Navigating the Data Soup: Web3, AI, and the Future of Healthcare Data

April 1, 2026

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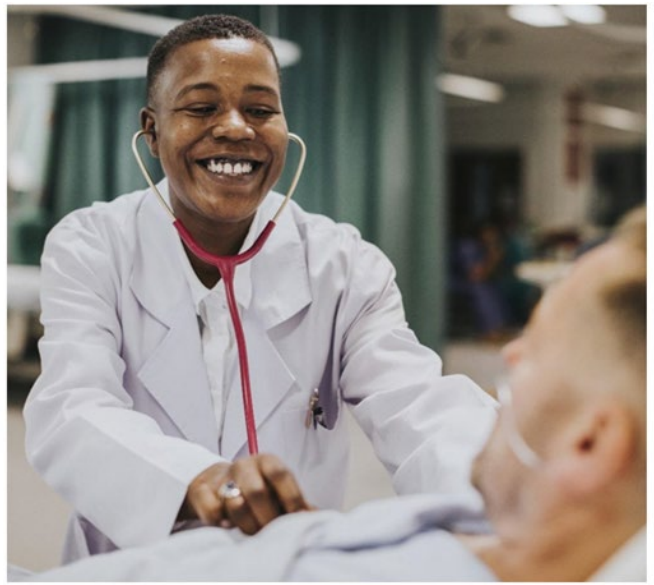

The Next Chapter

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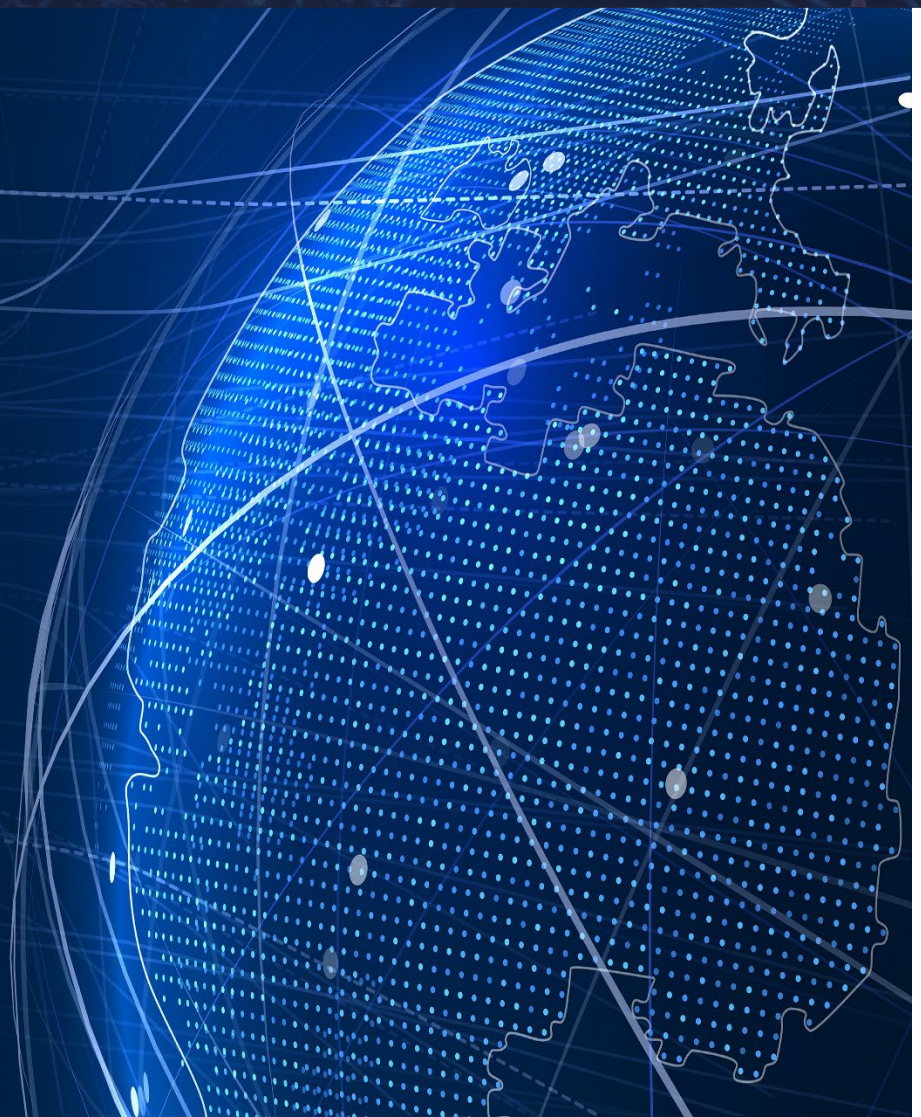

