




Development of PROMIS Item Banks

Jin-Shei Lai, PhD, OTR/L



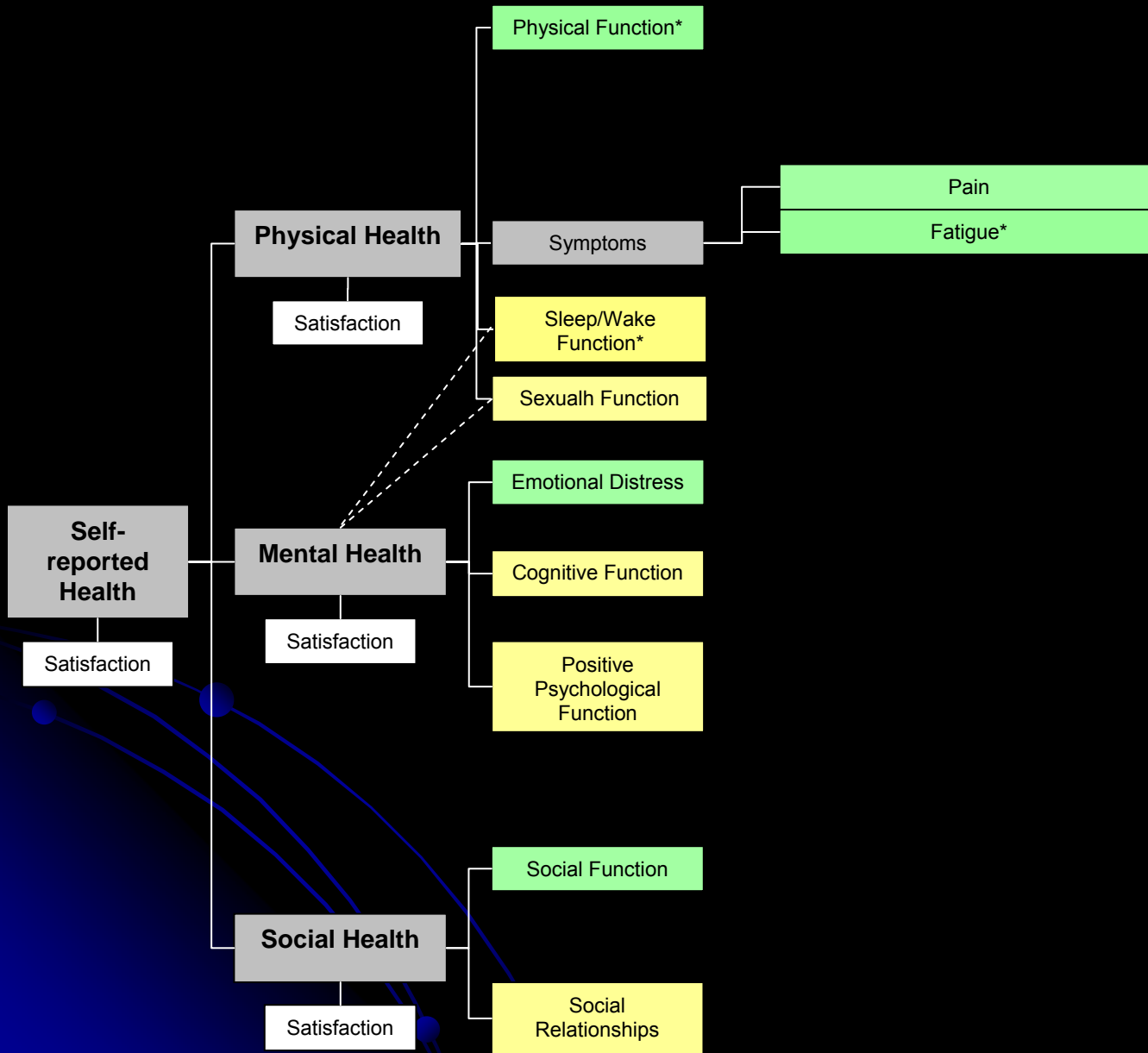
PROMIS Patient-Reported Outcomes Measurement Information System
Dynamic Tools to Measure Health Outcomes From the Patient Perspective



The Life Story of a PROMIS Item

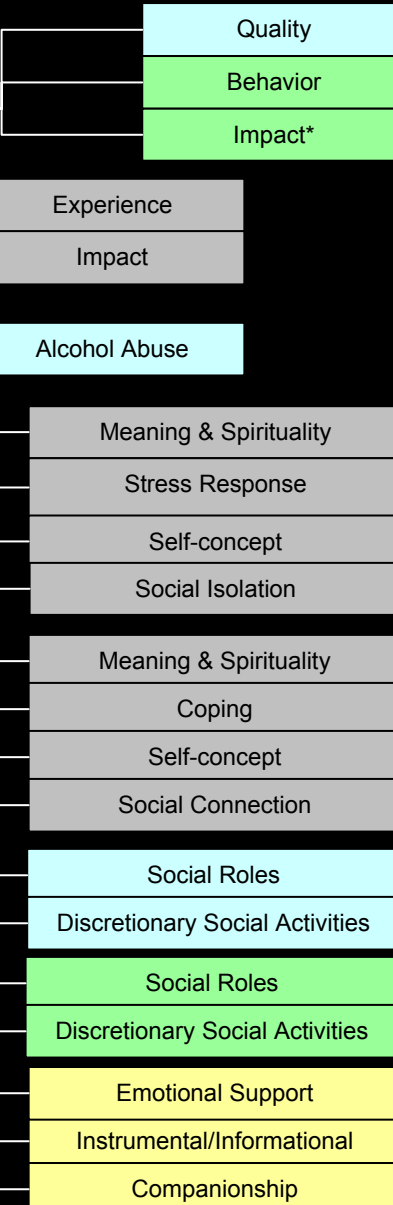
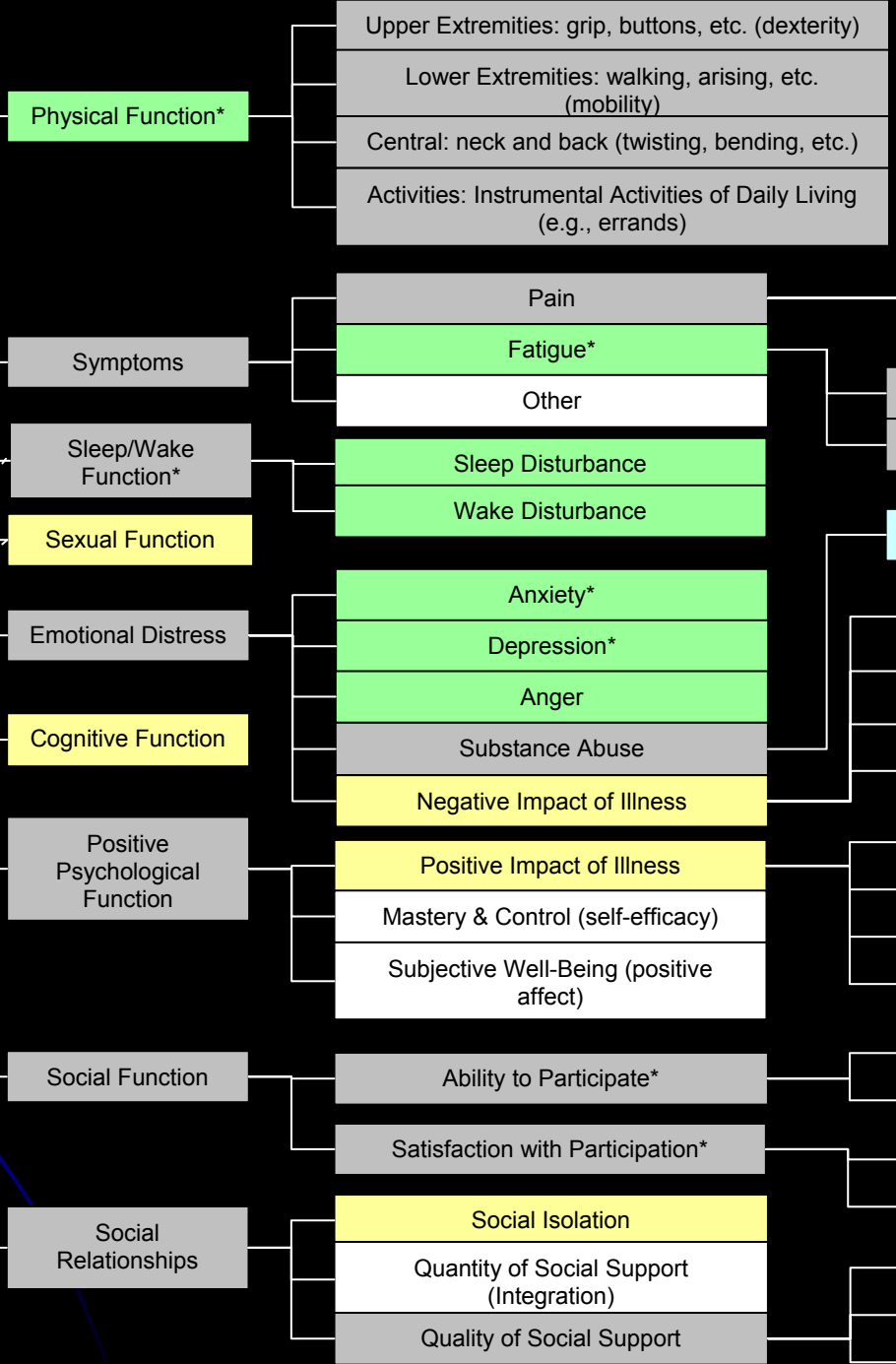
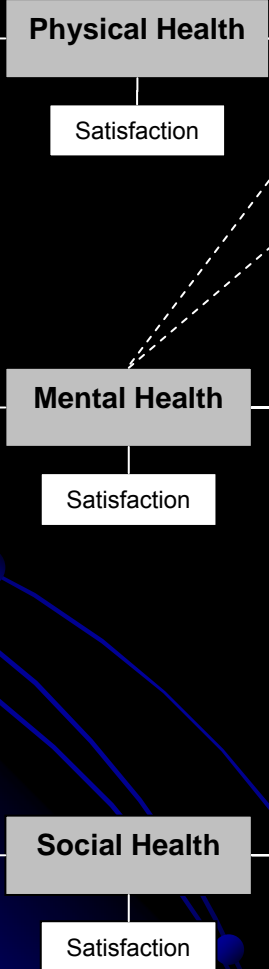
**Domain
Framework**



