CTT

Clinical Trials of Texas, Inc.

Promoting Health Through Research

A Top Quality Multispecialty Research Organization

Clinical Trials of Texas, Inc. (**CTT**) was founded in 2001 by Kay Scroggins, RN, CCRC. Prior to forming **CTT**, Kay had over 16 years of clinical experience as a registered nurse and over 10 years of clinical research experience, including serving as a CRA & CRA Manager for a Contract Research Organization (CRO) and as Director of Research for a doctor-owned research site. Kay's vision to successfully conduct pharmaceutical and device research studies with high integrity and exceptional quality is realized today through the outstanding group of research professionals and investigators affiliated with **CTT**.

CTT has a highly-equipped and versatile 15,000 sq. ft. facility capable of conducting Phase 1-4 studies in a multitude of therapeutic areas. In addition to our Medical Director, Douglas Denham, DO, over 50 board certified physicians, who practice in the San Antonio area, work with **CTT** to conduct studies in their respective medical specialties. This vast network of investigators has helped create one of the largest and most capable research sites in the United States. The top priorities of **CTT** can be quickly understood by simply reading our Mission & Vision Statement.

CTT Mission & Vision

To conduct clinical research protocols safely, ethically, efficiently and accurately to produce quality data for our sponsors.

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To meet sponsor timelines, protocol requirements and recruitment goals while always keeping subject safety a top priority.

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To treat research subjects with respect and dignity for the great service and sacrifice they make on behalf of the greater good of our society, and to provide them with the best possible customer service so that every participant has a positive experience.

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To maintain a professional and vibrant team who respect each other, support each other and promote positive thinking.

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To achieve long-term success for the benefit of each other and our families.

CTT has the capability to conduct clinical research studies in a multitude of therapeutic areas, phases and design types. We work with major pharmaceutical and device sponsors, CROs, as well as smaller bio-tech companies to successfully and safely advance their research and development projects. **CTT** provides exceptional value to sponsors with rapid start-up capabilities, successful recruitment strategies, an experienced clinical research team, rapid data entry and dedicated quality control.

Primary Specialties

- Vaccines
- Women's Health
- Psychiatry - Adult/Adolescent/Child
- Neurology - Adult/Adolescent/Child
- General Pediatrics
- Dermatology
- Ophthalmology
- Gastroenterology
- Orthopedics
- Sports Medicine
- Oncology
- Otolaryngology (ENT)
- Pain Management
- Surgical Procedures & Devices
- Neurostimulators
- Vascular Medicine & Surgery
- Radiology
- Internal Medicine
- Sleep Therapy
- Diabetes
- Devices
- Healthy Populations

Departments

- Phase 1 Services
- Clinical Research Operations (Phase 2-4)
- Medical Safety Director/Monitor
- Regulatory Compliance
- Subject Recruitment
- Clinical Laboratory
- Business Development
- Business Operations
- Quality Assurance

Physician Network

- Over 50 Board Certified Physician
- Over 20 Specialties
- GCP Certified Investigators
- Involved Oversight

Highlights

- Access-Controlled 15,000 sq. ft. Facility
- Phase 1 Inpatient Facilities
- Backup Generators
- -80°/-40°/-20°C Freezers
- 2-8°C Refrigerators
- Temperature Data Logging & Phone Alert System for All Monitored Areas
- Refrigerated Centrifuge
- Synchronous Atomic Clocks
- Programmable Medical Treadmill
- Cardiac Stress System
- ECG/EEG/Holter Capabilities
- Proprietary SOPs
- Large & Diverse Database of Potential Research Subjects
- DEA Drug Compliance
- X-Ray/MRI/CT/PET/Sonogram/DEXA
- Nerve Conduction Velocity Testing
- Pulmonary Function Testing
- Colonoscopy/Endoscopy Capabilities
- Limited-Access, Temperature-Controlled Drug Storage

PRESIDENT, CEO

Kay Scroggins, RN, CCRC

Leading CTT with vision, direction and innovation, Kay has shaped Clinical Trials of Texas, Inc. to become one of the most capable clinical research sites in the United States.

MEDICAL DIRECTOR

Douglas Denham, DO, CPI

As a Certified Clinical Research Investigator, Dr. Denham provides close medical oversight of clinical staff and studies conducted at CTT. His experience and leadership help ensure quality data and subject safety.

Phase I

CTT conducts inpatient studies requiring overnight observation and procedures.


