CTDashboard
Clinical Trial Safety Monitoring

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Classification: Validation Deliverable

This document is intended for use as supporting evidence in sponsor submissions and regulatory filings.

APPLICATION VALIDATION REPORT

Every number, independently verified.

CTDashboard is a desktop application for real-time safety monitoring of clinical trials. This report provides objective evidence that the application computes and displays correct values across all dashboard pages – from KPI cards and chart data to individual subject profiles.

161	0	100%	14
CHECKS PASSED	FAILED	PASS RATE	DOMAINS

80	14,088
SUBJECTS	RECORDS

VALIDATED All 161 checks passed. Every KPI, count, and aggregation matches the independently computed value.

Purpose. This report is generated automatically as part of the CTDashboard release process. It provides documented evidence that every value the application displays – KPIs, chart data, table counts, and derived analytics – is mathematically correct.

How it works. A validation engine loads the same CDASH-format CSV files into an independent Python process (using only pandas), then recalculates every metric from

scratch. The **Expected** column in each row shows the independently computed result. The **Actual** column shows the value CTDashboard produces. If they match, the check passes (green checkmark). Each check includes `computation evidence` – the exact formula or query used – so reviewers can trace each result back to the raw data.

Scope. 161 checks across 9 dashboard pages: demographics, safety overview, adverse events, laboratory data, vital signs, disposition, concomitant medications, survival analysis, and subject profiles. App screenshots are included alongside each section as visual evidence of the values being validated.

Data. 14 CDASH domains (14,088 total records, 80 subjects) loaded from CSV files. No data transformations are applied before validation – the same raw files the application reads are used by the independent validator.

Contents

Datasets Loaded

DOMAIN	RECORDS	SUBJECTS
AE Adverse Events	232	55
CM Concomitant Meds	165	80
DM Demographics	80	80
DS Disposition	240	80

DOMAIN	RECORDS	SUBJECTS
DV Deviations	4	3
EG ECG	2,800	80
EX Exposure	480	80
IE Inclusion/Exclusion	480	80
LB Labs	3,920	80
MH Medical History	167	80
PE Physical Exam	1,440	80
SC Subject Characteristics	160	80
SV Subject Visits	560	80
VS Vital Signs	3,360	80

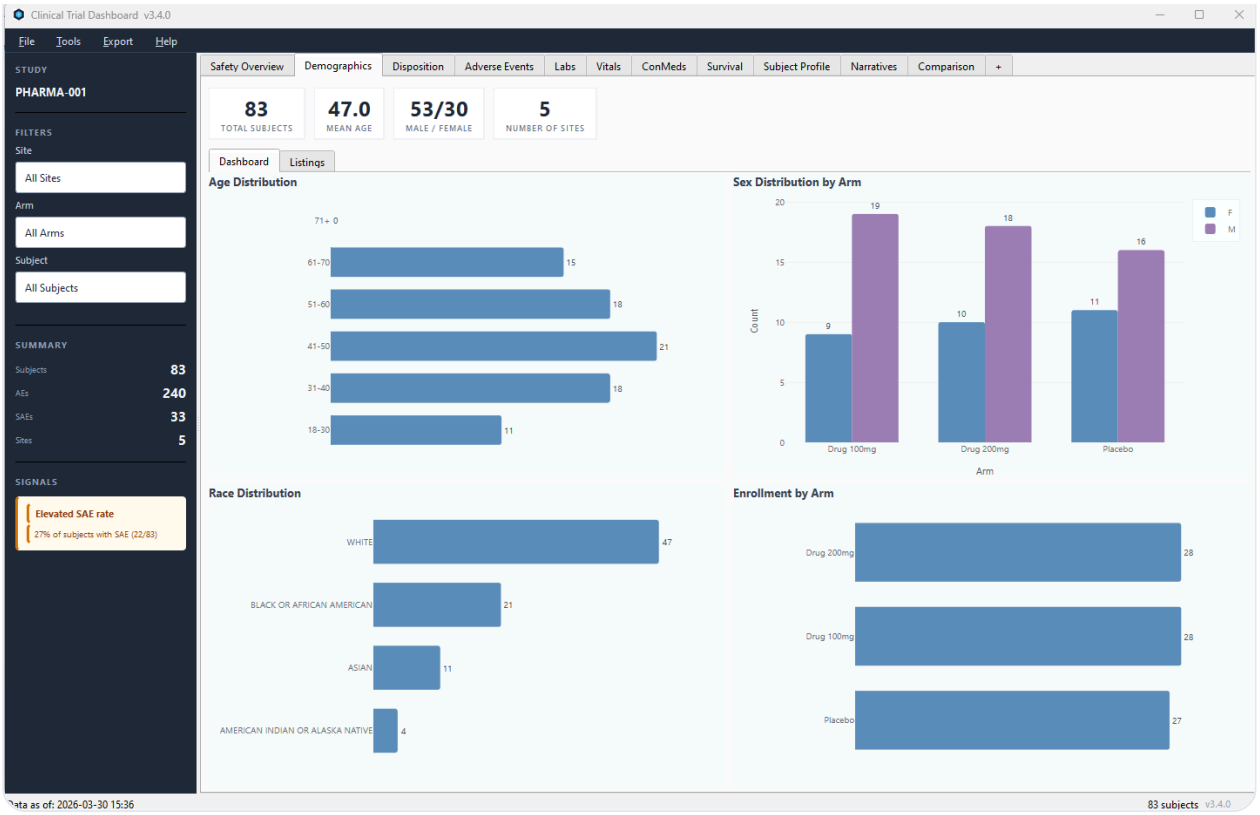
Validation Checks

Demographics & Enrollment 25/25

	CHECK	EXPECTED	ACTUAL
✓	Total Subjects (KPI) `dm[USUBJID].nunique() → 80`	80	80
✓	Mean Age (KPI): 46.9 range 25–69, median=47.0 `pd.to_numeric(dm[AGE]).mean() → 46.9`	46.9	46.9
✓	Male/Female (KPI): 51/29 `dm[SEX].value_counts() → M=51, F=29`	80	80
✓	Number of Sites (KPI): 5 `dm[SITEID].nunique() → 5`	5	5
✓	Age bin '18-30': 11 subjects `pd.cut(dm[AGE], bins) → 18-30 = 11`	11	11
✓	Age bin '31-40': 17 subjects `pd.cut(dm[AGE], bins) → 31-40 = 17`	17	17
✓	Age bin '41-50': 20 subjects `pd.cut(dm[AGE], bins) → 41-50 = 20`	20	20
✓	Age bin '51-60': 18 subjects `pd.cut(dm[AGE], bins) → 51-60 = 18`	18	18
✓	Age bin '61-70': 14 subjects `pd.cut(dm[AGE], bins) → 61-70 = 14`	14	14
✓	Sum of age bins equals total subjects `Sum of all age bins: 80`	80	80
✓	'Drug 100mg' — F: 9 `dm[(ARM==Drug 100mg) & (SEX==F)][USUBJID].nunique() → 9`	9	9
✓	'Drug 100mg' — M: 18 `dm[(ARM==Drug 100mg) & (SEX==M)][USUBJID].nunique() → 18`	18	18
✓	'Drug 200mg' — F: 9 `dm[(ARM==Drug 200mg) & (SEX==F)][USUBJID].nunique() → 9`	9	9

