ASSESSMENT CENTER OVERVIEW AND DEMONSTRATION STUDY

Nan Rothrock, Ph.D.
Department of Medical Social Sciences
May 17, 2011
ASSESSMENT CENTER
Why did we create it?

• PROMIS investment in creation of item banks that can be administered as CATs
• No off-the-shelf platform for CAT administration to participants
• All researchers have more than CATs in a single study
What is Assessment Center?

- Web-based research management tool
- Enables creation of study-specific URLs
  - Participant interface for data collection
  - Administration of PROMIS short forms and CATs
  - Administration of other PRO instruments
    - Can create custom short forms
- Single time-point or multiple timepoint studies
More Features

- Item Development features
  - Tracking item revisions
- Multiple study arms
- Multiple levels of randomization
- Researcher-completed instruments
Even More Features

- Automated accrual reports
  - NIH accrual report format
- Real-time data export
  - Separation of PRO data, registration data (PHI), and consent data (more PHI)
- Patient-level single-timepoint data reports
- Automated data dictionary
- Assessment Center Offline
  - Non-internet data collection platform
- Free
Assessment Center
Instrument Library

• Distribution mechanism for PROMIS item banks, short forms, and profiles
  • Adult and pediatric (pediatric proxy coming soon)
• Online administration or download PDFs
• Coming Soon to the Library:
  • PROMIS Cancer Supplement instruments
  • Neuro-QOL instruments
Planned New Features (2011-2013)

• Data collection for hand held device (e.g., smartphone)
• Increased reporting and tracking features
• Additional CAT engines
• Improved usability
2010 Assessment Center
Use Statistics

- >2600 registered researchers world wide
- >17,000 participants
- 1.6 million data points captured
Demonstration Study: Participant Interface

Welcome to the Quality of Life Study!

Thank you for your participation. The following survey will take about 15 minutes to complete. Contact Nan at the email below if you have questions.

If you already have a Login and Password, please enter them in the boxes and click Start below.

Login
Password

If you are a first time user, click Start below.

Start

If you have any questions or problems, please contact n-rothrock@northwestern.edu.
If you would like to bookmark this page, click this Add to Favorites link.
Optional Online Consent Forms

PAYMENT FOR PARTICIPATION:
You will not be paid for being in this study.

ADDITIONAL COSTS:
There is expected to be no additional cost to you from being in this research study.

EXPLANATION OF ABILITY TO WITHDRAW FROM STUDY:
Your participation in this research study is voluntary. If you decide not to be in this study, your membership in the American Chronic Pain Association will not be jeopardized. If you decide to participate now, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

YOUR RIGHTS AS A RESEARCH SUBJECT:
You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at (224) 364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

CONSENT TO PARTICIPATE:
I understand that the activities will be supervised by David Cell, Ph.D. and whomever he may designate as his assistants. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I have been told about all of my treatment options. I give permission for the research study procedures described in this consent form.
I have read and have had the opportunity to call or email to have any questions or concerns answered. I willingly consent to be a part of this study. I will be able to print an unsigned copy of this Consent Form.

I accept [ ]
Please type in your full name Rahm Emanuel [ ]
Continue
Demographic Information

Age: 52
Ethnicity: Not Hispanic or Latino
Gender: Female
Race: White

Continue
Protected Health Information

Assessment Center

Please complete all applicable registration information below.
All information will be kept confidential.

Last Name: Emanuel
First Name: Rahm

Continue
Login and Password Generation

Click the button below to begin the survey. Your participation in the study is appreciated. Below is your password for the study. Please write down this login and password for your records.

Your Login (J1037) and Password (fjj)

Begin
To begin, please answer some questions about your medical history.
When were you diagnosed with cancer?

- Feb
- 1987
- 1988
- 1989
- 1990
- 1991
- 1992
- 1993
- 1994
- 1995
- 1996
- 1997
- 1998
- 1999
- 2000
- 2001
- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
- 2008
- 2009
- 2010
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016

Previous  Next  Exit
Multiple Choice Item

Assessment Center

Are any of your current activities limited by your cancer?

No

Yes

Previous  Next  Exit
Drop List Item

Please select your "primary" cancer diagnosis from the list below (usually where the cancer started).

