ThermoFisher SCIENTIFIC

QUICK TO CARE™ PROGRAM

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- **EARLY & LATE PHASE DEVELOPMENT**
- CLINICAL TRIAL SOLUTIONS
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

patheon

Mike Pearson
Staff Program Manager,
Pharma Services,
Bend, OR

HOW LEVERAGING A GLOBAL NETWORK DELIVERED BIG RESULTS.

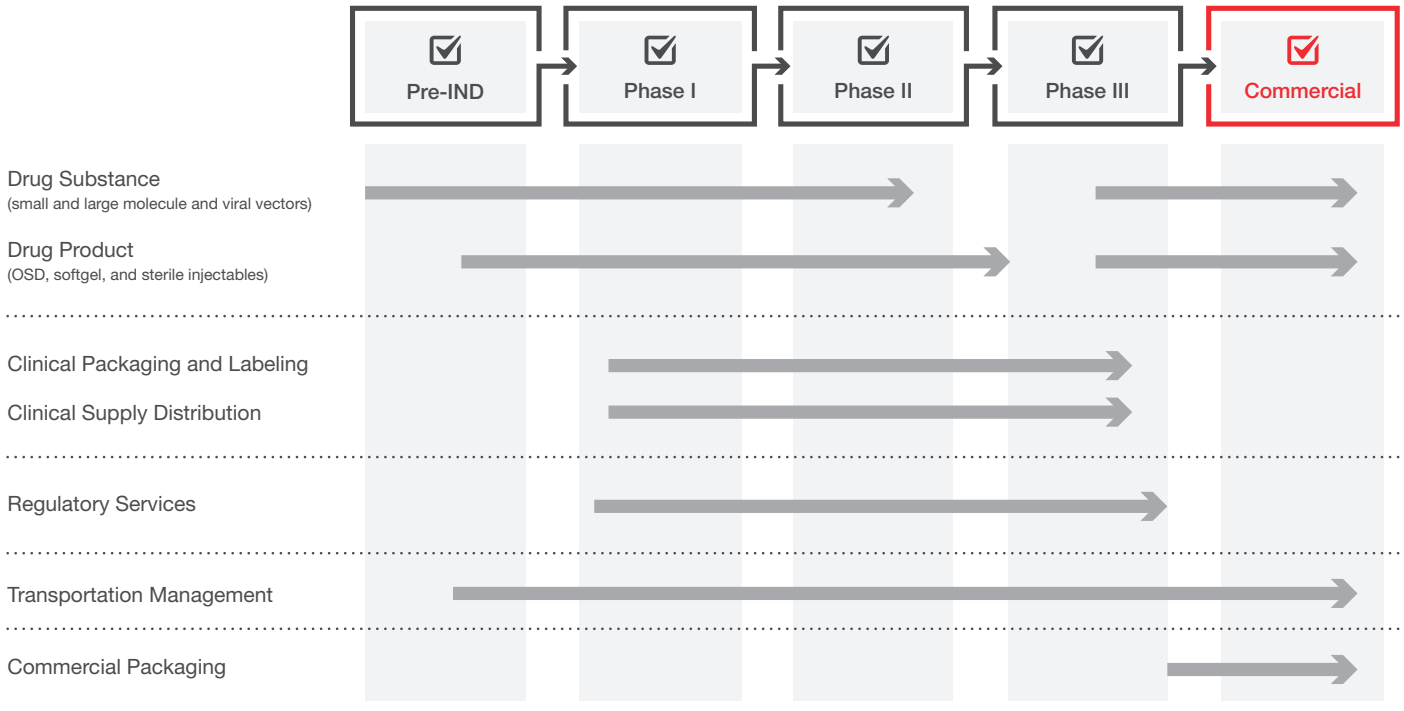
Mike's team in Bend, OR was only supposed to optimize the spray drying process for a particular medication while another, much larger, facility would handle the large-scale manufacturing. However, the other facility's equipment wouldn't be available in time to meet the client's aggressive IND filing schedule. It was time to leverage the power of the Thermo Fisher Scientific global network and Quick to Care™ program to offer the client their best chance for success. Through incredible effort and intensely coordinated activities, the team in Bend delivered nearly two orders of magnitude more material than typical projects before transferring the product to other Thermo Fisher sites to test, fill, and deliver to patients. Despite the change in plans, the right team stepped in to ensure all deadlines were met, and the client got a critical medicine to the patients who needed it most.

