



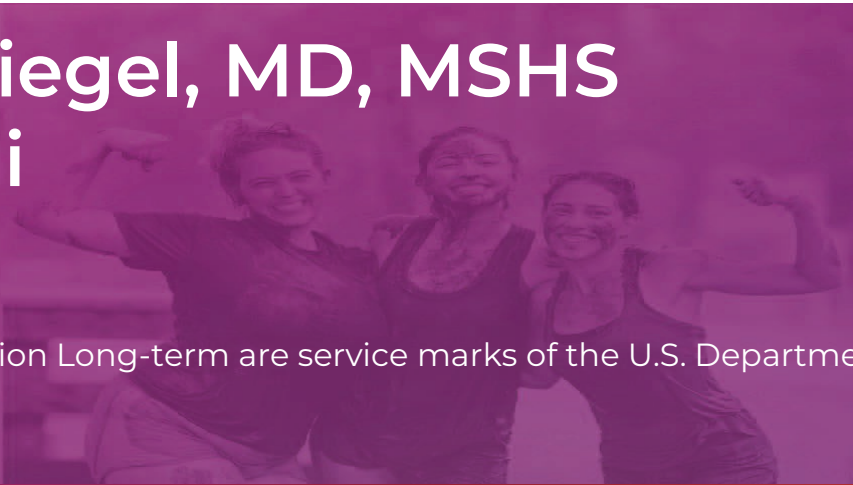
NIH
HEAL
INITIATIVE

BACPAC
Back Pain Consortium

COVID-Related Challenges and Solutions: Experiences from Cedars-Sinai Conducting a Remote Clinical Phase II Trial



Brennan Spiegel, MD, MSHS
Cedars-Sinai



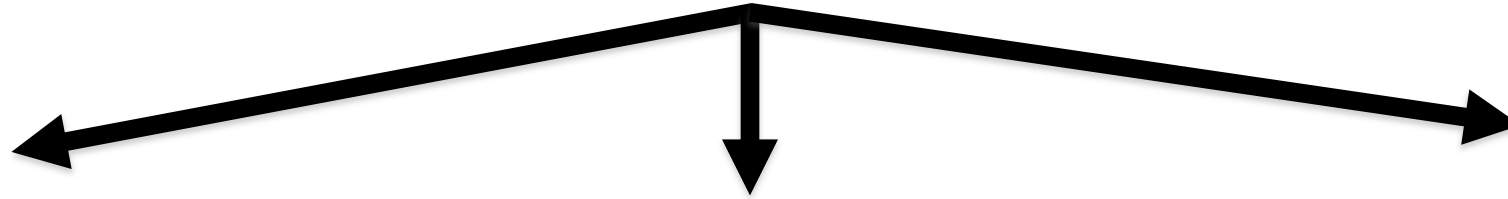
NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.

Clinical Trials Are Moving Out of the Lab and Into People's Homes

After the pandemic forced thousands of trials to shut down, researchers found clever ways to conduct human studies remotely — while reaching more people, quickly and cheaply.

There is also the unpredictable nature of human behavior. Dr. Brennan Spiegel, a gastroenterologist and the director of health services research at the Cedars-Sinai Health System, frequently uses Fitbits to monitor trial subjects remotely. But a participant once put the device on a dog. Several others sent their Fitbits through the wash. “You get a lot of steps all of a sudden — thousands and thousands of steps,” he said.

