WORLDWIDE
CLINICAL TRIALS

DEDICATED TO DELIVERING UNCOMMON EXPERTISE & PARTNERSHIPS

Last Update: 25082020

EXPERIENCE MATTERS. WORK WITH A PROFICIENT, TRUSTWORTHY PARTNER.

Does your CRO partner have the experience to back up its claims? With an early phase focus for over 20 years, we currently conduct approximately 100 clinical trials annually.

HEMATOLOGY/ONCOLOGY/ SUPPORTIVE CARE PORTFOLIO

- Advanced Solid Tumors
- Breast Cancer
- Cervical Cancer
- Chemo-induced Anorexia or Cachexia
- Colorectal Cancer
- Endometrial Cancer
- Glioblastoma (GBM)
- Hepatocellular Carcinoma
- Idiopathic Thrombocytopenia Purpura
- Leukemia, Acute Myeloid
- Lung Cancer, Non-Small Cell
- Melanoma
- Myelodysplastic Syndrome
- Non-Hodgkin's Lymphoma
- Ovarian Cancer
- Pancreatic Cancer
- Prostate Cancer
- Renal Cell Carcinoma
- Sickle Cell Disease
- Stomach Cancer

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SPECIALIZATION IN EARLY PHASE ONCOLOGY PROGRAMS FOR ACCELERATED TRIALS

Whether your study is a small focused single-region trial or a study that requires global reach, we have designed a **specialized oncology team** to work collaboratively and help you overcome the high-risk, high-cost, time-intensive challenges of early phase oncology drug development.

- Solid tumor and hematologic indications and therapies – **from traditional cytotoxic agents to cutting-edge cellular and immuno-oncology targeted therapies**.
- Every study is appointed a dedicated team of **in-house scientific solutions and operational advisors** who are committed to ensuring you get through the critical early stage of testing and on your way to FDA approval.
- With Worldwide, you get a **committed executive management team**, engaged at all times throughout the course of your program to help ensure the successful execution and delivery of your trial.
- Our relationships with **oncology key opinion leaders** provide you access to vital counsel – critical to understanding your product's life cycle as well as what is required to accelerate your treatment to market.

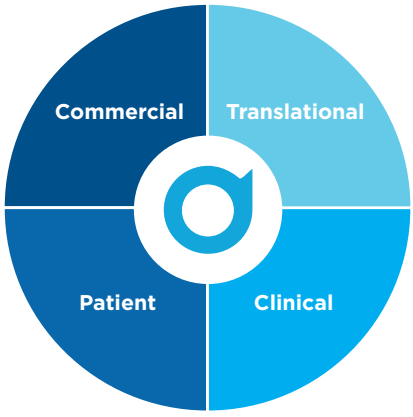
A STRATEGIC APPROACH TO PATIENT RECRUITMENT

Worldwide has formed a strategic alliance with Deep Lens, an AI-driven digital pathology company focused on disease diagnosis confirmation and clinical trial recruitment, to pair our expertise in clinical cancer research and global clinical trial operations with the Deep Lens VIPER™ digital pathology platform. This combination will accelerate cancer diagnoses and present clearer treatment and clinical trial options earlier in the process.

Through the strategic alliance, we seek to:

- Accelerate oncology patient recruitment for clinical trials
- Advance clinical research as a care option where the critical conversation with a patient is enabled at the point in their journey that is most impactful
- Create trusted networks of precision diagnosis and clinical research options
- Provide biopharmaceutical companies with a new platform for basket and umbrella study designs that can quickly process diagnosis and tumor response in real time
- Support pre-competitive research into better clinical trial approaches by organizing data clubs (disease-specific consortia) of industry stakeholders

WHY DEEP LENS?



Reorienting diagnosis and care coordination to catch up with the science

- **Translational** – Helping to "translate" and scale unique biomarkers and assays into the clinical/ provider workflow, while ensuring unique IP
- **Clinical** - Delivers precise pathology assistance and point-of-care confirmation of diagnosis to research and care teams
- **Patient** – True patient centricity through timely and rich discussion about research as a care option with the most important inclusion criteria for consent
- **Commercial** - Provider and health system primed for brand launch, digital channel design, and operationalizing the companion diagnostics

By working with Deep Lens on clinical trial recruitment, we can reach upstream from the oncologist to the pathologist, enabling identification of eligible patients at the time of their diagnosis – much sooner than current methods. Going straight to the source can fast-track your trial enrollment and shorten the duration of the trial.

