

15-minute Introduction to PROMIS

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Health Services Research

Roundtable Meeting on Measuring Burden of Illness

November 10, 2010 (1:50-2:05 pm)

RTI, Washington, DC

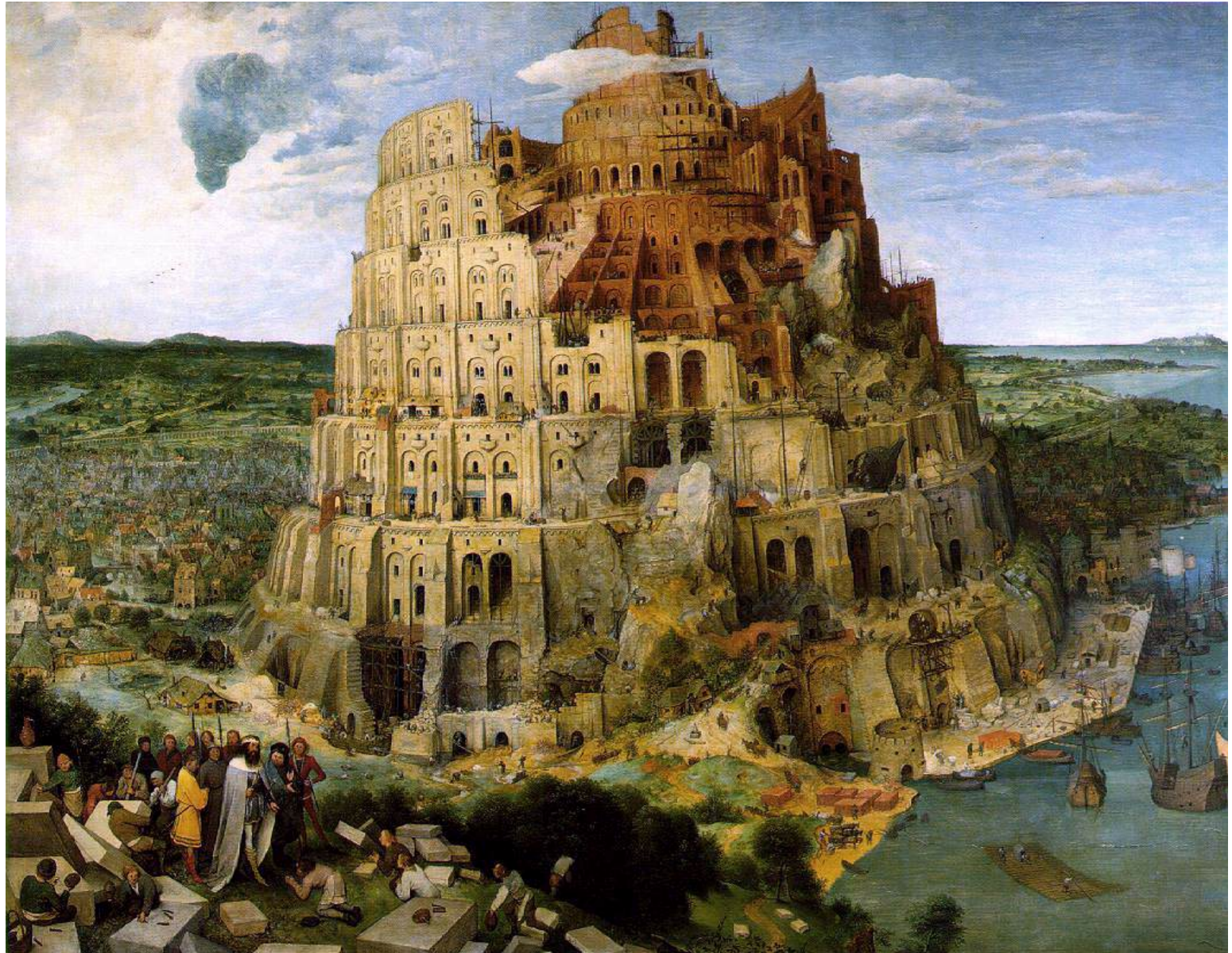


Patient-Reported Outcomes Measurement Information System
Dynamic Tools to Measure Health Outcomes From the Patient Perspective

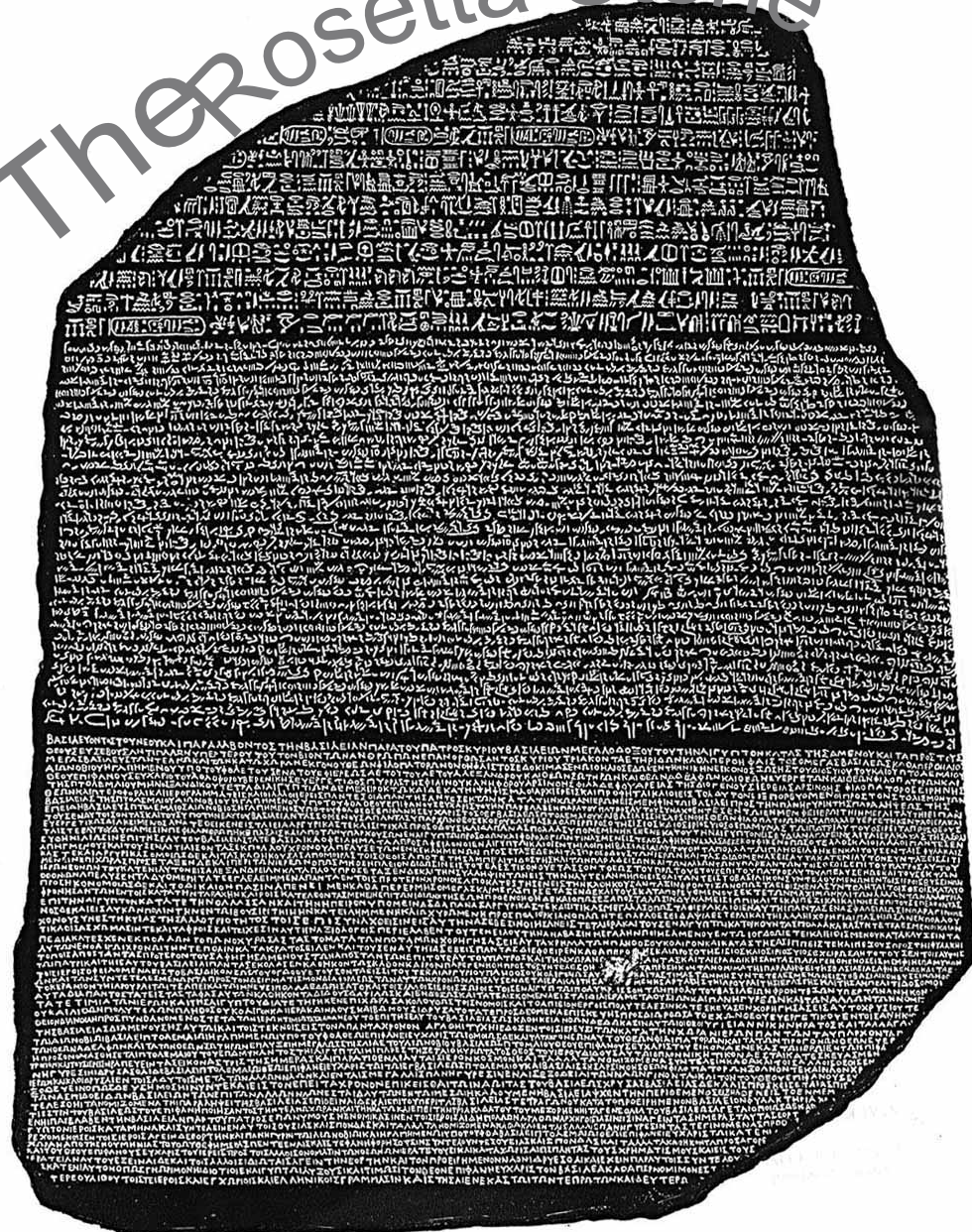
What is PROMIS?

