Revolutionizing Pharmaceutical R&D: The Power of AI and Generative AI

Accenture Life Sciences

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Kailash Swarna, Ph.D., MBA

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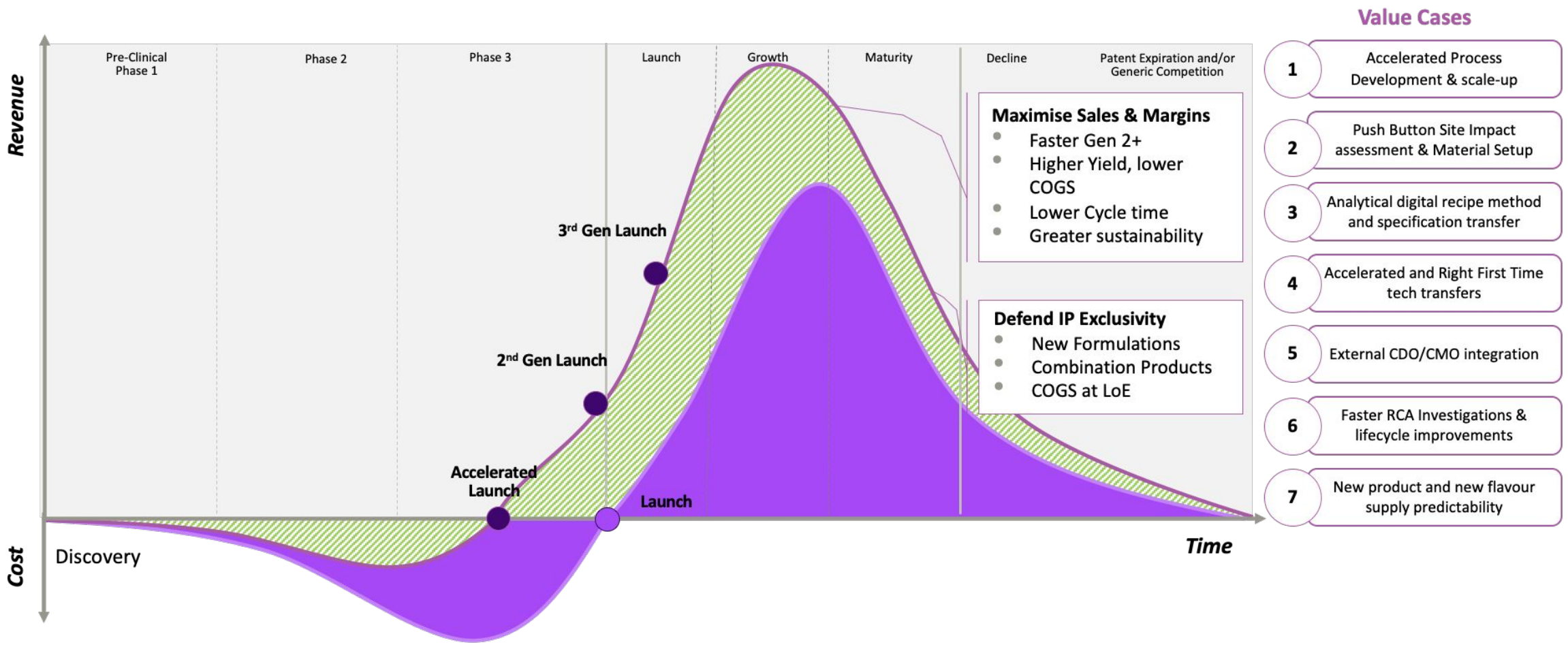
A defining moment for biopharma: working in human+machine mode

We work and live within interlinked realities: physical and digital. The interconnection grows more pervasive as technology and science thrive – creating new, radical possibilities across the biopharma value chain. Working in human+machine mode, industry innovation is surging. Scientists, patients, healthcare professionals (HCPs) and business leaders are driving it, powered by four technology trends.

In **Accenture's Technology Vision 2023 for Biopharma,** we explore how these four trends – *Our forever frontier, Generalizing AI, Your data, my data, our data and Digital identity* – are guiding different ways of working, operating, innovating, collaborating and growing.

We believe the time has come to further blur the lines and welcome the next wave of innovation and business transformation in biopharma.

Evolving macro-economic factors and the demand for greater and faster access to innovative medicines will drive change



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AI-Driven Performance Frontier

Move beyond today's standard to a new model of value creation. BioPharma companies must reexamine how they define and generate value and form a system that benefits all stakeholders in the value chain. They must rapidly test new and emerging technologies to fuel continuous

Create sustainable value

Sustainable value creation

Setting, measuring, and achieving balanced goals on equitable, sustainable outcomes

Applied Tech-Enabled Innovation

Persistent scanning, incubation, and acquisition of outside-in digital technology innovation

Accelerate growth

AI-led discovery

Rapid identification of targets that have a lower risk of failing during development and predictive modeling for lead identification & optimization

Lean, fast development

Future of development is established, with the use of new clinical trial methods (e.g., DCT, synthetic control arms), which dramatically reduce cycle times and improve efficiency

Dynamic portfolio management

Dynamic management of TAs, bio-platforms, modalities, technologies, and devices with their RWE, economics & pricing implications considered

Connected scientific innovation ecosystem

Diverse array of scientific partnership approaches that are modular and flexible; attract an array of partners in the pre-competitive space; leverage data, capabilities, and talent

Deliver value & optimize operations

Connected supply chain, manufacturing & quality

New Science necessitates transformation to more automated and digitized manufacturing and supply chain networks

Full value chain business planning

E2E visibility and predictability across value chain; win-win data partnerships; cross-functional planning

Modernized commercial model

ROI from data & analytics investments, innovative pricing & access models and launch capabilities, E2E marketing, omni-channel engagement and patient-centric experience design

Digitization and optimization of enabling functions

Evolution of the Enabling Functions (HR, IT, Proc, Fin) to accelerate business performance and harvest OpEx savings enabled by digitized and intelligent processes designed to deliver a simplified experience

Power your people

Thriving organizations

New workforce models; empowered employees through role structure and technology; intrapreneurial mindset

Modern Leaders

Progressive and purpose-driven culture; iconic leadership representative of workforce; risk-intelligence; data and tech fluency

