AI – Art of the Possible

Twenty-Fourth Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

October 26th, 2023

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Twenty-Fourth Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

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AI – Art of the Possible: an interactive panel on compliance considerations when delving into the world of AI

Gary DelVecchio, *Healthcare Compliance Officer, CVM, Janssen*

Anisa Dhalla, *Chief Ethics and Compliance Officer, UCB*

Emily Mason, JD, *Vice President, Worldwide Compliance and Business Ethics, Amgen*

Faiz Merchant, MS, *Principal, Technology Lead of Compliance, Privacy & Risk, ZS (Co-Moderator)*

Michael L. Shaw, JD, *Principal, Global Head of Compliance, Privacy & Risk, ZS; Former Senior Counsel, HHS OIG (Co-Moderator)*

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Discussion Topics

- How can AI accelerate compliance automation and support various business use cases
- Opportunities for targeted compliance monitoring inquiries vs. traditional dashboard approach
- How can AI leapfrog traditional chatbot capabilities to become an one-stop shop for intelligent and targeted compliance inquiries from the field
- What are potential operational/ethical challenges and the key compliance standards that need to be navigated

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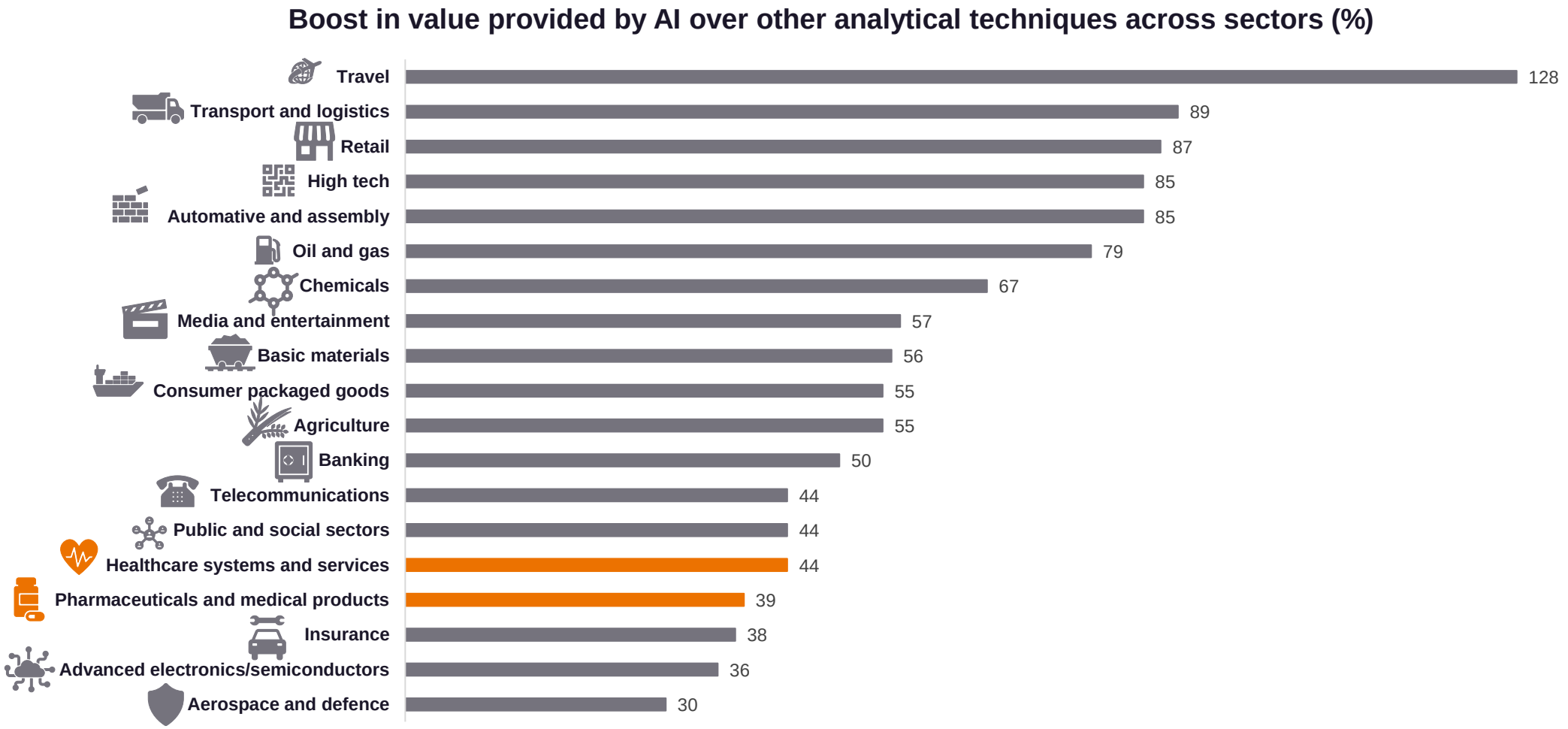
What are some potential explanations for why the use of AI in the pharmaceutics & medical products sector is slower than other sectors?



