

MEETING REQUIREMENTS OF REGULATORY AUTHORITIES WORLDWIDE

This concept note describes the key requirements of regulatory authorities in the European Union (EU), the China Food and Drug Administration (CFDA), and the Australian Therapeutic Goods Administration (TGA) and provides Indegene's perspective on clinical evaluation in these three geographies.

EUROPEAN UNION

The Medical Device Directive (MDD) regulates the safety and marketing of medical devices in the EU. For marketing a medical device in the EU, it needs to be affixed with a "Conformité Européene" (CE) marking, which confirms that the device adheres to the regulations of the EU. The CE marking of a device is being executed by EU-accredited autonomous organizations known as notified bodies (NBs).

The MDD has recently released MEDDEV 2.7/1 Rev 4 in June 2016, which effectively replaced the previous guidelines published in December 2009. These guidelines provide a more robust guidance on how a clinical evaluation should be performed in order to meet the essential requirements. Key requirements of the clinical evaluation include the characteristics of one equivalent device, state-of-the-art evaluation, risk-benefit ratio assessment, and post-market clinical follow-up (PMCF) plan.

CHINA

The approval process for medical devices in China is time consuming and relatively complex due to its dynamic regulatory landscape. The requirements of the CFDA CER include a detailed 16-point approach to establish equivalency with a medical device of the same kind and a literature search in China Academic Journals Full-text Database and Chinese clinical trial register. Literature appraisal and development of pivotal sections of the report specific to China datasets are typically done by a scientific writer who is also proficient in Mandarin.

AUSTRALIA

Before a medical device is launched in the Australian market, it must obtain pre-market approval from the TGA and must also be included in the Australian Register of Therapeutic Goods (ARTG). The CER is prepared in accordance with the Australian regulatory guidelines for medical devices (ARGMD), Version 1.1, May 2011. These guidelines align with international guidance documents, including International Medical Device Regulators Forum (IMDRF) and the European Commission "MEDDEVs."

INDEGENE PERSPECTIVE

Subject matter expertise and proficiency in native language in the geography of interest is required to better understand the constantly evolving regulatory requirements. Evaluators performing clinical evaluation should be periodically trained on geography-specific guidelines and should be well aware of manufacturer SOPs/protocols. Knowledge enhancement forums involving manufacturers, NBs, and clinical evaluators can further strengthen the robustness of the end-to-end clinical evaluation requirements and processes.