

Dutch-Flemish translation and validation of PROMIS

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1. PROMIS

- Conceptual model
- Item banks

2. Dutch-Flemish PROMIS

- Translation
- Validation
- Implementation

Patient Reported Outcomes Measurement Information System

Initiative of 6 US research groups and the National Institutes of Health (NIH), funded by the NIH (2004)

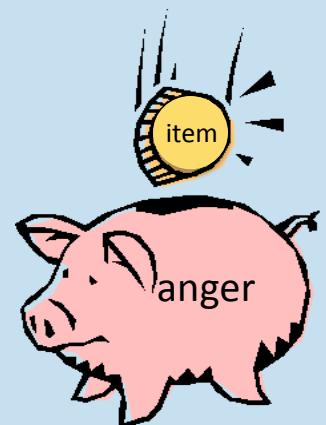
PROMIS aims to provide clinicians and researchers access to efficient, precise, valid, and responsive adult- and child-reported measures of health and well-being.

www.nihpromis.org



The PROMIS system

1. PROMIS consists of a collection of item banks
 - Large series of questions (items)
 - All measuring the same concept (unidimensional domains)
 - The concepts are generic, i.e. applicable in all (patient) populations
2. All items have been calibrated on the same scale using Item Response Theory (IRT) methods
3. Items can be selected from an item bank for use in research or clinical practice
 - As questionnaire
 - As Computer Adaptive Test (CAT)



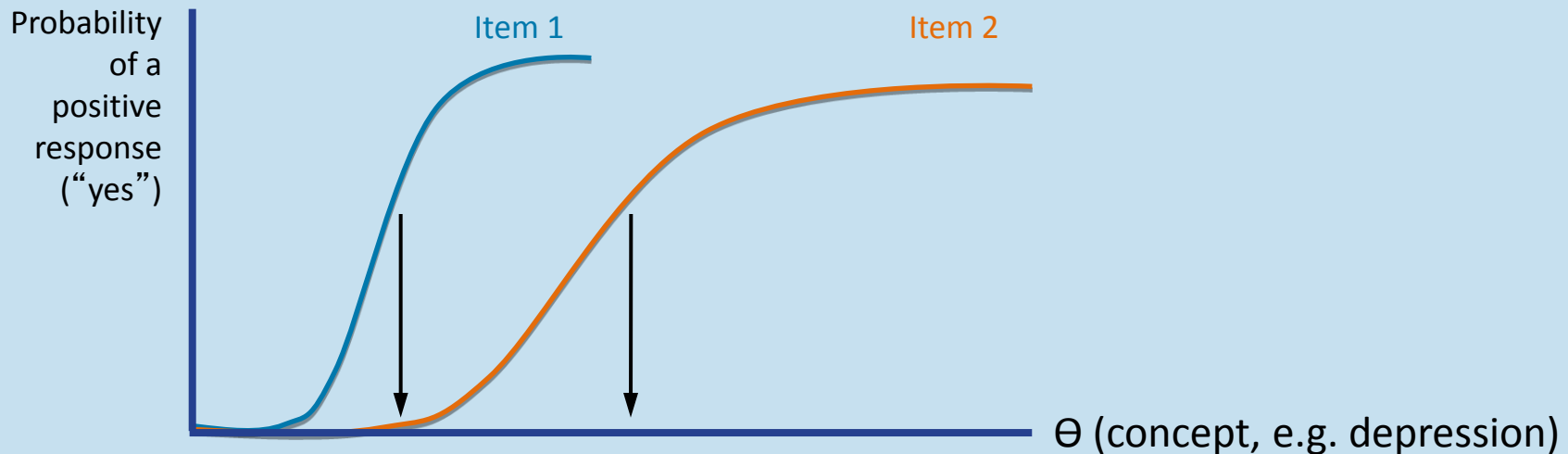
Item Response Theory (IRT)

- Characteristics of an IRT-based questionnaire:
 - Each item has its own 'location' on the scale
 - The items are ordered from 'easy' to 'difficult'
 - The distances between the item locations are known
 - Scores are on interval level instead of ordinal level
- Persons are placed on the same scale as the items



How does IRT work?

