AI IN PHARMACOVIGILANCE - INDUSTRY PERSPECTIVE

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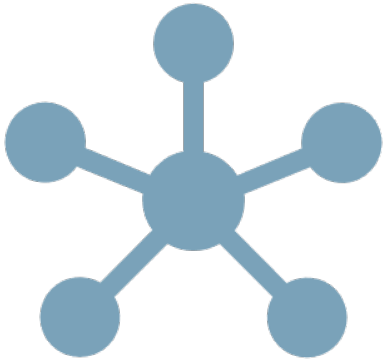
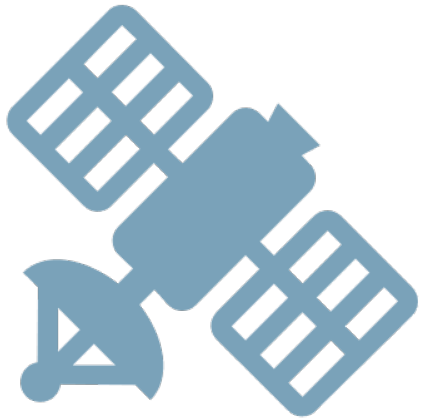
OPINIONS EXPRESSED ARE THOSE OF THE PRESENTER, NOT THE COMPANY OR ORGANISATION

DEVELOPED IN COLLABORATION WITH DR. ATTILA OLAH (M4E) AND DR. SVEN KOHLER (EFPIA)



Case Processing – efficiency, quality, compliance



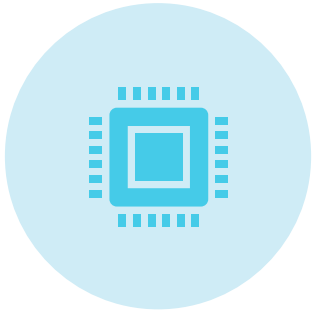
Steering of process – compliance, effectiveness, quality

Downstream processes – authoring, patient facing, prediction

AGENDA – DAY TO DAY APPLICATION AND GREATER POTENTIAL

AUTOMATION, AI, NEWEST TOPICS

Many automation topics can be adressed by rule based automation: specified, tested, validated, always producing what is wanted



AI in general is can be used for topics that cannot be adressed with rule based automation, e.g. free text analysis, unspecified actions based on previous data etc.

AI usage has downsides, e.g. and the biggest one, halluzination. AI does not have a fixed outcome and prompting techniques do not consistently produce the same outcome. Thus, it is not guaranteed that the requirements as written down are always fulfilled.

Agentic AI moves AI to a different level, introducing systems that are supposed to be ‚autonomous, providing insights, ‚thinking' and reasoning' – powerful and good when the right use case is there

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HOW TO INTRODUCE AI IN A VALIDATED SYSTEM FOR CASE PROCESSING – AN EXAMPLE IN USE AT BOEHRINGER INGELHEIM

- Use of GenAI for intake of information from forms, such as CIOMS or from partially structured mails – easy to read and check, but can be used for any unstructured info coming in
- On top and within a validated computer system, being described in the validation plan and integrated in release frameworks
- No self learning algorithms
- Two factor human oversight:
  - Transparency of which data are read via AI with ability to change the data if wrong
  - Monitoring of accuracy through reports about manual changes and thus performance of the model

