Update:

ACR Core Lab's Trials and Development Involving Response Evaluation Criteria In Solid Tumors (RECIST) Measurements

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ACR Imaging Core Laboratory

Strategically Located at the ACR's Clinical Research Facilities in Central Philadelphia and Supports:

QRRO
QUALITY RESEARCH IN RADIATION ONCOLOGY

ACRIN™
AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK

RTOG
RADIATION THERAPY ONCOLOGY GROUP

ACR IMAGE METRIX™

RECIST Overview:

- RECIST working group:
  - International in membership: NCI, NCRN-UK, EORTC…
  - Clinical researchers from industry, imaging experts and Cooperative Groups

- Intended for use in clinical trials with primary endpoint of objective treatment response

- Prospectively collected tumor measurement data from clinical trials: >6500 patients, >18,000 lesions

- Tumor burden assessed by summing longest diameters of all measurable lesions (unidimensional)

RECIST 1.0 and 1.1

Feature	RECIST 1.1	RECIST 1.0
Acceptable target lesions	• Target: ≥ 10 mm *	• Target: ≥ 10 mm spiral • Target: ≥ 20 mm non-spiral
	• **Target LN** ≥ 15 mm short axis • **Non-target** LN < 15 mm and ≥ 10 mm	• LN Not mentioned
Overall tumor burden	• **5 lesions (2 per organ)**	• 10 lesions (5 per organ)
Response target lesions	• CR: **LN < 10 mm short axis** • PD: 20%↑ from smallest sum on trial ***AND*** **≥ 5 mm** ↑ or new lesion	• CR: LN not mentioned • PD: 20%↑ from smallest sum on trial or new lesion
Response non-target lesions	• Unequivocal change representative of overall status	• Unequivocal progression

Assumes slice thickness ≤ 5 mm

Objective Response

Response	Criteria
CR	All target lesions disappear. All non-target lesions disappear. **All LN must reduce in size to < 10 mm short axis**
PR	≥ 30% decrease in sum of diameters of target lesions, taking as reference the *baseline sum*
PD	≥ 20% increase in sum of diameters of target lesions, taking as reference *the smallest sum* on study. **Sum must increase by an absolute ≥ 5 mm.** Unequivocal non-measurable Dz and new lesion is also progression.
SD	Neither PR nor PD, taking as reference the smallest sum diameters on study.

CR = complete response
PR = partial response
PD = progressive disease or death
SD = stable disease

Rationale for Tumor Volumetry

- Tumors not all spherical
  - Planar measurements do not reflect volumes
  - Primary lung neoplasms in particular
- Tumors may not change size symmetrically
- Observer variability
- Are four categories of response sufficient?

