Brief Report

Good Clinical Practice for Clinical Trials

Günther Forster, M.D., MPH*

The implementation of Good Clinical Research Practice (GCP) safeguards the protection of clinical trial subjects, patients or healthy volunteers, and guarantees the scientific approach in design conduct and analysis of clinical studies.

Standard Operating Procedures (SOP's) will support a less complicated implementation of GCP. These documents not only describe scientific aspects of a clinical trial, but moreover make one aware about the complexity of administrative procedures involved prior, during and after the conduct of a research project. Checklists and algorithm are very useful tools for committed research personnel to guide them through their difficult tasks. Responsibilities of investigators and sponsors describing requirements and necessities which have to be seen as prerequisites to make a clinical trial possible.

Finances provided are not enough to assume research can be conducted far more we have to assure that highly qualified human resources and standardized, quality controlled technical equipment are available.

Without research nurses, monitors, biostatisticians, technicians datamanagers, coordinators etc. modern research following ICH-Guidelines (International Conference on Harmonisation) is not possible. Investigators are very important indeed, out they can not run alone such projects.

As proper documentation is another requirement of GCP, we need to design protocols and Case Record Forms (CRFs) which describe and record in detail the objectives, methodology ethical and administrative aspects. Patient informed consent and patient information in local language needs to be submitted together with the research protocol and Investigational Drug Brochure (IDB) for the approval of an Ethical Committee (EC) in the hospital and or Ministry of Public Health (MOPH). Receiving the approval in writing indicates "Green Light" for further steps. If trial medication is supplied by the pharmaceutical industry being a possible sponsor, documents for importation of the investigational compounds have to be furnished. Packaging and labeling of medication has to be double checked as without proper drug accountability dispensing would not be according GCP. Also secured storage of trial medication is important.

Once the clinical trial was initiated patient screening according protocol eligibility criteria and randomization to one of the study arms is performed. Excellent communication and cooperation among all involved parties is a necessity to guarantee good compliance of patients as well as of research personnel. Without adequate motivation, particular large scale multi-centre multinational trials with long follow-up period (e.g. oncological trials) can not be completed or most likely with major delays. Thus, it is the responsibility of the monitor and research nurse to make sure that a smooth conduct in a convenient environment is established to keep given timelines (e.g. dateline of submission for publication at an international congress).

Simultaneously to the enrollment and follow-up of patients the CRFs have to be filled in completely, Source Document Verification (SDV) performed and data entry into the database, (by double entering

* *Medical Director of Roche Thailand Ltd., 555 Phaholyothin Rd., 19 Fl. Rasa Tower, Lard Yao, Chatuchak, Bangkok 10900, Thailand.*
Received for publication: January 2, 1998.
Reprint request: Günther Forster, M.D., MPH, Medical Director of Roche Thailand Ltd., 555 Phaholyothin Rd., 19 Fl. Rasa Tower, Lard Yao, Chatuchak, Bangkok 10900, Thailand.
Keywords: GCP, SOPs, Resources, Research personnel, CRFs, IDB, EC, MOPH, FDA, DSMB, ICH, Responsibilities, SDV, Datamanagement, FSR, QA, QC.

techniques) which was designed by the biostatistical team of the project.

The datamanager's role is to store, process and finally analyse all collected data. Once the database is considered clean and closed, the termination of a clinical trial is determined by the statistical design but can be influenced by a Data Safety Monitoring Board (DSMB), which is an independent group of experts that assesses at intervals the progress of a clinical trial, the safety data and the critical efficacy end points and gives recommendation to the sponsor (e.g. WHO or university) whether to continue, modify or stop the trial. Once the data have been analysed, the Final Study Report (FSR) has been written, additional efforts are essential to make a publication, preferred in a peer-reviewed international journal possible. It is the responsibility of researchers to share their study results with the public and demonstrate the validity of data generated.

Quality Assurance (QA) are those planned and systematic actions that are established to ensure the adherence to the applicable regulatory requirements. An audit (e.g. by the FDA) is an operational technique carried out as Quality Control (QC) measurement.

Following the ICH-GCP Guidelines, which apply for all phases (I-IV), data are valid internationally, independent where the clinical trials are conducted. Consequently, exchange of research data will be easy and reliable, preventing doublication or repetition of studies.

Finally, accepting and reenforcing GCP is to the benefit of our patients and we will reach our goal easier to develop better treatment-strategies leading to possible cures.