LIFECYCLE BRIEF

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# Phase II

## Accelerating development through ongoing process optimisation

In 2020, there were **362,552 registered clinical studies** worldwide.[1]

**After affirming a drug product's safety and dosage, phase II clinical trials focus on determining its efficacy and identifying any side effects.[2] During this phase, organisations are focused on continuing to optimise processes and maximise efficiency, as well as compiling the data, materials and documentation required by regulatory agencies.**

With just 1 in 3 products progressing past phase II,[2] it is important to take every possible measure to anticipate and overcome challenges, adhere to deadlines and carefully address a full range of regulatory requirements. Given the complexity of products in the pipeline today, it is more important than ever to work with an outsourced partner who has the specialised expertise and track record needed to help navigate the complexities of phase II.

### Below are some key areas that can present challenges for pharmaceutical and biotechnology organisations as they progress through phase II clinical trials.

#### Demanding deadlines

With clinical trials come significant time pressures. Organisations must continue to meet tight deadlines while delivering a product that adheres to stringent safety, quality and compliance standards. **Selecting an outsourced partner with robust API manufacturing expertise is critical to ensuring efficient and cost-effective manufacturing on a continued basis**.

#### Regulatory considerations

Before a product can progress to phase III clinical trials, organisations must identify a suitable regulatory starting material (RSM) and determine where cGMP processes are and are not utilised. Both of these steps help to define the standards that the programme will adhere to in its later stages. **A partner with a strong knowledge of the regulatory landscape will empower you to set appropriate standards while maintaining cost-effective manufacturing processes.**

#### Impurity assessments

Impurities can present a challenge at any stage, but it is especially important to identify and overcome them at the halfway point of clinical trials. With data from earlier phases and a stronger understanding of how processes will evolve as the project scales, phase II provides organisations the opportunity to implement controls and mitigate risk associated with potentially harmful impurities. **Look for a partner that values quality and purity, and has experience meeting stringent purity thresholds for a diverse range of projects.**

#### Process changes

After progressing past phase I trials, an organisation may seek new ways to optimise processes and manufacture its product more efficiently. Process improvement requires a holistic view of the entire lifecycle, including an understanding of historical and potential challenges. In addition, any and all changes must be backed by thorough process validation and reliable supporting data to ensure ongoing compliance. **Make sure to identify a partner that is not only focused on continual process improvement, but can also anticipate and address the associated regulatory implications.**

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 II clinical trials:

### Efficient and quality-focused manufacturing

We have been leaders in cGMP API manufacturing for more than 50 years. We put quality first, and we have the equipment, expertise and flexibility needed to support a wide range of manufacturing requirements and scale to meet changing demand. In addition, we are deadline driven, and our experience supporting customers through clinical trials enables us to understand the supply needed and deliver it in a timely manner.

### Regulatory support

Having supported customers around the world through successful clinical trials for many years, we have a profound understanding of regional regulatory requirements. Our dedicated CMC team provides tailored guidance to customers to aid in starting material selection and define an appropriate cGMP/non-cGMP interface. We aim to strengthen our customers' chances of regulatory success while containing costs and meeting their desired deadlines.

### Analytical expertise

Our team of skilled analysts has the specialised equipment and expertise needed to carry out comprehensive impurity assessments. In preparation for and throughout phase II, we perform robust stage-by-stage impurity investigations, as well as potential genotoxic impurity assessments in adherence with ICH M7 requirements. This enables us to develop controls to mitigate any harmful impurities in later stages and avoid potential setbacks.

### Continual process optimisation

Our team is continually seeking new ways to help our customers achieve greater efficiency, safety, quality and cost-effectiveness throughout their products' manufacture. We collaborate closely with customers to understand their unique objectives and identify ways to better meet them. Wherever process changes are implemented, we help our customers compile the necessary evidence and supporting documentation for continued regulatory adherence.

## Supporting phase II success through manufacturing and regulatory expertise

At Sterling, we have the equipment and expertise needed to position our customers for success during critical phase II clinical trials. By continually optimising processes and offering regulatory support, we have supported many customers in receiving approval to progress to phase III. As a PDMO®, or partnership development and manufacturing organisation, we deliver the comprehensive services and scientific collaboration our customers need to maximise success at every stage of their projects.

### 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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1. Total number of registered clinical studies worldwide since 2000. Statista. https://www.statista.com/statistics/732997/number-of-registered-clinical-studies-worldwide/ (accessed May 19, 2021).
2. Step 3: Clinical Research. US Food & Drug Administration. https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (accessed May 19, 2021).

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