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.

The New York Times

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.

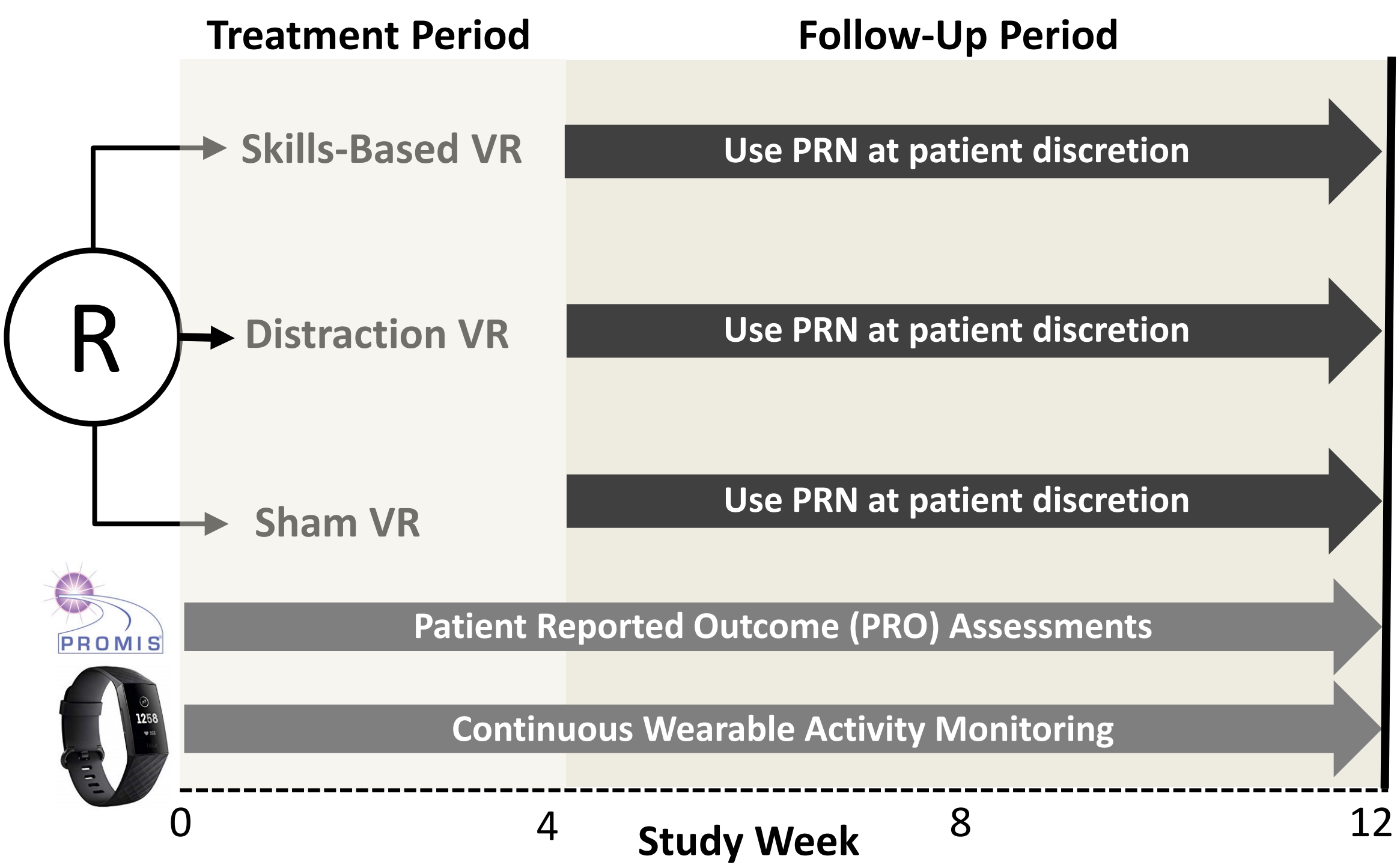
cLBP

Non-Immersive Sham VR

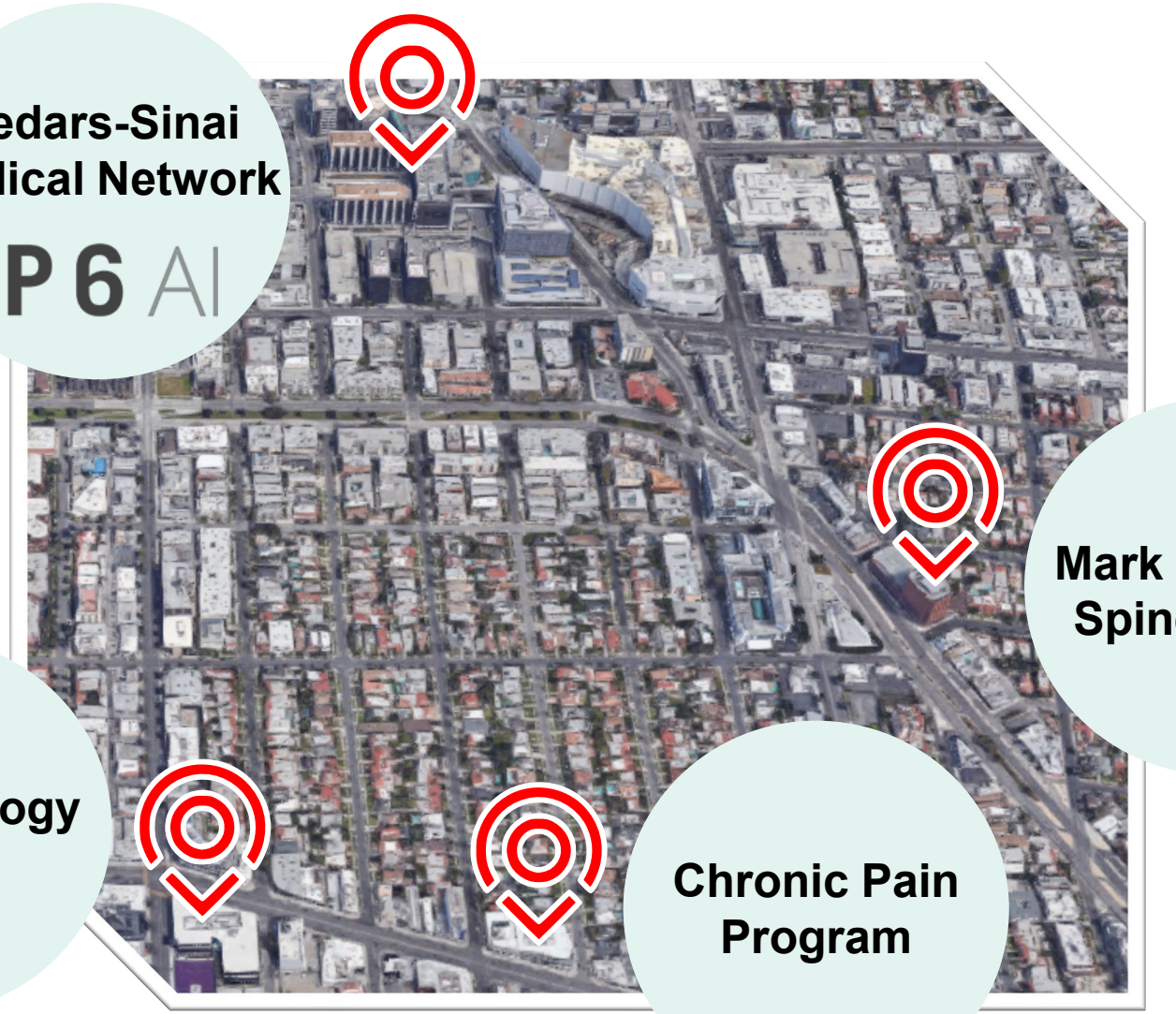
