

# Key Takeaways:



The pharmaceutical industry is undergoing a digital transformation driven by emerging technology, data proliferation, and artificial intelligence (AI).



Al is playing a pivotal role in clinical trials by handling complex tasks and analyzing massive health data sets with speed and precision to ultimately improve the efficiency of clinical research.



THL recently hosted a discussion about Pharma Tech advancements; joining the firm's Managing Directors Megan Preiner and Sam Hendler were TriNetX CEO Gadi Lachman, Syneos Health President of Technology and Data Solutions Baba Shetty, and Reify Health CEO & Co-Founder Ralph Passarella.

Bringing a new drug to market is a highly complex and lengthy process that, on average, takes 10-15 years, costs \$2.6 billion, and typically includes many failed trials.¹ Each step of the pharmaceutical value chain — R&D, drug discovery, clinical trials, regulatory approval, manufacturing and logistics, commercialization and distribution, and pharmacovigilance — is critical and often characterized by extensive regulatory requirements and the need for collaboration among key stakeholders, including pharmaceutical companies, pharmaceutical services companies, research institutions, healthcare providers, regulatory agencies, insurers, and patients.

But it doesn't have to take so long or cost so much. Advancements in technology, big data, and AI are transforming the pharmaceutical industry to help drug companies more efficiently bring lifesaving treatments to the patients who need them.

In Fall 2023, THL hosted a panel with healthcare thought leaders to discuss how these advancements are impacting the pharmaceutical landscape. THL Managing Director Megan Preiner and THL Managing Director Sam Hendler spoke to TriNetX CEO Gadi Lachman, Syneos Health President of Technology and Data Solutions Baba Shetty, and Reify Health CEO & Co-Founder Ralph Passarella. They shared their perspectives on the industry, how it has evolved, and where it is going — specifically as it relates to clinical trials.

## **Exponential Growth in Healthcare Data**

01

Thanks to increased innovation and changing healthcare practices, there has been an explosion of health data over the last decade. In fact, the healthcare industry today generates 30% of the world's data volume.<sup>2</sup> This data comes from a variety of sources, including electronic health records (EHRs), wearable devices, genomic tests, remote patient monitoring, medical images, clinical trials, public health records, and even insurance claims.

There's so much more available [that is] cheaper to mine and easier to match with other types of data, said Lachman.

There was always data, but it was very manual and hard to get and very fragmented and very different and broken and standards were not strong. But all those things are changing massively.

02

Applying health data to life sciences, in a controlled and privacy-safe manner, holds tremendous promise in diagnosing, treating, and preventing disease, so long as it's used to its full potential. Big data analytics and other technologies like AI and machine learning are becoming increasingly popular in pharma, with use cases across the full value chain. In 2020, the global data and analytics market in pharma alone was valued at \$1.4 billion.<sup>3</sup>

Providers in this space are already helping healthcare organizations generate valuable insights from their data, and more advancements are on the horizon — especially in clinical research.

## Opportunities Lie in Shared Clinical Research Pain Points

Running a clinical trial is an enormous effort. Regardless of the study in question, stakeholders face many of the same challenging bottlenecks.



#### **Decision overwhelm**

Major strategic decisions — like where trial sites will be, how to recruit and enroll patients, and what the protocol criteria will include — have a tremendous impact on how a trial goes. Then there are the day-to-day decisions (up to 3 million, according to research from Syneos Health) that need to be made to effectively run a trial and adhere to trial protocols.



## Research for planning

Trial sponsors often look to past similar trials to see if there are any lessons they could glean as they plan for their own trial. This is done manually, and often takes sigificant time..



#### **Patient recruitment**

People aren't enrolling in trials either because they don't know about them or because they or their physicians have concerns about their safety or purpose. Along the same lines, clinical trials often lack racial, ethnic, and gender diversity because recruiters don't know the most effective ways to target historically underrepresented groups.



#### **Protocol adherence**

Clinical trial protocols guide the entire research process and help ensure a trial's validity, safety, and ethical conduct. While they are often highly scientific, with many operational implications, the people who are executing against them may not be scientists themselves. So the interpretation of a protocol can be a challenge.

