Claim Guidance Document Review - continued (Mr. O’Donnell)

- Clinical performance thresholds needed to develop the Claim language
- The outlined steps for choosing technical performance values for the Claim statements were reviewed
  - Step 1: Serves as a touchstone
    - Develop a claim that can be applied to clinical use
    - New biomarker committees should be referred to section regarding clinical threshold in this step
  - Step 4: Dr. Garra provided an example of a clinical threshold for ultrasound and Dr. Perlman provided an example of a clinical threshold for nuclear medicine
- Mr. O’Donnell and Dr. Obuchowski to work offline regarding Claim Guidance revisions
- It was agreed that questions/considerations important to performance decision-making would be retained throughout this document

Next Call: Wednesday, April 6 at 3 PM CDT