



Patient-Reported Outcomes Measurement Information System
Dynamic Tools to Measure Health Outcomes From the Patient Perspective

Patient-Reported Outcomes Measurement Information System (PROMIS): An NIH Roadmap Initiative

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On behalf of the PROMIS network



Themes of the NIH Roadmap

- **New Pathways to Discovery**
- **Research Teams of the Future**
- **Re-engineering the Clinical Research Enterprise**
 - Implement new paradigms in how clinical research information is collected, used, and reported.
 - Incorporate advances in information technology, psychometrics, and qualitative, cognitive, and health survey research.
 - Develop new partnerships of research with organized patient communities, community-based health care providers, industry, and academic researchers.



Broad Objectives of PROMIS

RFA-RM-04-011

- Develop and test a large item bank measuring patient-reported outcomes (PROs)
- Create a computerized adaptive testing system that will allow for efficient, psychometrically robust assessment of patient-reported outcomes for a wide range of chronic disease outcome research
- Create a publicly available system that can be added to and modified periodically and that will allow clinical researchers access to a common item repository and to computerized adaptive testing



Why More Patient Report Measures?

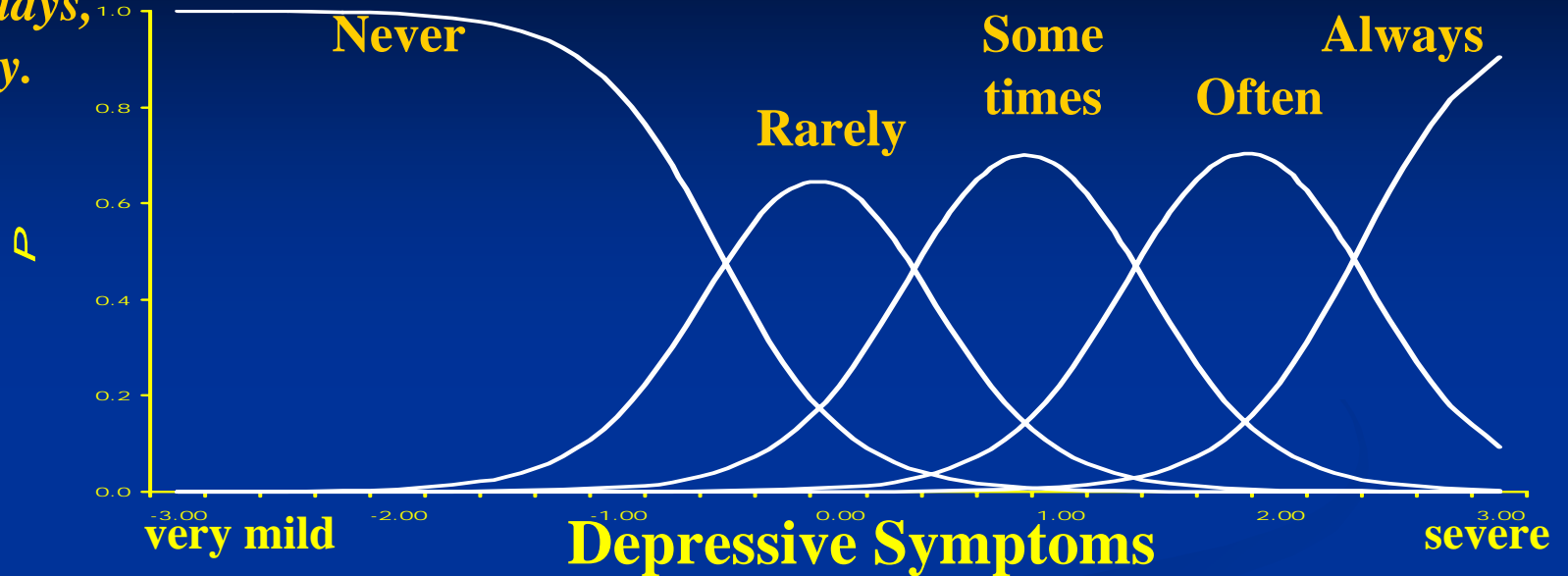
- Don't we need more “objective” measures?
- Aren't there already too many patient-report scales?
 - Widely varying item development and psychometric properties (leading FDA to provide draft guidance on PROs (Feb. 2006))
 - Lack of comparability between studies using different scales
- Is the development of PROs really innovative?
 - Leverage modern psychometric theory (e.g. IRT)
 - Leverage technology

