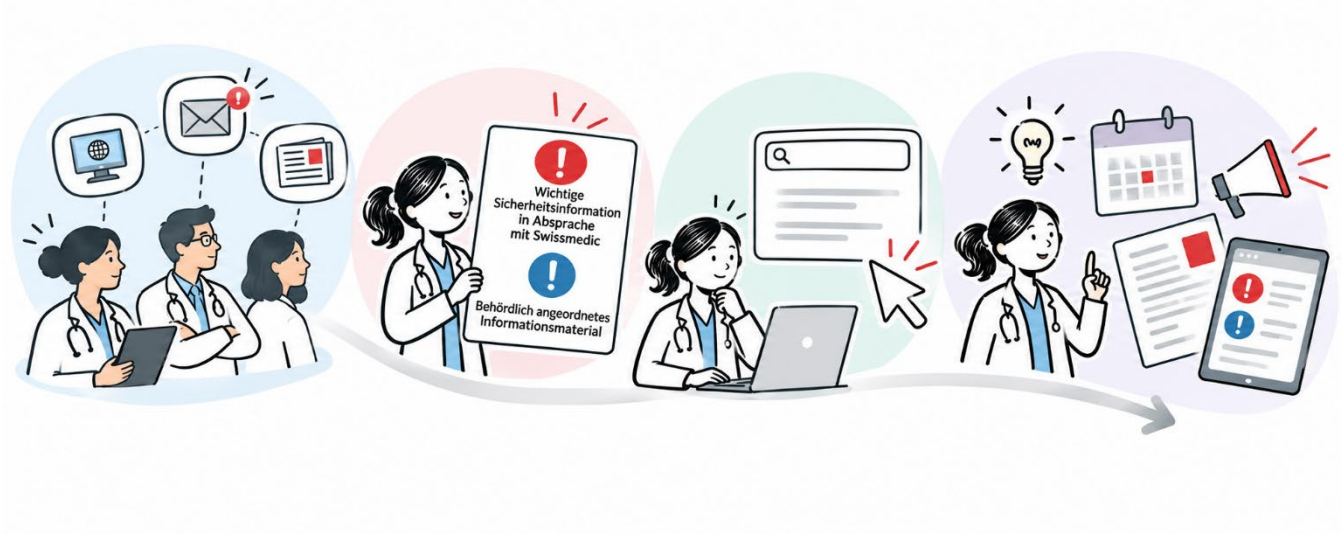
swissmedic

Innovations in risk communication and reporting tools (ElViS 2.0)

Stephanie Storre, Head of Risk Management
Thomas Stammschulte, Head of Pharmacovigilance

Focus of the Safety of Medicines Division: Improve the effectiveness of risk communication



swissmedic

Our approaches for effective risk communication

- Reliably reach the target groups

  Convey risk information where healthcare professionals get information.

- Clearly identify safety-related information

  Make risk information identifiable at first glance.

- Enable easier access to risk information

  Ensure information is centrally, reliably accessible.

- Maintain awareness of safety information

  Draw attention and raise awareness with regular publications.

Our goal is to ensure that risk information is not only received, but also understood and effectively implemented in everyday practice – to enhance medication and patient safety.

Risk information must reach healthcare professionals where they get information

- Swissmedic “Safety of medicines” newsletter

- Current publications in the Swiss medical journal “Schweizerische Ärztezeitung”:
  - Adverse drug reaction reports
  - RSV prevention: Beware of medication errors!
  - Prescribing safely with current information material

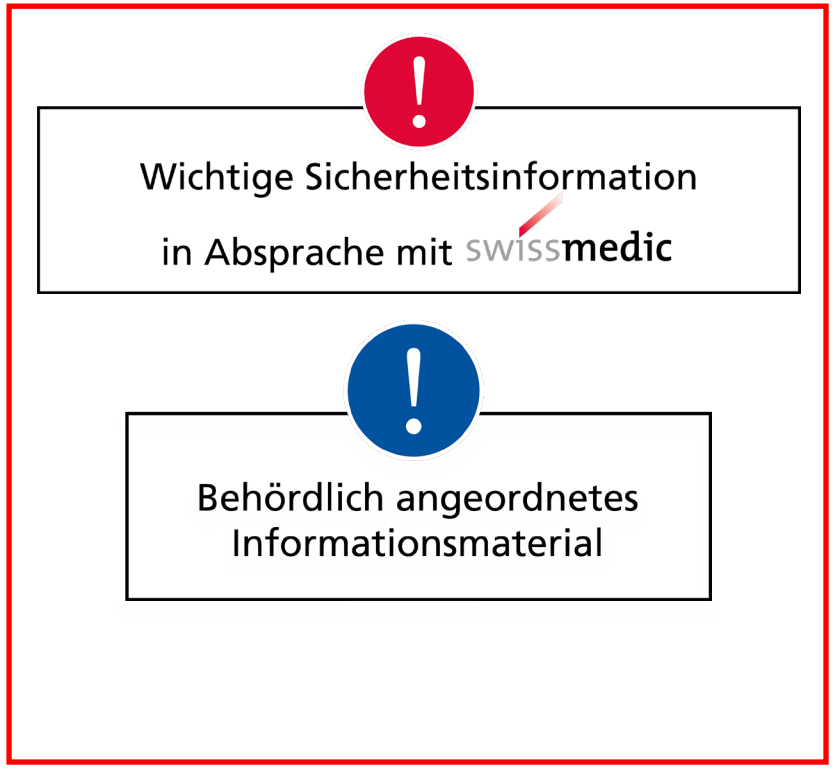


Risk information must be identifiable at first glance

Introduction of specific symbols to clearly identify safety-relevant information



Germany: Red hand logo (since 1969) and blue hand logo (since 2016)

