

FOCUS ON PATIENT REPORTED OUTCOMES (PROMIS MEASURES AND PRO DATA)

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PROMIS (Patient-Reported Outcomes Measurement Information System)

- PROMIS initiative is developing new ways to measure patient-reported outcomes (PROs), such as pain, fatigue, physical functioning, emotional distress, and social role participation that have a major impact on quality-of-life across a variety of chronic diseases.
- The goal of PROMIS is to improve the reporting and quantification of changes in PROs.
- Clinical measures of health outcomes, such as x-rays and lab tests, may have minimal relevance to the day-to-day functioning of patients with chronic diseases.
- Often, the best way patients can judge the effectiveness of treatments is by changes in symptoms.

PROMIS Initiative

- As the PROMIS initiative moves to a second phase it will continue to advance the field of patient self-reporting in clinical research and practice, by:
 - developing new items and domains;
 - translating current and future items and domains into other languages such as Spanish and Chinese to facilitate international studies;
 - conducting validation studies in large-scale clinical trials in a variety of clinical populations;
 - making PROMIS tools accessible to a wider range of clinical researchers and patient-care communities, and optimizing its usability for rapid adoption;
 - providing on-going education and outreach to familiarize users with new developments in PROMIS;
 - improving PROMIS tools to allow for better outcomes in clinical trials, and, potentially, better individual and clinical decisions; and
 - engaging stakeholders at all levels, by continuing interactions with other health-related federal agencies, forging new relationships with patients and patient organizations, and establishing public-private partnerships to sustain PROMIS once Roadmap funding ends.

What is the ASSESSMENT CENTERSM?

- Assessment CenterSM is a free, online data collection tool that enables researchers to create study-specific websites for capturing participant data securely online.
- Studies can include measures within the Assessment Center library as well as custom instruments entered by the researcher. The instrument library includes self- and proxy-report short forms, computerized adaptive tests (CATs), and batteries or profiles from:
 - Patient-Reported Outcomes Measurement Information System (PROMIS)
 - Quality of Life in Neurological Diseases (Neuro-QoL)
 - NIH Toolbox
 - Health LiTT
- Among other important features, Assessment Center also enables:
 - Downloading library instruments for administration on paper
 - Customization of items or instruments (e.g., format, randomization, skip patterns)
 - Real-time scoring of CATs and short forms
 - Storage of protected health information (PHI) in a separate, secure database
 - Automated accrual reports
 - Real-time data export
 - Ability to capture endorsement of online consent forms
- <http://www.assessmentcenter.net/>

PROMIS Scoring Manuals

- PROMIS Scoring Manuals describe how individual PROMIS instruments are scored. Additional information about how they compare with other measures is included. Scoring manuals are available for the domains listed below. Note that the instruments themselves can be accessed as PDFs within Assessment Center's "PDF" hyperlink (login to Assessment Center, PDF link in upper right corner).
- [PROMIS Ability to Participate in Social Roles and Activities Scoring Manual](#)
- [PROMIS Alcohol Use Scoring Manual](#)
- [PROMIS Alcohol Use - Negative Consequences Scoring Manual](#)
- [PROMIS Alcohol Use - Negative Expectancies Scoring Manual](#)
- [PROMIS Alcohol Use - Positive Consequences Scoring Manual](#)
- [PROMIS Alcohol Use - Positive Expectancies Scoring Manual](#)
- [PROMIS Anger Scoring Manual](#)
- [PROMIS Anxiety Scoring Manual](#)
- [PROMIS Applied Cognition - Abilities Scoring Manual](#)
- [PROMIS Asthma Impact Scoring Manual](#)
- [PROMIS Companionship Scoring Manual](#)
- [PROMIS Depression Scoring Manual](#)
- [PROMIS Emotional Support Scoring Manual](#)
- [PROMIS Fatigue Scoring Manual](#)
- [PROMIS Informational Support Scoring Manual](#)
- [PROMIS Instrumental Support Scoring Manual](#)
- [PROMIS Pain Intensity Scoring Manual](#)
- [PROMIS Pain Behavior Scoring Manual](#)
- [PROMIS Pain Interference Scoring Manual](#)
- [PROMIS Pediatric Profile Scoring Manual](#)
- [PROMIS Peer Relationships Scoring Manual](#)
- [PROMIS Physical Function Scoring Manual](#)
- [PROMIS Profile Scoring Manual](#)
- [PROMIS Psychosocial Illness Impact Negative Scoring Manual](#)
- [PROMIS Psychosocial Illness Impact Positive Scoring Manual](#)
- [PROMIS Satisfaction with Participation in Discretionary Social Activities Scoring Manual](#)
- [PROMIS Satisfaction with Participation in Social Roles Scoring Manual](#)
- [PROMIS Sleep Disturbance Scoring Manual](#)
- [PROMIS Sleep-Related Impairment Scoring Manual](#)
- [PROMIS Social Isolation Scoring Manual](#)
- [PROMIS Global Health short form](#)

