

Session 4:
**Social/Digital Media: The Future of
Qualitative Data Collection in the
Context of Labeling**

***FIFTH ANNUAL
PATIENT-REPORTED OUTCOME (PRO) CONSORTIUM WORKSHOP***

April 29 - 30, 2014 ■ Silver Spring, MD

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Session Objectives



- Gain greater understanding of techniques used to conduct qualitative research using digital media
- Provide examples of the implementation of some of these techniques used for concept elicitation with a single social media platform
- Discuss the advantages and disadvantages of using digital media to collect data used in the context of labeling
- Consider how the health care enterprise can move forward with the use of digital media to enhance our understanding of how patients experience their health and treatment.

Session Participants



- **Moderator**

- *Margaret Rothman, PhD* – Senior Director, PRO Group, Janssen Pharmaceutical Companies of Johnson and Johnson

- **Presenters and Panelists**

- *Trena M. Paulus, PhD* - Associate Professor and Coordinator of the Graduate Certificate in Qualitative Research Methods, Department of Educational Psychology and Counseling, University of Tennessee
- *Paul Wicks, PhD* – Vice President of Innovation, PatientsLikeMe
- *Elektra Papadopoulos, MD, MPH* – Team Leader, Study Endpoints Team, SEALD, OND, CDER, FDA
- *Tara Symonds, PhD* – Senior Director and Head, PRO Center of Excellence, Pfizer

Digital tools for qualitative data collection

Trena M. Paulus, Ph.D.

University of Tennessee

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Estimates from the New England Research Institutes (NERI) suggest developing a PRO from beginning to end takes **at least 24 months** and costs between **\$1m \$5m**, while estimates shared at the 2011 C-Path meeting suggest up to **4 years** for development and costs between **\$725k - \$2.1m**.

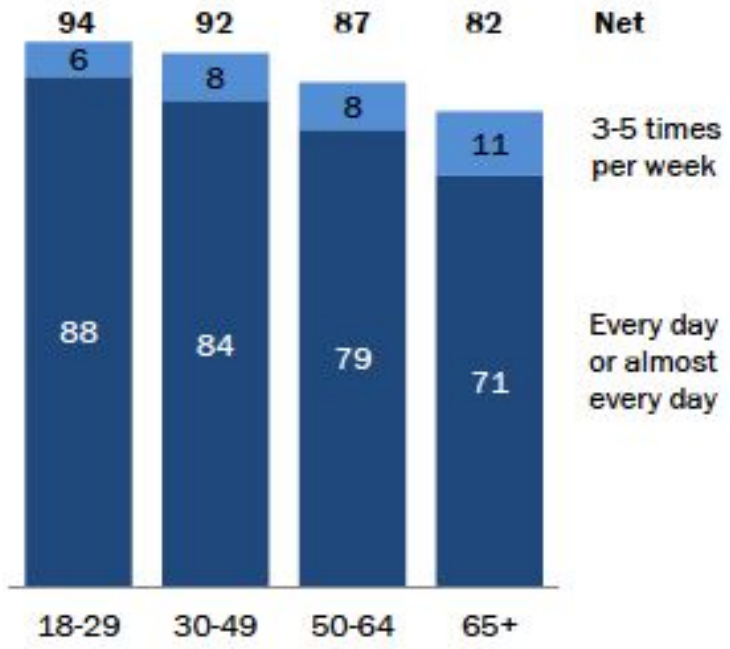
Hayes R. Patient-Reported Outcome (PRO) Instruments as Drug Development Tools (Session III). Consensus Science New Tools and Tactics for Next-Gen Drug Development., Washington, DC: 2011.

- Seven-in-ten (**72%**) adult internet users say they have searched online for information about a **range of health issues**, the most popular being specific diseases and treatments.
- One-in-four (**26%**) adult internet users say they have read or watched **someone else's health experience** about health or medical issues in the past 12 months.
- **16%** of adult internet users in the U.S. have gone online in the past 12 months to **find others who share** the same health concerns.

S. Fox (Jan 15, 2014) The social life of health information. Pew Research Center.

A majority of older internet users go online on a daily basis

% of internet users in each age group who go online ...



Pew Research Center's Internet Project July 18-September 30, 2013 tracking survey.

PEW RESEARCH CENTER

Qualitative data types

- **Researcher-generated** (technologies as **tools**)
 - Focus groups
 - Interviews
 - Surveys
 - *Online interviews & focus groups
 - *Mobile devices
- **Naturally-occurring** (technologies as **contexts**)
 - Observations
 - Conversations
 - Documents
 - *Online communities & social media interactions

Digital tools & qualitative data




1. Online interviews & focus groups
2. Online communities & social media
3. Mobile devices

Online interviews & focus groups

Online interviews & focus groups

- **Asynchronous** (different place, different time)
 - E-mail
 - Discussion forums
 - Social media (blurs the boundary)
- **Synchronous** (different place, same time)
 - (Phone, SMS/text messages)
 - Facebook chat
 - Skype video (with chat)
 - Google Hangout video (with chat)
 - Video messaging (blurs the boundary)

Online interviews & focus groups


Thread: type II diabetes  Be the first of your friends to like this.

Thread Tools Search Thread Dis


Hybrid View

- mosyalong type II diabetes** 12-14-2013, 00:27
 - Wise Old Owl** *Well you are in the right...* 12-14-2013, 00:32
 - JAK** *Interesting link. Love the...* 12-14-2013, 09:28
 - d3v** *type II diabetes is a piece...* 12-14-2013, 16:34
 - Slo-go\'en** *I don't think it's so much a...* 12-14-2013, 18:00
 - max patch** *I had a doctor who had me try...* 12-14-2013, 18:08
 - Donwood** *I will sav this in direct* 12-14-2013 10:31


12-14-2013, 00:27

mosyalong 
Registered User


Join Date:	12-01-2013
Location:	arkansas
Age:	63
Posts:	2


 **type II diabetes**

hello, I am mosyalong. I plan to hike in 2014. no experience. there have been some threads about type II diabetes. There is a web site that says whole food chromium will fix it in a matter of months. It's not a disease but a condition. www.notadoc.org. looking forward to the trail and meeting many of you.