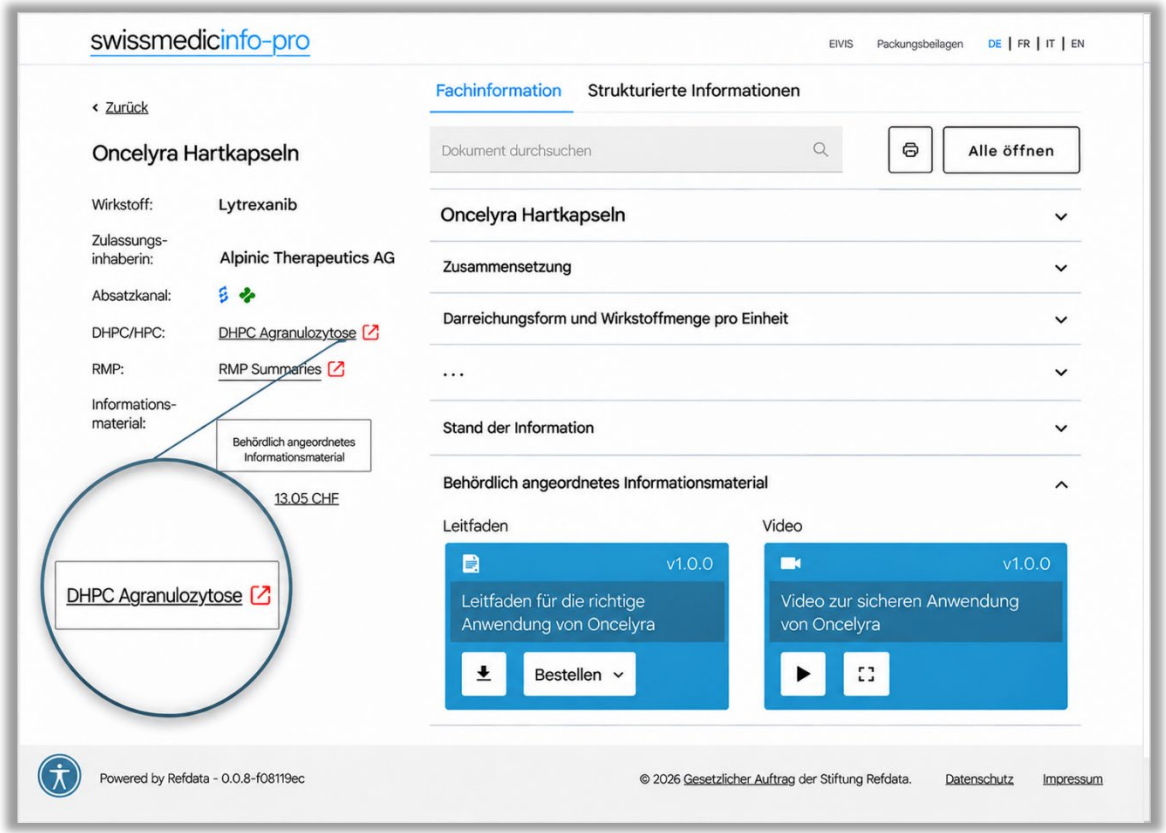




Specific DHPC identification in Italy (since 2026)

Risk information must be reliably accessible

- Keywords and direct DHPC links at www.swissmedicinfo-pro.ch for rapid orientation and targeted access to the information.
- Information material centrally, directly accessible since 1 November 2026 at www.swissmedicinfo-pro.ch and www.swissmedicinfo.ch.
- In the future: Obligatory reference to the information material in the medicinal product information.



swissmedic

Raise and maintain awareness of risk information: Pharmacovigilance in the spotlight

- Publication of selected individual case safety reports on the Swissmedic website
- 32 reports published between November 2022 and October 2026

12.10.2026
Neuroleptic malignant syndrome associated with antipsychotic treatment

24.04.2026
Hepatic and pulmonary side effects after the long-term administration of low-dose methotrexate

24.10.2025
Risk of intraoperative floppy iris syndrome in patients treated with tamsulosin

27.06.2025
Spironolactone and persistent hoarseness – a hormonally induced side effect

06.02.2026
Jarisch-Herxheimer reaction during antibiotic treatment of spirochaetal infections

12.09.2025
Drug-induced aseptic meningitis

02.05.2025
Finasteride and persistent side effects

06.01.2026
Phosphonorm® administered instead of Phoscap capsules

07.08.2025
Drug-induced taste disorders

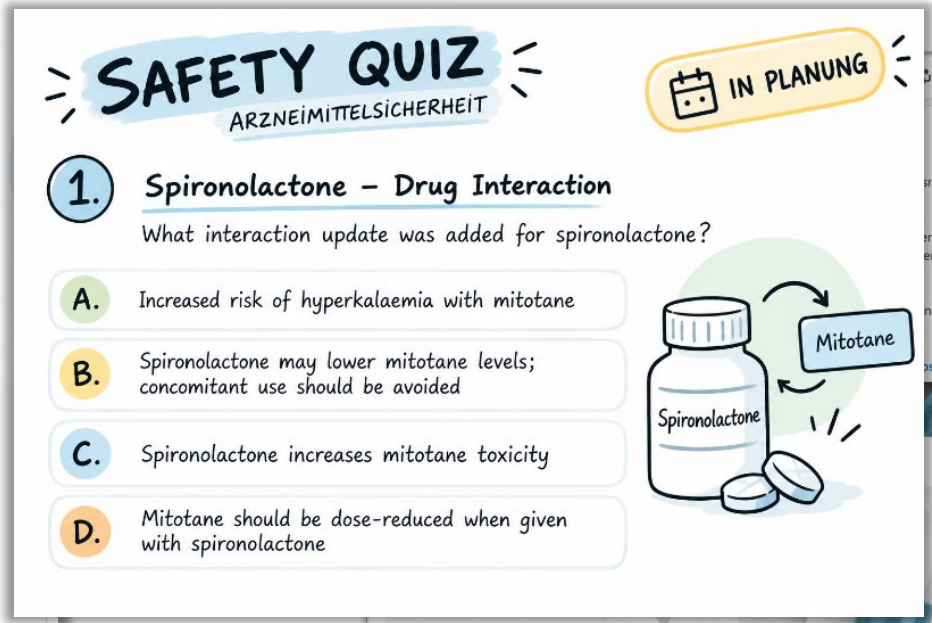
07.04.2025
Eosinophilic oesophagitis during oral immunotherapy for peanut allergy