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THERE'S NO SUBSTITUTE FOR UNCOMMON EXPERTISE. MEET YOUR PARTNERS.

Many large CROs offer "off-the-shelf" advice and solutions to their customers. Worldwide delivers tailored and pragmatic advice, regardless of the size or complexity of the project. Our collaborative and customized project team, with phase- and indication-specific expertise, will develop successful strategies for even the most novel therapies.

Gurpreet Brar, M.D., M.B.A.

Director, Project Management

Gurpreet has worked in clinical research for over 14 years (academia and industry sponsored combined), having managed global project teams, clinical teams, and has experience as both a field CRA and study coordinator. He excels at global team leadership, risk management, and training and development of both project teams and site staff. He has either worked in or led global teams in all regions of the world.

Gurpreet has extensive oncology experience, both as a CRA and project manager, having worked in Phases I-III in both solid tumor and hematologic malignancies. His past oncology therapeutic experience includes breast cancer, ovarian cancer, NSCLC, both Hodgkin's and non-Hodgkin's lymphomas, AML, MDS, multiple myeloma, and head and neck tumors. With his previous experience as a hematology-oncology study coordinator, he understands site patient pathways and is ideally situated to help support the patient recruitment and retention efforts and to help advise study sites in these efforts, as well as assist with managing any risks and training around the product reconstitution guidelines.

Gurpreet is multilingual across four different languages and holds a Doctor of Medicine from Rostov State Medical University in Rostov on Don, Russia. His M.B.A. was obtained in the US.

Rhonda Burdick

Senior Project Manager

Rhonda has 20 years of clinical research experience including 12 years of oncology experience and 15 years in global study project management. She possesses a strong clinical and project management background gained from experience as a Clinical Research Associate, Global Study Manager, and Project/Program Manager.

She has successfully managed small, medium, and large biotechnology and pharmaceutical company-sponsored studies, including Phases I-IV. Her oncology and hematology experience includes mantle-cell lymphoma, chronic lymphocytic lymphoma, amyloidosis, thrombocytopenia, hemophilia as well as cancers of the gastric system, breast, lung, ovary, and pancreas. She has worked on various therapies indicated for cancer and hematologic diseases including chemotherapy, molecular targeted agents (PD-1, PDL-1, and kinase inhibitors, cancer vaccines, and biosimilars.) She received her bachelor and master's degrees in animal science from Washington State University.

Mireille Cantarini, M.D.

Senior Medical Director, Medical Affairs

Dr. Cantarini brings a long history in clinical research to her role as medical and scientific affairs consultant at Worldwide. Sponsors focused on oncology appreciate her experience with the Oncology Early Clinical Development organization at AstraZeneca, where she was involved in Phase I/IIb studies across several cancer indications across global locations (including the EU, US, Southeast Asia, Japan, South America, South Africa, and China). Most recently, Dr. Cantarini was involved as Executive Medical Director in the Osimertinib (indication T790M-positive non-small cell lung cancer (NSCLC)) program, taking the clinical development from first dose-in-human to full regulatory approvals in all major territories (FDA, EMEA, Japan, and China) in four years. She has been board certified in Pharmaceutical Medicine (GMC specialist register) since 2005 and has a 30-plus-year record of publications in peer-reviewed journals.

Raffi Chamlian, BPharm

Director, Project Management

Raffi has 22 years of clinical research experience, including 6 years in oncology and 18 years in project management in both pharma and CRO environments. Raffi possesses strong scientific knowledge and global project management skills from his background as a pharmacist and in successful delivering over 35 Phase I to III trials in various therapeutic areas and indications such as oncology, hematology, cardiology, and CNS. His oncology and hematology experience includes Phase I/II trials in Non-Hodgkin's lymphoma, hemophilia B with gene therapy, metastatic breast and colon cancers, and diffuse-type tenosynovial giant cell tumors involving PD-1, CTLA4, MEK and kinase inhibitors as well as selective ER covalent antagonist.

He has extensive experience in site feasibility, investigator relationship, patient recruitment, and retention planning. He is a licensed pharmacist and graduated from the Faculty of Pharmacy from Université de Montréal in Canada.

