List of Products with Commentaries

Pseudonymization software
Software for two-stage pseudonymization of medical data for the development of research databases that can be used in the long term. Available since the end of 2009 following reconceptualization and reimplementation. In conjunction with tools for the administration of single-level pseudonyms it enables data protection-compliant development of new kinds of research databases with long-term merging of follow-up data sets and person-related feedback of research results. P000011

Generic data protection concepts
Generic templates for data protection concepts in networked research projects, coordinated with the Science working party and the Health and Social Issues working party of all the state and federal Data Protection Officers. Published as a book in the TMF book series in 2006. Based on the generic concepts, new data protection concepts for networked research projects can be developed more quickly and more reliably and, if necessary, also coordinated more speedily with up to 16 state Data Protection Officers. The time gained per research project is estimated to be 6 months on average. P000021

Documents on sponsor responsibility
Brief expert opinion on assuming responsibility as a sponsor in clinical studies, with specimen contracts for trial sites and contractors, plus a template for internal task assignment. Available as a free download on the TMF website since 2008, previously distributed via the TMF Office. Meanwhile most universities have regulations concerning sponsor responsibility for clinical studies conforming to the requirements of the German Medicinal Products Act ('AMG'). Most of the regulations are based on the results of the expert opinion commissioned by the TMF or also on the specimen texts presented. P000031 | P000032

Biobanking – legal expert opinion
Preparation of the legal framework for biobanking in biomedical research. They were published as a book in the TMF book series in 2006. The expert opinion clarified the legal framework for the operation of biobanks in Germany and provided a basis for further projects on informed consent declarations, data protection concepts, specimen contracts and for international exchange of samples. P010011

Biobanking – specimen contracts
Specimen texts and specimen contracts for the development and operation of biobanks. Available free as a download on the TMF website since 2006. Legally sound formulations, including ones for the transfer of property rights, provide operators of biobanks with new application and utilization options; drafting all the necessary contacts and regulatory documents is speeded up considerably; per institution it is possible to reduce the amount of qualified legal groundwork by a number of days. P010012

Biobanking – data protection concept
Data protection concept for various centralized and decentralized biobanking infrastructures, coordinated with the Science working party of all the state and federal Data Protection Officers. Available from the TMF Office since 2007. Allows more rapid, legally sound and plannable development of new sample collections and expansion of existing ones. P010021

Biobanking – quality management
Checklist for quality assurance in sample collections. Published as a book in the TMF book series in 2008. With the legal opinion and the data protection concept it is one of the basic documents required for the funding, development and expansion of quality-assured, legally sound biobanks in Germany. P010031

Biobanking – expert opinion for the German Parliament
Expert opinion for the German Parliament: Assessment and characterization of biobanks – systematization, scientific assessment, financing models and concepts on data protection and informed consent. The expert opinion was handed over to the Office of Technology Assessment at the German Bundestag ('TAB') in 2006 and the main parts of it were published by the TAB in 2006 within the scope of working report no. 112 "Biobanks for human medical research and application", by Revermann and Sauter. The expert opinion has made a considerable contribution toward communicating, in the political environment, an appreciation of biobanking and the associated legal, ethical and practical challenges as well as existing solution approaches. P999061

Biobank registry
Central registry and network of medically relevant biobanks in Germany. Transparent infrastructure to avoid redundant research on valuable resources from clinics, research institutes, and networks. As a platform it offers all the networked partners a common basis for quality-assured scientific exchange of information and particularly allows the implementation of legal and regulatory procedures concerning ethical issues for the protection of patients. P058011

Reference implementation of data protection concept A
Exemplary implementation of generic concept A, in which medical and identifying data of patients from separate servers is only merged on the PC of the attending physician. Freely available from the TMF Office since the beginning of 2006. The benefit is comparable with that of a feasibility study. Nowadays there are different techniques available for merging data from various web servers in a physician's browser. P014011

PID generator
Software component for generating pseudonyms that are safe in the long term, based on error-tolerant matching of identifying patient data. Freely available from the TMF Office since 2005. Makes it possible to develop innovative data infrastructures in a data protection-compliant manner, for example, the networking of registries with study-oriented or general research databases. Saves research projects time and money when developing pseudonymization solutions. P015011

Informed Consent – Checklist
Checklist and guide issued by the TMF concerning patient consent – fundamentals and guidance for clinical research. Published as a book in the TMF book series in 2006. Simplifies the creation of informed consent declarations for clinical research projects and speeds up the coordination process with data protection officers and ethics committees, especially in cross-institution and cross-border projects. Serves as a basis of the TMF online assistant for creating informed consent declarations. P017011

Informed Consent – Online assistant
Software assistant for web-based use of the checklist to create patient information leaflets and informed consent declarations. Available free of charge on the TMF website since fall

2007. Assists and speeds up the creation of legally compliant informed consent declarations and coordination thereof with data protection officers and ethics committees: Since the offering came into being, it has been used intensively 5 to 7 times a week on average. P017021