Advantages of Item Response Theory (IRT) and Computerized Adaptive Testing (CAT)

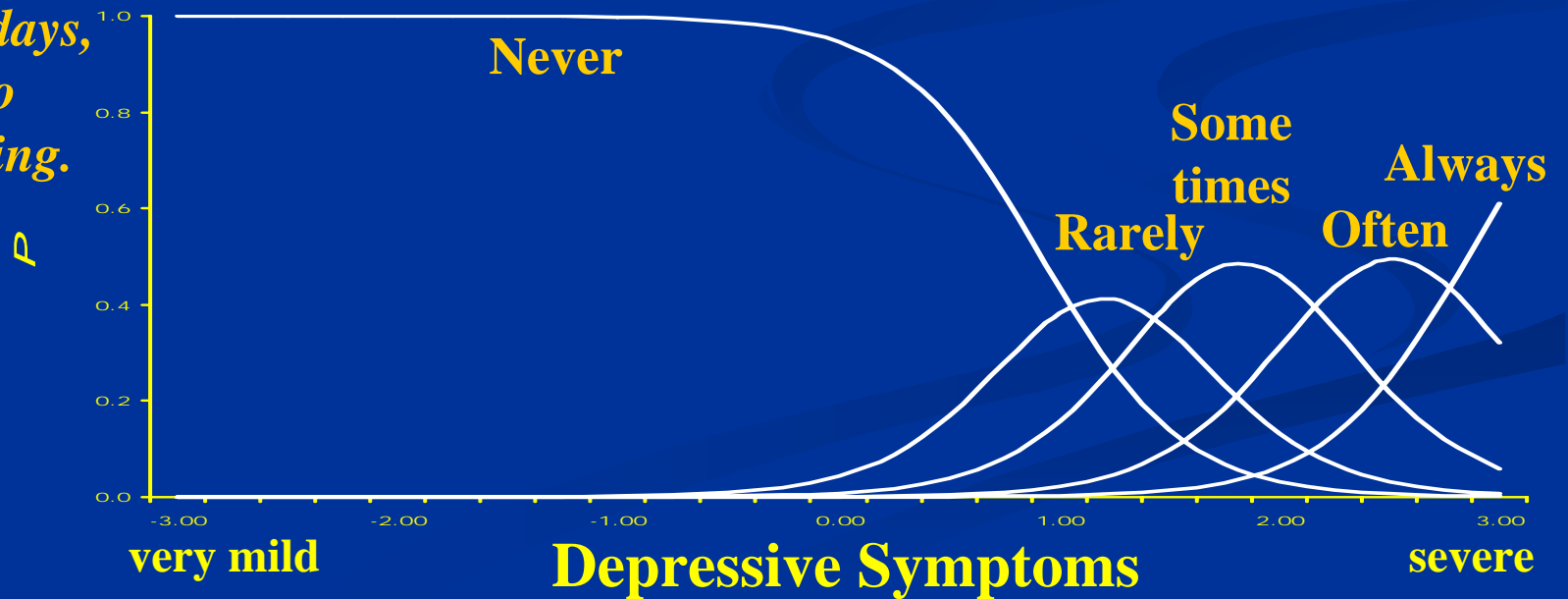
- Psychometric properties at the item level allow for item banks that can be flexibly administered and continuously refined
- Crosswalk with existing scales for comparability
- Improved efficiency (less respondent burden)
 - Automated administration, scoring and reporting
 - Tailored targeting of items
 - Item administration based on prior responses

