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Health informatics — Traditional Chinese medicine — Labelling metadata of human biological sample information

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National foreword

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 215, *Health informatics,* in collaboration with ISO/TC 249, *Traditional Chinese medicine*.

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.

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Introduction

Biobanks play an integral role in research and precision medicine by acquiring, processing, storing, and distributing high-quality, clinically annotated biological material. There are a lot of mature biobanks that can be utilized in Europe and the US. The construction of bio-sample databases for traditional Chinese medicine (TCM) is still evolving. Such databases imitate the labelling methods used in biomedicine samples. Information loss and ambiguity is unavoidable in these systems because of inconsistent content of labelling information for samples. For example, loss of TCM syndrome and physique information. There is no unified semantic information framework for labelling sample information, especially for clinical information of bio-samples in the TCM field. This lack of framework affects the effectiveness, safety and efficiency of data exchange and sharing between different organizations and databases and researchers.

The establishment of a unified semantic classification framework for clinical information labelling of TCM biological samples will greatly

— improve the completeness, accuracy and safety of clinical information labelling of TCM biological samples,

— establish a communication platform for basic research and clinical research of TCM, and

— lay a solid foundation for future information sharing and use.

At the same time, it can enhance the level of international scientific and technological cooperation of TCM and promote the modernization of TCM.

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Health informatics — Traditional Chinese medicine — Labelling metadata of human biological sample information

1 Scope

This document defines the metadata elements to accurately and consistency label clinical information in traditional Chinese medicine human biological samples.

Animal biological samples are outside the scope of this document. This document is not applicable for bioinformatics labelling of biological samples. Human biological samples obtained to support the clinical application of biomedical products of human origin are outside the scope of this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
metadata
data that defines and describes other data

[SOURCE: ISO/IEC 11179-1:2015, 3.2.16]

3.2
dataset
identifiable collection of data

[SOURCE: ISO 19115-1:2014, 4.3, modified — Note to entry removed.]

3.3
biological sample
specimen
discrete portion of a body fluid (e.g. blood, urine, saliva), breath, hair or tissue taken from the human body, which is assumed to represent the whole patient, to support the assessment, diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms.

Note 1 to entry: Human biological samples obtained to support the clinical application of biomedical products of human origin are out of this scope.

3.4
biological sample bank
biobank
legal entity or part of a legal entity that performs *biobanking* (3.12)

[SOURCE: ISO 20387:2018, 3.5, modified — Preferred term changed to "biological sample bank".]

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