TMF – A Common Platform for Medical Research Networks in Germany

Improving the Organisation and Infrastructure of Medical Research in Cooperative Structures

Today's multidisciplinary working environments, the increase of sub-specializations, the need for interdisciplinary cooperation, and internationalization all have an impact on health care as well as on health research: Nowadays, medical research can normally be carried out with success only when conducted on an interdisciplinary, often also interregional or even international, collaborative basis. Research groups at different institutions are working together: They collect, process, and exchange clinical data spanning distributed locations in order to build up clinical data banks or large patient cohorts.

At the same time, collaboration between research and health care is increasing: Medical treatment has to be adjusted as closely as possible to the latest research findings. To this end, the efficient transfer of knowledge from the sphere of research into that of health care is the most important precondition.

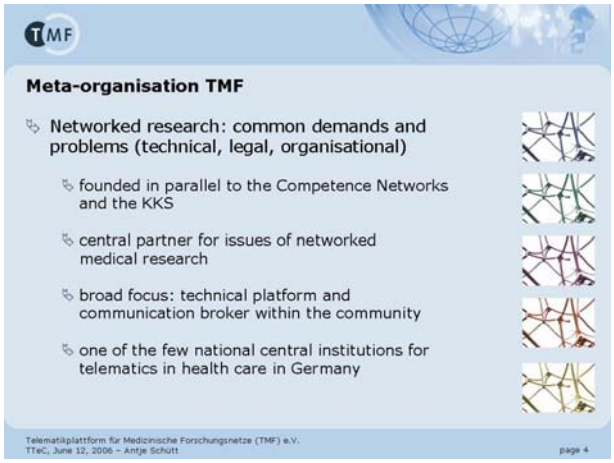
Vice versa, clinical research is dependent on obtaining data from health care which are both reliable and as extensive as possible. Thus the transfer of ideas, questions and data from the area of health care to that of research must be ensured. Only by doing so can efficient clinical research be organised on an enduring basis and, in turn, ultimately yield benefits in health care.

Taking this into account, the German Federal Ministry of Education and Research has initiated a

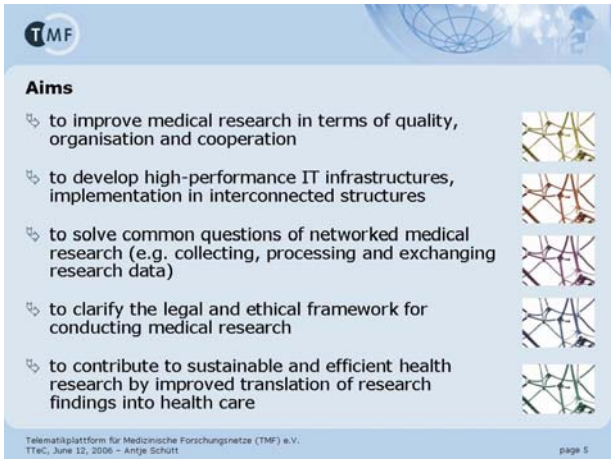
number of medical research networks during recent years. As an example, since 1999 17 Competence Networks in Medicine have been established in order to promote scientific excellence through disease-oriented research. In being specifically focussed on diseases with a high socio-economic impact, these networks are directed at innovative research as well as at the transfer and implementation of research results into practical and economically viable solutions.

The Coordinating Centres for Clinical Trials (KKS) as another example of the ministries funding initiative are located at university hospitals. As a centralised provider of services for researchers, a KKS supplies personnel and logistical resources on site for planning, conducting and evaluating clinical trials in compliance with internationally accepted quality standards.

Medical research at distributed locations entails common demands and problems of a technical, legal, and organisational nature that are often unconnected with the specific clinical problem and research focus of the single network. This is why, in parallel to the Competence Networks in Medicine and the Coordinating Centres for Clinical Trials, the ministry has initiated and funded TMF as a meta-organisation and central partner for issues of networked medical research in Germany.



TMF stands for Telematics Platform for Medical Research Networks, but meanwhile its focus is much broader than that of a pure technical platform: It is also a communication broker within the community of networked medical research. Scientists from the member networks collaborate in thematic working groups to identify common problems, to exchange their experience, and to develop solutions and new strategies for efficient high-quality medical research. Beyond this, TMF has evolved into one of the few national central institutions for telematics in health care within the German federal system.

