A SCIENTIFIC KEYNOTE

Clinical Research in the Age of Technology & AI

From the Laboratory to the Community — and the New Science of Who We Study

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THE ARGUMENT IN SIX MOVEMENTS

Where we are going

I The Objective

What clinical research is for

II The Triumph

What the RCT achieved

III The Limitation

Where the engine breaks

IV The Opening

What technology & AI dissolve

V The Model

CBPCR & the community backbone

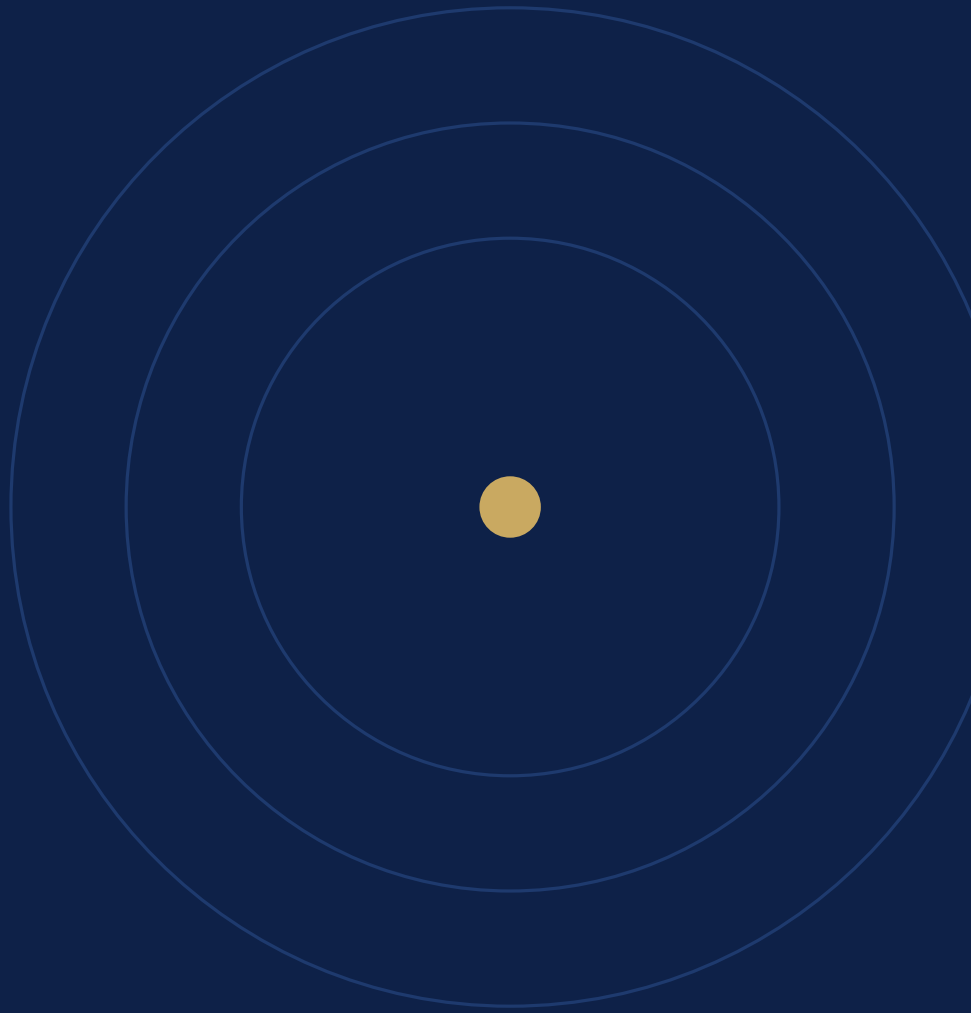
VI The Proof & Future

INSPIRE and the road ahead

I — THE OBJECTIVE

What is clinical research for?

First principles, before any critique.



Two purposes, often conflated

01

Does it work?

Internal validity — establishing whether an intervention produces a real effect under controlled conditions. The field has optimized this for a century.

02

For whom — in the real world?

External validity — establishing that the effect generalizes to the population we actually intend to treat. Historically neglected.

The entire critique that follows turns on this distinction.

Every trial is a chain of inference

The break is almost always at link 3: the sample does not represent the population we intend to treat. Internal validity survives; external validity collapses.

II — THE TRIUMPH

Honor what the trial achieved

Credibility requires celebrating the win first.

