

From Validation Reports to **Contextualized Submission Review**



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How do findings reach the human?

Agenda



- Background — traditional finding reports
- The shift in how we work with findings
- Three kinds of marking — and what color means
- Findings — where they sit, timing, and context
- Examples
- Cumba implementation
- Summary & Suggestion

The Reviewer's Reality - a typical day with a P21 report



Generate XPT 🦶 validate in P21 🦶 get Excel report 🦶 open Excel 🦶 pick a finding 🦶 switch to data viewer 🦶 scroll to the right cell 🦶 understand the message 🦶 decide if it's programmatic (fix it) or content-related (comment it) 🦶 switch back to Excel 🦶 document 🦶 Next finding

...for hours, sometimes days....

and often right before the deadline, when time is short. Re-run, and many of the same findings come back — now mixed with new ones. You sort, filter, mentally separate.

If you use the P21 internal tracker instead of Excel you get it without noise of old already documented findings.



The report has become the primary focus.

The data has become secondary.

That's backwards.



Slow searching

Tiring Jump back and forth

The data gets forgotten

Miss the data pattern

Findings
aren't only
paperwork
they risk to
break your
results

Yesterday

an issue table that references data.

Today

a dataset that displays issues.



- **Findings** sit on the data itself
- **Filtering** instead of tracing

The shape of the workflow changes



Yesterday: Issues in separate Report

1	Domain	RecordCount	Variables	Values	Pinacle 21	Message	Category
1449	SUPPEC		Variable	QEVAL	SD1082	Variable length is too long for actual data	Metadata
1450	SUPPEC		Variable	IDVAR	SD1082	Variable length is too long for actual data	Metadata
1451	SUPPEC		Variable	IDVARVAL	SD1082	Variable length is too long for actual data	Metadata
1452	SUPPEC		Variable	4, QORIG	SD1082	Variable length is too long for actual data	Metadata
1453	SUPPEC		Variable	RDOMAIN	SD1082	Variable length is too long for actual data	Metadata
1454	SV		Variable	169, VISIT	SD1082	Variable length is too long for actual data	Metadata
1455	SV		Variable	SVUPDES	SD1082	Variable length is too long for actual data	Metadata

1456 TA
1457 TE
1458 TE
1459 TI
1460 TS
1461 TS
1462 TS
1463 TS
1464 TS
1465 TS
1466 TS
1467 TS
1468 TS

SAS Universal Viewer - [ae.xpt]
File Tools Window Help
Address
Library Properties AE
Freeze Hide Show... Format Filter... Font... Find
Table View

STUDYID	DOMAIN	USUBJID	AESOC	AELINKID	AETERM	AESER	AESCAN	AESCONG	AESDISAB	AESDTH		
1	CDISCILOT01	AE	CDISC001	1	INJECTION SITE REACTION	MODERATE	N	DRUG WITHDR...	RELATED	NOT RECOVER...	N	N
2	CDISCILOT01	AE	CDISC001	2	FATIGUE	MODERATE	N	DOSE NOT CHA...	UNLIKELY REL...	NOT RECOVER...	N	N
3	CDISCILOT01	AE	CDISC002	1	INJECTION SITE REACTION	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
4	CDISCILOT01	AE	CDISC002	2	SHOULDER PAIN	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
5	CDISCILOT01	AE	CDISC002	3	JOINT DISLOCATION	MODERATE	N	DOSE NOT CHA...	NOT RELATED	RECOVERED/R...	N	N
6	CDISCILOT01	AE	CDISC002	4	INCONTINENCE	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
7	CDISCILOT01	AE	CDISC002	5	INJECTION SITE REACTION	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
8	CDISCILOT01	AE	CDISC002	6	SKIN LACERATION	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
9	CDISCILOT01	AE	CDISC002	7	CONFUSIONAL STATE	MODERATE	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
10	CDISCILOT01	AE	CDISC002	8	DYSPOEIA	MODERATE	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
11	CDISCILOT01	AE	CDISC002	9	SUDDEN DEATH	SEVERE	Y	DRUG WITHDR...	NOT RELATED	FATAL	N	N
12	CDISCILOT01	AE	CDISC003	1	HYPERHIDROSIS	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
13	CDISCILOT01	AE	CDISC003	2	STOMACH DISCOMFORT	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
14	CDISCILOT01	AE	CDISC003	3	PAIN	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
15	CDISCILOT01	AE	CDISC003	4	NASAL CONGESTION	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
16	CDISCILOT01	AE	CDISC003	5	MALISE	MODERATE	N	DOSE NOT CHA...	UNLIKELY REL...	NOT RECOVER...	N	N
17	CDISCILOT01	AE	CDISC003	6	MYALGIA	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
18	CDISCILOT01	AE	CDISC003	7	PHARYNGOLARYNGEAL PAIN	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
19	CDISCILOT01	AE	CDISC003	8	PRODUCTIVE COUGH	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
20	CDISCILOT01	AE	CDISC003	9	DIZZINESS	MODERATE	N	DOSE NOT CHA...	UNLIKELY REL...	RECOVERED/R...	N	N
21	CDISCILOT01	AE	CDISC003	10	DIZZINESS	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
22	CDISCILOT01	AE	CDISC003	11	CONFUSION	MILD	N	DOSE NOT CHA...	UNLIKELY REL...	RECOVERED/R...	N	N
23	CDISCILOT01	AE	CDISC003	12	HEADACHE	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
24	CDISCILOT01	AE	CDISC003	13	EPISTAXIS	MILD	Y	DOSE NOT CHA...	UNLIKELY REL...	NOT RECOVER...	N	N
25	CDISCILOT01	AE	CDISC003	14	INJECTION SITE REACTION	MILD	N	DOSE NOT CHA...	RELATED	NOT RECOVER...	N	N
26	CDISCILOT01	AE	CDISC003	15	RESPIRATORY TRACT CONGE...	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
27	CDISCILOT01	AE	CDISC003	16	RHINITIS	MILD	N	DOSE NOT CHA...	NOT RELATED	NOT RECOVER...	N	N
28	CDISCILOT01	AE	CDISC003	17	FEELING ABNORMAL	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
29	CDISCILOT01	AE	CDISC003	18	LIBIDO DECREASED	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
30	CDISCILOT01	AE	CDISC003	19	LISTLESS	MILD	N	DRUG WITHDR...	NOT RELATED	NOT RECOVER...	N	N
31	CDISCILOT01	AE	CDISC005	1	INJECTION SITE REACTION	MILD	N	DOSE NOT CHA...	RELATED	RECOVERED/R...	N	N
32	CDISCILOT01	AE	CDISC005	2	INJECTION SITE REACTION	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
33	CDISCILOT01	AE	CDISC005	3	INJECTION SITE REACTION	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	RECOVERED/R...	N	N
34	CDISCILOT01	AE	CDISC005	4	INJECTION SITE REACTION	MILD	N	DOSE NOT CHA...	POSSIBLY REL...	NOT RECOVER...	N	N
35	CDISCILOT01	AE	CDISC005	5	CHEST DISCOMFORT	MILD	N	DOSE NOT CHA...	NOT RELATED	RECOVERED/R...	N	N
36	CDISCILOT01	AE	CDISC005	6	HEADACHE	MILD	N	DOSE NOT CHA...	NOT RELATED	RECOVERED/R...	N	N
37	CDISCILOT01	AE	CDISC005	7	COUGH	MODERATE	N	DOSE NOT CHA...	NOT RELATED	RECOVERED/R...	N	N

