Common Data Elements
for NIH-funded Research

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COMET IV Conference - Rome
20 November 2014

Common Data Elements

What is a Common Data Element (CDE)?

- Fixed representation of a variable to be collected and analyzed in projects within a particular analytic or clinical domain.
- Consists of a precisely defined question and a specified format or set of permissible values for responses (answers).
- Ideally, a CDE is defined unambiguously in both human and machine-computable terms.
- Sets of CDEs can be combined into more complex questionnaires, survey instruments, and case report forms.

Why Common Data Elements?

- Facilitate cross-study comparison of results
- Enable aggregation of data from multiple studies – greater statistical power, detect weaker signals
- Speed study start up by selecting from existing measures, instruments
- Improve data quality via use of validated measures
- Improve replication and reproducibility

Some CDEs are COMs

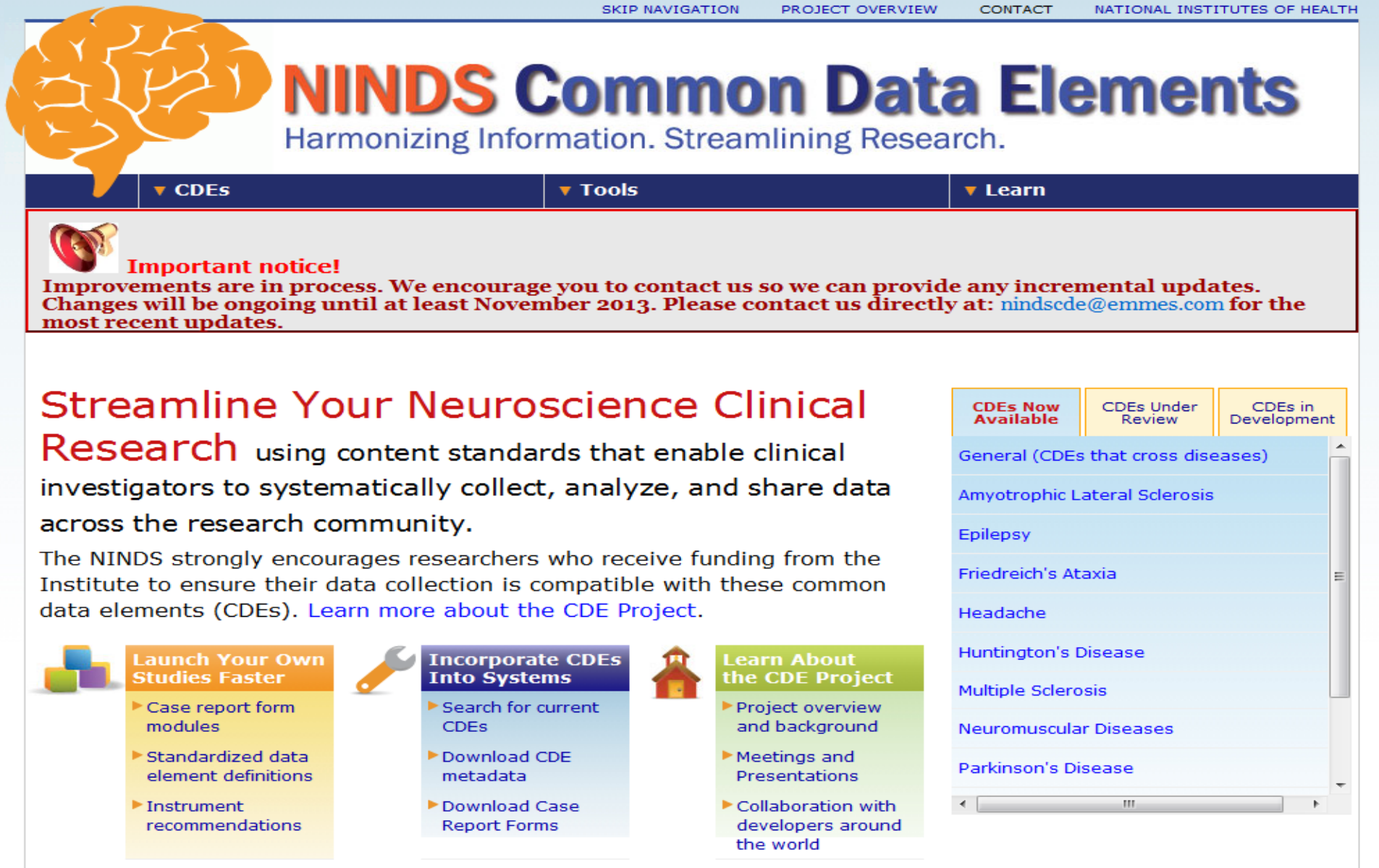
Asthma Outcomes (NHLBI, NIAID)

