

# PATIENT RECRUITMENT Parexel

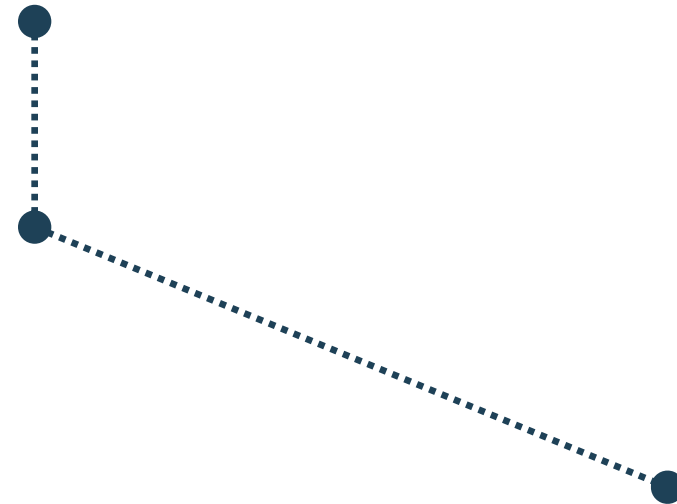
Full-Service Global Patient Recruitment  
Across All Therapeutic Areas

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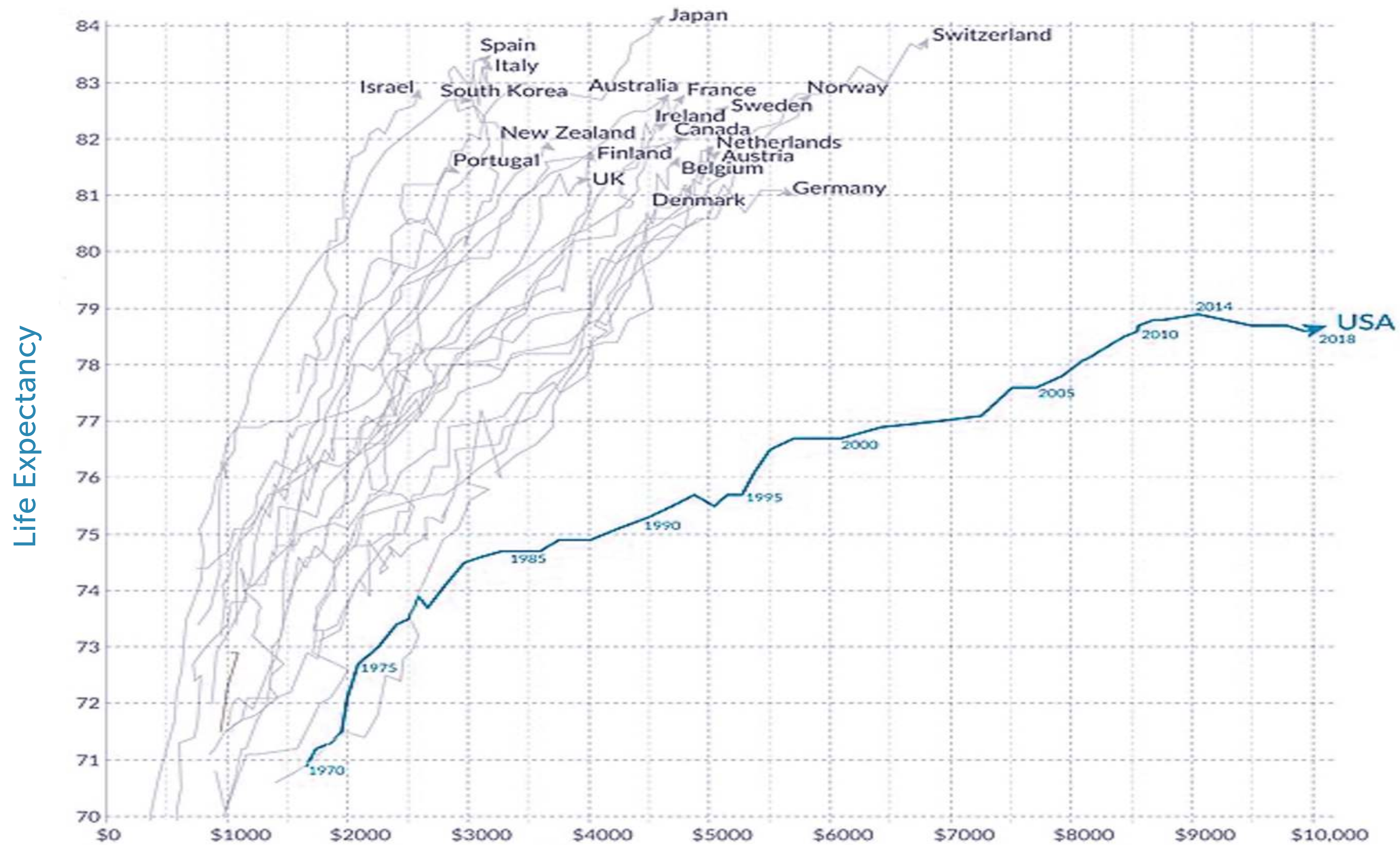


