



# **The Swedish approach to item banking: the PROMIS project**

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# THE SWEDISH NATIONAL ITEM BANK PROJECT

Pilot project: 1<sup>st</sup> May to 31<sup>st</sup> December 2016

Project management:

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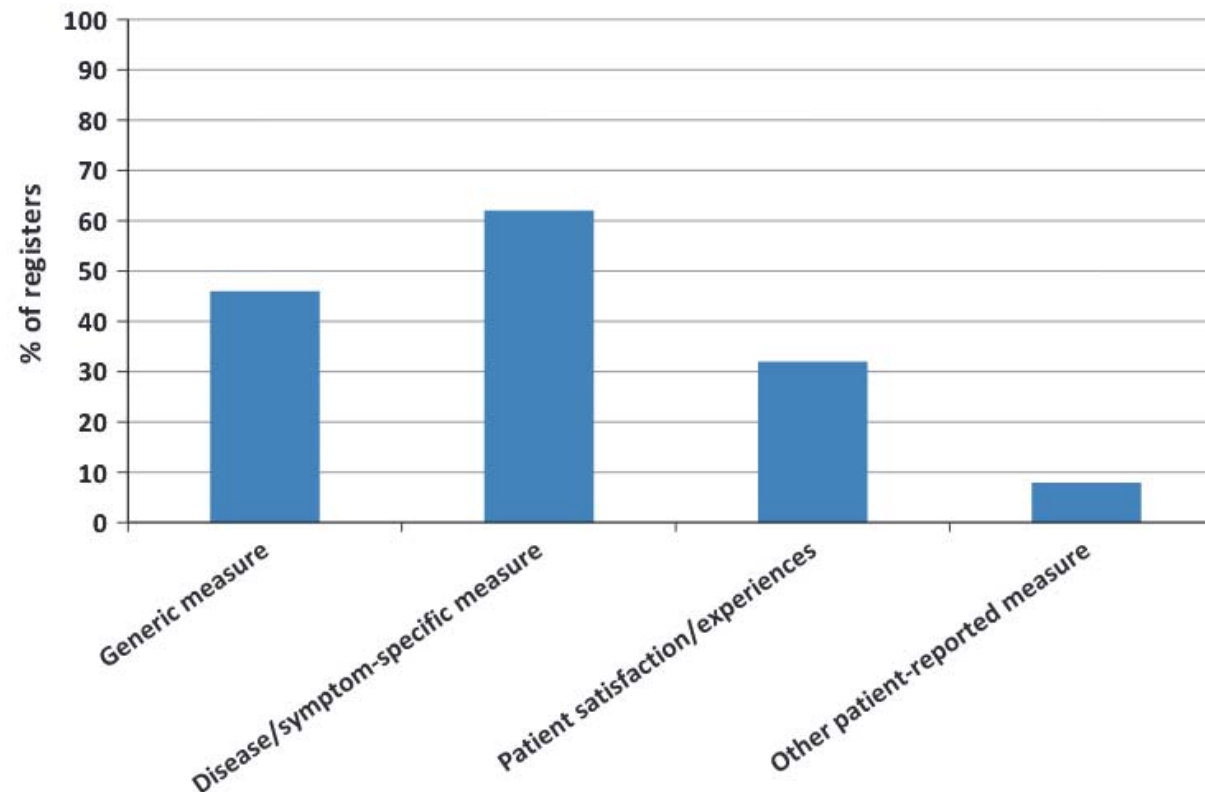
Steering group representing each of the six Swedish RC:s (Registry Centers): Staffan Lindblad (QRC Stockholm), Jack Lysholm (RCN), Anders Tennlind (RCSO), Thomas Troëng (RC Syd), Ulrika Frithiofsson (RC VGR) and Monica Sterner (UCR).

The project is funded by the Swedish National Quality Register organization. However, the use of the item banks will not be restricted to the Quality Registers, but will be available for the entire Swedish Health care system.

# Patient-reported outcomes in the Swedish National Quality Registers

■ E. Nilsson<sup>1,2</sup>, L. Orwelius<sup>3</sup> & M. Kristenson<sup>2</sup>

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**Fig. 2** The current self-reported inclusion of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) in the Swedish National Quality Registers. The most common generic PROMs were the EQ-5D (around 35 registers) and the short-form (SF)-36/ RAND-36 (around 10 registers). Of the approximately 10% of registers reporting not including any PROMs or PREMs, most reported planning for inclusion within the near future. Furthermore, several of the registers already including these measures reported planning extended use. 'Other patient-reported measures' included measures of work situation, lifestyle factors and burden of care from the perspectives of the relatives of the patient (from the 108 annual applications for funding for 2015).

## Challenges to PRO measurement

- Many measures of the same health concept
- Difficult to compare & combine across studies & conditions
- Varying quality
- Complex
- Long

## Aim of the Swedish project

To establish the viability of a nation-wide item banking system for patient reported outcomes

- that can be securely used by patients, linked to the national quality registries and available for clinical use.

# Item banking in Sweden

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## Aim

To evaluate the requirements for the integration of future item banks into the Swedish national quality registries (NQRs).

## Background

Sweden was a pioneer in starting NQRs in the 1970s. There are now over 100 different NQRs in Sweden, each focusing on a specific diagnosis, condition, or intervention, and containing individual patient data. NQRs will enable continuous quality improvement, both at the clinical level and at the political and administrative levels. NQRs are in the process of adding the patient perspective to their data collection.

