

SD08 - CLIQ

An AI-Native Framework for Unified Clinical Trial Data Quality Assurance

PHUSE US CONNECT 2026, Austin, Texas, USA
Monday 23rd March 2026

Transforming Clinical Data Quality Through AI-Native Intelligence

Care2Data transforms clinical trial data management through **Kwalify** — our intelligent validation & verification platform powered by the

CLIQ (Clinical Intelligence for Quality) framework

CLIQ combines clinical ontologies, knowledge graphs, and AI-native semantic reasoning to deliver validation that understands **clinical meaning**, not just data syntax.

CLIQ Framework = Clinical Ontologies + Knowledge Graphs + Semantic AI

What Kwalify Delivers Through CLIQ?



Semantic Intelligence

- ✓ CLIQ ontologies encode 25+ yrs expertise
- ✓ Cross-domain reasoning & validation
- ✓ Biomedical logic understanding
- ✓ 78% manual effort reduction



Knowledge Graph Power

- ✓ Patient journey as semantic network
- ✓ Temporal relationship validation
- ✓ Multi-domain consistency checks
- ✓ Context-aware quality scoring

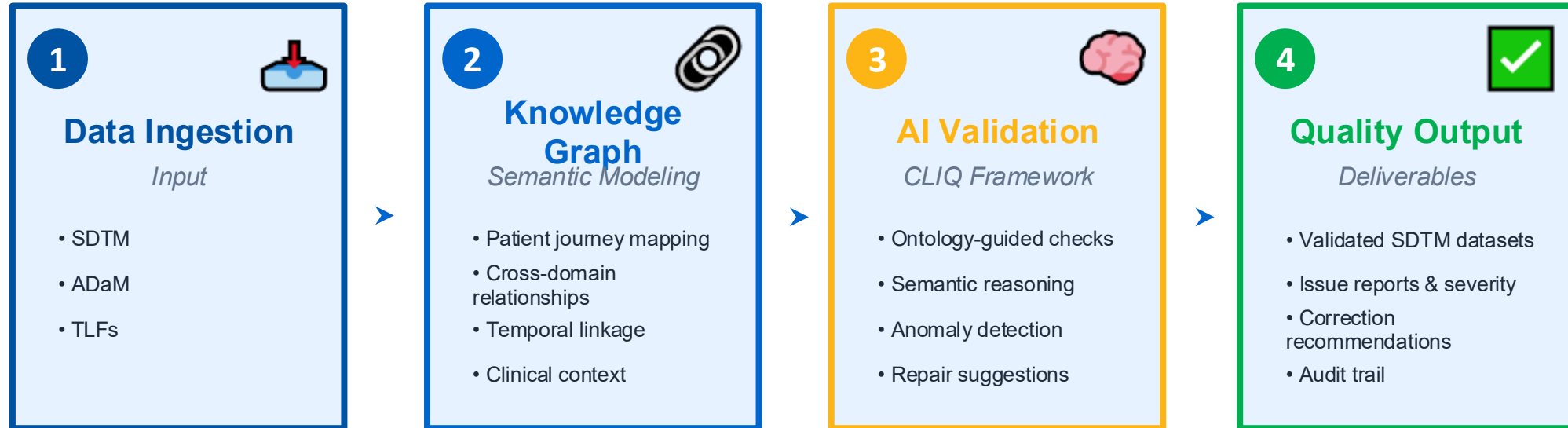


AI-Native Learning

- ✓ Schema-agnostic adaptation
- ✓ Learns from reference datasets
- ✓ 94% issue detection rate
- ✓ Explainable AI recommendations

Kwalify Functional Architecture

CLIQ-Powered End-to-End Validation Workflow



Foundation Layer: Clinical Ontologies + Knowledge Graphs + Machine Learning

Security & Compliance: 21 CFR Part 11, GDPR

Key Users:

