IMDRF International Medical Device Regulators Forum

Leveraging digital technologies for smarter PMS, André Breisinger, Swissmedic

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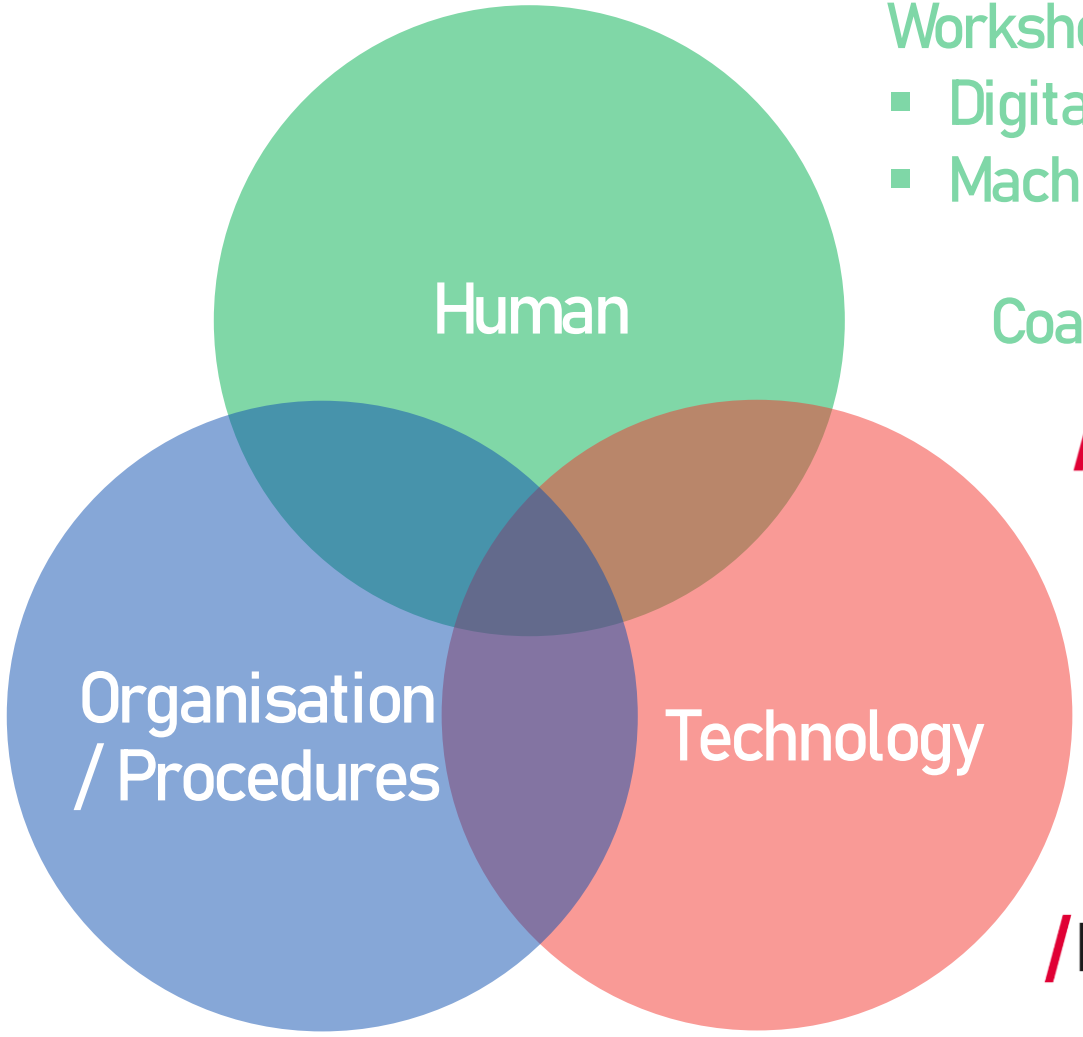
Three dimensions of our digital transformation initiative



