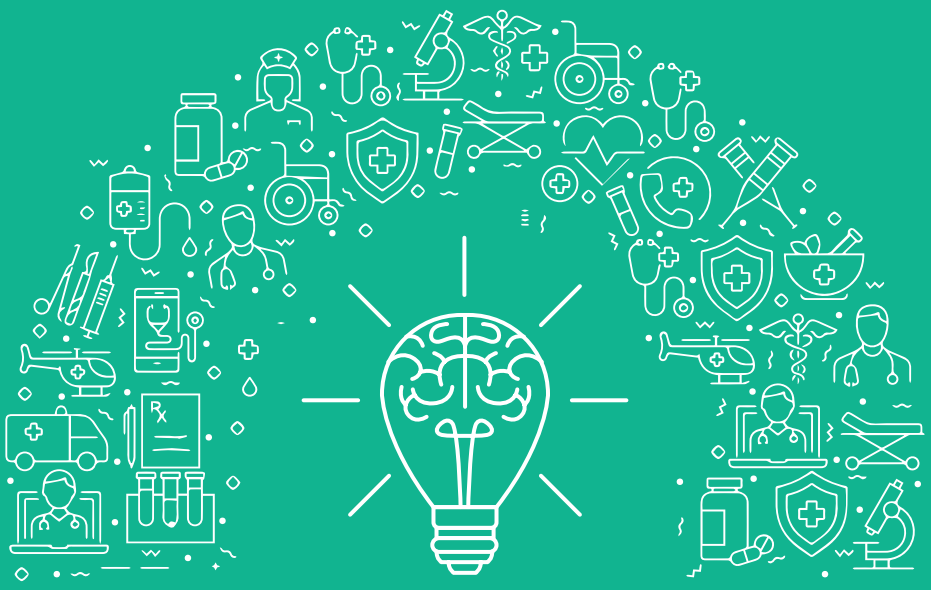


Trend 1: Generative AI promises innovation and enhancements to the life sciences value chain

- Generative AI in life sciences promises to drive both innovation and strong growth, offering faster drug discovery and development, better and earlier diagnosis, and insights from diverse sources of data.
- Life sciences leaders must tread a careful line between pushing for innovation and responding to very real concerns about data privacy and ethics as regulatory regimes around the world set standards and guardrails.
- If companies embed responsible AI at every stage, we expect that generative AI will significantly reduce time to market and increase effectiveness of R&D by accelerating drug discovery, optimizing clinical trial design, enhancing data analysis, and streamlining regulatory submission.

Generative AI burst into the mainstream in 2023, and companies are rapidly experimenting and developing exciting use cases, such as an AI tool capable of detecting tiny cancers almost invisible to the human eye. Tools like these have tremendous potential to transform life sciences in this decade. We anticipate that innovations built with generative AI will impact the entire life sciences value chain, from drug discovery to distribution – with drug development being the next frontier. Boston Consulting Group

has projected that the generative AI market in healthcare will grow from $1 billion now to $22 billion by 2027, a compound rate of 85%. Potential benefits include fewer bottlenecks, lower administrative burdens, faster drug discovery, and improved data analysis.

However, generative AI introduces and amplifies ongoing concerns about responsible AI, particularly data quality, privacy, ethics, and security. In life sciences, these risks could compromise patient records and drug safety. Life sciences companies are likely to face new regulations around AI, evolving as the technology matures and societal implications are better understood.

Life sciences firms must walk a tightrope of simultaneous rapid experimentation and risk mitigation to unlock value responsibly from generative AI. To realize business value while minimizing risk, it is imperative to understand patient impact, ensure ownership of AI models, and maintain strong data and AI governance. Ethics, governance, and transparency are vital to earn trust from the medical community, regulators, and the general public — and they are central to an AI-first approach. Looking ahead, we believe that taking this approach will lead to reduced time to market and will facilitate managing the increasing complexity in drugs, regulatory requirements, and patient expectations.

Exciting potential

As in all industries, generative AI investment in life sciences exploded in 2023. As companies across sectors continue to increase experimentation and use cases, 2024 looks to be the year when many get to grips with this transformative technology. In March 2024, the UK's National Health Service piloted an AI tool called Mia to detect cancer in the mammograms of more than 10,000 women. It found tiny tumors nearly invisible to the human eye in 11 of the mammograms. In another use case, a deep learning AI algorithm detected autism spectrum disorder using retinal images with a claimed 100% accuracy. However, since AI could spur overdiagnosis and associated concerns, providers will also need governance and a risk-based approach, such as humans-in-the-loop, to deploy these capabilities responsibly.

