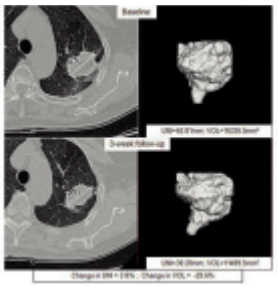
Vol-CT

[Volumetric Computed Tomography]

Purpose:

Develop the technical capability necessary for imaging vendors to support targeted levels of accuracy and reproducibility for use of volumetric CT as a biomarker in oncologic clinical trials.
This will be achieved through the development of implementation guidelines--profiles--for which initial groundwork will be required.



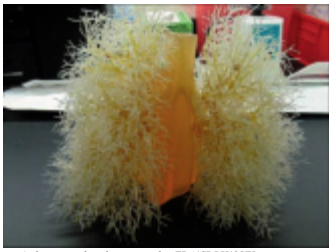
Correlation of tumor change in Volume 3-week targeted therapy
Courtesy of Drs. Binsheng Zheo and Lawrence H. Schwartz, MSKCC

Profiles will be built up in the following layers:

1. CT Volume Quantification Profile to allow users to perform, store and analyze basic spatial measurements on acquired data.
2. CT Tumor Volume Change Profile to allow users to determine tumor volume changes to a certain level of accuracy across multiple acquisitions.
3. CT Tumor Response Profile to allow users to evaluate tumor response/progression to a certain degree of confidence.

Groundwork to enable the description of these profiles is:

- Quantify treatment-induced changes in anatomical structures, such as neoplastic masses, with x-ray computed tomography (CT).
- Identify and create coping strategies for all meaningful sources of variability in measurements of volume with CT.
- Establish standards that will lead to the acceptance of 3D volumetric CT by regulatory agencies as proof of drug-induced changes in pathophysiology, aiding acceptance of future surrogate end-points for changes in the health status of patients.



Anthropomorphic phantom used in FDA/CDRH/OSEL acquisitions
Photograph courtesy of Kyle Myers, FDA

Main Subgroups have been formed to pursue the following actions:

- Retrospective analysis to characterize quantitative accuracy exploiting FDA-acquired anthropomorphic phantom images.
- Retrospective analysis to characterize quantitative accuracy exploiting standard and high-resolution clinical datasets (e.g., NCI-RIDER and others).
- Design and execution of a prospective study to characterize reproducibility given sources of variability utilizing Phantom Study Protocol.

Activities to Date:

A committee including practicing clinicians, professional society leaders, regulatory and governmental agencies, pharmaceutical industry representatives, academics, and imaging industry representatives has laid out a strategy, as well as commissioned the subgroups mentioned above. First activities included completing a systems engineering analysis of the sources of variability as well as identifying the clinical focus for the effort. Operational descriptions have been developed for how profiles would be written and utilized to meet the intended purpose while optimizing the imaging industry's interest and responsiveness.

Next Steps:

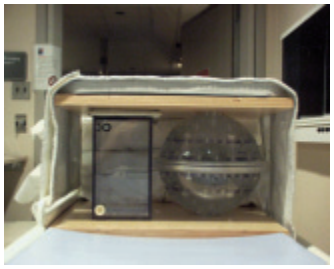
Identify funding mechanisms, project plans, and reporting means for the identified activities. Converge on a QIBA-accepted process to be utilized by all three QIBA technical committees. Define stakeholder expectations regarding focus and timing for principal objectives, including the pharmaceutical and imaging industries.

DCE-MRI

[Dynamic Contrast Enhanced Magnetic Resonance Imaging]

Purpose:

To enable the broad use of DCE-MRI as one imaging biomarker technique, by reducing the physical measurement variability associated with the generation and analysis of MR imaging data across the same or different vendors' scanners.