Mindset

E-Learnings

Data Literacy

Collabathons

Agile/ Scrum

Workshops on
- Digital Transformation
- Machine Learning

Coaching

/AskYourDocuments

/ScARA

/TRICIA

/MEDI /FederatedTricia

CRAWL

/LiSA

swissmedic 4.0

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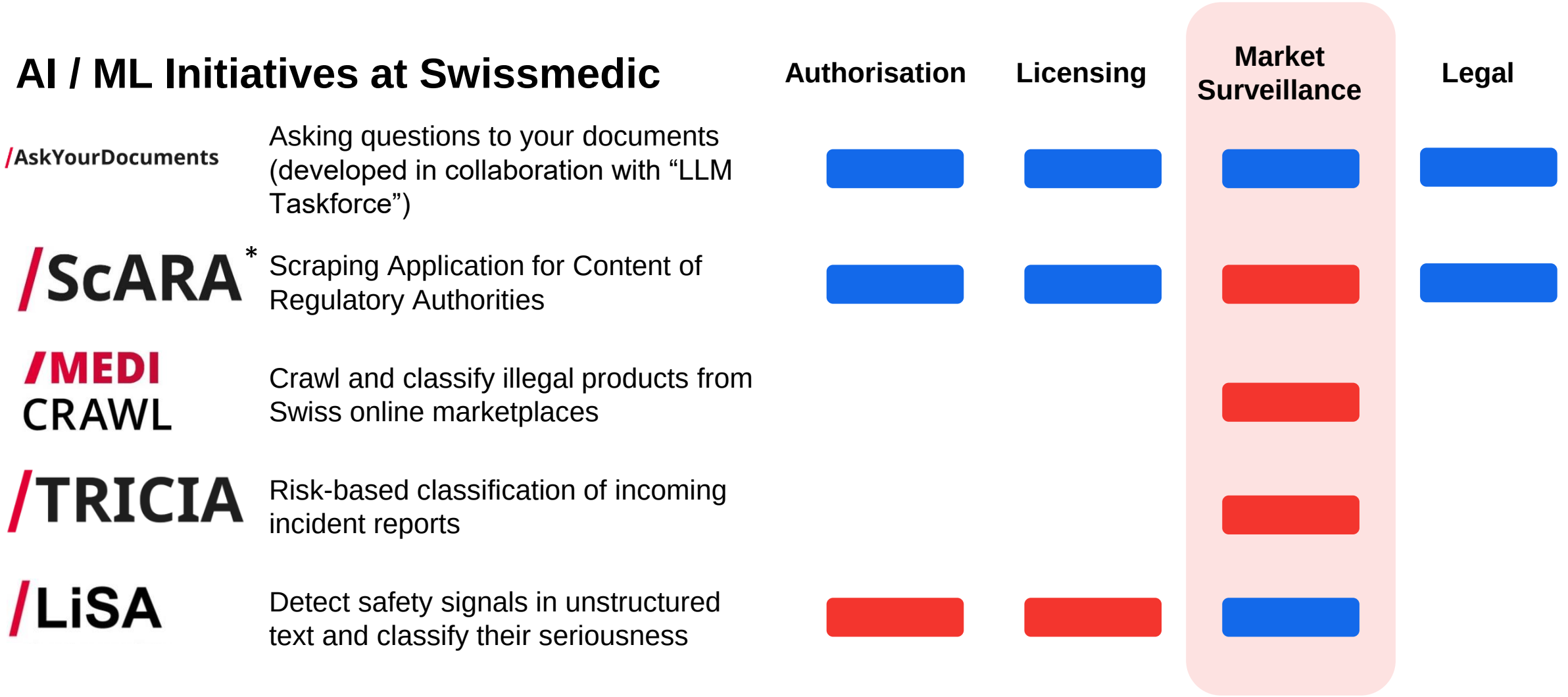
AI used

AI potential

AI / ML Initiatives at Swissmedic



* discontinued

Market surveillance search tools

Search tool	swissmedic 4.0	/ScARA	/MEDI CRAWL	
What?	Programmable search engine for keyword searches of interpretations/guidance on products	Search for manufacturers & products	Online offers	Regulatory News
Why?	Quick general search in MD sources	Streamline and standardise parts of the initial case assessment	Product offers, re-offered products	Continuous updates/monitoring depending on source selection
When?	retrospektive	retrospektive	Current day / future offerings	prospective (1-2 months retrospektive)
How?	Commercial service	Own development	Own development	Commercial service
Status?	Operational	discontinued	Operational	Operational