Source: McKinsey Global Institute Analysis

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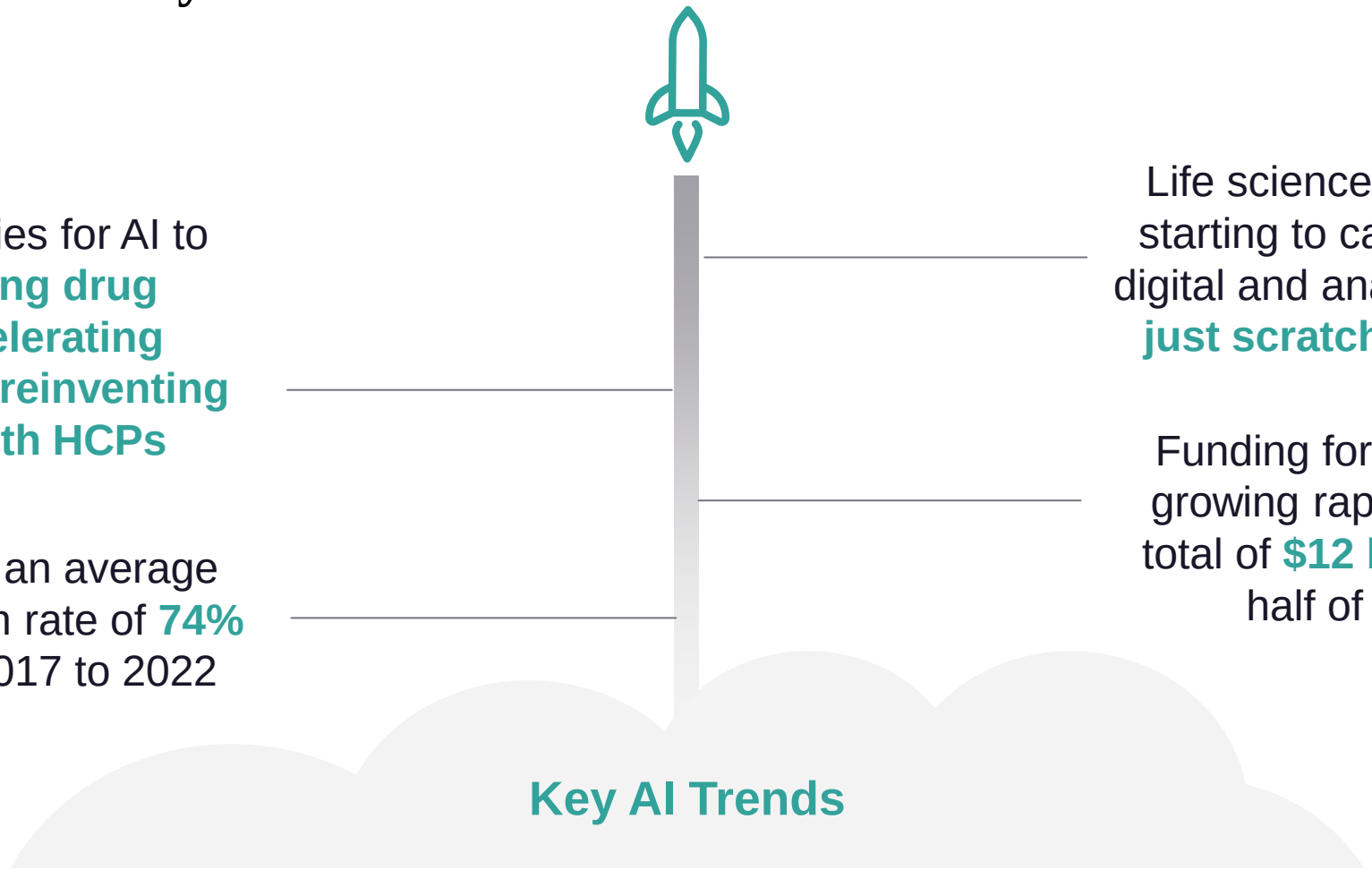
Current trends of use of AI across multiple industries, including pharmaceutical and medical device industry



What are some opportunities that generative AI could be strengthen compliance program elements?

