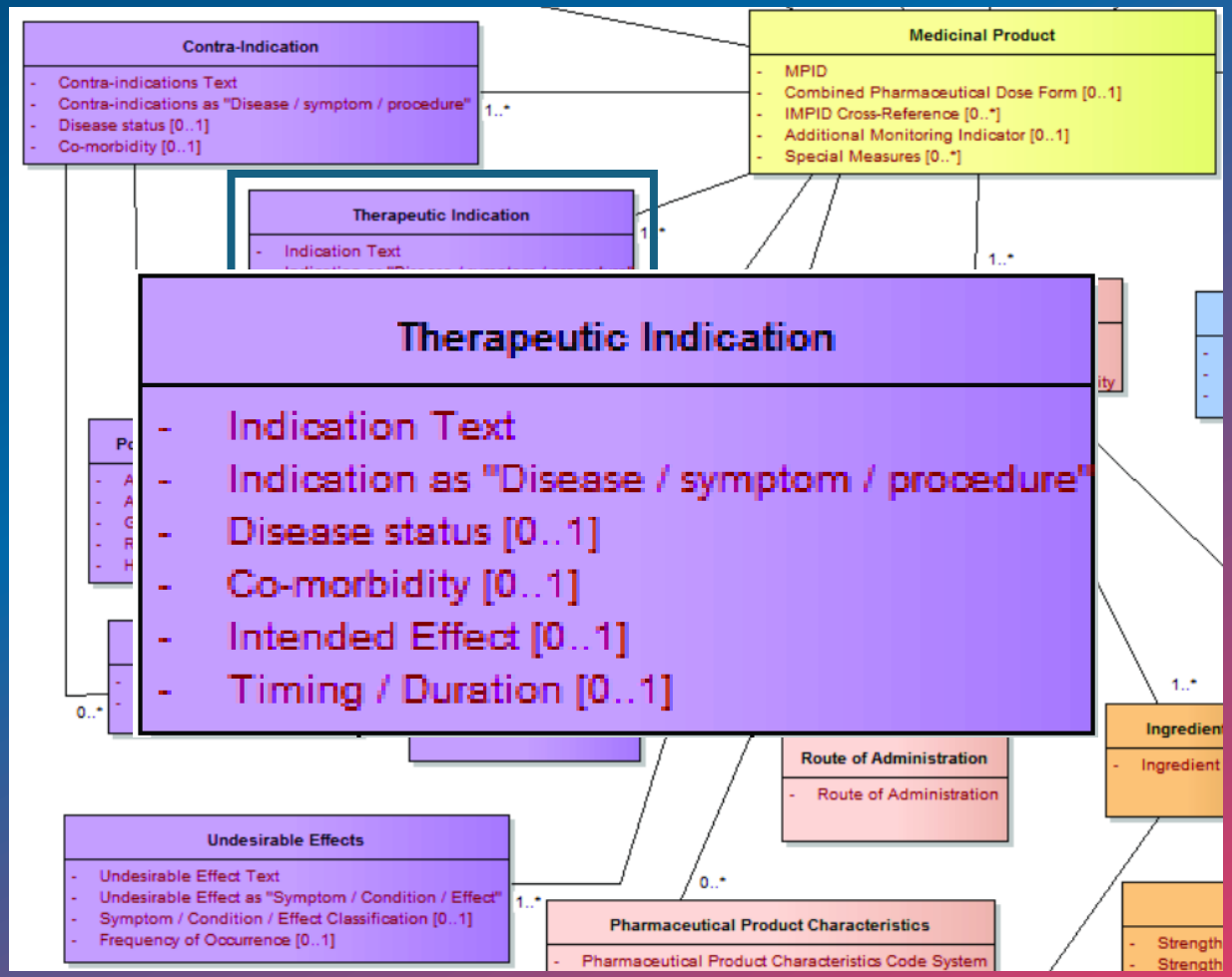
ISO IDMP foresees data elements that contain the actual text in the Labeling documents in addition to coding