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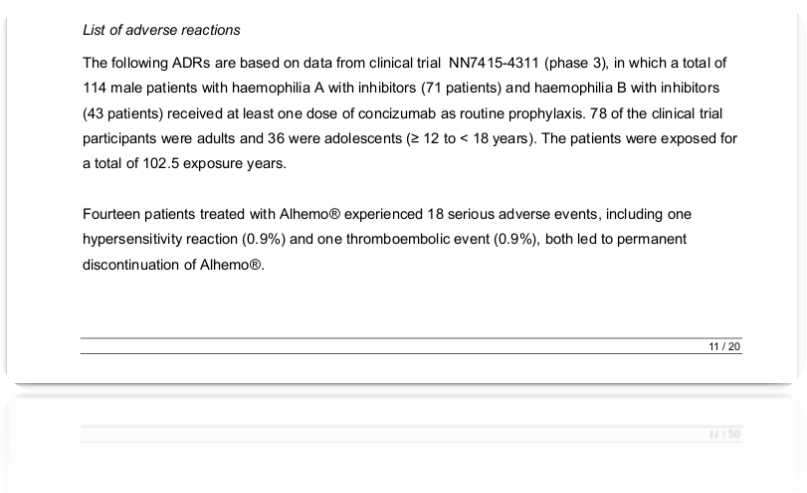
/AskYourDocuments An application that lets you ask questions to your documents.

Your documents +

SwissPAR_Alhemol.pdf

upload docs



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®.

11 / 20

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?

enter 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.

Response based on uploaded documents

Type a question for your documents...

/AskYourDocuments An application that lets you ask questions to your documents.

Impact and Learnings

Example of: How experts can be relieved by helping with document search and interpretation.

Shows: AI can provide tangible assistance when context, data protection and subject-matter expertise are ensured. AYD became a pilot for further applications in the regulatory environment.

Lesson: AI projects need proximity to domain experts and technical maturity - not pursued for their own sake.

/ScARA A one-click search tool that allows to search for manufacturers and their products across predefined sources to support initial case assessment and reporting.

Impact and Learnings

Example of: Conducting targeted, reproducible queries in predefined sources (e.g. commercial and regulatory registers, product databases, FSCA) and moving relevant hits into structured reports.

Shows: Inclusion of relevant hits into a consolidated report where sources and results are added on iteratively as searches continue (follow-ups, deeper lookups, adjusted filters).

Lesson: ScARA enabled one-click searches across multiple authority sites and databases, but maintaining reliable source integration was resource-intensive! The experiment was discontinued when the cost–benefit balance proved unfavorable.

