



# Getting the Client's Trust - Oncology Program

Case Study



**Cmed**

Clinical Services

[www.cmedresearch.com](http://www.cmedresearch.com)

## Case Study: Getting the Client's Trust - Oncology Program

### Introduction

Five years ago, a biopharmaceutical company chose Cmed to conduct a phase II oncology study. Cmed's performance of the study and the good relationship established with the Client led Cmed to be awarded a second oncology trial which a couple of years ago was followed by a third, fourth and fifth.

### Approach

The deepening of the relationship shown by this consistent build-up of work depended on the development of a stable mature relationship typified by the following characteristics:

#### Quality of work:

As an example, Cmed's attention to detail when reviewing one of the study protocols (developed by the Client) 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 and the Regulatory Authorities.

#### Flexibility:

As an example, when the Client 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 Client to approach the job with flexibility and an open mind.

Cmed successfully worked in close relationship with the Client, 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 client's internal use.

Additionally, an early challenge faced by Cmed was a request from the Client 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 Client's paper one, ensuring not only an efficient collection of SAE data (for the site staff) but also the Client's processes were implemented and followed correctly.

#### Pro-activity:

As an example, the first 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 and motivational visits to promote full and timely communication between the investigator teams. At some poorly recruiting sites Cmed acquired a deep understanding of hospital local practice and its influence on the study. This led to suggested alternative solutions to enhance recruitment. As a result, sites which had not recruited patients managed to enroll their first patients.

Enrolment finished successfully and the client 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".*

## Reliability:

As an example, when faced with the challenge of a change in Client Project Manager during study start-up activities, Cmed ensured the correct support was available to the new Client 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.

## Conclusion

Over the last ten years, Cmed has conducted and managed oncology studies all over the world ranging from Phase I through to global Phase III programs across many oncology indications.

Due to Cmed's experienced CRO staff and flexible data capture and management software (Timaeus), Cmed is able to offer service solutions which suit the ever changing requirements of oncology clinical development.

As the client said: *"It would be really good if all the CROs would be as efficient as Cmed"*.





## 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](http://www.cmedresearch.com).

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