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Article

The Pharmaceutical Industry: 2024 (and Beyond) Predictions

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Introduction

This year we can expect many recurring themes in the pharmaceutical industry, including decentralized clinical trials and a call for greater diversity.

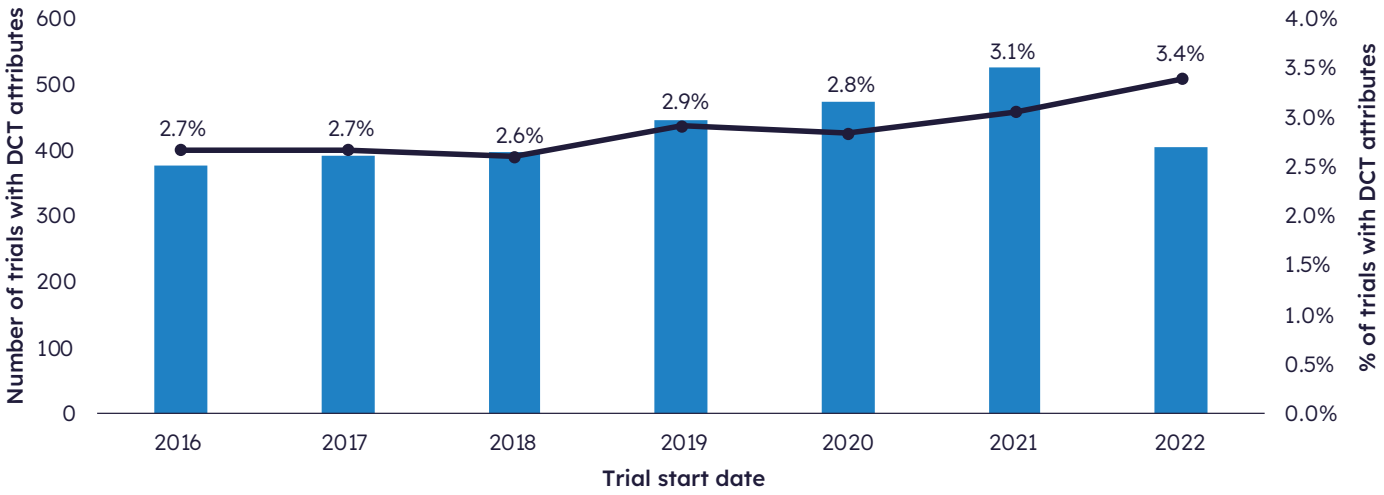
And, of course, no discussion of drug development — or just about any industry, for that matter — would be complete without mentioning artificial intelligence (AI).

Let's review some of 2023's most prevalent trends in pharma and see where they are headed for 2024.

Decentralized Clinical Trials (DCTs)

Initially spurred by necessity due to the coronavirus pandemic, DCTs have held their own. The acceptance and adoption of decentralized DCTs have become widespread, and sponsors are likely to continue employing them in the future.

Trials incorporating DCT attributes over the last seven years



Source: Trialtrove, February 2023

Both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) recognize the benefits of DCTs. In December 2022, the EMA issued recommendations on DCTs, addressing the roles and responsibilities of the sponsor and investigator, electronic informed consent, investigational medical product (IMP) delivery, trial-related procedures at home, data management, and monitoring. In May, the FDA issued a draft guidance on decentralized clinical trials (DCTs) aimed at supporting the use of such trials for drugs, biologics, and devices.

The biggest issue for DCT stakeholders is change management, "this concept of 'we're going to do things differently,'" says Catherine Gregor, chief clinical trial officer, Florence Healthcare, a software company focused on connecting sponsors and sites worldwide. Data integrity is an important consideration as well.

Lindsay Kehoe, senior project manager, Clinical Trials Transformation Initiative (CTTI), says study sponsors must take digital literacy into account. Some patients are less tech savvy than others, which can impact accessibility.

According to one industry report[1], the global decentralized clinical trials market size was valued at $4.52 billion in 2022 and will reach $10.58 billion in 2028, with a CAGR of 15.25% during 2022–2028.

Real-world Data (RWD)

Just as COVID was the impetus for DCTs, it also was a galvanizing event for the use of real-world data in drug development, according to an article in *Medical Marketing and Media*. The article quotes an FDA spokesperson who says RWD is now being used to expedite clinical trial enrollment and informing study design from endpoint selection to trial duration. RWD also has the potential to uncover previously unknown patient/drug interactions.

Real-world data can be leveraged to design and execute better, faster, more equitable clinical trials

Source: Norstella

In August, the FDA released guidance on the use of RWD and real-world evidence (RWE) in clinical research. The guidance applies to any type of RWD, from registries to medical claims, including data on products used in clinical practice under an emergency use authorization.