- A nine-year \$70 million commitment of NIH to improve and standardize measurement of patient-reported outcomes (PROs)
 - Self-reported health
- An answer to the PRO “Tower of Babel”

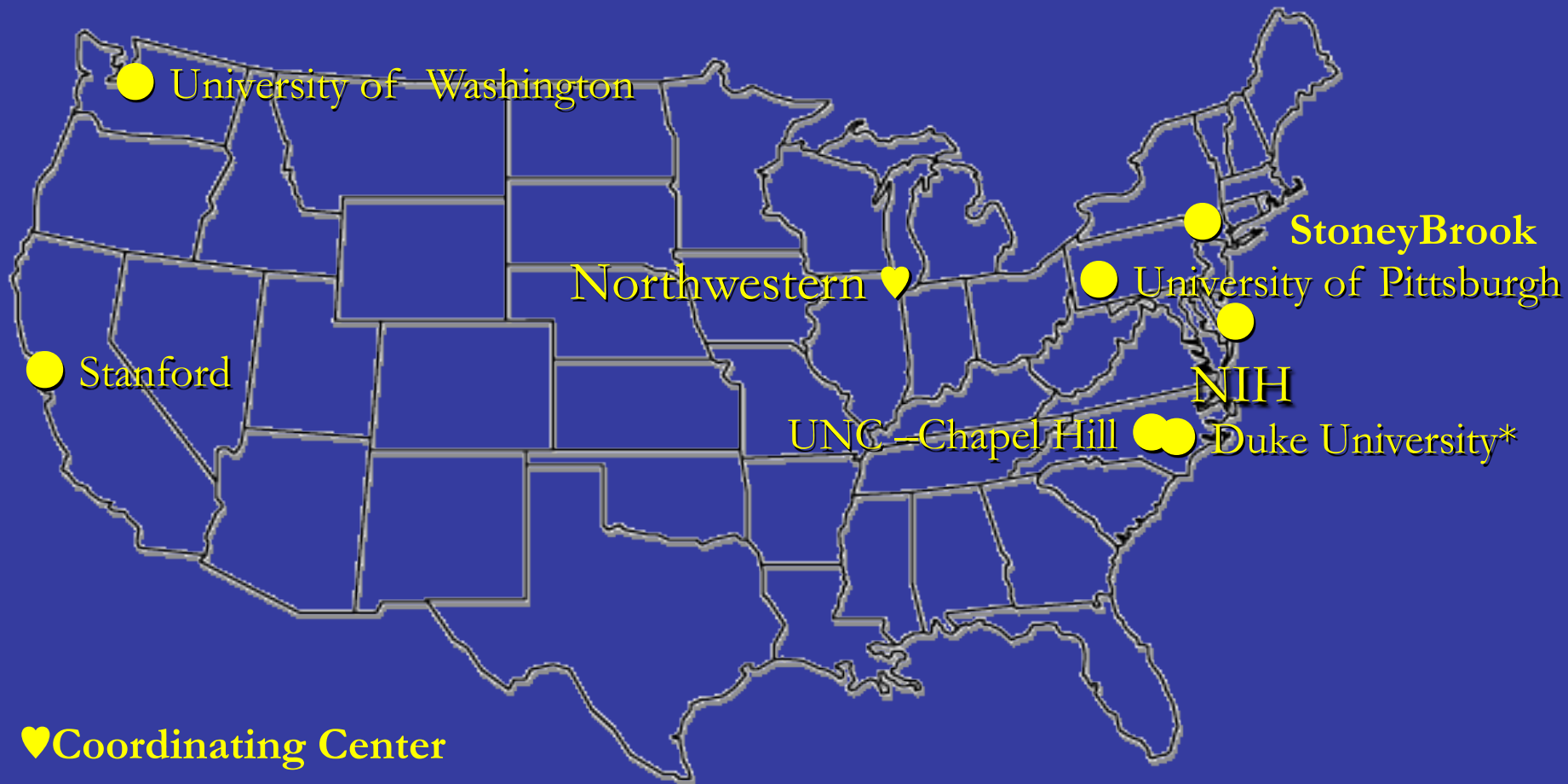
The Tower of Babel (Brueghel, 1563)



