MEDPACE

Q&A WITH CARDIOVASCULAR EXPERT, DR. SATYA SHREENIVAS

Dr. Satya Shreenivas is an interventional cardiologist with over 10 years of experience in clinical practice, academia, and clinical research. He has clinical experience in the cardiology space including coronary, structural heart, and heart failure care. Dr. Shreenivas has served as the section head of the catheterization lab and the director of the structural heart program at The University of Cincinnati. He is a key opinion leader with over 50 publications, books, and abstracts; he frequently presents at national cardiology conferences.

Tell us a little bit about your cardiovascular background and background in clinical development.

I am an interventional cardiologist with expertise in coronary and structural heart procedures. I trained at the University of Pennsylvania, was the section head of the catheterization lab and the director of the structural heart program at the University of Cincinnati, and have been sub-I or PI on roughly 50 cardiology clinical trials over the last 3-4 years.

In addition to the clinical and academic work, I found myself spending a lot of time on the question: how can we improve healthcare delivery? If you have the best doctors, nurses, pharmaceuticals, and devices but can't get them to the patient, healthcare doesn't work. I went back to school to learn; I went to Wharton to focus on healthcare innovation and received an MBA with a major in Entrepreneurship and Innovation.

The combination of clinical work and the additional education opened doors to working with startups – both medical devices and health technology. I have helped early-stage medical device companies with both product development (clinical needs, regulation, trial strategy, site selection) and business development (reimbursement, introduction to suppliers and commercial partners). I have also worked on product development for health tech startups focused on virtual healthcare, wearables, hospital at home, voice-first healthcare, and novel electronic medical record systems. Finally, I have experience on the finance side as a member of the investment team of a growth-stage healthcare-focused venture capital firm.

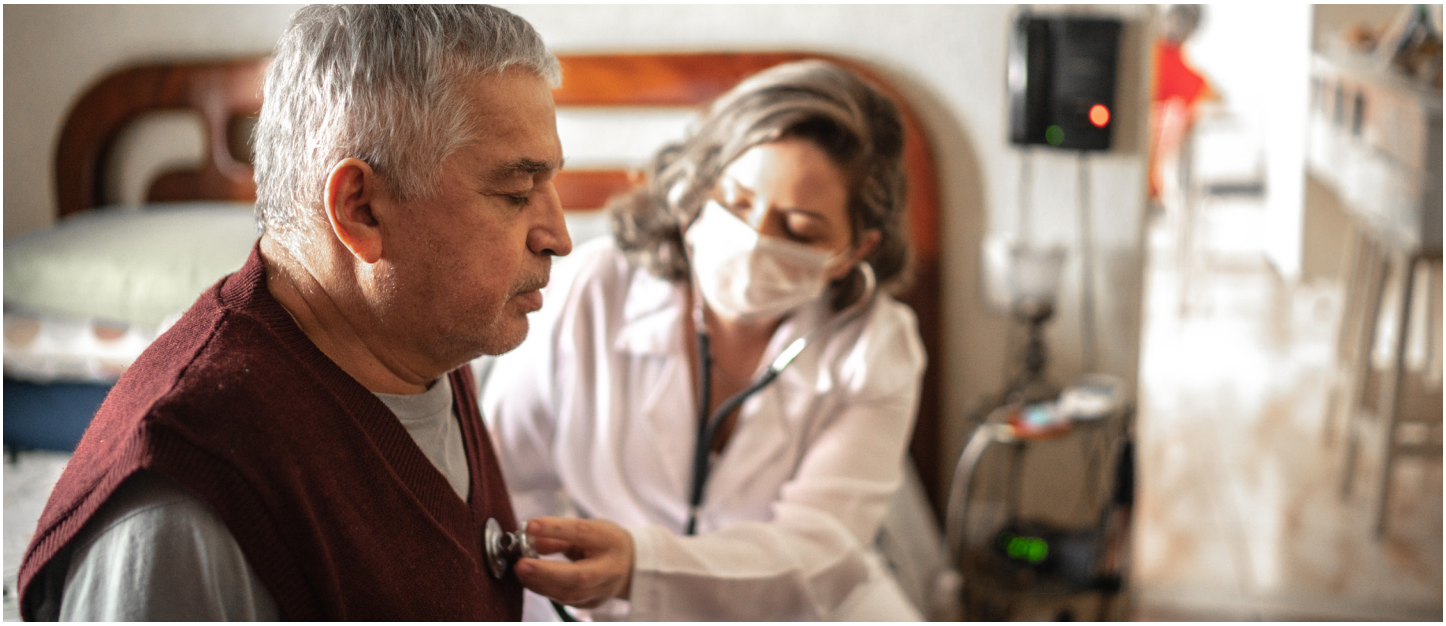
The combination of the clinical, operational, and finance work lead me to the realization that the biggest risk many healthcare startups face is the scientific risk. If we could be better at the operation of answering the scientific risk, namely executing clinical trials better, we could generate tremendous value for medical startups. I joined Medpace to apply my expertise in scientific risk asesssment, directly to clinical trails by our sponsors.