Despite RWD's benefits, a recent report found nearly half of life sciences organizations are not taking advantage of its potential. Dataversity reports that RWD/RWE analytics will generate more than $300 million year over year for the world's top 20 pharma companies over the next two to four years. The report concludes that RWD and RWE market for this industry will be worth $2.3 billion by 2026.

Clinical Trial Diversity

Although much discussion in the pharmaceutical world centers on diversity in clinical trials, the topic of diversity goes hand in hand with health equity. The Centers for Disease Control defines health equity as "the state in which everyone has a fair and just opportunity to attain their highest level of health." In fact, pharmaceutical companies are addressing diversity beyond the realm of clinical trials.

Data Sources and Data Collection

Clinical & Protocol Optimization

Feasibility Analysis

Site Engagement

Community Engagement

Patient Engagement

Clinical Trial Disclosure

Organizational Commitment

Inequities in healthcare have persisted for decades, underscoring the need for diversity in clinical trials. Efforts to improve in this area are underway on both sides of the pond. Last year, the FDA issued diversity guidance, requiring a diversity plan for all Phase III trials.

"Clinical trial diversity will require more digital relationship building in underserved communities," says Dezbee McDaniel, Co-Founder & CEO, CliniSpan Health. "The industry is behind on the ability to leverage tools like social media at its maximum to make clinical trials more diverse. Companies have generally been present only when trials are available, whether digitally or otherwise.

"Over the next year and moving forward, the industry will have to invest more into building digital communities and help the underserved with social determinants of health in order to gain more brand trust and validity from these diverse communities, something CliniSpan has found success in recently. Once more of this is enacted industry wide, the ability to enroll individuals in these communities will skyrocket. With the ability to build relationships digitally today, it can be done in a cost effective and efficient manner unlike ever before."

"Rubber will meet the road on diversity in 2024," says Ashley Schwalje, Senior Director of Clinical Solution Consulting for Citeline. "Pharmaceutical companies will tap deeper into real-world data to understand patient behaviors and social determinants of health to craft clinical trials that fit the needs of patients and create omnichannel, more personalized patient engagement strategies."

Artificial Intelligence (AI)

The global healthcare AI market holds much promise not only in terms of drug development but also for the investment community. In 2021, this market was worth around $11 billion and is expected to be worth $188 billion by 2030, increasing at a CAGR of 37% from 2022 to 2030.[2] More specifically, the AI in clinical trials market is projected to reach $4.8 billion by 2027 from $1.5 billion in 2022, at a CAGR of 25.6%.[3]

When most of us think of AI, ChatGPT comes to mind. But not all AI is created equal. Here are a few notable differences within the context of healthcare:

- **Traditional AI** – solves specific tasks with predefined rules (ex: robotic surgery)
- **Generative AI** – relies on deep-learning algorithms to create new content/data from lab notes, diagnostic images, medical charts, etc.
- **Assistive AI** – tools that help healthcare providers and investigators make decisions
- **Autonomous AI** – capable of actually making clinical and treatment decisions that impact patient care and outcomes

To put it into a more relatable context, the self-driving car industry is an example of the transition from assistive to autonomous AI.

So what does this mean in terms of drug development? According to Luca Parisi, Director of Clinical Analytics for Norstella, Citeline's parent company, 2023 was characterized by proofs of concept and proofs of value of generative AI in the life sciences industry. It marked the start of the "positive, tangible impact AI has made with large language models (LLMs) applied to the vast text data routinely generated and collected in the industry. From enhancing medical diagnostics and titrating treatments by mining and distilling electronic health records, to aiding the design of novel molecules and devising more efficient clinical trials, LLMs have helped to harness text data patterns that would have otherwise stayed latent for longer, thus accelerating the drug development pipeline and clinical trial planning."

However, researchers at Duke-National University of Singapore (NUS) Medical School say the pursuit of fair artificial intelligence (AI) algorithms in healthcare will require significant collaboration among clinicians, ethicists, and AI experts across industries and disciplines. In striving toward equity, factors such as age, gender, and race must be recognized.[4]

