



Risk-Driven AI Oversight in Healthcare – A Tiered Framework Using ISO, ICH Q9, & FMEA

Presented by

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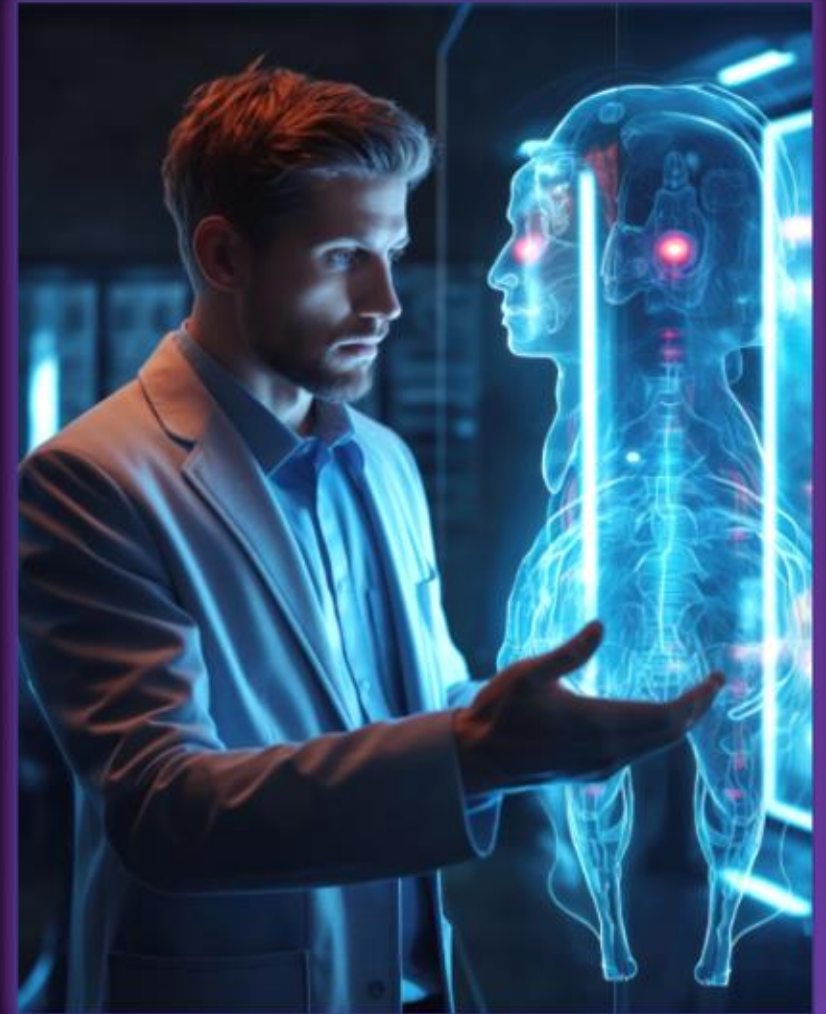


Question of Interest

Now, Question is not about
"Can we build powerful AI systems?"

but

"Can we govern them responsibly?"