Rows 1-74 of 74 Filter: Off Sort: AELINKID
z:\dataexchange-datase\sdm\vp\ae.xpt
Initializing...

3,1

Today: Issues embedded in Dataviewer

AE

SQL

by Treatment	AEREL Causality	AEOU Outcome of Adverse Event	AEENDTC End Date/Time of Adverse Event	AESCAN Involves Cancer	AESCONG Congenital Anomaly or Birth Defect	AESDISAB Persist or Signif Disability/Incapacity	AESDTH Results in Death
31	Not Changed	RELATED - Related	RECOVERED/RESOLVED - Recovered/Resolved	2013-02-07	N - No	N - No	N - No
32	Not Changed	POSSIBLY RELATED - Possibly Related	NOT RECOVERED/NOT RESOLVED - Not Rec...	2013-03-26	N - No	N - No	N - No
33	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved		N - No	N - No	N - No
34	Not Changed	POSSIBLY RELATED - Possibly Related	NOT RECOVERED/NOT RESOLVED - Not Rec...		N - No	N - No	N - No
35	Not Changed	NOT RELATED - Not Related	RECOVERED/RESOLVED - Recovered/Resolved	2013-06-24	N - No	N - No	N - No
36	Not Changed	NOT RELATED - Not Related	RECOVERED/RESOLVED - Recovered/Resolved	2013-06-24	N - No	N - No	N - No
37	Not Changed	NOT RELATED - Not Related	RECOVERED/RESOLVED - Recovered/Resolved	2013-07-26	N - No	N - No	N - No
38	Withdrawn	POSSIBLY RELATED - Possibly Related	NOT RECOVERED/NOT RESOLVED - Not Rec...		N - No	N - No	N - No
39	Not Changed	POSSIBLY RELATED - Possibly Related	NOT RECOVERED/NOT RESOLVED - Not Rec...		N - No	N - No	N - No
40	Not Changed	NOT RELATED - Not Related	RECOVERED/RESOLVED - Recovered/Resolved	2013-02-08	N - No	N - No	N - No
41	Withdrawn	NOT RELATED - Not Related	FATAL - Fatal	2014-10-31	N - No	N - No	Y - Yes
42	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved	2013-01-19	N - No	N - No	N - No
43	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved				
44	Not Changed	NOT RELATED - Not Related	NOT RECOVERED/NOT RESOLVED - Not Rec...				
45	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved				
46	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved				
47	Not Changed	RELATED - Related	RECOVERED/RESOLVED - Recovered/Resolved				
48	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved				
49	Not Changed	RELATED - Related	RECOVERED/RESOLVED - Recovered/Resolved				
50	Withdrawn	POSSIBLY RELATED - Possibly Related	FATAL - Fatal				
51	Not Changed	RELATED - Related	RECOVERED/RESOLVED - Recovered/Resolved				
52	Withdrawn	NOT RELATED - Not Related	NOT RECOVERED/NOT RESOLVED - Not Rec...				
53	Not Changed	POSSIBLY RELATED - Possibly Related	NOT RECOVERED/NOT RESOLVED - Not Rec...				
54	Not Changed	NOT RELATED - Not Related	RECOVERED/RESOLVED - Recovered/Resolved				
55	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved				
56	Not Changed	RELATED - Related	RECOVERED/RESOLVED - Recovered/Resolved				
57	Not Changed	RELATED - Related	RECOVERED/RESOLVED - Recovered/Resolved				
58	Withdrawn	UNLIKELY RELATED - Unlikely Related	NOT RECOVERED/NOT RESOLVED - Not Rec...				
59	Not Changed	NOT RELATED - Not Related	NOT RECOVERED/NOT RESOLVED - Not Rec...				
60	Not Changed	UNLIKELY RELATED - Unlikely Related	RECOVERED/RESOLVED - Recovered/Resolved				
61	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved				
62	Not Changed	UNLIKELY RELATED - Unlikely Related	RECOVERED/RESOLVED - Recovered/Resolved				
63	Not Changed	POSSIBLY RELATED - Possibly Related	RECOVERED/RESOLVED - Recovered/Resolved				
64	Withdrawn	RELATED - Related	RECOVERED/RESOLVED - Recovered/Resolved				
65	Not Changed	NOT RELATED - Not Related	RECOVERED/RESOLVED - Recovered/Resolved				
66	Not Changed	UNLIKELY RELATED - Unlikely Related	RECOVERED/RESOLVED - Recovered/Resolved	2012-12-26	N - No	N - No	N - No
67	Not Changed	NOT RELATED - Not Related	RECOVERED/RESOLVED - Recovered/Resolved	2013-01-19	N - No	N - No	N - No