Volumetric Issues

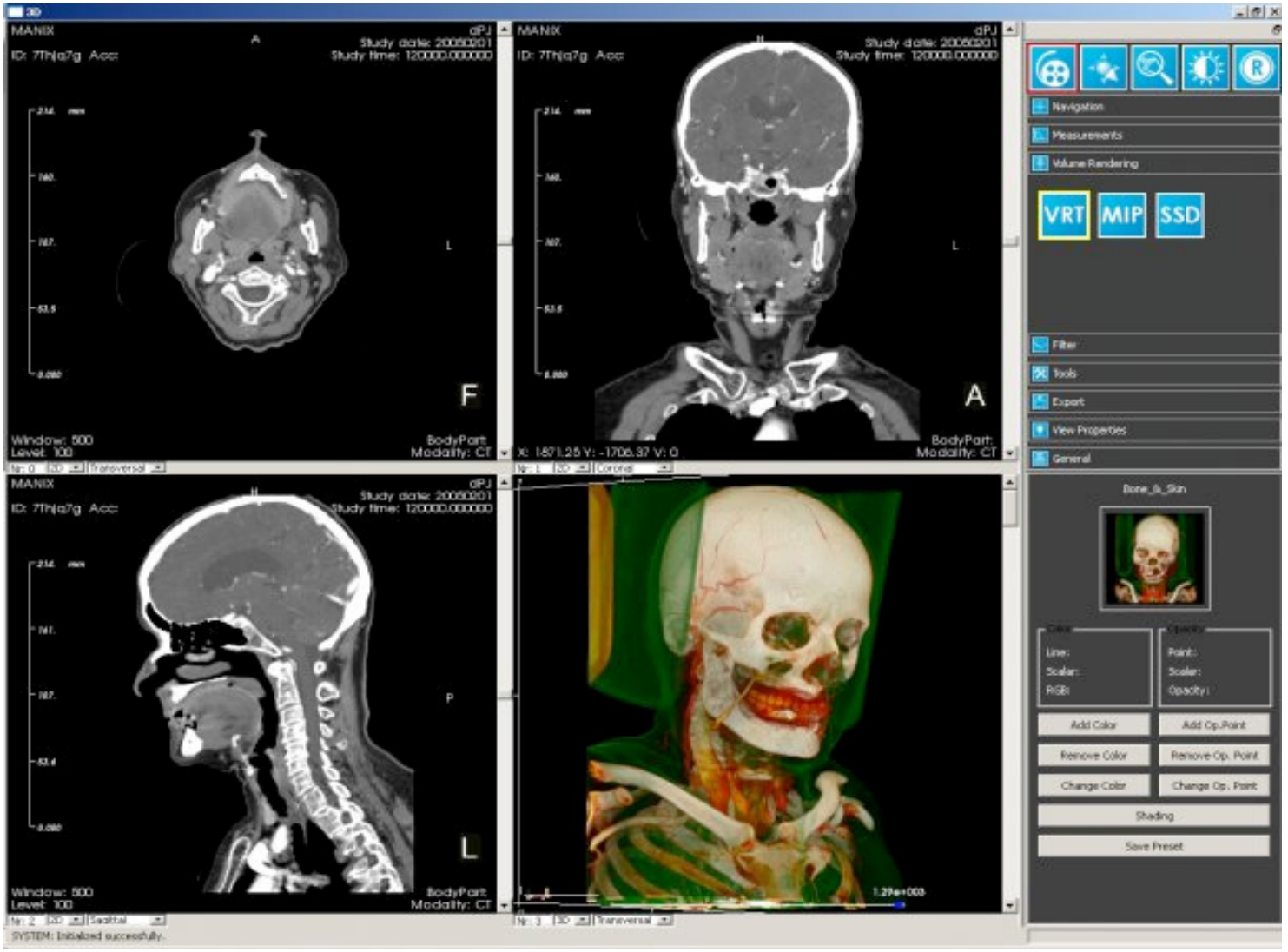
- Section thickness (Weiner-Muram)
  - Slice thickness: range 2-10 mm
  - Difference = 20% overall | 36% for smallest tumors
- Scanner type & isotropic resolution
- Partial volume effects → overestimation of true volume
  - Segmentation algorithm
  - Reconstruction kernel
  - Patient factors (breath-hold, motion)

Gavrielides MA, et al. Radiology 2009; 251:26-37.