A 20th-century achievement — and a fragile one

The randomized controlled trial transformed medicine from authority to evidence. That triumph is real. It is also extraordinarily expensive and inefficient.

$1.5–2B

Estimated cost to bring a single drug to market

~1 in 10

Agents entering clinical testing that reach the market

$0.8–1.4B

Capital lost per failed late-stage program

Source: Harrer et al., Trends Pharmacol Sci 2019 [11]

Beneath every trial sits one assumption

> ***"The sample reflects the population."***

This assumption is frequently false. When it fails, the science is internally valid and externally useless.

III — THE LIMITATION

The engine is breaking

Structural, not individual. Stated with respect.

The keystone evidence: most patients can never enter

55.6%

of the time, a trial is simply UNAVAILABLE to the patient

>3 of 4

cancer patients cannot participate — structural & clinical barriers

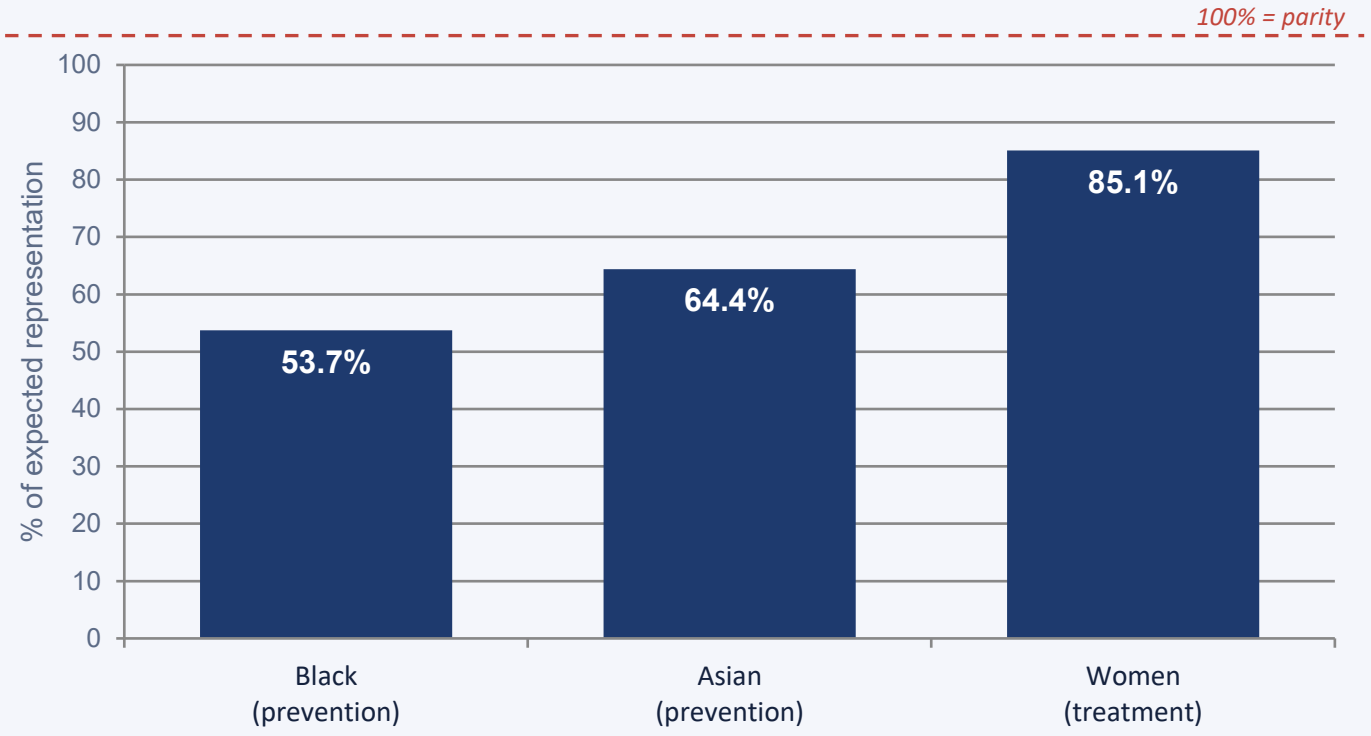
8.1%

ultimately enroll — fewer than 1 in 20 adults

These are not motivational failures. They are structural barriers built into where and how trials are run.

