Osteoarthritis – Analgesic Clinical Trial Training for Subjects and Research Staff

Osteoarthritis Analgesic Studies are Difficult: Get it Right

Clinical trials of analgesics for osteoarthritis are challenging. Increase your success rate through subject and staff education developed at Lotus Clinical Research, an acknowledged leader in analgesic studies. Our training package addresses challenges inherent to osteoarthritis investigations. It includes subject education on placebo response and the proper performance of common osteoarthritis questionnaires. Research staff are trained to optimize study conduct utilizing an interactive system of didactics and vignettes that can be deployed over the web or live at an Investigator’s Meeting.

Nearly 40% of analgesic registration studies in the past 20 years have been negative.¹ Successful pain research utilizing the OA model requires more than an efficacious drug and good protocol design; it also depends on flawless execution—both from study staff and enrolled subjects. Lotus Clinical Research, an acknowledged leader in analgesic studies, routinely achieves standardized effect sizes more than 50–90% higher than other study sites.² This success is due in part to established programs for subject education and interactive training for clinical coordinators and study managers. We are now licensing these programs for study wide use so they can be implemented at all sites participating in a clinical investigation. Lotus CR’s education and training packages have been licensed to multiple sponsors for use during proof-of-concept and multi-center registration studies. Our osteoarthritis package is specifically designed to overcome the barriers to success in this complex analgesic model. It includes subject education and interactive training for coordinators and investigators to optimize the conduct of an OA investigation.

OA Training Tools
- Maximize accuracy and precision in osteoarthritis questionnaire responses
- Reduce placebo response by training staff to avoid positive bias
- Increase data uniformity within and across study sites

Patient Education:
Video training on using common osteoarthritis questionnaires effectively, avoiding placebo response, and the proper use of rescue medication.

Investigator/Staff Training:
Interactive onsite or video training on appropriate study conduct — avoiding bias in participant communication, helping patients use OA questionnaires correctly, minimizing placebo response and providing proper instruction to study subjects on the use of rescue medication.

This package provides Lotus CR’s expertise and years of experience in conducting industry-leading analgesic clinical trials. Using these materials will help clinical coordinators and research physicians minimize variability, reduce placebo response, and increase effect size. Get the most out of your clinical trials, and most importantly—make progress toward new therapeutics for osteoarthritis pain.

References:
2. Singla, N. Baum, D. Chang, P. “Decreasing the number of clinical centers involved in an analgesic trial may increase effect size and reduce the probability of a false negative.” Lotus Clinical Research, LLC 2011 American Pain Society Meeting, May 16, 2012