- Brain
- Breast
- Colon or Rectum
- Gynecologic (Cervical, Ovarian, Uterine)
- Head Neck
- Leukemia/Lymphoma
- Lung
- Pancreas
- Prostate
- Urologic (Bladder, Kidney, Testis)
Have you had a recurrence of your cancer (i.e., has your cancer come back)?

- No
- Yes
- Not Sure
Has your cancer spread to any lymph nodes?

- No
- Yes
- Not Sure
Branching

Assessment Center

Do you currently have any numbness, tingling, or pain in your hands or feet?

No

Yes

Previous  Next  Exit
Branching

Assessment Center

Please rate the severity of your numbness, tingling, or pain in your hands or feet.

0 1 2 3 4 5 6 7 8 9 10
No pain Worst pain imaginable

Previous Next Exit
What treatment(s) have you received for your cancer in the past month? Check all that apply.

- [ ] Radiation therapy
- [ ] Hormonal therapy (e.g., Tamoxifen, Arimidex, Aromasin, Lupron)
- [x] Chemotherapy (by shot, infusion, or by pill)
- [ ] Immunotherapy (e.g., Interferon)
- [ ] Other
- [ ] I have not received any treatment for cancer in the past month
Patient Reported ECOG Performance Status

Please indicate which statement best describes your current activity level.

- Normal activities, without symptoms
- Some symptoms, but do not require bed rest during waking day
- Require bed rest for less than 50% of waking day
- Require bed rest for more than 50% of waking day
- Unable to get out of bed

Previous  Next  Exit
These next questions ask about your thinking.
In the past 7 days,

I have had to work harder than usual to keep track of what I was doing

- Never
- Rarely (Once)
- Sometimes (Two or three times)
- Often (About once a day)
- Very often (Several times a day)
Item 2

In the past 7 days
My thinking has been slow

- Never
- Rarely (Once)
- Sometimes (Two or three times)
- Often (About once a day)
- Very often (Several times a day)

Previous  Next  Exit
In the past 7 days

I have had trouble shifting back and forth between different activities that require thinking

- Never
- Rarely (Once)
- Sometimes (Two or three times)
- Often (About once a day)
- Very often (Several times a day)
Item 4

In the past 7 days

It has seemed like my brain was not working as well as usual

- Never
- Rarely (Once)
- Sometimes (Two or three times)
- Often (About once a day)
- Very often (Several times a day)
In the past 7 days

My ability to concentrate has been good

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much
In the past 7 days
My mind has been as sharp as usual

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much
Item 3

In the past 7 days
I have been able to think clearly without extra effort

Not at all
A little bit
Somewhat
Quite a bit
Very much
In the past 7 days
I have been able to mentally focus
Not at all
A little bit
Somewhat
Quite a bit
Very much
The next section asks questions about how you were *before* your illness and *now.*
Thinking about how your illness has affected you, please rate how true this statement was of you before your illness, and again now, since your illness.

I feel isolated from others

How true was this before your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

How true is this now, since your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much
Thinking about how your illness has affected you, please rate how true this statement was of you before your illness, and again now, since your illness.

I feel disconnected from others

How true was this before your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Clear Response

How true is this now, since your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Clear Response
Item 3

Thinking about how your illness has affected you, please rate how true this statement was of you before your illness, and again now, since your illness.

I have a negative attitude toward myself

How true was this before your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Clear Response

How true is this now, since your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Clear Response

Previous | Next | Exit
Thinking about how your illness has affected you, please rate how true this statement was of you before your illness, and again now, since your illness.

I feel helpless

How true was this before your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

How true is this now, since your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much
Thinking about how your illness has affected you, please rate how true this statement was of you before your illness, and again now, since your illness.

My life is meaningful

How true was this before your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

How true is this now, since your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much
Thinking about how your illness has affected you, please rate how true this statement was of you before your illness, and again now, since your illness.

I can appreciate each day fully

How true was this before your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

How true is this now, since your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Clear Response

Clear Response
Item 3

Thinking about how your illness has affected you, please rate how true this statement was of you before your illness, and again now, since your illness.