Immersive Distraction VR

Immersive Skills-Based VR

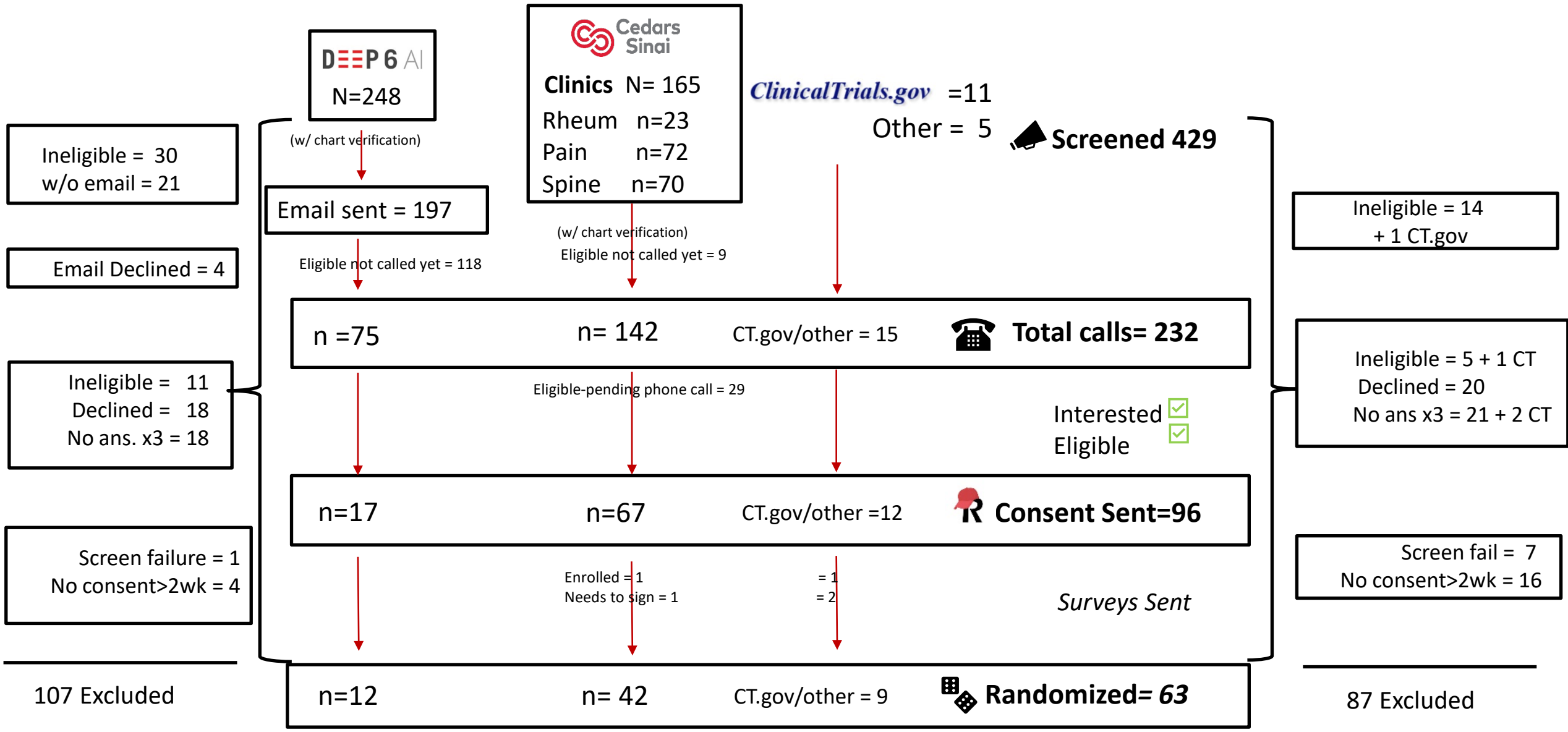
- ✓ Psychoeducation
- ✓ Pain education
- ✓ Breath training
- ✓ Relaxation training
- ✓ Executive functioning


Treatment Period
Follow-Up Period
R
Skills-Based VR
Distraction VR
Sham VR
Use PRN at patient discretion
Use PRN at patient discretion
Use PRN at patient discretion
PROMIS
Patient Reported Outcome (PRO) Assessments
Continuous Wearable Activity Monitoring
0
4
8
12
Study Week

