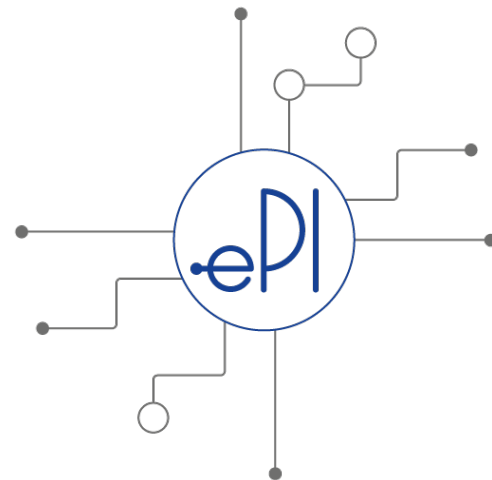


ePI proof-of-concept prototype

Information Workshop on electronic Product Information (ePI)

Elizabeth Scanlan
ePI set-up Project Manager, EMA



Set-up project: deliverables

Deliverable

#1

Create an **EU common standard** based on FHIR for ePI in the EU to support harmonised ePI across the EU and collaboration across the network

Deliverable

#2

Provide a **proof-of-concept prototype** using the common standard. The prototype will be used for a design and technical feasibility study to generate some example FHIR-based documents associated with products in SPOR to publish on a website. This is not a business-ready solution

Deliverable

#3

Provide a realistic medium-term **vision and road map** to achieve the benefits for stakeholders, HMA, EC, EMA MB, as outlined in the [Key principles for ePI on the EU](#)

ePI

Purpose of the proof-of-concept



**Provide a proof-of-concept prototype
using the common standard.**

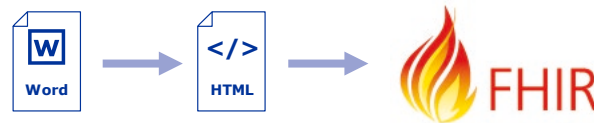
- Test the standard to assess:
 - **generation** of example FHIR-based ePIs
 - **associating** ePI with products in SPOR (data management services for master data on EU medicines that comply with ISO IDMP)
 - **publishing** ePI on a website
- Demonstrate ePI to stakeholders
- Gain knowledge for creation of business solutions and processes

