Ethan Basch, MD, MSc
Associate Member, Memorial Sloan-Kettering Cancer Center, Departments of Medicine and Epidemiology and Biostatistics

A Patient-Centered Approach to Drug Development

Needs: Understanding the symptoms patients experience in clinical trials is essential to multiple stakeholders including drug developers, regulators, payers, clinicians, and most importantly subsequent patients. Current methods for assessing patients’ symptoms in trials (and particularly symptomatic adverse events) underestimate prevalence and severity, rendering incomplete information for these stakeholders to make regulatory or clinical decisions.

Objectives: To recognize how symptom information (particularly symptomatic adverse event information) is currently collected in clinical trials; to understand how patient-reported outcomes can improve the accuracy and comprehensiveness of clinical trial symptom data; and to become informed about the National Cancer Institute’s PRO-CTCAE (Patient-Reported-Outcomes Version of the Common Terminology Criteria for Adverse Events) initiative.

There is No Corporate Support for These Activities.
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