Value: FATAL
Formatted: Fatal
Name: AEOU
Label: Outcome of Adverse Event
Type: STRING (string)
Length: 32
Format: \$Outcome of Event.
Role: Record Qualifier
SASFieldName: AEOU
OrderNumber: 23
Mandatory: No
dataType: STRING
targetDataType: UNKNOWN
KeySequence: -1
itemOID: IT.AE.AEOU
Validation Findings: 1
Finding: SD1347 (RuleViolation - Warning) - pinnacle21
Message: AEENDTC for fatal AE is not the same as DM.DTHDTC
Rows: 41, 50
Press F2 to focus!

Three kinds of highlighting content



1 · Structure

Always present → easier to read

Visual:

lines, light shading, italics,

Includes:

- Zebra striping
- By-group lines
- Pin USUBJID
- Varname+Label

2 · What you want to see

On demand → only if you want to see it

Visual:

borders instead of fills, different colors (eg. blue tones)

Includes:

- Filter
- Sort
- Pin columns
- Outlier marking
- Highlight selected USUBJID in all datasets

3 · Findings

Automatic → because something is wrong

Visual:

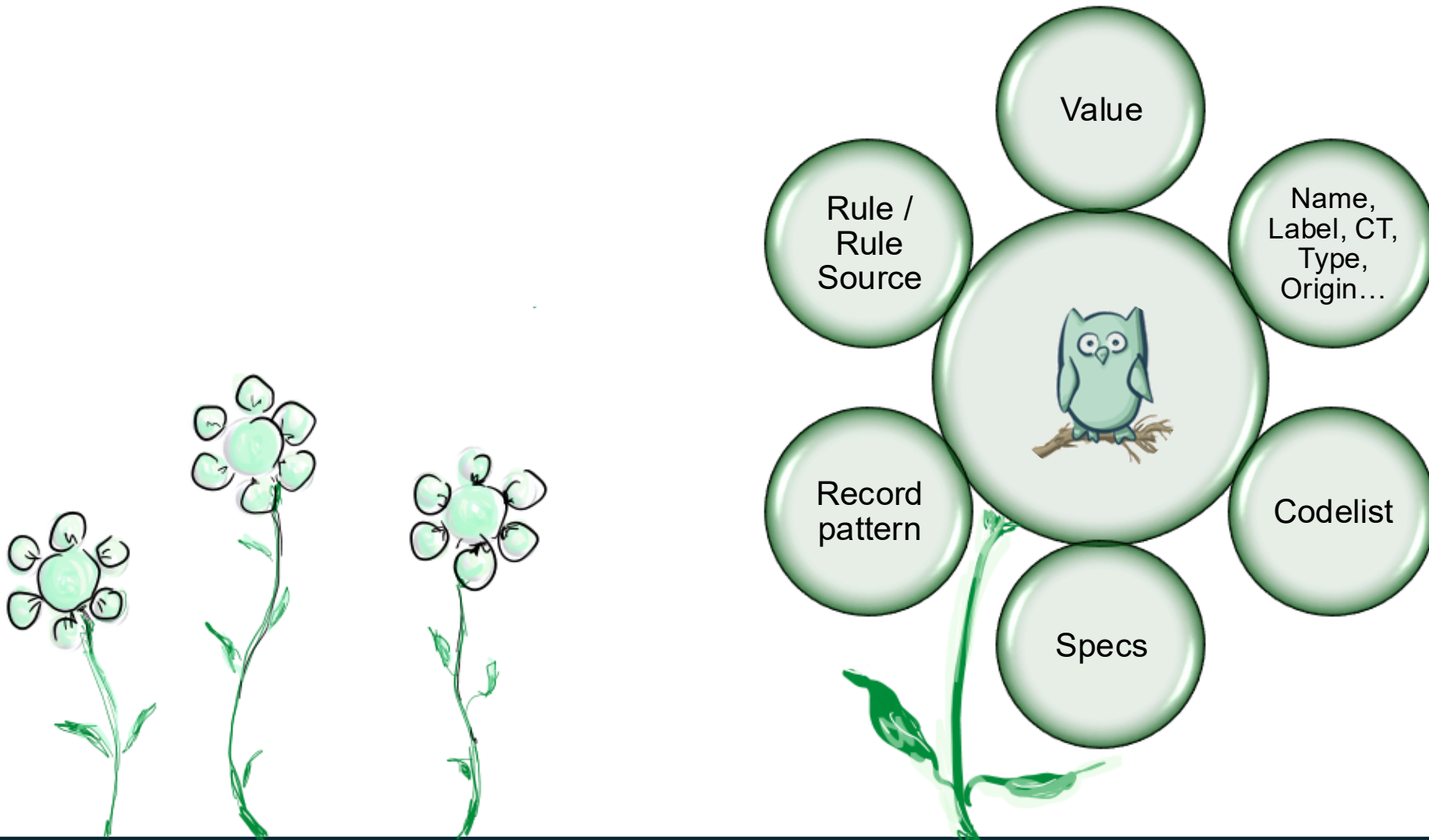
severity in traffic lights, markers

Includes:

- Validation checks (P21, CDISC CORE)
- Specs conformance
- Missing codelist entries
- Non printable chars
- Sponsor-specific rules
- Spelling mistakes

Color is only for findings. Everything else stays quiet, so the color stands out.

What you need to understand a finding?



Where do findings show up?

CDISC CORE calls this sensitivity

Level	Example finding
Cell	• Code not in the codelist • Value truncated • Invalid (date) value • Required value missing
Row	• Duplicate record • Not unique by keys
Column	• Label doesn't match the standard • Wrong type • Length too long
Dataset	• Required variable missing entirely • Wrong dataset label

Where do findings show up?

How to mark findings?

CDISC CORE calls this sensitivity

Level	Example finding
Cell	• Code not in the codelist • Value truncated • Invalid (date) value • Required value missing
Row	• Duplicate record • Not unique by keys
Column	• Label doesn't match the standard • Wrong type • Length too long
Dataset	• Required variable missing entirely • Wrong dataset label

