
**Health informatics — Classification of
traditional Chinese medicine data sets**

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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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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*.

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

With the application of information technology to traditional Chinese medicine, the collections of data produced in TCM clinical practice, scientific research, administrative management and other activities involved in TCM are increasingly rich. The data come from various organizations including hospitals, institutions, universities, enterprises and governments, etc. The data range from ancient times to the present. Classification should be established to give better management of these data sets, including the processing, integration, indexing and storage of data resources. Classification of traditional Chinese medicine data sets is a prerequisite and is vitally important in data retrieval, sharing and exchange. Making use of this classification and coding rules, traditional Chinese medicine data sets with the same features can be classified together, while those without any similarity can be kept separate. Thus, the data sets of traditional Chinese medicine can be managed effectively and accessed according to various retrieval approaches, which is beneficial for highly efficient query services. The order of all the classifications and codes in this standard only label their position in the classification system, and is not related to the importance.

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Health informatics — Classification of traditional Chinese medicine data sets

1 Scope

This document defines the classification rules and coding scheme for traditional Chinese medicine (TCM) data sets. It is applicable for investigation and management of TCM data resources as well as the description, integration, publication, index and retrieval of the TCM data sets.

This document excludes the Kampo medicine.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 11179-2:2005, *Information technology — Metadata registries (MDR) — Part 2: Classification*

ISO/IEC 20944-1:2013, *Information technology — Metadata Registries Interoperability and Bindings (MDR-IB) — Part 1: Framework, common vocabulary, and common provisions for conformance*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 11179-2, ISO/IEC 20944-1 and the following apply.

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

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

3.1

data set

identifiable collection of data

[SOURCE: ISO 19115-1:2014, 4.3]

3.2

traditional Chinese medicine

traditional medicine that originated in China, and is characterized by holism and treatment based on pattern identification/syndrome differentiation

[SOURCE: ISO/TS 17938:2014, 2.1]

3.3

classification

exhaustive set of mutually exclusive categories to aggregate data at a pre-prescribed level of specialization for a specific purpose

[SOURCE: ISO 17115:2007, 2.7.1]

**3.4
hierarchical classification**

classification of objects using hierarchical taxonomy. Hierarchical classification systems are developed classes that are subdivided from the most general subject to the most specific

[SOURCE: Reitz, Joan M. (2004). *Dictionary for library and information science*. Westport, CT: Libraries Unlimited]

**3.5
faceted classification**

system that allows the assignment of multiple classifications to an object, enabling the classifications to be ordered in multiple ways, rather than in a single, pre-determined, taxonomic order

Note 1 to entry: Faceted classification may actually employ hierarchy in one or more of its facets. Faceted classification systems allow the assignment of multiple classifications to an object, and enable those classifications to be applied by searchers in multiple ways, rather than in a single, predetermined order.

[SOURCE: Lambert M. Surhone, et al.(2010). *Faceted Classification*, Betascript Publishing, ISBN:978-613-1-40654-6, modified]

**3.6
facet**

grouping of concepts of the same inherent category

Note 1 to entry: A facet comprises “clearly defined, mutually exclusive, and collectively exhaustive aspects, properties or characteristics of a class or specific subject”.

[SOURCE: ISO 25964-1:2011, 2.20, modified]

**3.7
classification scheme**

descriptive information for an arrangement or division of objects into groups based on characteristics which the objects have in common

[SOURCE: ISO/IEC 11179-2:2005, 3.2]

**3.8
coded set**

set of elements that is mapped onto another set according to a code

[SOURCE: ISO/IEC 20944-1:2013, 3.7.2.2]

**3.9
code set**

code element set
result of applying a code to all elements of a coded set

[SOURCE: ISO/IEC 20944-1:2013, 3.7.2.4]

**3.10
code value**

result of applying a code to an element of a coded set

[SOURCE: ISO/IEC 20944-1:2013, 3.7.2.3]

**3.11
coding scheme**

collection of rules that maps the elements of coded set onto the elements of code set

[SOURCE: ISO/IEC 20944-1:2013, 3.7.2.1, modified]

4 Classification scheme and coding scheme

4.1 Classifying and coding Principle

4.1.1 Scientificity

TCM data sets include the collection of various data recorded in TCM activities such as clinical practice, scientific experiments, literature resources digitalization and statistic data report, etc. The most stable and essential properties or characteristics of TCM data sets should be identified as the basis of classification.

