BIO ASIA–TAIWAN 2026 · INNOVATION FORUM SESSION A-2

美商安美睿生技有限公司

Awareness Is Not Readiness

Building AI-Ready Clinical Development Systems

Awareness is a starting point. Readiness is an operating capability.

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President, Amarex Clinical Research (an NSF Company)

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FRAMING THE DISCUSSION

The Two Questions

01

What does readiness actually look like?

02

Where is your readiness gap?

The Gap Nobody Budgeted For

AWARENESS

Knowing what must change

An AI strategy deck

"AI will transform trials" — someday

Interest and pilots

READINESS

The capability to execute the change

An operating model that runs

Trials redesigned to be AI-ready — now

Enterprise execution – not experiments

AI cannot run on a workflow that was never designed for it

THE CASE FOR READINESS

When AI Meets an Unready Workflow

The most-cited AI failures were not just model failures. They were workflow, data, and governance failures.

1

Watson for Oncology

MD Anderson, 2013–2017

~$62M spent; system never reached clinical use.

Workflow gap: No interoperable data layer

2

Epic Sepsis Model

External validation, 2021

Sensitivity 33%; missed two-thirds of sepsis cases.

Workflow gap: Signals not pre-specified at the source

3

Industry Reality

Biopharma AI, 2025

89% of AI pilots do not scale; 96% report their data is not AI-ready.

Workflow gap: Operating model beneath AI is not real

None of these are AI failures. All three are readiness failures.

Source:
- MD Anderson–Watson: Becker's summary of UT System audit · AIAAIC incident record with primary-source links
- Epic Sepsis Model: Wong et al., JAMA Internal Medicine, June 2021 · editorial, Habib et al., JAMA Internal Medicine
- Pilot scaling: Discover Pharma survey of 116 life-sciences data leaders · IntuitionLabs review citing McKinsey life-sciences survey

THE REGULATORY DIRECTION IS SET.

The Standards Already Moved

Three frameworks. One direction: structured, data-oriented clinical development.

ICH E6(R3)

Good Clinical Practice

Quality and risk built in by design.

Effective EU Jul 2025 · FDA guidance Sep 2025 · Annex 2 Jun 2026

ICH M11 (CeSHarP)

Clinical Protocol

Structured, harmonized protocol content.

Adopted Step 4 · Nov 2025

FDA Real-Time Review

Oncology / RTOR

Continuous, data-oriented oversight.

Active review pathway

One direction: structured, data-oriented operating models

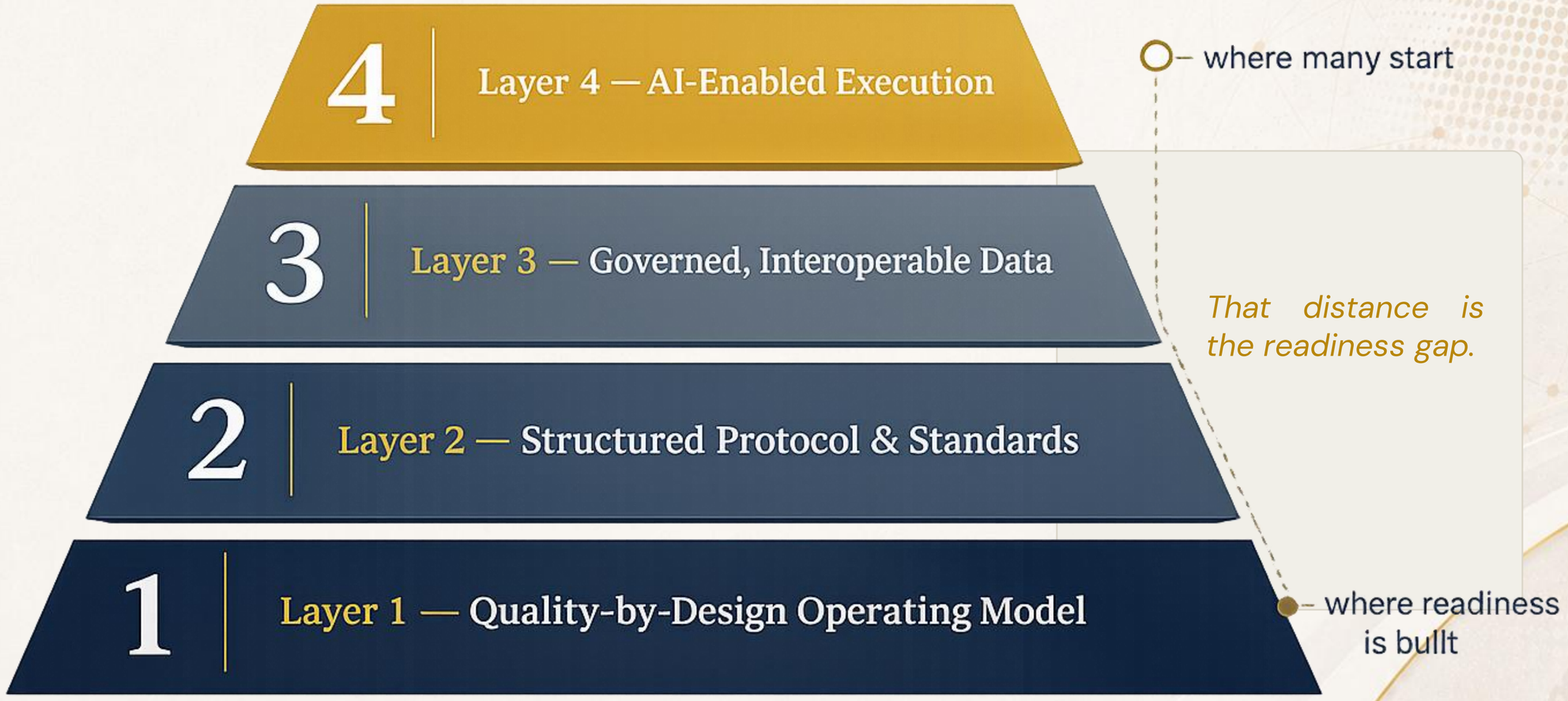
This is not a technology gap. It is a readiness gap.

