



# 2020 SIGNATURE SERIES: SUMMIT

## VOICE OF THE PATIENT

# VIRTUAL CLINICAL TRIALS: CARE FROM ANYWHERE

---

Recorded: October 16, 2020

# TWITTER Q&A



Ask questions in  
real-time by tagging  
**@CraigLipset** and  
**#AHPSummit20!**



**Craig Lipset, MPH**  
Advisor and Founder  
Clinical Innovation Partners

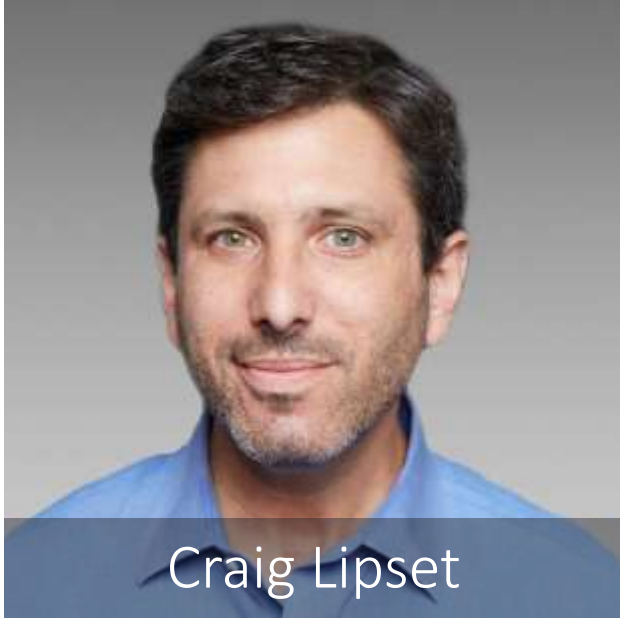


# Virtual Clinical Trials: Care from Anywhere

Alliance for Health Policy  
2020 Signature Series  
Voice of the Patient  
20 October 2020

Craig H Lipset  
@craiglipset





Craig Lipset

BOARD MEMBER



ADVISOR



MedStar Health Research Institute

FOUNDATION FOR SARCOIDOSIS RESEARCH

CIRCUIT CLINICAL®

FACULTY



FORMER

# Agenda



Early-COVID Trial Continuity

Mid-COVID Trial Stabilization

Pre-COVID  
Trial Trends

Forecasts for  
Beyond

# Clinical Trial Trends

## Pre-COVID

1

# Clinical Trial Trends Pre-COVID

## TRIAL DIGITIZATION



Real World Data /  
Real World Evidence



Artificial  
Intelligence



Mobile /  
Digital Endpoints



Automation

## PATIENT-CENTRICITY



Participant  
Experience



Information  
Resources



Study  
Access



# Early-COVID Trial Continuity

2



# Early-COVID Trial Continuity

OBJECTIVE:  
Monitor Patient Safety  
Avoid Missed Doses  
Avoid Missing Data



Investigational  
Product

Direct-to-patient supply chain  
In-home infusion



Clinical / Safety  
Monitoring

Remote/ central monitoring  
Data-driven/ risk-based monitoring



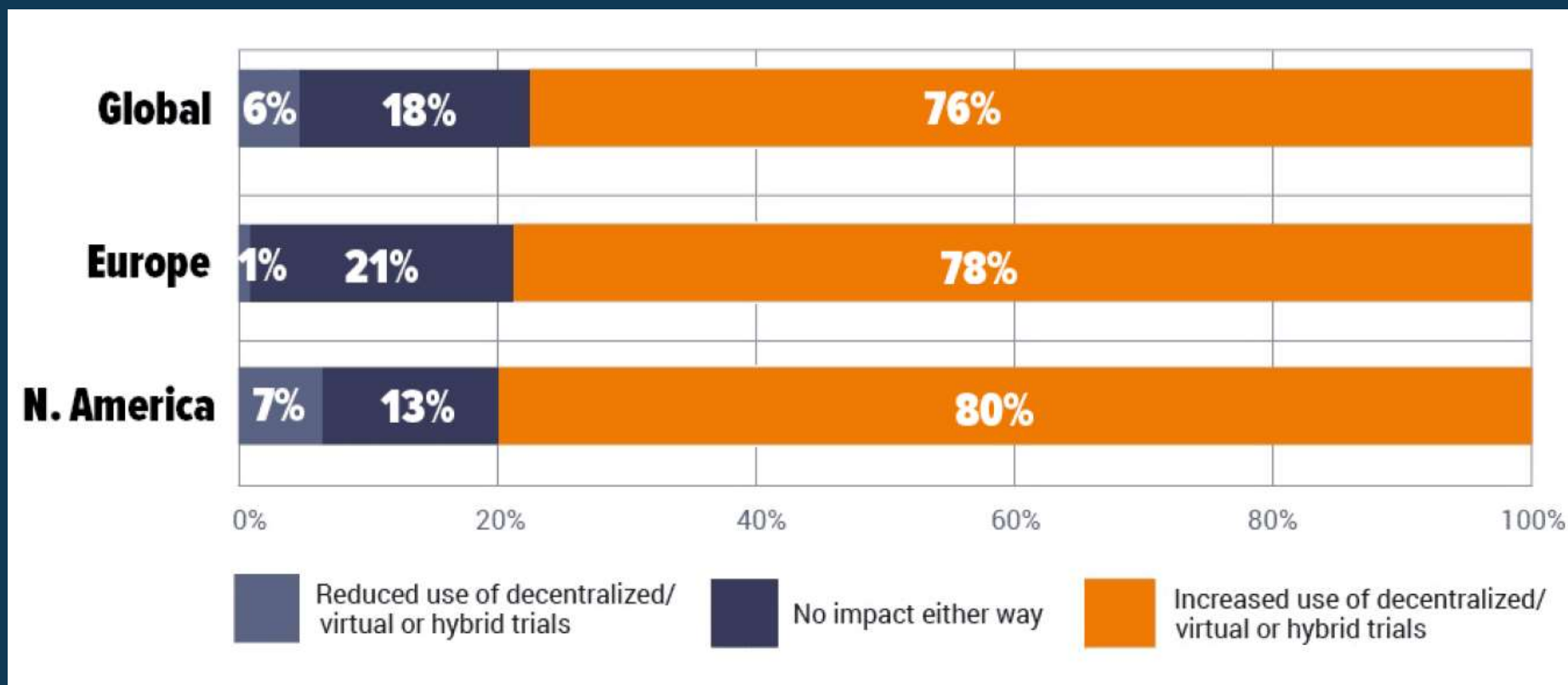
Patient Visits  
& Data Capture

Video/ tele-visits & home visits  
Shifting endpoint to digital  
Opportunities for modeling

# Early Shifts in Trial Conduct

## 79% of SPONSORS/CROs Increasing Virtual

*How has COVID-10 and associated lockdowns impact your use of decentralized trials?*

