

# National Institutes of Health (NIH) Helping to End Addiction Long-term® (HEAL) Common Data Elements (CDE) Program


Pain Course 2024

# Objectives

- Explain the biopsychosocial model of pain and its importance in assessing pain in research and clinical practice
- Understand the domains required of HEAL-funded pain studies involving human subjects
- Understand how and why HEAL standardized domain assessments across HEAL-funded studies
- Access and utilize the HEAL core CDEs and supplemental CDEs through the HEAL CDE Repository
- Understand the purpose of the HEAL Data Ecosystem, and how to access and use the tool

# Background: NIH Data Sharing Policy

- [NIH Policy for Data Management and Sharing \(DMS\) - 2023](#)
  - The NIH Institutes and Centers (ICs) may have specific data standards to enable **interoperability** (*ability for systems to exchange and use information*)
  - For example, HEAL-funded studies have their own [DMS](#)
    - HEAL-funded clinical pain studies are required to use the HEAL Common Data Elements (CDEs)

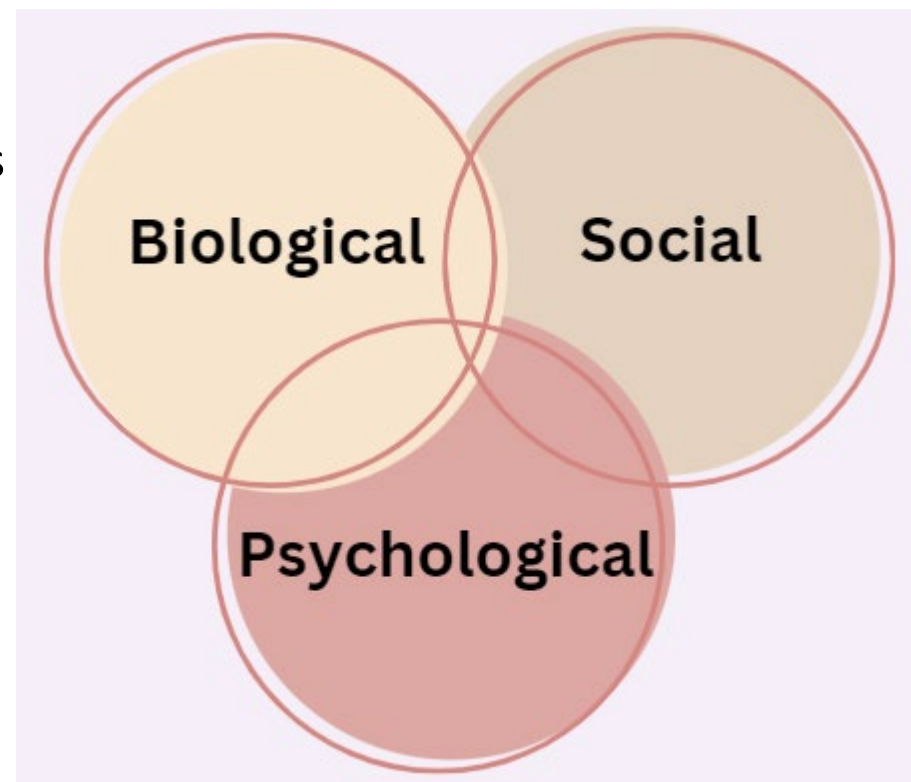
-  Determine if your proposed research is subject to the DMS policy.
-  Identify appropriate methods/approaches and repositories for managing and sharing scientific data.
-  Develop a Plan for managing and sharing scientific data and submit this Plan within the funding application or proposal.  
\* Note that applications subject to both the DMS Policy and the GDS Policy will submit a single Plan.
-  Estimate and request funds for data management and sharing activities if not already covered by institution or other sources.

# Background: Biopsychosocial Model

Biological, Psychological and Social factors contribute to a person's pain experience

- **Biological:** Factors/changes in the body
- **Psychological:** The mind and a person's experiences with others
- **Social:** Environmental conditions

- 
- *A holistic pain assessment goes beyond measuring pain intensity.*
  - *Trials should consider using outcome measures that assess participants from a biopsychosocial perspective.*



# Key Terms

- **Common Data Element (CDE):** standardized, precisely defined question that is paired with a set of specific allowable responses, and used systematically across different studies to ensure consistent data collection
- **Domain or Patient Reported Outcome (PRO):** a broad aspect of a health condition/disease that can be measured (“what” to assess); sometimes called “outcomes”
- **Patient Reported Outcome Measure (PROM):** measurement tool/questionnaire/case report form used to assess a domain/outcome
- **HEAL Core CDEs:** a minimal and defined set of patient reported outcome screening tools for each pain domain that are required to be collected by all HEAL-funded pain studies involving human subjects

Sources: <https://heal.nih.gov/data/common-data-elements>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5499094/>

# Key Terms: Examples

*Brief Pain Inventory Pain Severity*

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Patient-Reported Outcome Measure (PROM): Brief Pain Inventory

1) Please rate your pain by marking the number that best describes your pain at its worst in the last 24 hours.

