



AI / ML initiatives that were developed and are applied at Swissmedic

November 23, 2023

Michael Renaudin

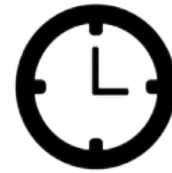
Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern, Schweiz
www.swissmedic.ch

SWISSmedic 4.0



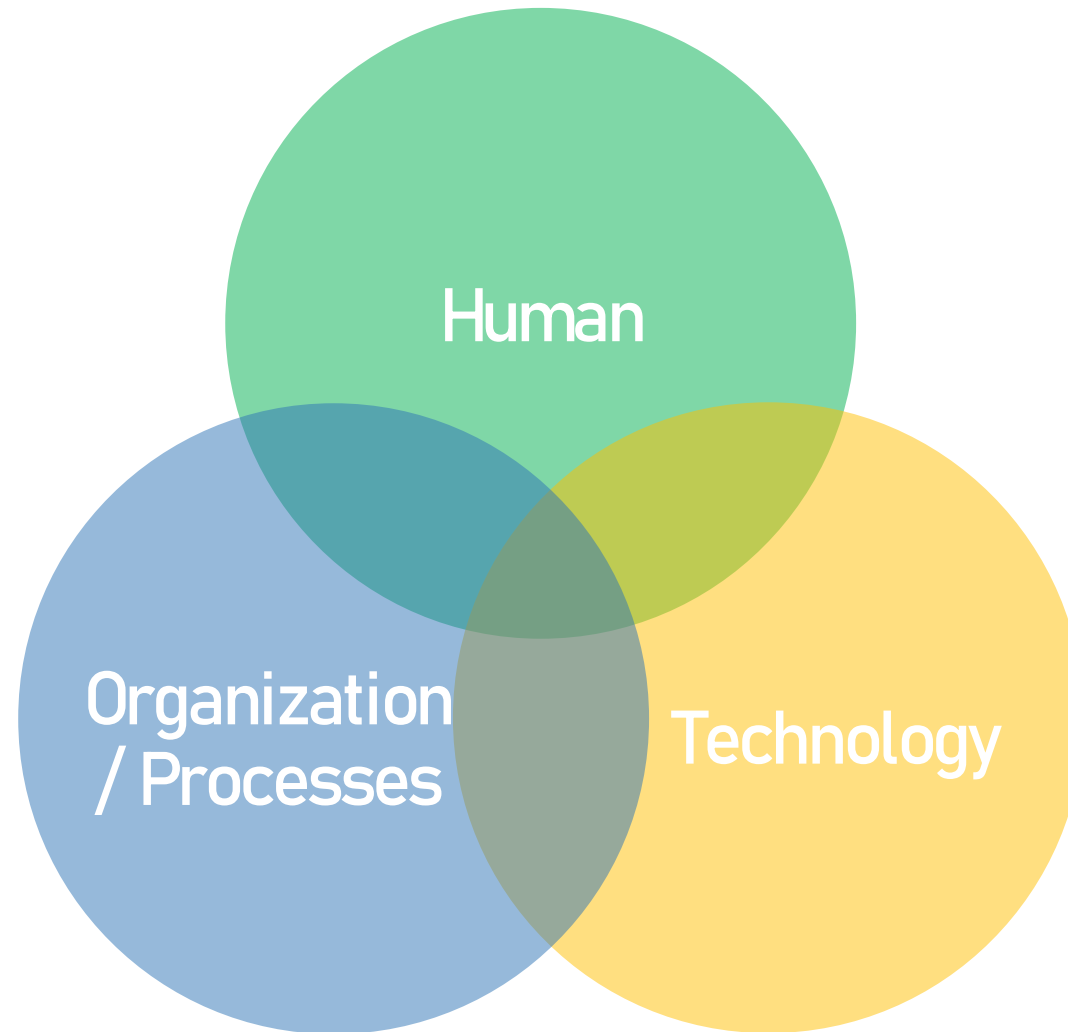
7



2020 - 2025

Swissmedic 4.0 is an innovation lab, an experimental field for change and innovation. The aim of the initiative is to promote interdisciplinary work and to design new digital business models. Unhindered by bureaucratic structures and processes, technological innovations and new forms of organisation and collaboration are to be evaluated.

