N-of-You

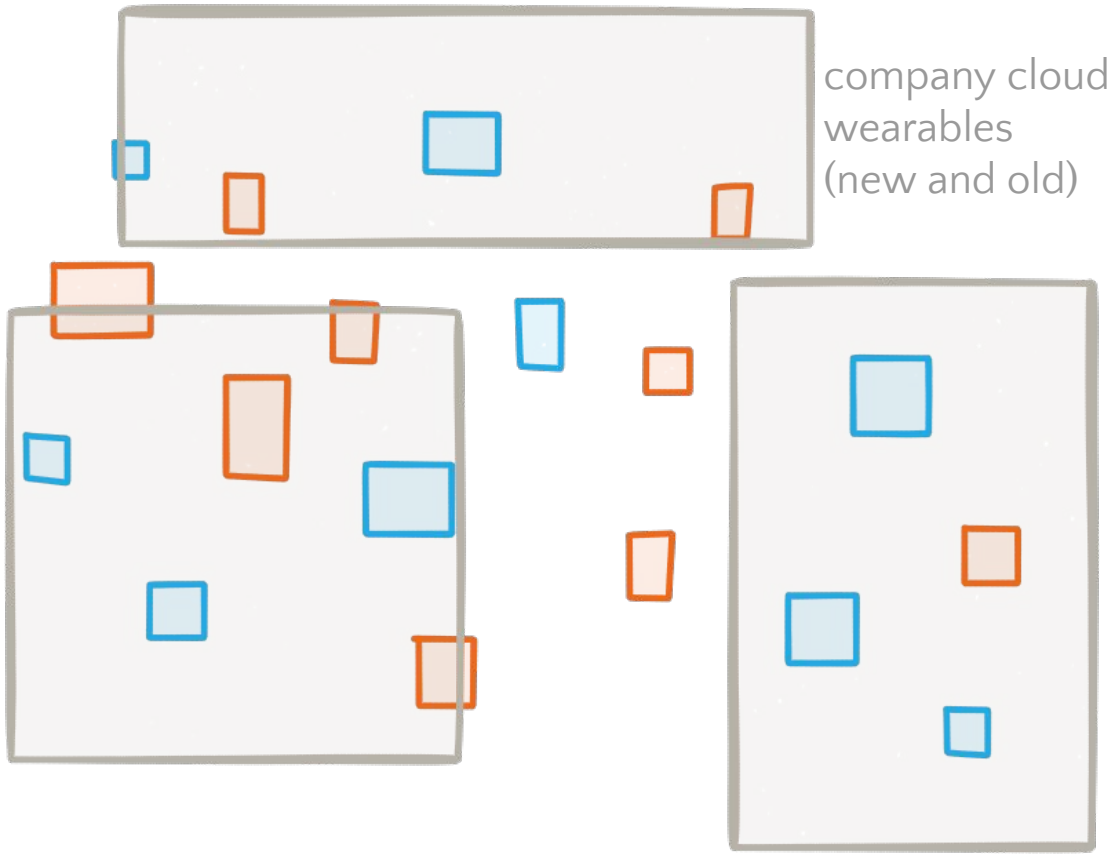
May 17, 2016

RANE

The State Of Affairs

- **Integrating Patient-generated data from outside the clinic** is really happening
- More people are **using apps and buying devices** to improve their health

But...a patient's health data is STILL trapped in silos



Open mHealth

Data's not only siloed. It's different.

- In format
  - HL7 and CCDA feeds for EHRs
  - flat files are used by researchers for Stata and R
  - public APIs producing custom XML, JSON
  - differences in naming, time formats, etc.

- In meaning
  - differences in units, time zone handling, etc.
  - differences in granularity, grouping
  - missing information

Open mHealth

Open mHealth is a non-profit startup making it easier to **access** and **use** mobile health data.

How Do We Do It?

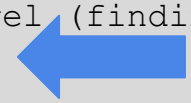
1. Open Standard

The first and only open standard for mobile health data

~100 different clinically-valid schemas

- Schemas are the **common language** needed to interoperate data between apps and devices and make it useful in a clinical environment
- These schemas represent clinical measurements

```
"references": [
{
  "description": "The SNOMED code represents Blood glucose level (finding)",
  "url": "http://purl.bioontology.org/.../SNOMEDCT/365812005"
}]
```



2. Open Source Platform

APIs And Libraries For

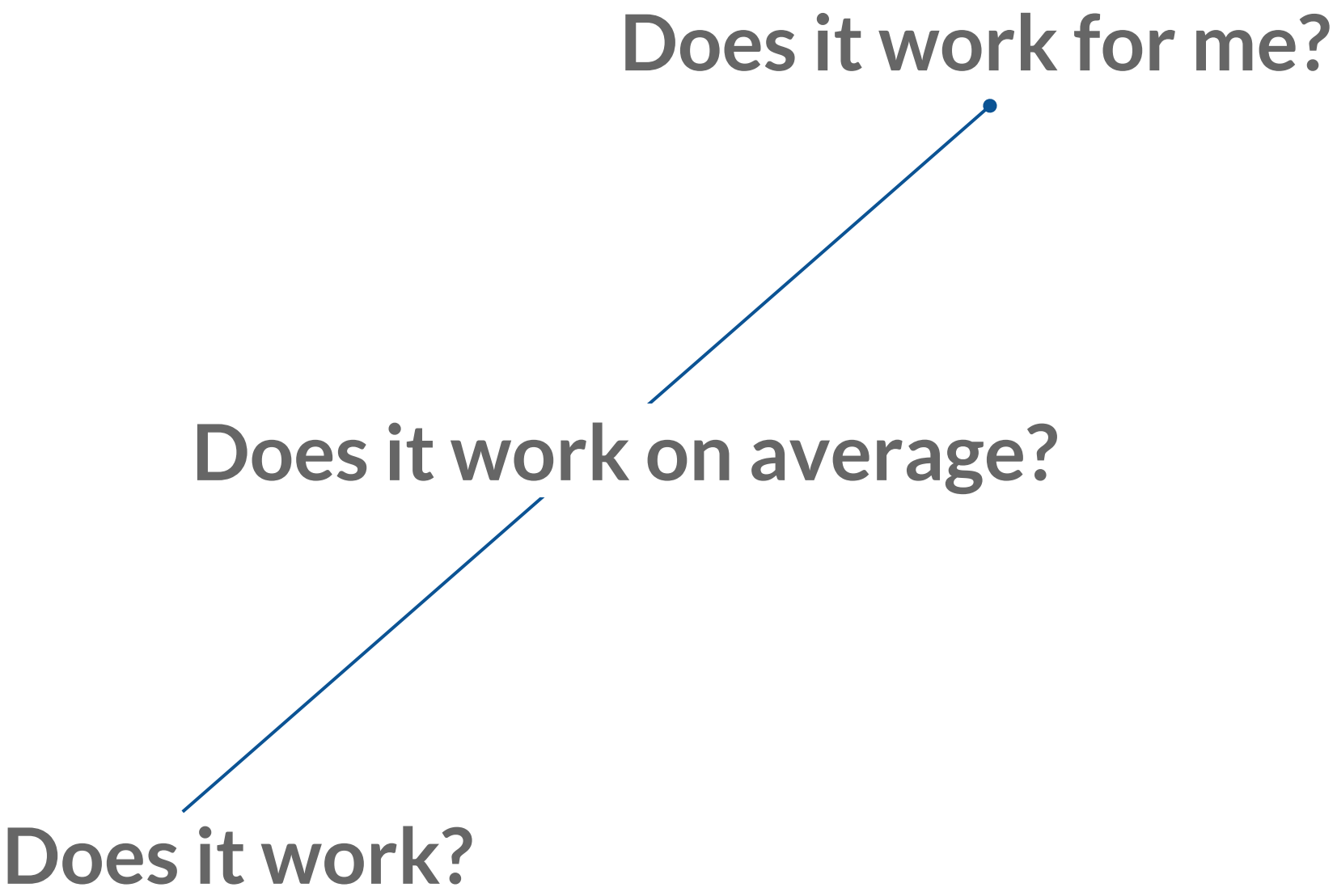
- Storage
- Data Integration
  - From Wearables and Apps through **Shimmer**
  - From Healthkit through **Granola**
  - From EHRs through **Pulse**
- Processing
- Visualization
- Data generation

Over 2,000+ downloads, stars and forks... and counting!

