TRAIL

*connecting a world of content*

# End-to-end electronic Labeling process

## *- Industry perspective -*

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Dr. Niklas Jänich, MDRA
Head of Global Labeling Operations & Digitization
Boehringer Ingelheim

Boehringer Ingelheim

# The promises of electronic Product Information (ePI)

- **Immediate provision** of updated product information to patients & health care professionals
- More **user friendly** (e.g. flexible font size, section navigation) and available also for impaired patients (audio/visualisation)
- Reduction of paper (**environment protection**, cost savings)
- **Supply chain resilience** (multi-language packaging, redistribution of packages without the need to replace the leaflet and repackaging)
- **Regulatory efficiency** (data-driven assessments, integrations)

For reference:
- https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf
- https://www.efpia.eu/media/589590/electronic-product-information-from-principles-to-actions.pdf

# Challenges from an industry perspective

- No global harmonization for ePI
- Regional/local differences
- Massive landscape of processes and documents using Labeling content
- Impact on Quality, Compliance and Pharmacovigilance (PV) System
- “Semi-structured” approaches to ePI

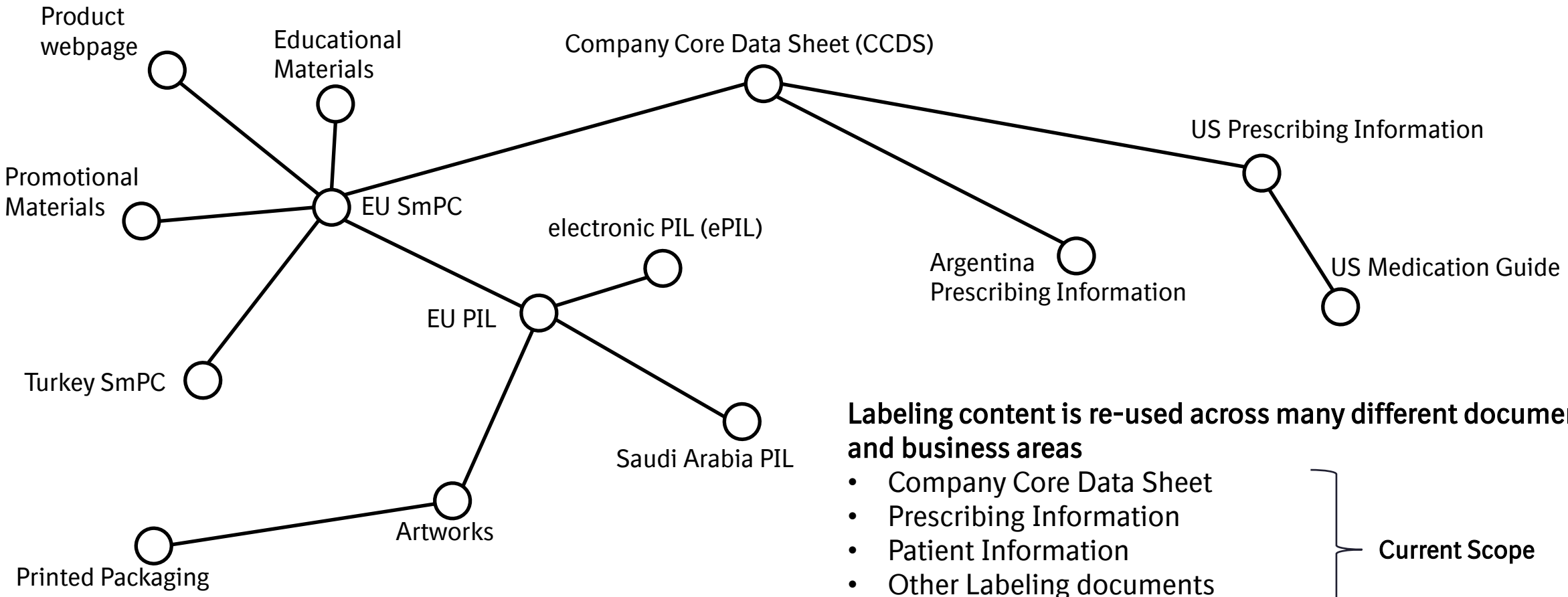
# No global harmonization for ePI

- There is **no world-wide harmonised definition** or understanding of the term, although it‘s widely used.
  - May refer to Prescribing Information, Patient Information or both
  - May be provided as PDF, Webpage or App
  - May be hosted by pharma companies, authorities or third parties
  - May be linked via QR code on the packs
- World-wide there are dozens of separate local/regional pilots or initiatives that work on this

