
Health informatics — Personal health data generated on a daily basis

*Informatique de santé — Données personnelles de santé générées sur
une base journalière*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO/TR 21835:2020](https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020)

[https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-
f30c4235464d/iso-tr-21835-2020](https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020)



iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO/TR 21835:2020

<https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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.....	v
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Use cases of health-related data.....	2
4.1 General.....	2
4.2 Patient Reported Outcomes (PRO).....	2
4.2.1 General.....	2
4.2.2 Clinical Data Interchange Standards Consortium (CDISC) — Questionnaires, Ratings, Scale (QRS).....	3
4.2.3 Patient Report Outcome Measures (PROMs).....	3
4.3 Social Determinants of Health (SDH).....	4
4.3.1 Social Determinants of Health — In general.....	4
4.3.2 Social Determinants of Health — At the local level.....	5
4.4 Observations of Daily Living (ODLs).....	6
4.5 Patient-generated Health Data.....	8
4.5.1 General.....	8
4.5.2 Meaningful Use Stage 3 Objective 6 — Coordination of Care through Patient Engagement.....	8
4.5.3 Life Record.....	9
4.5.4 Pain Assessment Notifier.....	9
4.5.5 Score Card Tool for Health Metrics Transparency.....	11
5 Categorization of health-related data.....	12
5.1 Patient-generated indirect data.....	12
5.1.1 Questionnaire report.....	12
5.1.2 Sociality.....	12
5.2 Patient-generated direct data.....	13
5.2.1 Breath capacity.....	13
5.2.2 Calories.....	13
5.2.3 Blood pressure.....	13
5.2.4 Blood sugar.....	13
5.2.5 Cholesterol.....	14
5.2.6 Step count.....	14
5.2.7 Sleep data.....	15
5.2.8 Stress.....	16
5.3 Patient and provider generated combination data.....	16
5.3.1 Allergy.....	16
5.3.2 Medication.....	17
5.3.3 Disease.....	17
5.3.4 Vaccination.....	17
5.3.5 Medical image report.....	17
5.4 Coded data elements.....	17
5.4.1 Questionnaire report.....	17
5.4.2 Allergy.....	17
5.4.3 Medication.....	17
5.4.4 Disease.....	17
5.4.5 Vaccination.....	18
5.4.6 Medical image report.....	18
5.4.7 Breath capacity.....	18
5.4.8 Calories.....	18
5.4.9 Blood pressure.....	18

5.4.10	Blood sugar.....	18
5.4.11	Cholesterol.....	18
5.5	Un-coded data elements.....	18
5.5.1	Step count.....	18
5.5.2	Sleep data.....	18
5.5.3	Stress.....	19
5.5.4	Sociality.....	19
Bibliography.....		20

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO/TR 21835:2020](https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020)

<https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020>

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*.

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 increasing number of smart phones, mobile applications and remote monitoring devices combined with EHRs, patient portals and PHR systems enhance the patient's engagement in healthcare services. However, patient health data, which are constantly created, recorded, gathered or inferred have not yet been actively utilized at the point of care.

Specifically, un-coded data are too subjective and informal. In order to be applicable to clinical environment, ambiguity should be minimized or eliminated, and more precise. The health-related data should accurately convey the concept they are intended to deliver. The ISO/IEEE 11073 series and IHE-PCD Rosetta work are one of candidates to accomplish this goal. For health-related data to be reliably integrated into the process of diagnostic and therapeutic decision making, they should be quality-assured, trusted in accordance to accuracy of measurements.

In terms of safety and interoperability, AAMI/UL 2800 defined safety and related specifications of Medical Device (MD) interface to be labelled or declared as Interoperable Medical Device. The standard specifies MD interface characteristics to operate in safety conditions and focus on the mitigation of risk associated with interoperability within the Integrated Clinical Environment (ICE) and Interoperable Scenario (IS). It might be complementary to ISO/IEEE 11073-20601, particularly in mobile environments for improving care delivery, optimizing workflow and reducing ambiguity.

The Personal Connected Health Alliance (PCHAlliance) released the Continua Design Guidelines (CDGs) to enable the secure, private, reliable and accurate sharing of patient generated health data with healthcare providers, built-on HL7 FHIR¹⁾ (Fast Healthcare Interoperability Resources) specifications. The Continua Design Guidelines define an open, flexible framework for end-to-end interoperability and the convenient collection and exchange of clinical grade health data for improved health, wellness and disease management. They are built on existing open, international standards and specifications including ISO/IEEE deliverables, IEC deliverables, HL7 deliverables, USB and Bluetooth. The International Telecommunication Union (ITU) recognizes the Continua Design Guidelines as an international standard for personal health systems and makes them available for global adoption in the several languages. Valuable tools and resources support product certification via the Continua Design Guidelines, including: the Continua Enabling Software Library (CESL), CODE for Healthcare and test tool development, representing millions of dollars worth of software development created by Continua to enable complete end-to-end functionality. PCHAlliance members have access to Continua Certified Experts (CCE), pre-market interoperability testing, Technical Operations Leads and brand support for Continua Certified products. PCHAlliance also participates in a series of events around the world to connect members with buyers, as well as Plugfests, Summits and an online Product Showcase highlighting Continua Certified products and services^[18].

