7.1: Introduction to trial governance

Since the first edition of this book was published in 1991, there has been a very large increase in the number of field trials of health interventions being conducted in LMICs and, in parallel with this expansion, an increasing number of regulations and guidelines put in place to govern the conduct of clinical trials. Most of these regulations have been developed in the context of clinical trials in HICs, particularly with respect to the evaluation of new drugs and vaccines, but there is a strong expectation, and in many instances a requirement, that these regulations are followed, no matter where a trial is conducted.

A particularly important development occurred in 1990 when representatives of regulatory authorities and pharmaceutical companies in Europe, Japan, and USA agreed on scientific and technical aspects of drug registration. Guidelines were developed from their deliberations called ‘The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use’, commonly known by the initials ‘ICH’. Since then, ICH has evolved, in response to the increasingly global nature of pharmaceutical development, with the mission to achieve greater harmonization in the planning, conduct, and reporting of trials to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner (<http://www.ich.org>).

In this chapter, we highlight aspects of trial design and conduct that have evolved significantly in recent years, particularly with respect to the role of the sponsor, the functioning of steering committees and data safety and monitoring boards (DSMBs) and requirements for trial registration.