RUTGERS
Robert Wood Johnson Medical School

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Leaders in Subspecialty Imaging

Management of Clinical Trial Imaging Data with Structured Voice Recognition Reports and Cloud Processing: A Novel Clinical Approach

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Introduction

- Radiologists and oncologists face the following challenges with clinical trials imaging analysis: non-structured radiology reports, inconsistent lesion measurement between time points, time-consuming and error-prone manual calculations for clinical trials protocols, and lack of dedicated storage and auditable signoff.

- We have piloted a cloud-based imaging platform that allows radiologists to provide oncologists with dedicated clinical trials imaging reads and calculations from non-proprietary standard radiology dictation and PACS software, using RECIST 1.1 and other tumor response criteria. It was initiated at several cancer centers between 2019 and 2021.

TECHNIQUE: Research read measurement and calculations were performed per specifications of RECIST [redacted] Data stored under identifiers of [redacted] 5/2/2022 10:15 AM

FINDINGS:

WEEK/CYCLE #: Status post cycle 6
PROTOCOL: [redacted]
EXAMINATION TYPE: CT chest abdomen and pelvis
EXAM DATE: 5/2/2022 10:15 AM
[ ]

NUMBER OF TARGET LESIONS (Up to five): 4

TARGET LESION 1:
Type: Extranodal
Anatomic location: Middle lobe lung nodule
Size(mm): Long axis 34 x Short axis 29
Series/Image #: 2/33
[ ]

TARGET LESION 2:
Type: Extranodal
Anatomic location: Left hepatic lobe medial segment, segment IV
Size(mm): Long axis 77 x Short axis 58
Series/Image #: 2/74
[ ]

TARGET LESION 3:
Type: Extranodal
Anatomic location: Right hepatic lobe posterior segment, segment VI
Size(mm): Long axis 13 x Short axis 9
Series/Image #: 2/77
[ ]

TARGET LESION 4:
Type: Extranodal
Anatomic location: Pancreatic head
Size(mm): Long axis 36 x Short axis 35
Series/Image #: 2/86
[ ]

TARGET LESION 5:
Type: [ ]
Anatomic location: [ ]
Size(mm): Long axis [ ] x Short axis [ ]
Series/Image #: [ ]
[ ]

NUMBER OF NON-TARGET LESIONS (Up to three): 3

NON-TARGET LESION 1:
Type of lesion: Ascites
Anatomic location: Abdominopelvic malignant ascites
Presence on current cycle: Present
Series/Image #: 2/131
[ ]

NON-TARGET LESION 2:
Type of lesion: Extranodal
Anatomic location: Abdominopelvic peritoneal carcinomatosis
Presence on current cycle: Present
Series/Image #: 2/129
[ ]

NON-TARGET LESION 3:
Type of lesion: Nodal
Anatomic location: Ill-defined, partially encasing proximal celiac artery
Presence on current cycle: Present
Series/Image #: 2/85
[ ]

NEW LESIONS (Since Baseline Study): No

NEW LESION 1:

