

Management of Image Collection, Quality Assurance, and Archiving in Multi-Center Clinical Trials

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ABSTRACT

For several years, we have managed image collection, quality assurance, and archiving for 4 NIH-sponsored multi-center clinical trials: Polycystic Kidney Disease (PKD) CRISP Trial (4 centers; 960 MR exams, 240 US exams; completed 2005); "Halt PKD" Trial (7; 1000 MR exams; 2006-2009); Silent Infarct Imaging Trial (28; 2,000 MR exams (projected); 2004-2009); National Lung Screening Trial (12; 48,000 CT exams; 2005-2007). While the trials, their centers, and their goals bear few similarities, the software and procedures implemented to manage the image activities are common. With very little trial-specific customization, these image management methods can be implemented in other trials.

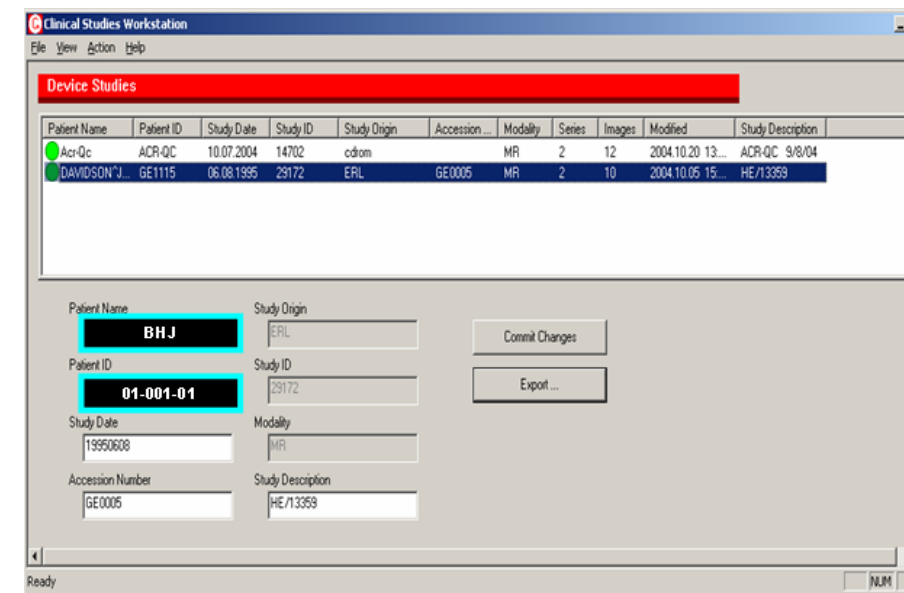
Each imaging site is provisioned with a laptop preloaded with virtual private network (VPN) and de-identification software (CSW) bundled with a GUI to facilitate exam harvesting from local archives and preparing DICOM format data for secure Internet transmission (VPN). Open source software packages facilitate data check-in, quality assurance, archiving, and workflow. Both reader studies and quantitative measurement protocols have been supported.

THE IMAGING CORE OF A MULTI-CENTER TRIAL PERFORMS A NUMBER OF FUNCTIONS:

- Image capture and accumulation
- De-identification and secure image and meta-data transport
- Quality Assurance and protocol compliance
- Workflow management
- Quantitative image analysis and/or human observer studies
- Collection, analysis, storage and distribution of imaging results

