



# Using Pinnacle 21 Enterprise™ for NMPA Data Submission

Presented by  
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## Using Pinnacle 21 Enterprise™ for NMPA Data Submission

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# Contents

- P21 企业版和社区版的区别（Difference between P21 Enterprise and P21 Community）
- 数据拟合（Data Fitness）
- 问题管理和追踪（Issue Management and Tracking）
- 定制标准和术语（Custom Standards and Terminology）
- Define-XML 的生成（Define-XML Generation）
- 审阅者指南（Reviewer's Guide）



# P21 企业版和社区版的区别 (Difference between P21 Enterprise and P21 Community)

## Enterprise

- Designed for teams to collaborate on
  - Regulatory submission preparation
  - Standards management
  - Continuous compliance
- Runs on cloud
- Used by FDA and PMDA

## Community

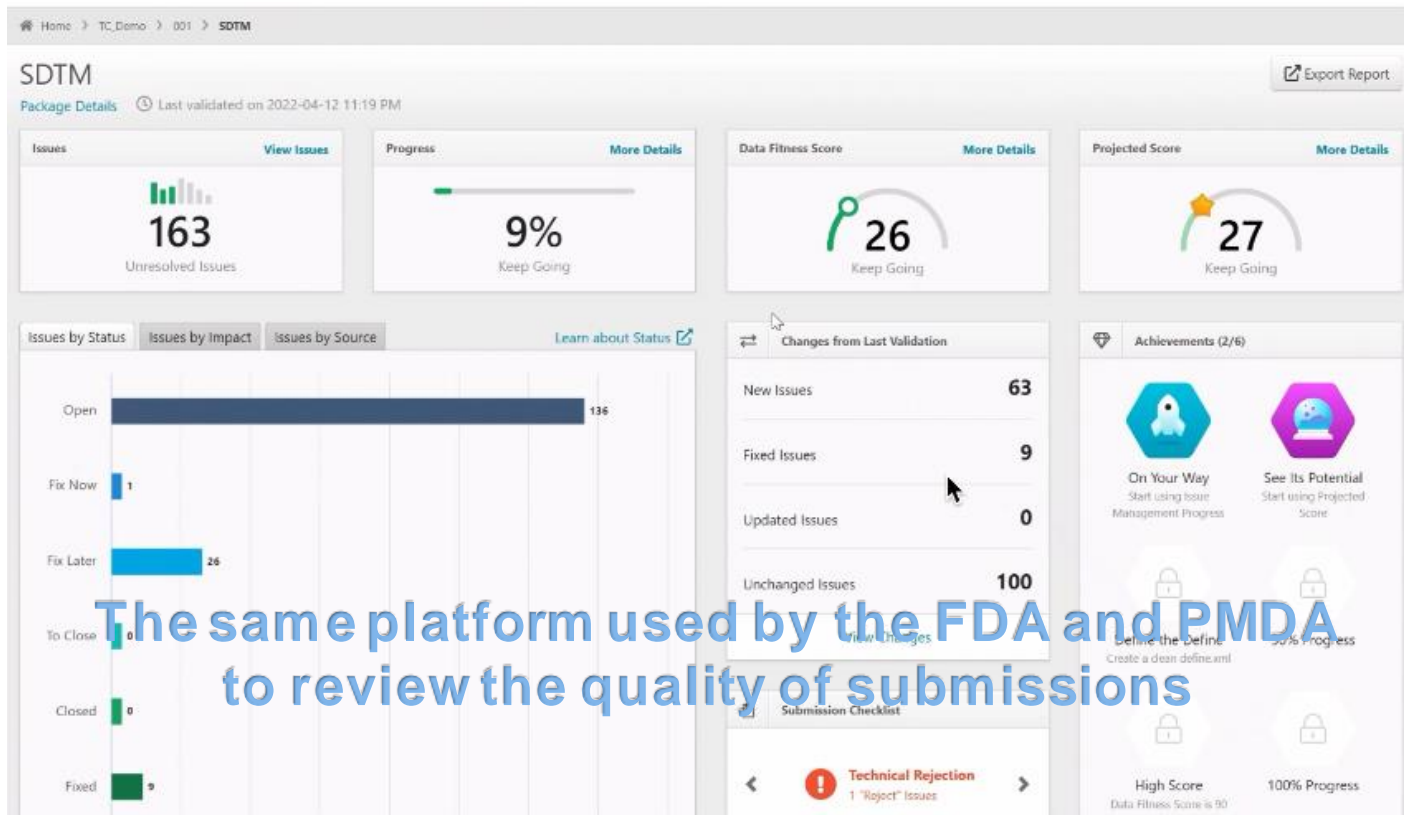
- Designed for programmers to QC their standardized deliverables
- Runs on desktop
- Open source