- Core outcomes for children (5-11 yrs) and adults - required
- Supplemental outcomes for children and adults - optional
- Domains: 1) biomarkers, 2) composite scores of asthma control, 3) exacerbations, 4) healthcare utilization and costs, 5) pulmonary physiology, 6) quality of life, and 7) symptoms.
- Categories: 1) Characterization of study population; 2) Prospective clinical trial efficacy/effectiveness outcomes; and 3) Observational study outcomes
- Published in Journal of Allergy and Clinical Immunology
  - http://www.jacionline.org/article/S0091-6749(11)02954-X/abstract ; \
  - http://www.ncbi.nlm.nih.gov/pubmed/22386504

Chronic Low Back Pain (NCCAM, NIAMS)

- Minimum data set for clinical research
- 40 date elements related to: 1) Demographics; 2) Treatment history; 3) Comorbidity (smoking, obesity, substance abuse); 4) Exams and imaging; 5) Self reports on physical function, depression, sleep disturbance, catastrophizing
- Published in Journal of Pain and 6 other journals
  - http://www.jpain.org/article/S1526-5900(14)00680-4/pdf ;
  - http://www.ncbi.nlm.nih.gov/pubmed/24787228

Some are More Complex



NINDS CDE – Diseases

- General (cross disease)
- ALS
- Epilepsy
- Friedreich's Ataxia
- Headache
- Huntington's Disease
- Multiple Sclerosis
- Traumatic Brain Injury
- Neuromuscular diseases
  - Congenital Muscular Dystrophy
  - Duchenne Muscular Dystrophy
  - Myasthenia Gravis
  - Spinal Muscular Atrophy
- Parkinson's Disease
- Spinal Chord Injury
- Stroke

NINDS CDE Example: TBI – Assessments & Examinations

CDE ID	CDE Name	Definition / Description	Classification (e.g., Core)	Version #	Version Date	CRF Module	© or TM
C17274	Electronystagmography result	Global result of electronystagmography testing	Supplemental	1.0	10/15/2012	Balance	
C17275	Rotational chair testing result	The result of rotational chair testing	Supplemental	1.0	10/15/2012	Balance	
C17276	Posturography testing result	Global result of posturography testing	Supplemental	1.0	10/15/2012	Balance	
C17277	Modified Romberg test result	The result of the Modified Romberg test	Supplemental	1.0	10/15/2012	Balance	
C17278	Vestibular evoked myogenic potential test result	The result of the vestibular evoked myogenic potential (VEMP) test	Supplemental	1.0	10/15/2012	Balance	
C17257	Air conduction result	The result of air conduction testing, or whether patient can detect all test signals at or below 25 dB	Supplemental	1.0	10/15/2012	Hearing	
C17258	Bone conduction result	The result of bone conduction testing, or whether patient can detect all test signals at or below 25 dB	Supplemental	1.0	10/15/2012	Hearing	
C17259	Speech reception threshold result	The result of speech reception threshold testing, or lowest dB level at which patient can correctly repeat 50% of words spoken	Supplemental	1.0	10/15/2012	Hearing	

NINDS CDE Example: TBI – Assessments & Examinations

CDE Detailed Report

This report contains detailed information about the selected CDEs.

Note: If at least one CDE was selected from a copyright- or trademark-protected instrument/scale then all of the CDEs from that instrument/scale are included in this report.

