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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. Many issues arise around specific populations especially the elderly. Speed and competitive enrollment verses a controlled calculated pace is a discussion mostly unique to vaccines. Other issues while not unique to vaccine studies, such as data entry, supplies, I.P., and randomization plans are amplified due to the large number of subjects these studies enroll. This session will discuss these differences and offer protocol 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. Dr. Smith is board certified in Nephrology, Internal Medicine, Cardiology and Critical Care Medicine.

Dr. Smith is the President and Founder of New Orleans Center for Clinical Research and Volunteer Research Group located within the University of Tennessee Medical Center. Dr. Smith has been involved as a Principal Investigator in over 1800 clinical research studies including cardiac disease, renal/hepatic disease, healthy volunteers, diabetes, women's health, HSDD, obesity, Parkinsons, Alzheimers, Multiple Sclerosis, smoking cessationandnumerous variations of PK trials.Dr. Smith has extensive experience conducting complex trials, including, Phase 1/special population trials, First-in-Human, POC, SAD-MAD and with vaccines, including Smallpox, H5N1, H1N1, Seasonal flu, Dengue Fever, TDAP, Bubonic Plague, Ebola, and others.