LIFECYCLE BRIEF

Sterling

Phase III

Supporting regulatory approval through high integrity processes and data

Phase III clinical trials typically last up to **four years.**[1]

Reaching phase III clinical trials is a significant accomplishment for pharmaceutical organisations. And yet, only 25-30% of drug products progress past this phase.[2] To maintain momentum and progress organisations must take care to ensure continued quality, safety and compliance during phase III, efficiently and effectively overcoming any potential issues before receiving commercial approval.

In addition, phase III is a critical time for organisations to start preparing for commercial-scale manufacturing. It is important to consider new drug application requirements and proactively plan ahead to ensure a seamless scale-up. The right outsourced partner is essential at this phase, particularly one that possesses a dynamic blend of manufacturing and regulatory expertise to support phase III requirements and prepare for your product's new phase.

Below are some key areas that can present challenges for pharmaceutical and biotechnology organisations through phase III clinical trials.

Full-lifecycle continuity

During phase III, organisations must begin to proactively plan for commercial-scale manufacturing. At the same time, phase III offers the opportunity to make adjustments before a product reaches the market, including addressing inefficiencies in earlier stages and finding ways to overcome them. **In order to navigate phase III seamlessly, look for a partner that has a comprehensive and proven understanding of the pharmaceutical product lifecycle, including full, commercial manufacture.**

Balancing speed and quality

Part of the reason for high failure in phase III is a widespread tendency to rush into this phase upon success in phase II.[2] While speed is critical, it is also exceedingly important to maintain high quality, safety and efficacy. It is imperative that organisations resist rushing into phase III without first addressing careful dosage selection, study design, data collection,[2] and other key considerations that can risk approval if overlooked. **The right partner can help you surface and address these considerations while maintaining momentum.**

Scale-up challenges

Phase III trials involve significantly more individuals than phases I and II, and organisations must be prepared to manufacture their products at a larger scale to meet clinical supply requirements. This brings about additional safety and efficiency considerations that may not have surfaced in earlier phases. **Make sure to identify a partner that can help you design safe and scalable processes early on, and ensure quality manufacturing at any scale.**

NDA submission

After successful phase III trials, organisations are required to file a comprehensive New Drug Application (NDA) to begin commercial sales.[3] This submission requires detailed information about the product, beginning with early phase development. **In order to support a successful NDA submission, your outsourced partner must provide extensive regulatory expertise as well as a deep understanding of API development and manufacturing best practices.**

At Sterling, we have the specialised teams, state-of-the-art facilities and equipment, and extensive expertise to support our customers' molecules through every stage of their journey to market, from early phase development through to full commercial manufacturing.

Here's how we support our customers through phase III clinical trials:

Full-lifecycle expertise

With extensive knowledge of the full pharmaceutical lifecycle, we help our customers see phase III in the context of their entire programme. By continually refining and optimising processes throughout a project, as well as designing them to be safe and scalable in anticipation of large-scale manufacturing, we position our customers for success during phase III and beyond.

Efficient and quality-focused manufacturing

We understand the importance of speed on a product's journey through clinical trials, but we also know that quality must always come first. Our team helps customers generate all of the necessary data for phase III trials, and we harness this data to support continued process optimisation and anticipate potential challenges along the way. As our customers enter phase III, we help them find an optimal balance between speed, quality and cost to maximise their chances of approval.

Seamless scale up capabilities

Our strengths and capabilities spanning the entire molecule lifecycle enable us to scale up our customers' products while ensuring continued safety, quality and efficiency. We offer cGMP manufacturing expertise and the ability to support a wide range of manufacturing considerations, including milling, hazardous chemistry, continuous processing and more.

Regulatory support

Our combination of analytical and regulatory expertise enables us to deliver all of the detail required to support successful NDA submissions. We harness deep familiarity with regulatory requirements around the world and process validation to compile comprehensive data and offer guidance for our customers. In addition, our CMC team can review data to draft the CMC portion of NDA submissions to make our customers' lives easier.

Maximising success at every stage

At Sterling, we have supported leading pharmaceutical and biotechnology organisations through successful phase III clinical trials. We hold a strong track record of empowering our customers as they prepare to shift from clinical-scale manufacturing to full commercialisation. Most importantly, as a PDMO®, or partnership development and manufacturing organisation, we deliver the level of scientific collaboration needed to enhance our customers' success at every stage.

Service

We pride ourselves on being easy to do business with, removing layers of complexity, maximising flexibility and adaptability to your requirements, and doing what we say we will do, again and again.

Passion

We promise to treat your molecule as our own, drive progress by continually exploring new and emerging capabilities, and do the right thing for people and planet.

Science

We combine our expertise in complex and hazardous chemistry, our world-class facilities and our full-lifecycle capabilities to place scientific excellence at the core of every solution we deliver.

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2. Shanley, A. Preventing Phase III Failures. Pharm Tech [Online] 2016, 1, 24-27. https://www.pharmtech.com/view/preventing-phase-iii-failures (accessed May 18, 2021).
3. New Drug Application. US Food & Drug Administration. https://www.fda.gov/drugs/types-applications/new-drug-application-nda (accessed May 18, 2021).