WHITE PAPER

Equity & Ethics

A How-To-Guide for Implementing AI in the biopharma industry

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Introduction

The healthcare industry drives a critical balance between innovation and necessity. Within its dynamic landscape, a new emerging technology has the ability to revolutionize drug development, decision-making within medical affairs and subsequently, the effective treatment of millions of patients.

Artificial Intelligence (AI) and Machine Learning (ML) have ripened in recent years, emerging as powerful technological forces. Yet, an understanding of different types of AI — such as large language models (LLMs) and generative AI (GenAI) — still largely eludes the general public and much of the healthcare industry. But with a primary commitment to ethical practices and safeguards, AI promises to be a transformative technology within the biopharmaceutical sector, from streamlining drug development, timelines and optimizing resource allocation to strategic planning and personalization within medical affairs teams.

AI can expeditiously sift through extensive data to provide faster analytics and predictions within early-stage research, generate insights on personalized medicine and even facilitate drug repurposing. These advancements result in alleviated stresses on medical affairs teams, operational cost savings, improved trial feasibility and better patient outcomes. However, ethical integration remains paramount — including issues of privacy, transparency compliance and bias mitigation.

AI is also reshaping healthcare in developmental processes and decision-making. This whitepaper will provide a wide-lens look at the state of AI in the biopharma industry and the best practices for integrating it into drug development and strategic planning, while prioritizing ethical standards of equity and accessibility.

The trials and tribulations of drug discovery and healthcare

Drug discovery is an intricate and multidisciplinary process that lies at the heart of the biopharmaceutical industry. It is the essential journey from identifying a promising molecular target associated with a disease to the development of a safe and effective therapeutic compound. Historically, drug discovery has been a laboriously long and resource-intensive process, with the average time to market at around 14 years and average costs hitting $2.6 billion — all for a single successful drug.[1]

Drug discovery processes include several key stages,[15] such as:

- *Target Identification and Validation*: Identifying and confirming disease-related biological targets for potential drug intervention.
- *Lead Discovery*: Scanning chemical libraries and designing molecules (lead compounds) that can interact with the target to find initial drug candidates.
- *Lead Optimization*: Refining and improving the lead compound's safety, efficacy and pharmacological properties.
- *Preclinical Development*: Assessing drug safety and efficacy in lab settings to prepare for human trials.
- *Clinical Trials*: Conducting human trials to evaluate safety and efficacy, with each phase involving more participants.
- *Regulatory Approval*: Submitting data to regulatory agencies for market authorization, such as the FDA or EMA.
- *Post-Market Surveillance*: Continuously monitoring drug safety and effectiveness in real-world patient populations to detect unexpected adverse events.

Historically, drug discovery has been a laboriously long and resource-intensive process, with the average time to market at around 14 years and average costs hitting $2.6 billion — all for a single successful drug

The traditional drug discovery process is not only resource-intensive but also characterized by a high rate of failure. In fact, 90% of phase I drug candidates fail to reach approval.[2] Many potential drug candidates don't make it past these early stages due to safety concerns or lack of efficacy.

The challenges of the drug discovery process, including its demanding timelines, information overload, complexity and clinical trial uncertainties, can place significant stress on Medical Science Liaisons (MSLs) and healthcare professionals. The burnout caused by constant pressure to stay updated, navigate evolving practices and cope with working conditions was shown to lead to mental health issues, substance abuse and even suicidal ideation. Healthcare professionals have historically shown higher suicide rates than any other vocation and twice that of the general population,[4] and this problem was only exacerbated by the COVID-19 pandemic.[5] These traumas also create ripple effects of medical errors, reduced productivity and higher physician turnover rates.[3]

This harmful combination of preexisting drug discovery challenges and high stress put on healthcare professionals underscores the importance of a more efficient, effective and supportive way to approach its processes.

NLP, MLMs and GenAI, oh my!

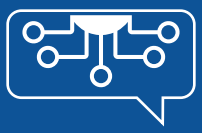
How different AI tools are changing the industry

The use of AI-driven tools in the healthcare industry is not a new initiative, with its use in scientific reasoning dating back to 1965.[6] But the maturation and capacity of these systems have only recently reached a place to actually ingest, integrate and generate new valuable content and drive a far more significant impact on the industry and its professional teams.