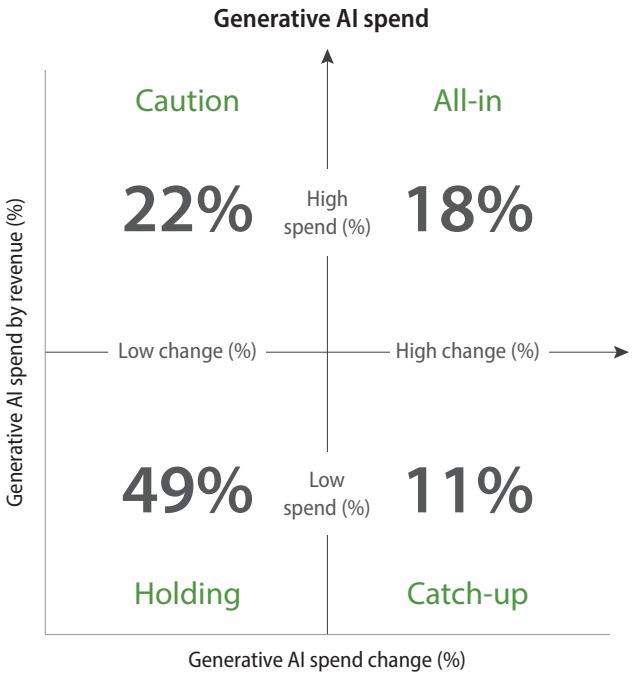
Transformative use cases such ad these indicate generative AI has the potential to impact every part of the life sciences value chain, from drug discovery to manufacturing. For example, our own work with AI assistants in clinical and regulatory operations indicates that companies can significantly reduce time to market. Executives' belief in this potential is reflected by their increased investment in AI. Enterprise spending on generative AI services, software and infrastructure is anticipated to increase from $16 billion in 2023 to $143 billion by 2027 at a compound annual growth rate of 73.3%. Life sciences and healthcare has increased spending in similar fashion. Research and development in generative AI use cases, which included protein and molecule generation and synthetic healthcare datasets, reached $983 million in fundraising in 2023. Meanwhile, $216 million was raised for commercial and medical projects within verticals such as predictive tools, patient-doctor interaction summaries, and patient data analysis. Life sciences leaders

are spending big on generative AI and have plans to accelerate even more.

According to an Infosys survey of 100 life sciences executives, 73% of respondents say they will spend $15 million a year or more on generative AI — more than they plan to spend on other technology initiatives.

Nearly one-third (29%) indicate that their investment in generative AI will grow by more than 40% from 2024 to 2026. As shown in Figure 1, spending amounts and projected spend change are beginning to diverge among life sciences businesses. The most popular industry application for generative AI is in drug discovery and early-stage development, which polled as the top choice for investments over the next five years.

Figure 1. Although AI spending is up, the cost and complexity of putting AI to work splits enterprises into distinct cohorts



Source: Infosys Knowledge Institute

Generative AI in drug discovery

Drug discovery is a high-risk, high-reward proposition. The discovery process can take up to 14 years, and 97% of potential cancer drugs fail during clinical trials. Generative AI can improve several stages of the discovery process through applications such as generative models for drug discovery, reinforcement learning, and drug-disease associations.

Life sciences researchers and companies have

> "For the first time in human history, biology has the opportunity to be engineering, not science ... We're going to have incredible tools that bring the world of biology into the world of computer science. And that is going to be profound."
>
> **Jensen Huang**
> CEO, NVIDIA, speaking at University of California, Berkeley

already put generative AI to practical use in their fields of expertise. Stanford Medicine has proven this point with SyntheMol, a generative AI model providing new drugs for antibiotic-resistant bacteria. Insilico developed an anti-fibrotic small molecule inhibitor that has progressed from origins in a generative AI algorithm to a Phase II clinical trial.

