ISO 14155:2020: Clinical evidence plays a larger role than before

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ISO 14155:2020 is the third edition of the reference standard ISO 14155 for the design, conduct, recording and reporting of clinical investigations of medical devices. It offers guidance on the implementation of GCP ("good clinical practice") for clinical investigations before and after medical devices are placed on the market. The standard has been in effect since July 2020, its publication date, with no transitional period. ISO 14155 contains general specifications and requirements for clinical investigations covering many different areas, particularly protection of rights, user safety and ensuring that clinical investigations are conducted in a scientific manner and yield credible results.

The new edition of ISO 14155 also includes explanations to facilitate compliance with other international standards, which were absent from previous versions. In particular, the US FDA (Food and Drug Administration) recognizes the ISO 14155:2020 standard for studies with medical devices and accepts clinical data under the conditions specified in ISO 14155:2020 even if the data was collected outside the US.

In particular, clinical evidence plays a greater role than before in the new ISO 14155:2020. "Clinical evidence" refers to clinical data and the results of clinical assessments of a device which are sufficient, in qualitative and quantitative terms, to enable a qualified assessment as to whether the device is safe and whether it accomplishes the sought-after clinical benefit when used properly and in accordance with the manufacturer's instructions. This strong emphasis on the role of clinical evidence can be found in the MDR as well.

The new standard also features an enhanced presentation of risk management principles in accordance with ISO 14971 for all phases of clinical investigations and improved guidance for the design of clinical studies. The previous version of ISO 14155 only referred to ISO 14971 with regard to "investigational device risks" and to the facilitation of risk-benefit assessments in order to meet the requirements for the design of clinical investigations. The new ISO 14155:2020 adds "clinical risk management" to the list of the sponsor's responsibilities and introduces the concept of clinical quality management processes.

Regardless of these changes, which are primarily of a clarifying and informative nature, ISO 14155:2020 is not expected to bring major changes for those who were already adhering to the most recent edition of the standard, ISO 14155:2011.

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