swissmedic 4.0

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

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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

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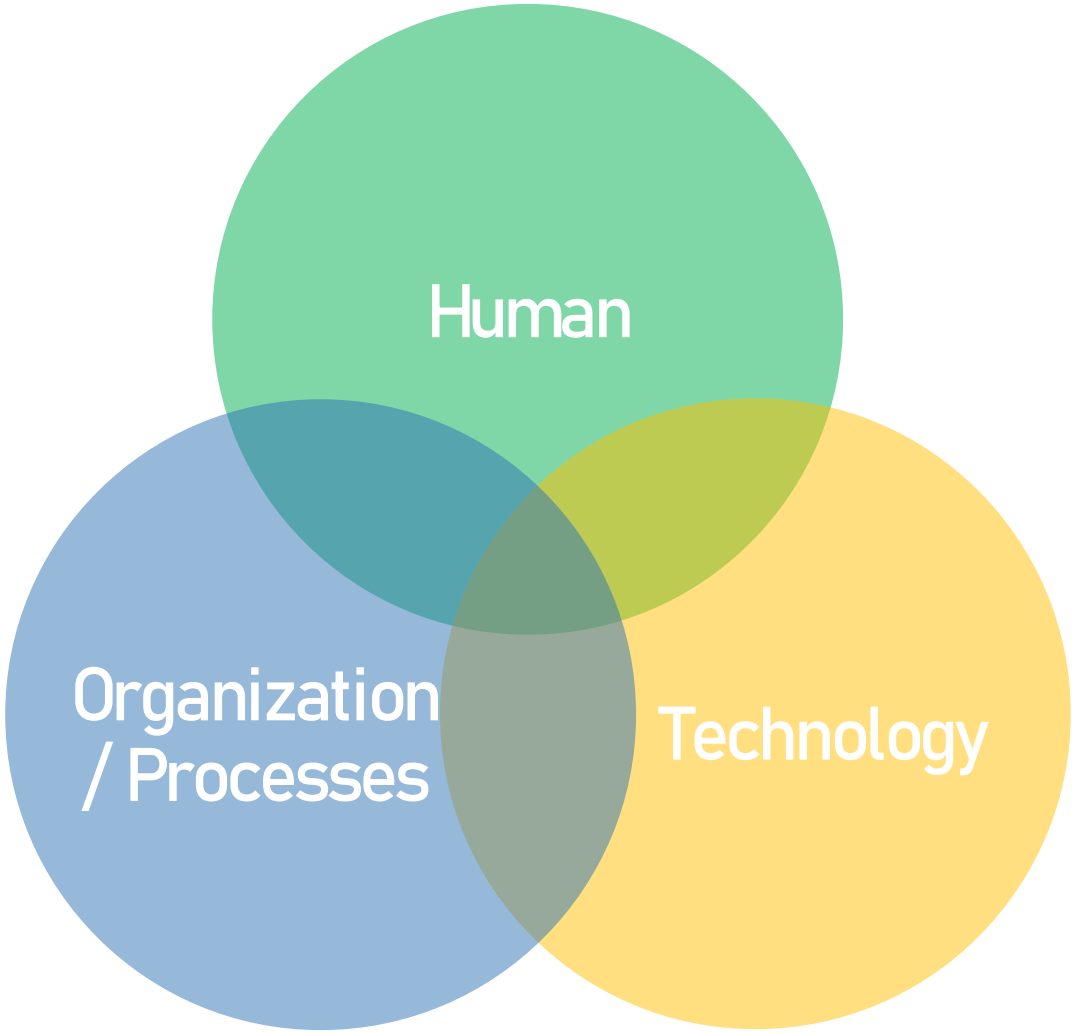
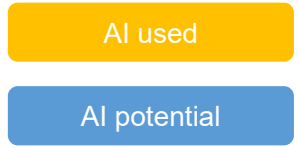
2020 - 2025

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



		Authorization	Licensing	Market Surveillance	Legal
/MEDI CRAWL	Crawl and classify illegal medicinal products from Swiss online marketplaces			AI used	
/LiSA	Detect safety signals in unstructured text and classify their seriousness	AI used	AI used	AI potential	
/TRICIA	Risk-based classification of incoming incident reports			AI used	
/AskYourDocuments	Asking questions to your documents (in collaboration with LLM Taskforce)	AI potential	AI potential	AI potential	AI potential