swissmedic

Raise and maintain awareness of risk information: Safety Update

- Monthly overview of safety-relevant updates to the Information for healthcare professionals
- Publication of 179 active substance-specific items of information since launch in November 2025

Active substance(s)	New safety information	Updated section(s)	(D)HPC
Apixaban	Alopecia	Undesirable effects	–
Bictegravir	Interaction with zinc: It is recommended that they are taken at different times.	Interactions	–
Bictegravir	Weight gain	Warnings and precautions; Undesirable effects	–
Caspofungin	Use of polyacrylonitrile membranes should be avoided in patients on continuous renal replacement therapy and treatment with caspofungin; an alternative membrane or a different antifungal agent should be used instead.	Warnings and precautions	DHPC – Caspofungi Labatec®, Caspofungi Leman®, Caspofungin Mepha®, Caspofungin Viatris, Caspofungin Sandoz® eco (Caspofungin)



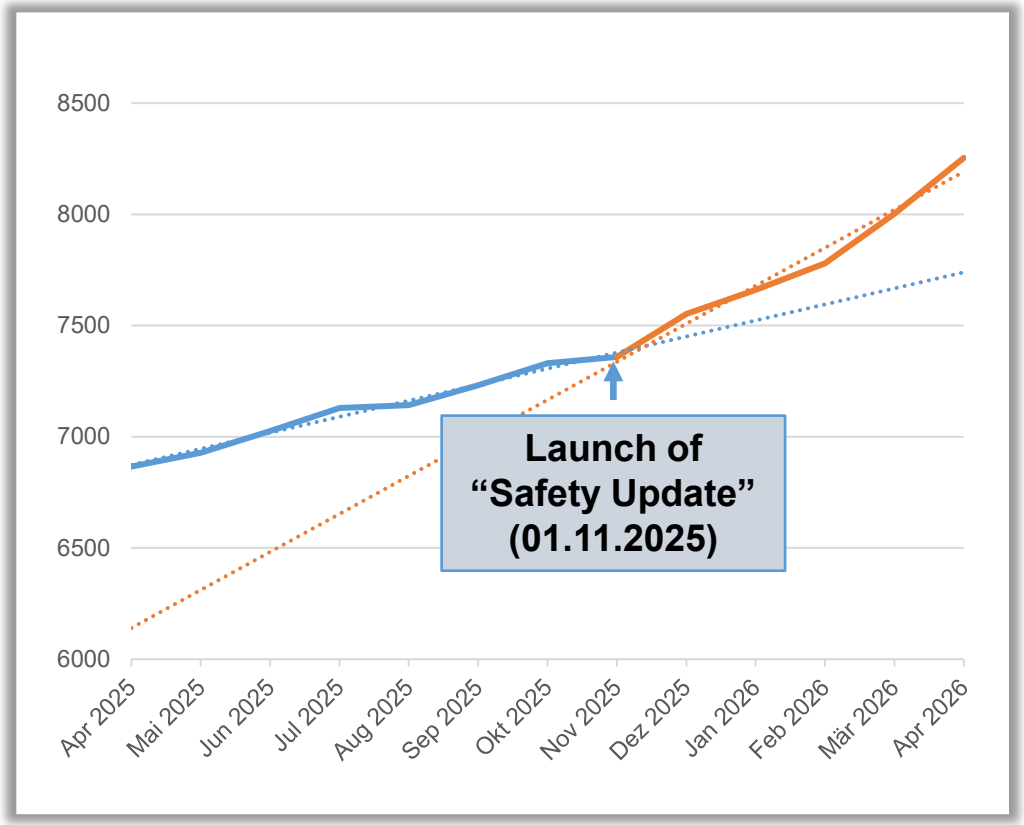
Raise and maintain awareness of risk information: Vigilance News

- Established communication tools since 2008
- Revised format: English full text plus online summary in four languages.



Our risk communication: Reach and benefit

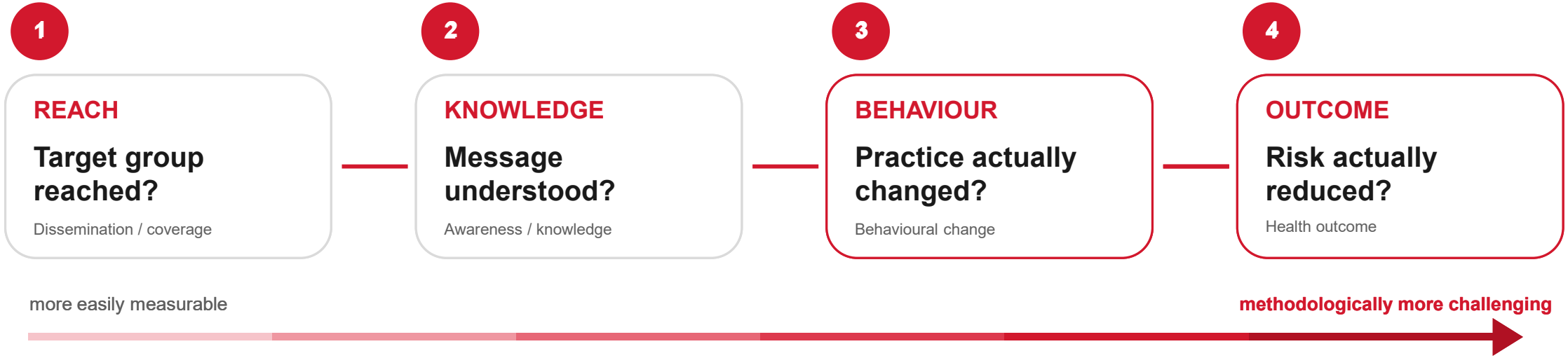
Communication tool	Reach
Pharmacovigilance in the spotlight	Accessed between 950 and 4,500 times; average 2,500 times
(D)HPC	Accessed between 1,100 and 8,300 times; average 2,700 times ((D)HPC medicinal product safety, 2024 – 09/2026)
Vigilance News (abstracts from new editions)	Accessed 2,373 or 2,837 times; around 500 downloads of the full PDF editions
“Safety of medicines” newsletter	> 8,500 subscribers (as at 09/2026)



