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He works with the Clinical Trials Transformation Initiative, a partnership between the U.S. Food and Drug Administration and Duke aiming to increase the quality and efficiency of clinical trials. He is a founding member of the Sensible Guidelines for the Conduct of Clinical Trials group, a collaboration between McMaster, Oxford, and Duke Universities.

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Fundamentals of Clinical Trials. It represents “a key research activity with the potential to improve the quality of health care and control costs through careful comparison of alternative treatments” [1]. It has been called on many occasions, “the gold standard” against which all other clinical research is measured.

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This course will provide an introduction to the scientific, statistical, and ethical aspects of clinical trials research. Topics include the design, implementation, and analysis of trials, including first-in-human studies (dose-finding, safety, proof of concept, and Phase I), Phase II, Phase III, and Phase IV studies.

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It is also of value to researchers and practitioners who must critically evaluate the literature of published clinical trials and assess the merits of each trial and the implications for the care and treatment of patients. The authors use numerous examples of published clinical trials to illustrate the fundamentals.

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