

Pinnacle 21 Community v3.0 - A Users Perspective

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ABSTRACT

Pinnacle 21, also previously known as OpenCDISC Validator, provides great compliance checks against CDISC outputs like SDTM, ADaM, SEND and Define.xml. This validation tool provides a report in Excel format which contains information categorized as errors, warnings, and notices. In May2019, Pinnacle 21 team had released Community v3.0. This paper will provide an overview of all major updates in Pinnacle 21 community v3.0 e.g. new validations checks, ADaM IG v1.1 support, latest Controlled Terminology support. Later, this paper will cover the SNOMED, MedDRA dictionaries installation process which is no longer supported by Pinnacle 21.

INTRODUCTION

In 2004, the Clinical Data Interchange Standards Consortium (CDISC) recommended the use of the Study Data Tabulation Model (SDTM) standard for submitting clinical data to a regulatory agency. Since that time the pharmaceutical and biotechnology industries have worked tirelessly to implement this standard for the submission of clinical data and its related metadata in order to facilitate the review process of determining the safety and efficacy of a drug. The Pinnacle 21 Community was established to build a framework for the implementation of the CDISC Standard. In fact, this community of professionals created the Pinnacle21 Validator tool that performs numerous checks on clinical data to ensure compliance with the standard. This tool validates both the submission data as well as its respective metadata.

This paper will cover Pinnacle 21 Community validator tool v3.0 which is widely used in the industry and user can download it at free of cost.

Admittedly, CDISC requirements for standardization are extensive, and always evolving. The validation process involves various types of checks to ensure compliance, including the metadata describing the clinical data. In fact, the clinical data, stored as SAS transport (XPT) data sets, must match that which is specified in the Case Report Tabulation – Data Definition (Define-XML) document. Pinnacle 21 uses both transport data sets and the Define-XML to perform the validation. Besides metadata checks, the application also checks for appropriate controlled terminology values (e.g. F, M, or U for the variable DM.SEX) and standard formats, such as using the ISO 8601 format for date/time values. Pinnacle 21 tool does not guarantee 100% compliance. However, it does a good job of detecting most data issues that could otherwise delay a submission.

PINNACLE 21 COMMUNITY VALIDATOR v3.0.x:

Pinnacle 21 Community Validator is the leading industry tool for validating SDTM and ADaM data sets against CDISC standards (for more information about CDISC standards, please see cdisc.org). So far, several version of Pinnacle 21 Community validators had been released. But, Pinnacle 21 Community v3.0.x is Pinnacle21's most ambitious release to date and they added support for new standards and rules, but most importantly they reinvented how the software is released, installed, and kept updated.

STEPS TO GET PINNACLE 21 COMMUNITY v3.0.x:

1. Go to the <https://www.pinnacle21.com/downloads> and click the [download](#) tab above and download the version 3.0.x for your operating system.
2. For Windows double-click the .exe file and follow set-up instructions.
3. For Mac double click the .dmg file and drag the Pinnacle 21 Community Icon into the Applications folder.
4. You are now ready to use Pinnacle 21 Community. Community v3.0.x now comes with a one-click installer that automatically deploys Community components in a location appropriate for your operating system. But most importantly, it makes My Documents folder the single place to

access all your validation reports, define files, dictionaries, terminologies, rule configs and log files.

