Profile Review

- Mr. O’Donnell provided an update of the latest Profile edits, with focus on the clinical context and claim.
- The answer to the key first question, “Has a change occurred?”, will determine which claims to follow:
  - Profile users will pursue Claims 1 – 3 if a change has occurred, and will then be directed to Claim 4 to determine the amount of change
    - Estimates of bias were deemed negligible with regard to groundwork studies
    - Profile users will be guided to use values from the table to avoid issues with bias and repeatability
      - The lung tumor data is obtained from the Cancer Imaging Archive by searching for the ‘test-retest’ subset of the RIDER Lung CT Dataset
  - Methods to obtain additional cases for use with feasibility testing were also discussed for version 2 of the Profile
    - To-be-determined criteria may be used to qualify feasibility testers using sequestered data
    - Mr. O’Donnell to follow up with Drs. McNitt-Gray and Schwartz
  - Mr. O’Donnell to make remaining minor updates and will re-distribute the latest Profile for internal review

**Action items:** Mr. O’Donnell (kodonnell@tmriusa.com) to distribute latest version of the Profile after the call

**Next Call:** Monday, May 9th at 11 am CT | Profile review | Next steps (?)