biorasi™

CLINICAL RESEARCH OPTIMIZED™

Biorasi's TALOS™ Platform and Unique Sites Win Unusual ANDA Trial

Flexibility and Strong Process-driven Planning Overcomes Regulatory Speedbumps

The Background:

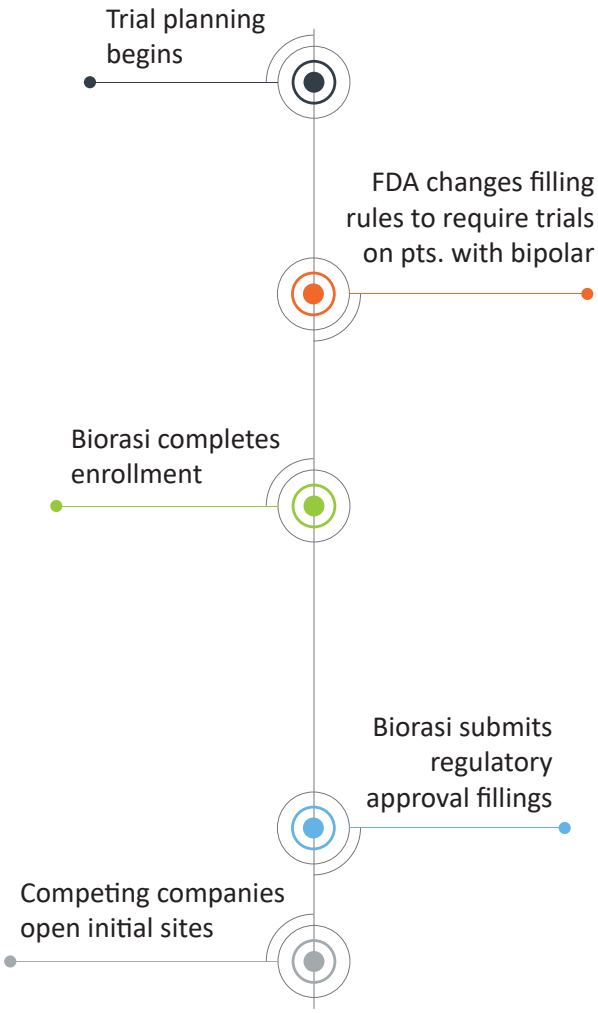
ANDA approval for therapies going off-patent are typically a staid affair. Timelines are established years in advance, procedures are standardized and well-tested, sites and patients are largely uniform and set up well in advance, and being first-to-file typically means that you submit your paperwork just a few minutes or hours before the next company. But what if several weeks into the process, the FDA changes the rules? What happens to a well-oiled but rarely thought-of machine when a regulatory wrench is thrown into the cogs?

The Challenge:

Biorasi was contacted by a large international pharmaceutical company when the FDA suddenly changed rules regarding what initially seemed like a standard ANDA procedure. Instead of testing the medication in healthy volunteers, the new rules required testing using patients with bipolar disorder, a drastic departure from normal protocol. Companies were scrambling to alter their trial methodologies while still winning the critical first-to-file race.

The Solution:

While other CROs may struggle to change protocols mid-stream, Biorasi has a major advantage: the TALOS™ platform and process. Since we customize solutions for every sponsor anyway, our method for planning trials is flexible and easily altered or reshaped to fit the needs of every particular trial. This made shifting gears mid-stream no problem. The changeover was bolstered by our unique access to specialized sites and networks, which allowed us to open sites, recruit patients, and complete the trial using the new guidelines long before competitors were even able to open a single site.



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