QIBA Profile Conformance

Self – Attestation

Document

QIBA profile title	FDG-PET/CT for response to cancer therapy
QIBA profile version	November 18, 2016
Company/Institution doing self-attestation	
Company/Institution responsible person	
Clinical trial identifier self-attestation was performed for	
Self-Attestation review requested (date)	
Self-Attestation reviewed by QIBA (date)	
Self-Attestation Conformance Statement publication date	
Expiration date	
Self-Attestation report available	

Some checklist items reference a required Assessment Procedure which may be found in the Profile Document.

Some checklist items have clarifications, rationale, or guidance in the corresponding Discussion section in the Profile Document.

To obtain a copy of the Profile Document, visit http://qibawiki.rsna.org/index.php/Profiles

If a QIBA Conformance Statement is already available for an actor (e.g., your acquisition device), a site may choose to provide a copy of that statement rather than confirming each of the requirements in that Actors checklist yourself.

Vendors publishing a QIBA Conformance Statement shall provide a set of "Model-specific Parameters" (as shown in Annex A) describing how their product was configured to achieve conformance. Vendors shall also provide access or describe the characteristics of the test set used for conformance testing.

QIBA Conformance Statements

QIBA Conformance Statements are documents prepared and published by vendors or sites to describe the intended conformance of their products, staff or institution to one or more QIBA Profiles.

Conformance requirements are defined in the QIBA Profile document for each Actor in the Profile. For some requirements, the Profile document also defines assessment procedures.

This conformance statement contains all relevant checklists for all relevant actors for site or product conformance. Supporting material is available on the QIBA wiki conformance section for the respective profile. Checklists in this conformance statement document need to be filled out.

Users can use Conformance Statements to determine whether their staff and products can be expected to deliver the biomarker performance described in the Profile Claim. Achieving the performance claim depends on all Actors described in the Profile being present at the site and conforming to the requirements.

A QIBA Conformance Statement is not intended to promote or advertise aspects of a product or site not directly related to its implementation of QIBA capabilities.

IMPORTANT NOTE: Vendors and sites are solely responsible for the accuracy and validity of their QIBA Conformance Statements. QIBA and its sponsoring organizations have not evaluated or approved any QIBA Conformance Statement or any related product, site or staff, and QIBA and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any QIBA Conformance Statement.

QIBA Conformance Statement for a Clinical Trial

QIBA Conformance Statement			
CRO	**BM/Trial**	**Version**	**Date**
Any CRO	BM		
This product conforms to all specifications required for the QIBA Profiles and Actors listed below:			
Profiles Implemented	**Actors Implemented**	**Notes**	
FDG-PET/CT for response to cancer therapy November 18, 2016			
Links to Additional Information			
Submitter's QIBA information: www.anymedicalsystemsco.com/qiba			
General information on QIBA: qibawiki.rsna.org			

Annex A: Conformance Notes

1. CRO and central imaging corelab

Clinical Sites - Acquisition Device Checklist

List of used acquisition devices for Self-Attestation at clinical sites

And list of clinical sites with level of QIBA profile conformance

It is assumed that for clinical sites that are claiming QIBA profile conformance respective SA conformance documents are filled in (see below)

Clinical site	QIBA profile conformance - SA	Acquisition device
Relevant BM:		

CRO Checklist

Parameter	Conforms (Y/N)	Requirement
Site management		
Site questionnaire /survey	□ *Yes* □ *No*	Shall check that site questionnaire/survey includes all relevant checklist items from QIBA profile as appropriate for the given trial
Clinical sites are QIBA profile conformant	□ *Yes* □ *No*	Shall check QIBA profile SA statement per site. At least three sites need to be SA registered.
Phantom images	□ *Yes* □ *No*	Shall check phantom image delivery in time if phantom imaging is required for the respective imaging BM
Clinical scan	□ *Yes* □ *No*	Shall check that clinical scan is delivered in time as requested by clinical trial protocol
Imaging Manual		
Imaging Manual	□ *Yes* □ *No*	Shall check that imaging manual includes all relevant checklist items from QIBA profile as appropriate for the given trial
Imaging Manual	□ *Yes* □ *No*	Shall check that implemented manual steps are followed for each phantom and clinical imaging time point
Imaging C		
Imaging charter	□ *Yes* □ *No*	Shall check that imaging charter includes all relevant checklist items from QIBA profile as appropriate for the given trial
Imaging charter	□ *Yes* □ *No*	Shall check that implemented charter steps are followed for each phantom and clinical imaging time point

CRO - Image Analysis Workstation

ACCEPTABLE: Actors that shall meet this specification to conform to this profile.