- Oversight, control, improvement through human pattern recognition

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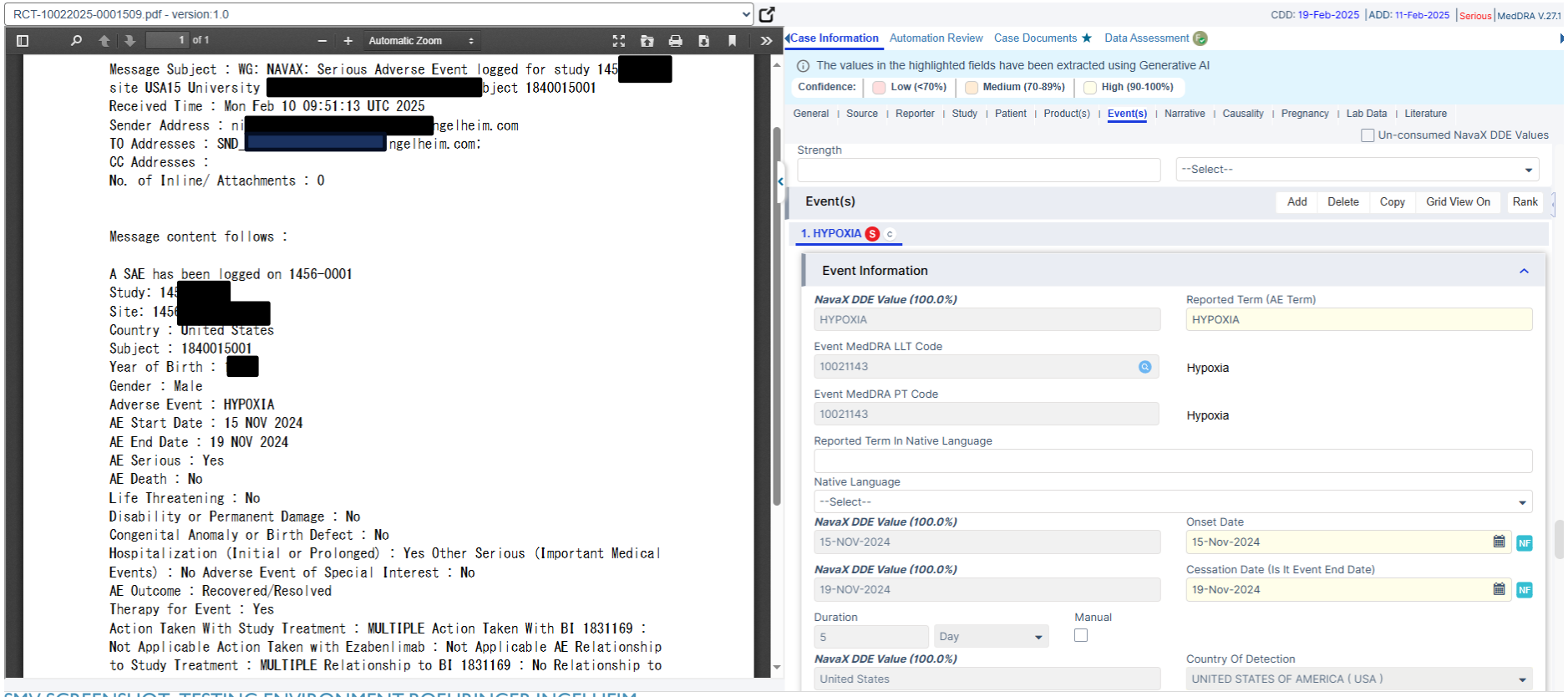
EXAMPLE

Source and screen view



NAVAX LSMV SCREENSHOT, TESTING ENVIRONMENT BOEHRINGER INGELHEIM

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ASSESSING EXTRACTION QUALITY – TEST CASE

