Quantitative Sciences and Artificial Intelligence: Opportunities and Considerations for Strategic and Responsible Application in Clinical Trials

Curtis Meinert Keynote
May 18, 2026

Cyrus Hoseyni, Ph.D.
Global Head, Quantitative Sciences & Clinical Pharmacology
J&J Innovative Medicine

SCT | 47TH ANNUAL MEETING

Disclosures

- The views expressed in this presentation reflect my own views, based on my observations and lessons in leadership. They should not be attributed to or taken as the official position of my employer

- I am currently employed by **Johnson & Johnson Innovative Medicine Research & Development (JJ-IMRD)** as Vice President and Global Head, **Quantitative sciences & Clinical Pharmacology (QSCP)**

Acknowledgements

I am grateful for the valuable insights and contributions provided by the following colleagues:

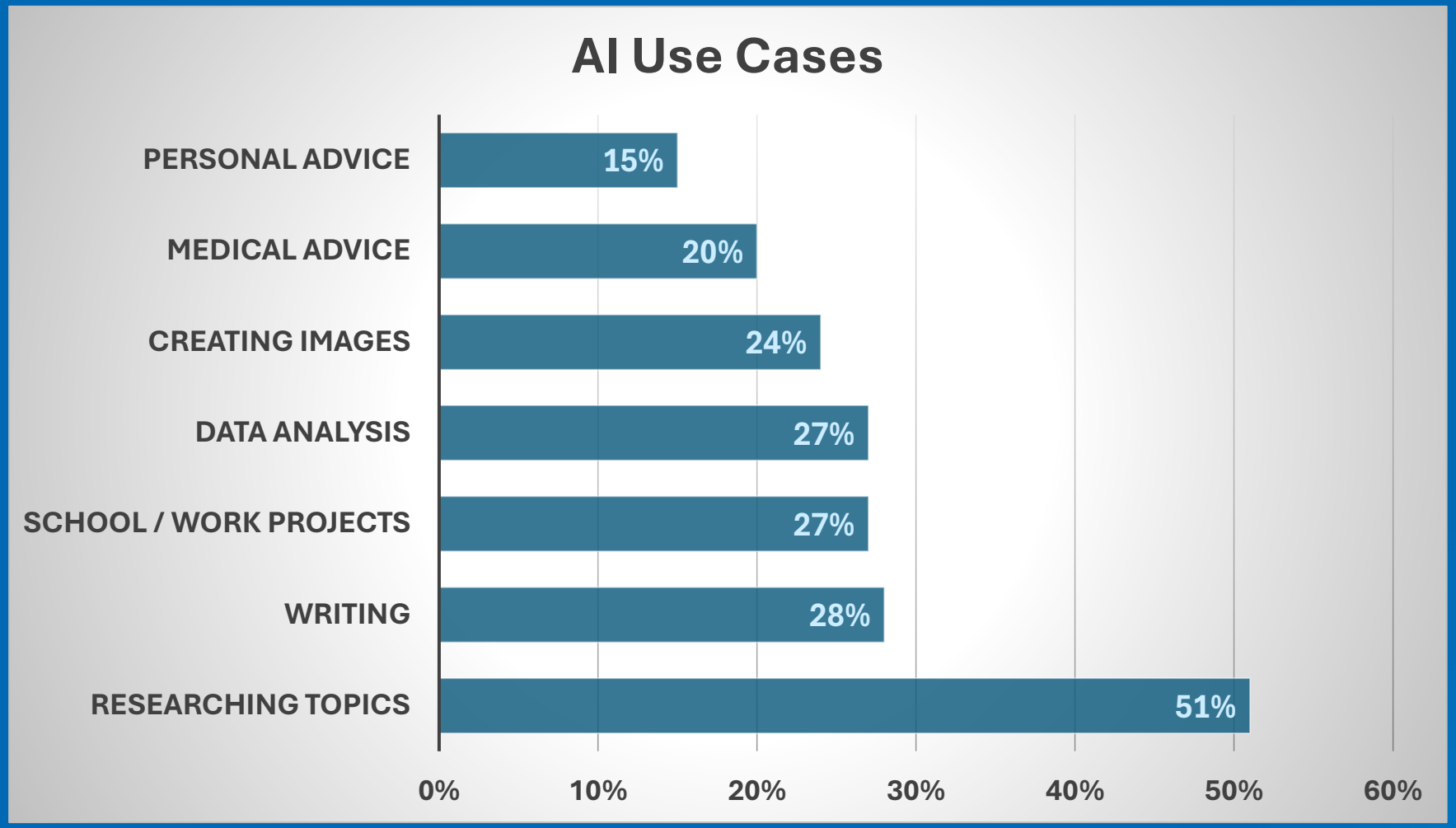
- Fei Chen
- Vlad Dragalin
- Michael Grayling
- Surya Mohanty
- Bhargava Reddy
- Darren Weston

“The Age Of Artificial Intelligence: Americans’ AI Use Increases While Views On It Sour…”

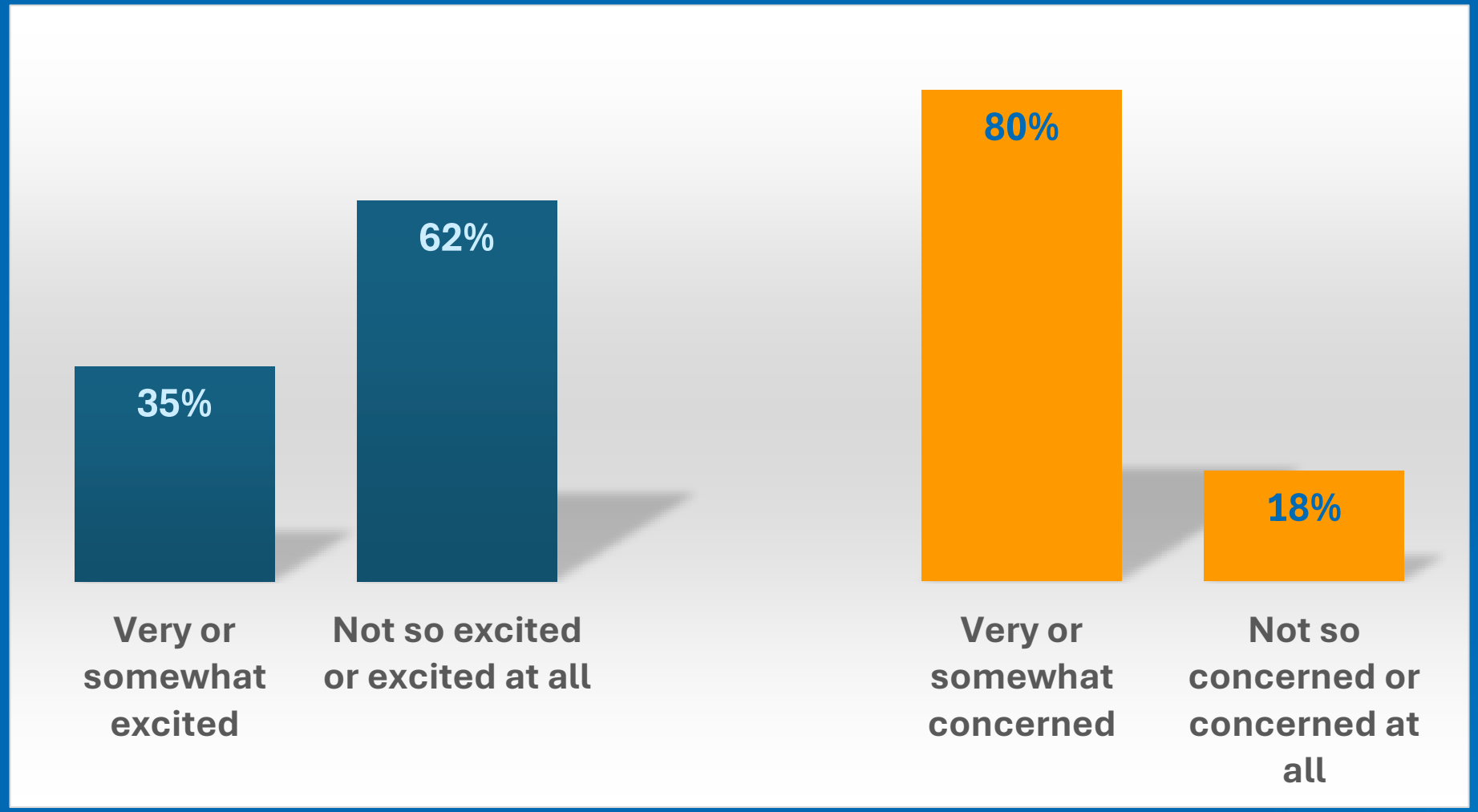
Quinnipiac University Poll
March 30, 2026

1,397 Adults (800 Employed)

