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Innovation, Celebration and Pharma Ingenuity

What were the standout drug development and manufacturing technologies launched in 2025?

On page 10, we celebrate our annual Innovation Awards. Amazing therapeutics are constantly being developed and launched by the industry and – rightly so – grabbing headlines. Our innovation awards shine a light on what goes on in the background by highlighting technology launches that help companies to develop and manufacture their groundbreaking medicines.

And there's more celebration on our website. I recently interviewed Scott Billman, who was one of the judges in ISPE's Facility of the Year Awards (FOYA). The initial focus of the award was on engineering expertise, but the times have changed and the awards have branched out to cover other areas, including supply chain, Industry 4.0, social impact, and more. "One of the things I love about FOYA is the diversity of the projects. Sure, we see billion-dollar mega-facilities, but we've also awarded smaller projects – sometimes just a single room or a single piece of equipment – because they brought something innovative to the table. You don't need a massive budget to win," says Billman.

Our print issue only includes a small amount of the content we have published this month. Check out our website for more. To access Scott Billman's article, scan the QR code.

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Trump Administration Strikes Landmark Deals with Pharma Giants to Slash Drug Prices

Eli Lilly and Novo Nordisk agree to major price cuts on GLP-1 and insulin therapies under TrumpRx initiative

Donald Trump has agreed new deals with major manufacturers to bring most-favoured-nation (MFN) pricing to US patients. According to a White House fact sheet issued in early November, deals with Eli Lilly and Novo Nordisk mark the latest federal intervention in prescription-drug pricing.

Under the agreements, the list-price of Ozempic and Wegovy will fall from $1,000 and $1,350 respectively to $350 per month when obtained through the new "TrumpRx" initiative. For next-generation pipeline agents such as Zepbound and Orforglipron, the monthly cost will drop from $1,086 to about $346 if approved. Importantly, for future orally-administered GLP-1 drugs these companies may launch, the initial dose would be priced at $150 per month.

Medicare and state Medicaid programs will pay $245 for Ozempic, Wegovy, Mounjaro, and Zepbound, while Medicare beneficiaries would face a co-pay of $50 per month. The deals also extend to other product classes. Eli Lilly for example will offer its migraine therapy Emgality at $299 per pen, and its diabetes agent Trulicity at $389 per month. Novo Nordisk will supply its widely used insulin products NovoLog and Tresiba at $35 per month.

The agreements require both manufacturers to guarantee MFN pricing on all new products they bring to market, repatriate surplus foreign revenues on existing products, and provide the same pricing terms to every state Medicaid programme.

The White House highlights that the US generates roughly 75 percent of global pharmaceutical profits, and pays more than triple what comparable OECD countries do for branded medicines. These measures are, according to the Administration, designed to end what it terms "global freeloading" on American-funded innovation.

Eli Lilly is committing at least $27 billion in new US manufacturing investment, while Novo Nordisk has pledged an additional $10 billion to expand its domestic footprint through plans to produce the Wegovy tablet in the US if approved. These supply chain investments frame the policy as not merely pricing reform but a broader industrial strategy for biopharma manufacturing and patient access.

This signals a move toward deeper government-mandated pricing concessions tied to investment commitments. Manufacturers will need to map out scenarios in which access-pricing, global revenue repatriation, and domestic-manufacturing mandates are interlinked. It opens a new era of pricing negotiations and supply chain planning in the US market. Whether this will prompt broader participation by other companies, and how commercial and R&D strategies shift in response, will be key areas to watch.

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Celebrating Pharma

The 2025 CPHI Pharma Awards were celebrated in Frankfurt in October. Winning companies included Corden Pharma, Evonik, Enzene, Schott Pharma and more.

QUOTE *of the month*

"We are also seeing people pushing to abandon technology – like mRNA – because they think it's too dangerous. We must push back. The evidence shows that the benefits far outweigh the risks. Abandoning mRNA now would put all of us at greater risk."

Quarraisha Abdool Karim, co-founder of CAPRISA and a scientist with an extraordinary career in epidemiology.
Read more on page 16

Data Irregularities Rock BMJ Stem Cell Study

Analysts uncover inconsistencies in high-profile heart-failure trial, prompting calls for investigation

In late October, the BMJ published a high-profile phase III trial claiming that stem cell therapy reduced heart failure risk after myocardial infarction *(https://doi.org/10.1136/bmj-2024-083382)*. Within a week, independent analysts found inconsistencies in the dataset and the study was placed under review. The trial reportedly enrolled over 400 patients in Shiraz, Iran, yet the underlying data included 127 patients older than the stated age cutoff of 65 – a "complete mismatch", according to professor of developmental neuropsychology at Oxford University Dorothy Bishop.

Further analysis revealed a suggestion of potential data fabrication in repeating patterns, and an unusually high number of weights reported as exact multiples of five kilograms. The BMJ's editorial office confirmed they were aware of the concerns. Corresponding author Armin Attar acknowledged an internal audit was underway, but critics maintain the discrepancies are unlikely to be accidental and are calling for a retraction.

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Why "Good Enough" is Not Acceptable in CRO Partnerships

Clinical trials are becoming more complex. And not all CROs are able to step up.

By Stephen Corson, Associate Director of Statistics and Technical Solutions at Phastar

Contract research organizations (CROs) play a pivotal role in supporting pharma and biotech companies, especially as big data, AI and other new technologies continue to shape the drug development landscape. With 4,321 CROs operating in the US alone in 2024, the global CRO market is expected to grow from $92.27 billion in 2025 to $175.53 billion by 2032, reflecting a CAGR of 9.6%. This trajectory marks not only growth, but the evolution of the sector's capabilities and strategic importance.

Sponsors need a CRO that has deep therapeutic expertise and regulatory knowledge, and that can accelerate drug development timelines without compromising on data quality or integrity. In many cases, sponsors are looking for specialists. Almost 8 in 10 pharma and biotech companies feel a "one-stop shop" CRO model is no longer cost effective, with biotech companies, in particular, feeling that big CROs are failing to deliver.

CROs must elevate their performance. In today's market, excellence isn't optional. It is expected – and customers won't tolerate less.

Rising complexity

In the past decade, trial complexity has increased by more than 10 percent and overall trial durations have increased by a third. These changes are driven by factors such as increased data inputs and evolving regulatory requirements. Turning complex clinical data into submission-ready evidence requires robust data collection, integration, and analysis. That said, the number of global companies with sufficient in-house expertise to meet this goal is limited. This talent gap is fuelling demand for CROs with the right mix of expertise in data management, biostatistics, and quality control. The right CRO can save between 6 and 11 weeks in the start-up phase of a clinical trial alone, so choosing the right partner is vital.

