Federal Ministry of Education and Research

OFFIS Health
INSTITUTE FOR INFORMATION TECHNOLOGY

swabik

SWABIK

Software Tools for the Exchange of Image Storage Media in Clinical Research (SWABIK)

This work is funded by the German federal ministry of research and education (grant 01 EZ 1023)

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3 Introduction

- Medical imaging plays an increasingly important role in extracting quantitative measurements for clinical trials.
- DICOM is used for the exchange of images for clinical use and research purposes.
  - Clinical routine: For patient care
  - Clinical research: For interchange of images in clinical trials
- DICOM storage media (so called patient CD/DVD) are usually used for the exchange of images in clinical trials.

4 Introduction: Clinical Trials

- DICOM provides a mechanism for identifying images acquired for subjects involved in clinical trials.
- In clinical trials, patient identification information needs to be removed
  - Protect patient's privacy
- However, certain information might be required to conduct a clinical trial analysis
  - For example, patient’s age or weight

5 Introduction: Definitions

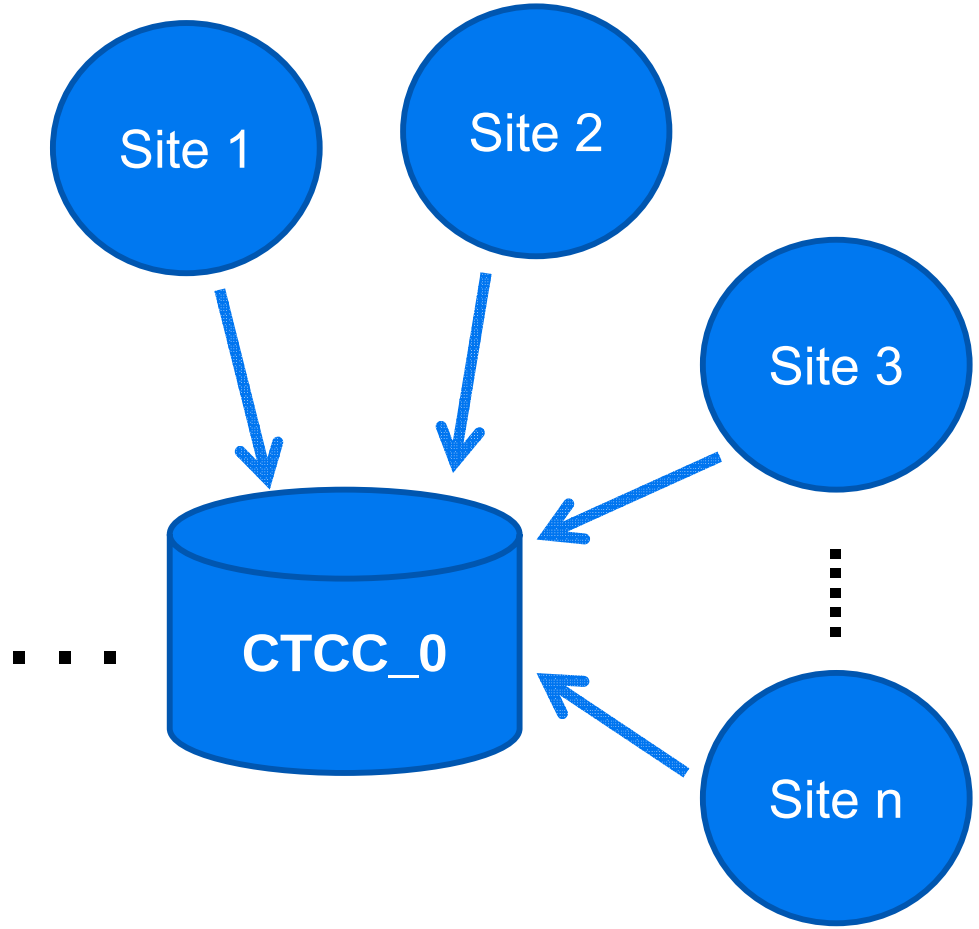
- **blind review.** Checking and assessing data prior to breaking the blind, for the purpose of finalizing the planned analysis. [Modified ICH E9]
- **clinical trial.** A research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device). [modified from ICH E6 Glossary, Directive 2001/20/EC] *Synonym: clinical investigation or study*.
- **protocol.** A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments. NOTE: Present usage can refer to any of three distinct entities: 1) the plan (i.e., content) of a protocol, 2) the protocol document, and 3) a series of tests or treatments (as in oncology). [ICH E6 Glossary]

