دانشگاه علوم پزشکی و خدمات بهداشتی درمانی گیلان

جمهوری اسلامی ایران
وزارت بهداشت، درمان و آموزش پزشکی

Data Management in Registries
Ensuring Quality and Integrity

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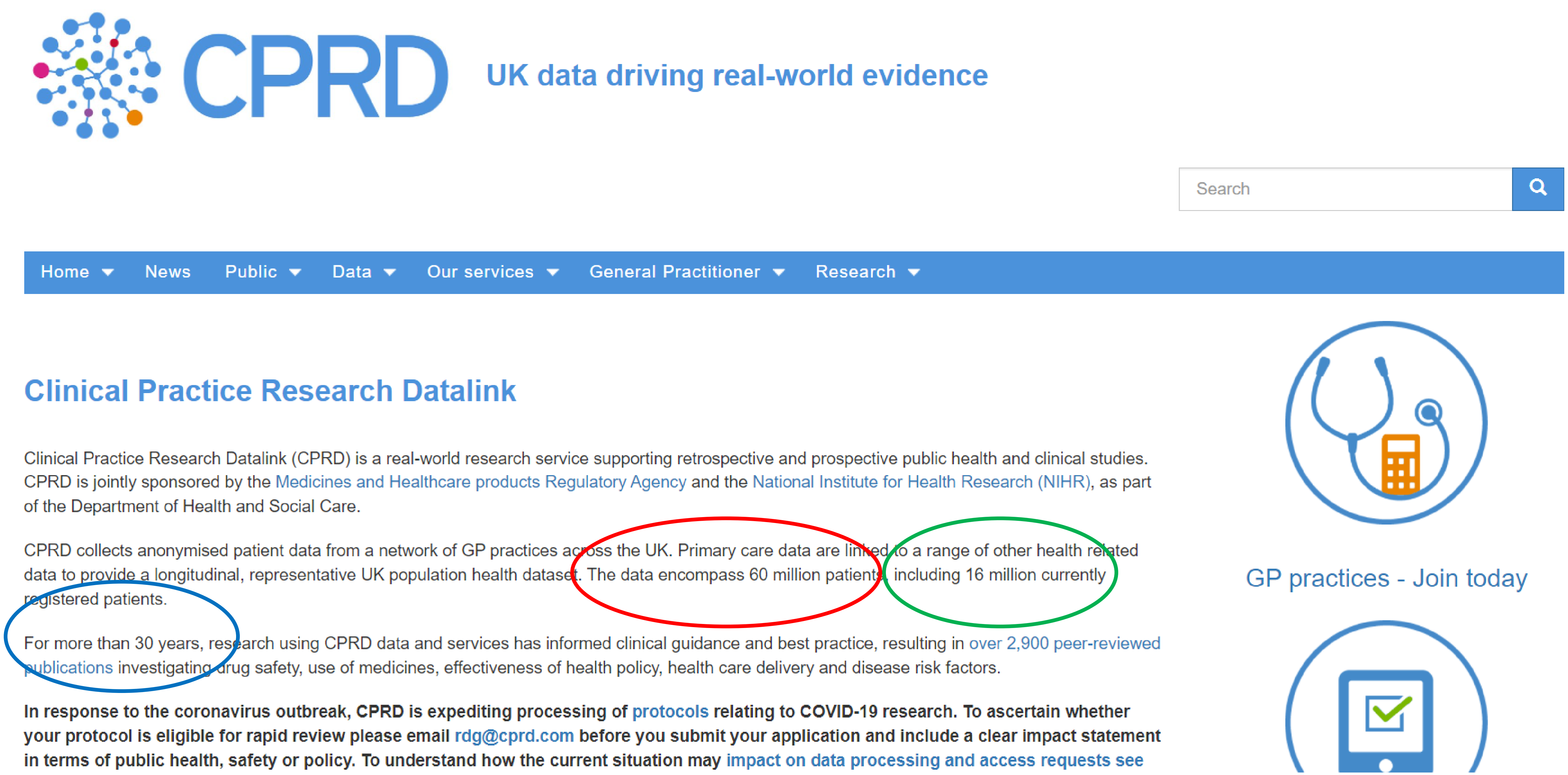
Defining Patient Registries

Patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate *specified outcomes* for a population defined by a **particular disease**, **condition**, or **exposure**, and that serves one or more stated scientific, clinical, or policy purposes.



Clinical Practice Research Datalink

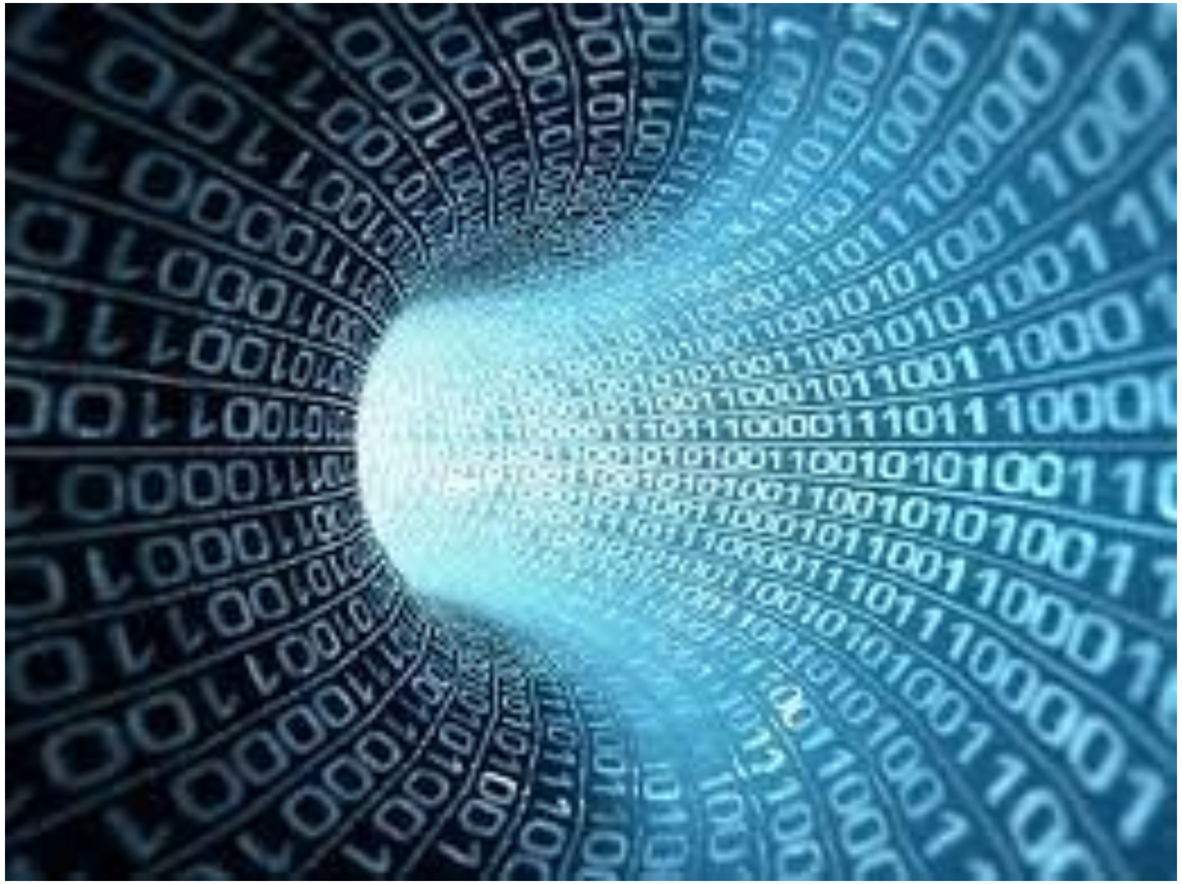
Clinical Practice Research Datalink (CPRD) is a real-world research service supporting retrospective and prospective public health and clinical studies. CPRD is jointly sponsored by the Medicines and Healthcare products Regulatory Agency and the National Institute for Health Research (NIHR), as part of the Department of Health and Social Care.

CPRD collects anonymised patient data from a network of GP practices across the UK. Primary care data are linked to a range of other health related data to provide a longitudinal, representative UK population health dataset. The data encompass 60 million patients, including 16 million currently registered patients.

For more than 30 years, research using CPRD data and services has informed clinical guidance and best practice, resulting in over 2,900 peer-reviewed publications investigating drug safety, use of medicines, effectiveness of health policy, health care delivery and disease risk factors.

In response to the coronavirus outbreak, CPRD is expediting processing of protocols relating to COVID-19 research. To ascertain whether your protocol is eligible for rapid review please email rdg@cprd.com before you submit your application and include a clear impact statement in terms of public health, safety or policy. To understand how the current situation may impact on data processing and access requests see

Today's Data, Tomorrow's Discoveries



Increasing Access to the Results of Research Funded by the National Science Foundation

National Science Foundation

March 18, 2015

This presentation is about:

- ➢ **Introduction to data management & sharing**

  - ○ Why Manage Your Data?
  - ○ Formatting and organizing the data
  - ○ Storage and Security of Data
  - ○ Data documentation and meta data
  - ○ Quality control & Version controlling
  - ○ Controlled Vocabulary
  - ○ Common Data Elements
  - ○ Data Sharing
  - ○ Data management plans

- ➢ **Examples for routine practices**
- ➢ **Examples for modern practices**

Background

1. Research funders are increasingly mandating open access to research data
2. Governments internationally are demanding transparency in research
3. The economic climate is requiring much greater reuse of data
4. Fear of data loss calls for more robust information security practices.
5. Journal publishers increasingly require submission of the data up on which publications are based for peer review.
6. **Researchers and data users recognize the long-term value of well-prepared data.**

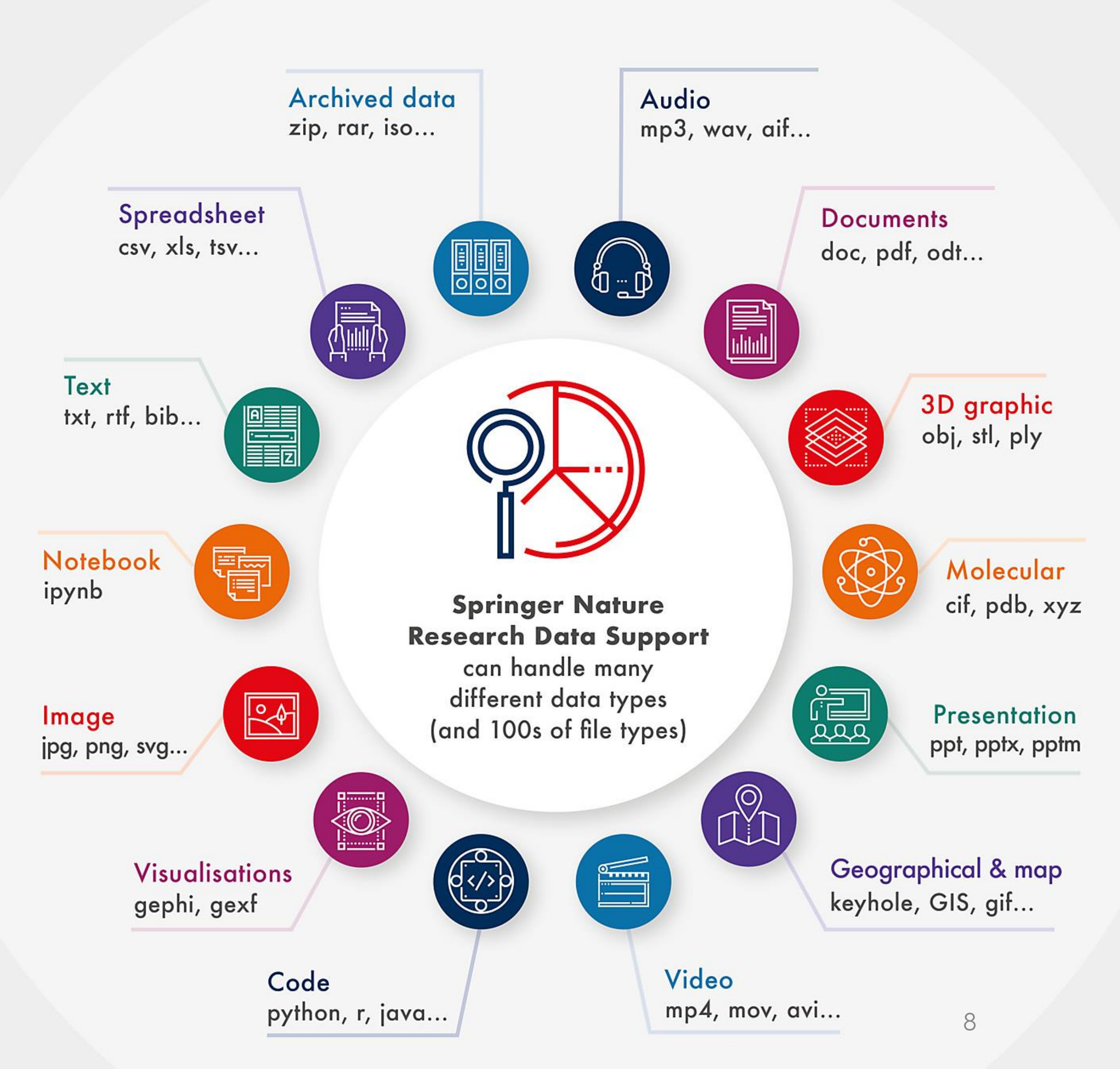
Why Manage Your Data?