TARGET: Meeting this specification is achievable with reasonable effort and adequate equipment and is expected to provide better results than meeting the ACCEPTABLE specification.

IDEAL: Meeting this specification may require extra effort or non-standard hardware or software but is expected to provide better results than meeting the TARGET.

Parameter	Entity/Actor	Specification	Conforms Y/N
Metadata	Image Analysis Workstation	Shall be able to accurately propagate the information collected at the prior stages and extend it with those items noted in the Image Analysis Workstation section.	
		Shall be able to display all information that affects SUVs either directly in calculation (e.g., patient weight, injected activity or indirectly (uptake time, plasma glucose concentration).	
Tracer Uptake Time: Display	Image Analysis Workstation	Shall be capable to display or include link to display the number of minutes between injection and initiation of imaging (as per derivation guidelines described in Section 4.2).	
Reference time for decay correction	Image Analysis Workstation	Shall use either the Acquisition Time field (0008,0032) or Radiopharmaceutical Start Time (0018,1072), if necessary. If a series (derived or not) is based on Acquisition Time decay correction, the earliest Acquisition Time (0008,0032) shall be used as the reference time for decay correction.	

Region of Interest definition

Parameter	Entity/Actor	Specification	Conforms Y/N
Voxel Inclusion Policy	Analysis Tool	Shall describe voxel inclusion methodology and weighting policy including placement criteria and total volume.	
		Use a method equivalent to weighting for partial voxels; fully included voxels use weight of 1.0. Weighting should be proportionate to volumes of voxels that are partly included.	
ROI Specifications	Analysis Tool	Shall describe capabilities and limits of ROI specification and placement.	
		Dimensions and center location of ROI (box, ellipse, or ellipsoid) shall be specifiable to ±1 mm. For SUVpeak measures, the location within a target search region that yields the highest mean value of a 1 cc region shall be found automatically and reproducibly.	
ROI Definition Tools	Analysis Tool	Shall provide a tool and user strategy to allow the placement of an ROI to determine the average value within the ROI. Shall provide a tool and user strategy to allow the placement of an ROI to determine the value and location of the voxel with the maximum value within an ROI. Shall provide a tool and user strategy to allow the placement of a 1 cm diameter ROI (either 2D or 3D) to determine the average value within the ROI.	
		Shall provide a tool and user strategy to allow automatic placement of a 1 cm diameter ROI (either 2D or 3D) such that	

Parameter	Entity/Actor	Specification	Conforms Y/N
		the average value within the ROI is maximized.	
Edge/Volume Detection	Analysis Tool	Shall provide threshold methods for defining an ROI based on image values. Shall clearly specify which threshold method is used and relevant parameters values.	
		Three ROI definition methods shall be provided: Fixed value, % of maximum voxel, or edge detection/segmentation methods.	
ROI saving/retrieve	Analysis/Archival	Shall have the capability to label, save, recall and edit ROIs.	
		Shall have the capability to track tumor information across longitudinal scans. In addition to lesion (and normal reference region) identification, this may include cross time point mapping of lesions tracked on the basis of consistent anatomic and/or functional activity. Other lesion characteristics, such as lesion name (with consistent anatomic labeling), lesion location, ROI/VOI size, corresponding anatomic (CT) image or slice number, SUV metric(s) and assessment of tumor heterogeneity may also be tracked and captured using standard DICOM objects.	
ROI Display Statistics	Analysis Tool	Shall have the capability to output to the screen display the selected statistics of the ROI. These include, but are not limited to: Area, volume, mean, maximum, minimum, standard deviation. Units can be	

Parameter	Entity/Actor	Specification	Conforms Y/N
		selectable as activity concentration [Bq/ml] or SUV [g/ml] (See Section 3.4.3). Shall have the capability to display results with at least two decimal places.	
		Shall output ROI Output Statistics to Structured Data Reporting DICOM files. Shall calculate results directly from the originally reconstructed voxels (not from interpolated and/or zoomed images).	