For example, in the rare disease space, a common obstacle is identifying eligible participants. Harnessing advanced statistical methods for trial design can help to overcome this obstacle by reducing the need for unfeasible large sample sizes. Bayesian trials using historical data, expert consensus, or both, to construct informative priors typically require substantially less participants than frequentist frameworks. However, utilizing these approaches effectively requires careful analysis and adjustment, which can only be delivered by specialists.

The evolving clinical trial landscape impacts more than just CROs; it is reshaping outsourcing strategies across pharma and biotech. While companies have historically been reluctant to share sensitive information with CROs, building long-term relationships with CROs as trusted strategic partners rather than simply service providers offers substantial benefits. Firstly, it allows CROs to build a better understanding of the aims and objectives of their partner, enabling a shift from reactive to proactive planning and risk mitigation. Strategic partners also enable feedback, learning and cycles of continuous development. In addition, when CROs are engaged early in the clinical trial life cycle, sponsors can make use of their geographical and regulatory knowledge more effectively.

Transparency at every stage of the process is key to success. Sponsor-CRO interactions built around the 'I am the client you are my vendor' framework invariably lead to breakdowns in communication, decreased quality and timeline disruption. With all stakeholders working together in partnership, there is increased knowledge of up and downstream activities, which in turn means teams can think more strategically and the study runs smoothly. In my experience, it is these relationships that reap the biggest benefits.

The clinical research sector is undergoing a profound evolution, and CROs must evolve with it. Faced with growing expectations for both operational agility and uncompromising quality, CROs must reimagine their roles. Success now hinges not on cost reduction, but on cultivating strategic alliances and recruiting – and maintaining – the right talent to deal with the increasing complexity of clinical trials.

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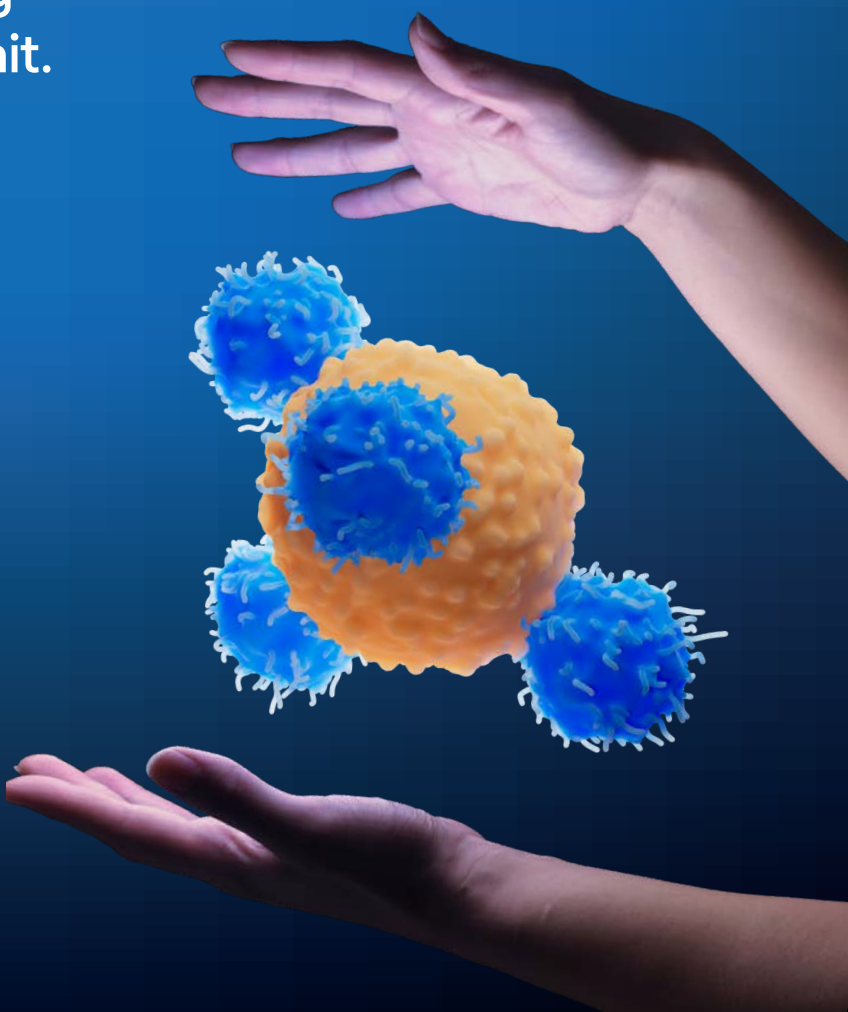

Scan to learn more

the Medicine Maker

INNOVATION *Awards*

What were the standout drug development and manufacturing technologies launched in 2025? Here's our list based on your nominations.

Welcome to our annual showcase of this year's top technology launches for drug development and manufacturing! Every year, The Medicine Maker asks readers to submit their nominations for the most inspiring, recently launched technology

This showcase has been compiled based on those nominations. Key trends include solutions for accelerating drug development and improving efficiency. In today's competitive market, speed is everything.

cartriQ 5 ml sterile cartridges

Large-volume glass cartridges for autoinjectors

SCHOTT Pharma

Until recently, the choice of containers for self-administration devices handling volumes above 3 ml was limited. While conventional prefilled syringe autoinjectors were available in volumes of up to 2.25 ml, cartridge-based autoinjectors were available in volumes of up to 3 ml. For higher volumes, on-body injectors represent the next established step.

SCHOTT Pharma's cartriQ 5 ml ready-to-use (RTU) cartridge enables high-volume, high-viscosity formulations to be administered via autoinjectors and pen injectors, bridging clinical-grade performance with at-home usability. Co-designed with SHL Medical to ensure seamless integation with Maggie 5.0 as well as patient-friendly usability, it features baked-on siliconization and ISO-compliant geometry for drug stability and reliable fill-and-finish integration.

CRA Agent

An agentic AI solution that proactively automates and optimizes clinical trial monitoring

Medable

According to early research by Medable, over 60 percent of a clinical research associate's time is spent on administrative tasks. The CRA Agent connects data across more than a dozen systems, monitors hundreds of trial variables in real time, and recommends actions. Automating routine tasks with oversight, CRAs can focus on building trust, supporting patients, and applying clinical judgment, keeping a "human-in-the-loop" to ensure patient safety.

CRA Agent is offered on Medable's Agent Studio – a no-code agent builder that enables clinical teams to quickly configure AI agents for various use cases. The platform has been shaped by insights from researchers, clinical trial operators, and regulators on the front lines of clinical development.