# THE CURRENT STATE OF CLINICAL TRIALS



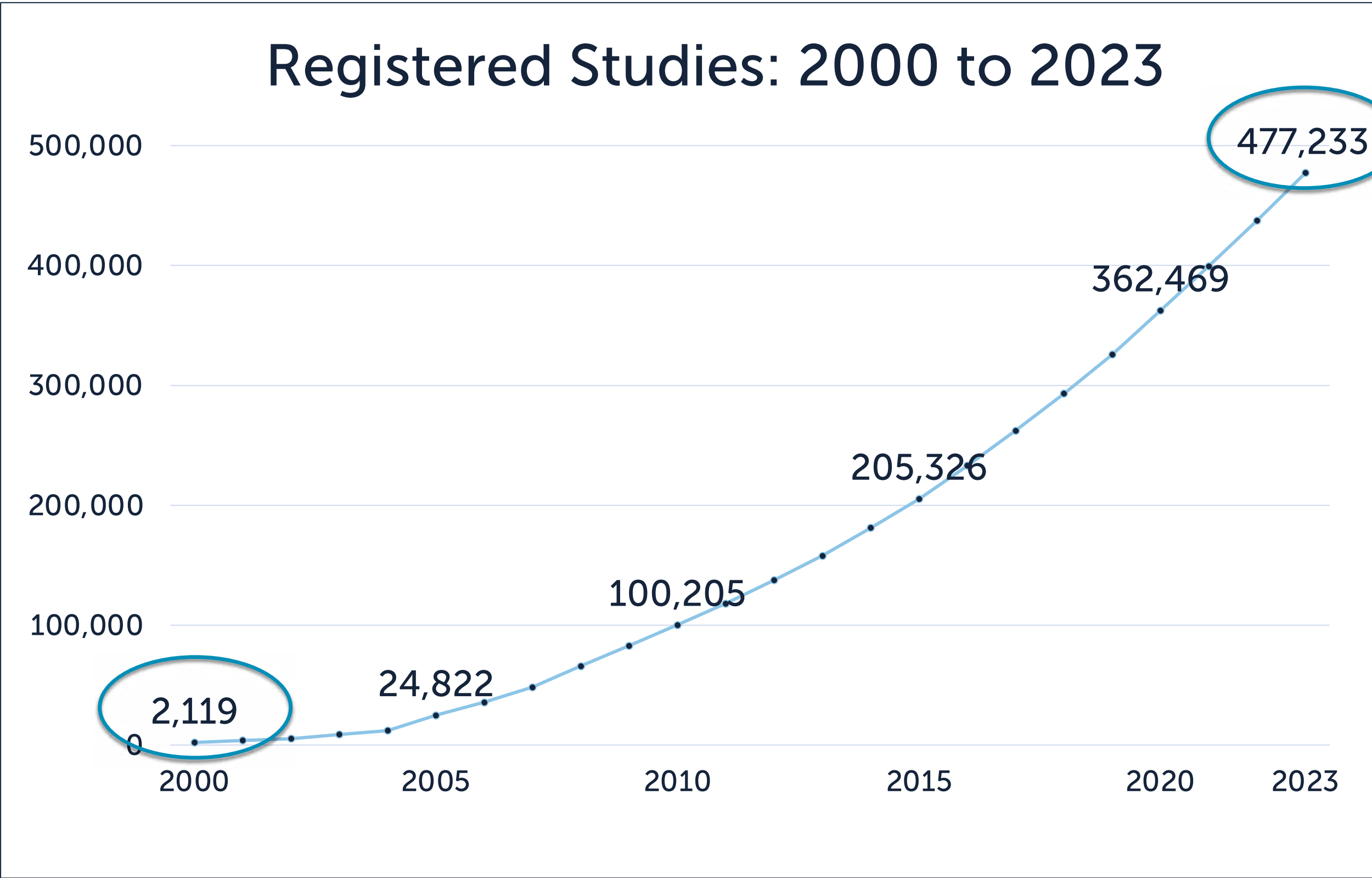


# LIFE EXPECTANCY VS HEALTH EXPENDITURE



Health Expenditure Per Capita  
Adjusted for Inflation & Price Differences Between Countries (PPP)

# INCREASE IN TRIALS – COMPARED TO LIFE EXPECTANCY



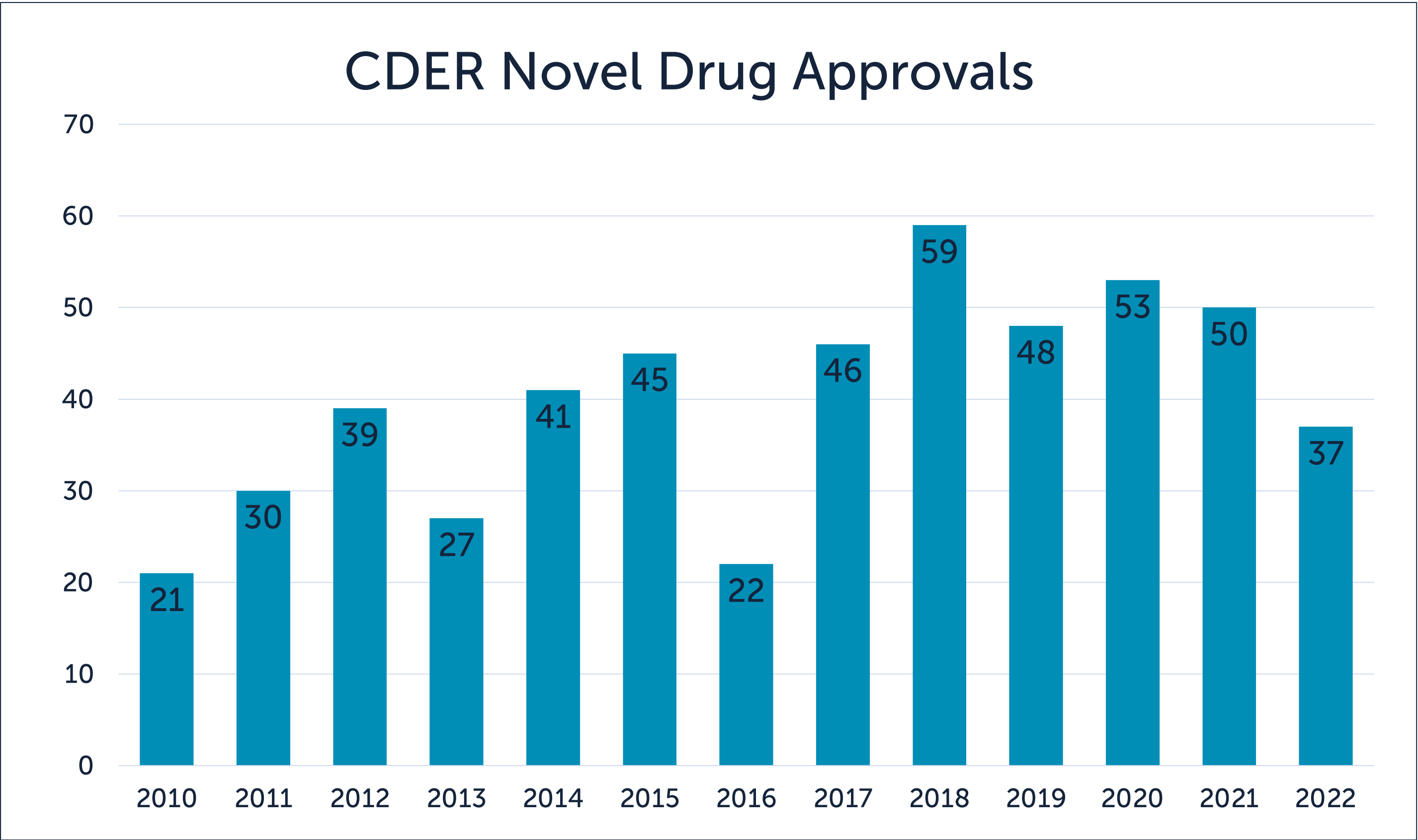
**Number of studies  
increased 22,521%!**

**US life expectancy  
dropped 2 years over  
the last 2 decades**

- Harvard School of Public Health

Source: <https://classic.clinicaltrials.gov/ct2/resources/trends>

# NEW 'NOVEL' DRUG APPROVALS



Source: FDA - 2020 Novel Drug Approvals Review, Aetion - The Role of Real-World Evidence in FDA Approvals, Internal Estimates



