The RTCT Readiness Scorecard

FDA Real-Time Clinical Trials: A 5-Question Self-Assessment for Clinical Development Teams

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> “Real-time clinical trials are not about faster data transfer. They are about whether your organization can produce regulator-ready signals earlier — without weakening the scientific discipline that makes clinical trials credible.

How to use this scorecard

This scorecard translates the five practical RTCT readiness questions into a more formal governance and operating-model self-assessment.

Score your program honestly. Award 1 point for each clear Yes, ½ point for Partial, and 0 for No. Use the scoring rubric on Page 2 to benchmark your current operating model. This instrument is designed for governance reviews, sponsor-CRO joint operating committees, and RTCT readiness workshops.

Program / Protocol: _____

Assessment Date: _____

Reviewer / Team: _____

Total Score: _____ / 5

Category	Readiness Domain	Question	Response
Signal Design & Statistical Discipline	1. Signal pre-specification	Have we prospectively defined the safety, efficacy, and operational signals that may be appropriate for early regulatory visibility, including thresholds, escalation pathways, and named medical and statistical owners before first patient dosed?	☐ Yes ☐ Partial ☐ No
	2. Endpoint & analysis interpretation	Have we defined how each critical endpoint or signal will be interpreted, including estimands where applicable, interim review safeguards, missing-data handling, and controls to avoid inappropriate unblinding or Type I error inflation?	☐ Yes ☐ Partial ☐ No
Data Traceability & Quality	3. Data traceability & quality at source	Can every signal-bearing data element be traced from source or eSource through EDC, eCOA, laboratory, imaging, wearable, or other data feeds to the regulator-facing view, with audit trails, validation checks, QTLs, and RBQM oversight?	☐ Yes ☐ Partial ☐ No

Category	Readiness Domain	Question	Response
Governance & Partnership	4. Cross-functional governance	Do we have a defined RTCT governance forum spanning medical, biostatistics, clinical operations, data management, regulatory, quality, safety, and technology, with agreed cadence, decision rights, and escalation rules before first patient dosed?	☐ Yes ☐ Partial ☐ No
	5. Sponsor-CRO & partner integration	Have the sponsor, CRO, and technology partners agreed on signal ownership, data-sharing architecture, joint decision rights, regulatory communication pathways, and documentation expectations using an actual protocol, not only a platform presentation or roadmap commitment?	☐ Yes ☐ Partial ☐ No

Scoring rubric

4.5 – 5	RTCT pilot-ready You have a defined signal model, traceable data flow, governance structure, and integrated operating model. Focus next on pilot selection, regulator engagement strategy, and continuous-learning loops.
3 – 4	Foundation present, integration incomplete You have meaningful components, but they are not yet functioning as an integrated system. Expect rework when the first signals are generated. Select one active or planned program to test RTCT readiness before scaling.
1.5 – 2.5	Early readiness You have some enabling capabilities, but the model is not yet operationally reliable. Start with signal pre-specification, data traceability mapping, and a cross-functional governance forum before investing heavily in the technology layer.
0 – 1	Not yet RTCT-ready Your current operating model is optimized for periodic review and database-lock-driven workflows. Begin with foundational work on protocol structure, signal ownership, RBQM maturity, and decision governance.

Note: This scorecard is intended as a governance and readiness discussion tool. It is not a regulatory compliance checklist and should be adapted to the specific product, phase, indication, trial design, and health authority context.

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 is involved in AI-enabled regulatory and quality workflow innovation, including the NSF/Microsoft Azure initiative featured as a Microsoft customer story.

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