# CDISC 相关文件中文翻译情况 (CDISC Translations - Chinese)

- 常用受控术语 ( Most Commonly Used Controlled Terminology )
- The Analysis Data Model (ADaM) v2.1
- ADaMIG v1.1
- ADaM OCCDS v1.0
- SDTMIG v3.2

# 数据拟合 (Data Fitness)



The same platform used by the FDA and PMDA to review the quality of submissions



# 数据拟合 (Data Fitness)

See how your data performs across six quality dimensions

- SDTM Compliance
- Controlled Terminology
- Regulatory Conformance
- Metadata
- Data Quality
- Analysis Support

# 问题管理和追踪 (Issue Management and Tracking)

**P21** VALIDATION

- Overview
- Issues
- Datasets
- Data Reports
- Define.xml
- Reviewer's Guide
- Trial Summary
- Annotated CRF
- Validate Data
- Validation Log
- Validation History

Home > Molecule A > Phase II Trial > SDTM

Progress **29%** Kens Going
Data Fitness Score **40** Progressing
Projected Score **70** Progressing

Actions

Status
Assignee
Source
Impact
Dataset
Explained
Change

Export Report
View

Rule	Message	Affected	Change	Impact	Status
<b>AE - Adverse Events (22 Issues)</b>					
<input type="checkbox"/>	SD0008 未能在MedDRA词典中找到AEDECOD的值			High	Fix Later
<input type="checkbox"/>	SD0064 未能在DM域中找到受试者的值	2		High	Fix Later
<input type="checkbox"/>	SD1089 AESTDY变量是估算值	1		High	Fix Now
<input type="checkbox"/>	SD1090 AESTDY变量值不正确	2		High	Fix Later
<input type="checkbox"/>	SD1093 AEENDY变量值是估算值	1		High	Fix Later
<input type="checkbox"/>	SD1094 AEENDY变量值不正确	2		High	Fix Later
<input type="checkbox"/>	SD1114 未能在MedDRA词典中找到AEBODSYS的值	1		High	Fix Later
<input type="checkbox"/>	SD0037 未能在(Action Taken with Study Treatment)用户定义的代码列表中找到AEACN变量的值	3		Medium	Open
<input type="checkbox"/>	SD0037 未能在(Causality)用户定义的代码列表中找到AEREL变量的值	3		Medium	Open
<input type="checkbox"/>	SD0037 未能在(No Yes Response (Yes only))用户定义的代码列表中找到AEPRESP变量的值	2		Medium	Open
<input type="checkbox"/>	SD0037 未能在(Outcome of Event in AE)用户定义的代码列表中找到AEOUT变量的值	3		Medium	Open
<input type="checkbox"/>	SD0037 未能在(Severity/Intensity Scale for AE)用户定义的代码列表中找到AESEV变量的值	3		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AEBDSYCD	1		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AEHLGT	1		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AEHLGTC	1		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AEHLT	1		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AEHLTCD	2		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AELLT	1		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AELLTCD	1		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AEPTCD	1		Medium	Open
<input type="checkbox"/>	SD0057 未能找到SDTM规定的期望变量AESOC	1		Medium	Open



# 问题管理和追踪 (Issue Management and Tracking)

The screenshot displays the Pinnacle 21 Enterprise Issue Management and Tracking interface. The main content area is divided into several sections:

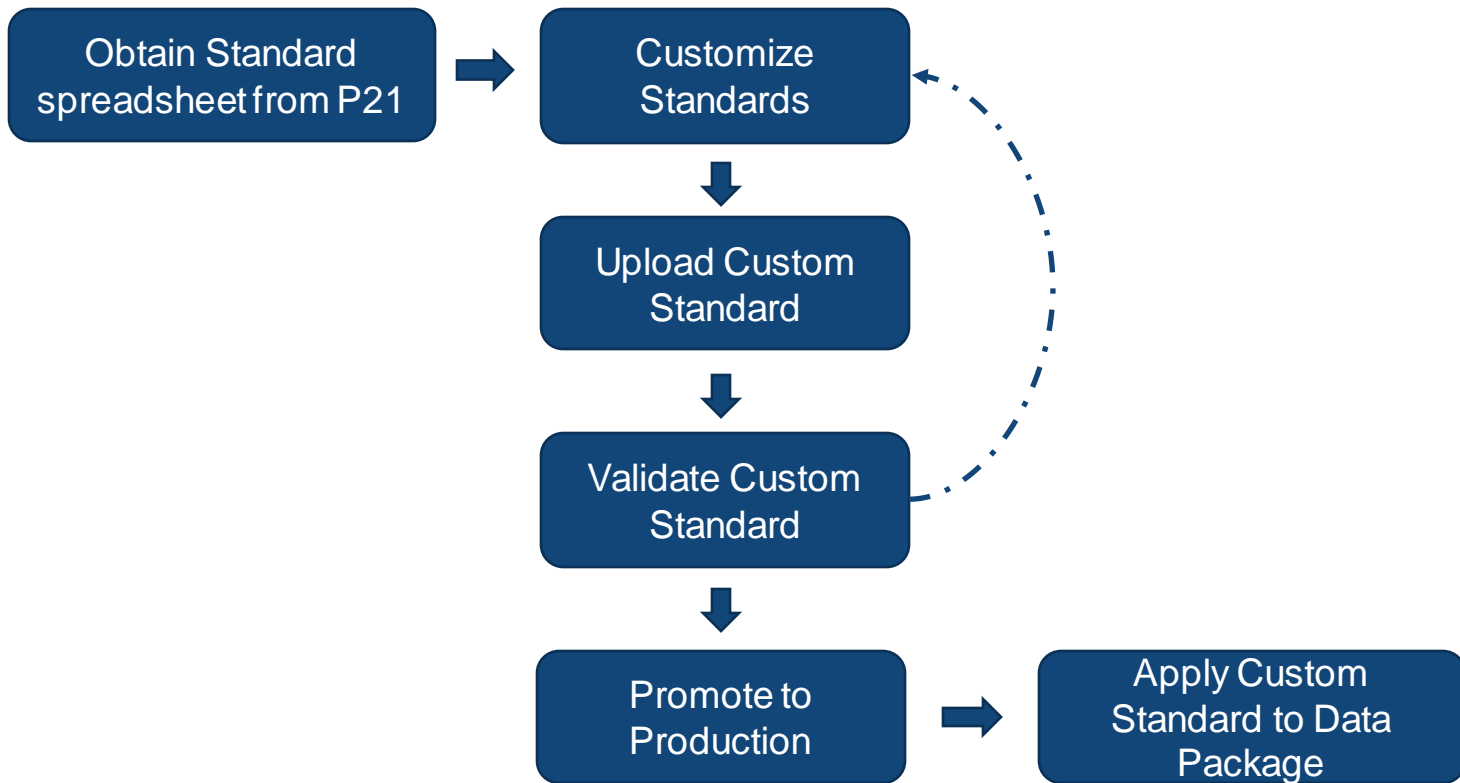
- Issue Details:** Shows the issue ID "SD0058: 变量在数据集中出现, 但是不在SDTM模型中". The description states that only variables listed in the SDTM model can appear in the dataset, and new variables cannot be added. It also provides "Fix Tips" with three examples and a note that only variables listed in the SDTM should appear in a domain. The issue is categorized as "Dataset: DM", "Impact: High", "Affected: 1", and "Type: Error".
- Manage Issue:** Includes a "Status" dropdown set to "Fix Later", an "Assignee" dropdown set to "菲利普", and a "Sources" dropdown set to "Mapping".
- Comments:** Shows a comment from "PJ" posted 2 minutes ago, asking "季白 我可以把这个任务分配给你吗?". There are "Edit" and "Delete" options for the comment.
- Search:** A search bar is located at the bottom left of the main content area.
- Bottom Panel:** A "VARIABLE" dropdown is set to "RFICTTC".
- Right Sidebar:** Contains a "Progress" gauge at 29% (Keep Going), a "Data Fitness Score" gauge at 40 (Progressing), and a "Projected Score" gauge at 70 (Progressing).

# 定制标准和术语 (Custom Standards and Terminology)

- Create a Custom Standard
- Validate Standards & Terminology
- Track Changes in Metadata

The template does not have a tab for codelists. If you are using a new codelist, you will need to upload the Custom Terminology first.

# 定制标准和术语 (Custom Standards and Terminology)



# Define-XML

## Phase II Trial

- Annotated Case Report Form [↗](#)
- ▼ 补充文件
  - Study Data Reviewer's Guide [↗](#)
- ▼ 数据集
  - TA (试验组)
  - DM (人口学)
  - AE (Adverse Events)
- ▼ 受控术语
  - ▶ 代码清单
  - ▶ 外部词典

## DM (人口学) - SPECIAL PURPOSE

位置: [dm.xml](#) [↗](#)

