

The Question Was a Real Puzzle – and the Answer Changed Everything

Things were complicated enough to start. The customer, conducting a Phase II/III dose-finding/pivotal study for an adult growth hormone drug, changed its protocol midstream in response to regulatory feedback and was rethinking other aspects of the trial, adding to its complexity.

For weeks, the sponsor's requirements changed almost daily, severely testing an incumbent lab vendor that was already struggling to provide real-time data to support 21 titration paths. That's when Premier Research stepped in and made a critical discovery that changed everything.

Something just wasn't right

When we took over the calculation of the standardized score, it quickly became evident something was not right. The whole point of the titration exercise was to determine how increasing or decreasing the drug dosage would affect patients, but the numbers didn't make sense. According to the calculations, patients would never need any dose adjustments, regardless of abnormally high or low laboratory results. This could have seriously compromised patient safety.

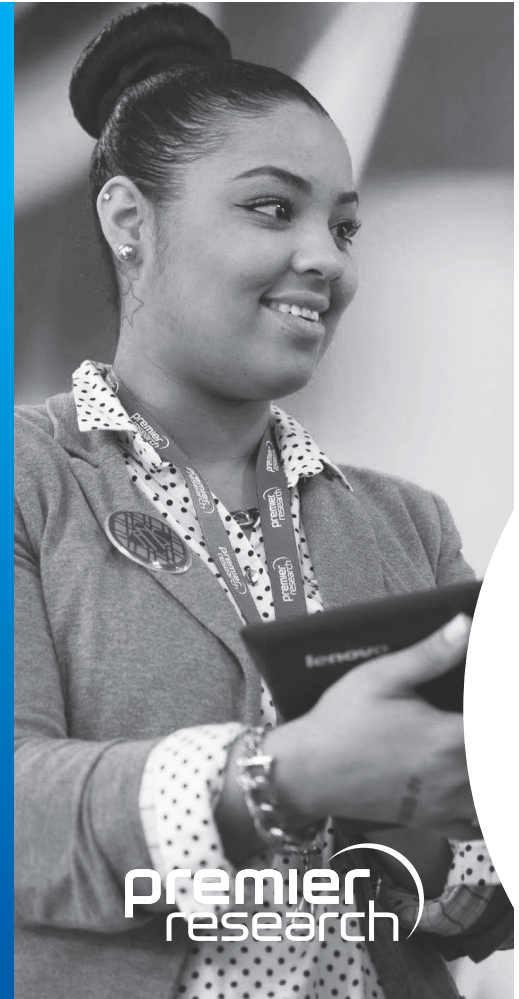
We took the finding to the sponsor, who confirmed that our methods were correct. In the meantime, our Interactive Response Technology and Biostatistics groups took a closer look and arrived at a plausible, if unlikely, explanation: what if a key formula being used in the calculations — taken from a published paper — was incorrect? These teams dissected the formula, published in 2014, and found the error.

The discovery put the study back on track. Absent this revelation, this trial and others would have been compromised hopelessly.

A culture of collaboration

Science is based on data, and data on accepted truths. But when something just doesn't look right, it's time to challenge those truths. Premier Research thrives on a culture of collaboration — both with clients and among our internal functions — to identify problems and find solutions that can elude those working in isolation.

BIOMETRICS



A Puzzling Problem Finds an Unlikely Answer, and a Study is Back on Track

Study Description:

Phase II/III dose-finding/pivotal study for an adult growth hormone drug.

Therapeutic Area:

Endocrine/Metabolic.

Geographic Scope:

Global.

Patient Population:

160 subjects.

Service:

Interactive Response Technology (IRT) and Biostatistics.

Duration of Study:

About nine months.

Outcome:

Discovering the key formula error put the study back on track. Absent this revelation, this trial and others would have been compromised.



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