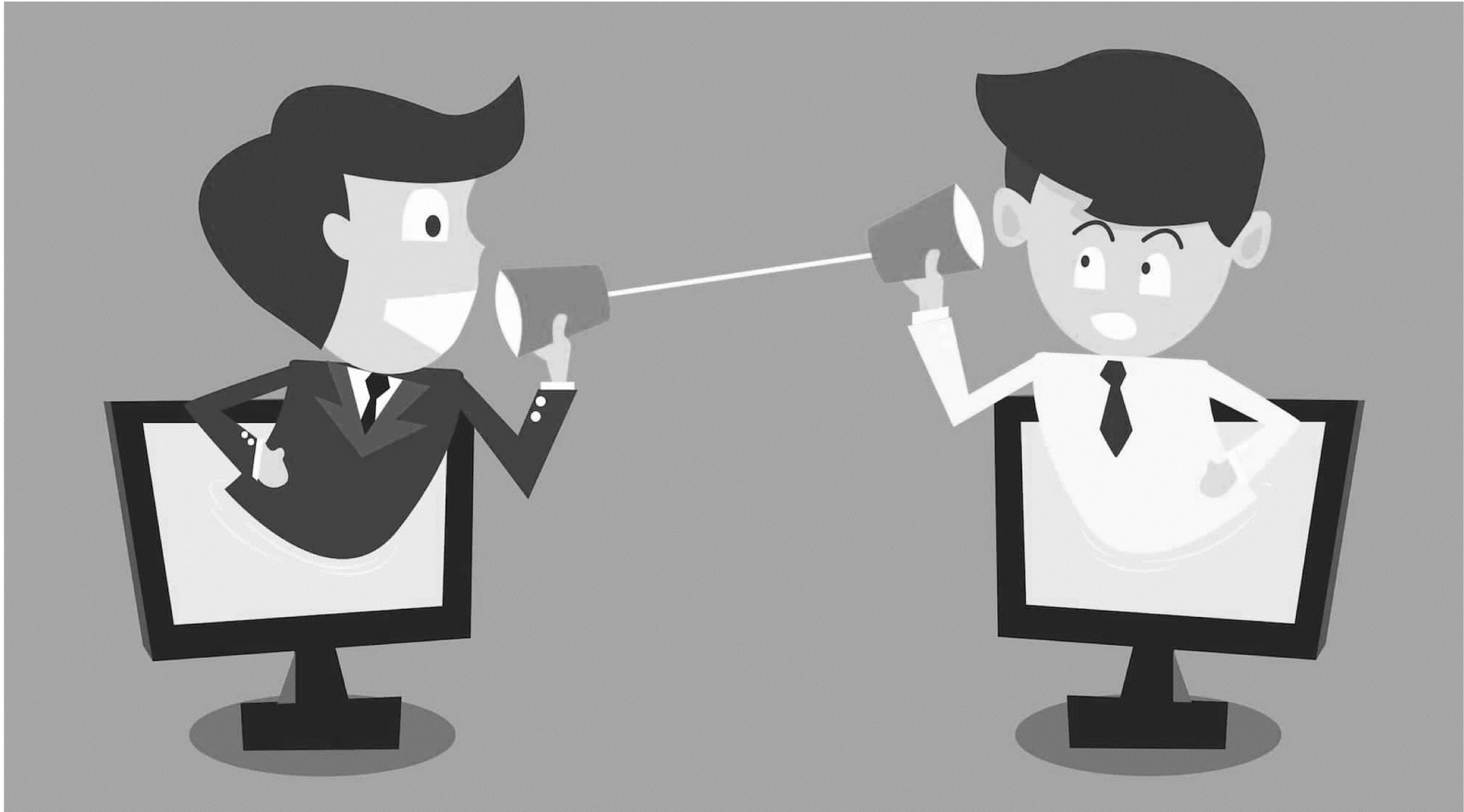


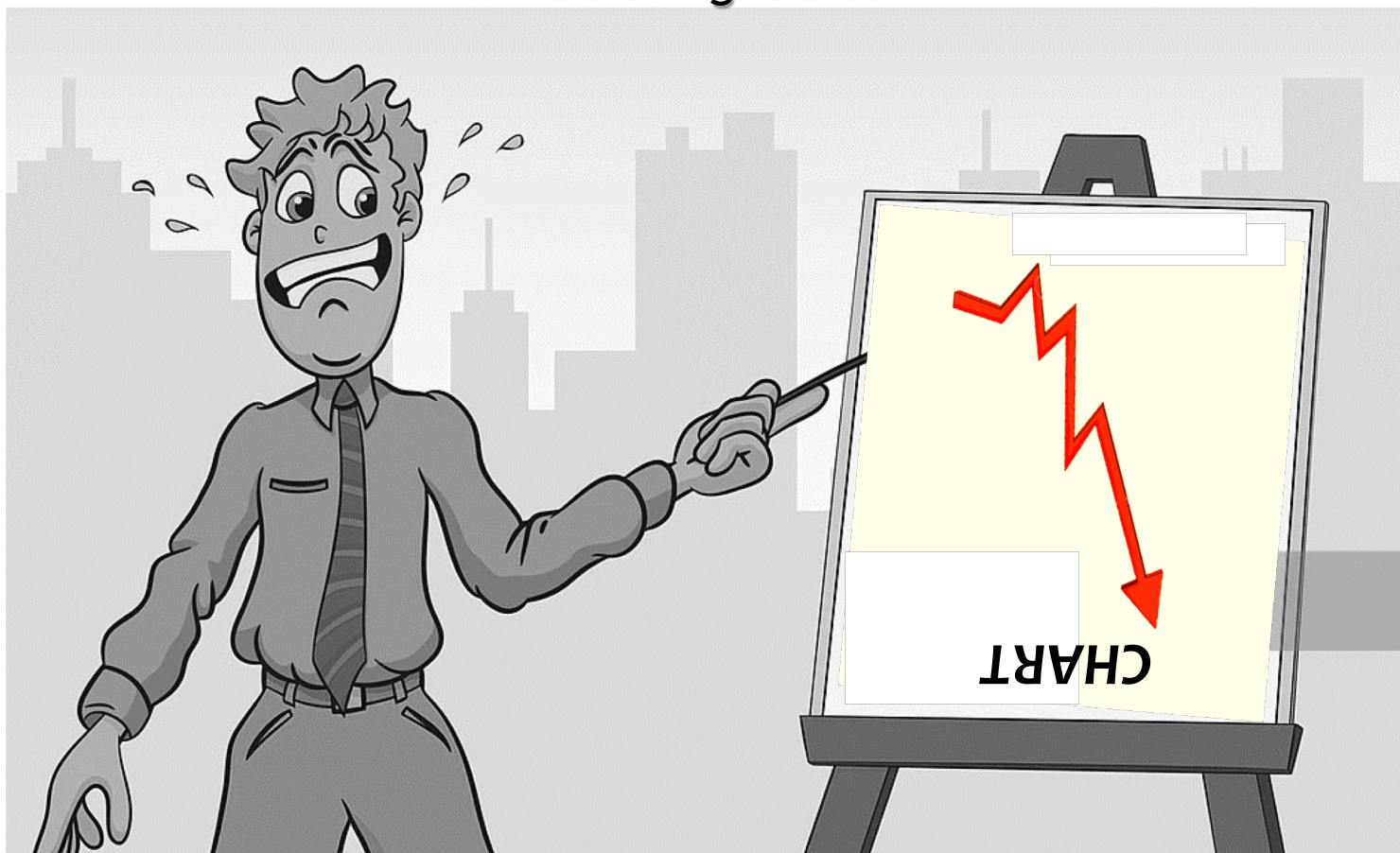
**Programmers are from Mars and
Statisticians are from Venus**



