

Supplementary Appendix

From Protocols to Publications: A Study in Selective Reporting of Outcomes in Randomized Trials in Oncology

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Table S1. List of randomized trials include in the analysis

S.No	Study Reference	PMID
1	Walker JL, Piedmonte MR, Spirtos NM et al. Recurrence and survival after random assignment to laparoscopy versus laparotomy for comprehensive surgical staging of uterine cancer: Gynecologic Oncology Group LAP2 Study. <i>J Clin Oncol.</i> 2012 Mar 1;30(7):695-700.	22291074
2	de Wit R, Skoneczna I, Daugaard G, et al. Randomized phase III study comparing paclitaxel-bleomycin, etoposide, and cisplatin (BEP) to standard BEP in intermediate-prognosis germ-cell cancer: intergroup study EORTC 30983. <i>J Clin Oncol.</i> 2012 Mar 10;30(8):792-9.	22271474
3	Bergh J, Bondarenko IM, Lichinitser MR et al. First-line treatment of advanced breast cancer with sunitinib in combination with docetaxel versus docetaxel alone: results of a prospective, randomized phase III study. <i>J Clin Oncol.</i> 2012 Mar 20;30(9):921-9.	22331954
4	von Tresckow B, Plütschow A, Fuchs M et al. Dose-intensification in early unfavorable Hodgkin's lymphoma: final analysis of the German Hodgkin Study Group HD14 trial. <i>J Clin Oncol.</i> 2012 Mar 20;30(9):907-13.	22271480
5	Han JY, Park K, Kim SW et al. First-SIGNAL: first-line single-agent irressa versus gemcitabine and cisplatin trial in never-smokers with adenocarcinoma of the lung. <i>J Clin Oncol.</i> 2012 Apr 1;30(10):1122-8.	22370314
6	Yun YH, Lee KS, Kim YW et al. Web-based tailored education program for disease-free cancer survivors with cancer-related fatigue: a randomized controlled trial. <i>J Clin Oncol.</i> 2012 Apr 20;30(12):1296-303.	22412149
7	Motzer RJ, Hutson TE, Olsen MR et al. Randomized phase II trial of sunitinib on an intermittent versus continuous dosing schedule as first-line therapy for advanced renal cell carcinoma. <i>J Clin Oncol.</i> 2012 Apr 20;30(12):1371-7.	22430274
8	Kelly WK, Halabi S, Carducci M et al. Randomized, double-blind, placebo-controlled phase III trial comparing docetaxel and prednisone with or without bevacizumab in men with metastatic castration-resistant prostate cancer: CALGB 90401. <i>J Clin Oncol.</i> 2012 May 1;30(13):1534-40.	22454414
9	Janssens GO, Rademakers SE, Terhaard CH et al. Accelerated radiotherapy with carbogen and nicotinamide for laryngeal cancer: results of a phase III randomized trial. <i>J Clin Oncol.</i> 2012 May 20;30(15):1777-83.	22508814
10	Baselga J, Segalla JG, Roché H et al. Sorafenib in combination with capecitabine: an oral regimen for patients with HER2-negative locally advanced or metastatic breast cancer. <i>J Clin Oncol.</i> 2012 May 1;30(13):1484-91.	22412143
11	Nosov DA, Esteves B, Lipatov ON et al. Antitumor activity and safety of tivozanib (AV-951) in a phase II randomized discontinuation trial in patients with renal cell carcinoma. <i>J Clin Oncol.</i> 2012 May 10;30(14):1678-85.	22493422
12	Kang JH, Lee SI, Lim do H et al. Salvage chemotherapy for pretreated gastric cancer: a randomized phase III trial comparing chemotherapy plus best supportive care with best supportive care alone. <i>J Clin Oncol.</i> 2012 May 1;30(13):1513-8.	22412140
13	Tveit KM, Guren T, Glimelius B et al. Phase III trial of cetuximab with continuous or intermittent fluorouracil, leucovorin, and oxaliplatin (Nordic FLOX) versus FLOX alone in first-line treatment of metastatic colorectal cancer: the NORDIC-VII study. <i>J Clin Oncol.</i> 2012 May 20;30(15):1755-62.	22473155