Study Sites

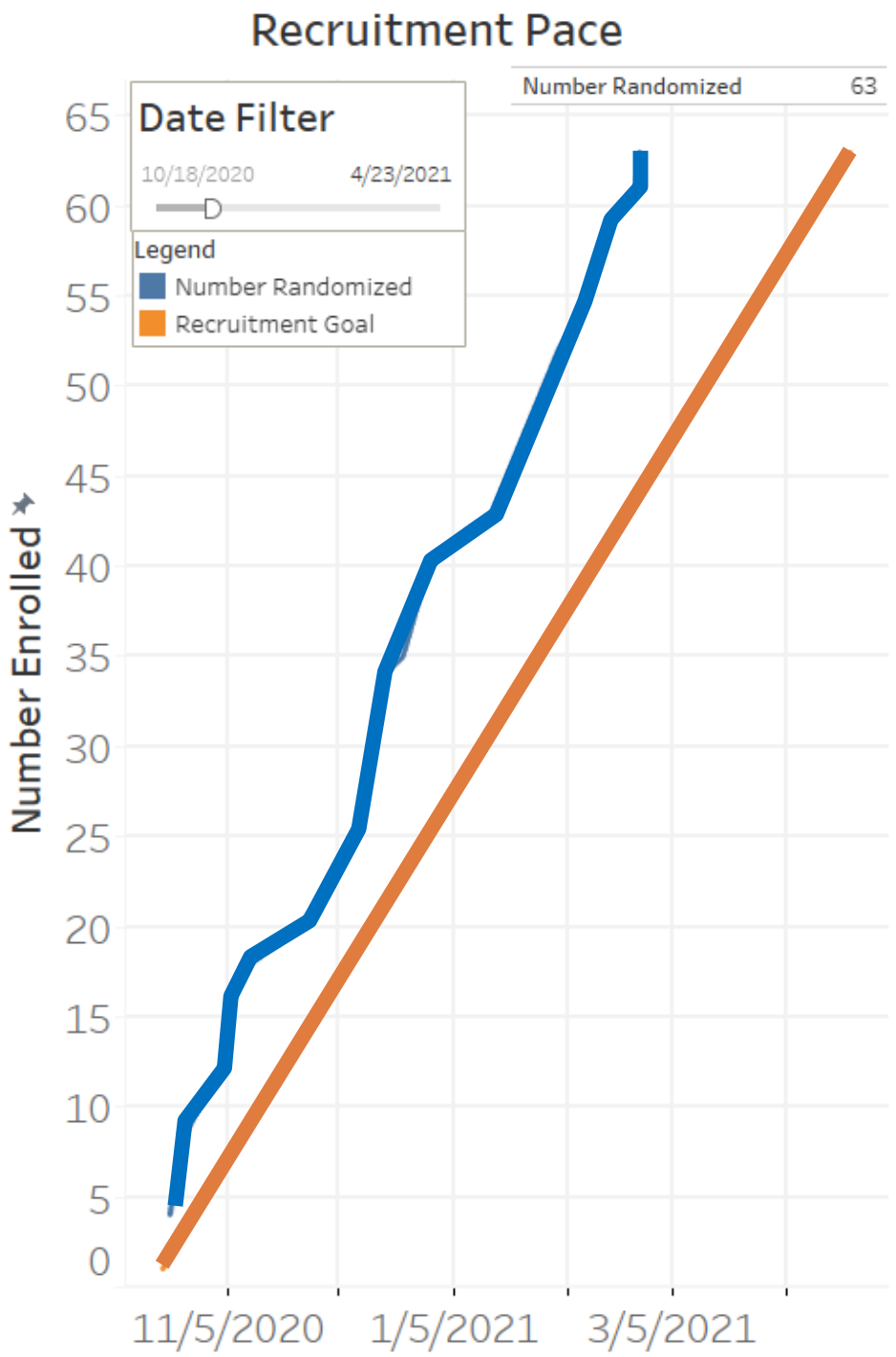

Cedars-Sinai Medical Network
DEEP 6 AI
Mark Goodson Spine Center
Rheumatology Clinic
Chronic Pain Program

Enrollment Update – February 24th, 2021



Recruitment Progress

(Through Feb 27th)



