

REporting recommendations for tumour MARKer prognostic studies (REMARK).

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Despite years of research and hundreds of reports on tumour markers in oncology, the number of markers that have emerged as clinically useful is pitifully small. Often initially reported studies of a marker show great promise, but subsequent studies on the same or related markers yield inconsistent conclusions or stand in direct contradiction to the promising results. It is imperative that we attempt to understand the reasons that multiple studies of the same marker lead to differing conclusions. A variety of methodologic problems have been cited to explain these discrepancies. Unfortunately, many tumour marker studies have not been reported in a rigorous fashion, and published articles often lack sufficient information to allow adequate assessment of the quality of the study or the generalisability of study results. The development of guidelines for the reporting of tumour marker studies was a major recommendation of the National Cancer Institute-European Organisation for Research and Treatment of Cancer (NCI-EORTC) First International Meeting on Cancer Diagnostics in 2000. As for the successful CONSORT initiative for randomised trials and for the STARD statement for diagnostic studies, we suggest guidelines to provide relevant information about the study design, pre-planned hypotheses, patient and specimen characteristics, assay methods, and statistical analysis methods. In addition, the guidelines suggest helpful presentations of data and important elements to include in discussions. The goal of these guidelines is to encourage transparent and complete reporting so that the relevant information will be available to others to help them to judge the usefulness of the data and understand the context in which the conclusions apply.