

Association Between Survival Benefits of Anticancer Drugs and Probability of FDA Approval: A Systematic Review

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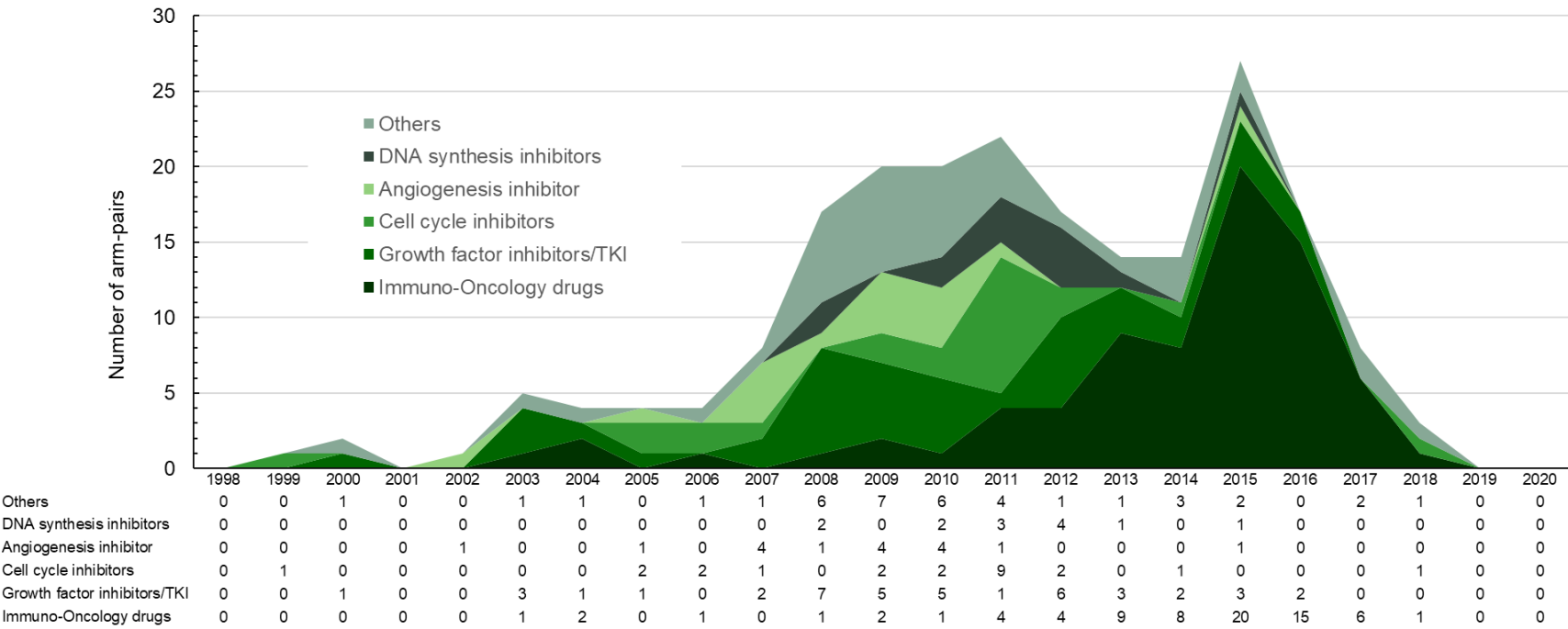
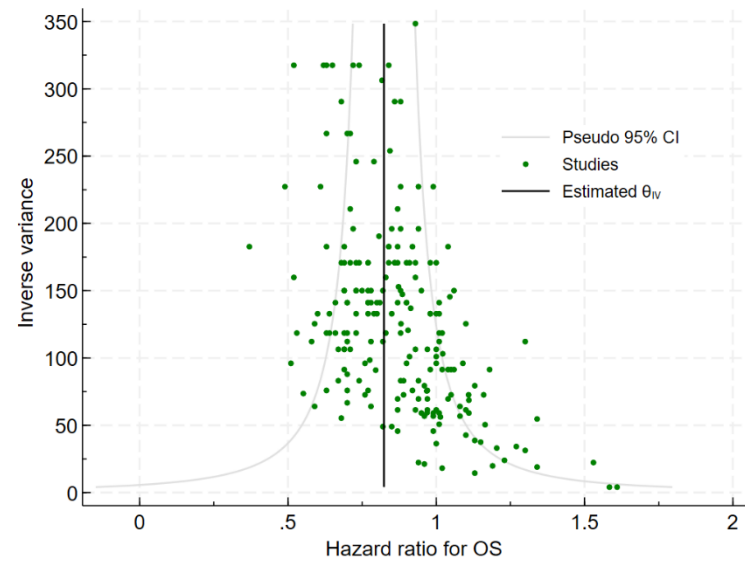


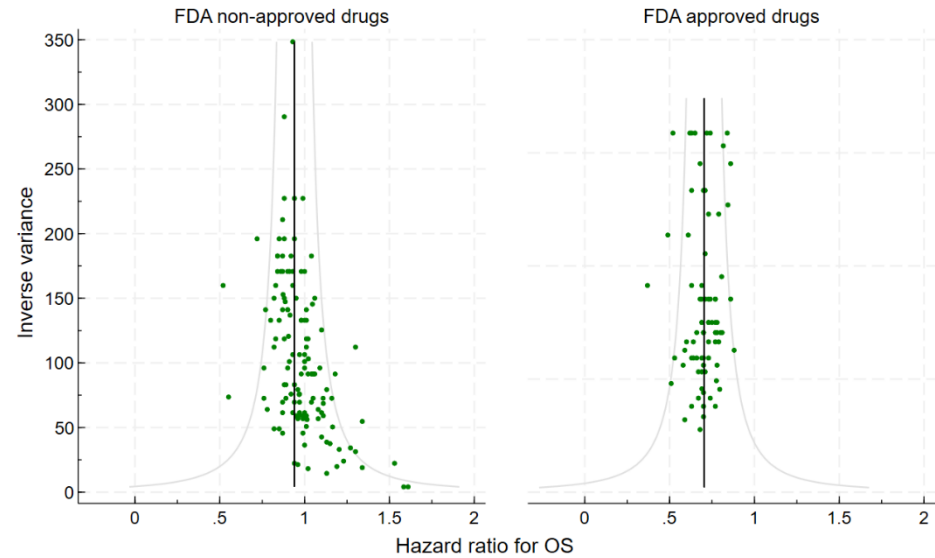
Fig. S 1 Chronological trends in therapeutic mechanisms

a: Funnel plot for Total 208 trials



Egger test for small-study effects: $p < 0.001$
Begg-Mazumdar test: $p < 0.001$

b: Funnel plot by FDA approval status



FDA non-approved drugs
Egger test for small-study effects: $p < 0.001$
Begg-Mazumdar test: $p < 0.001$

FDA approved drugs
Egger test for small-study effects: $p = 0.727$
Begg-Mazumdar test: $p = 0.403$

Fig. S 2 Funnel plot analysis for the evaluation of potential selection bias

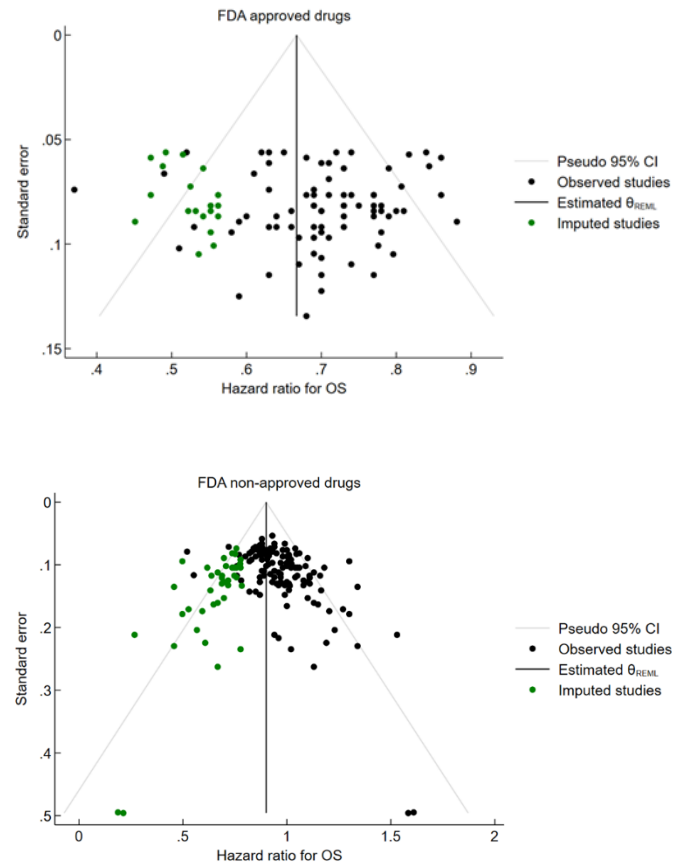


Fig. S 3 Adjusted funnel plot following nonparametric trim-and-fill method

Publication bias typically inflates effect sizes; however, in our dataset, the adjustment resulted in slightly stronger effect sizes for both FDA approved and non-approved drugs. We believe this is due to our study's focus on large-scale Phase 3 trials. In oncology, even negative Phase 3 results are frequently published due to their clinical impact. Given that oncology Phase 3 trials have a naturally high failure rate (approximately 60%) and typically yield modest effect sizes, the 'missing' trials estimated by the method likely reflect the mathematical assumption of symmetry.

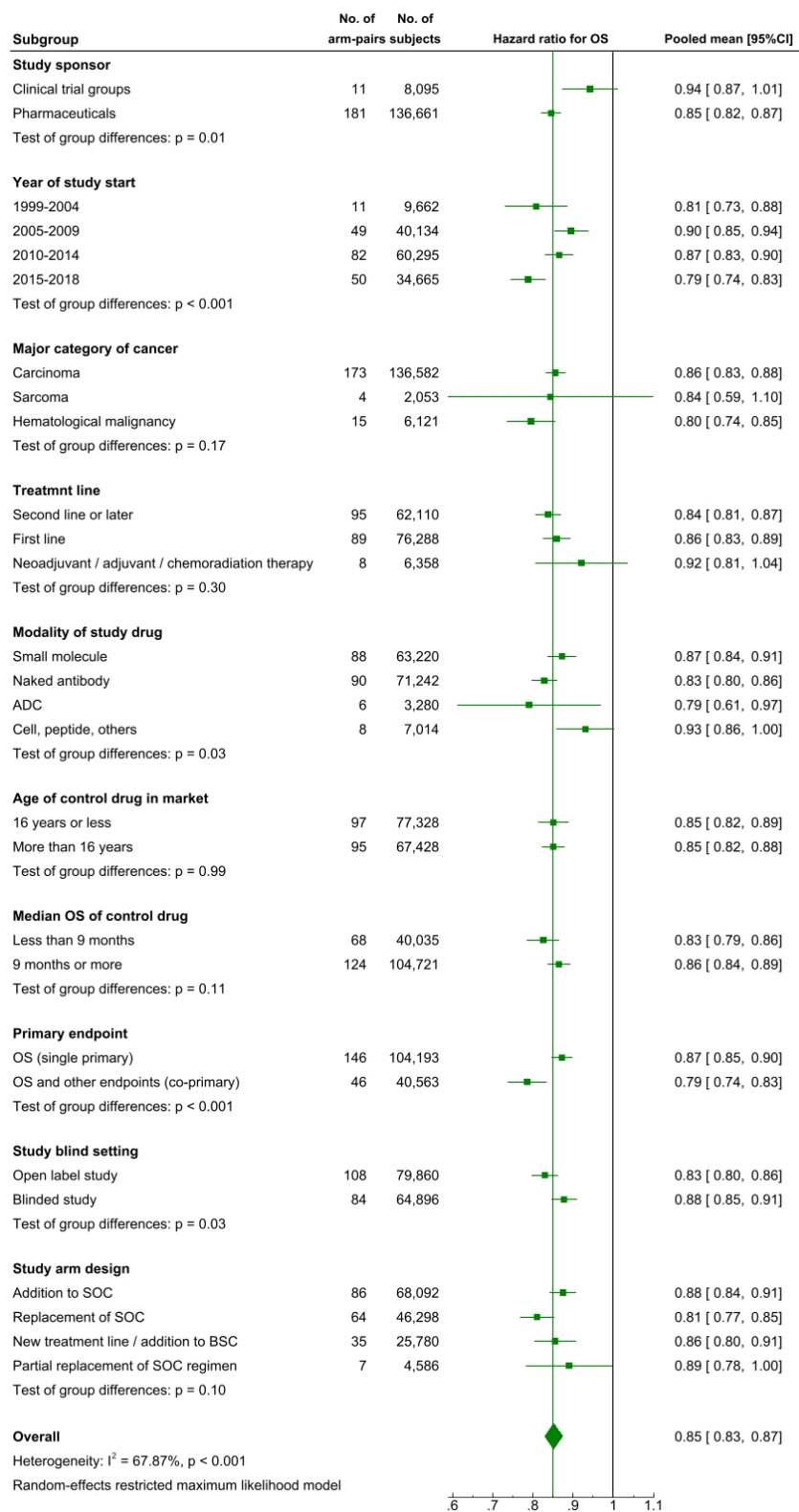


Fig. S 4 Forest plot of the hazard ratio for OS by study characteristics

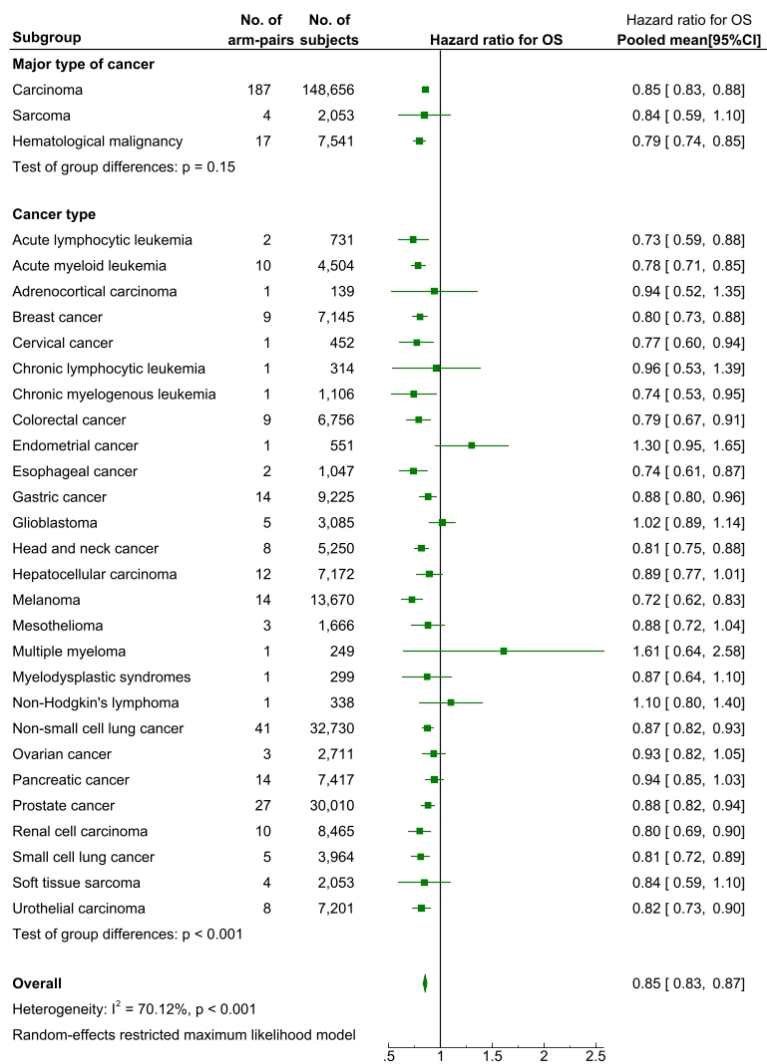


Fig. S 5 Forest plot of the hazard ratio for OS by cancer type

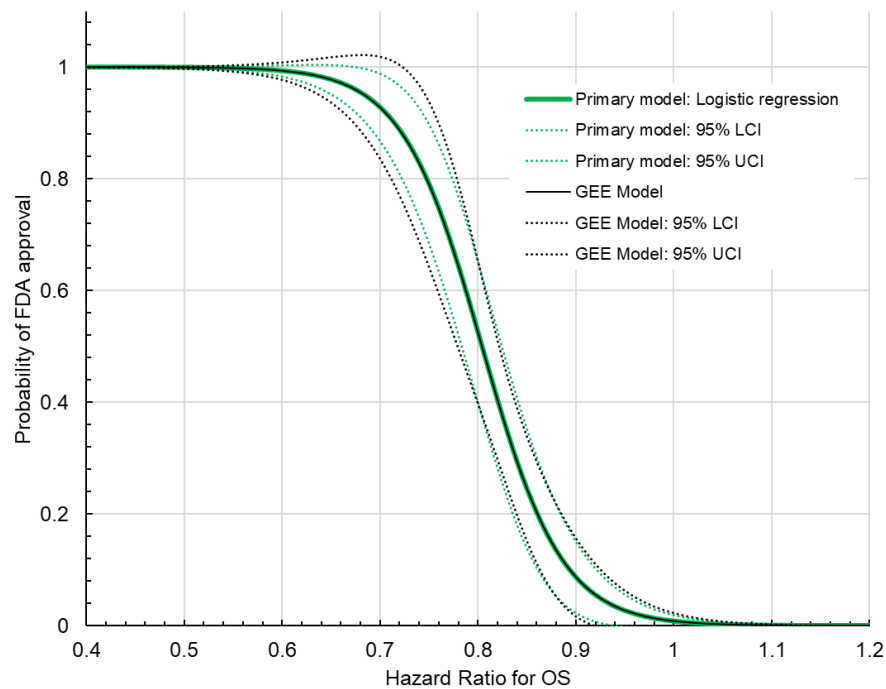


Fig. S 6 Comparison of predicted FDA approval probabilities between the primary and GEE models
 The primary model uses arm-paired samples, while the GEE model accounts for intra-trial correlation through trial-level clustering. Both models demonstrate consistent association between the OS hazard ratio and the probabilities of FDA approval.

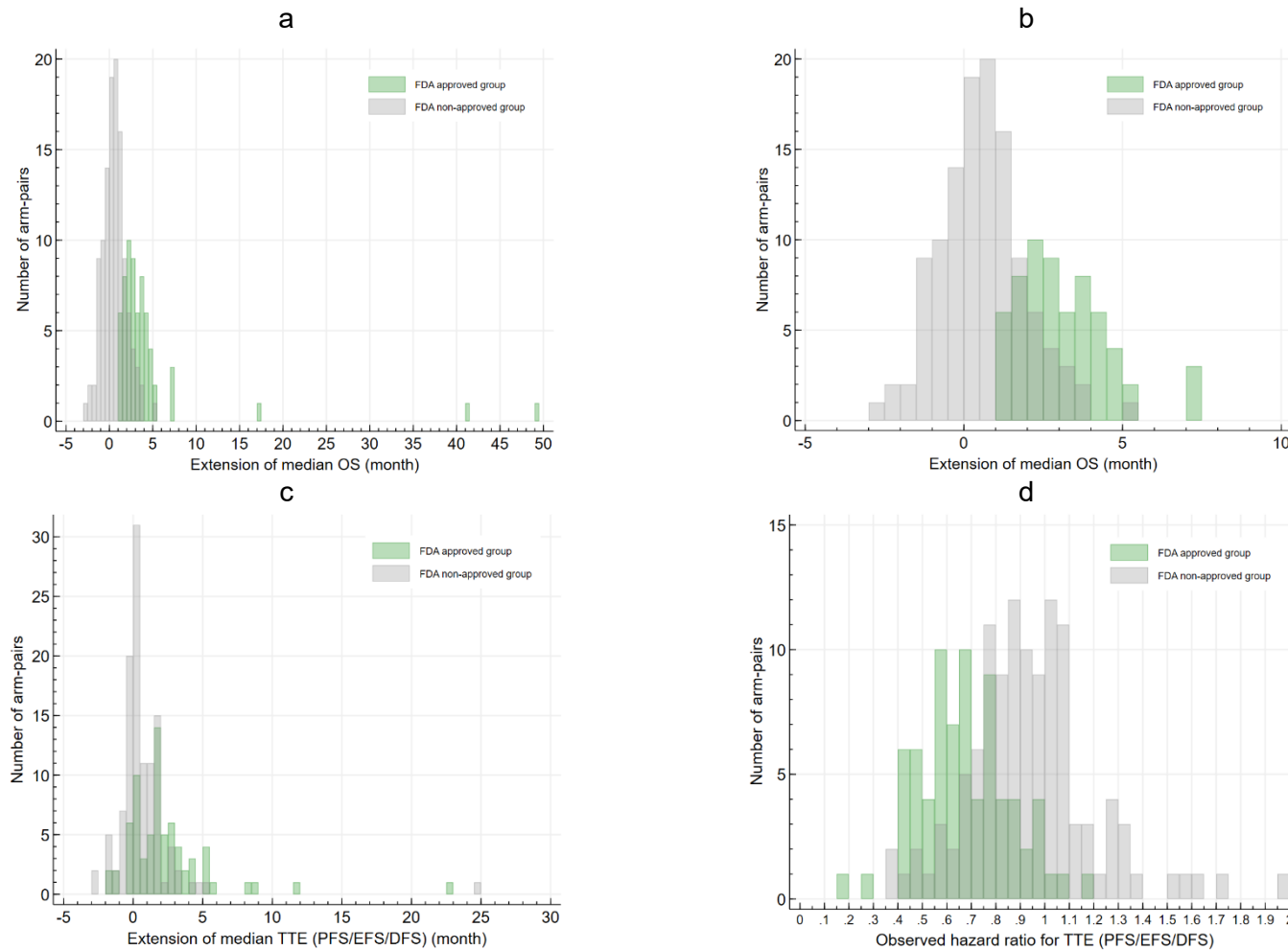


Fig. S 7 Observed extension of median OS, extension of median Time to Event(TTE), and hazard ratio for TTE by FDA approval status
a: Distribution of observed median OS extension colored by FDA approval status (full range). b: Distribution of observed median OS extension colored by FDA approval status (up to 10 months). c: Distribution of observed median time-to-event (PFS, EFS, or DFS) extension colored by FDA approval status. d: Distribution of observed hazard ratio for time-to-event (PFS, EFS, or DFS) colored by FDA approval status. Green bins represent approved drugs, and gray bins represent non-approved drugs.