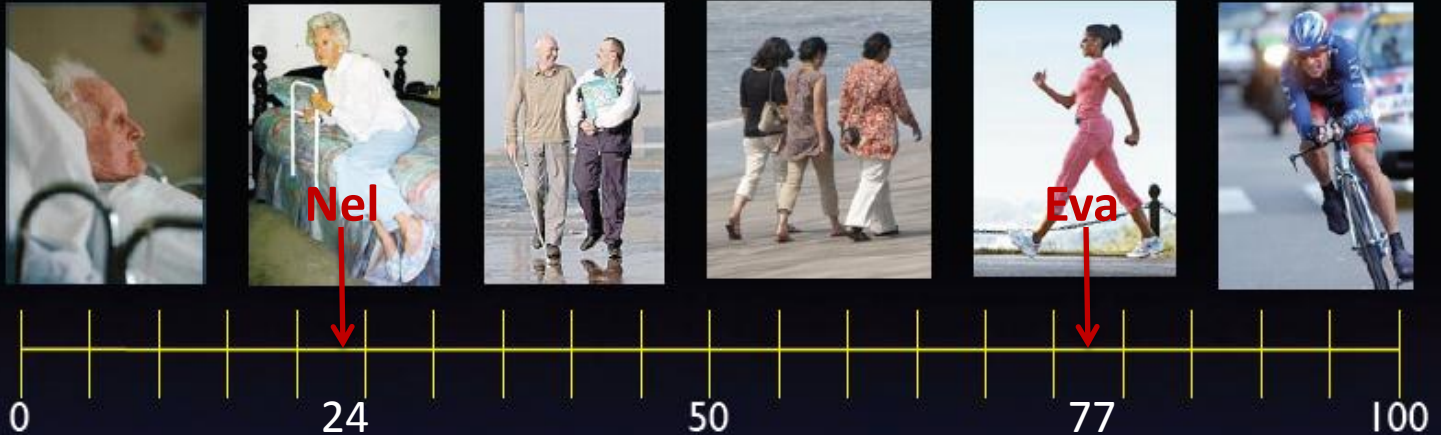
Each item has an Item Characteristic Curve



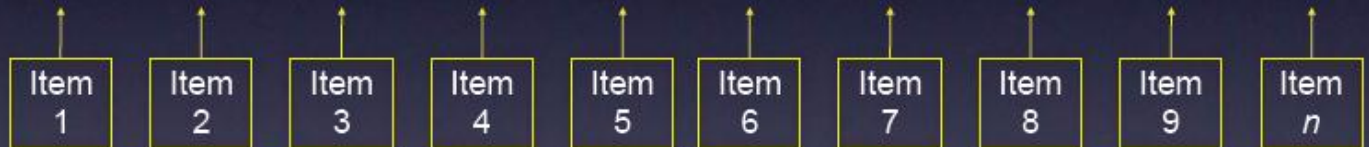
Item response function:
$$P_i(q) = \frac{e^{a(q-b_i)}}{1 + e^{a(q-b_i)}}$$

- Θ (theta) = concept being measured
- a = discriminative ability
- b = item location (difficulty)

Example IRT item bank



Physical Functioning Item Bank



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?