REDCap
Research Electronic Data Capture

PRO Data Capture

Epic

EHR Data Capture

CURES 2.0

Controlled Substance Data Capture

Data Acquisition

fitabase

Wearable Data Capture

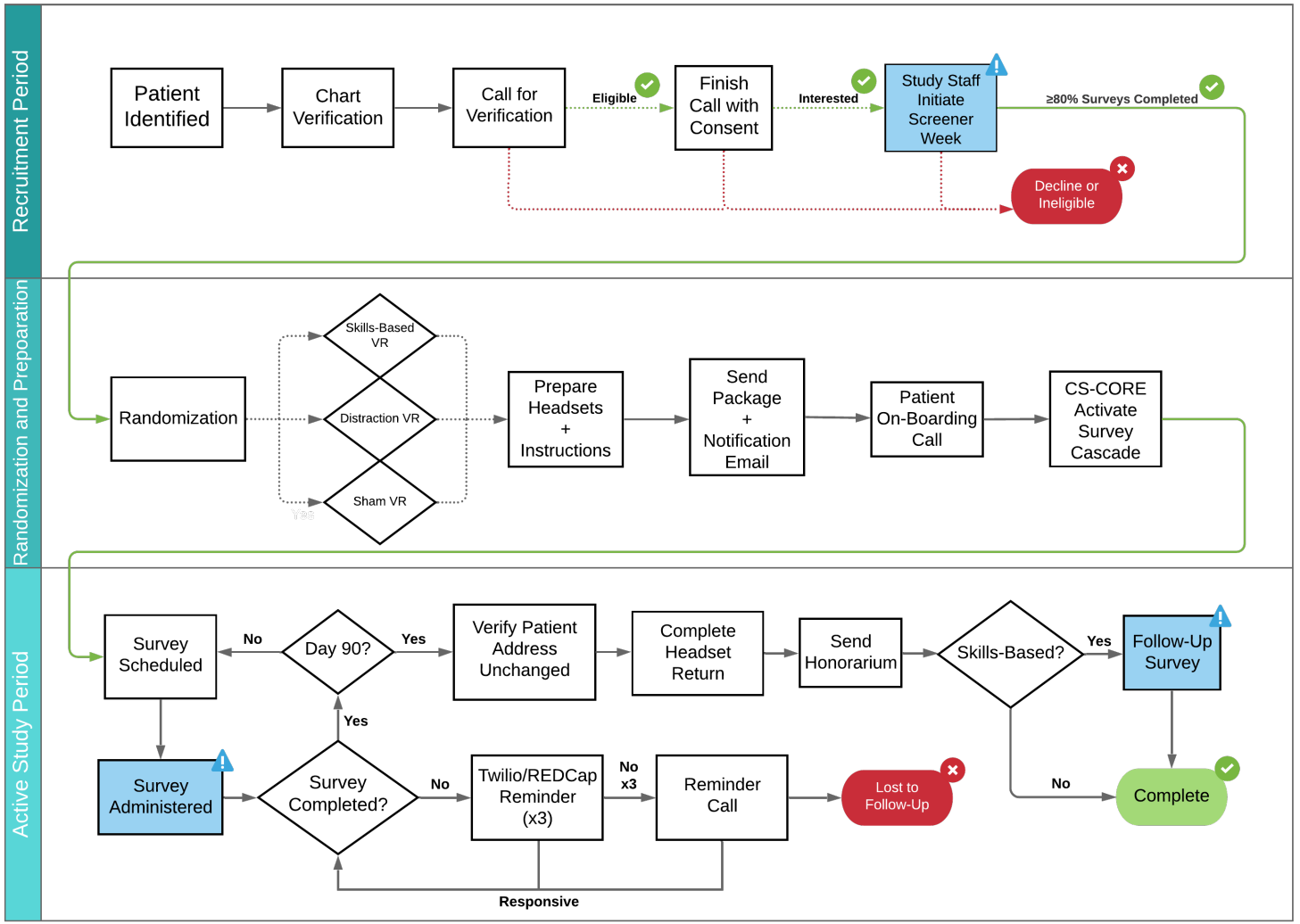
VR Headset Data Capture

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 Birckhead MD

Packaging and Sending Devices

Decontaminating Devices

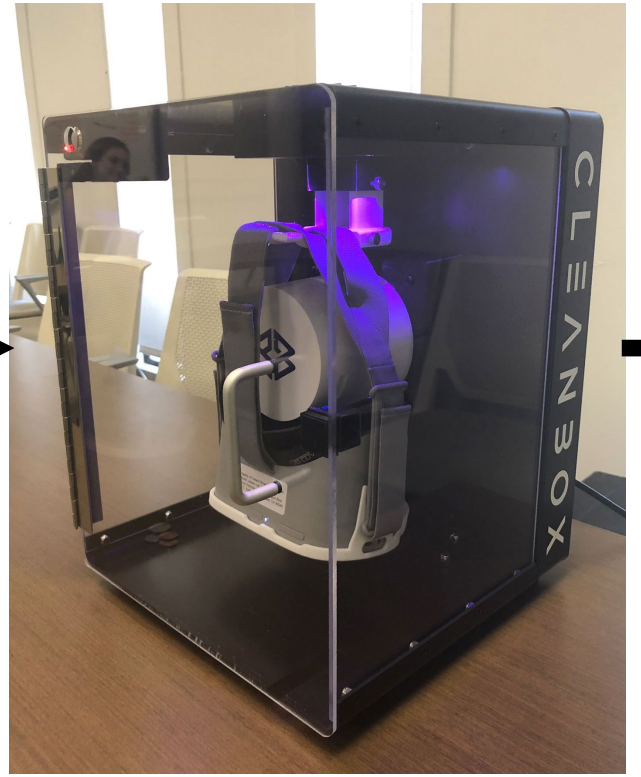
First