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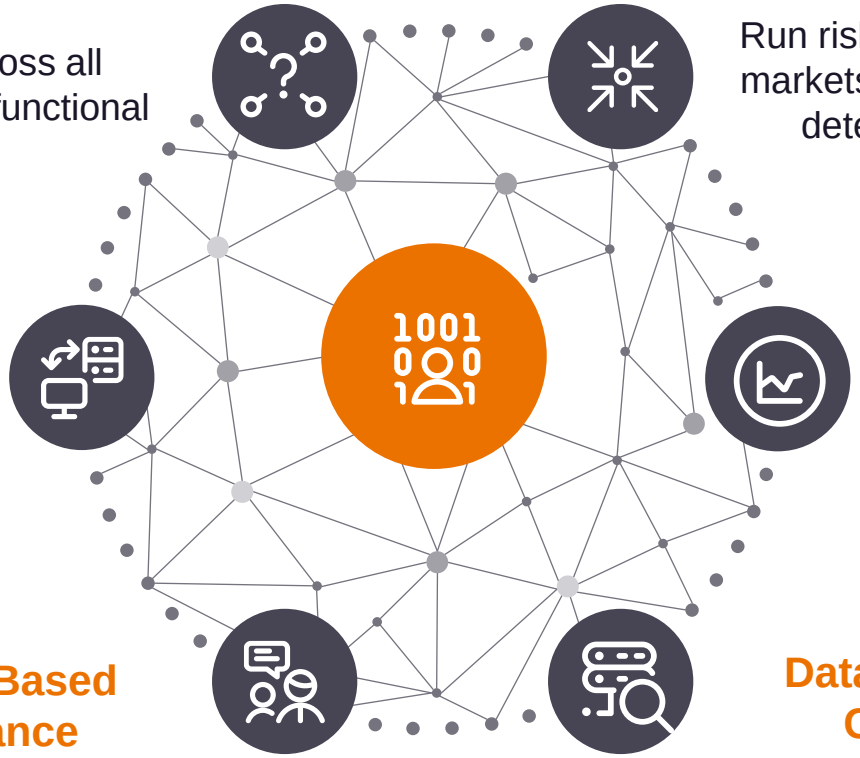
What are some opportunities for AI to support compliance operations based on what is observed in peer industries?

Employee-HCP/HCO Risk Monitoring Insights

Triangulate risk insights across all engagement types and cross-functional transfer of value

Audit Analytics

Run risk score analysis across markets, entities, processes to detect emerging trends



Insights From Unstructured Guidance Documents

Automate risk detection across unstructured and structured data for anomalies/trend detection

Executive Report Generation

Automate risk analytics executive reports generation to support strategic decision-making and investigations

Tailored Responses Based on Company Guidance

Translate unstructured policies and SOPs into targeted responses for specific scenarios

Data Discovery and Classification

Discover and classify sensitive and personal data in structured and unstructured datasets

Use cases listed above are not exhaustive

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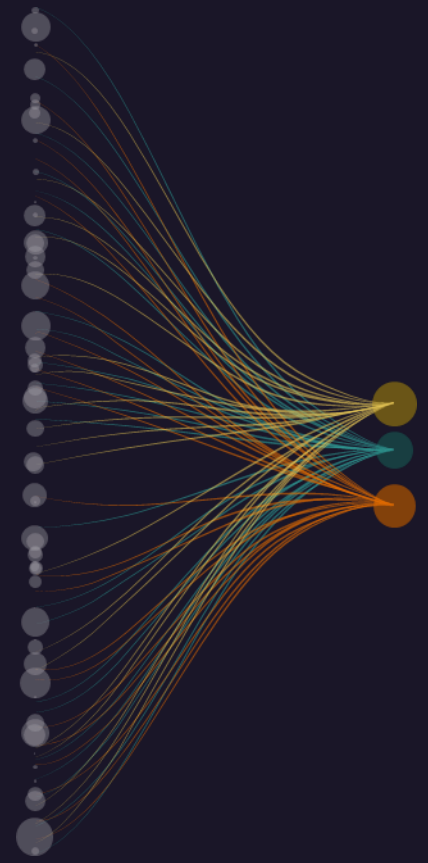
Key benefits of AI beyond foundational risk analytics capabilities for ongoing monitoring

