

Case study

Chronic Lymphocytic Leukaemia

Protocol Writing, Study Set-up, Monitoring, CRF Design, Data Management, Statistics, Study Closeout

The project

Indication: Chronic Lymphocytic Leukaemia IMP study utilising a new drug combination therapy

No. of Sites: 12 **Study Locations:** UK **No. of Subjects/Patients:** 100

Our client

A large Swiss pharmaceutical company wanting to work closely but retain flexibility with their outsourcing provider: PRN acted effectively as an extension of their clinical department supporting the International Study Programme Manager and International Medical Lead from the outset.

The challenge

Originally an investigator led study which came under the wing of the oncology business unit, the sites had already been selected as part of the initial feasibility conducted by the lead site. Many of the sites were commercial study naïve and therefore set-up proved challenging.

The PRN approach

PRN's experience in managing KOLs ensured that input into the protocol and study design was performed in the minimum amount of time whilst also maintaining the expectations of the Chief Investigator.

Given a list of 12 sites that all had to be used, PRN needed to negotiate with each site a study budget that was agreeable to both the client and the site. PRN guided the UK-naïve client through the use of the mCTA and all the required steps of setting up a study in the UK.

PRN successfully maintained investigator interest and relationships given the client announcing a 6 month delay to the availability of the protocol.

PRN went on to recruit the initial 50 subjects into the study ahead of schedule leading the client to increase the number of subjects to 100. The increased rate of recruitment has continued to grow and the study is expected to complete recruitment 3 months ahead of schedule.

PRN recently experienced a client audit and no major findings were shown. PRN was praised "for the level of commitment and knowledge to the study shown by the Project Manager" and the "diligence and hard work" of the CRAs.

From the outset PRN formulate both project and risk contingency plans based on the current study and operational areas- and their previous experience. This provides our client managers with continually up to date information as well as key plans that can be initiated

Outcome

The study continues to remain ahead of schedule. Data from the study is due to be presented at an international conference shortly.