Three dimensions



Current AI / ML Initiatives at Swissmedic 4.0

AI used

AI potential

/MEDI CRAWL

Crawl and classify illegal medicinal products from Swiss online marketplaces

	Authorization	Licensing	Market Surveillance	Legal
/MEDI CRAWL			AI used	
/LiSA	AI used	AI used	AI potential	
/TRICIA			AI used	
/AskYourDocuments	AI potential	AI potential	AI potential	AI potential

/LiSA

Detect safety signals in unstructured text and classify their seriousness

/TRICIA

Risk-based classification of incoming incident reports

/AskYourDocuments

Asking questions to your documents (in collaboration with LLM Taskforce)

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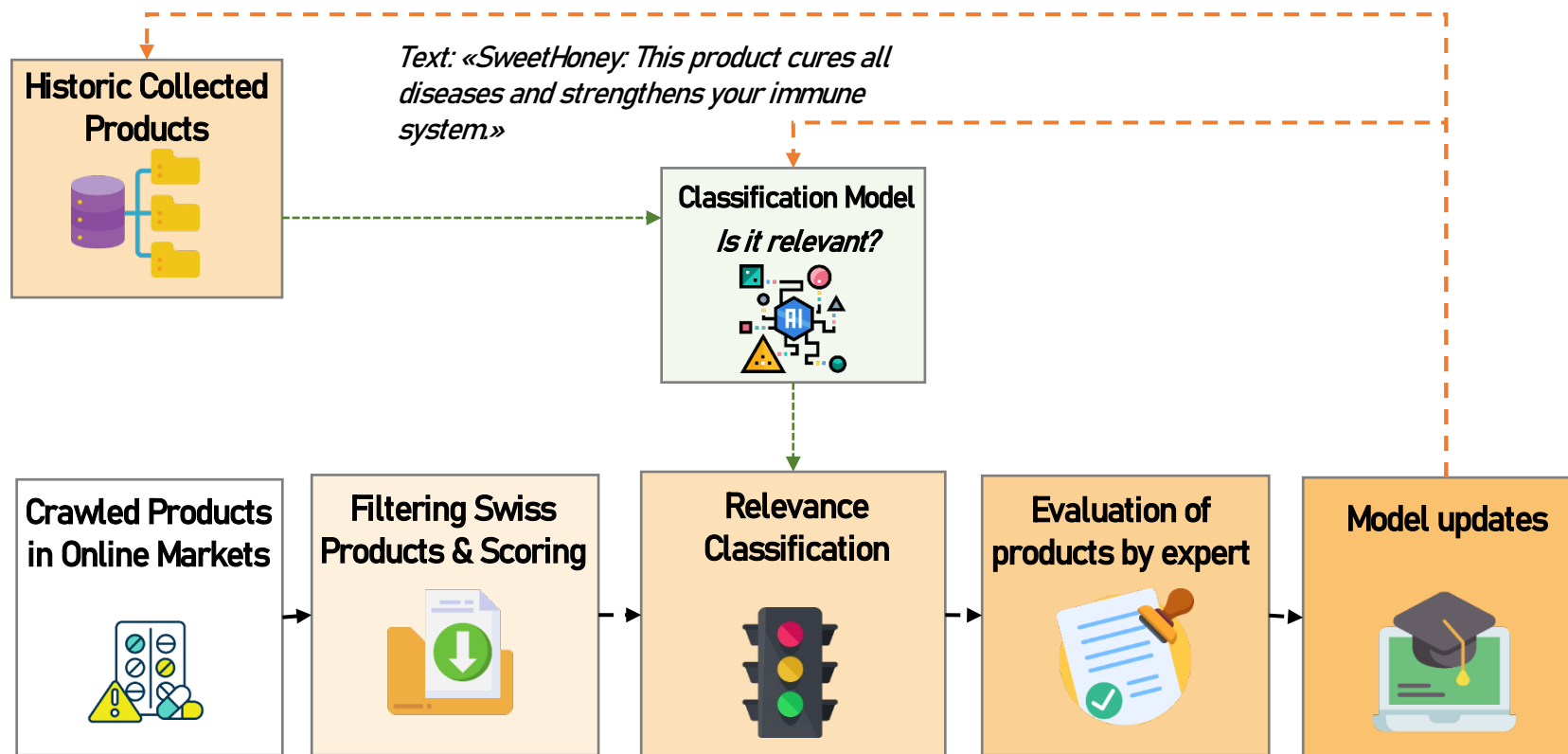
Risk-based classification of incoming incident reports