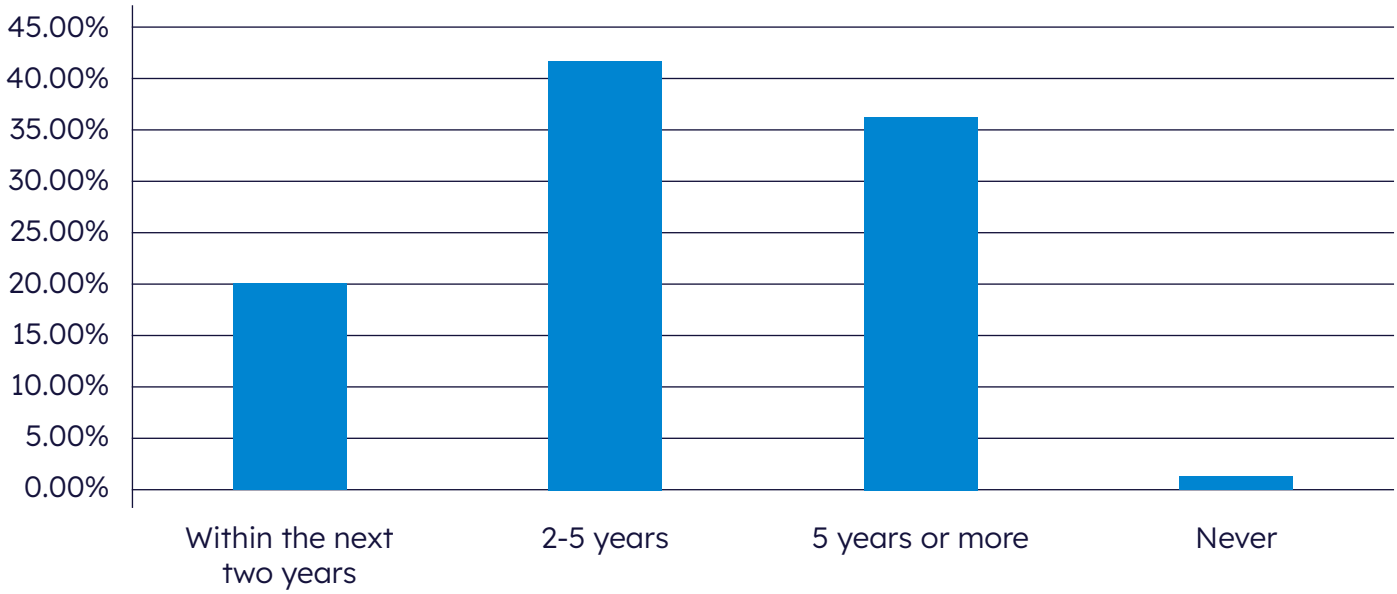
One area of healthcare that naturally lends itself to the use of AI is personalized or precision medicine. The National Human Genome Research Institute, under the auspices of the National Institutes of Health, defines personalized medicine as a "practice of medicine that uses an individual's genetic profile to guide decisions made in regard to the prevention, diagnosis and treatment of disease." The majority of AI-based products and tools used to advance personalized medicine focus on the diagnosis, prognosis and treatment of individuals. It should be noted that the application of AI for disease prevention is gaining a great deal of traction.[5]

This opportunity is not without its drawbacks. One argument is that many big-data analyses combining information on many individuals to identify patterns that reflect population-level relationships between data points do not address individual-level relationships.[6]

Parisi predicts a refinement of AI in the coming year: "We will likely witness a more mature, secure, and scalable deployment of LLMs-driven applications to further capitalize on the hidden patterns in clinical text data and continue to streamline drug design and clinical trial planning operations. The paradigm of personalized medicine will finally start becoming actualized, with multimodal, generative AI being a propulsive, transformational force for the entire drug development and clinical trial life cycle. The life sciences industry eagerly looks forward to harnessing it further and enhancing the predictability of trial execution strategies, through to drug repurposing."

Looking beyond 2024, the CPHI Annual Survey compiled the perspectives of more than 250 pharmaceutical executives. The majority of those surveyed expect the FDA to approve an AI-discovered drug withing two to five years.

How long will it be before we see a drug approved by the FDA that was originally discovered by an AI?



Source: CPHI Annual Report 2023

Inflation Reduction Act (IRA)

According to the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry organization, Medicare Part D plans use competition to obtain discounts for seniors on brand medicines and offer a range of coverage and treatment options. However, the price-setting policies in the IRA are predicted to lead to fewer choices and less robust access to medicines.

Additionally, the price-setting policies in the IRA change how doctors who administer selected Part B medicines are paid, making it even more difficult for them to provide needed medicines to their patients.

The act is designed to provide cost savings by, among other methods, lowering prescription drug prices. Starting in 2024, annual out-of-pocket costs in Medicare Part D will be capped. In 2025, this cap will drop to $2,000 and will be indexed annually going forward.

However, PhRMA cautions of its effects on the pharmaceutical industry: “Because the price-setting provisions in the Inflation Reduction Act can begin at pre-defined times after a medicine is initially approved, they ignore the R&D process that continues in the years following a medicine’s approval and discourage researchers from following promising scientific leads.”