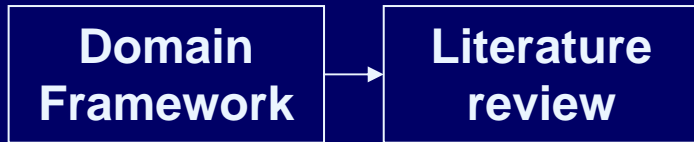


PROMIS v1.0 bank
CaPS bank in development
PROMIS area tested but no bank developed for v1.0
Area addressed (in part) by bank within lineage
Area not addressed yet

* = Cancer-specific version of PROMIS bank



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- Modified Delphi approach to identify PRO domains
- Review of extant items (e.g., MEDLINE, PROQOLID)
- Over 7500 items identified

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- Preliminary evaluation of existing items in core PROMIS domains
- 15 large datasets with PROs
- Classical and IRT analyses
- Results presented to domain working groups
- Goals:
 - Better understand dimensional structure of items from a domain
 - Inform item revision process, identify of most useful response sets, guide new item writing

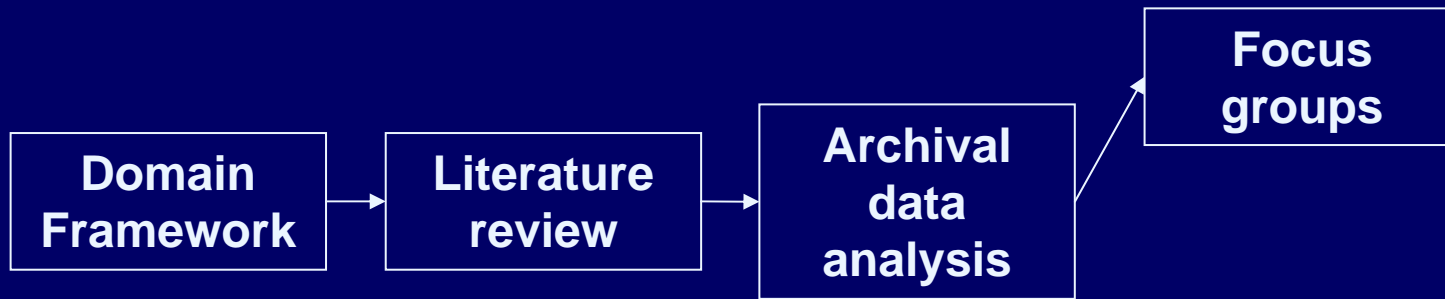
Fatigue Archival Data Analysis

Dataset	# of fatigue related items	Analyzed?
CHC (UBC Fatigue)	13	Yes
NWU/CORE Cancer Fatigue	72	Yes
WHOQOL	4	No
CHS	2	No
NGHS	0	No
DIG	0	No
CSSCD	0	No

Take Home Messages

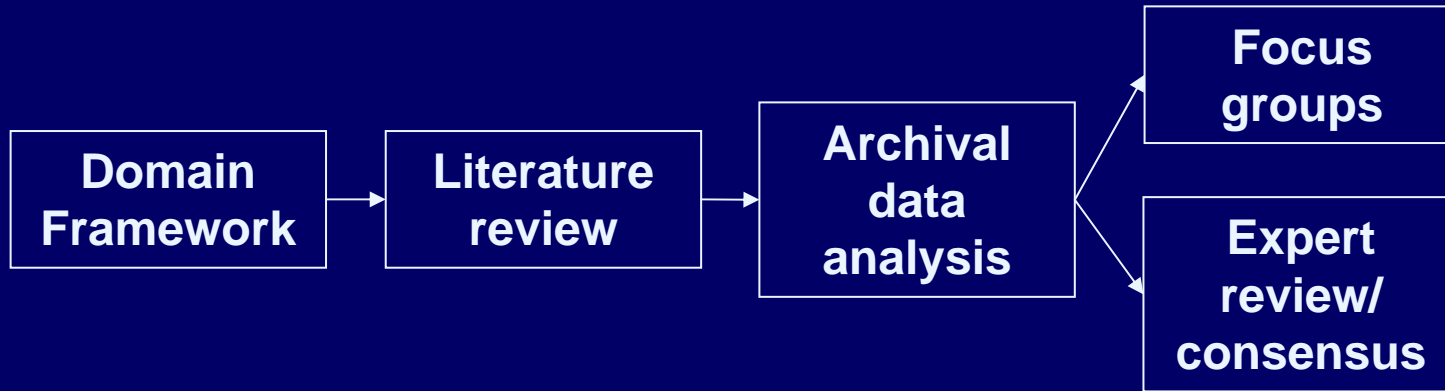
- *Items included in both CHC and Cancer Fatigue demonstrated sufficient unidimensionality and could be analyzed using an item response theory model.*
- *Though a seven-point rating scale worked well on a number of CHC items, results suggest that a 5-point (or less) rating scale would be an alternative choice for better measuring fatigue.*
- *Both item pools had good coverage of the fatigue continuum being measured.*

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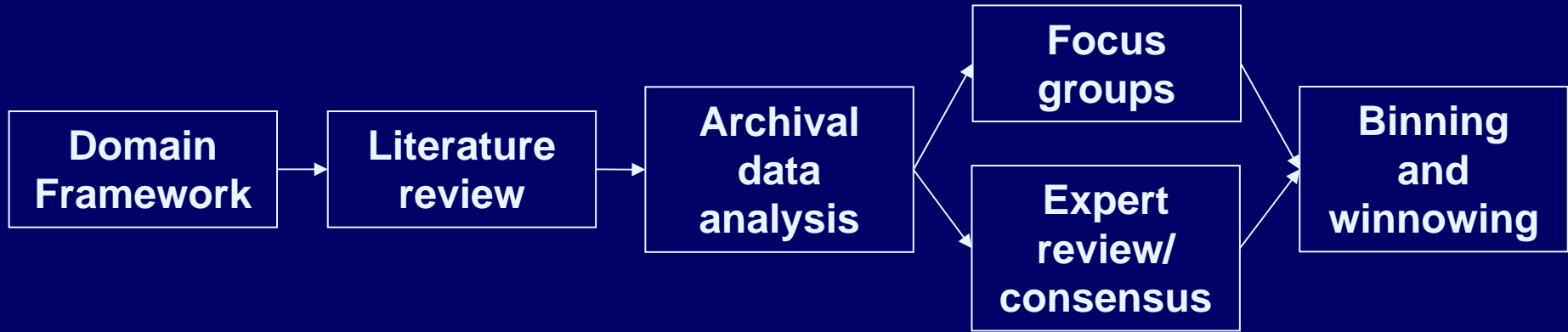
- 27 focus groups across 5 sites
- Multiple chronic illnesses and experiences
- Grouped participants by domain rather than disease (e.g., those who have experienced fatigue)
- Findings
 - Confirmation of selected domain importance
 - Confirmation of language describing domains
 - Elucidation of important areas of each domain for future banks

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- Address domain confirmation, consistency, response sets/time frames, ecological validity, clinical trial needs
- Developed PROMIS conventions to guide item development process
 - Time frame
 - Context statement
 - Response options