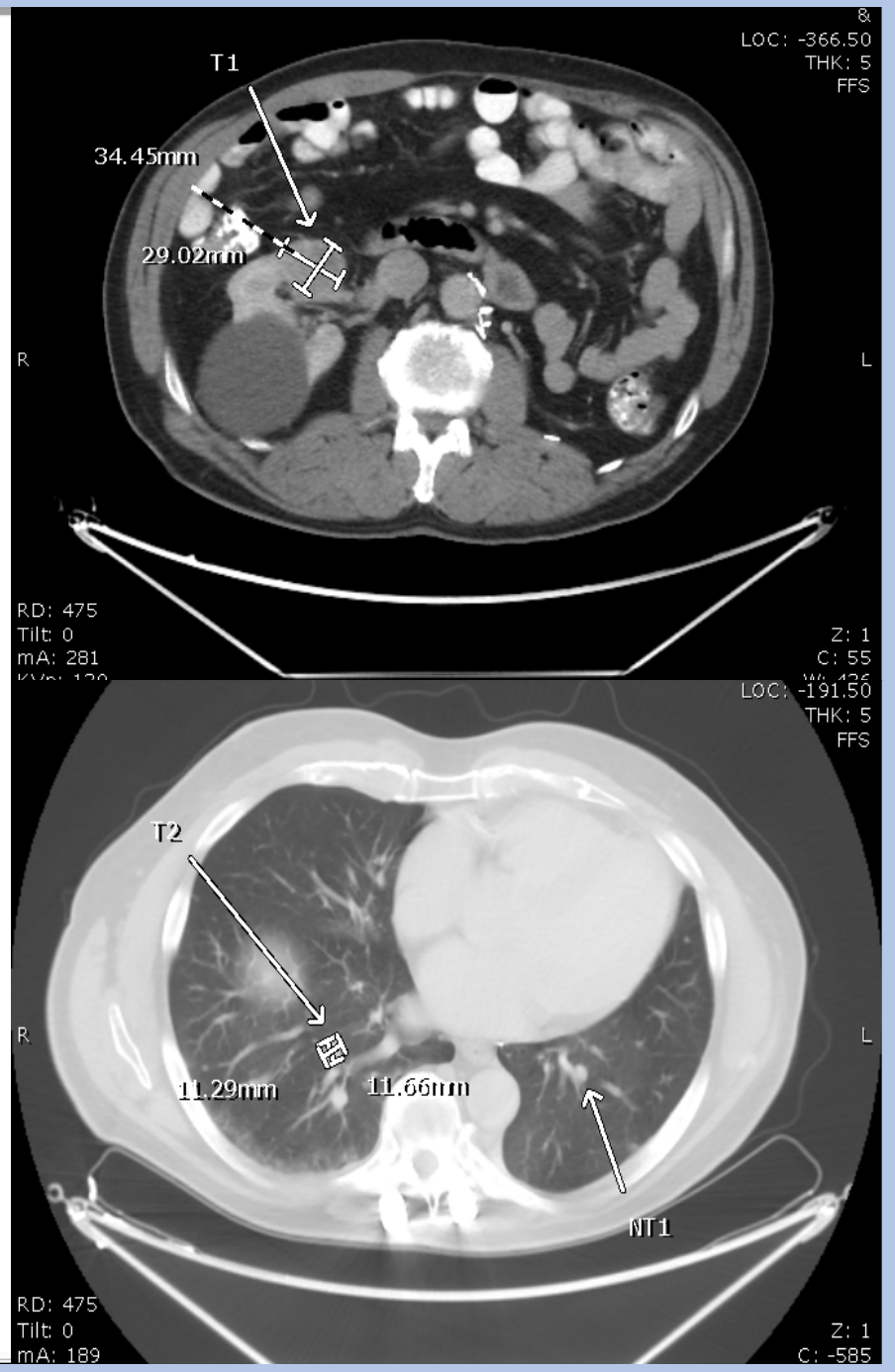

Figure 1A: *Structured RECIST 1.1 template and PACS images with the data points for time point 3 for the patient in figure 1B.*

Procedure	Protocol	Examination Type	Clinician	Radiologist	MRN	Patient
RECIST	[redacted]	CT chest abdomen and pelvis	[redacted]	Sokol, Levi	[redacted]	[redacted]

			2021-10-19 L.S. Baseline			2022-01-03 L.S. Time Point 1			2022-03-03 L.S. Time Point 2			2022-05-02 L.S. Time Point 3		
Target Lesions														
#	Location	Type	LDi (mm)	SDi (mm)	S/I #	LDi (mm)	SDi (mm)	S/I #	LDi (mm)	SDi (mm)	S/I #	LDi (mm)	SDi (mm)	S/I #
1	Middle lobe lung nodule	E	10	7	2/34	8	7	2/34	6	6	2/35	6	6	2/33
2	Left hepatic lobe medial segment, segment IV	E	14	13	2/85	10	6	2/83	9	6	2/87	7	5	2/74
3	Right hepatic lobe posterior segment, segment VII	E	20	15	2/87	14	13	2/83	15	10	2/88	13	9	2/77
4	Pancreatic head	E	53	43	2/96	38	37	2/93	37	37	2/97	36	35	2/86
	Sum of Diameters:			***97***			***70***			***67***			***62***	
	% Increase Since Nadir:						***0***			***0***			***0***	
	% Change Since Baseline:						***-28***			***-31***			***-36***	
Response of Target Lesions			**Baseline**			**SD**			**PR**			**PR**		
Non-Target Lesions														
#	Location	Type	Presence		S/I #	Presence		S/I #	Presence		S/I #	Presence		S/I #
1	Abdominopelvic malignant ascites	E	Present		2/147	Present		2/141	Present		2/142	Present		2/131
2	Abdominopelvic peritoneal carcinomatosis	E	Present		2/142	Present		2/137	Present		2/139	Present		2/129
3	Ill-defined, partially encasing proximal celiac artery	N	Present		2/98	Present		2/95	Present		2/98	Present		2/85
Response of Non-Target Lesions			**Baseline**			**SD**			**SD**			**SD**		
New Lesions														
#	Location	Type	LDi (mm)	SDi (mm)	S/I #	LDi (mm)	SDi (mm)	S/I #	LDi (mm)	SDi (mm)	S/I #	LDi (mm)	SDi (mm)	S/I #
Response of New Lesions			**Baseline**			**N/A**			**N/A**			**N/A**		
Evaluation of Best Overall Response			**Baseline**			**SD**			**PR**			**PR**		
Acceptance			**Accept** **Clinician:** [redacted] **Comment:** **2022-01-06 20:11:51**			**Accept** **Clinician:** [redacted] **Comment:** **2022-01-06 20:11:53**			**Accept** **Clinician:** [redacted] **Comment:** **2022-03-04 10:31:10**			**None** **Clinician:** **Comment:**		

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Figure 1B. PDF of RECIST 1.1 of a trial patient over 4 time points. Calculations of response to therapy are automated.

