

## QIBA key criteria for identifying biomarker opportunities

The QIBA criteria for defining biomarker opportunities include:

- **Transformational**
  - addresses a significant medical biomarker need with a likely considerable impact on public health, consistent with the future vision as delineated in the Imaging Biomarker roadmap
  - addresses a critical gap in the biomarkers qualification/validation process and/or may otherwise transform the process of how biomarkers are developed, approved, and applied in the future
- **Translational** — will likely result in significant improvement in the development, approval, or delivery of care to patients. The following characteristics are desirable:
  - Potential for biomarker to reduce size and increase objectivity of metrics in multicenter studies.
  - Opportunity for biomarker to move into clinical care
  - Preliminary data on biomarker performance and reproducibility are documented in the literature
  - Biomarker is currently in use as proof of mechanism/proof of concept (POM/POC) in a multi-center therapy development setting.
- **Feasible** — an idea or program whose end goals can likely be achieved in a specific timeframe and that has a reasonable prospect of producing the expected outcomes; ideal programs are those which could result in regulatory qualification of a biomarker in three years.
- **Practical** — leverages preexisting resources (e.g., intellectual capital, personnel, facilities, specimens, reagents, data) wherever possible; warrants access to RSNA resources and support.
- **Collaborative** — would uniquely benefit from the multi-stakeholder composition and approach of QIBA and could be feasibly executed under its policies e.g. resulting in extension or adoption in product development among hardware, software, or imaging agents. The biomarker has the support of the stakeholder community with the organizational impetus to sustain continued efforts.

August 2009