

Supplemental online content for:

Potential Impact of Revised NCI Eligibility Criteria Guidance: Prior Malignancy Exclusion in Breast Cancer Clinical Trials

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eTable 1: Data Variables Collected

eTable 2: Characteristics of 87 Protocols Included in the Analysis

eTable 1. Data Variables Collected

Trial characteristics

Activation year; accrual target; network group (ECOG, Alliance, NRG, SWOG); breast cancer stage; trial phase (I–IV); primary endpoint (response/toxicity/complications, survival, progression, recurrence, other); primary treatment modality (surgical, radiation, medical [chemotherapy, hormonal therapy, immunotherapy, targeted therapy], other)

Prior cancer diagnosis exclusion characteristics

Presence (yes/no); time frame of exclusion (current, within 2–3 years, within 5 years, within 10 years, ever, other); exceptions (eg, in situ cervical cancer, nonmelanoma skin cancer, other in situ cancer types, or other types of exceptions)

Prior cancer treatment exclusion characteristics

Presence (yes/no); treatment type (surgery, radiation, chemotherapy, other)

eTable 2. Characteristics of 87 Protocols Included in the Analysis

Trial	Trial Characteristics				Prior Cancer Exclusion		Estimated Trial Population With Prior Cancer		Estimated Patients Excluded		
	Cancer Stage	First-Line Treatment	First-Line Endpoint	Phase	Target Accrual n	Present	Exclusion Time Frame	Proportion (%)	Proportion Within Exclusion Time Frame (%)	Proportion (%)	Number
1991–1999											
CALGB-9741	III	chemo	recurrence	III	1,584	no	N/A	5.7	0	0.0	0
S9313	III	chemo	recurrence	III	3,000	no	N/A	5.7	0	0.0	0
CALGB-9840	IV	other	response/toxicity	III	580	no	N/A	5.8	0	0.0	0
E1196	IV	chemo	response/toxicity	II	33	yes	≤5 y	5.8	39.4	2.3	1
E1195	IV	other	response/toxicity	II	36	yes	≤5 y	5.8	39.4	2.3	1
E4195	IV	chemo	response/toxicity	II	45	yes	≤5 y	5.8	39.4	2.3	1
E2198	III	targeted	response/toxicity	II	220	yes	≤5 y	5.7	39.4	2.2	5
E2196	IV	targeted	progression	III	360	yes	≤5 y	5.8	39.4	2.3	8
E2190	III	chemo	survival	III	534	yes	≤5 y	5.7	39.4	2.2	12
E2197	III	chemo	recurrence	III	2,778	yes	≤5 y	5.7	39.4	2.2	64
E1199	III	chemo	recurrence	III	5,000	yes	≤5 y	5.7	39.4	2.2	115
NSABP-B-30	III	chemo	recurrence	III	5,300	yes	≤5 y	5.7	39.4	2.2	122
RTOG-98-04	I	hormonal	recurrence	III	1,990	yes	≤5 y	7	39.4	2.8	56
EB193	III	chemo	recurrence	III	3,000	yes	≤10 y	5.7	61	3.5	108
E5194	I	surgery	recurrence	III	1,176	yes	≤10 y	7	61	4.3	52
E8193	IV	chemo	response/toxicity	II	33	yes	ever	5.8	100	5.8	2
E3197	IV	targeted	progression	II	60	yes	ever	5.8	100	5.8	4
E3193	II	surgery	recurrence	III	1,684	yes	ever	5.7	100	5.7	102
2000–2009											
CALGB-49907	III	chemo	recurrence	III	1,800	no	N/A	5.7	0	0.0	0
CALGB-40601	III	chemo	response/toxicity	III	300	no	N/A	5.7	0	0.0	0
E2193	I	hormonal	response/toxicity	III	120	no	N/A	7	0	0.0	0
E2100	IV	targeted	progression	III	685	no	N/A	5.8	0	0.0	0
E1104	IV	targeted	response/toxicity	II	41	no	N/A	5.8	0	0.0	0
E2104	III	targeted	response/toxicity	II	212	no	N/A	5.7	0	0.0	0
CALGB-40603	III	targeted	response/toxicity	II	445	no	N/A	5.7	0	0.0	0
N083E	III	other	response/toxicity	II	30	no	N/A	5.7	0	0.0	0
E5103	III	other	recurrence	III	4,950	no	N/A	5.7	0	0.0	0
CALGB-40302	IV	other	progression	III	324	no	N/A	5.8	0	0.0	0
N02C1	III	other	response/toxicity	III	200	no	N/A	5.7	0	0.0	0
NSABP-B-37	III	chemo	recurrence	III	265	yes	current	5.7	23.5	1.3	4
CALGB-40503	IV	targeted	progression	III	442	yes	current	5.8	23.5	1.4	6
CALGB-40502	IV	chemo	progression	III	845	yes	current	5.8	23.5	1.4	12
E1100	IV	targeted	response/toxicity	II	34	yes	≤5 y	5.8	39.4	2.3	1
E2103	IV	other	response/toxicity	II	60	yes	≤5 y	5.8	39.4	2.3	1
E1103	IV	targeted	response/toxicity	II	70	yes	≤5 y	5.8	39.4	2.3	2