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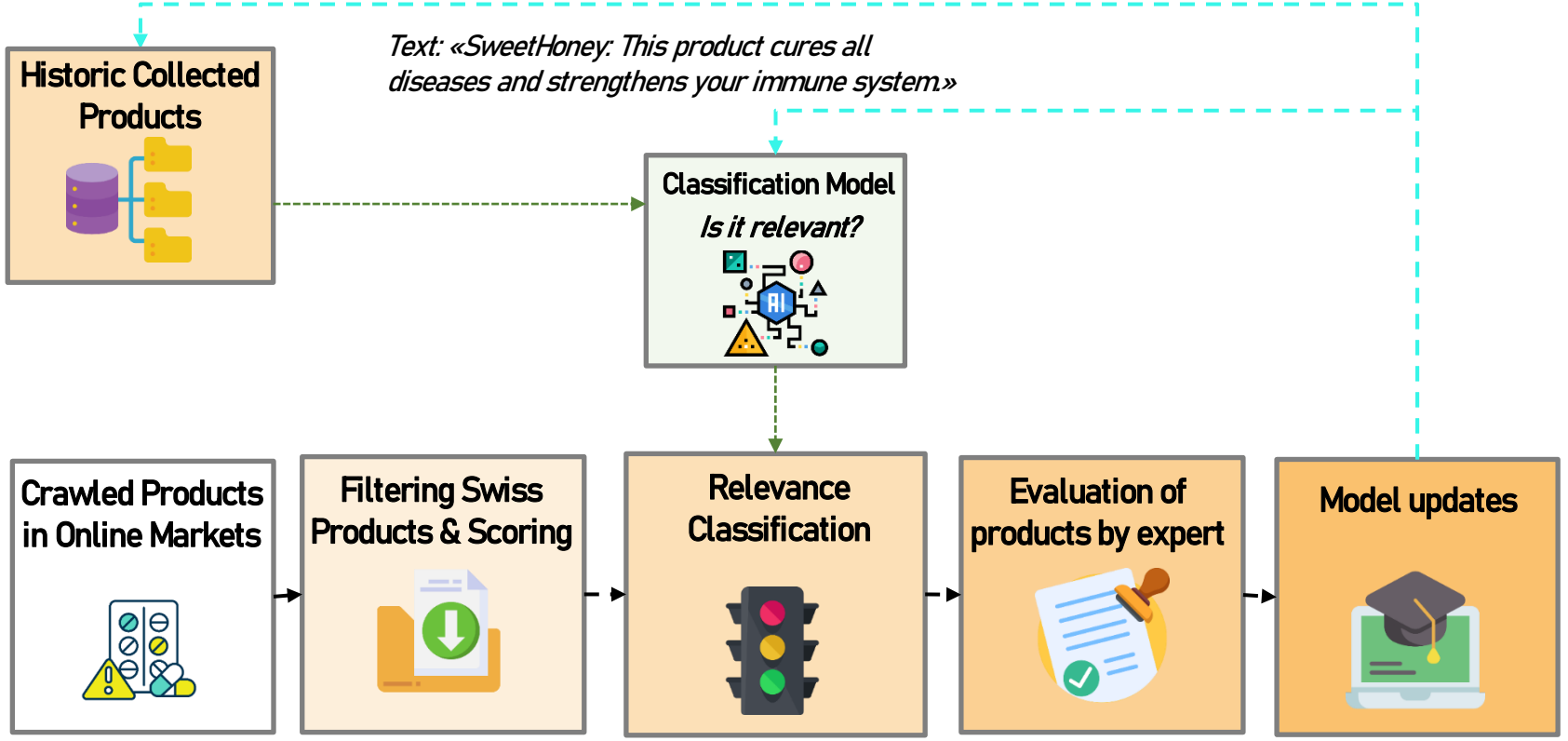
/MEDI CRAWL

An application that crawls e-commerce websites to find illegal products under Swiss law using keyword and image searches.



/MEDI CRAWL

An application that crawls e-commerce websites to find illegal products under Swiss law using keyword and image searches.

Impact and Learnings

Problem statement: Monitoring the market for illegal / counterfeit medical products has become increasingly challenging as a significant portion of the market has shifted online. Traditional methods of market surveillance are time-consuming and limited in scope.

Solution: A web crawler that automates the monitoring of online marketplaces for suspicious advertisements and illegal products. Keyword-based and image searches and filter results to identify and document relevant cases for risk assessment.

