

**Imaging Informatics Needs in
Clinical Research**

OR

**How to Use Informatics to
Better Orchestrate Clinical
Research**

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Assumptions

- # The potential of imaging is not being realized
- # Informatics could assist in extracting greater value from imaging in clinical research

Informatics Questions

- # What kinds of translational research projects will be enabled or facilitated by an improved imaging informatics infrastructure?

Informatics Questions

- # What kinds of translational research projects will be enabled or facilitated by an improved imaging informatics infrastructure?
- # What are the gaps in research imaging informatics infrastructure, tools or systems to accomplish #1?

Categories of Gaps

- # Design of the Experiment / Study
- # Acquisition of images
- # Collection of images
- # Verification of images
- # Processing & Measurement of image metrics
- # Study Management



Gaps: Experiment Design

- # Modeling of the experiment
 - # Information models and lexicons to assure data is collected in a fashion that won't impede getting an answer



Gaps: Acquisition

- # Can informatics help select the most informative images?
- # Can informatics help assure collection of the proper images?
- # Can informatics help assure proper operation of the imaging devices?

Gaps: Collection

- # Most investigators have built their own tools to collect images.
- # Lack of universal IRB acceptance of electronic data transmission
- # Challenge to configure and maintain electronic transfer infrastructure (DICOM, firewalls)

Gaps: Verification

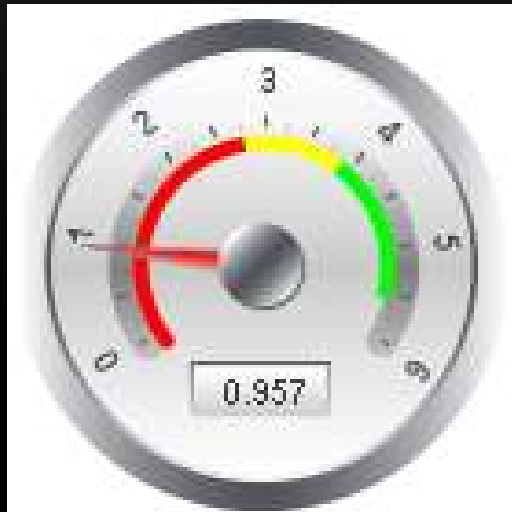
- # Tools to automatically detect scanner malfunctions (phantoms)
- # Tools to assure correct imaging parameters
 - # Need for a language to describe an imaging protocol
 - # Need for equivalence of data across vendors and software upgrades

Gaps: Processing & Measurement

- # Wonderful tools exist, but...
 - # Many are very task-specific
 - # Others are general and require significant expertise to tailor to a specific problem
- # If tools are not open source, tailoring may be a larger challenge
- # Many tools are not FDA certified, which can make it more challenging to submit data for approval of agent by FDA

Gaps: Study Management

Dashboard on status of study



% exams collected



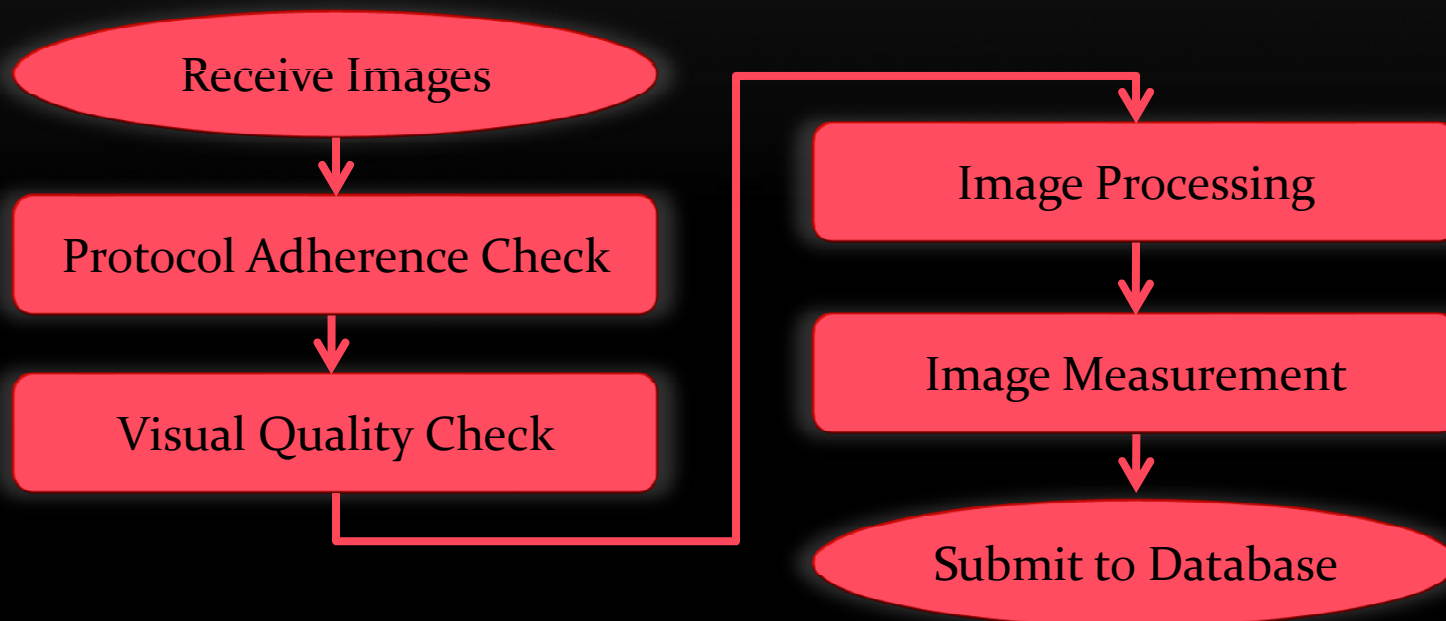
% exams processed



% approved/reported

Gaps: Study Management

- # Dashboard on status of study
- # Workflow to assist in efficient execution



Gaps: Study Management

- # Dashboard on status of study
- # Workflow to assist in efficient execution
- # Need for protocol description language describing steps
(Perhaps in Business Process Execution Language?)

Other Pieces

- # Security—patient privacy, researcher property protection
- # Standardization—develop a common process that FDA finds acceptable would be more efficient

Plan for this Session

- # Vignettes of image-based clinical research
 - # Look for common problems and solutions that have been or might be used
 - # What pieces seem most challenging to address
- # Will then discuss these to see if we can reach some agreement on the list

