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Leveraging the Company's Submission Library of Data Reviewer's Guides to Accelerate Data Validation with Pinnacle 21

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ABSTRACT

The Pinnacle 21 (P21) report, widely adopted in the industry, serves the core purpose of ensuring compliance of Study Data and Analysis Data Reviewer's Guides (cSDRG & ADRG) with regulatory standards.

Within the company, a vast repository contains numerous historically submitted documents from various studies. To fully leverage these valuable data resources, Python is employed to precisely extract information from PDF files and aggregate vast amounts of data, including detailed P21 issue datasets, encompassing rigorous validation information and corresponding in-depth explanations. Based on this, a comprehensive analysis is conducted to identify frequently occurring datasets and the underlying issues, categorize issue types, standardize explanations, and derive a series of valuable insights, including proactive preventive measures.

By integrating these actionable insights with cutting-edge emerging technologies, such as the interactive visualization capabilities of R Shiny and AI integration (RAG), the data validation process is streamlined, efficient and practical solutions are provided, and accurate explanations are automatically generated. This greatly enhances work efficiency and accelerates the preparation of Data Reviewer's Guides for submission.

INTRODUCTION

In the global pharmaceutical R&D sector, the complexity and compliance requirements of clinical data management continue to increase. As CDISC standards become the universal language for global drug registration, Pinnacle 21 (P21), recognized as the industry benchmark for compliance validation, has become the standard tool for data compliance checks. But P21 reports often involve various types of issues, and their resolution has long relied on manual review and expert judgment. A common phenomenon is that similar issues are repeatedly reviewed across different projects, with inconsistent interpretations and solutions. This traditional approach not only leads to low efficiency and makes it difficult to accumulate and reuse experience, but also increases the risk of compliance issues due to misjudgment or delays. Overcoming these bottlenecks and achieving automation, standardized knowledge accumulation, and efficient reuse in P21 report processing are key to improving data quality and review efficiency.

This paper proposes a new review process based on P21 reports from company submission projects. It establishes a standardized document for issue explanations and solutions, and develops the automated tool to enable standardization, automation, and knowledge sharing of P21 review at both the project and company levels, thereby improving review quality and efficiency and reducing compliance risks.

BACKGROUND AND CHALLENGES

P21 is a core tool for clinical data quality review. At key milestones, study teams rely on P21 to comprehensively check data and identify potential data issues, mapping issues, structure issues, and more. As a result, P21 reports often include many different types of issues. Traditionally, these issues have been reviewed and interpreted manually, which is time-consuming, labor-intensive, and highly dependent on individual experience, leading to low efficiency. There is also a lack of unified standards and collaboration across projects, resulting in inconsistent explanations and handling of similar issues between projects. This process reduces the efficiency of interdepartmental communication and issue resolution.

With the increasing volume of clinical research data and the growing complexity of project designs, traditional manual processing methods can no longer meet the needs for efficient, standardized, and

sustainable clinical data management. This not only affects project timelines but also increases data quality risks.

NEW PROCESS FRAMEWORK

To systematically address the above issues, our team has developed a new P21 review process centered on “report parsing –specific rule file – automation tool.” This process uses P21 reports from company submission projects as the data source, automatically extracting and analyzing all issues and their explanations or solutions through programming scripts, and regularly and continuously updating the company’s specific rule file (CSRF). Based on this, automated tool is used to classify issues in project-level P21 reports and automatically populate standardized explanations, enabling unified and automated review across the company.

Figure 1 provides a simple introduction to the workflow of the new solution framework.

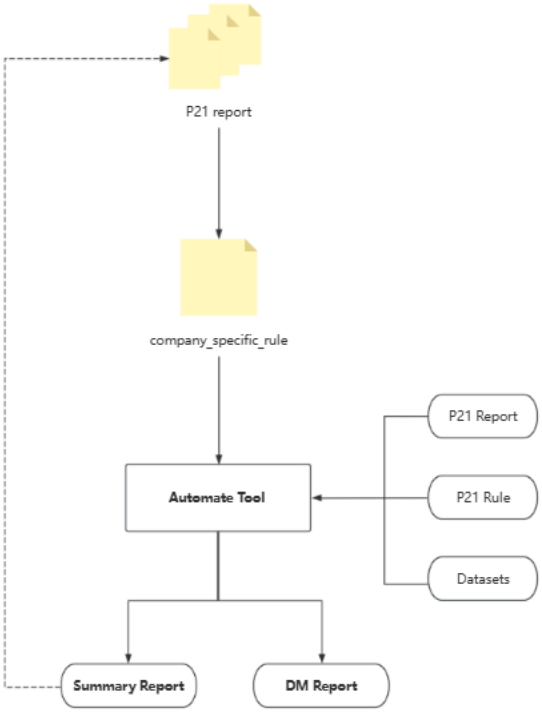

Figure 1. New Solution Framework.