[Good practice in Managing & sharing research data]()

Types of Research Data

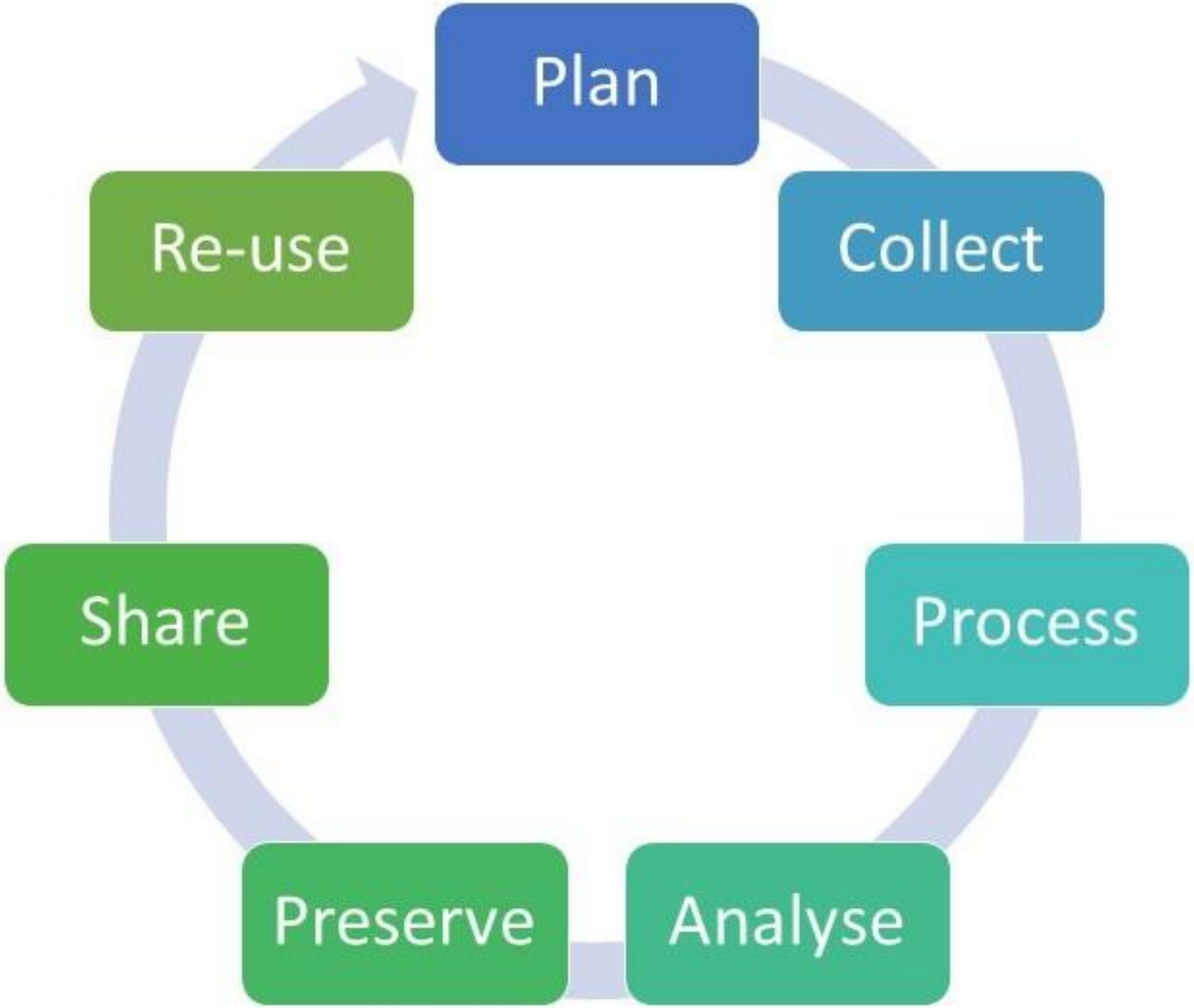
Research data can be many different things - it's not just spreadsheets and it's not just code!

It's a whole myriad of files that can be created through research...essentially all outputs that are not a research publication!



https://researchdata.springernature.com/posts/30232-infographic-types-of-research-data

Data Lifecycle



Plan

Collect

Process

Analyse

Preserve

Share

Re-use

By Data Management we mean all data practices, manipulations, enhancements and processes that ensure that research data are of a high quality, are well organized, documented, preserved, sustainable, accessible and reusable.

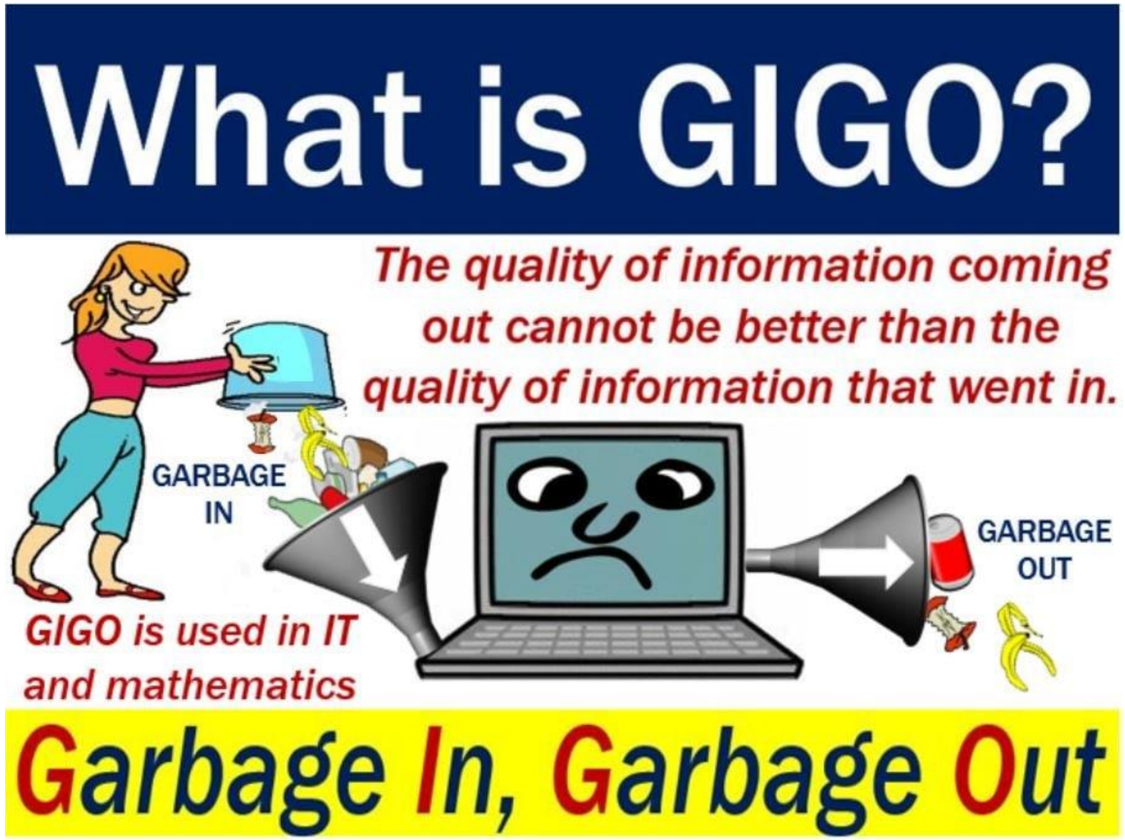
Management of medical, health and clinical data is a critical part of the research process. It enables:

✓Increased quality of your research

✓Increased transparency and trust in data you obtain

✓Reproducibility of research through increasing veracity of data

✓Strengthening of researchers’ reputation through increased citations and reach of all research outputs.



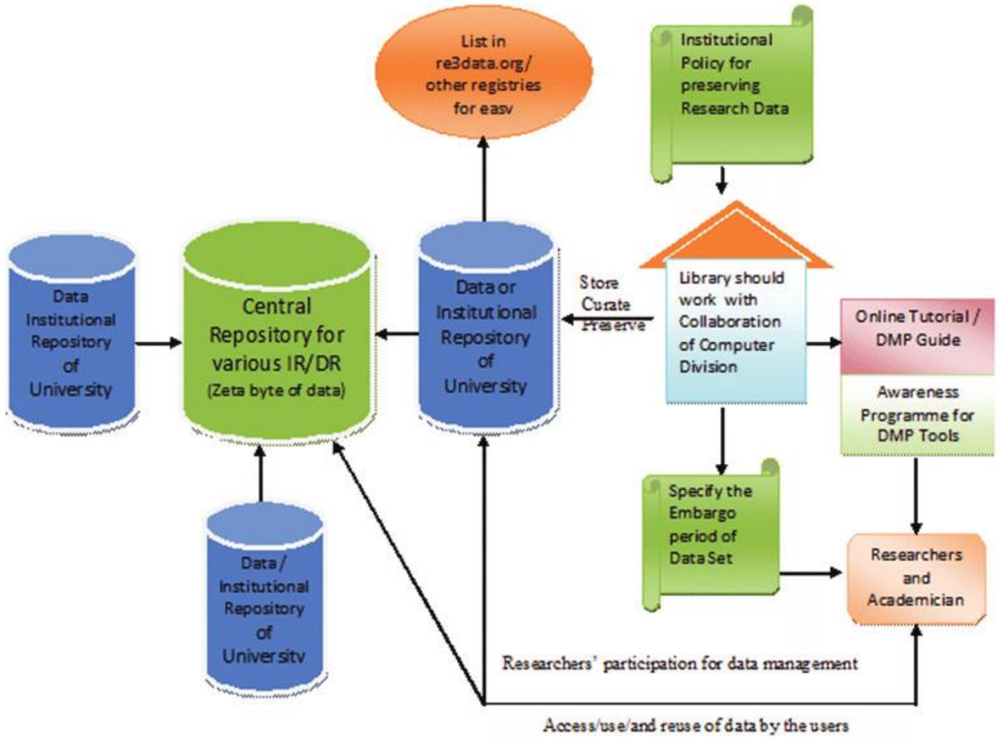
What is GIGO?

The quality of information coming out cannot be better than the quality of information that went in.

