MEDSTREAMING IS THE 1ST HEALTHCARE IT COMPANY TO INTEGRATE GUDID (GLOBAL UNIQUE DEVICE IDENTIFICATION DATABASE) IN THE CVIS (CARDIOVASCULAR INFORMATION SYSTEM) DOMAIN

A huge step toward registry-based clinical trials, announced during the 2016 RAPID Think Tank meeting at the FDA headquarters

Sep. 14, 2016, FDA Headquarters, White Oak Campus, Silver Spring, MD

Medstreaming became the 1st healthcare IT company to integrate GUDID (*Global Unique Device Identification Database)* in the CVIS (Cardiovascular Information System) domain. The announcement took place on September 14, 2016 during the RAPID Think Tank meeting at the FDA headquarters in Silver Spring, MD.

RAPID (Registry Assessment of Peripheral Interventional Devices) is part of MDEpiNet.The Medical Device Epidemiology Network Initiative (MDEpiNet): A Public-Private Partnership is part of the Epidemiology Research Program (ERP) at the FDA's Center for Devices and Radiological Health (CDRH).

MDEpiNet is bringing together leadership, expertise, and resources to build and operate a national device ecosystem supporting the development, regulation, and use of innovative medical devices.

MDEpiNet collaboratively provides tools including:

- Study design for distributed network based research collaboration.
- Advanced analytical overall methods such as multilevel analyses (hospital, surgeon, patient).
- Advanced analytical methods for confounding adjustment – propensity scores, instrumental variables.
- Cross design syntheses and Bayesian methods.
- Tools to help in strengthening relationships and stakeholder development.

Medstreaming to be the 1st healthcare IT company to integrate GUDID database in the CVIS domain is a huge step toward registry-based clinical trials.

Ahmed Saad, PhD, Medstreaming VP of Engineering and R&D while giving Medstreaming presentation during the 2016 RAPID Think Tank Meeting

Related Links

- RAPID Think Tank 2016 Meeting Agenda
- Medstreaming Presentation
- SVS/VQI Presentation

About RAPID Initiative

The Registry Assessment of Peripheral Interventional Devices **(RAPID)** project emerged from the **P**redictable **A**nd **S**u**S**tainable **I**mplementation **O**f **N**ational (**PASSION**) **R**egistries for **C**ardiovascular **D**evices program of the **M**edical **D**evice **E**pidemiology **N**etwork (**MDEpiNet**), a public-private partnership supported by the U.S. FDA to advance the nation's approaches to the evaluation of medical devices. It is one project in a series initiated to advance and demonstrate the interoperable flow of data and information across electronic health information systems as a precursor to the National Evaluation System for Health Technology (NEST) articulated by Drs. Shuren and Califf[1]. The MDEpiNet RAPID project designed to advance the foundational elements of a total product lifecycle (TPLC) approach for the evaluation of medical devices used to treat and manage peripheral artery disease.

RAPID is focused on devices for peripheral arterial intervention as an archetype of the envisioned TPLC ecosystem. Standard data elements related to the care and treatment of patients with peripheral artery disease are being developed for use with data elements from the **G**lobal **U**nique **D**evice **I**dentification **D**atabase (**GUDID**) database to create a structured dataset that supports pre- and post-market assessment, quality improvement, and safety surveillance of peripheral interventional devices (Phase I). Subsequent phases will validate the potential of the data elements for implementation in various healthcare information systems such that structured, interoperable data is collected at the point of care and is available for use by patient registries, clinical research and medical device evaluation initiatives. Additionally, the **RAPID** data elements will inform the development of a global case report form and data collection instruments needed in the interim. As such, this work facilitates peripheral interventional device development, addresses regulatory needs, and creates efficiencies that will reduce overall time and costs and support quality improvement efforts across the medical device lifecycle.

[1] Shuren J and Califf RM, Need for a national evaluation system for health technology. JAMA – published online July 11, 2016. doi:10.1001/jama.2016.8708.

Source: http://mdepinet.org/rapid/

About MDEpiNet

he Medical Device Epidemiology Network Initiative (MDEpiNet) is part of the Epidemiology Research Program (ERP) at the FDA's Center for Devices and Radiological Health (CDRH). The initiative is a collaborative program through which CDRH and external partners share information and resources to enhance our understanding of the safety and effectiveness of medical devices after they are marketed.

By bridging gaps in evidence, developing datasets and creating new methods of conducting robust analytic studies, MDEpiNet aims to develop new ways to study medical devices that improve the understanding of their safety and effectiveness throughout their life cycle.

CDRH is developing MDEpiNet in stages, with the expectation that it will ultimately become a self-sustaining, independent Public-Private Partnership between the FDA and participating partners. By providing more complete and accurate information on device use and performance, MDEpiNet will help the FDA, the medical device industry, medical professionals, and the American public make better, more informed health care decisions.

Sources: http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm , http://mdepinet.org

About Medstreaming®

Many challenges confront the medical industry due to an extremely fragmented data management environment. To address this fragmentation, Medstreaming created a Specialty-Based Cardiovascular, Vascular, and Radiology health workflow application which functions as a high performance layer in the inpatient workflow, tightly integrated with electronic medical records (EMR). Using this clinical workflow expertise, Medstreaming has also developed the industry's first "All in One" integrated platform application that runs as an outpatient EMR, image management & reporting, and practice management workflow solution. All Medstreaming solutions act as aggregators for structured and non-structured clinical data, which

in turn creates powerful data service offerings for multi-purpose, web based, data mining and data analytics. Medstreaming is headquartered in Redmond, WA. For more information, visit www.medstreaming.com.

About M2S®

M2S provides technology and services to the healthcare industry to manage clinical information, reduce costs, and improve the quality of patient care. Our extensive experience in medical imaging, data management, and outcomes analysis has positioned us as the leader in providing cost-effective, innovative healthcare performance management solutions to our customers. Through our M2S PATHWAYS clinical data performance platform, we support multiple medical specialty societies and their members by providing comprehensive tools for clinical data management, clinical outcomes assessment, and research needs. This secure, cloud-based solution enables physicians, institutions, and researchers to collect, manage, analyze, and disseminate their clinical data to achieve optimal outcomes. For more information, see www.m2s.com

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