17.1: Introduction to field laboratory methods

Laboratory tests may provide the definitive basis for the measurement of outcome variables in field trials, either directly by demonstration of the presence of the pathogenic agent under study or indirectly by demonstration of a host reaction or of biochemical changes due to the pathogen. They may also provide evidence of the mechanism of action of the intervention, for example, directly by measuring the drug or metabolic by-products or indirectly by measuring an immune response to a vaccine. In addition, they may be used to detect or confirm the presence of adverse reactions and prior exposure to an agent or to antimicrobials.

Rigorous laboratory process is crucial to the generation of good-quality data and may be important to ensure the safety of trial participants. Laboratories participating in trials are expected to adopt the Good Clinical and Laboratory Practice (GCLP) guidelines, which govern the conduct of clinical trials globally (Stevens, 2003; World Health Organization, 2009). GCLP provides a framework covering the spectrum of laboratory studies, from planning to analysis and storage of specimens and archiving of data. The WHO publication documents a set of minimum requirements for laboratory involvement in clinical trials, including the use of standard operating procedures (SOPs), monitoring, quality control (QC), and external quality assurance (QA) arrangements (World Health Organization, 2009).

The organization and operation of a field laboratory for the support of a field trial are different from those of a routine medical laboratory and have become more demanding in recent years. Laboratory accreditation (see Section 6) may be necessary when laboratory data are required for the process of product licensure. In field trials, the emphasis is often on the collection and processing of large numbers of samples, on which only a few specific tests will be performed. Aliquots of samples are usually required, so that different aliquots can be used for different tests, for storage as backup specimens, and for shipment for further analysis. Storage of specimens with computerized records, including electronic monitoring and bar coding, has been introduced, even in field laboratories in rural settings.

General aspects of the setting up and running of a field laboratory are discussed in this chapter. Other literature should
be consulted for information on specific laboratory tests and specific laboratory methods. Useful general texts containing relevant information for the operation of a field laboratory and for collecting specimens include Cheesbrough (1987), World Health Organization (2003), and World Health Organization (2009). See also Chapter 16.