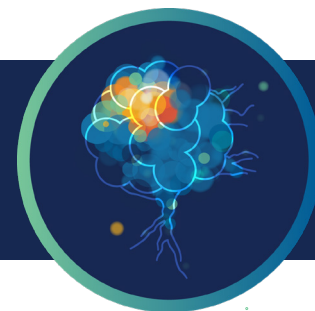


# A DEEPER DIVE INTO HEMATOLOGY AND ONCOLOGY



## AN INTEGRATED ADVANTAGE

With our proven full-service outsourcing model, Medpace delivers high-quality results. In the competitive field of hematology and oncology, we have earned a reputation for taking on some of the most complex and challenging cancer research studies.

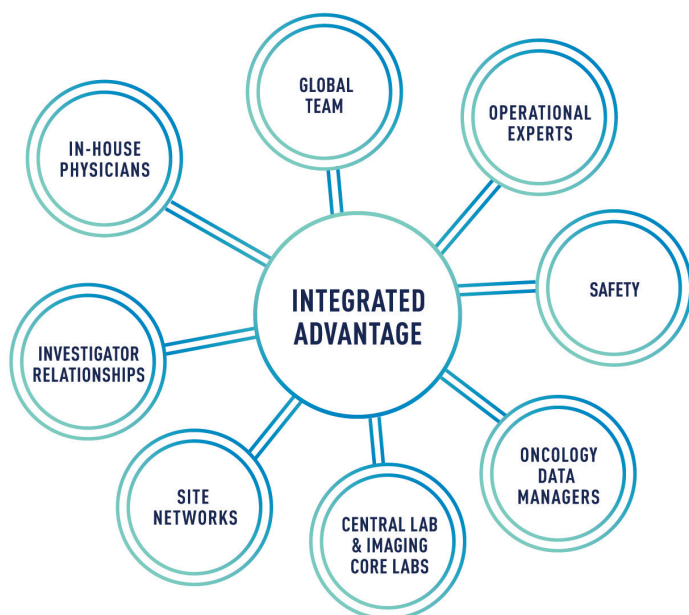
- Led by medical, operational, and regulatory experts experienced in hematology and oncology
- Integrated experts from Medpace business units including tumor imaging and central laboratory
- Deep hematology and oncology experience having managed Phase I-IV trials around the globe
- Preferred provider relationships with key sites expedites site start-up, enhances recruitment and maximizes trial efficiency
- Skilled in drug, device, and combination products

Medpace supports Sponsors who are advancing new anti-cancer therapies by providing specialized expertise in the design and management of clinical research. Our Sponsors gain a competitive edge with our integrated full-service approach in the ever-evolving landscape of drug and biologic clinical development.

## EXPERT INSIGHT

Our highly experienced medical, regulatory, and operational experts work collaboratively to execute clinical trials. We understand issues from the perspective of Sponsors, clinical investigators, scientific leaders, and the reviewers at regulatory agencies. With this insight, we can successfully define and execute clear development plans for drug, device and combination products from beginning to end.

***Medpace has the medical expertise, global experience, central labs, imaging labs and site relationships to complete successful studies for Sponsors.***



## EXPERIENCE

The Medpace hematology/oncology team has extensive clinical and research experience across a full range of solid tumor and hematologic indications and therapies from classic multi-cytotoxic agents to cutting-edge and targeted therapies. We have managed small, focused trials as well as large global studies.

### **Solid Tumor Including:**

- Brain
- Breast
- Gastrointestinal including colorectal and non-colorectal
- Genitourinary including prostate, renal and bladder cancers
- Gynecologic
- Head and neck
- Lung
- Skin including melanoma

### **Malignant Hematology Including:**

- Leukemia
- Lymphoma
- Myeloma

### **Non-Malignant Hematology**

### **Specialty Area Include:**

- Pediatric hematology/oncology
- Pediatric and adult hematopoietic stem cell transplantation
- Women's health and malignancies
- Regenerative medicine and cellular therapies
- Immunotherapies
- Gene therapies
- Precision medicine
- Adaptive study design
- Rare disease and orphan indications
- Medical device and combination products
- Diagnostics



*With our unique approach to clinical research, we have earned a reputation for taking on some of the most complex and challenging cancer research studies.*



## SCIENTIFIC-DRIVEN DEVELOPMENT

Medpace is unique in its scientifically-driven approach to clinical research. The Medpace model gives Sponsors the advantage of early and ongoing insight and guidance from therapeutic experts throughout the trial design and execution. Our highly experienced medical doctors provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. They are embedded throughout your studies, providing greater depth and the ability to tackle complex and challenging diseases.



