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ISO 20916:2019
In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice
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Abstract

This document defines good study practice for the planning, design, conduct, recording and reporting of clinical performance studies carried out to assess the clinical performance and safety of in vitro diagnostic (IVD) medical devices for regulatory purposes.

NOTE 1 The purpose of these studies is to assess the ability of an IVD medical device in the hands of the intended user, to yield results pertaining to a particular medical condition or physiological/pathological state, in the intended population.

The document is not intended to describe whether the technical specifications of the IVD medical device in question are adequately addressed by the clinical performance study.

This document identifies the principles that underpin clinical performance studies and specifies general requirements intended to

— ensure the conduct of the clinical performance study will lead to reliable and robust study results,

— define the responsibilities of the sponsor and principal investigator,

— assist sponsors, clinical research organization, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of IVD medical devices, and

— protect the rights, safety, dignity and well-being of the subjects providing specimens for use in clinical performance studies.

Analytical performance studies are out of the scope of this document.

NOTE 2 When the collection of specimens specifically for the analytical performance study creates an additional collection risk for subjects, some of the elements of this document (particularly the annexes) can be useful for ensuring subject safety.

Clinical performance studies that are performed for reasons other than pre- and post-market regulatory purposes, such as for re-imbursement purposes, are out of the scope of this document.

NOTE 3 Some of the elements of this document can be useful for the design of such studies, including subject safety and data integrity.

This document does not include safety information for laboratory workers or other personnel collecting the study specimens.

NOTE 4 Such information is included in other publications[1][12][13].

NOTE 5 Users of this document can consider whether other standards and/or requirements also apply to the IVD medical device which is the subject of the clinical performance study, for instance, in the situation for which there is an IVD medical device and a medical device used in an integrated system (e.g. a lancet, an IVD test strip, and a glucose meter), aspects of both this document and ISO 14155 can be considered.

General information

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Life cycle

- **Now**

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    Preliminary
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- 40
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  - 40.99 2018-06-20
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- 90.99
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- 95
  Withdrawal
  - 95.99
    Withdrawal of International Standard


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