Unger et al., J Natl Cancer Inst 2019; Unger et al., ASCO Educ Book 2016 [1,2]

Who does enroll does not look like who is sick



And we often don't even look

12.8%

of hearing-loss trials reported race or ethnicity at all. You cannot fix what you refuse to measure.

Xiao et al., JAMA Intern Med 2023[3] · *Pittman et al., JAMA Otolaryngol HNS 2021*[4]

Sometimes recruitment is impossible by arithmetic

29,142

participants targeted across early COVID-19 trials

~1.25 million

additional infections would have been required to recruit against — the eligible pool could not support the design.

The compounding cost

Infeasible recruitment is not a delay — it is sunk capital. With up to $0.8–1.4B lost per failed late-stage program, recruitment design is a financial and ethical act, not a logistical afterthought.

Cunniffe & Coles, BMJ Open 2020[5] · *Harrer et al., 2019*[11]

Three failures, one root cause

Unavailable

Trials don’t exist where patients are

Unrepresentative

Those enrolled don’t match those who are sick

Infeasible

Targets exceed the reachable pool

Clinical research is built APART from the communities it intends to serve.

IV — THE OPENING

Technology dissolves the old constraints

Walking the research lifecycle, stage by stage.

The research lifecycle is our spine

At each stage: name the old limitation, then the new opening.

LIFECYCLE · STAGE 1

Connecting to the source

THE OLD LIMITATION

The clinic was the source

The 'source' was whoever physically walked into an academic medical center. That single door selected the sample before science ever began.

THE NEW OPENING

The community is the source

Phones, social platforms, faith networks, employers, and community institutions let us connect to people where they already are — before they are ever patients.

LIFECYCLE · STAGE 1

New channels reach who the clinic never saw

Personal devices

Continuous, in-pocket reach

Social platforms

Population-scale, low-cost contact

Community institutions

Trusted, embedded partners

Employers & systems

Whole-population denominators

The connective tissue for every stage downstream.

LIFECYCLE · STAGE 2

Recruitment

THE OLD LIMITATION

Expensive, slow, captive

Recruitment was bound to the clinic's catchment — costly, slow, geographically trapped, and biased toward the already-included.

THE NEW OPENING

Digital, referral, decentralized

Social and digital recruitment, community referral, and decentralized enrollment reach beyond the catchment — measurably cheaper and at least as fast.

The economics have already flipped

$19.47

median cost per participant via social-media recruitment

68.3%

of comparisons matched or beat traditional recruitment rates

55.6%

of studies found social recruitment more cost-effective

Systematic review of 176 studies. Recruitment is no longer bound to the clinic's walls — or its budget.

Sanchez et al., Compr Psychiatry 2020 [10]

LIFECYCLE · STAGE 3

Conducting the trial

THE OLD LIMITATION

Bring the participant to the trial

Site-centric conduct imposes travel, time off work, and burden — filtering out exactly the populations we most need to include.

THE NEW OPENING

Bring the trial to the participant

Decentralized trials address the core RCT limits — cost, time, recruitment failure, and lack of diversity — by meeting people where they live.

Berwanger & Machline-Carrion, Stroke 2022 [6]

LIFECYCLE · STAGE 3

Six dividends of decentralized conduct

Wider reach

Better retention

Lower burden

Faster accrual

Lower cost

More diversity

Weber & Nohr 2023; Ranganathan & Pramesh 2023; Berwanger 2022 [6,7,8]

LIFECYCLE · STAGE 3

From snapshots to streams

THE OLD LIMITATION

Episodic snapshots

A clinic visit every three months captures a few data points — and misses everything that happens in real life between visits.

THE NEW OPENING

Continuous physiologic streams

Wearables and home sensors generate validated, continuous, lower-burden endpoints from the participant's real-world environment.

LIFECYCLE · STAGE 3

Continuous data can be rigorous data

175

children monitored with home-based wearables

94%

compliance with the derived digital endpoints

33–110

per-group sample sizes the endpoints could power

Validated digital endpoints — continuous, real-world, and lower-burden — without sacrificing statistical power.

Kruizinga et al., PLoS One 2021 [9]

LIFECYCLE · STAGE 4

Stewarding the data

THE OLD LIMITATION

Extractive by default

Data is taken from communities and returned as nothing. The relationship ends at collection — and so does the trust.

THE NEW OPENING

Community-held asset

Data governance authority rests with the community. Stewardship, not extraction — the precondition for durable trust.