Disease: Traumatic Brain Injury

SubDisease: Comprehensive

CRF: Balance

Item count: 1

CDE ID	CDE Name	Definition / Description	Permissible Value Group ID External URL Permissible Value ID / Code / Value / Description	Data Type	Disease Specific Instructions	Disease Specific References
C17274	Electronystagmography result	Global result of electronystagmography testing	⊟ **PG01025**	Alphanumeric	Choose one	White JW. Laboratory tests of vestibular and balance functioning. In: Hughes GB and Pensak ML (eds): Clinical Otology Third Edition, New York, Thieme Medical Publishers, 2007, pp. 132-149
			PV001259 Normal			
			PV001258 Abnormal			

Some CDEs for Genome/Phenome Studies

My Toolkit
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Using PhenX measures? Login to Register Your Study. Why?

Quick Start
QuickStart

Tutorial

Substance Abuse and Addiction

Welcome to the PhenX Toolkit

The Toolkit provides *standard* measures related to complex diseases, phenotypic traits and environmental exposures. Use of PhenX measures facilitates combining data from a variety of studies, and makes it easy for investigators to expand a study design beyond the primary research focus. All Toolkit content is available to the public at no cost.

Information about the project is available at www.phenx.org

More »

Please Read Toolkit Guidance

How to cite use of PhenX measures:

Measures incorporated in this study were selected from the PhenX Toolkit version September 15, 2014, Ver 5.8. More »

How to cite the PhenX Toolkit:

Hamilton, et al. (2011) The PhenX Toolkit: Get the Most From Your Measures. *American Journal of Epidemiology*, **174**(3), 253-60.

Funding for PhenX and the PhenX Toolkit was provided by NHGRI 5U01HG004597 and 3U01HG004597-03S3.

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Registration

You may browse the PhenX Toolkit, but to save your work, you need to Register. See additional benefits for registered users.

Existing users may login:

User ID:

Password:

PhenX Domains

- Alcohol, Tobacco and Other Substances (14)
  - Plus Substance Abuse and Addiction
- Substance Abuse and Addiction »
- Anthropometrics (16)
- Cancer (12)
- Cardiovascular (14)
- Demographics (15)
- Diabetes (15)
- Environmental Exposures (14) Gastrointestinal (12)
- Infectious Diseases and Immunity (15)
- Neurology (14)
- Nutrition and Dietary Supplements (12)
- Ocular (15)
- Oral Health (15)
- Physical Activity & Physical Fitness (14)
- Psychiatric (14)
- Psychosocial (15)
- Reproductive Health (15)
- Respiratory (14)
- Skin, Bone, Muscle and Joint (10)
- Social Environments (15)
- Speech and Hearing (15)
- Rare Genetic Conditions (under development)
- Tobacco Regulatory Research
- Mental Health Research

More than 340 measures in Toolkit

CDEs for Patient Reported Outcomes

- Physical function
- Mental function
- Social well-being

U.S. National Library of Medicine
National Institutes of Health

http://cde.nih.gov

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NIH Common Data Element (CDE) Resource Portal

Home | Resource Summaries | Glossary

Home

Home

NIH encourages the use of common data elements (CDEs) in clinical research, patient registries, and other human subject research in order to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records. This portal provides access to NIH-supported CDE initiatives and other tools and resources that can assist investigators developing protocols for data collection. What is a CDE?

NIH CDE Initiatives

Collections of CDEs that have been identified for use in particular NIH-supported research projects or registries after a formal evaluation and selection processes.

Summary Table | Subject Areas

NIH CDE Tools and Resources

Databases and repositories of data elements and case report forms that may assist investigators in identifying and selecting data elements for use in their projects.

Summary Table | Subject Areas

The CDE Resource Portal also includes Other CDE Resources and Relevant Standards. Descriptions of all four groups can be found in the Glossary.

The CDE Working Group of the Trans-NIH BioMedical Informatics Coordinating Committee (BMIC) developed this Portal to improve the coordination of CDEs. BMIC encourages researchers to use CDEs from the Resources in this Portal where applicable, and to consider existing CDE initiatives before starting additional initiatives.

Are we missing a CDE Resource? Contact us.

