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

William Riley, Ph.D.

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

PROMIS Grantees

David Cella, Ph.D. Northwestern U.	Westat UBH UCLA
Dagmar Amtmann, Ph.D. U. of Washington	
Jim Fries, M.D. Stanford University	Health Assessment Lab Quality Metric
Darren DeWalt, M.D. U. of North Carolina	Texas A&M Scott & White Mem Hosp
Paul Pilkonis, Ph.D. U. of Pittsburgh	Assessment Systems Boston U.
Arthur Stone, Ph.D. Stony Brook University	U. of Michigan
Kevin Weinfurt, Ph.D. Duke University	

Why More Patient Report Measurement Research?

- "Don't we already have more scales than we need?"
  - Widely varying item development and psychometric properties (leading FDA to provide draft guidance on PROs (Feb. 2006))
  - Difficulty comparing outcomes between studies using different scales
  - "Kitchen Sink" approach to assessment increases patient response burden
- "We need more objective measures, not subjective measures"

  Critical to pursue markers of disease processes, but also critical to accurately capture patient experiences, especially those known only to them
- "Questionnaires are not a sophisticated form of measurement"
  - Leverage technological advances to move from paper-and pencil to computer administered
  - Leverage modern psychometric theory (e.g. IRT) to produce precise, efficient scales

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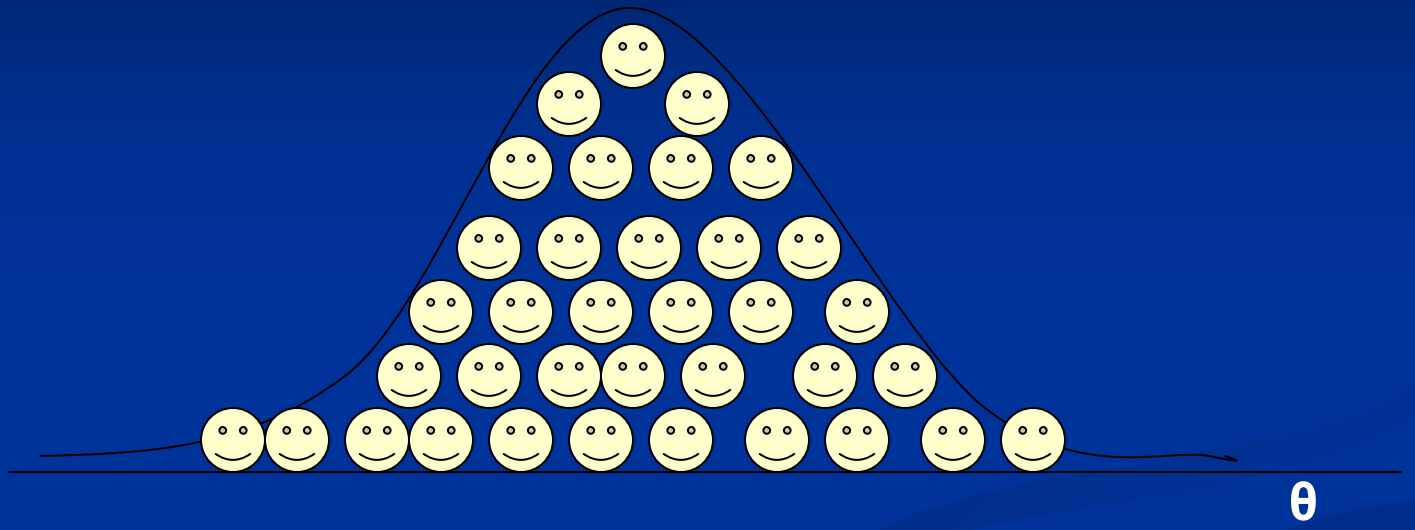
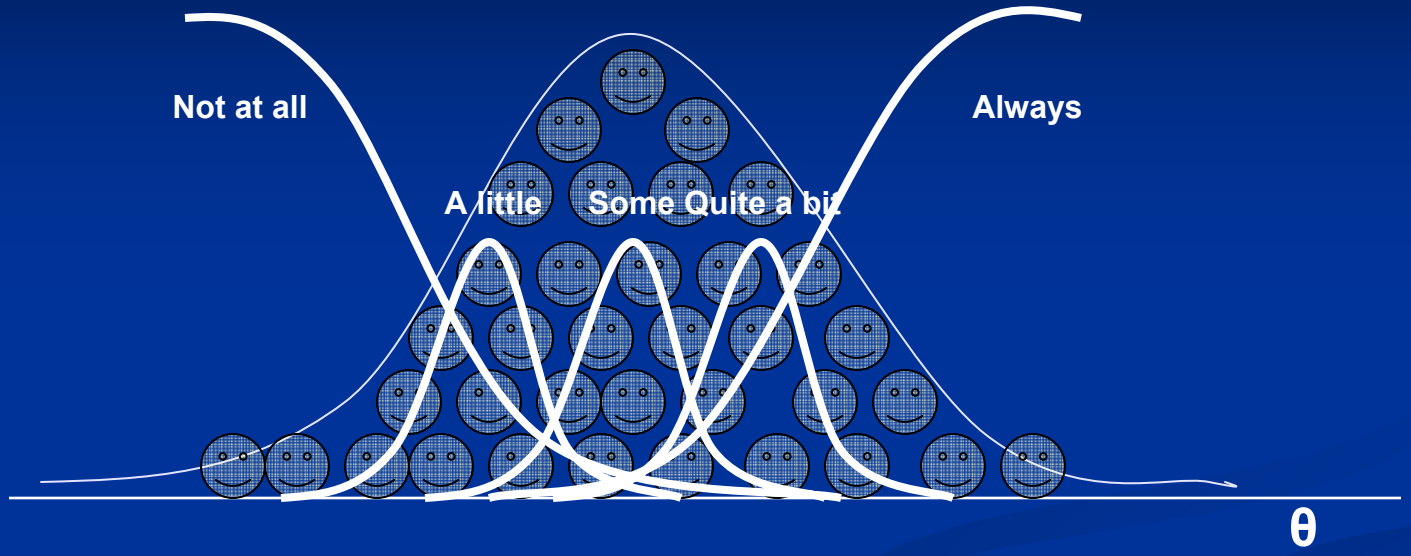
IRT Distributes People . . .