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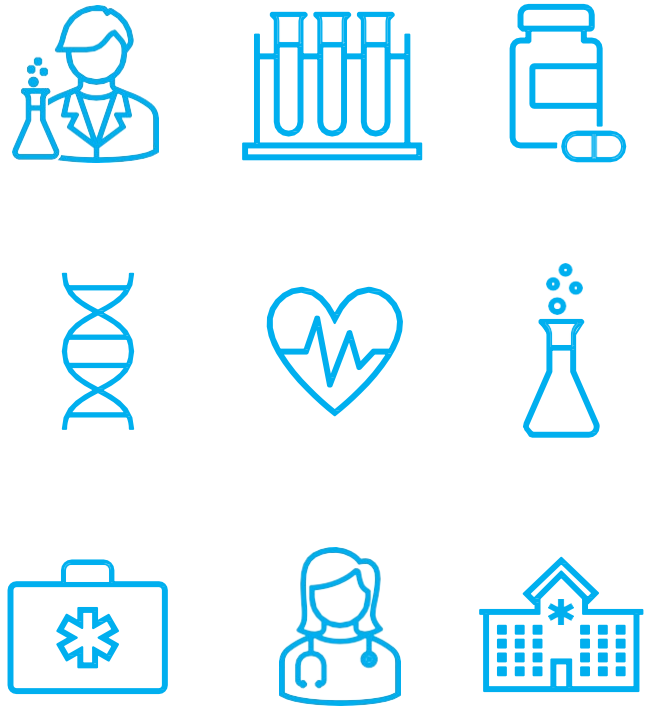

How To Engage

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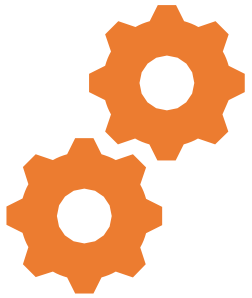
LEARN



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What Comes Next
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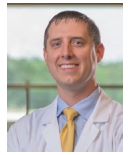
Dr. Jason McKnight

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The Idealized ClinicoGenomic Registry

Concept

A idealized clinicogenomic registry provides biospecimens, genetic, and regulatory-grade clinical annotation across the patient journey. The clinicogenomic registry presents data governance challenges that impede the flow of case level genomic data and case level clinical annotation from institutions to users such as policy agencies, researchers, drug developers, insurers, and the healthcare industry. The Texas A&M *Provenance Platform* is being developed to use digital technologies to enable a more dynamic model of patient-centric data governance in clinicogenomics registries.

Article

ACADEMIC MEDICINE
A JOURNAL OF THE AAMC

Academic Medical Centers as Innovation Ecosystems: Evolution of Industry Partnership Models Beyond the Bayh–Dole Act

