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.
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**
- 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.*
Nurse Practitioners Add a Patient’s Perspective

Our medical directors are supported by a team of experienced nurse practitioners 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. Nurse practitioners 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. Nurse practitioners 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.
Cesar Casimiro, MD  
**Medical Director, Hematology & Oncology**

Dr. Casimiro is a board certified medical oncologist bringing more than 20 years of professional medical experience in clinical trials to the Medpace team.

**Experience Summary**
- 20+ years of global experience in managing the design, supervision, and development of clinical trials across all phases
- Managed oncology development programs for numerous drug indications
- Medical Director in Clinical Research at global CROs and big pharma companies.
- Member of the Spanish Society on Medical Oncology (Sociedad Española de Oncología Médica (SEOM)).
- Key opinion leader and extensively published in the peer-reviewed medical and scientific literature

**Education Summary**
- Medical Degree, Faculty of Medicine at the Complutense University of Madrid
- Specialist in Medical Oncology, Conception Clinic, Jimenez Diaz Foundation, Autonomous University of Madrid
- Master in AIDS, Carlos III Health Institute, Complutense University of Madrid
- Master in Clinical Nutrition, Autonomous University of Madrid
- Post Grad Diploma in Medical Oncology University of Girona /Spanish Society of Medical Oncology
- Residency in Medical Oncology, Conception Clinic, Jimenez Diaz Foundation

Jamal Gasmi, MD, PhD  
**Senior Medical Director, Hematology and Oncology**

Dr. Jamal Gasmi is board certified in hematology and oncology, immunology, and internal medicine. He brings over 20 years’ experience in drug development in academia, biopharma and Clinical Research Organizations.

**Experience Summary**
- Extensive expertise in producing and implementing strategic clinical development plans
- Directed oncology development programs that led to approval of various anti-cancer agents
- Vice President and global leader for hematology and oncology at a global CRO
- Held global medical leadership positions at numerous biopharmaceutical companies including Chief Medical Officer and Head of Regulatory Affairs
- Deputy Head and Investigator at hematology and oncology academic centers

**Education Summary**
- Doctor of Medicine, Oncology, University Rene Descartes, Paris V
- European Board of Medical Oncology, London
- Doctor of Philosophy, Immunology, University Pierre et Marie Curie, Paris VI
- Master of Pharmacology, University Lariboisiere, Paris
- Master of Statistics and Trial Design, University Paris IX

Lyon Gleich, FACS  
**Vice President, Medical Department, Hematology and Oncology**

Dr. Lyon Gleich is board certified in otolaryngology and has provided medical leadership over Medpace’s oncology division for more than 12 years.

**Experience Summary**
- Extensive expertise in new drug development, biologic therapy development, gene therapy development, and multi-cytotoxic agent studies
- Previously: Professor, Department of Otolaryngology at the University of Cincinnati; Associate Professor, Department of Otolaryngology – Head and Neck Surgery; Director of Resident Research, Department of Otolaryngology
- Active ASCO and ASH member
- Key opinion leader with numerous publications in the field of hematology and oncology

**Education Summary**
- Doctor of Medicine, Summa Cum Laude, State University of New York, Health Science Center, College of Medicine
- Fellowship, Oncology, University of Cincinnati
- Bachelor of Arts, Summa Cum Laude, Brooklyn College
Jess N. Guarnaschelli, MD  
**Medical Director, Hematology and Oncology**

Dr. Guarnaschelli is board-certified in radiation oncology and brings more than 15 years of experience in clinical research, academia, and clinical oncology practice to the Medpace team.

**Experience Summary**
- Well-versed in the design and conduct of clinical trials having worked with many devices and drug indications.
- Extensive involvement in trials of women’s oncologic disease including breast, endometrial, cervical, and ovarian carcinoma.
- Clinical background includes chemotherapeutics, immuno-oncology, and solid tumors.
- Awarded 40 under 40 award for young leaders and innovators.
- Awarded Top Doctor award.
- Active member in multiple oncologic societies revolving around radiation oncology and medical oncology including ASCO, SITC, and the ASTRO.
- Well-published in the peer-reviewed medical and scientific literature.
- Peer reviewer for multiple oncology journals.
- Exam writer for American Board of Radiology, Radiation Oncology.

