

Medstreaming/M2S and the Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) Partner to Help Device Manufacturers Meet European Union Medical Device Regulations (EU MDR)

Redmond, WA and Chicago, IL – February 26, 2019, Medstreaming/M2S, a leading performance management solutions company that offers innovative technology and services for healthcare providers, medical societies, and industry partners, has collaborated with the Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) to provide real-world evidence data to help device manufacturers meet regulatory requirements, including the new European Union Medical Device Regulations (EU MDR).

One of the biggest challenges of the EU MDR is the active Post-Market Clinical Follow-up required to establish safety and performance during the total product lifecycle of a device. Manufacturers must report such data to maintain the CE mark for each device by May, 2020. The first project to utilize data from this collaborative effort provided Abbott with EU MDR reports for 10 of their vascular devices.

“As we sought data to meet the upcoming EU MDR requirements, we were pleased to learn that the SVS VQI registry was collecting the required data for many of our devices, with sufficient detail to allow appropriate reporting. We appreciated the speed and thoroughness with which the SVS VQI and Medstreaming/M2S were able to prepare these sophisticated EU MDR reports. Their attention to detail, quality data checks, and emphasis on clinical implications are consistent with what medical reviewers at Notified Bodies are requesting.” said David R. Rutledge, Pharm D, Director, Global Regulatory Operations, Abbott Medical Devices.

“VQI recognizes the importance of supporting manufacturers and regulators, both domestic and international, to ensure the safety and performance of vascular devices currently being used in daily practice. We were pleased to collaborate with Abbott Laboratories and Medstreaming/M2S to produce these first reports, which are designed to meet the needs of EU MDR. In addition to fulfilling our mission of assessing the safety and efficacy of vascular devices, funding from such projects helps the SVS VQI enhance quality improvement efforts and make improvements to its existing registries” said Jens Jorgensen, MD, Medical Director of the SVS VQI.

Medstreaming/M2S and the SVS VQI plan to broaden their offering of analyses in the Industry Insights platform to support EU MDR for all vascular device manufacturers. For devices not captured in registries, Medstreaming/M2S will work with both enterprise EMR users and outpatient interventional practices to obtain data required for EU MDR reporting.

“Because not all medical devices are captured in registries, additional data sources will be required to support our industry partners,” said Wael Elseaidy, PhD, CEO Medstreaming/M2S. “At Medstreaming, we have the unique opportunity to collaborate with users of our vascular and cardiac information system in both hospitals and physician offices to capture additional device data not found in registries. We can also capture such information from other EMR systems with our new data abstraction technology. This additional data can be added to the existing registry data and then be made available for analysis.”

In addition, Medstreaming/M2S is collaborating with the SVS VQI and the Society for Vascular Ultrasound to incorporate images into existing clinical data registries, which provides opportunities for full device trials and surveillance to be embedded within registries.

“We understand the challenges faced by manufacturers in collecting real-world clinical follow-up data about ALL their devices,” said Jack Cronenwett, MD, CMO Medstreaming/M2S. “We also recognize that some companies are now facing the removal of currently CE-marked devices from the European market

if they cannot access needed data. We believe that data derived from Medstreaming's collaborative efforts with the SVS VQI and other medical societies will become a primary data source for medical device manufactures to address their current and future regulatory challenges world-wide".

About Medstreaming-M2S

Medstreaming/M2S: Medstreaming has developed a full-service cardiovascular information system that collects structured data by the clinical workforce during the process of care and generates clinical reports and directly transfers data needed for registries. M2S has developed vascular imaging services, core laboratory function, and a sophisticated medical registry platform. Medstreaming acquired M2S in 2016 and the two companies now provide a comprehensive real-world evidence platform that offers innovative technology and services for healthcare providers, medical societies, and industry partners to manage clinical information and use that information to improve the quality of patient care and reduce costs. For more information, visit www.medstreaming.com.

About the Vascular Quality Initiative

The Vascular Quality Initiative®, a joint venture of M2S Inc. and the Society for Vascular Surgery, collects and analyzes data to improve the quality of vascular care. Currently, VQI has over 500 facilities and 3,000 physicians participating, and 500,000+ vascular procedures reported. Its 12 clinical registries are Carotid Endarterectomy, Carotid Artery Stenting, Open AAA Repair, Endovascular AAA Repair, TEVAR and Complex EVAR, Infra-Inguinal Bypass, Supra-Inguinal Bypass, Lower Extremity Amputation, Peripheral Vascular Intervention, Hemodialysis Access, Inferior Vena Cava Filter, Varicose Vein and Vascular Ultrasound. VQI is a collaboration between regional groups that use a Patient Safety Organization and the M2S PATHWAYS cloud-based system. For more information, visit www.vqi.org.

About the Society for Vascular Surgery

The Society for Vascular Surgery® (SVS) is a 6,100-member, not-for-profit professional medical society, composed of specialty-trained vascular surgeons and professionals, which seeks to advance excellence and innovation in vascular health through education, advocacy, research and public awareness. For more information, visit www.vascular.org.

About Abbott

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 99,000 people. Visit Abbott at www.abott.com and connect with us on Twitter at @AbbottNews.

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