

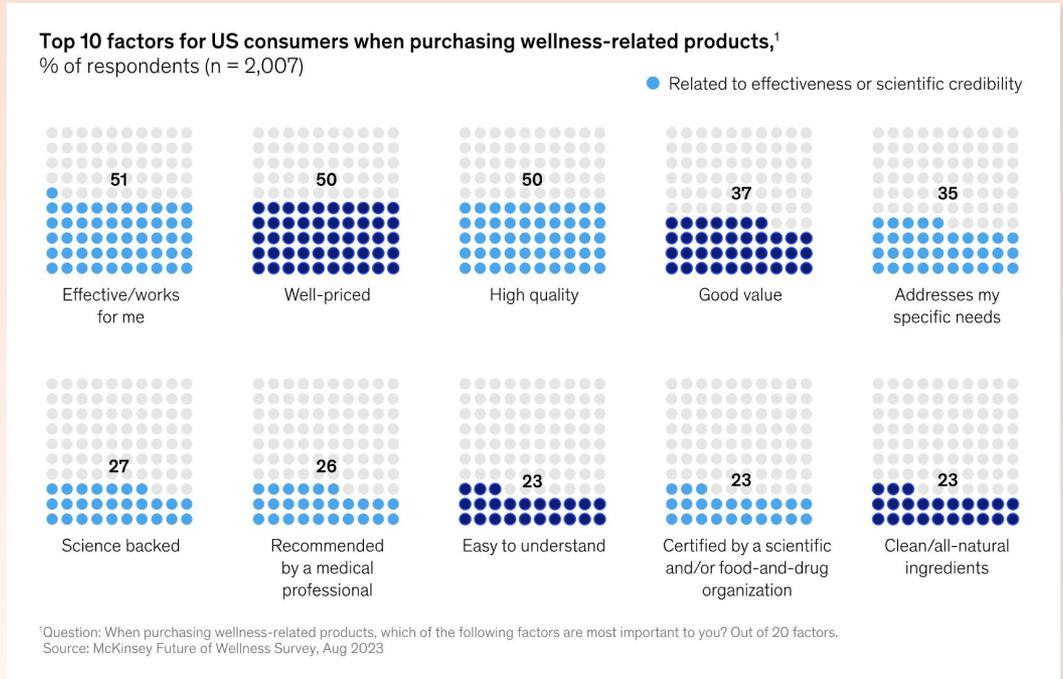
De-Risking Clinical Trials: A Smarter Path for Nutraceutical Innovation

Consumers Want Science-backed Brands

Efficacy & scientific credibility are the two most important factors to consumers.

Consumers want evidence:

- From "What supplements are trending?" to "What do I really need?"
- Consumers expect QR code-linked clinical data for "clinically substantiated" claims



The Evidence Chasm: 70% Unsubstantiated Products

A fragmented research process makes RCTs slow, risky, and costly.

Using Existing Literature

- Lack of differentiation from competitors
- WFM and Costco moving towards DCT requirements

The Evidence Chasm

Ingredients and brands with no existing literature nor RCT

Gold Standard RCT

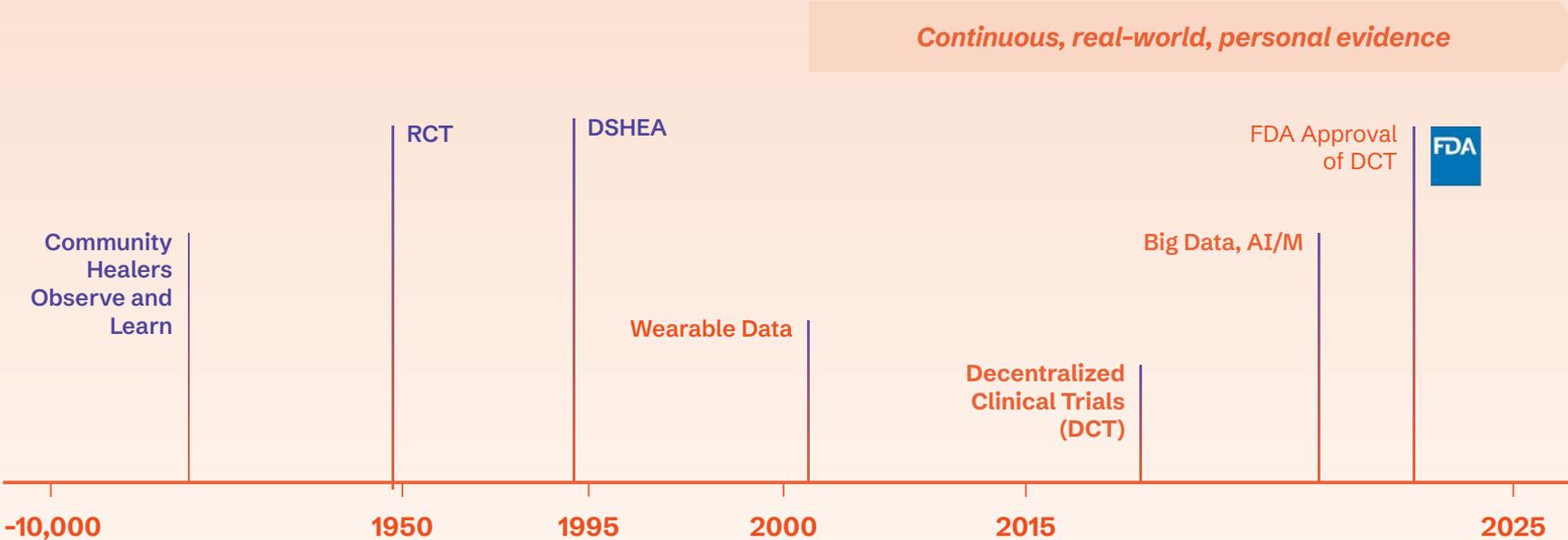
- Very expensive
- Slow-moving
- Lacking diversity