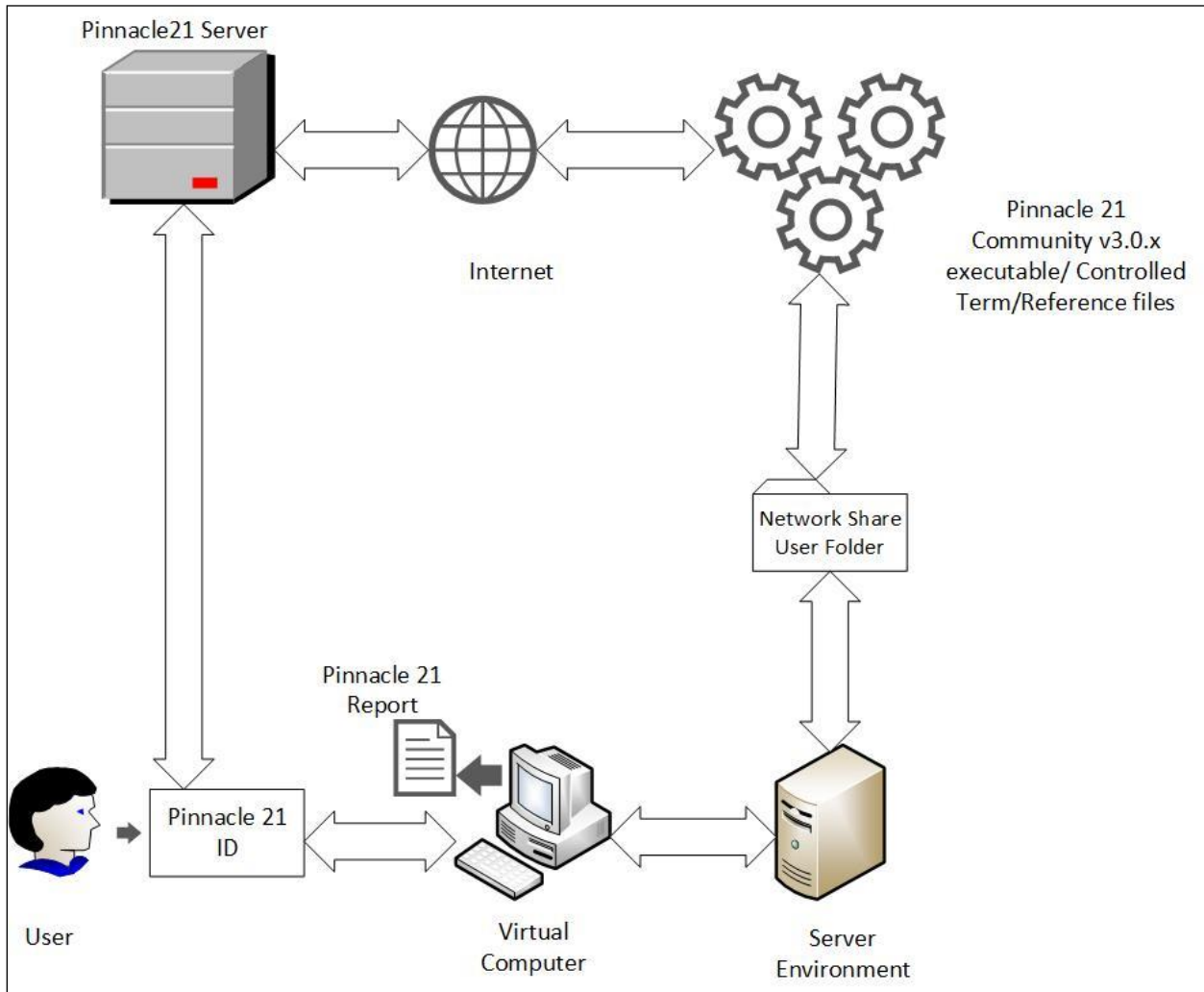
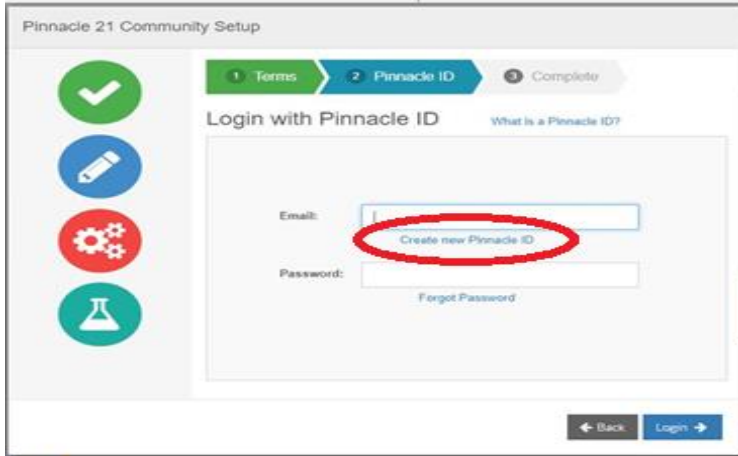


