Common Mistakes by Programmers & Remedies

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1. Column labels should be displayed correctly like INCLUSION should be "Inclusion", DIt should be "DLT" and YES/NO values should be "Yes/No"

Study 003 OPEN LABEL

Listing 16.03.01-12 (Page 1 of 1)
Listing of Dose Limiting Toxicities (DLTs) evaluation
Safety Set

Schedule: 1/ Dose Level: 50 mg/m² TID

Subject (Age/Sex/ Race)	INCLUSION Date	Date of First Dose (day)	Date of Last Dose (day)	DIt Evaluable? (YES/NO)	Reason why DLT is not Evaluable	Patient Experienced DIt? (Yes/No)
0004-052-/ 30001 (62/F)	17DEC2010 (-3)	20DEC2010 (1)	26MAY2011 (158)	Yes		No
0004-052-/ 30002 (61/F)	28DEC2010 (-6)	03JAN2011 (1)	14JUL2011 (193)	Yes		No
0004-052-/ 30003 (56/F)	07JAN2011 (-3)	10JAN2011 (1)	14JUL2011 (186)	Yes		No

2. No Footnote for given subscript [1] and Closing Parenthesis is going down

Table 14.01.05.2-1 (Page 1 of 1)
Summary of concomitant treatments during the study [1] - Phase II
Safety Set

Pharmacological Class/ Pharmacological Sub-Class/ Therapeutic Class/ Preferred Name	AL (N=18) n (%)	BL (N=17) n (%)	DCL (N=16) n (%)	MXB&W/L (N=15) n (%)	B-AL (N=18) n (%)	XL&ML (N=16) n (%)	Total (N=100) n (%)
Any	16 (88.9%)	15 (88.2%)	16 (100.0%)	14 (93.3%)	18 (100.0%)	16 (100.0%)	95 (95.0%)
Blood Substitutes and Perfusion Solutions	6 (33.3%)	11 (64.7%)	10 (62.5%)	8 (53.3%)	13 (72.2%)	10 (62.5%)	58 (58.0%)
+Blood and Related Products	6 (33.3%)	11 (64.7%)	9 (56.3%)	8 (53.3%)	13 (72.2%)	8 (50.0%)	55 (55.0%)
-Other Blood Products	6 (33.3%)	11 (64.7%)	9 (56.3%)	8 (53.3%)	12 (66.7%)	8 (50.0%)	54 (54.0%)
Platelets	4 (22.2%)	9 (52.9%)	7 (43.8%)	3 (20.0%)	7 (38.9%)	7 (43.8%)	37 (37.0%)
Red Blood Cells	2 (11.1%)	5 (29.4%)	4 (25.0%)	5 (33.3%)	2 (11.1%)	2 (12.5%)	20 (20.0%)
Platelets, Concentrated	2 (11.1%)	1 (5.9%)	0 (0.0%)	2 (13.3%)	2 (11.1%)	0 (0.0%)	7 (7.0%)
Red Blood Cells, Leucocyte Depleted	0 (0.0%)	1 (5.9%)	1 (6.3%)	0 (0.0%)	4 (22.2%)	0 (0.0%)	6 (6.0%)
Platelets, Human Blood	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	4 (22.2%)	0 (0.0%)	5 (5.0%)

n: Number of subjects with at least one disease in a given level
%: (n/N)*100 (N: Number of subjects by cohort)

3. These two columns were removed in updated /Current SAP

XYZ Pharm
2012-XY-003 (Page 1 of 1)

