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A Symbol of Excellence

Mitigating Development Risks through Adaptive Design

An Adaptive Design Case Study

The Challenge
A manufacturer developing an electrostimulation device for chronic pain was challenged with designing a trial that supported registration of the device as early as possible. An efficient trial design would be required to decrease time-to-submission, minimise delays and costs from enrolment of unnecessary subjects, and also mitigate risk of an underpowered trial.

The Solution
ICON's Medical Device & Diagnostics Research group designed and executed an adaptive trial with two prospectively planned interim analyses. Pre-set thresholds for the sham control response rate and observed treatment effect at the first and second interim analyses, respectively, allowed the manufacturer opportunities to right-size study enrolment for optimal statistical power or to terminate the study early on efficacy or futility grounds.

The Outcome
ICON advised the client to terminate the study early. This saved the manufacturer $1.9 million and five months of development time, which would be reinvested to accelerate the development of an improved device.

At the second interim analysis, after enroling only half of the total planned number of patients, ICON's proprietary adaptive design software, ADDPLAN®, identified a response rate much lower than the prospectively planned threshold. The manufacturer deemed the medical device ineffective and, with the financial resource and time saved due to early termination of the study, accelerated development of an improved treatment regime and delivery methodology that would be more efficient to prove in a future clinical study.

ICON's Value Add
The expertise of ICON's team in adaptive design protected the client's development capital by failing fast, which minimised patient exposure and allowed diversion of resources to engineer a better product.

– Saved $1.9 million and five months development time

– Early evidence of device futility, allowed early study termination, safeguarding the manufacturer's resources