Our Expertise

Our clients' interest in precision healthcare emphasizes the critical importance of matching the right therapy to the right patient. Thus, we continue to focus on the use of pharmacoepidemiologic and pharmacogenomics strategies for research on drug efficacy and safety, biomarker-based companion diagnostics (CDx), immuno-oncology, medication adherence, and clinical-decision support algorithms.

Our team brings value to our clients across the entire process of research, development, and commercialization. We provide **expert guidance** and **research leadership** on the determinants of drug efficacy and safety to improve the quality of healthcare.

Areas of Focus

Research and development
Expert third-party review of biomarker program and strategy
Evaluation of scientific literature for biological and clinical value

Optimization of study design and execution
Selection of appropriate sample types and analytical platforms
Biostatistical support for integration and analysis of multi-omic data

Clinical and regulatory strategy
Evaluation for accuracy and robustness for clinical translation
Development of CDx-related safety strategy and studies
Development of reimbursement strategies for CDx
Safety and regulatory guidance

Commercialization strategy
Review of market potential, current standard of care and competition
Product development risk assessment, strategy, and guidance

What Our Clients Say

Venebio provided impressive and timely scientific leadership and regulatory guidance for a major initiative at MWV Healthcare…
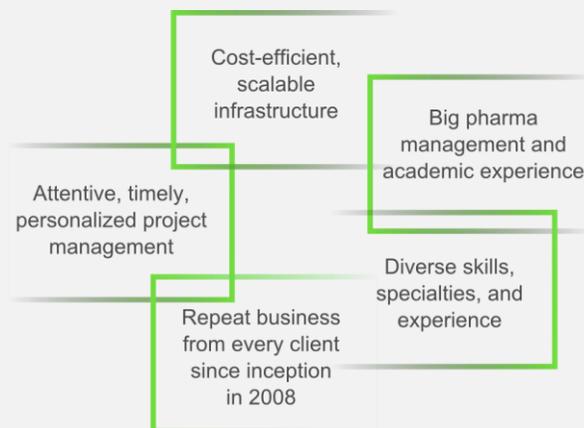
Venebio and its team of experts planned and spearheaded a remarkable research effort to establish the scientific evidence behind our regulatory approach…

We are extremely pleased with our collaboration with such a creative and forward-thinking organization.

Venebio Group, LLC

Venebio Group, LLC is a life sciences research consultancy that draws on a group of senior Principal Scientists and more than 225 Network Consultants to assemble a project team perfectly aligned with our clients' needs. Our clients are attracted to our model because they receive the right experts for each project, while also reaping the financial benefits of Venebio's minimal overhead design.

The Venebio Advantage

Cost-efficient, scalable infrastructure

Big pharma management and academic experience

Attentive, timely, personalized project management

Diverse skills, specialties, and experience

Repeat business from every client since inception in 2008

Representative Projects

Conducted proteomic, metabolomic, genomic, epigenomic, transcriptomic, and first ever phenomic analysis of smokers with and without COPD for biomarker discovery

Reviewed biomarker strategy and discovery/validation pipeline to support clinical trials for a major oncology immunobiologic

Consultant Profiles

Walter Carney, PhD

- PhD, Microbiology, Thomas Jefferson Medical College, Philadelphia, PA
- Harvard and NIH Fellow, Mass General Hospital, Virology and early investigation of T-cells and macrophages in HIV
- Primary area of scientific expertise in the development of blood based and tissue based biomarkers with the intent of converting them into companion diagnostics
- Extensively involved in the development of both research use and in-vitro diagnostics IHC/ELISA products and their inclusion in clinical trials
- Served as Head of Oncogene Science (as both President and CSO), involved in discovering the circulating form of the HER-2 protein and created an FDA cleared blood test to measure the extracellular domain of the HER-2 protein
- Published over 250 articles and abstracts, and has been awarded over 40 USA, European and Japanese patents.

Thomas O'Connell, PhD

- PhD, Chemistry, University of California, Santa Barbara
- Post-doctoral fellowship, Biophysics, Yale University School of Medicine, NIH, National Institute of Environmental Health Sciences.
- Research focus on cancer metabolism and associated metabolic derangement
- Developed computational methods for protein structure and ligand binding and built Metabolomics Laboratory at the University of North Carolina, Chapel Hill
- Developed NMR- and MS-based methods to determine the structure of drug impurities and metabolites
- Holds several patents for translation of metabolomics assays into clinical diagnostics

Maciek Sasinowski, MD, PhD

- PhD, Computational Plasma Physics, College of William and Mary
- MD, Medical College of Virginia; Residency, Riverside Family Medicine
- Decades of experience in leading multidisciplinary, multi-institutional collaborations in biomarker discovery and validation research
- Developed methods, algorithms and code for integrative, system-based analysis
- Conceived and led development of five commercial bioinformatics software packages
- Founded and served as CEO of INCOGEN, Inc., and founded Clemson University Genomics Institute Bioinformatics Center
- Attracted over $18 million in federal and state funding for biomarker and precision medicine research.

Selected Publications

Proteotranscriptomic analysis reveals stage specific changes in the molecular landscape of clear-cell renal cell carcinoma. Neely, B.A., et al. *PLoS ONE.* 2016.

O'Connell, T.M. and Markunas, C.A., DNA Methylation and MicroRNA-Based Biomarkers for Risk of Type 2 Diabetes. *Current Diabetes Reviews*, 12, 20, 2016.

Comparison between cardiometabolic risk biomarkers in a clinical laboratory patient cohort and the US adult population. Wolin, E., et al. *Journal of Clinical Lipidology.* 2015.

Functional genomics identifies novel genes essential for clear cell renal cell carcinoma tumor cell proliferation and migration. Von Roemeling, et al. *Oncotarget.* 2014.

Comprehensive biomarker testing glycemia, insulin resistance, and beta cell function has greater sensitivity to detect diabetes risk than fasting glucose and HbA1c. Varvel, S.A., et al. *Journal of Cardiovascular Translational Research.* 2014.

Beyond personalized medicine—Personalized lifestyle. Sasinowski, M. *Anti-Aging Medical News.* 2014

Circulating HER-2 Extracellular Domain is a Quantitative Biomarker of Prognostic Value in all Breast Cancer Patients. Carney, W.P., et al. *Biomarkers in Cancer* 2013: 5, 31-39.

Microfluidics and Circulating Tumor Cells. Dong, Y., et al. *Journal of Molecular Diagnostics* 2013, 15(2):149-57, March, 2013.

Metabolomic profiling to identify predictors of response to vitamin E for non-alcoholic steatohepatitis (NASH). Cheng, J., et al. *PLoS ONE.* 2012.

Carney, W.P., et al. *Breast Cancer Research*, 9:207, 2007

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