I look at things in a positive way

How true was this before your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Clear Response

How true is this now, since your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Clear Response
Thinking about how your illness has affected you, please rate how true this statement was of you before your illness, and again now, since your illness.

I have a sense of peace

How true was this before your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

How true is this now, since your illness?
- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much
Feel free to provide any additional comments about this survey.

Thank you for the opportunity to participate in this important study about cancer patients' quality of life.
Thank you for completing this survey. You will be contacted to complete a similar survey in about 3 months. This provides information on how people change over time. Contact n-rothrock@northwestern.edu if you have any questions.
Assessment Center Homepage
www.assessmentcenter.net

WHAT IS ASSESSMENT CENTER℠

Assessment Center℠ is a free, online research management tool. It enables researchers to create study-specific websites for capturing participant data securely. Studies can include measures within the Assessment Center library as well as custom instruments created or entered by the researcher. PROMIS instruments (short forms, CATs, profiles) are a central feature of the instrument library within Assessment Center. Any PROMIS measure can be downloaded for administration on paper or be included in an online study. Detailed statistical information and development history about PROMIS items and instruments is available for review.

Assessment Center enables customization of items or instruments (e.g., format, randomization, skip patterns), real-time scoring of CATs, storage of protected health information in a separate, secure database, automated accrual reports, real-time data export, graphing of individual CAT or profile scores, and ability to capture endorsement of online consent forms among many other features.

ANNOUNCEMENTS

Assessment Center Workshop

Learn more about PROMIS, item response theory, computerized adaptive testing, and Assessment Center at a full day workshop on May 20, 2011 in Chicago. For more information, click the Workshops hyperlink on the left.

New Scoring Manuals

From the Scoring Manual hyperlink on the left you can access PDFs of scoring information for the PROMIS original short forms, Profile short forms, and Computerized Adaptive Tests.

Demonstration CAT

Adapt a PROMIS Computerized Adaptive Test and get an instant score report. CATs include Emotional, Physical, and Social Health. Click here to begin.

Sponsors

PROMIS
Neuro-QOL
NIH Toolbox

Assessment Center reserves the right to have regular scheduled maintenance windows. Weekly maintenance may be performed on Sunday mornings from 7am to 9am CST. During this time, Assessment Center may be unavailable. We apologize for any inconvenience this may have. If you have any questions, please contact us at help@assessmentcenter.net.
Researcher Interface
Instruments Tab

### Study Content

**Click the Add button to add instruments to your study. Click the Create button to create custom instruments in your study.**

You have selected the following instruments for this study:

**Order** | **Name** | **Administration Study**
--- | --- | ---
1 | demo intro transition | Training Demonstration Study
2 | APOS Clinical | APOS Demonstration Study
3 | APOS ECMG patient | APOS Demonstration Study
4 | transition to cognition | APOS Demonstration Study
5 | PROMIS Bank v1.0 – Applied Cog General Concerns | PROMIS

**Include** | **Terms of Use**
--- | ---
✓ | Notes
✓ | Notes
✓ | Notes
✓ | Notes
✓ | Notes

To exclude an instrument from your study, click on the Include checkbox.
Set-Up Tab

Assessment Center

Basic Study Setup

- Data collection has begun on this study and some fields cannot be changed.

You may define participant registration forms below.

Start Date**: 2/11/2011
Accrual End Date**: 2/11/2013
Close data collection when sample size equals**: 100
Contact information for participant questions**: n-rothrock@northwestern.edu
URL Extension**: https://www.assessmentcenter.net/ac1/Assessments/APOSDemonstrationStudy

Login screen welcome message (maximum 10,000 characters)

Robert H. Lurie Comprehensive Cancer Center of Northwestern University
Administration Tab
# NIH Accrual Report

## Inclusion Enrollment Report

### PART A TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

<table>
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<tr>
<th>Ethnic Category</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
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<td>Ethnic Category: Total of All Subjects</td>
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<td>1</td>
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</tbody>
</table>

### Racial Category

<table>
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<tr>
<th>Racial Category</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
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<td>Black or African American</td>
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### APOS Clinical

