

Executive Insights

AI in Biopharma: Realizing the Promise

Artificial intelligence (AI) should enable biopharma companies to tackle the entrenched inefficiencies of the costly and time-consuming drug development process.

Drug approval rates, development costs, speed of delivery and patient compliance can all be improved with AI <u>(see AI in Life</u> <u>Sciences: The Formula for Pharma Success Across the Drug</u> <u>Lifecycle</u>). And yet, biopharma has been cautious in adopting AI solutions to date.

This reluctance to adopt reflects both the conservative nature of the industry and the very real issues that the industry must address before the promise of AI can be realized. In this *Executive Insights*, L.E.K. Consulting outlines the adoption barriers to AI in biopharma and identifies the key principles that biopharma and AI companies can follow to accelerate widespread adoption.

Addressing major drug development pain points

The development of new pharmaceuticals is a long and costly process (the largest 10 companies spend \$67 billion on an annual basis), with less than 10% of clinical drug candidates reaching approval. According to market participants surveyed by L.E.K., specific challenges exist at each stage of the drug development process (see Figure 1):

- Identification of relevant and druggable targets
- Efficient optimization of lead candidates
- Reliable testing of lead candidates
- Identification of appropriate target patient segments for clinical trials

Biopharma tends to be concerned with failures at the clinical stage, with approximately 70% of the total drug development costs incurred in the clinic. However, failure at this stage is often caused by suboptimal compounds, so enhancing earlier stages of drug development should result in higher success rates, highlighting the importance of addressing inefficiencies across the drug development spectrum.

There is widespread recognition among biopharma companies that the R&D process is inefficient and that this inefficiency will keep growing if left unaddressed. This dynamic is partly driven by the increasingly complex nature of the biology underpinning the discovery of new molecules and increasing regulatory requirements. Other contributing factors include the facts that most attainable targets or drugs have already been used and that defining clinical trials is getting harder as patient populations need to be defined more precisely to show the desired effect.

Al has the potential to help curb this trend through promising innovative solutions that address drug development pain points, focusing on:

- Improving the quality of candidates (e.g., improved target validation and lead optimization, drug repurposing)
- Optimizing clinical trial design (e.g., biomarker based screening, patient stratification)
- Reducing time to complete activities (e.g., ADME¹ parameter prediction, toxicology profiling, patient recruitment)
- Reducing costs (e.g., enhanced use of in silico databasetrained methods, optimized data collection and analysis)

¹ ADME = absorption, distribution, metabolism and excretion

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Figure 1 Drug development pain points and AI use cases



Source: L.E.K. analysis and research

In addition to streamlining steps across the R&D process, Al solutions also have the potential to redefine the process itself by cutting out steps altogether, for example by moving from target to lead directly, or bypassing the hit optimization process.

Caution holds back adoption

To date, biopharma has been more cautious in adopting AI than other industries, with a number of real issues holding back progress.

First, there are unclear "real-world" benefits. Publicly documented use cases demonstrate the efficacy of AI under specific conditions at specific stages of development, but they often fail to define the tangible impact on R&D cost, timelines or overall probability of success. AI companies have also only recently started to publicly share compelling evidence of their ability to address drug development pain points.

Second, due to the complex nature of machine learning, interpreting Al insights can be challenging. Biopharma stakeholders often find it hard to understand the decision-making process underpinning an Al solution, resulting in a lack of buy-in to findings.

Third, the availability of relevant and readily usable biopharma proprietary data is limited, and it often takes significant time

to clean, identify and extract the data required to enable AI. Information often resides in multiple locations and across functions, and the amount of data relevant to a given target or drug may be limited or hard to access.

Fourth, biopharma has an internal resistance to change, and the industry is known for its cautious nature. This is particularly true of R&D teams, which tend to be wary of new approaches given how much is at stake if things go wrong. This may be exacerbated by a lack of experience within the industry, as few biopharma stakeholders have the relevant expertise in AI to fully appreciate the potential and limitations of its application in drug development.

Finally, the AI landscape is evolving rapidly. New companies are emerging, and existing organizations are continuously evolving their propositions and business models. It is challenging for biopharma to "pick winners" at this nascent stage of market development.

Lowering the barriers

Despite the barriers to deployment, biopharma's interest in AI remains high. The major players are either investing in AI technology or leading an AI-focused effort, alone or jointly with others, and face pressure not to fall behind the competition. AI

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Figure 2 Strategic imperatives for biopharma and AI companies

providers are increasingly targeting their solutions to address specific industry needs, matching biopharma expectations and building trust by providing more precise, comprehensible and substantiated evidence.

To accelerate the advance of AI, biopharma companies and AI providers can follow a few key principles to lower barriers to adoption (see Figure 2).

Biopharma companies:

- Improve the collection and storage of internal data to improve suitability for AI-based approaches, and be ready to invest in data preparation.
- Facilitate data sharing across divisions and R&D projects, and potentially beyond the organization, such as with AI companies and other biopharma players through consortia or broader partnership agreements. AI approaches are more powerful when they leverage a rich dataset.
- Have realistic expectations regarding what AI can provide. By definition, machine learning is based on training and spotting familiar patterns.
- Lead a change management effort aimed at embracing Al. Communicate the value proposition of Al, offer specific training to consumers of Al (such as R&D staff) and adjust job roles as Al becomes integrated into a new R&D process.

AI providers:

- Secure sufficient biopharma expertise to develop AI solutions, and use it in customer outreach and sales to create common ground.
- Cater to customers' needs. Provide real-world evidence, explain the underlying AI processes and educate customers on how to interpret results. As possible, focus solutions on customers' disease areas or target drug types.
- Work with high-quality data, secured through licenses/ partnerships, and/or invest in cleaning it so that it can be used in Al.
- Be realistic about what can be achieved in this nascent space. Do not overpromise and fail to meet targets, which will reduce the credibility of AI in the minds of biopharma decisionmakers.
- Be patient, and do not interpret customer conservatism as a lack of interest. Biopharma has good reasons to move cautiously when adopting new technology.

The way ahead

After several years of experimentation and field-testing, it is time for biopharma players to plan the implementation of AI solutions more broadly in drug development. With the right focus from both AI companies and biopharma to address the barriers, L.E.K. expects that a significant proportion of R&D projects will have an AI component within the next five years.

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