What are some challenges, considerations, and risks that are specific to cardiovascular device and cardiovascular imaging?

Cardiovascular trials are challenging but also rewarding. Many therapeutic areas like infectious disease, nephrology, and oncology are pharmaceutically oriented. Cardiovascular trials are a broad group of trials that encompass pharmaceutical, device, and technological development. With cardiology it's not just pharmaceuticals (lipid lowering drugs, anti-hypertensives, novel therapies for amyloid, gene therapy, etc.); it's not just devices (heart failure therapies, new heart valves, wearable device-based treatments for resistant hypertension); and it's not just technology (remote patient monitoring and platforms for monitoring cardiac side effects for non-cardiovascular therapies) – it's all three.

Another challenge is that there's always a risk factor with cardiac issues in all clinical trials. Heart disease is the number one killer of people and affects even non-cardiology trials. For example, early phase clinical trials in oncology always examine the cardiac safety of the drug. But in cardiovascular trials, we don't typically worry about cancer risk from the therapy.

The wide prevalence, the fact that it affects even non-cardiac studies, and the fact that you need to have expertise around device, pharma, and technology aspects makes it a unique service line. Medpace excels in these areas because we have clinical expertise in the care of these patients as well as clinical trial experience in many of these therapeutics, in both clinical operations



and imaging. Medpace has a cardiovascular core lab with expertise in both cardiac safety monitoring and imaging seamlessly coordinates management of both kinds of assessments. This two-part expertise, clinical and operational, is key to the successful execution of a clinical trial.

How does imaging play a key role in cardiovascular research and what should a Sponsor look for in a partner?

I believe there are two forms of expertise in cardiovascular imaging. First, clinical expertise in a wide variety of imaging/monitoring: in-person, remote/virtual, EKG, echocardiogram, stress, MRI, molecular imaging, and understanding which type of imaging is best utilized for the given IP and indication. Second, the coordination amongst the imaging modalities and the other trial operations.

There are unique measurements that are well established but are not routinely done in many imaging laboratories, especially when looking at novel cardiac devices such as new heart valves or therapies designed for heart failure. Having a CRO with expertise in these measurements is key to making sure that studies are done with the rigor expected for the evolving device industry. Understanding how to measure the size of the heart valve of aortic regurgitation, severity around heart valves, the depth of implant, annulus size, and how to look for complications are all unique subsets in a field that's rapidly changing. We didn't even have percutaneous heart valves 12 to 14 years ago, so over the last decade we've seen remarkable progress in cardiac devices. The expertise to appropriately study those devices is added value that Medpace brings to our sponsors. Being at the forefront of this technology is something in which one can take pride.

What do you see in the future for trends in cardiovascular clinical trials?

Pharmaceutical and device trials are growing in complexity and number as the burden of cardiovascular (CV) disease continues to increase world-wide. Additionally, cardiovascular monitoring for non-CV trials is a growing area. We must consider cardiac imaging in non-cardiology areas, especially oncology and infectious disease. For example, an oncology therapeutic might need an echocardiography core lab to monitor for side effects.

The move toward remote monitoring (really, the push towards all things remote in our lives) involves gaining expertise in remote cardiovascular monitoring. Successfully gaining and implementing this expertise will be very important as we move forward. Patient recruitment for non-cardiac therapies might benefit from remote cardiovascular monitoring to improve patient compliance and trial retention. These cardiac tools and our ability to innovate and offer multiple therapies specific to each trial's need makes us flexible and improves the quality of the trial for our Sponsors.

What motivates you and your interest in clinical research – particularly in cardiovascular research?

I love helping founders of healthcare startups realize their vision of improving our health. Also, cardiovascular disease is still the number one source of morbidity and mortality in many parts of the world. Helping bring new therapeutics to treat cardiac disease has the potential to make a tremendous difference in our world. Successful execution will involve effectively managing the biggest risk to these startups, which is the scientific risk. If we can improve clinical trial operations and augment Sponsor team knowledge with our clinical expertise, we can help take concepts to a successful commercial product that will improve health.

Since our inception, Medpace been partnering with emerging biotechs to help accelerate clinical development. Our strong background in imaging and our deep experience with a wide variety of cardiovascular uniquely positions Medpace to support cardiovascular biotech startups succeed startups.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical, and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system , and anti-viral and anti-infective.