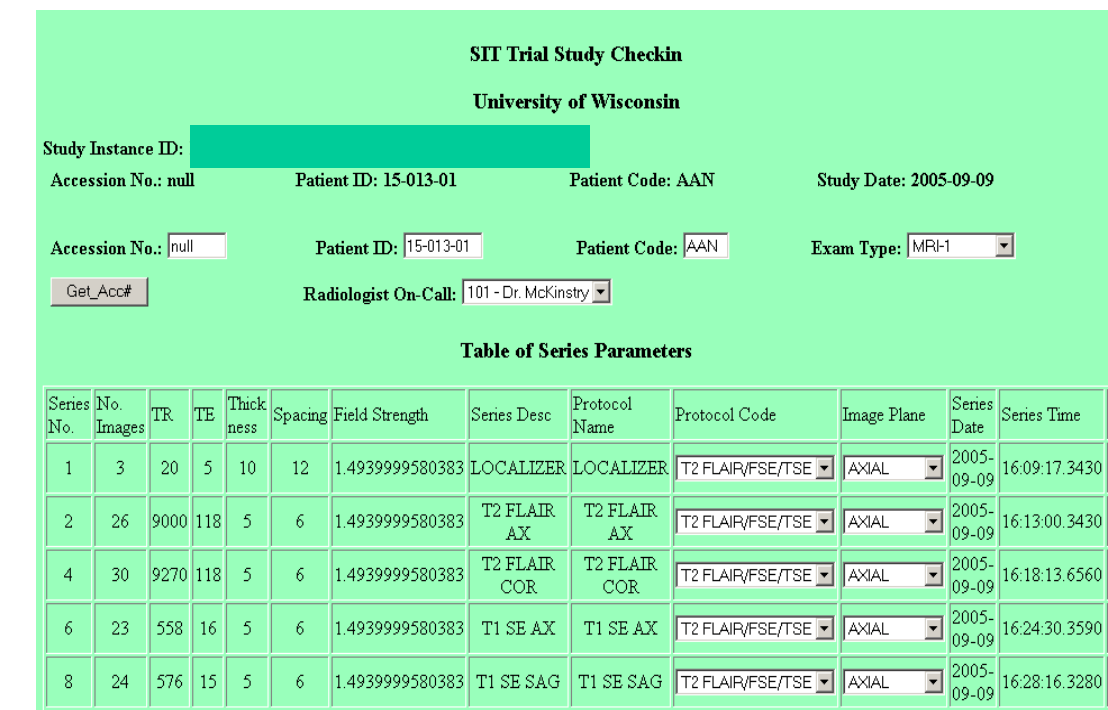
CSW SOFTWARE ANONYMIZES & TRANSFERS IMAGING STUDIES

- DICOM Image capture from modality or PACS
- PHI removal and insertion of Trial Specific Identifiers
