CARE2DATA
BRIDGING QUALITY | Kwalify™ CLINICAL DATA INTELLIGENCE PLATFORM

Stop Checking Data. Start Understanding It.

Kwalify™ operationalizes CARE2DATA's knowledge-driven validation framework — embedding semantic intelligence across linked clinical datasets to strengthen accuracy, traceability, and regulatory readiness before submission.

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PLATFORM CAPABILITIES

Clinical trials generate deeply interconnected datasets across subjects, treatments, outcomes, and safety signals. Validation tools that rely on **static rule execution are no longer sufficient**. Kwalify™ introduces a **semantic intelligence layer** — combining contextual reasoning, anomaly verification, and explainable AI to deliver knowledge-driven assurance, not just rule compliance. It reduces manual debugging time where individual errors take **30 minutes to 2 hours** to resolve.

TRADITIONAL VALIDATION

Most tools available today:

- ✗ Execute static rule libraries
- ✗ Return pass/fail flags only
- ✗ Escalate investigation to humans
- ✗ Provide limited cross-dataset reasoning

They detect symptoms. They do not diagnose causes.

KWALIFY™ INTELLIGENCE

Kwalify™ delivers:

- ✓ Semantic, context-aware validation across linked datasets
- ✓ Explainable insights — not just pass/fail outcomes
- ✓ Automated root cause analysis with AI-assisted reasoning
- ✓ Cross-domain intelligence and impact-aware validation

It connects signals. It diagnoses causes.

THE INTELLIGENCE DIFFERENCE

By combining **semantic reasoning**, anomaly verification, and contextual validation across linked datasets, Kwalify™ transforms validation from checklist execution into **knowledge-driven assurance** — enabling teams to understand the cause, impact, and resolution of data inconsistencies before submission.

ENTERPRISE IMPACT

Strengthened Data Integrity
Identify discrepancies at origin — before QA or regulatory review.

Faster Validation Cycles
AI-assisted investigation reduces manual debugging and accelerates resolution.

Reduced Regulatory Queries
Explainable AI validation outputs improve submission clarity and traceability.

Enterprise Scalability
Scales across therapeutic areas, studies, and global programs without added complexity.

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How Kwalify™ Operates

Ingestion (DATASET UPLOAD) → **Rule Validation** (FDA & CDISC) → **Cross-Domain** (CONTEXTUAL CHECK) → **Root Cause AI** (EXPLAINABLE INSIGHT) → **Anomaly Detection** (DATA VERIFICATION)

Platform Capabilities

CAPABILITY	WHAT IT DELIVERS	KEY OUTCOME
Regulatory Rule Validation	FDA & CDISC rule libraries · Conformance checks · Standard format support (SAS, CSV)	Submission-compliant datasets
Cross-Domain Validation	AE · Subject lifecycle · Treatment exposure · Safety signals & endpoints	Context-aware data integrity
AI Root Cause Analysis	Issue summary · Root cause · Regulatory impact · Step-by-step remediation	Faster investigation & resolution
Anomaly Detection	Temporal inconsistencies · Lifecycle contradictions · Sequence conflicts	True data integrity beyond rules
Validation Dashboard	Study progress · Domain violations · Compliance status · Trend analysis	Centralized operational visibility

Designed For

- ✓ CRO Leadership — scale validation across sponsors
- ✓ Pharmaceutical & Biotech Sponsors — global submission confidence
- ✓ Clinical Data Managers & SAS Programmers — faster issue identification
- ✓ QA & Regulatory Teams — defensible, traceable validation outputs

High-Frequency SDTM Issues Resolved

93%	79%	67%	63%
LB DOMAIN	CROSS-DOMAIN	AE DOMAIN	DM DOMAIN
Missing Reference Ranges	**Unit Mismatches**	**Duplicate AE Events**	**Missing RFSTDTC**

Kwalify™ transforms clinical data validation from binary rule checking into **enterprise-grade, knowledge-driven quality assurance** — eliminating the systemic inefficiencies that slow clinical validation teams today and enabling organizations to submit with **greater accuracy, consistency, and regulatory defensibility**.

Ready to Experience Intelligent Validation?

Request an executive demonstration or schedule a technical deep dive with our team.

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