

Statement of Support for Quantitative Imaging Biomarkers Alliance (QIBA) Profiles
December 2016

Endocyte is based on a hypothesis that our companion diagnostic PET and SPECT agents allow us to perform just-in-time whole body immunohistochemistry-like assessments of molecular target expression. Our data suggest that only those patients whose cancers over-express the target will respond to our companion therapeutic drugs. Quantification of these targets by PET or SPECT scans seems essential. High target expression appears to be associated with favorable responses. Expression that drops below a quantitative threshold seem unlikely to produce a response. Our mission in early drug development is to find that threshold, so that patients who are unlikely to benefit are excluded before exposure to drugs that will only cause toxicity.

CT volumetry is also essential to Endocyte. During early drug development, we strive to understand relationships between molecular target expression, as measured with quantitative PET or SPECT, and tumor growth kinetics. [Our data suggest that the higher the target expression, the more drug will enter the cell, and the slower the cancer will grow, even if the dose is entering the cell is not high enough to kill it.]

Although quantitative imaging biomarkers (QIBs) have great potential both as objective endpoints in cancer clinical trials and to improve productivity and quality of care in the clinic, the development and implementation of QIBs has been hampered by lack of reproducibility in technical performance. The goal of QIBA is to improve the reproducibility of quantitative imaging biomarkers across devices, patients and time.

I therefore endorse the motivation, goals and concepts of QIBA Profiles to standardize QIBs in cancer research and cancer care. Use of these standardized quantitative imaging QIBA Profiles will contribute significantly to improvements in the quality of cancer care, as well as substantially aiding in the development of novel therapeutics in oncology.

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