

Case Study



Fractional Chief Medical Officer for a Novel Early-Phase Development Programme

Overview

A biotechnology company advancing a highly novel programme — unique in its target, modality and disease area, sought expert guidance to design an effective early development and first-in-human (FIH) strategy.

Challenge

The company lacked internal early development expertise to plan and deliver FIH and proof of concept (PoC) studies for a complex, first-in-class asset.

Approach

tranScrip appointed an experienced pharmaceutical physician to lead clinical strategy, develop a bespoke early clinical development plan and FIH protocol, and integrate seamlessly within the client's multidisciplinary team.

Impact

tranScrip's leadership enabled a rapid and well-structured FIH approach, producing high-quality documentation to support investor discussions, while additional statistical input refined FIH endpoints and strengthened study design.