 Reply With

12-14-2013, 00:32

Wise Old Owl 
Section Hiker



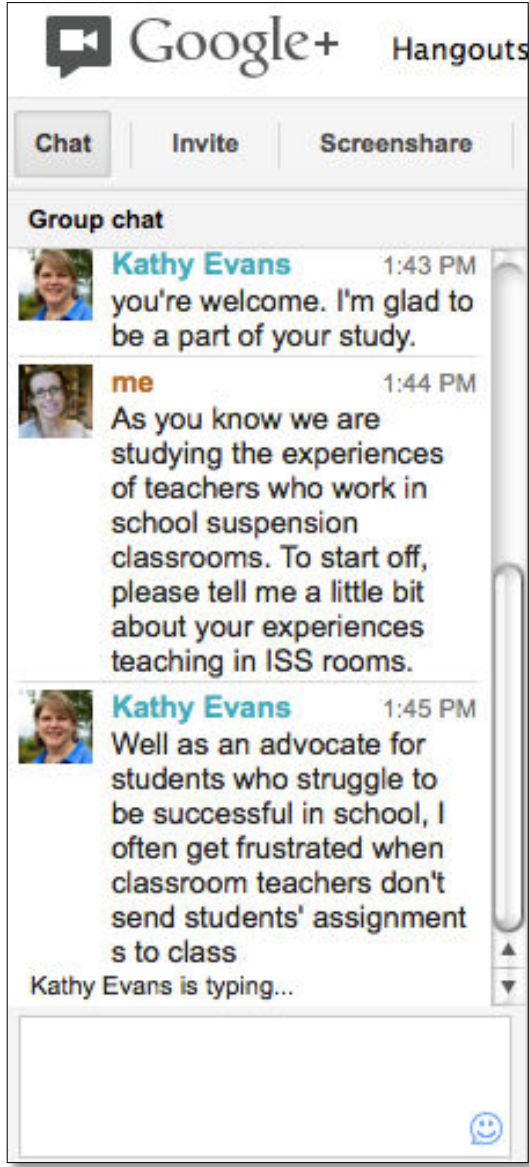
Join Date:	01-29-2007
Location:	High up in an old tree
Posts:	13,565



Well you are in the right place and welcome - I have no experience with Diabetes, but many here can help you. As a new member I hope you stick it out and if you need additional help I have a few friends in backpacking that can help you ...

- **Asynchronous focus groups** (Tates et al., 2009):
 - Access to hard to reach populations
 - Cost & time saving for researchers
 - Accurate & automatic capture of data
 - Participant convenience & comfort
 - Greater self-disclosure
 - Lack of time pressure & greater reflection
 - Selection bias
 - Digital divide
 - Lurkers
 - Lack of visual cues


Online interviews & focus groups





Google+ Hangouts

Chat | Invite | Screenshare


Group chat

 **Kathy Evans** 1:43 PM
you're welcome. I'm glad to be a part of your study.

 **me** 1:44 PM
As you know we are studying the experiences of teachers who work in school suspension classrooms. To start off, please tell me a little bit about your experiences teaching in ISS rooms.

 **Kathy Evans** 1:45 PM
Well as an advocate for students who struggle to be successful in school, I often get frustrated when classroom teachers don't send students' assignments to class

Kathy Evans is typing...



Online interviews & focus groups



A screenshot of a Skype video call window. The window title is "Skype". In the top left corner, there is a contact profile for "JNINALESTER" with a small profile picture and a balance of "\$25.31". In the top right corner, there are icons for home, a plus sign, and a search bar labeled "Search". The main area shows a video feed of a woman with long dark hair in a room with framed pictures on the wall. A smaller video feed of a woman with glasses is visible in the top right corner of the main video area. Below the video feeds is a chat history showing a "Call started" notification at 2:32 PM, a message from "trena paulus" saying "See page 359" at 2:58 PM, and a message from "JNINALESTER" saying "I have been wondering if perhaps we can re-consider our first theme." at 2:58 PM. At the bottom, there is a text input field with a speech bubble icon on the left and a smiley face icon on the right.

- **Synchronous focus groups** with young people (Fox et al. 2007)
 - Dynamic, immediate, more similar to talk
 - Emotions conveyed through emoticon use
 - Less threatening to young people
 - Must find common meeting time
 - Requires fast Internet connection
 - Chaotic turn-taking
 - Typing speed = power
 - More than 5 participants requires 2 moderators

Issues to consider

	Asynchronous	Synchronous
Technical requirements	Likely familiar technologies	Fast connection, webcam, audio/video, more technical difficulties likely
Skills	Writing skills	Typing speed Comfort with video
Visual cues	Largely absent	Present with video or emoticons or text abbreviations
Participation	Can ignore messages Can lurk Lag time for responses	Chaotic with too many participants
Response types	Reflective	Spontaneous, can respond to probes

See also Wilkerson et al. (2014). *Recommendations for Internet-based Qualitative Health Research with Hard to Reach Populations*. *Qualitative Health Research* 4(4), 561-574.