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/MEDI CRAWL

An application that crawls e-commerce websites, looking for illegal products according to swiss regulation





Avastin e Lucentis "sono identici"

I farmaci per il trattamento della maculopatia retinica Avastin e Lucentis dal punto di vista della sicurezza sono identici. È la conclusione a cui è giunto uno studio di revisione della letteratura scientifica condotto da un organismo indipendente e non profit su richiesta della Regione Emilia-Romagna.

Source: [rsi.ch](#)



Bookmark

In Progress

Not Relevant

Never Relevant



Sensilab SlimJOY FatBurn EXTREME

Beschreibung Dieser fruchtige Mango-Drink überzeugt mit 5 rein natürlichen Inhaltsstoffen. Yerba Mate, **Guarana**, L-Carnitin, Papaya-Extrakt und Vitamin B3 erzielen ein angenehmes Körpergefühl und können eine schöne Figur unterstützen. In den Sachets auch sehr praktisch für unterwegs. Verzehrempfehlung: Das Pulver in 250 ml Wasser a...

Source: [vitaleba.ch](#)



Bookmark

In Progress

Not Relevant

Never Relevant



Xenical Kaps 120 mg 84 Stk Kaps 120 mg Blist 84 Stk

Swissmedic-genehmigte Patienteninformation Xenical, Kapseln CPS Cito **Pharma Services GmbH** Was ist Xenical und wann wird es angewendet? Was sollte dazu beachtet werden? Wann darf Xenical nicht eingenommen werden? Wann ist bei der Einnahme von Xenical Vorsicht geboten? Darf Xenical während einer **Schwangerschaft** oder in der **Stillzeit** ein...

Source: [sunstore.ch](#)



Bookmark

In Progress

Not Relevant

Never Relevant

Sort by:

Highest Relevance

Filter

Search



Action for all results

Bookmark

In Progress

Not Relevant

Never Relevant

PDF-Export

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Literature Search Application for Safety Signals Monitoring

Why we started



Dependence on sponsor documents

Time-consuming search for relevant literature



No passive monitoring of safety signals

Limited knowledge sharing



Automatic Search

- AI-based search for learned concepts (e.g. diseases)
- Integration of various literature sources (e.g. PubMed, EMA- and FDA websites)

Relevant Results

- AI-based relevance determination of safety signals (seriousness and relevance).
- Feedback / «learning»

UX & Knowledge-Mgtm.

- History of all past searches
- Comments
- Further processing of the results in Excel / PDF

Welcome back, Alexander

Define new query

Enter a product name, active substance or indication

Your queries (18)

6 new / 0 serious

ABROCITINIB LLMs test
3021 hits / 85 serious
done
13 Oct 2023

FENQUIZONE LLM Test
0 hits / 0 serious
done
13 Oct 2023

IBRUTINIB / RITUXIMAB
75841 hits / 3315 serious
done
22 Sep 2023

4 queries per page

Previous



Back

SEBELIPASE AL...

