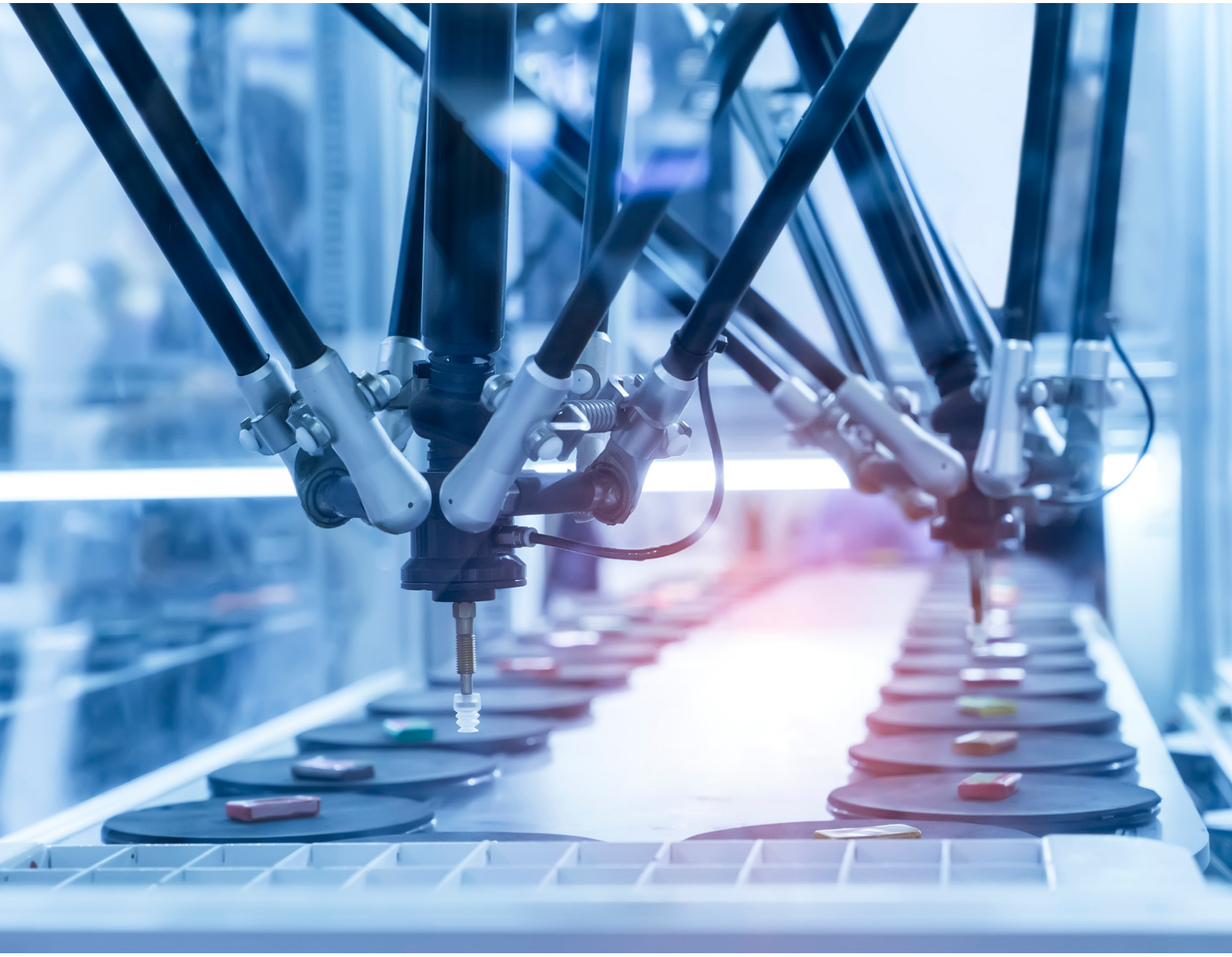
WHITE PAPER

Automating medical affairs:

How pharma can optimize medical affairs to get drugs to market faster



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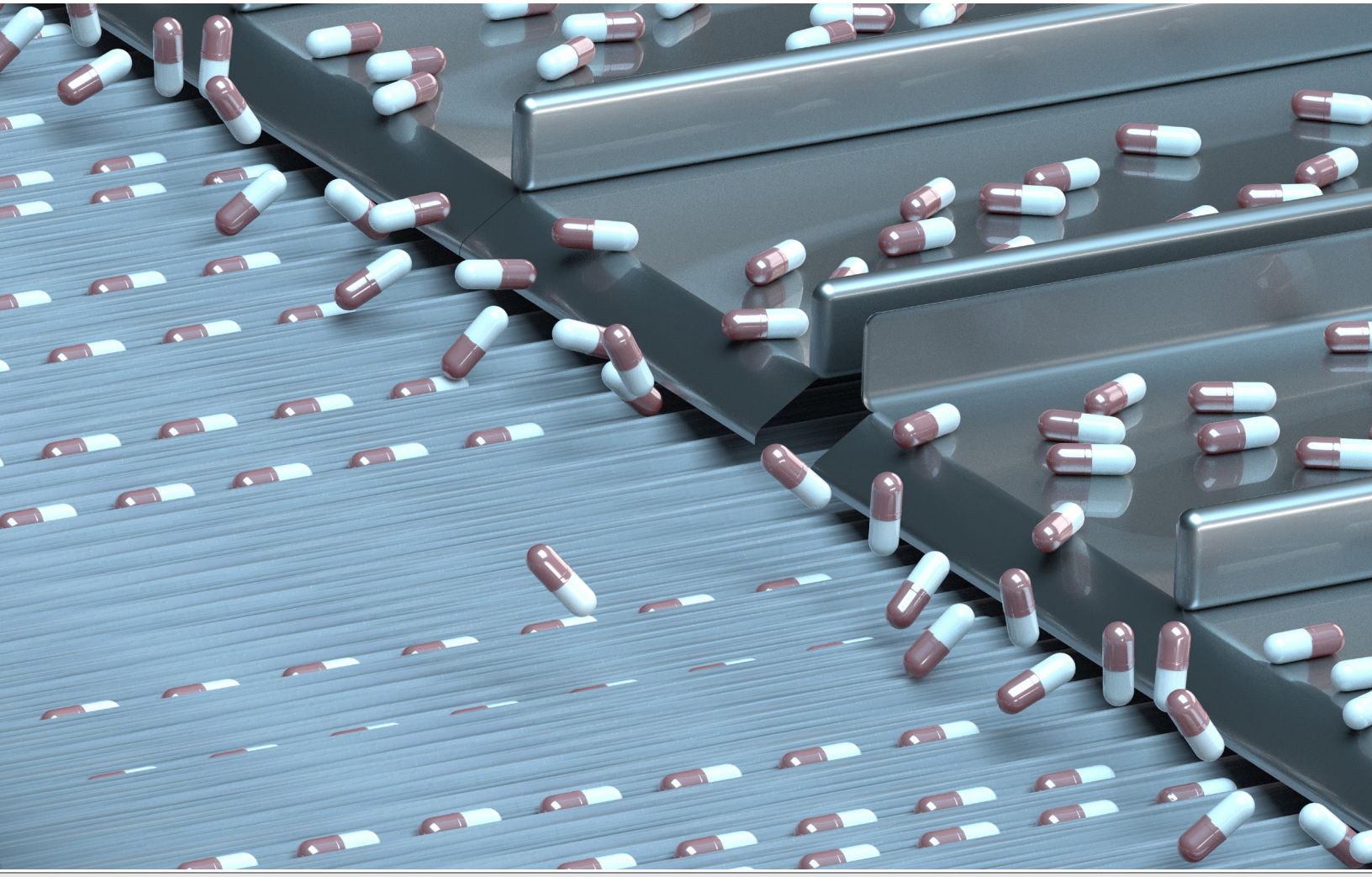
Introduction

Even before COVID-19 showed the world how fast the pharmaceutical industry could move, speed had become a strategic priority. The sooner a product hits the market, the sooner patients benefit, and the longer companies have to earn revenue from that product.

