This Checklist is organized by "Actor" for convenience. If a QIBA Conformance Statement is already available for an actor (e.g. your analysis software), you may choose to provide a copy of that statement rather than confirming each of the requirements in that Actors checklist yourself. Within an Actor Checklist the requirements are grouped by the corresponding Activity in the QIBA Profile document. If you are unsure about the meaning or intent of a requirement, additional details may be available in the Discussion section of the corresponding Activity in the Profile. Conforms (Y/N) indicates whether you have performed the requirement and confirmed conformance. When responding **N**, please explain why. Several of the requirements mandate the use of specific assessment procedures described in Section 4 in the main body of this Profile. Feedback on all aspects of the Profile and associated processes is welcomed.

ACQUISITION DEVICE CHECKLIST

Parameter	Conforms (Y/N)	Requirement
Sample Protocol		Shall prepare a sample protocol conformant with Section 3.4.2 "Protocol Design Specification"
Noise Performance		Shall demonstrate noise bias is ≤ ± 1 HU and standard deviation is ≤ 20 HU for lung equivalent foam (approximately -850 HU). See 4.1.2 Assessment Procedure: Voxel Noise and Noise Power Spectrum
In-plane spatial resolution		Shall demonstrate a Full-width at half-maximum (FWHM) ≤ 1.0 mm as described in Section 4.1.3.
Through-plane spatial resolution		Shall demonstrate a slice sensitivity profile with FWHM ≤ 1.0 mm as described in Section 4.1.4.
Edge Enhancement		Shall demonstrate an edge enhancement ≤ 3% for the edge response function as described in Section 4.1.3.
Acquisition speed		Shall be capable of whole lung coverage in < 10 s (i.e. a table feed of 3 cm/s or greater).
CT radiation exposure		As prescribed in Section 3.4.2.
Measured HU (Bias)		Shall demonstrate a mean measured HU of -1000 HU ± 6 HU for inside air (within phantom), and 0 HU ± 6 HU for water (within

		phantom)*
HU Stability (Repeatability)		Shall demonstrate a standard deviation of ≤ 1 HU for inside air (within phantom), lung equivalent foam (within phantom), and water (within phantom) measured across N=5 acquisitions
*This specification is only expected to apply in the COPD Gene, or similarly designed, phantom where uniform low-density regions are provided. Both systemic and stochastic noise sources in patient data are expected to introduce bias and reduce precision. This additional variance is accounted for by the repeatability meta-analysis in patient studies used to define the Claims.		

IMAGE ANALYSIS SOFTWARE

Parameter	Conforms (Y/N)	Requirement
Lung Density Analysis		Shall be able to calculate and output for the whole lung: • RA-950 HU • Perc15 • Lung Density Histogram • Total Lung Volume
Lung Density Analysis		Shall use a consistent lung segmentation procedure including the following steps: • Segmentation and removal of central pulmonary blood vessels. • Segmentation and removal of the central airways. Generation of the image histogram for the remaining lung parenchymal tissues
Reproducibility of Analysis Software		Shall calculate and output the whole lung the RA-950, Perc15 and Lung Density Histogram: • The same analysis software shall be identical for each longitudinal time point measured, and

		• Above measures shall be deterministic (yield identical results each time the software analysis is applied to the same patient data set) and therefore add no additional variance to the measurement. See section 4.2 for more detail on procedures
Absence of IV contrast		Shall confirm the absence of IV contrast
Lung Volume		Shall confirm the measured lung volume is within 10% of the baseline.

RADIOLOGIST CHECKLIST

Parameter	Conforms (Y/N)	Specification
Acquisition Protocol		Shall prepare a protocol to meet the specifications in this table. Shall ensure technologists have been trained on the requirements of this profile.
Use of intravenous contrast		Intravenous contrast Shall NOT be used.
Use of oral contrast		Oral contrast Shall NOT be used.
CT Dose		≤ 3mGy CTDIvol for a 75kg subject allowing for increased/decreased CT dose adjusted based on patient size and shape according to manufacturer.

PHYSICIST CHECKLIST

Parameter	Conforms (Y/N)	Specification
Qualification		Shall be a Qualified Medical Physicist (QMP) as defined by AAPM.

Parameter	Conforms (Y/N)	Specification
Monthly QA		Shall evaluate the following parameters for each conformant acquisition device at least monthly or after equipment service that may alter its performance.
Re-establishing Standardization		Shall, if the acquisition device fails Monthly QA, repeat Product Qualification (See 3.1.2) to re-establish standardization.
Scanner Calibration		Shall assess the current CT conformance for HU value and standard deviation, encompassing scanning the COPDGene phantom, and analyzing the images to prove conformance on a quarterly basis.
HU Stability		Shall confirm the longitudinal difference (i.e. drift) between subsequent monthly scans and baseline for air (within phantom) and water (within phantom) falls within ± 4 HU
In-plane Resolution		Shall validate that the protocol achieves a full width at half maximum (FWHM) of line spread function ≤ 1 mm.
Through-plane spatial resolution		Shall validate that the protocol achieves a slice sensitivity profile with FWHM ≤ 1.0 mm
Edge Enhancement		Shall validate that the protocol achieves a minimum edge enhancement of 3% for the edge response function as described in Section 4.
Voxel Noise		Shall validate that the protocol achieves a standard deviation of voxel noise that is ≤ 20HU for lung equivalent foam, air and water materials inside a phantom as described in Section 4.