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eTable 2. Characteristics of 87 Protocols Included in the Analysis (cont.)

Trial	Trial Characteristics				Prior Cancer Exclusion		Estimated Trial Population With Prior Cancer		Estimated Patients Excluded		
	Cancer Stage	First-Line Treatment	First-Line Endpoint	Phase	Target Accrual n	Present	Exclusion Time Frame	Proportion (%)	Proportion Within Exclusion Time Frame (%)	Proportion (%)	Number
2000–2009 (cont.)											
E3198	IV	targeted	response/toxicity	II	84	yes	≤5 y	5.8	39.4	2.3	2
E4101	IV	targeted	response/toxicity	II	148	yes	≤5 y	5.8	39.4	2.3	3
S0012	III	other	progression	III	350	yes	≤5 y	5.7	39.4	2.2	8
E1105	IV	targeted	response/toxicity	III	489	yes	≤5 y	5.8	39.4	2.3	11
CALGB-70305	III	other	response/toxicity	III	560	yes	≤5 y	5.7	39.4	2.2	13
Z1031	III	hormonal	response/toxicity	III	610	yes	≤5 y	5.7	39.4	2.2	14
S0500	IV	chemo	survival	III	651	yes	≤5 y	5.8	39.4	2.3	15
S0226	IV	hormonal	progression	III	690	yes	≤5 y	5.8	39.4	2.3	16
NSABP-B-40	III	chemo	recurrence	III	1,200	yes	≤5 y	5.7	39.4	2.2	28
NCIC-MA.21	III	chemo	recurrence	III	2,100	yes	≤5 y	5.7	39.4	2.2	48
NSABP-B-34	III	other	recurrence	III	2,400	yes	≤5 y	5.7	39.4	2.2	55
NSABP-B-33	III	hormonal	recurrence	III	3,000	yes	≤5 y	5.7	39.4	2.2	69
S0221	III	chemo	recurrence	III	3,250	yes	≤5 y	5.7	39.4	2.2	75
N9831	III	targeted	recurrence	III	3,700	yes	≤5 y	5.7	39.4	2.2	85
NSABP-B-42	III	hormonal	recurrence	III	3,840	yes	≤5 y	5.7	39.4	2.2	88
CALGB-40101	III	chemo	recurrence	III	4,646	yes	≤5 y	5.7	39.4	2.2	107
NSABP-B-38	III	chemo	recurrence	III	4,800	yes	≤5 y	5.7	39.4	2.2	110
NCIC-MA.27	III	hormonal	recurrence	III	6,840	yes	≤5 y	6.9	39.4	2.7	191
NSABP-B-36	II	chemo	recurrence	III	2,700	yes	≤5 y	5.7	39.4	2.2	62
PACCT-1	II	hormonal	recurrence	III	11,248	yes	≤5 y	5.7	39.4	2.2	258
NSABP-B-43	I	targeted	progression	III	2,000	yes	≤5 y	7	39.4	2.8	57
NSABP-B-35	I	hormonal	progression	III	3,000	yes	≤5 y	7	39.4	2.8	85
NSABP-B-39	I	radiation	recurrence	III	4,214	yes	≤5 y	7	39.4	2.8	120
N063D	III	targeted	recurrence	III	8,000	yes	≤10 y	5.7	61	3.5	288
2010–2016											
Z1071	III	surgery	other	II	660	no	N/A	5.7	39.4	2.2	6
A011104	II	surgery	recurrence	III	488	no	N/A	5.7	0	0.0	0
EA1131	III	chemo	recurrence	III	750	no	N/A	5.7	0	0.0	0
A011106	III	hormonal	recurrence	III	2,820	no	N/A	5.7	0	0.0	0
S1202	III	other	response/toxicity	III	294	no	N/A	5.7	0	0.0	0
E4112	I	other	progression	II	350	no	N/A	7	0	0.0	0
RTOG-1119	IV	radiation	response/toxicity	II	143	yes	≤2–3 y	5.8	29.5	1.7	2
N1031	IV	chemo	response/toxicity	II	50	yes	≤2–3 y	5.8	29.5	1.7	1
A011203	IV	hormonal	progression	II	80	yes	≤2–3 y	5.8	29.5	1.7	1
A011401	III	other	other	III	3,136	yes	≤2–3 y	5.7	29.5	1.7	54
S1008	III	other	other	II	25	yes	≤5 y	5.7	39.4	2.2	1
N093B	IV	other	response/toxicity	II	48	yes	≤5 y	5.8	39.4	2.3	1
ALLIANCE 8129	IV	targeted	response/toxicity	II	94	yes	≤5 y	5.8	39.4	2.3	2