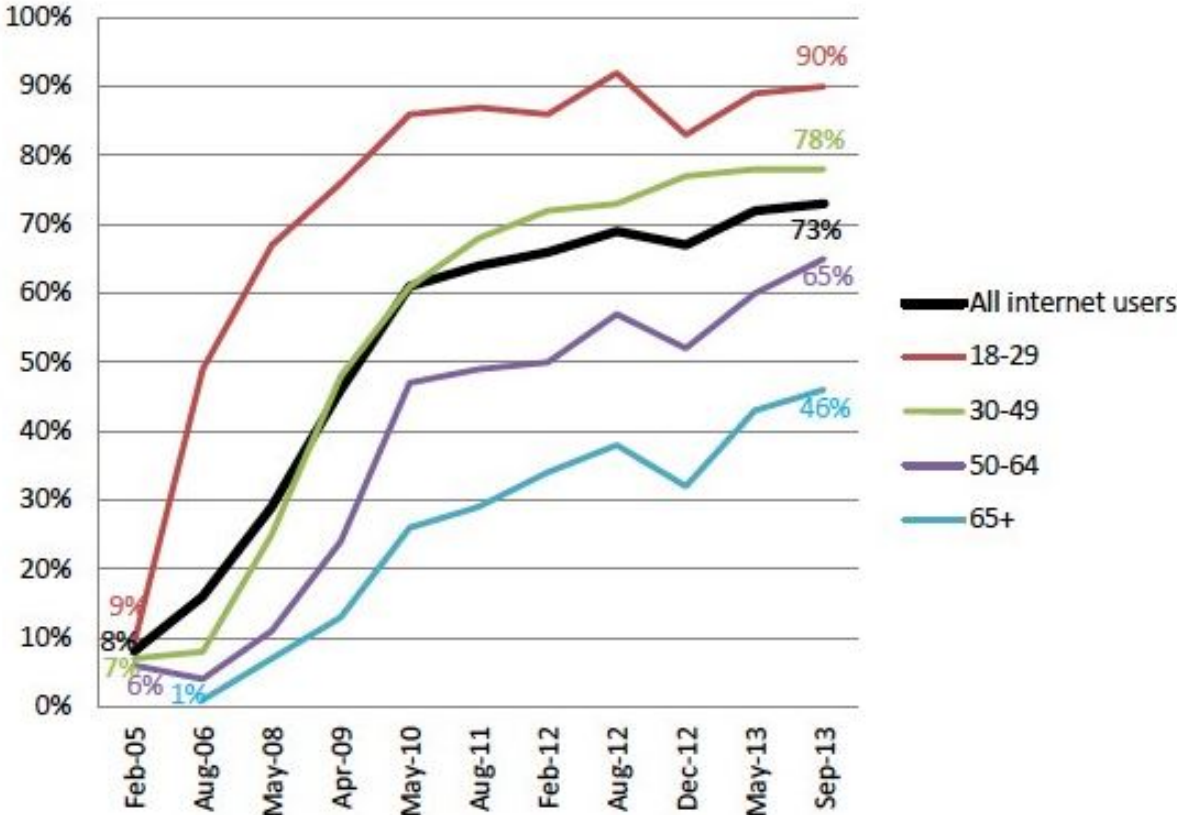
Online communities & social media



Online communities & social media

Social networking site use by age group, 2005-2013

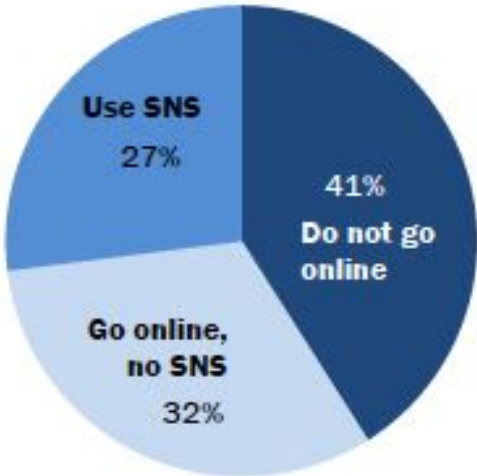
% of internet users in each age group who use social networking sites, over time



Source: Latest data from Pew Research Center's Internet Project Library Survey, July 18 – September 30, 2013. N=5,112 internet users ages 18+. Interviews were conducted in English and Spanish and on landline and cell phones. The margin of error for results based on internet users is +/- 1.6 percentage points.

One-quarter of seniors use online social networks


% of seniors who ...



Pew Research Center's Internet Project July 18-September 30, 2013 tracking survey.

PEW RESEARCH CENTER

- **Spontaneous** (unelicited)
 - WhiteBlaze.net (online hobby group)
 - Facebook
 - SecondLife
 - **Unknown** participants
- **Designed** (elicited)
 - [Patients Like Me](#)
 - [One Thousand Voices](#)
 - Online support groups (Varga & Paulus, 2014); online educational groups (Paulus & Lester, 2013)
 - **Known** participants

 High Glucose reading at Dr. visit

[Watch this](#)



Frisc

[View More Posts](#)

[Ignore](#)

I've had high blood pressure and I am on that forum. I'm 40 years old and have a physical job, I'm not obese, but do have the "spare tire" I'm 6 foot 5 and 260lbs. I was dieting last year and was about 230, but fell off the diet wagon and now I'm 260, again, mostly belly fat, which I have read is the worst.

So I went to my family Dr. to re-fill my RX for my blood pressure medicine and he decided to do some blood work. My cholesterol was a little high so he prescribed 10mg of [Lipitor](#), but the thing that scares me the most was my elevated glucose level. It was 118. The Dr. said it should be between 65 and 105. I now have to go take a 2 hour glucose tolerance test.

I don't have a family history of diabetes. The cholesterol doesn't bother me as much, as I am confident I can change that with my diet. I have already sworn off any fast food, junk food and sweets. All this happened yesterday after my appointment, but it's a real eye opener to me, and with that said, I have the [willpower](#) to eat nothing but salads, granola, grilled chicken, grilled salmon, and water.

I'm confused though because I was [talking](#) to a friend that has diabetes and has to take shots, and he said 118 wasn't bad. I know I definitely need to lose weight, and although I only started yesterday, I'm on that path and I am going to be eating right from now on. I'm just concerned as to why my Dr. requested I take the 2 hour test. Are there some other issues that can be uncovered in that test?

Any input would be greatly appreciated. I didn't get to talk to the Dr. the lab nurse called me late in the day Friday with the results and news that I needed to take the test. So obviously with this being the weekend, I'm stressing out about it.

Thanks

Posted on 04/19/14, 11:54 am

Online communities & social media






Diabetes Support

18 hours ago


Another Facebook fan could use your help! She writes: "I was wondering if any fellow pumpers get a lot of infections at the infusion site that requires strong Antibiotic or even lancing and packing? How often? I am getting them every 2-3 months. I'm really discouraged."

