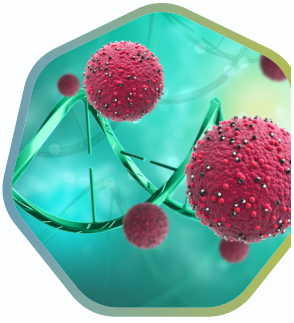
cliantha research

Expertise in Oncology Clinical Trials: Ensuring Precision with RECIST 1.1 Compliance.

Introduced in 2000, RECIST (Response Evaluation Criteria in Solid Tumors) guidelines were established to standardize tumor response assessment, aiming to ensure consistency within and across sites while minimizing any site-related bias. A subsequent version, RECIST 1.1, was unveiled in 2008, refining these standards for enhanced precision and applicability.



Standardized Guidelines

The guidelines offer clear directives for data collection and reporting at the baseline stage. Tumors and lesions are categorized into measurable (target) and non-measurable (non-target). Target lesions require accurate measurement in at least one dimension, with the longest diameter in the measurement plane to be recorded as per protocol.

Evaluating tumor growth and cancer cell proliferation in patients is important for assessing 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 emerging 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.

Leveraging our expertise, we enhance “Tumor Response Assessment” in imaging trials through RECIST 1.1 integration, ensuring heightened precision, consistency, and reliability.

Certain treatments may not reach patients in need not due to ineffectiveness, but rather due to shortcomings in study design, data collection, or analysis. Cliantha offers a competitive edge by bringing together a highly skilled team of scientific biostatisticians, programmers and data managers. Leveraging latest technology platforms and proficiency in adaptive designs, we empower you to comprehensively analyze your data and make informed decisions crucial for advancing clinical development.

RECIST 1.1 offers several benefits to data managers in oncology clinical trials:

Standardization: RECIST 1.1 standardizes tumor response assessment, ensuring consistent data interpretation across trials and sites, simplifying management, and facilitating study comparisons.

Efficiency: Clear guidelines, streamline tumor measurement and response evaluation, reducing data management time and effort for managers.

Accuracy: RECIST 1.1 guidelines enhance data managers' accuracy in interpreting imaging data and categorizing tumor responses, ensuring reliable trial results.

Regulatory Compliance: Adhering to guidelines aids data managers in ensuring regulatory compliance, simplifying the approval process for new treatments by meeting requirements set by regulatory agencies.

Improved Communication: The guidelines fosters clear communication among data managers, clinicians, researchers, and regulators, streamlining collaboration and decision-making in trials.

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