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: 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 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.