Syapse Announces Research Collaboration with the FDA Focused on the Regulatory Use of Real-World Evidence

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SAN FRANCISCO, Aug. 14, 2019 (GLOBE NEWSWIRE) -- Syapse and the U.S. Food and Drug Administration (FDA) Oncology Center of Excellence (OCE) have signed a multi-year Research Collaboration Agreement (RCA) focused on the use of real-world evidence (RWE) to support regulatory decision-making. Syapse and the OCE will work with stakeholders across the FDA to address key regulatory questions about testing and treatment patterns, dosing and safety, and outcomes in oncology, with a focus on precision medicine.

“Advances in real-world evidence present an opportunity to learn from patients and potentially translate those insights into safer and more effective therapies,” said Sean Khozin, MD, MPH, associate director for oncology regulatory science and informatics in the FDA’s Oncology Center of Excellence. “Real-world evidence from well-designed studies meeting appropriate data quality standards can help to inform decision-making and provide information regarding the impact of new therapies in real-world patient populations, particularly those not represented in clinical trials. This is especially critical in precision medicine, where understanding all of the factors that may drive safety and response is both imperative and difficult to capture at scale using traditional clinical trials.”

As part of this collaboration, Syapse and the FDA will investigate methods to derive RWE from multiple sources including, and going beyond, electronic health records (EHRs). The “Framework for FDA’s Real-World Evidence Program” describes the challenges in obtaining comprehensive data from EHRs and claims, and the difficulty in linking sources. This collaboration will utilize real-world data integrated from many source systems, including clinical data from EHRs and registries, and molecular data from testing labs, and seek to characterize the regulatory suitability of RWE derived from this multi-source approach.

Additionally, Syapse and the FDA will examine real-world endpoints for solid tumors and hematological malignancies, characterizing the usage and clinical impact of molecular testing, understanding outcomes and adverse events in patients receiving precision medicines relative to clinical trial populations, and incorporating patient-reported outcomes into RWE.

Alongside these direct collaboration efforts, Syapse will engage oncologists in its Learning Health Network in joint outcomes research. This work will support Syapse in enabling the use of RWE by oncology care providers to inform care decisions and outcomes research. In turn, Syapse will incorporate the outcomes derivation methodology into its Learning Health Network capabilities.

“Syapse is proud to collaborate with the FDA to enhance understanding of how patients respond to therapies outside of clinical trials to improve care and outcomes,” said Jonathan Hirsch, founder and president of Syapse. “Advancing a deeper understanding of real-world endpoints and analytical methodologies is critical to assuring that all stakeholders can have confidence in the quality of evidence produced and accelerating the use of RWE in regulatory decision-making. The network of health systems that Syapse represents offers a unique opportunity to learn from oncology patient journeys and populations not well represented in traditional clinical trials.”

About Syapse
Syapse is on a mission to deliver the best care for every cancer patient through precision medicine. Our insights platform, data sharing network, and industry partnerships enable healthcare providers to bring precision cancer care to every patient who needs it. By bringing together leading healthcare innovators into a unified ecosystem, we have built one of the world's largest learning health networks of provider-driven precision medicine data. In collaboration with our partners — including Advocate Aurora Health Care, CommonSpirit Health, Henry Ford Health System, Providence St. Joseph Health, and Seoul National University Hospital — we are working toward a future in which all cancer patients have access to the best personalized care, regardless of location or income.

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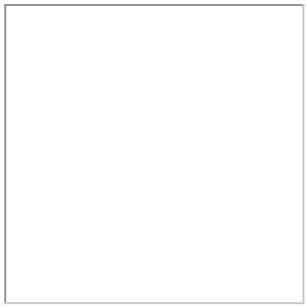

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