

A network diagram in the top left corner consisting of several orange circular nodes of varying sizes connected by thin grey lines. One node is significantly larger than the others.

Rows and Rows and Rows of Zeroes:

Their significance in summary tables and subgroup analyses

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What is this talk about?

How important is this issue?

- **Last-minute change**
- **Change in programmer**
- **Unnecessary anxiety**

So, should I add some zeroes or not?

- Use a thumb rule:

**Add zeroes if the table is related to
SDTM findings or intervention class, skip
the zeroes for the event class**

Event class example

Incidence of TEAEs by System Organ Class and Preferred Term

System Organ Class/ Preferred Term	Treatment A	Treatment B	Total
	(N=xxx)	(N=xxx)	(N=xxx)
	n (%)	n (%)	n (%)
Number of subjects with at least one TEAE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
System Organ Class A	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term A1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term A2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term A3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

No zeroes if there is no data

Intervention class example

Summary of Exposure

	Total (N=111)
Exposure (days)	
n	110
Mean	15.3
SD	1.41
Median	15.0
Min	10
Max	26
Range of Exposure (days)	
n	111
< 7	0
>= 7	110 (>99%)
Missing	1 (<1%)

Zeroes even if no data

Zeroes for verification of totals

Shift from Baseline in Hematology Laboratory Parameter

Treatment	Parameter (Unit)	Visit	Timepoint	Baseline level	Low n	Normal n	High n	Missing n	Total n
ABC xx mg (N = x)									
	Hemoglobin [g/dl]	Day 1	2H	Low	0	0	0	0	0
				Normal	3	70	1	3	77
				High	0	0	0	4	4
				Missing	0	0	0	0	0
				Total	2	70	1	7	81
		Day 2	24H	Low	0	0	1	0	1
				Normal	0	46	4	30	80
				High	0	0	0	0	0
				Missing	0	0	0	0	0
				Total	0	46	5	30	81

Zeroes for study conduct

Subject Disposition and Withdrawals

Number of Subjects		Treatment A	Treatment B	Total
Enrolled	N	4	28	32
Premature Discontinuation from Study Treatment	n (%)	5 (100.0)	27 (96.4)	32 (96.9)
Reasons for Discontinuation from Study Treatment				
Radiographic disease progression	n (%)	0	16 (57.1)	16 (50.0)
Clinical disease progression	n (%)	0	3 (10.7)	3 (9.4)
Unacceptable toxicity	n (%)	0	0	0
Withdrew consent	n (%)	0	0	0
Death	n (%)	0	1 (3.6)	1 (3.1)
Pregnancy	n (%)	0	0	0
Discontinued by investigator or the sponsor	n (%)	1 (25.0)	0	1 (3.1)
Significant protocol deviation	n (%)	0	0	0
Lost to follow-up	n (%)	1 (25.0)	0	1 (3.1)
Adverse event	n (%)	1 (25.0)	2 (7.1)	3 (9.4)
Other		2 (50.0)	5 (17.9)	7 (21.9)

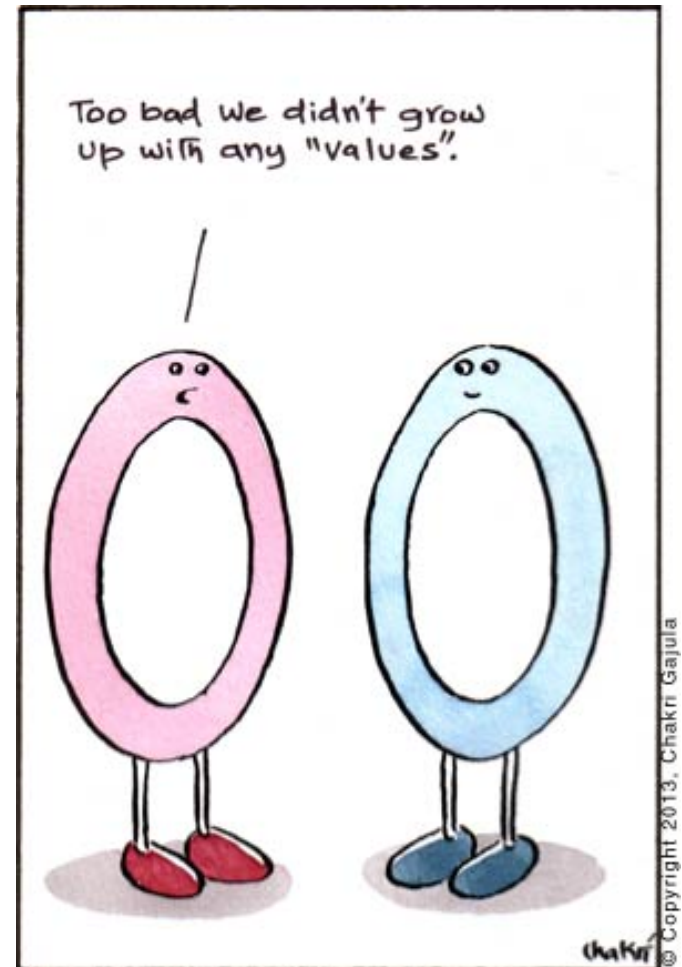
Zeroes for info on study population

Summary of Demographic Characteristics at Baseline

Characteristics	Statistic	Treatment A (N=xxx) n (%)	Treatment B (N=xxx) n (%)	Total (N=xxx) n (%)
Sex				
Male	n (%)	7 (53.8)	2 (33.3)	9 (47.4)
Female	n (%)	6 (46.2)	4 (66.7)	10 (52.6)
Ethnic Origin				
White	n (%)	7 (53.8)	4 (66.7)	11(57.9)
Black	n (%)	6 (46.2)	1 (16.7)	7 (36.8)
Hispanic	n (%)	0	1 (16.7)	1 (5.3)
Other	n (%)	0	0	0
Age (Years)	n	13	6	19
	Mean	13.2	13.7	13.3
	SD	1.5	1.6	1.5
	Median	13.0	13.5	13
	Min, Max	11, 15	12, 16	11, 16
Age group				
10 and Under	n (%)	0	0	0
Pre-teen	n (%)	5 (38.5)	2 (33.3)	7 (36.8)
Teen	n (%)	8 (61.5)	4 (66.7)	12 (63.2)

Summary

- Adding zeroes not just a programming decision
- A thumb rule helps, but is not exhaustive
- When in doubt, add them anyway



Thank you