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Investigator prospective on vaccine studies: Protocol development and execution

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The issues for investigators and for sites are somewhat unique for vaccine studies. The large number of subjects enrolled in a very short time, the number of minor AEs, the large total number and different types of specimens to process and the need for 1-5 year subject retention. This session will discuss these differences and offer practical considerations to assist with protocol development and execution.

Biography

William B Smith, MD, FACC, is currently a Professor of Medicine at the University of Tennessee Medical Center in Knoxville, Tennessee. He is board certified in Internal Medicine, Nephrology, Cardiology, and Critical Care Medicine. He is the Founder and President of Volunteer Research Group and New Orleans Center for Clinical Research at the University of TN Knoxville Medical Center and NOCCR on Canal Street in New Orleans, LA. With his colleagues, he has conducted 1800 clinical research studies (Phase I– IV, including first-in-man, cardiac, renal, hepatic, healthy, vaccines, urology, gynecology, obesity, devices, smoking cessation, diabetes, Alzheimer's, MS, and more).

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