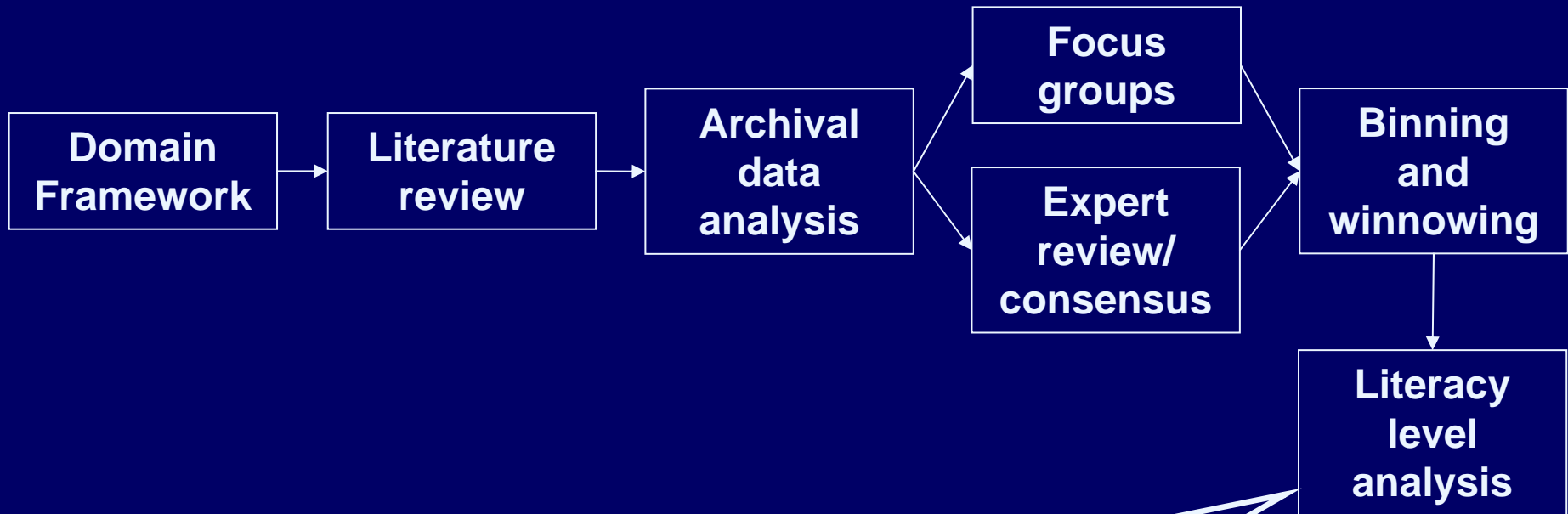
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Binning and Winnowing

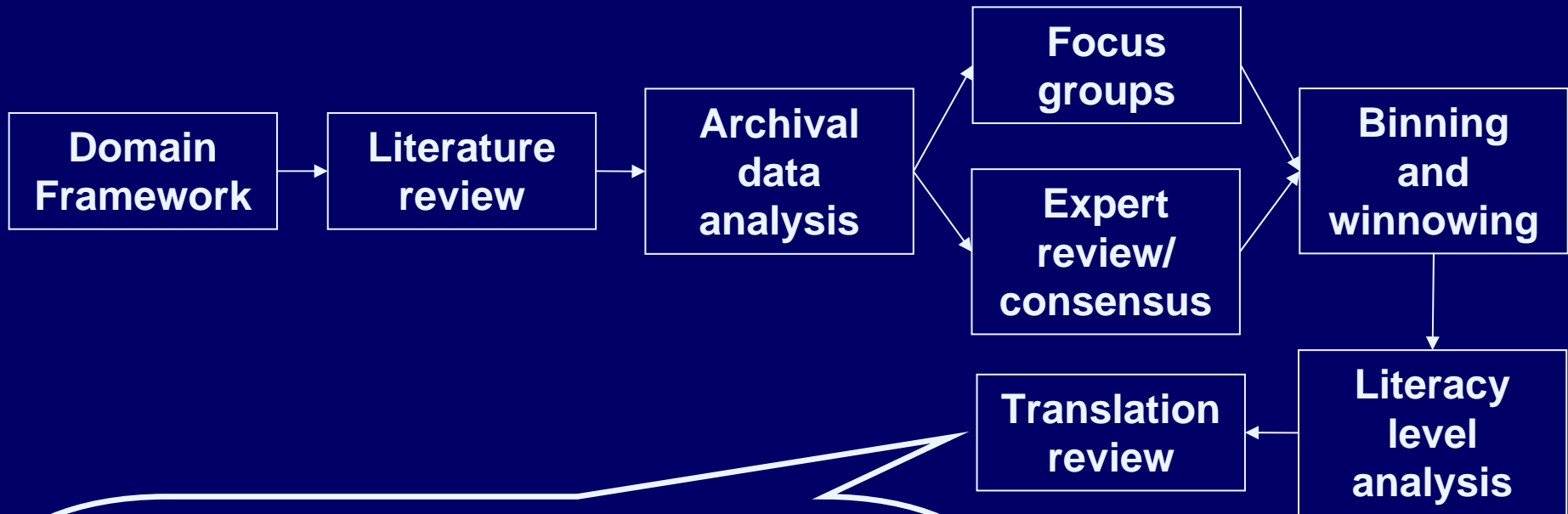
- Binning = systematic grouping items according to meaning and latent content
 - Goal to aid in identifying redundancy
 - Top-down approach to bin creation (with flexibility)
- Winnowing = reduce item pool to representative set of items
 - Consensus process of 2 or 3 experts
 - Eliminate redundancy, items outside of definition (e.g., satisfaction with physical functioning)

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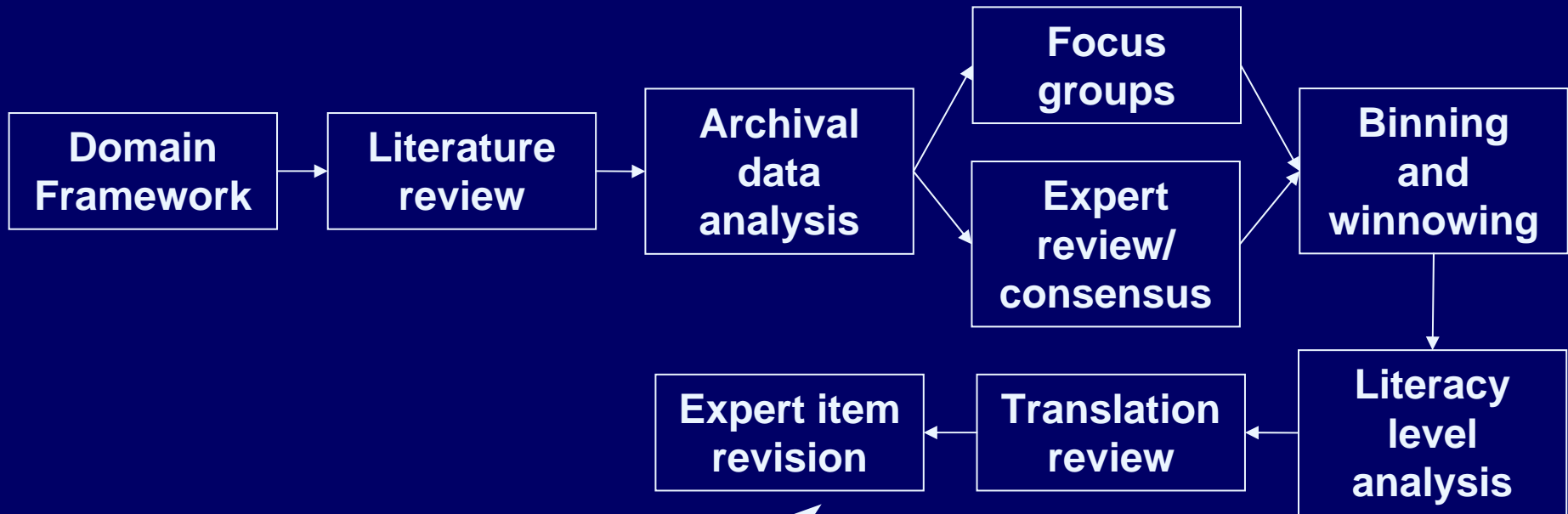
- All surviving items subjected to readability analysis (Lexile score)
- Aim for 6th grade reading level or less

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- Potential cultural issues
- Use of words that don't translate well (e.g., idiomatic expression like "fed up")
- Units of measure (e.g., "10 lb weight")
- Verb tenses that don't exist in other languages (e.g., gerunds, present perfect)

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- **Prototype items resulted from binning and winnowing process**
- **Rewrote each item with PROMIS conventions or created new item**
- **Simplified language when possible (to reduce literacy demands)**
- **Integrated input from translation specialists**
- **Item needed to stand alone on a screen**

Revision Example--Fatigue

Original	How much of the time during the past 4 weeks	Did you feel worn out?	1 = All of the time 2 = Most of the time 3 = Some of the time 4 = A little of the time 5 = None of the time
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Revised	In the past 7 days	How often did you feel worn out?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always
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Revision Example--ED

Original

How much of the time,
during the past month,
did you react slowly to
things that were said or
done

1 = All of the time
2 = Most of the time
3 = A good bit of the time
4 = Some of the time
5 = A little of the time
6 = None of the time

Revised

In the past 7
days

I reacted slowly to things
that were said or done

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

Revision Example--PF

Original

How much are you limited because of your health to climbing several flights of stairs

1 = Yes, limited a lot

2 = Yes, limited a little

3 = No, not limited at all

Revised

Are you able to climb several flights of stairs?