Session Objectives



Understand need for human oversight



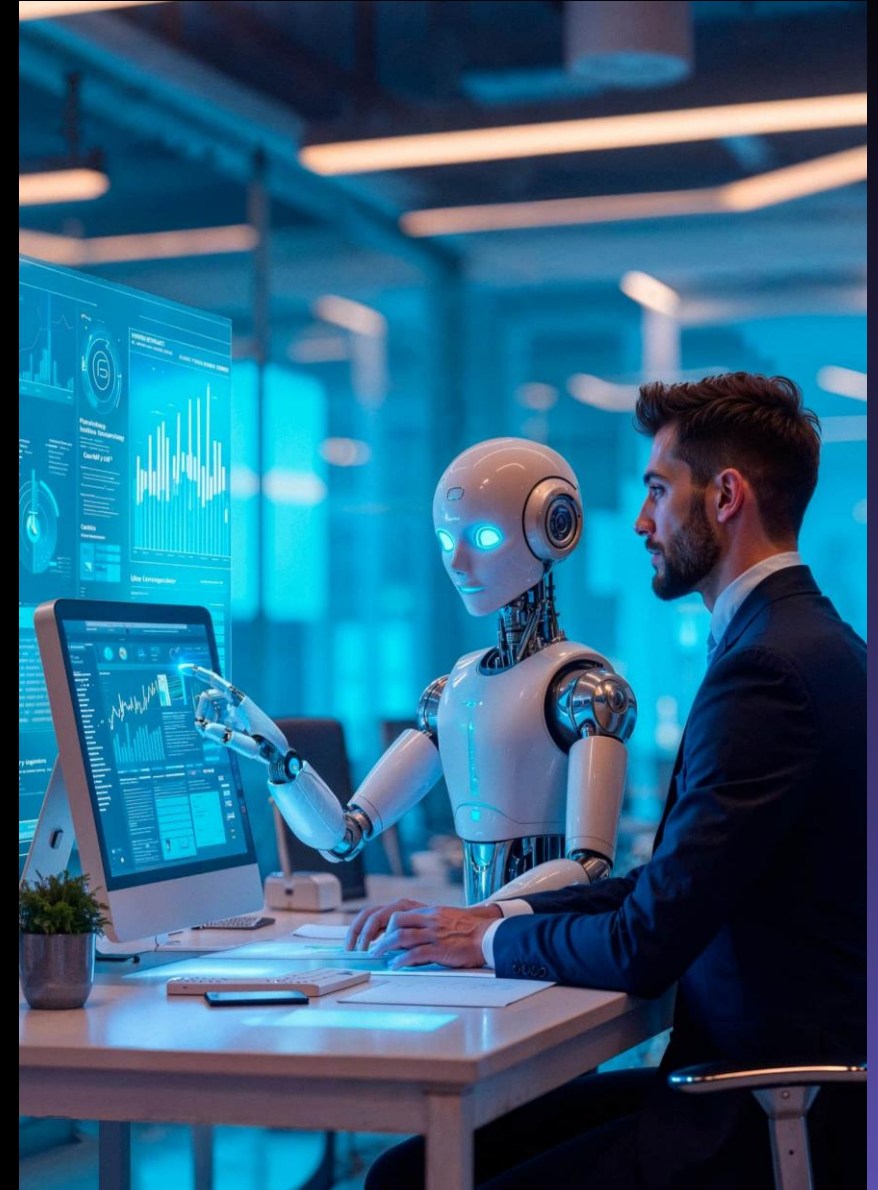
Overview of risk-based framework



Understand the risk assessment and application of human oversight

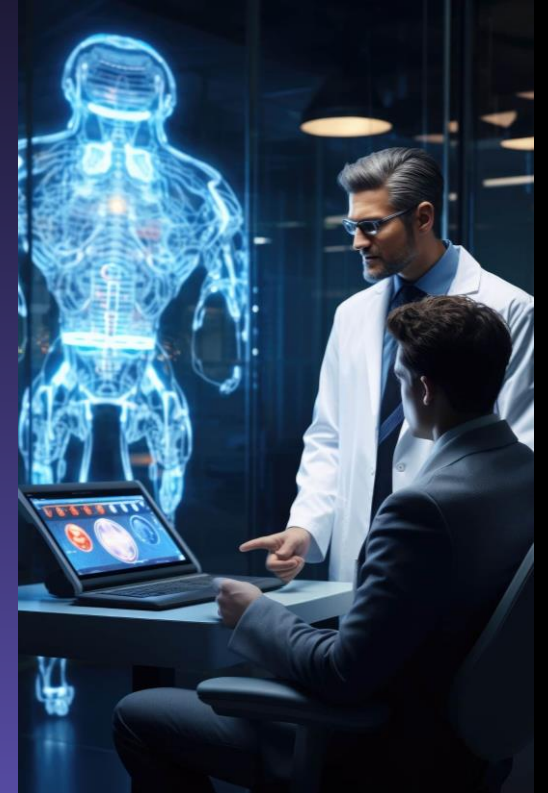


An example to illustrate how it works in practice



Introduction

- AI is rapidly transforming clinical research and healthcare
- AI is now being used to enhance clinical research processes from patient recruitment to data analysis and trial monitoring.
- Errors or bias in AI models may compromise trial integrity, data validity, or even patient safety.
- As AI capabilities grow, **human oversight becomes critical**



Human Agency and Human Oversight

Element

Preserving Human Agency

Why Human Oversight Matters

Regulatory Drivers

Content

Human agency is the capacity of individuals to make autonomous and informed decisions.