6 Introduction: Definitions

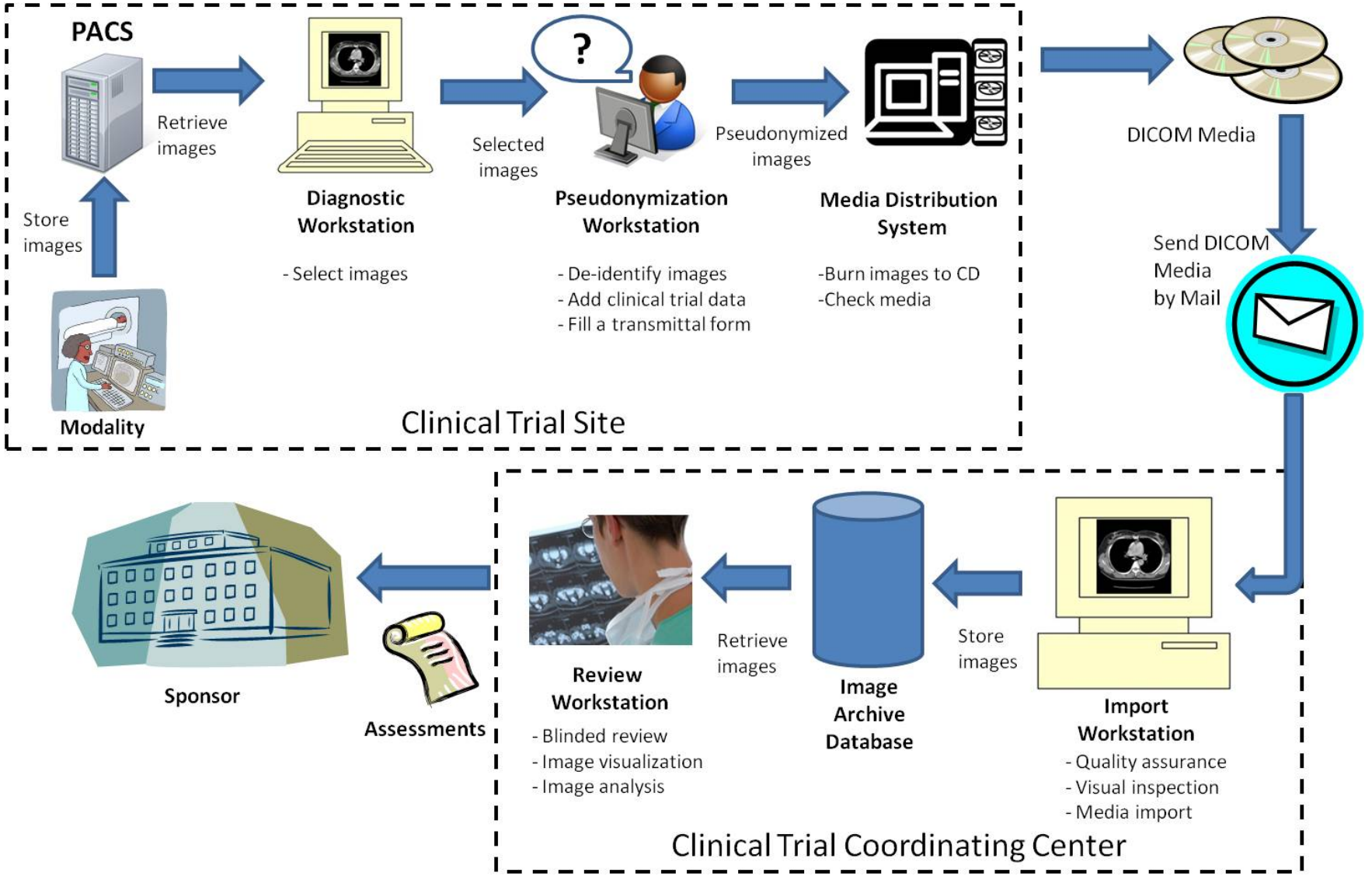
- **quality assurance (QA).** All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with good clinical practice (GCP) and the applicable regulatory requirement(s). [ICH]
- **quality control (QC).** The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled. [ICH]
- **clinical trial site.** identifies the institution where subjects' images are obtained and submitted.
- **clinical trial coordinating center (CTCC).** identifies the institution responsible for coordinating the collection, management, processing, and/or analysis of images of subjects in a clinical trial.
- **investigator.** An individual who actually conducts a clinical investigation.

7 Clinical Research: General Workflow

- The workflow depends on the trial setup
- Clinical trial sites are responsible for assembling images, pseudonymization and sending DICOM media to a central facility.
- Multiple CTCC could be involved in a clinical trial.
- A transmittal form is attached to each submitted DICOM medium to inform the recipient about the type of medium content and to provide information about the subject and the protocol in which the patient is enrolled.



