Call Summary

In attendance
Andrew Buckler, MS (co-chair)                             Yuanxin Rong, MD, MPH
Lawrence Schwartz, MD (co-chair)                           Daniel Sullivan, MD
David Gustafson, PhD                                      David Vining, MD
Philip F. Judy, PhD                                        Binsheng Zhao, DSc
Grace Kim, PhD                                              RSNA
John Lu, PhD                                                Fiona Miller
Michael McNitt-Gray, PhD                                   Joe Koudelik
James Mulshine, MD                                          
Kevin O’Donnell                                            
Nicholas Petrick, PhD

Group 1A Data Analysis (Drs Kim, Lu and Petrick)

1D, 2D, 3D Measurements
- Reader variability discussed for each measurement method (1D, 2D, 3D)
- 1D-2D-3D inter-comparisons beyond current project scope; additional preliminary data needed
- More discussion required of what numbers mean; will evolve as data is presented
- Intra-reader variability was the main approach for 1A analysis
- Examining ‘cut’ values proposed to superimpose across techniques
- 1D conversion to 2D for spherical nodules straightforward; spiculated nodules more difficult
- Working with 3D readouts is very new; may lead to structured reporting
- Alignment on axial slices needed for 1D and 2D measurement; not required for 3D
- 3D (volume) more accurate with odd shapes; may not be better, but never worse than 1D or 2D; 3D thin sections result in the lowest bias and a narrow standard deviation
- Volume better to show ‘real’ lesion change
- Need to apply numbers to characterize that volume deals with odd shapes better; this would lead to better measurements
- Measurement of performance of a longitudinal marker based on a Kaplan-Meier format discussed; consensus that it is too soon to make such a connection
- 1A output is static, not longitudinal, but results may help in establishing thresholds and criteria for 1B design

Slice thickness
- Not much statistical variation overall; subset may show greater variability
- 0.8mm sections routinely underestimated 1D and 2D
- 5.0mm sections routinely underestimated all measures
- Lowest nodule volume bias seen with thin sections; all other combinations underestimate volume

Nodule alignment
- Alignment on axial slices needed for 1D and 2D measurement; not required for 3D
- 3D thin section result in the lowest bias and narrow standard deviation
• 3D (volume) more accurate with odd shapes; may not be better, but never worse than 1D or 2D

**Conclusion:**
• 3D with 0.8mm sections resulted in the least variance – bias close to 0 with narrow standard deviation

**Next Steps**
• Continue 1A data analysis discussions and data interpretation
• Continue discussion on draft FDA Briefing Document
• Next call scheduled for Monday, Feb 22 at 11 am CST