

Automate Pinnacle 21 Review (DS05)



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The logo for Pinnacle 21, featuring the word "PINNACLE" in orange with a small orange triangle above the 'A', and the number "21" in grey to its right.

- Pinnacle 21 Community to check compliance to CDISC
- Pinnacle 21 Community report is used to check the compliance of SDTM, ADaM and associated define.xml

Electronic Submissions



- Data Conformance Summary : a required section of Reviewer's Guides (cSDRG, ADRG) to document Pinnacle 21 issues

Pinnacle 21 community report review – huge amount of work

Processed Sources								
Domain	Label	Class	Source	Records	Rejects	Errors	Warnings	Notices
GLOBAL	Global Metadata	--	--	--	0	0	0	0
AE	Adverse Events	EVENTS	ae.xpt	5136	0	1124	34	0
CM	Concomitant Medications	INTERVENTIONS	cm.xpt	16661	0	17	82	0
DD	Death Details	FINDINGS	dd.xpt	39	0	7	1	0
DM	Demographics	SPECIAL PURPOSE	dm.xpt	246	0	515	348	0
DS	Disposition	EVENTS	ds.xpt	809	0	8	11	1
DV	Protocol Deviations	EVENTS	dv.xpt	1218	0	54	34	0
EX	Exposure	INTERVENTIONS	ex.xpt	13344	0	14	1320	0
FA	Findings About Events or Interventions	FINDINGS	fa.xpt	5049	0	19	3852	0

Dataset Summary Issue Summary Details Rules (+)

Display 1. Dataset Summary Tab View

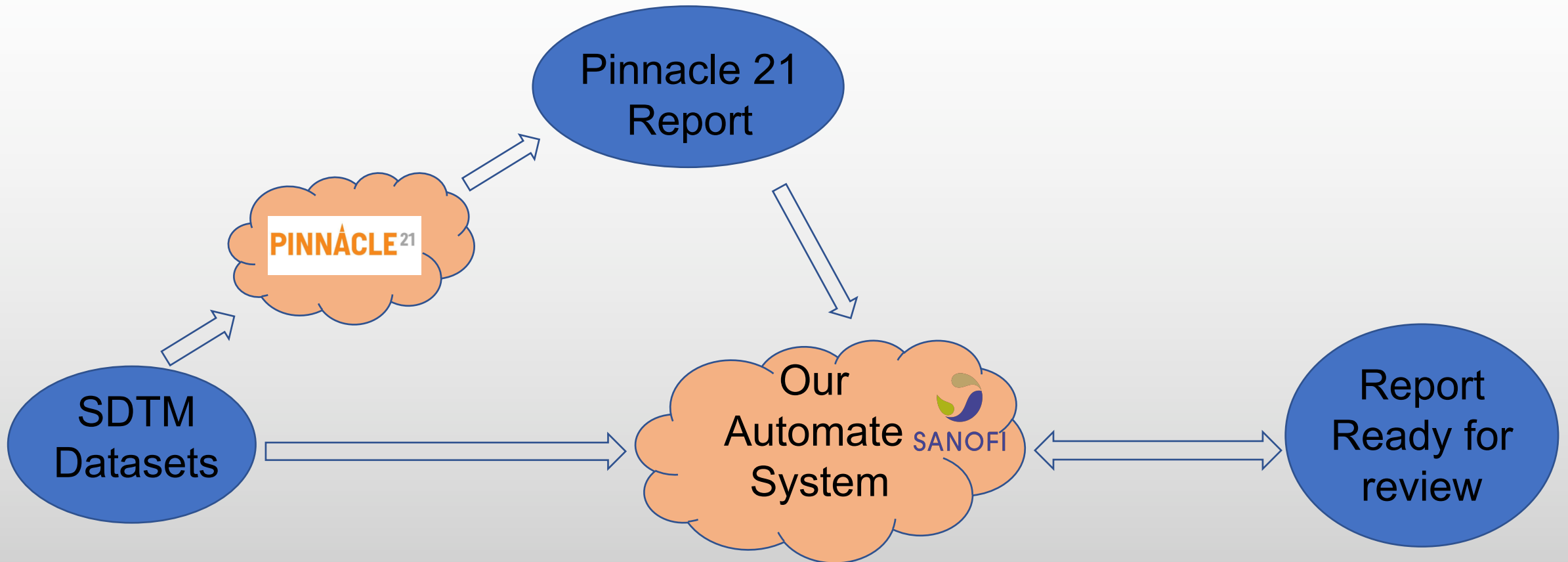
Issue Summary					
Source	Pinnacle 21 ID	Publisher ID	Message	Severity	Found
AE					
	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Error	52
	SD0009	FDAC206	No qualifiers set to 'Y', when AE is Serious	Error	5
	SD0080	FDAC208	AE start date is after the latest Disposition date	Error	1033
	SD0090	FDAC209	AESDTH is not 'Y', when AEOUT='FATAL'	Error	13
	SD0091	FDAC210	AEOUT is not 'FATAL', when AESDTH='Y'	Error	1
	SD1082	FDAC036	Variable length is too long for actual data	Error	20
	SD0021	FDAC117	Missing End Time-Point value	Warning	6
	SD0031	FDAC122	Missing values for AESTDTC, AESTRF and AESTRTPT, when AEENDTC, AEENRF or AEENRTPT is provided	Warning	3
	SD1021	FDAC018	Unexpected character value in AETERM variable	Warning	0