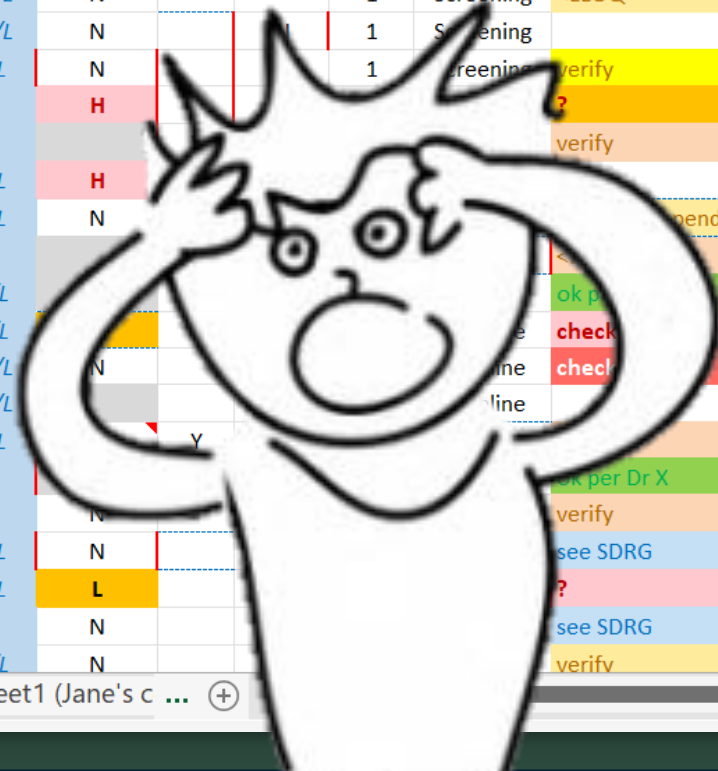


Next exit:
Column length too short

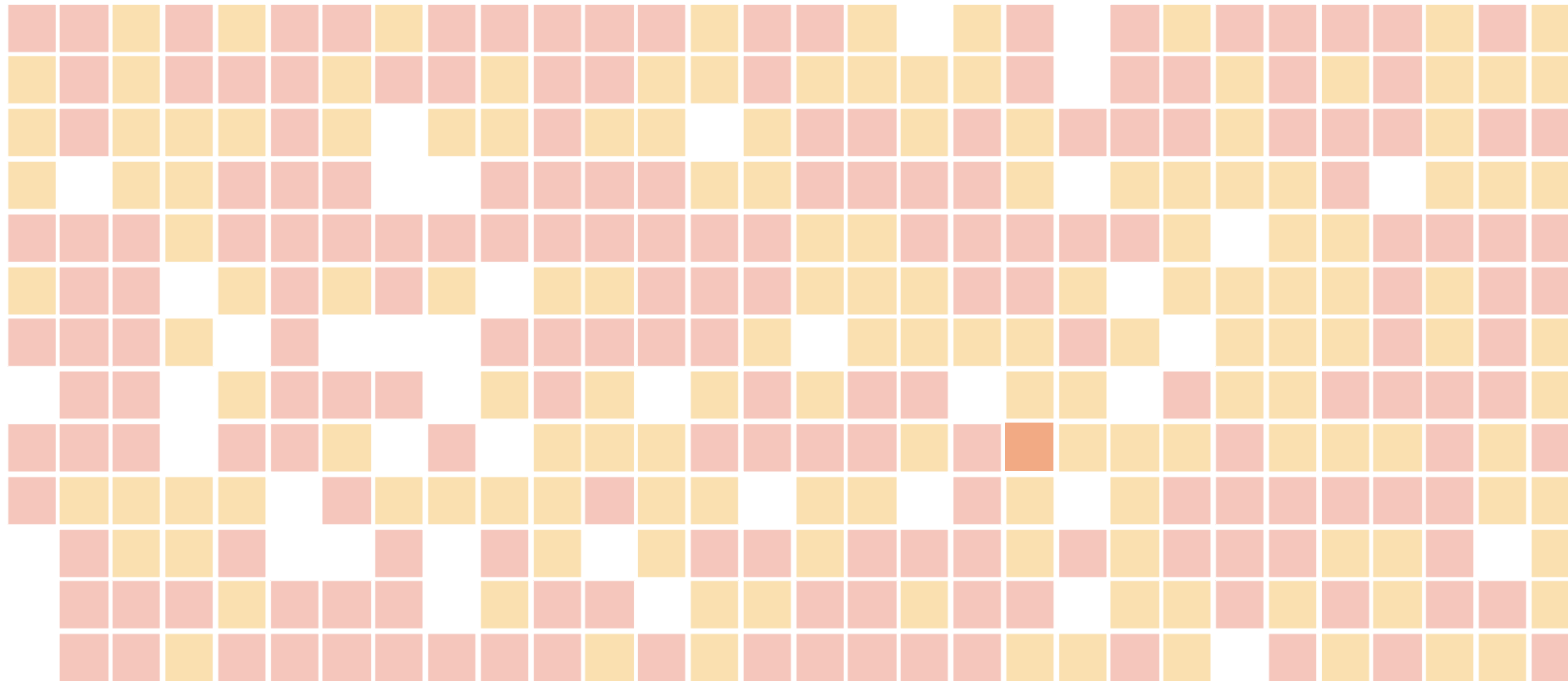


This is not what's meant ...

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
STUDYID	DOMA	LBSE	LBTEST	LBTEST	LBORRES	LBORRES	LBSTRESS	LBSTRESS	LBSTRESS	LBNRIND	LBBLF	LBFACT	VISITN	VISIT	Reviewer Comment	DM Status	Stat Note
STUDY-001	LB	1	ALT	Alanine Aminotransferase	52.64	U/L	52.64	52,64	U/L	N		N	1	Screening		locked	
STUDY-001	LB	2	AST	Aspartate Aminotransferase	25.01	U/L	25.01	25,01	U/L	N			1	Screening	see SDRG	Resolved	exclude from analysis
STUDY-001	LB	3	CREAT	Creatinine	1.83	mg/dL	1.83	1,83	mg/dL	H		N	1	Screening	OK	FROZEN	transform log
STUDY-001	LB	4	GLUC	Glucose	142.93	mg/dL	142.93	142,93	mg/dL	H		Y	1	Screening		PENDING	
STUDY-001	LB	5	HGB	Hemoglobin	18.16	g/dL	18.16	18,16	g/dL	N			1	Screening		PENDING	transform log
STUDY-001	LB	6	WBC	White Blood Cell Count	4.65	10^9/L	4.65	4,65	10^9/L	L			1	Screening	OK	Query open	outlier
STUDY-001	LB	7	PLAT	Platelets	357.18	10^9/L	357.18	357,18	10^9/L	H			1	Screening	check w/ PI	FROZEN	transform log
STUDY-001	LB	8	NA	Sodium	162.13	mmol/L	162.13	162,13	mmol/L	N			1	Screening	<LLOQ	Resolved	use as imputed
STUDY-001	LB	9	K	Potassium	4.05	mmol/L	4.05	4,05	mmol/L	N			1	Screening		Cleaned	exclude from analysis
STUDY-001	LB	10	BUN	Blood Urea Nitrogen	18.4	mg/dL	18.4	18,4	mg/dL	N			1	Screening	verify	PENDING	
STUDY-001	LB	11	ALT	Alanine Aminotransferase	60.56	U/L	60.56	60,56	U/L	H					verify	locked	