Merck has used a small molecule generative AI tool produced by Variational AI to explore a wider range of potentially therapeutic compounds. Insilico managed to develop its pulmonary fibrosis drug candidate within 18 months using Pharma.AI. A year later, in 2022, the company announced that its total time from target discovery to phase I took less than 30 months, thanks to its generative AI.

Within the same sector, firms Ordaōs Bio and Absci are focusing on the use of generative AI to further pharma breakthroughs within the protein vertical. Ordaōs Bio is using deep learning and proprietary "generative perception systems" to create mini-proteins for pharma and biotech companies. Absci uses zero-shot learning — a type of deep learning that makes inferences about concepts it has not been directly shown — to validate and design de novo antibody candidates to reduce cycle time for drug discovery.

NVIDIA is collaborating with Amgen, the pharma giant specializing in biological medications through advanced genetics, to build generative AI models for drug discovery. NVIDIA CEO Jensen Huang believes that what he terms "digital biology" will be the "next amazing revolution," with the revolution already underway in fields such as genomics, cell engineering and synthetic biology.

The next frontier

On the development side, generative AI has become the new paradigm, with its significant potential to impact the entire cycle of clinical trials, from study design to patient recruitment to analyzing data. (See also Trend 7). It can also help reduce cost and accelerate clinical trials. (See also Trend 4.)

A recent article in Nature describes ways generative AI is revolutionizing clinical trials. In addition to design, recruitment and analysis, generative AI also has the potential to deliver prompts and encouragement that keep trial participants enrolled and engaged in trials, Nature notes. Recruitment and retention are well-known major challenges in getting a trial to completion.

On the analysis front, generative AI and AI algorithms can potentially process and analyze complex datasets quickly, identifying patterns and correlations that might be missed by traditional methods. This capability allows for more adaptive and flexible trial designs, where adjustments can be made based on interim results.

In addition to generative AI's potential to propel clinical trials, it might also allow companies to develop drugs via synthetic data, or computer-generated data used as a replacement of data from humans or real-world events. In the quest to treat diseases, clinical research needs high quality data.

As disease-study grows more specific, the datasets can grow thin.

Here, generative AI applied to quality small data sets can be used to synthesize larger datasets that can advance research and treatment. Published research shows success using this approach in studying leukemia.

Augmenting existing solutions

While more modest than new miracle drugs and game-changing innovations, generative AI also augments existing processes. Solutions driven by generative AI to enhance process across pharmacovigilance, clinical trials, personalized medicine, data management and analysis, and administration significantly reduce time to market and costs.

As generative AI models are trained to detect adverse events, they can enhance pharmacovigilance. Patient reactions are analyzed using data from multiple sources to alert for issues or clinical trial complexities. Data ingestion and trend detection improve pharmacovigilance, understanding patterns that could contribute to adverse reactions.

As with the United Kingdom's NHS's success in reading mammograms, generative AI-fueled innovation extends beyond crafting novel therapeutics to diagnostic innovations. A recent study shows that generative AI can detect sepsis in patients, and Paige.AI uses generative AI to improve early detection of prostate cancer. It is the first firm to win FDA approval for the use of AI in digital pathology.

Personalized, precision medicine is another area that directly benefits from the analytical and interpretive capabilities of generative AI. Access to vast quantities of data offers deeper patient insights, allowing for physicians, healthcare organizations, and pharmaceutical companies to create treatment plans that reflect the individuality of the patient.

Previously, it was not possible to achieve this level of personalization across a detached medical history, and at scale. Patients visiting multiple doctors across different specialties did not receive cohesive care due to fractured datasets and limited visibility.

However, generative AI through large models creates a holistic patient picture and uses that information to develop a personalized care plan for that individual. While the technology is in place, access to all this patient data is constrained by healthcare regulators (e.g., HIPAA in US, NIH in UK).

In a similar vein, generative AI organizes disparate data sources, gives structure to unstructured data, and brings together apparently unrelated information in ways that deliver new meaning.

Generative AI has the capacity to absorb and analyze data from billions of sources, so it could potentially collate data from multiple sources to extract insights, manage administration, refine patient interactions, and collect historical medical knowledge.

This is especially valuable for clinical trials. For example, data held within traditionally fractured sources such as physician notes, laboratory notes, clinical trial insights and

historical medical knowledge could be ingested and analyzed to build health and pharma intelligence.

