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STN	**Zdravotnícka informatika Zdroje klinických poznatkov Metaúdaje (ISO 13119: 2022)**	**STN EN ISO 13119 84 8101**

Health informatics - Clinical knowledge resources - Metadata (ISO 13119:2022)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/23

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Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13119

November 2022

ICS 35.240.80

Supersedes EN ISO 13119:2012

English Version

Health informatics - Clinical knowledge resources - Metadata (ISO 13119:2022)

Informatique de santé - Ressources des connaissances cliniques - Métadonnées (ISO 13119:2022)

Medizinische Informatik - Klinische Wissensresourcen - Metadaten (ISO 13119:2022)

This European Standard was approved by CEN on 26 September 2022.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 13119:2022 E

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European foreword

This document (EN ISO 13119:2022) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 13119:2022 has been approved by CEN as EN ISO 13119:2022 without any modification.

INTERNATIONAL STANDARD

ISO 13119

Second edition
2022-10

Health informatics — Clinical knowledge resources — Metadata

Informatique de santé — Ressources des connaissances cliniques — Métadonnées

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 13119:2012), which has been technically revised.

The main changes are as follows:

— a new Document Type has been added – Health Technology Assessment.

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

The internet is rapidly changing the way people access medical knowledge. Health professionals use web-based knowledge sources and databases, and patients/ individuals turn to the web to search for knowledge. There is a need for mechanisms to assess and clearly describe the quality and authenticity of such knowledge sources. Rather than trying to ban bad quality information, it is preferable to assist individuals, health professionals and software developers to find the type of information they request by making quality criteria behind a knowledge resource easily accessible.

Instead of reviewing the content of the medical knowledge resources, it is possible to define structures and processes behind their development, including quality assurance principles in general, peer review, professional education, etc. This area requires collaboration among many types of actors such as professional associations, publishers and health authorities.

One feasible and important approach is to establish a set of metadata to describe the content and procedures behind its production.

Many different types of documents are produced with the broad intent of providing "clinical knowledge", e.g. advice to patients for certain clinical problems, reports of research in the medical literature, guidelines issued by governmental authorities and researcher's protocols for clinical trials.

Some types of documents can have legal implications. Some guidelines are based on extensive high-quality scientific review/meta quality systems involving scientific reviews and can be influenced also by other (e.g. financial) considerations. In many areas of clinical care, the patients and professionals use advice of lesser status produced by one or a group of qualified experts. Such clinical guidelines are increasingly available on the internet and it is very important to provide information to assist in judgment about the nature, status and scientific background of such documents.

This document will not only be useful for the assessment of a knowledge resource but also to facilitate search and retrieval of knowledge resources.

This document for metadata is based on the general purpose Dublin Core Metadata Initiative which developed the first set of fifteen metadata elements, later published as ISO 15836:2009[1)], which has been revised as the ISO 15836 series.

This document provides an international set of health care specific extensions to this set. Some of the issues covered by health specific metadata tags in the CEN/TS 15699 have been replaced by corresponding Dublin Core qualifiers now available. This area is in a rapid development.

The basic structure (taken from Dublin Core) and the extensions provided in this document constitutes a source for possible use for a specific use case. An international set is certainly preferable when there is an audience for the knowledge resource outside of the country of origin. This is common for clinical knowledge resources in languages with users in many countries such as English, Spanish, French and Arabic.

However, for many use cases of metadata, it is important to provide a vocabulary that is easily understood perhaps also by laypersons and corresponding to the language used in the resource itself. This document can serve as an example for defining such national metadata vocabularies.

It is also emphasized that the extensive set of possible metadata elements defined in this document can be useful as a subset for a specific set of resources.

1) Withdrawn.

INTERNATIONAL STANDARD **ISO 13119:2022(E)**

Health informatics — Clinical knowledge resources — Metadata

1 Scope

This document specifies a number of metadata elements that describe resources containing medical knowledge, primarily digital documents provided as web resources, accessible from databases or via file transfer, but can be applicable also to paper documents, e.g. articles in the medical literature.

The metadata elements

— support unambiguous and international understanding of important aspects to describe a resource, e.g. purpose, issuer, intended audience, legal status and scientific background,

— are applicable to different kinds of digital resources, e.g. recommendation from consensus of a professional group, regulation by a governmental authority, clinical trial protocol from a pharmaceutical company, scientific manuscript from a research group, advice to patients with a specific disease, review article,

— are possible to present to human readers including health professionals as well as individuals/patients, and

— are potentially usable for automatic processing, e.g. to support search engines to restrict matches to documents of a certain type or quality level.

The metadata elements defined in this document are not intended to

— describe documents about a single patient, such as medical records,

— describe details of the medical content of the resource (but some idea of the content can be described via keywords or codes), or

— prescribe criteria for the quality of the resource content.

2 Normative references

There are no normative references in this document.