

AI Continues to Move the Needle in the Pharma Industry

(Source: An article by Arnaub Chatterjee for MedCity News)

Recent years have shown a significant increase in artificial intelligence (AI) across the healthcare industry, including drug discovery, medical imaging, disease modeling, and in clinical trials. AI can also assist drug study teams solve operational, scientific and ethical challenges, as well as help to revolutionalize the way in which we perform research, treat disease and work with patients.

For example, AI-enabled disease modeling provides a more indepth understanding of the etiology, transmission and progression of illnesses such as motor neuron disease, cancer and HIV. One of the most promising frontiers in this space, however, is the conduct of clinical trials and the enhancement of the probability of regulatory or technical success.

Increasing a clinical trial's chance of success requires the careful alignment of several different factors, with clinical trials sponsors looking for solutions which minimize timelines while maximizing outcomes. Risk of various operational and scientific decisions that are made in the clinical trial process through AI is now being incorporated into the clinical trial process by study teams to solve some of the challenges they face.

From an operational standpoint, trial sites can vary in terms of their performance, particularly with regard to speed and diversity of patient enrollment. Through AI analysis, sponsors and contract research organizations can leverage historical trial data or realworld data to better under understand site performance and make more informed decisions about time and resource allocation.

This knowledge and oversight can result in shortened development timelines, which ultimately benefit the patient. This use of AI has been particularly important during the COVID-19 pandemic. AI has proven invaluable in rare disease and oncology trials as well by assisting sponsors in making rapid pivots based on real-time predictions and insights based on backlogs at trial sites due to an influx of COVID patients.

AI is now being used to augment the intelligence underpinning a trial. By analyzing multiple sets of inputs such as trial designs and drug biology, it allows protocols to be more refined and more accurate predictions of trial success to be made.

Another challenge of clinical trials has been a lack of diversity of trial participants. From both a scientific and ethical perspective, it is essential to address the under-representation of certain populations with trials. Research that fails to address different ethnicities, ages, genders, and lifestyles will not result in an impactful treatment path that is representative of patient populations. AI can play a role in bridging this gap through identifying which trial sites are best positioned to serve under-

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• McKesson Corporation reported financial results, with revenues of US\$66.1 billion for Q4 of 2022. For fiscal year 2022, the company reported revenues of US\$263.97 billion up 11% year-over-year. Revenues for the U.S. Pharmaceutical and Specialty Solutions segment were US\$53.68 billion up 14% year-over year, primarily driven by market growth and a higher volume of specialty products. International segment revenues were US\$8.53 billion, up 3% on a constant currency basis, courtesy of sales to new customers in the Canadian business and volume recovery from COVID-19 on a year-over-year basis.

• AmerisourceBergen report that during its Q2 2022 ended March 31, 2022 revenues increased 17.4% yearover-year to US\$57.7 billion. "Our strong results in the first half of the year and updated fiscal 2022 guidance reflect the commitment and achievements of our 42,000 purposedriven team members as we continue to deliver on our strategic imperatives," said *Steve Collis*, ABC Chairman, President and CEO. "As we move into the second half of our fiscal year with significant momentum, we remain focused on execution and continuing to help our partners navigate the complex and evolving healthcare landscape."

• **Cardinal Health** reported strong earnings for its third quarter 2022 with revenues of US\$44.8 billion, up 14% year-over-year. Pharmaceutical segment revenue came in

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AmerisourceBergen Convenes with Biopharma Companies at *ThinkLive* Commercialization Conference

(Source: Company Press Release)

Global healthcare company AmerisourceBergen (ABC) gathered with leaders and innovators across the biopharmaceutical industry for its *ThinkLive* Commercialization Summit, an annual event centered on strategies and solutions that help companies maximize success at every stage of the product lifecycle. During the summit in Las Vegas, leaders discussed the challenges and considerations companies face when bringing a product to market, and how ABC is strengthening its portfolio of global clinical and commercialization services to help partners launch products, drive success and enhance patient outcomes.

"As the pace of transformation in healthcare continues to accelerate, biopharmaceutical companies need to be flanked by a partner that can help navigate the challenges of a dynamic and everchanging market. We continue to make strategic investment and deploy new solutions to ensure we're best positioned to support our partners' evolving needs—whether it's cryogenic storage to

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represented communities. By simulating patient models, certain conclusions and hypotheses can be reached about the proportion of patients in a subgroup who will respond to a particular treatment. This can inform how clinical trial teams think about recruitment and the diversity of trial participants.

Synthetic control arms (SCAs) are also known as external control arms, and are another innovative tool enabled by big data, powerful computing and advanced analytics. While AI serves to mimic real life, SCAs use actual, patient-level data and biostatistical methods to replicate a control arm, removing the need for a placebo group.

