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Generative AI in Life Sciences

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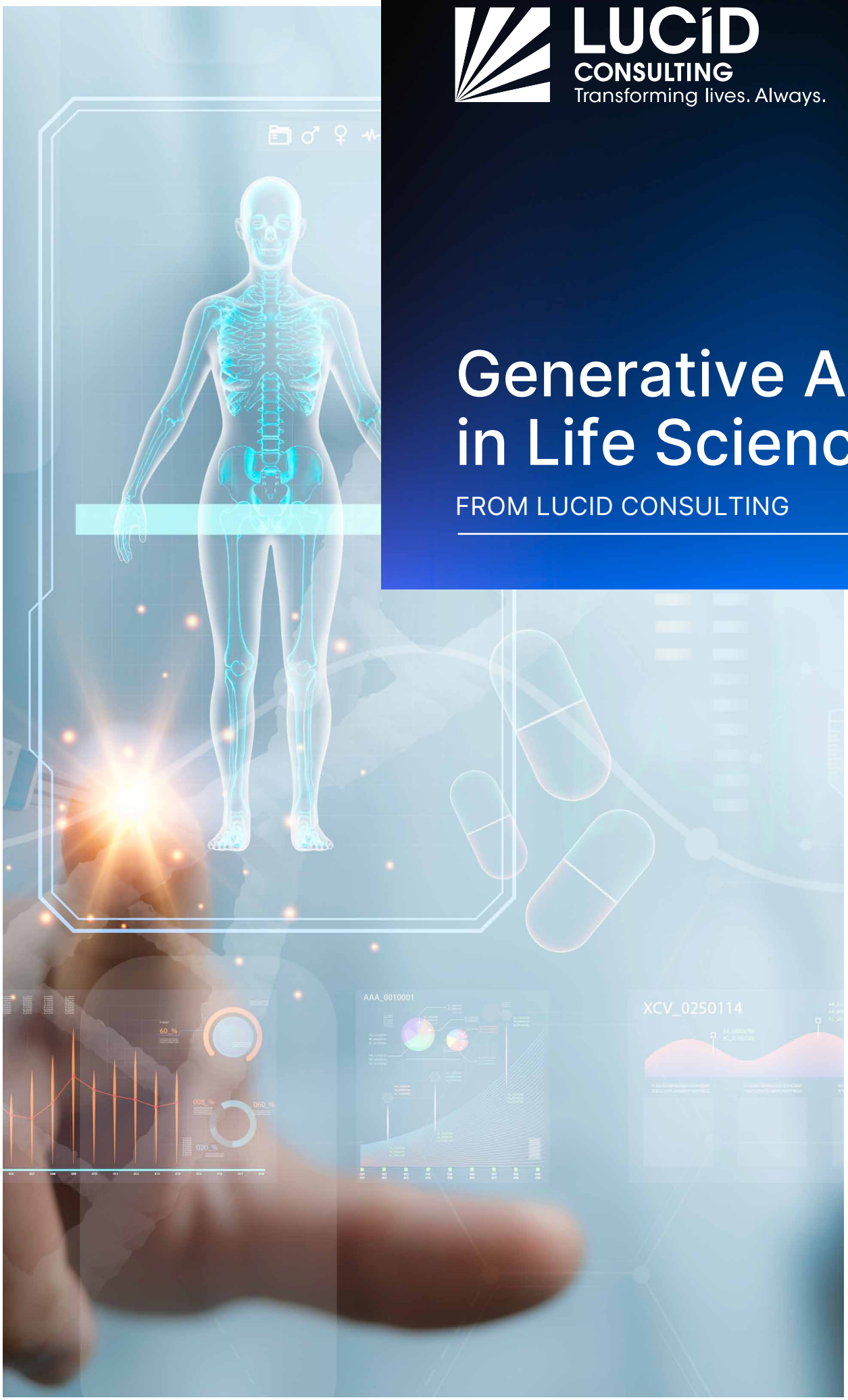

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GENERATIVE AI IN DEVELOPMENT, MEDICAL AND COMMERCIAL: ARE OUR PROCESSES READY, AND DO WE HAVE THE DATA?

There is opportunity as well as hype for generative AI in life sciences. Extensive value is not yet being realised in many areas. Company leaders need to better orient key elements of their operating models toward digitisation and AI – including strategy, governance, processes and data – before they can realise the full benefits of AI.

