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Participation in Phase II/III Clinical Trials

Therapeutic Area/Drug Class	Consulting Activities
Oncology/metastatic colorectal cancer (cytotoxic)	Protocol development; statistical analysis plan; regulatory interactions
Psychiatric/major depressive disorder (serotonin agonist)	Prepared statistical overview of efficacy for FDA submission
Nephrology/end-stage renal disease (soluble iron)	Protocol development; statistical analysis plan; regulatory interactions
Respiratory/ventilator-acquired pneumonia (oral rinse)	Meta-analysis; manuscript preparation
critical care/distributive shock (nitric oxide inhibitor)	Protocol development; statistical analysis plan; regulatory support
Ophthalmology/ophthalmic diseases – AMD and retinitis pigmentosa (growth factor-emitting ocular implant)	Protocol development; regulatory meetings; statistical analysis; report and manuscript preparation
ophthalmology/ocular hypertension, glaucoma (topical beta-blocker)	Protocol development; statistical analysis; report preparation; NDA submission and regulatory meetings
Respiratory/chronic obstructive pulmonary disease (vaccine)	Protocol development; statistical analysis; FDA submission
Nephrology/urology/chronic renal disease	Protocol development; statistical analysis; regulatory submissions
Cardiovascular/peripheral vascular system/ hypertension/congestive heart failure (aldosterone inhibitor)	Clinical development plan; member of scientific advisory group
Neurology - Parkinson's Disease	Clinical development plan; member of scientific advisory group
Anti-psychotic - schizophrenia	Interim analysis; implemented adaptive design
Gastrointestinal/irritable bowel syndrome	Statistical analysis plan
Endocrinology/diabetes (insulin antagonist, sulfonyleurea)	Protocol development; statistical analysis
Cardiovascular/peripheral vascular system/hypertension (aldosterone antagonist)	Protocol development; statistical analysis; manuscript preparation
Cardiovascular/peripheral vascular system/congestive heart failure (aldosterone antagonist)	Protocol development; statistical analysis; manuscript preparation
Diagnostic imaging (contrast agent)	Response to FDA approvable letter
Oncology/multiple myeloma (immunomodulatory drug)	Statistical consultant; statistical analysis
Thoracic surgery (fibrin glue)	Protocol development
Multiple drug resistant tuberculosis (gamma interferon)	Protocol development; statistical analysis; interim analysis; unblinded DSMB statistician
Hematology/bloodstream infections (antibiotic)	Protocol development; statistical analysis
Venipuncture (dermal anesthetic)	Data integration; preparation of ISS/ISE

Therapeutic Area/Drug Class	Consulting Activities
drug/device combination)	
Analgesic – dysmenorrhea	Statistical analysis; preparation of ISS/ISE
Antibiotic - bacterial vaginitis	Preparation of ISS and ISE
Cardiovascular disease/Cholesterol Ester Transfer Protein (CETP) inhibitor	Statistical analysis plan
Idiopathic pulmonary fibrosis (gamma interferon)	Protocol development; statistical analysis; interim analysis
Oncology/non-Hodgkin’s lymphoma (hematopoietic growth factor)	Clinical development plan; protocol development; statistical analysis
Oncology/non-small cell lung cancer (anti-angiogenic agent)	Protocol development; statistical analysis
Oncology/prostate cancer (monoclonal antibody)	Protocol development; sequential data monitoring plan
Oncology/cutaneous T-cell lymphoma (interferon gamma)	Clinical development plan; protocol development
Oncology/head/neck cancer (monoclonal antibody)	Protocol development; statistical analysis; unblinded statistician for DSMB
Oncology/prostate cancer (monoclonal antibody)	Protocol development; statistical analysis
Oncology/colorectal cancer (monoclonal antibody)	Protocol development; statistical analysis; ISS preparation
Autoimmune disease/multiple sclerosis (potassium channel blocker)	Protocol development; statistical analysis; report writing; ISS preparation
Spinal cord injury (potassium channel blocker)	Protocol development; statistical analysis; report writing