SEBELIPASE ALFA

Filters

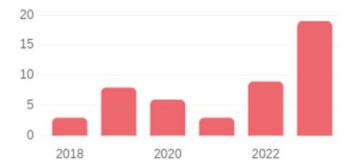
- Show marked for Report only
- Show only serious outcomes

LiSA-relevance

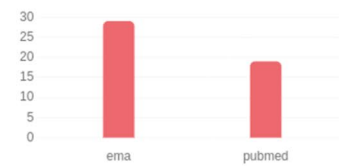


Publication Date

Publication Year



Article Source



Reset all filters

679 Signals

adverse events

48 Articles

Search

Newest first

Select all

EMA: minutes prac meeting 11 14 january 2021 en

H1: Scope: Fifth interim report for study ALX-LALD-501: a non-interventional, multicentre, prospective disease and clinical outcome registry of patients with lysosomal acid lipase deficiency (LAL-D) to further understand the disease, its progression and any associated complication, and to evaluate the long-term efficacy and safety of sebelipase alfa) 17.5.10.

- Not relevant
- Somehow relevant
- Relevant
- Critically relevant

EMA
N/A (publication date) • 10 AUG 2023 (date found)

EMA: minutes prac meeting 7 10 february 2022 en

H1: Scope: Sixth interim report for study ALX-LALD-501: a non-interventional, multicentre, prospective disease and clinical outcome registry of patients with lysosomal acid lipase deficiency (LAL-D) to further understand the disease, its progression and any associated complication, and to evaluate the long-term efficacy and safety of Kanuma (sebelipase alfa) 17.5.8.

EMA
N/A (publication date) • 10 AUG 2023 (date found)

EMA: minutes prac meeting 6 9 july 2020 en

H1: Pharmacovigilance Risk Assessment Committee (PRAC) EMA/PRAC/672654/2020 Page 68/96 analysis of already submitted studies (namely study LAL-CL04: an open label multicentre extension study to evaluate the long-term safety, tolerability, and efficacy of sebelipase alfa (SBC-102) in adult subjects with liver dysfunction due to lysosomal acid lipase deficiency (LAL-D) who previously received treatment in study LAL-CL01; study LAL-CL03: an open label, multicentre, dose escalation study to evaluate the safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of SBC-102 in children with growth failure due to LAL-D; study LAL-CL06: a multicentre, open-label study of sebelipase alfa in patients with LAL-D; study LAL-CL08: a phase 2, open label, multicentre study to evaluate the safety, tolerability, efficacy, and pharmacokinetics of sebelipase alfa in infants with rapidly progressive LAL-D; study LAL-CL02: a multicentre, randomized, placebo-controlled study of SBC-102 in patients with LAL-D) and updated population pharmacokinetic (PK) analyses in children and adults.

EMA
N/A (publication date) • 10 AUG 2023 (date found)