The life sciences industry and world beyond are bullish about generative AI

Life sciences industry leaders, consultants and vendors are generally extremely bullish on the possibilities for AI to revolutionise the industry. Predictions associated with high use of AI include increases in operating profits of $60bn to $250bn in the coming decade[1,2], with large impacts across Discovery, Commercial and Development productivity. In the current environment, it is almost impossible for top biopharmaceutical leaders to be anything other than positive, as AI adoption and the anticipated forward value is already priced into the stock market valuations of scientific and high-tech companies.

The role of regulators is critical in life sciences innovation, and they appear to be seeking to encourage AI use in a measured way. Key regulators have begun to lay out how they expect AI to be used by industries generally (such as through the EU AI Act) and drug and device development specifically – such as in FDA[3], EMA[4,5], NMPA[6] and PMDA[7] papers and initiatives.

It is also worth noting that underlying technology is evolving very rapidly. While the forecasted benefits are closely linked to existing deep learning and large language models, some AI industry leaders and thinkers including Sam Altman, Demis Hassabis and Leopold Aschenbrenner[8] predict the development of superhuman artificial general intelligence (AGI) within the next 5 years. This is far faster than the median 2040-2050 time period most AI observers predict, and could have a huge impact on decision making across the drug development life cycle. Definitions of AGI may vary, but the next step will almost certainly be the use of AI 'agents' that can memorise, plan, act, use tools and emulate reasoning in real-world situations. In pharmaceutical companies, an example could be virtual business development executives taking business and product development investment decisions with minimal or even without human intervention.

[1]'Re-inventing Pharma with Artificial Intelligence', Strategy& (2024). Estimate of up to $254bn annual profit increase.

[2]Generative AI in the pharmaceutical industry: Moving from hype to reality, McKinsey (2024). Estimate of $60-110bn annual profit increase.

[3]Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products | FDA, FDA (2025)

[4]Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle_240903, EMA (2024)

[5]EMA multi-annual AI work plan 2023-2028, EMA (2023)

[6]https://chinameddevice.com/digital-health-nmpa-ai/

[7]The 5th Subcommittee on AI (Artificial Intelligence) | Pharmaceuticals and Medical Devices Agency, PMDA

[8]As of Jan 2025, CEO of OpenAI, CEO of Google DeepMind, and former OpenAI researcher and author of 'Situational Awareness' respectively

But are we seeing the value yet?

Artificial intelligence has been with us for some time. Across industries including life sciences, however, the business value of AI implementation is not yet obvious. Examples of challenges include:

- Economists are struggling to detect productivity benefits in the data. For example, only about 5% of US business said they used AI to produce goods and services in 2024. In Britain, 20% report doing so, albeit according to a different definition. Yet British GDP growth is weak and has performed well below that of the US.
- Companies focused on AI-driven R&D have delivered only high profile failures to date, including those of Deep Genomics, BenevolentAI, Exscientia and Recursion, as well as Sumimoto's AI-driven schizophrenia candidate which failed in 2023[9]. These failures suggest that AI drug discovery might not yet increase chances of a candidate reaching the market. This may be at least in part because we lack sufficient data to predict efficacy and tolerability at the human system level. This challenge will remain for some time to come.
- Initial feedback even on high profile use cases has been mixed, such as the widely-cited pharma company CIO who cancelled Microsoft's CoPilot AI assistant in 2024 due to its high costs and low value[10], including its 'middle school level' PowerPoint presentations.
- Draft regulator guidelines outline expectations that are entirely reasonable to ensure patient safety in drug development, but potentially hard to deliver for a generative AI tool in practice. Expectations include the need to engage regulators early on plans for applying AI to drug development, to describe each proposed model and how it operates, to demonstrate relevance and reliability of training data, and to evaluate the model using independent assessment data, while demonstrating absence or control of data drift or model bias. In effect, this means that an AI tool must go through its own development program before it can be applied to a drug development process and, depending on the use case, validity may need to be demonstrated each time to account for important variables such as therapy area, study approach, and patient characteristics.

There are also future challenges. As a notable example, the costs to power AI compute are extremely high. This may limit the scalability of the most powerful technologies, at least initially.

OpenAI's Pro subscription which gives access to its latest public models currently costs $200 per month per user, and is still loss-making. OpenAI's o3 model recently used up to $3000 per query on compute to pass a human-like reasoning test[11]. On the other hand, Chinese models such as Deepseek and Qwen suggest innovations may be possible on far more reasonable budgets, and Mistral AI are a French company focused on developing scalable models that reduce computing cost while maintaining accuracy.

[9]See e.g.: Revolution, interrupted: Why AI has failed to live up to the hype in drug development, Globe and Mail (2024)

[10]Morgan Stanley research note (2024)

[11]'OpenAI's latest model will change the economics of software', Economist (Jan 20, 2025)

What should life sciences companies be doing to capture the value of AI?