Listing 16.2.6.1
Dialysis Visit
Enrolled Analysis Set
Study Arm : Front Location

Subject ID Age/sex/ race/ ethnicity	Date/ Time of Dialysis	Port Access Used	Prescribed/ Total Fluid Removed (mL)	Timing	Weight (kg)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Heart Rate (per min)
F002/57/M/B/N	16JUN2016T6:41	AV Fistula	4500	Final	101	124	67	82
				Initial	104.9	189	94	82
F008/65/M/B/N	05JUL2016T12:00	AV Fistula	4500	Final	109.1	141	81	94
				Initial	114.1	184	84	65
F011/29/F/B/N	08JUL2016T11:15	AV Fistula	3500	Final	119	130	70	82
				Initial	122	132	78	77
F015/49/M/B/N	11JUL2016T8:13	AV Fistula	4500	Final	144	160	82	66
				Initial	147.8	189	91	71
F017/50/F/B/N	12JUL2016T12:09	Catheter	4000	Final	133.4	148	84	64
				Initial	136.5	168	108	65
F018/64/F/W/N	13JUL2016T6:20	AV Fistula	2000	Final	90.9	107	54	76
				Initial	92.5	122	66	86

Note: A = Asian; B = Black or African American; F = female; H = Hispanic or Latino; I = American Indian / Alaska Native; M = male; N = not Hispanic or Latino; P = Native Hawaiian or Other Pacific Islander; W = White

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4. The order of visit variable is not correct

Listing 11 Clinical Chemistry: By Visit Comparisons Part I

Patient ID/Site	Sex/ Age	Lab ID	Visit	Date:Time	Albumin (g/L) (CTC Grade)	Alkaline Phosphatase (U/L) (CTC Grade)	ALT (U/L) (CTC Grade)	AST (U/L) (CTC Grade)	Calcium (mmol/L) (CTC Grade)
1001/1101	F/63	1101LAB01	SCREENING (DAYS -14 TO 0)	22JAN2007 :10:47	ND	139 H (1)	43	35 H (1)	2.32
			CYCLE 1 DAY 1	29JAN2007 :10:29	39.00	129 H (1)	48	40 H (1)	ND
			CYCLE 1 DAY 15	12FEB2007 :10:43	38.00	123 H (1)	65 H (1)	61 H (1)	2.27
			CYCLE 1 DAY 8	05FEB2007 :11:42	37.00 L (1)	118 H (1)	38	36 H (1)	2.20
			CYCLE 2 DAY 1	19FEB2007 :11:42	39.00	132 H (1)	28	29	2.26
			CYCLE 2 DAY 15	05MAR2007 :09:28	39.00	116 H (1)	ND	ND	2.27
			CYCLE 3 DAY 1	12MAR2007 :12:26	41.00	122 H (1)	42	42 H (1)	2.26
			CYCLE 3 DAY 8	19MAR2007 :09:22	ND	ND	ND	ND	ND

5. Date of Extraction (19JUN2014) was after Run time (02JAN2014) which is not right

Subject Disposition	Statistic(s)	ITT: N = 455	SP: N = 451
Not Treated	n (%)	4 (0.9)	0
Treatment phase			
Ongoing	n (%)	187 (41.1)	187 (41.5)
Discontinued	n (%)	264 (58.0)	264 (58.5)
Primary reason for discontinuation from study treatment			
Death	n (%)	40 (8.8)	40 (8.9)
Adverse event	n (%)	29 (6.4)	29 (6.4)
Pregnancy	n (%)	0	0
Progressive disease	n (%)	165 (36.3)	165 (36.6)
Lack of efficacy	n (%)	1 (0.2)	1 (0.2)
Recovery	n (%)	0	0
Withdrew consent	n (%)	14 (3.1)	14 (3.1)
Non-compliance with study drug	n (%)	0	0
Lost to follow-up	n (%)	1 (0.2)	1 (0.2)
Study terminated by sponsor	n (%)	0	0
Transition to commercially available treatment	n (%)	1 (0.2)	1 (0.2)
Protocol violation	n (%)	0	0
Other	n (%)	12 (2.6)	12 (2.7)

ITT = Intention to treat population; SP = Safety population.