	CHECK	EXPECTED	ACTUAL
✓	'Drug 200mg' — M: 18 `dm[(ARM==Drug 200mg) & (SEX==M)][USUBJID].nunique() → 18`	18	18
✓	'Placebo' — F: 11 `dm[(ARM==Placebo) & (SEX==F)][USUBJID].nunique() → 11`	11	11
✓	'Placebo' — M: 15 `dm[(ARM==Placebo) & (SEX==M)][USUBJID].nunique() → 15`	15	15
✓	Race 'WHITE': 46 `dm[RACE==WHITE] → 46`	46	46
✓	Race 'BLACK OR AFRICAN AMERICAN': 20 `dm[RACE==BLACK OR AFRICAN AMERICAN] → 20`	20	20
✓	Race 'ASIAN': 10 `dm[RACE==ASIAN] → 10`	10	10
✓	Race 'AMERICAN INDIAN OR ALASKA NATIVE': 4 `dm[RACE==AMERICAN INDIAN OR ALASKA NATIVE] → 4`	4	4
✓	Sum of race categories equals total `dm[RACE].value_counts().sum() → 80`	80	80
✓	Enrollment 'Drug 100mg': 27 `dm[ARM==Drug 100mg][USUBJID].nunique() → 27`	27	27
✓	Enrollment 'Drug 200mg': 27 `dm[ARM==Drug 200mg][USUBJID].nunique() → 27`	27	27
✓	Enrollment 'Placebo': 26 `dm[ARM==Placebo][USUBJID].nunique() → 26`	26	26
✓	Sum of arm enrollment equals total `dm[ARM].value_counts().sum() → 80`	80	80

APP SCREENSHOT – DEMOGRAPHICS & ENROLLMENT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+
83
TOTAL SUBJECTS
47.0
MEAN AGE
53/30
MALE / FEMALE
5
NUMBER OF SITES
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Age Distribution
71+ 0
61-70 15
51-60 18
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Sex Distribution by Arm
Count
Arm
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F
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Race Distribution
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Enrollment by Arm
Drug 200mg 28
Drug 100mg 28
Placebo 27
Data as of: 2026-03-30 15:36
83 subjects v3.4.0

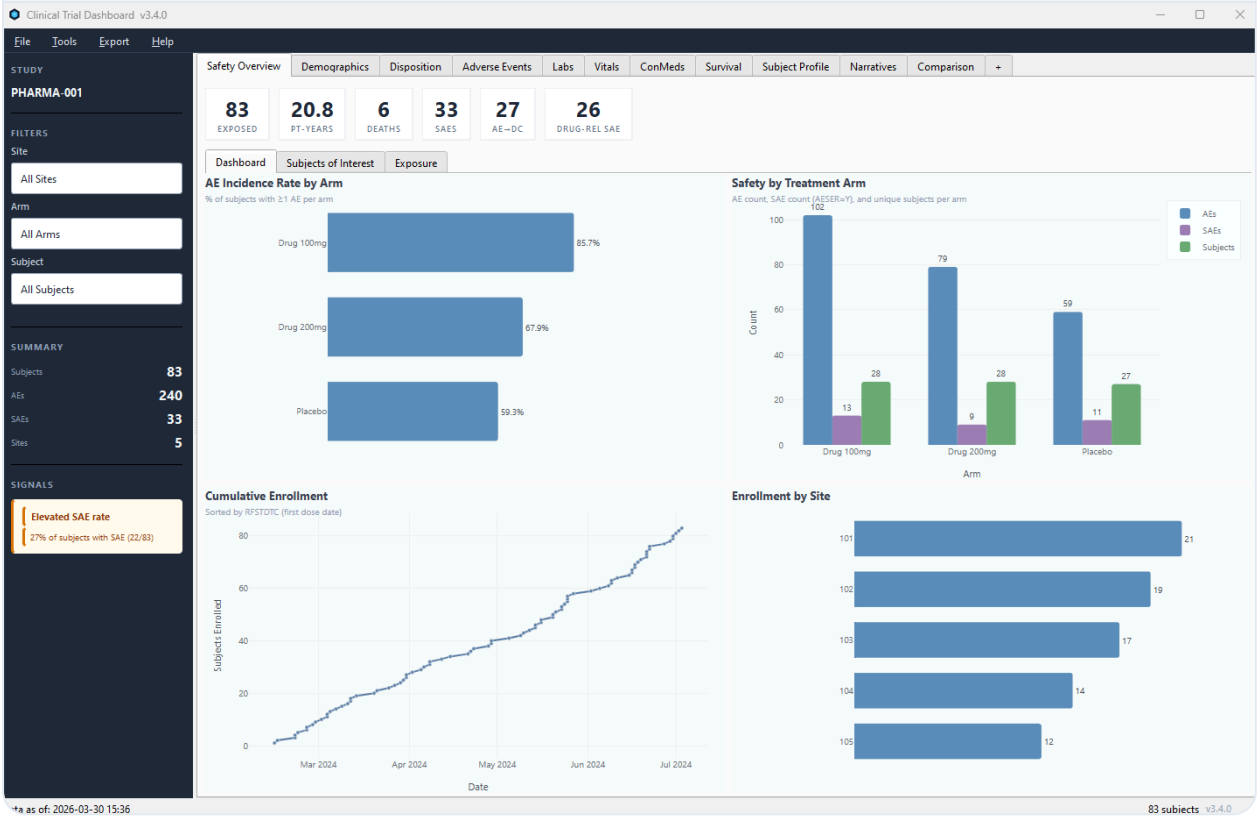
Safety Overview 27/27

	CHECK	EXPECTED	ACTUAL
✓	Total exposed subjects `dm[USUBJID].nunique() → 80`	80	80
✓	Deaths ae[AESDTH==Y].sum() → 6 (DS had 0, fell back to AE rows) `ae[AESDTH==Y].sum() → 6 (DS had 0, fell back to AE rows)`	6	6
✓	SAE count (events) 21 unique subjects `ae[ae[AE_SERIOUS]==Y] → len = 32 events, 21 subjects`	32	32
✓	AEs leading to discontinuation Column: Action Taken `ae[ae[Action Taken].str.contains(DRUG WITHDRAWN|DISCONTINUED)] → 27 rows`	27	27
✓	Drug-related SAEs `SAE rows where Causality not in (NOT RELATED, UNRELATED) → 25`	25	25
✓	Total patient-years Sum of exposure days / 365.25 `For each subject: (max EXENDTC − min EXSTDTC).days; total_days=7290 / 365.25 → 20.0`	20.0	20.0
✓	Subjects with Grade 3/4 lab abnormalities `LBORRES > 3×ULN or < 0.25×LLN → 0 subjects`	0	0
✓	AE incidence rate: Drug 100mg 23 of 27 subjects `100 × ae_subjects_in_arm / dm_subjects_in_arm = 100 × 23/27 → 85.2%`	85.2	85.2
✓	AE incidence rate: Drug 200mg 18 of 27 subjects `100 × ae_subjects_in_arm / dm_subjects_in_arm = 100 × 18/27 → 66.7%`	66.7	66.7
✓	AE incidence rate: Placebo 14 of 26 subjects `100 × ae_subjects_in_arm / dm_subjects_in_arm = 100 × 14/26 → 53.8%`	53.8	53.8

	CHECK	EXPECTED	ACTUAL
✓	'Drug 100mg' — Total AEs `ae[arm==Drug 100mg] → 99 AE records`	99	99
✓	'Drug 100mg' — SAEs `ae[arm==Drug 100mg & AESER==Y] → 12`	12	12
✓	'Drug 100mg' — Subjects `dm[ARM==Drug 100mg][USUBJID].nunique() → 27`	27	27
✓	'Drug 200mg' — Total AEs `ae[arm==Drug 200mg] → 76 AE records`	76	76
✓	'Drug 200mg' — SAEs `ae[arm==Drug 200mg & AESER==Y] → 9`	9	9
✓	'Drug 200mg' — Subjects `dm[ARM==Drug 200mg][USUBJID].nunique() → 27`	27	27
✓	'Placebo' — Total AEs `ae[arm==Placebo] → 57 AE records`	57	57
✓	'Placebo' — SAEs `ae[arm==Placebo & AESER==Y] → 11`	11	11
✓	'Placebo' — Subjects `dm[ARM==Placebo][USUBJID].nunique() → 26`	26	26
✓	Cumulative enrollment (final count) Date column: RFSTDTC `pd.to_datetime(dm[RFSTDTC]).dropna() → 80 enrollment dates; cumulative final = 80`	80	80
✓	Enrollment period: 2024-02-15 to 2024-06-30 `Earliest: 2024-02-15, Latest: 2024-06-30 (sorted RFSTDTC)`	True	True
✓	Site 101 enrollment `dm[SITEID==101][USUBJID].nunique() → 20`	20	20
✓	Site 102 enrollment `dm[SITEID==102][USUBJID].nunique() → 18`	18	18