Growth in subscribers to “Safety of medicines” newsletter

swissmedic

Risk communication: The impact is crucial



The success of the risk communication is not measured solely by its reach, but its impact on medicinal product safety.

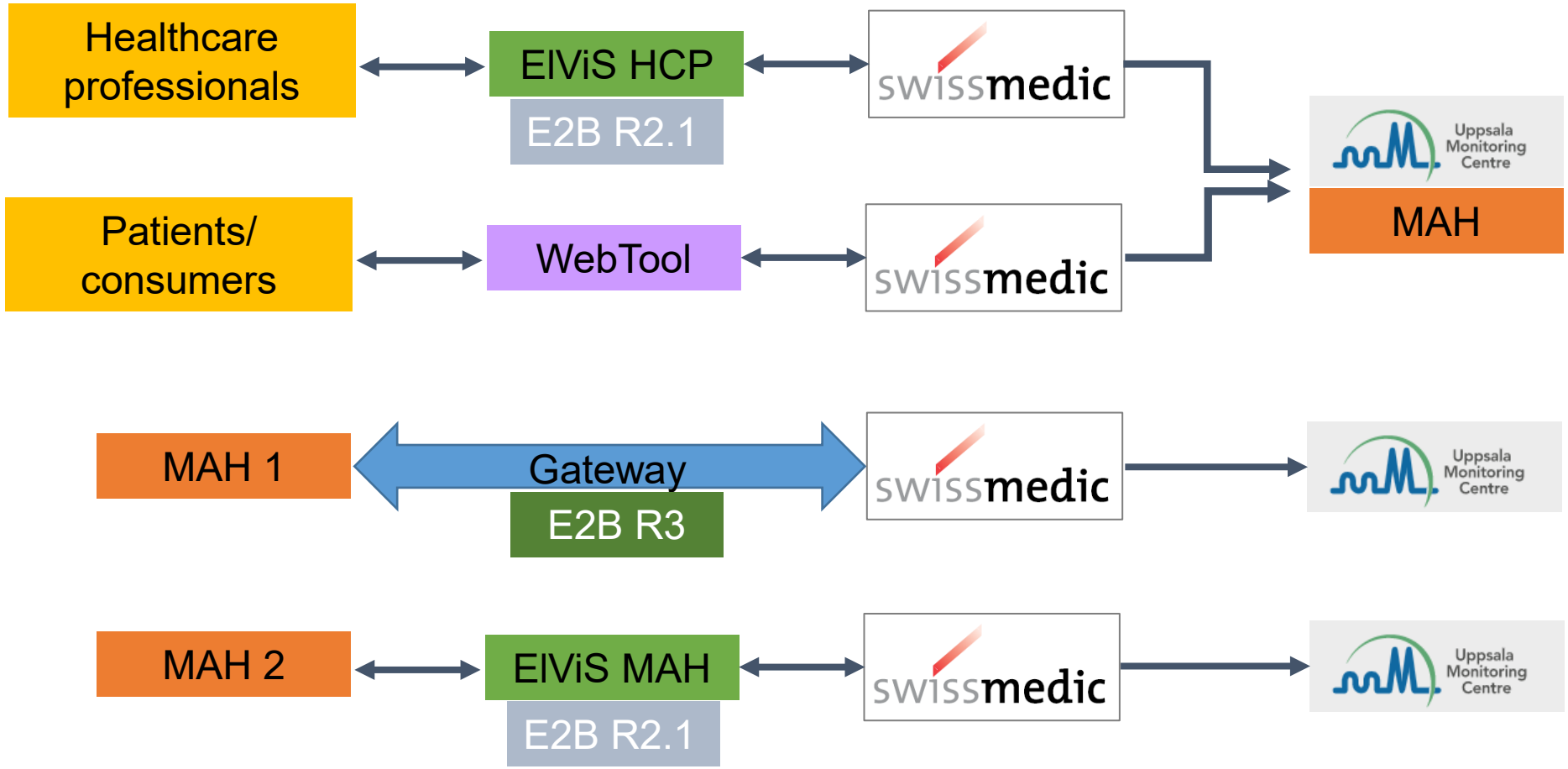
EMA GVP Module XVI Rev. 3; Module XVI Addendum II