AI cannot yet add value without sufficient relevant data and fit-for-purpose frameworks to operate in. Regardless of how impressive generative AI capabilities are in theory, Development, Medical and Commercial functions in life sciences companies must **address their processes and operating models first**, while focusing on use cases that current generation AI is most fit for.

We recommend leaders:

1. **Ensure accountability and drive, but be wary of developing an 'AI strategy'**
   An innovation mindset is required to incorporate AI into business processes – using expertise to understand the art of the possible, identify prime opportunities, to experiment, and to succeed or fail fast if necessary. However, generative AI is a potentially highly disruptive tool, but not a business process or outcome in itself. AI goals and initiatives should therefore be considered and managed in the context of how they contribute to overall business and functional strategies, with the associated best practices of performance management that entails. A separate AI strategy risks separating the tool from the desired outcomes. Guiding principles will however be useful to set expectations in terms of processes and governance when dealing with AI pilots and initiatives.

2. **Clarify, centralise and standardise key processes where possible, then digitise and apply automation**
   Most companies annually meddle – often unnecessarily - with core processes that can be overseen at the central level of the function or business, and highly standardised. This makes digitisation and then automation practically difficult and expensive, as each change can create the need for adaptation of background systems and tools. Well-practiced processes like asset planning, Medical Information management, MLR review and integrated evidence generation planning are prime examples where AI can support automation and reduce operational burden, while keeping a 'human in the loop' for compliance or other decision-making reasons.

3. **Review and foster AI initiatives centrally, and shift to steady-state where RoI is most achievable**
   Current AI models are useful for ideation, pattern identification, and automation in established processes with large amounts of existing data[12]. They do not (yet) do well at abstract reasoning or solving complex business problems, as needed for much drug development and commercial decision-making.

   Many large and mid-sized companies have multiple AI pilots running in different functions and locations. Initiatives are focused most in Discovery, then Commercial, Development and general operations[2]. Both business-wide and functional initiatives should be assessed through central governance, to identify and share where scalability and/or return on investment (RoI) are being - or close to being - achieved, and to potentially terminate or hold where they are not.

4. **Get a handle on the data – access, relevance and reliability are key**
   To gain valuable insights and real world evidence using AI, companies must combine internal data with externally available large datasets, including genomics, proteomics, claims and electronic health records (EHR) where appropriate.

   In this complex technological and regulatory environment, data strategy and management have never been more important. Robust data inventories should capture the data available, and what it is valid for. Governance is key to ensure appropriate permissions and protections are in place to use data in AI

[12]Such as internal document drafting, protein folding modelling, and provision of standard self-service Medical Information based on common external stakeholder queries

models, especially where data is sourced from or processed by external parties. Expertise with international data is also important, as processes for obtaining non-US healthcare datasets can be cumbersome and time-consuming, yet these data are vital to achieve representative results with relevance for national decision makers.

Statistical science expertise is also critical to understand what can be achieved with the available data. Even in an unlikely future where industry ever collaboratively shared all its data, this dataset would pale in comparison to the training data of the well-known LLMs, which comprises the entire internet! It is also vital to identify requirements early enough to gain timely access – particularly where non-US healthcare datasets are involved.

5. **Clarify the role of vendors**
   Since LLMs came online, there has been an eruption of vendors offering generative AI services and targeting the healthcare industry. These vendors are often not differentiated, and typically need to ingest company data to apply their models and generate insights. However many life sciences companies don't want to share their proprietary data with third parties, nor to sign costly long-term subscription contracts for a capability they can build internally, so in house development of LLM tools has been common in mid- to large-size organisations. This may continue except in areas where vendors have genuine differentiators and specific expertise – simply having a modified LLM and offering an insight consulting service is typically not good enough. For smaller organisations, vendors are more likely to provide a valuable service which is not economical to build and maintain internally. In cases where vendors are involved, an internal vendor management capability that is knowledgeable about AI is a prerequisite. This is partly to ensure a mutually beneficial partnership is formed with transparent RoI tracking, but also to ensure a company does not become overly reliant on vendors for a core capability that can be built internally, or tied to a specific vendor when better value alternatives may become available.

Striking the balance: Don't be left behind, but don't be a first adopter?

There has been a tendency to overhype AI's potential, which is slowly cooling as executives realise that productivity accrual will be a gradual process. However it would be a mistake to disregard AI's obvious potential. Biopharmaceutical and device companies should engage with the technology, but in the right way. A focus on leveraging valuable early use cases, establishing fit-for-AI processes and governance, maintaining robust data strategies, and appropriate skills sourcing will all be critical to generate value and competitive advantage in the use of AI.

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