

Strategy Before Systems. Intelligence at Every Stage.



Care2Data delivers six structured engagement models — from initial strategic consulting through knowledge model implementation, data quality governance, and full team enablement — designed to operationalise clinical data intelligence across the entire trial lifecycle.

Clinical data challenges rarely originate at submission. They accumulate across planning, design, execution, and integration — driven by **unclear assumptions, inconsistent standards alignment, and undefined criteria for submission readiness**. Care2Data's engagement framework addresses each phase with structured, knowledge-driven services that build on each other — ensuring every deliverable strengthens long-term data integrity, traceability, and regulatory defensibility.

THE CHALLENGE Most organisations address clinical data quality reactively — identifying issues at QA or submission review when correction costs are highest. Care2Data's engagement approach shifts this pattern: structural clarity is established early, validated under real conditions, and embedded as **operational intelligence** — reducing rework, regulatory queries, and submission delays.

SIX ENGAGEMENT MODELS

ENGAGEMENT 01
Solution Consulting
Strategy Before Systems

Establish structural clarity before system build begins. Care2Data maps clinical data flows, aligns assumptions with regulatory expectations, and defines defensible submission-readiness criteria.

ENGAGEMENT 02
Proof of Concepts
Validate Assumptions Early

PoCs are designed to expose structural weaknesses — not demonstrate features. Real clinical datasets are used to stress-test validation logic, traceability, and cross-domain consistency.

ENGAGEMENT 03
Design & Development
Built for Scrutiny

Regulatory-grade clinical data architecture engineered for inspection readiness — with embedded validation controls, CDISC-compliant pipelines, and end-to-end traceability from the ground up.

ENGAGEMENT 04
Data Quality Checking
Validation Is Governance

V&V of clinical trial data delivered through Kwalify™ — detection, classification, root-cause analysis, and audit-ready evidence documentation across the clinical trial lifecycle.

ENGAGEMENT 05
Knowledge Model
Knowledge as Infrastructure

Clinical definitions, mapping logic, and regulatory interpretations engineered as an active architectural layer — driving consistent interpretation, validation, and governance across systems.

ENGAGEMENT 06
Training & Handover
Ownership Is the Deliverable

Structured enablement through Care2Data's Build-Operate-Transfer (BOT) model — equipping teams to independently operate, defend, and scale clinical data intelligence systems.

Engagement Journey



Capability Overview

| ENGAGEMENT | WHAT IT DELIVERS | KEY OUTCOME |
|-----------------------------------|--|-----------------------------------|
| ● Solution Consulting | Data flow mapping · Regulatory alignment · Submission-readiness criteria · Semantic modelling | Structural clarity before build |
| ● Proof of Concepts | Real dataset testing · Assumption stress-testing · Traceability & lineage evaluation · Semantic gap analysis | Risk identified before go-live |
| ● Design & Development | Reg-grade architecture · Embedded V&V controls · CDISC-compliant pipelines · Audit-ready traceability | Systems built for inspection |
| ● Data Quality Checking | Kwalify™-powered V&V · Root-cause analysis · Issue lifecycle management · Submission readiness validation | Governed, defensible data quality |
| ● Knowledge Model | Ontology & taxonomy design · Mapping logic embedding · Validation rule integration · Metadata provenance | Knowledge as active intelligence |
| ● Training & Handover | Clinical data flow training · Kwalify™ enablement · Governance & lifecycle management · BOT model transfer | Full team independence |

Designed For

- ✓ Pharmaceutical & Biotech Sponsors — end-to-end clinical data governance
- ✓ CRO Leadership — scalable delivery across multiple sponsors and studies
- ✓ Clinical Data Managers — structured V&V with traceable outcomes
- ✓ Regulatory & QA Teams — defensible, audit-ready data at every stage
- ✓ IT & Data Architecture Teams — reg-grade system design and integration

Enterprise Value

- ✓ Structural clarity established before system build — reducing rework cycles
- ✓ Risk identified through PoCs before it becomes regulatory exposure
- ✓ Knowledge embedded as infrastructure — not locked in documents or individuals
- ✓ Submission-ready data quality with full traceability and audit evidence
- ✓ Teams enabled to independently operate and scale clinical intelligence systems

Care2Data's engagement framework transforms clinical data operations from **reactive quality management into proactive, knowledge-driven governance** — ensuring that structural integrity, regulatory defensibility, and operational scalability are embedded from the earliest stage of every clinical program through to **full team ownership and independent capability**.

Ready to Engage?

Speak to our team to identify which engagement model fits your current clinical data challenge.

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