ePI

Generation of ePI from existing PI

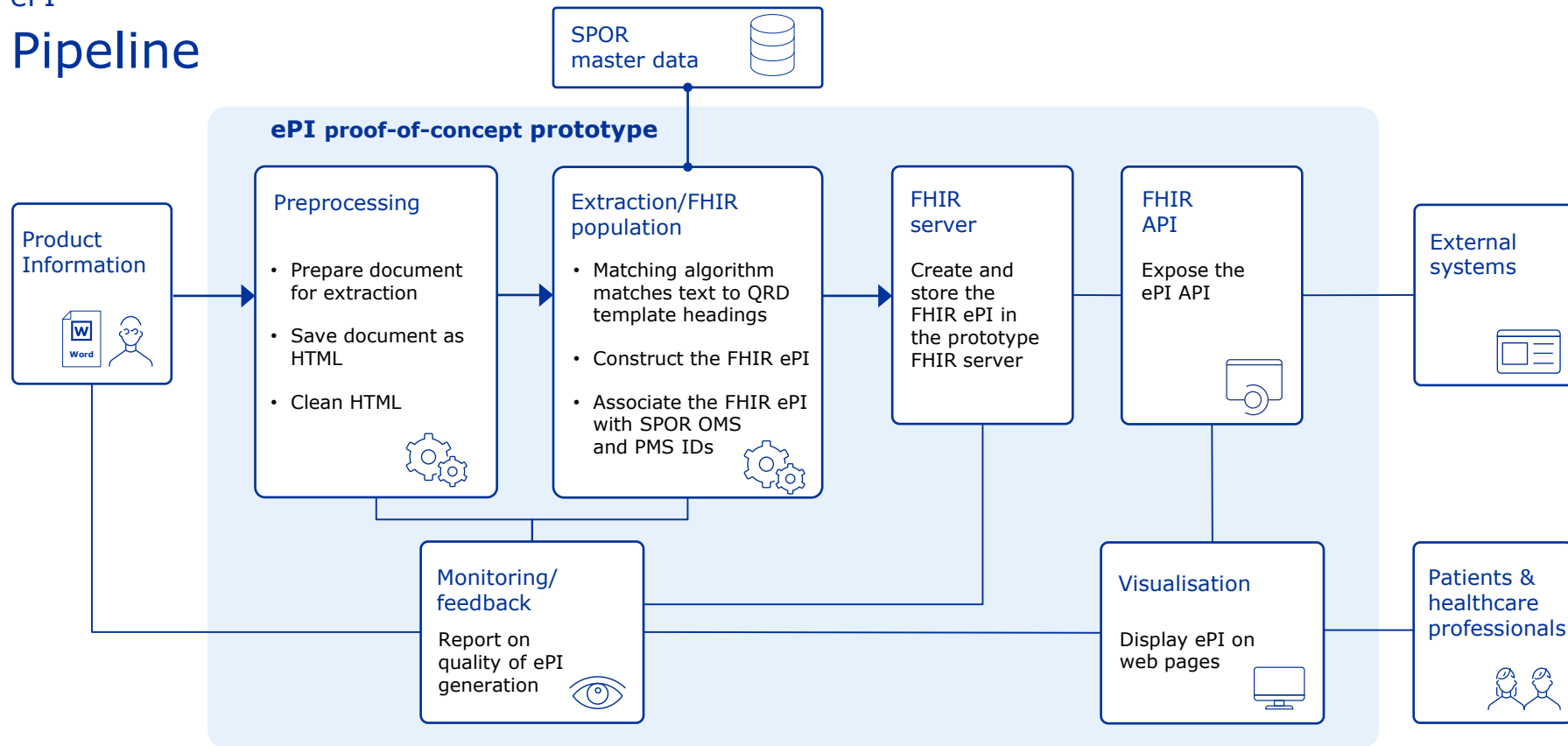


- **High number** (22 documented) of issues with formatting (e.g. text alignment), content (e.g. missing symbols) and structure (e.g. bullets deleted)



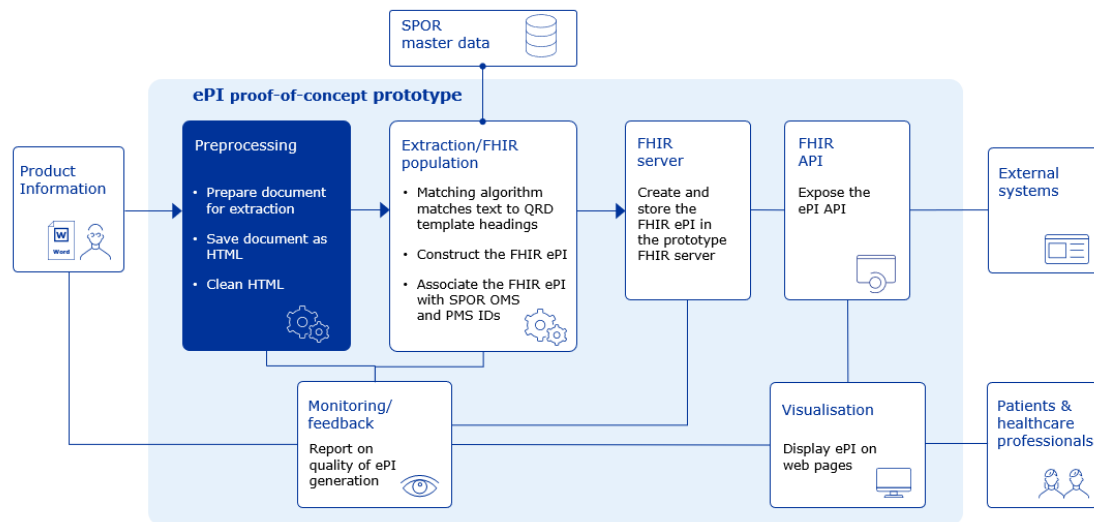
- **Lower number** (11 documented) of issues with formatting and content
- Workarounds identified for all issues

ePI Pipeline



ePI

Pipeline: Preprocessing

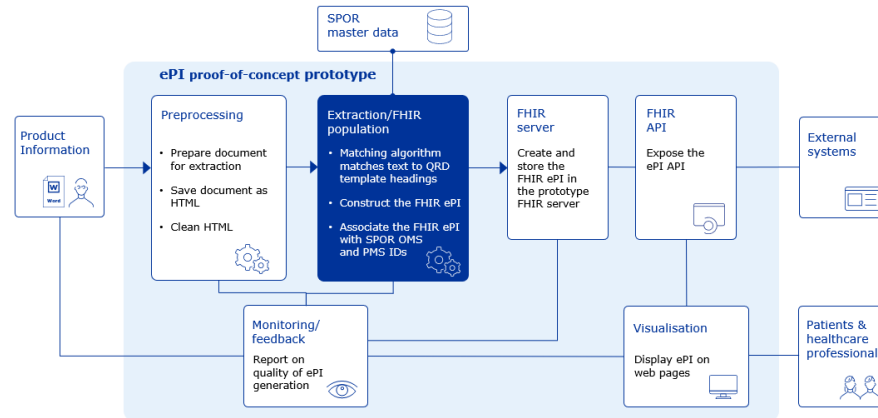


- Preparatory steps to resolve issues seen when transforming Word to HTML
- Save documents as HTML and remove some unnecessary HTML

