TECHNICAL SPECIFICATION

ISO/TS 5568

First edition
2022-11

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

Reference number
ISO/TS 5568:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

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.

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".]

3.5
clinical information
information about a person relevant to their health or healthcare

3.6
labelling
process of applying a classification, name or data to describe a sample

Note 1 to entry: Labelling of information includes health information, disease information and treatment information of samples related to traditional Chinese medicine. Accurate and comprehensive labelling is beneficial for identification, use, storage and retrieval of samples.

3.7
traditional Chinese medicine
TCM
traditional medicine that originated in china, and is characterized by holism and treatment based on pattern identification/syndrome differentiation

[SOURCE: ISO/TS 17948:2014, 2.2]

3.8
metadata element
resource property name that can be used in metadata and that can be given a value

Note 1 to entry: A metadata element is referred to as metadata attribute in other communities.

[SOURCE: ISO 24622-1:2015, 2.12, modified — Example deleted.]

3.9
metadata entity
set of *metadata elements* (3.8) describing the same aspect of data

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

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

EXAMPLE Sample type, sample test method

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

3.10
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 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 acquisitioning 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.

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
1. Identification section	1.1 dataset Name		
	1.2 dataset Identifier		
	1.3 dataset Publisher - Unit Name		
	1.4 Key word		
	1.5 dataset Language	International Standard used	

Table 1 *(continued)*

Sections	Elements	Element refinements and encoding scheme	Element refinements and encoding scheme
2. Content section	2.1 Sample information Labelling	2.1.1 demographic information	2.1.1.1 sex
			2.1.1.2 date of birth
			2.1.1.3 occupation
			2.1.1.4 ID
			2.1.1.5 marriage status and date
			2.1.1.6 home address and recording date
			2.1.1.7 contact number
		2.1.2 basic information	2.1.2.1 material type
			2.1.2.2 processing time
			2.1.2.3 security level
			2.1.2.4 coding system
		2.1.3 collecting and distribution information	2.1.3.1 collection method
			2.1.3.2 collection time
			2.1.3.3 collection personnel
			2.1.3.4 reception time
			2.1.3.5 transportation mode
			2.1.3.6 distribution method
		2.1.4 storage information	2.1.4.1 storage address
			2.1.4.2 storage method
			2.1.4.3 storage container and equipment
			2.1.4.4 storage sign
			2.1.4.5 delivery time
			2.1.4.6 destruction method
			2.1.4.7 destruction time
	2.2 Clinical information labelling	2.2.1 medical history	
		2.2.2 observation information	
		2.2.3 diagnosis of diseases and syndromes in TCM	2.2.3.1 diagnosis of TCM diseases
			2.2.3.2 diagnosis of TCM syndromes
		2.2.4 biomedicine diagnosis	2.2.4.1 biomedicine diseases diagnosis
			2.2.4.2 biomedicine pathological diagnosis
		2.2.5 intervention method	2.2.5.1 TCM Intervention
			2.2.5.2 biomedicine intervention
			2.2.5.3 physical therapy

6 Element dictionary

6.1 General

TCM labelling Metadata Entity consists of two sections: sample information labelling, clinical information labelling. Listed below are descriptions of each section and element.

NOTE "Obligation" indicates whether a description symbol is mandatory (M), conditional (C) or optional (O).

6.2 Sample information Labelling

6.2.1 Demographic information

Demographic information is used to identify the source of the sample and to classify those specimens based upon common population and socioeconomic characteristics, including age, sex, occupation, address.

NOTE Obligation=O.

6.2.2 Basic information

6.2.2.1 Material type

The nature of the biological samples that make up the sample collection.

EXAMPLE Whole blood, plasma, serum, urine, saliva, cerebrospinal fluid, DNA, RNA, tissue, faeces, etc. [12]

NOTE Obligation=M.

6.2.2.2 Processing time

Sample processing time refers to the difference (in m/s) between the start and end of sample processing.

NOTE Obligation=C.

6.2.2.3 Security level

The required processes and or tools needed to maintain the quality of the sample.

NOTE Obligation=M.

6.2.2.4 Coding system

Mainly including collection date, type, storage mode and storage location.

EXAMPLE CHOP-IT-1800910-BS-F-02, representing threatened abortion, stored on September 10, 2018, serum, frozen storage, second duplicate.

NOTE Obligation=M.

6.2.3 Collecting and distribution information

6.2.3.1 Collection method

Biological sample collection is the first step of biological sample collection. It needs to follow strict rules and be undertaken by appropriate professionals.

NOTE Obligation=C.

6.2.3.2 Collection time

The accurate time of biological sample collection.

NOTE Obligation=M.

6.2.3.3 Collection personnel

The person who collected the sample.

NOTE Obligation=C.

6.2.3.4 Reception time

The time and date when a biological sample is received by the biological sample bank.

NOTE Obligation=C.

6.2.3.5 Transportation mode

The method of how biological samples are carried from collection place to sample bank or other places.

NOTE Obligation=O.

6.2.3.6 Distribution method

The process of how biological sample are allocated to recipient(s)/user(s).[4]

NOTE 1 This element defines data required to describe collection and distribution.

NOTE 2 Obligation=C.

6.2.4 Storage information

6.2.4.1 Storage address

The specific location of sample maintenance.

NOTE Obligation=C.

6.2.4.2 Storage method

The maximum and minimum temperature, optimum humidity and pressure range, and other related requirements of sample storage.

NOTE Obligation=M.

6.2.4.3 Storage container and equipment

The suitable containers and equipment for sample storage.

NOTE Obligation=M.

6.2.4.4 Storage sign

A label used to record information about the temperature, location, and time of storage of a sample.

NOTE Obligation=C.