Change of perspective

Adding IDMP coding to content

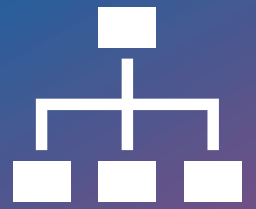
instead of

Adding Labeling content into an IDMP database



Source: https://www.ema.europa.eu/en/documents/presentation/presentation-international-activities-idmp-panagiotis-telonis-rik-smithies_en.pdf

Key principles



01

We manage content, not documents

Focus on the content with a view on user needs and channels

02

We connect information items

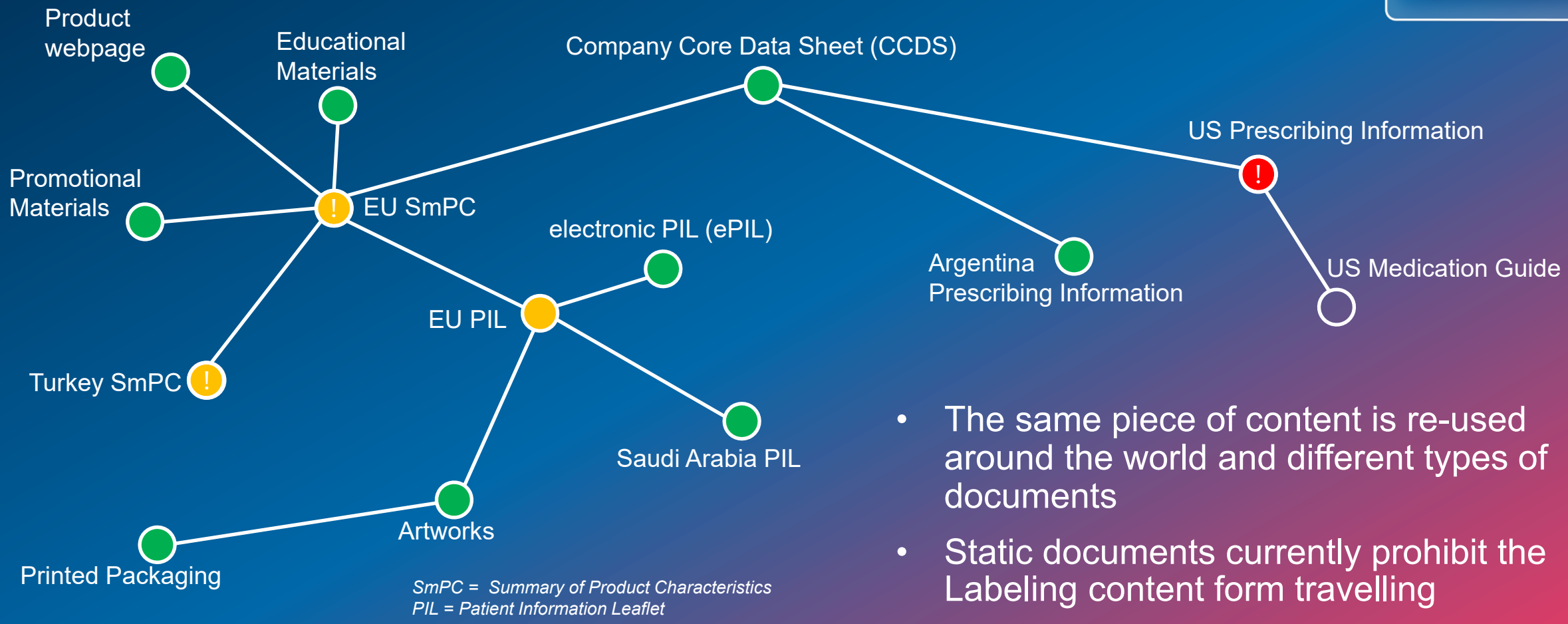
Keep content connected across channels, processes and business areas.