Source: EMA, FDA E6(R3), ICH M11

LOCATE YOURSELF

The Clinical Development Readiness Stack

Each layer enables the one above it. Most organizations reach for Layer 4 on a Layer 1 foundation.

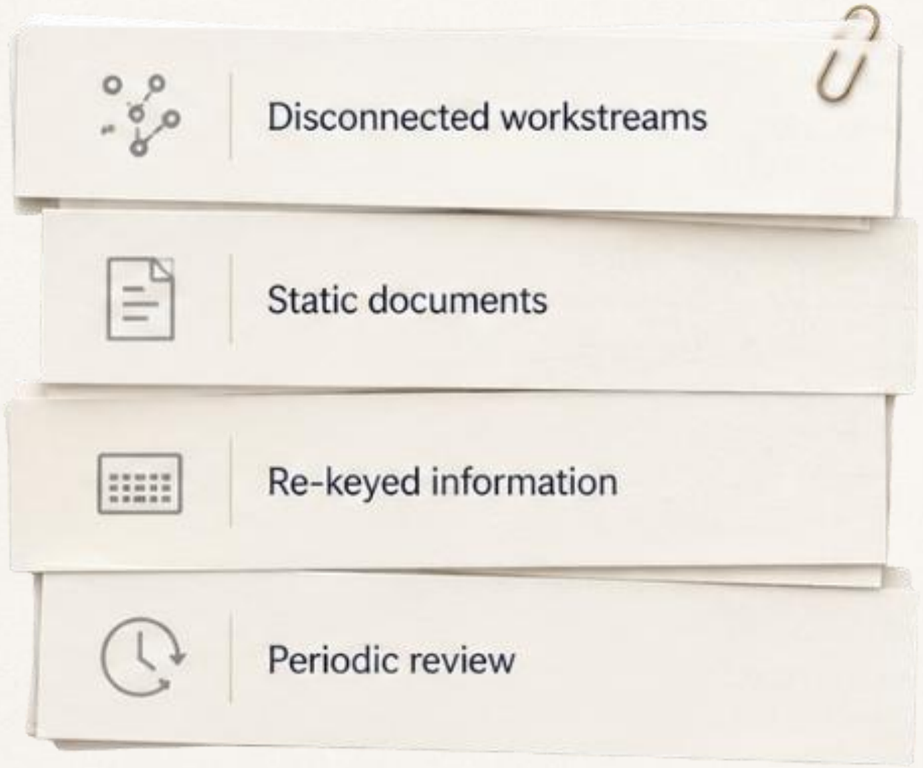


Your readiness is defined by your weakest foundational layer.

