

April Marshall, RN, CCRC
05 MAR 2021

APRIL MARSHALL, RN, CCRC

109 Bridge Street, Suite 300, Danville, VA 24541 (Spectrum Medical, Inc.)
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CCRC CERTIFICATION

CRC Certified since April 5, 2003

- Academy of Clinical Research Professionals

DANGEROUS GOODS

IATA Certification since March 17, 2008

EXPERIENCE

Mar 2006- present Spectrum Medical, Inc. (Formerly Danville Orthopedic Clinic, Inc.) Danville, VA

Site Director/Certified Clinical Research Coordinator

- Coordinate all aspects of clinical trials for D.O.C. and Danville Internal Medicine, Inc. under the direction of the principal investigator
- Research availability of new studies
- Prepare and negotiate budget/contract for each protocol
- Regulatory submissions (CDA, FDF, 1572, CV, IRB)
- Acts as a liaison between the site and the sponsor/CRO
- Supervise research personnel
- Staff and Patient Education
- Organize the study program (create and produce source documentation, train staff on new protocols, etc)
- Marketing (Create site pamphlets, websites, advertising, etc)
- Maintain CV's for research personnel
- Investigational Product Accountability, Administration & Dispensing
- Obtain and Document Informed Consent
- Report and Document Adverse Events and Endpoints
- Conduct study required tests and procedures (start IV's, EKG's, Phlebotomy, vital signs, collect medical history & demographics)
- Complete CRF's and queries (paper or electronic data capture)

Jan 2000- Mar 2006 Danville Regional Medical Center Danville, VA

Clinical Research & Development- Clinical Research Coordinator

- Assists principal investigators to implement research protocols at various clinical sites using good clinical practice.
- Organizes the study program
- Conducts study required tests and procedures (start IV's, EKG's, Phlebotomy, administer study medication)
- Completes CRF's (including electronic data capture)
- Acts as a liason between the site and the sponsor
- Data entry utilizing Microsoft and Excel

Dec 1997- Jan 2000 Danville Regional Medical Center Danville, VA

Staff Nurse- 2A Orthopedics and Neurosurgical Unit

- Assumed staff nurse responsibilities on surgical unit
- Nursing Preceptor
- Phlebotomy Preceptor
- Acted as charge nurse on rotating basis

May 1996 – Dec 1997 Piney Forest Health Care Center Danville, VA

Nursing Supervisor

- Responsible for managing a 120 bed extended care facility
- Quality assurance monitoring
- Assisted Director of Nursing with day-to-day operations
- Education / CEU for staff
- Responsible for developing schedules for employees
- Hiring of new employees, annual evaluations, and trouble shooting on a day-to-day basis.

May 1995 - May 1996 Piney Forest Healthcare Center Danville, VA

Staff Nurse- skilled unit

- Assumed skilled nursing responsibilities (IV therapy, sterile dressing changes, trach care, medication administration, etc.)
- Acted as supervisor on prn basis

EDUCATION

Current EDC: iMedidata, Datalabs, OCRDC, Inform, Syncapture, Axiom Fusion, eCaselink

3rd Party Vendors: EPX/ERT (Invivodata, ePro, SITEpro, DIARYpro)

Synarc, Medical Metrics (MMI), Bioclinica – Xray/MRI

Canfield- Photo images

May 2020-CITI Good Clinical Practice

May 2020- Mayo Clinic Dangerous Goods

April 2019- CITI Good Clinical Practice

March 2018- Mayo Clinic Dangerous Goods

March 2017- Transcelerate ICH GCP Training

March 2016- Mayo Clinic Dangerous Goods

October 2015- Transcelerate GCP Training

February 2015- CITI GCP Training

March 2014- NIH Protecting Human Research Participants

March 2014- Mayo Clinic Dangerous Goods Training

April 2013 ACRP Annual Conference

April 2012 Saf-T-Pak Dangerous Goods Training

February 2012 Quintiles ICH/GCP Training (Modules 1-6)