3. Community

Open Standard + Platform + Community

n-of-1 clinical trials


Does it work for me?
Does it work on average?
Does it work?

A → B → A*

~2,000

Open Standard + Platform + Community + N-of-1

Trialist

Trialist Participant Setup

Information About Prescribing Opioids | Logout

trialist-setup-help@ohmage.org

Patient Information

Patient's Login: A.Patient

Study Protocol

Regimen A:

- [x] Tylenol (acetaminophen)
- [ ] Any NSAID (e.g., ibuprofen, naproxen, sulindac)
- [ ] Codeine combination product (e.g., Tylenol with codeine, Tylenol #3)
- [ ] Tramadol (e.g., Ultram, Ryzolt, ConZip, Rybix)
- [ ] Hydrocodone combination product (e.g., Vicodin, Norco)
- [ ] Oxycodone combination treatment (e.g., Percocet)
- [ ] Complementary treatment: including but not limited to physical activity (exercise, stretching, yoga), mindfulness (meditation, relaxation, music therapy)

Regimen B:

- [ ] No specific treatment to be tested against Regimen A
- [ ] Tylenol (acetaminophen)
- [x] Any NSAID (e.g., ibuprofen, naproxen, sulindac)
- [ ] Codeine combination product (e.g., Tylenol with codeine, Tylenol #3)
- [ ] Tramadol (e.g., Ultram, Ryzolt, ConZip, Rybix)
- [ ] Hydrocodone combination product (e.g., Vicodin, Norco)
- [ ] Oxycodone combination treatment (e.g., Percocet)
- [ ] Complementary treatment: including but not limited to physical activity (exercise, stretching, yoga), mindfulness (meditation, relaxation, music therapy)

Do you intend to prescribe or continue any pain treatments in addition to the ones selected above?

- ( ) Yes
- (•) No

Study Start Date: 2014-10-14

Period Length: 7 days

Number of Cycles: 3 → Your study will end on Mon Nov 24 2014.

Trialist Participant Setup

Information About Prescribing Opioids | Logout

trialist-setup-help@ohmage.org

Patient Information

Patient's Login: A.Patient

Study Protocol

Regimen A:

- [x] Tylenol (aceta
- [ ] Any NSAID (e.g., ibuprofen, naproxen, sulindac)
- [ ] Codeine combination product (e.g., Tylenol with codeine, Tylenol #3)
- [ ] Tramadol (e.g., Ultram, Ryzolt, ConZip, Rybix)
- [ ] Hydrocodone combination product (e.g., Vicodin, Norco)
- [ ] Oxycodone combination treatment (e.g., Percocet)
- [ ] Complementary treatment: including but not limited to physical activity (exercise, stretching, yoga), mindfulness (meditation, relaxation, music therapy)

Regimen B:

- [ ] No specific treatment to be tested against Regimen A
- [ ] Tylenol (acetaminophen)
- [ ] Any NSAID (e.g., ibuprofen, naproxen, sulindac)
- [x] Codeine combination product (e.g., Tylenol with codeine, Tylenol #3)
- [ ] Tramadol (e.g., Ultram, Ryzolt, ConZip, Rybix)
- [ ] Hydrocodone combination product (e.g., Vicodin, Norco)
- [ ] Oxycodone combination treatment (e.g., Percocet)
- [ ] Complementary treatment: including but not limited to physical activity (exercise, stretching, yoga), mindfulness (meditation, relaxation, music therapy)

Do you intend to prescribe or continue any pain treatments in addition to the ones selected above?

- ( ) Yes
- (•) No

Study Start Date: 2014-10-14

Period Length: 7 days

Number of Cycles: 3 → Your study will end on Mon Nov 24 2014.

ADVISORY

×

You have selected an **opioid** or **tramadol** as part of your patient's treatment regimen. As a reminder, good clinical practice is to increase opioids *gradually* over the first few days. Decreases in both opioids and tramadol should also be done gradually over a few days to prevent withdrawal symptoms. Because of this, most n-of-1 trials involving opioids or tramadol should use **2-week treatment periods** (not 1-week periods). Patients should be advised that if they become drowsy, they should stop the medication and seek your advice.

Do you intend to prescribe or continue any pain treatments in addition to the ones selected above?

○ Yes ◉ No

Study Start Date: 2014-10-14

Period Length: 7 days

Number of Cycles: 3 → Your study will end on Mon Nov 24 2014.

Mandatory Outcomes

These are outcomes that will be tracked by every participant in the study.

- A daily questionnaire about pain intensity and interference.
- A daily question about how much fatigue you felt in the past day.
- A daily question about how drowsy you felt during the current day.
- A daily question about problems moving your bowels.
- A daily question about the previous night's sleep.

Pain medicines can sometimes affect our thinking or concentration. Please select one of the following questions about your thinking or concentration to track every day.

✓ My thinking has been foggy ...
I have had to work harder than usual to keep track of what I was doing ...

Optional Neuropathic Pain Outcome

Does the patient have pain accompanied by burning, pins and needles, itching, or a sensitive or unpleasant sensation on the skin?

◉ Yes ○ No

→ Your patient will receive daily questions about neuropathic pain.

Create and Assign Protocol

Do you intend to prescribe or continue any pain treatments in addition to the ones selected above?

○ Yes ◉ No

Study Start Date: 2014-10-14

Period Length: 7 days

Number of Cycles: 3

Success

The phone app for Trialist is ready to go! Welcome to the PREEMPT study.

Patient Login	A.Patient
Regimen A	Tylenol (acetaminophen)
Regimen B	Any NSAID (e.g., ibuprofen, naproxen, sulindac)
Period Length	7 days
Number of Cycles	3
Start Date	Sun Oct 12 2014
End Date	Mon Nov 24 2014

Mandatory Outcomes

These are outcomes that will be tracked by ev

- A daily questionnaire about pain intens
- A daily question about how much fatig
- A daily question about how drowsy yo
- A daily question about problems movi
- A daily question about the previous nig

Pain medicines can sometimes affect our thinking or concentration. Please select one of the following questions about your thinking or concentration to track every day.

My thinking has been foggy ...