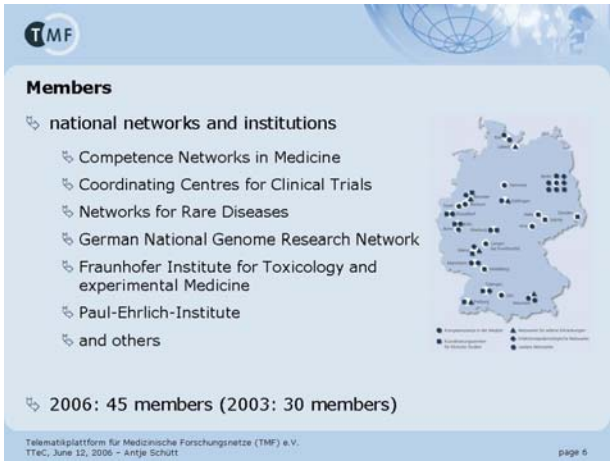


The aims of the joint work in TMF are:

- to improve medical research in terms of quality, organisation and cooperation;
- to develop and further extend high-performance IT infrastructures and to support their implementation in interconnected, cross-institutional structures;

- to solve common questions of networked medical research which arise in collecting, processing and exchanging research data;
- to clarify the legal and ethical framework for conducting medical research;
- to contribute to sustainable and efficient health research by means of improved translation of research findings into the practice of health care.

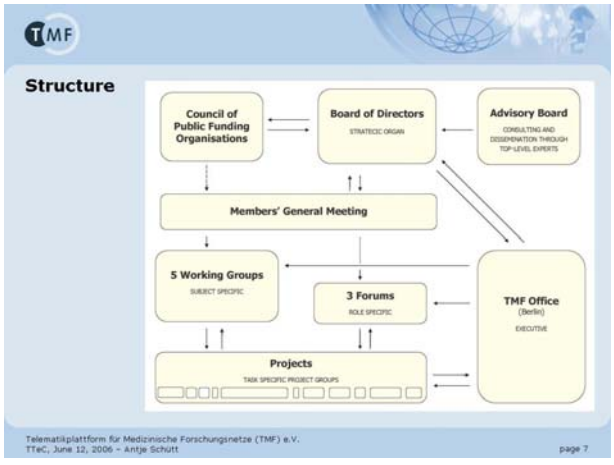
The members of TMF are national networks as well as research institutions working on a network basis. These are not only the Competence Networks in Medicine and the Coordinating Centres for Clinical Trials I mentioned earlier, but also several Networks for Rare Diseases, the German National Genome Research Network, the Fraunhofer Institute for Toxicology and experimental Medicine or even the Paul-Ehrlich-Institute, which is a higher Federal authority in Germany.



Moreover, the topics and results have attracted the interest of several patients' self-help-organizations which are funding research themselves or building up biobanks, especially for rare diseases.

The number of members has increased from about 30 by the end of 2003 – when TMF changed from a pure funding initiative into a members' association – to 45 members in 2006.

Some words on the structure of TMF. The research networks with the Members General Meeting are the central organ. On a strategic level, we have the Board of Directors which is nine persons elected from the member networks. As TMF and a large majority of its members are financed by public funds, there is a Council of Public Funding Organisations monitoring the working orientation and the financial planning of TMF in order to guarantee proper use of the resources. There is an Advisory Board of top-level experts in the field of telematics in health care, as well.



On the executive level, we have the working groups and the forums as well as numerous specific project groups. Moreover, to support all the TMF activities, there is our Office in Berlin where internal and external communication is assembled. The team at the Office accompanies the projects – from

advice on developing new plans and drawing up proposals, via expert consultancy and administrative coordination, to finalising, publicising, and implementing the results of the projects.

A large proportion of TMF's work takes place in the scope of the working groups. Currently, there are five working groups running on

- IT infrastructure and Quality management,
- Data protection,
- Biobanks, and
- Management of clinical trials.

A working group on Molecular Medicine is about to be initiated.

The working groups initiate numerous and diverse projects which can be grouped according to TMF's main topics as there are:

- Legal and ethical framework conditions,
- IT infrastructure for clinical research,
- Interconnection of research and health care,
- Standards and terminology, and
- Quality management.

From the beginning, one of the core tasks of TMF was to analyse the existing legal and ethical general framework conditions for medical research networks.

