IMDRF International Medical Device Regulators Forum

# Final Document

## International Medical Device Regulators Forum

**Title:** Statement regarding Use of ISO 14155:2011 "Clinical investigation of medical devices for human subjects – Good clinical practice"

**Authoring Group:** IMDRF Management Committee

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**Use of ISO 14155:2011 "Clinical investigation of medical devices for human subjects – Good clinical practice" in each jurisdiction**

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| Australia<br><br>Therapeutic Goods Administration (TGA) | As is common to all standards for devices, compliance with ISO14155:2011 is not mandatory, and the sponsor of a device is free to choose to demonstrate conformity to the Essential Principles (including EP 14 – Clinical Evidence) by other means such as by using clinical evidence from literature, or using data from trials which are not compliant with ISO 14155:2011. However, if alternative methods are used to demonstrate compliance with the Essential Principles, then a sound justification must also be provided. If a trial for a device complies with ISO14155:2011, then EP14 is deemed to be satisfied. |
| Brazil<br><br>National Health Surveillance Agency (ANVISA) | The ISO 14155:2011 is one of the main references to the Resolution RDC n 10/2015 published on March 3rd, 2015 for clinical trials involving medical devices, particularly for Good Clinical Practice topics.<br>The ISO14155:2011 is also referenced in the text of the Brazilian guidance as a standard to be followed in clinical trials audits. |
| Canada<br><br>Health Canada (HC) | HC publishes a list of recognised standards to facilitate the regulatory review of medical device license applications. Included on the list is the standard entitled "Clinical investigation of medical devices for human subjects – Good clinical practice" (ISO 14155:2011/Cor.1:2011.). In Canada, conformance to particular standards are not mandatory requirements, but can be used as part of the evidence to demonstrate compliance with the requirements of medical devices regulations. In general practice, during review HC will typically utilize the criteria from the ISO14155:2011 standard to question license applicants regarding the validity of a clinical study conducted in a country that do not have equivalent regulatory and Institutional Review Board (IRB) oversights to those in North America.<br>While this standard specifically excludes In vitro diagnostic medical devices, several elements within ISO 14155:2011 are considered to be relevant (e.g. planning, ethical considerations, conduct of the study, responsibilities, etc. ). |
| China<br><br>China Food and Drug Administration (CFDA) | In 1997, China released the medical device industry standard: YY/T 0297-1997, which was equivalent to the ISO 14155:1996, and it is a recommended standard, not a mandatory standard. In China, the clinical trials of medical device should comply with the requirements of the provision on medical device clinical trials (SFDA decree No.5) now. CFDA started to draft the medical device GCP(good clinical practice), during the process, we considered the requirements of new version of ISO 14155. |

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| Europe<br><br>European Commission (EC) | The European regulatory system for medical devices includes legal requirements for clinical investigations, where harmonized standards provide presumption of conformity with the important aspects. EN ISO 14155:2011 [Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)] is a European harmonized standard, which provides broad presumption of conformity with the relevant legal essential requirements on clinical investigation, covering also aspects of good clinical practice (GCP) for medical devices. The use of this standard therefore provides one solution for compliance with those legal provisions. Compliance with the legal requirements can however be ensured also by other means. |
| Japan<br><br>Ministry of Health, Labour and Welfare (MHLW)<br>Pharmaceuticals and Medical Devices Agency (PMDA) | The Ministerial Ordinance No. 36 in 2005 is the medical device GCP in Japan, which aligns with ICH-GCP. Clinical trial data obtained from clinical trials outside of Japan have been accepted as a part of application dossier when all of the following are met: i) the standards for conducting clinical trials have a legal basis in the country or region where the trials were performed, ii) the standards are equivalent to or more complete than medical device GCP in Japan, and iii) the clinical trials were conducted in accordance with the standards or considered to be of equivalent quality as required with the standards.<br><br>In this context, the guidance for the Japanese medical device GCP issued in February 2013 (No. 0208-1) clearly states that ISO 14155:2011 is an equivalent standard to the Japanese GCP.<br><br>It is noted that GCP inspections (desk-top or on-site inspection) are applied even if the clinical trials are conducted in accordance with ISO 14155: 2011 or other equivalent standards. |
| Russia<br><br>Russian Ministry of Health<br>Roszdravnadzor | The ISO 14155:2011 is now translated into Russian and is included in Russian system of standards. It will supersede previous version of ISO 14155 (part 1 and part 2) on 01.06.2015. ISO 14155 is not mandatory in Russian Federation, but it is very important in cases, when clinical data have to be generated during clinical investigation of medical devices on human subjects. |
| The United States of America<br><br>US Food and Drug Administration (US FDA) | Overall, based on the principles it represents and on its successful use currently within FDA we believe that the ISO 141155:2011 can successfully serve as a global standard to medical device GCP's. Global recognition and conformity to the standard will help promote harmonization of GCP, and ensure the reliability and integrity of the data submitted in support of marketing applications while ensuring that human research subjects are adequately protected.<br><br>In February 2013 FDA published a federal register notice of its proposed rule to amend the current device regulations to require that |

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| | clinical studies conducted outside the United States in support of marketing applications from FDA be conducted in accordance with GCP. The rule is currently under review however ISO 14155:2011 has been cited in the notice as a reference to device GCP which can be used currently and in the future to adequately satisfy potential changes in the regulations. |