Table S 1 List of source documents for study characteristics and outcomes**FDA approved group**

ID	NCT Number	Investigational drug	Cancer type	Clinical reference	Regulatory reference
A-1	NCT01607957	TAS-102	Colorectal cancer	Mayer RJ, Van Cutsem E, Falcone A, Yoshino T, Garcia-Carbonero R, Mizunuma N, Yamazaki K, Shimada Y, Tabernero J, Komatsu Y, Sobrero A, Boucher E, Peeters M, Tran B, Lenz HJ, Zaniboni A, Hochster H, Cleary JM, Prenen H, Benedetti F, Mizuguchi H, Makris L, Ito M, Ohtsu A; RECURSE Study Group. Randomized trial of TAS-102 for refractory metastatic colorectal cancer. <i>N Engl J Med</i> . 2015 May 14;372(20):1909-19. doi: 10.1056/NEJMoa1414325. PMID: 25970050.	USPI: LABEL Summary Review: 207981Orig1s000SumR.pdf
A-2	NCT01774344	Regorafenib plus BSC	Hepatocellular carcinoma	Bruix J, Qin S, Merle P, Granito A, Huang YH, Bodoky G, Pracht M, Yokosuka O, Rosmorduc O, Breder V, Gerolami R, Masi G, Ross PJ, Song T, Bronowicki JP, Ollivier-Hourmand I, Kudo M, Cheng AL, Llovet JM, Finn RS, LeBerre MA, Baumhauer A, Meinhardt G, Han G; RESORCE Investigators. Regorafenib for patients with hepatocellular carcinoma who progressed on sorafenib treatment (RESORCE): a randomised, double-blind, placebo-controlled, phase 3 trial. <i>Lancet</i> . 2017 Jan 7;389(10064):56-66. doi: 10.1016/S0140-6736(16)32453-9. Epub 2016 Dec 6. Erratum in: <i>Lancet</i> . 2017 Jan 7;389(10064):36. PMID: 27932229.	USPI: label Summary Review: Approval Package
A-3	NCT00638690	Abiraterone acetate plus prednisone	Prostate cancer	de Bono JS, Logothetis CJ, Molina A, Fizazi K, North S, Chu L, Chi KN, Jones RJ, Goodman OB Jr, Saad F, Staffurth JN, Mainwaring P, Harland S, Flaig TW, Hutson TE, Cheng T, Patterson H, Hainsworth JD, Ryan CJ, Sternberg CN, Ellard SL, Fléchon A, Saleh M, Scholz M, Efstathiou E, Zivi A, Bianchini D, Loriot Y, Chieffo N, Kheoh T, Haqq CM, Scher HI; COU-AA-301 Investigators. Abiraterone and increased survival in metastatic prostate cancer. <i>N Engl J Med</i> . 2011 May 26;364(21):1995-2005. doi: 10.1056/NEJMoa1014618. PMID: 21612468; PMCID: PMC3471149.	USPI: label
A-4	NCT00844649	Nab-paclitaxel followed by gemcitabine	Pancreatic cancer	Von Hoff DD, Ervin T, Arena FP, Chiorean EG, Infante J, Moore M, Seay T, Tjulandin SA, Ma WW, Saleh MN, Harris M, Reni M, Dowden S, Laheru D, Bahary N, Ramanathan RK, Tabernero J, Hidalgo M, Goldstein D, Van Cutsem E, Wei X, Iglesias J, Renschler MF. Increased survival in pancreatic cancer with nab-paclitaxel plus gemcitabine. <i>N Engl J Med</i> . 2013 Oct 31;369(18):1691-703. doi: 10.1056/NEJMoa1304369. Epub 2013 Oct 16. PMID: 24131140; PMCID: PMC4631139.	USPI: ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) Summary Review: ABRAXANE for Injectable Suspension
A-5	NCT01597908	Dabrafenib plus trametinib	Melanoma	Robert C, Grob JJ, Stroyakovskiy D, Karaszewska B, Hauschild A, Levchenko E, Chiarion Sileni V, Schachter J, Garbe C, Bondarenko I, Gogas H, Mandalá M, Haanen JBAG, Lebbé C, Mackiewicz A, Rutkowski P, Nathan PD, Ribas A, Davies MA, Flaherty KT, Burgess P, Tan M, Gasal E, Voi M, Schadendorf D, Long GV. Five-Year Outcomes with Dabrafenib plus Trametinib in Metastatic Melanoma. <i>N Engl J Med</i> . 2019 Aug 15;381(7):626-636. doi: 10.1056/NEJMoa1904059. Epub 2019 Jun 4. PMID: 31166680.	USPI: TAFINLAR (dabrafenib) capsules label Summary Review: Approval Package
A-6	NCT02105636	Nivolumab	Head and neck cancer	Ferris RL, Blumenschein G Jr, Fayette J, Guigay J, Colevas AD, Licitra L, Harrington K, Kasper S, Vokes EE, Even C, Worden F, Saba NF, Iglesias Docampo LC, Haddad R, Rordorf T, Kiyota N, Tahara M, Monga M, Lynch M, Geese WJ, Kopit J, Shaw JW, Gillison ML. Nivolumab for Recurrent Squamous-Cell Carcinoma of the Head and Neck. <i>N Engl J Med</i> . 2016 Nov	USPI: OPDIVO (nivolumab) injection, for intravenous use Label Summary Review: 125554Orig1s022.pdf

				10;375(19):1856-1867. doi: 10.1056/NEJMoa1602252. Epub 2016 Oct 8. PMID: 27718784; PMCID: PMC5564292.
A-7	NCT00651261	Midostaurin plus standard chemotherapy	Acute myeloid leukemia	Stone RM, Mandrekar SJ, Sanford BL, Laumann K, Geyer S, Bloomfield CD, Thiede C, Prior TW, Döhner K, Marcucci G, Lo-Coco F, Klisovic RB, Wei A, Sierra J, Sanz MA, Brandwein JM, de Witte T, Niederwieser D, Appelbaum FR, Medeiros BC, Tallman MS, Krauter J, Schlenk RF, Ganser A, Serve H, Ehninger G, Amadori S, Larson RA, Döhner H. Midostaurin plus Chemotherapy for Acute Myeloid Leukemia with a FLT3 Mutation. N Engl J Med. 2017 Aug 3;377(5):454-464. doi: 10.1056/NEJMoa1614359. Epub 2017 Jun 23. PMID: 28644114; PMCID: PMC5754190. USPI: 207997Orig1Orig2s000lbl.pdf Summary Review: Drug Approval Package: RYDAPT (MIDOSTAURIN) CAPSULES
A-8	NCT01103323	Regorafenib plus BSC	Colorectal cancer	Grothey A, Van Cutsem E, Sobrero A, Siena S, Falcone A, Ychou M, Humblet Y, Bouché O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz HJ, Goldberg RM, Sargent DJ, Cihon F, Cupit L, Wagner A, Laurent D; CORRECT Study Group. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial. Lancet. 2013 Jan 26;381(9863):303-12. doi: 10.1016/S0140-6736(12)61900-X. Epub 2012 Nov 22. PMID: 23177514. USPI: STIVARGA (regorafenib) Label Summary Review: 204369Orig1s000SumR.pdf
A-9	NCT01696084	CPX-351(daunorubicin and cytarabine liposome)	Acute myeloid leukemia	Lancet JE, Uy GL, Cortes JE, Newell LF, Lin TL, Ritchie EK, Stuart RK, Strickland SA, Hogge D, Solomon SR, Stone RM, Bixby DL, Kolitz JE, Schiller GJ, Wieduwilt MJ, Ryan DH, Hoering A, Banerjee K, Chiarella M, Louie AC, Medeiros BC. CPX-351 (cytarabine and daunorubicin) Liposome for Injection Versus Conventional Cytarabine Plus Daunorubicin in Older Patients With Newly Diagnosed Secondary Acute Myeloid Leukemia. J Clin Oncol. 2018 Sep 10;36(26):2684-2692. doi: 10.1200/JCO.2017.77.6112. Epub 2018 Jul 19. PMID: 30024784; PMCID: PMC6127025. USPI: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209401s000lbl.pdf Summary Review: Drug Approval Package: VYXEOS (DAUNORUBICIN AND CYTARABINE)
A-10	NCT01327885	Eribulin	Soft tissue sarcoma(Liposarcoma)	Schöffski P, Chawla S, Maki RG, Italiano A, Gelderblom H, Choy E, Grignani G, Camargo V, Bauer S, Rha SY, Blay JY, Hohenberger P, D'Adamo D, Guo M, Chmielowski B, Le Cesne A, Demetri GD, Patel SR. Eribulin versus dacarbazine in previously treated patients with advanced liposarcoma or leiomyosarcoma: a randomised, open-label, multicentre, phase 3 trial. Lancet. 2016 Apr 16;387(10028):1629-37. doi: 10.1016/S0140-6736(15)01283-0. Epub 2016 Feb 10. PMID: 26874885. USPI: label
A-11	NCT01642004	Nivolumab	Non-small cell lung cancer	Brahmer J, Reckamp KL, Baas P, Crinò L, Eberhardt WE, Poddubskaya E, Antonia S, Pluzanski A, Vokes EE, Holgado E, Waterhouse D, Ready N, Gainor J, Arén Frontera O, Havel L, Steins M, Garassino MC, Aerts JG, Domine M, Paz-Ares L, Reck M, Baudalet C, Harbison CT, Lestini B, Spigel DR. Nivolumab versus Docetaxel in Advanced Squamous-Cell Non-Small-Cell Lung Cancer. N Engl J Med. 2015 Jul 9;373(2):123-35. doi: 10.1056/NEJMoa1504627. Epub 2015 May 31. PMID: 26028407; PMCID: PMC4681400. USPI: label

A-12	NCT03069352	Venetoclax plus LDAC	Acute myeloid leukemia	Wei AH, Montesinos P, Ivanov V, DiNardo CD, Novak J, Laribi K, Kim I, Stevens DA, Fiedler W, Pagoni M, Samoilova O, Hu Y, Anagnostopoulos A, Bergeron J, Hou JZ, Murthy V, Yamauchi T, McDonald A, Chyla B, Gopalakrishnan S, Jiang Q, Mendes W, Hayslip J, Panayiotidis P. Venetoclax plus LDAC for newly diagnosed AML ineligible for intensive chemotherapy: a phase 3 randomized placebo-controlled trial. Blood. 2020 Jun 11;135(24):2137-2145. doi: 10.1182/blood.2020004856. PMID: 32219442; PMCID: PMC7290090.	USPI: label Summary Review: Review
A-13	NCT02899299	Nivolumab plus ipilimumab	Mesothelioma	Baas P, Scherpereel A, Nowak AK, Fujimoto N, Peters S, Tsao AS, Mansfield AS, Popat S, Jahan T, Antonia S, Oulkoir Y, Bautista Y, Cornelissen R, Greillier L, Grossi F, Kowalski D, Rodríguez-Cid J, Aanur P, Oukessou A, Baudelet C, Zalcman G. First-line nivolumab plus ipilimumab in unresectable malignant pleural mesothelioma (CheckMate 743): a multicentre, randomised, open-label, phase 3 trial. Lancet. 2021 Jan 30;397(10272):375-386. doi: 10.1016/S0140-6736(20)32714-8. Epub 2021 Jan 21. Erratum in: Lancet. 2021 Feb 20;397(10275):670. PMID: 33485464.	USPI: label Press release: FDA approves nivolumab and ipilimumab for unresectable malignant pleural mesothelioma FDA
A-14	NCT00561470	Aflibercept plus FOLFIRI	Colorectal cancer	Van Cutsem E, Tabernero J, Lakomy R, Prenen H, Prausová J, Macarulla T, Ruff P, van Hazel GA, Moiseyenko V, Ferry D, McKendrick J, Polikoff J, Tellier A, Castan R, Allegra C. Addition of aflibercept to fluorouracil, leucovorin, and irinotecan improves survival in a phase III randomized trial in patients with metastatic colorectal cancer previously treated with an oxaliplatin-based regimen. J Clin Oncol. 2012 Oct 1;30(28):3499-506. doi: 10.1200/JCO.2012.42.8201. Epub 2012 Sep 4. PMID: 22949147.	USPI: label Summary Review: 125418Orig1s000SumR.pdf
A-15	NCT00974311	Enzalutamide	Prostate cancer	Scher HI, Fizazi K, Saad F, Taplin ME, Sternberg CN, Miller K, de Wit R, Mulders P, Chi KN, Shore ND, Armstrong AJ, Flaig TW, Fléchon A, Mainwaring P, Fleming M, Hainsworth JD, Hirmand M, Selby B, Seely L, de Bono JS; AFFIRM Investigators. Increased survival with enzalutamide in prostate cancer after chemotherapy. N Engl J Med. 2012 Sep 27;367(13):1187-97. doi: 10.1056/NEJMoa1207506. Epub 2012 Aug 15. PMID: 22894553.	USPI: XTANDI (enzalutamide) capsules Label Summary Review: 203415Orig1s000SumR.pdf
A-16	NCT00417079	Cabazitaxel plus prednisone	Prostate cancer	de Bono JS, Oudard S, Ozguroglu M, Hansen S, Machiels JP, Kocak I, Gravis G, Bodrogi I, Mackenzie MJ, Shen L, Roessner M, Gupta S, Sartor AO; TROPIC Investigators. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. Lancet. 2010 Oct 2;376(9747):1147-54. doi: 10.1016/S0140-6736(10)61389-X. PMID: 20888992.	USPI: JEVTANA (cabazitaxel) injection Label Summary Review: 201023s000SumR.pdf
A-17	NCT02013167	Blinatumomab	Acute lymphocytic leukemia	Kantarjian H, Stein A, Gökbuget N, Fielding AK, Schuh AC, Ribera JM, Wei A, Dombret H, Foà R, Bassan R, Arslan Ö, Sanz MA, Bergeron J, Demirkan F, Lech-Maranda E, Rambaldi A, Thomas X, Horst HA, Brüggemann M, Klapper W, Wood BL, Fleishman A, Nagorsen D, Holland C, Zimmerman Z, Topp MS. Blinatumomab versus Chemotherapy for Advanced Acute Lymphoblastic Leukemia. N Engl J Med. 2017 Mar 2;376(9):836-847. doi: 10.1056/NEJMoa1609783. PMID: 28249141; PMCID: PMC5881572.	USPI: label

A-18	NCT02231749	Nivolumab and ipilimumab	Renal cell carcinoma	Motzer RJ, Tannir NM, McDermott DF, Arén Frontera O, Melichar B, Choueiri TK, Plimack ER, Barthélémy P, Porta C, George S, Powles T, Donskov F, Neiman V, Kollmannsberger CK, Salman P, Gurney H, Hawkins R, Ravaud A, Grimm MO, Bracarda S, Barrios CH, Tomita Y, Castellano D, Rini BI, Chen AC, Mekan S, McHenry MB, Wind-Rotolo M, Doan J, Sharma P, Hammers HJ, Escudier B; CheckMate 214 Investigators. Nivolumab plus Ipilimumab versus Sunitinib in Advanced Renal-Cell Carcinoma. N Engl J Med. 2018 Apr 5;378(14):1277-1290. doi: 10.1056/NEJMoa1712126. Epub 2018 Mar 21. PMID: 29562145; PMCID: PMC5972549.	USPI: OPDIVO (nivolumab) injection, for intravenous use
A-19	NCT00065468	Temsirolimus	Renal cell carcinoma	Hudes G, Carducci M, Tomczak P, Dutcher J, Figlin R, Kapoor A, Staroslawska E, Sosman J, McDermott D, Bodrogi I, Kovacevic Z, Lesovoy V, Schmidt-Wolf IG, Barbarash O, Gokmen E, O'Toole T, Lustgarten S, Moore L, Motzer RJ; Global ARCC Trial. Temsirolimus, interferon alfa, or both for advanced renal-cell carcinoma. N Engl J Med. 2007 May 31;356(22):2271-81. doi: 10.1056/NEJMoa066838. PMID: 17538086.	USPI: 022088lbl.pdf Summary Review: Drug Approval Package: TORISEL (TEMSIROLIMUS) INTRAVENOUS SOLUTION
A-20	NCT01006980	Vemurafenib	Melanoma	Chapman PB, Hauschild A, Robert C, Haanen JB, Ascierto P, Larkin J, Dummer R, Garbe C, Testori A, Maio M, Hogg D, Lorigan P, Lebbe C, Jouary T, Schadendorf D, Ribas A, O'Day SJ, Sosman JA, Kirkwood JM, Eggermont AM, Dreno B, Nolop K, Li J, Nelson B, Hou J, Lee RJ, Flaherty KT, McArthur GA; BRIM-3 Study Group. Improved survival with vemurafenib in melanoma with BRAF V600E mutation. N Engl J Med. 2011 Jun 30;364(26):2507-16. doi: 10.1056/NEJMoa1103782. Epub 2011 Jun 5. PMID: 21639808; PMCID: PMC3549296.	USPI: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/202429s000lbl.pdf Summary Review: Summary Review
A-21	NCT01494506	Nanoliposomal irinotecan and fluorouracil and folinic acid	Pancreatic cancer	Wang-Gillam A, Li CP, Bodoky G, Dean A, Shan YS, Jameson G, Macarulla T, Lee KH, Cunningham D, Blanc JF, Hubner RA, Chiu CF, Schwartzmann G, Siveke JT, Braiteh F, Moyo V, Belanger B, Dhindsa N, Bayever E, Von Hoff DD, Chen LT; NAPOLI-1 Study Group. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. Lancet. 2016 Feb 6;387(10018):545-557. doi: 10.1016/S0140-6736(15)00986-1. Epub 2015 Nov 29. Erratum in: Lancet. 2016 Feb 6;387(10018):536. PMID: 26615328.	USPI: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207793lbl.pdf Summary Review: Drug Approval Package: ONIVYDE
A-22	NCT00073307	Sorafenib	Renal cell carcinoma	Escudier B, Eisen T, Stadler WM, Szczylik C, Oudard S, Siebels M, Negrier S, Chevreau C, Solska E, Desai AA, Rolland F, Demkow T, Hutson TE, Gore M, Freeman S, Schwartz B, Shan M, Simantov R, Bukowski RM; TARGET Study Group. Sorafenib in advanced clear-cell renal-cell carcinoma. N Engl J Med. 2007 Jan 11;356(2):125-34. doi: 10.1056/NEJMoa060655. Erratum in: N Engl J Med. 2007 Jul 12;357(2):203. PMID: 17215530.	USPI: 021923lbl.pdf Summary Review: Drug Approval Package: NEXAVAR (SORAFENIB) TABLETS
A-23	NCT01212991	Enzalutamide	Prostate cancer	Beer TM, Armstrong AJ, Rathkopf DE, Loriot Y, Sternberg CN, Higano CS, Iversen P, Bhattacharya S, Carles J, Chowdhury S, Davis ID, de Bono JS, Evans CP, Fizazi K, Joshua AM, Kim CS, Kimura G, Mainwaring P, Mansbach H, Miller K, Noonberg SB, Perabo F, Phung D, Saad F, Scher HI, Taplin ME, Vennert PM, Tombal B; PREVAIL Investigators. Enzalutamide in metastatic prostate cancer before chemotherapy. N Engl J Med. 2014 Jul 31;371(5):424-33. doi: 10.1056/NEJMoa1405095. Epub 2014 Jun 1. PMID: 24881730; PMCID: PMC4418931.	USPI: XTANDI (enzalutamide) capsules for oral use

