

# The Protocol Readiness Scorecard

ICH M11 + ICH E6(R3): A 10-Point Self-Assessment for Clinical Development Teams

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“M11 gives the protocol structure. E6(R3) gives it the quality discipline. The readiness question is whether your organization can operate both as one system.

## How to use this scorecard

Score your program honestly: award 1 point for each clear Yes. Use the scoring rubric at the end to benchmark your current operating model. This tool is designed for governance reviews, executive offsites, and M11/E6(R3) readiness workshops.

Program / Protocol: \_\_\_\_\_

Assessment Date: \_\_\_\_\_

Reviewer / Team: \_\_\_\_\_

Total Score: \_\_\_\_\_ / 10

Category	Readiness point	Question	Response
Protocol Design & Quality Planning	1. CtQ workshop before authoring	Have we run a Critical-to-Quality workshop before protocol authoring and produced a CtQ register mapped to specific protocol sections?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	2. Objectives, endpoints & estimands	Have we modeled objectives, endpoints, and estimands as repeatable protocol components, applying the ICH E9(R1) estimand framework to each primary and key secondary endpoint?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	3. QTL linkage	Have we pre-specified Quality Tolerance Limits, linked to CtQ factors, and paired with escalation pathways consistent with the E6(R3) quality management approach?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Structured Content & Data Standards	4. Structured authoring environment	Are we authoring in, or transitioning toward, a CeSHarP-conformant, USDM-compatible environment rather than treating Word as the long-term system of record?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	5. Controlled terminology ownership	Do we have a terminology steward and a structured-content editor on the protocol team alongside the medical writer?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	6. Protocol as dataset	Do we version-control the protocol as a structured data asset, not just a document, with a named owner for the structured-content lifecycle?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Category	Readiness point	Question	Response
Operational Interoperability	7. Downstream reuse	Does our protocol data populate EDC build, IRB/ethics submission, CTMS setup, and other downstream workflows without re-keying the same information?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	8. Amendment impact	Do we understand the structured-data delta of a typical amendment, not just the tracked-changes count, so downstream rework can be forecast?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Vendor & Governance Readiness	9. Vendor evidence	Have CROs and technology partners demonstrated M11/USDM readiness using a real protocol, not only a roadmap slide or sales demonstration?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	10. Cross-functional governance	Do we operate a joint M11 + E6(R3) governance forum across medical writing, biostatistics, clinical operations, data management, regulatory, quality, and technology?	<input type="checkbox"/> Yes <input type="checkbox"/> No

### Scoring rubric

8 - 10	You are operating in the new model. Focus on continuous improvement and portfolio scaling.
5 - 7	You have useful components, but not yet a system. Expect rework at submission or during downstream study setup.
0 - 4	You are running a 20th-century document workflow against a 21st-century data-exchange expectation. Start with a CtQ-first pilot this quarter.

### 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, regulatory strategy, and CRO 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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