PROMIS Scoring Manuals

- **PROMIS Sexual Function**

- Calibrated Sexual Function measures are scored automatically within Assessment Center. Information on how to score and interpret Sexual Function measures can be found in the PROMIS Sexual Function User Manual. This manual is available in the User Manuals page at <http://assessmentcenter.net/UserManuals.aspx>.

- **Neuro-QOL**

- Calibrated Neuro-QOL measures are scored automatically within Assessment Center. Information on how to score and interpret Neuro-QOL measures can be found in the Neuro-QOL User Manual. This manual is available on the Neuro-QOL website at <http://www.neuroqol.org/Resources/Neuro-QoLReports-Manuals/Pages/default.aspx>.
- Note that Neuro-QOL short forms (as PDFs) can be obtained by clicking the “Request PDFs of Neuro-QoL Instruments” button on the right side of the Assessment Center home page. After endorsing Terms and Conditions, you will receive an email with a link to the folder that contains the English and Spanish instrument PDFs. You can copy the entire folder or just the instruments you need onto your computer.

- **NIH Toolbox Scoring and Interpretation Guide**

- NIH Toolbox measures are scored automatically within Assessment Center. The NIH Toolbox Scoring and Interpretation Guide is a comprehensive resource that provides general information about the NIH Toolbox scoring approach and the scores generally available for each test, along with specific information on the scoring and interpretation of each measure. The guide can be found on the NIH Toolbox website (www.nihtoolbox.org) by following the “How Do I” link.

More Information

- For more information on the Re-engineering the Clinical Research Enterprise Dynamic Assessment of Patient-Reported Chronic Disease Outcomes initiative, contact Wm. Phil Tonkins, Dr. PH., National Institute of Arthritis and Musculoskeletal and Skin Diseases, tonkinsw2@mail.nih.gov, 301-594-5032.

Priorities in Pediatric Epilepsy Research

- Workshop held in spirit of patient-centered and patient-driven mandates for developing best practices in care, particularly for epilepsy beginning under age 3 years
- Priorities:
 - Patient Outcomes
 - Seizure Control – top priority for parents*
 - Behavioral
 - Academic
 - Social Functioning

Berg AT, Baca CB, Loddenkemper T, Vickrey BG, Dlugos D. Priorities in pediatric epilepsy research. *Neurology* 2013;81:1166-1175



NINDS Common Data Elements

Harmonizing information. Streamlining research.

