Robert P. Wereski

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PROFESSIONAL EXPERIENCE

President, Principal Clinical Research Consultant ***November 2004- Present***
RKW Consulting, Inc., Glenview, IL
A consulting company providing a variety of services to the pharmaceutical/ biotech industry.

- Clinical Research Consultant in the clinical workspace for numerous pharmaceutical, biotech, and healthcare companies.
- In depth knowledge of entire clinical drug and device life cycles (phases I-IV), clinical operations, and clinical regulatory requirements on a global scale.
- Experience with management processes and deliverables including client contract execution and payments, vendor management, clinical trial report completion, protocol review and design, and FDA premarket approval process.
- Effectively utilized as well as trained clinical personnel on numerous software platforms used in clinical trial applications (EDC, IVRS, CTMS).
- Experience with using numerous EHR/EMR enterprise solutions to review patient/ study subject information for clinical trial applications.
- Effectively and efficiently operate all aspects of a small business including accounting practices and information technology operations.
- Knowledgeable in FDA/ BIMO Inspections including site prep and support, Subject Matter Expert for Sponsor BIMO inspections, and foreign regulatory agency audits.
- Broad Spectrum of clinical studies work including biologic Phase I-IV studies, device trials, In-Patient, Diagnostic, Radiologic, Vaccine, and Registry studies.
- Ability to complete translations for essential documentation from Polish to English.

Sr. Regional Clinical Research Associate ***December 2001 – October 2004***
PPD Development, (Wilmington, NC)
Global Contract Research Organization

- Clinical Research Associate on phase II-III clinical drug trials.
- Responsible for recruitment and monitoring of global research sites.
- Prepared regulatory document packages at study onset and during ongoing maintenance of study sites and study master files.

Clinical Research Associate II ***October 1998 – December 2001***
ICON Clinical Research, (Chicago, IL & Frankfurt, Germany)

- CRA II: Clinical Research Associate on Phase II and III International Clinical Drug Trials.

- Experience with global projects and country specific regulatory processes (submitted clinical study data in US, Canada, Poland, Germany, United Kingdom, and Ireland).

EDUCATION

University of Illinois, Champaign-Urbana, IL ***1994-1998***
B.S., Biology

THERAPEUTIC EXPERIENCE

- Ophthalmology: Diabetic Retinopathy, Diabetic Macular Edema, AMD, Uveitis
- Infections/Parasitic Disease: HIV/AIDS
- Cardiology/ Circulatory: Advanced Heart Failure (LVAD device), Ischemic Heart Failure, Hypercholesterolemia, Hyperlipidemia, Coronary Stents, CRT Devices, Valve Repair, Cath Lab Trials
- Respiratory: COPD, Cystic Fibrosis, Emphysema
- Endocrine/Metabolic: Diabetes
- Nephrology: Hemodialysis, CKD
- Oncology: Cervical Cancer, Breast Cancer, Collection Studies spanning numerous Cancer types, monoclonal antibody treatment, Solid Tumors
- Digestive System: IBS, Dyspepsia, Constipation (Adult/Pediatric)
- Nervous System/ Pain Management: Post Herpetic Neuralgia, HIV Neuropathy, Diabetic Neuropathy, Migraines, Lower Back Pain, Osteoarthritis
- Phase I, II, III, and IV studies with both Domestic and International (Canada, Poland, Germany, Ireland, UK) monitoring experience
- Clinical Device Studies: Ventricular Assisted Device (Bridge to Transplant and Destination Therapies), Cardiac Stents, Wound Closure (Diabetic Ulcers and Amputations, Abdominal Wounds, Open Fractures, Pressure Ulcers, Venous Stasis), Plantar Fasciitis, Uveitis, Hemodialysis, HIV, Neurostimulation secondary to Bronchoconstriction, Ischemic Heart Failure, Cardiac Surgery (LAA exclusion), CRT, Joint Prosthetics, Cervical Disc Replacements, Orthopedic Shoulder Replacement
- Diagnostic: In-Vitro Fertilization
- Vaccine Trials: Hepatitis B, Anthrax, Pediatric Influenza

PROFESSIONAL DEVELOPMENT

- Completed foundation training courses at ICON Clinical Research and Pharmaceutical Product Development (PPD), Inc.
- ACRP certified Clinical Research Associate (CCRA), September, 2005.

SYSTEMS EXPERIENCE

Microsoft Windows, MS Office -All desktop and online versions (Word, Excel, Access, Project, PowerPoint, Sharepoint), Google G Suite, Electronic Data Capture Systems (Medidata RAVE, Inform, Medrio, Oracle, VieDoc, SmartTrial, IBM Clinical, Etrials, Phoenix, TrialMaster, DataLabs, SynCapture,), IVRS systems, numerous EMR/EHR platforms, CTMS enterprise systems, eTMF systems (Egnyte, Trial Interactive, VeevaVault, Oracle, Sharepoint, Florence), Unix/ Linux, HTML, Photoshop. Previous course work in Fortran, C+, Basic, Mathematica, and Autocad.