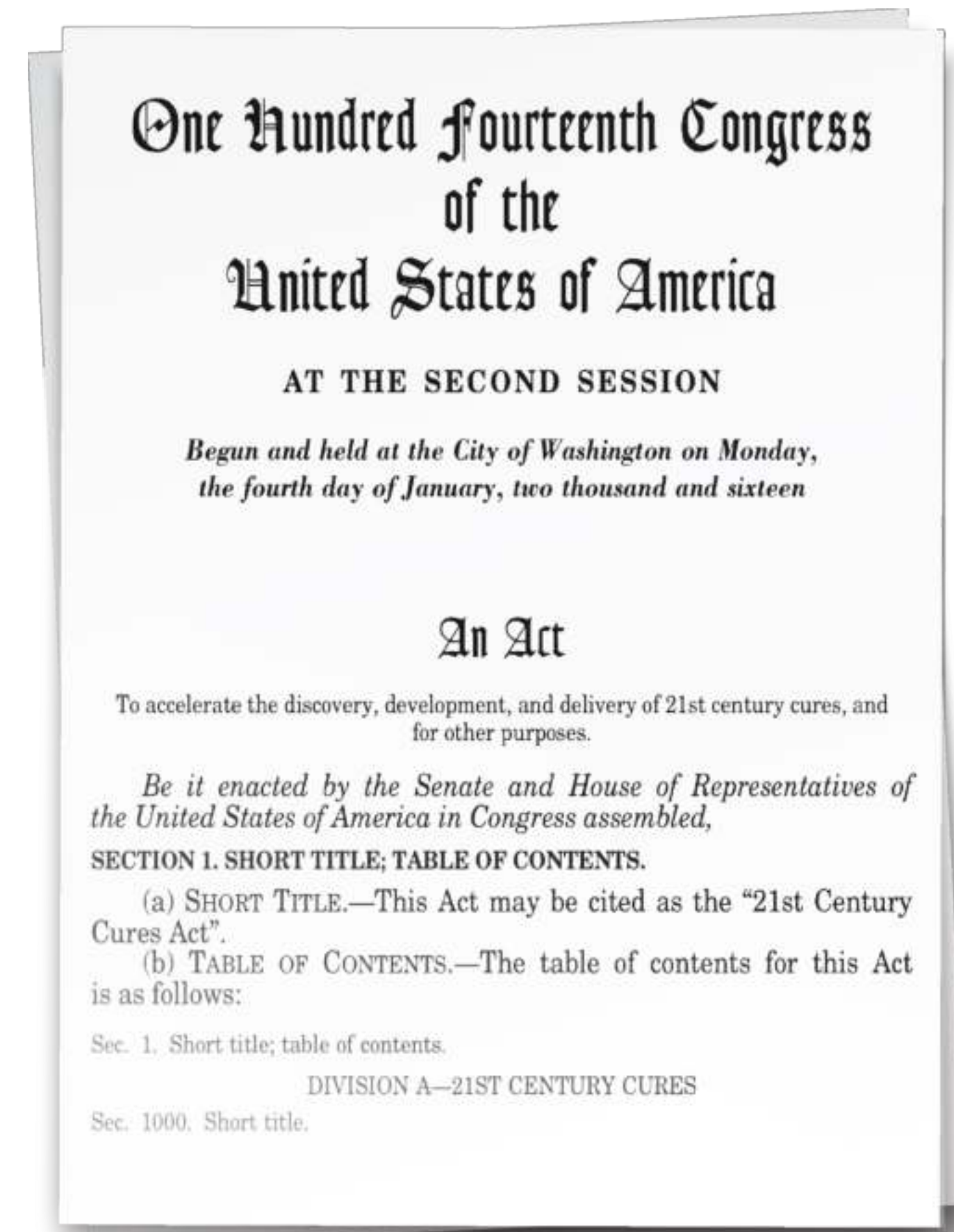
# 2016 – 21ST CENTURY CURES ACT



Accelerate medical product development and bring innovations to patients

Incorporate the patient perspective into development of drugs, biological products, and devices

Modernize clinical trial design by utilizing RWE





Include relevant and objective data that is accurate and **representative of the population and data that is meaningful to the patient**

Measures effect of disease on patient's daily activities, meaningful functioning, and QoL

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## Patient-Focused Drug Development: Collecting Comprehensive and Representative Input

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

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Extends daily activities and QoL to physical and role function.

To understand:

- Disease-related symptoms
- Symptomatic Adverse Events
- Overall impact of side effects

“Patients would better like to understand symptoms they may experience and how a cancer therapy will affect their quality of life”

– Dr. Pazdur, Director of the FDA’s Oncology Center of Excellence and acting Director of the Office of Oncologic Diseases for Drug Evaluation.

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## Core Patient-Reported Outcomes in Cancer Clinical Trials Guidance for Industry

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*DRAFT GUIDANCE*





## FDA made modifications to:

- Protocol-specified procedures
- Digital health technologies to aid in the rescue of clinical trials and assist with remote data acquisition.

## Goals:

Obtain continuous measurements, document rare events, obtain RWD from patients, and **increase convenience of remote participation in trials.**

