

## **The Complete Workflow Solution for Quantitative Imaging Assessment of Tumor Response for Oncology Clinical Trials**

A. Cruz<sup>1</sup>, B. Lankhorst<sup>1</sup>, H. McDaniels<sup>1</sup>, E. Weihe<sup>1</sup>, E. Correa<sup>2</sup>, D. Nacamuli<sup>2</sup>, B. Somarouthu<sup>2</sup>, G.J. Harris<sup>2</sup>

<sup>1</sup>UC San Diego Moores Cancer Center, <sup>2</sup>Yunu

### **1. Background**

Oncology clinical trials have increasingly 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 picture interpretation while also boosting reviewer efficiency.

### **2. Goals**

Our objective is to speed up tumor measurements while also enhancing protocol adherence by removing inconsistencies that could influence patient treatment decisions. By using an internal centralized tumor metrics service, the following objectives have been met:

- Elimination of electronic spreadsheets
- Establishment of an image-based longitudinal record
- Improved management of tumor metric requests, results turnaround time, accessibility, and protocol adherence
- Reduction of incorrect requests (i.e., wrong patient, study, or response criteria)
- Increased reliability and reproducibility of results
- Improved efficiency in preparing for data locks, monitoring visits, audits, and financial compliance

### **3. Solutions and Methods**

The UC San Diego Moores Cancer Center deployed the Yunu clinical trials imaging informatics system in late 2022. Yunu provides a web-based workflow solution for impartial site evaluations that features:

- Access via secure website—any scan, anytime, anywhere—to assessments and results, including annotated images and graphs
- Online training and certification to ensure specific study protocol compliance
- Integrated conformance checks to guardrail the imaging response assessments as per the trial requirements
- After electronic sign-off, the assessment is locked and the clinical team is automatically alerted that results are ready
- On-time results ensure that the clinical team receives independent confirmation of progression/response before the patient is seen in clinic

### **4. Outcomes**

Prior to Yunu, over 50 percent of scans had assessment problems due to calculation errors, selection of inappropriate overall response, application of incorrect response criteria, or incomplete/conflicting data records. After implementation of Yunu, assessment errors have decreased to less than 2 percent after response criteria checks were applied and sign-off compliance has been enhanced.

*Category: Network Operations, Decentralized Trials, and Multi-site Research - Completed project*

Utilization of Yunu improves the assessment of treatment response or tumor growth, resulting in time and cost savings for sponsors and improved efficiency and confidence for investigators.

#### **5. Lessons Learned and Future Directions**

Clinical trials need sophisticated imaging informatics instruments that meet site read requirements and go beyond the basic needs of research organizations. The Yunu system was created especially for cancer centers, and it is still being refined thanks to input from the clinical research teams, radiologists, and oncologists that utilize it.

A future development goal is to add analysis tools to promote advanced visualization and statistical exploration of trial data. In the era of molecularly targeted therapies, the evaluation of treatment efficacy may be impacted by inconsistencies in response patterns, which may not be uncovered until after the trial has been closed. Yunu will 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.