\_\_0 \_\_1 \_\_2 \_\_3 \_\_4 \_\_5 \_\_6 \_\_7 \_\_8 \_\_9 \_\_10

No pain

Pain as bad as you can imagine

CDEs: Individual questions with set of permissible values

2) Please rate your pain by marking the number that best describes your pain at its least in the last 24 hours.

\_\_0 \_\_1 \_\_2 \_\_3 \_\_4 \_\_5 \_\_6 \_\_7 \_\_8 \_\_9 \_\_10

No pain

Pain as bad as you can imagine

Note: PROMs are referred to "Case Report Forms" or "CRFs" in the HEAL CDE resources.

# Example of a Common Data Element (CDE)

CRF Question #	CDE Name	Variable Name	Definition	Short Description	Additional Notes (Question Text)	Permissible Values	PV Description	Data Type	Disease Specific Instructions	Disease Specific References	Population	Classification	CRF Name
1	Brief Pain Inventory (BPI) - worst pain rating scale	BPIWorstPainRatingScl	Scale indicating the rating of the worst pain, as part of the Brief Pain Inventory (BPI) form.	Scale indicating the rating of the worst pain, as part of the Brief Pain Inventory (BPI) form.	Please rate your pain by marking the number that best describes your pain at its worst in the last 24 hours.	0;1;2;3;4;5;6;7;8;9;10	0 = No pain;10 = Pain as bad as you can imagine	Numeric Values	Mark the one number that describes your pain at its worst during the past 24 hours. Use the scale of 0 = No pain and 10 = Pain as bad as you can imagine	Daut R. et al. Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. Pain, 1983; 17: 197-210. Keller et al. Validity of the brief pain inventory for use in documenting the outcomes of patients with noncancer pain. Clin J Pain 2004; 20: 309-318.	Adult;Pediatric	Core	Brief Pain Inventory Pain Severity
2	Brief Pain Inventory (BPI) - least pain rating scale	BPILeastPainRatingScl	Scale indicating the rating of the least pain experienced by the subject, as part of the Brief Pain Inventory (BPI) form.	Scale indicating the rating of the least pain experienced by the subject, as part of the Brief Pain Inventory (BPI) form.	Please rate your pain by marking the number that best describes your pain at its least in the last 24 hours.	0;1;2;3;4;5;6;7;8;9;10	0 = No pain;10 = Pain as bad as you can imagine	Numeric Values	Mark the one number that describes your pain at its least during the past 24 hours. Use the scale of 0 = No pain and 10 = Pain as bad as you can imagine	Daut R. et al. Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. Pain, 1983; 17: 197-210. Keller et al. Validity of the brief pain inventory for use in documenting the outcomes of patients with noncancer pain. Clin J Pain 2004; 20: 309-318.	Adult;Pediatric	Core	Brief Pain Inventory Pain Severity

# Key Terms: Example

## HEAL Core CDEs: 10 Core Domains for Adult Acute Pain

Pain Intensity	Pain Interference	Physical Functioning	Quality of Life	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with treatment	Substance Use Screener	MME	Demographics
BPI Pain Severity	BPI Pain Interference	PROMIS Physical Functioning Short Form 6B	WHOQOL-BREF - 2	PROMIS Sleep Disturbance 6A + Sleep Duration Question	PCS-6 or PCS-13	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	PGIC	TAPS1	Components of MME + total MME	Adult demographics

