PINNACLE 21: ENTERPRISE
STANDARDS MANAGEMENT & REGULATORY COMPLIANCE

THE ENTERPRISE-WIDE SOLUTION BUILT TO ENSURE CDISC COMPLIANCE: A PREREQUISITE FOR FDA APPROVAL

01 **VALIDATION SCORECARD**
Know precisely what to address by viewing a list of Pass/Fail grades on your data quality, standards compliance, etc.

02 **ISSUE ORGANIZATION**
View, organize, and tag various data issues through our intuitive interface. Add comments and assign tasks in a snap.

03 **ISSUE MANAGEMENT**
Communicate and collaborate with CROs, developers, and others to resolve timely issues through our simple messaging tool.

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

05 **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.

06 **DEFINE.XML 2.0 DESIGNER**
Create Define.xml 2.0 for SDTM, ADaM, SEND and legacy datasets, and convert Define.xml 1.0 files into Define.xml 2.0 with ease.
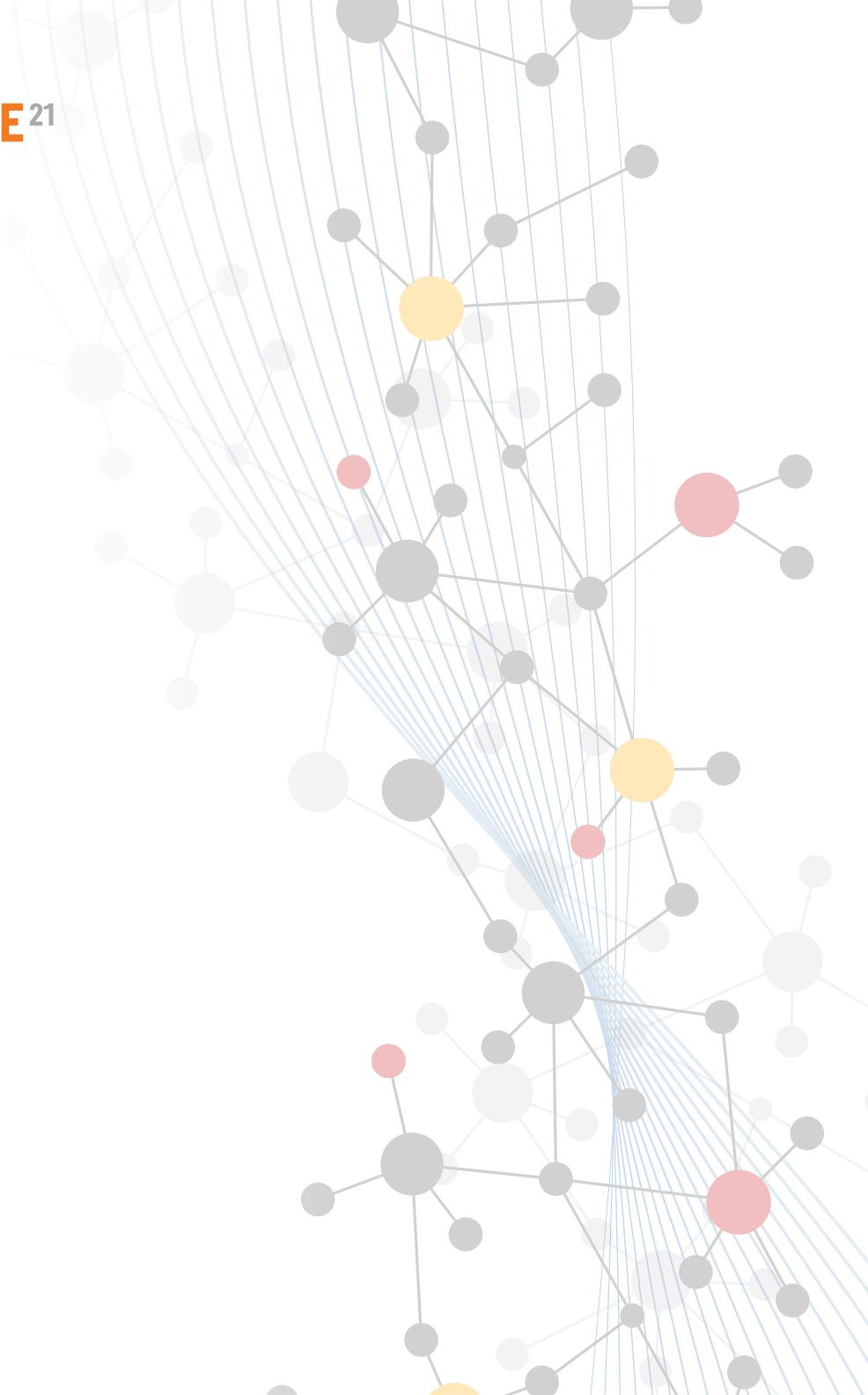
07 **CUSTOMIZING DOMAINS**
Easily customize your datasets to support near-CDISC standards — like SDTM+ — or sponsor defined formats.

08 **CUSTOMIZING RULES**
Customize rules through our easy-to-use GUI to meet your specific requirements, and share them enterprise-wide.

SEE WHICH VERSION OF PINNACLE 21 IS RIGHT FOR YOUR COMPANY

DATA VALIDATION FEATURES	COMMUNITY	ENTERPRISE
Validate SDTM, SEND, ADaM, and Define.xml	✓	✓
Metadata driven and configurable	✓	✓
Data composition and quality reports		✓
FDA 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		✓
Design rules for projects, studies, and partners		✓
DEFINE.XML FEATURES		
Create Define.xml 2.0 for SDTM, SEND and ADaM	✓	✓
Convert Define.xml 1.0 files into Define.xml 2.0	✓	✓
Extract metadata from SAS datasets	✓	✓
Extract origin 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		
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	✓	✓
Professional email and telephone support		✓
Rigorous QA, performance, and scalability testing		✓
GxP and 21 CFR Part 11 compliant		✓
Service level agreement		Customizable

CERTARA | PINNÁCLE²¹

About Certara

Certara accelerates medicines using biosimulation software and technology to transform traditional drug discovery and development. Its clients include more than 1,650 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 61 countries.

For more information, visit **www.certara.com**.