

# Beyond the Algorithm

## The Human-AI Partnership in Pharmacovigilance

**March 2026, London**

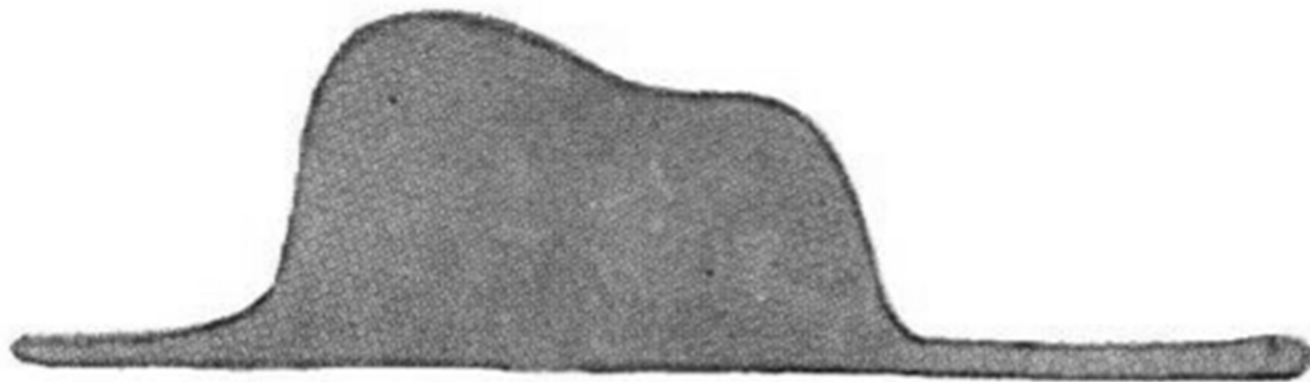
Dr. Sabine Poltermann  
Head Patient Safety Switzerland & Liechtenstein

The opinions expressed in the presentation are my own and do not reflect the opinions of my employer

# Disclaimer



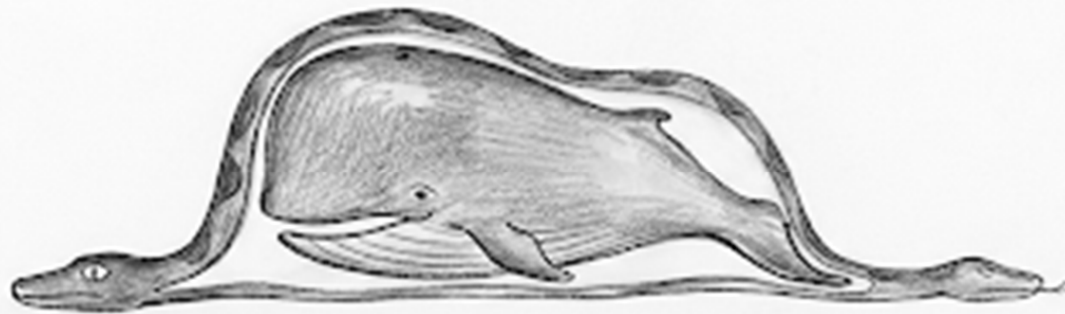
- This presentation might include a bit of irony here and there.
- It's all meant to give you some food for thought and encourage reflection.
- Enjoy and think critically!
  
- No animals were harmed in the making of this slide deck.