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2010–2016 (cont.)											
S0800	III	targeted	response/ toxicity	II	200	yes	≤5 y	5.7	39.4	2.2	5
E3108	IV	other	other	other	240	yes	≤5 y	5.8	39.4	2.3	6
Z1041	III	targeted	response/ toxicity	III	270	yes	≤5 y	5.7	39.4	2.2	6
NSABP-B-52	III	hormonal	recurrence	III	312	yes	≤5 y	5.7	39.4	2.2	7
E2108	IV	other	survival	III	368	yes	≤5 y	5.8	39.4	2.3	9
E2112	IV	other	survival	III	600	yes	≤5 y	5.8	39.4	2.3	14
NRG-BR003	III	chemo	progression	III	990	yes	≤5 y	5.7	39.4	2.2	23
E1Z11	III	other	response/ toxicity	other	1,000	yes	≤5 y	5.7	39.4	2.2	23
NSABP-B-55	III	targeted	recurrence	III	1,500	yes	≤5 y	5.7	39.4	2.2	34
A011502	III	other	recurrence	III	2,936	yes	≤5 y	5.7	39.4	2.2	67
NSABP-B-47	III	targeted	recurrence	III	3,260	yes	≤5 y	5.7	39.4	2.2	75
NSABP-B-49	III	chemo	recurrence	III	4,200	yes	≤5 y	5.7	39.4	2.2	96
Z11102	II	surgery	recurrence	II	265	yes	≤5 y	5.7	39.4	2.2	6
A011202	II	radiation	progression	III	2,918	yes	≤5 y	5.7	39.4	2.2	67
A221405	III	hormonal	other	other	500	yes	ever	5.7	100	5.7	30
Total	–	–	–	–	–	–	–	–	–	–	3,107

Abbreviations: chemo, chemotherapy; N/A, not applicable.