



# EU 2025

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16–19 November  
CCH – Congress Center Hamburg

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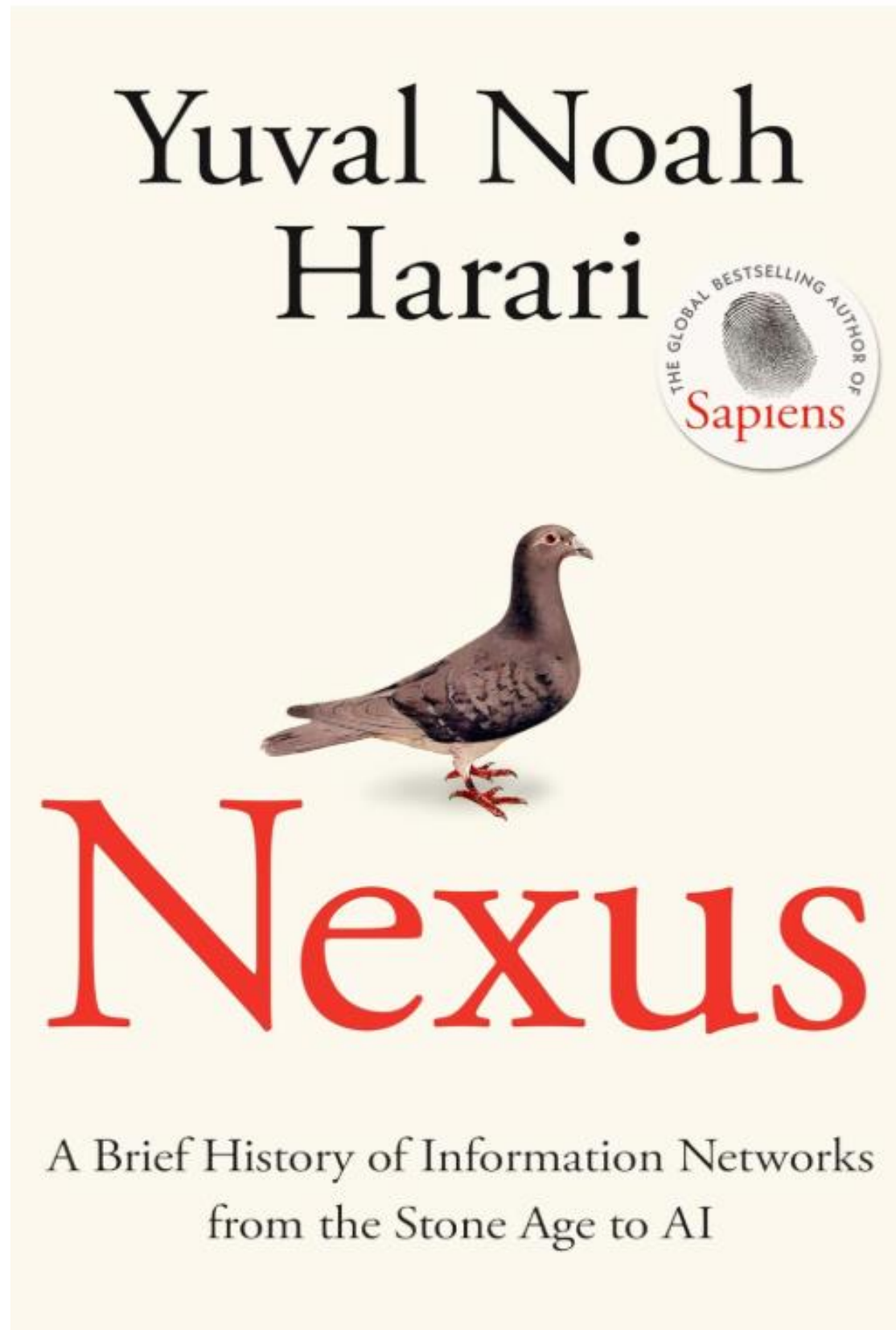
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# "Human in" or "Human out" of the loop

Olivier Bouchard, Principal  
Business Solution manager,  
Global HLS Advisory, SAS

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# My Summer Read



*“There’s very little need and this sounds cynical and I’m not really, I hope not, a very cynical person, but there really isn’t a need for a lot of manual interface when you can have it done by AI, except in the loop. For now, at least, humans in the loop is required. I wonder why that always is a requirement because we don’t have explainability of the human brain and we assume we always do things better, which is not the case.”*

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THOMAS SENDEROVITZ, SENIOR VICE PRESIDENT OF DATA SCIENCE, NOVO NORDISK