5 = Without difficulty

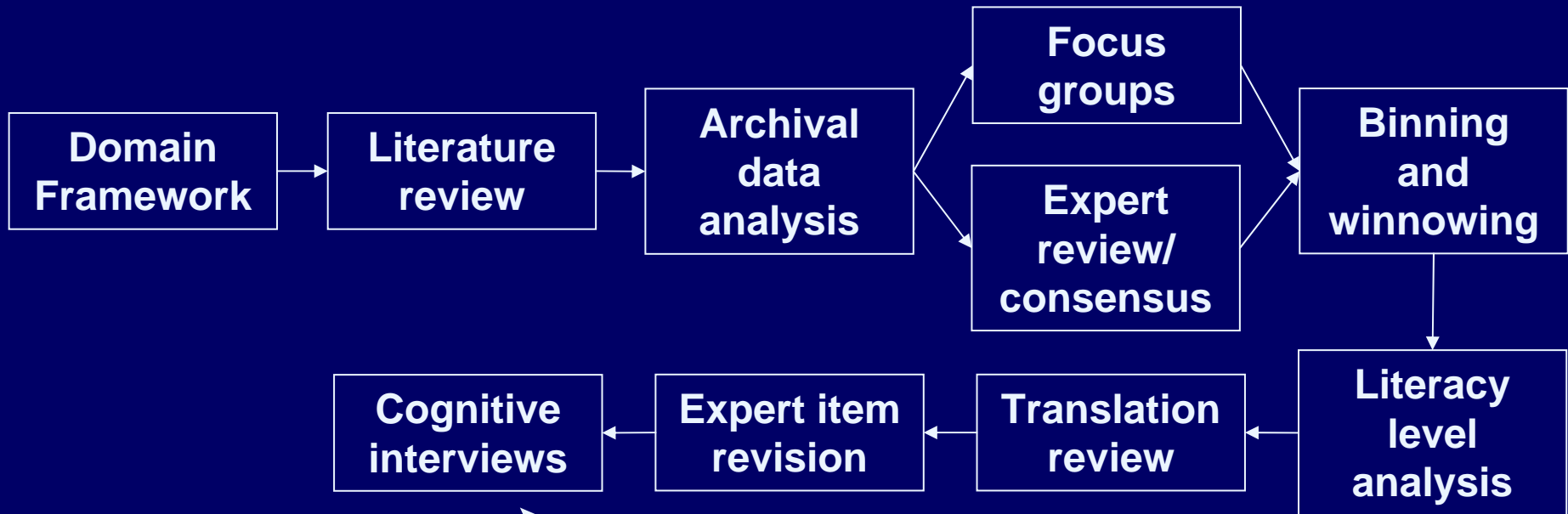
4 = With a little difficulty

3 = With some difficulty

2 = With much difficulty

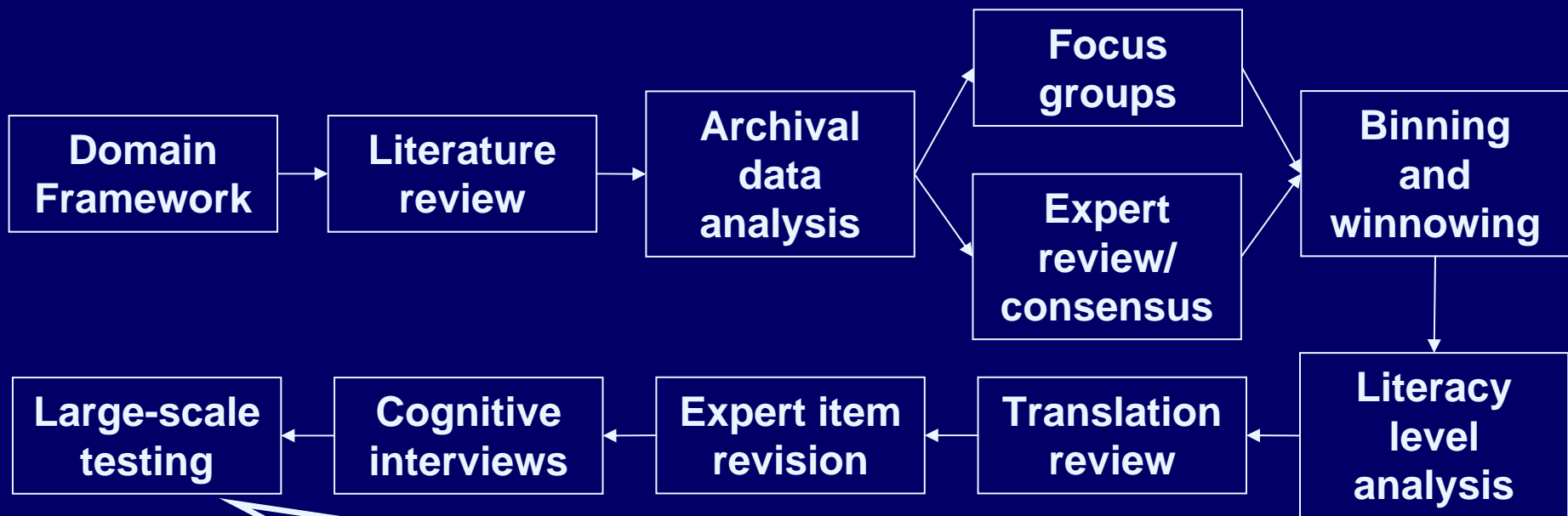
1 = Unable to do

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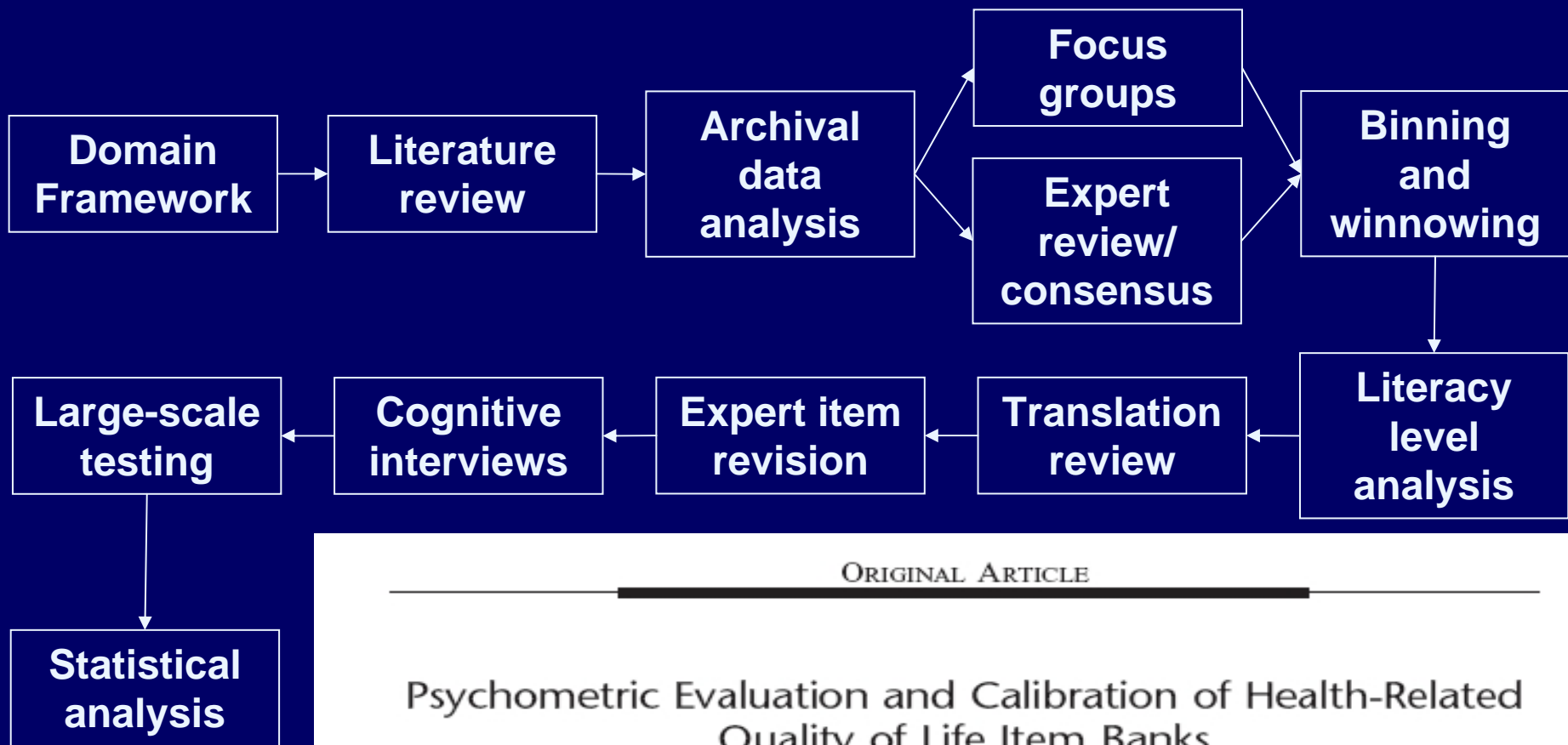
- Started with 777 items
- Performed 141 interviews across PROMIS
 - Evaluation of individual items
- Substantially modified 152 items
 - Feedback on language, understandability, ambiguity
- Deleted 53 items
 - Usefulness of response sets
 - Consistency of interpretation
 - Examine ecological validity

