UNICOM

Up-scaling the global univocal identification of medicines

Unicom knowledge transfer - FINLAND

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

fimea

Agenda

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

Presenters

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- Anu Ollikainen, Research Coordinator, Fimea
- Markus Mäkelä, Systems Specialist, Fimea
- Juha Jokimäki, Software Architect, Solita

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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)

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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

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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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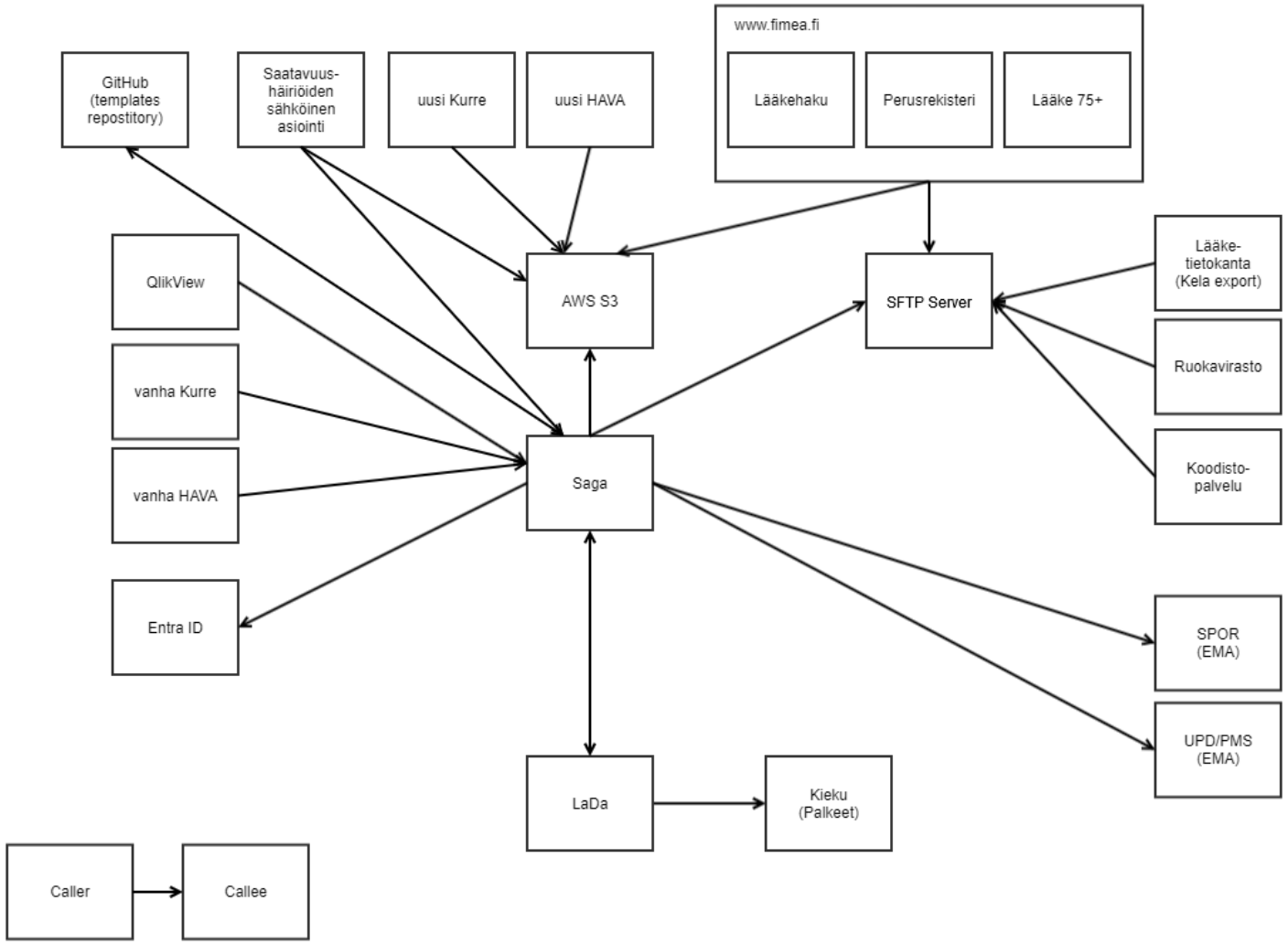
Saga Integrations



