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Labelling metadata of human biological sample information

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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. www.iso.org/directives (see www.iso.org/directives).

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The committee responsible for this document is ISO/TC 215.

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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 ~~USA~~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.

~~While related western medical biological sample information base was built 30 years ago, which is experienced in the labelling of biological samples and formed a relatively perfect labelling framework. Especially, the standards for collecting, preserving, transporting and destroying physical samples, including organ tissues and body fluids, tends to be mature.~~

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.

~~This document defines the metadata within the field of TCM sample labelling to address these problems.~~

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Health Informatics — ~~traditional~~informatics — Traditional Chinese medicine labelling — Labelling metadata of human biological sample information

1 Scope

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

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 ~~terminological~~terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp> <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/> <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 — 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.

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Note 1 to entry: Can contain one or more metadata entities.

Note 2 to entry: Equivalent to a class in UML terminology.

EXAMPLE ~~sample~~Sample type, sample test method

[SOURCE: ISO 19115-1:2014, 4.12, modified — Example added.]

3.10 metadata section

subset of *metadata* (3.1) which consists of a collection of related *metadata entities* (3.9) and *metadata elements* (3.8)

Note 1 to entry: equivalent to a package in UML terminology.

EXAMPLE ~~demographic~~Demographic information, sample information

[SOURCE: ISO 19115-1:2014, 4.13, modified — Example added.]

3.11 element refinement

property of a resource which shares the meaning of a particular element but with narrower semantics

[SOURCE: ISO/TS 17948:2014, 2.7]

3.12 biobanking

process of acquisition and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data

[SOURCE: ISO 20387:2018, 3.6]

3.13 four examinations

collective expression for inspection, listening and smelling, inquiry and palpation

4 Structure

The metadata of TCM information labelling of biological samples includes two metadata parts:

- Identification subset
- Subset of ~~Content Information~~content information

5 Standard table of traditional Chinese medicine labelling metadata of human biological sample information

Table 1 — Table of TCM labelling metadata

Sections	Elements	Element refinements and encoding scheme	Element refinements and encoding scheme

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