Last reviewed: 03 January 2013
Last updated: 03 January 2013
First published: 18 June 2012
Metadata | Permanence level: Permanent: Dynamic Content

Launched in January 2013

Links from BMIC, OER Sharing, and CDE Initiatives web pages

Summary Table for NIH CDE Initiatives

This table lists summary information for NIH CDE Initiatives. More information on NIH CDE Initiatives: Subject Areas, Detailed Summaries.

Show 50 entries Search:

Link to Homepage	Link to CDEs	Brief Summary	Subject Area	Number of Elements	CDE Resource Contact
Early Detection Research Program	EDRN	CDEs for use in describing samples and data collected as part of cancer biomarker research. More...	Cancer. More...	1,600	NCI
National Ophthalmic Disease Genotyping Network	eyeGENE	As part of eyeGENE, common data elements have been developed for collecting phenotypic data associated with more than 30 inherited ophthalmic diseases. More...	Ophthalmology. More...	300+	NEI
Global Rare Diseases Patient Registry and Data Repository	GRDR	CDEs to facilitate standardized data collection into the GRDR and to assist organizations in establishing rare disease registries that contribute information to GRDR. More...	Rare diseases. More...	70	ORDR
Quality of Life Outcomes in Neurological Disorders	Neuro-QOL	A core set of quality-of-life questions that address chronic neurologic disorders, plus sets of supplemental questions specific to targeted diseases or subgroups of patients. More...	Neurological disorders. More...	500	NINDS
NIDA Substance Abuse Electronic Health Record Data Elements	NIDA EHR	A set of brief screening and initial assessment tools for substance use disorders (SUDs) for use in general medical settings. More...	Substance Use Disorders. More...	45	NIDA
NIH Toolbox for Assessment of Neurological and Behavioral Function	NIH Toolbox	An integrated set of tools for measuring cognitive, emotional, motor and sensory function. More...	Cognitive, emotional, motor, and sensory function. More...	4 batteries of tests, each with 5-24 tests	NIH
NINDS Common Data Elements	NINDS CDEs	A core set of data elements for use in NINDS-funded studies, including core and supplementary sets of data elements for use in disease-specific studies. More...	Neurological disorders. More...	7,000+ variables, 100s of instruments	NINDS
Consensus Measures for Phenotypes and eXposures	PhenX	Standard measures related to complex diseases, phenotypic traits and environmental exposures for inclusion in genome-wide association studies (GWAS) and other large-scale genomic and epidemiologic research efforts. More...	Genome-wide association studies. More...	15,000+ variables, 428 protocols	NHGRI
Patient Reported Outcomes Measurement Information System	PROMIS	A system of item banks measuring patient-reported health status for various domains of physical, mental, and social health across clinical populations (i.e. not disease-specific). More...	Physical, mental, and social health. More...	50 item banks	NIAMS

Showing 1 to 9 of 9 entries

Promulgate Lessons Learned

1. Don't reinvent the wheel – Use existing CDEs if possible
2. Don't work alone – Coordinate with others
3. Use validated data elements/instruments when possible.
4. Use data elements that conform to existing data standards and are freely available, whenever possible.
5. Engage full range of needed expertise: domain experts, informatics experts, patient representatives, others
6. Plan ahead to update CDEs over time
7. Gain support of the user community
8. Develop a communications strategy
9. Develop policies to promote the use of CDEs
10. Monitor compliance and uptake

Harmonizing CDEs Across NIH (and Beyond)

XX indicates that the subject area is a major focus, while X indicates that the subject area is a minor focus. Subject areas listed here may change as additional Resources are added to the CDE Resource Portal or as existing Resources are expanded into new subject areas (subject areas assessed in January 2013).