**Lyon Gleich, MD, FACS**  
Senior Vice President, Medical Department



**Franklin O. Smith, III, MD, FAAP, FACP**  
Senior Vice President, Medical Department



**Blythe Thomson, MD**  
Senior Vice President, Medical Department



**Ann Woolfrey, MD**  
Vice President, Medical Department



**Cesar Casimiro, MD**  
Senior Medical Director



**Gaston Demonty, MD**  
Senior Medical Director



**Kiyoshi Hashigami, MD**  
Senior Medical Director



**Mariko DeWire-Schottmiller, MD**  
Senior Medical Director



**James Fan, MD, MBBS**  
Senior Medical Director



**Jamal Gasm, MD, PhD**  
Senior Medical Director



**Jess Guarnaschelli, MD**  
Senior Medical Director



**Gregory Hale, MD, FAACP**  
Senior Medical Director



**Agnes Slater, MBBS, PhD**  
Senior Medical Director



**Karine Cadren, MD**  
Medical Director



**Amanda Goldrick, MD**  
Medical Director



**Francis LeBlanc, MD, PhD**  
Medical Director



**Beata Paluchowska, MD, PhD**  
Medical Director



**Morihiro Watanabe, MD, PhD**  
Medical Director

## ADVANCED CLINICAL PRACTITIONERS ADD A PATIENT'S PERSPECTIVE

Our medical directors are supported by a team of experienced ACPs whose unique perspective brings added value to the clinical development team. These highly-trained experts with advanced degrees and hands-on clinical experience provide an additional layer of knowledge and insights that can streamline your studies and address potential challenges early in the study planning. ACPs are embedded in the teams to ensure your study is feasible and operationalized for efficient execution by looking at the protocol through the lens of the patient and site staff. ACPs also help with the review of safety events, ongoing team education, recruitment strategies, and study document review. Their understanding of what works in a clinical setting makes them a valuable part of our embedded medical expertise model.



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## IN-HOUSE PEDIATRICIAN BIOGRAPHIES

### **Lyon Gleich, MD, FACS**

*Senior Vice President, Medical Department*

- Leading Medpace Oncology team since 2004 and experience as an oncology Investigator
- Extensive oncology clinical trial experience including immuno-oncology and new drug development, targeted therapies, biologic therapy development, multi-cytotoxic agent studies, and AE coordination
- Recognized expert in new molecular therapeutics, cancer gene therapy, and cancer immunotherapy
- Active in multiple societal memberships, including the American Society of Hematology and ASCO
- Based in Cincinnati, OH

### **Franklin O. Smith, III, MD, FAAP, FACP**

*Senior Vice President, Medical Department*

- 38 years of experience in clinical, translational, and basic research
- PI on hematology, oncology, hematopoietic cell transplantation, and gene therapy clinical trials
- Senior leadership: Adult and pediatric hematology/oncology/HCT programs, cancer centers, cooperative cancer groups, FACT, FACT Consulting, Leukemia and Lymphoma Society
- Senior Vice President of the Medical Department with leadership specifically focused on Medpace's hematology studies
- 180 medical and scientific publications, book chapters and books
- Professor of Medicine and Pediatrics, University of Cincinnati
- Based in Cincinnati, OH

### **Blythe Thomson, MD**

*Senior Vice President, Medical Department*

- +25 years' experience in hematology/oncology clinical trials and +9 years in biotech/CRO
- Board certified pediatric hematologist/oncologist, fellowship at UW/Fred Hutchinson Cancer Research and former Clin. Prof at Seattle Children's, Outpatient Oncology Director, Pediatric Apheresis Director and Leukemia Investigator
- Medical director including medical component of global oncology and malignant hematology programs (pediatric and adult) in biotech company and CRO

### **Ann Woolfrey, MD**

*Vice President, Medical Department*

- +25 years' experience in translational & clinical research in hematologic malignancies and hematopoietic cell transplant at Fred Hutchinson Cancer Research Center (FHCRC), University of Washington, and Yale University
- Board certified in Internal Medicine & Pediatric Hematology/Oncology
- Emeritus full professor, Clinical Research Division, FHCRC/UW
- Past PI of numerous clinical trials focused on treatment of malignant & nonmalignant diseases including trials of cell and gene therapies
- >150 medical & scientific publications