	CHECK	EXPECTED	ACTUAL
✓	Site 103 enrollment `dm[SITEID==103][USUBJID].nunique() → 16`	16	16
✓	Site 104 enrollment `dm[SITEID==104][USUBJID].nunique() → 14`	14	14
✓	Site 105 enrollment `dm[SITEID==105][USUBJID].nunique() → 12`	12	12
✓	Sum of all sites equals total subjects `Sum of per-site counts: 20 + 18 + 16 + 14 + 12 = 80`	80	80

APP SCREENSHOT – SAFETY OVERVIEW

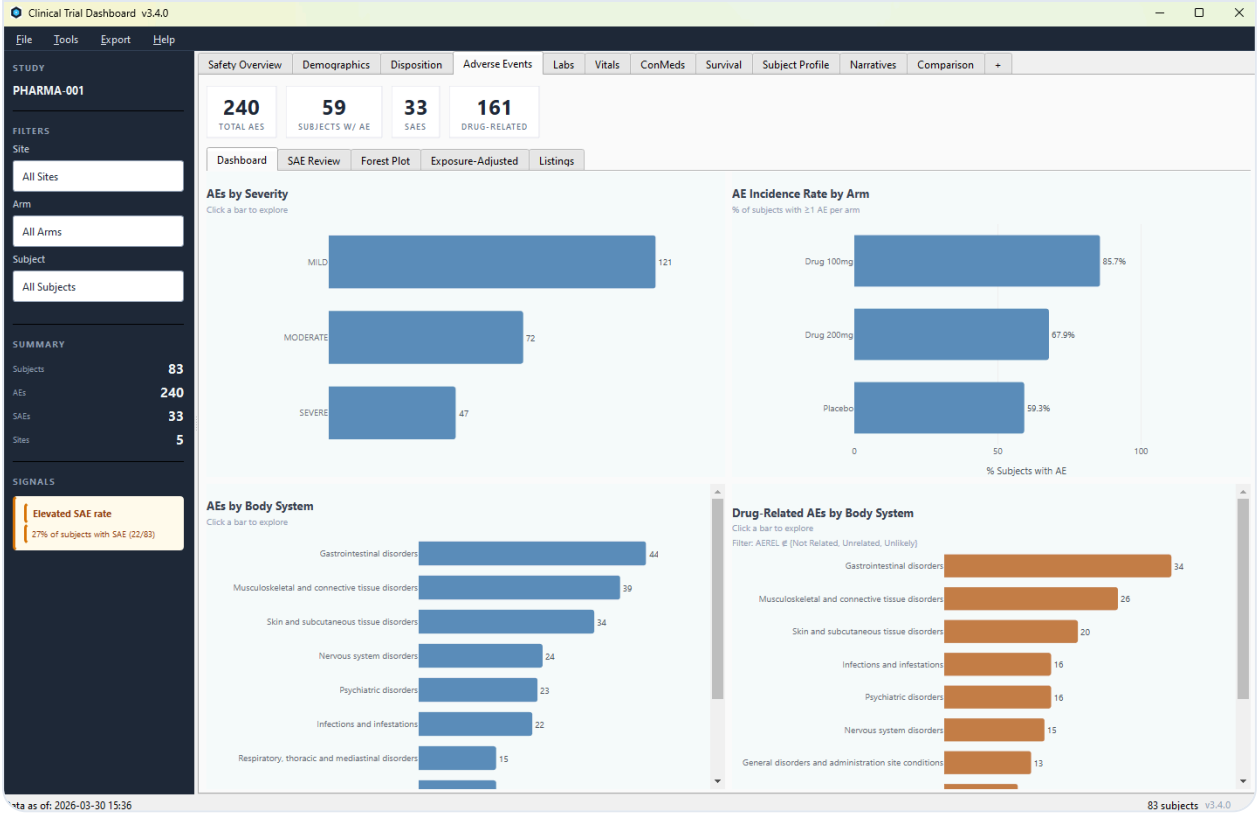


Adverse Events 17/17

	CHECK	EXPECTED	ACTUAL
✓	Total AE records `len(ae) → 232`	232	232
✓	Subjects with at least one AE `ae[USUBJID].nunique() → 55`	55	55
✓	Drug-related AEs (KPI) `ae[Causality] not in (NOT RELATED, UNRELATED, blank) → 155`	155	155
✓	AE count for 'NAUSEA' `len(ae[ae[AEDECOD]==NAUSEA]) → 18`	18	18
✓	AE count for 'MYALGIA' `len(ae[ae[AEDECOD]==MYALGIA]) → 17`	17	17
✓	AE count for 'RASH' `len(ae[ae[AEDECOD]==RASH]) → 17`	17	17
✓	AE count for 'PRURITUS' `len(ae[ae[AEDECOD]==PRURITUS]) → 16`	16	16
✓	AE count for 'NASOPHARYNGITIS' `len(ae[ae[AEDECOD]==NASOPHARYNGITIS]) → 14`	14	14
✓	AE count for SOC 'Gastrointestinal disorders' `len(ae[ae[AEBODSYS]==Gastrointestinal disorders]) → 43`	43	43
✓	AE count for SOC 'Musculoskeletal and connective tissue disorders' `len(ae[ae[AEBODSYS]==Musculoskeletal and connective tissue disorders]) → 39`	39	39
✓	AE count for SOC 'Skin and subcutaneous tissue disorders' `len(ae[ae[AEBODSYS]==Skin and subcutaneous tissue disorders]) → 33`	33	33
✓	AE count for SOC 'Infections and infestations' `len(ae[ae[AEBODSYS]==Infections and infestations]) → 22`	22	22
✓	AE count for SOC 'Psychiatric disorders'	22	22

	CHECK	EXPECTED	ACTUAL
	`len(ae[ae[AEBODSYS]==Psychiatric disorders]) → 22`		
✓	Severity distribution totals to all AEs Distribution: MILD: 115, MODERATE: 72, SEVERE: 45 `ae[AE_SEVERITY].value_counts().sum() → 232`	232	232
✓	AE incidence rate for 'Drug 100mg' 23/27 subjects `100 × (subjects_with_ae_in_arm / total_in_arm) = 100 × 23/27 → 85.2%`	85.2	85.2
✓	AE incidence rate for 'Drug 200mg' 18/27 subjects `100 × (subjects_with_ae_in_arm / total_in_arm) = 100 × 18/27 → 66.7%`	66.7	66.7
✓	AE incidence rate for 'Placebo' 14/26 subjects `100 × (subjects_with_ae_in_arm / total_in_arm) = 100 × 14/26 → 53.8%`	53.8	53.8

