Medical Metrics Selected as Imaging Core Lab for Multiple FDA Metal-on-Metal Hip Studies

The Associated Press

HOUSTON--(BUSINESS WIRE)--Dec 11, 2012--Medical Metrics, Inc. (MMI), a leading provider of imaging core lab services for orthopedic clinical trials, has been selected by five leading orthopedic device manufacturers to support multiple cross-sectional, post-market, FDA surveillance studies of metal-on-metal (MoM) hip implants. MMI will independently evaluate radiographs and MRI to assess long-term outcomes in patients implanted with MoM hips. Over 2,000 subjects will be evaluated at one to ten years post-implantation.

The goal of these studies is to comply with the FDA’s 522 order requiring manufacturers of MoM hip implants to conduct clinical surveillance of the effect of device wear in implanted patients. Rates of reaction to metal wear debris are of particular interest in patients with MoM implants. Reactions are assessed from clinical examination, MRI, and blood tests of metal ion concentration. MMI developed the MR imaging sequences and analysis protocols that will be used for these studies. At this time, two studies have been approved to begin enrollment, and the others are expected to be approved soon.

MMI’s imaging experts integrated current scientific knowledge with prior clinical experience to develop the imaging sequences for assessing the tissues around the implants. Dr. Timothy Mosher, Orthopedic Faculty Director at MMI and Chief of Musculoskeletal Radiology at Penn State College of Medicine, oversaw development of the specialized sequences. Using MRI to assess soft tissue reactions around metal implants can be challenging due to artifact that may obscure the periprosthetic tissues. MMI's technical expertise and knowledge of current advances in clinical MRI played a key role in developing the Metal Artifact Reduction Sequences (MARS) that will be used in these studies.

“Data from carefully-designed imaging studies will advance our knowledge and understanding of the long-term performance of MoM hip implants,” says Dr. Mosher. “Coordinating multiple studies through a single core lab using a standard analysis protocol will provide a unique opportunity for harmonization. By using a common framework to collect and evaluate data on local tissue response, results may be pooled and compared across studies. Ultimately, this level of harmonization will improve our understanding of patient outcomes and provide important data for improving patient management.” MMI is proud to be the imaging core lab selected by leading orthopedic sponsors to support these important studies.

About Medical Metrics Medical Metrics, Inc. (MMI) is an ISO 9001:2008 certified provider of independent imaging core lab services for clinical trials of medical devices, drugs, and biologics. For more than 10 years, MMI has partnered with clinical trial sponsors to conduct comprehensive imaging evaluations of treatments

for musculoskeletal, cardiovascular, and neurological disorders. Trials range from pre-clinical and early-phase clinical testing to pivotal studies and post-approval surveillance. With an ISO-certified quality management system, 510(k)-cleared image management platform, and core group of radiology and cardiology thought leaders, MMI is uniquely positioned to deliver high-quality image management and review services for global clinical trials. For more information, please visit www.medicalmetrics.com [1].

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