ePI

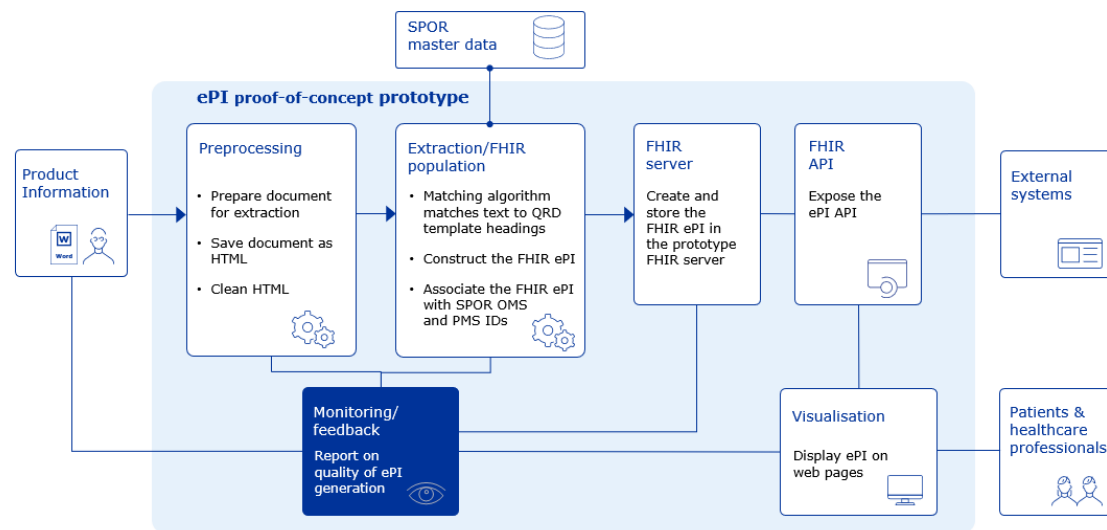
Pipeline: Extraction/FHIR population

- **Matching algorithm** maps text onto the QRD template headings for **25 languages**:
 - Basic Natural Language Processing techniques (text matching algorithms)
 - Language-specific rulebooks
 - Heading allocation based on hierarchy and text style
- **Matching algorithm can be extended to different document structures and languages**
- Headings and content transformed to FHIR
- **Lookup of the SPOR API to annotate ePI** with SPOR master data IDs



ePI

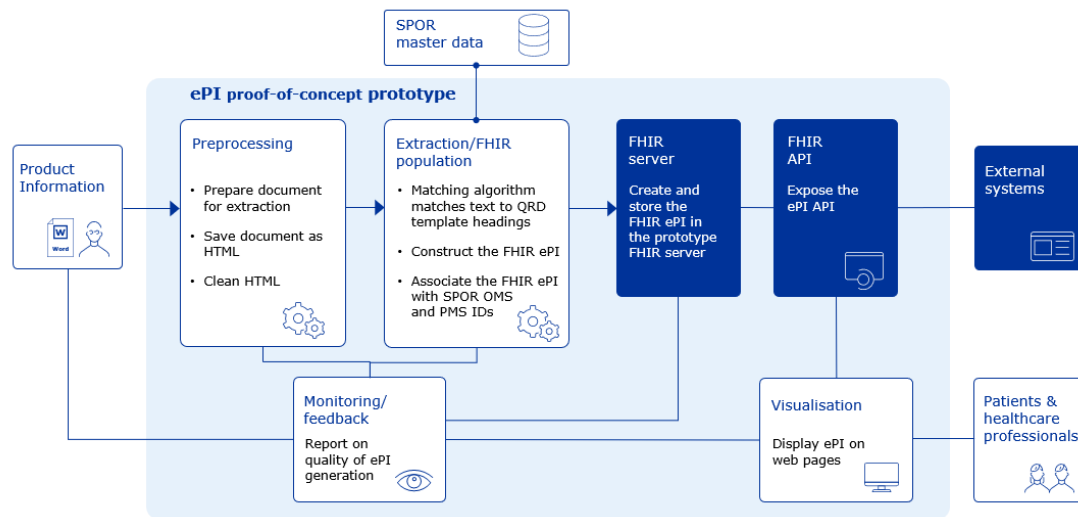
Pipeline: Monitoring/Feedback



- A report can be generated detailing KPIs of the ePI generation such as:
 - Number of mandatory headings detected/missing

