

PROMIS INTERNATIONAL COLLABORATIONS

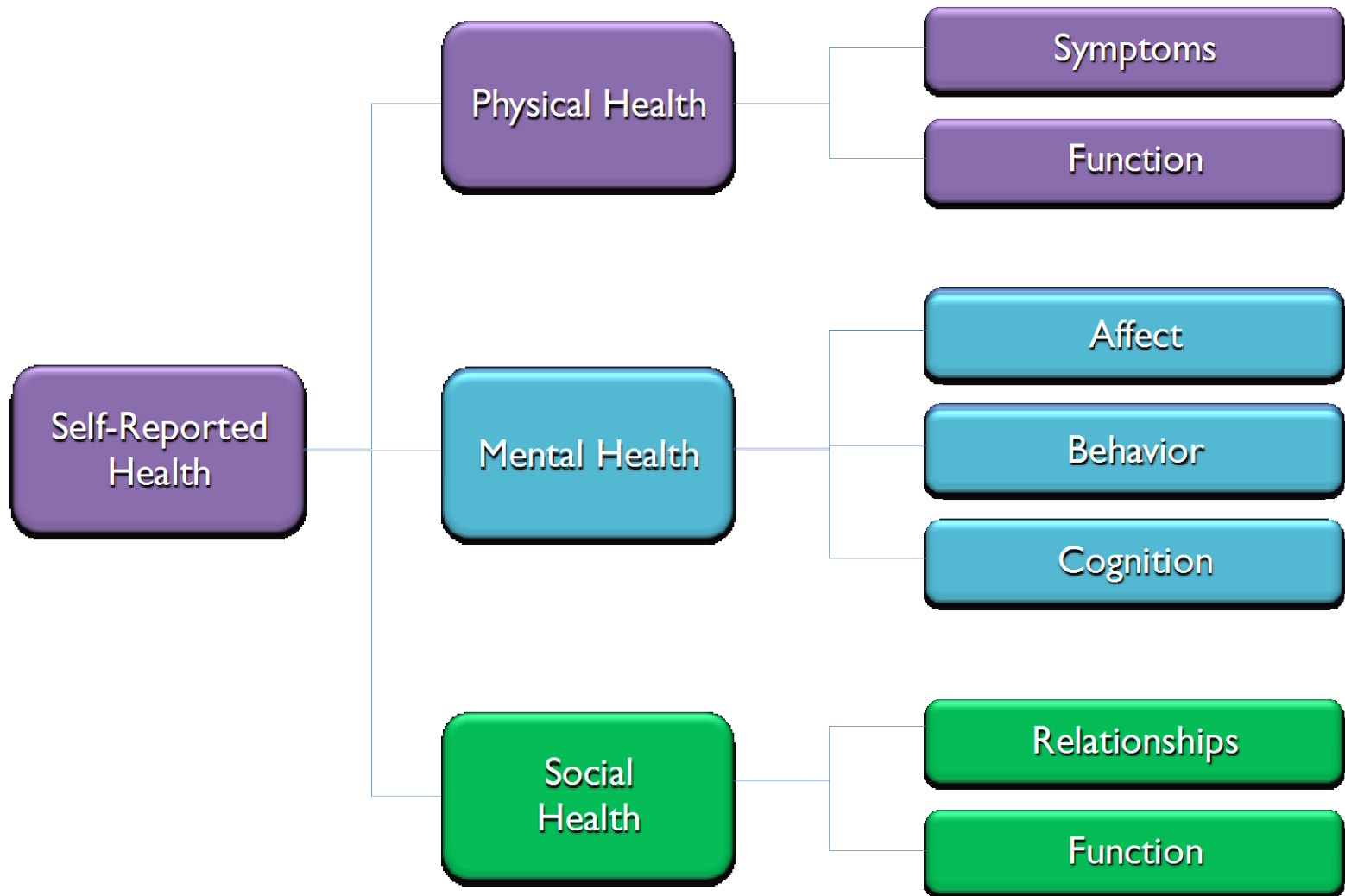
Bringing Everyone to the Table

David Cella, PhD

IT'S YOUR PROMIS

- 10 minute guide to engagement

PROMIS Domain Framework



PROMIS[®] Adult Banks: v1.0

Domains	Items in Bank	Items in Short Form
Emotional Distress – Anger	29	8
Emotional Distress – Anxiety	29	7
Emotional Distress – Depression	28	8
Fatigue	95	7
Pain – Behavior	39	7
Pain – interference	41	6
Physical Function	125	10
Satisfaction with Discretionary Social Activities	12	7
Satisfaction with Social Roles	14	7
Sleep Disturbance	27	8
Wake Disturbance (sleep related impairment)	16	8
Global Health		10