Like · Comment · Share 4


 135 people like this. Recent Activity ▾

 **Sue Champagne Soulière** like
Like · Reply · about an hour ago

 **Sarah McEwan** When I first started on the pump I got infections quite quickly where the cannula was and needed antibiotics, but as long as I change my cannula every 2 days I'm okay now.
Like · Reply · about an hour ago

 **Crystal Ferrill Morris** I use omnipod and you have to change it every 3 days. My Medtronic sites use to get irritated when I used it but not with omnipod.
Like · Reply · 2 hours ago

 **Jackie McDonald** Pump for 4 years and never had an infection. Hit a blood vessel once which caused a huge bruise but otherwise no issues.
Like · Reply ·  3 · 15 hours ago

 **Crystal Ferrill Morris** I have done that before and wow yes huge bruise lol
Like · 2 hours ago

Online communities & social media



Anne Geraghty @aningerag · 16h
Luke ripped out my pump! 🤢 #diabeticProbs #cgm #medtronic #pumpprobs #type1 #diabetes [instagram.com/p/nMb6ddggd2/](https://www.instagram.com/p/nMb6ddggd2/)
Expand ↩ Reply ↻ Retweet ★ Favorite ⋮ More



Toan Huynh @toanbhuynh · 21h
#Medtronic among The 50 Best Employers In America [businessinsider.com/best-employers...](https://www.businessinsider.com/best-employers...)
📄 View summary ↩ Reply ↻ Retweet ★ Favorite ⋮ More



Lionbridge Life Sci @LionbridgeLife · Apr 24
#Medtronic launches a massive #clinicaltrial that could widen the use of #ICDs in #emergingmarkets bit.ly/1rpjOJM
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C. Michael Gibson MD @CMichaelGibson · Apr 24
#Medtronic allowed to continue selling #CoreValve as injunction for patent infringement delayed [medpagetoday.com/Cardiology/Arr...](https://www.medpagetoday.com/Cardiology/Arr...)
📄 View summary ↩ Reply ↻ Retweet ★ Favorite ⋮ More

- **Detecting** health conditions (Prieto et al 2014)
- **Sharing** treatments and experiences of care (McGregor et al 2014)
- **Recruiting** survey participants (O'Conner et al 2013)

Issues to consider

Username	Tweet	Time
nutritionXP	@ Lswensen it's just awful to watch! He's clocking up 3,000 calories! #fastfoodbaby1	22/03/2012 1
65reevesmm	Can't believe how these kids rule over their parents - shocking #fastfoodbaby1	22/03/2012 1
nutritionXP	The parents are creating a recipe for diabetes, heart disease and cancer #fastfoodbaby1	22/03/2012 1
LSwensen1	@65reevesmm this baby is drinking 6 cans of Cola a day! I feel sick :(#fastfoodbaby1	22/03/2012 1
65reevesmm	Nothing wrong with takeaway every now and again,	22/03/2012 1

QSR Nvivo's [Ncapture](#) tool

Issues to consider

Public vs Private	Topic Sensitivity	Degree of Interaction	Subject Vulnerability	Is Consent Necessary?
Private	High	High	High	Likely
↑ ↓	↑ ↓	↑ ↓	↑ ↓	↑ ↓
Public	Low	Low	Low	Not Likely

Figure 5.1 Heuristic for making informed consent decisions in Internet research (adapted from McKee and Porter, 2009, p. 88)

Mobile devices

- 90% of American adults have a **cell phone** (including 77% of older adults)
- 58% of American adults have a **smartphone** (including 18% of older adults)
- 32% of American adults own an **e-reader**
- 42% of American adults own a **tablet** computer

Cell phone activities

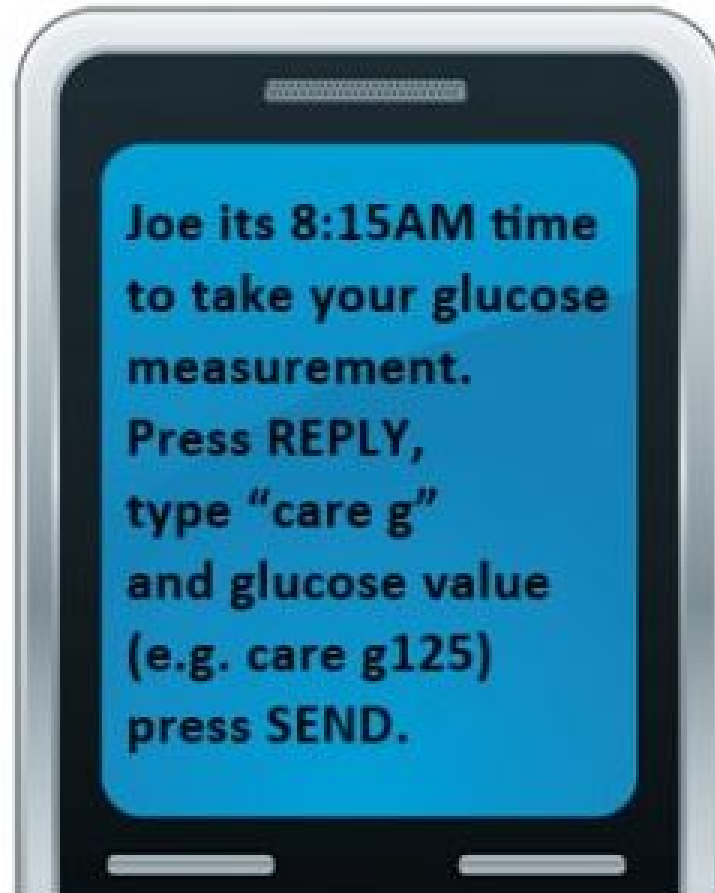
The % of cell phone owners who use their cell phone to...

81	send or receive text messages
60	access the internet
52	send or receive email
50	download apps
49	get directions, recommendations, or other location-based information
48	listen to music
21	participate in a video call or video chat
8	"check in" or share your location

Source: Pew Research Center's Internet & American Life Project Spring Tracking Survey, April 17 – May 19, 2013. N=2,076 cell phone owners. Interviews were conducted in English and Spanish and on landline and cell phones. The margin of error for results based on all cell phone owners is +/- 2.4 percentage points.