变量	标签/描述	类型	角色	长度或显示格式	受控术语或ISO格式	来源/源/方法/注释
STUDYID	研究标识符	text	Identifier	6		Protocol
DOMAIN	域名缩写	text	Identifier	2		Assigned
USUBJID	受试者唯一标识符	text	Identifier	11		Derived
SUBJID	受试者标识符	text	Topic	11		
RFSTDTC	受试者参照开始日期/时间	date	Record Qualifier		ISO 8601	Derived
RFENDTC	受试者参照结束日期/时间	date	Record Qualifier		ISO 8601	Derived
RFXSTDTC	首次研究治疗日期/时间	date	Record Qualifier		ISO 8601	
RFXENDTC	末次研究治疗日期/时间	date	Record Qualifier		ISO 8601	
RFICTTC	null	date			ISO 8601	
RFPENDTC	参与结束日期/时间	date	Record Qualifier		ISO 8601	
SITEID	研究中心标识符	text	Record Qualifier	5		Assigned
INVNAM	研究者姓名	text	Synonym Qualifier	13		Assigned
BRTHDTC	出生日期/时间	date	Record Qualifier		ISO 8601	
AGE	年龄	integer	Record Qualifier	8		Derived
AGEU	年龄单位	text	Variable Qualifier	5	<a href="#">Age Unit</a> • "YEARS"	Assigned
SEX	性别	text	Record Qualifier	1	<a href="#">Sex</a> • "F" • "M"	
RACE	种族	text	Record Qualifier	45	<a href="#">Race</a> • "夏威夷原住民或其他太平洋岛国人" • "白人" • "美国印第安人或阿拉斯加原住民" • "阿拉斯加人" • "黑人或非洲裔美国人"	
ETHNIC	族群	text	Record Qualifier	24	<a href="#">Ethnic Group</a> • "西班牙或拉丁裔" • "非西班牙或拉丁裔"	



# Define-XML

To create a Define.xml, we can:

- Start with a blank Define (Start from Scratch)
- Copy another study or standard (Copy from Standard)
- Copy from another Define (Copy from Define)
- Import Excel Specification
- Import Define.xml
- Import metadata after a validation (Create from a Validation)

Create from Validation utilizes transport files (“ .xpt” files) previously validated using P21 Enterprise. This is my recommended method and will benefit from the full spectrum of functions, capabilities, and quality checks that P21 Enterprise offers.



# Define-XML

What can P21E do for you automatically:

- Extract Metadata & Merge Standards
- Compare Studies and Versions
- Real-time Validation



# 审阅者指南 (Reviewer's Guide)

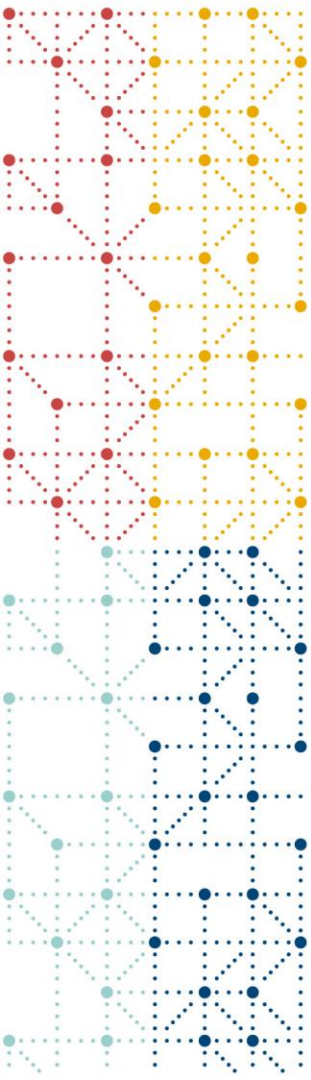
P21E can export the reviewer's guide and pre-populate many information, include but not limit to:

- Study Data Standards and Dictionary Inventory(section 1.3)
- Trial Design Datasets (section 2.3)
- Do the submission datasets include screen failures? (section 3.1)
- SDTM Subject Domains (section 3.4)
- Data Conformance Summary(section 4.1-Conformance Inputs & section 4.2- Issues Summary)

# 审阅者指南 (Reviewer's Guide)

验证规则ID	诊断信息	严重程度	数据集	次数 (问题发生率)	解释
SD0057	未能找到SDTM规定的期望变量AELLT		AE	1 (100.00%)	示例1：解释您无法解决问题的原因
SD0057	未能找到SDTM规定的期望变量AEHLT		AE	1 (100.00%)	示例1：解释您无法解决问题的原因
SD0057	未能找到SDTM规定的期望变量AEPTCD		AE	1 (100.00%)	示例1：解释您无法解决问题的原因
SD0057	未能找到SDTM规定的期望变量AEHLGT		AE	1 (100.00%)	示例1：解释您无法解决问题的原因
SD0057	未能找到SDTM规定的期望变量RFICDTC		DM	1 (100.00%)	示例1：解释您无法解决问题的原因
SD0057	未能找到SDTM规定的期望变量DTHFL		DM	1 (100.00%)	示例1：解释您无法解决问题的原因
SD0057	未能找到SDTM规定的期望变量DTHDTC		DM	1 (100.00%)	示例1：解释您无法解决问题的原因
验证规则ID	诊断信息	严重程度	数据集	次数 (问题发生率)	解释
SD0058	变量在数据集中出现, 但是不在SDTM模型中		DM	1 (4.35%)	示例1：解释您无





**THANK YOU!**

**cdisc**