

Cardiovascular Expertise Results in Faster Enrollment Speed

Quintiles' staff cardiologists and clinical research scientists have more than a century of combined cardiovascular experience.



Mega-trials require mega-expertise, especially when the global study is for an innovative cardiovascular drug to treat patients with acute coronary syndrome who have also undergone coronary artery bypass surgery.

The major pharmaceutical company wanting to launch this program selected Quintiles, specifically because of our global reach and ability to get the study up and operating quickly. With Quintiles' outstanding track record involving more than 220,000 cardiovascular patients

worldwide, and over 400 CRAs with specialized cardiovascular experience, we were a clear choice.

The plan was to enroll 9,000 patients at nearly 450 investigative sites in 23 countries.

To be successful, this trial required superb communications among all the organizations involved: the steering committee, the data and safety monitoring board, the ECG core lab, the endpoint validation committee, and investigators. In total, over 1,000 people ►

For more information about Quintiles' clinical development services, please contact us at clinical.info@quintiles.com or visit quintiles.com/cardiovascular.



worked on this global study, including 200 clinical monitors.

With sites in the United States, Canada, Australia, New Zealand, Western Europe, and Israel, Quintiles had to set up a total of 11 investigator meetings in eight countries. By the end of the study, there were more than 600,000 case report form pages and 10,000 monitoring visits.

A remarkable achievement from the customer's perspective was the enrollment speed. While eighteen months had been allocated, Quintiles completed enrollment six months ahead of schedule. In fact, it was this escalation that enabled the customer to recognize – early enough to act – the need to enlarge the sample size. And we were able to respond: we enrolled an additional 3,000 patients within the original timeline of eighteen months.

More good news: the trial was completed efficiently, thanks, in part, to a powerful asset that is unique among CROs:



Quintiles' Clinical Event Validation and Adjudication Services (CEVA). This internal group managed the endpoint data collection and review process so efficiently that they were able to submit reports at accuracy and completion levels far beyond the norm. Only a tiny percentage of reports – just 1% to 2% — were sent back for additional documentation. And that attention to detail translated directly to faster enrollment.

After all, it's all about results.

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