Integrating eHealth and Medical Research
The TMF Data Protection Scheme

CeHR Regensburg, 3. Dezember 2007

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Gefördert vom
Bundesministerium für Bildung und Forschung

Medical Research Networks

- **Disease Specific Networks**
  - funded (initially) by the German Ministry of Education and Research (BMBF)
  - “Competence Networks”
    - e. g. Paediatric Oncology and Haematology, Congenital Heart Diseases, ...
  - Coordinating Centres for Clinical Trials (KKS)
  - Networks for Rare Diseases
    - e. g. Epidermolysis Bullosa, Hereditary Movement Disorders, ...
  - National Genome Research Network (NGFN)
  - ...
- **Goal: Integrate eHealth and Medical Research**
  - Advance diagnostic and therapeutic knowledge
  - Keep data and samples for future research

Medical Research Networks

- Profit for patients:

  Get optimal care under supervision by leading experts.

- Profit for experts:

  Accumulate a large treasure consisting
  of a large data basis
  and biomaterial (samples)
  for translational research.

What is TMF?

Telematics Platform for Medical Research Networks

- Association of Research Networks
- (indirectly) funded by the research ministry

Goals:

- Advance interdisciplinary, interregional, and international collaboration
- Help in building a suitable infrastructure, define standards, construct prototypical solutions
- Solve common technical, legal, and organisational problems about
  - interconnection of research and healthcare
  - standards and terminology
  - legal and ethical frameworks
  - quality management
  - technology assessment
  - public relations

Legal and Ethical Obstacles

- Rules of ethics
- rules of professional discretion
- national and international data protection laws

require

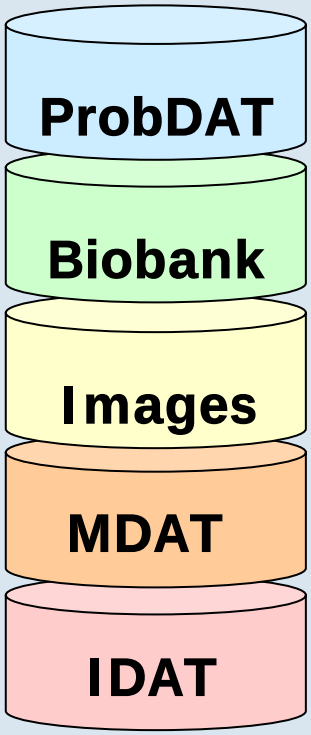
- *strict separation between treatment and research*
- using data and samples only for a specific purpose that is known and consented in advance.

To compensate for

- vaguely specified purpose
- unlimited storage time

we need additional safeguards to protect patients' data and samples.

Approaching a Solution, Part 1: Separate Informational Powers



Data from genetic analyses

Biomaterials, associated data

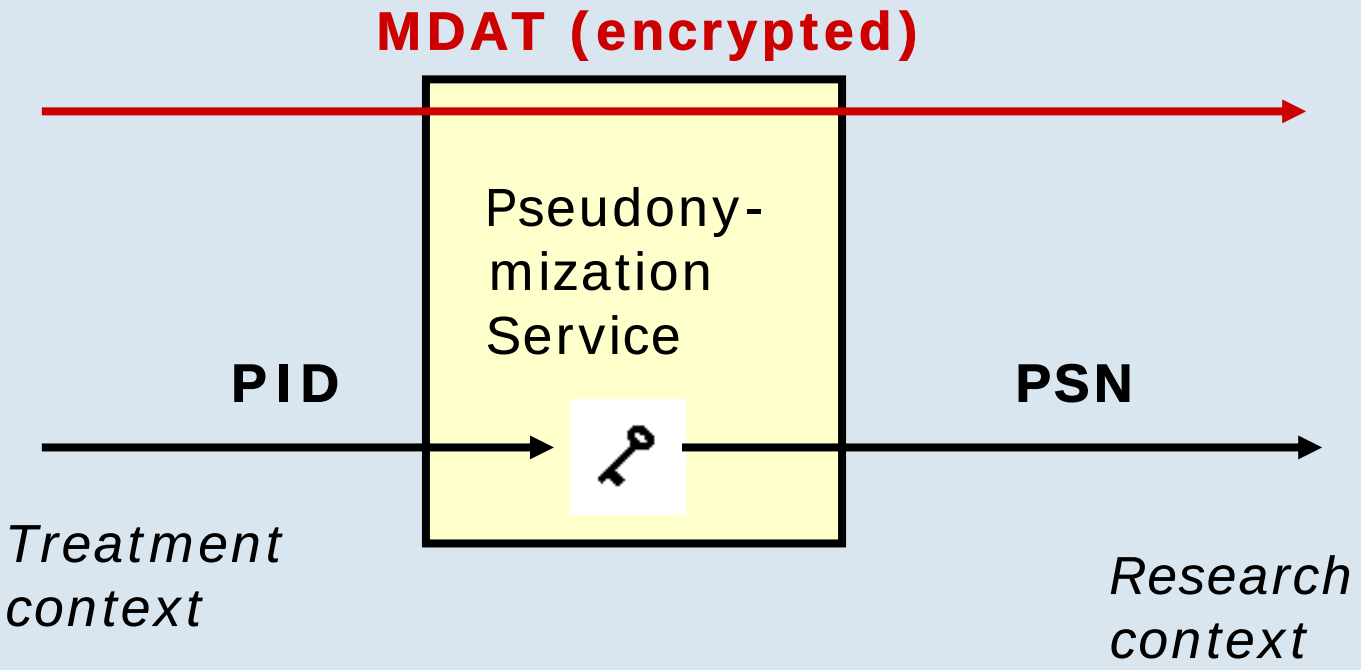
Images and associated data

Medical data (diagnoses, therapy)

Identifying data

Keep information at distinct locations
with independent supervision.
Let Trusted Third Parties control data flows.

Approaching a Solution, Part 2: Pseudonymize Identifying Data



A pseudonym (PSN) is an encrypted unique Patient Identifier (PID).

***A pseudonym allows controlled re-identification*.**

Use *distinct* pseudonyms for MDAT, Biomaterials, Images

The TMF Data Protection Scheme

... is a “generic” model with variants for the processing of information in research networks and biobanks.

Methods:

- Separation of informational powers
- Pseudonymization
- Templates for informed consent, policies, contracts
- Standard Operating Procedures

In the (future) revised scheme:

- Modular approach, scalability of measures according to criteria of adequacy
- Better integration of healthcare and research structures
- Better specification of the processes of quality assurance
- Integration of clinical multicenter studies, registries, image data bases
- Proposals for (TMF wide) central services

Results and Discussion

- Several networks adapted the TMF scheme, others will follow.
- The German Data Protection Commissioners approved the scheme.
- A major revision is in progress – taking into account the past experiences.

The TMF Scheme enables long time medical research data bases and biobanks, fulfils the privacy requirements, and gives freedom for medical research while protecting patients' rights.
The revision adds modularity and scalability.