# **DEEP DIVE**

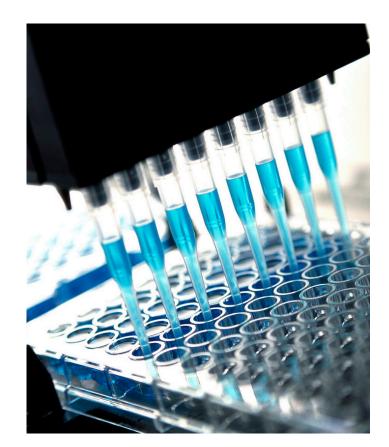
# MEDPACE

# SPOTLIGHT ON SCIENTIFIC LEADERSHIP IN CENTRAL LABORATORIES

In an increasingly complex clinical development environment, access to highly-qualified PhDs who can provide insights to formulate testing strategies are instrumental in delivering seamless and efficient service.

Medpace is known for putting scientific guidance at the forefront of client relationships. Our team of PhD scientists bring specialized knowledge in a variety of testing methodologies and therapeutic clinical development including:

- Biochemistry
- Bioinformatics
- Clinical assay development
- Clinical chemistry
- Coagulation
- ELISA
- Enzyme kinetic assays
- Flow cytometry
- Immunoassay systems
- Ligand binding assays
- Molecular oncology
- Nephelometry assays
- Next Gen Sequencing
- PCR, RTPCR
- Sanger Sequencing
- Toxicology
- Translational immunology
- Urinalysis
- Virology



With scientific expertise embedded in each study, we provide a tailored solution from start to finish in a way that isn't readily available elsewhere. We believe that the science of each study comes first, and these leaders help facilitate that philosophy.

# **GLOBAL LEADERSHIP**



Vice-President MRI

Operations & MARC



Chris Daniels, PhD Director, Clinical Laboratory Sciences





Evan Stein, MD, PhD

Director Emeritu:

Paul Thiam Joo Tan. PhD

Director, Clinica

Laboratory Services

Santica Marcovina, PhD, ScD FAHA Senior Director, Clinical Laboratory

# LAB LEADERSHIP

# Traci Turner, MD

Vice-President, MRL Operations & MARC

Dr. Traci Turner is board certified in internal medicine and brings 15 years' experience in central laboratory operations in drug development.

## **Experience Summary**

- Board-certified in Internal Medicine and is a Diplomate with the American Board of Clinical Lipidology
- Principal Investigator for over 50 clinical trials with lipid modifying therapies, encompassing Phase 1-3 trials
- Has overseen the successful completion of >250 lipid trials with multiple indications such as hypertriglyceridemia, dyslipidemia, non-FH and FH hypercholesterolemia, lipodystrophies, and FCS, including providing efficacy analyses for PCSK9 inhibitors that supported acceptance of FDA BLAs, European and global filings, and subsequent approvals
- Active member of the American Heart Association, National Lipid Association, and holds certification in Medical Technology from the American Society of Clinical Pathologists

#### **Education Summary**

- Doctor of Medicine, University of Cincinnati Cincinnati, OH
- Residency, Internal Medicine, University Hospital – Cincinnati, OH
- Bachelor of Science in Medical Technology, University of Cincinnati – Cincinnati, OH

# **Christopher Daniels, PhD**

Director, Clinical Laboratory Sciences, US

Dr. Daniels is a PhD scientist specialized in clinical chemistry, ligand binding assays, and biochemistry and brings six years of clinical research experience to Medpace.

#### **Experience Summary**

- Well-versed in clinical laboratory operations ensuring accurate, precise, and medically reliable data is being generated
- Experienced in CAP/CLIA, GCP, GCLP, and GLP regulatory environments
- Strong background in biomarker development in ligand binding assays
- Served as Principle Investigator in several pre-clinical studies
- Extensive experience in the molecular and cellular basis of heart failure
- Strong background in molecular cell signaling and targeted therapies for cardiovascular diseases
- Well-published in several peer-reviewed scientific journals and posters
- Member of the American Association for Clinical Chemistry

- Doctor of Philosophy in Biomedical Sciences, James H. Quillen College of Medicine – Johnson City, TN
- Bachelor of Science in Sociology and Health Sciences, East Tennessee State University – Johnson City, TN

# Paul Thiam Joo Tan, PhD

Director, Clinical Laboratory Services, Asia-Pac

Dr. Tan is an experienced PhD scientist specialized in next-generation sequencing in pathology and oncology in clinical research.