The entire process consists of three key steps:

1. Automatically collecting and structuring issues and their corresponding explanations and solutions from P21 reports.
2. Achieving efficient linkage between project-level P21 report and company-level rule files through the automated tool, to support standard issue classification and provide targeted explanations and solutions.
3. Conducting necessary review and decision-making based on the output (summary report and DM report), and supplementing new issues and solutions into the CSRF.

In practice, team members only need to upload the project’s P21 report and related datasets (SDTM/ADaM) via the automated tool. The tool can then automatically parse the report, identify issues, and retrieve standard explanations and recommended solutions from the rule file, greatly improving processing efficiency. Newly identified issues can also be regularly added to the knowledge base for reuse in future projects.

BUILDING AND MAINTAINING COMPANY SPECIFIC RULE FILE

The cornerstone of our process is the systematic construction and continuous refinement of a CSRF. This file transforms P21 report data into actionable intelligence, directly addressing the inconsistencies and inefficiencies inherent in manual review. Our methodology leverages the company's extensive submission library – a rich repository of historical wisdom. We employ automated scripts to regularly retrieve the latest P21 reports. These scripts meticulously parse each report, automatically extracting every identified Issue, along with its corresponding P21 message, and the explanation or solution documented during previous reviews. This structured information is then integrated with the company's existing classification framework, which categorizes issues into data issue, programming issue, structure issue, false issues caused by ongoing processes or other reasons.

This process serves multiple critical functions. It not only validates, corrects, and supplements the original classification framework but, more significantly, generates a repository of standardized, company-validated explanations and solutions for each identified issue category. This CSRF ensures a consistent and standardized approach to P21 review interpretations and resolutions across the entire organization, regardless of the project or reviewer.

DELVING INTO P21 REPORTS: FOCUSING ON ISSUE SUMMARY

In data review guidelines, the <Issue Summary> section is essential, used to refine and summarize compliance findings. A key point is that Issue Summary for all projects adhere to a unified, standardized template. The below Figure 2 shows an example of an Issue Summary from the cSDRG Package from PHUSE.

Dataset	Diagnostic Message	Severity	Count	Explanation
CM	Start Date/Time of Observation (--STDTC) or Start Relative to Reference Period (--STRF) should not be NULL, when End Date/Time of Observation (--ENDTC) or End Relative to Reference Period (--ENRF) is not NULL	Warning	37	The start date for historical corticosteroids was not reported for 37 subjects.

Figure 2. Issues Summary Example

According to the guidelines, each diagnostic message must be accompanied by an explanation, and each message is associated with a unique Pinnacle Rule ID, as shown in Figure 3. It is precisely based on this standardized reporting and explanation template that we can extract its tabular content and convert it into CSV files, thereby establishing the foundational data source for the CSRF.

Rule ID	Message	Description	Domains
SD0031	Missing values for --STDTC, --STRF and --STRTPT when --ENDTC, --ENRF or --ENRTPT is provided	Start Date/Time of Observation (--STDTC), Start Relative to Reference Period (--STRF) or Start Relative to Reference Time Point (--STRTPT) should not be null when End Date/Time of Observation (--ENDTC), End Relative to Reference Period (--ENRF) or End Relative to Reference Time Period (--ENRTPT) is not null.	EVENTS, INTERVENTIONS, SE, SM, SV

Figure 3. Pinnacle Rule ID SD0031.

For instance, we systematically collected a total of 194 cSDRG and 229 ADRG-related P21 report PDF files from past company submissions. After comprehensive data extraction, cleaning, and transformation into a structured CSV format, approximately 15,000 valid records were compiled. This large-scale dataset forms the empirical foundation for the CSRF. By conducting frequency analysis on all identified issue

types, we generated a high-frequency issue list. This list is invaluable, guiding targeted quality control efforts and focusing review resources on the most prevalent and impactful issues.