03

We re-use content

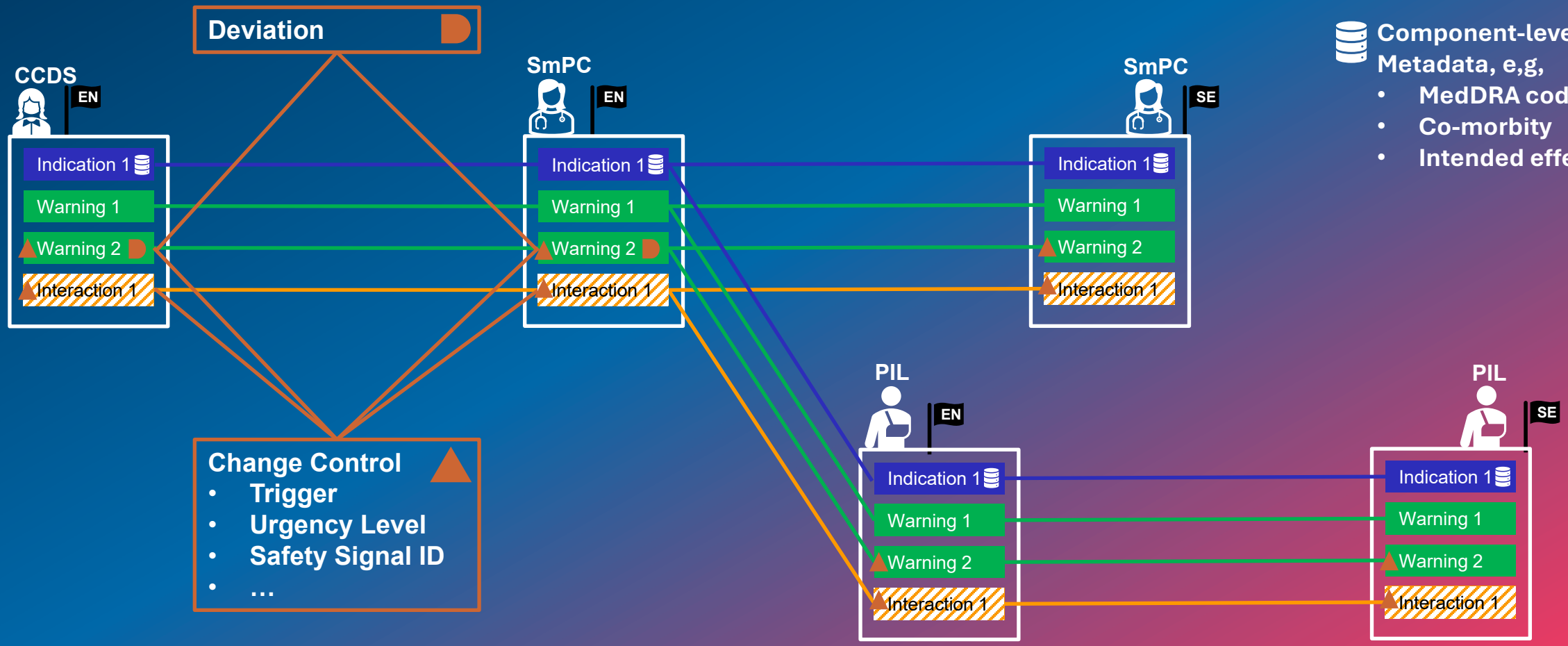
Enforce the structure through technology and repurpose as needed