## **Experience Summary**

- 10+ years' experience in the direct research and development within a clinical laboratory
- Experienced in the direct management and operations of multi-country laboratories to ensure safe, cost-effective productivity and quality in all laboratory operations
- Previously served as laboratory director for laboratories in Singapore, Hong Kong, and Indonesia
- Pioneered and streamlined whole-genome sequencing workflow for the discovery of novel pathogens and infectious biomarkers using Roche 454 Junior Next Generation Sequencing platform
- Therapeutic area experience includes nextgeneration sequencing in pathology and oncology, genomics, immunology, blood stem cell banking, infectious diseases, and molecular diagnostics
- Well-published in several scientific journals and posters
- Member of the College of American Pathologists

## **Education Summary**

- Doctor of Philosophy in Bioinformatics, National University of Singapore Singapore
- Bachelor of Applied Science National University of Singapore – Singapore

# Santica M Marcovina, PhD, ScD, FAHA

Senior Director, Clinical Laboratory Sciences, US

Dr. Marcovina is a scientist with an international reputation for her research in Lipoprotein(a), production of monoclonal antibodies and assay development, lipoprotein and apolipoprotein method standardization and laboratory management.

#### **Experience Summary**

- 35+ years of experience in performing research in academic setting
- Principal Investigator for >60 NIH-funded, multi-center clinical studies primarily on diabetes, obesity, and diabetes complications both in youths and adults and Phase 1-3 trials
- Strong experience in assay standardization having been the chairman of the International Federation of Clinical Chemistry (IFCC) working group for the standardization of apo AI and apo B, member of the American Diabetes Association working group for the standardization of insulin, member of the NIDDK consortium for the standardization of GAD-65 and IA-2 autoantibodies, and director of one of the Center for Disease Control (CDC) reference laboratories for standardization of lipids
- Fellow American Heart Association, member of the American Diabetes Association, Clinical Chemistry Association, European Atherosclerosis Society, National Lipid Association, European Association for the Study of Diabetes
- Author of 550 papers published in peer-reviewed Journals, >150 of which on Lipoprotein(a)

- Doctor of Philosophy in Biological Sciences with major in Biochemistry of Proteins, University of Pavia – Pavia, Italy
- Doctor of Science in Sociology with major in Sociology of Communication, University of Urbino – Urbino, Italy
- Bachelor in Medical Technology, School for Medical Technologists, Ospedale Umberto I – Ancona, Italy

# **KOL LEADERSHIP**

# Evan Stein, MD, PhD

**Director Emeritus** 

Dr. Stein, a founder of Medpace's laboratories, is considered a foremost expert on the study of lipids.

- Founded and built Medical Research Laboratories in 1987
- Founded Medpace Labs in 2006 with the same experienced team
- Has been part of the central lab for virtually all lipid lowering agents approved and marketed since 1986
- Member of the NIH NCEP Lab Committee for methods and standardization of lab guidelines
- Advisor to the NIH NHLBI and CDC Lipid Standardization branch
- Served on FDA Clinical Chemistry and Clinical Toxicology Advisory Panel
- Consults with biopharma companies on the development programs for lipid-lowering drugs and participates in Scientific Advisory Boards

# MEET THE PhD TEAM



Serena Allen, PhD Senior Scientis





El Mustapha Bahassi, PhD Associate Director. Clinical Laboratory

Kritika Kachapati, PhD



Fary Diop, PhD Scientist



Eric Hugo, PhD Scientist



Andre Olsson, PhD Senior Scientis



Wenvi Qin, PhD John Robbins, PhD **Bioinformatics Scientist** Senior Scientist



Scientist



Victor Van Puvenbroeck, PhD Scientist



Ting Wen, PhD Senior Scientist



Rebecca Wilson, PhD Senior Scientist

# Serena Allen, PhD

Senior Scientist. US

Dr. Allen is a PhD senior scientist experienced in pharmacology and toxicology clinical research.

# **Experience Summary**

- Experienced in research and development with direct oversight of assay validation and implementation
- Specialized in development of in-house analytical chemistry methodologies
- Drove preclinical research projects to successfully characterize the in-vivo pharmacology and toxicology of synthetic drug compounds in animal models
- Member of the American Society for Pharmacology and Experimental Therapeutics and the American Chemical Society
- Well-published in several scientific journals and posters

- Doctor of Philosophy in Biomedical Sciences, East Tennessee State University -Johnson City, TN
- Master of Science in Medicinal and Biological Chemistry, University of Edinburgh – Edinburgh, United Kingdom
- Bachelor of Science in Pre-Medicine, the University of Tennessee at Chattanooga – Chattanooga, TN







# El Mustapha Bahassi, PhD

Associate Director, Clinical Laboratory, US

Dr. Bahassi brings 20 years of clinical laboratory research experience specialized in molecular oncology to Medpace.

