



Figure 8.1 Flow chart showing milestones in a typical pharmacology clinical trial. The chart contains a run-in period, and includes the numbers of subjects enrolled in the ITT group, in the modified ITT group, and in the per protocol group, and provides the different reasons for excluding certain subjects from these groups. The flow chart is a composite from publications of various clinical trials

a. Flow chart showing subjects included in the ITT analysis, modified ITT analysis, and PP analysis

Modified ITT analysis is clearly documented by flow charts appearing in many published accounts of clinical trials (Fig. 8.1). This type of flow chart is not a study schema. This kind of flow chart is totally different from the schema. Flow charts of the same type, which identify the number of subjects in the ITT group, modified ITT group, and per protocol group, can be found in reports for many other clinical trials, as