

# 分子イメージングバイオマーカーの 世界標準化に向けて： QIBAの取り組みと医薬品開発への応用

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## Toward the global standardization of molecular imaging biomarkers: Activities of QIBA and its utilization for drug development

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### Abstract

Quantitative Imaging Biomarkers Alliance (QIBA) is an initiative aiming at improvement of the value and practicality of quantitative imaging biomarkers, established by the Radiological Society of North America (RSNA) in 2007. They are engaged in development of procedures of assessment and validation of imaging biomarkers of various imaging modalities such as PET (positron emission tomography); MRI (magnetic resonance imaging); CT (computed tomography), and US (ultra sound), etc., to be utilized in both clinical practice and therapeutic drug development. Main participants are radiologists and medical physicists, collaborating with stake holders such as industries of diagnostic devices, software, therapeutic drugs, as well as regulatory authorities, such as United States Food and Drug Administration (FDA) and governmental institutes such as National Institute of Standards and Technology (NIST). They have formed several working groups of each modality to develop “QIBA profiles” which describe “claims” and “requirements” needed for assessment, validation, and standardization for the utility of each imaging biomarker, which would be incorporated into specifications of imaging tools, as medical products.

In 2016, Japan Radiological Society (JRS) set up a working group to take part in QIBA's initiative and has been facilitating collaboration with international participants in this activity with prospects for the future possibility of global standardization of imaging biomarkers to be utilized in clinical practice, as well as drug development.

### Key words

Quantitative Imaging Biomarkers Alliance (QIBA), Radiological Society of North America (RSNA), Japan Radiological Society (JRS), Uniform Protocols for Imaging in Clinical Trials (UPICT), positron emission tomography (PET)

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