

# The Confluence of Change – AI Impact, Tactically and Strategically

## 2025 Ennov User Conference



**GENS**  
& ASSOCIATES

# Session Learning Goals

- The start of a New Era
- AI Implementation Tipping Point
- Confluence of Change
- Implications
- Our Fall Research



Steve Gens MSOD  
Managing Partner

sgens@gens-associates.com

<https://www.linkedin.com/in/steve-gens-msod-252627/>



# We have 5 interactive polls today; please have your devices handy



Join by Web [PollEv.com/stevegens478](https://PollEv.com/stevegens478) Join by Text Send **stevegens478** and your message to **22333**



## What one word would you use to describe how you feel about AI?

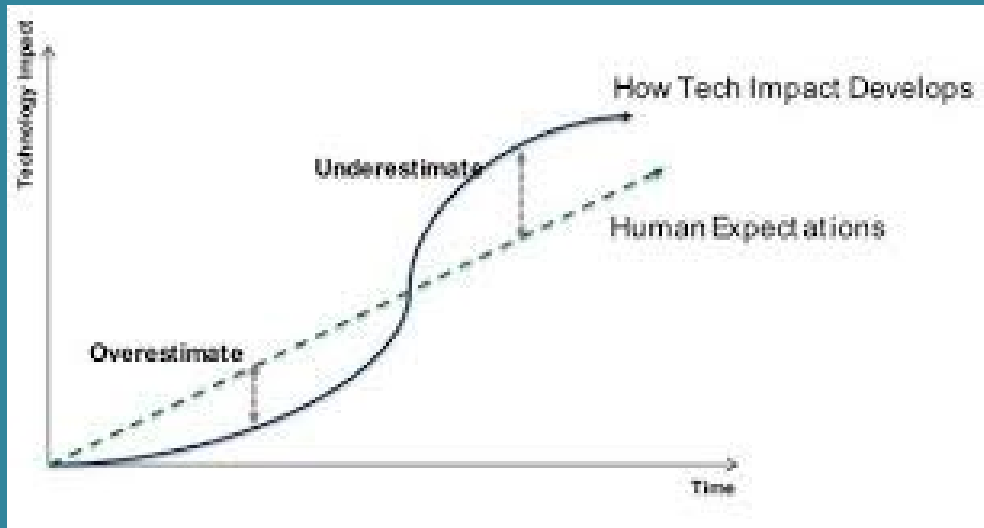
## What one word would you use to describe how you feel about AI?



# I think this fits for AI...

*Amara's Law is the basis for the Gartner Hype Curve*

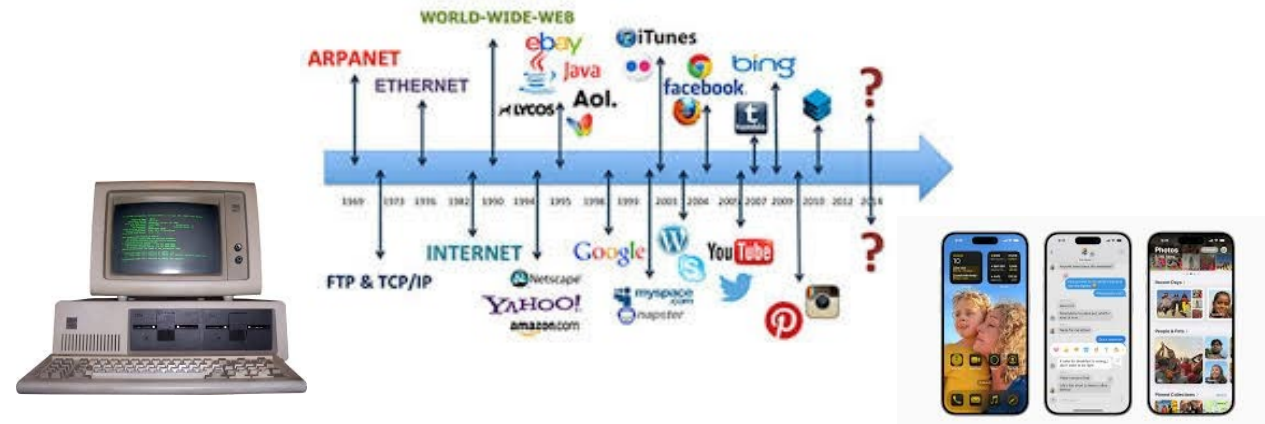
## Amara's Law



**Overestimation in the short run:** When a new technology emerges, excitement and optimistic predictions about its immediate impact often lead to unrealistic expectations.



*WE ALWAYS OVERESTIMATE THE CHANGE THAT WILL OCCUR IN THE NEXT TWO YEARS AND UNDERESTIMATE THE CHANGE THAT WILL OCCUR IN THE NEXT TEN. DON'T LET YOURSELF BE LULLED INTO INACTION.” – BILL GATES*