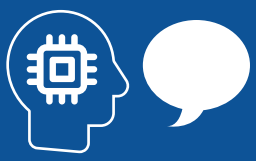
The advent of three particularly pivotal AI technologies — Natural Language Processing (NLP), Generative AI (GenAI) and Machine Learning Models (MLMs), including large language models (LLMs) — are redefining the way researchers approach drug discovery and pharmaceutical research.

- *NLP:* a branch of AI that focuses on enabling machines to understand, interpret and generate human language. It enables computers to process, analyze and extract meaning from text and speech data, bridging the gap between human communication and computational comprehension. The significance of NLP lies in its capacity to sift through the ever-expanding sea of biomedical information, empowering scientists to make informed decisions and accelerating the pace of discovery.
- *GenAI:* generates new, original content, often in the form of text and images but can be in the form of other data. These systems use sophisticated algorithms and neural-like networks to produce outputs based on patterns and data they have learned from existing examples. GenAI algorithms have the notable ability to generate novel molecular structures and compounds, offering a treasure trove of potential drug candidates. By simulating the creativity of medicinal chemists and exploring chemical space more

3 PIVOTAL AI TECHNOLOGIES:



Natural Language Processing (NLP)
Enables machines to understand, interpret and generate human language.



Generative AI (GenAI)
generates new, original content, often in the form of text and images but can be in the form of other data.

Machine Learning Models (MLMs)
use algorithms, statistical patterns to enable computers to learn from data and make predictions.

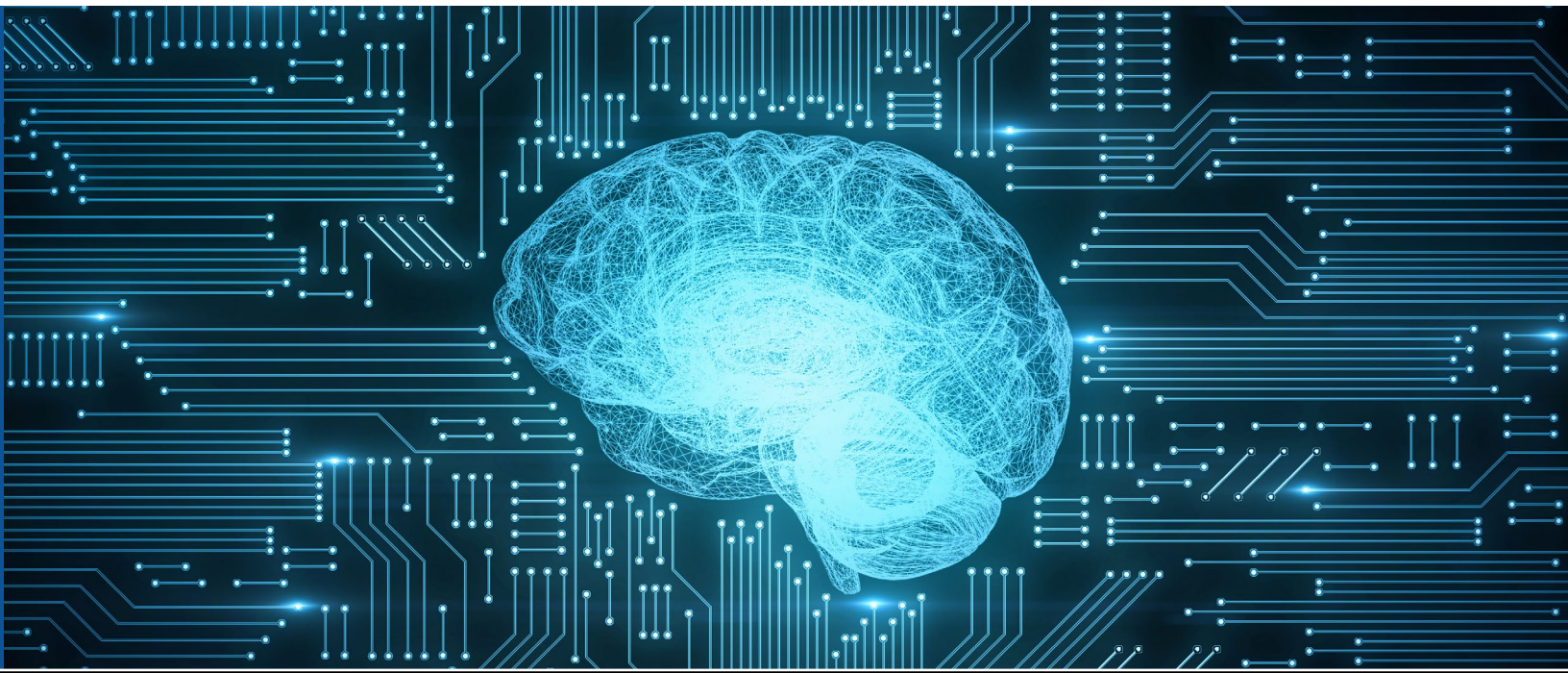
efficiently, GenAI accelerates lead discovery and optimization processes, potentially shortening the timeline to find new therapies for the most challenging diseases.