Item Response Theory (IRT): Category Response Curves

*In the past 7 days,
I felt unhappy.*

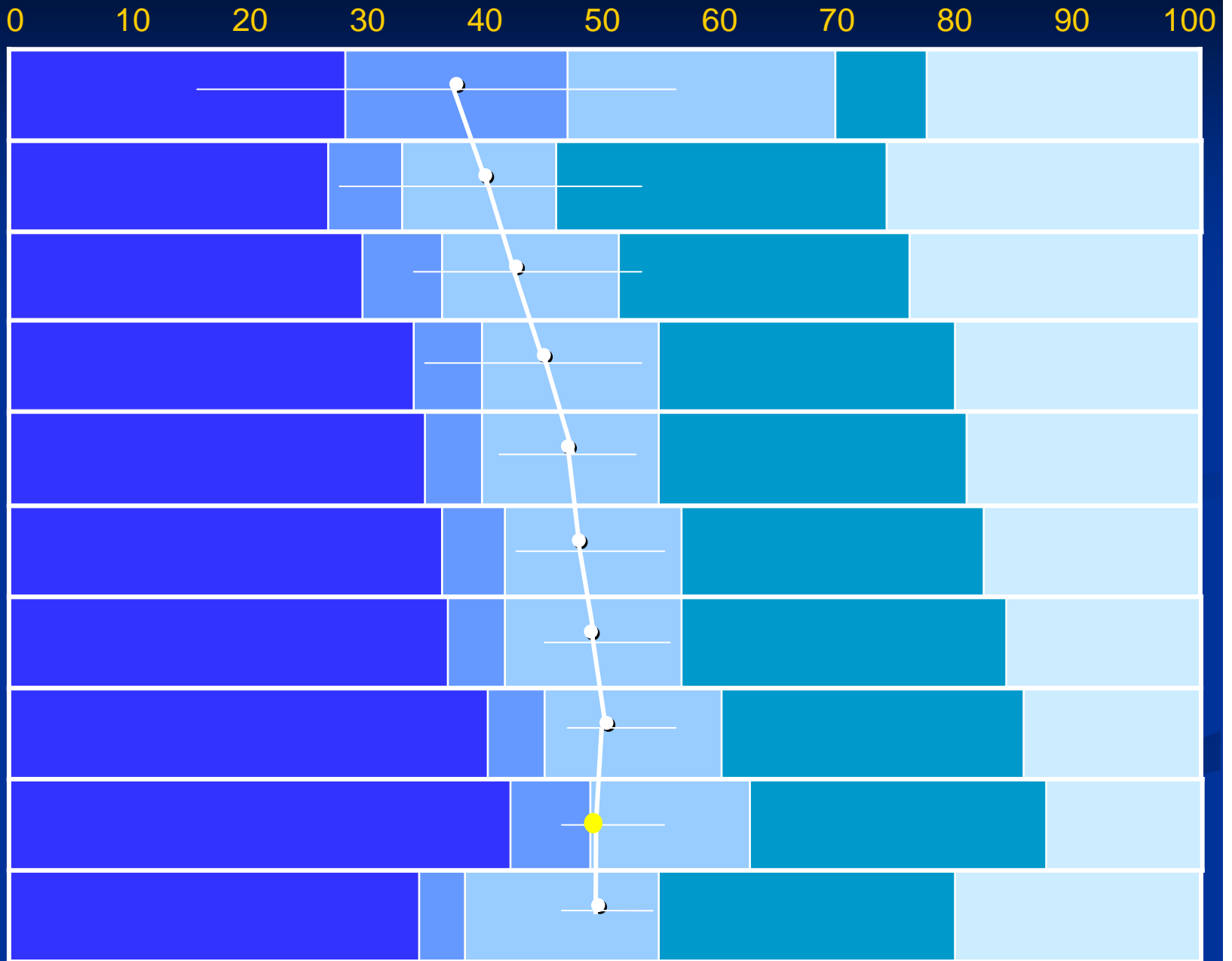


*In the past 7 days,
I felt I had no