## Methods

The evaluation will consider the processes, goals, and outcomes of PROs in relation to the needs and structure of the NQRs in Sweden. We will:

- ❖ interview representatives from all significant stakeholder groups,
- ❖ carry out documentation reviews to examine the current use of NQRs,
- ❖ evaluate processes, goals, and outcomes against the needs of the Swedish system taking into account the values and cultural aspects of measurement, scalability, and performance.

## Challenges to introducing item banks in Sweden

- ❖ Limited availability of validated and reliable item banks in Swedish.
- ❖ Resistance to replacing established PRO instruments.
- ❖ Incompatibility with prior PRO data collection.
- ❖ Limited awareness of item banking.
- ❖ Training requirements.
- ❖ Long development period for the introduction of item banking.
- ❖ Limited information about computer assisted testing (CAT) applications in routine clinical procedures.

## Advantages to Sweden

- ❖ Improves the psychometric quality of PRO data.
- ❖ Reduces respondent burden.
- ❖ New tests, with predictable characteristics, can be developed easily.
- ❖ Increases the possibilities of web-based CAT.
- ❖ Establishes a common language for discussing health goals and patients' objectives.
- ❖ Enhances the comparability of health outcomes measures for follow-up, and national/international comparisons.
- ❖ Contributes to the competitiveness of Swedish healthcare services in Europe.

## Take-home message

A centralized approach is required in order to achieve the wide adoption of item banking in Sweden.

## Requirements for a comprehensive approach


- ❖ Generic and disease-specific measures.
- ❖ Ability to make comparisons across conditions and between national and international healthcare systems.
- ❖ Provision of both electronic and paper-and-pencil administration.

## PROMIS

Patient Reported Outcomes Measurement Information System (PROMIS), funded by the National Institute of Health (NIH), is being considered by Sweden for national implementation.

PROMIS would allow Swedish NQRs to facilitate meta-analyses, leading to the development of improved health policy.

## Why use PROMIS in Quality registries?

- Covers the whole spectrum of:
  - general and disease specific conditions,
  - from severe to mild problems.
- Flexible – items can be added / removed
- Demonstrated use in both clinic and research.
- Adaptable to a computer data collection system.
- Recommended by the International Consortium for Health Outcomes Measurement  **ICHOM**



# PROMIS<sup>®</sup>



Dynamic Tools to Measure Health Outcomes from the Patient Perspective



Patient-rapporterade resultatet Measurement informationssystem (PROMIS<sup>®</sup>), syftar till att ge kliniker och forskare tillgång till effektiva, giltig och lyhörd självrapporterade mått på hälsa, inklusive symtom, funktion och välbefinnande. Promis instrument är förankrade i modern mätning teorin. De utvecklades med blandade kvalitativa och kvantitativa metoder som används för att informera varandra i en iterativ process.

**PROMIS international Sverige**





# Where does the idea come from?

## “roadmap” for medical research in the 21st century

- 2002 NIH aimed to identify major opportunities and gaps in biomedical research. (1) New Pathways to Discovery, (2) Research Teams of the Future, and (3) Re-engineering the Clinical Research Enterprise.
  - Area 3. Accelerate and strengthen the clinical research process by adopting a systematic infrastructure to better and more efficiently serve the field of scientific discovery.
    - One of the programs with area 3 was dynamic assessment of patient-reported chronic disease outcomes.
  - 2004 a multi-centre cooperative group - Patient-Reported Outcomes Measurement Information System (PROMIS).
  - *“The clinical outcomes research enterprise would be enhanced greatly by the availability of psychometrically validated and dynamic system to measure PROs in a wide range of chronic diseases”*



# The big idea!



- Develop PROs for physical, mental and social health
- Use across chronic conditions
- Improve measurement quality and precision
- Harness modern psychometric methods – IRT / CATs
- No cost



# The original PROMIS network of clinicians, clinical researchers, and measurement experts

- The PROMIS network of clinicians, clinical researchers, and measurement experts was organized around 6 primary research sites and a statistical coordinating centre, all of whom work closely with NIH.
- The main contact point for PROMIS is the assessment centre
  - coordinates, facilitates, and maintains information exchange and dissemination of the item banks, protocols, study procedures and forms; develops end-user training materials for clinicians who will use the item banks and the CAT system.