A-24	NCT00917384	Ramucirumab	Gastric cancer	Fuchs CS, Tomasek J, Yong CJ, Dumitru F, Passalacqua R, Goswami C, Safran H, Dos Santos LV, Aprile G, Ferry DR, Melichar B, Tehfe M, Topuzov E, Zalberg JR, Chau I, Campbell W, Sivanandan C, Pikiel J, Koshiji M, Hsu Y, Liepa AM, Gao L, Schwartz JD, Tabernero J; REGARD Trial Investigators. Ramucirumab monotherapy for previously treated advanced gastric or gastro-oesophageal junction adenocarcinoma (REGARD): an international, randomised, multicentre, placebo-controlled, phase 3 trial. <i>Lancet</i> . 2014 Jan 4;383(9911):31-39. doi: 10.1016/S0140-6736(13)61719-5. Epub 2013 Oct 3. PMID: 24094768.	USPI: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/1254771bl.pdf Summary Review: 125477Orig1s000SumR.pdf
A-25	NCT01168973	Ramucirumab plus docetaxel	Non-small cell lung cancer	Garon EB, Ciuleanu TE, Arrieta O, Prabhash K, Syrigos KN, Goksel T, Park K, Gorbunova V, Kowalyszyn RD, Pikiel J, Czyzewicz G, Orlov SV, Lewanski CR, Thomas M, Bidoli P, Dakhil S, Gans S, Kim JH, Grigorescu A, Karaseva N, Reck M, Cappuzzo F, Alexandris E, Sashegyi A, Yurasov S, Pérol M. Ramucirumab plus docetaxel versus placebo plus docetaxel for second-line treatment of stage IV non-small-cell lung cancer after disease progression on platinum-based therapy (REVEL): a multicentre, double-blind, randomised phase 3 trial. <i>Lancet</i> . 2014 Aug 23;384(9944):665-73. doi: 10.1016/S0140-6736(14)60845-X. Epub 2014 Jun 2. PMID: 24933332.	USPI: label
A-26	NCT03215706	Nivolumab, ipilimumab and platinum based chemotherapy	Non-small cell lung cancer	Paz-Ares L, Ciuleanu TE, Cobo M, Schenker M, Zurawski B, Menezes J, Richardet E, Bennouna J, Felip E, Juan-Vidal O, Alexandru A, Sakai H, Lingua A, Salman P, Souquet PJ, De Marchi P, Martin C, Pérol M, Scherpereel A, Lu S, John T, Carbone DP, Meadows-Shropshire S, Agrawal S, Oukessou A, Yan J, Reck M. First-line nivolumab plus ipilimumab combined with two cycles of chemotherapy in patients with non-small-cell lung cancer (CheckMate 9LA): an international, randomised, open-label, phase 3 trial. <i>Lancet Oncol</i> . 2021 Feb;22(2):198-211. doi: 10.1016/S1473-2045(20)30641-0. Epub 2021 Jan 18. Erratum in: <i>Lancet Oncol</i> . 2021 Mar;22(3):e92. PMID: 33476593.	USPI: label Summary Review: 125554Orig1s080.pdf
A-27	NCT01808573	Neratinib plus capecitabine	Breast cancer	Saura C, Oliveira M, Feng YH, Dai MS, Chen SW, Hurvitz SA, Kim SB, Moy B, Delaloge S, Gradishar W, Masuda N, Palacova M, Trudeau ME, Mattson J, Yap YS, Hou MF, De Laurentis M, Yeh YM, Chang HT, Yau T, Wildiers H, Haley B, Fagnani D, Lu YS, Crown J, Lin J, Takahashi M, Takano T, Yamaguchi M, Fujii T, Yao B, Bechuk J, Keyvanjah K, Bryce R, Brufsky A; NALA Investigators. Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in HER2-Positive Metastatic Breast Cancer Previously Treated With ≥ 2 HER2-Directed Regimens: Phase III NALA Trial. <i>J Clin Oncol</i> . 2020 Sep 20;38(27):3138-3149. doi: 10.1200/JCO.20.00147. Epub 2020 Jul 17. PMID: 32678716; PMCID: PMC7499616.	USPI: label
A-28	NCT02603432	Avelumab maintenance plus BSC	Urothelial carcinoma	Powles T, Park SH, Voog E, Caserta C, Valderrama BP, Gurney H, Kalofonos H, Radulović S, Demey W, Ullén A, Loriot Y, Sridhar SS, Tsuchiya N, Kopylov E, Sternberg CN, Bellmunt J, Aragon-Ching JB, Petrylak DP, Laliberte R, Wang J, Huang B, Davis C, Fowst C, Costa N, Blake-Haskins JA, di Pietro A, Grivas P. Avelumab Maintenance Therapy for Advanced or Metastatic Urothelial Carcinoma. <i>N Engl J Med</i> . 2020 Sep 24;383(13):1218-1230. doi: 10.1056/NEJMoa2002788. Epub 2020 Sep 18. PMID: 32945632.	USPI: label Summary Review: Review
A-29	NCT00333840	Imatinib	Chronic myelogenous leukemia	Hochhaus A, Larson RA, Guilhot F, Radich JP, Branford S, Hughes TP, Baccarani M, Deininger MW, Cervantes F, Fujihara S, Ortmann CE, Menssen HD, Kantarjian H, O'Brien SG, Druker BJ; IRIS Investigators. Long-Term Outcomes of Imatinib Treatment for Chronic Myeloid Leukemia. <i>N Engl J Med</i> . 2017 Mar 9;376(10):917-927. doi: 10.1056/NEJMoa1609324. PMID: 28273028; PMCID: PMC5901965.	USPI: label

A-30	NCT00699751	Radium-223 dichloride	Prostate cancer	Parker C, Nilsson S, Heinrich D, Helle SI, O'Sullivan JM, Fossá SD, Chodacki A, Wiechno P, Logue J, Seke M, Widmark A, Johannessen DC, Hoskin P, Bottomley D, James ND, Solberg A, Syndikus I, Kliment J, Wedel S, Boehmer S, Dall'Oglio M, Franzén L, Coleman R, Vogelzang NJ, O'Bryan-Tear CG, Staudacher K, Garcia-Vargas J, Shan M, Bruland ØS, Sartor O; ALSYMPCA Investigators. Alpha emitter radium-223 and survival in metastatic prostate cancer. <i>N Engl J Med</i> . 2013 Jul 18;369(3):213-23. doi: 10.1056/NEJMoa1213755. PMID: 23863050.	USPI: Xofigo (radium Ra 223 dichloride) Injection Summary Review: 203971Orig1s000SumR.pdf
A-31	NCT00981058	Necitumumab, gemcitabine and cisplatin	Non-small cell lung cancer	Thatcher N, Hirsch FR, Luft AV, Szczesna A, Ciuleanu TE, Dediu M, Ramlau R, Galiulin RK, Bálint B, Losonczy G, Kazarnowicz A, Park K, Schumann C, Reck M, Depenbrock H, Nanda S, Kruljac-Letunic A, Kurek R, Paz-Ares L, Socinski MA; SQUIRE Investigators. Necitumumab plus gemcitabine and cisplatin versus gemcitabine and cisplatin alone as first-line therapy in patients with stage IV squamous non-small-cell lung cancer (SQUIRE): an open-label, randomised, controlled phase 3 trial. <i>Lancet Oncol</i> . 2015 Jul;16(7):763-74. doi: 10.1016/S1470-2045(15)00021-2. Epub 2015 Jun 1. PMID: 26045340.	USPI: Xofigo (radium Ra 223 dichloride) Injection Summary Review: 203971Orig1s000SumR.pdf
A-32	NCT01668784	Nivolumab	Renal cell carcinoma	Motzer RJ, Escudier B, McDermott DF, George S, Hammers HJ, Srinivas S, Tykodi SS, Sosman JA, Procopio G, Plimack ER, Castellano D, Choueiri TK, Gurney H, Donskov F, Bono P, Wagstaff J, Gauler TC, Ueda T, Tomita Y, Schutz FA, Kollmannsberger C, Larkin J, Ravaud A, Simon JS, Xu LA, Waxman IM, Sharma P; CheckMate 025 Investigators. Nivolumab versus Everolimus in Advanced Renal-Cell Carcinoma. <i>N Engl J Med</i> . 2015 Nov 5;373(19):1803-13. doi: 10.1056/NEJMoa1510665. Epub 2015 Sep 25. PMID: 26406148; PMCID: PMC5719487.	USPI: label
A-33	NCT02684006	Avelumab plus axitinib	Renal cell carcinoma	Motzer RJ, Penkov K, Haanen J, Rini B, Albiges L, Campbell MT, Venugopal B, Kollmannsberger C, Negrier S, Uemura M, Lee JL, Vasiliev A, Miller WH Jr, Gurney H, Schmidinger M, Larkin J, Atkins MB, Bedke J, Alekseev B, Wang J, Mariani M, Robbins PB, Chudnovsky A, Fowst C, Hariharan S, Huang B, di Pietro A, Choueiri TK. Avelumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma. <i>N Engl J Med</i> . 2019 Mar 21;380(12):1103-1115. doi: 10.1056/NEJMoa1816047. Epub 2019 Feb 16. PMID: 30779531; PMCID: PMC6716603.	USPI: label
A-34	NCT00887198	Abiraterone acetate plus prednisone	Prostate cancer	Ryan CJ, Smith MR, de Bono JS, Molina A, Logothetis CJ, de Souza P, Fizazi K, Mainwaring P, Piulats JM, Ng S, Carles J, Mulders PF, Basch E, Small EJ, Saad F, Schrijvers D, Van Poppel H, Mukherjee SD, Suttman H, Gerritsen WR, Flaig TW, George DJ, Yu EY, Efsthathiou E, Pantuck A, Winquist E, Higano CS, Taplin ME, Park Y, Kheoh T, Griffin T, Scher HI, Rathkopf DE; COU-AA-302 Investigators. Abiraterone in metastatic prostate cancer without previous chemotherapy. <i>N Engl J Med</i> . 2013 Jan 10;368(2):138-48. doi: 10.1056/NEJMoa1209096. Epub 2012 Dec 10. Erratum in: <i>N Engl J Med</i> . 2013 Feb 7;368(6):584. PMID: 23228172; PMCID: PMC3683570.	USPI: label Summary Review: accessdata.fda.gov/drugsatfda_docs/nda/2012/202379Orig1s005.pdf
A-35	NCT02500043	TAS-102	Gastric cancer	Shitara K, Doi T, Dvorkin M, Mansoor W, Arkenau HT, Prokharau A, Alsina M, Ghidini M, Faustino C, Gorbunova V, Zhavrid E, Nishikawa K, Hosokawa A, Yalçın Ş, Fujitani K, Beretta GD, Cutsem EV, Winkler RE, Makris L, Ilson DH, Tabernero J. Trifluridine/tipiracil versus placebo in patients with heavily pretreated metastatic gastric cancer (TAGS): a randomised, double-blind, placebo-controlled, phase 3 trial. <i>Lancet Oncol</i> . 2018 Nov;19(11):1437-1448. doi: 10.1016/S1470-2045(18)30739-3. Epub 2018 Oct 21. Erratum in: <i>Lancet Oncol</i> . 2018 Dec;19(12):e668. PMID: 30355453.	USPI: label

A-36	NCT02252042	Pembrolizumab	Head and neck cancer	Cohen EEW, Soulières D, Le Tourneau C, Dinis J, Licitra L, Ahn MJ, Soria A, Machiels JP, Mach N, Mehra R, Burtneess B, Zhang P, Cheng J, Swaby RF, Harrington KJ; KEYNOTE-040 investigators. Pembrolizumab versus methotrexate, docetaxel, or cetuximab for recurrent or metastatic head-and-neck squamous cell carcinoma (KEYNOTE-040): a randomised, open-label, phase 3 study. <i>Lancet</i> . 2019 Jan 12;393(10167):156-167. doi: 10.1016/S0140-6736(18)31999-8. Epub 2018 Nov 30. Erratum in: <i>Lancet</i> . 2019 Jan 12;393(10167):132. PMID: 30509740.	USPI: 125514s117.s118lbl.pdf
A-37	NCT02578680	Pembrolizumab plus platinum based chemotherapy or pemetrexed	Non-small cell lung cancer	Gandhi L, Rodríguez-Abreu D, Gadgeel S, Esteban E, Felip E, De Angelis F, Domine M, Clingan P, Hochmair MJ, Powell SF, Cheng SY, Bischoff HG, Peled N, Grossi F, Jennens RR, Reck M, Hui R, Garon EB, Boyer M, Rubio-Viqueira B, Novello S, Kurata T, Gray JE, Vida J, Wei Z, Yang J, Raftopoulos H, Pietanza MC, Garassino MC; KEYNOTE-189 Investigators. Pembrolizumab plus Chemotherapy in Metastatic Non-Small-Cell Lung Cancer. <i>N Engl J Med</i> . 2018 May 31;378(22):2078-2092. doi: 10.1056/NEJMoa1801005. Epub 2018 Apr 16. PMID: 29658856.	USPI: label Summary Review: Review
A-38	NCT02421939	Gilteritinib	Acute myeloid leukemia	Perl AE, Martinelli G, Cortes JE, Neubauer A, Berman E, Paolini S, Montesinos P, Baer MR, Larson RA, Ustun C, Fabbiano F, Erba HP, Di Stasi A, Stuart R, Olin R, Kasner M, Ciceri F, Chou WC, Podoltsev N, Recher C, Yokoyama H, Hosono N, Yoon SS, Lee JH, Pardee T, Fathi AT, Liu C, Hasabou N, Liu X, Bahceci E, Levis MJ. Gilteritinib or Chemotherapy for Relapsed or Refractory FLT3-Mutated AML. <i>N Engl J Med</i> . 2019 Oct 31;381(18):1728-1740. doi: 10.1056/NEJMoa1902688. Erratum in: <i>N Engl J Med</i> . 2022 May 12;386(19):1868. PMID: 31665578.	USPI: label Summary Review: Review
A-39	NCT01673867	Nivolumab	Non-small cell lung cancer	Borghaei H, Paz-Ares L, Horn L, Spigel DR, Steins M, Ready NE, Chow LQ, Vokes EE, Felip E, Holgado E, Barlesi F, Kohlhäufel M, Arrieta O, Burgio MA, Fayette J, Lena H, Poddubskaya E, Gerber DE, Gettinger SN, Rudin CM, Rizvi N, Crinò L, Blumenschein GR Jr, Antonia SJ, Dorange C, Harbison CT, Graf Finckenstein F, Brahmer JR. Nivolumab versus Docetaxel in Advanced Nonsquamous Non-Small-Cell Lung Cancer. <i>N Engl J Med</i> . 2015 Oct 22;373(17):1627-39. doi: 10.1056/NEJMoa1507643. Epub 2015 Sep 27. PMID: 26412456; PMCID: PMC5705936.	USPI: label
A-40	NCT00388726	Eribulin mesylate	Breast cancer	Cortes J, O'Shaughnessy J, Loesch D, Blum JL, Vahdat LT, Petrakova K, Chollet P, Manikas A, Diéras V, Delozier T, Vladimirov V, Cardoso F, Koh H, Bougnoux P, Dutcus CE, Seegobin S, Mir D, Meneses N, Wanders J, Twelves C; EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389) investigators. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomised study. <i>Lancet</i> . 2011 Mar 12;377(9769):914-23. doi: 10.1016/S0140-6736(11)60070-6. Epub 2011 Mar 2. PMID: 21376385.	USPI: Halaven (eribulin mesylate) Injection Summary Review: 201532Orig1s000SumR.pdf
A-41	NCT00105443	Sorafenib	Hepatocellular carcinoma	Llovet JM, Ricci S, Mazzaferro V, Hilgard P, Gane E, Blanc JF, de Oliveira AC, Santoro A, Raoul JL, Forner A, Schwartz M, Porta C, Zeuzem S, Bolondi L, Greten TF, Galle PR, Seitz JF, Borbath I, Häussinger D, Giannaris T, Shan M, Moscovici M, Voliotis D, Bruix J; SHARP Investigators Study Group. Sorafenib in advanced hepatocellular carcinoma. <i>N Engl J Med</i> . 2008 Jul 24;359(4):378-90. doi: 10.1056/NEJMoa0708857. PMID: 18650514.	USPI: 021923s004s005s006s007lbl.pdf
A-42	NCT00065442	Sipuleucel-T	Prostate cancer	Kantoff PW, Higano CS, Shore ND, Berger ER, Small EJ, Penson DF, Redfern CH, Ferrari AC, Dreicer R, Sims RB, Xu Y, Frohlich MW, Schellhammer PF; IMPACT Study Investigators. Sipuleucel-T immunotherapy	USPI: download

				for castration-resistant prostate cancer. N Engl J Med. 2010 Jul 29;363(5):411-22. doi: 10.1056/NEJMoa1001294. PMID: 20818862.	
A-43	NCT02853331	Pembrolizumab plus axitinib	Renal cell carcinoma	Rini BI, Plimack ER, Stus V, Gafanov R, Hawkins R, Nosov D, Pouliot F, Alekseev B, Soulières D, Melichar B, Vynnychenko I, Kryzhanivska A, Bondarenko I, Azevedo SJ, Borchellini D, Szczylk C, Markus M, McDermott RS, Bedke J, Tartas S, Chang YH, Tamada S, Shou Q, Perini RF, Chen M, Atkins MB, Powles T; KEYNOTE-426 Investigators. Pembrolizumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma. N Engl J Med. 2019 Mar 21;380(12):1116-1127. doi: 10.1056/NEJMoa1816714. Epub 2019 Feb 16. PMID: 30779529.	USPI: label Summary Review: 125514Orig1s052.pdf
A-44	NCT02569242	Nivolumab	Esophageal cancer	Kato K, Cho BC, Takahashi M, Okada M, Lin CY, Chin K, Kadowaki S, Ahn MJ, Hamamoto Y, Doki Y, Yen CC, Kubota Y, Kim SB, Hsu CH, Holtved E, Xynos I, Kodani M, Kitagawa Y. Nivolumab versus chemotherapy in patients with advanced oesophageal squamous cell carcinoma refractory or intolerant to previous chemotherapy (ATTRACTION-3): a multicentre, randomised, open-label, phase 3 trial. Lancet Oncol. 2019 Nov;20(11):1506-1517. doi: 10.1016/S1470-2045(19)30626-6. Epub 2019 Sep 30. Erratum in: Lancet Oncol. 2019 Nov;20(11):e613. PMID: 31582355.	USPI: label Summary Review: 125554Orig1s081.pdf
A-45	NCT02409342	Atezolizumab	Non-small cell lung cancer	Herbst RS, Giaccone G, de Marinis F, Reinmuth N, Vergnenegre A, Barrios CH, Morise M, Felip E, Andric Z, Geater S, Özgüroğlu M, Zou W, Sandler A, Enquist I, Komatsubara K, Deng Y, Kuriki H, Wen X, McClelland M, Mocchi S, Jassem J, Spigel DR. Atezolizumab for First-Line Treatment of PD-L1-Selected Patients with NSCLC. N Engl J Med. 2020 Oct 1;383(14):1328-1339. doi: 10.1056/NEJMoa1917346. PMID: 32997907.	USPI: label
A-46	NCT01183780	Ramucirumab plus FOLFIRI	Colorectal cancer	Tabernero J, Yoshino T, Cohn AL, Obermannova R, Bodoky G, Garcia-Carbonero R, Ciuleanu TE, Portnoy DC, Van Cutsem E, Grothey A, Prausová J, Garcia-Alfonso P, Yamazaki K, Clingan PR, Lonardi S, Kim TW, Simms L, Chang SC, Nasroulah F; RAISE Study Investigators. Ramucirumab versus placebo in combination with second-line FOLFIRI in patients with metastatic colorectal carcinoma that progressed during or after first-line therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (RAISE): a randomised, double-blind, multicentre, phase 3 study. Lancet Oncol. 2015 May;16(5):499-508. doi: 10.1016/S1470-2045(15)70127-0. Epub 2015 Apr 12. Erratum in: Lancet Oncol. 2015 Jun;16(6):e262. PMID: 25877855.	USPI: label
A-47	NCT01170663	Ramucirumab plus paclitaxel	Gastric cancer	Wilke H, Muro K, Van Cutsem E, Oh SC, Bodoky G, Shimada Y, Hironaka S, Sugimoto N, Lipatov O, Kim TY, Cunningham D, Rougier P, Komatsu Y, Ajani J, Emig M, Carlesi R, Ferry D, Chandrawansa K, Schwartz JD, Ohtsu A; RAINBOW Study Group. Ramucirumab plus paclitaxel versus placebo plus paclitaxel in patients with previously treated advanced gastric or gastro-oesophageal junction adenocarcinoma (RAINBOW): a double-blind, randomised phase 3 trial. Lancet Oncol. 2014 Oct;15(11):1224-35. doi: 10.1016/S1470-2045(14)70420-6. Epub 2014 Sep 17. PMID: 25240821.	USPI: label
A-48	NCT01866319	Pembrolizumab (every 2 weeks)	Melanoma	Robert C, Schachter J, Long GV, Arance A, Grob JJ, Mortier L, Daud A, Carlino MS, McNeil C, Lotem M, Larkin J, Lorigan P, Neyns B, Blank CU, Hamid O, Mateus C, Shapira-Frommer R, Kosh M, Zhou H, Ibrahim N, Ebbinghaus S, Ribas A; KEYNOTE-006 investigators. Pembrolizumab versus Ipilimumab in Advanced Melanoma. N Engl J Med. 2015 Jun 25;372(26):2521-32. doi: 10.1056/NEJMoa1503093. Epub 2015 Apr 19. PMID: 25891173.	USPI: Keytruda Label