Receipt No.	Sender Org	Field Name	Section	Extracted Data	Current Data	Data Changed?
RCT-26022025-0002229	BRAVE	Country of Detection	Case Specific Information -> General	UNITED STATES OF AMERICA	UNITED STATES OF AMERICA	No
RCT-26022025-0002229	BRAVE	Primary Source Country	Case Specific Information -> General	UNITED STATES OF AMERICA	UNITED STATES OF AMERICA	No
RCT-26022025-0002229	BRAVE	Latest Received Date	Case Dates -> General	2025-02-26 13:13:23	2025-02-26 13:13:23	No
RCT-26022025-0002229	BRAVE	Report Type	Case Report -> General	Report from study	Report from study	No
RCT-26022025-0002229	BRAVE	Sender Organization	Source[25#NEW]		BRAVE	Yes
RCT-26022025-0002229	BRAVE	Patient DOB	Patient Identifiers -> Patient	1961-01-01 00:00:00	1961-01-01 00:00:00	No
RCT-26022025-0002229	BRAVE	Sex	Patient Identifiers -> Patient	Male	Male	No
RCT-26022025-0002229	BRAVE	Cessation date	Events[HYPOXIA]	2024-11-19 00:00:00	2024-11-19 00:00:00	No
RCT-26022025-0002229	BRAVE	Reported Term	Events[HYPOXIA]	HYPOXIA	HYPOXIA	No
RCT-26022025-0002229	BRAVE	Outcome	Events[HYPOXIA]	Recovered/Resolved	Recovered/Resolved	No
RCT-26022025-0002229	BRAVE	Onset date	Events[HYPOXIA]	2024-11-15 00:00:00	2024-11-12 00:00:00	Yes
RCT-26022025-0002229	BRAVE	Death?	Events[HYPOXIA]	No	No	No

- Comparison of data in defined fields at **entry and exit of Intake&Assessment**
- Runs daily and displays all SAE Alerts that exited I&A on the previous day
- Identifies process gaps (people changing data where they should not) and technology gaps

- Cumulative report will be created for **trending**
  Findings to be discussed with vendor → update of prompts, configurations, or fix

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OTHER POTENTIAL USE CASES IN CASE PROCESSING

Intelligent coding of adverse events

- For everything that goes beyond an exact match
- Important in the process: the user has to be able to see what is a direct match, a synonmy file approved match and an AI generated match which needs review
- External application: UMC

Fully AI based case processing

- requires a lot of review and checking
- Does not differentiate the mix of rule based automation and AI technologies
- Not seen yet

Data extraction from full text literature articles

- Abstract extraction the easy use case
- Full text, more complex, requires module to be able to extract info from graphs and tables.

Gen AI based narrative writing in ICSR processing

- Extract from structured fields or from an already templated narrative
- Integrates reporter comments with company narrative
- Doable, needs review

Avoid review fatigue, have a clear QC mechanism, ensure critical thinking can still be applied

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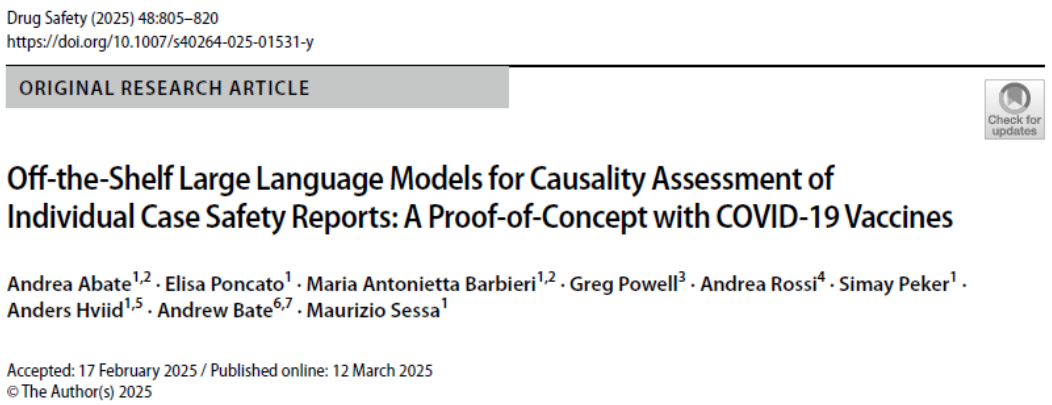
ACADEMIA ON AI BASED CAUSALITY ASSESSMENT – ONE EXAMPLE

- Drug Safety Group at University of Copenhagen
  - Automating Causality Assessment with AI precision: how to harness the power of AI to systematically evaluate and determine the likelihood of a causal relationship between a drug or a vaccine and an adverse event.
    - Prompting
    - LLM
    - Algorithm



