Orthopedic expertise

As a sponsor, you are very aware of the unique challenges found in orthopedic trials. When barriers such as design & execution, sample size, and the need for patient-centered outcomes are overcome, evidence from trials can have a positive impact on surgical practice. That is why you need a fast, efficient, and focused approach for your device. At genae, we tap into our wide range of orthopedic and spine product experience to guide you through every step of your clinical journey.

Having conducted more than 25 local and global orthopedic studies of all sizes and during all phases, we know what is needed to achieve success -- from the earliest stage to a targeted and efficient design to regulatory approval and final delivery. Our full-service approach helps clients provide crucial data to make evidence-based clinical decisions.

Case study

genae led and managed a clinical investigation for a global orthopedic manufacturer that develops bone void fillers. With up to 230 subjects to be enrolled by 37 sites in four countries across the U.S. and Europe, we provided full services including monitoring, site & project management, safety reporting, DSMB and CEC adjudication, data management and EDC.

230	**4**	**37**
patients	countries in USA & EU	sites

What were the challenges?

Hindering the study were a few key issues which affected patient participation and created delays in moving the trial forward. Slow enrollment was the first. As a result, the sponsor was compelled to add more sites at a later stage. This meant CRAs were not only focused on monitoring/site management, but also on site start-up and initiation. Patient population was the second problem. Subjects often sustained injuries from vehicle accidents, resulting in additional injuries than just the broken bone which was the focus of this investigation. These additional injuries potentially made them illegible for the study which again affected enrollment. The final challenge related to the sheer size of the study which included sites in diverse and varied geographies: 19 sites in the U.S. and 18 sites in the EU.

What did we do?

To ensure adequate patient recruitment, genae recognized the importance of unifying and standardizing the study's approach and communications. With this in mind, we crafted detailed communications plans to maximize recruitment, retention and data quality throughout all sites. Setting up bi-weekly meetings between CPMs and CRAs allowed all teams to share progress, issues, and best practices across this large, global project. To tackle slow enrollment, genae proposed closer follow up on screenings, conducted roundtables, acknowledged high enrollers by a shout-out in newsletters, and much more.

How did we help?

Still ongoing, the study is expected to complete enrollment in 2020 and the study itself, one year later. We continue to deliver current recruitment and data management services according to planned timelines. To increase the efficiency of the study, we follow up on outstanding items, offer feedback based on our experience and propose strategy changes. Throughout the investigation, the manufacturer has repeatedly emphasized their trust in genae, stating 'that we do not simply execute the study, but are very much part of the project team'.