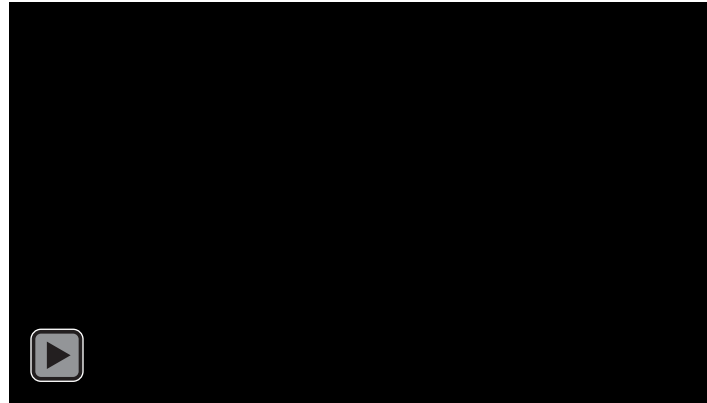
cLBP



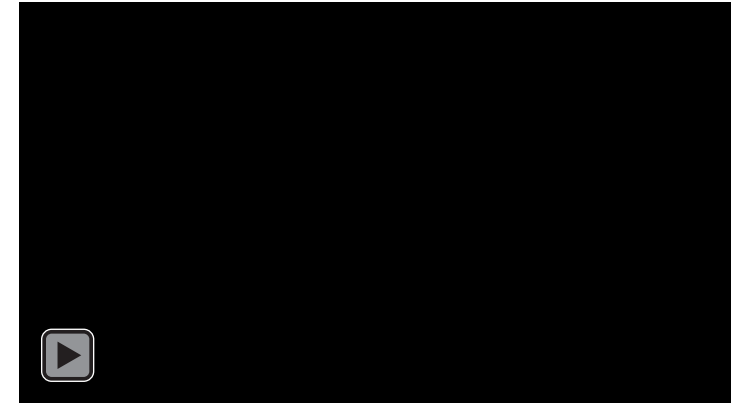
Non-Immersive
Sham VR



Immersive
Distraction VR



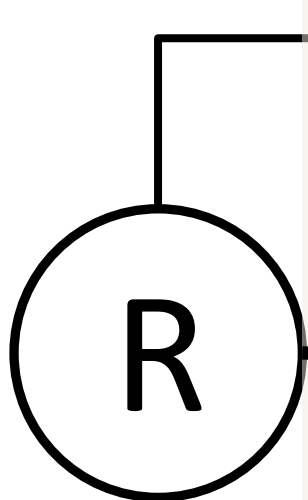
Immersive Skills-
Based VR



- ✓ Psychoeducation
- ✓ Pain education
- ✓ Breath training
- ✓ Relaxation training
- ✓ Executive functioning

