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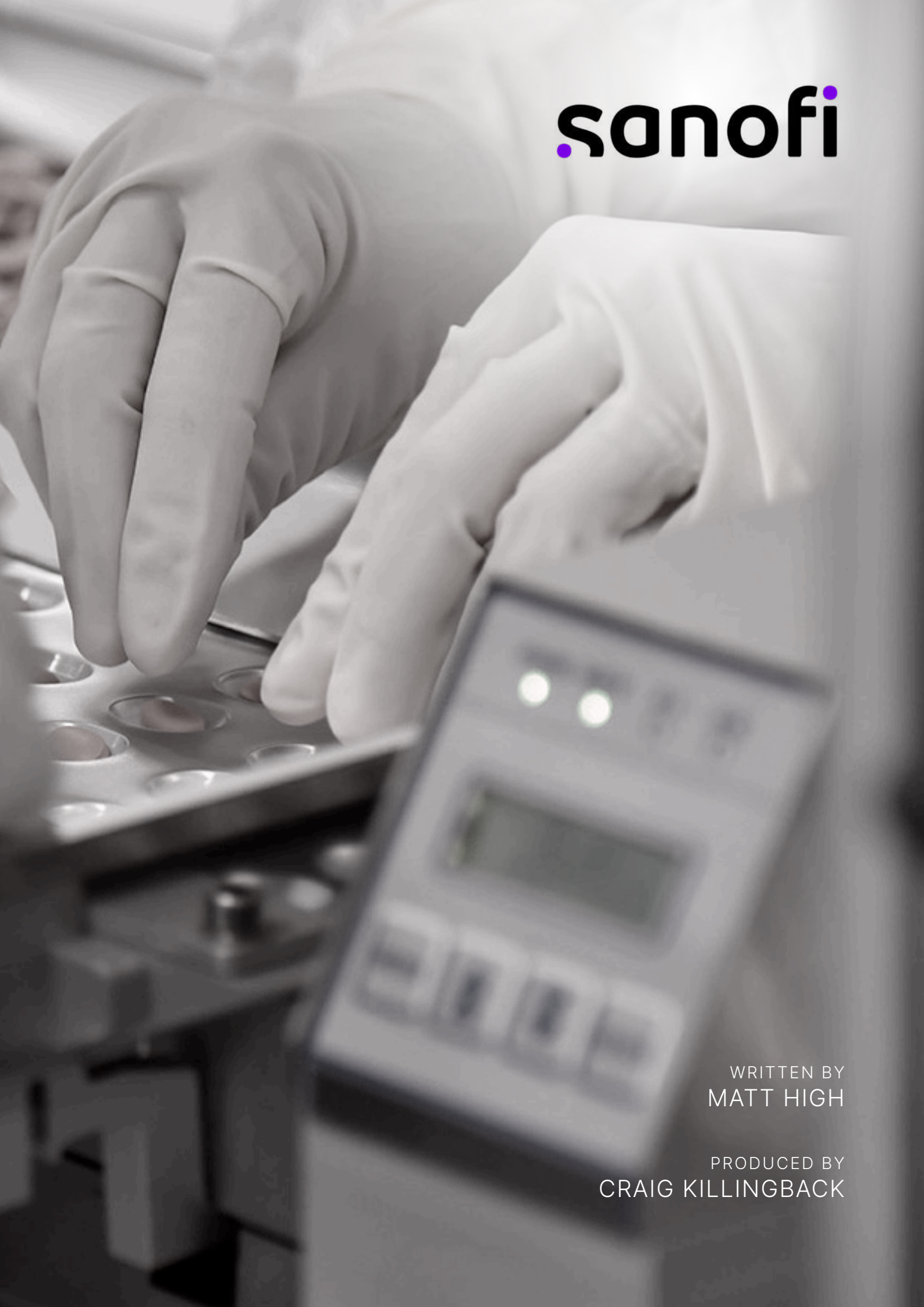
Clinical supply chain innovation

Landry Giardina, Sanofi's Global Head of Clinical Supply Chain Operations Innovation & Technology talks data-driven performance, resilience, agility and operational excellence within the clinical supply chain area



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Sanofi has a mission: to chase the miracles of science to improve people's lives, and sometimes that means starting over with Plan B, Plan C, or even Plan Z. To do so means to work across the most complex disciplines to solve problems, to push the boundaries and not be afraid to take smart risks, and to dedicate everything to making life better for people everywhere. None of that happens without continuous and groundbreaking R&D and clinical trials to prove the medicines and vaccines it creates are safe and efficient for millions of people around the world. Which makes Landry Giardina and his colleagues' jobs absolutely essential.

