

Example Data Monitoring Committee Open Meeting Report

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1 Introduction

This is a sample of the part of an open meeting Data Monitoring Committee report that contains software generated results. Study design and interpretation components are not included. This report used a random sample of data from a randomized clinical trial. The date and time that the analysis file used here was last updated was 2002-09-26 22:43:50.

2 Subject Accrual

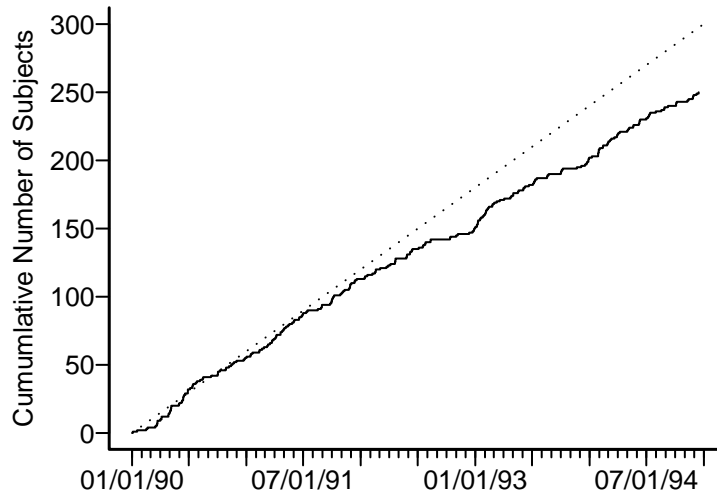


Figure 1: Subjects randomized over time. The target enrollment duration was defined from 01/01/90 to 12/31/94. The dotted straight line depicts target accrual. The solid black line depicts randomized subjects.

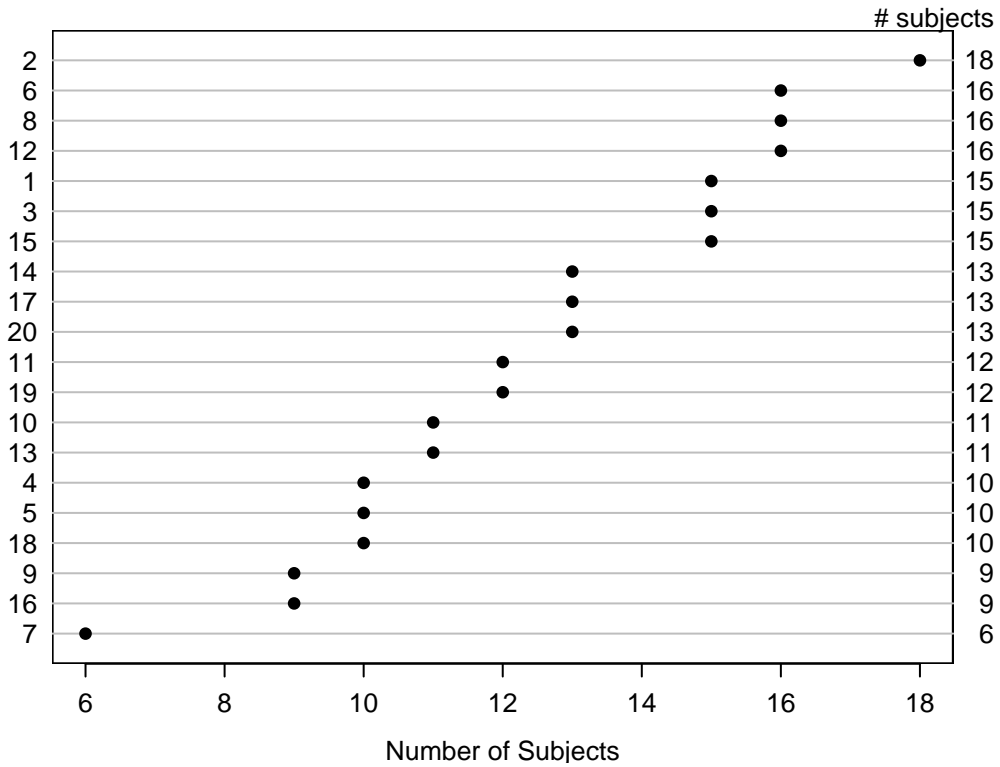


Figure 2: Numbers of subjects randomized by site. Numbers to the right of the chart show the values that each dot represents (i.e., the number of subjects randomized within each site).