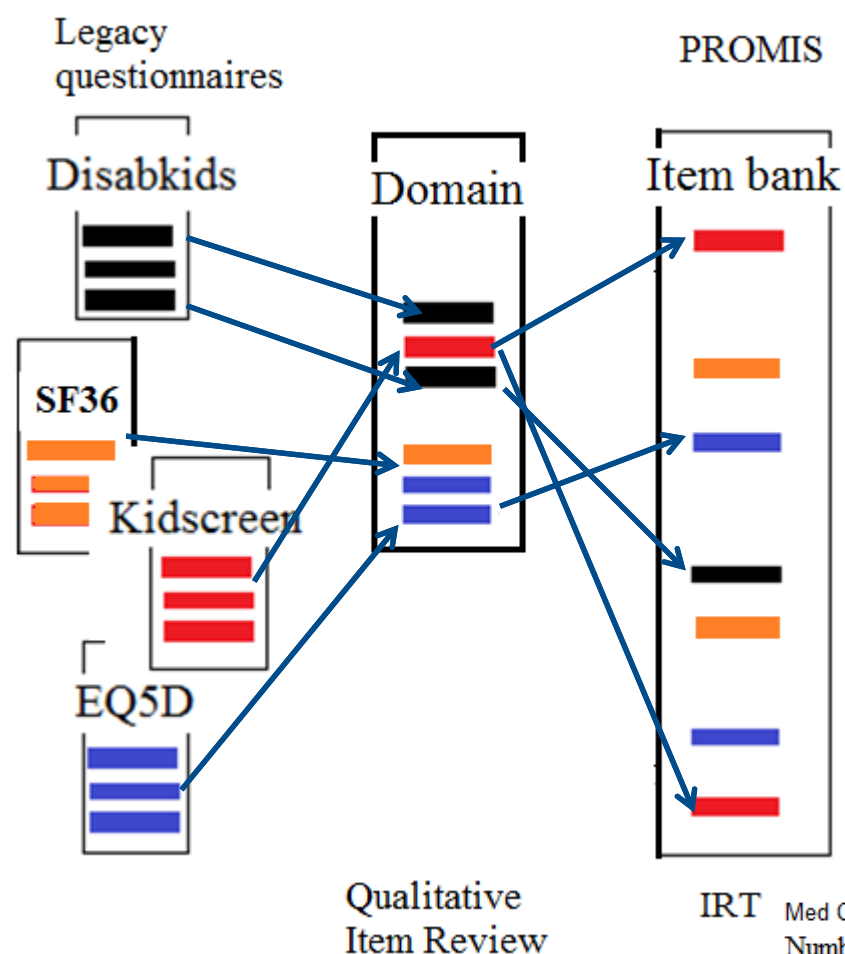


# What is PROMIS?



- Methodology - guidelines for PRO development
- Measures - item banks, short forms, profiles; adult and child & parent proxy
- Software - for delivery of the item banks, CATs

# Relationship to the legacy instruments



- PROMIS consists of items drawn from other questionnaires (legacy instruments).
- 10,000 entries, approximately 7000 of which relate to the 5 health domains chosen for initial bank development.
- Qualitative Item Review - “binning and winnowing”
- Cognitive assessments with patient populations.
- Items revised as needed to improve clarity, precision, readability, translatability, and fit to a CAT framework.

Med Care. 2007 May; 45(5 Suppl 1): S12-S21.

Numbers of Items Identified by Searches for Extant Items

	Emotional Distress	Fatigue	Social Function	Physical Function	Pain
Number of items identified	2187	1066	1781	1860	644
Items for cognitive interviewing	299	135	129	247	191
Final item pool	224	112	112	224	168