# What we know today....

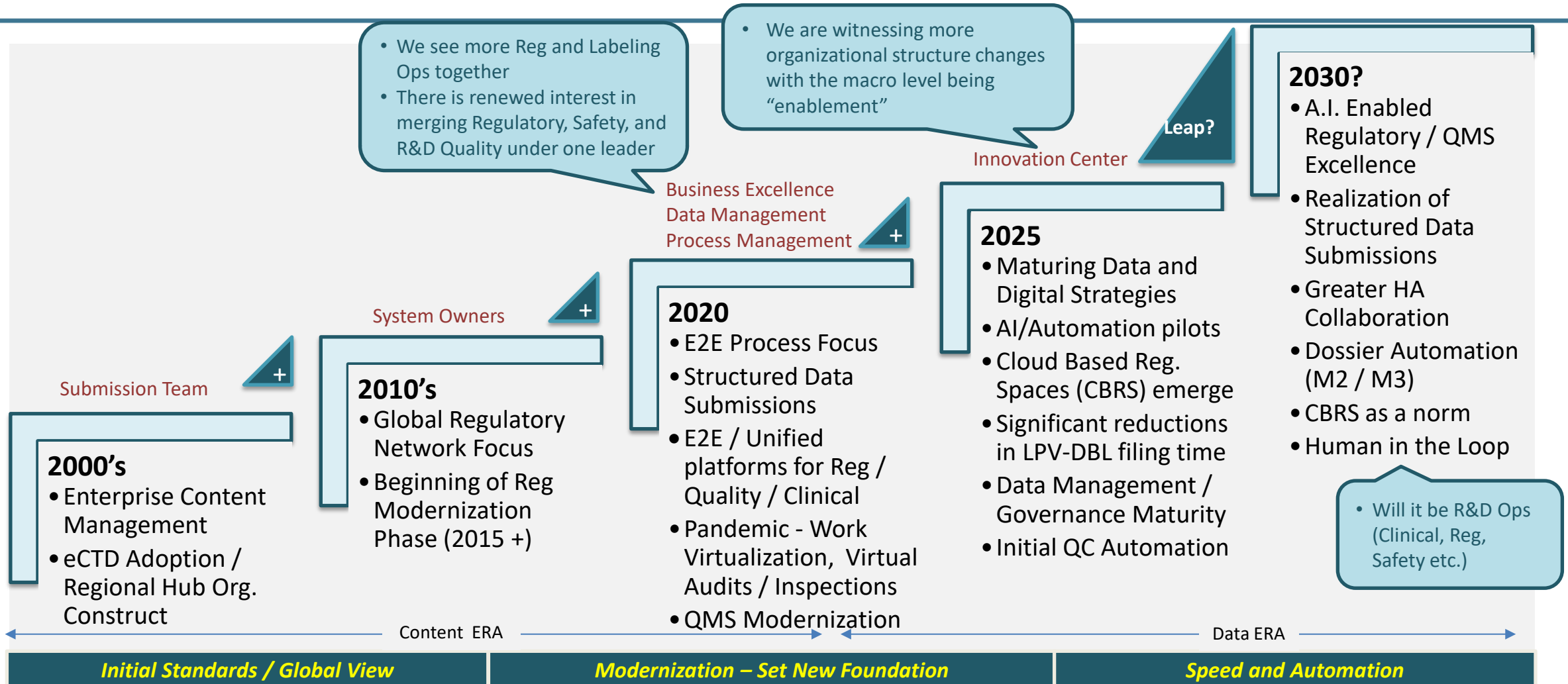
We are entering a new era, the next 2 – 3 years will bring clarity to the degree of the AI/Automation shift and impact on skills, roles, jobs

Workforce development may be challenging during this period as we “anticipate” the benefits of the AI technology shift (hypothesis vs reality)

Some organizations are mandating AI skills (e.g. prompting) and placing them in job descriptions and annual goals

Embracing this new technology is similar to other eras (e.g. office and collaboration tools) – you just need to be competent in them!

# Organization remits are rapidly evolving with many new responsibilities and evolving required skillsets



# We are now in “The Neutral Zone”: One foot in the old and one in the new!

"A change can work only if the people affected by it can get through the transition it causes successfully." – William Bridges 2003

## OLD ERA

- Global systems at the center
- Processes with many manual steps
- Inconsistent system usage and data quality challenges
  - Resource intensive analysis
- Still have those local systems, xls, SP

## Transition Period – ‘Neutral Zone’

- ✓ Old is gone, but the new way isn't fully operational
- ✓ There is a Learning Curve for new processes, methods, tools etc.
- ✓ Build expertise, confidence, and competency

***What are the emerging skills / roles that need to be considered during workforce planning?***

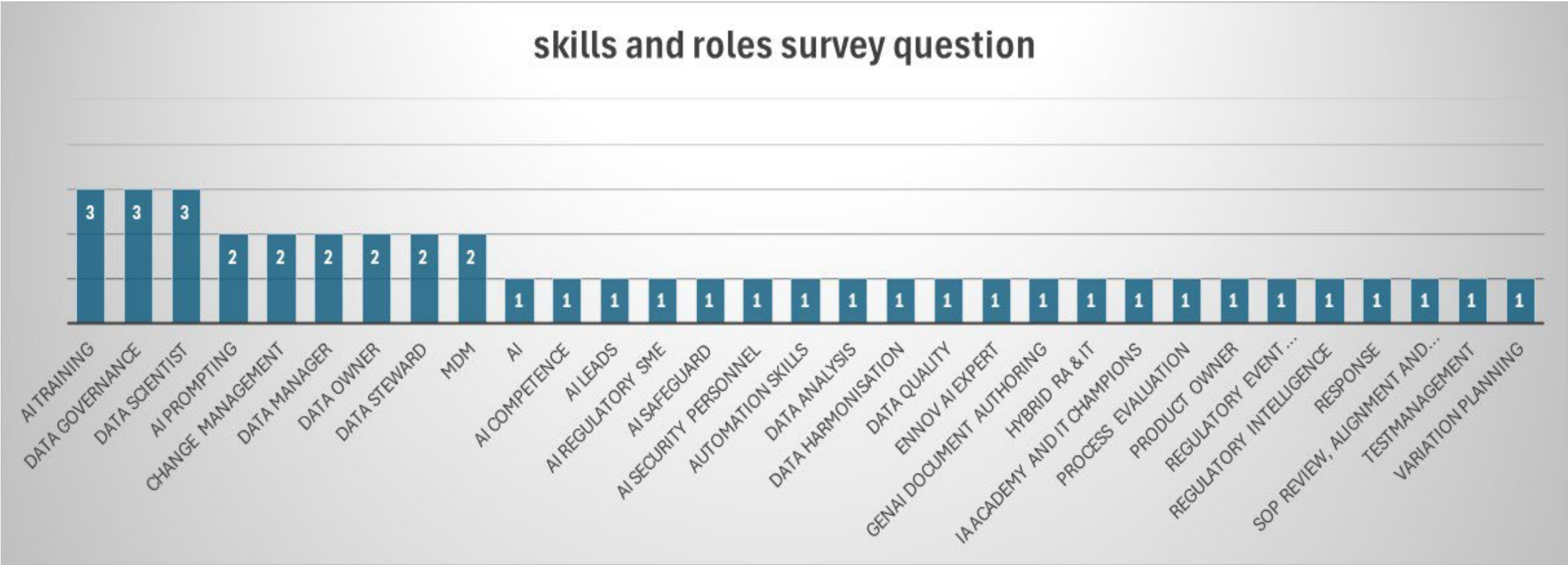
- 1) Digital Lead
- 2) Prompt Engineering: *A role or a skill set for all professionals?*
- 3) Data Officer or Data Governance Lead
- 4) Agent Trainers / Owners: *What's your roadmap for upskilling staff to leverage AI agents and automation?*
- 5) International Coordinator: *How do we ensure equitable support for Tier 2 & 3 countries. How will CBRS alter reg. strategy?*