Foundational Risk Analytics

Offers a set itinerary of storyline (via established indicators/reports) to navigate through risk identification process



AI Capabilities

Choose your own adventure approach of navigating through risk identification

- Bypass fixed monitoring dashboard reports/ analyses to extend beyond defined dashboard script
- Transform known dashboard views into self-serve risk insights to provide ad-hoc deep-dive analytics for HCP/employee risk for routine investigations
- Accelerate risk analytics dashboard development to allow users to pin ad-hoc analytics visualizations for ongoing use

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Comparison of chatbot capabilities and AI capabilities

Traditional Chatbot	VS	AI
Low complexity, basic answer and response machines		Complex and focused, can manage complex dialogues, goes beyond conversations,
Allow for simple integration		Integrate with multiple back-end systems, specialize in completing tasks interacting with multiple systems
Need explicit training for every scenario (not “intelligent”)		Can self-learn and improve over time, can anticipate user needs,
Require low back-end effort		Require high back-end effort

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What are some potential operational/ethical challenges that AI solutions will need to navigate?

Challenges	Potential Solutions
Responses may be biased LLMs can be biased based on the training data used, providing responses that may not always be grounded in reality and may perpetuate biases	**Guardrails to mitigate (but not eliminate) risks** Intentionally use diverse datasets in the tool training process, moderate API end-points, self-consistency approaches, iterative decomposition, etc.
Tool learning and inconsistency across responses Tools may not be sufficiently trained, providing inconsistent responses across inquiries	**Launch AI pilot within limited audience** Launch pilot within limited audience (e.g., Compliance) to maximize tool learning and ensure analytics/insights quality prior to broader distribution
The AI cannot always do what you want it to do Prompt engineering is an art, and even when prompted correctly there are times when long documents are not able to be handled and code generated is not valid	**Use specific techniques to improve effectiveness** Auto-prompting techniques can be used to get the model to do what you want, retrieval augmentation can be used to handle the limits of long documents
Data governance and data privacy Prior search history and exposure of potential PHI/PII/PCI data requires robust safeguards	**Define governance and leverage HIPAA-compliant AI services** Develop targeted policy on data security and data retention business rules

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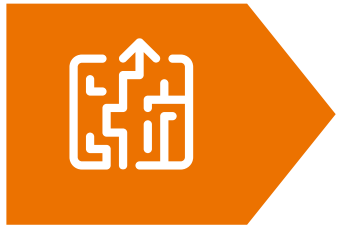
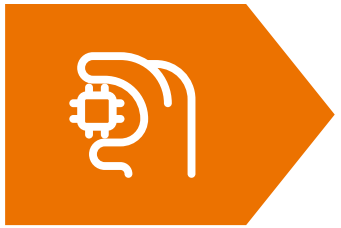
Key questions to support your discussion with internal IT partners evaluate AI solution feasibility and readiness



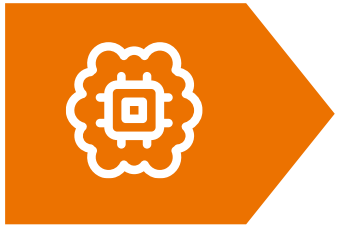
What are the **key enterprise guidelines** and considerations for Gen AI usage?

- E.g., councils, security, quality, cost, centralize vs. federated



What have companies done to **expedite this journey methodically**?

- E.g., pseudonymize data, pilots, evaluation multiple solutions, clarify roles and responsibilities/RACI, educate on LLMs, legal involvement, quality – hallucinations/bias



Are companies heading in one direction or another when it comes to **picking solutions**?

- E.g., OpenAI, open-source models

What is the **expected collaboration between business and IT** to improve accuracy of Gen AI models over time?

- E.g., data/use case/testing/context from business and model training/infrastructure/ operations from IT

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