Domains

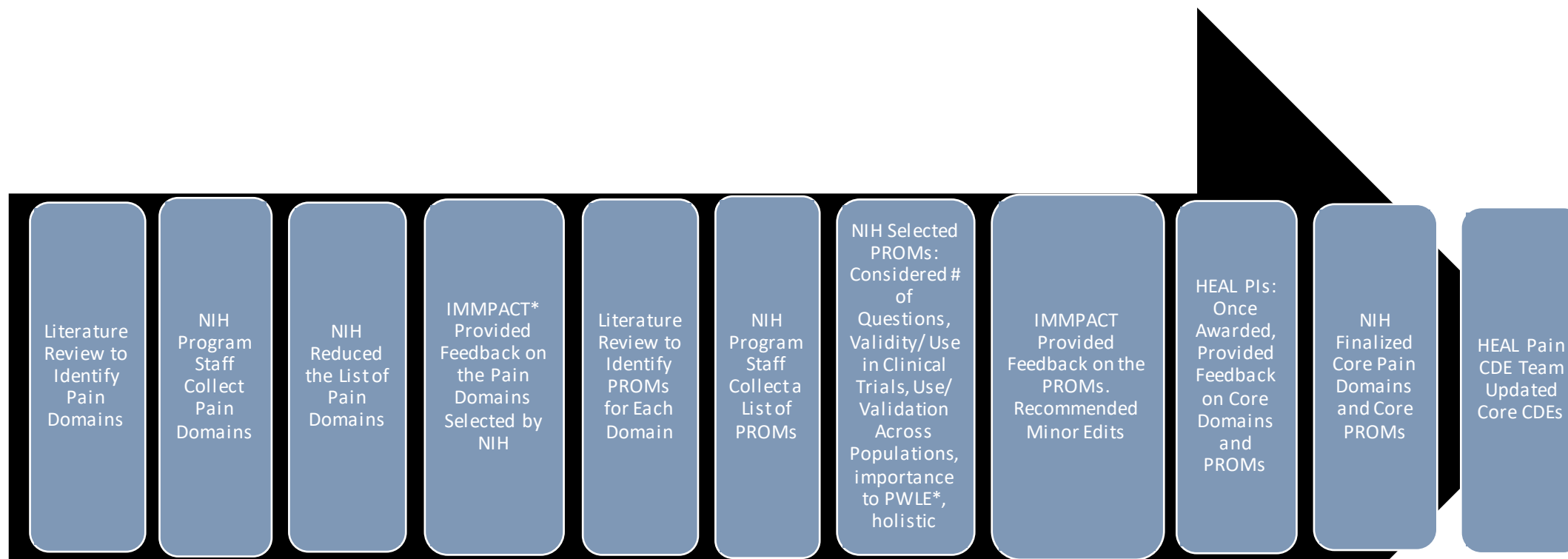
PROMs



# Rationale for the HEAL Pain CDE Program

- Facilitate cross-study comparisons and improve the interpretability of findings for patient-reported outcome measures (PROMs)
- Opportunity for pain research community to access quality data across pain conditions, in diverse populations, and across multiple interventions
- Ability to compare results across trials to quantify the impact of interventions

# Identification of the core CDEs



\*NIH staff sought to emphasize biopsychosocial domains that would capture experiences of persons with lived experience (PWLE) in studies

# Results: Core Domains and Questionnaires

## Adult – Chronic Pain

Pain Intensity	Pain Interference	Physical Functioning	Quality of Life	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with treatment	Substance Use Screener	MME	Demographics
BPI Pain Severity	BPI Pain Interference	PROMIS Physical Functioning Short Form 6B	WHOQOL-BREF (2 Qs)	PROMIS Sleep Disturbance 6A + Sleep Duration Question	PCS-6 or PCS-13	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	PGIC	TAPS1	Components of MME + total MME	Adult demographics + SDOH (1 Q)

## Adult – Acute Pain

Pain Intensity	Pain Interference	Physical Functioning	Quality of Life	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with treatment	Substance Use Screener	Opioid MME	Demographics
PEG		PROMIS Physical Functioning Short Form 6B	WHOQOL-BREF (2 Qs)	PROMIS Sleep Disturbance 6A + Sleep Duration Question	PCS-6 or PCS-13	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	PGIC	TAPS1	Components of MME + total MME	Adult demographics + SDOH (1 Q)

\*Questions are required to be asked at two time points

# Core Domains and Questionnaires (Pediatric)

Respondent	Pain Intensity	Pain Interference	Physical Functioning	Quality of Life	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with treatment	Substance Use Screener	MME	Demographics
Child	BPI Pain Severity	BPI Pain Interference	PedsQL Version 4.0	PedsQL Version 4.0	AWS + Sleep Duration	PCS for Children	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	PGIC	NIDA Modified Assist Tool - 2		
Parent	N/A	N/A	N/a	PedsQL Version 4.0	N/A	PCS for Parent	PHQ-2 or PHQ-8 or PHQ-9	GAD-2 or GAD-7	N/A	N/A	Components of MME + total MME	Child demographics + SDOH