Methods

- An anonymous survey was sent out to the oncologist and research coordinators who have experience using the software. The survey was designed to gauge the effectiveness of the software.
- Questions asked included the decrease in turnaround time between initiation of scan and completion of research protocol calculations, and regarding the decrease in time the oncologists personally need to make calculations.
- Additionally, respondents were inquired regarding the accuracy of the data, and how much time they had to spend verifying the integrity of the data. Finally, users were also asked if there were any changes regarding the number of audit requests.

Results

- The survey was sent to approximately 170 recipients, with 46 respondents.
- 82% of respondents said they strongly agreed or agreed that there was a decreased turnaround time between scan initiation, and completion of research protocol calculations, and 18% were neutral.
- 81% strongly agreed or agreed that there was a decreased time they personally performed the calculations, and 18% were neutral.
- 24% said they saved less than 5 minutes per time point personally performing the calculations, 36% said 5-15 minutes, 21% said 15 to 30 minutes, 14% 30-60 minutes, and 5% of people responded that they saved greater than 60 minutes per time point.

Results Continued

- Users were also asked regarding their time spend verifying the data. 69% of people spent less than 5 minutes per time point verifying the integrity and quality of the data*:*
  - 18% spent 5-15 minutes, 11% spent 15-30 minutes, and 2% 30-60 minutes. No one spent greater than 60 minutes verifying the data.

- *67% of people strongly agreed that they were confident in the accuracy of the data, 23% agreed, and 9% neither agreed or disagreed.*

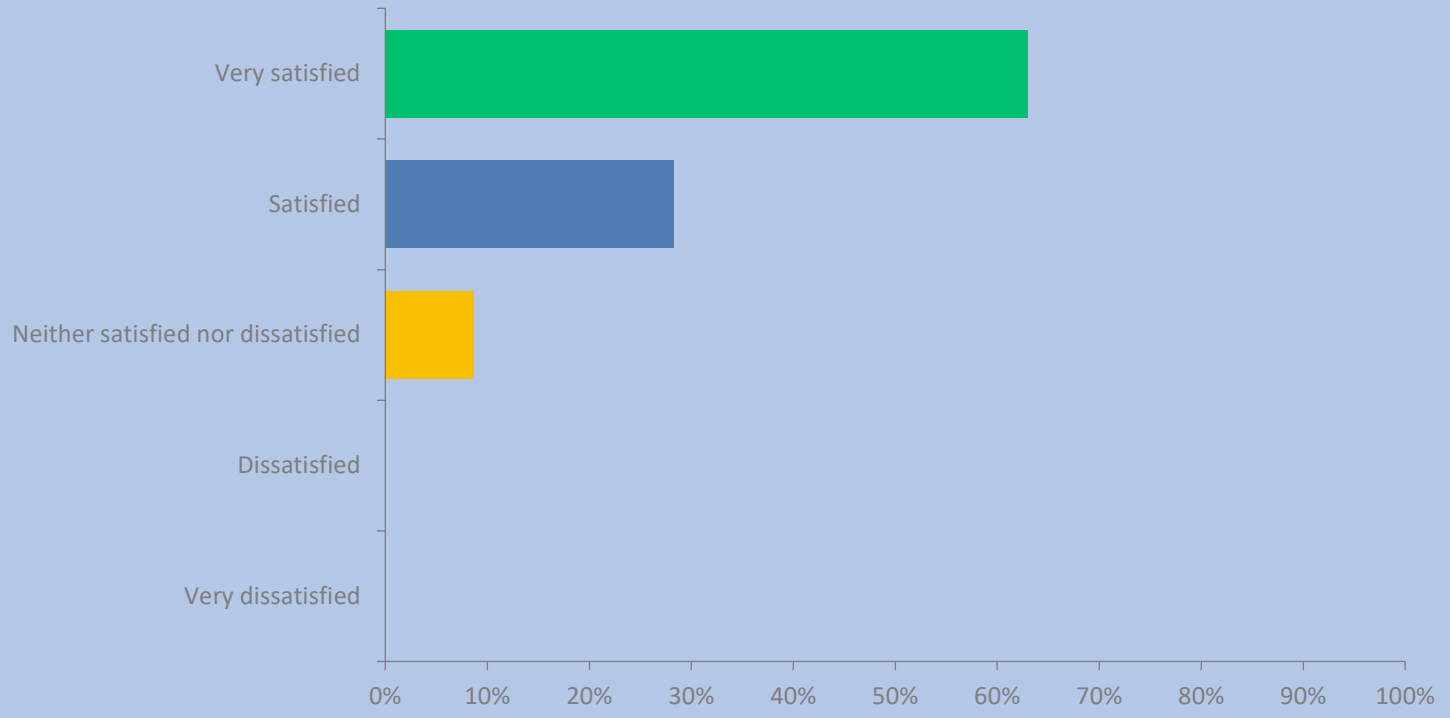

Figure 2: Bar Graph with responses to the question: “How satisfied are you with the clinical trials imaging network?”

Discussion

- We have piloted an approach to provide clinical trials imaging metrics to oncologists using non-proprietary technology that runs from any standard radiology voice recognition system and PACS.
- The majority of respondents agreed that they would recommend this system for its time-saving, automated calculation and ease of use, user features.