STUDY-001	LB	12	AST	Aspartate Aminotransferase	41.61	U/L	41.61	41,61	U/L						verify	FROZEN	
STUDY-001	LB	13	CREAT	Creatinine	1.72	mg/dL	1.72	1,72	mg/dL	H						Query open	outlier
STUDY-001	LB	14	GLUC	Glucose	85.6	mg/dL	85.6	85,6	mg/dL	N					pending	Resolved	use as imputed
STUDY-001	LB	15	HGB	Hemoglobin	11.57	g/dL	11.57	11,57	g/dL						<	locked	
STUDY-001	LB	16	WBC	White Blood Cell Count	8.98	10^9/L	8.98	8,98	10^9/L						ok p	Cleaned	transform log
STUDY-001	LB	17	PLAT	Platelets	157.79	10^9/L	157.79	157,79	10^9/L						check	Cleaned	exclude from analysis
STUDY-001	LB	18	NA	Sodium	171.5	mmol/L	171.5	171,5	mmol/L	N					line	FROZEN	transform log
STUDY-001	LB	19	K	Potassium	2.91	mmol/L	2.91	2,91	mmol/L						line	PENDING	exclude from analysis
STUDY-001	LB	20	BUN	Blood Urea Nitrogen	14.92	mg/dL	14.92	14,92	mg/dL			Y				Query open	use as imputed
STUDY-001	LB	21	ALT	Alanine Aminotransferase	51.71	U/L	51.71	51,71	U/L						ok per Dr X	FROZEN	transform log
STUDY-001	LB	22	AST	Aspartate Aminotransferase	29.04	U/L	29.04	29,04	U/L	N					verify	Cleaned	
STUDY-001	LB	23	CREAT	Creatinine	1.11	mg/dL	1.11	1,11	mg/dL	N					see SDRG	Query open	transform log
STUDY-001	LB	24	GLUC	Glucose	68.27	mg/dL	68.27	68,27	mg/dL	L					?		
STUDY-001	LB	25	HGB	Hemoglobin	12.62	g/dL	12.62	12,62	g/dL	N					see SDRG	Resolved	
STUDY-001	LB	26	WBC	White Blood Cell Count	10.29	10^9/L	10.29	10,29	10^9/L	N					verifv	Query open	use as imputed