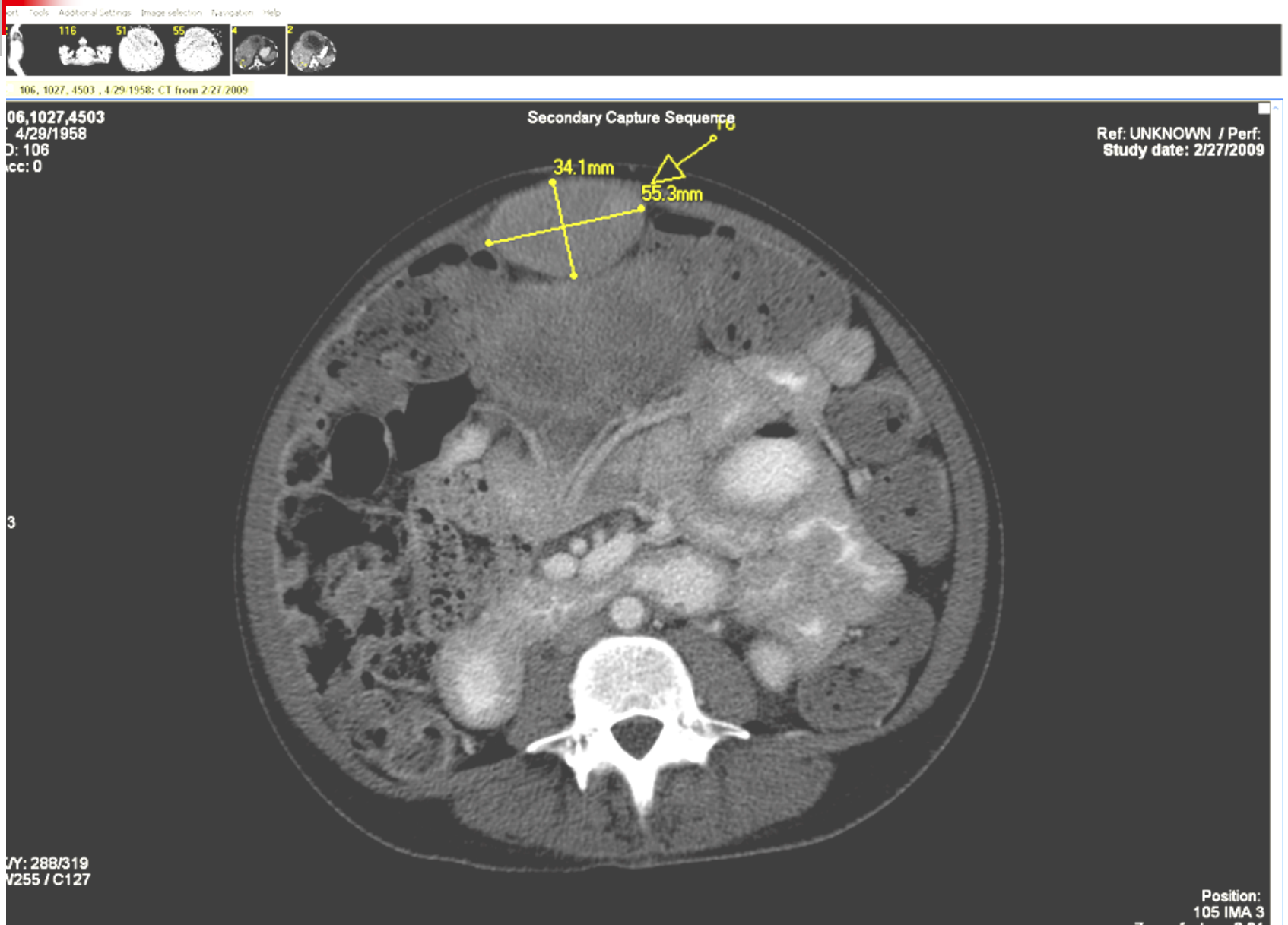
Future directions for Volumetry

- Realistic phantoms for ground truth
- Monte Carlo simulations to generate images with systematic variations in acquisition, nodule characteristics
- Use of image registration and analysis
- Image libraries (LIDC | RIDER | NLST)
- QIBA (Quantitative Imaging Biomarkers Alliance) to define application-specific acquisition protocols

RECIST @ ACR Core Lab



RECIST @ ACR Core Lab



Core Lab's RECIST FORM

R1

ACRIN 4503
RECIST MEASUREMENT FORM

If this is a revised or corrected form, please √box. ☐

ACRIN Study 4503
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

Baseline: ☐	Exam Date: ____-____-____	Gender: ☐ M ☐ F
Follow-up: ☐ _____ weeks	Modality: ☐ CT ☐ MRI	
	Area / Slice thickness: ☐ Head ____ mm ☐ Abdomen ____ mm ☐ Neck ____ mm ☐ Pelvis ____ mm ☐ Chest ____ mm ☐ Other ____ mm _____	Interpretation Date: ____-____-____

