

Workshop on Information Technology II

IT for clinical trial support

Monday, 01 / 28 / 2008
13:00 – 16:00 h

Conference room I, DKFZ,
Im Neuenheimer Feld 280, Heidelberg, Germany

13:00 – 13:45 h J. Drepper, A. Pollex-Krüger, S. Semler
(Berlin/Germany)

**TMF – A Common Platform for Medical Research Networks in
Germany**

13:45 – 14:30 h A. Fischer (Munich / Germany)
**Informed MACRO® - Electronic Data Capture
according to GCP**

14:30 – 14:45 h
Coffee break

14:45 – 15:30 h F. Meineke (Leipzig / Germany)
OncoWorkstation - Studymanager and Therapyplanner

15:30 – 16:00 h
General discussion



ELN IT Workshop, Heidelberg 28.01.2008

Abstract TMF

TMF – A Common Platform for Medical Research Networks in Germany

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. Starting as a telematics platform, TMF's mission is to harmonize and improve conditions for medical research in Germany, addressing demands for technical as well as legal and organisational solutions.

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

Project results, which have been developed into products and services of TMF are (selection):

- Hosting Service for remote access to specialized software (e.g. management and reporting of Serious Adverse Events (SAE))
- Checklists and online wizard for creation of informed consent documents
- Pseudonymisation and privacy tools
- Tools and training concepts for validation of IT systems according to GCP guidelines
- Analysis and reporting of clinical trials based on CDISC standards



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Infermed MACRO[®] - Electronic Data Capture according to GCP A. Fischer (Munich / Germany)

Clinical trials conventionally collect the patient's medical data by sending paper forms to the investigator and getting back bulks of paper. The medical information is then transferred from paper CRF into an electronic database by double entry procedure.

This method is now being displaced by EDC (Electronic Data Capture). The presentation sets EDC in contrast to paper-based data capture and recommends it as a progressive trial instrument.

The software MACRO[®] is a tool for capturing patient data in an electronical manner. It provides a modern and efficient as much as GCP according way of data management. Investigators at sites far away enter data in prepared eCRFs on the computerscreen. With data validation and plausibility checks the quality of data is improved instantly at inputting stage. Then data is transferred to the coordinating study center by use of a secure internet connection. With EDC the number of arising queries is extremely diminished.

MACRO[®] implements all requirements of good clinical practice, which every inventional clinical trial has to be compliant with. The presentation shows selected features of MACRO[®] that increase data quality and support trial staff by intuitive, convenient work flows.

ELN project 3 (CISC) offers MACRO[®] and supporting IT services to all trials conducted in cooperation with ELN.

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OncoWorkstation - Studymanager and Therapyplanner

F. Meineke (Leipzig / Germany)

We demonstrate a web-based system for definition, access and application of chemotherapeutic trial protocols and non trial based therapy schemes in adult and child oncology. It is designed as a link between trial centers, which may use it to define protocols in a standardized, recommended way, and clinical users, which may adapt these controlled recommendations e.g. with local standards in order to generate quality assured therapy plans - replacing inadequate spreadsheet or word processing solutions. It has been successfully introduced for use in adult oncology in a large hospital in Germany and different hospitals of the Competence Network on Pediatric Oncology and Hematology.

Workshop evaluation form:

Your feedback is critical for CICS to ensure we are meeting your educational needs. We would appreciate if you could take a few minutes to share your opinions with us so we can serve you better.

	Excellent	Very Good	Good	Fair	Poor	Not applicable
1. The program overall	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Information (Invitation, Confirmation) in the run-up of the workshop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Organisation of the workshop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Lecture: TMF – A Common Platform for Medical Research Networks in Germany J. Drepper, A. Pollex-Krüger, S. Semler (Berlin/Germany)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Lecture: Infermed MACRO® - Electronic Data Capture according to GCP A. Fischer (Munich / Germany)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Lecture: OncoWorkstation - Studymanager and Therapyplanner F. Meineke (Leipzig / Germany)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Too short		Right length		Too long	
7. Given the topic, was this workshop	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Introductory		Intermediate		Advanced	
8. In your opinion, was this workshop	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Yes		No			
9. Are you interested in a second ELN IT - Workshop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Which date do you favour?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	day before annual symposium 2009		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	day after annual symposium 2009		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other day		
11. Which topics do you favour?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pseudonymisation		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bioinformatics information system		
	Other topics, please specify:					
12. Other suggestions, please specify:						

Many thanks for your visit and your participation in the evaluation of the ELN IT Workshop. Please return this form to the instructor or organizer at the end of the workshop.