Unicom knowledge transfer - FINLAND
Agenda

1. Introduction to Fimea
2. Medicinal product database demo
3. Lessons learned

Presenters

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Introduction to Fimea

- NCA handling both Human and VET medicinal products
- A government authority operating under the Ministry of Social Affairs and Health
- Supervises, safeguards and develops medicines, medical devices, blood and tissue products (SOHO sector) and the pharmaceutical sector
- The staff number is currently about 350
  - Marketing authorization unit about 130 persons
  - IT about 10 persons
- Fimea is located in Helsinki, Kuopio, Tampere, Turku and Oulu.
- Unicom in Finland
  - WP2 & WP4 Fimea
  - WP5 & WP6 Kela (eHealth organization)
Saga Fimea’s Marketing authorization system

- Development of Saga started in 2018 to replace old iRis system
- Joint project between Fimea and Solita
- Saga was taken to use end of 2020 and development continues
- New system build IDMP compatible
- Build on opensource building blocks.
- System is modern container based and uses opensource components and PostgreSQL database
- Originally build on-prem but moved to AWS cloud in 2022/2023
Fimea registry platform

- Saga platform was used as basis for a general registry platform in Fimea. Now consisting of 5 registries and 2 eService channels
  - **Saga** – Marketing authorization system 2020
  - **Cere** – Medicinal devices registry 2021
  - **Cere SA** – eService for medicinal device makers to register devices to Fimea 2023
  - **Meds75+** - database of medication for older persons is to support the clinical decision-making on the pharmacotherapy of persons over 75 years of age 2020
  - **Saha** – Medicine shortage database 2023
  - **Saha SA** – eService for marketing authorization holders to report upcoming medicine shortages 2023
  - **Lada** – Invoicing system for Saga, Cere and Saha 2021
  - **Erkka** - Upcoming special permit system for medicines not generally authorized for market
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Medicinal product database demo
Lessons learned

➢ Challenges of IDMP for both end users and developers
   ➢ Grasping the complex conceptual model, even finding good translations
   ➢ Working with legacy data
   ➢ Motivation to model and to input data in a detailed level

➢ What worked well
   ➢ Incremental and iterative development
     1. The register renewal project took initial steps toward IDMP
     2. Gap analysis
     3. Starting with a simpler model
   ➢ Weekly meetings to discuss the data model and anomalies in the legacy data
   ➢ Visualisations

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Thank you!