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VERISTAT

Accelerate Your Oncology Breakthroughs with Veristat

Navigating oncology clinical trials presents significant challenges for investigators, sites, and patients. From complex study designs and evolving regulations to time-sensitive treatment protocols, success requires expertise and precision. At Veristat, we specialize in overcoming these obstacles with knowledge in the biology of cancer, experience researching novel and innovative therapies, and an understanding of the patient experience. Our science-first approach supports drug development across the clinical trial continuum to accelerate the success of your therapy.

In the past 5 years, Veristat's experienced teams have helped sponsors with:

480+ oncology and hematology studies

90+ studies for rare cancers

30+ US and European regulatory marketing applications

Key Elements of Successful Oncology Trials

Robust Trial Designs

Developing well-structured protocols that may include adaptive approaches and patient-centric hybrid models.

Right-Sized Data Collection

Collecting the necessary patient information at a pre-specified cadence to minimize patient burden while ensuring trial integrity.

Well-Defined Statistical Methods

Including defining endpoints, establishing an appropriate sample size, and ensuring sufficient data will be collected to answer the study objectives.

Transformative Initiatives

Implementing clinical development programs under new regulatory initiatives, including programs such as Project FrontRunner, which encourages the evaluation of new therapies in first- or second-line settings for advanced or metastatic diseases.

Efficient Clinical Operations

Facilitating efficient sample collection, genomic testing, and data interpretation for biomarker-driven trials for seamless execution.

Regulatory Expertise

Developing tailored strategies and navigating global regulatory pathways to expedite development and approval.

Oncology Success Stories

1 Successful IND Submission Enables Phase I Clinical Trial for Cancer Therapy

A small biotechnology company partnered with Veristat to navigate the regulatory landscape for its novel cancer therapy platform. Facing budget overruns and delays, Veristat provided strategic consulting, project management, medical affairs, and regulatory publishing support. Our team guided the sponsor through a pre-IND meeting with the FDA, securing feedback that streamlined their approach. Despite late-stage CMC challenges, Veristat seamlessly integrated new data, ensuring an on-time IND submission. The FDA approved the IND with no clinical hold, allowing the sponsor to launch a global Phase I clinical trial, now currently being managed by Veristat's operations team. **Learn more ›**

2 Successful Full-Service, Randomized Pancreatic Cancer Phase II Trial: Unanimous Safety Review Committee Decision to Advance to Phase III

A clinical-stage biopharmaceutical company partnered with Veristat for a multi-center, randomized Phase II study evaluating a modified synthetic peptide in metastatic exocrine pancreatic cancer. Facing slow recruitment, data management challenges, and complex site processes, Veristat deployed targeted solutions, including enhanced site engagement, optimized data cleaning, and streamlined document management. Following a unanimous Safety Review Committee decision, the sponsor closed Phase II early, having met the primary endpoint with no safety concerns. Veristat now continues full-service support in the Phase III study, paving the way for a future NDA submission. **Learn more ›**

3 Regulatory Approval Secured for Ultra-Rare Hematologic Malignancy Treatment

A small biotech engaged Veristat early to support a novel biologic being tested for the treatment of an ultra-rare and aggressive hematologic malignancy with no effective therapies available. Due to the rarity of the condition, the biologic had to be tested in a single-arm study. Breakthrough therapy designation was secured by presenting a well-structured strategy to regulatory authorities. Our expert support in strategic consulting, biostatistics, programming, and medical writing enabled a smooth marketing application process, leading to FDA and EMA approval. **Learn more ›**

Accelerate your Novel Oncology Therapies to Approval and Commercial Success

Reduce your development costs, strengthen your submission data, and accelerate your path to regulatory approval with Veristat. Our expertise spans radiopharmaceuticals, vaccines, cell and gene therapies, immunotherapies and traditional cancer treatments. Visit veristat.com/contact-us to talk to our experts or Request a Proposal at veristat.com/rfp.

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