14	Guarneri V, Frassoldati A, Bottini A et al. Preoperative chemotherapy plus trastuzumab, lapatinib, or both in human epidermal growth factor receptor 2-positive operable breast cancer: results of the randomized phase II CHER-LOB study. <i>J Clin Oncol.</i> 2012 Jun 1;30(16):1989-95.	22493419
15	Bergh J, Jönsson PE, Lidbrink EK et al. FACT: an open-label randomized phase III study of fulvestrant and anastrozole in combination compared with anastrozole alone as first-line therapy for patients with receptor-positive postmenopausal breast cancer. <i>J Clin Oncol.</i> 2012 Jun 1;30(16):1919-25.	22370325
16	Kirshner JJ, Heckler CE, Janelsins MC et al. Prevention of pegfilgrastim-induced bone pain: a phase III double-blind placebo-controlled randomized clinical trial of the university of Rochester cancer center clinical community oncology program research base. <i>J Clin Oncol.</i> 2012 Jun 1;30(16):1974-9.	22508813
17	Peiffert D, Tournier-Rangear L, Gérard JP et al. Induction chemotherapy and dose intensification of the radiation boost in locally advanced anal canal carcinoma: final analysis of the randomized UNICANCER ACCORD 03 trial. <i>J Clin Oncol.</i> 2012 Jun 1;30(16):1941-8.	22529257
18	Aghajanian C, Blank SV, Goff BA et al. OCEANS: a randomized, double-blind, placebo-controlled phase III trial of chemotherapy with or without bevacizumab in patients with platinum-sensitive recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer. <i>J Clin Oncol.</i> 2012 Jun 10;30(17):2039-45.	22529265
19	Scagliotti GV, Krzakowski M, Szczesna A et al. Sunitinib plus erlotinib versus placebo plus erlotinib in patients with previously treated advanced non-small-cell lung cancer: a phase III trial. <i>J Clin Oncol.</i> 2012 Jun 10;30(17):2070-8.	22564989
20	Lammers RJ, Witjes WP, Janzing-Pastors MH et al. Intracutaneous and intravesical immunotherapy with keyhole limpet hemocyanin compared with intravesical mitomycin in patients with non-muscle-invasive bladder cancer: results from a prospective randomized phase III trial. <i>J Clin Oncol.</i> 2012 Jun 20;30(18):2273-9.	22585689
21	Faderl S, Wetzler M, Rizzieri D et al. Clofarabine plus cytarabine compared with cytarabine alone in older patients with relapsed or refractory acute myelogenous leukemia: results from the CLASSIC I Trial. <i>J Clin Oncol.</i> 2012 Jul 10;30(20):2492-9.	22585697
22	Jacobsen PB, Wells KJ, Meade CD et al. Effects of a brief multimedia psychoeducational intervention on the attitudes and interest of patients with cancer regarding clinical trial participation: a multicenter randomized controlled trial. <i>J Clin Oncol.</i> 2012 Jul 10;30(20):2516-21.	22614993
23	Kindler HL, Karrison TG, Gandara DR et al. Multicenter, double-blind, placebo-controlled, randomized phase II trial of gemcitabine/cisplatin plus bevacizumab or placebo in patients with malignant mesothelioma. <i>J Clin Oncol.</i> 2012 Jul 10;30(20):2509-15.	22665541
24	Garderet L, Iacobelli S, Moreau P et al. Superiority of the triple combination of bortezomib-thalidomide-dexamethasone over the dual combination of thalidomide-dexamethasone in patients with multiple myeloma progressing or relapsing after autologous transplantation: the MMVAR/IFM 2005-04 Randomized Phase III Trial from the Chronic Leukemia Working Party of the European Group for Blood and Marrow Transplantation. <i>J Clin Oncol.</i> 2012 Jul 10;30(20):2475-82.	22585692
25	Oberlin O, Rey A, Sanchez de Toledo J et al. Randomized comparison of intensified six-drug versus standard three-drug	22665534

