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FOR IMMEDIATE RELEASE: 9/13/19

Strategic Partnership Announcement – TrackMy Solutions and Device Events Partnering on a Proactive Approach – Leveraging Adverse Event Data Prior to a Recall



KANSAS CITY, MO, September 13th, 2019

As TrackMy Solutions continues to grow our market footprint around implantable medical device recall tracking, and focusing on the e2i2 of healthcare (Engage, Educate, Inform, Involve), it is very important to continue to innovate and think outside the box around a central goal of increasing patient safety. We are announcing a Strategic Partnership with:

Device Events - Founder – Madris Tomes; DeviceEvents.com

Today, (the simplistic understanding) there are two paths a medical implant gets recalled – an FDA mandated recall and/or a device manufacturer voluntary recall. Through TrackMy technology, we are well positioned to notify patients, care teams, surgeons, hospitals once a device recall takes place (assuming we are working with said care team, surgeon, hospital, or a patient takes it on themselves to create a free account at trackmyapp.us and inputs/stores their medical device information), however there are a lot of complications that arise for patients prior to an actual recall taking place – this is where the tracking and usage of adverse event data is very important (an adverse event in this market is defined as a medical implant device product problem experienced by a patient/provider).

There can be thousands of adverse events reported to the FDA prior to an enforcement action taking place (there is no set threshold of events, yet history tells us that the more adverse events start to be logged a product eventually leads to being recalled; enforcement action can be a recall or a withdrawal of a product from the market). 2/3 of recalls begin as adverse event reports, making these reports the most critical tool to early identification of a product problem. On average, the FDA takes 2 months to 2 years to identify a product problem and take enforcement action. In those 2 years, the products continue to be used by providers and patients.

Device Events focuses on adverse events, and leverages this data to improve patient outcomes, gain strategic insight into medical device options, and manage overall risk by identifying adverse event reports submitted by other providers/patients. TrackMy and Device Events are partnering to leverage the power of adverse event data, and build algorithms/use cases to be proactive around increasing patient safety and overall improve outcomes. This innovation and partnership will only help us be better in serving our marketplace and our vision. The time is NOW to make a positive change in healthcare, and increase safety!

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About Device Events

Device Events, LLC offers online software and services that provide clients with the adverse event reporting history and trends for medical devices. Our online software service quickly and easily extracts medical device adverse event reports (MDRs) and alternative summary reports (ASRs) submitted to the FDA. MDRs are submitted by patients, healthcare providers, lawyers, and manufacturers daily and are accumulated by the FDA. The current FDA MAUDE database has over 8.5 million adverse event reports, and approximately 85,000 new reports are added each month.

Device Events offers clients in need of important medical device data the following services:

- Online Subscription Software Service
- Medical Device Post-Market Surveillance Report Services
- Expert Witness Services

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TrackMy Solutions Team