

The Rise of Decentralized Clinical Trials

Remote Patient Participation is a viable solution
EVEN for Complex Cardiovascular Clinical Trials.

Jodi J. Akin, MSN

Hawthorne

E F F E C T

Direct-to-patient clinical trial participation platform



Pre-COVID

80%

didn't finish on time

79%

critical missing data

50%

Missed or late visits over time

As a result:

- Fewer than 1 in 10 drugs ultimately make it to market
- Market introduction of cures are delayed
- 10% YOY increases in spend, passed on to the system/public
- Data validity and generalizability questioned
- Incongruities of health burden to population in clinical trials cost trillions

With decentralized model we expect:

- 25% accelerated enrollment timeline due to broader catchments
- 75%-95% improvement on missing data
- 90% retention improvement (patients stay in trial when they have HEROs)
- Close the gender/ethnicity gaps addressed (matching HEROs to communities)
- \$ millions in budgets reduced
- Numbers of trials on new molecules and therapies can increase

*est.

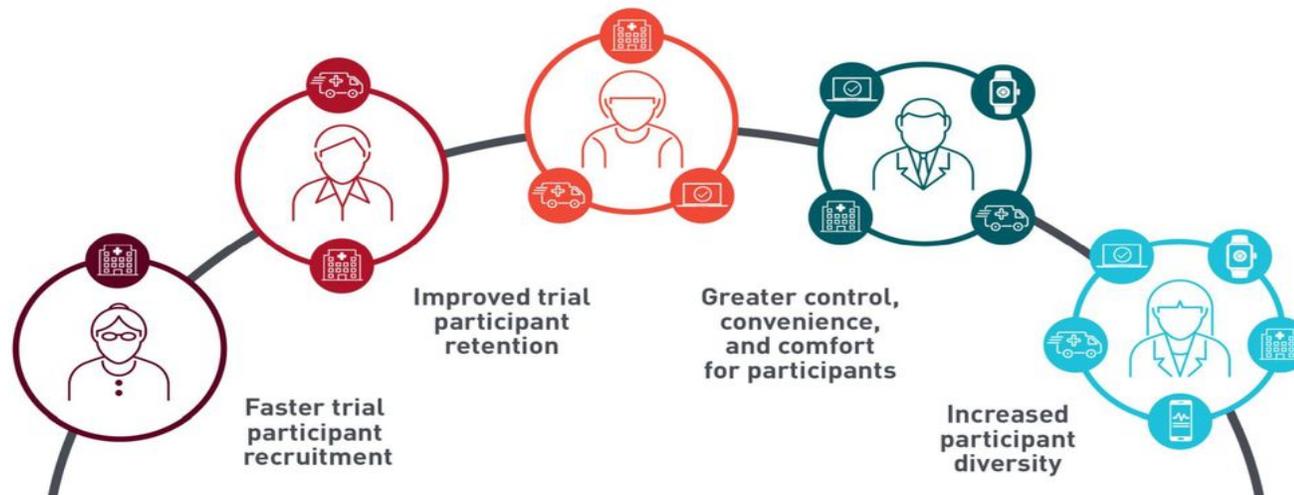


Decentralized Clinical Trial technologies have been on the horizon for years, but not generalized.

From Virtual

Virtual –
No patient
contact

Benefits of Using Decentralized Trials



Decentralized

- Fully Remote, data from wearables, telemedicine and other devices
- Fully decentralized – Data from telemedicine and Patient contact but not brick and mortar site
- Hybrid- Some visits at sites while other done at home or remotely



Many companies offer products that span across categories. To keep the map simple, the logo is in the "primary" product. Have an update? Share via www.ElektraLabs.org/decentralized-trials

Software-Enabled Clinical Trials

Design Protocol



Start-Up Study¹



Recruit Patients



Conduct Study

Manage Operations²



Drug & Supply Logistics



Collect and Analyze Patient-Level Data

Patient Data Management (e.g., EDC, eCOA, Digital Biomarkers)³



Decentralized Trials



⁰ Unlike the other for-profit ventures on this map, CTTI is a Public-Private partnership & AllTrials is a registered charity