swissmedic

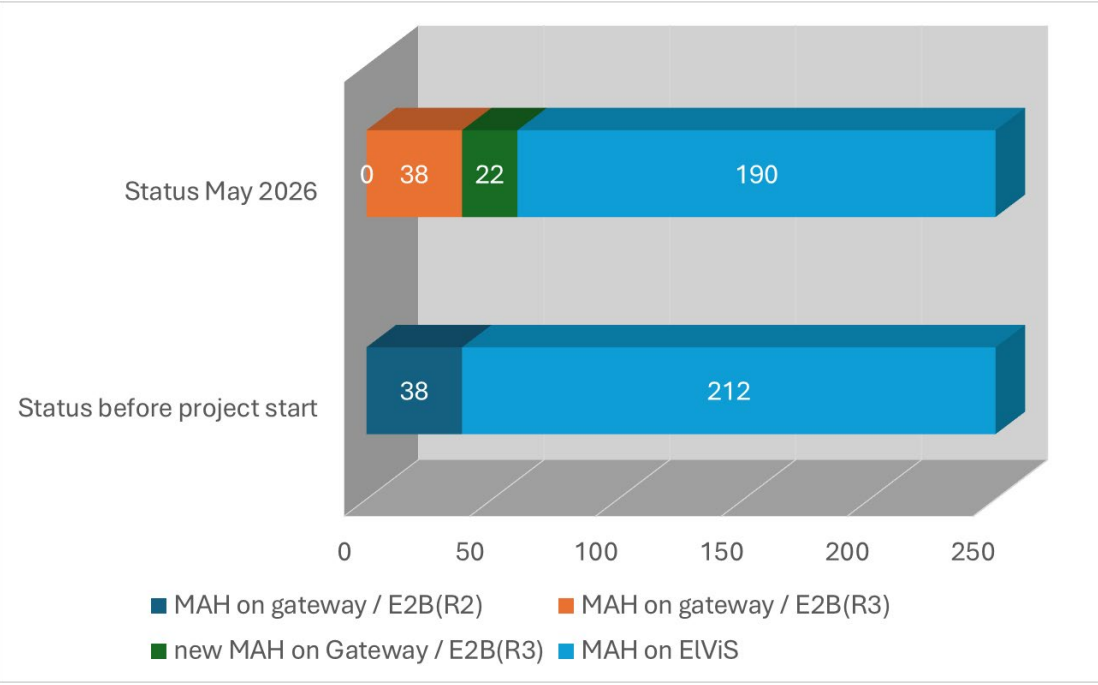
Launch of ElViS 2.0
(Electronic Vigilance System)

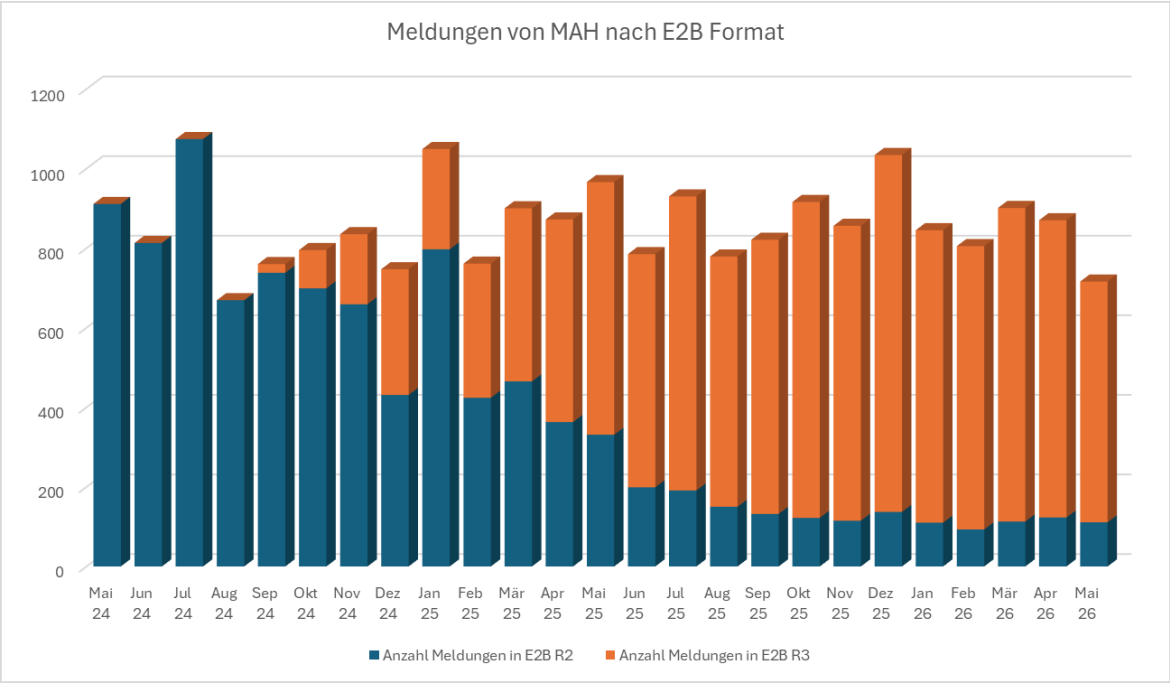
swissmedic

Electronic exchange of individual case safety reports (ICSRs) with Swissmedic



Introduction of E2B(R3): Number of MAHs / number of ICSRs by format





swissmedic

Launch of Electronic Vigilance System 2.0 (ElViS 2.0)

- Necessary step in the comprehensive introduction of the E2B(R3) format in Switzerland
- ElViS is now technically outdated and has to be replaced
- ElViS 2.0 is an integrated platform with direct communication with the Swissmedic database
- Tailored different input screens for HCPs and MAHs
- New: Message function for direct contact within the reporting tool
- Go-live planned for 21 December 2026

Selection of important changes in E2B(R3)

- Data structure
- Numbering of data elements
- New data elements added / data elements removed
- Some data sections are repeatable
- Increased character count in free text fields
- Improved user guidance
- Use of object identifiers and nullFlavors
- Attachments