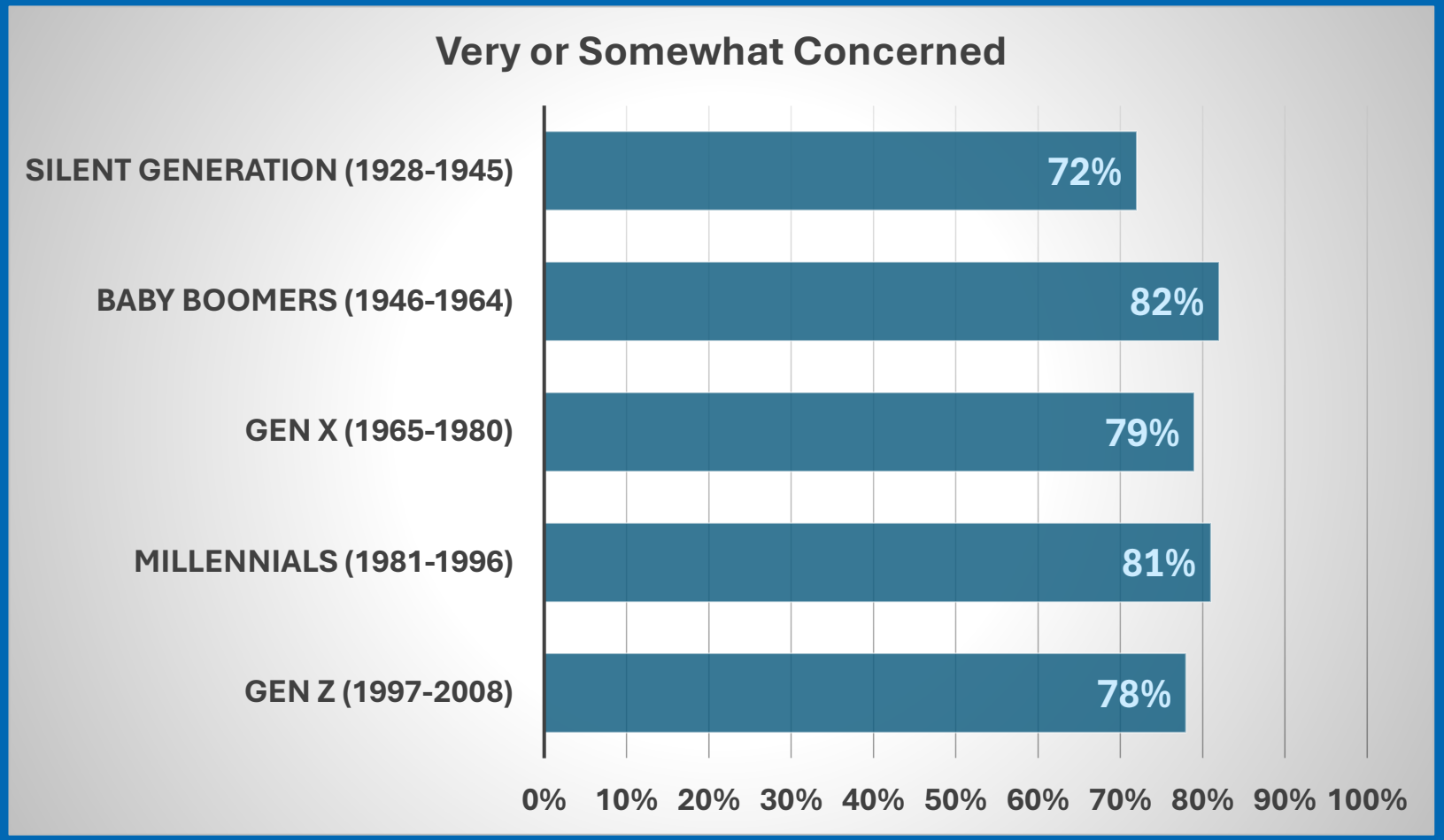
AI Use


AI Use Cases
PERSONAL ADVICE
15%
MEDICAL ADVICE
20%
CREATING IMAGES
24%
DATA ANALYSIS
27%
SCHOOL / WORK PROJECTS
27%
WRITING
28%
RESEARCHING TOPICS
51%
0%
10%
20%
30%
40%
50%
60%

