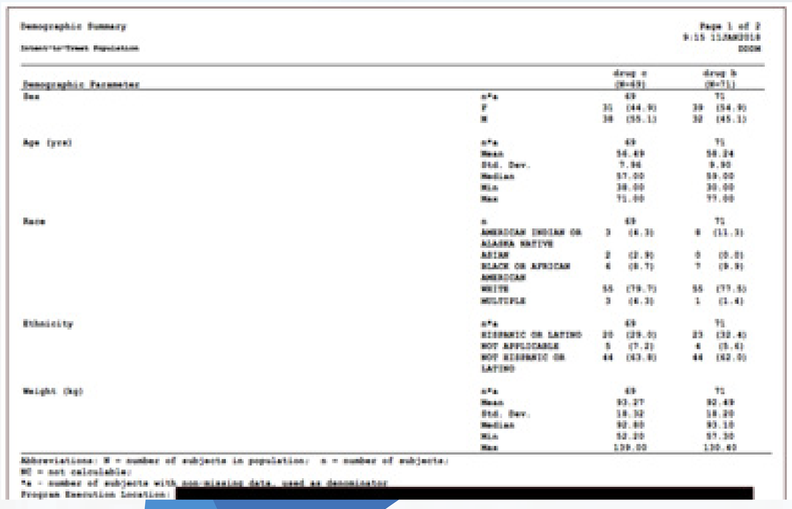
Chris Decker

#KILLTFLs: Providing Analysis with Context

Without context, data has little meaning

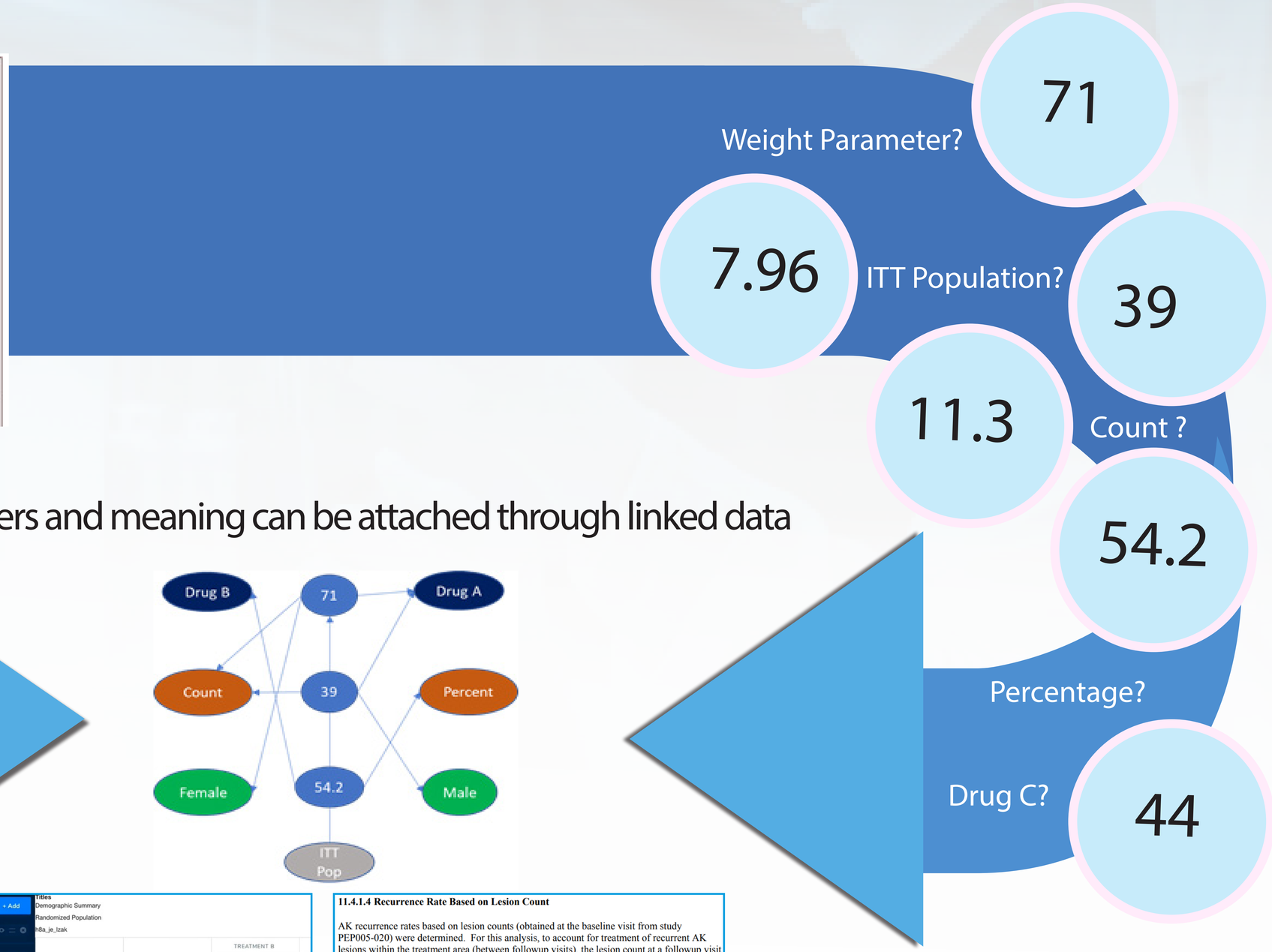
40 years of the same static report, used once, and thrown away