Optional Neuropathic Pain Outcome

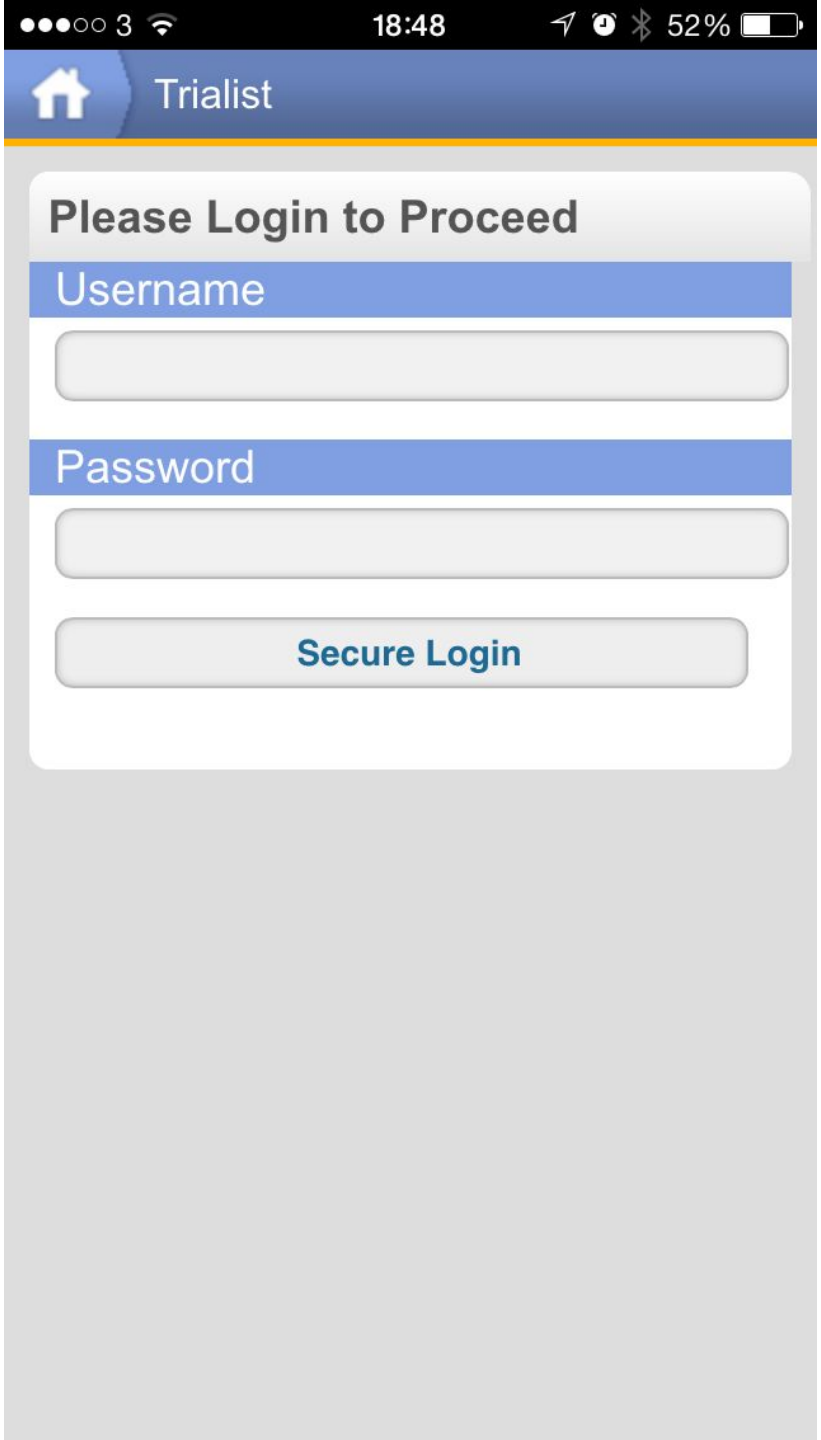
Does the patient have pain accompanied by burning, pins and needles, itching, or a sensitive or unpleasant sensation on the skin?

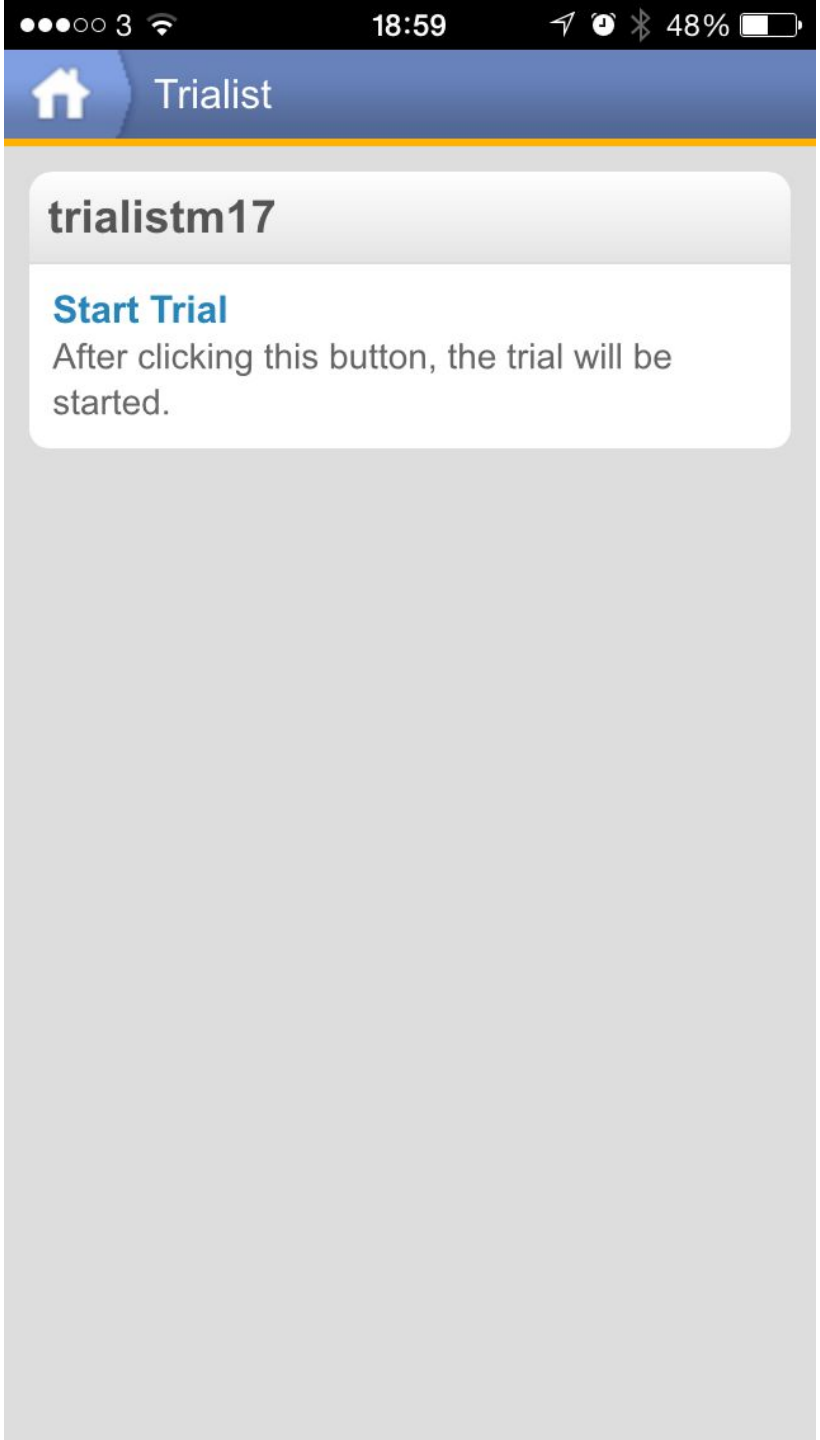
◉ Yes ○ No

→ Your patient will receive daily questions about neuropathic pain.