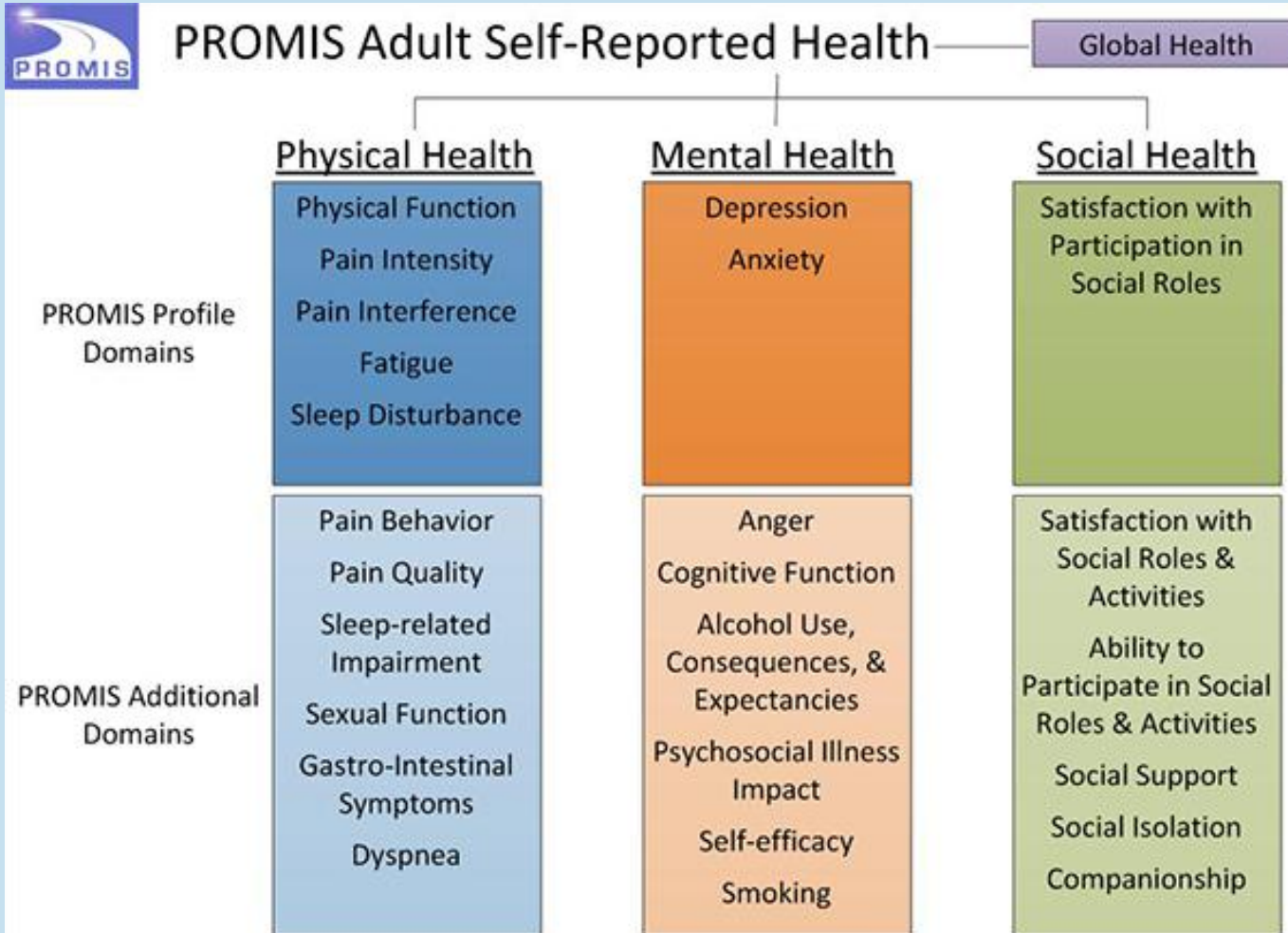
How does CAT work?

- Questionnaires are administered by computer
- The computer selects items from an item bank
- The items are selected based on answers to previous items (adaptive)
- After each item theta (with confidence interval) is being estimated
- When the confidence interval becomes small enough the computer stops asking questions (average 3-7 items)

Demo: www.assessmentcenter.net



PROMIS domain framework



2012:

- 502 active studies with 26,365 participants

2014:

- >285 publications

PROMIS is being used in

- DSM-5 field trials
- US Department of Defense management
- Population health monitoring
 - National Health Interview Survey (since 1957)
 - RAND American Life Panel
 - Healthy People 2020

New gold
standard for
measuring
PROs



- Dr. Caroline Terwee, VU Medisch Centrum, Afdeling Epidemiologie en Biostatistiek
- Dr. Leo D. Roorda, Reade, Centrum voor Revalidatie en Reumatologie
- Dr. N. Smits, Vu, Afdeling Klinische psychologie
- Prof.dr.ir. Riekje de Vet, VU Medisch Centrum, Afdeling Epidemiologie en Biostatistiek
- Prof.dr. Joost Dekker, VU Medisch Centrum, Afdeling Revalidatiegeneeskunde en Afdeling Psychiatrie
- Prof.dr. René Westhovens, Katholieke Universiteit Leuven, Afdeling Reumatologie
- Jaap van Leeuwen, CEO Leones Group bv
- Dave Cella, Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, US
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- Prof.dr. Martha Grootenhuis, Academisch Medisch Centrum, Universiteit van Amsterdam, Afdeling Kindergeneeskunde
- Dr. Lotte Haverman, Academisch Medisch Centrum, Universiteit van Amsterdam, Afdeling Kindergeneeskunde, Emma Kinderziekenhuis
- Prof.dr. Hein Raat, Erasmus MC, Maatschappelijke GezondheidsZorg
- Dr. Eline van Dulmer-den Broeder, VU Medisch Centrum, Afdeling Kindergeneeskunde
- Dr. Marion van Rossum, Academisch Medisch Centrum, Universiteit van Amsterdam, Afdeling Kinder Immunologie en reumatologie
- Prof.dr. Karel Hoppenbrouwers, Katholieke Universiteit Leuven, Afdeling Jeugdgezondheidszorg

