

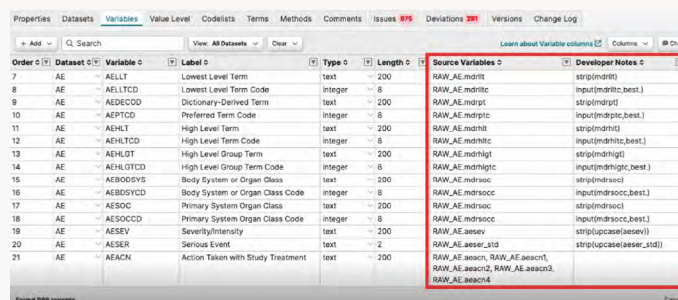
Pinnacle 21[®] - SDTM Specification Management

Map faster from source to SDTM

Mapping SDTM specifications with spreadsheets is repetitive and error-prone. The lack of version control and traceability only adds to the issue.

Reusable mapping specs save time and ensure both quality and consistency. The Pinnacle 21 Enterprise SDTM mapping software tool provides a purpose-built platform for programmers to quickly create compliant, reusable mapping specs – right from study setup.

Now you can define, validate and manage your SDTM mapping specs in one collaborative workspace.



The screenshot shows the Pinnacle 21 software interface with a table of mapping specifications. The table has columns for Order, Dataset, Variable, Label, Type, Length, Source Variables, and Developer Notes. The Source Variables column is highlighted with a red box, showing a list of source variables for each mapping spec.

Order	Dataset	Variable	Label	Type	Length	Source Variables	Developer Notes
7	AE	AELLT	Lowest Level Term	text	200	RAW_AE.mdrdt	strip(mdrdt)
8	AE	AELLTCD	Lowest Level Term Code	integer	8	RAW_AE.mdrdtc	input(mdrdtc_best)
9	AE	AEDCCD	Dictionary-Derived Term	text	200	RAW_AE.mdrdt	strip(mdrdt)
10	AE	ADPTCD	Preferred Term Code	integer	8	RAW_AE.mdrdtc	input(mdrdtc_best)
11	AE	AELHL	High Level Term	text	200	RAW_AE.mdrdt	strip(mdrdt)
12	AE	AELHLTCD	High Level Term Code	integer	8	RAW_AE.mdrdtc	input(mdrdtc_best)
13	AE	AELHLOT	High Level Group Term	text	200	RAW_AE.mdrdt	strip(mdrdt)
14	AE	AELHLOTCD	High Level Group Term Code	integer	8	RAW_AE.mdrdtc	input(mdrdtc_best)
15	AE	AESODSYS	Body System or Organ Class	text	200	RAW_AE.mdrdt	strip(mdrdt)
16	AE	AESODSYS	Body System or Organ Class Code	integer	8	RAW_AE.mdrdtc	input(mdrdtc_best)
17	AE	AESOC	Primary System Organ Class	text	200	RAW_AE.mdrdt	strip(mdrdt)
18	AE	AESOC	Primary System Organ Class Code	integer	8	RAW_AE.mdrdtc	input(mdrdtc_best)
19	AE	AESSEV	Severity/Intensity	text	200	RAW_AE.mdrdt	strip(mdrdt)
20	AE	AESER	Serious Event	text	2	RAW_AE.mdrdt	strip(mdrdt)
21	AE	AEACN	Action Taken with Study Treatment	text	200	RAW_AE.mdrdt, RAW_AE.mdrdtc, RAW_AE.mdrdtc2, RAW_AE.mdrdtc3, RAW_AE.mdrdtc4	

Escape the limitations of Excel with these powerful mapping features

Spec reuse

Forget starting from scratch every time! Import existing mapping specs from previous studies or from your library of approved standards.

In-stream validation

Why wait until the end and risk delays? In-cell validation instantly flags errors for resolution. And compliance with regulatory and proprietary standards is also subject to validation checks.

Real-time collaboration

Say goodbye to inefficient email chains and spreadsheets! Integrated chat functionality allows teams to discuss and resolve issues directly in the platform.

Version control

Hard to keep track of the latest version? Version tracking means all changes are captured, providing a complete audit trail to track, revert and collaborate efficiently, without conflicts.

Traceability

No more guesswork needed! Gain full visibility of why changes were made, understand relationships and dependencies, assess the impact of changes and more.

Why use Pinnacle 21 Enterprise SDTM mapping software?



Accelerate submissions

- Now that you can create compliant SDTM mapping specs at study setup, submission-ready data is available sooner, and costly end-of-study delays can be avoided.



Increase quality

- In-stream validation checks safeguard against errors and non-compliance in real-time.
- Reusing standardized mapping specs reduces the risk of errors and inconsistencies commonly found with repetitive manual work.



Maximize resources

- Automation reduces the time and resources spent managing specs in spreadsheets.
- Expert programming resources can be diverted to more complex projects.

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

Want to see how to accelerate specs with our SDTM mapping software?

Watch the webinar



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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