

Clinical Trial Services

Harnessing Vascular Biomarkers for
Next-Generation Therapies

Neurological Disorders



Respiratory Diseases



Cardiovascular Disorders



Oncology



Inflammatory Diseases



Infectious Diseases



Pain



Metabolic Diseases



Women's Health



CONNECT[®]
Health

SphygmoCor® sets the gold standard in vascular health assessment, offering unparalleled insights into the heart's health beyond traditional cuff blood pressure measurements. *This cutting-edge technology accurately analyzes central blood pressures and arterial stiffness – clinically meaningful information that standard cuff measurements simply cannot capture.*

Clinical Trial Services



Transform Drug Discovery with Vascular Phenotyping

Vascular phenotyping utilizes vascular biomarkers to evaluate arterial stiffness and cardiovascular function. This approach offers critical insights into the effects of new compounds and devices on the vascular system, aiding in the identification of potential efficacy and adverse reactions. Early quantification of these biomarkers allows researchers to more precisely predict clinical outcomes, speeding up the development of promising candidates and reducing the risk of costly late-stage failures.



Enhance the Success of Every Trial

Monitoring vascular biomarkers can help identify specific profiles that predict patient responses to treatments, enhancing trial stratification and ensuring that only likely beneficiaries are included. This precision improves trial outcomes and reduces risks and costs associated with ineffective treatments. By leveraging these biomarkers, researchers can swiftly adjust treatment protocols to optimize safety and efficacy. Overall, the use of vascular biomarkers in clinical trials enables more personalized, efficient, and effective development of new medical interventions.

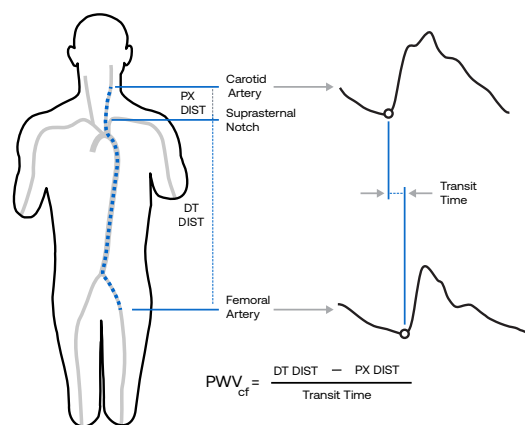
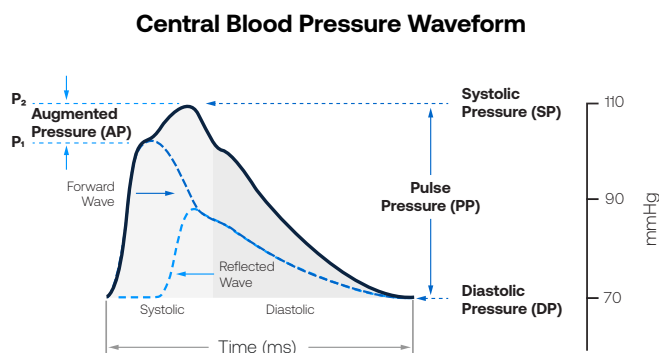
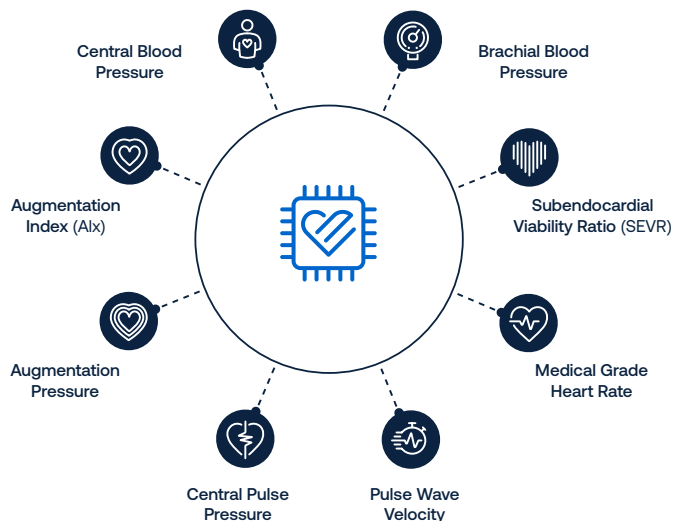


Vascular Biomarkers Explained

Vascular biomarkers are revolutionizing not only cardiovascular health management but also clinical research and personal wellness strategies.

These critical indicators offer a comprehensive evaluation of the cardiovascular system's health across a broad spectrum, from clinical trials to individual health monitoring. By assessing key markers such as endothelial function, arterial stiffness, and coronary flow reserve, they enable a nuanced understanding of cardiovascular risks and conditions.

This valuable insight facilitates early intervention, personalized health optimization, and the development of targeted treatments in clinical settings, significantly advancing patient care and wellness initiatives.



Pulse Wave Analysis (PWA)

Pulse wave analysis involves analyzing the characteristics of the arterial pulse wave. It goes beyond traditional blood pressure measurements by providing valuable insights into the elasticity and compliance of arterial walls. These measurements (shown below) offer a more comprehensive understanding of vascular health and can aid in the early detection of cardiovascular risk.