LIFECYCLE · STAGE 4

Who owns the data decides who is served

EXTRACTIVE MODEL

- Data flows out of the community
- Findings rarely return
- Communities are subjects
- Trust erodes with each study

COMMUNITY-OWNED MODEL

- Community holds governance authority
- Value returns continuously
- Communities are owners
- Trust compounds across studies

LIFECYCLE · STAGE 5

Analysis & dissemination

THE OLD LIMITATION

Single-site, slow to spread

Findings emerged from one institution and diffused slowly — limiting both statistical power and reach.

THE NEW OPENING

Federated, multi-site, fast

Multi-site and multi-country federated analysis is becoming the norm — raising the stakes for getting representation right upstream.

LIFECYCLE · CROSS-CUTTING

AI across the lifecycle — promise with guardrails

THE PROMISE

- Smarter trial design
- Targeted recruitment & retention
- EHR phenotyping at scale
- Faster, federated analysis

THE GUARDRAIL

AI trained on unrepresentative data amplifies the very inequities we are trying to fix. Representativeness upstream is the precondition for trustworthy AI downstream.

Harrer et al. 2019; Lu et al., BMJ Open 2024 [11,12]

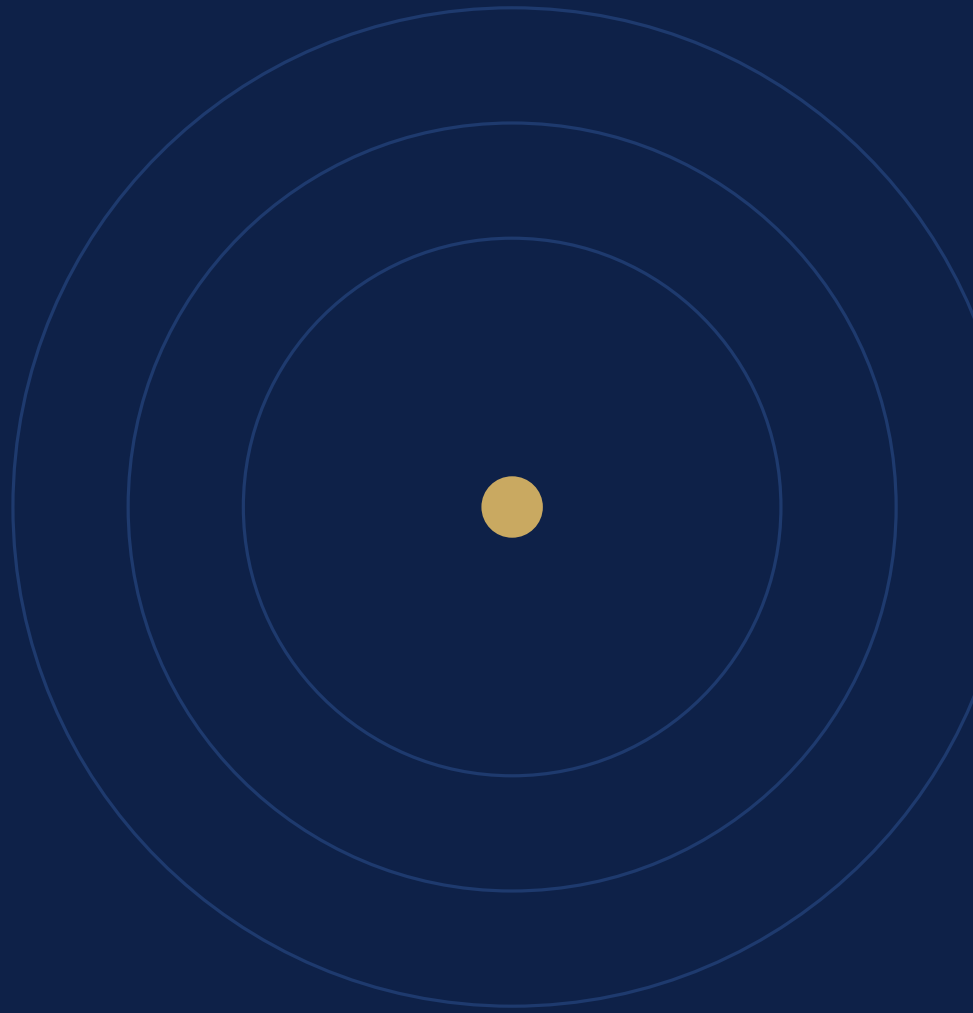
Technology is the enabler. It is not the answer.