GIGO is used in IT and mathematics

Garbage In, Garbage Out

Different Processes in Research Data Management



Key Characteristics of Data Management

- Data Collection Process
    - Types of Data Collected
    - Methods of Data Collection
- Data Quality Assurance
    - Importance of Data Quality
    - Strategies for Ensuring Data Accuracy
- Data Security Measure
    - Importance of Data Security
    - Compliance with Privacy Regulations

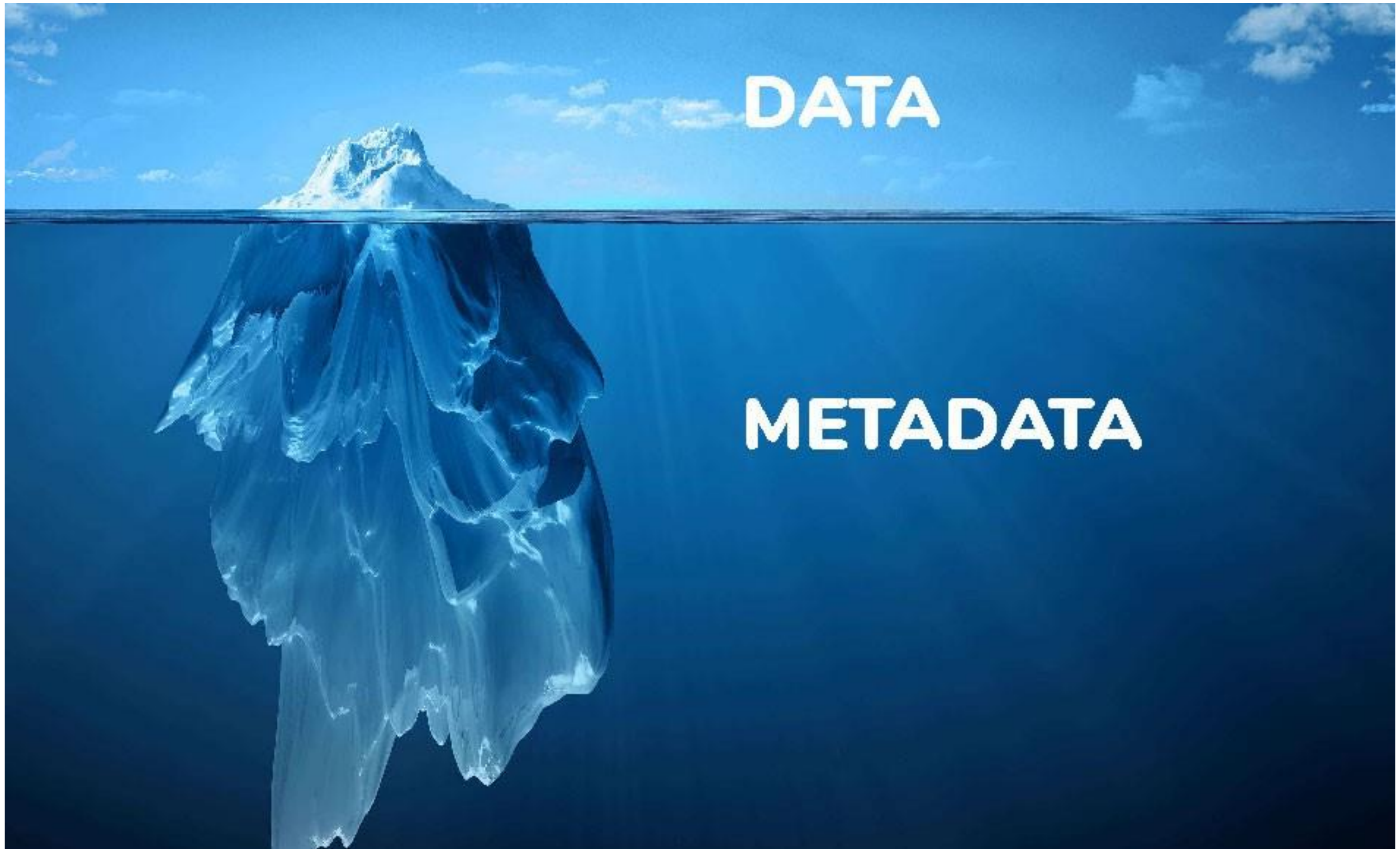
Formatting and organizing the data

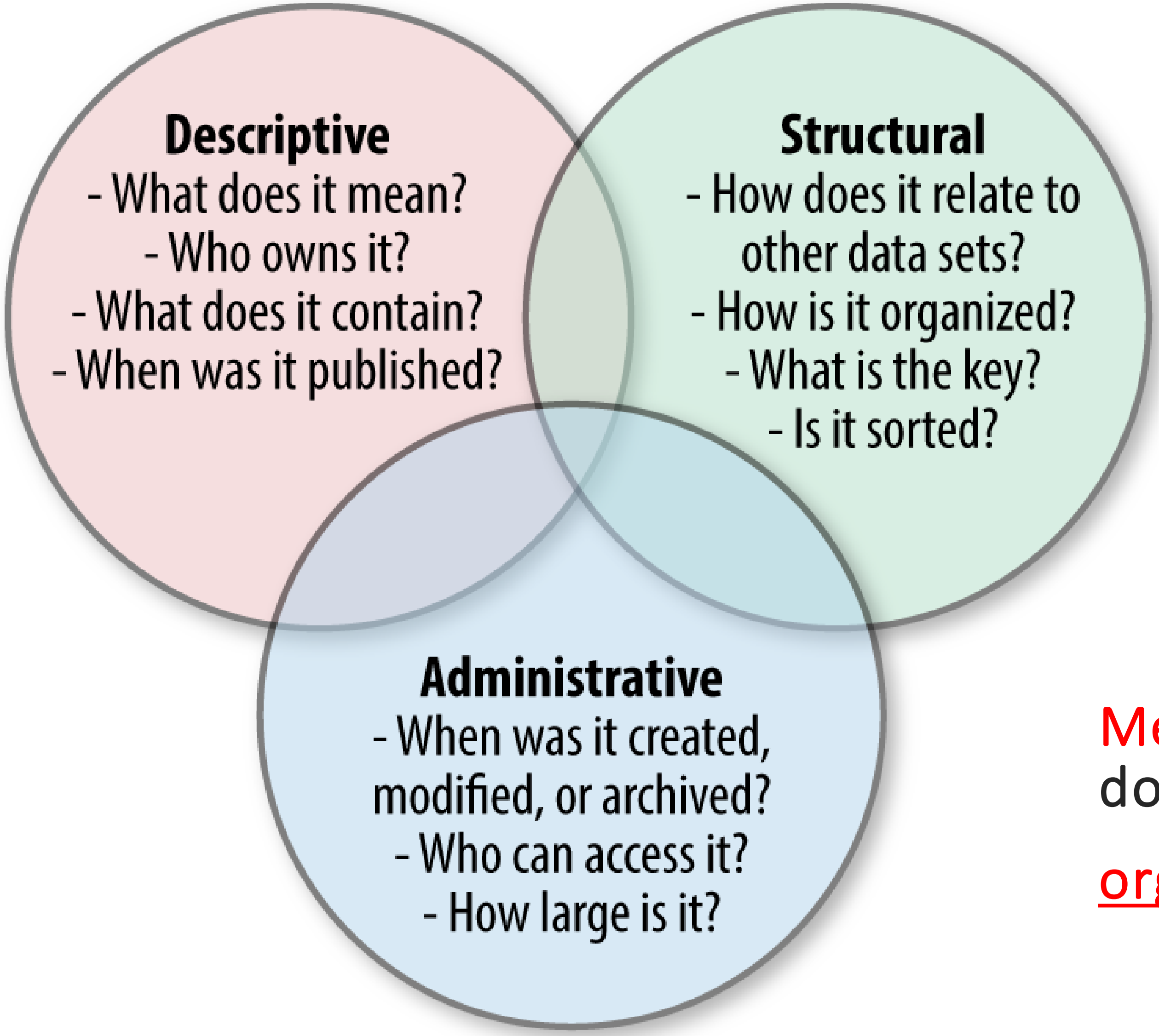
- Choosing File Formats
  - Format best suited for data creation
  - Format best suited for data analyses and other planned uses;
  - Format best suited for long-term sustainability and sharing of data
- Data conversion
- File Names
- Best Practice for File/folder Structure

Data documentation and Meta Data

Metadata = Data about data

Metadata vs. Data





Descriptive
- What does it mean?
- Who owns it?
- What does it contain?
- When was it published?

Structural
- How does it relate to other data sets?
- How is it organized?
- What is the key?
- Is it sorted?

Administrative
- When was it created, modified, or archived?
- Who can access it?
- How large is it?

Metadata are a specific subset of data documentation that provides

organized searchable information

Data documentation and Meta Data

- Study-level data documentation

- Data - level data documentation

Data Dictionary

Good study-level data documentation includes:

Research design and context of data collection

Data collection methods

Structure of data files, with number of cases, records, files and variables, as well as any relationships among such items;

Secondary data sources used and provenance

Data validation, checking, proofing, cleaning and other quality assurance procedures

Modifications made to data over time since their original creation and identification different versions of datasets;

Information on data confidentiality, access and any applicable conditions of use;

Publications, presentations and other research outputs that explain or draw on the data.

Good data-level data documentation includes:

- Names, labels and descriptions
- Value code labels
- Coding and classification schemes
- Codes for missing values
- **Derived new concepts from other variables**
- Weighting variables

فرا داده و فرهنگ لغت مطالعه قند و لیپید تهران

پژوهشکده علوم غدد درون ریز و متابولیسم
دانشگاه علوم پزشکی شهید بهشتی

گروه آمار و اپیدمیولوژی
۱۳۹۹
ویرایش دوم

فهرست مطالب

عنوان **صفحه**

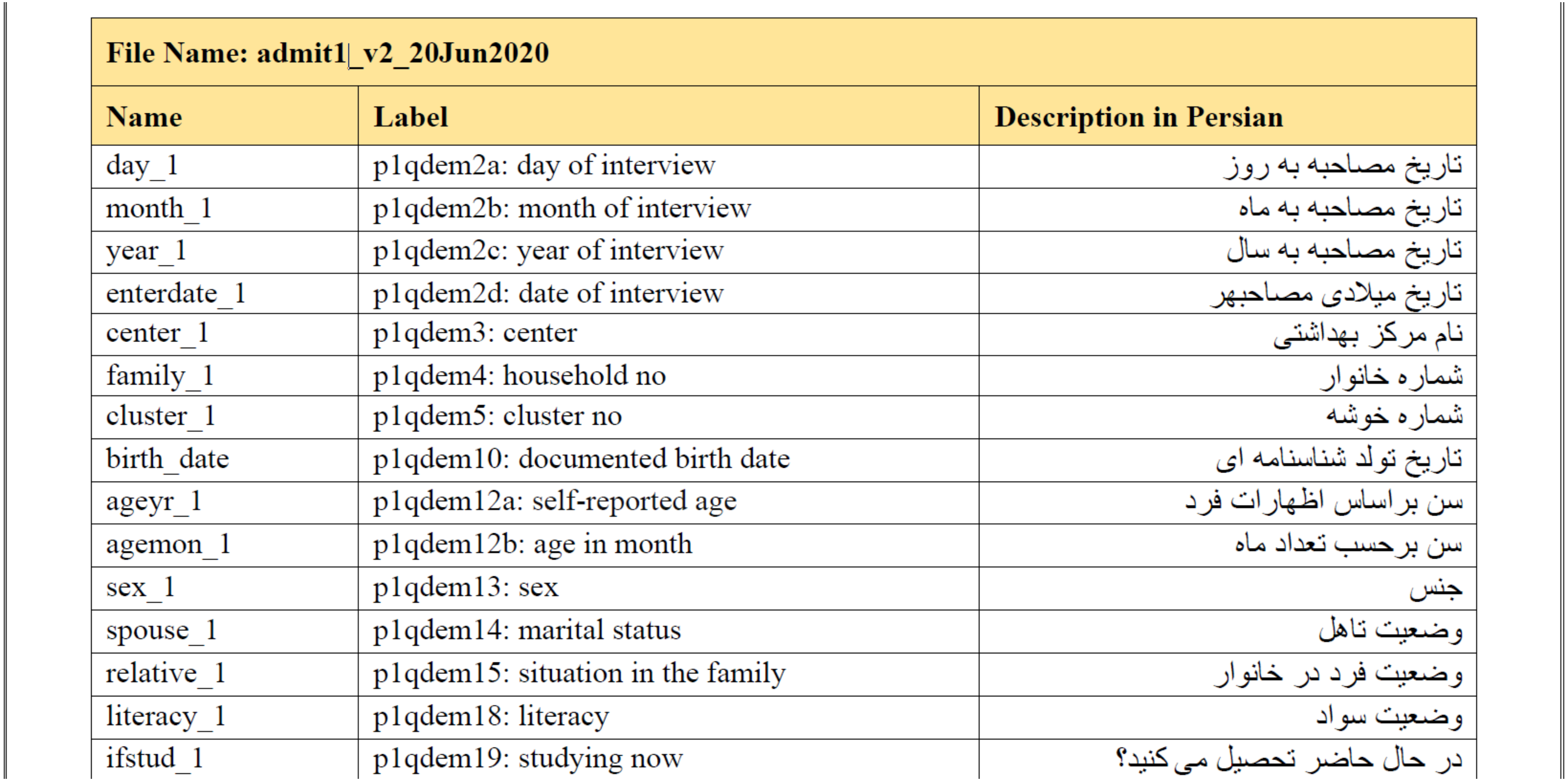
فصل اول

فصل دوم

جدول های فرهنگ لغت داده ها

حیطه های موجود در پرسشنامه قند و لیپید تهران شامل موارد زیر است:

ردیف	اصطلاح فارسی	اصطلاح انگلیسی	مخفف حیطه	مخفف روش جمع آوری داده ها
۱	اطلاعات دموگرافیک	Demographic information	DEM	Q
۲	سوابق پزشکی	Past medical history	PMH	Q
۳	عادات مصرف دخانیات نوجوانان	Adolescent smoking	ASS	Q
۴	عادات مصرف دخانیات بالغین	Adult smoking	ADS	Q
۵	فعالیت بدنی نوجوانان	Adolescent physical activity	ASP	Q
۶	فعالیت بدنی بالغین	Adult physical activity	ADP	Q
۷	درد سینه و لنگش متناوب	Chest pain & claudication	ROS	Q
۸	سوالات خانمها	Women	WMN	Q
۹	تغذیه	Nutrition	NUT	Q
۱۰	معاینات پزشکی	Medical examinations	MED	E
۱۱	تن سنجی	Anthropometric measurement	ANT	E
۱۲	نوار قلب	ECG	ECG	E
۱۳	آزمایشگاه	Lab	LAB	P
۱۴	پیامد	Outcome	OUT	F
۱۵	تاریخ پیگیری	Followup date	FUD	F



File Name: admit1_v2_20Jun2020

Name	**Label**	**Description in Persian**
day_1	p1qdem2a: day of interview	تاریخ مصاحبه به روز
month_1	p1qdem2b: month of interview	تاریخ مصاحبه به ماه
year_1	p1qdem2c: year of interview	تاریخ مصاحبه به سال
enterdate_1	p1qdem2d: date of interview	تاریخ میلادی مصاحبهر
center_1	p1qdem3: center	نام مرکز بهداشتی
family_1	p1qdem4: household no	شماره خانوار
cluster_1	p1qdem5: cluster no	شماره خوشه
birth_date	p1qdem10: documented birth date	تاریخ تولد شناسنامه ای
ageyr_1	p1qdem12a: self-reported age	سن براساس اظهارات فرد
agemon_1	p1qdem12b: age in month	سن برحسب تعداد ماه
sex_1	p1qdem13: sex	جنس
spouse_1	p1qdem14: marital status	وضعیت تاهل
relative_1	p1qdem15: situation in the family	وضعیت فرد در خانوار
literacy_1	p1qdem18: literacy	وضعیت سواد
ifstud_1	p1qdem19: studying now	در حال حاضر تحصیل می کنید؟

راهنمای اخطار در ستون وضعیت

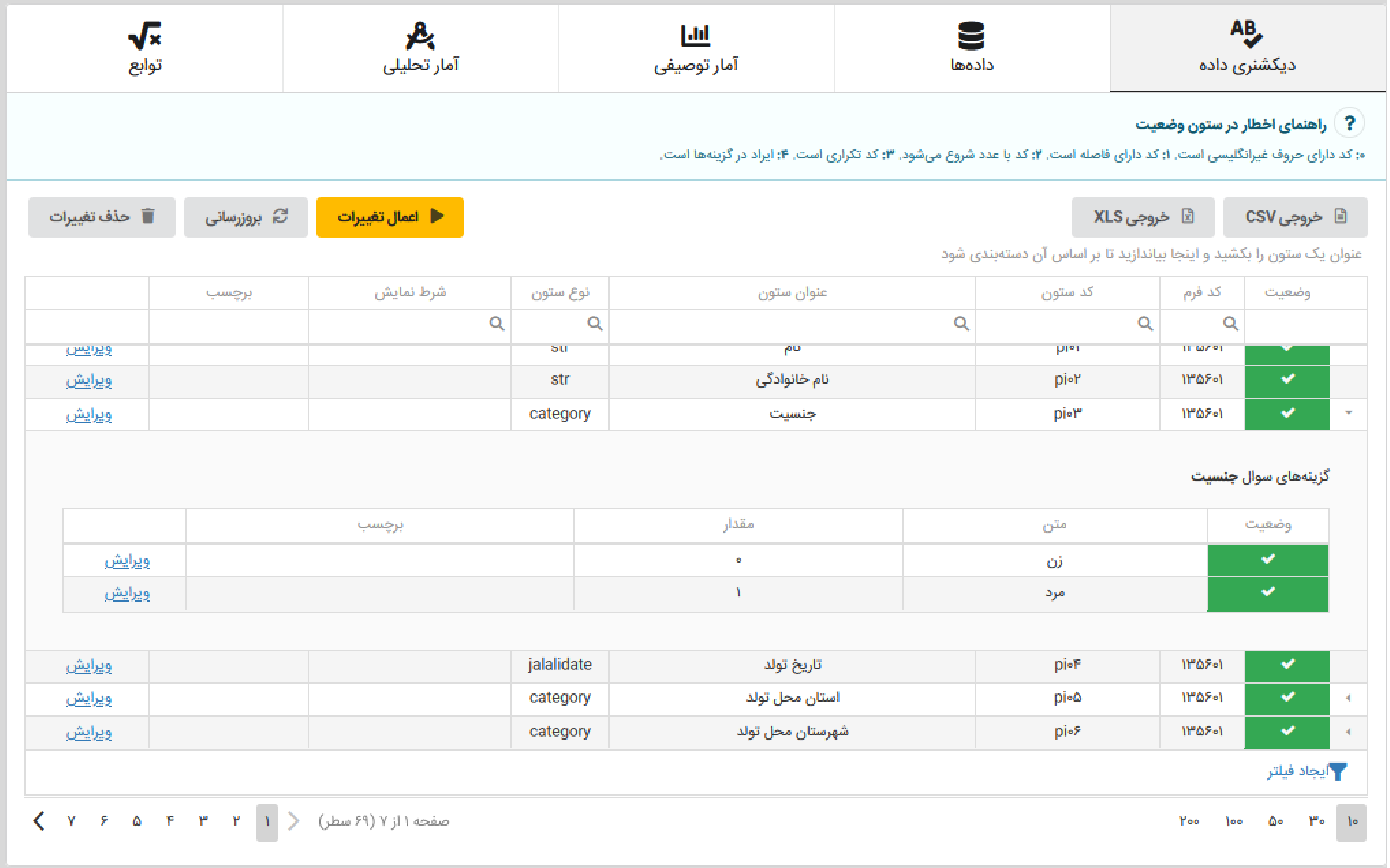
۰: کد دارای حروف غیرانگلیسی است. ۱: کد دارای فاصله است. ۲: کد با عدد شروع می‌شود. ۳: کد تکراری است. ۴: ایراد در گزینه‌ها است.

عنوان یک ستون را بکشید و اینجا بیاندازید تا بر اساس آن دسته‌بندی شود

	وضعیت	کد فرم	کد ستون	عنوان ستون	نوع ستون	شرط نمایش	برچسب	
	✓	۰	pid	کد	numeric			ویرایش
	✓	۰	fullName	نام و نام خانوادگی	str			ویرایش
	✓	۰	questioner	پرسشگر	str			ویرایش
	✓	۰	questionerId	کد پرسشگر	str			ویرایش
	✓	۱۳۵۶۰۱	pi۰۱	نام	str			ویرایش
	✓	۱۳۵۶۰۱	pi۰۲	نام خانوادگی	str			ویرایش
◂	✓	۱۳۵۶۰۱	pi۰۳	جنسیت	category			ویرایش
	✓	۱۳۵۶۰۱	pi۰۴	تاریخ تولد	jalalidate			ویرایش
◂	✓	۱۳۵۶۰۱	pi۰۵	استان محل تولد	category			ویرایش
◂	✓	۱۳۵۶۰۱	pi۰۶	شهرستان محل تولد	category			ویرایش

صفحه ۱ از ۷ (۶۹ سطر)

الله



راهنمای اخطار در ستون وضعیت

۰: کد دارای حروف غیرانگلیسی است. ۱: کد دارای فاصله است. ۲: کد با عدد شروع می‌شود. ۳: کد تکراری است. ۴: ایراد در گزینه‌ها است.

عنوان یک ستون را بکشید و اینجا بیاندازید تا بر اساس آن دسته‌بندی شود

وضعیت	کد فرم	کد ستون	عنوان ستون	نوع ستون	شرط نمایش	برچسب	
✓	۱۳۵۶۰۱	pi۰۱	نام	str			ویرایش
✓	۱۳۵۶۰۱	pi۰۲	نام خانوادگی	str			ویرایش
✓	۱۳۵۶۰۱	pi۰۳	جنسیت	category			ویرایش

گزینه‌های سوال جنسیت

وضعیت	متن	مقدار	برچسب	
✓	زن	۰		ویرایش
✓	مرد	۱		ویرایش

وضعیت	کد فرم	کد ستون	عنوان ستون	نوع ستون	شرط نمایش	برچسب	
✓	۱۳۵۶۰۱	pi۰۴	تاریخ تولد	jalalidate			ویرایش
✓	۱۳۵۶۰۱	pi۰۵	استان محل تولد	category			ویرایش
✓	۱۳۵۶۰۱	pi۰۶	شهرستان محل تولد	category			ویرایش

Quality Control & Data Checking

- They are fit for their intended uses in operations, decision making and planning.
- Completeness
- Validity
- Reliability
- Consistency
- Timeliness

Version controlling and tracking

- In the case of research data, a new version of a dataset may be created when an existing dataset is **reprocessed**, **corrected** or appended with **additional data**.
- Versioning is one means by which to track changes associated with **‘dynamic’** data that is not static over time.

- Decide how many versions of a file to keep
- Identity milestone versions to keep
- Uniquely identity different versions of files using a systematic naming convention, such as using version numbers or dates
- Record changes made to a tile when a new version is created

Working with sensitive data

Sensitive data are data that can be used to identify an individual, species, object, or location that introduces a risk of discrimination, harm, or unwanted attention.

A person’s identity can be disclosed from:

- Direct identifiers such as names, addresses, postcode information, telephone numbers or pictures
- Indirect identifiers which, when linked with other publicly available information sources, could identify someone, for example information on workplace, occupation or exceptional values of characteristics like salary or age.

List of PHI (Protected Health Information)

- Names
- Dates
- Addresses / Zip Codes / Geocodes
- Phone Numbers
- Fax Numbers
- Email Addresses
- Social Security Numbers
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate /License Numbers
- Device Identifiers
- Vehicle Identifiers
- URLs
- IP Addresses
- Biometric Identifiers
- Facial Images
- Any Other Unique Identifiers

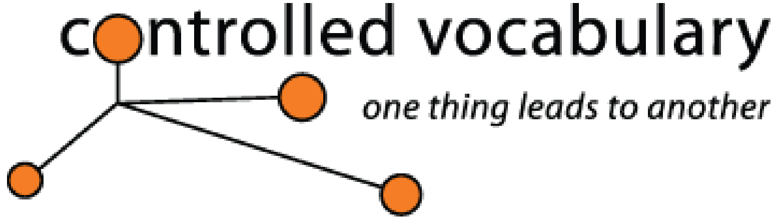
IRI
Total Data Management

Selecting and Defining Exposure & Outcome Measures for Registries

The selection and definition of patient outcomes of interest together with the exposures(s) of interest, is a critical step in designing a patient registry.

Standard terminologies not only improve efficiency in establishing registries but also promote more effective sharing, combining, or linking of datasets from different sources.

Controlled Vocabulary



- Controlled vocabularies ensure shared understanding of the terminologies used in taxonomies and classifications.

- Using established vocabularies promotes interoperability, discovery and re-use of data.