If everything is flagged, nothing is



950 of 1000 are noise. The one that matters drowns.

Alert Fatigue — the silent killer of validation reports



Every run produces a fresh report — everything in it, old and new.

Same findings, again and again. After a few rounds, no one opens the report anymore.

Findings without filter are noise.

No one reads noise.



Findings travel badly through time.

Catch them early, while the dataset is still in your head.



Some finding examples follow ...

.....each one harder, slower, or impossible to handle with a classical report.

Example (1): Showing the data better avoids findings in the first place



Before: things that are **invisible** turn into findings. Now: you **see** what's really there.

Numeric precision

1.4999999999997 → ≈ 1.5

- ➔ Smart Number Display
clean on screen, full precision in the tooltip.
- ➔ Avoids our known “equal” problems.

Code vs decode confusion

1 → 1 – Placebo

2 → 2 – Low Dose

- ➔ Traceability and comprehension



The code is for the machine. The label is for the human.



Example (2): Missing CT entries



Are all Codes valid?

- A column has a format applied — but does every value match the CT?
- On open, the data is scanned: any value not defined will be shown in the viewer/browser
- One-click filter: "show me the rows with values outside the CT"
- Same if the CT is entirely missing. Highlight. Even before a P21 check has run

ID	RACE ⚠	AGE	WT
01	WHITE	42	78.4
02	ASIAN	55	88.1
03	SMURF	22	69.0
04	BLACK	38	74.2





Example (3): Why are they not equal?

Some characters are invisible — and they break things

- Non-printable characters: line breaks, page breaks, tabs hidden in cell text
- Zero-width characters (e.g. U+200B Zero-Width Space)
- ➔ break equality checks, filters, groupings, and downstream table layouts.

The worst case: characters that look identical

- Placebo (Latin e) vs. Placebo (Cyrillic e)
- Visually identical, different codepoints, equal condition fails
- Often a single extra space is enough to make the match fail

Looks fine		What's really there
Placebo	→	Plac[U+0435]bo
MILD	→	MILD[U+0020]
HEADACHE	→	HEAD[U+200B]ACHE
Same on screen — different to the machine. Equal fails, the filter misses the row, the merge breaks. Reveal it in red and the cause is obvious.		

We implemented our own data browser called Cumba



All topics discussed so far we implemented in Cumba with 2 options:

Option A: P21 excel reports can be imported to view findings **right on your data**

Option B: Cumba has a CDISC core engine embedded to view findings **right on your data**

Following Examples show how we use highlighting, coloring, filtering to view findings



- An SDTM library is open: The linked Pinnacle 21 validation report will automatically be loaded as well
- All findings are now integrated into the data view

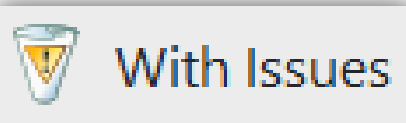
Library	Assessment Number	Assessment Name	Category for Assessment	Result or Finding in Original Units
MH - Medical History				
OE - Ophthalmic Examination				
QSPH - Questionnaires				
QSSL - Questionnaires	15	HAMD115 - HAMD1-Hypochondriasis		
RELREC - Related Record	32	HAMD115 - HAMD1-Hypochondriasis		
RS - Disease Response	16	HAMD116B - HAMD1-Loss of Weight		
SE - Subject Elements	16	HAMD116B - HAMD1-Loss of Weight		
SUPPDM - Supplemental Data	33	HAMD116B - HAMD1-Loss of Weight		
SUPPEC - Supplemental Data	33	HAMD116B - HAMD1-Loss of Weight		
SV - Subject Visits	17	HAMD117 - HAMD1-Insight		
TA - Trial Arms				
TE - Trial Elements				
TI - Trial Inclusion				
TS - Trial Score				
	36	HAMD118 - HAMD1-Total Score		
	35	HAMD118 - HAMD1-Total Score		
	37	HAMD118 - HAMD1-Total Score		

