Direct-to-Participant Trials

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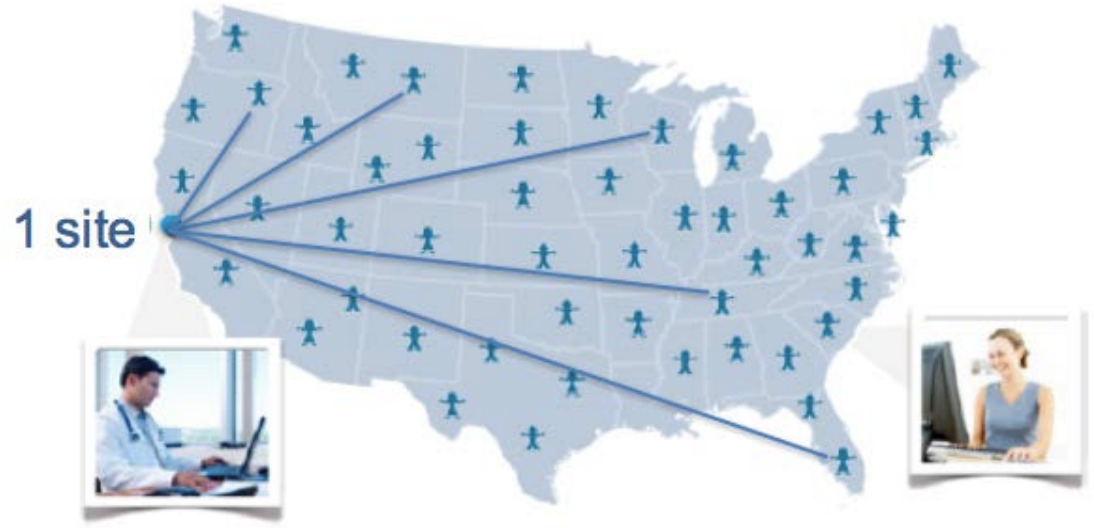
UC San Francisco

Acknowledgements

No relevant financial interests

Direct-to-Participant (D2P) trials

No physical clinical sites. No geographic limit on recruitment.



Not ~~“Virtual:”~~ Patients are real and relationships are essential

Not “~~Internet-based~~:” D2P trials use other means

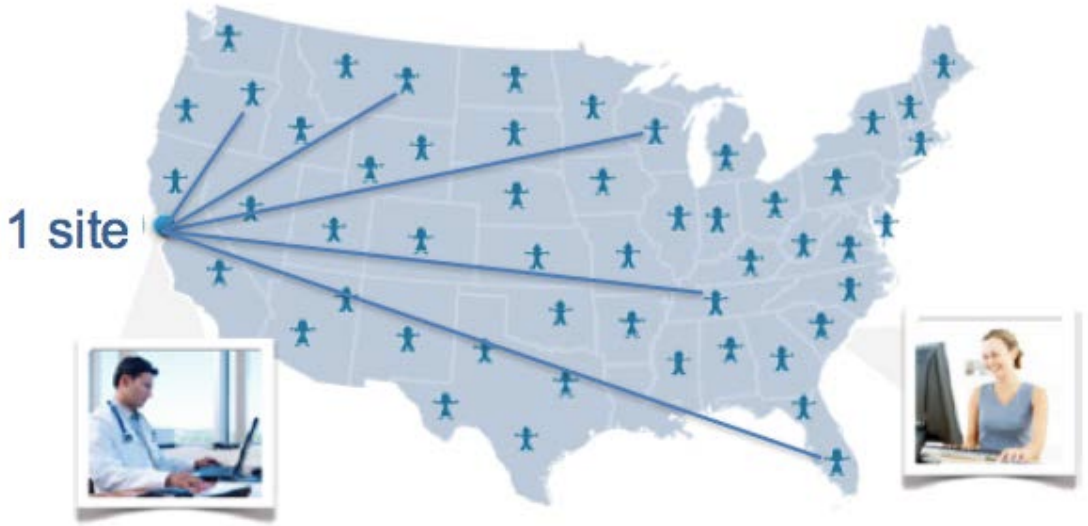
Outline

Stories of 3 trials

- KALM
- REMOTE
- HOME

Lessons:

- Simplicity
- Participant perspective



KALM

Jacobs, et al. Medicine 2005,84:197

History

- 1998: Dr. Susan Love asked: ”How can I use my online ‘Army of Women’ for research?”

- Started “1747” in 2000
  - $900k from eLilly Ventures
  - To conduct a proof-of-concept D2P trial

KALM (2000)

- Proof of concept & build key elements
- RCT of Kava-kava and Valerian root vs. placebo
- For anxiety and insomnia
- Enrolled people with anxiety or insomnia by questionnaire
- Few exclusions
- Endpoints: less anxiety, better sleep, and AEs at 4 weeks

Jacobs, et al. Medicine 2005,84:197

KALM elements

One Center

- Participant-facing EDC and website
  - No paper
- Identity confirmed by ‘Idiology’ using public databases
- Participants stablished e-signatures
- eConsent with quiz. Approved by WIRB
- Managed study ‘drugs’: FedEx delivery with proof of I.D.
- Recruit: ads on websites; emails to friends and groups
- Simple: 15 screens and <10 steps to enroll and follow-up

Jacobs, et al. Medicine 2005,84:197

KALM Results

In 8 weeks

- 1,551 screened, 391 randomized from 45 states
- >80% adherence
- All groups improved
  - No significant differences

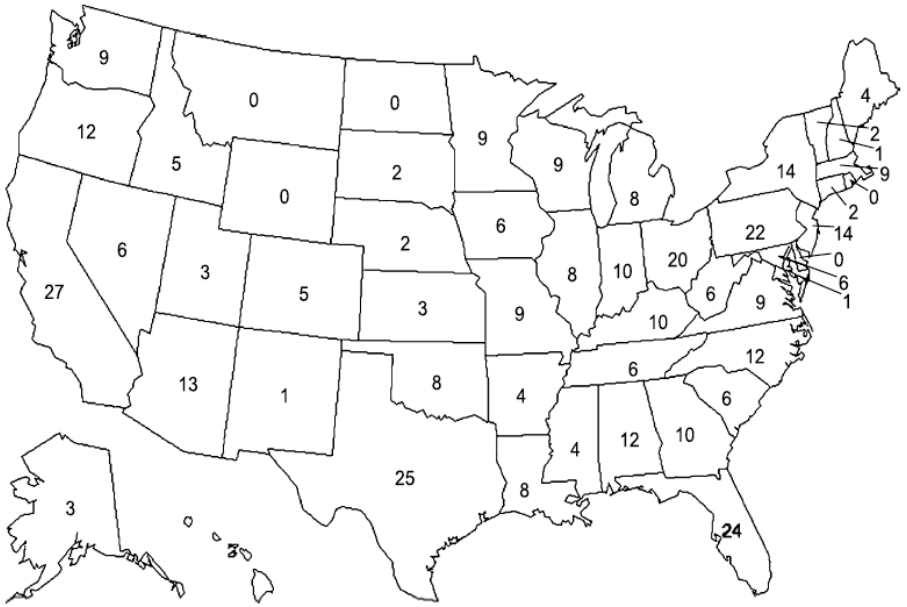


FIGURE 1. Study recruitment by state (n = 391). Numbers represent the number of participants enrolled in the trial for each state. Participants were from 45 states including Hawaii and Alaska.

Jacobs, et al. Medicine 2005,84:197

KALM Results

- Results analyzed within 1 hour of ‘last data in’
- Sent individual results to participants within 1 day

- Cost: $3,224 / participant
  (Adjusted for inflation)

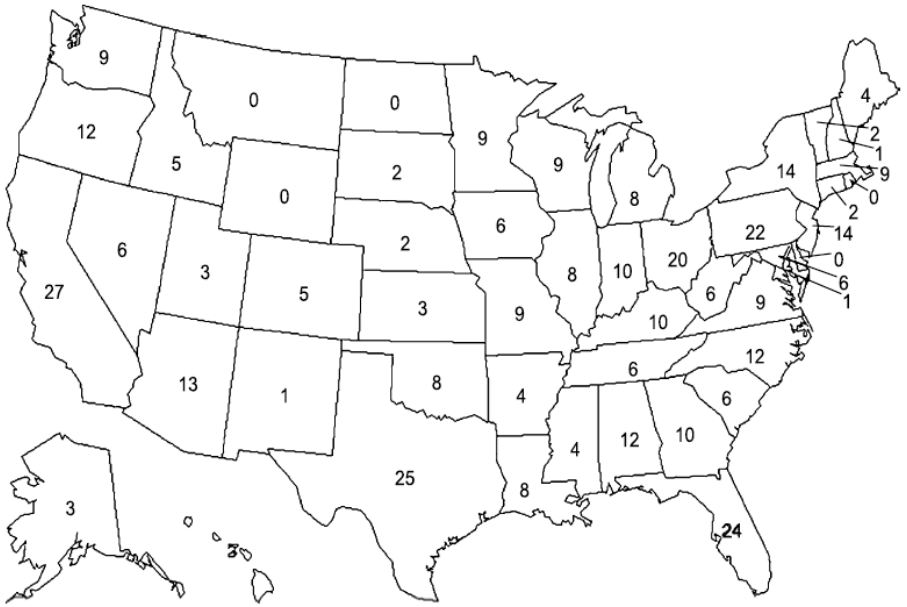


FIGURE 1. Study recruitment by state (n = 391). Numbers represent the number of participants enrolled in the trial for each state. Participants were from 45 states including Hawaii and Alaska.

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Lilly adopted the technology

- A trial of Cialis (for erectile dysfunction)
- Run by Operations, Regulatory, Legal & Data
- Became complex and used sites at baseline
  - They were concerned about confirming I.D. and consent
- “The most expensive study per patient we have done”
- Abandoned the model

Jacobs, et al. Medicine 2005,84:197

REMOTE

Conception and Birth of “REMOTE”

- About 2009
- We proposed a simple trial for Overactive Bladder (OAB)
- Use a urodynamics validated “3IQ” to enroll patients
- Tested Detrol, an established treatment
- Andy Lee (Pfizer, Operations)
  - Tried to enroll in KALM
  - Helped design, promote, and secure Pfizer funding.
  - Then moved to Genzyme.

REMOTE by Pfizer

- Pfizer’s goal: Mimic a clinic site-based trial for OAB
- Run by project management, Ops, Legal, Regulatory, Security took control
- Got FDA approval; allowed study drug shipment to home

- Early support from Bob Temple (2008)
  - “I don’t see any insurmountable barrier.”
  - “We are interested in more efficient methods…this fits.”
  - “The attitude here is going to be favorable.”
- He assembled the FDA team to approve “REMOTE”

REMOTE Process

All the elements of D2P trial

- Run from a single center by 

- Web-based recruitment
- Establish identity (public data bases)
- e-signature
- Interactive eConsent with quiz
- Shipped study drug to homes
- Approved by WIRB