Health Vocabulary examples

PLANETREE

Australian Doctor Command Language (DOCLE)

Australian Medicines Terminology

SNOMED CT
The global language of healthcare

AIHW Authoritative information and statistics to promote better health and wellbeing

MeSH

OpenGALEN

OBI
Ontology for Biomedical Investigations

MedDRA

TENTH REVISION
ICD-10
INTERNATIONAL CLASSIFICATION OF DISEASES
ICD-10 is a new code set for reporting medical diagnoses & inpatient procedures

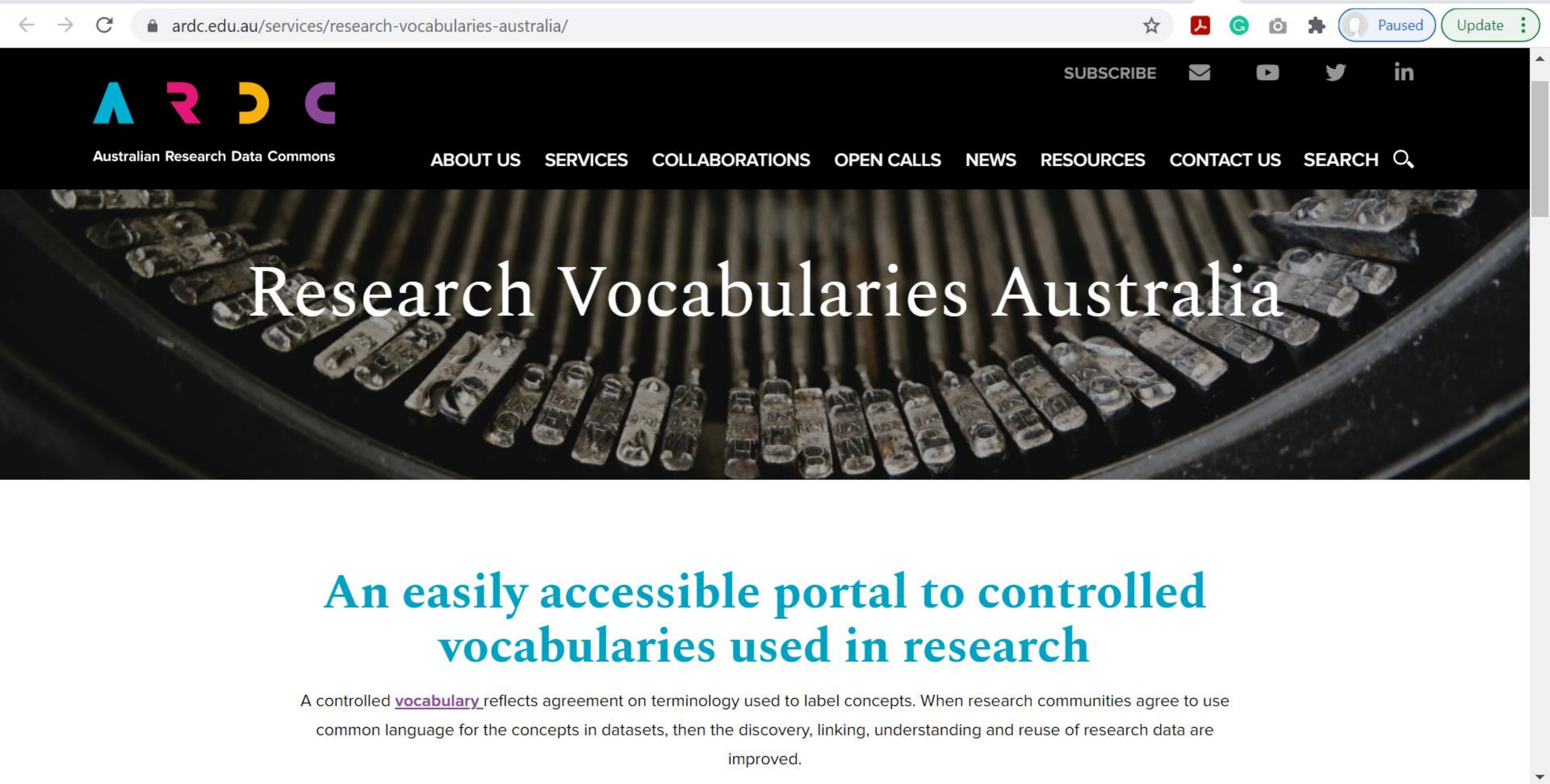
Victorian Admitted Episodes Dataset (VAED)

How do you say glucose?
LOINC

R_xNorm

Cumulative Index of Nursing and Allied Health Literature (CINAHL)

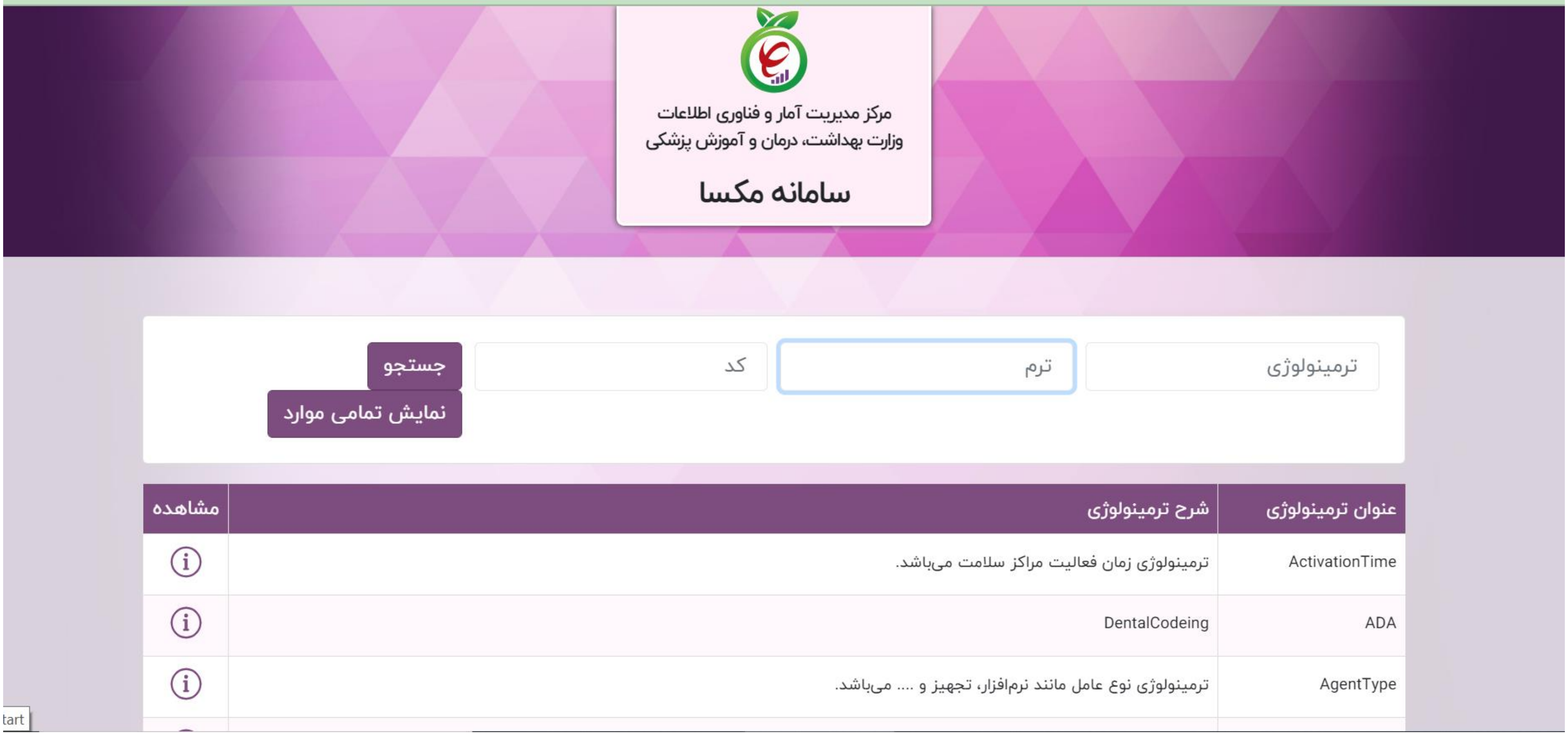
ands



Research Vocabularies Australia

An easily accessible portal to controlled vocabularies used in research

A controlled vocabulary reflects agreement on terminology used to label concepts. When research communities agree to use common language for the concepts in datasets, then the discovery, linking, understanding and reuse of research data are improved.



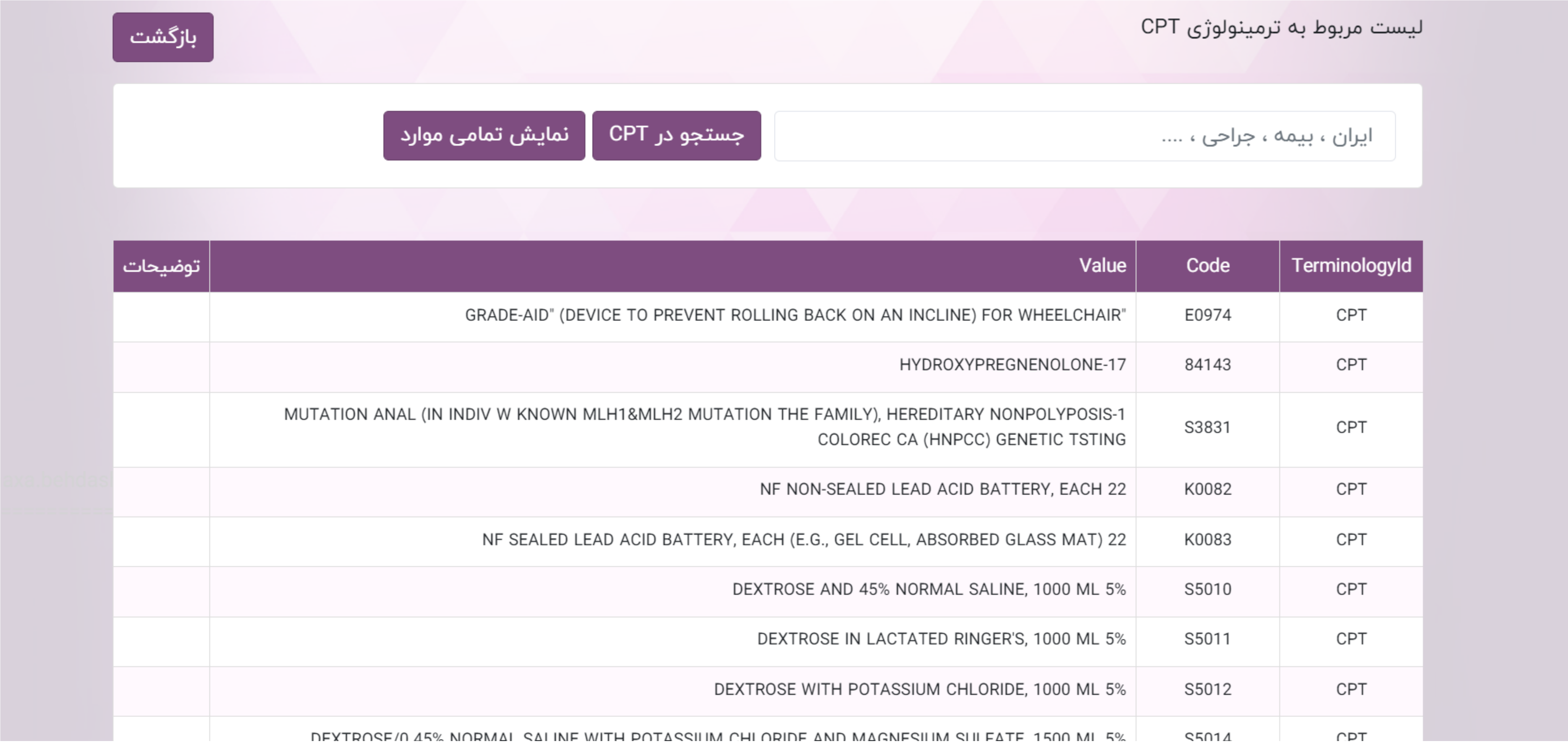
مرکز مدیریت آمار و فناوری اطلاعات
وزارت بهداشت، درمان و آموزش پزشکی