How we built it in Cumba(2): filter down to findings



Drilling into a finding — and filtering down

- Hover a yellow cell → tooltip with the full P21 message
- Right-click → context menu filter with issues
- One click → 375 rows reduce to 8 with issues
- Reviewer is now looking only at findings — no scrolling past clean records



library

Library

sdm

FORMATS

AE - Adverse Events

CM - Concomitant Medication

DD - Death Details

DI - Device Identifiers

DM - Demographics

DS - Disposition

EC - Exposure as Collected

EX - Exposure

FA - Findings About Events or

FT - Functional Tests

IE - Inclusion/Exclusion Criteri

LB - Laboratory Test Results

MH - Medical History

OE - Ophthalmic Examination

RS

RSSEQ
Sequence
Number

RSTESTCD
Assessment Short Name

RSTEST
Assessment Name

	RSSEQ Sequence Number	RSTESTCD Assessment Short Name	RSTEST Assessment Name
33	33	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...
51	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...
86	33	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...
104	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...
158	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...
212	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...
248	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...
320	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...

Value: HAMD116B

Formatted: HAMD1-Loss of WT According to WK Meas

Name: RSTESTCD

Label: Assessment Short Name

Type: STRING (string)

Length: 8

Format: \$Hamilton Depression Rating Scale - 17 Item Clinical Classification Test Code.

Role: Topic

SASFieldName: RSTESTCD

OrderNumber: 5

KeySequence: 3

Mandatory: Yes

dataType: STRING

targetDataType: UNKNOWN

KeySequence: 3

itemOID: IT.RS.RSTESTCD

Validation Findings: 1

Finding: SD1231 (RuleViolation - Warning) - pinnacle21

Message: RSORRES value is longer than defined max length 42 when (RSTESTCD == 'HAMD116B')

Rows: 33, 51, 86, 104, 158, 212, 248, 320

Press F2 to focus!

	RSSEQ Sequence Number	RSTESTCD Assessment Short Name	RSTEST Assessment Name	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	
33	33	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	1
51	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	1
86	33	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	1
104	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	1
158	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	1
212	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	1
248	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	1
320	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According tc...	HAMD 17 - Hamilton Depression...	Probable weight loss associated ...	1

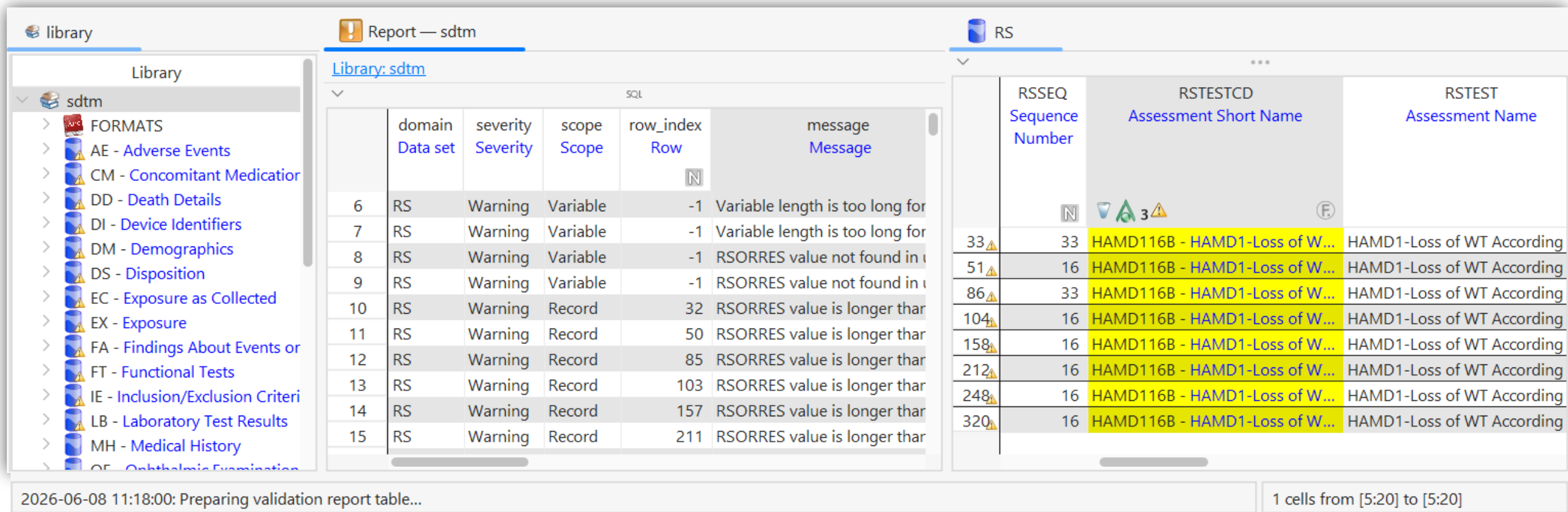
How we built it in Cumba (3): the findings table, linked back



The findings table — linked back

- Open the findings table as its own tab  Show Validation Report
- Each row is a finding (issue ID, message, severity, dataset, variable, row)
- Click a row → Cumba jumps to that cell in the data view, scrolled into focus

Report and data side by side — one is a list, the other is the live view, both are the same workspace.



The screenshot displays the Cumbase interface with three main panels: Library, Report — sdtm, and RS.

