QIBA Profile:
Magnetic Resonance Diffusion-Weighted Imaging (DWI) of the Apparent Diffusion Coefficient (ADC)

Appendix F: Checklists

F.1. Site Checklist

Parameter	Conforms (Y/N)	Requirement
Site Qualification (Section 3.2)		
Qualification activities	□ Yes □ No	Shall perform qualification activities for Acquisition Device, Scanner Operator, and Image Analyst to meet equipment, reconstruction SW, image analysis tool and phantom ADC performance metrics as specified in Table 3.2.2 and by trial-specific protocol 3.6.2
Periodic QA (Section 3.5)		
Periodic DWI QA	□ Yes □ No	Shall perform annual periodic QA (and after major hardware or software changes) for Acquisition Device that includes assessment of ADC bias, random error, linearity, DWI SNR, DWI image artifacts, *b*-value dependence (linearity) and spatial uniformity (3.2.2)
Equipment	□ Yes □ No	Same, pre-qualified equipment and SW shall be used over the length of trial, and all preventive maintenance shall be documented over the course of the trial. Re-qualification shall be performed in case of major SW or hardware upgrade. Study of each patient shall be performed on the site pre-qualified scanner using approved receiver coil and pre-built profile-conformant scan protocol (3.6)

F.2. Acquisition Device Checklist

Parameter	Conforms (Y/N)	Requirement
Site Qualification (Section 3.2)		
DWI Tags	□ Yes □ No	Shall preserve tags related to DWI, including private tags, which may be vendor-specific. Some key tags are specified in Appendix D.
Short-term (intra-exam) ADC repeatability at/near isocenter	□ Yes □ No	RC $\leq 1.5 \times 10^{-5}$ mm^2/s and wCV $\leq 0.5\%$ for ice-water phantom or other quantitative DWI phantom
Long-term (multi-day) ADC repeatability at/near isocenter	□ Yes □ No	RC $\leq 6.5 \times 10^{-5}$ mm^2/s and wCV $\leq 2.2\%$ for ice-water phantom or other quantitative DWI phantom
DWI *b*=0 SNR	□ Yes □ No	SNR (b=0) $\geq 50 \pm 5$ for ice-water phantom or other quantitative DWI phantom.
ADC *b*-value dependence	□ Yes □ No	< 2% for ice-water phantom or other quantitative DWI phantom over *b*-value pairs 0-500; 0-1000; 0-1500; and 0-2000 s/mm^2
Maximum |bias| within 4 cm of isocenter	□ Yes □ No	< 4% for uniform known ADCs within DWI phantom

Parameter	Conforms (Y/N)	Requirement
ADC error at/near isocenter	□ Yes □ No	ADC random error ≤ 2% for ice-water phantom or other quantitative DWI phantom
Optional: Additional requirements for studies involving off-center ADC measurement:		
R/L offset 4–10 cm (A/P and S/I < 4 cm)	□ Yes □ No	< 10% for uniform known ADCs within DWI phantom
A/P offset 4–10 cm (R/L and S/I < 4 cm)	□ Yes □ No	< 10% for uniform known ADCs within DWI phantom
S/I offset 4–10 cm (R/L and A/P < 4 cm)	□ Yes □ No	< 10% for uniform known ADCs within DWI phantom
Protocol Design (Section 3.6)		
Scan Protocol Parameters, DICOM Conformance, and Image Reconstruction	□ Yes □ No	Device scan protocol parameters shall be within organ-specific ranges listed in the protocol specification tables (3.6.2). Shall be capable of performing reconstructions and producing images with all the parameters set as specified. Shall meet DICOM header and image registration requirements specified in 3.10.2, including storage of *b*-values, DWI directionality, image scaling and units tags, as specified in DICOM conformance statement for the given scanner SW version, as well as the model-specific Reconstruction Software parameters utilized to achieve conformance.
Image Distribution (Section 3.12)		
Image DICOM	□ Yes □ No	DICOM tags essential for downstream review and diffusion analysis shall be maintained including pixel intensity scaling [114], *b*-value, and DWI directionality vs. trace, and ADC scale and units. Trace DWI DICOM at each *b*-value shall be archived in the local PACS.

F.3. SCANNER OPERATOR CHECKLIST

Parameter	Conforms (Y/N)	Requirement
Site Qualification (section 3.2)		
Acquisition Protocols	□ Yes □ No	Shall prepare scan protocols conformant with section 3.6.2 "Protocol Design Specification" and phantom qualification (Appendix D) and ensure that DWI acquisition parameters (*b*-value, diffusion direction) shall be preserved in DICOM and shall be within ranges allowed by study protocol (both for phantom and subject scans). Shall check for protocol conformance, consistent patient positioning (orientation, target lesion location relative to isocenter), and that all subject-specific adjustments (i.e., to suit body habitus) are consistent across serial scans.
Acquisition Device Performance	□ Yes □ No	Shall perform assessment procedures (Section 4) for site qualification and longitudinal QA for the acquisition devices participating in trial to

Parameter	Conforms (Y/N)	Requirement
		document acceptable performance for phantom ADC metrics as specified in table 3.2.2
Acquisition Device	□ Yes □ No	The same scanner shall be used for baseline and subsequent longitudinal measurements for detecting change in ADC.†
Image Data Reconstruction (section 3.10)		
Trace DWI and ADC map generation across subjects and time	□ Yes □ No	Number and magnitude of *b*-values shall be consistent across TPs for patients. ADC maps shall be generated in a consistent manner across TPs, including post-processing, fit model, and image registration.
b-value record	□ Yes □ No	Scanner operator shall verify that the reconstruction SW records *b*-values, or if not shall manually record the *b*-values, that are used to generate the ADC map.
ADC maps	□ Yes □ No	ADC maps shall be preserved with DICOM scale tags. ADC map scale/units and *b*-values used for generation shall be recorded.