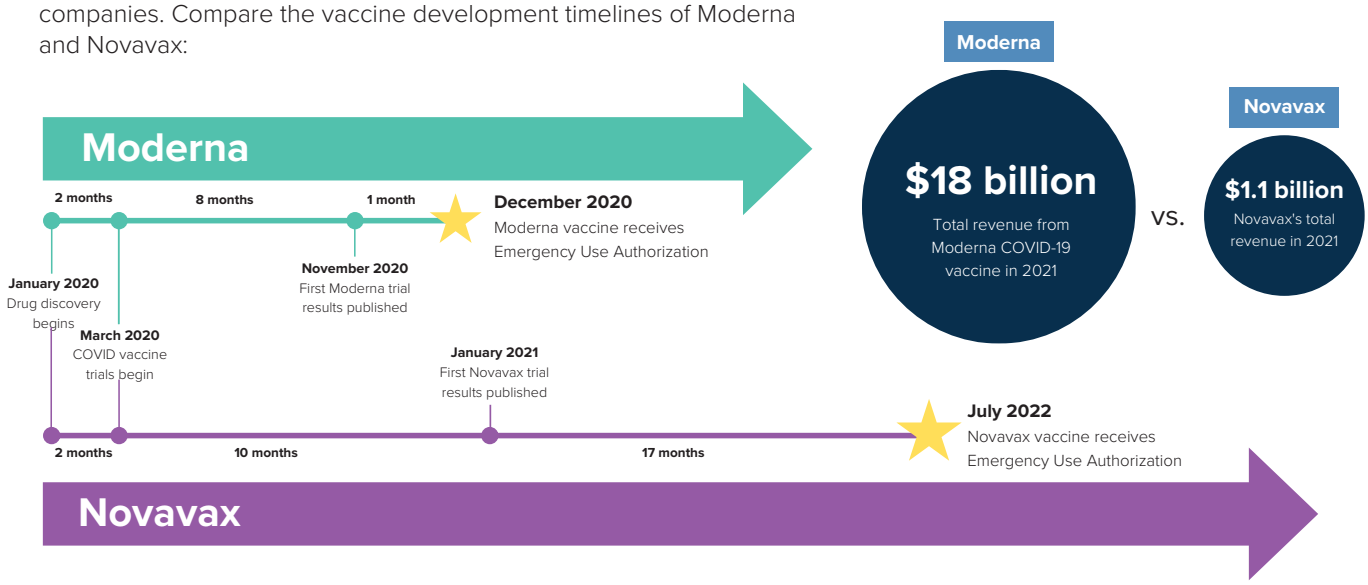
To expedite the time from discovery to product launch, pharma companies are innovating processes and implementing new technologies across departments and throughout a product's lifecycle. Amgen, for example, fast-tracks its most promising products by using adaptive trial designs, activating high-performing sites and incorporating real-world data, among other strategies. As a result, it has accelerated time to approval from about 10 years to 33 months.[1]

To make an impact on timeline, medical affairs teams must improve communication and collaboration and can leverage technology to do so. Process automation software is one of the easiest solutions to implement, and it yields immediate results. It helps medical affairs streamline processes, improve accuracy and ultimately become an even more effective partner in the race to commercialization.



The Value of Speed

The race to develop safe, effective drugs during the COVID-19 pandemic proved that speed to market is critical for pharmaceutical companies. Compare the vaccine development timelines of Moderna and Novavax:



Reducing drug development timelines by as little as 18 months can make the difference between first and last to market and billions of dollars in revenue. For example, Moderna and Novavax each have one product on the market: a COVID-19 vaccine, similarly effective. Moderna received Emergency Use Authorization from the FDA for its COVID-19 vaccine in December 2020. It earned $18.5 billion in revenue from the vaccine in 2021 and projects about $22 billion in 2022.[3] Novavax, which received an EUA in July 2022 for its COVID-19 vaccine, reported $1.1 billion in total 2021 revenue.[4]

The digitization of medical affairs

Over the past two decades, medical affairs has evolved from a supportive scientific role to a third strategic pillar in pharmaceutical organizations' corporate structure, working alongside research and development and commercial teams. Today's medical affairs departments have a hand in the entire product lifecycle, from discovery to post-marketing safety studies. While medical affairs teams continue to support commercial objectives by communicating nonpromotional scientific information, they also liaise with a broader set of stakeholders while analyzing a greater depth and breadth of information.

