

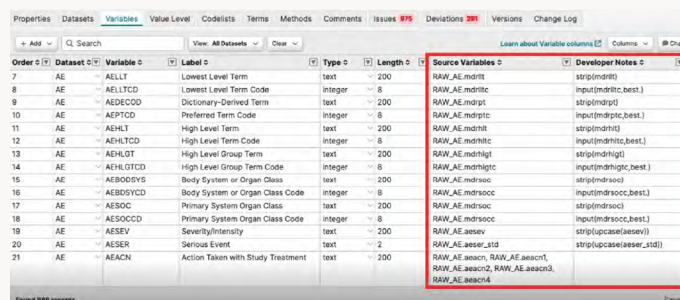
# Pinnacle 21 – SDTM Specification Management

## 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.



| 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.aesev                                           | strip(upcase(aesev))       |
| 20    | AE      | AESER     | Serious Event                     | text    | 2      | RAW_AE.aeser, \$10                                     | strip(upcase(aeser, \$10)) |
| 21    | AE      | AEACN     | Action Taken with Study Treatment | text    | 200    | RAW_AE.aeser, RAW_AE.aeser, RAW_AE.aeser, RAW_AE.aeser |                            |

## 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.

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

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Book a free no-obligation demo



## 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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