Dataset Summary Issue Summary Details Rules (+)

Display 2. Issue Summary Tab View

- Who can solve the issue?
- What is this issue?
- How to track the previous review?
- How to document remaining issues in cSDRG?

“Automate Pinnacle 21 Review”



➤ Who can solve the issue?

➤ The first step is to categorize each issue according to these 4 types of issues :

Type of issues	Adequate person/Team at Sanofi
Data	Data Manager
Structure	Programming Standard Expert (standard team)
Derivation	Statistical programmers
Due to ongoing patient	Waiting for Patient end of study

P21 Details

P21 Issue Summary

➤ What is this issue?

➤ What is this issue?

➤ Add SDTM data in report

➤ What is this issue?

➤ Add SDTM data in report

Pinnacle 21 Issue – Lack of generic information

pinnacle_21_id	Domain	Record	Count	Variables	Values	Message	Severity
pinnacle_21	Domain						
pinnacle_21	Abbreviat	Recor	Cou	Variable	Values	Message	Severit
SD0047	NV	1795		NVORRES, NVSTAT	null, null	Missing value for NVORRES, when NVSTAT or NVDRVFL is not populated	Warning

➤ What is this issue?

➤ Add SDTM data in report

Pinnacle 21 Issue – Lack of generic information

pinnacle_21_id	Domain	Record	Count	Variables	Values	Message	Severity	Reviewed	Reviewer_Comments	SDTM data				
pinnacle_21_id	Domain	Record	Count	Variables	Values	Message	Severity	Reviewed (Yes/No)	Reviewer Comments (Data Manager)	USUBJID	NVSEQ	NVTESTCD	NVTEST	NVCAT
pinnacle_21_id	Domain	Record	Count	Variables	Values	Message	Severity	Reviewed (Yes/No)	Reviewer Comments (Data Manager)	Unique Subject Identifier	Sequence Number	Short Name of Nervous Test	Name of Nervous Test	Category for Nervous Test
SD0047	NV	1795		NVORRES, NVSTAT	null, null	Missing value for NVORRES, when NVSTAT or NVDRVFL is not populated	Warning	No		XXXXXX-124-0002-00006	59	DCRSMTON	Decreased Muscle Tone	MOTOR EXAMINATION

➤ What is this issue?

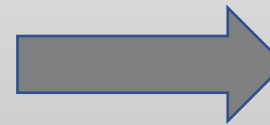
➤ Add SDTM data in report

Pinnacle 21 Issue – Lack of generic information

pinnacle_21_id	Domain	Record	Count	Variables	Values	Message	Severity	Reviewed	Reviewer_Comments	SDTM data				
pinnacle_21	Domain	Record	Count	Variables	Values	Message	Severity	Reviewed (Yes/No)	Reviewer Comments	USUBJID	NVSEQ	NVTESTCD	NVTEST	NVCAT
pinnacle_21	Abbreviation	Record	Count	Variable	Values	Message	Severity	Automatically populated	Reviewer Comments (Data Manager)	Unique Subject Identifier	Sequence Number	Short Name of Nervous Test	Name of Nervous Test	Category for Nervous Test
SD0047	NV	1795		NVORRES, NVSTAT	null, null	Missing value for NVORRES, when NVSTAT or NVDRVFL is not populated	Warning	No		XXXXXX-124-0002-00006	59	DCRSMTON	Decreased Muscle Tone	MOTOR EXAMINATION

➤ Original P21 Details are split per domain:

	A	B	C	D	E	F	G	H	I	J
1	Domain	Record	Count	Variables	Values	Pinnacle 21 ID	Publisher ID	Message	Category	Severity
2	AE			VARIABLE	EPOCH	SD1076	FDAC031	Model permissible variable added into standard domain	Metadata	Warning
3	AE	140		AEDECOD	null	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Presence	Error
4	AE	391		AEDECOD	null	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Presence	Error
5	AE	495		AEDECOD	null	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Presence	Error
6	AE	651		AEDECOD	null	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Presence	Error
7	AE	821		AEDECOD	null	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Presence	Error
8	AE	823		AEDECOD	null	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Presence	Error
9	AE	1363		AEDECOD	null	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Presence	Error
10	AE	1395		AEDECOD	null	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Presence	Error
11	DS			VARIABLE	VISITNUM	SD1076	FDAC031	Model permissible variable added into standard domain	Metadata	Warning
12	DS			VARIABLE	VISIT	SD1076	FDAC031	Model permissible variable added into standard domain	Metadata	Warning
13	DS		69	DSCAT, DSDECOD	DISPOSITION EVENT, LAST CONTACT	CT2005	FDAC344	DSDECOD value not found in 'Completion/Reason for Non-Completion' extensible codelist when DSCAT == 'DISPOSITION EVENT'	Terminology	Warning
14	DS	17		DSDECOD	null	SD0002	FDAC018	NULL value in DSDECOD variable marked as Required	Presence	Error
15	DS	17		DSTERM	null	SD0002	FDAC018	NULL value in DSTERM variable marked as Required	Presence	Error
16	DS	56		DSDECOD	null	SD0002	FDAC018	NULL value in DSDECOD variable marked as Required	Presence	Error
17	DS	56		DSTERM	null	SD0002	FDAC018	NULL value in DSTERM variable marked as Required	Presence	Error
18	DS	68		DSDECOD	null	SD0002	FDAC018	NULL value in DSDECOD variable marked as Required	Presence	Error
19	DS	68		DSTERM	null	SD0002	FDAC018	NULL value in DSTERM variable marked as Required	Presence	Error
20	DS	76		DSDECOD	null	SD0002	FDAC018	NULL value in DSDECOD variable marked as Required	Presence	Error
21	DS	76		DSTERM	null	SD0002	FDAC018	NULL value in DSTERM variable marked as Required	Presence	Error
22	DS	81		DSDECOD	null	SD0002	FDAC018	NULL value in DSDECOD variable marked as Required	Presence	Error



AE	CM	DM	DS	DV
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➤ How to track the previous review?

➤ To ensure follow-up, in next reports :

- ✓ Previous comments are retrieved
- ✓ Message previously reviewed is highlighted in orange

Source	Pinnacle ID	Publisher ID	Message	Severity	Found	Role	Reviewer Comment	Previous Reviewer Comments	Previous found
AE							###	###	0
AE	SD0002	FDAC018	NULL value in AEDECOD variable marked as Required	Error	8	DM_ISSUE			4
AE	SD0008	FDAC346	Value for AEDECOD not found in MedDRA dictionary	Error	2	DM_ISSUE			
AE	SD0013	FDAC107	AESTDTC is after AEENDTC	Error	1	DM_ISSUE		MG-2020-04-20 : Query sent	2
AE	SD0080	FDAC208	AE start date is after the latest Disposition date	Error	792	DM_ISSUE, ONGOING_STUDY			734
AE	SD1082	FDAC036	Variable length is too long for actual data	Error	18	STAT_PROG_ISSUE			19
AE	SD0031	FDAC122	Missing values for AESTDTC, AESTRF and AESTRTPT, when AEENDTC, AEENRF or AEENRTPT is provided	Warning	11	DM_ISSUE			3
AE	SD1076	FDAC031	Model permissible variable added into standard domain	Warning	1	PSE_ISSUE		Model permissible variable EPOCH was added to the domain as per FDA's requirements.	1



Follow-up depends on feasibility to merge (= identical key variables)

➤ How to document remaining issues in cSDRG?

➤ Some common explanations automatically retrieved like :

- ✓ Model permissible variable XXXXX was added to the domain as per FDA's requirements.
- ✓ The sorting keys defined by the check are not sufficient to identify a unique record. XXXXX (*Label*) should be added to ensure uniqueness.
- ✓ and so on