Treatment Period

Follow-Up Period



Skills-Based VR

Use PRN at patient discretion

Distraction VR

Use PRN at patient discretion

Sham VR

Use PRN at patient discretion



Patient Reported Outcome (PRO) Assessments



Continuous Wearable Activity Monitoring

0

4

Study Week

8

12

Study Sites

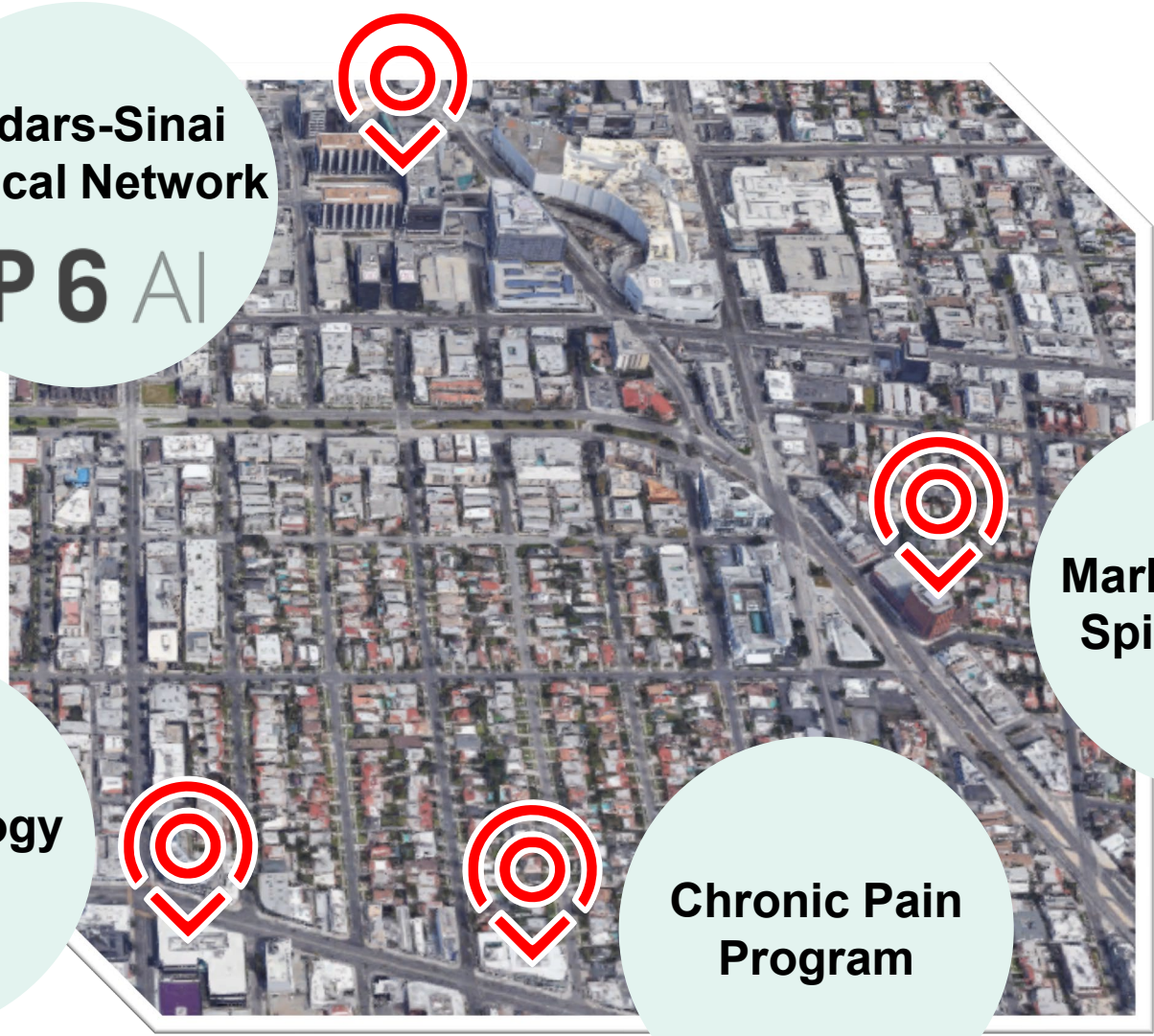
DEEP 6 AI

**Cedars-Sinai
Medical Network**

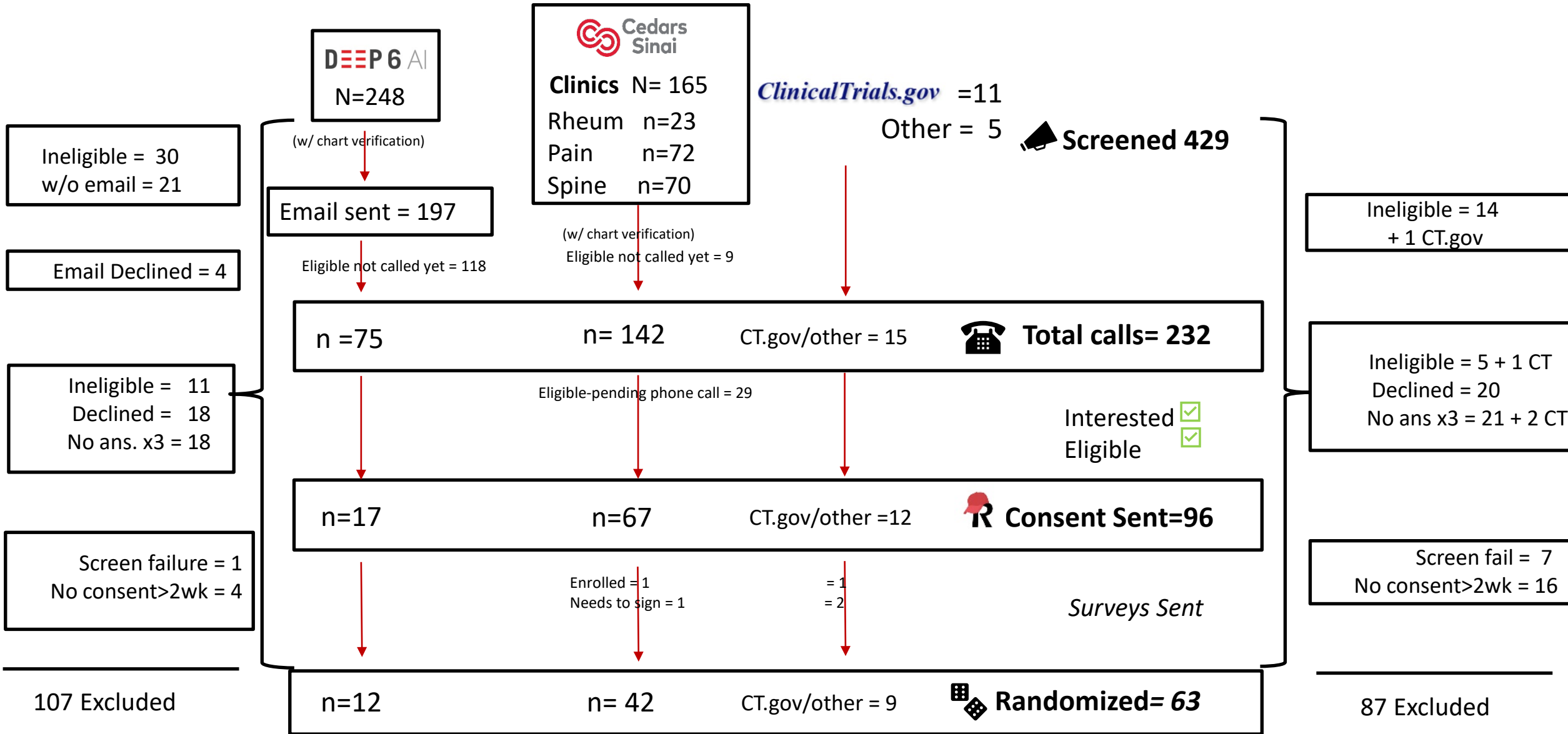
**Rheumatology
Clinic**

**Chronic Pain
Program**

**Mark Goodson
Spine Center**