Already during its first years, generic data protection strategies for medical research networks have been developed by TMF. These strategies constitute an important precondition for the electronic exchange of research data between the research groups and the hospitals or medical practices. TMF has succeeded in coordinating these strategies with the Data Protection Officers of the German federal states. The agreed strategies are now seen by these representa-

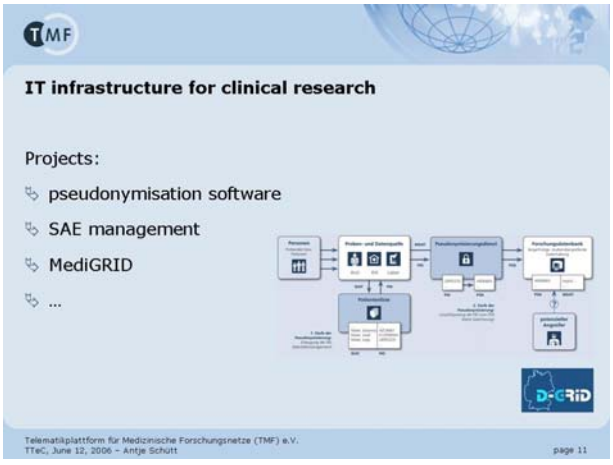
tives as setting the reference model for all similarly structured cooperative projects in medical research. Few months ago, the concepts have been published as the first issue of the TMF publication series.

The working group on data protection has given advice for numerous research networks – both within and outside TMF – in developing specific data protection concepts on the basis of the generic concepts. The intensive collaboration of TMF with the Data Protection Officers has led to a common language and a common perception of data protection problems in networked medical research. As a result, the approval procedure for the respective research projects could be highly accelerated.

Furthermore, a comprehensive set of guidelines for declarations of patients' informed consent in clinical research has been developed. These guidelines have been approved by the Ethics Committee and the Data Protection Officers, too.

Similarly, TMF is working on issues relating to the legal and organisational framework parameters of biobanks. As you know, collecting and storing of biomaterials is gaining ever greater significance, in particular where answers are sought to questions on molecular genetics in medical research. In this field, however, there is still considerable need for clarification of certain legal and organisational questions: How to protect donor's personal rights? How to handle the material whilst doing justice to data protection? Or: How to sustain long-term usability of the material for research aims which are not yet determined? TMF is currently finishing a large-scale project on these issues, comprising legal opinions, checklists and basic guidelines.

Building up and supporting the IT infrastructure for networked medical research belongs to TMF's core tasks.



As an example, a web based pseudonymisation software has been developed on the basis of the strategies formulated in the data protection concepts: Long-term data storage is characteristic for medical databanks which are established in cooperative research projects more and more frequently. Data is also stored trial-spanning which allows meta-analyses as a measure of quality assurance in research. To ensure highest security standards in this process, the TMF data protection concepts demand two-step encryption of the ID and separated storage of the patients' identifying data and medical data.

The TMF data protection concepts will be presented in detail in tomorrow's poster session. Professor Klaus Pommerening, who is one of the project leaders, is here and may surely respond to your questions on the concepts.

TMF supports transposing European directives into national law and develops tools and trainings for their practical application. As an example, TMF is supplying the research networks with a software solution for the announcement of Serious Adverse Events in investigator initiated trials to the national and European authorities (e.g. EMEA), which in Germany is requested by law since 2004.

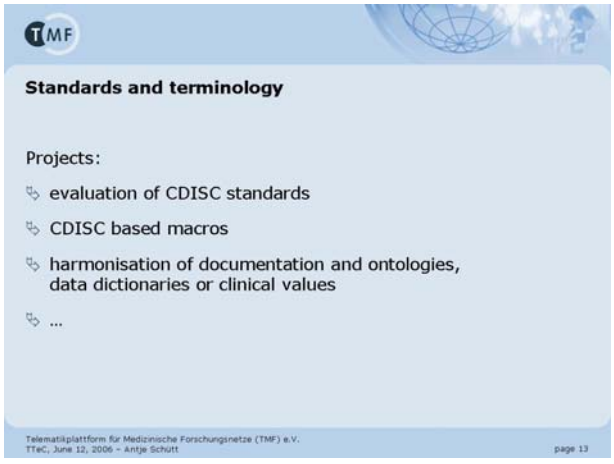
To show the spectrum of TMF's work, I would also like to mention the activities within the German health grid project: TMF is coordinating a cooperative project called 'MediGRID' which aims at developing a Grid-Middleware-integration platform and eScience services for biomedical research. This project is also funded by the German Federal Ministry of Education and Research.