LANGUAGES

Fluent in Polish
Dual Citizenship: USA and European Union (Poland)

CLINICAL TRIAL EXPERIENCE

- Medical Device/ Cardiac: A prospective, single-arm multi0center study to evaluate the safety and function of XXX Trans-Septal System for MR reduction
- Medical Device/ Cardiac: Advancing Cath Lab Results with XXXX Coronary Physiology Assessment
- Medical Device/ Cardiac: Evaluation of the XXXX Ventricular Assist System (VAS) for the Treatment of Advanced Heart Failure. **multiple (6+) protocols
- Medical Device/ Cardiac: Prospective, multicenter, non-randomized trial to evaluate acute safety and efficacy of the XXXX XXXX XXXX for the Closure of the LAA.
- Medical Device/ Nephrology: Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements Study: a prospective, multi-center, observation clinical study to compare the all-cause hospitalizations on daily hemodialysis using XXXX hemodialysis device to thrice-weekly conventional in-center dialysis using a matched cohort from the US Renal Data System (USRDS) database.
- Medical Device/ Cardiac: Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders, Previously Untreatable and High-risk Upgrade Patients
- Nephrology: Comparison of Nocturnal Hemodialysis (NHD) and Short Daily Hemodialysis (DHD) with XXXX.
- Infections/Parasitic Disease: A Phase III randomized, double-blind, multi-center study to assess the efficacy, safety, and tolerability of XXX vs. XXX in combination with open-label NRTIs in NNRTI-naive HIV-1 infected subjects who have failed their 1st and only antiretroviral treatment which must have contained a single, non-boosted PI and two NRTIs
- Infections/Parasitic Disease: A Phase III randomized, double-blind, multi-center study to assess the efficacy, safety, and tolerability of XXX vs. XXX each in combination with XXX in antiretroviral naive HIV infected subjects
- Circulatory: Long-Term, Safety and Tolerability Study of XXXX or Placebo in Addition to XXXX in Subjects with Primary Hypercholesterolemia
- Circulatory: A multinational, multi-center, randomized, double-blind, parallel group, dose-ranging study to evaluate the efficacy and safety of a reductase inhibitor 1mg, 2mg, 4mg, and 8mg compared to placebo in patients with primary mixed or combined Hyperlipidemia
- Endocrine/Metabolic: Effect of XXXX on Diabetic Retinopathy in type 1 diabetic patients with retinopathy. A double-blind, randomized, placebo-controlled, parallel-group study
- Endocrine/Metabolic: Effect of XXXX on Diabetic Retinopathy in type 2 diabetic patients with retinopathy

- Digestive System: A phase III Twelve Week, Randomized, Double-Blind, Placebo-Controlled Study of XXXX 0.5mg or 1.0mg BID in females with Functional Dyspepsia
- Digestive System: An eight week, randomized, double-blind, placebo controlled study of XXXX in non-constipated adolescents with irritable bowel syndrome (80 sites, 300 patients)
- Pain Management: A randomized, double-blind, controlled dose finding study of XXXX for the treatment of Postherpetic Neuralgia
- Pain Management: A randomized, double-blind, controlled dose finding study of XXXX for the treatment of Painful HIV-associated distal symmetrical polyneuropathy
- Nervous System: A phase III, multi-center (41 sites, 1550 patients) randomized, double-blind, double-dummy, parallel group study to compare the efficacy and safety of four fixed doses of an intranasal investigational compound with an oral dose of the same compound and placebo in patients with migraine headaches
- Pain Management: A Randomized, Open-Label Study of the Tolerability of Three Local Anesthetic Formulation Conjunction with XXXXX for the Treatment of Neuropathic Pain
- Pain Management: A multi-center, randomized, double-blind, active comparator study to determine the efficacy and safety of XXXX or XXXX versus XXXX in subjects with moderate to severe low back pain.
- Pain Management: A multi-center, randomized, double-blind, active comparator study to determine the efficacy and safety of XXXX or XXXX versus XXXX in subjects with moderate to severe Osteoarthritis pain.
- Medical Device/ Wound Care: A randomized, controlled, multi-center trial of XXXX in the treatment and blinded evaluation of Open Abdominal Wounds
- Medical Device/ Wound Care: A randomized, controlled, multi-center trial of XXXX in the treatment and blinded evaluation of Venous Stasis Ulcers
- Medical Device/ Wound Care: A randomized, controlled, multi-center trial of XXXX in the treatment and blinded evaluation of Diabetic Foot Ulcers
- Medical Device: A clinical study to determine the safety and effectiveness of extracorporeal shockwave treatment with XXXX for chronic proximal plantar fasciitis.
- Medical Device / Ophthalmology: A Prospective, Multi-Center, Randomized, Double-Masked, Safety, Tolerability and Efficacy Study of Four Iontophoretic Doses of XXXX in Patients with Non-Infectious Acute Anterior Segment Uveitis.
- Gastrointestinal: A Phase 1B, Randomized, Single-Blind, Parallel Groups Study of the Gastroduodenal Tolerance of XXX and XXX with or without XXX in Healthy Volunteers.
- Digestive: A Multicentre, Randomised, Placebo-Controlled, Double-blind Study of the Efficacy, Safety, and Pharmacokinetics of XXXX in Paediatric Subjects Aged >6 Years to <18 Years with Functional Constipation
- Digestive: A Randomized, Double-dummy , Multicenter, Parallel Group Study Comparing the Pharmacodynamics, Pharmacokinetics, and Safety of Both Liquid and Oral Capsule Forms of XXXX in Adult Subjects with Chronic Idiopathic Constipation
- Ophthalmology: A Phase 2, Randomized, Double-Masked, Placebo-Controlled, Dose-Ranging Clinical Study to Assess the Safety and Efficacy of Subconjunctival Injections of XXXX in Patients with Diabetic Macular Edema Secondary to Diabetic Retinopathy.
- Ophthalmology: A Phase 2, Randomized, Masked, Controlled Clinical Study to Assess the Safety and Efficacy of XXXX plus XXXX versus XXXX plus Placebo in Patients with Sub-Foveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration
- Infectious Disease/ Medical Device: XXXX System for the Treatment of Patients with Human Immunodeficiency Virus (HIV)
- Medical Device: To Evaluate the Safety and Effectiveness of Neurostimulation for the Relief of Acute Bronchoconstriction.