Translation

- 26 item banks (17 adults, 9 children)
- 4 forward translations (2 NL, 2 BE)
- 1 reconciled version
- 2 back translations
- 3 independent reviews (2 NL, 1 BE)
- Preliminary translation

Testing

- Pilot testing in ≥ 75 people from the Dutch and Flemish general population
- Final translation
- 9 item banks (16 items) have a separate Dutch and Flemish version

Terwee CB, Roorda LD, de Vet HCW, Dekker J, Westhovens R, van Leeuwen J, Cella D, Correia H, Arnold B, Perez B, Boers M. Dutch-Flemish translation of 17 item banks from the Patient Reported Outcomes Measurement Information System (PROMIS). Qual Lif Res 2014 Jan 9. [Epub ahead of print].

Volwassenen	# items
Boosheid	22
Angst	29
Depressie	28
Vermoeidheid	95
Reacties op pijn	39
Belemmeringen door pijn	40
Lichamelijk functioneren	121
Slaap stoornissen	27
Problemen door slaapstoornissen	16
Vermogen aandeel te hebben in sociale rollen en activiteiten	35
Tevredenheid met sociale rollen en activiteiten	44
Gezelschap	6
Emotionele steun	16
Steun bij het verkrijgen en begrijpen van informatie	10
Praktische steun	11
Sociale isolatie	14
Global	10
Total	563

Kinderen	# items
Boosheid	5
Angst	13
Asthma	17
Depressieve klachten	13
Vermoeidheid	23
Lichamelijk functioneren- Mobiliteit	23
Lichamelijk functioneren- bovenste Extremititeit	29
Belemmeringen door pijn	13
Relaties met peers	15
Total	151

Short forms:

- Availability of good validation data previous to the translation and a **good quality translation**

Item banks/CATs

- Preliminary release: Availability of good validation data previous to the translation and a good quality translation
- Full release: an evaluation of **Differential Item Functioning** (DIF) between language groups and within relevant sub-groups

Aims

- Calibration of IRT model (model fit, item quality)
- Differential Item Functioning language (EN/NL)

Design

- Cross-sectional studies
- Relevante patient populations
- Sample size: > 1000 for calibration
- IRT analyses: assumptions of unidimensionality, local independence, monotonicity; GRM fit, item parameters, DIF