### **Digital Health Technologies for Remote Data Acquisition in Clinical Investigations**

Guidance for Industry, Investigators,  
and Other Stakeholders

*DRAFT GUIDANCE*

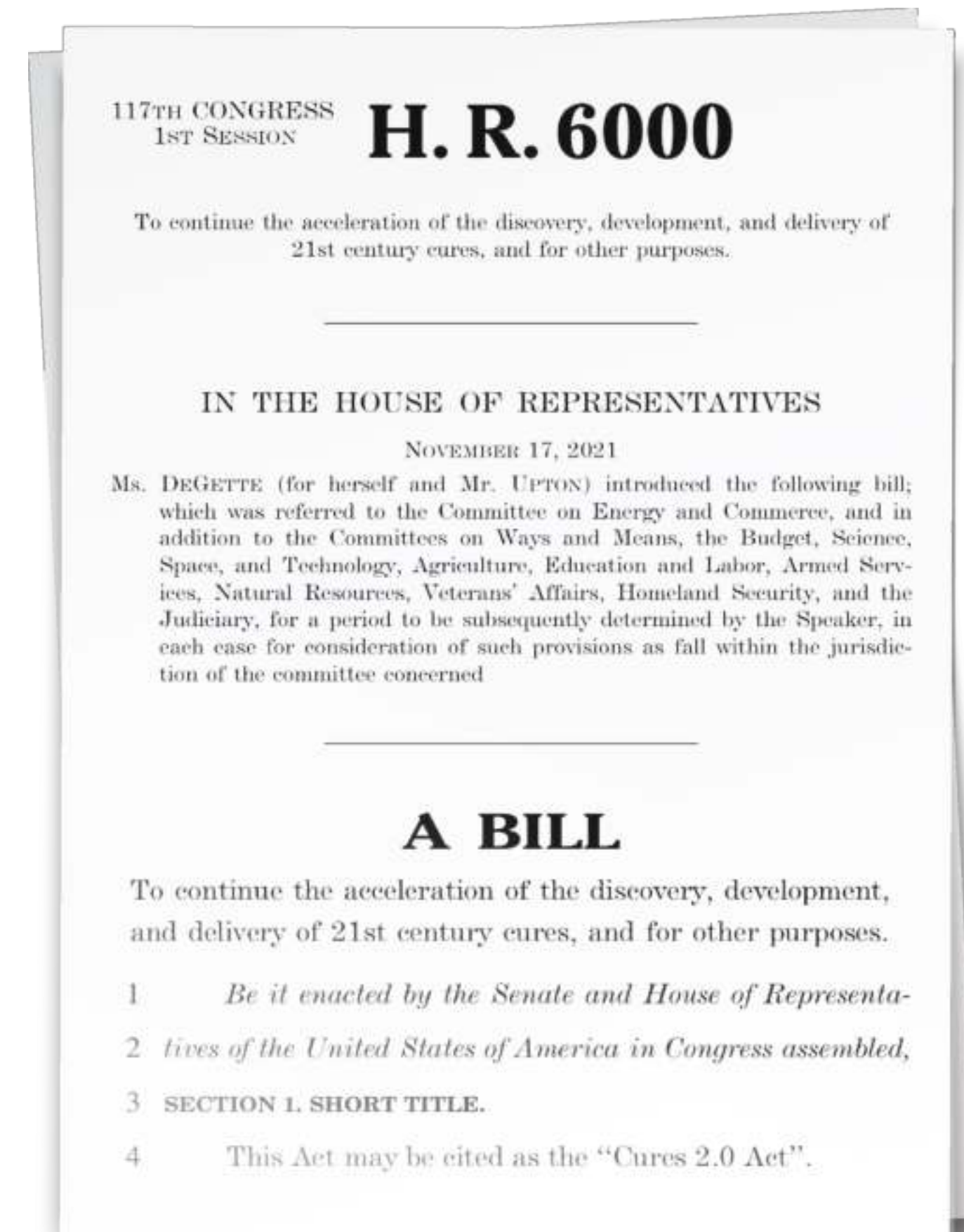


# 2023 – CURES ACT 2.0



This 173-page bipartisan bill will have the greatest impact for all clinical trials moving forward.

- Accelerates medical research and **increase patient access to NOVEL therapeutics.**
- Creates a **new agency, Advanced Research Projects Agency for Health (ARPA-H), within the National Institutes of Health (NIH) – tasked with developing novel treatments to challenging diseases such as cancer, diabetes, ALS, and Alzheimer’s.**





# RCT & RWE – THE FACTS



RCT's are the current “gold” standard.

New legislation in the US & EU moving quickly to RWE. •————→

TA demographics for RWE studies:

- 24% Oncology
- 15% Infectious Disease
- 11% Central Nervous System

Sponsor study demographics with RWE:

- 33 studies: Abbvie
- 13 studies: AstraZeneca, but with the most RWE currently live
- Remaining studies: Novartis and Bristol-Myers Squibb

116 FDA approvals incorporated RWE with the proportion of approvals incorporating RWE increasing

2X as many  
RWE data trials  
in 2022 vs. 2020



RWE is the true value  
of a decentralized trial,  
giving meaningfulness  
to the patient in how  
the drug interacts.

In 2022



# THE PRODUCT REVENUE EQUATION



$$\text{Product Revenue} = (\text{Patient Recruitment}) + (\text{Speed to Market}) \times (\text{Yield Time Savings})$$

## Trials with RWE:

- **Representative diversity in trials:** Help identify potential disparities in healthcare utilization or outcomes.
- **Decreased sample size by at least 40%.**
- **Accelerate speed to market:** Recruiting fewer patients yields time savings of at least 6 months.
  - + millions in saved trial execution costs
  - + potentially hundreds of millions in product revenue
- **Cost savings can vary significantly:**
  - Top-10 pharma company savings = \$500M-\$1B p/yr
  - Top-20 pharma company savings = \$300M





# Why SubjectWell

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# SUBJECTWELL TRANSCENDS PATIENT ACCESS

We hold the IP for one of the largest and rapidly growing direct patient access databases – A highly advanced, living, breathing marketplace of patients



**100k+**  
RANDOMIZED  
PATIENTS



**700+**  
STUDIES



**350k+**  
REFERRALS



**10+**  
YEARS OF  
PATIENT  
RECRUITMENT



SUCCESS



# SUBJECTWELL ALREADY HAS THE PATIENTS YOU NEED



**14M+**  
Patients with known conditions in marketplace

**47%**  
Patients of color in marketplace

**6.7**  
Average # of conditions per patient

**300K**  
New patients join monthly

**125+**  
Strategic partners in media network

**3K+**  
Patients screened daily





# CURES DON'T START WITH PROTOCOLS - THEY START WITH A PASSION!

"If you change the way you look at things, the things you look at change."