A-49	NCT01866319	Pembrolizumab (every 3 weeks)	Melanoma	Robert C, Schachter J, Long GV, Arance A, Grob JJ, Mortier L, Daud A, Carlino MS, McNeil C, Lotem M, Larkin J, Lorigan P, Neyns B, Blank CU, Hamid O, Mateus C, Shapira-Frommer R, Kosh M, Zhou H, Ibrahim N, Ebbinghaus S, Ribas A; KEYNOTE-006 investigators. Pembrolizumab versus Ipilimumab in Advanced Melanoma. N Engl J Med. 2015 Jun 25;372(26):2521-32. doi: 10.1056/NEJMoa1503093. Epub 2015 Apr 19. PMID: 25891173.	USPI: Keytruda Label
A-50	NCT01844505	Nivolumab plus ipilimumab	Melanoma	Larkin J, Chiarion-Sileni V, Gonzalez R, Grob JJ, Rutkowski P, Lao CD, Cowey CL, Schadendorf D, Wagstaff J, Dummer R, Ferrucci PF, Smylie M, Hogg D, Hill A, Márquez-Rodas I, Haanen J, Guidoboni M, Maio M, Schöffski P, Carlino MS, Lebbé C, McArthur G, Ascierto PA, Daniels GA, Long GV, Bastholt L, Rizzo JI, Balogh A, Moshyk A, Hodi FS, Wolchok JD. Five-Year Survival with Combined Nivolumab and Ipilimumab in Advanced Melanoma. N Engl J Med. 2019 Oct 17;381(16):1535-1546. doi: 10.1056/NEJMoa1910836. Epub 2019 Sep 28. PMID: 31562797.	USPI: label
A-51	NCT01844505	Nivolumab	Melanoma	Larkin J, Chiarion-Sileni V, Gonzalez R, Grob JJ, Rutkowski P, Lao CD, Cowey CL, Schadendorf D, Wagstaff J, Dummer R, Ferrucci PF, Smylie M, Hogg D, Hill A, Márquez-Rodas I, Haanen J, Guidoboni M, Maio M, Schöffski P, Carlino MS, Lebbé C, McArthur G, Ascierto PA, Daniels GA, Long GV, Bastholt L, Rizzo JI, Balogh A, Moshyk A, Hodi FS, Wolchok JD. Five-Year Survival with Combined Nivolumab and Ipilimumab in Advanced Melanoma. N Engl J Med. 2019 Oct 17;381(16):1535-1546. doi: 10.1056/NEJMoa1910836. Epub 2019 Sep 28. PMID: 31562797.	USPI: label
A-52	NCT00094653	Ipilimumab plus glycoprotein100	Melanoma	Hodi FS, O'Day SJ, McDermott DF, Weber RW, Sosman JA, Haanen JB, Gonzalez R, Robert C, Schadendorf D, Hassel JC, Akerley W, van den Eertwegh AJ, Lutzky J, Lorigan P, Vaubel JM, Linette GP, Hogg D, Ottensmeier CH, Lebbé C, Peschel C, Quirt I, Clark JI, Wolchok JD, Weber JS, Tian J, Yellin MJ, Nichol GM, Hoos A, Urba WJ. Improved survival with ipilimumab in patients with metastatic melanoma. N Engl J Med. 2010 Aug 19;363(8):711-23. doi: 10.1056/NEJMoa1003466. Epub 2010 Jun 5. Erratum in: N Engl J Med. 2010 Sep 23;363(13):1290. PMID: 20525992; PMCID: PMC3549297.	USPI: label Summary Review: Summary Review
A-53	NCT00094653	Ipilimumab	Melanoma	Hodi FS, O'Day SJ, McDermott DF, Weber RW, Sosman JA, Haanen JB, Gonzalez R, Robert C, Schadendorf D, Hassel JC, Akerley W, van den Eertwegh AJ, Lutzky J, Lorigan P, Vaubel JM, Linette GP, Hogg D, Ottensmeier CH, Lebbé C, Peschel C, Quirt I, Clark JI, Wolchok JD, Weber JS, Tian J, Yellin MJ, Nichol GM, Hoos A, Urba WJ. Improved survival with ipilimumab in patients with metastatic melanoma. N Engl J Med. 2010 Aug 19;363(8):711-23. doi: 10.1056/NEJMoa1003466. Epub 2010 Jun 5. Erratum in: N Engl J Med. 2010 Sep 23;363(13):1290. PMID: 20525992; PMCID: PMC3549297.	USPI: label Summary Review: Summary Review
A-54	NCT03511664	177Lu-PSMA-617 plus standard care treatment	Prostate cancer	Sartor O, de Bono J, Chi KN, Fizazi K, Herrmann K, Rahbar K, Tagawa ST, Nordquist LT, Vaishampayan N, El-Haddad G, Park CH, Beer TM, Armour A, Pérez-Contreras WJ, DeSilvio M, Kpamegan E, Gericke G, Messmann RA, Morris MJ, Krause BJ; VISION Investigators. Lutetium-177-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med. 2021 Sep 16;385(12):1091-1103. doi: 10.1056/NEJMoa2107322. Epub 2021 Jun 23. PMID: 34161051; PMCID: PMC8446332.	USPI: label Summary Review: Drug Approval Package: PLUVICTO

A-55	NCT02125461	Durvalumab	Non-small cell lung cancer	Antonia SJ, Villegas A, Daniel D, Vicente D, Murakami S, Hui R, Yokoi T, Chiappori A, Lee KH, de Wit M, Cho BC, Bourhaba M, Quantin X, Tokito T, Mekhail T, Planchard D, Kim YC, Karapetis CS, Hiet S, Ostoros G, Kubota K, Gray JE, Paz-Ares L, de Castro Carpeño J, Wadsworth C, Melillo G, Jiang H, Huang Y, Dennis PA, Özgüroğlu M; PACIFIC Investigators. Durvalumab after Chemoradiotherapy in Stage III Non-Small-Cell Lung Cancer. <i>N Engl J Med</i> . 2017 Nov 16;377(20):1919-1929. doi: 10.1056/NEJMoa1709937. Epub 2017 Sep 8. PMID: 28885881.	USPI: label
A-56	NCT00273546	Docetaxel, cisplatin and fluorouracil followed by chemoradiation	Head and neck cancer	Posner MR, Hershock DM, Blajman CR, Mickiewicz E, Winquist E, Gorbounova V, Tjulandin S, Shin DM, Cullen K, Ervin TJ, Murphy BA, Raez LE, Cohen RB, Spaulding M, Tishler RB, Roth B, Viroglio Rdel C, Venkatesan V, Romanov I, Agarwala S, Harter KW, Dugan M, Cmelak A, Markoe AM, Read PW, Steinbrenner L, Colevas AD, Norris CM Jr, Haddad RI; TAX 324 Study Group. Cisplatin and fluorouracil alone or with docetaxel in head and neck cancer. <i>N Engl J Med</i> . 2007 Oct 25;357(17):1705-15. doi: 10.1056/NEJMoa070956. PMID: 17960013.	USPI: 020449s045lbl.pdf
A-57	NCT03474107	Enfortumab vedotin	Urothelial carcinoma	Powles T, Rosenberg JE, Sonpavde GP, Loriot Y, Durán I, Lee JL, Matsubara N, Vulsteke C, Castellano D, Wu C, Campbell M, Matsangou M, Petrylak DP. Enfortumab Vedotin in Previously Treated Advanced Urothelial Carcinoma. <i>N Engl J Med</i> . 2021 Mar 25;384(12):1125-1135. doi: 10.1056/NEJMoa2035807. Epub 2021 Feb 12. PMID: 33577729; PMCID: PMC8450892.	USPI: label
A-58	NCT03434379	Atezolizumab plus bevacizumab	Hepatocellular carcinoma	Finn RS, Qin S, Ikeda M, Galle PR, Ducreux M, Kim TY, Kudo M, Breder V, Merle P, Kaseb AO, Li D, Verret W, Xu DZ, Hernandez S, Liu J, Huang C, Mulla S, Wang Y, Lim HY, Zhu AX, Cheng AL; IMbrave150 Investigators. Atezolizumab plus Bevacizumab in Unresectable Hepatocellular Carcinoma. <i>N Engl J Med</i> . 2020 May 14;382(20):1894-1905. doi: 10.1056/NEJMoa1915745. PMID: 32402160.	USPI: label
A-59	NCT02775435	Pembrolizumab plus carboplatin and paclitaxel/nab-paclitaxel	Non-small cell lung cancer	Paz-Ares L, Luft A, Vicente D, Tafreshi A, Gümüş M, Mazières J, Hermes B, Çay Şenler F, Csósz T, Fülöp A, Rodríguez-Cid J, Wilson J, Sugawara S, Kato T, Lee KH, Cheng Y, Novello S, Halmos B, Li X, Lubiniecki GM, Piperdi B, Kowalski DM; KEYNOTE-407 Investigators. Pembrolizumab plus Chemotherapy for Squamous Non-Small-Cell Lung Cancer. <i>N Engl J Med</i> . 2018 Nov 22;379(21):2040-2051. doi: 10.1056/NEJMoa1810865. Epub 2018 Sep 25. PMID: 30280635.	USPI: label Summary Review: Review
A-60	NCT02564263	Pembrolizumab	Esophageal cancer	Kojima T, Shah MA, Muro K, Francois E, Adenis A, Hsu CH, Doi T, Moriwaki T, Kim SB, Lee SH, Bennouna J, Kato K, Shen L, Enzinger P, Qin SK, Ferreira P, Chen J, Giotto G, de la Fouchardiere C, Senellart H, Al-Rajabi R, Lordick F, Wang R, Suryawanshi S, Bhagia P, Kang SP, Metges JP; KEYNOTE-181 Investigators. Randomized Phase III KEYNOTE-181 Study of Pembrolizumab Versus Chemotherapy in Advanced Esophageal Cancer. <i>J Clin Oncol</i> . 2020 Dec 10;38(35):4138-4148. doi: 10.1200/JCO.20.01888. Epub 2020 Oct 7. PMID: 33026938.	USPI: label
A-61	NCT02763579	Atezolizumab plus carboplatin and etoposide	Small cell lung cancer	Horn L, Mansfield AS, Szczesna A, Havel L, Krzakowski M, Hochmair MJ, Huemer F, Losonczy G, Johnson ML, Nishio M, Reck M, Mok T, Lam S, Shames DS, Liu J, Ding B, Lopez-Chavez A, Kabbinar F, Lin W, Sandler A, Liu SV; IMpower133 Study Group. First-Line Atezolizumab plus Chemotherapy in Extensive-Stage Small-Cell Lung Cancer. <i>N Engl J Med</i> . 2018 Dec 6;379(23):2220-2229. doi: 10.1056/NEJMoa1809064. Epub 2018 Sep 25. PMID: 30280641.	USPI: label Summary Review: Review

A-62	NCT02367781	Atezolizumab plus carboplatin and nab-paclitaxel	Non-small cell lung cancer	West H, McCleod M, Hussein M, Morabito A, Rittmeyer A, Conter HJ, Kopp HG, Daniel D, McCune S, Mekhail T, Zer A, Reinmuth N, Sadiq A, Sandler A, Lin W, Ochi Lohmann T, Archer V, Wang L, Kowanetz M, Cappuzzo F. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. <i>Lancet Oncol</i> . 2019 Jul;20(7):924-937. doi: 10.1016/S1470-2045(19)30167-6. Epub 2019 May 20. PMID: 31122901.	USPI: label
A-63	NCT02489318	Apalutamide plus ADT	Prostate cancer	Chi KN, Agarwal N, Bjartell A, Chung BH, Pereira de Santana Gomes AJ, Given R, Juárez Soto Á, Merseburger AS, Özgüroğlu M, Uemura H, Ye D, Deprince K, Naini V, Li J, Cheng S, Yu MK, Zhang K, Larsen JS, McCarthy S, Chowdhury S; TITAN Investigators. Apalutamide for Metastatic, Castration-Sensitive Prostate Cancer. <i>N Engl J Med</i> . 2019 Jul 4;381(1):13-24. doi: 10.1056/NEJMoa1903307. Epub 2019 May 31. PMID: 31150574.	USPI: label
A-64	NCT01564784	Inotuzumab ozogamicin	Acute lymphocytic leukemia	Kantarjian HM, DeAngelo DJ, Stelljes M, Martinelli G, Liedtke M, Stock W, Gökbüget N, O'Brien S, Wang K, Wang T, Paccagnella ML, Sleight B, Vandendries E, Advani AS. Inotuzumab Ozogamicin versus Standard Therapy for Acute Lymphoblastic Leukemia. <i>N Engl J Med</i> . 2016 Aug 25;375(8):740-53. doi: 10.1056/NEJMoa1509277. Epub 2016 Jun 12. PMID: 27292104; PMCID: PMC5594743.	USPI: LABEL Summary Review: Drug Approval Package: BESPONSA (INOTUZUMAB OZOGAMICIN) LYOPHILIZED POWDER
A-65	NCT03043872	Durvalumab plus Platinum-Etoposide	Small cell lung cancer	Paz-Ares L, Dvorkin M, Chen Y, Reinmuth N, Hotta K, Trukhin D, Statsenko G, Hochmair MJ, Özgüroğlu M, Ji JH, Voitko O, Poltoratskiy A, Ponce S, Verderame F, Havel L, Bondarenko I, Kazarnowicz A, Losonczy G, Conev NV, Armstrong J, Byrne N, Shire N, Jiang H, Goldman JW; CASPIAN investigators. Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a randomised, controlled, open-label, phase 3 trial. <i>Lancet</i> . 2019 Nov 23;394(10212):1929-1939. doi: 10.1016/S0140-6736(19)32222-6. Epub 2019 Oct 4. PMID: 31590988.	USPI: label
A-66	NCT02872116	Nivolumab plus XELOX or FOLFOX	Gastric cancer	Janjigian YY, Shitara K, Moehler M, Garrido M, Salman P, Shen L, Wyrwicz L, Yamaguchi K, Skoczylas T, Campos Bragagnoli A, Liu T, Schenker M, Yanez P, Tehfe M, Kowalyszyn R, Karamouzis MV, Bruges R, Zander T, Pazo-Cid R, Hitre E, Feeney K, Cleary JM, Poulart V, Cullen D, Lei M, Xiao H, Kondo K, Li M, Ajani JA. First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-oesophageal junction, and oesophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial. <i>Lancet</i> . 2021 Jul 3;398(10294):27-40. doi: 10.1016/S0140-6736(21)00797-2. Epub 2021 Jun 5. PMID: 34102137; PMCID: PMC8436782.	USPI: label
A-67	NCT02993523	Venetoclax plus azacitidine	Acute myeloid leukemia	DiNardo CD, Jonas BA, Pullarkat V, Thirman MJ, Garcia JS, Wei AH, Konopleva M, Döhner H, Letai A, Fenaux P, Koller E, Havelange V, Leber B, Esteve J, Wang J, Pejsa V, Hájek R, Porkka K, Illés Á, Lavie D, Lemoli RM, Yamamoto K, Yoon SS, Jang JH, Yeh SP, Turgut M, Hong WJ, Zhou Y, Potluri J, Pratz KW. Azacitidine and Venetoclax in Previously Untreated Acute Myeloid Leukemia. <i>N Engl J Med</i> . 2020 Aug 13;383(7):617-629. doi: 10.1056/NEJMoa2012971. PMID: 32786187.	USPI: label

A-68	NCT00803062	Bevacizumab plus chemotherapy	Cervical cancer	Tewari KS, Sill MW, Long HJ 3rd, Penson RT, Huang H, Ramondetta LM, Landrum LM, Oaknin A, Reid TJ, Leitao MM, Michael HE, Monk BJ. Improved survival with bevacizumab in advanced cervical cancer. N Engl J Med. 2014 Feb 20;370(8):734-43. doi: 10.1056/NEJMoa1309748. Erratum in: N Engl J Med. 2017 Aug 17;377(7):702. PMID: 24552320; PMCID: PMC4010094.	USPI: AVASTIN (bevacizumab) Summary Review: 125085Orig1s301SumR.pdf
A-69	NCT00021060	Bevacizumab plus paclitaxel and carboplatin	Non-small cell lung cancer	Sandler A, Gray R, Perry MC, Brahmer J, Schiller JH, Dowlati A, Lilenbaum R, Johnson DH. Paclitaxel-carboplatin alone or with bevacizumab for non-small-cell lung cancer. N Engl J Med. 2006 Dec 14;355(24):2542-50. doi: 10.1056/NEJMoa061884. Erratum in: N Engl J Med. 2007 Jan 18;356(3):318. PMID: 17167137.	USPI: CPY Document Summary Review: eCopy, Inc.
A-70	NCT00829166	T-DM1 (Trastuzumab emtansine)	Breast cancer	Verma S, Miles D, Gianni L, Krop IE, Welslau M, Baselga J, Pegram M, Oh DY, Diéras V, Guardino E, Fang L, Lu MW, Olsen S, Blackwell K; EMILIA Study Group. Trastuzumab emtansine for HER2-positive advanced breast cancer. N Engl J Med. 2012 Nov 8;367(19):1783-91. doi: 10.1056/NEJMoa1209124. Epub 2012 Oct 1. Erratum in: N Engl J Med. 2013 Jun 20;368(25):2442. PMID: 23020162; PMCID: PMC5125250.	USPI: label
A-71	NCT02928224	Encorafenib plus cetuximab	Colorectal cancer	Kopetz S, Grothey A, Yaeger R, Van Cutsem E, Desai J, Yoshino T, Wasan H, Ciardiello F, Loupakis F, Hong YS, Steeghs N, Guren TK, Arkenau HT, Garcia-Alfonso P, Pfeiffer P, Orlov S, Lonardi S, Elez E, Kim TW, Schellens JHM, Guo C, Krishnan A, Dekervel J, Morris V, Calvo Ferrandiz A, Tarpgaard LS, Braun M, Gollerkeri A, Keir C, Maharry K, Pickard M, Christy-Bittel J, Anderson L, Sandor V, Tabernero J. Encorafenib, Binimetinib, and Cetuximab in BRAF V600E-Mutated Colorectal Cancer. N Engl J Med. 2019 Oct 24;381(17):1632-1643. doi: 10.1056/NEJMoa1908075. Epub 2019 Sep 30. PMID: 31566309.	USPI: Approval [Rx ONLY]
A-72	NCT02425891	Atezolizumab plus nab-paclitaxel	Breast cancer	Schmid P, Adams S, Rugo HS, Schneeweiss A, Barrios CH, Iwata H, Diéras V, Hegg R, Im SA, Shaw Wright G, Henschel V, Molinero L, Chui SY, Funke R, Husain A, Winer EP, Loi S, Emens LA; IMpassion130 Trial Investigators. Atezolizumab and Nab-Paclitaxel in Advanced Triple-Negative Breast Cancer. N Engl J Med. 2018 Nov 29;379(22):2108-2121. doi: 10.1056/NEJMoa1809615. Epub 2018 Oct 20. PMID: 30345906.	USPI: label
A-73	NCT01905657	Pembrolizumab (10mg/kg)	Non-small cell lung cancer	Herbst RS, Baas P, Kim DW, Felip E, Pérez-Gracia JL, Han JY, Molina J, Kim JH, Arvis CD, Ahn MJ, Majem M, Fidler MJ, de Castro G Jr, Garrido M, Lubiniecki GM, Shentu Y, Im E, Dolled-Filhart M, Garon EB. Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial. Lancet. 2016 Apr 9;387(10027):1540-1550. doi: 10.1016/S0140-6736(15)01281-7. Epub 2015 Dec 19. PMID: 26712084.	USPI: KEYTRUDA (pembrolizumab)
A-74	NCT01905657	Pembrolizumab (2mg/kg)	Non-small cell lung cancer	Herbst RS, Baas P, Kim DW, Felip E, Pérez-Gracia JL, Han JY, Molina J, Kim JH, Arvis CD, Ahn MJ, Majem M, Fidler MJ, de Castro G Jr, Garrido M, Lubiniecki GM, Shentu Y, Im E, Dolled-Filhart M, Garon EB. Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial. Lancet. 2016 Apr 9;387(10027):1540-1550. doi: 10.1016/S0140-6736(15)01281-7. Epub 2015 Dec 19. PMID: 26712084.	USPI: KEYTRUDA (pembrolizumab)

A-75	NCT02008227	Atezolizumab	Non-small cell lung cancer	Rittmeyer A, Barlesi F, Waterkamp D, Park K, Ciardiello F, von Pawel J, Gadgeel SM, Hida T, Kowalski DM, Dols MC, Cortinovis DL, Leach J, Polikoff J, Barrios C, Kabbinar F, Frontera OA, De Marinis F, Turna H, Lee JS, Ballinger M, Kowanetz M, He P, Chen DS, Sandler A, Gandara DR; OAK Study Group. Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): a phase 3, open-label, multicentre randomised controlled trial. <i>Lancet</i> . 2017 Jan 21;389(10066):255-265. doi: 10.1016/S0140-6736(16)32517-X. Epub 2016 Dec 13. Erratum in: <i>Lancet</i> . 2017 Apr 8;389(10077):e5. PMID: 27979383; PMCID: PMC6886121.	USPI: label
A-76	NCT02256436	Pembrolizumab	Urothelial carcinoma	Bellmunt J, de Wit R, Vaughn DJ, Fradet Y, Lee JL, Fong L, Vogelzang NJ, Climent MA, Petrylak DP, Choueiri TK, Necchi A, Gerritsen W, Gurney H, Quinn DI, Culine S, Sternberg CN, Mai Y, Poehlein CH, Perini RF, Bajorin DF; KEYNOTE-045 Investigators. Pembrolizumab as Second-Line Therapy for Advanced Urothelial Carcinoma. <i>N Engl J Med</i> . 2017 Mar 16;376(11):1015-1026. doi: 10.1056/NEJMoa1613683. Epub 2017 Feb 17. PMID: 28212060; PMCID: PMC5635424.	USPI: label
A-77	NCT02358031	Pembrolizumab plus platinum based chemotherapy and 5-FU	Head and neck cancer	Burtneß B, Rischin D, Greil R, Soulières D, Tahara M, de Castro G Jr, Psyrri A, Brana I, Basté N, Neupane P, Bratland Å, Fuereder T, Hughes BGM, Mesia R, Ngamphaiboon N, Rordorf T, Wan Ishak WZ, Ge J, Swaby RF, Gumuscu B, Harrington K. Pembrolizumab Alone or With Chemotherapy for Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma in KEYNOTE-048: Subgroup Analysis by Programmed Death Ligand-1 Combined Positive Score. <i>J Clin Oncol</i> . 2022 Jul 20;40(21):2321-2332. doi: 10.1200/JCO.21.02198. Epub 2022 Mar 25. PMID: 35333599; PMCID: PMC9287281.	USPI: label Summary Review: 125514Orig1s052.pdf
A-78	NCT02358031	Pembrolizumab	Head and neck cancer	Burtneß B, Rischin D, Greil R, Soulières D, Tahara M, de Castro G Jr, Psyrri A, Brana I, Basté N, Neupane P, Bratland Å, Fuereder T, Hughes BGM, Mesia R, Ngamphaiboon N, Rordorf T, Wan Ishak WZ, Ge J, Swaby RF, Gumuscu B, Harrington K. Pembrolizumab Alone or With Chemotherapy for Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma in KEYNOTE-048: Subgroup Analysis by Programmed Death Ligand-1 Combined Positive Score. <i>J Clin Oncol</i> . 2022 Jul 20;40(21):2321-2332. doi: 10.1200/JCO.21.02198. Epub 2022 Mar 25. PMID: 35333599; PMCID: PMC9287281.	USPI: label Summary Review: 125514Orig1s052.pdf
A-79	NCT02435433	Ramucirumab	Hepatocellular carcinoma	Zhu AX, Kang YK, Yen CJ, Finn RS, Galle PR, Llovet JM, Assenat E, Brandi G, Pracht M, Lim HY, Rau KM, Motomura K, Ohno I, Merle P, Daniele B, Shin DB, Gerken G, Borg C, Hiriart JB, Okusaka T, Morimoto M, Hsu Y, Abada PB, Kudo M; REACH-2 study investigators. Ramucirumab after sorafenib in patients with advanced hepatocellular carcinoma and increased α -fetoprotein concentrations (REACH-2): a randomised, double-blind, placebo-controlled, phase 3 trial. <i>Lancet Oncol</i> . 2019 Feb;20(2):282-296. doi: 10.1016/S1470-2045(18)30937-9. Epub 2019 Jan 18. PMID: 30665869.	USPI: label