<table>
<thead>
<tr>
<th>APOS Clin7</th>
<th>When were you diagnosed with cancer?</th>
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<tbody>
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<td></td>
<td>TEXT_DATE</td>
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</tbody>
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<table>
<thead>
<tr>
<th>APOS Clin1</th>
<th>Are any of your current activities limited by your cancer?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>1</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>APOS Clin2</th>
<th>Please select your &quot;primary&quot; cancer diagnosis from the list below (usually where the cancer started).</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Brain</td>
</tr>
<tr>
<td>2</td>
<td>Breast</td>
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<tr>
<td>3</td>
<td>Colon or Rectum</td>
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<tr>
<td>4</td>
<td>Gynecologic (Cervical, Ovarian, Uterine)</td>
</tr>
<tr>
<td>5</td>
<td>Head/Neck</td>
</tr>
<tr>
<td>6</td>
<td>Leukemia/Lymphoma</td>
</tr>
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<td>7</td>
<td>Lung</td>
</tr>
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<td>8</td>
<td>Pancreas</td>
</tr>
<tr>
<td>9</td>
<td>Prostate</td>
</tr>
<tr>
<td>10</td>
<td>Urologic (Bladder, Kidney, Tests)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>APOS Clin3</th>
<th>Have you had a recurrence of your cancer (i.e., has your cancer come back?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>1</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Not Sure</td>
</tr>
</tbody>
</table>
Researcher-Completed Instrument
Data Exports

Study Overview

To view a list of participants in this study, click the Participant List button below.

To create a new participant record, click the Find/Create Login button.

Table above and Exports are updated every 20 minutes. Last updated: 2/15/2011 5:23:17 PM

NIH Inclusion Enrollment Report
Data Dictionary Report
Enrollment Report
Data Extract
Export Assessment Data
Export Assessment Scores
Export Registration Data
Export Consent Data
Export Pivot Assessment Data
Pivoted Assessment Data Export

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## Consent Data Export

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Demographic/PHI Data Export

Study Name: APOS Demonstration Study

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### PROMIS Instrument Scores Export

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WHAT IS ASSESSMENT CENTER™

Assessment Center™ is a free, online research management tool. It enables researchers to create study-specific websites for capturing participant data securely. Studies can include measures within the Assessment Center library as well as custom instruments created or edited by the researcher. PROMIS instruments (short forms, CATs, profiles) are a central feature of the instrument library within Assessment Center. Any PROMIS measure can be downloaded for administration on paper or be included in an online study. Detailed statistical information and development history about PROMIS items and instruments is available for review.

Assessment Center enables customization of items or instruments (e.g., format, randomization, skip patterns), real-time scoring of CATs, storage of protected health information in a separate, secure database, automated accrual reports, real-time data export, graphing of individual CAT or profile scores, and ability to capture endorsement of online consent forms among many other features.

ANNOUNCEMENTS

Assessment Center Workshop

Learn more about PROMIS, item response theory, computerized adaptive testing, and Assessment Center at a full day workshop on May 20, 2011 in Chicago. For more information, click the Workshops hyperlink on the left.

New Scoring Manuals

From the Scoring Manual hyperlink on the left you can access PDFs of scoring information for the PROMIS original short forms, Profile short forms, and Computerized Adaptive Tests.
PROMIS has many assessment options available to measure self-reported health for clinical research and practice. PROMIS assessment instruments are drawn primarily from calibrated item banks (sets of well-defined and validated items) measuring concepts such as pain, fatigue, physical function, depression, anxiety and social function. These calibrated item banks can be used to derive short forms (typically requiring 4-10 items per concept), or computerized adaptive testing (typically requiring 3-7 items per concept for more precise measurement). Assessments are available for children and adults. Most PROMIS instruments are available through Assessment Center (www.assessmentcenter.net). Those which are not yet available on Assessment Center can be obtained by contacting the PROMIS Statistical Center through help@assessmentcenter.net. Assessment Center can be utilized for online or offline computer-based administration or instruments can be downloaded for paper administration or entry into other data collection platforms.

Tables 1 and 2 list the calibrated item banks, short forms, and profiles (a fixed collection of short forms measuring 7 of the most important PROMIS concepts). Table 3 highlights instruments soon to be available in Assessment Center.