Show 50 entries Search:

Subject Area	EDRN	eyeGENE	GRDR	Neuro-QOL	NIDA EHR	NIH Toolbox	NINDS CDEs	PhenX	PROMIS
Alcohol, Tobacco, and Other Substances	X				XX		X	XX	
Cancer	X							XX	
Demographics and Patient Contact Info.	X	X	XX				XX	XX	
Environmental Exposures	X						X	XX	
Excretory	X						X		
Gastrointestinal	X						X	XX	
Laboratory Tests	X	XX					X	X	
Medical History	X		XX				XX	X	
Medications, Devices, and Treatments	X		XX				XX	X	
Physical Function	X		X	XX		X	XX	XX	X
Reproductive	X		X				X	XX	X
Respiratory	X						X	XX	X
Study Details	X		XX				X		
Biospecimens			XX						
Anthropometrics			XX				XX	XX	
Cardiovascular and Circulatory							XX	XX	
Diabetes and Other Endocrine							X	XX	
Infectious Diseases and Immunity							X	XX	
Neurology				XX		XX	XX	XX	
Nutrition and Dietary Supplements			X				X	XX	
Ocular		XX					X	XX	
Oral							X	XX	
Physical Symptoms (incl. pain, fatigue)			X	XX			X		XX
Psychiatric			X	XX		XX	XX	XX	X
Psychosocial				XX		X	XX	XX	XX
Skin, Bone, Muscle and Joint							XX	XX	
Social Environments				X			X	XX	XX
Speech and Hearing				X			X	XX	

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Spreading the Word: Outreach to Users

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Posted on February 28, 2013 by NIH Staff

Improving Access to NIH-supported Common Data Element Initiatives

A growing number of NIH institutes and centers are enhancing opportunities for combining and comparing data from multiple studies by identifying sets of common data elements (CDEs). In January, NIH launched a web portal to improve access to information about NIH-supported CDE initiatives and assist investigators with tools and resources for developing protocols for data collection. The portal serves as both an entry point for NIH investigators seeking CDEs to use in their studies and as a means of coordinating work with other organizations that are interested in developing CDEs for their relevant research communities. Users can browse descriptive summaries of the CDE initiatives, identify the subject areas to which they apply, and link out to sources of additional information, including repositories of the data elements themselves. The portal currently contains information on 16 NIH-supported initiatives, tools, and resources, and will expand as additional initiatives are initiated and identified. For more information, visit http://cde.nih.gov.

Encouragement of Use of CDEs

Use of Common Data Elements in NIH-funded Research

- *NIH **encourages** the use of common data elements (CDEs) in basic, clinical, and applied research, patient registries, and other human subject research to facilitate broader and more effective use of data and advance research across studies.*
- *CDEs are data elements that have been identified and defined for use in multiple data sets across different studies. Use of CDEs can facilitate data sharing and standardization to improve data quality and enable data integration from multiple studies and sources, including electronic health records.*
- *NIH ICs have identified CDEs for many clinical domains (e.g., neurological disease), types of studies (e.g. genome-wide association studies (GWAS)), types of outcomes (e.g., patient-reported outcomes), and patient registries (e.g., the Global Rare Diseases Patient Registry and Data Repository).*
- *NIH has established a "Common Data Element (CDE) Resource Portal" (http://cde.nih.gov/) to assist investigators in identifying NIH-supported CDEs when developing protocols, case report forms, and other instruments for data collection. The Portal provides guidance about and access to NIH-supported CDE initiatives and other tools and resources for the appropriate use of CDEs and data standards in NIH-funded research.*
- *Investigators are **encouraged** to consult the Portal and describe in their applications any use they will make of NIH-supported CDEs in their projects.*

Mandating Use of CDEs in NIH Research

In Funding Announcements. . .

- **NINDS**
  - **Parkinson's Udall Centers of Excellence** ". . . must utilize the **NINDS** Common Data Elements Resource when constructing data element forms."
  - **Phase III trials** "expects. . . Investigator Initiated Phase III trial[s] will use the NINDS Common Data Elements resource when constructing data collection forms."
  - **Traumatic Brain Injury** – "A data sharing plan should include use of the TBI Common Data Elements"
- **NIMH –** in clinical trials, "Investigators are encouraged to . . . describe in their applications any use they will make of NIH-supported CDEs in their projects.
- **NINR - Centers of Excellence in Self-Management Research -** "Investigators are encouraged to . . . describe in their applications any use they will make of NIH-supported CDEs in their projects."
- **NIDA** strongly encourages investigators involved in human-subjects studies to incorporat[e] the measures from the Core and Specialty collections, which are available in the Substance Abuse and Addiction Collection. . ."
- **NCATS** – "Organizations who are establishing rare diseases patient registries are strongly encouraged to use the [ORD]/Global Rare Diseases Patient Registry Data Repository Common Data Elements. . .
- **BD2K** - Early Stage Development of Technologies in Biomedical Computing, Informatics, and Big Data Science – "Investigators are encouraged to . . . describe in their applications any use they will make of NIH-supported CDEs in their projects

