

# 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.

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**Xiaolong Qi**



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