

CASE STUDY | SEVERE INFLAMMATORY ACNE

Successful management and on-time completion of a key clinical study

Business Challenge

A midsize pharma company approached Advanced Clinical to manage a 24-site Phase IV study evaluating a topical gel in combination with a tetracycline antibiotic in severe inflammatory acne. This sponsor had mixed experiences with CROs in the past and was counting on Advanced Clinical to successfully manage the study for a submission to a national Managed Care Formulary Board.

Goals

Advanced Clinical was contracted to perform the study with a five month enrollment period and total study duration of 14 months. The scope of work included all study start-up, investigator selection, grants and contracts administration, vendor management including coordination of an Investigator's Meeting, project management, clinical monitoring and site management, medical management, safety, data management, biostatistics, and medical writing.

Approach

Advanced Clinical deployed a highly effective project team to effectively manage the project. Through proactive planning, proper site selection, effective patient advertising, and a prospective plan for remote study data review, the study completed on time and under budget.

Recognizing enrollment solutions are not one-size-fits-all, the project team worked closely with investigators and site staff to fully understand the challenges for each site. The team developed a mixture of localized solutions to maximize enrollment (e.g., advertising using social media, local print ads, flyers, or radio spots) depending on that sites unique needs.

Results

- Achieved EDC build under compressed milestones
- Successful on-time enrollment
- All project milestones achieved on-schedule with Last Patient In date achieved ahead of schedule
- Visit trip report metrics exceeded targets for both average time to draft and average time to final report
- eTMF workflows within target
- Study completed under budget



SPONSOR FEEDBACK:

“Advanced Clinical takes ownership and responsibility for the project, and that’s something Sponsors don’t always see. **Advanced Clinical is like a breath of fresh air...** other CROs work in silos and don’t communicate, which means the Sponsor has to coordinate the different functions – we don’t see that at Advanced Clinical”.



Advanced Clinical, LLC
10 Parkway North, Suite 350
Deerfield, IL 60015

847-267-1176
www.advancedclinical.com