

QIBA key criteria for identifying biomarker opportunities

The QIBA criteria for defining biomarker opportunities include:

- **Transformational** - addresses a critical gap in the imaging biomarker qualification/validation process and/or may otherwise transform the process of how imaging biomarkers are developed, approved, and applied in the future
- **Translational** — addresses a significant medical biomarker need (either in clinical care or research), with a likely considerable impact on public health. 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 (e.g., use as an endpoint in drug development or integration into clinical practice) can likely be achieved in a specific timeframe (e.g., 3 – 5 years) and that has a reasonable prospect of producing the expected outcomes.
- **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 enough support in the stakeholder community to sustain continued efforts.

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