Digital core

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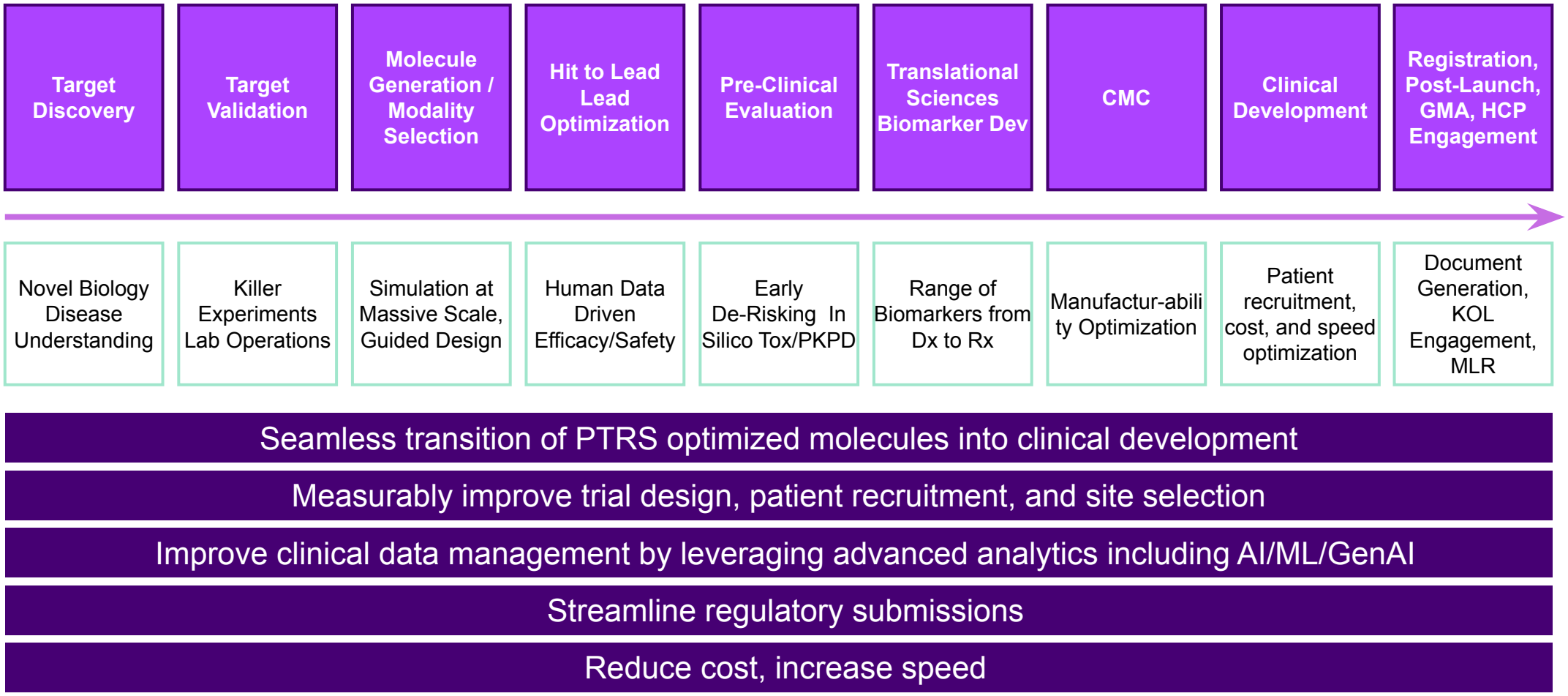
AI/ML/GenAI has the potential to fundamentally transform R&D



Market provocations are met with new capabilities and enablement from a strong digital core

Life Science Provocation..	Requires these Primary NPF Capabilites…	Are enabled by these digital core capabilities…
Discovery Startups outperform incumbents by championing AI-led discovery with multi-disciplinary computational and scientific teams to reduce cycle times and discovery cost	**AI-led discovery**	• **Multidisciplinary** computational and experimental teams • Scaled R&D portfolio via **AI-led discovery using platforms** which are embedded in the scientific operating model • **Adaptive strategy** to identify priority opportunities, launch and scale market-changing products for resilient growth • Scaled **AI to simplify and accelerate clinical development** • **Integrated data, analytics and AI/ML** help profile and define patient populations to predict response to treatment at earlier trial stages • **Data and experience-driven clinical trials** that accelerate time to market • **Entrepreneurial approach** within the ecosystem to experiment and build new capabilities • **Integrate** multiple **digital platforms** across different players to enable more robust, integrated stakeholder connections
Clinical Development New R&D approaches leverage digitally powered and patient-centric design, using data, advanced analytics and technology.	**Lean, fast development** **Applied tech-enabled innovation** **Connected scientific innovation ecosystem**	

