Exhibit : LL-IN3115

RMS: A Workflow and Information Management Solution for Translational Research

Fred Prior[1], Lawrence Tarbox[1], Stephen Powell[2], Steve Moore[1], David Perry[2]

[1]Dept. of Radiology[1] Washington University in St. Louis, MO, USA, [2]Eastman Kodak, Summerside, PEI, Canada

LEARNING OBJECTIVES

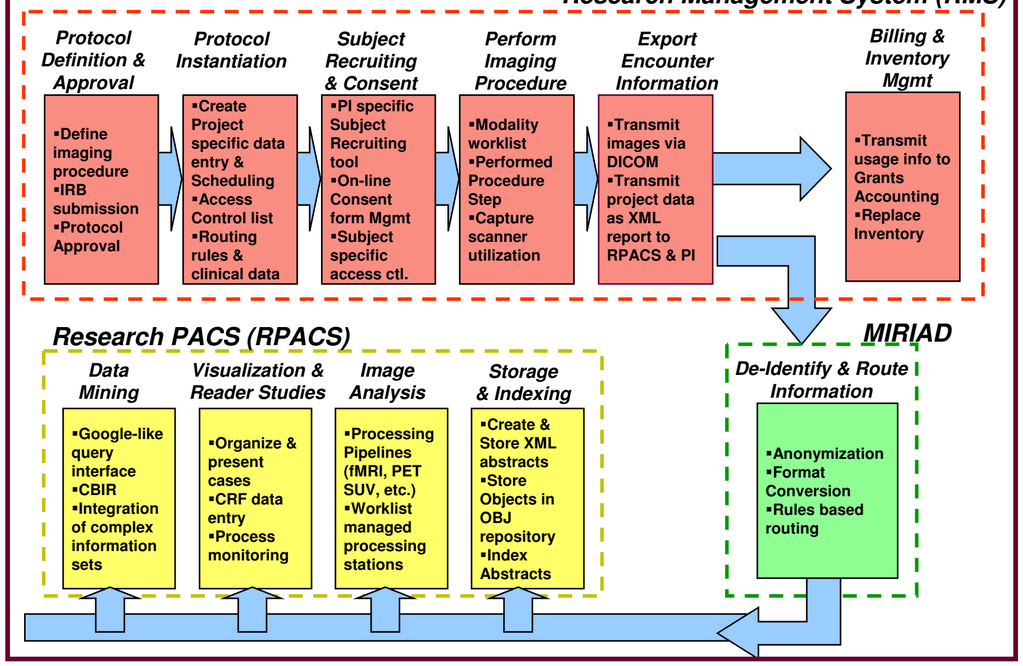
1) Describe the "standard" workflow model for image based translational research.
2) Demonstrate the information management functions we have developed to support this workflow.
3) Demonstrate examples of augmented content (e.g. protocol specific reports and data entry).

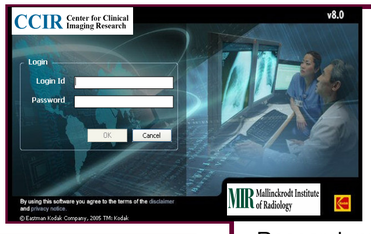
ABSTRACT

Research workflow differs from clinical practice. Imaging procedure scheduling and image acquisition may be similar, but each specific research project has these additional requirements: documentation of a research protocol, subject recruitment, informed consent, anonymization, information distribution, and analysis. A research imaging facility also requires management functions such as inventory control and billing services that differ from their clinical counterparts.

A Research Management System (RMS) capable of supporting these functions is not commercially available; however the Kodak Carestream RIS provides a unique platform for the development of an RMS. It is designed to be easily reconfigured to address new applications. All graphical user interfaces can be redesigned using a tool-kit included in the product and it is easy to extend the database schema. Starting from this platform we have created a prototype RMS that is currently in beta test at Washington University.

CCIR WORKFLOW MODEL



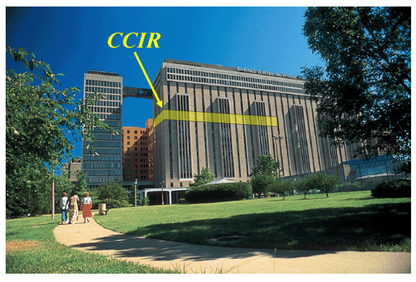


RESEARCH MANAGEMENT SYSTEM

Developed under a research partnership with Eastman Kodak, the RMS is based on the Carestream Radiology Information System. The unique architecture of Carestream RIS makes it easy to adapt to this new application domain. Additional functions such as research protocol management have been added as web services. The Primary RMS Functions include:

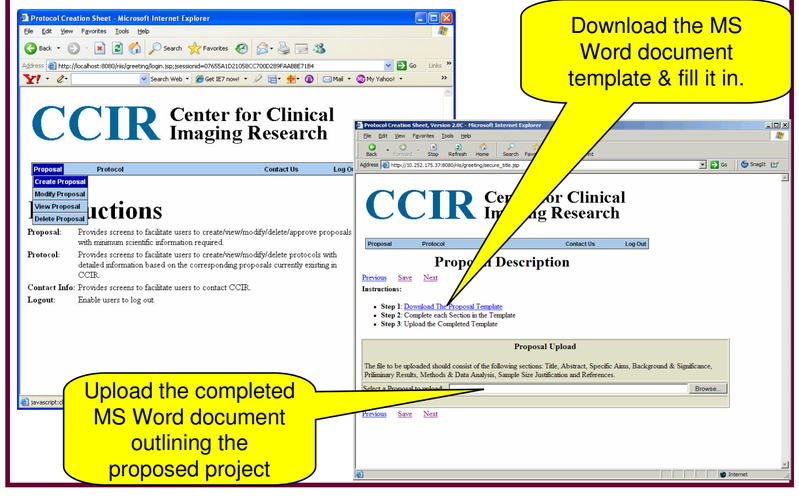
- Research protocol creation
- Subject consent management
- Subject registration
- Protocol Specific Scheduling
- Protocol Specific data capture (e.g. CRFs)
- Billing to Grants Accounting
- User Account Management
- Integration with eIRB and CTMS
- Research protocol management
- Subject consent management
- Research Master Subject Index
- DICOM Modality Worklists
- Speech to Text Digital Dictation
- Billing to Hospital via CTMS
- Access Control
- Inventory Management