- Motion **sensor** to trigger physical activity recall (Dunton et al, 2014)
- Text-message/SMS **prompts** (Bobrow et al, 2014; Tsai et al, 2007)
- Mobile phone-assisted personal **interviewing** (van Heerden et al., 2014)

Mobile devices



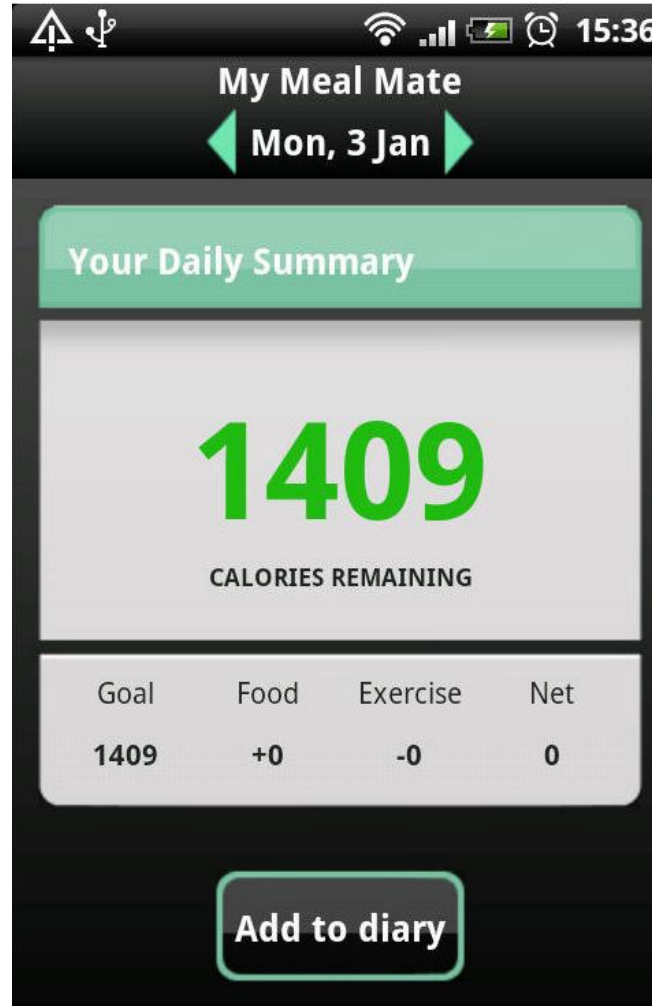
Mobile devices

What have you been DOING between
1:35 PM and 2:05 PM?
(Choose all that apply)

- Reading or doing homework
- Using technology (TV, phone)
- Eating/Drinking
- Sports/Exercising
- Going somewhere
- Hanging out
- Other

Next

Mobile devices



Issues to consider





Your poll will show here

1

Install the app from
pollev.com/app

2

Make sure you are in
Slide Show mode

Still not working? Get help at pollev.com/app/help

or

[Open poll in your web browser](#)



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- Special issue of *Health Affairs*: [*Early evidence, future promise of connected health*](#) (data security & privacy)
- Bamboo DiRT: [*Digital research tools*](#)
- Visualizing data: [*Tools for collecting and handling data*](#)

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Advances in Online Tools for Accelerating PRO Development

Paul Wicks, PhD

PatientsLikeMe

Vice President of Innovation

FIFTH ANNUAL

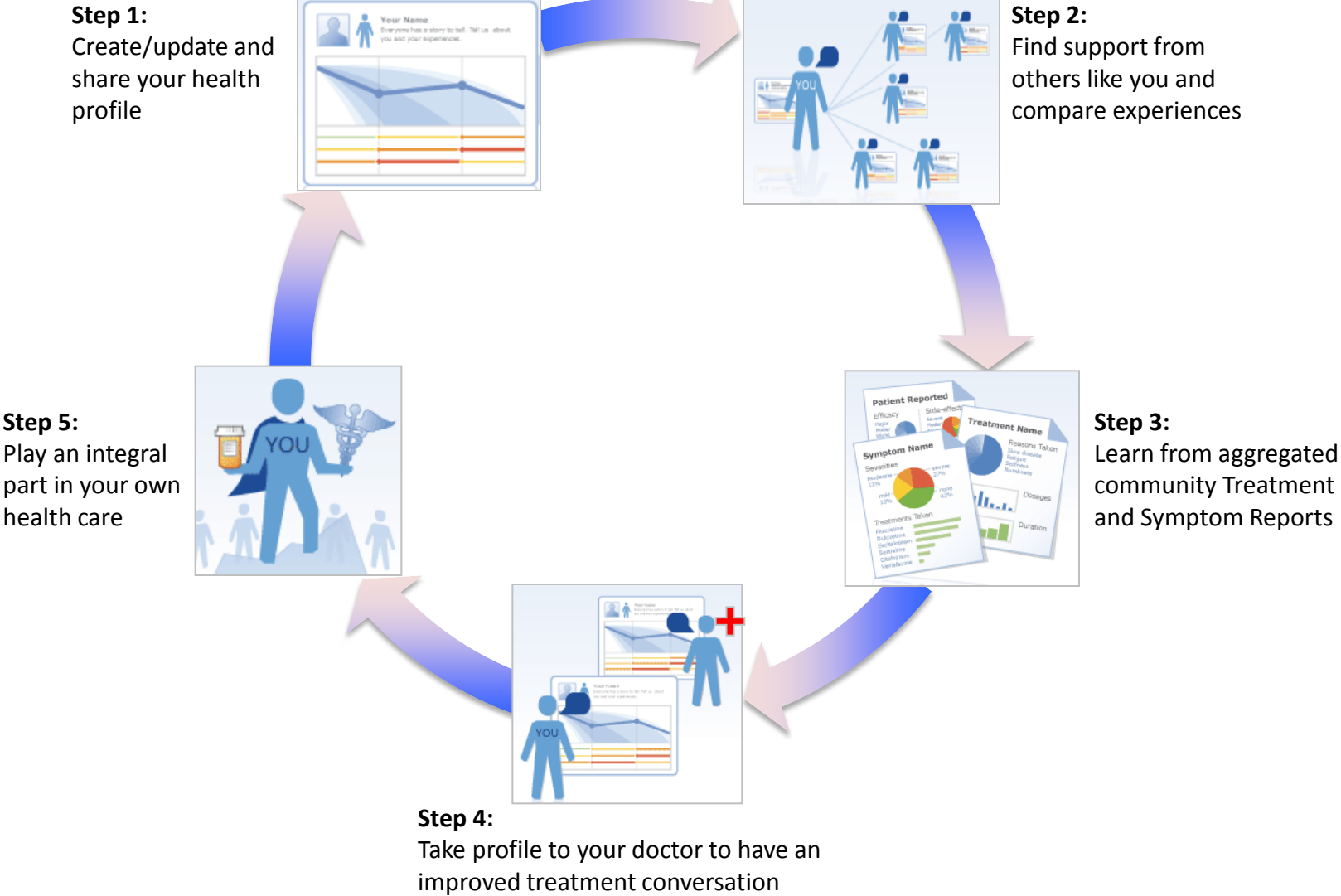
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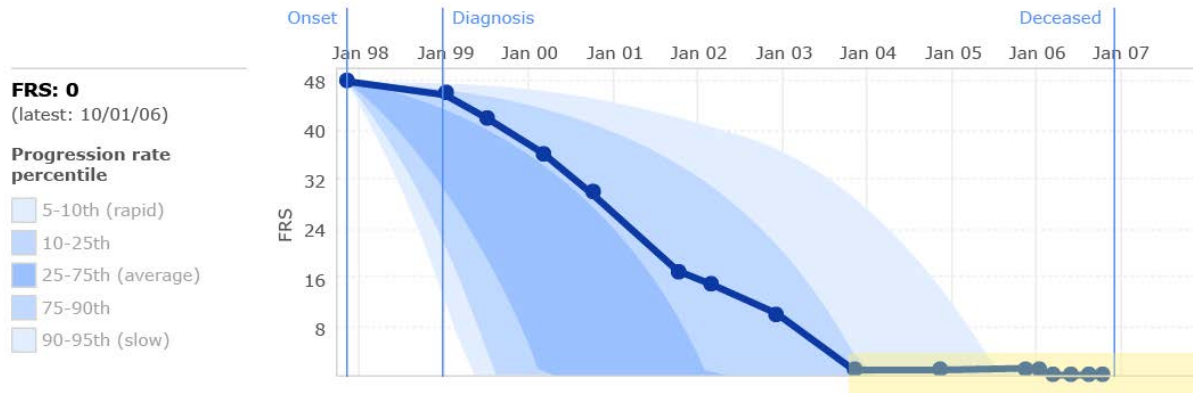
Co-sponsored by