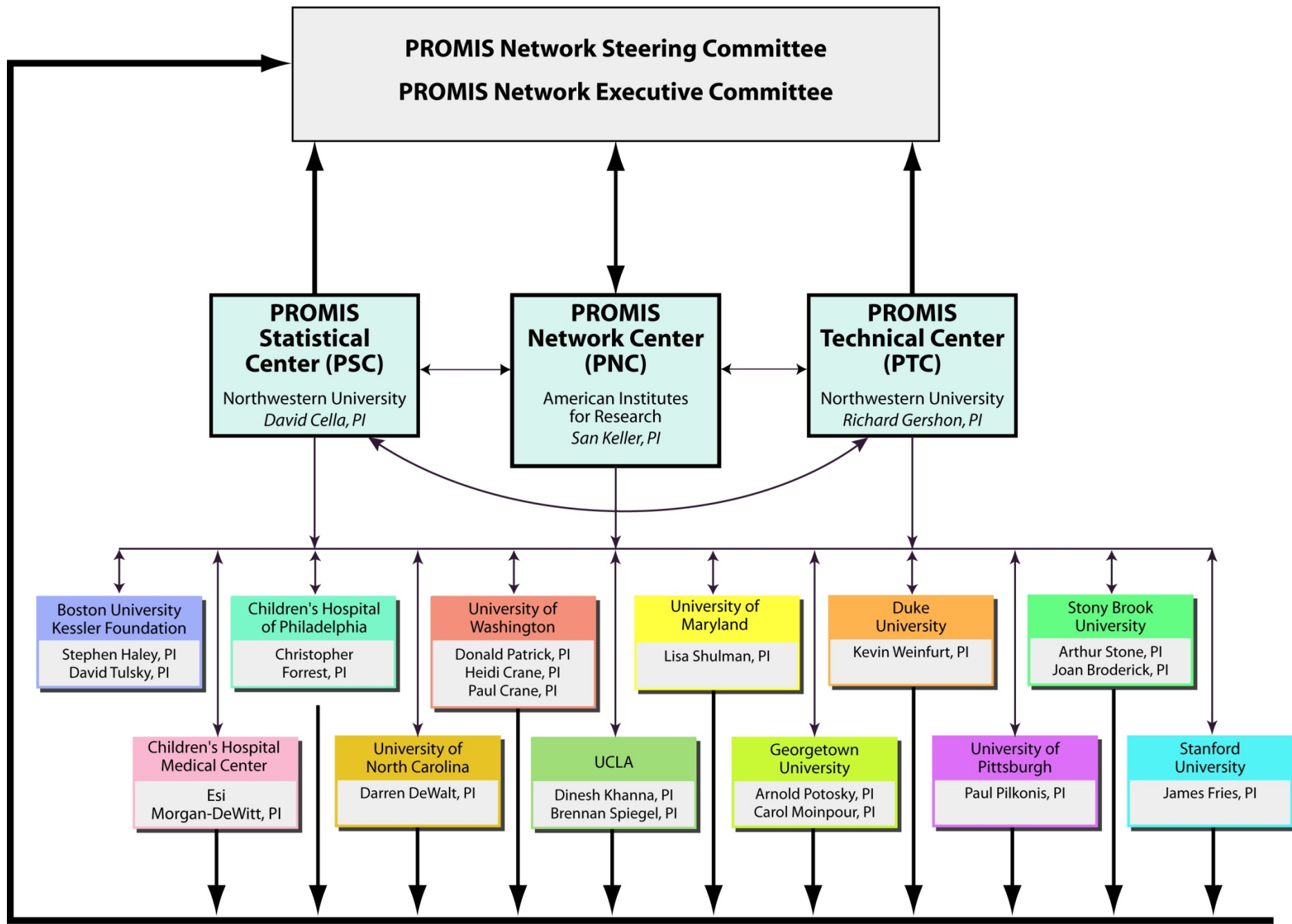
The Rosetta Stone

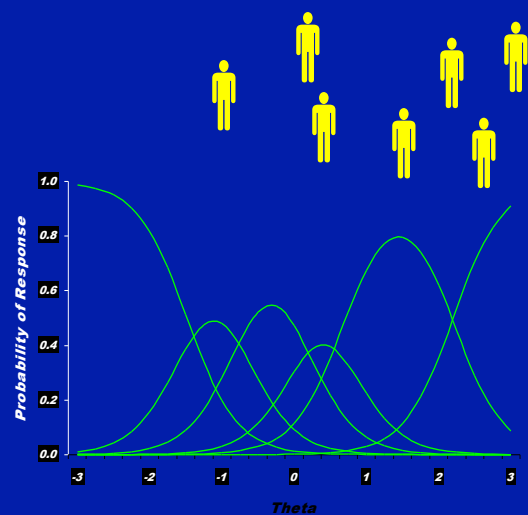
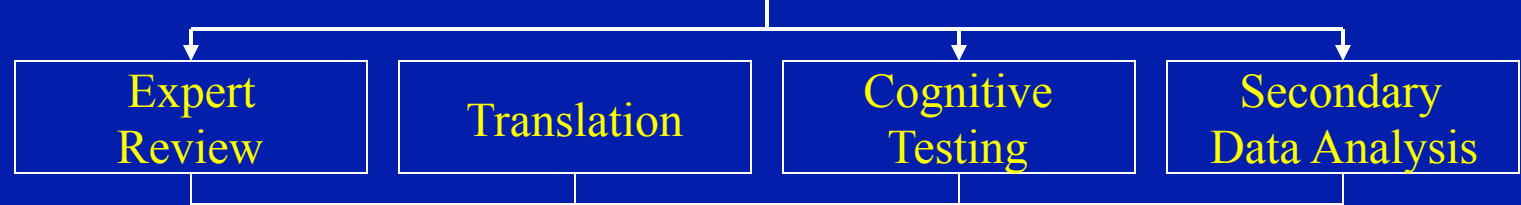
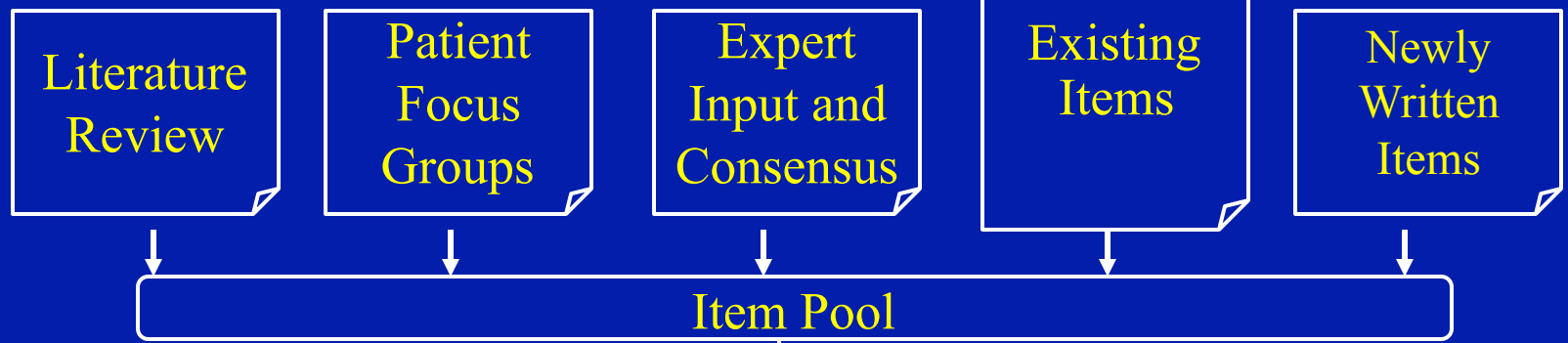


PROMIS-1 Network: 2004-2009



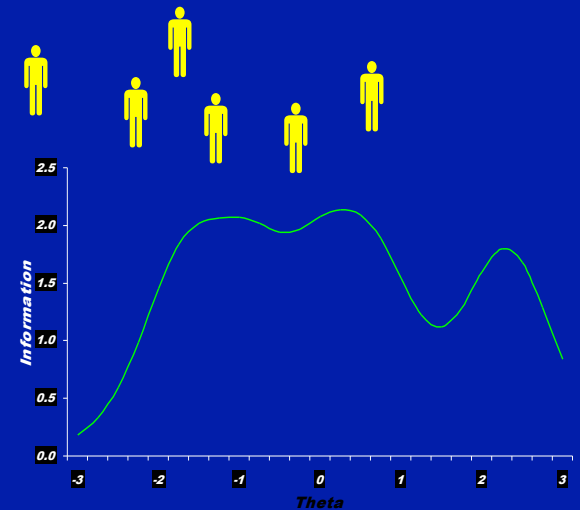
PROMIS II Network Diagram





Questionnaire administered to large representative sample

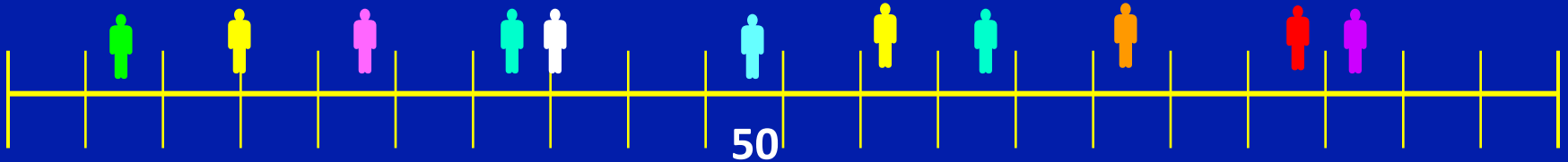
Psychometric Testing



Item Bank
(IRT-calibrated items)

Short Form Instruments





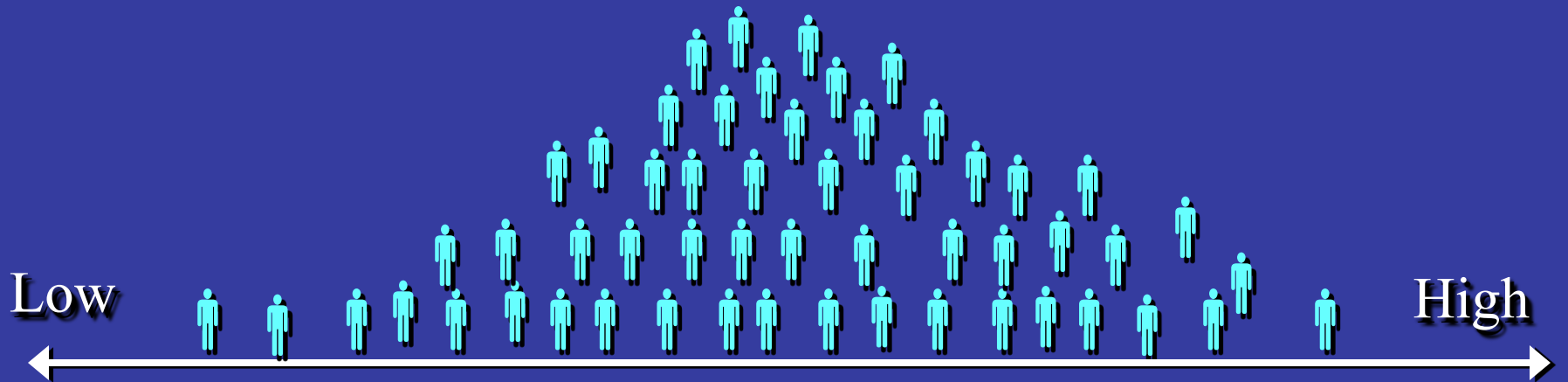
Physical Functioning Item Bank

↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Item	Item	Item	Item	Item	Item	Item	Item	Item	Item
1	2	3	4	5	6	7	8	9	<i>n</i>

- Are you able to get in and out of bed?
- Are you able to stand without losing your balance for 1 minute?
- Are you able to walk from one room to another?
- Are you able to walk a block on flat ground?
- Are you able to run or jog for two miles?
- Are you able to run five miles?

