Research ethics and sponsors' accountability

Who would agree to take part in a clinical trial? Some patients do, trusting that their participation will "advance medical science" and thereby be of use to other patients.

This is only the case, however, if the trial was designed to show whether the study treatment constitutes an advance over current standard care. If the comparator was chosen wisely. If the endpoints are relevant. If the number of participants and trial duration are sufficient to demonstrate differences in effects between the groups, if any differences exist. If the adverse effects are recorded properly. If the results are published, even if they are unfavourable to the study treatment.

And so on.

Trial participants are risking their own health. In practice, what is the point of their commitment if protocol breaches render the results uninterpretable, if negative results are massaged by conducting an unplanned statistical analysis, or if the stopping rules in the protocol are weighted in favour of the treatment? This month's issue contains one example of such practices in the evaluation of *dinutuximab* (pp. 33-37).

Clinical trials are among the most important tools we have for comparing and learning more about treatments in order to optimise patient care. The sponsors of these trials, whatever their interests, are accountable to trial participants and should ensure that the risks they take are not in vain. It is simply unethical to enrol patients in trials that are not useful.

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