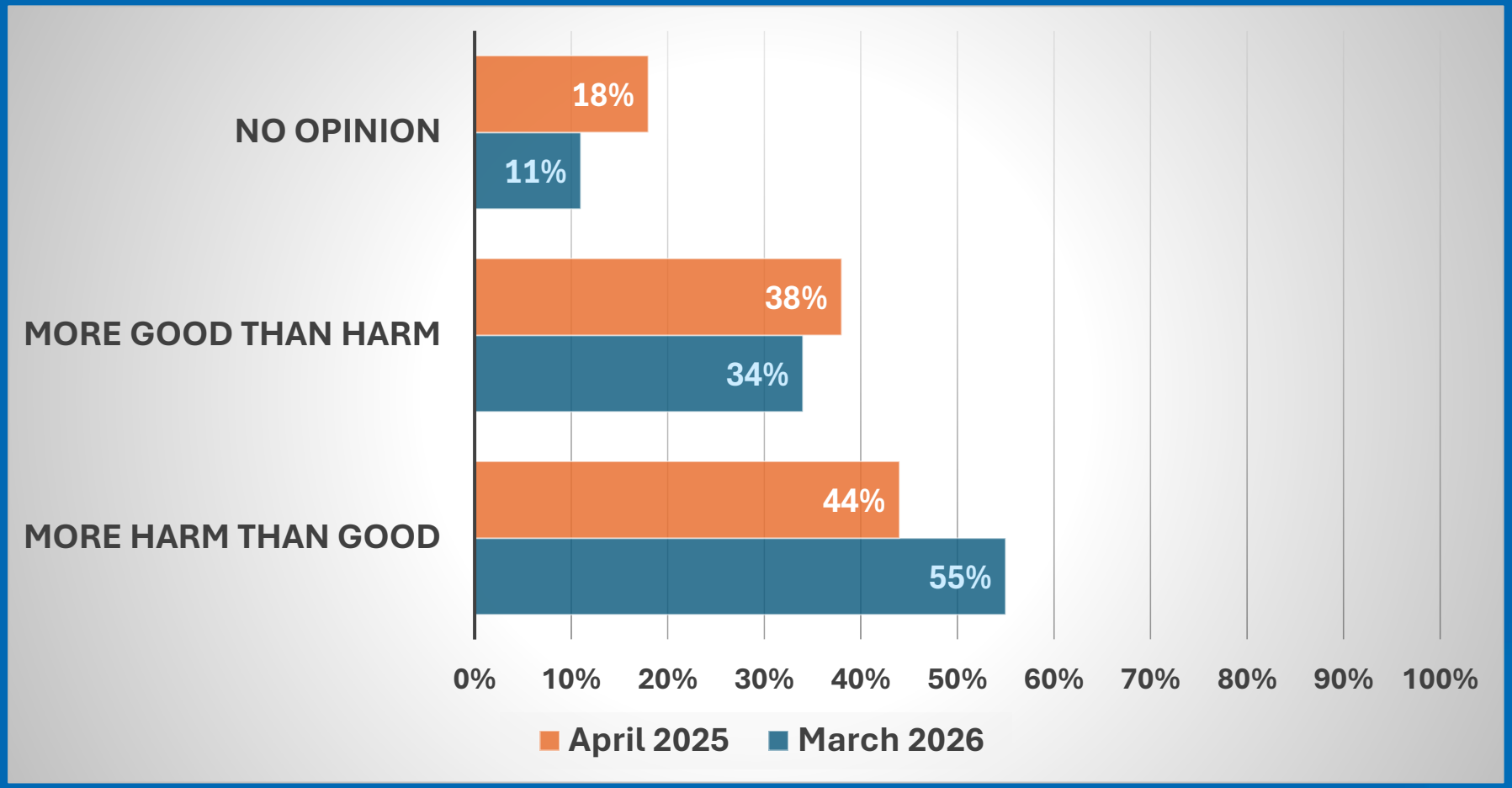
AI Sentiment: Excitement vs Concern



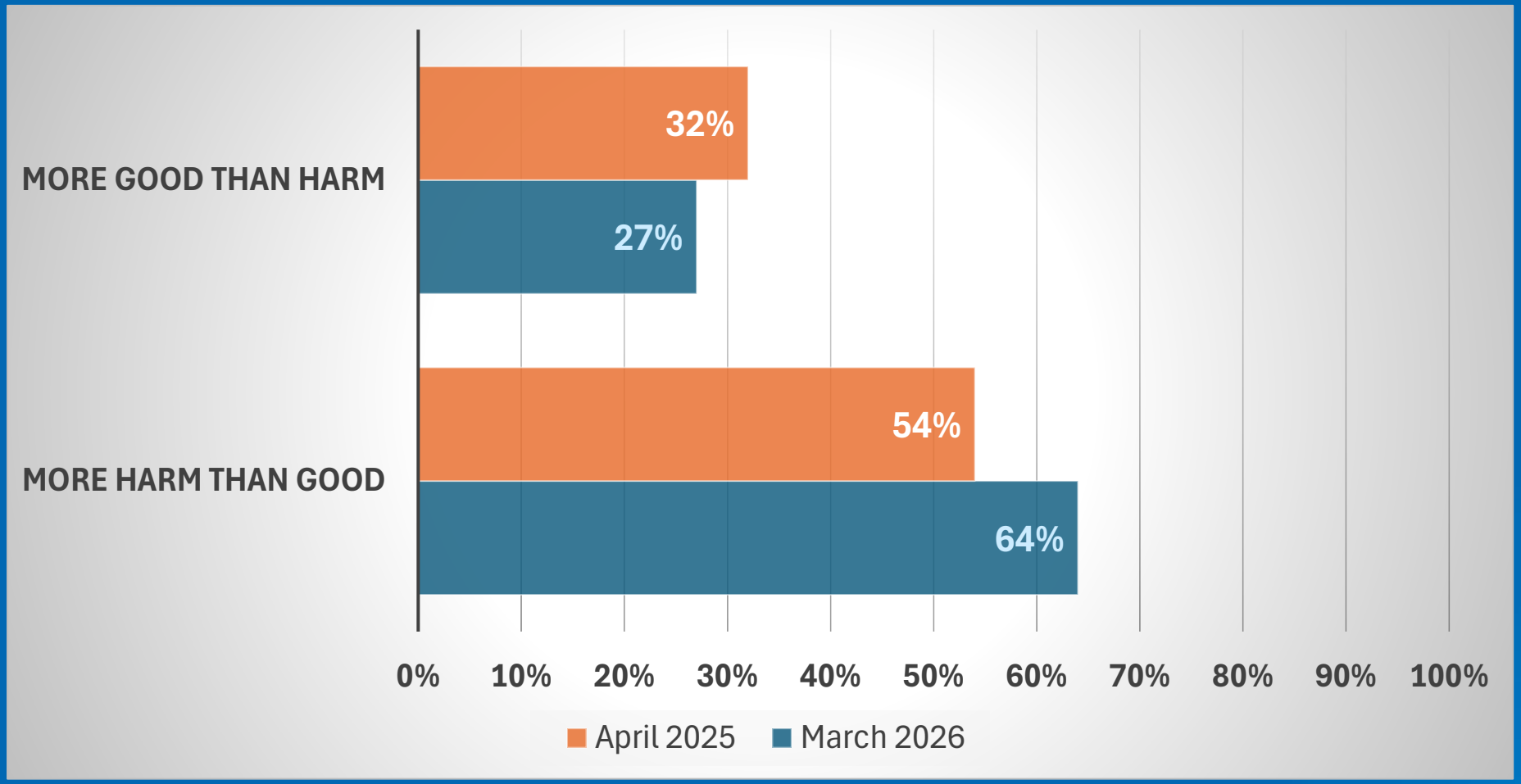
Concern by Age Group



Impact: Day-to-Day Lives

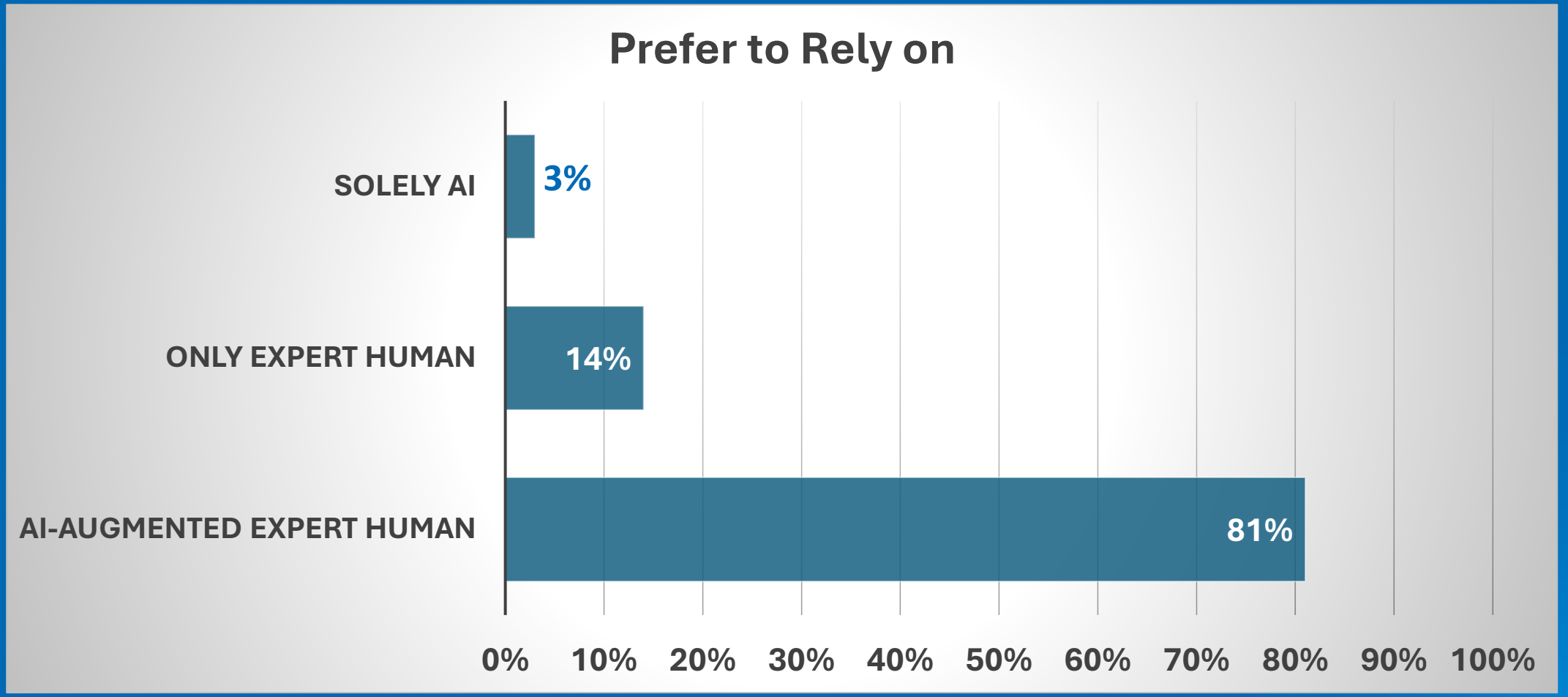


Impact: On Education

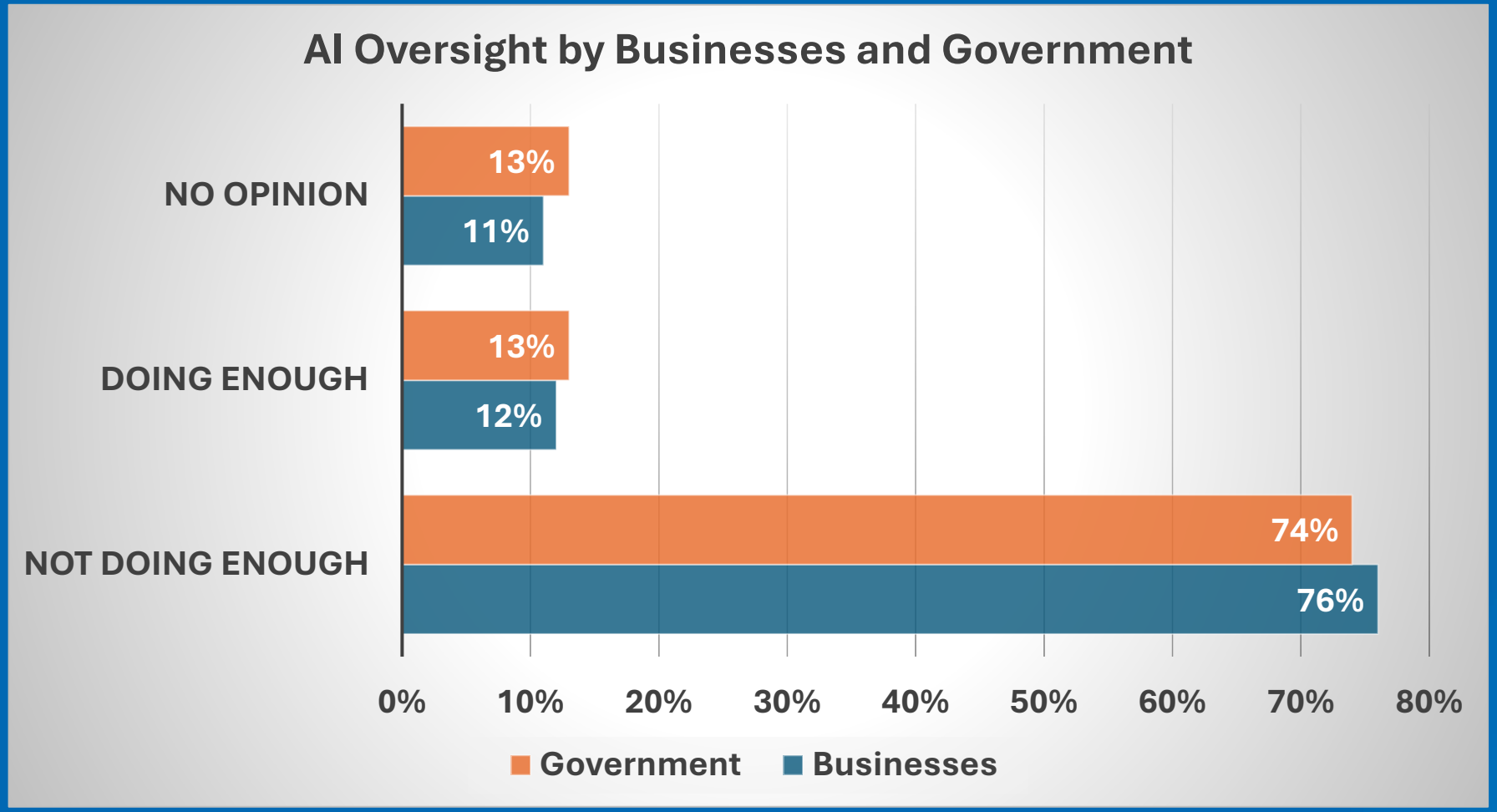


Health Care: Human vs. AI

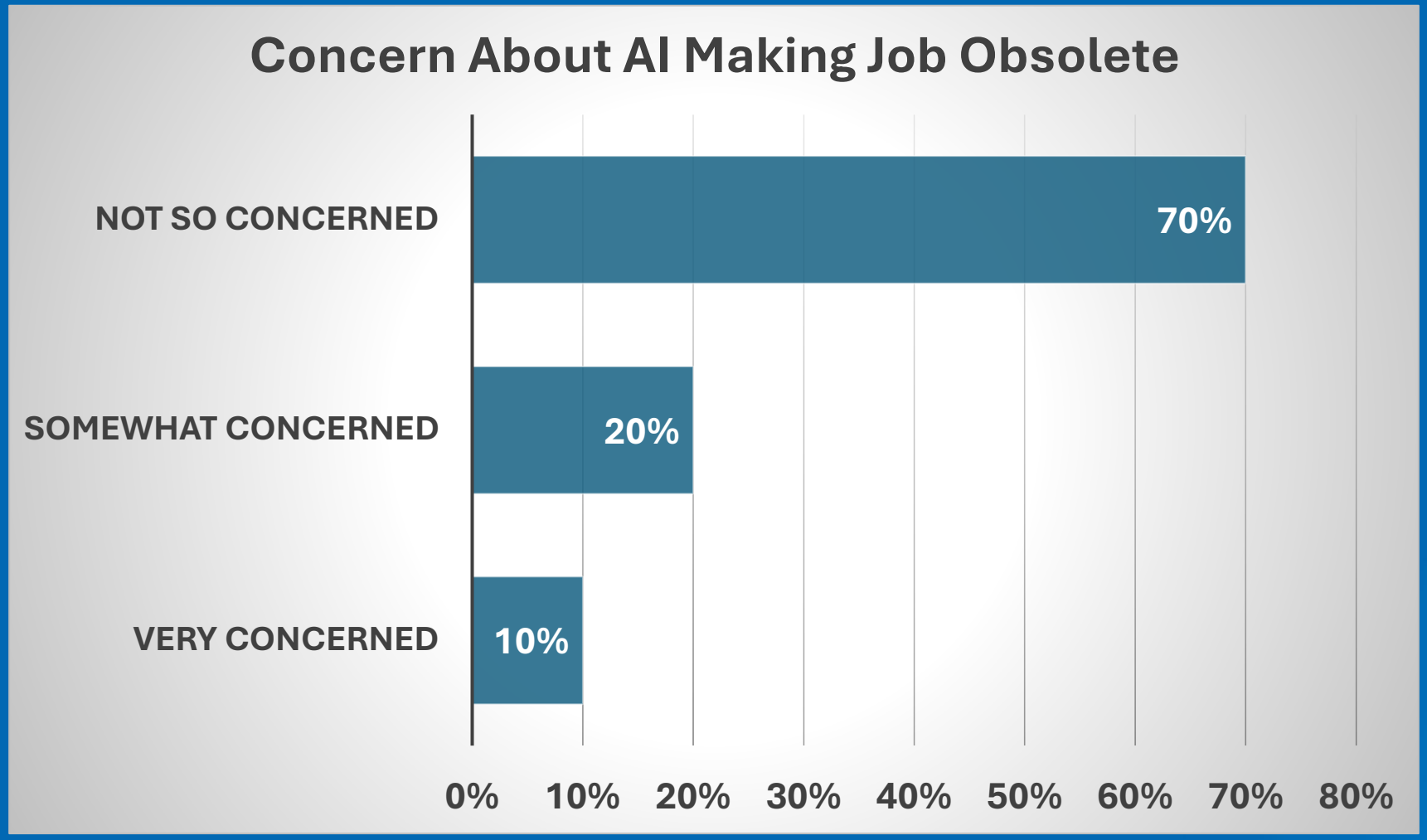
"If an AI tool proven more accurate than a human in reading medical scans"