Data Managers

Clinical
Programmers

Biostatisticians

Medical
Reviewers

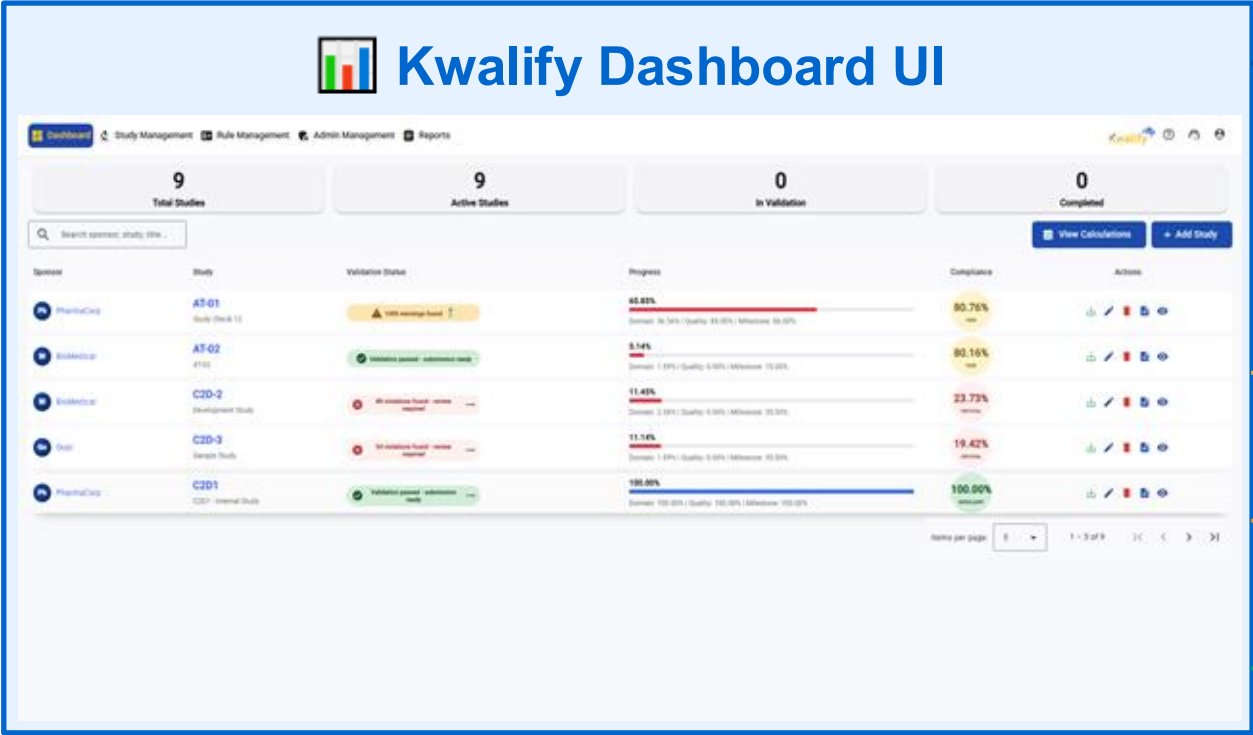
QC Analysts

Regulatory
Affairs

Kwalify User Interface

Intuitive Design for Clinical Data Professionals





Kwalify Dashboard UI

9 Total Studies | 9 Active Studies | 0 In Validation | 0 Completed

Sponsor	Study	Validation Status	Progress	Completion	Actions
Pharmacia	A7-01	100% message based	85.83%	80.76%	[Icons]
Novartis	A7-02	100% message based	5.14%	80.16%	[Icons]
Novartis	C2D-2	40% message based	11.48%	23.73%	[Icons]
Novartis	C2D-3	30% message based	11.54%	19.42%	[Icons]
Pharmacia	C2D1	100% message based	100.00%	100.00%	[Icons]

Study Selection

Data Upload

Validation Engine

Issue Analysis

Reports & Export

Interactive walkthrough of key Kwalify features

 **LIVE DEMONSTRATION**

Kwalify – SDTM Validation Dashboard



SDTM Validation Dashboard

Study Validation

Rule Management

Admin Management

Reports

Kwalify

?

6

Total Studies

6

Active Studies

5

In Validation

1

Completed

Q

Search sponsor, study, title...

View Calculations

+ Add Study

Sponsor	Study	Study Dataset Upload	Validation Status	Progress	Compliance	Actions
Ph PharmaCorp	BD-P1 BD-P1	⬆	✖ 22 violations found - review required ✔ 3 resolved ⬆	42.78% Domain: 46.43% Quality: 25.71% Milestone: 55%	66.71% POOR	✎ ✖ 📄
Ph PharmaCorp	BD-SAS BD-SAS	⬆	✖ 22 violations found - review required ➡	34.78% Domain: 60.71% Quality: 0% Milestone: 35%	66.28% POOR	✎ ✖ 📄
Bi BioMedical	C2D-2 Development Study	⬆	✖ 16 violations found - review required ✔ 79 resolved ⬆	36.71% Domain: 9.09% Quality: 75.24% Milestone: 35%	69.47% POOR	✎ ✖ 📄
Go Gopi	C2D-3 Sample Study	⬆	✖ 15 violations found - review required ✖ 1 new issues ⬇	44.1% Domain: 7.69% Quality: 81.75% Milestone: 55%	69.79% POOR	✎ ✖ 📄
Ph PharmaCorp	C2D1 C2D1 - Internal Study	⬆	✔ Validation passed - submission ready ✔	100% Domain: 100% Quality: 100% Milestone: 100%	100% EXCELLENT	✎ ✖ 📄
Bi BioMedical	S-Test-3 S-Test-3	⬆	✖ 7 violations found - review required ➡	14.5% Domain: 10% Quality: 0% Milestone: 35%	75.97% FAIR	✎ ✖ 📄