AI risks reinforcing biases, encouraging blind adherence to algorithmic decisions

The European Union AI Act advocates for "strict regulatory oversight" (Article 14).

Growing need for oversight

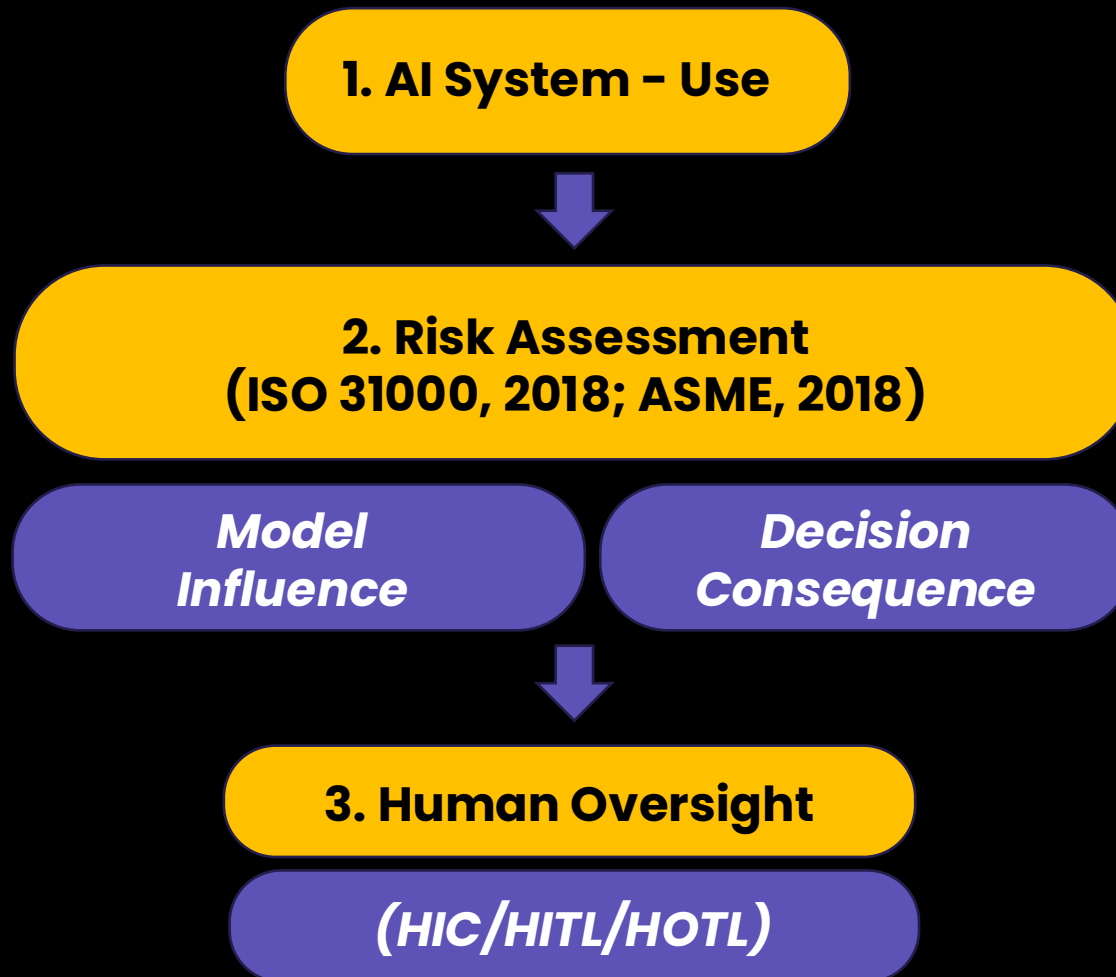
Blackbox &
Lack of
Explainability

Risk to Patient
Safety &
Ethical
Considerations

Bias,
Hallucinations
and unsafe
outputs

Data Privacy,
Security &
Accountability
Issues

Risk Based Framework



AI System

Context of Use

what question the AI is addressing.
How its output meant to be used?