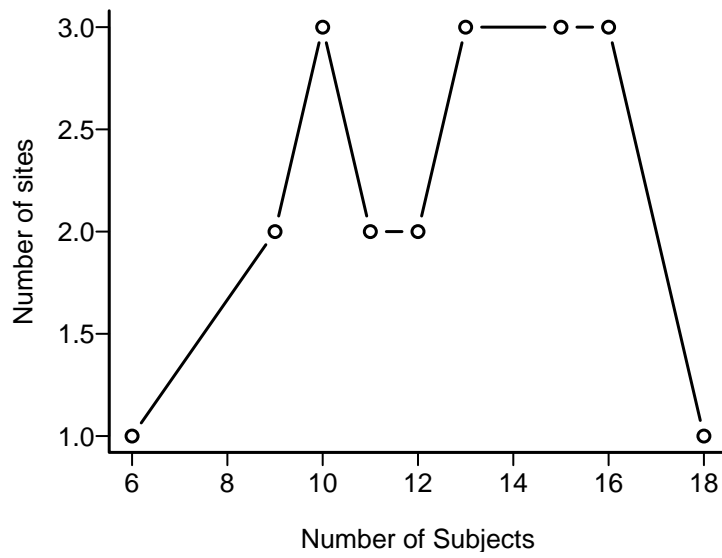


Figure 3: Number of sites having a given number of subjects randomized.

3 Data Availability and Completeness

For the 8 baseline variables, the number of subjects having values entered was 250.

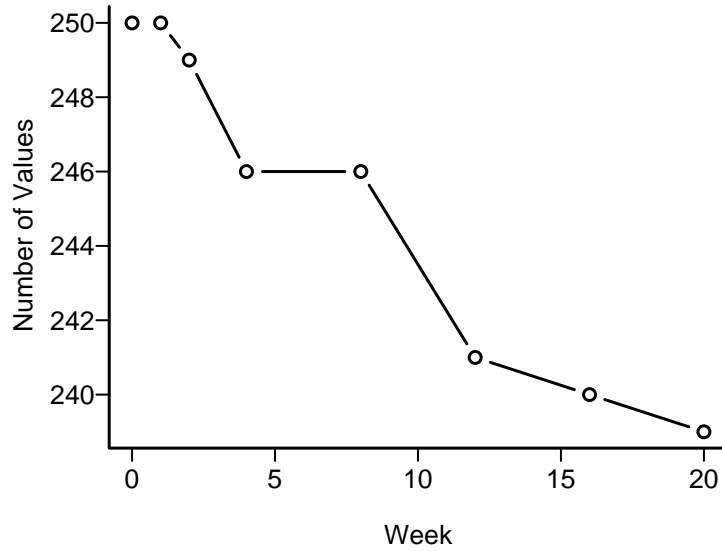


Figure 4: Completeness of adverse events. The *y*-axis displays the number of values measured for `headache`, `ab.pain`, `nausea`, `dyspepsia`, `diarrhea`, `upper.resp.infect`, `coad`.

Codes used in Figure 5 are as follows:(a):`axis`, `corr.qt`, `qrs`, `uncorr.qt`, `hr`.

Codes used in Figure 6 are as follows:(a):`hematocrit`, `hemoglobin`, `platelets`, `rbc`, `wbc`; (b):`basophils`, `eosinophils`, `lymphocytes`, `monocytes`.