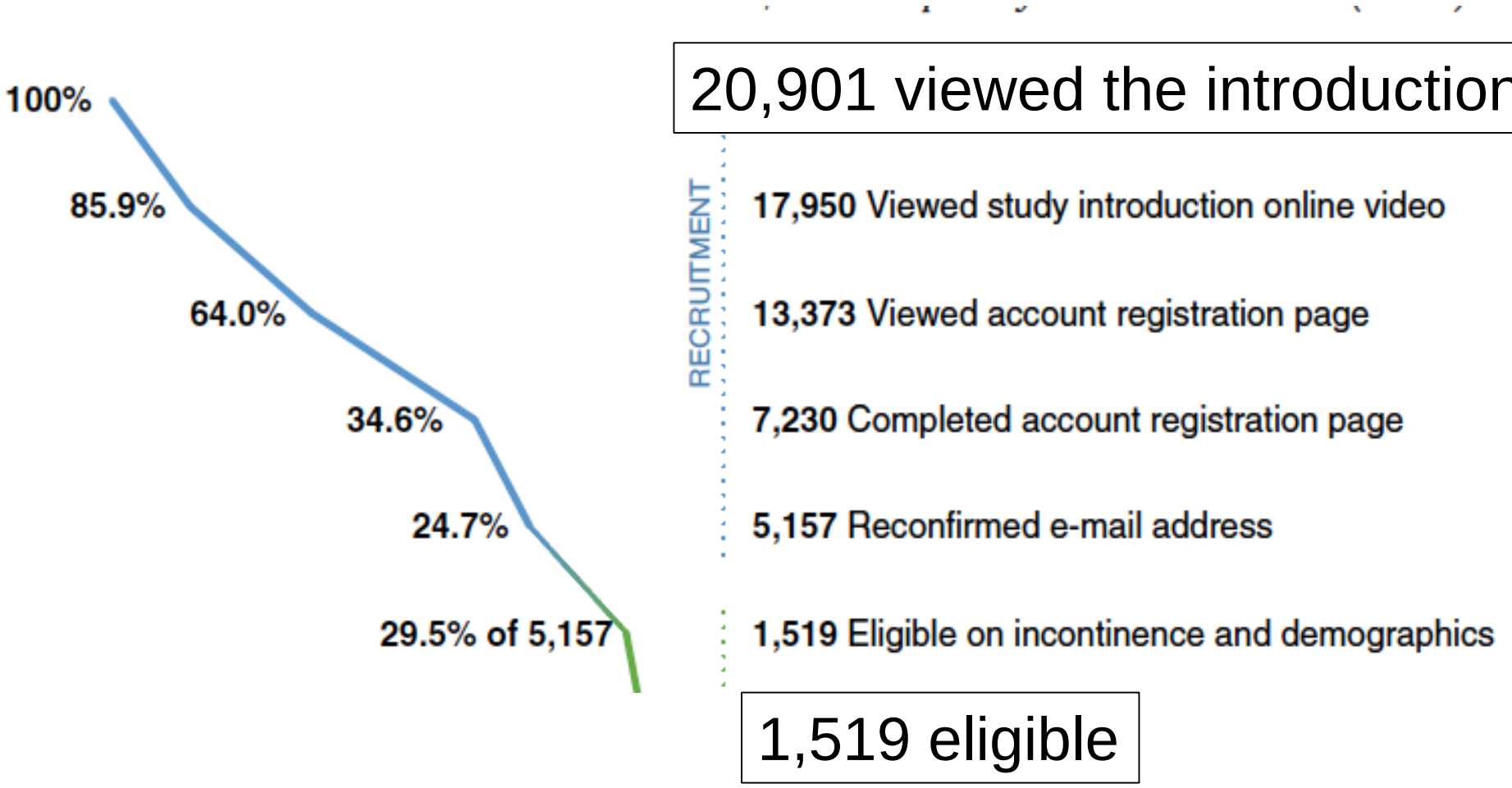
To replicate site-based trials
A complex protocol

- Women with OAB are older and many not internet saavy
- The protocol had many steps
  - >100 screens and >90 interactions to enroll

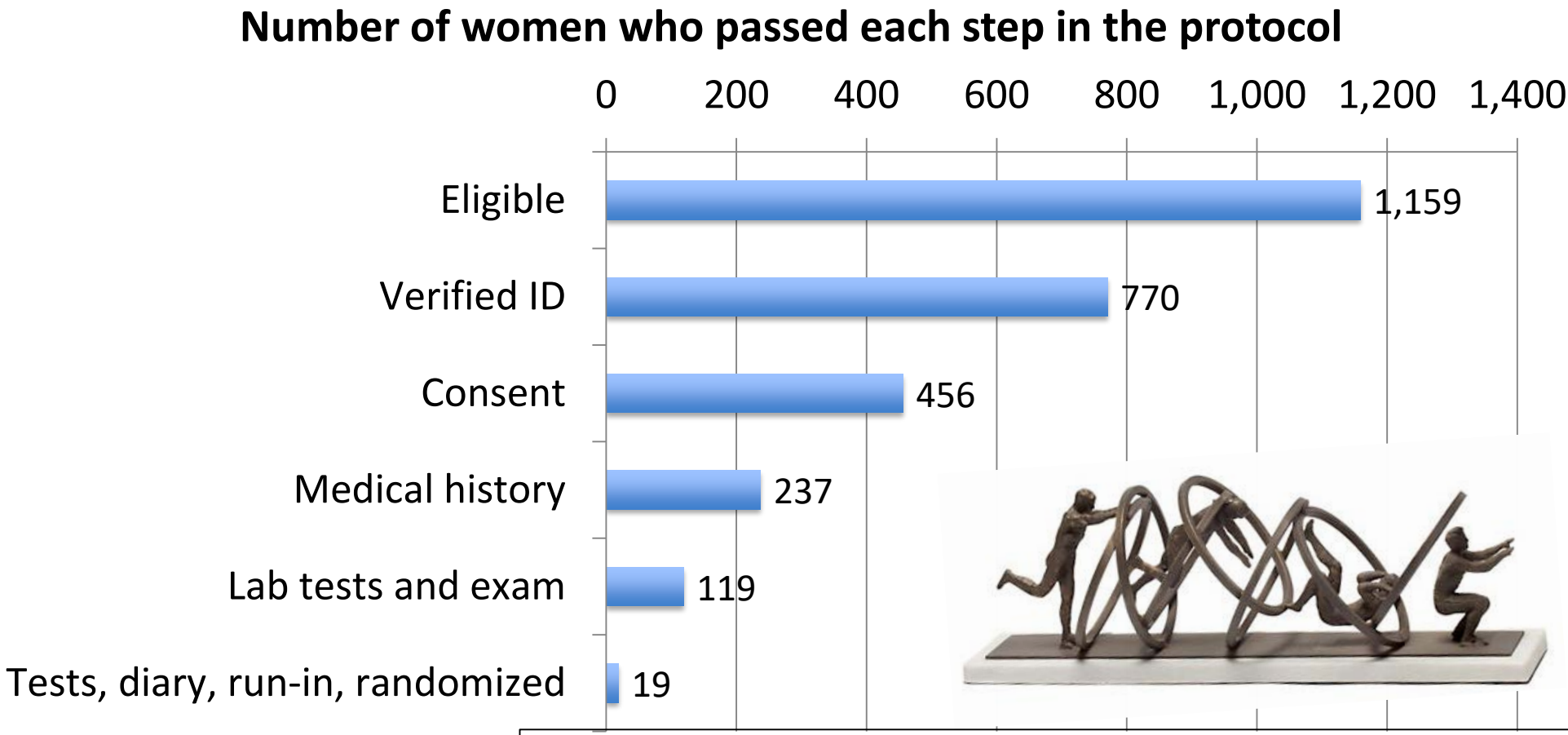
Examples of the complexity

- Prescribing laws limited recruitment to 9 states, some required exams by (impersonal) contract MDs
- “To prevent hacking:” getting an eSignature required Captcha recognition and 2-factor authentication
- Many lab tests and stringent exclusions (‘bacteruria’)
- Run-in: carry a plastic ’hat’ all day to measure urine
  - Mobile e-diary to enter volumes. Entry error meant exclusion
- After eConsent, staff had to read the full consent by phone

Web-based recruitment from many sources



We lost 44-84% of interested and eligible women at each step



Only 1.6% of eligible and interested women made it through all of the hoops

A recruitment problem?
Complexity strains recruitment

If 25% (instead of 2%) of interested and eligible women had avoided hurdles, the trial would have achieved it’s goal of 283

Worry about an FDA audit

- Pfizer assigned 1 to 3 site monitors to stay in the coordinating center most days during recruitment and enrollment
- Despite an EDC with no paper source documents, the monitors required that web entries and (redacted) email correspondence be printed and reviewed and archived
- Over 20 binders of paper

A trial in children and families with autism

Autism: A trial with the

Dr. Bent (REMOTE P.I.) ran a ‘pilot’ placebo-controlled trial of omega-3 fatty acid for hyperactivity.

Reached the goal in 6 weeks:

- 864 e-mails to the network, 127 (15%) families responded
- 96 completed informed consent
- 57 kids (and teachers) from 28 states were randomized
- 100% completion
- “Thanks!” from rural families for a chance to join research

Bent et al. J. Am. Acad. Child Adolesc. Psychiatry, 2014;53:658–666

HOME

Applying lessons learned to design
a trial with an FDA-approved drug
Funded by NIA

Preventing Fractures in Parkinson's Disease

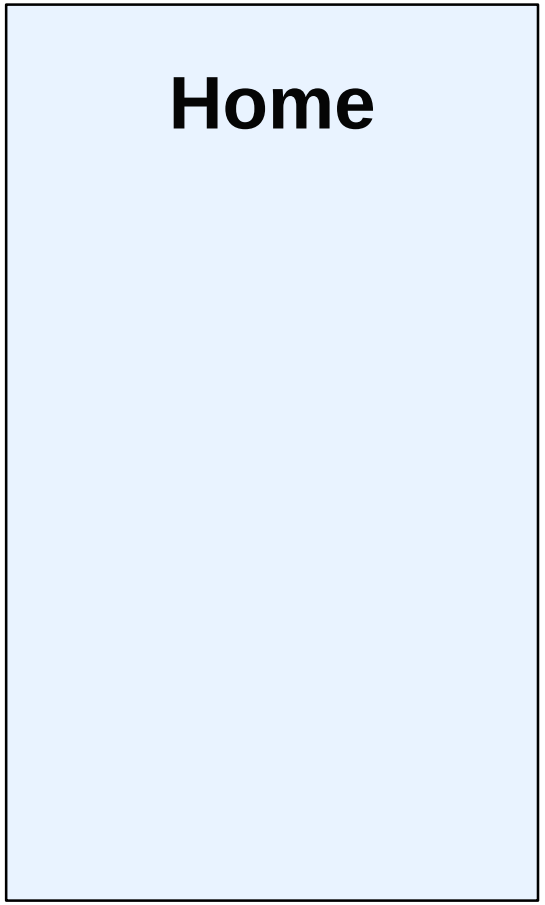
- ≥ 65 y.o, PD patients have a 10-15% annual risk of fractures
- Due to multiple falls, poor protective reflexes
- Test zoledronate vs. placebo
  - Increases bone density
  - Reduced fractures in other groups
  - One I.V. infusion lasts ≥ 2 years
  - FDA-approved; generic

Parkinson’s Fracture Prevention Trial

- 3,500 participants > age 65
- Will need nationwide recruitment not limited by sites
- Partnered with Parkinson’s Foundation: the patient’s view
- No clinic visits. Conducted from patients’ homes.
  - Patient surveys: 90% liked the home-based design
  - Easier for disabled or cognitively impaired who may benefit most

The HOME Team

SFCC (data system; endpoints), K. Lyles (Duke: MD lead); Parkinson's Foundation, P.S.G., PCORnet, UCSF (tele-neurology & eConsent) PCM Trials (nurses & drug management)



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Simple criteria
PD, ≥ 65 y.o.
Few exclusions
Recruitment sources
Foundation community
Health systems
PD Trialists (P.S.G.)

