

Columbia University-QIBA Funded Project Update T-Con
13 September 2012 at 3 PM CDT (GMT-4)
Call Summary

In attendance:

Lawrence Schwartz, MD (Co-Chair)

James J. Conklin, MS, MD (Co-Chair)

Andrew Buckler, MS

David A. Clunie, MBBS

Barbara Croft, MD

Marios Gavrielides, PhD

Justin Kirby

Shing Lee, PhD

John Lu, PhD

Nicholas Petrick, PhD

Ying Tang, PhD

Bingsheng Zhao, DSc

Luduan Zhang, PhD

RSNA:

Joe Koudelik

Madeleine McCoy

NIBIB funded project update—Columbia (Drs. Zhao and Lee)

- Status of Current Merck Dataset and Issue Hindering Analysis
 - Initial dataset included 478 patients with a baseline and at least one follow-up scan.
 - Patients without a treatment start date, without a baseline scan or with no follow-up scans were deleted.
 - Data biased due to lack of survival follow-up data . Follow-up data is only available for those who died.
 - Appropriate time for baseline scan to start of treatment was discussed-the RECIST rule for a baseline scan is 30 days. The study will allow for baseline scan to be up to 6 weeks from the start of treatment.
 - The change in post-treatment scan at 6 weeks should be a staggered window of \pm 3weeks, i.e., 4-8 weeks. This will also apply for the change at 12 week.
- Survival Variables
 - The date of last follow-up for those who are alive at the end of the study is not available.
 - 147 Expired (121 Progressed and then died; 26 died without progressing)
 - 331 Survived (143 Progressed, 188 without progression)
 - Minimal demographics at baseline, e.g., the age specification is ≥ 65 or age < 65
 - The names and categories of variables need deciphering; a future discussion with Merck is planned.
- Analysis Plan
 - The necessity of creating an analysis plan was discussed.
 - Dr. Lee will work on this plan which will describe the steps, review the challenges and review the status of data.

Next steps

RSNA staff will follow-up with Drs. Schwartz, Lee, Mozley, Zhao and Mr. Buckler to schedule update t-cons. RSNA Staff to schedule regular calls.