Amloid Imaging

**Amloid Imaging Importance in clinical trials and patient care**

Beta amyloid plaques are a hallmark of Alzheimer's disease, accumulating years prior to symptom onset. Fibrillar amyloid can be measured using PET and there are now three FDA approved F-18 tracers, while 11C-PIB is years prior to symptom onset. A Digital Readout Object (DRO) developed through a QIBA Grant Program to establish testing of image workation software linearity and repeatability, and in the future can be used to test accuracy.

**Amloid Imaging Scope**

- Initial focus on late timeframe in which the tracer has come to "pseudo-equilibrium", during which a Standard Tissue Ratio (SUVR: Target region value / reference region value) is calculated.
- Focus chosen due to the number of imaging sites able to implement, and the data that has been / is being acquired using this approach.
- Potential benefits of full dynamic modeling are also described.

**Amloid Imaging Claims**

Claims describe the performance achievable when profile guidelines are followed, or the claims focused on applications for:

- Confidence interval for a single scan in an individual
- Information to calculate number of subjects required to detect a particular longitudinal change or reduction of change rate

An accuracy (cross sectional magnitude) claim is anticipated for version 2.

**Amloid Imaging Activities and Guidelines**

The profile identifies critical factors and recommendations impacting test-retest variability at each stage in image acquisition, processing and analysis, with highlights summarized here.

**SUBJECT HANDLING**

- Tracer preparation, amount injected, and injection time window should be consistent and according to manufacturer label
- Subject positioning should ensure complete brain coverage, distracted from edge of scanner field of view, with subject comfortable and firmly secured to prevent head motion.

**IMAGE ACQUISITION**

- Same scanner should be used to acquire serial images within-subject.
- Time window: Same post-injection time window should be used from scan to scan.
- Subject motion: Major contributor to error, must minimize between and within transmission and emissions.
- Frames: Multiple timeframes should be used (<5 min. each) to enable realignment if subject motion occurs.

**IMAGE RECONSTRUCTION AND POST PROCESSING**

- Same reconstruction method and parameters should be used, as based on a QIBA groundwork project, within-subject regional changes can be 10%, lower when cortical average is used.
- Emission – Transmission scan alignment is critical as differences can introduce several percent error as quantified in a QIBA groundwork project
- Intra-scan inter-frame motion correction is an important contribution to test-retest variability due to motion induced tissue misalignment.

**IMAGE ANALYSIS**

- Co-registration and warping must be consistent with goodness of fit verification, serial PET to PET co-registration can provide greater alignment, reducing variability
- Reference region should be selected to minimize methodological complexity.
- Cerebral cortex can optimize sensitivity, but can be vulnerable to scanner noise and subject motion, and its low-activity location relative to target regions can create longitudinal error from scanner axial variability. Region including whole matter and/or superior slices can reduce variability (florbetapir studies).
- Target regions must be placed consistently. Use of a cortical average must be considered. Atrophy rate may influence measurement.

**QUALITY CONTROL**

The Quality Control section and Appendices provide guidelines on procedures such as phantom imaging to ensure equipment and site quality, and examples of results.

**Conformance Testing**

The Conformance Testing section of the Profile specifies conformability criteria and evaluation methods to ensure that an imaging site, equipment, and analysis workation software meet the requirements described in the Profile as necessary to meet the QIBA Profile claim.

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For more information, visit http://www.qiba.org.