Similarly to AI, these advanced statistical methods and analytics require huge amounts of data to accurately emulate real life. While well-established biostatistical approaches may fall outside the definition of "AI", it is important to note that traditional methods paired with high quality data have shown great promise and success in regulatory settings.

Beyond diversity, patient recruitment comes with additional challenges, including time pressure to recruit as quickly as possible, as well as the ethical implications of recruiting for a control arm of a trial for conditions where there may not be effective treatments available, such as many rare diseases. Synthetic control arms create a proxy for real clinical trial patientlevel data and can offer representative datasets that provide critical information about a disease, indication or treatment.

The advancement of AI and its inclusion in areas such as clinical trials and drug studies has most certainly made a positive impact on the overall improvement of patient safety and patient enrollment while giving pharmaceutical companies the critical insights and analysis needed to evaluate how their drugs work. But the industry has only begun to scratch the surface of what is achievable. The potential is enormous and AI is well on its way to becoming an essential part of clinical research and drug development in years to come.

ThinkLive (cont.)...

support cell and gene therapies or innovate services to increase speed-to-therapy," said Bob Mauch, Executive Vice President & Group President at ABC. *"ThinkLive* Commercialization serves as a critical opportunity for us to connect with our partners and discuss emerging challenges and opportunities as we work together to advance pharmaceutical innovation and access."

This year's conference programming included remarks from Mauch and ABC's Chairman, President & CEO Steve Collis, as well as dynamic panel discussions and presentations on new solutions. The panel discussions covered a variety of topics, including policy and the impact to biopharmaceutical companies and the role of data and technology in increasing speed-to-therapy and optimizing product success. During a leadership panel, ABC executives discussed key priorities, strategic investment and partnerships the company is exploring to improve access to advanced therapies globally and enhance the support it provides to biopharmaceutical companies.

Attendees also heard directly from ABC leaders on the company's expanding portfolio of solutions and services, which include *FormularyDecisions*, a secure platform that facilitates the exchange of information between biopharmaceutical companies

and healthcare decision makers, and *FirstView Financial*, a fintech provider that delivers innovative digital payment processing services to support patient affordability and access programs. Following the new solutions session, attendees joined breakout sessions focused on solutions that ABC is developing or expanding.

"Our biopharmaceutical partners are at the forefront of medical innovation—working daily to develop novel products to address unmedical needs. As their partner, we are focused on delivering best-in-class support across the product lifecycle to simplify the path to commercialization, unlock product potential and accelerate patient access to innovative therapies," said Willis Chandler, President of Manufacturer Services, Global Sourcing and Commercial Solutions at ABC. "Through these sessions at ThinkLive, we had the unique opportunity to present the solutions we are developing or exploring to a room full of our partners. Their feedback will help inform the next stages of development and ultimately enable us to strengthen the value we offer across the commercialization journey."

ABC will host its first combined *ThinkLive* event in October, which will offer customized content for all attendees. For more in-depth perspective from *ThinkLive* Commercialization and ABC on commercialization strategies, innovative therapies and more, please visit *https://amerisourcebergen.com/manufacturer-solutions/how-to-maximize-your-drug-commercialization-investments*.

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at US\$41 billion, up 17% from the prior year. Separately, Cardinal named *Megan Maltenfort* as its new Vice President of ESG. Maltenfort brings a wealth of experience to her new position from her prior 15-year career with Campbell's Soup where she served as Director of Corporate Responsibility and Sustainability.

• The National Association of Chain Drug Stores (NACDS) has elected three new officers and two new executive committee members for the coming year, as well as re-elected nine board members whose terms were set to expire. *Brian Nightengale*, president of AmerisourceBergen's Good Neighbor Pharmacy (and an NACDS board member) was elected Chairman of the NACDS board of directors, succeeding *Colleen Lindholz*, who was re-elected to the NACDS board. *Andre Persaud*, EVP and Chief Retail Officer at Rite Aid was elected Vice Chairman and *Mike Wysong*, CEO of Care Pharmacies Cooperative was elected Treasurer. Persaud is new to the NACDS board, along with *Dain Rusk*, VP of Pharmacy for Publix Super Markets and *Karen Staniforth*, Chief Pharmacy Officer at Rite Aid.

• Six months after partnering with **Biohaven Pharma** on its migraine drug, **Pfizer** will buy the remaining Biohaven shares for US\$11.6 billion, along with its CGRP inhibitor portfolio. Pfizer expects to grow Biohaven's oral CGRP franchise to more than US\$6 billion in peak sales. This will contribute to Pfizer's existing plan to add US\$25 billion in risk-adjusted revenues by 2030 through business development.

(Sources: Business Wire, Company Press Releases, FiercePharma, HealthWorld.com, and NASDAQ)