Current AI / ML Initiatives at Swissmedic 4.0

AI used

AI potential

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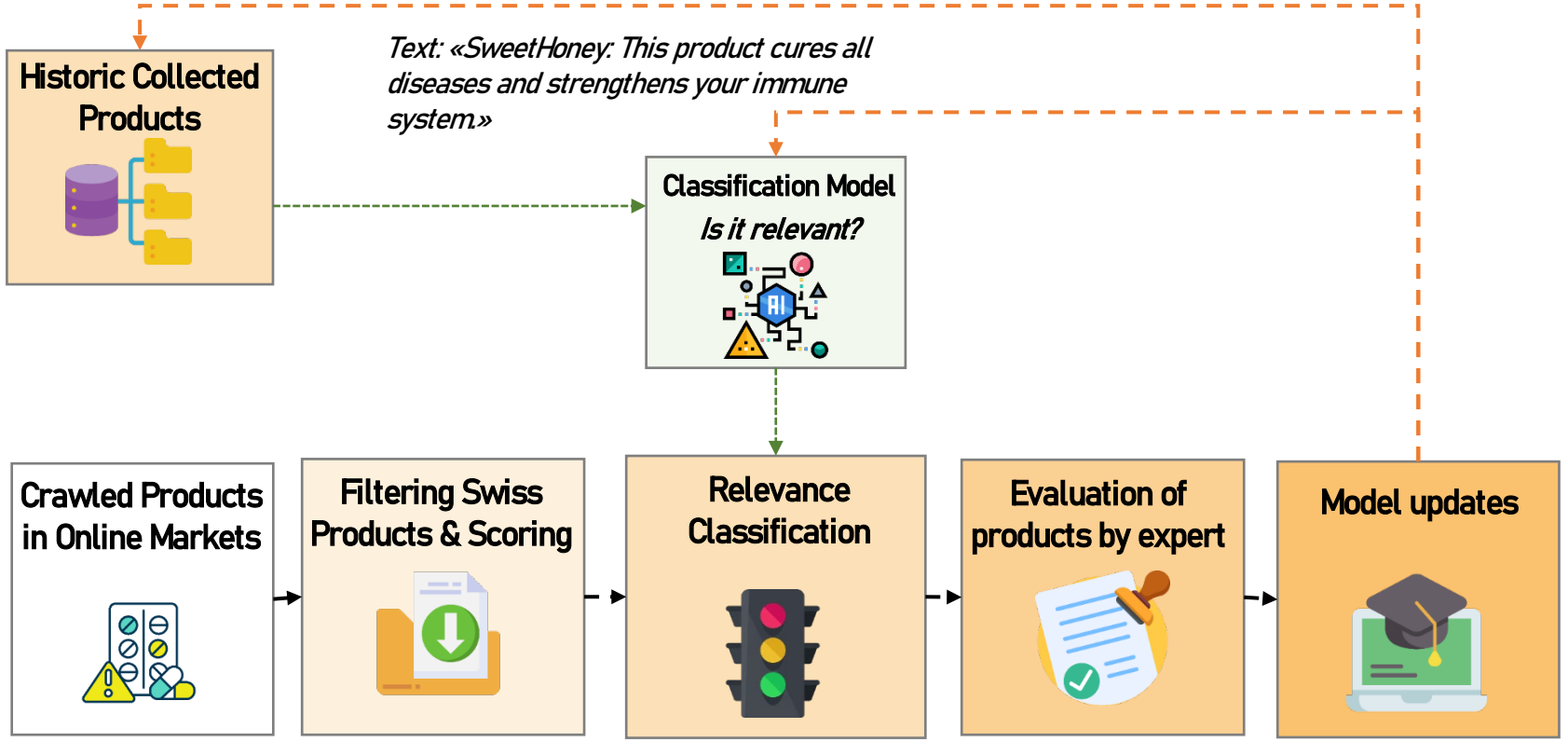
/MEDI CRAWL

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



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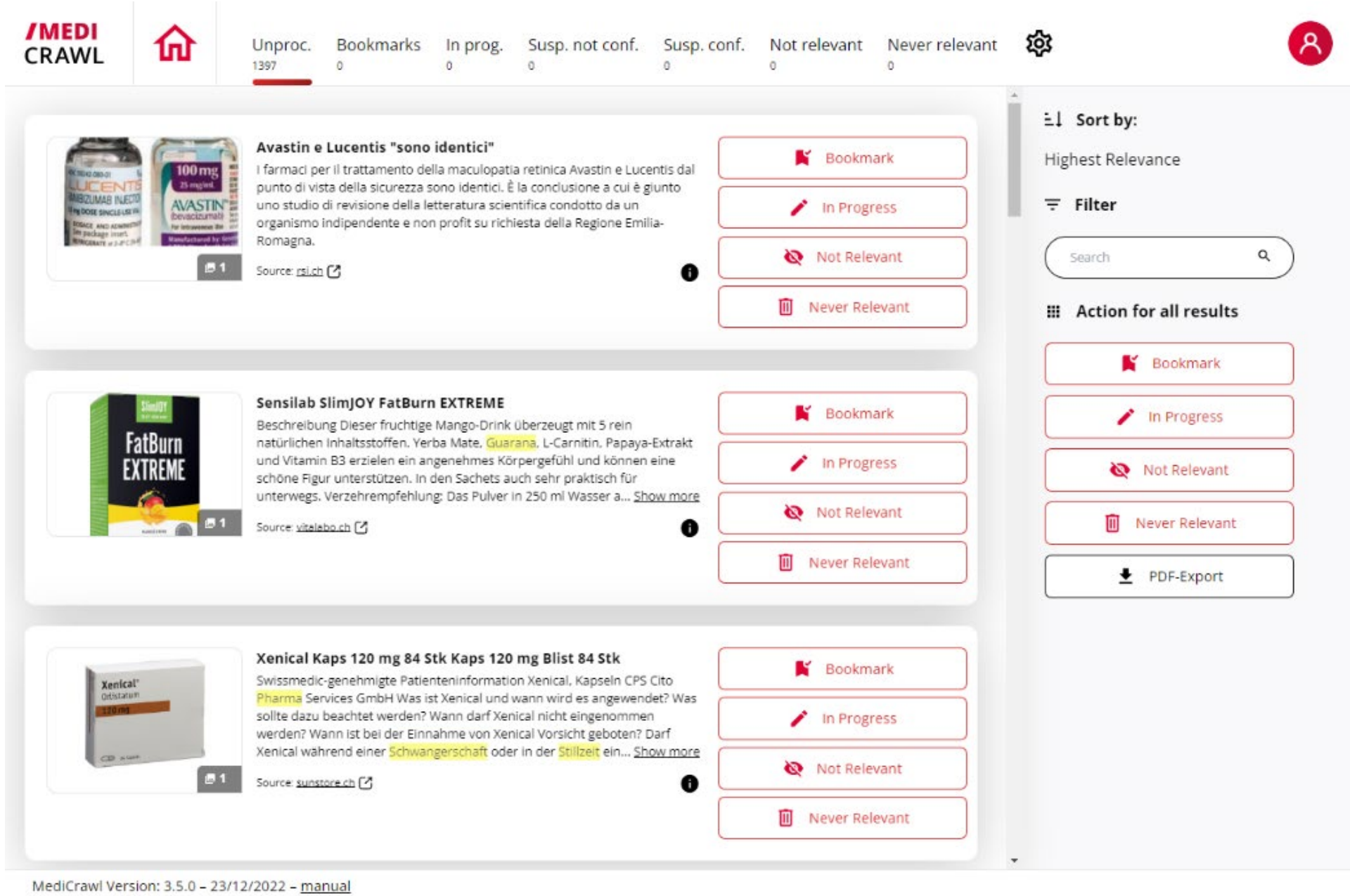
CRAWL