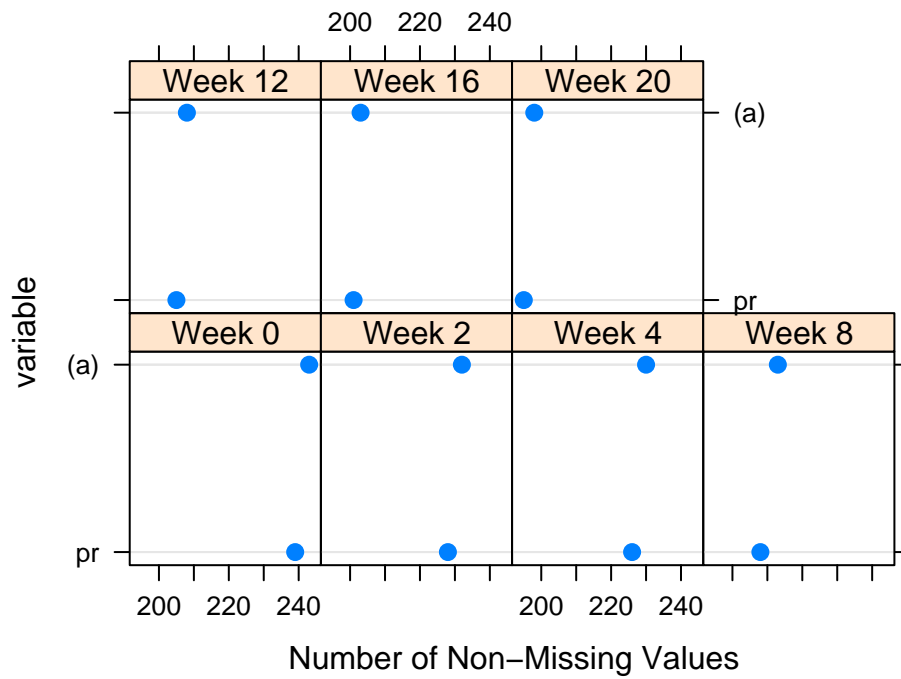


Figure 5: Completeness of EKG. Letters in parentheses indicate groups of variables having the same number of values measured, defined elsewhere.

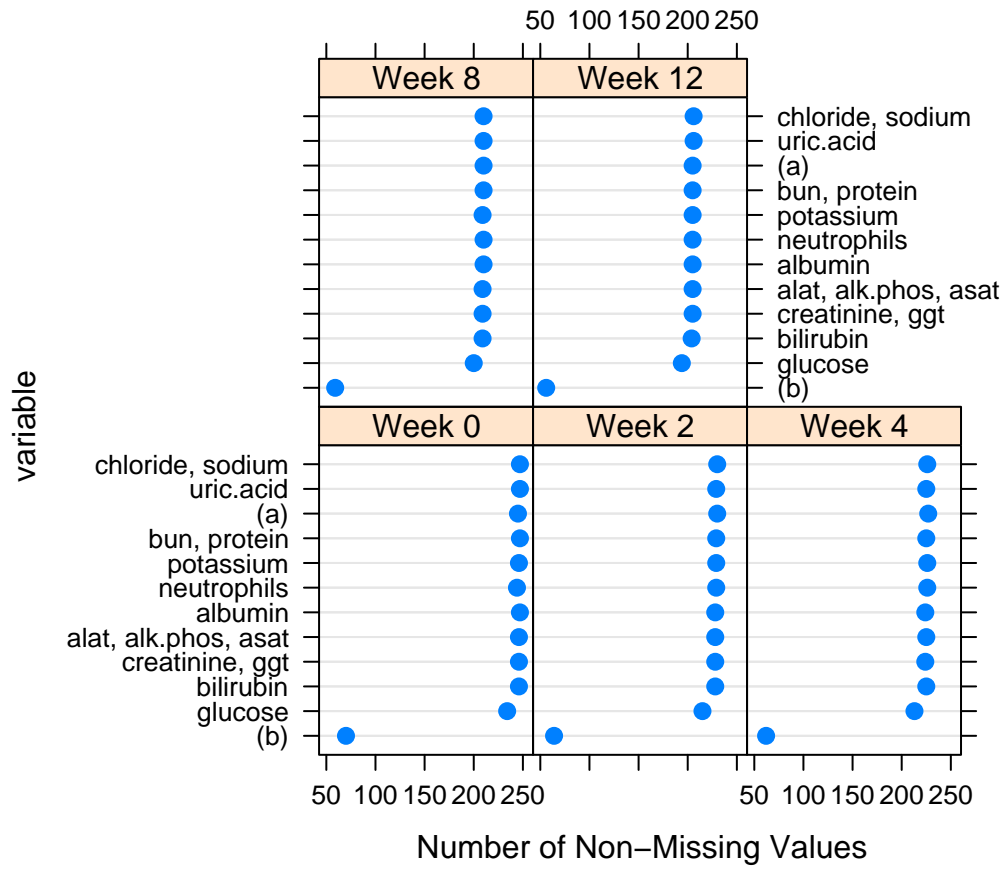


Figure 6: Completeness of clinical chemistry. Letters in parentheses indicate groups of variables having the same number of values measured, defined elsewhere.

4 Baseline Variables

Table 1: Baseline

	N			
age	250	60.2	67.0	73.0
Sex : male	250	0		1
Race : Black	250	0		1
Caucasian				
Oriental				
Other				
height	250	164	168	174
weight	250	63.0	74.2	85.9
bmi	250	22.9	25.8	29.4
smoking	250	0		1
pack_yrs	250	30.0	43.5	60.0

a b c represent the lower quartile *a*, the median *b*, and the upper quartile *c* for continuous variables. *N* is the number of non-missing values. Numbers after percents are frequencies.