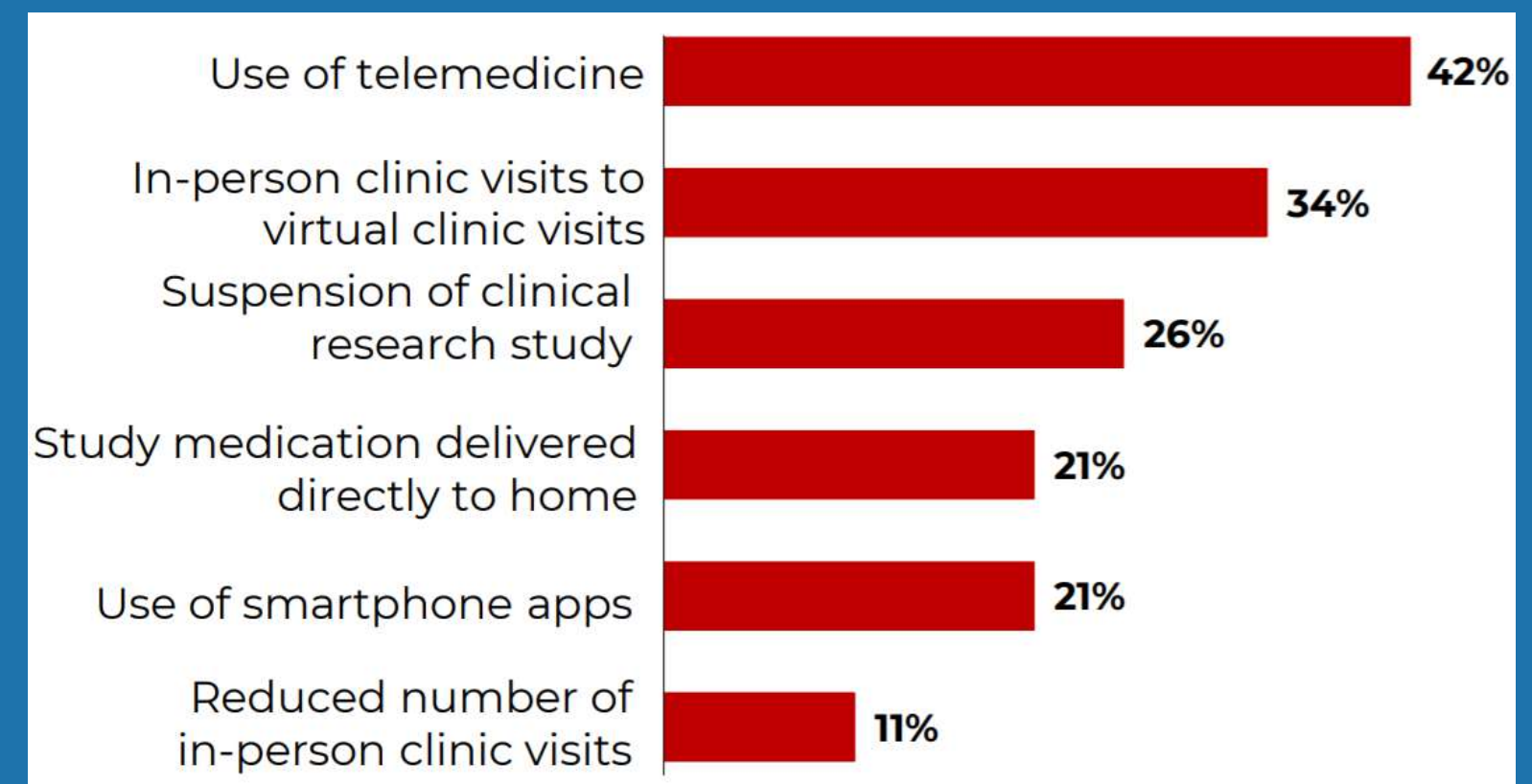


Fully remote/virtual

Clinical Trials Europe, May 2020, n=184

## 90% of PARTICIPANTS Impacted

*What changes have you experienced in your clinical trial as a result of the COVID-19 pandemic?*



CISCRP 2020, n=38

# RISK

innovation

*What  
Drove The  
Change?*

Culture still risk averse,  
only the environment  
changed.

What had been viewed as  
risk months early,  
now became risk mitigation.

*Will The  
Change  
Last?*

SOP Waivers &  
Protocol Deviations  
Do Not Make  
A “New Normal”



# Mid-COVID Trial Stabilization

3



# Sites Anticipated Difficulty Resuming Studies

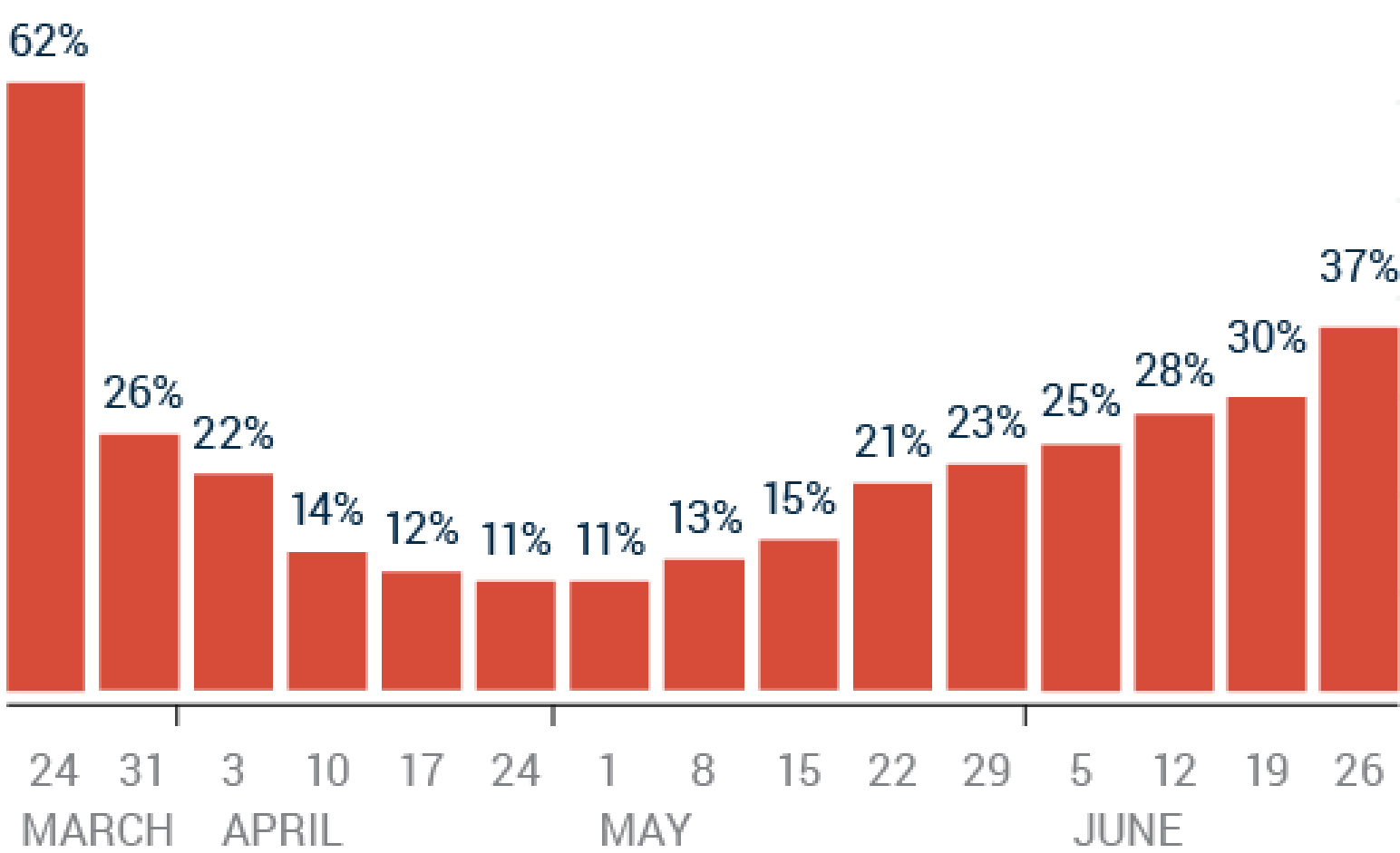
What is the Most Important Challenge in Restarting Clinical Trials at Sites?



