Tempus Submits PMA Application to the FDA for its xT-Onco Assay

August 17, 2021

Tempus, a leader in artificial intelligence and precision medicine, today announced the submission of a Premarket Approval (PMA) application for its proprietary broad-panel DNA sequencing assay to the U.S. Food and Drug Administration (FDA).

Tempus is seeking approval for its xT-Onco assay, a broad-panel next-generation sequencing-based, *in vitro* diagnostic device. The submission includes companion diagnostic claims, tumor profiling claims, and microsatellite instability status, using DNA isolated from formalin-fixed paraffin embedded tumor tissue specimens, and matched normal specimens. Tempus xT-Onco will be performed at Tempus' next-generation sequencing lab in Chicago.

"Oncologists throughout the country leverage Tempus' sequencing assays to inform data-driven treatment decisions and deliver personalized patient care," said Lauren Silvis, Senior Vice President, Regulatory Affairs at Tempus. "This regulatory milestone demonstrates our commitment to expanding the promise of precision medicine in oncology to more patients and providers."

The PMA submission builds on Tempus' existing precision medicine platform, adding the regulatory component to provide a comprehensive suite of solutions for novel drug development programs. Sponsors can leverage Tempus' next-generation sequencing platform, clinical trial matching capabilities and its vast library of clinical and molecular data to support therapeutic innovation. The combination of these components, along with Tempus' advanced artificial intelligence capabilities, distinguishes Tempus' unique approach to precision medicine.

About Tempus

Tempus is a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare. With what we consider to be one of the world's largest libraries of clinical and molecular data, and an operating system to make that data accessible and useful, Tempus enables physicians to make real-time, data-driven decisions to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. The goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as Tempus gathers more data. For more information, visit tempus.com.