Diagram 1: Pinnacle 21 Architecture Diagram

5. In order to get latest CTs in Pinnacle 21 Community v3.0.x it is mandatory for all users to create a Pinnacle21 ID on Pinnacle21.com using their email ID as the username. Once user login to Pinnacle21 server then automatic updates feature is turned on which will install latest available configuration and reference files automatically (see diagram below) on your PC or Shared environment. For previous version, user needs to add configuration and reference files manually which was time consuming and prone to error. If Pinnacle ID is not used and user decided to run the validator on offline mode, then very limited features are available. User can either use below screenshot or use following link to create their Pinnacle21 ID
<https://www.pinnacle21.com/user/register>

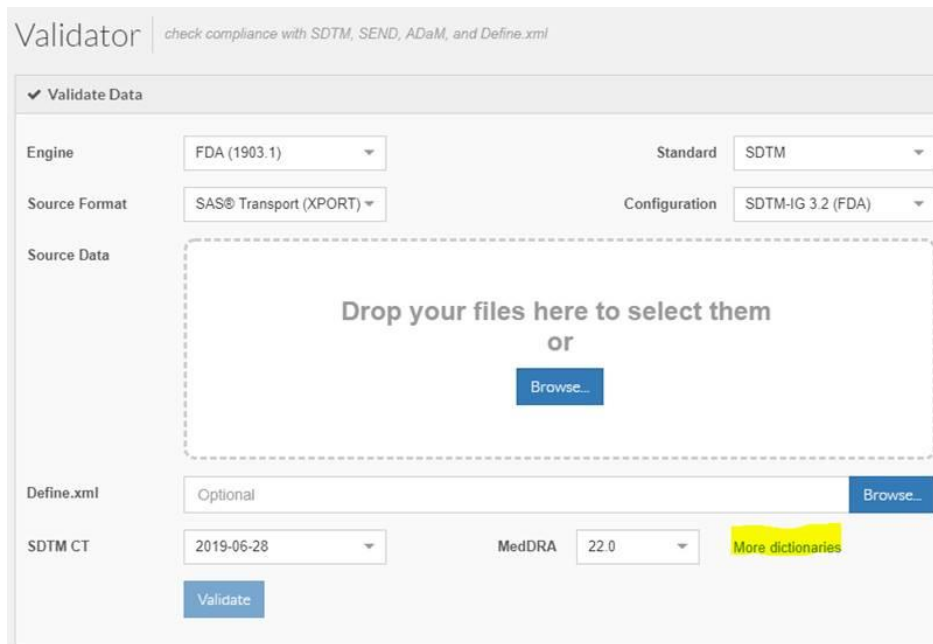


Display 1 Pinnacle User ID Screen

6. Adding Dictionaries

Pinnacle 21 Community v3.0.x expects MedDRA and SNOMED dictionaries to be installed when running the validator. Follow steps below

- a) From the validator menu, select “More dictionaries” at the bottom right. Later, you will see all available dictionaries on Pinnacle 21.GUI (Graphical User Interface)



Display 2 Dictionaries Set up

Dictionary	Version	Action
CDISC CT	2019-12-20	
MedDRA	22.0	+
SNOMED	2019-03-01	+
UNII	2019-07-12	
NDF-RT	2018-02-05	

OK

Display 3 Dictionaries List

b) MedDRA Dictionary Installation:

Medical Dictionary for Regulatory Activities (MedDRA) is used for coding Adverse Events and helps facilitate safety and regulatory review of clinical data. For more information, please see section 6.3.1 of the Technical Conformance Guide. Since MedDRA is only available through a commercial subscription, it's not included as part of Pinnacle 21 Community Validator distribution and must be provided by you or your company. If you need more detail on MedDRA then visit <https://www.meddra.org/>

When provided, the Pinnacle 21 Validator uses five files (listed below) from the MedDRA dictionary to perform coding compliance checks. The MedDRA dictionary includes more files but only the ones listed below are needed for validation.