Source: WCG CenterWatch™

# Study Enrollment Recovery Began in May

Clinical Research Sites Open to Enrollment



Source: WCG Knowledge Base™

# Mid-COVID Trial Stabilization

*Committing To Change*



Policies & Procedures



Partners & Vendors



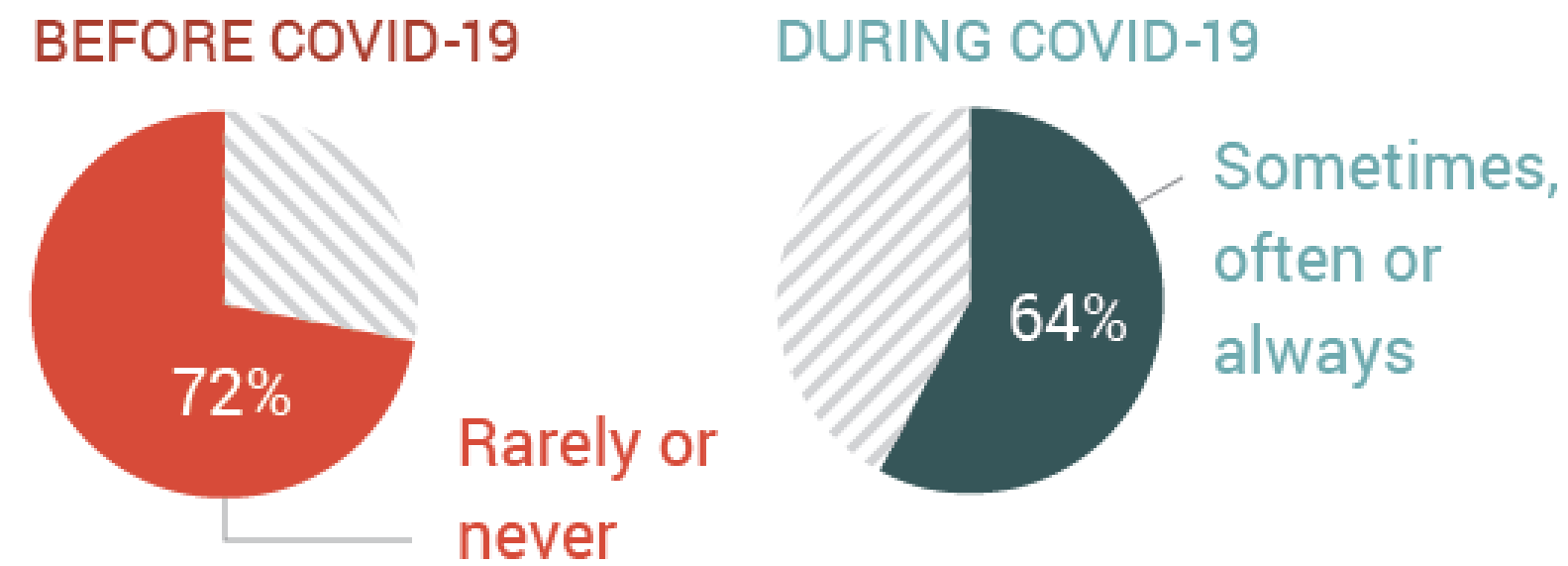
Training & Culture



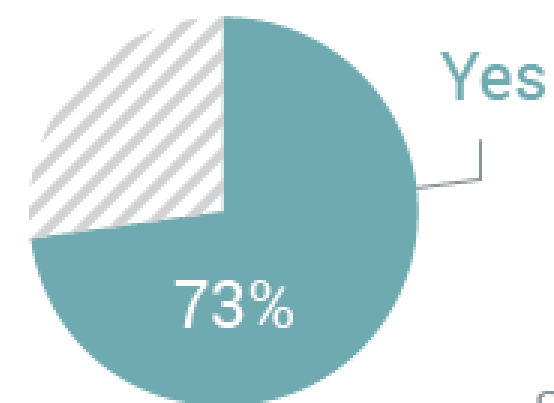
Rethinking Protocols

# By July Most Sites Indicate Committing to Change

How are sites using telemedicine for trial participants?