¹ Includes startup tools like eConsent and site training

² Includes clinical trial management systems, risk-based monitoring, site monitoring, payment automation

³ Includes EDC (electronic data capture), informed consent, Imaging, Lab Data, Digital Biomarker Data and Validation, eCOA (Electronic Clinical Outcomes Assessment)

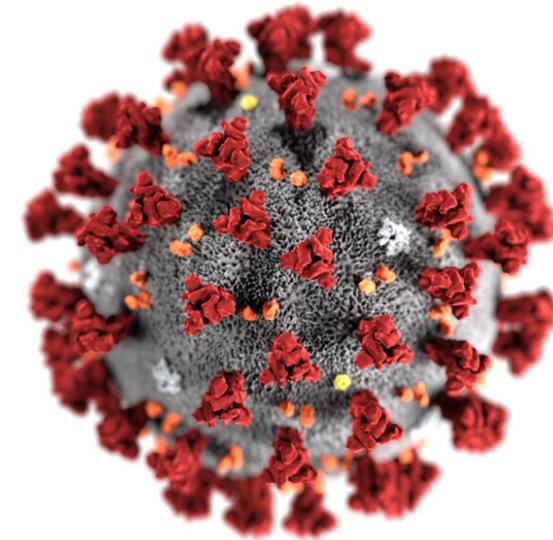
2018 by @AndreaCoravos



Then COVID-19 Happened

Amplified the Problem of Clinical Trial Continuity

1. Overall, there was a 70% decline in enrollment or new study starts post COVID, now recovering slowly and indeterminate loss to follow-up.
2. Due to local, state and institutional guidance, clinical trial follow-up was considered “non-essential” and essentially abandoned or relegated to phone or virtual visits for 90 days in most institutions.
3. The “decentralized” clinical trial movement has received a major boost with sentiment moving from reluctance to a mandate.
4. Health disparity has also been amplified in the COVID crisis.
5. Making trials accessible to patients in their homes is the ultimate expression of patient-centricity and should become a new standard of practice.



Elements of Decentralized Clinical Trials

From Pilot to MANDATE post COVID-19

Elements of decentralization	
Electronic data capture	The first frontier
Participant recruitment and screening	Internet, digital ads, EMR (AI)
Consent process	E-consent, remote consent honoring the code of conduct
Supply and drug management	Distribution models with chain of control and traceability
Adherence	Assuring compliance (drug trials)
Sites and site management	The meta-site, hybrid models
Subject engagement tools	PROM, prompts
Study management	Remote monitoring, safety oversight
Study visit management	Compliance, completeness, consistency, source documentation
Data acquisition and transfer	HIPAA, PHI security, Interoperability
Remote data monitoring	Not just via EMRs...



Considerations and Barriers to Adoption of Decentralized Clinical Trials

Barriers to change

- Complexity of assessments required for trial
- Quality and consistency of ascertainment
- Patient adoption of technology, virtual visits
- Perception of regulatory adoption
- Adoption by all stakeholders
- Seamless integration from site-based to decentralized
- Economics

Over-emphasis on technology solutions alone

- Do not address complex ascertainment
 - Physical
 - Biometrics
 - Imaging
 - Functional
- Patient affinity or accessibility to tech, internet, etc.
- Compliance in fact worse, not better
- Does not address the vulnerable populations, cultural considerations



Hawthorne Effect is a platform that offers **ACCESS** to clinical trials and **Quality Data**