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## **Gaston Demonty, MD**

*Senior Medical Director*

- Medical Oncologist trained in Argentina
- +20 years of clinical research experience in Europe
- +15 years of pharmaceutical industry experience at international level, both R&D and Medical Affairs
- Based in Leuven, Belgium

## **Kiyoshi Hashigami, MD**

*Senior Medical Director*

- US-trained physician with +15 years of clinical and research experience
- Prior leader in clinical development for major pharmaceutical
- Based in Tokyo, Japan

## **Mariko DeWire-Schottmiller, MD**

*Senior Medical Director*

- +10 years' experience in oncology clinical trial development and management with a focus on neuro-oncology
- Former faculty at Cincinnati Children's Hospital Medical Center, Cancer and Blood Disease Institute, in Cincinnati, OH
- Numerous publications in peer-reviewed medical and scientific journals
- Held leadership roles in The International DIPG/DMG Registry, Pediatric Brain Tumor Consortium (Investigator and Medical Monitor), and the Children's Oncology Group

## **James Fan, MD**

*Senior Medical Director*

- Trained in medical university hospital as a certified physician of internal medicine for 11 years
- +23 years of clinical research experience in CRO and Biotech companies in Singapore, Taiwan, and Shanghai
- Based in Shanghai

## **Jamal Gasmi, MD, PhD**

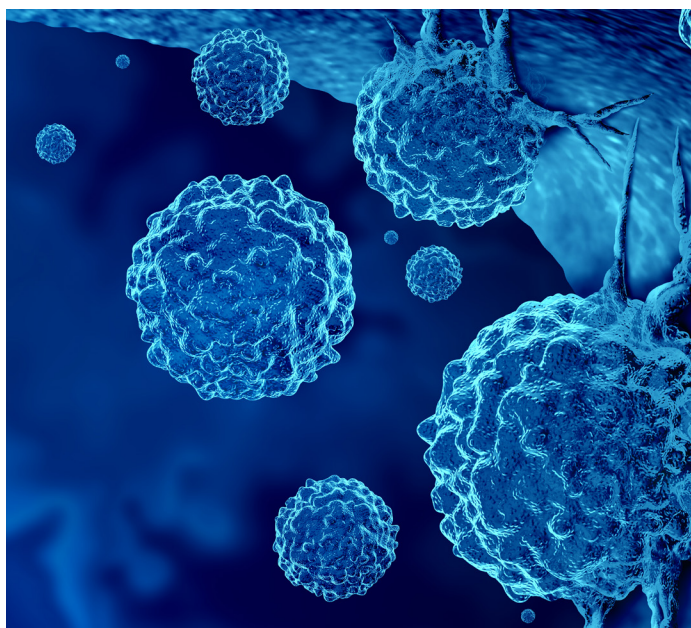
*Senior Medical Director*

- Board certified medical oncologist with 27 years' experience in clinical development in oncology and hematology
- Medical Monitor for oncology Phase I/II trials with various IMP including immuno-oncology compounds and radiopharmaceuticals
- Held global medical leadership positions at numerous biopharmaceutical companies including Chief Medical Officer and Head of Regulatory Affairs
- Deputy Head and Investigator at oncology and hematology academic centers
- Active member of ASCO, ASH, AACR, and ESMO
- Based in France

## **Jess N. Guarnaschelli, MD**

*Senior Medical Director*

- Board Certified through American Board of Radiology in Radiation Physics, Radiation Biology, and Radiation Oncology
- Senior Director, MM, and Investigator in Phase I-III trials including oncology, radiopharmaceuticals, and radiation oncology
- 20 years of experience in radiation oncology and multidisciplinary research teams
- Medical Scientific Head of Medpace Radiopharmaceutical Leadership Forum
- Office based in Cincinnati, OH



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## **Gregory Hale, MD, FAAP**

*Senior Medical Director*

- +27 years' experience in translational and clinical research
- Academic Investigator with focus on hematologic malignancies, cell, and gene therapy
- Authored more than 210 manuscripts and chapters
- Board certified in General Pediatrics and Pediatric Hematology/Oncology
- Former Children's Oncology Group (COG) PI and national committee member
- Former PI in Therapeutic Advances in Childhood Leukemia Lymphoma (TACL)
- Leadership positions in NMDP, FACT, AAP, CIBMTR and NCI Cancer Centers
- Invited expert, NCI PDQ Pediatric AML guidance and FDA cell and gene therapy committee