	chemotherapy for high-risk nonmetastatic rhabdomyosarcoma and other chemotherapy-sensitive childhood soft tissue sarcomas: long-term results from the International Society of Pediatric Oncology MMT95 study. <i>J Clin Oncol.</i> 2012 Jul 10;30(20):2457-65.	
26	Kantarjian HM, Thomas XG, Dmoszynska A et al. Multicenter, randomized, open-label, phase III trial of decitabine versus patient choice, with physician advice, of either supportive care or low-dose cytarabine for the treatment of older patients with newly diagnosed acute myeloid leukemia. <i>J Clin Oncol.</i> 2012 Jul 20;30(21):2670-7.	22689805
27	Bonanni B, Puntoni M, Cazzaniga M et al. Dual effect of metformin on breast cancer proliferation in a randomized presurgical trial. <i>J Clin Oncol.</i> 2012 Jul 20;30(21):2593-600.	22564993
28	Ater JL, Zhou T, Holmes E et al. Randomized study of two chemotherapy regimens for treatment of low-grade glioma in young children: a report from the Children's Oncology Group. <i>J Clin Oncol.</i> 2012 Jul 20;30(21):2641-7.	22665535
29	Carey LA, Rugo HS, Marcom PK et al. TBCRC 001: randomized phase II study of cetuximab in combination with carboplatin in stage IV triple-negative breast cancer. <i>J Clin Oncol.</i> 2012 Jul 20;30(21):2615-23.	22665533
30	Bachelot T, Bourcier C, Cropet C et al. Randomized phase II trial of everolimus in combination with tamoxifen in patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative metastatic breast cancer with prior exposure to aromatase inhibitors: a GINECO study. <i>J Clin Oncol.</i> 2012 Aug 1;30(22):2718-24.	22565002
31	Sawka AM, Straus S, Rotstein L et al. Randomized controlled trial of a computerized decision aid on adjuvant radioactive iodine treatment for patients with early-stage papillary thyroid cancer. <i>J Clin Oncol.</i> 2012 Aug 10;30(23):2906-11.	22753906
32	Sonneveld P, Schmidt-Wolf IG, van der Holt B et al. Bortezomib induction and maintenance treatment in patients with newly diagnosed multiple myeloma: results of the randomized phase III HOVON-65/ GMMG-HD4 trial. <i>J Clin Oncol.</i> 2012 Aug 20;30(24):2946-55.	22802322
33	Gridelli C, Ciardiello F, Gallo C et al. First-line erlotinib followed by second-line cisplatin-gemcitabine chemotherapy in advanced non-small-cell lung cancer: the TORCH randomized trial. <i>J Clin Oncol.</i> 2012 Aug 20;30(24):3002-11.	22778317
34	Shaw EG, Wang M, Coons SW et al. Randomized trial of radiation therapy plus procarbazine, lomustine, and vincristine chemotherapy for supratentorial adult low-grade glioma: initial results of RTOG 9802. <i>J Clin Oncol.</i> 2012 Sep 1;30(25):3065-70.	22851558
35	Paz-Ares LG, Biesma B, Heigener D et al ; NSCLC [non-small-cell lung cancer] Research Experience Utilizing Sorafenib (NExUS) Investigators Study Group. Phase III, randomized, double-blind, placebo-controlled trial of gemcitabine/cisplatin alone or with sorafenib for the first-line treatment of advanced, nonsquamous non-small-cell lung cancer. <i>J Clin Oncol.</i> 2012 Sep 1;30(25):3084-92.	22851564
36	Lannering B, Rutkowski S, Doz et al. Hyperfractionated versus conventional radiotherapy followed by chemotherapy in standard-risk medulloblastoma: results from the randomized multicenter HIT-SIOP PNET 4 trial. <i>J Clin Oncol.</i> 2012 Sep 10;30(26):3187-93.	22851561
37	Roscoe JA, Heckler CE, Morrow GR et al. Prevention of delayed nausea: a University of Rochester Cancer Center Community Clinical Oncology Program study of patients receiving chemotherapy. <i>J Clin Oncol.</i> 2012 Sep 20;30(27):3389-95.	22915657

