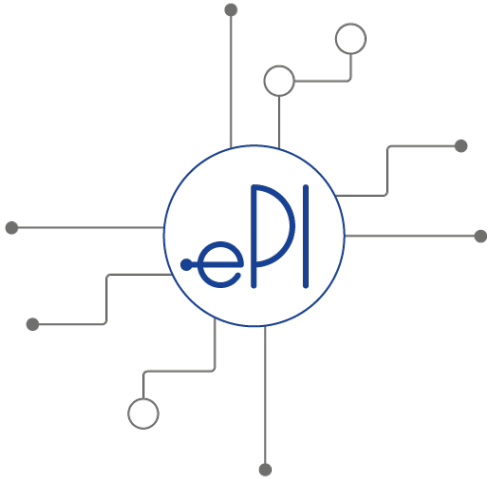
Next steps for ePI and roadmap development

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

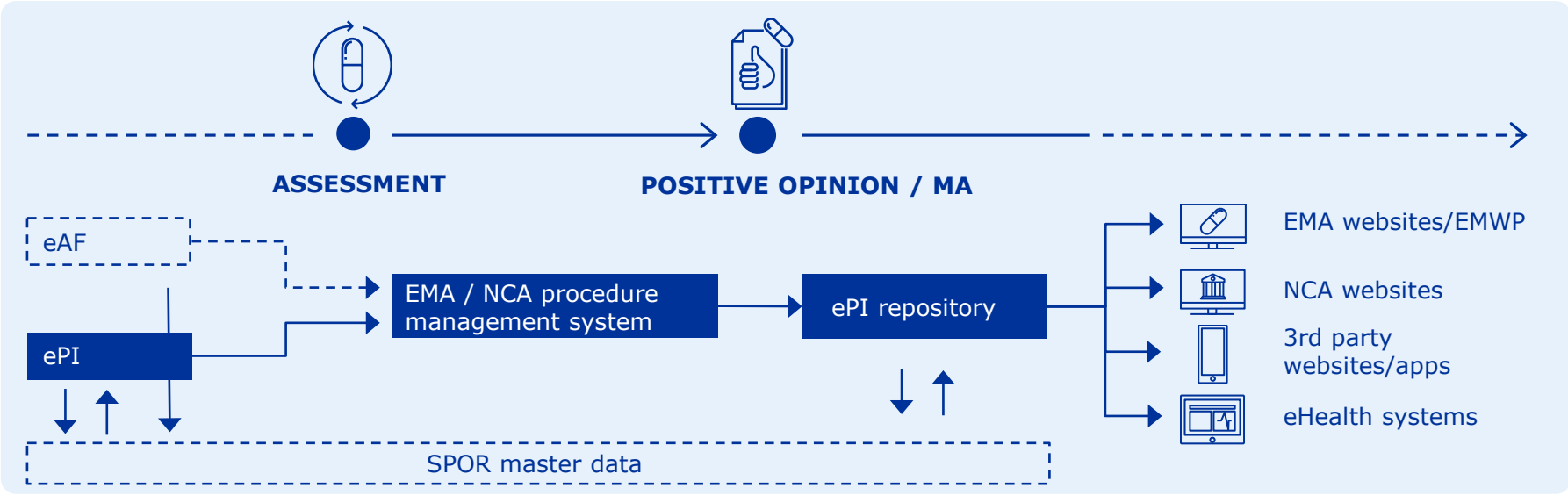
Provide a **proof-of-concept prototype** using the common standard. The prototype will be used for a design and technical feasibility study to generate some example FHIR-based documents associated with products in SPOR to publish on a website. This is not a business-ready solution

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**

Future vision

- ePI from submission, through assessment, to authorisation and dissemination
- Seamless integration with all EMA/NCA systems supporting medicines assessment



Roadmap in preparation

- Roadmap towards ePI that fulfils the agreed key principles
- Based on learnings from EU Common Standard development and proof-of concept
- Roadmap to be a living document
- Agile principles of incremental development strategy
- EMA and early adapter NCAs to pilot and lead implementation

Strategic importance

- **EC Pharmaceutical Strategy for Europe**
  Recognises importance of ePI for delivery of multilingual medicines information to patient and HCPs and to support wider availability of medicines across Member States
- **European Medicines Agencies Network Strategy**
  Notes that ePI facilitates marketing of medicines in all Member States and redistribution to countries experiencing shortages
- **EU4Health** to fund subsequent deliverables for the set-up and follow-up pilot of ePI

Flexible implementation

- EU electronic standard agreed by EU Regulatory Network and stakeholders – basis for harmonised EU implementation
- EMA and NCAs to implement ePI according to a defined timeline
- Flexibility will allow for different timelines for implementation, as these will still ultimately allow a harmonised approach for ePI across the EU

Interfaces and interactions with other systems and business processes

- ePI will link to SPOR master data services
- Alignment with business process for electronic application form
- Data consistency throughout workflows
- ePI can be used in future for veterinary medicines

Projects

ePI set up project defines common standard, performs proof of concept and creates roadmap

Pilot by EMA and some NCAs tests ePI and assesses impact on current processes

Thank you for listening

Further information

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