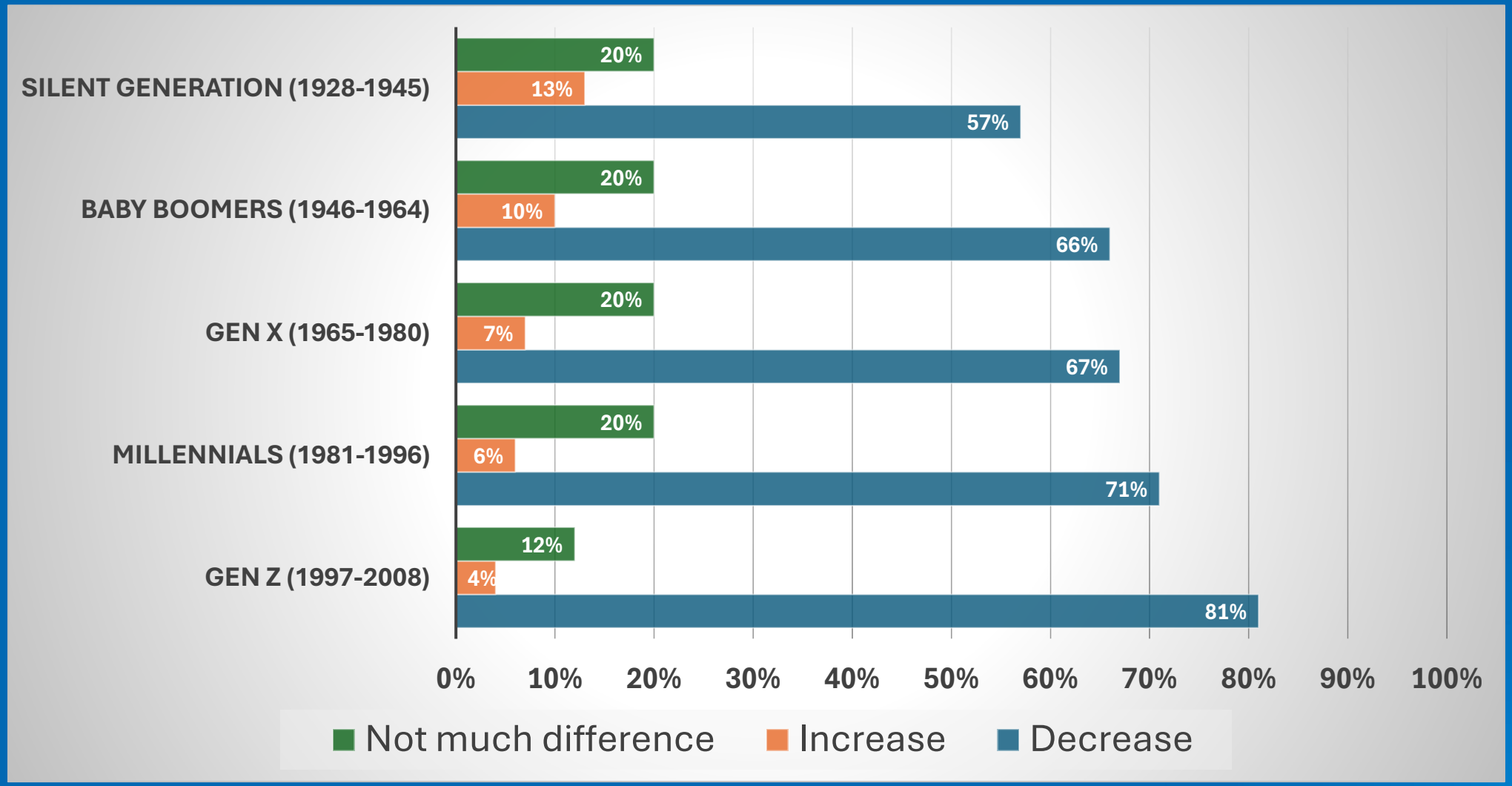
Transparency & Regulation Sentiment



Jobs Outlook: Among Those Employed



Jobs Outlook: Job Opportunities



Lessons from History About Transformative Technology

Every era of technological change has followed a recognizable pattern

The future could be less frightening than it seems with **deliberate, thoughtful leadership**

Fear Is Rational

Every major technology caused genuine concern in early stages

Fear has never successfully stopped transformative technology

Societies adapt, safeguards emerge

What once felt threatening becomes ordinary

The Worst Predictions are Less Likely to Materialize

Steam: Machines will replace all labor

Electricity: The Invisible Killer

Automobiles: Speed panic and leg atrophy

Television: Families will stop talking

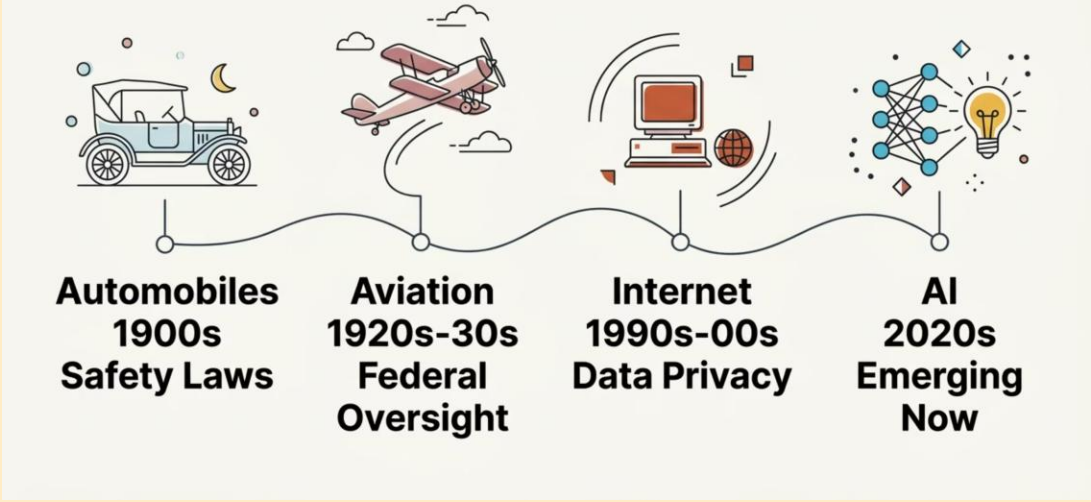
Internet: The end of community

Regulation Follows — and it Matters

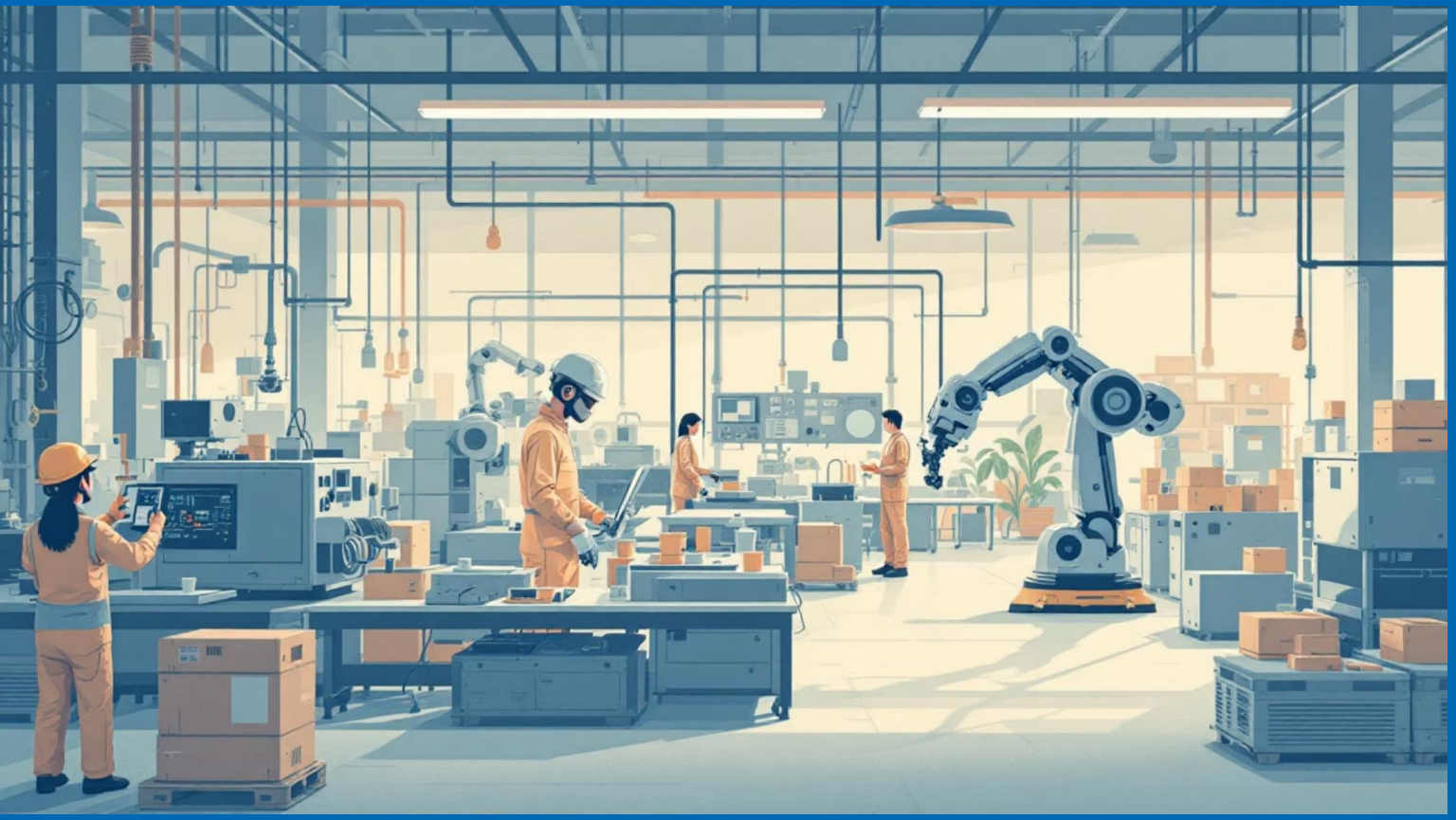
Every transformative technology was eventually regulated

The question was never *whether* to regulate, but **how wisely to do it, and how quickly**

The goal is smart governance, not a choice between nothing and prohibition



Job Losses Were Often Overestimated



New technology eliminates certain roles

It also **creates entirely new categories of work** that couldn't have been imagined beforehand

The net outcome, across every major technological wave in history, has consistently been new industries and different work

Integration Takes Longer Than Expected

Electricity, and the internet each took **20–40 years** to fully reshape the economy and impact productivity

While AI access/use is growing rapidly, real impact/productivity will likely unfold over the next decade, not overnight

An **intentional** and **thoughtful** approach to **adoption** has consistently demonstrated to be more effective than impulsive reactions

Leadership in the Eye of the Storm

Creating Calm When Others Panic

Bring focus to what really matters:

What is the problem we're trying to solve?