4.1.2 Systematicness

The attributes or characteristics of TCM data sets are systematically arranged according to internal relations to ensure reasonable categories, clear hierarchy and reduced redundancy. Classification should put the partial problems into the system as a whole from the point of view of system engineering to achieve system optimization.

4.1.3 Scalability

The categories are set up to ensure that the established classification system will not be disturbed when a new code element and code value was added. The classification codes allow sufficient space for expansion for the subordinate information management system which is built based on this classification system.

4.1.4 Practicability

The classification and codes should satisfy the requirement of simple, clear and ease of use, and conform to the common sense of the users.

4.2 Classification scheme

Hierarchical classification and faceted classification were combined together in this standard in order to fully reveal the feature of TCM data sets. A TCM data set can be classified into different kinds of types by data creator type, data source type and subject type, and each kind of type which is a 'facet' can be combined together to a new complex classification by the sequence of data creator type, data source type and subject type. For data source type and subject type themselves, they use hierarchical classification respectively.

4.3 Coding scheme

The classification code structure consists of four parts:

- Traditional Chinese medicine (TCM) label,
- creator type code,
- data source type code,
- subject type code.

Period "." is used as separator between each part ([Figure 1](#)). Code value is Arabic numerals with fixed digits which is half-width character except for TCM label.

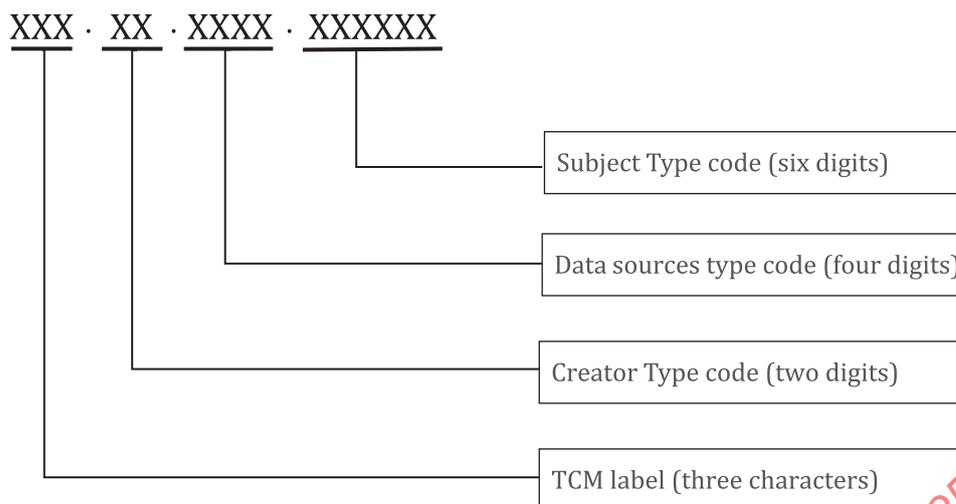


Figure 1 — The classification code structure

5 Classification and code list

5.1 TCM label

In order to identify data sets of traditional Chinese medicine, three characters, namely 'TCM', are used to represent all the data sets generated by the activities in the business domain of traditional Chinese medicine.

5.2 Creator type

The *creator type* relates to the type of an entity primarily responsible for making the content of the data set. According to the business domain of the traditional Chinese medicine, 10 types are specified with two-digit codes, including universities and educational agency, academic institutions, hospital and medical centre, commercial company and manufacturer, government, international organization, professional association/society, publishers, individual and others (Table 1).

