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Global regulatory best practices: Companion diagnostics

Abhishek Harde
Cognizant Technology Solutions Limited, USA

Companion Diagnostics (CDxs) are commonly in vitro diagnostic (IVD) medical devices that detect a specific biomarker, related biomarkers, or a pattern of related biomarkers for a specific patient. CDxs are defined in the US, EU and Japan as follows

US: A Companion Diagnostic (CDx) is defined by the U.S. FDA as an, "in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product."

EU: The IVD medical devices directive defines CDxs as the tests that are developed and/or used in direct combination with specific medicinal products or which are co-developed with newmedicinal products and may be used for the selection of patients suitable for therespective medication, for optimal and individualized dosing of medicinal products, for the exclusion of populations expected to suffer from severe adverse side effects and/or other medicinal products-related indications.

Japan: The Pharmaceutical and Food Safety Bureau's Evaluation and Licensing Division of the PMDA defines companion diagnostics as IVDs and medical devices used to 1) Identify patients more likely to respond to specified drugs such as molecular targeted therapies, 2) identify patients with a high risk of adverse reactions to these drugs, and 3) Optimize the administration and dosage regimen or determine when administration should be discontinued.

abhishekharde@gmail.com