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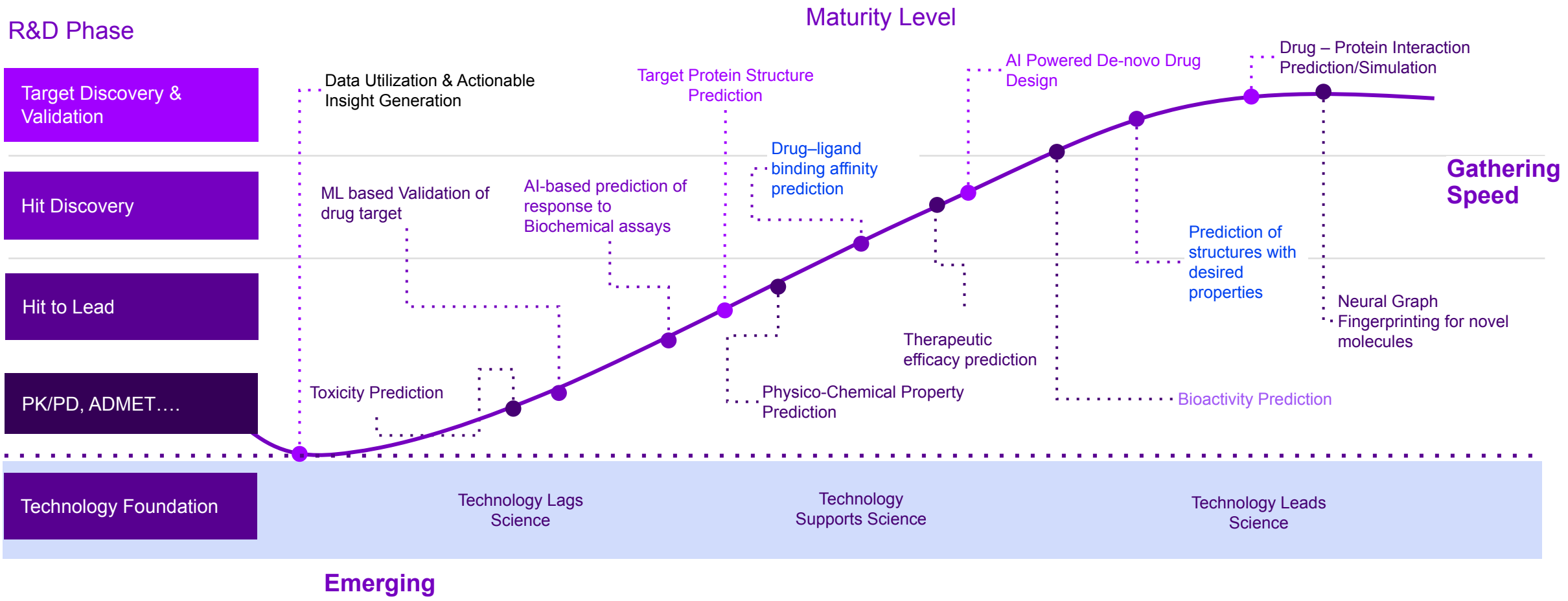
Data, advanced analytics, and AI/ML/GenAI are changing drug discovery…

Illustrative



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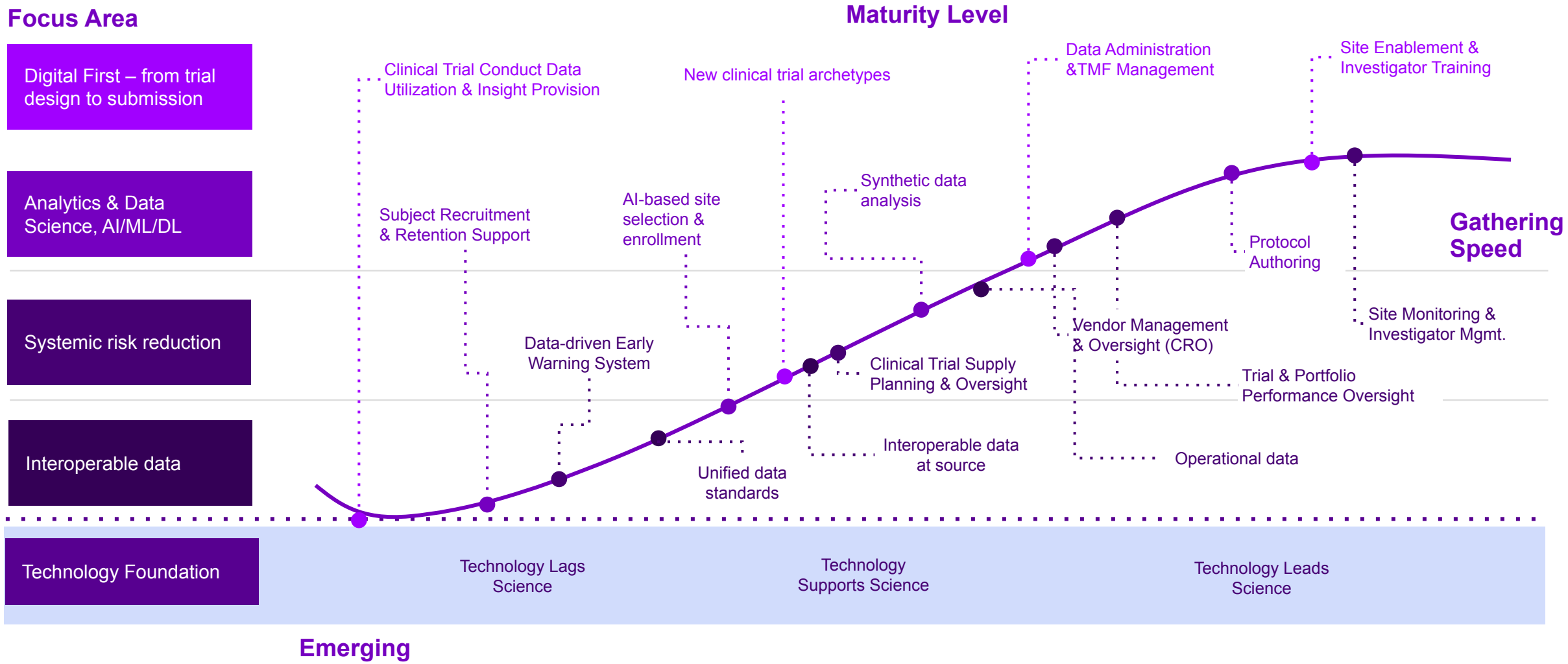
… with even greater impact in clinical development

Illustrative



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Generative AI is the next step in the evolution of AI/ML/DL

Machine Learning

NETFLIX
Movie recommendations

Newsfeed

amazon
Book recommendations

Learn to learn

- Decision trees
- Logistic/Linear regression
- Clustering
- Classification

Deep Learning

a type of machine learning

Google
Search

amazon alexa
Voice assistant

Apple face recognition

TESLA
Autonomous vehicles

Mastery of perceptual data

- Image, object recognition
- Speech and facial recognition
- Fraud detection
- Reinforcement learning
- Neural network

Generative AI

a type of deep learning using Large Language Models and foundation models

"Everywhere" Education, business, arts, history, personal, and creative

Learn once and adapt in many ways

- **Language mastery** across context, sentiment, emotion, grammar, syntax, etc.
- AI takes a more **autonomous** role to generate actions or content