## NEW ERA

- Data as a strategic asset
- Cloud Based Regulatory Spaces (norm)
- Continuous optimization: ~ 30% of today's work is automated
- AI as the preferred assistant
  - Human in the loop
- Enhanced R&D value



# Poll: What new roles and/or skills are you investing in over the next 12 months?



# AI / Automation and process investments are realizing significant business results

Recent McKinsey Study that tracks LPLV – DBL – Filing

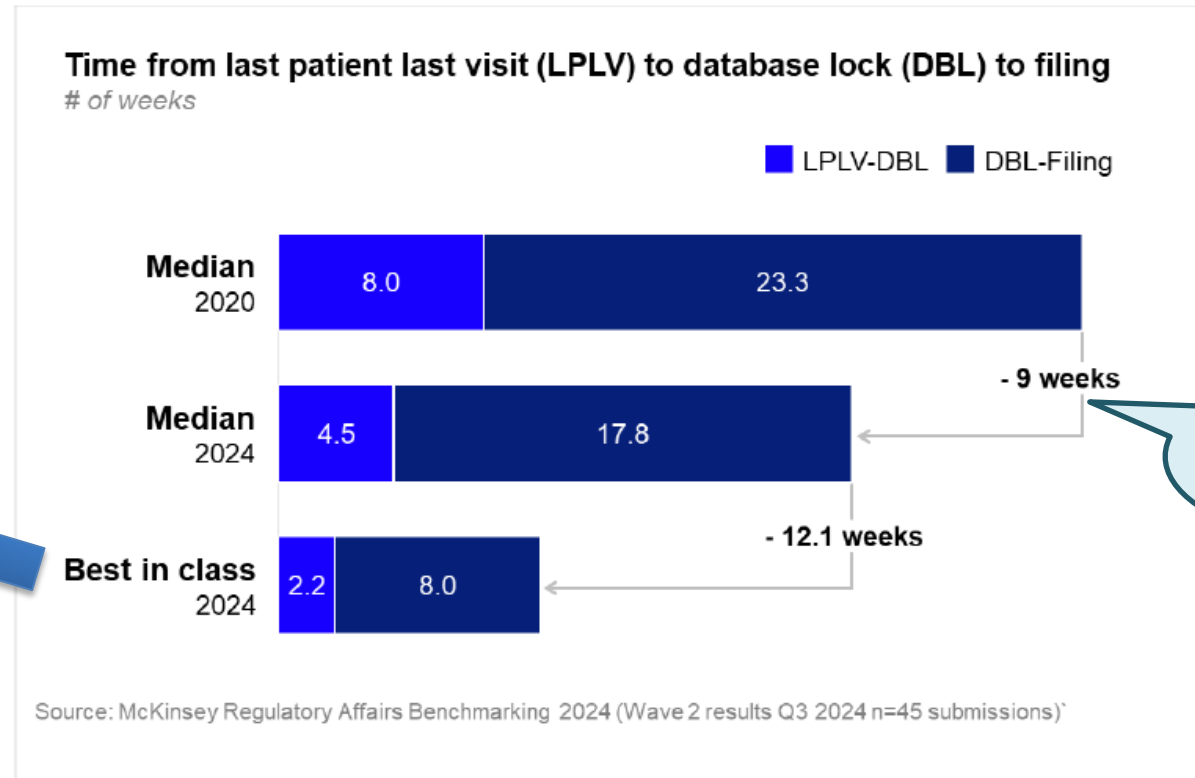
## What are the contributors? (G&A opinion)

- Authoring disruption (GenAI / SCA / Agentic AI)
- Document review process optimization
- Targeted automation / process optimization
- Cross functional Information connectivity (reg., quality, clinical, safety, supply chain etc.)

We reviewed the “Best in Class” companies to our 2024 World Class RIM study data. We found all have:

- ✓ Formal data strategy, a Data Quality Office, and clear data ownership
- ✓ Achieved global RIM adoption
- ✓ Formal data management / governance practices
- ✓ Formal Business Excellence dept.
- ✓ Track the % of documents that are submission ready (right the first-time quality metric)
- ✓ Effective Health Authority Interactions capability
- ✓ Effective cross-functional collaboration