PROMIS[®] Pediatric Banks: v1.0

Domains	Items in Bank	Items in Short Form
Emotional Distress – Anger	n/a	6
Emotional Distress – Anxiety	15	8
Emotional Distress – Depression	14	8
Fatigue	23	10
Pain – Interference	13	8
Physical Function-Mobility	125	10
Physical Function-Upper Extremity	29	8
Peer Relationships	15	8
Asthma	17	8

The PROMIS Metric

T Score

Mean = 50

SD = 10

Referenced to the US General
Population

PROMIS Basic Tools

Derived from Item Banks

Computerized Adaptive Testing (CAT)

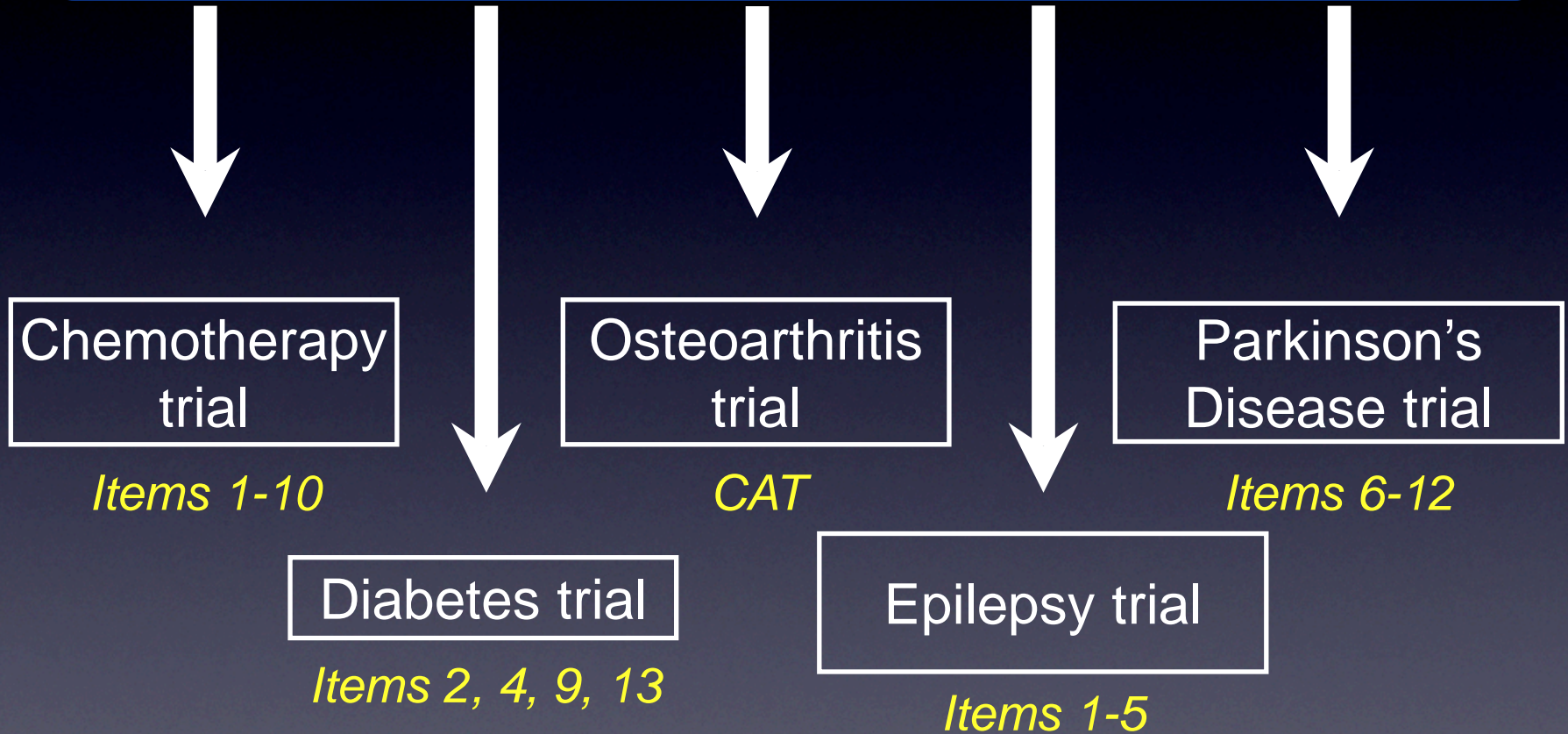
- Dynamic testing averaging 6 items per domain

