

GAP ANALYSIS BETWEEN QIBA AMYLOID PROFILE AND ADNI AMYLOID PET PROCEDURES

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A review of the QIBA Amyloid imaging profile and the ADNI 2 AV-45 PET Technical Procedures Manual v1.0, 2011, shows a high level of consistency in procedures. This is expected as many of the QIBA recommendations are based upon the procedures that were developed over time by ADNI, benefitting from their experience. Both documents emphasize the importance of subject positioning and motion prevention. There is an apparent inconsistency in wording regarding the stringency of the 50 minutes post-injection start time in the ADNI protocol. The ADNI protocol is strict regarding image reconstruction parameters, and numerous scans have been rejected for payment and admission by ADNI QC for being found not in compliance. ADNI protocols do not address processing and analysis. Neither the QIBA profile circulated for public comment nor the ADNI protocol address the error that can be introduced into longitudinal measurement if standard axial uniformity requirements (+/-10%) are implemented and patient head position varies. A discussion with ADNI might focus on aligning the post-injection timing via clarification and the axial uniformity stringency.

QIBA Profile		ADNI PET Technical Procedures Manual (2011)
3.1	No requirements on diet or other pre-scan activities.	No requirements on diet or other pre-scan activities.
3.1	Sedation usually avoided; indicates that effects not fully characterized.	No sedation allowed.
3.1.2	Subject voids prior to scan, seated comfortably.	Subject voids prior to scan, seated comfortably.
3.1.2	Document any fluid intake	Not addressed; may assume no intake allowed
3.1.3	Specifies mfr recommendations for 3 different tracers. Does not provide a +/- % range. Does not specify no saline to be added.	370 MBq (consistent with QIBA profile) +/- 10%; no saline to be added
3.1.3	Record any residual activity	Measure, record, and adjust for residual activity if residual activity is 0.1 mCi or greater
3.1.3	Record any infiltration event observed	Does not address infiltration, but notes watching for damage
3.2	CT quality checks, contains additional detail and references vs. ADNI	Less detailed but consistent wrt QIBA profile CT checks; follow mfr instructions for blood glucose monitor; typical QC for dose calibrator
App D	Scanner quality control – specific checks and frequency	Less detailed but consistent wrt daily QC/blank scan, up to date calibration, normalization on date of each imaging session.
	Profile version circulated for public comment allowed the standard +/- 10% axial variability, which is problematic for longitudinal scans.	Silent on the standard +/- 10% axial variability, which is problematic for longitudinal scans.
App F	Hoffman phantom instructions	Uses Hoffman phantom for qualification; images reviewed centrally
3.2	Use same scanner for all longitudinal scans. Does not mention changes to hardware or software within same scanner. Notify Sponsor if change to scanner.	Use same scanner for all scans in study. Do not change hardware or software. Notify ADNI if change occurs and may need to re-do phantom scan to re-qualify.

QIBA Profile		ADNI PET Technical Procedures Manual (2011)
3.2	Use same acquisition parameters for all longitudinal scans	Prescribes same parameters for all scans though does not additionally stress importance for longitudinal scans.
3.2.1.1	Use same time interval from start to completion	Prescribes same time interval from start to completion for all scans but does not additionally stress importance for longitudinal scans.
3.2.1.1	Use same start time post-tracer injection.	Prescribes 50 minutes post-tracer injection. However, another section preceding says “approximately 50 minutes” and suggests a re-scan immediately following the first scan if reconstruction shows artifact or excessive motion.
3.2.1.2	Strong emphasis on subject positioning	Strong emphasis on subject positioning. Goes further in strongly recommending use of laser aligned markings.
3.2.1.2	Strong emphasis on securing subject in head holder and avoiding subject motion	Strong emphasis on securing subject and avoiding subject motion
3.2.1.3	Ensure complete anatomic coverage	Ensure complete anatomic coverage
3.2.1.4	Acquire in list mode or using multiple frames with a maximum of 5 minutes per frame	Always acquire using four frames of 5 minutes each (specific to florbetapir)
3.2.1.4	Use consistent CT acquisition; provides guidelines	Use consistent CT acquisition; provides guidelines
3.3.1	Reconstruction. Current version references tables that are not present. Reconciling.	Reconstruction specifically prescribed, always the same for a given scanner