phuse

Single Day Event

Hexaware Technologies, Chennai
September 19, 2026

CEPHEUS
Smart Software Migrations

Strategic Partner of Capgemini

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DATA | PEOPLE | BETTER HEALTH TOMORROW

The Four Pillars

Trusted Clinical Evidence

PEOPLE
SCIENCE
DATA
BETTER DECISIONS

01 SUBJECTS

Real patients, real biology – the retrospective or prospective data source

02 SPONSORS

The accountable party that commissions the work and owns the outcome

03 SCIENCE & TECHNOLOGY

Statisticians, programmers, epidemiologists, biostatisticians and the systems they use

04 GOVERNANCE

Regulators and ethics bodies that set the rules and grant or deny permission to proceed

THE EVIDENCE CHAIN

CREATION → ANALYSIS → REPORTING → COMPLIANCE → CONSUMPTION

A weakness introduced today can travel through the evidence chain — and affect decisions and people years later

The Framingham Heart Study

Creation → Consumption

1948
Study launched; NIH created same year

1961
"Risk factor" coined in landmark paper

1971
Offspring Cohort enrolled

2002
Third Generation Cohort

2026
78 yrs; $31.5M Brain Aging renewal

STUDY DESIGN

- **Prospective**
- **Longitudinal**
  Full exam every ~2 years
- **Whole-community**
  True incidence rates
- **Multi-generational**
  3 cohorts under matched protocol isolate heredity vs. lifestyle

BY THE NUMBERS

5,209
Original Cohort

~5,124
Offspring Cohort

~4,095
Third Gen. Cohort

2M+
Biosamples collected

3,000+
Peer-reviewed papers

78 yrs
Continuously running

GOVERNANCE

- Funded by NHLBI (NIH) since 1948 - one of the longest federally funded studies in U.S
- Run jointly with Boston University since 1971.
- Overseen by a Steering Committee and Observational Study Monitoring Board.

DATA ACCESS

- BioLINCC (NHLBI): lists datasets; routed to FHS
- dbGaP: genomic data, controlled access
- framinghamheartstudy.org: direct request

1948–2026 | 78 years | 15,000+ participants | 3 generations

Evidence Outlives Its Creators

Source: Framingham Heart Study / NHLBI

Eight Decades Of Safeguards - Built In Response To Failure

Trust Was Earned Through Transparency, Long Follow-up And Enforced Accountability.

Global Governance Has Enforcement Teeth

2012 | GSK / Avandia
Pleaded guilty and paid $3B to resolve U.S. charges including failure to report safety data to the FDA

2013 | Ranbaxy USA
Pleaded guilty and paid $500M over manufacturing violations and false statements concerning drug-quality testing.

2026 | ClinicalTrials.gov

In April 2026, FDA sent compliance reminders to more than 2,200 sponsors and researchers after finding nearly 30% of legally required trial results had not been posted.

The Framingham example shows how creation and consumption can involve different populations - a structural risk that predates AI.

Readiness Is The Binding Constraint

The Gap Between Adoption Rhetoric And Operational Reality

01	**Adoption Rhetoric**	**AI is a game changer** High expectations, rapid narratives, broad claims
02	**Operational Reality**	**Validated data • Audit Trail • Trained People** Execution requires data, processes, and people
03	**Regulatory Signal**	**Structured AI governance** Evidence that can be defended
04	**Analyst Signal**	**ROI skepticism** Proven value, not adoption theater

PEOPLE
SCIENCE
DATA
BETTER DECISIONS

Two Signals Converge

REGULATORS / QUALITY

More structured AI governance.

ANALYSTS

Most AI investments not yet showing measurable return.

KEY ENABLERS OF READINESS

Validated data | Auditable documentation | Trained staff | Proven ROI

BOTTOM LINE

The constraint is increasingly the readiness of the system around AI –

not the capability of the AI itself.