سامانه مکسا

عنوان ترمینولوژی	شرح ترمینولوژی	مشاهده
ActivationTime	ترمینولوژی زمان فعالیت مراکز سلامت می‌باشد.	ⓘ
ADA	DentalCodeing	ⓘ
AgentType	ترمینولوژی نوع عامل مانند نرم‌افزار، تجهیز و .... می‌باشد.	ⓘ

لیست مربوط به ترمینولوژی Country

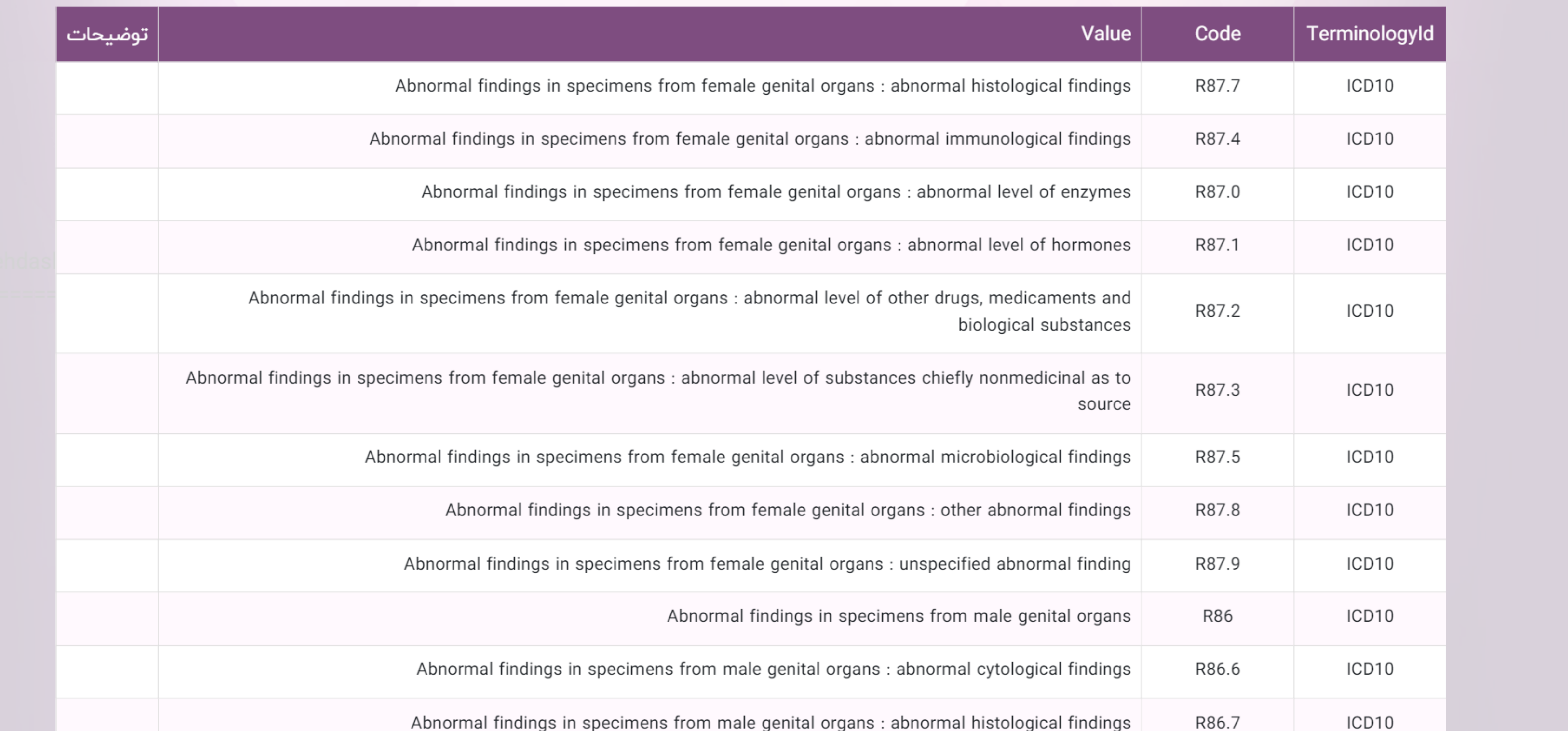
TerminologyId	Code	Value	توضیحات
Country	AR	آرژانتین	
Country	AW	آروبا	
Country	ZA	آفریقای جنوبی	
Country	AL	آلبانی	
Country	DE	آلمان	
Country	AG	آنتیگوا و باربودا	
Country	AD	آندورا	
Country	AO	آنگولا	
Country	AI	آنگویلا	



لیست مربوط به ترمینولوژی CPT

TerminologyId	Code	Value	توضیحات
CPT	E0974	GRADE-AID" (DEVICE TO PREVENT ROLLING BACK ON AN INCLINE) FOR WHEELCHAIR"	
CPT	84143	HYDROXYPREGNENOLONE-17	
CPT	S3831	MUTATION ANAL (IN INDIV W KNOWN MLH1&MLH2 MUTATION THE FAMILY), HEREDITARY NONPOLYPOSIS-1 COLOREC CA (HNPCC) GENETIC TSTING	
CPT	K0082	NF NON-SEALED LEAD ACID BATTERY, EACH 22	
CPT	K0083	NF SEALED LEAD ACID BATTERY, EACH (E.G., GEL CELL, ABSORBED GLASS MAT) 22	
CPT	S5010	DEXTROSE AND 45% NORMAL SALINE, 1000 ML 5%	
CPT	S5011	DEXTROSE IN LACTATED RINGER'S, 1000 ML 5%	
CPT	S5012	DEXTROSE WITH POTASSIUM CHLORIDE, 1000 ML 5%	
CPT	S5014	DEXTROSE/0.45% NORMAL SALINE WITH POTASSIUM CHLORIDE AND MAGNESIUM SULFATE, 1500 ML 5%	

SNOMEDCT	80050220	Abdominal aortic pulse, function (observable entity)	
SNOMEDCT	271860004	Abdominal mass (finding)	توده شکمی
SNOMEDCT	21522001	Abdominal pain (finding)	درد شکم
SNOMEDCT	74704000	Abdominal pain through to back (finding)	درد شکم و پهلوها
SNOMEDCT	43478001	Abdominal tenderness (finding)	تندرنس شکم
SNOMEDCT	284973007	Able to dress (finding)	قادر به لباس پوشیدن
SNOMEDCT	288884008	Able to eat (finding)	قادر به غذا خوردن است
SNOMEDCT	282600008	Able to jump (finding)	قادر به پرش
SNOMEDCT	285170004	Able to recognize faces (finding)	توانایی شناسایی چهره ها
SNOMEDCT	285168008	Able to recognize faces by sight (finding)	قادر به تشخیص چهره
SNOMEDCT	282620009	Able to roll (finding)	قابلیت غلت زدن
SNOMEDCT	282474007	Able to run (finding)	قادر به دویدن است
SNOMEDCT	302040002	Able to sit unsupported (finding)	نشستن بدون کمک
SNOMEDCT	288375004	Able to turn pages (finding)	توانایی ورق زدن
SNOMEDCT	263654008	Abnormal (qualifier value)	[illegible]



TerminologyId	Code	Value	توضیحات
ICD10	R87.7	Abnormal findings in specimens from female genital organs : abnormal histological findings	
ICD10	R87.4	Abnormal findings in specimens from female genital organs : abnormal immunological findings	
ICD10	R87.0	Abnormal findings in specimens from female genital organs : abnormal level of enzymes	
ICD10	R87.1	Abnormal findings in specimens from female genital organs : abnormal level of hormones	
ICD10	R87.2	Abnormal findings in specimens from female genital organs : abnormal level of other drugs, medicaments and biological substances	
ICD10	R87.3	Abnormal findings in specimens from female genital organs : abnormal level of substances chiefly nonmedicinal as to source	
ICD10	R87.5	Abnormal findings in specimens from female genital organs : abnormal microbiological findings	
ICD10	R87.8	Abnormal findings in specimens from female genital organs : other abnormal findings	
ICD10	R87.9	Abnormal findings in specimens from female genital organs : unspecified abnormal finding	
ICD10	R86	Abnormal findings in specimens from male genital organs	
ICD10	R86.6	Abnormal findings in specimens from male genital organs : abnormal cytological findings	
ICD10	R86.7	Abnormal findings in specimens from male genital organs : abnormal histological findings	

Common Data Elements and Standards - Definitions

- Data Element
  - information that describes a piece of data to be collected in a study
- Common Data Elements
  - a data element that is common to multiple datasets across studies
  - a combination of a precisely defined question (variable) paired with a specified set of responses to the question that is common to multiple datasets or used across different studies
- Every effort should be made to use common data elements (CDEs) to facilitate data sharing across research projects. CDEs describe the type of data to be collected and use standardized language for the question as well as the associated values.

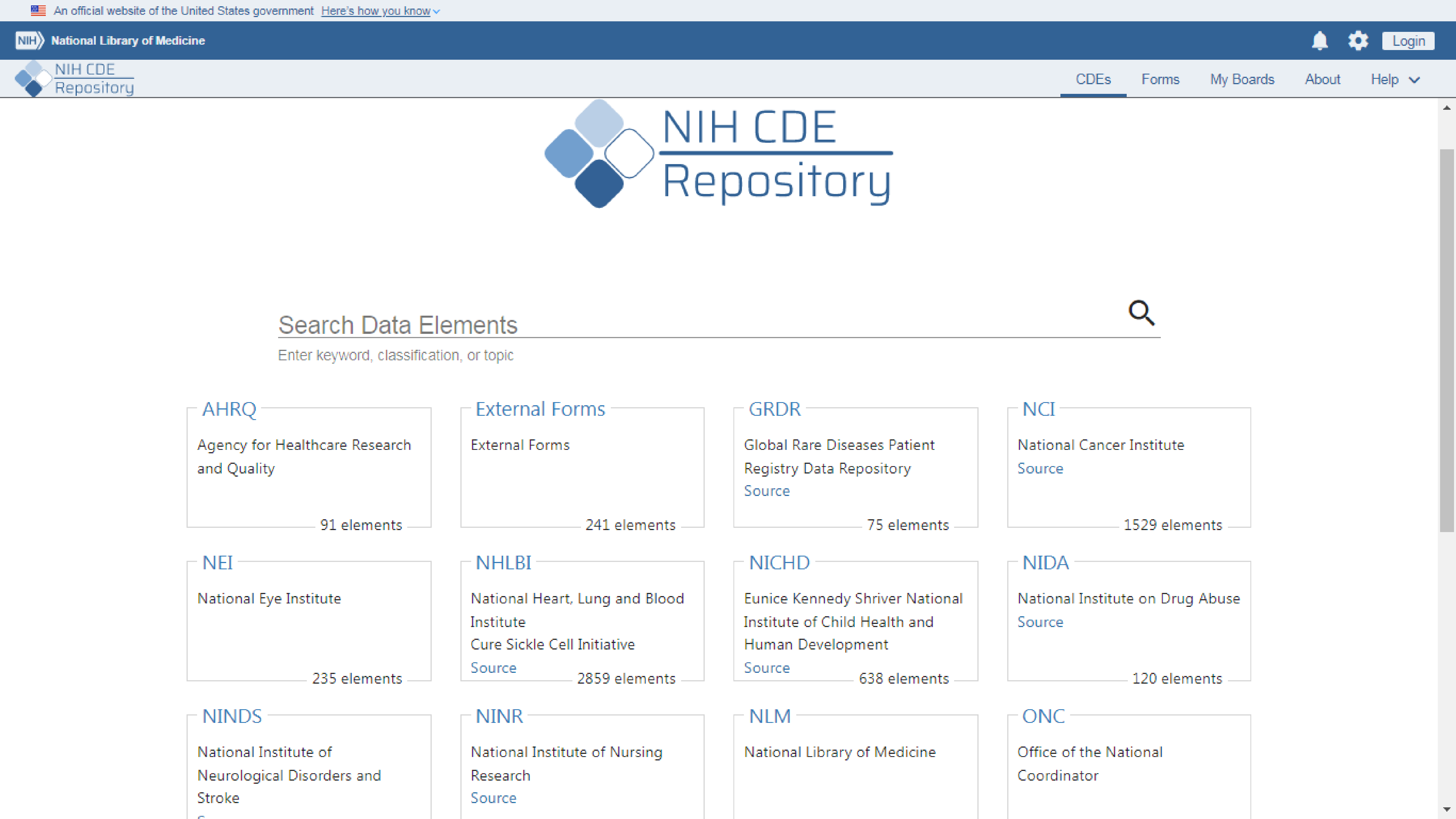
Typical Data Elements Captured in Studies