Fixed Length Forms

- By individual domain (8-10 items)
- By health profile (-29, -43, -57)

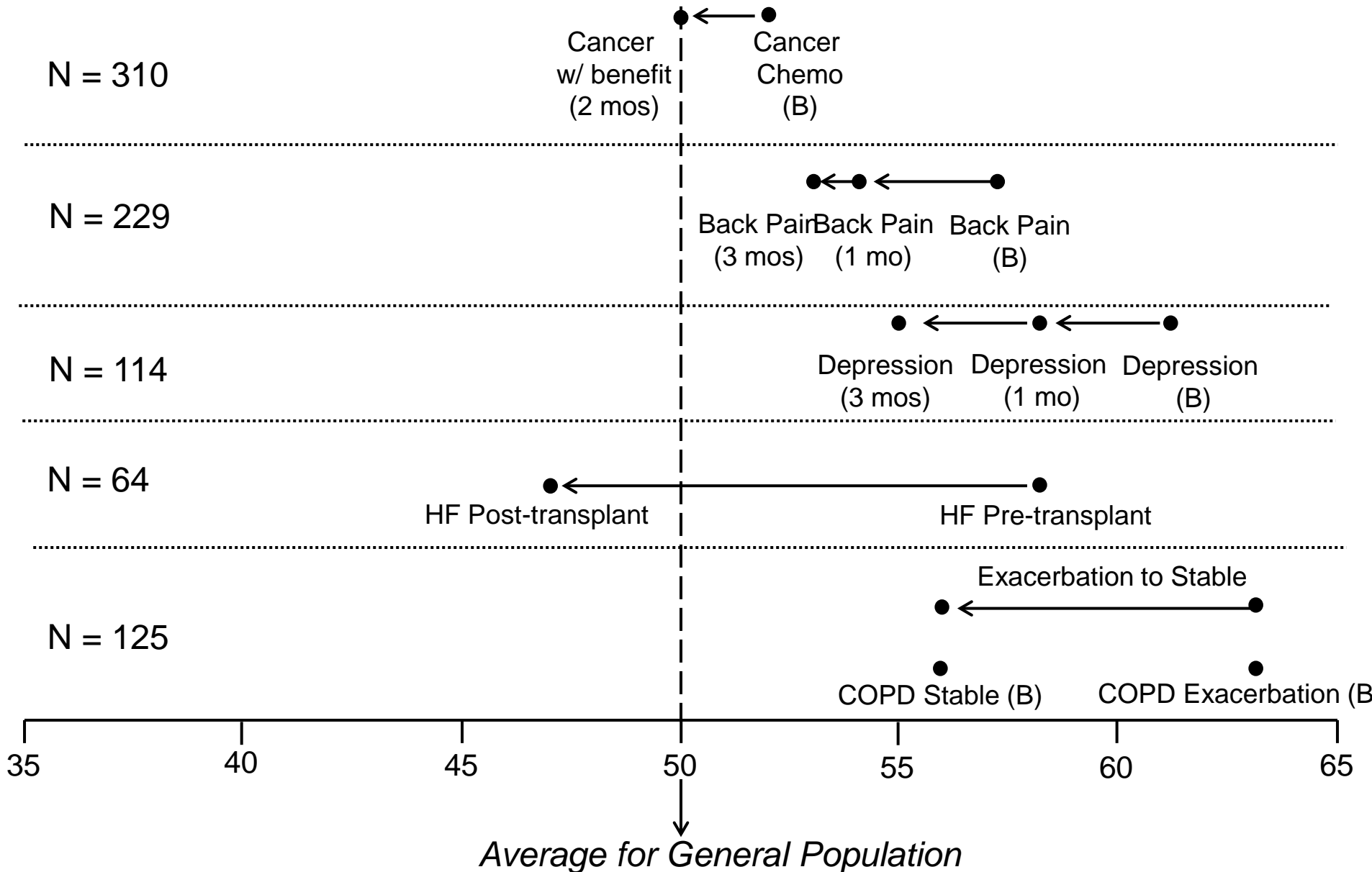
Global Health Index

Fatigue Item Bank



Same metric, same meaning

PROMIS Fatigue Across Five Clinical Conditions



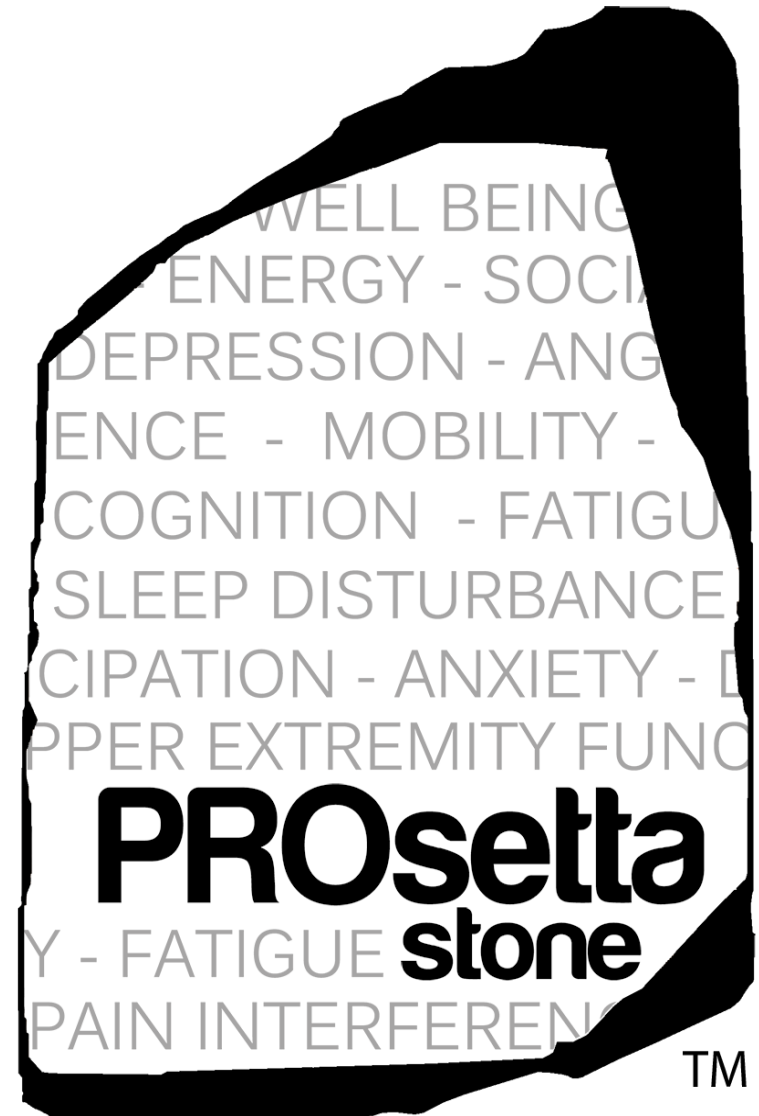


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**A Rosetta Stone for
Linking Patient-Reported
Outcome Measures**

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USPHS Grant No. RC4 CA157236-01



TM

Raw Score to T-Score Conversion Table (IRT Fixed Parameter Calibration Linking) for PHQ-9 to PROMIS



PHQ-9 Score	PROMIS T-score	SE
0	37.4	6.4
1	42.7	5.3
2	45.9	4.8
3	48.3	4.7
4	50.5	4.3
5	52.5	4.0
6	54.2	3.8
7	55.8	3.7
8	57.2	3.6
9	58.6	3.5
10	59.9	3.4
11	61.1	3.3
12	62.3	3.3
13	63.5	3.2
14	64.7	3.2
15	65.8	3.2
16	66.9	3.2
17	68.0	3.1
18	69.2	3.2
19	70.3	3.2
20	71.5	3.2
21	72.7	3.3
22	74.0	3.4
23	75.3	3.5
24	76.7	3.6

