For Immediate Release

07 February 2019

Promoting Software as Medical Device (SaMD): Amarex Speaks Up

Germantown, MD, USA (February 07, 2019) – Global Biotechnology Monthly recently interviewed Dr. Kazem Kazempour, President & CEO of Amarex Clinical Research, about the US FDA's continued support for the development and marketing of digital health application products.

Technological advances have impacted all areas of health care, including software used in the operation of digital applications in medical devices and as medical devices. In 2013, the International Medical Device Regulatory Forum (IMDRF) chartered the SaMD Working Group to develop a regulatory framework for SaMDs, to establish key definitions and to arrange clinical evaluation of SaMDs. FDA adoption of these principles provided the initial framework and allowed for the publication of the first draft guidance entitled "Software as a Medical Device (SaMD): Clinical Evaluation" in Dec 2017.

With support from the US FDA, and through their 2017/2018 proposed Digital Health Innovation Action Plan and Software Precertification Pilot Program, the biotech industry will be able to participate in streamlined premarket review and opportunities to collect and leverage real-world postmarket data. Dr. Kazem Kazempour stated that, "Health-related apps are accessible by anyone with access to a smart phone, and the biotech industry, having recognized this high level of use, is working hard to meet provider, patient and regulatory requirements for validated SaMDs."

The full article, titled 'Kazem Kazempour: Several medical generations are coming to the FDA to actively promote SaMD', was published in Global Biotechnology Monthly Vol. 60 on February 01, 2019, and can be viewed at http://www.gbimonthly.com/2019/02/39858/.

About Amarex
Amarex is a global, full service Contract Research Organization (CRO), whose leadership team has significant expertise conducting biomedical research, and whose combined experience includes the design and conduct of several hundred clinical research projects in many therapeutic indications. Amarex provides comprehensive services in Project Management (Phase I-IV, BE/BA, PK/PD), Regulatory Affairs, FDA Applications and Submissions, Applications and Submissions to international Health Authorities, GxP Compliance Audits, Clinical Operations, Adaptive Study Designs, Statistical Analysis, Data Management and General Consulting. Amarex has taken clients' products through the entire approval process from writing the initial product approval strategy to the marketing approval application with a growing list of approved products. Amarex is committed to cost effective, high quality clinical product development. For more information, visit www.amarexcro.com.

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