FDA non-approved group

ID	NCT Number	Investigational drug	Cancer type	Clinical reference	Regulatory reference
N-1	NCT02039726	Quizartinib	Acute myeloid leukemia	Cortes JE, Khaled S, Martinelli G, Perl AE, Ganguly S, Russell N, Krämer A, Dombret H, Hogge D, Jonas BA, Leung AY, Mehta P, Montesinos P, Radsak M, Sica S, Arunachalam M, Holmes M, Kobayashi K, Namuyinga R, Ge N, Yver A, Zhang Y, Levis MJ. Quizartinib versus salvage chemotherapy in relapsed or refractory FLT3-ITD acute myeloid leukaemia (QuANTUM-R): a multicentre, randomised, controlled, open-label, phase 3 trial. <i>Lancet Oncol.</i> 2019 Jul;20(7):984-997. doi: 10.1016/S1473-2045(19)30150-0. Epub 2019 Jun 4. Erratum in: <i>Lancet Oncol.</i> 2019 Jul;20(7):e346. PMID: 31175001.	This trial did not contribute to FDA approval for the investigated indication.
N-2	NCT01746979	Evofosfamide plus gemcitabine	Pancreatic cancer	Borad MJ, Reddy SG, Bahary N, Uronis HE, Sigal D, Cohn AL, Schelman WR, Stephenson J Jr, Chiorean EG, Rosen PJ, Ulrich B, Dragovich T, Del Prete SA, Rarick M, Eng C, Kroll S, Ryan DP. Randomized Phase II Trial of Gemcitabine Plus TH-302 Versus Gemcitabine in Patients With Advanced Pancreatic Cancer. <i>J Clin Oncol.</i> 2015 May 1;33(13):1475-81. doi: 10.1200/JCO.2014.55.7504. Epub 2014 Dec 15. PMID: 25512461; PMCID: PMC4881365.	This trial did not contribute to FDA approval for the investigated indication.
N-3	NCT01450761	Ipilimumab, etoposide and platinum based chemotherapy	Small cell lung cancer	Reck M, Luft A, Szczesna A, Havel L, Kim SW, Akerley W, Pietanza MC, Wu YL, Zielinski C, Thomas M, Felip E, Gold K, Horn L, Aerts J, Nakagawa K, Lorigan P, Pieters A, Kong Sanchez T, Fairchild J, Spigel D. Phase III Randomized Trial of Ipilimumab Plus Etoposide and Platinum Versus Placebo Plus Etoposide and Platinum in Extensive-Stage Small-Cell Lung Cancer. <i>J Clin Oncol.</i> 2016 Nov 1;34(31):3740-3748. doi: 10.1200/JCO.2016.67.6601. Erratum in: <i>J Clin Oncol.</i> 2019 Dec 1;37(34):3327. PMID: 27458307.	This trial did not contribute to FDA approval for the investigated indication.
N-4	NCT01285609	Ipilimumab, paclitaxel and carboplatin	Non-small cell lung cancer	Govindan R, Szczesna A, Ahn MJ, Schneider CP, Gonzalez Mella PF, Barlesi F, Han B, Ganea DE, Von Pawel J, Vladimirov V, Fadeeva N, Lee KH, Kurata T, Zhang L, Tamura T, Postmus PE, Jassem J, O'Byrne K, Kopit J, Li M, Tschaika M, Reck M. Phase III Trial of Ipilimumab Combined With Paclitaxel and Carboplatin in Advanced Squamous Non-Small-Cell Lung Cancer. <i>J Clin Oncol.</i> 2017 Oct 20;35(30):3449-3457. doi: 10.1200/JCO.2016.71.7629. Epub 2017 Aug 30. PMID: 28854067.	This trial did not contribute to FDA approval for the investigated indication.
N-5	NCT01989572	Peptide vaccination sargramostim	Melanoma	Lawson DH, Lee S, Zhao F, Tarhini AA, Margolin KA, Ernstoff MS, Atkins MB, Cohen GI, Whiteside TL, Butterfield LH, Kirkwood JM. Randomized, Placebo-Controlled, Phase III Trial of Yeast-Derived Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) Versus Peptide Vaccination Versus GM-CSF Plus Peptide Vaccination Versus Placebo in Patients With No Evidence of Disease After Complete Surgical Resection of Locally Advanced and/or Stage IV Melanoma: A Trial of the Eastern Cooperative Oncology Group-American College of Radiology Imaging Network Cancer Research Group (E4697). <i>J Clin Oncol.</i> 2015 Dec 1;33(34):4066-76. doi: 10.1200/JCO.2015.62.0500. Epub 2015 Sep 8. PMID: 26351350; PMCID: PMC4669592.	This trial did not contribute to FDA approval for the investigated indication.
N-6	NCT00789633	Masitinib plus gemcitabine	Pancreatic cancer	Deplanque G, Demarchi M, Hebbar M, Flynn P, Melichar B, Atkins J, Nowara E, Moyé L, Piquemal D, Ritter D, Dubreuil P, Mansfield CD, Acin Y, Moussy A, Hermine O, Hammel P. A randomized, placebo-controlled phase III trial of masitinib plus gemcitabine in the treatment of advanced pancreatic cancer. <i>Ann Oncol.</i> 2015 Jun;26(6):1194-1200. doi: 10.1093/annonc/mdv133. Epub 2015 Apr 9. PMID: 25858497; PMCID: PMC4516046.	This trial did not contribute to FDA approval for the investigated indication.

N-7	NCT01480479	Rindopepimut with temozolomide	Glioblastoma	Weller M, Butowski N, Tran DD, Recht LD, Lim M, Hirte H, Ashby L, Mechtler L, Goldlust SA, Iwamoto F, Drappatz J, O'Rourke DM, Wong M, Hamilton MG, Finocchiaro G, Perry J, Wick W, Green J, He Y, Turner CD, Yellin MJ, Keler T, Davis TA, Stupp R, Sampson JH; ACT IV trial investigators. Rindopepimut with temozolomide for patients with newly diagnosed, EGFRvIII-expressing glioblastoma (ACT IV): a randomised, double-blind, international phase 3 trial. <i>Lancet Oncol.</i> 2017 Oct;18(10):1373-1385. doi: 10.1016/S1470-2045(17)30517-X. Epub 2017 Aug 23. PMID: 28844499.	This trial did not contribute to FDA approval for the investigated indication.
N-8	NCT00883116	Ixabepilone	Endometrial cancer	McMeekin S, Dizon D, Barter J, Scambia G, Manzyuk L, Lisyanskaya A, Oaknin A, Ringuette S, Mukhopadhyay P, Rosenberg J, Vergote I. Phase III randomized trial of second-line ixabepilone versus paclitaxel or doxorubicin in women with advanced endometrial cancer. <i>Gynecol Oncol.</i> 2015 Jul;138(1):18-23. doi: 10.1016/j.ygyno.2015.04.026. Epub 2015 Apr 26. PMID: 25925990.	This trial did not contribute to FDA approval for the investigated indication.
N-9	NCT01755767	Tivantinib (ARQ 197)	Hepatocellular carcinoma	Rimassa L, Assenat E, Peck-Radosavljevic M, Pracht M, Zagone V, Mathurin P, Rota Caremoli E, Porta C, Daniele B, Bolondi L, Mazzaferro V, Harris W, Damjanov N, Pastorelli D, Reig M, Knox J, Negri F, Trojan J, López López C, Personeni N, Decaens T, Dupuy M, Sieghart W, Abbadessa G, Schwartz B, Lamar M, Goldberg T, Shuster D, Santoro A, Bruix J. Tivantinib for second-line treatment of MET-high, advanced hepatocellular carcinoma (METIV-HCC): a final analysis of a phase 3, randomised, placebo-controlled study. <i>Lancet Oncol.</i> 2018 May;19(5):682-693. doi: 10.1016/S1470-2045(18)30146-3. Epub 2018 Apr 3. PMID: 29625879.	This trial did not contribute to FDA approval for the investigated indication.
N-10	NCT00656136	Afatinib plus BSC	Non-small cell lung cancer	Miller VA, Hirsh V, Cadranel J, Chen YM, Park K, Kim SW, Zhou C, Su WC, Wang M, Sun Y, Heo DS, Crino L, Tan EH, Chao TY, Shahidi M, Cong XJ, Lorence RM, Yang JC. Afatinib versus placebo for patients with advanced, metastatic non-small-cell lung cancer after failure of erlotinib, gefitinib, or both, and one or two lines of chemotherapy (LUX-Lung 1): a phase 2b/3 randomised trial. <i>Lancet Oncol.</i> 2012 May;13(5):528-38. doi: 10.1016/S1470-2045(12)70087-6. Epub 2012 Mar 26. Erratum in: <i>Lancet Oncol.</i> 2012 May;13(5):e186. PMID: 22452896.	This trial did not contribute to FDA approval for the investigated indication.
N-11	NCT01454934	Eribulin plus chemotherapy	Non-small cell lung cancer	Katakami N, Felip E, Spigel DR, Kim JH, Olivo M, Guo M, Nokihara H, Yang JC, Iannotti N, Satouchi M, Barlesi F. A randomized, open-label, multicenter, phase 3 study to compare the efficacy and safety of eribulin to treatment of physician's choice in patients with advanced non-small cell lung cancer. <i>Ann Oncol.</i> 2017 Sep 1;28(9):2241-2247. doi: 10.1093/annonc/mdx284. PMID: 28911085; PMCID: PMC5834051.	This trial did not contribute to FDA approval for the investigated indication.
N-12	NCT00699374	Sunitinib	Hepatocellular carcinoma	Cheng AL, Kang YK, Lin DY, Park JW, Kudo M, Qin S, Chung HC, Song X, Xu J, Poggi G, Omata M, Pitman Lowenthal S, Lanzalone S, Yang L, Lechuga MJ, Raymond E. Sunitinib versus sorafenib in advanced hepatocellular cancer: results of a randomized phase III trial. <i>J Clin Oncol.</i> 2013 Nov 10;31(32):4067-75. doi: 10.1200/JCO.2012.45.8372. Epub 2013 Sep 30. PMID: 24081937.	This trial did not contribute to FDA approval for the investigated indication.
N-13	NCT01836432	Algenpantucel-L plus chemotherapy and chemoradiation	Pancreatic cancer	Hewitt DB, Nissen N, Hatoum H, Musher B, Seng J, Coveler AL, Al-Rajabi R, Yeo CJ, Leiby B, Banks J, Balducci L, Vaccaro G, LoConte N, George TJ, Brenner W, Elquza E, Vahanian N, Rossi G, Kennedy E, Link C, Lavu H. A Phase 3 Randomized Clinical Trial of Chemotherapy With or Without Algenpantucel-L (HyperAcute-Pancreas) Immunotherapy in Subjects With Borderline Resectable or Locally Advanced Unresectable Pancreatic Cancer. <i>Ann Surg.</i> 2022 Jan 1;275(1):45-53. doi: 10.1097/SLA.0000000000004669. PMID: 33630475.	This trial did not contribute to FDA approval for the investigated indication.

N-14	NCT00409188	Tecemotide (emepepimut-S)	Non-small cell lung cancer	Butts C, Socinski MA, Mitchell PL, Thatcher N, Havel L, Krzakowski M, Nawrocki S, Ciuleanu TE, Bosquée L, Trigo JM, Spira A, Tremblay L, Nyman J, Ramlau R, Wickart-Johansson G, Ellis P, Gladkov O, Pereira JR, Eberhardt WE, Helwig C, Schröder A, Shepherd FA; START trial team. Tecemotide (L-BLP25) versus placebo after chemoradiotherapy for stage III non-small-cell lung cancer (START): a randomised, double-blind, phase 3 trial. <i>Lancet Oncol.</i> 2014 Jan;15(1):59-68. doi: 10.1016/S1470-2045(13)70510-2. Epub 2013 Dec 9. PMID: 24331154.	This trial did not contribute to FDA approval for the investigated indication.
N-15	NCT01578655	Custirsen (OGX-011), cabazitaxel and prednisone	Prostate cancer	Beer TM, Hotte SJ, Saad F, Alekseev B, Matveev V, Fléchon A, Gravis G, Joly F, Chi KN, Malik Z, Blumenstein B, Stewart PS, Jacobs CA, Fizazi K. Custirsen (OGX-011) combined with cabazitaxel and prednisone versus cabazitaxel and prednisone alone in patients with metastatic castration-resistant prostate cancer previously treated with docetaxel (AFFINITY): a randomised, open-label, international, phase 3 trial. <i>Lancet Oncol.</i> 2017 Nov;18(11):1532-1542. doi: 10.1016/S1470-2045(17)30605-8. Epub 2017 Oct 9. PMID: 29033099.	This trial did not contribute to FDA approval for the investigated indication.
N-16	NCT00130728	Bevacizumab plus erlotinib	Non-small cell lung cancer	Herbst RS, Ansari R, Bustin F, Flynn P, Hart L, Otterson GA, Vlahovic G, Soh CH, O'Connor P, Hainsworth J. Efficacy of bevacizumab plus erlotinib versus erlotinib alone in advanced non-small-cell lung cancer after failure of standard first-line chemotherapy (BeTa): a double-blind, placebo-controlled, phase 3 trial. <i>Lancet.</i> 2011 May 28;377(9780):1846-54. doi: 10.1016/S0140-6736(11)60545-X. PMID: 21621716; PMCID: PMC4134127.	This trial did not contribute to FDA approval for the investigated indication.
N-17	NCT01419197	T-DM1 (Trastuzumab emtansine)	Breast cancer	Krop IE, Kim SB, González-Martín A, LoRusso PM, Ferrero JM, Smitt M, Yu R, Leung AC, Wildiers H; TH3RESA study collaborators. Trastuzumab emtansine versus treatment of physician's choice for pretreated HER2-positive advanced breast cancer (TH3RESA): a randomised, open-label, phase 3 trial. <i>Lancet Oncol.</i> 2014 Jun;15(7):689-99. doi: 10.1016/S1470-2045(14)70178-0. Epub 2014 May 2. PMID: 24793816.	This trial did not contribute to FDA approval for the investigated indication.
N-18	NCT00686959	Pemetrexed plus cisplatin and thoracic radiation therapy	Non-small cell lung cancer	Brade AM, Wenz F, Koppe F, Lievens Y, San Antonio B, Iscoe NA, Hossain A, Chouaki N, Senan S. Radiation Therapy Quality Assurance (RTQA) of Concurrent Chemoradiation Therapy for Locally Advanced Non-Small Cell Lung Cancer in the PROCLAIM Phase 3 Trial. <i>Int J Radiat Oncol Biol Phys.</i> 2018 Jul 15;101(4):927-934. doi: 10.1016/j.jrobp.2018.04.015. Epub 2018 Apr 12. PMID: 29976505.	This trial did not contribute to FDA approval for the investigated indication.
N-19	NCT01191801	Vosaroxin plus cytarabine	Acute myeloid leukemia	Ravandi F, Ritchie EK, Sayar H, Lancet JE, Craig MD, Vey N, Strickland SA, Schiller GJ, Jabbour E, Erba HP, Pigneux A, Horst HA, Recher C, Klimek VM, Cortes J, Roboz GJ, Odenike O, Thomas X, Havelange V, Maertens J, Derigs HG, Heuser M, Damon L, Powell BL, Gaidano G, Carella AM, Wei A, Hogge D, Craig AR, Fox JA, Ward R, Smith JA, Acton G, Mehta C, Stuart RK, Kantarjian HM. Vosaroxin plus cytarabine versus placebo plus cytarabine in patients with first relapsed or refractory acute myeloid leukaemia (VALOR): a randomised, controlled, double-blind, multinational, phase 3 study. <i>Lancet Oncol.</i> 2015 Sep;16(9):1025-1036. doi: 10.1016/S1470-2045(15)00201-6. Epub 2015 Jul 30. PMID: 26234174; PMCID: PMC4822512.	This trial did not contribute to FDA approval for the investigated indication.
N-20	NCT01327885	Eribulin	Soft tissue sarcoma(liposarcoma and leiomyosarcoma)	Schöffski P, Chawla S, Maki RG, Italiano A, Gelderblom H, Choy E, Grignani G, Camargo V, Bauer S, Rha SY, Blay JY, Hohenberger P, D'Adamo D, Guo M, Chmielowski B, Le Cesne A, Demetri GD, Patel SR. Eribulin versus dacarbazine in previously treated patients with advanced liposarcoma or leiomyosarcoma: a randomised, open-label, multicentre, phase 3 trial. <i>Lancet.</i> 2016 Apr 16;387(10028):1629-37. doi: 10.1016/S0140-6736(15)01283-0. Epub 2016 Feb 10. PMID: 26874885.	This trial did not contribute to FDA approval for the investigated indication.

N-21	NCT01287585	ADI-PEG 20 plus BSC	Hepatocellular carcinoma	Abou-Alfa GK, Qin S, Ryoo BY, Lu SN, Yen CJ, Feng YH, Lim HY, Izzo F, Colombo M, Sarker D, Bolondi L, Vaccaro G, Harris WP, Chen Z, Hubner RA, Meyer T, Sun W, Harding JJ, Hollywood EM, Ma J, Wan PJ, Ly M, Bomalaski J, Johnston A, Lin CC, Chao Y, Chen LT. Phase III randomized study of second line ADI-PEG 20 plus best supportive care versus placebo plus best supportive care in patients with advanced hepatocellular carcinoma. <i>Ann Oncol</i> . 2018 Jun 1;29(6):1402-1408. doi: 10.1093/annonc/mdy101. PMID: 29659672.	This trial did not contribute to FDA approval for the investigated indication.
N-22	NCT00548548	Bevacizumab plus cisplatin and capecitabine	Gastric cancer	Ohtsu A, Shah MA, Van Cutsem E, Rha SY, Sawaki A, Park SR, Lim HY, Yamada Y, Wu J, Langer B, Starnawski M, Kang YK. Bevacizumab in combination with chemotherapy as first-line therapy in advanced gastric cancer: a randomized, double-blind, placebo-controlled phase III study. <i>J Clin Oncol</i> . 2011 Oct 20;29(30):3968-76. doi: 10.1200/JCO.2011.36.2236. Epub 2011 Aug 15. PMID: 21844504.	This trial did not contribute to FDA approval for the investigated indication.
N-23	NCT00762034	Pemetrexed plus carboplatin and bevacizumab	Non-small cell lung cancer	Patel JD, Socinski MA, Garon EB, Reynolds CH, Spigel DR, Olsen MR, Hermann RC, Jotte RM, Beck T, Richards DA, Guba SC, Liu J, Frimodt-Moller B, John WJ, Obasaju CK, Pennella EJ, Bonomi P, Govindan R. PointBreak: a randomized phase III study of pemetrexed plus carboplatin and bevacizumab followed by maintenance pemetrexed and bevacizumab versus paclitaxel plus carboplatin and bevacizumab followed by maintenance bevacizumab in patients with stage IIIB or IV nonsquamous non-small-cell lung cancer. <i>J Clin Oncol</i> . 2013 Dec 1;31(34):4349-57. doi: 10.1200/JCO.2012.47.9626. Epub 2013 Oct 21. PMID: 24145346; PMCID: PMC4881367.	This trial did not contribute to FDA approval for the investigated indication.
N-24	NCT02119663	Ruxolitinib plus capecitabine	Pancreatic cancer	Hurwitz H, Van Cutsem E, Bendell J, Hidalgo M, Li CP, Salvo MG, Macarulla T, Sahai V, Sama A, Greeno E, Yu KH, Verslype C, Dawkins F, Walker C, Clark J, O'Reilly EM. Ruxolitinib + capecitabine in advanced/metastatic pancreatic cancer after disease progression/intolerance to first-line therapy: JANUS 1 and 2 randomized phase III studies. <i>Invest New Drugs</i> . 2018 Aug;36(4):683-695. doi: 10.1007/s10637-018-0580-2. Epub 2018 Mar 6. PMID: 29508247; PMCID: PMC6752723.	This trial did not contribute to FDA approval for the investigated indication.
N-25	NCT02117479	Ruxolitinib plus capecitabine	Pancreatic cancer	Hurwitz H, Van Cutsem E, Bendell J, Hidalgo M, Li CP, Salvo MG, Macarulla T, Sahai V, Sama A, Greeno E, Yu KH, Verslype C, Dawkins F, Walker C, Clark J, O'Reilly EM. Ruxolitinib + capecitabine in advanced/metastatic pancreatic cancer after disease progression/intolerance to first-line therapy: JANUS 1 and 2 randomized phase III studies. <i>Invest New Drugs</i> . 2018 Aug;36(4):683-695. doi: 10.1007/s10637-018-0580-2. Epub 2018 Mar 6. PMID: 29508247; PMCID: PMC6752723.	This trial did not contribute to FDA approval for the investigated indication.
N-26	NCT01244191	Tivantinib (ARQ 197) plus erlotinib	Non-small cell lung cancer	Scagliotti G, von Pawel J, Novello S, Ramlau R, Favaretto A, Barlesi F, Akerley W, Orlov S, Santoro A, Spigel D, Hirsh V, Shepherd FA, Sequist LV, Sandler A, Ross JS, Wang Q, von Roemeling R, Shuster D, Schwartz B. Phase III Multinational, Randomized, Double-Blind, Placebo-Controlled Study of Tivantinib (ARQ 197) Plus Erlotinib Versus Erlotinib Alone in Previously Treated Patients With Locally Advanced or Metastatic Nonsquamous Non-Small-Cell Lung Cancer. <i>J Clin Oncol</i> . 2015 Aug 20;33(24):2667-74. doi: 10.1200/JCO.2014.60.7317. Epub 2015 Jul 13. PMID: 26169611.	This trial did not contribute to FDA approval for the investigated indication.
N-27	NCT01074047	Azacitidine	Acute myeloid leukemia	Dombret H, Seymour JF, Butrym A, Wierzbowska A, Selleslag D, Jang JH, Kumar R, Cavenagh J, Schuh AC, Candoni A, Récher C, Sandhu I, Bernal del Castillo T, Al-Ali HK, Martinelli G, Falantes J, Noppeney R, Stone RM, Minden MD, McIntyre H, Songer S, Lucy LM, Beach CL, Döhner H. International phase 3 study of azacitidine vs conventional care regimens in older patients with newly diagnosed AML with >30% blasts. <i>Blood</i> . 2015 Jul 16;126(3):291-9. doi: 10.1182/blood-2015-01-621664. Epub 2015 May 18. PMID: 25987659; PMCID: PMC4504945.	This trial did not contribute to FDA approval for the investigated indication.