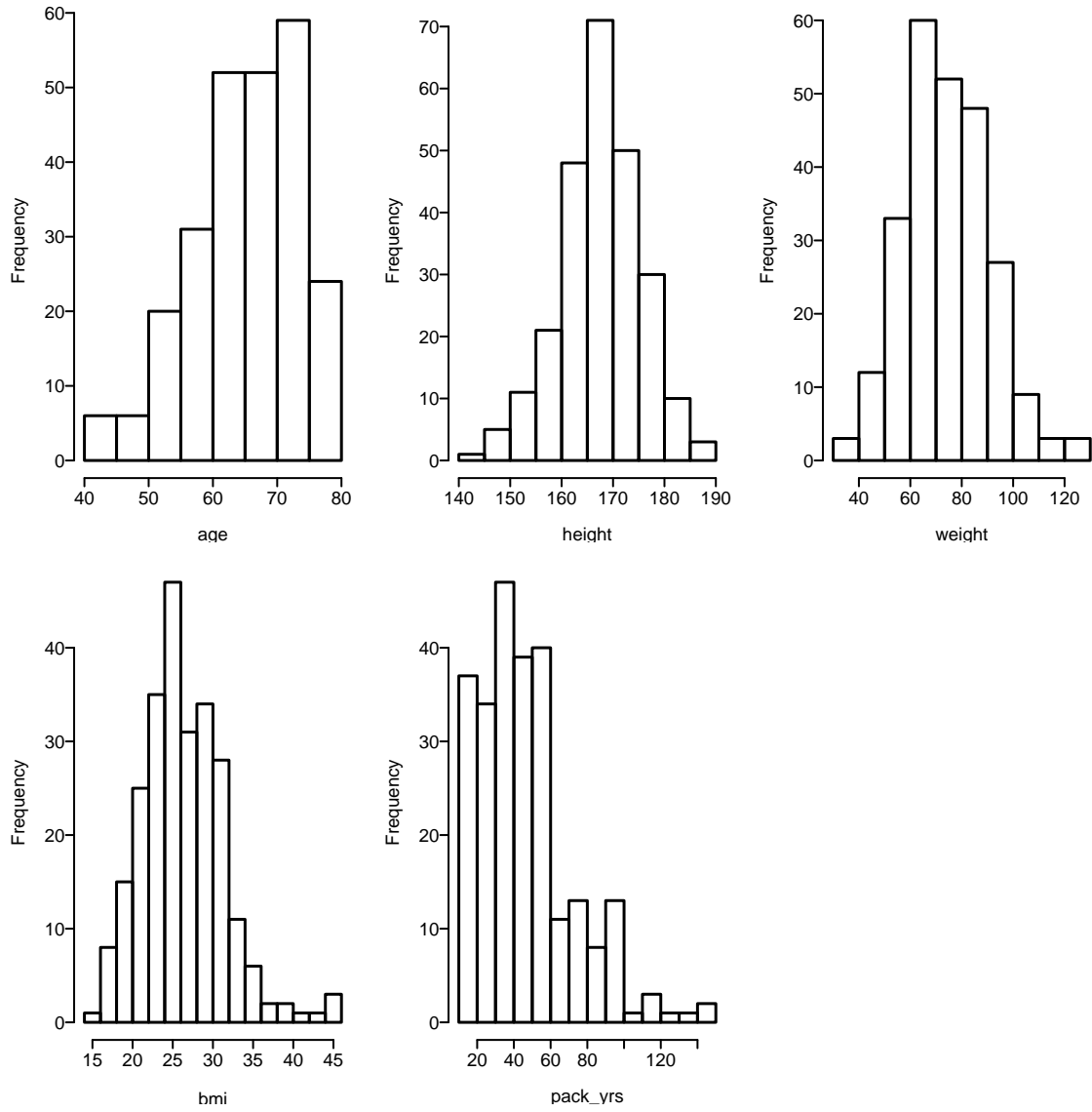


Figure 7: Distributions of the continuous variables in the 'baseline' table

5 Interrelationships Among Variables

A variable clustering diagram is shown in the figure which follows. Variables are grouped according to how they are correlated with one another, as measured by the square of the Spearman ρ rank correlation coefficient computed on all pairs of variables. Variables connected on lower branches are more highly correlated with one another. Variables missing in more than 0.75 of the observations or categorical variables having more than 20 levels are ignored. Categories less than 0.1 prevalent are pooled with other rare categories.

