Digital Imaging and Electronic Data Capture in Multi-Center Clinical Trials

Thomas M. Deserno\textsuperscript{a}, Verena Deserno\textsuperscript{b}, Daniel Haak\textsuperscript{a}, Klaus Kabino\textsuperscript{a}

\textsuperscript{a}Department of Medical Informatics, Uniklinik RWTH Aachen, Germany
\textsuperscript{b}Clinical Trial Center Aachen (CTC-A), Uniklinik RWTH Aachen, Germany

Abstract

While medical image data is managed in picture archiving and communication systems (PACS) via the digital imaging and communications in medicine (DICOM) protocol, electronic data capture systems (EDCS) in clinical trials lack PACS interfacing. This complicates the trial workflow and increases errors, time, and costs. In this work, four system architectures of image integration for multi-center trials are analyzed with respect to data, function, visual, and context integration levels. We propose an open source-based architecture composed of OpenClinica, DCM4CHE, and Weasis for EDCS, PACS, and Viewer, respectively.

Keywords: Clinical Trials, Clinical Research, Imaging Biomarkers, Image-based Surrogates, Image Management System Integration, Workflow Integration

Introduction

Providing surrogate endpoints in clinical trials, medical imaging has become increasingly important in personalized medical research [1]. Electronic data capture systems (EDCS) are used to record research data while picture archiving and communication systems (PACS) manage subject’s imaging data. Despite the digital imaging and communications in medicine (DICOM) protocol, EDCS and PACS are currently not interconnected. Particularly in multi-center trials, manual data interchange yields errors, delays, and additional costs.

Materials and Methods

The clinical PACS is separated from the research PACS, where all DICOM data is de-identified but linked to the subject matrix and electronic case report form (eCRF) in the EDCS. For storage, the research nurse might operate in either system as the leading component. For retrieval, DICOM objects might be viewed via stand-alone DICOM viewer or integratively via Web-based browsers (Figure 1).

Using EDCS as primary system, there are four system architectures:

1. Image data are stored via EDCS as binary large object (BLOB). Retrieval may be supported via a Web-based DICOM viewer.
2. DICOM data are transferred via EDCS to the research PACS for storage, de-identification, and retrieval.
3. DICOM data are directly sent to the research PACS, and identifiers are handed back to EDCS’ subject matrix.
4. Results from manual or automatical image analysis are stored in the PACS (e.g., DICOM Structured Reporting).

Results

For Level 1, EDCS and viewer have to support BLOB and DICOM data, respectively. Level 2 requires DICOM functionality in the EDCS, and both PACS and viewer have to support web access to DICOM persistent objects (WADO). To accept DICOM objects in the PACS directly, appropriate links to EDCS are required. For Level 4, the viewer component must support advanced DICOM services yielding full data, function, visual, and context integration.

We suggest OpenClinica, DCM4CHE, and Weasis as open source components for EDCS, PACS, and Web viewer.

Discussion & Conclusions

The successive levels of EDCS/PACS integration provide increasing functionality in multi-center trials. At all levels, the EDCS is considered as primary system best supporting the research nurses’ workflow. This is in contrast to van Herk, who tightly integrates the medical PACS as primary system, transferring the DICOM identifiers into the eCRF [2].

References


Address for correspondence

Thomas Deserno, deserno@ieee.org, +49 241 80 88793