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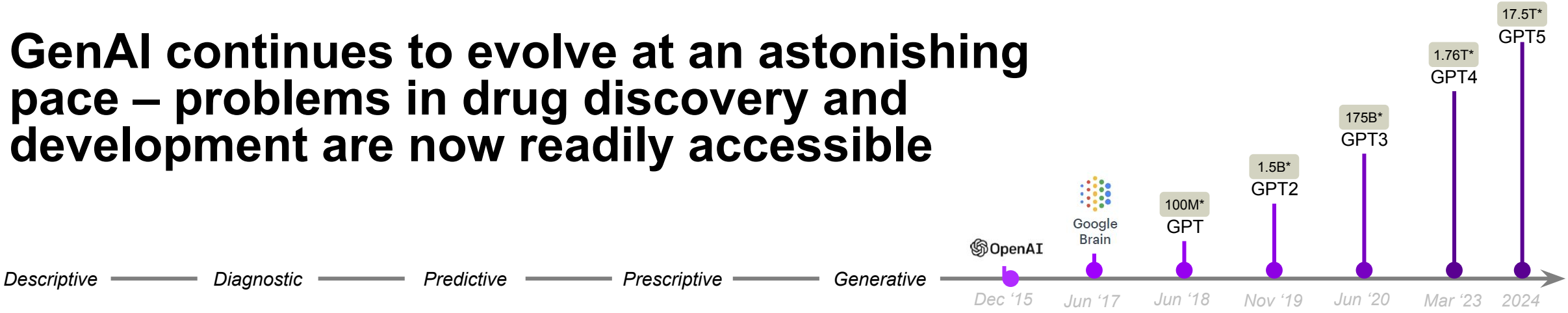
GenAI continues to evolve at an astonishing pace – problems in drug discovery and development are now readily accessible



Analytics

Finding answers and gaining insights for problems that we know

Data Science

Establish solutions of questions that are not yet discovered

Machine Learning

Develop software (i.e., trained models) that can access data, make inferences, and improve

LLM's & Generative AI

Utilize large 'pre-trained' models to analyze data and generate new content

Selected Accenture - Client POC

Protein Structure

Extension of Alphafold

Advances in Stable Diffusion driven LLMs have led to a generational shift in the ability to determine protein structure – from years to days.

Watson, J.L., Juergens, D., Bennett, N.R. et al. De novo design of protein structure and function with RFdiffusion. Nature (2023). https://doi.org/10.1038/s41586-023-06415-

Molecule Design

GenAI driven by purpose-built LLMs now allows scientists to **convert concepts to molecules – in seconds to minutes**, at machine scale.

Morehead A, Cheng J. Geometry-Complete Diffusion for 3D Molecule Generation and Optimization. ArXiv [Preprint]. 2023 Jun 17:arXiv:2302.04313v4. PMID: 36798459; PMCID: PMC9934735.

Protocol Design & Trial Optimization

Accelerated Optimization of Trial Design and Patient Recruitment

"**Ideal Protocol**" a protocol parametrization and fingerprinting methodology for advanced simulation of clinical trials – recruitment, cost and speed optimization.

Patient Recruitment Optimization

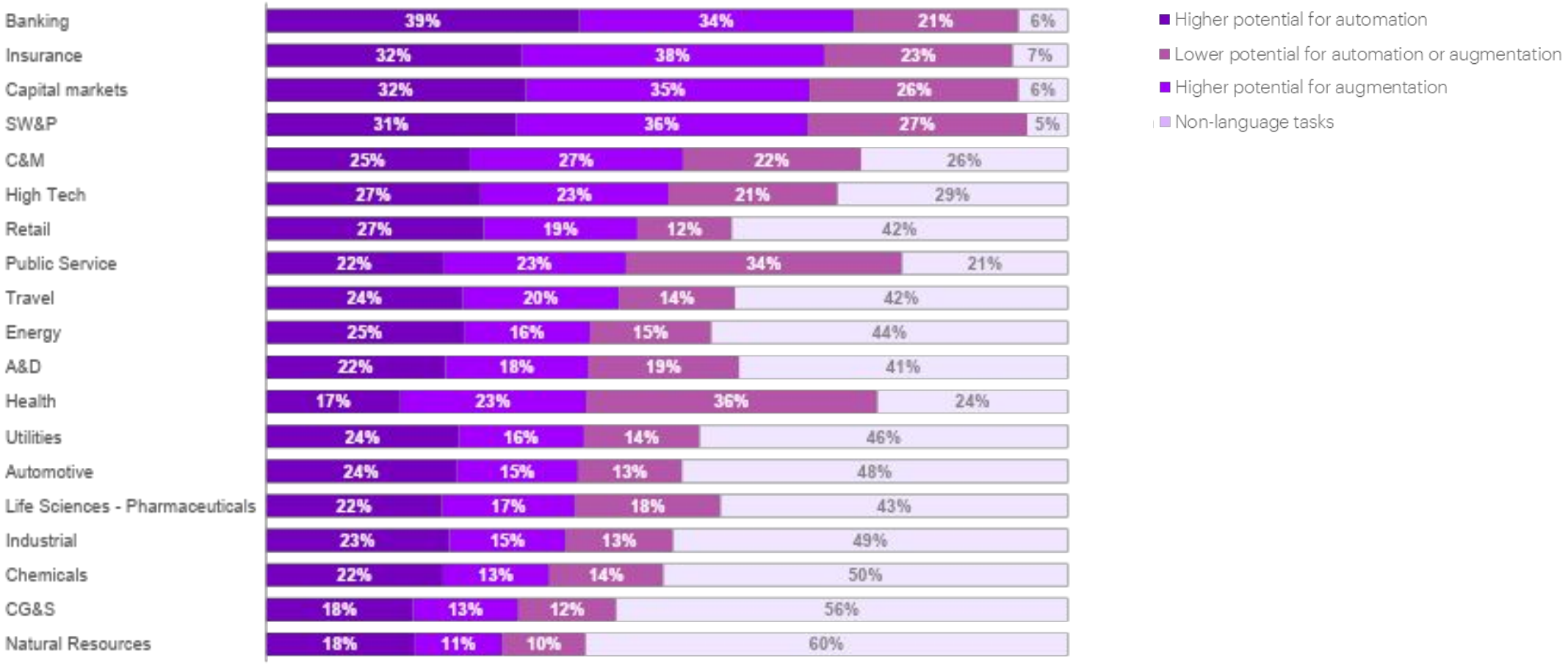
Enhanced effectiveness in **identifying, activating, and randomizing patients** into clinical trials with novel foundation models.

