Medical Writers as Strategic Partners in RBQM

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Agenda

- Why involve medical writers early?
- Conceptual and Regulatory Alignment
- Workflow, data, and medical writer's role
- QbD in Protocol Development
- Risk Management to Risk Reporting
- Strategic Partnerships: Stakeholder interfaces
- Leveraging AI-integration and Automation
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Why involve medical writers early?

- Protocol design and risk discussions
- Positioning RBQM as integral to documentation strategy
- Setting expectations for collaboration across functions
- Traceability and consistency across documents for regulatory trust and compliance

Writers are the continuity link between design intent and regulatory reporting

The protocol is the risk blueprint

Eligibility, endpoints and visit burden set the risks. Writers read the whole document and see inconsistencies and complexity before finalisation.

Fewer downstream surprises

Clear critical-to-quality (CtQ) factors reduce avoidable amendments and deviations that later need explaining in the CSR.

One consistent story

Rationale, risk controls and reported outcomes stay aligned across protocol, monitoring plan, SAP and CSR.

Conceptual and Regulatory Alignment

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Guidance	RBQM-relevant expectation	Writer touchpoint
ICH E6(R3)	Quality by design, proportionate risk-based approach, CtQ factors, documented quality management	Embedding and consistency across protocol and CSR sections
ICH E8(R1)	CtQ factors identified at design stage with stakeholder input	Justification of design choices
ICH E9(R1)	Estimands, intercurrent events, missing data strategy	Objectives and estimand wording aligned with SAP
ICH E3	CSR risk reporting including data quality assurance and protocol deviations	CSR Sec. 9.6, 10.2, Appendix 16.2.2
ICH M11	Harmonised structured protocol template and technical specification	Standard placement and reuse of content
EMA reflection paper on RBQM (2013)	Risk-proportionate quality management; critical processes and data identified up front	Risk rationale in protocol; quality management summary in CSR
FDA guidance on risk-based monitoring (2013)	Monitoring tailored to trial risks, incl. centralised monitoring	Monitoring approach and deviations reported in CSR
TransCelerate RBQM guidance	RBQM framework, risk assessment tool (RACT), KRIs, central monitoring, issue management	RACT inputs to protocol; KRI and issue outcomes to CSR

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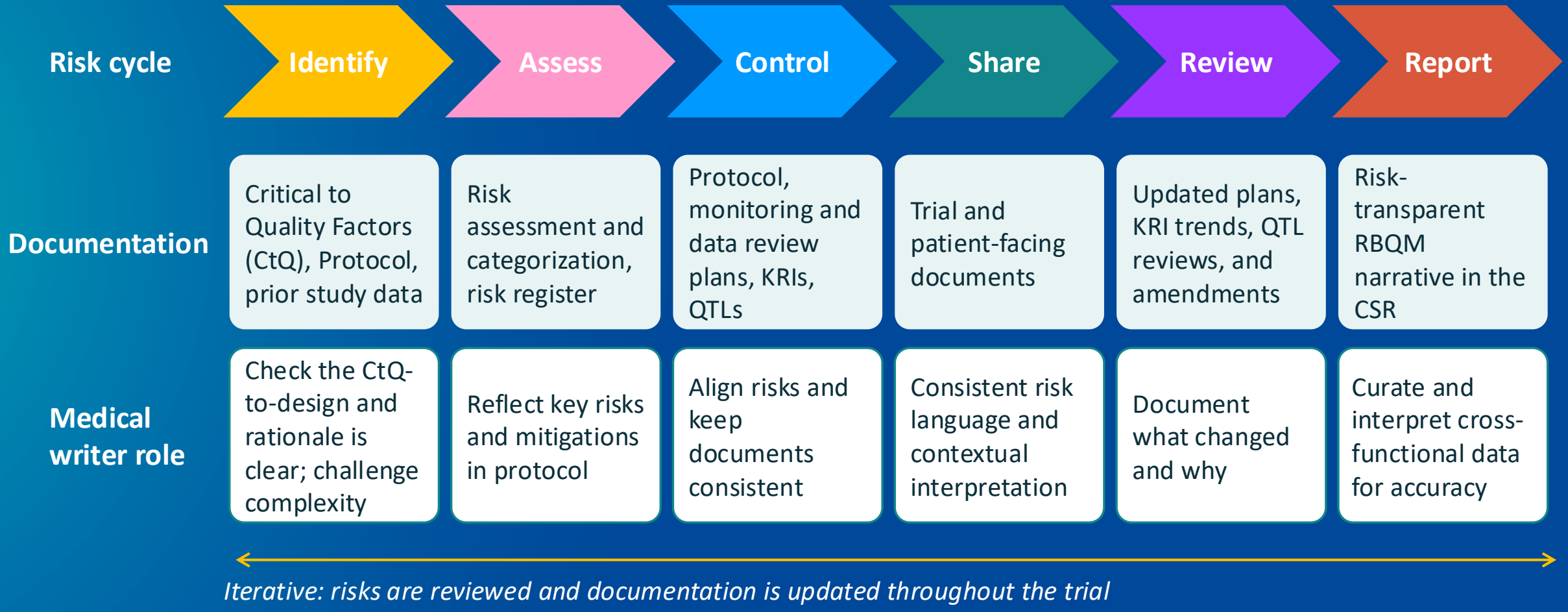
Workflow, Data, and Medical Writer's Role



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Quality by Design in Protocol Development

