

Swissmedic's digitalisation journey – development of the Swissmedic Portal

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# Digitalisation and authority – can it work?



# Why is digitalisation important for Swissmedic?

- "Digital" international collaboration is becoming increasingly important.
- The way we handle digital tools is changing.
- Data are playing a growing role in informed decisions.
- We need to facilitate the use of innovative technologies to boost efficiency.

Digitalisation is turning into the central element of our strategic objectives.

At the interplay of regulation, data protection, information security and innovation.



### **Our vision**

In 2026, Swissmedic can ...

... work on a data-centric basis with the therapeutic products industry and other authorities, across national borders, safely and securely (data focus).

..., by developing and operating new secure, stable, data-centric systems, provide support for efficient and effective work within the authority.

**Vision:** The modern platforms form the basis of a digitalised "Leading Agency Swissmedic", making a decisive contribution to the performance of Swissmedic and patient safety in Switzerland.



# The big picture of digitalisation

swissmedic

Enable communication through Communication International standards and platforms standardised and structured data externally Market access Market surveillance Boost services and capabilities Strategic objectives 2023-2026 through a data-centric approach Stakeholders Penal law Standards (information) Services and capabilities Improve decisions in business case Establish the new Swissmedic Portal and administration other projects Business case administration Static reporting Optimise the evaluability of our data Implement the data strategy Self-service BI Data lab The Swissmedic Data analytics platform context

# Can we do digitalisation?

We're learning digitalisation!



# Swissmedic's digitalisation journey



- Business strategy 2023-2026
- · Functional strategy IT
- Data strategy (data centring)
- Cloud strategy (modern technologies)
- Sourcing strategy (a digital free hand)
- Technology upskilling and establishment of software development
- Establish information security and data protection
- Start transformation programme
- WTO tenders for technology partnerships
- · Switch to agile working
- · Establish Swissmedic cloud access

- Start Swissmedic Portal implementation project
- Start Authorisation implementation project
- Establish data platform
- Go-live SwissGMDP database
- Go-live swissdamed (medical devices)
- Go-live first release Swissmedic Portal

- Later releases of implementation projects (licences, authorisation, medical devices)
- Moving SAP into the cloud (SAP RISE)
- Transfer of IT infrastructure to new provider (sourcing)
- Later releases of implementation projects
- (licences, authorisation, medical devices)
- Implementation projects data science & reporting
- Completion of SAP platform renewal



# The new Swissmedic Portal – the central element of our digitalisation journey



# Our mission to provide a new Swissmedic Portal

#### Solution



The new Swissmedic Portal replaces the current SAP CRM and other applications/platforms. The processes and data involved are optimised. The new work environment for our in-house employees and our external partners features standardised data, user friendliness and process and media consistency.

#### Collaboration



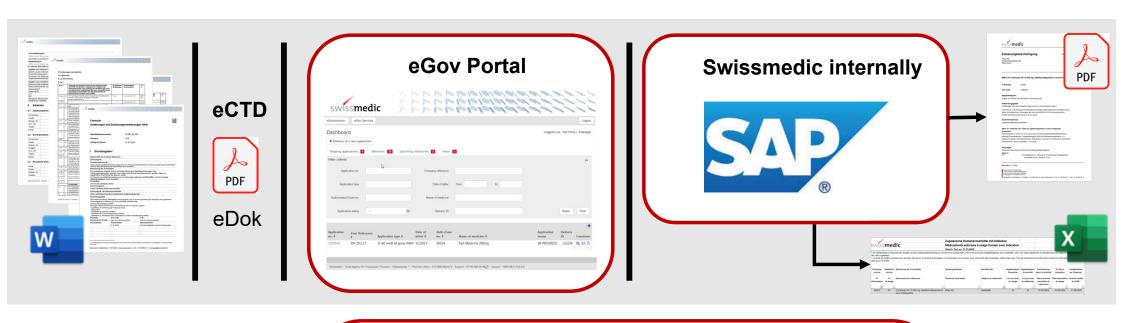
External partners will play an **active part** in data entry and maintenance. Requests and enquiries can be processed more **rapidly**, **securely and effectively** thanks to data availability and analytical options (using AI).