No 'web-based' recruitment
By MDs or groups they know

Home

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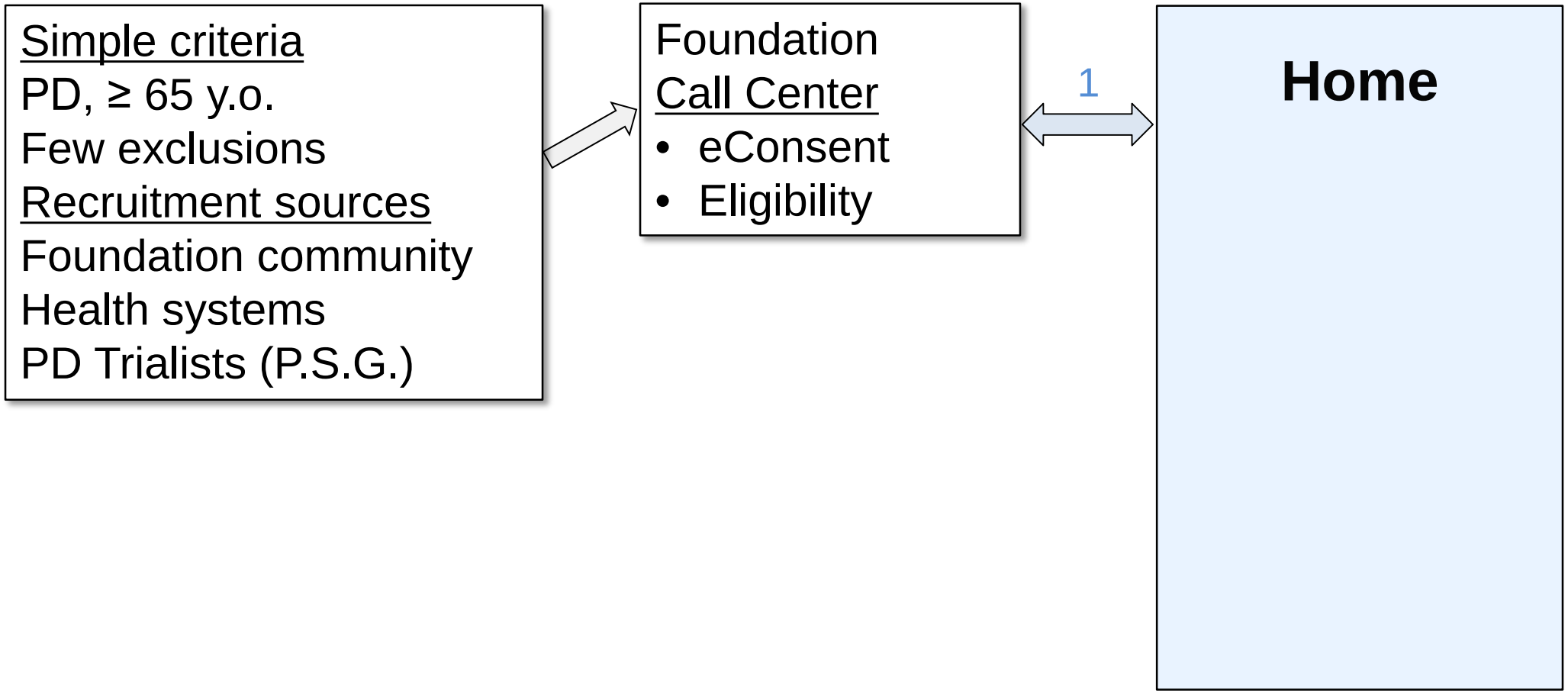

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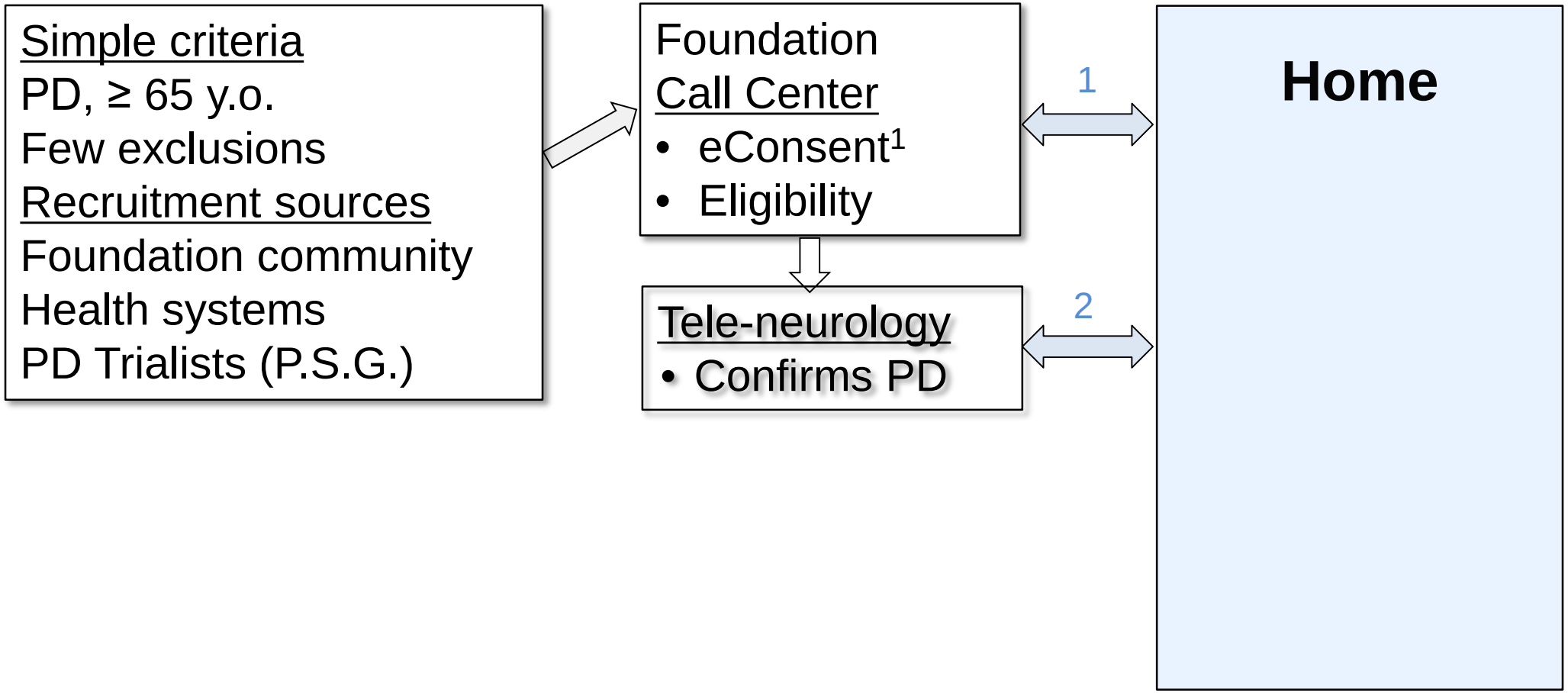

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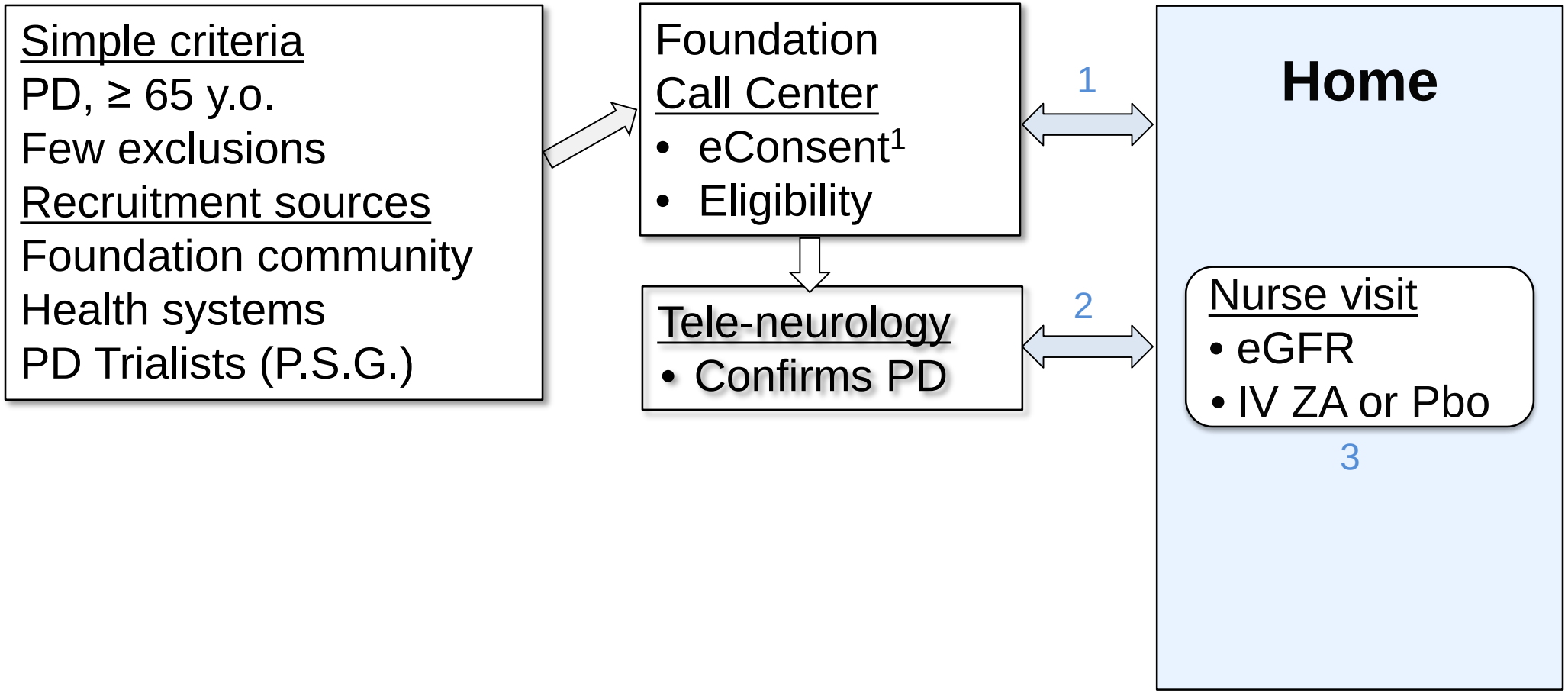

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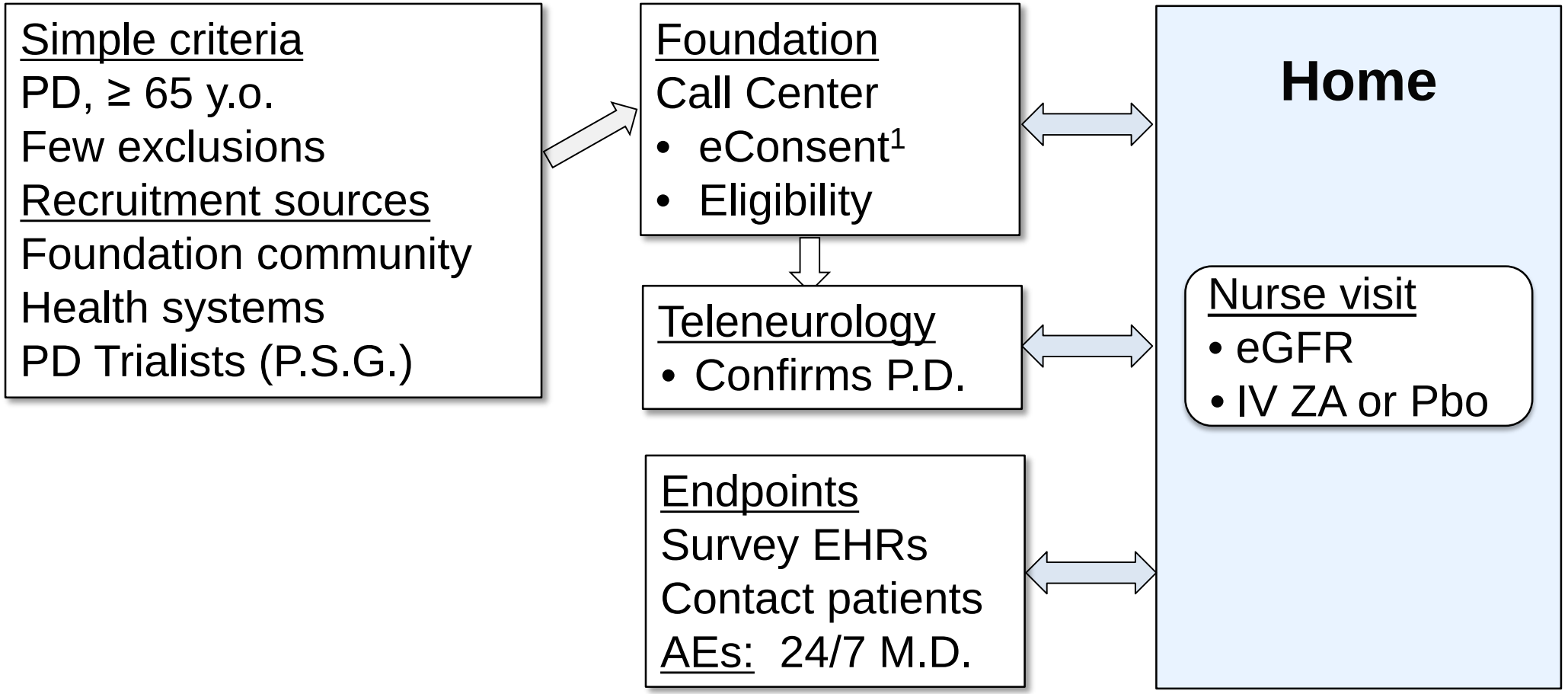

