Cmed's Mobile Data Management Solution

Case Study

Cmed
Clinical Services
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Introduction

The trial presented to Cmed was a randomized, double blinded, placebo and active controlled study to evaluate the cardiac safety of multiple doses of [study drug] in health volunteers.

The pharmaceutical company, who were into the second year of development of a potential blockbuster compound for the treatment of chronic myelogenous leukaemia (CML), were requested by the FDA to design a trial to provide information on the cardiac safety of different dose levels of the study drug in healthy adult volunteers. The primary objective of the study was specifically to find the maximum tolerated dose before QTc levels became unsafe. All development of the compound was put on hold until the results of this study were submitted to the FDA and approval granted for the compound to progress into full development.

The pharmaceutical company realized that although they had an in-house EDC solution, the technology and IT infrastructure would not allow them to set up, conduct and report the results of this study in the timeframe required to get the development of the compound back on track.

Cmed were invited to plan and implement a solution that would allow the pharmaceutical company to receive interpretable results of the clinical study on an ongoing basis every 48 hours. Database lock needed to occur immediately after the last data was available to facilitate the clinical study report completion within ten days after last patient last visit. Cmed received the protocol six weeks prior to the planned first patient first visit.

The Logistics of the Project

The study was placed in a specialized phase I unit in Arkansas, USA. The site had no previous EDC experience and very limited access to the internet.

A team of three site coordinators were identified by the site and allocated for the duration of the project. The study would involve up to three hundred and forty volunteers with up to forty volunteers concurrently participating in a study dose level at any one time. In addition to the clinical data being collected on site, electronic EKG tracings were sent to a central EKG site in the north east of America and laboratory samples were sent to a local laboratory outside of the phase I unit.

Implementation

Due to the unique architecture of Cmed's data collection and management technology (Timaeus), it was decided that the most appropriate and advantageous solution to meet the pharmaceutical company's needs would be to set up a completely remote office at the site in Arkansas. Cmed would then send a mobile data management team to process and manage all of the clinical data and thus, eradicate any exposure to site staff to any technology outside their skill set. Cmed worked closely with the client to produce a paper Case Report Form according to the existing CRF standards within one week of receiving the protocol to allow production and shipping of the CRFs to the site prior to FPFV.

Cmed identified a project manager to lead the group of data managers working on site. The selection of this individual was based on experience in both therapeutic area and familiarity and exposure of dealing with a high pressure project of this magnitude. The project manager was responsible for ensuring that all clinical data was collected and reported on time and that all third party vendors worked together, and acted as the main point of contact for the site and client. The project manager created and maintained a project completion plan which detailed exactly when specific tasks had to be completed so that the goals of the project would be met.

The Result

Cmed worked in conjunction with the site coordinators and clinical monitors to create a "conveyor belt" type work flow through the site. This allowed the CRFs to flow seamlessly from point of result entry, through source data verification and into the hands of the data management team to enter/quality control and clean within hours of the examination or test taking place.

The project manager received the external laboratory data on an ongoing basis every 24 hours and performed reconciliation with the CRF data at site to ensure accuracy. Any findings or discrepant data were resolved over the telephone, to ensure immediate turnaround of accurate data from the third party vendors were loaded into the clinical database.

The project manager worked in conjunction with the Cmed programming group to collate all of the datasets into the client specified format. Cmed delivered all clean clinical data back to the client according to the pre-planned target of every 48 hours which allowed the client to run safety outputs of the data and make safe clinical decisions on the data. Cmed successfully locked the clinical database, including all third party data and laboratory data two days after the last results were available to the data management team.

Conclusions

The pharmaceutical industry, in conjunction with global health authorities, has placed a greater emphasis on getting potentially lifesaving compounds to market faster. In order to be successful in these initiatives, protecting patient safety becomes even more critical and any concerns must be investigated immediately and before the development of the compound can proceed. In these cases, the classic EDC or paper based clinical data collection models may not always fit and alternatives are sought. Cmed are able to offer an alternative due to the unique architecture of their intelligent data acquisition and management solution and flexible win-win approach of the CRO.

Timaeus accurately provides pharmaceutical companies with true real time clinical results within a single database and facilitates rapid safety information to be gathered, ultimately providing the decisions that can get the clinical development of life saving medications back on schedule.

Cmed Clinical Services

About Cmed Clinical Services

Cmed Clinical Services is a long-established, flexible CRO with offices in the UK, US and Romania offering project management, clinical monitoring, data management, biostatistics, medical affairs, regulatory, consulting, and medical writing services. While Cmed's area of specialization is the design and delivery of both innovative and traditional phase I to IIb clinical trials, Cmed increasingly uses its experience and capabilities for existing clients phase III programs and for functional service provision of biometrics. Cmed Clinical Services is a privately held subsidiary of Cmed Group Ltd. To learn more, please visit **www.cmedresearch.com.**

Main Office:
Cmed (Clinical Research Services) Ltd
Holmwood, Broadlands Business Campus
Langhurstwood Road
Horsham RH12 4QP United Kingdom
Tel: +44(0)1403 755 050
Fax: +44(0)1403 755 051
Email: info@cmedresearch.com

United States:
Cmed Inc
430 Mountain Avenue, 4th Floor
Murray Hill, NJ 07974 United States
Tel: +1 908 795 2020
Fax: +1 908 665 9030
Email: info@cmedresearch.com

4620 Creekstone Drive
Suite 160
Durham, NC 27703 United States
Tel: +1 919 595 6900
Fax: +1 919 595 6901
Email: info@cmedresearch.com

Romania:
Cmed SRL
Str. Coriolan Brediceanu, Nr. 10
Timisoara, 300011 România
Tel: +40 356 43 39 02
Fax: +40 356 00 43 64
Email: info@cmedresearch.com