Table 1: PROMIS Item Banks and Short Forms Available on Assessment Center (www.assessmentcenter.net)

<table>
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<th>Pediatric - # items</th>
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Scoring Manuals

PROMIS Scoring Manuals describe how individual PROMIS instruments or measures are scored. Additional information about how they are available for the measures listed below. Note that the instruments themselves can be accessed within Assessment Center’s “Resources” hyp

Overview
PROMIS Global Health short form
PROMIS Pediatric short forms

Adult v1.0 Short Forms
Introduction
Anger
Anxiety
Depression
Fatigue
Pain Behavior
Pain Interference
Physical Function
Satisfaction with Participation in Discretionary Social Activities
Sleep Disturbance
Sleep-Related Impairment

Adult v1.0 Profile short Forms
Introduction
Anxiety
Depression
Sample Scoring Manual

SCORING THE INSTRUMENT

Each question has five response options ranging in value from one to five. To find the total raw score, sum the values of the response to each question. For example, for the eight-item form, the lowest possible raw score is 8; the highest possible raw score is 40 (Table 1).

You can use Table 1 to translate the total raw score into a T-score for each participant. The T-score rescales the raw score into a standardized score with a mean of 50 and a standard deviation (SD) of 10. Therefore, a person who has a T-score of 40 is one SD below the U.S. general population mean. These conversions are accurate ONLY when all questions on the short form have been answered. For the 8-item form, a raw score of 24 converts to a T-score of 61.6 with a standard error (SE) of 1.8. Thus, the 95% confidence interval around the actual observed score ranges from 58.1 to 65.1 (T-score ± 1.96*SE) = 61.6 ± 3.5 = 58.1 to 65.1.

**Important:** A higher PROMIS T-score represents more of the concept being measured. For negatively-worded concepts like depression, a T-score of 60 is one SD worse than average. By comparison, a depression T-score of 40 is one SD better than average.

You can upload data to a free computer program called PROMIScore, which will score your data one person at a time or as a group. PROMIScore is particularly useful because it can calculate T-scores even when there are missing responses. The PROMIScore software and user manual are available for download at nihpromis.org.

STATISTICAL CHARACTERISTICS

There are three key features of the score for depression:

- **Reliability:** The degree to which a measure is free of error. It can be estimated by the internal consistency of the responses to the
Welcome to PROMIS

PROMIS®
Patient-Reported Outcomes Measurement System®
Health Outcome Measures from the Patient Perspective.

The Patient-Reported Outcomes Measurement Information System (PROMIS) is a network of NIH-funded primary research sites and coordinating centers working collaboratively to develop a series of dynamic tools to reliably and validly measure patient-reported outcomes (PROs). PROMIS provides an opportunity to improve healthcare outcomes by giving decision makers hard data on how healthcare affects what patients are able to do and how they feel. The information is derived from patient responses to a set of rigorously designed questions about different aspects of health-related quality of life (pain, fatigue, anxiety, depression, social functioning, physical functioning, quality of sleep, etc.). Each measure is subjected to a multi-stage development and testing program to ensure that the information meets scientific standards of reliability with the goal to enable clinicians and researchers to have access to efficient, precise, valid, and responsive indicators of a person’s health status. These measures are available for use across a wide variety of chronic diseases and conditions and in the general population. PROMIS efforts are supported through three main centers that include the PROMIS Statistical Center (PSC), PROMIS Network Center (PNC) and the PROMIS Technical Center (PTC).

PROMIS® Statistical Center

The PROMIS Statistical Center℠ (PSC) advises and educates members of the network on a range of qualitative and quantitative research methods, develops and implements processes to ensure data quality; provides leadership in the development of PROMIS approved translations of new and extant domains; assists in the development and implementation of protocols; provides consultation on research design, sample size, sampling plans and power estimates for item bank testing; provides psychometric and statistical support for the network; and works collaboratively with the PROMIS Network to create sustainability.
More Information

PROMIS:  www.nihPROMIS.org
- Live CAT demonstration with score report
- Item development histories, protocols

Assessment Center:  www.assessmentcenter.net
- Assessment Center User Manual
- Assessment Center Online Help

Training Workshops
- www.assessmentcenter.net
Acknowledgements

• National Institutes of Health (Grants U54 AR 057943, U05 AR 057951, U01 AR 052177)