System validation master plan with training documentation and audit concepts
Comprehensive guide for the validation of computerized systems in clinical research with concepts for internal audits or vendor audits and training documentation. Available free of charge from the TMF Office since 2007, offered as a free download on the website since 2008. The project has created a basis for appreciating the quality-assured development, installation and use of software and hardware in accordance with GCP requirements at the academic sites in Germany. Most coordination centers for clinical trials and most centers for clinical trials nowadays use variations of the jointly developed validation plan. P019011 | P019012 | P019013

Data quality guideline with statistical tables and software package
Guideline for adaptive management of data quality in cohort trials and registries with statistical background material and web-based software for monitoring and controlling data quality. The guideline was published as a book in the TMF book series in 2007. The statistical tables are available as a free download and the software can be obtained from the Office free of charge. The guideline helps data managers of research registries to achieve reliable data quality. P020011 | P020021 | P020031

SAS macros for clinical studies
Over 40 parameterizable SAS macros for creating standardized analyses and reports in clinical studies. Available as a free download on the TMF website. Since it is possible to download anonymously, there are no accurate user figures. Several academic trial sites already take advantage of the saving and quality improvement potential of standardized evaluation 'at the press of a button'. P021011

Legal expert opinion and specimen texts concerning utilization issues
Legal expert opinion on value creation in data exchange between medical care and research with information and specimen texts concerning contractual terms and conditions for knowledge and data transfer. The expert opinion was published as a book in the TMS book series in 2008 and the specimen texts are available as a download on the TMF website free of charge. Knowledge of utilization law principles in the environment of biomedical research is a key prerequisite for the stabilization of research infrastructures. This comprehensibly written summary together with the text templates is a valuable aid. P022021 | P022022

QM manual for health portals
Manual for quality assurance of health information on the Internet. Available as a download on the TMF website free of charge. The manual helps PR employees in research networks with the structuring, design and maintenance of Internet offerings. Preparing information systematically can save time and thus improve the findability of web offerings via search engines. P023011

Author portal for guideline development
Web portal for cooperative creation and coordination of medical guidelines, originally hosted by the Charité Hospital on behalf of the TMF and now operated by "User Group – Med. Leitlinienentwicklung e. V." The portal has been available at www.leitlinienentwicklung.de on fixed terms since 2008. With the aid of the portal the results of research can be summarized

in guidelines more quickly and more cost-effectively than used to be the case. The greatest benefit is provided by the portal in the required regular updating of guidelines because then all the guideline information to date is also available in a structured form ready for revision. P024011

Checklist for the legal framework of IITs
Checklists on carrying out investigator initiated trials (IITs) as per the 12th German Medicinal Products Act ('AMG') amendment. Available as a download on the TMF website free of charge. The increased quality, regulatory and documentation requirements for IITs according to the 12th AMG amendment of 2004 still represent a major challenge for many academic trial sites. The support from the checklists and training sessions based on them have considerably speeded up implementation of the requirements. P028011

Training documentation for the legal framework of IITs
Training documentation on carrying out investigator initiated trials (IITs) as per the 12th AMG amendment, based on the checklist. In 2005 the training documentation was used in 5 fee-based training sessions with a total of 72 participants. Since then it has been available from the TMF Office free of charge. After 2005 as well the training documentation was still used in a number of events, including the KKS Network, and it has thus helped to effectively communicate the new requirements for IITs. P027011

Training materials for medical device development
Training materials for the clinical evaluation and clinical testing of medical devices. The documentation was evaluated within the scope of a pilot seminar in 2011 and after revision it has proved successful in several other one-day seminars. It is chiefly aimed at developers from universities, research centers, and SMEs, at clinical investigators and study nurses, as well as employees of manufacturers, producers and CROs who help to implement the regulatory requirements. Available as a download on the TMF website free of charge. Modules: Legal basis, development and structure of a clinical evaluation, decision to hold a clinical trial and responsibilities, planning a clinical trial, holding a clinical trial, completing a clinical trial. P075011

Checklist for clinical evaluation, clinical trials and HTA for medical devices
Thematic introduction and practical aids for medical device development: regulatory framework, clinical evaluation, clinical testing, clinical trials, and Health Technology Assessment (HTA). Published as a book in the TMF book series in 2011. Assists medical device developers with the regulatory classification of their products and definition of the necessary development steps, depending on the relevant risk class and intended use. Provides practical aids along the entire process chain, in the form of checklists, decision trees, Reporting Guidelines, and SOP lists with commentaries. P075011

Standard Operating Procedures (SOPs) for clinical studies
Harmonized Standard Operating Procedures for holding clinical studies. At present there are about 60 SOPs and the associated attachment documents available as downloads on the TMF website free of charge, including English translations in some cases. Saves study directors the effort involved in creating new SOPs and thus saves at least one week of work per study. Brings about an improvement in the quality of studies because the pooled expertise of the KKS Network and the TMF has been incorporated in the SOPs. P032XXX

SDTM converter

Software for the transformation of clinical study data from a CDISC-ODM structure to SDTM format. Available to German users from the TMF Office free of charge since the beginning of 2008. Serves to intermesh CDISC standards for the operational phase of clinical studies and the final tabular arrangement of data for analysis and submission. If study data management systems increasingly support the operational model, the converter can be used to streamline data management and speed up the final preparation of data for submission and analytical purposes. For example, it is then possible to use the TMF's SAS macros for reporting and analysis without the need for any additional conversion. P034011