† Not using the same scanner and image acquisition parameters for baseline and subsequent measurements does not preclude clinical use of the measurement but will exclude meeting the requirements of the Profile claim.

F.4. IMAGE ANALYST CHECKLIST

Parameter	Conforms (Y/N)	Requirement
Staff Qualification (section 3.1)		
Qualification	□ Yes □ No	Shall be a radiologist, technologist, physicist, or other scientist with documented and authorized training in terms of: anatomical location and image contrast(s) used to select measurement target; understanding key principles of diffusion weighting, directionality, and diffusion test procedures; procedures to maintain diffusion-related DICOM metadata content along the network chain from Scanner to PACS and analysis workstation; the use of the Image Analysis Tool, including ADC map generation from DWI (if not generated on the scanner), and ADC map reduction to statistics with ROI/VOI location(s)
Site Qualification (section 3.2)		
Image Analysis Tool Performance	□ Yes □ No	Shall test Image Analysis Tool to ensure acceptable performance according to 3.13.2 specifications for study image visualization, DICOM and analysis meta-data interpretation and storage, ROI segmentation, and generation of ADC maps and repeatability statistics for qualification phantom (below)
Phantom ADC ROI	□ Yes □ No	Shall confirm that phantom ADC ROI is 1–2 cm diameter (> 80 pixels without interpolation) for all Acquisition Device specifications in Table 3.2.2

Parameter	Conforms (Y/N)	Requirement
Phantom ADC metrics	□ Yes □ No	Shall evaluate and record phantom ADC metrics (bias, linearity and precision) according to Table 3.2.2 specifications for Acquisition Device qualification and periodic QA using QIBA-provided or qualified site Image Analysis Tool, or QIBA-certified 3rd party analysis services
Image Analysis (section 3.13)		
ROI Determination	□ Yes □ No	Shall segment the ROI on ADC maps consistently across time points using the same software / analysis package guided by a fixed set of image contrasts and avoiding artifacts

F.5. RECONSTRUCTION SOFTWARE

Parameter	Conforms (Y/N)	Requirement
Image Data Reconstruction (Section 3.10)		
Trace DWI	□ Yes □ No	Trace DWI shall be auto-generated on the scanner and retained for all $b > 0$. For equal b-value on 3 orthogonal directions, trace DWI is the geometric average of the 3-orthogonal directional DWI.

F.6. IMAGE ANALYSIS TOOL CHECKLIST

Parameter	Conforms (Y/N)	Requirement
Image Analysis (section 3.13)		
ROI geometry	□ Yes □ No	Screenshot(s) documenting ROI placement on ADC maps shall be retained in the subject database for future reference ROI as a binary pixel mask in image coordinates is desired in the subject database for future reference. Ideally, ROI shall be saved as a DICOM segment object
Image Display	□ Yes □ No	Software shall allow operator-defined ROI analysis of DWI/ADC aided by inspection of ancillary MR contrasts Ideally, above plus multi view-port display where DWI/ADC and ancillary MR contrasts from the same scan date are displayed side-by-side and geometrically linked per DICOM (e.g., cursor; crosshair; ROI; automatically replicated in all view-ports); ROIs/VOIs may include multiple noncontiguous areas on one slice and/or over multiple slices
Analysis Procedure	□ Yes □ No	Analysis steps, derived metrics and analysis software package shall be held constant for all subjects and serial time points

Parameter	Conforms (Y/N)	Requirement
ADC statistics	□ Yes □ No	Shall allow display and retention of ROI statistics in patient DICOM database (PACS). Statistics shall include ADC mean, standard deviation, and ROI/VOI area/volume Ideally, ADC pixel histogram, additional statistics for ADC maximum, minimum, exclusion of "NaNs", and explicit recording of inclusion or exclusion of "zero-valued pixels shall be retained with the statistics
Fit algorithm type	□ Yes □ No	The specific choice of the fit algorithm (e.g., linear fit to logarithmic SI vs. non-linear fit with Rician noise, a particular scanner software version, etc.) shall be recorded, held constant within a study and reported with any dissemination of study findings.
Fit algorithm bias	□ Yes □ No	For offline ADC map generation, the mean ADC shall agree with scanner-generated, or DRO ground truth, ADC values to within one ROI standard deviation.
b-value and direction	□ Yes □ No	Software shall extract *b*-values and diffusion axis direction from DICOM header
Phantom ADC QC metrics	□ Yes □ No	Software with independent QA option shall evaluate and report phantom scan protocol compliance and ADC metrics including bias, random error, linearity, DWI SNR, *b*-value dependence, and spatial uniformity according to Table 3.2.2 to enable performance assessment for Site qualification (3.2) and periodic QA (3.5)