**Education Summary**
- Doctor of Medicine, University of Louisville School of Medicine - Louisville, KY.
- Bachelor of Arts, Biological Sciences, Brown University - Providence, RI.
- Internship, General Surgery, Indiana University, Indianapolis, IN.
- Residency, Radiation Oncology, University of Louisville School of Medicine - Louisville, KY.
- Chief Resident, Radiation Oncology, University of Louisville School of Medicine - Louisville, KY.

Gregory Hale, MD, FAAP  
**Senior Medical Director, Hematology and Oncology**

Dr. Gregory Hale is a board-certified pediatric hematologist-oncologist with over 24 years of clinical trial experience in bone marrow transplantation, cellular and gene therapies, and hematologic malignancies.

**Experience Summary**
- Held a variety of director level roles at nationally recognized academic institutions where he served as a principal investigator or co-investigator for pilot, phase 1, phase 2, and phase 3 clinical trials.
- Investigator experience in trials involving benign hematology, vaccines, immunotherapy, chemotherapy, cellular and gene therapies, hematopoietic cell transplantation in pediatrics, adolescents and adults.
- Leadership roles in Center for International Blood and Marrow Transplant Research (CIBMTR), National Marrow Donor Program (NMDP), Foundation for the Accreditation of Cellular Therapy (FACT), and American Academy of Pediatrics (AAP).
- Thought leader with more than 200 peer-reviewed manuscripts, book chapters, and review articles.
- Previously Professor of Oncology and Pediatrics at Johns Hopkins University School of Medicine and Medical Director, Pediatric Hematology Oncology, Johns Hopkins All Children’s Hospital.
- Previously Clinical Director, Division of Blood and Marrow Transplantation, and Medical Director, Transplant and Gene Therapy Clinical Research Office, St. Jude Children’s Research Hospital.
- Board certified in General Pediatrics and Pediatric Hematology/Oncology.
- Active member of ASH, ASCO, ASBMT, AAP, ISCT, ASGCT, ACRP, DIA.

**Education Summary**
- Doctor of Medicine, Summa Cum Laude, Joan C. Edwards School of Medicine at Marshall University.
- Residency in Pediatrics, Children’s Hospital of Pittsburgh of UPMC.
- Fellowship, Pediatric Hematology/Oncology, St. Jude Children’s Research Hospital.
Glynis Neagle, MD
Vice President, Medical Department, Hematology and Oncology

Dr. Glynis Neagle is an oncology specialist who brings more than 20 years of clinical trial and drug development experience to the Medpace medical team.

Experience Summary
- Held senior level positions including Chief Medical Officer in medical affairs and clinical drug development for both pharmaceutical companies and Clinical Research Organizations
- Experience includes NCEs, Vaccines, Biological and Immunological therapeutics and ranges from small single center Phase 1 studies to multi-center Phase II and pivotal phase III global trials
- Drug development experience in oncology, metabolic/endocrine and immunology
- Extensively participated in a variety of scientific advisory boards, chaired international meetings, and provided crucial expert opinion on global drug development strategy
- European QPPV providing oversight of European Pharmacovigilance regulatory requirements
- Affiliated with the Royal Society of Medicine and Faculty of Pharmaceutical Medicine
- Member of ASMO and ESMO

Education Summary
- Bachelor of Science, Biochemistry and Immunology, University of Glasgow
- Doctor of Medicine, University of Glasgow
- GMC registered with a license to practice medicine

Petr Seidl, MBA, MD
Senior Medical Director, Hematology and Oncology

Dr. Seidl is board certified in urology and brings over 20 years of biopharmaceutical and CRO clinical research experience to Medpace’s medical leadership team.