Emotional contagion - Leaders set the tone for their teams

- Calm decision-making
- Ethical accountability
- Steadiness in chaos

Marcus Aurelius
121-180 AD

Charting the Course

Our Ongoing Efforts & Areas of Focus

AI Awareness Programs

Create shared language and guardrails for responsible AI use

AI augments expert decision-making – it does not replace it

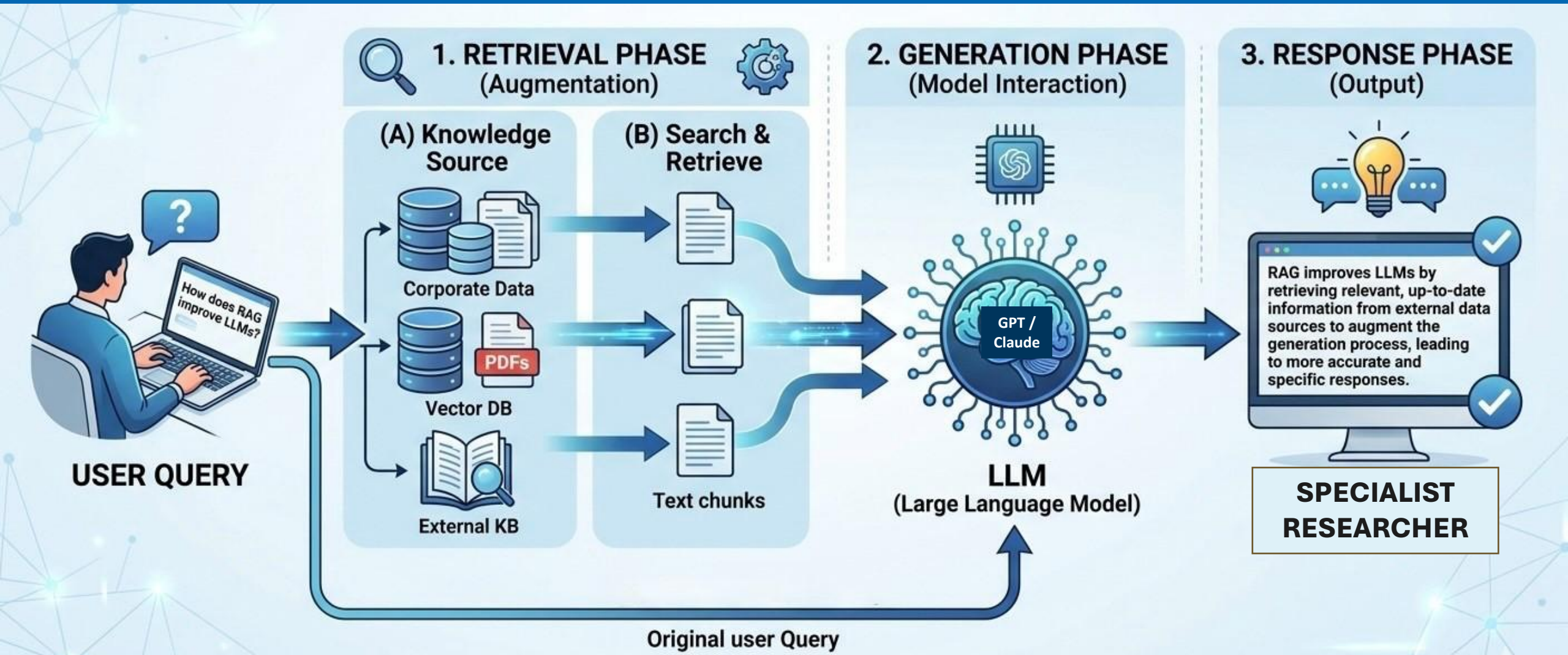
Risks	Controlled Adoption	AI Fundamentals
• Hallucinated content • Privacy exposure • Intellectual property • Ensuring expert human oversight	• Pilot programs • Governance • AI awareness programs • AI fundamentals • Focus on augmented expert decision-making	• Generative AI (GenAI) • Predictive AI (PredAI) • Agentic AI • Retrieval-Augmented Generation (RAG) / Model Context Protocol (MCP)

Expert-Human-in-the-Loop accountability for all material decisions

AI Landscape: Predictive - Generative - Agentic

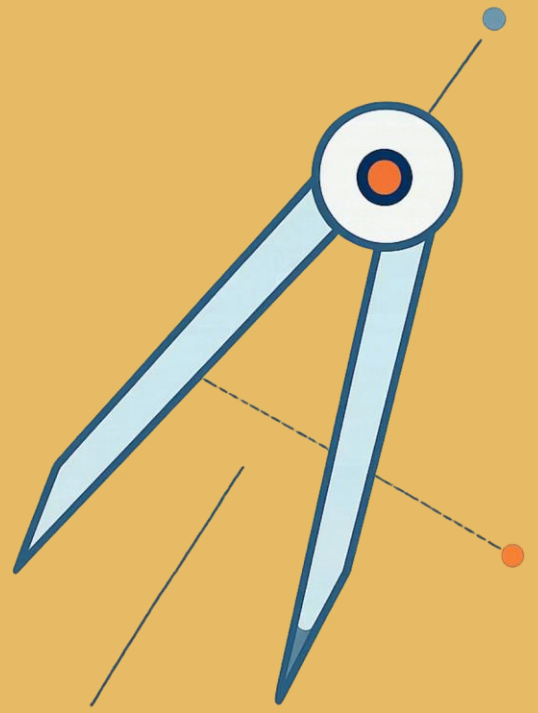
CATEGORY	PRIMARY STRENGTH	TYPICAL OUTPUTS	KEY RISKS	BEST CONTROLS
Predictive AI (ML)	Forecasting from historical data	Risk scores, probabilities, classifications	Bias, drift, overfitting, poor generalization	External validation, monitoring, model documentation
Generative AI (LLMs)	Language and content generation	Drafts, summaries, code scaffolds, Q&A	Hallucinations, privacy/IP leakage, prompt sensitivity	RAG grounding, human-in-the-loop review, data controls
Agentic AI	Multi-step task execution across tools	Automated workflows, tool calls, plans + actions	Silent failures, tool misuse, permission creep	Role-based access, audit logs, constrained agent roles

Retrieval-Augmented Generation (RAG) Workflow



Statistical Sciences in the Design of Operations: Predictable Performance

Proactive statistical engagement transforms trial execution — from reactive problem-solving to proactive, measurable control of timelines and quality



SCT | 47TH ANNUAL MEETING

Statistical Innovation in Clinical Trial Operations

Business impact: 53% (2012) and 37% (2023) of trials failed to enroll on time globally*, driving costly extensions and added sites; clinical trial drug supply waste is estimated around 50%**.

Approach: Statistical sciences can bring forecasting, uncertainty quantification, simulation-guided and decision analytics to reduce delays and inefficiency in trial execution.

*Lamberti, M. J., Dirks, A., Kikuchi, N., et al. (2024). Benchmarking site activation and patient enrollment. *Therapeutic Innovation & Regulatory Science*, *58*, 696–703. https://doi.org/10.1007/s43441-024-00638-1

**McKinsey & Company. (2021). *Clinical supply chains: How to boost excellence and innovation*. https://www.mckinsey.com/industries/life-sciences/our-insights/clinical-supply-chains-how-to-boost-excellence-and-innovation

Missed Timelines & Inferential Challenges

Beyond execution problem: Operational variability propagates directly into statistical issues. Track **distributions**, not just averages:

- Activation cycle
- Accrual vs. forecast
- Missing data
- Endpoint tracking

Practical Engagement Model

Stats + Ops + Site Monitoring

Design

Accrual assumptions & uncertainty; power / timeline trade-offs; missing data prevention strategy

Start-Up

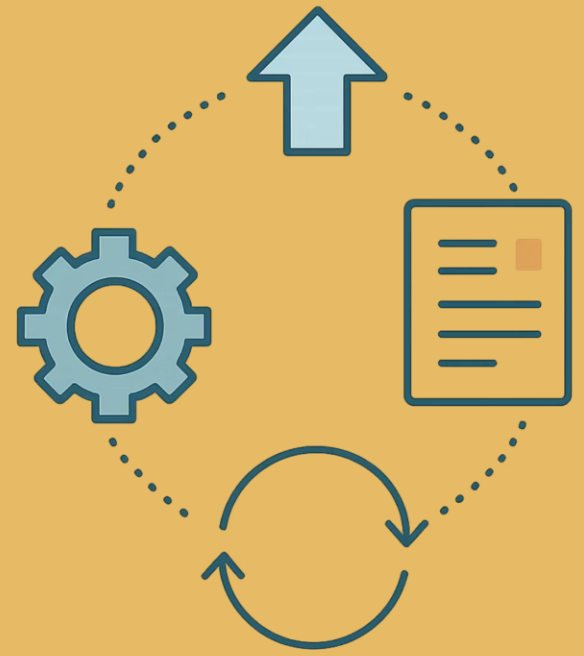
Site selection using empirical priors; readiness

Conduct

Ongoing accrual forecasting; KRIs/KQIs; QbD: predefined mitigation triggers and impact estimates

Close-Out

Assess operational learnings; update empirical priors for the next study



Tighter forecast error, fewer avoidable missing data events and deviations, earlier mitigation, and stronger evidentiary confidence for regulators and decision-makers.

Dashboards, Early Detection, and Risk-Based Quality

Visibility

A single source of truth for accrual, data timeliness, deviations — accessible to stats, operations, and sites

Statistical Signal Detection

Key Risk Indicators, and trend detection convert raw data into timely actionable measures

Risk-Based Quality Alignment

Define critical-to-quality factors, measurement plans, and escalation rules that are inspectable / reproducible.

Patient-centric Design

- Protocol complexity & patient burden assessment
- Schedule of Activities (SoA) designer

Site-Friendly Design

Actionable indicators at the coordinator level — e.g., *"patients at risk of missed visits in the next 14 days."*

Protect the Estimand

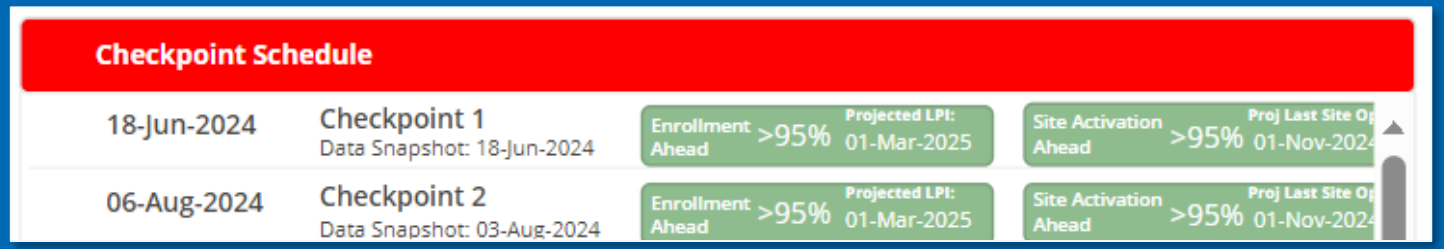
Monitor visit adherence, EDC lag, critical data fields.