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- **July 2006 to March 2007 data collection**
- **N=21,133 (Online panel and clinic recruitment)**
 - **Heart disease (n = 1,156), cancer (n = 1,754), rheumatoid arthritis (n = 557), osteoarthritis (n = 918), psychiatric illness (n = 1,193), chronic obstructive pulmonary disease (n = 1,214), spinal cord injury (n = 531), and other conditions (n = 560)**

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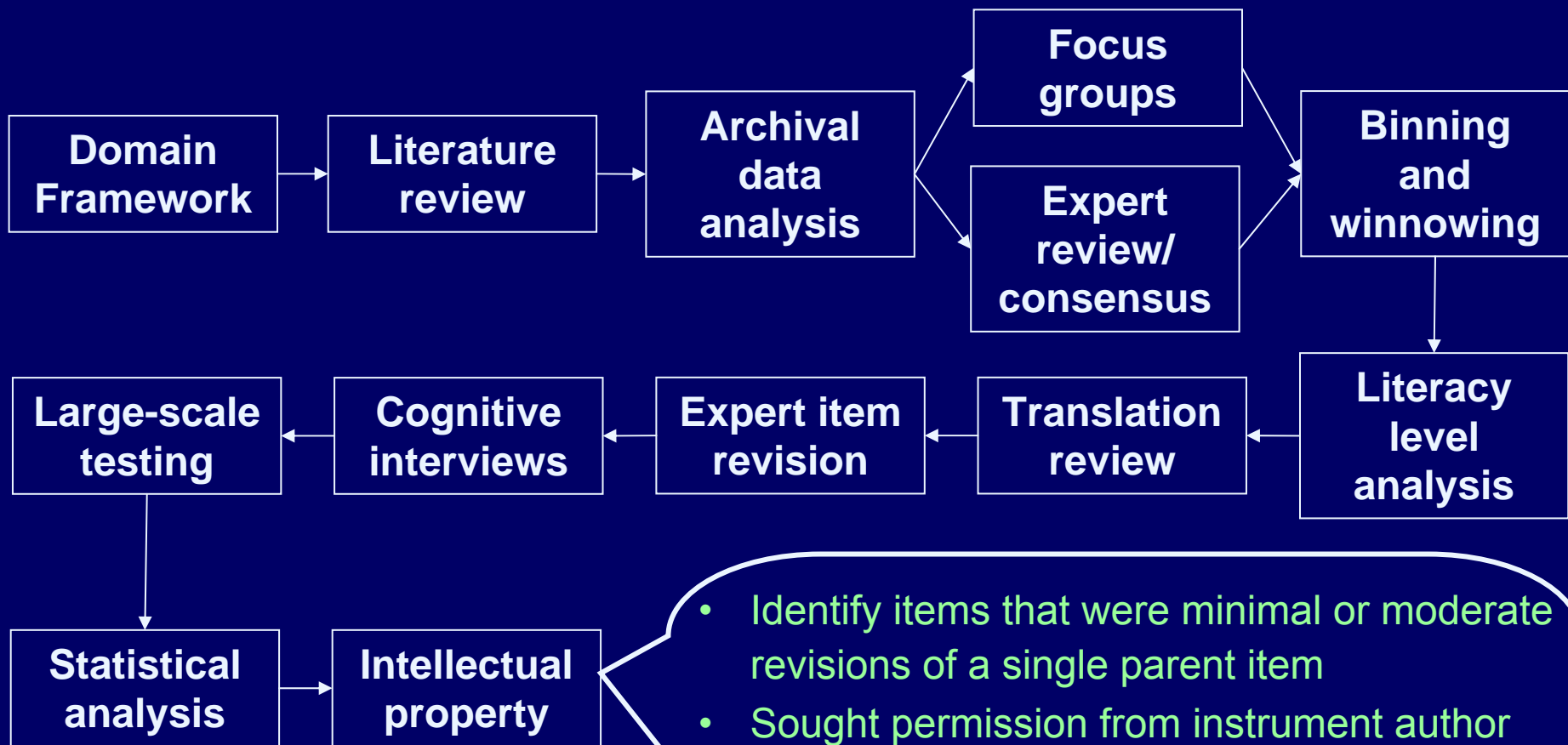


ORIGINAL ARTICLE

Psychometric Evaluation and Calibration of Health-Related
Quality of Life Item Banks
*Plans for the Patient-Reported Outcomes Measurement Information
System (PROMIS)*

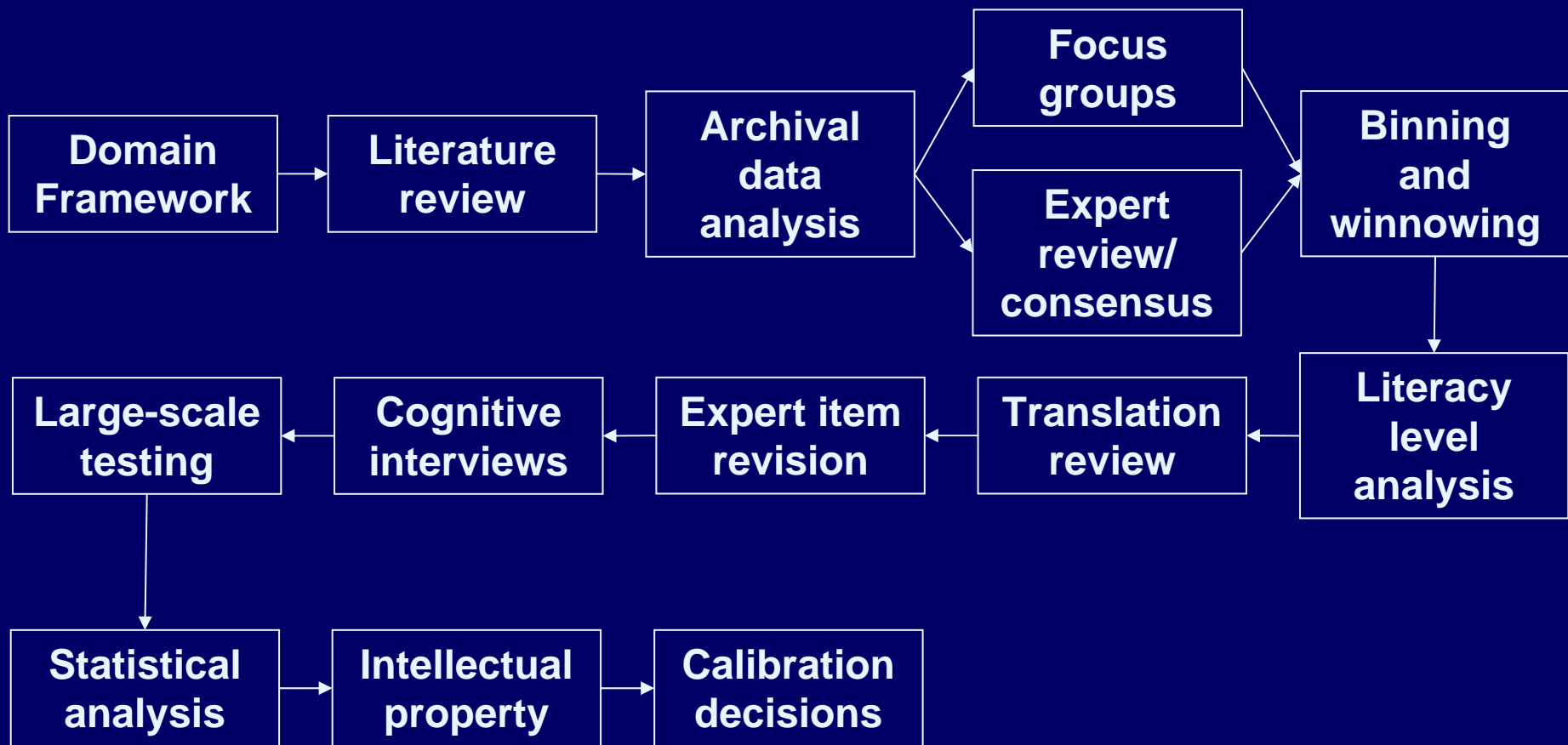
Bryce B. Reeve, Ron D. Hays,† Jakob B. Bjorner,‡ Karon F. Cook,§ Paul K. Crane,||
Jeanne A. Teresi,¶ David Thissen,|| Dennis A. Revicki,** David J. Weiss,†† Ronald K. Hambleton,‡‡
Honghu Liu,†† Richard Gershon,§§ Steven P. Reise,†† Jin-shei Lai,§§ and David Cella,§§
on behalf of the PROMIS Cooperative Group*