Landry has been at the business for close to 20 years, beginning in science-oriented roles around downstream purification and manufacturing vaccines, before making a conscious choice to move into the global clinical supply chain sector. Here he worked across several areas, including drug needs translation, heading up comparator drug sourcing, and leading digital clinical supplies, until taking his latest role – Global Head of Innovation & Technology within Clinical Supply Chain Operations – in 2022.

"It's a digitally-focused, and innovation and performance-driven position," says Landry, expanding on the scope of his and his team's work. "From forecasting to operations, our role is to understand the complex needs and challenges of the clinical supply chain. Then, we translate them into operational activities to optimise supply strategy . It allows our entity to influence R&D decisions in order to optimise supply strategy, and to welcome the many new and evolving challenges the organisation faces.

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– *Landry Giardina,*
Global Head of Clinical Supply Chain
Operations Innovation & Technology, Sanofi

"To do that effectively, I have three core teams focused on different areas: building strong foundations in robust processes, standard operating procedures and training; software and solutions management and enhancement for new projects; and lastly, implementing new technologies, tools and innovations that drive R&D in clinical trials."

These trials, and the supply chain that supports them, are essential to provide quality and safe medicines and products that improve people's lives. Sanofi works worldwide to provide life-changing treatment options and life-saving vaccine protection to millions of people. For half a century the company has led innovation and science in healthcare. It was the first worldwide supplier of the injectable polio, influenza, meningitis, and rabies vaccines; it has innovated in mRNA technology to develop future vaccines; it played an important role in establishing standards of care in diabetes innovation; and has led the way in innovation in immunology, neurology, and rare diseases.

Clinical trials, designed to either validate a new drug or vaccine, or define patient populations in which a potential treatment would be most effective, underpin this legacy. They allow researchers to determine whether a new way to prevent or treat a disease is safe and effective for human beings and often follow years or decades of research. In recent years,

as clinical trials have increased and the pharma market evolved, the clinical drug supply chain has become a critical factor for success.

"The clinical supply chain is the part of the organisation that ultimately translates the needs from a clinical protocol, but also in terms of non-clinical requirements. It's absolutely key," Landry explains. "The supply chain has to understand all the constraints, whether they're scientific (storage conditions, batch size or shelf-life related), regulatory-specific depending on country or location, equipment, plan and dose escalation and, of course, the dose regimen for our patients. All of this happens with effective forecasting and simulation.

LANDRY GIARDINA

Global Head of Clinical Supply Chain Operations Innovation & Technology

20y+ experience within the pharmaceutical industry, especially within clinical supply chain, digital development, and innovation.
Landry's career started as a biochemist engineer, and he has moved progressively to drug manufacturing process development, GMP production, comparator supply and material flow management, and then innovation and technology for clinical supplies.
Key drivers of his career are continuous improvement, factual based decision and valuable innovation implementation.

ABOUT US

Sanofi is an innovative global healthcare company, driven by one purpose: chasing the miracles of science to improve people's lives. Its team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible by discovering, developing, and delivering medicines and vaccines for millions of people around the world.

Its portfolio includes medicines for the treatment of immune-inflammatory diseases, cancers, rare diseases, multiple sclerosis, and diabetes; and human vaccines to protect infants and adults against various bacterial and viral diseases; and other products.

Sanofi's R&D efforts focus on advancing drugs to increase the effectiveness of treatments and on advancing formulation of new biologics to produce precision medicines. It has operations in Europe, the Americas, Asia-Pacific, China, Japan, Africa, and the Middle East. Sanofi is headquartered in Paris, Ile-de-France, France.

The department is also responsible for operations and manufacturing, distribution, and logistics. And in our real world both forecasting and operations have to be compiled and continuously updated."