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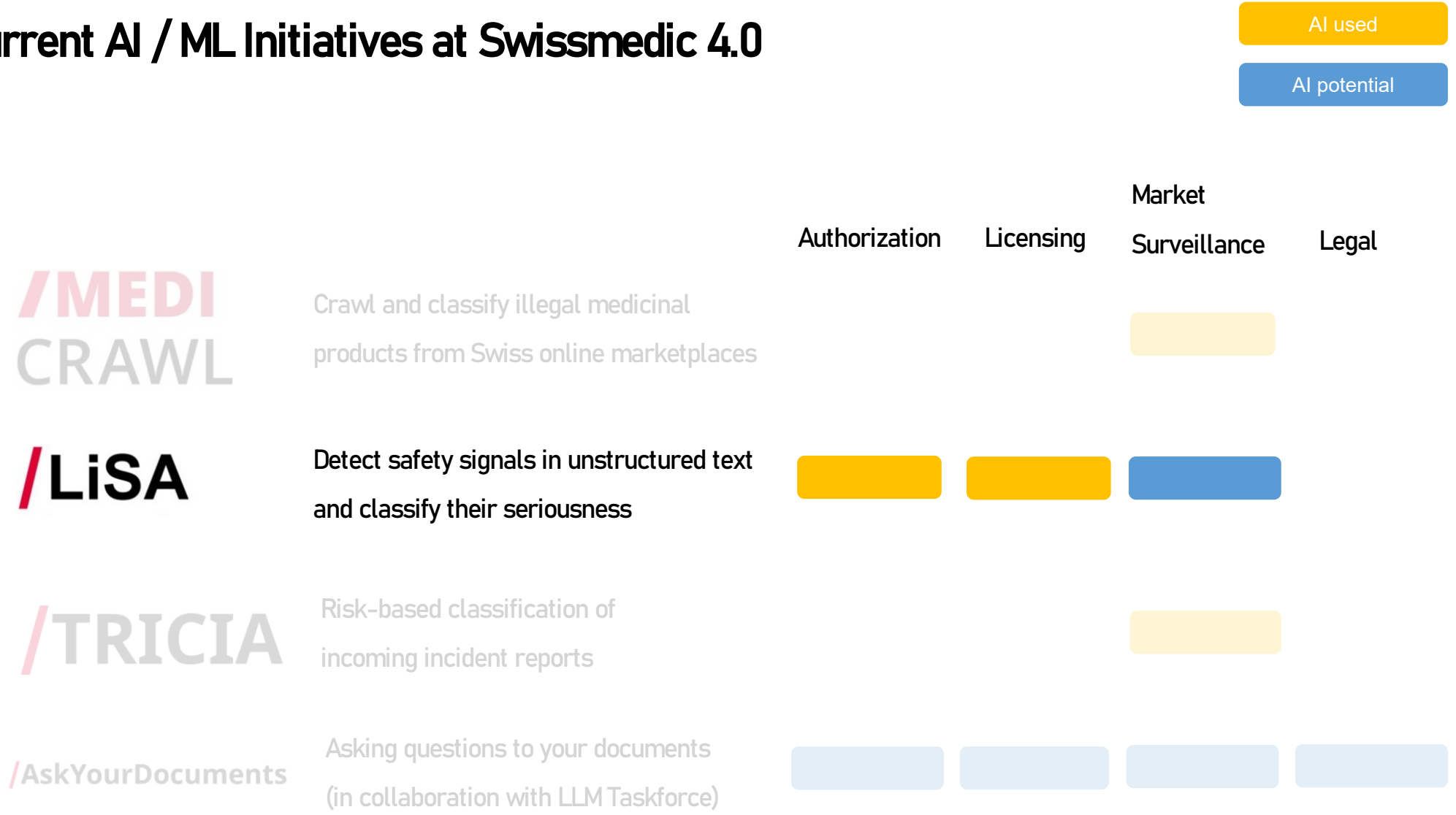


