



## **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

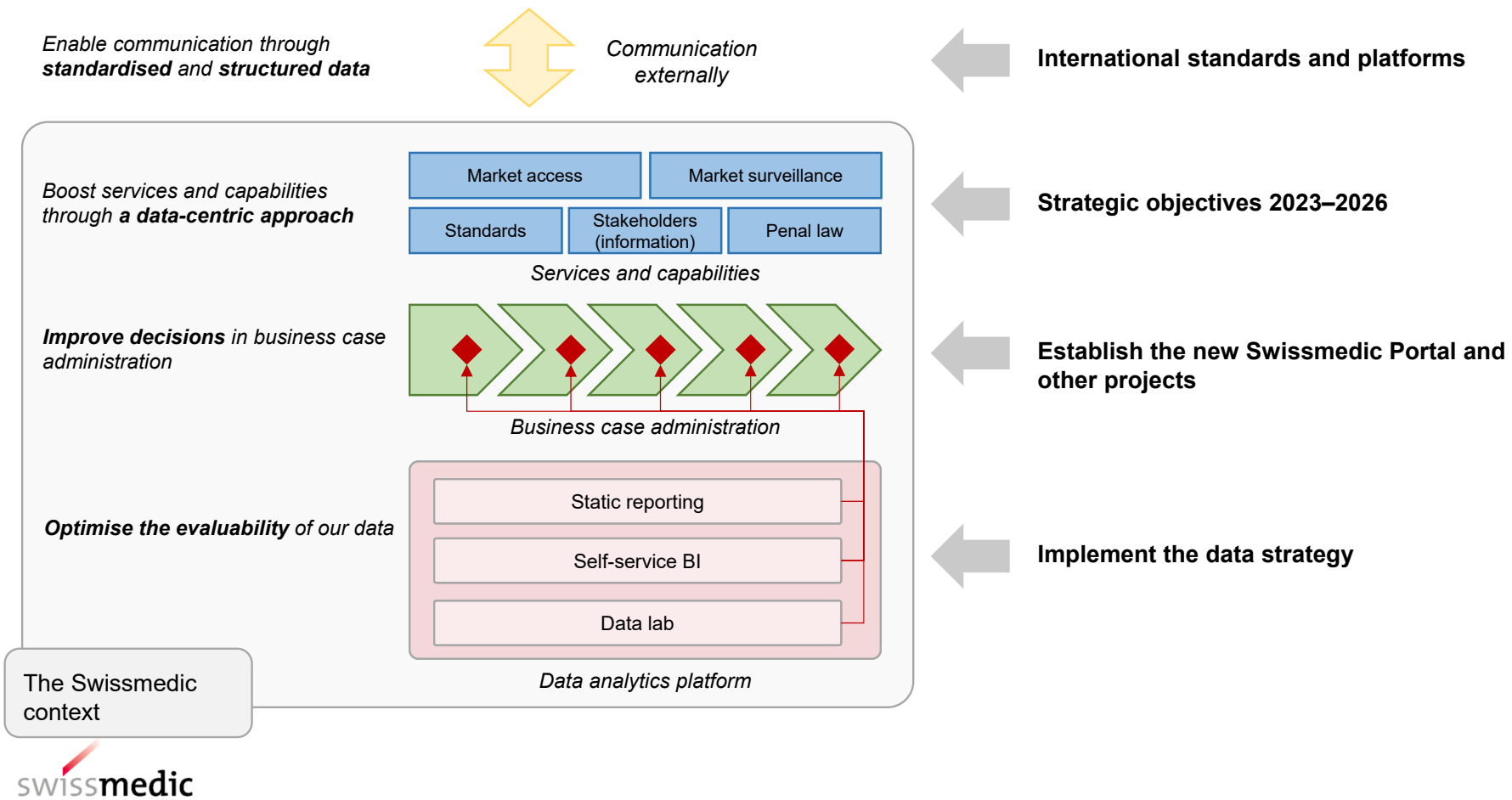
## In 2026, Swissmedic can ...