Design2Optimize

A digital twin-driven platform that streamlines small molecule API development via smart, optimized experimentation

Lonza

By integrating model-based design of experiments, digital twin simulations, and advanced multi-criterial optimization, Design2Optimize aims to enable faster, smarter, and more cost-effective development. The platform identifies the most valuable experiments, builds predictive models, and runs thousands of in silico simulations in seconds. This approach dramatically reduces lab time and resource use, enabling researchers to make faster decisions and unlock innovations earlier in the process. Its optimization engine ensures processes are fine-tuned for yield, throughput, and efficiency. According to Lonza, the platform can ensure optimal processes and faster clinical readiness. By minimizing physical experimentation and maximizing digital insight, it accelerates innovation (especially in early-phase, highly disruptive and innovative projects) and enhances scalability.

Domina

DOMINA is a modular technological platform for Pharma 4.0 manufacturing excellence

IMA S.p.A

This tablet press is designed as a modular technological platform that allows pharmaceutical manufacturers to configure the ideal setup for any powder and tablet type. Its plug-and-play architecture allows seamless transitions between mono and bilayer production, even with hard-to-compress powders. It features a patented 'Dynamicam' filling system, feeding solutions with single-motorized paddles, and Preforma, a special compaction cam that can make the difference in enhancing powder de-aeration, reducing the risk for lamination and capping. It also integrates Pharma 4.0 principles with advanced automation, adaptive diagnostics, and the Kortex MAX HMI system, ensuring data integrity, cybersecurity, and predictive analytics. Domina's adaptability to different formulations and production needs allows manufacturers to respond quickly to market demands.

IDFILL

RFID solution for prefillable syringes designed to improve traceability

BD

Drug mix ups are expensive and color-coded product identification has limitations in accuracy and scalability. To address this, BD has developed prefillable syringes pre-tagged with unique serial numbers referred to as the Container Unique Identifier (CUID) to enable unit-level traceability throughout the product lifecycle, aiming at supporting compliance and manufacturing excellence.

The CUID can be scanned at various stages of the manufacturing process, from filling to assembly. The approach is designed to support continuous verification and data integrity across the production workflow. The syringe external dimensions remain unchanged to ensure compatibility with secondary devices and the barrel remains clear for visual inspection. Beyond traceability, the solution has the potential to create a digital backbone that unifies process and equipment data around the CUID. This integrated dataset enables advanced analytics and AI applications, predictive quality control, and parametric release, transforming fragmented workflows into a connected manufacturing ecosystem. CDMO ten23 health has been involved in piloting the solution.

Immucise

Intradermal injection system designed to deliver vaccines and other approved drugs to the dermal layer of the skin

Terumo Pharmaceutical Solutions

The dermis is extremely rich in various resident and recruited types of dendritic cells, which play a critical role in the human immune response by capturing antigens and presenting them to T cells. Intradermal administration of vaccines can potentially result in quantitatively or qualitatively superior immune responses compared to intramuscular or subcutaneous injection (1).

The Immucise intradermal injection system is designed to be simple enough to handle easily and is expected to reduce risks of damaging tissues, such as blood vessels and peripheral nerves, due to its thin and short needle (2).

Reference

1. *PATH, WHO, "Intradermal Delivery of Vaccines. A review of the literature and the potential for development for use in low- and middle income countries" (August, 2009).*
2. *R Arakane et. al., "Immunogenicity and safety of the new intradermal influenza vaccine in adults and elderly: A randomized phase 1/2 clinical trial," Vaccine, 33, 6340–6350 (2015).*

MEDELLAPRO

An ultra-low endotoxin gelatin

Gelita

MEDELLAPRO is part of Gelita's endotoxin-controlled excipient portfolio. It is a purified gelatin that features ultra-low levels of endotoxins (reaching <= 10 endotoxin units/g), making it suitable for high-standard applications in bioscience development where gelling properties and purity are key, such as 3D bioprinting, scaffolds, cell culturing, and more. As a natural biomaterial, it is well tolerated by mammalian cells and human tissue. Gelita's endotoxin removal process was developed efficiently over approximately two and a half years, culminating in the submission of a patent application. The company claims that this is the first ultra-low endotoxin gelatin in the market that uses food-grade phospholipids for endotoxin depletion without cytotoxic substances.

NK.SET Synthetic Promoter Library

Synthetic promoters that enable tuneable gene expression for NK cell immunotherapies

SynGenSys

Promoter selection is a critical yet often overlooked step in CGT development, with many manufacturers opting for natural promoters that come with fixed sizes, activity profiles, and regulatory behaviors, thus hindering development by limiting access to precise, cell-specific, tuneable transgene expression. NK.SET synthetic promoter library enables cell-specific control over gene expression. With a range of compact de novo sequences of ~200-600 bp with customizable expression levels, each promoter is designed to reduce off-target activity and can be tailored to meet specific needs.

Nuvia wPrime 2A Media

Tunable, scalable weak anion exchange hydrophobic interaction mixed-mode chromatography resin

Bio-Rad Laboratories

Nuvia wPrime 2A Media helps to enhance the efficiency, yield, and economics of biopharmaceutical manufacturing. The resin's tunable binding and milder elution profiles help preserve target molecule stability, reduce aggregation, and enable processing therapies that might otherwise be lost or damaged using harsher chromatographic conditions.

As a mixed-mode chromatography resin, the resin supports process intensification, reducing the number of chromatography steps, material, labor, and operating costs. Unlike strong AEX and AEX-HIC resins that remain fully positively charged across pH ranges, Nuvia wPrime 2A Media's weak AEX component can be modulated by adjusting the buffer pH, enabling milder elution conditions and increased control over binding/elution behavior. The Nuvia polyacrylamide bead matrix is engineered for chemical and mechanical resilience, maintaining dynamic binding capacity even under demanding flow rates, harsh cleaning (including NaOH), or exposure to strong solvents.

PhysioMimix Core

Single-organ, multi-organ, and higher-throughput configurations in one scalable platform

CN Bio

The drug discovery and development sector has reached an inflection point, with recent moves by the FDA paving the way for regulators to embrace new approach methodologies. Built on the industry-leading PhysioMimix brand, leveraging over a decade of organ-on-a-chip expertise, PhysioMimix Core combines the capabilities of CN Bio's suite of instruments within an all-in-one system. Offering easy transitions between three performance-validated configurations for single-organ, multi-organ, and high-throughput of up to 288 samples per run, the core system allows researchers to adopt, adapt, and scale workflows as experiments evolve. The benchtop design has a range of features, from tubeless microfluidic engineering to ample material recovery for multi-omics analysis.

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The Mindset of Science for Humanity

Quarraisha Abdool Karim discusses COVID-19 and why the industry must continue to invest in mRNA – and take the public along with them

By Stephanie Vine

"Excellence is non-negotiable, but excellence doesn't mean perfection or having the most expensive equipment or the fanciest labs. It's a mindset. It's about doing science that matters – and doing it well for the service of humanity."

