CLINICAL TRIAL SERVICES

Advanced Hemodynamic Assessment For Improved Insights

ATCOR

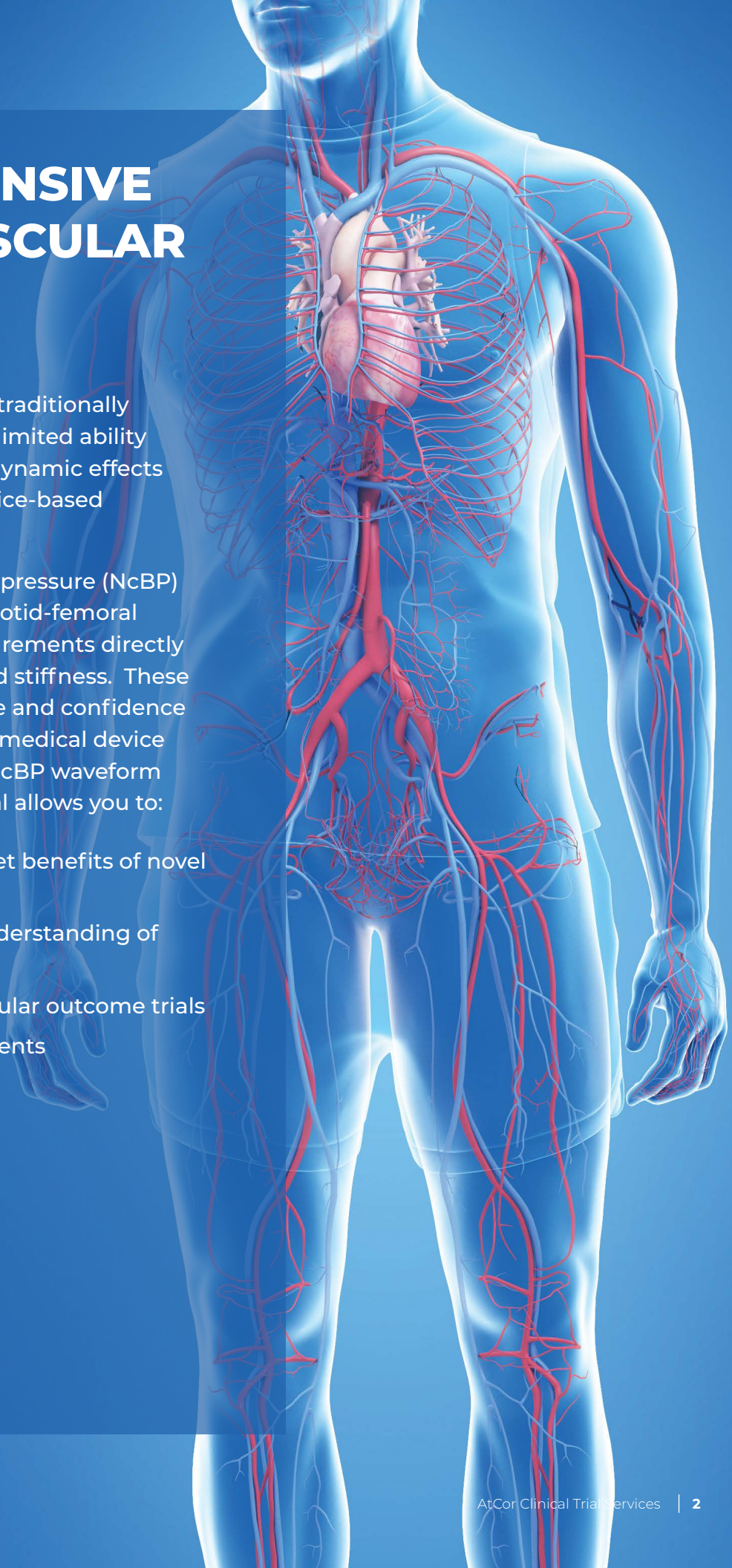
Personalized. Preventive. Precise.

COMPREHENSIVE CARDIOVASCULAR INSIGHT

Standard evaluation tools traditionally used in clinical trials have limited ability to characterize the hemodynamic effects of pharmacological or device-based interventions.

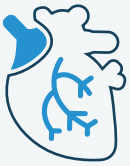
Noninvasive central blood pressure (NcBP) waveform analysis and carotid-femoral pulse wave velocity measurements directly assess aortic pressures and stiffness. These measurements bring value and confidence to drug development and medical device interventions. Including NcBP waveform analysis in your clinical trial allows you to:

- Assess potential off-target benefits of novel interventions
- Improve mechanistic understanding of medical interventions
- Inform future cardiovascular outcome trials
- Facilitate safety assessments



CLINICAL TRIAL SERVICES

WE PROVIDE A COMPREHENSIVE SUITE OF SERVICES FOR CENTRAL HEMODYNAMIC DATA COLLECTION FOR CLINICAL TRIALS



AtCor Technology

Central arterial PWA

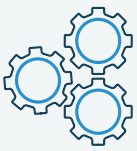
Carotid-femoral PWV

Ambulatory Blood Pressure Monitoring

Design & Development

Protocol design assistance

Study-specific user manuals and training materials



Data Management

Core lab data over-read/QA

Data transfers

Archiving

Implementation

Equipment logistics

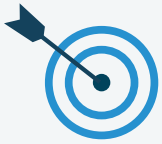
Simple, encrypted data transfer

24/7 site support

Training & Certification

Study-specific training

Operator certification



Technical Experience

Dedicated team of technical experts

15 years experience

Involvement in all phases of trial implementation

Therapeutic Experience

Hypertension, heart failure, chronic kidney disease, COPD, diabetes, gout and others.