... 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.

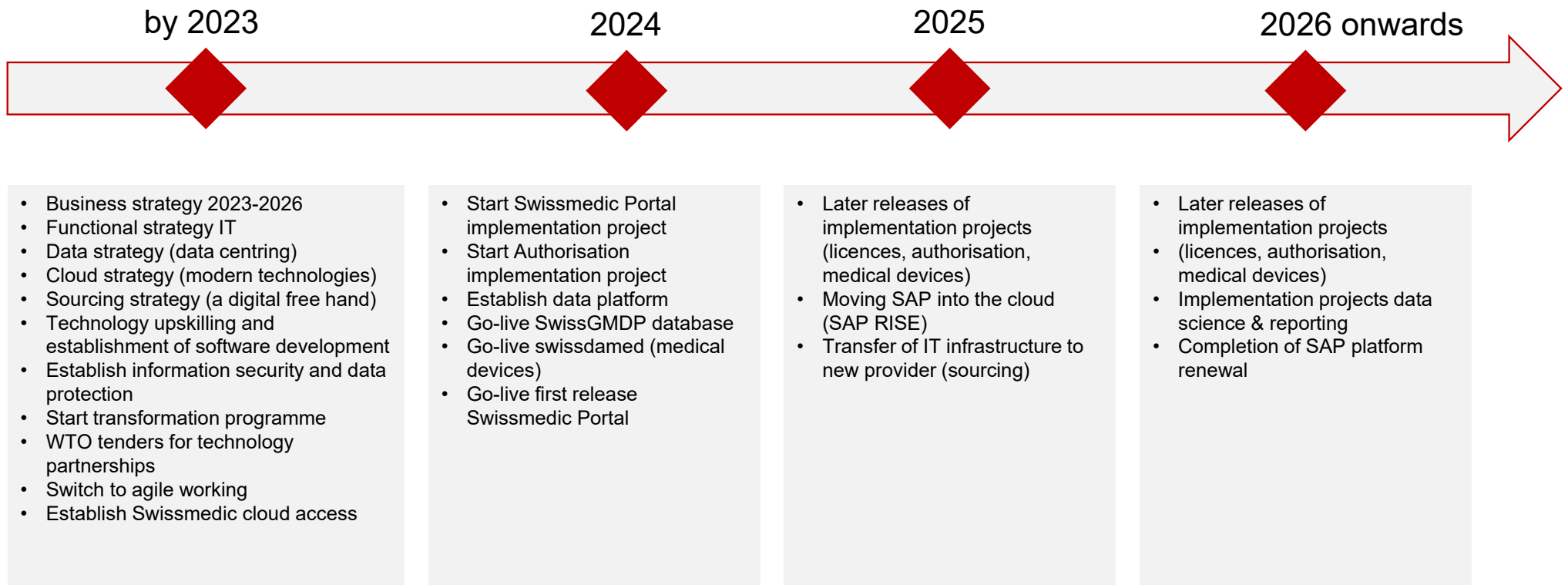
# The big picture of digitalisation



**Can we do digitalisation?**

**We're learning digitalisation!**

# Swissmedic's digitalisation journey



# **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.

Formular  
Antrag auf Zulassung eines Arzneimittels

eCTD



eDok

### eGov Portal

Dashboard

Originating applications: 1, Deliveries: 2, Upcoming milestones: 3, Index: 4

Filter criteria:

Application no. [input] Company reference [input]

Application type [input] Date of letter from [input] to [input]

Authorization/Case no. [input] Name of medicine [input]

Application status [input] Delivery ID [input]

Application no.	Your Reference	Application type	Date of letter	Auth./Case no.	Name of medicine	Application status	Delivery ID	Functions
1209534	RH 29.12.17	G-AT mvd AI gross/HAM	02.2017	95024	Test Medicine 200mg	IN PROGRESS	122234	Q, E, D