Data source: ADSL Safetv\t dism.SAS Data extraction date: 19JUN2014 Run time: 02JAN2014 /12:43

6. Truncation of Treatment variable with treatment info

EISAI Study E7389-G000-305 Database incomplete and queries outstanding Page
Listing 6 Adverse Events Part II

Patient ID/Site	System Organ Class	Preferred Term	Onset Cycle	Start Date/ Stop Date	SAE	Study Drug Action Taken	Treatment Given
1001/1101	BLOOD AND LYMPHATIC SYSTEM DISORDERS	*NEUTROPENIA	1	05FEB2007/ 19FEB2007	No	Dose Delayed	No
	BLOOD AND LYMPHATIC SYSTEM DISORDERS	*LEUKOPENIA	1	05FEB2007/ 12FEB2007	No	No Action Taken/Dose Not Changed	No
	BLOOD AND LYMPHATIC SYSTEM DISORDERS	*MONOCYTOPENIA	1	05FEB2007/ 12FEB2007	No	No Action Taken/Dose Not Changed	No
	NERVOUS SYSTEM DISORDERS	*PARAESTHESIA	3	12MAR2007/ 30JUL2007	No	No Action Taken/Dose Not Changed	No
	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	*INFLUENZA LIKE ILLNESS	3	13MAR2007/ 19MAR2007	No	No Action Taken/Dose Not Changed	Ye
	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	*FATIGUE	4	10APR2007/ 30JUL2007	No	No Action Taken/Dose Not Changed	No

7. Based on the title, only => 5% PTs should display in the table

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Table S.6.28
Adverse Events Reported (PT =>5%) During the Treatment Period
All Treated Subjects

System Organ Class (SOC) (%) Preferred Term (PT) (%)	Treatment A N=104
Total Subjects with AE	89 (21.2)
Infections and Infestations	19(18.3)
Urinary Tract Infection	2(1.9)
Bronchitis	2(1.9)
Bursitis Infective	1(1.0)
Herpes Zoster	5(4.8)
Influenza	1(1.0)
Nasopharyngitis	3(2.9)
Respiratory Tract Infection	1(1.0)
Rhinitis	1(1.0)
Tonsillitis	3(2.9)
Vaginal Infection	1(1.0)
Vulvovaginal Mycotic Infection	1(1.0)
Gastrointestinal Disorders	25 (24.0)
Nausea	18 (17.3)
Abdominal Pain Upper	5 (4.8)
Haematochezia	12 (11.5)
Paraesthesia Oral	4 (3.8)
Nervous System Disorders	4 (3.8)
Headache	2 (1.9)
Burning Sensation	1 (1.0)
Dizziness	1 (1.0)

8. Count and Percentages are not matching for Sex

Study XYZ

Table 14.01.2-1 (Page 1 of 1)
Summary of demographics
Included Set

		Placebo (N=18)	Trt A (N=17)	Trt B (N=16)	Total (N=51)
Remaining report is not displayed					
Sex	Total	18	17	16	
Male	n (%)	9 (50.0%)	7 (41.2%)	10 (62.5%)	26 (51.0%)
Female	n (%)	10 (55.5%)	10 (58.8%)	6 (37.5%)	26 (51.0%)

Sex values for Placebo 9+10=19 but total no. of patients (N=18), and even percentages also wrong.

9. Patients with at least 1 AE is more than No. of patients in treatment

Table 14.03.05.2-3 (Page 1 of 1)
Treatment-emergent adverse events (TEAEs) by system organ class and preferred term - Phase II
Safety Set

Disease category: AL (N= 18)

System Organ Class Preferred Term	# Subjects Affected	# of Subjects At Risk	# of Non-serious Events	# Subjects Affected by Related Non-serious Events	# of Related Non-serious Events
Subjects having at least 1 adverse event	20	18	267	18	219
Blood and lymphatic system disorders	13	18	177	13	164
Thrombocytopenia	12	18	128	12	117
Anaemia	5	18	19	4	18
Neutropenia	4	18	30	3	29

Adverse events that started or worsened from the date of the first dose of study drug up to 30 days after the date last dose of study drug and all possibly related or related AEs are considered Treatment Emergent (TEAE). Subjects with multiple events for a given preferred term or system organ class are counted once only under each referred term or system organ class, respectively. If a subject had multiple events for a given preferred term or system organ class, all events will be counted for the number of events system organ class, respectively. Adverse events are coded by MedDRA Version 18.0.