"We are also seeing people pushing to abandon technology – like mRNA – because they think it's too dangerous. We must push back. The evidence shows that the benefits far outweigh the risks. Abandoning mRNA now would put all of us at greater risk."

Recently I had the privilege of interviewing Quarraisha Abdool Karim about her career – and how she became involved with so many influential organizations, including the Global Virus Network, the Centre for the AIDS Programme of Research in South Africa (CAPRISA), and the World Academy of Sciences.

Abdool Karim describes the role of an epidemiologist as being like a firefighter: you don't run away from the flames, you run into them. For her, science is not only about advancing knowledge, but about meeting urgent human needs and serving communities who are often left behind.

Born and raised in South Africa, she has always been deeply aware of inequality and the importance of resilience. As co-founder of CAPRISA, she has helped shape global understanding of HIV, particularly the risks faced by young women, while also addressing the burden of TB. As president of the World Academy of Sciences, she has championed science as a global good – something that must be accessible and beneficial to all, not just the privileged few. And as part of the Global Virus Network, she has worked to strengthen collective preparedness for the next outbreak, whatever form it may take.

In this interview, she discusses the lessons of COVID-19, the value of surveillance and collaboration, and why we need to continue to invest in mRNA – with the public included in the journey every step of the way.

What are the priorities for the Global Virus Network (GVN) right now?

We focus on everything. And we can do this because we are a network.

Outbreaks happen because there are always pathogens circulating at a low level, so surveillance is critical. An outbreak is when you suddenly see more infections than expected, either in one place or in several locations. The first step is to immediately check vaccination coverage – because this can contain an outbreak quickly before it becomes an epidemic.

Epidemics are larger, but still have a geospatial location, such as one country or one region. Once it spreads beyond that, you have a pandemic.

COVID-19 started as just a few cases in Wuhan – and many in the scientific community disagreed about how infectious it was. Some assumed it would be another MERS or SARS that we would be able to contain. Others were more pessimistic. Ultimately, the worst turned out to be true and COVID-19 rapidly became a pandemic.

Surveillance is crucial to prevent future pandemics. We must monitor known pathogens and ensure we have capacity to detect new ones. This involves monitoring animals, the environment, and people. A new threat could emerge in water bodies or in a bat cave. Understanding how viruses cross from animals to humans is crucial and requires collaboration across many disciplines.

In today's world, a disease can spread very quickly. Conflict plays a big role in this. Wars create displacement, and today we have more displaced people than at any other time in history. Wars cause instability, social breakdown, and the collapse of health systems. I sometimes joke that I sound like a beauty queen when I say, "We need peace in the world," but it's true. Without peace, we won't control epidemics.

GVN's international headquarters are now hosted at the University of South Florida, and it conducts ongoing surveillance and monitoring, issuing alerts where outbreaks or epidemics might emerge, and conducting research to see if new threats are appearing. There are about 2,000 coronaviruses, for instance, and it's only a matter of time before another crosses into humans.

Viruses mutate rapidly. We now have the tools to track mutations, but we need to understand what they mean. When does a mutation change disease severity? When does it affect mortality? And then we need to ask: are our current tools still effective, or do we need new ones? This is constant work.

The process always comes down to three things: prevent, diagnose, and treat. To do that, you need lab infrastructure, surveillance systems, and clinical acumen. This is why the network matters. GVN includes scientists across the world with different skills, which means we can pivot much more quickly when something new appears. If an outbreak or epidemic is contained early, then everyone benefits. Stockpiling after something has already become a pandemic is wasteful. During COVID-19, everyone stockpiled and so much was wasted.

How did you become involved with the response to the COVID-19 pandemic?

Once the genetic sequence for SARS-CoV-2 became available, we used our infrastructure to set up diagnostics locally. We used surveillance systems to track what was happening, generating intelligence and advising the government on how to respond. We were also involved in the vaccine trials. When I say "we," I'm referring to myself, my husband, our partners,

collaborators, and the communities we work with. It was a collective effort.

Because of the previous work we'd done in HIV, we were in a position to advise people at the highest levels, including the WHO Director-General and the UNAIDS Director.

Both my husband (Salim Abdool Karim) and I are firm believers in innovation and in science as a global public good. Excellence is non-negotiable, but excellence doesn't mean perfection, or having the most expensive equipment or the fanciest labs. It's a mindset. It's about doing science that matters – and doing it well for the service of humanity.

That thread really runs through my whole life and connects back to my roots in Tongaat. My grandfather, for instance, was an accountant, but he set up and chaired the malaria control program. People used to ask, "Why an accountant in public health?" But for him, it wasn't about being a scientist. It was about caring for his community, which at the time was being devastated by malaria. He showed me that everyone – even accountants – have a place in public health if they are committed to serving people.

GVN recently put out a statement reaffirming its support for mRNA vaccines and collaborative vaccine research. Why is this area so important to you?

For decades in Africa, parents didn't name their children until after their first birthday because infant mortality was so high. Vaccines changed that, and coverage rates are high in the region because parents know the value.

COVID-19 was catastrophic, but vaccines changed the story by preventing hospitalizations and deaths. It was extraordinary – and yet people have quickly forgotten.

Historically with vaccines, going right back to Jenner and cowpox, we often didn't know what the causative agent was, but we intervened with what made sense at the time. With SARS-CoV-2, in less than 90 days of the sequence becoming available, groups were able to pivot and move to clinical trials. This was amazing – and shows how far we've come as a global community in terms of knowledge generation. Centuries of investment in science brought us to this point.

mRNA experts like Katalin Karikó or Drew Weissman will tell you that mRNA isn't new. Katalin began working with mRNA 40 years ago. She was looking at mRNA for therapeutic applications, but it became the basis for vaccines. History is full of examples where pursuing something for one specific purpose ultimately transformed another area entirely.

What mRNA offers is a platform. When you have a genetic sequence, you can rapidly turn it into a vaccine candidate using mRNA. The technology has now moved beyond COVID-19 to cancer, autoimmune diseases, and more.

And this is why ongoing investment in science is so important. The US leads on that front; the collective budget for South African scientists is about a quarter of what a single US statutory body for medical research may receive. The US disproportionately invests in science, and has been leading on many fronts, including mRNA.

mRNA is not the only way to make vaccines, of course. Many of the historical approaches are still being used, but mRNA is about moving forward. For humanity to advance, we must constantly improve and use the best tools available. We're not sitting in caves anymore. We are in offices surrounded by modern tools. That is what progress is. For me, mRNA represents progress. It's not about replacing everything else, but about giving us a way to be faster, more adaptable, and better prepared for whatever comes next.

During COVID-19, what did we learn about manufacturing capacity?