TECHNOLOGIST CHECKLIST

Parameter	Conforms (Y/N)	Requirement
Scanner Calibration		Shall assess the current CT conformance for HU value and standard deviation, encompassing scanning the COPDGene phantom, and analyzing the images to prove conformance on a quarterly basis.
Total Collimation Width		Shall set to Greater than or equal to 16mm.
Nominal Tomographic Section Thickness		Shall set to Less than or equal to 1mm.
Scan Duration		Shall achieve a table speed of at least 4cm per second (in order to cover the full lung within a 10s breath-hold).

CT Dose		≤ 3 mGy CTDIvol for a medium sized (75 kg) subject with the amount of radiation adjusted based on patient size and shape according to manufacturer.
Reconstruction Protocol		Shall prepare a protocol to meet the specifications in this table. Shall ensure technologists have been trained on the requirements of this profile. Shall select a protocol that has been previously prepared and validated for this purpose. Shall report if any parameters are modified beyond those specifications.
Reconstructed Image Thickness		Shall set to 1.0 mm or less.
Subject Positioning		Shall place the subject in a supine position, arms positioned comfortably above the head in a head-arm rest with lower legs supported.
Table Height		Shall adjust the table height for the mid-axillary plane of the chest to pass through the isocenter.
Subject Alignment		Shall position the subject such that the “sagittal laser line” lies along the sternum (e.g. from the suprasternal notch to the xiphoid process).
Scout Scans		Shall perform a lateral scout and verify that the mid-axillary plane of the bronchial tree, at the level of the carina, is within 2 cm of iso-center. Shall perform an AP (or PA) scout and verify that the subject is correctly centered at horizontal iso-center within 2 cm.
Lung Coverage		Shall match the display field of view between time points to insure consistency of spatial resolution. Shall adjust the Cephalad/caudal coverage of the lungs from apex to base between the TLC and expiratory CT acquisitions to cover the lungs within the limits of the lung apex and base, e.g. no more than 2 cm cephalad to the apical or 5 cm caudal to the basal lung borders.
Breath-hold Coaching		Shall coach the subject on Breath-holding as specified above.
Use of intravenous contrast		Intravenous contrast Shall NOT be used.
Use of oral		Oral contrast Shall NOT be used.

contrast		
Artifact Sources		Shall remove or position potential sources of artifacts (specifically including breast shields, metal-containing clothing, EKG leads and other metal equipment) such that they will not degrade the reconstructed CT volumes.
Acquisition Protocol Selection		Shall select a protocol that has been previously prepared and validated for this purpose (See section 3.4.2 "Protocol Design Specification"). Shall report if any parameters are modified beyond the specifications in section 3.4.2 "Protocol Design Specification".
Acquisition Protocol Selection		If acquiring a longitudinal time point, shall select a protocol on the same CT scanner with equivalent acquisition and reconstruction parameters to that of the baseline CT scan.
Scan Plane		Axial / Transverse
Scout (Topogram, Scanogram)		Shall confirm the absence of metal or other artifacts
Anatomic Coverage		Shall ensure the Full Lung, from 2cm above the apex to 5cm below the base, is covered by the scan
Axial field of view		Shall confirm the display field of view is no more than 2 cm outside maximal lung extent. Shall match the display field of view to that of the Baseline scan, if available.
CT Dose		≤ 3mGy CTDIvol for a 75kg subject allowing for increased/decreased CT dose adjusted based on patient size and shape according to manufacturer.
Adequate coverage		Shall confirm the lung volume is fully represented in the field of view
Motion		Shall evaluate for respiratory motion (cardiac motion is unavoidable and acceptable) and confirm that the lung parenchyma is sufficiently clear and uncorrupted by motion
Spatial resolution.		Shall confirm the image headers (Single Slice Collimation (0018,9306) and Slice Thickness (0018,0050)) indicate the acquired and reconstructed resolutions ≤ 1 mm
CT dose		Shall confirm the image header (CTDIvol (0018,9345)) indicates the CTDIvol is “Per protocol.”

Conformance to baseline.		Shall confirm the Protocol is consistent with the baseline. Shall confirm the FOV (Data Collection Diameter (0018,0090)) are within 10% of baseline except when allowing for specific adjustment to accommodate substantial changes in subject size.

CLINICIAN OR STATISTICIAN CHECKLIST

Parameter	**Conforms (Y/N)**	**Requirement**
Real Change?		Determine if disease progressed or is stable.
Magnitude of Change		Determine if magnitude of the change *is* or *is not* significant with respect to the hypothesis of the proposed study.