Patrick J. Silva, PhD, MBA, and Kenneth S. Ramos, MD, PhD

Abstract

Innovation ecosystems tied to academic medical centers (AMCs) are inextricably linked to policy, practices, and infrastructure resulting from the Bayh–Dole Act in 1980. Bayh–Dole smoothed the way to patenting and licensing new drugs and, to some degree, medical devices and diagnostic reagents. Property rights under Bayh–Dole provided significant incentive for industry investments in clinical trials, clinical validation, and industrial scale-up of *products* that advanced health care. Bayh–Dole amplified private investment in biotechnology drug development and, from the authors' perspective, did not significantly interfere with the ability of AMCs to produce excellent peer-reviewed science. In today's policy environment, it is increasingly difficult to patent and license products based on the laws of nature—as the scope of patentability has been narrowed by case law and development of a suitable clinical and business case for the technology is increasingly a gating consideration for licensees. Consequently, fewer academic patents are commercially valuable. The role of technology transfer organizations in engaging industry partners has thus become increasingly complex. The partnering toolbox and organizational mandate for commercialization must evolve toward novel collaborative models that exploit opportunities for future patent creation (early drug discovery), data exchange (precision medicine using big data), cohort assembly (clinical trials), and decision rule validation (clinical trials). These inputs contribute to intellectual property rights, and their clinical exploitation manifests the commercialization of translational science. New collaboration models between AMCs and industry must be established to leverage the assets within AMCs that industry partners deem valuable.

In the 1960s and 1970s, there was little transfer of technology from U.S. government–funded academic labs to the private sector, largely because the government owned patents resulting from federally funded research and had a policy to only engage in nonexclusive licensing.[1] There were no financial incentives for the private sector to make investments in research, development, or clinical trials—as subsequent nonexclusive licensees had the ability to enter the market after a pioneer, avoiding the risks of failure. The Bayh–Dole Act (P.L. 96-517, also known as the University and Small Business Patent Procedures Act of 1980, or the Patent and Trademark Act Amendments of 1980) was designed to incentivize private investment. Bayh–Dole effectively required institutions receiving federal grants to administer their assets, giving rise to technology transfer offices and creating a path for private investment in translating scientific knowledge into societal impacts. Indeed, Bayh–Dole has been particularly effective in catalyzing investment in products spawned by biotechnology research in academia. As illustrated by Press,[2] science suffers an "appropriability conundrum," meaning that the rewards of scientific research are not easily or directly recovered by the investors in that research. Consequently, this conundrum tips the balance of private research and development (R&D) investment toward "D," where investments are more directly appropriable to commercial outcomes. The appropriability conundrum and research investment in academic science were precisely the problems Bayh–Dole was designed to solve (at least for research spawning a subset of selected ideas worthy of patent protection and downstream investment). Effectively, Bayh–Dole created a mechanism to privatize select assets of high potential and enable their delivery to the marketplace.

The Positive Impact of Bayh–Dole

Let's begin with an example. Protropin is likely the first drug approved involving use of university technology rights, though the specifics were litigated between the University of California, San Francisco School of Medicine and Genentech for over a decade.[3,4] The key issue of contention was whether tangible research materials (expression vectors encoding human growth hormone) and the patents[5] that arose to cover these materials were made independently by scientists who worked for either of these organizations. The protropin case exemplifies the power and potential of academic–biotech collaborations but also the utility of thoughtful, forward-looking collaboration agreements between academic medical centers (AMCs) and biomedical corporations. We argue that research institutions sometimes operate as biotechnology enterprises and beyond the so-called precompetitive space, bringing commercial considerations into research contracting.

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Journal of *Personalized Medicine*

MDPI

Article

An Idealized Clinicogenomic Registry to Engage Underrepresented Populations Using Innovative Technology

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Abstract: Current best practices in tumor registries provide a glimpse into a limited time frame over the natural history of disease, usually a narrow window around diagnosis and biopsy. This creates challenges meeting public health and healthcare reimbursement policies that increasingly require robust documentation of long-term clinical trajectories, quality of life, and health economics outcomes. These challenges are amplified for underrepresented minority (URM) and other disadvantaged populations, who tend to view the institution of clinical research with skepticism. Participation gaps leave such populations underrepresented in clinical research and, importantly, in policy decisions about treatment choices and reimbursement, thus further augmenting health, social, and economic disparities. Cloud computing, mobile computing, digital ledgers, tokenization, and artificial intelligence technologies are powerful tools that promise to enhance longitudinal patient engagement across the natural history of disease. These tools also promise to enhance engagement by giving participants agency over their data and addressing a major impediment to research participation. This will only occur if these tools are available for use with all patients. Distributed ledger technologies (specifically blockchain) converge these tools and offer a significant element of trust that can be used to engage URM populations more substantively in clinical research. This is a crucial step toward linking composite cohorts for training and optimization of the artificial intelligence tools for enhancing public health in the future. The parameters of an idealized clinical genomic registry are presented.