We are in the age of technology & data

What if new technology existed to allow for **accessible, consumer-centered evidence** at the **product level**?

The Shift: New Technology is Making Data Affordable

Continuous data generates insights, guides RCTs, and personalizes evidence.



Decentralized Clinical Trials (DCTs)

Science that meets people where they are.

What: Remote studies collecting real-world continuous data

How: using digital tools, wearables, and at-home consumer-grade biosampling kits

Outcome: build differentiated, personalized, and credible evidence

Traditional in-clinic Trials	Decentralized Trials
Observation in clinic	Real world
Only real time when in clinic	Real time monitoring
Restricted population size	Broader, scalable population
Limited diversity	More diverse
Higher dropout	Higher retention
Expensive (staff, clinics,...)	More affordable
Slower	Faster (especially recruitment)
Less data, manual collection	More data collected more often

DCTs Meet Regulatory Standards, If Done Right

Rigorous DCTs meet FDA/FTC standards for substantiating claims.

DCTs have challenges.

Technology barrier: participants need internet/app

Data standardization: consistent sample collection and protocol adherence

Regulatory Compliance: HIPAA compliant, medical oversight, adverse events monitoring

Shipping & sample collection logistics

Poor accountability

But high rigor *is* possible.

Well designed user-friendly apps & tech support

Standardize wearable data, use bigger study groups

Build HIPAA/GDPR compliant & de-identified data handling with audit trails, eConsent, remote safety monitoring

Use commercial grade FDA-approved at-home biosampling

Triggered digital check-in touchpoints

Build Evidence at Every Stage of the Product Life Cycle

Faster, leaner, and richer evidence creation to refine formulation, derisk RCTs and personalize customers' experiences.

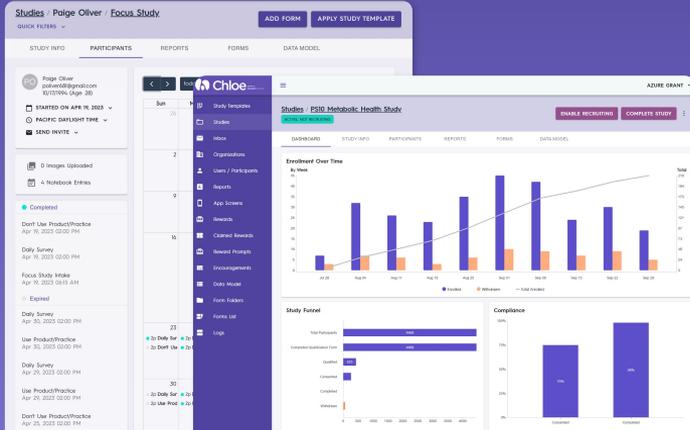


Meet Chloe:

Research Made Simple, Rigorous & Affordable.

THE PLATFORM

Combining data management and patient engagement functionality, Chloe operationalizes studies from recruitment to data analysis.



THE APP

Study participants have a mobile app on their smartphone and communicate directly with the study team. Study results can easily be shared.



Streamline operations— everything you need in one place for ease.