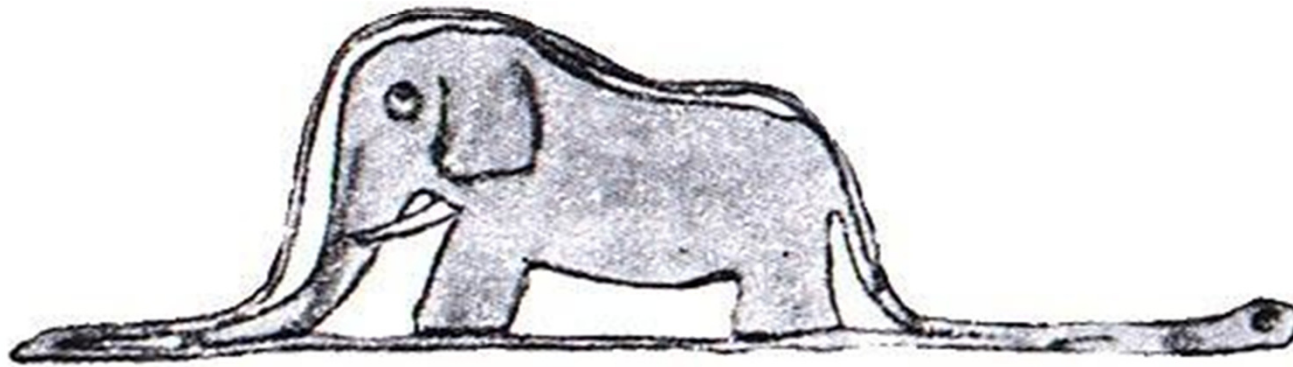
**What do you see here?**

# What do you see here?





# What it is



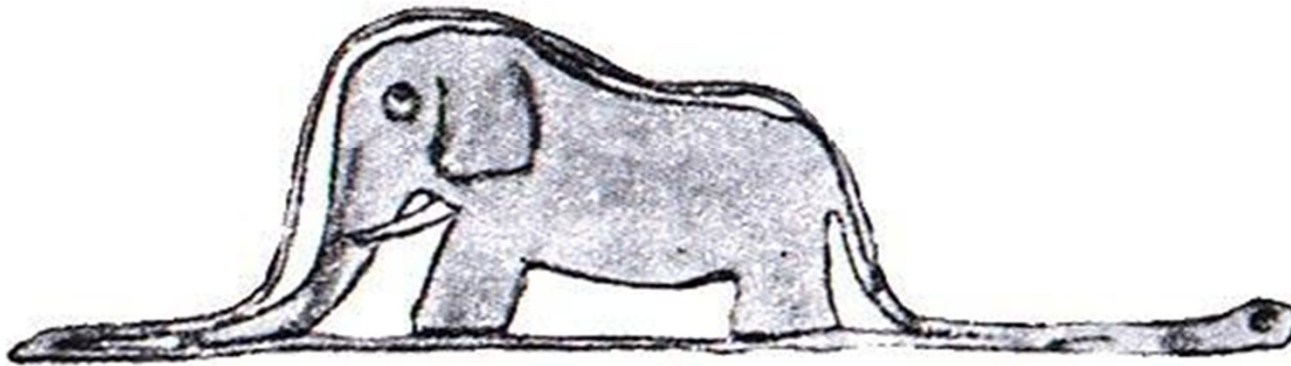
**What it really is**

# ChatGPT

- This image is a famous illustration from "The Little Prince" by Antoine de Saint-Exupéry.
- At first glance, it resembles a simple drawing of a hat.
- However, within the story, it is revealed to be a drawing of a boa constrictor that has swallowed an elephant - the outline represents the snake digesting its meal.



# The AI-lephant in the room



We are all scared that AI will take our job, aren't we?

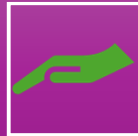
# When AI is mentioned in PV... what is the very first reaction in the room?

- Officially?

- Excitement.
- Strategic alignment.
- Digital transformation slides.



Unofficially? A very quiet thought:



*'What does this mean for my role?'*



## Pharmacovigilance

- Detecting signals early
- Assessing risk vs. benefit
- Escalating when needed
- Preventing harm
- Protecting trust

“Is this safe for the patient?”

## Human Nervous System

- Scanning for danger (neuroception)
- Activating fight / flight when threat is perceived
- Shutting down when overwhelmed
- Allowing connection & creativity when safe

“Am I safe?”

Two Safety Systems. Same Mission.

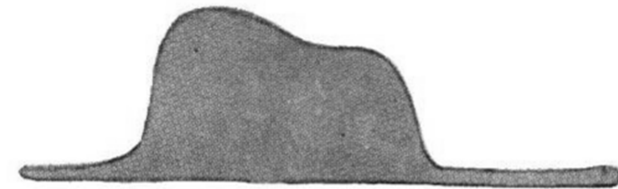
## “Am I safe?”

### NO

- Fight → I critique this AI into compliance.
- Flight → We automate everything by Friday.
- Freeze → Let's schedule a meeting to schedule the meeting.
- Shutdown
- **Hello, survival mode...**

### YES

- What else is possible?
- How could this augment us?
- What new PV roles might emerge?
- **Hello, curiosity & creativity...**



What could this be?

Safety is not only procedural. Safety is psychological.

Which reaction shows up most in your teams –  
and what does it look like day-to-day?



# AI implementation is a neurobiological event

- When you introduce AI, you are not just installing software.
  - You are triggering nervous systems.
- **Leadership becomes regulation.**

## Ventral vagal (safe & connected)

- Curious, collaborative, open to innovation

## Sympathetic (fight/flight/freeze)


- “Will I be replaced?”
- Defensiveness, over-control, micromanagement

## Dorsal vagal (shutdown)

- Withdrawal
- Passive resistance
- “Let’s just wait and see.”

Do your teams feel safe enough to use AI tools?

# Rekindling Childlike Curiosity and Creativity



Curiosity requires psychological safety.  
Innovation requires cognitive flexibility.  
Creativity requires permission to experiment.

The biological truth:

- Curiosity is incompatible with fear.
- Innovation is a nervous system privilege.

You cannot demand creativity from a team that feels replaceable.

**Leadership Before Process**

AI processes signals.  
Humans create safety.

- both biological safety for patients and psychological safety for teams.



- Changes require:
  - Psychological safety
  - Regulation of team anxiety
  - Holding ambiguity
  - Sensing moral tensions
  - Resolving conflicts
- Those are ventral vagal capacities.
- **AI cannot do this.**

# Leadership Before Process

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Create space for uncertainty

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Model calm curiosity

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Speak transparently about AI impact

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Separate identity from performance

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Encourage experimentation

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Reward learning

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Encourage thoughtful dissent

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Define human accountability

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# Create Clarity.