10. Grouping not done for 2 variables

Listing 3 Prior and Concomitant Medications

Patient ID/Site	(1)	Prior Med or Conmed	WHO Preferred Term	Drug Name	Start Date/ Stop Date	Total Daily Dose	Route	Reason for Use
1001/1101	Con		AMOXICILLIN	AMOXICILLINE	27FEB2007/ 08MAR2007	3 Other	Oral	Adverse experience: DENTAL EXTRACTION
1001/1101	Con		IBUPROFEN	IBUPROFEN	27FEB2007/ 06MAR2007	600 mg	Oral	Adverse experience: DENTAL EXTRACTION
1001/1101	Con		PARACETAMOL	DAFALGAN	13MAR2007/ 15MAR2007	500 mg	Oral	Adverse experience: FLU LIKE SYNDROM
					19MAR2007/ ONGOING	500 mg	Oral	Adverse experience: BREAST PAIN
				PARACETAMOL	27FEB2007/ 08MAR2007	500 mg	Oral	Adverse experience: DENTAL EXTRACTION
1001/1101	Con		POVIDONE-IODINE	ISOBETADINE BUCCAL	27FEB2007/ 08MAR2007	15 cc/mL	Oral	Adverse experience: DENTAL EXTRACTION
1001/1101	Con		TRAMADOL HYDROCHLORIDE	CONTRAMAL	10APR2007/ ONGOING	10 drops	Oral	Adverse experience: BREAST PAIN

11. Derivation of ITT or PP flags wrong

Page 1 of 1

Table 14.1.1
Subject Population Summary
All subjects

	MP-513 5 mg	MP-513 10 mg	MP-513 20 mg	MP-513 40 mg	Placebo	Total
Number of Subjects Screened						835
Number of Subjects Randomised	87	93	91	89	88	448
Number of Subjects in Safety Set	87 (100.0%)	93 (100.0%)	91 (100.0%)	88 (98.9%)	88 (100.0%)	447 (99.8%)
Number of Subjects in ITT Set	77 (88.5%)	82 (88.2%)	81 (89.0%)	86 (97.7%)	85 (96.6%)	411 (91.7%)
Number of Subjects in PP Set	78 (89.7%)	81 (87.1%)	86 (94.5%)	87 (98.9%)	69 (78.4%)	401 (89.5%)

Source: Listing 16.2.1.4

12. Median & Max variables were inter changed and may be missing age was included under <=65 or > 65 group as we have 19 patients but N=18 only

Study 001 OPEN LABEL

Table 14.01.1-3 (Page 1 of 1)
Summary of demographics
Safety Set

		ABC (N=18)	BCL (N=17)	XCL (N=16)	BCL&M/LL (N=15)	L-CL (N=18)	CL&LT (N=16)	Total (N=100)
Age (years)	Total	18	17	16	15	18	16	100
	Mean ± SD	59.7 ± 14.2	61.8 ± 13.4	70.9 ± 6.6	66.8 ± 8.8	60.7 ± 9.4	68.2 ± 8.8	64.5 ± 11.2
	Median	83.0	85.0	83.0	78.0	78.0	80.0	85.5
	Min ; Max	32 ; 61	38 ; 63	59 ; 69	52 ; 69	47 ; 61	46 ; 68	32 ; 66
<=65 years	n (%)	14 (72.2%)	9 (52.9%)	3 (18.8%)	5 (33.3%)	12 (66.7%)	6 (37.5%)	48 (48.0%)
> 65 years	n (%)	5 (27.8%)	8 (47.1%)	13 (81.3%)	10 (66.7%)	6 (33.3%)	10 (62.5%)	52 (52.0%)

