Accelerating Time to Market and Eliminating $5 Million in Development Costs through Adaptive Design

An Adaptive Design Case Study

The Challenge

An orthopaedics manufacturer developing a disc replacement device as an alternative to the widespread practice of fusion surgery in patients with degenerative disc disease was conducting a trial to test non-inferiority of its device. Promising initial data spurred plans to conduct another trial to prove superiority, a rare claim in the space. However, designing a new study and restarting engagement with new sites and patients proved costly for the manufacturer.

The Solution

ICON's Medical Device & Diagnostics Research group proposed a midstream change to the on-going non-inferiority trial to enable evaluation of superiority claims. ICON supported negotiations with the FDA to allow collection of superiority data in the study, as well as designed and executed an adaptive design that would provide a patient-sparing, efficient approach to address both claims in a single trial. The study utilised a composite endpoint of pain, neurological function, safety, and subsequent surgery.

The Outcome

The manufacturer successfully demonstrated the non-inferiority claim and the superiority claim in the trial. ICON's adaptive design trial reduced the manufacturer's clinical development expenses by more than $5 million and accelerated time-to-market with a stronger value proposition.

ICON's Value Add

ICON's team provided all of the statistical, regulatory, and operational expertise and technologies to design and execute a successful adaptive trial.

- Accelerated time-to-market with a superiority claim
- Saved $5 million by combining non-inferiority and superiority trials