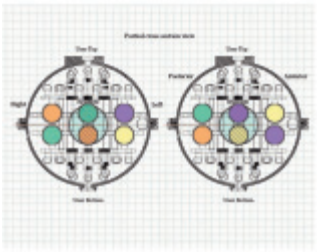
Phantom Image for DCE-MRI

Main Subgroups:

- Phantom study group
- Clinical test-retest study group
- Data simulation group

Activities to Date:

The DCE-MRI team has started with the design of a phantom suitable for measurement quality assessment and the creation of a generic imaging protocol for comparable cross-vendor imaging. After finishing this definition phase in early August, the group is now designing a study using the phantom and protocol in a phantom study at selected academic sites. This will be followed by a clinical test-retest study.



Sketches of DCE-MRI Phantom

Next Steps:

- Translate the generic imaging protocol into current GE, Philips, and Siemens MR imaging protocols while using existing vendor sequences
- Test those imaging protocols at some sites and compare first parameters for better understanding of the problem space
- Select imaging sites for phantom study
- Define phantom study protocol
- Define scope of data simulation, modeling, and test data generation activities
- Conduct phantom study
- Analyze outcome
- Define clinical test-retest study protocol

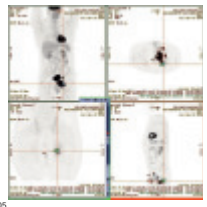
Images courtesy of M.H. Buonocore, MD, Joshua Levy Phantom Laboratory

FDG-PET/CT

[Fluorodeoxyglucose-Positron Emission Tomography/Computed Tomography]

Purpose:

To foster adoption of pragmatic standards for accurate and reproducible quantitation of tumor metabolism via serial measurements by FDG-PET/CT.



2005
• CT showed residual disease in left inguinal and rt. axillary areas.
• PETCT confirmed CT findings and showed bony structure involvement.

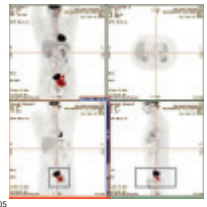
Objectives:

- Identify clinically significant covariates in the quantification of FDG signal and recommend recording and normalization standards.
- Compare the various vendors' computations for quantification and make recommendations to ensure any patient's images would yield the same numbers, irrespective of vendor.
- Define the parameters for automated setting of regions of interest.
- Develop a Digital Reference Object (image database) for quality control.
- Enable tracking of software versions.

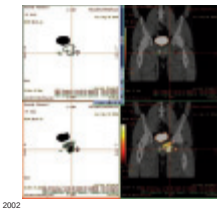
Achievements:

The Digital Reference Standard subcommittee has
- acquired images of a single reference phantom from multiple vendors' scanners,
- compared the DICOM header information,
- harmonized the standard with the AAPM/SNM Task Group 146.

Next Steps:
- establish a procedure for distributing and beta-testing a digital image set,
- test on third-party review stations, initiate the QIBA process for dissemination.



2005
• Patient treated by surgical removal of disease in right axilla and 5 cycles of chemotherapy
• Follow-up PET/CT shows complete remission

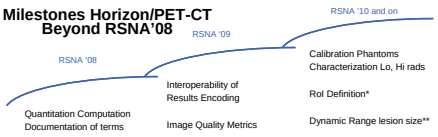


2002
• Patient diagnosed with Right Testicular Seminoma
• Right testes was removed and patient received radiation therapy

Subcommittee Topics [chair]:

Quantification Computation	[David Clunie, MBBS]
Software Version Tracking	[Daniel Gagnon, PhD]
Digital Reference Objects – Images	[Paul Kinahan, PhD]
Covariates Rationale (Normalization)	[Yuying Hwang, PhD]
ROI Definition (and then Adoption)	[Tim Turkington, PhD]

Milestones Horizon/PET-CT Beyond RSNA'08



Value H, M, L	High	High Medium	High High High
Feasibility H, M, L	High	High High	High High High
Priority H, M, L	Quick Hits	High	*Adoption 2010-11, Defined in 2008 **Ideal Phantom 2010-11 Current phantom by 2008