Keywords: genomic; registry; chronic disease; health disparity; electronic medical record; cancer

check for updates

Citation: Silva, P.; Dahlke, D.V.; Smith, M.L.; Charles, W.; Gomez, J.; Ory, M.G.; Ramos, K.S. An Idealized Clinicogenomic Registry to Engage Underrepresented Populations Using Innovative Technology. *J. Pers. Med.* **2022**, *12*, 713. https://doi.org/10.3390/jpm12050713

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1. Introduction

Precision medicine and health disparities are inextricably linked [1], as existing disparities are amplified in oncology where access to, and the use of, molecular testing remains limited [2,3]. Consequently, knowledge about the distribution and clinical actionability of certain molecular pathologies remains poorly characterized in underrepresented populations [4]. These disparities are well documented and reviewed thoroughly elsewhere [5]. For example, in pharmacogenomics, the gray area between variants of unknown significance and clinically actionable genetic variants tends to be occupied by rarer and emergent variants [6]. Progress toward the clinical interpretation and actionability of emergent variants has been impeded because adequate documentation of the relevant clinical context is at a nascent stage. The underrepresentation of populations harboring rarer variants in research (the Preferred Cohort effect, [7,8]) has limited the availability of the clinical outcome data and mechanistic insights necessary to define clinically actionable pathways and guidelines for those variants. The absence of such characterization can also limit referrals of patients to interventional trials, where the enrollment criteria for experimental

The PROVENANCE Model:
A Digital Evolution of Health Data Stewardship

HEALTH

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The **PROVENANCE** model transitions health data management from static "electronic filing cabinets" to a dynamic, digitally-validated supply chain. While it does not **replace legacy legal frameworks** (DUAs), it empowers participants with **real-time auditability**, blockchain-based accountability, and granular patient agency.

Legacy Processes: The "Honor System" Era

Manual & Sequential Workflows

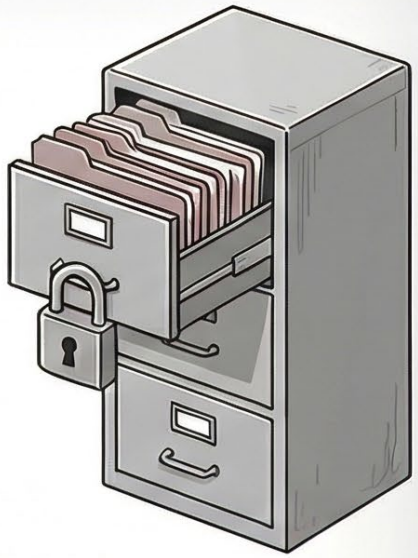
Serial processes often take months and are vulnerable to management gaps.

Retroactive Forensic Auditing

Audits are tedious manual exercises with no visibility for data administrators.

Limited Privacy & Consent

Rely on assumed project-level consent and irreversible de-identification tools.

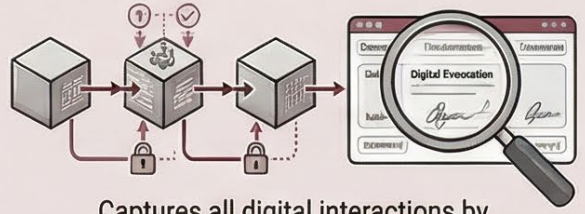


PROVENANCE Architecture: The "Trust Anchor"

Real-Time Risk & Revocation

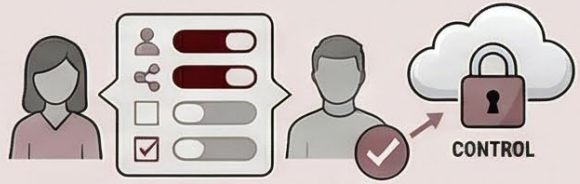
Enables parallel evaluation of risks and immediate digital revocation of access.

