



VERISTAT

A Teamwork Case Study



MONITORING SUCCESS WITH TEAMWORK

Site Monitoring Succession in Europe.

Background

A European-based clinical stage firm with a focus in developing innovative immuno-oncology therapies engaged Veristat to provide succession monitoring because their contract CRA retired. While the study's first two cohorts were being run in 2 countries, Veristat took over the site management and monitoring activities for the final cohort which included 3 sites in the United Kingdom.

The project team for the study was very small and included many functions provided by a multitude of different vendors. For example, the Project Management is being conducted by another CRO and they provided oversight of the Veristat CRA. Because all the team members are working very closely together in collaboration, the project has so far met the client's milestones and is expected to be completed in mid-2018.

Study Demographics

INDICATION:

Pancreatic Cancer Vaccine/Immuno-therapy

STUDY PHASE:

I/II

PRIMARY SERVICES PROVIDED:

Site Monitoring



3 UK Sites



13 Patients



Project Team consisted of
2 CROs, 2 Central Labs, IP
Supply and CRF Vendor

GOAL

The sponsor required that 3 key milestones be reached over the course of 2016 and 2017. The study timeline of milestones included:



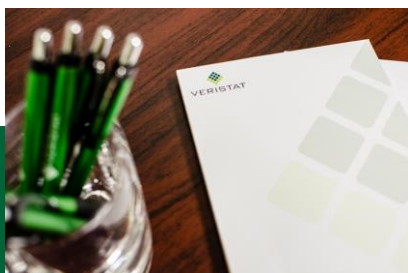
SOLUTION

Veristat joined the study team in January 2016, taking over for a CRA who started monitoring the UK sites, but retired. To achieve the timelines, the Veristat CRA met with site teams on a weekly basis to ensure that recruitment, patient identification and screening activity was on track. This continued until the recruitment of the needed 13 patients was complete.

In addition, the Veristat CRA worked meticulously with site teams to ensure the timely entry of data so that data verification and database lock for each of the planned interim analyses were performed on time.

RESULT

Veristat completed the enrollment of 13 patients across the 3 UK sites on time. All data for the UK sites was entered and verified prior to the March 2016 and March 2017 interim analyses. Veristat continues its interim monitoring visits for the sites and will continue until the sites close which is projected for the middle of 2018.



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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