March 2011, "Hidden Cost of Conducting Clinical Research"

RXTrials Institute, Baltimore, MD 3/23/11-3/24/11

October 2010, NIH "Protecting Human Research Participants"

Certificate Number: 559693

October 2010, Johnson & Johnson GCP Training

April 2010, Dangerous Goods

April 2009 ACRP Annual Conference

October 2007 "How to Prepare for an FDA Audit" ACRP Course

October 2007 "Legal Agreements, Litigation and Leadership in Clinical Research"

April 2007 Shipping Class 6.2 Dangerous Goods Compliance Training

October 2006 ACRP Annual Conference

December 2006 Human Participants Protection Education for Research

December 2006 Good Clinical Practice Training, Pfizer

March 2006 HIPPA Training for Researchers

December 2005 American Heart Association CPR update, Danville, VA

April 2005 Nursing Law Update, Lynchburg, VA

February 2005, Home study Series, ACRP Continuing Education Program

January 2004 American Heart Association CPR update, Danville, VA

April 5-9, 2003 ACRP Annual Conference

April 2003 ACRP Certification- CCRC , Philadelphia, PA

March 2003 ACRP Certification Preparation Course for CRC's

January 2003 HIPPA training , Danville, Virginia

January 2002 American Heart Association CPR update, Danville, VA

August 2001 Communications Seminar, Virginia Beach, Virginia

June 2001 Fundamental of Clinical Research, ACRP, New Orleans, LA

April 2000 Nursing Law Update, Roanoke, VA

Nov 2002 American Heart Association Annual Conference, Chicago, IL

May 1995 DRMC School of Nursing Danville, VA
▪ Diploma in Nursing (Registered Nurse)
May 1990 George Washington High School Danville, VA

RESEARCH TRIALS/DRUG STUDIES

Coordinated many pharmaceutical research studies over the past 21 years in all therapeutic areas (cardiac, orthopedic, internal medicine, rheumatology, spine, pain management, ie):

Prospective, Randomized, Controlled, Multicenter, Clinical Investigation evaluating the safety of XXX in Spine Surgery. 2020-Present

Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Subjects with Fibromyalgia. Phase 2. (2021-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. (2020-Present)

A phase 3 Prospective, multicenter, double-blind, randomized, placebo-controlled study to evaluate the efficacy of XXX in in patients with osteoarthritis of the knee.(2020-Present)

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study of XXX in Patients with Systemic Lupus Erythematosus. 2020-Present

Study is designed to validate the the XXX Lyme Assay using samples from patients clinically diagnosed with Lyme disease and also to compare test results to other standard diagnostic tests.(2020-Present)

Phase 2, Randomized, Double-Blind, Placebo Controlled study of the safety and efficacy of XXX for the treatment of adhesive Capsulitis of the Shoulder (2020-Present.)

A Randomized, Controlled Pragmatic Phase 3B/4 Study of XXX in Patients with Rheumatoid Arthritis (2020-Present).

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

A Randomized, Double-Blind, Placebo Controlled, Parallel group study to evaluate the efficacy and safety of XXX in patients with Hip Osteoarthritis. (2019-2020).

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. (Jan 2019-2021).

A Randomized, Multicenter, Open-label, Parallel Group Study in Postmenopausal Women with Osteoporosis to Evaluate the Non-inferiority of subjects administered XXX via auto injector/pen vs. Healthcare provider administered XXX via prefilled syringe. (Jan 2018-2019).

A Phase 4, Randomized, Double-Blind, Multicenter, Placebo Controlled Study to Evaluate the Safety and Efficacy of XXX in combination with XO1 compared with XO1 alone, in subjects with Gout and Estimated Creatinine Clearance 30 to <60 mL/min who have not achieved target serum uric acid levels on an XO1 Alone. (Aug 2017-Feb 2019).

