Madison clinical research unit

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Facility overview and capabilities

The Fortrea clinical research unit (CRU) in Madison, Wisconsin, is a 30,000-square-foot, purpose-built clinic with 88 beds and more than 50 years of experience conducting Phase I trials with healthy participants, including absorption, metabolism and excretion (AME), first-in-human (FIH) and complex study designs. Located on a single floor, the spacious clinic includes 22 four-bed rooms separated by lockable bathrooms for secure sample collection. Clinical activities take place in the bedrooms, a purpose-designed phlebotomy room or a large, flexible clinical space designed for streamlined delivery.

Participant engagement is central to the site experience. The clinic offers two areas for participant entertainment and relaxation, including a secure outdoor garden.

- The site also includes three separate ^{14}C AME bathrooms for secure collection
- At the center of the clinic is a full processing laboratory and an adjacent freezer room for processed samples awaiting dispatch. All freezers and refrigerators are REES temperature controlled

A separate clinical area that opened in 2023 supports participant screening, outpatient visits and study check-in. This self-sufficient space has its own processing laboratory and sample freezer storage.

Our staff includes three physicians, five registered pharmacists and more than 50 full-time medical and technical personnel.

The unit has two fully equipped crash carts on the clinic floor and a nurse call system throughout the facility, including every bed, bathroom and shared space. Five emergency rooms in the Madison area are within 10 minutes of the site.

SITE FEATURES

- Total capacity: 88 beds
- Safety monitoring: 16 beds
- Participant database: 22,500
- Longest continuous in-house stay: 142 days
- cGMP pharmacy, including two sterile and three non-sterile manufacturing suites
- Emergency response time: < five minutes
- On-site Nuclear Pharmacists, Radiation Safety Officer, Radiation Safety Committee and physician-authorized users
- Conducted more than 485 AME studies over the past 30 years

Fortrea

The on-site cGMP pharmacy includes two sterile rooms and three nonsterile rooms for manufacturing and assembling clinical doses, including ^{14}C-labeled compounds.

The Madison clinic has extensive experience conducting radiolabeled clinical studies. Its team includes three nuclear pharmacists, two of whom are board-certified nuclear pharmacists, and a radiation safety officer who supports consistent compliance with FDA, NRC/ Agreement State and DOT regulations across Fortrea sites. Real-time radioanalysis for recovery is performed on-site to help determine each participant's discharge date.

The cGMP pharmacy includes two sterile and three nonsterile manufacturing suites that can handle high-potency and hazardous drugs.

On-campus laboratories provide services ranging from bioanalysis to metabolite identification and profiling.

A radioanalysis case study

A biotechnology client contracted with Fortrea for a human AME study using ^{14}C to determine the excretory pathway, identify metabolites and assess potential enterohepatic recycling. The Fortrea CRU team in Madison administered the radiolabeled drug to participants, collected samples, analyzed data and reported results each day of the trial against a target threshold of 90% recovery. The sponsor planned to compare the clinical study results with preclinical data to inform decisions about the drug's further development.

Understanding the challenge

- Accurate and timely collection of samples and data
- Same-day analysis and interpretation of results
- Daily reporting against target of 90% recovery
- Scientific knowledge to aid decision-making

An on-campus clinic and radioanalysis laboratory deliver real-time data and analysis

A dedicated Fortrea team administered doses of the radiolabeled drug to participants at the CRU. The team then collected blood, urine and fecal samples during the two-week study. Rigorous collection techniques supported accurate assessment of drug metabolites, drug excretion and potential enterohepatic recycling. The clinic immediately delivered samples to the on-campus radioanalysis laboratory for same-day processing. Data was captured electronically for timely, reliable analysis.

CRU and radioanalysis lab

1 Campus

Allows for virtual real-time data and analysis

Supporting every effort to achieve a recovery of

90%

Analysis showed that the drug remained in participants' blood and plasma longer than expected, with an increasing blood-to-plasma ratio over time and preferential binding to plasma. Radiolabeled drugs typically produce recovery rates of 91%–92%; this compound produced a lower rate of 88%. The delayed recovery of ^{14}C suggested that the compound was reappearing in the blood and being excreted more slowly than the sponsor anticipated. Because these results differed from the sponsor's preclinical data, the Fortrea team reviewed the results with the client each day.

Near-real-time data helped the sponsor interpret results promptly while maintaining study objectives, timelines and budgets. The client determined that further analysis and development were needed to understand the drug's circulation pattern. Fortrea then offered its HAME service to collect bile samples from participants dosed with the ^{14}C-labeled drug and quantitatively assess the importance and extent of the drug's metabolism through the biliary route.

Fortrea helps sponsors determine an appropriate radiation dose for trials based on extensive experience. U.S. regulations may allow higher radiation levels than those permitted in other countries. Approximately 60% of U.S. studies use 100 µCi, while about 20% use doses between 150 and 600 µCi. This approach can detect low systemic levels of a ^{14}C-labeled compound to evaluate enterohepatic recycling in humans.

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