

Christi Stephens 14 FEB 2022

CHRISTI STEPHENS

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GCP TRAINING (CURRENT)

- CITI GCP Expires 02Nov2023

DANGEROUS GOODS

- Mayo Clinic IATA 1.5 Expires DEC2023

EXPERIENCE

Nov 2019 - present Spectrum Medical, Inc. (formerly Danville Orthopedic Clinic, Inc.), Danville, VA

Clinical Research Coordinator

- Coordinate all aspects of clinical trials for D.O.C. under the direction of the principal investigator
- Obtain and document Informed Consent process as delegated by PI
- Investigational Product Accountability, Administration & Dispensing
- Conducts study required tests and procedures as delegated by PI
- (Collect medical histories, demographics, vital signs, obtain EKG's, questionnaires, perform lab procedures, etc.)
- Complete and maintain source documents, case report forms, and queries
- Experience using electronic data capture and IVRS/IWRS
- Acts as a liaison between the site and the sponsor (query resolution, coordinating of monitoring visits, etc)
- Report and Document Adverse Events and Endpoints
- Patient Education

Jun 2016- Oct 2019 Spectrum Medical, Inc. (formerly Danville Orthopedic Clinic, Inc.), Danville, VA

Certified Medical Assistant-Rheumatology

- Assist physician in clinic
- Scheduling: appointments, surgery, referrals, procedures,
- Completion of Authorizations (procedures, surgery, referrals, etc)
- Phlebotomy
- Injections (sc, IM, intradermal)

- Vital signs (including height, weight, BP, pulse, and temp)
- Obtain ECG's
- Medication Accountability

EDUCATION

December 2021 Mayo Clinic, Dangerous Goods Training

November 2021 CITI GCP Training

November 2019 Mayo Clinic, Dangerous Goods Training

November 2019 CITI GCP Training

June 2016- Associate Degree in Science, American National University
Danville, VA

2006- George Washington High School, Danville, VA

RESEARCH EXPERIENCE

Coordinator for pharmaceutical research studies:

A Phase 3, multicenter, 22 week, double blind and 30 week open label study to evaluate the efficacy, safety, and pharmacokinetics of XXX in relief of the pain for subjects with OA of the KNEE. (10/2021-PRESENT)

A Randomized, Double-Blind, Placebo-Controlled **Phase 3** Efficacy Study of an XXX vaccine in the prevention of Lower Respiratory Tract Disease caused by RSV in Adults Aged 60 years and older. (8/2021-Present).

A Phase 2, Randomized, Double-blind, Placebo-controlled study to evaluate the efficacy and safety of XXX in subjects with pain associated with OA of the knee.
5/2021-Present.

A **Phase 2**. Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Subjects with Fibromyalgia. (2/2021)-Present.

A **Phase 3** Prospective, multicenter, double-blind, randomized, placebo-controlled study to evaluate the efficacy of XXX in patients with osteoarthritis of the knee. 12/2020-Present.

A Phase 3, 14-Day, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Multicenter Study of the Efficacy and Safety of XXX in subjects with pain due to Acute Back Muscle Spasm. (12/2020-1/2022).

A Randomized, Double-Blind, Placebo-Controlled, Multi-center Pilot Study of a Single Injection Cross-linked XXX Combined with YYY to Provide Symptomatic Relief of OA of the Knee. (10/2020-Present). **Phase 2**.

A Randomized, Controlled Pragmatic Phase 3b/4 Study of XXX in patients with Rheumatoid Arthritis.

A 5 Year Prospective Observational Registry to assess Adverse Events of Interest and Effectiveness in Adults with Active, Autoantibody-Positive Systemic Lupus Erythematosus Treated with or without XXX.

Study designed to validate the XXX Lyme Assay using samples from patients clinically diagnosed with Lyme disease and also to compare test results to other standard diagnostic tests.

A Phase 2, Randomized, Double-blind, Placebo Controlled, Parallel-Group Study to Assess the Safety and Efficacy of XXXX in Patients with Glenohumeral Osteoarthritis or Shoulder Adhesive Capsulitis.

A Randomized, Double-Blind, Placebo-Controlled, 2-Injection, 52-Week study to evaluate the Efficacy and Safety of Intra-articular injections of XXX in Subjects with Chronic, Moderate to Severe Osteoarthritis knee pain. Phase 3.

A Randomized, controlled, double-blind study to evaluate the efficacy and safety of an intra-articular injection of XXX in adults with pain due to severe osteoarthritis of the knee. Phase 3.

REFERENCES

Available upon request