38	Pérol M, Chouaid C, Pérol D et al. Randomized, phase III study of gemcitabine or erlotinib maintenance therapy versus observation, with predefined second-line treatment, after cisplatin-gemcitabine induction chemotherapy in advanced non-small-cell lung cancer. <i>J Clin Oncol.</i> 2012 Oct 1;30(28):3516-24.	22949150
39	Cortes JE, Kim DW, Kantarjian HM et al. Bosutinib versus imatinib in newly diagnosed chronic-phase chronic myeloid leukemia: results from the BELA trial. <i>J Clin Oncol.</i> 2012 Oct 1;30(28):3486-92.	22949154
40	Hoff PM, Hochhaus A, Pestalozzi BC et al. Cediranib plus FOLFOX/CAPOX versus placebo plus FOLFOX/CAPOX in patients with previously untreated metastatic colorectal cancer: a randomized, double-blind, phase III study (HORIZON II). <i>J Clin Oncol.</i> 2012 Oct 10;30(29):3596-603.	22965965
41	Schmoll HJ, Cunningham D, Sobrero A et al. Cediranib with mFOLFOX6 versus bevacizumab with mFOLFOX6 as first-line treatment for patients with advanced colorectal cancer: a double-blind, randomized phase III study (HORIZON III). <i>J Clin Oncol.</i> 2012 Oct 10;30(29):3588-95.	22965961
42	Ramlau R, Gorbunova V, Ciuleanu TE et al. Afibercept and Docetaxel versus Docetaxel alone after platinum failure in patients with advanced or metastatic non-small-cell lung cancer: a randomized, controlled phase III trial. <i>J Clin Oncol.</i> 2012 Oct 10;30(29):3640-7.	22965962
43	Hardy J, Quinn S, Fazekas B et al. Randomized, double-blind, placebo-controlled study to assess the efficacy and toxicity of subcutaneous ketamine in the management of cancer pain. <i>J Clin Oncol.</i> 2012 Oct 10;30(29):3611-7.	22965960
44	Cruciani RA, Zhang JJ, Manola J et al. L-carnitine supplementation for the management of fatigue in patients with cancer: an eastern cooperative oncology group phase III, randomized, double-blind, placebo-controlled trial. <i>J Clin Oncol.</i> 2012 Nov 1;30(31):3864-9.	22987089
45	Colombo N, Kutarska E, Dimopoulos M et al. Randomized, open-label, phase III study comparing patupilone (EPO906) with pegylated liposomal doxorubicin in platinum-refractory or -resistant patients with recurrent epithelial ovarian, primary fallopian tube, or primary peritoneal cancer. <i>J Clin Oncol.</i> 2012 Nov 1;30(31):3841-7.	22987083
46	Ngan SY, Burmeister B, Fisher RJ et al. Randomized trial of short-course radiotherapy versus long-course chemoradiation comparing rates of local recurrence in patients with T3 rectal cancer: Trans-Tasman Radiation Oncology Group trial 01.04. <i>J Clin Oncol.</i> 2012 Nov 1;30(31):3827-33.	23008301
47	Burnett AK, Russell NH, Hills et al. Addition of gemtuzumab ozogamicin to induction chemotherapy improves survival in older patients with acute myeloid leukemia. <i>J Clin Oncol.</i> 2012 Nov 10;30(32):3924-31.	22851554
48	Womer RB, West DC, Krailo MD et al. Randomized controlled trial of interval-compressed chemotherapy for the treatment of localized Ewing sarcoma: a report from the Children's Oncology Group. <i>J Clin Oncol.</i> 2012 Nov 20;30(33):4148-54.	23091096
49	Duijts SF, van Beurden M, Oldenburg HS et al. Efficacy of cognitive behavioral therapy and physical exercise in alleviating treatment-induced menopausal symptoms in patients with breast cancer: results of a randomized, controlled, multicenter trial. <i>J Clin Oncol.</i> 2012 Nov 20;30(33):4124-33.	23045575
50	Schmidt J, Abel U, Debus J et al. Open-label, multicenter, randomized phase III trial of adjuvant chemoradiation plus interferon Alfa-2b versus fluorouracil and folinic acid for patients with resected pancreatic adenocarcinoma. <i>J Clin Oncol.</i>	23008325