Integrate wearable tech for passive/ active data collection



Randomize participants according to your protocol



Select tasks/surveys from a library or create custom tools



Invite participants into Chloe by custom text or email



Communicate in-app with individuals



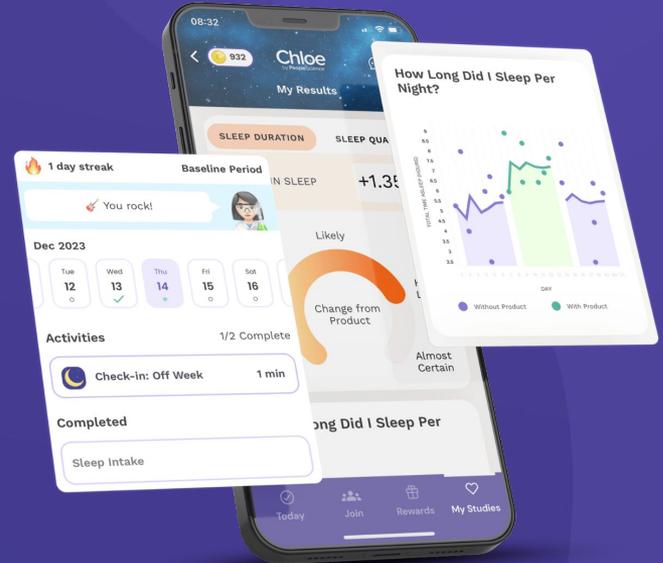
Build eConsents and eligibility/ enrollment logic



Automate study event and message notifications and reminders

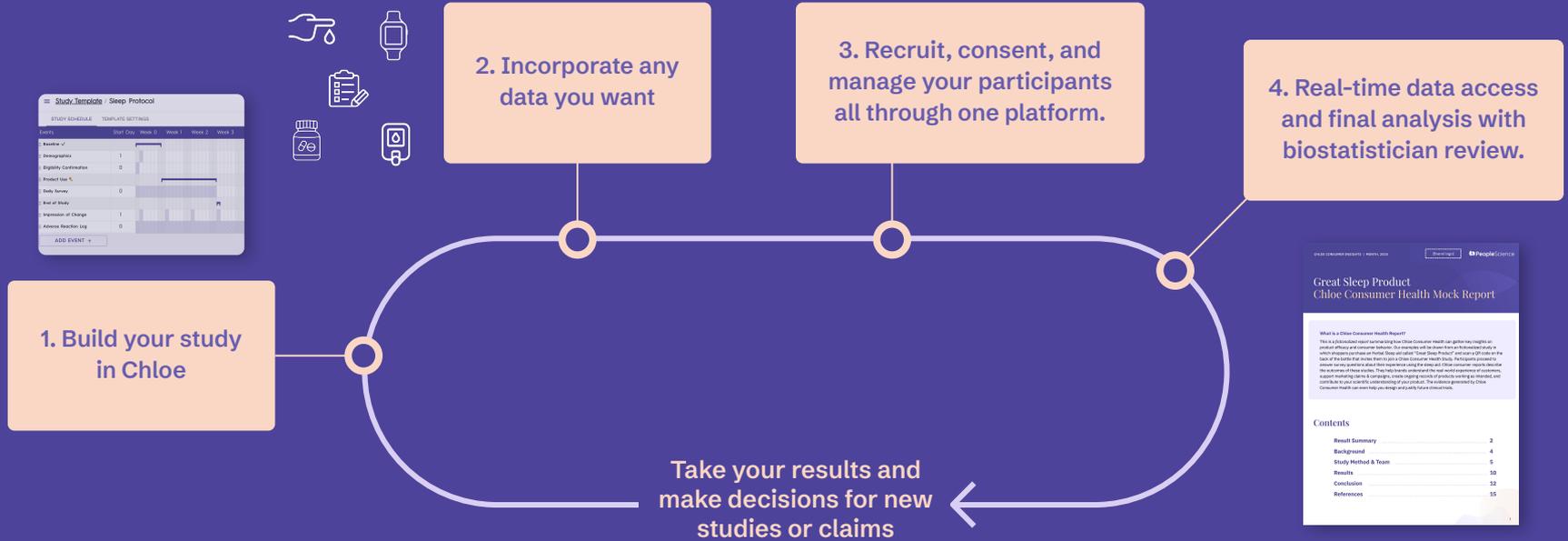


Pull compliance data into custom reports for analysis or visualize using dashboards



From Study Conception to Analysis

Collect all the data that you need to iterate and make the best decisions for your consumers and your brand.