Streamlining supply chain and accelerating development

It is estimated that on average, the cost to bring a new medicine through development into commercial is $985 million.[1] Available data is based on new and emerging companies between 2009–2018, with products in certain therapeutic areas. These include priority review, breakthrough therapy, fast track and orphan drug, all of which create the need for an expedited approval process.[2] A single vendor solution that streamlines the supply chain and accelerates the development timeline is critical in ensuring that these new medicines are brought to market on time. Coordinating multiple vendors requires additional time, resources, and expertise to manage the various projects and timelines associated with drug development. This often leads to delays in development and miscommunication between vendors.

In 2015, Thermo Fisher Scientific introduced our Quick to Care™ program, the industry's first-of-its-kind, end-to-end, integrated, and customizable solution covering all development phases. The program streamlines and accelerates your discovery by combining drug substance and drug product development, clinical trials supply solutions including packaging, labeling, storage and distribution, regulatory services, transportation management, commercial manufacturing and packaging.

Quick to Care™ Program – Comprehensive, Flexible, Integrated Solution



"Patheon pharma services has the right expertise, great team and flexibility to meet customers' needs."

— Biotechnology company focused on cancer medicines, USA

MEETING OUR CUSTOMERS' DRUG DEVELOPMENT AND CLINICAL SERVICE NEEDS

With a complex drug development path, many challenges can occur in the form of detours and roadblocks, leading to unexpected delays, missed milestones, and delayed timelines. We understand these challenges and our dedicated global team of experts can provide you with the experience and guidance needed to develop a program designed to reduce your development timeline and get you to commercial success, faster. Our solution to these challenges is the Quick to Care™ program, which integrates our broad, industry-leading capabilities into a single solution that is tailored to the needs of your program and covers all development phases and commercial manufacturing.

TAILORED SOLUTIONS JUST FOR YOU

Whether your goal is out-licensing at Phase IIb or taking your molecule to full commercialization, it requires a dedicated, trusted and experienced partner that understands your complex program needs. Our team of global experts provide unified program management, scientific and technical insight, and reduce redundancies to ensure success in your drug development journey. By partnering with us, you're able to create and customize your own flexible integrated offering based on your specific needs, all while working alongside our team of experts to find a solution tailored just for you. We are patient-centric focused and offer customizable solutions that include:

- Clinical Supply Planning
- Viral Vector Development & Manufacturing
- Drug Substance Development & Manufacturing
- Drug Product Development & Manufacturing
- Clinical Trial Packaging & Labeling
- Clinical Material Distribution & Logistics
- Transportation Management
- Commercial Manufacturing & Packaging

BENEFITS OF PARTNERING WITH US

We understand the unique needs of small companies—more than 78 percent of our clients are emerging and mid-size pharma/biopharma organizations. The Quick to Care™ program was designed with you in mind, and combines world-class drug substance, drug product, and clinical supply development and manufacturing services into a single, customizable, integrated program for your molecule, and further reduces the amount of effort you put into managing the supply chain. Benefits include:

- Simplification
- Time savings
- Reduced risk

The program provides a customizable solution designed to fit your journey. Our single vendor solution integrates drug substance and drug product development, clinical manufacturing, clinical supply forecasting, demand planning, and clinical trial supply services—all of which are designed to accelerate your discovery. We provide you with access to a vast global network of scientific experts and technicians as well as a dedicated program manager assigned to your project, all united with one shared commitment to your drug development success. This connected and accessible team brings deep experience in their specialties to solve your challenges faster—all while simplifying and accelerating the development of your molecule into commercial manufacturing.

> ***"For a small company, having a technically competent, customer focused team supporting us is critical to our success.***
>
> — Pharmaceutical company focused on women's health, USA

