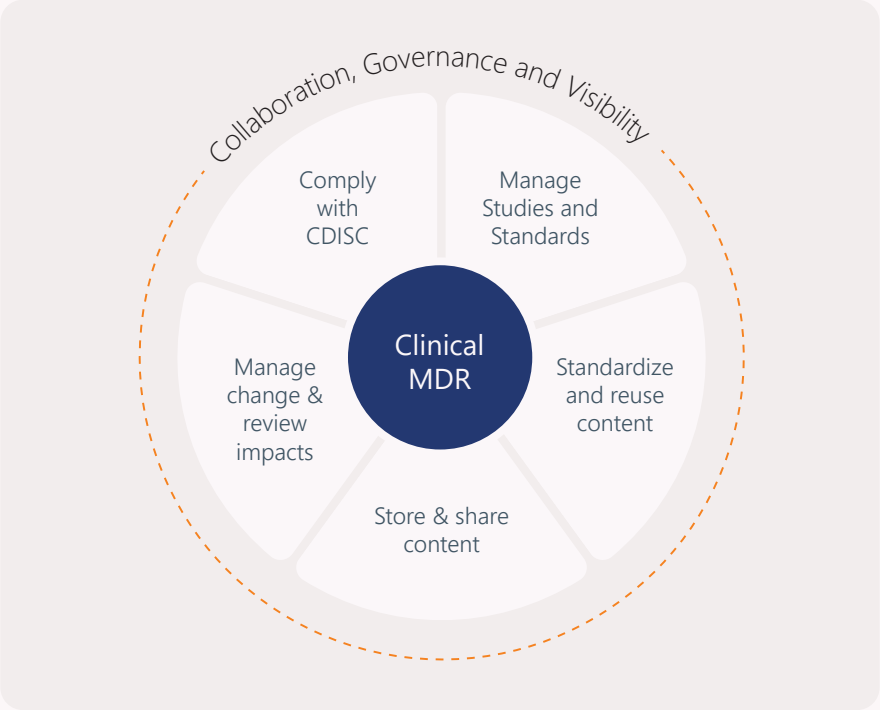
CERTARA
Pinnacle 21

Fact sheet

Clinical Metadata Repository

Your Source for Standards Truth

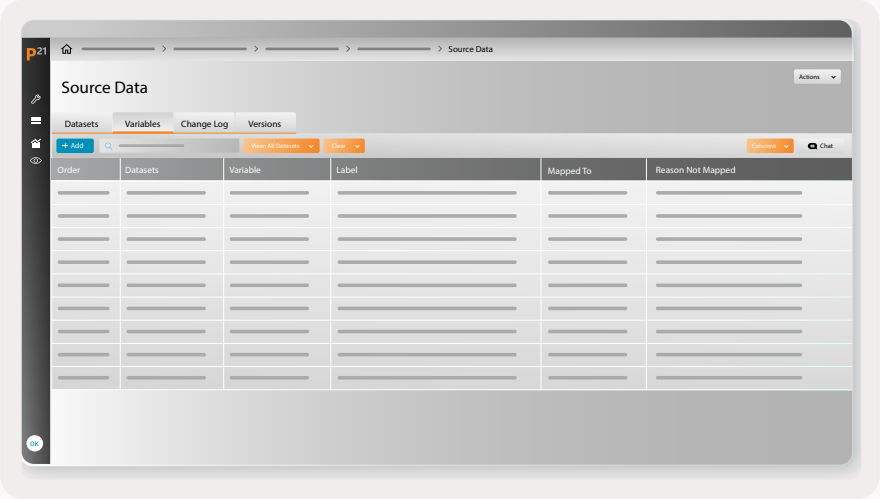
Re-usable standards save time and ensure quality. With Pinnacle 21's clinical metadata repository (CMDR), you can manage your clinical metadata, the key to standardization, in one centralized library. Our integrated ecosystem—comprised of our CMDR, Data Exchange, a form studio, and Pinnacle 21 Enterprise—means that your CMDR supports data collection, submission dataset metadata design, and validation across all your studies.



Designed for All Standards

Our CMDR is purpose-built to make navigation, governance, and adaptation easy for every type of standard, giving you control from study design and build to dataset validation.

- CDISC Trial Design Domains
- eCRF forms, questions, and groups
- Data Transfer specifications
- Reference data
- Controlled terminology
- Edit checks
- Derivation methods
- Datasets, variables, and value-level metadata
- Analysis results metadata
- Annotations
- Mappings



Not just content, but capability

Our CMDR isn't just a warehouse. It's a collaborative workshop with every possible tool for standards governance and study-specific modification.

- Upholds globally recognized data integrity practices
- Contains extendable industry standards
- Allows modeling of clinical metadata in standard formats (e.g. CDISC)
- Enables creation of study-level metadata from existing standards and studies
- Facilitates comparison of metadata at any level
- Tracks deviations from standards within a study
- Includes change request workflows
- Fosters collaborative metadata curation
- Provides clear versioning and audit history
- Offers secure and discrete access control and governance
- Allows for the export of metadata in human- and machine-readable formats
- Supports REST API to share metadata across systems

Support for Every Stakeholder

Our CMDR is designed to make navigating your content easy for all stakeholders. This common source of truth helps teams align upfront on metadata, making data collection more efficient and eliminating confusion that arises as you map to SEND, SDTM, and ADaM.

Standards Managers

- Create and update metadata assets before data collection begins.
- Govern all study-specific changes requested by data managers and biostatisticians.

Data Managers

- Build your study and all forms in weeks, not months.
- Conduct impact analysis—see how a standard change will affect all forms and tables across your studies.

Biostatisticians and Statistical Programmers

- Set mapping specs to more easily generate study-specific SEND, SDTM, and ADaM datasets.
- Create data conformant define.xml and xRDGs

About Pinnacle 21

Certara's Pinnacle 21 offers a unified solution for standardization and validation, backed by a 17-year history of unmatched CDISC expertise and technical innovation. Today, we're making the journey from study build to submission-ready dataset more seamless than ever before.

See the difference that upfront standardization can make on data quality and time to insight.

Learn more about the Pinnacle 21 Clinical MDR