CASE STUDY - Exploratory Research

Validating Multi-nutrient Effects in Real-World Women's Health Use

FullWell

“

XX

”

STUDY DETAILS

Goal: To generate comparable data on the impact of various FullWell supplements across different people and products, including tolerability, adherence, and impact on specific health factors.

Participants: Up to 500 volunteers will participate, selecting the FullWell products they have purchased.

Setting: Open-label, observational evaluation of real-world women.

Timeline: A 3-day baseline period, followed by a 12-week product use period, and up to a 4-day end-of-study experience period.

Methods: xxx

OUTCOMES

- **Highlighting their commitment to science with their customers**
- **Building data to validate RCT choices for next year**



CASE STUDY - RCT

Peer Reviewed RCT: GABA Probiotic Lp815 for Symptoms of Stress



“

Our trial with People Science was a clear success and allowed us to make the key business decision to pursue both mood and now potentially the sleep market. They offered essential guidance. The experience and critical thinking of the scientists and staff were invaluable for this trial.

”

STUDY DETAILS

Goal: Clinically evaluate the impact of two doses of LP815 probiotic versus a placebo on symptoms of stress to drive product development and claims.

Participants: 83 participants, 63% female, recruited in 10 days.

Setting: Double-blind, placebo-controlled, randomized, decentralized trial approved by the IRB.

Timeline: Participants collected 1 week of baseline data followed by 6 weeks of product or placebo use. Participants could opt into an Open Label Extension.

Methods: Non-parametric statistics (Holm's and Dunn's corrected Kruskal-Wallis) and Mann-Kendall tests

OUTCOMES

- **Peer-reviewed publication in Beneficial Microbes**
- **$p=0.04$ Reduced Feelings of Irritability and Annoyance**
- **88% completion, 91% compliance**
- **Participants Education:** All participants received personalized in-app results at the end of the study, as well as first access to the overall study results



CASE STUDY - Consumer Perception

The Future of Gut Health Innovation: Empowering Consumer-Driven Tracking



“

XX

”

STUDY DETAILS

Goal: xxx.

Participants: xxx).

Setting: xxx.

Timeline: xxx.

Methods: xxx

OUTCOMES

→ xxx



Elevating Evidence: Beyond Sales to Systems Change

The Next Frontier: Building evidence for collective impact across communities

Societal - Population based studies

MAJOR HEALTH SYSTEM

Implementation Research

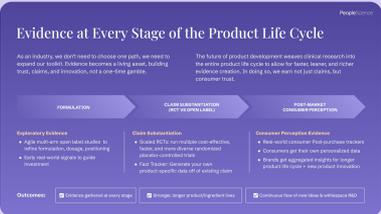
PEER SUPPORT GROUPS

Symptom Trackers

Business-Consumer based studies



Policy Changes



Community Education

CASE STUDY - PARTICIPATORY RESEARCH

Classroom Experiments in a School of Herbalism On Skullcap

“

This experience empowered our students and clinical herbalists to participate in and design studies, deeply aligning with our mission to bring forth evidence-based knowledge about herbal medicines that can create a positive impact in people's lives.

”

STUDY DETAILS

Goal: Teach herbalism students about clinical research while evaluating **Herb Pharm** Skullcap glycerite on stress, anxiety, sleep, mood, digestion, and pain.

Participants: 18 third-year clinical herbalism students (mean age ~42; ~94% female).

Setting: Land of Verse School of Clinical Herbal Medicine; classroom-based, participatory model.

Timeline: 1 week intake, 1 week baseline, 1 week skullcap usage.

Methods: Open-label AB design; GAD-7 for anxiety, PSS for stress; daily subjective metrics. Non-parametric (Mann-Whitney U) statistical tests.

OUTCOMES

- **Stress (PSS):** Significant drop ($p=0.03$) after one week.
- **Overall benefit felt by students:** 87% felt better overall.
- **Usability & satisfaction:** Study experience scored 8.8/10
- **Expanding knowledge:** educational tool reinforcing learning through doing



The Future of Evidence: Rigorous, Decentralized, Consumer-Centered Science to Benefit All

The future belongs to brands that make science alive, open, and personal—bridging herbal wisdom with modern evidence.

- **Research as a living process:** Continuous, scalable, and accessible at every stage.
- **Science built in:** Decentralized platforms embed evidence throughout development, accelerating consumer-focused health insights.
- **Transparency that empowers:** Open data turns consumers into partners, fostering trust and collaboration.

Can the newest technology enable
evidence-building for our most traditional
healing method: plants?

*Building Better Products.
Creating Better Health.
For All.*

Thank you!

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