The innovation and technology provided by Landry's team give the right processes and solutions to all departments in charge to achieve the clinical supplies. The clinical supply chain, he says, walks a tight line of balancing the three core aspects of the project management 'golden triangle': quality, productivity, and timelines. Quality, bearing in mind Sanofi's work and the patient outcomes it delivers is non-negotiable. Across both productivity and timelines digital solutions play a pivotal role, whether it's making processes leaner and more efficient, optimising ways of working, minimising waste material volume or non-operational time, or introducing new solutions.

"If you want to grow or evolve that triangle, technology is the only solution," Landry says. "That means serving the core objectives across three main drivers that influence the clinical supply chain: data-driven performance through business intelligence (BI), AI and the effective use of data; the ability to anticipate, understand and take action upon the new challenges we may face; and improving operational agility through forecasting, manufacturing, and distribution and logistics."

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30% Average supply cost savings

2-6 Months reduction in time to market

100% Patient service level

GET IN TOUCH TODAY

Streamlining the clinical supply chain

Transparency. Good partnerships need it to survive.

For N-SIDE and Sanofi, it has been a key ingredient to what has made the partnership successful for the past eight years.

Since late 2015, N-SIDE has established and built on a strategic partnership with France-based pharmaceutical company Sanofi, aimed at optimizing the firm's clinical trial supply chain. The partnership helped digitalize Sanofi's clinical supply chain while driving greater performance and waste reduction.

Amaury Jeandrain, Vice President of Strategy, Life Sciences at N-SIDE, has witnessed first-hand the development of the partnership since he joined the company in January 2016. "Very quickly, the value of risk management and waste reduction was perceived internally and this partnership ended up growing to become one of our largest. Today, Sanofi is the company at the forefront of a lot of the innovation co-created with N-SIDE."

Pharmaceutical companies of varying sizes use N-SIDE solutions to avoid supply chain bottlenecks in their clinical trials, decrease risks and waste, control costs, reduce time-to-market and speed up the launch of new trials. N-SIDE's focus is on four key pillars to bring high levels of efficiency into Sanofi's clinical supply chain: best-in-class supply chain, people, analytics and innovation.

Charlotte Tannier, Vice President of Life Sciences Services at N-SIDE, adds that the key differentiator is the transparency between her organization and Sanofi. "We trust each other and know that we can be fully open with them," she explains. "We like to build new things together and co-develop innovative solutions."

Having defined a clear route to success through the Sanofi partnership, Amaury is keen to point out that the relationship has acted as something of a catalyst for future business collaborations with other companies. "There are a lot of good practices that were initiated with Sanofi that now became a standard in our industry," he discusses.

Looking ahead, the future of the partnership looks bright and is showing no signs of slowing down. Charlotte explains that the next step is all about "integration." "For the moment, we have multiple teams and departments that are using the N-SIDE solutions, and many other software are used as well within the organization. The focus in the short term will be to enable a unified IT landscape and environment," she reveals. "The objective will be to be fully integrated and to increase the impact of the data they own. Because we believe, with Sanofi, that the way forward is through data. We are also planning to help Sanofi leverage more of the data that we're generating together to increase its impact."

As technology continues to evolve and organizations become even more digitally mature, partnerships built on transparency and trust will be in demand. N-SIDE and Sanofi already have that head start.

DATA-DRIVEN SUPPLY CHAIN

Landry places a premium on the impact of powerful and effective data-driven performance on the clinical supply chain. Data, he says, plays a critical role in monitoring and enhancing existing productivity and performance but, when combined with AI, also in providing Sanofi's researchers with far greater predictive capabilities to guide market intelligence and knowledge, and inform decision making on potential new projects and areas of focus.

"Performance is key to us reinvesting in new drug development for patients, and the effectiveness of our business," says Landry, "and that's right across everything from forecasting and the way we perform our operations, through to how we manage distribution and work with our vendors. Data allows us to do that, but first, we have to ensure we are absolutely clear on our

objectives and strategies, then understand what that means in terms of clinical trials and supply chain KPIs. The first step of improvement is measurement, so that is why this is a foundation for our supply chain.