Example

Usage of a computer-vision
AI system to inspect vials.



Risk Assessment (ISO 31000 vs ASME 2018)

Risk Assessment (ISO 31000)

Risk Identification

Risk Analysis

Risk Evaluation

Risk Treatment

Monitoring & Review

AI Specific Concept (ASME 2018, FDA)

Model Influence, Decision

Consequence

Risk Matrix (Influence × Consequence)

Risk against acceptance criteria

Oversight Mechanism

Dynamic Oversight

Risk Assessment

(Model influence vs Decision Consequence)

Dimension	Description	Role in Assessment
Model Influence	Pertains to the relative weight attributed to the AI system's outputs.	High influence means the AI output forms a critical basis for the decision
Decision Consequence	Addresses the potential impact of an erroneous decision based on AI output.	A systematic evaluation must consider three elements (FMEA): Severity of potential harm, Probability of occurrence, and Detectability of an error prior to adverse outcomes

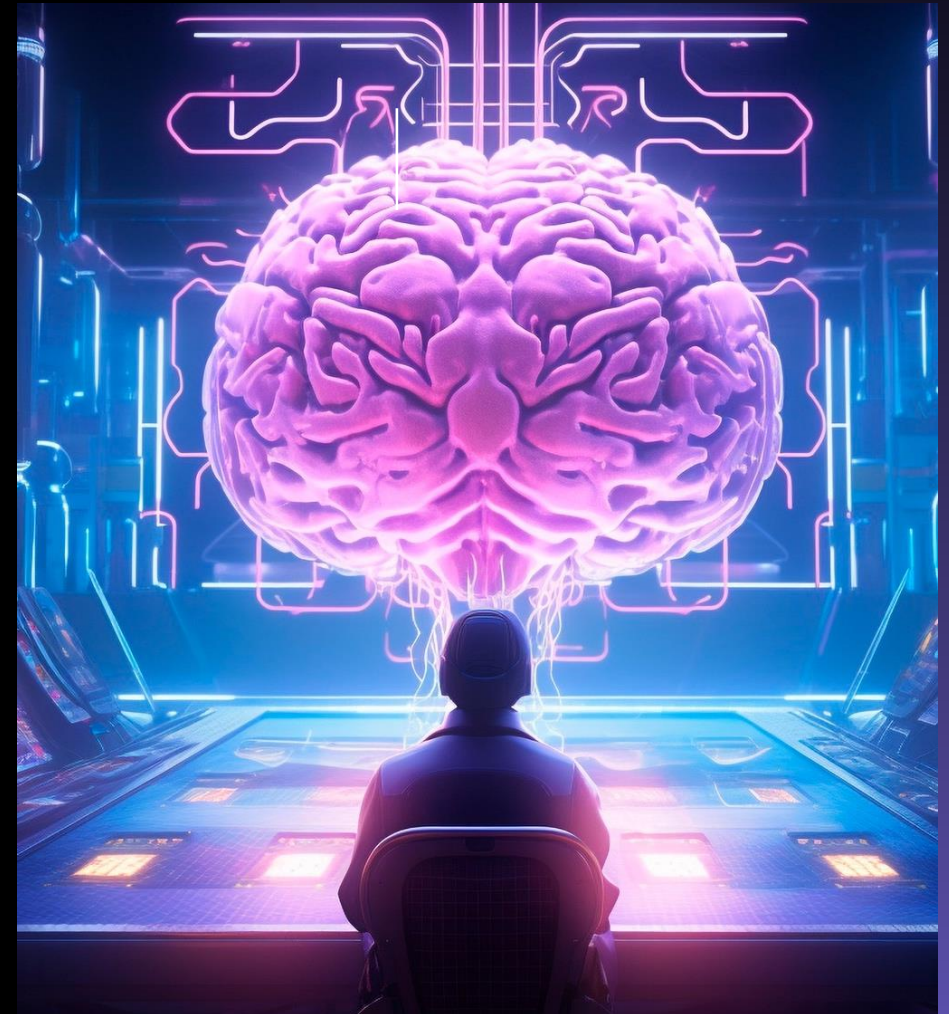
Decision Consequence

Dimension	Score	Level
Severity	1	Low
	2	Medium
	3	High
Probability	1	Low
	2	Medium
	3	High
Detectability	1	Low
	2	Medium
	3	High