Integrate with EHR Data Standards

- Match CDEs to standards and terminologies required for "meaningful use" of certified EHRs (i.e., SNOMED, LOINC, RxNORM)
- Several NIH CDE initiatives now mapped to LOINC (Logical Observation IDs, Names & Codes)
- NLM Value Set Authority Center (VSAC) for Quality Measures
- Facilitate research use of clinical records (see http://bd2k.nih.gov/bd2k_workshop/index.html)
- Structured Data Capture Initiative

NIH Trans-NIH BioMedical Informatics Coordinating Committee (BMIC) Common Data Elements WG

Prototype Data Element Repository

NLM CDE Search Boards Quick Board (empty) Log In

Welcome to the NLM Common Data Elements Repository.

The NLM Common Data Elements (CDE) Repository is a prototype. It 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, including those required for 'Meaningful Use' of electronic health records, as established under the HITECH law.

The Repository is a platform for identifying related data elements in use across diverse areas, for harmonizing data elements, and for linking CDEs to other existing standards and terminologies, including the value sets in the Value Set Authority Center (VSAC).

Quick CDE Search:

All Organizations | Search | Reset

Search

For individual data elements, by definition, users or sources
For sets of data elements ("boards") identified by a particular group for a particular use(e.g particular research solicitation)

Search CDEs »

Compare / Harmonize

Analyze and resolve differences between data elements
Assure that your forms are using variables that will be usable by certified EHRs

Create

Draw upon the experience of colleagues and others to design unique data elements and measures

Log in or register »

Inter-agency collaboration: FDA

Drugs

Priority Therapeutic Areas for Development

Standardizing key study data specific to therapeutic areas (TAs) will facilitate clinical research and the evaluation of medical products. In 2011, CDER identified a set of therapeutic areas that could benefit from further standardization, organizing them into three tiers of priority. Several factors were considered at the time: (1) areas of particular medical need, (2) areas with existing data standardization projects underway, and (3) areas with greater drug development pipeline activity. The number and ordering of these areas may change as stakeholder input and further analyses are considered.

The roadmap below displays the TAs in priority groupings and suggests a series of standardization projects over time to achieve significant results by December 2017. This roadmap assumes standardization projects for therapeutic areas are scoped narrowly enough to be accomplishable within a 12-month period, and that subsequent projects in those areas build on the results. Periodically, updates to the timeline will be provided as progress, opportunity and additional information is available. The tabular version, also listed below, provides the current status information for all identified TAs.

FDA, CDISC, and the Critical Path Institute are collaborating on efforts to support development of therapeutic area standards. FDA is also collaborating with HL7's Clinical Interoperability Council and other consortia to define related clinical concepts. We encourage stakeholders to engage in and, where possible, support these data standardization efforts.
Questions and comments can be forwarded to CDERDataStandards@fda.hhs.gov.

- Roadmap for Development of Priority Therapeutic Area Standards (PDF)
- Table of Priority Therapeutic Area Standards (PDF)

* Recent Development *

Announced 19 November 2014
http://www.nih.gov/news/health/nov2014/od-19.htm

- **Registration and Summary Results Submission** to ClinicalTrials.gov
- **Notice of Proposed Rulemaking (NPRM):**
  - Clinical Trial Registration and Results Submission under the FDA Amendments Act of 2007
- **Proposed NIH Policy**
  - Dissemination of NIH-Funded Clinical Trial Information

Thank You

For Additional Information

- CDE Web Portal
  http://cde.nih.gov
- ClinicalTrials.gov
  http://clinicaltrials.gov
- BMIC Website
  http://nlm.nih.gov/NIHbmic
- NLM Website
  http://www.nlm.nih.gov