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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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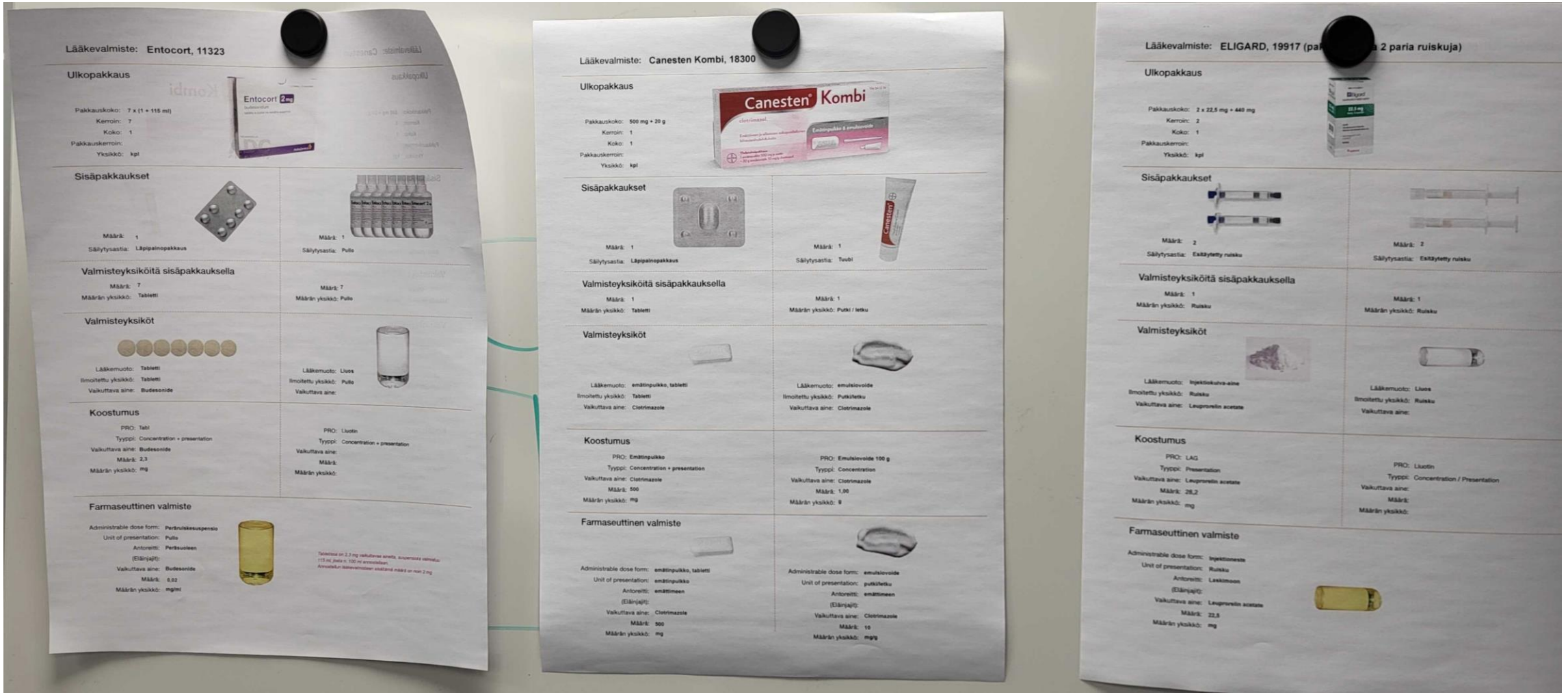

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Thank you!