Decision Consequence

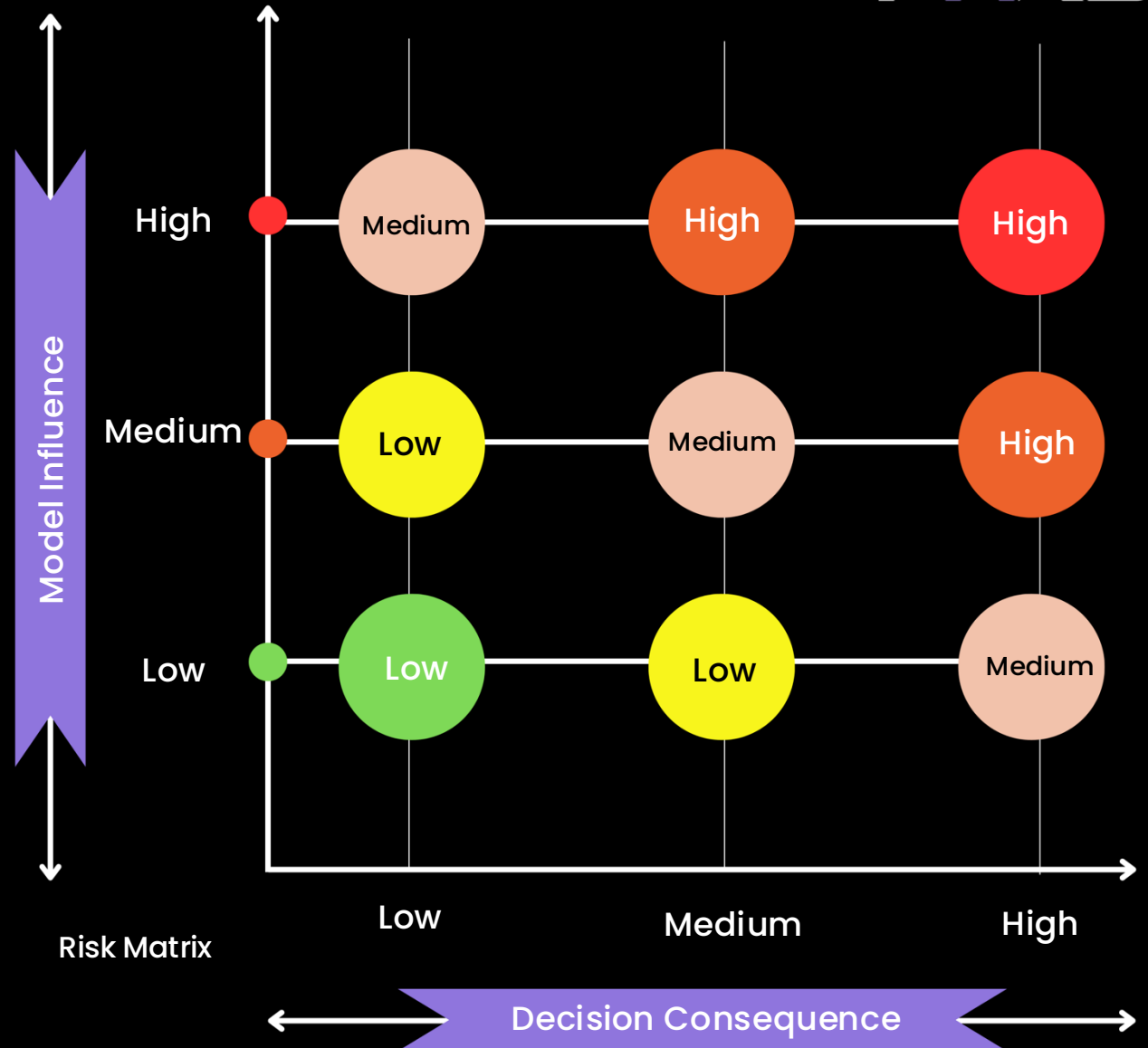
Risk Priority Number =
Severity x Probability x Detectability

RPN Range	Risk Priority
1 – 6	Low
7 – 14	Medium
15 – 27	High



Risk Assessment Matrix

Risk Matrix involves assessing model influence and decision consequence to define risk levels ranging from Low to High.