Furthermore, Health-related data have in-depth relevance with IoT and related technologies because health-related data are usually created by IoT devices. In order to ensure quality and safety of Health-related data along with IoT, the Standard Development Organizations (SDOs) should collaborate with each other more effectively.

1) FHIR[®] is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

Health informatics — Personal health data generated on a daily basis

1 Scope

This document provides an environmental scan of common data elements that are captured through various modalities such as cell phones, smart phones, mobile applications and remote monitoring devices that are combined with EHRs, patient portals and PHR systems which can ultimately be applicable to a variety of healthcare service environments.

The Health-related data can be used to supplement existing clinical data, filling in gaps in information and providing a more comprehensive picture of ongoing patient healthcare.

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 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

assessment

measurement, evaluation or judgment for a study variable pertaining to the status of a subject

3.2

biometric

use of specific attributes that reflect unique personal characteristics, such as a fingerprint, an eye blood-vessel print, or a voice print, to validate the identity of entities

3.3

clinician

health professional who delivers health services directly to a patient/client

3.4

disorder

alterations or attributes of the health status of an individual which might lead to distress, interference with daily activities, or contact with health

3.5

experience

facts, information and skills acquired through experience, reasoning or education

3.6

personal health data

personal data relevant to the health of an identified or identifiable natural person

3.7 individual
single discrete entity

3.8 measure
collect quantifiable data about a function or process

3.9 monitor
medical device designed to acquire, display, record, and/or analyse patient data and to alert caregivers of events needing their attention

3.10 observation
measurement of a single variable or single value derived logically and/or algebraically from other measured or derived values

3.11 pain
health condition that results in some disability, pain and/or activity limitation

3.12 patient
synonym for a subject of care

3.13 symptom
untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment

3.14 treatment
medical or surgical management of a patient

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO/TR 21835:2020](https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020)

<https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020>

4 Use cases of health-related data

4.1 General

Health is more than healthcare. The County Health Rankings^[20] are based on a model of community health that emphasizes the many factors that influence how long and how well we live. According to the County Health Rankings Model, health factors help communities understand what will impact their health in the future. Health factors are composed of Physical Environment (10 %), Social and Economic Factors (40 %), Health Behaviours (30 %), and Clinical care (20 %). The following are health-related data use cases that patients / customers write or report in a non-hospital setting.

4.2 Patient Reported Outcomes (PRO)

4.2.1 General

A PRO is a health outcome directly reported from patient who experienced it. It is different from an outcome reported by someone else, like physician-reported outcome, a nurse-reported outcome, and so on. PRO methods, such as questionnaires, are used in clinical trials or other clinical setting, to help better understand a treatment's efficacy or effectiveness.

Incorporating the patient perspective through patient reported outcome measures is a crucial element for clinical care, quality performance management and clinical research. PROs are any report coming directly from patients regarding their health condition and treatment, including symptoms, functional status and health-related quality of life. Some PRO measures are generic and appropriate for use in

a wide range of conditions, while others focus on the specific symptoms and side effects of a given disease, condition or treatment.

A PRO is a measurement based on a report that comes from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's report by a clinician or anyone else. Symptoms or other unobservable concepts known only to the patient (e.g., pain severity or nausea) can only be measured by PRO measures.

EXAMPLE Sheehan Disability Scale (SDS).

4.2.2 Clinical Data Interchange Standards Consortium (CDISC) — Questionnaires, Ratings, Scale (QRS)

Clinical Data Interchange Standards Consortium is an open, non-profit organization that develops and supports global data standards to improve the quality and interoperability of medical research and healthcare. CDISC standards are widely used for study planning and data collection, tabulation, analysis, and submissions to the US Food and Drug Administration (FDA) and other regulatory agencies internationally.

Questionnaires, Ratings, Scale instrument is a series of questions, tasks or assessments used in clinical research to provide a qualitative or quantitative assessment of a clinical concept or task-based observation^[1].

Questionnaire instruments are stored in the Questionnaires domain and are named, standalone instruments designed to provide an assessment of a concept. Questionnaires often have a defined standard structure, format, and content, consist of conceptually related items that are typically scored; and usually document methods for administration and analysis. Questionnaires consist of defined questions with a defined set of potential answers. Most often, the primary purpose of questionnaires is to generate quantitative statistic to assess a qualitative concept. If the instrument is a Rating or Grading Scale in which the intent of the instrument is to evaluate a single body system, it would be stored in the morphology/physiology domain, which represents that body system. Other Rating or Grading Scales related to multiple body systems and all Composite Score type instruments would be represented as a Clinical Classification in the RS domain.

Examples of QRS:

- 6 Minute Walk Test.
- Airway Questionnaire.
- Alcohol Use Disorders Identification Test – Self-Report Version.
- Alzheimer's Disease Assessment Scale - Cognitive (ADAS-Cog).

