DiSCHARGE

WP5:
Clinical Data management

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WP5: Work package lead

- **KKS = Koordinierungszentrum für Klinische Studien der Charité**
  (Coordination Center for Clinical Studies)

- **Funded by the BMBF in June 2002, official opening: January, 17th 2003**

- **Service provider** of the faculty to support the clinical research, especially for **investigator initiated trials** at the Charité

- **offering the services of a CRO:**
  Provide **know how** (Regulatory affairs, DM, Statistics etc)
  Provide **technology** (Study software, Randomization tool)
  Provide **staff** (Study nurse, Coordination, Monitoring etc)

WP5: Team members

Data management

- Hoang Do
- Felix Frömel
- Gerald Splettstößer
- Maria Wiese

Biostatistics

- Alexander Krannich

Study software: Overview

- **Softwareplatform: SecuTrial® (InterActive Systems GmbH,** iAS**)**
- **Create and provide electronic Case Report Forms (eCRF) for Remote Data Entry (RDE)**
- **Software fully web-based** (no need for any local installation or requirements)

- **Compliant to** GCP, FDA 21 CFR Part 11, German Pharmaceuticals Act
- **Certified by BioMedion GmbH (Göttingen, April 2007)**

Study software: Highlight

- **Data capture according to Good Clinical Practice (GCP)**
- **Enhanced data quality** (compared with Paper-CRF)
  - **by system & plausibility checks, programmed rules**
  - **Realtime data entry**
- **Interactive Query-management tools**
  (Dialogsystem between CRA und Clinical investigator)
- **Various study overview: Reports & Lists**
  (e.g. Recruting level, Randomlist, study termination etc.)
- **Integrated Online randomisation**
- **Data export in various formats: SAS, SPSS, CDISC-ODM, CSV**

Study database

- Study data store in a central database
- available worldwide 24/7
- Safety access (Firewalling, SSL encryption, Authentification, Logs)
- Administration: configurable rolls and rights
- Backup the database periodically

At client side

Requirement:

- **PC or Laptop with** (fast) **Internet connection**
- **Screen resolution: min. 1024x768 pixels**
- **Standard Internet browser** (Firefox, Internet Explorer, Chrome …)
- **No further software installation necessary**
- **No local storage of data**

WP5: Objectives/Tasks

- **Provide a** (central) **study database**
- **Implementation of eCRF for Remote Data Entry (RDE)**
- **Hosting of study data**
- **Periodically quality control of study data**

WP5: Data management

- **Design and creation of database** (Month 1 – 6)
- **Design and programming of eCRF** (With system and plausibility checks)
- **Validating and release of eCRF**

During the study

- **Administration: database/eCRF** (Logins, roles and rights)
- **User support** (Reset password, technical problems etc.)
- **Query management** (data checks periodically)

- **Delivery of the cleaned data for statistical analysis** (Month 57)

WP5: Expected time line