

QIBA: FDG-PET/CT Profile: Status Update & Plan

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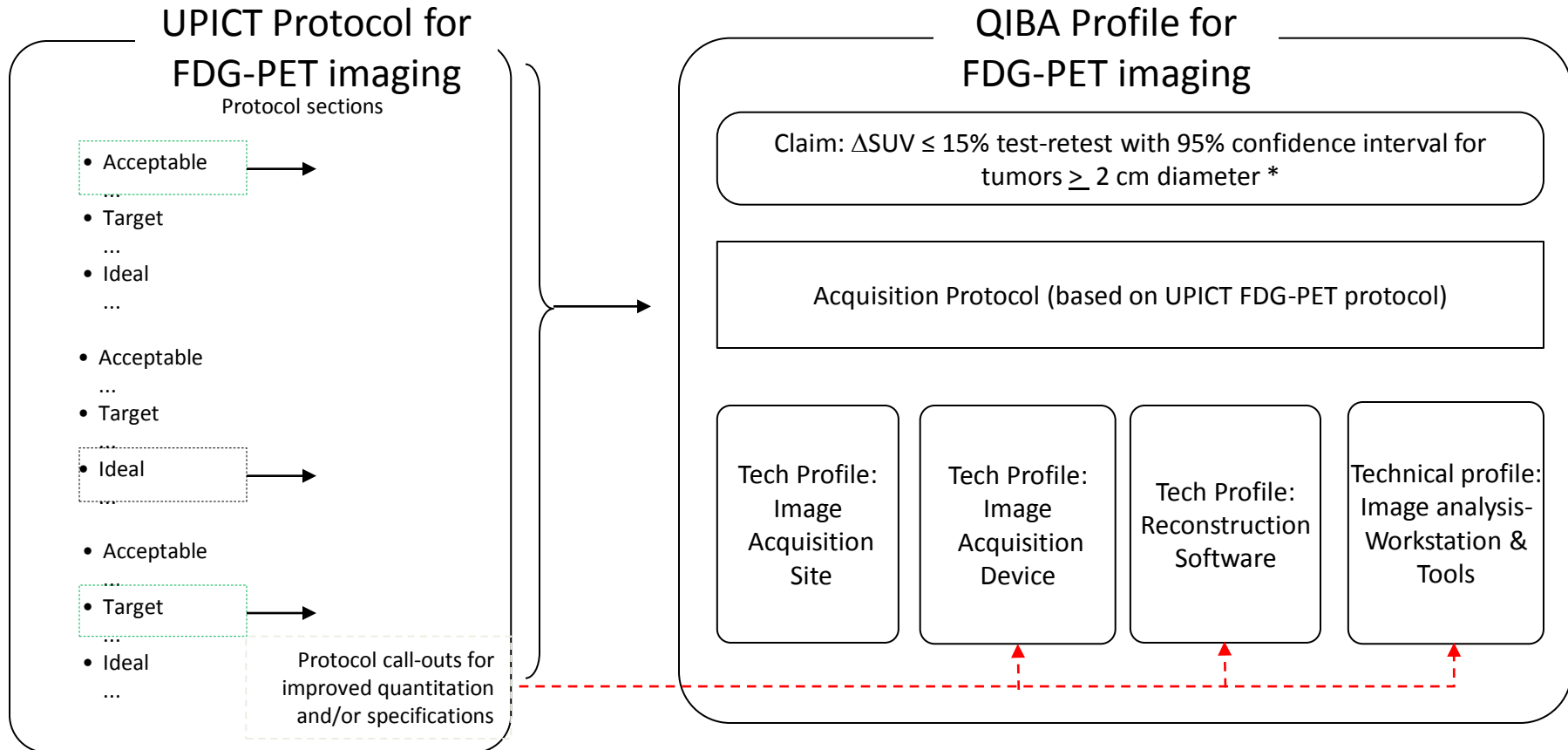
Profile Content / Format

- FDG-PET/CT UPICT Protocol
- FDG-PET/CT QIBA Tech Committee outputs:
 - Subcommittee reports/notes
 - List of Requests ('asks')
 - Top 10 Suggestions
- QIBA DCE-MRI & Vol. CT Profile formats

Protocol - Profile relationship

FDG-PET Biomarker Qualification Claim

Data on correlations between FDG-PET imaging and outcomes



Not final claim language; Two part claim –

1. Historical statement of fact for single center
2. Hypothesis of same (or slightly 'weaker') for multi-center

Profile:

Document Organization

- I. Executive Summary
- II. Clinical Context & Claim(s)
- III. Profile Details
- IV. Compliance

Section III. Profile Details

Subsections:

1

2

3

4

5



AND Quality Control (Subsection 6):

- Image Acquisition Facility
 - Scanner
 - Other Devices/Instruments
 - Personnel
 - Phantom Imaging
- PET/CT Image Output (= the study)
- Interpretation

Section IV: Compliance - Technical Specifications

1. Image Acquisition Site/Facility
2. Acquisition Device
3. Reconstruction Software
4. Analysis Software
 - Pixel voxel/sphere specification
 - ROI/VOI
 - Characteristics of Data
 - Performance Specifications (DRO)

Quality Control (Section III.6) vs. Compliance (Section IV)

COMPLIANCE

- Image Acquisition Facility
- Acquisition Device
- Reconstruction Software
- Analysis Software

“basal state”

QUALITY CONTROL

- Image Acquisition Facility
 - Scanner
 - Other Instruments
 - Personnel
 - Process
- PET/CT Image Output
- Interpretation

“production state / in action”

Specification Strategy:

Essential (to comply) vs. desirable (to exceed)

Lesion Analysis Tool: Metabolic Activity	Analysis Tool	Shall provide tools to measure and report SUV/SUL mean
		Ideally, would provide tools to measure and report SUV/SUL mean and SUV/SULpeak

Blood Glucose Level	Technologist	Shall document subject blood glucose on Form or in Electronic database
	Acquisition Device	Ideally, would have a DICOM tag for the Subject's blood glucose

Open Action Items

- *Claim language to be finalized*
- Revision of Figure 1: tbd
- Consider text revision for Profile Detail subsections
- Missing content? (e.g. handling odd matrix sizes inter-device)
- How to handle specification for SW tracking/compatibility
- Review rows re: essential (compliant) vs. desirable (ideally,)
- DRO thresholds (performance specifications) - tbd
- References / Bibliography
- Committee member listing
- *Appendices*
 - *Background Detail*
 - *Manufacturer specific issues*