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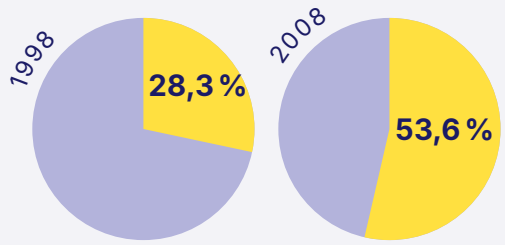
The Clinical Trial Abundance Movement

What Is Clinical Trial Abundance?

The Problem

The costs of generating human biomedical data have exploded over the last half-century. From the 1980s to the 1990s, the cost of clinical trials increased five times faster than the cost of preclinical research. Whereas trials accounted for 28.3% of R&D costs in 1998, by 2008 their share had grown to 53.6%.



Trial cost share of R&D costs.

The Goal

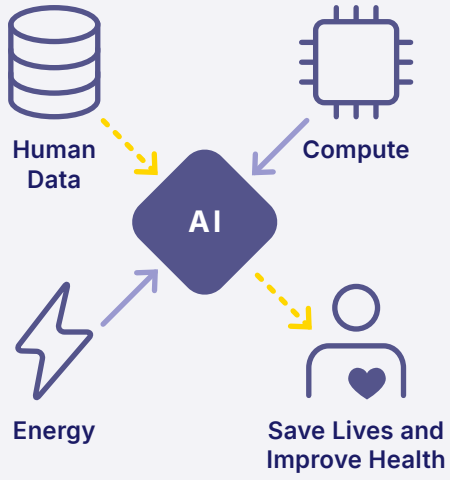
Build a movement toward cheaper, higher-quality human data to enable prevention, diagnosis, and cure diseases.

The Target

In ten years, 10× the valuable human subject evidence at 1/10th the current average cost.

The Thesis

In an AI boom, the three scarce inputs to progress will be data, energy, and compute. Unless the trend of greater data costs can be dramatically reversed, the human data bottleneck will strangle AI's capacity to save lives and improve health.



The Vision

A golden age of progress on par with the mid-20th century, when innovations like antibiotics, radiography, and modern surgical techniques transformed medicine.

Synopsis

This document lays out: (1) the substantive changes needed to achieve the target, (2) the policy and cultural vehicles towards achieving those changes, (3) a movement-building plan to influence those vehicles, and (4) three axes of advance for an advocacy campaign to prioritize.

1	**What Changes Are Needed?**	3
	1.1 Clinical Trials – Faster, Cheaper, Better	3
	1.2 Data Volunteerism	4
	1.3 Real-World Evidence	5
2	**Vehicles for Achieving Changes**	6
	2.1 Vehicles for Changing Policy	6
	2.2 Vehicles for Changing Expectations and Culture	7
3	**How to Get There: Advocacy Mechanisms and Key Priorities**	9
	3.1 Advocacy Mechanisms	9
4	**Key Axes of Advance**	9
	4.1 Policy Advocacy	9
	4.2 Pioneer Technology Campaigns	9
	4.3 Data Volunteerism	9

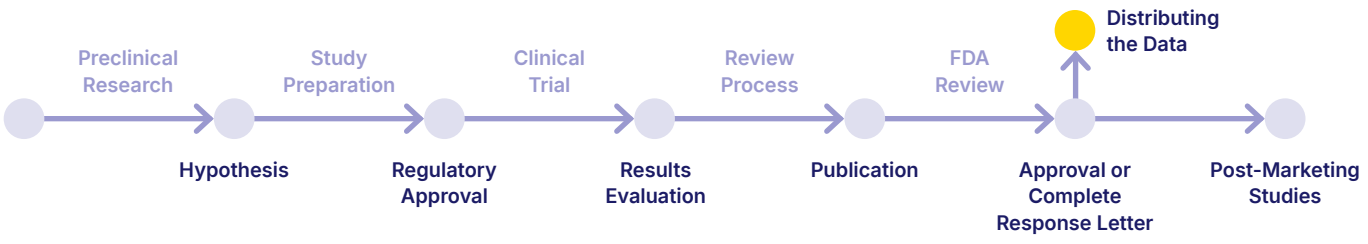
1 What Changes Are Needed?

1.1 Clinical Trials – Faster, Cheaper, Better

The prohibitive cost and protracted timeline of entering the clinic lengthen the feedback loop between developing a hypothesis in the lab and testing it in humans. Since scientific results compound, this prolongs the time and resources needed to make progress, putting many goals out of reach. Driving down costs, accelerating speed, and improving data sharing compress the discovery cycle, unlocking avenues for advancement.