One lesson was stark. Countries with manufacturing capacity, or those that could pay, had quick access. Poor countries – even when they were ready to pay – were left waiting. This is part of why SARS-CoV-2 is still with us. We didn't think globally and we didn't act globally.

We need to distribute manufacturing capacity more equitably, particularly in the Global South. WHO, in partnership with philanthropies, is supporting this. In South Africa, for instance, Afrigen Biologics is building capacity for Sub-Saharan Africa, and also serving other regions. But you can't build facilities to just sit idle until the next crisis. They need to be producing other vaccines and products, so that when something new emerges, the systems are already running.

This is why mRNA is so important to the region. mRNA is a flexible platform that can be applied to multiple targets. It's the same principle as when we had PCR platforms for HIV. When the gene sequences for SARS-CoV-2 became available – even before we knew it as SARS-CoV-2 – we could quickly adapt the PCR technology to set up diagnostics. That's the value of having platforms in place.

What else have your learned from your work with GVN?

Science communication is very important to us. As scientists, we're used to publishing in peer-reviewed journals, presenting at conferences, and talking to each other. But if science is going to be the hope for our future – and I really believe it is – then we have to do a much better job at communicating with the public. We can't leave it to a handful of people to define and shape the narrative.

One of the new GVN board members is Heidi Larson, who founded the Vaccine Confidence Project. Heidi and her team have been helping us to think more about communication.

We need to get better at demystifying science and helping people to understand the scientific method. Science progresses through arguments, debates and dialogue, but there's a growing sense in the public that if scientists disagree then it means we can't be trusted. During COVID-19, the public saw discussions and arguments play out and interpreted it as chaos or disagreement, even though it was all about refining, testing and improving.

Multiple analyses show that the benefits of mRNA outweigh the risks, but of course there are always risks – for any medicine. The point is always to weigh benefits against risks, and to continue to understand. The more we learn about risks, the more we can investigate them, understand them mechanistically, and improve.

Too often now, there is a mentality of: "The public doesn't understand it, so let's abandon it." This is wrong. If the public doesn't understand something, then it means we need to do better at communicating.

We are also seeing people pushing to abandon technology – like mRNA – because they think it's too dangerous. We must push back. The evidence shows that the benefits far outweigh the risks. Abandoning mRNA now would put all of us at greater risk.

We need to keep investing in platforms like mRNA. We may end up with something even better in the future, but for now, mRNA is the best we have. It gives us flexibility, resilience, and the ability to hit the ground running when something new emerges. It also has applications beyond COVID-19 – making it commercially viable and widely useful. It deserves the chance to reach its full potential. However, we can't just use the technology blindly. There are responsibilities as well as opportunities.

It's the same with artificial intelligence. There are huge opportunities here, but we can't allow it to be controlled by a handful of people in developed countries while the rest of the world is left behind or held to ransom. How we invest and how we act now will define where we go and whether we can ensure planetary security and health for future generations.

I encourage everyone to support and invest in groups like GVN, as well as in resilience-building initiatives, better surveillance, and stronger science communication. GVN helps to connect the dots. It rises above geopolitics. We bring the best science and the best minds together. And we are committed to doing better public education so that the public walks the journey with us.

NEXTGEN

Inside the GLP-1 Phenomenon

With remarkable successes come inevitable hurdles. Find out what experts had to say about GLP-1 drug development during an AAPS workshop.

Earlier this year, AAPS conducted a two-day workshop, Beyond GLP-1s: Where the Science Will Take Business Next, to explore the GLP-1 landscape, including successes so far, the ongoing science and, of course, the challenges.

Moderator Carissa Jones opened day one by saying that GLP-1s are one of the most exciting and rapidly evolving areas of modern medicine. She is absolutely correct. GLP-1 receptor agonists have transformed the management of type 2 diabetes in ways that go far beyond glucose control. Unlike older therapies, which often worked regardless of blood sugar levels and carried a significant risk of hypoglycemia or weight gain, GLP-1s stimulate insulin release only when glucose levels are elevated and suppress inappropriate glucagon secretion. This dual action not only improves glycemic control but does so with a lower risk of dangerous lows. At the same time, GLP-1s slow gastric emptying and act on satiety pathways, leading to meaningful weight loss, which is important given that excess weight drives both the onset and progression of type 2 diabetes.

The impact that GLP-1s can have on weight loss has also caught the attention of the wider public – and the result has been skyrocketing market values for companies like Eli Lilly and Novo Nordisk.

Speaking during day one of the workshop, Tim Opler (a managing director in Stifel's Global Healthcare Group) recalls a time in 2022 when he met up with a relative. "We're just having breakfast to catch up and he's like: 'Tim, how do I get some of that Ozempic stuff?' I replied, 'I don't know. Go talk to your doctor.' But he told me they didn't have it. There's a moment in time where our entire country became obsessed with Ozempic. And that phenomenon remains even today."

Drugs that can combat obesity are urgently needed. Rates of obesity are rising globally – and with obesity comes a host of other health issues. "In the US, 36.2 percent of the population has a BMI over 30," says Opler. "I think you could argue that obesity is the central issue in public health in our country, and one way to think about that is to look at the effect of obesity on human mortality … The average obese American lives about three years less than they should because of their physical condition. There are over 200 disease complications associated with obesity."

Some people still see obesity as a moral failing. In his presentation on day two, Jim Macguire, CEO of Biologics and More Consulting, says he often hears the questions: "Why can't people pull themselves together?" or "Well, I quit smoking, why can't people just lose weight the same way?"

Collage images sourced from Adobestock.com

"Although GLP-1s are seeing striking results for weight management, there are limitations. Lean mass is often lost and weight loss tends to plateau after about one year."

But McGuire explained: "It's not as simple as saying people just need more self-control. Obesity has become so widespread, with such complex biological underpinnings, that its associated comorbidities will only continue to rise – just as complications from type 1 and type 2 diabetes have risen over time."

The market opportunities and manufacturing challenges

Beyond the health benefits of GLP-1s, there are also societal pressures at play that have served to supercharge demand. Consumers want to be thin, and they are willing to spend money to achieve this – which is unusual in the pharmaceutical world. Opler noted that pharmaceuticals aren't usually something that people want to pay for. When doctors recommend something, patients will take the prescription, but they don't want to personally go out and spend hundreds of dollars on medications.

But even without full insurance or Medicare reimbursement, consumers are actively going out to buy drugs for weight loss. "They're doing it on the basis of aesthetics or appearance. The consumer wants three things. First, affordability. Second, they want to optimize how they look. And third, they want tolerability," said Opler.

All of this means that the market size could be enormous – with Opler predicting the reality will go far beyond expectations. He cited a story from Investor's Business Daily in 2022 that predicted the market would rise to $25 billion. In 2024, however, the market was valued at $54 billion. He said: "We think that the estimates of the market size are actually too low in general. A lot of brokerage houses are saying it might go to over $100 billion. We think that the real market size is $200 to $400 billion."