Moor, M., Banerjee, O., Abad, Z.S.H. et al. Foundation models for generalist medical artificial intelligence. Nature 616, 259–265 (2023). https://doi.org/10.1038/s41586-023-05881-4

*indicates the number of parameters

AI/ML/Gen AI will transform the nature of work

Work time distribution by industry and potential LLMs impact
weighted by their employment levels in the US in 2022



Note: Pharmaceuticals segment in Life Sciences industry corresponds to code 3254 in NAICs classification for economic activity.
*Source: Accenture Research based on US BLS May 2023 and O*Net.*

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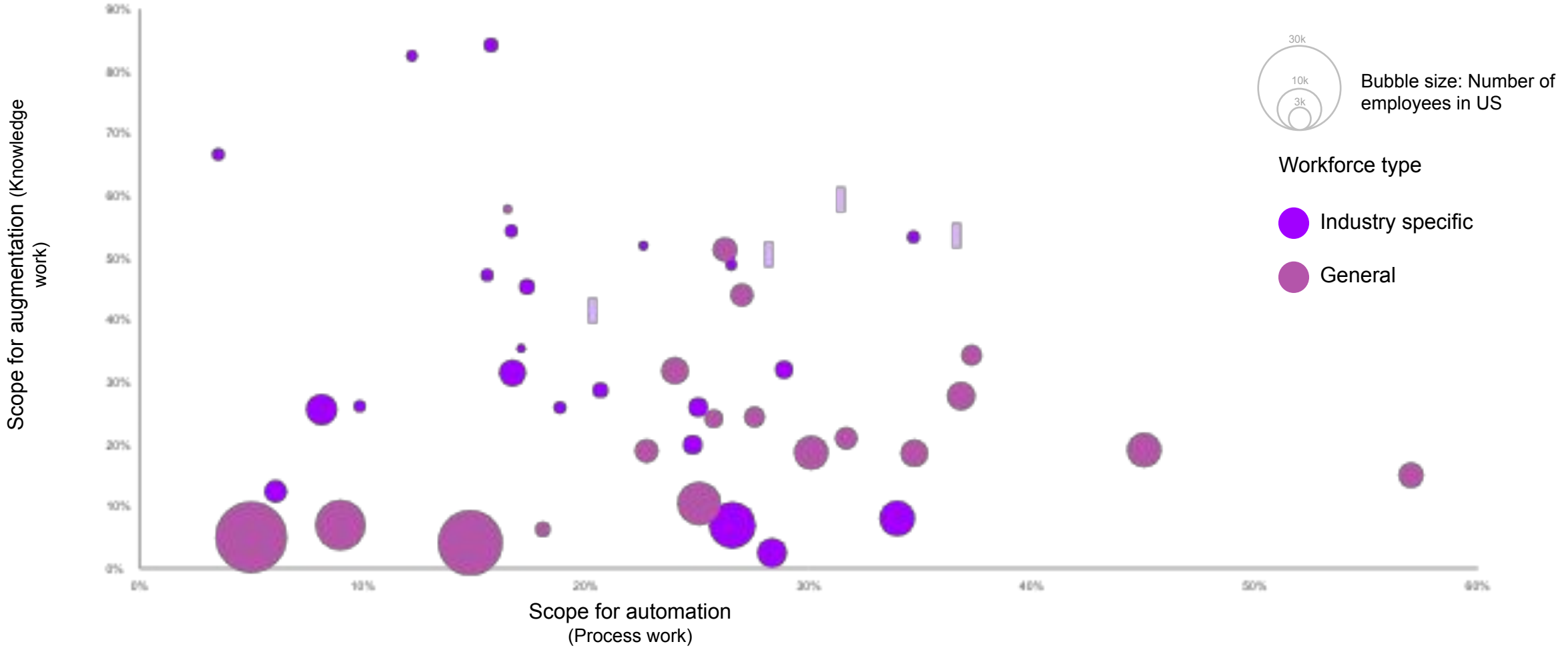
AI/ML/GenAI will impact how we work



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Driving value for Life Sciences companies

The future of biopharma reimagined with GenAI means identifying better candidates, bringing products to market faster (with higher quality), and maximizing sales and customer experience. A GenAI-infused biopharma also enables greater equity and sustainability.

Research

Drug Discovery

Drive speed of drug discovery and identify better candidates

- Increase speed to clinical (7)
- Better identify candidates (3)

Development

Clinical Trials and Operations

PV, Regulatory & Medical

Bring new products to market faster, expediate the regulatory approval process and increase the safety profile of new products

- Shorten time to market (9)
- Improve data quality and speed (7)
- Improve Medical support (5)
- Expedite regulatory approval (7)

Supply Chain

Manufacturing & Supply chain

Optimize manufacturing speed, uptime and quality

- Increase uptime and quality (8)
- Shorten timeline to production (6)

Commercialization

Content & Strategic Planning

Field Force & Patient/ HCP Support

Drive an increase in sales as well as a more personalized customer experience for both patients and HCPs

- Increase product sales (19)
- Improve customer experience (6)

(n) = # of detailed use cases currently identified

Enabling Functions: IT, Finance, HR, Legal

IT

Enable code generation for rapid development (6)

Finance

Prepare financial commentary and automate financial reporting (6)

HR

Develop employee training, eliminate bias from recruiting (6)

Legal

Prepare legal contracts for initial review (4)

Future Workforce

Redesign talent source, development, and career paths with the augmentation that GenAI provides to employee productivity