### Swissmedic internally

Zulassungsbescheinigung

SWISSMEDIC (Zulassung) AI 1.042 mg Tabletten/Präparat in einer Packung



Zugewiesene Humanarzneimittel mit Indikation  
Medicaments authorized to usage human with indication



HL7 FHIR



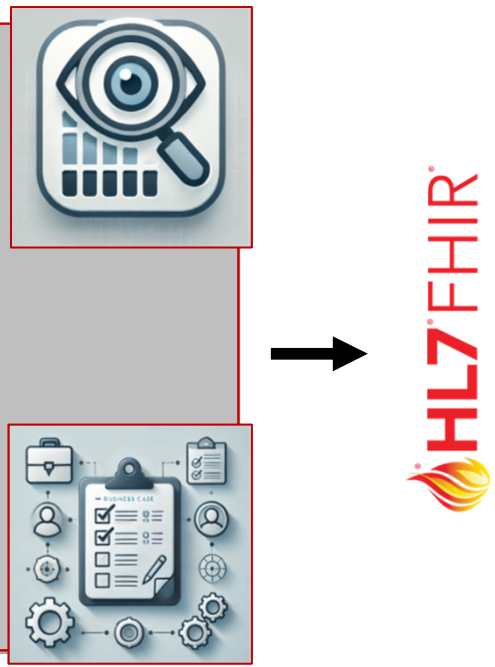
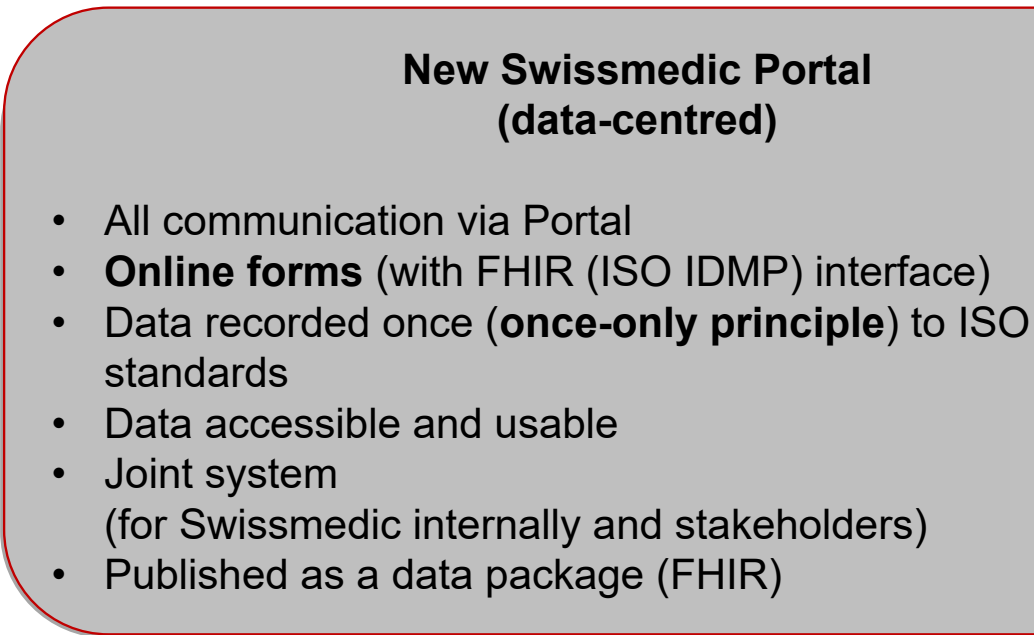
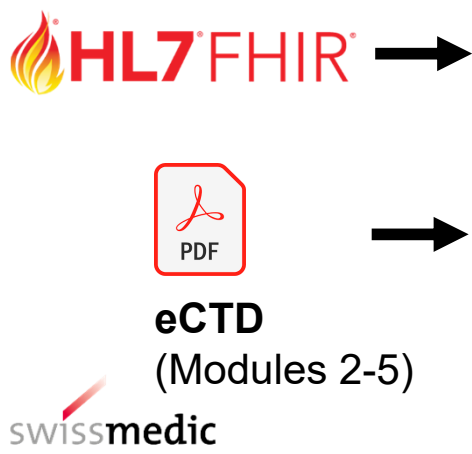
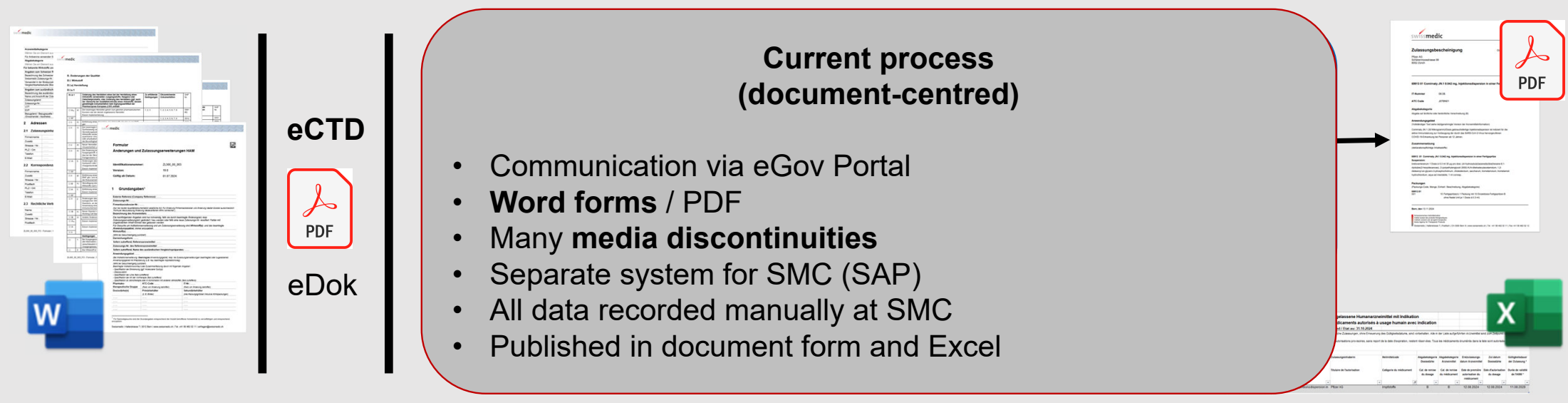
eCTD (Modules 2-5)



