

M E D P A C E

ACROMEGALY STUDIES

Experts. Experience. Execution.

Discover the **POWER OF X™**



Medpace Strategy for Acromegaly Studies

Medpace specialty teams with noted medical experts, highly experienced clinical trial management teams, central labs, and core imaging labs can accelerate your next study.

Acromegaly is a rare disease characterized by overproduction of growth hormone (GH), and affects approximately 40 – 60 patients per million population. In adults, a benign pituitary tumor is the most common cause of excess GH production. The signs and symptoms of the disease include enlarged bones in the face, feet, and hands, enlarged tongue, weight gain and arthritis. Acromegaly is associated with hypertension, diabetes and increased cardiovascular risk.

First generation Somatostatin Analogues (SSAs) have been used for many years to treat acromegaly, and are effective in a majority of patients in reducing GH and insulin-like growth factor-1 (IGF-1) levels. Newer 'second generation' SSAs have been approved more recently, and offer a potentially better efficacy profile. Pharmaceutical companies are currently evaluating newer SSAs in clinical studies - which may offer more convenient dosing eg, oral formulations. A significant unmet clinical need in acromegaly is new treatment options which can improve cardiovascular risk, or other acromegaly-related comorbidities.

Acromegaly is a disease which affects all regions in the world including North America, Europe, Asia Pacific and South America. Medpace, a global full service CRO with deep experience in Endocrinology and Metabolic diseases, is a key CRO with experience in acromegaly. The Medpace scientifically-driven model, combined with Medpace Central Labs and Core Imaging Services, combines to accelerate acromegaly studies on a global platform.

Why choose Medpace for an Acromegaly Study?

- Scientifically-driven approach takes advantage of our deep clinical trial experience and scientific expertise in the endocrinology and metabolic disease, and more specifically in acromegaly studies
- Full service capabilities inclusive of Central Lab and Core Imaging Lab.
- We have recently conducted 2 global Phase III studies, involving >200 acromegaly patients and have been the Metabolic Research Laboratory (MRL) provider for 2 further Phase III acromegaly studies
- Existing investigative site relationships with local KOLs who specialize in acromegaly patient recruitment
- Strong operational experience in running acromegaly studies eg, Medpace has Global Clinical Trial Managers (CTMs) who have run acromegaly studies

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Medpace Central Labs with Biomarker Services Supporting Acromegaly Studies

With laboratories in the US, Europe, China and Singapore, Medpace Labs has the global reach and capabilities to conduct acromegaly studies in concert with Medpace CRO or as a standalone service.

Biomarker Strategic Services

Medpace Labs' test menu includes: GH, IGF-1, TSH, HbA1c and other biomarkers of insulin resistance (eg, proinsulin/insulin ratio).

Core Imaging Expertise for Studies

Medpace Imaging Core Lab provides holistic central imaging services including site assessment, qualification and training, recording equipment, provisioning, image processing (blinding and quality control) and expert evaluation. In particular, Medpace has expertise with Magnetic Resonance Imaging (MRI) - to support brain imaging if necessary.

Recruitment and Global Site Relationships

Medpace has strong relationships with established Investigator contacts in acromegaly. The ability to recruit acromegaly study participants requires a comprehensive site feasibility assessment, a well-designed study, and established relationships with key opinion leaders and principal investigators.

Therapeutic Experience

We have significant experience in the Endocrinology and Metabolic therapeutic disease area, and have conducted >300 studies in this field, in all phases of clinical development.

Our Endocrinology and Metabolic Experience includes the following disease areas:

- Acromegaly
- Diabetes Mellitus
- Obesity
- Cushing's Disease
- Hypogonadism
- Growth Hormone Deficiency
- Dyslipidaemias

For example, we have conducted over 90 diabetic trials involving more than 22,000 Type I and II diabetes patients globally. In obesity, we have conducted large pivotal Ph III studies – the largest involving 3,750 patients across 93 sites, emphasizing the global reach of our company.



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North America

Europe

Latin America

Asia

Africa

Middle East

Australia

Recent Acromegaly Experience Summary

With laboratories in the US, Europe, China and Singapore, Medpace Labs has the global reach and capabilities to conduct acromegaly studies in concert with Medpace CRO or as a standalone service.

Study Design	Sites	Patients	Medpace Services Geographical Coverage (Region)
Phase III, Acromegaly	33	155	Full Service, MRL. North America, EU, South America
Phase III, Acromegaly	28	84	Biostatistics, Clinical Monitoring, Data Management, Project Management North America, EU
Phase III, Acromegaly	45	80	MRL



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North America Europe Latin America Asia Africa Middle East Australia

Expertise in Acromegaly Studies

The Medpace global physicians are noted in their fields of specialty. Acromegaly is considered a rare or orphan disease, and successful conduct of clinical development studies in this field requires strong collaborative links with KOLs, established relationships with site investigators, and study design and execution. Our Medpace physicians can fulfill these roles.

Douglas Lee MB BCh, MRCP, MBA

Senior Medical Director

Dr. Lee is an experienced drug developer with about 20 years of experience in both clinical medicine and drug development, with therapeutic expertise in Endocrinology and Metabolic Disease. Prior to joining Medpace, Dr. Lee was the Global Senior Medical Director for a large pharmaceutical company where he designed, oversaw and executed global development plans involving early and late phase assets. In 2012 -13, he led a team that gained Marketing Authorization Approval (MAA) for 3 Endocrinology and Metabolic products, under the European Centralized Procedure. Dr. Lee received his Bachelor of Medicine, Bachelor of Surgery at the Queens University Medical School in the United Kingdom (UK) and achieved his Membership of the Royal College of Physicians in UK. He also earned his MBA from the Imperial College London in 2013.

Phillippa Miranda, MD

Senior Medical Director

Dr. Miranda received her M.D. from Duke University School of Medicine and completed her residency in Internal Medicine and her fellowship in Endocrinology at Duke. She served on the faculty in the Division of Endocrinology at Duke University Health System for five years prior to transitioning to industry. Dr. Miranda is board certified in Endocrinology, Diabetes, and Metabolism. Her therapeutic expertise covers a wide range of metabolic indications with significant medical monitoring experience in the areas of type 2 diabetes, type 1 diabetes, and obesity. Dr. Miranda has over seven years of experience conducting clinical research studies with a large CRO and is well versed in the conduct of Phase 2 and 3 studies in endocrinology.

About Medpace

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective. Headquartered in Cincinnati, Ohio, Medpace employs approximately 2,500 people across 35 countries.



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