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Diabetes Study Using the EmpiraMed™ PRO Portal™ Platform to Capture Real World Patient Experience Published in the Journal of Diabetes Science and Technology

Study Participants Averaged 5 eDiary PRO Portal Entries per Person per Week

Maynard, MA — October 30, 2017 — EmpiraMed, Inc., a leader in the field of patient engagement software to capture real world evidence, today announced that our Chief Medical Officer, Neil Minkoff MD, has co-authored a paper, "A Pilot Observational Study of Hypoglycemia: Patient Reporting Using a Web-Based Portal Compared to Paper Surveys" which has been published by the *Journal of Diabetes Science and Technology (JDST)*. This post-market, observational, real world study is also available on PubMed, the NIH's online study library. The lead author and Principal Investigator was Kalyani Murthy MD MS of Lahey Hospital and Medical Center (LHMC). EmpiraMed contracted with LHMC to perform this pilot observational study funded by Merck Sharp & Dohme, a subsidiary of Merck & Co, Inc., Kenilworth, NJ USA.

The literature in diabetes has established rates of severe hypoglycemia, while real-world rates of mild and moderate hypoglycemia are not well documented. This 100 subject post-market, non-interventional, observational pilot study was to investigate approaches for capturing real world hypoglycemic events and weight gain in adults with Type 2 diabetes Mellitus (T2D) and to evaluate the effectiveness of the EmpiraMed™ PRO Portal™ Software Platform (Portal) to assess and document hypoglycemia.

According to co-author Dr. Minkoff, "We are very happy to note that the use of the EmpiraMed PRO Portal in this study was integral to this publication in the *Journal of Diabetes Science and Technology*. EmpiraMed contributes to clinical research through its technology and methods to

improve patient engagement. What we found in this particular study is that our PRO Portal leads to high levels of study compliance.”

Despite over half of the study participants being 65 years of age or older, the patients in the study used the PRO Portal eDiary 5 times per week, on average, to report their health related experiences. The mean time between eDiary entries was only 2.7 days. Also, the electronic surveys issued through the PRO Portal had no missing responses; there was a 0% missed response rate for the electronic surveys. In comparison, the two paper surveys completed at the healthcare clinic at the start and end of the study had 7% and 14%, respectively, missed response rates. In addition, 87.6% of the study participants found the PRO Portal electronic surveys “easy to use.”

Real world, observational studies may provide the healthcare industry with a cost-effective way to measure the impact of under-reported or undocumented patient experiences, such as mild to moderate hypoglycemia. While almost 40% of patients in this study reported at least one episode of hypoglycemia, most episodes had little or no interruption in patient daily activities. This lack of effect on activity indicates that these events were mostly mild to moderate episodes of hypoglycemia, which are usually not found in the clinical record or claims data. The most commonly reported symptoms of hypoglycemia in this study were shakiness, dizziness, and sweating.

Dr. Minkoff stated, “Measuring patient experience not found in a bill or a note is a common problem across disease states where patients do not seek medical care frequently. This pattern of under-reporting clinical or claims hypoglycemia data is evident for other measures in other chronic diseases such as migraine, asthma, psoriasis, gout, and other conditions with sporadic symptoms experienced outside the clinic.”

Another missed opportunity in clinical care is merging patient reported outcomes with clinical data from the EHR to create a 360 degree view of the patient. In this study, clinical data from the clinic EHR and patient glucometer data were integrated into the PRO Portal for a comprehensive look at the overall care of these patients with Type 2 Diabetes. The JDST study

authors noted that for this study “there was no significant variability in HbA1c for the groups with varying numbers of hypoglycemic events throughout the course of the study.”

According to Dr. Minkoff, “The high utilization of the EmpiraMed PRO Portal demonstrates that electronic tools can be a more cost-effective way to capture Patient Reported Outcomes and Real World Evidence. The fact that the study participants accessed the PRO Portal eDiary frequently and that electronic surveys had a lower missed response rate compared to paper surveys are indicators of the ability of technology like the EmpiraMed PRO Portal Software Platform to capture larger amounts of data in a manner that is more engaging and compelling to patients.”

The JDST publication can be accessed at <https://www.ncbi.nlm.nih.gov/pubmed/28918651>

About EmpiraMed

EmpiraMed has developed a patient engagement software platform called the PRO Portal to capture *Real World Evidence* and to execute *Outcomes Based Contracts* and *Quality Improvement Intervention Programs*. For Randomized Clinical Trials (RCTs), our system captures *ePROs* (electronic Patient Reported Outcomes) and feeds the study EDC system. For observational studies, our platform becomes the EDC housing all study data. Our unique rules-based approach completely automates all patient interactions via the web and any mobile device while seamlessly integrating healthcare personnel patient recruitment and follow-up to execute projects in less time, at lower cost, and with greater flexibility. Combining our completely automated study execution system with novel patient recruitment methods, EmpiraMed offers study sponsors the most robust *Virtual Trial* (or Digital Trial) solution available today. Post-market, observational (non-interventional), RWE studies typically suffer from poor patient participation so our portal includes innovative technology to reduce response burden and to provide incentives that have raised compliance to 3X what was possible. Our customers have seen dramatic increases in patient participation, engagement, and wearable device utilization (*Passive Monitoring*) through our ground-breaking Rewards Program, which is the only incentive program approved by several blue-chip pharmaceutical compliance departments for clinical research. EmpiraMed also offers an EHR integration framework with proprietary validity analytics to support source data validation and verification to reduce bias inherent in

self-reported patient information. A critical application of the PRO Portal is ***Outcomes Based Contracting***. Our solution expands OBC beyond claims by capturing a greater variety of outcomes to more accurately tie the true value of treatments back to payments. Once RWE is assessed, healthcare stakeholders need to improve the outcomes measured. In addition to monitoring patients, our real-time, dynamic system can trigger educational content and intervention alerts at any time for any event to directly improve patient care as part of a Disease Management ***Quality Improvement Intervention Program***. EmpiraMed has implemented the PRO Portal™ Platform for many large biopharmaceutical companies and has a proven track record of exceptional patient engagement. Our customers have included Merck Sharp & Dohme, Biogen, Janssen, Sanofi, United Therapeutics, and Teva. Please visit <http://www.EmpiraMed.com> for more information.

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