Leanne Drummond

Director, Project Management

Leanne has more than 25 years of clinical research experience with 20 of those years in oncology with a focus on Phase I-II studies. She has extensive experience working with small to midsized companies, covering development strategy design and implementation from lead candidate selection through to end of clinical phase II. Her development programs have including CMC, pharmacology, toxicology, and regulatory in addition to clinical studies. Leanne's oncology and hematology experience includes breast, colorectal, non-small cell lung, ovarian, prostate, gastric, and bladder cancers, melanoma, cutaneous metastases, glioblastoma, NHL, AML, and thrombocytopenia. Treatment modalities have included cytotoxic, cell lysing, stem cell stimulation, T-cell engagement, and receptor blocking agents. She received her bachelor's degree in marine biology from Texas A&M University.

Rebecca Eskew

Executive Director, Project Management

Rebecca has worked in clinical research for over 20 years, joining Worldwide Clinical Trials in May 2019 as a therapeutic and operational advisor for oncology and rare indications. She began her career in research as an in-house CRA for a large, global CRO and then moved into a regional CRA role for the same company. Rebecca was promoted to project management and led a successful Phase III global pivotal program, which resulted in successful FDA and EMEA registration for a product to treat chronic lymphocytic leukemia.

Rebecca has approximately 15 years in oncology, Phases I through III, including first-in-human trials. She has led or overseen trials of several first-in-class compounds, including CAR-T therapies and other immuno-oncology drugs. She has participated in regulatory inspections and has been part of four successful BLA submissions and subsequent FDA and EMEA approval for new immuno-oncology products. She has experience writing protocols and safety summaries, INDs, and CSRs. She was most recently the head of clinical operations for a small biotechnology company focused in CAR-T (both autologous and allogeneic) and bispecific therapies. In this role, she was responsible for all clinical operations activities, including liaising with the manufacturing team to ensure on-time delivery of patient T-cell products. Rebecca has experience with autologous, non-engineered T-cell therapy, autologous engineered T-cell therapies, and allogeneic T-cell therapies. Rebecca has a Bachelor of Science degree in zoology/pre-medicine from The University of Oklahoma and is in pursuit of her Master of Science degree.

Alaeddin Homsi, M.S., B.S.

Executive Director, Project Management

Alaeddin Homsi is an effective oncology clinical research leader with strong experience across biotech, large pharma, and the CRO space. This includes successful management of every phase of clinical trials and program-level management experience, overseeing operations on multiple clinical development portfolios while at Novartis Oncology. His strong therapeutic expertise spans both solid tumors and hematologic malignancies and includes various therapy types such as chemotherapies, cellular therapies, targeted therapies, hormonal therapies, immunomodulator therapies, immune checkpoint inhibitors, bispecific antibody T-cell engagers, and supportive care. Alaeddin serves on Worldwide's Oncology leadership team, and is focused on exceeding client expectations. Alaeddin brings a proactive and accountable leadership style that delivers upon its promises from early during proof-of-concept out to finalizing the clinical study report. His numerous accomplishments include several studies' on-time or ahead of scheduled enrollment, quality delivery of data ahead of interim analysis and DBLs, and successful post-NDA inspections.

Alaeddin holds a Master of Science degree in Clinical Research Administration, with distinction, from the George Washington University, in Washington, DC. He also graduated summa cum laude from Montclair State University in New Jersey with a Bachelor of Science degree in biology.

Katie Hurley

Senior Project Manager

Katie has more than 15 years clinical research experience, spanning early phase through global trials, primarily within oncology. She has been a Global Clinical Project Manager for 8 years, responsible for overseeing all aspects on Phase I-III studies across regions of EU, Asia, and South America. Her experience in oncology clinical trials includes immunotherapy and vaccine trials. She has extensive experience with dose escalation trials and global registration trials.

Katie has worked on various therapies indicated for cancer and hematologic diseases including chemotherapy, molecular targeted agents (PD-1, PDL-1 and kinase inhibitors, cancer vaccines, and biosimilars). Currently, she is managing a supportive care trial in prostate cancer. Earlier on, she had experience as the lead CRA in the area of antiviral anti-infectives, leading a first in man HIV vaccine trial and several HEP B and HEP C vaccine trials. Katie also has experience with a successful NDA filing. She graduated from the University of New Hampshire with a bachelor's degree in psychology and pre-med., Honors Program. She is currently studying for the PMP certification.