A Randomized, Double-Blind Placebo Controlled Study to access the effects of XXX on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease who are statin intolerant. **Phase 3.** (Oct 2018-Present)

Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, study of XXX in Patients with Systemic Lupus Erythematosus. (2018-Present).

A Randomized, Double-Blind Placebo Controlled, Parallel-group, Multicenter, Dose-Ranging Study to evaluate the Safety and Efficacy of XXX in Severely Obese Patients with Type 2 Diabetes Mellitus. **Phase 2.** (May 2018-2019)

A **Phase 3**, multi-center, multi-national, placebo controlled, randomized, double-blind 26 week study to access the safety and efficacy of XXX in patients with severe hypertriglyceridemia. (April 2018-2020)

An integrated assessment of safety and effectiveness of XXX for the management of essential hypertension (2017-2019).

A **Phase 3**, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of the analgesic efficacy and safety of a dose titration regimen for the subcutaneous administration of XXX in subjects with osteoarthritis of the hip of knee. (2016-2018).

A **Phase 2A**, Randomized, Double-Blind, Placebo Controlled crossover study of the Safety and Efficacy of XXX in subjects with Osteoarthritis of the knee. (2016-2017).

A **Phase 3**, Randomized Withdrawal Double Blind Study of XXXX Monotherapy Compared to XXXX Monotherapy for Maintenance of Remission in Subjects With Rheumatoid Arthritis. (2015-2018).

A **Phase 3**, Multi-Center Double-Blind, Randomized Controlled Study of XXXX and XXXX in Combination or as Monotherapy in Subjects with Psoriatic Arthritis. (2015-2017).

A **Phase 3B**, Randomized, Double-Blind Clinical Trial to Evaluate the Efficacy and Safety of XXXX SC in Combination with XXXX Compared to XXX Monotherapy in Achieving Clinical Remission in Adults with Early Rheumatoid Arthritis who are XXXX Naïve. (2015-2018).

Efficacy, Safety, and Immunogenicity of XXXX versus XXXX in patients with Active Rheumatoid Arthritis: A Randomized, Double-blind, Parallel-arm, Multiple Dose, Active Comparator. **Phase 3. (2015-2018)**

A Randomized, open-label, parallel group real world pragmatic trial to assess the clinical and health outcomes of XXX compared to commercially available basal insulins for initiation of therapy in insulin naïve patients with uncontrolled T2DM. **Phase 4.** (2015-2018).

Glycemic Control and Treatment Satisfaction Using XXX vs YYY for initiating bolus insulin dosing in T2DM patients not achieving glycemic targets on basal insulin with/without antihyperglycemic agents. (2015-2018). **Device Study.**

A Randomized, Multicenter Study to Evaluate Cardiovascular Outcomes with XXX in Patients Treated with SOC for T2DM. **Device Study** (2015).

Prospective, Multicenter, Single Arm Pilot Clinical Investigation Evaluating the use of a Surface Bleeding Severity Scale and the Safety and Efficacy of a new hemostatic **device** in abdominal and orthopedic lower extremity surgeries. (2015-2016).

Prospective, Multi-Center, Randomized, Three-Arm, Parallel group, clinical study to evaluate the superiority of 3 weekly intra-articular doses of 2ml of Investigational Product as compared to Placebo and XXXX injected into the target knee for the treatment of pain in subjects with Osteoarthritis. (2015). **Device Study.**

Double Blind, Placebo-controlled, Randomized, Parallel-group Study to Determine the Safety and Efficacy of a Topical Patch (XXXX) Following Daily Administration for 2 Weeks in Patients with Chronic Low Back Pain. **Phase 2.** (2015-2015)

A Randomized, Sham-Controlled Pilot Study of XXXX Therapy in the Treatment of Persistent Post-Operative Pain following a Total Knee Arthroplasty (**Device Study**). (2015-2016).