- Secure Transmission to the Imaging Core via VPN over the internet



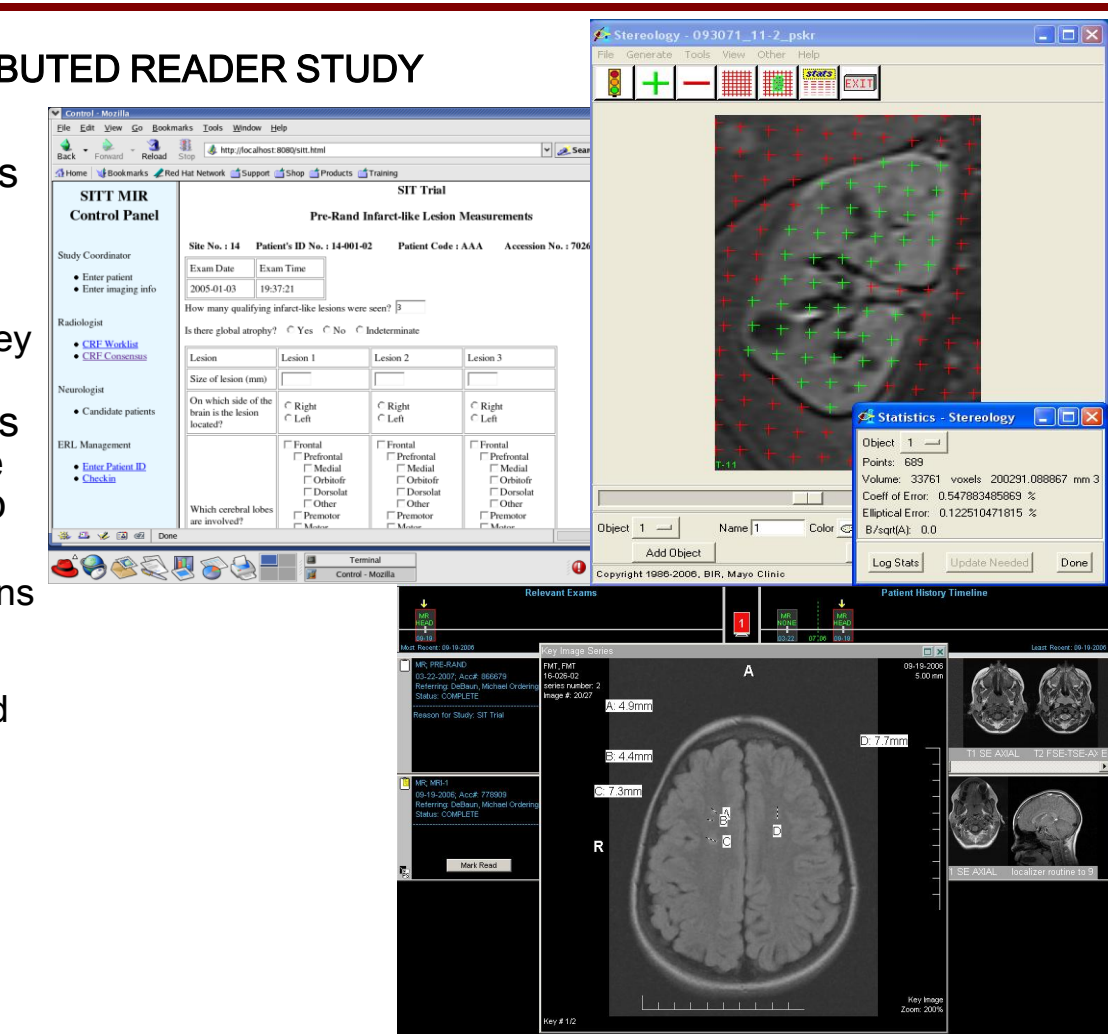
WHEN A STUDY ARRIVES AT THE IMAGING CORE