# However...

## Measuring and Mitigating Racial Disparities in Large Language Model Mortgage Underwriting

Donald E. Bowen III  
*Lehigh University*

S. McKay Price  
*Lehigh University*

Luke C.D. Stein  
*Babson College*

Ke Yang  
*Lehigh University*

This version: September 24, 2024

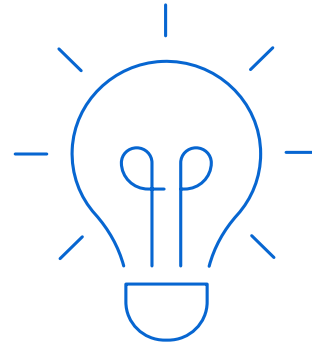


*LLMs recommend **more denials** and **higher interest rates** for Black applicants than identical White applicants.*

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SSRN

Source: Donald E. Bowen III, S. McKay Price, et al. 2024



# Responsible innovation begins with responsible innovators.

—  
Reggie Townsend, Vice President of Data Ethics

# Blockers & Barriers : what LS has to overcome

Source: [Your journey to a GenAI future: A strategic path to success in life sciences and pharma](#)

To unlock the technology's full potential and effectively manage risks, GenAI integration needs expert knowledge and planning. As adoption expands, organizations across all sectors are facing similar challenges. But for the life sciences industry, some issues are particularly pressing.

## Top implementation challenge

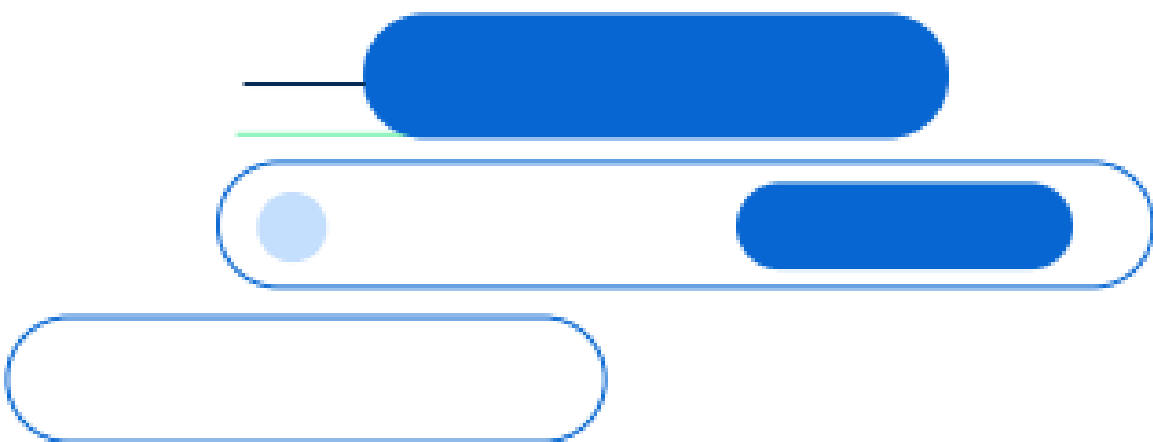
**49%** are finding it difficult to transition GenAI from the conceptual phase to a practical use, and the same number say using both public and proprietary data sets effectively is a concern.

## Biggest worries

**79%** of life sciences leaders say they are uneasy about data privacy when it comes to using GenAI in their organization.

**74%** say the same for data security.

**59%** are anxious about governance.

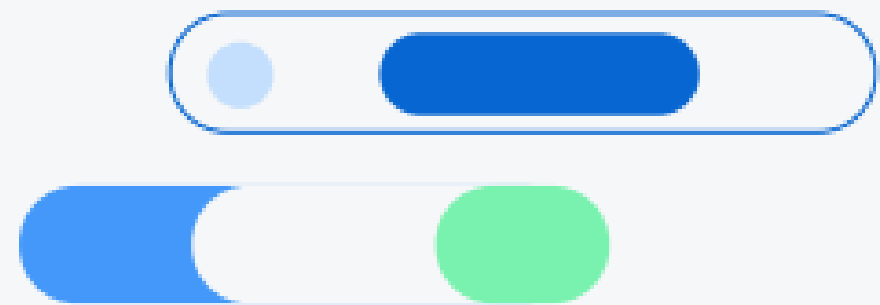


## Technical hurdles

**30%** indicated that technological limitations are the greatest impediment to implementing effective governance and monitoring.

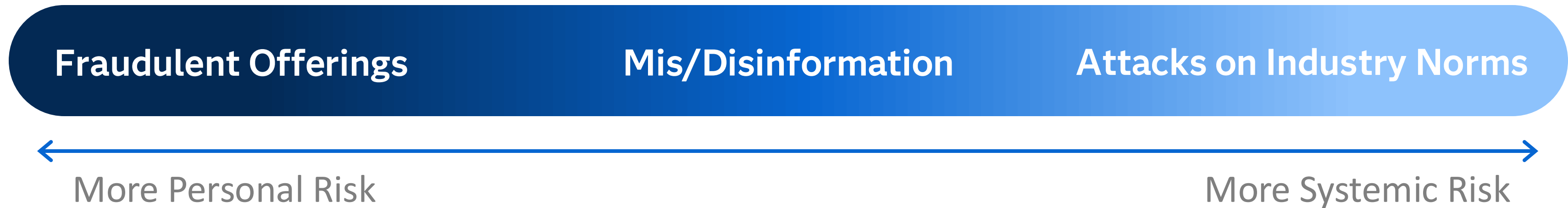
## Funding issues

**17%** of life sciences leaders say insufficient funding is a significant challenge in implementing effective GenAI governance and monitoring, higher than any other sector.



