

# Workflow-based Integration of EDCS and PACS Supporting Image-based Surrogates in Clinical Trials

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## Introduction

Image-based surrogates became increasingly important in controlled clinical trials developing novel drugs and medical devices. However, there is as yet no structured way to collect digital imaging and communications in medicine (DICOM) objects in electronic data capture systems (EDCS), i.e., the trial database systems. Recently, van Herk obtained a tight connection of electronic case report forms (eCRFs) and picture archiving and communication systems (PACS) [1]. In this work, we suggest a workflow-based architecture integrating EDCS as the leading component.

## 1. Methods

OpenClinica (OC), one of the most common EDCS systems for clinical trials is used. In previous work, OC has been enriched by OC-Big to handle binary large objects [2]. The PACS selected is DCM4CHEE, again one of the leading open source systems. The research nurse logs into OC and enters the appropriate eCRFs. She sends patient's DICOM data to the EDCS using OC-Big. Here, the study-specific subject ID is already known and passed to the PACS along the DICOM data. After this, a token is sent back and stored in the eCRF. Clicking the link opens a web-based DICOM viewer, which fetches the image data via web access to DICOM persistent objects. Because of its superior functionality [3], we use the free medical viewer WEASIS.

## 2. Results

DICOM image handling is demonstrated in clinical trials embedding a PACS node into the EDCS. Full DICOM functionality is integrated in the EDCS and interaction with PACS is completely hidden for research nurse and radiologist. This includes hanging protocols and other basic DICOM services.

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### **3. Discussion**

In contrast to van Herk's architecture, DICOM data is instantaneously linked with the subject context of the trial. Having a DICOM node connected to the eCRF allows further integration of image post-processing, de-identification, search and structured reporting.

### **References**

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