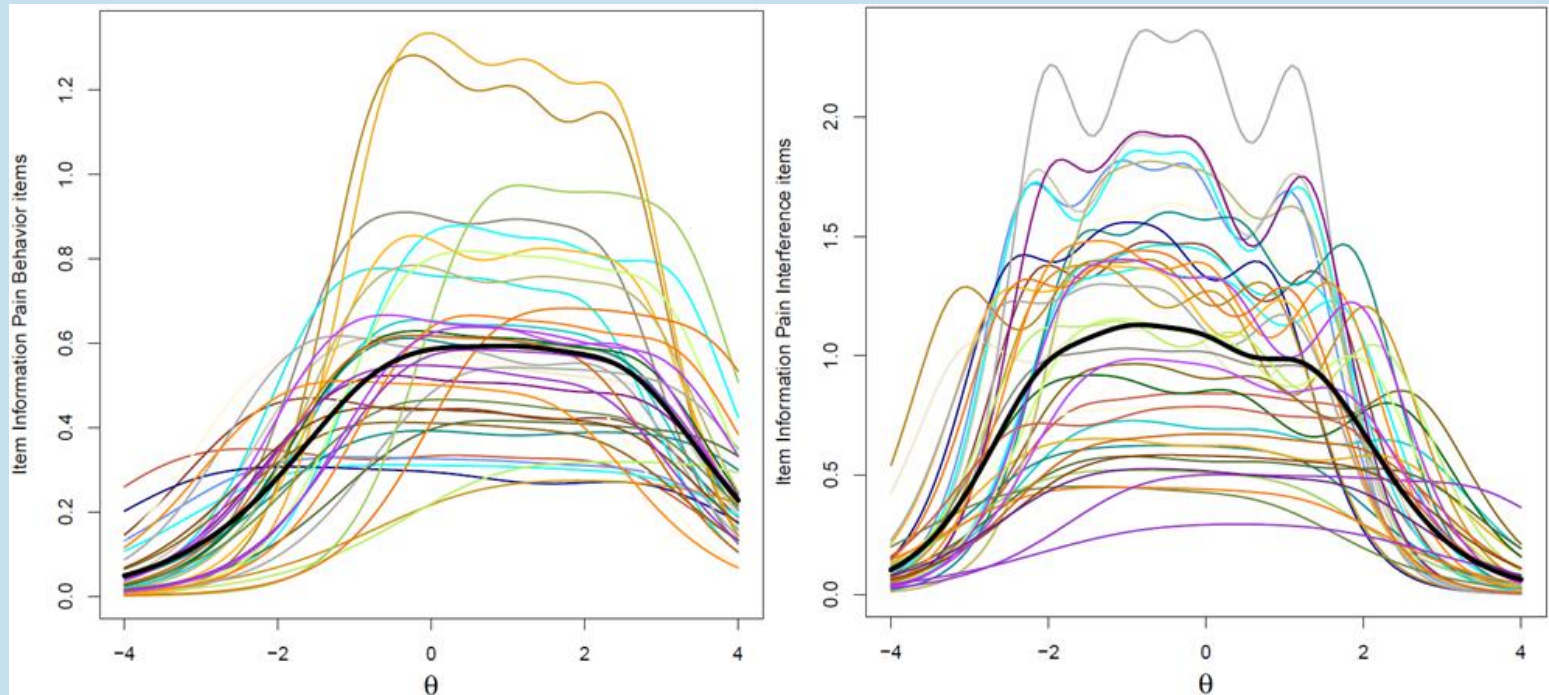
1. Reade: physical functioning, pain behavior, pain interference, global health in >1000 chronic pain patients
2. Twente: physical functioning in 690 RA patients
3. Dutch Society orthomanual physicians: pain behavior, pain interference in >1000 chronic pain patients
4. Stichting Benchmark GGZ: anxiety, depression in >1000 patients treated in GGZ
5. Hoensbroek: ability to participate in social roles and activities, satisfaction with social roles and activities in 500-1000 patient receiving rehabilitation:
6. KNGF: physical functioning in 1000 patients receiving physiotherapy
7. Vumc, pediatrics: sleep disturbances, sleep-related impairment in >1000 adolescents

8. Reade, CHECK: physical functioning in early OA
9. Reade, Leuven: pain behaviour, pain interference, fatigue, global health in RA patients
10. AMC, pediatrics: Juvenile arthritis
11. Twente: COPD patients
12. WKZ-UMC Utrecht: fatigue in children with SMA