- pt.asc
- soc.asc
- llt.asc
- hlt.asc
- hlgt.asc

To install MedDRA, select the "+" next to MedDRA, then fill out the version number (e.g. 22.1) and point to the path where dictionaries are located in your local drive e.g. [\Dictionaries\MedDRA\22.1\MedAscii](#). Later, to confirm installation of the dictionary, you can navigate to your Documents folder, then <Documents\Pinnacle 21 Community\configs\data\MedDRA\22.1> and note the list of above five .asc files.

Install MedDRA Dictionary

Give us the version and location of your MedDRA files and we will install them for you.
[Learn more](#)

Version

Location of the folder
 [Browse...](#)

[Install](#) [Close](#)

Display 4 MedDRA Dictionary Set up

c) SNOMED Dictionary Installation:

Systematized Nomenclature of Medicine (SNOMED) is used for coding of clinical terms. It is used in the Trail Summary (TS) domain of SDTM to identify the medical condition or problem that an investigational product in a study is intended to affect. For more information, please see section 6.6.1 of the Technical Conformance Guide. Since SNOMED is only available through a commercial subscription, it's not included as part of Pinnacle 21 Community Validator distribution and must be provided by you or your company. When provided, the Pinnacle 21 Validator uses **sct2_Description_Full-en.txt** from the SNOMED dictionary to perform coding compliance checks of the TS domain. For more detail on SNOMED dictionary visit <http://www.snomed.org/>

For the SNOMED dictionary installation, follow the same steps e.g. "+" next to SNOMED but point to the folder where the SNOMED Dictionaries are located e.g. [\Dictionaries\SNOMED\20190301](#) and select file sct2_Description_Full-en

Install SNOMED Dictionary

Give us the version and location of your SNOMED file and we will install it for you.
[Learn more](#)

Version

Location of the dictionary file
 [Browse...](#)

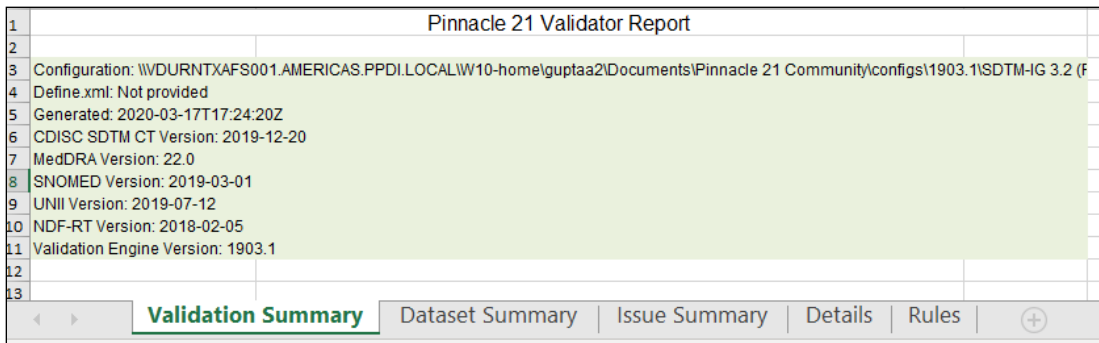
[Install](#) [Close](#)

Display 5 SNOMED Dictionary set up

PINNACLE21 COMMUNITY v3.0.x MAJOR UPDATES AND ENHANCEMENTS:

1. General Updates and Enhancements

1. Added Pinnacle ID (new feature). Users with Pinnacle ID will now get access to P21 web services and enjoy a new level of user experience. With Pinnacle ID and web services, user Community installation will receive automatic updates to validation engines, rules, CDISC terminologies, and NDF-RT, MED-RT and UNII dictionaries.
 - Added ability to select MedDRA and SDTM-CT for ADaM Validation (enhancement)
 - Added Validation Summary tab to the validation report (new feature)