# AI Risks Threatening Life Sciences

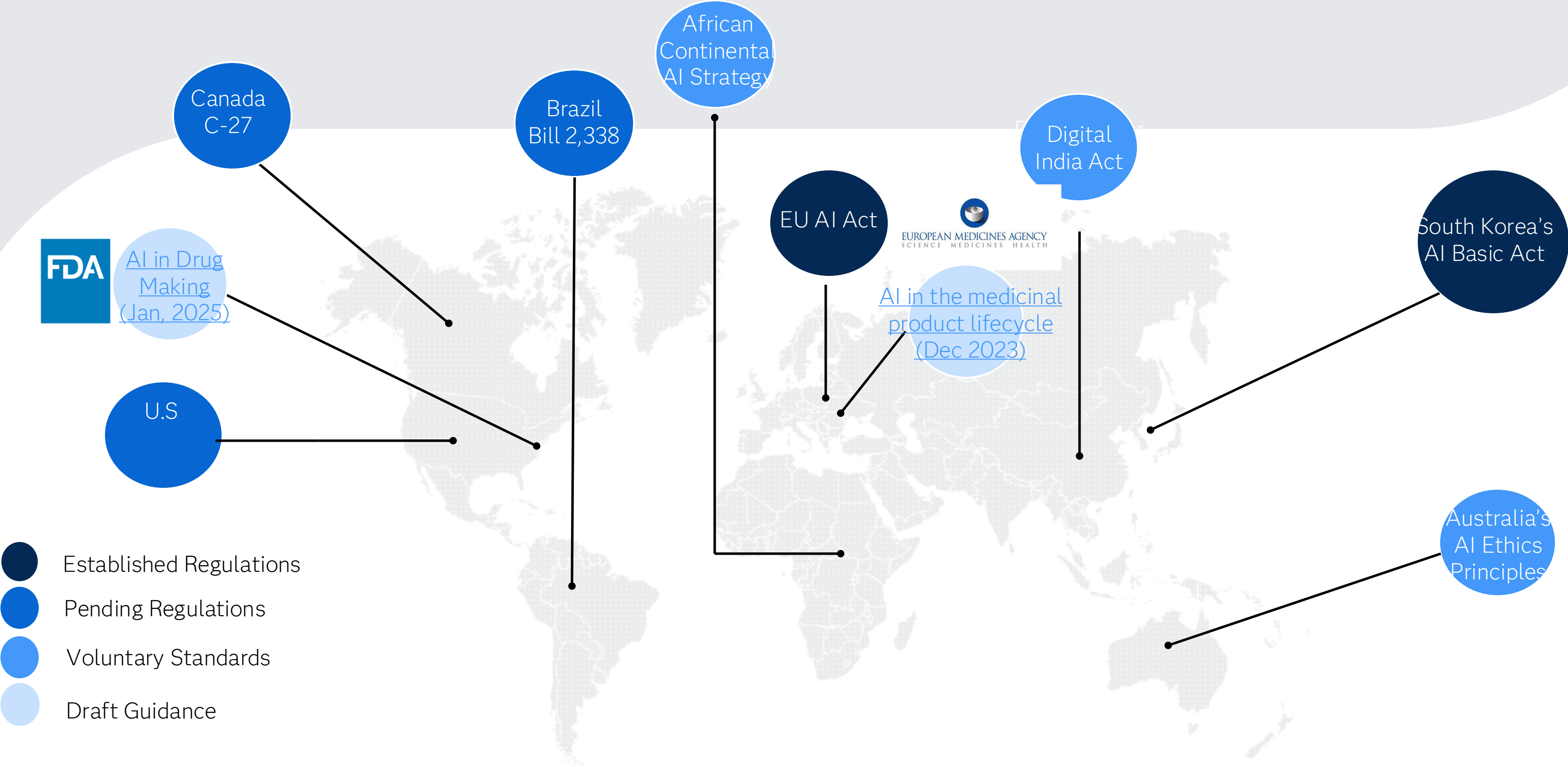
Strategic considerations for proactive planning