A Multicenter, Randomized, Sham-Controlled, Double-Blind Study of XXXX Therapy in the Treatment of Persistent Post-Operative Pain Following Lumbar Discectomy (**Device Study**).

A **Phase 3**, Randomized, Double-Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy

and Safety of XXX, XXX, XXX, XXX in Subjects with Gout. (2014-2016).

A, Double-blind, Randomized, Parallel Group, Dose-Ranging Study to Assess the Safety and Efficacy of XXXX for the Treatment of Pain in Patients with Osteoarthritis of the Knee. (2014-2015).

A Randomized, Double-Blind, Placebo-Controlled **Phase 3** Study to Evaluate the Efficacy, Safety, and Effect on Radiographic Progression of XXXX in Subjects with Psoriatic Arthritis. (2014-2015)

A Multicenter, Randomized, Double-Blind, Parallel, Active Controlled Non-Inferiority Clinical Trial Comparing Three Weekly Intra-Articular Injections of XXXX Versus Three Weekly Intra-Articular Injections of XXX for the Treatment of Osteoarthritis Pain of the Knee. (2014-2015). (**Device Study**)

A Randomized, Placebo-controlled, Double-Blind Study to Evaluate the Efficacy and Safety of a single intra-articular injection of XXX in adults with pain due to osteoarthritis of the knee. (1/2014- 10/2014). 2 Week Enrollment Period.

A Randomized, Double-Blind, Placebo Controlled Study of the Safety and Efficacy of XXX for the Treatment of Adhesive Capsulitis of the Shoulder. (12/2013-11/2014)

A Randomized, Double-Blind, Placebo Controlled, Parallel Group Study to Evaluate the Effect of Long Term Treatment with XXX on the Incidence of Major Adverse CV events and conversion to T2DM in obese and overweight subjects with CV disease or multiple risk factors. Phase 3B/4. (4/2014-Present).

A Phase IIb, Multi-center, Randomized, Double-Blind, Placebo Controlled, Multidose, 24 Week Study to Evaluate the Efficacy and Safety of XXX in Subjects with Systemic Lupus Erythematosus (SLE). (Dec 2013-2015).

Randomized, Double-Blind, Placebo Controlled, Parallel-Group, Multicenter, Worldwide, Proof of Concept Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of XXX in Subjects with Active Rheumatoid Arthritis and Inadequate Response or Intolerance to Anti-TNF Therapy. (May 2013-October 2013).

Placebo Controlled, Double Blind Evaluation of the Efficacy and Safety of XXX for the treatment of Ankle Sprain. (Nov. 2013-2015).

A Randomized, Placebo-Controlled, Double-Blind Study to Evaluate the Efficacy and Safety of XXX in Adults with Pain due to Osteoarthritis of the knee. **Phase 2**. (April – August 2013) Intra-articular injection.

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate Cardiovascular Outcomes of XXX in addition to Standard of Care in Subjects with Type 2 Diabetes and with CV Disease Or Multiple Risk factor for CV Disease. (2013-2014).

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 8 Week Study to Evaluate the Safety and Efficacy of XXX and YYY as a fixed dose combination in Patients with Stage 1 or 2 Essential Hypertension. (2012-2013). Phase 3.

A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Active-Controlled, Parallel-group, Multicenter Trial of XXX to assess the analgesic efficacy and the management of opioid induced constipation in opioid experienced subjects with moderate to severe chronic low back pain and a history of opioid induced constipation who require around the clock opioid therapy. Phase: 3 (2012)

A Randomized, double Blind, active controlled study of XXX prefilled syringes or XXX reconstituted lyophilizate or YYY for treating acute gouty arthritis flares in frequently flaring patients. Phase 3. (5/2011- 2013)

A Phase III, Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of XXX and YYY compared to YYY alone At lowering Serum Uric Acid and Resolving Tophi in subjects with tophaceous gout. Phase 3. (3/2012-2015).