CENTER FOR CLINICAL IMAGING RESEARCH



The pace of biomedical imaging research and the use of imaging based biomarkers are rapidly increasing. Unfortunately, clinical and translational investigators are frequently unable to make full use of imaging technologies because of limited access to imaging modalities, unfamiliarity with the latest imaging techniques and the complexity of image analyses. The Center for Clinical Imaging Research (CCIR) at Washington University School of Medicine has been designed to eliminate these barriers. Located in an 8,900 square foot space on the 10th floor of the Barnes-Jewish Hospital, CCIR will dedicate six, state-of-the-art imaging modalities to the support of clinical and translational research. A dedicated staff and a unique information technology environment provide researchers the tools and support they need.

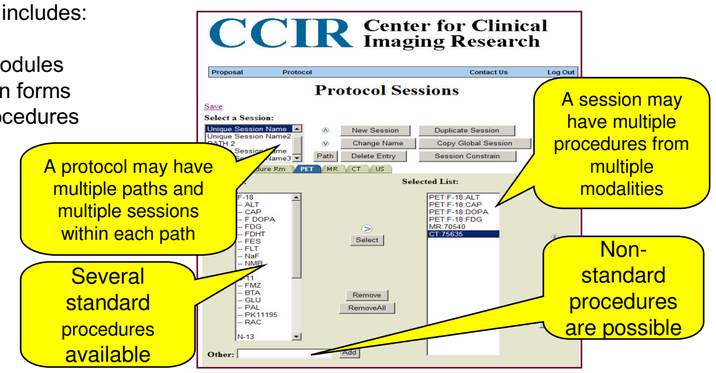
RESEARCH STUDY PROTOCOL CREATION



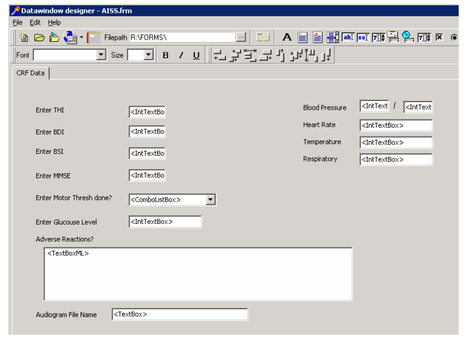
INSTANTIATING A RESEARCH PROTOCOL

The PI or Study Coordinator will use the RMS to describe their experiment & the data to be collected. This information is needed to set up CCIR IT infrastructure and data entry forms and it forms the basis for 'recipe book' to guide CCIR technologists. The PI may use pre-defined or custom protocols. Once this information has been gathered the PI will work with a CCIR Protocol Instantiation Expert to complete a one-time instantiation of that research protocol. Instantiation includes:

- Set up scheduling modules
- Define data collection forms
- Outline scanning procedures
- Create routing rules & data formats
- Define access rules
- Set up processing & analysis pipelines



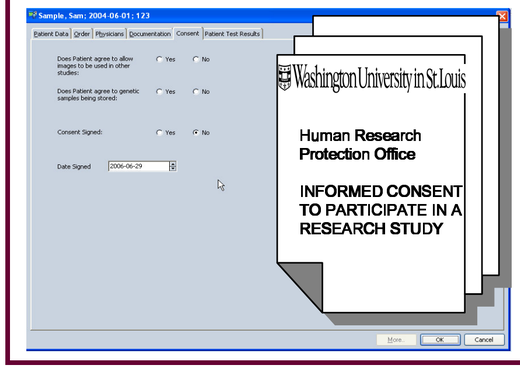
RE-ENGINEERING: FROM RIS TO RMS:



FrmDesigner

The user interface of Kodak's Carestream RIS can be easily modified using a graphical form design package. New protocol specific data entry screens can be custom designed for each project with fields tied to new tables and attributes in the database. A totally new workflow model can be implemented, making use of RIS functions where appropriate (e.g. scheduling) and adding totally new functions, (e.g. consent management). All data captured in CCIR is returned to the PI in XML or Text format.

CONSENT MANAGEMENT



Approved consent forms are down-loaded from the eIRB system and stored in the RMS database. They can be printed, signed, and scanned back into the system, or signed electronically. The RMS permanently stores all consent forms and automatically disables subject scheduling when the IRB approval elapses. Key information from the consent form is captured by the consent management screen and is used to control access to this subject's information.

CONCLUSIONS

- An imaging center dedicated to clinical and translational research has workflow & information management requirements that differ substantially from the clinical norm.
- A Research Management System can be designed to facilitate research workflow and automate many administrative and procedural tasks
- Modifying a clinical RIS for this new environment allows us to retain common solutions such as scheduling and yet adapt them to the new domain.
- The solution is robust, and flexible to meet the needs of a very dynamic research environment
- For an overview of all of the IT solutions being designed for CCIR see our companion electronic poster: Abstract ID: 4435904