

Case study

Hip Fracture

Feasibility, Study Set-up, Monitoring, Data Management, Study Closeout

The project

Indication: Fracture IMP study utilising a new self injection device delivery system

No. of Sites: 6

Study Locations: European

No. of Subjects/Patients: 120

Our client

A local affiliate of a larger US Pharmaceutical company - wanting to work closely with the outsourcing provider but retain flexibility. PRN acted effectively as an extension of their clinical department supporting the study programme managers from the outset.

The challenge

Set-up of several KOLs amongst 10 sites in a short period of time, whilst managing a diverse group of highly enthused investigators. Having achieved site set-up the sponsor had an unexpected 5 month delay in the supply of the injector device.

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 integrity of the study.

With a short lead in time, PRN negotiated a competitive set-up approach with all sites where first sites with local institutional contracts signed off were enrolled into the study. This proved a highly effective manoeuvre and provided a group of motivated sites with the right patient population, time and resource to perform the study accordingly.

Given the competitive set-up, PRN then went on to successfully maintain investigator interest and positive relationships despite the client announcing a 5 month delay to the injector device.

PRN managed all ethics submissions for both the product and device as well as the implementation of local institutional contracts utilising our local resource in each country. In addition, working with local affiliates PRN recommended and developed IMP shipment procedures, removing potential drug import delays.

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

Outcome

The study continues to remain ahead of schedule, despite the sponsor delays. In the interim PRN have highlighted and resolved a potential issue regarding utilisation of a non-regulated vitamin supplement dose required in the UK.

