TABLE 9.1 Data From a Clinical Trial for Calculating the Hazard Ratio[a]

Months (i)	Group 1 (Study Drug) r_{1i} (r_{1i} is number of subjects alive and not censored, just before time t_i)	Group 2 (Control) r_{2i} (r_{2i} is number of subjects alive and not censored, just before time t_i)	d_i Total Deaths at Time t_i
1	25	24	0
3	24	24	0
5	24	23	0
6	23	23	6
8	21	19	2
9	21	17	0
10	20	17	2
12	17	17	6
13	13	14	0
15	11	14	0
16	10	13	0
18	9	12	0
20	9	10	1
22	8	9	0
24	8	8	2
27	6	7	0
28	5	7	0
30	5	4	1
32	5	2	1
33	4	2	0
34	4	1	0
36	3	1	0
42	1	1	1
44	1	0	0

[a]*Machin D, Gardner MJ. Calculating confidence intervals for survival time analyses. Brit. Med. J. 1988;296:1369–71.*

IV. DATA USED FOR CONSTRUCTING THE KAPLAN–MEIER PLOT ARE FROM SUBJECTS ENROLLING AT DIFFERENT TIMES

In a typical clinical trial, the sequence of events for each subject involves responding to an advertisement, contacting the sponsor, and undergoing screening and enrollment.

It is usually *not the case* that the sponsor enrolls the desired number of subjects, and then administers the study drug or control treatment to all of the subjects *on exactly the same day*. What is indicated at "day 0" on the Kaplan–Meier plot may correspond, in actuality, to hundreds of different days spread out over the course of a year. The fact that study drug and control treatments are started for each subject, shortly after the subject becomes available and immediately after the subject is properly enrolled in the trial, has prompted some investigators to compare differences in the subjects' baseline characteristics, for subjects enrolled early in the trial with subjects enrolled late in the trial. Jacobs et al. (33) provide a good example of this comparison.

In nutritional studies, all of the enrolled subjects are typically started on experimental and control treatments on exactly the same day. The ample supply of healthy subjects willing to participate in a nutritional study enables this kind of study design. Moreover, the requirement for keeping nutritional study subjects confined in a "metabolic unit" during the course of the study, to prevent subjects from consuming nonstudy foods, necessitates that all subjects begin the trial on the same date (34).

[33]Jacobs LD, Cookfair DL, Rudick RA, et al. Intramuscular interferon beta-1a for disease progression in relapsing multiple sclerosis. The Multiple Sclerosis Collaborative Research Group (MSCRG). Ann. Neurol. 1996;39:285–94.

[34]Margen S, Chu JY, Kaufmann NA, Calloway DH. Studies in calcium metabolism. I. The calciuretic effect of dietary protein. Am. J. Clin. Nutr. 1974;27:584–89.