PatientsLikeMe



Measuring Advanced ALS



- ALS patient noticed ALSFRS-R wasn't sensitive enough to capture function in advanced ALS, “floor effect” of measure
- 200+ patients participated in study to construct and pilot a new, more sensitive instrument
- 3 new items were selected to be included in the new ALSFRS-EX measure
- Being used by the VA biobank and academic studies

European Journal of Neurology 2009, 16: 353-359

doi:10.1111/j.1468-1331.2008.02434.x

Measuring function in advanced ALS: validation of ALSFRS-EX extension items

P. Wicks^a, M. P. Massagli^a, C. Wolf^b and J. Heywood^a

^aPatientsLikeMe Inc., Research & Development, Cambridge, MA, USA; and ^bPerson living with ALS, patient member of Patients-LikeMe.com

Keywords:

ALS, ALSFRS-R, clinical rating scale, floor effect

Background: With the aid of assistive technology, some patients with amyotrophic lateral sclerosis (ALS) are able to live for several years past the lowest measurable level of function on the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS-R), a widely used end-point in ALS assessment. There is a research need to monitor patient function at the end of life, particularly in the face of severe impairment or ‘locked in syndrome’. **Methods:** We used an online community for people with ALS (PALS) (PatientsLikeMe) to construct and pilot a number of new items to add to the

Received 19 August 2008
Accepted 18 November 2008

Challenges in PRO Development Today

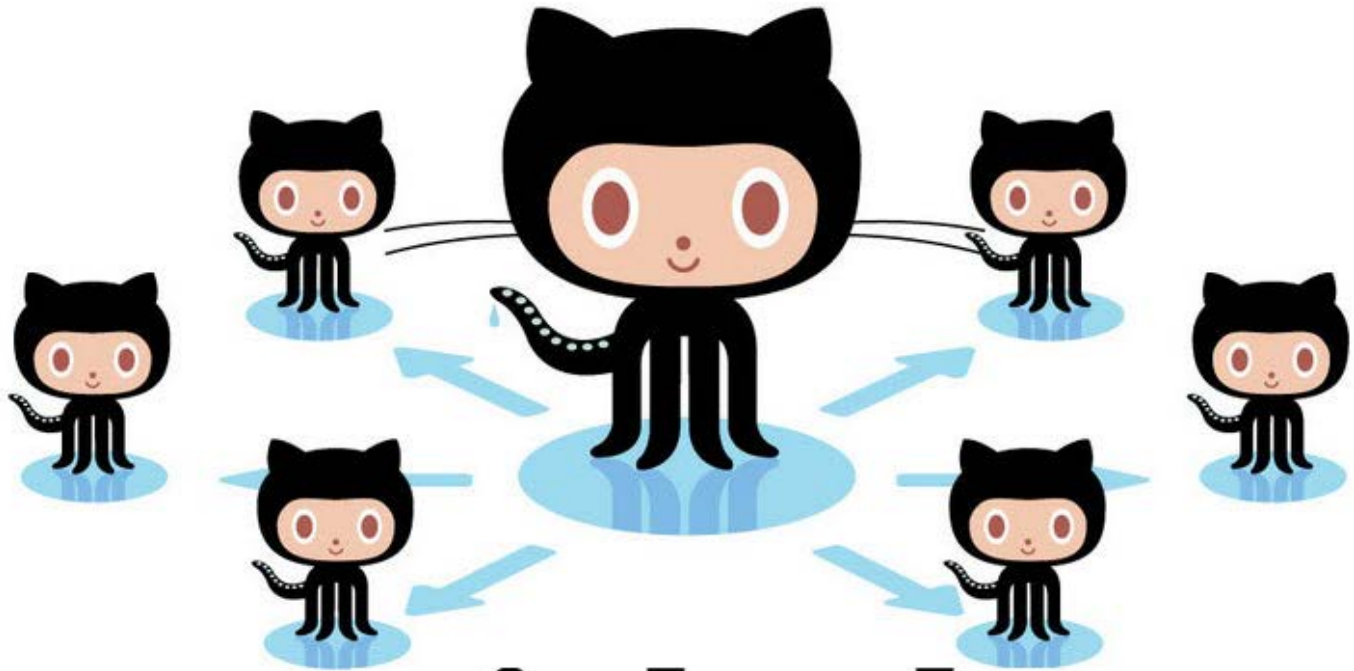


- Slow (2-4 years) & expensive to develop (\$725k-\$2.1m)
- Only available in few diseases
- Typically license fee for use
- Many lack patient input in design
- Outdated e.g. home shopping, internet, smartphones

Rosen R. Development of Patient Reported Outcome (PRO) Measures: How Feasible is a PRO for Asymptomatic PCa Treatment? FDA Public Workshop Clinical Trial Design Issues Drug and Device Development for Localized Prostate Cancer, 2013.