The Life Story of a PROMIS Item



- Identify items that were minimal or moderate revisions of a single parent item
- Sought permission from instrument author
- Signed agreement from authors for use of derived item in PROMIS
- Terms and Conditions
 - Cannot distribute, translate, or modify
 - Work with PROMIS collaborator

The Life Story of a PROMIS Item



- Identify good performing items and create calibrations
- Identify items with concerns that want to retain but not in bank (e.g., sparse cells)
- Exclude items based on analyses (e.g., misfit, local dependence, DIF)

Tired?



Fatigue Domain Structure

Fatigue

Experience (54 items)

- Core feeling: energy (n=11)
- Core feeling: general fatigue (n=31)
- Core feeling: quality (n=3)
- Impact of fatigue: general functioning (n=3)
- Impact of fatigue: negative emotion (n=3)
- Temporal characteristics (n=3)

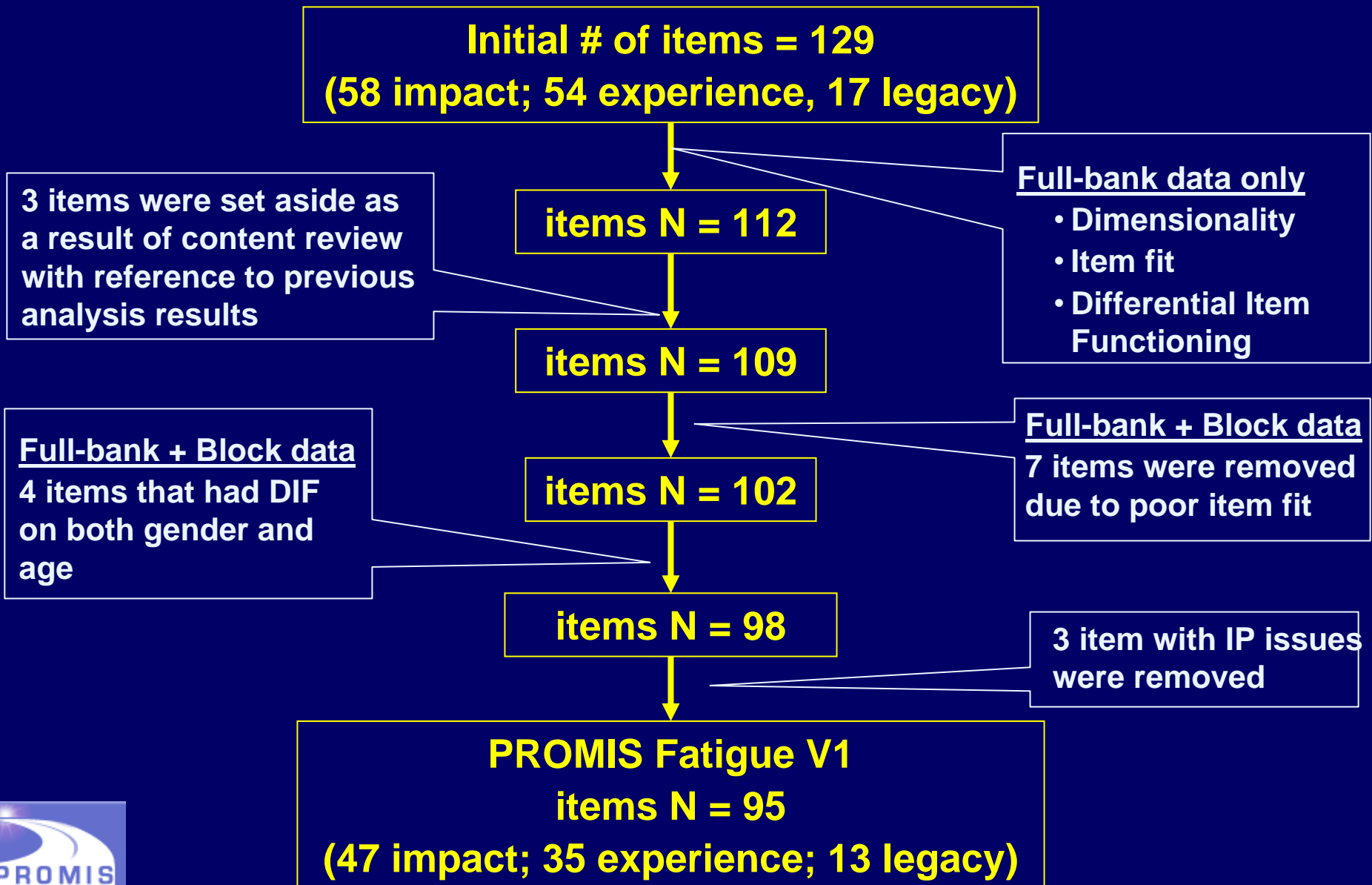
Impact (58 items)

- Core feeling (n=2)
- Impact of fatigue: ADL, occupation, and social function (n=18)
- Impact of fatigue: general functioning (n=12)
- Impact of fatigue: mental process (n=20)
- Impact of fatigue: negative emotion (n=2)
- Not caused, symptoms (n=2)
- Bothered by fatigue (n=2)