	2012 Nov 20;30(33):4077-83.	
51	Shulman LN, Cirrincione CT, Berry DA et al. Six cycles of doxorubicin and cyclophosphamide or Paclitaxel are not superior to four cycles as adjuvant chemotherapy for breast cancer in women with zero to three positive axillary nodes: Cancer and Leukemia Group B 40101. J Clin Oncol. 2012 Nov 20;30(33):4071-6.	22826271
52	Molassiotis A, Bardy J, Finnegan-John J et al. Acupuncture for cancer-related fatigue in patients with breast cancer: a pragmatic randomized controlled trial. J Clin Oncol. 2012 Dec 20;30(36):4470-6.	23109700
53	Ardizzoni A, Tiseo M, Boni L et al. Pemetrexed versus pemetrexed and carboplatin as second-line chemotherapy in advanced non-small-cell lung cancer: results of the GOIRC 02-2006 randomized phase II study and pooled analysis with the NVALT7 trial. J Clin Oncol. 2012 Dec 20;30(36):4501-7.	23109689
54	Ledermann J, Harter P, Gourley C et al. Olaparib maintenance therapy in platinum-sensitive relapsed ovarian cancer. N Engl J Med. 2012 Apr 12;366(15):1382-92.	22452356
55	James ND, Hussain SA, Hall E et al; BC2001 Investigators. Radiotherapy with or without chemotherapy in muscle-invasive bladder cancer. N Engl J Med. 2012 Apr 19;366(16):1477-88.	22512481
56	Schlumberger M, Catargi B, Borget I et al; Tumeurs de la Thyroïde Refractaires Network for the Essai Stimulation Ablation Equivalence Trial. Strategies of radioiodine ablation in patients with low-risk thyroid cancer. N Engl J Med. 2012 May 3;366(18):1663-73.	22551127
57	van Hagen P, Hulshof MC, van Lanschot JJ et al.; CROSS Group. Preoperative chemoradiotherapy for esophageal or junctional cancer. N Engl J Med. 2012 May 31;366(22):2074-84.	22646630
58	Palumbo A, Hajek R, Delforge M et al. MM-015 Investigators. Continuous lenalidomide treatment for newly diagnosed multiple myeloma. N Engl J Med. 2012 May 10;366(19):1759-69.	22571200
59	McCarthy PL, Owzar K, Hofmeister CC et al. Lenalidomide after stem-cell transplantation for multiple myeloma. N Engl J Med. 2012 May 10;366(19):1770-81.	22571201
60	Attal M, Lauwers-Cances V, Marit G et al; IFM Investigators. Lenalidomide maintenance after stem-cell transplantation for multiple myeloma. N Engl J Med. 2012 May 10;366(19):1782-91.	22571202
61	Fassnacht M, Terzolo M, Allolio B et al; FIRM-ACT Study Group. Combination chemotherapy in advanced adrenocortical carcinoma. N Engl J Med. 2012 Jun 7;366(23):2189-97.	22551107
62	Wilt TJ, Brawer MK, Jones KM et al; Prostate Cancer Intervention versus Observation Trial (PIVOT) Study Group. Radical prostatectomy versus observation for localized prostate cancer. N Engl J Med. 2012 Jul 19;367(3):203-13.	22808955
63	Kluin-Nelemans HC, Hoster E, Hermine O et al. Dreyling MH. Treatment of older patients with mantle-cell lymphoma. N Engl J Med. 2012 Aug 9;367(6):520-31.	22873532
64	Mehta RS, Barlow WE, Albain KS et al. Combination anastrozole and fulvestrant in metastatic breast cancer. N Engl J Med. 2012 Aug 2;367(5):435-44.	22853014
65	Scher HI, Fizazi K, Saad F et al; AFFIRM Investigators. Increased survival with enzalutamide in prostate cancer after chemotherapy. N Engl J Med. 2012 Sep 27;367(13):1187-97.	22894553
66	Verma S, Miles D, Gianni L et al; EMILIA Study Group. Trastuzumab emtansine for HER2-positive advanced breast	23020162