Create and Assign Protocol

Open mHealth

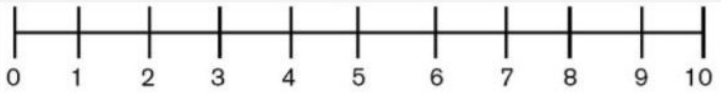

●●●○○ 3
18:48
52%
Trialist
Please Login to Proceed
Username
Password
Secure Login


●●●○○ 3
18:59
48%
Trialist
trialistm17
Start Trial
After clicking this button, the trial will be started.

●●○○○ 3 18:43 53%

Trialist

What number best describes your pain on average during the past 24 hours?



No pain — Pain as bad as you can imagine

\+

5

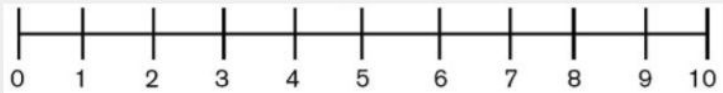
\-

Next

●○○○○ 3 18:43 53%

Trialist

What number best describes how much pain has interfered with your enjoyment of life during the past 24 hours?



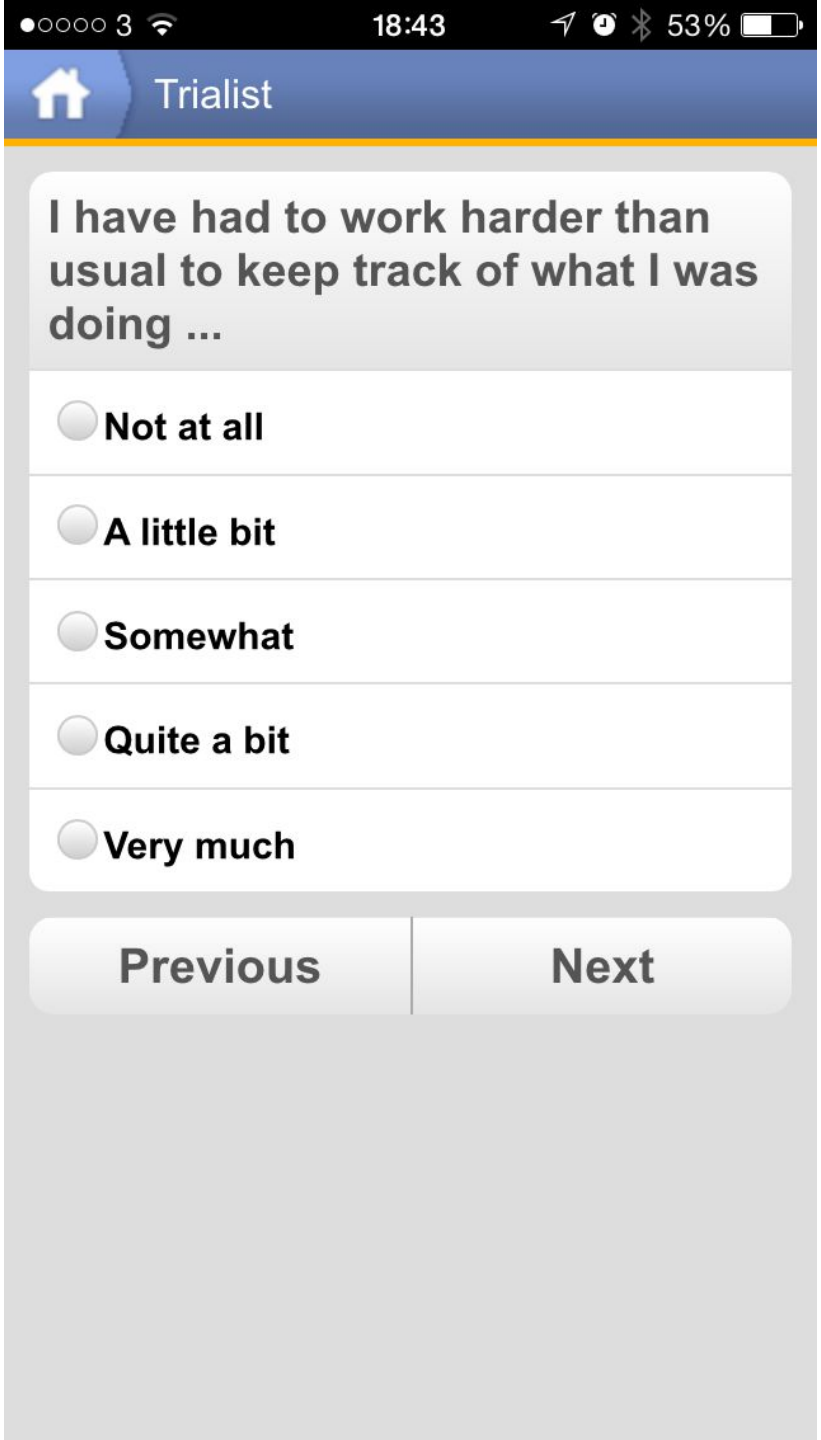
Does not interfere — Completely interferes