➤ Information of P21 Issue Summary are copied in reviewer's guide

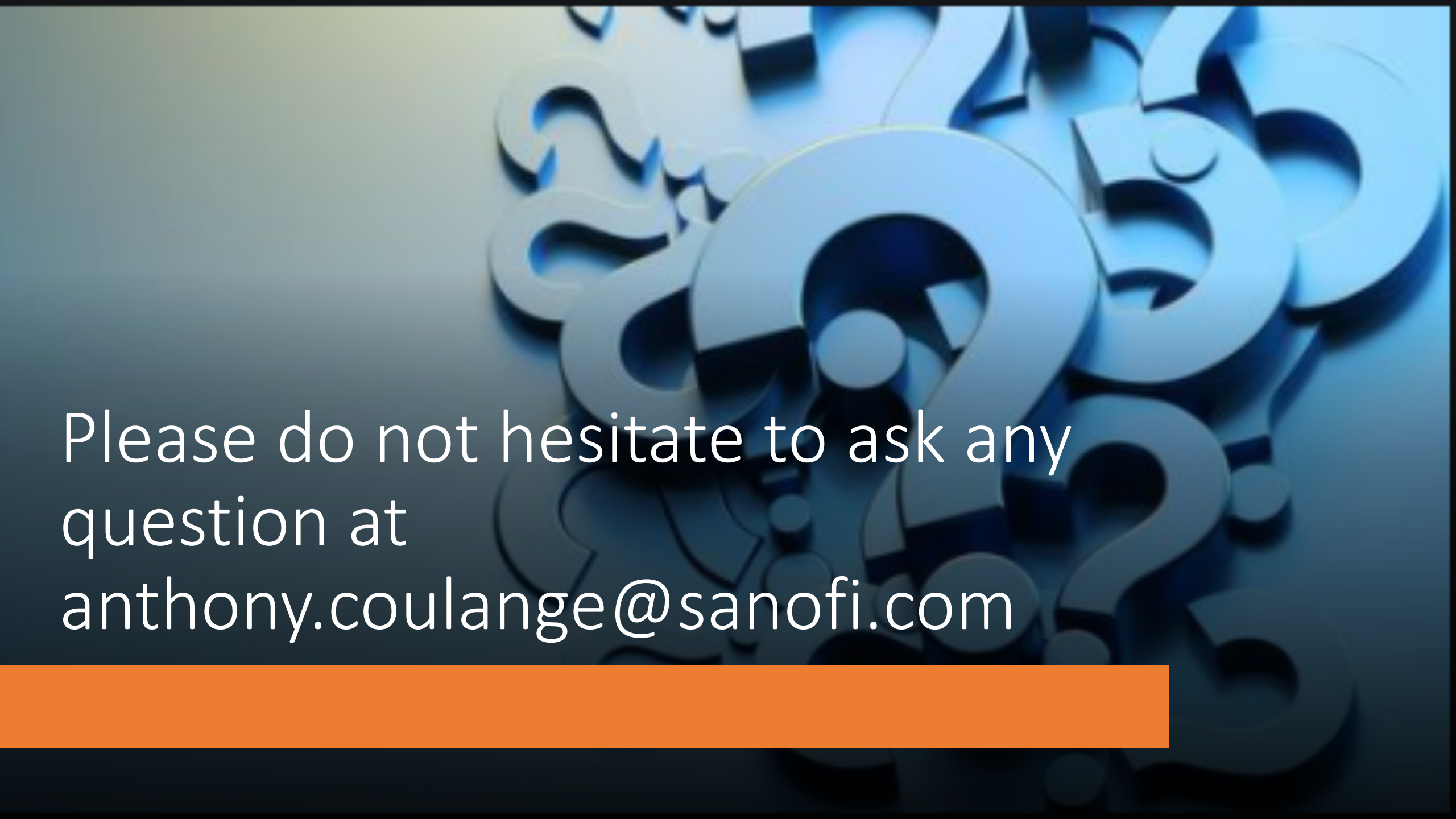
4.2 Issues Summary

Dataset	Pinnacle 21 ID	Publisher ID	Diagnostic Message	Severity (FDA)	Count	Explanation
AE	CT2001	FDAC340	AEACN value not found in 'Action Taken with Study Treatment' non-extensible codelist	Error	3033	As per SDTMIG, the value MULTIPLE is allowable.
	SD0080	FDAC208	AE start date is after the latest Disposition date	Error	528	The last disposition date has not been reached for some patients at the time of cutoff date as the study was still ongoing.

Automate P21 review ⇔ Significant Gain of time

- This tool is in testing phase on a high priority compound
- According to users, this process offers :
 - an easier way to understand the issues
 - adequate sharing of issues between stakeholders
 - the simplest manner to follow resolving of issues
 - an optimized way to document remaining issues in the reviewer's guide
- At least 30% gain of time.

[illegible]

The background of the slide features a dark blue gradient with several large, 3D-style question marks in a lighter blue color. These question marks are scattered across the upper and middle portions of the slide. At the bottom, there is a solid orange horizontal bar that spans the width of the slide.

Please do not hesitate to ask any
question at
anthony.coulanges@sanofi.com