. . . and item responses



I feel sad

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

- Improved measurement precision (reliability)
- Psychometric properties at the item level allow for item banks that can be flexibly administered and continuously refined
- "Cross-walk" scores between two or more instruments intended to measure the same construct
- Improved efficiency (less respondent burden)
  - Automated administration, scoring and reporting
  - Tailored targeting of items to sample
  - Item administration based on prior responses

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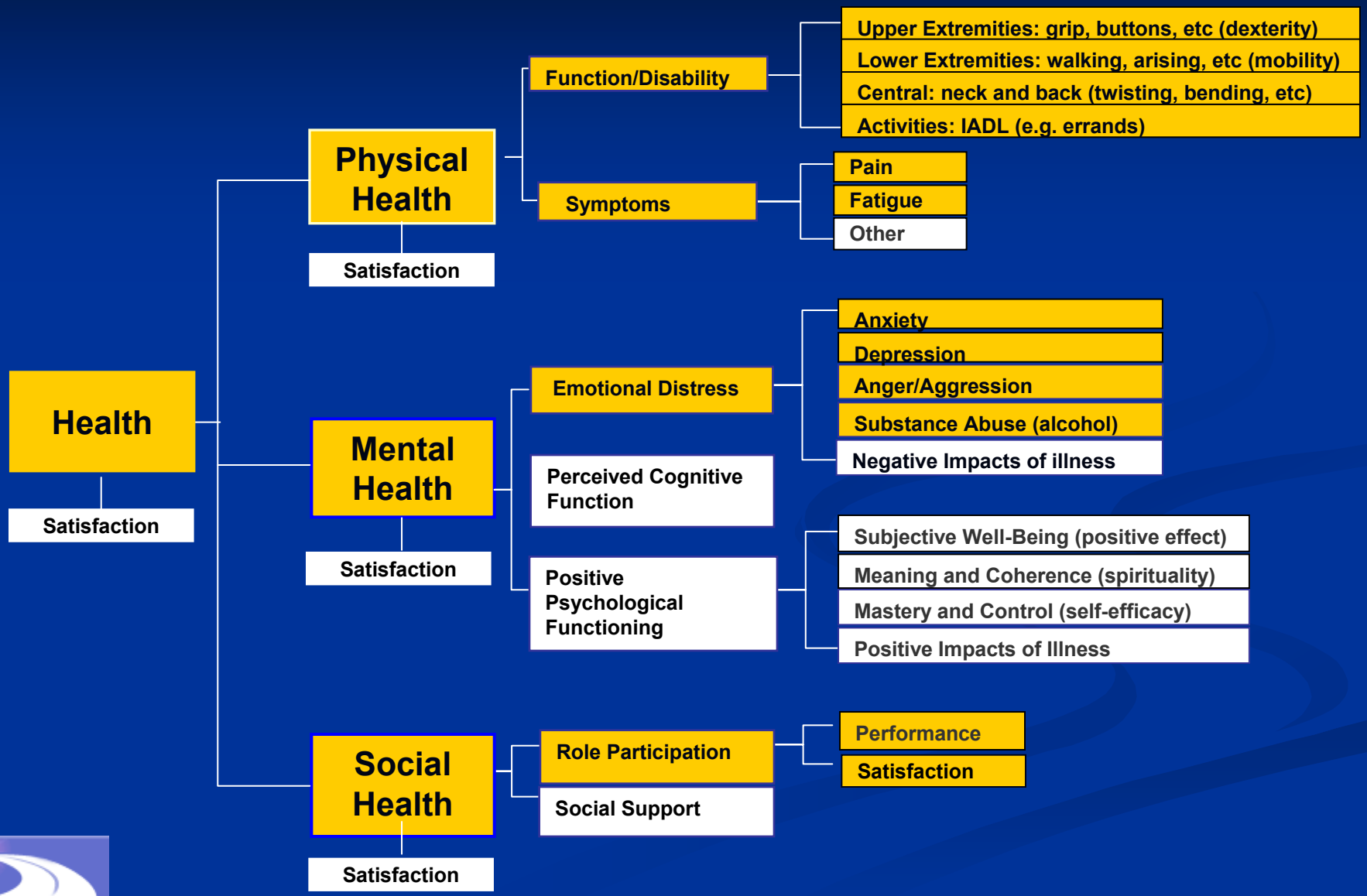
PROMIS Domain Framework



Additional Domain Development

- Network Domains
  - Physical Functioning (upper, lower, central, IADL)
  - Pain (quality, behavior, interference)
  - Fatigue (experience, impact)
  - Emotional Distress (depression, anxiety, anger, alcohol)
  - Social Role Participation (performance, satisfaction)
- Independent and Supplement Domains
  - Pediatric Core Domains (Physical, Emotional, Social, School/Cognitive)
  - Pediatric Asthma
  - Sleep/Wake Functioning
  - Sexual Functioning
  - Perceived Cognitive Functioning
  - Illness Impact (CA)
  - Social Alienation/Connectedness
- Collaborations with other projects (e.g. NeuroQOL, Kidscreen)

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 translatability
- 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 Demographics

	All Sample (N = 20811)	Gen. Pop. (N = 13042)	Clinical Pop. (N = 7769)
Age (M/SD)	53.1 (17.2)	50.8 (18.4)	57.0 (14.1)
% Age (18-39)	24.5	31.5	12.5
% Age (40-64)	47.5	42.1	56.2
% Age (65 +)	28.2	26.3	31.2
Female %	52.2	55.1	47.2
White %	81.8	79.1	86.4
Black %	8.5	9.4	7.1
Hispanic %	8.9	12.0	3.8