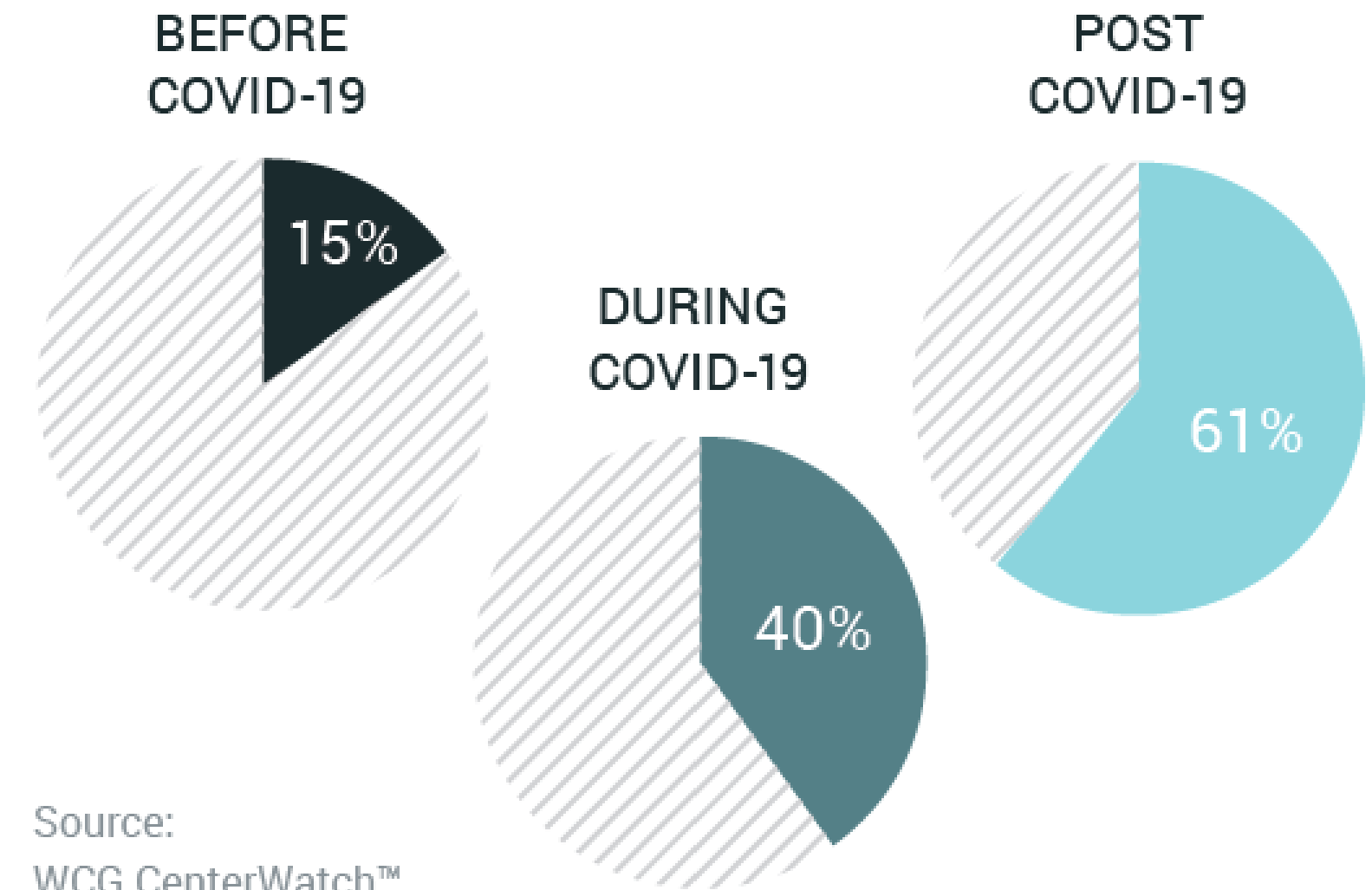


Will sites use telemedicine after COVID-19?



Source: WCG CenterWatch™

How Are Sites Using, Or Planning To Use, Remote Coordinators?



Source:  
WCG CenterWatch™



*Virtual Trials*

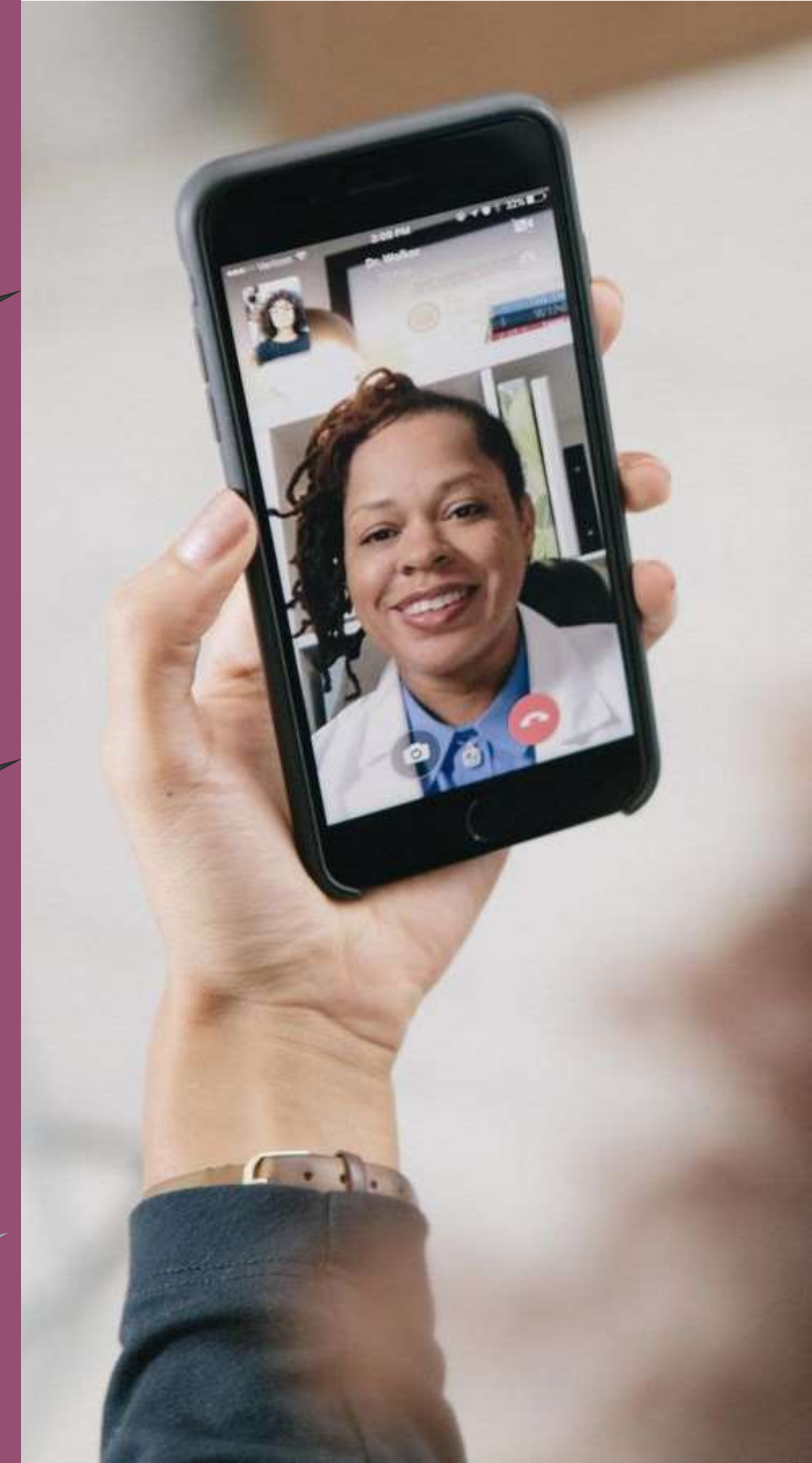
*Siteless Trials*

*Remote Trials*

*Digital Trials*

*Direct to Patient  
Trials*

*Decentralized Trials*





# 79%

Home nursing visits would make participation in a trial somewhat/very appealing.