Germicidal Wipes

Second

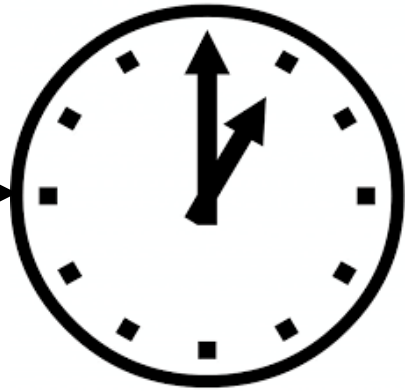
Alcohol-based Lens Wipes

Third



UV Light Box

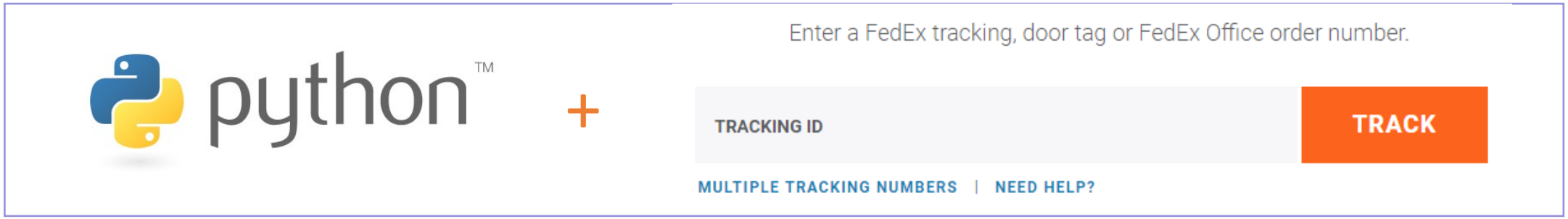
Fourth



3-day Quarantine

Packaging and Sending Devices

Tracking Receipt of Devices




```python
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&cntry_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:
                    Patient Name   status_matls  matls_delivered_date
