R&D INFLUENCERS

Influencers have the power to positively change the status quo because of their authority, knowledge, position, or relationship with their audience.

431

NUMBER OF FDA NME APPROVALS

anticipated from current clinical pipeline.

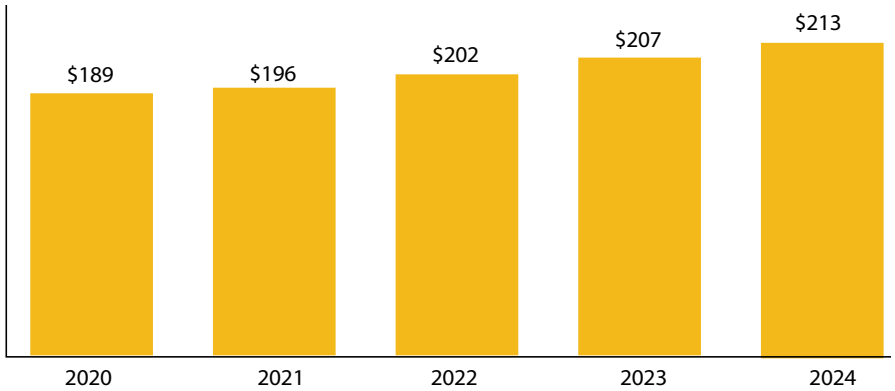
Source: Evaluate Pharma

The United States is the largest market for biopharmaceuticals, accounting for about one-third of the global market, and is the world leader in biopharmaceutical R&D. According to PhRMA, U.S. firms conduct more than half the world's R&D in pharmaceuticals ($75 billion) and hold the intellectual property rights on most new medicines. The overall economic impact of the biopharmaceutical industry on the U.S. economy is substantial. The industry accounted for more than $1.3 trillion in economic output, representing 4% of total U.S. output in 2015 alone. This total economic impact includes $558 billion in revenue from biopharmaceutical businesses and $659 billion from suppliers and worker spending.

More than 800,000 people work in the biopharmaceutical industry in the United States across a broad range of occupations, including scientific research, technical support, and manufacturing. Directly and indirectly, the industry supports more than 4.7 million jobs across the United States. The industry requires a highly skilled and educated workforce from the administrative level up to and including Ph.D. scientists.

New reports from the FDA indicate a total of 56 novel new medicines were approved in 2019. Among these, 48 were approved by the Center for Drug Evaluation and Research (CDER) and eight were approved by the Center for Biologics Evaluation and Research (CBER). While medicine approval numbers vary each year, 2019 saw exciting advancements in drug development. These strong approval figures demonstrate biopharmaceutical companies' unwavering commitment to developing innovative treatments for patients, offering hope for improved health outcomes.

Total global pharmaceutical research R&D spending from 2020 to 2024 (in billion U.S. dollars)



Source: Statista

R&D INFLUENCER

Dr. Joanne Santomauro
CEO
Ancillare LP

Dr. JOANNE Santomauro

ANCILLARE
Clinical Supply Chain, Simplified™

Our mission is to maintain the integrity, quality, and flow of the global pharmaceutical supply chain so our customers can focus on their mission to develop innovative therapies for patients.

Tackling Ancillary Supply Challenges with Innovative Solutions

When a pharmaceutical client came to Joanne Santomauro nearly 15 years ago with a request to help with a complex and expensive ancillary supply challenge, she didn't hesitate. She launched Ancillare and began the journey to create and revolutionize ancillary supply chain management for the clinical research industry. Ancillare, which is a certified woman's owned business, offers dynamic clinical trials process management services, including ancillary and clinical supply management, regulatory compliance services, and global logistics management. "Pharma companies are looking for better, faster, less expensive ways to bring a new drug to market, ancillary supply is one piece of that equation," Joanne says.

At the time, the industry's processes were haphazard, with very little standardization. To overcome early challenges, Joanne began by educating herself and her people to understand what was special about ancillary products and their impact on clinical trials.

"I worked closely with our customers to understand the space, what were their pain points, why were they experiencing these pain points, and the different needs of each therapeutic area," she says. "For example, oncology has different needs than a metabolic or vaccine product."

She brought in experts and innovators — IT experts who really know the pharmaceutical space as well as quality and medical experts who understand the products that need to be moved around the world. And three years ago, she obtained her doctorate, with a focus on innovation and the supply chain. She found that while there is a lot of research available on drug supply, there was nothing on ancillary supply, largely because the space is so new, complex, and diverse.

Innovation, she believes, needs to be informed by research, both academic and practitioner. "I think about how applying a new model or innovation will work in ancillary supply, what are the risks, and what the market needs," she says. "For me, it's all about research, research, research, learn, design, pilot, test, release, and then test, test, test again." To drive innovation at Ancillare, Joanne engages her teams and pharma clients to share ideas. The key she says is understanding how an innovation will affect the lives of patients.