#### **Experience Summary**

- 20 years of experience in the direct research and development within a clinical laboratory
- Served as Laboratory Director and Principal Investigator for ten years with the University of Cincinnati in both the department of Cancer Biology and department of Internal Medicine, division of hematology/oncology in Cincinnati, OH
- Developed a translational line of research where he worked closely with clinical oncologists to develop new companion diagnostics using cutting-edge genomic technologies
- Experienced in biomarker development in liquid biopsies using both circulating tumor cells and circulating tumor DNA
- Strong background in molecular cell signaling and targeted therapies for breast, lung and brain tumors
- Strong experience in immune-therapy modalities especially CAR-T based therapies
- Well-published in numerous peer-reviewed scientific journals and posters
- Member of several organizations including the American Association of Neurosurgeons and the American Association for Cancer Research

## **Education Summary**

- Doctor of Philosophy in Molecular Biology and Biotechnology
- Master of Science in Molecular Biology and Biotechnology

# Priscillia Bresler, PhD

Scientist, Belgium

Dr. Bresler is a PhD scientist with specialized experience in immunology and analytical assay development using flow cytometry.

## **Experience Summary**

- Well-versed in laboratory operations ensuring accurate, precise, and medically reliable data
- Experienced in the management of laboratory research and clinical development
- Extensive experience investigating neuroinflammation on microglial cells and hiPSC (human induced Pluripotent Stem Cells)
- Strong background investigating the role of microglial cells in neurodegenerative diseases at UCB Pharma in Braine-L'alleud, Belgium
- Specialized experience in mucosal immunology by studying the development and characteristics of innate lymphoid cells at the Necker-Enfants Malades Institute in Paris, France
- Previously studied the inhibitory activity of patient's neutrophils in response to Aspergillus Fungus at Pitié-Salpêtrière University Hospital in Paris, France
- Well-published in several scientific journals and posters
- Holds a Master of Animal Experimentation certificate

- Doctor of Philosophy in Immunology, Paris Descartes University – Paris, France
- Master of Science in Technologies and Health, Pierre et Marie Curie University – Paris, France
- Master of Science in Molecular & Cellular Biology, Pierre et Marie Curie University – Paris, France
- Master of Science in Cancerology, Paris-Sud XI University – Paris, France
- Bachelor of Science in Cellular Biology & Physiology, University of Sherbrooke – Quebec, Canada

# Fary Diop, PhD

Scientist, Belgium

Dr. Diop is a PhD scientist with specialized experience in hematology and clinical research.

# **Experience Summary**

- Well-versed in laboratory operations ensuring accurate, precise, and medically reliable data
- Extensive experience researching activities on hematological diseases through a next-generation sequencing approach
- Previous experience with diagnostic activities on hematological diseases using molecular biology techniques
- Well-published in several scientific journals and posters

# **Education Summary**

- Doctor of Philosophy in Science and Medical Biotechnologies, University of Eastern Piedmont – Novara, Italy
- Master of Science in Medical Biotechnologies, University of Eastern Piedmont – Novara, Italy
- Bachelor of Science in Biological Sciences, University of Eastern Piedmont – Alessandria, Italy



# Eric Hugo, PhD

#### Scientist, US

Dr. Hugo is a PhD scientist with over 20 years specialized experience in adipocyte and cancer biology clinical research and leadership roles in academia.

# **Experience Summary**

- Expertise in multiple scientific areas including cell and molecular biology, with in-depth knowledge of cancer biology
- Participated in drug discovery using high throughput screening with in-house developed bioassays
- Developed immunohistochemical procedures for identifying new tumor biomarkers in breast and head and neck cancers
- Extensive knowledge of adipocyte biology including human cell line creation
- Skilled with CRISPR-based genomic editing and recombinant lentivirus design and production
- Extensively published in multiple scientific journals and posters
- Over 15 years' experience as a grant reviewer for NIH, GACR, and ANR
- Postdoctoral training in protein biophysics at Washington University School of Medicine
- Postdoctoral training in endocrinology, metabolism and cancer biology at the University of Cincinnati College of Medicine
- Member of the American Society of Biochemistry and Molecular Biology

- Doctor of Philosophy in Molecular Genetics, The Ohio State University – Columbus, OH
- Master of Science in Microbiology, The Ohio State University Columbus, OH
- Bachelor of Science in Biology, Northern Kentucky University – Highland Heights, KY



# Kritika Kachapati, PhD

Scientist, US

Dr. Kachapati is a PhD scientist with specialized experience in immunology and clinical research.

