

Approach to maintaining comparability of biochemical data during long-term clinical trials.

Cull,CA; Manley,SE; Stratton,IM; Neil,HA; Ross,IS; Holman,RR; Turner,RC; Matthews,DR

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Our objective was to design a structured approach to maintaining comparability of biochemical data during a long clinical trial. Maintaining the comparability of clinical and biochemical data obtained in long-term studies is essential, even though analytical methods in the laboratory may be changed, conventions on specimen handling and storage revised, calibration procedures updated, quality-control systems replaced, and secular changes may occur. The United Kingdom Prospective Diabetes Study (UKPDS), a large randomized control trial investigating therapy for type 2 diabetes, was the setting for the study. Data were collected from 5102 subjects randomized since 1977. Our techniques included quality control, external quality assurance, direct comparison of laboratory methods when updating assays and statistical techniques for the detection of unsuspected changes in assay bias, laboratory comparisons of new with old assay methodologies, the realigning of data to current methods, the use of a suitable reference population for long-term monitoring, and rules to aid decision-making about clinical vs statistical significance. Procedures by which comparability of data is assured should be specified for all long-term trials and, where possible, comparison with reference methods should be detailed to allow results from different laboratories to be compared.