## Examples

|                                   |                                         |                               |                                          |                                           |                                              |
|-----------------------------------|-----------------------------------------|-------------------------------|------------------------------------------|-------------------------------------------|----------------------------------------------|
| Misleading personalization claims | Undisclosed side effects                | Manipulated pre-clinical data | Off-label use scams / viral social dares | Deluge of AI-generated patent filings     | Democratizing biotech leads to bioweapons    |
| Ghost/AI-written research papers  | Synthetic data masquerading as observed | Artificial supply constraints | Premature breakthrough announcement      | False, persistent claims about regulators | False safety claims designed to foment panic |

# Regulatory Landscape



# Human in the Loop & EU AI ACT – Capabilities needed

HIGH-RISK AI SYSTEMS

AI SYSTEMS

## Requirements

[Article 9:](#) Risk management system

[Article 10:](#) Data and data governance

[Article 11:](#) Technical documentation

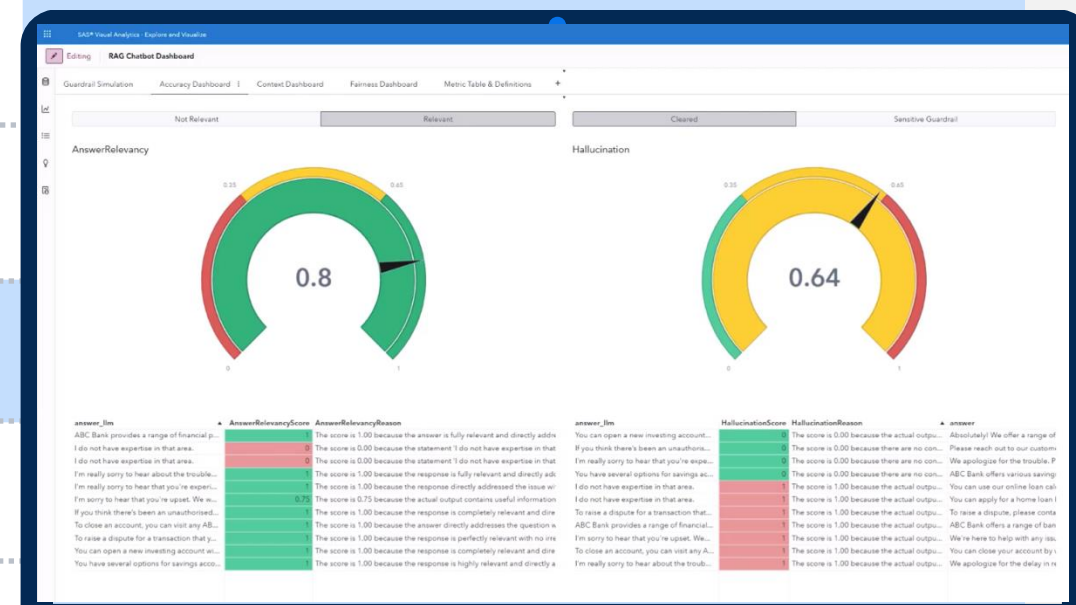
[Article 13:](#) Transparency and provision of information to deployers