# **Experience Summary**

- Well-versed in laboratory operations ensuring accurate, precise, and medically reliable data
- Experienced in the management of laboratory research and clinical development
- Previously conducted research on the role of soluble CD137 producing T regulatory cells mediated diabetes suppression at The University of Cincinnati in Cincinnati, OH
- Well-published in several scientific journals and posters

## **Education Summary**

- Post-Doctorate Degree in Immunology, University of Cincinnati – Cincinnati, OH
- Doctor of Philosophy in Immunology, University of Pittsburgh Pittsburgh, PA
- Bachelor of Science in Biology, Hood College Frederick, MD

#### Mauricio Macossay Castillo, PhD Scientist, Belgium

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Dr. Macossay Castillo is a PhD scientist with experience in fundamental research, as well as in the hospital clinical laboratory and clinical research.

# **Experience Summary**

- Experienced in the study of the relationship between protein structure and function through bioinformatics approaches
- Well-versed in several areas of the hospital clinical laboratory, such as hematology, coagulation, microscopy, clinical chemistry, urinalysis, immunoassay, nucleic acid extraction, viral load, and T-cell count
- Participated in the development of a molecular test for the detection of viremia and genotyping of the hepatitis C virus
- Well-published in several scientific journals and posters

- Doctor of Philosophy in Bioengineering Sciences, Vrije Universiteit Brussel – Brussels, Belgium
- Master of Science in Molecular Biology, Vrije Universiteit Brussel – Brussels, Belgium
- Bachelor's Degree in Pharmacy, Chemistry and Biology, Universidad Autonoma de Yucatan – Merida, Mexico

# Nazanin Navabi, PhD

Scientist, US

Dr. Navabi is a PhD scientist with specialized experience in gastroenterology, immunobiology, and clinical research.

# **Experience Summary**

- Well-versed in laboratory operations ensuring accurate, precise, and medically reliable data
- Extensive experience in the management of laboratory research and clinical development
- Previously studied the interaction between host-pathogens in gastrointestinal tract in the Department of Gastroenterology at Cincinnati Children's Hospital Medical Center
- Completed a three-year clinical research fellowship program in the Department of Immunobiology at the Cincinnati Children's Hospital Medical Center
- Well-published in numerous peer-reviewed scientific journals and several poster and oral presentations in international conferences in her field

# **Education Summary**

- Doctor of Philosophy in Medicine, Gothenburg University – Gothenburg, Sweden
- Master of Science in Biology, Gothenburg University – Gothenburg, Sweden
- Bachelor of Science in Applied Chemistry, University of Mazandaran – Babolsar, Iran

# Andre Olsson, PhD

Senior Scientist, US

Dr. Olsson is an experienced PhD senior scientist specialized in experimental hematology as well as immunobiology.

# **Experience Summary**

- Extensive experience in multiple scientific areas including cell and molecular biology with focus on myeloid cell fate
- Well versed in developing multiparametric flow cytometry assays for detection of hematopoietic cell populations
- Previously combined flow cytometry sorting with single cell RNA-seq and single cell ATAC seq for novel discovery of cell lineage decisions
- Well-published in top tier scientific journals and have made several poster and oral presentations at international meetings in his field

# **Education Summary**

- Doctor of Philosophy in Experimental Hematology, Lund University – Lund, Sweden
- Master of Science in Molecular Biology, Lund University – Lund, Sweden

# Wenyi Qin, PhD

**Bioinformatics Scientist, US** 

Dr. Qin is a PhD scientist with specialized experienced in bioinformatics and clinical research.

## **Experience Summary**

- Well-versed in the analyzation of experimental data produced by next-generation sequencing
- Developed novel data integration statistical framework in identifying disease-related genes and pathways
- Well-published in several scientific journals and posters
- Previous experience with the Yale University School of Medicine as a Postdoctoral Research Associate, Department of Genetics

- Doctor of Philosophy in Bioinformatics, the University of Illinois at Chicago – Chicago, IL
- Bachelor of Science in Biological Science, Fudan University – Shanghai, China

# John Robbins, PhD

Senior Scientist, US

Dr. Robbins is an experienced PhD scientist specialized in clinical assay development, enzyme kinetics, protein dynamics, molecular biology, ELISA, hematology, coagulation, and urinalysis.