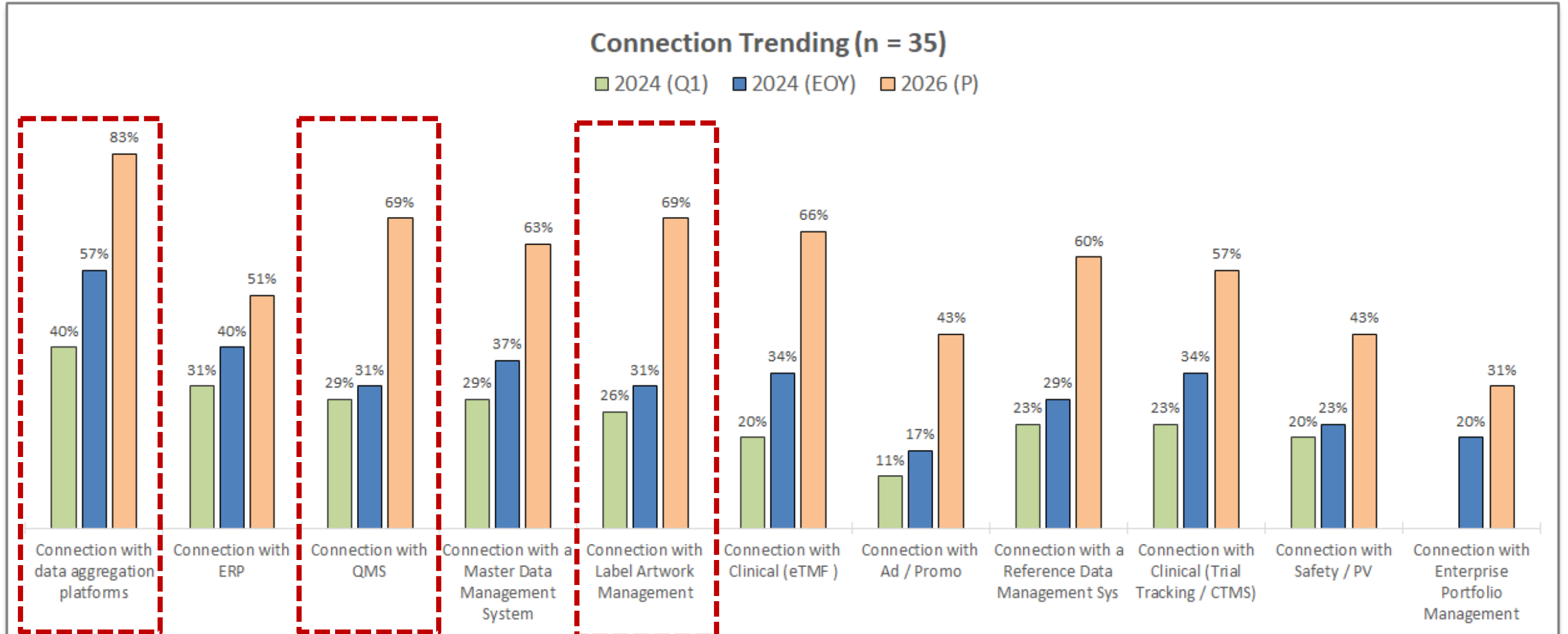
## Exhibit 1. Some companies now file regulatory submissions three times faster than the industry average from four years ago.



There was a 31% increase in RIM capability efficiency over this time period<sup>1</sup>

# There is a priority for Regulatory and Quality Information Connectivity

## Large and Mid-Tier Companies



# Session Learning Goals

- The start of a New Era
- AI Implementation Tipping Point
- Confluence of Change
- Implications
- Our Fall Research

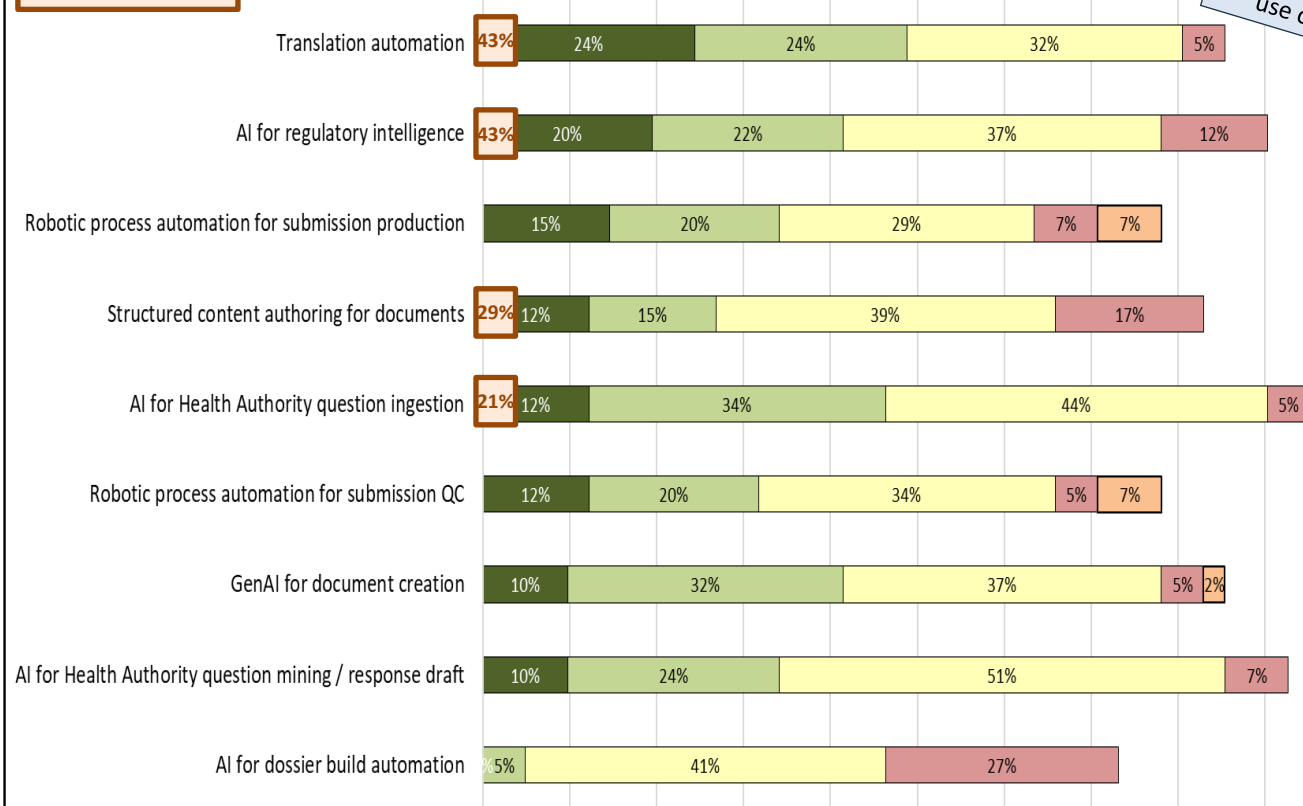


## Most companies “feel they are behind” – Our benchmarks show the Advanced Tech Implementation Tipping point is projected to be 2026/2027

