

CENTRAL LABORATORIES

INDUSTRY LEADER IN CARDIOVASCULAR,
METABOLIC & LIPID DISEASES & DISORDERS

GLOBAL EXPERIENCE



NEW BIOMARKERS VALIDATED IN AN INDUSTRY
LEADING 10-12 WEEKS

INDICATIONS

CARDIOVASCULAR DISEASES	METABOLIC DISORDERS	LIPID DISORDERS
<ul style="list-style-type: none"> • Acute coronary syndromes • Arrhythmias • ASCVD • Dilated cardiomyopathy • Heart failure • Peripheral arterial disease • Stroke • Thromboembolic diseases 	<ul style="list-style-type: none"> • Acromegaly • Acute intermittent porphyria • Adrenal disorders • Cushing's syndrome • Diabetes mellitus type I • Diabetes mellitus type II • Electrolyte disturbances • Hereditary angioedema • Hypertension • NAFLD • NASH • Wilson's disease 	<ul style="list-style-type: none"> • Familial chylomicronemia syndrome • Heterozygous familial hypercholesterolemia • Homozygous familial hypercholesterolemia • Hyperlipoproteinemia (a) • Hypertriglyceridemia • Hypoalphalipoproteinemia • Lecithin cholesterol acyltransferase deficiency • Lipid storage diseases • Lipodystrophy • Lipoprotein lipase deficiency • Mixed dyslipidemia • Primary hypercholesterolemia

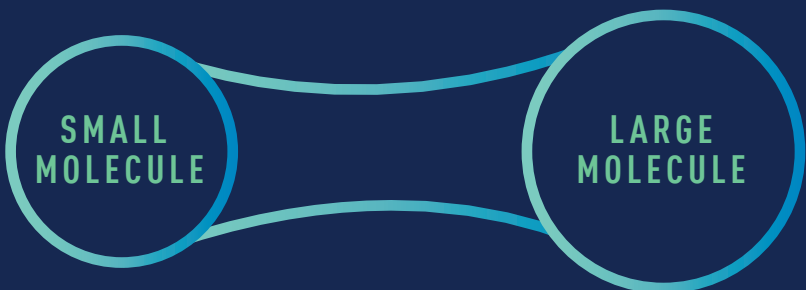
HIGHLIGHTS

FROM DISCOVERY AND PROOF OF CONCEPT THROUGH
LARGE, LONG TERM GLOBAL TRIALS

- Since 1985, Medpace central laboratory operations has been part of virtually every successful New Drug Application (NDA) involving lipid modifying therapies including, but not limited to, all “statins”, apo B antisense, and omega-3 agents.
- Provided efficacy analysis for two Proprotein convertase subtilisin/kexin type 9 (PCSK9) mAb inhibitors that supported acceptance of the FDA biologics license application (BLA), European & Global filing, and subsequent approvals by the FDA and EMEA.
- Supported Phase I – IV trials involving numerous lipid altering mechanisms including Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibition involving monoclonal antibodies, RNA interference, and fusion proteins, cholesterylester transfer protein (CETP) inhibition, Diacylglycerol Transferase (DGAT-1) inhibition, peroxisome proliferator-activated receptor (PPAR) agonism, omega-3 fatty acids, niacin analogs, and modifications of other biomarkers known to affect lipid metabolism such as Apo CIII and ANGPTL3 (angiopoietin-like 3).

BIOANALYTICAL LABS

PROVIDING ACCURATE, HIGH-QUALITY RESULTS IN A TIMELY, SECURE, AND COST-EFFECTIVE MANNER



- PK ASSAYS
 - CHIRAL MOLECULES
 - ICP-MS
 - GC-MS
 - METABOLITE ID
 - BIOMARKERS
- PK ASSAYS
 - ADA ASSAYS
 - NAB ASSAYS
 - ANA ASSAYS
 - PCR ASSAYS
 - FLOW CYTOMETRY
 - BIOMARKERS



- METHOD DEVELOPMENT, FEASIBILITY, AND VALIDATION
- PRE-CLINICAL AND CLINICAL SAMPLE ANALYSIS
- ANALYTICAL SUPPORT FOR
 - CLINICAL PK AND ADA STUDIES
 - NON-CLINICAL TK STUDIES
 - BIOEQUIVALENCE, BIOAVAILABILITY, DOSE ESCALATING STUDIES
- PHARMACODYNAMICS / BIOMARKER STUDIES

MEDPACE LABS STAND OUT

EXPERIENCED AND HIGHLY-TRAINED SCIENTISTS SUPPORTED BY EXPERT STAFF

WHAT'S THE DIFFERENCE?	ADVANTAGE
Experience with small and large molecule biomarkers	Diverse experience to expedite research
Expert leaders with years of experience	Anticipates problems and prepares solutions
Fully-integrated with Medpace CRO	Delivers efficient and streamlined execution with high quality results
Good Laboratory Practice (GLP) compliant	Ensures the highest quality testing and results
State-of-the-art equipment and instrumentation	Advanced knowledge of necessary instruments
Quality assurance present on site	Streamlines communication of all data
Local storage units with large capacity	Stores all study samples in one centralized location

MULTI-PHASE SUPPORT

A PARTNER THROUGHOUT DRUG DEVELOPMENT