In the above example, how to provide QRS to the user conveniently is a matter to be solved by Advanced UI/UX and natural language processing technologies. FHIR questionnaire adoption is also expected to ensure interoperability of this kind of QRS data collected from cohort studies.

4.2.3 Patient Report Outcome Measures (PROMs)

In the UK, the National Health Service (NHS) collects survey data from patients who received specific surgical treatment^[2].

- a) Knee replacement.
- b) Hip replacement.
- c) Groin hernia.
- d) Varicose veins.

These PROMs data measure

- patient's health status, and
- health-related quality of life at the single point.

This health status information is collected before and after a procedure and provides an indication of the outcomes or quality of care delivered to NHS patients^[3].

To facilitate the inclusion of PROs in the EHR, and address the barriers to doing so, a multidisciplinary team was formed to develop this "Users' Guide for Integrating Patient Reported Outcomes in Electronic Health Records". It addresses 11 key questions for integrating PROs in the EHR:

1. What strategy will be used for integrating PROs in EHRs?
2. How will the PRO-EHR system be governed?
3. How can users be trained and engaged?
4. Which populations and patients are most suitable for collection and use of PRO data, and how can EHRs support identification of suitable patients?
5. Which outcomes are important to measure for a given population?
6. How should candidate PRO measures be evaluated?
7. How, where, and with what frequency will PROs be administered?
8. How will PRO data be displayed in the EHR?
9. How will PRO data be acted upon?
10. How can PRO data from multiple EHRs be pooled?
11. What are the ethical and legal issues?

ITEH STANDARD PREVIEW
(standards.iteh.ai)

ISO/TR 21835:2020
<https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-30c4235464d/iso-tr-21835-2020>

4.3 Social Determinants of Health (SDH)

4.3.1 Social Determinants of Health — In general

The social determinants of health are linked to the economic and social conditions and their distribution among the population that influence individual and group differences in health status. They are health promoting factors found in one's living and working conditions (such as the distribution of income, wealth, influence, and power), rather than individual risk factors (such as behavioural risk factors or genetics) that influence the risk for a disease, or vulnerability to disease or injury^[19].

The social determinants of health are the conditions in which people are born, grow, live, work and age.

These social determinants of health include

- a) social gradients (life expectancy is shorter and disease is more common further down the social ladder),
- b) stress (including stress in the workplace),
- c) early childhood development,
- d) social exclusion,
- e) unemployment,
- f) social support networks,

- g) addiction,
- h) availability of healthy food,
- i) availability of healthy transportation / active travel, and
- j) religion, caste, all the social diversities.

4.3.2 Social Determinants of Health — At the local level

There is widespread interest in the role of local social determinants of health at the local level. Federal, state, and local government agencies, academic institutions, and community organizations are increasingly recognizing the need to understand and address the socioeconomic contexts within which people work and play in order to improve their health and welfare.

12 dimensions of the social environment:

- a) Economy
- b) Employment
- c) Education
- d) Political
- e) Environmental
- f) Housing
- g) Medical
- h) Governmental
- i) Public Health
- j) Psychosocial
- k) Behavioural
- l) Transport

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO/TR 21835:2020](https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020)

<https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020>

According to the World Health Organization (WHO), the social determinants of health are the conditions in which people are born, grow, live, work and age, and these are influenced by the way of wealth and resources are distributed ^[19]. It affects a wide range of health, functioning and quality of life outcomes, and risks.

20 SDH domains covered in six of the most widely used SDH screening tools in the US (see [Table 1](#)) have been identified, including the following:

- a) the NAM's 2014 Recommended Social and Behavioral Domains and Measures report, which is the basis for the ONC Social, Psychological, and Behavioral data certification criterion for EHRs17;
- b) the National Association of Community Health Center's PRAPARE survey;
- c) the Center for Medicare & Medicaid Innovation's Accountable Health Communities (AHC) survey;
- d) the Health Leads questionnaire36;
- e) the University of Maryland's SEEK tool37;
- f) the WE CARE survey.

Table 1 — SDH screening tools

Access to healthcare
Childcare
Clothing
Education
Employment
Finances Income/poverty Financial stress
Food
Housing Housing instability / insecurity Housing quality
Immigration / migration
Incarceration
Primary language
Race / ethnicity
Residential address
Safety Intimate partner violence Child abuse Neighbourhood safety
Social connections / isolation
Stress
Transportation
Utilities
Veteran status
General SDH (non domain-specific)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/b9429946-037b-487c-ba76-f30c4235464d/iso-tr-21835-2020>

4.4 Observations of Daily Living (ODLs)

The Project Health Design demonstrates how to improve participant’s health and well-being by capturing and interpreting ODLs information^[4]. ODLs include attending to cues such as the quantity and quality of sleep, the confidence one feels in self-management, the tenor of family dinner conversations, the cadence of speech, or the ease of doing daily tasks like opening a jar^[4].

ODLs can be the following:

- a) Quantity and quality of sleep;
- b) Moods experienced in day-to-day life;
- c) The ease with which an individual completes daily tasks;
- d) Level of pain experienced throughout the day;
- e) Fluctuations in day-to-day stress.