Alzheimer’s Disease

Overview & Facts

- Alzheimer’s disease (AD) is a type of dementia which manifests as progressive cognitive and behavioral impairment.
- Of the estimated 5.3 million Americans with AD, most patients are 65 or older.
- By the year 2050, it is estimated that 13.8 million people in the U.S. will have AD.
- AD is the sixth leading cause of death in the U.S. It is the only one of top 10 causes of death that cannot be prevented, cured or slowed down until this time.
- There have been significant advances in the scientific understanding of the pathophysiology of the disease, but there is much to learn.
- Pathologic hallmarks of the disease include extracellular beta-amyloid (Aβ) plaque formation and neurofibrillary tangles associated with hyperphosphorylated tau protein.

Amyloid-PET Tracers

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Amyloid PET Overview

Profile Status

The Amyloid PET Profile, the current lingual standards address assessment of the change in beta-amyloid deposition in florbetapir.

Change in ADIC from 0% to 4% indicates a true change has occurred (P < 0.05).

The clinical utility of the PET technique is for the purpose of assessing the efficacy of potential novel therapeutic approvals, to detect disease progression, and to identify patients with AD biomarkers.

Key Findings

- Florbetapir PET images were superior to performance with lower Variance, accuracy levels when using Florbetapir PET compared to other radiotracers.

Workflows & Technical Requirements

- The Profile addresses each of the tasks in the workflow from technical requirements of the PET scanner and the process of preparing and performing the amyloid PET scan to the analysis and interpretation of the data. Below are examples of some of the basic requirements defined within the Profile.
- The Profile is intended for PET facilities that perform amyloid PET scans on patients with Alzheimer disease and related dementias.
- The Profile includes a series of amyloid DROs simulating an range of anatomical variants, with an array of amyloid PET distributions.

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QIBA PET Biomarker Committee: Overview and 2016 Update


QIBA PET in context of other activities

Efforts by the QIBA Amyloid PET BC complement the work of other concert and collaborative efforts, including:

- The American Society of Neuroradiology (ASNR) Quality Initiative Project, which works with regulatory agencies (FDA, EMA) to achieve qualification of imaging and other biomarkers for use in clinical decision-making.
- The Coalition Against Major Depression (CAMD) (Analog of the Critical Path Initiative), which is a public-private partnership that seeks to improve the efficiency and efficacy of clinical development processes and accelerate innovation in antidepressive disease and mood disorders.
- The DIAS trial (Imaging Dementia—Evidence for Amyloid Scanning). A $100 million multi-site study for more than 18,000 patients with mild cognitive impairment or dementia of uncertain origin that is being funded by the Centers for Medicare and Medicaid Services (CMS) to determine the effect of florbetapir amyloid imaging on patient outcomes, to support positive reimbursement by Medicare and other third party payers.

Planned Activities 2017

Profile: Writing the Profile has been the Amyloid PET Biomarker Committee’s (BC) primary activity to date. The committee’s goal is to produce a published Profile by 4Q2016 with a Public Consensus version by 1Q2017.

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Amyloid PET Overview Issues

- The Amyloid PET Biomarker Committee is composed of volunteers who work together in a pre-competitive, international forum. The current composition of the group is indicated by stakeholder affiliation. Members are drawn from the following groups: academic, industry, government, other stakeholder.
- Questions or comments about QIBA or regarding material on this poster should be addressed to qiba@rsna.org

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QIBA PET in 2016

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QIBA Project Title Primary Investigator Project Summary

Quantification of reconstituted method impact on measured amyloid

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Development of digital phenter for software and validation

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