Hayes R. Patient-Reported Outcome (PRO) Instruments as Drug Development Tools (Session III). Consensus Science New Tools and Tactics for Next-Gen Drug Development., Washington, DC: 2011.

Open source model and PROs



github
SOCIAL CODING

Open Research Exchange (ORE)



- **A PRO builder toolset modeled on open source software**
- Includes versioning, branching, contributions, feedback
- **Social Architecture** for collaboration, credentialing, credit
- **Automated psychometric statistics** for PRO improvement
- **Database of instruments** and supporting data
- **Scientific support** from experts at PatientsLikeMe & SAB

ORE advisory board



Ethan Basch, M.D.
*University of North Carolina School of Medicine,
Lineberger Comprehensive Cancer Center*



Erin Holve, Ph.D.
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Patricia Brennan, R.N., Ph.D.
*University of Wisconsin-Madison School
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David Cella, Ph.D.
*Northwestern University Feinberg School of
Medicine, Department of Medical Social Sciences*



Sara Riggare
PhD student, Karolinska Institutet



Ari Gnanasakthy
Head of Patient Reported Outcomes, Novartis



Sharon Terry
President and CEO, Genetic Alliance



Hugh Hempel
*Co-Founder, Solution Therapeutics and
Parent Advocate, The Addi and Cassi Fund*



John Wilbanks
*Chief Commons Officer at Sage
Bionetworks; Founder, Consent to
Research; Senior Fellow in
Entrepreneurship,
Ewing Marion Kauffman Foundation*

5 Phases of PRO development

Qualitative phase

Quantitative/psychometric phase

Concept Elicitation

Feedback

Test

Retest

Follow up

- To obtain input from patients
- Opportunity to examine patient experience at a large scale
- Item generation process
- **Based on open-ended questions**

- Equivalent to cognitive debriefing
 - To evaluate clarity, relevance, and adequacy of response options for each item
- Item review based on patient feedback
- **4 feedback questions are displayed below each evaluated item**

- Psychometric evaluation of the new instrument (validity and reliability)
 - Flexible study design
 - Ongoing patient input available through item-level and post-survey feedback

- To evaluate the ability to detect change

Ongoing Collaborations (not using ORE)

- Patient-Relevant Concepts in Chronic Lymphocytic Leukemia (Janssen)
 - 50 adults with CLL recruited via PatientsLikeMe
 - 78% reported at least one symptom
 - 369 descriptions of CLL symptoms including fatigue (40%), tiredness (38%), night sweats (38%), swollen lymph nodes (32%)
 - Supplemental telephone interviews included for a subset
 - Concept saturation was achieved using the web-only technique
- Ovarian Cancer – “In your own words” (AstraZeneca)
 - 30 adults with Ovarian cancer recruited via PatientsLikeMe
 - Symptoms leading to diagnosis, patient journey
 - Symptom fluctuations, worst symptom over course
 - Impact of treatment(s) and description of follow-up care

Item- Level Feedback

Quantitative Feedback

- How well did this question apply to you?
 - Very well, Reasonably well, A little bit, Not at all
- How easy was this question to understand?
 - Very easy , Easy , Somewhat easy, Not easy at all
- How well did the response choices fit the way you think about this question?
 - Very well, Reasonably well, A little bit, Not at all

Qualitative Feedback

In the past 4 weeks, how often did you feel restless because of your sleeping problems?

- "Not sure what was meant by 'restless'. Does that mean not being able to fall asleep? Waking up during the night and not being able to get back to sleep? Feeling agitated during the day? 'Restless Legs Syndrome'

In the past 4 weeks, how often did you feel more emotional than usual because of your sleeping problems?

- "The way this is written makes it seem like it is asking whether I feel more emotional over the last 4 weeks than I did previously. Is that what was intended?"

In the past 4 weeks, how often didn't you feel your best because of your sleeping problems?

- "When I have to read the question 4 times to figure out the question...it was not easy for me to understand"

Feedback: Overall Comments

Did this survey give you any new insights into your own health situation? Please explain.

- “Yes. It showed me how interconnected everything in the body is. My lack of sleep, due to Fibromyalgia, makes my pain, which is constant, even worse than usual. In turn, I nap in the afternoon, so I am wide awake when it's time to go to bed.”

Are there other things missing from this survey that are important for researchers to consider, given your own experience?

- “A question that should be asked is if the individual feels their lack of sleep is due to: meds, depression, illness, etc.”

What, if anything, should we change to improve this survey, make it more relevant to your condition, or make it more understandable?

- “You need to know what illnesses people have other than insomnia, whether they use a CPAP machine, oxygen, sleep alone, if the sleep on a bed or recliner.”

Please add any other comments you may have about the questions used in this survey.

- “I appreciate that I had genuine choices in answering this survey.”

Real-time Psychometric Stats



View results for **Study 1 - Test of Psoriasis Survey**

Export

Descriptive **Qualitative** Performance & details N = 357 of 400 invited: Multiple Sclerosis, No Diabetes, Ages 18-65, 207 M / 193 F, USA, MSRS-R 7.0-10.0, Dx Date 3+ yrs

Group Descriptive Results

Show for **Layout 1** > **New PRO items** > **All Domains** **Print**

Q1: STIFF1 Domain: Stiffness Avg. time: 17 s

How long have you experienced joint stiffness?

