CERTARA | PINNACLE 21

FDA SUBMISSION READINESS SERVICES

FROM THE RECOGNIZED LEADER IN CDISC COMPLIANCE

PINNACLE 21 is the recognized industry leader in software for managing CDISC compliance, clinical data quality and FDA submission readiness. We also provide a full suite of services to help move your submission through the approval process. Pinnacle 21's staff advises the FDA's JumpStart and DataFit programs, and is a Platinum member of CDISC — and we can apply our expertise to help you in three critical ways.

1. DATA FITNESS ASSESSMENT

Through Pinnacle 21's Data Fitness Assessment, we'll ensure that your study data and supporting documentation are compliant with FDA's requirements, and ready to support the regulatory review process. When the reviewer fully understands your data and has all the information needed, your review will be more efficient and effective — enabling you to get your product to market sooner.

Our Data Fitness Assessment services include:

- Review Study Data Package and Supporting Documents
- Validate CDISC Compliance
- Evaluate Study Data Quality
- Review Traceability between CRFs, SDTM, and ADaM
- Assess Data's Fitness to support FDA standard review and analysis tools
- Recommend a fix or an explanation for found issues

2. CREATING DEFINE.XML

Define.xml files are cited by the FDA as the most common to be invalid and needing remediation. At Pinnacle 21, we have the expertise, and the software, to create valid quality Define.xml files based on your requirements.

If you're struggling with Define.xml, you can rely on Pinnacle 21 for:

- Define.xml Creation — We will create submission-ready Define.xml for you based on your study datasets (SDTM and ADaM), requirements and other specifications.
- Training & Review — Our experts can also train your staff to create Define.xmlusing Pinnacle 21 Enterprise, and review those files to ensure they meetFDA reviewer requirements.
- Unparalleled Experience — As long-time members of the CDISC Define.xml team and validation subgroup, our expertise is unparalleled.

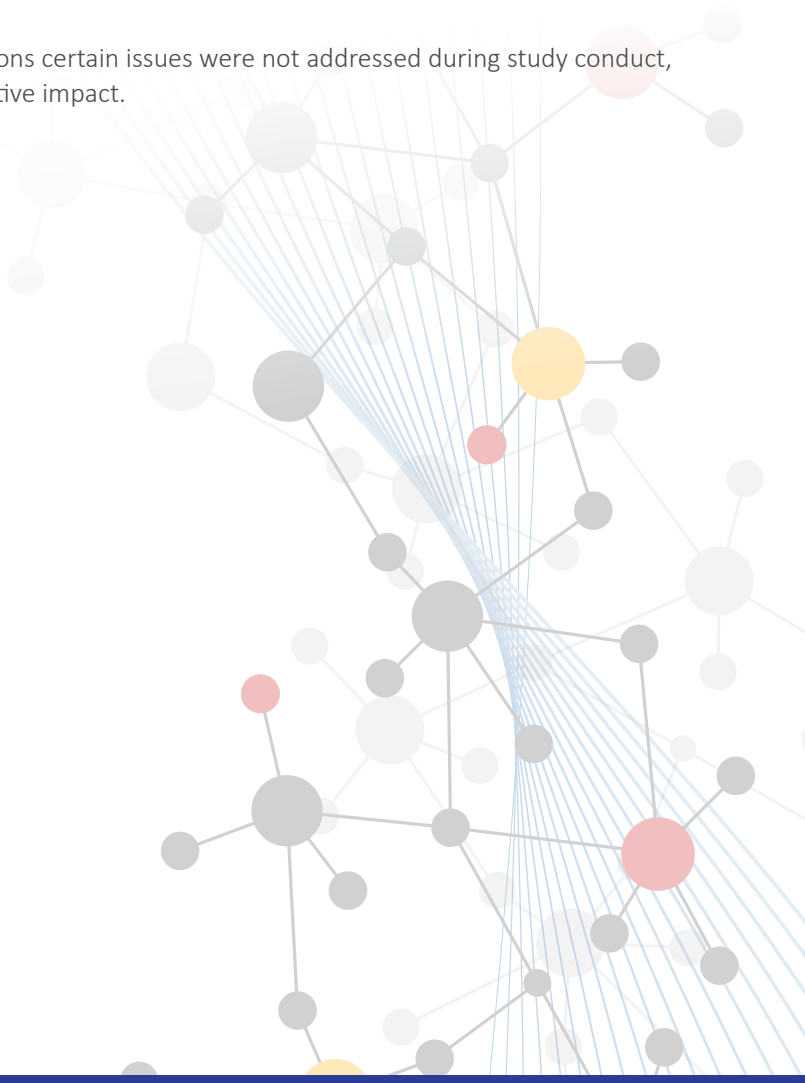
CERTARA | PINNACLE 21

3. CREATING STUDY DATA REVIEWER'S GUIDE (SDRG)

The Study Data Reviewer's Guide (SDRG) is a requested component of eCTD's Module 5 SDTM documentation. The easier your SDRG is to read and follow, the smoother your review.

The experts at Pinnacle 21 have the experience and expertise to create quality SDRGs that will:

- Guide FDA reviewers with the additional information they need for each study in your submission.
- Supplement Define.xml with guidance regarding mapping decisions, sponsor-defined domains, and sponsor-defined controlled terminology.
- Explain the sponsor's data validation issues — specifically, reasons certain issues were not addressed during study conduct, mapping, and submission preparation — to help mitigate negative impact.



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**.