

The Scout logo is positioned in the top left corner of the page. It features the word "Scout" in a white, sans-serif font against a dark blue background that includes a stylized illustration of a tent and trees.

CASE STUDY:

Crohn's Disease and Ulcerative Colitis

Exploring the effects of patient support services in gastroenterology studies.



BACKGROUND

Sponsor is conducting Phase III studies in Russia and Belarus to evaluate the effectiveness of their drug on the maintenance remission of patients with Crohn's and UC. The studies are 58 weeks in duration. Once patients are randomized to the studies, it will be key to ensure that they are able to complete all study visits over the duration of the trials.

CHALLENGES

The countries involved in the trials, as well as the remote locations of the patients in relation to site facilities, result in difficulty ensuring that patients will complete their study visits. Additionally, Russia, a key country in the trials, has extremely stringent data privacy laws which require constant review and, in some cases, updates to system requirements to maintain compliance.

SCOUT'S APPROACH

Upon review of the study design, country requirements and necessary logistics support, we suggested a scope of services to include:

1. Taxi transportation to and from patient homes as well as train and accommodation as needed based on patient distance from the site.
2. Due to the regulatory and financial requirements in Russia and Belarus, it was recommended that all potential out of pocket expenses be mitigated for visits rather than processing expense reimbursement.

SCOPE

Provide transportation and travel services and reduce financial burden for 800 patients participating in Phase III gastroenterology studies managed by overlapping sites in Russia and Belarus.

SPECIALIZED SOLUTIONS

Because Scout Clinical's online system is compliant with all data handling and processing requirements and data is stored locally in Russia, the sponsor, CRO, and sites participating in the trial are able to access the system and enter patient data with full confidence and evidence that the system meets all standards of privacy.

The sites in Russia and Belarus were activated in the Scout portal within two business days of receipt of site information and began requesting support for patient transportation within one week of launch of the system. Due to the number of visits and quick visit turnaround time for patients involved in the study, travel requests are made and fulfilled on a daily basis. Communication was maintained between the Scout Clinical team in-country to support local language interaction and time zones.

The Scout team quickly and competently provided individualized travel and regulatory support while maintaining compliance to stringent data privacy laws, thereby ensuring no patients dropped out of the studies due to financial or logistical barriers.