

[Download key passages/title pages as a PDF](#)

**Daniels M (1950)**. Scientific appraisal of new drugs in tuberculosis. *American Review of Tuberculosis* 61:751-756.

### Key passages

Some essential details are omitted from the report, possibly because of required brevity. This leads one to consider if it is possible, in planning a trial, in reporting the results, or in assessing the published reports of trials, to apply criteria which must be satisfied if the analysis is to be entirely acceptable. Any criteria one attempts to formulate must not ignore the many difficulties besetting scientific investigations involving human beings; Walker and Barnwell, from their Veterans Administration experience, have well described these limitations (*Ann. New York Acad. Sc.*, 1949, *52*, 742). A high standard must be set, however, not only in order to assess the validity of the results, but also because pioneering investigations of this type may in many ways serve as a model and lesson to future investigators. A basic principle one can set up is that, just as in a laboratory experiment report, it is at least as important to describe the techniques employed and the conditions in which the investigation was conducted, as to give the detailed statistical analysis of results. One must know, for instance, how cases are selected for the trial; if the trial is concerned with pulmonary tuberculosis, what type of disease makes patients qualify from among the many hundreds of patients available. If cases are allotted to a control group or to a treatment group, or to one of several treatment groups, what method of random selection is used? With what frequency are routine examinations made? Are all cases bacteriologically confirmed, and what are the criteria of a "negative" sputum test? The dosage and duration of treatment, the numbers given collapse therapy in each group, must be stated. The roentgenographic assessment must have been made by an independent panel and after equivalent periods of observation or treatment in each group. It is essential also that all cases be accounted for; a large percentage unexamined leaves too many open questions.