For TMF interconnecting medical research with health care represents the key challenge for the coming years. This "vertical networking" is also one of the core tasks of the Competence Networks in Medicine.

One concern of TMF is to find out how medical research can participate and benefit from integration into the processes of the electronic health card and the health professional card which are now being introduced in Germany.

Other aspects include IT support for the development and evaluation of clinical guidelines as well as the establishment of interfaces between documentation systems in doctor's practices and research networks.

Creating cross-linked network solutions demands the consistent implementation of IT standards. Similarly, standardisation in terminology is essential for the exchange of data between the information systems of the participating institutions. In this field, TMF conducts several projects.

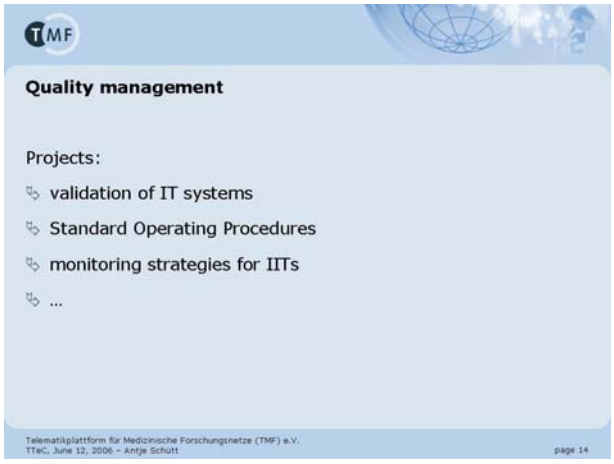


One example is the evaluation of standards in the area of clinical trials for the research networks, as defined by the Clinical Data Interchange Standards Consortium (CDISC).

In one of the TMF projects, CDISC based macros are developed for trial analysis and for compilation of submission reports.

Moreover, there is work in the area of harmonisation of documentation and ontologies, data dictionaries or clinical values (as LOINC, CDISC-LAB, or SCIPHOX).

An integrated and universal quality management is essential for the success of cooperative medical research. Above all, this refers to the IT structures and the specific software employed, but at the same time it applies to the working processes, both in conducting clinical trials and concerning collaboration within large-scale interlinked projects.

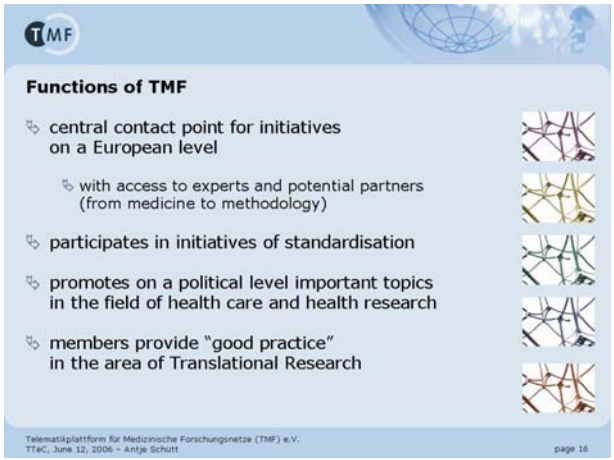


TMF develops recommendations on quality assurance in medical research networks, on validation of IT systems supporting clinical trials (e.g. Electronic Data Capture systems), on the development of Standard Operating Procedures as well as on the evaluation of alternative monitoring strategies for IITs.

Considerable experience with networked medical research has been gained in a national context in Germany over the recent years. Especially the model of the vertical networks is unique, so far, and may serve as good practice for establishing research networks on a European level. Numerous of the TMF member networks are already involved in European cooperations, where initially national issues – such as data security – gain a broader and more complex dimension that has to be tackled reverting to successful prior experiences.

Besides, the European Commission increasingly addresses questions that arise in networked medical research such as “Interoperability”, “Patient Safety”, or “Translational Research”. TMF as the umbrella organisation of the medical research networks in Germany may therein have several functions:

- TMF is the central contact point for initiatives on a European level with access to experts and potential partners with a broad range of issues from medicine to methodology.



- TMF participates in initiatives of standardisation.
- On a political level, TMF promotes important topics in the field of health care and health research.
- TMF members provide “good practice” in the area of Translational Research.

Thank you for your attention.