VISION
Clinical Research

Our History

Vision Clinical Research (VCR) originally functioned as a subsidiary of Vision Biotechnology Consulting (VBC). VBC was founded in 1996 by Mark J. Sarno, eJD. VBC has guided biotech and pharmaceutical companies to more than 100 successful regulatory approvals, clearances, or CLIA waivers in the United States and multiple CE Mark certifications or marketing authorization application (MAA) approvals in foreign countries. In synergy with VBC, Dr. Sarno brought together the talents of VBC and other long-term collaborators and scientific colleagues to build the VCR subsidiary as a contract research organization (CRO) service provider to existing and new clients in the in vitro diagnostic (IVD), medical device, and pharmaceutical industries. Eventually, VCR reorganized as an independent limited liability company (LLC) with the same staff retained under the independent entity.

The VCR staff has designed, managed, monitored, analyzed, and reported medical device and IVD studies up to several thousand patients and Phase I-IV drug studies in multiple clinical areas. As such, VCR presents clients with a long pedigree of success in IVD, medical device, and pharmaceutical development. Biographies of the VCR LLC principals and staff are presented at right.

Our Team

– Mark J. Sarno, eJD – Chief Executive Officer

Dr. Sarno has over 40 years' experience in research, development, clinical/regulatory, biostatistics, and project management within the pharmaceutical, *in vitro* diagnostics, and medical device fields. He has developed products covering such diverse clinical areas as oncology, cardiovascular disease, diabetes, infectious disease, metabolic bone disease, rheumatology, fetal aneuploidies, newborn screening, thrombophilia, asthma, and gastroenterology. He is a patented inventor, member of the United States Patent Bar and an associate member of the California Lawyers Association. He founded Vision Biotechnology Consulting, which has for 27 years assisted companies in design, development, clinical research, and regulatory affairs resulting in 51 FDA clearances and approvals. He was also previously Director of Product Development, at NovaDx Inc., which developed the first specific *in vitro* diagnostic test for rheumatoid arthritis and osteoarthritis. As a biostatistician, Dr. Sarno has analyzed some of the seminal epidemiological studies in cardiovascular disease including the Atherosclerosis Risk in Communities (ARIC) study as well as international oncology studies such as REDUCE. He has authored book chapters including a chapter in the Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, and published in many prestigious journals such as Journal of Urology, Urology, Diabetes Care, Food and Drug Law, Journal of the American College of Cardiology, Journal of Clinical Pharmacology, Clinical Chemistry, Clinical Biochemistry, Prostate Cancer and Prostatic Disease, Gynecologic Oncology, Fertility and Sterility, and Cancer Research. In his occasional spare time, Dr. Sarno enjoys running, flying airplanes, riding motorcycles, rescuing German Shepherds, and playing drums, keyboards, and bass guitar.

– Michael Lichtman, BS – Chief Operating Officer

Mr. Lichtman has over 27 years of both basic research and clinical trials experience and has worked extensively in all four pharmaceutical phases, and *in vitro* diagnostic trials. He has assisted past companies in regulatory affairs, clinical monitoring and project management of trials resulting in 18 FDA approvals or clearances. He was also previously on the research team at NovaDx Inc. which successfully developed *in vitro* diagnostic tests for rheumatoid and osteoarthritis. At Vision Clinical Research, Mr. Lichtman specializes in providing study operations planning and execution, clinical site identification and activation, and site management of trials. In addition to project and site management, he is actively involved in protocol/CRF design; informed consent creation; CRA training; development of study specific documents and tracking tools; investigator selection; and study site contract negotiations. Mr. Lichtman holds a BS Degree in Biology from California State University, San Marcos. In his free time, this Marine Corp Veteran enjoys flying airplanes, running, and surfing. He serves as Treasurer and Board of Director for a local 501(c)(3) non-profit, and is a volunteer wildlife rescuer.

– Laura Sarno, BS – Chief Information Officer

Ms. Sarno has 43 years combined experience in academia and industry. Her academic research scientist experience was at Stanford University Medical School in the departments of pediatric infectious diseases and pediatric endocrinology. Her extensive industry experience includes leadership responsibilities as a research scientist, product development scientist, clinical scientist, regulatory affairs professional, project manager/director, and data management director. She has worked extensively in multiple clinical fields including breast and prostate cancer, general urology, dermatology/dermatologic surgery, Alzheimer's disease, metabolic bone disease, maternal fetal medicine, and asthma. Ms. Sarno holds a BS Degree in Biological Sciences from the University of California, Irvine. She currently directs the data management function within Vision Clinical Research for all ongoing studies. Her other pursuits include 7 years as a managing member in a German Shepherd Dog Rescue volunteer organization. She obtained IRS 501(c)(3) nonprofit certification for the Rescue and served 3 years as Secretary/Treasurer for the nonprofit.