The decisive question is who OWNS the research enterprise. If communities stay subjects, technology only makes extraction more efficient. If communities become owners, technology becomes the great equalizer.

V — THE MODEL

Community-Based Participatory Clinical Research

CBPCR — a field. CDU is one early site, not its container.



This is not new — it is proven, and now extended

~100

reviews of community-engaged scholarship synthesized in one health-equity meta-review

Ortiz et al., Annu Rev Public Health 2020[13]

CBPR's evidence base is mature

Community-Based Participatory Research has decades of evidence associating participatory principles with improved health-equity outcomes. CBPCR does one thing: it carries that rigor into the regulated clinical-trial context — Phase I–IV, FDA-registrable, GCP-compliant.

Three governing principles

1

Community before the laboratory

Discovery begins with the community, not the bench. The community is where the science lives.

2

Technology as the great equalizer

Used for ownership rather than extraction, technology closes the access gap instead of widening it.

3

Diversity as a scientific resource

Not a compliance checkbox — a direct source of external validity.

Inclusion is not charity. It is methodology.

A representative sample is a more valid sample.

Diversity serves the second purpose we defined at the very start — external validity. Recall link 3 of the chain of inference: representation is how the sample finally matches the population.

Participatory does not mean less rigorous

Regulatory phase	Full Phase I–IV
Registration	FDA-registrable endpoints
Conduct standard	GCP-compliant throughout
Governance	Community authority added, rigor retained

Community governance and methodological rigor are complementary — not competing.

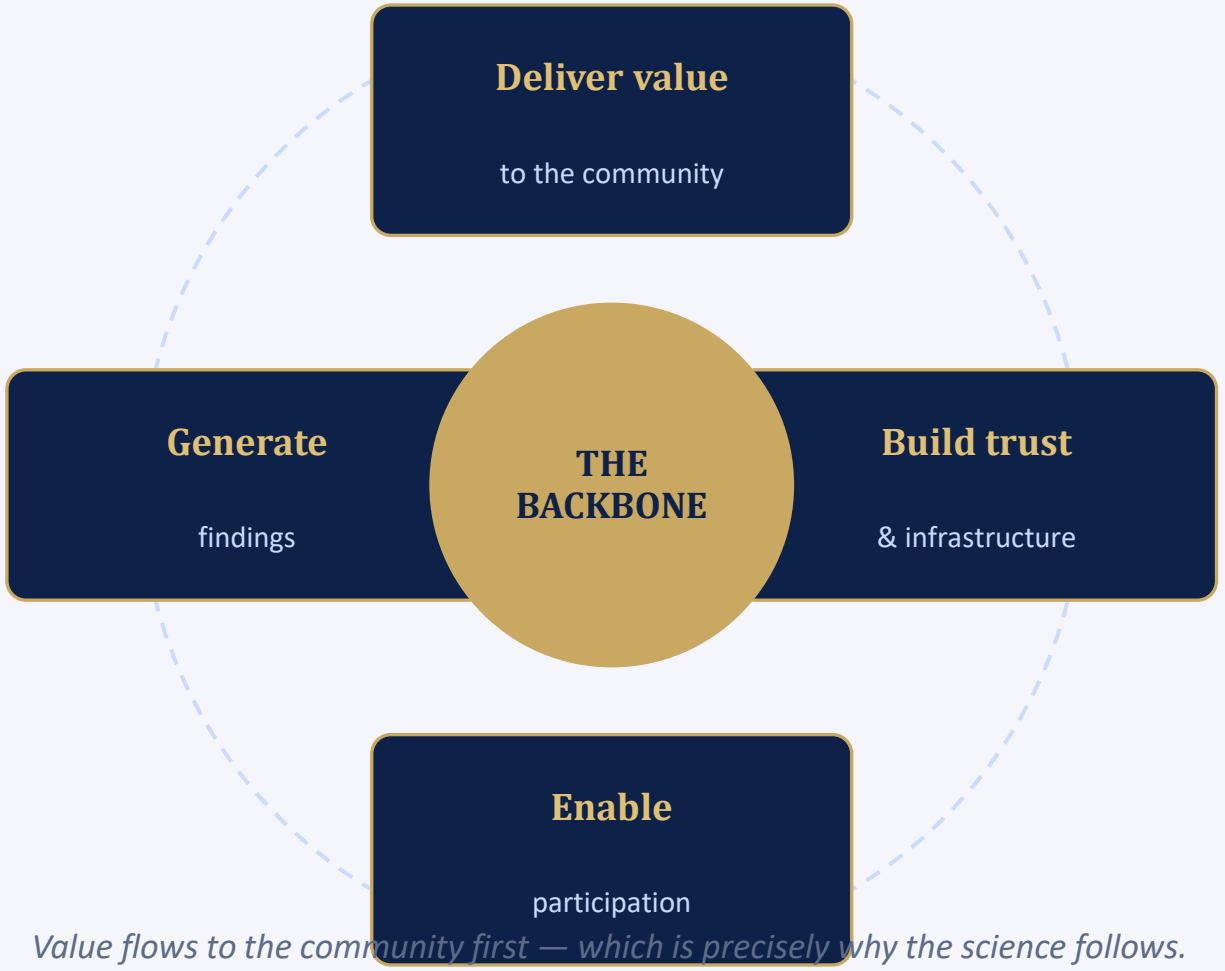
What makes it self-sustaining?