ANALYISES ABOUT P21 REPORTS

Taking cSDRG-related issues as an illustrative example, Figure 4, Table 1, and Table 2 highlights the prevalence and count of certain issues. Among all reports, the most frequently occurring issue types are CT2002 (Variable value not found in extensible codelist), SD1076 (Model permissible variable added into standard domain), and SD1229 (Variable value is null when value-level condition occurs). However, the issues with the highest counts are CT2002, SD1117 (Duplicate records), and SD0029 (Missing value for --STRESU, when --STRESC is provided) – collectively accounted for nearly 85% of all reported issues within this subset. Among these, CT2002 is currently the most common in P21 reports. This data underscores a critical insight: accurately identifying and applying standardized resolutions for these few high-frequency issue types can yield disproportionate improvements in both overall data quality and review efficiency.

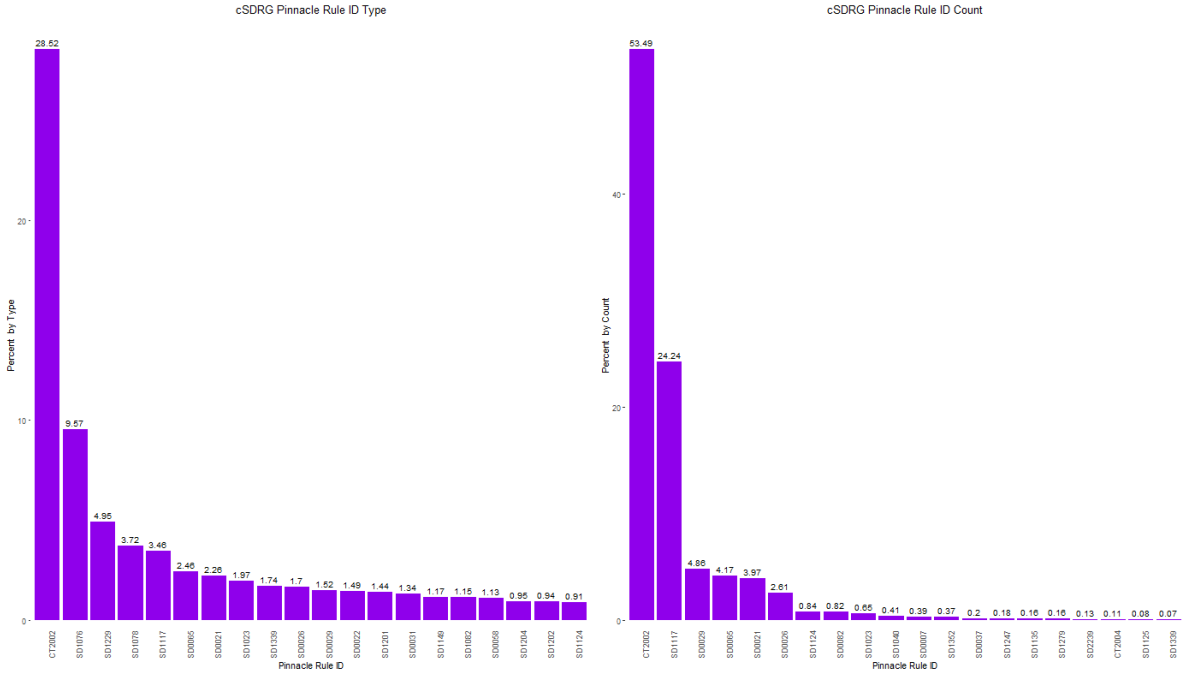

Figure 4. Frequency Analysis Results for cSDRG-related Issues.

Pinnacle Rule ID	Message	Count
CT2002	Variable value not found in extensible codelist	2818
SD1076	Model permissible variable added into standard domain	946
SD1229	Variable value is null when value-level condition occurs	489
SD1078	Permissible variable with missing value for all records	368
SD1117	Duplicate records	342
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	243
SD0021	Missing End Time-Point value	223
SD1023	VISIT/VISITNUM values do not match TV domain data	195

Pinnacle Rule ID	Message	Count
SD1339	Missing EPOCH value, when a start or observation date is provided	172
SD0026	Missing value for --ORRESU, when --ORRES is provided	168
SD0029	Missing value for --STRESU, when --STRESC is provided	150
SD0022	Missing Start Time-Point value	147
SD1201	Duplicate records in domain	142
SD0031	Missing values for --STDTC, --STRF and --STRTPT, when --ENDTC, --ENRF or --ENRTPT is provided	132
SD1149	Expected variable with missing value for all records	116
SD1082	Variable length is too long for actual data	114
SD0058	Variable appears in dataset, but is not in SDTM model	112
SD1204	--ENDTC date is after RFPENDTC	94
SD1202	--STDTC date is after RFPENDTC	93
SD1124	Missing value for --REASND, when --STAT is 'NOT DONE'	90

Table 1. Type Analysis Results for cSDRG-related Issues.