Interpretation

Person Fatigue Score



Likely

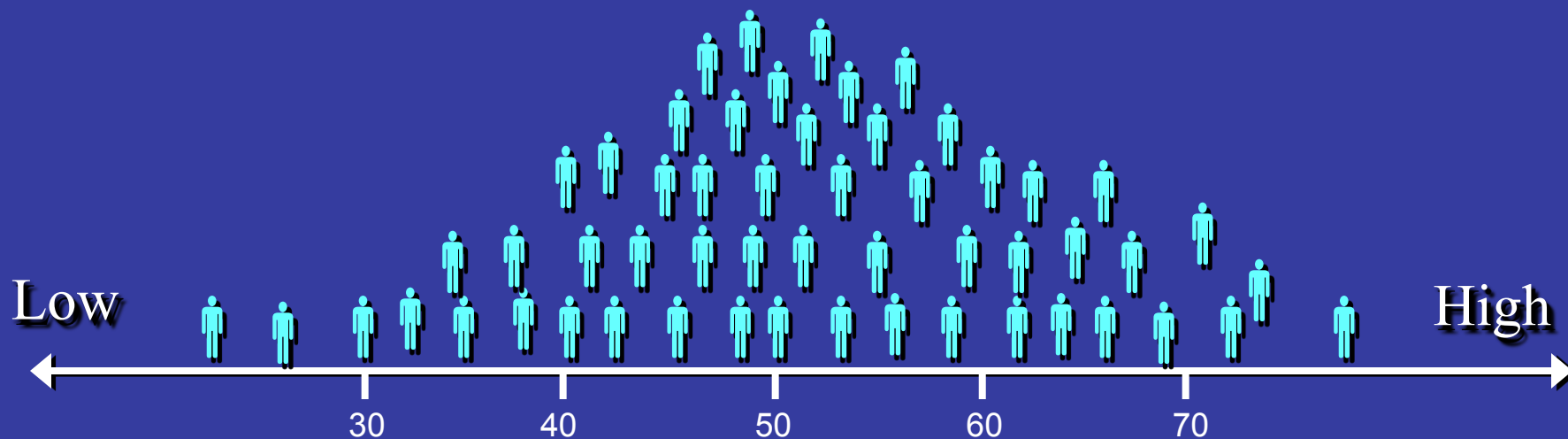
“I get tired
when I run
a marathon”

Unlikely
“I get tired
when I get
out of a
chair”

Item Location

Interpretation Aids

PRO Bank Person Score

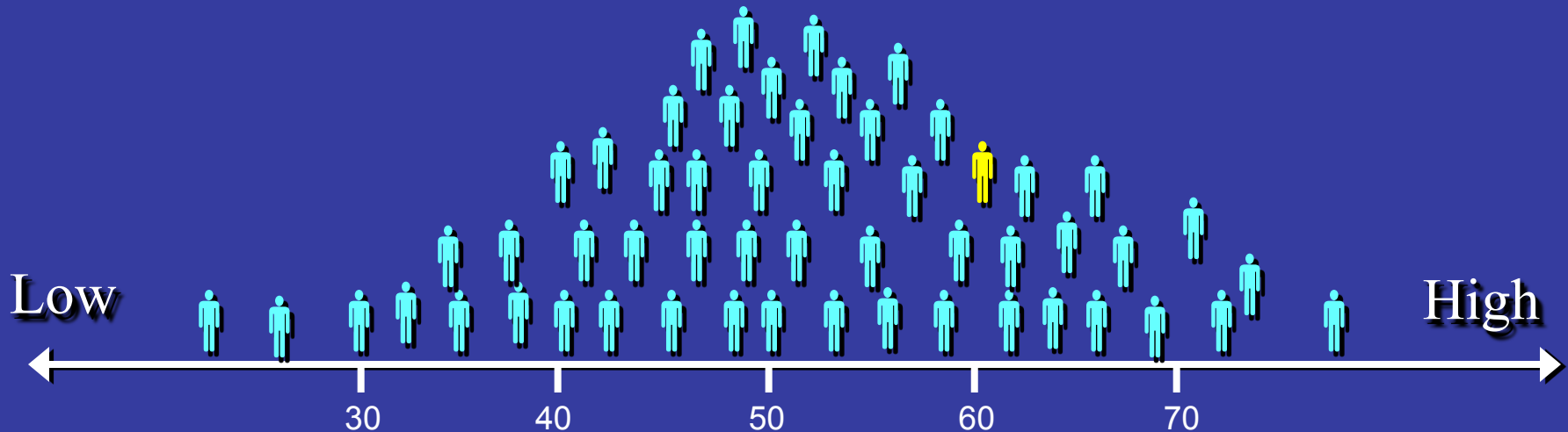


$$\underline{M} = 50, \underline{SD} = 10$$

$$T = (z * 10) + 50$$

Example of high fatigue

Fatigue Score=60



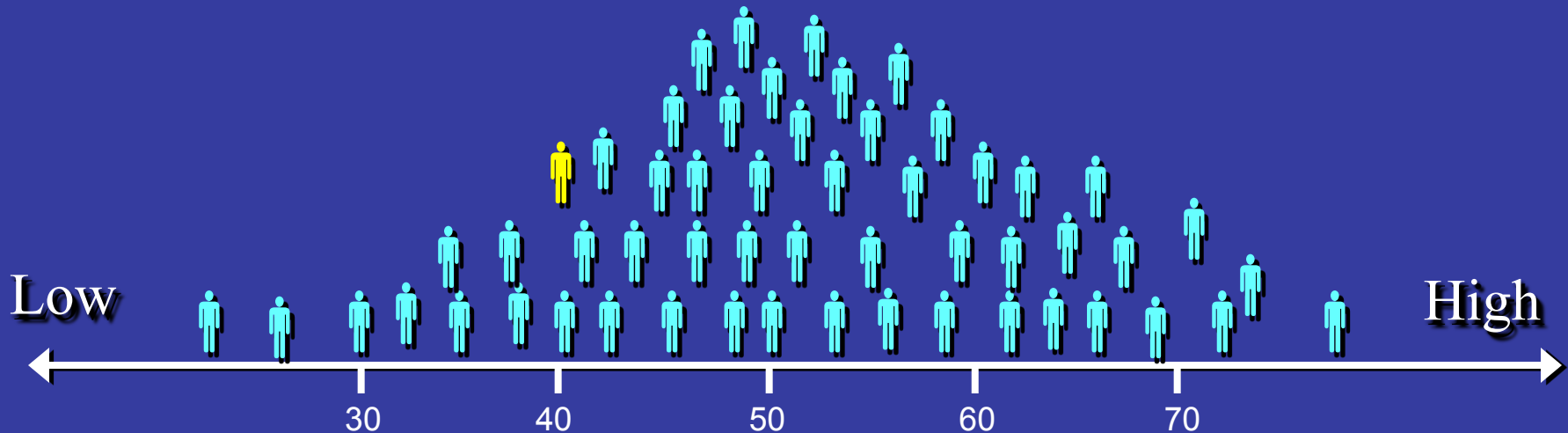
This patient's fatigue score is 60, significantly worse than average (50). People who score 60 on fatigue tend to answer questions as follows:

..."I have been too tired to climb one flight of stairs: VERY MUCH

..."I have had enough energy to go out with my family: A LITTLE BIT

Example of low fatigue

Fatigue Score=40



This patient's fatigue score is 40, significantly better than average (50). People who score 40 on fatigue tend to answer questions as follows:

..."I have been too tired to climb one flight of stairs: SOMEWHAT

..."I have had enough energy to go out with my family: VERY MUCH

Computerized Adaptive Testing (CAT)

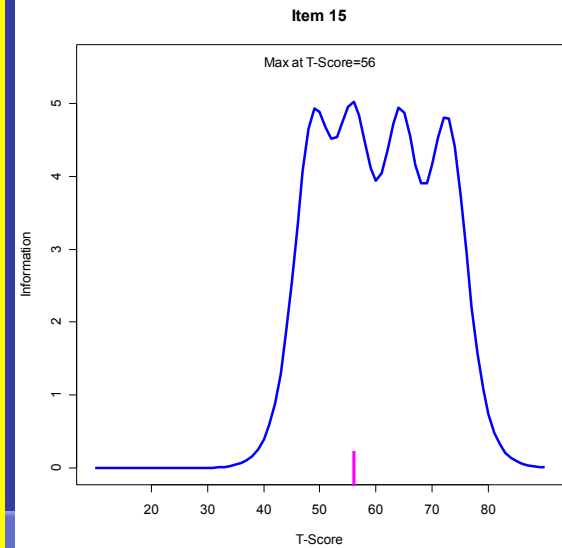
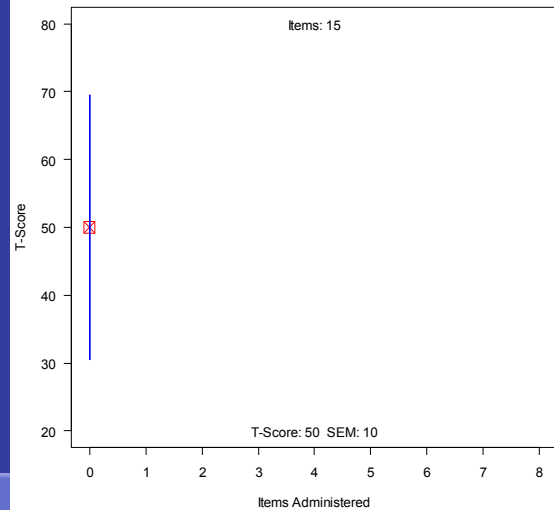
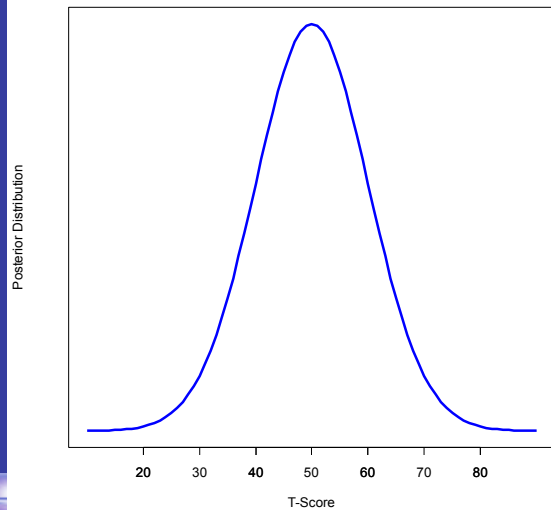
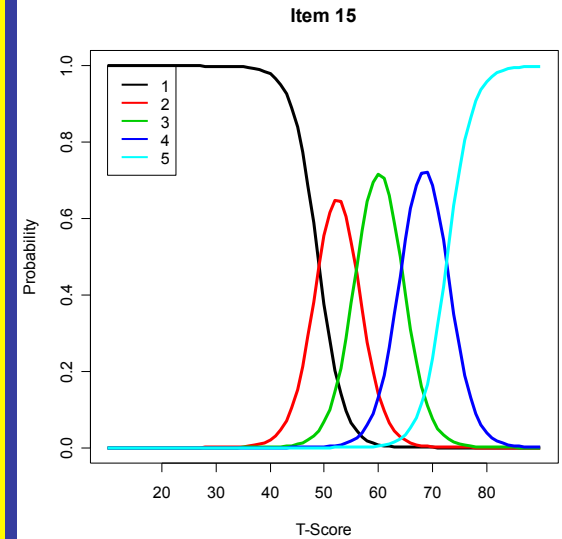
- Select questions based on a person's response to previously administered questions.
- Iteratively estimate a person's standing on a domain (e.g., fatigue, depressive symptoms)
- Administer most informative items
- Desired level of precision can be obtained using the minimal possible number of questions.

Beginning of CAT

T-Score = **50**

SE = **10**

Best Item—I felt depressed



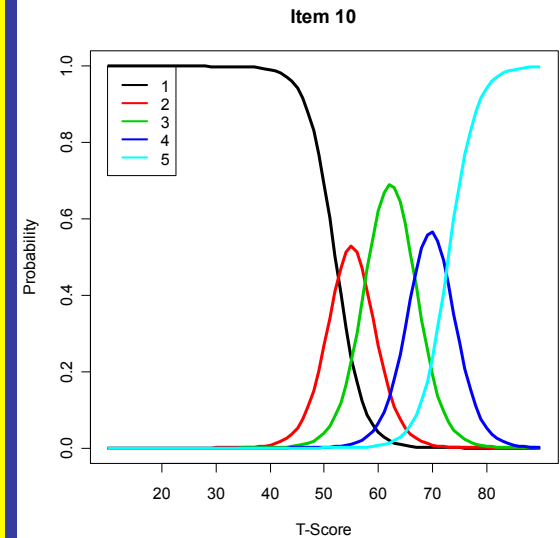
I felt depressed

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

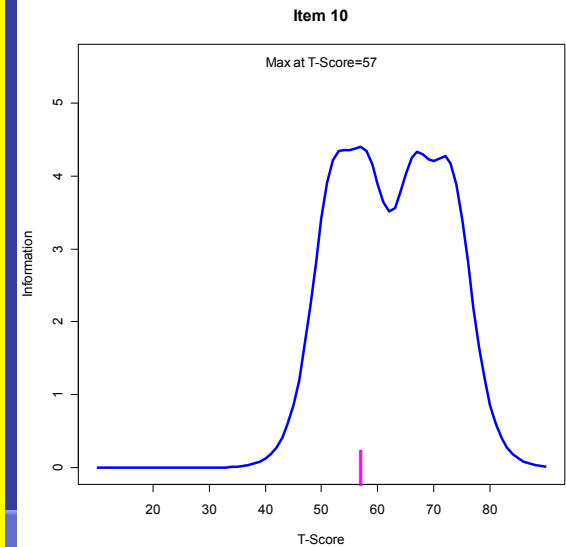
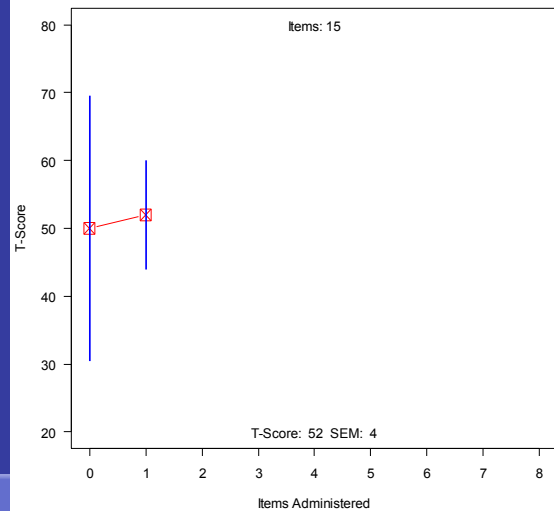
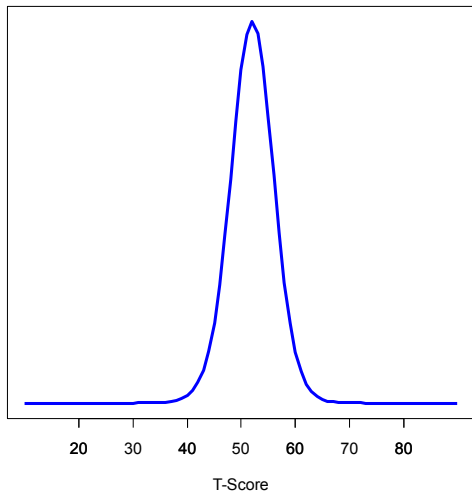
T-Score = **52**