Exam Room


Phase 1 Lounge

Inpatient Facilities

Our Phase 1 facility is connected to two major hospitals and provides safe and comfortable accommodations for study subjects. Our facility has:

- Comfortable Lounge
- Computer Work Stations
- Wireless Internet
- Kitchen/Dining Areas
- Entertainment Options

ACLS Certified

- Investigators
- Nurses
- EMTs
- Research Coordinators

Inpatient Study Experience

- Pharmacokenetics/Pharmacodynamics
- First-in-Human
- Food Effect
- Cardiac Holter Monitoring
- Multiple Ascending Dose (MAD)
- Single Ascending Dose (SAD)
- Devices
- Healthy Populations
- Elderly Populations
- Pediatric Populations
- Sleep Apnea

Subject Safety

- Access-Controlled Facility
- 24-Hour Video Surveillance
- Emergency Pull-Cord System at each bedside and in bathrooms
- Crash Cart
- AED
- ACLS Certified Investigator and Staff
- Phase 1 Emergency SOPs


In-House Sleeping Quarters


Handicap Accessible Showers

Therapeutic Experience

Women's Health:
Overactive Bladder, Contraception, Weight Loss, Vaginal Atrophy, Osteoporosis, HPV, Sexual Dysfunction, Fibrocystic Breast Disease, Anemia, Heavy Uterine Bleeding, Endometriosis, Uterine Fibroids, Hormone Replacement Therapy, Premenstrual Dysphoric Disorder

Psychiatry - Adult/Pediatric:
Depression, Bipolar I and II, Anxiety, Sexual Dysfunction, Alzheimer's Disease, Adjunct Therapy, Obsessive Compulsive Disorder

Pain Management/Anesthesiology:
Opioid Induced Bowel Dysfunction, Implanted Devices, Chronic Pain, Low Back Pain, Knee Pain

Internal Medicine:
Hypertension, Dyslipidemia, Erectile Dysfunction, Osteoarthritis, Influenza, Congestive Heart Failure

Gastroenterology:
GERD, Ulcerative Colitis, Diverticulitis, Gastric Ulcers, Irritable Bowel Syndrome

Vascular Medicine:
Peripheral Arterial Disease, Vascular Surgery, Venous Leg Ulcers

Pediatrics:
Pediatric Vaccines, Asthma

Dermatology:
Rosacea, Surgical Wound Management Systems, Cosmetics, Laser Treatments, Psoriasis

Neurology - Adult/Pediatric:
Migraines, Peripheral Neuropathic Pain, Post Herpetic Neuralgia, Tourette's Syndrome, Stroke

Endocrinology:
Diabetes I and II, Obesity

Radiology:
PET, MRI, CT, Angiography, Ultrasound

Vaccines:
HPV, MMRV, RSV, Flu, Traveler's Diarrhea, Pneumococcal, Meningitis

Sleep Studies:
Sleep Apnea, Restless Leg Syndrome, Narcolepsy, Insomnia

Device Studies:
Wound Dressing Systems, Implantable Devices

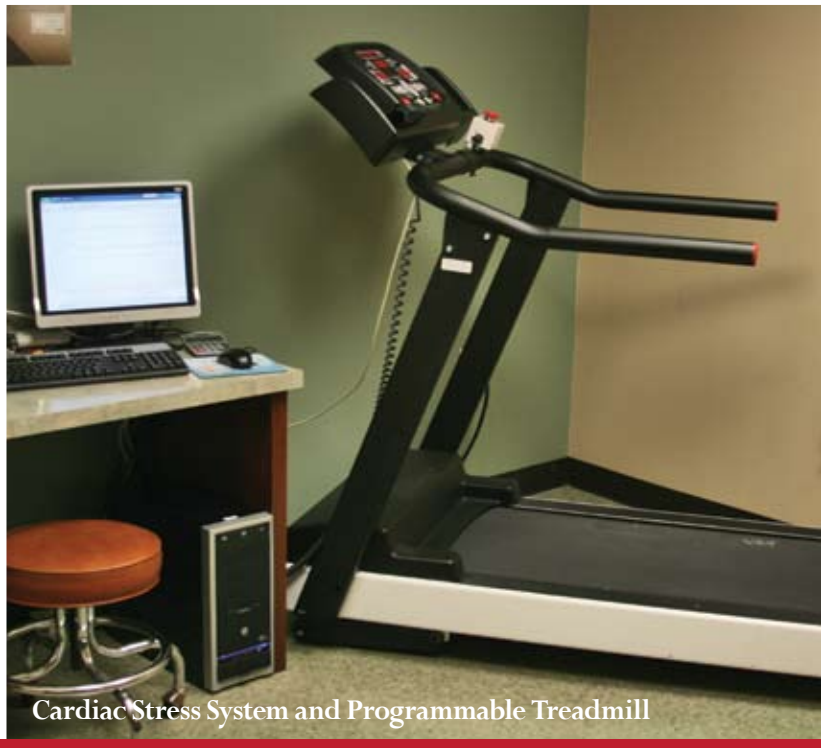
ENT:
Otitis Media/Externa, Sinusitis, Allergic Rhinitis