Top Performers  
have a higher  
deployment in  
4 areas

When Adv Tech Will Be in Production in Regulatory (n=41)

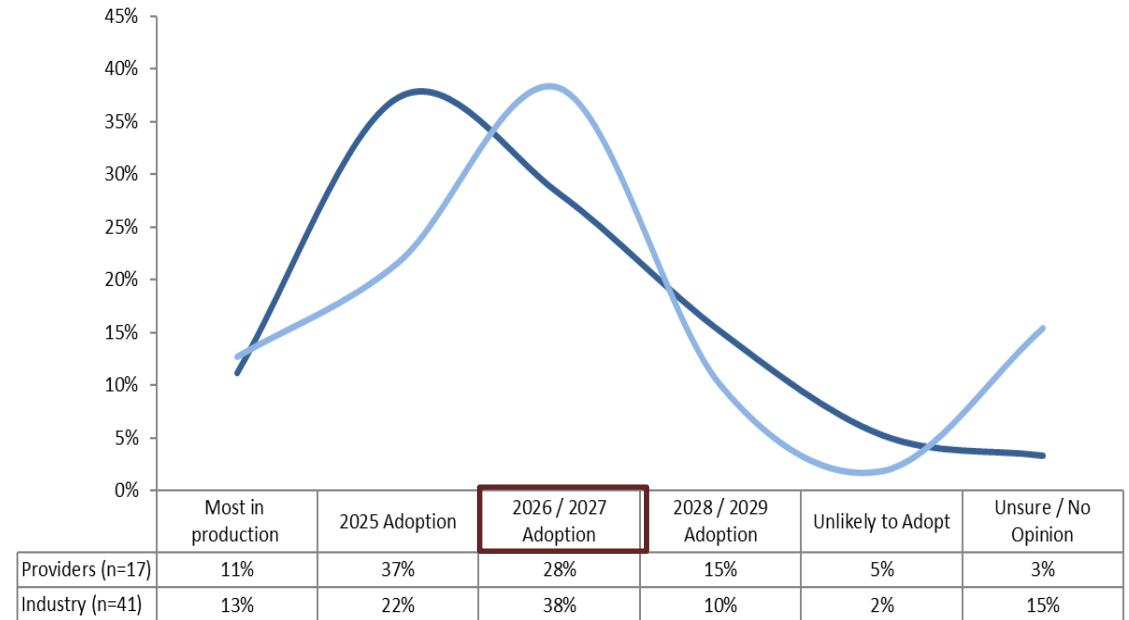
■ In Production ■ 2025 ■ 2026 / 2027 ■ 2028 / 2029 ■ Not Viable Technology



Average of all  
use cases

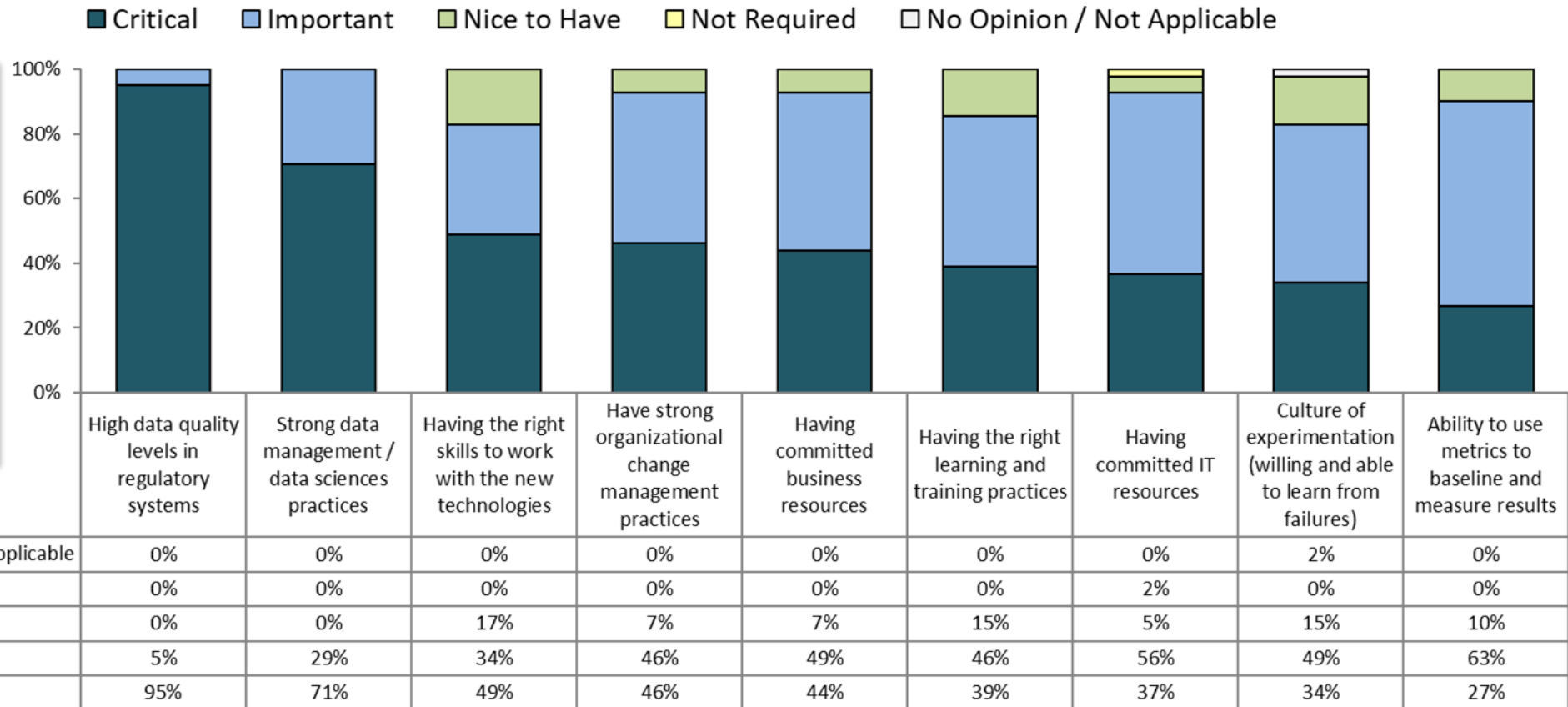
Expected Advanced Automation Time Frame (Provider vs. Industry)

