

Role of Imaging in Alzheimer's Disease Trials: Impact on Trial Planning, Patient Recruitment and Retention

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Abstract : Background: MRI and PET are now extensively utilized in Alzheimer's disease (AD) trials for patient eligibility, efficacy assessment, and safety evaluations but including imaging in AD trials impacts site selection process, patient recruitment, and patient retention. Methods: PET/MRI are performed at baseline and at multiple follow-up timepoints. This requires prospective site imaging qualification, evaluation of phantom data, training and continuous monitoring of machines for acquisition of standardized and consistent data. This also requires prospective patient/caregiver training as patients must go to multiple facilities for imaging examinations. We will share our experience form one of the largest AD programs. Lesson learned: Many neurological diseases have a similar presentation as AD or could confound the assessment of drug therapy. The inclusion of wrong patients has ethical and legal issues, and data could be excluded from the analysis. Centralized eligibility evaluation read process will be discussed. Amyloid related imaging abnormalities (ARIA) were observed in amyloid- β trials. FDA recommended regular monitoring of ARIA. Our experience in ARIA evaluations in large phase III study at > 350 sites will be presented. Efficacy evaluation: MRI is utilized to evaluate various volumes of the brain. FDG PET or amyloid PET agents has been used in AD trials. We will share our experience about site and central independent reads. Imaging logistic issues that need to be handled in the planning phase will also be discussed as it can impact patient compliance thereby increasing missing data and affecting study results. Conclusion: imaging must be prospectively planned to include standardizing imaging methodologies, site selection process and selecting assessment criteria. Training should be transparently conducted and documented. Prospective patient/caregiver awareness of imaging requirement is essential for patient compliance and reduction in missing imaging data.

Keywords : Alzheimer's disease, ARIA, MRI, PET, patient recruitment, retention

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