VERISTAT

New Tumor Evaluation Modality

Using intratumor RECIST (itRECIST) criteria to measure effectiveness of cancer therapeutics

Background

Veristat was brought on to write a sponsor's protocol for a novel treatment that injects engineered exosomes into solid tumors. The application of a set of nuanced response criteria required information collected from injected lesions and non-injected lesions to determine a tumor's response to the treatment.

Study Demographics

Indication:
Advanced metastatic recurrent injectable solid tumors

What Kind of Trial:
Immunotherapy with intratumoral delivery

Primary Services Provided:
- Strategic consulting
- Protocol development
- Statistical analysis plan development
- Project management

SOLUTION

A new way to record and analyze response criteria for intratumoral immunotherapies

When testing a new treatment of solid tumors and evaluating the tumor response under the Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1), a subset of tumors is identified as "target tumors" and remaining tumors are documented as "non-target" tumors.

When testing new intratumoral (IT) immunotherapy, target tumors must be further categorized into those "injected" and "non-injected." To track the tumor response and overall disease progression, investigators can monitor the change in injected tumor size from one treatment administration to the next, as well as changes from baseline in non-injected tumors (target and non-target). This nuanced approach supports a new response criteria developed for IT immunotherapy, itRECIST.

Veristat as itRECIST development partner

itRECIST criteria were used in this scenario to measure changes in tumor size; but as this is a new method for tracking a novel treatment, protocols had to be developed. In the new field of targeted exosome therapeutics, developing a protocol for how to apply intratumoral response criteria was not straightforward. The developer sought out Veritstat to ensure the tumor response data were captured appropriately and to describe the methodology to effectively apply itRECIST.

The challenge came when applying a newer type of criteria and defining appropriate methodology for collection and data analysis in a protocol prior to the start of data collection. The Veristat team were able to identify how the itRECIST could be applied in an accessible way for investigators to measure, record, and understand in conjunction with the treatment schedule for the novel therapy. Through this exercise, a series of endpoints were identified in collaboration with the sponsor to understand the relative impact of the IT treatment in injected lesions as well as residual impact on non-injected lesions. Once strategic development of the protocol and authoring of the statistical analysis plan were complete, Veristat worked collaboratively across vendors to review data tables, listings, figures, etc.

Veristat collaborated with the sponsor's clinical operations personnel, including their CMO and heads of departments, so that the trial is executed properly and summarized appropriately.

IMPACT

Veristat provided support for three studies in the client's program including guidance, strategic review of documents, and development of statistical analysis plans studies.

At present, test subjects are being enrolled and dosed, and data collection and programming are underway to track and measure results.

ABOUT VERISTAT

Specialized oncology CRO

Veristat has assembled a scientific team of experts who are adept at strategy and execution across the clinical development journey. Whatever the study's unique considerations – patients, products, process, follow-up, regulatory – Veristat can help you successfully get through it.

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