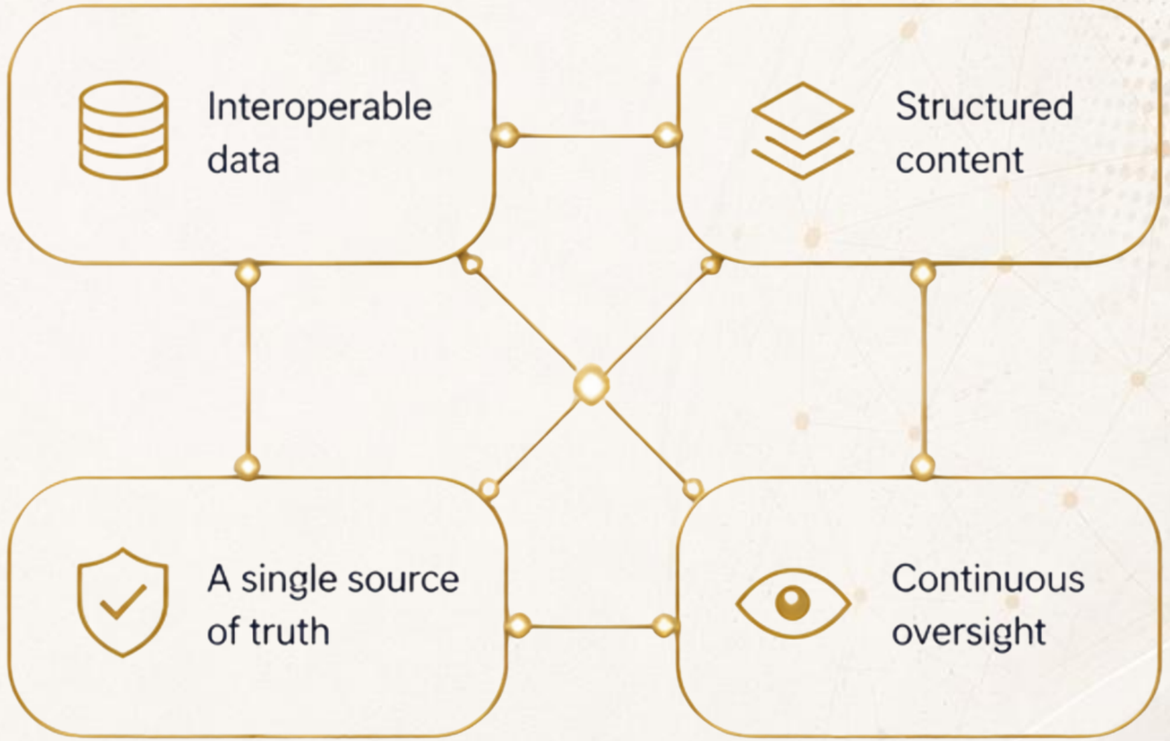
THE MECHANISM

The Unit of Work Has Changed

Document-Driven (Legacy)



Data-Oriented (AI-Ready)



AI operates on structured data — not on PDFs.

FROM FIVE WORKSTREAMS TO ONE MODEL

The Protocol Becomes the Operating Asset

Stop running five workstreams. Run one model.

From: protocol → documents → manual interpretation → five disconnected workstreams

To: structured protocol → connected data → automated workflows → one coherent operating model