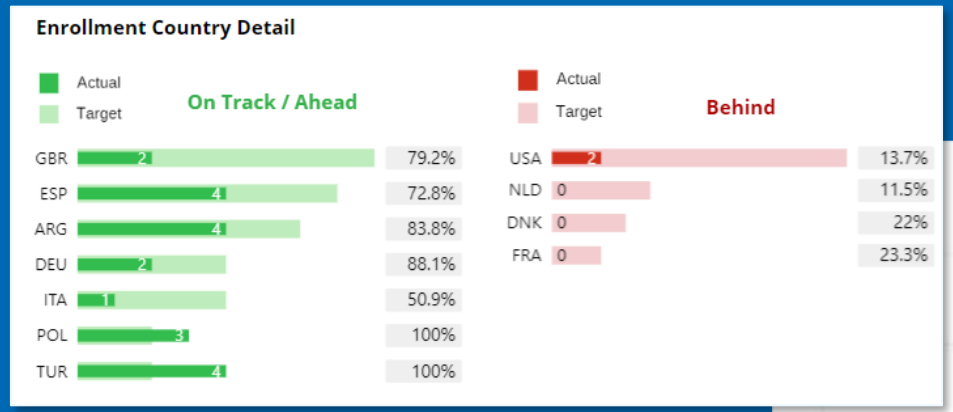
Trigger site support **before** data become irrecoverable.

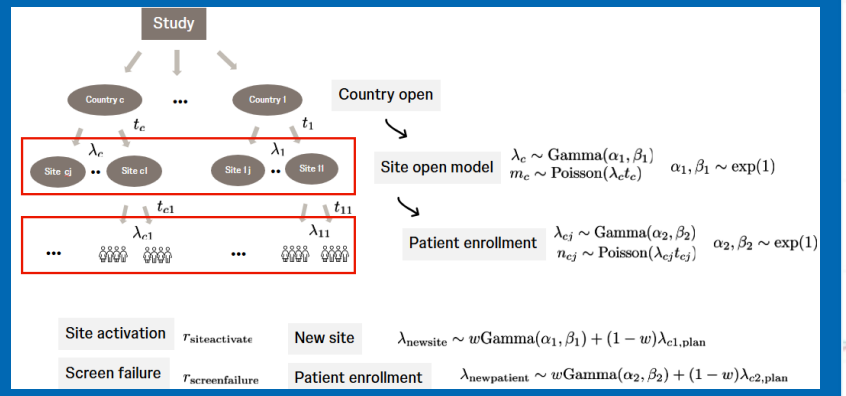
Operational Viability and Planning (OVAP)

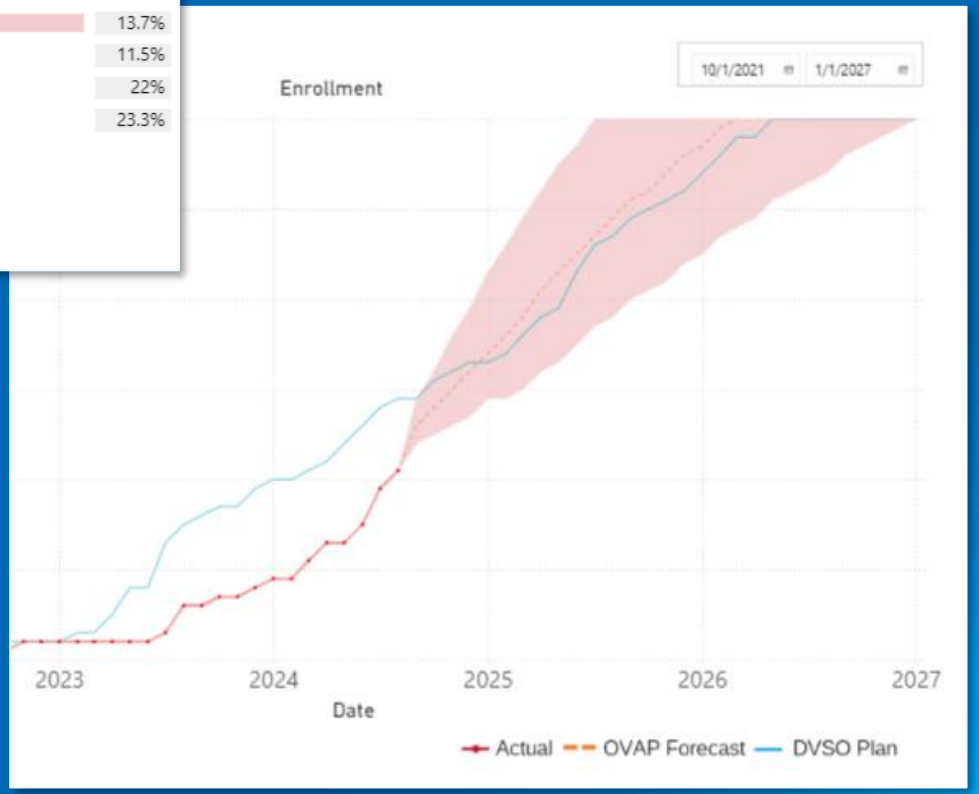
What it does:

- Highlight recruitment risks and pre-identify opportunities for mitigations
- Study health checkpoints with a foundation in statistical modelling to detect material impacts to LPI
- Actuals and projected enrollment curves with confidence intervals
- Likelihood of operational execution success (meeting LPI & enrollment targets)
- Country level tracking and monitoring; drug supply module
- Gamma-Poisson distribution





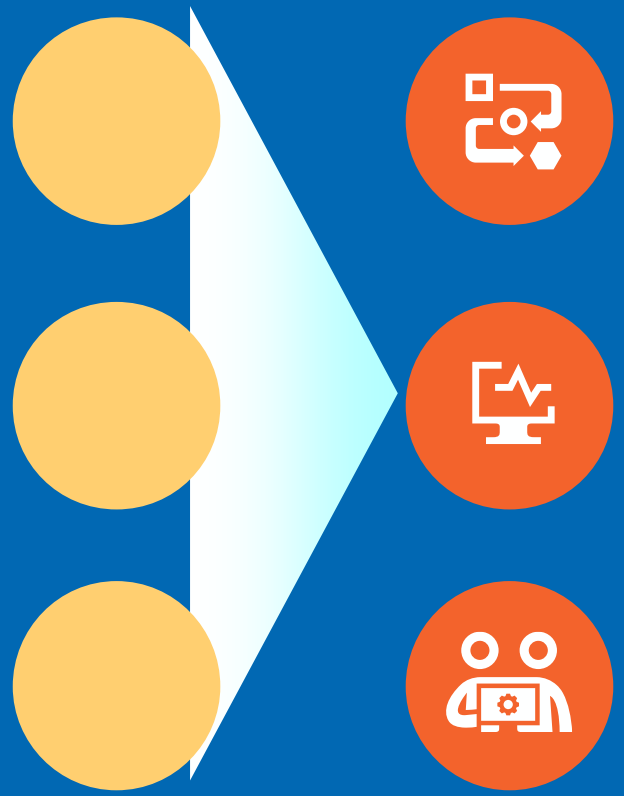




SCT | 47TH ANNUAL MEETING

Clinical Studio: Enhancing clinical trial productivity through data-driven decision making

Challenge	Solution
Costly and Complex Trials Increasing **costs**, **complexity**, **patient burden** and **site burden**	**Productivity Enablement** Develop fit-for-purpose protocols considering cost, complexity, and **burden trade-offs**
Lack of Transparent Decision-Making **Siloed data** hinders ability to tie **decisions to rationale**, **outcomes** and **future learnings**	**Integrated User Experience** Facilitates **scenario creation** and increases **transparency**
Inconsistent & Subjective Process Inconsistency in **contingency planning** and **timeline expectations** with limited **accountability** for site selection decisions	**Cross-Functional Collaboration** Support **shared decision making** and **clear accountability**



SCT | 47TH ANNUAL MEETING

Efficiency+

Cross-Industry Collaboration: Enhancing Clinical Trial Efficiency Through Advanced Statistics and AI

ASA BIOP Scientific Working Group: Efficiency+

Formed as an ASA Biopharmaceutical Section Scientific Working Group (2025) to create a statistical community focused on trial operational efficiency

Mission: Advance statistical innovations in trial operations to increase efficiency via cross-pharma, interdisciplinary research

- Share methods
- Identify gaps
- Reduce waste
- Accelerate “lab to patient”

ASA BIOP Scientific Working Group: Efficiency+

- 30+ members, 10+ Sponsors
- Cross-pharma, cross-functional collaborative research:
  statistics + clinical ops + supply chain + data management + regulatory planning:
  - Design of Operations
  - Recruitment
  - Trial Monitoring
  - Clinical Supply Chain

https://efficiencyplustrials.github.io

Efficiency+ Areas of Focus

Recruitment Monitoring/ Forecasting & Site Selection	Dynamic Trial Monitoring & Data Quality	Study Design  Operations Impact	Clinical Supply Chain
Vlad Anisimov (Amgen) **Clara Cali Mella** (Bayer)	**Palanikumar Ravindran** (BMS)	**Dooti Roy** (Boehringer Ingelheim)	**Christi Kleoudis** (AstraZeneca)

Efficiency+ Areas of Focus

Recruitment Monitoring/ Forecasting & Site Selection

Vlad Anisimov (Amgen)
Clara Cali Mella (Bayer)

Models utilizing historical, real-world, and accumulating trial data

Predictive site selection
(Poisson-Gamma approaches)

Clinical Supply Chain

Christi Kleoudis (AstraZeneca)

Efficiency+ Areas of Focus

Recruitment Monitoring/ Forecasting & Site Selection

Vlad Anisimov (Amgen)
Clara Cali Mella (Bayer)

Dynamic Trial Monitoring & Data Quality

Palanikumar Ravindran (BMS)

AI/ML + statistical signals for real-time risk detection

Underperforming-site identification

Dropout prediction, proactive oversight

Efficiency+ Areas of Focus

Quantify innovative designs (adaptive/platform/seamless) impact on timelines/resources

Operational realities informing design choices

Study Design

Operations Impact

Dooti Roy
(Boehringer Ingelheim)

Clinical Supply Chain

Christi Kleoudis
(AstraZeneca)

Efficiency+ Areas of Focus

Recruitment Monitoring/ Forecasting & Site Selection

Vlad Anisimov (Amgen)
Clara Cali Mella (Bayer)

Simulation-based drug demand forecasting

Vial/kit optimization & waste reduction

Potential multimillion-dollar impact per program

Clinical Supply Chain

Christi Kleoudis (AstraZeneca)

Expanding Collaboration

Invitation to connect

Regulators, clinical operations professionals, and statisticians/data scientists with Bayesian, AI/ML, simulation, or supply chain analytics experience.