CISCRP Perceptions & Insights Study, 2019

## Race/Ethnic Differences in Preference

85% Black

81% White

75% Hispanic/LatinX

66% Asian

# 58%

Percent of Patients More Likely To Participate In A Trial That Offers Telehealth Services.

SubjectWell Patient Attitudes Survey, May 2020

# 60%

Percent of Japanese Research Participants That Would Value Alternatives to Hospital Visits.

*Continuum Clinical / 3HMedi Survey, May 2020*

# A Clinical Trial From Home

---



Drug trial (tolterodine tartrate)  
Fully remote/virtual

## REMOTE:

*Research on Electronic Monitoring of  
OAB Treatment Experience*

Safety & efficacy of Detrol LA  
for overactive bladder

600 patients from 10 states

2 lab assessments

5 mobile based e-diary assessments

# Web-based trial to evaluate the efficacy and safety of tolterodine ER 4 mg in participants with overactive bladder: REMOTE trial

Miguel Orri <sup>a, 1</sup>, Craig H. Lipset <sup>b</sup>, Bradly P. Jacobs <sup>c, d</sup>, Anthony J. Costello <sup>c</sup>, Steven R. Cummings <sup>c, d, e</sup>

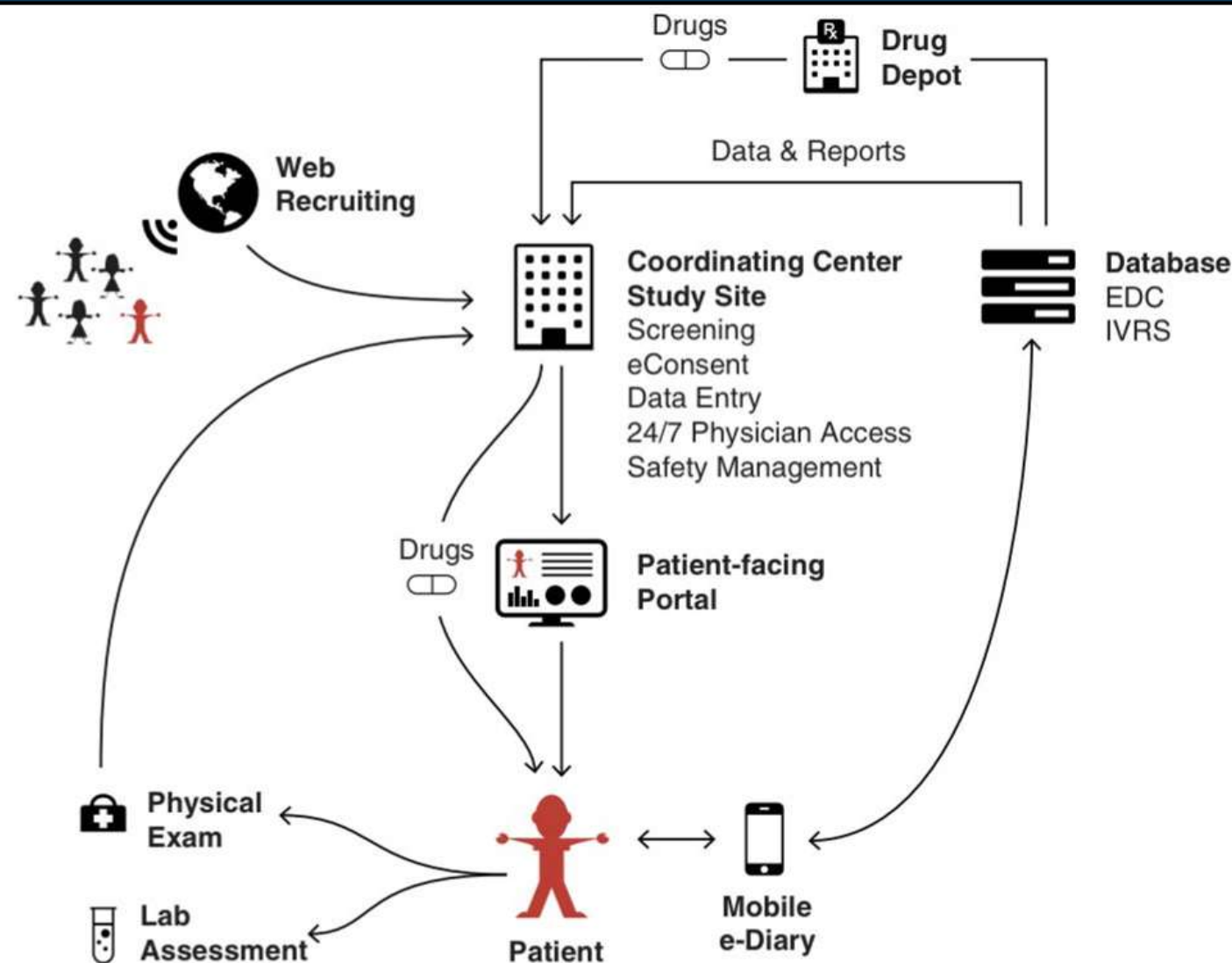


Fig. 2. Electronic data collection and management. EDC = electronic data capture, IVRS = interactive voice response system.

