QIBA Ultrasound Shear Wave Speed Biomarker Committee Breakout Session Report

Thursday, May 7, 2015

Topics of Discussion

- Conversation with Dr Maren Laughlin (NIDDK) regarding potential ultrasound biomarkers
- Feedback on Round 5 Shear Wave Speed Biomarker Committee proposals
- Plans for Round 6 funding!
  - Yes, we are optimists
- Plans for Thursday Breakout Session
**Topics of Discussion**

- Conversation with Dr Maren Laughlin (NIDDK) regarding potential ultrasound biomarkers for “internal medicine”
  - Echo signal spectrum-based biomarkers
  - Liver steatosis quantification, among others
- Contrast-enhanced ultrasound
- Microvascular flow assessment
- Assessment of brown fat
- Steatosis and glycogen utilization in metabolic disorders
- Inflammatory biomarkers

**Topics of Discussion**

- Feedback on Round 5 Shear Wave Speed Biomarker Committee proposals
- Finite Element Modeling simulations (digital reference object)
- Clinical study to establish the least-detectable change in serial SWS estimation across different systems, fibrosis stages under clinical conditions
Topics of Discussion

• Feedback on Round 5 finite element modeling simulations
  • Round 4 proposal
    – Creating particle displacement fields that can be used by manufacturers to test their shear wave speed estimation algorithms against a known reference standard
  • Round 5 proposal
    – Simulate the raw echo signals (based on known particle displacement fields)
    – Allows manufacturers to “inject into their system” one step earlier in the chain
    – Estimate particle displacement $\rightarrow$ shear wave speed
    – Determine bias and variance in SWS estimates

Topics of Discussion

• Feedback on Round 5 finite element modeling simulations
  • Blind the studies with an unaffiliated party who can de-identify results
    • Manufacturer A, B, C, etc.
  • Publish blinded results
    • Each manufacturer will know which data are theirs and how their data compares with other manufacturers compared to the known SWS
  • Create phantoms with known acoustically aberrating layer to compare with simulation results
  • Prioritize deliverables in the proposal
Topics of Discussion

• Feedback on Round 5 clinical study
  • Establish the least-detectable change in serial SWS estimation across different systems, fibrosis stages under clinical conditions
  • Concerns stated regarding the small number of observers to estimate components of variance
  • Inent is to provide a set of compliance tests
    • What should we include in a profile for a site to do to demonstrate conformance?
    • What is the suite of tests to perform?
    • Who are the patients to be scanned?

• Plans for Round 6 funding!
  • Conformance issues
    • How can a manufacturer demonstrate conformance?
      • SWS estimate results from QIBA-compliant phantoms
    • How can a site/participant demonstrate conformance?
      • Correct ranking of a small set of subjects with classically defined fibrosis stage
  • Field tests to attempt to technically confirm the Profile
Topics of Discussion

• Plans for Thursday Breakout Session
  • Coordination with MRE biomarker committee
  • Proposals for new ultrasound biomarkers