UPICT template structure as modified by QIBA VolCT Technical Committee June 25, 2009

The QIBA VolCT Technical Committee modified and used the UPICT template for a VolCT profile on CT Lung Nodule Volume Measurement for Primary/Regional Nodes and Metastatic Sites. The organizational structure, derived from the UPICT template and used by the VolCT group, is below.

The entire draft VolCT profile on CT Lung Nodule Volume Measurement in the modified UPICT template can be found on the QIBA Wiki at http://qibawiki.rsna.org/index.php?title=Profile:_CT_Lung_Nodule_Volume_Measurement_for_Primary/Regional_Nodes_and_Metastatic_Sites

Section 1: Title Page

Version

Acknowledgement

Suggestion for attribution

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Section 2: Executive Summary, Introduction and Background Information

Section 3: Imaging Protocol: Overview

3.1 Utilities and Endpoints of the Imaging Protocol within the Clinical Trial

3.2 Management of Pre-enrollment Imaging Tests

3.3 Timing of Imaging Tests within the Clinical Trial Calendar

3.4 Management of On-protocol Imaging Performed Off-schedule

3.5 Management of Off-protocol Imaging

3.6 Subject Selection Criteria Related to Imaging (mainly exclusionary in nature)

Section 4: Subject Preparation

4.1 Interval Timing (e.g., oral and/or IV intake, vigorous physical activity, timing relative to non-protocol-related medical interventions, etc.)

4.2 Specific Pre-imaging Instructions

4.2.1 Prior to Arrival

4.2.2 Upon Arrival (including ancillary testing associated with the imaging and downstream actions relative to such testing)

Section 5: Imaging Procedures: General

5.1 Imaging Agent Preparation and Specification (Contrast agent or radiopharmaceutical)

5.1.1 Contrast administration: (agent, dose, route)

5.1.2 Contrast Dose Reduction Based On Creatinine Clearance: (renal function)

5.2 Imaging Data Acquisition

5.2.1 Subject Positioning

5.2.2 Instructions to Subject during Acquisition (e.g., breathing)

5.2.3 Timing (e.g., relative to previously administered imaging agents / enhancers; inter-time point standardization)

Section 6: Universal Parameters (independent of vendor, platform, and version)

6.1 Devices

6.2 # of channels

6.3 Detail: Protocol retrieval

6.4 Detail: Anatomical Coverage

6.5 Detail: Slice Width

6.6 Detail: Slice interval

6.7 Detail: Isotropic Voxels

6.8 Detail: Field of View: Voxel Size

6.9 Detail: Scan Plane

6.10 Detail: Motion Artifact

6.11 Detail: Noise Level

6.12 Detail: Noise

6.13 Detail: Spatial Resolution

6.14 Detail: KVP

6.15 effective mAs (medium patient)

6.16 Detail: Rotation Speed

6.17 Detail: Collimation width (total nominal beam width - often not specified on scanner interface)

6.18 Detail: Mode

6.19 Detail: Table speed

Section 7: Specific Parameters (vendor, platform, and/or version-dependent)
May be contained in associated tables

7.1 Hardware and Set-up

7.2 Software (if appropriate, provide as electronic file for direct implementation on to the imaging platform if appropriate)

Section 8: Inherent Image Data Reconstruction / Processing (e.g., data correction, smoothing)

8.1 Reconstruction Kernel Characteristics

8.2 Reconstruction Interval

8.3 Reconstruction Interval Overlap

Section 9: Archival Requirements for Primary Source Imaging Data

9.1 Detail: Data should be archived in DICOM 3.0 format or the current version of DICOM recommended by XXX WG YY of the XXX.

9.2 De-identification / Anonymization Schema(s) to Be Used

9.3 Archival and Transmission of Image Data

9.4 Requirements for Local Retention of Imaging Data

9.5 Requirements for Central Management of Imaging Data and Imaging Metadata (e.g., the results of image analysis)

Section 10: Post-processing (i.e., anything not done on an acquisition platform that affects DICOM image data and/or pixel / voxel values)

None prior to importation into free standing image analysis software package (Editor's note: The analyses on the free-standing image analysis software package or independent workstation is the content intended for Section 10)

Appendices

Appendix 1. Definitions of Terms and Abbreviations

Appendix 2. Acquisition Parameters and Settings for Specific Makes, Models, and Software Versions

Appendix 3. Imaging-associated Risks and Risk Management

Appendix 4. Reader Training

Appendix 5. Site Selection, Qualification and Protocol-specific Training

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Appendix 1. Definitions of Terms and Abbreviations

Appendix 2. Acquisition Parameters and Settings for Specific Makes, Models and Software Versions

Appendix 3. Imaging-associated Risks and Risk Management

A3.1 Radiation Dose and Safety Considerations

A3. 2 Imaging Agent Dose and Safety Considerations

A3.3 Imaging Hardware-specific Safety Considerations

Appendix 4. Reader Training

Appendix 5. Site Selection, Qualification and Protocol-specific Training

A5.1 Necessary Site Characteristics (e.g., support infrastructure, internet capability, image de-identification and transmission capability)

A5.2 Personnel

A5.2.1 Qualifications

A5.2.1.1 Technical

A5.2.1.2 Physics

A5.2.1.3 Physician

A5.2.2 Protocol-specific Training

A5.2.2.1 Technical

A5.2.2.2 Physics

A5.2.2.3 Physician

A5.3 Availability of Relevant Imaging Equipment

A5.4 Baseline Quality Control Metrics and Capability for Quality Control Procedures (Pertinent to the Clinical Trial)

Quality Control (QC)

QC.1 Quality Control Associated with Individual Subject Imaging

Activity: Acquisition System Calibration

QC.1.1 Phantom Imaging and/or Calibration

QC.1.2 Quality Control of the Subject Image and Image Data

QC.1.3 Documentation of Phantom Imaging and Calibration

QC.2 Quality Control Associated with Imaging Agent Administration

QC.3 Management and Reporting of Adverse Events Associated with Imaging Agent and Enhancer Administration

QC.4 Management and Reporting of Adverse Events Associated with Image Data Acquisition

QC.5 Quality Control of Inherent Image Data Reconstruction / Processing

QC.5.1 Universal

QC.5.2 Vendor-, Platform- and/or Version-specific

QC.6 Quality Control of Image Analysis and Interpretation

QC.7 Site-Related Quality Control

QC.7.1 Mandatory for Site-Selection (e.g., routine and periodic QC measures and documentation)

QC.7.2 Mandatory to Submit Prior to Patient Accrual

QC.7.3 Mandatory to Submit Periodically During the Trial

Required Documentation (RD)

RD .1 Subject preparation

RD .2 Imaging agent dose calculation

RD .3 Imaging agent-related

RD .4 Image data acquisition-related

RD .5 Inherent image data reconstruction / processing

RD .6 Image analysis and interpretation

RD .7 Site selection and Quality Control