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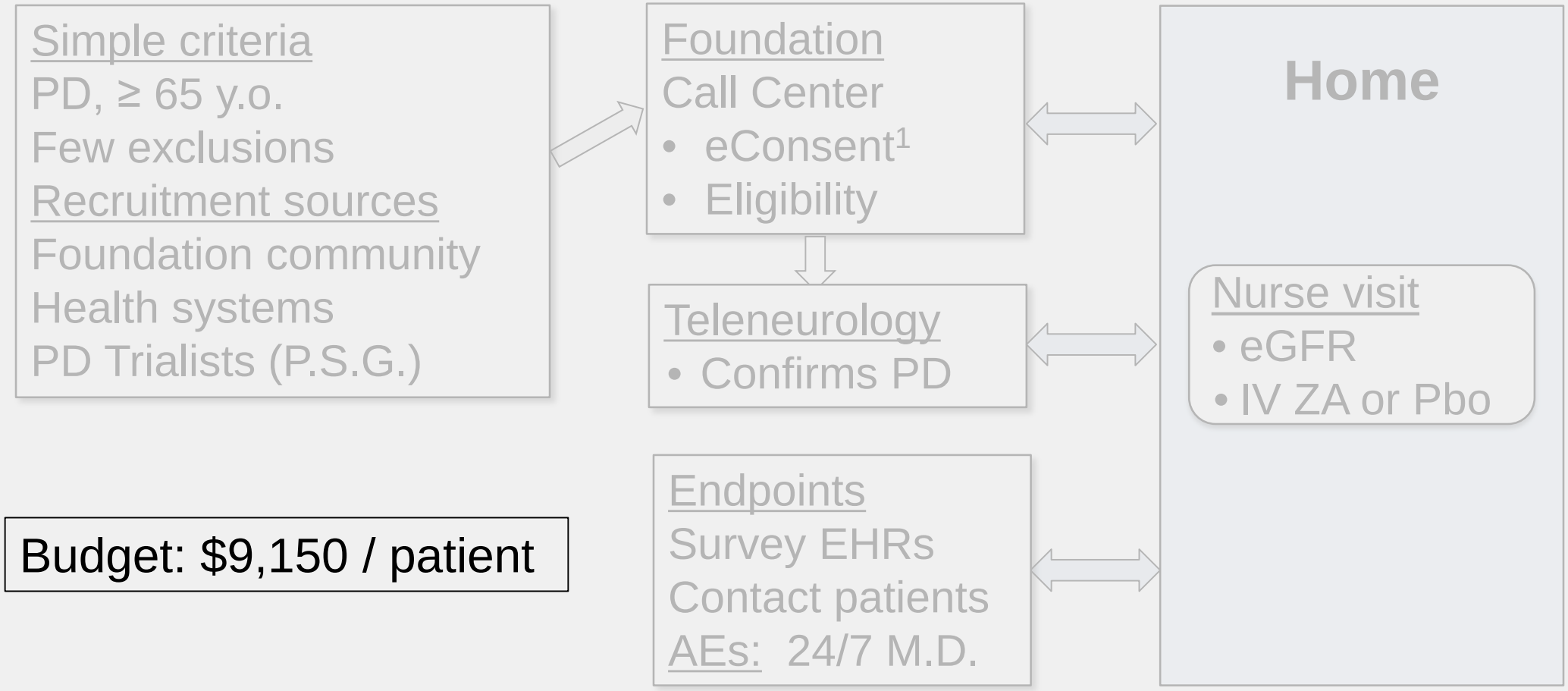


Budget: $9,150 / patient

- A successful example
- A trial comparing 2 doses of aspirin by DCRI
- Simple protocol
- Recruiting from PCORnet health systems
- Has enrolled >15,000 of its 20,000 goal

Summary

- Methods for D2P trials are established
- Simplicity for the participant is essential
- Recruiting from communities and providers participants know may be more successful than from the web
- Change state laws to allow shipping ‘study drugs’

Thanks to Pioneers

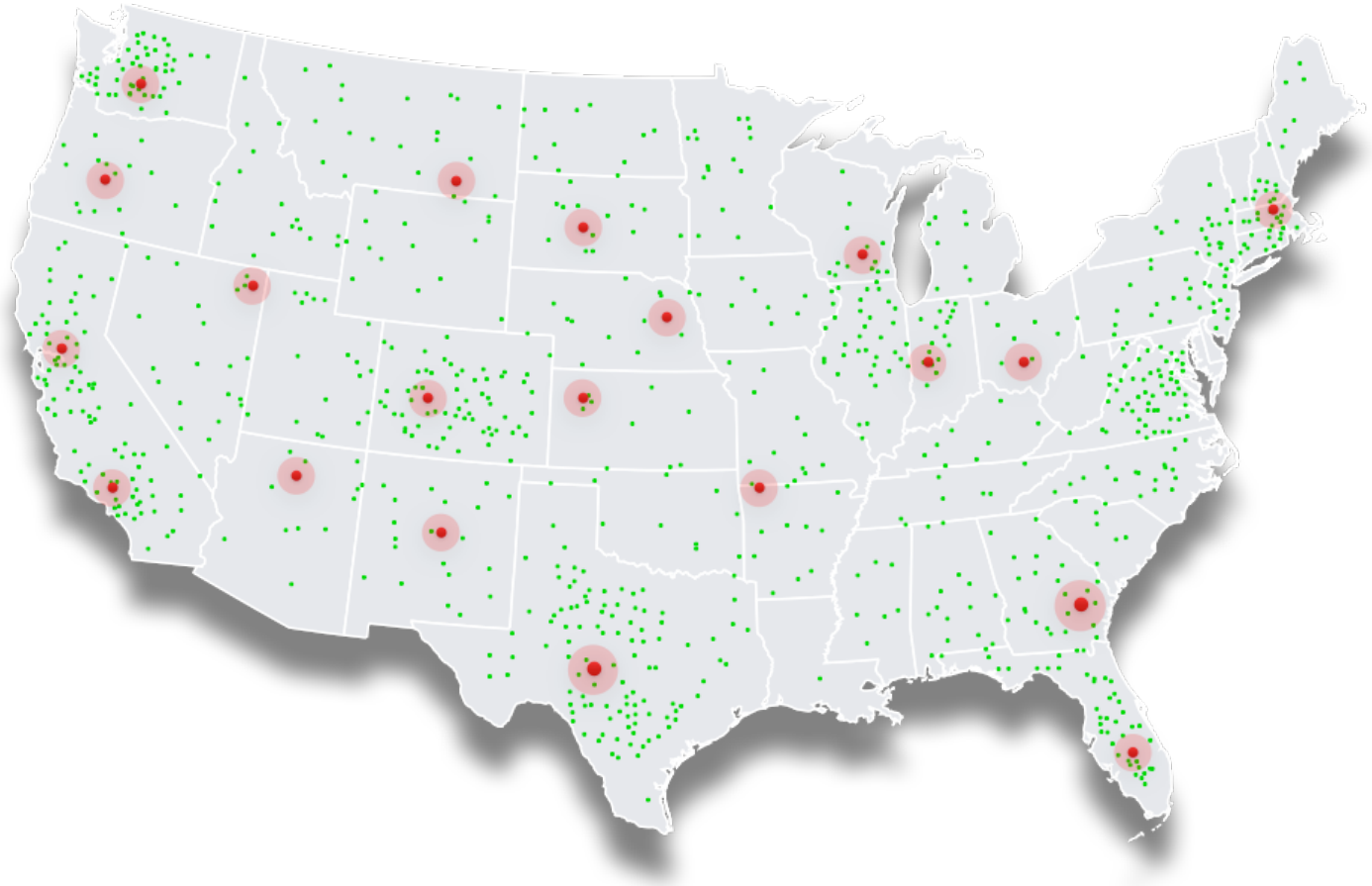
- Susan Love, MD (Susan Love Foundation)
- Bradly Jacobs, MD (UCSF, 1747, Mytrus,)
- Steve Bent, MD (UCSF, 1747, Mytrus)
- Andy Lee, MD (Pfizer → Genzyme → Merck COO)
- Anthony Costello (Mytrus, Medidata)
- Bob Temple, FDA


Thank you

Summary and Lessons
Direct-to-Participant Trials

- The concept and technologies work well
- FDA is supportive
- eConsent has taken off, online and in sites
- REMOTE: an example of how to kill innovation
  - Force innovation to adapt to your system
  - Be risk averse
- Simplify protocols
- Involve participants in planning

Site-based trials



History

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- Started 1747 in 2000
  - $900k from eLilly Ventures
  - Alph Bingham & Will Dere

Site-based trials

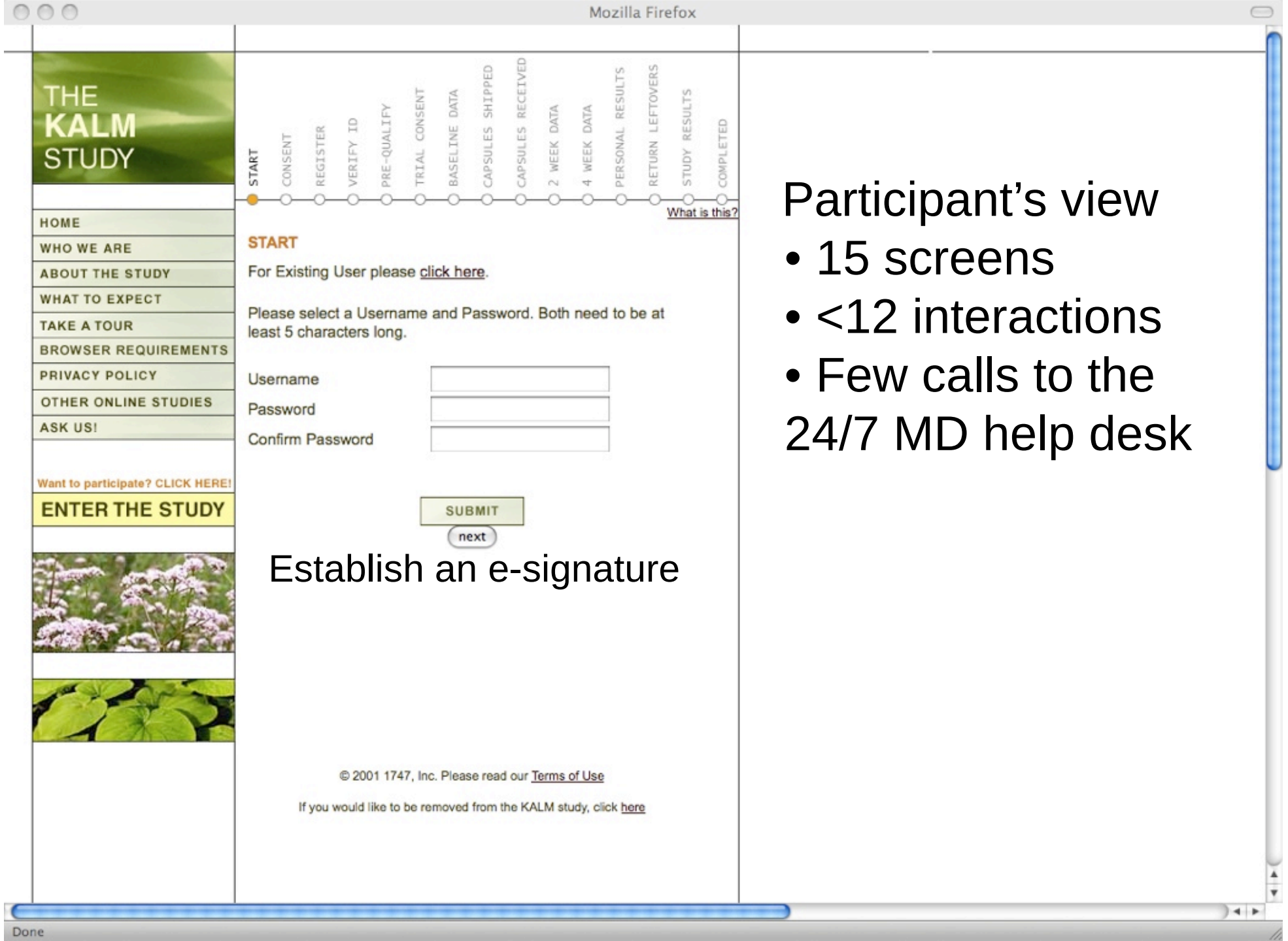
Slow recruitment
Limited access
Sites are expensive

Direct-to-Participant (D2P) Trials

Faster recruitment?
Less expensive?