EMA: minutes prac meeting 30 september 03 october 2019 en

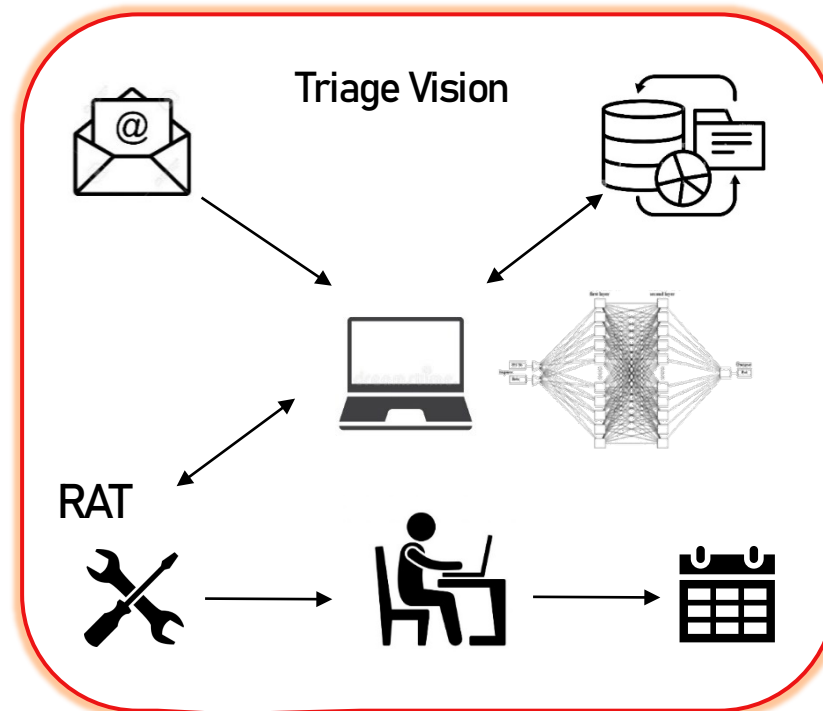
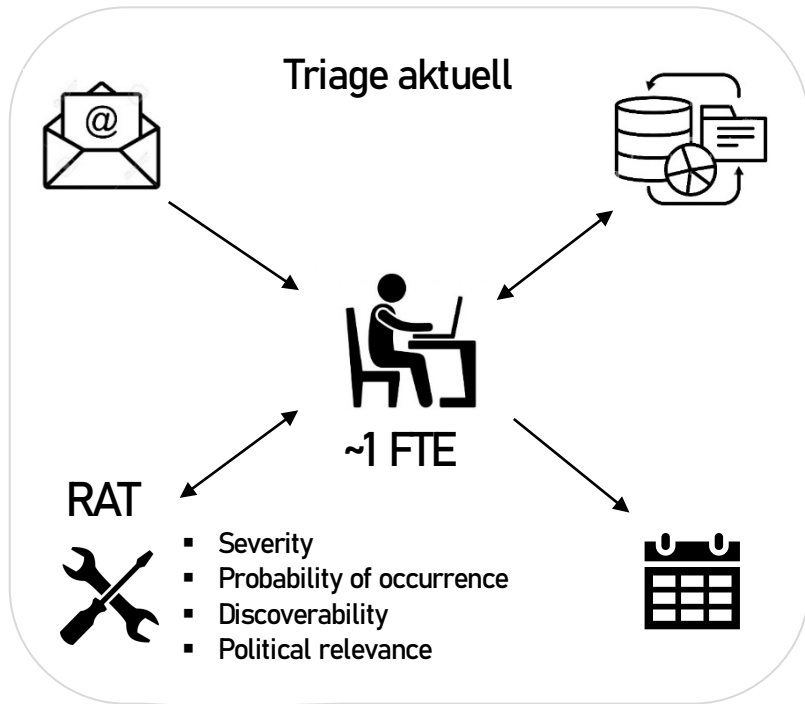
