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FDA provides new guidelines for medical devices

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The US Food and Drug Administration (FDA) has finalised new guidelines to promote medical device innovation and provide patients with fast access to beneficial technologies.

The new steps include three new guidance documents to allow efficient and predictable development, along with establishing modern tools for measurement of device safety and performance.

The organisation has completed the first qualification of a medical device development tool (MDDT), which is a 23-item questionnaire designed to measure information such as health status and clinical symptoms reported by heart failure patients.

MDDT is intended to help in designing heart failure devices for accurate and efficient quantification of the device to ensure actual improvement in a patient's quality of life.

The organisation recommends development of such medical device tools, primarily for wearable technologies, to potentially avoid animal studies, minimise testing time and improve ability to analyse benefit and risk.

The first new draft guidance by the FDA is Breakthrough Devices Programme that offers quick access to certain devices that could effectively diagnose or treat life-threatening or irreversibly debilitating diseases or conditions. It has been developed by the 21st Century Cures Act.