Contact **fchen6@its.jnj.com**, or
visit **efficiencyplustrials.github.io**

Agentic AI–Enabled Clinical Trial Design & Simulation

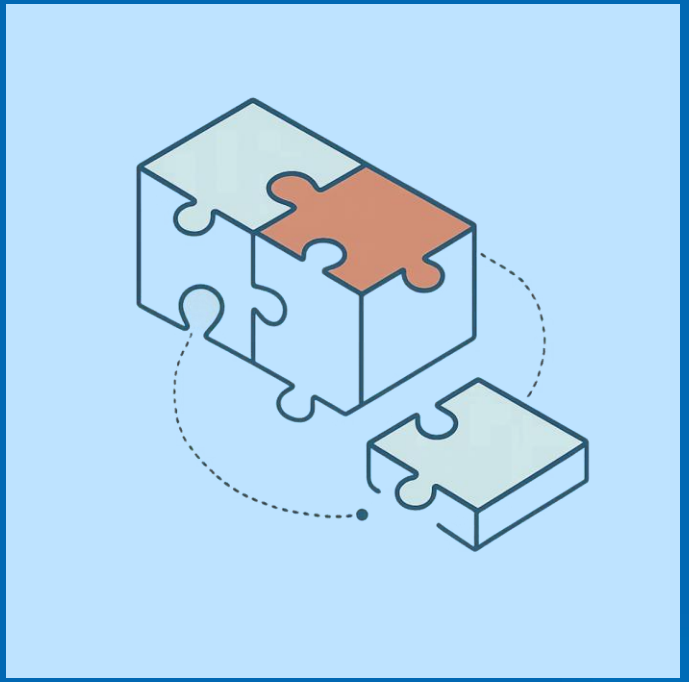
A modular, integrated simulation architecture consolidating trial design, operational parameters, uncertainty modeling, and regulatory readiness within a comprehensive, reproducible decision support system — transforming the planning, evaluation, and justification of clinical trials

Orchestrating evidence synthesis, uncertainty quantification, and adaptive trial optimization

SCT | 47TH ANNUAL MEETING

The Case for Integration

Clinical trial decisions require **simultaneous consideration** of statistics, operations, and regulation — yet existing workflows remain fragmented across tools, teams, and misaligned assumptions.



Integrated Evaluation

Design, ops, and regulatory views unified in one platform

Reproducibility

Full transparency and auditability across all runs

Modular Architecture

Extensible across phases and study archetypes

Why Agentic AI for Clinical Trial Design?

The Challenge

Trial design integrates evidence synthesis, uncertainty analysis, simulation, and regulatory trade-offs — each a specialist task

Fragmented Workflows

Prior elicitation/MBMA, power calculations, simulation, and reporting: Siloed tools and teams

Assumption Opacity

Key design assumptions (effect size, drop-out rates, variability) are often inadequately substantiated

Lack of Optimization

Re-running simulations for each design scenario; designs are rarely optimized vis-à-vis clinical operations parameters

Uncertainty Overlooked

Point estimates are used where distributions should drive scenario analyses

Regulatory Risk / PoS

Justification for the proposed designs; costly late-stage failures

Reproducibility Gaps

Hand-offs between statisticians, PMX modelers, and clinicians

Clinical Trial Design End-to-End Agentic Orchestration

Orchestrator Agent — Plans · Delegates · Monitors · Synthesizes · Delivers

Evidence Synthesis	Assumption Framework	Trial Simulation	Design Evaluation	Design Optimization	Report & Rationale
Literature Review/ MBMA	Priors + Distributions	Scenario Generation	OC Assessment	Adaptive Refinement vis-à-vis Operational Parameters	Regulatory package

Sub-Agents: MBMA Agent · Assumption Agent · Simulation Agent · Evaluation Agent · Optimization Agent · Reporting Agent

Expert-Human-in-the-Loop checkpoints after evidence synthesis, assumption finalization, and design selection

Clinical Trial Design End-to-End Agentic Orchestration

Orchestrator Agent — Plans · Delegates · Monitors · Synthesizes · Delivers

Evidence Synthesis

Evidence Ingestion
Effect Size Estimation
Covariates

Literature Review / MBMA

Design Optimization

Adaptive Refinement vis-à-vis Operational Parameters

Report & Rationale

Regulatory package

Sub-Agents: MBMA Agent · Assumption Agent · Simulation Agent · Evaluation Agent · Optimization Agent · Reporting Agent

Expert-Human-in-the-Loop checkpoints after evidence synthesis, assumption finalization, and design selection

Clinical Trial Design End-to-End Agentic Orchestration

Orchestrator Agent — Plans · Delegates · Monitors · Synthesizes · Delivers

Evidence Synthesis

Literature Review/ MBMA

Assumption Framework

Treatment Effect
Placebo Response; D/O Rate
Between Patient Variability
Correlations (endpoints)

Priors + Distributions

Report & Rationale

Regulatory package

Sub-Agents: MBMA Agent · Assumption Agent · Simulation Agent · Evaluation Agent · Optimization Agent · Reporting Agent

Expert-Human-in-the-Loop checkpoints after evidence synthesis, assumption finalization, and design selection

Clinical Trial Design End-to-End Agentic Orchestration

Orchestrator Agent — Plans · Delegates · Monitors · Synthesizes · Delivers

Evidence Synthesis

Literature Review/ MBMA

Assumption Framework

Priors + Distributions

Trial Simulation

Design Library
Simulation Engine
Uncertainty Propagation

Scenario Generation

Sub-Agents: MBMA Agent · Assumption Agent · Simulation Agent · Evaluation Agent · Optimization Agent · Reporting Agent

Expert-Human-in-the-Loop checkpoints after evidence synthesis, assumption finalization, and design selection

Clinical Trial Design End-to-End Agentic Orchestration

Orchestrator Agent — Plans · Delegates · Monitors · Synthesizes · Delivers

Evidence Synthesis

Literature Review/ MBMA

Assumption Framework

Priors + Distributions

Design Evaluation

Type I error
Expected Power
Assurance
Design Metrics

Operating Characteristics Assessment

Sub-Agents: MBMA Agent · Assumption Agent · Simulation Agent · Evaluation Agent · Optimization Agent · Reporting Agent

Expert-Human-in-the-Loop checkpoints after evidence synthesis, assumption finalization, and design selection

Clinical Trial Design End-to-End Agentic Orchestration

Orchestrator Agent — Plans · Delegates · Monitors · Synthesizes · Delivers

Evidence Synthesis

Literature Review/ MBMA

Assumption Framework

Priors + Distributions

Design Optimization

Enrollment Rate
Regional Representation
Budget
Regulatory Min F/U

Adaptive Refinement vis-à-vis Operational Parameters

Sub-Agents: MBMA Agent · Assumption Agent · Simulation Agent · Evaluation Agent · Optimization Agent · Reporting Agent

Expert-Human-in-the-Loop checkpoints after evidence synthesis, assumption finalization, and design selection

Clinical Trial Design End-to-End Agentic Orchestration

Orchestrator Agent — Plans · Delegates · Monitors · Synthesizes · Delivers

Evidence Synthesis

Literature Review/ MBMA

Assumption Framework

Priors + distributions

Report & Rationale

Design Rationale
SAP
Dose PK/PD
Simulation Reports
Protocol Synopsis

Regulatory package

Sub-Agents: MBMA Agent · Assumption Agent · Simulation Agent · Evaluation Agent · Optimization Agent · Reporting Agent

Expert-Human-in-the-Loop checkpoints after evidence synthesis, assumption finalization, and design selection

Data Review and Monitoring

Clinical Data Review Environment: Current

Data review distributed across multiple roles with several supporting applications detecting outliers and anomalies

Applications generate efficiencies in review and cleaning activities **at individual role level**

Multiple roles generating multiple queries of limited value on the same datapoint

Increasing site burden, delays in database locks

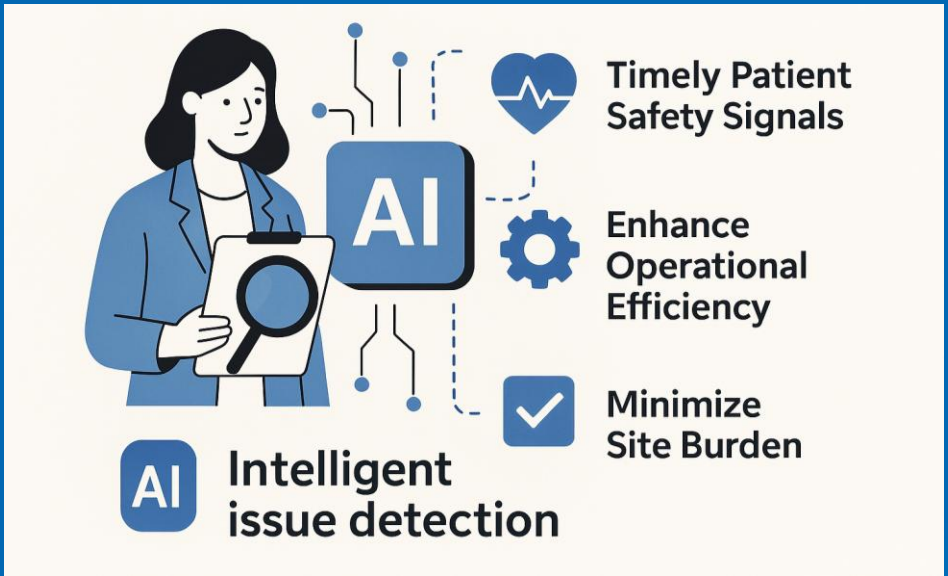
Future-State Data Review and Monitoring

AI-Enabled Capabilities

- Next-Gen Central Statistical Monitoring (CSM)
- Next-Gen Query Generation & Management

Core Requirements

- Connected Data Layer
- Expertise / Decision Rights
- Consistent Risk-Based Workflows



