



Finding and enrolling specialized patient populations for Phase I trials can be a daunting process. The Medpace secret? You just have to know the right people.

Medpace CPU was a recent first place finisher for a Sponsor with a specialized cardiac patient population, coming in well before other sites had enrolled even one patient. In this multi-center Phase I example, the client picked Medpace. It was their first experience with Medpace CPU, but not their last.

In 2008, Medpace opened a state-of-the-art 65-bed Phase I Clinical Pharmacology Unit (CPU) on a campus neighboring an investigative research clinic site, bioanalytical and central laboratory facilities, and CRO services. In the fast-paced, precise environment of Phase I research, Medpace knows planning is critical. Quality execution in the safest environment for patients is non-negotiable.

Since opening, Medpace has amassed a database of over 6,700 volunteers from the region. With an unparalleled outreach effort, commitment from the area's best physicians, and dedication to regulatory rigor, Medpace is quickly emerging as one of the finest research facilities in the Midwest US to conduct Phase I research.

Recruitment includes metabolic and endocrine disorders, patients with acute cardiac diagnosis, osteoporosis, post-menopausal females, elderly patients, renal compromised groups, and more.

CHALLENGE:
Find the right patients;
conduct patient screening,
randomization, and
enrollment; and integrate
state-of-the-art platelet
aggregating technology into
the process to conduct the
trial in record time.

Finding the correct patients was just the beginning. The Sponsor's protocol required specific technology to conduct the trial. Integrating that technology with on-site medical expertise in cardiovascular disorders, as well as conducting Phase I projects, demanded a full service partner to integrate all development services in a seamless fashion.

SOLUTION:
Choose the best CRO
with full service Phase I
capabilities, access to
specialized patient
populations, and the best
process to integrate all
facets of the project.

The Sponsor chose a number of investigator sites, including Medpace CPU. Medpace CPU not only had the relationship with a noted lead investigator in the area of cardiovascular research, but was able to meet the Sponsor's required numbers by adding an active patient recruiting media campaign. In

addition, the close working relationship of the Phase I unit with both Investigator and Medpace on-site medical experts allowed them to initiate platelet aggregating technology at the request of the Sponsor to conduct the trial well before other sites had recruited their first patient.

Access to Key Investigator Sites for Specialized Patient Population

Medpace CPU utilized affiliate Metabolic and Atherosclerosis Research Center (MARC), as a site devoted to treatments of specialized populations of patients with defined cardiovascular and metabolic patient populations.

This relationship, combined with active patient recruiting and integrated start-up processes, allowed Medpace access to these patients for faster project start-up.

Patient Recruitment and Retention

The Recruiting and Community Affairs group within the CPU is dedicated to the recruitment and retention of volunteers. Medpace CPU maintains an active and current volunteer database of over 6,000 recruited patient volunteers—this is ensured by continual contact with the volunteers through periodic phone calls, mailings, and advertisements. Volunteers are identified through a variety of mass media and web enabled tactics.

Medpace CPU active volunteer database demographics (as of March 25, 2010):

Population	No. of Patients
Normal Healthy Volunteers (18-64 yrs, BMI <30)	2202
Asthma	470
Cardiovascular Disease	501
Diabetes	1131
Hyperlipidemia	1341
Hypertension	2004
Obesity (BMI >30)	2782
Postmenopausal (natural or surgically sterile)	1229
Elderly (65+ yrs, BMI 19-35)	432
TOTAL	9171*

**Some patients have more than one condition; therefore, the total is not the sum of the various populations.*

RESULT:
The Sponsor reported back to Medpace that the patient recruiting and start-up process was completed much more quickly than any other investigative site.

Medpace was able to provide this service through a well integrated project team, by their close relationship with MARC's well developed patient database, and the on-site medical experience of Medpace therapeutic experts, to speed project start-up in comparison to the other investigator sites.

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