AbstractID: 7989 Title: Imaging Biomarkers – Role of the Medical Physicist

Imaging is increasingly important in biomedical research, where innovation and growth are now directed at the development and testing of pharmaceuticals. Disease or therapeutic effects can be measured by *in vivo* biomedical imaging and molecular imaging in particular, as well as other *in vitro* or laboratory methods. Recent work has shown that biomedical imaging can provide information on disease mechanisms or an early indication of drug response by use of X-ray, MRI, US, CT or PET-CT.

Basic and clinical research share a need for advanced imaging, but the systems and methods are different. Translation from animal imaging to clinical systems presents unique challenges of scale, resolution, timing, and software. Despite availability of numerous modalities (optical, x-ray, MRI, ultrasound, nuclear) and the intrinsic complexity of these instruments, many of the key elements including instrumentation and diagnostic contrast agents, may be the same for very different applications. The development of infrastructure for image data collection, quality control and benchmarking of change analysis software tools, as well as image-specific statistical methods, could significantly reduce the sample size requirements in animal studies or patients in clinical trials for drug response. Pre-clinical testing of new agents and elucidation of their biological effects have similar requirements.

The majority of clinical trials evaluate changes in tumor size using RECIST, but very few do so in a standardized fashion, or incorporate independent blinded image evaluations. Currently, the use of imaging as a biomarker to evaluate response, disease-free survival (DFS), or progression-free-survival (PFS) is limited. Overall survival (OS) continues to be the primary endpoint for assessment of therapeutic response.

Growing evidence in the scientific literature suggests that FDG-PET and DCE-MRI may be significantly more sensitive in predicting therapeutic response than anatomic imaging, such as CT and MRI. New imaging biomarkers must be qualified and validated for use in regulatory and clinical decision making.

The current state of imaging biomarkers and their application to drug development and evaluation will be explained with expectations for the future.