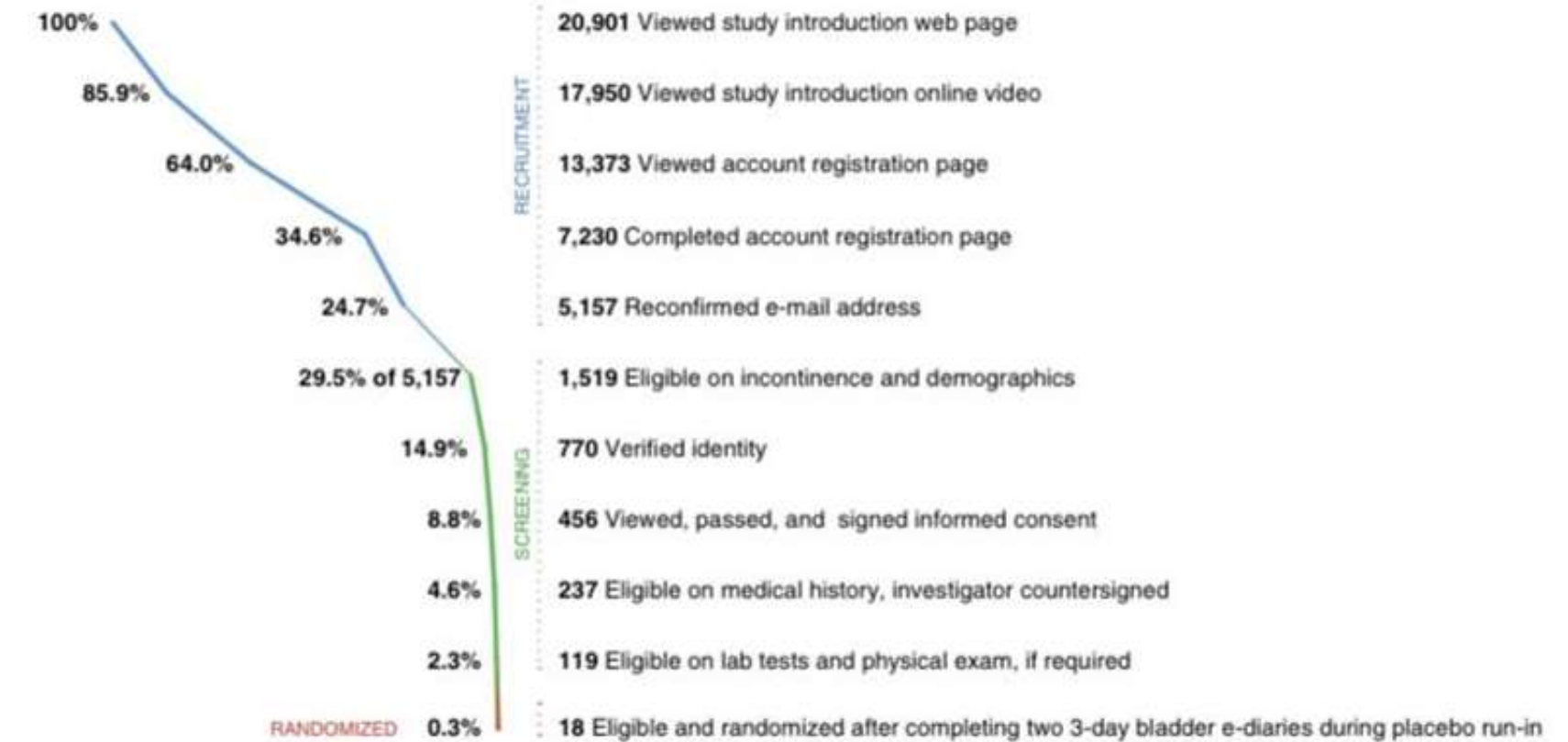


Fig. 3. Participant disposition. Percentages at each step of recruitment were calculated using the number of participants who viewed the study introduction web page as the denominator. Percentages at each step of screening were calculated using the number of participants who reconfirmed their e-mail address as the denominator.



# The 17-Year History of Decentralized Trials



2003

2004

2005

2006

2007

2008

2009

2010

2011

2012

2013

2014

2015

2016

2017

2018

2019

2020

McAllindon  
feasibility study  
for internet trials

**BOSTON UNIVERSITY** Internet-  
based RCT for  
Glucosamine in OA

**Lilly** tadalafil  
hybrid trial under  
FDA IND

**UCSF** Internet-  
based RCT for Kava  
in anxiety/insomnia

US patent for "Trials  
Over the Internet"  
**BOSTON UNIVERSITY**

Initial internal pitch  
for **Pfizer**  
REMOTE trial

**mytrus**  
launched to  
support  
REMOTE trial

**Pfizer** REMOTE  
trial announced:  
Fully-remote trial  
of tolterodine  
under FDA IND  
enrolling in  
10 states  
**mytrus** **PAREXEL**  
**exco** **Intouch** **Quest**  
**Diagnostics**  
**greenphire**