Table 1 — Code list for creator type

Codes	Creator type
01	Universities and Educational agency
02	Academic Institutions
03	Hospital and Medical centre
04	Commercial company and Manufacturer
05	Government
06	International organization
07	Professional Association/Society
08	Publishers
09	Individual
99	Others

5.3 Data source type

Data source type represents the type of the original source which the data were derived from. *Data source type* can be divided into two category hierarchies (top level categories, sub-categories if desired). The top level categories are specified in this document, but the sub-categories are not specified so that

users can decide to further divide or not when using the standard. The four-digit Arabic numerals “0100” to “9900” are applied to code the type. The first two digits are used to designate the top level category and sequenced from “01” to “99”. “99” is used to designate “other source” since there might be some new sources added on the list in the future. The last two digits are assigned to be flexible and allow for future extension and occupied by “00” in this document (Table 2).

Table 2 — Codes of data sources type

Code	Data source type	Scope
0100	Historical materials	Information recorded in the ancient literature, especially the ancient books which were made prior to the use of modern printing technology.
0200	Academic publication	Information recorded both in printed works such as books and Journals, and also electronic resources such as the electronic versions of books and periodicals. The sub types of publications include technical standard, technical report, Patent, academic paper, thesis, dissertation, dictionary, etc.
0300	Primary records	Original source or evidence which is an artefact, a document, manuscript, a recording, or any other source of information that was created at the time under study. It serves as an original source of information about the topic, including medical records, health records, and experimental records, etc.
9900	Other source	Other sources not included in the above.

5.4 Subject type

The subject type of data sets can be divided into three category hierarchies (of top level categories, sub-categories and sub-sub-categories if desired). The six-digit Arabic numerals “010000” to “990000” are applied to code the type. The first two digits are used to designate the top level category and sequenced from “01” to “99”. “99” is used to designate “other subject types” since there might be some new subjects added on the list in the future. Each top level category has sub-categories which were designated by the middle two digits. The last two digits are assigned to be flexible and allow for future extension when users need to further divide the subject and occupied by “00” in this document (Table 3).

Table 3 — Codes of subject type

Code	Subject type	Description
010000	Management of TCM	The data sets are generated by the activity of traditional Chinese medicine administrative management, medical management, health care management, scientific research management, education management, industrial management, cultural management, international development and other activities.
010100	TCM administrative management	This subject involves human, financial, material and other management elements, including the data generated by human resource management, financial management, material management, office affair management and other activities.
010200	Medical management	The subject involves the management of medical process, patient information, medical examination, medical technology, medical equipment and medical quality of TCM medical institutions, including the management of patients' in-and-out transfer, medical quality and safety, medical technology management, medical record management and pharmaceutical management activities.

Table 3 (continued)

Code	Subject type	Description
010300	Health care management	The data sets are generated in the process of the management of health cultivation and health care activities carried out by TCM medical and health care institutions, including TCM health management, treatment pre-diseases management and other related management activities.
010400	Scientific research management	The data sets are generated in the process of management of scientific research projects and their outcomes.
010500	Education management	The data sets are generated by academic education, continuing education and other training activity carried out by TCM institutions.
010600	Industrial management	The subject involves the industrial policy and planning, including the data sets which are generated during the management of operating, manufacturing and quality controlling, etc.
010700	Cultural management	The data sets are generated in the process of TCM culture communication, including the bibliographic information of library and museum, the data about traditional knowledge protection and the intangible cultural heritage, etc.
010800	International development	The data sets are generated in the process of international development of TCM.
019900	Others	TCM relative information which is not included in the above 8 sub-categories.
020000	Traditional Chinese Medical Science	The subject involves TCM basic theory, clinical practice, health preservation and integrative medicine
020100	Basic theory	The data sets focus on basic theory research of TCM with traditional and modern method based on the historical literature, contemporary literature and modern experimental research, etc.
020200	Clinical practice	The data sets focus on the diagnosis, treatment, nursing and rehabilitation of disease, disorders, TCM patterns, injury, and other physical and mental impairments in humans, including the technique, method, experience, and instruments for handling all kinds of syndrome and patterns.
020300	Health preservation	The subject focuses on maintaining health, preventing illnesses and life cultivation.
020400	Integrative medicine	The subject involves integrative medicine of Western conventional medicine with traditional Chinese medicine.
029900	Other subjects	TCM relative information which is not included in the above 4 sub-categories.
030000	Chinese Medicines	The subject involves substance or combination of substances used under the guidance of TCM theory for prevention and treatment of diseases, disorders and TCM patterns.
030100	Chinese materia medica	The subject involves the information of medicinal plants, animals, mineral resources and their medicinal parts, including the cultivation, geographical distribution, collecting, preliminary processing, identification, and safety evaluation of pesticide residues, heavy metal content.
030200	Chinese medicinal pharmacology	The subject involves Chinese medicinal Pharmacology, including experimental pharmacology, clinical pharmacology, network pharmacology, and pharmacokinetic-pharmacodynamic (PK/PD).
030300	Chinese medicinal chemistry	Subject involves separation and purification of active ingredients, chemical analysis and synthesis of Chinese medicines.