– Diane L. Crombie Hogan, BA – Associate Member

Ms. Hogan holds a B.A. in Animal Physiology from the University of California, San Diego and has over 30 years of experience in research and drug development, including more than 14 years monitoring clinical trials. She serves as liaison between the sponsor and the investigator, traveling to investigational sites to conduct site evaluation, initiation, periodic monitoring, and termination visits to verify that the rights and well-being of human subjects are protected; that the reported trial data are complete, accurate, and verifiable per source documents; and that the trial is conducted in compliance with the currently approved protocol, Good Clinical Practice, and standard operating procedures. In addition, she also mentors junior clinical research associates (CRAs). Areas of experience include men's and women's health, Preeclampsia, oncology (bladder, prostate, head and neck, gynecological), gastroenterology, diabetes, obesity, insulin sensitivity, and hypertension. She has published over 45 papers, book chapters and abstracts in peer-reviewed medical journals.

– Christine Kavanaugh, BHS, MT (ASCP) – Associate Member

Ms. Kavanaugh has over 33 years in the clinical laboratory and research fields. She started her career as a Clinical Laboratory Scientist at Humana Hospital in Lexington, KY. While there she also served on the Safety and Chemical Hygiene team. She entered the clinical research arena in the mid-1990s as a Clinical Research Associate. She has broad clinical trials experience encompassing numerous therapeutic areas including complex protocols in neurology, oncology, pulmonary, and ophthalmology. Ms. Kavanaugh has worked on all phases of clinical trials from first-in-human to post-marketing, and with all manner of investigational product, i.e. drugs, biologics, devices, and diagnostics. Ms. Kavanaugh has participated in global studies, adult and pediatric populations, inpatient /outpatient settings, and studies for orphan diseases. Companies she has worked with include Genentech, Teva Neurosciences, Gilead, Astra Zeneca, and Progenity, as well as the National Institutes of Health. Her primary areas of focus have been Stroke, Parkinson's Disease, Multiple Sclerosis, Alzheimer's Disease, Multiple System Atrophy, Macular Degeneration, Cystic Fibrosis, Preeclampsia, Hypertension, *in vitro* diagnostics, Diabetes, Infectious Diseases, Arthritis, hematologic malignancies, and stem cell transplant.

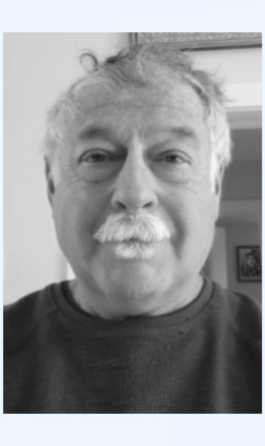
Ms. Kavanaugh has been associated with several FDA approvals including: Lucentis (ranibizumab) approved to treat age-related Macular Degeneration, Azilect (rasagiline) for Parkinson's Disease, and Enbrel (etanercept) approved for treatment of Psoriatic Arthritis.

Ms. Kavanaugh holds a Bachelor of Health Sciences degree from the University of Kentucky and is board certified by the American Society of Clinical Pathologists. She currently functions as a Project Manager for Vision Clinical Research.

– Howard Civian Birndorf, MS ScD – Business Development

Dr. Birndorf is a biotechnology entrepreneur and one of the founders of the biotech industry in San Diego, California. Along with former University of California professor and current venture capitalist Ivor Royston, Birndorf founded San Diego's first biotech in 1978, the monoclonal antibody company Hybritech. The company was subsequently bought by Eli Lilly and Company in 1986, and Birndorf went on to found a number of other successful companies including Gen-Probe, IDEC Pharmaceuticals (which merged with Biogen to form Biogen-Idec), and Ligand Pharmaceuticals. Birndorf was also involved in the formation of Gensia (Sicor), and was a founding Director of Neurocrine Biosciences. He was the founder and co-chair of the Coalition for 21st Century Medicine and was founder, Chairman and CEO of Nanogen, Inc. Birndorf received his B.A. in Biology from Oakland University, an M.S. in Biochemistry from Wayne State University, and has received honorary Doctor of Science degrees from Oakland University and Wayne State University.