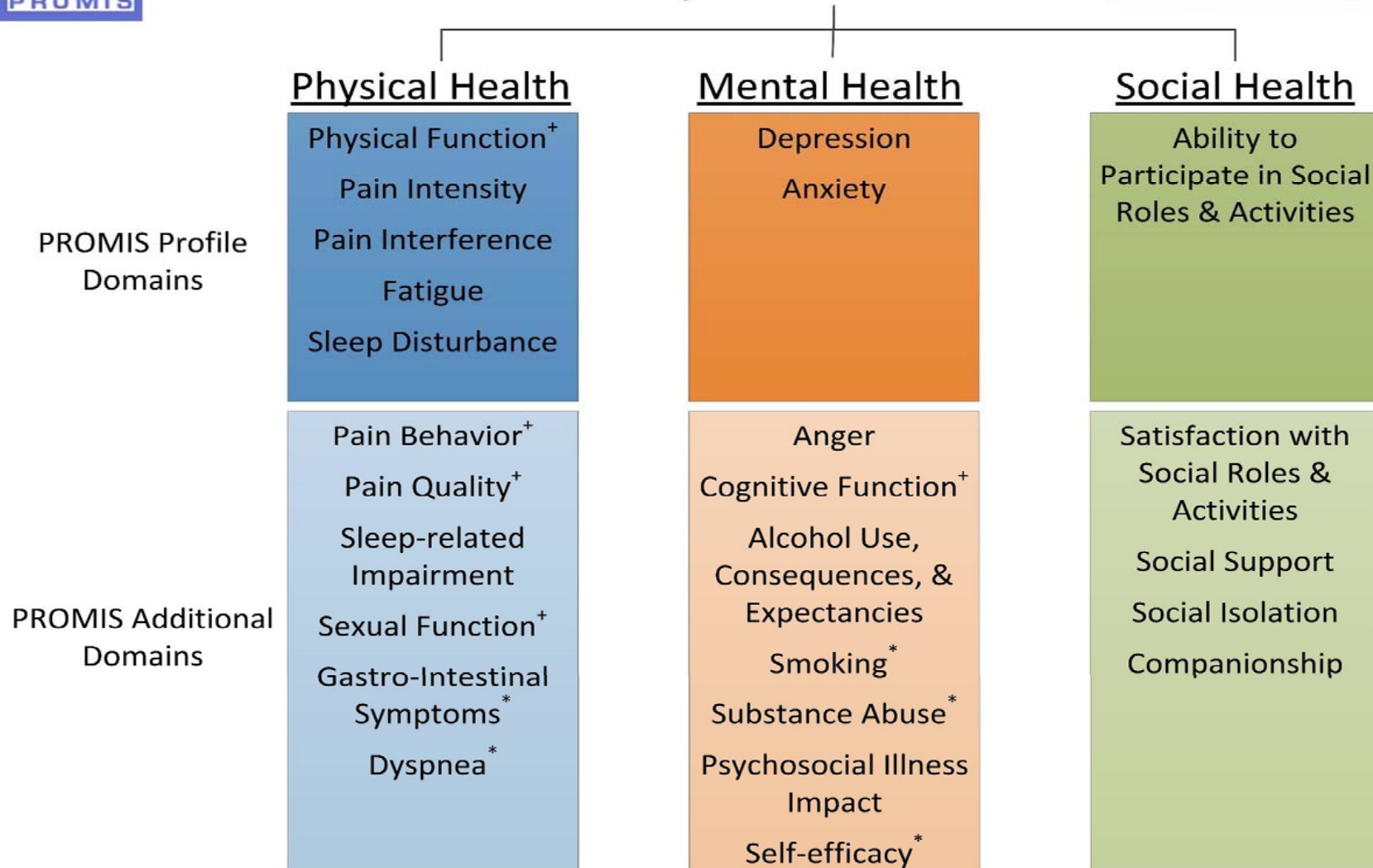




# What is PROMIS?



## PROMIS Adult Self-Reported Health — Global Health





# What is PROMIS?



## PROMIS Pediatric Self- and Proxy-Reported Health

Global Health

### Physical Health

Mobility  
Upper Extremity  
Function  
Pain Intensity  
Pain Interference  
Fatigue

PROMIS Profile  
Domains

Asthma Impact  
Pain Behavior  
Pain Quality  
Physical Activity  
Physical Stress  
Experiences  
Strength Impact

PROMIS Additional  
Domains

### Mental Health

Depressive  
Symptoms  
Anxiety

Anger  
Cognitive Function  
Life Satisfaction  
Meaning and  
Purpose  
Positive Affect  
Psychological  
Stress Experiences

### Social Health

Peer Relationships

Family  
Relationships



# Respondents



- Adults (18+)
- Paediatric self report (8-17)
- Parent proxy report for child (child 5-7)



# PROMIS tools



Item banks can be use to create:

- Computerized Adaptive Testing (CAT) –dynamic
- Short forms - static
- Profiles (eg. Profil-29)
  - Depression, anxiety, fatigue, physical function, pain interference etc.

## Pain Interference – Short Form 6b

Please respond to each item by marking one box per row.

**In the past 7 days...**

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAIN05	How much did pain interfere with your enjoyment of life?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN02	How much did pain interfere with your ability to concentrate?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN03	How much did pain interfere with your day to day activities?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN10	How much did pain interfere with your enjoyment of recreational activities?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAIN14	How much did pain interfere with doing your tasks away from home (e.g., getting groceries, running errands)?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
	<b>In the past 7 days...</b>					
		Never	Rarely	Sometimes	Often	Always
PAIN20	How often did pain keep you from socializing with others?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5



