

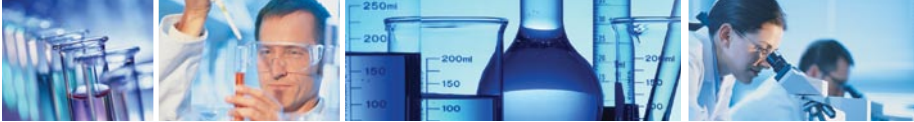


Rapid Enrollment, Low Dropout Rates in Clinical Trials with Synarc's CCBR

Subject recruitment can slow a clinical trial down, according to a study by market researcher Cutting Edge Information. The process of screening and enrolling subjects can consume as much as 30% of the clinical timeline. The cost of delays can be enormous: a drug's sponsor can lose as much as \$8 million each day if the compound is a potential blockbuster.¹

It's no wonder that biopharmaceutical companies turn to the Center for Clinical and Basic Research (CCBR) for clinical trials to expedite recruitment. Our 10 investigative sites routinely exceed the enrollment and retention rates of other clinical sites.

"We are focused on patients, subject recruitment, high compliance, and high performance," says CCBR Clinical Study Operations (CSO) General Manager Anette Møllgaard. "We reduce sponsors' total costs and development time through our dedicated clinics."



Localized recruitment strategies bring results

Our localized recruitment strategies are key to achieving rapid enrollment. Each CCBR clinic manager has a strong understanding of the communities from which to recruit subjects, and works to achieve specific monthly recruiting targets from these populations.

CCBR clinic managers use outreach techniques such as advertising, direct and indirect mailing campaigns, community programs, and local medical and scientific study forums. They also leverage our patient database and local country registries to meet goals.

CCBR makes it easy to participate in clinical studies, which helps to keep study dropout rates low. The attentive staff treats subjects courteously and professionally during each clinic visit. Reminder cards, breakfast or lunch during clinic visits, and travel reimbursements also demonstrate to subjects that their time and participation are valued. Other clinic activities, such as social events and annual gifts, also help to increase retention.



A track record of success

While CCBR is known for subject recruitment, it also excels at providing high-quality trial data. All CCBR clinics are staffed by qualified physicians, study nurses, lab techs, and clinical research associates. Their clinical-trial experience and expertise have a direct impact on study results. In addition, CCBR clinics are fully equipped with x-ray, DXA, mammography, MRI, blood and urine sampling, drug storage, and pharmacy. This means that there is a greater degree of control over study procedures.

CCBR places a high priority on compliance. Its sites go through 10 to 15 inspections annually—from the FDA, EMEA, local authorities, sponsors, and CROs—with no major findings. All clinical services are conducted according to ICH-GCP guidelines, applicable CCBR standard operating procedures, and the clinical-study protocol.

As a subsidiary of Synarc, CCBR adds Synarc services in medical image-analysis and biochemical markers to its already robust clinical-trial services. The combination leverages both companies' strengths and allows them to expand worldwide into service and therapeutic areas of interest to customers.

CCBR Therapeutic Expertise

- Asthma
- Cardiology
- CNS
- Diabetes
- Gynecology
- Metabolic disorders
- Obesity
- Osteoarthritis
- Osteoporosis
- Rheumatology
- Women's health

CCBR Clinical Research Facilities

- Aalborg, Denmark
- Ballerup, Denmark (Headquarters)
- Beijing, China
- Bucharest, Romania
- Pardubice, Czech Republic
- Rio de Janeiro, Brazil
- Tallinn, Estonia
- Vejle, Denmark
- Vilnius, Lithuania
- Warsaw, Poland

SPOTLIGHT

Amgen Selects CCBR for Denosumab Phase 3 Clinical Trials

When biotech pioneer Amgen wanted to begin phase 3 clinical trials for denosumab, they turned to one of the biggest clinical-trial centers in the world: CCBR.

Denosumab is an investigational therapy from Amgen that shows great promise to help arrest bone loss across a wide range of diseases, including osteoporosis, rheumatoid arthritis, and multiple myeloma.

The denosumab program, with more than 10,000 patients enrolled worldwide, is Amgen's largest development program.

CCBR doctors Claus Christiansen and Bente Riis led the enrollment of more than 25% of the total enrolled subjects to test denosumab for osteoporosis. The enrollees came from 10 different countries, including Denmark, Poland, Hungary, and Brazil.

"Osteoporosis is a serious medical condition for which patients have few options for long-term treatment," says Dr. Christiansen. "We are thrilled to participate in a clinical trial that could potentially lead to another therapeutic choice for this debilitating condition."²



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IMAGING ANALYSIS
SUBJECT RECRUITMENT
BIOCHEMICAL MARKERS

1. Accelerating clinical trials: budgets, patient recruitment and productivity. Cutting Edge Information Web site. <http://www.cuttingedgeinfo.com/acceleratingclinicaltrials>. Published May 2004.
2. Amgen 2005 Annual Report. Amgen Web site. http://www.amgen.com/investors/AnnualReport2005/develop_fighting_boneloss.html. Published March 2006.



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