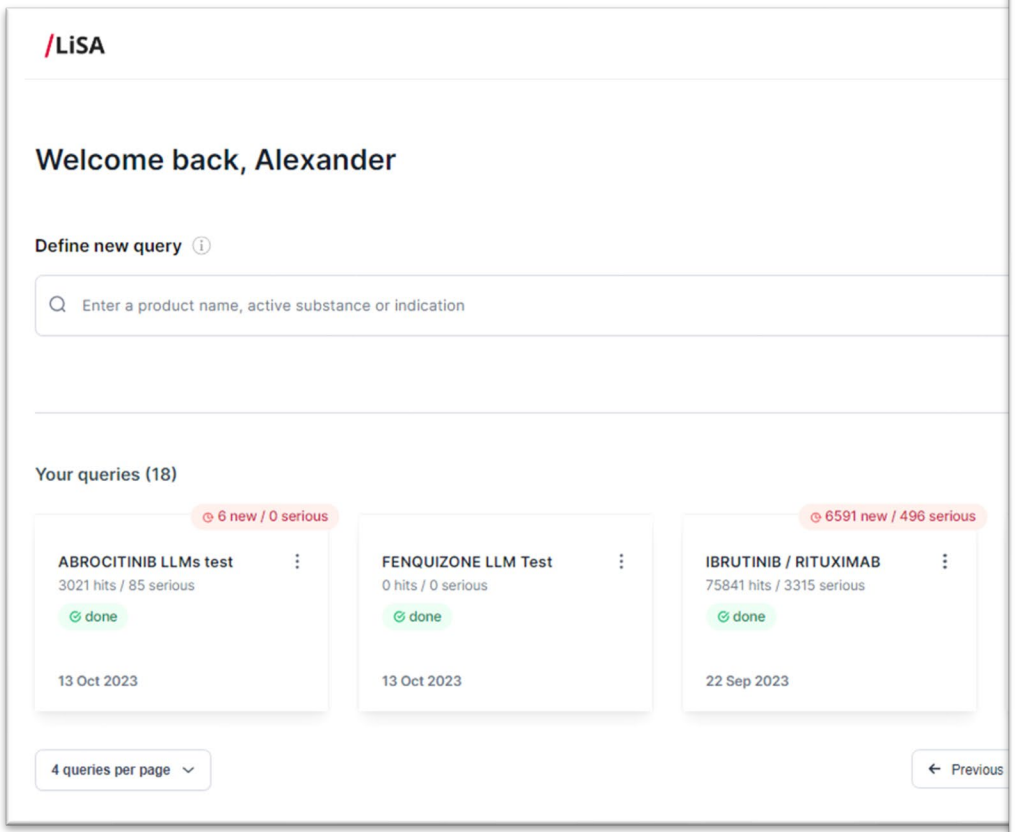
/LiSA

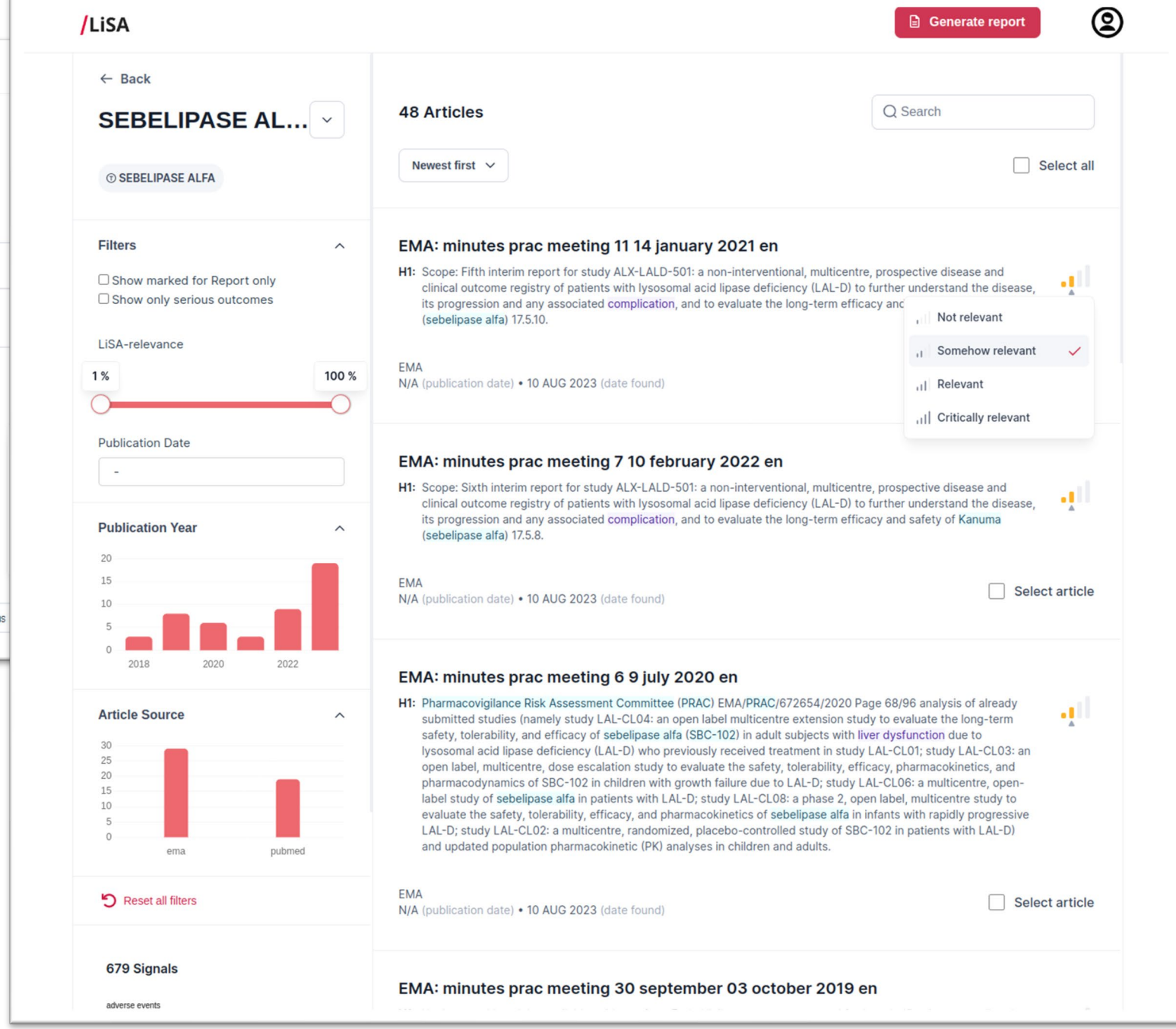
Literature Search Application for Safety Signals Monitoring

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