SE = **4**

Next Best Item—I felt like a failure



Posterior Distribution



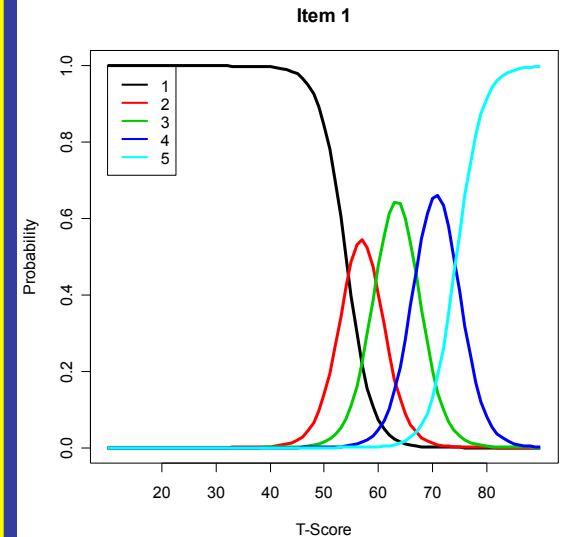
I felt like a failure

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

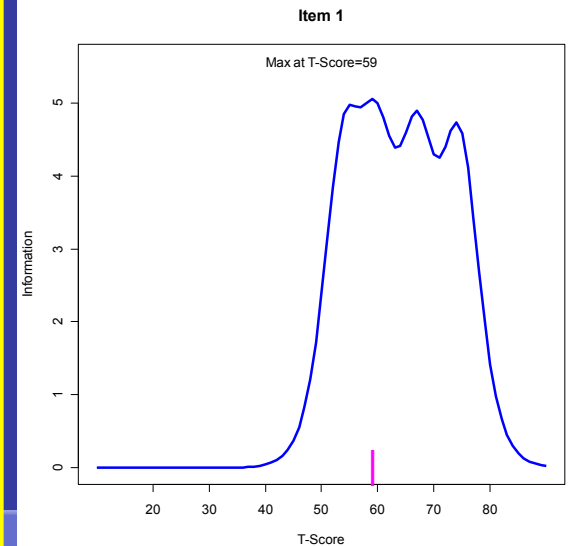
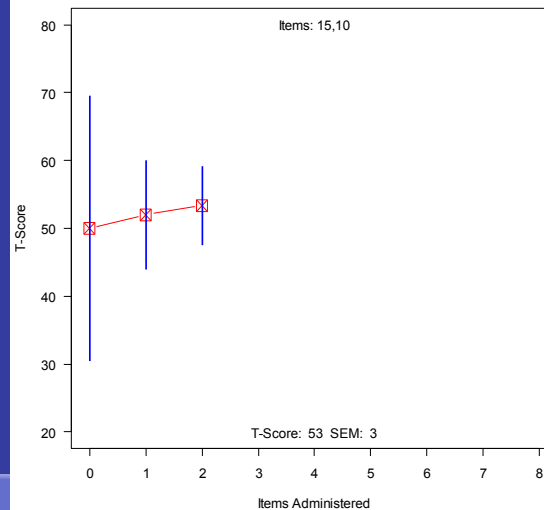
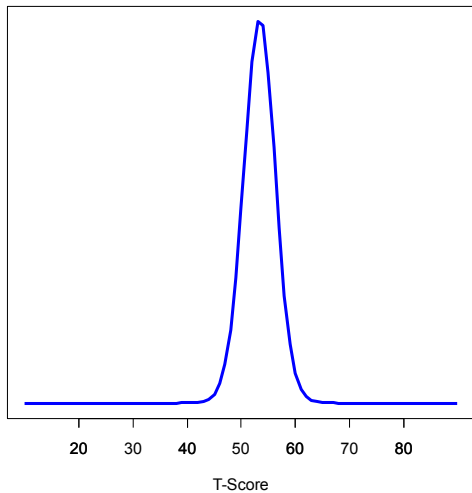
T-Score = **53**

SE = **3**

Next Best Item—I felt worthless



Posterior Distribution



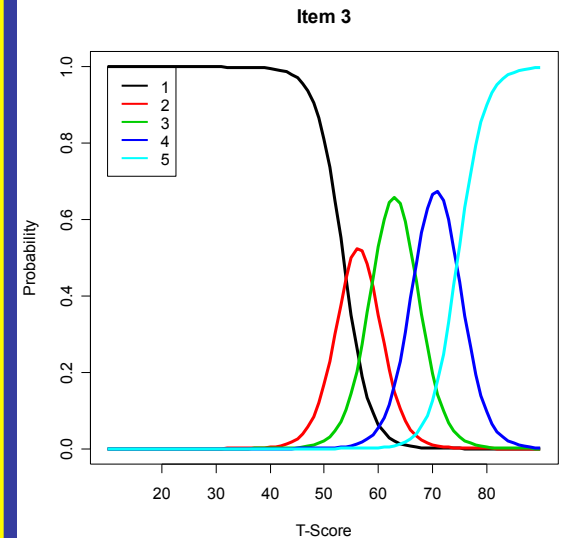
I felt worthless

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

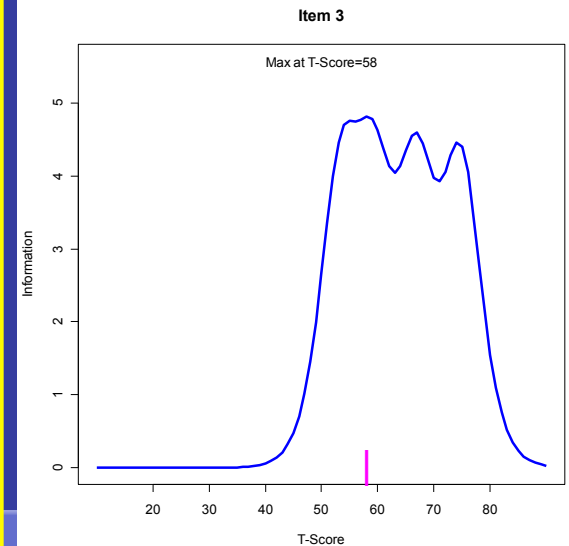
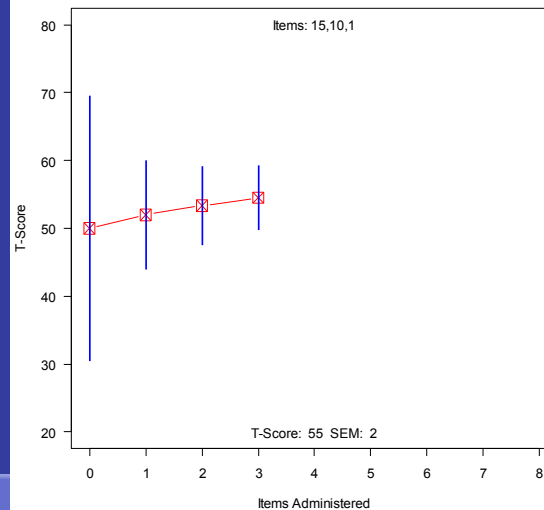
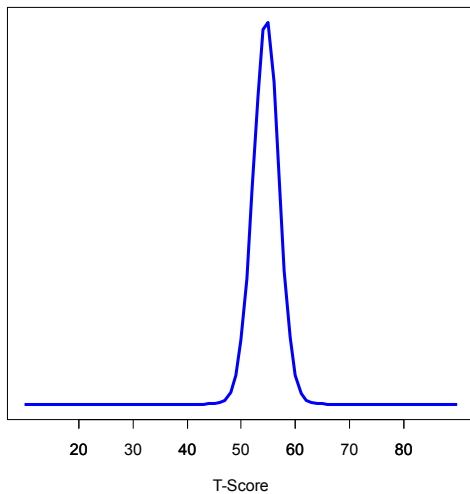
T-Score = **55**

