KAREN C. CARMINES, B.S.
CARMINES CONSULTING LLC

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CAREER SUMMARY

Self-motivated, highly-skilled regional Senior Clinical Research Associate with over 25 years in experience in clinical research. Demonstrated ability to deliver quality work on time. Detail-oriented with excellent organizational, planning, documentation, and communication skills. Strong interpersonal skills with ability to effectively interface with principal investigators and staff. Experienced project team member (national and internationally) involved in Phase II-IV studies across multiple therapeutic areas. EDC and IWRS experience and other vendor-specific portals.

THERAPEUTIC EXPERTISE

MONITORING:

Cardiology/Vascular Disease:
Hypertension, Congestive Heart Failure, Carotid Stent
Medical Devices:
Carotid Stent
Retrospective:
Heart Failure Registry Study
Anti-Infective Study
Dental:
Anesthesia reversal
Dermatology:
Skin Tag removal (OTC), Itchy Skin (OTC), Pediculosis Capitis, Acne Vulgaris, Atopic Dermatitis (pediatric), Alopecia
Gastroenterology:
Peptic Ulcer Bleed, Postoperative Ileus, Chronic Constipation / IBS-C, Gastro-esophageal Reflux (pediatric), Heartburn, Crohn's Disease, Gastric Ulcer/Erosive Esophagitis
Immunology/Infectious Diseases:
Anti-Infective, HIV Antibody Test
Nephrology/Urology:
Benign Prostatic Hyperplasia (OTC), Overactive Bladder (OTC)
Neurology:
Transient Insomnia, Chronic Pain
Oncology:
Ovarian Tubal & Peritoneal Ca.
Pediatrics:
Atopic Dermatitis, Gastro-esophageal Reflux
Pulmonary/Respiratory Diseases:
Chronic Obstructive Pulmonary Disease, Smoking Cessation, Cough Suppression
Rheumatology:
Rheumatoid Arthritis, Osteoarthritis/Pain

DATA MANAGEMENT:

Anti-Infectives
Dermatology
Internal Medicine
Immunology

PROFESSIONAL EXPERIENCE

INDEPENDENT CLINICAL RESEARCH ASSOCIATE **Oct 1999 - Present**
CARMINES CONSULTING LLC, PRINCIPAL
Independent regional CRA, based in Phoenix, Arizona area. Site manager - responsible for monitoring clinical trials to assure data integrity and compliance with ICH Guidelines. Serve as a liaison between sponsor and site.

- Review protocols and case report forms.
- Assist with investigator recruitment and collection of pre-study documents.
- Perform site evaluation, initiation, monitoring, and close-out visits.
- Develop study specific documents and site management tools.
- Ensure compliance with IRB regulations.
- Review and submission of regulatory documents.
- Submission of CRFs and other study documents.
- Source document verification to ensure data validity and protocol adherence.
- Review and track serious adverse events.
- Review and track drug accountability.
- Generate, interpret, and resolve data queries.

KENDLE INTERNATIONAL INC., Cincinnati, OH **1998 – 1999**
Senior Clinical Research Associate, Clinical Services
Regional CRA managing trials throughout the US with emphasis in arthritis studies. Responsible for monitoring clinical trials to assure data integrity and compliance with FDA regulations.

CHRYSALIS INTERNATIONAL, Austin, TX **1996 - 1998**
Clinical Research Associate, Clinical Services-North America
Regional CRA managing trials throughout the US with emphasis in cardiovascular studies. Responsible for monitoring clinical trials to assure data integrity and compliance with FDA regulations. Assisted with training of site personnel and entry-level CRAs.

HOECHST ROUSSEL PHARMACEUTICALS, INC., Somerville, NJ **1985 - 1994**
Medical Data Coordinator, Clinical Data Management
Database designer/manager working with various clinical sections to design, collect, query, and analyze data from investigational trials. Responsible for CRF design, database design and set-up, programming of data validation rules (queries), and completion of databases for statistical evaluation in Phase III/IV clinical trials. Worked closely with CRAs and medical directors across many therapeutic areas including anti-infectives, dermatology, internal medicine, immunology, and also with service groups such as biostatistics, drug safety, medical writing and project management to insure timely, accurate, and complete databases for statistical analysis and, ultimately, NDA submissions.

EDUCATION

B.S., Sociology, Virginia Polytechnic Institute and State University (Virginia Tech), Blacksburg, Virginia

TECHNICAL SKILLS

- Case Report Form Design; Database Design and Setup
- Database Programming for Quality Assurance (queries)
- EDC
- IVRS/IWRS