– Philip E. Silkoff, MB – Medical Monitor and Consulting Pulmonologist



Philip E Silkoff is an adult pulmonary physician who transitioned from academia to industry in 2004. His academic research focused on the measurement of exhaled nitric oxide (NO) as it pertains to respiratory medicine. Exhaled NO is a marker of airway inflammation, and Phil developed patented techniques for NO measurement in man, chaired several societal workshops that developed the guidelines for exhaled NO measurement, and published extensively in the field of biomarkers in asthma and COPD. His pharmaceutical career has focused on late phase projects in asthma and COPD, culminating in a successful sNDA filing in 2008 for a COPD therapeutic at AstraZeneca. He subsequently worked in early pulmonary drug development in asthma, COPD, ILD, and sarcoidosis at Janssen. In 2016, he became chief medical officer at Third Pole Therapeutics in Boston which is developing inhaled NO for the treatment of pulmonary hypertension. Phil was involved in a clinical trial run by VCR in 2016 and in 2020 joined VCR as a pulmonary consultant for VCR's projects.

– Dennis L. Broyles, BA, MSHS, RAC, CCRP, CCRA - Project Manager

Mr. Broyles is an experienced assay developer and clinical scientist with over 35 years in the IVD industry. His prior work at Hybritech, Inc. and Beckman Coulter, Inc. includes a number of PMA, de novo 510(k), and 510(k) products in the areas of prostate cancer, women's reproductive health, infectious disease, hematology, immunology, bone remodeling, and molecular diagnostics. He is well versed in GCP and all aspects of clinical operations, including strategic planning, protocol development, and interacting with FDA. He is certified through the Regulatory Affairs Professionals Society (RAPS), the Association of Clinical Research Professionals (ACRP), and the Society of Clinical Research Associates (SoCRA). Dennis earned his MSHS degree in Clinical Research Administration from the George Washington University and his BA in Biology from UCSD. He has co-authored ten peer reviewed papers, a book chapter on the PSA isoform [-2]proPSA, and over 25 posters presented at scientific meetings. Dennis enjoys mountain biking, camping and fishing, and has practiced and taught martial arts for more than 32 years.

– T. Che Jarrell, BSPH, MPIA, RAC - Regulatory/QA Specialist

Che has worked in the biotech sector since the mid-90s. He began his career as a SAS statistical programmer and clinical data analyst for the private sector after graduating from the University of North Carolina at Chapel Hill's Biostatistics undergraduate program. He later diversified his industry understanding via entering the University of California San Diego's international affairs graduate degree program. Upon graduation and subsequent obtainment of the Regulatory Affairs Certification (RAC) through the Regulatory Affairs Professional Society (RAPS) in the mid-2000's, Che had transitioned from clinical trial analytics to quality assurance and regulatory affairs. After working for the Johns Hopkins Health System in a regulatory affairs and quality assurance capacity over a nearly 9-year period (six years with the Sydney Kimmel Comprehensive Cancer Center/School of Medicine and nearly three with the Johns Hopkins All Children's Hospital), Che's professional contributions were recognized by the Journal of Clinical and Translational Science *(Jarrell et al, A paired training curriculum and internal monitoring program for clinical research regulatory compliance in the emerging era of the single Institutional Review Board, Journal of Clinical and Translational Science, Volume 1 Issue 4 August 2017)*. Most recently, Che has leveraged these experiences to provide Vision Clinical Research with support in regulatory affairs/submissions, GCP auditing/monitoring/compliance, project management, and training/curriculum development. In his time outside VCR, Che has also been a frequent guest lecturer for the Society of Clinical Research Associates (including the 2017 SOCRA Annual Conference), the Johns Hopkins Health System, and other related biomedical product organizations.

– Jewell Wright, BS ASCP – Senior Clinical Research Associate

Ms. Wright has over 40 years in the clinical laboratory and research fields. She started her career as a Clinical Laboratory Medical Technologist (ASCP) at Hendrick Hospital in Abilene, Texas. A short time later she became the Chief Technologist at a neighboring hospital and later moved on to become the Lab Director at Hurst-Euless-Bedford Hospital in the Dallas-Ft. Worth area.