[Article 14:](#) Human oversight

[Article 15:](#) Accuracy, robustness and cybersecurity

[Article 4:](#) AI literacy

## Human in the Loop and on the Loop



Monitoring of AI system performance with alerts

Model Interpretability and Fairness Assessment

Route tasks requiring manual intervention

# EU AI ACT – More Capabilities needed

HIGH-RISK AI SYSTEMS

AI SYSTEMS

## Requirements

[Article 9:](#) Risk management system

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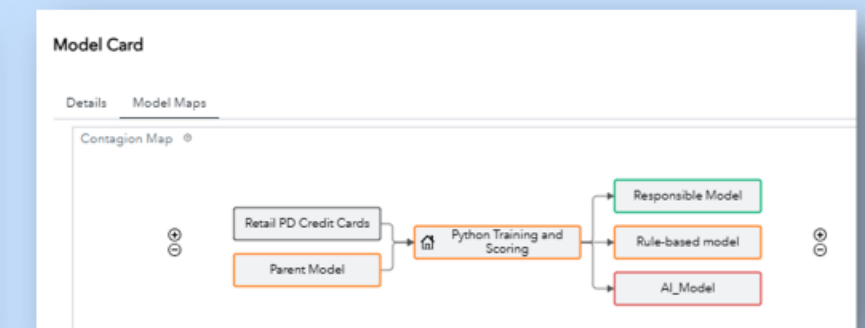
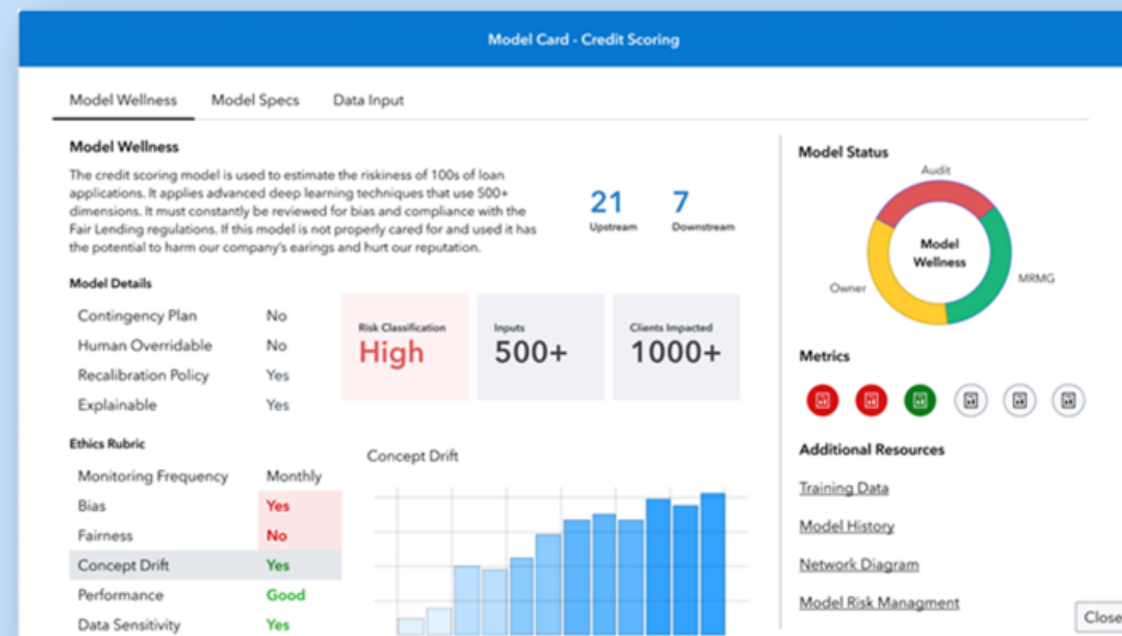
[Article 15:](#) Accuracy, robustness and cybersecurity

[Article 4:](#) AI literacy

## AI System Governance

Auditable workflow-controlled process

- Centralized model information Management
- Documentation
- Model governance and performance monitoring
- Model cards
- Central dashboard



