

# Topics for Discussion

Profile progress and status

Question on public comment worksheet post

Claim, Supporting paragraphs, and Appendix B

Kinetic modeling Appendix I

Phantom and cross-scanner reconciliation

Next steps

# Question on public comment worksheet post

Include names and emails of submitters or not?

# Claims and examples

We have addressed prior concerns regarding practical application and reference to appropriate studies with input from team members

Limitations noted:

Two studies of three small populations (2 AD, 1 HC) met criteria for short term and alignment with guidelines

Several studies are available using 2 year longitudinal data (caveat on actual accumulation), and comparing reference regions, methods

Chen: 3 of 3 cases fit within short term wCV for Am- subjects

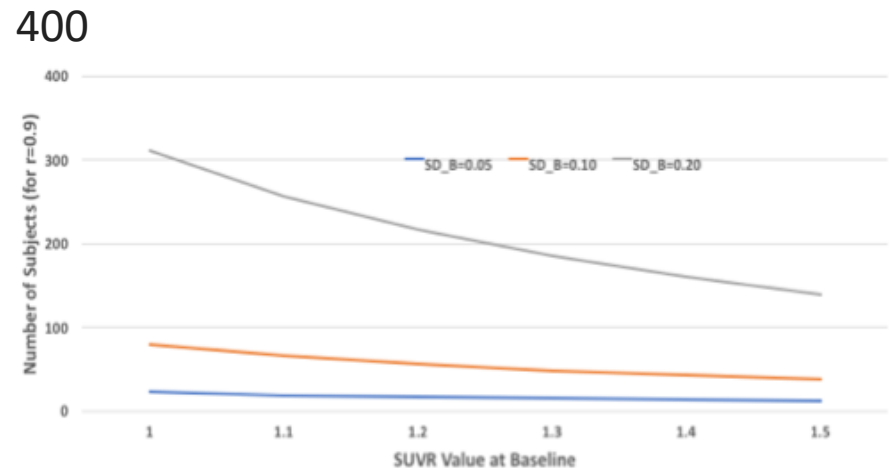
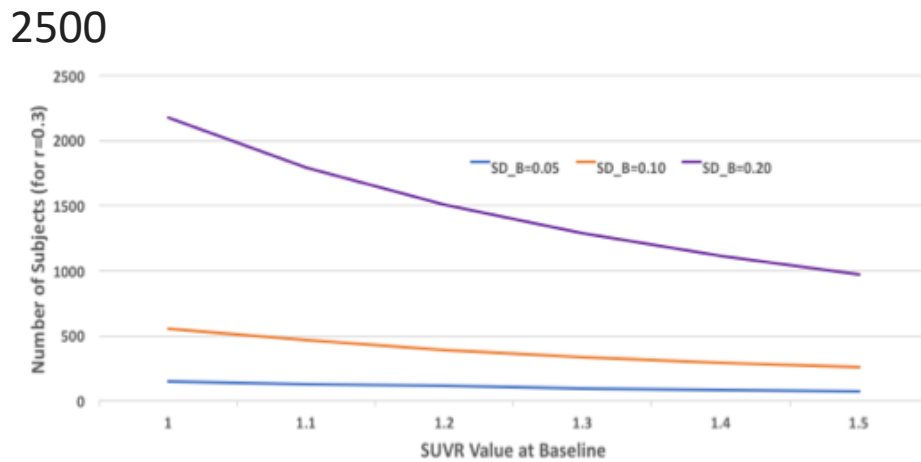
Brendel: 1 case was greater (3.38% vs. max of 1.94%). Difference was reference region selection and definition (e.g. different vulnerabilities to technical factors quantified in Round 5 and 6 projects)

# Clinical trial usage examples

## Powering a clinical trial to measure rate of amyloid accumulation

Graphs show for:

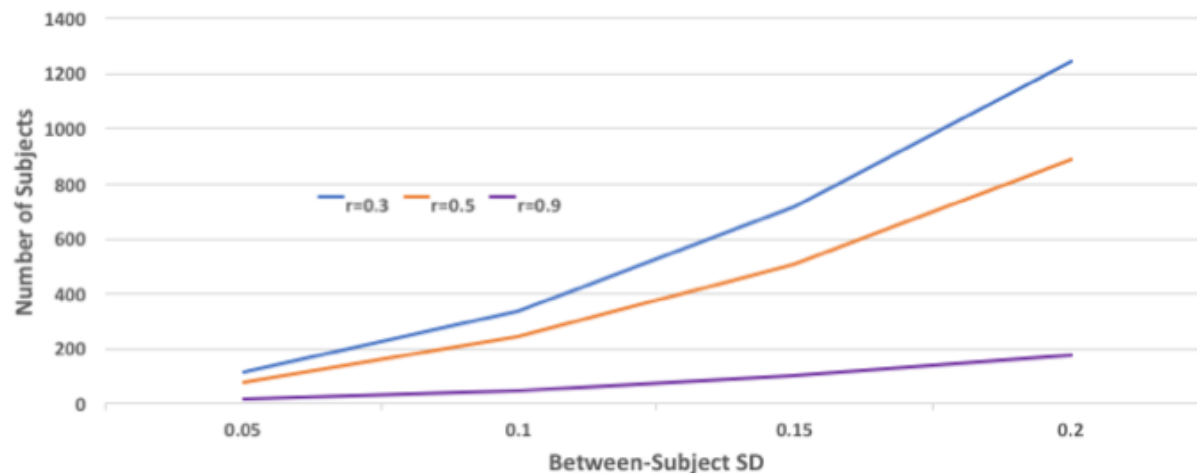
- 3 different correlation coefficients between baseline and follow up
- 3 different between subject SDs
- range of baseline SUVRs



# Clinical trial usage examples

## Powering a clinical trial to measure a reduction in the rate of amyloid accumulation (e.g. due to treatment intervention).

If the likely rate of amyloid accumulation is 1.5% per year, the mean SUVR at baseline is 1.5, the between-subject standard deviation is between 0.05 and 0.2, and the correlation between the paired measurements from a subject is between 0.3 and 0.9, then the following figure illustrates the number of subjects needed per arm to detect a 50% reduction in the rate of accumulation over a 2-year period with 80% power.



# Clinical trial usage examples

## Minimum detectable Increase for individual subject

For an individual's SUVR measurements of Y1 at baseline and Y2 at follow-up, the 95% confidence interval for the true change associated with the wCV of Claim 1 is given by the equation:  $(Y2-Y1) \pm 1.96 \times \sqrt{[Y1 \times 0.0194]^2 + [Y2 \times 0.0194]^2}$ .

# Phantom Appendix H

Updated to add missing text

Appendix H describes MATLAB script for analysis in great detail but does not provide; it was suggested that we contact Bioclinica to see if script could be provided

Appendix H describes 90 slice digital Hoffman phantom but does not provide link. This requires permission from Ron Jaszczak and Bob Koeppel. Apparent concerns by Ron with use of file to 3D print phantom. It was suggested that the profile give contact info for one of these two, or perhaps have a conversation asking if QIBA / RSNA could be the holder.

# Next Steps

Please review updated profile and responses to public comments of interest and (preferably) the overall document

Please submit any additional comments to us:

Format / channel for that?

Loose ends re phantom section or other sections

Conformance testing