



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Demo of ePI authoring tool

Gravitate Health Technology Community Event

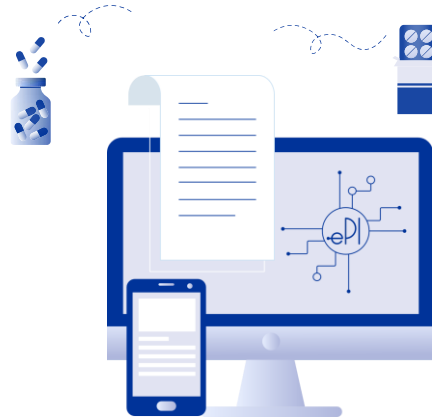
Presented by Elizabeth Scanlan on 20 March 2023
ePI Product Owner, European Medicines Agency

An agency of the European Union



Electronic product information (ePI) for EU medicines

ePI is authorised, statutory product information for medicines (i.e. **summary of product characteristics, package leaflet and labelling**) in a semi-structured format created using the **EU ePI Common Standard**, which is based on FHIR. ePI is adapted for electronic handling and allows dissemination via the world wide web, e-platforms and print.



ePI Minimum Viable Product consists of:

- **ePI authoring portal**

For ePI creation, rich-text editing, update, upload download

- **Repository and API**

ePI stored in FHIR server and made available via the ePI application programming interface



Developed with funding by the European Union



ePI Roadmap

- EU ePI Common Standard developed
- Public consultation
- EU ePI Common Standard adopted.

2021

- MVP development
- NCA product owner and SMEs onboarded

2022

- **MVP development**
- **Pilot begins**
- Results of pilot feed back to tooling and guidance.

2023-2024

- CAP implementation
- Phased implementation NAPs
- EU ePI Common Standard evolves
- Controlled up-versioning.

2024-





Any questions?

Further information

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