Imagine a continuous community lifestyle-health program — one that delivers real value to people every week.

As a byproduct, it builds:

- Research awareness in the community
- Access and trusted infrastructure
- Community ownership of the science

The backbone is a flywheel



Value flows to the community first — which is precisely why the science follows.

VI — THE PROOF & FUTURE

From principle to practice

The worked example — and where this goes.

THE BACKBONE, NAMED

INSPIRE

A community lifestyle-health program that doubles as research infrastructure. Real, recurring value to participants — and, as a byproduct, awareness, access, trust, and community ownership of the science.

INSPIRE Faith — deep & place-based

The partnership

Implemented with a faith-based community institution as a true partner — not a recruitment site. The community holds a seat in how the science is run.

The science

An enrolled cohort with paired baseline and follow-up measures — biomarker and cognitive data — collected through a community-embedded pipeline. Early, qualitative, and promising.

THE PROOF · WORKED EXAMPLE

INSPIRE California — broad & digital-first

The reach

A statewide, digital-first arm — IRB-approved and launching mid-2026 — designed to enroll across California without a single physical catchment.

The signal

Strong organic pre-enrollment accrued before any advertising — early evidence that a community-owned model can scale beyond a single site, and that demand is real.

THE PROOF · WORKED EXAMPLE

Two arms, one backbone

FAITH

Deep · place-based

Goes narrow and deep with a trusted local institution.