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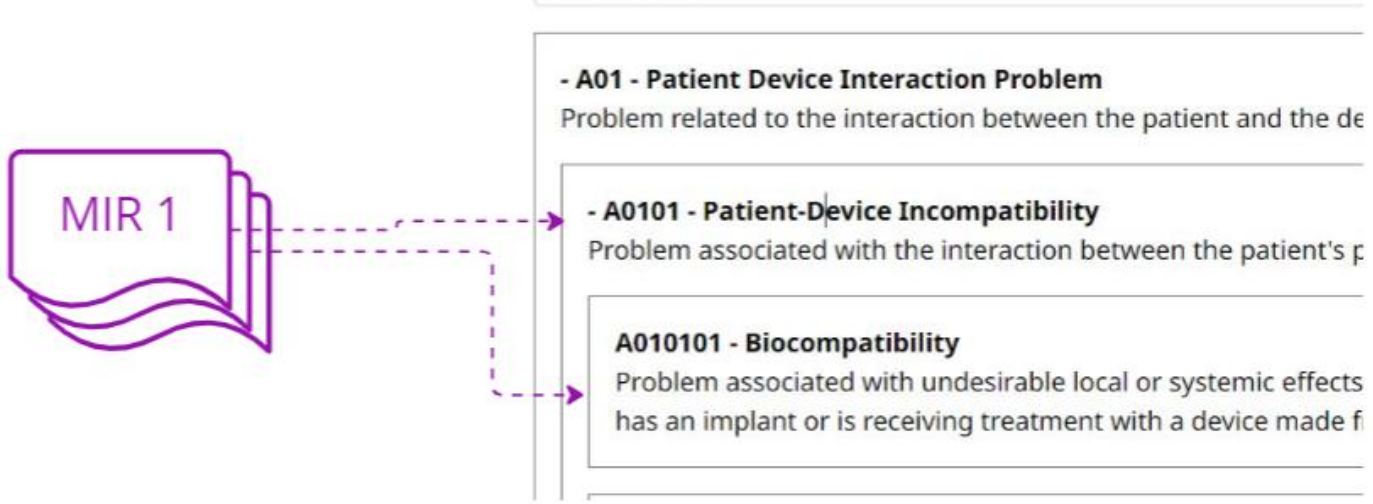
“Yuki” - Proof of concept (PoC): Post-coding IMDRF Adverse Event Terminology annex A / E codes) using AI

Use case: MD manufacturers self declare the IMDRF annex codes in their manufacturer incident report forms (MIR) and send them to Swissmedic.

Problem statement: We suspect that sometimes codes are assigned on varying hierarchies to mask trends affecting medical devices.



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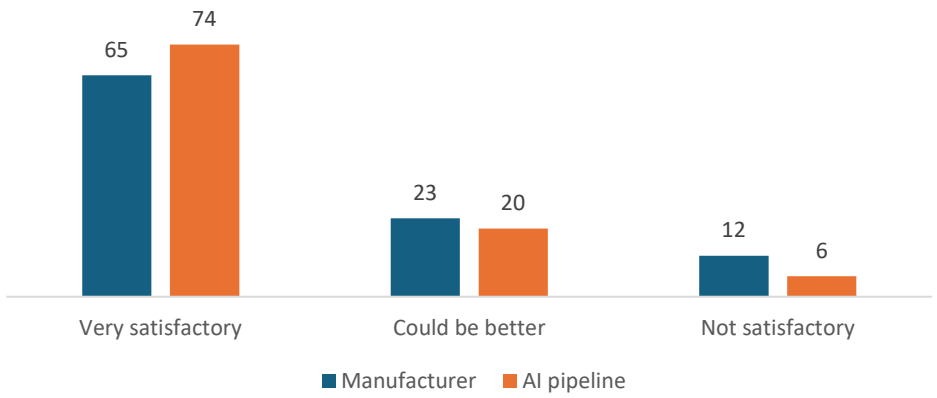
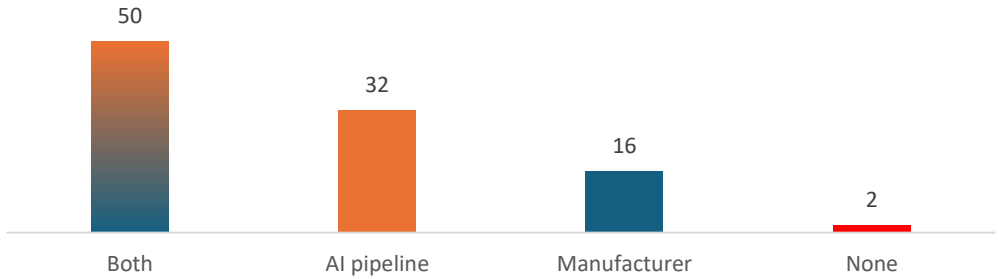
"Yuki" - PoC: Expert evaluation of manufacturer vs. AI pipeline codes: a comparative analysis of 100 cases[1]

Sample:[1] 50 examples of insulin pumps & accessories and 50 examples of Continuous Glucose Monitoring (CGM), with 25 cases each where the manufacturers and the AI pipeline agreed on the codes, and 25 cases where the codes differed.
Approach: Scientific officers assessed the manufacturers' codes alongside the AI-generated codes and compares the two sets.

