R. Scott Sykes, MD has more than 30 years of experience in clinical research and pharmacovigilance experience. This unique experience includes clinical research in the areas of respiratory (inhaled beta-agonists, corticosteroids), GI, and oncology (serotonin antagonist). Pharmacovigilance experience includes pre and post marketing experience in almost all therapeutic areas, including all aspects of individual and aggregate safety data review, safety-related signal detection, risk-management, product labeling, periodic reporting (PADER, PSUR, DSUR, etc.), training, staff development, FDA presentations and negotiations, and management of teams ranging from 5 to 80 staff members. Management experience includes VP North American Product Surveillance (Glaxo Wellcome), Chief Medical Officer/VP (Salix), VP Corporate Drug Safety (Schwarz Biosciences), and Head Medical-Safety Evaluation (Merz North America).

As a consultant Dr. Sykes has served in a number of capacities for pharmaceutical companies and CROs throughout the industry, including audits, gap analyses, safety data review for the purpose of labeling updates/additions, developing internal pharmacovigilance departments with necessary adverse event database installation, standard operating procedures, working practices, audit/legal protection strategies, safety-related data review procedures and documentation, and strategic overview of existing departments.

Dr. Sykes received his BA in Chemistry at UNC-Charlotte, his medical degree from UNC – Chapel Hill and completed internship at Shands Hospital – University of Florida in Gainesville, Florida.

When he is not working, Scott is an avid golfer. He also enjoys gardening and dog rescue.