This may sound exciting, but it also brings with it logistical challenges. McGuire believes that we are at the start of a wave that could reshape Chemistry, Manufacturing, and Controls (CMC) capacity across the entire industry. Although Novo Nordisk and Eli Lilly have not published many details about CMC, both semaglutide and tirzepatide are known to have complex production processes. For example, semaglutide is semi-recombinant. Most of the peptide chain is made recombinantly, but two other

fragments are synthesized chemically and then linked together in solution-phase chemistry. Because different dose strengths are available for semaglutide and tirzepatide, a number of different pen injectors are also in circulation, further complicating supply chains.

Already the companies have struggled to keep pace with demand, so what happens if demand further increases? According to McGuire, a 15 or 16 percent CAGR in the market will mean that a three-fold increase in manufacturing will need to be found.

"To the best of my knowledge this doesn't exist today, so it will need to be carved out of what's already out there or built new. And the increases could be even higher," he said. "Both Novo Nordisk and Lilly are preparing for this in a big way. Lilly has plans for a new factory in Indianapolis, and Novo is gearing up both in Denmark and the US for what's to come. And these are only the things that have been made public."

Further improvements

Although GLP-1s are seeing striking results for weight management, there are limitations. Lean mass is often lost and weight loss tends to plateau after about one year. Once treatment stops, the patient will often regain weight. McGuire explained: "In fact, in the extension phase of the Novo Nordisk STEP 1 study, the group that had lost the most weight regained it quickly, closing the gap with the placebo group. This rebound phenomenon is common in the real world, and it means that ongoing therapy is required to sustain weight loss. Understandably, this can frustrate patients and lead to a cycle of starting, stopping, and restarting GLP-1 therapy."

One solution could be that a patient uses GLP-1s for a defined period and then transitions to a different therapy that can help keep the weight off. Other potential avenues to improve GLP-1s include reducing side effects and gastrointestinal intolerance, and developing an oral formulation – something that Lilly is focusing on.

Looking further ahead, Opler suggested potential for a direct-to-patient market – perhaps even OTC products – as well as other pharmaceutical innovations that cater to modern consumers. A large portion of GLP-1 consumers are women – because societal pressures often lead women to want to be thin. There are also pressures on men. Opler explains that men often want to be fit, which means there could be consumer interest in muscle building drugs.

THE ORIGINS OF GLP-1S

One of the first sessions on day one of the AAPS workshop was a presentation from Jens Holst, who is based at the Department of Biomedical Sciences and the Novo Nordisk Foundation Center for Basic Metabolic Research at the University of Copenhagen. His lab isolated and sequenced natural GLP-1 and demonstrated its biological activity.

The story began when his group noticed that cells in the human intestinal mucosa lit up with antibodies against glucagon. "Now, you may think: glucagon is not supposed to be in the gut. And that's true, but nevertheless, we found these cells in the gut. Back in the early 1970s, we realized that we had cells lighting up with antibodies against glucagon. At the time, we were hunting for peptides from the gut that could stimulate insulin secretion. Since glucagon itself is known to stimulate insulin secretion, this looked interesting."

After 10 years, his group discovered that a molecule called glicentin was responsible for the immunoreactivity in cells. However, glicentin does not stimulate insulin secretion, so it couldn't be the full story. With the rise of molecular biology, other researchers began sequencing proglucagon and found additional glucagon-like stretches: GLP-1 and GLP-2. Holst's group quickly synthesized and tested these peptides. While predicted fragments had no effect, the naturally processed GLP-1 powerfully stimulated insulin secretion and also inhibited glucagon release. For the first time, they had identified a hormone with a dual mechanism for controlling blood glucose.

Human studies confirmed the promise. Physiological infusions of GLP-1 lowered blood glucose by boosting insulin, suppressing glucagon, and even slowing gastric emptying. It also reduced appetite and food intake in a dose-dependent manner – although higher doses came with nausea, which limited tolerability.

There was also the problem that GLP-1 is degraded within minutes by the enzyme DPP-4. This led to two parallel therapeutic strategies. One was to inhibit DPP-4, inspired by the success of ACE inhibitors in hypertension. Holst's early studies in pigs showed that blocking DPP-4 protected GLP-1 from degradation and enhanced its activity, a finding that later translated into the first generation of DPP-4 inhibitors. These drugs improved glucose control but lacked weight loss or cardiovascular benefits.

The other strategy was to design GLP-1 receptor agonists resistant to both enzymatic degradation and renal clearance. Structural modifications, such as attaching fatty acid chains to bind albumin, extended the half-life from minutes to hours, days, and even a week. This principle underpins today's blockbuster GLP-1 therapies.

"The conclusion is that GLP-1 is an ileal brake hormone that also promotes nutrient disposal via insulin secretion," said Holst. "It has effects on food intake and appetite. It acts via afferent neurons and the CNS. It is degraded by DPP-4 and cleared by the kidneys. The DPP-4 inhibitors are effective in diabetes therapy, but do not provide cardiovascular disease protection or cause weight loss – and that is why they are likely to be forgotten soon."

The AAPS workshop featured more than ten experts, including Richard DiMarchi, Caroline Geisler, Adam Mendelsohn, Jonathan Duoros, and more.

Learn more about the workshop at:

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Smarter Cell Line Development for Better Biologics with AI

Drug manufacturing is under pressure as biologics become more complex. To simplify progress, cell line development is evolving with AI and automation

Biologic pipelines are no longer dominated by standard monoclonal antibodies. Multispecifics, fusion proteins, and other complex modalities bring new challenges to drug development. At the same time, there is increasing pressure to accelerate development timelines, reduce costs, and ensure consistent quality from the earliest stages.

Modern CLD approaches harness automation and machine learning, and allow developers to tailor strategies to individual molecules. Smarter CLD strategies not only help manufacturers to keep pace with complex biologics, but also support the broader goal of better therapies and more affordable medicine.

Why is CLD so important and what are the consequences of getting it wrong?
CH: CLD is positioned at a very early stage of drug development but ultimately influences the success and profitability of the entire CMC process. The main goal of a CLD platform is to identify a robust and highly productive cell clone. Moreover, it helps to accelerate time to clinic.

If the wrong clone is selected – such as one that is less productive or has product quality issues – it will significantly impact downstream processing and the effectiveness of the entire drug manufacturing process.

