

### Introduction

Oncology clinical trials have turned to image-based surrogate endpoints for evaluation therapies. The demand for prompt and dependable results is making evaluation complex, and radiologists may struggle to meet local site and multicenter imaging needs. These challenges underscore the need for advanced cancer imaging informatics tools that ensure protocol-compliant image interpretation while also boosting reviewer efficiency.

### Goal

Accelerating tumor response assessments which will influence patient's treatment decisions while enhancing protocol adherence by removing inconsistencies.

### Solutions & Methods

UCSD Moores Cancer Center implemented the Yunu clinical trials imaging informatics system in 2022. Yunu provides a web-based workflow solution for impartial site evaluations that features:

- Access via secure website to assessments, results, on-line training & certification to ensure compliance.
- Conformance checks to guard rail the imaging response assessments as per trial requirements.
- Automated e-mail notifications alerting clinical teams with imaging assessments' results that are processed in 21 CFR Part 11 compliant system.
- On-time results ensure that clinical team receives independent confirmation of progression/response.

### Discussion

- Clinical trials need sophisticated imaging informatics tools that meet site-read requirements, transparent workflow with cross-departmental collaboration, tracking etc. that go beyond basic needs of research organizations.
- Yunu's cloud-based platform enables imaging stakeholder collaboration, workflow optimization, data preservation, and best practice sharing across all sites in each trial and across all trials at each site. Yunu continues to evolve to meet cancer center needs.

### Future Directions

- Analysis tools to promote advanced visualization and statistical exploration of trial data.
- Customized dashboards to help investigators better visualize a patient's response pattern, create analyses to test their hypotheses, and apply them to all patients enrolled in a trial in real-time

Figure 1

Attending Physician: Speciality: Radiology  
 Progress Notes: Signed  
 Encounter Date: 10/10/2022

CTO Clinical Trial Measurements

CT chest, abdomen, pelvis scans performed on:  
 Baseline: 12/1/21

Follow ups:  
 2/19/22  
 4/23/22  
 10/8/22

Measurements from axial images of single phase or PV phase exams unless otherwise specified.

Target Lesions:

1. Right lung lesion conglomerate #1  
 12/1/21: 2.9 x 1.8 cm (lm51)  
 2/19/22: 0.6 x 0.6 cm (lm54)  
 4/23/22: 0.7 x 0.6 cm (lm60)  
 10/8/22: 0.6 x 0.4 cm (lm55)
2. Right lung lesion #2  
 12/1/21: 1.2 x 0.8 cm (lm42)  
 2/19/22: Barely visible, about 0.5 x 0.3 cm (lm43)  
 4/23/22: Barely visible, about 0.5 x 0.2 cm (lm49)  
 10/8/22: resolved
3. Right perirenal conglomerate lesion  
 12/1/21: 7.0 x 4.2 cm (lm26)  
 2/19/22: 2.6 x 1.7 cm (lm25)  
 4/23/22: 2.5 x 1.3 cm (lm21)  
 10/8/22: 1.3 x 0.5 cm (lm20)
4. Right infrarenal conglomerate lesion  
 12/1/21: 3.6 x 2.9 cm (lm53)  
 2/19/22: 0.7 x 0.6 cm (lm51)  
 4/23/22: 0.4 x 0.4 cm (lm46)  
 10/8/22: 0.4 x 0.3 cm (lm42)

Non-target lesions:

1. Abdominal implants, overall substantially decreased on 2/19/22, except 1 possible implant vs fluid collection along the inferior aspect of the right kidney, attention on follow up.  
 -Stable to slightly de-creased on 4/23/22.  
 -Smaller/resolved on 10/8/22.
2. Lymph nodes, stable to improved on 2/19/22.  
 Stable to slightly decreased on 4/23/22, 10/8/22.
3. Lung nodules, decreased on 2/19/22.  
 Stable on 4/23/22, 10/8/22.

Note: measurements above are for research purposes only. For clinical interpretations, please refer to the clinical report associated with each scan.