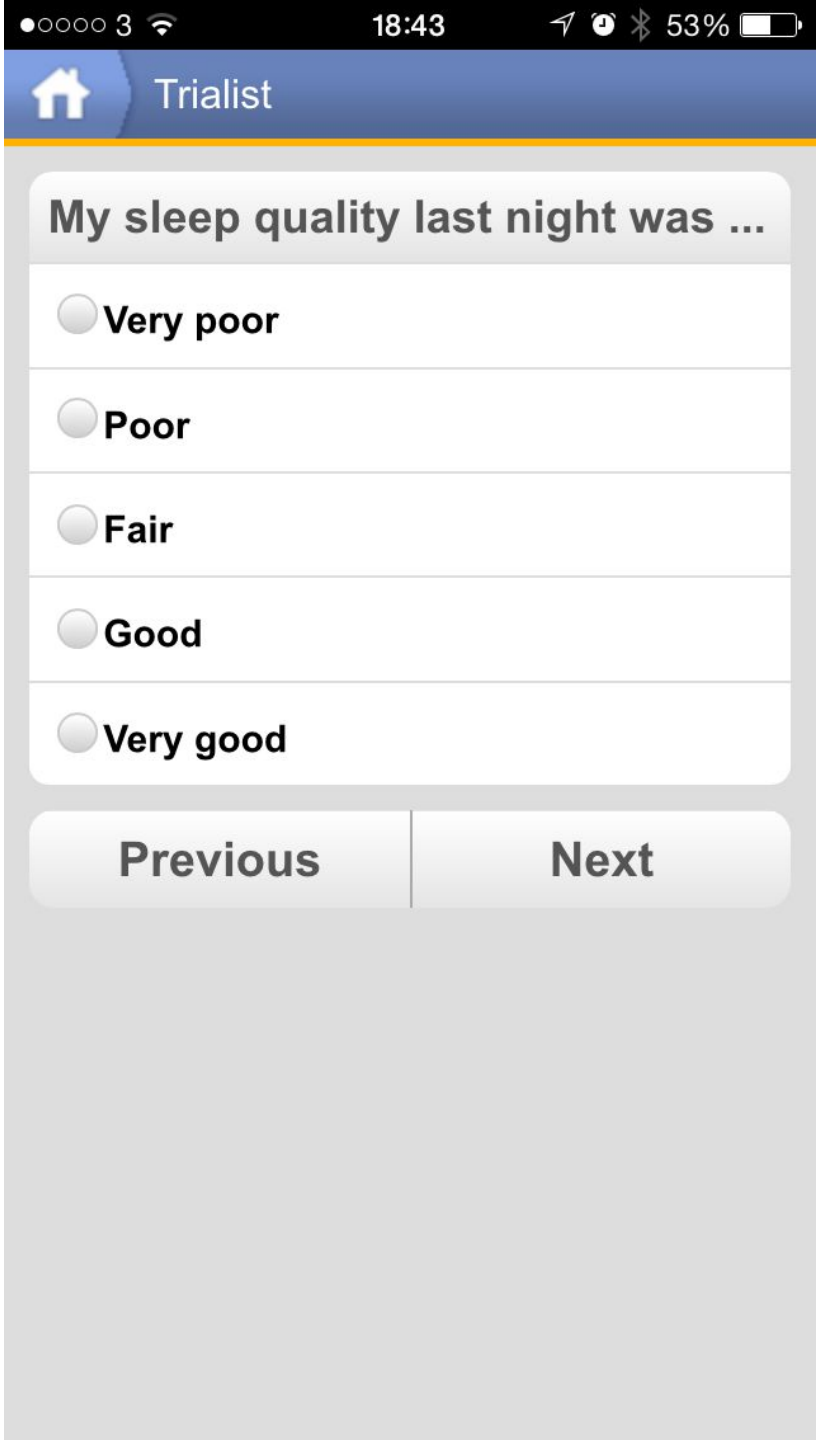
\+

5

\-

Previous | Next


●○○○○ 3
18:43
53%
Trialist
I have had to work harder than usual to keep track of what I was doing ...
Not at all
A little bit
Somewhat
Quite a bit
Very much
Previous
Next


●○○○○ 3
18:43
53%
Trialist
My sleep quality last night was ...
Very poor
Poor
Fair
Good
Very good
Previous
Next

Trialist Participant Results

Logout

trialist-setup-help@ohmage.org

Comparison of Treatments

[redacted]

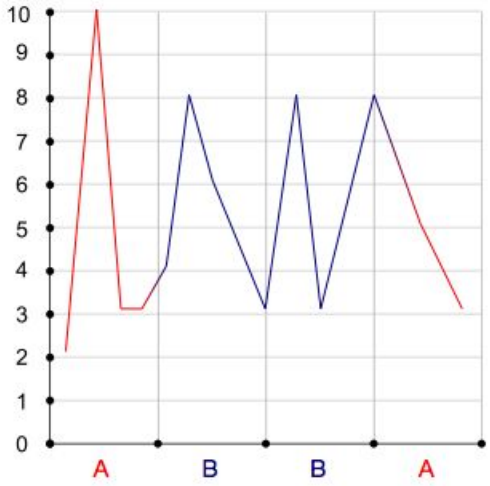
From: 2014-[redacted] To: 2014-[redacted]

Tylenol (acetaminophen)

Any NSAID (e.g., ibuprofen, naproxen, sulindac)

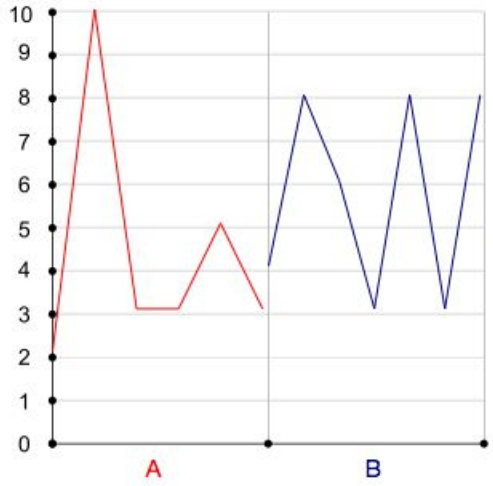
Pain Intensity Chronology

(Zero is no pain)

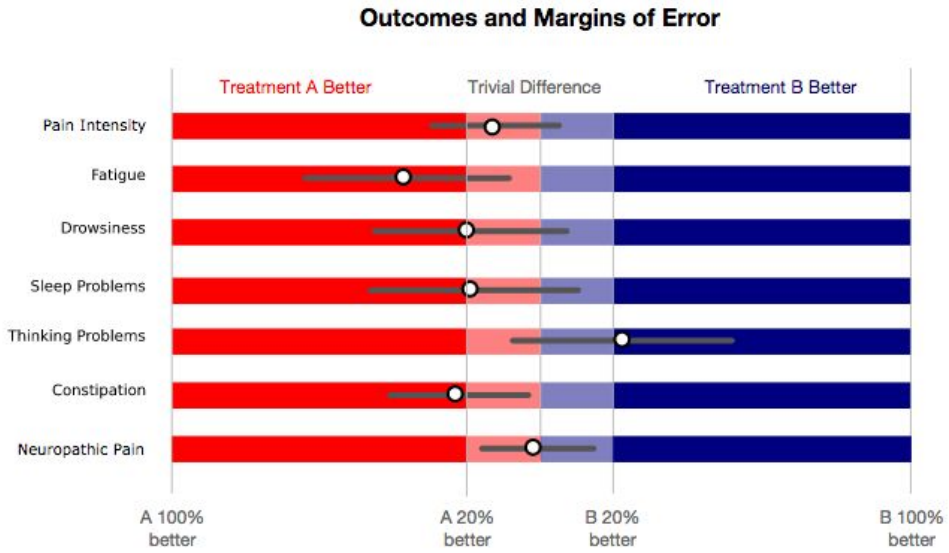


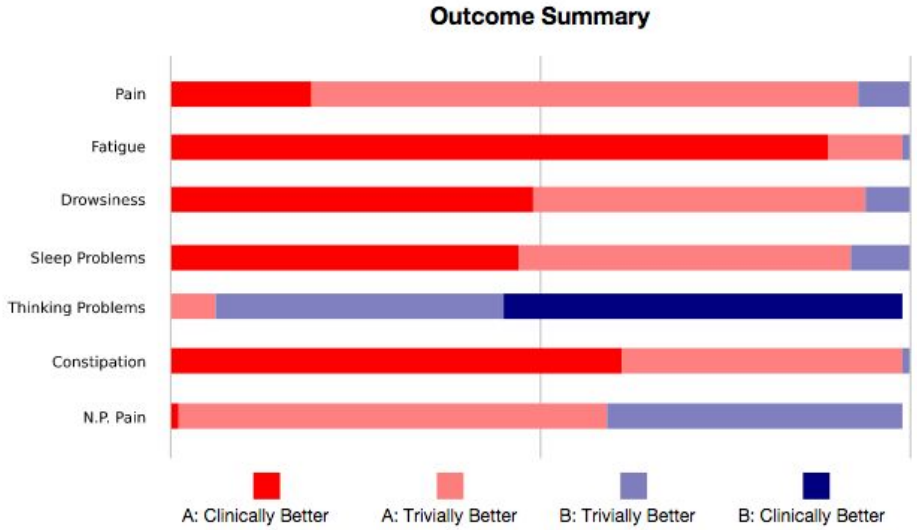
Pain Intensity by Treatment

(Zero is no pain)



