

AbstractID: 10343 Title: QA procedures for Multi-modality Preclinical Tumor Drug Response Testing

Purpose: There are growing expectations that imaging biomarkers can speed preclinical testing of anti-tumor drugs in rodent models. The only presently accepted imaging biomarker by the US Food and Drug Administration (FDA) is tumor size measurement based on WHO or RECIST criteria. Standardized Tumor Response QA procedures are needed to allow accurate tumor size measurements in rodent models coming from multiple devices and laboratories. This project tests the hypothesis that development and testing of new anti-tumor drugs with imaging biomarkers can be facilitated and speeded by the development of effective QA procedures for preclinical drug testing in rodent tumor models. **Methods and Materials:** A multi-modality Rodent Tumor Response (RTR) QA procedure was constructed using two sets of measurements on a special purpose calibration phantom: A. Tumor Diameter - low contrast spheres with 2, 4, 7, 10 and 14mm diameters, B. Tumor Volume - five low contrast spheres ranging 4.2 to 1436.8 mm³. Repeated images (n = 3) were obtained with 10 and 35 MHz ultrasound scanners, animal cone beam μ -CT and a 7T MR animal imager to develop "RTR-QA Standardized Measurement Protocols" for each device. The capacity of RTR-QA methods to standardize tumor drug response measurements was validated using measurements of Head and Neck rat tumor models (SCC-4) ranging in tumor size from 2, 4, 7, 10, 14mm (three rats per group). Results of **Standardized RTR-QA** were compared against gold standard measurements of NIST referenced mass and size of surgically extracted tumors. Statistical comparisons of WHO and RECIST data precision and accuracy were made. **Results:** Tumor size measurements in rat tumor models using **Standardized RTR-QA** procedures showed more accurate results. **Conclusions:** We conclude that accurate measurements of tumor response from multiple laboratories/instruments are possible using imaging size biomarkers with **Standardized RTR-QA** RECIST and WHO procedures.