## **Experience Summary**

- Extensive experience in the research and development of assay validation and implementation
- Previously conducted research aimed at the development of novel biocatalysts by complementing data-driven protein engineering processes with traditional mechanistic and kinetic enzymology techniques and analyses
- Extensively published in multiple scientific journals and posters
- Registered Agent with the United States Patent and Trademark Office
- Member of the American Chemical Society, American Society of Biochemistry and Molecular Biology, and National Association for Patent Practitioners

# **Education Summary**

- Doctor of Philosophy in Biochemistry, Auburn University – Auburn, AL
- Bachelor of Science in Chemistry, Hampden-Sydney College – Hampden-Sydney, VA



# Victor Van Puyenbroeck, PhD

Scientist, Belgium

Dr. Van Puyenbroeck is an experienced PhD scientist specialized in virology and chemotherapy clinical research.

## **Experience Summary**

- Well-versed in laboratory operations to verify that accurate, precise, and medically reliable data are being generated
- Experienced in conducting DNA vaccine method development and validation, upscaling throughput of antiviral drug screening methods
- Previously worked at KU Leuven in the Translational Research Laboratory for Virology and Chemotherapy
- Well-published in several scientific journals and posters

- Doctor of Philosophy in Biomedical Sciences, KU Leuven – Leuven, Belgium
- Master of Science in Bioscience Engineering/ Cell and Gene Technology, KU Leuven – Leuven, Belgium

## Ting Wen, MD PhD

Senior Scientist, US

Dr. Wen integrates his 20 years of basic and translational research experience, as well as his MD training, into the practice in clinical labs at Medpace.

#### **Experience Summary**

- Extensive experience in translational research in top US institutions, performing immunological studies with both rodent models and human disease samples
- Served as a Principal Investigator for 6 years in Division of Allergy and Immunology with several federally funded projects
- Developed the very first molecular diagnostic panel (96 genes) for human allergic disorders and invented the innovative algorithm for low density qPCR array results interpretation with patents granted in the US and EU
- Strong backgrounds in NGS pipeline and subsequent bioassay validation for candidate genes, being the first in the field to define tissue residing pathogenic T cells by FACS and single cell RNA sequencing
- Demonstrated experience in Flow Cytometry for innovative human disease diagnosis and novel murine leukocyte adoptive transfer
- Robust publication records with 47 NCBI publications in decent journals in a decade, plus 3 renowned book chapters

## **Education Summary**

- Doctor of Philosophy in Cell Biology and Neuroscience, Rutgers University – New Brunswick, NJ
- MD training in Clinical Medicine, Capital Medical University – Beijing, China

# Rebecca Wilson, PhD

Senior Scientist, US

Dr. Wilson is an experienced PhD scientist specialized in immunology and nephelometry assays in clinical research.

#### **Experience Summary**

- Extensive experience in the research and development of validated assays in cGMP environment
- Well-versed in the design and formulation of pharmaceutical and cosmetic products for clinical application
- Experienced in several types of analytical chemistry techniques as well as molecular assays, including Polymerase Chain Reaction (PCR), cloning, and protein purification
- Well-published in several scientific journals and posters
- Member of the American Chemistry Society

- Doctor of Philosophy in Biomedical Sciences, East Tennessee State University – Johnson City, TN
- Bachelor of Science in Biological Sciences, University of Cincinnati – Cincinnati, OH

# **GLOBAL CENTRAL LABORATORIES**

Medpace provides customized, high-quality central laboratory services to pharmaceutical and biotech clinical development industries. Our four whollyowned laboratories offer full-service support to six continents for phase I-IV studies in a wide range of complexity and scale. Our standardized testing platforms, comprehensive test menu, scientific leadership, and stellar project management teams allow Medpace to set up fully customized projects for our clients.

#### **Central Laboratories Highlights:**

- Serving some of the world's largest, most complex clinical trials
- Extensive capacity and global scalability in state-of-the-art facilities
- Fully-harmonized, high throughput instrumentation delivering high quality data
- On-time data transfers
- Biomarker development, validation and PD analysis
- Industry-leading quick validation timelines
- Web-based data portal ClinTrak<sup>®</sup> Lab provides seamless data management delivered in a single integrated global database



# **SUPPORTING CLINICAL TRIALS IN 70+ COUNTRIES**

MAKING THE COMPLEX

SEAMLESS<sup>®</sup>



# FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization 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.

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