- **First-in-Human Data:** Lower the cost of entering the clinic by (a) reforming regulatory processes such as Institutional Review Board (IRB) and FDA review, (b) reducing regulatory barriers by modifying Good Clinical Practice and Good Manufacturing Practice requirements for the early clinical stage, (c) empowering research volunteers in low- and middle-income countries to participate in studies, (d) reducing requirements to do animal studies, (e) instating expedited trial designs for platform technologies validated as low safety risk, and (f) improving safety predictions in silico.
- **Better Data Sharing:** Share discoveries more quickly and more broadly by reducing lags in data dissemination, automating clinical trial reports, and conditioning better and faster FDA review on sponsor data-sharing commitments.
- **Reduce Trial Costs:** Lower the expense of running trials by (a) reducing recruitment costs by improving ClinicalTrials.gov and other matching tools, (b) expanding the use of human challenge studies to generate early-stage data more quickly and affordably, and (c) streamlining operations through incentivizing increased adoption of risk-based monitoring and simplified regulatory requirements.
- **Platform Trials:** Build rolling platform trials that test a range of products and interventions for the same patient population. This reduces cost and time by lowering study launch costs and achieving economies of scale across multiple sponsors and academic teams.
- **Decentralized Telehealth Trials:** Advance current guidance and remote-visit allowances from the FDA to allow fully decentralized trials using telehealth platforms. This model could dramatically cut costs by reducing dependence on academic medical centers as trial sites and simplifying large enrollment at scale.

Current Process



1.2 Data Volunteerism

Just as the decreased cost of intelligence from AI will increase the societal value of data, it also increases the value of data to individuals. If everyone has the equivalent of a medical student on their phone, at first wellness hobbyists and then the general public will want to use wearables, access their medical records, and participate in studies to understand and improve their health. Facilitating and incentivizing the sharing of this data with researchers can create immense scientific value.

Hobbyists: People who work out and prioritize health optimization have a natural incentive to track their progress. Parents, effective altruists, and longevity enthusiasts may also be good groups to mobilize. During COVID-19, for example, the "RaDVaC" project's team members voluntarily self-administered their own peptide vaccine prototype. 1Day Sooner similarly emerged during the pandemic to advocate for volunteers interested in human challenge trials.

Patient Communities: Historically, patients have not received their personal health data or been informed about trial results after the study has concluded. Biopharma is beginning to explore how to return meaningful individual data to empower patients to make more informed decisions for their personal care. Patient advocacy groups and disease-specific associations are encouraging patients to share their data to advance medical research for their conditions (e.g., Inspire and patientslikeme).

Medical Research Subjects: Jill Fisher has written about the sociology of professional research subjects. If data collected about those individuals across multiple studies could be shared, they could be a particularly interesting patient population.

Making this likely secular trend towards medical hobbyism socially productive requires improvements in: 1. turning an individual's medical data into helpful predictions and guidance for that individual and 2. facilitating sharing that data with scientists. Without 1. data can increase people's anxiety about health or their commercial activity without making them healthier, without 2. data collection can benefit individuals without benefits accruing to society at large.

Turning people's private desire to collect and use their own data into a socially beneficial sharing of data that the government can use will require innovation. People would ideally begin to see data sharing as a virtuous and esteemed act, and the creation of new data platforms would make sharing easy and potentially lucrative. Enshrining an effective right to data portability would allow people to easily access and share their own data from studies, government datasets, and medical records.

1.3 Real-World Evidence

As more health data is generated outside traditional clinical trials, its value depends on how effectively it can be incorporated into regulatory and reimbursement pathways. Properly integrated, real-world evidence can shorten feedback loops between clinical practice and policy, improve prediction of clinical trial and real world outcomes, accelerate patient access to therapies, and provide a more representative picture of safety and effectiveness across populations. Standardization, governance, and translation pipelines need to be established as data generation accelerates, so that human data becomes evidence for regulators, clinicians, and patients. Some ways to accomplish this are:

- **Government Dataset Accessibility:** Data that governments already collect can be made useful by creating a standard pathway for researchers to access anonymous health data, and allowing data integration from various government sources to enrich basic health data.
- **Data Portability:** Providing people the right and ability to access, download, and host the data generated about them in medical records, government files, and research studies will help proliferate health data by freeing it from existing gatekeepers.
- **Electronic Health Record Integration:** Researchers can gain a more detailed understanding of health records through a standardized form that collates EHR data, making the data easier to use while maintaining strict privacy protections.
- **Data Ethics Guardrails:** Treats participants as data owners with a default right to access, portability, revocation, and notification of secondary uses consistent with consent. Engage with patient and investigator groups (ex. clinical research advocacy organizations like ACRO) to prioritize and integrate needs for data storage, governance, and protection modes to minimize aversion.
- **Improved Post-Market Surveillance:** Aligning regulatory approval more closely to real-world outcomes can bridge the gap between clinical trial performance and everyday effectiveness. By embedding continuous evidence collection into reimbursement and coverage decisions, policymakers can ensure that therapies are rewarded in proportion to the value they deliver in practice. This approach lowers patient and payer risk, while creating strong incentives for developers to generate reliable, real-world data.
- **FDA Predictive Transparency:** To improve public trust, the FDA should maintain a simple and legible digital readout for each product it approves, including both evidence of its efficacy and safety to date, as well as a prediction of its effects in the population. After a drug has been approved, evidence of its real-world effects should update this readout in real-time, along with updates to the predicted effect and tracking of the prediction's accuracy.

2 Vehicles for Achieving Changes

2.1 Vehicles for Changing Policy

Regulatory Rulemaking

There are several regulatory reforms that could help make clinical trials faster and cheaper: (1) The FDA's Good Clinical Practice (GCP) regulations could be streamlined to expedite trials while maintaining safety: (2) IRBs are unnecessarily burdensome and could be improved via regulatory change. (3) Full Good Manufacturing Practices (GMP) requirements for Phase 1 trials add millions in costs and years-long delays, despite brief drug exposure, while other countries safely conduct such trials with relaxed standards. Congress could exempt early-stage research from full GMP compliance. (4) The Platform Technology Designation Program needs clearer guidance and stronger incentives to fulfill its promise of accelerating medical countermeasure development.

Prescription Drug User Fee Act (PDUFA)

The PDUFA is legislation that sets the terms for the FDA to charge user fees for drug review submissions. (User fees fund about half the FDA's budget). It comes up for renewal in 2027 and offers an attractive legislative vehicle for policy reform. For example, it could be a good way to require data sharing (or incentivize data sharing in exchange for faster review) or to strengthen post-market surveillance requirements.

Open Data Plan

HHS recently announced an Open Data Plan and has committed to update it by December 1, 2025 (though this timeline will likely slip due to the government shutdown). Currently, the plan is lacking in important details, particularly in integrating HHS data with other agencies and ensuring consistency in access policies for outside researchers. This creates an advocacy opening to directly pitch those policies to the relevant decision-makers and direct attention to these priorities from the wider administration.

National Priority Vouchers

National priority vouchers are a new program recently announced by former FDA Commissioner Marty Makary. Inspired by priority review vouchers, they would speed up FDA review for a priority subset of products (with an intention to accelerate the FDA response time for a New Drug Application from ten months to one month). Vouchers like this could be tied to data-sharing agreements or other concessions. Vouchers could also be expanded to novel criteria (ex. trial design) to more directly incentivize priority drugs.

AI in FDA

AI can strengthen the FDA's regulatory toolkit by using in silico safety prediction models to identify potential toxicities and adverse effects before human testing, thereby reducing reliance on slower and riskier trial-and-error methods. More broadly, predictive modeling can help regulators anticipate drug efficacy, optimize trial design, and better allocate resources, accelerating development while improving safety oversight. Under former FDA Commissioner Makary, the agency completed its first AI-assisted scientific review pilot using generative AI to streamline repetitive reviewer tasks, and is now rolling out an agency-wide deployment of this AI system, known as Elsa, across all FDA centers. Makary had also prioritized integrating AI into regulatory decision-making workflows, including building shared databases, using generative AI in post-approval surveillance, and exploring partnerships to accelerate drug evaluation processes. AI to redact trade secrets could be used to facilitate the release of Complete Response Letters, Common Technical Documents, and other useful documentation.

NIH Grant Agreements

Requiring recipients of NIH funding to guarantee data portability would give study participants the right to easily download and share all the information generated about them in a trial. This not only empowers participants as data owners and incentivizes them to join studies, it also promotes reproducibility, accelerates secondary research, and builds public trust in federally funded science.