WORLDWIDE PRESENCE

Our expertise in cardiovascular hemodynamic data collection has been demonstrated in clinical trials throughout the world in all phases of development, from single to several hundred site studies. Sponsors range from start-ups to top 10 pharmaceutical companies.

ATCOR TECHNOLOGY

SPHYGMOCOR® IS THE INDUSTRY STANDARD FOR NONINVASIVE CENTRAL BLOOD PRESSURE (NcBP) AND ARTERIAL STIFFNESS ASSESSMENT; VITAL DATA THAT DELIVER DEEP, INDIVIDUAL CLINICAL INSIGHTS

The SphygmoCor® XCEL System derives the central aortic pressure waveform using a standard blood pressure cuff. The procedure is easy to perform, reproducible, and can be seamlessly integrated into a clinical trial study visit.

The Oscar 2 with SphygmoCor® Inside ambulatory blood pressure monitor adds SphygmoCor® central aortic pressure waveform analysis to traditional ABPM.

SphygmoCor® XCEL **Oscar 2** *powered by SphygmoCor®*

THE CLINICAL TRIAL SERVICES TEAM PROVIDES EXPERTISE FOR A VARIETY OF TECHNOLOGIES

- Office pulse wave analysis (PWA) and brachial blood pressure
- Carotid-femoral pulse wave velocity (PWV)
- 24-hour ambulatory brachial and central blood pressure
- 24-hour ambulatory pulse wave analysis

All “Top 20 Hospitals” use SphygmoCor® technology to measure central blood pressure (cBP)

1,400+ studies using SphygmoCor® technology have been published in peer-reviewed clinical publications

8 out of Top 10 Pharma companies have used SphygmoCor® technology in their clinical trials

Over 11,000 patients have been tested with SphygmoCor® technology in pharmaceutical trials

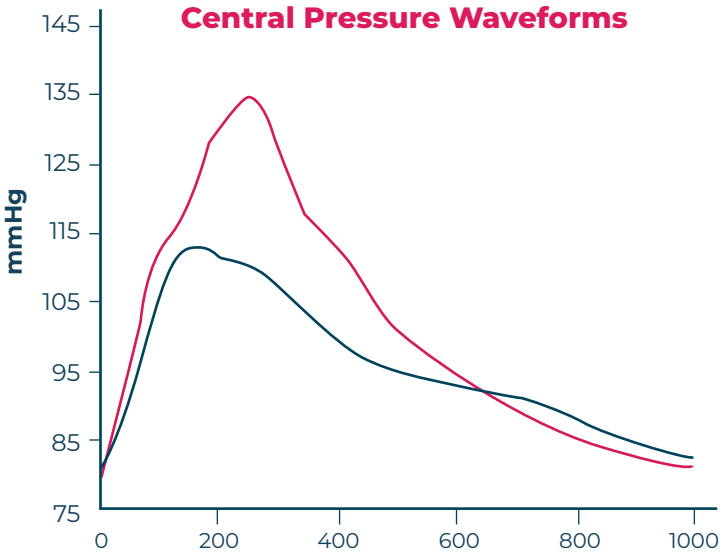
PULSE WAVE ANALYSIS (PWA)

SPHYGMOCOR® TECHNOLOGY ENABLES NONINVASIVE MEASUREMENT OF THE CENTRAL AORTIC PRESSURE WAVEFORM

The predictive superiority of central blood pressure over brachial blood pressure is primarily due to the proximity of the ascending aorta to important target organs such as the heart, brain, and kidneys.[1]

Three aspects of central arterial PWA are especially important:

1. Individual variability in the difference between central and brachial pressures can be significant and clinically important. [2-4]
2. Central pressures cannot be reliably inferred from brachial pressures. [2-4]
3. Medications may have significantly different effects on brachial blood pressure than on the central arterial pressure waveform. [5-7]



	Brachial BP	Central BP
Patient 1	140/80	136/80
Patient 2	140/80	115/82

Two patients with identical brachial blood pressures can have significantly different central waveforms and central pressure indices, leading to different treatment decisions.