	cancer. N Engl J Med. 2012 Nov 8;367(19):1783-91.	
67	Engert A, Haverkamp H, Kobe C et al; German Hodgkin Study Group; Swiss Group for Clinical Cancer Research; Arbeitsgemeinschaft Medikamentöse Tumortherapie. Reduced-intensity chemotherapy and PET-guided radiotherapy in patients with advanced stage Hodgkin's lymphoma (HD15 trial): a randomised, open-label, phase 3 non-inferiority trial. Lancet. 2012 May 12;379(9828):1791-9.	22480758
68	Hauschild A, Grob JJ, Demidov LV et al.. Dabrafenib in BRAF-mutated metastatic melanoma: a multicentre, open-label, phase 3 randomised controlled trial. Lancet. 2012 Jul 28;380(9839):358-65.	22735384
69	Lee JS, Hirsh V, Park K et al. Vandetanib Versus placebo in patients with advanced non-small-cell lung cancer after prior therapy with an epidermal growth factor receptor tyrosine kinase inhibitor: a randomized, double-blind phase III trial (ZEPHYR). J Clin Oncol. 2012 Apr 1;30(10):1114-21.	22370318
70	Scagliotti GV, Vynnychenko I, Park K et al. International, randomized, placebo-controlled, double-blind phase III study of motesanib plus carboplatin/paclitaxel in patients with advanced nonsquamous non-small-cell lung cancer: MONET1. J Clin Oncol. 2012 Aug 10;30(23):2829-36.	22753922
71	Anasetti C, Logan BR, Lee SJ et al; Blood and Marrow Transplant Clinical Trials Network. Peripheral-blood stem cells versus bone marrow from unrelated donors. N Engl J Med. 2012 Oct 18;367(16):1487-96.	23075175
72	Crook JM, O'Callaghan CJ, Duncan G et al. Intermittent androgen suppression for rising PSA level after radiotherapy. N Engl J Med. 2012 Sep 6;367(10):895-903.	22931259
73	Flaherty KT, Robert C, Hersey P et al. METRIC Study Group. Improved survival with MEK inhibition in BRAF-mutated melanoma. N Engl J Med. 2012 Jul 12;367(2):107-14.	22663011
74	Mallick U, Harmer C, Yap B et al. Ablation with low-dose radioiodine and thyrotropin alfa in thyroid cancer. N Engl J Med. 2012 May 3;366(18):1674-85.	22551128

**The Lancet Oncology and The Journal of the American Medical Association (JAMA) was not included in the study since they did not have appended protocols available for the reported randomized trials during the time-interval of the study.*

Table S2. Definition of data elements collected for the study

Data Element¹	Abbreviation	Definition	Stated in Protocol	Stated in Report
Primary Endpoints	PEPs	Primary outcome measure for the study as specified in the protocol in either "endpoint" or "objective" or "statistical plan" sections. ²	✓	✓
Planned Non-primary Endpoints	NPEPs	All other outcome measures (excluding PEPs) for the study as specified in the protocol in either "endpoint" or "objective" or "statistical plan" sections. ^{2,3}	✓	Variable
Non-reported Non-primary Endpoints	Non-reported NPEPs	All NPEPs for the study specified in the protocol but not mentioned in the published reports.	✓	✗
Unplanned Endpoints	UEPs	All outcome measures for the study that are mentioned in the published reports but not specified as outcomes in the protocol (either primary or non-primary).	✗	✓
Unplanned Analyses	UPAs	All statistical analyses performed for either PEPs or NPEPs in the study that are mentioned in the published reports but not specified and/or implied in the protocol. ^{4,5}	✗	✓

¹ Protocols were taken as gold standard and all outcomes reported or not-reported were evaluated in the light of what was specified in the protocol.

² In case of incongruity between "endpoint" or "objective" or "statistical plan" sections, preference was given to "endpoint", "objective", "statistical plan" sections in this order. In case there was no clear distinction between primary and non-primary endpoints in the protocol, the endpoint used to calculate sample size was regarded as the PEP.

³ These include secondary, exploratory, correlative, translational objectives/endpoints.

⁴ Any statistical analyses performed on UEPs were not included as UPAs.

⁵ A change in statistical test used for comparison was not considered to be a UPAs. As long as testing was specified or implied, studies were given credit for the same.