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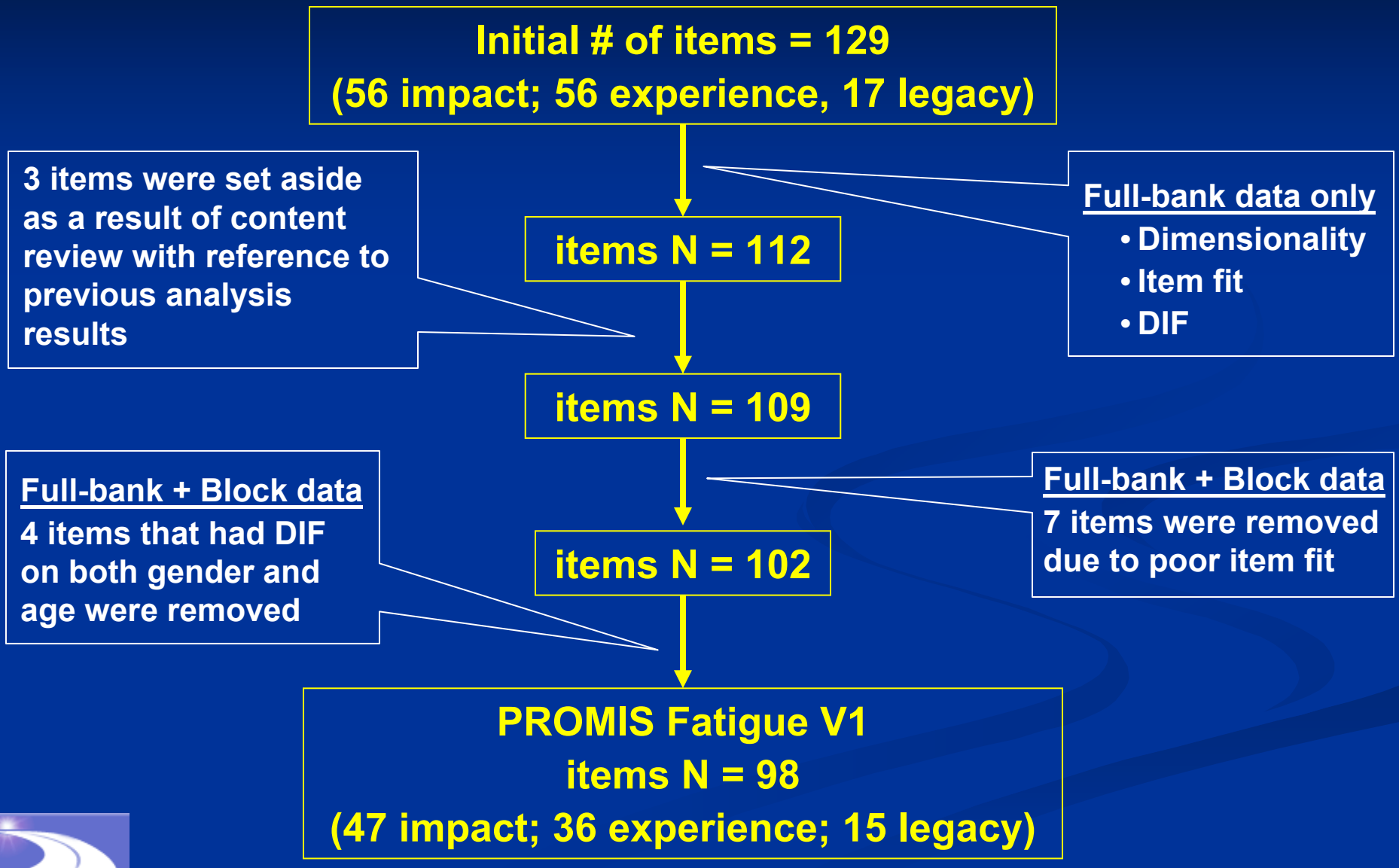