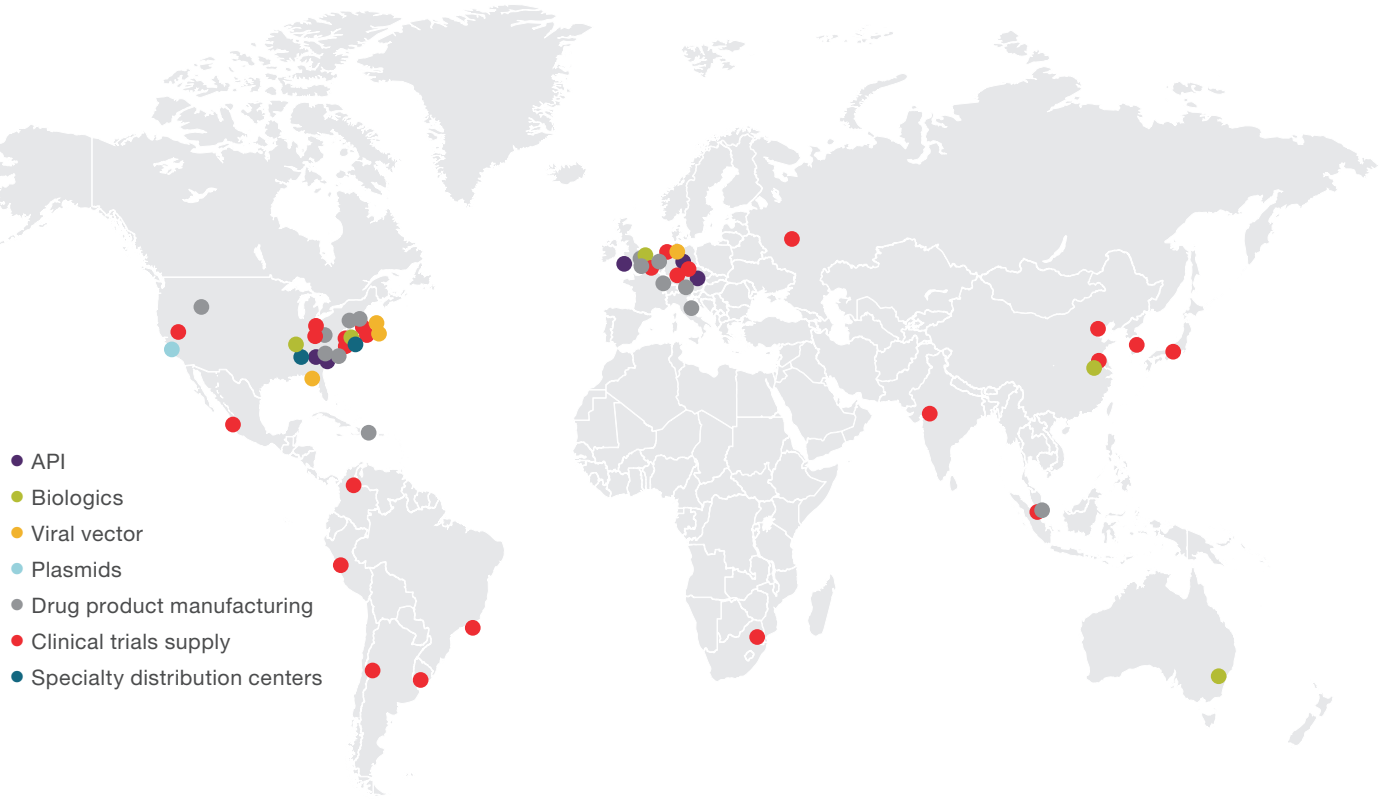
Delivering global excellences

Our client-focused mindset and global expertise implement a best-in-class integrated offering to position your molecule for greater therapeutic and financial success. Our experience guiding new and emerging clients through each phase of drug development has resulted in saving time and cost. Our integrated network of technical, quality, and customer engagement teams are ready to support your drug development journey. The Patheon pharma services network has 55+ sites across five continents and employs more than 3,500 scientists, technicians, and engineers with deep technical expertise all working together to ensure the success of your molecule. We currently offer manufacturing locations in the United States, Europe, and Australia, which provides you with simplified logistics and R&D tax advantages.

We offer a broad range of solutions that include:

- Clinical labeling services
- Demand planning and supply optimization
- Clinical trial packaging and storage
- Cold chain storage and logistics
- Distribution and logistics
- Clinical ancillary management

Integrated global network of technical, quality and customer engagement teams to support the drug development journey



