

EHB 2015 Invited Lecture

Exact Name

Thomas Martin Deserno, né Lehmann

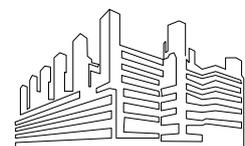
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Title

IT Support for Clinical Trials Approving Biomedical Technologies

Abstract

Controlled clinical trials are considered as adequate mean to prove effectivity of medical technologies. Following the FDA requirements, many European countries have regulated the marketing and use of medical technology accordingly, and software is considered as part of such technology. As of today, clinical trials are still performed separately from any medical information standard, and just recently, electronic data capture systems (EDCS) and clinical trial management systems (CTMS) have been established. However, any system interconnection is missing. In this talk, we share experience in developing, operating, and interconnecting CTMS and EDCS for both, clinical trials and medical registries, with particular focus image and signal data acquired in this trials. Merging picture archiving and communication systems (PACS), mobile recording, and smart technologies with electronic case report forms (eCRF) supports signal- and image-based biomarkers in medical technology development. Developed for the Clinical Trial Center Aachen (CTC-A), we have contributed interfaces that allow – for instance – photographic documentations of skin lesions, where a smartphone App records the image, transfer it to a server, and based on optical character recognition (OCR) technologies, the study subject is recognized and the data is transferred into the eCRF without being stored on the mobile device. In addition, automatic image processing is invoked via remote procedure calls (RPC), and results of data analysis are returned into the eCRF as image-based biomarkers. The architecture is based on Web services to exchange information coded according to the Clinical Data Interchange Standards Consortium (CDISC) operational data model (ODM).



Short Bio

Thomas M. Deserno (born as Lehmann) received the Diploma in electrical engineering, the PhD in computer science, and the habilitation in medical informatics from the RWTH Aachen University, Aachen, Germany, in 1992, 1998, and 2004, respectively. Since 2007, he is full professor at Uniklinik RWTH Aachen, where he is leading the Image & Data Management Group at the Department of Medical Informatics. His research interests include medical image processing applied to quantitative measurements for computer-assisted diagnoses and medical research in controlled clinical trials, mobile health, as well as seamless workflow integration of image and signal analysis into the user's workflow. He serves as Data Security Officer for the Clinical Trial center Aachen (CTC-A).

Dr. Deserno is senior member of the Institute of Electrical and Electronics Engineers (IEEE) and the Society of Photo-Optical Instrumentations Engineering (SPIE), where he is member of the Program Committee of the annually International Symposium of Medical Imaging (both, CAD and PACS tracks). He serves on the International Editorial Boards of Dentomaxillofacial Radiology, Methods of Information in Medicine, World Journal of Radiology, GMS Medical Informatics, Biometry and Epidemiology (MIBE), Acta Informatica Medica, and he is Co-editor Europe of the International Journal of Healthcare Information Systems and Informatics. In 2015, he became Associated Editor of SPIE Journal of Medical Imaging.

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