Calculation of SUV

Parameter	Entity/Actor	Specification	Conforms Y/N
SUV Calculation	Analysis Tool	Shall have the capability to correctly calculate SUVs according to the vendor-neutral pseudo-codes for SUV calculation given in Appendix G.	
Volume of Distribution Surrogate	Analysis Tool	Shall have the capability to calculate SUVs using as a surrogate for the Volume of Distribution: body weight, lean body mass, and body surface area (BSA). Lean body mass shall be calculated according to the formula of James [James 1976, Hallynck 1981]: Males: LBM = 1.10(w) – 128(w^2/h^2) Females: LBM = 1.07(w) – 148(w^2/h^2) Body surface area shall be calculated according to the Du Bois formula: BSA (m^2) = (0.007184)((w)^(0.425))((h)^(0.725)) [Vu 2002] Where w = weight in kg and h = height in cm.	

Software version tracking

Parameter	Entity/Actor	Specification	Conforms Y/N
Software Version tracking	Acquisition Device	Shall record the software version(s) used for acquisition and reconstruction in appropriate DICOM field(s).	
Software version back-testing compatibility	Workstation	Shall provide mechanism to provide analysis of the image data using updated as well as prior (platform-specific) versions of analysis software.	

2. QIBA Conformance Statement for a Site

To be filled in per contributing site in the clinical trial

QIBA Conformance Statement		
Site Name	**Responsible Person**	**Date**
This site conforms to all specifications required for the QIBA Profiles and Actors listed below:		
Profiles Implemented	**Actors Implemented**	**Notes**
FDG-PET/CT for response to cancer therapy November 18, 2016	Clinical Site	
Links to Additional Information		
Submitter's QIBA information: www.anymedicalsystemsco.com/qiba		
General information on QIBA: qibawiki.rsna.org		

#	***Site and Personnel Qualifications***	***Status***
1.	The site is accredited (ACR, IAC, TJC, etc.) or has Qualified status for clinical trials (ECOG-ACRIN, SNMMI-CTN, EARL, CROs, etc.)	yes __no
2.	The site has the support of technologists, physicists, and physicians experienced in the use of FDG-PET/CT, and meeting the qualifications described below.	yes __no
3.	Technologists: PET studies are performed by technologists whose certification is equivalent to the recommendations published by the representatives from the Society of Nuclear Medicine Technologists Section (SNMTS) or the American Society of Radiologic Technologists (ASRT) and should also meet all local, regional, and national regulatory requirements for the administration of ionizing radiation to patients.	yes __no
4.	Physicists: The medical physicist is certified in Medical Nuclear Physics or Radiological Physics by the American Board of Radiology (ABR); in Nuclear Medicine Physics by the American Board of Science in Nuclear Medicine (ABSNM); in Nuclear Medicine Physics by the Canadian College of Physicists in Medicine; or equivalent certification in other countries; or have 3 years of PET experience. Regardless of certification, the physicist should have specific experience in PET and its quantitative use.	yes __no
5.	Physicians overseeing and interpreting PET/CT scans are qualified by the ABR (Diagnostic and/or Nuclear Radiology) or American Board of Nuclear Medicine (ABNM) or equivalent within the United States or an equivalent entity appropriate for the geographic location in which the imaging study(ies) will be performed and/or interpreted.	yes __no
	Imaging Procedures	
6.	Patient height and weight are entered into scanner during PET/CT acquisition.	yes __no
7.	Blood glucose is measured for each patient within 2 hours preceding FDG administration. Measured value and measurement time are documented.	yes __no
8.	If and when glucose threshold is exceeded, the reason shall be documented.	yes __no
9.	For each patient, the pre-injection FDG activity is measured, and injected, and residual activity is measured. Initial and residual measurement times and injection time are entered into the console.	yes __no
10.	FDG is administered through a 24-gauge or larger indwelling catheter placed anatomically remote to any sites of suspected pathology, preferably in an antecubital vein. Intravenous ports should not be used, unless no other venous access is available. In the case of manual administration, a three-way valve system should be attached to the intravenous cannula to allow at least a 10 cc normal (0.9% NaCl) saline flush following FDG injection. For automated injection devices alternate flushing mechanisms are allowed.	yes __no
11.	For follow-up scans, patients are imaged with the same workflow (i.e., patient handling, imaging acquisition, image processing, and image analysis) as for baseline scans.	yes __no
12.	The FDG uptake time (from injection to scan) is 60 minutes, with an acceptable range of 55-75 minutes. When repeating a scan on the same subject, uptake time for the 2nd scan is within 10 minutes of that for the first scan.	__ yes no
13.	If the patient is observed to take a deep breath during the CT scan it is documented, and a repeat CT study is considered.	yes __no

