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***SURVEY SHOWS THAT THE DEVELOPMENT OF CLINICAL DECISION SUPPORT SOFTWARE IS
BEING SIGNIFICANTLY IMPEDED BY FDA REGULATORY UNCERTAINTY.***

In a survey of clinical decision support (or CDS) developers, one third reported having to abandon CDS product development efforts because of FDA regulatory uncertainty. Of those who pressed ahead despite the uncertainty, almost two thirds encountered significant delays. Those delays were greater than one year in 20% of those cases.

The CDS Coalition conducted the online survey to better understand the impact of FDA policy, or more specifically the lack of FDA policy, on CDS. Forty-eight companies participated, providing a range of information intended to better understand the nature of the industry, including the sophistication and size of companies developing this software. The survey results indicate that the industry is comprised of both venture backed startups as well as large, healthcare oriented companies such as pharmaceutical companies. The software these companies are developing is aimed at improving patient outcomes, increasing adherence to treatment and reducing errors and adverse events, among other things.

The survey's objective was to evaluate the impact on CDS development of the lack of any clear FDA guidelines addressing when such software is regulated. FDA has been publicly promising to develop that guidance since [2011](#), but has yet to do so. The development of this FDA guidance document was one of the agency's highest priorities in 2015, the agency's so-called A list, according to the agency's [website](#). But so far, FDA has not issued even a draft for public input.

Dr Michael Robinson, a practicing endocrinologist in Marina del Rey, California who uses various clinical calculators when treating patients with diabetes, explains "With the enormous explosion in clinical information, and with the digitalization of patient health records, CDS can help doctors dramatically improve the quality of care. I am anxiously awaiting mobile apps that will allow me to better guide my patients in such areas as the titration of the new long-acting long-acting basal and pre-meal insulins. There also are several areas of my practice where I would welcome new clinical decision support software to help me sort through the many options."

According to Manan Trivedi, MD, MPP, a practicing hospitalist and Chief Medical Officer of Clinovations Government + Health, “CDS offers doctors important insights into the best care for a particular patient, and challenges doctors to think more deeply about possible alternatives.” Based in Washington, D.C., Clinovations Government + Health works to support and educate clients in understanding the implications of health IT policy and regulations. Trivedi observes, “Unfortunately, many potentially important CDS products are stuck in the pipeline because developers lack clear guidance from FDA.”

Congress is considering legislation to bring some clarity to the scope of FDA regulation, including the Medical Electronic Data Technology Enhancement for Consumers' Health (MEDTECH) Act (S. 1101), sponsored by Sens. Orrin Hatch (R-Utah) and Michael Bennet (D-Colo.). The purpose of the legislation is to resolve the ambiguity so that developers know the rules of the road. The legislation is slated to be discussed as a part of a March 9, 2016 executive session of the Senate Health committee in regard to the committee’s biomedical innovation bills.

For more information concerning the survey, please read the white paper found [here](#).

About the CDS Coalition: The CDS Coalition is a diverse group of stakeholders consisting of software providers, IT infrastructure manufacturers, healthcare providers, medical device and pharmaceutical manufacturers, trade groups, and members of the clinical community. Focused clinical decision support software (CDS), the coalition’s goal is to ensure a risk-based and clearly defined regulatory system for such software that appropriately balances the need for regulatory oversight with the need for innovation and access to new technology.