\*Questions are required to be asked at two time points

# Core Demographics (Adult and Pediatric)

- Date of Birth
- Age
- Sex at Birth
- Gender Identity
- Ethnicity, Race
- Zip Code
- Highest Level of Education
- Employment Status
- Relationship Status
- Annual Household Income
- Applied for Disability Insurance
- Pain Duration
- RUCA Code (based on Zip code)
- Social Determinates of Health

\*Demographics are, for the most part, [CDISC](#) compliant

# Opioid Morphine Milligram Equivalent (MME) Calculation

Clinical pain studies funded by the NIH HEAL Initiative are required to monitor legitimate prescription opioid use reported in morphine milligram equivalents (MME).

Studies must report the following information:

- Name of opioid
- Dose of opioid
- Prescription duration
  - Total days exposed (if different from prescription duration)
  - Days elapsed during follow-up, hospital stay or enrollment (if different)
- MME conversion factor pdf **83.69 kb**
  - If known: MME value
    - If MME value is provided, please indicate how it was calculated (i.e., Total Days Supply, On-therapy Days, Fixed Observation Window, or Maximum Daily Dose)

# Supplemental Questionnaires

- **Supplemental CDEs** = screening tools outside of core CDEs selected by HEAL PIs
  - May be unique to the study (pain condition-specific or study-relevant measures)
  - ~ 600 distinct supplemental questionnaires accepted by HEAL (in [repository](#))
  - **Not required, but beneficial**
  - Studies can locate questionnaires used by similar studies
  - Allows for collecting data (in addition to the core CDEs) for the HEAL Data Ecosystem

Example:

Description	File Name	Language	Core or Supplemental	Research Topic
The Migraine Disability Assessment (MIDAS) questionnaire assesses headache-related disability with the aim of improving migraine care	<ul style="list-style-type: none"> <li>• File <a href="#">midas-crf.docx</a> (23.14 KB)</li> <li>• File <a href="#">midas-cde.xlsx</a> (21 KB)</li> </ul>	English	Supplemental	Headache/Migraine

## What to consider when choosing PROMs?

- What is the treatment you are trying to assess?
- What have other (similar) studies used as outcomes?
- How can I assess the treatment holistically (biopsychosocial model of pain)?
- What outcomes are important to people with lived experience?
- What will the burden on study participants/patients/researchers be?
- Are there required CDEs you need to use for your study?
  - e.g. HEAL vs NIMH vs NIDA requirements?
  - If you do have to use multiple CDEs, please compare the requirements and speak to the POC managing the CDEs.





# Demonstration: HEAL CDE Repository

Enter Keywords  Search [Advanced Search Options](#)

[Download List](#)

