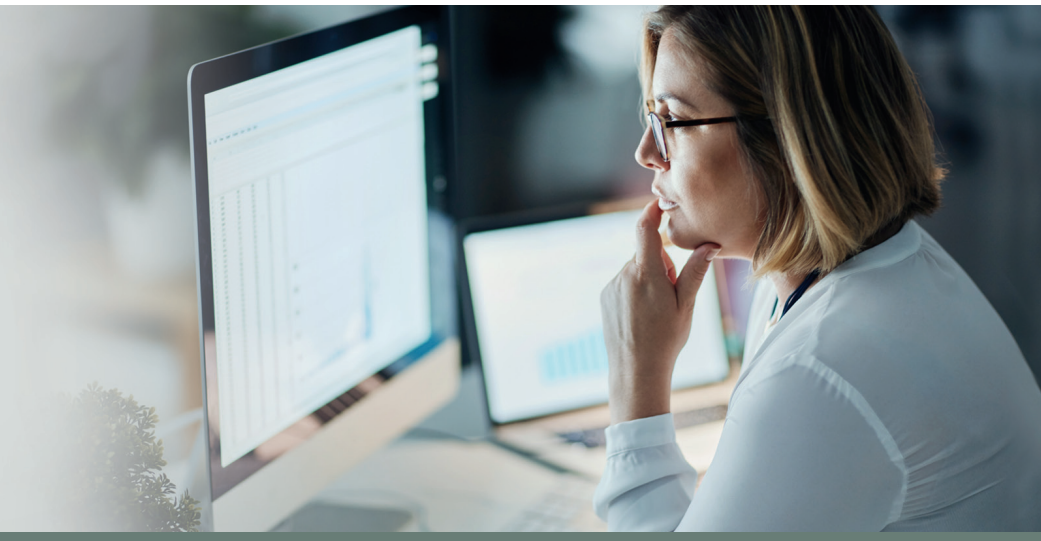
Scientific Input

Study Design

Consulting



Generic Study Protocol Design and Development

NEED

- The client successfully performed a bioequivalence study for European submission on a nonsteroidal androgen compound using a panel of 32 subjects
- Since the formulation demonstrated bioequivalence to the European reference product, the client indicated interest in conducting a similar study against the United States reference product for approval by the FDA

APPROACH

- Thorough review of data by protocol scientist, experienced with FDA regulations for the design and conduct of bioequivalence studies for submission to the U.S.
- Partnering with Celerion's statistician, the protocol scientist advised the client that based on the ratio and variability derived from the previous study, a panel of 20 subjects rather than 32 would be sufficient to conclude bioequivalence with adequate statistical power

BENEFITS

- Designed a study that was less expensive than originally planned—the client saved approximately 30% on each of the two studies required for FDA submission
- Optimized sampling schedule maximizes potential to characterize the formulation in-vivo performance
- Thorough statistical assessment can optimize chances of concluding bioequivalence whilst minimizing cost to the client by avoiding unnecessary trial execution costs

See Other Case Studies

Responding to an Unexpectedly High Drop Rate

High Throughput Bioanalytical Analysis

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