Table 3 (continued)

Code	Subject type	Description
030400	Processing and preparation	The subject involves technology for physical or chemical alteration of Chinese materia medica into raw and cooked decoction pieces and form of prepared drugs.
030500	Clinical pharmacy	The subject involves clinical trials, Chinese medicinal property theory, clinical rational drug use, adverse drug reaction and poisonous effect of Chinese medicines, and prescription medicinals under the direction of TCM theory.
030600	TCM formula	The subject involves combination of decoction pieces and treatment of TCM formula with diseases.
030700	Trade of Chinese medicinal products	The subject involves the trade of Chinese medicinal products and the data set is created from a system or network of market, including the price, storage and production of information.
039900	Other subjects	Chinese medicine relative information which is not included in the above 7 sub-categories.
040000	Acupuncture and moxibustion	The subject of acupuncture, moxibustion and meridian related information
040100	Acupoints and Meridian	The subject involves the anatomical landmarks of the body surface, physiological function and traditional theory of acupoints. Information on the direction and route of the meridians, physiological function, and theory of meridians. Traditional theory based on ancient book
040200	Modern mechanism research	The subject involves modern mechanism, function principle and scientific connotation of acupuncture and moxibustion mainly using experimental method.
040300	Acupuncture and moxibustion Instrumentation	Information on instrument for diagnosis and treatment by stimulating meridians or acupoints.
040400	Clinical application	The subject includes acupuncture prescription, acupuncture anaesthesia and related information of clinical practice and clinical research with acupuncture therapy.
049900	Other acupuncture subjects.	Acupuncture information which is not included in the above 4 sub-categories.
990000	Other subject types	TCM relative information which is not included in the above 4 categories.

6 Examples for classifying and coding

It is suggested that one set of classification code be allocated when the data set has a single and definite subject, and multiple classification codes be allocated when the data set has multiple subjects.

Dataset name: Dataset of adverse drug reaction (ADR) monitoring of Chinese medicines