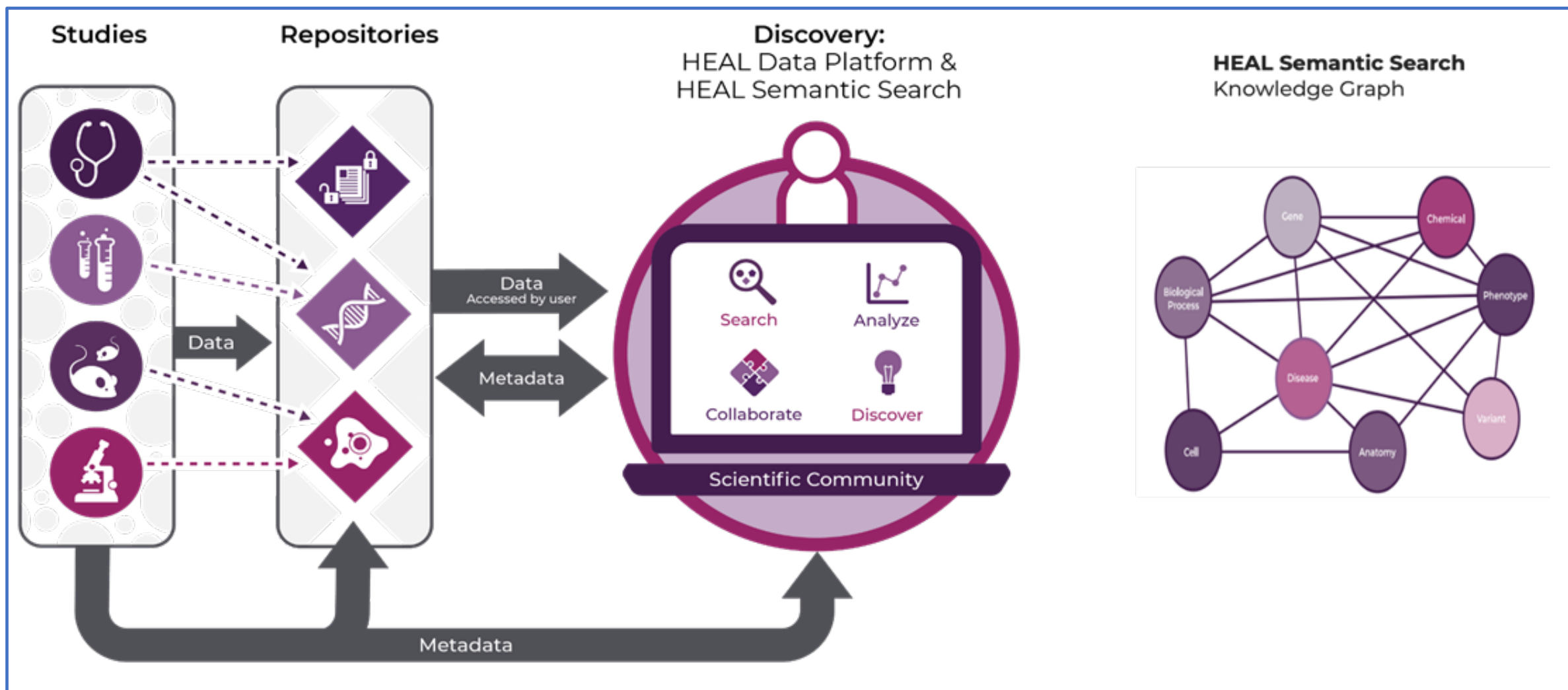
Selected 0 items  
 Select / deselect all results (all pages, 412 total)

[Download selected files](#)

Select	Description	File Name	File Language	Core or Supplemental	Research Topic
<input type="checkbox"/>	The Brief Pain Inventory (BPI) pain severity questions assess the severity of the participants pain in the past 24 hours.	<ul style="list-style-type: none"> <li>File <a href="#">bpi-pain-severity-korean.docx</a> (32.7 KB)</li> <li>File <a href="#">bpi-pain-severity-cdes.xlsx</a> (19.35 KB)</li> </ul>	Korean	<ul style="list-style-type: none"> <li>All Core</li> <li>Adult Chronic</li> <li>Adult Acute</li> <li>Pediatrics</li> </ul>	Pain Intensity
<input type="checkbox"/>	The World Health Organization Disability Assessment Schedule (WHODAS 2.0) measures health and disability across cultures.	<ul style="list-style-type: none"> <li>File <a href="#">whodas-12-item-crf.docx</a> (21.73 KB)</li> <li>File <a href="#">whodas-12-item-cde.xlsx</a> (14.17 KB)</li> </ul>	English	<ul style="list-style-type: none"> <li>Supplemental</li> </ul>	Disability
<input type="checkbox"/>	The Brief Pain Inventory (BPI) pain severity questions assess the severity of the participants pain in the past 24 hours.	<ul style="list-style-type: none"> <li>File <a href="#">bpi-pain-severity-crf-japanese.docx</a> (32.01 KB)</li> <li>File <a href="#">bpi-pain-severity-cdes.xlsx</a> (19.35 KB)</li> </ul>	Japanese	<ul style="list-style-type: none"> <li>All Core</li> <li>Adult Chronic</li> <li>Adult Acute</li> <li>Pediatrics</li> </ul>	Pain Intensity

- Link to repository: <https://heal.nih.gov/data/common-data-elements-repository>
- Locate CDEs and Case Report Forms (CRFs)
  - Instructions on obtaining copyrighted CDEs\*
- Utilizing the search functions
- Questions? Contact [heal\\_cde@hsc.Utah.edu](mailto:heal_cde@hsc.Utah.edu)

# HEAL Data Ecosystem Strategy and Tools



# What are Metadata?

## Concepts/Variables measured in SPRINT

Name  
Date of Birth  
Age  
Ethnicity  
...  
...  
Pediatric Anxiety  
Fatigue  
Chronic Pain Acceptance  
...  
...  
Pressure Pain  
Threshold\_Shoulder  
Pressure Pain  
Threshold\_Knee  
...