2.2 Vehicles for Changing Expectations and Culture

Pioneer Technology Campaigns

Policy change requires practical prototypes to be brought to life. Surging forward in specific technologies and diseases – such as longevity, neurotech, antimicrobial resistance, and ending respiratory infection – can generate the energy needed to overcome the friction of novelty and pilot cheaper and faster ways of collecting data.

Patient Groups

These groups are a key contributor to improving evidence gathering and incentivizing individuals to collect and share their data. This can take the form of large disease-specific groups (like the American Heart Association or American Cancer Society), rare disease advocates, and self-organized social media communities. Identify and integrate patient preferences for the storage, governance, and protection of data to remove barriers to adoption.

Tool Building

Building platforms and consumer applications to make it easy to collect and share data in useful ways will lower the barrier to adoption. Enhancing data portability for government datasets and medical research will encourage individuals to learn about their health and engage with the scientific community. Venture capital can support the development of these consumer health tools and link them to pioneer technology campaigns funded in part by tech philanthropy.

Fitness and Wellness Communities

Fitness and wellness communities are naturally inclined toward data collection, using wearables and tracking tools to monitor and improve performance. By offering them user-friendly platforms, integrating with social fitness ecosystems (like Strava), and promoting a culture of data sharing as aspirational and socially impactful, we can transform this self-interest into a powerful force for population-scale health research and evidence generation.

MAHA

In theory, this citizen-driven science, where people can see and generate data for themselves about their own health, slots neatly into the MAHA movement's goal of improving childhood health and increasing transparency. Additionally, advancing real-world evidence underscores the verifiability of government statements and empowers individuals to make informed choices.

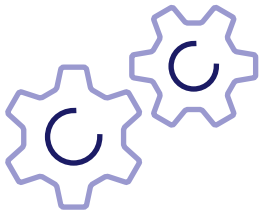
Collective Cultural Change Under New Practices E6(R3)

In E6(R3), the ICH emphasized risk-proportionality and quality-by-design elements in trial conduct. However, investigators (especially independent or small research teams) are left unclear on how to translate these new GCP concepts into faster and cheaper trials. By building and distributing best practices and guidance targeted toward naive investigators, the new E6(R3) guidance can materialize into expedited trial outcomes.

3 How to Get There: Advocacy Mechanisms and Key Priorities

3.1 Advocacy Mechanisms

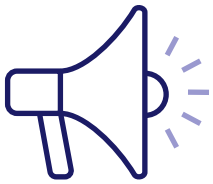
- **Technical Assistance:** Supply proposals, justifications, and operative text for the policy changes outlined above.
- **Event Series:** Convene experts, policymakers, and funders to legitimize and publicize the movement and acquire resources. Build a community of practice to develop and implement ideas.
- **Communications:** Explain ideas publicly and grow the community of minds working on this problem. Reach wellness, fitness, and patient groups and recruit public champions.
- **Community Organizing:** Groups of interest include Silicon Valley, fitness and wellness communities, effective altruists, and patient groups.
- **Development of Pioneer Campaigns:** Recruit philanthropic, government, and private capital for campaigns to demonstrate faster/cheaper data generation processes, possibly tying in to a national voucher program.



4 Key Axes of Advance

4.1 Policy Advocacy

Drive policy change via input into existing processes such as the HHS Open Data Plan, FDA AI initiative, and PDUFA negotiations. Recruit expert practitioners with clinical trial and drug development experience to improve policy recommendations. Build missing capacities by cultivating legislative champions, securing White House champions, and connecting with industry. Utilize an event series to build those capacities, increase the scale and diversity of perspectives to inform policymaking, and generate further ideas. Create a community of practice to advance this work in the long-term.



4.2 Pioneer Technology Campaigns

Attempt to find high-profile demonstration projects in areas like longevity research, antimicrobial resistance, and ending respiratory infections to prove that faster, cheaper data generation is possible. Use the event series to recruit leading experts in specific therapeutic verticals who can champion novel approaches and attract both philanthropic and government funding. These campaigns will serve as practical prototypes that generate energy and overcome regulatory friction while piloting innovative data collection methods that can be scaled across other disease areas.

4.3 Data Volunteerism

Though the furthest from implementation, focus initial efforts on building user-friendly platforms and consumer applications that make health data collection and sharing seamless and appealing. An event series can help generate leads among fitness communities, patient groups, and wellness enthusiasts who could become early adopters. Leverage 1Day Sooner's participant advisory committee as a model for organizing motivated volunteers, ultimately transforming individual health tracking into a socially beneficial movement that contributes valuable research data at scale.