Progress to Date: Oct, 2013



PROMIS Domain	# Links	Legacy Instrument
Anger	1	BPAQ
Anxiety	8	MASQ-GD, MASQ, GAD-7, SF-36/MH, K6, NQ Anx., HADS, PANAS
Cognitive Function	4	FACT-Cog (Imp), FACT-Cog (Abil), NQ (Gen. Concerns), Peds PCF
Depression	8	CES-D, SF-36/MH, PHQ-9, PHQ-2, NQ Dep., BDI-II, K6, PANAS
Fatigue	3	FACIT-F, SF-36/VT, NQ Fatigue
Global Health (Mental & Physical)	4	VR-12 (Sums & Weighted)
Pain Interference	3	BPI Interference, BPI Severity, SF-36/BP
Physical Function	4	HAQ-DI, SF-36 PF-10, NQ Mobility, NQ Upper Extremity
Satisfaction w/ SRA v2.0	2	PROMIS Satisfaction w/DSA v1.0, Satisfaction w/SR v1.0
Sleep Disturbance	3	NQ Sleep Dist., PROMIS Sleep Imp., PSQI
Sleep-related Impairment	2	PSQI, NQ Sleep Dist.
*NQ Positive Affect & Well-being	3	Toolbox Life Satis., Meaning, Positive Affect
*Peds PCF	1	Peds NQ Applied Cognition - general
Peds Anxiety	1	Peds NQ Anxiety
Peds Depression	3	Peds CES-D, Peds NQ Depression, SMFQ
Peds Fatigue	1	Peds FACIT Fatigue
Peds Peer Relationships	1	Peds NQ Interaction w/Peers
Peds Physical Function - Mobility	1	Peds NQ Mobility
Total number of links:	53	

PROMIS CORE VALUES

Science

Commitment to leading innovation and advancing PRO science by supporting the research and development of PROMIS

Collaboration

Collaboration across academic institutions, government, supporting organizations, businesses, and individuals to foster a diversity of ideas

Openness

Dissemination of PROMIS items and tools so that they are publically available, easily accessible, easy to use, and free of cost

Responsibility

Individuals strive to fulfill the PHO's mission, values, and goals as a responsibility to the PROMIS community and ultimately the patient

Expertise

Demonstration of knowledge, skill, and expertise in the services we provide by grasping the science and technology behind PROMIS

PROMIS International

ISOQOL Agenda, Miami, October 2013

4.30pm:	Welcome
4.35pm-5.00pm:	Standards document
5.00pm-5.25pm:	Document on language prioritization
5.25pm-5.50pm:	Prioritization of domains to translate
5.50pm-6.00pm:	Discussion of funding strategies
6.00pm-6.10pm:	PROMIS International SOPs

i.e. discussion of procedures how new enquiries from countries outside the US are being handled

PROMIS International - EU efforts

Dutch and German groups with translations and psychometric advances (DIF, linking, norming)

HORIZON 2020 – WORK PROGRAMME 2014-2015

Health, demographic change and wellbeing

framework program for research within the EU...ongoing calls for targeted large-scale research efforts

WHAT IS THE PROMIS HEALTH ORGANIZATION (PHO)?

- **Common Goal:** Advance PROMIS to bring the patient's voice to forefront of clinical research and practice
 - Focus on sustainability of PROMIS measures
 - Coordinate and maintain PROMIS resources
 - Maintain financial growth and health
- Private side of public-private partnership
- **Purpose:** Moving PROMIS forward

PURPOSE OF THE PHO

- The purposes of the PHO are exclusively scientific, educational, and charitable within the meaning of Section 501(c)(3) of the Internal Revenue Code.
- More specifically, the purposes are to:
 - Advance the science of health outcomes assessment;
 - Disseminate standardized and validated health outcome metrics;
 - Foster development of new patient-reported health outcomes for diverse populations; and
 - Educate the scientific and clinical communities on the science of patient-reported outcomes.
- The PHO is organized to develop, maintain, and encourage the application of PROMIS-based measures to provide efficient and valid measures of relevant health outcome domains.

Translating PROMIS for Global Use

- The PROMIS Health Organization (PHO) and the PROMIS International Group are seeking international financial support for a large scale translation effort referred to as PRISM (PROMIS International Standards and Measures).
- Main goal: translation and cultural adaptation of items from a core set of domains most likely to be used by researchers and clinicians, in the languages most sought after by users.

Language selection process

- Languages spoken by the largest numbers of people in the world.
- Languages most frequently requested through Assessment Center and the PROMIS website.
- Languages most frequently requested by pharmaceutical companies:
 - In the context of PROMIS and Neuro-QoL.
 - In the experience of two translation service providers: FACITtrans and MAPI)
 - Listed in a report of the European Medicines Agency (EMA)/DIA about the location of clinical trials and patient recruitment from 2005 to 2011
- Presence of interested and engaged collaborators

