MEDICAL METRICS BACKGROUND

MMI is an FDA-registered, ISO-certified provider of independent Imaging Core Laboratory services for multi-center clinical trials. Our services include imaging protocol development, medical image analysis, data management and scientific consulting. Since 2000, we have supported over 300 studies of Class III medical devices, biologics and surgical procedures. Over a third of these have been FDA-regulated. Another third have been international studies spanning more than 40 countries on six continents. We also support many pre-clinical and post-market studies resulting in important product advances and scientific publications.

METHODIST DEBAKEY AFFILIATION

Through partnership with the world-renowned Methodist DeBakey Heart and Vascular Center (MDHVC) in Houston, Texas, we provide access to leading experts in vascular, valvular, aortic and coronary artery disease and treatment. Our experts are recognized leaders in cardiovascular, cardiothoracic and peripheral vascular medicine. They include editors of high-impact journals, presidents of major professional societies, division chiefs of surgery, advisors to FDA and lifetime achievement awardees. Our depth and diversity of experts allows us to provide support for *all* major diagnostic imaging modalities in a *single* core lab. Our imaging expertise includes cardiac echo, duplex, angio, MRA, CTA, IVUS, OCT and nuclear medicine.

EXPERTISE IN CARDIAC ECHO

Our medical director for cardiology trials is Dr. Miguel Quiñones, Chair of the Department of Cardiology at The Methodist Hospital in Houston and an internationally-recognized expert in cardiac ultrasound. He is a pioneer of methods for quantitative assessment of left ventricular function and a Lifetime Achievement Award Winner from the ASE. Other experts include Dr. William Zoghbi and Dr. Sherif Nagueh. Dr. Zogbhi is the Chief of Cardiac Imaging at The Methodist Hospital in Houston and a former president of the ASE *and* ACC. Dr. Nagueh is a board member of the ASE and the International Commission for Accreditation of Echocardiography Laboratories. Short bios for these and other experts are provided on the following page.

As evidence of our clinical leadership in echocardiography, key publications authored by MDHVC experts are listed below. These articles feature published recommendations, standards and guidelines on cardiac imaging endorsed by major cardiology societies.

- Nagueh SF, *et al*. **Recommendations for the evaluation of left ventricular diastolic function by echocardiography.** *JASE* 2009; 22:107-33 and *EJE* 2009;10:165-193
- Quiñones MA, *et al*. **Recommendations for Quantification of Doppler Echocardiography: A Report From the Doppler Quantification Task Force of the Nomenclature and Standards Committee of the American Society of Echarcardiography**. *JASE* 2002;15(2):167-84
- Zoghbi, *et al.* **Recommendations for Evaluation of Prosthetic Valves with Echocardioagraphy and Dopper Ultrasound**. *JASE* 2009; 22:975-1014
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- Nagueh SF, *et al*. **American Society of Echocardiography clinical recommendations for multimodality cardiovascular imaging of patients with hypertrophic cardiomyopathy: Endorsed by the American Society of Nuclear Cardiology, Society for Cardiovascular Magnetic Resonance, and Society of Cardiovascular Computed Tomography.** *JASE* 2011; 24:473-498

MEDICAL DIRECTORS & REPRESENTATIVE EXPERTS

The following cardiologists and vascular surgeons are representative of the experts and key opinion leaders available to consult on protocol design, study planning, execution, data interpretation and post-study publication through MMI.

- **Miguel Quiñones, M.D., FACC – Medical Director**

  - Chairman of the Department of Cardiology at the Methodist Hospital, Houston, Texas
  - 32 years' experience in clinical research, practice and teaching
  - Widely recognized pioneer in the field of cardiac ultrasound
  - Recipient of national and international recognition for his contributions in the field of echocardiography
  - Developed echocardiographic methods that are now the standard of care to measure left ventricular volumes and ejection fraction, cardiac output, regurgitant fractions in mitral and aortic insufficiency, and valve area in aortic stenosis
  - More recently developed methods to evaluate diastolic function and estimate left ventricular filling pressures
  - More than 185 manuscripts in peer-reviewed journals, 12 book chapters and 225 published abstracts

- **Sherif Nagueh, M.D., FACC, FAHA, FASE**

  - Practicing cardiologist and Medical Director of the Echocardiography Laboratory at the MDHVC
  - Board certified in cardiovascular disease with subspecialty certification in echocardiography
  - Specialist in cardiac imaging and hypertrophic cardiomyopathy and an active researcher in these areas
  - Author of published guidelines and recommendations on cardiac imaging endorsed by cardiology societies
  - Board member of the International Commission for Accreditation of Echocardiography Laboratories (ICAEL)
  - Editorial board member of *Circulation*, the *Journal of the American College of Cardiology* (JACC), *JACC Imaging*, *Clinical Science*, *Cardiosource*, *Journal of the American Society of Echocardiography* (JASE) and others
  - Authored nearly 200 scientific articles and book chapters as well as many invited lectures internationally

- **Alan Lumsden, M.D., ChB, RVT, FACS – Medical Director**

  - Professor of Cardiothoracic Surgery, Weill Cornell Medical College
  - Chair of Cardiovascular Surgery and Medical Director of MDHVC, The Methodist Hospital
  - Past President of the Society of Clinical Vascular Surgery
  - Recognized leader in endovascular surgery and novel treatments for peripheral vascular disease
  - Expert in stent grafting, endarterectomy and minimally invasive venous disease therapies
  - 200+ publications as well as numerous abstracts, books, book chapters and presentations

- **Neil S. Kleiman, M.D., FACC**

  - Professor of Cardiothoracic Surgery, Weill Cornell Medical College
  - Director of the Cardiac Catheterization Laboratories, MDHVC, The Methodist Hospital
  - Expert in interventional cardiology, angioplasty, stenting and coronary artery disease
  - Editorial board member of many leading journals including *Circulation*, *American Heart Journal*, *JACC*, *Journal of Interventional Cardiology* and *European Heart Journal*
  - Principal or associate investigator on more than 125 research studies and clinical trials
  - 325 peer-reviewed journal articles, 17 book chapters, 1 book and 150 scientific abstracts

- **William Zoghbi, M.D., MACC, FAHA, FASE**

  - Director of the Cardiovascular Imaging Institute and Chief of Cardiac Imaging at The Methodist Hospital
  - Past President of the American College of Cardiology and the American Society of Echocardiography
  - Recognized leader in the field of cardiovascular imaging and echocardiography
  - Developer of numerous techniques for non-invasive evaluation of diastolic function with Doppler echo and detection of ischemic heart disease with stress and contrast echo
  - Author of key recommendations on the evaluation of prosthetic valves and native valvular regurgitation using echo
  - Associate Editor of *Circulation* and *JACC-Cardiovascular Imaging*
  - Over 200 scientific papers in major cardiovascular journals; delivered hundreds of invited lectures worldwide

***SAMPLE* PUBLICATIONS BY MMI-MDHVC EXPERTS FEATURING CARDIAC ECHO** *[full bibliography available upon request]*

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