SID
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

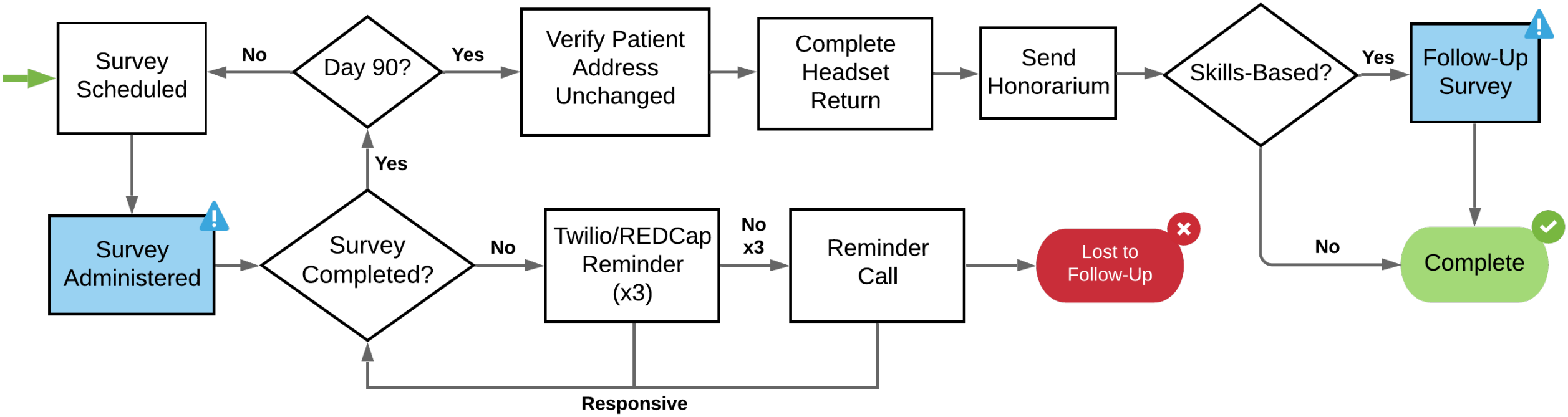
Survey Response Monitoring with REDCap

REDCap
Research Electronic Data Capture

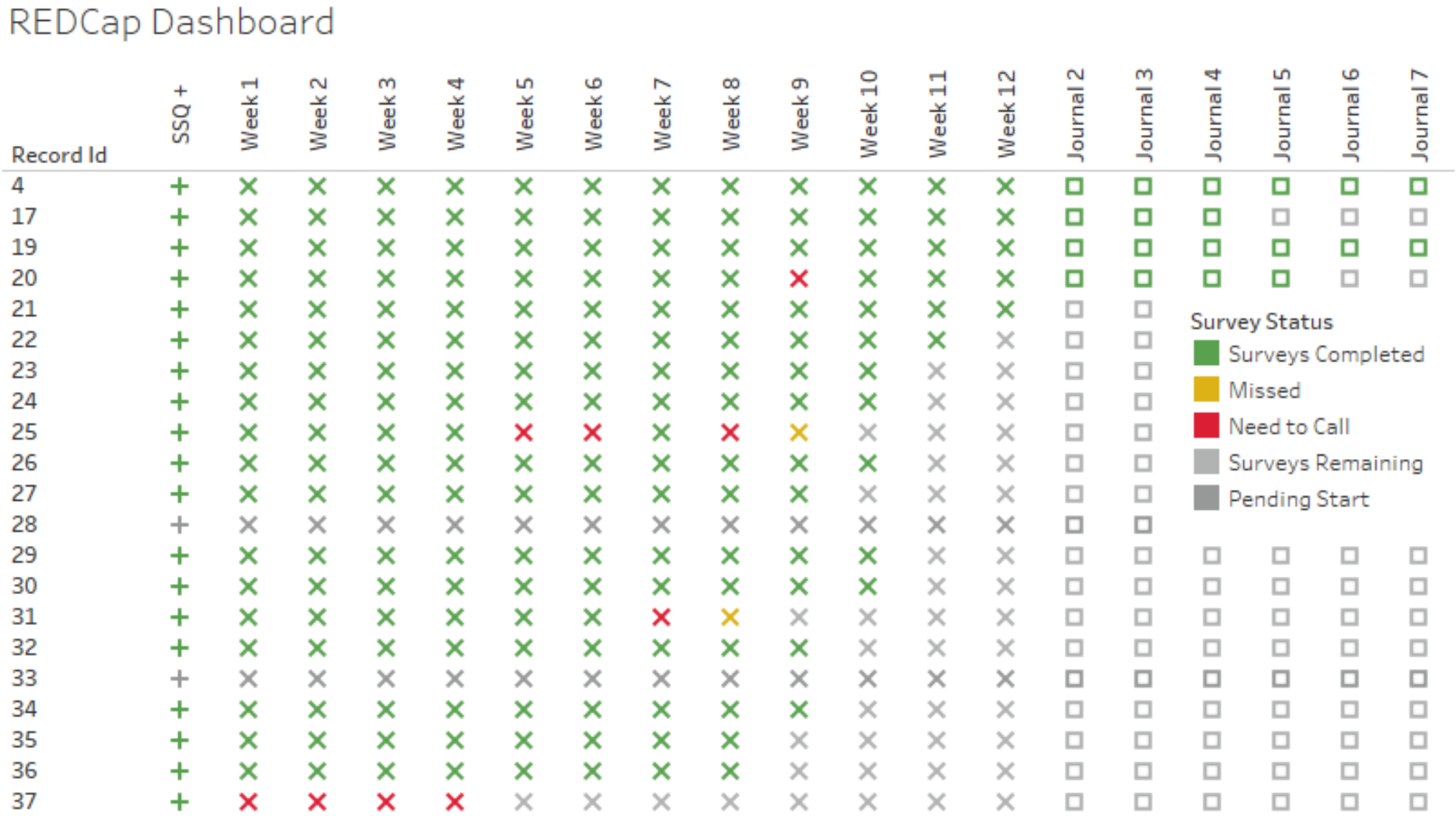
twilio

Record ID	vey	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
	rtup vey ll)	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)	End of Study Survey