CLINICAL EVIDENCE
REAL-WORLD IMPACT
A HEALTHIER TOMORROW

Where AI Readiness Is Won-or Lost

Five Practical Readiness Questions, Anchored In Current 2025–2026 Evidence

Five Dimensions

01 Data & Technical Readiness for Reliable AI
Clean • Standardized • Interoperable • Monitorable

02 Regulatory Readiness
Documented • Validated • Fit-for-Purpose • Defensible

03 Governance Readiness
Human Oversight • Transparency • Accountability

04 Are people ready to use AI in practice?
Trained • Equipped • Competent • Operationally Ready

05 Can AI value be separated from the hype?
Evidence • ROI • Expectations • Real-World Value

Evidence Anchors

11% fully implemented AI/ML in trials

55% sites reporting >5-month activation timelines

1 in 5 AI investments showing measurable ROI

1 in 50 AI investments delivering transformational value

1. IEEE SA - Active PAR P4158.3
2. FDA - Draft Guidance, Jan 2025 • FDA-2024-D-4689
3. WCG - 2026 Clinical Research Trends & Insights
4. WCG 2026 + ICON Site Activation Survey, Dec 2025
5. Gartner - Worldwide AI Spending Will Total $2.5T in 2026

Adoption Is Moving Ahead Of Readiness Across Data, Regulation, Governance, People And Measurable Value

Not All “AI ROI” Signals Mean The Same Thing

General-purpose Adoption Vs. Controlled, Auditable

ENTERPRISE-WIDE AI

- **Chatbots**
- **Generic copilots**
- **Broad productivity tools**

Industry commentary often groups these investments into one broad “AI” category.

ROI skepticism here does not describe narrow, validated use in a regulated trial pipeline.

≠

REGULATED AI USE

- **Narrow scope**
- **Defined context of use**
- **Validated performance**
- **Auditable evidence**

Relevant Questions

- Where AI Is Being Applied
- Under What Evidence Standard

- GCP / 21 CFR Part 11 operate around traceability, validation and controlled processes
- The evidence standard is materially different from generic AI experimentation

It is not **“AI vs. no AI”**

Regulated Industries - A Window of Opportunity

Build Credibility To Use AI Responsibly — Before The Market Settles

WHY THIS WORKFORCE IS DIFFERENT

Regulatory discipline builds readiness

- Traceable
- Controlled
- Defensible

Applied to AI claims:

1. Define the use
2. Understand the evidence
3. Challenge the output
4. Preserve the audit trail.

The Implementation Gap Is An Opportunity

Acceleration Is Not The Opposite Of Rigor

Faster Clinical Development Needs Structured Urgency — Not Reduced Controls

The Historical Precedent

What Legitimate Compression Adds

- More frequent sponsor–regulator meetings
- Rolling review of completed sections
- Defined post-market obligations
- Continued accountability

The Principle Is Consistent:

- The timeline can compress
- The governance structure does not

The Test Is Not Whether AI Is Fast - It Is What Gets Compressed

Accelerate With AI, Without Compromising Accountability

Legitimate Compression

Faster, Not Looser

AI shortens the timeline for:

- Data cleaning
- Signal detection
- Documentation and evidence assembly

while the four pillars remain intact:

- Subjects protected
- Sponsors accountable
- Technologists produce a credibility package
- Governance signs off

Illegitimate Compression

A Pillar Is Removed

AI adoption is used to:

- Skip validation
- Bypass documentation
- Substitute vendor assurance for an auditable credibility trail

That is **not "fast"** in the FDA sense.

A model in place of the missing control

The Difference **Work Is Compressed** ≠ **Accountability Is Removed**

The Practical Test For AI In Clinical Research

Does It Accelerate The Work While Keeping The Evidence Chain Intact?

THE FOUR-PILLAR TEST

01	SUBJECTS	Protected	No loss of participant protection or evidence integrity.
02	SPONSORS	Accountable	The sponsor remains responsible for the outcome and evidence.
03	TECHNOLOGISTS	Credible	Validation, monitoring and the credibility package remain defensible.
04	GOVERNANCE	In control	Oversight, documentation and sign-off remain intact.

Responsible AI is not a new exception to the clinical evidence lineage - it is its continuation at a higher speed.