Demographic Summary — Page 1 of 2
Intent-to-Treat Population — 9:15 11JAN2015 — DDDM

Demographic Parameter		drug a (N=69)	drug b (N=71)
Sex	n*a	69	71
	F	31 (44.9)	39 (54.9)
	M	38 (55.1)	32 (45.1)
Age (yrs)	n*a	69	71
	Mean	56.49	58.24
	Std. Dev.	7.96	9.80
	Median	57.00	59.00
	Min	38.00	30.00
	Max	71.00	77.00
Race	n	69	71
	AMERICAN INDIAN OR ALASKA NATIVE	3 (4.3)	8 (11.3)
	ASIAN	2 (2.9)	0 (0.0)
	BLACK OR AFRICAN AMERICAN	6 (8.7)	7 (9.9)
	WHITE	55 (79.7)	55 (77.5)
	MULTIPLE	3 (4.3)	1 (1.4)
Ethnicity	n*a	69	71
	HISPANIC OR LATINO	20 (29.0)	23 (32.4)
	NOT APPLICABLE	5 (7.2)	4 (5.6)
	NOT HISPANIC OR LATINO	44 (63.8)	44 (62.0)
Weight (kg)	n*a	69	71
	Mean	93.27	92.49
	Std. Dev.	18.92	18.20
	Median	92.80	93.10
	Min	52.20	57.30
	Max	139.00	130.60

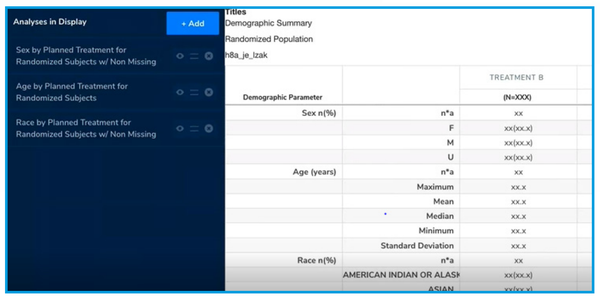
Abbreviations: N = number of subjects in population; n = number of subjects;
NC = not calculable;
*n = number of subjects with non-missing data, used as denominator
Program Execution Location: [redacted]

But these numbers have meaning; the meaning just needs to be attached to the number



Numbers and meaning can be attached through linked data

Cross Study Analyses

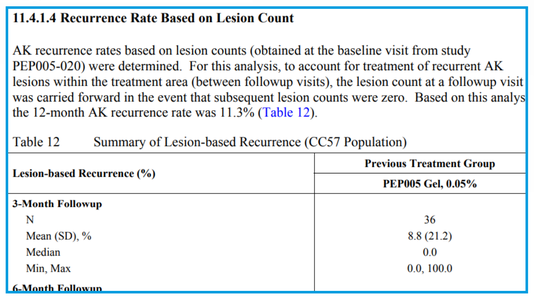

Analyses in Display — + Add

- Sex by Planned Treatment for Randomized Subjects w/ Non Missing
- Age by Planned Treatment for Randomized Subjects
- Race by Planned Treatment for Randomized Subjects w/ Non Missing

Titles
Demographic Summary
Randomized Population
h8a_je_lzak

Demographic Parameter		TREATMENT B (N=XXX)
Sex n(%)	n*a	xx
	F	xx(xx.x)
	M	xx(xx.x)
	U	xx(xx.x)
Age (years)	n*a	xx
	Maximum	xx.x
	Mean	xx.x
	Median	xx.x
	Minimum	xx.x
	Standard Deviation	xx.x
Race n(%)	n*a	xx
	AMERICAN INDIAN OR ALASK	xx(xx.x)
	ASIAN	xx(xx.x)

CSR Automation


11.4.1.4 Recurrence Rate Based on Lesion Count

AK recurrence rates based on lesion counts (obtained at the baseline visit from study PEP005-020) were determined. For this analysis, to account for treatment of recurrent AK lesions within the treatment area (between followup visits), the lesion count at a followup visit was carried forward in the event that subsequent lesion counts were zero. Based on this analys the 12-month AK recurrence rate was 11.3% (Table 12).

Table 12 Summary of Lesion-based Recurrence (CC57 Population)

Lesion-based Recurrence (%)	Previous Treatment Group PEP005 Gel, 0.05%
3-Month Followup	
N	36
Mean (SD), %	8.8 (21.2)
Median	0.0
Min, Max	0.0, 100.0
6-Month Followup	

Dynamic Reports

	Study 1	Study 2	Study 3	Study 4	Study 5	Study 6	Study 7	Study 8
Which studies analyzed blood pressure for females and display those analyses?	✔		✔	✔		✔		
Which of my studies collected a LOCF pain score analysis at week 8 and combine those analysis?	✔	✔	✔		✔		✔	
How many subjects in my safety population across these 3 pivotal studies?	42	38	121	26	98	34	61	432

d-wise