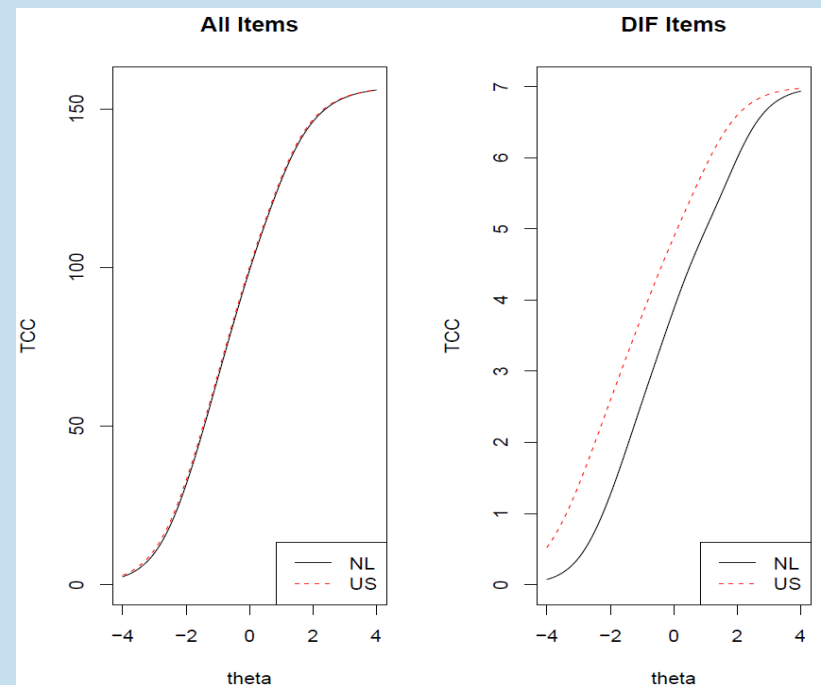
- Reade: 1046 chronic pain patients
- PROMIS pain behavior (39) and PROMIS pain interference (40) item banks
- Good fit to a one-dimensional model:
 - *Pain behavior: CFI=0.963, TLI=0.961, 42% of the variance explained by the first factor*
 - *Pain interference: CFI=0.961, TLI=0.987, 66% of the variance explained by the first factor*

First results

Acceptable information ($SE < 0.3$) for theta between -1.9 and 3.6 for pain behavior and between -3.3 and 2.8 for pain interference



- 23 out of 741 (3%) pain behavior item pairs and 62 out of 820 (7.6%) pain interference item pairs marked as possibly locally dependent
- No DIF with respect to age, gender, and survey version
- DIF with respect to language: 6 DF-PROMIS-PB items and 2 DF-PROMIS-PI items
- The impact of DIF on the total item scores is minimal



*Relation of total item score (TCC) and Theta, for all items and the Items with DIF
Left: pain behavior Right: pain interference*

Conclusions

- The item banks pain behavior and pain interference fit a GRM and demonstrate good coverage across the range of the pain behavior and pain interference domain
- Nearly all Dutch item parameters match the American item parameters and likely Dutch-specific item calibrations are not needed
- The item banks can be used to develop a CAT

BIG ISSUE

- >35 CATs, many users

Need

- CAT software (CAT generating software)
- Central web-based management tool
 - *Server*
 - *Database*
 - *Participant interface for completing CATs*
 - *Administration*
 - *Feedback, reports*
 - *Security, privacy, link to EPD*
- Expertise
- Money



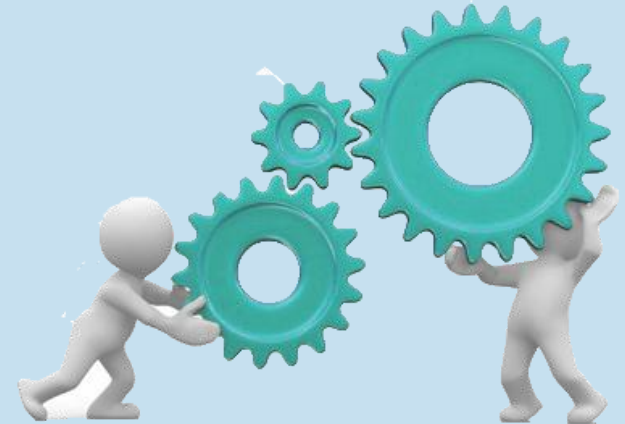
Developing functional design

Exploring possibilities

- www.assessmentcenter.net
- Cooperate with commercial companies
- Open-source software

Pilot test June 2014 (SBG)

Sustainability



- Oct 2006 First conversation with Dave Cella
- Dec 2008 First meeting Dutch-Flemish PROMIS group
- Juli 2010 Grant for translation (Reumafonds)
- April 2011 Signed contract with FACITtrans and PROMIS
- May 2011 Letter of permission to translate PROMIS
- June 2012 Translation of first item bank ready
- Sep 2012 Start first validation study
- Nov 2012 Translation of 26th item bank ready
- March 2013 Launch www.dutchflemishpromis.nl
- Jan 2014 First publication (Terwee et al QLR 2014)
- Feb 2014 Release of first short forms
- *June 2014 First 2 CATs running*