- ✓ Improved patient safety
- ✓ Improved data quality
- ✓ Reduce duplicate query generation
- ✓ Reduce site burden
- ✓ Enhanced compliance

From Traditional Roles to New AI & Human **Personas**

Virtual Monitoring Partner (VMP)
AI flags emerging RBQM signals; Clin Ops / Clin Sci determine actions

Adaptive Cleaning Orchestrator (ACO)
ACO proposes resolutions with traceability based on strategy set by expert data manager, who also provides contextual validation

Human-in-the-loop accountability
Experts validate AI outputs, adjudicate risk, and approve final data and decisions

The Leadership Compass

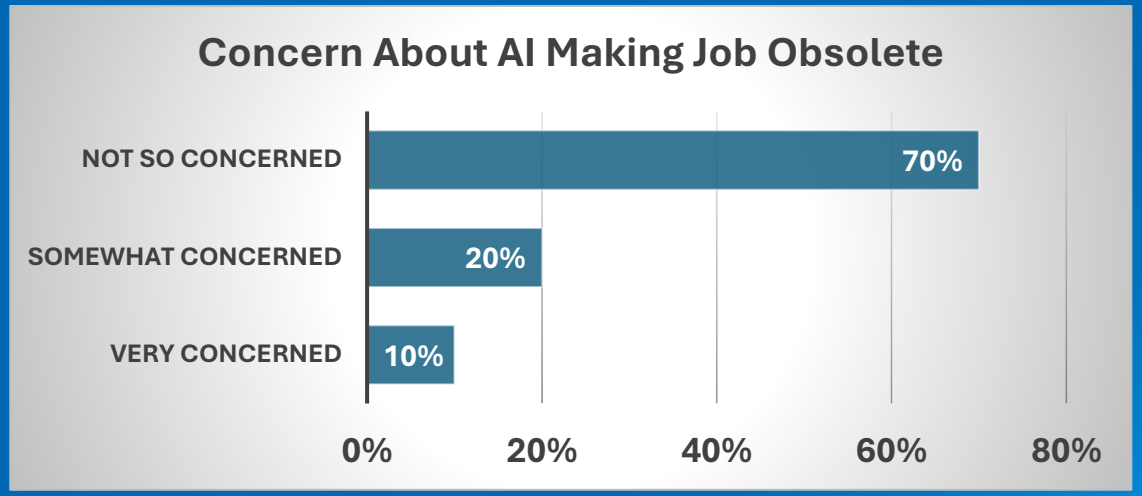
Guiding Responsible AI Adoption

Fear of Becoming Obsolete (FOBO)

FOBO is rising: ~30% of U.S. workers believe they could be made professionally obsolete

Early-in-career workers feel it more

Can drive disengagement, reduced productivity, and helplessness when critical thinking is most needed for innovation



Why AI Adoption Stalls

Widespread AI use, disappointing returns

Usage without real commitment ≠ Adoption

Psychological/contextual challenge, not technical

The Belief-Anxiety Paradox

Erin Eatough, Keith Ferrazzi, Wendy Smith and Shonna Waters, Harvard Business Review. Feb 17, 2026

The Contrasting Duality

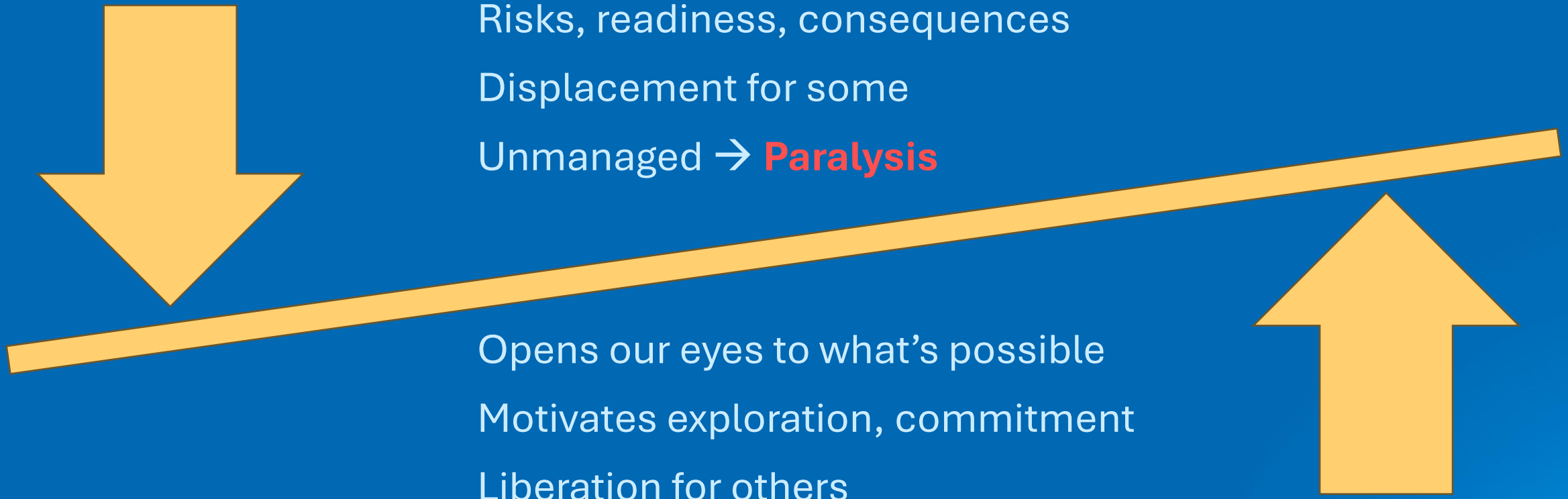
Apprehension

Keeps us from walking off a cliff

Risks, readiness, consequences

Displacement for some

Unmanaged → **Paralysis**



Opens our eyes to what's possible

Motivates exploration, commitment

Liberation for others

Unchecked → **Reckless adoption**

Excitement

Harnessing the Tension

Psychological Safety
Acknowledge both reactions openly

Tension as a signal
Address constructively

Dangerous Adopters
Those who feel only one of the two

Move faster, sustainably
Normalize “I’m excited and concerned”

Establishing a “North Star”

Augmentation as Copilot ***Amplifying Human Skills*** Reinforce: Value comes from human + AI partnership, not replacement	**Realistic Timeline** Change is significant but not instantaneous
Entry-level positions Redesign work (AI-enabled) / protect development opportunities	**Industry – Academia Partnership** Education and training of *Next-Gen* Leaders
Reskilling / Upskilling Visible and accessible learning pathways Aligned training to roles and progression	**Mutual Mentoring** Pair “early-in-career” talent with experienced tenured SMEs/leaders

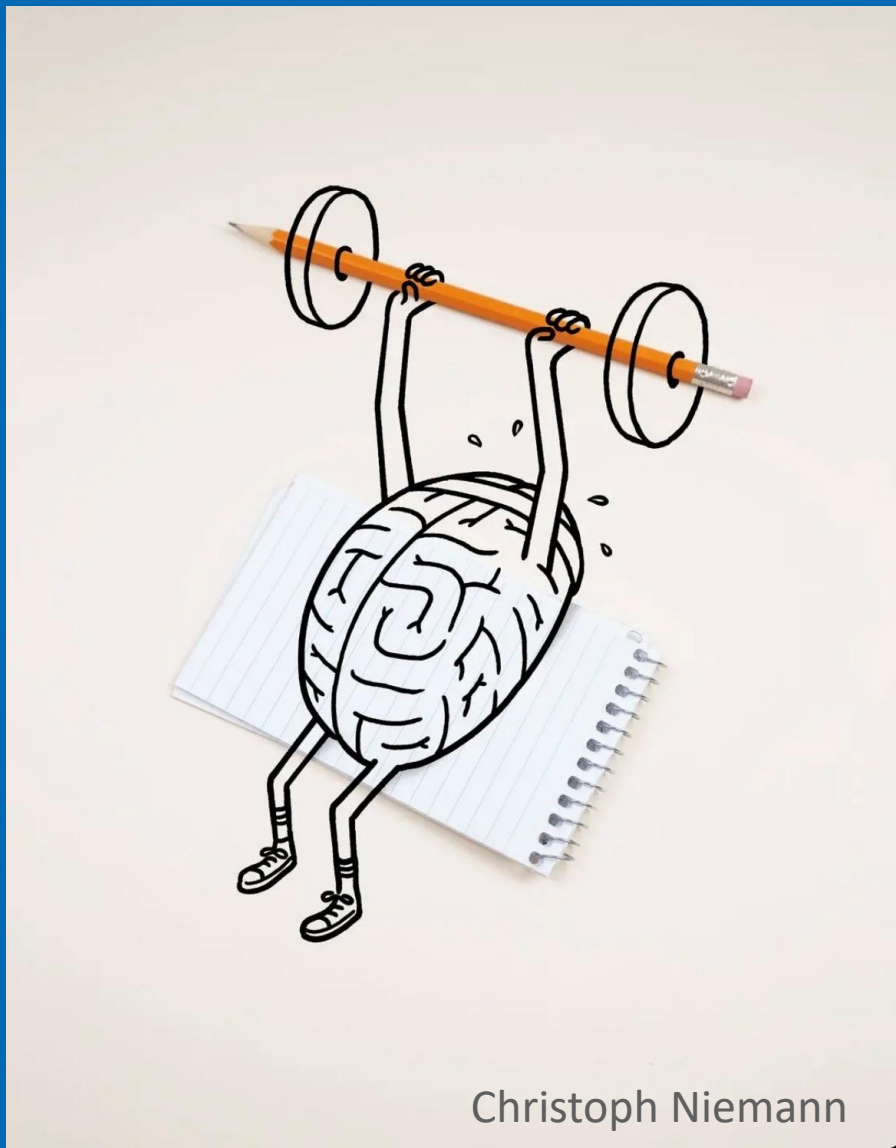
AI & Cognitive Health

OPINION
GUEST ESSAY

There's a Good Reason You Can't Concentrate

Cal Newport's article extends his earlier work on "deep work" to argue that we are no longer merely distracted — we are losing the capacity for deep thinking itself. AI tools, particularly large language models, are now a central part of this concern.

New York Times (March 27, 2026)



Christoph Niemann

Principles for Responsible Use of AI

Protect Cognitive Autonomy	• AI Should augment human thinking, not replace it • Humans make decisions
Audit AI Touchpoints for Cognitive Impact	• Assess whether they are replacing or supporting human cognition/decision-making
Prioritize Transparency and Public Education	• Communicate clearly about AI's cognitive risks – not just its productivity gains
Build for Long-term Human Capacity	• Tools should be built to scaffold human learning, not create dependency

AI poses as much of a leadership challenge as it does a technological one

Thank You