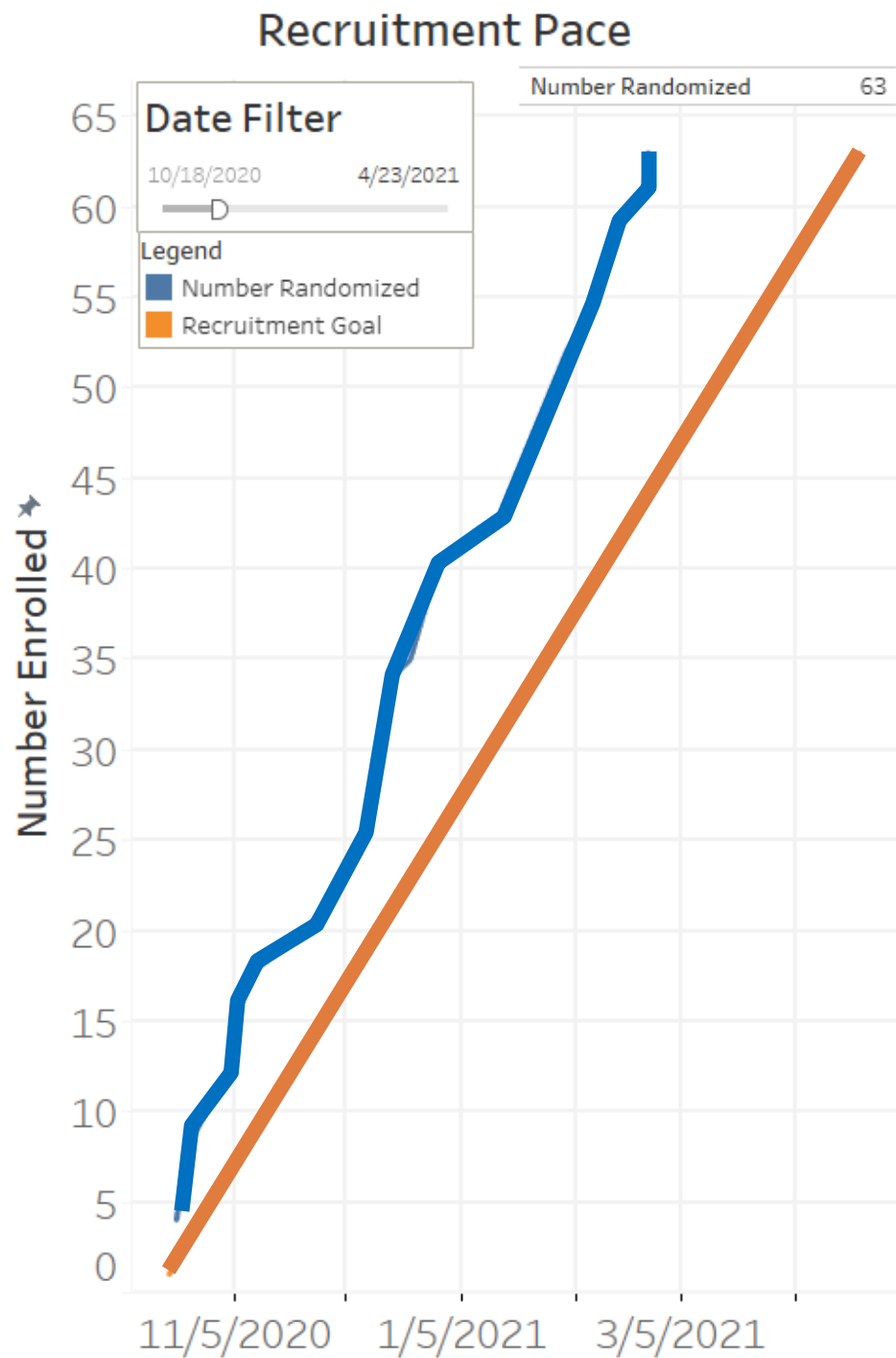


Enrollment Update – February 24th, 2021



Recruitment Progress

(Through Feb 27th)





**PRO Data
Capture**



**EHR Data
Capture**



**Controlled
Substance Data
Capture**



Data Acquisition

The diagram consists of a central text "Data Acquisition" in a dark blue font. It is flanked by two large, light blue L-shaped brackets that point towards the central text. The top-left bracket is light green, and the top-right bracket is light blue.