SE = **2**

Next Best Item—I felt helpless



Posterior Distribution

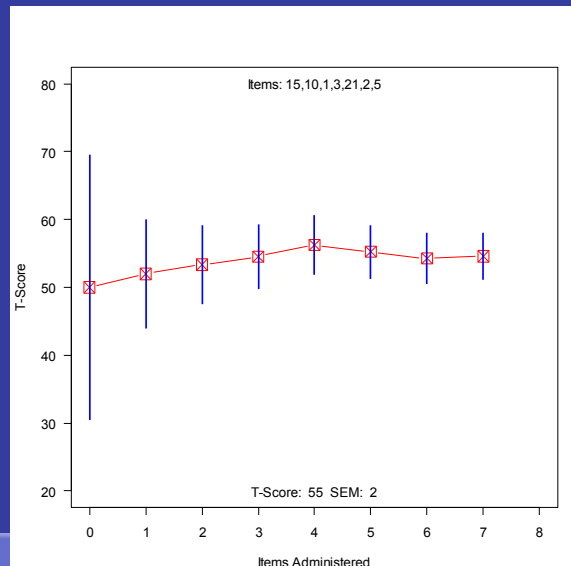
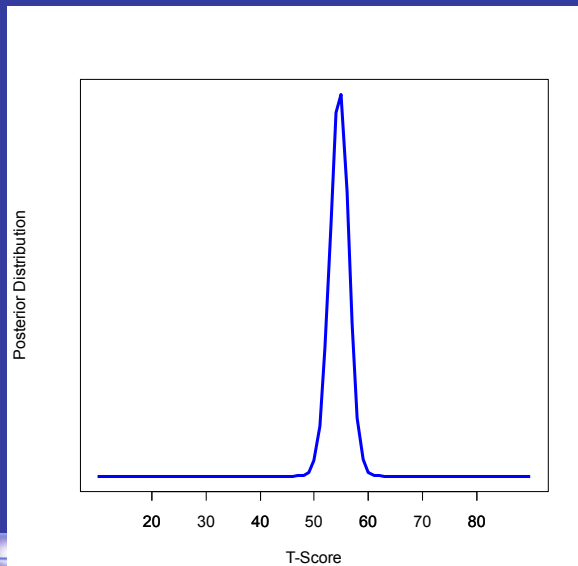


I felt helpless

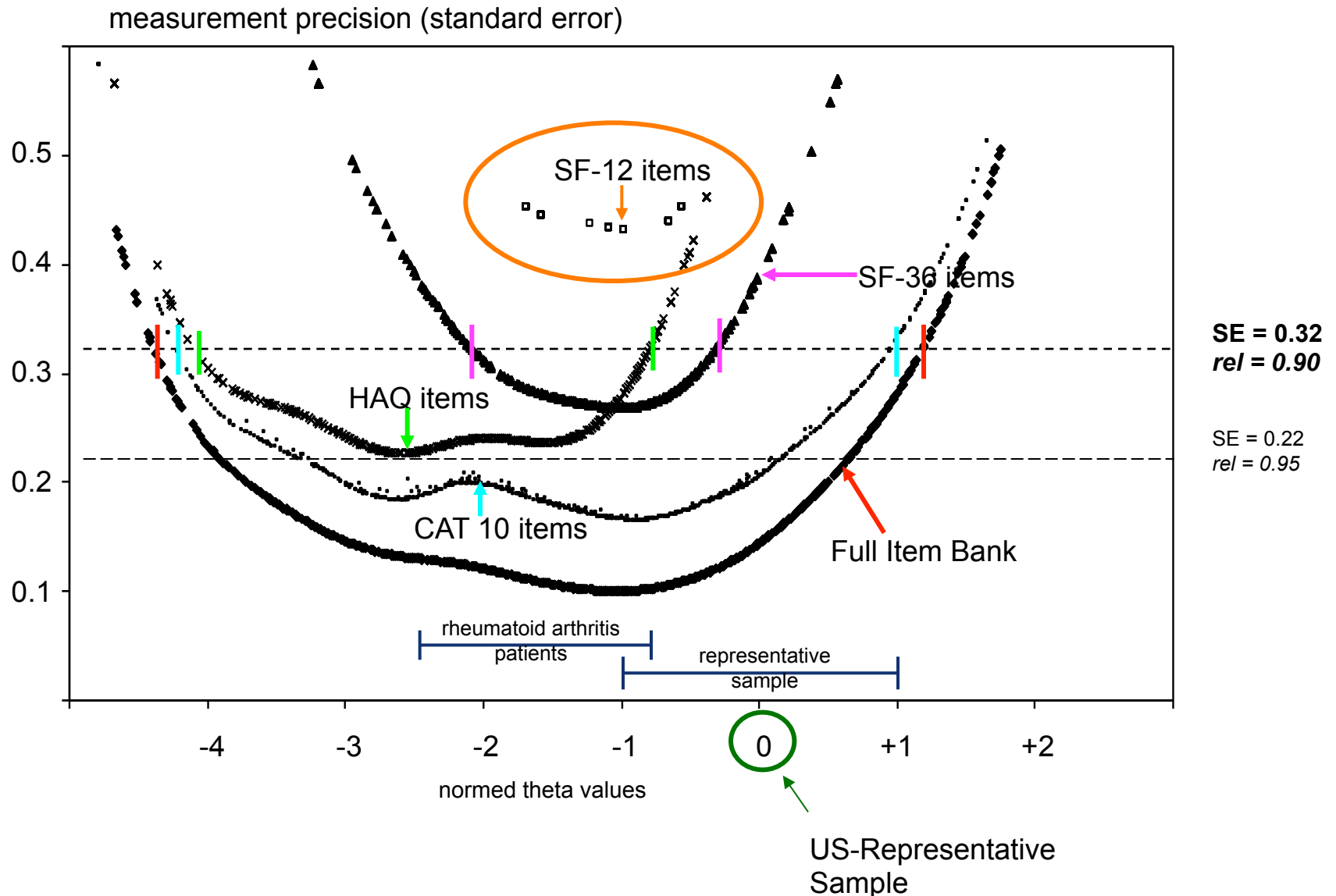
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = **55**