# Regional/local differences

- Templates
  - Significantly different templates world-wide
    (e.g. US Prescribing Information vs EU Summary of Product Characteristics)
- Wordings/Content
  - Different opinions by regulators on labeling content
    (the same statement could be worded in multiple different ways)
- Regulatory framework
  - Implementation of content can stretch over years
    (e.g. countries waiting for reference countries)

# Labeling document landscape




*SmPC = Summary of Product Characteristics*
*PIL = Patient Information Leaflet*

**Labeling content is re-used across many different documents and business areas**

- Company Core Data Sheet
- Prescribing Information
- Patient Information
- Other Labeling documents
- Depending Countries

**Current Scope**

- Artwork & Printed Packaging
- Electronic Labeling
- Labeling-related documentation

Future Scope

# Quality, Compliance and PV System

- ePI connected to packs → impact on GMP domain
- Additional possibility for errors
- Traceability of safety updates, i.e. logistical implementation

# “Semi-structured” approaches to ePI

Most currently available standards foresee fragmentation only on **section level** (e.g. US SPL, EU eQRD). As consequence:

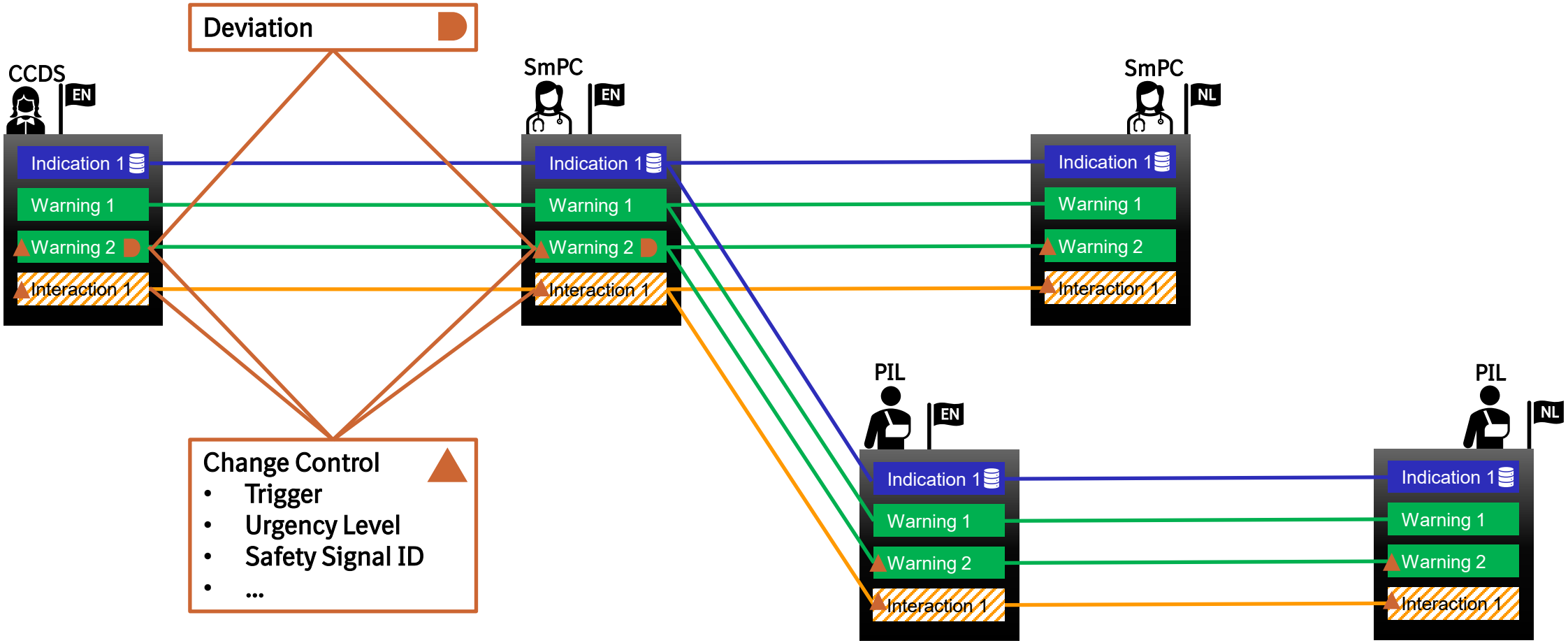
- Due to different templates world-wide & large size of sections, little to no content re-use possible
- Distinct statements (e.g. indication, warning, interaction) are no data elements
  - cannot efficiently be connected to IDMP clinical particulars or other metadata
  - limit content-based review and highlighting of updates

