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MD Anderson and Bayer collaborate to create symptom assessment questionnaires in clinical trials

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When cancer patients take part in a clinical trial to develop new therapies, they and their physicians want to know how they will feel and function during treatment. A new collaboration between Bayer and The University of Texas MD Anderson Cancer Center will go straight to the patients to learn how certain investigational new drugs affect them. The project will involve the use of questionnaires to assess how a drug may impact a patient's disease-related symptoms.

"Fit-for-purpose patient-reported-outcome (PRO) measures are an invaluable resource for helping us to better understand how patients are actually being affected by new therapies," said Charles Cleeland, Ph.D., chair of symptom research at MD Anderson. "This will be especially important in the developmental pathway of new drugs, given that these PRO measures will enhance information about treatment tolerability and potential symptom-reduction benefit earlier in the drug development process."

The information will be beneficial in further evaluating the drug if it progresses to later stages of clinical development and is tested in larger numbers of patients. The importance of having data on the symptom burden or benefit conferred by therapy is often not recognized until late in that process.

"For patients and their physicians, knowing the probable effects of a

treatment can help with decisions among treatment options when therapeutic outcomes are similar but symptomatic effects are not," said Cleeland.

The need for information on cancer-related and treatment-related symptom "burden" was one of the top six high-priority topics in a report from the American Society of Clinical Oncology. The report highlighted the need for a more comprehensive set of quality-of-care measures to address gaps in cancer care and for a focus on patients rather than providers. Patients, physicians, federal drug regulators and insurance companies may all benefit from this new information.

The Bayer-MD Anderson collaboration aims to capture through patient interviews the symptoms patients are experiencing as a result of their disease and the treatments they are receiving, and then to design short PRO measures that capture these symptoms, their severity and their interference with quality of life. Patients will provide detailed feedback on symptoms they are experiencing and rate how severe these symptoms are. These questionnaires will be used in the Phase II and III clinical development programs for Bayer compounds.

"The ultimate goal is to develop patient-centered measures that will provide new understanding about the patient's experience with experimental therapies," said Ferran Prat, Ph.D., J.D., vice president for strategic industry ventures at MD Anderson. "This new venture is an exciting model for delivering previously uncaptured information that will directly benefit patients."

The collection of PRO data, including symptom ratings, has not historically been part of early cancer drug development. One reason is that gathering symptom and other PRO data has been seen as adding more difficulty and cost at the clinical trial stage, and thus, too "logistically burdensome." Development of PROs have also been thought

to add to the timeline for regulatory approval, and consequently, for delivery of a new drug to the market place. The hope is that employing fit-for-purpose measurement scales to capture symptoms across the entire drug-development process will more completely describe a patient's experience.

Provided by University of Texas M. D. Anderson Cancer Center

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