reason for living.*



Simulate Measure = 48

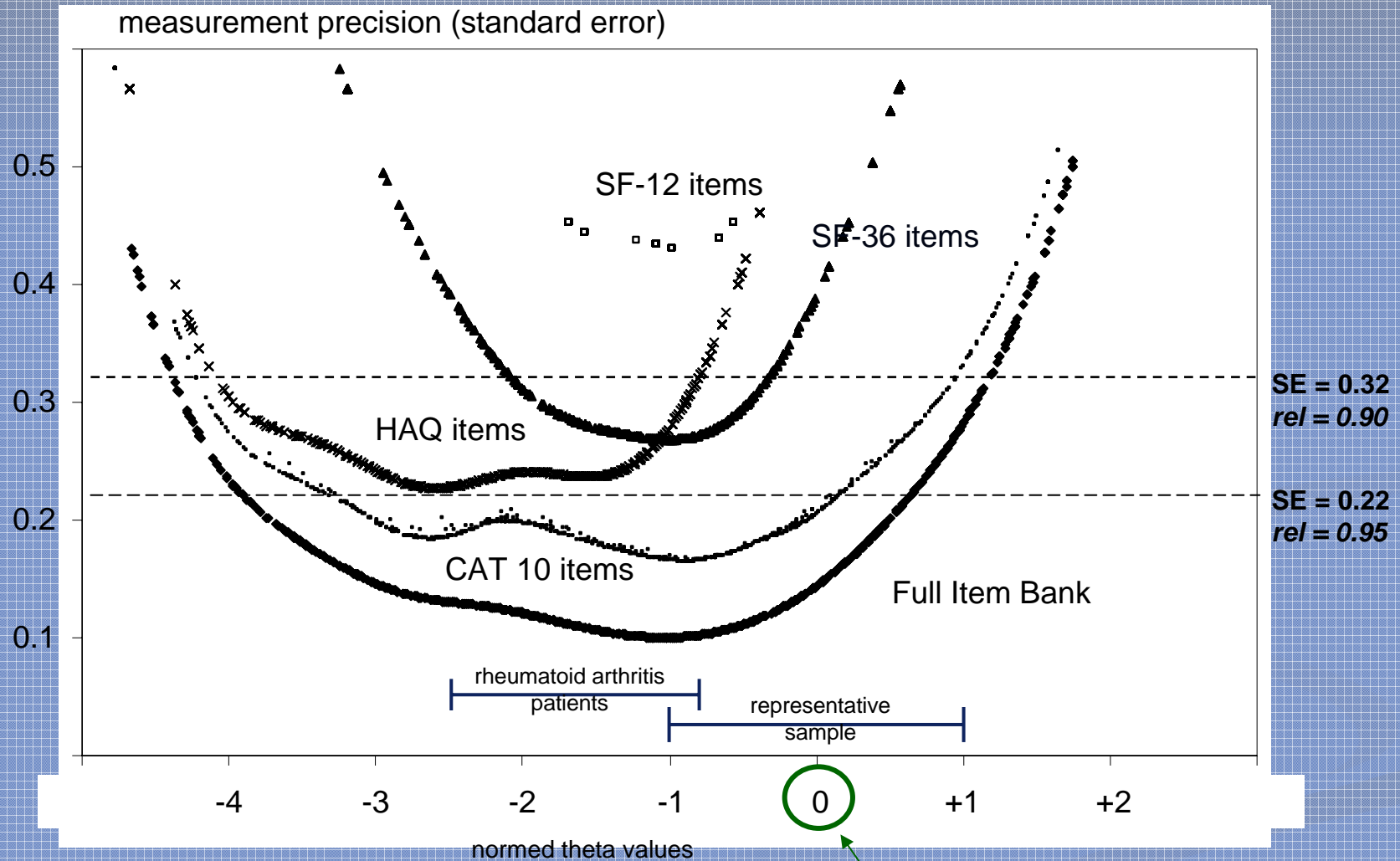
Item	Meas	SE
1	37	21
2	40	12
3	42	9
4	44	8
5	45	7
6	46	7
7	47	6
8	48	6
9	47	5
10	48	5