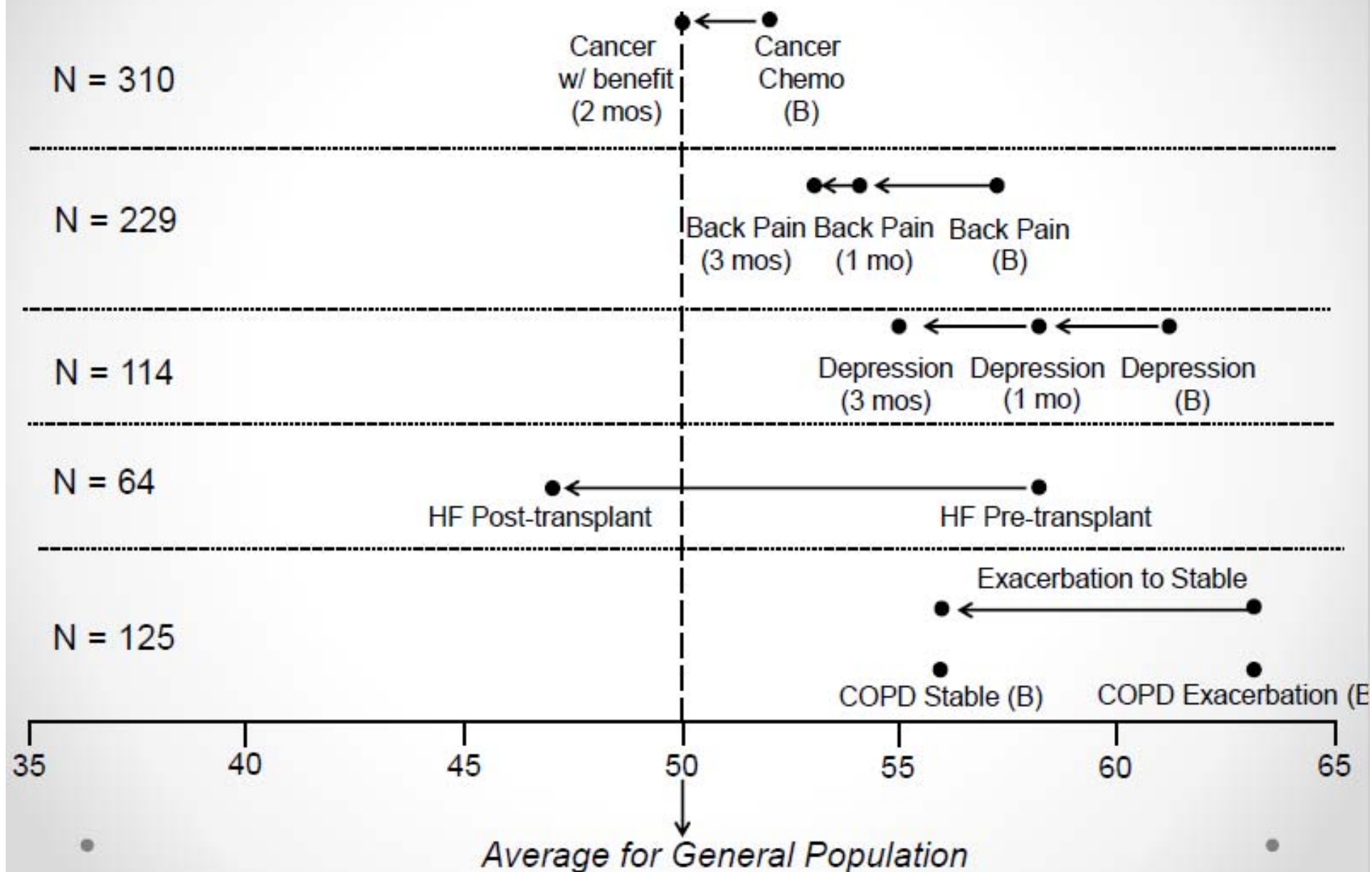


## PROMIS metric



- All instruments are scored using a T-score
  - Mean = 50
  - Standard deviation = 10
  - US reference population – until we collect enough data
  - High scores = more of that domain

# PROMIS Fatigue Across Five Clinical Conditions





# How to score the instruments

- US Assessment Centre calculates scores using item-level parameters
- PROMIS scoring manuals
- APIs available for stand alone and mobile devices

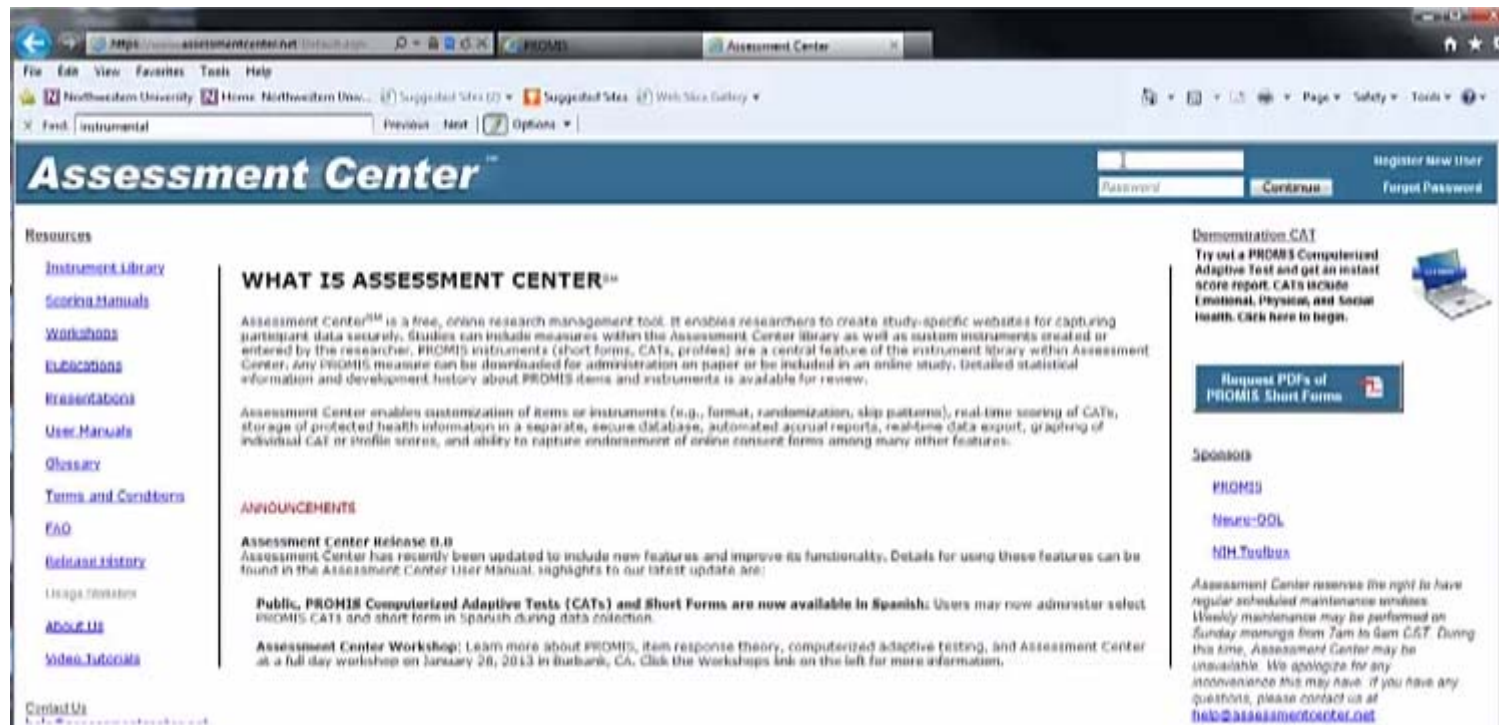


# How to get copies of the instruments



## Assessment centre

- Homepage: download zip file of selected short forms
- Download zip files of all PROMIS instruments after simple registration and login



## Comparison studies to the legacy quesitonnaires

ORIGINAL RESEARCH  
SPINE

### Correlation of the Patient Reported Outcomes Measurement Information System with Legacy Outcomes Measures in Assessment of Response to Lumbar Transforaminal Epidural Steroid Injections

L. Shahgholi, K.J. Yost, R.E. Carter, J.R. Geske, C.E. Hagen, K.K. Amrami, F.E. Diehn, T.J. Kaufmann, J.M. Morris, N.S. Murthy, J.T. Wald, K.R. Thielen, D.F. Kallmes, and T.P. Maus

Spearman correlation coefficients between PROMIS scores and EQ-5D on the first day and from 3- and 6-month evaluations in the Transforaminal Epidural Steroid Injection group.