## HEAL Supplemental CDE

Pediatric Anxiety SF8a [PROMIS]

[HEAL CDE Repo link](#)

## Study identifiers (Study-level Metadata)

Name: SPRINT (Signature for Pain Recovery IN Teens)  
Project Number: 1R61NS114926-01  
Research Focus Area: Preclinical and Translational Research in Pain Management  
PI: Laura E. Simons  
Institutions: Stanford University  
Administering ICs: NINDS  
Year Grant Awarded: 2019

## Variable-level Metadata (data dictionaries)

	Variable Name	Label	Field Type	Permissible Values
Date of Birth	brthdte	Date of Birth (MM/DD/YYYY)	Text	

	Variable Name	Label	Field Type	Permissible Values
Pediatric Anxiety	ppanx1	I felt like something awful might happen	Radio	1,2,3,4,5
	ppanx2	I felt nervous	Radio	1,2,3,4,5
	ppanx3	I felt scared	Radio	1,2,3,4,5
	ppanx4	I felt worried	Radio	1,2,3,4,5
	ppanx5	I worried when I was at home	Radio	1,2,3,4,5
	ppanx6	I got scared really easy	Radio	1,2,3,4,5

# The Value of Metadata

Back Pain Consortium (BACPAC) Research Program Data

Integration, Algorithm Development and Operations

Management Center

HDP00258

healdata.org/mds/metadata/HDP00258

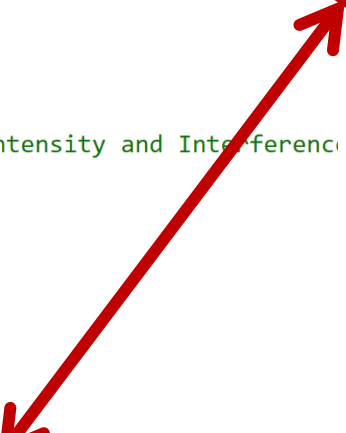
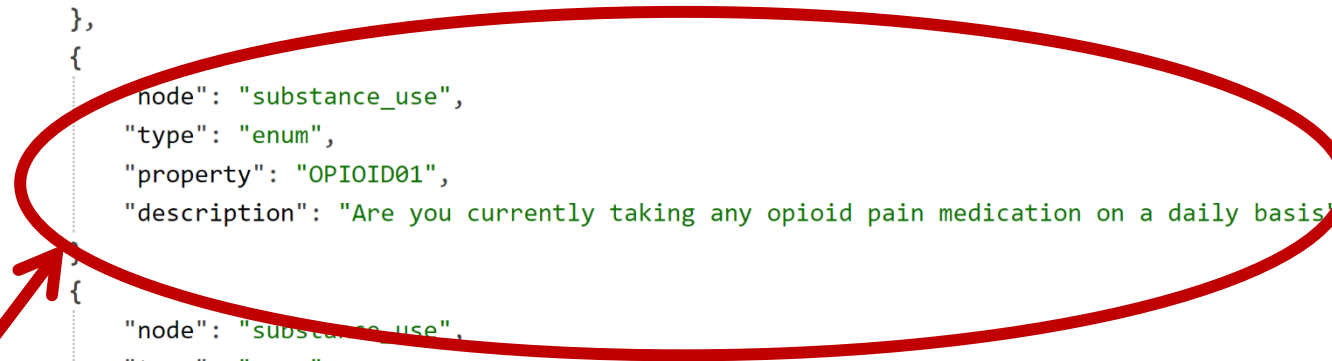
```
"clinicaltrials_gov": {
  "protocolSection": {
    "designModule": {
      "phases": [...], // 1 item
      "studyType": "INTERVENTIONAL",
      "designInfo": {...}, // 3 items
      "enrollmentInfo": {...} // 2 items
    },
    "statusModule": {...}, // 3 items
    "outcomesModule": {
      "primaryOutcomes": [
        {
          "measure": "Change in Patient-Reported Pain Intensity and Interference"
        }
      ],
      "secondaryOutcomes": [
        {
          "measure": "Change in Pain Interference"
        },
        {
          "measure": "Incidence of Any Opioid Use"
        }
      ]
    }
  }
}
```

