

New criteria for measuring tumor size and progression will help ease workloads in clinical trials

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The first, formal revision of specific guidelines, known as RECIST, used by clinicians to measure tumour size and response to treatment, has been published today (Tuesday 20 January) in a special issue of the *European Journal of Cancer*. The authors say that the revisions will ease the workload involved in running clinical trials, without compromising study outcomes.

RECIST (Response Evaluation Criteria in Solid Tumours) were first published in 2000 and are used by investigators in phase II and phase III clinical trials of new anti-cancer drugs as a way of measuring the efficacy of the treatment. Tumour shrinkage (objective response) and time to the development of disease progression are both important endpoints in trials, and, increasingly in recent years, trials have been using time to progression (or progression-free survival) as their main endpoint on which to base conclusions about the efficacy of a drug.

The new RECIST (RECIST 1.1 to distinguish them from the original RECIST) answer some of the questions and issues that have arisen since 2000 as a result of changing methodologies and available treatments.

Professor Jaap Verweij (Erasmus University Medical Centre, The Netherlands), the EJC's clinical oncology editor and a co-editor of the special issue on RECIST, said: "This special issue is very important for the cancer community as the updated criteria will affect all clinicians

who are running clinical cancer trials. RECIST 1.1 describes a standard approach to solid tumour measurement and definitions for objective assessment of change in tumour size for use in adult clinical trials."

Co-editor, Professor Elizabeth Eisenhauer (National Cancer Institute of Cancer, Ontario, Canada), stressed that the goal of developing RECIST 1.1 was to improve the consistency and standardisation of trials. "Drug development and clinical cancer research is a global enterprise. The more consistent we are in describing what we have seen, and in using the same measures and endpoints, the more reliably we are able to interpret the results from a variety of sources," she said.

Key changes in RECIST 1.1 that will simplify, optimise and standardise the assessment of tumour burden in clinical trials are as follows:

- A reduction in the number of lesions to be assessed for response from a maximum of ten to five, and from five to a maximum of two per organ;
- New guidance on making robust measurements of lymph node involvement;
- Confirmation of response is required for trials with objective response as a primary endpoint, but is no longer required for randomised studies, since the control arm of these studies provides appropriate means for interpreting results of the experimental arm;
- The definition of disease progression has been refined so that it not only includes a 20% increase in the size of the lesion, but also a 5 mm absolute increase as well, so that changes of just a few mms in very small tumours, which may be within the range of measurement error, are not unnecessarily described as disease progression;
- Guidance on imaging, including its use in the detection of new lesions and the interpretation of FDG-PET scan assessment.

Prof Eisenhauer stressed that the recommendations are evidence-based:

"They are grounded in the literature and where such information didn't exist - as was the case in some areas - we set about generating the evidence to guide and support the changes. The EORTC Data Centre, under the leadership of Jan Bogaerts and Patrick Therasse (co-authors of RECIST 1.1), undertook to create a warehouse of data from clinical trials of solid tumours from both industry and cooperative groups. We were able to test the recommendations on these data to look at the impact of proposed changes and decide whether the evidence supported the change or not."

The database consisted of over 6500 patients with more than 18000 target lesions, and was used to investigate the impact of a variety of questions, such as the number of lesions needing to be measured. "Our consequent recommendation that the number of lesions measured should be reduced from ten to five will have a big implication for the workload in clinical trials and we found that it will have no impact on described study outcomes," said Prof Eisenhauer. "This change can be made without any loss of information."

Professors Verweij, Eisenhauer and Therasse (who is also co-editor of the special issue and now based at GlaxoSmithKline Biologicals, Rixensart, Belgium) say that in the future it would be desirable to incorporate the use of modern functional imaging techniques in assessing benefit to treatment. "Although there are many exciting developments in this field, none of these techniques was considered as ready to substitute for anatomical endpoint assessment in clinical trials yet, since their use...awaits validation in large datasets and their availability in trial centres is limited," they write in their introduction to the special issue. A discussion paper in the issue describes the process and the level of evidence that would be needed before functional imaging could be used in addition to, or instead of, anatomical imaging in clinical trials.

Professor Alexander M.M. Eggermont, president of ECCO (the European CanCer Organisation), welcomed the publication of RECIST 1.1. "This is an important and timely publication for all clinicians working in cancer clinical trials. I'm particularly pleased that some of the amendments will contribute to lessening the workload on trial investigators. This revision of the RECIST guidelines will enable researchers to work smarter and more effectively so that, ultimately, patients will benefit from improved treatments reaching them sooner."

Paper: European Journal of Cancer, Vol 45, issue 2 (January 2009), pages 225-310. "Response assessment in solid tumours (RECIST): Version 1.1 and supporting papers."

Source: ECCO-the European CanCer Organisation

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