Case Study

Investigational Product: Amino salicylate anti-inflammatory
Therapeutic Area: Gastroenterology
Indication: Ulcerative colitis
Study Phase: III
Sponsor: Pharmaceutical; medium-size; private; Germany.
Study design: Double-blind, double-dummy, randomized, multi-center, comparative Phase III clinical study.
Total number of patients: 306

Sponsor's goals: To expedite patient enrollment into the clinical trial to meet the marketing objectives.

Our solution: Eastern Europe and Russia have been proven to act as some of the top recruiting geographies in the past. We leveraged the centralized healthcare system and dense populations to tap into the patient pool and drive recruitment forward. We selected Russia, Ukraine, Latvia, and Lithuania.

Case Study Metrics

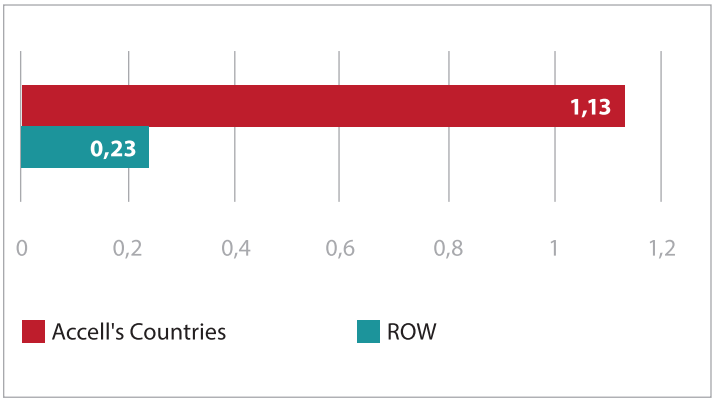
Patient Recruitment by Accell

	Russia	Ukraine	Latvia	Lithuania	Accell Total	Overall Study Total *
Enrollment Period (months)	10	5	14	14	**14**	**14**
Active Sites	13	6	4	4	**27**	**41**
Patients Enrolled	122	73	34	29	**258**	**306**
Enrollment Rate (patients/site/month)	0,94	2,43	0,61	0,52	Accell's average: **1,13**	Study Average: **0,74**

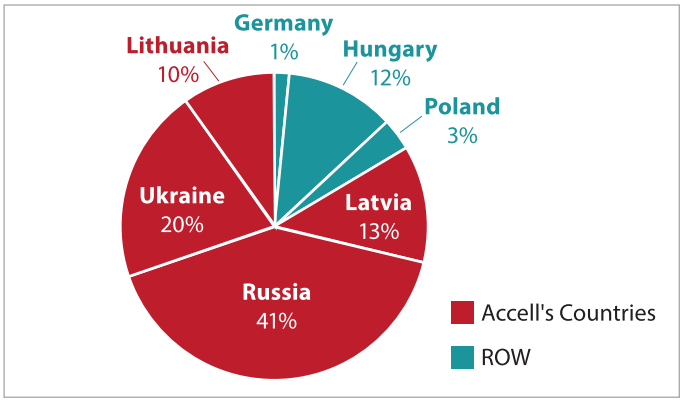
* Investigational sites in Germany, Hungary, and Poland also participated in this clinical study.

Ukrainian investigational sites achieved notable patient recruitment rates due to a large number of patients meeting the protocol-specific criteria, highly organized and well-planed work of the investigational teams at sites, and close support and management by Accell's clinical staff.

Average Number of Patients per Site per Month



% Patients Randomized per Country



Accell recruited 84% of total patients for this clinical trial, with only 65% of total number of study sites. Two Russian sites were sponsor audited, and one Lithuanian site was subject to a regulatory inspection, all without critical findings. **The Sponsor was able to end recruitment earlier than planned**, as the interim analysis goals were met. **Fast recruitment and the reduction of the number of active sites can ultimately lead to a reduction of direct and indirect costs of clinical research**, making Eastern Europe and Russia attractive regions for clinical study conduct.