+

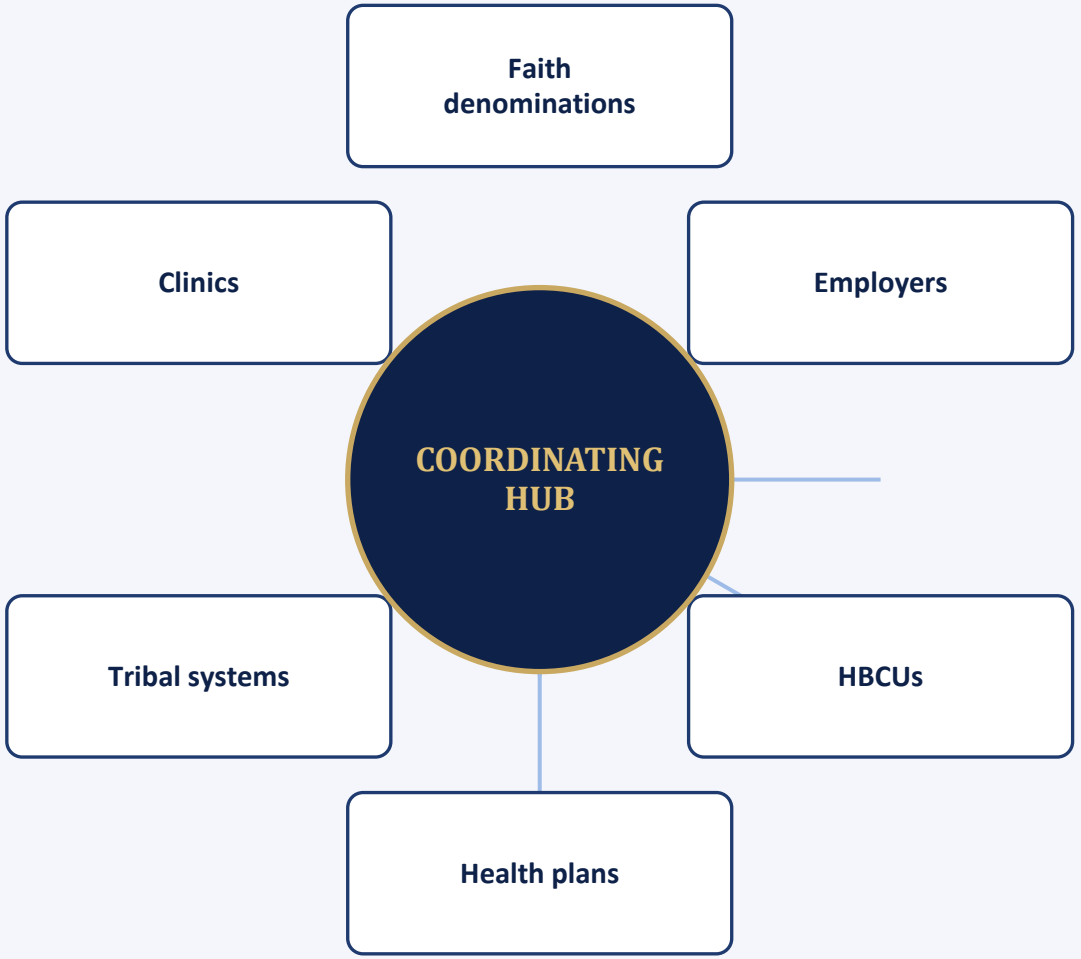
CALIFORNIA

Broad · digital-first

Goes wide and scalable across an entire state.

The same backbone proves it works both deep and wide.

INSPIRE Commons — a federated network



Community-owned nodes, one shared scientific infrastructure — scaling from founding nodes toward a national network.

Flagship trials the backbone enables

IMPACT-MIND

Cognitive health & Alzheimer's prevention

IMPACT-HEART

Cardiovascular & hypertension

IMPACT-DETECT

Cancer early detection

IMPACT-BLOOM

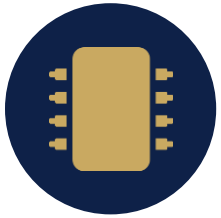
Maternal & child health

THE FUTURE · THE MOMENT

Why now — three forces converge

The old model's limits are undeniable

Unavailability, unrepresentativeness, and infeasible recruitment are documented, not debated.



Technology has dissolved the constraints

Decentralized conduct, digital endpoints, and population-scale recruitment are validated and available.

The science of engagement is mature

Decades of CBPR evidence give participatory clinical research a rigorous foundation.

The questions the field must answer together

- ? Governance — who holds decision authority, and how?
- ? Data ownership — what does community control mean operationally?
- ? Sustainability — how are backbone programs funded for the long term?
- ? Rigor at scale — can participatory methods hold across hundreds of nodes?
- ? Benefit-sharing — how does value return equitably to communities?

Intellectual humility is not a weakness in this argument — it is the credibility.

The broken link, repaired

When the community is the partner, the sample finally represents the population. Internal AND external validity — together.

THE THESIS

Community ownership of clinical research may be the most important innovation in healthcare research of our era.

Not a new molecule. A new relationship.

What we ask of the field

1. **Adopt participatory principles inside regulated trials**
2. **Build community-owned data governance**
3. **Invest in backbone programs that return value first**
4. **Share methods openly across institutions**
5. **Train the next generation in CBPCR**
6. **Hold representativeness as a validity standard**

An invitation, not a sermon.

THE FUTURE · THE PRACTICAL

What this changes, concretely

Where we recruit	From clinic catchment → community institutions & digital reach
Who governs data	From institution-only → community-held authority
How we measure	From episodic visits → continuous, validated digital endpoints
What 'diversity' means	From compliance checkbox → external-validity requirement
Who benefits first	From findings-out → value returns to the community continuously

None of this requires abandoning rigor. All of it requires changing the relationship.

Where Community Is the Science

The engine of clinical research runs best when the community is not the fuel — but the engineer.

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A NOTE ON METHOD

Every marquee statistic was verified

Verification standard. Each headline statistic in this talk was checked directly against its PubMed record — confirming author, year, journal, and identifier (PMID / DOI) — before it appeared on a slide.

Supporting claims. Statements not individually cited reflect the consensus of the literature above and are flagged for a full verification pass; sources are available on request.

Pre-publication data. INSPIRE results are presented qualitatively. No pre-publication figures are shown.

Let's build the field together

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