Immutable Blockchain Ledger



Captures all digital interactions by administrators and researchers on a ledger.

Dynamic Patient Agency



Provides granular control over data sharing and real-time consent validation.

Category	Legacy Model	PROVENANCE Model
Compliance Posture	Retroactive & manual audits	**Automated, real-time blockchain ledger**
Data Visibility	Static 'Electronic Filing Cabinets'	**Dynamic 'Supply Chain' management**
Trust Model	'Honor System' DUAs	**Digitally enforced smart contracts**

THE PROVENANCE MODEL DOES NOT REPLACE LEGACY DUA AND DATA ADMIN PROCESSES, ONLY EMPOWERS PARTICIPANTS WITH DIGITAL TOOLS AND TRANSPARENCY.

HEALTH

PROVENANCE: From Assumed Compliance to Digitally Enforced Integrity

An **AI-native integrity infrastructure** managing the clinicugenomic data supply chain, replacing legacy "honor systems" with blockchain, smart contracts, and **DRM** for real-time, granular control.

LEGACY SYSTEMS: ASSUMED COMPLIANCE (HONOR SYSTEM)

'Electronic Filing Cabinets'

MANUAL DUA MONITORING

STATIC TABLE/FILE LEVEL ACCESS

Legacy Data Use Agreements rely on "honor systems".

NON-COMPLIANT ACCESS POSSIBLE, LEGAL RECOURSE POST-HDC

	FEATURE	LEGACY DATA WAREHOUSE	PROVENANCE PLATFORM
1	**Compliance**	Assumed (Honor System)	**Digitally Validated & Enforced**
2	**Access Control**	Static Table/File Level	**Granular** (Variable/Patient/Study)
3	**Governance**	Manual DUA Monitoring	**Automated Smart Contracts & DRM**

PROVENANCE PLATFORM: DIGITALLY ENFORCED INTEGRITY

DATA SUPPLY CHAIN: SPECIMEN TO PUBLICATION

SPECIMEN COLLECTION

BARCODE-TO-HASH BLOCKCHAIN TRACKING

Metadata is tracked via cryptographic hashes from initial collection to final research publication.

AI-NATIVE HONEST BROKER PROGRAM

REGULATORY ON/OFF SWITCH

OFF ON

INTEGRATED DIGITAL RIGHTS MANAGEMENT (DRM)

RESEARCH MODULE

GRANULAR PERMISSION CONTROLS

(Stakeholders modify permissions at variable/patient level)

ADMIN MODULE

DIGITALLY VALIDATED INSTITUTIONAL PROVENANCE

(Validated ledger of data lineage, compliance, usage)

PUBLICATION & RESEARCH CREDIT

Solving the **"Appropriability Conundrum"**: End-to-end visibility ensures patients and institutions gain agency and credit for contributions.

SMART CONTRACTS digitally enforce terms, block non-compliant access instantly.

