

CASE STUDY

Global Response

Large-Scale HIV Study Expands Access 50%; Lowers Costs

Study Description

Expanded-access program trial

Study Objectives

- > *To make the study drug available to patients who failed combination therapy with commercially available antiretroviral drugs*
- > *To obtain additional safety data and to make the study drug available to patients who had received it in a previous study*

Study Compound

Protease inhibitor

Patient Population

Patients infected with HIV

Treatment Period

Open-ended

Primary Efficacy Parameter

None

Study Specifics

- > *Active sites: 830*
- > *Patients randomized: 14,521*
- > *Recruitment period: 23 months*

Participating Countries

32 – United States, Canada, Argentina, Brazil, Columbia, Mexico, Peru, Puerto Rico, Uruguay, Austria, Belgium, Czech Republic, Finland, France, Germany, Greece, Hong Kong, Hungary, Israel, Italy, Malaysia, Poland, Portugal, Romania, Singapore, South Africa, Spain, Switzerland, Taiwan, Thailand, Netherlands, United Kingdom

Quintiles Services

Project Management, Regulatory, Drug Supply, Pharmacovigilance, Clinical Monitoring, Data Management, IVRS

Overview

Successful global trials require extensive logistics, resources, and coordination. Quintiles has the infrastructure and the experience to manage large-scale studies conducted at sites around the world, providing assistance and facilitation to ensure results.

Key Challenges

Knowing that this study would be of high interest to large numbers of activists and patient groups, the customer planned an early, expanded-access program. Because the only qualification for site inclusion was that a qualified clinician take responsibility for patients taking the drug, numerous sites, activist groups, and individual patients contacted a central call center to enroll in the program.

Broad Scale

The customer initiated the program in all 32 countries where a site expressed interest. Site motivation proved challenging because most monitoring was done via telephone and on-site monitoring was limited to the few countries that required it. In addition, site investigators were not paid and had to complete CRFs for patients to continue receiving the drug.

Due to its global reach and extensive experience, Quintiles successfully managed 830 sites in 32 countries and recruited 14,521 patients — nearly 50% more than originally anticipated. Quintiles' efficient project management resulted in a 10% reduction in cost from original budget estimates.

Specialized Variables

A monthly per-patient drug delivery schedule required significant effort in ordering, tracking, and logistics. The amount of available drug varied each week, necessitating creation of a waiting-list system. As additional data became available, dose modifications, changes in allowable concomitant medication, and changes in entry criteria resulted in 7 protocol amendments within 15 months.

How Were These Challenges Met?

- > An experienced Quintiles' global project team established multi-lingual call centers in Europe and the US. From these call centers, CRAs managed the sites and monitored their progress.
- > Local CRAs managed sites where local language capability was not possible or where on-site monitoring was required.
- > Regional pharmacovigilance centers in Europe, Latin America, Asia Pacific, and the U.S. managed SAE reporting.
- > A CRF in simple checklist format and Quintiles' FaxCollect system made it easy for sites to send data to regional data management centers.
- > Quintiles' clinical-trials-supplies units in Europe, Asia Pacific, and the U.S. used Quintiles' IVRS system to manage the complicated drug supply process.



Outcome

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Contact Us:

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