What are the challenges associated with traditional cell line development approaches?
CH: Traditional CLD workflows are time-consuming. Productivity measurements of clones are typically performed at a late stage, after a lot of time and effort has already been invested. If, at this point, you realize productivity is not sufficient, you must start over. One of the key advantages of the Sartorius CHO CLD platform is that we assess productivity much earlier, which allows for more informed early decision-making that can help de-risk the process. The platform also reflects Sartorius' wider commitment to "Simplifying Progress" – removing unnecessary complexity from development, reducing risk, and enabling manufacturers to focus on getting promising therapies to patients faster.

AS: Conventional approaches to CLD are very labor intensive. They tend to rely heavily on trial-and-error screening, which makes the process slow and less predictable. Sartorius aims to make CLD as robust as possible by incorporating modeling approaches, AI, and machine learning.

What's the developmental story behind the Sartorius CHO CLD platform?
CH: The history of the platform goes back to 2005. Ambitious scientists that recognized the potential of CLD, connected with business partners, and the result was the launch of the company Cellca – which was acquired by Sartorius in 2015.

Cellca developed the core CLD technology, but it has been continuously optimized and refined since then. Over the past five years, we have reduced the timeline from DNA to research cell bank from around 14 weeks in 2020 to nine weeks today. The single cell cloning strategy and clone selection stages were completely redesigned, making it much more streamlined and efficient.

The platform is suitable for a wide variety of complex molecules. How is this possible?
CH: The number of complex biologics in pipelines is increasing and there isn't a one-size-fits-all approach. You need tailored solutions for CLD that consider the specific properties and challenges of each molecule. For example, the number of screened clones that might be sufficient for a standard antibody may be inadequate for a complex multispecific or multichain molecule.

Our CLD platform is well suited to complex molecules because it incorporates automation and machine learning. We determine clone productivity at a very early stage and can even predict a clone's performance at later stages of CLD.

For particularly complex proteins, we use a toolbox approach. This includes, for example, broader screening strategies with higher numbers of clones, and an additional pool phase that allows for pre-selection prior to the single-cell cloning stage. We can also integrate process and media optimization using design-of-experiment methodologies, analytical method transfer and implementation, and change the production mode, such as moving to perfusion or high inoculation strategies.

AS: In the latest generation of our CLD platform, we began adopting a data-driven

Meet the Experts

Ali Safari (PhD) is a data scientist in the Innovation Team within the Advanced Therapy Solutions group at Sartorius. His role involves developing and supporting innovative, machine-learning and modeling-related solutions in biopharma research and development, including cell line, process, and media development.

Christiane Hartmann (PhD) is a CLD scientist focusing on customer projects. As the scientific lead within projects teams, she conducts data evaluations and engages in scientific discussions with Sartorius customers.

approach that leverages the data we have been generating during CLD. Using automation and AI, we can learn from historical data and predict the behavior of clones in future experiments. We use a multimodal approach that applies different machine learning algorithms. By setting stringent criteria for selecting cells and identifying high-producing clones, we can ensure both accuracy and quality in the cell line selection process.

How do you ensure reliability and precision in AI and machine learning?

AS: We integrate expertise from diverse fields – data science, machine learning, AI, biology, and biotechnology – to forge a comprehensive approach. By collaborating closely with subject matter experts, we ensure that the data input into our models is accurate and meaningful. This strategic alignment helps us circumvent issues like irrelevant data, excessive noise, and the risk of overfitting our models.

We also build in evaluation steps and validate each predictive model experimentally. For example, we compare its predictions against traditional methods of clone selection or even random selection, and check whether the model gives a significant improvement in productivity or other key performance indicators. Another aspect is continuous learning. We don't just build a model once and leave it. We continuously feed new data into the system so that the model is always evolving and improving.

With our data analytics team, we have transformed a complex modeling approach into a user-friendly, click-based solution within the Sartorius MVDA software SIMCA. This enhancement significantly simplifies daily lab work for non-data scientists.

Sartorius has established a CLD Center of Excellence. Why is this such a valuable resource?

CH: The CLD Center of Excellence is located in Ulm, Germany. The center began operations in 2020 and allowed us to expand and bring together all our CLD capabilities under one roof. The facility itself is about 6,000 square meters and includes state-of-the-art laboratories and instrumentation. We have everything we need to perform CLD at the highest level.

AS: The site is excellent, both in terms of instruments and technologies. Data scientists, including myself, work closely with the CLD and process development teams, which allows us to better understand the biotechnology aspects behind our data science methods. With this insight we can analyze data more effectively, to detect problems more clearly – and to understand where machine learning and AI can make the most impact. Implementing machine learning and AI has become more straightforward due to the availability of robust capabilities. The more pressing challenge now lies in determining how, where, and when these tools should be integrated into processes. As machine learning implementation continues to simplify, the focus will shift to enhancing interdisciplinary collaboration between data scientists and lab scientists to effectively leverage the benefits of AI.

What can people expect from a free project consultation with Sartorius?

CH: Every CLD project request is handled by our experienced sales development specialists. Depending on the project, they involve experts, such as scientists in cell line development, protein analytics specialists, or experts in cell bank testing and cell banking.

Together, we design the best strategy for the specific project. The customer gets all their questions about CLD answered and receives a detailed proposal that lists all suggested work packages.

How do you measure success beyond cell line performance – for example, in terms of customer satisfaction or project efficiency?

CH: At the end of each project, we ask for honest feedback and ideas for improvement. Together, we identify both successes and areas where we can do better.

Thereafter, we stay closely connected with customers. We regularly follow up and make ourselves available for any questions that arise during subsequent upstream or downstream process development.

It is important for us to be a true partner for all our clients. We focus on minimizing risk, optimizing outcomes, reducing timelines, and increasing flexibility in CLD. Ultimately, we want to enable our customers to move promising therapies forward for our common goal – for better health for more people.

SARTORIUS


"While it's important to celebrate the successes we've had, it's equally important to recognize how much further we need to go."

AbbVie's Eleni Lagkadinou on the Future of Cancer

What comes next for cancer drug development? AbbVie's Eleni Lagkadinou discusses precision, AI, and her hope for turning cancer into a more chronic, manageable condition.

How did you come to specialize in oncology?
From a medical perspective, cancer is one of the greatest challenges we face. When I worked with patients, there were so many moments where there was nothing left to offer. I will never forget that feeling – and it's what pushed me toward R&D. I wanted to create hope and options where none existed before.

How has the science behind cancer changed over your career?
One of the most significant shifts has been moving away from the idea of cancer as ONE disease. We now recognize its complexity and heterogeneity, and pursue deep understanding of the disease from bench to bedside toward novel treatment approaches with meaningful improvements for patients.

Thanks to our deeper understanding of the molecular makeup of tumors – whether it's specific genetic mutations and cellular pathways or the proteins decorating the surface of cancer cells – we can now design more precise therapies. Molecularly targeted therapies and more recently, antibody-drug conjugates (or ADCs), are great examples of this progress.

