CERTARA

Pinnacle 21 Enterprise

Fact sheet

Dataset validation & submission readiness

You're delivering your hard work to regulators and new possibilities to patients. Don't let non-conforming CDISC packages stand in the way of success. Ensure that your data is "fit to submit" and accompanied by a comprehensive Define.xml file and Data Reviewer's Guide for clear interpretation.

The enterprise-wide solution built to ensure CDISC compliance, a prerequisite for regulatory approval

1

Validation scorecard

With a simple upload, instantly check your submission datasets against acceptance criteria for a detailed log of issues to resolve. The FDA and Japan's PMDA use our validation engine to review the quality of submissions.

2

Issue management

Collaborate with CROs, developers, and others in a central workspace to resolve issues discovered during validation. Proceed issue by issue or rule by rule according to impact, commenting and assigning tasks along the way.

3

Change tracking

Produce and review a simple report that details only what has changed since you last validated your data.

4

Validation history

In a single click, create a chart that shows the quality of your data over time, to ensure you're moving in the right direction.

5

Define/spec designer

Create and convert Define.xml 2.0 and 2.1 for SDTM, ADaM, and SEND datasets with ease.

6

Data reviewer's guide creator

Advocate for your data and share their full story in our xDRG creator. Our tool automates your content aggregation and formatting to create informative cSDRG, ADRG, and nSDRG files.

7

Customizing standards/ controlled terminology

Easily customize standard metadata or controlled terminology and validate your datasets against internal standards and CT.

8

Trial design module

Create and edit trial design datasets from imported files or standards. Real-time validation ensures you're on the right track and the chat feature captures centralized collaboration with your team.

Learn more about Pinnacle 21 Enterprise

See which version of Pinnacle 21 is right for your organization

Data validation features	Community	Enterprise
SDTM, SEND, ADaM, and Define.xml validation	✓	✓
Metadata driven and configurable	✓	✓
Data composition and quality reports		✓
FDA and PMDA Data Fitness assessment scorecards		✓
Manage issues throughout the study lifecycle		✓
Communicate and collaborate with partners		✓
Monitor data quality improvement over time		✓
Track changes across validations		✓
Customize specs for SDTM+ or sponsor formats		✓
Validate BIMO clinsite datasets		✓
Define.xml features		
Create Define.xml 2.0 and 2.1 for SDTM, SEND, ADaM	✓	✓
Convert Define.xml 2.0 files into Define.xml 2.1 files and vice versa	✓	✓
Extract metadata from XPT datasets	✓	✓
Extract Origin and Page Numbers from annotated CRFs		✓
Merge metadata from external specifications		✓
Generate Define.pdf		✓
Validate Define.xml content in real-time		✓
Compare content with standards and other studies		✓
Create Analysis Results Metadata (ARM)		✓
Other features		
Reviewer's Guide		✓
Trial Design Module		✓
Deployment Options	Desktop	Web hosted
Automated software and rule updates	✓	✓
Central configuration and management		✓
Sandbox environment for training and testing		✓
Increased scalability		✓
Software license	Open source	Subscription
Quality, compliance, and support		
Community support forum	✓	
SME and Help Desk support		✓
Live and recorded training, help center, user guides		✓
Rigorous QA, performance, and scalability testing		✓
GxP and 21 CFR Part 11 compliant		✓
Service level agreement		Customizable

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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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