Hawthorne Cloud

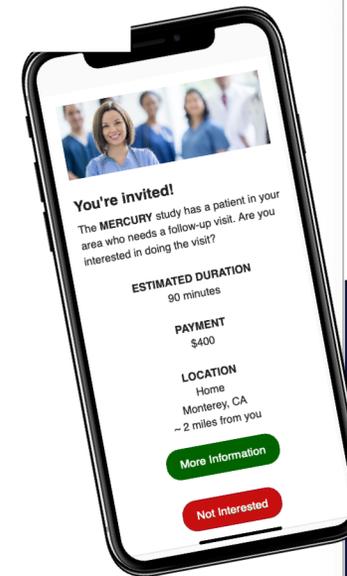
Scientific Precision



Hawthorne Hero™

Clinical Compassion

The screenshot displays the Hawthorne Cloud interface. At the top, there's a navigation menu with 'About', 'Table of Assessments', 'Subjects', 'Subjects Map', 'Visits', and 'Project Documents'. The main area features a 'Table of Assessments' grid with columns for '30 Day', '4 Month', '12 Month', '2 Year', '3 Year', '4 Year', '5 Year', '6 Year', and '7 Year'. The grid contains green and grey cells representing data points. Below the grid, there's a map showing the geographic distribution of subjects. On the right side, there are several circular callouts with icons and text, including 'Other III Protocol', 'About the Heart Biomarker Study', 'Ugura Woman UTI Protocol Training', 'Cardiac Sonography - TAUR Partner 2 & 3', 'PI Roles and Responsibilities', and 'Getting Started with the Hawthorne PI'. A central icon shows a laptop with a cloud and arrows, symbolizing data integration.



Martina Speight

HERO+

"Being a Hawthorne HERO has given me the unique opportunity to broaden my practice and connect with patients in a unique way. It is quite special to feel like a guest in a patient's home! When patients are comfortable in their environment, it makes for a more meaningful visit."

Background

Martina Kelly Speight, RN, MS, FNP-BC is a nurse practitioner in the field of surgical and interventional cardiovascular therapeutics. Martina received her BS in Nursing in 2001 from Dominican University of California and was accepted into one of two positions in the New Graduate Critical Care Training Program at Stanford University Medical Center. She worked as a critical care nurse in the Stanford cardiothoracic intensive care unit followed by the intensive care unit at the Queen's Medical Centre in Nottingham, UK. Martina took the role of research and clinical coordinator at Stanford University Medical Center in the Department of Cardiovascular Medicine in 2007. In this role, Martina coordinated various clinical research trials before turning her focus to the research in the area of transcatheter heart valve therapies. Martina is an integral part of the Stanford Heart Valve Team with respect to both patient care, research, and program development. She is a nationally recognized leader and sought after speaker in heart valve therapies. Martina received her MS in Nursing in 2012 from San Francisco State University and is board certified through the American Nurses Credentialing Center.



Digital Schedule of Visits

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About

Table of Assessments

Subjects

Subjects Map

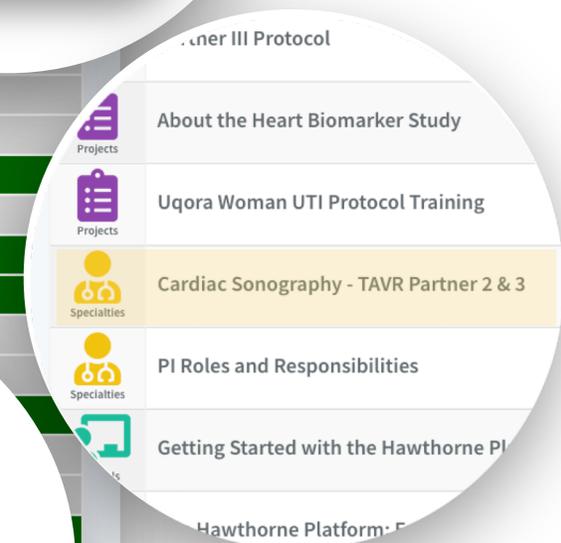
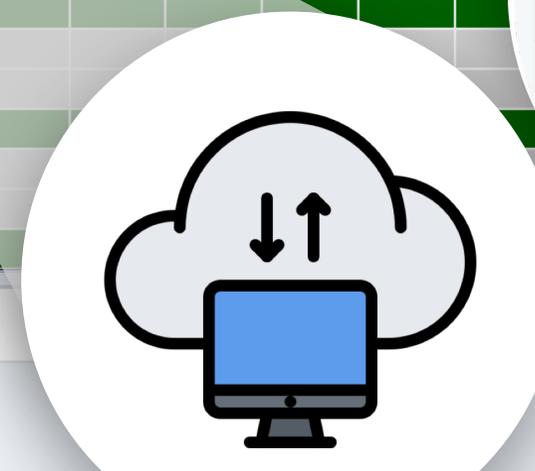
Visits