PMC full text: [Value Health. Author manuscript; available in PMC 2013 Jan 1.](#)

PROMIS CAT	CES-D	FACIT-Fatigue	SF-BP	SF-PF	Sleep index	SF_SF
Depression 1.0	0.67	0.44	0.31	0.20	0.33	0.46
Fatigue 1.0	0.59	0.76	0.59	0.51	0.49	0.59
Pain Behavior 1.0	0.44	0.53	0.66	0.38	0.37	0.47
Phys. Function 1.0	0.46	0.72	0.56	0.82	0.43	0.55
Sleep Disturb 1.0	0.50	0.37	0.23	0.24	0.75	0.28
Social Sat Discretionary 1.0	0.56	0.62	0.48	0.54	0.46	0.61

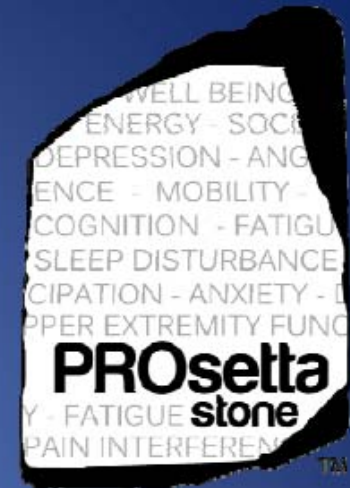
PMC full text: [Qual Life Res. 2009 Aug; 18\(6\): 783–791.](#)

Mean actual and predicted EQ-5D index scores by gender and age groups in PROMIS general population sample ( $n = 2,722$ )

Age groups	Males		Females		Total	
	Actual	Predicted	Actual	Predicted	Actual	Predicted
<35	0.89	0.89	0.88	0.86	0.88	0.87
35–44	0.87	0.86	0.85	0.84	0.86	0.85
45–54	0.87	0.86	0.79	0.79	0.82	0.82
55–64	0.84	0.85	0.81	0.82	0.82	0.83
65–74	0.86	0.88	0.84	0.85	0.85	0.86



# PROsetta Stone



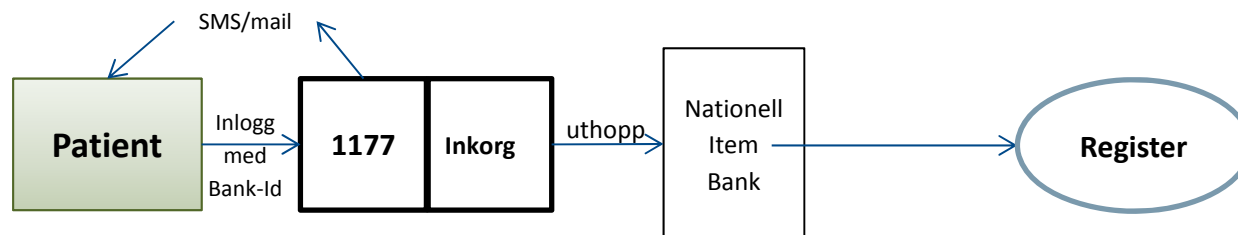
- Linking tables
  - Legacy instruments to PROMIS metric
- BPI, CES-D, FACIT, HAQ, SF-36, PHQ-9, etc
- [www.prosettastone.org](http://www.prosettastone.org)

SF-36/PF Score	PROMIS T-score	SE
10	24.5	4.0
11	28.3	2.8
12	30.3	2.5
13	32.0	2.2
14	33.4	2.1
15	34.8	2.0
16	36.0	2.0
17	37.2	2.0
18	38.4	1.9
19	39.5	1.9
20	40.7	1.9
21	41.8	1.9
22	42.9	1.9
23	44.1	2.0
24	45.2	2.0

# Planned activities within the project

- The Swedish project, with close guidance from patient representation, will test the possibilities of using PROMIS item banks as an application within a national e-health service (1177) and evaluate possibilities for integration of item banking into the existing Swedish national registries.

## Infrastruktur för nationell Item Bank



Separat formulärmotor som kan nå  
av registerplattformarna



# Planned activities within the project





- Establishment of a Swedish network of active users and researchers working with item banks in general and with PROMIS in particular.
- Translation and validation of PROMIS domains according to a priority list.
- Workshops and seminars to inform and identify potential future users and stakeholders.
- An outline of a national strategy for the establishment of patient reported outcomes via item banking in Sweden from 2017 and forward.