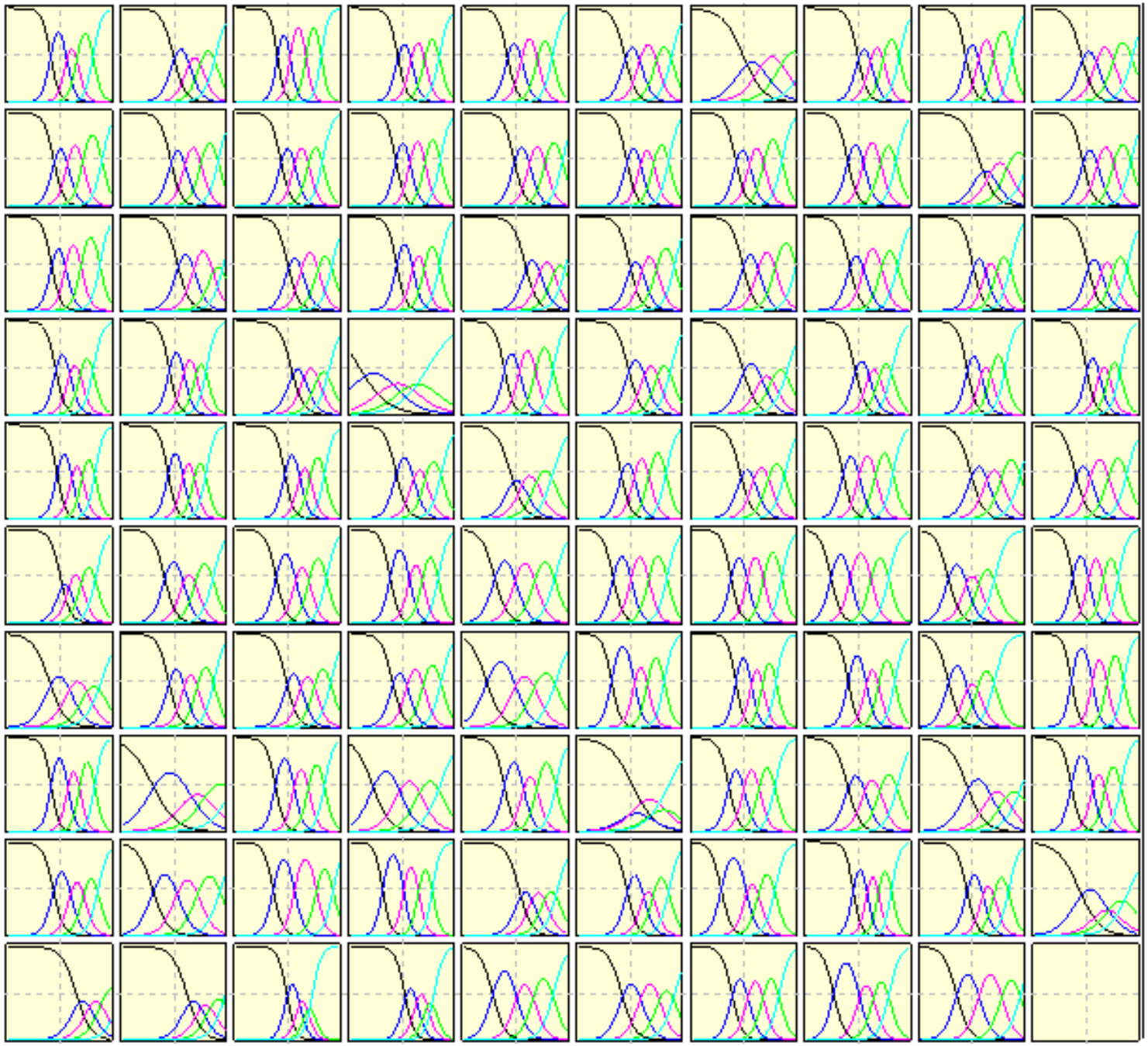
Fatigue Item Bank Process