Lesion #	Organ	Site Description	LN	Targeted	New Lesion	InD	Phase on Contrast	Series #	Image #	Long Axis (mm)	Short Axis (mm)	W/L	Interpretable Measurable Y / N
1			☐	Y N	☐	☐	N A P D NA					B L ST LI	
2			☐	Y N	☐	☐	N A P D NA					B L ST LI	
3			☐	Y N	☐	☐	N A P D NA					B L ST LI	
4			☐	Y N	☐	☐	N A P D NA					B L ST LI	
5			☐	Y N	☐	☐	N A P D NA					B L ST LI	
6			☐	Y N	☐	☐	N A P D NA					B L ST LI	
7			☐	Y N	☐	☐	N A P D NA					B L ST LI	
8			☐	Y N	☐	☐	N A P D NA					B L ST LI	
9			☐	Y N	☐	☐	N A P D NA					B L ST LI	
10			☐	Y N	☐	☐	N A P D NA					B L ST LI	
11			☐	Y N	☐	☐	N A P D NA					B L ST LI	
12			☐	Y N	☐	☐	N A P D NA					B L ST LI	
13			☐	Y N	☐	☐	N A P D NA					B L ST LI	
14			☐	Y N	☐	☐	N A P D NA					B L ST LI	
15			☐	Y N	☐	☐	N A P D NA					B L ST LI	

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Institution _____ Institution No. _____
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Series Capture

