7.2: The trial sponsor

Whenever a field or clinical trial is conducted that involves human participants, it is necessary that an individual, or more commonly an institution, has legal responsibility for the trial, ensures that the trial is conducted properly, according to a defined protocol, and has overall responsibility for the management and financing of the study. This person, or institution, is known as the sponsor of the trial. While, in principle, the PI of a trial may act as the sponsor, for legal reasons most institutions prohibit members of their staff from taking on this role and insist that there is institutional sponsorship. In the case of the trial of a new pharmaceutical product, the sponsor is usually the company that is developing the product. With respect to trials of licensed products or trials that do not involve specific products (for example, hygiene interventions), the sponsor would generally be the agency that is funding the trial or the research institution or university of those conducting the trial. Many funding agencies are not prepared to act as the sponsor for the studies they fund, unless those conducting the study are directly employed by the agency, and, in such cases, the institution employing the PI will generally take on the role of sponsor. In such situations, the sponsor is not responsible for financing the trial directly but does have responsibility for arranging that the funds needed to conduct the trial to a high standard are available from the funding agency and for administering the grant. The sponsor also has legal liability for any harm that might arise during the conduct of the trial.

The sponsor must ensure that the trial meets all relevant standards and regulations and must ensure that arrangements are put in place for carrying out the trial, for monitoring that it is being conducted properly, for meeting all required ethical standards (see Chapter 7), and for reporting the results of the trial at the end of the study. The sponsor also has responsibility for ensuring the safety and well-being of participants in the trial and for ensuring that treatment and care are available, usually free of charge, for any trial participants who are harmed as a consequence of their involvement in the trial.

Usually, sponsors will delegate different elements of their responsibility to the trial’s PI, steering committee, or DSMB, but the sponsor remains ultimately accountable for all aspects of the governance of the trial, whether or not some...
components have been delegated.

For clinical trials of drugs and vaccines and, in some cases, also for other interventions, national regulatory authorities usually require that the sponsor has insurance or indemnity for any potential liabilities of the sponsoring institution and the investigators in the trial. Whether or not this is required, it is a good idea, as the cost of any legal action taken against the trial could be considerable. The regulations will also often require that the sponsor ensures that the trial conforms to GCP (see Chapter 17), for which guidelines have been also produced by ICH (International Conference on Harmonisation, 1996).

The PI of a trial is accountable directly to the sponsor. Furthermore, although any reports from a steering committee or DSMB are formally to the sponsor, the sponsor may delegate responsibility for receiving and acting upon such reports to the PI. Similarly, the sponsor has the formal responsibility for liaison with those who have an oversight responsibility for the trial, such as the funding agency and relevant ethics committees. Formally, therefore all communication between these bodies and, for example, the trial steering committee or the DSMB, and vice versa, should be through the sponsor.