"We're moving products that touch the sickest patients who are looking for cures," she says. "With the innovations that we implement — whether IoT or AI or data analytics — we need to be sure what we're predicting is really what will work in the marketplace, because the patient is at the end of that line." PV

R&D INFLUENCER

Bert Hartog, Ph.D.

Senior Director, Janssen Clinical Innovation

Janssen Pharmaceutical Companies of Johnson & Johnson

Bert Hartog, Ph.D.

UNLOCKING CLINICAL BOTTLENECKS

We need to make more trials more accessible to more people.

Bert Hartog, Ph.D., senior director at Janssen Clinical Innovation, Janssen Research & Development LLC is driven to eliminate the challenges preventing patients from participating in clinical trials.

"The number of people who know about trials is in the 5% to 10% range," he says. "The number of people participating in trials is even lower, yet all these trials are important. Patients are waiting for solutions that we can't investigate fast enough."

One of the key barriers, according to Dr. Hartog, is related to patient recruitment. He believes technology is one of the ways in which to make clinical trials more accessible to a diverse populations across multiple geographies.

"To make trials more accessible, we are focusing on what patients need and expect," he says. To understand their needs, Dr. Hartog and his team have spent a great deal of time gathering insights through a number of breakthrough initiatives. "First, we needed to demystify the perception that pharmaceutical companies couldn't connect with patients," he says.

Then Dr. Hartog and his team utilized a range of methods to invite patients to share their insights through question-and-answer surveys, focus groups, and clinical trial simulations, in which they recreate the essence of a new trial into a four-hour workshop. Using this approach, in a relatively small amount of time, they are able to collect the best feedback to optimize the design and implementation of a trial that otherwise they could only learn from running the trial.

Another exciting area Dr. Hartog and the team is exploring is digital health solutions, including voice technologies, AI chat bots, etc. He believes that by embedding these technologies into a scientific portfolio of tools or methods for capturing the various measurements inherent in clinical trials, it would allow people to stay at home and feel good about having access to trials as an alternative to standard of care.

"A virtual trial setup or a direct-to-participant trial setup allows people to participate in research who can't spend as much time in the clinic for a traditional trial because they live too far away, or because of employment, or family obligations," he says. "If we can move appropriate approaches from the clinic into a home setting we can potentially reduce some hurdles and allow more people, specifically those deeper into the communities, to participate in clinical research, which can accelerate trials and allow new science to become available to people who need it." PV

R&D INFLUENCER

Jill Johnston

President, Study Planning and Site Optimization Division
WCG, Clinical Services Organization

BREAKING DOWN THE ROADBLOCKS TO SITE ACTIVATION

My focus is on getting life-saving drugs to patients as quickly as possible by reducing the time it takes sites to enroll patients into trials.

There's a big difference between people with a vision and those who can execute on that idea. Jill Johnston, president of WCG's study planning and site optimization division, has proven she can do both.

Jill is committed to helping sponsors and investigational sites reduce the time and cost of the clinical study start-up process — from getting patients into studies faster, and enabling those studies to be completed on time or ahead of schedule. She's also committed to furthering WCG's focus on the patient voice by bringing industry leaders together to talk about the challenges patients face — everything from informed consent, to payments for patients, to simply making it easier for patients to participate in clinical trials.

Some of biggest roadblocks to site activation, she says, are: quick IRB turnaround; contract and budget delays between sponsors, CROs, and sites; and identifying the right investigators in the first place. Another barrier is communication, especially at the start of a trial. Jill says there are a thousand tasks that have to be done concurrently at the beginning of a clinical study, and the people who do well in that space are exceptionally organized and great communicators.

Jill has proven she has what it takes to move mountains. While at a previous company, she headed the Fast 50 project, which sought to reduce time and cost with Phase II and III clinical trials by 50%. To do this, the team had to think big, throw out the traditional model, and start afresh. And while the team didn't quite achieve 50%, it did consistently get to 35% — a remarkable achievement. This was a pivotal career point for Jill, who discovered that her blend of clinical development and operations experience, technology and data knowledge, and business acumen was rare. "I've done it all, except for medical monitoring and stats, but I know how this works when done well," she says. "I also know how the business needs to use technology and I know the value of the data within those systems. The third piece is my strong business acumen and the passion to make changes within the industry."

Today at WCG, she's bringing her innovative approach to problem solving to her global team, counting in the hundreds, which is focused on the front end of clinical trials, study start-up, and study planning. She encourages team members to think outside the box. "One of WCG's main goals is to reduce the time and costs of a clinical trial," she says. "We are committed to getting rid of the major delays in clinical research by doing things differently. This is what attracted me to my role, and I get to do this every single day I walk into the office. I couldn't be happier having free rein to figure out how to change our outdated approaches and continue to improve on it every day. I encourage my teams to think big and not to be afraid to try something new."

It's not easy to bring about change in a risk-averse industry, but Jill says if people have the right mindset, they can do wonderful things to speed up the clinical trial process. PV

JILL JOHNSTON