COMPLEXITY. SPECIALTY PROCEDURES. COLLABORATION.

A SKELETAL MUSCLE ATROPHY STUDY

A large biotechnology company approached Covance to perform a Phase I study determining if their drug would impact skeletal muscle atrophy. The trial would involve recruiting healthy volunteers, replicating atrophy with limb immobilization during an extended domicile period, administering drug treatment and measuring results. Muscle biopsies, strength tests and muscle metabolism studies would provide data for analysis, following study participants for 156 days. The trial also mandated collaboration with the sponsor's vendors for data collection and analysis of unique end points.

Understanding the Challenge

- Expertise for specialty procedures
- Recruitment for extended study
- Collaboration with partners

Expertise with Specialty Procedures Yields Results

The Covance Evansville, Indiana, CRU routinely takes on the challenges of specialty procedures – having extensive expertise in muscle biopsy studies. Using a robust database and social media advertising, the dedicated team recruited 34 healthy male volunteers for this extended study. To mimic muscle atrophy in a dominant lower extremity, we immobilized one of the participants' legs using a leg brace and asked them to walk with crutches for 28 days. Staying on-site at the clinic under medical supervision, volunteers received doses of the drug plus an anticoagulant to prevent blood clots.

The team collaborated with a nearby hospital to organize periodic MRIs of volunteers' legs. On-site at the CRU, specially trained experts collected muscle biopsies for comparison – both from subjects' immobilized legs and normal legs. The staff received specialized training for measuring muscle metabolism in subjects and also performed before-and-after strength testing.

We conducted the study in seven small groups to accommodate the complex procedures throughout the extended timeline, as volunteers resided in the clinic for 42 days, then had follow-up to day 156. The team was able to maintain the core group of volunteers throughout the eight-month study.

Performing specialty procedures on-site allowed us to maintain the rigor and control associated with a Phase I CRU for the duration of the study. This resulted in excellent subject adherence and clean data, which allowed the sponsor to clearly evaluate active and placebo treatments.

Along with collecting samples and providing trial database management, Covance collaborated with the sponsor's vendors for data collection and unique end point analysis. Clinical monitoring assured that procedural training was complete and data were accurate, as part of full-service trial management.

Covance Inc., headquartered in Princeton, NJ, USA, is the drug development business of Laboratory Corporation of America Holdings (LabCorp). COVANCE is a registered trademark and the marketing name for Covance Inc. and its subsidiaries around the world.

The Americas + 1.888.COVANCE (+1.888.268.2623) + 1.609.452.4440
Europe / Africa + 00.800.2682.2682 +44.1423.500888
Asia Pacific + 800.6568.3000 +65.6.5686588

© 2016 Covance Inc. CSCDS090-0117

COVANCE®
SOLUTIONS MADE REAL®