PWA DATA ELEMENTS

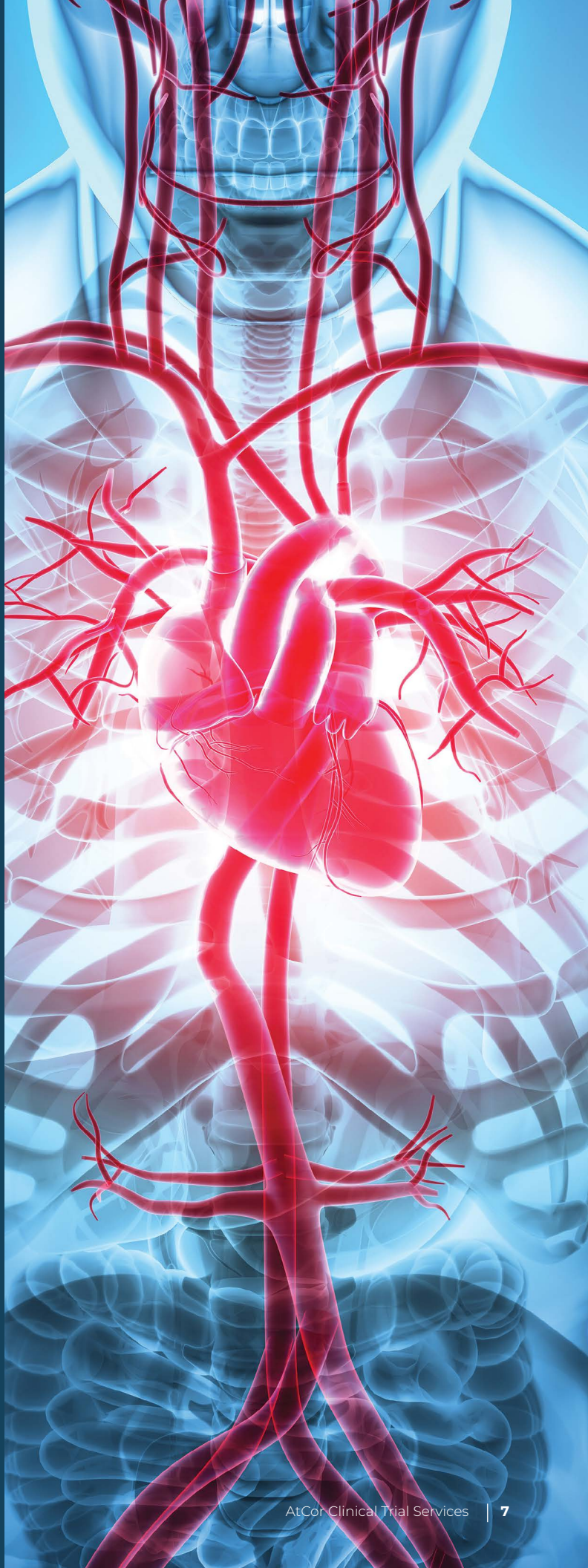
Key output parameters for the SphygmoCor® XCEL and the Oscar 2 with SphygmoCor® Inside include:

- Aortic Augmentation Pressure
- Aortic Augmentation Index
- Aortic Systolic Blood Pressure
- Aortic Diastolic Blood Pressure
- Forward Wave Amplitude
- Reflected Wave Amplitude
- Reflection Magnitude
- Mean Arterial Pressure

CAROTID-FEMORAL PULSE WAVE VELOCITY (PWV)

Carotid-femoral PWV is the AHA's recommended method for noninvasive measurement of arterial stiffness.[8] It is considered by many to be the most powerful cardiovascular risk factor and a valuable biomarker for cardiovascular risk prediction.

Elevated PWV (increased aortic stiffness) is a precursor to hypertension and its persistent elevation during treatment is associated with high risk for an adverse outcome in those with established disease.



SPHYGMOCOR® XCEL INTENDED USE

The SphygmoCor® XCEL System provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a Brachial cuff. It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. Additionally, the SphygmoCor® XCEL System automatically measures Systolic blood pressure and Diastolic blood pressure. The SphygmoCor® XCEL Pulse Wave Velocity (PWV) option is intended to obtain PWV measurements. The PWV option is used on adult patients only.

SPHYGMOCOR® XCEL REGULATORY APPROVALS

- FDA Clearance: Sphygmocor XCEL 510(k) NUMBER K122129
- EU CE Mark (MDD,ANNEX II, Class IIa)
- TGA, Australia
- EN/IEC 60601-1 / Electromedical Equipment Safety Standard
- EN/IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility
- IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

REFERENCES

1. Hashimoto J. Tohoku J Exp Med 2014;233:1-8. **2.** O'Rourke et al. Br J Clin Pharmacol 2001;51:507-22. **3.** Sharman JE et al. J Hum Hypertens 2008; Dec 22(12):838-844. **4.** McEniery et al. Hypertension 2008; 6(51):1476-1482. **5.** Protogerou, AD et al. Curr Pharmaceut Des 2009; 15:272-289. **6.** McEniery, CM. Current Hypertension reports, 2009; 11:253-259. **7.** Townsend, RR et al. J Clin Hypertens 2015 Jul; 17(7):503-13. **8.** Townsend,RR et al. Hypertension 2015 Sep; 66(3); 698-722.

TO LEARN MORE

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ATCOR
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