Labeling content travels around the world

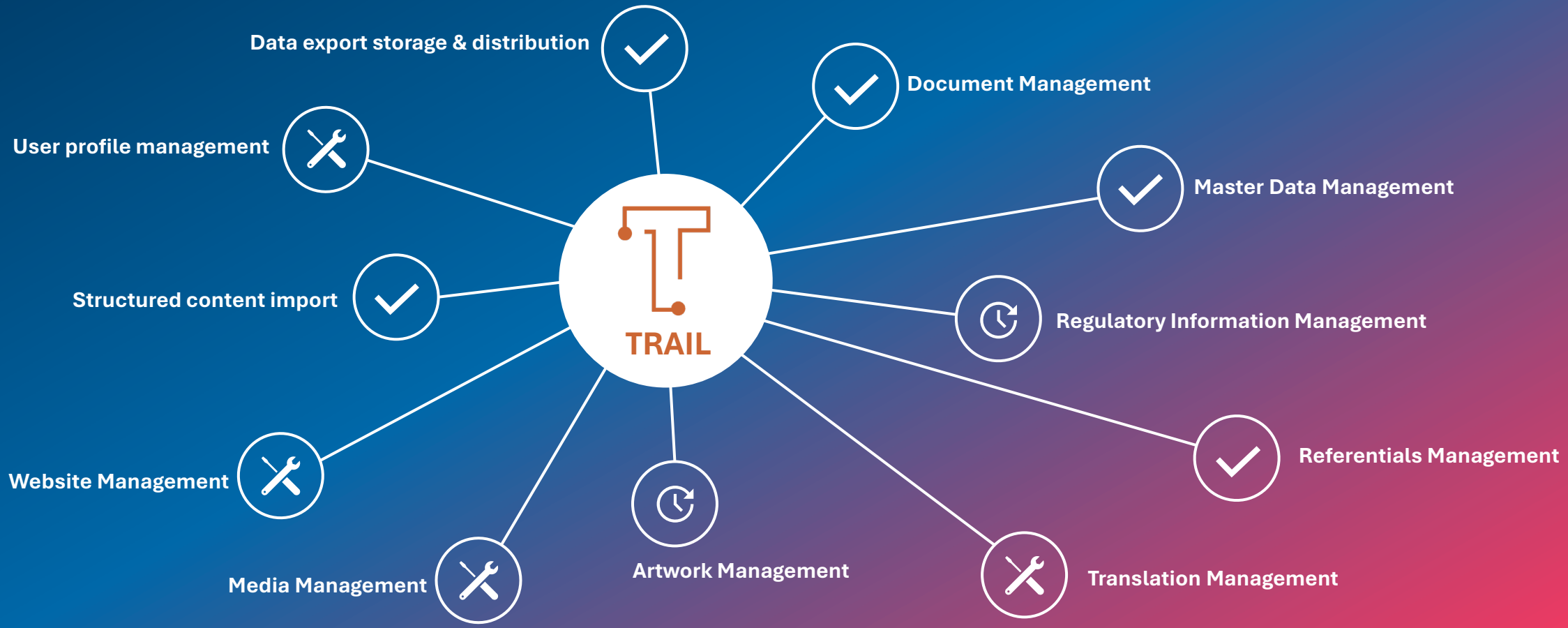


- The same piece of content is re-used around the world and different types of documents
- Static documents currently prohibit the Labeling content form travelling

Labeling content implementation in the new world



Integration & Digital Data Flow



Business benefits

IDMP

Code Core Data Sheets and inherit into local Labeling (e.g. SmPC)

ePI

Automate internal ePI and structured outputs (e.g. FHIR). Patient centricity.

