NORTHWESTERN
UNIVERSITY

Addendum I:
More about FDA
The actual grant application

Pattanasak Mongkolwat PhD
Research Associate Professor of Radiology

David S. Channin MD
Associate Professor of Radiology
Chief, Imaging Informatics

FDA Issues and Ideas

- "Base workstation" has clinical mode (FDA 510K)
- Switches to research mode on demand
  - Clearly marked to user
  - Automatic de-identification
  - Some users can only be in research mode
    - Site determination / IRB
- DICOM WG23 plug-ins: 2 kinds
  - Approved (Vendor/FDA)
  - WIP (works in progress)
    - Only available in research mode

FDA Issues and Ideas: Process

- Current **NA-MIC/vTK/iTK** builds/dashboards, etc.
  - **NECESSARY** but not **SUFFICIENT**
- Must extend robust process back to design
  - UML? Sparx Systems Enterprise Architect?
- Goal: Introduce process to **FDA** stepwise
  - Versus at end of development
- Goal: Freeze base workstation and take changes through **FDA** within 90 days

The Grant

- 1R01-124379-01

  "A Translation Workstation for Cancer Research Imaging"

- Submitted: January 17, 2006

- Pending Review: July 2006 (Yikes!)

- Assigned:
  - NCI
  - NIBIB
  - Roadmap Intitiatives
  - NIGMS

The Team

- Northwestern
  - Pat Mongkolwat PhD
  - Alex Kogan
  - 2 x SW Engineer TBD
  - 2 x Grad Students TBD
  - 1 x Undergrad TBD
- Isomics
  - Stephen Pieper PhD
  - Alex Yarmarkovich PhD

Two Specific Aims

1. Enhance **NA-MIC**'s flagship software Slicer with:

    1. Clinical functionality

    2. Standards based interoperability

2. Test the null hypothesis:

    There is no difference in the time it takes a diagnostic radiologist to perform a set of tasks related to interpreting a lung cancer imaging research study using a state-of-the-art commercial workstation and the time it takes to perform the same tasks on the enhanced Slicer workstation.

Clinical Functionality

- Authoring tool for DICOM S/R objects
- Basic medical image display and manipulation
  - All 17 DICOM image objects (!)
  - Mapping DICOM objects directly into Slicer model (Isomics)
- DICOM WG23 support
- Hanging Protocols
- Annotation and Measurement
- Normal and Structured Reports (dictation out of scope)
- Security and de-identification

IHE Interoperability

- IHE Consistent Presentation of Images

- IHE Reporting Workflow

- IHE Key Image Note

- IHE Teaching File and Clinical Trial Export

- IHE Evidence Document (for SIAM)

- IHE Audit Trail and Node Authentication

Can we improve the research process?

- Give accession number to radiologist
- Retrieve study from worklist
- Retrieve historical case
- View current study
- View historical study
- Measure mass in new study

- Measure mass in old study
- Dictate report
- Export images from PACS
- Load study into 3D workstation
- Perform volumetric calculation of mass
- Dictate research report (from template)