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N-28	NCT00943826	Bevacizumab plus temozolomide and radiotherapy	Glioblastoma	Chinot OL, Wick W, Mason W, Henriksson R, Saran F, Nishikawa R, Carpentier AF, Hoang-Xuan K, Kavan P, Cernea D, Brandes AA, Hilton M, Abrey L, Cloughesy T. Bevacizumab plus radiotherapy-temozolomide for newly diagnosed glioblastoma. <i>N Engl J Med</i> . 2014 Feb 20;370(8):709-22. doi: 10.1056/NEJMoa1308345. PMID: 24552318.	This trial did not contribute to FDA approval for the investigated indication.
N-29	NCT00519285	Aflibercept plus docetaxel and predonisone	Prostate cancer	Tannock IF, Fizazi K, Ivanov S, Karlsson CT, Fléchon A, Skoneczna I, Orlandi F, Gravis G, Matveev V, Bavbek S, Gil T, Viana L, Arén O, Karyakin O, Elliott T, Birtle A, Magherini E, Hatteville L, Petrylak D, Tombal B, Rosenthal M; VENICE investigators. Aflibercept versus placebo in combination with docetaxel and prednisone for treatment of men with metastatic castration-resistant prostate cancer (VENICE): a phase 3, double-blind randomised trial. <i>Lancet Oncol</i> . 2013 Jul;14(8):760-8. doi: 10.1016/S1470-2045(13)70184-0. Epub 2013 Jun 4. PMID: 23742877.	This trial did not contribute to FDA approval for the investigated indication.
N-30	NCT02576977	Pembrolizumab plus pomalidomide and dexamethasone	Multiple myeloma	Mateos MV, Blacklock H, Schjesvold F, Oriol A, Simpson D, George A, Goldschmidt H, Larocca A, Chanan-Khan A, Sherbenou D, Avivi I, Benyamini N, Iida S, Matsumoto M, Suzuki K, Ribrag V, Usmani SZ, Jagannath S, Ocio EM, Rodriguez-Otero P, San Miguel J, Kher U, Farooqui M, Liao J, Marinello P, Lonial S; KEYNOTE-183 Investigators. Pembrolizumab plus pomalidomide and dexamethasone for patients with relapsed or refractory multiple myeloma (KEYNOTE-183): a randomised, open-label, phase 3 trial. <i>Lancet Haematol</i> . 2019 Sep;6(9):e459-e469. doi: 10.1016/S2352-3026(19)30110-3. Epub 2019 Jul 18. PMID: 31327687.	This trial did not contribute to FDA approval for the investigated indication.
N-31	NCT00065468	Temsirolimus plus interferon alpha	Renal cell carcinoma	Hudes G, Carducci M, Tomczak P, Dutcher J, Figlin R, Kapoor A, Staroslawska E, Sosman J, McDermott D, Bodrogi I, Kovacevic Z, Lesovoy V, Schmidt-Wolf IG, Barbarash O, Gokmen E, O'Toole T, Lustgarten S, Moore L, Motzer RJ; Global ARCC Trial. Temsirolimus, interferon alfa, or both for advanced renal-cell carcinoma. <i>N Engl J Med</i> . 2007 May 31;356(22):2271-81. doi: 10.1056/NEJMoa066838. PMID: 17538086.	This trial did not contribute to FDA approval for the investigated indication.
N-32	NCT01308567	Cabazitaxel 20 mg/m2	Prostate cancer	Oudard S, Fizazi K, Sengeløv L, Daugaard G, Saad F, Hansen S, Hjälm-Eriksson M, Jassem J, Thiery-Vuillemin A, Caffo O, Castellano D, Mainwaring PN, Bernard J, Shen L, Chadjaa M, Sartor O. Cabazitaxel Versus Docetaxel As First-Line Therapy for Patients With Metastatic Castration-Resistant Prostate Cancer: A Randomized Phase III Trial-FIRSTANA. <i>J Clin Oncol</i> . 2017 Oct 1;35(28):3189-3197. doi: 10.1200/JCO.2016.72.1068. Epub 2017 Jul 28. PMID: 28753384.	This trial did not contribute to FDA approval for the investigated indication.
N-33	NCT01308567	Cabazitaxel 25 mg/m2	Prostate cancer	Oudard S, Fizazi K, Sengeløv L, Daugaard G, Saad F, Hansen S, Hjälm-Eriksson M, Jassem J, Thiery-Vuillemin A, Caffo O, Castellano D, Mainwaring PN, Bernard J, Shen L, Chadjaa M, Sartor O. Cabazitaxel Versus Docetaxel As First-Line Therapy for Patients With Metastatic Castration-Resistant Prostate Cancer: A Randomized Phase III Trial-FIRSTANA. <i>J Clin Oncol</i> . 2017 Oct 1;35(28):3189-3197. doi: 10.1200/JCO.2016.72.1068. Epub 2017 Jul 28. PMID: 28753384.	This trial did not contribute to FDA approval for the investigated indication.
N-34	NCT02451943	Olaratumab plus doxorubicin	Soft tissue sarcoma	Tap WD, Wagner AJ, Schöffski P, Martin-Broto J, Krarup-Hansen A, Ganjoo KN, Yen CC, Abdul Razak AR, Spira A, Kawai A, Le Cesne A, Van Tine BA, Naito Y, Park SH, Fedenko A, Pápai Z, Soldatenkova V, Shahir A, Mo G, Wright J, Jones RL; ANNOUNCE Investigators. Effect of Doxorubicin Plus Olaratumab vs Doxorubicin Plus Placebo on Survival in Patients With Advanced Soft Tissue Sarcomas: The ANNOUNCE Randomized Clinical Trial. <i>JAMA</i> . 2020 Apr 7;323(13):1266-1276. doi: 10.1001/jama.2020.1707. PMID: 32259228; PMCID: PMC7139275.	This trial did not contribute to FDA approval for the investigated indication.
N-35	NCT01774786	Pertuzumab plus trastuzumab and chemotherapy	Gastric cancer	Tabernero J, Hoff PM, Shen L, Ohtsu A, Shah MA, Cheng K, Song C, Wu H, Eng-Wong J, Kim K, Kang YK. Pertuzumab plus trastuzumab and chemotherapy for HER2-positive metastatic gastric or gastro-oesophageal junction cancer (JACOB): final analysis of a double-blind, randomised, placebo-controlled phase 3 study. <i>Lancet Oncol</i> . 2018 Oct;19(10):1372-1384. doi: 10.1016/S1470-2045(18)30481-9. Epub 2018 Sep 11. PMID: 30217672.	This trial did not contribute to FDA approval for the investigated indication.

N-36	NCT01494506	Nanoliposomal irinotecan	Pancreatic cancer	Wang-Gillam A, Li CP, Bodoky G, Dean A, Shan YS, Jameson G, Macarulla T, Lee KH, Cunningham D, Blanc JF, Hubner RA, Chiu CF, Schwartzmann G, Siveke JT, Braiteh F, Moyo V, Belanger B, Dhindsa N, Bayever E, Von Hoff DD, Chen LT; NAPOLI-1 Study Group. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. <i>Lancet</i> . 2016 Feb 6;387(10018):545-557. doi: 10.1016/S0140-6736(15)00986-1. Epub 2015 Nov 29. Erratum in: <i>Lancet</i> . 2016 Feb 6;387(10018):536. PMID: 26615328.	This trial did not contribute to FDA approval for the investigated indication.
N-37	NCT00596830	Figitumumab plus paclitaxel and carboplatin	Non-small cell lung cancer	Langer CJ, Novello S, Park K, Krzakowski M, Karp DD, Mok T, Benner RJ, Scranton JR, Olszanski AJ, Jassem J. Randomized, phase III trial of first-line figitumumab in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin alone in patients with advanced non-small-cell lung cancer. <i>J Clin Oncol</i> . 2014 Jul 1;32(19):2059-66. doi: 10.1200/JCO.2013.54.4932. Epub 2014 Jun 2. PMID: 24888810; PMCID: PMC4067944.	This trial did not contribute to FDA approval for the investigated indication.
N-38	NCT01798485	Ganetespib plus docetaxel	Non-small cell lung cancer	Pillai RN, Fennell DA, Kovcin V, Ciuleanu TE, Ramlau R, Kowalski D, Schenker M, Yalcin I, Teofilovici F, Vukovic VM, Ramalingam SS. Randomized Phase III Study of Ganetespib, a Heat Shock Protein 90 Inhibitor, With Docetaxel Versus Docetaxel in Advanced Non-Small-Cell Lung Cancer (GALAXY-2). <i>J Clin Oncol</i> . 2020 Feb 20;38(6):613-622. doi: 10.1200/JCO.19.00816. Epub 2019 Dec 12. PMID: 31829907.	This trial did not contribute to FDA approval for the investigated indication.
N-39	NCT00680901	Lapatinib plus capecitabine and oxaliplatin	Gastric cancer	Hecht JR, Bang YJ, Qin SK, Chung HC, Xu JM, Park JO, Jeziorski K, Shparyk Y, Hoff PM, Sobrero A, Salman P, Li J, Protsenko SA, Wainberg ZA, Buyse M, Afenjar K, Houé V, Garcia A, Kaneko T, Huang Y, Khan-Wasti S, Santillana S, Press MF, Slamon D. Lapatinib in Combination With Capecitabine Plus Oxaliplatin in Human Epidermal Growth Factor Receptor 2-Positive Advanced or Metastatic Gastric, Esophageal, or Gastroesophageal Adenocarcinoma: TRIO-013/LOGIC--A Randomized Phase III Trial. <i>J Clin Oncol</i> . 2016 Feb 10;34(5):443-51. doi: 10.1200/JCO.2015.62.6598. Epub 2015 Nov 30. PMID: 26628478.	This trial did not contribute to FDA approval for the investigated indication.
N-40	NCT00087022	Girentuximab	Renal cell carcinoma	Chamie K, Donin NM, Klöpfer P, Bevan P, Fall B, Wilhelm O, Störkel S, Said J, Gambra M, Hawkins RE, Jankilevich G, Kapoor A, Kopyltsov E, Staehler M, Taari K, Wainstein AJA, Pantuck AJ, Beldegrun AS. Adjuvant Weekly Girentuximab Following Nephrectomy for High-Risk Renal Cell Carcinoma: The ARISER Randomized Clinical Trial. <i>JAMA Oncol</i> . 2017 Jul 1;3(7):913-920. doi: 10.1001/jamaoncol.2016.4419. PMID: 27787547; PMCID: PMC5824229.	This trial did not contribute to FDA approval for the investigated indication.
N-41	NCT00884741	Bevacizumab	Glioblastoma	Gilbert MR, Dignam JJ, Armstrong TS, Wefel JS, Blumenthal DT, Vogelbaum MA, Colman H, Chakravarti A, Pugh S, Won M, Jeraj R, Brown PD, Jaeckle KA, Schiff D, Stieber VW, Brachman DG, Werner-Wasik M, Tremont-Lukats IW, Sulman EP, Aldape KD, Curran WJ Jr, Mehta MP. A randomized trial of bevacizumab for newly diagnosed glioblastoma. <i>N Engl J Med</i> . 2014 Feb 20;370(8):699-708. doi: 10.1056/NEJMoa1308573. PMID: 24552317; PMCID: PMC4201043.	This trial did not contribute to FDA approval for the investigated indication.
N-42	NCT01193257	Orteronel (TAK-700) plus prednisone	Prostate cancer	Fizazi K, Jones R, Oudard S, Efstathiou E, Saad F, de Wit R, De Bono J, Cruz FM, Fountzilas G, Ulys A, Carcano F, Agarwal N, Agus D, Bellmunt J, Petrylak DP, Lee SY, Webb IJ, Tejura B, Borgstein N, Dreicer R. Phase III, randomized, double-blind, multicenter trial comparing orteronel (TAK-700) plus prednisone with placebo plus prednisone in patients with metastatic castration-resistant prostate cancer that has progressed during or after docetaxel-based therapy: ELM-PC 5. <i>J Clin Oncol</i> . 2015 Mar 1;33(7):723-31. doi: 10.1200/JCO.2014.56.5119. Epub 2015 Jan 26. PMID: 25624429; PMCID: PMC4879718.	This trial did not contribute to FDA approval for the investigated indication.

N-43	NCT00879333	Everolimus plus BSC	Gastric cancer	Ohtsu A, Ajani JA, Bai YX, Bang YJ, Chung HC, Pan HM, Sahmoud T, Shen L, Yeh KH, Chin K, Muro K, Kim YH, Ferry D, Tebbutt NC, Al-Batran SE, Smith H, Costantini C, Rizvi S, Lebwohl D, Van Cutsem E. Everolimus for previously treated advanced gastric cancer: results of the randomized, double-blind, phase III GRANITE-1 study. J Clin Oncol. 2013 Nov 1;31(31):3935-43. doi: 10.1200/JCO.2012.48.3552. Epub 2013 Sep 16. PMID: 24043745; PMCID: PMC5950503.	This trial did not contribute to FDA approval for the investigated indication.
N-44	NCT00744497	Dasatinib plus docetaxel	Prostate cancer	Araujo JC, Trudel GC, Saad F, Armstrong AJ, Yu EY, Bellmunt J, Wilding G, McCaffrey J, Serrano SV, Matveev VB, Efsthathiou E, Oudard S, Morris MJ, Sizer B, Goebell PJ, Heidenreich A, de Bono JS, Begbie S, Hong JH, Richardet E, Gallardo E, Paliwal P, Durham S, Cheng S, Logothetis CJ. Docetaxel and dasatinib or placebo in men with metastatic castration-resistant prostate cancer (READY): a randomised, double-blind phase 3 trial. Lancet Oncol. 2013 Dec;14(13):1307-16. doi: 10.1016/S1470-2045(13)70479-0. Epub 2013 Nov 8. PMID: 24211163; PMCID: PMC5478530.	This trial did not contribute to FDA approval for the investigated indication.
N-45	NCT01351415	Bevacizumab plus SOC	Non-small cell lung cancer	Gridelli C, de Castro Carpeno J, Dingemans AC, Griesinger F, Grossi F, Langer C, Ohe Y, Syrigos K, Thatcher N, Das-Gupta A, Truman M, Donica M, Smoljanovic V, Bennouna J. Safety and Efficacy of Bevacizumab Plus Standard-of-Care Treatment Beyond Disease Progression in Patients With Advanced Non-Small Cell Lung Cancer: The AvaALL Randomized Clinical Trial. JAMA Oncol. 2018 Dec 1;4(12):e183486. doi: 10.1001/jamaoncol.2018.3486. Epub 2018 Dec 13. Erratum in: JAMA Oncol. 2018 Dec 1;4(12):1792. PMID: 30177994; PMCID: PMC6440713.	This trial did not contribute to FDA approval for the investigated indication.
N-46	NCT00673049	Figitumumab plus erlotinib	Non-small cell lung cancer	Scagliotti GV, Bondarenko I, Blackhall F, Barlesi F, Hsia TC, Jassem J, Milanowski J, Popat S, Sanchez-Torres JM, Novello S, Benner RJ, Green S, Molpus K, Soria JC, Shepherd FA. Randomized, phase III trial of figitumumab in combination with erlotinib versus erlotinib alone in patients with nonadenocarcinoma nonsmall-cell lung cancer. Ann Oncol. 2015 Mar;26(3):497-504. doi: 10.1093/annonc/mdu517. Epub 2014 Nov 13. PMID: 25395283.	This trial did not contribute to FDA approval for the investigated indication.
N-47	NCT02152631	Abemaciclib plus BSC	Non-small cell lung cancer	Goldman JW, Mazieres J, Barlesi F, Dragnev KH, Koczywas M, Göskel T, Cortot AB, Girard N, Wessler C, Bischoff H, Nadal E, Park K, Lu S, Taus A, Cobo M, Estrem ST, Wijayawardana SR, Turner K, Oakley GJ 3rd, Hurt KC, Chiang AY, Hossain AM, John WJ, Paz-Ares L. A Randomized Phase III Study of Abemaciclib Versus Erlotinib in Patients with Stage IV Non-small Cell Lung Cancer With a Detectable KRAS Mutation Who Failed Prior Platinum-Based Therapy: JUNIPER. Front Oncol. 2020 Oct 26;10:578756. doi: 10.3389/fonc.2020.578756. PMID: 33194700; PMCID: PMC7649422.	This trial did not contribute to FDA approval for the investigated indication.
N-48	NCT01846611	Trabectedin and pegylated liposomal doxorubicin	Ovarian cancer	Monk BJ, Herzog TJ, Wang G, Triantos S, Maul S, Knoblauch R, McGowan T, Shalaby WSW, Coleman RL. A phase 3 randomized, open-label, multicenter trial for safety and efficacy of combined trabectedin and pegylated liposomal doxorubicin therapy for recurrent ovarian cancer. Gynecol Oncol. 2020 Mar;156(3):535-544. doi: 10.1016/j.ygyno.2019.12.043. Epub 2020 Jan 8. PMID: 31924332.	This trial did not contribute to FDA approval for the investigated indication.
N-49	NCT01721746	Nivolumab	Melanoma	Weber JS, D'Angelo SP, Minor D, Hodi FS, Gutzmer R, Neyns B, Hoeller C, Khushalani NI, Miller WH Jr, Lao CD, Linette GP, Thomas L, Lorigan P, Grossmann KF, Hassel JC, Maio M, Sznol M, Ascierto PA, Mohr P, Chmielowski B, Bryce A, Svane IM, Grob JJ, Krackhardt AM, Horak C, Lambert A, Yang AS, Larkin J. Nivolumab versus chemotherapy in patients with advanced melanoma who progressed after anti-CTLA-4 treatment (CheckMate 037): a randomised, controlled, open-label, phase 3 trial. Lancet Oncol. 2015 Apr;16(4):375-84. doi: 10.1016/S1470-2045(15)70076-8. Epub 2015 Mar 18. PMID: 25795410.	This trial did not contribute to FDA approval for the investigated indication.

