

KKSK

Koordinierungszentrum
für Klinische Studien
der Universität zu Köln



Mobile Computing in the German HIV registry project

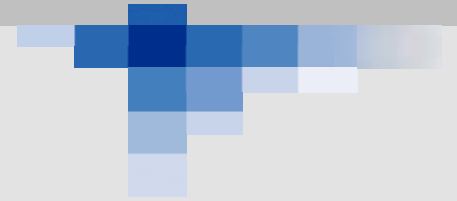
TMF Workshop – Mobile Computing

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Thomas Bratke

Coordination Centre for Clinical Trials Cologne,
University Hospital Cologne, Germany



- Background information
 - Cooperation partners
- German HIV registry project
 - Characteristics
 - Offline EDC / Data security
 - Results
- Identified problems

- Background information / Cooperation partners -

■ **KKS Cologne**

The Coordinating Centre for Clinical Trials Cologne is an institution of the Medical Faculty of the University of Cologne and has the task of efficiently supporting all processes involved in clinical trials and improving the quality of multi-centre clinical trials and registers.

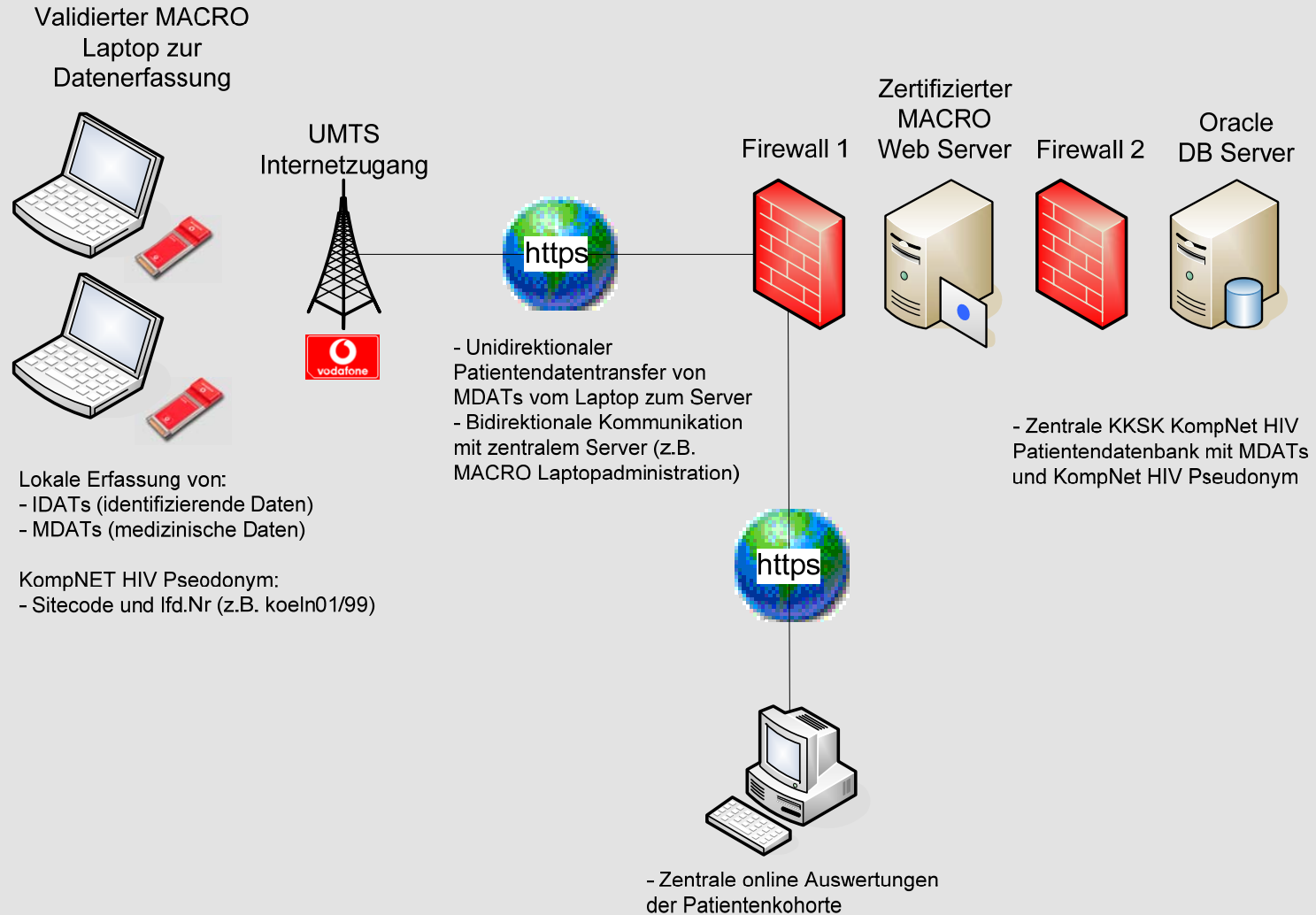
■ **Competence network HIV / AIDS**

The HIV and AIDS Network is a national research system that brings together major study groups in Germany. These groups deal both with clinical care and clinically oriented basic research into HIV infection and AIDS to improve quality of life and life expectancy of HIV-infected patients.

- Characteristics -

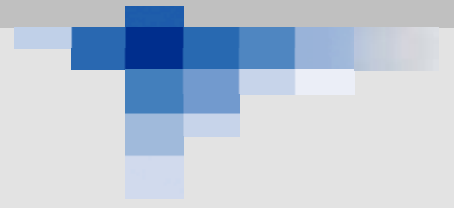
- The Competence network HIV / AIDS registry project is a main project and an infrastructural basis for different subprojects
- Prospective patient data collection according to quality standards and regulation aspects of clinical trials (i.e. EU Directive 2001/20/EC, Monitoring) is required
- Patient data import or export for different HIV documentation projects and clinical trails are requested
- Patient identification data documentation requires a mandatory national data security concept (i.e. German federal state laws)

- Offline EDC / Data security -



- Results -

- EDC Software MACRO was chosen because of offline EDC capability (i.e. local data collection with the ability to synchronize only selected data items into a central database)
- ~50 validated MACRO laptops were shipped out and sites were trained since June 2004
- 9571 documented patients until December 2005
- ...



- Problems -

- Laptop configuration and administration
 - Secure laptop usage
 - Software patches
 - Backup and Restore (i.e. Laptop theft)
- Laptop connectivity
 - Local firewalls vs. 3G (UMTS) network availability and costs
- Help Desk availability and services in academic environment
- Register availability on different devices (Palm, Handheld etc.)