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Swissmedic digital platforms – Swissmedic Portal

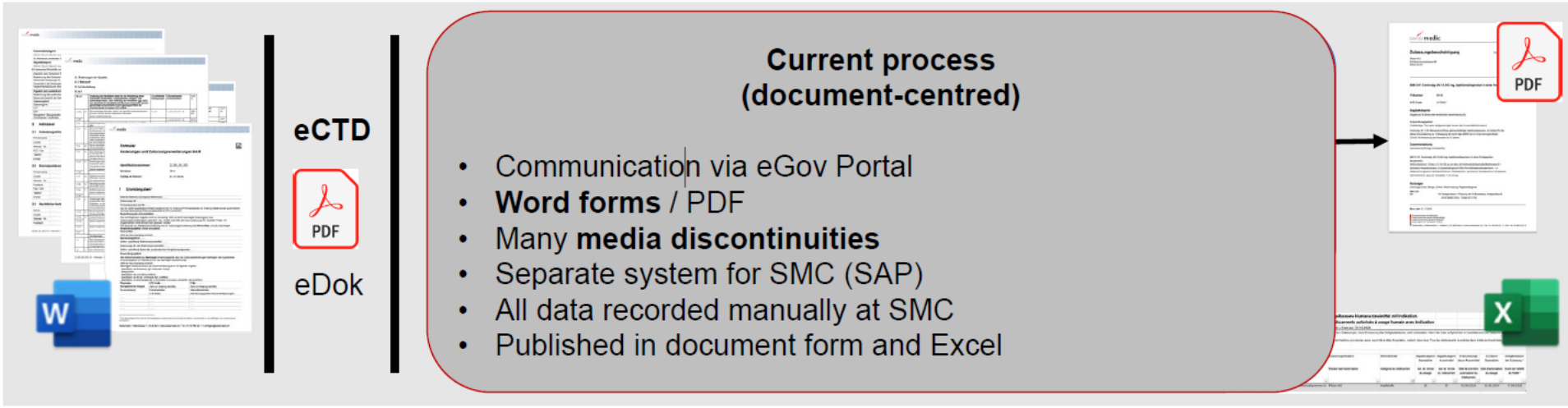
Ulrich Vogler, Head of IT

Why digitalisation at Swissmedic?

Ten years ago, regulatory processes mainly consisted of documents. In the future, they will increasingly be based on data.

The vision: From document to data

Regulatory & Beyond 2024



HL7 FHIR

PDF

eCTD
(Modules 2-5)

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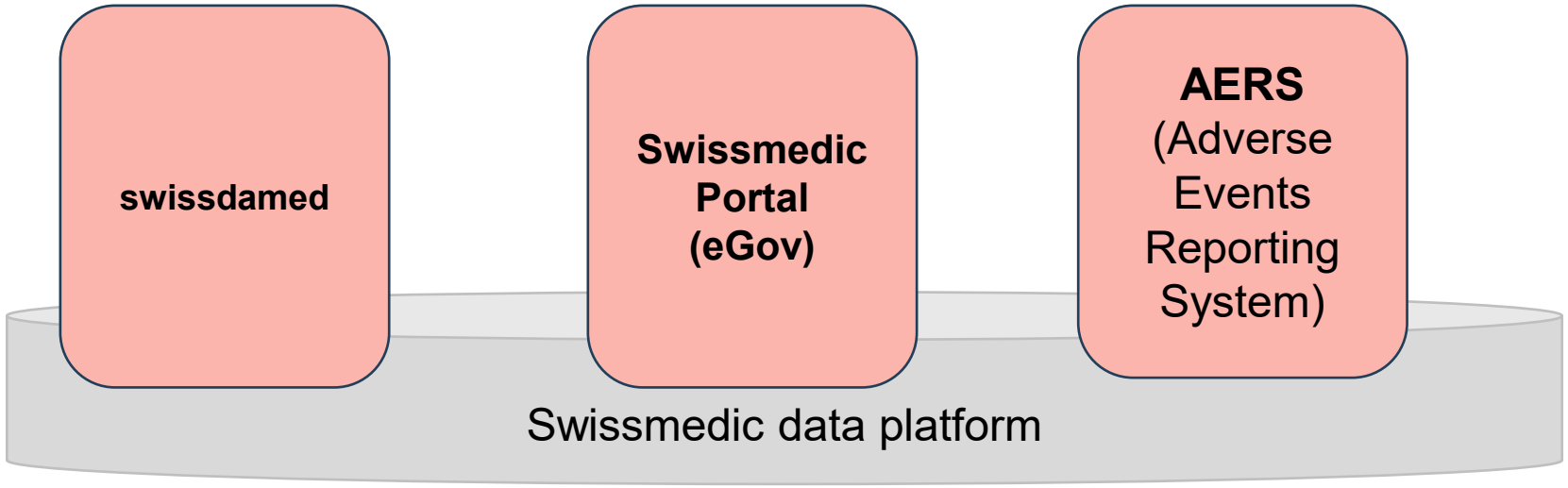
New Swissmedic Portal
(data-centred)