- Demographic data
- Eligibility criteria
- Family history
- Patient history and physical examination including performance status
- Surgical history
- Prior treatment
- Concomitant medications
- Laboratory and radiology results
- Pathology
- Review of current symptoms
- During the study
- Study treatment (dosing, frequency)
- Laboratory and radiology results
- Concomitant medications including over-the-counter medications and
- indications
- Adverse events
- Toxicities
- Hospitalizations
- Treatment response
- Study termination
- Treatment stop date and reason
- Follow-up
- Disease status
- Nonprotocol treatment
- Long-term adverse events
- Date of death
- Cause of death
- Autopsy results if performed

Ref: St Germain, Diane C. (2018). *Principles and Practice of Clinical Research || Data Management in Clinical Trials. 531–545.*
DOI: 10.1016/B978-0-12-849905-4.00030-7

Common Data Elements and Standards - Tools

- The NIH Common Data Elements (CDE) Repository
  - The NIH Common Data Elements (CDE) Repository has been designed to provide access to structured human and machine-readable definitions of data elements that have been recommended or required by NIH Institutes and Centers and other organizations for use in research and for other purposes
- PhenX Toolkit
  - The PhenX Toolkit (consensus measures for **Phen**otypes and e**X**posures) provides recommended standard data collection protocols for conducting biomedical research.
- METeOR
  - METeOR is Australia’s repository for national metadata standards for health, housing and community services statistics and information.
- The United States Health Information Knowledgebase (USHIK)
  - The United States Health Information Knowledgebase (USHIK) is an on-line, publicly accessible registry and repository of healthcare-related metadata, specifications, and standards.
- The Clinical Data Interchange Standards Consortium (CDISC)
  - CDISC is an international, nonprofit group working to develop consensus-based standards to enhance interoperability in clinical research.



AHRQ
Agency for Healthcare Research and Quality
91 elements

External Forms
External Forms
241 elements

GRDR
Global Rare Diseases Patient Registry Data Repository
Source
75 elements

NCI
National Cancer Institute
Source
1529 elements

NEI
National Eye Institute
235 elements

NHLBI
National Heart, Lung and Blood Institute
Cure Sickle Cell Initiative
Source
2859 elements

NICHD
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Source
638 elements

NIDA
National Institute on Drug Abuse
Source
120 elements

NINDS
National Institute of Neurological Disorders and Stroke

NINR
National Institute of Nursing Research
Source

NLM
National Library of Medicine

ONC
Office of the National Coordinator

Storage and Security of Data

- Backup Your Data
- Physical data security
- Network Security
- Security of computer systems
- Data Encryption
- Access controlling and security

Data sharing

Data Governance

International statements on data sharing:

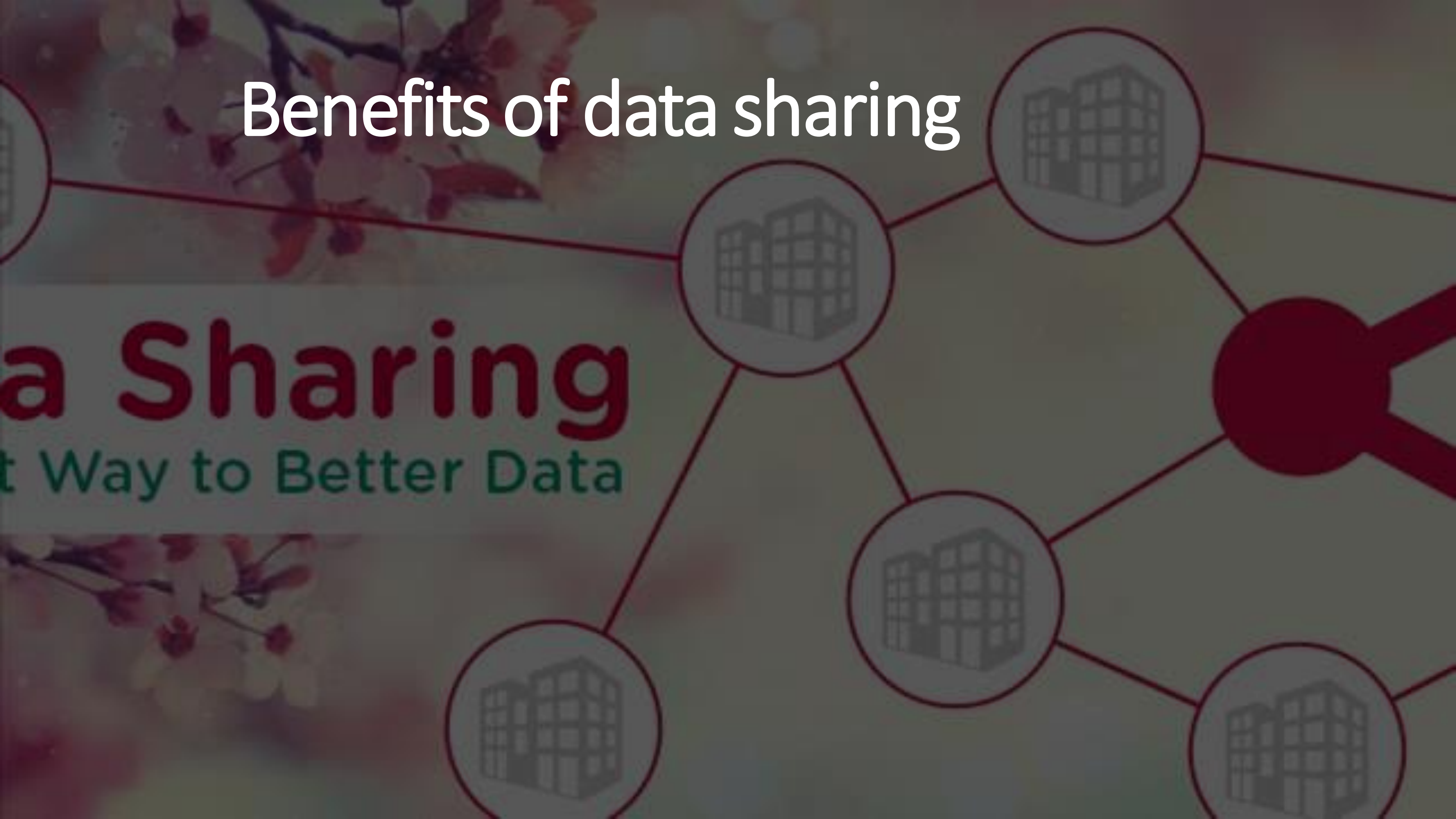
- Berlin Principles
- OECD
- NSF
- NIH
- OA 2020
- European Commission
- NRC

Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities

Open access contributions include original scientific research results, raw data and metadata, source materials, digital representations of pictorial and graphical materials and scholarly multimedia material.

https://openaccess.mpg.de/Berlin-Declaration

Benefits of data sharing



Benefits for researchers

- Increases visibility of scholarly work;
- Likely to increase citations rates,
- Enables new collaborations;
- Encourages scientific enquiry and debate;
- Promotes innovation and potential new data uses;
- Establishes links to next generation of researchers.

Benefits for research funders

- Promotes primary and secondary use of data;
- Makes optimal use of publicly funded research;
- Avoids duplication of data collection;
- Maximizes return on investment.

Benefits for the scholarly community

- Maintains professional standards of open inquiry;
- Maximizes transparency and accountability;
- Promotes innovation through unanticipated and new uses of data;
- Enables scrutiny of research findings;
- Improves quality from verification, replication and trustworthiness;
- Encourages the improvement and validation of research methods;
- Provides resources for teaching and learning.

Benefits for research participants

- Allows maximum use of contributed information;
- Minimizes data collection on difficult-to-reach or over-researched populations;
- Allows participants' experiences to be understood as widely as ethically possible.

Benefits for the public

- Advances science to the benefit of society;
- Adopts emerging norms such as open access publishing
- To be, and appear to be, open and accountable;
- Complies with openness laws and regulations.

Barriers for data sharing

Inappropriate Use of Data

- There are concerns that others will use the data inappropriately or out of context from the original purpose of the research.

Data confidentiality

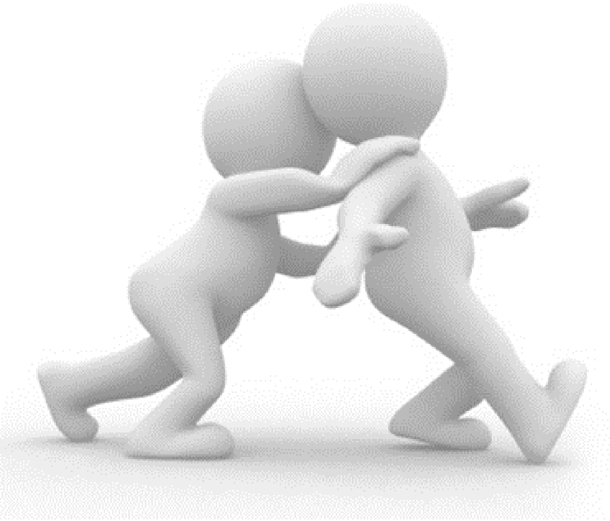
- Data may have sensitive information, and apprehensions about maintaining confidentiality are reasonable.

Appropriate Acknowledgement

- Researchers may be uneasy about the prospect of not receiving acknowledgement by others who use their data, or that others will use their data to gain a competitive advantage.

Why some researchers remain reluctant to share their own research data?

- 42% Intellectual property or confidentiality issues
- 36% My funder/institution does not require data sharing
- 26% I am concerned that my research will be scooped
- 26% I am concerned about misinterpretation or misuse
- 23% Ethical concerns
- 22% I am concerned about being given proper citation credit or attribution
- 21% I did not know where to share my data
- 20% Insufficient time and/or resources
- 16% I did not know how to share my data
- 12% I don’t think it is my responsibility
- 12% I did not consider the data to be relevant
- 11% Lack of funding
- 7% Other