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Explain the why

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Be transparent about impact

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Define human accountability

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Define what AI will and will not do

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Communicate boundaries and decision ownership

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Explain role evolution, not role elimination

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Share timelines and learning paths

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Address concerns openly and early

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Document accountability and oversight

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Reiterate that humans remain in charge of judgement

# Create Clarity. Clarity reduces threat.

## AI will

- Transform signal detection and safety analytics
- Transform case processing and documentation
- Draft narratives and structured reports
- Process data faster and at greater scale
- Cluster patterns beyond human capacity
- Reduce manual and repetitive workload
- Generate insights and risk signals
- Suggest classifications and options
- Surface patterns humans may miss
- Analyse massive datasets
- Detect subtle statistical deviations
- Learn and improve through iteration
- Adapt when trained
- Optimise based on defined parameters

## AI will not

- Replace professional judgement
- Replace ethical decision-making
- Replace benefit–risk assessment
- Replace experience and contextual wisdom
- Carry moral or legal accountability
- Sense ethical discomfort
- Feel the weight of patient impact
- Defend positions before authorities
- Make value-based decisions
- **Attend the inspection for you (and definitely not take the oath).**

**BE HUMAN**

# Case Study: Pregnancy Prevention Advisory Tools

## Situation

- 6 months after introducing a **PPP**, you notice a small cluster of cases indicating **pregnancy exposure** despite “high distribution” of:
  - Prescriber Checklist
  - Patient Alert Card

## Findings

- **Prescriber Checklist:**
  - Not aligned to clinic workflow
  - Ambiguous verbs (consider vs must)
  - Key steps not visually dominant
- **Patient Alert Card:**
  - STOP action not prominent
  - Contraception timing easy to misread
  - Too much text for a ‘pocket tool’

The checklist was perfect - if you had 20 minutes and a quiet room.

The card was perfectly readable - if your patient had a highlighter, reading glasses, and no reason to panic.

**What AI can do:**  
consistency + clarity + layout + key messages checks

**What AI cannot do:**  
medical correctness, compliance, testing, sign-off, audit trail

**Is this effective  
in real life?**

# Case Study: Distribution of aRMMs

## Situation

- Mailing of updated aRMM, 100% rejection rate from one hospital
- Compliance rate or distribution: 100%

## Human Action

- Contact hospital PV responsible
  - To ensure the info reaches the HCPs

## Reaction from HCPs

- **What is this?**

## Human Action

- Contact hospital PV responsible
  - To ensure her oversight
  - To enable her to do evaluate potential training needs

Would an AI  
have done that?

Empathy is not a dataset.

Judgement is contextual.

Context is human.



If PV loses its human discernment, it loses its legitimacy

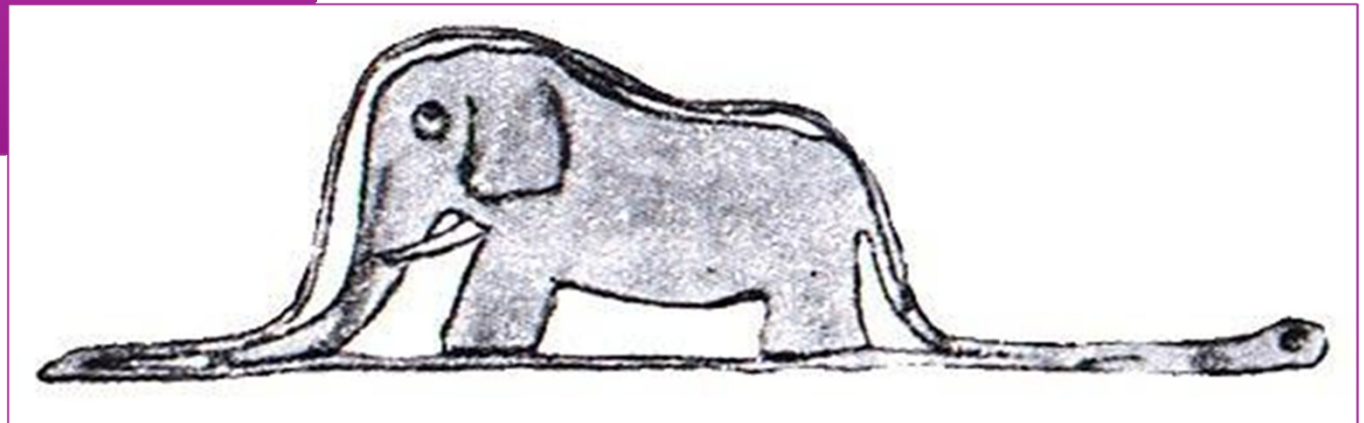
AI cannot lead change.  
But neither can a  
dysregulated nervous  
system.

The future of PV  
depends on both,  
intelligent systems and  
regulated humans.



AI can't lead change. That's your job.

See the AI-lephant.  
Name it.  
Lead it.



THANK YOU