Firmenbasisdossier

Aufgaben

HL7 FHIR

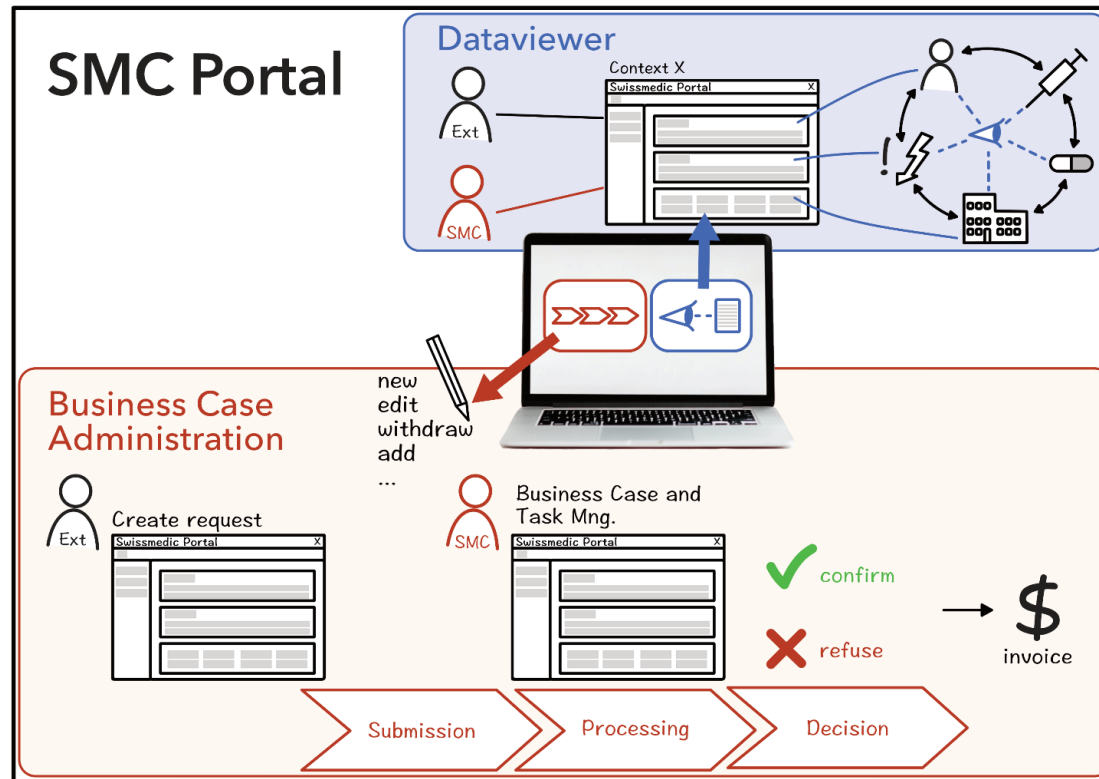


# The new Swissmedic Portal



**Business case administration**

#processingdailybusiness



**Centralised data viewer**  
#360degreecustomerview

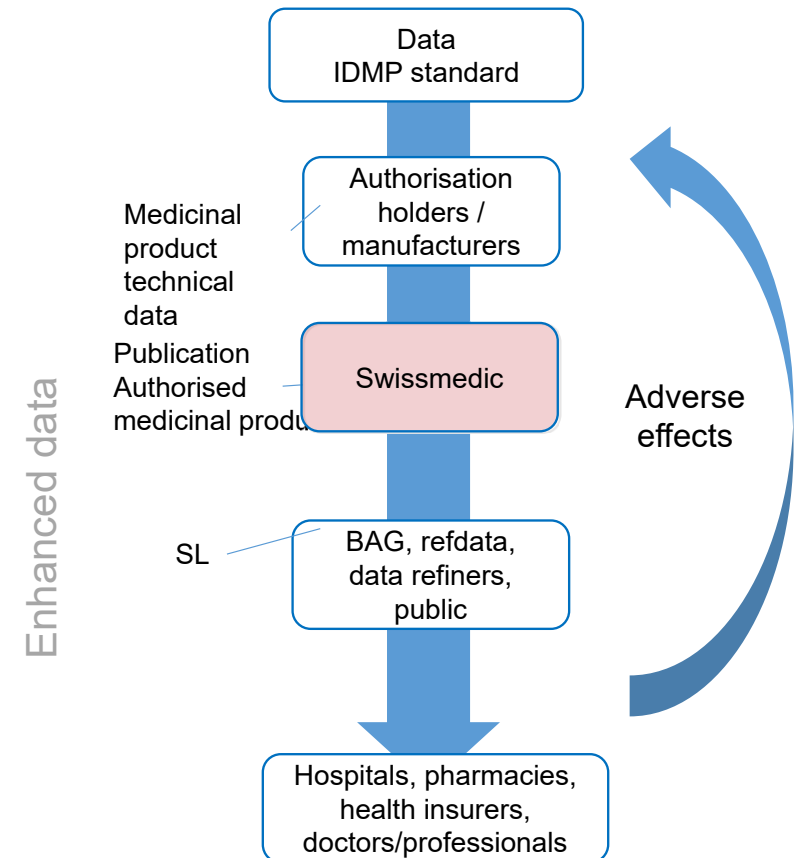
# Swissmedic in the data flow

## 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

**Thank you for your attention**