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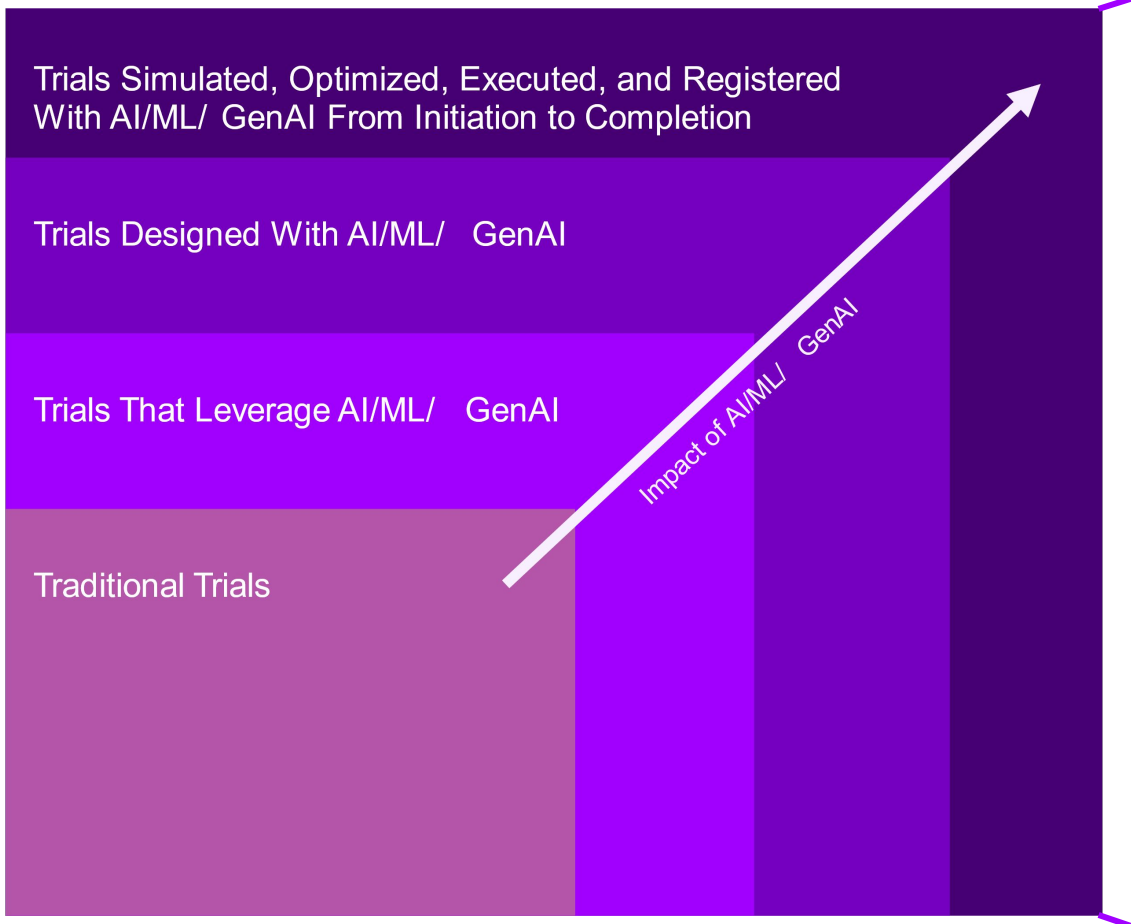
INDUSTRY PERSPECTIVE

Clinical Trials are poised to become digitally native



- **Adaptive Trial Design**: GenAI can simulate various clinical scenarios to recommend real-time modifications to trial design, allowing for more efficient resource allocation and potentially shortening the trial duration.
- **Patient Stratification and Recruitment**: AI/ML can analyze historical and real-time data to identify the most suitable patient cohorts for a trial, optimizing efficacy assessments and minimizing risks, thereby potentially leading to more targeted therapies.
- **Advanced Data Integration**: ML technologies can seamlessly integrate disparate types of data, such as clinical, imaging, and omics data, into a unified framework for more comprehensive analyses and interpretations.
- **Automated Data Validation**: AI-driven systems can automatically identify inconsistencies, missing data, or outliers, thereby improving data quality and integrity, which is critical for the reliability of clinical trial outcomes.
- **Real-Time Safety Monitoring**: AI/ML algorithms can continuously analyze patient data for early detection of adverse events and safety signals, facilitating immediate intervention and thereby enhancing patient safety.

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Impact of AI/ML/GenAI in clinical development

Area of Application	Technology	Benefit
Patient recruitment and identification	AI, ML, NLP	Streamlines patient identification by analyzing EHRs and databases for eligibility criteria
Protocol design and optimization	AI, NLP	Analyzes historical data, literature, and real-world evidence for efficient trial design
Site selection and investigator	AI	Identifies suitable trial sites and investigators based on historical performance
Predictive analytics and adaptive trials	ML	Analyzes ongoing trial data for trends, enabling data-driven decisions and adjustments
Monitoring and risk-based quality management	AI, ML	Develops risk-based monitoring strategies prioritizing high-risk sites or areas
Data management and cleaning	NLP, ML	Processes unstructured data and identifies/corrects data inconsistencies
Real-time safety monitoring	AI	Monitors and analyzes adverse events in real-time for faster identification of safety concerns
Patient engagement and retention	AI, NLP	Develops personalized communication strategies using chatbots and virtual assistants
Automated clinical trial matching	AI, ML, NLP	Matches patients with suitable clinical trials based on medical history and eligibility

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INDUSTRY PERSPECTIVE

Clinical data management and AI/ML/GenAI

Data Management	Potential Impact	Example Technologies
Data Collection	Automated data capture methods improve the quality and speed of data collection.	Electronic Data Capture (EDC) Systems with AI algorithms for real-time data validation.
Data Integration	ML algorithms enable integration of various types of data (clinical, omics, imaging) into a unified dataset.	Data integration platforms with ML capabilities for omics and clinical data.
Data Validation	AI algorithms can identify and flag anomalies, missing data, and inconsistencies for rapid resolution.	AI-powered data validation tools for detecting outliers and inconsistencies.
Data Quality Control	Constant ML monitoring can ensure that data meets regulatory and company standards.	ML models that assess the data quality in real-time.
Safety Monitoring	Real-time AI algorithms can identify safety signals and adverse events quicker than traditional methods.	AI algorithms for Pharmacovigilance and safety signal detection.
Adaptive Trial Design	GenAI can model complex trial scenarios to adapt trial design in real-time.	Simulation software using GenAI for optimizing adaptive trial designs.
Patient Stratification	ML models can predict patient responses to interventions, improving the design and analysis of clinical trials.	Predictive analytics tools for selecting appropriate patient cohorts.
Endpoint Detection	AI can automate the analysis of complex trial endpoints such as imaging or biomarkers.	AI-based medical imaging analysis for endpoint evaluation.
Statistical Analysis	Advanced AI algorithms can perform complex statistical analyses more efficiently.	AI-powered statistical software for survival analysis, multi-factorial tests, etc.
Regulatory Submission	AI tools can automatically generate necessary documents and ensure compliance with regulatory standards.	AI-powered regulatory compliance and document generation tools.
Data Security	ML algorithms can monitor data access and flag unauthorized or suspicious activities.	AI/ML-based cybersecurity solutions for data protection.
Post-Market Surveillance	AI algorithms can continually monitor real-world data to evaluate long-term efficacy and safety.	Real-World Evidence platforms employing AI for post-market surveillance.

