Einzelschritte für Klinische Prüfung	PRC/02-01 Version ox

Änderungen gegenüber der letzten Fassung:

1 Client meeting - definition of objectives

Confidentiality agreement

Evaluation of product data

Literature review

Regulatory consulting

Consulting on project design

Expert committee meeting

First cost estimation

Project timing

Contract

2 Preparation of product documentation

(product brochures)

Translation of documents

Preparation of protocol outline for clients

Statistical methodological planning

Analytical method selection

Draft protocol

Selection of centres and investigators

Preparation of final protocol and amendments

Preparation of final CRF

Preparation of patient information

Preparation of patient consent form

Patient insurance

Documentation of Ethics Committee

Documentation of regulatory authorities

local regulatory procedure (CTX?)

Ethics comittee approval
Randomization
Preparation of randomizations envelopes
Printing CRFs
Preparation of other complmentary documents
diary cards, investgators study files

3 Clincial supplies

preparation of medication labbeling and appproval
Packaging and labelling of medication
supply of complementary medication
Medication accountability and storage
medication shipment from CRO
Documentation shipment from CRO

4 Volunteer selection

Contact and selection of volunteers
volunteer consent
volunteer insurance
volunteer catering planning and dietary requirements
medical screening
drug screening pre-study
serological screening
volunteer randomization
sample labelling preparation
obtaining samples
sample QC and temporal storage
clinical laboratory tests during study and post study
special pharmacodynamic measurements
sample transportation
final medical examination

5 Analytical procedures

Method development and standardization

Analysis of samples

Analytical QC

Analytical documentation

Analytical reporting

6 study monitoring

Monitoring plan, timing, management and logistics

Monitors internal prestudy meeting

Investigator prestudy visist, selection for participation in the study and GCP inspection

investigator study file

handling of protocol amendments

Monitoring visits for study placement

investigators meeting

study initiation site visit and delivery of study materials

Regular investigator monitoring vissits on site and telephone contact

Monitoring documentation and follow-up

follow up of serious adverse events and documentation

Review of completed CRFs

Source data verification

drug accountability check

CRF trasnportation

CRF corrections

Visits for study closure

7 Project management

Project coordination national/international

Status report

Notification of regulatory authorities

investigators payment

study budget and time schedule follow-up

periodical client meeting

Clinical phase GCP study site and documentation audit

Strategic meetings with investigators and client

8 Quality control, filing and medication accountability

study master file preparation

study administration and communication

quality control check of CRFs (central unit) prior to data entry

CRF clean to data entry

duplication of CRFs

drug accountability

Return of unused material to client

sample storage

9 Data management and Evaluation

Database preparation

Data coding

Database screen formatting

Data entry

Data listing

Quality control check

Table preparation descriptive analysis

statistical analysis

first draft report

Presentation of the results

Quality control check of report

final clincal report and approval

final report corrections and signature

report printing

Publication

Archiving of study documentation

Freigabevermerk

Fahrdorf, den Autor