Compared to Scan: _____	*	N	C	A	P
Progressed ☐	Arterial	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___
Partial Response ☐	Portal	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___
Stable ☐	Delayed	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___
Complete Response ☐	Pre Contrast	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___
Indeterminate ☐	MRI T2	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___	___ ___ ___ / ___ ___ ___

The Overall Status of NT Lesions				Measured by *(initials)*:
Present	Y	N	NA	Recorded by *(initials)*:
Progressed	Y	N	NA	
Comments:				

Organ code table

1	AB	Abdomen	17	OC	Oral Cavity/Tongue
33	AW	Abdominal Wall	18	OV	Ovary
2	AD	Adrenal	19	PA	Pancreas
3	BL	Bladder	20	PG	Parotid Gland
4	BO	Bone	21	PE	Pelvis
5	CW	Chest Wall/Axilla	37	PP	Peri-Portal
6	CN	CNS (Brain, Spinal Cord, Meninges, Dura)	22	PO	Peritoneum/Omentum
			23	PH	Pharynx
7	CO	Colon	24	PL	Pleura
8	DU	Duodenum	25	PR	Prostate
9	ES	Esophagus	26	RE	Rectum
34	HP	Heart/Pericardium	38	RP	Retroperitoneum
35	HI	Hila	27	SK	Skin/Subcutaneous Tissues
10	KI	Kidney	28	SB	Small Bowel
11	LA	Larynx	29	SP	Spleen
12	LI	Liver	30	ST	Stomach
13	LU	Lung	31	TH	Thyroid
14	MS	Mediastinum	32	UT	Uterus
36	ME	Mesentery	88	OT	Other
16	NE	Neck			

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KEY SHEET

H = Head
N = Neck
C = Chest
A = Abdomen
P = Pelvis
LN = Lymph Node
InD = Indeterminate

Phase of Contrast
* For each scanned area, place the series number portraying that injection phase

Compare to Scan:
☐ Check the box if YES

Overall Status of NT (Non target) Lesions
Y = Yes **N** = No **N/A** = Not Applicable or neither

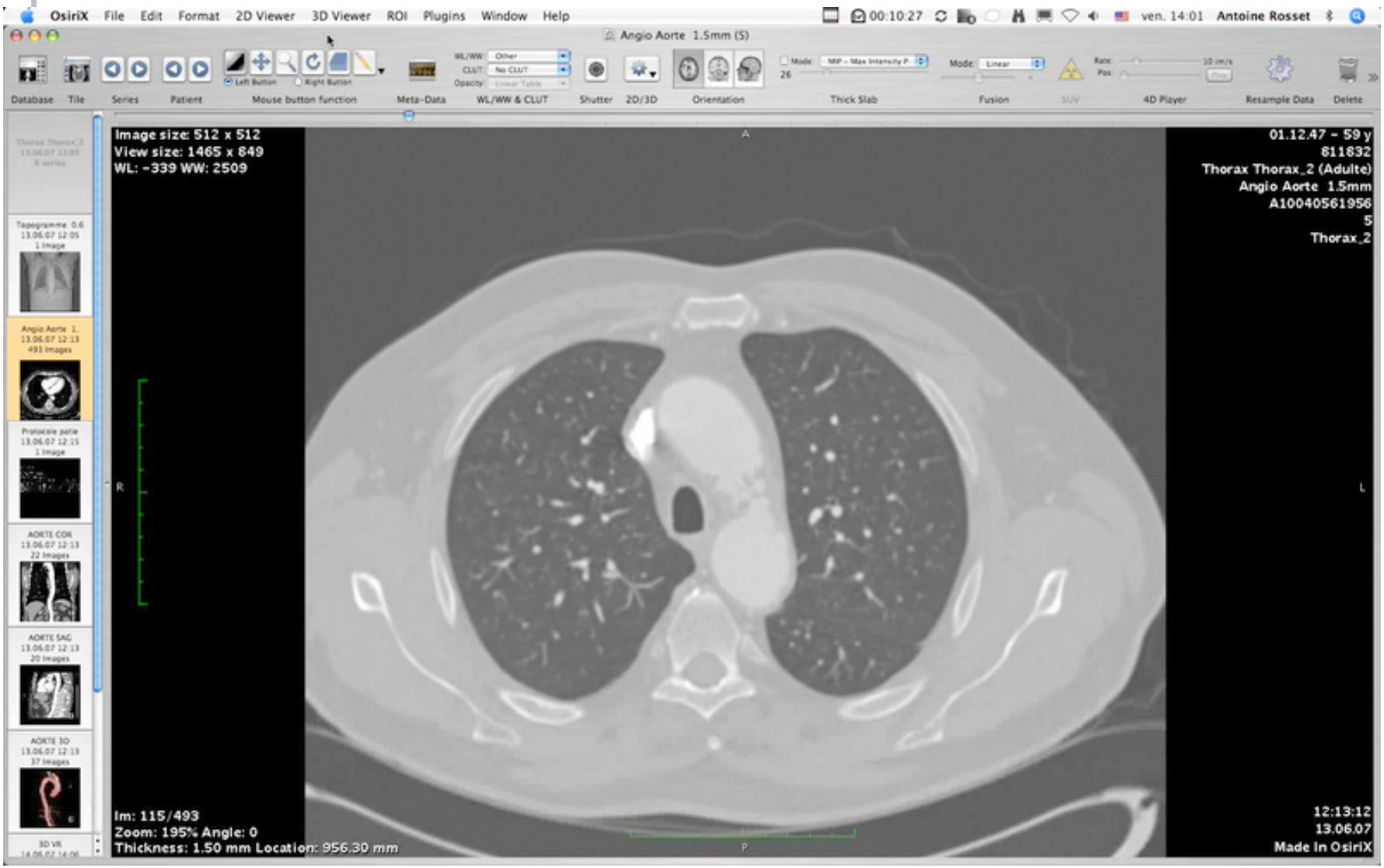
W/L = Window Level
B = Bone
L = Lung
ST = Soft Tissue
LI = Liver
N/A = Not Applicable

