Advancing BOLD Functional MR Imaging Technology – Roadmap for Developing a Quantitative Imaging Biomarker

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QIBA fMRI Subcommittee

Composition: the fMRI Subcommittee is composed of multiple stakeholders representing Academic, Industry, Clinical and Pharmaceutical perspectives[1].

Mission: Develop a methodology (profile) to assess and improve the reproducibility, accuracy and precision of functional imaging biomarkers that result from BOLD imaging, thereby improving the quality of clinical fMRI exams and ultimately patient care, and creating an imaging biomarker for use in future applications (e.g. clinical trials).

Deliverables: A standard set of guidelines for implementing and optimizing fMRI protocols and associated outcome measures, defining what the quantitative outcome measures are for the specific use case.

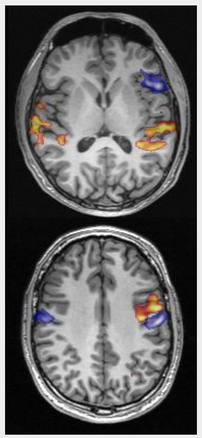
Profile Development for Initial Use-Case : A Profile is a document used to record the collaborative work by QIBA participants. The Profile establishes a standard for each biomarker by setting out claims and details. Our first use case involves specification of the procedures and quantitative parameters under which BOLD fMRI is an accurate and reliable predictor of brain function (i.e., as a valid imaging biomarker for medically meaningful changes in brain activity elicited by a particular task in the context of presurgical brain mapping.) Groundwork activities are described below:

Groundwork Activities for Profile Development

Claims Construction

Describe the Biomarker and establish performance expectations

- **What are readout measures?**
  - Location of activation
  - 3D extent of activation
  - Distance to lesion
  - Laterality
- **What is achievable?**
  - Reproducibility
  - Accuracy
  - Sensitivity
  - Specificity
- **Assessment of test-retest results**
  - Retrospective
  - Prospective



System Characterization

Describes the 'system' required to successfully implement the Biomarker

- **What infra-structure is required?**
  - People
  - MR scanner capabilities
  - Additional hardware and software components
  - Component integration
- **What steps must be taken to support claimed behavior?**
  - Quality Control
  - Peripheral equipment design/functionality
  - Paradigm design
  - Patient compliance and patient monitoring

Transition to Practice

Guidance to imaging professional to facilitate consistent implementation of the Biomarker

- **Clinical Practice Professionals**
  - Recipes for success and best practices
- **Industry**
  - Add to product/market requirements
  - Provide implementation and test guidelines[2]
  - Applicable to MR vendors and providers of 3rd Party Hardware & Software
- **Standard Groups**
  - User community needs for HL-7 / IHE / DICOM

References:
[1] http://qibawiki.rsna.org
[2]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM230597.pdf