Drug Safety (2025) 48:805–820
https://doi.org/10.1007/s40264-025-01531-y

ORIGINAL RESEARCH ARTICLE

Check for updates

Off-the-Shelf Large Language Models for Causality Assessment of Individual Case Safety Reports: A Proof-of-Concept with COVID-19 Vaccines

Andrea Abate[1,2] · Elisa Poncato[1] · Maria Antonietta Barbieri[1,2] · Greg Powell[3] · Andrea Rossi[4] · Simay Peker[1] · Anders Hviid[1,5] · Andrew Bate[6,7] · Maurizio Sessa[1]

Accepted: 17 February 2025 / Published online: 12 March 2025
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AGENTIC AI – POTENTIAL FOR USE IN STEERING OF PROCESSES

What is it?

- Focuses on autonomous systems that can make decisions and perform tasks with limited or no human intervention.
- Intelligent agents working together
- A goal needs to be set, context needs to be given, data are used to derive actions

- Next level of potential that also brings a next level of risk if used without awareness

Potential

- Multiple intellligent agents can work on PV data available and derive quality suggestions, based on available checks, data in the past, changes made in corrections in the past and current data.
- User instructions: ‚this program has never had a patient from this country', ‚no pediatric indication, check age and potential for off label use'
- Avoidance of quality issues has to be the leading thought for such a use case
- Case workflow steering/compliance – avoidance of case ageing, suggestions for backlog handling

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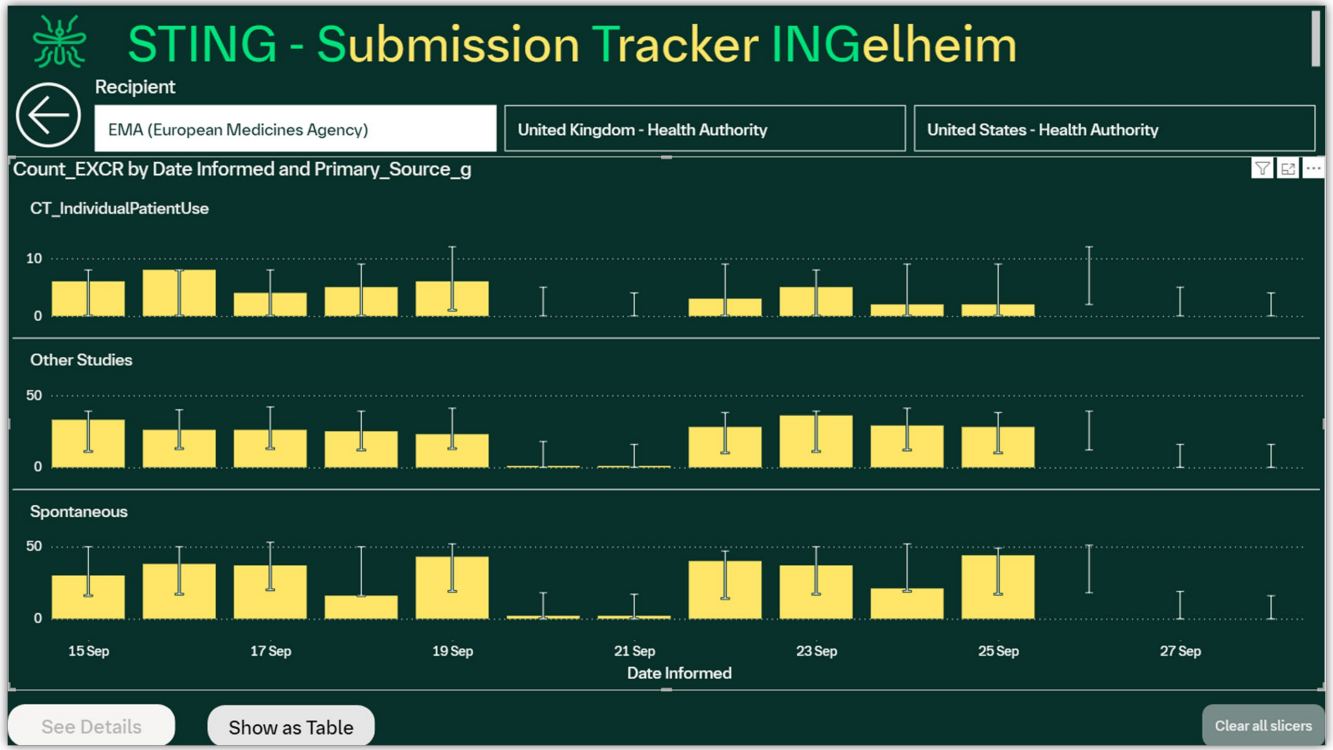
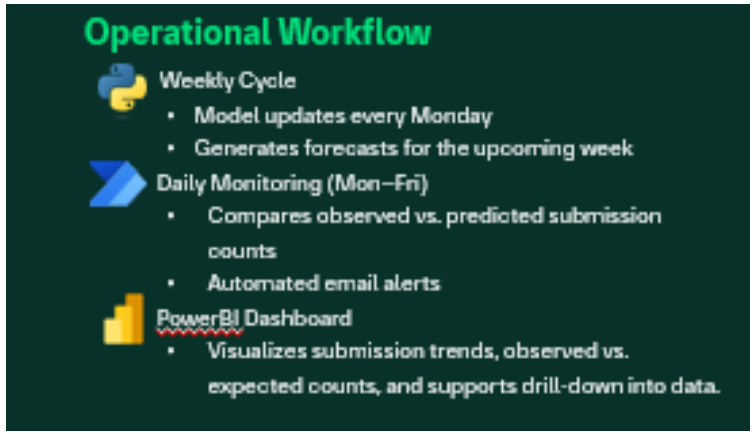
A PRECURSOR ACTIVITY AS A PREP FOR AN AGENT





