Aim: Ensuring correct and complete source data in clinical trials is of utmost importance. Journal audits in the Dept. of Oncology revealed that source data were not always complete and thus the need to identify specific areas and extent of deficiencies.

Methods: Coupling of data from patient’s clinical records and electronic medicine ordering records with findings by research nurse at point of CRF data entry, thereby identifying areas with missing or erroneous data. A questionnaire was developed.

Results: From June to September 2013, 382 patient visits were examined. 187 of these had at least one or more deficiency which corresponds to 49% of the total registrations. Of these, deficiencies regarding Adverse Events (AE) are the most common (77%). For AEs, deficiencies were found in three main groups: Omissions in completing forms registering AEs per patient/visit: 39.6%; omission to register relationship to IMP: 37.4%; omitting start/stop dates: 21.2%. Of the 278 AE registrations with error/omissions there were 26 potentially significant errors which correspond to 10.7% of the registrations. Significant errors: should have led to dose modification, essential for patient safety or should have triggered a medical treatment/examination). Most deficiencies (57%) were found in investigator initiated trials and 5 doctors of 55 were linked to 39% of deficient registrations.

Conclusions: A review of source data in clinical protocols revealed one or more deficiency in approximately half of all registrations. The findings were not satisfactory from an efficacy and quality point of view, but it did not have major effect on the trial conduction when monitored by external audit. Several causes could explain the findings: insufficient documentation tools; lack of time to perform protocol requirements, poor understanding of GCP in clinical trials etc.. Multi-targeted interventions will be planned to improve the production/efficacy, pending further analyses. The conducted survey is an important tool to improve efficacy and quality.

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