- Cardiac: An Open Label Dose Escalation Study to Evaluate the Safety of a Single Escalating Dose of XXXX Administered by Endomyocardial Injection to Cohorts of Adults with Ischemic Heart Failure
- Medical Device: A Prospective, Randomized, Controlled Multicenter Clinical Trial to Evaluate the Safety and Effectiveness of XXXX for the Treatment of Severe Emphysema
- Vaccine: An Observer-Blinded, Randomized, Parallel-Group, Multi-Center Study Comparing the Safety and Immunogenicity of XXXX to Licensed Vaccine (XXXX) among Healthy Subjects 40 to 70 Years of Age
- Vaccine: An Observer-Blinded, Randomized Study Comparing the Safety and Immunogenicity of XXXX to Licensed Vaccine (XXXX) among Adults (18 to 70 Years of Age) with Chronic Kidney Disease (CKD)
- Vaccine: Phase 2 Multicenter, Randomized, Partially-Blinded, Placebo-Controlled Trial Comparing and Evaluating the Safety, Tolerability and Immunogenicity of XXX Anthrax Vaccine Dose Range and Vaccination Schedule
- Vaccine: A Phase 3, Randomized, Multicenter, Observer-Blinded, Noninferiority Study to Evaluate the Immunogenicity and Safety of a XXXX Quadrivalent Inactivated Influenza Virus Vaccine (XXXX QIV) with a US Licensed 2015-2016 Quadrivalent Inactivated Comparator Influenza Vaccine (Comparator QIV) in a Pediatric Population 5 Through 17 Years of Age
- Pulmonary: A Phase 3, Multi-Center, Multinational, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXX In Stable Cystic Fibrosis Patients.
- Diagnostic: A prospective study to predict successful implementation of *in-vitro* fertilization and detect pregnancy through the collection and analysis of biospecimens from women visiting *in-vitro* fertilization clinics
- Oncology: XXXXX-001 The Circulating Cell-free Genome Atlas (CCGA) Study
- Oncology: XXXXX-002 The XXXXXX Study: Breast Cancer Screening Cohort for Development of Assays for Early Cancer Detection
- Medical Device: Clinical Validation Study for Noninvasive Cardiopulmonary Management Device
- Medical Device/ DDD: A Multi-center, prospective, historically controlled pivotal trial comparing the safety and effectiveness of the XXXX to anterior cervical discectomy and fusion in patients with one-level symptomatic cervical degenerative disc disease.
- Medical Device/ Orthopedic: Pivotal, non-randomized, historically controlled, prospective, multi-center clinical study of the XXXX Reversed Shoulder System.
- Oncology: A Phase 1 Study of XXXXX (Monoclonal Antibody) administered in subjects with released or refractory advanced solid tumors.
- Medical Device/ DDD: A Muti-Center, Prospective, Historically Controlled Pivotal Trial Comparing the Safety and Effectiveness of the XXXXX Disc to Anterior Cervical Discectomy and Fusion in Patients With One-Level Symptomatic Cervical Degenerative Disc Disease (DDD).
- Oncology Observational: Deep learning-Enabled Exploration of Predictive signatures in a multicenter retrospective and prospective observational study allowing the analysis of the aggregation of multimodal clinical, biological, genomic and radiomics data associated with the response to treatment and prognosis of patients with stage IV non-small cell lung cancer
- Oncology: A Phase 1 Study of XXXXX Administered in Subjects with Relapsed or Refractory Advanced Solid Tumors
- Oncology: A Phase 1 Study of XXXXX in Subjects with Advanced or Metastatic Solid Tumors
- Phase 1: A 3-Part Phase 1, Randomized, Double-Blinded, Placebo-Controlled, Single Ascending Dose, Food Effect, and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXXXX in Healthy Adult Subjects