Public Comment Resolution:
- The comment period closed on December 18, 2019
- Dr. Garra is working on public comment resolution and a conformance checklist for the Profile
- Once comments have been addressed, Dr. Garra will submit them for posting on the QIBA wiki Comment Resolutions Page, and the
- BC and CC voting will follow in efforts to publish the Profile as “Consensus” (Stage 2)

Profile v2.0:
- Dr. Garra proposed pursuing a second Profile that builds on the first Profile
- Profile v1.0 has data only for elastic phantoms; v2.0 would include a reconciliation of FibroScan data with viscoelastic phantom data
- The inclusion of FibroScan is important because it is the most commonly used technique in the field
- It will be necessary to consider how to compare QIBA results with FibroScan results to address value differences
- BC members agreed that a literature search would be a logical next step
  o Drs. André, Ozturk, and Souquet have agreed to organize a small task force to lead a literature search and provide data back to the BC
- Data in a study that Dr. Andre is currently working on are being collected from GE, Siemens, and FibroScan, with comparable trends thus far
- Creating a correction factor (with validation) for the data may be difficult, as a mechanism that would allow for substitution of one vendor for another may impinge on proprietary details
- Other studies that are exploring the correction factor topic include:
  o The Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE), funded by the Foundation for the National Institutes of Health (fNIH)
    ▪ NIMBLE will utilize multiple modalities (MR, FibroScan, SWS) and include several vendors and will measure repeatability and reproducibility
  o Review of recent study data needed to modify the Profile’s statement of clinical applicability
  o A study in Japan which includes regression equations for FibroScan
  o The study that Dr. André is working on at UCSD, which includes patient context with hepatologist input, and comparisons of Shear Wave, MR, and FibroScan
  o A study at Massachusetts General Hospital
    ▪ Mendeleev may be used to compile the literature search, though unfortunately, Dr. Garra cannot access this system; so, he will need a Word document or spreadsheet of the compiled references
- The claims in v1.0 of the Profile primarily deal with variance, though bias in implied
- According to Dr. Obuchowski, 5% is negligible in terms of variability
  o Providing data that shows variance is only 5%, would be of great benefit
- If a more obvious claim for bias is needed, bias would be measured against a reference system

Profile Approval Process: See voting and balloting process links: http://qibawiki.rsna.org/index.php/Process

QIBA US Schedule:

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<tr>
<th>Date</th>
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<tr>
<td>02/28</td>
<td>US Coordinating Committee at 11 am CT</td>
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<tr>
<td>03/06</td>
<td>SWS BC</td>
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<tr>
<td>03/13</td>
<td>CEUS BC</td>
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