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CLINICAL RESEARCH OPTIMIZED™
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STUDY HEALTH CHECKUP

OVERALL STUDY RESULTS

Health Assessment of Your Clinical Study: **High Risk**

Taking into consideration the enrollment projections of your clinical study, Biorasi predicts that your clinical trial will complete at least 25 weeks past the planned completion date. Your study is likely to complete near 5/23/2018, assuming that no other issues arise in achieving later milestones, such as database lock, study results, and CSR delivery.

With additional months tacked onto your timeline, we expect your study will run approximately 30% over-budget.

RECOMMENDED COURSE OF ACTION

Your study is 'unhealthy' and would likely benefit from an intervention.

Studies can be rescued in a variety of ways, ranging from in-house intervention, the hiring of a supplementary CRO, to full CRO replacement.

We highly encourage you to seek a full study assessment, allowing us to look deeper into the root causes of your specific study's underperformance. By providing us with a deeper insight into your clinical trial, Biorasi will be able to recommend the best course of action for you with regards to time, budget, and, of course, quality.

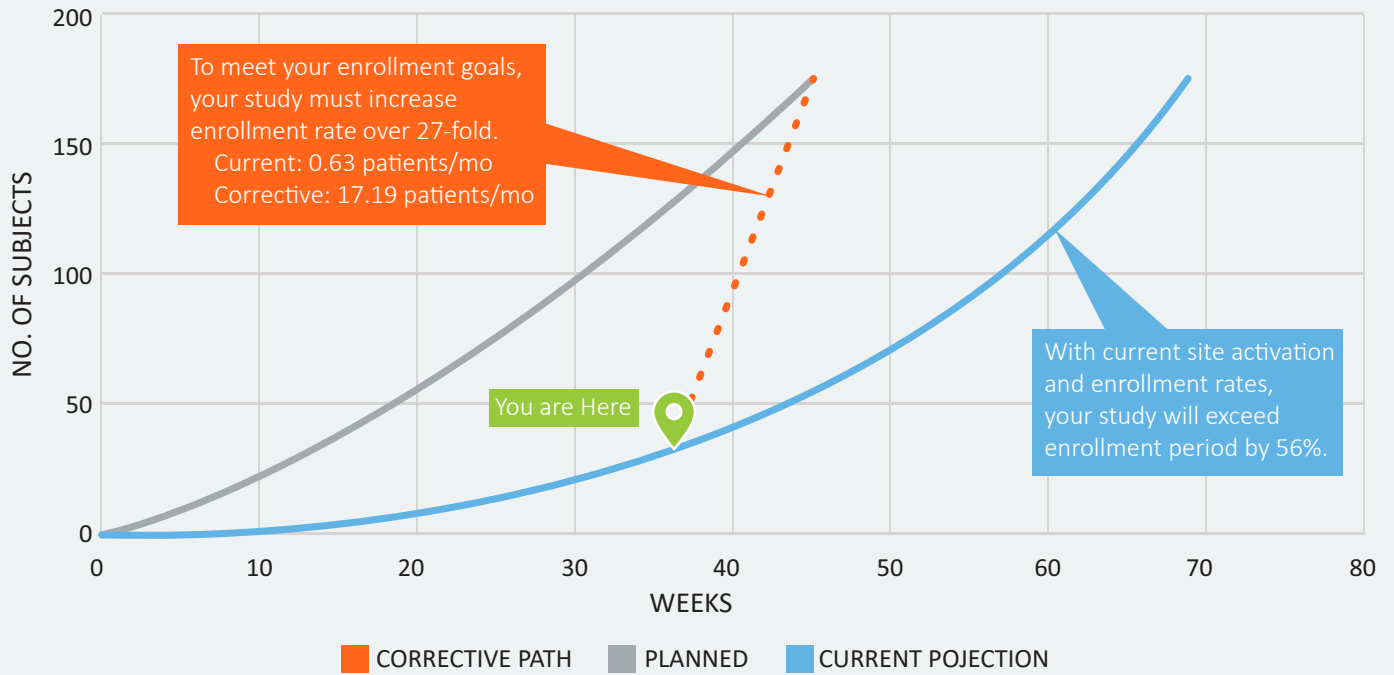
AREAS OF CONCERN



YOUR CLINICAL TRIAL HEALTH STATUS: *HIGH RISK*



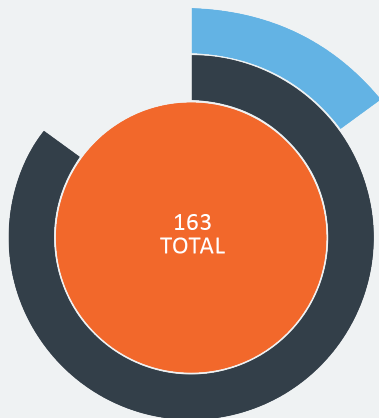
PATIENT ENROLLMENT



ENROLLMENT

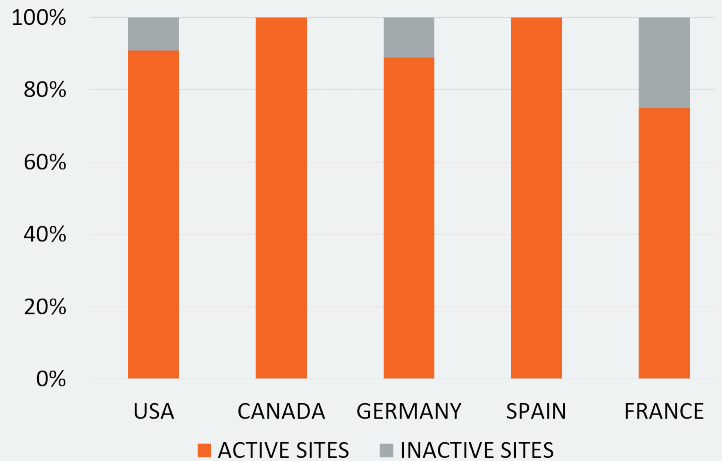
23
ACTUAL
TO DATE

127
TARGETED
TO DATE



To complete enrollment of **163** subjects over the planned 45 week enrollment period, your study should now have **127** subjects enrolled. Your study is currently operating at **15%** of its planned enrollment rate.

SITE ACTIVATION



Despite site activation being almost complete, enrollment lags behind targets. causes can include enrollment issues at individual sites, or regulatory or logistics issues. A high number of protocol amendments seems to have brought enrollment to a halt.

ADDITIONAL COMMENTS AND OBSERVATIONS

- Several vendors are not contracted or are active, yet unsatisfactory
- SDV O/S has not been completed
- High number of protocol amendments is causing significant delays in study execution.