Table S3. Discrepancies in primary endpoints (PEPs) between protocols and published reports

Description	Trials	Protocol Specified PEPs	Reported PEPs	P-value ¹
Reporting of new PEPs	1	Event-free survival	Event-free survival Overall survival	NR ²
Omission of planned PEPs	1	Progression-free survival Overall survival	Progression-free survival	0.01
Changed PEPs	3	Time to progression	Progression-free survival	0.88
		4-year event-free survival	5-year event-free survival	0.10
		Time to progression	Progression-free survival	0.007
Changed terminology of PEPs³	4	Disease-free interval	Recurrence -free interval	NR ²
		Disease-free survival	Progression-free survival	0.15
		Disease-free survival	Relapse-free survival	0.77
		Time to progression	Progression-free survival	0.71
¹ P-value mentioned in the published report for the discrepant PEP. ² Not reported ³ Definition of the primary endpoint similar in both the protocol and the report.				

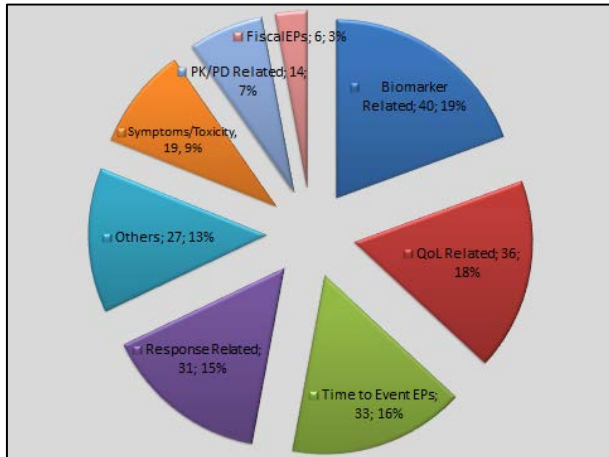
Table S4. Association of study endpoints and analyses reporting with regards to study size, sponsor, outcome and year of initiation

Variable	Study Size				P ¹	Study Sponsor				P ¹
	Small		Large			Industry		Non-Industry		
	N	Percent	N	Percent		N	Percent	N	Percent	
Any change in primary endpoints										
Yes	4	5.4	5	6.8	1.00	3	4.1	6	8.1	0.29
No	33	44.6	32	43.2		37	50.0	28	37.8	
Number of planned non-primary endpoints										
≤ 6	20	27.0	13	17.6	0.16	17	23.0	16	21.6	0.82
> 6	17	23.0	24	32.4		23	31.1	18	24.3	
Non-primary endpoints not reported										
No	10	13.5	9	12.2	1.00	10	13.5	9	12.2	1.00
Yes	27	36.5	28	37.8		30	40.5	25	32.8	
Unplanned endpoints reported										
No	24	32.4	22	29.7	0.23	25	33.8	21	28.4	1.00
Yes	10	13.5	18	24.3		15	20.3	13	17.6	
Unplanned analyses reported										
No	17	23.0	23	31.1	0.64	22	29.7	18	24.3	1.00
Yes	17	23.0	17	23.0		18	24.3	16	21.6	
Variable	Study Outcome ²				P ¹	Year of Initiation				P ¹
	Positive		Negative			1994-2005		2006-2010		
	N	Percent	N	Percent		N	Percent	N	Percent	
Any change in primary endpoints										
Yes	3	4.1	6	8.1	0.48	7	9.5	2	2.7	0.03
No	33	44.6	32	43.2		25	33.8	40	54.1	
Number of planned non-primary endpoints										
≤ 6	16	21.6	17	23.0	1.00	16	21.6	16	21.6	0.48
> 6	20	27.0	21	28.4		17	23.0	25	33.8	

Non-primary endpoints not reported										
No	10	13.5	9	12.2	0.79	9	12.2	10	13.5	0.79
Yes	26	35.1	29	39.2		23	31.1	32	43.2	
Unplanned endpoints reported										
No	22	29.7	24	32.4	1.00	18	24.3	28	37.8	0.47
Yes	14	18.9	14	18.9		14	18.9	14	18.9	
Unplanned analyses reported										
No	19	25.7	21	28.4	1.00	15	20.3	25	33.8	0.35
Yes	17	23.0	17	23.0		17	23.0	17	23.0	
¹ P values computed by Fisher's exact test. Only highlighted P values are significant. ² Study outcome was considered positive if the study met its primary endpoint (in cases of multiple primary-endpoints, study outcome was categorized as positive if any of the primary endpoint was met).										