Pulse wave analysis is widely used in cardiovascular research to investigate the impact of various interventions, medications, and diseases on arterial function. It contributes to a better understanding of the pathophysiology of cardiovascular conditions.

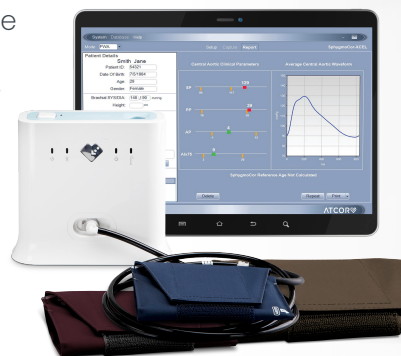
Pulse Wave Velocity (PWV)

Pulse wave velocity is the speed at which the arterial pulse travels through the circulatory system, specifically between two defined points, typically measured across the aorta. It serves as a key indicator of arterial stiffness, as stiffer arteries transmit the pulse wave more rapidly. Elevated PWV is associated with increased cardiovascular risk and is considered an independent predictor of adverse cardiovascular events.

Monitoring PWV is instrumental in assessing vascular aging and guiding interventions aimed at preserving or improving overall cardiovascular health.

Traditional Clinical Trials

SphygmoCor® XCEL offers precise, non-invasive measurements of vascular biomarkers including central blood pressure and arterial stiffness. By integrating these measurements into clinical trials, the device enhances the precision of patient selection and efficacy assessments, ultimately accelerating the development pipeline and improving the safety profile of new therapies.



Decentralized Clinical Trials

CONNEQT Pulse streamlines remote health data collection, gathering real-time physiological and vascular biomarker data without the need for participants to visit clinical sites. This approach enhances participant engagement, reduces logistical burdens, and expands participant reach to remote areas. By improving data quality and quantity while accelerating trial timelines, CONNEQT Pulse facilitates more adaptable, inclusive, and diverse clinical trials.



Capture Ambulatory Data

Oscar 2 excels as a leading ambulatory monitor, capturing vascular biomarkers continuously over 24 hours in non-clinical settings. By monitoring blood pressure dynamics and arterial health in real-world conditions, it enhances the reliability of vascular biomarker assessments, expediting the development of new therapies.



Clinical Trials Management

Our comprehensive clinical trial management service encompasses a suite of offerings tailored to streamline the collection and analysis of vascular biomarkers. From protocol design to data management and analysis, we ensure precise and efficient capture of vascular health data throughout your trial. Our cutting-edge technology enables real-time insights into patient responses, enhancing trial accuracy and accelerating the pathway to regulatory approval and market entry for new therapies.

With our expertise in clinical trial management and vascular biomarker analysis, we provide a seamless and efficient solution to meet your trial's needs, ensuring compliance with regulatory requirements and achieving scientific and medical objectives.



Design and Development

- **Study-Specific Protocols:** Creation of customized protocols tailored to the specific needs and goals of each clinical trial, ensuring compliance with regulatory standards and scientific rigor.
- **User Manuals and Training Materials:** Development of comprehensive user manuals and training materials to facilitate proper usage of trial equipment and adherence to protocols.



24/7 Study Support

- **Global Logistics:** Coordination of international logistics to ensure timely delivery and setup of trial equipment and supplies across multiple sites.
- **Training and Servicing of Devices:** Ongoing support for the training and maintenance of trial devices, ensuring optimal performance and minimizing downtime.



Training & Certification

- **Individual Protocol Training:** Customized training programs designed to meet the specific needs of each trial protocol, ensuring all personnel are adequately prepared.
- **Certification Programs:** Implementation of certification programs to validate the proficiency and compliance of trial staff, enhancing the credibility and reliability of trial outcomes.



Technical Expertise

- **Highly Trained Staff:** Access to a team of experienced professionals who have managed hundreds of clinical trials across various phases of drug and medical device development.
- **Specialized Knowledge:** Technical expertise in digital vascular biomarkers and advanced data analytics, providing valuable insights and support throughout the trial.



Comprehensive Data Management

- **Quality Control Processes:** Implementation of robust quality control measures to ensure data integrity and reliability throughout the trial.
- **Encrypted Global Data Transfers:** Secure and compliant data transfer processes to support global studies, ensuring data privacy and regulatory compliance.
- **Core Lab Services:** Provision of essential laboratory services, including sample analysis and data processing, to support the trial's scientific objectives.

Expert Assistance from Start to Finish

Planning

- Protocol Development
- Study Design
- Study Manual of Procedures
- Outsourcing Coordination
- QC Method Formation Development



Initiation

- Site Assessment
- IT Infrastructure Setup
- Trial Master File Setup
- Data Management Plan
- Site Quality Plan
- GCP Training



Startup

- Site Initiation
- Clinical Team Training
- Clinical Trial Equipment setup
- Equipment Logistics
- Site and Personnel Certification



Conduct

- Data Safety Monitoring and Management
- Ongoing GCP Training
- Clinical Team Training
- Clinical Trial Equipment Setup
- Equipment Logistics
- Site and Personnel Certification



Closeout

- Site Closeout
- Project Closeout
- Database Cleanup
- Database Lock
- Database Delivery
- Clinical Trial Report



