

Case Study: Outperforming in an Onco-Hematology Clinical Trial



Investigational Product: Kinase Inhibitor

Therapeutic Area: Oncology

Indication: Multiple Myeloma (Relapsed, Refractory)

Study Phase: III

Sponsor: Biotechnology Company (Public, Market Cap \$250M+)

Study design: A Randomized Controlled Phase III Study of the Study Drug and Best Available Therapy

Total number of patients under Accell management: 61 patients in Russia

Sponsor's goals: Knowing that multiple myeloma is a challenging indication for patient recruitment, the Sponsor sought a solid strategy for recruitment and retention of patients to ensure that study timelines will be met.

Our Solution

Accell entered the stage when a number of countries has already been identified by the Sponsor. We advised to revise the country list and to look for underutilized countries with fewer competing studies, in addition to countries already identified. We felt that the motivation of the patients and investigators would be high absence of significant competition, and given the interesting and promising nature of the kinase inhibitor being developed.

Site Selection Strategy

After a robust feasibility process involving more than 10 Eastern European countries, we recommended including Russia in the trial. Importantly, Russian sites were compliant with European standards of care. We considered those that promised recruitment of a minimum 6 patient per year.

The site selection strategy focused on large hospitals with demonstrated industry-sponsored clinical study experience in onco-hematology and the ability to include patients from their reference network.



As a consequence of a carefully planned strategy and marked operational efficiency, **Russian sites under Accell's management demonstrated the best recruitment result out of 12 countries participating in the global clinical study.**

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Russia

Enrollment – 0,67 pts/site/month



Number of Sites – 9



Western Europe

Enrollment – 0,3 pts/site/month **



Average Number of Sites – 7 **



USA

Enrollment – 0,1 pts/site/month



Number of Sites – 4

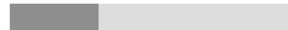


Australia & New Zealand

Enrollment – 0,46 pts/site/month*



Average Number of Sites – 6*



** Numbers show average enrollment rate and average number of sites per country in 8 European countries (Belgium, Czech Republic, France, Germany, Hungary, Italy, Netherlands, United Kingdom);

*Numbers show average enrollment rate and an average number of sites of both Australia and New Zealand.

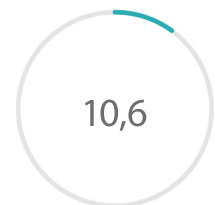
Quality of Data

Along with the high recruitment rate the Sponsor also marked a high quality of provided data: there were only 5,2 Data Management (DM) queries per patient's visit in Russia in comparison to 10,6 DM queries in the rest of the world (ROW).

Above all, Accell's sites commanded positive feedback about their quality of work, with 2 Sponsor audits completing without major findings.



Russia
5,2 DM Queries



ROW
10,6 DM Queries