Project Documents

Table of Assessments

Assessments	30 Day	6 Month	12 Month	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year
Adverse Events	■	■	■	■	■	■	■	■	■
Medications	■	■	■	■	■	■	■	■	■
12-Lead ECG	■	■	■	■	■	■	■	■	■
Echocardiography (TTE)	■	■	■	■	■	■	■	■	■
Modified Rankin Scale	■	■	■	■	■	■	■	■	■
NIH Stroke Scale	■	■	■	■	■	■	■	■	■
MMSE (Mini-Mental)	■	■	■	■	■	■	■	■	■
NYHA Classification	■	■	■	■	■	■	■	■	■
6 Minute Walk Test (6MWT)	■	■	■	■	■	■	■	■	■
SF-36 (v2)	■	■	■	■	■	■	■	■	■
Physical Examination	■	■	■	■	■	■	■	■	■
CBC (w/diff and platelet count)	■	■	■	■	■	■	■	■	■
Creatinine	■	■	■	■	■	■	■	■	■
KCCQ	■	■	■	■	■	■	■	■	■
proBNP N-Terminal	■	■	■	■	■	■	■	■	■
EQ-5D-5L	■	■	■	■	■	■	■	■	■
Medical Records Release (Penn)	■	■	■	■	■	■	■	■	■

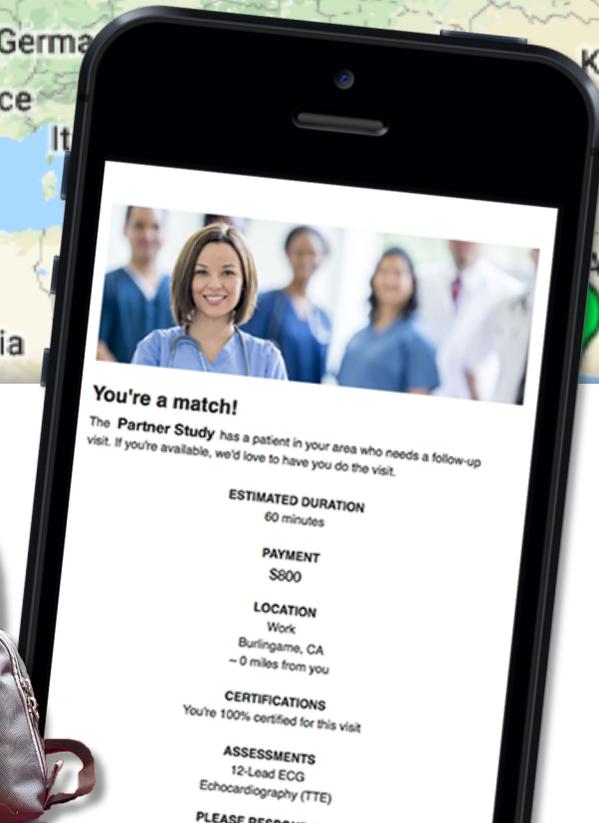
■ Not part of protocol ■ Hawthorne Effect ■ Other



Reaching patients anywhere, anytime. Physically, virtually, or both.