84																	
85																	
86																	
87																	
88																	
89																	
90																	
91																	

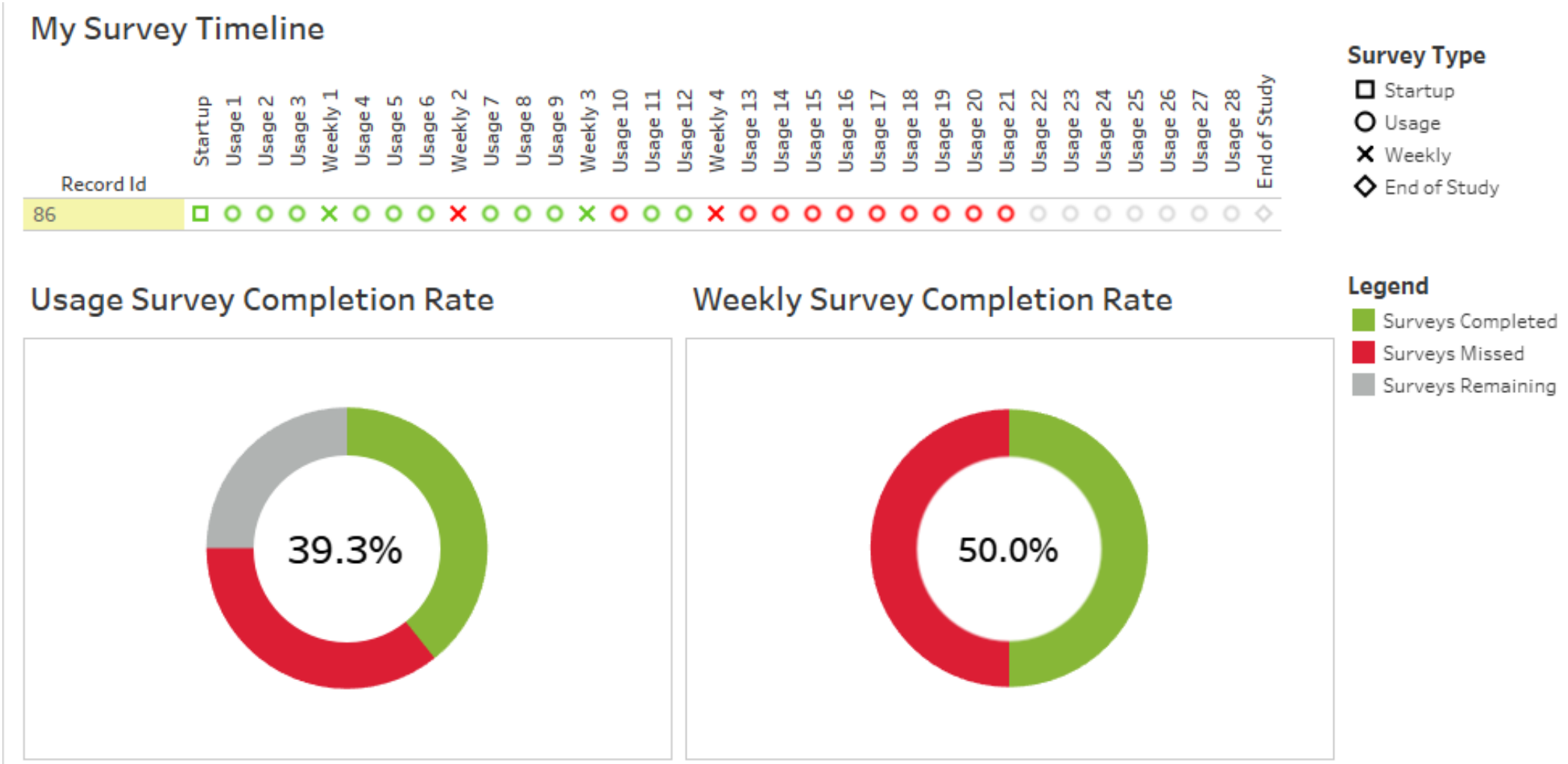
With Remote Trials, It's Vital to Keep Engaging



Identifying Nonadherent Participants At-a-Glance



Making REDCap More Readable and Motivating



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

Cedars Sinai