The 4-Layer AI-Readiness Scorecard

Inside the Stack: Anatomy & Self-Assessment for AI-Ready Clinical Development

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> *"Awareness is a starting point. Readiness is an operating capability. Your readiness is defined by your weakest foundational layer — so start where the foundation is thinnest."*

The four layers at a glance

Each layer enables the one above it. Reach for Layer 4 on a Layer 1 foundation and the distance between them is your readiness gap. Your readiness is defined by your weakest foundational layer.

Layer 1 · Quality-by-Design Operating Model — Quality designed in, not inspected in. Critical-to-quality factors, risk-proportionate oversight, and decision rights are defined before the protocol is written. Enabled by ICH E8(R1) and E6(R3).

Layer 2 · Structured Protocol & Standards — The protocol becomes a machine-readable asset, not a static document. One change reconfigures downstream systems instead of triggering re-keying. Enabled by ICH M11 and CDISC USDM.

Layer 3 · Governed, Interoperable Data — Data AI can safely act on. Every value has a source, a lineage, an owner, and a use policy. Enabled by CDISC SDTM/ADaM, Dataset-JSON, and FAIR.

Layer 4 · AI-Enabled Execution — A deliberate portfolio of use cases, not a procurement. It only compounds where Layers 1–3 are strong underneath it. Enabled by E6(R3) validated-systems principles and internal AI governance.

How to use this scorecard

This companion to the four-question on-stage diagnostic goes one level deeper. For each of the four readiness layers it sets out the anatomy — components, inputs, outputs, and the standards that already exist (each linked to its source) — and a short self-assessment. For each question, mark where you are today: Aware, Building, or Ready. Your overall readiness is set by your weakest layer.

Use it alongside the two focused instruments — the ICH M11 + E6(R3) Protocol Readiness Scorecard (10 points) and the RTCT Readiness Scorecard (5 questions) — all at kushdhody.com/scorecard.

HOW TO INTERPRET YOUR RESULT

- Your organization is only as ready as the weakest layer it can reliably operate.
- If any foundational layer is marked Aware, treat the overall system as Aware.
- If Layers 1-3 are Building but Layer 4 is Ready, the AI use case is not yet production-ready.
- Use the lowest-scoring layer as your starting point.

LAYER 1 — QUALITY-BY-DESIGN OPERATING MODEL

Quality Designed In, Not Inspected In

QbD is an operating model with named components — not a phrase in an SOP.

COMPONENTS

- Critical-to-quality (CTQ) factors
- Risk assessment framework
- Integrated quality management system
- RBQM operating rhythm
- Escalation and IDMC triggers
- Quality culture

INPUTS

- Protocol objectives
- Patient-population risk profile
- Regulatory context
- Prior-study learnings

OUTPUTS

- Pre-specified CTQs
- Risk-proportionate monitoring plan
- Defined QTLs and KRIs
- Decision rights

STANDARDS & TOOLS

- ICH E8(R1) General Considerations
- ICH E6(R3) Principles + Annex 1
- E6(R3) Annex 2 (Step 4, Jun 2026)

Where are you — honestly?

Readiness question	Aware	Building	Ready
Have you named the critical-to-quality factors in each of your last three protocols?	☐	☐	☐
Is your monitoring plan proportionate to those CTQs - can you point to the specific risks that changed the monitoring approach?	☐	☐	☐
Have you defined quality tolerance limits with pre-specified actions that trigger before a breach, not after?	☐	☐	☐
Does your governance model assign decision rights, not just establish committees?	☐	☐	☐

LAYER 2 — STRUCTURED PROTOCOL & STANDARDS

The Protocol as a Machine-Readable Asset

ICH M11 + USDM turns the protocol from prose into an operating object.

COMPONENTS

- ICH M11 CeSHarP template + technical spec
- CDISC USDM v4 logical model
- Controlled terminology
- Schedule of Activities as the digital backbone
- Versioning & amendments as structured diffs

INPUTS

- Study design decisions
- Endpoints
- Populations
- Interventions
- Eligibility criteria

OUTPUTS

- A structured protocol object that downstream systems (EDC, IRT, site systems, submission) can consume without re-keying

STANDARDS & TOOLS

- ICH M11 (Step 4, 19 Nov 2025)
- CDISC Digital Data Flow / USDM
- FDA M11 finalization (May 2026)
- HL7 Vulcan Digital Protocol (UDP)

Where are you — honestly?

Readiness question	Aware	Building	Ready
Does a single change to the protocol reconfigure your downstream systems automatically - or does someone re-key it?	☐	☐	☐
Does your Schedule of Activities function as a reusable digital backbone for downstream systems - or is it still recreated manually?	☐	☐	☐
When a protocol amendment occurs, can your team identify the structured-data delta and downstream impact before systems are rebuilt?	☐	☐	☐

LAYER 3 — GOVERNED, INTEROPERABLE DATA

Data AI Can Safely Act On

Every value needs a source, a lineage, an owner, and a use policy.

COMPONENTS

- Data governance model
- FAIR principles (Findable, Accessible, Interoperable, Reusable)
- Master data management
- Subject / site / study identity
- Data lineage & provenance
- Interoperability layer / common data models

INPUTS

- Clinical data streams
- Operational data streams
- Safety data
- Real-world data
- Source-system metadata

OUTPUTS

- A governed data plane where every value has a source, a lineage, an owner, and a use policy

STANDARDS & TOOLS

- CDISC SDTM / ADaM
- Dataset-JSON
- FAIR data principles (GO FAIR)
- PMDA electronic study data
- IDMP product / substance identity

Where are you — honestly?

Readiness question	Aware	Building	Ready
For any value in your clinical database, can you answer "where did this data point come from, and who is accountable for it?"	☐	☐	☐
Is your data findable and accessible across trials - or does every study rebuild its own data model?	☐	☐	☐
When you submit to a regulatory body, are you assembling structured data from a governed layer - or generating datasets for the submission event?	☐	☐	☐

LAYER 4 — AI-ENABLED EXECUTION

A Portfolio, Not a Procurement

AI-enabled execution is a deliberate use-case portfolio, not a tool inventory.

COMPONENTS

- Protocol authoring copilots
- Site & patient matching
- AI-assisted RBQM triage
- Safety signal monitoring support
- TMF metadata assistants
- Submission content assembly & QC

INPUTS

- The outputs of Layers 1–3:
  a structured protocol,
  governed data,
  a defined risk framework

OUTPUTS

- Cycle-time compression
- Higher-quality evidence at lower marginal cost
- Human decision-makers with better inputs

STANDARDS & TOOLS

- ICH E6(R3) validated systems & data integrity
- Internal AI governance (model cards, validation, monitoring)
- Human-in-the-loop by design

Where are you — honestly?

Readiness question	Aware	Building	Ready
For each Layer 4 use case you have selected, are Layers 1, 2, and 3 strong enough underneath it that the investment will actually compound?	☐	☐	☐
For each AI use case, have you documented the intended use, input data, decision owner, human-review step, and audit trail?	☐	☐	☐
Are selected AI use cases tied to measurable operating outcomes, not just pilot completion?	☐	☐	☐

About the author

Kush Dhody, M.D., M.S. is a physician-scientist and clinical development executive with more than 20 years of experience leading global clinical programs, protocol design, regulatory strategy, and clinical operations across multiple therapeutic areas. He currently serves as President of Amarex Clinical Research, LLC, An NSF Company, and contributes to AI-enabled regulatory and quality workflow innovation, including the NSF/Microsoft Azure initiative featured as a Microsoft customer story.

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