**Pfizer** REMOTE  
trial terminated  
due to enrollment

**Pfizer** REMOTE  
trial published  
**Science 37**  
launched

**Science 37** \$6.5M  
series A includes  
dRx  
(**NOVARTIS**)

**SANOFI** launches  
VERKKO study of  
glucose monitor  
with **CLINPAL**

**AOBIOME**  
launches Ph2b  
virtual trial in  
acne with  
**Science 37**

**mytrus**  
launches 20,000  
patient aspirin  
trial with PCORI

**gsk** launches  
ResearchKit  
study in RA

**Science 37**  
\$31M series B  
includes **SANOFI**

**medidata**  
acquires  
**mytrus**

**Science 37** \$35M  
series C includes  
**AMGEN** & **Google**

**NOVARTIS**  
announces 10  
studies with  
**Science 37**  
**IQVIA** launches  
virtual trial  
solutions

**Boehringer** announces  
partnership with **Science 37**

**VIRTRIAL** announces  
training partnership  
with **SCRS**

**transparency LS** launches  
VISITOR study

**verily** launches study  
platform partnership with  
4 pharma

**J&J** and **PRA Health Sciences**  
announce CHIEF-HF  
registration trial

**Science 37** \$35M raise  
includes **PPD**

Lightship  
\$30M series  
B includes  
**McKESSON**

COVID-19

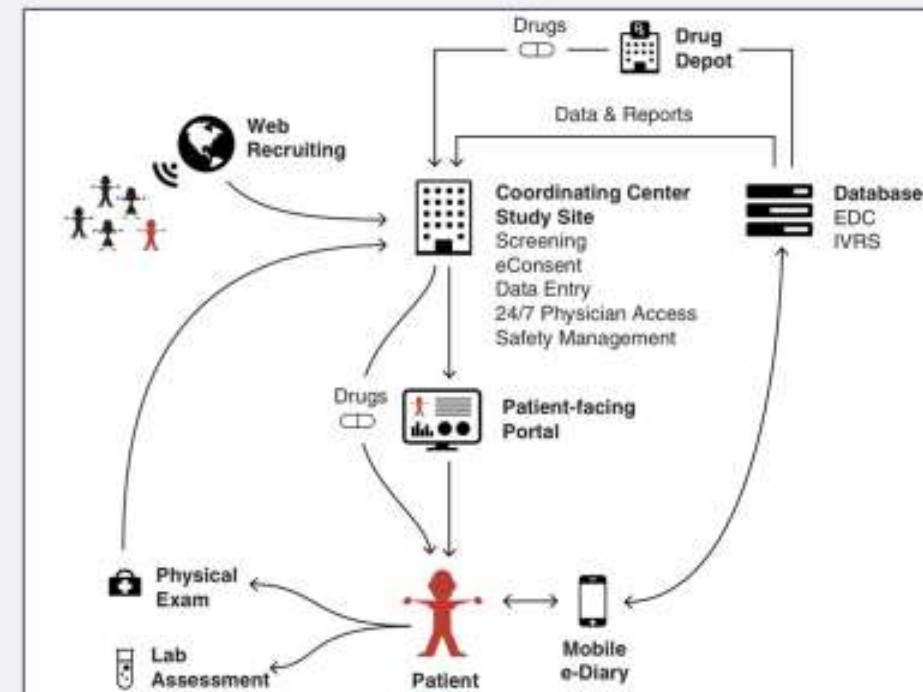
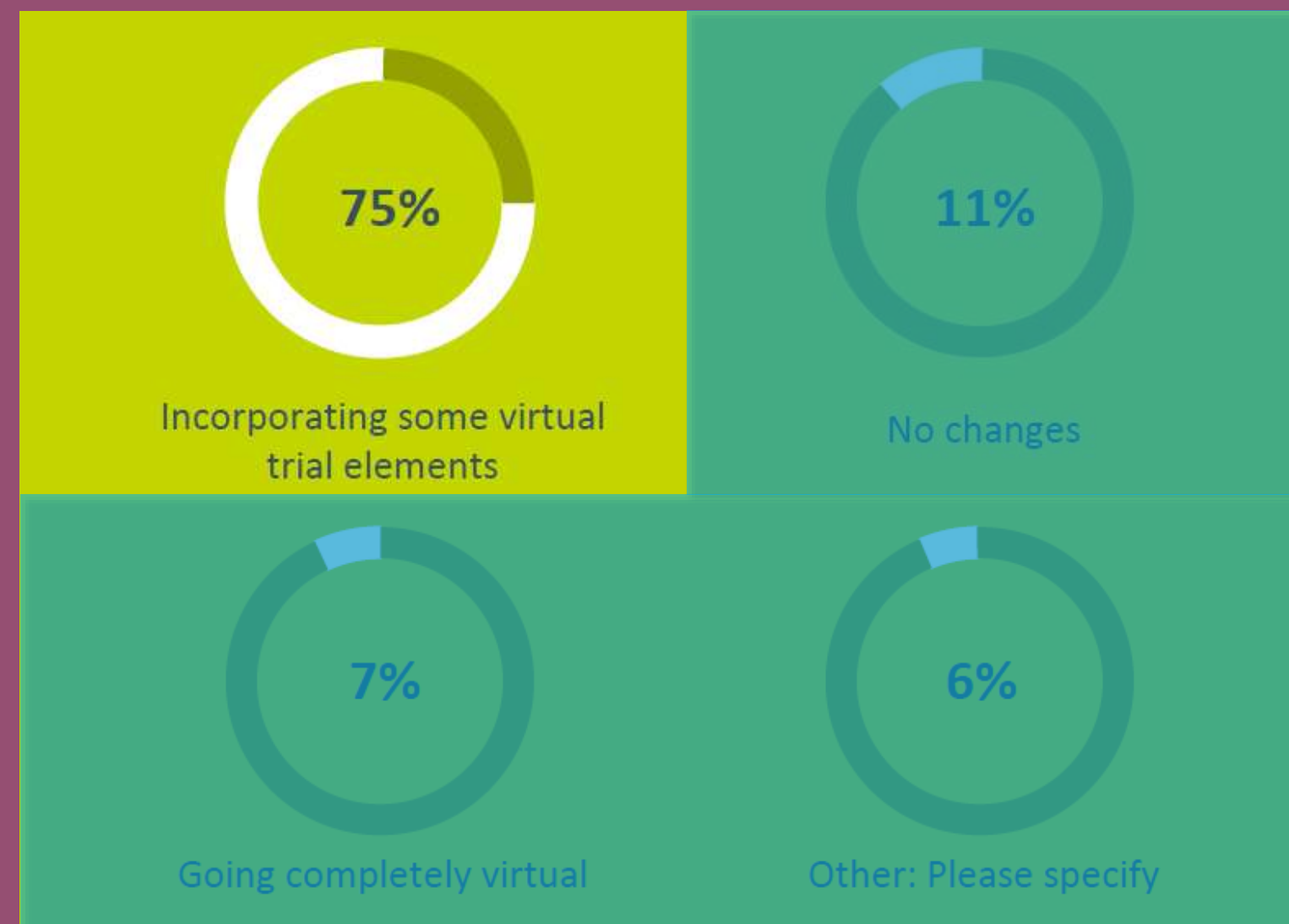


Fig. 2. Electronic data collection and management. EDC = electronic data capture, IVRS = interactive voice response system

# Hybrid Trials

---

*What changes are you making to existing trial models to address the challenges of the COVID-19 pandemic?*



*ERT Survey Report: Virtual Trials and the COVID-19 Pandemic*



Brick-and-Mortar Sites  
*Conventional  
investigator site visits*



Hybrid Studies  
*Some visits  
scheduled at home*



Fully Virtual  
*All visits from  
the home*



# Forecasts for Beyond

4

# Post-COVID Everything is Hybrid

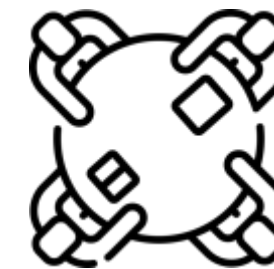
People expect  
**CHOICE**  
in engagement



Grocery



Education



Business



Healthcare







US online grocery went from 3-4% of grocery spending earlier this year up to 10-15% at the pandemic peak.

As the crisis recedes expect online grocery to level at 5-10%.

Bain&Co



# The Researcher's View of Hybrid Trials

	Visit #1	Visit #2	Visit #2	Visit #4	Visit #5	Visit #6	Visit #7
Protocol-defined Location	In-Clinic 	At-Home 	In-Clinic 	At-Home 	In-Clinic 	At-Home 	In-Clinic` 