Dataset classification and code: TCM·05·0300·030500

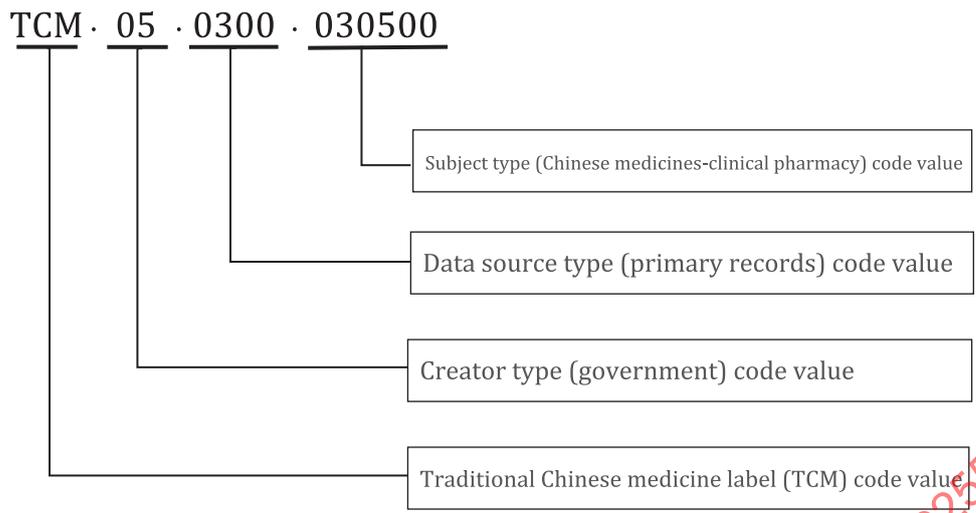


Figure 2 — Classification code structure analysis for data set of ADR monitoring of Chinese medicines

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Annex A (informative)