— Providers (n=17) — Industry (n=41)



# What are the characteristics and practices needed in the Regulatory organization to effectively maximize AI's potential?

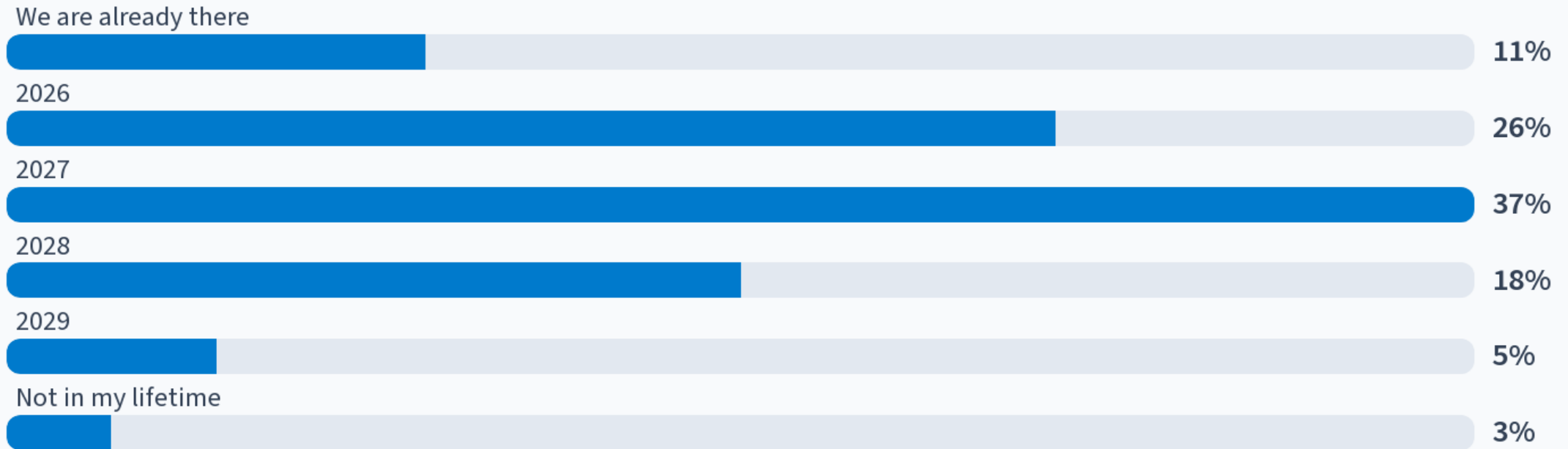
Reg Org Characteristics for AI Success (n=41)



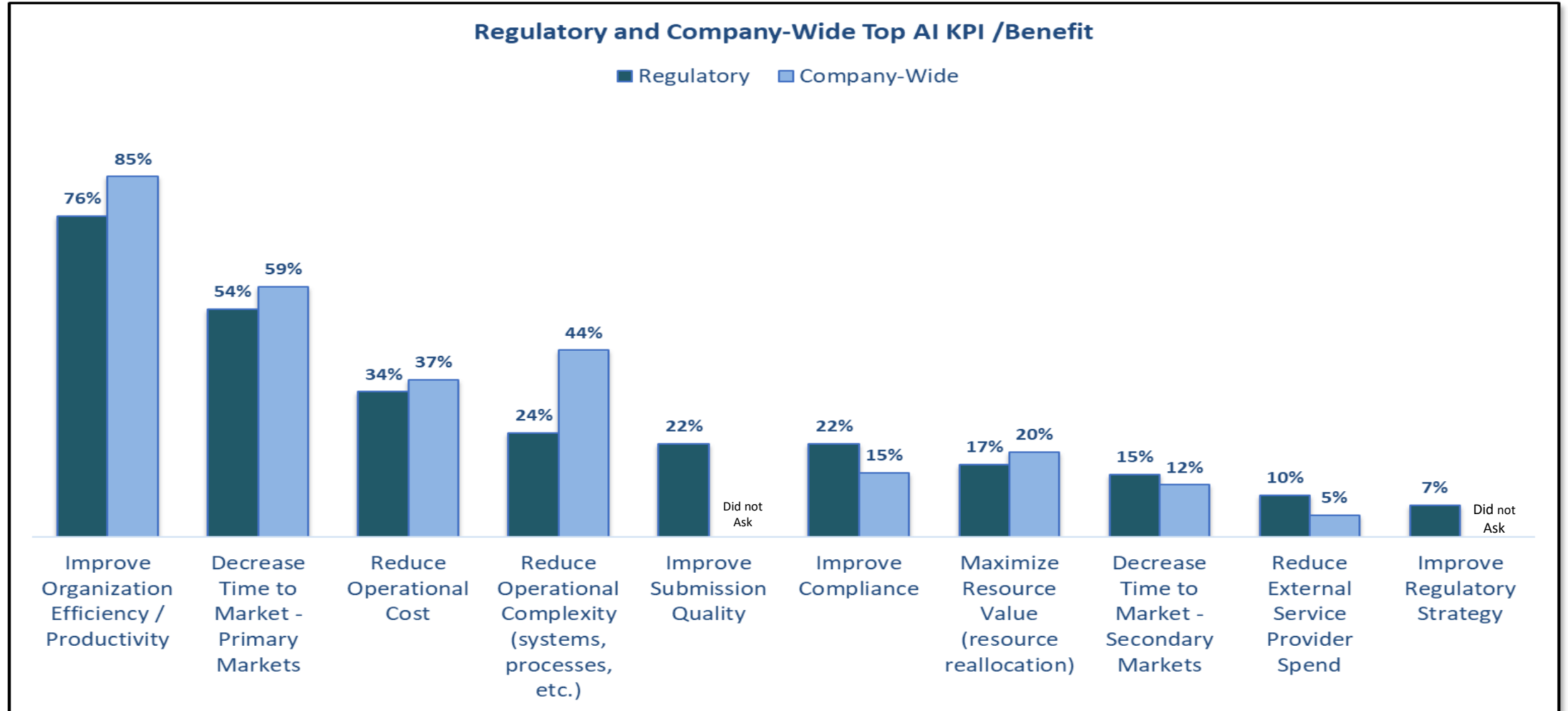
- We see strong data management practices as the foundation to high data quality levels (see next slide)
- *We believe these results are a strong endorsement for a holistic approach to AI implementation – data, organization, process and technology*