Levels of Human Oversight

Human-in-Command (HIC)

Humans are the ultimate authority over AI systems,.

Human-in-the-Loop (HITL)

Active human involvement in real-time decision-making processes.

Human-on-the-Loop (HOTL)

Humans monitor performance and intervene only when anomalies occur.

Mapping Risk to Human Oversight

AI system with human oversight

AI Risk	Low	Medium - High	High
Human Oversight	<i>HOTL</i>	<i>HITL</i>	<i>HIC</i>

Example – HOTL

Context

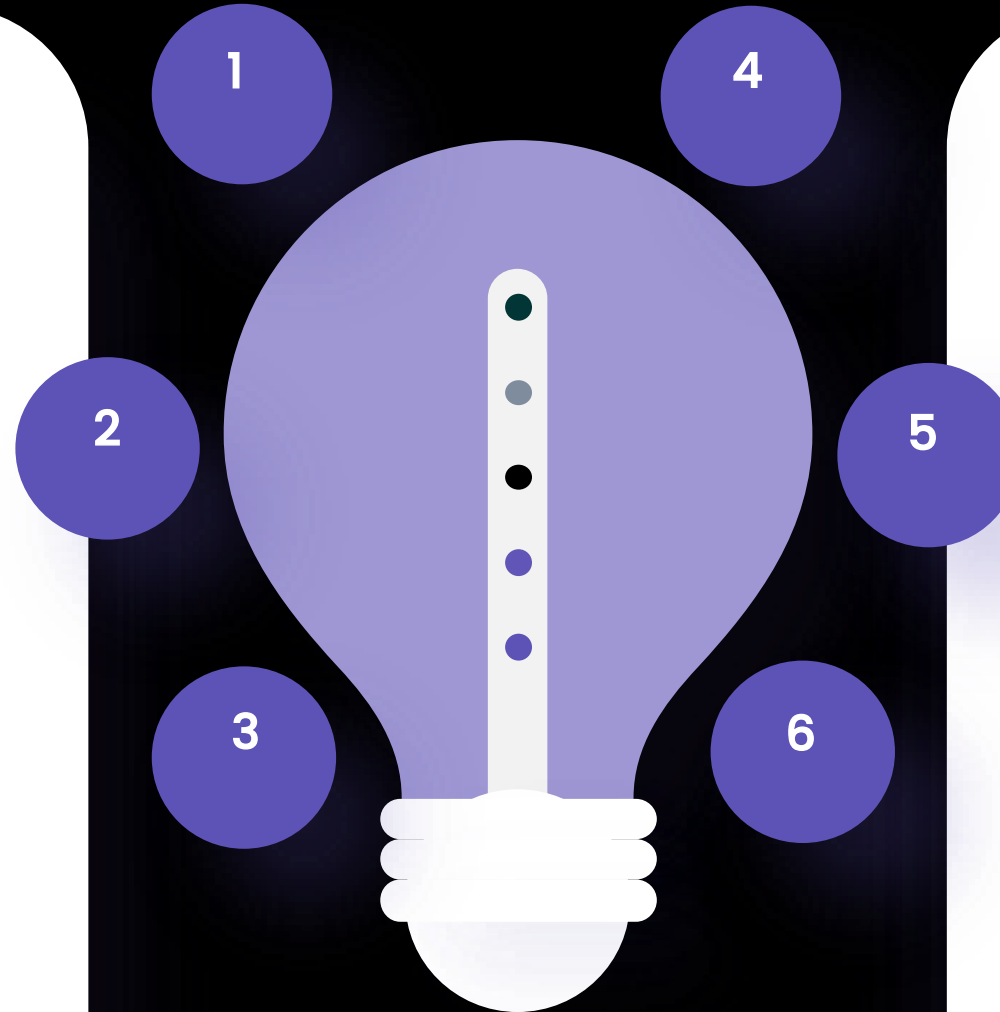
An AI system automates patient appointment scheduling in a clinic or hospital.