Code accuracy and satisfaction level



Who produced more accurate codes?



Conclusion: Overall code accuracy was either very satisfactory or acceptable.
The AI pipeline (82 points) delivered more satisfactory codes than the manufacturers (66 points)

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“Yuki” - Enhancing the AI pipeline at various stages

Pre-processing

- **IMDRF codes update by experts:**The codes can be refined to group together those that are very similar or those whose level of precision is not necessary.
- **Clean problem descriptions:** Clean the data to retain only what is necessary for the models to establish the link with the IMDRF classification.

Top K selection

- **Adjust semantic similarity thresholds:** Currently only the rank is considered without looking at the similarity score. This step can be refined by introducing a threshold below which a code is not retained.
- **Explore alternative Top K aggregation methods:** Currently, we prioritize the codes obtained from other 'problem descriptions' and complete the list with codes from the IMDRF code repository, but other options are possible (e.g., taking only the closest problem descriptions)

Large Language

- **Benchmark other LLMs:** Benchmark larger, potentially more performant LLMs. (So far, small quantized LLM from Mistral has been used.
  Improve prompts with examples: Create a repository of relevant examples for each manually validated code/group of codes to enrich the prompts dynamically, by including examples that coincide with the top K.
- **Enable LLM to Indicate Prediction Uncertainty:** Enable the model to state “I cannot conclude” for expert review

Post-processing

- **Post-processing with business rules:** Apply business rules to capture all relevant signals. For instance, if the AI pipeline predicts code E2403 (No clinical signs, symptoms or conditions), always adopt the manufacturer’s code.

Top-K selection is the process of choosing the K items with the highest (or lowest) scores from a set.

“Yuki” – Vision of an interactive AI-powered tool for analyzing IMDRF codes alerts and trends

SOLUTION

- A decision support tool that allows for easy visualisation and export of detected alerts and trends directly embedded into Swissmedic’s vigilance database.
- Available at the level of AI pipeline predictions, as well as the manufacturers' data, and both for comparison purposes

This illustration is a fictional mockup intended solely to demonstrate the tool, but further UX work is needed to advance it.

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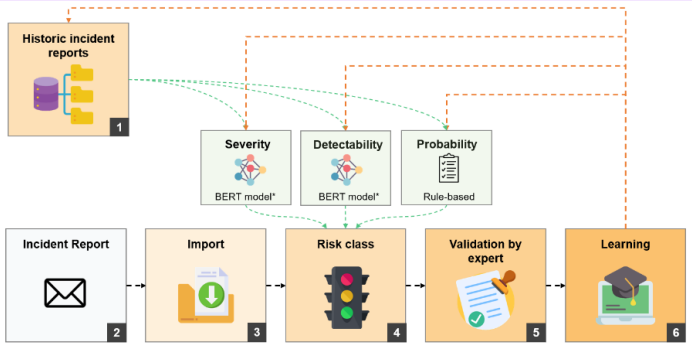
Where we want to go next…

/TRICIA

Risk-based classification of incoming incident reports



Build a **platform** that allows to collaboratively train models allowing to overcome challenges as data sparcity and overcoming the need to disclose any confidential data (=Federated Learning)

