A Deeper Dive into Hematology and Oncology

Medpace supports our sponsors who are advancing new anti-cancer therapies by providing specialized expertise in the design and management of your programs. We have assembled a team of therapeutically focused physicians and professional staff who have extensive experience designing and conducting Hematology/Oncology clinical trials and understand the issues from the perspective of the sponsor, the clinical investigator, the scientific leader, and the reviewer at the regulatory agencies. From beginning to end, Medpace can define and execute a clear development plan for your drug, device or combination product.

Scientifically-Driven Clinical Development

In-House Medical Expertise

Medpace, a global drug and medical device Clinical Research Organization (CRO), 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 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.

Nurse Practitioners—Adding perspective through the lens of the patient and site staff

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.

Meet our team of Hematology and Oncology Physicians
EXPERTS

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 LaBoursiere, Paris
- Master of Statistics and Trial Design, University Paris IX

Lyon Gleich, MD, FACS
Vice President, Medical Affairs, 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

Gregory Hale, MD, FAAP
Senior Medical Director, Hematology & 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
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 I 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

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

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 4 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
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. 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.

Hematology/Oncology experience highlights

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 areas 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
EXECUTION

Driving Efficiencies and Consistency of Data for Global Studies

Medpace demonstrates a commitment to quality and a united dedication to conducting full-service studies in an exacting manner to produce the highest quality results. Keys to successful execution include:

- **Committed Teams:** Your studies are assigned the best team from the onset and with turnover rates that are lower than the industry standard, that team is with you from project initiation to completion. As a result, we typically develop better team dynamics that are 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 supports oncology and hematology trials with its wholly-owned business units as well as partnerships with specialty labs. We provide and coordinate services for central lab, tumor imaging, biomarker development, validation and analysis, PK/PD analysis, and specialty genomics and anatomical pathology. This integrated model creates a highly effective environment for collaboration between our medical doctors, scientists, technicians, radiologists, physicists, clinical operations staff and project managers.

**ClinTrak® Study Management Technology**

Medpace’s proprietary study management technology - ClinTrak® - provides a cohesive platform that enhances communication and enables fast data exchange.

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.