Noor Khaskhely, M.D., Ph.D.

Sr. Medical Director, Medical Affairs

Dr. Noor Khaskhely brings more than 20 years of clinical research experience both in the academic and industry environment, including CRO. Dr. Khaskhely has experience designing and monitoring clinical studies conducted in inflammation/immunology, oncology, IO, CNS, infectious diseases, and vaccines. Dr. Khaskhely provided scientific and clinical consultation on primary and secondary end points for inflammatory/immunology and oncology studies, supported by the collaboration with number of KOL from the fields of inflammation/immunology and oncology. His experience encompasses all phases of clinical development, from first-in-human to post-marketing studies and monitoring of global studies. He has substantial experience in pre-clinical research, as well. During his tenure at several medical colleges, he was the liaison between Departments of Human Research Protection, Biomedical Institutional Review Boards, and Centers for Coordination of Clinical Education and Management. He is well published and frequently presents at scientific conferences and meetings. He speaks 6 languages, including Japanese.

Jennifer Mangum, RN, MSN

Senior Project Manager

Jennifer has over 20 years of clinical research experience, managing single service to complex, global, multinational trials. She has gained valuable experience in the positions she has held including Clinical Research Coordinator and Clinical Research Associate, which she has implemented into her Project Management practice. Her accomplishments include on-time milestone delivery with quality, multiple DBLs and NDA submission support. Her clinical experiences include multiple years of oncology, endocrinology, cardiovascular and women's health across various therapeutic areas. Jennifer's oncology and hematology research experience has been mainly focused on early phase malignancies for the following indications: breast, glioblastoma, NSCLC, ovarian, AML, prostate, GIST, solid tumor, multiple myeloma, and lymphomas.

Jennifer graduated from East Carolina University with a BSN degree and is a licensed Registered Nurse. She also holds a MSN with a focus in clinical research administration from George Washington University.

Gaurav Sharma, M.Pharm, PMP, C.Sci, FIBMS, MICR

Senior Vice President, Therapeutic Area Leader, Oncology & Hematology

Gaurav is a strategic and tactical operations leader, with a wealth of experience building and managing high-performing teams and developing innovative, creative, and quality-driven solutions for clients. Gaurav brings strong and varied therapeutic expertise and strategic leadership skills, developed across franchise areas within several CROs and now to Worldwide. Prior to joining Worldwide, Gaurav was a Senior Vice President and Head of Global Project Management with Premier Research. More recently, Gaurav was responsible for overall successful delivery of clinical programs involving immune checkpoint inhibitors for the treatment of solid tumors and hematological malignancies.

Gaurav has also worked extensively in acute myeloid leukemia, cutaneous T-cell lymphoma, and prostate cancer. He was program director for a large program with tyrosine kinase inhibitor (TKI) involving several studies, including pivotal study for patients with EGFR mutated NSCLC, leading to marketing authorization. Gaurav is a Project Management Institute (PMI) certified Project Management Professional, a Certified Director by the World Council for Corporate Governance and a Chartered Scientist (C.Sci) by the Science Council in the United Kingdom, with a wealth of experience working with pharmaceutical companies, such as Lundbeck, Allergan, Takeda, and global CROs, such as IQVIA, Parexel, Icon, Premier Research, and ClinTec.

Margo Smith

Project Manager

Margo has been working in clinical research for nearly 20 years and has worked in academic research, as well as small and large CROs. She started her career as a manager of a tumor bank for bladder and prostate cancer and progressed to positions of CRA, Manager of Clinical Operations, LCRA, Clinical Team Lead and is now a Project Manager. She started with Worldwide Clinical Trials in September 2016. Her broad range of therapeutic expertise includes oncology, rare disease, gastroenterology, CNS, rheumatic, woman's health, virology, psychiatry, and pulmonary diseases; her specific oncology expertise includes working across Phases I-IV in indications of lung, pancreatic, gastric, advanced solid tumor, and prostate. Furthermore, in oncology she has worked in first in human, checkpoint inhibitors, monoclonal antibodies, small molecule, vaccines, as well as other therapies.

Margo graduated from the University of Otago in New Zealand with a B.S. in mathematics and a B.A. in classical studies with minors in psychology and Latin.