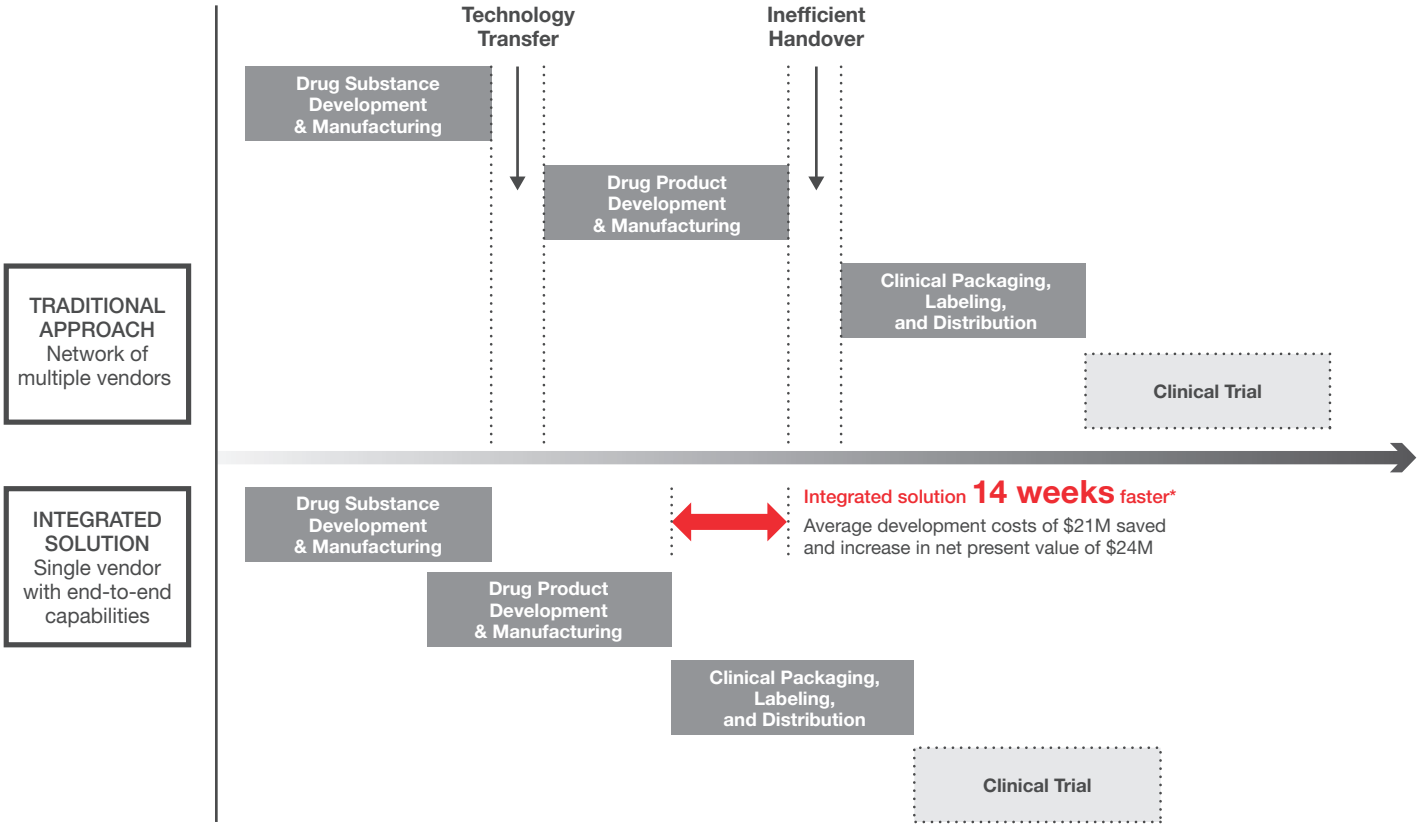
~17,000
colleagues in 55+ sites

~3,500
scientists, technicians and engineers with deep technical expertise

~3,000
quality specialists

Accelerating development timelines

The Quick to Care™ program has allowed our clients to develop their small molecule candidates an average of 8–12 weeks faster, and large molecules an average of 14–20 weeks faster than the industry standard. Our clients have reduced their drug development timelines by an average of 14 weeks, which translates to a total net gain of approximately $44 million, as reported by the Tufts Center for the Study of Drug Development.[3]



*Integrated solution consisting of drug substance and drug product. Time savings for integrated solution consisting of drug substance, drug product, and clinical supply believed to be greater.

Source: DiMasi JA, Smith Z, Getz KA. Assessing the Financial Benefits of Faster Development Times: The Case of Single-source Versus Multi-vendor Outsourced Biopharmaceutical Manufacturing. *Clin Ther*. 2018 Jun;40(6):963-972.

"Patheon pharma services provides exceptional speed and responsiveness."

— Biotechnology company focused on oncology, USA

Dedicated project management

The Quick to Care™ program begins with a dedicated program manager who is assigned to your program from the outset. The program manager is the integrator that pulls together our broad, industry-leading capabilities into a single, integrated solution. They are responsible for reaching across our extensive network to pull together a team of technical experts to focus on your program. Your program manager is your advocate who establishes and manages the governance process.

Our experienced and dedicated global program managers have the knowledge necessary to provide clients with a proactive, timely, and seamless approach to position your molecule for greater therapeutic and financial success.