- *MLMs:* use algorithms and statistical patterns to enable computers to learn from data and make predictions or decisions without being explicitly programmed for specific tasks. These models are designed to recognize complex patterns and relationships within datasets, allowing them to provide insights, classify data and make recommendations. In pharmaceutical research, MLMs, including LLMs, leverage extensive medical data to predict drug interactions, optimize clinical trial designs and uncover hidden insights within biological datasets. LLMs, with their ability to process and comprehend vast amounts of text-based information, enable researchers to contextualize findings, identify knowledge gaps and make data-driven decisions.

The growing connectivity and accessibility of these tools and their substantial computing power has ushered in a transformative era for drug discovery. AI algorithms can more comprehensively and quickly analyze genomics, proteomics, clinical trial data and vast chemical libraries, unveiling novel insights and trends that have been historically elusive.[7,11]

AI also provides a key ability to simulate and predict complex drug interactions and outcomes. Drug discovery often necessitates predicting the three-dimensional structures of potential target proteins from only their amino acid sequence, and recently, an AI system — AlphaFold2 — won a Critical Assessment of Structure Prediction (CASP) competition in doing just that.[11]

These computer models serve as invaluable tools in drug discovery, expediting the identification of potential drug candidates and significantly shortening the timeline for bringing life saving medications to market.



AI in early-stage drug development: the perks and pitfalls

Industry leaders in the pharmaceutical sector are increasingly leveraging AI for early-stage research, but they are still grappling with the challenge of defining its overall value and impact on healthcare.

In the process of target identification, one of the first stages is establishing data about how the disease and the potential targets might interact with each other. ML algorithms can analyze data across gene expression profiles, interactions of different protein networks, and genomic and proteomic data to find these potential targets and analyze the possible relationships. Additionally, NLP systems offer critical abilities to find potential target disease pairs from existing literature, which is a primary source of information for target-disease interactions and relationships.[11]

Then, by introducing the generative component of newer technologies like GenAI, this molecule modeling can expand into developing and testing new molecules corroborated by previously gathered data and clinical trials.[8]

Because of how clinical trials are run — which includes high degrees of monitoring and extensive, detailed collection of data — they are well suited to take advantage of these AI technologies. “You have a lot of data that factor into the story that you tell as a company when you roll out a new drug,” Rob Consalvo, H1 Senior Director of Strategic Engagement, explained.[8]

By plugging AI into that story, everything becomes streamlined thanks to extensive pre existing data within the field of drug development. Newer generative AI applications only become valuable when there is deep and dimensional data for them to interpret and integrate into their iterations.