Interpretable / Measurable Y/N *(if no select reason / mark all that apply)*

☐ Motion
☐ Artifacts
☐ Contrast Media
☐ DICOM header
☐ Missing anatomic coverage
☐ Poor S/N
☐ Other, specify _____

Complete
a) Qualitative Assessment ☐ Check the box if YES
b) Overall Status of NT Lesions
Y = Yes
N = No
N/A = Not Applicable or neither

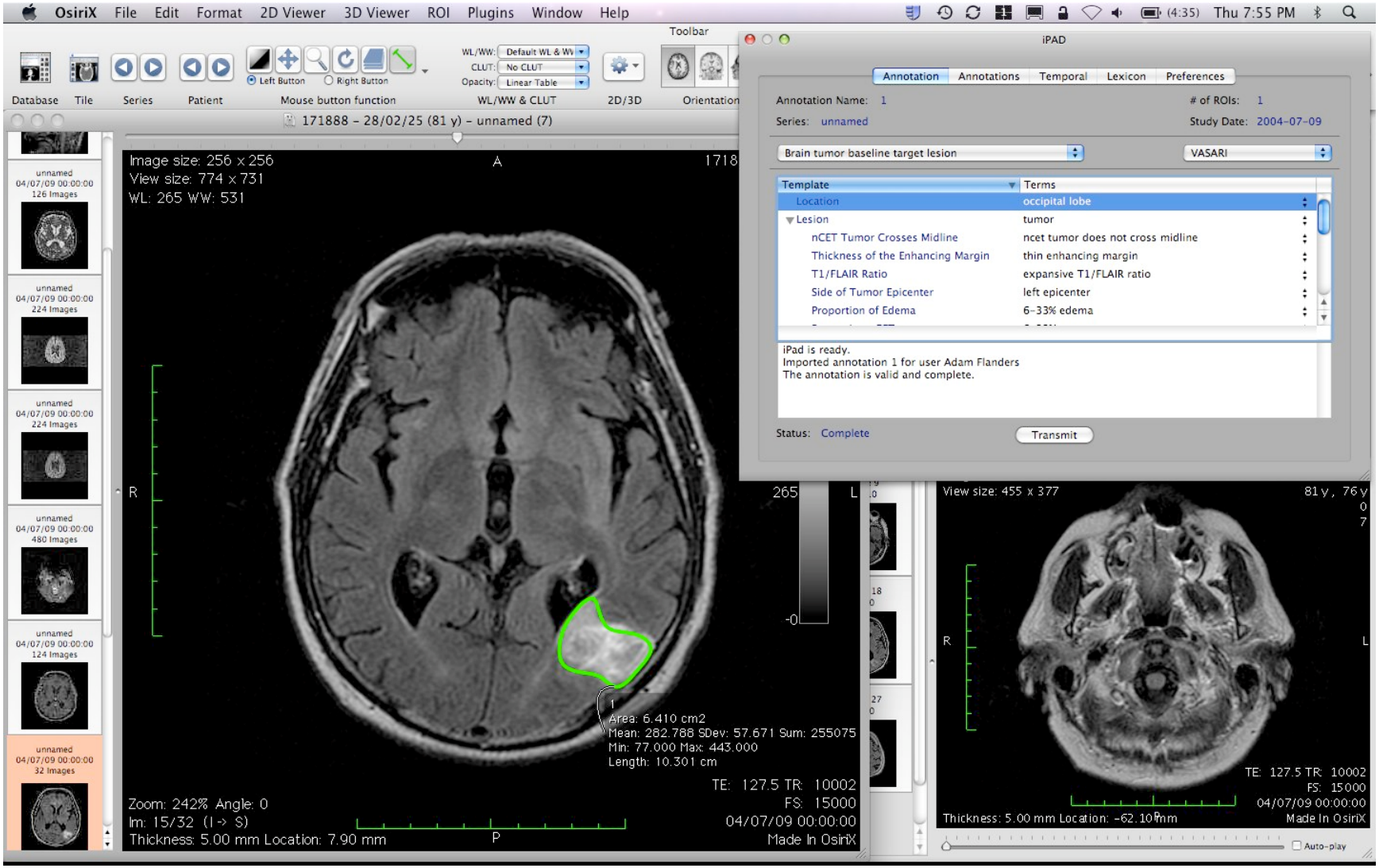
OSIRIX


OsiriX File Edit Format 2D Viewer 3D Viewer ROI Plugins Window Help
00:10:27 ven. 14:01 Antoine Rosset
Angio Aorte 1.5mm (5)
Database Tile Series Patient Mouse button function Meta-Data WL/WW & CLUT Shutter 2D/3D Orientation Thick Slab Fusion 4D Player Resample Data Delete
Image size: 512 x 512
View size: 1465 x 849
WL: -339 WW: 2509
01.12.47 - 59 y
811832
Thorax Thorax_2 (Adulte)
Angio Aorte 1.5mm
A10040561956
5
Thorax_2
Im: 115/493
Zoom: 195% Angle: 0
Thickness: 1.50 mm Location: 956.30 mm
12:13:12
13.06.07
Made In OsiriX