Healthcare providers and pharma companies can then use this intelligence to personalize medicine, discover bottlenecks in healthcare or operations, and improve clinical trial outcomes.

The Truveta Language Model is an large language model designed to overcome the complexity of siloed and inaccessible healthcare data. It's being used to turn electronic health record (EHR) data into accurate data points for drug, disease, or device research. Its goal is to simplify access to data and improve patient outcomes.

Finally, within the broader generative AI category, Google has consistently worked to build a safe, consumer-focused EHR record since 2008. The company's Google Health project was shut down in 2012, but the tech giant has continued to work toward more connected health applications through the use of generative AI, including two new models launched toward the end of 2023. These focus on improving administrative tasks and research development.

The need for guardrails

To reap any benefit from generative AI, life sciences companies must put in place guardrails that address the security, privacy, ethical, data quality, and trust concerns its existence brings into play.

Life sciences companies must address these concerns before generative AI is implemented at scale. Specific solutions are emerging to address the sector's major challenges of access to universal data and shared insights.

However, even as generative AI solutions offer "black box" solutions, they raise other thorny problems. Any generative AI data solution must answer ethical, accessibility and security questions about non-transparent and potentially biased data use that could impact patient trust and outcomes. Experts currently advocate for a glass box model that treats data ethically and transparently.

Placing humans at the center of these innovations and ethical practices provides a

> "Embedding personal generative AI assistants into everyday work processes to improve speed and productivity is not a choice of "if to do it" but rather "when to do it."
>
> **Martin Woergaard**
> Chief executive officer, BASE Life Science

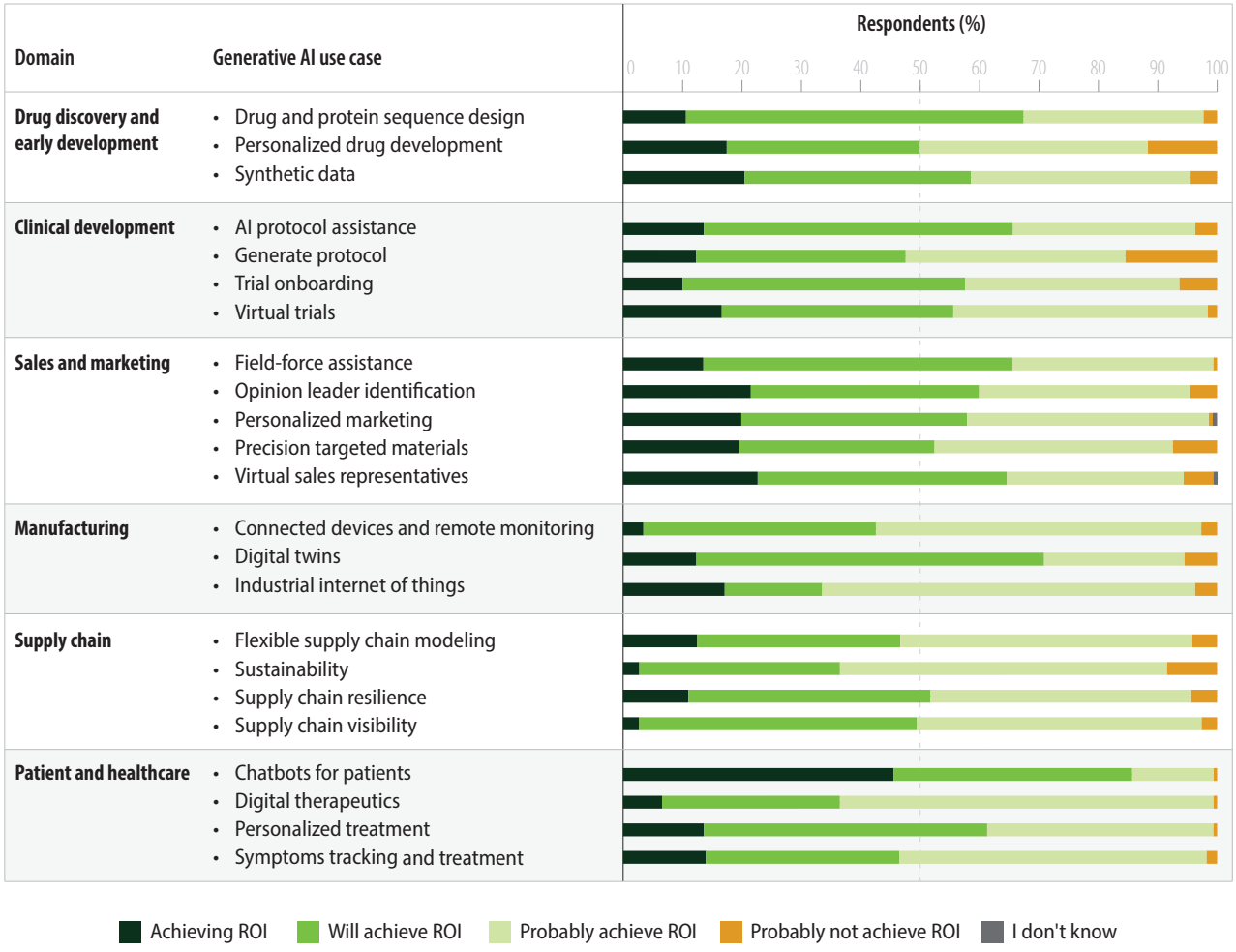
simple yet effective guide for generative AI implementation and will create a safer path to improve patient and practitioner outcomes.