# How we are solving it:
## *End-to-end electronic Labeling process*

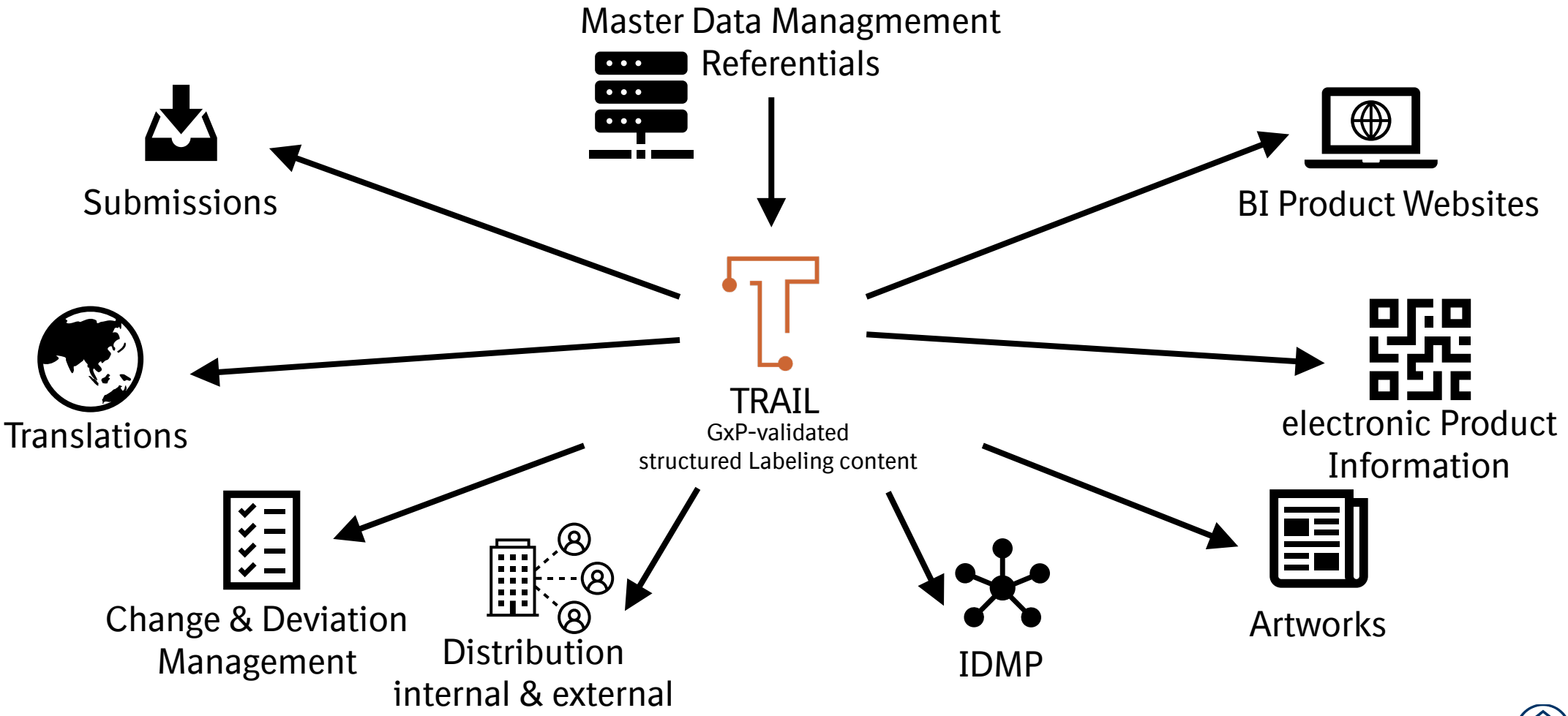
- Based on fully structured, connected, coded content
- Integrates change control and deviation management
- Happens in GxP-validated system → source of truth for structured Labeling content
- Applies to all internal stakeholders, who directly interact with the structured content (e.g. authors, reviewers, approvers)

