Case Study

tranScrip

Rapid Delivery of a Complex Phase 1 MAD Study in Severe Asthmatics

Challenge

A small US-based start-up faced a critical challenge: they needed to rapidly deliver a complex Phase 1 Multiple Ascending Dose (MAD) study in patients with severe asthma. This was a crucial step in their drug development programme, requiring a specialised and swift execution. The start-up encountered several hurdles:

Insufficient Internal Resources:
The start-up lacked the internal capacity and experience necessary to manage and execute a complex clinical trial.

Vendor and Site Limitations:
Initially, they identified a vendor and clinical site in New Zealand to conduct the study. However, the site struggled with patient enrolment, putting the study timeline and data integrity at risk.

These challenges necessitated a rapid revaluation and realignment of the study's execution strategy to ensure timely and accurate delivery.

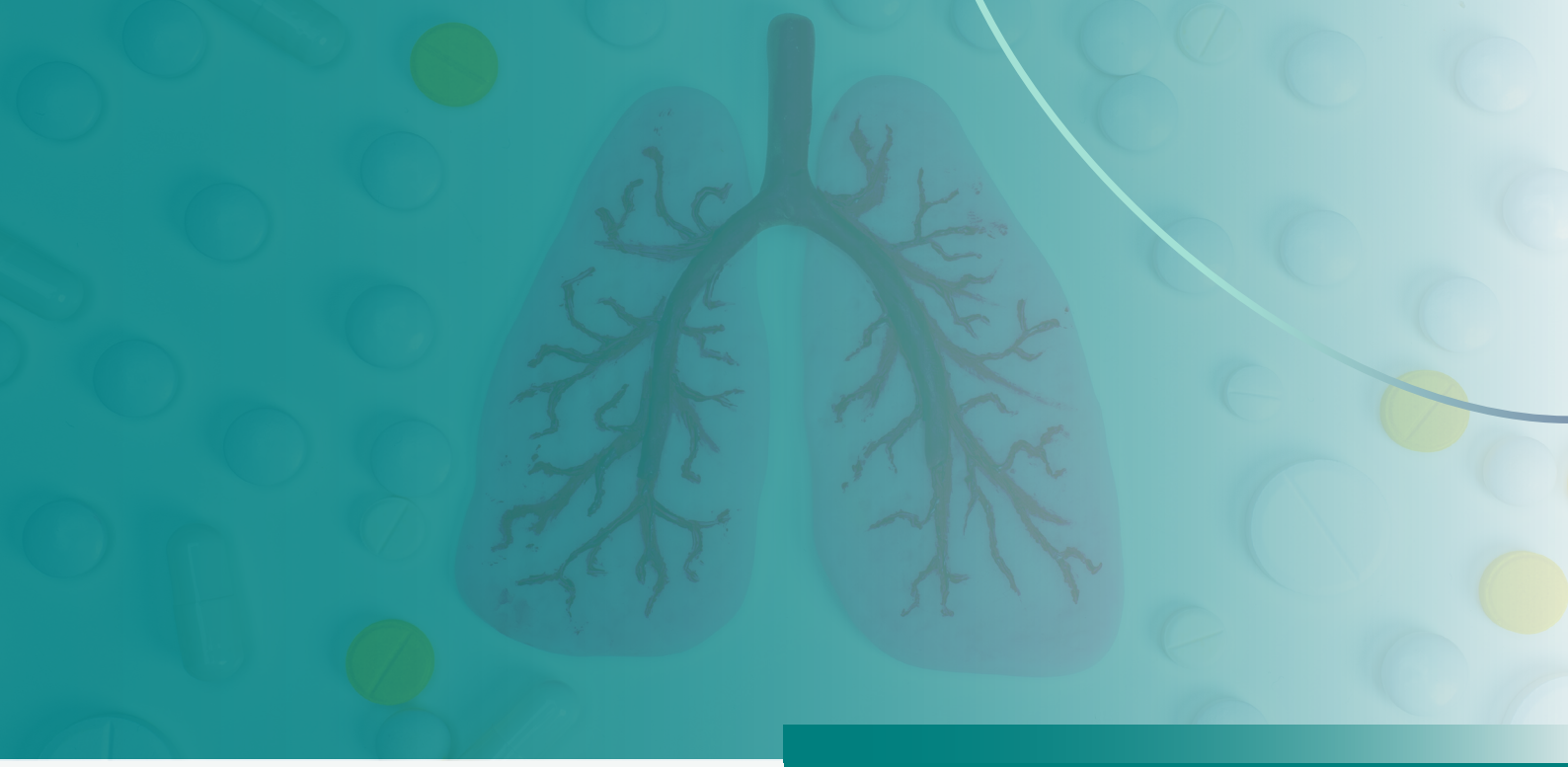
Solution

To address these challenges, the start-up engaged tranScrip to provide comprehensive clinical trial support. The solution included:

Strategic Decision to Relocate the Study
tranScrip recommended moving the study to the UK, selecting three capable clinical sites known for their ability to enrol severe asthmatic patients promptly. This decision was based on the need for rapid patient recruitment and better resource availability.

End-to-End Study Management:

- **Study Management Team and Cross-Functional Leadership:** tranScrip deployed an experienced team to oversee all aspects of the study, ensuring smooth coordination and execution.
- **Vendor Identification, Selection, and Oversight:** The team identified and selected vendors with the requisite capabilities and experience, managing them closely to maintain quality and compliance.
- **Regulatory Support and Submissions:** tranScrip provided comprehensive regulatory support, including preparing and submitting documentation to regulatory authorities, ensuring all legal and compliance requirements were met.



- **Clinical Site Monitoring and Management:** Continuous monitoring and management of the clinical sites were conducted to maintain study integrity and data quality.
- **Pharmacovigilance (PV) and Medical Monitoring:** The team provided ongoing safety monitoring and medical oversight to ensure patient safety and data reliability.

Outcome

The rapid intervention and expert management led to a successful outcome:

Rapid Start-Up:
The study experienced a swift initiation, with all three UK sites becoming active quickly.

First Patient In (FPI):
The study was on the brink of enrolling the first patient, demonstrating the effective turnaround in site performance and patient recruitment.

Following this success, the client further engaged tranScrip to deliver a second Phase 1 study, a Japan Bridging study, using the same comprehensive and effective approach.

Conclusion

This case study illustrates the importance of adaptive strategies and expert external support in clinical trials, particularly for small companies with limited internal resources.

tranScrip's involvement was crucial in overcoming initial challenges, ensuring the study's rapid execution and quality. The successful delivery of the Phase 1 MAD study and subsequent engagement for another study underscored the value of comprehensive clinical trial management and support in navigating complex regulatory and operational landscapes.

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