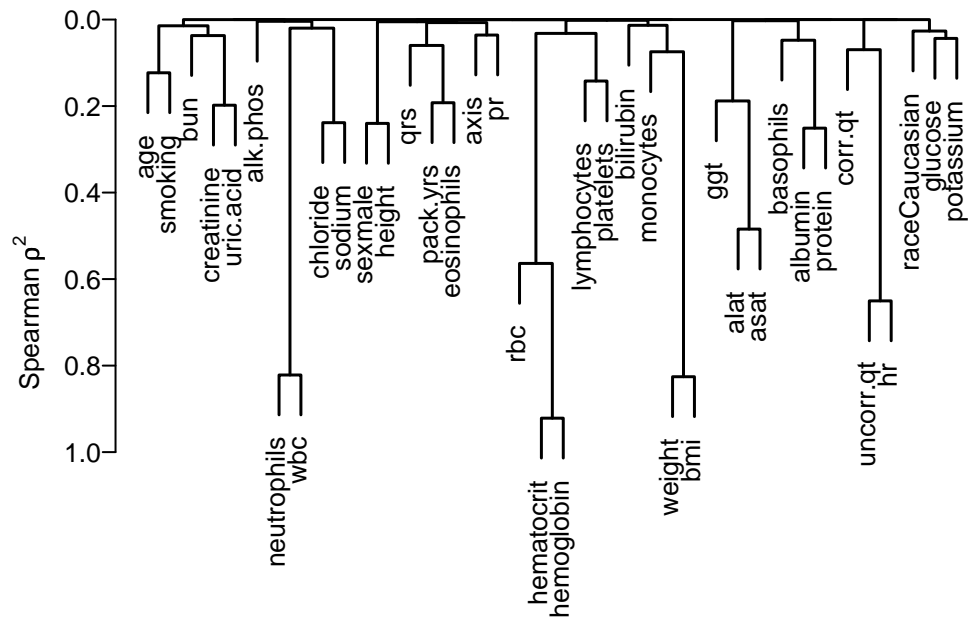


Figure 8: Clustering of variables at baseline

6 Compliance to Assigned Treatments

Table 2: Compliance

	N	Compliance
Week		
2	250	1.00
4	250	0.99
8	250	0.98
12	250	0.95
16	250	0.81
20	250	0.73
Overall	1500	0.91

7 Dropouts

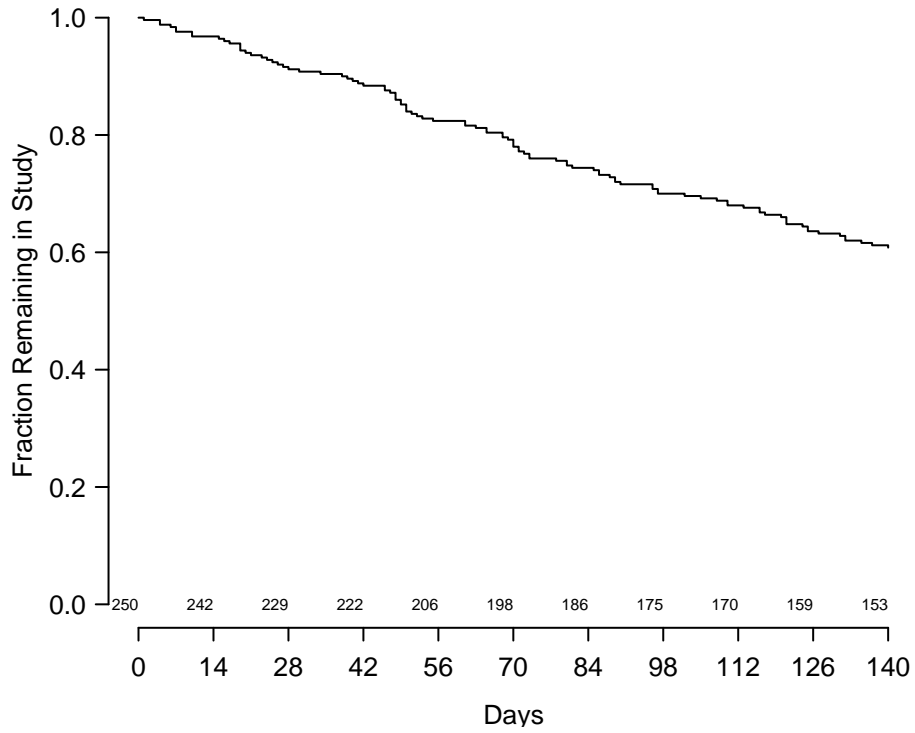


Figure 9: Distribution of time until dropout from study