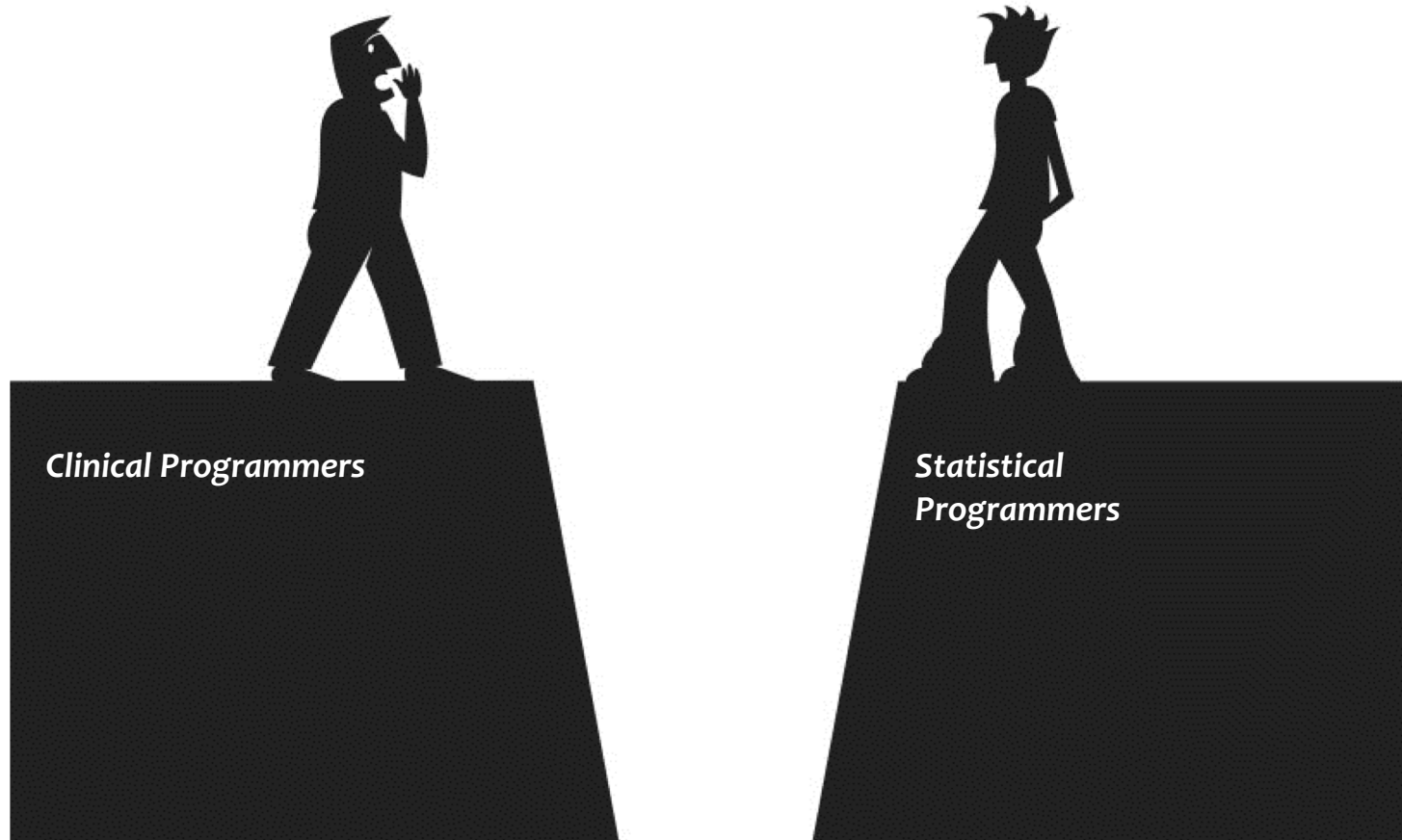
Outsourcing: Communication becomes a Headache



Numbers Might Lie!



Gaps when Multiple Teams were Involved



When Statisticians are Forced to Manage Programmers!!



Understand the Story!



When the Operation is Unsuccessful

Table 4. Snapshot of Exposure data

Subject	Treatment Duration (days)		
	Period 1	Period 2	Overall
001-001	5	3	8
001-002	5	3	8
002-001	5	.	(5 or Missing?)
002-002	5	3	8
003-001	5	2	7
003-003	5	3	8

Table 5. Summary of Treatment Exposure – Safety Population

	Period 1 (N=6)	Period 2 (N=5)	Overall (N=6)	
			(+)	(sum)
Treatment Duration (days)				
n/nmiss	6/0	5/1	5/1	6/0
Mean	5.0	2.8	7.8	7.3
Standard Deviation	0.00	0.45	0.45	1.21
Median	5.0	3.0	8.0	8.0
Min, Max	5, 5	2, 3	7, 8	5, 8

Understand the Relationships!