think big *(multiple usecases),*
start small *(TRICIA)*

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/FederatedTricia

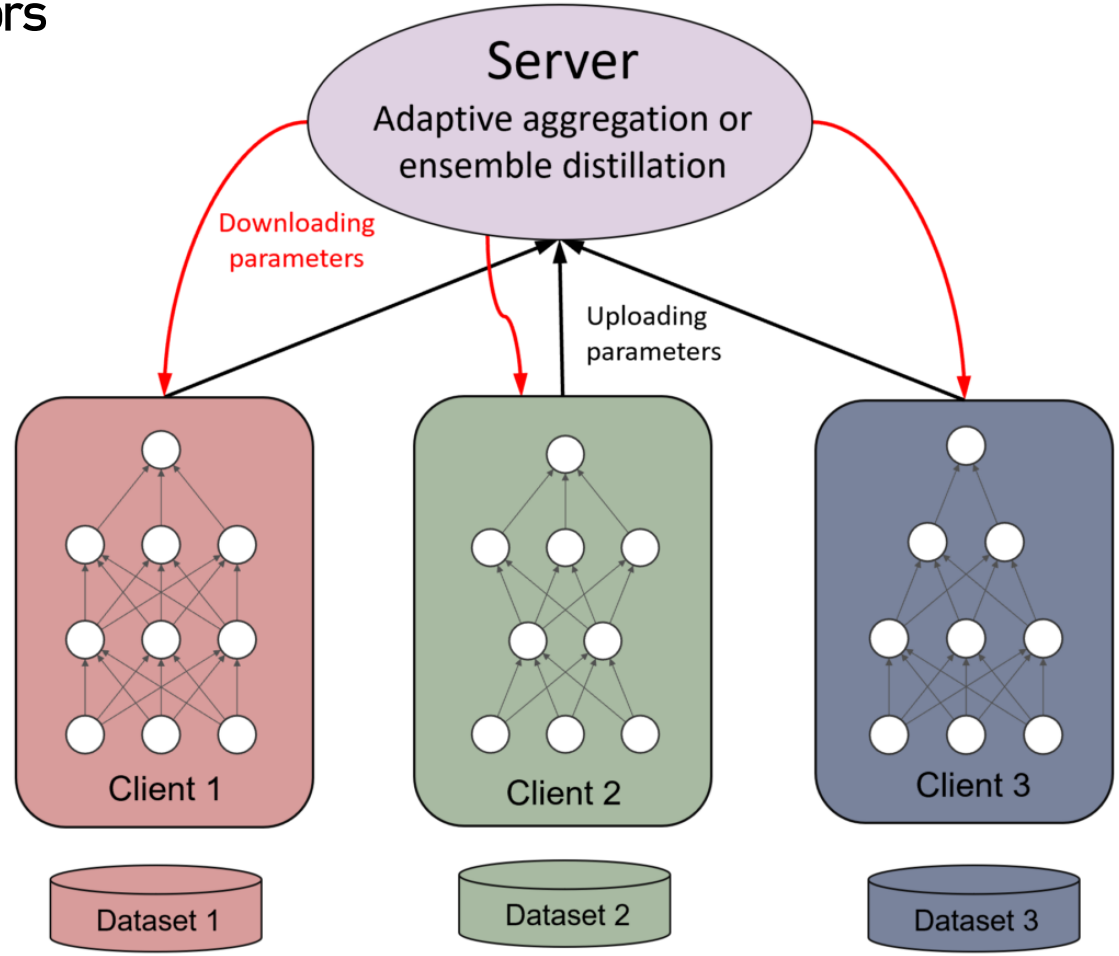
Joint model for risk assessment that can seamlessly be shared across regulators

Joint effort producing a scientific paper[1] on **federated learning**[2] for privacy-preserving, international AI risk assessment of MD incident reports, which can be seamlessly shared across regulators.

Collaborators: US FDA, DKMA and Swissmedic

The paper covers:

- **Federated learning** as a method to develop shared AI models without exchanging sensitive data
- Practical insights on governance, data protection and interoperability
- A TRICIA proof-of-concept showing LLMs can identify relevant risk signals in incident reports



Learn more: [1] Federated learning: a privacy-preserving approach to data-centric regulatory cooperation

[2] *Federated Learning: Protect your data and privacy* (20 December 2022).

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Thank you/Questions

Do you want to learn more about the AI tools used in Swiss administration?
Check out the CNAI - Competence Network for Artificial Intelligence

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