DATA SOVEREIGNTY PILLARS

RESEARCHER
Empowered Data Access

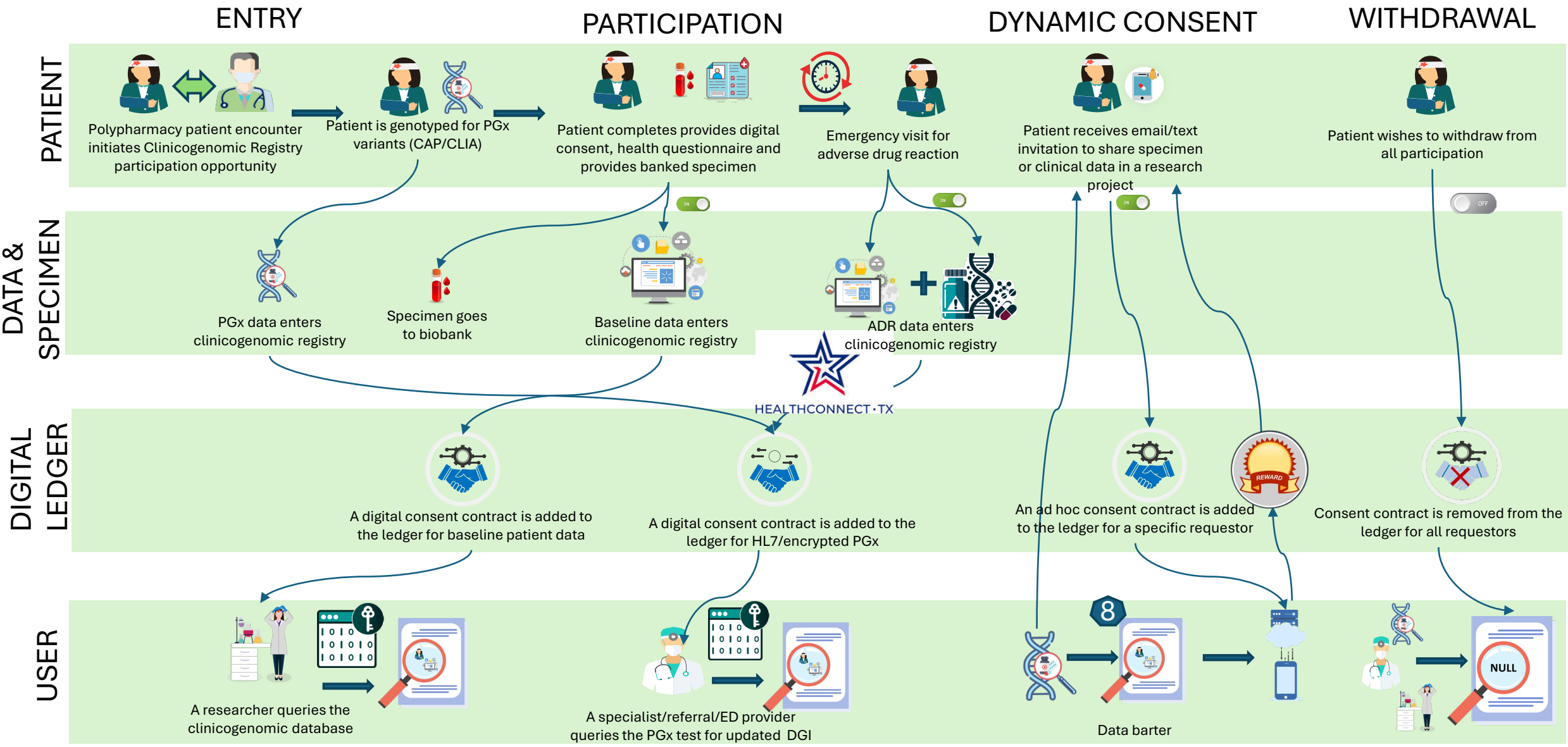
PATIENT
Consent & Agency

INSTITUTIONAL ADMINISTRATOR
Compliance & Governance

ADMINISTRATIVE WORKFLOW AND DATA GOVERNANCE

	INTAKE	REVIEW	ITERATION	APPROVAL	SUSPENSION
HONEST BROKER		✓ Scientific Merit/Alignment w/ Priorities ✓ Human Subjects Determination		A digital consent contract is **added** to the ledger for patient data	A digital consent contract is **removed** from the ledger for patient data
HSPO/ IRB		✓ Ethical reviews ✓ Auxiliary Reviews ✓ Continuing Review		A digital consent contract is **added** to the ledger for patient data	⊗ Violations/Deviations A digital consent contract is **removed** from the ledger for patient data
PRIVACY / COMPLIANCE		✓ Deidentification Validation ✓ Review Data Schema		A digital consent contract is **added** to the ledger for patient data	A digital consent contract is **removed** from the ledger for patient data
RESEARCHER		✓ Workscope ✓ Competitive Implications ✓ Limitations on Use	**Ping workflows per checkpoint limits**	A digital consent contract is **added** to the ledger for patient data	A digital consent contract is **removed** from the ledger for patient data

