



Welcome !

TMF projects on IT infrastructure for clinical research

R. Speer

Telematikplattform für Medizinische Forschungsnetze (TMF) e.V.
Berlin

Telematikplattform für Medizinische Forschungsnetze

- ↪ Head organization of medical Research Networks in Germany
- ↪ Funded by the *German Ministry for Education and Research (BMBF)*
- ↪ 1999 established as platform for IT-projects parallel to
 - ↪ Competence networks in Medicine (CN)
 - ↪ Coordination Centres for Clinical Trials (KKS)
- ↪ community-driven
- ↪ central office and working groups / forums



gefördert vom
Bundesministerium
für Bildung
und Forschung

↪ Working groups

- ↪ Cover a broad range of themes and areas (e.g. data security)
- ↪ Discuss new ideas and project proposals
- ↪ (Scientific) administration and controlling projects

↪ Project groups

- ↪ Special for projects (e.g. system validation)
- ↪ May exist longer than the project

↪ Task forces

- ↪ Special tasks (e.g. TMF-website)
- ↪ Should not exist longer than the task ;-)

↪ Project types differ in their aims and processes

1. Environment und Infrastructure Projects
2. Process and Quality Management
3. Standards and harmonization

↪ Aims

- ↪ support professional infrastructure in research networks with software

↪ Projects

- ↪ Content management systems
- ↪ Study management systems
- ↪ Telemedicine infrastructure
- ↪ Pseudonymization Tools, ...

↪ Process

- ↪ Requirements (Questionnaire, Interviews)
- ↪ Evaluation (market analysis, workshops, presentations)
- ↪ Recommendations and Purchasing
- ↪ Installation and Validation

- ↪ Aim: support the information management in the research networks with professional content management systems
- ↪ Timeline 2 years
- ↪ Solutions for 11 research networks
 - ↪ High class: VIP Gauss
 - ↪ Mid class: Reddot
 - ↪ Open Source: Zope
- ↪ Add-on project: Web quality management

↪ Aims

- ↪ support processes and quality management in research networks

↪ Projects

- ↪ System Validation
- ↪ Safety management
- ↪ eArchiving
- ↪

↪ Process

- ↪ Requirements
- ↪ Concepts and recommendations
- ↪ Evaluation and training

- ↪ Aims: support the validation of computerized systems used in clinical trials
 - ↪ System validation masterplan
 - ↪ SOPs
 - ↪ Templates, Checklists
 - ↪ Training courses (Online, Classroom)
 - ↪ Concepts for Vendor Assessment and Audits

↪ Aims

- ↪ support the use of standards in research networks

↪ Projects

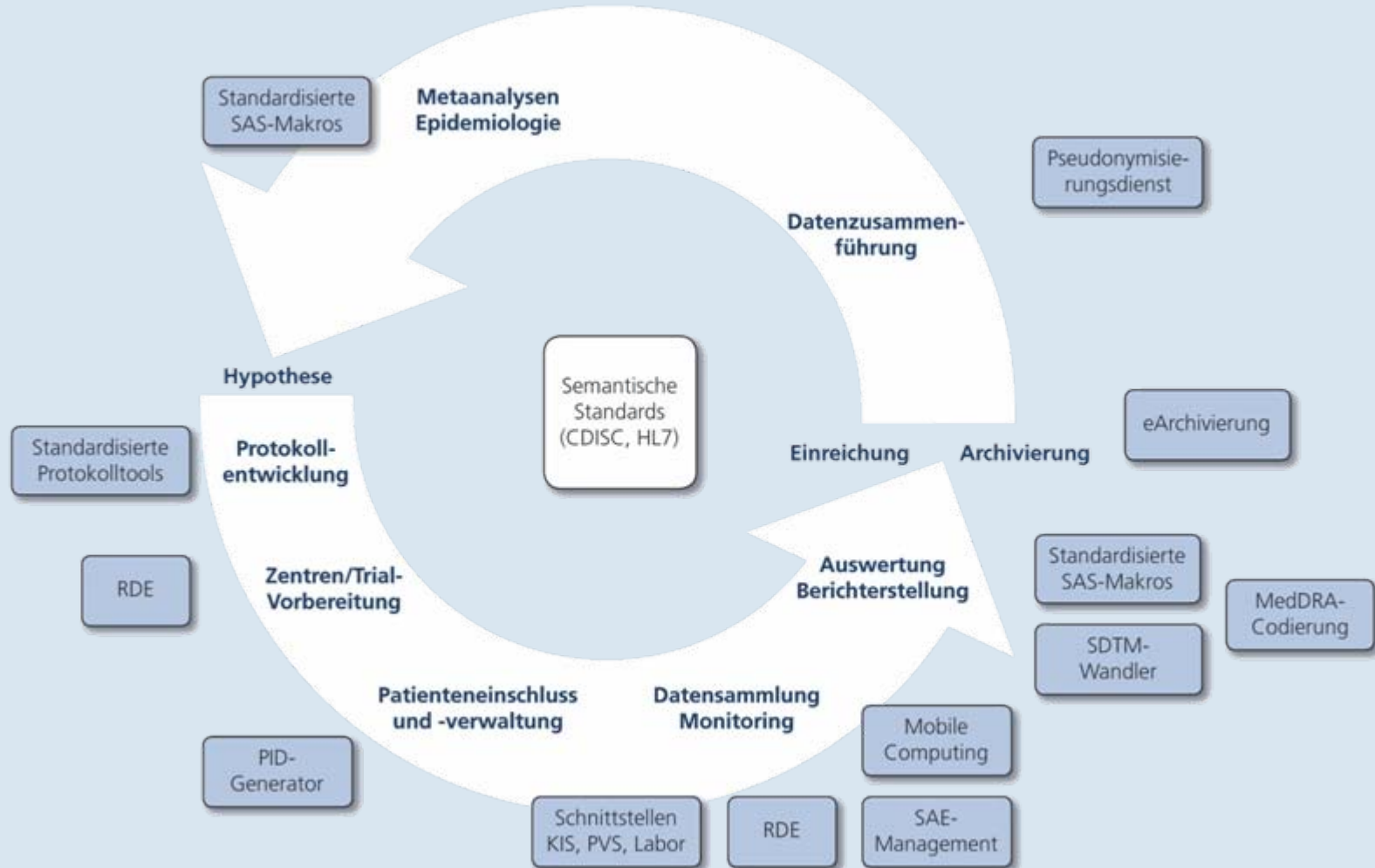
- ↪ CDISC – Use Cases
- ↪ CDISC – SAS-Macros
- ↪ CDISC – SDTM-Mapper
- ↪ Web Quality Standards, ...

↪ Process

- ↪ Requirements
- ↪ Concepts / Recommendations
- or
- ↪ Development, Installation and Validation

- ↪ Mapping of CDISC-ODM Items to CDISC-SDTM Items
 - ↪ Necessary for the submission of trial data to the FDA and the use of CDISC SAS-Macros (developed in an other TMF-Project)
 - ↪ Market analysis
 - ↪ Requirements
 - ↪ Development
 - ↪ Installation and Validation





- ↪ Standards !? (*Which, Why, When ???*)
- ↪ limited resources (*personnel, hardware, software*)
- ↪ not enough IT-experts, but too many specialists
- ↪ too heterogeneous partner with different requirements in the project
- ↪ communication between project partner and/or end user
- ↪ too many or too less people in the project
- ↪ Follow-up costs (*support, personnel, ...*)



Thank You!

<http://www.tmf-ev.de/>