Clinical Coordinating Center performs all functions

- Recruits participants
- Informed consent
- Dispense study drug
- Collect data
- Manage adverse events
- Analyze results
- Return results to participants



Establish an e-signature

Participant's view

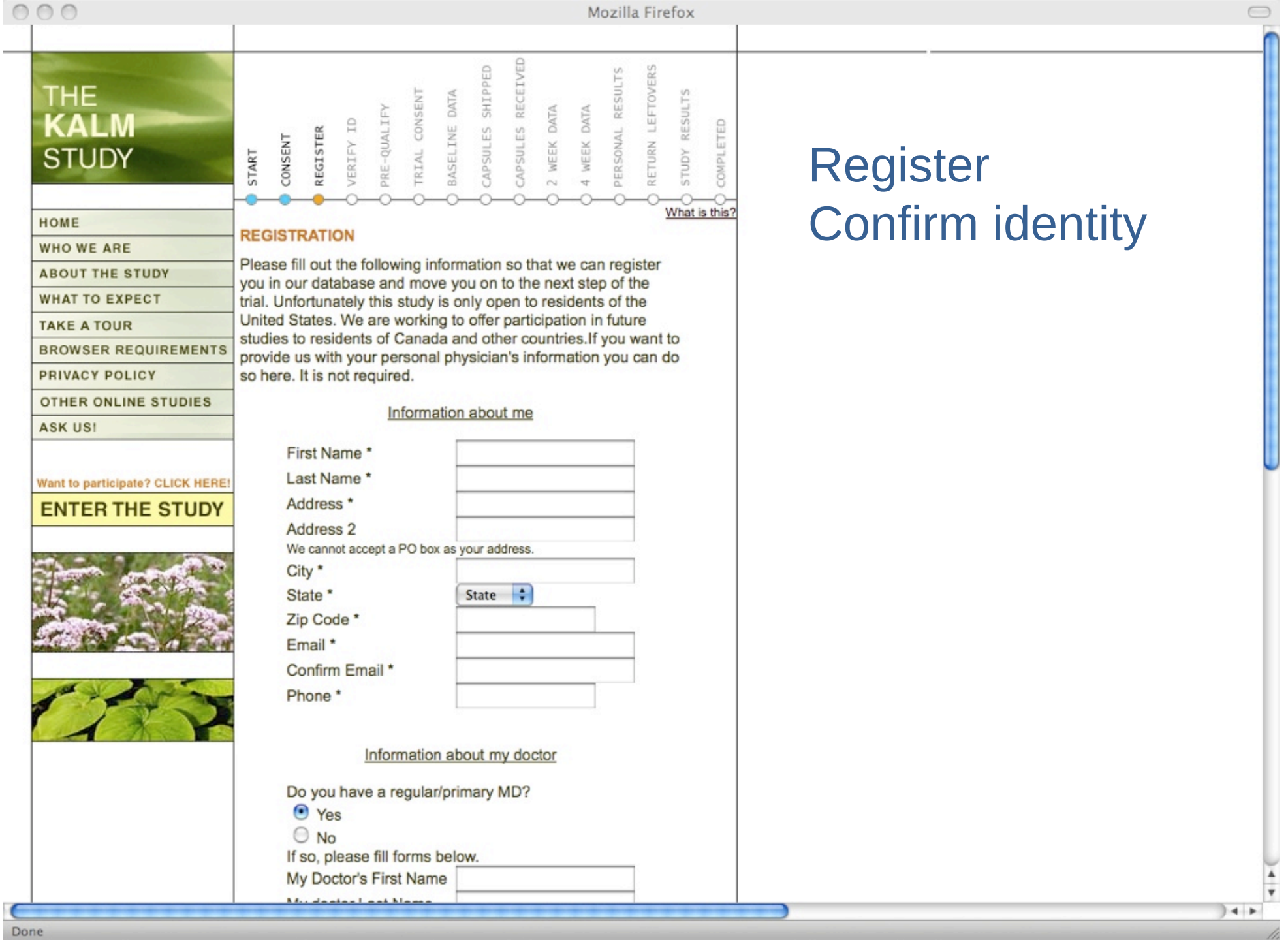
- 15 screens
- <12 interactions
- Few calls to the 24/7 MD help desk

KALM

One Center

- Participant-facing EDC and website
  - No paper
- Identity confirmed by Idiology
- Established an e-signature
- Interactive eConsent with quiz; approved by W.I.R.B.
- Managed study ‘drugs’: FedEx delivery with proof of I.D.
- Recruit: ads on websites; emails to friends and groups
- Approved by Western IRB

Jacobs, et al. Medicine 2005,84:197

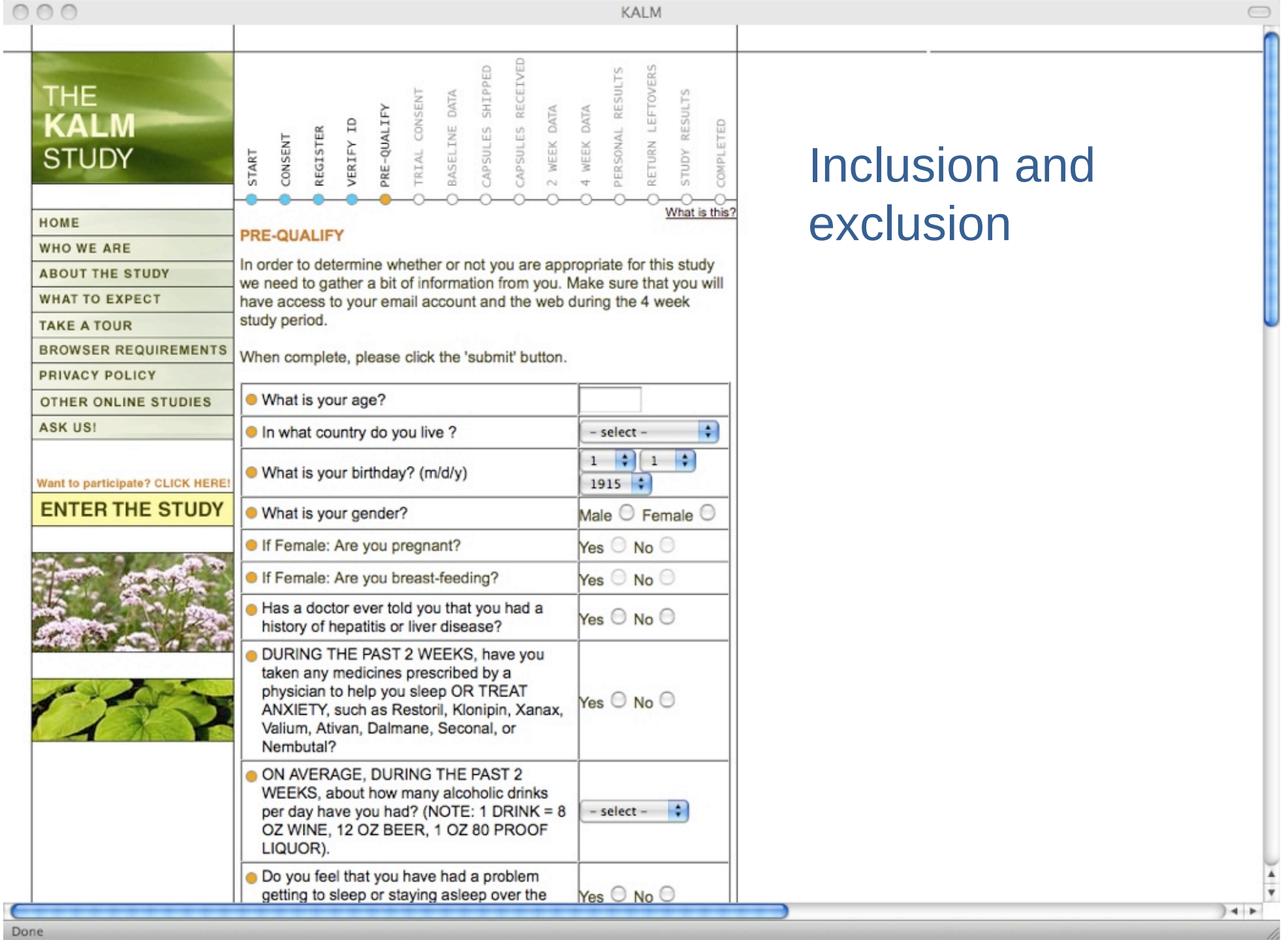


Register
Confirm identity

"On the Internet, nobody knows you're a dog."

Answer 3 questions unique to you

by Idiology



Inclusion and exclusion

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THE KALM STUDY

- HOME
- WHO WE ARE
- ABOUT THE STUDY
- WHAT TO EXPECT
- TAKE A TOUR
- BROWSER REQUIREMENTS
- PRIVACY POLICY
- OTHER ONLINE STUDIES
- ASK US!

Want to participate? CLICK HERE!

ENTER THE STUDY

START · CONSENT · REGISTER · VERIFY ID · PRE-QUALIFY · TRIAL CONSENT · BASELINE DATA · CAPSULES SHIPPED · CAPSULES RECEIVED · 2 WEEK DATA · 4 WEEK DATA · PERSONAL RESULTS · RETURN LEFTOVERS · STUDY RESULTS · COMPLETED

What is this?

TRIAL CONSENT

This is a form required of all people who participate in research. Read all the lines. If you have questions or don't understand, you can send questions by email before you press the consent form submit button.

CONSENT TO BE A PARTICIPANT IN A RESEARCH STUDY

A RANDOMIZED TRIAL OF HERBAL TREATMENTS, KAVA AND VALERIAN, FOR STRESS, ANXIETY AND INSOMNIA

PURPOSE AND BACKGROUND

Dr. Brad Jacobs and his associates are conducting a study to learn about the effects of two herbal products, Kava and Valerian Root, on stress, anxiety and sleep.

We are inviting you to participate in this study because you have indicated that you have have at least some symptoms that might be associated with stress, namely anxiety or trouble sleeping.

PROCEDURES

If you agree to participate in this study, the following will happen:

You will answer some questions about your level of stress, anxiety, sleep and daytime sleepiness and some questions about other things, such as how much coffee you drink.

If your answers to the questions indicate that you are eligible for the study, you will be randomly assigned to one of three groups and study medicine will be sent to the mailing address that you provide. A member of the study staff will contact you by telephone to ensure that you received the package of study medicine and to answer any questions .

You will have one chance of receiving Kava (Group K), one chance of receiving Valerian (Group V), and one chance of

Done

Informed consent document

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ASSESSMENT OF UNDERSTANDING OF THE INFORMED CONSENT

If you wish to participate, please take a moment to answer the following questions to let us know that you have understood some key points about this study. To answer these, you may refer back to the previous information in this form.