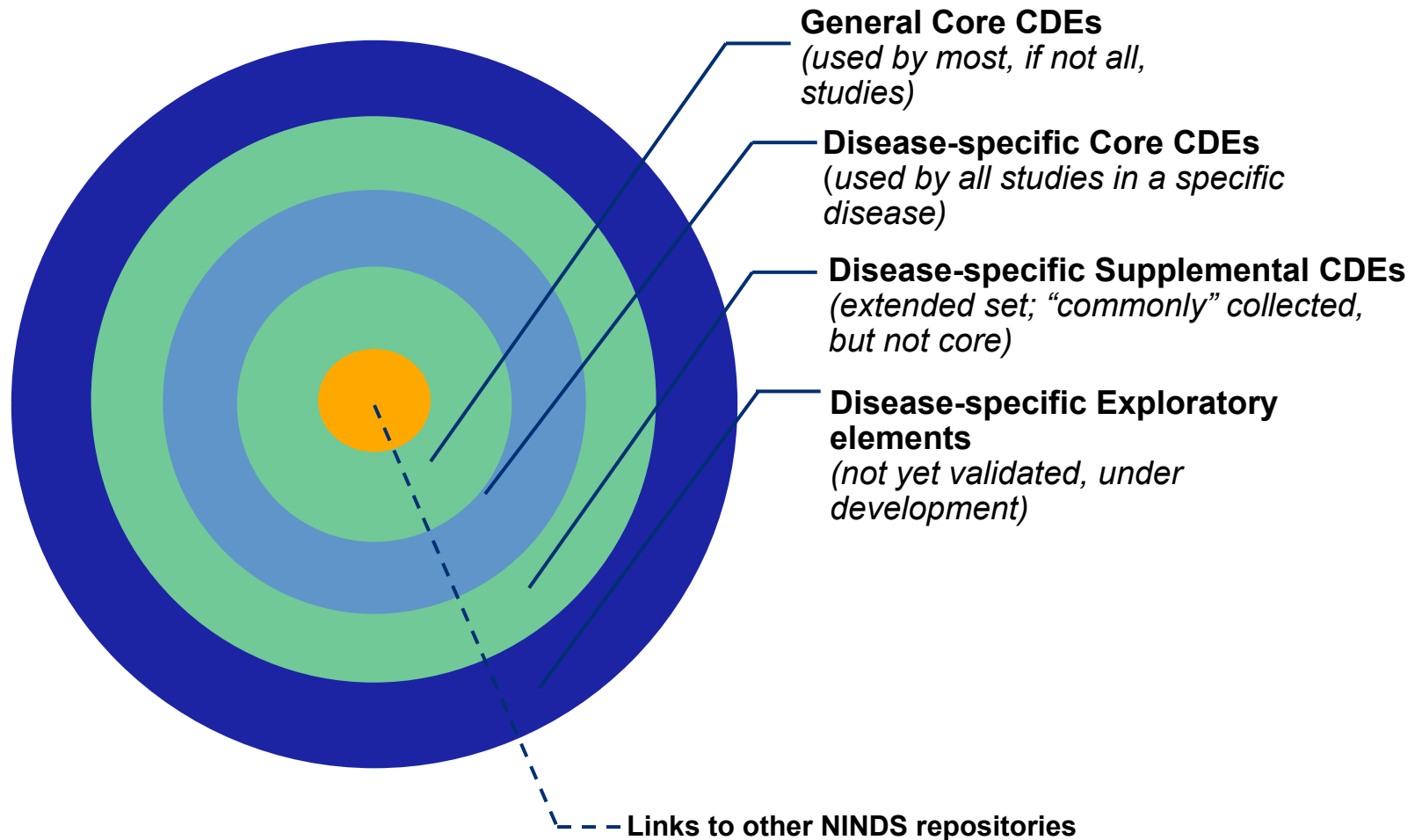
What is a Common Data Element (CDE)?

- A logical unit of data, pertaining to one kind of information
- Has a name, precise definition, and clear enumerated values (codes) if applicable
- Example
 - Element name: *Year of initial diagnosis*
 - Definition: *Year physician first diagnosed disorder*
 - Code value: *YYYY (4-digit numeric)*

[http://
www.commondataelements.ninds.nih.g
ov/](http://www.commondataelements.ninds.nih.gov/)

Google: “common data elements”

Classification of CDEs



**Patient-Reported Outcomes Measurement
Information System (PROMIS®):
From Basics to Applications in Clinical
Research, Practice, and Population Health**

May 14-15, 2015

Philadelphia Marriott Downtown

Philadelphia, PA, USA

Validation of Pediatric Patient Reported Outcomes in Chronic Disease (PEPR) Consortium (U19)

- The National Institutes of Health (NIH) is announcing the release of a funding opportunity announcement (FOA) titled, “[Validation of Pediatric Patient Reported Outcomes in Chronic Diseases \(PEPR\) Consortium \(U19\)](#).”
- This Consortium will capitalize on recent advances in the science of patient reported outcomes to assess the health of children with a variety of chronic diseases and conditions in clinical research and care settings. The PEPR Consortium will use the [Patient Reported Outcomes Measurement Information System \(PROMIS®\)](#) pediatric self-report and parent proxy instruments.
- All investigators interested in patient reported outcomes in chronic diseases affecting pediatric populations are encouraged to apply.
- Letters of intent are due **May 2, 2015**. Applications are due **June 2, 2015**