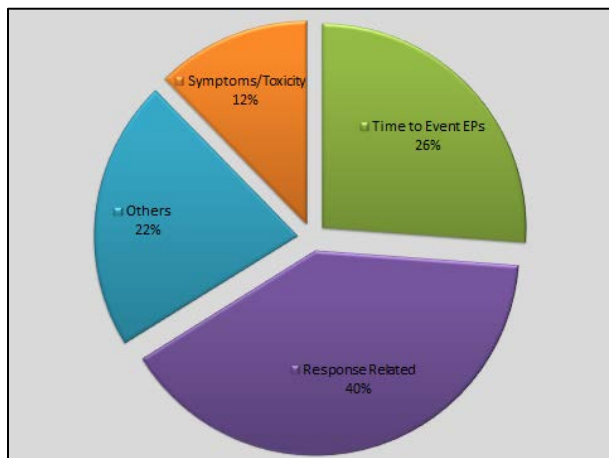
Figure S1. Distribution of non-reported planned non-primary endpoints and unplanned endpoints and analyses.

Figure S1A. Planned non-primary endpoints not reported in published reports.



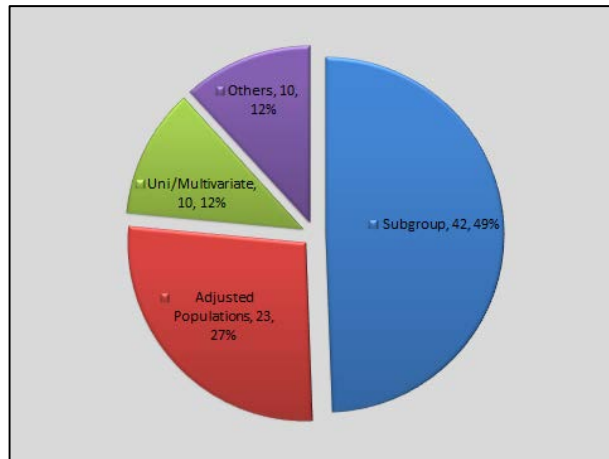
Among the 206 planned non-primary endpoints that were not reported, biomarker related endpoints were the most common, followed by quality of life (QoL) and time to event endpoints (such as event-free survival).

Figure S1B. Unplanned endpoints reported in published reports.



Among the 65 unplanned endpoints that were reported in published reports, response related endpoints were the most common, followed by time to event endpoints (such as event-free survival).

Figure S1C. Unplanned analyses reported in published reports.



Among the 85 unplanned analyses that were reported in published reports, subgroup analyses were the most common, followed by adjusted population analyses and univariate/multivariate analyses.

Table S5. Comparison of selective reporting of study endpoints in current cohort of published randomized trials with appended protocols (published after 2011) and cohort of published randomized trials without appended protocols (published prior to 2011)

Variable	Prior Data	Our Data	P-value
Change in PEP	47% (64/136)	12% (9/74)	< 0.0001
Studies with NPEP NR	86% (32/37)	74% (55/74)	0.22
Studies with UPEPs	50% (6/6)	38% (28/74)	0.53
Studies with UPAs	31% (30/96)	26% (19/74)	0.49
*Data derived from studies included in the meta-analysis of published or unpublished cohort studies comparing protocols with published trial reports performed by Dwan et al (Ref: <i>Dwan K, Altman DG, Cresswell L, et al. Comparison of protocols and registry entries to published reports for randomised controlled trials. Cochrane Database of Systematic Reviews 2011, Issue 1. Art. No.: MR000031.</i>).			

Figure S2. Reporting of unplanned endpoints and unplanned analyses in reports with respect to the type of protocols appended (complete or redacted)