1. Kava and Valerian root are (Mark only one):

○	Drugs you normally get by doctor's prescription
○	Herbs that do not require a doctor's prescription

2. Which of the following side effects have been noted in people who have taken Kava during other studies? (You may select more than one answer; Mark answers that are correct)

☐	Skin rash
☐	Nausea
☐	A stuffy or runny nose
☐	Pain in joints

3. Which of the following side effects have been noted in people who have taken Valerian during other studies? (You may select more than one answer; Mark answers that are correct)

☐	Nightmares
☐	Headache
☐	Diarrhea
☐	Drowsiness

4. Which of the following things should you avoid while you are participating in this study? (Mark answers that are correct). You should not:

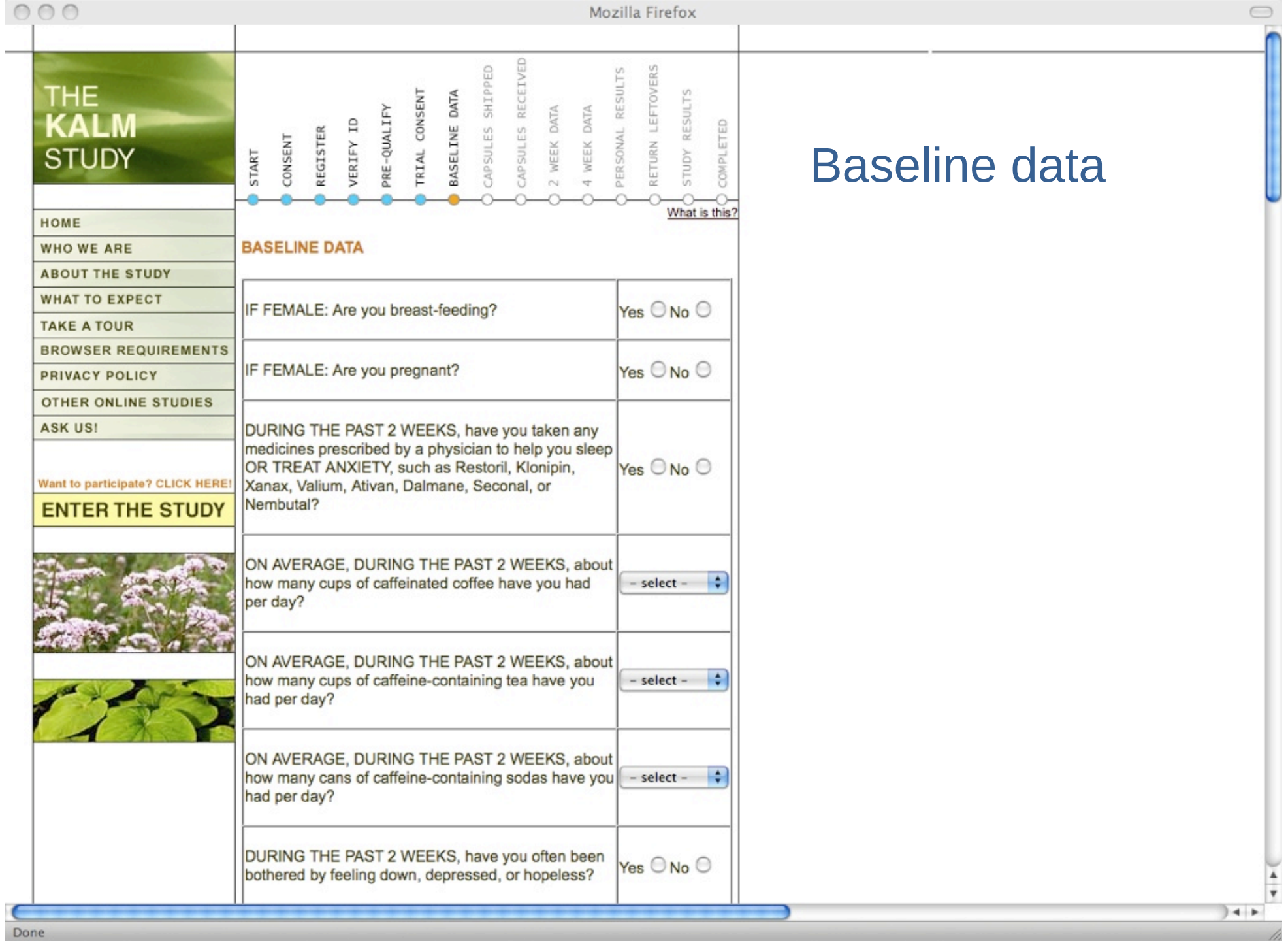
☐	Take sedatives or medicines for sleep
☐	Engage in strenuous exercise
☐	Take prescription medicines for high blood pressure

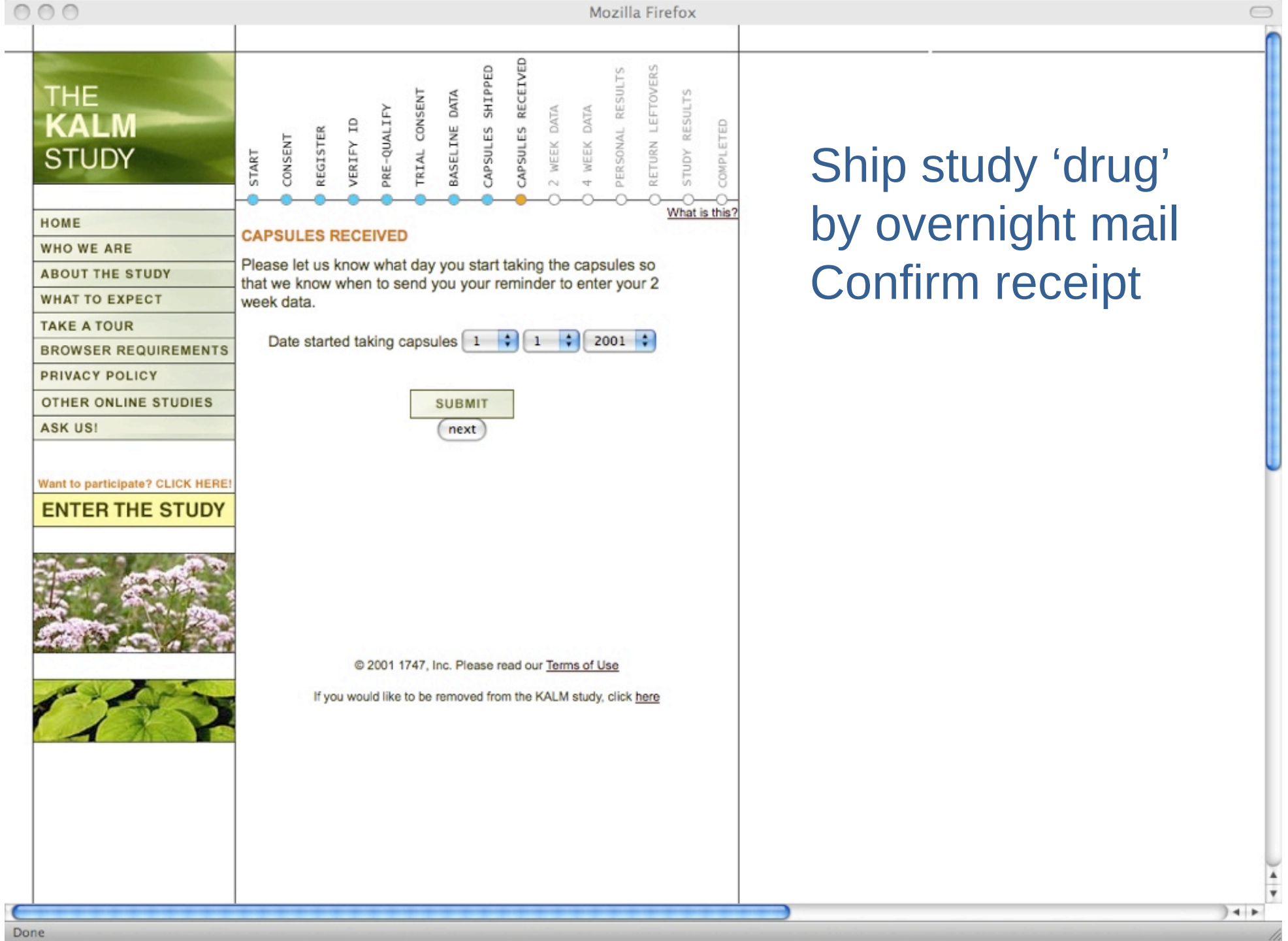
5. If you agree to participate you will receive either Kava, or

Done

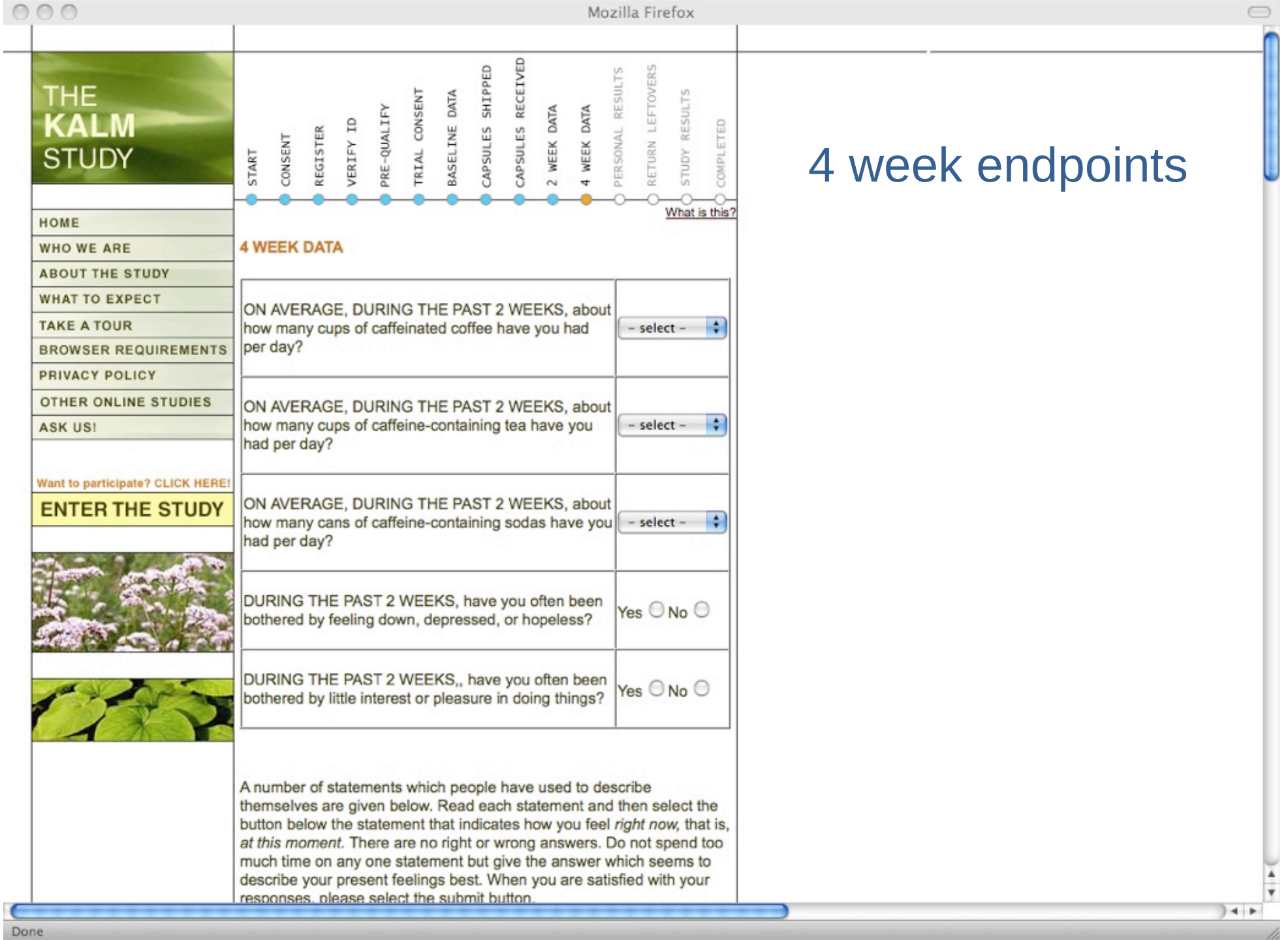
Quiz about consent (must get 100%)

Baseline data





Ship study ‘drug’
by overnight mail
Confirm receipt

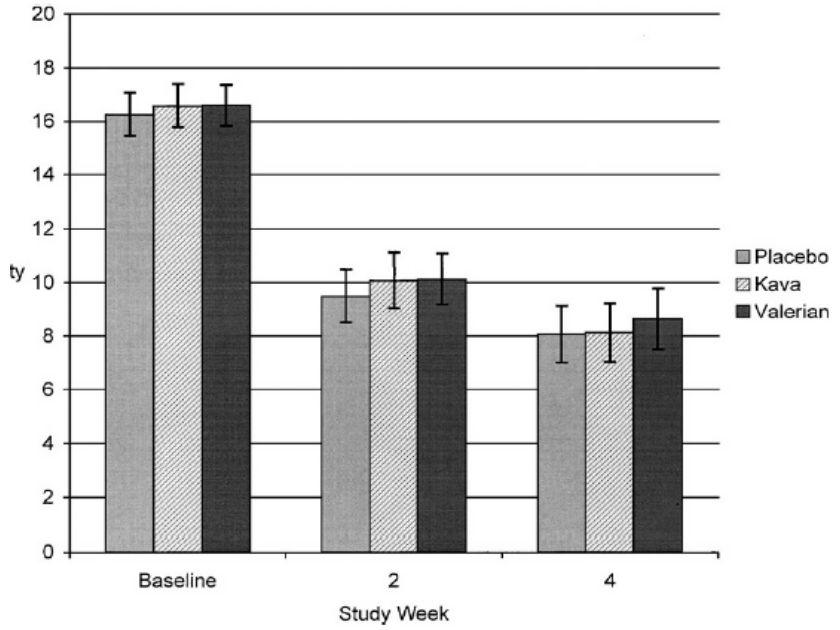


4 week endpoints

Results

- Preplanned analysis was done within 1 hour of last participant's data entry
- Participant results sent by email within 24 hours
- No differences

ISI score



To mention

- Adaptable – health system recruitment; e-consent
- Migraine: 2 trials
  - Personal connection more successful
  - No visits a major plus

To mention

- HOME
  - Patient-centered; designed with input from patients: advocate and Parkinson's Foundation
  - Designed to be conducted from home
  - Phone, text, email…
  - 3 sources of competitive recruitment
  - Teleneurology scoring
  - Include patients with dementia
  - Home exam & testing and IV drug vs. pbo
  - EMR reporting but plan direct queries and x-ray confirmation

-centric Trial

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What is this?