## When do you expect the AI / Automation Tipping Point to be realized in your organization?



## What Key Performance Indicators (benefits) are you trying to move with your AI initiatives?



## What do you believe will be the biggest AI / Automation benefit for your organization? (pick your top 3 please)

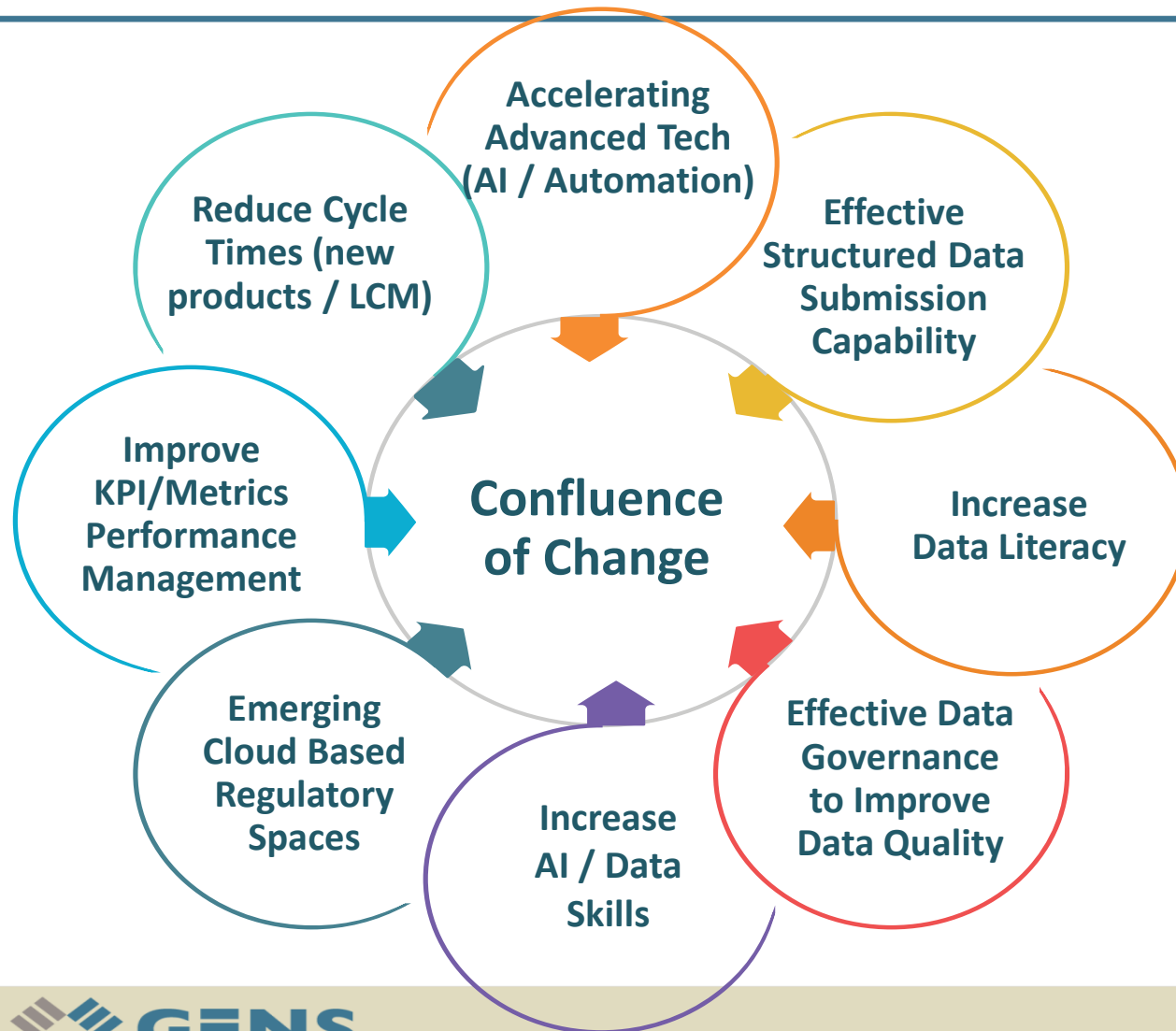


# Session Learning Goals

- The start of a New Era
- AI Implementation Tipping Point
- Confluence of Change
- Implications
- Our Fall Research



Today, we are witnessing a “Confluence of Change” with many dimensions of change hitting at the same time... *What would you add? – our next poll*