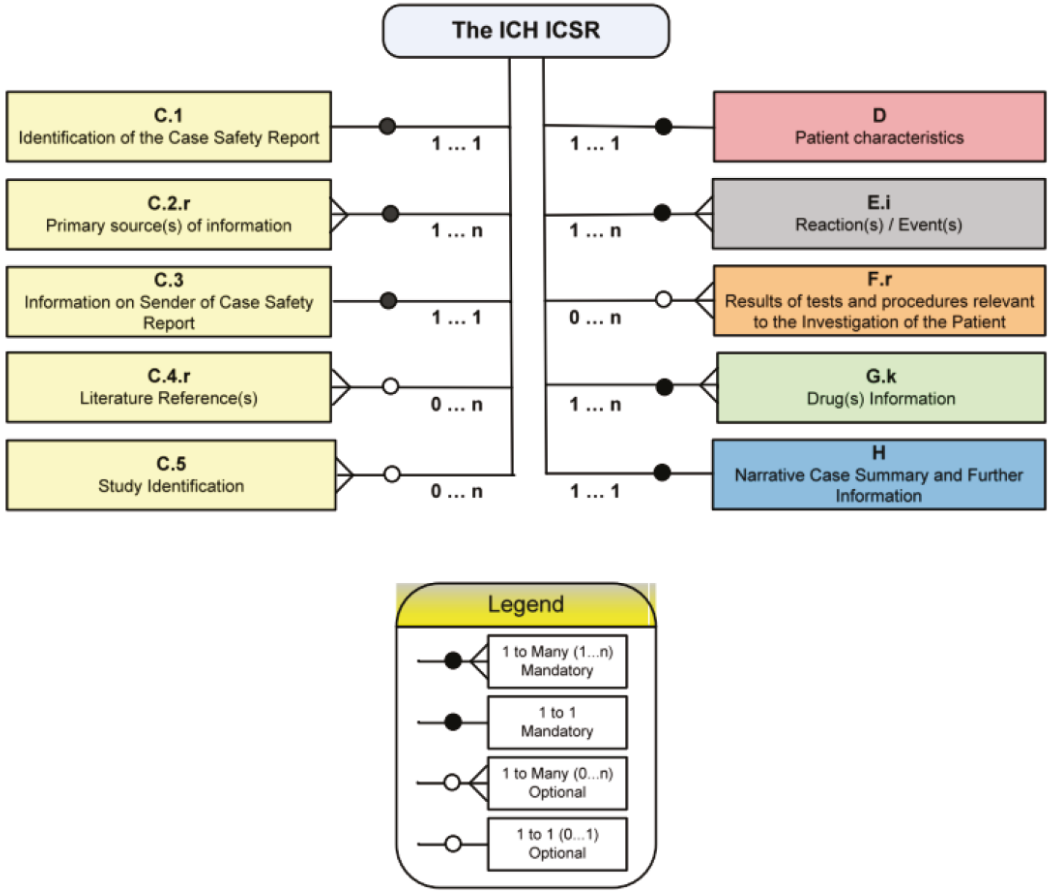


Figure 1. The ICH ICSR Structure [4]. [Legend] 1...1 (unique & mandatory);0...1 (unique & optional);1...n (one to many & mandatory); or 0...n (one to many & optional). ICH, international council for harmonization of technical requirements for pharmaceuticals for human use; ICSR, individual case safety reports.

Seo J et al. Application of electronic data standard for drug safety reporting in Korea. J Health Info Stat 2017;42(3):199-207.

swissmedic

ElViS 2.0 MAH



ElViS 2.0 HCP



swissmedic

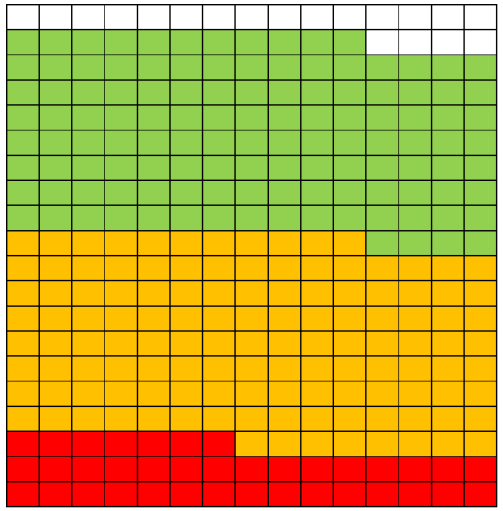
AI-generated image Artlist

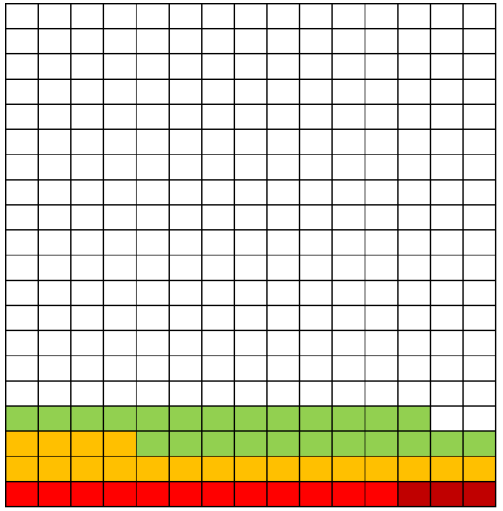
ElViS 2.0 MAH

ElViS 2.0 HCP



Number of input fields in E2B(R3)