**Wearable
Data Capture**

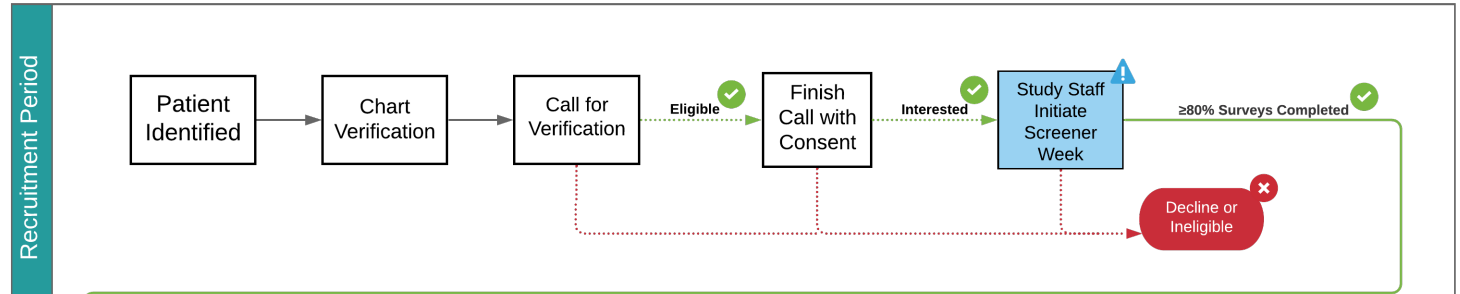
fitabase

**VR Headset
Data Capture**

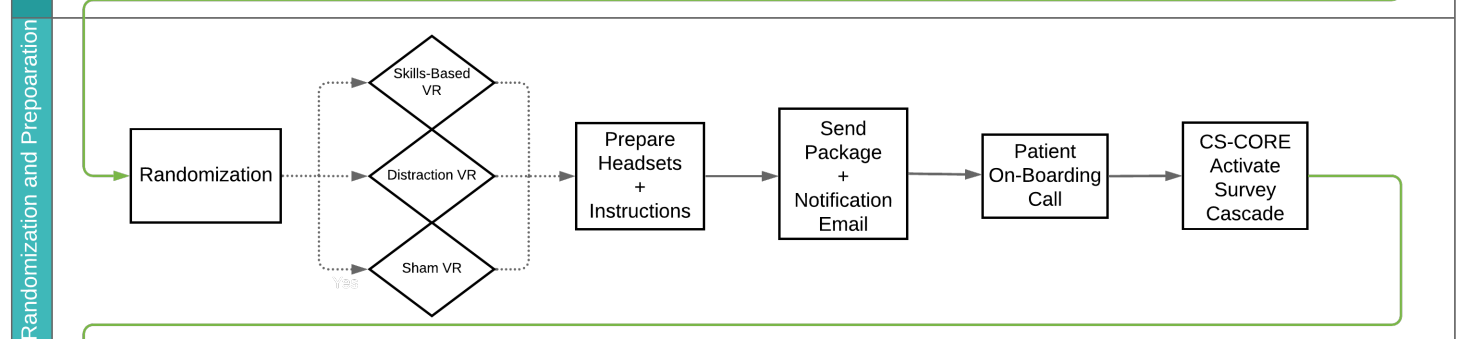


Study Flow Does Not Require In-Person Contact

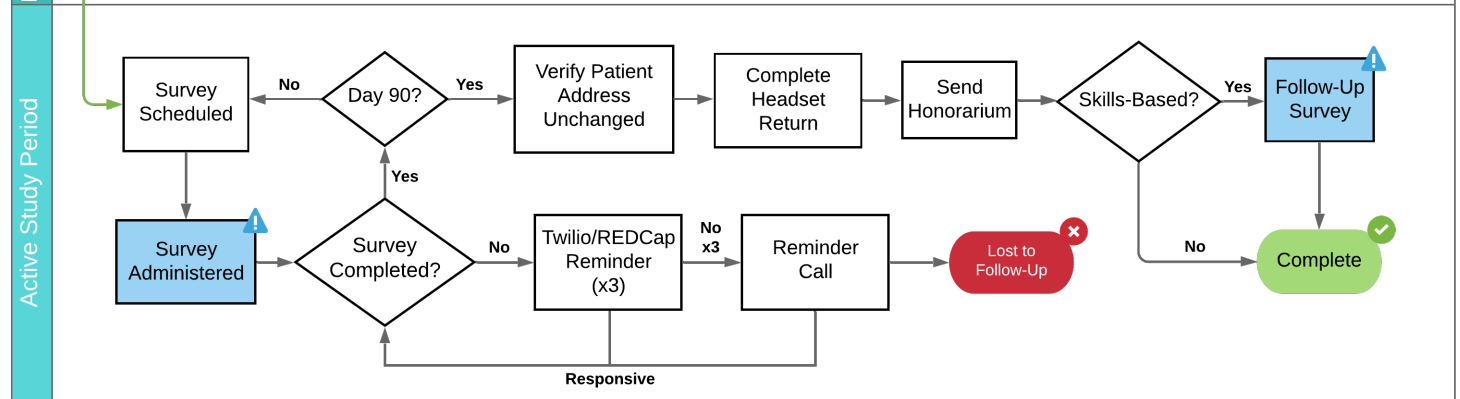
I. Recruitment Period



II. Randomization & Preparation




III. Active Study Period



Remote e-Consenting

DocuSign



Samuel Eberlein sent you a document to review and sign.

