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Global regulatory best practices: Companion diagnostics

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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.

Diagnostic biomarkers may be recognized as potentially meaningful at any stage of the drug development process and the development of the diagnostic biomarker may proceed at any stage of the therapeutic drug development or even in the post market phase.

CDxs are categorized into two major types based on their use:

1) Predictive: helps to identify patients more likely to respond to a therapeutic

2) Prognostic: helps to identify patients with a greater likelihood of having a disease-related event or a substantial worsening in condition.

Not all diagnostic tests qualify as a CDx. A sponsor should work with Health Authorities (HAs) to determine if a potential biomarker assay will be considered a CDx. In the US, the Office of *In Vitro* Diagnostic Device and Radiological Health (OIR) in the Center for Devices and Radiological Health (CDRH) is responsible for review of IVDs, in consultation with the primary drug review division. An Investigational Device Exemption (IDE) may be considered for use in clinical studies; however, CDxs may be evaluated in clinical studies via an IND only. Though an IDE submission is not an absolute requirement, it is highly recommended, prior to initiation of registration-enabling clinical trials if a speed strategy is anticipated on PoC (i.e., Accelerated approval, Breakthrough therapy, and Conditional marketing application). For approval, the Sponsor should work with CDRH to determine the type of application needed. The types of CDx applications include a Premarket Approval Application (PMA) or a 510(k).

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Brazilian pharmaceutical regulation on productive partnerships for development of priority drugs

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Productive Partnerships for Development ("PDPs") of priority drugs are in the center of the discussions about the supply of drugs for the Brazilian public market. Under PDPs, public laboratories receive technology for priority drugs which have been developed by private pharmaceutical companies. The public laboratory then on sells the drugs to the Brazilian government. The purpose is that the public laboratories are able to supply the public sector in the long term and the PDP ultimately equips it with the technology (including the access to cell banks) and skills to do so. However, until the technology transfer has occurred – which demands a certain maturity - the public laboratory buys the product manufactured by the private company.

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