14.	When a patient is rescanned, the same scan direction is used.	yes __no
15.	Reconstructed PET images, with and without attenuation correction, and CT images are archived at the imaging site.	yes __no
	QA/QC	
16.	The site performs all PET/CT scanner QA/QC procedures recommended by the manufacturer and at the recommended frequency (e.g., daily, weekly, quarterly) and assures that the output values are acceptable.	yes __no
17.	Daily QA procedures are performed prior to any subject scan.	yes __no
18.	A water or water-equivalent phantom is scanned and evaluated daily, and acceptable output is ensured.	yes __no
19.	Dose calibrator constancy is evaluated daily on the F-18 setting. Day-to-day differences no greater than 2.5% are allowed. Cs-137, Co-57, or simulated F-18 may be used.	yes __no
20.	The dose calibrator accuracy is evaluated monthly with measured values differing no more than 2.5% from the actual source value. Cs-137, Co-57, or simulated F-18 may be used.	yes __no
21.	Dose calibrator linearity is assessed at least annually over a range of 37-1110 MBq, with deviation of no more than 2.5% over the entire range.	yes __no
22.	Scales for patient weight measurement are evaluated annually or after any repair by qualified personnel, with error no more than 2.5% from expected values using a NIST-traceable or equivalent standard.	yes __no
23.	The glucose measuring device is measured and tested according to a CLIA-approved, CLIA-cleared, or equivalent (if outside the United State) procedure.	yes __no
24.	The PET/CT scanner computer and all clocks in the imaging facility used to record activity/injection measurements are synchronized to standard time reference within +/-1 minute. Synchronization of all clocks used in the conduct of the FDG-PET/CT study is checked weekly and after power outages or civil changes for Daylight Savings (North America) or Summer Time (Europe).	yes __no
25.	Quantitative Calibration Accuracy: PET scanner quantitative accuracy relative to the dose calibrator is verified quarterly and after scanner upgrades, maintenance or repairs, new setups and modifications to the dose calibrator via a uniform phantom scan of activity measured in the dose calibrator, achieving a large central ROI mean SUV value of 1.0 (acceptable range 0.9-1.1).	yes __no
26.	Axial Uniformity: Using a uniform cylinder phantom or equivalent shall obtain a slice-to-slice variability of less than 10% for the slices within the central 80% of the axial FOV.	yes __no
27.	PET Resolution: Cold rods (as in the Jaszczak or ACR PET phantoms) of diameter 9.5 mm or smaller must be visible. A hot cylinder (as in the ACR PET phantom) of 12 mm or smaller must be visible OR the 13 mm sphere of the NEMA image quality phantom must be visible.	yes __no
28.	PET noise: In a uniform phantom of 0.1 to 0.2 µCi/ml F-18 concentration the coefficient of variation of voxel values within a rectangular or circular region of at least 3 cm (side or diameter) must be no greater than 15% for all slices within the central 80% of the axial FOV.	yes __no

	Specific Personnel Responsibilities	
29.	A ~~technologist or~~ physicist assesses uniformity (within-plane and across slices) and compares with previous results. Quarterly and following software upgrades.	yes __no
30.	A ~~technologist or~~ physicist shall perform the Quantitative Calibration Accuracy test. Quarterly and following software upgrades or changes to the dose calibrator	yes __no
31.	A physicist shall perform and document performance of a quantitative assessment (using a phantom with differing size defined targets such as the ACR or NEMA IQ phantoms processed with routine image reconstruction protocols) for lesion resolution. Annually.	yes __no
32.	A physicist shall perform a quantitative assessment of image noise in phantom images to be of consistent and acceptable quality. Annually.	yes __no