



CLINICAL RESEARCH OPTIMIZED™
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Trial Planning Saves ALBP Trial Some Pain

Leveraging experience to predict problems before
they affect clinical trial deliverables



The Challenge:

Not every study presents a completely new and unique set of challenges. That's not to say that the trial is generic, or not complex, but rather that Biorasi's past work covers a large breadth and depth of experience. That experience allows us to see a lot of potential trial-stopping issues before they happen, and account for them in our planning. When we were asked to complete a trial on an acute lower back pain medication, we needed to identify potential pitfalls early in the planning process to make sure they wouldn't lead to surprises later.

The Solution:

The common barriers to acute pain trials are exclusions for non-pharmacological alternative treatments, onset time-frames, and follow-up compliance. These fairly common clinical trial issues had fairly common solutions. Rather than wait for these issues to present and then adjust the protocol to overcome them, Biorasi began the trial with these issues in mind. An increased stipend and an upper-limit ODI score helped alleviate the use of alternatives. A shorter screening period and extended onset period overcame any potential onset exclusion. Extended, flexible follow-up visits helped keep compliance within limits. Finally, a multi-venue approach with sites across three countries kept enrollment moving along smoothly and quickly.

The Result:

Not every trial needs results that jump out from the page. For this trial, Biorasi delivered exactly what was presented in the trial plan, on time and on budget, and with a minimum of fuss. For busy sponsors, that's often the best result possible: everything they wanted, with absolutely no unpleasant surprises.

786.888.1820 | www.Biorasi.com

19495 Biscayne Blvd., Suite #900 · Aventura, Florida 33180