#### Macro Influencers

- Geopolitical
- Tariffs
- Workforce Distribution
- Evolving Health Authority Policy

#### Early 2025 Sentiment from our Pulse Survey

- **76%** see AI as “an assistant”
- **59%** believe AI will make us **more strategic**
- **7%** believe AI will **not result in fewer jobs** while **59%** believe some colleagues in their org believe job loss will happen with AI
- **83%** believe **having the rights skills** to work with the new technology is critical or important

# Poll Results – What other dimensions would you add to the “confluence of change”?

Equipment data and EQMS linkages via API for data metric creation.
Young generations and their relationship/motivation to work
Growing complexity of electronic quality form attribute fields for meaningful data metric outputs.
Focus on Reg strategy
How change management will be changed.
Organisational impact
Integrated Digitalisation
Documentation harmonization
Growing Regulatory complexity in Export market
Data review and regulatory requirements fulfilment
Set Regulatory Strategies
Remove bulk work and time waste
Structured data / content authoring
Increased regulatory requirement changes
HA interactions/collab



# Session Learning Goals

- The start of a New Era
- AI Implementation Tipping Point
- Confluence of Change
- Implications
- Our Fall Research



# Viewpoint: Ways of Working Implications

## Tactical (next 2 years)

- Skill Development / Workforce Planning
- Document Automation
- HA Interaction Automation
- QC Agent Introduction
- Regulatory Intelligence Insights
- SOP Development Automation
- AI Generated Training Content



## Strategic (further out)

- AI Competency as a core Job Requirement
- Dossier Automation
- Cloud Based Regulatory Spaces
- QC Agent Maturity (~30% of the work)
- Regulatory Intelligent Agents
- Global SOP Consistency Agents
- Personalized AI Generated Training Content

## What do you see as the biggest challenge as you move forward?

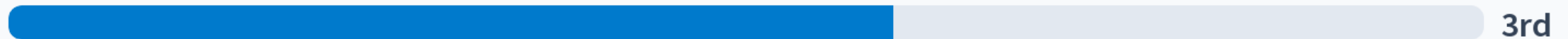
Data readiness (structure + quality = usability)



Evolving our skills / capabilities



Shifting our culture



Adopting our processes



Keeping pace with technology

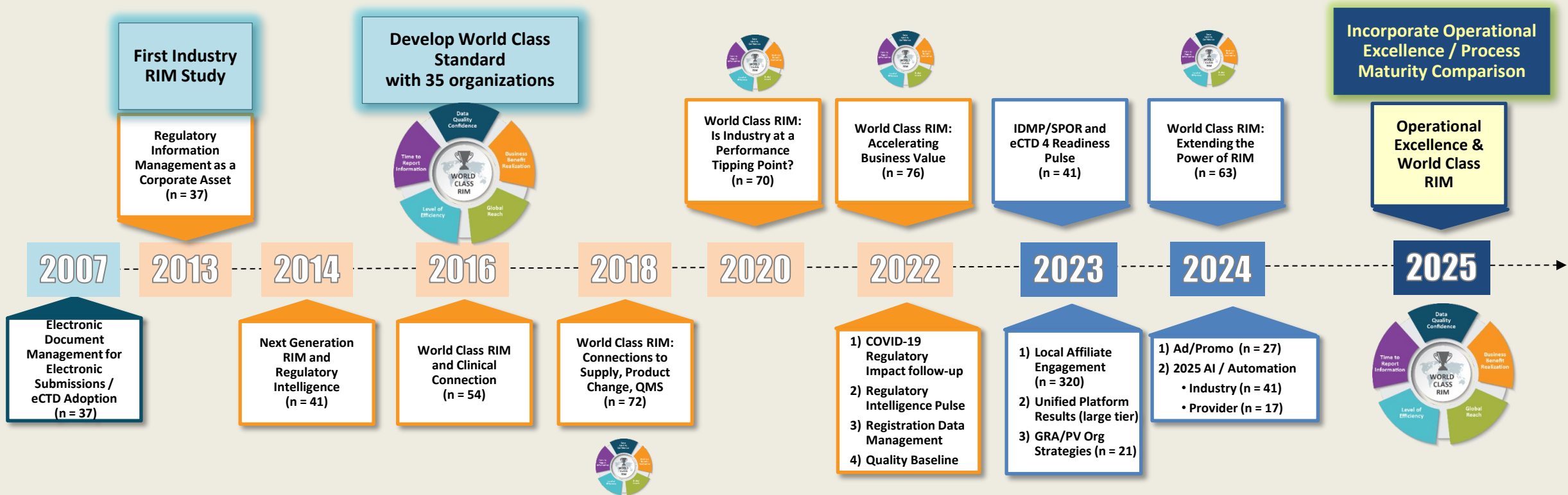


# Session Learning Goals

- The start of a New Era
- AI Implementation Tipping Point
- Confluence of Change
- Implications
- Our Fall Research



# Research History: 46 studies tracking trends and performance status of the regulatory eco-system and critical touchpoints (quality, safety, clinical, etc.)



First Generation Global Electronic Submission

Regulatory Globalization and Modernization

Maximizing Regulatory Value / Information Connectivity

# Study #47: 2025 Operational Excellence & World Class RIM<sup>SM</sup> Survey Timeline





# Conclusion and.. Merci pour votre temps / Thank you for your time

- ❖ Confluence of change is significant and will fundamentally alter the working environment
- ❖ Investments are focused on a series of incremental improvements; however, the combination will have strategic impact
- ❖ Skill development is now mission-critical as the AI/Automation Tipping Point of 2026/2027 is fast approaching
- ❖ Data Strategy, Data Governance, Data Literacy requires strong workforce development



Steve Gens MSOD

Managing Partner

[sgens@gens-associates.com](mailto:sgens@gens-associates.com)

<https://www.linkedin.com/in/steve-gens-msod-252627/>