PROVENANCE DATA GOVERNANCE ARCHITECTURE (PREEMPTIVE PHARMACOGENOMICS)



ClinicalTrials.gov ID NCT06726590

Content developed using SlideTeam and You.com generative AI

The PROVENANCE Ecosystem: A Blockchain-Integrated Patient & Data Journey

Visualizing the end-to-end workflow of the TAMU TREC Registry, illustrating how multimodal patient data is captured, governed via blockchain, and transformed into actionable clinical and research insights.

1. THE INPUT LAYER & PATIENT JOURNEY

MULTIMODAL DATA COLLECTION

Wearables
(HRV, Sleep, Gait, Activity, Environmental SDOH)

PGx & Genomic Data
(Pharmacogenomic sequencing, .VCF files)

Clinical Standards
(HL7CDA, SNOMED, ICD-10, LOINC, MedDRA)

PRIMARY STAKEHOLDERS & CONTRIBUTORS

Patients
Researchers
Administrators
HealthConnect Texas (HIE)

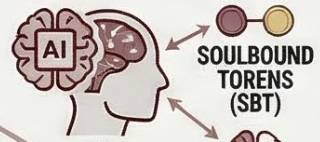
DYNAMIC CONSENT & ENTRY

Patients enter the registry via digital consent contracts added to the blockchain ledger.

2. INTEGRITY INFRASTRUCTURE & TECH STACK

BLOCKCHAIN INTEGRATED STACK

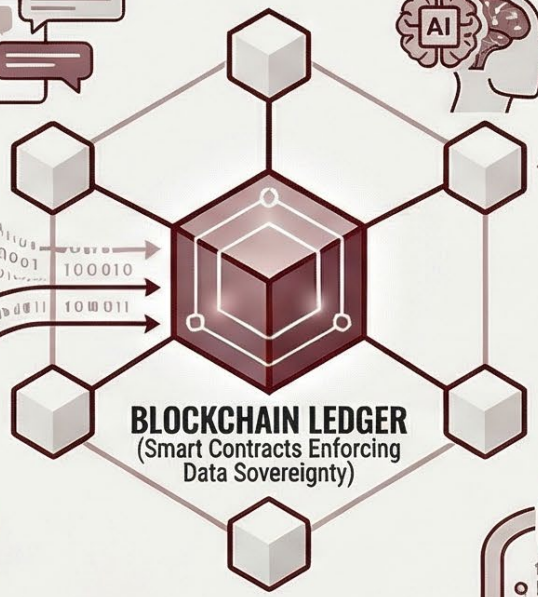
DIGITAL USER INTERACTIONS
(SQL, Chat Logs)



PROVENANCE-AWARE AI & GOVERNANCE

SOULBOUND TORENS (SBT)

FEDERATED LEARNING



BLOCKCHAIN LEDGER
(Smart Contracts Enforcing Data Sovereignty)

THE "DATA REFINERY" & AIRLOCK

Secure computational sandboxes (BurstIQ/Aggie STAR) de-identify data and enforce smart contract compliance.

3. INSIGHTS & HIGH-IMPACT USE CASES

CLINICAL & POPULATION APPLICATIONS

CLINICAL DECISION SUPPORT (CDS)

GWAS
(Genome-Wide Association Studies)

REAL-WORLD EVIDENCE

POPULATION DATA MOSAICS

THE DIGITAL TWIN FOUNDATION

Continuous sensor data and clinical annotation fead virtual replicas for predictive healthcare.

PATIENT-TO-PUBLICATION PROVENANCE

BIOBANK SAMPLE

RESEARCH

RESEARCH PUBLICATION

Transparently tracking data use from the biobank through to final research publication.

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Navigating the Healthcare Data Ecosystem: Stakeholder Needs and Governance Solutions

Effective healthcare AI and data management require a "Medical Data Element Ecosystem" (MDEE) that balances speed, breadth, and capability, addressing data sharing and privacy through smart contracts, blockchain, and multi-stakeholder engagement.

