



Fact Sheet

Medical Review

Why Medical Review?

The Medical Review, an added value to automated data cleaning processes in clinical trials, is often neglected due to different reasons, e.g., financial constraints, lack of competent resources, tight timelines, and limited knowledge or experience of the involved persons. The consequence of underestimating its relevance is a lack of trial data quality resulting in questionable reliability and validity of study results and conclusions, which may additionally cause significant delays of the whole study. The implementation of preventive actions before the occurrence of foreseeable risks will mitigate the need of corrective actions during the conduct of the study. Therefore, the early and accurate preparation and subsequent conduct of the Medical Review in a clinical trial are playing a crucial role for the quality of study results.

What We Can Do for Our Customers

PPH plus ensures an effective and timely conduct of the Medical Review of clinical trial data, comprising the appropriate documentation and processing of the findings in accordance with the Medical Review Plan and/or Clinical Data Review Plan (CDRP), the Data Validation Plan (DVP) of the relevant study, and any other applicable document, working instructions, or guidelines. As a rule, the Medical Review will be performed by an experienced PPH plus Medical Advisor (physician) on critical study data (inclusion/exclusion criteria, concomitant medication/treatment, adverse events, pregnancies, drop-outs due to adverse events, primary endpoints) according to the requirements of the sponsor. An additional QC check of 5 % of the reviewed subject data (performed by a second person) is always recommended and included in PPH plus Medical Review services.

The Medical Reviewer will always closely cooperate with Clinical Operations, Data Management and Drug Safety to set up and continuously improve the Medical Review process, providing feedback regarding the quality of clinical data and study results on an ongoing basis.

The Medical Review provided by PPH plus encompasses complete or partial responsibility for the following tasks and duties:



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Set-up phase

Preparation and/or review of:

- Medical Data Review Plan
- Patient data review listings
- Special reports on data review
- Listings of parameters of special interest
- Tracking tables
- Protocol violation/deviation criteria
- Medical coding guidelines

Maintenance phase

- Review of patient data
- Medical query generation
- Review of line listings (trend identification)
- Review of protocol violations/deviations
- Support in SAE reconciliation
- Medical review of MedDRA- and WHO Drug Dictionary-coded terms

Customer Benefit

PPH plus provides an efficient and cost-effective Medical Review of trial data by experienced Medical Advisors who are used to work within multidisciplinary international project teams in compliance with regulatory requirements for quality management. The efficacy and accuracy of the Medical Review determines the quality of study results. Based on our experience the Medical Reviewer will detect an average of three medical queries per patient comprising new AE during data cleaning of a moderately complex study. In addition, about 10 % coding changes or need for queries occur as a result of medical coding review (auto-coding plus manual coding according to coding specifications/guidelines). Thus, Medical Review is the indispensable method to increase data quality and integrity of any clinical trial to the level required for valid conclusions on product performance.