# Item banks to be translated


Suggested Item banks for translation in first round	Items
Fatigue + cancer version	$95 - 7(-4) = 88$
Emotional depression + cancer	$28 - 4 = 24$
Pain – Interference/ intensity + cancer	$40 - 5 = 35$
Physical Function + cancer + mobility + upper body + movement disabled	
Adult	$121 - 4 = 117$
Child	$23 - 4 = 19$
Ability to Participate in Social Roles and Activities (v2.0)	$35 - 4 = 31$
<b>Total</b>	<b>314</b>

# PROMIS Adult – Sept 2016



PROMIS	Item banks	Num. of Items	Patient group	Research group	Item bank project 2016
ADULT	<b>Fatigue short form-7</b>	7	post-polio	Department of Rehabilitation Medicine, Skåne University Hospital in Lund	95 items + cancer version
	<b>Sexual function (selected items)</b>	43/72	cancer patients & gen pop 16-39yrs	Dept. Neurobiology, Care Sciences and Society, Karolinska Institutet, Stockholm	 <b>Karolinska Institutet</b>
	PROMIS-29 profile	29	Systemic sclerosis	Department of Clinical Sciences, Dept of Rheumatology Lund University  (SMBD Jewish General Hospital, Montreal, Quebec, Canada.)	 <b>LUND UNIVERSITY</b>
	Emotional Distress – Anxiety	4			28 items + cancer
	Emotional Distress – Depression	4			95 items
	Fatigue	4			40 items + cancer
	Pain – Interference	4			121 items + cancer + mobility + upper body + movement disabled
	Pain – Intensity	1			35 items
	Physical Function	4			
	Sleep Disturbance	4			
	Ability to Participate in Social Roles and Activities (v2.0)	4			





PROMIS	Item banks	Item bank project 2016	Nordic connections
ADULT	Fatigue short form-7	95 items + cancer version	PROMIS-57v2 Norway Fatigue 8a
	Sexual function (selected items)		 Sunnaas sykehus HF
	PROMIS-29 profile		
	Emotional Distress – Anxiety		PROMIS-57v2 Norway Anxiety 8a NIH Toolbox Emotion - Clinical Neuropsychology, Helsinki Uni
	Emotional Distress – Depression	28 items + cancer	PROMIS-57v2 Norway Depression 8a
	Fatigue	95 items	PROMIS-57v2 Norway Fatigue 8a
	Pain – Interference	40 items + cancer	PROMIS-57v2 Norway Pain Interference 8a
	Pain – Intensity		PROMIS-57v2 Pain Intensity item (Global07)
	Physical Function	121 items + cancer + mobility + upper body + movement disabled	PROMIS-57v2 Norway Physical Function 8b PROMIS Adult Physical function - National Institute for Health and Welfare, Finland, Helsinki
	Sleep Disturbance		PROMIS-57v2 Norway Sleep Disturbance 8a PROMIS Sleep Disturbance 8b Helsinki University Finnish Psychiatric Association
	Ability to Participate in Social Roles and Activities (v2.0)	35 items	PROMIS-57v2 Norway Ability to Participate in Social Roles and Activities 8a

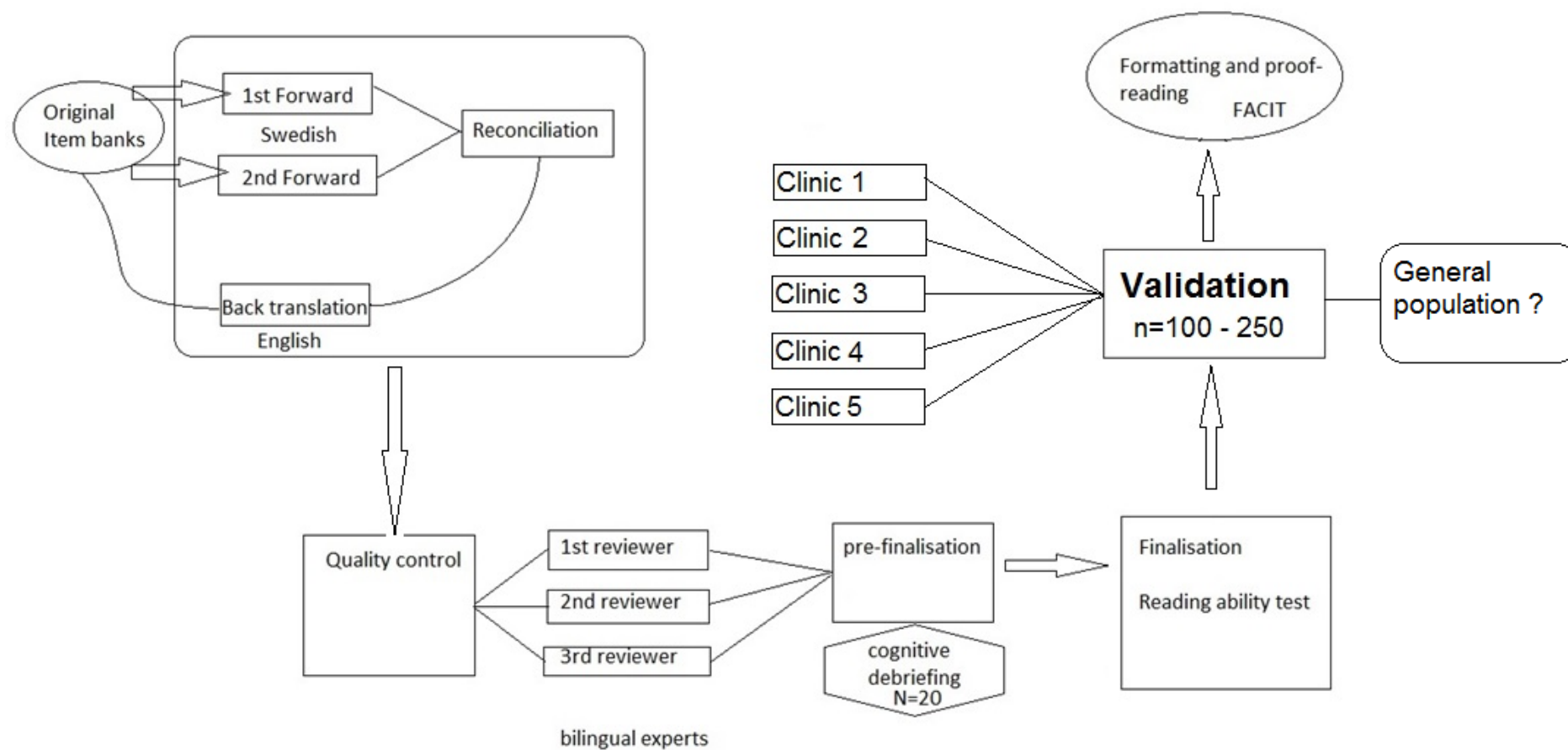
NeuroQoL	Item banks	Num. of Items	Patient group	Research group	Item bank project 2016
Adult	Fatigue	19		Commercial company	
	Cognition general concerns	18	Multiple sclerosis	Dept of Clinical Neuroscience, Karolinska Institute	 Swedish Neuro Registries
	Ability in social roles and activities	8			
	Participation in social roles and activities	8			
	Lower extremity function	8			
	Upper extremity function	8			
	Positive affect and well-being	9			

