

Treatment responses and late normal tissue injury are conventionally assessed months or years after the completion of therapy by standard clinical endpoints, such as local progression free survival or late fibrosis. This conventional paradigm presents two major weaknesses. First, at the time of the treatment outcomes being determined, it is often too late to change the outcome of patients. Secondly, takes a large number of patients and a long time to determine the efficacy of the tested treatment. It is urgent for clinical scientists to change this conventional paradigm and to assess the therapeutic response early, i.e. prior to the end of planned therapy. For early assessment of therapeutic responses, conventional clinical endpoints are no longer adequate. Functional, metabolic, and molecular imaging could provide a means or a marker for early assessment of normal tissue injury or of treatment responses prior to anatomic measurements of disease progression, thereby permitting re-optimization of individual patient treatment strategies. This lecture will provide examples how to integrate multi-modality imaging in clinical trials for early assessment of treatment response and normal tissue toxicity. The implications of the results will also be discussed.

Learning Objectives:

1. Understand the time courses of response and toxicity
2. Appreciate windows of opportunity for early assessment
3. Introduce clinical trial design issues for early assessment