"Our approach to data-driven performance has been based around that mindset," he adds. "Our team first collaborated with our clinical supply chain colleagues to understand the burning objectives and overarching strategy. Then, together with our digital team, we worked on developing and implementing the necessary technology that would allow us to collect and manage data in the most effective way, and created dashboards that our colleagues could use. This way, data gives you a complete view of current performance so you can deploy and drive targets and KPIs that achieve business outcomes.

"But we knew that wasn't enough," continues Landry. "For the kind of continuous improvement we target, it's essential to have data with obligation, make it mandatory to assess and understand, and then to take action on the information it gives. That's true data-driven performance – we are able to see and analyse trends, understand how our supply chain productivity and performance evolves against the specific goals and objectives, and learn from the statistics to continuously evolve. It's made a significant impact. Over the last two years, we have improved productivity in the clinical supply chain by more than 30% and we're now looking to make at least the same impact on lead time."

Data and the technologies implemented in Landry's department are also contributing to supply strategy selection and business strategy by giving clear, concise, and factual information on key decision-making metrics. Various objectives inform this process, he says, including around positive impact on strategic KPIs, business case and investment/ROI (return of investment). As a result, innovation projects are now factually ranked and selected.

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> *Global Head of Clinical Supply Chain*
> *Operations Innovation & Technology, Sanofi*

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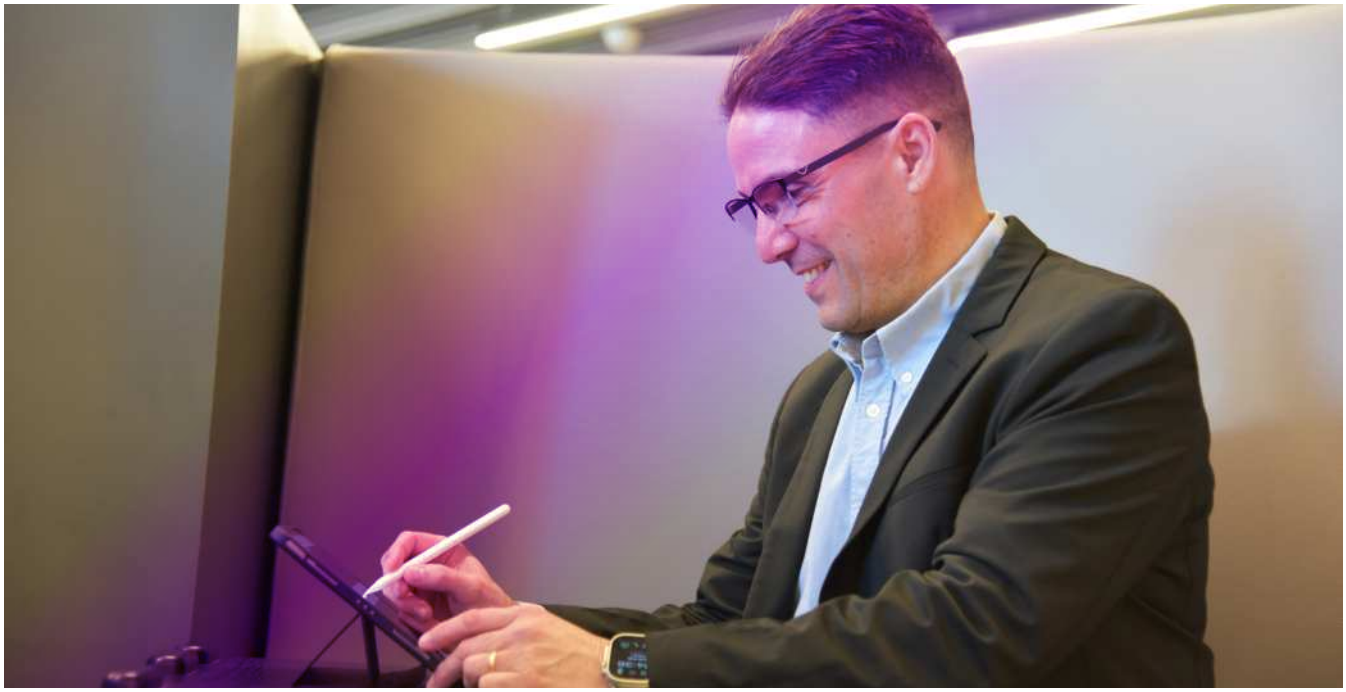

"Factual data on all these points informs the potential project decision, and to measure that effectively we use technology, methodology and partners," he explains. "We have the technology and data, but we've also collaborated with market intelligence partners so we can benchmark key metrics. If we don't have clarity on business value, cost, timelines, market impact, and strategic goals then we don't launch a project."

