Item 4b. Settings and locations where the data were collected

Example—“The study took place at the antiretroviral therapy clinic of Queen Elizabeth Central Hospital in Blantyre, Malawi, from January 2006 to April 2007. Blantyre is the major com‑ mercial city of Malawi, with a population of 1000000 and an estimated HIV prevalence of 27% in adults in 2004.”

Explanation—

Along with the eligibility criteria for participants (see item 4a) and the description of the interventions (see item 5), information on the settings and locations is crucial to judge the applicability and generalisability of a trial. Were participants recruited from primary, secondary, or tertiary health care or from the community? Healthcare institutions vary greatly in their organisation, experience, and resources and the baseline risk for the condition under investigation. Other aspects of the setting (including the social, economic, and cultural environment and the climate) may also affect a study’s external validity. Authors should report the number and type of settings and describe the care providers involved. They should report the locations in which the study was carried out, including the country, city if applicable, and immediate environment (for example, community, office practice, hospital clinic, or inpatient unit). In particular, it should be clear whether the trial was carried out in one or several centres (“multicentre trials”). This description should provide enough information so that readers can judge whether the results of the trial could be relevant to their own setting. The environment in which the trial is conducted may differ considerably from the setting in which the trial’s results are later used to guide practice and policy. Authors should also report any other information about the settings and locations that could have influenced the observed results, such as problems with transportation that might have affected patient participation or delays in administering interventions.