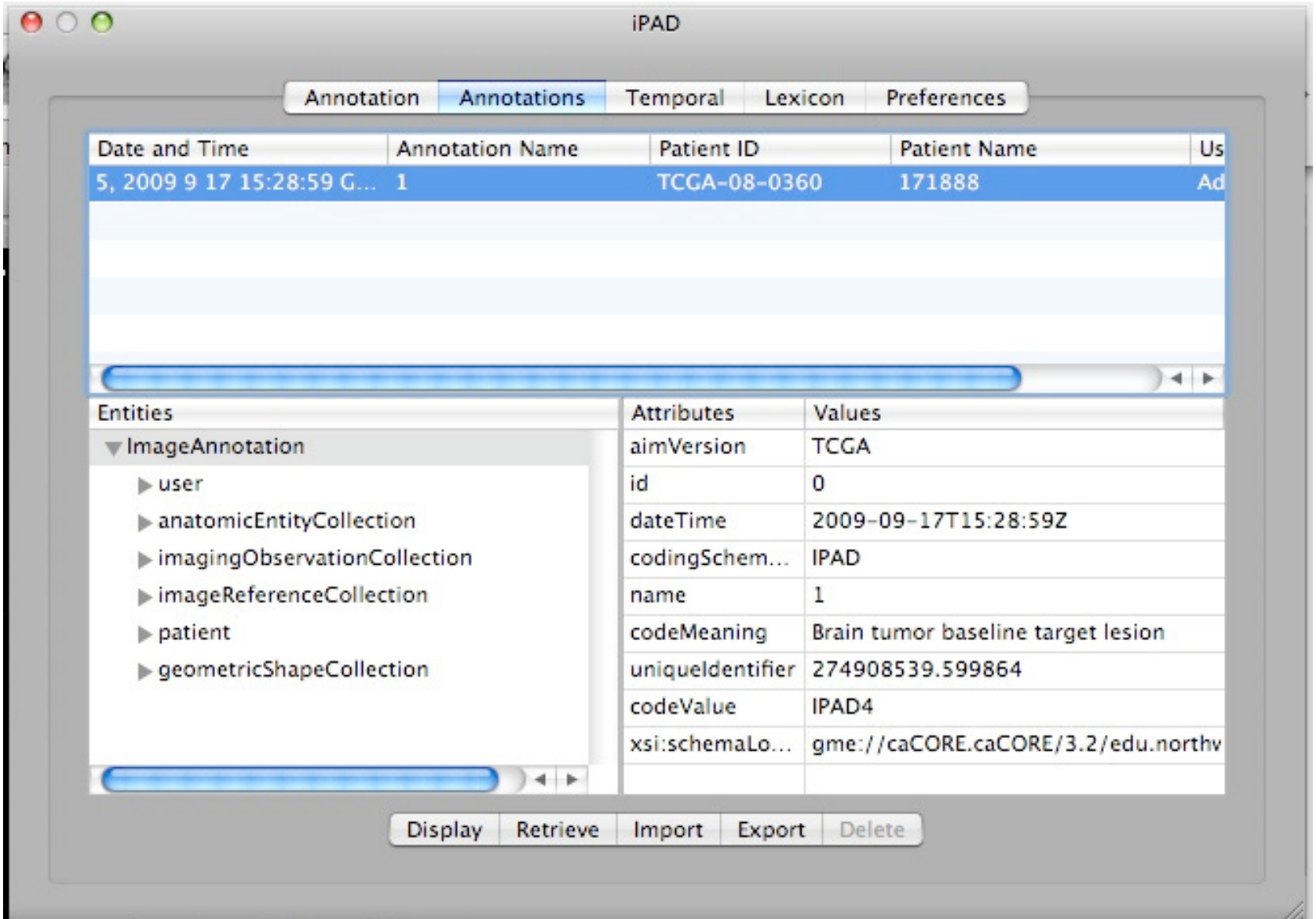
iPAD Annotation Tool

- A new tool developed by the AIM team to compliment the core AIM product.
- It implements the AIM standard (Annotation and Image Markup) of the caBIG project.
- iPAD also supports the RadLex controlled terminology for describing anatomic entities and observations in images.
- The purpose of iPAD is to make the semantic content (the meaning and other key metadata in the images) explicit and machine-accessible for query and data mining.

iPAD


OsiriX File Edit Format 2D Viewer 3D Viewer ROI Plugins Window Help
Toolbar
Database Tile Series Patient Mouse button function WL/WW & CLUT 2D/3D Orientation
171888 - 28/02/25 (81 y) - unnamed (7)
iPAD
Annotation Annotations Temporal Lexicon Preferences
Annotation Name: 1
# of ROIs: 1
Series: unnamed
Study Date: 2004-07-09
Brain tumor baseline target lesion
VASARI
Template
Terms
Location
occipital lobe
Lesion
tumor
nCET Tumor Crosses Midline
ncet tumor does not cross midline
Thickness of the Enhancing Margin
thin enhancing margin
T1/FLAIR Ratio
expansive T1/FLAIR ratio
Side of Tumor Epicenter
left epicenter
Proportion of Edema
6-33% edema
iPad is ready.
Imported annotation 1 for user Adam Flanders
The annotation is valid and complete.
Status: Complete
Transmit
Image size: 256 x 256
View size: 774 x 731
WL: 265 WW: 531
Area: 6.410 cm2
Mean: 282.788 SDev: 57.671 Sum: 255075
Min: 77.000 Max: 443.000
Length: 10.301 cm
TE: 127.5 TR: 10002
FS: 15000
04/07/09 00:00:00
Made In OsiriX
Zoom: 242% Angle: 0
Im: 15/32 (I -> S)
Thickness: 5.00 mm Location: 7.90 mm
View size: 455 x 377
Thickness: 5.00 mm Location: -62.10 mm
Auto-play