# EU AI ACT – More Capabilities needed

HIGH-RISK AI SYSTEMS

AI SYSTEMS

## Requirements

[Article 9:](#) Risk management system

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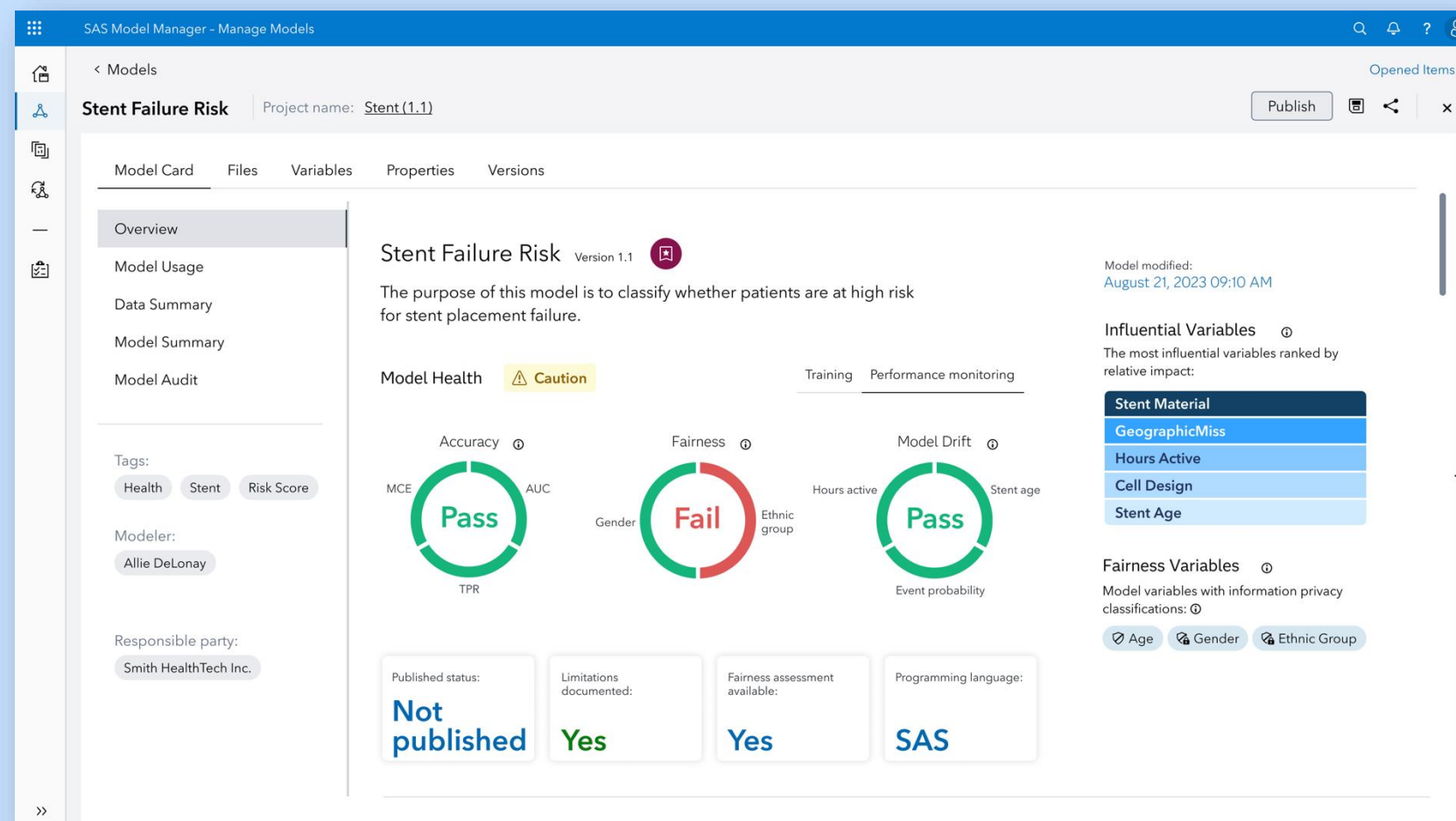
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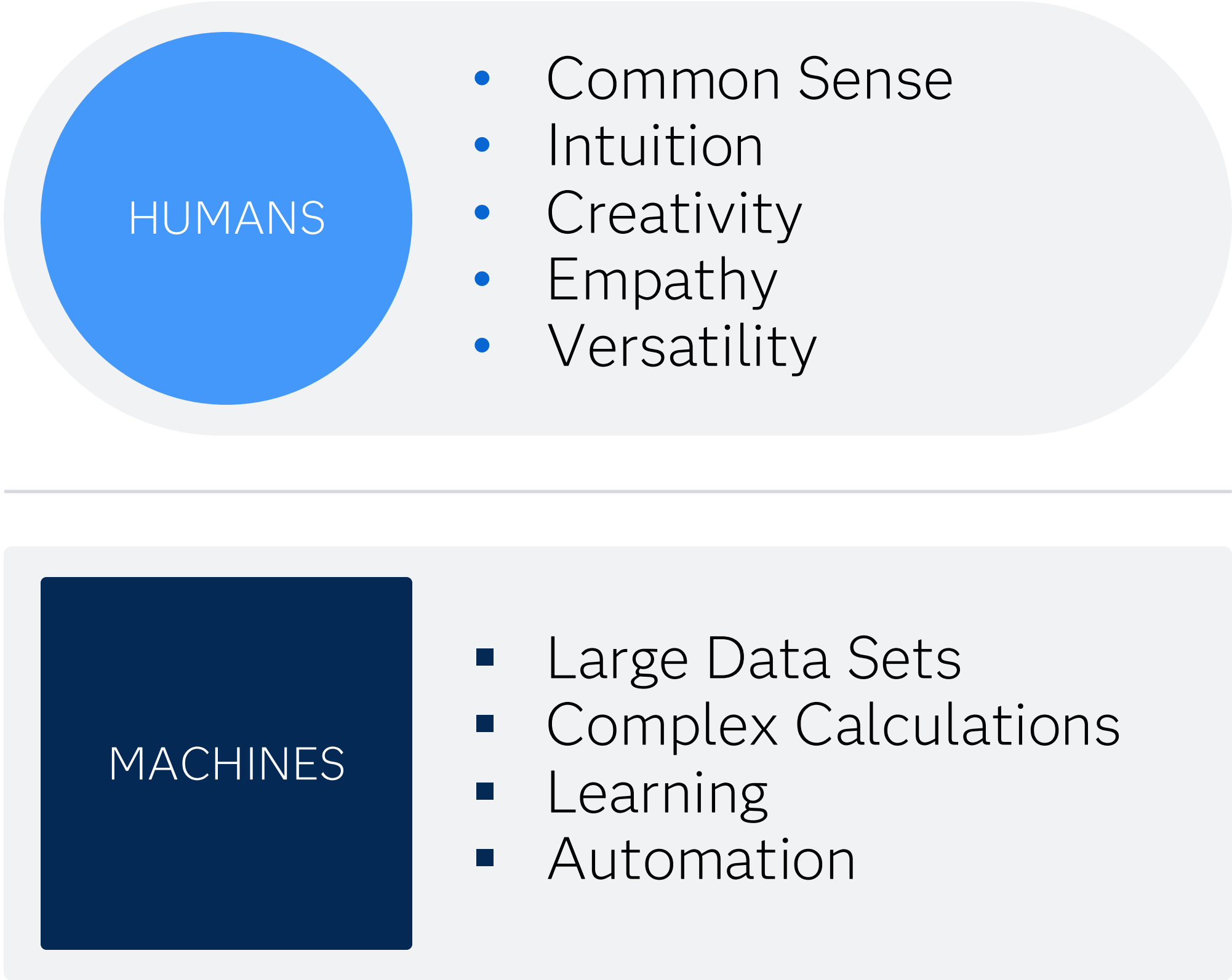
## Model Cards

“Nutrition labels for models”  
provide critical insight



- Summary of a model's training data
- Performance
- Accuracy, transparency and fairness.

