

Enabling Access to Clinical Research:

AN ACTION PLAN FOR POLICY AND PRACTICE CHANGE

The problem: a system that impedes the research it is meant to enable. US clinical research is governed by dozens of entities, creating fragmentation and burden. Additional dysfunction is produced by cultural inertia, not regulation. Practices are more restrictive than rules demand.

The vision: a system that works for the people it serves. Every American should have opportunities to participate in cutting-edge research and access innovative products to improve their health. Research can be more streamlined; this should be executed within a framework that is *patient-centered*, *embedded* in routine care, *accessible* to communities, and *tech-enabled*.

The plan: finding Cures in Community. More US-based, *patient-centered*, and *embedded* research, *accessible* in community settings, requires acting immediately on existing authorities while pursuing targeted change.

Recommendations to Make Trials Patient-Centric

- Designing more inclusive studies
 - Use real-world data (RWD) to inform realistic eligibility criteria.
 - Design for inclusivity, not only protection.
 - Systematically involve communities in planning.
- Modernizing informed consent
 - Design for participant understanding.
 - Make patient-centric eConsent the default.
- Removing financial barriers
 - Cover trial-related routine care uniformly.
 - Compensate participants routinely.
 - Remove structural financial barriers from law.
- Returning study results to patients
 - Require plain-language summaries.
 - Harmonize participants' rights under Clinical Laboratory Improvement Amendments (CLIA) and Health Insurance Portability and Accountability Act (HIPAA).
 - Return results systematically.

Recommendations to Embed Research in Care

- Embracing pragmatic trial designs
 - Launch a national Cures in Community demonstration program.
 - Normalize research processes designed for community-based sites.
 - Unify federal pragmatic trials approach.
 - Reimburse providers participating via routine practice.
- Streamlining data collection
 - Avoid unjustified data collection by design.
 - Facilitate digital tools and streamlined processes.
- Making electronic health records (EHRs) work for research
 - Ensure EHR platforms are research-ready.
 - Expand data standards to include research-specific data elements.
- Leveraging decentralized and digital technologies
 - Close the gap between decentralized clinical trials (DCTs) and digital health technology (DHT) guidance and practice.
 - Codify telehealth and remote prescribing rules for DCTs.
 - Standardize Institutional Review Board (IRB) evaluation of DCT/DHT components.

Call to action: exercising existing authorities. Many needed actions are already permissible. Organizations can drive change by utilizing existing authorities, joining pilots, and adopting less risk-averse defaults.

Call for change: pursuing targeted change. Where cultural change is insufficient, we identify structural changes across policy levers and actors.

US Department of Health and Human Services and cross-agency alignment

- National Cures in Community demonstration program
- Unified pragmatic trials framework
- IRB equity mandate
- Compensation standards harmonization
- CLIA-HIPAA conflict resolution
- Mandatory plain-language summaries
- Model state legislation on telehealth use in DCTs

National Institutes of Health funding and grant requirements

- RWD feasibility requirements in grant review
- Documentation of patient and community engagement in grant review
- Return of results in scoring criteria

US Food and Drug Administration guidance, rulemaking, and demonstration

- New guidance on RWD for better eligibility criteria
- eConsent specifications and default expectations
- Pragmatic study risk-level clarification and proportionate requirements
- Center for Clinical Trial Innovation expansion
- Digital health technology standardization for clinical outcome assessments
- Critical to quality factor justification and data element necessity guidances
- Return of results requirements via informed consent process
- New approaches socialized with review divisions

Centers for Medicare & Medicaid Services coverage and reimbursement

- Consistent coverage of routine care costs during research
- Quality improvement credits for provider research participation
- Streamlined Medicare Coverage Analysis requirements
- Research inclusion in Data at the Point of Care, Interoperability Framework, and Health Tech Ecosystem

- Technology-Enabled Meaningful Patient Outcomes pilot expansion and digital health technology reimbursement

Office of the National Coordinator for Health Information Technology and EHR interoperability

- Research-capable EHR certification
- Research as a Trusted Exchange Framework and Common Agreement Exchange Purpose
- Regulatory-grade research standards gap analysis
- United States Core Data for Interoperability specification to include research elements

IRBs and accreditation bodies

- IRB accreditation quality standards from participants' perspectives
- Participant compensation framework
- DCT/DHT evaluation competency

Legislative actions

- Internal Revenue Service code amendment on participant compensation
- Federal Food, Drug, and Cosmetic Act modernization for DCTs and DHTs
- CLIA exception clarifying return of individual research results
- Research exceptions for remote prescribing of controlled substances in trials

Private-sector actors

- Standard operating procedure updates on eligibility, patient engagement, and results return
- Default eConsent with technical assistance for sites
- Ethical compensation for participants
- Pragmatic/DCT pilot participation and scaling
- Data element necessity scrutinized

Together, these actions represent a coordinated, systemic agenda required to build a clinical research system that works for the people it is meant to serve.

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