Pinnacle Rule ID	Message	Count
CT2002	Variable value not found in extensible codelist	46826174
SD1117	Duplicate records	21219451
SD0029	Missing value for --STRESU, when --STRESC is provided	4252173
SD0065	USUBJID/VISIT/VISITNUM values do not match SV domain data	3654377
SD0021	Missing End Time-Point value	3478993
SD0026	Missing value for --ORRESU, when --ORRES is provided	2286411
SD1124	Missing value for --REASND, when --STAT is 'NOT DONE'	736658
SD0082	Exposure end date is after the latest Disposition date	721559
SD1023	VISIT/VISITNUM values do not match TV domain data	566114
SD1040	--SCAT value is redundant with other variable values	358359
SD0007	Inconsistent value for Standard Units	345581
SD1352	Duplicate records in domain	322221
SD0037	Value for variable not found in user-defined codelist	178733
SD1247	ECDOSE is not greater than 0 when ECOCCUR does not equal 'N' and ECDOSTXT is null	157614
SD1135	Negative value of Study Day variable	140612
SD1279	ECDOSTXT is null when ECDOSE is null and ECOCCUR does not equal 'N'	138379
SD2239	Inconsistent value for --TPT	115104

Pinnacle Rule ID	Message	Count
CT2004	Variable value not found in non-extensible codelist when value-level condition occurs	93857
SD1125	Inconsistent value for --ELTM within --TPT, --TPTREF and/or VISITNUM	72345
SD1339	Missing EPOCH value, when a start or observation date is provided	64152

Table 2. Count Analysis Results for cSDRG-related Issues.

Table 3 starkly illustrates the inconsistency problem we aimed to solve. It summarizes the varied explanations provided for CT2002 issues across different studies, despite often conveying similar underlying reasons. For example, explanations ranged from “New terms were added…” to simply “Study-specific values were added…”

Pinnacle ID	Explanation in different submission	Standard Explanation
CT2002	The code list is extensible and additional terms were added to meet study needs. The following values were not found in ‘XX’ extensible codelist: <item value> <item value> collected in CRF was not found in 'XX' extensible codelist. <item value> was in XX of Measure. Looks like validator generate misleading message. Study specific - Start time for linear regression, and <item value> were not found in XX extensible codelist. Study specific - <item value> were not found in XX extensible codelist. 1 New term was added to extensible codelist to reflect data collected: <item value> 92 New term was added to extensible codelist to reflect data collected: <item value> 57268 New term was added to extensible codelist to include this domain	New terms were added to extensible codelist to reflect the data collected: <item value>

Table 3. Explanations for some issues in the P21 report.

COMPANY SPECIFIC RULE FILE

A high-quality guidance document is built upon two core components: first, precise problem classification; and second, a detailed and standardized remediation and verification process, supplemented by illustrative examples of explanatory verification issues. These two components are decisive for the effectiveness of the data quality management system and the rigor of the quality issue review process.

Identifies Sources of Issues

Precise problem classification not only reveals the potential sources of data quality issues but also clearly defines responsibility, thereby determining which specific functional department the issue should be delegated to (for example, data-level issues should be handed over to the data management department).

In the practical implementation of problem classification, we categorize various issues into five main categories based on P21 validation rules, P21 reports (extract from submitted projects), and the company-level standard rules: Data Issue, Programming Issue, Mapping Issue, Ongoing Study, and False Positive. It is worth noting that due to the variability of data environments and the diversity of related data domains, the same issue may be classified into different categories in different observational records or different data domains. To address this situation, we introduce additional identification content (<where-clause>) to achieve more precise classification.

Practice for Standard Explanation

Establishing a standardized explanation can streamline the preparation of data review documents and enhance the quality of submissions. Moreover, it increases transparency and reviewability of the data, which in turn accelerates the submission process.