Data governance and working with key technology partners has been essential for deploying this kind of data-driven performance across Sanofi's clinical supply chain. For the former, Landry says the team has introduced a data lake to store, process, and secure the large amounts of structured, semistructured, and unstructured data available to the organisation. They have also introduced policies around effective data catalog governance, data modelling to ensure applications can 'speak' with each other, and cleaning data so the information on dashboards and in reports is optimised for stakeholders.

The adoption and use of key BI tools and technologies, in particular Microsoft Power BI has brought significant benefit to clinical supply chain operations since implementation, says Landry. But decision making based on past information, data and market metrics can only bring so much success in a sector that's both complex and ever-evolving in the challenges it faces.

"At some point, you have to go beyond that," Landry affirms. "That's where AI will become increasingly important – and it's a technology we're actively exploring. We need to be able to predict future outcomes and generate advice and strategy based on the information available, and AI can connect those parameters. In summer 2023 we rolled out plai (from Aily company), an industry-leading AI app that gives a 360-degree view across all Sanofi activities, and provides insights and personalised 'what if' scenarios based on internal data to support decision making and speed patient breakthroughs. We're also partnering with N-side to enhance our predictive capabilities, forecasting and simulation. These companies help us to move to the next optimisation level and explode the determinist approach glass ceiling."

FACING NEW CHALLENGES

Predictive capabilities underpinned by strong and data-driven foundations are crucial for navigating change and challenges. In the case of the clinical supply chain this goes far beyond the typical supply chain issues that professionals the world over have faced recently such as increased risk, geopolitical tension, and disruption. Landry also points to sector-specific and highly complex challenges including balancing risk and efficiency, new regulatory requests, portfolio changes that require fast and agile changes to supply strategy, tooling and processes, and new modalities or methods of treatment.

"We're in R&D and innovation, change is our world," he says. "Most importantly, our organisation must welcome these changes and be prepared to anticipate, benchmark, assess our options, and then act on the information and data available. We operate at the forefront of scientific research, and that brings potential for constant change – at the most basic level, ongoing changes and product development happens even as we're providing medicines and collecting more data about optimum shelf life, storage conditions, dosage and more.

"Our portfolio can change, depending on patient needs and scientific discoveries, on competition or the need to move into new or developing areas like gene therapy, a greater focus on immuno-inflamation, biomolecules, small molecules and, as in recent years, more research and development into messenger RNA (mRNA)," adds Landry. "These shifts, as well as new or changing modalities and therapeutic areas, mean the supply chain model, our processes, and the collaboration with our vendors has to change rapidly."

Technology helps alleviate these challenges. Landry points to Interactive Response Technology (IRT) as playing a

particularly important role. IRT, sometimes referred to as 'randomisation and trial supply management', helps clinical trial sponsors and investigators manage the patient and drug supply logistics across the entire clinical trial process. Because it offers control and flexibility while also increasing efficiency, IRT helps pharma companies organise their data to mitigate risk and to reduce time and costs in their trials.

"It requires an open and transparent relationship with vendors, in which both parties are collaborating for scientific and patient benefit," says Landry. "In terms of managing that relationship, it's an approach based on methodology, governance, and then technology. In my team I have people specialised in IRTs and who are in charge of vendor collaboration for 3 main objectives:

- Assess the relationship: quality, cost and timelines results
- Oversee and pace the troubleshooting and enhancement in progress
- Anticipate evolution and align our roadmaps

A good example is around free picking, or just-in-time dispatch. Our head of operations needed a specific treatment, so we engaged with our IRT provider to assess free picking for supply chain strategy optimisation. It was a change in the way we operate and is only effective with strong partners such as Suvoda, with which you can implement technology quickly, but it has sped up our operations and improved risk management and treatment continuity. Many other initiatives have been launched with the same spirit: prediction, analytics, interfaces with our ecosystem."