-Dr. Wayne Dyer



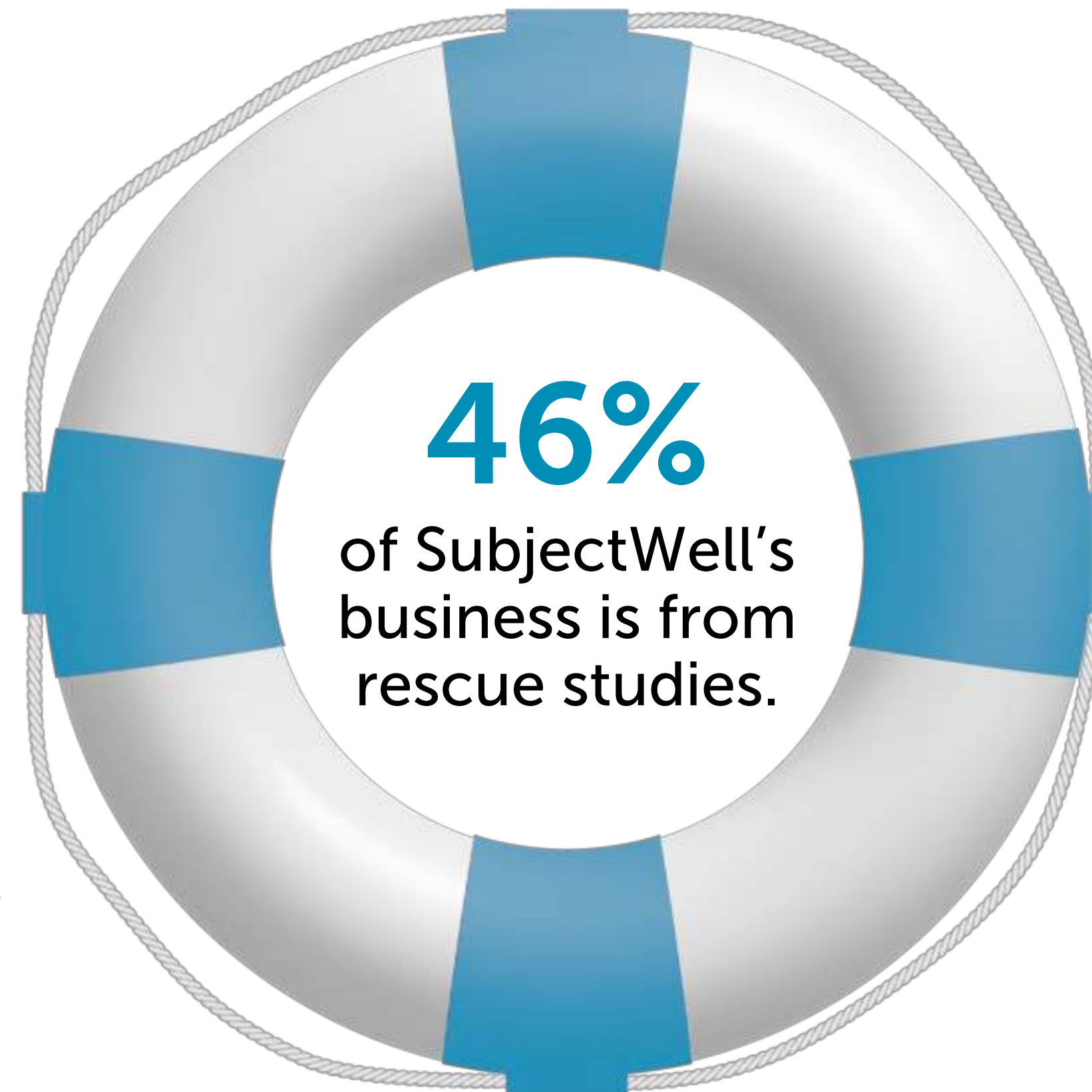


# CLINICAL TRIAL RESCUES



“We will choose the most cost-effective recruitment bid”

“We can use our sites for recruitment”



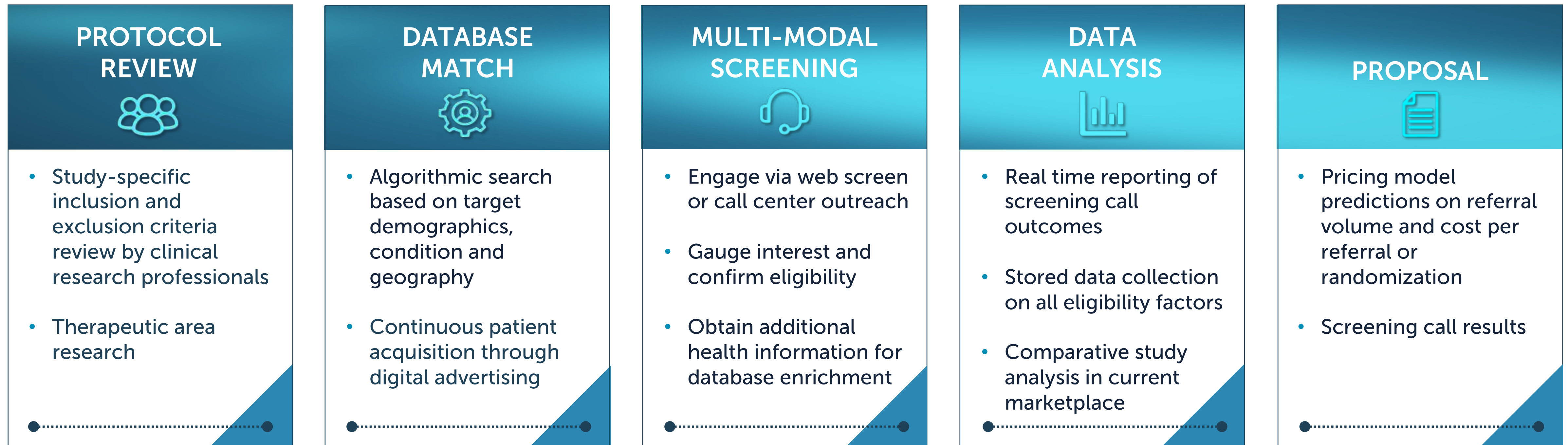
“We think the recruitment vendor can find these patients”

“We always assume patients are accurately screened”

# STUDY SIMULATION AT RISK



SubjectWell completes a two-week simulation of our real-world recruiting efforts, speaking with actual patients.



For a minimal fee, we run a complete simulation based on your protocol / synopsis to measure the success of the patient recruitment, sites, and randomization.

- If the simulation does not produce any issues, we apply the small fee towards your contracted service agreement.
- This is part of our risk sharing model. We give you your statistical success rates before we ask you to sign a contract.