Quality/Compliance

Avoid risks related to content propagation and increase oversight

Speed

Increase speed for content creation and downstream processing

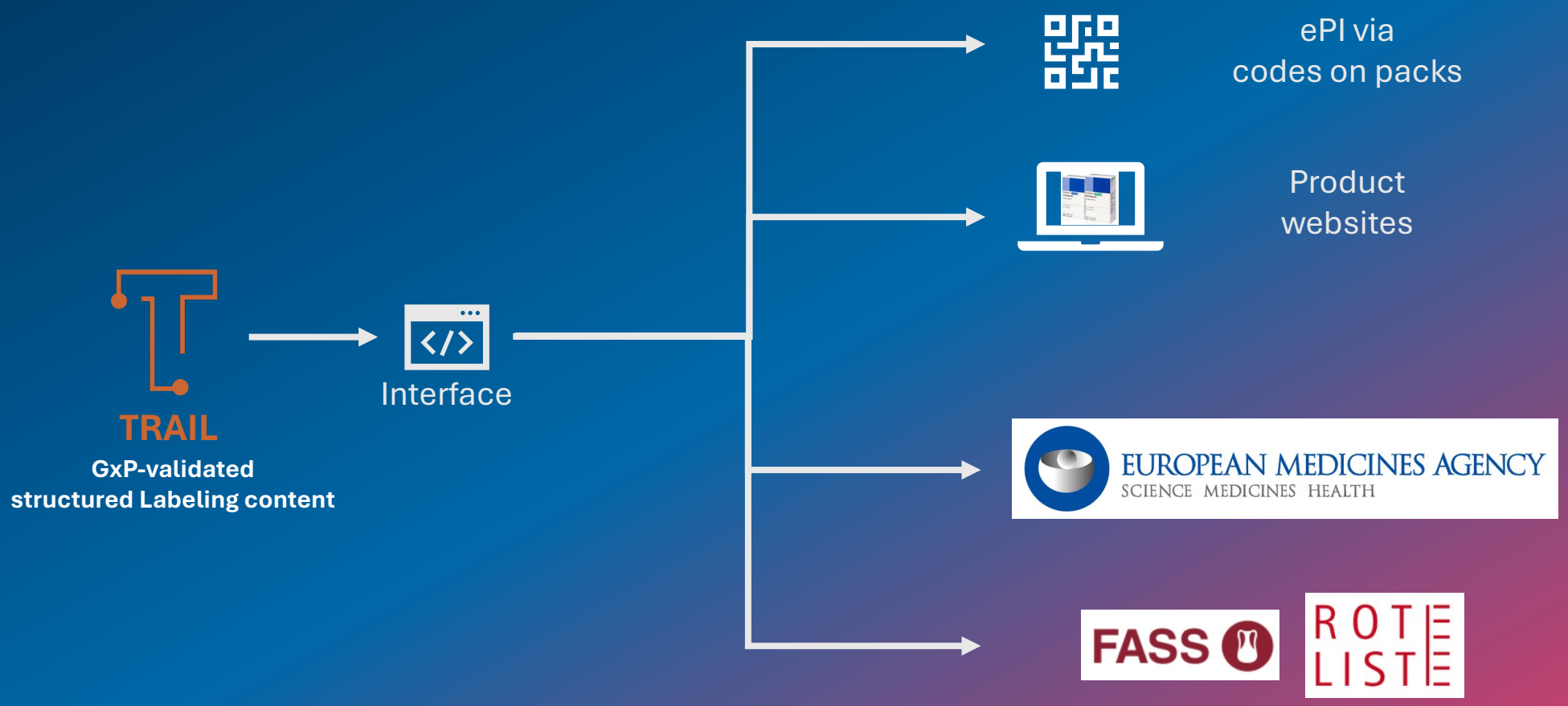
Regulatory requirements

Fulfil diverse and highly complex requirements around the world

Integrations

Connect Labeling data across systems and processes

Connecting structured content and ePI



Structured, connected, coded Labeling and the future of ePI

Contraindications	Do not take <X>
• Resting heart rate below 70 beats per minute prior to treatment	• if you have heart failure which has recently become worse
• Severe hepatic insufficiency	• if you suffer from severe liver problems
• Severe hypotension (< 90/50 mmHg) **NEW!**	• if you suffer from very low blood pressure **NEW!**

Contra-Indication

- Contra-indications Text
- Contra-indications as "Disease / symptom / procedure"
- Disease status [0..1]
- Co-morbidity [0..1]

Thank You for Your Attention!

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