The importance of strong data collection naturally segues the discussion into key challenges to overcome for AI in drug development:

- *Quality and quantity of data:* Thorough data collection is the backbone of AI making informed predictions and decisions — ensuring its accuracy, reliability and chiefly its safety in pharmaceutical research.
- *Bias and generalization*: Biased datasets, and moreover bias-unconscious datasets lead to biased AI models. Ensuring that AI algorithms do not perpetuate existing biases is a critical challenge (which will be discussed further in the ethics section of this paper).
- *Interpretability*: Many AI models, especially deep learning models, are considered "black boxes," which are systems with internal workings invisible to the user, making it challenging to understand how they arrive at certain conclusions. This can be a serious concern in critical decision-making.
- *Complexity of biological systems*: AI models may oversimplify the complexity of biological systems without extensive data training, potentially leading to inaccuracies in predictions.
- *Regulatory compliance*: Meeting regulatory standards while using AI in drug development can be complex. Ensuring that AI-driven processes adhere to regulatory guidelines is a significant challenge.
- *Integration with existing processes*: This describes adapting AI tools to work seamlessly with existing research and development processes and technologies.
- *Validation and reproducibility*: Validating AI models and ensuring the reproducibility of results is vital but can be time-consuming and resource-intensive.
- *Cost and resource allocation*: Implementing AI requires investment in infrastructure, talent and ongoing maintenance, which may pose financial and training challenges.

Alongside these logistical and technical barriers to work through, one of the larger adoption challenges actually lies within establishing human trust in the technology. Earning this trust will be particularly key in the medical industry where the stakes are unyieldingly high.

Just as training a doctor is critical, the effective training of these knowledge bases will make or break the technology's perceived value as well as its trust from medical professionals. "These are life and death decisions that have a very human impact, which is ultimately also why you have to convince people to trust AI as a meaningful AND human centric tool," Consalvo contended.[8]

Integrating AI into strategic planning and medical affairs teams

Just as AI can transform the technical aspects of drug development research, it also bears the potential to radically improve the strategic planning and medical affairs teams — in medical information and decision-making processes.

Particularly within strategic planning, AI becomes exponentially effective in helping plot and predict scenarios, contingent on the system being sufficiently informed about the market landscape, customer relationship management systems (CRMs), sales data, claims data and a long line of other internal data sources.[8,12]

These include (but are not limited to):

- Internal records, systems and processes
- Call center data
- Previous result data
- Government filings
- Consulting reports
- Competitive intelligence
- Complaint data

AI algorithms themselves have reached a place to eventually revolutionize the automation and interconnection of this data for an improved and interoperable digital infrastructure.[13] In the shorter term, this means unloading large amounts of grunt work for MSLs and medical affairs teams, chiefly in the automation of medical information and CRMs.[8] AI will not be a replacement for professionals in medical affairs teams, rather it will augment their jobs by aiding in tasks like data ingestion and retrieval. Beyond automation of data entry, AI can actively record and categorize customer interaction history for the complete lifecycle of interacting with a patient.[8,14]

These benefits present significant improvements for both patient care and healthcare professionals' working environments. But in order for that to be actualized, a shift needs to occur. Many pharma companies and life sciences consider the patient as an endpoint. "We have to start considering patient needs as a flywheel. Patients are a vital component of the process of iteration and provide evidence for improving outcomes… It's a mindset shift. And it's about remembering that patients aren't just a data point, they're people, and people have expectations and needs."[8]

Ethical considerations in AI-driven pharma research

With all of the aforementioned challenges in using AI — both in early-stage drug discovery and medical affairs teams — perhaps the most important issue to address is that of AI's ethical implementation.

Many areas of ethical considerations exist, including (but not limited to):

- *Privacy and data security*: Healthcare data intrinsically contains highly confidential and sensitive information. Protecting patient data is paramount.
- *Bias and fairness*: Addressing systems of prejudice and bias within AI algorithms must be prioritized to promote fairness in decision-making.
- *Informed consent and transparency*: AI models' reasonings and data used to reach insights must be made clear to patients and stakeholders.
- *Regulatory compliance*: Medical data and AI-driven decisions, research and strategy must comply with current regulatory frameworks.
- *Balancing innovation with ethics*: AI-led decision-making must constantly align with ethical standards in pharma research.