Per ICH E6 R3 -

- **Risk-proportionate adaptability into the protocol with prospective design and factors.**
- **Clear, concise and operationally feasible protocol.**
- **Simplify visit schedules and study procedures to reduce unnecessary participant and site burden.**
- **Flexibility and proactive risk management throughout the trial.**

1	**Critical-to-quality factors**	*e.g. Reliable primary endpoint data*
2	**Risks to those factors**	*e.g. Missed or late assessments*
3	**Design and control decisions**	*e.g. Streamlined schedule, KRI and QTL*
4	**Protocol documentation**	*e.g. Rationale, monitoring approach, QTL*

Medical writer's QbD checks (few examples)

- **Traceability**: Study Objectives, Endpoints, Eligibility criteria to applicable CtQ factors and thresholds
- **Alignment:** Procedures, assessments, trial documentation with CtQ/QTL and balance scientific need with minimal patient burden
- **Consistency:** Definitions, risk terms, and thresholds across documents
- **Narrative coherence and risk transparency**: (CtQ → QTL → Mitigation → Oversight)

Potential Value-Addition of Medical Writers in Risk Discussions

Therapeutic area context

Disease-specific risks, standard of care, endpoint and population norms from same Sponsor or published trials.

Same-drug or device studies

Investigator's brochure, earlier protocols and CSRs, DMC outputs, safety signals.

Regulatory feedback

Scientific advice, agency queries and prior review comments.

Lessons learned

Monitoring findings and risk narratives from comparable trials.

Site and patient burden

Feedback on feasibility, visit load and procedures.

Historical data

Past deviation patterns, screen failure, dropout and amendment history.



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Risk management to Risk Reporting







Medical writers curate and interpret cross-functional data into credible risk reporting

Information required by the medical writer to draft accurate and transparent risk-narrative in CSR:

- Study-specific CtQs with corresponding parameters and QTLs
- QTL Thresholds (primary upper and lower limits)
  - Justification and rationale of the parameter
  - Risk review frequency
  - Acceptable ranges (QTLs) breach.
  - QTLs that were important protocol deviations (report details in appropriate CSR section).
  - Quality issue, impact, and risk mitigation done for breached limits.

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Strategic Partnerships

What is required for successful cross-functional collaborations

Data to the Medical Writer: What, When and How

What: data input in protocol and CSR	Stakeholders	How: source document examples and format	When: Availability for Protocol/CSR
CtQ factors and critical processes / data	Clinical science, RBQM lead, Biostatistics	Risk workshop output and RACT (spreadsheet or tool export); CtQ factor list	Concept to protocol synopsis
Risk evaluation and control strategy for protocol rationale and oversight text	Clinical operations, Data management, Biostatistics, Safety	Risk register / integrated quality risk management plan (report); draft monitoring strategy	Protocol drafting
KRI and acceptable range (QTL) definitions	RBQM, Biostatistics, Programming	KRI / QTL specification (document); monitoring and data review plans pdfs	Before first participant in
Risk review outcomes, signals and issues	Central monitoring, Data surveillance, Clinical operations	KRI dashboards and trend reports; risk review minutes; issue and escalation log	Ongoing; snapshot at interim and pre-lock
Important deviations and acceptable range excursions	Clinical operations, Data management, Biostatistics, QA	Deviation listings and summary tables (Appendix 16.2.2); blinded data review minutes; CAPA log	Before database lock and draft TLFs
Risk reporting: quality management approach and remedial actions	Biostatistics, RBQM / Quality, Safety, QA	End-of-study RBQM summary report; quality issues, quality breach records (root cause analysis and mitigation);TMF index	CSR drafting (E6(R3) Sec. 3.10 risk reporting; E3 Sec. 9.6)

Stakeholder Interfaces

Clinical Science
CtQ rationale, endpoints

Biostatistics
SAP, TLFs, QTL analyses

RBQM / Central Monitoring
Risk assessment, KRIs, QTLs, Data surveillance



Clinical Operations
Site performance, deviations

Quality Assurance
Audit and compliance

Data Management
eCRF Completion guidelines, Data listings

Regulatory Affairs
Submission expectations

Patient Safety
Safety signals, narratives

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Leveraging AI-integration and Automation

	Automation enables	AI Augments	The writer's strategic role
Protocol development Quality by Design	• Structured, template-driven content replaces free-text files • Objectives and endpoints authored once, reused downstream • Review, comments and versions in one workflow	• Drafts sections from templates and prior protocols • Checks objectives, endpoints and schedule for consistency • Flags design elements that add burden or risk	• CtQ factors into clear protocol design choices • Challenges avoidable complexity before first patient in • Ensures CtQ traceable to its risk controls
CSR authoring Risk reporting	• Source-linked blocks show where each statement came from • Automated QC replaces manual number checking • KRI and QTL data still arrive by export or custom feed	• Drafts CSR sections from protocol, SAP and TLFs • Summarizes deviation and monitoring listings • Cross-checks numbers and terms against source	• Contextual and scientific reporting • Links outcomes back to CtQ factors and the risk assessment • Verifies AI drafts and owns accuracy, consistency and narration

Accountability **Ownership** **AI-Governance** **Leadership oversight** **Regulatory compliance**

Positioning to Strategic Partners

- ✓ **Protocol Precision & Quality by Design (QbD)**
- ✓ **Risk Identification & Traceability**
- ✓ **Cross-Functional Collaboration**
- ✓ **Regulatory Alignment**
- ✓ **Data-driven Efficiency & Compliance**
- ✓ **Strategic Positioning** from being "end-stage authors" to *strategic partners*, shaping how risks are contextualized and communicated to regulators and stakeholders.



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