A Phase III, Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of XXX and YYY compared to YYY alone In subjects with Gout who

have had an Inadequate hypouricemic Response to SOC YYY. Phase 3. (3/2012-2015).

A Phase III Multicenter, Double-Blind, Crossover Design Study to evaluate Lipid altering Efficacy and Safety of XXX in Patients with Primary Hypercholesterolemia or Mixed Dyslipidemia (5/2011-4/2012). Phase 3

A Multicenter, Randomized, Active Control, Phase 3B Study to Evaluate the Cardiovascular Safety of XXX and YYY in Subjects with Gout and Cardiovascular Co-Morbidities. Phase 3B. (4/2011-2017)

A Multicenter, Randomized, Double-Blind Study to Evaluate the Effect of XXX vs PLACEBO on Renal Function in Gout Subjects with Hyperuricemia and Moderate to Severe Renal Impairment. Phase 2. (4/2011-2012)

A Randomized, Double-Blind, placebo-controlled, event driven trial of quarterly subcutaneous XXX in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP. (2011-2018).Phase III.

A Phase 3, Multicenter, Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of XXX in patients with Systemic Lupus Erythematosus (SLE). (2011-2015)

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of XXX as Add-On to YYY Therapy for Type 2 Diabetes Mellitus. Phase 3b/4. (2011-2012).

Multinational, prospective, Observational Study to characterize and assess the burden of refractory gouty arthritis on patients over one year. (2010-2011)

A Randomized, Multicenter, Double-Blind Factorial Comparator and Placebo Controlled Phase III Trial to Evaluate the Efficacy, Tolerability, and Safety of XXX in the treatment of ankle sprains. (2010-2011)

A Randomized, Multicenter, Double-Blind Factorial Comparator and Placebo Controlled Phase III Trial to Evaluate the Efficacy, Tolerability, and Safety of XXX in the treatment of Tendonitis and Bursitis of the Shoulder (2010-2011)

Phase III, Randomized, controlled study of XXX on the treatment and prevention of gout flares in patients with frequent flares for whom NSAIDs and/or colchicine are contraindicated, not tolerated or ineffective. (2010-2011)

A Randomized, Multicenter, Double Blind, Parallel, Placebo Controlled Study of the Effects of XXX on cardiovascular outcomes in Adult Subjects With Type 2 Diabetes Mellitus. Phase 3. (Jan 2010-2017)

A 24 week, multicentre, randomized, double-blind, age-stratified, placebo controlled phase III Study with a 28 week extension period to evaluate the efficacy and safety of XXX in patients with type 2 diabetes, cardiovascular disease and hypertension, who exhibit inadequate glycaemic control on usual care. Phase 3. Sponsor: (2010-2011)

A 26-week randomized, confirmatory, controlled, open label, multicentre, multinational treat-to-target trial comparing the efficacy and safety of xxx and yyy, both injected once daily in combination with oral anti-diabetic drugs (OADs), in insulin naïve subjects with type 2 diabetes mellitus currently treated with OADs qualifying for intensified treatment. Phase 3a. (Note:Back-up site) 2010.

A randomized, controlled study of xxx on the treatment and prevention of gout flares in patients with frequent flares for whom NSAIDs and/or colchicine are contraindicated, not tolerated or ineffective. Phase 3. (2010-2012).

A randomized, double blind, placebo controlled study to determine the efficacy of XXX in the treatment of pain caused by osteoarthritis of the knee. Phase 3. (2009)

A randomized, Multicenter, Double-Blind, Placebo controlled study to evaluate the Efficacy and Safety of XXX in the treatment of pain associated with mild to moderate ankle sprain. Phase 3. (2009-2010).

Observational Registry of Patients Using Prescription Medications Containing XXX for the treatment of pain. Phase 4. (2009).

Phase III, Open Label, Randomized, Referred Care-Controlled, Clinical Trial to Evaluate the Efficacy and Safety of XXX on Vitamin D Adequacy in the Treatment of Osteoporosis in Postmenopausal Women. (2008-2010).