REVIEW DOCUMENTS

Samuel Eberlein
Samuel.Eberlein@cshs.org

Hello

This is the consent form for the digital pain reduction study. After you have signed this consent form we will be able to mail a TENS unit (pain reduction massage pad) to your home that is free for you to use throughout the study and after. There is a chance you may also get a virtual reality system that is made to reduce pain which would be mailed to you as well. Feel free to call 310-423-5434 if you have any questions

Best,
Brandon Birkhead MD

START

DocuSign Envelope ID: B0649699-0F94-4BF6-93A7-CA79B47C0835
CSMC IRB NO: F10000490137 MOD000000900
CSMC Date Effective: 12/10/2019

(8) You have been provided with a copy of the “Experimental Subject’s Bill of Rights”, if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and a copy of the Experimental Subject’s Bill of Rights.

SIGNATURE BY THE PARTICIPANT Required - Sign Here

Sam Eberlein		4/23/2020
_____ Name of Participant (Print)	_____ Signature of Participant	_____ Date of Signature

SIGNATURE BY THE INVESTIGATOR:

I have personally explained the research to the participant in non-technical terms, answered all questions, and attest that he/she freely consents to participate. The participant has been provided with the Experimental Subject’s Bill of Rights.

_____ Signature of the Investigator Who Obtained Consent	_____ Date of Signature
---	----------------------------

Packaging and Sending Devices



Decontaminating Devices

First



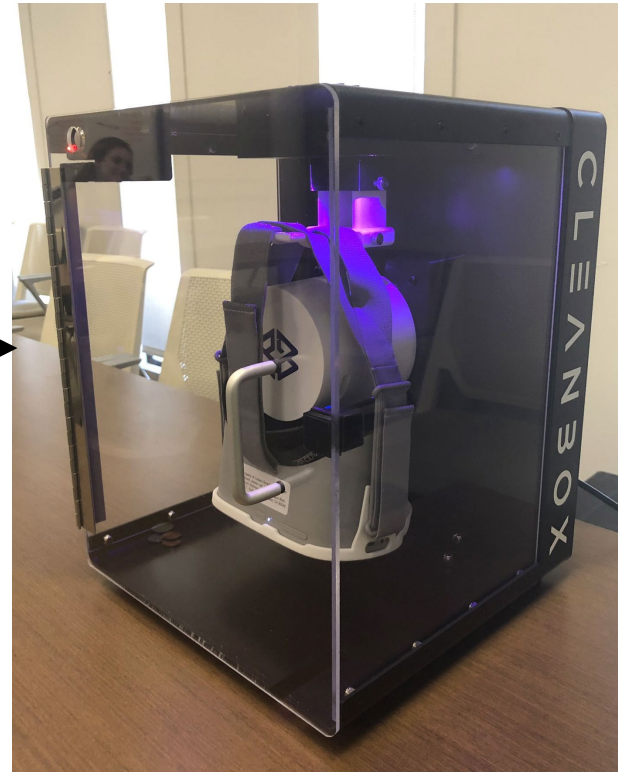
**Germicidal
Wipes**

Second



**Alcohol-based Lens
Wipes**

Third



UV Light Box

Fourth



3-day Quarantine

Packaging and Sending Devices



Tracking Receipt of Devices

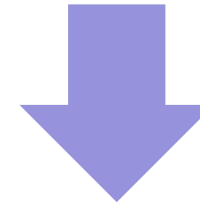


Enter a FedEx tracking, door tag or FedEx Office order number.

TRACKING ID

TRACK

[MULTIPLE TRACKING NUMBERS](#) | [NEED HELP?](#)



```
def get_package_details(track_no):
    try:
        header = {
            "Origin": "https://www.fedex.com",
            "User-Agent": "Mozilla/5.0 (X11; Linux x86_64) AppleWebKit/537.36 (KHTML, like Gecko) "
            "Chrome/59.0.3071.115 Safari/537.36",
            "Content-Type": "application/x-www-form-urlencoded; charset=UTF-8",
            "Accept": "*/*",
            "X-Requested-With": "XMLHttpRequest",
            "Referer": "https://www.fedex.com/apps/fedextrack/?tracknumbers=%s&locale=en_CA&entry_code=ca_english"
            % (str(track_no)),
            "Accept-Encoding": "gzip, deflate, br",
            "Accept-Language": "en-US,en;q=0.8,fr;q=0.6,ta;q=0.4,bn;q=0.2",
        }

        data = {
            "action": "trackpackages",
            "data": '{"TrackPackagesRequest":{"appType":"WTRK","appDeviceType":"DESKTOP","uniqueKey":"","processingParameters":{"trackingInfoList":[{"trackNumberInfo":{"trackingNumber":"%s","trackingQualifier":"","trackingCarrier":""}}]}% (str(track_no)),
            "format": "json",
            "locale": "en_CA",
            "version": "1",
        }

        url = "https://www.fedex.com/trackingCal/track"

        # print("Sending request ...")
```

Scraping FedEx delivery server...