As pharma and other life sciences organizations have integrated digital technology into their workflows, medical affairs departments have also adapted to meet healthcare practitioners' changing needs. Short informational videos sit alongside peer-re-

viewed journal articles. On-demand virtual presentations and social media activity coincide with now-limited face-to-face interactions. Medical science liaisons identify and engage with both key opinion leaders and digital opinion leaders in addition to patient engagement teams, patient advocacy groups and payers.

"Medical affairs has come up with new ways to digitally connect with stakeholders both during and after product launch," says Steve Altschuler, director of strategic accounts for BP Logix, a business process automation provider to the life sciences industry. "Social media has become an even more effective way to get product information to the right people at the right time."

Now that the industry has emerged from the worst of the COVID-19 crisis—an especially difficult time for therapeutic areas with limited or poor current treatment options—medical affairs must reinvent itself again. With Operation Warp Speed, the industry saw how, with intention and funding, products could move through development to regulatory approval in a fraction of the typical timeline. Similarly, with the dramatic acceleration of telehealth and videoconferencing, the industry saw how effective and efficient virtual engagements can be.

As pharma companies are evaluating technology and processes to find new ways to reduce drug development time and improve operational efficiency, they're asking how they can apply what they are learning to medical affairs.

Manual processes and siloed ways of working hinder operational efficiency within medical affairs as well as throughout the entire organization, which can slow timelines and increase risk of errors and oversights. Process automation provides a solution that can mean the difference between being first and last to market.

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Filling the technology gaps in medical affairs

Whether by breaking down departmental silos or automating rote tasks, medical affairs has many opportunities to up its game through technology. According to a survey conducted by ZS, a management consulting firm, only 22% of medical affairs leaders surveyed had a clear digital strategy in their organization. About half (51%) reported no digital strategy in their organization but were implementing digital initiatives.[5]

Absent these digital initiatives, medical affairs teams often rely on outdated systems, inefficient workflows, and manual processes. Information critical to drug development lies in multiple spreadsheets, increasing risk of errors and omissions due to disorganization. Disjointed communication—or no communication—between divisions creates what one pharmaceutical company representative described as self-sabotage:

> *"Field medical, in-house clinical and global medical were all siloed. Strategic objectives were difficult to access and not followed. We had all these studies, but we had no system to register or keep track of them. There was no integration. These groups have different roles, but they needed to work together as well as with the larger organization."*

As scientific information grows in volume and complexity, relying on ad-hoc systems and spreadsheets creates costly bottlenecks. Process automation can not only help integrate groups within medical affairs, but also keep projects running on time while avoiding potential compliance issues.

Publication planning is a "quick win" area where medical affairs can implement process automation relatively easily. Integration with existing systems limits disruption to existing workflows.

Publication planning and management: Maintaining compliance and deadlines

Publication planning and management are critical functions of an effective medical communications strategy. Based on evidence generated, publications teams develop strategies for presenting and publishing studies at medical congresses, annual meetings, and conferences as well as in peer-reviewed medical and scientific journals. Publication planning requires collaboration among multiple internal and external authors and reviewers, organization of multiple document versions, and compliance with multiple regulations.

The challenge: managing reviews, revisions, and timelines

Developing and executing publication strategies involves input from multiple individuals. Reviewers may include both third-party experts and internal experts. Each study has a specific protocol. One overlooked step leads to unnecessary delays and possible compliance issues. A missed deadline or failure to follow proper guidelines could lead to a delay in publication or a rejected submission—both costly oversights when a pharma company wants to get information to as many HCPs as possible, as soon as possible.