ePI

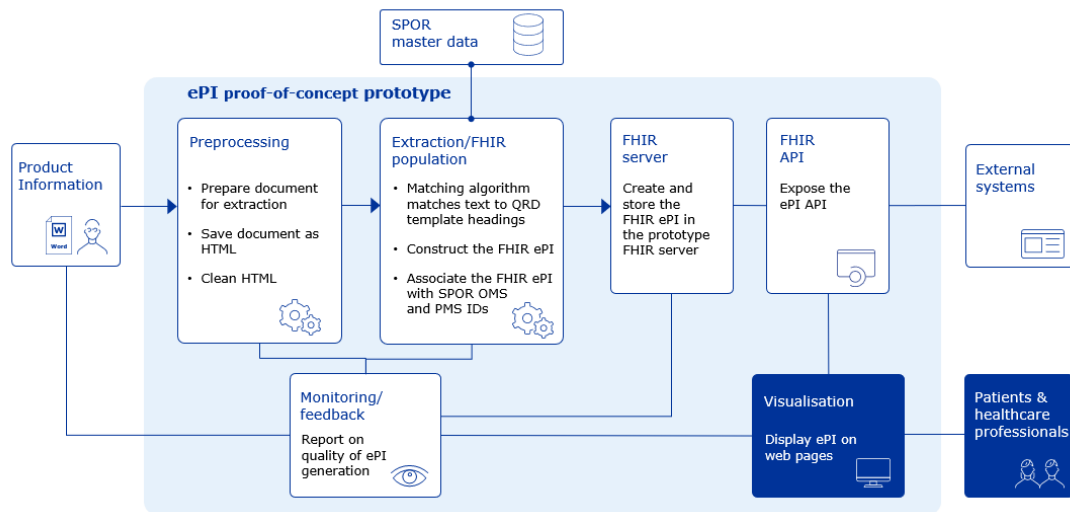
Pipeline: FHIR server/FHIR API/External systems



- ePI stored in FHIR server
- API allows machine-to-machine communication according to FHIR standard and API ePI specification

ePI

Pipeline: Visualisation/Patients and healthcare professionals



- Website uses ePI API to pull ePI to display
- PoC provides pared-down web display
- Web user experience could be enhanced to incorporate features such as:
 - Innovative search using AI
 - Versioning (supported by FHIR)
 - AAA accessibility



ePI

Demonstration of ePI display

Search

Catalog

Contact

Table of contents

1. NAME OF THE MEDICINAL PRODUCT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM

4. CLINICAL PARTICULARS

5. PHARMACOLOGICAL PROPERTIES

6. PHARMACEUTICAL PARTICULARS

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

Elocta

Share

Language

en

de

bg

da

es

el

SmPC	AnnexII	Labelling	Package leaflet
1. NAME OF THE MEDICINAL PRODUCT ELOCTA 250 IU powder and solvent for solution for injection ELOCTA 500 IU powder and solvent for solution for injection ELOCTA 750 IU powder and solvent for solution for injection ELOCTA 1000 IU powder and solvent for solution for injection ELOCTA 1500 IU powder and solvent for solution for injection ELOCTA 2000 IU powder and solvent for solution for injection ELOCTA 3000 IU powder and solvent for solution for injection ELOCTA 4000 IU powder and solvent for solution for injection 2. QUALITATIVE AND QUANTITATIVE COMPOSITION <u>ELOCTA 250 IU powder and solvent for solution for injection</u> Each vial contains nominally 250 IU efmoctocog alfa. ELOCTA contains approximately 83 IU/mL of recombinant human coagulation factor VIII, efmoctocog alfa after reconstitution. <u>ELOCTA 500 IU powder and solvent for solution for injection</u> Each vial contains nominally 500 IU efmoctocog alfa. ELOCTA contains approximately 167 IU/mL of recombinant efmoctocog alfa after reconstitution. <u>ELOCTA 750 IU powder and solvent for solution for injection</u> Each vial contains nominally 750 IU efmoctocog alfa. ELOCTA contains approximately 250 IU/mL of recombinant efmoctocog alfa after reconstitution. <u>ELOCTA 1000 IU powder and solvent for solution for injection</u> Each vial contains nominally 1000 IU efmoctocog alfa. ELOCTA contains approximately 333 IU/mL of recombinant efmoctocog alfa after reconstitution. <u>ELOCTA 1500 IU powder and solvent for solution for injection</u> Each vial contains nominally 1500 IU efmoctocog alfa. ELOCTA contains approximately 500 IU/mL of recombinant efmoctocog alfa after reconstitution. <u>ELOCTA 2000 IU powder and solvent for solution for injection</u>			





ePI

Purpose of the proof-of-concept

- ePI based on the draft EU common standard is:
 - Multilingual
 - Accessible
 - User-friendly
 - Interoperable with SPOR master data providing benefits of structured data
- Prototype generated ePI from existing Word PI

Learnings from proof-of-concept are informing ePI roadmap development

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- **Steering committee:** Melanie Carr, César Hernández, Juan García Burgos, Georg Neuwirth, Aleksandra Dacic-Pilcevic, Alexios Skarlatos
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