Electronically signed by MD at 10/10/2022 11:37 PM

Figure 1: Pre-Yunu: > 50% of scans had assessment problems due to calculation errors, selection of inappropriate overall response, or incomplete/conflicting data records.

Figure 2: Post-Yunu: Assessment errors down to <2% as sign-off compliance (2a) has been enhanced, and real-time response criteria checks (2b) were implemented. Fig. 2c shows individual lesion charts across the time points.

Figure 2a

Trial: 191075 Criteria: RECIST1.1

All measurements shown in mm	12-Dec-2021 Baseline	19-Feb-2022 Follow Up 1	23-Apr-2022 Follow Up 2	08-Oct-2022 Follow Up 3
1 Other:Right lung lesion conglomerate #1 Y	29 x 18 (S-999, I-51)	6 x 6 (S-999, I-54)	7 x 6 (S-999, I-60)	6 x 5.0 (S-999, I-55)
2 Other:Right lung lesion #2 Y	12 x 8 (S-999, I-42)	5 x 5.0 (S-999, I-43)	5 x 5.0 (S-999, I-49)	CR x CR (S-999, I-999) CR
3 Other:right perirenal conglomerate lesion Y	70 x 42 (S-999, I-26)	26 x 17 (S-999, I-25)	25 x 13 (S-999, I-21)	13 x 5 (S-999, I-20)
4 Other:right infrarenal conglomerate lesion Y	36 x 29 (S-999, I-53)	7 x 6 (S-999, I-51)	5.0 x 5.0 (S-999, I-46)	5.0 x 5.0 (S-999, I-42)
5 Abdominal Peritoneum/Omentum N	NM (S-999, I-999)	SD (S-999, I-999)	SD (S-999, I-999)	SD (S-999, I-999)
6 Lymph Node Other N	NM (S-999, I-999)	SD (S-999, I-999)	SD (S-999, I-999)	SD (S-999, I-999)
7 Lung Multiple Sites: N	NM (S-999, I-999)	SD (S-999, I-999)	SD (S-999, I-999)	SD (S-999, I-999)
RECIST1.1	147.0	44.0	42.0	24.0
% Change from Baseline	0%	-70.07%	-71.43%	-83.67%
% Change from Nadir	0%	-70.07% (Baseline)	-4.55% (Follow Up 1)	-42.86% (Follow Up 2)
% Change from Prior	0%	-70.07%	-4.55%	-42.86%
Response	BL	PR	PR	PR

Radiologist and Approval Date: UCSD Legacy Data Entry (ID: 198) 13-Jan-2023 12:44PM

12-Dec-2021 Baseline Reviewed by Dr.

19-Feb-2022 Follow Up 1 Non-target abdominal implants, overall substantially decreased, except 1 possible implant vs fluid collection along the inferior aspect of the right kidney, attention on follow up.

23-Apr-2022 Follow Up 2 Non-target abdominal implants, stable to slightly decreased.

08-Oct-2022 Follow Up 3 Non-target abdominal implants -smaller/resolved.

Figure 3: Current response rate donut graph for entire trial based on real-time data.

Figure 4: Best response rate waterfall for entire trial based on real-time data.