# What are Humans and Machines good at?



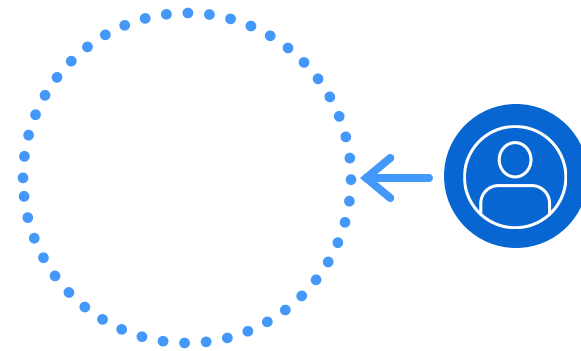
## HUMANS

- Common Sense
- Intuition
- Creativity
- Empathy
- Versatility

## MACHINES

- Large Data Sets
- Complex Calculations
- Learning
- Automation

# ← Agentic AI →



## Human out of the Loop

Act on behalf of humans



## Human in the Loop

Engage humans when needed



## Human on the Loop

Require human oversight

Complexity

Low

High

Determinism

High

Low

Speed

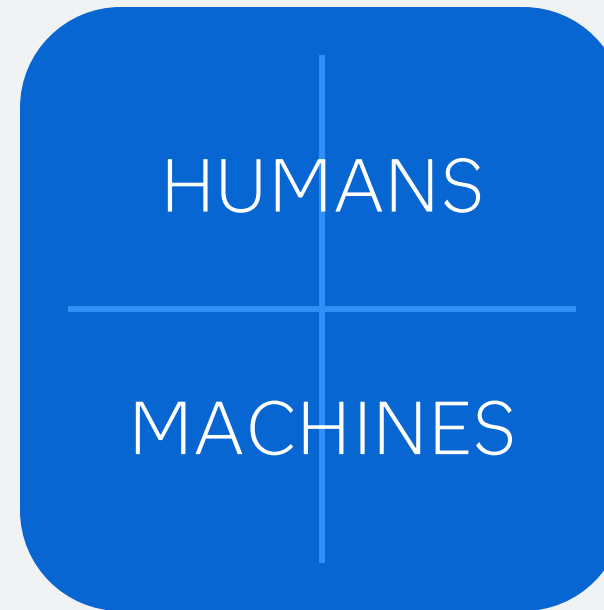
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Governance

