VERISTAT

Guidelines for Response Criteria for Use in Oncology Trials

RECIST 1.1 vs. iRECIST vs. itRECIST

RECIST (Response Evaluation Criteria in Solid Tumors) guidelines were introduced in 2000 to provide a standard for evaluating tumor response, with the goal of maintaining consistency at sites and across sites as well as limiting any site bias. Version 1.1 was released in 2008.

Standardized Guidelines

The guidelines provide Baseline instructions for data collection/reporting. At Baseline, tumors and lesions will be categorized into measurable (target) and non-measurable (non-target). The target lesions must be accurately measured in at least one dimension (longest diameter in the plane of measurement to be recorded).

Assessing tumor growth and cancer cell proliferation in patients is important for judging the effectiveness of individual treatment and for the evaluation of therapies in clinical trials. RECIST 1.1 provides a simple and pragmatic methodology to evaluate the activity and efficacy of new cancer therapeutics in solid tumors.

New Guidelines for Novel Cancer Treatments

The approval of intratumoral (IT) immunotherapy, the direct inoculation of immune-stimulating agents into the tumor itself, for metastatic melanoma and the active development of numerous novel IT drugs has created a need for standardized evaluation of response to this unique treatment strategy.

RECIST 1.1 and iRECIST were designed only to assess response to systemic therapy so are not suitable for assessing responses separately for injected and non-injected tumors.

IT immunotherapy RECIST (itRECIST) is proposed for use to capture data and assess local and systemic responses in a standardized fashion for clinical trials involving IT immunotherapies.

itRECIST response criteria is new and for now relatively unvalidated or untested. itRECIST does not dictate which lesions to inject, but provides guidelines for collecting data and assessing response as treatment evolves.

RECIST 1.1

Uses validated and consistent criteria to assess changes in tumor burden and is effective for targeted treatment as well as classical chemotherapy; helps determine whether tumor measurement data can support the conclusion that a patient's disease has improved, stayed about the same, or worsened.

iRECIST

A variation that standardizes data management and collection for testing and validating RECIST for trials of immunotherapy.

IT immunotherapy RECIST (itRECIST)

Proposed for use to capture data and assess local and systemic responses in a standardized fashion for clinical trials involving IT immunotherapies.

Advancing a Novel Therapy Through Clinical Development Is Complicated

Some therapies fail to make it to patients in need not because they did not work, but because the design, data collection and/or analysis were not done right. To give you an advantage, Veristat has assembled an extraordinary team of scientific-minded biostatisticians, programmers, data managers and data standards experts. We apply the power of industry-leading technology platforms and expertise in adaptive designs to help you understand your data and make critical clinical development decisions.

Contact Veristat

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