Advantages of Item Response Theory (IRT) and Computerized Adaptive Testing (CAT)

- Psychometric properties at the item level allow for item banks that can be flexibly administered and continuously refined
- Improved efficiency (less respondent burden)
 - Automated administration, scoring and reporting
 - Tailored targeting of items to severity level
 - Item administration based on prior responses
- **Improved measurement precision (reliability)**

Improved Precision vs. Legacy Measures



PROMIS Grantees

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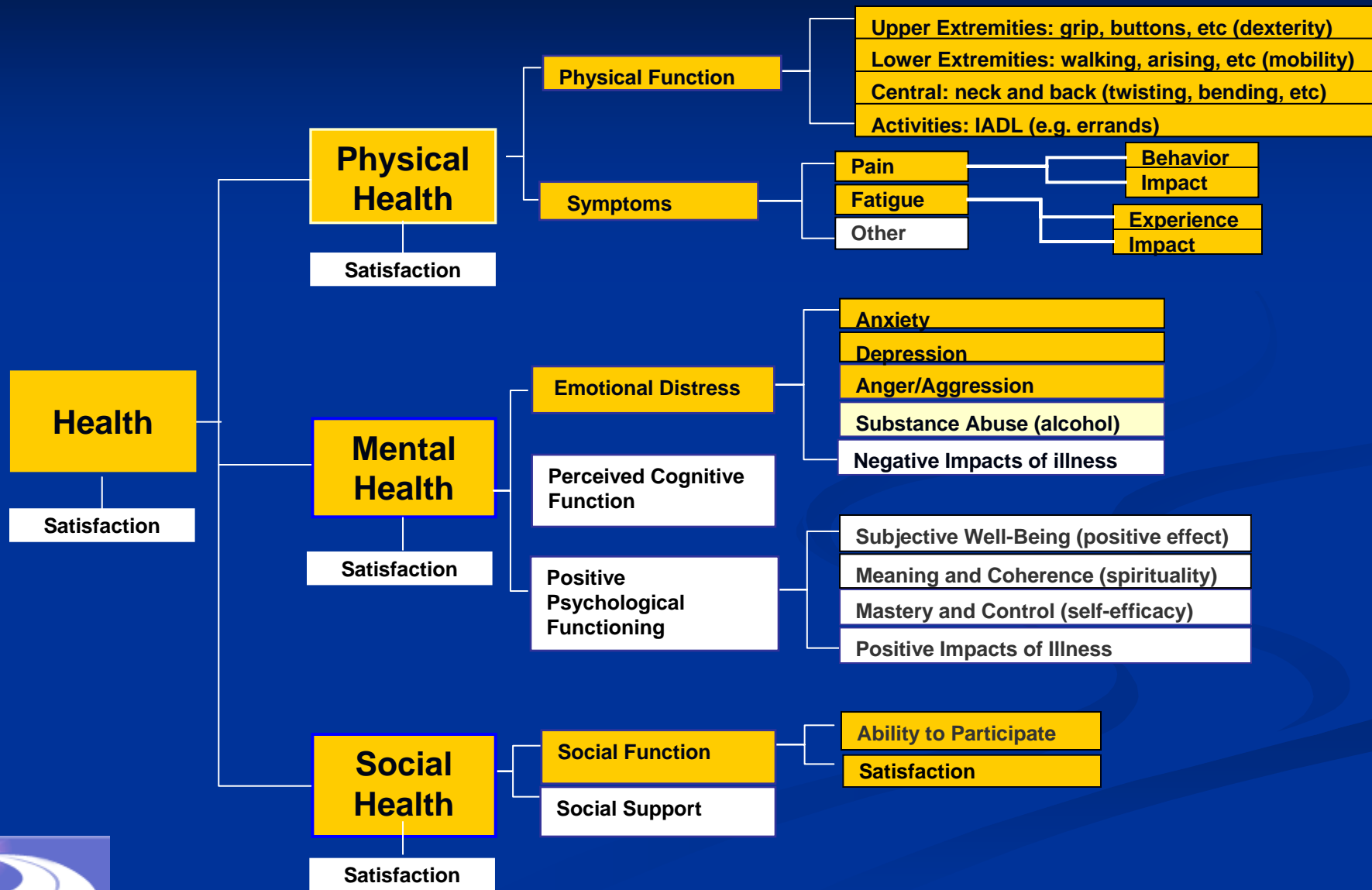
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Timetable

