

Gaining Trust from Sponsors

Experienced people.
Innovative technology.

Cmed brings it all together to deliver your oncology studies.

An Oncology Program Case Study

Introduction

A biopharmaceutical company chose Cmed to conduct a phase II oncology study. Cmed's performance of the study and the good relationship which was established with the Sponsor led Cmed to be awarded a second oncology trial, which was then followed by a third, fourth and fifth. This program of work will run beyond 2018.

Approach

The deepening of the relationship shown by this consistent build-up of work depended upon the development of successful, collaborative, stable and mature relations typified by the following characteristics:

Competence

Support Sponsor goals for the study/ project

Each of these studies are producing data of both medical and commercial interest and so a continuous series of publications for meetings and congresses have followed. The timelines to generate the necessary data sets and resulting tables/ figures are unpredictable and short. Cmed have provided the data, tables and figures to meet the deadlines required to keep the Sponsor's flow of publications on track, thus supporting the Sponsor's study goals. All of these activities were not part of the original contract and the administrative element of contractual change has also been completed in a timely way to fulfil the needs of the project.

Quality of work

As an example, Cmed's attention to detail when reviewing one of the study protocols (developed by the Sponsor) led to some text changes to improve clarity in the protocol prior to study start. While this caused a short delay in study submissions, it ensured a faster "first review" approval by the Ethics Committees/ IRB and the Regulatory Authorities.

Consistency

Learn as study /project progresses

As an example of consistent support of the Sponsor's goals, a change was required to the filing structure and nature of the TMF (to an electronic DIA zone model TMF). These sorts of change are common for long term studies and Cmed used experience of similar changes on other studies to not only complete the change efficiently but also to assist in further training of Sponsor staff in their new process.

Reliability

As an example, when faced with the challenge of a change in Sponsor Project Manager during study start-up activities, Cmed ensured the correct support was available to the new Sponsor Project Manager: correct information flow, pro-activity and excellent communication, were key.

Cmed's experience in conducting clinical trials was crucial to guarantee a seamless change. Both parties can openly learn from success as well as address obstacles which are inevitably found along the way.

Contribute to project success

Flexibility

When the Sponsor piloted new procedures for risk-based, remote monitoring, Cmed contributed to the development of the process and particularly its execution in oncology studies. As with any new process, this required both Cmed and the Sponsor to approach the job with flexibility and an open mind.

Cmed successfully worked in close relationship with the Sponsor, supporting the new process not only with suggestions based on knowledge and experience, but also with the creation of presentations and study plans for the Sponsor's internal use. Furthermore, when faced with a request from the Sponsor to use Cmed's in-house eClinical technology, Timaeus, for accepting, managing and reporting SAEs electronically, Cmed's experienced Programmers developed an electronic SAE form exactly mimicking the Sponsor's paper one, ensuring not only an efficient collection of SAE data (for the site staff) but also the Sponsor's processes were implemented and followed correctly.

Pro-activity

As an example, the first multinational study involved oncology treatment coupled with surgery and thus required the involvement of both an oncology and a surgical team who, in certain countries such as the UK, were based in different hospitals. Communication and logistics were therefore essential between the medical and surgical teams so the very demanding patient selection criteria could be determined.

To drive enrolment Cmed conducted ad-hoc site meetings to promote full and timely communication between the investigator teams and to motivate the site. At some poorly recruiting sites Cmed acquired a deep understanding of hospital local practice and its influence on the study. This led to Cmed suggesting alternative solutions to enhance recruitment. As a result, sites which had not recruited patients managed to enroll their first patients.

Enrollment finished successfully and one of the Sponsor International Clinical Trial Manager's said:

"It has been a great pleasure working with you on the project! Thank you very much for all your achievements including finishing the recruitment and cleaning all the data on time for the analysis".

Conclusion

Since 2004, Cmed has conducted and managed oncology studies in greater than 1,400 investigator sites spread globally, ranging from Phase I through to global Phase III programs across many oncology indications.

Cmed's enthusiasm and determination to make a difference in oncology research coupled with staff experienced in this field and its flexible data capture and management software (Timaeus), Cmed is able to offer true advantages for its customers. These include an in-depth understanding of the potential operational challenges, tried and tested solutions, a database of high performing investigator sites and highly experienced project teams.

As another Sponsor International Clinical Trial Manager said:

"It would be really good if all the CROs would be as efficient as Cmed".

About Cmed

Cmed is technology-lead CRO, bringing together experienced people with technology, providing customers with a friendly, proactive service, and delivering this service using advanced clinical data capture, management and reporting software and processes. Cmed has a strong reputation for delivering complex, demanding and innovative clinical trials. Its main therapeutic strength is in oncology and rare diseases.



inspiring progress

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