Quantifying Responses to Treatment with CT Volumetry

Establish 3D CT Volumetry as Surrogate Endpoint Biomarker for Tumor Response

Specific Areas
To develop methods and processes for accurate and reproducible measurements of anatomic structures and masses.

Stakeholders
FDA, NIST, NCI, ACR, manufacturers and developers, IQIN, PSI, and academic centers.

Progress during past year:
• Characterization of spatial and temporal performance under image acquisition scenarios.
• Demonstrated methodology for variability in repeated evaluations of clinical data.
• Filed two production-related documents under Public Comment and Fast-Track processes.

Clinicin Sizing of Synthetic Spherical and Non-Spherical Lung Nodules

Aim: To estimate bias-variance of nodule volume measurements.

Sizing Techniques
• Automated
• Manual 2D size
• Semi-automated 3D volume

Anatomorphic Phantom

Results: Variability, Pooled Analysis - All readers, All lesions

Summary: Overall, 3D method provided low bias estimates of nodule volumes.

Next Steps
• Repeat protocol and allow all readers to use the new data for algorithm development.
• Use Variance Estimates to determine minimum detectable change.

Determination of Minimum Detectable Change and Comparing Sizing Methods in Patient Datasets

Aim: To determine the minimum detectable change in lesion size due to treatment over time.

Methods
• Clinical data from patients with lung cancer.
• Two-week intervals between scans.
• 10 patients with 10 lesions per patient.

Validation of Volumetric CT as Biomarker for Predicting Patient Survival

Current Status
• Drafted by the QIBA Technical Committee on Quantifying Volumes.
• Profile published for Public Comment during Aug-Sept 2011.

Problems: technical challenge, need for large datasets.

Profiles: technical specification documents
• Profile published for Public Comment during Aug-Sept 2011.

Validation of Volumetric CT as Biomarker for Predicting Patient Survival

Aim: To determine in- and out-of-algorithm variability by estimating the volume of synthetic lung nodules.

Methods
• 50 patients with lung cancer.
• 10 lesions per patient.
• 2 week intervals between scans.
• 3D volumes estimated by different methods.

Profile for advanced esophageal disease

Aim: To use the QA tools to identify promising candidates for clinical trials.

Methods
• Measure volumes of 10 lesions with a technical variation below 15%.
• (Measurements will be performed with the same radiology group and equipment.)
• Pearson correlation coefficient, area under receiver operating characteristic curve.

Profile for advanced renal cell carcinoma

Aim: To evaluate the utility of volumetric CT as a biomarker.

Methods
• Measure 3D volumes of 10 lesions with a technical variation below 15%.
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Contact
• Contact person: [Name]
• Address: [Address]
• Phone: [Phone]
• Email: [Email]

Profile for advanced prostate cancer

Aim: To determine the minimum detectable change in treatment response.

Methods
• Measure volumes of 10 lesions with a technical variation below 15%.
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Primary and Secondary Endpoints of the Study

Investigation 1 is started: 3A (current focus):
• Challenge QIBA, RSNA and NIST.
• Expand TTF/NPS measurement to 3D.
• Expected Completion 4.

Method of Prostate Imaging Scanners

Pivotal
• 4 Radiologists
• 80 datasets (1 scanner * 2 doses * 2 thicknesses * 2 scans * 10 nodules)
• 2 reading sessions per dataset

Pilot
• 4 Radiologists
• 20 datasets (1 scanner * 1 dose * 1 thickness * 1 scan * 5 nodules)
• 2 reading sessions per dataset

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Investigation 2:
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Investigation 3:
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