Another major leap has come from immuno-oncology. Being able to harness the patient's own immune system to fight cancer has completely changed the landscape. This isn't just a shift in how we treat cancer; it also opened the door to entirely new therapeutic modalities.

Where are the biggest unmet needs today?
While it's important to celebrate the successes we've had, it's equally important to recognize how much further we need to go.

In pancreatic cancer, colorectal cancer, and small cell lung cancer, survival outcomes remain very poor, so we urgently need more effective therapies and novel approaches.

At AbbVie, we place great emphasis on understanding where those high unmet needs are and focusing our efforts there. This includes hard-to-treat tumors both in blood cancers, where we've made strong progress in the past, and increasingly in solid tumors as well.

We also like to take a global perspective. We must make sure that our therapies reach patients around the world. There are disparities when it comes to access to new therapies across regions, populations, and healthcare systems. This is why inclusive research and diversity in clinical trials are also crucial priorities for us.

What are the challenges that drug developers like AbbVie face?
One key challenge – and opportunity – is building the right capabilities around emerging modalities. Today, there is a wide array of therapeutic options which creates both complexity and potential. AbbVie is especially interested in targets that allow us to differentiate between tumor cells and normal cells. However, it's not just about identifying a promising target. We must also figure out the best modality to go after that target, within the specific disease and clinical context. This is where a lot of the thinking and problem solving comes in.

There are still so many patients with very limited treatment options. At AbbVie, we're driven to solve for these unmet needs. That's especially true in areas like immuno-oncology and so-called "cold tumors," where the immune system doesn't naturally recognize or attack the cancer. We're actively working on how to address these types of tumors and potentially extend the benefits of immunotherapy to more patients.

ADCs are seeing a lot of attention in drug development. Why is there a resurgence now and why have they struggled in the past?
One key component is our much deeper understanding of cancer biology. We can now better characterize tumors and identify antigens that are more selectively expressed on cancer cells, which enables us to design ADCs that can deliver highly potent payloads directly to tumor cells – in a way that maximizes therapeutic benefit while minimizing harm to healthy tissue. AbbVie has developed a novel ADC platform through several decades of research and brings unique strengths in antibody engineering, drug-linker chemistry, and payload research.

Overall, we've also made significant strides in the payloads themselves and have a deeper understanding of how receptors internalize and behave, which plays a big role in the effectiveness of ADCs.

Finally, there's the precision of the conjugation process. We can now do this in a very stable and specific way, which improves both safety and efficacy. This kind of precision requires a high level of manufacturing capability and quality.

One part of the equation is advancing solid, well-founded novel science into the clinic quickly. But the other part is integrating translational, clinical, and technological tools to improve the precision, speed, and quality of decision-making.

At AbbVie, we place strong emphasis on this integration. Sometimes, despite doing everything right, the science might not translate. It's important to recognize when a program isn't working and to stop it early. Those decisions need to be based on robust scientific data.

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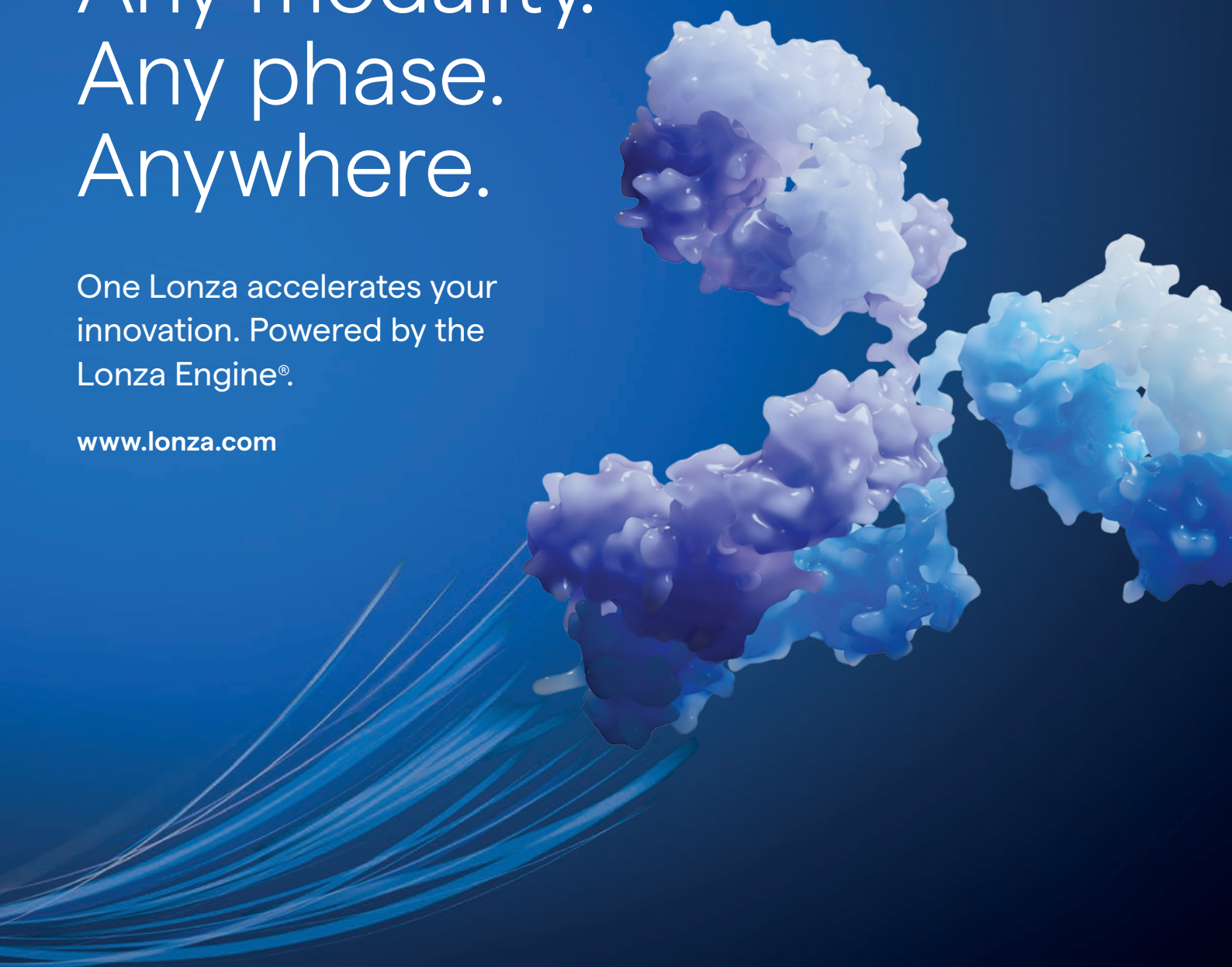

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