FHIR and the EU common standard for ePI

Information Workshop on electronic Product Information (ePI)

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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](#).
Data, standards, interoperability and APIs

• The need to increase the use of data to support decisions is very prominent inside and outside of the EMA

  Fun fact: the word “data” is present 215 times in the EMA's Regulatory Science Strategy to 2025

• Data is an asset that can only be leveraged if it is “understood” (syntactically and semantically)

• Data is typically managed by multiple information systems that need to collaborate (interoperability)

• Data format and exchange standards are the cornerstone for system inter-operability

• The EMA and the EMRN are committed to interoperable solutions and APIs based on standards

• SPOR (SMS and PMS) already are based on FHIR APIs
API – what it is and what it is not

An API is

• Application Programming Interface

• Meant to be used for machine-to-machine communication

• "It expresses a software component in terms of its operations, inputs, outputs, and underlying types" (source Wikipedia)

• A “contract” published by a system describing the means and the rules to communicate with it

An API is not

• A database or a server

• A software component that you install on a computer

• A process that automates human activities
What is FHIR?

- **FHIR** is a recent standard from HL7 that makes it easy and quick to build REST(*) based APIs for healthcare applications. FHIR solutions are built from a set of modular components called "Resources"

- A general introduction to FHIR can be found here: [http://hl7.org/fhir/summary.html](http://hl7.org/fhir/summary.html)
FHIR in one slide

**Fast**

**Healthcare**

**Interoperability**

**Resources**

a set of XML (and/or JSON) health data resources, plus a REST API for accessing them

- New free and open healthcare data API
- Builds on simplicity of HL7 V2
- With modern (web) standards
  - XML, JSON, HTTP, REST, UML
  - Familiar to new generation of developers
- Easy to implement the basics
- Getting very rapid take up
Advantages of FHIR

• Focus on implementation – fast and easy to implement
  (multiple developers have had simple interfaces working in a single day)

• Specification is free for use with no restrictions

• Multiple (free) implementation libraries – many examples available to kick-start development

• Interoperability "out of the box" – base resources can be used as is, but can also be adapted for local requirements

• Strong foundation in Web standards – XML, JSON, HTTP, OAuth, etc.

• Support for RESTful architectures, exchange of information using messages or documents, and service based architectures

• Concise and easily understood specifications

• A human-readable serialization format for ease of use by developers

• Getting very successful and widely adopted
FHIR Resources

Resources are:

- Small, logically discrete units of exchanged data
- Defined behaviour and meaning
- Known identity/ location
- Smallest unit of transaction
- Connected by "references"
FHIR Resources

- All FHIR resources are publicly described [here](#) and can be used by anyone.
- There is a wealth of tools that help to build applications based on FHIR.
- Changes to resources are governed by the FHIR community (HL7+members) and is strongly pragmatic (based on general use).
Feasibility analysis of FHIR for ePI conclusion

- FHIR ‘Composition’ resource fit for purpose for PI documents
- Composition references other elements (Medicinal Products or images)

Use a ‘Bundle’
# QRD representation in FHIR

**Hierarchical support in FHIR** [Composition/Section](#)

## PI Document (SmPC)

<table>
<thead>
<tr>
<th>SmPC</th>
<th>Content</th>
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<tbody>
<tr>
<td>1. Name of Medicinal Product</td>
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<tr>
<td>2. Qualitative and Quantitative Composition</td>
<td>Content</td>
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<td>3. Pharmaceutical form</td>
<td>Content</td>
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<tr>
<td>4. Clinical Particulars</td>
<td>Content</td>
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<tr>
<td>4.1 Therapeutic indication</td>
<td>Content</td>
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<td>4.2 Posology and method of administration</td>
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## ePI FHIR Bundle (SmPC)

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FHIR in ePI and SPOR master data

- SPOR uses FHIR to represent IDMP-compatible Products and Substances
- ePI uses FHIR to represent unstructured documents in a more structured way
- ePI and SPOR resources do not currently overlap, they interconnect
- Both systems share data interoperability principles, standard, conventions and best practices
- The same FHIR tools and expertise can be leveraged by both systems
Public consultation on EU common standard for ePI

• The consultation is being carried out on the following documents, published on GitHub:
  - ePI API Specification (PDF) and the associated ePI API service list (Excel)
  - A FHIR XML template based on the Quality Review of Documents (QRD) template for human medicines
• An instance of an ePI sample message is provided in XML and HTML, along with a sample XSL transformation
• Consultation feedback is collected via a linked survey
Any questions?

Further information

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