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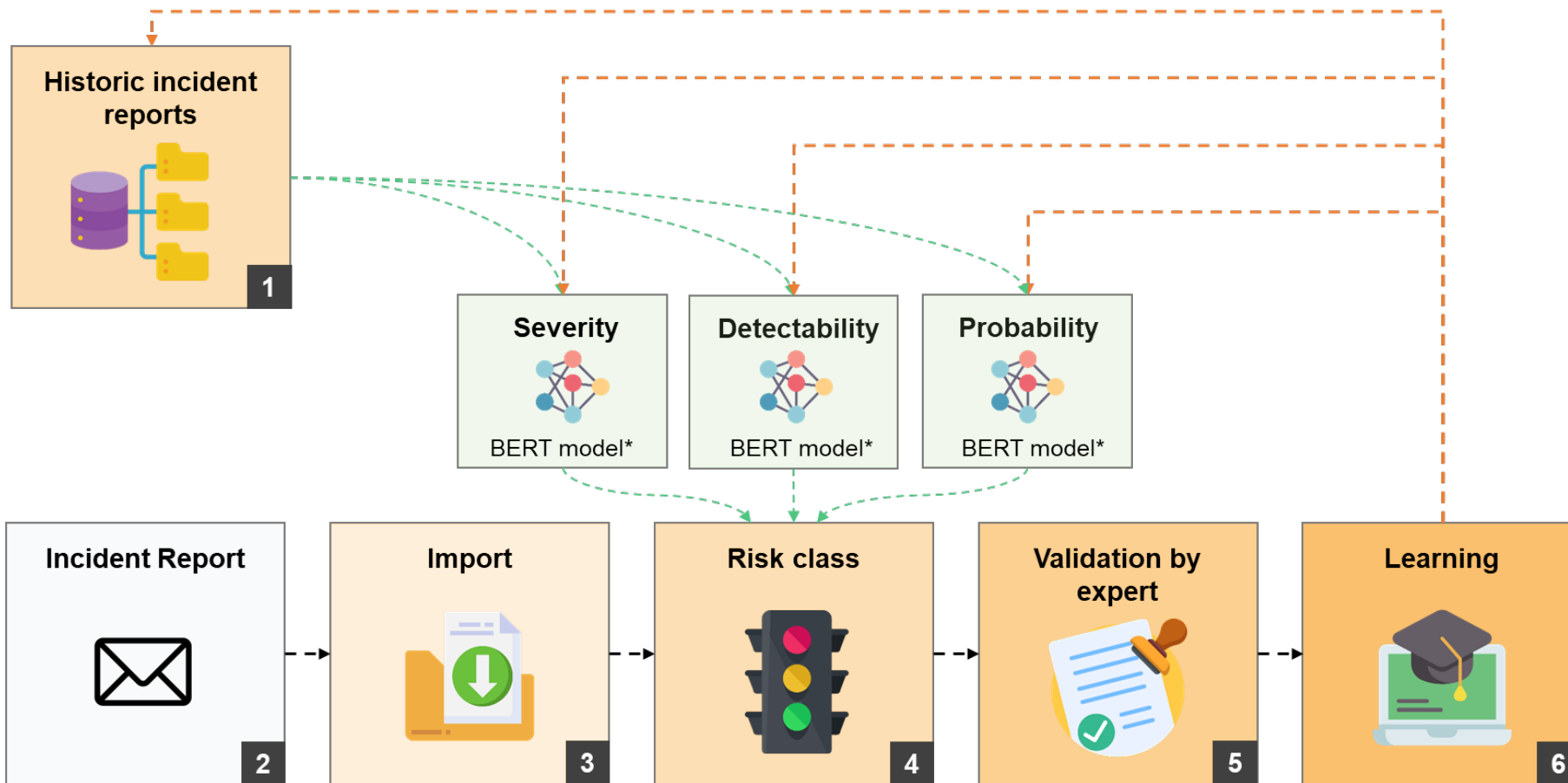
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Your documents +