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Gen AI can be used in two ways

Consume

- Generative AI and LLM applications are **easily accessible**
- Tailored to a small degree through **prompt tuning and prefix learning**

Customize

- Most companies will need to customize models by fine-tuning them with their **own data**
- Allows models to support more downstream tasks across the business and **unlock new performance frontiers**

Customizable Models

Proprietary

Google
Lamda

cohere

ANTHROP\C

OpenAI

AI21 labs

Open

BigScience
Bloom

Bloom

databricks
Dolly

Meta
LLaMA

SambaNova SYSTEMS

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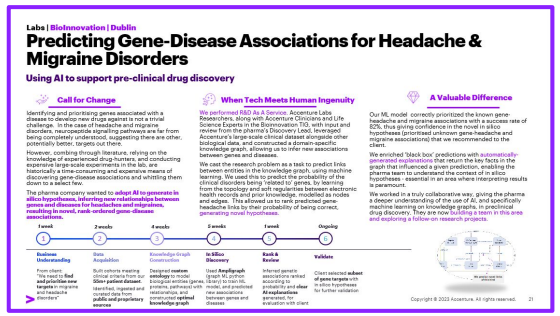
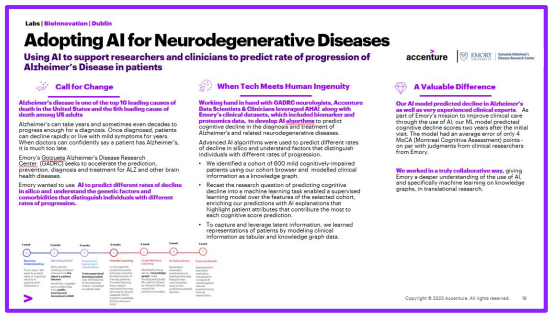
Case Studies

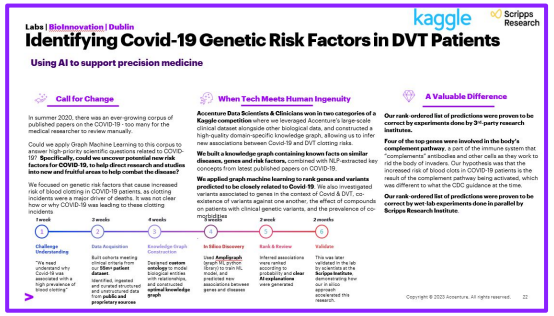
Using AI to support pre-clinical drug discovery



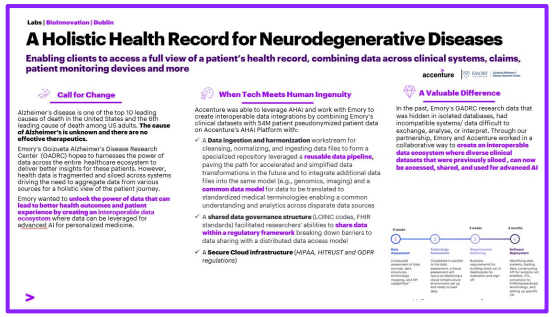
Using AI to predict rate of progression of Alzheimer's Disease in patients



Using AI to support precision medicine and improve patient outcomes

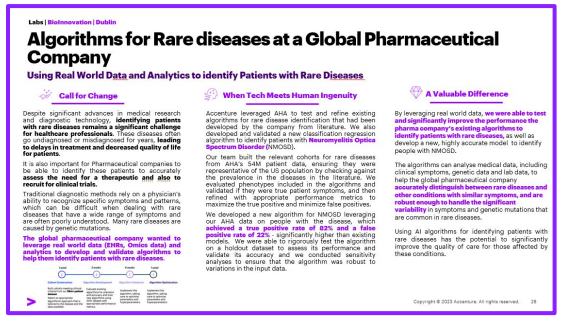


Access a full view of a patient's health record



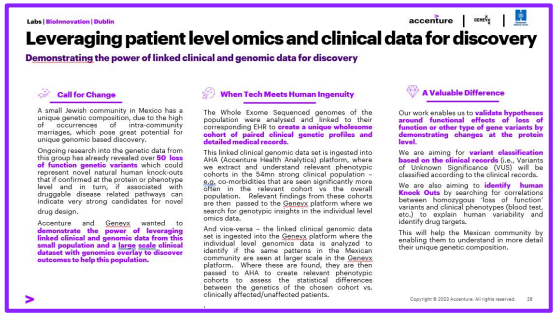
Develop data-led clinical trial solutions

Using Real World Data & Analytics to identify Patients with Rare Diseases



Leverage Real World Data to identify patient sub-populations for precision medicine

Ability to link clinical and genomic data for discovery



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A word of caution…

Without a robust security strategy, GenAI products pose a heighted risk of compromise. Building on your existing Ethical Guidelines, industry needs to consider model risk, plagiarism and copyright infringement.

Top Considerations Relevant to Life Sciences

Copyright Infringement and Plagiarism
In bringing together information from the internet, GenAI tools might use copyright protected content. We're already seeing plagiarism claims made and detection tools being developed.

Intellectual Property and Privacy
As tools continuously learn, data submissions are at risk of being used to generate content. Sensitive data could be used to train models. Italy temporarily banned ChatGPT on such privacy concerns.

Cybersecurity
While GenAI will improve tools that defend against cyber attacks, cyber attacks themselves will continue to become more sophisticated.

Inaccurate or Misleading Information
Whilst GenAI tools can delight with creative responses, these tools may produce inaccurate information or "fill in the blanks" which can produce misleading insights.

Human Bias
Since GenAI tools are trained on human-created data, there will be a risk that human bias can infiltrate the generated content.

Human trust
It is increasingly difficult to determine which outputs have been artificially generated, which translates to a need for a system that allows for positive human involvement.

The market is responding

There are new models, frameworks, and technologies available that help guide AI programs forward with trust, security, and privacy.