- 1900+ HEROs, covering all 50 states (EU early 2021)
- Vetted, credentialed, certified, insured, equipped
- Multi-specialties, skills, versatility
- Visits performed in rural and far reaches
- Ecosystem from HERO onboarding to patient follow-up and data in the cloud works through an integrated platform "HEHQ"



HEROs are equipped with cutting edge digital mobile tools for comprehensive visits



Meet Opal



- At 86, her heart was failing but she was full of life
- She enrolled in a breakthrough heart valve trial
- The trial required travel more than 1000 miles each way
- She would have to make **10 study visits**
- She was going to drop out

With decentralized follow-up, at 93 years old she continues her follow-up

- She has HEROs
- Her study data, echocardiogram, ECG, bloodwork and 10 clinical assessments were delivered to her investigators in the cloud via Hawthorne Effect's platform.
- Remote transfer of source docs, allows remote monitoring!



COVID Stakes are high for clinical trials: Saving The RHAPSODY Trial

- Sponsor: Kiniksa
- Phase 3 drug trial with critical dosing milestones
- COVID-19 halted follow-up
- Sample size- 86 patients
- Hawthorne completed 30 critical visits for 12 sites in 15 days
- One third of study sample would have been lost, costing a est. 6 months in trial time, possibly millions in trial budget



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Home / Projects / RHAPSODY - Mayo Clinic - PPDS - site 406

PROJECT

About the Study

Table of Assessments

Subjects

Subjects Map

Visits

Visit Matrix

Project Documents

Data Export

Project Setup

About the Study

KINIкса

Study: RHAPSODY
Sponsor: Kiniksa Pharmaceuticals
Sponsor Study Number: KPL-914-C002
NCT Number: NCT03737110

[LEARN MORE](#)

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Study Name
 PHASE 3, DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED WITHDRAWAL STUDY WITH OPEN-LABEL EXTENSION, TO ASSESS THE EFFICACY AND SAFETY OF RILONACEPT TREATMENT IN SUBJECTS WITH RECURRENT PERICARDITIS – Rilonacept inHibition of interleukin-1 Alpha and beta for recurrent Pericarditis: a pivotal Symptomatology and Outcomes stuDY

Short Name
 RHAPSODY

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Home / Projects

Projects

Study	Site/Organization
RHAPSODY	Virginia Commonwealth University - 402
RHAPSODY	Cardiology Consultants of Philadelphia - 404
RHAPSODY	Mayo Clinic - PPDS - 406
RHAPSODY	Arthritis and Rheumatology of Georgia - 407
RHAPSODY	Cincinnati Childrens Hospital Medical Center - 408
RHAPSODY	Minneapolis Heart Institute Foundation - 413
RHAPSODY	University of Vermont Medical Center - 414
RHAPSODY	Cleveland Clinic - 416
RHAPSODY	Intermountain Healthcare - 419
RHAPSODY	Loretto Hospital - 420
RHAPSODY	Cedars-Sinai Heart Institute - 423
RHAPSODY	Swedish Medical Center - 427



Pivotal Valve Trial

- Pivotal trial with critical complex visits including echo
- Vetted by clinical team and core lab
- Hawthorne Partnered with 50 clinical sites to share the study visits for the 6M, 18M and long-term follow-up
- Primary endpoint visits assigned to sites, but Hawthorne a safety net
- COVID-19- no disruption in continuity, including 30-day visits that would have been missed!

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Home / Projects / TRILUMINATE - University of Colorado

PROJECT

- About the Study
- Table of Assessments
- Subjects
- Subjects Map
- Visits
- Visit Matrix
- Project Documents
- Data Export
- Project Setup

About the Study

Study: TRILUMINATE
Sponsor: Abbott Vascular
Sponsor Study Number: CRD_946
NCT Number: NCT03227757

[LEARN MORE](#)

TRILUMINATE - University of Colorado

Study Title
Clinical Trial to Evaluate Cardiovascular Outcomes in Patients Treated with the Tricuspid Valve Repair System Pivotal

About the Trial
to demonstrate the safety and effectiveness of the TriClip™ device in improving clinical outcomes in symptomatic patients with severe TR, who are at intermediate or greater estimated risk for mortality with tricuspid valve surgery. This randomized controlled trial will compare the investigational device (TriClip™ device) to Control (Medical Therapy).

