Dallas clinical research unit

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Facility overview and capabilities

The Fortrea clinical research unit (CRU) in Dallas is a top-tier facility with more than 55,000 square feet of space. The CRU occupies over four floors and includes a cGMP pharmacy and dedicated ophthalmology procedure rooms, plus dedicated screening and outpatient visit areas. The cGMP pharmacy includes three sterile and two non-sterile manufacturing suites, which can manage and handle high-potency and hazardous drugs. An advanced telemetry system enables the team to perform continuous high-quality data monitoring, enabling staff to better monitor study participants and quickly make necessary adjustments to treatment regimens.

With more than 25 years of research experience, the Dallas site has conducted over 700 inpatient and outpatient Phase I-IV clinical trials of investigational medications. In addition to healthy normal populations, we have experience in special populations such as type 1 and type 2 diabetes, healthy elderly, high cholesterol, overweight/obese individuals, postmenopausal women and ethnobridging populations.

The site also has experience supporting complex study procedures, including muscle biopsies, and routinely collaborates with local medical providers and specialized vendors to support study activities, including cardiologists, optometrists and imaging centers. As the ninth largest city in the U.S. and the fourth largest metropolitan area, Dallas offers a tremendous opportunity for recruiting study participants and experienced staff. Our extensive database, which contains more than 60,000 active participants, has a unique racial distribution: 50% Caucasian, 43% African American and 7% American Indian/Alaskan Native, Native Hawaiian or Other Pacific Islander, or Asian (including Japanese and Chinese). Of the total population, 82% are healthy Non-Hispanic and 18% are healthy Hispanic.

SITE FEATURES

- Total capacity—100 beds
- Participant database—60,000+
- Longest continuous in-house stay—90 days
- Emergency response time of less than five minutes
- TransAir 3 PFT System capable of dynamic static spirometry, DLCO, lung volumes via nitrogen recovery and more
- Dedicated opthalmology suite
- cGMP pharmacy, including three sterile and two non-sterile manufacturing suites
- Telemetry monitoring system

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Understanding the challenge

- cGMP quality for patient safety
- Fast turnaround to meet study timelines
- Flexibility for adaptive trial design
- Control over costs and decision-making



Game-changing solution: cGMP manufacturing and clinical trial on one campus

Fortrea proposed that our cGMP Pharmacy manufacture a small quantity of the client's formulation for the Phase I clinical trial. Their auditors were assured of quality and oversight by reviewing our documented cGMP process. On-site manufacturing ensured drug quality and patient safety plus fast delivery—a concern when some formulations may be stable for only minutes or hours.

With the pharmacy and trial site located on one campus, our team could quickly deliver doses from manufacture to clinic. A CMO would normally be expected to add distance and shipping time between manufacture of the product and delivery to the clinic. Fortrea removed the time and distance gap between pharmacy and trial site for fast turnaround.

The client also gained flexibility to adjust their formulation on the fly based on observed trial results. A CMO could only deliver one formulation and one dosage, with the expectation of a large run. Our adaptive trial design provided for formula or dosage adjustment in response to trial indications—with less waste of API.

With cGMP manufacturing, the client gained control and cost savings during the trial. Instead of one large CMO run of one formulation, Fortrea delivered cost-efficiency for small runs, with the ability to change or halt the process without delay or material loss.

Phase I cGMP manufacturing potential

25-50%

drug protection costs savings

Significant when total manufacturing costs for drug development are

20-40%

The client met their study timeline with quality cGMP drugs produced in small runs for flexible formulation, expedient regulatory review, controlled costs and informed decision-making.

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