#### Mindset & skills



Interdisciplinary teams are jointly responsible for the successful specialised and technical design, ongoing development and replacement of systems and processes. Cooperation with internal and external stakeholders and users is characterised by openness, respect and flexibility. Swissmedic's employees have the specialised, methodological and individual skills required to ensure this.





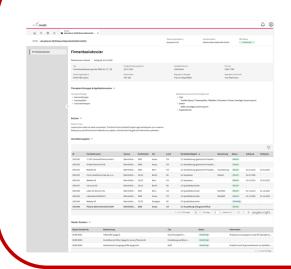


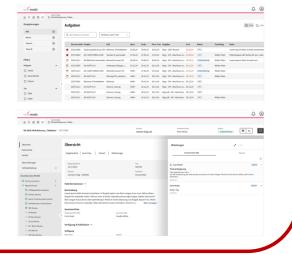




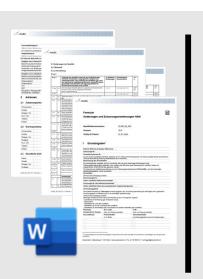
eCTD (Modules 2-5)















eDok

#### **Current process** (document-centred)

- Communication via eGov Portal
- Word forms / PDF
- Many media discontinuities
- Separate system for SMC (SAP)
- All data recorded manually at SMC
- Published in document form and Excel









**eCTD** 

(Modules 2-5) swissmedic

#### **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)





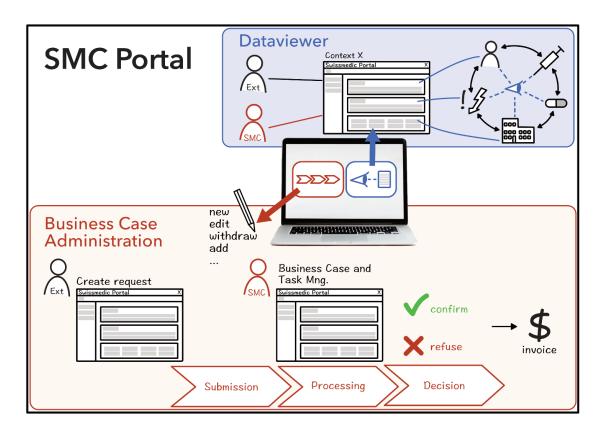
HL7FHIR



## The new Swissmedic Portal



Business case administration #processingdailybusiness





Centralised data viewer #360degreecustomerview



#### Swissmedic in the data flow

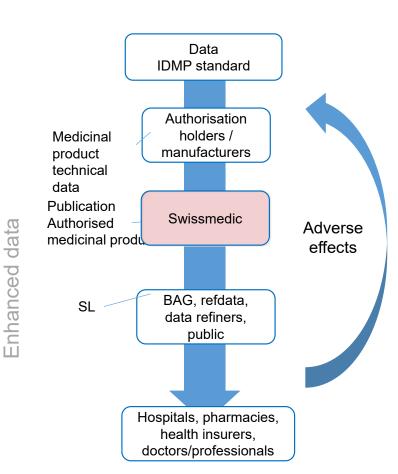
#### Interest in medicinal product data

- Authorisation holders / manufacturers
- Authorities (Swissmedic, FOPH, etc.)
- Hospitals, pharmacies, druggists
- Doctors / professionals
- Health insurers
- General public

#### Swissmedic approach to IDMP implementation

- No CH legislation, but the Swissmedic Portal requires an IDMP-compatible data structure
- Data structure aligned with EU
- Data capture: by analogy with Electronic Application Form (eAF; EMA)
- Data exchange: FHIR message
- Tests in pilot projects





# Digitalisation as a team sport



### Stakeholder involvement

#### *Information*

- Participation in events (round tables, other)
- Regular updates in the form of online demos planned

#### Involvement

- Participation of selected stakeholders in user groups, advisory group, pilot groups
- Usability tests / surveys and workshops on specific topics
- → More information about this at the "Transformation of Swissmedic Platforms (TSP) project" stand