APP SCREENSHOT – ADVERSE EVENTS

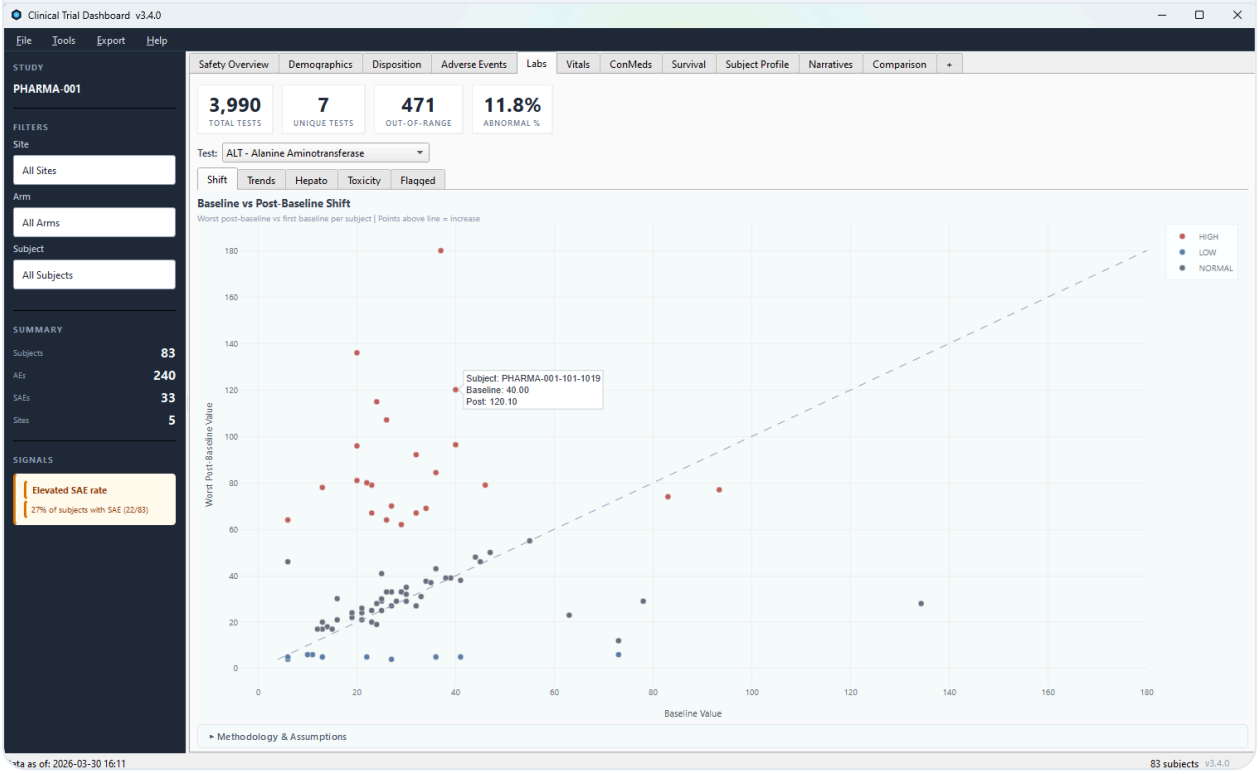


Laboratory Data 11/11

	CHECK	EXPECTED	ACTUAL
✓	Total lab records `len(lb) → 3920`	3920	3920
✓	Unique lab tests: 7 ALT, AST, BILI, CREAT, HGB, PLAT, WBC `lb[LBTESTCD].unique() → 7 distinct codes`	7	7
✓	Out-of-range lab values (KPI) of 3920 total records `lb[LBNRIND].isin([HIGH,LOW,H,L,ABNORMAL]).sum() → 469`	469	469
✓	Abnormal % (KPI) 469 out-of-range / 3920 total × 100 `100 × 469 / 3920 → 12.0%`	12.0	12.0
✓	Shift analysis: baseline VISITNUM=2, 7 tests with both baseline and post-baseline data Tests: ALT, AST, BILI, CREAT, HGB, PLAT, WBC `Baseline VISITNUM=2 (from VISIT/VISITNUM); tests with data in both periods: 7`	True	True
✓	ALT shift: subjects with HIGH post-baseline (>56) 80 subjects with shift data `Per subject: worst post-BL ALT > ULN(56) → 22 of 80`	22	22
✓	AST shift: subjects with HIGH post-baseline (>40) 80 subjects with shift data `Per subject: worst post-BL AST > ULN(40) → 20 of 80`	20	20
✓	BILI shift: subjects with HIGH post-baseline (>1) 80 subjects with shift data `Per subject: worst post-BL BILI > ULN(1) → 16 of 80`	16	16
✓	CREAT shift: subjects with HIGH post-baseline (>1) 80 subjects with shift data `Per subject: worst post-BL CREAT > ULN(1) → 16 of 80`	16	16
✓	HGB shift: subjects with HIGH post-baseline (>17) 80 subjects with shift data `Per subject: worst post-BL HGB > ULN(17) → 14 of 80`	14	14
✓	Hy's Law cases (FDA criteria) (ALT/AST ≥ 3×ULN) AND (BILI ≥ 2×ULN) AND (ALP < 2×ULN or missing)	0	0

CHECK	EXPECTED	ACTUAL
Per-subject peak xULN; filter (ALT≥3 or AST≥3) & BILI≥2 & (ALP<2 or missing) → 0		

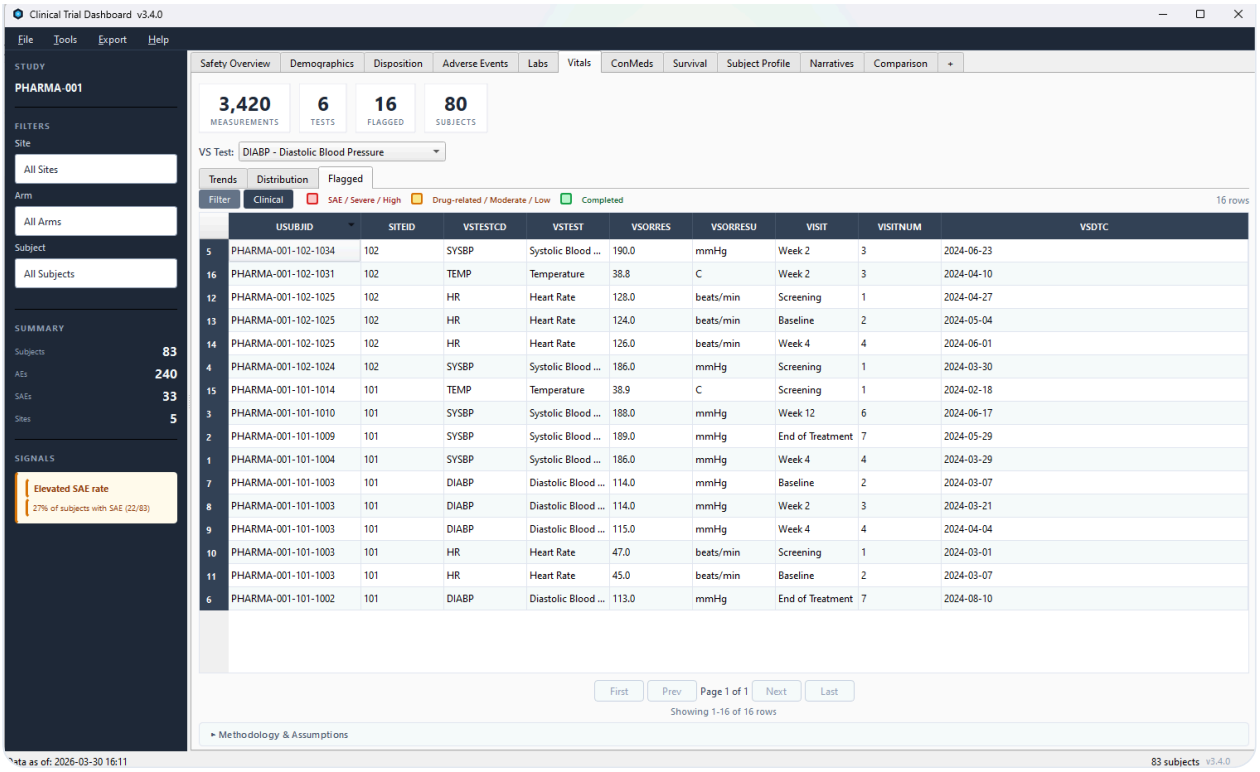
APP SCREENSHOT – LABORATORY DATA



Vital Signs 8/8

	CHECK	EXPECTED	ACTUAL
✓	Measurements (KPI) `len(vs) → 3360`	3360	3360
✓	Tests (KPI): 6 DIABP, HR, RESP, SYSBP, TEMP, WEIGHT `vs[VSTESTCD].unique() → 6 distinct codes`	6	6
✓	Subjects (KPI) `vs[USUBJID].nunique() → 80`	80	80
✓	Flagged (KPI) 10 unique subjects `Row-by-row: VSORRES outside [SYSBP: 90-180, DIABP: 50-110, HR: 50-120, PULSE: 50-120, TEMP: 35.0-38.5] → 16 records`	16	16
✓	DIABP flagged values (outside 50–110) 560 total DIABP measurements `vs[VSTESTCD==DIABP][VSORRES] outside [50, 110] → 4 of 560`	4	4
✓	HR flagged values (outside 50–120) 560 total HR measurements `vs[VSTESTCD==HR][VSORRES] outside [50, 120] → 5 of 560`	5	5
✓	SYSBP flagged values (outside 90–180) 560 total SYSBP measurements `vs[VSTESTCD==SYSBP][VSORRES] outside [90, 180] → 5 of 560`	5	5
✓	TEMP flagged values (outside 35.0–38.5) 560 total TEMP measurements `vs[VSTESTCD==TEMP][VSORRES] outside [35.0, 38.5] → 2 of 560`	2	2