References

1 Global Decentralized Clinical Trials Market – 360 Market Updates

2 AI in healthcare market size worldwide 2030 | Statista

3 Artificial Intelligence (AI) in Clinical Trials Market worth $4.8 billion by 2027 - Exclusive Report by MarketsandMarkets™ (prnewswire.com)

4 Liu, M., Ning, Y., Teixayavong, S. *et al.* A translational perspective towards clinical AI fairness. *npj Digit. Med.* 6, 172 (2023). Available at: https://doi.org/10.1038/s41746-023-00918-4 [Accessed Nov. 8, 2023]

5 Schork NJ. Artificial Intelligence and Personalized Medicine. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7580505/ [Accessed Nov. 8, 2023]

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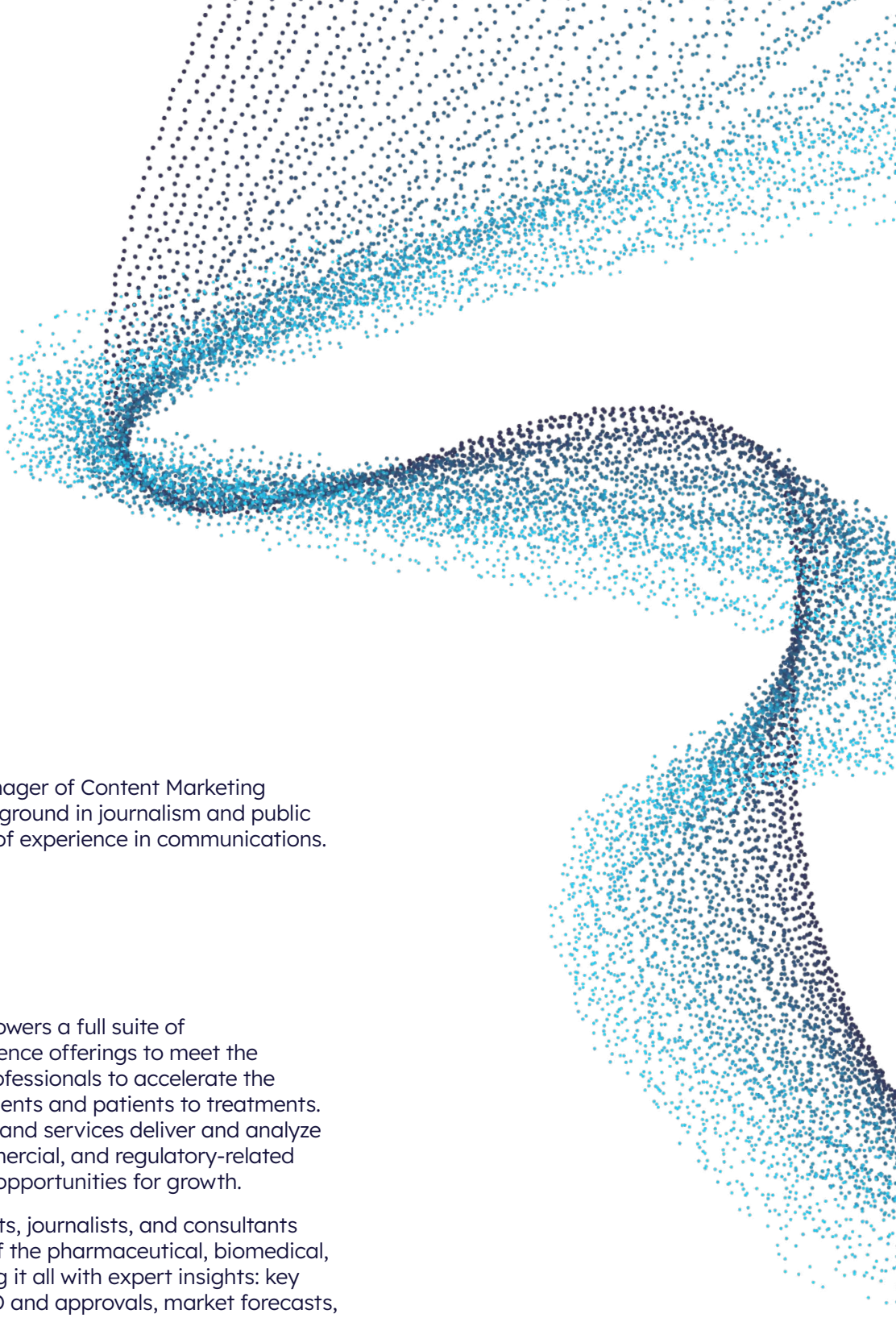

About the Author

Darcy Grabenstein is Senior Manager of Content Marketing Strategy at Citeline. With a background in journalism and public relations, she has 30-plus years of experience in communications.

About Citeline

Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory-related decisions and create real-world opportunities for growth.

Citeline's global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts, and more. For more information on one of the world's most trusted health science partners, visit Citeline and follow on LinkedIn and X.