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WHITEPAPER

# Getting to first-in-human clinical trials: a make-or-break milestone for small biopharmas

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# Abstract

“Faster and better” has become the mantra for biopharmaceutical companies as they face intense pressure to get therapies to market quicker than ever before. The incentive of securing market share with first-to-market offerings is felt by all industry players. Pressure mounts from here for small companies, which often must meet certain milestones before receiving funding from investors. Quickly proving efficacy in first-in-human (FIH) trials is a make-or-break milestone for cash-strapped companies whose hopes for success hinge upon just one or two molecules.

Speed and revenue are also intertwined at Large Pharma. As Large Pharma struggles with R&D productivity, companies need to fill pipelines with promising options. Many large biopharma companies have numerous molecules with therapeutic potential but screening them at the same time and determining the best ones to pursue in FIH trials is a challenge. Speed to market takes on even greater urgency when you consider that many biopharmaceuticals are intended for treating chronic, serious and/or life-threatening conditions. Many patients cannot wait years for therapies to enter the clinic and come to market. Thus, whether biopharmaceutical companies have one candidate or 100, the directive is clear: moving quickly into FIH testing is essential. But, how?

## Key strategies for speeding time to clinic

In response to this pressure, CDMOs are focusing on reducing timelines for producing high-quality clinical supply. For instance, the Quick to Clinic™ program for biologics uses three chief elements to move from cell line development to drug substance for clinical trials in as little as 14 months.

**Every day a drug is not on the market equates to lost revenue and delays in a patient feeling better. Time matters, and so does the flexibility and expertise a CDMO can offer for getting to FIH testing as fast as possible.**

1

### Cell line development flexibility

When sponsor clients are restricted to using only the CDMO's proprietary cell line and media for development product services, their flexibility to make strategic manufacturing decisions is greatly limited. We believe in the opposite approach. We offer clients options that are best suited to their molecule's needs. With our Quick to Clinic™ approach, clients can use their own cell line or ours. In either scenario, we follow a pre-established set of parameters for process development that gives clients flexibility, can remove certain mandatory fees and make more efficient use of critical preclinical time. Alternatively, we can work with our client's cell line and develop a slightly longer, more custom route.

2

### Seamless transitions

Companies can move to the clinic faster and less expensively if they use one qualified CDMO partner to seamlessly take a project from cell line development to a released drug substance and into drug product. In addition to better communication, clients can benefit from parallel development. While collecting stability data to file an IND, CDMOs with broad experience can start working on product filling/packaging/labeling, for instance. Likewise, CDMOs that can couple drug substance and drug product manufacturing save assay transfer costs and time since they can provide testing for both. Other benefits come from more efficient production scheduling.

3

### Broad technology portfolio

Patheon pharma services cuts the time it takes to move from drug substance to product by taking advantage of Thermo Fisher's range of wide nutritional medias for CHO and other cells as well as Poros™ Cation Exchange Resins. No other CDMO offers this same breadth of services to clients.

## About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. Built on a reputation for scientific and technical excellence, we provide pharma and biotech companies of all sizes instant access to a global network of facilities and experts across the Americas, Europe, Asia and Australia. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to CareTM program. Our Quick to ClinicTM programs for large and small molecules help you balance speed and risk during early development so you can file your IND quickly and successfully. Digital innovations such as our mysupply Platform and Pharma 4.0 enablement offer real-time data and a streamlined experience. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.

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