Region	Patients recruited	Notes
EU/EEA/EFTA	38.1%	EU=European Union; EEA= European Economic Area; EFTA= European Free Trade Agreement. This includes western, northern, southern and nine eastern European countries.
North America	34.1%	US and Canada
Central/South America	9.4%	Non-English languages include Spanish in great majority of countries; Portuguese in Brazil; French in French Guiana, Guadalupe, Haiti and Martinique; Dutch in Aruba and Suriname.
Middle East/Asia/Pacific	9.4%	Includes Arabic, Chinese, Hebrew, Hindi, among many others. English applies most of the countries of the Pacifics.
CIS region	4.4%	CIS = Commonwealth of Independent States. Participating countries are 12 former Soviet Republics: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan.
Africa	2.6%	Many languages
Australia-New Zealand	1.5%	English applies
Eastern Europe-non EU	0.5%	

MAPI - Languages most often requested by pharmaceutical companies in 2012 -	FACITtrans - Languages most requested by pharma - by tier
German for Germany	German
Spanish for Spain	Spanish
Spanish for the US	Spanish
Polish for Poland	Polish
French for France	French
Italian for Italy	Italian
French for Canada	French
Czech for Czech Republic	Czech
Russian for Russia	Russian
Hungarian for Hungary	Hungarian
	Dutch
	Afrikaans
	Danish
	Finnish
	Norwegian
	Portuguese
	Swedish
	Chinese –S
	Chinese –T
	Japanese
	Korean
	Arabic
	Hebrew
	Estonian
	Latvian
	Lithuanian

BHAG: COMMITMENT TO PROVIDING PROMIS MEASURES

- PROMIS measures royalty-free and license-free to all users
- Expect revenue stream based on providing technical and consulting services
- Working collaboratively with researchers worldwide

KEY SUSTAINABILITY FACTORS

- We aim to be ...
 - AdvancedReliable, valid, sound psychometrics
 - TrustworthyNon-profit (cost) neutrality
 - Inclusiveacross language, age, disability, etc.
 - Focusedon PROMIS, end users, and the patient
 - Collaborative...foster a clinical and research community

CONCLUSION

PROMIS Welcomes International Partners

Centralized curation and updating

- Common standards
- Common translations
- Common calibrations

Decentralized activity and scientific advancement

- Distributed participation
- Population (country, etc) - specific reference values

Language	Mainly spoken in	Native speakers (millions)	% of world population
Mandarin	China, Taiwan, Singapore	935	14.1
Spanish	Official language in 21 countries; Hispanic America, Spain, United States, Equatorial Guinea, Western Sahara, Pacific islands	387	5.85
Hindi	India, Fiji, Nepal	295	4.46
Arabic	Official language in 26 countries; North Africa, Western Asia (Middle East), East Africa	280	4.23
Portuguese	Angola, Brazil, Cape Verde, Mozambique, Portugal, São Tomé and Príncipe, Timor-Leste (also off. lang. in Guiné-Bissau)	204	3.08
Bengali	Bangladesh, West Bengal (India), Tripura (India), Assam (India)	202	3.05
Russian	Russia , former Republics of the Soviet Union , Mongolia , Israel	160	2.42
Japanese	Japan	127	1.92
German	Austria, Belgium (Eupen-Malmedy), Germany, Luxembourg, Liechtenstein, Switzerland, South Tirol (in Italy)	92	1.39
Javanese	Java (Indonesia)	82	1.25
Malay/Indonesian	Indonesia, Malaysia, Brunei, Singapore	77	1.16
Vietnamese	Vietnam	76	1.14
Korean	North Korea, South Korea	76	1.14
French	Belgium, Canada, France, Switzerland, Francophone Africa, French Caribbean, French Polynesia, islands in the Indian and Pacific Oceans.	74	1.14
Persian	Iran, Afghanistan, Tajikistan	65	0.99
Turkish	Turkey, Cyprus, Bulgaria	63	0.95
Italian	Italy, Switzerland, San Marino	59	.90
Cantonese	Guangdong (Canton), southern Guangxi (southern China), Hong Kong, Macau	59	0.85
Polish	Poland, US, Germany, England, Belarus, western Ukraine, Lithuania	40	0.61
Ukrainian	Ukraine	30	0.46
Tagalog	Manila and Northern Philippines	28	0.42
Swahili	Kenya, Tanzania, Uganda	26	0.39
Romanian	Romania , Moldova	24	0.34
Dutch	Belgium, Netherlands and Suriname	21	0.32
Serbo-Croatian	Serbia, Croatia, Bosnia and Montenegro	19	0.28
Hungarian	Hungary	13	0.19
Greek	Greece, Cyprus	12	0.18
Czech	Czech Republic	10	0.15
Swedish	Sweden, Finland	8.7	0.13
Xhosa	South Africa	7.6	0.11