Sample trial

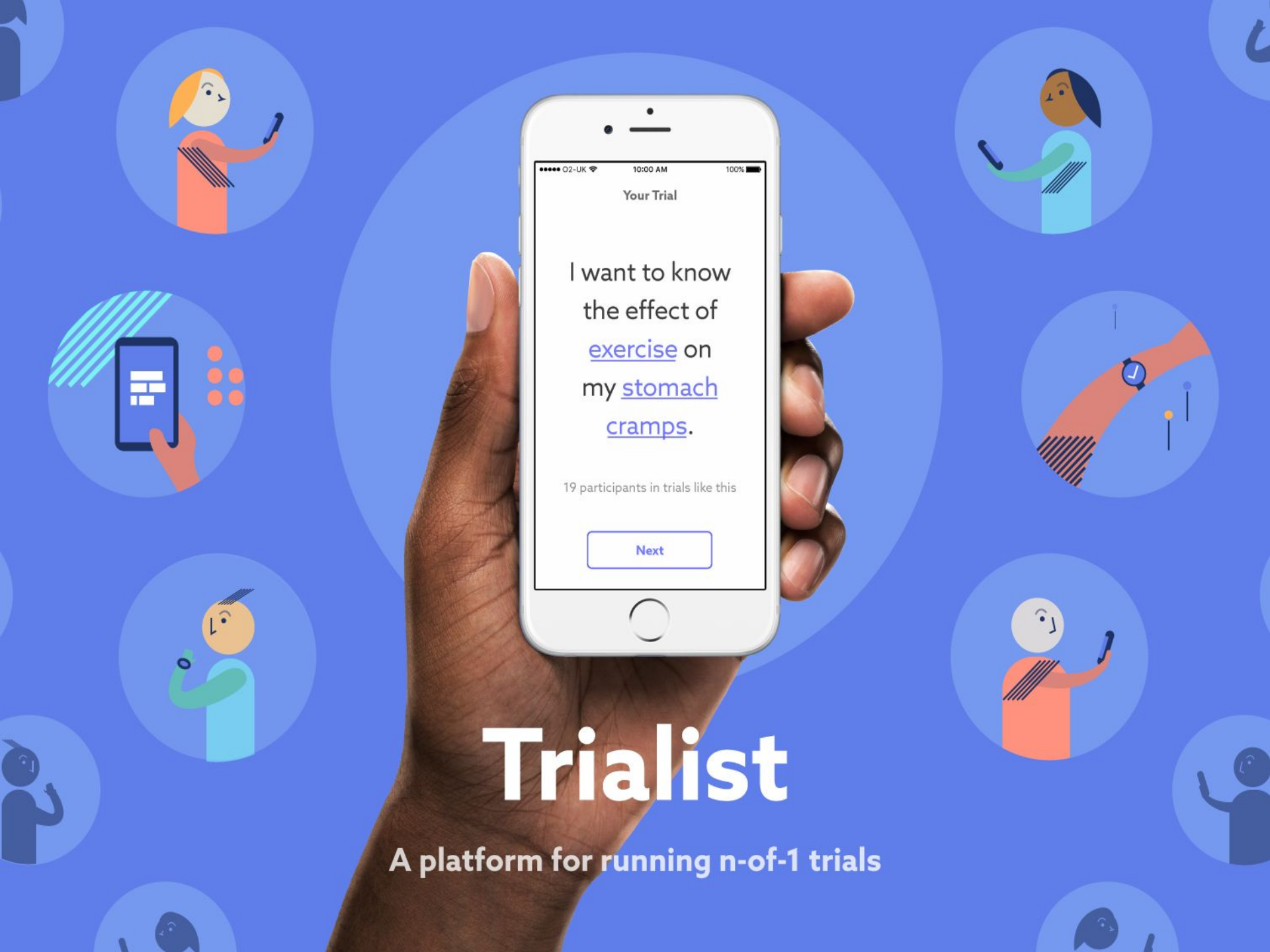




Sample trial

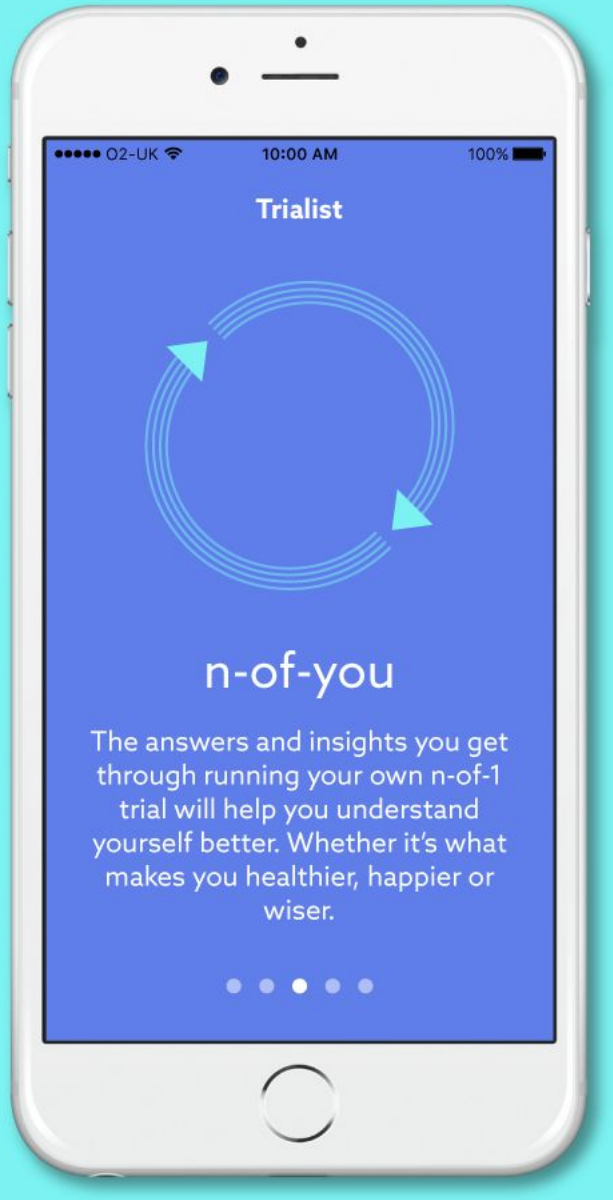
Hide Outcome Summary

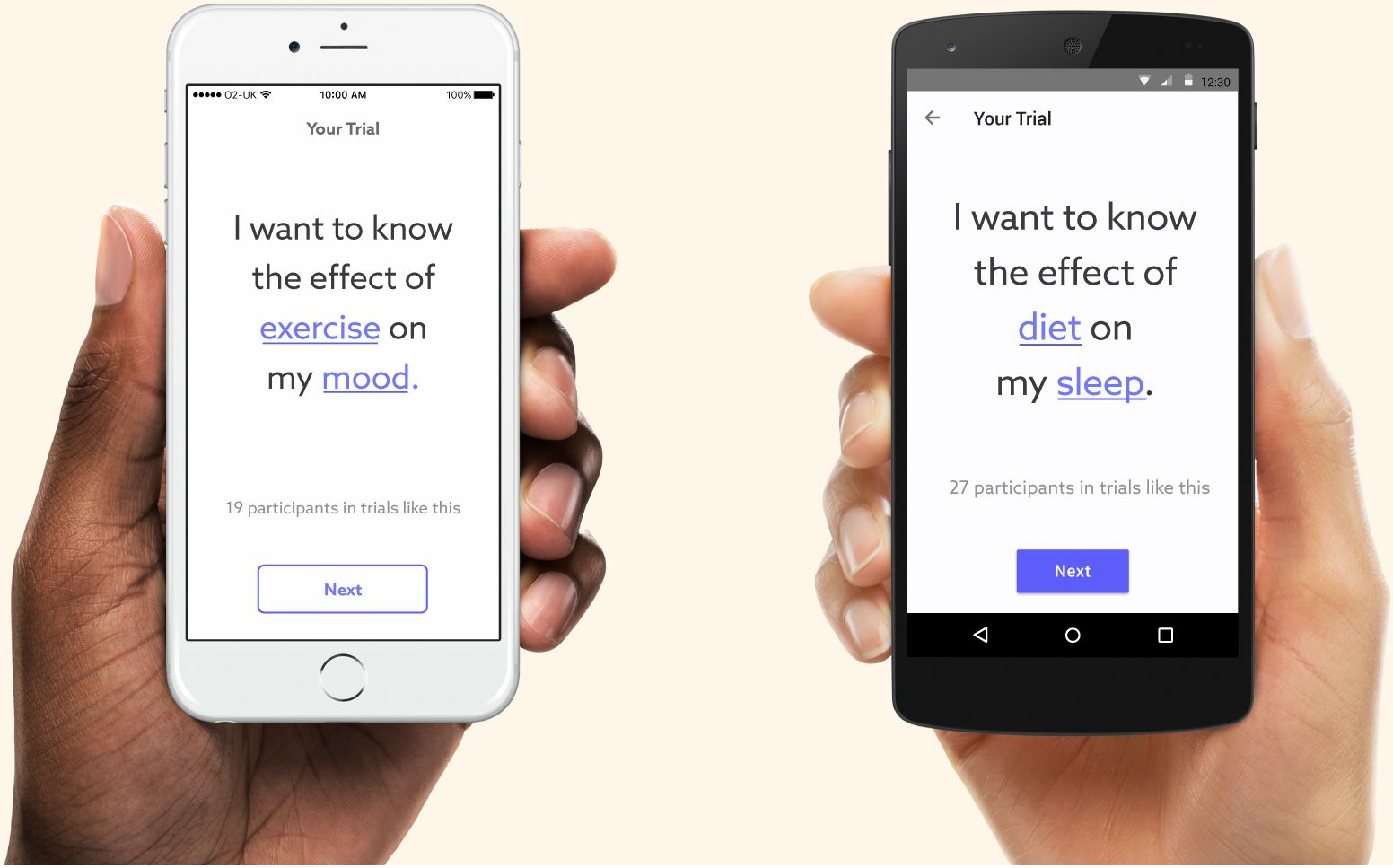
What’s next?