# The Researcher's View of Grocery Shopping

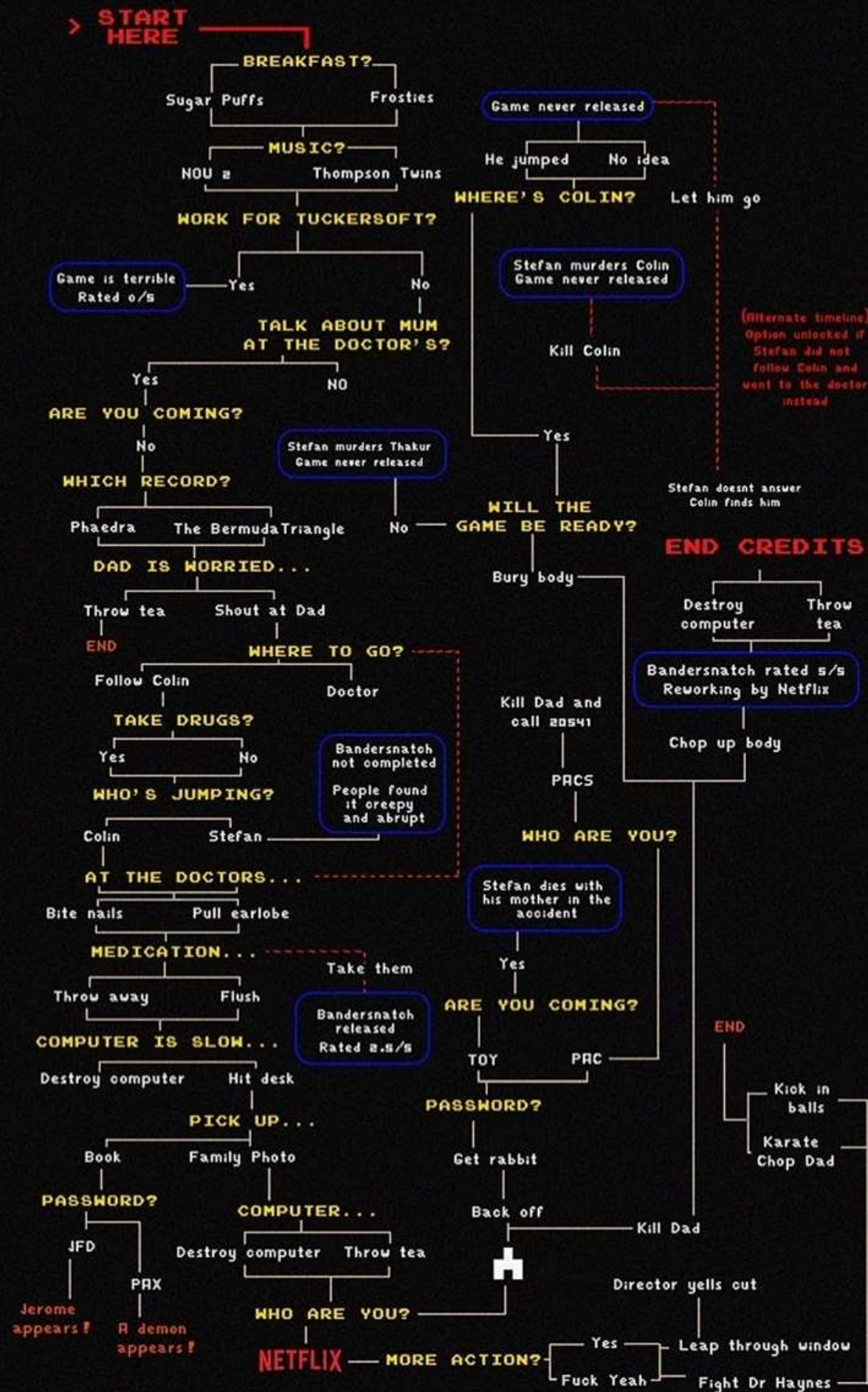
	Visit #1	Visit #2	Visit #2	Visit #4	Visit #5	Visit #6	Visit #7
Grocery-defined Location	In-Store 	At-Home 	In-Store 	At-Home 	In-Store 	At-Home 	In-Store 



# BANDERSNATCH

## POSSIBLE ENDINGS

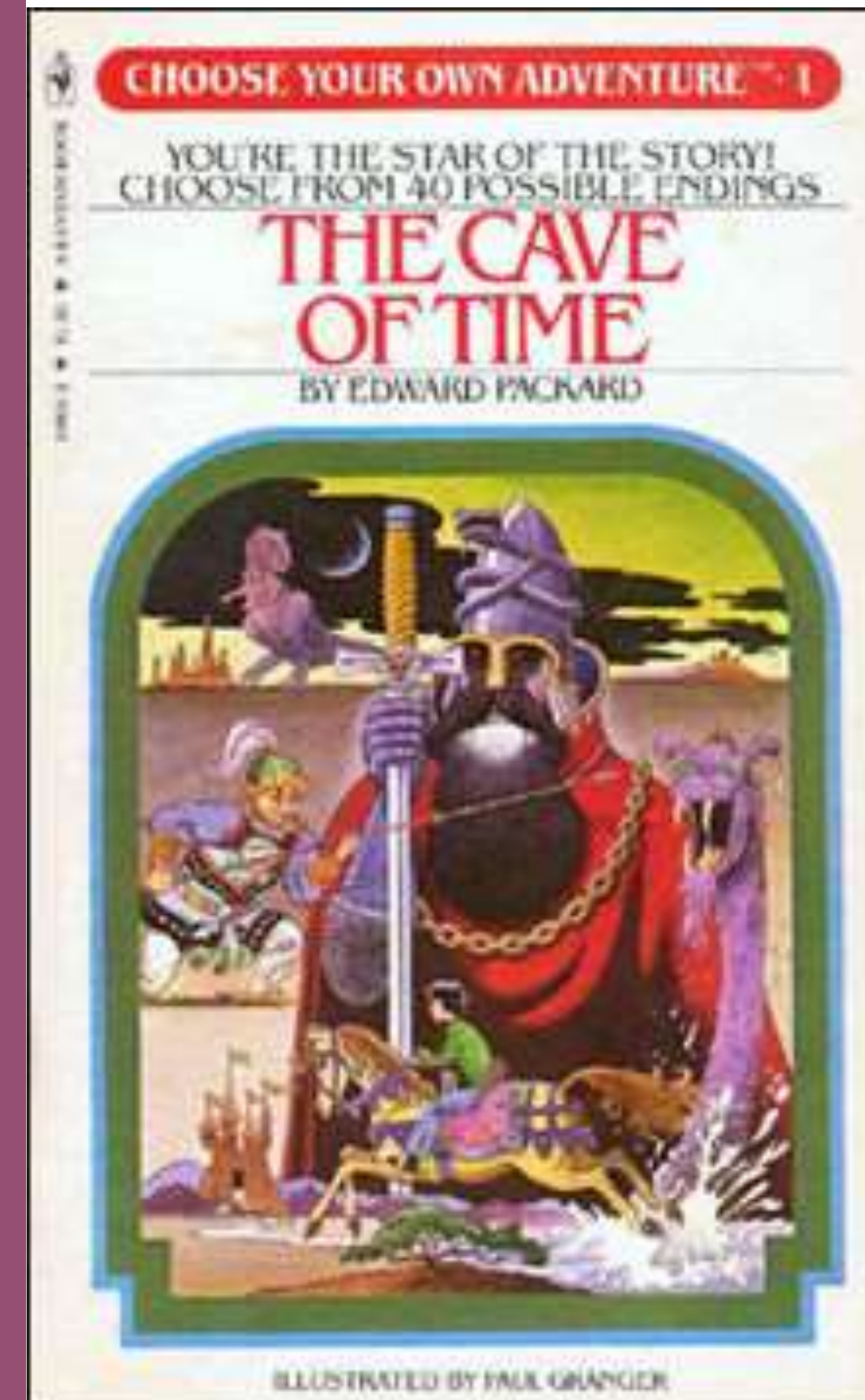
By @KubricksCube



# Next Generation Hybrid Trials

## *Trials with Choice*

## *Adapt to Patient Preferences & Journey*





# Path Forward for Research Sponsors

---

## Fit-For Portfolio Solutions



External  
Environment

Partner solutions  
Competitive intelligence  
Environmental risk  
Regulatory perspective



Internal  
Environment

Therapeutic areas  
Patient insights  
Geographic footprint  
Culture

x

## Build a Toolkit of Decentralized Methods...



...To Pair With Portfolio and Patient Needs



# Virtual Clinical Trials: Care from Anywhere

Alliance for Health Policy  
2020 Signature Series  
Voice of the Patient  
20 October 2020

Craig H Lipset  
@craiglipset