EMA
FDA
PubMed
Health Canada
swissmedic
TGA Health Safety Regulation
MHRA

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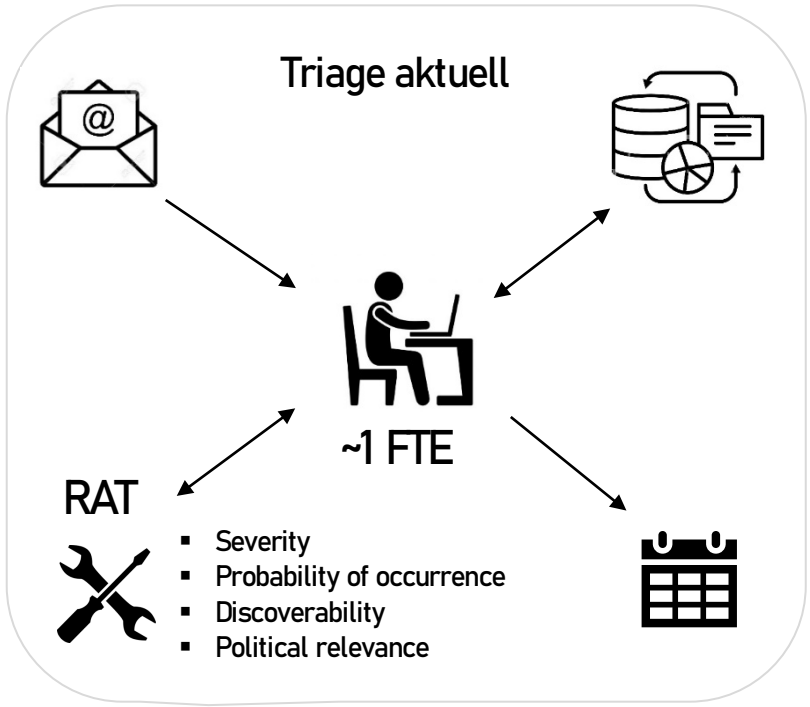