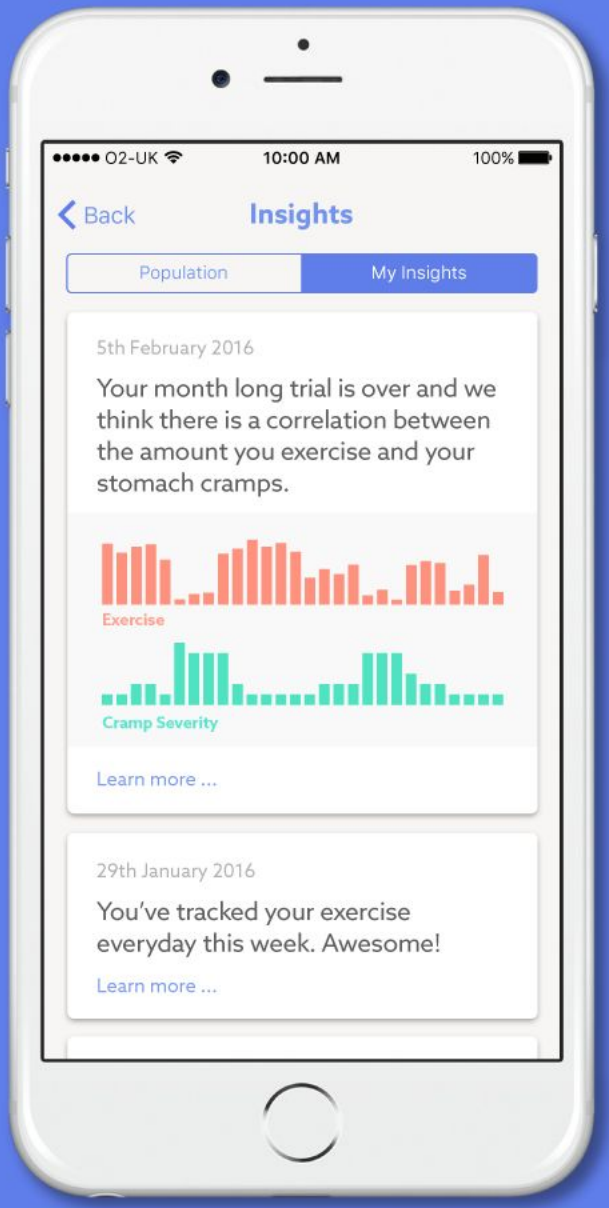


Trialist

A platform for running n-of-1 trials

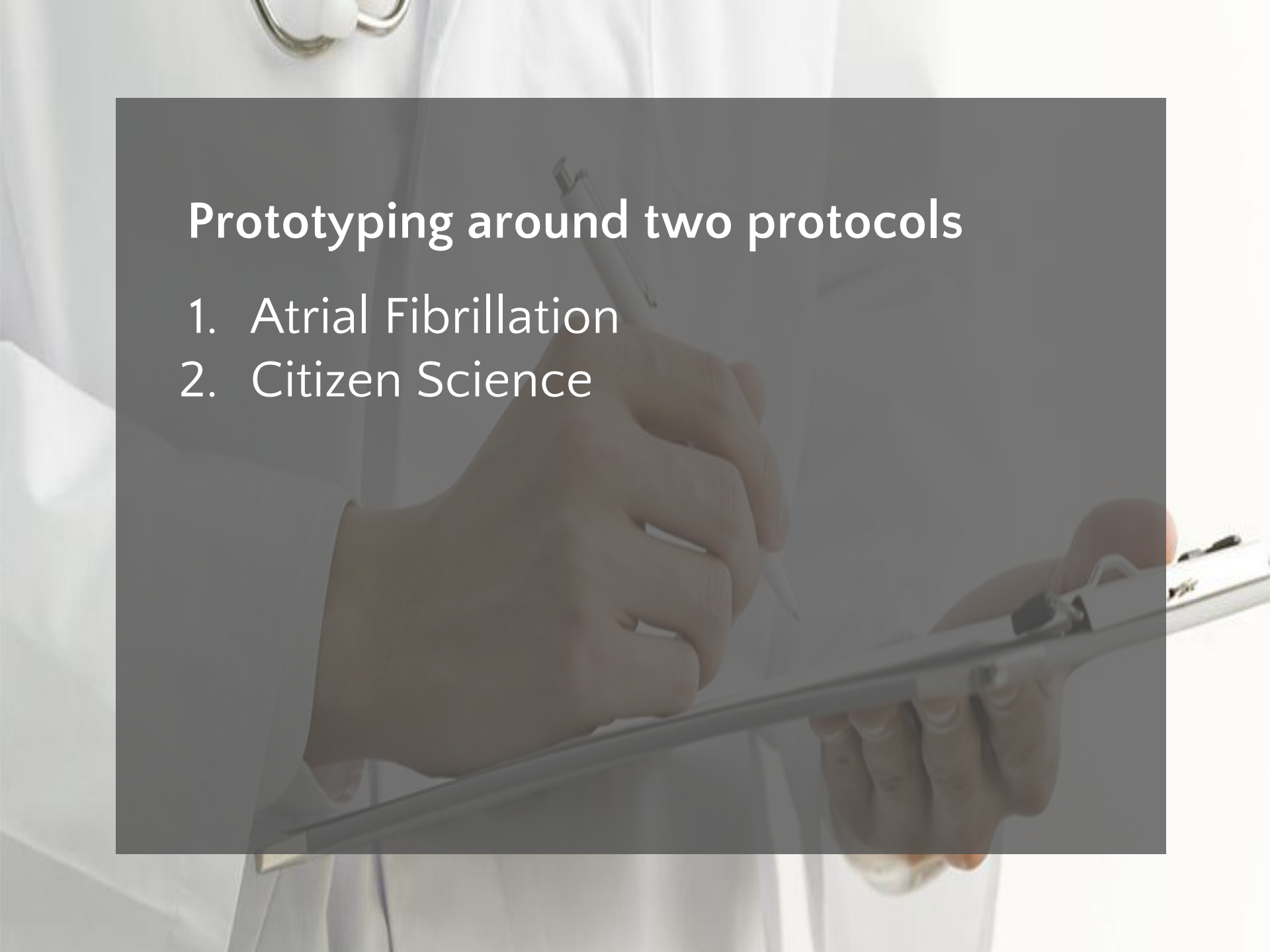

O2-UK
10:00 AM
100%
Trialist
n-of-you
The answers and insights you get through running your own n-of-1 trial will help you understand yourself better. Whether it's what makes you healthier, happier or wiser.


O2-UK
10:00 AM
100%
Your Trial
I want to know the effect of exercise on my mood.
19 participants in trials like this
Next
12:30
Your Trial
I want to know the effect of diet on my sleep.
27 participants in trials like this
Next


O2-UK
10:00 AM
100%
Back
Insights
Population
My Insights
5th February 2016