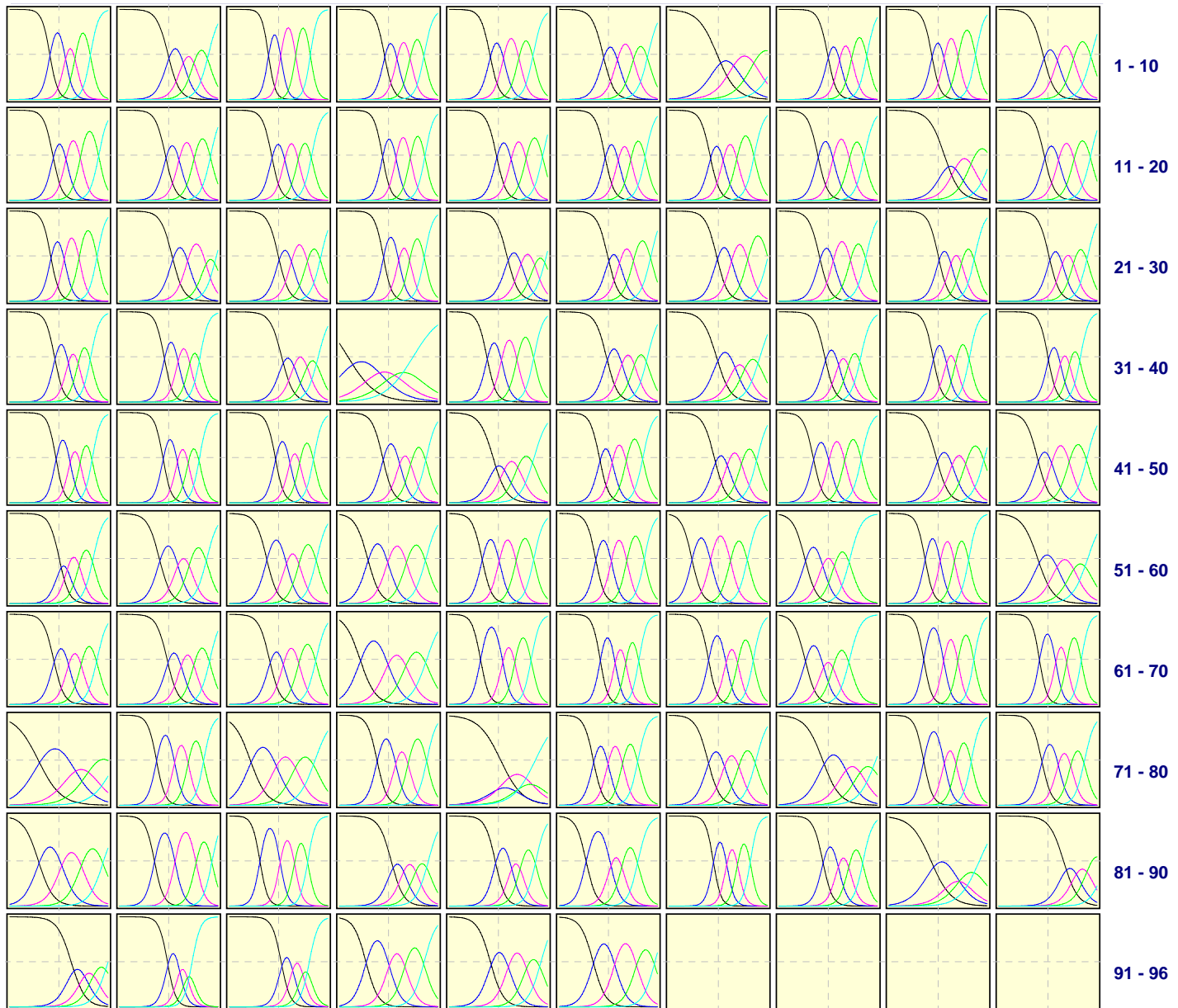
Analysis Overview

- **Descriptive Statistics**
 - (Spearman's $\rho > 0.3$; Item-scale correlation > 0.3)
- **Scalability**
 - Lovinger's H at item and scale levels
- **Local Dependency (LD)**
 - Residual correlation < 0.2
- **Sufficient Unidimensionality**
 - Confirmatory factor analysis
 - Bi-factor model
 - Fit index: S- G2 and S- χ^2
- **Differential Item Functioning**
 - Ordinal logistic regression (gender, age, education)

Evolution of PROMIS Fatigue Item Bank

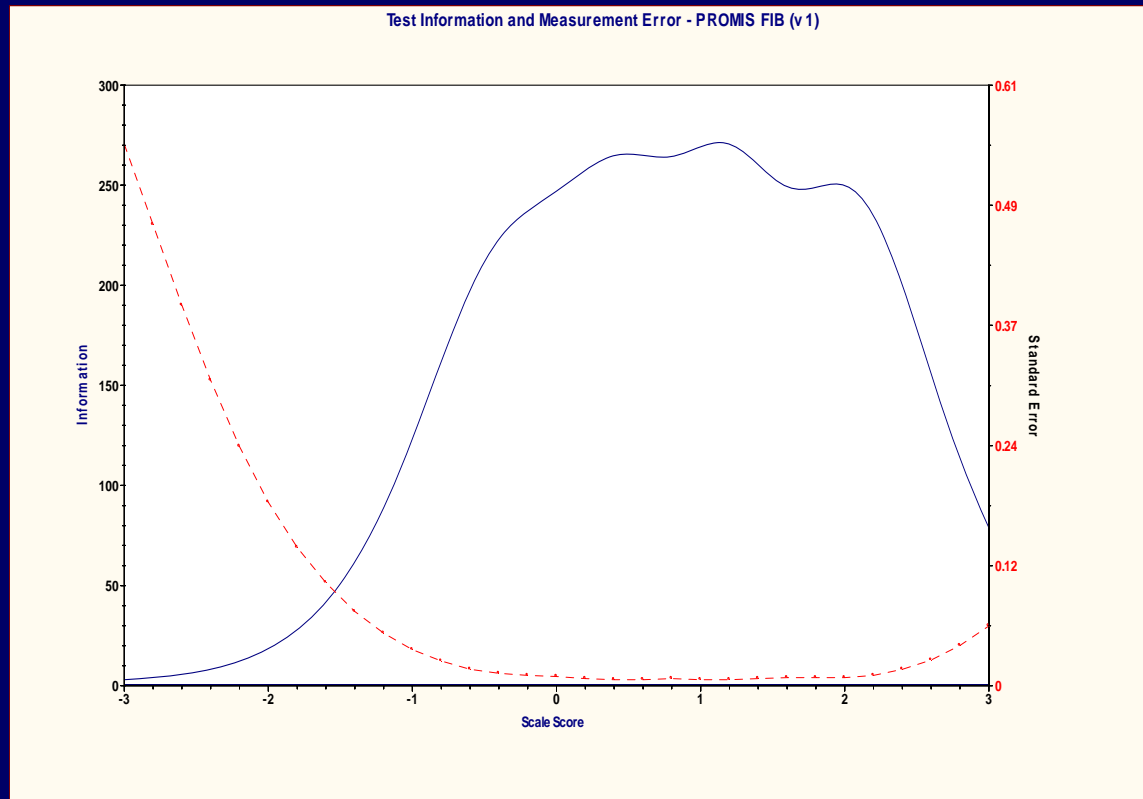


Matrix Plot of Item Characteristic Curves (95 FIB-v1 + 1 Global item)



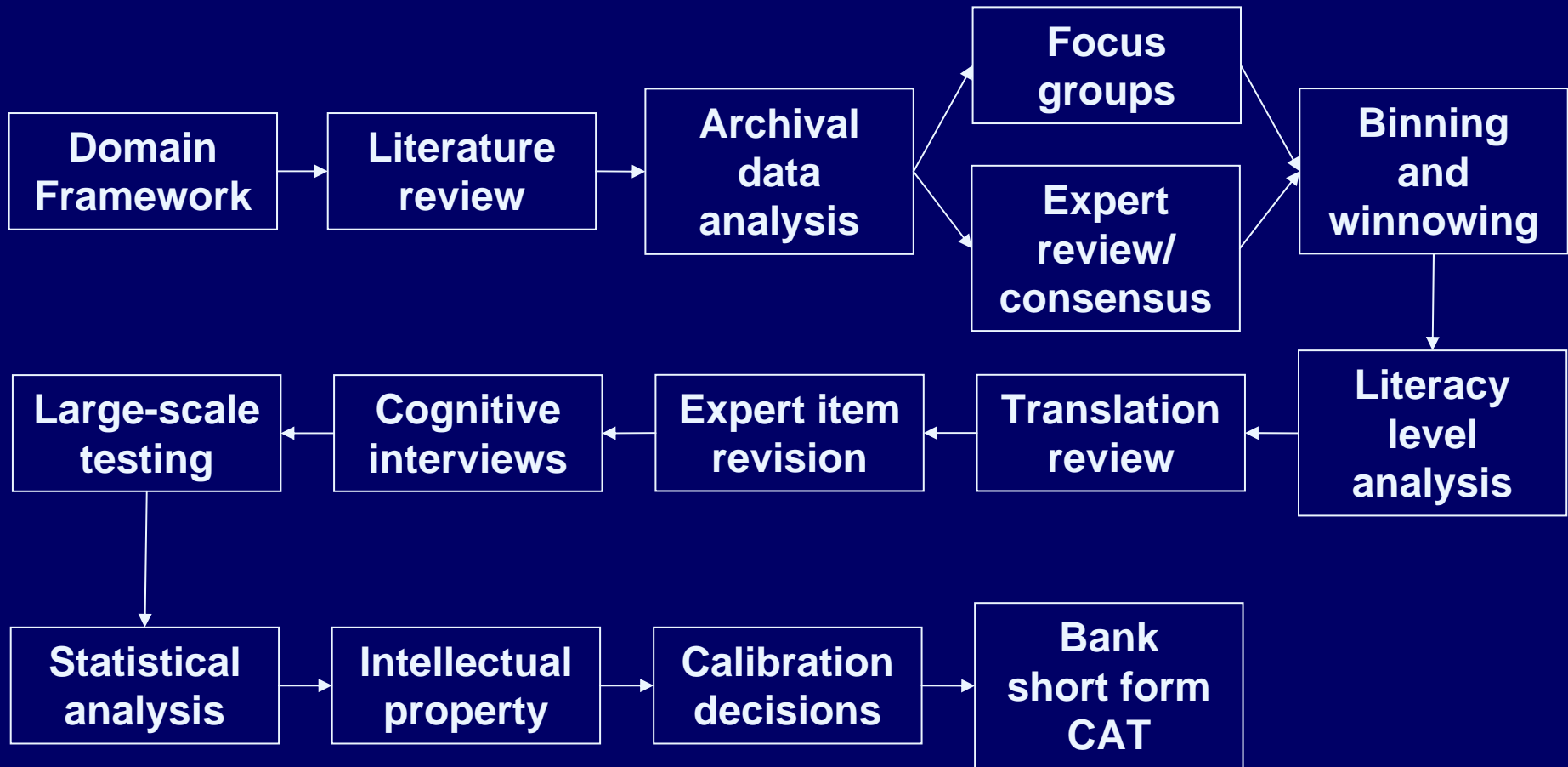
Item Parameter Estimation

- Graded Response Model
- Slope parameter: ranged from 1.199 to 4.896
- Threshold parameters ranged from -2.514 to 3.468.