Library Panel: Shows a tree view of data sources under 'sdtm', including FORMATS, AE - Adverse Events, CM - Concomitant Medication, DD - Death Details, DI - Device Identifiers, DM - Demographics, DS - Disposition, EC - Exposure as Collected, EX - Exposure, FA - Findings About Events or, FT - Functional Tests, IE - Inclusion/Exclusion Criteria, LB - Laboratory Test Results, MH - Medical History, and OF - Ophthalmic Examination.

Report — sdtm Panel: Displays a table of findings with columns: domain (Data set), severity (Severity), scope (Scope), row_index (Row), and message (Message). The table contains 15 rows of findings, all with a severity of 'Warning'.

	domain Data set	severity Severity	scope Scope	row_index Row	message Message
6	RS	Warning	Variable	-1	Variable length is too long for
7	RS	Warning	Variable	-1	Variable length is too long for
8	RS	Warning	Variable	-1	RSORRES value not found in
9	RS	Warning	Variable	-1	RSORRES value not found in
10	RS	Warning	Record	32	RSORRES value is longer than
11	RS	Warning	Record	50	RSORRES value is longer than
12	RS	Warning	Record	85	RSORRES value is longer than
13	RS	Warning	Record	103	RSORRES value is longer than
14	RS	Warning	Record	157	RSORRES value is longer than
15	RS	Warning	Record	211	RSORRES value is longer than

RS Panel: Displays a table of data with columns: RSSEQ (Sequence Number), RSTESTCD (Assessment Short Name), and RSTEST (Assessment Name). The table contains 10 rows of data, all with a sequence number of 33.

	RSSEQ Sequence Number	RSTESTCD Assessment Short Name	RSTEST Assessment Name
33	33	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According
51	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According
86	33	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According
104	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According
158	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According
212	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According
248	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According
320	16	HAMD116B - HAMD1-Loss of W...	HAMD1-Loss of WT According

Status Bar: 2026-06-08 11:18:00: Preparing validation report table... 1 cells from [5:20] to [5:20]

How we built it in Cumba (4): findings switch & run corej engine



Cumba Clinical Data Browser - 0.5.0.272

Columns Sort Filter Tools Help

DM

	OTC Time th	AGE Age	AGEU Age Units	SEX Sex	RACE Race	ETHNIC Ethnicity
1		84	YEARS - Years	M - Male	WHITE	NOT HISPANIC OR LA...
2		76	YEARS - Years	F - Female	WHITE	NOT HISPANIC OR LA...
3		61	YEARS - Years	M - Male	WHITE	NOT HISPANIC OR LA...
4		63	YEARS - Years	F - Female	WHITE	NOT HISPANIC OR LA...

library

Library

> sdtm

Check Using CORE

CDISC Standard: sdtmig

Standard Version: 3-2

TIG Use Case:

Define-XML Version: 2.1

Define-XML File: ige-DatasetJson/sdtm/json/define.xml

CT Packages: define-xmlct-2020-12-18, sdtmct-2020-12-18

Reference Library:

Use Data Sets: ALL

Use Rules: ALL

Rules Directory:

Extra Rule Files:

Rule Worker Threads: 1

OK Cancel

Summary - How findings should reach you?



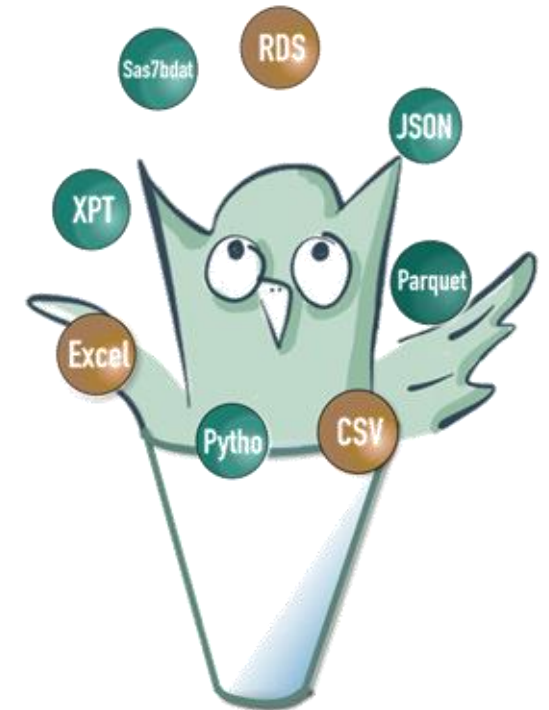
1. **At the source.** Right where the problem is — the cell, the row, the code — not in a separate document.
2. **Right away.** While you're working on the data — not months later in a separate validation run.
3. **In plain language.** Something a programmer reads and understands — not a cryptic message.
4. **Without the flood.** Filtered, not 1000 findings where 950 are noise — or you give up and read none.
5. **Easy on the eye, and switchable.** Color that's clear, and you can turn it on or off when you want.

Cumba uses: Highlight / Tooltip / Markers / Filter / Jump

Every checking tool writes findings its own way.
We have standards for data, metadata, rules - but not for the findings...

Suggest to share an issue notation carrying

- location cell / row / column / dataset
- Severity
- Source
- ID



Thank you

Questions & Discussion

<http://www.cumba.net> · info@p-300.com · Elena Glathe & Michael Weiss, June 2026

