

In Clinical Trials, Success Isn't Always Where You Expect It

When does a clinical trial that falls short of its goal still constitute success?

When the experience reveals invaluable lessons in how to avoid a repeat performance — and identifies a highly productive location for siting future studies.

A large, multinational study of a drug to control inflammation in patients with recurring high-grade malignant glioma was in trouble. It had been underway for a year, and its data collection was compromised from the start when a requirement that all MRIs be read at a single facility proved unworkable.

Getting packages through customs

The CRO had no way to electronically transmit these large files to the reader in Canada, making it necessary to send disks through snail mail, wrangling them through customs in countries such as Russia and India. Consequently, delivery was hit and miss — and when Premier Research took over the stalled study, it had a lot of backtracking to do.

It was a complex trial, too: Engaging about 150 patients and operating from more than 40 sites in Germany, Austria,

Russia, India, and Israel, it resembled a master class in logistics. Language was a major barrier, with the informed consent form alone requiring translation and back-translation in seven Indian languages.

Success — of a sort

So what happened? We righted the ship and ran the study for five years, but the results were baffling. Patients in India and Israel showed a survival rate of only about two years, while subjects in Germany, Austria, and Russia lived up to five years, despite there being no significant difference in treatment. With no clear endpoints, there were no definitive answers to questions about the drug's efficacy.

Still, we and our partners learned a lot about the need for discipline and following protocol. And our experience at six trial sites in Russia verified that country's importance as a host for drug studies. It's not perfect — for instance, we found few English speakers — but patients are easy to recruit. Thank a lack of government- or employer-sponsored health care that leaves patients to shoulder the high cost of treatments.

ONCOLOGY



Despite Inconclusive Results, a Wealth of Useful Insight

Study Description:

Phase II trial involving patients with recurring high-grade malignant glioma and anaplastic astrocytoma involving use of a TGF-beta 2 specific oligonucleotide immunotherapy.

Therapeutic Area:

Oncology.

Indication:

Recurring high-grade malignant glioma.

Geographic Scope:

40-plus sites in Austria, Germany, India, Israel, and Russia.

Patient Population:

150.

Enrollment Period:

12 months.

Outcome:

Results were inconclusive after five years of study, with widely disparate survival rates that could not be explained. The study did yield important lessons, however; including identifying Russia as a highly desirable site for clinical trials.



IT'S WHAT WE DO. BEST.™