When “More Data” Is Not A Strategy

Rare Adverse Events, Pediatric Populations And Rare Diseases

The Data-volume Assumption

More Records → More Patients → More signal

That logic breaks when the population limits what can **ethically or practically be collected**

The constraint is structural - not simply a shortage of effort or funding

Where It Breaks

- **Rare Adverse Events**
  ~1 IN 10,000
  A serious event can remain **too sparse** for conventional testing
  Enrolling enough patients becomes ethically and economically difficult.

- **Pediatric Populations**
  Ethical Limit
  Large placebo-controlled trials duplicating established adult knowledge may be impractical or unethical.

- **Rare Diseases**
  Hundreds
  The entire global patient population may number in the hundreds.
  There is no scalable “more data” regime.

The Bayesian Culture

Concurrent data + prior trials + adult data + historical controls + registries → one defensible estimate

Bayesian analysis is coherent precisely - these populations cannot simply be expanded

Framework Is Moving - Four Pillars Are Not Equally Ready

Regulatory | Operational Evidence | Tooling Maturity | Synchronized Global Governance

January → September Snapshot

	JAN		SEP	
Subjects	JAN	Borrowing is explicitly intended to reduce unnecessary burden on children and rare-disease patients.	SEP	Benefit is not yet realized in practice; Sponsors and Technologists must operationalize the framework.
Sponsors	JAN	Draft guidance published; 60-day comment window opens.	SEP	Comments closed Mar 13; sponsors remain in a clarification-seeking phase.
Technologists / Tools	JAN	High technical bar: pre-specified priors, conflict assessment, simulation and computational transparency.	SEP	Prior classification and methodological questions remain active; tooling is not yet routine.
Governance	JAN	FDA draft + EMA concept paper begin parallel movement.	SEP	FDA remains draft; EMA targets a full reflection paper only by 2028. Global governance is not synchronized.

The Sharpest AI-Readiness Test

An AI model cannot clear the bar by training on more data alone

Justified models • Documented borrowing rationale • Simulation-validated OC • Computational transparency.

Modeling

Sparsity

Heterogeneity

Adversity

Combined Evidences

Early Promise | Safety Concerns |Actions |Journey Of Evidence, Litigation & Resolution

Regulatory & Litigation Timeline

1999
Approved & Launched
Promise begins

2000–2005
Warning Signs Emerge
Risk signals surface

May 2007
Major Scientific Alarm
The turning point

2007
FDA Issues Warnings
Scrutiny becomes official

2010
Major Restrictions
Regulatory flashpoint

2011
REMS & Limited Access
Access becomes highly restricted

2012
Litigation Explodes
Legal & financial fallout

2013
Restrictions Relaxed
Evidence picture becomes more complex

2015
Most Private Lawsuits Settled
Litigation winds down

2024
Final Settlement
Litigation legacy largely closes

The Bigger Picture

Better evidence

Stronger decisions Greater trust

A Decade of τ² Methodology: 2017–2026

Alternate & Derived Forms · Aberration Behavior

Truncated at 0 | Truncated at 0.01 | No truncation | † = iterative

MOM
Method of Moments
CA | DL | PM†
Alternate forms
2SCA | 2SDL | HM | PDL | BDL† | APM

VCT *Variance-Component Type*
HE | HS

MEV *Model Error Variance*
SJ
Alternate forms
ASJ

LIK
Likelihood-Based
ML† | REML†
Alternate forms
AREML†

AI Preparedness Is Not Knowing Every Model. It Is Knowing Which Model to Trust, When — and Why.

Governance through Models to Build Evidence, so Trust is Earned.

Not assumed. Not claimed. ***Earned - through evidence*** *the organisation holds, verifies, and owns.*

Governance
Sets the framework and guardrails

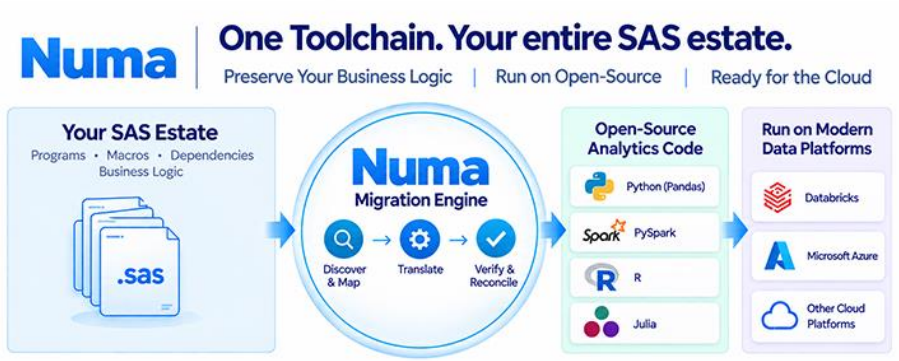
Models
Integrate data and generate insights