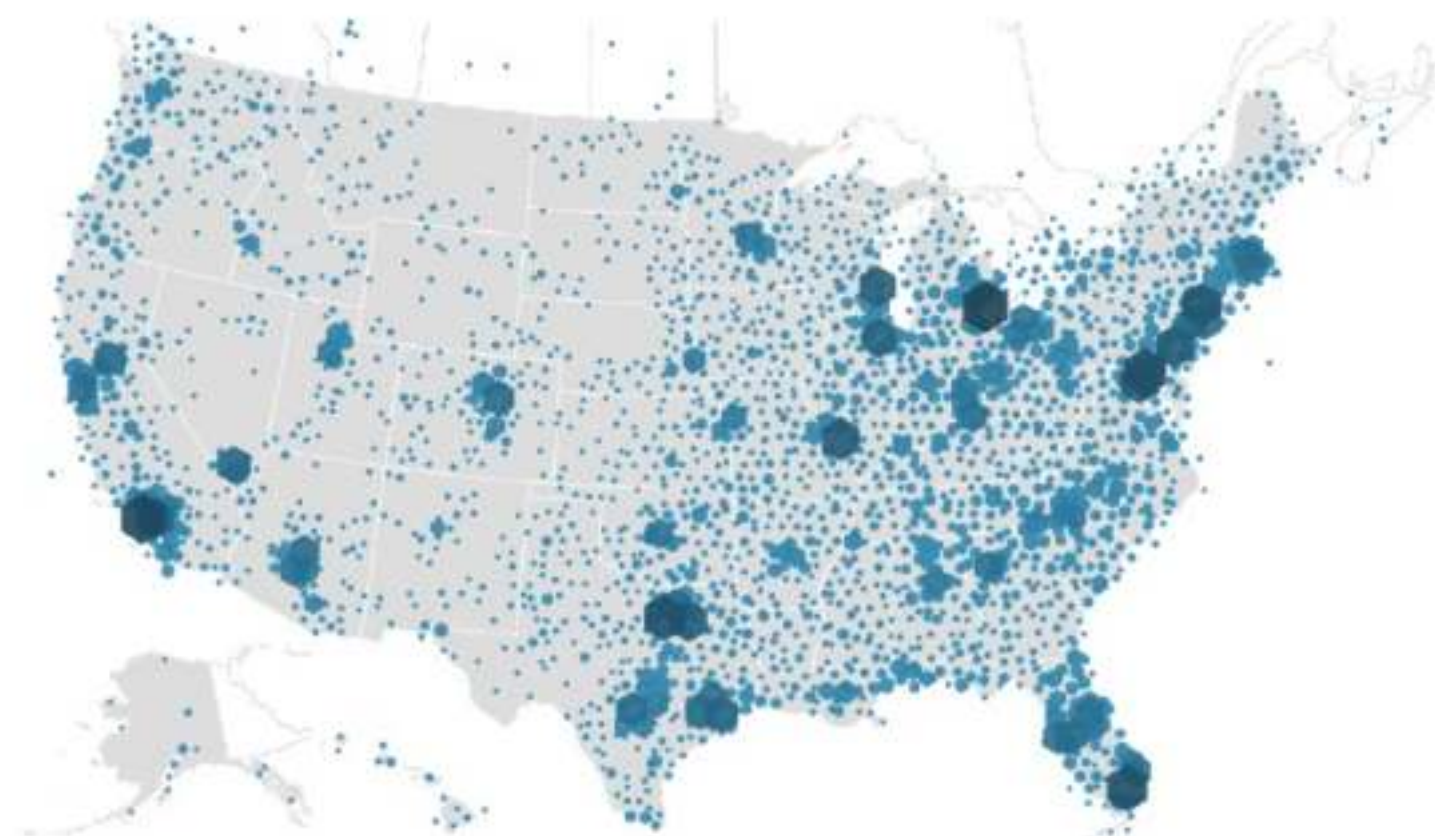


# DETAILED RECRUITMENT ASSESSMENT

Target patient distribution

Patient interest rates

Understand pass rates by I/E criteria



Relative Distribution of Target Population

Anticipated Active Sites: 80  
Expected Patients Contacted: ~2000-2500 patients per month  
Expected Patients Interested in Participation: 65%

Simulated Phone Screen Criteria	Qualifying Response	Pass Rate
Have you been diagnosed with asthma for six months or longer?	Yes	97%
Do you use a daily ICS inhaler, such as QVAR, Pulmicort, Flovent, Asmanex or Alvesco, or a combination ICS/LABA inhaler such as Advair, Symbicort, Dulera, or Breo?	Yes	73%
Have you had a life-threatening asthma attack in the last year? This would include any attack that required intubation or resulted in a loss of consciousness or respiratory arrest.	No	91%
Have you been diagnosed with COPD?	No	75%

Are you a current smoker OR a former smoker who smoked more than one pack a day for over ten years?	No	60%
Have you received any of the following treatments for asthma in the past 6 months? - Xolair (Omalizumab) - Nucala (Mepolizumab) - Cinqair (Reslizumab) - Fasenra (Benralizumab) - Dupixent (Dupilumab)	No, Unsure	93%
Have you taken any immunosuppressive medications for any other medical condition in the last 6 months?	No, Unsure	90%
Have you ever been diagnosed with or treated for cancer- excluding skin cancer that has been successfully removed?	No	93%
Would you be willing to perform daily lung function tests at home throughout the study duration?	Yes, Unsure	95%
Total Expected Pass Rate		20%

Expected Referrals Per Month: ~260-325 patients per month  
Anticipated Entered Screening Per Month: ~17-22

Anticipated Demographics:  
White/Caucasian: 52%  
Black/African American: 30%  
Hispanic or Latino: 18%

Reported Screen Fail Rate: 50%  
Potential Randomizations Per Month: ~8-11  
Price Per Referred Patient: \$200  
Price Per Referred Patient w/Rand Kicker: \$10,200  
Price for Recruitment Agency Services: *by service*

Expected pass rate

Monthly referrals

Demographics

Pricing options

# Solutions

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# GUIDED RECRUITMENT

Our custom recruitment workflows and in-house medical contact center engage and guide each patients to ensure high referral quality.

## ADVANTAGES



**Rigorous Patient Screening**  
by our medically trained recruiters



**Quality Over Quantity**  
reduces site burden



**Advanced screening**  
powered by proprietary technology



**47% Patients of color**  
in the marketplace



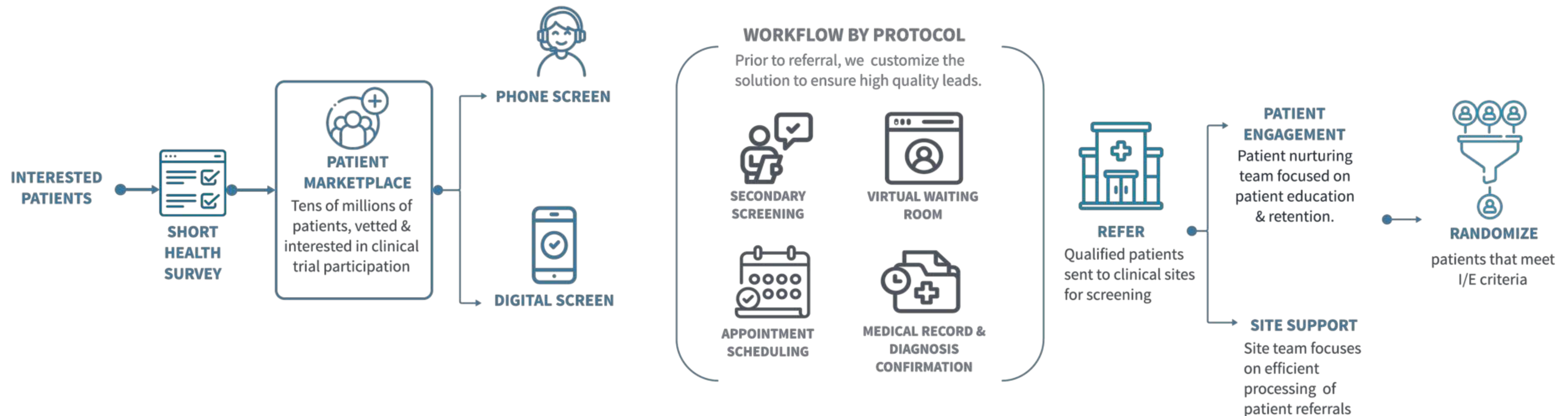
## YOU NEED

Qualified patients sent to your enrolling sites.