Use case analysis

A.1 Graphical description of use case

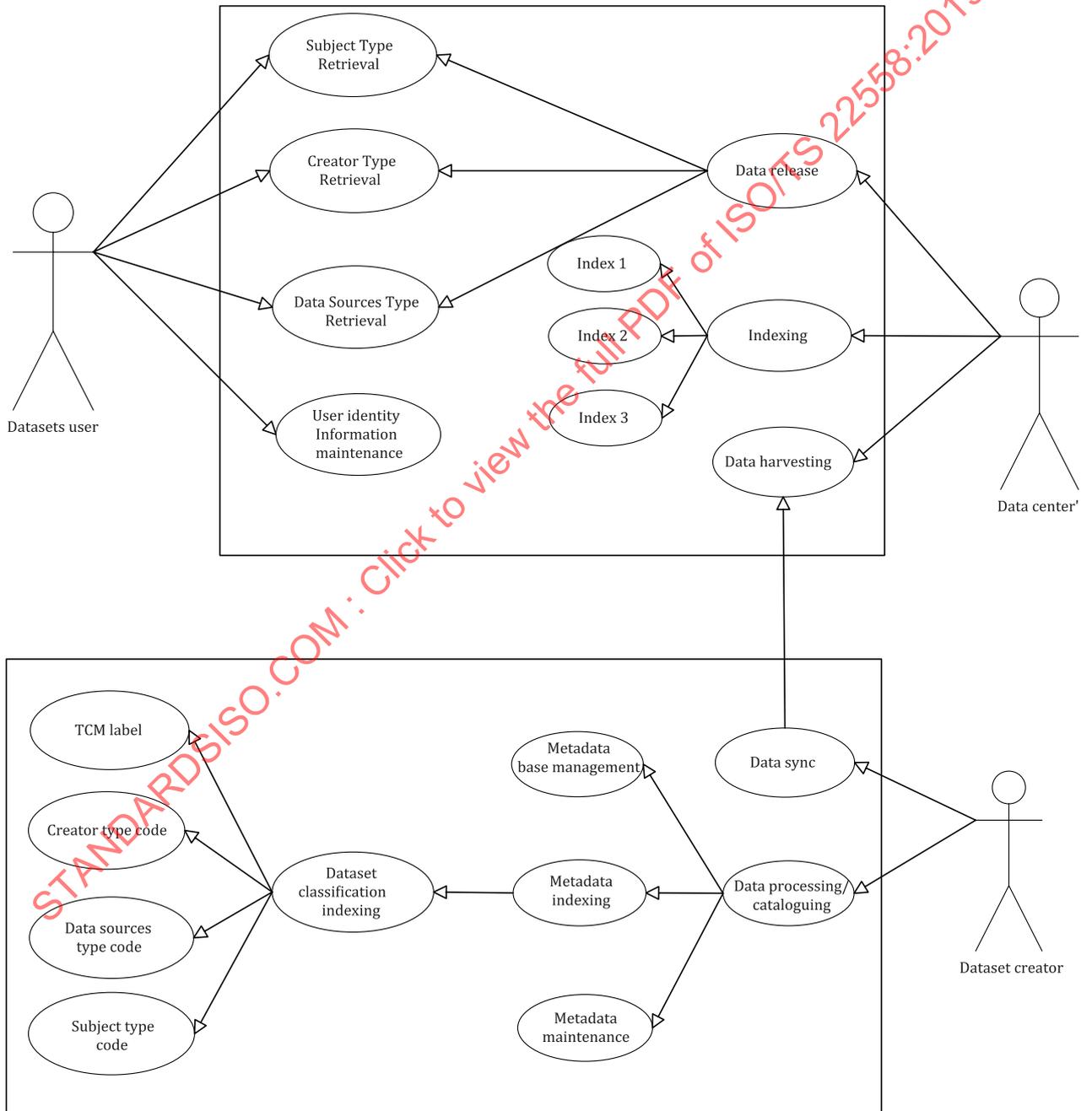


Figure A.1 — Graph of use case

A.2 Data processing/cataloguing

Use case name: Data processing/cataloguing
Description: Data creators use cases to complete data processing and cataloguing, such as metadata management, metadata indexing (including data set classification indexing), metadata maintenance, etc.
Identifier: uc1
Role: Data set creator
Precondition: Data creator has successfully logged in the system and has data set field maintenance, data set classification indexing, meta database management and metadata indexing permission.
<p>Main Flow:</p> <ol style="list-style-type: none"> 1. Data sets creator chooses login system option and use case begins. 2. Data sets creator inputs username and the system checks the effectiveness of username according to the rules. <ul style="list-style-type: none"> A1: Invalid username. 3. Data set creator inputs password and check it. <ul style="list-style-type: none"> A2: Password error. 4. Show the login success message. 5. Data sets creator manages meta database, and the system determines whether to create a new meta database according to the rules. <ul style="list-style-type: none"> A3: Select existing meta database 6. Create a new meta database: Data sets creator fills in the basic information of the meta database. 7. Data sets creator selects meta database, manages and maintains metadata. 8. Metadata processing indexing 9. Complete the data set classification indexing, custom selection of the corresponding TCM domain code, creator type code, data source type code and subject type code. 10. Meta database synchronization. 11. Use case ends.
<p>Other Flow:</p> <p>A1: Invalid username of data sets creator.</p> <ol style="list-style-type: none"> (1) Show message: invalid username. (2) Return to the main flow step 2. <p>A2: Password error.</p> <ol style="list-style-type: none"> (1) Show message: password error. (2) Return to the main flow step 3. <p>A3: Select existing meta database.</p> <ol style="list-style-type: none"> (1) Show metadata details. (2) Return to the main flow step 7.
Post condition: The system successfully updates the processed metadata to the meta database.
Special requirements: Null.

A.3 Metadata harvesting

Use case: Metadata harvesting
Description: Data centre harvests and synchronizes the data sets creator submitting metadata.
Identifier: uc2
Role: Data centre
Precondition: Data centre has successfully logged in the system and has data management and releasing permission; Data sets creator has submitted data.
<p>Main Flow:</p> <ol style="list-style-type: none"> 1. Data sets centre chooses login system option and use case begins. 2. Data sets centre inputs username and the system checks the effectiveness of username according to the rules. <ul style="list-style-type: none"> A1: Invalid username. 3. Data sets centre input password and check it. <ul style="list-style-type: none"> A2: Password error. 4. Show the login success message. 5. Data sets centre selects data harvesting/ synchronization, use case begins. 6. Select a location to read the source database. 7. Select a location to write to the target database. 8. Confirm synchronization. 9. Use case ends.
<p>Other Flow:</p> <p>A1: Data sets centre's username is invalid.</p> <ol style="list-style-type: none"> (1) Show message: Invalid username. (2) Return to the main flow step 2. <p>A2: Password error</p> <ol style="list-style-type: none"> (1) Show message: Password error. (2) Return to the main flow step 3.
Post condition: Null.
Special requirements: Null.

A.4 Indexing and releasing

Use case: Indexing and releasing
Description: Data centre sets the index for the data set creator and releases it to system front end.
Identifier: uc3
Role: Data centre
Precondition: Data centre has successfully logged in the system and has data management and releasing permission.