Kwalify – Study Validation



[Home](#) / [Study Management](#) / [Study - BD-SAS](#) / [Validation](#)

Study

BD-SAS - BD-SAS

Sponsor

PharmaCorp

Phase

Phase II

Status

CRITICAL

Progress (%)

34.78

Compliance

66.28

Validation

Domain Details

Issue Details

Anomalies

Regulator

FDA

Start Validation

Run Anomaly Detection

Report

475

Rules Applied

44

Rules Failed

22

Violations

42

Warnings

6

Info

6824

Records Validated

Validation History

Run ID	User	Date	Rules Failed	Violations	Warnings	Info	Total Issues	Action
Run8	Swetha	17/02/2026, 11:56 am	44	22	42	6	70	
Run7	Swetha	17/02/2026, 11:29 am	44	22	42	6	70	
Run6	Swetha	16/02/2026, 09:02 am	44	22	44	6	72	
Run4	Giri	13/02/2026, 08:35 am	42	23	29	6	58	
Run2	Giri	13/02/2026, 06:33 am	42	23	29	6	58	
Run1	Minaz	10/02/2026, 11:31 am	36	23	10	6	39	

Items per page:

10

1 – 6 of 6

Kwalify – Study Validation Issue

Drill-down analysis

← EX →

🔍

Search by violations...

9 issues found ☐ Expand All

SD0005

✓ Duplicate value for --SEQ variable within USUBJID or POOLID 1 1

EX SEQ Uniqueness Check

SD1089

> --STDY variable value is imputed 1 1

SD1090

> Incorrect value for --STDY variable 1 1

SD1093

> --ENDY variable value is imputed 1 1

SD1094

> Incorrect value for --ENDY variable 1 1

SD1135

> Negative value of Study Day variable 2 2

SD1205

> EXSTDTC date is before RFXSTDTC 1 1

SD1352

> Duplicate records in domain 1 1

SD0005: Duplicate value for --SEQ variable within USUBJID or POOLID

Violation ⓘ 📄 📄

Domain: ALL Impact: Low Validation Category: Cross Field Dependency

The value of Sequence Number (--SEQ) variable must be unique for each record within a domain and within each Unique Subject Identifier (USUBJID) or Pool Identifier (POOLID) variables value when they are present in the domain. Exclusions are DO, DT, DU and DX domains.

Affected Records 12 affected

Record ID	USUBJID	EXSEQ	Field	Value
47	CTJ301UC201-S02-012	1	EXSEQ	1
			POOLID	Missing
			USUBJID	CTJ301UC201-S02-012
48	CTJ301UC201-S02-012	2	EXSEQ	2
			POOLID	Missing
			USUBJID	CTJ301UC201-S02-012
49	CTJ301UC201-S02-012	3	EXSEQ	3
			POOLID	Missing
			USUBJID	CTJ301UC201-S02-012
			EXSEQ	4

Analysis & Explanation

Duplicate value detected for the Sequence Number (EXSEQ) variable within a domain for the same USUBJID or POOLID. Per SDTM structural principles, EXSEQ functions as a record-level unique key within each subject (USUBJID) or pool (POOLID) context. Duplicate EXSEQ values indicate violation of intra-subject record uniqueness, compromising dataset structural integrity and relational traceability across SDTM domains (excluding DO, DT, DU, DX as per rule definition).

Root Cause

- Source domain date variables may be correctly mapped from source systems, but downstream transformation logic required to derive study-level variables is missing or incomplete.
- The sequence number (--SEQ) variable is expected to uniquely identify records within each domain and within each USUBJID or POOLID context. Duplicate values indicate violation of the SDTM intra-subject record uniqueness constraint.
- Incorrect manual entry of clinical or structural data values during data capture, transcription, or migration processes, resulting in inaccurate or duplicated SDTM variable values.

Impact Analysis

Recommended Fix

- Implement enforced uniqueness validation for EXSEQ within each USUBJID and POOLID during dataset generation.
- For data entry processes, introduce automated sequence assignment controls and duplicate detection checks.
- For programmatic derivations, revise transformation logic to ensure deterministic, incremental, and subject-scoped sequence generation, with pre-submission validation checks integrated into the ETL or SDTM conversion pipeline.

Example:

USUBJID =101, --SEQ =1, --TRT = Drug A; USUBJID =101, --SEQ =2, --TRT = Drug B

Related Errors

6 errors in other rules

- SD1089
- SD1090
- SD1093
- SD1094
- SD1205
- SD1352



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Thank You