Below is key point for preparing the good explanations.

- Explanations must be provided for each unsolved issue.
- Explanations text should include:
  - What: the specific and comprehensive data causing the issue.
  - Why: the reason why the issue remains unresolved.
  - How: the potential impact on data quality and analysis, if applicable.
- Explanations need to be clear and transparent, offering sufficient information for reviewers to understand without requiring extra effort.
- Consistency in explanations should be maintained within a study compound and, ideally, across the entire organization.

Structure for Company Specific Rule File

Based on the considerations outlined above, the CSRF primarily consists of two core components. The first part focuses on the key identifiers for issue classification, specifically including: <P21 ID> (identifying a specific P21 validation rule or error), <Domain> (indicating the data domain involved in the issue), <P21 Message> (the text description of the original validation error or warning), and <Role> (potentially referring to the data issue category). For issues that may be classified differently in various contexts, the <whereclause> field provides additional contextual information to specify the exact conditions or subset of data under which the issue occurs, thereby ensuring consistency in classification.

The second part provides potential explanations and recommended solutions for various types of issues. For data issues, the <additional information> field is used to describe in detail the specific context of the underlying raw data, providing background support for issue localization. For programming or structural issues, the <message-cSDRG> field consolidates explanatory content extracted from P21 reports, recommended solutions, and incorporates best practices advocated by P21 rules, forming a structured and practically guiding set of solutions.

Table 4 presents selected entries from the company-specific rule file.

P21 ID	Domain	Message	Role	WHERE_CLAUSE	Additional_information	Message cSDRG
CT2002	GLOBAL	Variable value not found in extensible codelist	False Positive			New terms were added to extensible codelist to reflect the data collected: <item value>
SD1117	GLOBAL	Duplicate records	Structure Issue			If duplicate: add more key variables

P21 ID	Domain	Message	Role	WHERE_CLAUSE	Additional_information	Message cSDRG
						If not duplicate: Non duplicate records with keys: xxx, xxx, xxx
SD0029	GLOBAL	Missing value for --STRESU, when --STRESC is provided	Data Issue		Standard Units (--STRESU) should not be NULL, when Character Result/Finding in Std Units (--STRESC) is provided.	If data issue: report to DM If not data issue: Not an issue: Results for xxx/xxx have no units
SD0021	AE	Missing End Time-Point value	Data Issue	AEOUT IN ('RECOVERED/RESOLVED', 'RECOVERED/RESOLVED WITH SEQUELAE')	One of End Time-Point variables values is expected to be populated when an event occurred. E.g., AEENDTC, AEENRF, AEENRTPT	Report to DM
			Ongoing Study	AEOUT NOT IN ('RECOVERED/RESOLVED', 'RECOVERED/RESOLVED WITH SEQUELAE')		The study is ongoing, missing end time when the AE isn't over.

Table 4. Company-specific Rule File.

APPLICATION AND DETAILED FUNCTIONALITY OF AUTOMATED TOOL

We have a core tool for automating the P21 review process. Users only need to specify the storage paths for the P21 report and related datasets, and the tool can automatically complete the review workflow. The automated tool intelligently compares issues in the report against the company's special rule file, automatically classifies issues, assigns responsible personnel, and populates potential explanations and solutions. It then generates two well-structured and consistent Excel review reports to facilitate internal team review and confirmation. Ultimately, the automated tool splits the original P21 report into a summary report for Programmers and a DM report for Data Management to review data issues, accelerating cross-functional collaboration during P21 review.

MAIN FEATURES OF AUTMOMATED TOOL

The main functions of the tool include:

1. Intelligent issue classification and responsibility assignment: Automatically tags each issue and assigns preliminary responsible personnel; for example, data issues are compiled into a dedicated DM report for data management.
2. Automated parsing and explanation population: Automatically identifies issue types and calls standard explanations and recommendations from the knowledge base.
3. Split domain handling optimization: Automatically identifies and classifies datasets about Split Domain-related issues, reducing manual workload.
4. Multi-version comment tracking: Supports multi-version reports and automatically manages historical review comments, making issue tracking and corrective action assessment easier.

Figure 5 illustrates the internal processing logic of tool and provides descriptions of some key information.

