Prism Ideas

Case study

# Placement of a Clinical Development Leader

## Background

*...evolving companies need to add resource to their teams, providing specific knowledge and understanding*

The transition of a new drug from first in man studies to phase II development is a complex operation requiring both therapeutic area and clinical development expertise. Decisions made at this juncture in a products lifecycle can have long lasting implications upon the success of the regulatory study program, eventual market dose and indication. This is often a time when evolving companies need to introduce additional resource to their teams to augment their existing base, providing specific knowledge and understanding of the challenge at hand.

Prism Ideas' Physicians have collaborated with many emerging Pharma and Biotech clients to help establish the best development path and oversee the implementation of plans.

## Challenge

A pharmaceutical company with a substantial heritage in virology had decided to make a strategic move into oncology, and had more assets in early development than the in-house physicians were able to effectively support. However, the company was unable to employ a permanent Clinical Development Lead for its most recent clinical development candidate, which had just commenced its first dose finding study. The sponsor's Chief Medical Officer (CMO) had a clinical background outside the cancer arena and needed an experienced Pharmaceutical Physician to provide direction and guidance to their regulatory and clinical operations colleagues.

## Solution

*...review and completion of a clinical development plan approved later by the company's senior management committee.*

Prism agreed an initial 3-month contract to provide the client with Director Pharmaceutical Physician assistance on a one third full time equivalent basis. Initially they acted as the project lead physician for the solid tumour clinical development program, progressing to the review and completion of a full clinical development plan which was approved by the company's senior management committee.

Thereafter, the Prism Physician provided medical oversight of a new protocol development and trial design, during which time the initial contract was extended for a further 12 months. After the outcome of the first in man study was favourable, the Prism Physician assisted in more diverse activities to support the company's wider team, including the development of target product profiles and other business case-related activities, provision of market awareness, and identification of areas with unmet medical need.

The Prism Physician worked alongside the CMO to provide medical expertise for regulatory communication and submissions, including a successful application for orphan drug designation. In addition, they supported the client's clinical operations team on an *ad hoc* basis in relation to issues outside the program, which was their principal responsibility

## Conclusions

*Prism provides excellence throughout all its clinical support services, placements can be relied upon to deliver right from the start.*

Prism Ideas recognises the critical importance of patient safety and emergent clinical trial data. The Prism Physician ensured the safe conduct of this clinical study, including the management of a potentially significant safety signal that emerged during its latter stages. The client was pleased with the overall outcome and was extremely happy with Prism Ideas' support and has since commissioned support for two further programs. Prism provides excellence throughout all its clinical support services, providing placements who can be relied upon to deliver right from the start.