AI use through an ML model in the forecasting part
Potential to weave into a ‚submission alerts agent‘
- measure - processed and submitted
- forecast - expected submissions
- compare and alert - actual submissions
- analyse – hint on faulty process

POSTER PRESENTATION SARA CIUCCI, BOEHRINGER INGELHEIM - STING FOR MONITORING AND FORECASTING OF EXPEDITED ICSRS

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USE CASES IN PV IN DOWNSTREAM PROCESSES

Authoring of aggregate safety documents

- The ideal:
  - Use existing aggregate report
  - Use new data, available assessments during reporting period and actions taken
  - Draft new aggregate report
- What is needed:
  - Pre-work on the documentation of assessments and actions taken
  - Data availability and usage potential
  - Good prompting!
- Great potential for agentic AI: data and document retrieval, data analysis, comparison, writing, hyperlinking, checking – all designed for aggregate PV reports
- Keep in mind that when writing the aggregate report is not the time we look at the data first time for the period. We summarize an ongoing process.

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FRAMEWORK AROUND USE OF AI

- Ensure every user is trained on risks of AI
- Ensure that system owner and process owners are aware of the technology and what it does so a risk based assessment can be made in an informed way
- Ensure that you are aware if AI or rule based automation is used
- Ensure that the recommendations provided are transparent and beware of hallucinations or other gaps
- Ensure human is in the loop and understands the concept if false negatives
- Ensure data confidentiality and following the principles of the EU AI act
- Ensure process is documented

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MORE OF A BRAINSTORMING STAGE RIGHT NOW AND BEYOND PHARMACOVIGILANCE – WHAT IF

… we could predict probability of success in the development process

- Prediction from tox data and previous data into the human studies
- Potential to minimize risk right in the studies

… we could prevent events from happening or worsening?

- Find digital biomarkers that build up before an event happens
- Find algorithms to predict this
- Instruct HCPs and patients on positive interventions
- Use AI and automation where we cannot use paper and instructions

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THANK YOU