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In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice

Dispositifs médicaux de diagnostic in vitro — Études des performances cliniques utilisant des prélèvements de sujets humains — Bonnes pratiques d'étude

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

In vitro diagnostic (IVD) medical devices are used to conduct tests outside of the human body to provide valuable information regarding a person's health or physiological status. They include tests and related devices, such as test strips and reagents, using specimens such as blood, tissue or urine, to carry out screening, diagnosis, prognosis, predictive testing, and monitoring of conditions. IVD medical devices are fundamentally different from other medical devices because they perform their function outside of the body on specimens taken from the human body. Human subjects are typically not exposed to risks with the performance testing of IVD medical devices, except for the risk associated with specimen collection procedures or when the obtained information is used for patient management. The specimens are obtained via normal body functions (e.g. urine) or through the use of invasive medical devices to allow for the specimen to be obtained (e.g. biopsy). The specimens are never reintroduced into the human body. These differences make the performance and risk characteristics of IVD medical devices different and unique from other medical devices.

Most of the studies for IVD medical devices are performed using samples resulting from the remnants of specimens taken for purposes of standard of care (leftover or archived). In these studies, there is no risk for the subjects arising from either the information provided by the IVD medical device or from the collection procedure of the specimen. However, when leftover specimens are not used, additional requirements should be considered

— when the specimens are collected specifically for the study and the specimen collection procedures present additional risk of direct harm for the subject (e.g. lumbar puncture or tissue biopsy, blood collection from neonates or critically ill patients), and/or

— when the information obtained from the IVD medical devices during the study is used to make patient management decision (i.e. interventional studies), presenting a risk of indirect harm for the subject (e.g. false negative or false positive result leading to inappropriate patient management decisions).

For the majority of IVD clinical performance studies, issues related to the use of vulnerable subjects might not arise but should be considered on a case by case basis.

Considering the reliance on specimens taken from the body and the absence of direct contact of the IVD with the patient, issues related to procedures for obtaining informed consent for IVD clinical performance studies differ from those associated with other medical devices, especially for studies with leftover or archived specimens. This document will provide guidance on the requirements for the various situations described above for IVD medical devices.

This document is intended for clinical performance studies as these studies involve specimens taken from the human body. When specimens other than leftover or archived specimens are used, there might be additional collection risks for the subject. Also in interventional studies, there might be a risk for the subject coming from the information provided by the result of the IVD under investigation.

This document is specific for IVD medical devices and therefore uses definitions and concepts that are appropriate for IVD medical devices. It is a stand-alone standard for clinical performance studies for IVD medical devices. 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), the respective jurisdiction's regulation will define it as either an IVD medical device or a medical device and subsequently, aspects of both this document and ISO 14155 might need to be considered.

Except for these situations, this document should not be read in conjunction with ISO 14155, which excludes IVD medical devices from its scope.

The flowchart represented in Figure 1 provides guidance on how to use this document.

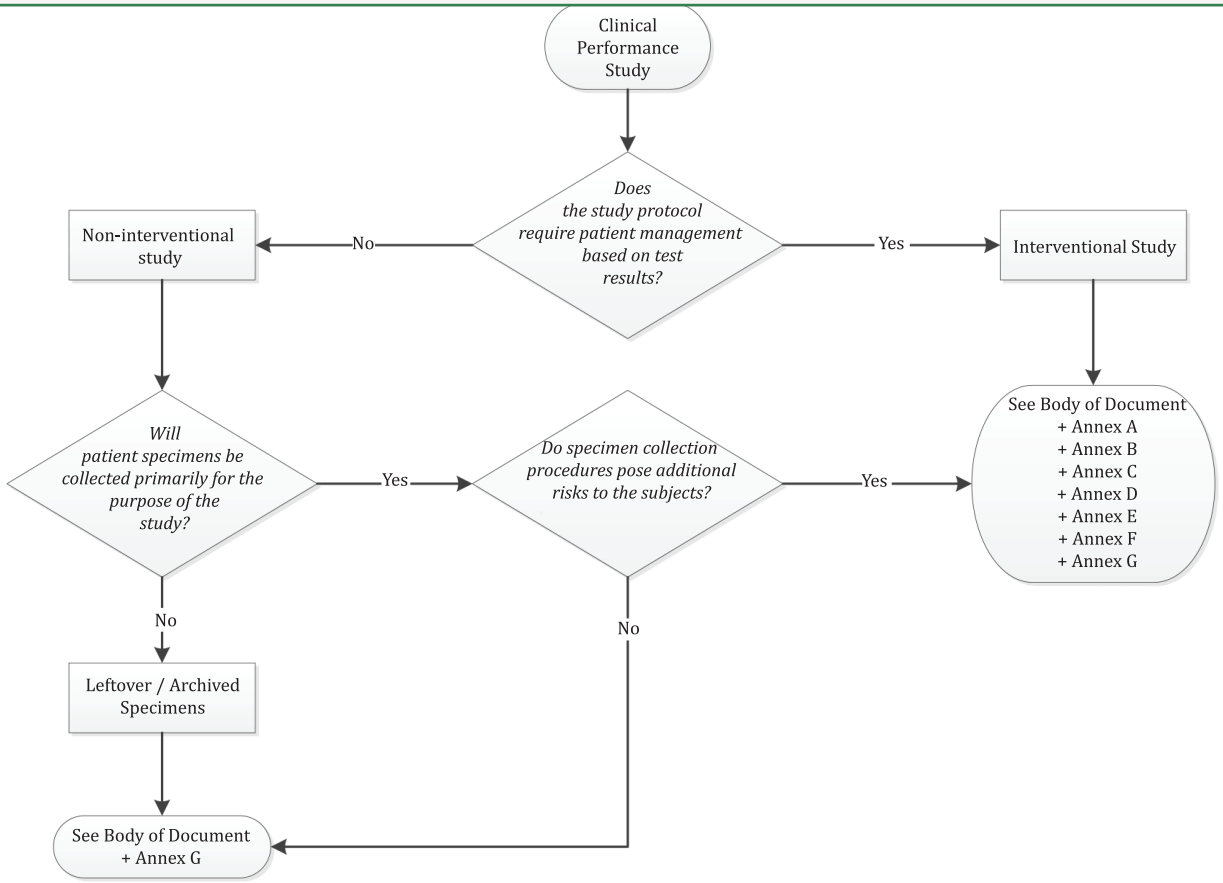

Figure 1 — Clinical performance study flow chart

The main body of the document, in addition to Annex G, includes minimum requirements for all studies. No additional requirements apply for studies using leftover/archived specimens or studies with specimen collection procedures that pose no additional risks to the subject.

However, additional requirements for interventional studies, and those studies in which the specimen collection procedures pose a risk to subjects primarily recruited for the study, are found in Annexes A to F. The nature of these studies warrants an increased level of stringency in the requirements for conduct of the study. The flowchart indicates the annexes which describe the additional requirements for each type of more complex studies. When necessary, the annexes describe differences in the requirements for the different types of study. Additionally, informative annexes are included to provide information on good study practice documentation (see Annex H) and auditing (see Annex I).