ACROSS THE TRIAL LIFECYCLE

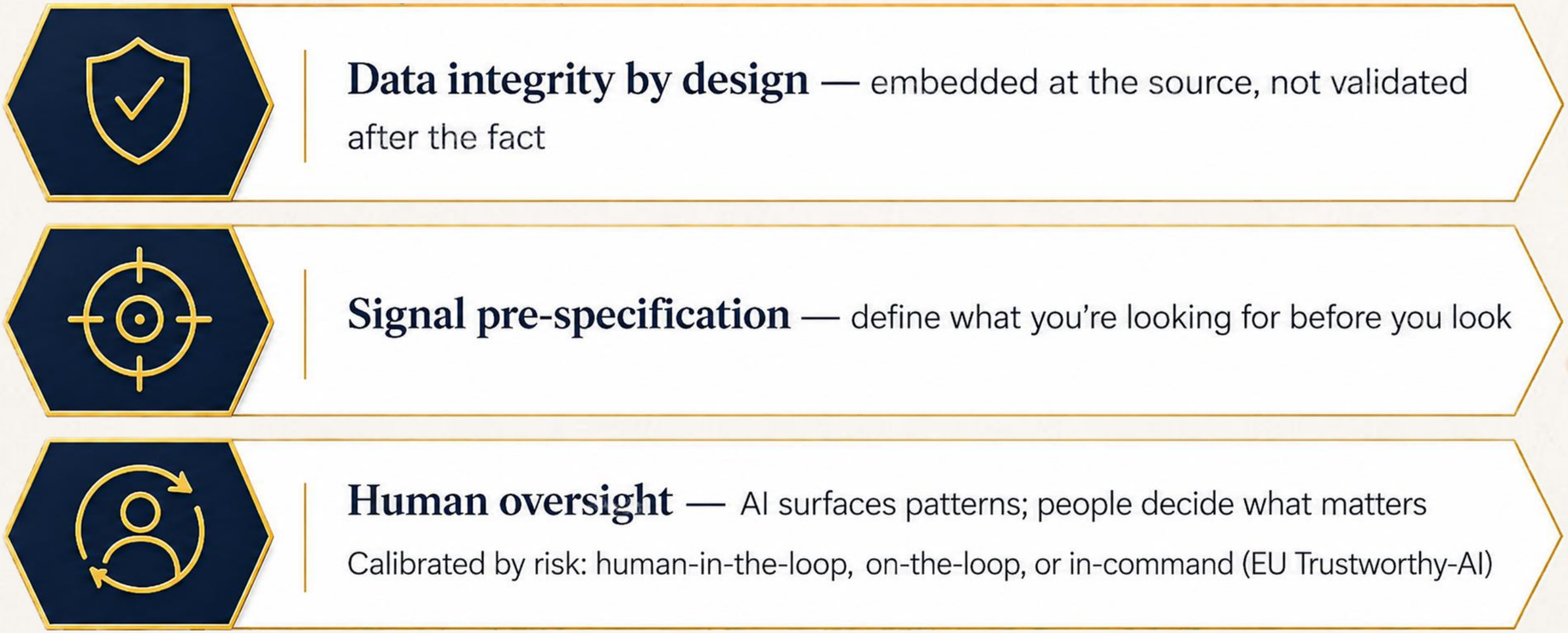
The Shift, Row by Row

WORKSTREAM	LEGACY STATE	AI-READY STATE	ENABLING STANDARD / ASSET
1 **Protocol authoring**	Word template; PDF final	**Machine-readable** digital protocol; single source of truth	ICH M11 + CDISC USDM v4
2 **Amendments**	Redlines; manual downstream propagation	**Structured diff;** systems reconfigure from the model	USDM versioning + HL7 Vulcan UDP
3 **Site selection**	Spreadsheets, relationships, gut	**Fit-for-purpose** RWD cohort feasibility	ICH E8(R1) CTQ + RWD frameworks
4 **Data capture**	eCRF re-keyed from source; late cleaning	**Pre-specified** edit checks; computable eligibility	CDISC CDASH + Dataset-JSON
5 **Monitoring**	100% SDV on scheduled visits	**Signal-driven** KRI/QTL review	ICH E6(R3) Annex 1 RBQM
6 **Safety review**	Periodic aggregate review; narrative drafting	**Continuous** signal detection under human sign-off	E2B(R3) + pre-specified thresholds
7 **TMF**	Repository; inspection-driven checks	**Event-driven** metadata connected to protocol	TMF terminology / integration
8 **Submission**	eCTD assembly from parallel streams	**Re-use** from digital protocol and analysis results	FDA RTOR + PMDA eCTD / e-study data

FASTER DATA RAISES THE BAR

Why Governance Matters More, Not Less

Data governance is designed in, not bolted on — the right data, generated, structured, connected, and traceable from the beginning.



Earlier access to accumulating data does not reduce the need for governance. It raises it.

PRACTICAL IMPLEMENTATION EXPERIENCE

Lessons From Building It

Drawn from NSF and Amarex's collaboration with Microsoft, applying Azure AI to clinical operations.

1

Readiness precedes technology

The operating model must be ready before AI can be effective.

2

Governance is the foundation, not the finish

Governance designed at the start outperforms what is bolted on later.

3

The operating model decides the outcome

The algorithm amplifies what already exists — it does not create it.

A successful pilot is not an enterprise capability.
Build for production, not proof of concept.

Microsoft NSF AMAREX

DIAGNOSTIC — NOT A SURVEY

Where Are You — Honestly?

Readiness is not where you aspire to be. It's the lowest layer you can actually operate.

Readiness question	Aware	Building	Ready
L1 Is quality designed in, or inspected in?	QbD in SOPs	CTQs defined per protocol	CTQs drive monitoring & IDMC triggers
L2 Is the protocol an asset, or a document?	Word/PDF template	M11 fields mapped	USDM object feeds downstream
L3 Is your data interoperable and pre-specified?	Data lake exists	Lineage for key assets	Source-to-submission traceable
L4 Can oversight run on live data?	AI pilots discussed	1–2 governed use cases	Production use cases with ROI

Download the 4-Layer AI Readiness Scorecard

THE PATH FORWARD

Build Before You Buy

1

Build the foundation

Start at Layer 1 — quality-by-design is the prerequisite, not the option.

2

Close the gap

Assess honestly; the readiness gap is an operating-model problem, not a technology one.

3

Modernize one trial at a time

Design operating models, not isolated workflows. Govern before you automate.

AI is not something you buy.

It is a capability you build.

The question is not whether clinical development becomes AI-ready — it is whether your organization leads or follows.

Questions & Discussion

Thank you

Let's build readiness—not just awareness.

Kush Dhody, MD, MS · President, Amarex Clinical Research (an NSF Company)

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Let’s continue the conversation:

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