SE = **2**



CAT assessments can achieve higher precision than fixed forms



PROMIS Domain Framework

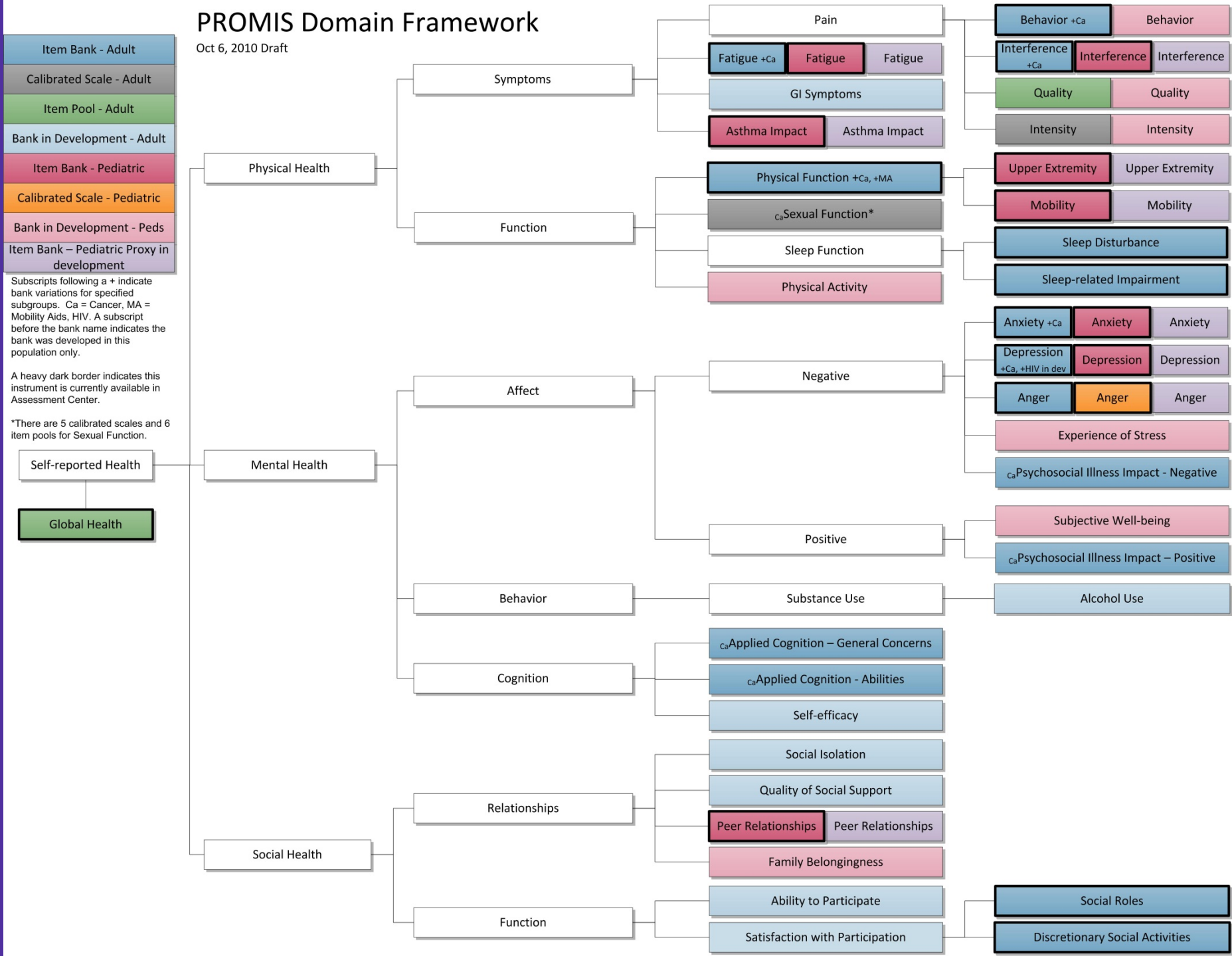
Oct 6, 2010 Draft

Item Bank - Adult
Calibrated Scale - Adult
Item Pool - Adult
Bank in Development - Adult
Item Bank - Pediatric
Calibrated Scale - Pediatric
Bank in Development - Peds
Item Bank – Pediatric Proxy in development

Subscripts following a + indicate bank variations for specified subgroups. Ca = Cancer, MA = Mobility Aids, HIV. A subscript before the bank name indicates the bank was developed in this population only.

A heavy dark border indicates this instrument is currently available in Assessment Center.

*There are 5 calibrated scales and 6 item pools for Sexual Function.



PROMIS Domains in AC, 2010

Domains	# Items Adult Bank	# Items Adult Short Forms	# Items Peds Bank	# Items Peds Short Form
Emotional Distress – Anger	29	8		6
Emotional Distress – Anxiety	29	4, 6, 7, 8	15	8
Emotional Distress – Depression	28	4, 6, 8a, 8b	14	8
Fatigue	95	4, 6, 7, 8	23	10
Pain – Behavior	39	7		
Pain – Interference	41	4, 6a, 6b, 8	13	8
Physical Function	124	4, 6, 8, 10, 20		
-- Mobility			23	8
-- Upper Extremity			29	8
Asthma Impact			17	8

PROMIS Domains in AC, 2010

Domains	# Items Adult Bank	# Items Adult Short Forms	# Items Peds Bank	# Items Peds Short Forms
Satisfaction with Discretionary Social Activities	12	7		
Satisfaction with Social Roles	14	4, 6, 7, 8		
Peer Relationships			15	8
Sleep Disturbance	27	4, 6, 8a, 8b		
Sleep-Related Impairment	16	8		
Global Health		10		

2010 PROMIS Profile Instruments

Domains	PROMIS-29	PROMIS-43	PROMIS-57
Emotional Distress – Anxiety	4	6	8
Emotional Distress – Depression	4	6	8
Fatigue	4	6	8
Pain – Interference	4	6	8
Pain – Intensity	1	1	1
Satisfaction with Social Role	4	6	8
Sleep Disturbance	4	6	8
Physical Function	4	6	8

Thank you



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

This Site



HOME

What is PROMIS?

- Position on Roadmap
- Goals
- Research Objectives
- Network Structure

Network Activities

- Bank Construction
- Network Testing
- Data Analysis

Item Banks and Outcome Tools

- Preliminary Item Banks (2006)
- Version 1.0 Item Banks
- Assessment Center

Reference Materials

- Publications
- Conference Presentations
- Domain Framework
- Domain Definitions

FAQ's

About the NIH Roadmap

Audiences

- Clinicians

Announcements

Title

PROMIS User Manual

Release of an unpublished version of the PROMIS User Manual for citation Oct 15-March 15, 2009

Please Note: This is an unpublished manual from October 15, 2008 through March 15, 2009, please cite as follows: PROMIS Cooperative Group. Unpublished Manual for the Patient-Reported Outcomes Measurement Information System (PROMIS) Version 1.1. October, 2008: www.nihpromis.org

After March 15, 2009, please refer to www.nihpromis.org for proper citation(s)

Summary of PROMIS Wave II Protocols

Click Here to view the Summary of the PROMIS Wave 2 protocols

FDA on PROMIS

"FDA joins NIH in the goal of ensuring that PROMIS results in meaningful measurement of the impact of medical product treatment."

Laurie Burke, MPH, RPh

Director, Study Endpoint and Label Development

Center for Drug Evaluation and research

U.S. Food and Drug Administration

Assessment Center Training Workshops

The PROMIS Statistical Coordinating Center will be offering the following Assessment Center Training Workshops:

*** Monday, December 15, 2008 (Chicago, IL)**

8:00 AM-5:00 PM at the MicroTek computer training facility
at 230 W. Monroe, Suite 550 in downtown Chicago.

ASSESSMENT CENTER

Body

View Richard Gershon's "Introduction to PROMIS, Item Response Theory, Computerized Adaptive Testing, and Assessment Center" slide presentation.

Title

Introduction to PROMIS, Item Response Theory, Computerized Adaptive Testing, and Assessment Center Slide Presentation

Assessment Center

ENTER ASSESSMENT CENTER

Whats New

- See Description of Assessment Center Release 3 Capabilities
- Summary of PROMIS Wave 2 Protocols
- Unpublished version of the PROMIS User manual
- Sleep/Wake Function: domain definitions for sleep disturbances and wake disturbances
- Calibration Analysis Summary for Sleep-Wake Disturbance and Pain Impact

What's Coming Soon...

Title

Assessment Center Release 3 expected 12.01.2008

Links

www.nihpromis.org

