

Equity as a Dimension of Quality

Embedding Equity into RBQM

From regulatory expectation → operational signal → inspection-ready evidence

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Equity Is a Dimension of Quality

When equity gaps exist:

- Underrepresentation
- Access barriers
- Health literacy challenges

They directly impact:

- Data integrity
- Trial execution
- Interpretability of outcomes

So, equity must move:

From aspiration to:

→measurable risk

→defensible, inspection-ready evidence

Therefore:

Equity must be managed as a quality risk

Why Equity Is No Longer Optional

Regulatory Signals

- **ICH E6(R3)** — risk-based quality systems
- **ICH E8(R1)** — population relevance by design
- **FDA** — measurable diversity plans
- **EMA** — justify representativeness
- **Global bodies (AMA/WHO/CIOMS)** — ethics & engagement expectations

So what?

Equity is now:

- ✓ A regulatory expectation
- ✓ A quality system requirement
- ✓ An inspection topic
- ✓ A funder mandate

The Gap in Traditional RBQM

What RBQM already does well

- ✓ Centralized monitoring
- ✓ Safety/data integrity signals
- ✓ SDV optimization

Where RBQM falls short

- ✗ Representativeness trends
- ✗ Access/literacy barriers
- ✗ Differential dropout signals

Why this matters

These are leading indicators of downstream quality failures and inspection risk.

The real gap isn't intent — it's operationalization.

Turning Equity Into Quality Signals

Equity Risk → KRI → QTL → Mitigation → Evidence

Make it a signal by:

- Define risk
- Measure (KRI)
- Control (QTL)
- Defend (inspection)

Examples

Risk Area	KRI	QTL
Diversity	Enrollment vs epidemiology	$\geq 20\%$ URP
Access	Travel or missed visits	≤ 50 miles
Retention	Subgroup dropout	$\leq 10\%$ diff

Inspection-ready equity = measurable controls in RBQM

From Signal to Action: Central Monitoring in Practice

Monitor

- Trends over time
- Direction & rate of change
- Site vs study patterns
- Subgroup differences

Act

- Targeted site support
- Community/satellite sites
- Flexible visits & scheduling support
- Plain-language materials

Intervene early — before QTL breach

Why it's inspection-ready

- Protects participants
- Improves data reliability
- Aligns with ICH E6(R3)
- Documents rationale

From Inspection Readiness to Strategic Value

Inspectors expect:

- Defined risks
- Ongoing monitoring
- Documented action

This framework delivers:

- Traceability
- Clear decisions
- Defensible oversight

Strategic value

Sponsors — stronger, defensible submissions

CROs — differentiated, inspection-ready capability

Industry — more representative, actionable evidence

Participants — more relevant, trustworthy trials

RBQM evolves from monitoring data to stewarding trial quality.

Equity as Quality, Quality as Outcomes



Equity risks are quality risks.



RBQM tools work — when used intentionally.



Defensible quality comes from measured, documented action.

Result

- ✓ Better participant outcomes
- ✓ Stronger evidence
- ✓ Fewer inspection surprises

**When equity is measurable, it becomes manageable.
When it is manageable, it becomes defensible.**