Materials sent:

SID	Patient Name	status_mats	mats_delivered_date
138	John Doe	Delivered	Wed 2/26/2020 16:10
193	Jane Doe	Delivered	Thu 2/27/2020 15:00
192	John Doe	Delivered	Thu 2/27/2020 14:43
191	Jane Doe	Delivered	Thu 3/05/2020 14:31
211	John Doe	Label created	TBD

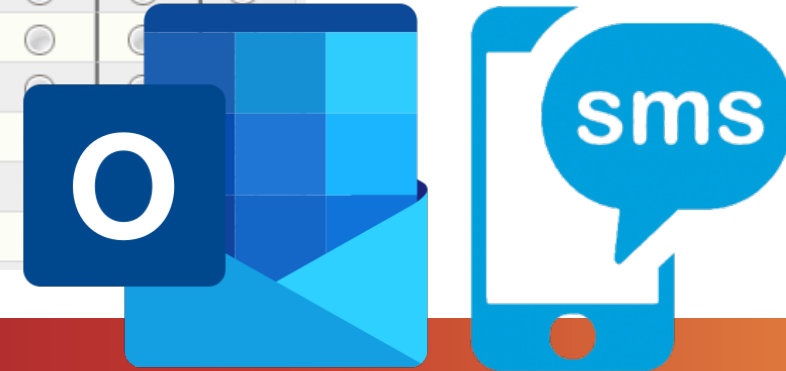
Bugs Will Bite



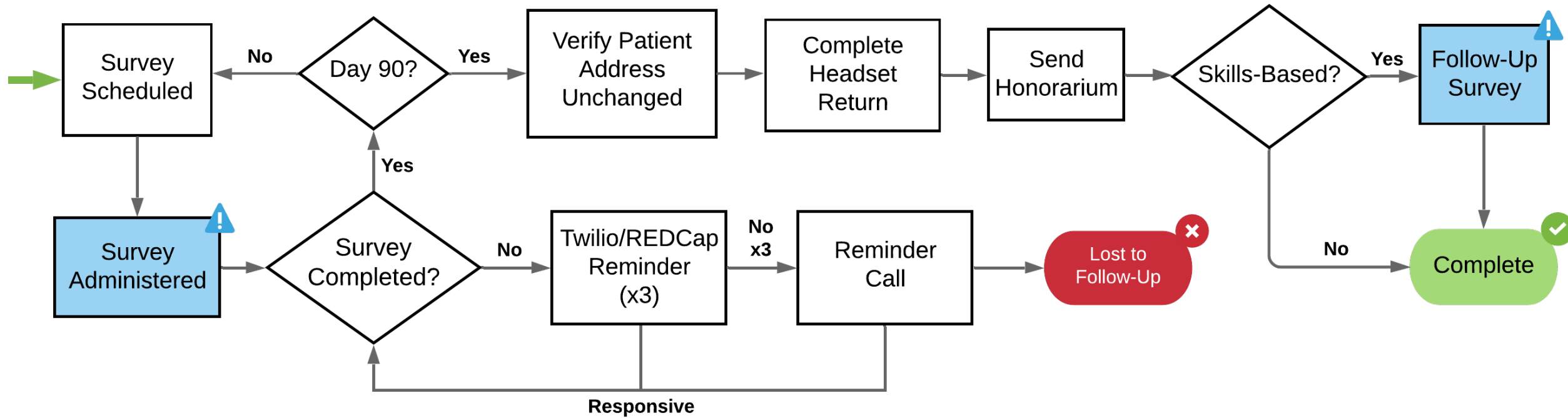
Survey Response Monitoring with REDCap



Record ID	Survey	Month 2: Usage 14 (c)	Month 2: Usage 15 (c)	Month 2: Usage 16 (c)	Month 2: Usage 17 (c)	Month 2: Usage 18 (c)	Month 2: Usage 19 (c)	Month 2: Usage 20 (c)	Month 2: Usage 21 (c)	Month 2: Usage 22 (c)	Month 2: Usage 23 (c)	Month 2: Usage 24 (c)	Month 2: Usage 25 (c)	Month 2: Usage 26 (c)	Month 2: Usage 27 (c)	Month 2: Usage 28 (c)	End of Study Survey
		Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)	Daily Survey (Control)
84	Setup Survey (All)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
85		<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
86		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
87		<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
88		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
89		<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
90		<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
91		<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