Fortunately, pharma technology providers exist to help trial teams overcome these challenges by leveraging the various bits of data at their disposal. As Shetty said, "We can exploit the full analytical potential of the underlying data." Doing so can help speed decision-making, optimize planning and recruitment, and keep protocol adherence in check. Though the benefits and use cases don't end there.



# Common Use Cases for AI in Pharmaceutical Clinical Trials

Al can play a pivotal role in big data analytics for clinical trials and there are seemingly endless use cases for both classical Al and machine learning as well as the more recent generative Al.

During an active trial, for example, there is an "untapped reservoir of knowledge that lives at each of the sites to inform how sponsors do manage a given study and how you can course correct or, even if a trial is on track, maybe we could get it closed faster, get it done sooner, said Passarella.

There's some pretty clear applications of generative AI there to understand how the study is running, how it can be improved kind of midstream, that we're pretty excited about.

This is just one example. Other use cases can be categorized across five broad areas. As Shetty explained during the panel, these include:

## 01

## **Knowledge work optimization:**

To help every decision maker better plan their trials and interpret the large swaths of data they collect at each step. Shetty posed, "What if every decision maker involved had [an] expert assistant sitting right next to them that has instantaneous recall of every bit of medical, scientific, operational expertise that could help that particular decision?"

## 02

## **Signal detection:**

To catch a critical detail or error that a human being might overlook.

## 03

## **Process optimization:**

To understand which operational and process implications would produce the most favorable timeline or outcome.

## 04

## **Reducing administrative burdens:**

To automate routine administrative tasks for smoother trial operations, improved data quality, and reduced costs.

## 05

## **Interaction optimization:**

To understand how to engage with each stakeholder in a trial.

As AI continues to transform these areas, the pharmaceutical industry – and the healthcare industry as a whole – is moving one step closer to improving patient outcomes with faster and less expensive therapies.

# Other Trends and the Future of Pharma Tech

Several other key trends in the pharmaceutical space point to durable long-term change.



## Regulatory support

Regulatory bodies like the FDA have been generally supportive of the use of AI and other technologies in the pharmaceutical industry. This support encourages innovation and technology adoption.



## Pharma's growing sophistication

Pharma companies have become more sophisticated buyers and are increasingly focusing on ROI and practicality. They are also taking a more active role in understanding and improving the patient journey to improve the overall trial process. "They are very innovative companies operating in a heavily regulated industry," said Lachman.



## Patient-centric approach

There is a growing emphasis on patient-centricity, which involves tailoring experiences and communications to individual patients' needs and preferences. This extends to understanding each patient's journey (or journeys) and making clinical trials more patient-friendly. As Passarella said, 'We're seeing an appreciation of the kind of need to treat and engage with patients and sites like consumers of clinical trials."



#### **Data-driven clinical trials**

The industry is moving towards data-driven clinical trials, where parts of trials are conducted using existing data, thereby reducing the need to enroll patients. This is not mainstream yet, but Lachman predicts it will be very soon.



You think about the idea that a clinical trial is fundamentally a task that is carried out manually by well-intentioned human beings doing the best they can in the moment with what they know that's right in front of them, said Shetty.

And you think about the benefit that could happen if each of those decisions in a given clinical trial was optimized by all the available data that could be brought to bear to help make a better decision, and the kind of impact that that would make.

As THL Managing Director Megan Preiner said, The pace of change in the pharma services industry has never been higher and we are excited about the opportunity to help patients get access to critical pharmaceuticals faster and more safely than ever before

And we believe that the impact will be huge.

Watch the panel discussion here and contact us today to hear more about our decades-long experience in Healthcare and Pharma Services investing.

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<sup>&</sup>lt;sup>1</sup>Research & Development Policy Framework. PhRMA. September 30, 2021

<sup>&</sup>lt;sup>2</sup>The Healthcare Data Explosion. RBC Capital Markets.

<sup>&</sup>lt;sup>3</sup>Big Data in Pharmaceuticals - Thematic Research. GlobalData Plc. Report Code: GDHCHT316-TH. March 31, 2022.