YOUR PERSONAL RESULTS

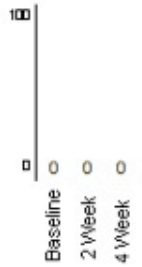
We want to thank you again for your participation which will help further our understanding of these herbs. We'd love to hear from you. Please submit any comments or suggestions by emailing us.

We will contact you via email when all the participants have completed the final questions so that you may see the results of the full trial. Please send back any unused study drug in the pre-paid envelope you received at the beginning of the study.

YOUR PERSONAL RESULTS: Your study drug was Kava and Valerian Placebo.

Explanation of graphs: Time is depicted along the horizontal axis. Study commencement starts on the left side and study completion is on the right side of the line on the horizontal axis.

Below are the total points for the "I feel calm", "I feel secure" questions. Lower numbers mean less stress and higher numbers mean more stress.



The following graphs are for the sleeping habits questions:

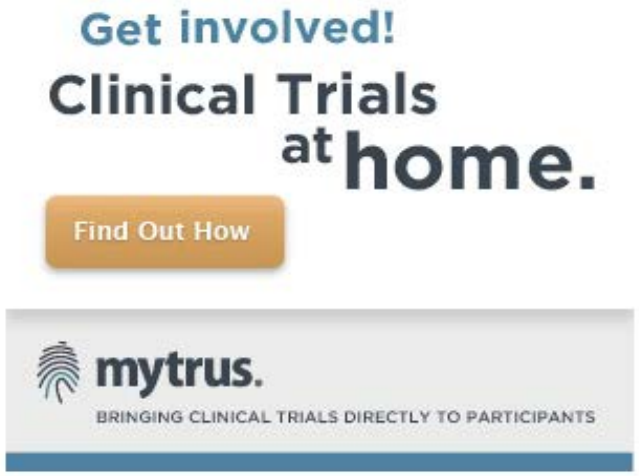
Done

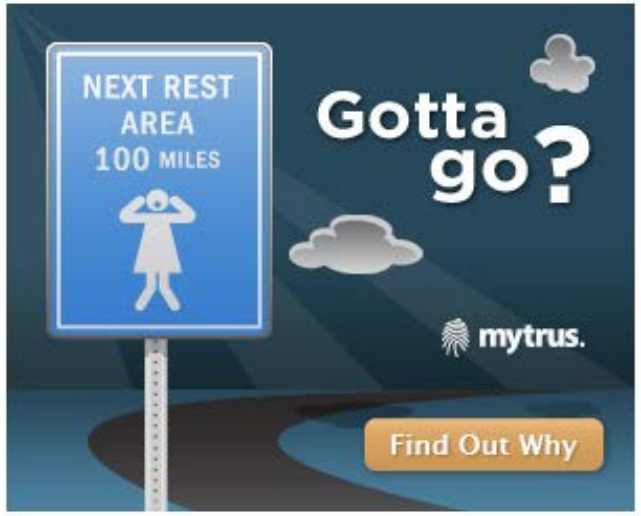
The participant's own results were reported within 1 day

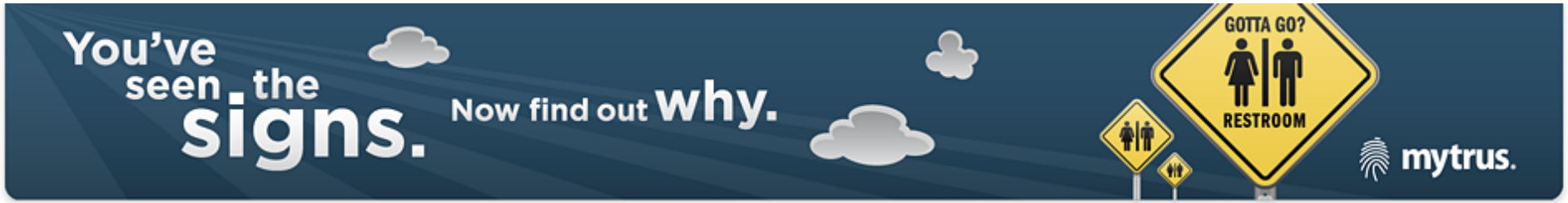
Some of the complexity

- States require local exams to prescribe “study drug” by mail; limited to 8 states
- Collected urine all day and enter volumes
  - Mobile device did not allow correction of errors
- “Security:” CAPTCHA plus 2-step I.D. with time limit “to prevent hacking”
- In case of FDA visit, full-time monitor(s), eg reviewed redacted emails. Volumes of paper.
- Required reading consent to participants
  - Even after successful eConsent.

Intensive recruitment
online ads and targeted emails







What?

Dr. Stephen Bent
Associate Professor at UCSF

Dr. Stephen Bent and Mytrus Inc. are looking for women [illegible]tting accidents" for a clinical research study sponsored by Pfizer.

The trial will will test the effectiveness and safety of Detrol (tolterodine ER), an approved medication, for reducing wetting accidents among women who have an overactive bladder (urge urinary incontinence).

Who?

Women who...

- Live in the United States
- Have regular internet access
- At least 21 years old
- Have overactive bladder symptoms (urge urinary incontinence). Take our survey now to find out.
- Are NOT planning to become pregnant.
- Are NOT taking a medication to treat their symptoms.

How?

Convenience

- You will participate from your home or work using the internet!

Safety

- Your identity will be verified over the internet.
- Blood and urine tests will be done at the beginning and end of the research study.
- Dr. Bent and his study team will contact you before you start the study and are always available.

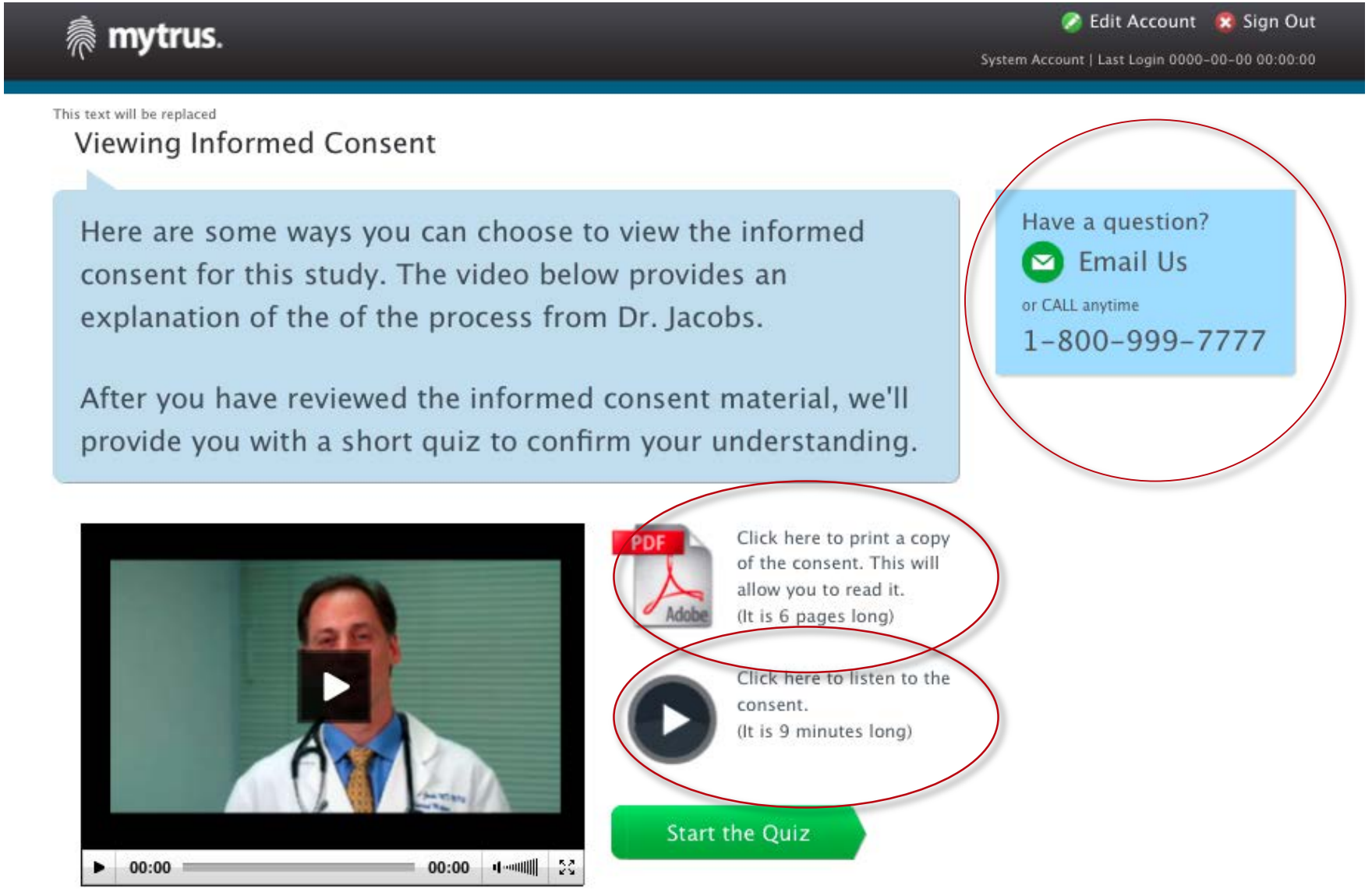
Compensation

- You will be paid for your time and effort.

If you feel you're eligible and interested in learning more, please click the button to proceed.

Proceed

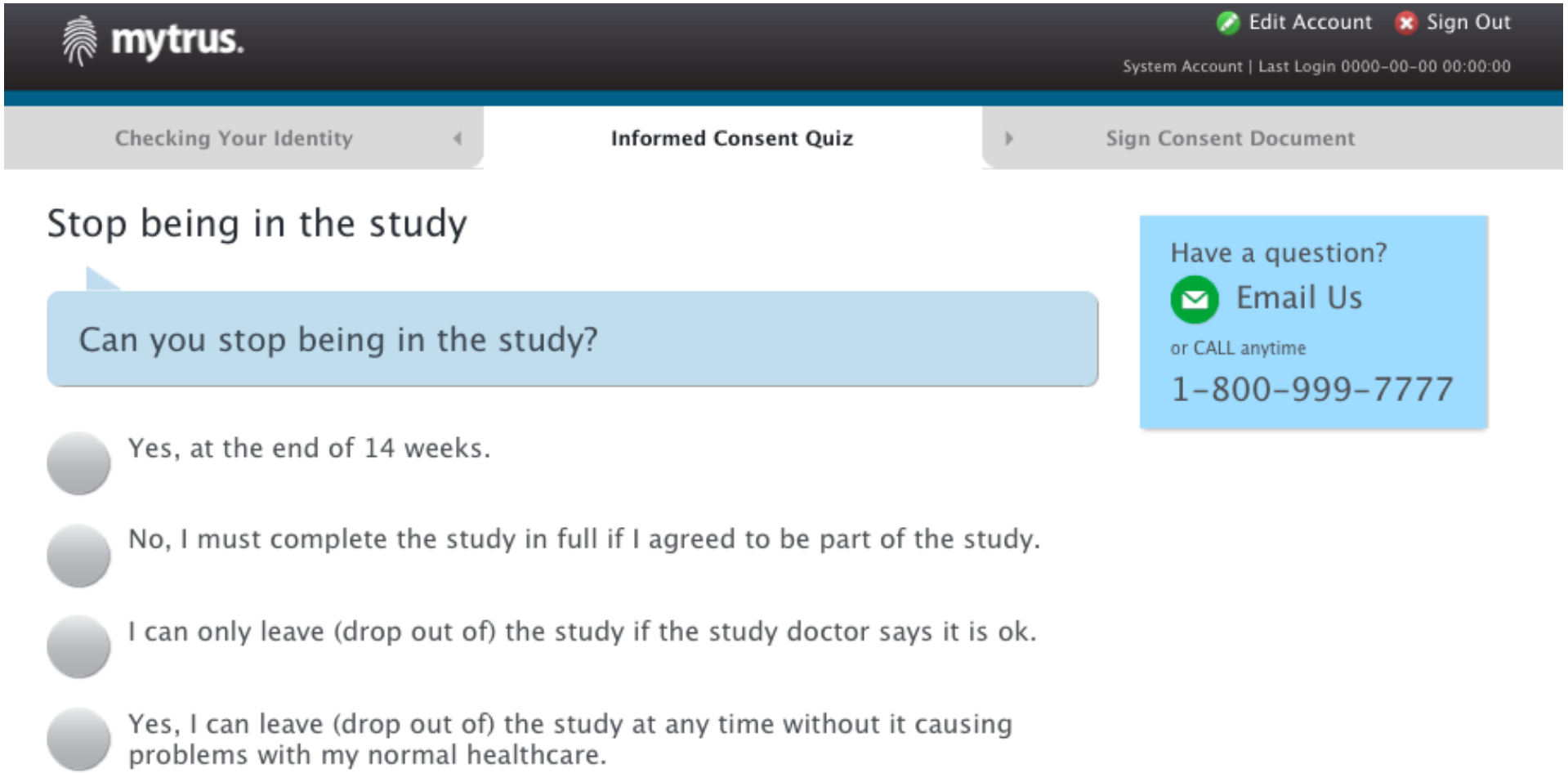
Consent: Video, text, and audio



FDA

- Bob Temple arranged internal FDA meetings
- Final meeting with Pfizer & Mytrus team approved with key variance; delivery of drug across state lines; not dispensed by investigator