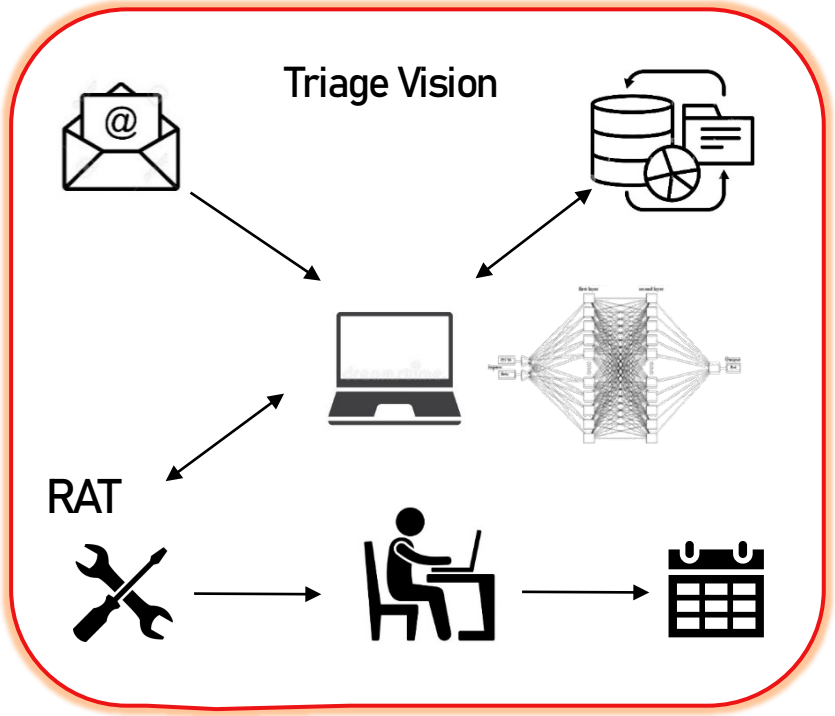

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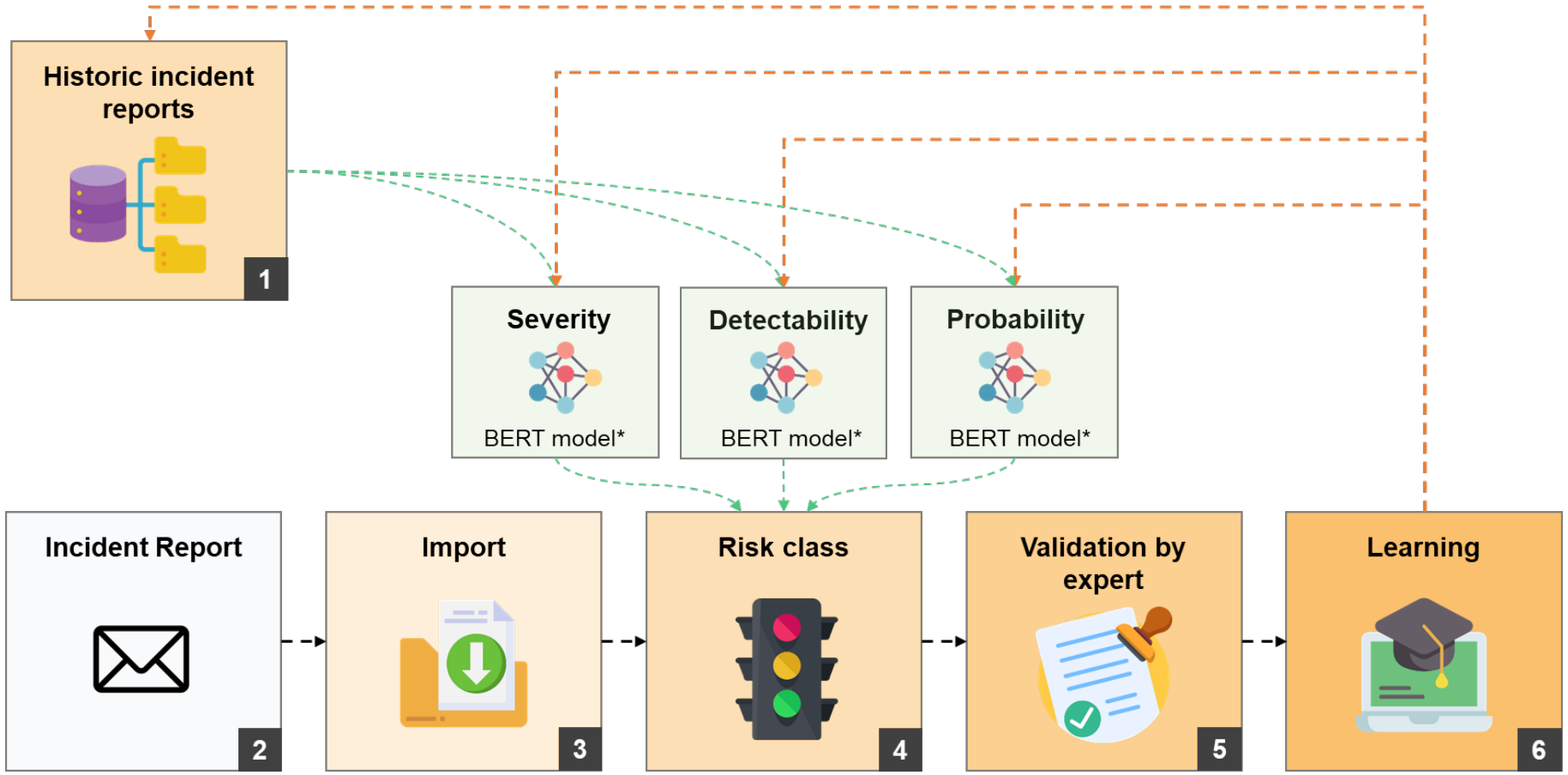