Evidence
Produces verifiable, reproducible results

Verification
Holds, validates and owns

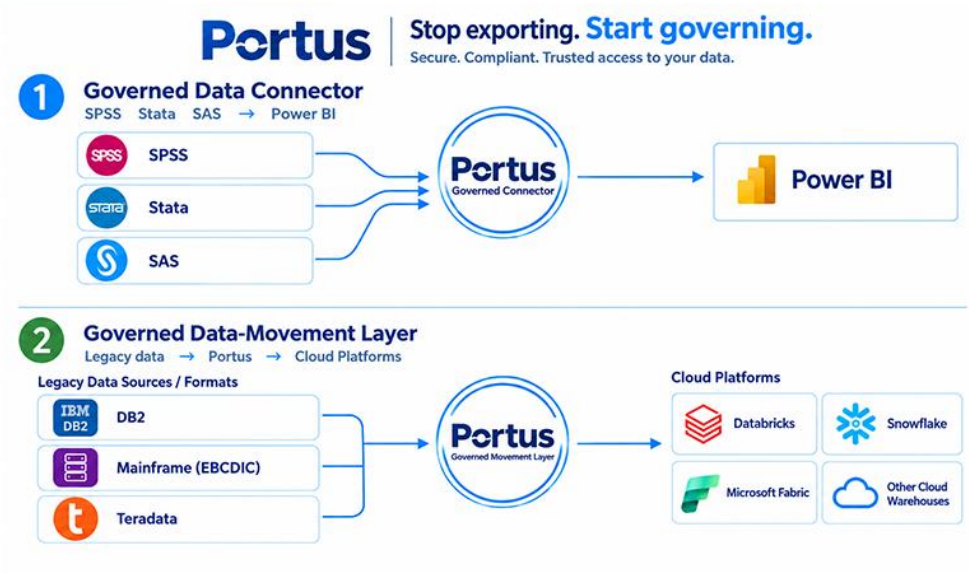
Trust
Is Earned

Cepheus: Intelligent Migration for the Business Outcomes



Intelligent Migration to the Modern Data Stack

Preserving what matters. Modernizing what must change.



Responsible AI Is Not A New Standard For Clinical Research

It Is A Higher Standard For Carrying The Existing Responsibility Forward

AI Should Strengthen The Evidence Chain - Not Merely Accelerate It

01 **More Rigorous**
Explicit assumptions, appropriate methods and demonstrated performance.

02 **More Accountable**
Clear ownership, traceability and evidence behind conclusions.

03 **More Transparent**
Reproducible methods, provenance and computational transparency.

04 **More Prudent**
Appropriate consent, responsible data use, privacy and security.

05 **More Governable**
Oversight that keeps pace with capability and risk.

06 **More Useful To Future Generations**
Preserve the integrity of the evidence base, not merely its speed.

Better Evidence Is Essential

Faster Evidence Is Valuable

Responsible AI Must Deliver Both

Responsibility Is Shared: Clinicians, Sponsors, Scientists, Technologists, Regulators, & Policymakers

Connect With Us

Strategic Partner of Capgemini

Migration Solutions

SAS → Open Source → Modern Cloud

Modernize legacy analytics and data estates.

Capability Development Programs

Machine Learning · Data Science · Bayesian · Frequentist

Build advanced analytical capability within your teams.

MODERNIZE YOUR PLATFORMS. BUILD CAPABILITY FOR WHAT'S NEXT.

Our responsibilities

- Protect people
- Ensure integrity
- Build transparency
- Maintain strong governance
- Use AI to advance responsibly

Clinical Evidence Is Built Across Generations

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