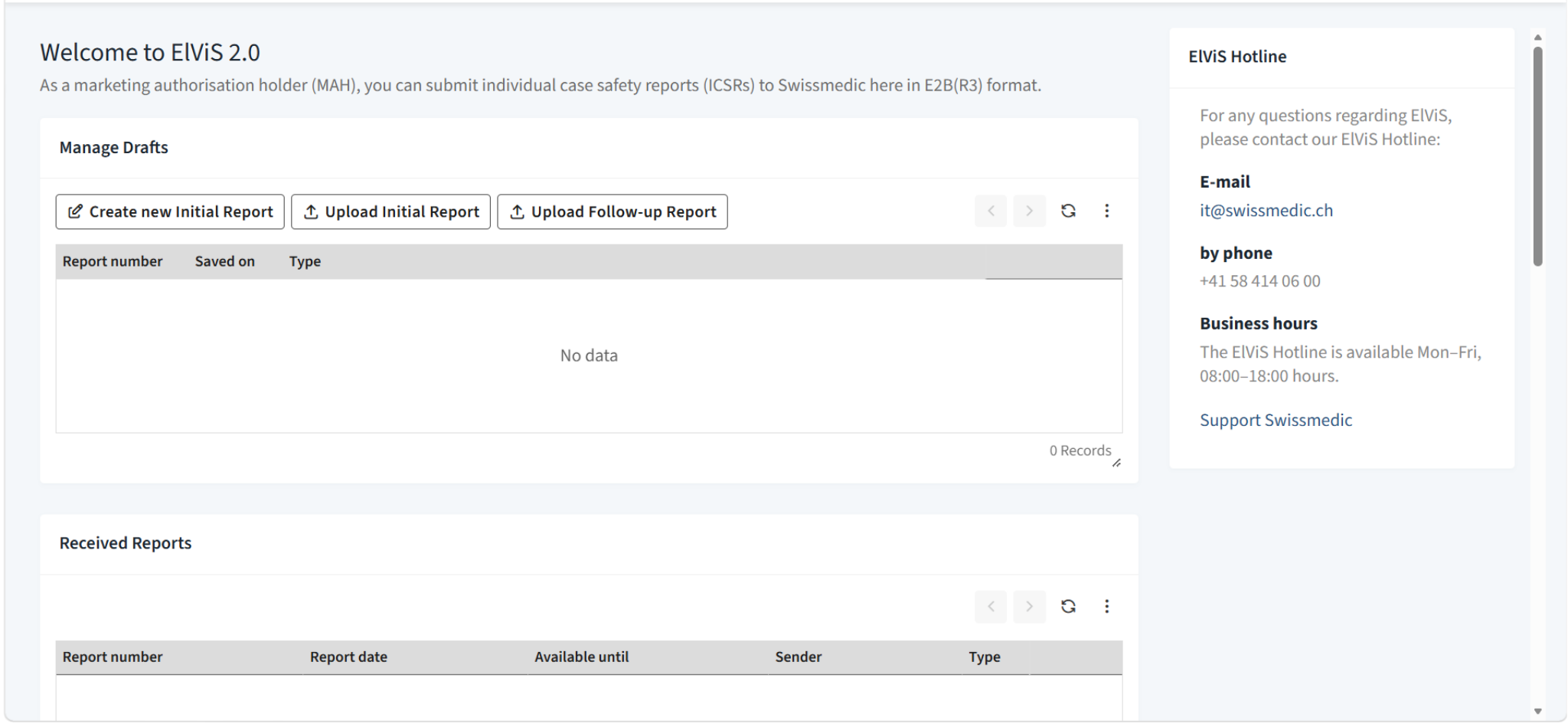
Optional
Conditional mandatory
Mandatory
Plus 0…1 or 1…1 fields