N-50	NCT00988208	Lenalidomide plus docetaxel and prednisone	Prostate cancer	Petrylak DP, Vogelzang NJ, Budnik N, Wiechno PJ, Sternberg CN, Doner K, Bellmunt J, Burke JM, de Olza MO, Choudhury A, Gschwend JE, Kopyltsov E, Flechon A, Van As N, Houede N, Barton D, Fandi A, Jungnelius U, Li S, de Wit R, Fizazi K. Docetaxel and prednisone with or without lenalidomide in chemotherapy-naïve patients with metastatic castration-resistant prostate cancer (MAINSAIL): a randomised, double-blind, placebo-controlled phase 3 trial. <i>Lancet Oncol.</i> 2015 Apr;16(4):417-25. doi: 10.1016/S1470-2045(15)70025-2. Epub 2015 Mar 3. PMID: 25743937.	This trial did not contribute to FDA approval for the investigated indication.
N-51	NCT02555657	Pembrolizumab	Breast cancer	Winer EP, Lipatov O, Im SA, Goncalves A, Muñoz-Couselo E, Lee KS, Schmid P, Tamura K, Testa L, Witzel I, Ohtani S, Turner N, Zambelli S, Harbeck N, Andre F, Dent R, Zhou X, Karantza V, Mejia J, Cortes J; KEYNOTE-119 investigators. Pembrolizumab versus investigator-choice chemotherapy for metastatic triple-negative breast cancer (KEYNOTE-119): a randomised, open-label, phase 3 trial. <i>Lancet Oncol.</i> 2021 Apr;22(4):499-511. doi: 10.1016/S1470-2045(20)30754-3. Epub 2021 Mar 4. PMID: 33676601.	This trial did not contribute to FDA approval for the investigated indication.
N-52	NCT02788279	Atezolizumab plus cobimetinib	Colorectal cancer	Eng C, Kim TW, Bendell J, Argilés G, Tebbutt NC, Di Bartolomeo M, Falcone A, Fakih M, Kozloff M, Segal NH, Sobrero A, Yan Y, Chang I, Uyei A, Roberts L, Ciardiello F; IMblaze370 Investigators. Atezolizumab with or without cobimetinib versus regorafenib in previously treated metastatic colorectal cancer (IMblaze370): a multicentre, open-label, phase 3, randomised, controlled trial. <i>Lancet Oncol.</i> 2019 Jun;20(6):849-861. doi: 10.1016/S1470-2045(19)30027-0. Epub 2019 Apr 16. Erratum in: <i>Lancet Oncol.</i> 2019 Jun;20(6):e293. PMID: 31003911.	This trial did not contribute to FDA approval for the investigated indication.
N-53	NCT02788279	Atezolizumab	Colorectal cancer	Eng C, Kim TW, Bendell J, Argilés G, Tebbutt NC, Di Bartolomeo M, Falcone A, Fakih M, Kozloff M, Segal NH, Sobrero A, Yan Y, Chang I, Uyei A, Roberts L, Ciardiello F; IMblaze370 Investigators. Atezolizumab with or without cobimetinib versus regorafenib in previously treated metastatic colorectal cancer (IMblaze370): a multicentre, open-label, phase 3, randomised, controlled trial. <i>Lancet Oncol.</i> 2019 Jun;20(6):849-861. doi: 10.1016/S1470-2045(19)30027-0. Epub 2019 Apr 16. Erratum in: <i>Lancet Oncol.</i> 2019 Jun;20(6):e293. PMID: 31003911.	This trial did not contribute to FDA approval for the investigated indication.
N-54	NCT01697072	Rilotumumab plus epirubicin, cisplatin, and capecitabine	Gastric cancer	Catenacci DVT, Tebbutt NC, Davidenko I, Murad AM, Al-Batran SE, Ilson DH, Tjulandin S, Gotovkin E, Karaszewska B, Bondarenko I, Tejani MA, Udrea AA, Tehfe M, De Vita F, Turkington C, Tang R, Ang A, Zhang Y, Hoang T, Sidhu R, Cunningham D. Rilotumumab plus epirubicin, cisplatin, and capecitabine as first-line therapy in advanced MET-positive gastric or gastro-oesophageal junction cancer (RILOMET-1): a randomised, double-blind, placebo-controlled, phase 3 trial. <i>Lancet Oncol.</i> 2017 Nov;18(11):1467-1482. doi: 10.1016/S1470-2045(17)30566-1. Epub 2017 Sep 25. PMID: 28958504; PMCID: PMC5898242.	This trial did not contribute to FDA approval for the investigated indication.
N-55	NCT00861614	Ipilimumab	Prostate cancer	Kwon ED, Drake CG, Scher HI, Fizazi K, Bossi A, van den Eertwegh AJ, Krainer M, Houede N, Santos R, Mahammed H, Ng S, Maio M, Franke FA, Sundar S, Agarwal N, Bergman AM, Ciuleanu TE, Korbenfeld E, Sengeløv L, Hansen S, Logothetis C, Beer TM, McHenry MB, Gagnier P, Liu D, Gerritsen WR; CA184-043 Investigators. Ipilimumab versus placebo after radiotherapy in patients with metastatic castration-resistant prostate cancer that had progressed after docetaxel chemotherapy (CA184-043): a multicentre, randomised, double-blind, phase 3 trial. <i>Lancet Oncol.</i> 2014 Jun;15(7):700-12. doi: 10.1016/S1470-2045(14)70189-5. Epub 2014 May 13. PMID: 24831977; PMCID: PMC4418935.	This trial did not contribute to FDA approval for the investigated indication.
N-56	NCT00676650	Sunitinib plus prednisone	Prostate cancer	Michaelson MD, Oudard S, Ou YC, Sengeløv L, Saad F, Houede N, Ostler P, Stenzl A, Daugaard G, Jones R, Laestadius F, Ullén A, Bahl A, Castellano D, Gschwend J, Maurina T, Chow Maneval E, Wang SL, Lechuga MJ, Paolini J, Chen I. Randomized, placebo-controlled, phase III trial of sunitinib plus prednisone versus prednisone alone in progressive, metastatic, castration-resistant prostate cancer. <i>J Clin Oncol.</i> 2014	This trial did not contribute to FDA approval for the investigated indication.

				Jan 10;32(2):76-82. doi: 10.1200/JCO.2012.48.5268. Epub 2013 Dec 9. PMID: 24323035.	
N-57	NCT01000025	Dacomitinib	Non-small cell lung cancer	Ellis PM, Shepherd FA, Millward M, Perrone F, Seymour L, Liu G, Sun S, Cho BC, Morabito A, Leighl NB, Stockler MR, Lee CW, Wierzbiicki R, Cohen V, Blais N, Sangha RS, Favaretto AG, Kang JH, Tsao MS, Wilson CF, Goldberg Z, Ding K, Goss GD, Bradbury PA; NCIC CTG; Australasian Lung Cancer Trials Group; NCI Naples Clinical Trials Unit. Dacomitinib compared with placebo in pretreated patients with advanced or metastatic non-small-cell lung cancer (NCIC CTG BR.26): a double-blind, randomised, phase 3 trial. <i>Lancet Oncol.</i> 2014 Nov;15(12):1379-88. doi: 10.1016/S1470-2045(14)70472-3. Epub 2014 Oct 15. PMID: 25439692.	This trial did not contribute to FDA approval for the investigated indication.
N-58	NCT01605227	Cabozantinib	Prostate cancer	Smith M, De Bono J, Sternberg C, Le Moulec S, Oudard S, De Giorgi U, Krainer M, Bergman A, Hoelzer W, De Wit R, Bögemann M, Saad F, Cruciani G, Thiery-Vuillemin A, Feyerabend S, Miller K, Houédé N, Hussain S, Lam E, Polikoff J, Stenzl A, Mainwaring P, Ramies D, Hessel C, Weitzman A, Fizazi K. Phase III Study of Cabozantinib in Previously Treated Metastatic Castration-Resistant Prostate Cancer: COMET-1. <i>J Clin Oncol.</i> 2016 Sep 1;34(25):3005-13. doi: 10.1200/JCO.2015.65.5597. Epub 2016 Jul 11. PMID: 27400947.	This trial did not contribute to FDA approval for the investigated indication.
N-59	NCT02752074	Epacadostat plus pembrolizumab	Melanoma	Long GV, Dummer R, Hamid O, Gajewski TF, Caglevic C, Dalle S, Arance A, Carlino MS, Grob JJ, Kim TM, Demidov L, Robert C, Larkin J, Anderson JR, Maleski J, Jones M, Diede SJ, Mitchell TC. Epacadostat plus pembrolizumab versus placebo plus pembrolizumab in patients with unresectable or metastatic melanoma (ECHO-301/KEYNOTE-252): a phase 3, randomised, double-blind study. <i>Lancet Oncol.</i> 2019 Aug;20(8):1083-1097. doi: 10.1016/S1470-2045(19)30274-8. Epub 2019 Jun 17. PMID: 31221619.	This trial did not contribute to FDA approval for the investigated indication.
N-60	NCT00662597	Vadimezan (ASA404) plus carboplatin and paclitaxel	Non-small cell lung cancer	Lara PN Jr, Douillard JY, Nakagawa K, von Pawel J, McKeage MJ, Albert I, Losonczy G, Reck M, Heo DS, Fan X, Fandi A, Scagliotti G. Randomized phase III placebo-controlled trial of carboplatin and paclitaxel with or without the vascular disrupting agent vadimezan (ASA404) in advanced non-small-cell lung cancer. <i>J Clin Oncol.</i> 2011 Aug 1;29(22):2965-71. doi: 10.1200/JCO.2011.35.0660. Epub 2011 Jun 27. PMID: 21709202.	This trial did not contribute to FDA approval for the investigated indication.
N-61	NCT00774345	Lenalidomide	Chronic lymphocytic leukemia	Chanan-Khan AA, Zaritskey A, Egyed M, Vokurka S, Semochkin S, Schuh A, Kassis J, Simpson D, Zhang J, Purse B, Foà R. Lenalidomide maintenance therapy in previously treated chronic lymphocytic leukaemia (CONTINUUM): a randomised, double-blind, placebo-controlled, phase 3 trial. <i>Lancet Haematol.</i> 2017 Nov;4(11):e534-e543. doi: 10.1016/S2352-3026(17)30168-0. Epub 2017 Sep 25. PMID: 28958469.	This trial did not contribute to FDA approval for the investigated indication.
N-62	NCT02511405	Ofranergene obadenovec (VB-111) plus bevacizumab	Glioblastoma	Cloughesy TF, Brenner A, de Groot JF, Butowski NA, Zach L, Campian JL, Ellingson BM, Freedman LS, Cohen YC, Lowenton-Spier N, Rachmilewitz Minei T, Fain Shmueli S; GLOBE Study Investigators; Wen PY. A randomized controlled phase III study of VB-111 combined with bevacizumab vs bevacizumab monotherapy in patients with recurrent glioblastoma (GLOBE). <i>Neuro Oncol.</i> 2020 May 15;22(5):705-717. doi: 10.1093/neuonc/noz232. PMID: 31844890; PMCID: PMC7229248.	This trial did not contribute to FDA approval for the investigated indication.

N-63	NCT01492101	Etirinotecan pegol	Breast cancer	Perez EA, Awada A, O'Shaughnessy J, Rugo HS, Twelves C, Im SA, Gómez-Pardo P, Schwartzberg LS, Diéras V, Yardley DA, Potter DA, Mailliez A, Moreno-Aspitia A, Ahn JS, Zhao C, Hoch U, Tagliaferri M, Hannah AL, Cortes J. Etirinotecan pegol (NKTR-102) versus treatment of physician's choice in women with advanced breast cancer previously treated with an anthracycline, a taxane, and capecitabine (BEACON): a randomised, open-label, multicentre, phase 3 trial. <i>Lancet Oncol</i> . 2015 Nov;16(15):1556-1568. doi: 10.1016/S1470-2045(15)00332-0. Epub 2015 Oct 22. PMID: 26482278.	This trial did not contribute to FDA approval for the investigated indication.
N-64	NCT00938652	Iniparib plus gemcitabine and carboplatin	Breast cancer	O'Shaughnessy J, Schwartzberg L, Danso MA, Miller KD, Rugo HS, Neubauer M, Robert N, Hellerstedt B, Saleh M, Richards P, Specht JM, Yardley DA, Carlson RW, Finn RS, Charpentier E, Garcia-Ribas I, Winer EP. Phase III study of iniparib plus gemcitabine and carboplatin versus gemcitabine and carboplatin in patients with metastatic triple-negative breast cancer. <i>J Clin Oncol</i> . 2014 Dec 1;32(34):3840-7. doi: 10.1200/JCO.2014.55.2984. Epub 2014 Oct 27. PMID: 25349301.	This trial did not contribute to FDA approval for the investigated indication.
N-65	NCT01193244	Orteronel plus prednisone	Prostate cancer	Saad F, Fizazi K, Jinga V, Efsthathiou E, Fong PC, Hart LL, Jones R, McDermott R, Wirth M, Suzuki K, MacLean DB, Wang L, Akaza H, Nelson J, Scher HI, Dreicer R, Webb IJ, de Wit R; ELM-PC 4 investigators. Orteronel plus prednisone in patients with chemotherapy-naïve metastatic castration-resistant prostate cancer (ELM-PC 4): a double-blind, multicentre, phase 3, randomised, placebo-controlled trial. <i>Lancet Oncol</i> . 2015 Mar;16(3):338-48. doi: 10.1016/S1470-2045(15)70027-6. Epub 2015 Feb 18. PMID: 25701170.	This trial did not contribute to FDA approval for the investigated indication.
N-66	NCT01241500	Rigosertib	Myelodysplastic syndromes	Garcia-Manero G, Fenaux P, Al-Kali A, Baer MR, Sekeres MA, Roboz GJ, Gaidano G, Scott BL, Greenberg P, Platzbecker U, Steensma DP, Kambhampati S, Kreuzer KA, Godley LA, Atallah E, Collins R Jr, Kantarjian H, Jabbour E, Wilhelm FE, Azarnia N, Silverman LR; ONTIME study investigators. Rigosertib versus best supportive care for patients with high-risk myelodysplastic syndromes after failure of hypomethylating drugs (ONTIME): a randomised, controlled, phase 3 trial. <i>Lancet Oncol</i> . 2016 Apr;17(4):496-508. doi: 10.1016/S1470-2045(16)00009-7. Epub 2016 Mar 9. PMID: 26968357.	This trial did not contribute to FDA approval for the investigated indication.
N-67	NCT01655693	Doxorubicin-loaded nanoparticles	Hepatocellular carcinoma	Merle P, Blanc JF, Phelip JM, Pelletier G, Bronowicki JP, Touchefeu Y, Pageaux G, Gerolami R, Habersetzer F, Nguyen-Khac E, Casadei-Gardini A, Borbath I, Tran A, Wege H, Saad AS, Colombo M, Abergel A, Richou C, Waked I, Yee NS, Molé A, Attali P, Le Boulicaut J, Vasseur B; RELIVE Investigators. Doxorubicin-loaded nanoparticles for patients with advanced hepatocellular carcinoma after sorafenib treatment failure (RELIVE): a phase 3 randomised controlled trial. <i>Lancet Gastroenterol Hepatol</i> . 2019 Jun;4(6):454-465. doi: 10.1016/S2468-1253(19)30040-8. Epub 2019 Apr 4. Erratum in: <i>Lancet Gastroenterol Hepatol</i> . 2019 Jul;4(7):e6. Erratum in: <i>Lancet Gastroenterol Hepatol</i> . 2020 Feb;5(2):e1. PMID: 30954567.	This trial did not contribute to FDA approval for the investigated indication.
N-68	NCT01232556	Inotuzumab ozogamicin plus rituximab	Non-Hodgkin's lymphoma	Dang NH, Ogura M, Castaigne S, Fayad LE, Jerkeman M, Radford J, Pezzutto A, Bondarenko I, Stewart DA, Shnaidman M, Sullivan S, Vandendries E, Tobinai K, Ramchandren R, Hamlin PA, Giné E, Ando K. Randomized, phase 3 trial of inotuzumab ozogamicin plus rituximab versus chemotherapy plus rituximab for relapsed/refractory aggressive B-cell non-Hodgkin lymphoma. <i>Br J Haematol</i> . 2018 Aug;182(4):583-586. doi: 10.1111/bjh.14820. Epub 2017 Jul 5. PMID: 28677896; PMCID: PMC6200343.	This trial did not contribute to FDA approval for the investigated indication.
N-69	NCT00324155	Ipilimumab plus dacarbazine	Melanoma	Robert C, Thomas L, Bondarenko I, O'Day S, Weber J, Garbe C, Lebbe C, Baurain JF, Testori A, Grob JJ, Davidson N, Richards J, Maio M, Hauschild A, Miller WH Jr, Gascon P, Lotem M, Harmankaya K, Ibrahim R, Francis S, Chen TT, Humphrey R, Hoos A, Wolchok JD. Ipilimumab plus dacarbazine for previously untreated metastatic melanoma. <i>N Engl J Med</i> . 2011 Jun 30;364(26):2517-26. doi: 10.1056/NEJMoa1104621. Epub 2011 Jun 5. PMID: 21639810.	This trial did not contribute to FDA approval for the investigated indication.

N-70	NCT02106546	Veliparib plus carboplatin and paclitaxel	Non-small cell lung cancer	Ramalingam SS, Novello S, Guclu SZ, Bentsion D, Zvirbule Z, Szilasi M, Bernabe R, Syrigos K, Byers LA, Clingan P, Bar J, Vokes EE, Govindan R, Dunbar M, Ansell P, He L, Huang X, Sehgal V, Glasgow J, Bach BA, Mazieres J. Veliparib in Combination With Platinum-Based Chemotherapy for First-Line Treatment of Advanced Squamous Cell Lung Cancer: A Randomized, Multicenter Phase III Study. <i>J Clin Oncol</i> . 2021 Nov 10;39(32):3633-3644. doi: 10.1200/JCO.20.03318. Epub 2021 Aug 26. PMID: 34436928; PMCID: PMC8577684.	This trial did not contribute to FDA approval for the investigated indication.
N-71	NCT01999673	Bavituximab plus docetaxel	Non-small cell lung cancer	Gerber DE, Horn L, Boyer M, Sanborn R, Natale R, Palmero R, Bidoli P, Bondarenko I, Geronpre P, Ghizdavescu D, Kotsakis A, Lena H, Losonczy G, Park K, Su WC, Tang M, Lai J, Kallinteris NL, Shan JS, Reck M, Spigel DR. Randomized phase III study of docetaxel plus bavituximab in previously treated advanced non-squamous non-small-cell lung cancer. <i>Ann Oncol</i> . 2018 Jul 1;29(7):1548-1553. doi: 10.1093/annonc/mdy177. PMID: 29767677; PMCID: PMC6887726.	This trial did not contribute to FDA approval for the investigated indication.
N-72	NCT01057810	Ipilimumab	Prostate cancer	Beer TM, Kwon ED, Drake CG, Fizazi K, Logothetis C, Gravis G, Ganju V, Polikoff J, Saad F, Humanski P, Piulats JM, Gonzalez Mella P, Ng SS, Jaeger D, Parnis FX, Franke FA, Puente J, Carvajal R, Sengeløv L, McHenry MB, Varma A, van den Eertwegh AJ, Gerritsen W. Randomized, Double-Blind, Phase III Trial of Ipilimumab Versus Placebo in Asymptomatic or Minimally Symptomatic Patients With Metastatic Chemotherapy-Naive Castration-Resistant Prostate Cancer. <i>J Clin Oncol</i> . 2017 Jan;35(1):40-47. doi: 10.1200/JCO.2016.69.1584. Epub 2016 Oct 31. PMID: 28034081.	This trial did not contribute to FDA approval for the investigated indication.
N-73	NCT02369874	Durvalumab plus tremelimumab	Head and neck cancer	Ferris RL, Haddad R, Even C, Tahara M, Dvorkin M, Ciuleanu TE, Clement PM, Mesia R, Kutukova S, Zholudeva L, Daste A, Caballero-Daroqui J, Keam B, Vynnychenko I, Lafond C, Shetty J, Mann H, Fan J, Wildsmith S, Morsli N, Fayette J, Licitra L. Durvalumab with or without tremelimumab in patients with recurrent or metastatic head and neck squamous cell carcinoma: EAGLE, a randomized, open-label phase III study. <i>Ann Oncol</i> . 2020 Jul;31(7):942-950. doi: 10.1016/j.annonc.2020.04.001. Epub 2020 Apr 12. PMID: 32294530.	This trial did not contribute to FDA approval for the investigated indication.
N-74	NCT02369874	Durvalumab	Head and neck cancer	Ferris RL, Haddad R, Even C, Tahara M, Dvorkin M, Ciuleanu TE, Clement PM, Mesia R, Kutukova S, Zholudeva L, Daste A, Caballero-Daroqui J, Keam B, Vynnychenko I, Lafond C, Shetty J, Mann H, Fan J, Wildsmith S, Morsli N, Fayette J, Licitra L. Durvalumab with or without tremelimumab in patients with recurrent or metastatic head and neck squamous cell carcinoma: EAGLE, a randomized, open-label phase III study. <i>Ann Oncol</i> . 2020 Jul;31(7):942-950. doi: 10.1016/j.annonc.2020.04.001. Epub 2020 Apr 12. PMID: 32294530.	This trial did not contribute to FDA approval for the investigated indication.
N-75	NCT01322490	Rilimogene galvacirepvec plus G-CSF	Prostate cancer	Gulley JL, Borre M, Vogelzang NJ, Ng S, Agarwal N, Parker CC, Pook DW, Rathenborg P, Flaig TW, Carles J, Saad F, Shore ND, Chen L, Heery CR, Gerritsen WR, Priou F, Langkilde NC, Novikov A, Kantoff PW. Phase III Trial of PROSTVAC in Asymptomatic or Minimally Symptomatic Metastatic Castration-Resistant Prostate Cancer. <i>J Clin Oncol</i> . 2019 May 1;37(13):1051-1061. doi: 10.1200/JCO.18.02031. Epub 2019 Feb 28. PMID: 30817251; PMCID: PMC6494360.	This trial did not contribute to FDA approval for the investigated indication.
N-76	NCT01322490	Rilimogene galvacirepvec	Prostate cancer	Gulley JL, Borre M, Vogelzang NJ, Ng S, Agarwal N, Parker CC, Pook DW, Rathenborg P, Flaig TW, Carles J, Saad F, Shore ND, Chen L, Heery CR, Gerritsen WR, Priou F, Langkilde NC, Novikov A, Kantoff PW. Phase III Trial of PROSTVAC in Asymptomatic or Minimally Symptomatic Metastatic Castration-Resistant Prostate Cancer. <i>J Clin Oncol</i> . 2019 May 1;37(13):1051-1061. doi: 10.1200/JCO.18.02031. Epub 2019 Feb 28. PMID: 30817251; PMCID: PMC6494360.	This trial did not contribute to FDA approval for the investigated indication.