Response option	Code	Freq.	%	Cum. freq.	Cum. %	Avg. time
Less than 1 week	0	228	15.49%	228	15.49%	12 s
Less than one month	1	339	23.02%	795	38.51%	19 s
Less than one year	2	397	26.97%	1192	65.48%	15 s
Less than 5 years	3	254	17.26%	1446	82.74%	15 s
More than 5 years	4	254	17.26%	1700	95.25%	16 s
I prefer to skip	-97	10	2.31%	1710	97.31%	5 s
I don't know	-98	5	1.65%	1715	100.00%	12s
Does not apply	-99	0	0.00%	0	100.00%	---
Forced skip	-100	0	0.00%	0	100.00%	---
Did not complete	-999	0	0.00%	0	100.00%	---

Quantitative Feedback Responses

Does it apply?	Freq.	%
Very well	5	27.7
Reasonably well	8	44.4
A little bit	3	16.7
Not at all	2	11.1

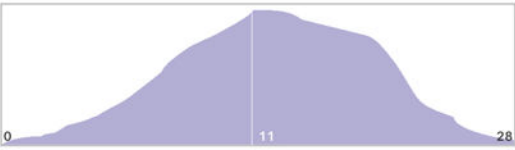
Easy to understand?	Freq.	%
Very easy	5	27.7
Easy	8	44.4
Somewhat easy	3	16.7
Not easy at all	2	11.1

Do responses fit?	Freq.	%
Very well	3	27.7
Reasonably well	9	44.4
A little bit	4	16.7
Not at all	3	11.1

Q2: SPAS1 Domain: Spasticity Avg. time: 17 s

How many times have you experienced severe joint spasticity in the last month?

Min: 0
 Max: 28
 Mean: 11.5
 Median: 11
 Mode: 11
 SD: 2.76



Missing Responses	Code	Freq.	%	Avg. time
I prefer to skip	-97	10	2.31%	5 s
I don't know	-98	5	1.65%	12s
Does not apply	-99	0	0.00%	---
Forced skip	-100	0	0.00%	---
Did not complete	-999	0	0.00%	---

Quantitative Feedback Responses

Does it apply?	Freq.	%
Very well	5	27.7
Reasonably well	8	44.4
A little bit	3	16.7
Not at all	2	11.1

Easy to understand?	Freq.	%
Very easy	5	27.7
Easy	8	44.4
Somewhat easy	3	16.7
Not easy at all	2	11.1

Do responses fit?	Freq.	%
Very well	3	27.7
Reasonably well	9	44.4
A little bit	4	16.7
Not at all	3	11.1

Patient-Level Data Display



View results for **Study 1 - Test of Psoriasis Survey**

[Export](#)

Descriptive | Qualitative | **Performance & details** | N = 357 of 400 invited: Multiple Sclerosis, No Diabetes, Ages 18-65, 207 M / 193 F, USA, MSRS-R 7.0-10.0, Dx Date 3+ yrs

Performance summary

Show for **Layout 1** > **New PRO items**

[Print](#)

<p>Chronbach's alpha</p> <p>● Stiffness</p> <p>.89 12 items 95% CI .88 - .92</p>	<p>Chronbach's alpha</p> <p>● Pain</p> <p>.78 16 items 95% CI .86 - .81</p>	<p>Chronbach's alpha</p> <p>● Mood</p> <p>.72 8 items 95% CI .71 - .74</p>	<p>Chronbach's alpha</p> <p>● Fatigue</p> <p>.72 3 items 95% CI .71 - .74</p>	<p>● Completion time</p> <p>13.7 45 items min(avg)</p>	<p>Time distribution</p>	<p>● Reported relevance</p> <p>92% Very relevant</p>
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Response details

Show: Item text Only responses with comments Excluded responses | 1-15 of 373 participants | [<](#) [1](#) [2](#) [>](#)

Aggregated responses				M 40	W 23	? 32	W 30	M 36	M 28	W 22	W 39	W 26	M 22	M 38	W 38	M 33	W 27	M 37	
Item	Distribution	No response	Avg. Time	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Clinical and Demographic Items																			
1		1	10 s	1	1	3	4	3	3	1	1	2	2	1	3	1	2	3	2
2		5	12 s		2	1	3	1	1	4	4	4	2	2	2	4	1	4	
3		2	15 s	2	1	1	3	1	1	3	3	6	2	3	1	4	3	1	3
4		17	24 s	6	1	2	2	2	3	4	1	2	4	4	4	2	4	4	
5	text response	13	35 s	1															
6		20	20 s	4	4	4	2	3	3	4	2	2	4	4	4	1	4	1	
New PRO Items																			
7		1	15 s		1	3	4	3	3	1	1	2	2	1	3	1	2	3	2
8		5	12 s	3	2	1	3	1	1	4	4	4	2	2	2	4	1	4	
9		2	19 s	2	1	1	3	1	1	3	3	6	2	3	1	4	3	1	3
10		17	23 s		1	2	2	3	3	4	1	2	4	4	4	1	4	4	
11		13	29 s	1	10/10/10	12/01/42	11/02/14	12/22/98	3/15/98	8/15/13	3/15/11	6/22/68	4/12	5/1/66	7/8/12	1/11/11	12/19/39	5/17/72	
12		20	14 s	1	4	4	2	3	4	4	3	2	4	4	4	1	4	1	

1-15 of 373 participants | [<](#) [1](#) [2](#) [>](#)

Adaptations in response to feedback



- **Patient Verification**
 - 80% of patient asked agreed we could contact their physician
- **Comparative validity**
 - Follow-up over telephone produced highly similar results
- **Representativeness**
 - Use of population weightings and stratified sampling
- **Ease of use**
 - Partnering with patients-led PRO, move to self-service
- **Item Response Theory**
 - Supporting CAT item banks, minimize burden, leverage PROMIS
- **Appropriate Credit & Version control**
 - Work in progress to ensure balance of quality and accessibility

Pros / Cons of Online Research

- Participatory
- Speed
- Anonymity
- Patient-centric
- Global reach
- Longitudinal
- Openness
- High Touch
- Errors propagate
- Validation
- Verification
- Localization
- Attrition
- Security

Panel Discussion

Session Participants



- **Moderator**

- *Margaret Rothman, PhD* – Senior Director, PRO Group, Janssen Pharmaceutical Companies of Johnson and Johnson

- **Presenters and Panelists**

- *Trena M. Paulus, PhD* - Associate Professor and Coordinator of the Graduate Certificate in Qualitative Research Methods, Department of Educational Psychology and Counseling, University of Tennessee
- *Paul Wicks, PhD* – Vice President of Innovation, PatientsLikeMe
- *Elektra Papadopoulos, MD, MPH* – Team Leader, Study Endpoints Team, SEALD, OND, CDER, FDA
- *Tara Symonds, PhD* – Senior Director and Head, PRO Center of Excellence, Pfizer

Discussion and/or Questions?