Your month long trial is over and we think there is a correlation between the amount you exercise and your stomach cramps.
Exercise
Cramp Severity
Learn more ...
29th January 2016
You've tracked your exercise everyday this week. Awesome!
Learn more ...

We need your help.

Open mHealth



Prototyping around two protocols

1. Atrial Fibrillation
2. Citizen Science

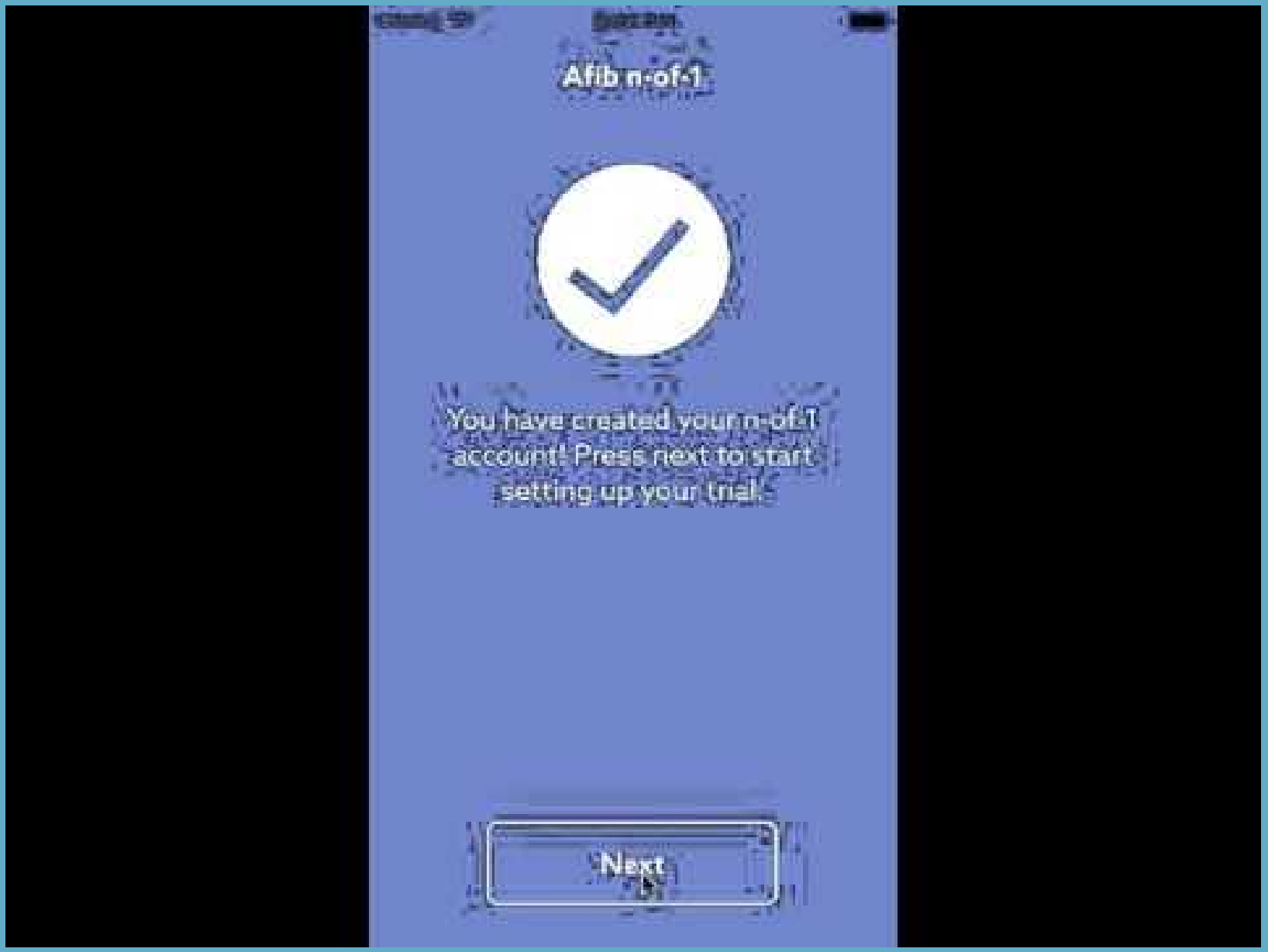
Looking for researchers to…

1. Pilot and test
2. Willing to make anonymized results publicly available

If you'd like to help us pilot Trialist, email me today. Thanks.

david@openmhealth.org

Open mHealth


Afib n-of-1
You have created your n-of-1 account! Press next to start setting up your trial.
Next