AI-generated image Artlist

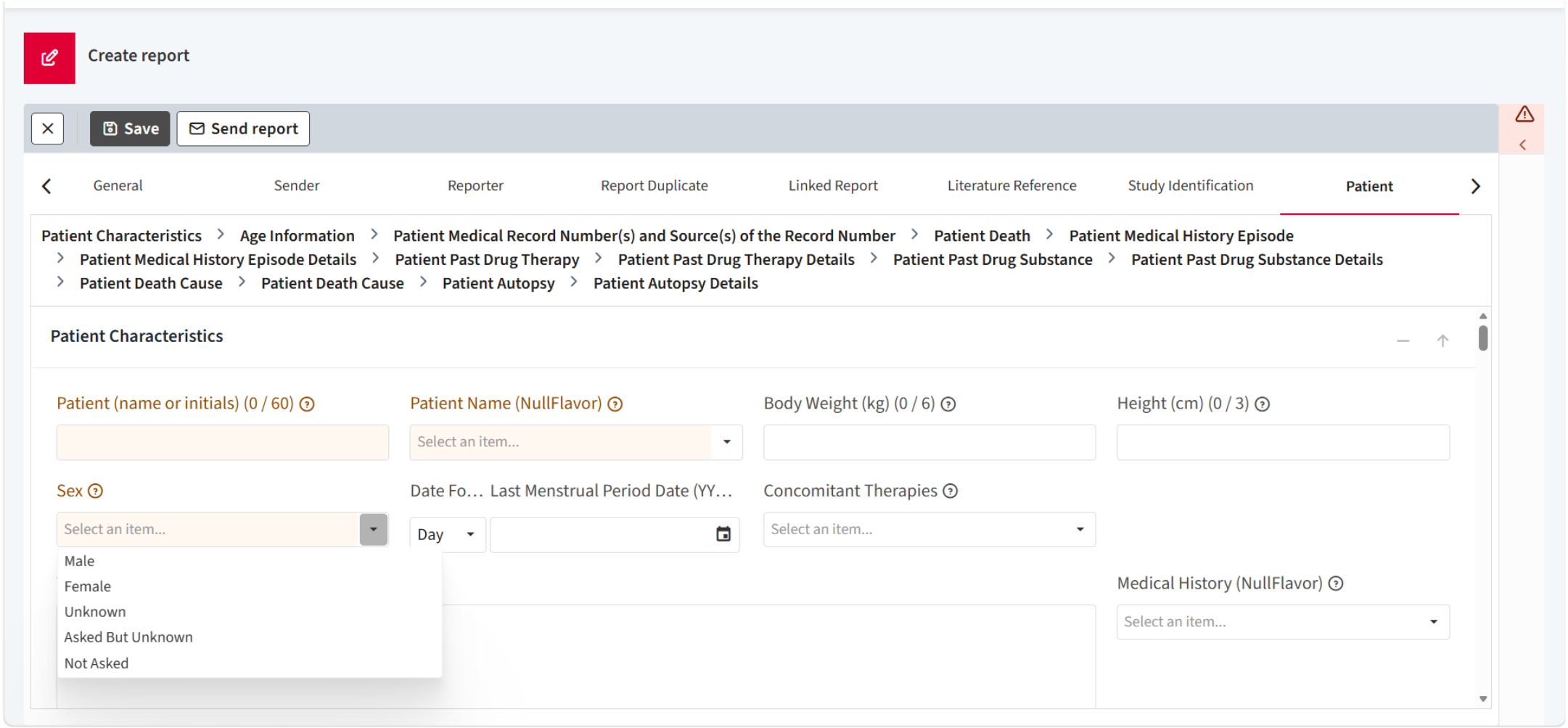
swissmedic

ElViS 2.0 MAH



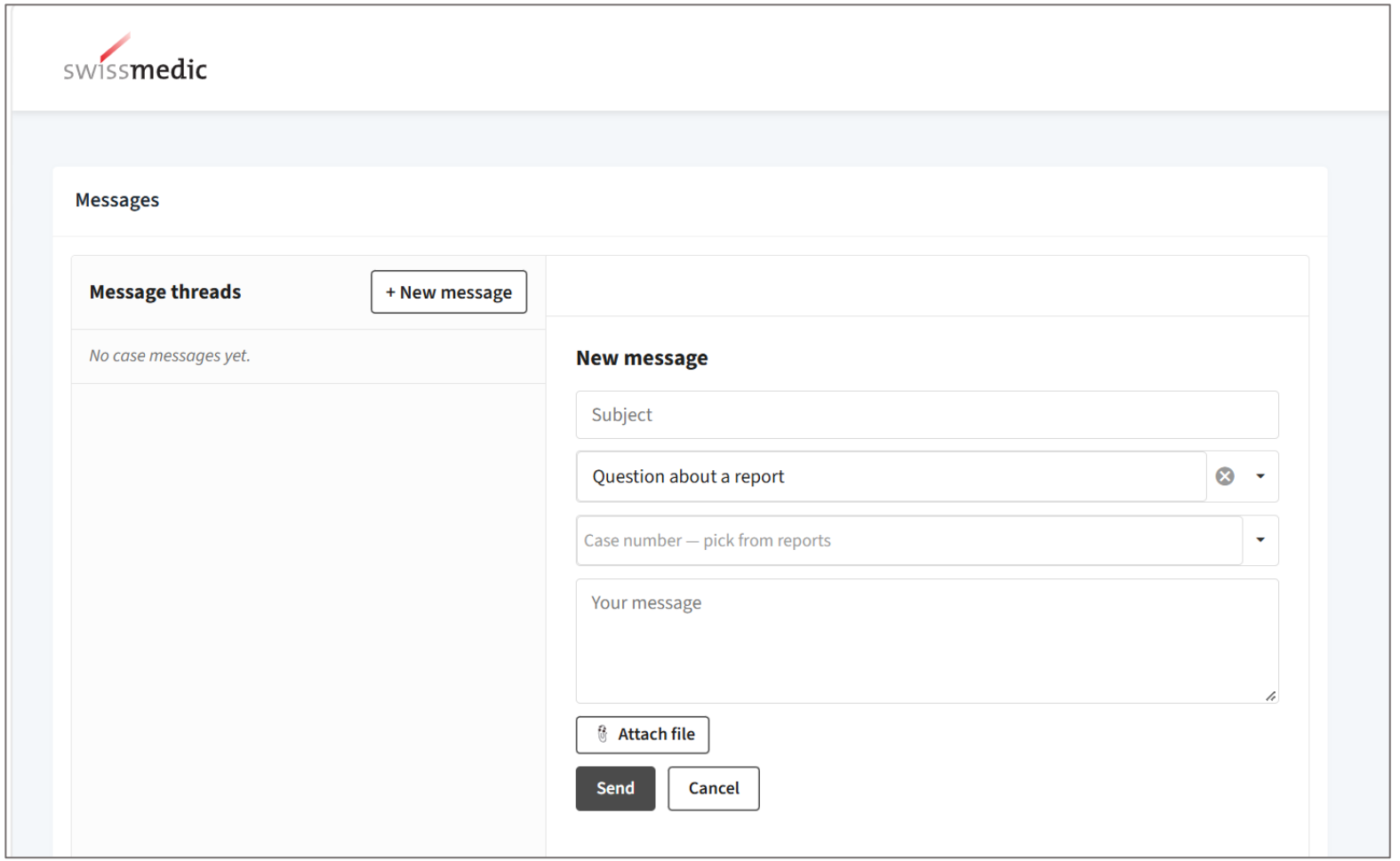
swissmedic

EIViS 2.0 MAH: *Example of patient characteristics*



swissmedic

ElViS 2.0: *Message function*



Next steps

- Online training on two dates in the first half of December
- Uploading of files in E2B R2.1 format will remain possible initially. Files are upgraded to R3 through post-processing and validation before being sent to the Swissmedic database.
- A guidance document on using EIViS will be published on the Swissmedic website in December.
- Updated terms of use will be available and must be signed within 6 months. It will be possible to use EIViS 2.0 before signing.
- Go-live on 21 December 2026.
- You can see a live demo and ask questions at the Safety of Medicines stand.