SwissPAR_Alhemol.pdf



Uploaded Documents



Hi, start by either uploading some documents on the left or start by typing your first question below...

what are the most frequent ADRs for treatment with alhemol based on the underlying data?



Query



The following ADRs are based on data from clinical trial NN7415-4311 (phase 3), in which a total of 114 male patients with haemophilia A with inhibitors (71 patients) and haemophilia B with inhibitors (4 patients) received at least one dose of concizumab as routine prophylaxis.



List of adverse reactions

The following ADRs are based on data from clinical trial NN7415-4311 (phase 3), in which a total of 114 male patients with haemophilia A with inhibitors (71 patients) and haemophilia B with inhibitors (43 patients) received at least one dose of concizumab as routine prophylaxis. 78 of the clinical trial participants were adults and 36 were adolescents (≥ 12 to < 18 years). The patients were exposed for a total of 102.5 exposure years.

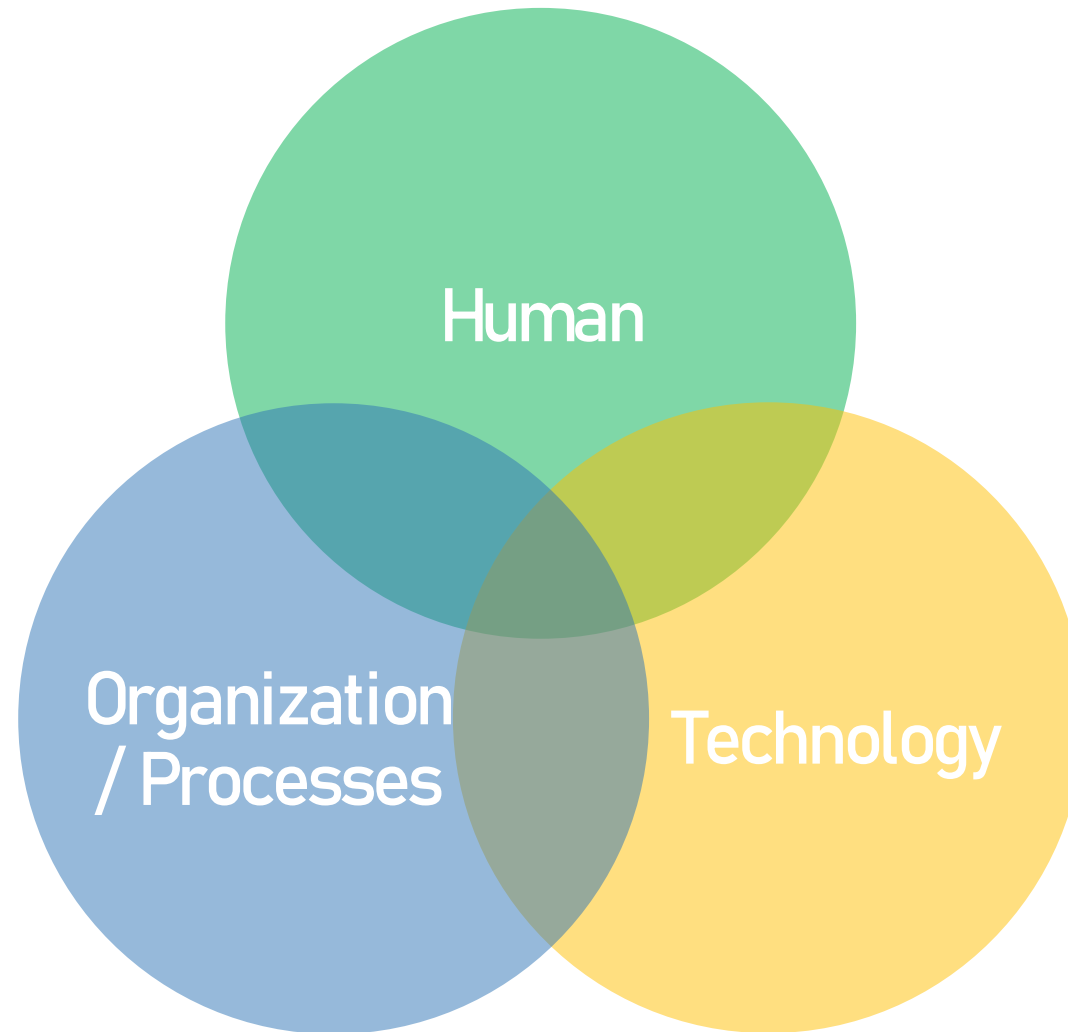
Fourteen patients treated with Alhemo® experienced 18 serious adverse events, including one hypersensitivity reaction (0.9%) and one thromboembolic event (0.9%), both led to permanent discontinuation of Alhemo®.

Type a question for your

Copyright

Code available at <https://github.com/smc40/askyourdocs>

Three dimensions





Questions? Feedback? Remarks? Happy if you
reach out to us:

Michael Renaudin
4.0@swissmedic.ch