Model Influence

Medium

Decision Consequence

Low



Overall Risk

Low (Medium Influence vs. Low Consequence).

Required Oversight

Human-on-the-Loop (HOTL)

HOTL Action

Humans monitor the system outputs and intervene only if anomalies occur.

Example – HITL

Context

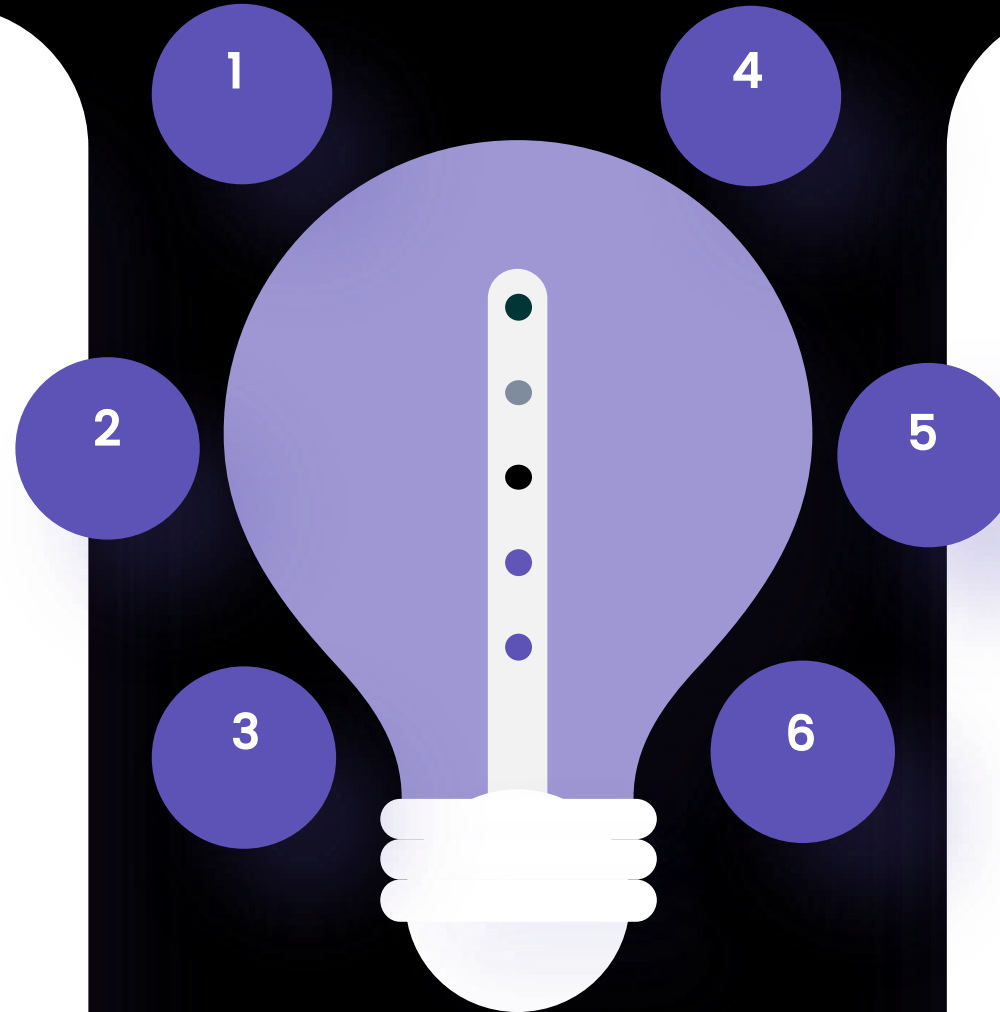
Clinical data quality management agent

Model Influence

Medium

Decision Consequence

Medium



Overall Risk

Medium (Medium Influence vs. Medium Consequence).

Required Oversight

Human-in-the-Loop (HITL).

HITL Action

Humans routinely review AI-generated alerts.