Study Objectives
to evaluate the safety and effectiveness of the TriClip™ device in improving clinical outcomes in symptomatic patients with severe tricuspid regurgitation (TR) who have been determined by the site's local heart team to be at intermediate or greater estimated risk for mortality with tricuspid valve surgery.

Primary Endpoint

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Clinical Study Manager

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Projects

Search: Triluminate

Study	Site/Organization	Site #
	USC University Hospital	
	University of Colorado Hospital	
	University of Virginia Medical Center	US0604
	North Shore University Hospital	US0086
	Palm Beach Garden Medical Center	US1752
	Advocate Health and Hospitals Corporation	
	Albany Medical Center	
	Allegheny General Hospital - ASRI	US0919
	Aurora Medical Group	
	Banner University Medical Center - Phoenix	
	Baylor Scott and White Heart and Vascular Hospital	US1414
	St. Vincent Hospital	
	University of Pittsburgh Medical Center	
	NY Presbyterian - Columbia University Medical Center	US4856
	New York University Hospital	US0035
	Morton Plant Valve Clinic	US4843
	Intermountain Medical Center	US2822
	Cleveland Clinic Foundation	US0146
	Brigham and Women's Hospital	
	Christ Hospital	US1228
	Baptist Hospital of Miami	US0710
	Hawthorne Effect	
	Cardiovascular Research Institute of Kansas	US4534