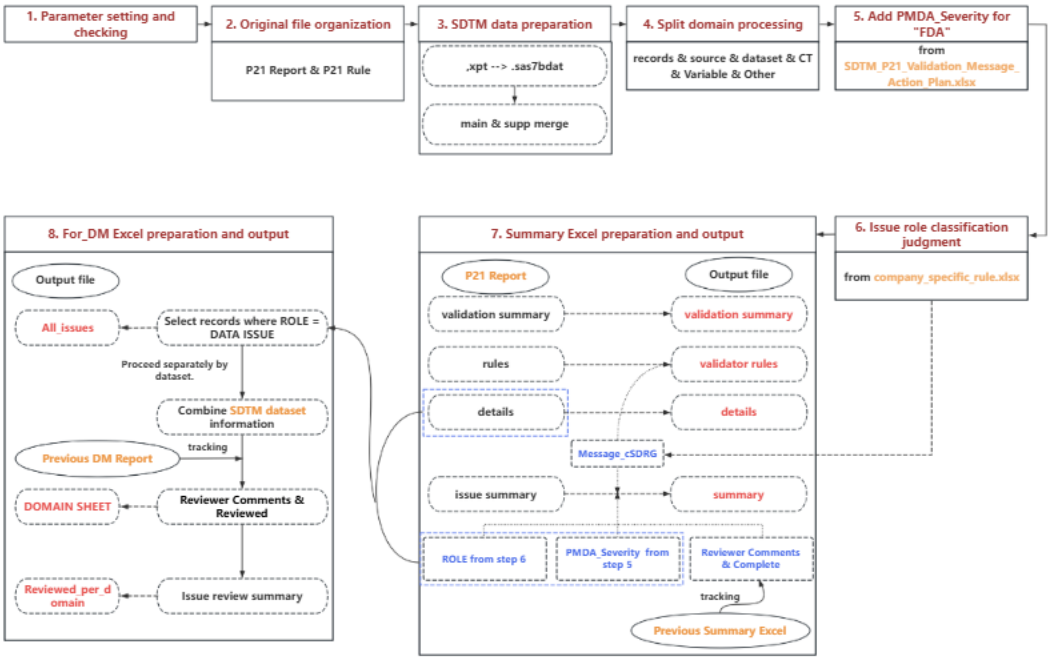

Figure 5. Processing Logic of Automated Tool.

KEY OUTPUT DELIVERABLES

Ultimately, the tool converts the original P21 report into two well-structured and information-rich reports: a Summary report and a DM report. Summary report is an extended version of the original P21 report, supplemented with additional information such as issue category (Role), PMDA_Severity, reviewer comments, review status (Complete), and possible explanations (Message_cSDRG) extracted from the CSRF and the P21 rule file. DM report will include only issues classified as data issues and will supplement them with relevant dataset information to facilitate traceability for the Data Manager team. Figure 6 and Figure 7 respectively show sample outputs of the Summary report and the DM report.

Source	Pinnacle_21_ID	Message	Severity	Foun	PMDA_Severity	Role	Reviewer Comments	Complete	Message_cSDRG
GLOBAL							###		
GLOBAL	DD0101	Missing define.xml file	Reject	1		DERIVATION ISSUE			
GLOBAL	SD1115	Missing TS dataset	Reject	1	Error	DERIVATION ISSUE			Click here for more details
AE							###		
AE	CT2002	EPOCH value not found in 'Epoch' extensible codelist		9	Warning	DERIVATION ISSUE	This rule fired for 'RESIDUAL-TREATMENT' values in EPOCH. These values were added to reflect the study design and could not be mapped to CDISC CT, but the EPOCH codelist is extensible.	Y	New terms were added to extensible codelist to reflect the data collected: <RESIDUAL-TREATMENT>
AE	SD0002	NULL value in AEDECOD variable marked as Required		25	Reject	DATA_ISSUE	Report to DM	Y(Warning-difference in FOUND)	Click here for more details
AE	SD0002	NULL value in AETERM variable marked as Required		2	Reject	DATA_ISSUE	Report to DM	Y(Warning-difference in FOUND)	Click here for more details
AE	SD1333	AEOUT = RECOVERED/RESOLVED, but an end date or collected duration is not provided		1	Warning	DATA_ISSUE			Click here for more details
AE	SD1449	Missing values for one or more variables subject to MedDRA: AELLT, AELLTCD, AEDECOD, AEPTCD, AEHLT, AEHLTCD, AEHLGT, AEHLGTCD, AEBODSYS, AEBDSYCD, AESOC, AESOCCD		24		Proposal: DATA_ISSUE	Report to DM	Y	Click here for more details
FAAE							###		
FAAE	SD0026	Missing value for FAORRESU when FAORRES is provided		1	Warning	DATA_ISSUE	Not an issue: Results for Count have no units	Y	Not an issue: Lab results for pH and Specific Gravity have no units
FAAE	SD0029	Missing value for FASTRESU when FASTRESC is provided		1	Warning	DATA_ISSUE	Not an issue: Results for Count have no units	Y	Click here for more details