iPAD


iPAD
Annotation
Annotations
Temporal
Lexicon
Preferences
Date and Time
Annotation Name
Patient ID
Patient Name
Us
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1
TCGA-08-0360
171888
Ad
Entities
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user
anatomicEntityCollection
imagingObservationCollection
imageReferenceCollection
patient
geometricShapeCollection
Attributes
Values
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dateTime
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IPAD
name
1
codeMeaning
Brain tumor baseline target lesion
uniqueIdentifier
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codeValue
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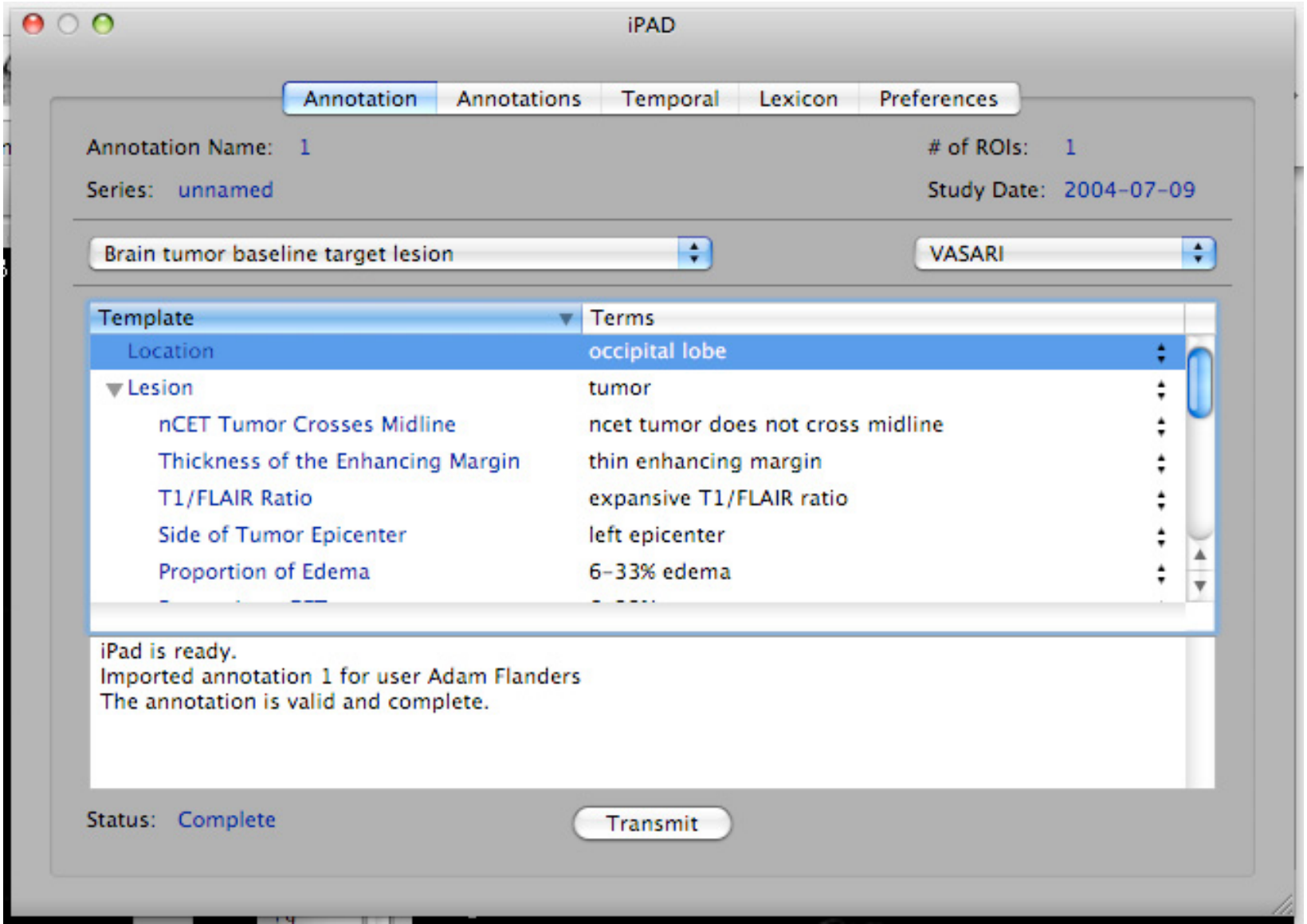
gme://caCORE.caCORE/3.2/edu.northv
Display
Retrieve
Import
Export
Delete

iPAD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Future Development

- Cloud-Based Virtual Workstation Environment (Shared Software Licenses)
  - **Reduce Cost:** limited number of software licenses
  - **Security**
  - **Flexibility**: Organizational Agility (i.e. upgrades, validation)
  - **More Mobility:** Employees can access information wherever they are, rather than having to remain at their desk

Future Direction

- Web-Based PACS Solution
  - Decentralized Image Viewing
  - Improved Workflow
  - Simplify System Administration
  - Accelerated Decision Making
  - Decrease Hardware Costs
  - Reduce Readers' Travel Cost

Future Direction

- Application Hosting within TRIAD 3.0
- iCAD Server, NCI-Core Lab Collaboration
- Vendor Workstations Upgrade
- Improved Centralized Radiology Reading Rooms
  - Better Monitors
  - DICOM Viewers
  - Improved Data Collection
  - Better Workflow
  - Radiology Information System