How process automation helps:

Automation streamlines and expedites the review process in multiple ways. With a flexible architecture, medical affairs teams can develop a system tailored to each project. Each reviewer is assigned a "task" in the system, and the system escalates and re-routes tasks to help ensure tasks get completed on time. Automated task escalation occurs when an author or reviewer has not completed a task by the assigned due date. In accordance with each publication's attributes, the system facilitates timely participation from all parties who are responsible for review-related tasks. As a result, medical affairs teams can adhere to company SOPs while ensuring compliance and helping prevent unnecessary delays.

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The challenge: juggling multiple deadlines
With pivotal data to share, medical affairs teams must meet multiple, strict deadlines to communicate information to healthcare practitioners as soon as is practical. Medical congresses typically do not accept late abstract or session proposals, and a delay in journal article submission means a delay in publishing.

How process automation helps:
Solutions based on process automation track submission due dates so medical affairs teams can stay on top of deadlines, ensuring on-time publication. With automatic routing and approval, tasks move forward without human reminders and documents get into the right hands at the right time.

The challenge: lack of visibility
With individuals and teams operating independently using manual processes, it's difficult to know where bottlenecks lie. Cloud-based file-sharing platforms like Google Drive and Microsoft OneDrive improve visibility, but they become unwieldly when managing large-scale projects.

How process automation helps:
Dedicated publication planning and management solutions can identify bottlenecks without human intervention thanks to automation and analytics. Users can analyze each step in the publication process over time to optimize workflows for future studies.

The challenge: time-consuming compliance challenges

Medical affairs must make sure prospective authors and others involved in a publication are not debarred from participating in U.S. federal health care programs. Authors must also meet International Committee of Medical Journal Editors (ICMJE) and/or other authorship criteria.

Conducting external author checks, facilitating authorship agreements, and other compliance-related tasks often rest with either a medical communications agency or the pharma company. In either case, the process is tedious and time-consuming because it involves multiple database searches and collaboration with multiple departments. However, accuracy is paramount.

How process automation helps:

With process automation, external contributor checks happen almost instantly. Relevant government lists get checked to screen all external contributors, which helps ensure compliance with Good Publication Practices and other regulations. Automating this type of screening can shave weeks off a publication's timeline. Also, making sure authorship agreements are in place avoids potential conflicts of interest and clarifies any compensation considerations.

Medical affairs: Future outlook

As the life sciences industry continues its digital transformation, medical affairs must continue to play a key role in resolving the inefficiencies that slow it down. Process automation software is an easy cost-effective way to automate manual processes, improve visibility between departments, and resolve time-consuming, expensive compliance issues, all of which results in a more effective, productive medical affairs team.

The organizations that devote the time and resources to streamline medical affairs will have a leg up in the race to discover, develop, and launch life-changing, lucrative products. "The pharmaceutical companies that deploy technology to better define and understand their audiences and their patient populations will come out ahead," says Altschuler. "If you're not acting now, you're falling behind."

The organizations that devote the time and resources to streamline medical affairs will have a leg up in the race to discover, develop, and launch life-changing, lucrative products.

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BP LOGIX

BP Logix Inc., headquartered near San Diego, is a business process automation provider to the pharmaceutical and life sciences industry with a focus on early-stage and high-growth organizations. Our flagship medical affairs product, PubPro, delivers several critical benefits such as increased speed of publication, publication accuracy, and compliance in this highly regulated industry. We deliver these key benefits by automating processes and eliminating bottlenecks in a single, integrated platform specifically tailored to the needs of early stage and high growth life science companies.

BP Logix helps leaders in regulated industries transform the way they get work done. Our powerful low-code automation platform, Process Director, empowers citizen developers and IT teams alike to:

- Create custom, scalable business applications that automate their most complex processes
- Conquer compliance gaps with 24/7 audit tracking, electronic signatures, user access permissions, and more.
- Reduce costs and knock out backlogs with an agile low-code platform that is 20x faster than custom coding.