healdata.org/mds/metadata/HDP00258

```
{
  "_guid_type": "discovery_metadata",
  "nih_reporter": {...}, // 57 items
  "gen3_discovery": {...}, // 51 items
  "clinicaltrials_gov": {...}, // 1 item
  "variable_level_metadata": {
    "data_dictionaries": {
      "BACPAC_dd.csv": "5b01d8ab-2657-486b-a31b-b3a9c3bda40f"
    }
  }
}
```

https://healdata.org/mds/metadata/5b01d8ab-2657-486b-a31b-b3a9c3bda40f

```
{
  "node": "substance_use",
  "type": "enum",
  "property": "OPIOID01",
  "description": "Are you currently taking any opioid pain medication on a daily basis"
},
{
  "node": "substance_use",
  "type": "enum",
  "property": "TAPS1Q1",
  "description": "How often have you used any tobacco product"
},
{
  "node": "substance_use",
  "type": "enum",
  "property": "TAPS1Q2",
  "description": "How often have you had 5 or more drinks in one day"
}
```



Variable-level metadata provides rich context for exploring study data elements

File Edit View Run Kernel Tabs Settings Help

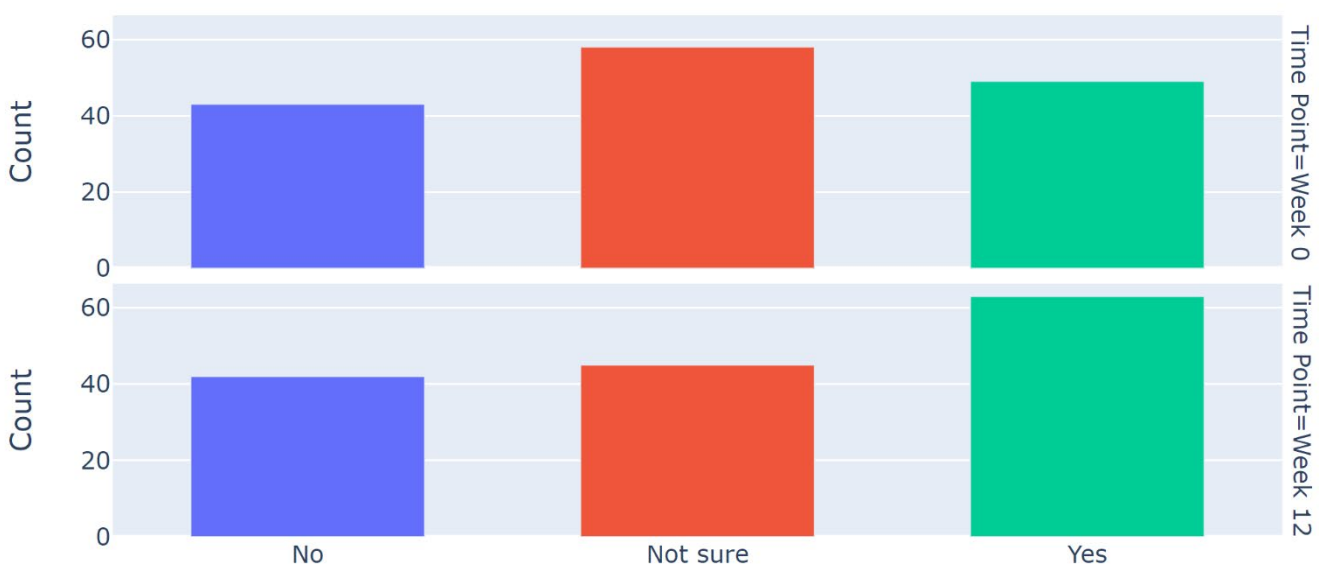
BACPAC\_Synthetic\_Data\_Ana substance\_use\_SMART.tsv participant\_SMART.tsv

Delimiter: tab

	submitter_id	type	visits.submitter_id	OPIOID01	TAPS1Q1	TAPS1Q2
1	SMART-0201-00001_sc	substance_use	SMART-0201-00001_...	Yes	Daily or almost daily	Daily or almost daily
2	SMART-0201-00001_sc	substance_use	SMART-0201-00001_...	Yes	Less than monthly	Never
3	SMART-0201-00002_sc	substance_use	SMART-0201-00002_...	No	Monthly	Less than monthly
4	SMART-0201-00002_sc	substance_use	SMART-0201-00002_...	Not sure	Daily or almost daily	Never
5	SMART-0201-00003_sc	substance_use	SMART-0201-00003_...	Yes	Monthly	Monthly
6	SMART-0201-00003_sc	substance_use	SMART-0201-00003_...	No	Less than monthly	Never
7	SMART-0201-00004_sc	substance_use	SMART-0201-00004_...	No	Daily or almost daily	Never
8	SMART-0201-00004_sc	substance_use	SMART-0201-00004_...	Not sure	Less than monthly	Less than monthly
9	SMART-0201-00005_sc	substance_use	SMART-0201-00005_...	Not sure	Weekly	Daily or almost daily
10	SMART-0201-00005_sc	substance_use	SMART-0201-00005_...	Yes	Weekly	Weekly
11	SMART-0201-00006_sc	substance_use	SMART-0201-00006_...	Yes	Never	Monthly
12	SMART-0201-00006_sc	substance_use	SMART-0201-00006_...	No	Never	Less than monthly