Figure 6. Summary Report.

pinnacle_21_id	Domain	Record	Count	Additional_information	Category	Severity	PMDA_Severity	Reviewed	Reviewer_Comments	Keys_Information	STUDYID	USUBJID	SUBJID	AESEQ	AEGRPID
SD0002	AE	51		Required variables (where Core attribute is 'Req') cannot be NULL for any records.	Presence		Reject	No		key: STUDYID, USUBJID, SUBJID, AEREFID, AEDECOD, AESTDTC	STUDYxxx	AAA-BBB-CCC	xxxxxx	7	
SD0002	AE	70		Required variables (where Core attribute is 'Req') cannot be NULL for any records.	Presence		Reject	No		key: STUDYID, USUBJID, SUBJID, AEREFID, AEDECOD, AESTDTC	STUDYxxx	AAA-BBB-CCC	xxxxxx	2	
SD0002	AE	88		Required variables (where Core attribute is 'Req') cannot be NULL for any records.	Presence		Reject	No		key: STUDYID, USUBJID, SUBJID, AEREFID, AEDECOD, AESTDTC	STUDYxxx	AAA-BBB-CCC	xxxxxx	6	
SD0002	AE	123		Required variables (where Core attribute is 'Req') cannot be NULL for any records.	Presence		Reject	No		key: STUDYID, USUBJID, SUBJID, AEREFID, AEDECOD, AESTDTC	STUDYxxx	AAA-BBB-CCC	xxxxxx	1	
SD0002	AE	124		Required variables (where Core attribute is 'Req') cannot be NULL for any records.	Presence		Reject	No		key: STUDYID, USUBJID, SUBJID, AEREFID, AEDECOD, AESTDTC	STUDYxxx	AAA-CCC-DDD	xxxxxx	2	
SD0002	AE	160		Required variables (where Core attribute is 'Req') cannot be NULL for any records.	Presence		Reject	No		key: STUDYID, USUBJID, SUBJID, AEREFID, AEDECOD, AESTDTC	STUDYxxx	AAA-CCC-DDD	xxxxxx	2	
SD0002	AE	169		Required variables (where Core attribute is 'Req') cannot be NULL for any records.	Presence		Reject	No		key: STUDYID, USUBJID, SUBJID, AEREFID, AEDECOD, AESTDTC	STUDYxxx	AAA-CCC-DDD	xxxxxx	4	
SD0002	AE	181		Required variables (where Core attribute is 'Req') cannot be NULL for any records.	Presence		Reject	No		key: STUDYID, USUBJID, SUBJID, AEREFID, AEDECOD, AESTDTC	STUDYxxx	AAA-CCC-DDD	xxxxxx	3	
				Required variables (where Core attribute											

Reviewed_per_domain | All_issues | AE | FAAE | FACE

Figure 7. DM Report

CONCLUSION

By tightly integrating automated scripts, CSRF, and the automated tool, we have achieved automation and standardization of the P21 report processing workflow within the company, significantly improving the efficiency of P21 reviews. Based on preliminary internal feedback and initial calculations, the overall processing efficiency for P21 reports has increased by an average of approximately 50%. The establishment and reuse of CSRF have also significantly improved consistency in understanding and handling data quality issues across projects and teams.

As the volume of clinical research data continues to grow and project complexity steadily increases, we will continue to optimize and expand this system. One clear direction is to introduce more advanced intelligent recommendation features. For example, based on historical data and issue patterns, automatically predict potential high-risk areas or recommend more optimized solutions for specific issues. Additionally, we plan to enhance the knowledge base's automatic learning capabilities, enabling it to continuously "learn" from each new issue processed and team feedback, automatically optimizing classification logic and explanation suggestions. This will make the knowledge base and the tool increasingly intelligent, adaptive, and practical

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