APP SCREENSHOT – VITAL SIGNS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All Arms
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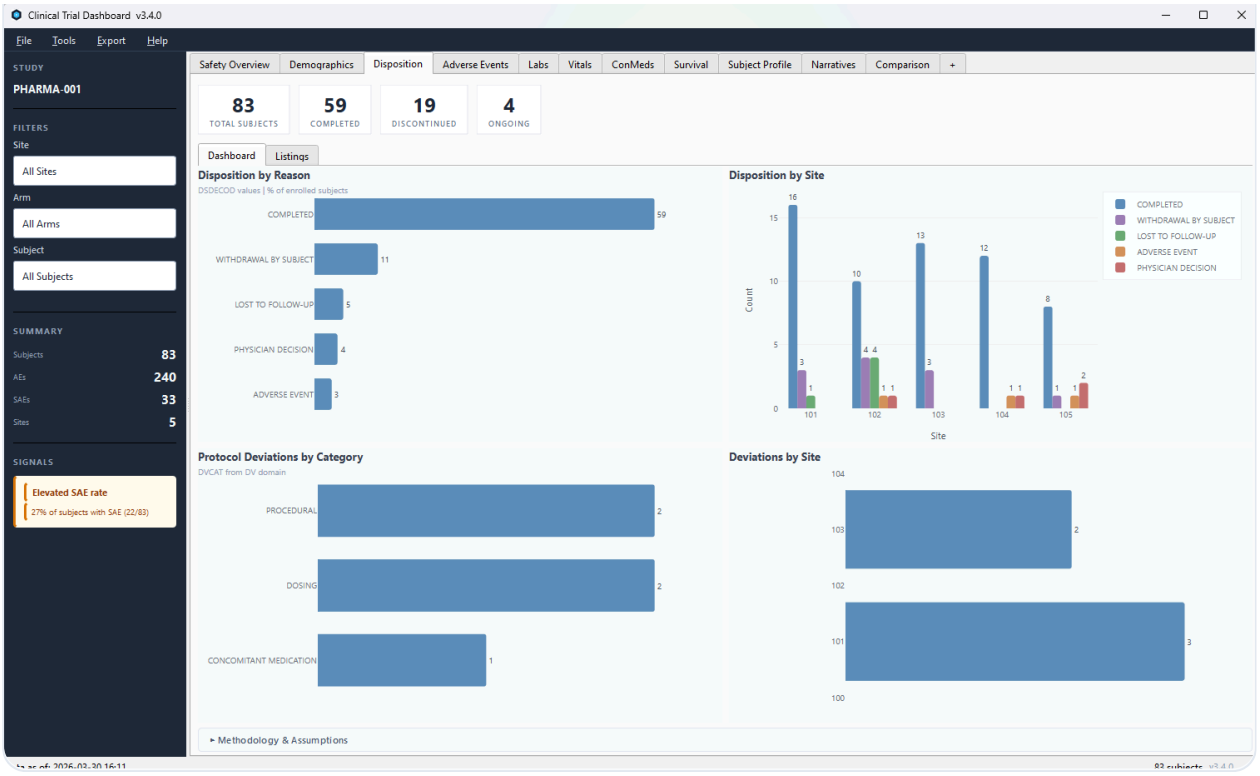
AEs 240
SAEs 33
Sites 5
SIGNALS
Elevated SAE rate
27% of subjects with SAE (22/83)
Safety Overview Demographics Disposition Adverse Events Labs Vitals ConMeds Survival Subject Profile Narratives Comparison +
3,420 MEASUREMENTS
6 TESTS
16 FLAGGED
80 SUBJECTS
VS Test: DIABP - Diastolic Blood Pressure
Trends Distribution Flagged
Filter Clinical SAE / Severe / High Drug-related / Moderate / Low Completed
16 rows
USUBJID SITEID VSTESTCD VSTEST VSORRES VSORRESU VISIT VISITNUM VSDTC
5 PHARMA-001-102-1034 102 SYSBP Systolic Blood ... 190.0 mmHg Week 2 3 2024-06-23
16 PHARMA-001-102-1031 102 TEMP Temperature 38.8 C Week 2 3 2024-04-10
12 PHARMA-001-102-1025 102 HR Heart Rate 128.0 beats/min Screening 1 2024-04-27
13 PHARMA-001-102-1025 102 HR Heart Rate 124.0 beats/min Baseline 2 2024-05-04
14 PHARMA-001-102-1025 102 HR Heart Rate 126.0 beats/min Week 4 4 2024-06-01
4 PHARMA-001-102-1024 102 SYSBP Systolic Blood ... 186.0 mmHg Screening 1 2024-03-30
15 PHARMA-001-101-1014 101 TEMP Temperature 38.9 C Screening 1 2024-02-18
3 PHARMA-001-101-1010 101 SYSBP Systolic Blood ... 188.0 mmHg Week 12 6 2024-06-17
2 PHARMA-001-101-1009 101 SYSBP Systolic Blood ... 189.0 mmHg End of Treatment 7 2024-05-29
1 PHARMA-001-101-1004 101 SYSBP Systolic Blood ... 186.0 mmHg Week 4 4 2024-03-29
7 PHARMA-001-101-1003 101 DIABP Diastolic Blood ... 114.0 mmHg Baseline 2 2024-03-07
8 PHARMA-001-101-1003 101 DIABP Diastolic Blood ... 114.0 mmHg Week 2 3 2024-03-21
9 PHARMA-001-101-1003 101 DIABP Diastolic Blood ... 115.0 mmHg Week 4 4 2024-04-04
10 PHARMA-001-101-1003 101 HR Heart Rate 47.0 beats/min Screening 1 2024-03-01
11 PHARMA-001-101-1003 101 HR Heart Rate 45.0 beats/min Baseline 2 2024-03-07
6 PHARMA-001-101-1002 101 DIABP Diastolic Blood ... 113.0 mmHg End of Treatment 7 2024-08-10
First Prev Page 1 of 1 Next Last
Showing 1-16 of 16 rows
Methodology & Assumptions
ata as of: 2026-03-30 16:11
83 subjects v3.4.0

Disposition 10/10

	CHECK	EXPECTED	ACTUAL
✓	Total Subjects (KPI) `dm[USUBJID].nunique() → 80`	80	80
✓	Disposition event records (after filtering) DSCAT in (DISPOSITION EVENT, STUDY COMPLETION, TREATMENT) `ds filtered by DSCAT in (DISPOSITION EVENT, STUDY COMPLETION, TREATMENT) → 80 rows`	80	80
✓	'COMPLETED' count `disp[DSDECOD==COMPLETED] → 58`	58	58
✓	'WITHDRAWAL BY SUBJECT' count `disp[DSDECOD==WITHDRAWAL BY SUBJECT] → 10`	10	10
✓	'LOST TO FOLLOW-UP' count `disp[DSDECOD==LOST TO FOLLOW-UP] → 5`	5	5
✓	'PHYSICIAN DECISION' count `disp[DSDECOD==PHYSICIAN DECISION] → 4`	4	4
✓	'ADVERSE EVENT' count `disp[DSDECOD==ADVERSE EVENT] → 3`	3	3
✓	Completed (KPI) `DSDECOD containing COMPLET → 58`	58	58
✓	Discontinued (KPI) Keywords: DISCONT, WITHDRAW, LOST, DEATH, ADVERSE `DSDECOD matching discontinuation keywords → 18`	18	18
✓	Ongoing (KPI) `Remaining disposition reasons (not completed, not discontinued) → 4`	4	4

