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Singapore launches national reference to guide clinical investigations of medical devices

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Strengthening Singaporeâ??s position as a trusted location for medtech clinical research



As more medical devices move from the laboratory into first use in patients, Singapore has launched a national reference to make clinical investigations more consistent and predictable. The new reference sets out what a well-prepared device study application should contain, including expectations around design control and documentation, helping to clarify and streamline the ethics review process.

Technical Reference (TR) 151:2026 – Clinical Investigation of Medical Devices was developed under the Biomedical and Health Standards Committee (BHSC) of the Singapore Standards Council (SSC), administered by Enterprise Singapore (EnterpriseSG) and supported by the Duke-NUS Centre of Regulatory Excellence – Standards Development Organisation (CoRE-SDO).

The TR explains how to apply ISO 14155:2026, the international standard for good clinical practice in medical device investigations, when planning and reviewing device studies in Singapore.

It closes a long-standing gap in the healthcare innovation industry—much of the current guidance for clinical trials was developed with medicines in mind and offers limited direction on device-specific aspects. As a result, device study applications vary widely in content and depth, with innovators lacking a common understanding of what ethics committees expect to see.

This lack of standard practices and consistency often leads to repeated rounds of clarification, where the cost falls hardest on start-ups and small and medium-sized enterprises (SMEs), which have limited regulatory resources.

TR 151 aims to clarify the level of design control, testing, risk management and documentation that a study team should show at an ethics review, in proportion to the device’s risk class and stage of development. It also gives reviewers a framework for assessing submissions, including first-in-human, early feasibility studies. The guide covers investigational medical devices, meaning devices that are still experimental for their intended use.