Figure 3

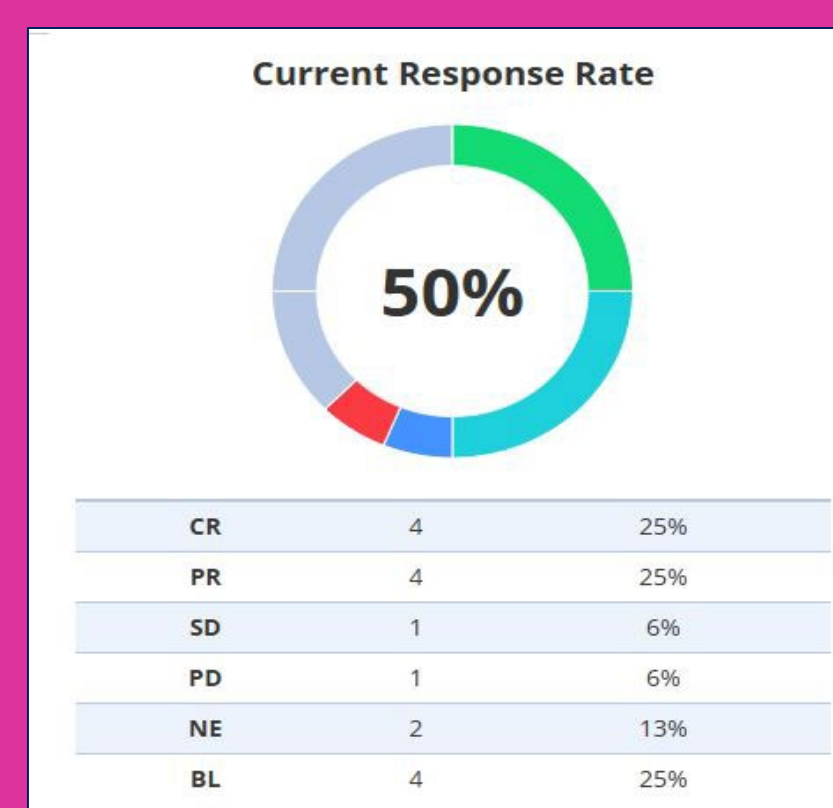


Figure 4

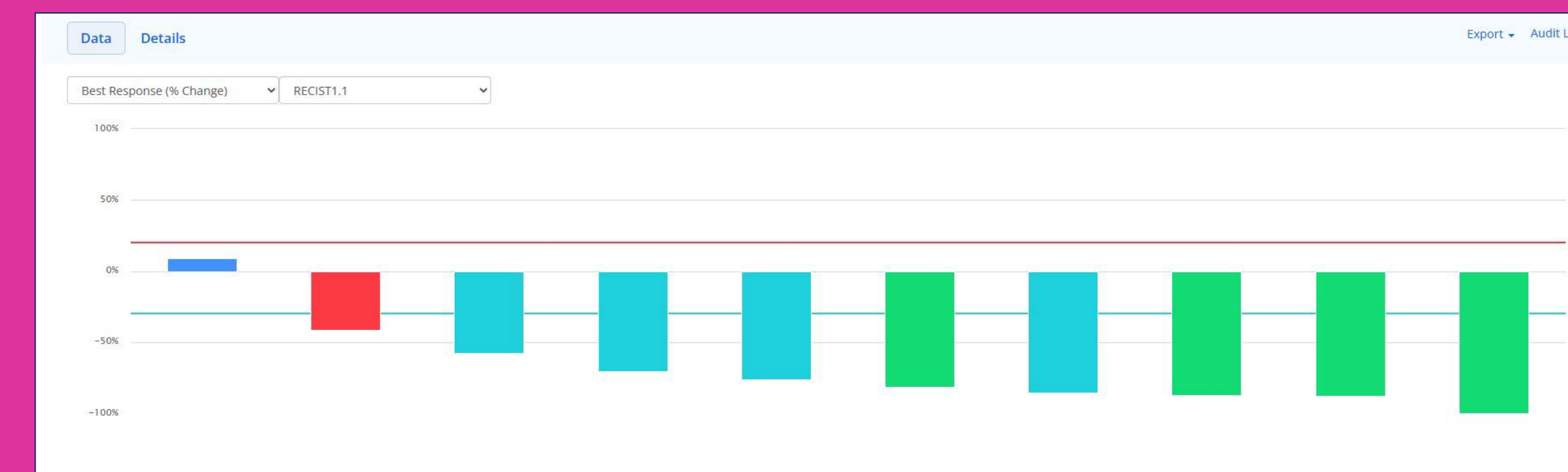


Figure 2b

Criteria nonconformities:

1. The maximum number of targets in organ group liver (2) has been exceeded
2. Estimated lesion must be >= 10mm longest diameter on CT scans

Figure 2c

