Progress Report

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QIBA Committee/Subgroup: Volumetric CT Technical Committee

Project Title: Validation of Volumetric CT as a Biomarker for Predicting Patient Survival

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Project Overview: The goal of this project is to validate volumetric CT as a better imaging biomarker for predicting patient survival using a retrospective dataset from a large, multicenter Phase II/III clinical trial in advanced colorectal cancer treated with a targeted therapy. About 450 patients enrolled to this clinical trial had measureable disease per RECIST definition and will be included and analyzed in this study. Our in-house lesion segmentation algorithms developed for solid tumors will be applied to assist radiologists in obtaining tumor volumes. The expected outcomes of this project include (1) (**Aim #1**) obtaining the knowledge about the levels of intra-reader and inter-reader variability in measuring total tumor volume/burden and change in tumor volume/burden (unidimensional and bidimensional measurements as well), and (2) (**Aim #2**) evaluating the value of the volumetric CT in predicting patient survival.

Project Update (Aim #1):

Status:

We have completed all measurement experiments and finished the quality checking on the acquired data/measurements. Originally, we proposed two participating radiologists, but we have ended up with three participating radiologists for the inter-reader variability study. The measurements were just sent to our statistician for analyses.

What have we collected?

- A subset of 30 patients' three CT scans (i.e., images at three time-points) including baseline, follow up at 6 weeks (+/- 1 day) and follow up at 12 weeks (+/- 1 day);
- Target lesions (up to 5 lesions/organ; 10 lesions/patient) on baseline selected by each of the three radiologists;
- Three radiologists' independent measurements (for inter-reader variability); one radiologist's blinded repeat measurements (for intra-reader variability);
- Each radiologist's measurements on the target lesions selected by himself/herself and three radiologists' measurements on a common set of the target lesions determined by one radiologist;
- Manual uni and bi measurements and computer-aided uni, bi and volume measurements on all three scans of all 30 patients;

The collected data will allow us to compare the variability in measuring total tumor burden and tumor burden change with and without considering an additional factor (besides the measurement variation) that is the selection of target lesions.

Project Update (Aim #2)

Status:

To date, we have completed the tumor volume measurements (uni and bi as well) on all of the available CT scan time-points in 98 patients out of a total of 451 patients.