NOTE: Parameter estimation is centered on a norming sample that matches education and race/ethnicity distributions of the 2000 US census data

The Life Story of a PROMIS Item



PROMIS Fatigue Short-Form

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

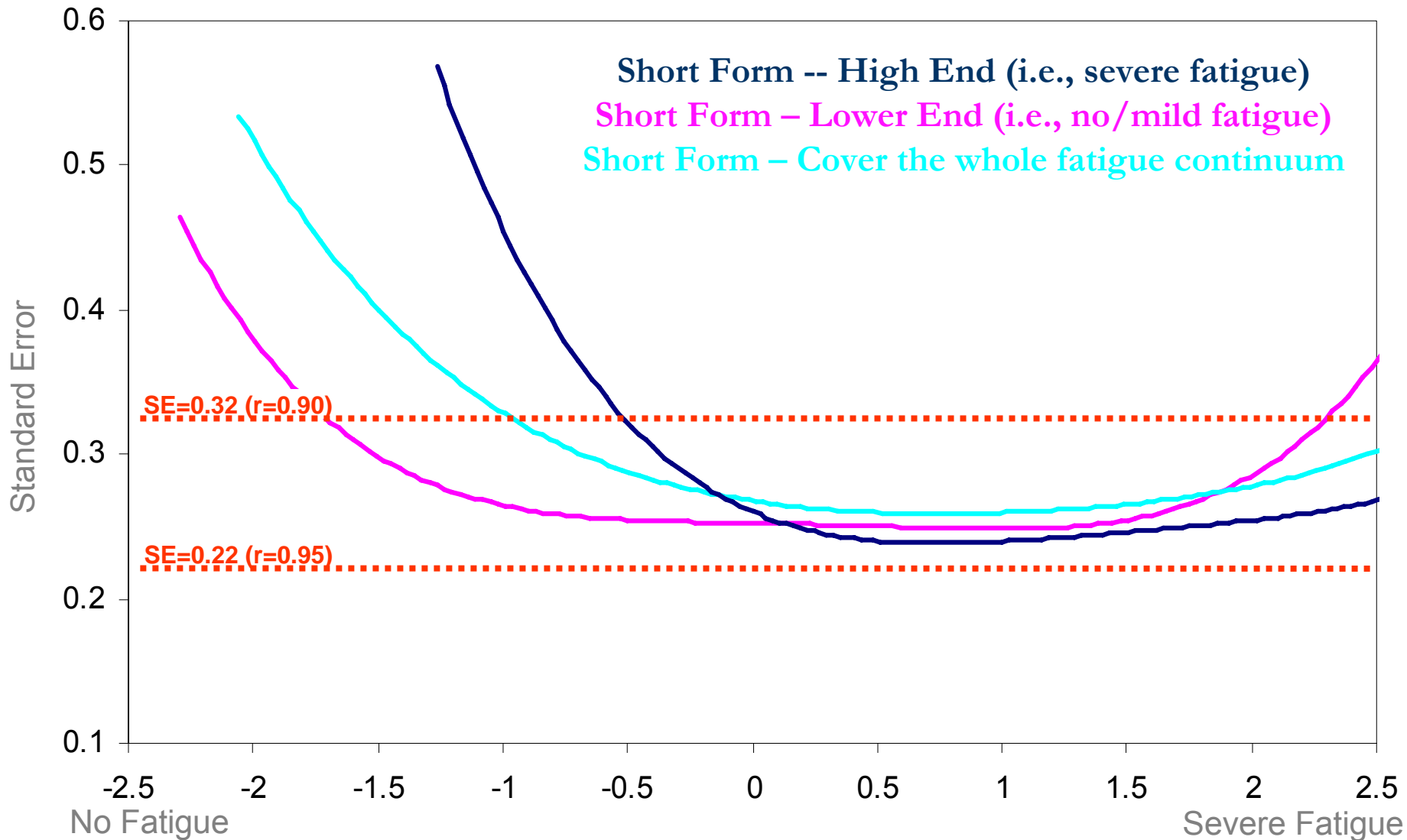


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Precision Comparison: 3 short-forms

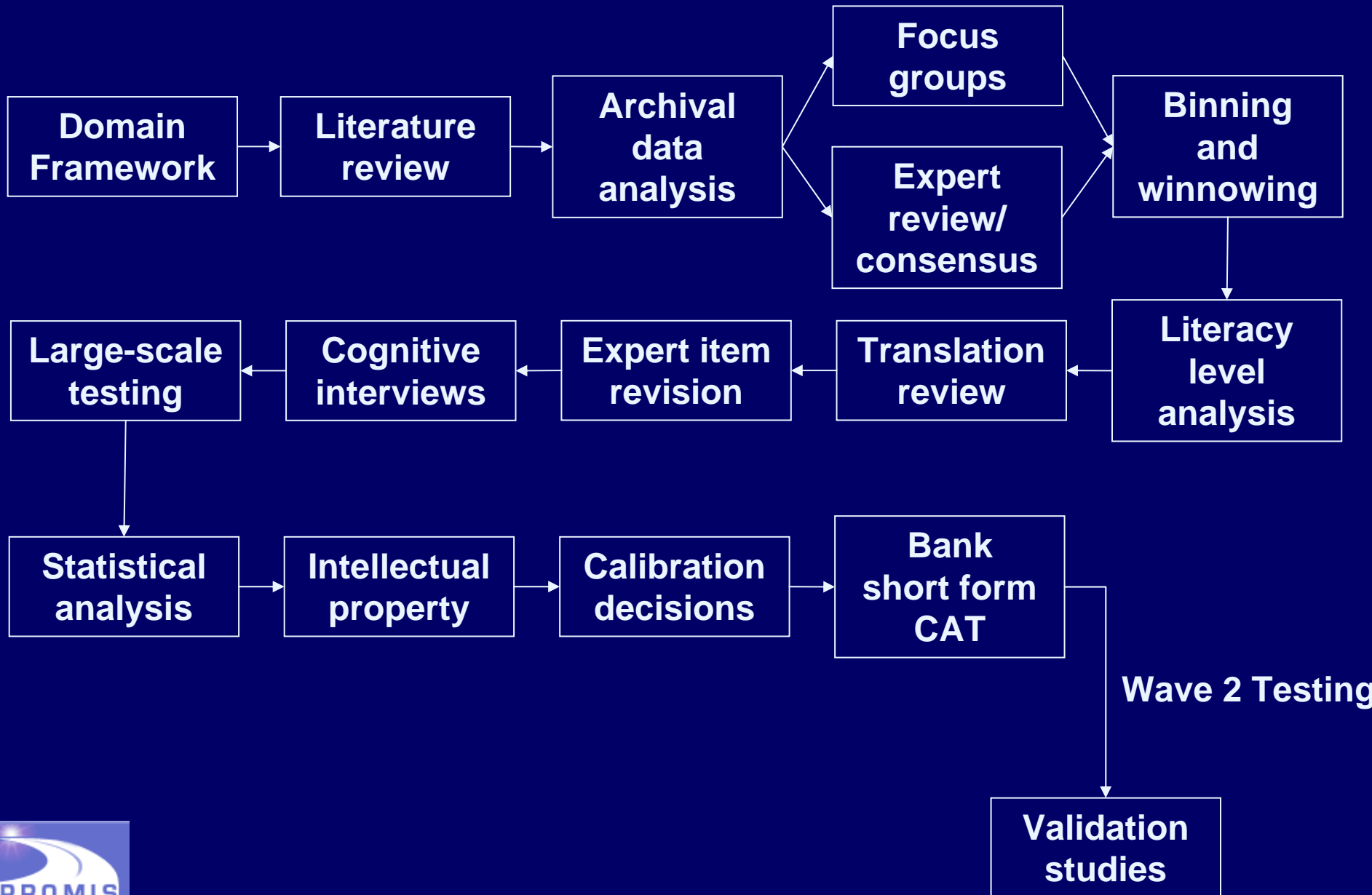


Available PROMIS Measures

<u>Domain</u>	<u>Item Bank # of Items</u>	<u>Short Form # of Items</u>
Emotional Distress – Anger	29	8
Emotional Distress – Anxiety	29	7
Emotional Distress – Depression	28	8
Fatigue	95	7
Pain – Behavior	39	7
Pain – Impact	41	6
Physical Function	125	10
Satisf w/ Discretionary Activities	12	7
Satisf w/ Social Roles	14	7
Sleep Disturbance	27	8
Wake Disturbance	16	8
Global Health	--	10



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