8 Clinical Research Workflow: A Use Case



9 Motivation

- DICOM CDs sometimes unreadable
  - Many reasons, e.g: viewer install problems, DICOM format errors, DICOM image compression, ...etc.
- Problem of exchanging DICOM media addressed by DRG certificate project for clinical routine (www.dicom-cd.de)
  - However, not for research context!
- Already DICOM CD testing tools available, but
  - Might show hundreds of errors for a single CD

  -> Inappropriate for doctors, nurses or even hospital‘s IT staff

10 Aim of SWABIK

- Supporting exchange of DICOM storage media in clinical research
- Best-practice guidelines for supporting users who are creating and importing DICOM media in the clinical trials context
- Development of standardized software tools for
  - Creating pseudonymized patient CD
  - Importing of clinical trial DICOM media into image archives (PACS)
  - Checking media for quality assurance

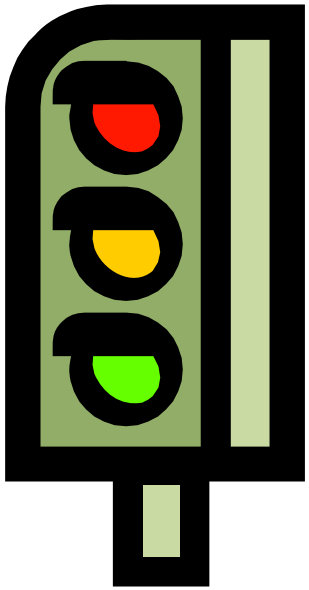
11 Aim of SWABIK: Import and Export Tools

- For DICOM Storage Media Export:
  - Mark and collect images
  - Pseudonymize images
  - Add clinical trial data attributes
  - Burn patient CD
  - Check media
- For DICOM Storage Media Import
  - Check media
  - Import media to PACS

12 Aim of SWABIK: A Tool for Quality Assurance

- DICOM media validation results to be shown in an adequate and comprehensible format

- Different features conceivable:
  - Simple traffic light (green, yellow, or red) indicating probability to run on other systems
  - Indication maybe depending on designated use (i.e. visualization, statistics from specific DICOM fields, etc.)
  - Show error details if desired



13 Software Requirements

- Freely available for download
- Open source
- Simple to use (also for doctors or other hospital staff)
  - User manual
- Flexibility
  - Should be configurable to support different types of clinical trials
- Portability
- Cross-platform (Windows, Linux, Mac OS X, ...etc)
  - Based on DCMTK and QT
  - No other significant external dependencies (“.Net framework”, Java, …)
- Maintainability
  - Extensible in the future
  - Decent source code documentation

14 Timeline

Milestone Number	Deadline	Work Package
MS1	2010-11-30	WP1: Best-practice guidelines
MS2	2011-03-31	WP2: Concept for selecting Images for export
MS3	2011-07-31	WP3: Concept for de-identification
MS4	2011-11-30	WP4: Concept for labelling clinical studies
MS5	2012-01-31	WP5: Concept for composing storage media
MS6	2012-04-30	WP6: Concept for quality assurance
MS7	2012-06-30	WP7: Tool for DICOM Media export
MS8	2012-08-31	WP8: Tool for DICOM Media import

- Project start: 1st September 2010
- Runs for two full years

15 Project Partners

Federal Ministry of Education and Research

- SWABIK is funded by the German federal ministry of research and education (grant 01 EZ 1023)
- Two project supporting organizations:
  - Working Group Information Technology (AGIT) of the German Society of Radiology (DRG)
    - Focuses on the support, development and dissemination of standards (DICOM, IHE, …) and recommendations for information exchange and workflow in radiology
    - Pre-work together with OFFIS in DICOM CD certification (http://www.dicom-cd.de)
  - Network of Coordinating Centers for Clinical Trials (KKS Network)
    - Initiated by the Federal Ministry for Education and Research (BMBF)
    - Forms platform for transparent, patient-oriented development of new drugs and therapeutic principles
    - Provides various clinical trial coordination centers
    - Comprehensive advice and support for planning, conducting and evaluating clinical research projects

16 References

- DICOM Standard http://medical.nema.org
- Integrating the Healthcare Enterprise (IHE) http://ww.ihe.net
- DICOM supplement 142: „Clinical Trial de-identification profiles“
- DICOM supplement 70: „Clinical Trial Identification“
- The DRG Certificate Project http://ww.dicom-cd.de
- AGIT Association of DRG: http://www.uni-mainz.de/FB/Medizin/Radiologie/agit/Welcome.html
- KKS-Network: http://www.kks-netzwerk.de
- SWABIK project website: http://www.dicom-cd.org
- Clinical Research Glossary http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/CRO%2FSponsor/CDISC-Clinical-Research-Glossary/ArticleStandard/Article/detail/648647?contextCategoryId=44907