VERISTAT

A Look At A European
Site Monitoring
Rescue Case Study

KEEPING UP WITH AN OVER-PERFORMING SITE

How to Stay on Top of Data Verification & Review

Background

A small, clinical stage biopharmaceutical firm approached Veristat in May of 2015 to rescue the site management and monitoring activities for a single site in Italy. The sponsor was seven months into patient enrollment at the site when Veristat took over and twenty patients had been enrolled thus far.

This study was challenging due to the high volume of recruitment for a single site to handle, numerous protocol amendments (currently on Protocol Version #8) and the continuous evolution of the project parameters and processes. Veristat's project team remained flexible and adaptable to the changing needs of the sponsor and used their expertise to train and support the site team, who was managing an overwhelming volume of data in a short time.

Study Demographics

INDICATION:

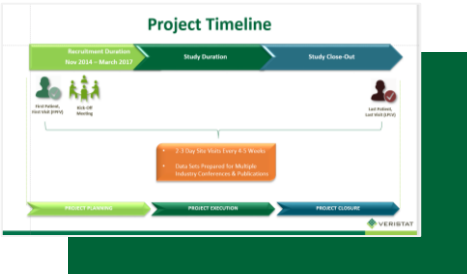
Hematologic Malignancies and Genetic Blood Disorders in Children

STUDY PHASE:

Phase I/II Rescue Study

PRIMARY SERVICES PROVIDED:

Site Monitoring Services



1 Site in Italy

 # > 100 Pediatric Patients

Orphan Drug Designation Granted by FDA and EMA

GOAL

The goal of the study evolved over time and the sponsor requested numerous clean and verified datasets for review throughout the study to support the publication of data and presentations at global industry conferences. Even the main recruitment targets changed over the course of the study, where the final goal was to enroll 100 evaluable patients.

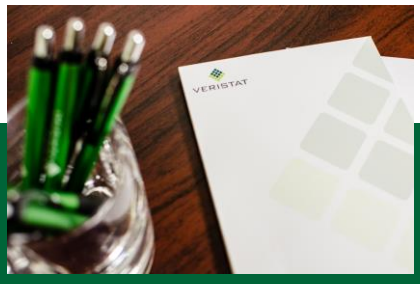
SOLUTION

Veristat provided the sponsor with a dedicated team of two local CRAs, who conducted 2-3 day monitoring visits every 4-5 weeks to ensure there was no backlog in data entry or verification at the site. At each site visit the CRAs ensured that the site was trained every time there was a protocol amendment and that the sites were closely adhering to the protocol. They also worked collaboratively with the site's team to make sure that they followed all of the regulatory requirements for the study.

The frequent and consistent monitoring allowed Veristat to provide the sponsor with all the data required for their data reviews within the sponsors scheduled timelines.

RESULT

Veristat achieved the goal of enrolling 110 patients and expects that to lead to the total of 100 evaluable patients within the next month. As a result of our frequent and thorough monitoring plan, the sponsor has received all of the data required to allow them to present their milestone results at their targeted industry conferences. The project is still ongoing, but as of now, the sponsor is more than thrilled with the progress provided by Veristat this far.



Contact Veristat Today

To learn more about Veristat and how we can help you achieve success with your trial or development program and regulatory submission, reach out to us today.

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