

TABLE 7-4

Total Number of Patients Required to Detect an Improvement in Survival Rate Over a Baseline Survival Rate

BASELINE P_1	IMPROVEMENT IN SURVIVAL RATES ($P_2 - P_1$)									
	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
0.05	664(615)* 497(459)†	232(209) 174(156)	133(116) 100(87)	92(78) 69(59)	71(58) 53(44)	58(46) 43(34)	49(38) 37(29)	43(32) 32(24)	38(27) 29(21)	35(24) 26(18)
0.10	1289(1128) 963(843)	395(335) 295(251)	207(171) 155(128)	135(108) 101(30)	98(76) 73(57)	76(57) 57(43)	63(45) 47(34)	53(37) 40(28)	46(31) 35(23)	41(26) 31(20)
0.15	1894(1562) 1415(1167)	544(435) 406(325)	272(211) 204(158)	170(128) 127(95)	120(87) 90(65)	91(64) 68(48)	73(49) 55(37)	61(39) 46(29)	52(32) 39(24)	45(27) 34(20)
0.20	2445(1895) 1827(1416)	676(507) 505(379)	328(238) 245(178)	200(140) 150(105)	138(93) 104(70)	103(67) 77(50)	81(51) 61(38)	66(40) 50(30)	56(32) 42(24)	48(26) 36(20)
0.25	2927(2122) 2187(1585)	788(551) 589(412)	375(253) 280(189)	224(146) 168(109)	152(95) 114(71)	112(67) 84(50)	87(50) 65(37)	70(39) 63(29)	59(31) 44(23)	50(25) 38(19)
0.30	3330(2247) 2487(1679)	879(571) 657(427)	411(257) 307(192)	243(145) 192(109)	163(93) 122(70)	118(65) 89(49)	91(47) 68(36)	73(36) 55(27)	60(28) 45(21)	51(23) 39(17)
0.35	3647(2279) 2724(1703)	949(569) 709(425)	438(251) 327(188)	255(140) 191(105)	169(89) 127(66)	122(61) 91(45)	93(44) 70(33)	74(33) 55(25)	60(25) 46(19)	51(20) 39(15)
0.40	3876(2228) 2895(1665)	995(547) 744(409)	454(238) 339(178)	262(131) 196(98)	172(81) 129(61)	123(55) 92(41)	93(39) 70(29)	73(29) 55(22)	60(22) 45(17)	50(17) 38(13)
0.45	4014(2107) 2999(1574)	1019(509) 762(381)	460(218) 344(163)	263(118) 197(88)	171(72) 128(54)	121(48) 91(36)	91(34) 68(25)	71(24) 54(18)	58(18) 44(14)	48(14) 37(11)
0.50	4061(1929) 3034(1441)	1020(459) 763(343)	456(193) 341(145)	258(103) 193(77)	166(62) 125(46)	116(40) 88(30)	87(28) 65(21)	67(20) 51(15)	55(15) 42(11)	
0.55	4017(1707) 3001(1275)	998(399) 746(298)	441(165) 330(123)	247(86) 185(64)	158(51) 119(38)	110(33) 83(24)	81(22) 61(17)	63(15) 48(12)		
0.60	3881(1455) 2900(1087)	953(333) 713(249)	417(135) 312(101)	231(69) 173(52)	146(40) 110(30)	101(25) 76(19)	74(16) 56(12)			
0.65	3654(1187) 2730(887)	896(265) 663(198)	382(105) 286(78)	209(52) 157(39)	131(29) 99(22)	89(17) 68(13)				
0.70	3337(917) 2493(685)	796(199) 596(149)	338(76) 253(57)	182(36) 137(27)	112(19) 85(15)					
0.75	2930(659) 2190(492)	684(136) 512(102)	284(49) 214(37)	150(22) 114(17)						
0.80	2436(426) 1821(318)	551(82) 413(62)	222(27) 168(21)							
0.85	1854(231) 1387(173)	398(39) 300(30)								
0.90	1189(89) 892(66)									

* Upper figure: $\alpha = 0.05$, $\beta = 0.10$ † Lower figure: $\alpha = 0.05$, $\beta = 0.20$

(Freedman LS: Stat Med, 1; 121, 1982)

random treatment assignments must be generated. They are IIIB and KPS 80 to 100; IIIB and KPS 50 to 70; IVA and KPS 80 to 100; IVA and KPS 50 to 70. In each stratum, the researcher must decide at which point in the block there should be balance. If it is after four treatment assignments, then there are six possible sequences, XYYY, YXXY, YXXY, YXXY, and YXXX.

A random number table equating X with odd numbers and Y with even numbers can be used to generate each block in every stratum. Tables for treatment assignments should be prepared ahead of time and be kept secret from the investigators who enter the patients so that their choices are not influenced by the knowledge of the next treatment assignment. This would severely compromise the integrity of the randomization procedure and thus the study.

The number of stratifying factors used should be kept to a

minimum. If they are not, there exists a possibility of introducing a serious imbalance in the distributions of the treatment assignments across the strata. For multiinstitution studies, one may wish to include institution as a stratification variable to prevent serious treatment imbalances from occurring within an institution and to ensure that each institution treats approximately the same number of patients with the experimental and the standard programs. Unfortunately, it is virtually impossible to include "institution" in a stratified randomization procedure if the number of participating institutions is large, such as in RTOG. Zelen provided a solution to this problem.⁵⁰ At the time of randomization by telephone, a tentative treatment assignment is determined by taking the next assignment from the appropriate stratum as defined by the patient's prognosis. The difference between the number of patients assigned to the treatment with the tentative assignment and the number on the