Study for the validation of XXX for Assessing Opioid-Induced Constipation/ Device Study (2008-2009)

A Multicenter, Randomized, Double-Blind, Placebo Controlled Trial of three injections of XXX For the treatment of Chronic Shoulder Pain Associated with Glenohumeral Osteoarthritis. (2008-2009).

A Phase III, Flexible-Dose Titration Followed by a Randomized Double Blind Study of Controlled Release XXX Compared to Placebo in Patients with Osteoarthritis Pain (2008). Opioid Study.

A Randomized, Open Label, Blinded-Endpoint, Parallel Group Trial of GI Safety of XXX compared with NSAIDS in Osteoarthritis Patients . (2007-2010).

A Randomized, Double-Blind, Parallel-Group Study of Cardiovascular Safety in Osteoarthritis or Rheumatoid Arthritis Patients with or at High Risk for Cardiovascular Disease Comparing XXX with YYY and ZZZ. (2006-2016).

A Randomized, Double-Blind, Active- And Placebo Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of XXX In Subjects Awaiting Primary Joint Replacement Surgery for End-Stage Joint Disease. (2007).

A six week Double-Blind, Randomized, Multicenter Comparison Study of the Analgesic Effectiveness of XXX Compared to YYY in Subjects with Chronic Low Back Pain (2006).

Multinational, multicenter, double-blind, randomized, placebo-controlled Parallel group study assessing the efficacy of intravenous XXX in Preventing subsequent osteoporotic fractures after a hip Fracture.(2002- 2007)

Multicenter, double-blind, placebo controlled, Randomized, Parallel Group study to compare the efficacy and tolerability of XXX vs. YYY In treatment of acute ankle sprains. (2002-2003).

A randomized, double-blind, Active-comparator controlled, Parallel Group study to evaluate the safety of XXX in patients with Osteoarthritis Or Rheumatoid Arthritis. (2002-2006).

Observational study of men and women with osteoporosis who have been Prescribed XXX. (2004-2010).

Phase IIb, multi-center, randomized, double-blind, double dummy dose ranging study of two doses of XXX versus YYY in patients with non-ST elevation acute coronary syndromes. (2002-2003).

Efficacy and Safety Study of the Oral Direct Thrombi Inhibitor XXX compared with Dose-Adjusted YYY in the Prevention of Stroke and Systemic Embolic Events in Patients with Atrial Fibrillation. (2001-2003).

A Phase IV, multi-center, open label evaluation of patient satisfaction with XXX administered at the first sign of pain for up to three migraines in patients who are not satisfied with their current triptan therapy. (2001)

A Randomized, Double-blind, Placebo Controlled Trial of the Effect of Weekly XXX on the Incidence of Coronary Artery Disease in subjects with evidence of exposure to C. Pneumonia. (2000-2002).

REFERENCES

Available Upon Request

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS

David E. Brown, D.C., Director

Jay P. Douglas, MSM, RN, CSAC, FRE
Executive Director
(804) 367-4515

BOARD OF NURSING

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License to Practice as a Registered Nurse- Multi-State Privilege

APRIL T. MARSHALL

Expires
03/31/2022

Status
Current Active

Number
0001144048

For Information About This License, visit our website: www.dhp.virginia.gov
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Association of Clinical Research Professionals

through its independent affiliate, the Academy of
Clinical Research Professionals, bestows upon

April Marshall

THE DESIGNATION OF

Certified Clinical Research Coordinator

for having satisfied the standards of ethical and responsible clinical research, including substantial professional experience performing role-specific essential duties, demonstrating proficiency through a comprehensive examination, and committing to ongoing professional development in the practice of clinical research.



Barbara Grant Schliebe, MS, CCRC, CCRA, FACRP
Chair, Academy of Clinical Research Professionals

CERTIFICATION DATE: Apr 05, 2003
EXPIRATION DATE: May 31, 2023



This program meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.