With Remote Trials, It's Vital to Keep Engaging



Identifying Nonadherent Participants At-a-Glance

REDCap Dashboard

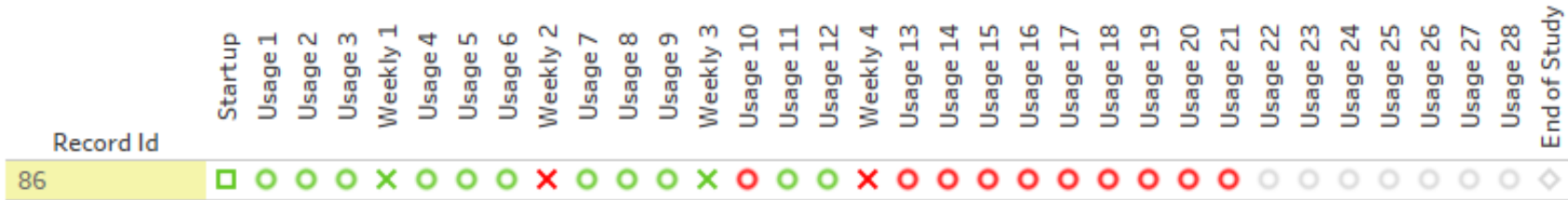
Record Id	SSQ +	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Journal 2	Journal 3	Journal 4	Journal 5	Journal 6	Journal 7
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17	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
19	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
20	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
21	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
22	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
23	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
24	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
25	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
26	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
27	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
28	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
29	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
30	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
31	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
32	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
33	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
34	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
35	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
36	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□
37	+	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□

Survey Status

- Surveys Completed
- Missed
- Need to Call
- Surveys Remaining
- Pending Start

Making REDCap More Readable and Motivating

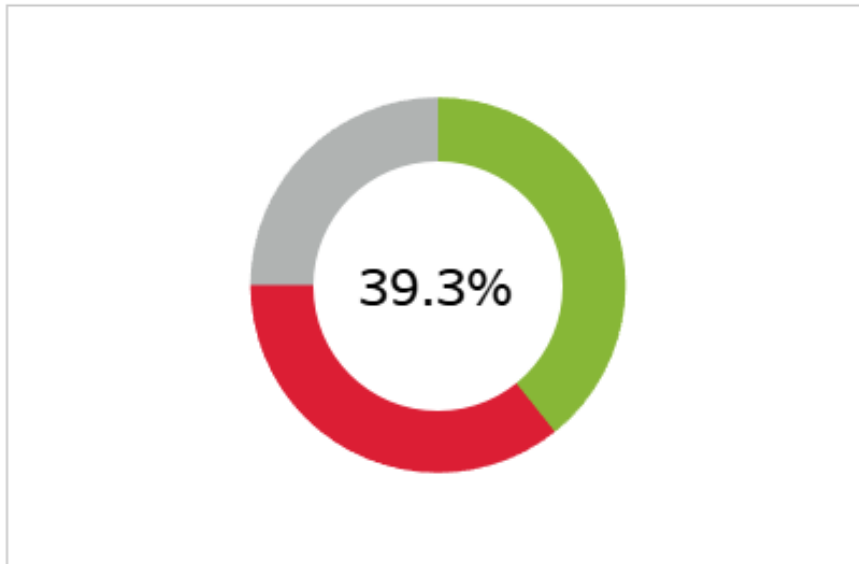
My Survey Timeline



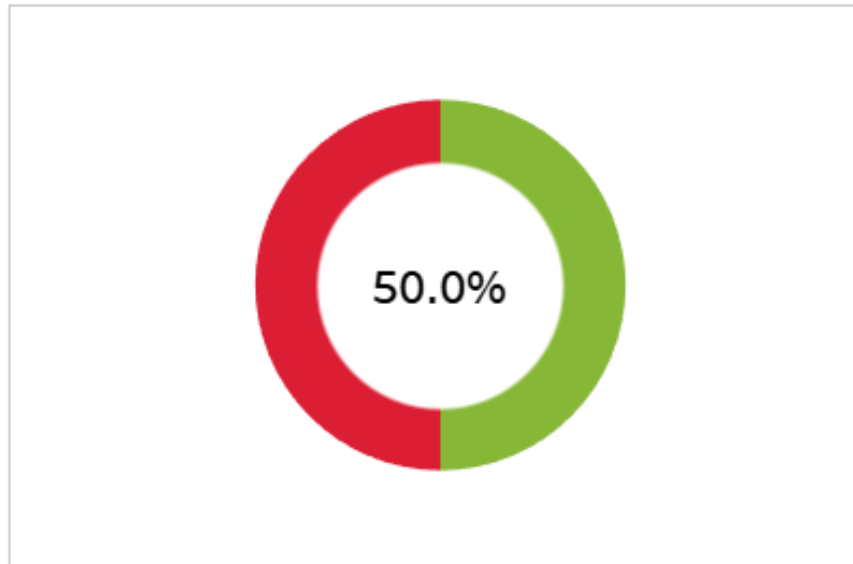
Survey Type

- Startup
- Usage
- × Weekly
- ◇ End of Study

Usage Survey Completion Rate



Weekly Survey Completion Rate



Legend

- Surveys Completed
- Surveys Missed
- Surveys Remaining

Key Points

- Remote patient trials have proven successful during COVID-19
- Cohort builders (eg. Deep 6 AI) can expedite recruitment at a time when fewer patients have been visiting their clinicians
- Use of wearables allows remote biometric monitoring
- Use of web-based platforms allows remote PRO monitoring
- Critical to run a tight ship (we're literally a shipping station)
- Develop streamlined digital monitoring dashboards
- Find ways to engage patients outside of the clinical environment

Thank you