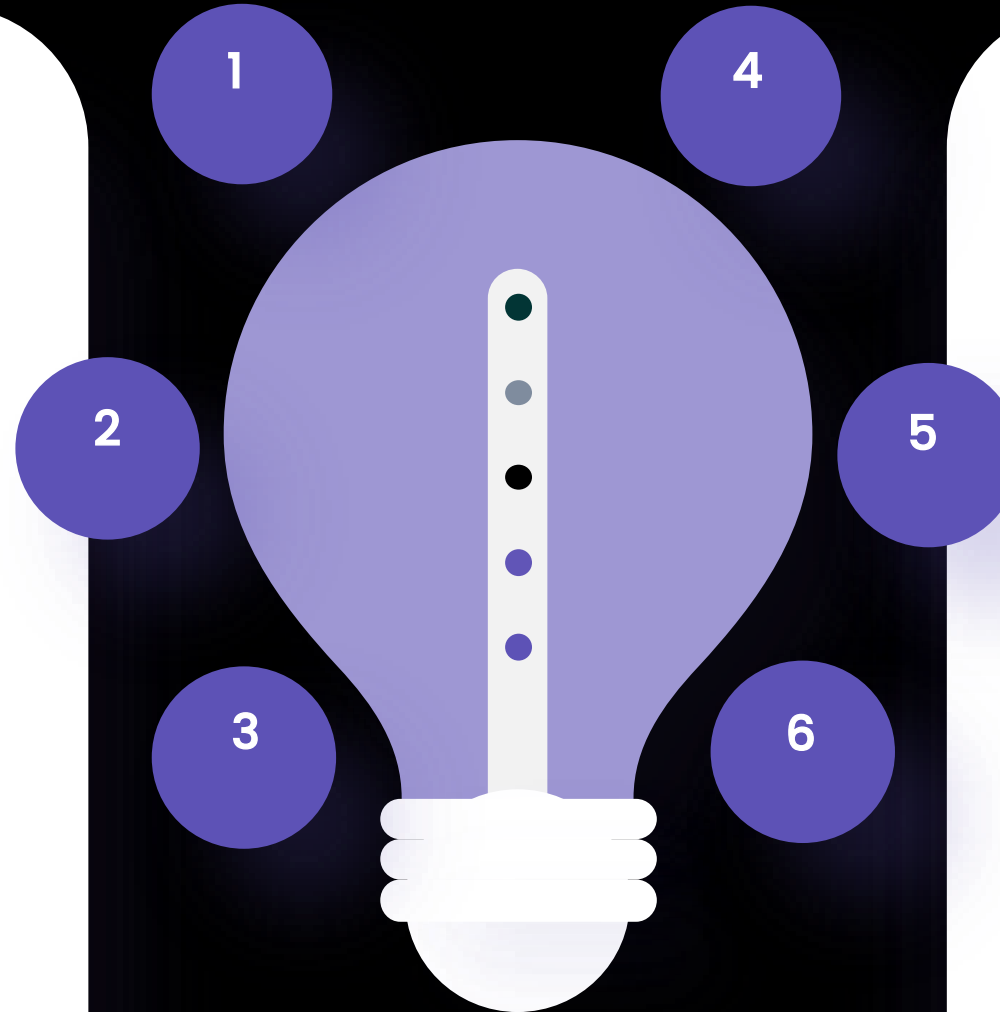
Example – HIC

Context

An AI system generates and maintains clinical trial documents

Model Influence
High

Decision Consequence
High



Overall Risk

High (High Influence vs. High Consequence).

Required Oversight

Human-in-command (HIC).

HIC Action

Humans have ultimate authority to accept, modify, or reject all AI-generated content.

Key Benefits and Challenges

Benefits

- Improves Trust and Accountability
- Prevents Bias, hallucination and unsafe outputs
- Add Transparency
- Supports Regulatory compliance

Challenges

- Skill Gap – Need Training
- Time Consuming
- Unclear Governance
- Risk of Over- or Under-Oversight
- Continuous risk assessment

Is Human Oversight Enough?

Additionally,

- **Appropriate control measures**



Technical Controls



Procedural Controls , and



Organizational Controls

- **are recommended to operationalize trust and ensure compliance.**



Key Take aways



Human oversight ensures safety and trust

Not all AI use is equal

Oversight requires readiness: people, process & governance

Continuous monitoring & adaptability are key

Balancing benefit vs risk — maximizing value while minimizing harm

Q&A

Thank you for your time!

Open to questions & discussion.

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