CERTARA
Pinnacle 21®

Empowering CROs to elevate sponsor service and outcomes with Pinnacle 21 Enterprise

While Pinnacle 21 Community supports basic clinical data validation, the Pinnacle 21 Enterprise platform transforms validation into a centralized, scalable compliance framework – allowing CROs to improve sponsor outcomes while driving operational efficiency and competitive advantage.

How Enterprise helps CROs deliver faster, higher-quality sponsor submissions at scale

Faster deliverables – speedier submissions

Automated validation, centralized issue management, and Define. xml and SDRG generation reduce manual effort and accelerate compliant sponsor submissions.

Greater compliance confidence

Validation aligned with the same engine trusted by global regulators helps ensure sponsor deliverables meet the very latest regulatory requirements.

Greater transparency and auditability

Full validation history, issue lifecycle tracking, and change reports allow CROs to demonstrate complete traceability to clients throughout the study lifecycle.

Submission readiness visibility

Data Fitness Scores provide measurable compliance insight, giving CROs confidence in their clients' submission readiness.

Reduced risk

Early and continuous in-stream validation catches conformance issues before submission, minimizing the risk of delays to client submissions.

Faster sponsor submissions	Stronger compliance confidence
Lower regulatory risk	Full audit transparency

Core features designed for CRO scale and multi-study oversight

- Secure, cloud-based, centrally managed validation environment
- Alignment with the latest global regulatory validation engines (FDA, PMDA, MHRA)
- Centralized CDISC standards and controlled terminology governance
- 'Data Fitness Scores' with submission readiness indicators and actionable compliance guidance
- Full issue lifecycle management with impact prioritization
- Validation history and change tracking across cycles
- Portfolio-level dashboards and cross-study analytics
- Automated Define.xml and Study Data Reviewer's Guide

Data Fitness Score

20 Keep Going

Goal 90 or above

What is it?
The Data Fitness Score shows whether data are fit to submit. It is based on the data's conformance to CDISC standards and regulatory guidance. It factors in issue frequency and impact, the logical relationships among records, and consistency between the define/spec and the data.

How to Improve Your Data Fitness Score

Fix 1 Reject Issue	+26 points
Fix all 24 High Issues	+26 points
Fix all 50 Medium Issues	+23 points
Fix all 19 Low Issues	+5 points

The business benefits for CROs with Enterprise adoption

Increased operational efficiency
Centralized validation and issue workflows reduce repetitive manual effort across studies – allowing CROs to take on more studies with the same resources.

Stronger competitive advantage
Demonstrating measurable submission readiness and regulator-aligned validation at scale strengthens sponsor trust and market positioning.

Protect margins
Improved resource efficiency allows CROs to expand client capacity while protecting margins and maximizing profitability.

Reduced compliance risk exposure
Continuous validation reduces rework, helping CROs avoid costly submission delays and protect delivery timelines.

Avoid delays and reduce risk. Deliver submission-ready sponsor outcomes with confidence.

Learn more about Pinnacle 21 Enterprise

About Certara

Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions and regulatory agencies across 70 countries.

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