We provide a global network integrated by program managers to deliver coordination, commitment, and accountability across the entire supply chain. Our managers oversee and manage 45 programs as of 2020 and have 24+ years of combined drug development experience. They are the human connector that integrates the sites and capabilities into a single network, by having:

- One team approach
- Harmonized global practices and procedures
- Decreased administrative tasks
- Streamlined and focused communications

Single, comprehensive, integrated plan enabled by communication and coordination

Global Network: Expertise & Capabilities

- Involved from concept to delivery
- Leveraged across supply chain
- Network of technical experts solving your challenges

Key Client Contact

- Client advocate integrating and coordinating overall program

Governance

- Global framework to make decisions and escalate issues

Global Communication

- Communication and visibility across network provides complete view of program
- Positioned to identify and respond to obstacles

"The Patheon pharma services team always delivers quality results rapidly."

— Biotechnology company focused on innovative therapeutics, USA

SHAPING OUTCOMES

From drug development, to commercial manufacturing, packaging, labeling, distribution, and clinical trials, the Quick to Care™ program is a premier integrated offering solution that is comprehensive and flexible. The new business model of the biopharmaceutical industry that focuses on the unmet needs of smaller patient populations has diversified today's pipelines and brought new hope to patient care. By offering multiple services in one solution, the program gives you an opportunity to improve efficiency in delivery and, as a result, bring drugs to patients faster.

Kaleido Biosciences, a clinical-stage healthcare company, approached Thermo Fisher asking for very individual approaches to their drug substance, drug product, and clinical trial packaging needs. These fragmented needs are what often drive smaller companies to work with multiple suppliers, stretching resources thin and ultimately adding considerable risk and time to the critical path of their molecule. Thermo Fisher was able to meet Kaleido's needs using the customizable and integrated Quick to Care™ program. Learn more here: *Kaleido Biosciences Successfully Meets Aggressive IND Filing Date Thanks to Strategic Partnership*.

CASE STUDY

How Kaleido Biosciences met an aggressive IND filing date

Kaleido™

SUMMARY: Kaleido's lead candidate, KB195, is intended to treat urea cycle disorders (UCD), which affects a small orphan population of patients who inherit this serious and life-threatening disease. To bring KB195 to patients, Kaleido had a very aggressive timeline to file an IND.

CHALLENGE: Kaleido did not have the resources to create the material and consolidate CMC data to support the IND submission. Reaching out to a list of suppliers for each step of the development process requires a significant amount of effort and time to coordinate.

SOLUTION: Designed specifically for new and emerging companies such as Kaleido, The Quick to Care™ program is a customizable integrated solution that combines drug substance and drug product development, clinical manufacturing, early demand planning and clinical trial supply execution.

"Being a small company with limited resources, the Quick to Care program was a strong fit for us, because it allowed us to be able to manufacture across multiple sites while having the core program manager help us communicate and maintain relationships across the site to make sure that all the activities were completed under a tight timeline. One thing the Thermo Fisher team was very good at was understanding what our milestone was but also projecting what our next milestones would be."

– Kim Hocknell, VP, Technical Operations, Kaleido Biosciences

Our proven track record of quality, reliability and expertise can support your drug development journey

NEW AND EMERGING CLIENTS

69%
of our product development new business in 2020

278
drug development projects in 2020 alone:

139	57	82
Phase I projects	Phase II projects	Phase III projects

109 NDA APPROVALS 3X MORE
than our closest competitor

Thermo Fisher Scientific is your global partner of choice for an integrated solution to streamline your drug development program. We understand the complex journey ahead and are experienced in working with new and emerging clients. In 2020, 69 percent of our new business in product development was with new and emerging clients – 278 drug development projects in 2020 alone, including 139 Phase I projects, 57 Phase II projects, and 82 Phase III projects. As an industry-leading partner with a proven track record, we have outsourced 109 NDA approvals in the last decade—that's more than three times the number of the next-ranking CDMO.

With our breadth of experience, vast access to scientific experts, and a global integrated network, we can provide you with a customizable solution that works to reduce your development timeline. We apply a science-driven, risk-based approach to every step of the development and manufacturing process, while providing you with a global footprint and the scientific and therapeutic expertise to ensure your discovery makes it to the patients who need it most. We have one shared commitment—your drug development success.

[1] Olivier J. Wouters, PhD; Martin McKee, MD, DSc; Jeroen Luyten, PhD. "*Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*". JAMA. 2020;323(9):844-853. doi:10.1001/jama.2020.1166

[2] Novel Drug Therapy Approvals Annual Reports, 2015 to 2019

[3] DiMasi, J., et.al., Clinical Therapeutics, Volume 40, Number 6, 2018

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Published 04/21

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