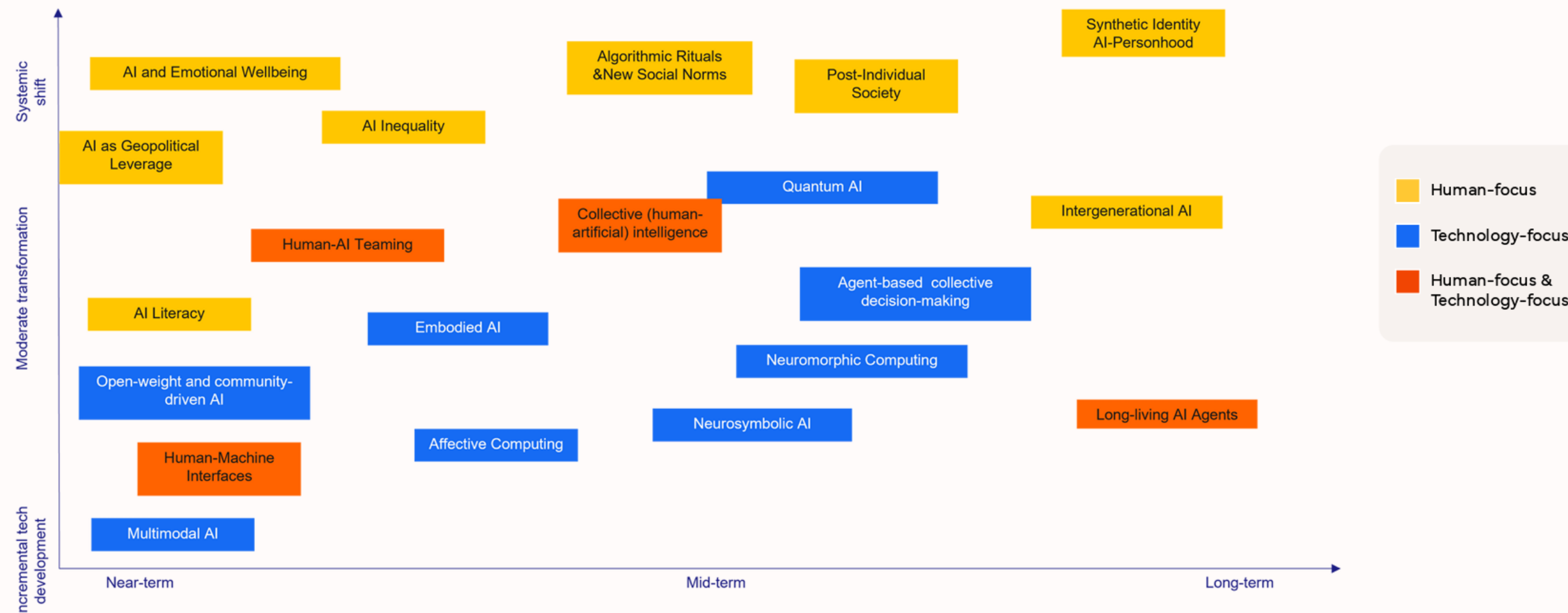


# When are humans and machines better together?



- + Making sense of patterns and trends surfaced from large data sets
- + Interpreting results from complex calculations
- + Assessing impacts of simulated scenarios
- + Handling exceptional cases apart from those that can be automated

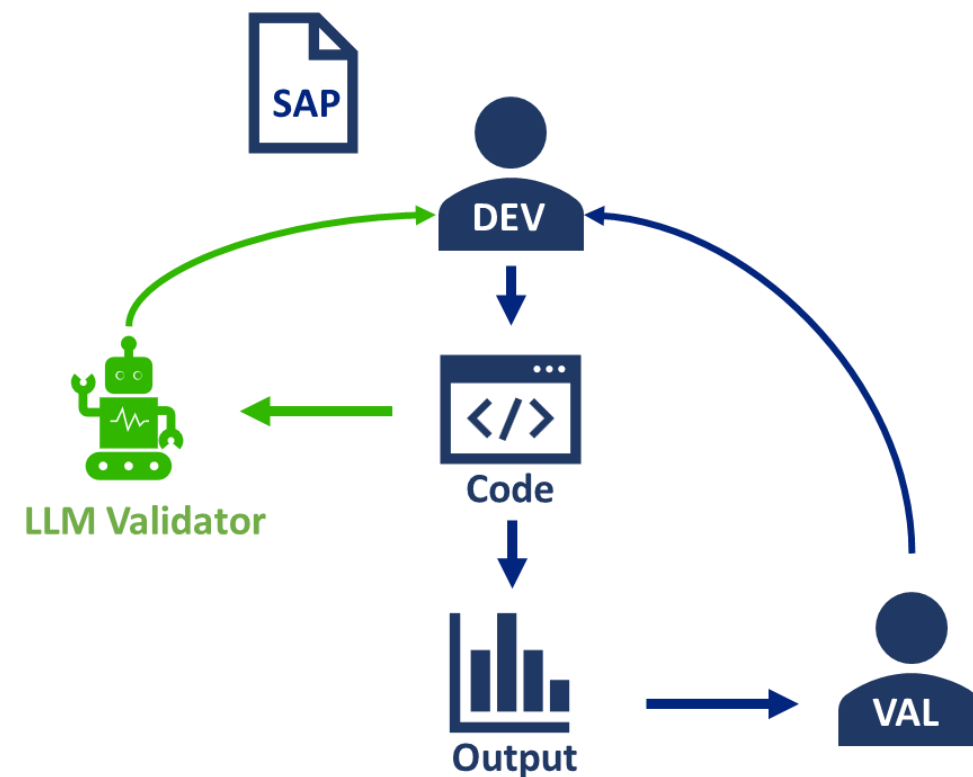
## What's next? AI's impact beyond technology



EUR-IDC-RE-AI-In-EMEA-2025

# "Human in" or "Human out" of the loop

## Solution: AI Agent for Code Validation



### LLM Input

- SAP + Code
- Pre-processing required

### LLM Validation

- By Section
- Incremental

## Results

  
DEV  
Original

```
else if kupcase(vstestcd) eq 'DIABP' then do;
  ATOXGRHN = 0 + (aval ge 141) + (aval ge 151) + (aval gt 155);
  if not missing(atoxgrhn) then ATOXDSCH = 'HYPERTENSION (DIASTOLIC)';
end;
```

  
LLM Update

```
else if kupcase(vstestcd) eq 'DIABP' then do;
  /* Corrected the ranges for Hypertension (Diastolic Blood Pressure) */
  ATOXGRHN = 0 + (aval ge 91) + (aval ge 96) + (aval gt 100);
  if not missing(atoxgrhn) then ATOXDSCH = 'HYPERTENSION (DIASTOLIC)';
end;
```

# Thanks!



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