The screenshot displays the 'Pinnacle 21 Validator Report' interface. The main content area is a table with the following rows:

1	
2	
3	Configuration: \\WDURNTXAFS001.AMERICAS.PPDI.LOCAL\W10-home\guptaa2\Documents\Pinnacle 21 Community\configs\1903.1\SDTM-HG 3.2 (F
4	Define.xml: Not provided
5	Generated: 2020-03-17T17:24:20Z
6	CDISC SDTM CT Version: 2019-12-20
7	MedDRA Version: 22.0
8	SNOMED Version: 2019-03-01
9	UNII Version: 2019-07-12
10	NDF-RT Version: 2018-02-05
11	Validation Engine Version: 1903.1
12	
13	

At the bottom, there is a navigation bar with the following tabs: Validation Summary (selected), Dataset Summary, Issue Summary, Details, Rules, and a plus sign icon.

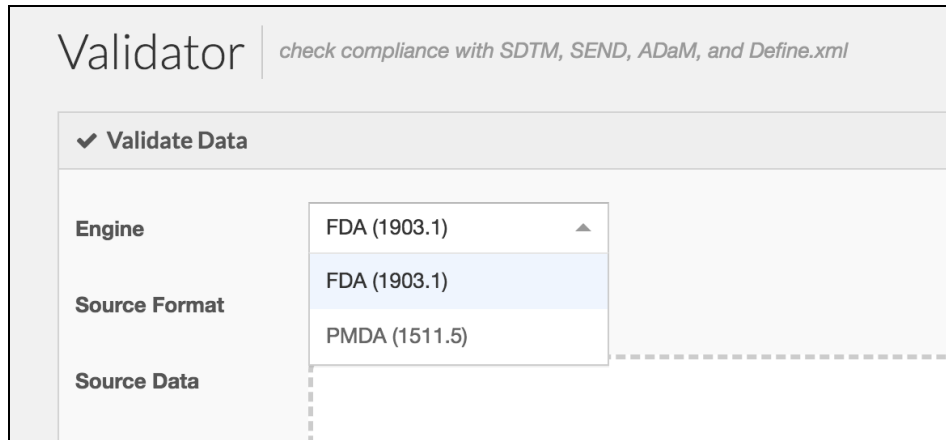
Display 6 New Validation Summary Tab

- Updated validation report to always be excel because CSV was rarely used (enhancement) Removed validator settings; validation report name will have the format pinnacle21-report-yyyymmddThh-mm.xlsx (enhancement)
 - Community 3.0 also includes wizard-driven dictionary installs for MedDRA and SNOMED.
- ### 2. FDA- and PMDA-specific Validation Engines

A validation engine is a combination of open source P21 Validator and open source implementation of FDA or PMDA published rules. While the rest of Community contains the desktop graphical user interface (GUI), Define.xml Generator, Data Converter, and Clinical Trials.gov Miner. Historically, regulators at FDA and PMDA have embraced data standards, conformance rules and Pinnacle 21 technology at different rates. Therefore, based on the current PMDA and FDA published users preparing for PMDA submissions were recommended to use previous version of Community e.g. 2.1.3, while users preparing for FDA submissions were asked to use upgraded version e.g. 2.2.0. This in effect locked out our Japanese users from any future bug fixes and enhancements, a problem that didn't sit well with team.

With Community 3.0, Pinnacle 21 solved this problem by making the validation engine a selectable option in Community. With this enhancement user can now select and run any FDA or PMDA compatible version of the validation engine within the latest version of Community.

In the screenshot below, you can see how a user can select to run either the FDA or PMDA compatible validation engine. The engines are versioned based on the year and month released and a patch number. So, FDA engine version of 1903.1, means it was released in March 2019 and it has been patched once.



Display 7 Validation Engines

3. Community 3.0 also brings a major update to FDA validation rules, including support for ADaM-IG 1.1 and SEND-IG 3.1, and implementation of over 250 new validation rules covering
 - FDA Business Rules v1.4
 - FDA Validator Rules v1.3
 - CDISC SDTMIG v3.2 Conformance Rules v1.0
 - CDISC ADaM Conformance Rules v2.0
4. All Validation Rules can be access on Pinnacle 21 website using following link.