AGILITY THROUGH INNOVATION

Irrespective of industry, one crucial phrase is relevant for all supply chains: agility. Landry refers to operational agility as the engine room of both the clinical supply chain and Sanofi at large. And while the organisation can respond quickly and flexibly through the use of subcontractors to absorb peak activity, he explains the best approach is internal agility supported by technology across three core areas of forecasting, manufacturing, and distribution and logistics.

"We forecast constantly, it's not just something that happens before a trial starts," he says. "We operate in an industry where we have to manage our capacity and ensure we deliver to partners, and that means forecasting before, during, and after a trial has taken place. Our role is to translate, optimise, and influence, by selecting the

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> *– Landry Giardina, Global Head of Clinical Supply Chain Operations Innovation & Technology, Sanofi*

right scenario and continuously assessing workload and capacity. It requires using technology to have an exhaustive view of end-to-end management and performance, and having simulations and full awareness of supply strategy decisions. We work with a partner, N-side, which provides forecasting and simulation technology that links with IRT and brings us considerable benefit around working with vendors, productivity and speeding up patient supplies. It helps us to make well informed decisions based on efficiency and risk awareness."

As the industry becomes more complex and the challenges facing clinical supply chains continue, Landry explains that he and his team will explore and implement new technologies to improve areas like forecasting further. In particular, he says, this helps move forecasting from a deterministic approach which considers that future events are determined by specific causes and are therefore inevitable, to a probabilistic outlook that considers risk across all possible scenarios, as well as their likelihood and associated impacts.

"Being deterministic is ultimately not enough if you wish to take your work to the next level," he continues. "We're looking at advanced planning systems that can add probabilistic data and understand the many factors that influence how we deliver the best results. Digital twins will also play a crucial role in these areas as we develop. If we can mimic what we're doing and collect real life data, we can influence our supply strategy and manage the growing number of crises we're seeing, from earthquakes and natural disasters through to conflict or geopolitics issues."

Much of Sanofi's manufacturing is on-demand, meaning short timelines and the need for optimised operations alongside strong forecasting. Areas of constraint like labelling design and validation mean IP on demand is essential, but Landry and team also face challenges around batch record (a package of documents that includes information on new developed drug products). The size and complexity of these documents means manufacturing on demand and in an agile way is challenging, so the team has started to use electronic batch record (eBR) technology to meet release timelines and avoid project money and resources wastage. They work on the release by exception instead of checking each data. Technology can secure data entry, highlight anomalies and then allow the team to focus on high value decisions only. In addition to that, avoiding wastage is important for economic aspects, but also for ecological footprint.

"Many of the challenges we face in distribution and logistics should ring true for everyone working in the supply chain sector," adds Landry. "We use technology across the board, including for essential aspects like smart packaging to ensure effective temperature management of medicines and vaccines to optimise reconciliation. It's mandatory to know exactly what we've produced, where we've shipped it, where it's stored, what's been destroyed and what's been used for patients, for example. It can also help the patient and investigator about the treatment adherence. It's mainly paper-based at present, which is challenging when you have to aggregate everything. We use technologies like QR codes to simplify that process and improve the track and trace of all our drugs."

INDUSTRY-WIDE CHANGE

Looking ahead, Landry and his team remain committed to implementing a data-driven approach to the clinical supply chain. Beyond Sanofi, however, he advocates for greater sharing of techniques, strategies, and technology transformations across the pharma industry backed by a shared aspiration to make the world better for patients.

"We act for change," he says. "In the short term that means data-driven technology transformation at Sanofi, making sure my team and the supply chain can anticipate, address, and act on new challenges on the horizon, and deliver superior and agile performance. We don't want to watch the technology train passing — we want to drive it.

"Technology gives us an exhaustive view of end-to-end management and performance, and provides simulations and full awareness of supply strategy decisions"

– *Landry Giardina, Global Head of Clinical Supply Chain Operations Innovation & Technology, Sanofi*

But there's a bigger, and more important message here. We're in a competitive market, but I feel there's greater opportunity to learn from each other to collectively develop. Supply chain is an area in which we should be more open, share ideas, benchmark the technologies and strategies we have, and push ourselves at the best level – it's the only way we'll make real improvement. And, because of the medicines and vaccines we provide, it's essential for everyone on the planet that we do so." ■