Legal expert opinion on data protection in medical research
Clarification of data protection issues concerning the pseudonymization required by the German Medicinal Products Act ('AMG'), concerning the use of patient care data and the electronic health card ('eHC') for research purposes, and concerning the relevance of the German Medical Devices Act ('MPG'). Available in the download area of the TMF website free of charge since 2008. The expert opinion is chiefly used for preparing other projects, for example, the revision of generic data protection concepts or the R&D project co-financed by the German Federal Ministry of Health ('BMG') concerning eHC applications in accordance with §291a SGB V. In Investigator Initiated Trials (IITs), pseudonymization management can be simplified by referring to the expert opinion. P039031

Legal expert opinion on electronic archiving
Legal expert opinion on the electronic storage of documents and files within the scope of clinical trials. Available in the download area of the TMF website free of charge since 2008. Used in a preparatory manner in order to further clarify legally compliant, low-cost archiving solutions for clinical research in Germany. P042011

Expert opinion on conventional file formats for electronic archiving
The electronic documents generated in clinical studies initially have various file formats, some of which are unsuitable for electronic archiving. The expert opinion evaluates numerous file formats with regard to their suitability for electronic archiving in clinical studies. P042021

Expert opinion on electronic archiving with CDISC-ODM
Nowadays the CDISC-ODM standard is generally accepted to be the global open standard for the exchange of clinical data and clinical metadata and it is also often regarded as being ideal for archiving existing clinical data and legacy data. The present expert opinion provides a necessary comprehensive analysis of the pros and cons of using the CDISC-ODM standard for archiving clinical data. P042031

Expert opinion on the cost-effectiveness of electronic archiving
Commercial analyses in this expert opinion are of a prospective nature with a view to the introduction of electronic archiving solutions and are tailored to the member networks of the TMF and comparable institutions. The focus is on the archiving of documents and files from clinical studies. P042041

Legal expert opinion, checklist, and specimen contract on electronic data custodianship
Description of the legal framework of electronically based data custodianship in networked medical research projects, together with a checklist and a specimen contract. Available in the download area of the TMF website free of charge since 2008. Based on the expert opinion results, other projects and available services of the TMF for networked research can be

planned and implemented. If reference is made to the expert opinion, it is possible to avoid having to engage the services of a Notary Public to ensure that stored patient data is protected from being confiscated, a precaution that has so far been required by data protection officers in certain cases. P052011 | P052012

Hosting and license granting for SAE software
Centrally hosted, client-capable software solution for the management and electronic reporting of Serious Adverse Events (SAEs) in clinical studies. The hosting software has been available at cost price since 2006 and as a result of a framework agreement with the software vendor there are reduced-rate licensing terms for members of the TMF. This service represents a low-effort, low-cost solution that meets all the regulatory requirements and can also support electronic reporting of SAEs to the superior government agencies. At the beginning of 2012, 17 licenses were being used in 8 TMF member networks. 8 sites were taking advantage of the TMF's hosting service. P999021 | P999031

Information stand accessories
Hire of banner displays and accessories for research network information stands at events. The materials have been available since 2006. They make it easier for research networks and member networks to participate in trade shows, events and specialist conferences with their own stand at low cost and thus support joint PR. P046011

Quiz software
Software for the creation of a quiz to test knowledge, for use at events with moderation or as a single station version. Available to members of the TMF since 2007. The software offers an entertaining way of communicating the technical content of research, which, since it is obtained through the TMF, represents a low-cost add-on to PR. P999011

Software for subjecting SNP genotyping data to quality control
repliCheckSNP: Software for subjecting SNP genotyping data to quality control when merging data from different sources or replicating genotyping studies. The software reads the analytical results made available by the various sources for a study in a standardized data format. RepliCheckSNP has 4 modules that handle the various QM measures:

- checkASSAY checks the accompanying genomic sequence (e.g. NCBI Build 37)
- checkBLAT aligns the accompanying sequence with the genome and determines the (+/-) strand.
- checkPOS checks the genomic position of the checkBLAT alignment.
- checkHWE checks the minor allele frequency and p(HWE) for consistency with HapMap data from the same population (e.g. CEU).

P999081

Accompanying form for genotyping data
Specimen form for the collection and transmittal of accompanying information when making genotyping data available. P999091

Catalog of fluorescence cluster types
Approved nomenclature for non-canonical fluorescence clusters of SNPs on Illumina genotyping chips. From the data of 980 DNA samples that were genotyped on the Illumina 550K Bead Chip the distinguishable cluster types were compiled in this document. In addition to the 'canonical' types with one cluster (only one allele or only one genotype), 2 clusters

and 3 clusters (homozygote for the first allele, heterozygote, homozygote for the second allele) 11 other distinguishable cluster types were defined. The enclosed catalog includes not only a description of the cluster type but also pictures of examples, in Cartesian and polar coordinates. P999101