# Structure & Process flow

Component-level Metadata, e,g,
- MedDRA code
- Co-morbity
- Intended effect

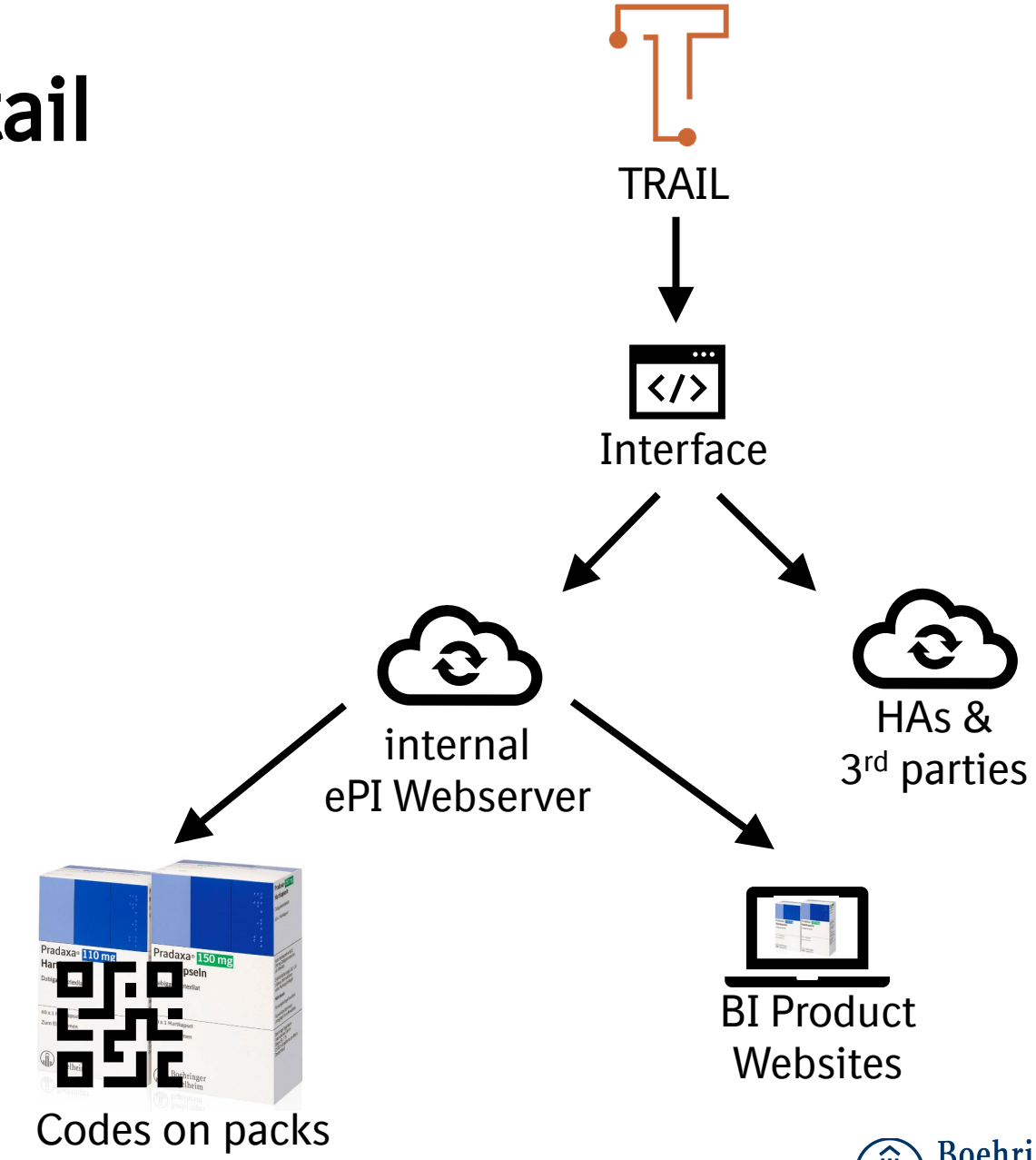


# Leveraging structured Labeling content



# The ePI use case in more detail

- Basis for ePI is structured Labeling content
- Export architecture creates different outputs (internal JSON, FHIR ePI XML, etc.)
- Based on readiness of stakeholders & maturity of standards, different datasets can be transferred, e.g.
  - Depict regulatory procedure including Labeling discussions
  - Leverage additional data layers for patient-centric ePI



# Questions & Discussion