- All communication via Portal
- **Online forms** (with FHIR (ISO IDMP) interface)
- Data recorded once (**once-only principle**) to ISO standards
- Data accessible and usable
- Joint system
  (for Swissmedic internally and stakeholders)
- Published as a data package (FHIR)

HL7 FHIR

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Our digital platforms in combination



The platforms address different regulatory domains but follow the same principles:

digital interaction, greater transparency and better data quality through standardised processes and data formats

What has been achieved in the Swissmedic Portal since 2025?

Oct. 2025

- Basic company dossier
- Master dossier and single notifications

March 2026

- IDMP-compliant starting materials for specified substances

May 2026

- Usability workshop with specialist representatives

May 2026

- Details page of basic company dossier
- Complementary and herbal substance database

Aug. 2026

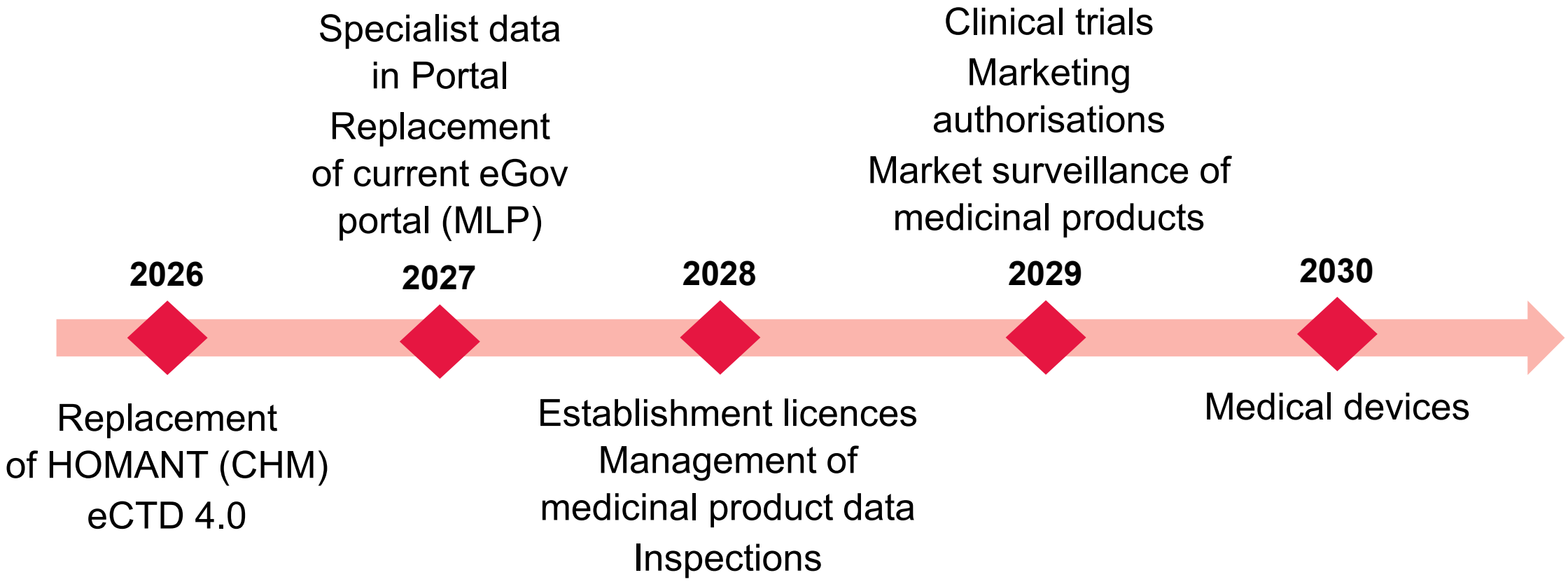
- Optimisation of navigation
- Internal overview of all establishment licences

Sept. 2026

- Major changes (Art. 42 para. 2 MPLO)
- External provision of CHM specialist data

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Next milestones in the Swissmedic Portal



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Target vision for a common digital future

- User experience
  - Easier interaction
- Consistent digital processes
  - Fewer media discontinuities
- Data quality and standards
  - Harmonisation

- *More digital end-to-end processes*
- *Greater degree of automation*
- *Even closer digital collaboration with stakeholders*