

Simulate Clinical Data. Validate Without Risk.

4
KEY
CAPABILITIES

TrialGen™ enables the generation of statistically consistent, regulation-aware synthetic clinical datasets — allowing teams to test, validate, and refine workflows without exposure to sensitive patient data.

Clinical data teams often face a fundamental constraint — **real data is either unavailable, restricted, or incomplete** when it is needed most. TrialGen™ removes this dependency by enabling teams to simulate **realistic, CDISC-aligned clinical datasets on demand** and validate systems before real data is available. Built to support clinical trial simulations, system testing, and validation workflows across the full clinical data lifecycle.

THE CHALLENGE Without accessible synthetic data, validation workflows are delayed, testing relies on limited or non-representative datasets, edge cases remain untested until late stages, and privacy constraints restrict data usage across teams — resulting in systems validated **reactively, not proactively**.

KEY CAPABILITIES

CAPABILITY 01

Realistic Data Simulation

Generate synthetic datasets aligned with clinical standards — including CDISC structures, domains, and relationships — that faithfully replicate the statistical behaviour of real clinical trial data without compromising privacy or compliance.

CAPABILITY 02

Validation Readiness

Test validation rules, workflows, and data pipelines under fully simulated trial conditions — ensuring systems perform as expected before live deployment and enabling proactive, not reactive, quality assurance.

CAPABILITY 03

Privacy-Safe Data Environments

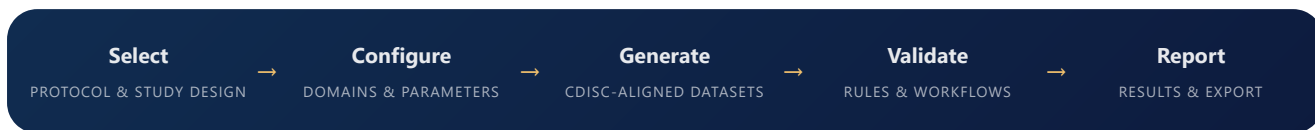
Eliminate dependency on sensitive or restricted datasets during development, testing, and training. TrialGen™ provides compliant, privacy-safe synthetic data that can be shared freely across teams and environments.

CAPABILITY 04

Scenario-Based Testing

Simulate edge cases, data anomalies, and complex domain interactions for robust system validation. Configure specific study designs, subject profiles, and visit schedules to match exact testing requirements.

TrialGen™ Workflow



Capability Detail

CAPABILITY	WHAT IT DELIVERS	KEY OUTCOME
● Realistic Data Simulation	CDISC-structured synthetic datasets · Statistical consistency · Domain relationships	Representative test data on demand
● Validation Readiness	Rule testing · Pipeline validation · Workflow simulation · Kwalify™ integration	Proactive validation before go-live
● Privacy-Safe Environments	No real patient data · Compliant across teams · Shareable across environments	Compliance without data restrictions
● Scenario-Based Testing	Edge case simulation · Anomaly injection · Custom visit schedules & subject profiles	Robust, comprehensive test coverage

Use Cases

- ✓ Clinical trial simulation before study execution
- ✓ System and pipeline testing (EDC, SDTM, downstream workflows)
- ✓ Validation framework testing (including Kwalify™)
- ✓ Training and sandbox environments

Business Value

- ✓ Accelerates development and validation cycles
- ✓ Improves confidence in data and system behaviour
- ✓ Enables proactive, not reactive, validation
- ✓ Scales across studies, domains, and complexity levels

TrialGen™ transforms synthetic data from a workaround into a **strategic validation layer** — enabling life sciences organizations to move beyond reactive testing toward **proactive, governed, and inspection-ready clinical data validation** across the full trial lifecycle.

Ready to Validate Without Risk?

Talk to our team about how TrialGen™ can accelerate your clinical data validation workflows.

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