APP SCREENSHOT – DISPOSITION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83 TOTAL SUBJECTS
59 COMPLETED
19 DISCONTINUED
4 ONGOING
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WITHDRAWAL BY SUBJECT 11
LOST TO FOLLOW-UP 5
PHYSICIAN DECISION 4
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PHYSICIAN DECISION
Protocol Deviations by Category
DVCAT from DV domain
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DOSING 2
CONCOMITANT MEDICATION 1
Deviations by Site
► Methodology & Assumptions

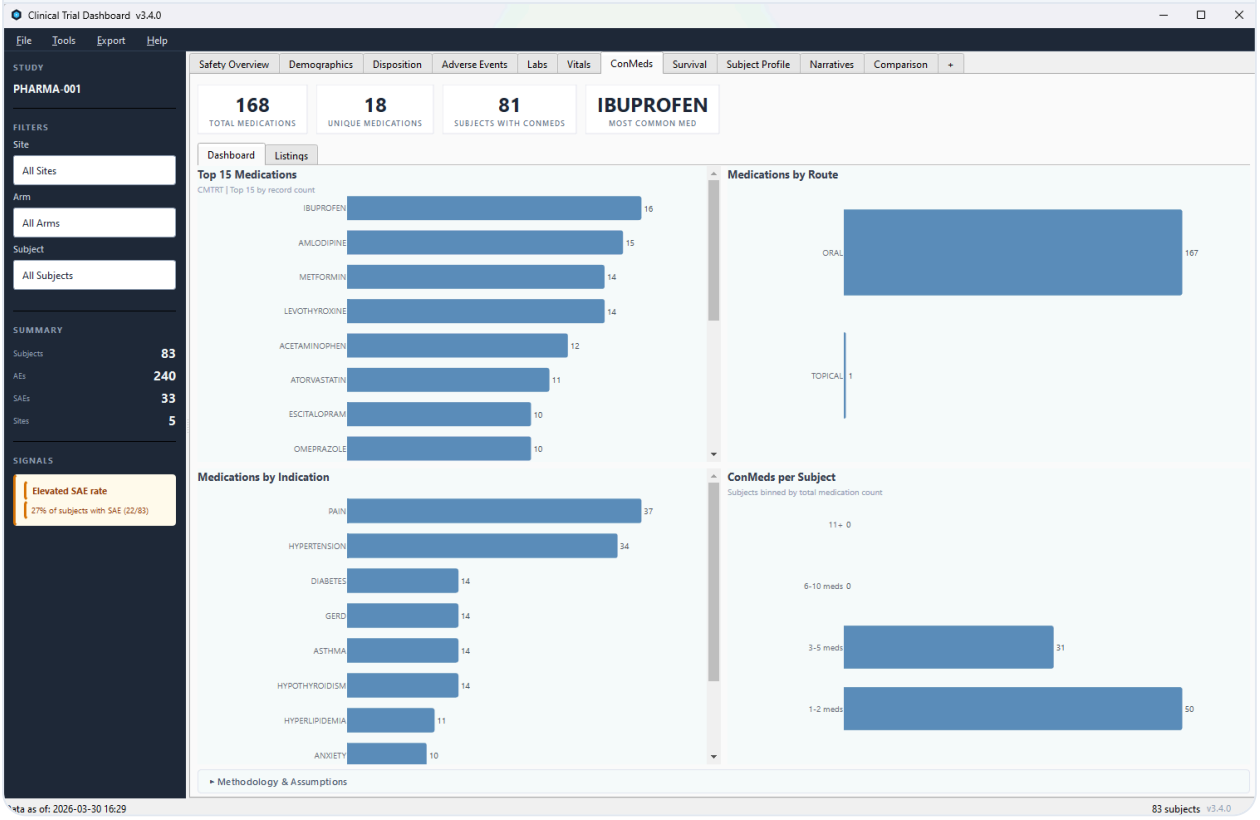
Concomitant Medications 35/35

	CHECK	EXPECTED	ACTUAL
✓	Total Medications (KPI) `len(cm) → 165`	165	165
✓	Unique Medications (KPI): 16 `cm[CMTRT].nunique() → 16`	16	16
✓	Subjects with ConMeds (KPI): 80 `cm[USUBJID].nunique() → 80`	80	80
✓	Most Common Med (KPI): IBUPROFEN 16 records `cm[CMTRT].value_counts().idxmax() → IBUPROFEN (16)`	IBUPROFEN	IBUPROFEN
✓	Top med 'IBUPROFEN': 16 `cm[CMTRT==IBUPROFEN] → 16`	16	16
✓	Top med 'AMLODIPINE': 15 `cm[CMTRT==AMLODIPINE] → 15`	15	15
✓	Top med 'LEVOTHYROXINE': 14 `cm[CMTRT==LEVOTHYROXINE] → 14`	14	14
✓	Top med 'METFORMIN': 14 `cm[CMTRT==METFORMIN] → 14`	14	14
✓	Top med 'ATORVASTATIN': 11 `cm[CMTRT==ATORVASTATIN] → 11`	11	11
✓	Top med 'ACETAMINOPHEN': 11 `cm[CMTRT==ACETAMINOPHEN] → 11`	11	11
✓	Top med 'ASPIRIN': 10 `cm[CMTRT==ASPIRIN] → 10`	10	10
✓	Top med 'LISINOPRIL': 10 `cm[CMTRT==LISINOPRIL] → 10`	10	10
✓	Top med 'ESCITALOPRAM': 10 `cm[CMTRT==ESCITALOPRAM] → 10`	10	10
✓	Top med 'OMEPRAZOLE': 10 `cm[CMTRT==OMEPRAZOLE] → 10`	10	10

	CHECK	EXPECTED	ACTUAL
✓	Top med 'MONTELUKAST': 9 `cm[CMTRT==MONTELUKAST] → 9`	9	9
✓	Top med 'GABAPENTIN': 9 `cm[CMTRT==GABAPENTIN] → 9`	9	9
✓	Top med 'HYDROCHLOROTHIAZIDE': 9 `cm[CMTRT==HYDROCHLOROTHIAZIDE] → 9`	9	9
✓	Top med 'SERTRALINE': 8 `cm[CMTRT==SERTRALINE] → 8`	8	8
✓	Top med 'ALBUTEROL': 5 `cm[CMTRT==ALBUTEROL] → 5`	5	5
✓	Route 'ORAL': 165 `cm[CMROUTE==ORAL] → 165`	165	165
✓	Indication 'PAIN': 37 `cm[CMINDC==PAIN] → 37`	37	37
✓	Indication 'HYPERTENSION': 34 `cm[CMINDC==HYPERTENSION] → 34`	34	34
✓	Indication 'DIABETES': 14 `cm[CMINDC==DIABETES] → 14`	14	14
✓	Indication 'GERD': 14 `cm[CMINDC==GERD] → 14`	14	14
✓	Indication 'HYPOTHYROIDISM': 14 `cm[CMINDC==HYPOTHYROIDISM] → 14`	14	14
✓	Indication 'ASTHMA': 14 `cm[CMINDC==ASTHMA] → 14`	14	14
✓	Indication 'HYPERLIPIDEMIA': 11 `cm[CMINDC==HYPERLIPIDEMIA] → 11`	11	11
✓	Indication 'ANXIETY': 10 `cm[CMINDC==ANXIETY] → 10`	10	10
✓	Indication 'NEUROPATHIC PAIN': 9	9	9

	CHECK	EXPECTED	ACTUAL
	`cm[CMINDC==NEUROPATHIC PAIN] → 9`		
✓	Indication 'DEPRESSION': 8 `cm[CMINDC==DEPRESSION] → 8`	8	8
✓	ConMeds/Subject bin '1-2 meds': 50 `cm.groupby(subj).size() <= 2 → 50 subjects`	50	50
✓	ConMeds/Subject bin '3-5 meds': 30 `cm.groupby(subj).size() in [3,5] → 30 subjects`	30	30
✓	ConMeds/Subject bin '6-10 meds': 0 `cm.groupby(subj).size() in [6,10] → 0 subjects`	0	0
✓	ConMeds/Subject bin '11+': 0 `cm.groupby(subj).size() > 10 → 0 subjects`	0	0
✓	Sum of bins equals subjects with ConMeds `50+30+0+0 = 80`	80	80

