Case Study

tranScrip

Navigating the Development Path for Novel Immunological Biological Products

A prominent pharmaceutical company, with a robust pipeline of immunological therapies, faced a significant challenge in managing two highly novel biological products. The first product was in the preclinical stage, while the second, licensed from a small biotech, was already in Phase 1. Both products showed substantial potential across various immunological indications, but the company needed a strategic approach to determine their development paths and manage them efficiently until an internal clinical team could be established.

Challenge

The primary challenge was to oversee the development of both immunological products during a transitional phase. The company required a comprehensive and strategic approach to:

Draft Clinical Development Strategies:
- Create tailored clinical development plans for each product.

Navigate Regulatory Landscape:
- Utilise regulatory precedents and literature to guide the development process.

Ensure Effective Oversight:
- Manage and monitor the clinical progress of both products.

Prepare for Internal Transition:
- Develop a transition plan for when the company would assume control of the products.

Solution

To address these challenges, the pharmaceutical company engaged tranScrip, which assembled a specialised translational team. The team consisted of:

Three Translational Physicians:
- To provide expert guidance on clinical and preclinical aspects.

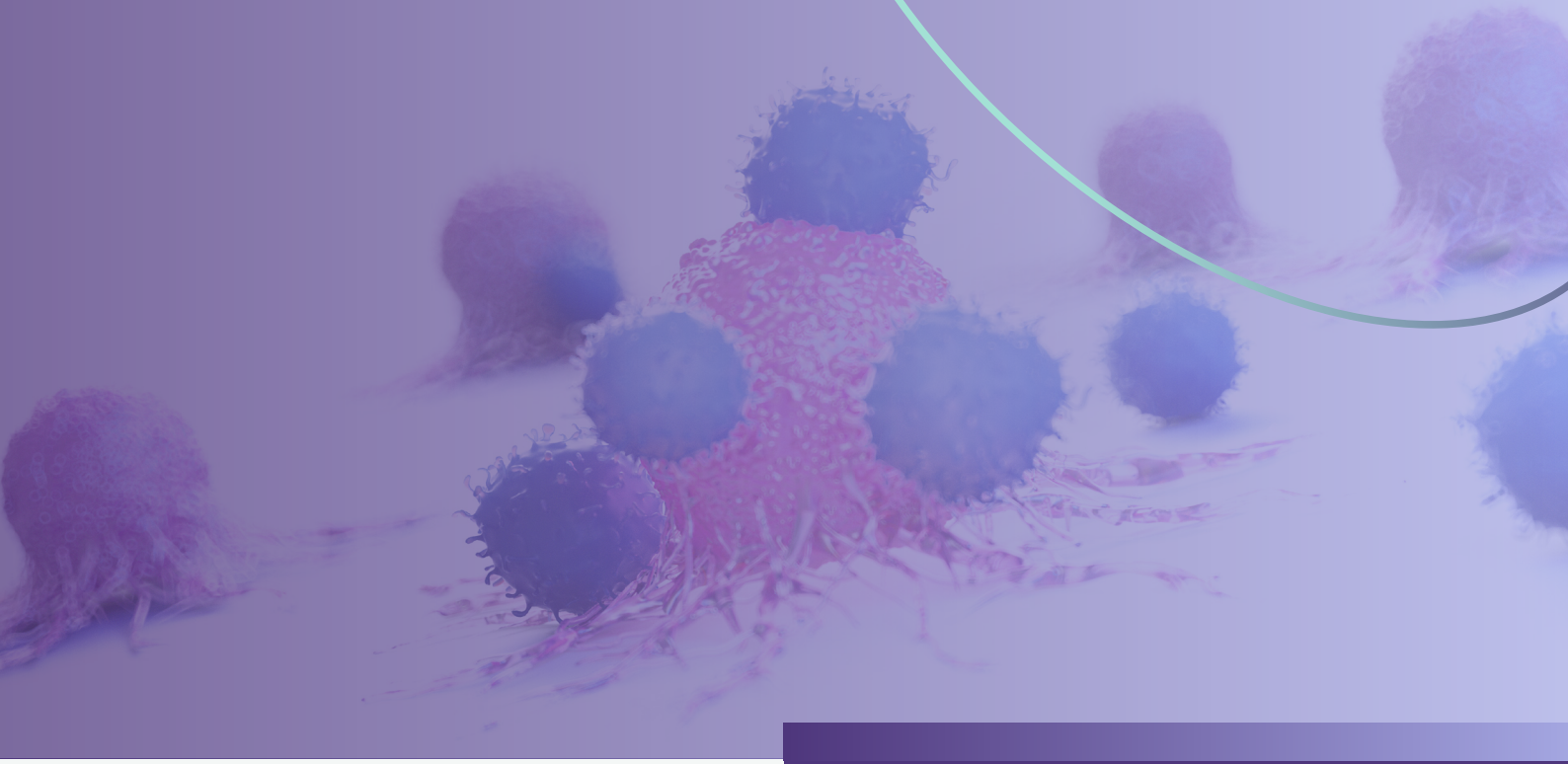
Pharmacovigilance (PV) Physician:
- To oversee safety and monitoring.

Commercial Strategist:
- To align the development strategy with market needs and opportunities.

Scientific Support:
- To provide detailed scientific analysis and support.

Medical Writers:
- To create clear and comprehensive documentation.

Project Management:
- To ensure smooth execution and coordination.



Steps Taken

Development of Draft Clinical Strategies:
- The team created preliminary clinical development strategies for both products, considering their novel mechanisms and potential indications.

Regulatory and Literature Support:
- Extensive research into regulatory precedents and literature was conducted to inform the development plans.

Regulatory Advice and Programme Design:
- Regulatory advice was sought to ensure compliance and feasibility. Development programmes and clinical protocols were crafted for both products.

Vendor Identification and Monitoring:
- Vendors for necessary services were identified, and Phase 1 monitoring was provided to ensure adherence to protocol and safety.

Outcome

The comprehensive strategy and oversight provided by tranScrip led to a pivotal decision by the pharmaceutical company:

Advancement of Both Compounds:
- The company decided to advance both products into further clinical stages.

Internal Team Transition:
- The company moved forward with hiring their own clinical team to continue development.

Programme Adjustments:
- One product retained its original programme objectives. However, the other product's initial indication in a rare disease was altered to a different disease based on further exploration of regulatory and market considerations.

Conclusion

The engagement with tranScrip successfully guided the pharmaceutical company through a critical transitional phase, ensuring that both novel immunological products were positioned effectively for further development.

By leveraging expert advice, regulatory insights, and comprehensive development strategies, the company was able to make informed decisions about the future of its products. The tailored approach not only facilitated the advancement of both compounds but also ensured a smooth transition to an internal clinical team, setting a solid foundation for continued progress in the immunological domain.

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