Perhaps one of the most highly discussed areas of concern around AI implementation is data privacy and security. Particularly within healthcare, the data is sensitive and inconsistently stored — often in siloed systems — which is not currently well-optimized for AI adoption.[9] Well-structured data implementation and security will dictate the efficacy and value of AI integrations.

But equally as important yet under-discussed is the issue of fairness and data bias within AI algorithms.

Humans are biased, and therefore AI engines running on biased data will only intensify that problem. This means a deeper commitment to the pre existing gaps in the core principles of diversity, equity and inclusion (DE&I) will be needed in the era of AI and ML in healthcare to ensure patients of all backgrounds are able to be served.

Historically marginalized communities are the most likely to face bias and discrimination within healthcare systems. While discussions on ethical issues like data privacy and transparency have been instigated, there is a notable lack of research and efforts supporting this particular ethical issue within AI integrations.[9]

AI systems have also already been shown to perpetuate bias — even when the algorithm in itself is not biased.[9,10] That stems from an algorithm that is developed from human mindsets that actively or subliminally reflect racism, sexism, classicism, ableism, homo- and transphobia, ableism or other issues. It then makes predictions and decisions based on that data. As an example, U.S. medical appointment scheduling algorithms predicted Black patients were more likely to be a no-show (based on its existing data sets) than non-Black patients. This resulted in Black patients being overwhelmingly scheduled in appointment slots with longer wait times.[10] "I don't think enough people as humans are first able to consider what their own unconscious biases are. Without first doing that, you can't dissect the unconscious biases that exist in your creations."[8]

Just as DE&I teams are established to dissect and redress deeply embedded discriminations and inequities within an organization, AI implementation in healthcare will demand the same advocacy to ensure that DE&I principles and practices are found throughout the entirety of the technologies' lifecycles.

The intentional connection of both the quantitative and qualitative data exposing historical bias and inequality must be prioritized in AI training for it to better process and serve the lived experiences of people of color and marginalized communities within the U.S. "The melding of the qualitative lived experience of the patient and the quantitative aspects of their treatment journey is going to be the only way that we can ethically build AI... Ethical tenants have to be observed, because all of us need to be ethical actors when it comes to the health of the patient."[8]

The most damaging cultural pattern that could continue in massive AI adoption is bad actors sacrificing ethics for profit, as has been done prolifically throughout history. The brief history of the United States has not reflected excellence in adapting to its previous technological revolutions; still, AI will equally reflect the efforts of good actors, too.[8]

For AI to instigate a paradigm shift in this pattern — to be an improving technology for the systems of humanity — it must be created consciously and given enough context of what it is doing to be aware of historical oppression and to hold leaders accountable for these systems moving forward.

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>
> **–Rob Consalvo, H1 Senior Director of Strategic Engagement**

Conclusion

The impact of AI on early-stage research, personalized medicine and drug repurposing cannot be overstated. It offers the promise of faster analytics, improved resource allocation, reduced operational costs, enhanced trial feasibility and ultimately, better patient outcomes.

And its potential to revolutionize is not limited to drug development; it also services the broader landscape of medical affairs. By analyzing vast datasets and providing real-time insights, AI enables medical affairs professionals to make informed decisions, tailor engagement strategies and identify key opinion leaders more effectively. AI's ability to provide personalized insights and automate routine tasks empowers medical affairs teams to focus their expertise where it matters most — improving patient outcomes and the overall quality of healthcare delivery.

Yet, it is imperative that the adoption of AI is conducted with unwavering attention and commitment to ethical standards. These encompass safeguarding patient privacy, dedication to transparency, adherence to regulatory compliance and perhaps most significantly redressing human bias and discrimination perpetuated in AI algorithms.

In navigating the transformative power of AI in healthcare, it is essential to strike a balance between safety and innovation and to underpin the human-first pursuit of improving healthcare outcomes for all. The essential guard rail for AI integration will be striking a balance between AI- and human-led decision-making and ensuring that the prioritized principles in practice are that of equity and human health.

For more information about how AI can be integrated across the drug development lifecycle, visit https://h1.co/ai/

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