APP SCREENSHOT – CONCOMITANT MEDICATIONS

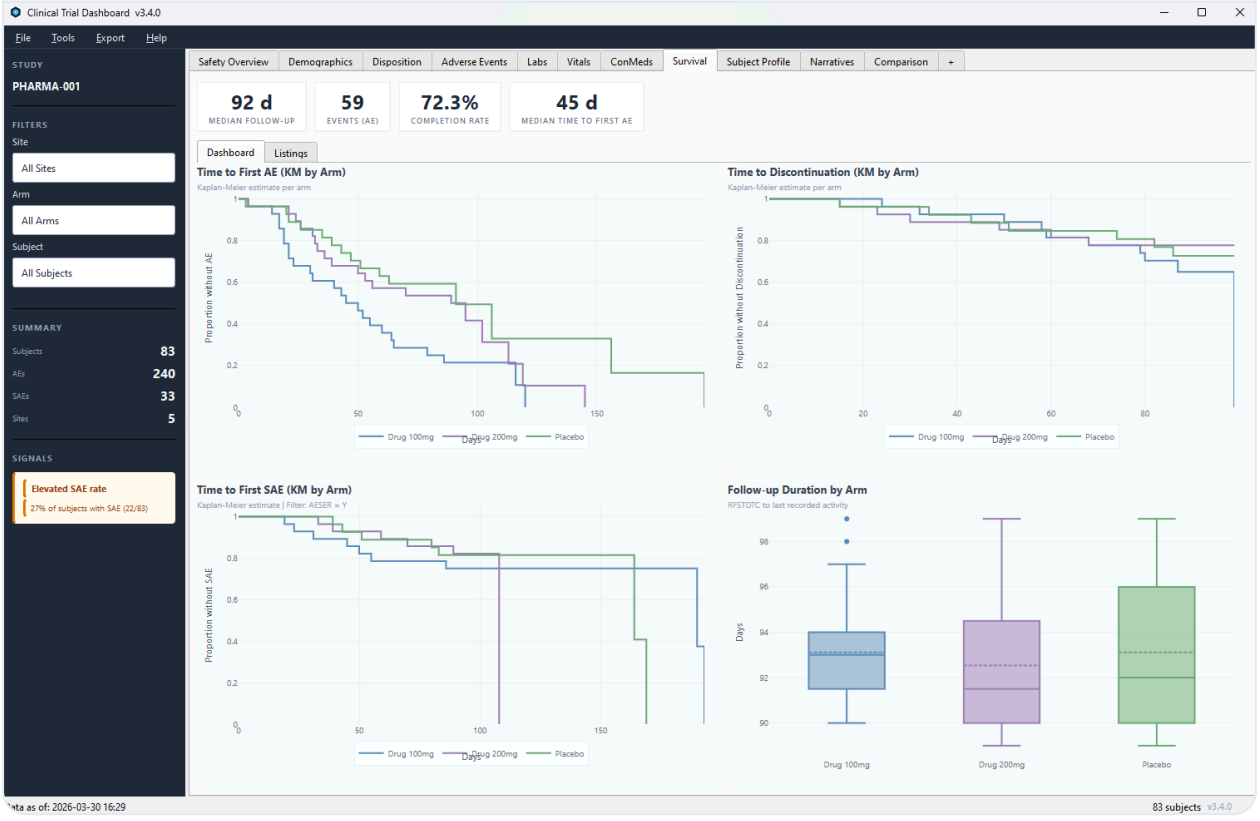


Survival Analysis 16/16

	CHECK	EXPECTED	ACTUAL
✓	Median Follow-up (KPI): 92 d `Per-subject follow-up days, median → 92`	92	92
✓	AE Events (KPI): 55 `Subjects with at least one AE → 55`	55	55
✓	Completion Rate (KPI): 72.5% 58 of 80 subjects `Subjects with dc_event==0: 58/80 × 100 → 72.5%`	72.5	72.5
✓	Median Time to First AE (KPI): 47 d `tte_ae where ae_event==1, median → 47`	47	47
✓	'Drug 100mg' — AE events: 23/27 `Subjects in Drug 100mg with ae_event==1 → 23 of 27`	23	23
✓	'Drug 100mg' — SAE events: 8/27 `Subjects in Drug 100mg with sae_event==1 → 8 of 27`	8	8
✓	'Drug 100mg' — Discontinuations: 9/27 `Subjects in Drug 100mg with dc_event==1 → 9 of 27`	9	9
✓	'Drug 200mg' — AE events: 18/27 `Subjects in Drug 200mg with ae_event==1 → 18 of 27`	18	18
✓	'Drug 200mg' — SAE events: 6/27 `Subjects in Drug 200mg with sae_event==1 → 6 of 27`	6	6
✓	'Drug 200mg' — Discontinuations: 6/27 `Subjects in Drug 200mg with dc_event==1 → 6 of 27`	6	6
✓	'Placebo' — AE events: 14/26 `Subjects in Placebo with ae_event==1 → 14 of 26`	14	14
✓	'Placebo' — SAE events: 7/26 `Subjects in Placebo with sae_event==1 → 7 of 26`	7	7
✓	'Placebo' — Discontinuations: 7/26 `Subjects in Placebo with dc_event==1 → 7 of 26`	7	7
✓	'Drug 100mg' — Median follow-up: 93 d `Follow-up days for Drug 100mg, median → 93`	93	93

	CHECK	EXPECTED	ACTUAL
✓	'Drug 200mg' — Median follow-up: 91 d `Follow-up days for Drug 200mg, median → 91`	91	91
✓	'Placebo' — Median follow-up: 92 d `Follow-up days for Placebo, median → 92`	92	92

