QIBA Organizational Structure, Procedures and Committee Responsibilities

Steering Committee is established by the RSNA

- Responsible for managing the strategic direction, processes and infrastructure for QIBA and overall oversight of QIBA activities and committees

Coordinating Committees are established by the Steering Committee

- Responsible for coordinating modality and other cross-cutting areas of QIBA, and to formalize (i.e., vote on) decisions when needed.

Biomarker Committees are established by a Coordinating Committee

- Responsible for selecting biomarkers, and coordinating the work of the subordinate Task Force Groups and groundwork.

Task Forces are established by a Biomarker Committee

- Created as needed to draft Profiles or UPICT protocols, carry out specific groundwork projects, or perform other designated tasks needed by the Biomarker Committee.

Committee Membership

- **Steering Committee** members are appointed by the RSNA.
- **Coordinating Committee** members are self-nominated.
    - **Voting Privileges:** A Member that is not present at three consecutive meetings (including teleconferences) will be considered lapsed, forfeits the privilege of voting on any Committee matter and will not be counted towards a quorum for voting purposes. A lapsed Member shall have his or her voting privilege restored upon and at the attendance of two successive committee meetings. That Member will be allowed to vote at that second successive meeting.
    - Each company, institution or other entity will have only one vote. If there are multiple Coordinating Committee members from a single company, institution or other entity, they must decide among themselves who will be the voting member and notify RSNA staff or the Coordinating Committee co-chairs at the time of a vote.
- **Biomarker Committees and Task Forces** are "open" committees
    - **"Open" committees** are open to anyone with a relevant interest.
    - **Committee and Task Force Co-Chairs** can direct RSNA staff to add names to the roster
- **Rosters** for each committee are posted on the Wiki.

Decision-Making

- Goal: group consensus and imaging-community input and endorsement on major decisions
- Recorded vote required for procedural decisions
    - key group decisions, such as public dissemination of documents, are subject to approval by Coordinating Committees
    - majority of participating members passes
    - negative votes must be discussed
- For recorded votes:
    - meeting attendee names and vote outcome will be recorded in minutes.

Committee Functions

Steering Committee:

- Manage Relationships and Optimize Communications
  - Create a collaborative, multidisciplinary environment that fosters communication among imaging groups and other medical disciplines involved in the research, approval, and use of quantitative imaging biomarkers (QIBs)
  - Educate stakeholders about Profiles.
  - Provide content and administrative support of web sites/Wikis.
  - Support face-to-face meetings.
- Determine and Manage Process
  - Develop ways of working, organizing, etc. across the various entities.
  - Utilize principles from imaging science to understand clinical image information content and utility.
  - Adopt a statistically rigorous framework for determining and reducing sources of variation.
  - Lay out a process for certification of compliance to QIBA Profiles.
- Coordinate Quantitative Imaging Biomarker Activities
  - Develop and maintain public infrastructure for biomarker-specific data and associated metadata.
  - Oversee outputs and works-in-progress of teams; maintain scorecard.
- Influence Imaging Biomarker Implementation
  - Clarify and optimize pathways for imaging biomarkers to become widely available.
  - Develop process guidance with regulatory agencies inclusive of drug development and patient care.
- Explore Self-funding Models
  - Define what size and scope of effort is sustainable and over what period of time.

Coordinating Committees (Most of this work is delegated to Biomarker Committees)

- Based on the clinical context and needs, identify and prioritize biomarkers to pursue ("work item selection")
  - Propose
  - Evaluate proposals
  - Approve
- For each selected biomarker:
  - Develop Profile
    - Production
      - Provisional goals
      - UPICT protocol, if relevant
      - Draft and Review text
      - Collect and Resolve Public comment
    - Real world validation ("Field-testing")

        - Approve field-test proposals
        - Trial implementation
        - Collect and Resolve feedback
    - Publication
        - Prepare final documents
        - Approve drafts
        - Publish
- Develop Reference Object(s) and Support Material(s) for Experimentation and Quality Control (QC)
    - Phantoms traceable to recognized physical standards.
    - Digital Reference Objects, if relevant.
    - Definition of comprehensive QC program, including data analysis and reporting requirements.
- Identify Technical Characteristics and Standards
    - Assess intrinsic scanner variability, minimum detectable change, and limits of quantification.
    - Identify and assess intra- and inter-reader bias and variance across scanners and centers.
- Perform Clinical Performance Groundwork
    - Develop a process map detailing steps to meet regulatory and payer requirements.
    - Perform studies necessary if literature does not provide data to fully support the process map. These may be retrospective or prospective (e.g., assessment of intra- and inter-reader sensitivity and specificity for specific clinical utility.)
- Perform Clinical Efficacy Groundwork
    - Characterize value in clinical trials
    - Characterize value in clinical practice.
    - Compare new biomarker and 'accepted-as-standard' method.
    - Develop/merge databases from trials in support of achieving statistical power.
- Pursue FDA Qualification, if relevant
    - Request Letter
    - Briefing document(s)
    - Full data package
- Determine compliance testing methods
    - Acquisition
    - Post-processing
    - Device version tracking