Code

Self-Report of Opioid Pain Medication Use at Baseline and Twelve Weeks



Taking Opioid  
 No  
 Not sure  
 Yes

Reliably conduct analysis in Platform workspaces leveraging rich data, metadata, and computational resources

HEAL Data Platform  
<https://healdata.org/landing>

HEAL Ecosystem GitHub:  
<https://github.com/HEAL>

HEAL Data Stewards  
[www.healdatafair.org/](http://www.healdatafair.org/)

Fresh FAIR webinar series:  
<https://www.healdatafair.org/webinar>

# Key Takeaways

- **Biopsychosocial Model:** Pain research should assess biological, psychological and social factors.
- **Core CDEs:** HEAL has developed a core set of standardized CDEs for pain studies involving human subjects
  - **Customizing Study Outcomes:** Researchers can select additional outcomes based on needs of their study and population(s).
  - The HEAL CDEs do not have to be the primary outcome of your study.
- **Benefits of CDEs for Research and Data Comparison**
  - Standardized CDEs enable **data harmonization**, helping researchers understand pain treatments by comparing results across studies.
  - HEAL's Data Ecosystem supports **secondary data analysis**, allowing for comparisons of outcomes, conditions, interventions and populations across HEAL-funded research.
- **Importance of early data harmonization:** Extra effort up front to align outcomes and PROMS leads to:
  - **Easier data comparison** across studies
  - **More effective analysis** of study results
  - **Enhanced Treatments** for pain

# Helpful Links:

- [NIH HEAL Common Data Elements Webpage](#)
- [NIH HEAL CDE repository](#)
- [HEAL Data Ecosystem](#)
- [HEAL Data Platform](#)
- [Search the Data Ecosystem](#)
- [Discover related biomedical concepts, studies, or variables](#)
- [HEAL Platform Tutorials](#)
- [National Library of Medicine CDE Repository](#)
- [NINDS Case Report Form \(CRF\) Repository](#)
- [National Institute of Mental Health \(NIMH\) Data Archive \(NDA\) CDE Requirements](#)
- [National Institute of Drug Abuse \(NIDA\) Clinical Trials Network \(CTN\) recommended CDEs](#)

# Relevant Webinars/Resources:

- [Webinar: Common Data Elements \(CDEs\): Getting More Common All the Time](#)
- [Webinar: Advancing Open Science with the HEAL Data Ecosystem](#)



# Resources for HEAL-Funded PIs

- [Webinar: Hands-on HEAL Data Sharing Requirement Guidance](#)
- [Webinar: Crafting a HEAL-Compliant Data Management and Sharing Plan](#)
- [Webinar: Register your Study with HEAL](#)
- [Tutorial: HEAL Data Platform Study Registration - Step 1 of 2](#)
- [Tutorial: HEAL Data Platform Study Registration - Step 2 of 2](#)
- [Webinar: Sharing Data in HEAL-Compliant Repositories: Requirements and Guidance](#)

# Want more information?

## HEAL Common Data Elements:

HEAL Pain CDE Program

Managers: [heal\\_cde@hsc.utah.edu](mailto:heal_cde@hsc.utah.edu)

Giulia Bova: [Giulia.bova@nih.gov](mailto:Giulia.bova@nih.gov)

Carolyn Conlin: [Carolyn.Conlin@nih.gov](mailto:Carolyn.Conlin@nih.gov)

Laura Wandner: [Laura.Wandner@nih.gov](mailto:Laura.Wandner@nih.gov)

## HEAL Data Ecosystem:

HEAL Stewards: [HEALStewards@renci.org](mailto:HEALStewards@renci.org)

HEAL Data Platform: [heal-support@gen3.org](mailto:heal-support@gen3.org)