7.3: Steering committee

It is common in large trials, particularly multicentre trials, for a steering committee to be set up, to which the PI reports and from which the PI may seek guidance or authorization, with respect to aspects of the conduct of the trial. These will include any significant protocol amendments, which will also usually have to be approved by the ethics committees which approved the original protocol for the trial. There is no obligation on an investigator to set up such a committee (unless required by the funding agency), and, for smaller trials, a steering committee may be considered unnecessary. Such a committee should usually consist of senior investigators in the trial, together with appropriate independent experts.

The role of a trial steering committee is to provide overall supervision of the trial and ensure that it is being conducted in accordance with the principles of GCP and the relevant regulations. The trial steering committee should agree the trial protocol and any protocol amendments and provide advice to the investigators on all aspects of the trial. The steering committee often has responsibility for approving the analytic plan for a trial (see Chapter 21, Section 3)—see also the ICH guidelines on statistical principles for clinical trials (International Conference on Harmonisation, 1998). The committee will usually have some members who are independent of the investigators, and, in particular, the chairperson should be independent. Decisions about continuation or termination of the trial or substantial amendments to the protocol are usually the responsibility of the trial steering committee, advised by the DSMB (see Section 4).

The trial steering committee is distinct from a trial management group, which normally includes those individuals responsible for the day-to-day management of the trial such as the PI, statistician, trial manager, and data manager. The role of the management group is to monitor all aspects of the day-to-day conduct and progress of the trial to ensure that the protocol is adhered to and to take appropriate action to safeguard participants.