# THE SUBJECTWELL MACHINE



IN-HOUSE MEDICAL CONTACT CENTER

PROPRIETARY TECHNOLOGY PLATFORM



# VIRTUAL WAITING ROOM

Keep patients engaged until requirements are met and confirmed by our medically trained recruiters

## ADVANTAGES



10,000+  
patients opt in  
to VWR



28% of VWR  
patients qualify  
for referral to site



6.6% of  
patients  
randomize  
from a VWR  
referral

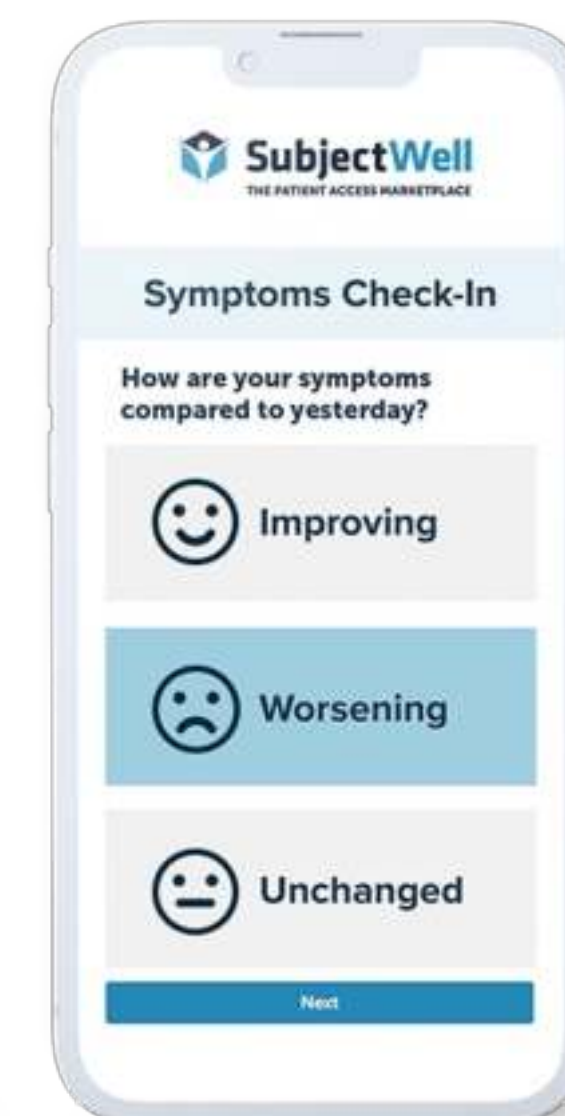


73.5% of  
sites  
participate



## YOU NEED

Recruitment for a condition with a flare component or reoccurring symptoms.







# RECRUITMENT AGENCY

Modular, custom patient recruitment solutions are created by SubjectWell's in-house ad agency

## ADVANTAGES



Leverage global infrastructure for recruitment across 6 continents



Meet diversity goals with custom artwork, translations and targeted outreach



Find patients for rare conditions and difficult protocols



## YOU NEED

Recruitment for a global trial across any therapeutic area.



# Q&A

JEREMY WESTFALL – VP OF BUSINESS DEVELOPMENT

[Jeremy.Westfall@SubjectWell.com](mailto:Jeremy.Westfall@SubjectWell.com)

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# Case Studies

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# CASE STUDY

## DIRECT CONNECT CARDIOVASCULAR RECRUITMENT SUCCESS



### BACKGROUND

#### SUBJECTWELL PARTNERED WITH A RECRUITMENT AGENCY:

- Direct Connect provided a complementary source of patient traffic, adding to in-house search and social.
- Cost-per-click (CPC) was higher, but motivated patients from Direct Connect translated into lower costs per lead (CPL), pre-screened patient, and randomization.
- The agency shut down in-house search and social after 1 month, leveraging Direct Connect to reach recruitment goals in just 3 months.

#### AT ONE MONTH

CHANNEL	CLICKS	CPC	LEADS	CPL	PRE-SCREENED LEADS	COST-PER-PRE-SCREENED LEAD	RANDS	COST-PER-RAND
Social	4,958	\$4.70	239	\$97	36	\$647	0	-
Search	7,343	\$2.25	244	\$68	19	\$869	0	-
Direct Connect	17,336	\$8.75	4,071	\$37	787	\$193	20	\$7,585