# PROMIS Child - Sept 2016

PROMIS	Swedish translations	Items translated	Patient group	Research group	Item bank project 2016
PEDIATRIC	Emotional distress- Anxiety + proxy	13	Narcolepsy	Center for Health Care Sciences Örebro University Hospital, Örebro   <b>Universitetssjukhuset Örebro</b> ÖREBRO LÄNS LANDSTING	
	Emotional distress – Depression + proxy	13			
	Peer Relationships + proxy	15			
	Fatigue + proxy	22			
	Pediatric Profile-25		Orthopedic Musculoskeletal	Swedish pediatric orthopedic register (SPOQ)   <b>SPOQ</b> Svenskt Pediatriskt Ortopediskt kvalitetsregister	23 items + upper body
	Physical Function Mobility	4			
	Anxiety	4			
	Depression	4			
	Fatigue	4			
	Peer relationships	4			
	Pain Interference items	4			
	Pain Intensity item	1			

PROMIS	Swedish translations	Item bank project 2016	Nordic connections
PEDIATRIC	Emotional distress- Anxiety + proxy		NIH Toolbox Emotion Clinical Neuropsychology, Helsinki Uni
	Emotional distress – Depression + proxy		
	Peer Relationships + proxy		
	Fatigue + proxy		
	Pediatric Profile-25		
	Physical Function Mobility	23 items + upper body 	PROMIS Pediatric Mobility - National Institute for Health and Welfare, Finland, Helsinki
	Anxiety		
	Depression		
	Fatigue		
	Peer relationships		
	Pain Interference items		
	Pain Intensity item		

# Translation and validation procedure



# Ongoing validation studies

- Pediatric Orthopedic Quality Registry (SPOQ)
  - PROMIS-25 + 7
  - 100-250 patients from 5 clinics (possible 21 clinics)
- Adult
  - Global-10







- Validation in process

	Please respond to each item by marking <u>one box per row</u>	Excellent	Very good	Good	Fair	Poor						
Global 01	In general, would you say your health is:	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
Global 02	In general, would you say your quality of life is:	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
Global 03	In general, how would you rate your physical health?	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
Global 04	In general, how would you rate your mental health, including your mood and your ability to think?	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
Global 05	In general, how would you rate your satisfaction with your social activities and relationships?	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
Global 09	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
		Completely	Mostly	Moderately	A Little	Not At All						
Global 06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
	In the past 7 days	Never	Rarely	Sometimes	Often	Always						
Global 10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
		None	Mild	Moderate	Severe	Very Severe						
Global 08	How would you rate your fatigue on average?	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>1</div>						
Global 07	How would you rate your pain on average?	<div><input type="checkbox"/></div> <div>0</div>	<div><input type="checkbox"/></div> <div>1</div>	<div><input type="checkbox"/></div> <div>2</div>	<div><input type="checkbox"/></div> <div>3</div>	<div><input type="checkbox"/></div> <div>4</div>	<div><input type="checkbox"/></div> <div>5</div>	<div><input type="checkbox"/></div> <div>6</div>	<div><input type="checkbox"/></div> <div>7</div>	<div><input type="checkbox"/></div> <div>8</div>	<div><input type="checkbox"/></div> <div>9</div>	<div><input type="checkbox"/></div> <div>10</div>
		No Pain								Worst Imaginable Pain		

(0 No pain =**5**; 1, 2, or 3 =**4**; 4, 5, or 6 =**3**; 7, 8, or 9 =**2**; 10 worst pain imaginable =**1**)



**QRC**||STHLM  
KVALITETSREGISTERCENTRUM

# Conference: **PROMIS®: MEASURING HEALTH OUTCOMES AROUND THE WORLD**



Sunday, October 23 - Monday, October 24, 2016

Radisson Blu Scandinavia, Copenhagen, Denmark

Registration: <https://www.regonline.com/PHO2016conference>

## **Conference Fees:**

- Professionals: \$200 USD
- Students: \$100 USD