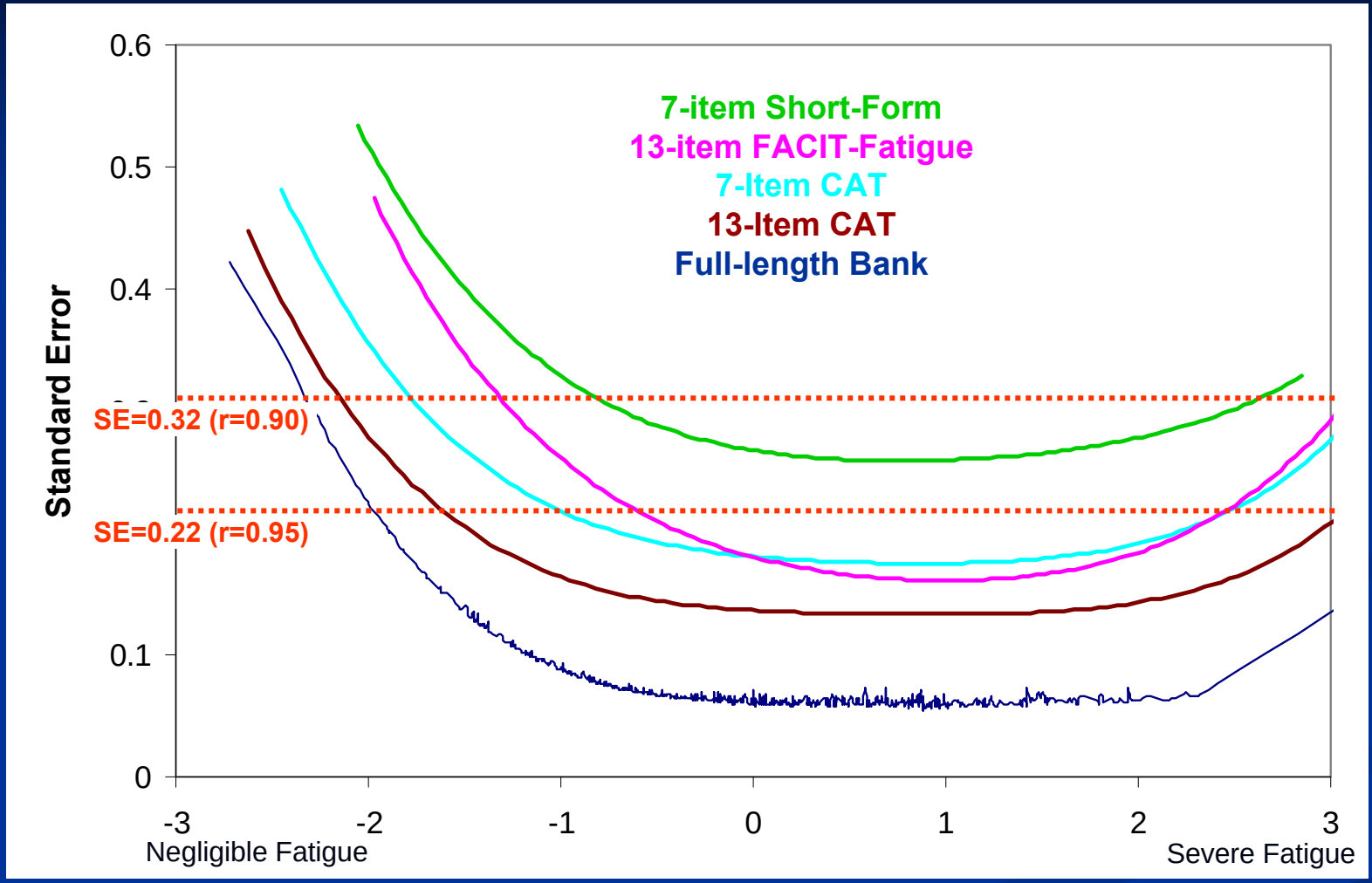
FATIGUE SHORT-FORM

	In the past 7 days …	Never	Rarely	Some-times	Often	Always
FATEXP 20	How often did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP 5	How often did you experience extreme exhaustion?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP 18	How often did you run out of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP 33	How often did your fatigue limit you at work (include work at home)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP 30	How often were you too tired to think clearly?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP 21	How often were you too tired to take a bath or shower?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATIMP 40	How often did you have enough energy to exercise strenuously?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Matrix Plot of Item Characteristic Curves - Fatigue 99 (including global item) centered



Comparison of Measurement Precision



NOTE: 7-item short-Form is the one shown in the previous slide; 7-item CAT and 13-item CAT were generated via Firestar. Vitality scale was not compared as 2 (of 4) items were not included in the PROMIS Fatigue Item Bank version 1 based on the psychometric analysis results

Remaining Tasks

- Complete Wave 1 analyses and publish findings
- Make initial item bank (and all associated material) publicly accessible
- Complete development of software for internet and PC to administer PROMIS via short forms and CAT
- Insure compatibility of output with data standards
- Translate items into Spanish
- Additional validity trials (e.g. sensitivity to change)
- Establish a public-private partnership to sustain PROMIS post-Roadmap funding

Information

PROMIS: www.nihPROMIS.org

Roadmap: www.nihroadmap.nih.gov

NIH Science Officers:

- William Riley, NIMH
- Bryce Reeve, NCI
- Larry Fine, NHLBI
- Lou Quatrano, NICHD
- Susan Czajkowski, NHLBI
- Suzana Serrate-Sztein, NIAMS

NIH representatives from numerous other institutes