Patients Can Participate on their terms

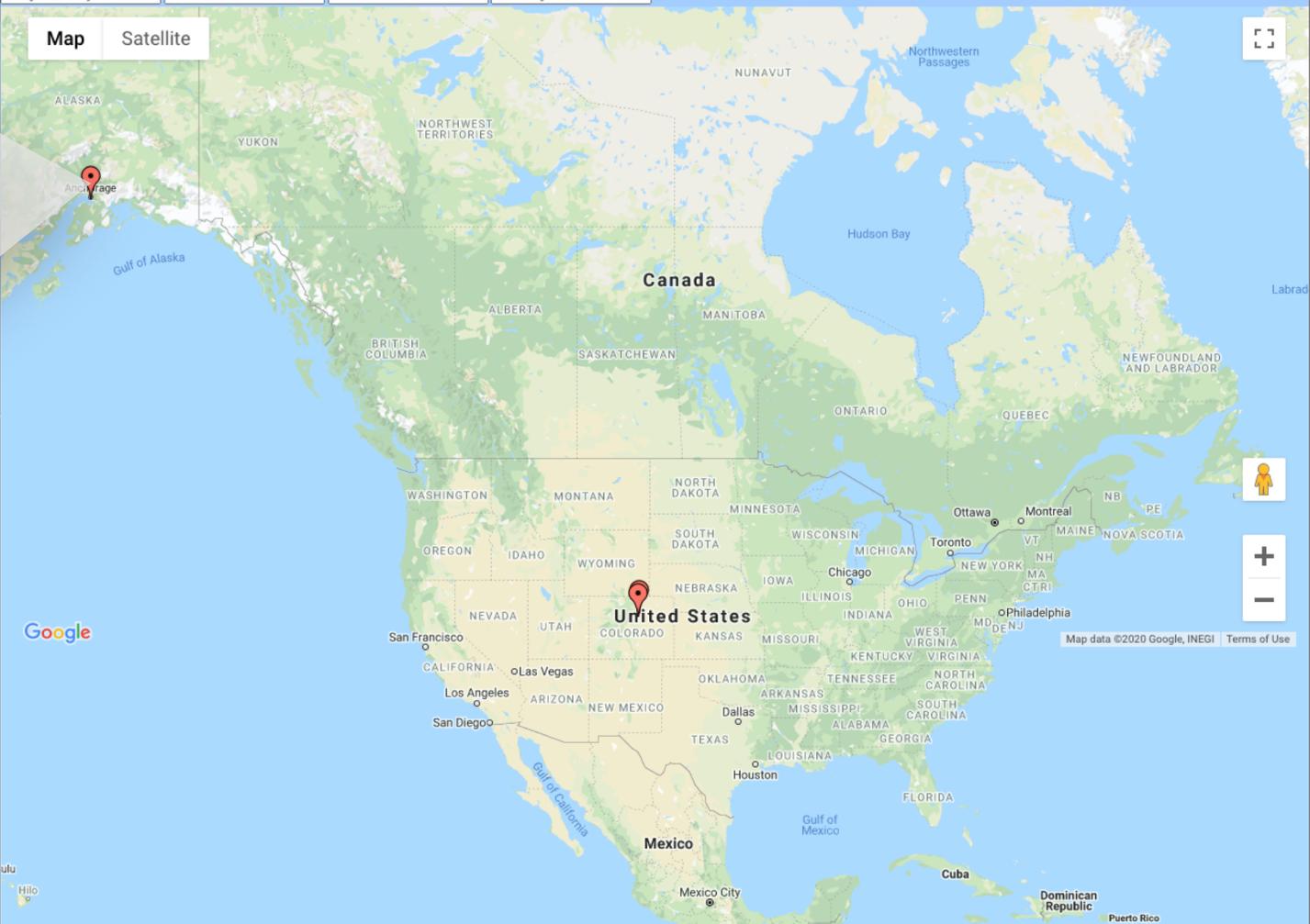


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PROJECT Subjects Only All Credentials All Roles All Subjects

Map Satellite

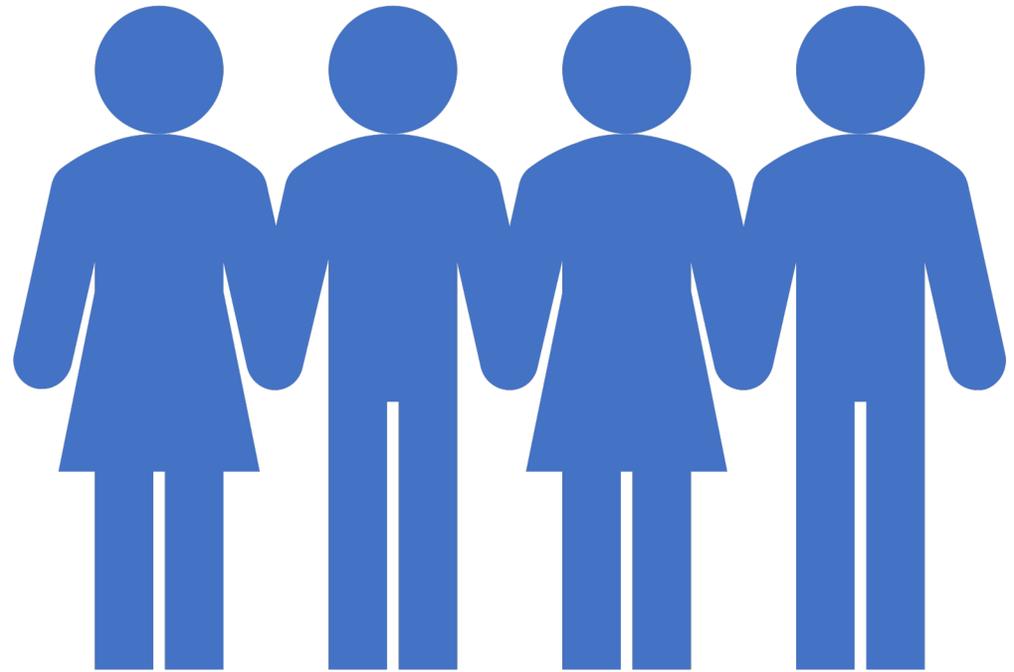


Google

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“The Profound
Influence of
Place” Dr. Clyde
Yancy



COVID-19 Accelerated E-Commerce Growth '4 To 6 Years'

John Koetsier Senior Contributor
Consumer Tech



Same for Decentralized Clinical Trials

**Make Clinical Trials Accessible and Convenient
for Everyone, Everywhere**