<https://www.pinnacle21.com/validation-rules/adam>

Rule ID	Publisher ID	Message	Description	Domains	FDA	PMDA 1511.6	PMDA 1810.3	FDA Severity	PMDA Severity	1.0	1.1
AD0038B	38, 285, 291, 297 (v1.1)	Inconsistent value for *GRy	Within a study, All *GRy values must be the same for each unique value of *GRyN when primary variable *GRy is populated. ADaM IG v1.0 p.11 general variable naming conventions #10: If any combining of the SDTM character categories is done, the name of the derived ADaM character grouping variable should end in GRy and the name of its numeric equivalent should end in GRyN where y is an integer from 1-9 representing a grouping scheme. CDISC created 3 new explicit rules for ADAE which were already covered by this general rule. Considering only those rows on which both variables are populated	ADAMOTHER, BDS, ADAE, OCCDS, ADSL	X						X

Display 8 Pinnacle21 Validation Rules page

5. Alerts to Avoid Common Errors

Just like any desktop software, P21 Community needs to be installed, configured, managed and operated correctly to ensure consistent validation results. Community 3.0 introduces additional checks that will be executed every time you run a validation. Are MedDRA and SNOMED configured? Is validation engine compatible with FDA/PMDA? Are there are problems with operating system support, file integrity, or connection to web services? These and other alerts will

show up on the Validation Summary and help you diagnose and avoid common installation and operational errors.

Pinnacle 21 Validator Report		
Configuration: /Users/inna/Documents/Pinnacle 21 Community/configs/1903.1/SDTM-IG 3.2 (FDA).xml Define.xml: /Users/inna/Downloads/PHUSE Pilot Update (2018)/UpdatedCDISCPilot-define.xml Generated: 2019-05-07T23:18:31-04:00 CDISC SDTM CT Version: 2018-12-21 UNII Version: 2018-10-25 NDF-RT Version: 2018-02-05 Validation Engine Version: 1903.1		
Problems with your Validator installation detected which may cause inaccurate validation results		
Problem	Details	Link
MedDRA not configured	MedDRA is a licensed dictionary, therefore it is not included in Pinnacle 21 Community. Community users must configure MedDRA manually. Without MedDRA configured, validation rules that check the quality of Adverse Events coding will not be executed. Please follow the link on the right for instructions.	How to configure MedDRA
SNOMED not configured	SNOMED is a licensed dictionary, therefore it is not included in Pinnacle 21 Community. Community users must configure SNOMED manually. Without SNOMED configured, validation rules that check Trial Indication and Diagnosis Group in Trial Summary will not be executed. Please follow the link on the right for instructions.	How to configure SNOMED