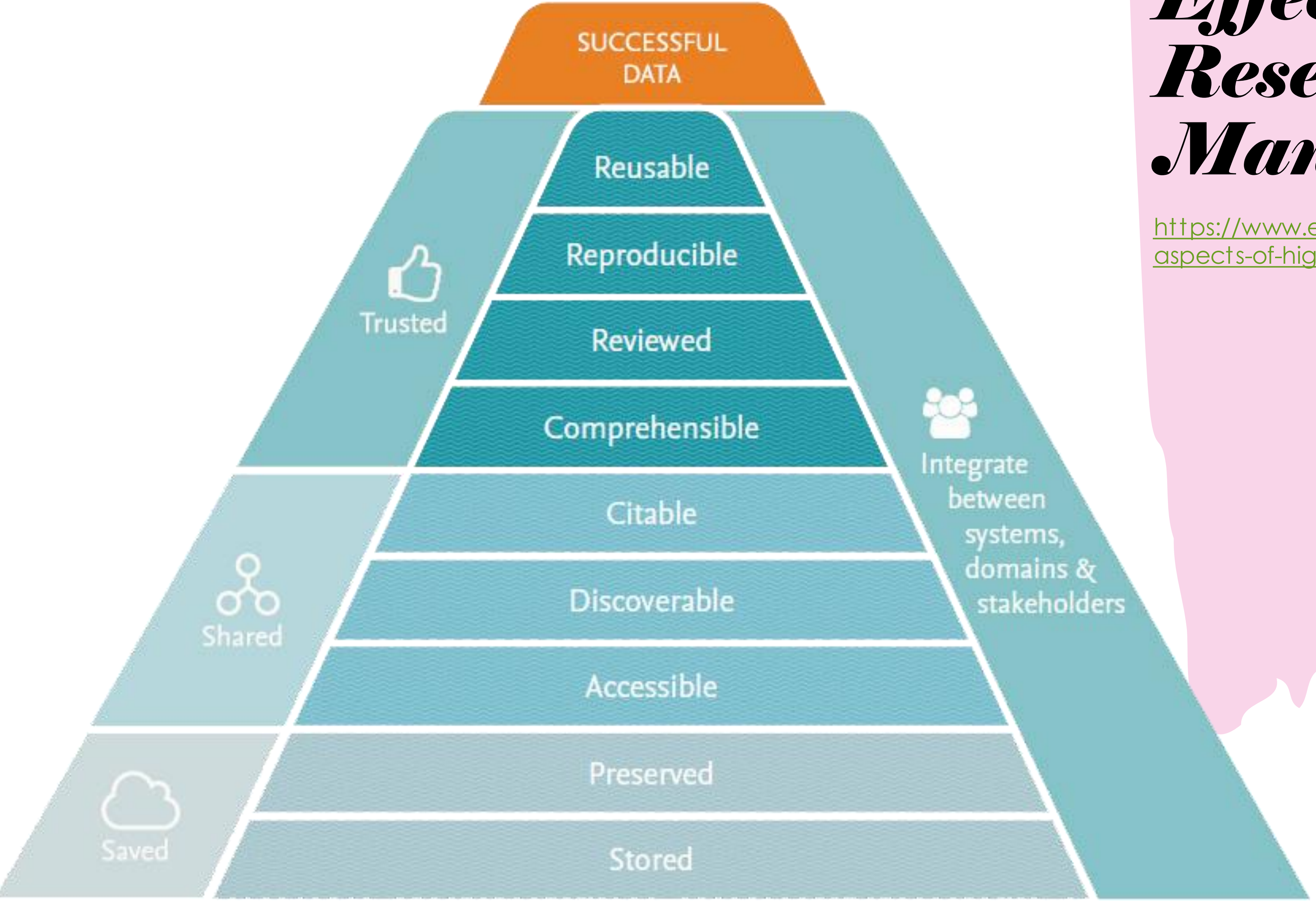
Considerations before data sharing

- Good data management
- Meeting ethical and legal obligations
- Intellectual property rights
- Data licensing
- Meta data schema and cross-walking

Data can only be shared if they are of high quality, well-curated, well-documented, and can be referenced and indexed.

Effective Research Data Management

https://www.elsevier.com/connect/10-aspects-of-highly-effective-research-data



قوانین داخلی

1. کلیه دستگاهها و نهادهایی که از بودجه عمومی کشور استفاده مینمایند موظفند نسبت به در اختیار قراردادن بانکهاي رقومی (دیجیتالی) خود به استثناء موارد طبقه بندي شده، حریم خصوصی و مواردي که در قوانین افشاء اطلاعات ممنوع شده است، اقدام نمایند (قانون برنامه پنجم توسعه)

2. قانون انتشار و دسترسی آزاد به اطلاعات

شماره ابلاغیه : 56348/32 تاریخ ابلاغیه : 1388/11/04

- https://rc.majlis.ir/fa/law/show/780303

قانون انتشار و دسترسی آزاد به اطلاعات

اطلاعات

- هر نوع داده که در اسناد مندرج باشد یا به صورت نرم افزاری ذخیره گردیده و یا با هر وسیله دیگری ضبط شده باشد.

اطلاعات شخصی

- اطلاعات فردی نظیر نام و نام خانوادگی، نشانی‌های محل سکونت و محل کار، وضعیت زندگی خانوادگی، عادت‌های فردی، ناراحتیهای جسمی، شماره حساب بانکی و رمز عبور است.

اطلاعات عمومی

- اطلاعات غیرشخصی نظیر ضوابط و آیین نامه ها، آمار و ارقام ملی و رسمی، اسناد و مکاتبات اداری که از مصادیق مستثنیات فصل چهارم این قانون نباشد.

قانون انتشار و دسترسی آزاد به اطلاعات

ماده 2

- هر شخص ایرانی حق دسترسی به اطلاعات عمومی را دارد، مگر آن که قانون منع کرده باشد. استفاده از اطلاعات عمومی یا انتشار آنها تابع قوانین و مقررات مربوط خواهد بود.

ماده 5

- مؤسسات عمومی مکلفند اطلاعات موضوع این قانون را در حداقل زمان ممکن و بدون تبعیض در دسترسی مردم قرار دهند.

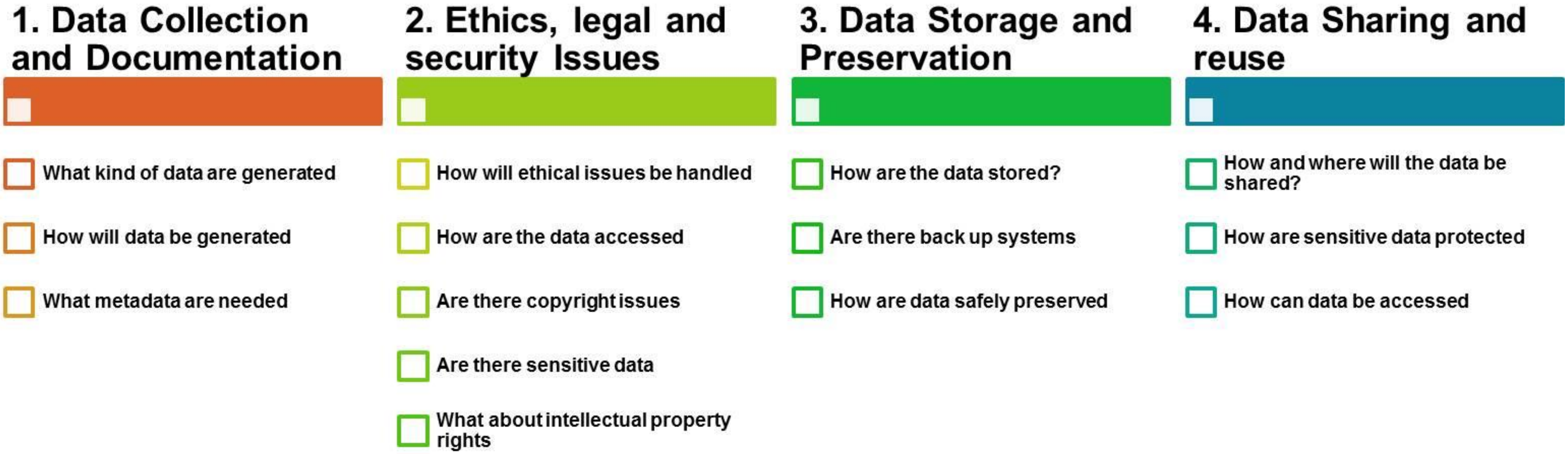
ماده 7

- مؤسسه عمومی نمی تواند از متقاضی دسترسی به اطلاعات هیچ گونه دلیل یا توجیهی جهت تقاضایش مطالبه کند.

Data management plans

- A Data Management Plan (DMP) document show data will be managed, stored and shared during and after a research project.
- Some research funders and human research ethics committees are now requesting that researchers submit a DMP as part of their project proposal.
- By planning ahead, the research team can improve research efficiency, guard against data loss, enhance data security, and ensure research data integrity and replicability.
- Many Data Management Plan templates are now freely available for reuse.

Data Management Plan



1. Data Collection and Documentation

- ☐ What kind of data are generated
- ☐ How will data be generated
- ☐ What metadata are needed

2. Ethics, legal and security Issues

- ☐ How will ethical issues be handled
- ☐ How are the data accessed
- ☐ Are there copyright issues
- ☐ Are there sensitive data
- ☐ What about intellectual property rights

3. Data Storage and Preservation

- ☐ How are the data stored?
- ☐ Are there back up systems
- ☐ How are data safely preserved

4. Data Sharing and reuse

- ☐ How and where will the data be shared?
- ☐ How are sensitive data protected
- ☐ How can data be accessed

Case Report

Identifying the capabilities for creating next-generation registries: a guide for data leaders and a case for "registry science"

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*Corresponding author: Steven E. Labkoff, MD, Quantori, 1 Broadway, 11th Floor, Cambridge, MA 02142, United States (Steven.Labkoff@Quantori.com)

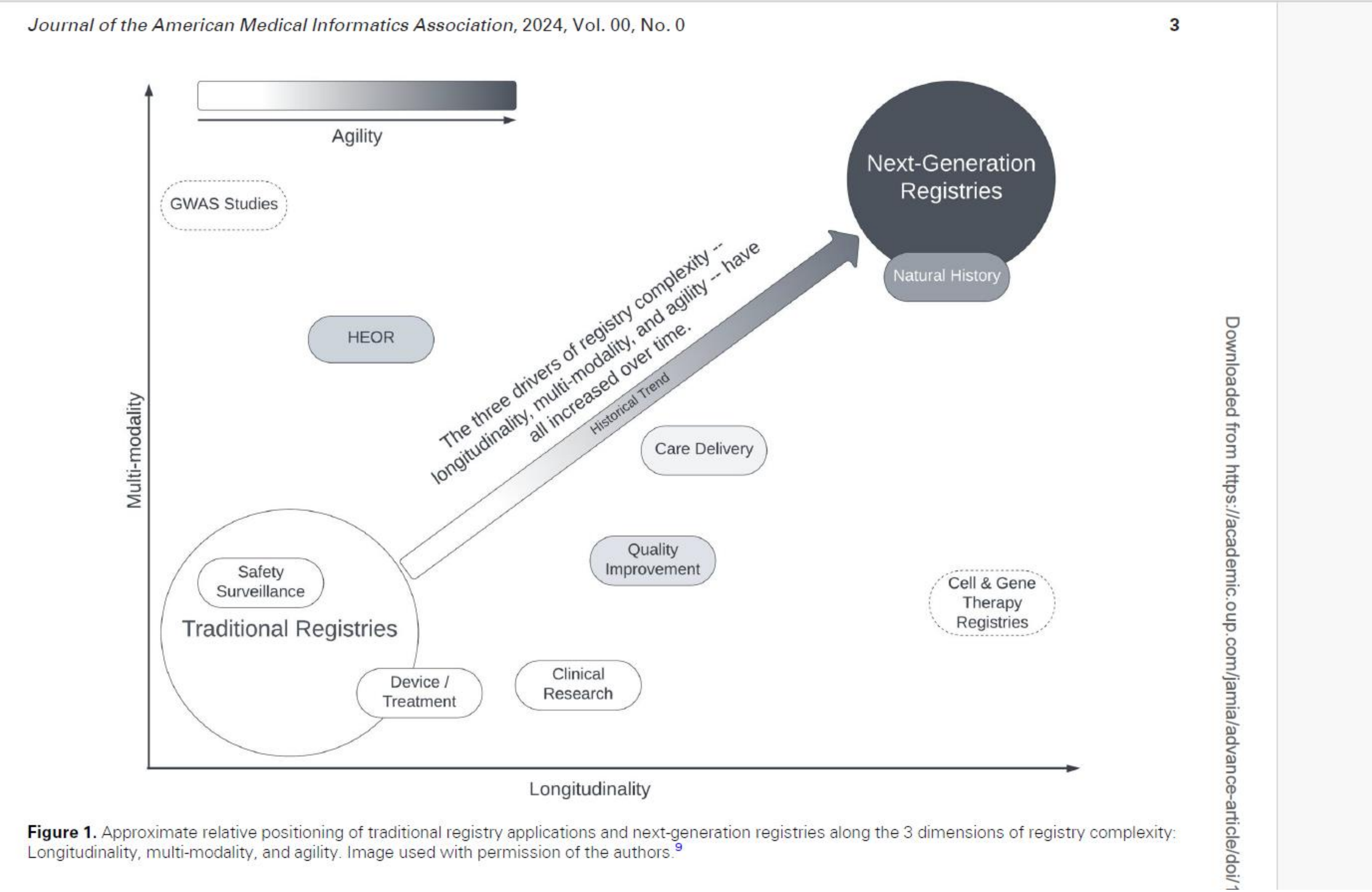

Figure 1. Approximate relative positioning of traditional registry applications and next-generation registries along the 3 dimensions of registry complexity: Longitudinality, multi-modality, and agility. Image used with permission of the authors.[9]

Thank you