PATIENT & PUBLIC ADVOCACY

Patient-Centric Governance

Patients prioritize control over their genetic information and transparency in secondary data use (Ahmed & Shabani, 2019).

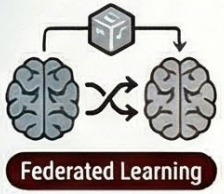
Retrograde Data Flow & Provenance

What scientific publications did my participation contribute to? What happens if researchers discover something in my genetics?

Exclusionary Rights

Patients require mechaniams to exclude data sharing with for-profit entities (Mackey et al.; Rozenblit et al., 2025).

THE RESEARCH & COMPLIANCE WORKFLOW



Secure Collaborative Research

Researchers use Federated Learning to train AI models without directly viewing or copying raw variables.

Smart Contract Enforcement

Automated protocols can pause data access if a study becomes inconsistent with the Data Use Agreement (DUA).

Compliance & De-identification

Officers verify if outbound batches are truly de-identified and if every patient is properly consented (Hudson et al., 2008).

PERSONA-BASED USE CASE TABLE

MAPPING STAKEHOLDER QUESTIONS TO GOVERNANCE FUNCTIONS

RESEARCHER	COMPLIANCE OFFICER	3RD PARTY AUDITOR	PRIVACY OFFICER
Issue: Federated Learning	**Issue:** Regulatory Alignment	**Issue:** Provenance	**Issue:** Compliance
Question: Can I train AI models without my collaborator seeing or copying my variables?	**Question:** Is every patient in this outbound data table properly consented?	**Question:** Who interacted with my shared data and what exactly was it used for?	**Question:** Is this outbound batch of data truly de-identified?

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☐ = major contributors to Idealized ClinicoGenomic Registry

Clinicogenomics Research Programs

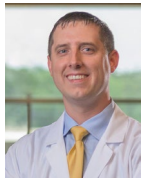

Dr. Kenneth Ramos


Rick Silva, PhD


Dr. Gabriel Neal


Marcia Ory, PhD


Fen Wang, PhD


Dr. Jason McKnight

Multidisciplinary Team

15 TAMU faculty from Colleges of Medicine, Pharmacy, Public Health; Institute of Biosciences and Technology Center for Genomic and Precision Medicine; Center for Population Health and Aging, Department of Family Medicine and Population Health, Institute of Data Science.

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TEXAS A&M Medicine

TEXAS A&M HEALTH Center of Excellence in Cancer Research

TEXAS A&M Pharmacy

Collaborators

TEXAS A&M Institute of Data Science

TEXAS A&M UNIVERSITY Center for Population Health and Aging

TEXAS A&M Public Health

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George Udeani, Pharm D.


Dr. Nora Janjan


Wendy Charles, PhD
CSO, BurstIQ

Industry partners

Goldblatt

burst iQ

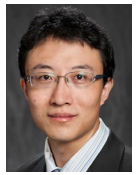
Geneial

iC42 integrated solutions in systems biology clinical research & development

ActX

Digital Twins Collaborators


Paula Shireman MD


Jian Tao, PhD


Nick Duffield, PhD

Students

Julie Aponte
Filipp Voronov
Jordan Moore
Cindy Lam
Aaron Liu
Dr. Ching Chih Huang
Joshua Robert
Nick Griffin
Sophie Lamothe

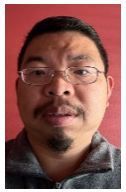
The folks who help us get things done

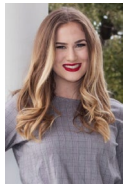

Matt Walton


John Pryde


Linda Saenz


Dee Bacote


Qiang "John" He


Bailey Feder

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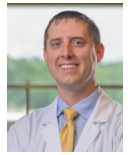
Dr. Gabriel Neal


Dr. Marcia Ory


Dr. Fen Wang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…on Clinical AI Implementation topics…

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