- Study Check-in
 - Checked for proper Site code and ID
 - Checked for PHI
 - QA process:
 - All series present
 - Correct imaging protocols used
 - Full anatomy captured
 - No obvious obscuring artifacts
- Transmitted to image server
- Assigned to radiologist or analyst for processing

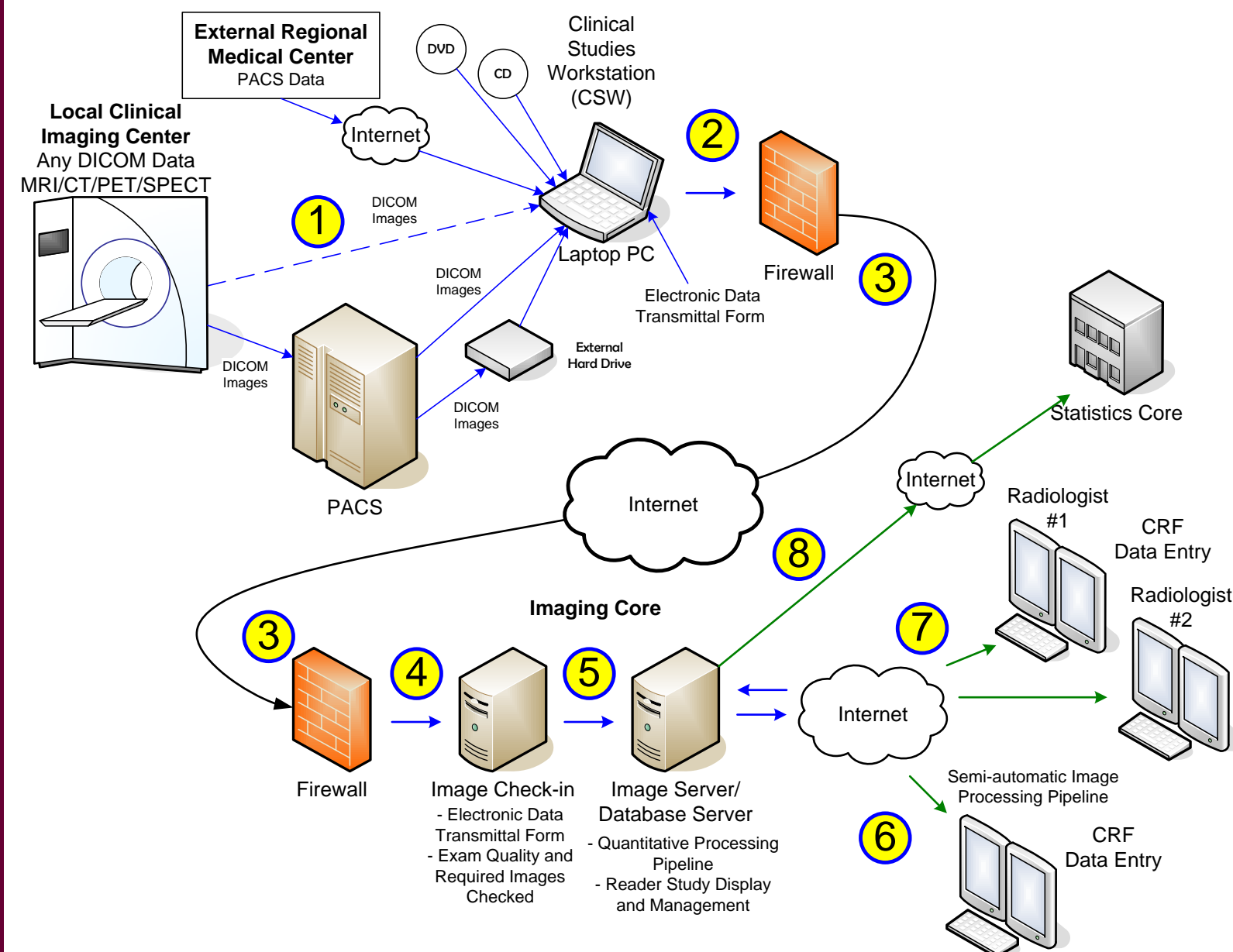


QUANTITATIVE ANALYSIS OR DISTRIBUTED READER STUDY

- Images may be routed to analysis pipelines for detailed quantitative analysis
 - For example: volumetric determination of Polycystic Kidney Disease lesion burden
- Blinded consensus reader studies are also supported by routing the images after QA checks to a web based research PACS
 - Radiologists at multiple institutions read each case independently, then confer to reach consensus
 - Presentation state objects record the independent determinations and the consensus
 - Web based Case Report Forms capture detailed results and document findings.
 - For example: Silent Cerebral Infarcts in Sickle Cell patients



IMAGING TRIAL MANAGEMENT SYSTEM AND DIGITAL WORKFLOW



1. DICOM images are sent to the Clinical Studies Workstation (CSW) either directly from the modality or a picture archiving and communication system (PACS) or via DVD/CD or external hard drive at a Local Clinical Imaging Center. Data from an External Regional Medical Center can also be transmitted to the CSW.
2. The CSW software modifies the DICOM header to remove protected health information and adds unique trial specific identifier information.
3. Images are transferred across a virtual private network (VPN) connection to a DICOM receiver software located in the Imaging Core.
4. The DICOM study and an Electronic Data Transmittal Form are received and checked for image quality and the required number of series/images.
5. Studies that pass quality assurance tests are uploaded to the image viewing and database system.
6. Results may be produced by semi-automatic image analysis and measurement procedures and input into Case Report Forms (CRFs), OR
7. One or more radiologists use VPN connections to remotely access the image viewing system and input data in the CRFs.
8. The Imaging Core organizes the results and sends the data electronically to the Statistics Core.

CONCLUSIONS

- CSW software pre-installed on a laptop is easily distributed and installed and facilitates digital image capture, de-identification and transmission.
- Flexible, reprogrammable data check-in and quality assurance software combined with trial specific procedures is effective and efficient.
- Web based case report forms and a dedicated, web-based research PACS permit efficient and secure management of distributed reader studies.
- Digital image management facilitates quantitative image analysis.

REFERENCES

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2. Clark KW, Gierada DS, Moore SM, Maffitt DR, Koppel P, Phillips SR, Prior FW, "Creation of a CT Image Library for the Lung Screening Study of the National Lung Screening Trial", J Digit Imaging , 20(1): 23-31, 2007.