## **Agnes Slater, MBBS, PhD**

*Senior Medical Director*

- +20 years of clinical and research experience in immuno-oncology, targeted, advanced and combination therapies in solid tumors and hematologic malignancies
- Extensive experience in medical monitoring and pharmacovigilance surveillance through the Asia-Pacific region for Phase I-IV global clinical trials
- Active member of ASCO, ESMO
- Based in Singapore

## **Karine Cadren, MD**

*Medical Director*

- Board certified onco-hematologist
- 6 years clinical experience – private and public practice
- Experience in pharma industry as medical science liaison/ medical advisor in hematology
- 5 years' experience in clinical research focused on oncology and hematology
- Based in Barcelona, Spain

## **Amanda Goldrick, MD**

*Medical Director*

- +25 years of clinical experience as medical oncology and palliative medicine physician
- +10 years research experience developing hematology-oncology products
- Phase 1-3 clinical trial experience
- Based in Sydney, Australia

## **Francis LeBlanc, MD, PhD**

*Medical Director*

- Pediatric Hematologist/Oncologist and PhD in Molecular Medicine
- Multiple publications in peer-reviewed high-impact medical and scientific journals
- +5 years experience in clinical and translational research
- Based in Cincinnati, OH

## **Beata Paluchowskak, MD, PhD**

*Medical Director*

- Board certified Medical Oncologist with +15 years of experience as Medical Monitor and 10 years of clinical experience treating adults with solid tumors and hematological malignancies
- Medical Monitor experience with Phase I-III oncology trials
- Based in Warsaw, Poland

## **Morihiro Watanabe, MD, PhD**

*Medical Director*

- Experienced oncologist with +25 years clinical trial experience
- Prior leader of clinical development in Japan for major pharmaceutical
- Based in Tokyo, Japan

