VERISTAT

Exceptional Hematology Clinical Trial Experience

Millions of people are affected by blood disorders each year.[1] Treatments continue to advance in the hematology field with 1,900 clinical trials currently recruiting patients.[2] Whether the disease is genetic or acquired, whether it has invaded the blood cells, platelets, bone marrow, vascular endothelium, or plasma proteins, Veristat is equipped to help bring your hematology therapies to market.

Veristat has guided clients through the conduct of more than 100 clinical trials and nearly 20 regulatory agency submissions for blood diseases. Our experience spans clinical development consulting, full clinical trial oversight, and regulatory submission preparation for rare genetic blood disorders and autoimmune blood diseases, as well as blood cancers.

10% of the work we do is hematology

>100 hematology trials

>15 regulatory submissions prepared

Veristat Experience in Malignant Blood Disorders	
✓ Blastic Plasmacytoid Dendritic Cell Neoplasm	✓ Multiple Myeloma
✓ Chronic Lymphocytic	✓ Myeloid Leukemia (Acute & Chronic)
✓ Cutaneous T-Cell Lymphoma	✓ Myelofibrosis
✓ Diffuse Large B-Cell Lymphoma	✓ Myelodysplastic Syndromes
✓ Follicular Lymphoma	✓ Peripheral T-Cell Lymphoma
✓ Hodgkin's Lymphoma	✓ Non-Hodgkin's Lymphoma
✓ Mantle Cell Lymphoma	✓ Waldenstrom's Macroglobulinemia

Veristat Experience in Non-Malignant Blood Disorders	
✓ Aplastic Anemia	✓ Polycythemia
✓ Diabetes (Blood Glucose Meter)	✓ Sickle Cell Disease
✓ Cold Agglutinin Disease (CAD)	✓ Thalassemia
✓ Hemophilia	

FDA Approval – The True Proof Of Success

Veristat supports the first targeted therapy for adult patients with Relapsed/ Refractory Acute Myeloid Leukemia and an IDH1 mutation

"I have personally had the privilege to work with a dedicated Agios team on the IND application, phase I study, and NDA submission for ivosidenib. I am thrilled to see TIBSOVO® receive FDA approval and look forward to seeing this therapy help improve the lives of patients with R/R AML."

Barbara Balser, VMD, Veristat Executive VP & Chief Scientific Officer

[1] https://www.nhlbi.nih.gov/science/blood-disorders-and-blood-safety

[2] https://clinicaltrials.gov/ct2/results?cond=Blood+Disorder&Search=Apply&recrs=a&age_v=&gndr=&type=&rslt=

CASE STUDY

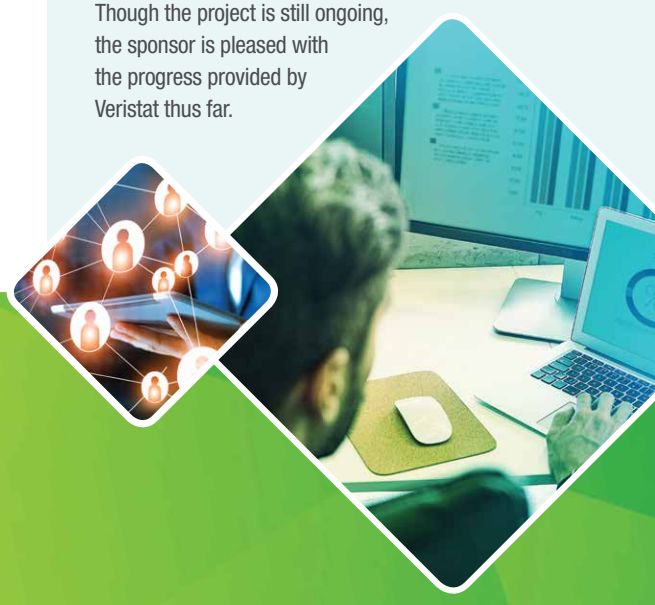
Keeping Up with an Over-Performing Site

Staying on top of data verification and review for hematologic malignancies and genetic blood disorders in children

Situation: A clinical stage biopharmaceutical firm approached Veristat to rescue the site management and monitoring activities for a single site. The sponsor was seven months into patient enrollment when Veristat took over and twenty patients had been enrolled thus far. This study was challenging due to high volume of recruitment for a single site to handle, numerous protocol amendments, and the continuous evolution of the project parameters and processes.

Solution: Veristat provided the sponsor with a dedicated team who conducted regular monitoring visits to ensure there was no backlog in data entry or verification at the site. The frequent and consistent monitoring allowed Veristat to provide the sponsor with all the data required for their data reviews within the sponsor's scheduled timelines.

Impact: Veristat achieved the patient enrollment goal, and because of our monitoring plan, the sponsor has received all the data required to allow them to present their milestone results at industry conferences. Though the project is still ongoing, the sponsor is pleased with the progress provided by Veristat thus far.



Contact Veristat Today

To learn more about Veristat or how we can assist you with your hematology clinical trials, reach out to us today.

www.veristat.com

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