Display 9 Pinnacle 21 report screenshot

6. Check following link for full Pinnacle21 validation engines updates

<https://bitbucket.org/p21-community/configs/src/master/CHANGELOG.txt>

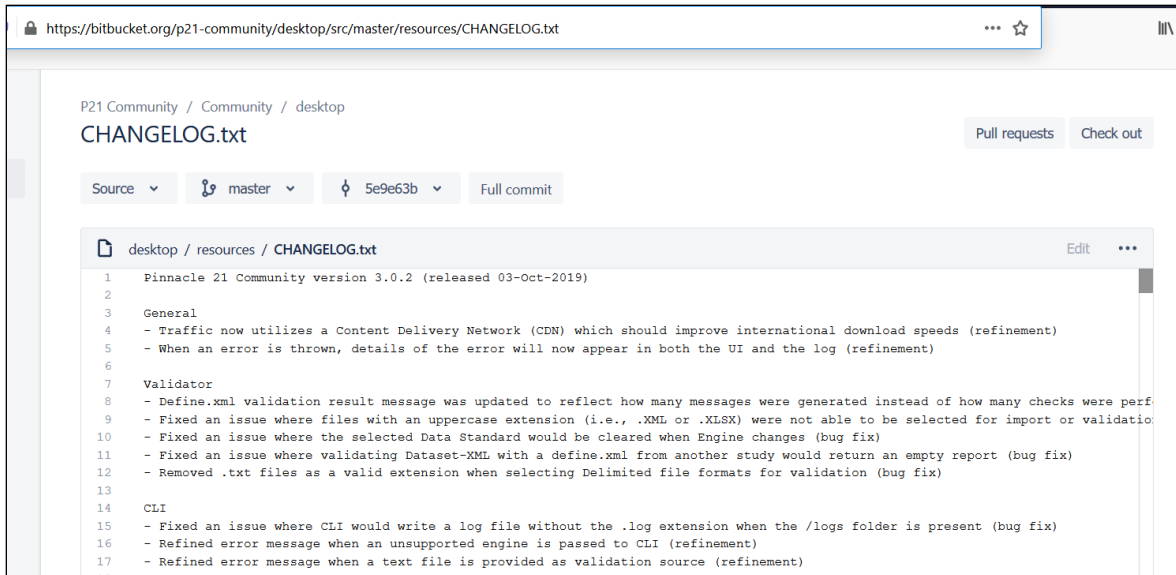
```

1 Pinnacle 21 Community validation engine 1810.3 (released 20-Nov-2019)
2
3 SDTM rules
4 - Added 60 new rules (enhancement):
5   SD1071, SD1332, SD1333, SD1334, SD1335, SD1336, SD1337, SD1338, SD1339, SD1340,
6   SD1342, SD1343, SD1344, SD1345, SD1346, SD1347, SD2270, SD2271, SD2272, SD2273,
7   SD2274, SD2275, SD2276, SD2277, SD2278, SD2279, SD2280, SD2281, SD2282, SD2283,
8   TS0001, TS0006, TS0007, TS0008, TS0009, TS0014, TS0015, TS0016, TS0017, TS0019,
9   TS0020, TS0021, TS0022, TS0023, TS0024, TS0039, TS0040, TS0041, TS0042, TS0043,
10  TS0044, TS0047, TS0048, TS0049, TS0050, TS0051, TS0052, TS0055, TS0056, TS0057
11 - Removed 2 rules as redundant (maintenance):
12   SD1142, SD1145
13 - Modified algorithm for 38 rules (bug fix or enhancement):
14   SD0005, SD0006, SD0021, SD0022, SD0038, SD0042, SD0047, SD0056, SD0064, SD0065,
15   SD0069, SD0070, SD0079, SD0087, SD0088, SD0090, SD1076, SD1011, SD1083, SD1085,
16   SD1087, SD1089, SD1091, SD1093, SD1096, SD1117, SD1125, SD1201, SD1212, SD1213,
17   SD2240, SD2241, SD2242, SD2243, SD2245, SD2247, SD2248, SD2256
  
```

Display 10 Pinnacle21 engines updates

7. Check following link for full Pinnacle21 application updates

<https://bitbucket.org/p21-community/desktop/src/master/resources/CHANGELOG.txt>



Display 11 Pinnacle 21 Application updates

CONCLUSION

Pinnacle Community 3.0 brings some major update to FDA validation rules, support for ADaM-IG 1.1 and SEND-IG 3.1. Also, users with Pinnacle ID will now get access to P21 web services and enjoy a new level of user experience. With Pinnacle ID and web services, Community installation will receive automatic updates to validation engines, rules, CDISC terminologies, and NDF-RT, MED-RT and UNII dictionaries. These features provided by Pinnacle Community v3.0.x will expediate the review process and improve quality of submissions.

REFERENCES

Gupta Ajay, 2016. Enhanced OpenCDISC Validator Report for Quick Quality Review Proceedings of the PharmaSUG 2016 Conference, paper AD07.

Gupta Ajay, 2019. Common Pinnacle 21 Report Issues: Shall we Document or Fix? Proceedings of the PharmaSUG 2019 Conference, paper DS119.

<https://www.pinnacle21.com/blog/introducing-p21-community-3>

<https://www.pinnacle21.com/>

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