- **FY 2005:** Choose specific domains, identify instruments and items, conduct qualitative item review
- **FY 2006:** Adopt core items, develop software for data collection, initiate large-scale data collection
- **FY 2007:** Continue data collection, initiate data analyses
- **FY 2008:** Complete data analyses, develop and test CAT
- **FY 2009:** Evaluate feasibility of item bank and CAT, develop strategies and form partnerships for ongoing development and maintenance

PROMIS Domain Framework



Additional Domain Development

■ Independent and Supplement Project Domains

- Pediatric Core Domains (Physical, Emotional, Social, School/Cognitive)
- Pediatric Asthma
- Sleep/Wake Functioning
- Sexual Functioning
- Perceived Cognitive Functioning
- CA Illness Impact

■ Recent Roadmap Supplement Efforts

- Modified item banks for patients using wheelchairs and assistive devices
- Parent-proxy item banks that parallel the pediatric item banks

■ Collaborations with Other Federally Funded Initiatives

- NINDS NeuroQOL
- NIH Toolbox (Sensory, Motor, Cognitive, Emotional)
- CMS Post-Acute Care Demonstration Project

■ Collaborations with Test Developers and End Users



PROMIS Item Bank Development

- Extant review of existing items (legacy items)
- Development of new and modified items (approx. 8000 total new and derived items)
- Binning and winnowing of items (1064 items)
- Revisions for readability, consistency, and translation
- Patient focus groups
- Cognitive interviews (784 items)

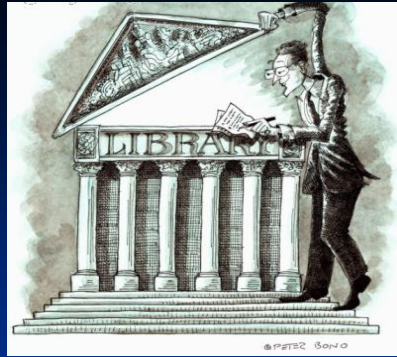


Wave 1 Testing

- Large general population sample obtained from Internet survey/polling panel
- Chronic disease samples obtained from those self-identified in the panel and from various clinic samples (e.g. arthritis, cancer, heart disease, outpatient mental health, general med)
- Over 20,000 total sample completing assigned subsets of the total item pool via the Internet

Wave 1 Analyses and Item Bank Selection

- Dimensionality and Other Assumptions
- Item Fit (Statistical and Content Fit)
- Differential Item Functioning
- Calibrate Retained Items for Bank



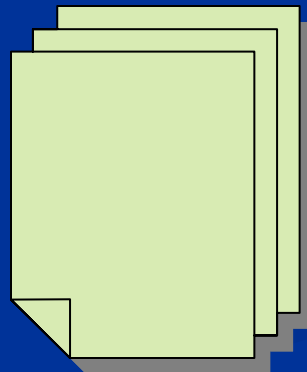
Item Bank



CAT



Pick-a-PRO



Build-a-PRO



Assessment Center Features

- Study set-up
- Select PROMIS short-forms or CAT
- Add non-PROMIS scales/items for computerized administration
- Study administration and maintenance
- Data Export

Assessment Center and all documentation at:

www.nihpromis.org

