

# The Russian Connection: Recruiting Hard-to-Find Patients from a Specific HLA Subgroup

*At first glance, it seemed no more complex than any other global, randomized Phase III study. The devil turned up in the details.*

## **First challenge: overcome early patient screening failure rate of 70 percent**

At first, screening failure rates were discouraging at best – between 60 and 70 percent. We responded quickly, by expanding the number of sites from 100 to 130, eliminating non-performing sites and encouraging the most successful sites with ongoing training and motivational programs.

Our relationships with key opinion leaders in Russia helped turn the tide. Despite 228 screening failures, the 20 sites we selected in Russia successfully enrolled an impressive 113 patients out of a total enrollment of 339. We completed enrollment within 19 months of startup, one month ahead of our 20-month target.

## **Next: managing a major change of direction with no major loss of time**

The study started with a single idea, but ended up including four different investigational medicinal products. It could have been a nightmare. Instead, it ended up as an opportunity to show Premier Research at its best, effectively dealing with the unexpected.

We instituted new protocols, renegotiated contracts with investigators, revamped CRA and site staff training and developed a whole new data collection and management plan. With surprisingly little disruption.

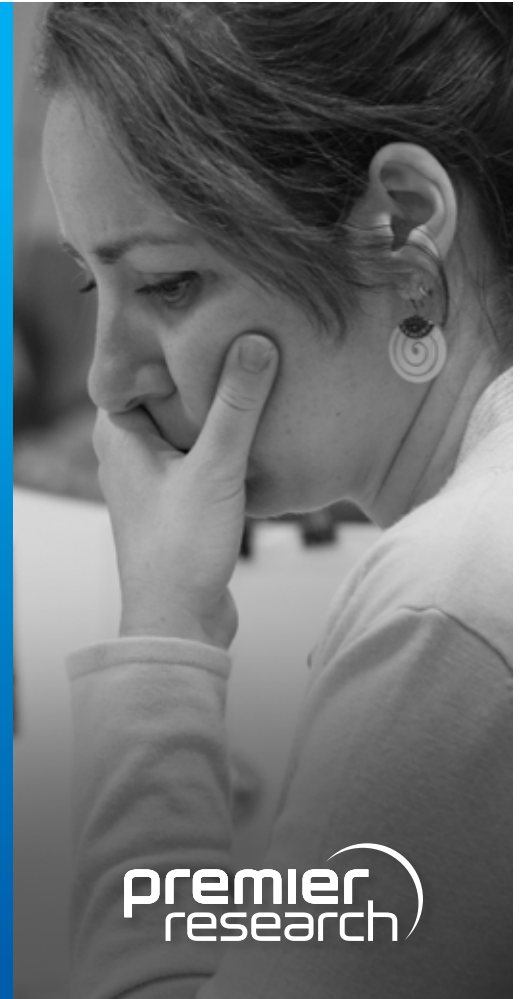
## **Lesson learned: never stop learning**

It's always been true: every trial is a learning experience. Every one is different, and every one presents new challenges. And we confirmed that Premier Research can field the kind of teams it takes to win out over almost any challenge, from experienced yet never doctrinaire Project Managers to CRAs expert at motivating as well as monitoring sites. Above all, we learned how important it is to be the kind of people sponsors want to work with, and come back to again and again.

# ONCOLOGY



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# The Kind of People Sponsors Want to Work With

## Study Description:

A multicenter, multi-national,  
Phase III randomized study

## Therapeutic Area:

Oncology

## Indication:

Renal cell carcinoma

## Services Provided:

Full service, 2010-2015

## Geographic Scope:

Ten countries planned, 11 actually included:  
France, Germany, Hungary, Italy, Netherlands,  
Norway, Poland, Romania, Russia,  
United Kingdom, U.S.

## Patient Population:

339 patients receiving first-line therapy  
for renal cell carcinoma and belonging  
to a specific HLA subgroup

## Enrollment Period:

20 months; completed in 19

## Treatment Period:

Five months/19 months follow-up

## Outcome:

All obstacles overcome to sponsor's  
satisfaction. Study still ongoing at this writing.



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