Addendum I:
More about FDA
The actual grant application

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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 Initiatives
  – 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)