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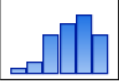
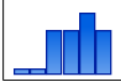
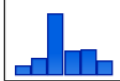

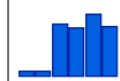




The Impact of Unrealistic Optimism on Informed Consent in Early-Phase Oncology Trials

Table 1.*
Demographic Characteristics

<i>Patient demographic characteristics</i>	<i>Number of patients (N = 171)</i>	<i>%</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>	<i>Standard deviation</i>
Age			58.64	18	85	12.78
Age group	(18-49)	31	18.13			
	(50-64)	73	42.69			
	(65-74)	57	33.33			
	(75 +)	10	5.85			
Study site	Site 1	85	49.71			
	Site 2	86	50.29			
Gender	Male	84	49.12			
	Female	87	50.88			
Race	White (non-Hispanic)	146	85.38			
	African American or Black of U.S. origin	17	9.94			
	Other	8	4.68			
Education	Grade school or high school	54	31.58			
	College	81	47.37			
	Graduate or professional school	36	21.05			
Religion	Protestant	65	38.01			
	Catholic	26	15.2			
	Agnostic	12	7.02			
	Other	68	39.77			
Cancer problem	Blood cancer	54	31.58			
	Lung cancer	26	15.2			
	Breast cancer	23	13.45			
	Other	68	39.77			
Domestic status (Do you live alone?)	Yes	31	18.13			
	No	140	81.87			
Marital status	Single	28	16.47			
	Married	115	67.65			
	Divorced	17	10			
	Widowed	10	5.88			
Participation in previous research study	Yes	53	30.99			
	No	118	69.01			
Phase of clinical trial	Phase I	89	52.05			
	Phase II	63	36.84			
	Phase I/II	19	11.11			

*A nearly identical table (with the same data but stylistic differences) appears in Jansen LA, Mahadevan D, Appelbaum PS, et al. Dispositional optimism and therapeutic expectations in early-phase oncology trials. *Cancer* 2016;122(8):1238-1246. Reprinted with permission from John Wiley and Sons, Inc., license 3812530116377.

Table 3.
Association of Research-Related Questions of the Comparative Risk-Benefit Assessment Questionnaire

 cancer_controlled	$r = 0.79$ $p < 0.0001$	$r = 0.16$ $p = 0.040$	$r = 0.43$ $p < 0.0001$	$r = 0.64$ $p < 0.0001$	$r = 0.62$ $p < 0.0001$	$r = 0.63$ $p < 0.0001$	$r = 0.46$ $p < 0.0001$	$r = 0.26$ $p = 0.001$
 health_benefit	$r = 0.21$ $p = 0.005$	$r = 0.39$ $p < 0.0001$	$r = 0.57$ $p < 0.0001$	$r = 0.57$ $p < 0.0001$	$r = 0.53$ $p < 0.0001$	$r = 0.47$ $p < 0.0001$	$r = 0.26$ $p = 0.001$	
 health_problem_rev	$r = 0.21$ $p = 0.005$	$r = 0.14$ $p = 0.065$	$r = 0.28$ $p = 0.0002$	$r = 0.23$ $p = 0.002$	$r = 0.13$ $p = 0.096$	$r = 0.52$ $p < 0.0001$		
 cancer_cured	$r = 0.38$ $p < 0.0001$	$r = 0.42$ $p < 0.0001$	$r = 0.59$ $p < 0.0001$	$r = 0.33$ $p < 0.0001$	$r = 0.28$ $p = 0.0002$			
 life_increase	$r = 0.72$ $p < 0.0001$	$r = 0.59$ $p < 0.0001$	$r = 0.38$ $p < 0.0001$	$r = 0.28$ $p = 0.0002$				
 spread_slow	$r = 0.73$ $p < 0.0001$	$r = 0.44$ $p < 0.0001$	$r = 0.29$ $p = 0.0001$					
 spread_stop	$r = 0.42$ $p < 0.0001$	$r = 0.24$ $p = 0.002$						
 pain_control	$r = 0.21$ $p = 0.007$							
 be_sicker_rev								

r -- Spearman coefficient
 p -value -- based on Spearman correlation (degrees of freedom = 169)

Table 4.*
Association of Research-Related Questions of the Comparative Risk-Benefit Assessment
and Demographic and Clinical Characteristics

Variable	Level	Total Optimism Bias Score			
		N	Mean	SD	P-value
Study site	Site 1	85	0.93	0.78	0.195
	Site 2	86	1.07	1.13	
Age group	(18-49)	31	0.85	0.88	0.288
	(50-64)	73	1.03	0.97	
	(65-74)	57	0.98	1.06	
	(75 +)	10	1.40	0.71	
Gender	Male	84	1.09	0.88	0.237
	Female	87	0.92	1.05	
Ethnicity	White (non-Hispanic)	146	0.99	0.91	0.684
	African American or Black of U.S. origin	17	0.97	1.39	
	Other	8	1.19	1.08	
Education	Grade school or high school	54	0.94	1.07	0.795
	College	81	1.06	0.92	
	Graduate or professional school	36	0.97	0.95	
Religion	Agnostic	12	0.63	0.52	0.179
	Protestant	65	0.91	0.98	
	Catholic	26	1.19	0.88	
	Other	68	1.09	1.04	
Cancer problem	Blood cancer	54	0.96	0.88	0.636
	Breast cancer	23	1.18	1.16	
	Lung cancer	26	1.16	0.99	
	Other	68	0.91	0.97	

* A similar but longer table appears in Jansen LA, Mahadevan D, Appelbaum PS, et al. Dispositional optimism and therapeutic expectations in early-phase oncology trials. *Cancer* 2016;122(8):1238-1246. (Some stylistic changes have been made to this reprinted portion, but the data remains the same.) Table partially reprinted with permission from John Wiley and Sons, Inc., license 3812530116377.

Table 6.
Association between Understanding (Purpose) Question and Appreciation and Voluntariness Questions

		<i>Frequency (Percentage)</i>			<i>P value *</i>
		<i>Understanding N = 101</i>	<i>Combination responses N = 20</i>	<i>Lack of understanding N = 50</i>	
Role in study	Appreciation	41 (40.59)	2 (10.00)	8 (16.00)	0.001 **
	Lack of appreciation	60 (59.41)	18 (90.00)	42 (84.00)	
Treatment in study	Appreciation	20 (19.80)	3 (15.00)	13 (26.00)	0.583
	Lack of appreciation	81 (80.20)	17 (85.00)	37 (74.00)	
Ability to decline	Recognition	48 (47.52)	9 (45.00)	18 (36.00)	0.421
	Lack of recognition	53 (55.48)	11 (55.00)	32 (64.00)	

* P-values from Fisher's exact test

** Significant at 0.05 significance level

Figure 1.

Error Bar Plot (Mean \pm Standard Error) of Total Unrealistic Optimism Scores for Elements of Informed Consent Defined by Appreciation, Voluntariness, and Understanding (Purpose) Questions