Confidence over ROI

The life sciences and healthcare sectors have struggled to realize benefits from AI, despite heavy investment. In fact, it lags other industries in return on AI investment – possibly because of the greater volume of data that must be analyzed. Computer processing power and capacity must increase before complex conditions can be mapped and addressed with confidence. Also, healthcare data requires considerable curation before it can be used in AI models.

Generative AI provides an opportunity for life sciences to significantly increase their return on AI investment. As shown in Figure 2, chatbots currently demonstrate the

Figure 2. Life sciences leaders are confident generative AI will provide ROI in the next three years



Note. Percentages do not total to 100 due to rounding.

Source: Infosys Knowledge Institute

highest ROI for life sciences enterprises. This is not surprising, as chatbots are a mature technology, developed well before the recent wave of generative AI innovation.

Other areas demonstrate ROI as well, with sales and marketing as the most productive use cases. In fact, our research shows each area of potential generative AI-assisted innovation demonstrates some return. While this points to a positive future, prioritization and adoption challenges must be overcome to realize this potential. The area most anticipated to increase ROI in the coming years is drug, gene, and protein sequence design, with nearly six in 10 life sciences leaders saying that this area will drive returns.

Evolving law and regulation

AI legislation and regulation will be codified in the coming years, as countries take note of the 2024 EU AI Act and study its impacts. In the meantime, guidance is being formulated for the life sciences sector. In the US, the Department of Justice is concerned that the use of generative AI in health records could result in fraud or faulty recommendations, while the Office of the National Coordinator for Health Information Technology has released a draft federal health IT strategic plan that highlights the need for education and transparency around the use of generative AI.

The Coalition for Health AI (CHAI) has developed a blueprint for generative AI in healthcare, and the its efforts are echoed by the Generative AI Council to Advance Life Sciences Innovation, a group of leaders from pharma, academia, and technology.

However, the industry is also wary. Our research shows that life sciences leaders are keenly aware of the barriers that hinder implementation and adoption, based on previous technology initiatives and their pervasive regulatory environment.

Half of all leaders cited legislation and/or regulatory barriers as either significant or highly significant obstacles to their use of new technologies, including generative AI. This is a looming challenge for lindustry leaders. Investment and innovation with generative AI are accelerating. But trust, regulation and legislation move more slowly, and are perceived as obstacles by half of life sciences leaders. This creates a gap between the confidence to invest in the tech and the confidence to use it in a legally and ethically sound, compliant way. This is particularly relevant in life sciences, where misuse, mistakes, and bias can impact on human life.

Guardrails must include accountability, ethics, awareness, transparency, and regulatory compliance at the very least. Designing these now into how organizations use generative AI, at the beginning of their journey, will embed these principles as part of responsible AI and an AI-first mindset.

Generative AI has the potential to dramatically uplift life sciences, improving R&D, engagement, and efficiency. The research insights reinforce the imperative for responsible leadership to guide this exciting technology. Enthusiastic experimentation will transition to methodical adoption. Enterprises that balance these factors can create significant value while serving patients better.