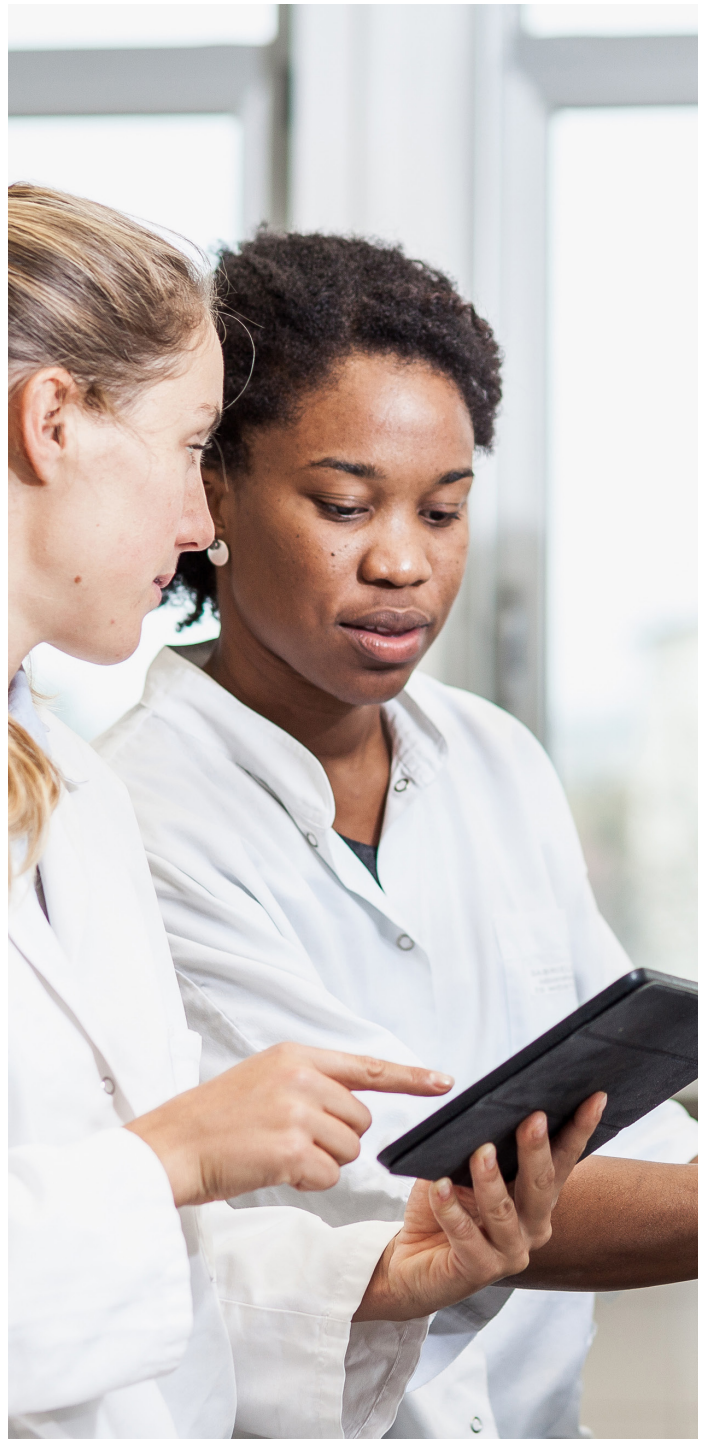


## DRIVING EFFICIENT AND CONSISTENT DATA FOR GLOBAL STUDIES

Achieve quality results, meet deadlines, and maximize efficiencies by partnering with a CRO that excels in execution. Medpace demonstrates a commitment to quality and a dedication to conducting full-service studies in an exacting manner to produce the highest quality results.

### KEYS TO SUCCESSFUL EXECUTION

- **Committed Teams:** With turnover rates that are lower than the industry standard, our team is with you from project initiation to completion. As a result, we typically develop better team dynamics based on trust and respect
- **Resourcefulness:** Medpace promotes a culture of problem-solving. Our global operational staff proactively identify potential issues and communicate solutions, ensuring your sites and studies are managed effectively and efficiently
- **Site and KOL relationships:** Due to Medpace's hematology and oncology experience and relationships with Investigators and opinion leaders worldwide, we can select the best sites for your specific program. This provides an advantage in meeting your recruitment timelines with high quality data. Medpace has received multiple awards recognizing Medpace as a leading global CRO, particularly noting the excellence and training of our CRAs
- **Regulatory Support:** Medpace offers a dedicated global regulatory submissions team as well as global regulatory affairs for comprehensive support



## Hematology/Oncology Lab Support:

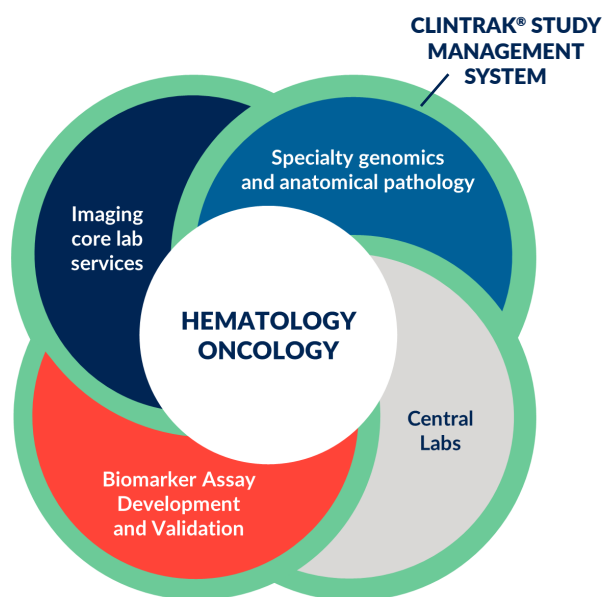
Medpace offers comprehensive and fully-integrated laboratory services including global central labs and an imaging core lab. The built-in collaboration and efficiencies of working with a single vendor facilitates a streamlined strategy for executing complex global studies.

### Central Lab

- PK/PD analysis
- Biomarker development
- Flow Cytometry
- Specialty genomics and anatomical pathology

### Imaging Core Lab

- Modalities
- Response Criteria including Sample Specialties



## CLINTRAK® STUDY MANAGEMENT TECHNOLOGY

Medpace offers an innovative suite of proprietary, leading edge technology with ClinTrak® Clinical Suite. The ClinTrak Lab component is a full-scale Laboratory Information Management System (LIMS) that provides access to: daily lab reports, management information, cumulative results and trend graphing, secure role-based access, and study specific project management pages.

The ClinTrak Imaging component integrates image tracking, quantitative and qualitative analysis, and data management to store and manage data from all imaging and reading centers. Integrated clinical trial services deliver efficient and streamlined execution.

## 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.

**WE CAN'T SIMPLIFY  
CLINICAL DEVELOPMENT –  
BUT WE CAN EXECUTE  
IT SEAMLESSLY.**

HO-0002-R0824

MAKING THE COMPLEX  
**SEAMLESS®**

