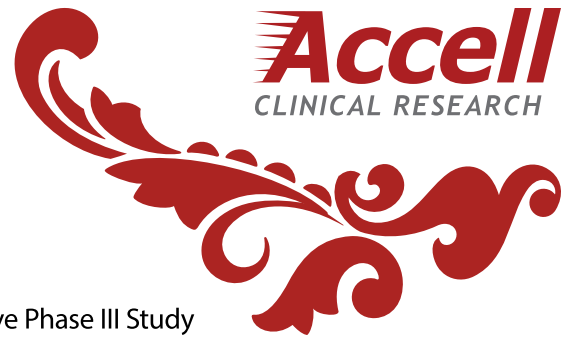


## Case Study



**Investigational Product:** Oncolytic Virus

**Therapeutic Area:** Oncology

**Indication:** Squamous Cell Carcinoma of the Head and Neck

**Study Phase:** III

**Sponsor:** Biotechnology public company; Canada

**Study design:** Randomized, Double-blind, Multicenter Two-Stage Adaptive Phase III Study

**Total number of patients:** 167

**Sponsor's goals:** Having chosen the first slate of countries (USA, Canada, UK, Belgium), the Sponsor was facing slow recruitment globally and expecting study delays; thus, it needed to accelerate dramatically patient enrollment in other regions to meet the marketing objectives.

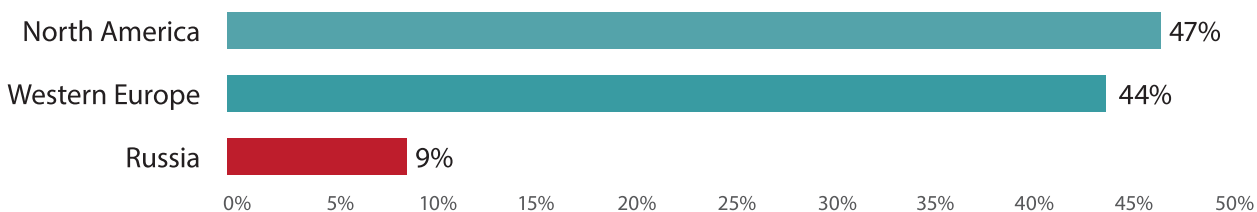
**Our solution:** After 16 months of slow recruitment, Sponsor addressed Accell Clinical Research to add an emergency country to rescue the study. In the past Russia has proven itself to be one of the top recruiting geographies in oncology. Having completed all formalities and regulatory requirements, **Accell had only 6 months for recruitment in Russia.**

## Case Study Metrics

### Total Patient Recruitment

	North America	Western Europe	Russia
Enrollment Period (months)	26	26	6
Active Sites	14	32	10
Patients Enrolled	32	99	36
Enrollment Rate (patients/site/month)	0.08	0.1	0.6

### Number of Queries (9 months)



Enrollment period in Russia was only 23% of the total enrollment period, and Russia had only 27% of sites globally; nevertheless, the **enrollment rate in Russia was 6 times higher** than in Europe and North America, and Accell recruited **21.6% of total patients in just 6 months.**

Accell Clinical Research facilitated greatly the successful and timely outcome of the Sponsor's phase III study and made it possible for the drug to reach the market within initially planned schedule. A relatively small number of queries and no critical findings in Accell's region clearly demonstrate a high quality of data received during the trial. Russia has proven itself once again to be a favorable region for fast, efficient, and cost-effective clinical trials conduct that resulted in eventual Sponsor's success.