### RESULTS

**17 Times**

more likely to convert clicks into leads compared to search

**78% Lower Cost**

per pre-screened leads compared to search

**93%**

of all pre-screened patients delivered by Direct Connect

# CASE STUDY

## GUIDED RECRUITMENT – FROZEN SHOULDER

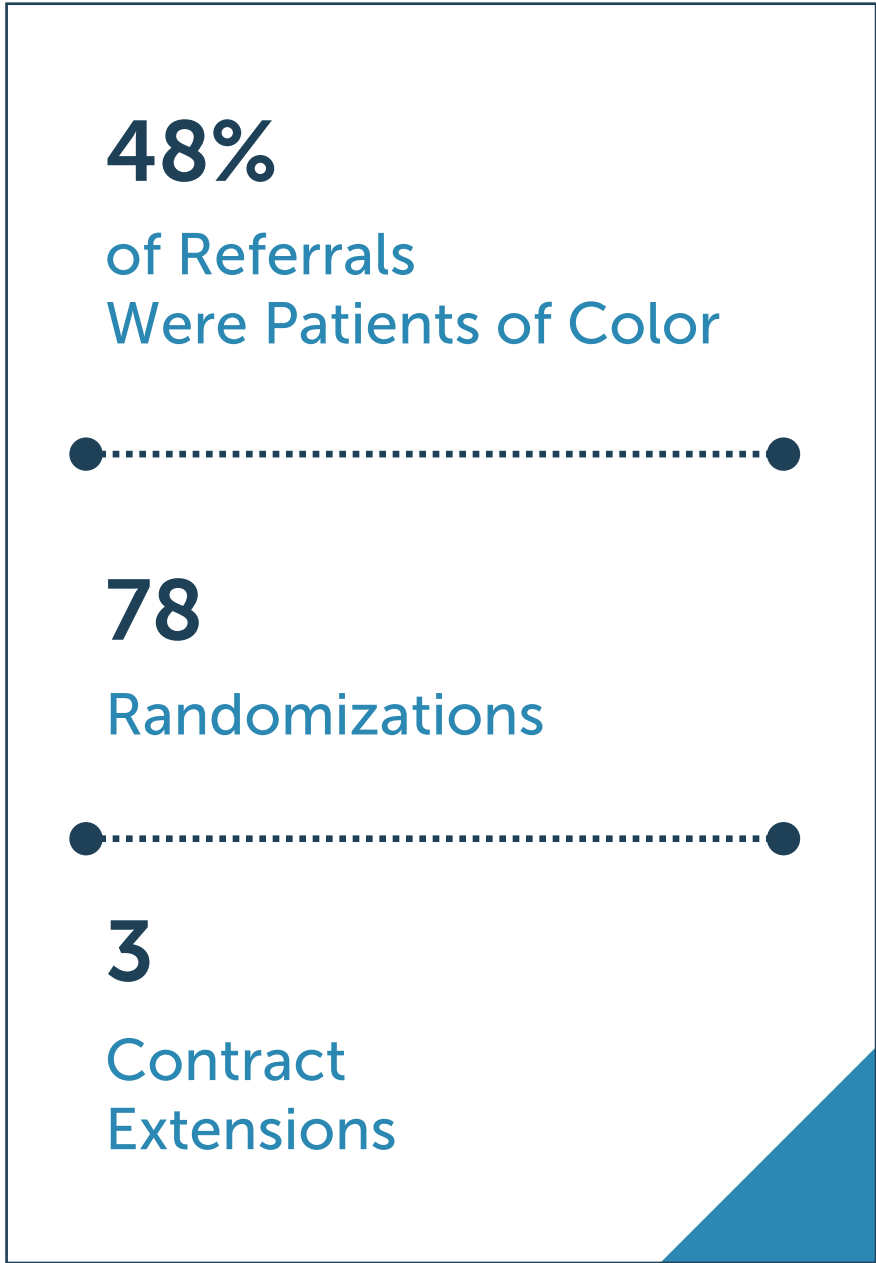


BACKGROUND

Sponsor wanted to bring in LPI by 4 months, but recruitment was lagging. SubjectWell updated the screener to more accurately filter for exclusion criteria, increasing referral volume and reducing confusion during the screening process. After contract extensions, SubjectWell contributed 39% of all randomizations.

INJECTABLE MEDICATION FOR THE TREATMENT OF ADHESIVE CAPSULITIS	
Contract	Original – 20 randomizations Final – 80 randomizations after 3 extensions
Recruiting Timeline	15 months
Referrals	3,281
Randomizations	78

RESULTS





# CASE STUDY

## VIRTUAL WAITING ROOM



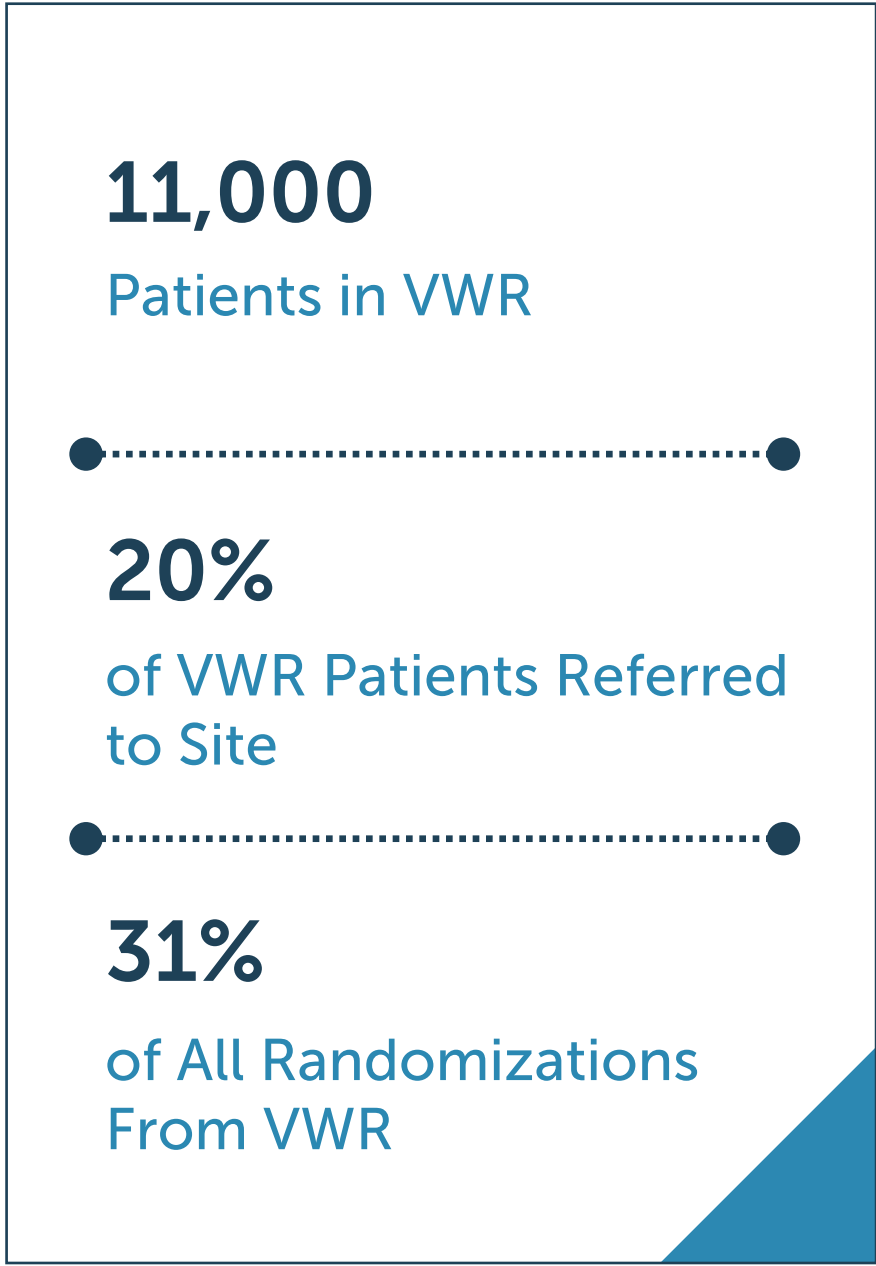
### BACKGROUND

Sponsor was experiencing slow recruitment for a trial with a timing component. SubjectWell partnered with two North American pharmacy networks and placed interested patients in the VWR after being prescribed existing treatments. Patients were sent checkup messages. Qualified patients were referred into the study, **resulting in 135 randomizations**.

#### ORAL MEDICATION FOR THE TREATMENT OF RECURRENT VIRAL INFECTION

Contract	130 randomizations
Recruiting Timeline	10 months
Referrals	2,065
Randomizations	135

### RESULTS





# CASE STUDY

## RECRUITMENT AGENCY – ADPKD



### BACKGROUND

A top 10 Sponsor needed patients in a low prevalence condition for a global clinical study. SubjectWell designed a **digital recruitment solution with localized outreach in the US, Japan and Germany**, meeting complex data privacy requirements.

#### TACTICS:

- Customized website, pre-screener, and ads.
- Outreach via search, social, and patient society.
- Utilized global call center for outreach and site recruitment support, with local country partners.

### RESULTS

**4,000+**

Patient Inquiries

**4%+**

Pre-Screened  
to Randomized

**520+**

Pre-Screened  
Patients

**22**

Randomizations  
(>20% of Enrollment  
Target)