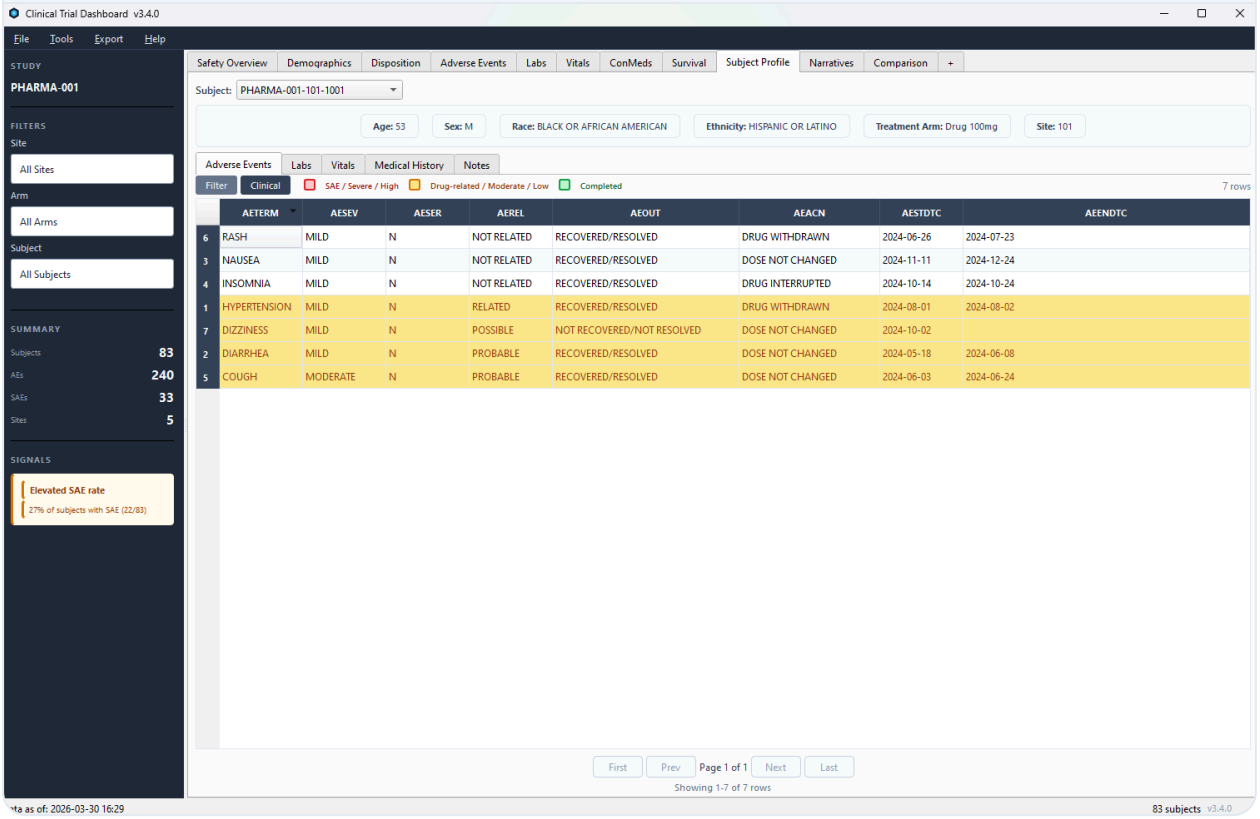
APP SCREENSHOT – SURVIVAL ANALYSIS



Subject Profile 12/12

	CHECK	EXPECTED	ACTUAL
✓	Subject PHARMA-001-101-1001 — Age: 53 `dm[USUBJID==PHARMA-001-101-1001][AGE] → 53`	53	53
✓	Subject PHARMA-001-101-1001 — Sex: M `dm[USUBJID==PHARMA-001-101-1001][SEX] → M`	M	M
✓	Subject PHARMA-001-101-1001 — Race: BLACK OR AFRICAN AMERICAN `dm[USUBJID==PHARMA-001-101-1001][RACE] → BLACK OR AFRICAN AMERICAN`	BLACK OR AFRICAN AMERICAN	BLACK OR AFRICAN AMERICAN
✓	Subject PHARMA-001-101-1001 — Ethnicity: HISPANIC OR LATINO `dm[USUBJID==PHARMA-001-101-1001][ETHNIC] → HISPANIC OR LATINO`	HISPANIC OR LATINO	HISPANIC OR LATINO
✓	Subject PHARMA-001-101-1001 — Treatment Arm: Drug 100mg `dm[USUBJID==PHARMA-001-101-1001][ARM] → Drug 100mg`	Drug 100mg	Drug 100mg
✓	Subject PHARMA-001-101-1001 — Site: 101 `dm[USUBJID==PHARMA-001-101-1001][SITEID] → 101`	101	101
✓	Subject PHARMA-001-101-1001 — AE records: 6 `ae[USUBJID==PHARMA-001-101-1001] → 6 rows`	6	6
✓	Subject PHARMA-001-101-1001 — Lab records: 49 `lb[USUBJID==PHARMA-001-101-1001] → 49 rows`	49	49
✓	Subject PHARMA-001-101-1001 — Vital records: 42 `vs[USUBJID==PHARMA-001-101-1001] → 42 rows`	42	42
✓	Subject PHARMA-001-101-1001 — ConMed records: 2 `cm[USUBJID==PHARMA-001-101-1001] → 2 rows`	2	2
✓	Subject PHARMA-001-101-1001 — Medical History records: 2 `mh[USUBJID==PHARMA-001-101-1001] → 2 rows`	2	2
✓	All 80 subjects accessible in Subject Profile `dm[USUBJID].unique() → 80 subjects`	80	80

APP SCREENSHOT – SUBJECT PROFILE



Methodology & Assumptions

The following documents every methodological decision made by CTDashboard's analytics engine. Each assumption is disclosed here so that reviewers can assess whether the logic is appropriate for their study design and regulatory context.

Safety Overview

METRIC	METHODOLOGY
Exposed	Unique subjects in DM domain (one row per subject assumed).
Patient-Years	Per subject: (max EXENDTC – min EXSTDTC) / 365.25. If EXENDTC is missing, the start date is used (zero duration). Gaps between dosing periods are *included* in the calculation, not subtracted. Falls back to DM reference dates (RFSTDTC/RFENDTC) if no EX data.
Deaths	DS domain: count of rows where DSDECOD = "DEATH". If zero, falls back to AE domain: count of rows where AESDTH = "Y". This is a *row count*, not unique subjects – one subject with two death-flagged AE rows counts as 2.
SAEs	AE records where AESER = "Y" (row count). Multiple SAEs per subject are each counted.
AE → DC	AE records where AEACN contains "DRUG WITHDRAWN" or "DISCONTINUED" (regex, case-insensitive).
Drug-Related SAEs	SAE records where AEREL is *not* "NOT RELATED" or "UNRELATED". Unknown or missing causality is conservatively treated as drug-related.
Grade 3/4 Labs	Unique subjects with LBTOXGR = 3 or 4. If LBTOXGR unavailable, derived as LBORRES > 3×ULN or < 0.25×LLN (aligned with CTCAE generic thresholds).

Adverse Events

METRIC	METHODOLOGY
AE Incidence Rate	(Unique subjects with ≥1 AE in arm / total subjects in arm from DM) × 100. Denominator includes all DM subjects regardless of exposure status.
Drug-Relatedness	Exclusion-based: AEREL not in ("NOT RELATED", "UNRELATED", blank). "UNKNOWN" and missing values are treated as related.
Severity	AESEV normalized: numeric 1–5 mapped to MILD/MODERATE/SEVERE/LIFE-THREATENING/FATAL. Unmapped values passed through as-is.
Exposure-Adjusted	Events per 100 patient-years, using EX domain cumulative exposure per arm.

Laboratory Data

METRIC	METHODOLOGY
Out-of-Range	Uses LBNRIND column (HIGH/LOW/H/L/ABNORMAL) if present. Otherwise compares LBORRES to LBORNRHI/LBORNRLO numerically. Missing reference ranges → value treated as in-range.
CTCAE Grading	Uses LBTOXGR if available. Otherwise derives generic grades: Grade 1: >1–1.5×ULN, Grade 2: >1.5–3×, Grade 3: >3–10×, Grade 4: >10× (high side); <0.75×, <0.5×, <0.25× LLN (low side). **These are generic thresholds, not test-specific CTCAE criteria.**
Hy's Law	(ALT or AST ≥ 3×ULN) AND (BILI ≥ 2×ULN) AND (ALP < 2×ULN or missing). Per FDA guidance, ≥ is used (not strict >). Missing ALP is conservatively treated as criterion met. Peak xULN values used across all visits.
Baseline	Determined from LBBLFL='Y' (mode VISITNUM among flagged rows). Fallback: VISIT containing "BASELINE"/"BL". Final fallback: lowest VISITNUM (may be screening, not true baseline).
Shift Analysis	Worst post-baseline value vs. mean of all baseline values per subject per test. "Worst" = furthest outside reference range.

Vital Signs

METRIC	METHODOLOGY
Flagged Values	Hardcoded population-level thresholds: SysBP 90–180 mmHg, DiaBP 50–110 mmHg, HR/Pulse 50–120 bpm, Temp 35.0–38.5°C. *No age, sex, or baseline adjustment applied.* A value of 38.8°C is flagged because it exceeds the 38.5°C upper threshold for TEMP, while the DiaBP range of 50–110 applies only to DIABP measurements. Each test has its own threshold range.
QTc Prolongation	EG domain: EGTESTCD containing "QTC" with value > 500 ms. No sex-stratified thresholds (female guideline is typically > 460–480 ms).

Disposition

METRIC	METHODOLOGY
Events	DS records where DSCAT = “DISPOSITION EVENT” (excludes protocol milestones: INFORMED CONSENT, RANDOMIZED, etc.).
Completed	Disposition event records where DSDECOD contains “COMPLET” (case-insensitive).
Discontinued	Disposition event records where DSDECOD matches any of: DISCONT, WITHDRAW, LOST, DEATH, ADVERSE (case-insensitive substring match).
Ongoing	Disposition event records whose DSDECOD does *not* match completed or discontinued keywords. These are remaining reasons not classifiable as either completed or discontinued.