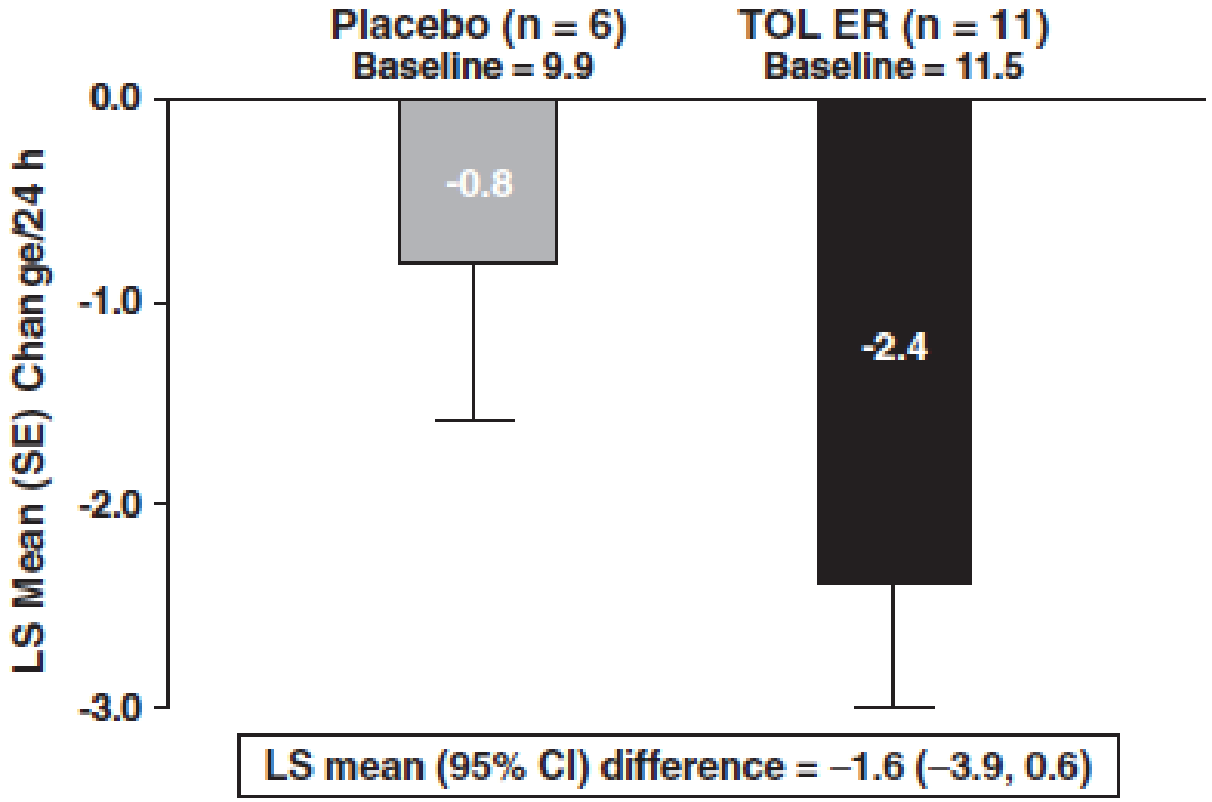
Quiz to confirm understanding



- Get 100%
- Electronic signature

states). After the study investigator reviewed the test results, women who remained eligible were enrolled in the placebo run-in phase. At this point, participants were sent single-blind study medication by courier to their home. Participants were asked to confirm receipt of trial medication via the study website and were instructed to take one capsule once daily. Participants also received a mobile feature phone (Nokia 6301) with a custom application installed for entering bladder e-diary data, together with detailed instructions on completing the e-diary; the use of the e-diary was validated before beginning patient recruitment. Women were instructed to collect and measure the volume of 24 hours of urine on days 5 and 12, report all micturitions and UUI episodes and the time of occurrence on days 5 through 7 and 12 through 14, and enter this information into the e-diary. At the end of the placebo run-in phase, women who had polyuria (>3000 mL per 24 hours), a voided volume >500 mL for any single micturition, a mean of <8 micturitions per 24 hours in a 3-day e-diary, or a mean of <1 UUI episode per 24 hours in a 3-day e-diary were automatically excluded. Women who were unable to enter e-diary data also were automatically excluded. The study investigator also reviewed all screening data against protocol eligibility criteria and excluded any ineligible subjects. The investigator could not

Detrol worked!



interactive autism network

An Internet-Based Randomized Controlled Trial of Omega-3 Fatty Acids for Hyperactivity in Children with autism

Kennedy Krieger Institute

Linking the autism community and researchers

share. research. discover.

Sponsored by Autism Speaks, the Simons Foundation, and National Institute of Mental Health

AUTISM SPEAKS™ It's time to listen.

SIMONS FOUNDATION

NIMH National Institute of Mental Health

Study Team and Funding

- Kennedy Krieger / Johns Hopkins
  - Paul A. Law, MD, MPH (Principal Investigator)
  - Tara Zandi, MA
  - Kiely Law, MD, MPH
  - Jay Nestle, BS
  - Amy Daniels, PhD
- University of California, San Francisco
  - Stephen Bent, MD (Principal Investigator)
  - Robert Hendren, DO
  - Felicia Widjaja, BS
  - Jae Eun Choi, MS

- Funded by
  - NIH CTSA Supplement Grant (Advancing Study Designs for Comparative Effectiveness Research)
  - Simons Foundation SFARI Pilot Award

Objectives

- DETERMINE IF OM3 reduces hyperactivity in children with autism
- Assess change in social functioning
- Evaluate performance of an Internet Based-Randomized Controlled Trial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Explore IAN Community
IAN research
Interactive Autism Network • Linking Autism Researchers and Families
IAN User ID:
mary8
Password:
>forgot my password or IAN ID:
share
research
discover
"Every child is different. And unless we as parents tell the researchers what is specific to our child, how will they know?"
-IAN Participant
What is IAN Research?
Thousands of people from around the world are coming together through IAN Research, an innovative online initiative connecting researchers with individuals and families affected by autism spectrum disorders (ASD). The information being shared by those living with an ASD is already helping researchers discover new insights about the disorder and is assisting community leaders advocating for improved services. This dynamic exchange is the largest autism research study and is making remarkable strides to improve the lives of individuals and families affected by ASD. This collaborative effort strives to accelerate important breakthroughs about causes, diagnosis, and treatments which may lead to the discovery of a possible cure.
Why participate in IAN Research?
Each year, many important ASD studies are significantly delayed or not completed because researchers can not find enough qualified participants. As a result, valuable opportunities to learn about ASD are lost. IAN Research is changing this trend by facilitating research recruitment and participation. To date, nearly 40,000 individuals have joined IAN Research and over 300 research studies have been able to move forward.
By providing basic information on the diagnosis, family background, home environment, and services received, you can help researchers, educators, policy makers, and others better understand the impact of this puzzling group of disorders. It takes approximately one to two hours to complete the secure, online questionnaires, and you can do it as your schedule allows, without ever leaving home.
We all have questions. Together we'll find answers.
Join the Largest Online Autism Research Effort
By sharing your experiences and knowledge, you'll help researchers and advocates as they fight to improve the lives of those with ASD.
JOIN NOW
How do I join?
Click on the "Join Now" button and follow the instructions to create your IAN ID and password.
OR
If you are already a member of IAN community and have an IAN ID and password, enter them into the "returning members" sign-in at the top of this page. You will be asked to provide additional information about yourself and to complete the consent process. If you are enrolling a child (under the age of 18) or an adult under your guardianship, you will also need to provide information about this individual and complete the consent process.
What Happens Next?
Once registration is completed, you will be able to add other eligible family members and complete your online research questions. It takes approximately one to two hours to provide this basic information. You may invite other eligible adult family


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Participate in IAN research
IAN RESEARCH LAUNCHES A SURVEY ABOUT BULLYING
Children with ASD are vulnerable to bullying and IAN's new survey will help us understand more about the problem.
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The Journey to Adulthood
Sharing Through Research
Searching Smaller Haystack Reveals Promising Findings
The Social Brain and ASD
Preliminary Results of Elopement and Wandering Survey
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About ASDs
Simons Simplex Community
Newly Diagnosed
Challenging Behaviors
Therapies & Treatments
All About Research
Adults
For Researchers
IAN Articles
RECENT DISCUSSIONS view all
Does your child wander or bolt from safe places? (April 20)
Animal-assisted therapies and service dogs (January 31)
Telling children about their ASD (October 14)
Bullies in the school or neighborhood? (September 1)
Discuss pregnancy, birth factors, and ASD (August 10)
Talk about our report on grandparents (April 6)
What happens between first
MOST EMAILED view all
IAN Home
Driving with ASD
ASD and Romantic Relationships
Grandparents Part 1
Telling a Child About His ASD
Asperger's Syndrome: Meltdowns
IAN Research Report: Family Stress -- Part 1
Bullying
Grandparent Survey
POLL OF THE WEEK past polls
I would like IAN Community to feature more articles on:
Adult and transition issues
School issues
Treatments and therapies
Research into causes
Family impact
Issues of daily living
Can't decide! All are important to me.
VOTE NOW

Methods

- **Sample Selection: 5-8 y.o. with autism and hyperactivity**
- **Recruitment: Children in IAN with an established diagnosis**
- **Screening: Hyperactivity questionnaire**
- **Consent: online**
- **Baseline measures: Aberrant Behavior Checklist (ABC)**
- **Randomization: Automated, overnight mail of meds**
- **Data Collection: All online using IAN (JAWS) platform**
- **FDA: IND approved.**

Results

- In 6 weeks (Sept-Oct 2012)
  - 864 e-mails sent to children of target age
  - 127 families expressed interest (15%)
  - 96 families completed informed consent
  - 57 children (and their teachers!) from 28 states were eligible and randomized

- In 3.5 months (end of Dec 2012)
  - All 57 children and all 57 teachers completed final outcomes (100% completion rate)

Results – Change in Primary Outcome Measure

	Placebo (n=28)	Omega-3 (n=29)	Difference in change*	95% CI	P-value
ABC-Hyperactivity	-3.4	-5.3	1.9	-2.2 to 5.2	0.38
ABC-Irritability	-2.1	-2.0	-0.1	-3.3 to 2.8	0.50
ABC-Stereotypy	-0.5	-2.0	1.6	0.0 to 3.2	0.05
ABC-Lethargy	0.1	-2.1	2.2	0.5 to 4.1	0.01
ABC-Innapp. Speech	-0.9	-0.6	-0.3	-1.4 to 1.0	0.73