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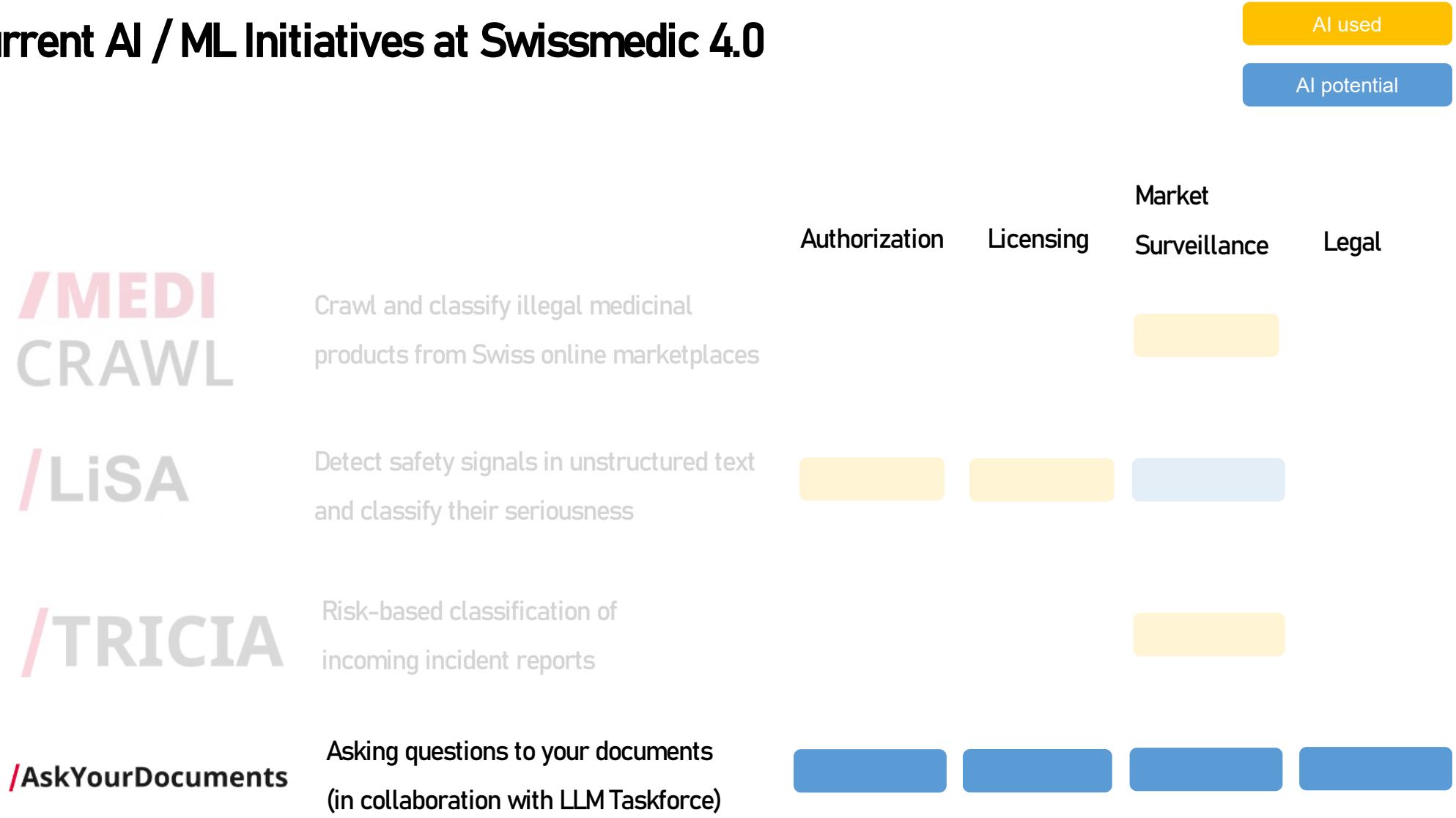