Emerging Startup Ecosystem

Emerging tech companies are working to secure AI

Companies formed in the last year have raised between $5 - $10M to develop security components of GenAI.

Hidden Layer, Robust Intelligence, Troj.AI, and CalypsoAI are racing to provide solutions.

Accenture tracks these projects to provide leverage to clients.

MITRE ATLAS™

Adversarial Threat Landscape for Artificial-Intelligence Systems

Research giant MITRE has produced a framework for evaluating the risks of current and future AI systems.

Accenture applies this framework to client projects to provide a holistic approach to securing GenAI uses.

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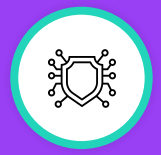
Recognizing the importance of responsible AI, amplified by the unique risks posed by Gen AI

Workforce Displacement

Unreliable Outputs



Confidentiality & Security

Liability & Compliance

Bias & Harm

While **95%** of businesses believe they will be impacted by EU AI Act, [1]

… only **6%** have built a Responsible AI foundation and put principles into practice. [1]

...and **80%** of business say they'll commit 10% or more of their total AI budget to meeting regulatory requirements by 2024.

Recent Accenture survey revealed that **92% of the companies support some level of government regulations** around AI

References

[1] From AI compliance to competitive advantage

[2] Salesforce Ethical Leadership and Business report

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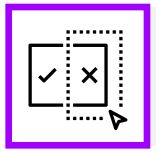
Gen AI risks and how to mitigate them

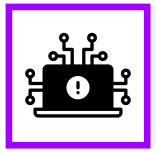
Key Gen AI risks

IP infringement, plagiarism and legal risks



Misinformation

Proprietary and confidential information



Prompt hacking

Language toxicity

Protection of AI output and security

Biased questions and answers

Inaccuracy

Workforce displacement and readiness

Proactive mitigation strategies

01 Clear governance and accountability

02 Updates to internal ways of working

03 A risk intelligent selection strategy for foundation models

04 Full model ownership and governance

05 ‘Run-time’ technical controls

06 Human in the loop

07 Ethics and AI training

08 Responsible AI

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Responsible AI is critical in highly regulated industries like LS

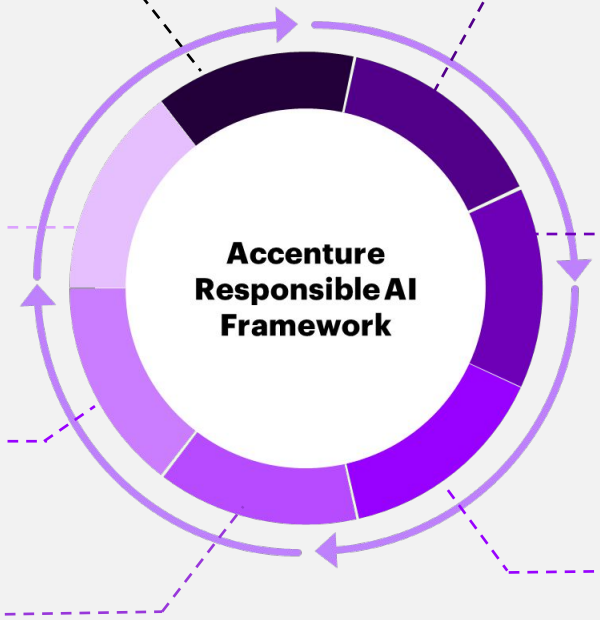
Responsible AI is the practice of designing, building and deploying AI in accordance with clear principles to empower businesses, respect people, and benefit society — allowing companies to engender trust in AI and to scale AI with confidence

Soundness
- Context & Comprehension
- Data Quality
- Model Performance & Validation

Transparency
- Interpretability & Explainability
- Understanding
- Traceability

Privacy
- Data Ethics
- Human Rights
- PII Privacy & Regulation

Sustainability
- Environmental Sustainability
- Human-centric design
- Socio-economic wellbeing



Fairness
- Anticipating bias
- Encouraging Diversity

Robustness
- System Security & Safety
- System Resilience
- Response Plan

Accountability
- Governance
- Human Oversight
- Auditability

Our framework is based on 7 interconnected dimensions. This approach is required to become **Responsible by Design**

It is designed based on the **EU AI** Act and joint research/partnership with Alan Turing Institute, **MIT**, Oxford University and Stanford University

Both business and IT capabilities are necessary across each dimension to develop the necessary tools, processes, controls, governance and trainings with **no regrets moves**

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Illustrative – For Discussion Only

Getting to the right AI operating model

What are Generative AI implications?

WHAT WE ANTICIPATE	KEY IMPLICATIONS FOR ENTERPRISE
GenAI has the potential to impact the entire value chain. Parts of industry that have been less exposed to analytics will need to be engaged to maximise GenAI value	**Design an overarching GenAI strategy and approach** to reduce risks of divergence from a fully federated approach
Innovation with AI will become more democratised. The pace of experimentation will be more rapid given the bar to using LLMs has been significantly lowered	**Refine/augment existing route to live methodologies** for AI powered applications, balancing pace of innovation with robust release management
industry's ecosystem landscape will evolve rapidly. industry's strategic partners will most likely develop diverse capabilities inspired by Co -Pilot and ChatGPT	**Streamline partnership strategy** to build an overarching view of the GenAI ecosystem and strategic partner roadmaps and ensure a joined -up approach
The pace of GenAI innovation risks siloed solutions and adoptions. The wide range of tech and deployment options introduces the risks of disjointed solutions	**Introduce LLM design & technical authority** to oversee reference architecture and consistent model selection & application deployment patterns
Guardrails will need to evolve at pace. To ensure compliance across all industry functions on legal, Responsible/Ethical AI, sustainability, security matters	**Adopt pragmatic, cross -organisational guardrails** for data privacy, legal, IP and responsible and ethical AI to keep pace with the latest innovations
GenAI will create new roles and skills. New roles and practices will be needed to conduct activities such as prompt engineering	**Build centralised expertise** in the short term in order to reach a critical mass of GenAI skills
The impact on the current workforce is likely to be high. Though the impact of GenAI on the regular workforce are not yet fully understood, it should not be underestimated	**Formulate a coordinated impact assessment and skilling strategy** to enable workforce readiness in the future world of work

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Thank You

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Kailash Swarna, Ph.D., MBA

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