Not all relationship are Complicated

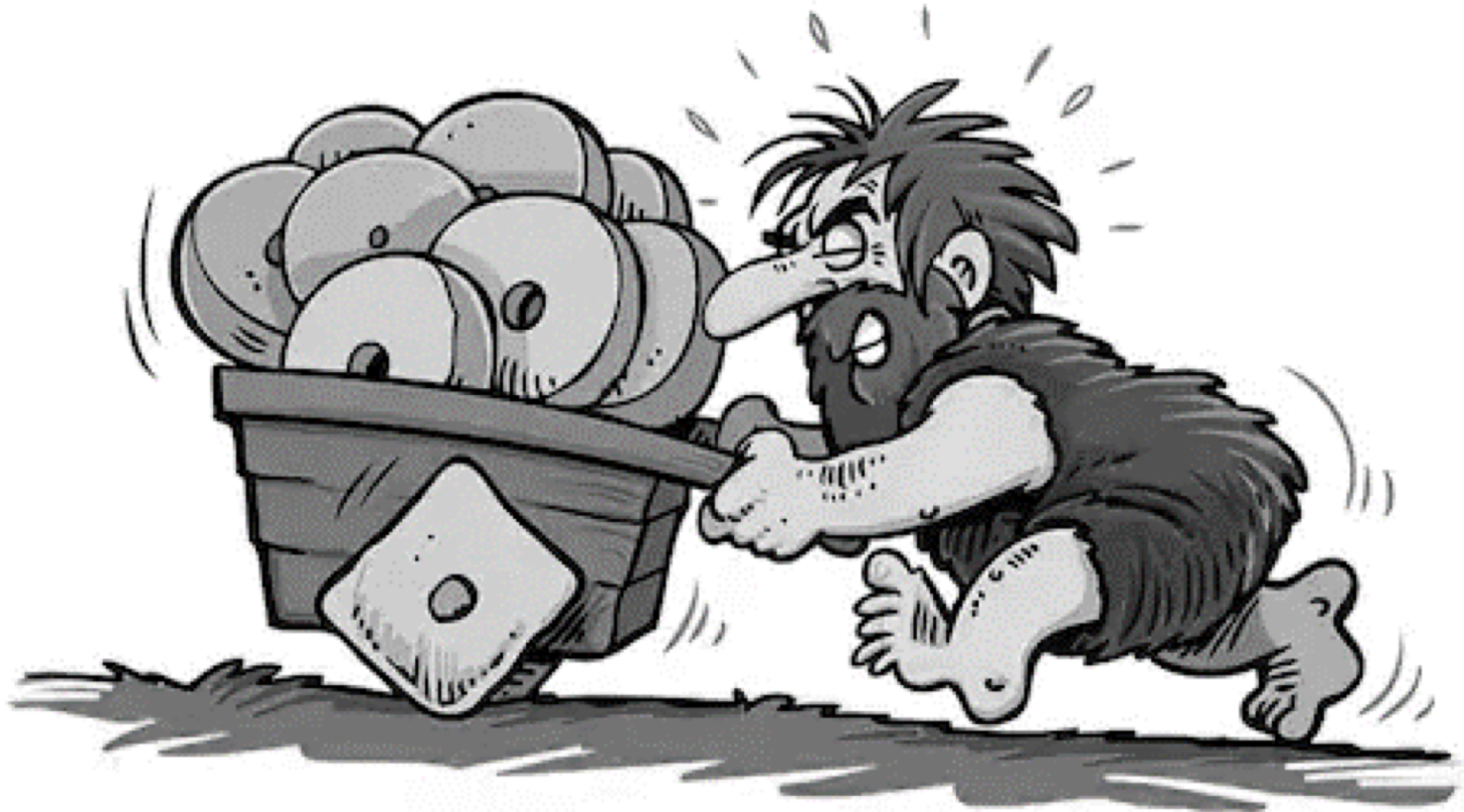
Table 2. Overview of All Adverse Events – Safety Population

	Treatment (N=10)	Placebo (N=10)	Total (N=20)
All adverse events	5 (50.0 %)	1 (10.0 %)	6 (30.0 %)
Serious adverse events	0	0	0
Treatment Emergent adverse events	2 (20.0 %)	1 (10.0 %)	3 (15.0 %)
Adverse Events leading to Death	2 (20.0 %)	0	2 (10.0 %)

Table 3. Summary of Subject Disposition – Intent to Treat Population

Reason for Withdrawal	Treatment (N=10)	Placebo (N=10)	Total (N=20)
Lost to Follow-up	1 (10.0 %)	0	1 (5.0 %)
Withdrawal of Consent	0	0	0
Protocol violation	2 (20.0 %)	1 (10.0 %)	3 (15.0 %)
Death	1 (10.0 %)	0	1 (5.0 %)
Physician decision	0	0	0

Do Not Re-invent the Wheel



Static or Dynamic?

Table 6. Summary of Adverse Events – Safety Population

System Organ Class Preferred Term	Treatment (N=21)	Placebo (N=10)	Total (N=31)
General Disorders	15 (71.4%)	5 (50.0%)	20 (64.5%)
Fever	12 (57.1%)	3 (30.0%)	15 (48.4%)
Cold	7 (33.3%)	3 (30.0%)	10 (32.3%)
Lungs	2 (9.5%)	2 (20.0%)	4 (21.9%)
Lung Carcinoma	0	1 (10.0%)	1 (3.2%)
Not Coded	2 (9.5%)	1 (10.0%)	3 (9.7%)
Not Coded	2 (9.5%)	1 (10.0%)	3 (9.7%)

Note: Subjects are counted once per System Organ Class and once per Preferred Term.

Data Traps



Outliers or Liars?

Table 9. Summary of ECG Parameters – Safety Population

Parameter Statistic	Treatment (N=21)	Placebo (N=10)	Total (N=31)
PR Interval (msec)			
n/nmiss	20/1	10/0	30/1
Mean	234.73	183.34	187.28
Standard Deviation	35.921	11.429	30.984
Median	189.50	190.40	189.50
Min, Max	115.3, 1005.0	127.4, 205.3	115.3, 1005.0



Thank You!



**ACCELERATING RESEARCH &
DEVELOPMENT**