EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Demo of ePI authoring tool

Gravitate Health Technology Community Event

Presented by Elizabeth Scanlan on 20 March 2023
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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

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ePI Roadmap

2021

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

2022

- MVP development
- NCA product owner and SMEs onboarded

2023-2024

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

2024-

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

Any questions?

Further information

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