Ms. Wright entered the clinical research arena in 1999 as a Clinical Research Associate. She has broad clinical trials experience with over 40 clinical studies. These studies encompassed numerous therapeutic areas including protocols in infectious diseases, oncology, psychiatry, cardiology and sleep disorders. Ms. Wright has worked on Phase II and III clinical trials with a variety of investigational products including drugs, biologics, devices, and diagnostics. Companies she has worked with include Bayer, Pfizer, Astra Zeneca and Novartis. Her primary areas of focus have been Severe Sepsis, Community Acquired Pneumonia, Ventilator Acquired Pneumonia, Renal Cell Carcinoma, Non-small Lung Cell Carcinoma, Metastatic Breast Cancer, Clinical Depression, Hypertension, Diabetes, Sleep Disorders and Hyperlipidemia. Ms. Wright also has experience with point-of-care devices for sexual health as well as an *in vitro* assay for the rapid detection of influenza A and B. Most recently, she conducted remote monitoring and data entry for a COVID-19 rapid PCR testing device in the NBA bubble. In addition, she screened and identified sites for another COVID-19 anti-viral study.

Ms. Wright has been associated with several FDA approvals including: Cephalon's Provigil (modafinil) approved to treat narcolepsy, obstructive sleep apnea, and shift-work sleepiness; C.R. Bard's silver-coated endotracheal tube approved for the reduction of ventilator acquired pneumonia; Cyberonic's VNS device/pacemaker for the brain, approved to treat clinical depression; Cerexa's Teflaro (ceftaroline) for community acquired pneumonia, AccessBio's CareStart *in vitro* assay for influenza A and B, and Visby Medical's *in vitro* assay for sexually transmitted infections.

Ms. Wright holds a Bachelor of Science degree in Medical Technology from Hardin-Simmons University in Abilene, Texas and is board certified by the American Society of Clinical Pathologists. She currently functions as a Senior CRA for Vision Clinical Research.

– Jacqueline M. Aussie, BA – Senior Clinical Research Associate

Jacqueline has worked in all four divisions of the biotechnology industry, including pharmaceutical drugs, biologics, diagnostics and devices. Jacqueline began her biotechnology career in 1995, starting out as a Clinical Operations Clerk at Amylin Pharmaceuticals and then over the years moving up to CRA. About half of her career was in Clinical Affairs/Clinical Operations and about half in Drug Safety Surveillance/Pharmacovigilance. She was honored to have worked for several prestigious companies on very exciting projects including IDEC Pharmaceuticals, Agouron Pharmaceuticals, Quintiles, Gen-Probe Inc., GenMark Diagnostics, Prometheus Labs, and Illumina. Jacqueline is well versed in all phases of site monitoring, vendor management and relations, protocol and CRF design, site regulatory compliance, contract negotiations, and database design/entry/verification, AE/SAE reporting including expedited reports, annual reports and Periodic Safety Update Reports (PSURs). Jacqueline enjoys the challenge and reward of the biotechnology industry and could not imagine a better fit for her personality and her interests in helping others improve their health. Jacqueline has her Bachelors of Arts degree from the University of San Diego and has also earned certificates from UCSD Extension in Clinical Trials Management and Design as well as Regulatory Affairs. Jacqueline has been a member of San Diego Regulatory Affairs Network (SDRAN), Association of Clinical Research Professionals, Southern California Research Associates (SoCRA) and BioCom.

– Celine Koropchak, BS – Clinical Research Scientist

Ms. Koropchak recently joined Vision Clinical Research after serving as Project Manager in the Department of Medicine at Duke University Medical Center. She brings with her 19 years of experience overseeing multiple clinical studies in the fields of palliative care, cardiology, oncology, nephrology and managed care. This experience involved all aspects of project management including staff supervision, regulatory oversight and compliance, data management, protocol development, manuscript preparation and fiduciary responsibilities. In addition, Ms. Koropchak has over 21 years of experience in research laboratory work in pediatric infectious disease and biochemistry at both Stanford and Duke Universities. She graduated from Bucknell University in Lewisburg, PA with a BS degree in Biology and has over 30 publications in scientific journals. She currently lives in North Carolina on her blueberry farm where she harvests over 3000 pounds of berries each season. In her spare time, she writes and teaches locally.

VCR, LLC also maintains project managers, regulatory affairs consultants, SAS programmers, medical monitors, medical officers, DSMB members, data entry specialists, medical writers, pharmacologists/toxicologists, molecular biologists, chemistry, manufacturing, and controls specialists, and additional clinical site monitors as sub-contracted resources. These individuals are assigned to projects as needed. This enables VCR to staff up and down to provide our clients the most cost-effective resource loading based on individual project needs.

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