13. Age value less than 18 yrs so it may be data issue or wrong calculation of Age variable

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Listing 12.2.4.1 Demographic characteristics (all subjects)

Centre	ECode	Treatment	Age at randomization (Years)	Sex	Weight (kg)	Height (cm)	BMI (kg/m²)	Race	Ethnic Group
582	E0102001	Lower dose AZD1656	68	Male	75	158	30.0	White	Hispanic or Latino
583	E0103002	Higher dose AZD1656	48	Female	68	155	28.3	White	Hispanic or Latino
584	E0104001	Glipizide	51	Female	96	175	31.3	White	Hispanic or Latino
	E0104002	Glipizide	56	Female	60	157	24.3	White	Hispanic or Latino
	E0104004	Higher dose AZD1656	63	Male	90	169	31.5	White	Hispanic or Latino
	E0104008	Fixed dose AZD1656 40 mg	61	Female	92	157	37.3	White	Hispanic or Latino
	E0104013	Placebo	18	Male	90	185	26.3	White	Hispanic or Latino
586	E0106001	Glipizide	50	Male	105	178	33.1	White	Hispanic or Latino
	E0106002	Lower dose AZD1656	62	Male		166	31.9	White	Hispanic or Latino
	E0106005	Fixed dose AZD1656 40 mg	63	Ma					Hispanic or Latino
587	E0107002	Higher dose AZD1656	47	Ma					Hispanic or Latino
	E0107004	AZD1656 open label dose	54						Hispanic or Latino
	E0107005	Glipizide	17	Female	93	151	40.8	White	Hispanic or Latino
	E0107009	Glipizide	58	Female	86	157	34.9	White	Hispanic or Latino
	E0107010	Higher dose AZD1656	62	Female	101	160	39.5	White	Hispanic or Latino

Age values are very different from other values

Ecode Enrolment code
Lower dose AZD1656 = 10 - 140 mg; Higher dose AZD1656 = 20 - 200 mg.

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14. Last dose date is later than study termination date

Study BAC1023 OPEN LABEL

Listing 16.03-1.1 (Page 1 of 1)
Safety Set

Subject/ (Age/Sex)	Histology	Last dose date (Study day)	Study termination date (Study day)	Death date (Study day)
00039/ (68/F)	Extranodal Marginal Zone B-Cell Lymphoma of Malt Type	14JAN2016/ (1746)		
00201/ (49/M)	Follicular Lymphoma	10DEC2015/ (2350)	02NOV2015/ (2291)	
01115/ (53/F)	Follicular Lymphoma	19MAR2015/ (1240)	30MAR2015/ (1241)	
01118/ (41/F)	Follicular Lymphoma	12NOV2015/ (1443)	23NOV2015/ (1451)	
01147/ (46/F)	Follicular Lymphoma	20SEP2015/ (1332)	18NOV2015/ (1383)	
01160/ (56/F)	Follicular Lymphoma	23JUL2015/ (1216)	16AUG2015/ (1240)	
01161/ (75/M)	Marginal Zone B Cell Lymphoma	11OCT2015/ (1282)		

Simple Remedies

- Before submitting for validation need to double check all the labels are displayed correctly or not
- Always use the final version of study documents
- Check for Subscripts and corresponding information, extra spaces before submitting for validation
- Need to confirm the display of decimal places for derived variables with stat if not mentioned in SAP or study docs.

 Review the report to check any column values are **truncating**
- Give a glance to see the percentages are matching correctly
- Check for "Are we using correct **macro variables** to create percentages"
- Use **defensive** coding to avoid loosing the data.
- Check the study documents and raise issue with DM.

Simple Mantra

"Self Validation" and "Continuous Learning" are the best methods to avoid 50 to 60% of mistakes

Try to work towards "First Time Right Approach(FTRA)"

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