/AskYourDocuments

Your documents +

SwissPAR_Alhemol.pdf

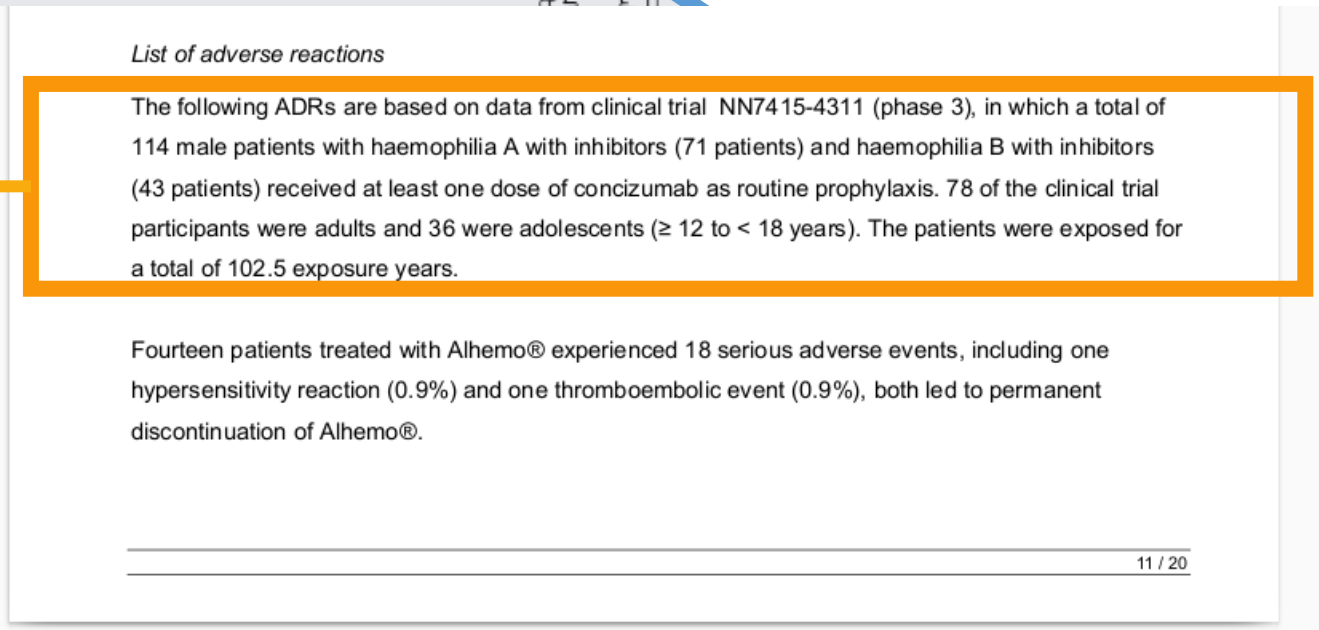
Uploaded Documents

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 haemophia 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®.

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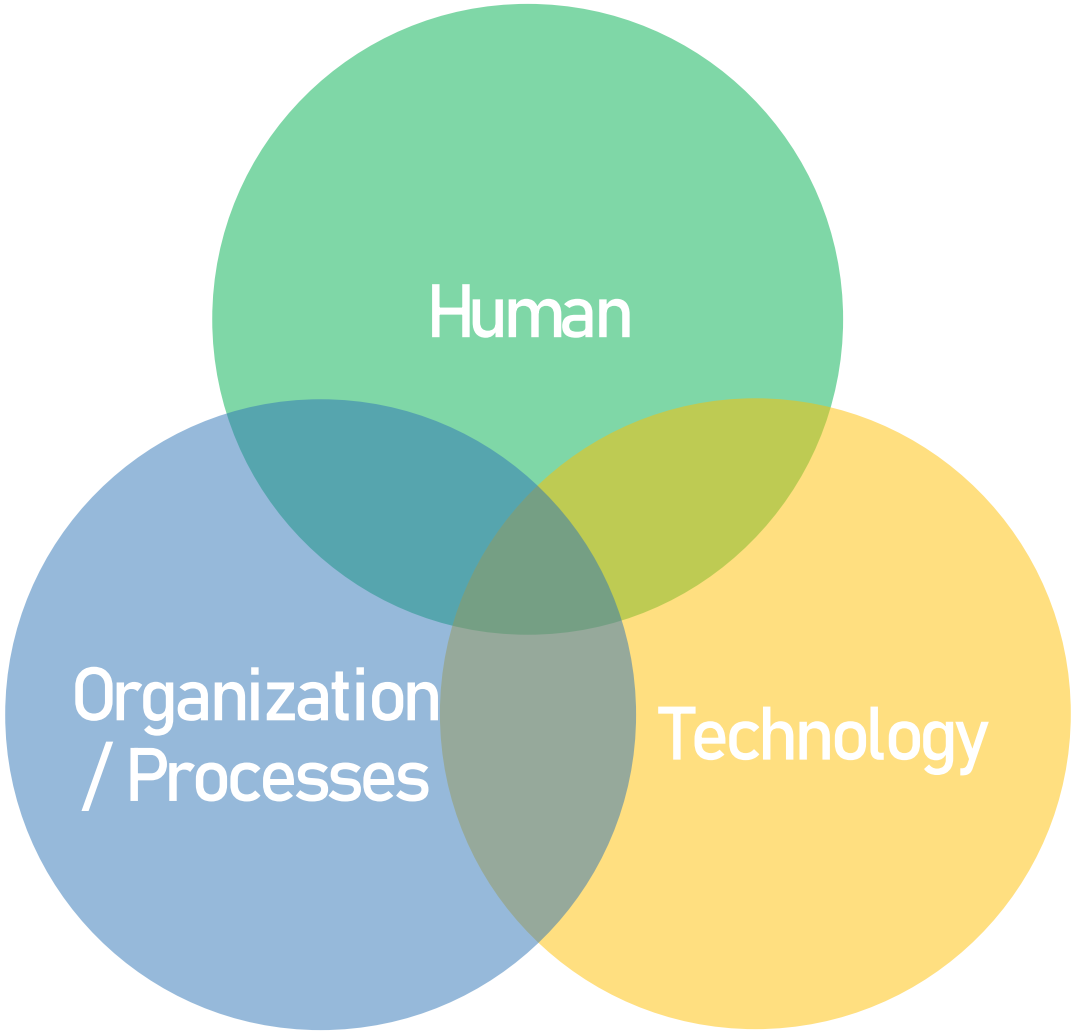
Type a question for your

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