Pulmonary:
COPD, Asthma

Capabilities

- Pharmaceutical Drug Studies
- Medical Devices
- Vaccines
- Surgical Procedures & Devices
- Wound Care Dressings
- Drug Delivery Systems
- Radiological Contrast Agents
- PK Studies
- In- & Out-Patient Hospital Studies

Secure Drug and Specimen Storage



Cardiac Stress System and Programmable Treadmill

Rapid Start, Quality Execution, On-Time Data Delivery

From study start to study end, **CTT** leads the industry in meeting sponsor timelines and delivering exceptional quality data. By streamlining study execution through SOPs, policies and procedures and an effective team approach, **CTT** can work with accelerated study timelines without compromising quality. With a dedicated Quality Assurance Department, **CTT** achieves high quality control of every data point that is delivered to sponsors.

CTT focuses on quality through training.

Subject Recruitment

Today's complicated protocols with increasing subject eligibility criteria require more creative recruiting resources and innovative thinking than ever before. **CTT**'s dedicated recruiting department leads the industry in effective subject recruiting strategies. Recruitment begins with a criteria-matching search of **CTT**'s own research-specific database of volunteers. Additionally, **CTT**'s network of over 50 investigators helps identify potential subjects from their own private patient databases. Innovative advertising campaigns coupled with strategic mass-media placement means that sponsors can save on recruitment costs when compared to large central ad agencies. Our presence and great reputation in the local community help bring new volunteers into our facility every day.

Media Utilization:

- Television
- Radio
- Print
- Search Engine Marketing – YAHOO! Google
- Social Media –

Quality Assurance

CTT's QA/QC & Data Entry Department performs a Quality Assurance and Quality Control of study data prior to delivery to sponsors. In addition to GCP/FDA/protocol compliance, our skilled Quality Assurance Team ensures that all data meet our P.A.C.T.* System requirements. Dedicated data-entry personnel input reviewed data into CRFs/eCRFs ahead of sponsor timelines. Medical oversight provided by our Medical Director and board certified investigators help ensure medical safety and data integrity.

***Our P.A.C.T. System ensures that data is**

Punctual
Accurate
Complete
True

Clinical Team

Our team of research professionals includes:

- ACRP Certified Medical Director
- Board Certified Investigators
- Nurse Practitioners
- Registered Nurses
- Certified Clinical Research Coordinators
- IATA Certified Lab Technicians and Study Coordinators
- Knowledgeable, Efficient Regulatory Specialists
- Highly Skilled Data Entry Personnel
- GCP & Safety Trained Staff
- EMTs
- ACLS Certified Staff

CTT Specializes in Vaccine Studies:

With years of experience, **CTT** has streamlined the processes required for executing large cohort, fast-enrolling studies. Also important, **CTT** has an outstanding record of subject retention with a greater than 92% overall retention rate in vaccine studies. Our facility and staff make **CTT** one of the most capable vaccine sites in the country.

	Demographics	Enrollment Goal	Actual Enrollment	Enrollment Duration
Vaccine Study #1	M/F 18-64 years	96 Subjects	116 Subjects	3 Weeks
Vaccine Study #2	M/F 60+ years	67 Subjects	127 Subjects	4 Weeks
Vaccine Study #3	M/F 18-64 years	120 Subjects	129 Subjects	3 Weeks
Vaccine Study #4	M/F 18-64 years	75 Subjects	109 Subjects	6 Weeks

Vaccine Study #1

- 50/50 male to female ratio required by sponsor.

Vaccine Study #2

- Challenging population of healthy, elderly subjects.

Vaccine Study #3

- Short enrollment period of three weeks.

Vaccine Study #4

- Over-enrolled in just six weeks to meet strict enrollment timelines.

We have always met enrollment goals, even when time was not on our side.

15,000 Sq. Ft. Facility

Temperature Excursion Alert System

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