Experience Summary
- Extensive oncologic background working in solid tumors (prostate cancer, bladder cancer, renal cancer, breast cancer, ovarian cancer, lung cancer), hematology-oncology (leukemias, lymphomas) and rare diseases (Fabry, Gaucher, Pompe)
- Clinical research experience working with various technology platforms including small molecules, therapeutic proteins, monoclonal antibodies, antibody-drug conjugates, antisense drugs and advanced therapy medicinal products
- Regional experience with Phase I/II and global experience with Phase II and Phase III clinical trials as well as early access programmes, named patient use / compassionate use and disease registries.
- Held global medical leadership positions at other global CRO’s and biopharmaceutical companies

Education Summary
- Doctor of Medicine, Charles University in Prague, Czech Republic
- Master of Business Administration, The Open University Business School, Milton Keynes, England
**Agnes Slater, MBBS, PhD**  
*Senior Medical Director, Hematology and Oncology*

Dr. Slater is a clinical research physician specialized in oncology and brings over 20 years’ of drug development experience in healthcare, academia and pharmaceutical industry.

**Experience Summary**
- Clinical research expertise in solid tumors and adult hematologic malignancies; surgical oncology; biosimilars and innovative adaptive trial designs
- Contributor to product approval in oncology, metabolic disease and seizure disorders
- Medical oversight of phase I (FIH), II, III and IV global studies for various medical indications
- Extensive experience in medical monitoring and safety surveillance through the Asia-Pacific Region
- Member of ASCO, ESMO and SSO

**Education Summary**
- Bachelor of Arts, Chinese Studies – Eötvös Loránd University, Budapest, Hungary
- Bachelor of Medicine, Bachelor of Surgery - Peking Medical University, Beijing, China
- Doctor of Philosophy, Pharmacology - National University of Singapore, Singapore
- Postdoctoral Fellowship in Surgery - National University Hospital, Singapore

**Franklin O. Smith, III, MD, FAAP, FACP**  
*Vice President, Medical Department, Hematology and Oncology*

Dr. Frank Smith is a clinical hematologist/oncologist with over 30 years of experience as a Principal Investigator on clinical trials.

**Experience Summary**
- Over three decades of academic clinical practice in pediatric hematology/oncology and adult hematopoietic stem cell transplantation
- Principal Investigator or co-investigator on numerous Phase I, II, and III clinical and translational research studies in acute myeloid leukemia, fanconi anemia, cord blood transplantation and gene therapy
- More than 170 peer-reviewed scientific manuscripts, reviews, chapters and books
- Professor of Medicine and Pediatrics, University of Cincinnati College of Medicine
- Previously: Clinical Director, University of Cincinnati Cancer Institute; Director, Division of Hematology/Oncology, Cincinnati Children’s Hospital Medical Center; Vice-Chair, Children’s Oncology group

**Education Summary**
- Doctor of Medicine, University of South Carolina School of Medicine
- Residency in Pediatrics, University of Florida College of Medicine
- Fellowship, Pediatric Hematology/Oncology, University of Washington and the Fred Hutchinson Cancer Research Center

**Anne Woolfrey, MD**  
*Senior Medical Director, Hematology and Oncology*

Dr. Ann Woolfrey is a board-certified pediatric hematologist-oncologist. She brings 24 years’ experience in pediatric hematology, stem cell, and research from entities such as academia, clinical research, and hospitals.

**Experience Summary**
- Held a director level role at a nationally recognized academic institution and cancer research center
- Faculty member at a leading cancer research center and at a recognized academic institution for over 20 years, rising to Full Member and Professor ranks, respectively
- Active member in four professional affiliations revolving around pediatrics, hematology, bone marrow transplant, and histocompatibility and immunogenetics
- Board Certified in internal medicine as well as pediatric hematology and oncology
- Key opinion leader with over >150 publications and presentations in the fields of hematology, oncology, and pediatrics
- Experience in clinical research for 22 years

**Education Summary**
- Bachelor of Arts in Chemistry, Saint Olaf College
- Doctor of Medicine, University of Minnesota
- Residency in Pediatrics and Internal Medicine, University of Chicago Hospitals and Clinics
- Fellowship, Pediatric Hematology/Oncology, Children’s Hospital and Medical Center/Fred Hutchinson Cancer Research Center
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.