N-77	NCT02785952	Nivolumab plus ipilimumab	Non-small cell lung cancer	Gettinger SN, Redman MW, Bazhenova L, Hirsch FR, Mack PC, Schwartz LH, Bradley JD, Stinchcombe TE, Leighl NB, Ramalingam SS, Tavernier SS, Yu H, Unger JM, Minichiello K, Highleyman L, Papadimitrakopoulou VA, Kelly K, Gandara DR, Herbst RS. Nivolumab Plus Ipilimumab vs Nivolumab for Previously Treated Patients With Stage IV Squamous Cell Lung Cancer: The Lung-MAP S1400I Phase 3 Randomized Clinical Trial. JAMA Oncol. 2021 Sep 1;7(9):1368-1377. doi: 10.1001/jamaoncol.2021.2209. PMID: 34264316; PMCID: PMC8283667.	This trial did not contribute to FDA approval for the investigated indication.
N-78	NCT00460265	Panitumumab plus cisplatin and fluorouracil	Head and neck cancer	Vermorken JB, Stöhlmacher-Williams J, Davidenko I, Licitra L, Winkvist E, Villanueva C, Foa P, Rottey S, Skladowski K, Tahara M, Pai VR, Faivre S, Blajman CR, Forastiere AA, Stein BN, Oliner KS, Pan Z, Bach BA; SPECTRUM investigators. Cisplatin and fluorouracil with or without panitumumab in patients with recurrent or metastatic squamous-cell carcinoma of the head and neck (SPECTRUM): an open-label phase 3 randomised trial. Lancet Oncol. 2013 Jul;14(8):697-710. doi: 10.1016/S1470-2045(13)70181-5. Epub 2013 Jun 6. PMID: 23746666.	This trial did not contribute to FDA approval for the investigated indication.
N-79	NCT01641939	T-DM1 (Trastuzumab emtansine)	Gastric cancer	Thuss-Patience PC, Shah MA, Ohtsu A, Van Cutsem E, Ajani JA, Castro H, Mansoor W, Chung HC, Bodoky G, Shitara K, Phillips GDL, van der Horst T, Harle-Yge ML, Althaus BL, Kang YK. Trastuzumab emtansine versus taxane use for previously treated HER2-positive locally advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma (GATSBY): an international randomised, open-label, adaptive, phase 2/3 study. Lancet Oncol. 2017 May;18(5):640-653. doi: 10.1016/S1470-2045(17)30111-0. Epub 2017 Mar 23. PMID: 28343975.	This trial did not contribute to FDA approval for the investigated indication.
N-80	NCT01265901	IMA901 plus sunitinib	Renal cell carcinoma	Rini BI, Stenzl A, Zdrojowy R, Kogan M, Shkolnik M, Oudard S, Weikert S, Bracarda S, Crabb SJ, Bedke J, Ludwig J, Maurer D, Mendrzyk R, Wagner C, Mahr A, Fritsche J, Weinschenk T, Walter S, Kirner A, Singh-Jasuja H, Reinhardt C, Eisen T. IMA901, a multi-peptide cancer vaccine, plus sunitinib versus sunitinib alone, as first-line therapy for advanced or metastatic renal cell carcinoma (IMPRINT): a multicentre, open-label, randomised, controlled, phase 3 trial. Lancet Oncol. 2016 Nov;17(11):1599-1611. doi: 10.1016/S1470-2045(16)30408-9. Epub 2016 Oct 3. PMID: 27720136.	This trial did not contribute to FDA approval for the investigated indication.
N-81	NCT00337103	Eribulin mesylate	Breast cancer	Kaufman PA, Awada A, Twelves C, Yelle L, Perez EA, Velikova G, Olivo MS, He Y, Dutcus CE, Cortes J. Phase III open-label randomized study of eribulin mesylate versus capecitabine in patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane. J Clin Oncol. 2015 Feb 20;33(6):594-601. doi: 10.1200/JCO.2013.52.4892. Epub 2015 Jan 20. PMID: 25605862; PMCID: PMC4463422.	This trial did not contribute to FDA approval for the investigated indication.
N-82	NCT00574275	Aflibercept plus gemcitabine	Pancreatic cancer	Rougier P, Riess H, Manges R, Karasek P, Humblet Y, Barone C, Santoro A, Assadourian S, Hatteville L, Philip PA. Randomised, placebo-controlled, double-blind, parallel-group phase III study evaluating aflibercept in patients receiving first-line treatment with gemcitabine for metastatic pancreatic cancer. Eur J Cancer. 2013 Aug;49(12):2633-42. doi: 10.1016/j.ejca.2013.04.002. Epub 2013 Apr 30. PMID: 23642329.	This trial did not contribute to FDA approval for the investigated indication.
N-83	NCT00617669	Zibotentan plus docetaxel	Prostate cancer	Fizazi K, Higano CS, Nelson JB, Gleave M, Miller K, Morris T, Nathan FE, McIntosh S, Pemberton K, Moul JW. Phase III, randomized, placebo-controlled study of docetaxel in combination with zibotentan in patients with metastatic castration-resistant prostate cancer. J Clin Oncol. 2013 May 10;31(14):1740-7. doi: 10.1200/JCO.2012.46.4149. Epub 2013 Apr 8. Erratum in: J Clin Oncol. 2014 Oct 20;32(30):3461. Fizazi, Karim S [Corrected to Fizazi, Karim]. PMID: 23569308.	This trial did not contribute to FDA approval for the investigated indication.

N-84	NCT01456325	Onartuzumab plus erlotinib	Non-small cell lung cancer	Koeppen H, Yu W, Zha J, Pandita A, Penuel E, Rangell L, Raja R, Mohan S, Patel R, Desai R, Fu L, Do A, Parab V, Xia X, Januario T, Louie SG, Filvaroff E, Shames DS, Wistuba I, Lipkind M, Huang J, Lazarov M, Ramakrishnan V, Amler L, Phan SC, Patel P, Peterson A, Yauch RL. Biomarker analyses from a placebo-controlled phase II study evaluating erlotinib+onartuzumab in advanced non-small cell lung cancer: MET expression levels are predictive of patient benefit. Clin Cancer Res. 2014 Sep 1;20(17):4488-98. doi: 10.1158/1078-0432.CCR-13-1836. Epub 2014 Mar 31. PMID: 24687921; PMCID: PMC4504679.	This trial did not contribute to FDA approval for the investigated indication.
N-85	NCT01098266	NGR-hTNF plus chemotherapy or BSC	Mesothelioma	Gregorc V, Gaafar RM, Favaretto A, Grossi F, Jassem J, Polychronis A, Bidoli P, Tiseo M, Shah R, Taylor P, Novello S, Muzio A, Bearz A, Greillier L, Fontana F, Salini G, Lambiase A, O'Brien M. NGR-hTNF in combination with best investigator choice in previously treated malignant pleural mesothelioma (NGR015): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet Oncol. 2018 Jun;19(6):799-811. doi: 10.1016/S1470-2045(18)30193-1. Epub 2018 May 9. PMID: 29753703.	This trial did not contribute to FDA approval for the investigated indication.
N-86	NCT02625623	Avelumab	Gastric cancer	Bang YJ, Ruiz EY, Van Cutsem E, Lee KW, Wyrwicz L, Schenker M, Alsina M, Ryu MH, Chung HC, Evesque L, Al-Batran SE, Park SH, Lichinitser M, Boku N, Moehler MH, Hong J, Xiong H, Hallwachs R, Conti I, Taieb J. Phase III, randomised trial of avelumab versus physician's choice of chemotherapy as third-line treatment of patients with advanced gastric or gastro-oesophageal junction cancer: primary analysis of JAVELIN Gastric 300. Ann Oncol. 2018 Oct 1;29(10):2052-2060. doi: 10.1093/annonc/mdy264. PMID: 30052729; PMCID: PMC6225815.	This trial did not contribute to FDA approval for the investigated indication.
N-87	NCT02302807	Atezolizumab	Urothelial carcinoma	Powles T, Durán I, van der Heijden MS, Loriot Y, Vogelzang NJ, De Giorgi U, Oudard S, Retz MM, Castellano D, Bamias A, Fléchon A, Gravis G, Hussain S, Takano T, Leng N, Kadel EE 3rd, Banchereau R, Hegde PS, Mariathasan S, Cui N, Shen X, Derleth CL, Green MC, Ravaud A. Atezolizumab versus chemotherapy in patients with platinum-treated locally advanced or metastatic urothelial carcinoma (IMvigor211): a multicentre, open-label, phase 3 randomised controlled trial. Lancet. 2018 Feb 24;391(10122):748-757. doi: 10.1016/S0140-6736(17)33297-X. Epub 2017 Dec 18. Erratum in: Lancet. 2018 Oct 20;392(10156):1402. PMID: 29268948.	This trial did not contribute to FDA approval for the investigated indication.
N-88	NCT00626548	Zibotentan	Prostate cancer	Yu EY, Miller K, Nelson J, Gleave M, Fizazi K, Moul JW, Nathan FE, Higano CS. Detection of previously unidentified metastatic disease as a leading cause of screening failure in a phase III trial of zibotentan versus placebo in patients with nonmetastatic, castration resistant prostate cancer. J Urol. 2012 Jul;188(1):103-9. doi: 10.1016/j.juro.2012.03.008. Epub 2012 May 12. PMID: 22583636; PMCID: PMC3473078.	This trial did not contribute to FDA approval for the investigated indication.
N-89	NCT02395172	Avelumab	Non-small cell lung cancer	Barlesi F, Vansteenkiste J, Spigel D, Ishii H, Garassino M, de Marinis F, Özgüroğlu M, Szczesna A, Polychronis A, Uslu R, Krzakowski M, Lee JS, Calabrò L, Arén Frontera O, Ellers-Lenz B, Bajars M, Ruisi M, Park K. Avelumab versus docetaxel in patients with platinum-treated advanced non-small-cell lung cancer (JAVELIN Lung 200): an open-label, randomised, phase 3 study. Lancet Oncol. 2018 Nov;19(11):1468-1479. doi: 10.1016/S1470-2045(18)30673-9. Epub 2018 Sep 24. Erratum in: Lancet Oncol. 2018 Nov;19(11):e581. PMID: 30262187.	This trial did not contribute to FDA approval for the investigated indication.
N-90	NCT01285557	TS-1(Tegafur/gimeracil/oteracil) plus cisplatin	Gastric cancer	Ajani JA, Abramov M, Bondarenko I, Shparyk Y, Gorbunova V, Hontsa A, Otchenash N, Alsina M, Lazarev S, Feliu J, Elme A, Esko V, Abdalla K, Verma U, Benedetti F, Aoyama T, Mizuguchi H, Makris L, Rosati G; DIGEST Study Group. A phase III trial comparing oral S-1/cisplatin and intravenous 5-fluorouracil/cisplatin in patients with untreated diffuse gastric cancer. Ann Oncol. 2017 Sep 1;28(9):2142-2148. doi: 10.1093/annonc/mdx275. PMID: 28911091.	This trial did not contribute to FDA approval for the investigated indication.

N-91	NCT02149108	Nintedanib	Colorectal cancer	Van Cutsem E, Yoshino T, Lenz HJ, Lonardi S, Falcone A, Limón ML, Saunders M, Sobrero A, Park YS, Ferreiro R, Hong YS, Tomasek J, Taniguchi H, Ciardiello F, Stoeher J, Oum'Hamed Z, Vlassak S, Studeny M, Argiles G. Nintedanib for the treatment of patients with refractory metastatic colorectal cancer (LUME-Colon 1): a phase III, international, randomized, placebo-controlled study. <i>Ann Oncol.</i> 2018 Sep 1;29(9):1955-1963. doi: 10.1093/annonc/mdy241. PMID: 30010751; PMCID: PMC6158765.	This trial did not contribute to FDA approval for the investigated indication.
N-92	NCT01140347	Ramucirumab	Hepatocellular carcinoma	Zhu AX, Kang YK, Yen CJ, Finn RS, Galle PR, Llovet JM, Assenat E, Brandi G, Pracht M, Lim HY, Rau KM, Motomura K, Ohno I, Merle P, Daniele B, Shin DB, Gerken G, Borg C, Hiriart JB, Okusaka T, Morimoto M, Hsu Y, Abada PB, Kudo M; REACH-2 study investigators. Ramucirumab after sorafenib in patients with advanced hepatocellular carcinoma and increased α -fetoprotein concentrations (REACH-2): a randomised, double-blind, placebo-controlled, phase 3 trial. <i>Lancet Oncol.</i> 2019 Feb;20(2):282-296. doi: 10.1016/S1470-2045(18)30937-9. Epub 2019 Jan 18. PMID: 30665869.	This trial did not contribute to FDA approval for the investigated indication.
N-93	NCT01006252	Tasusulam	Melanoma	Hamid O, Ilaria R Jr, Garbe C, Wolter P, Maio M, Hutson TE, Arance A, Lorigan P, Lee J, Hauschild A, Mohr P, Hahka-Kemppinen M, Kaiser C, Turner PK, Conti I, Grob JJ. A randomized, open-label clinical trial of tasusulam sodium versus paclitaxel as second-line treatment in patients with metastatic melanoma. <i>Cancer.</i> 2014 Jul 1;120(13):2016-24. doi: 10.1002/cncr.28635. Epub 2014 Mar 26. PMID: 24676877.	This trial did not contribute to FDA approval for the investigated indication.
N-94	NCT00471146	Axitinib plus gemcitabine	Pancreatic cancer	Kindler HL, Ioka T, Richel DJ, Bennouna J, Létourneau R, Okusaka T, Funakoshi A, Furuse J, Park YS, Ohkawa S, Springett GM, Wasan HS, Trask PC, Bycott P, Ricart AD, Kim S, Van Cutsem E. Axitinib plus gemcitabine versus placebo plus gemcitabine in patients with advanced pancreatic adenocarcinoma: a double-blind randomised phase 3 study. <i>Lancet Oncol.</i> 2011 Mar;12(3):256-62. doi: 10.1016/S1470-2045(11)70004-3. PMID: 21306953.	This trial did not contribute to FDA approval for the investigated indication.
N-95	NCT00982111	Necitumumab plus pemetrexed and cisplatin	Non-small cell lung cancer	Paz-Ares L, Mezger J, Ciuleanu TE, Fischer JR, von Pawel J, Provencio M, Kazarnowicz A, Losonczy G, de Castro G Jr, Szczesna A, Crino L, Reck M, Ramlau R, Ulsperger E, Schumann C, Miziara JE, Lessa AE, Dediu M, Bálint B, Depenbrock H, Soldatenkova V, Kurek R, Hirsch FR, Thatcher N, Socinski MA; INSPIRE investigators. Necitumumab plus pemetrexed and cisplatin as first-line therapy in patients with stage IV non-squamous non-small-cell lung cancer (INSPIRE): an open-label, randomised, controlled phase 3 study. <i>Lancet Oncol.</i> 2015 Mar;16(3):328-37. doi: 10.1016/S1470-2045(15)70046-X. Epub 2015 Feb 18. PMID: 25701171.	This trial did not contribute to FDA approval for the investigated indication.
N-96	NCT01844505	Nivolumab plus ipilimumab	Melanoma	Larkin J, Chiarion-Sileni V, Gonzalez R, Grob JJ, Rutkowski P, Lao CD, Cowey CL, Schadendorf D, Wagstaff J, Dummer R, Ferrucci PF, Smylie M, Hogg D, Hill A, Márquez-Rodas I, Haanen J, Guidoboni M, Maio M, Schöffski P, Carlino MS, Lebbé C, McArthur G, Ascierto PA, Daniels GA, Long GV, Bastholt L, Rizzo JI, Balogh A, Moshyk A, Hodi FS, Wolchok JD. Five-Year Survival with Combined Nivolumab and Ipilimumab in Advanced Melanoma. <i>N Engl J Med.</i> 2019 Oct 17;381(16):1535-1546. doi: 10.1056/NEJMoa1910836. Epub 2019 Sep 28. PMID: 31562797.	This trial did not contribute to FDA approval for the investigated indication.
N-97	NCT02436668	Ibrutinib plus nab-paclitaxel and gemcitabine	Pancreatic cancer	Tempero M, Oh DY, Tabernero J, Reni M, Van Cutsem E, Hendifar A, Waldschmidt DT, Starling N, Bachet JB, Chang HM, Maurel J, Garcia-Carbonero R, Lonardi S, Coussens LM, Fong L, Tsao LC, Cole G Jr, James D, Macarulla T. Ibrutinib in combination with nab-paclitaxel and gemcitabine for first-line treatment of patients with metastatic pancreatic adenocarcinoma: phase III RESOLVE study. <i>Ann Oncol.</i> 2021 May;32(5):600-608. doi: 10.1016/j.annonc.2021.01.070. Epub 2021 Feb 1. PMID: 33539945.	This trial did not contribute to FDA approval for the investigated indication.

N-98	NCT03066778	Pembrolizumab plus etoposide and platinum based chemotherapy	Small cell lung cancer	Rudin CM, Awad MM, Navarro A, Gottfried M, Peters S, Csősi T, Cheema PK, Rodriguez-Abreu D, Wollner M, Yang JC, Mazieres J, Orlandi FJ, Luft A, Gümüş M, Kato T, Kalemkerian GP, Luo Y, Ebiana V, Pietanza MC, Kim HR; KEYNOTE-604 Investigators. Pembrolizumab or Placebo Plus Etoposide and Platinum as First-Line Therapy for Extensive-Stage Small-Cell Lung Cancer: Randomized, Double-Blind, Phase III KEYNOTE-604 Study. J Clin Oncol. 2020 Jul 20;38(21):2369-2379. doi: 10.1200/JCO.20.00793. Epub 2020 May 29. PMID: 32468956; PMCID: PMC7474472.	This trial did not contribute to FDA approval for the investigated indication.
N-99	NCT00924989	Linsitinib	Adrenocortical carcinoma	Fassnacht M, Berruti A, Baudin E, Demeure MJ, Gilbert J, Haak H, Kroiss M, Quinn DI, Hesseltine E, Ronchi CL, Terzolo M, Choueiri TK, Poondru S, Fleege T, Rorig R, Chen J, Stephens AW, Worden F, Hammer GD. Linsitinib (OSI-906) versus placebo for patients with locally advanced or metastatic adrenocortical carcinoma: a double-blind, randomised, phase 3 study. Lancet Oncol. 2015 Apr;16(4):426-35. doi: 10.1016/S1470-2045(15)70081-1. Epub 2015 Mar 18. PMID: 25795408.	This trial did not contribute to FDA approval for the investigated indication.
N-100	NCT01231347	Ganitumab 20 mg/kg plus gemcitabine	Pancreatic cancer	Fuchs CS, Azevedo S, Okusaka T, Van Laethem JL, Lipton LR, Riess H, Szczylak C, Moore MJ, Peeters M, Bodoky G, Ikeda M, Melichar B, Nemecek R, Ohkawa S, Świeboda-Sadlej A, Tjulandin SA, Van Cutsem E, Loberg R, Haddad V, Gansert JL, Bach BA, Carrato A. A phase 3 randomized, double-blind, placebo-controlled trial of ganitumab or placebo in combination with gemcitabine as first-line therapy for metastatic adenocarcinoma of the pancreas: the GAMMA trial. Ann Oncol. 2015 May;26(5):921-927. doi: 10.1093/annonc/mdv027. Epub 2015 Jan 21. PMID: 25609246; PMCID: PMC4804122.	This trial did not contribute to FDA approval for the investigated indication.
N-101	NCT01231347	Ganitumab 12 mg/kg plus gemcitabine	Pancreatic cancer	Fuchs CS, Azevedo S, Okusaka T, Van Laethem JL, Lipton LR, Riess H, Szczylak C, Moore MJ, Peeters M, Bodoky G, Ikeda M, Melichar B, Nemecek R, Ohkawa S, Świeboda-Sadlej A, Tjulandin SA, Van Cutsem E, Loberg R, Haddad V, Gansert JL, Bach BA, Carrato A. A phase 3 randomized, double-blind, placebo-controlled trial of ganitumab or placebo in combination with gemcitabine as first-line therapy for metastatic adenocarcinoma of the pancreas: the GAMMA trial. Ann Oncol. 2015 May;26(5):921-927. doi: 10.1093/annonc/mdv027. Epub 2015 Jan 21. PMID: 25609246; PMCID: PMC4804122.	This trial did not contribute to FDA approval for the investigated indication.
N-102	NCT01147939	Elacytarabine	Acute myeloid leukemia	Roboz GJ, Rosenblat T, Arellano M, Gobbi M, Altman JK, Montesinos P, O'Connell C, Solomon SR, Pigneux A, Vey N, Hills R, Jacobsen TF, Gianella-Borradori A, Foss Ø, Vetthusand S, Giles FJ. International randomized phase III study of elacytarabine versus investigator choice in patients with relapsed/refractory acute myeloid leukemia. J Clin Oncol. 2014 Jun 20;32(18):1919-26. doi: 10.1200/JCO.2013.52.8562. Epub 2014 May 19. PMID: 24841975.	This trial did not contribute to FDA approval for the investigated indication.
N-103	NCT01009593	Linifanib	Hepatocellular carcinoma	Cainap C, Qin S, Huang WT, Chung IJ, Pan H, Cheng Y, Kudo M, Kang YK, Chen PJ, Toh HC, Gorbunova V, Eskens FA, Qian J, McKee MD, Ricker JL, Carlson DM, El-Nowiem S. Linifanib versus Sorafenib in patients with advanced hepatocellular carcinoma: results of a randomized phase III trial. J Clin Oncol. 2015 Jan 10;33(2):172-9. doi: 10.1200/JCO.2013.54.3298. Epub 2014 Dec 8. Erratum in: J Clin Oncol. 2017 Aug 1;35(22):2590. PMID: 25488963; PMCID: PMC4279237.	This trial did not contribute to FDA approval for the investigated indication.
N-104	NCT00075686	Cetuximab plus gemcitabine	Pancreatic cancer	Philip PA, Benedetti J, Corless CL, Wong R, O'Reilly EM, Flynn PJ, Rowland KM, Atkins JN, Mirtsching BC, Rivkin SE, Khorana AA, Goldman B, Fenoglio-Preiser CM, Abbruzzese JL, Blanke CD. Phase III study comparing gemcitabine plus cetuximab versus gemcitabine in patients with advanced pancreatic adenocarcinoma: Southwest Oncology Group-directed intergroup trial S0205. J Clin Oncol. 2010 Aug 1;28(22):3605-10. doi: 10.1200/JCO.2009.25.7550. Epub 2010 Jul 6. PMID: 20606093; PMCID: PMC2917315.	This trial did not contribute to FDA approval for the investigated indication.

N-105	NCT01035229	Everolimus plus BSC	Hepatocellular carcinoma	Zhu AX, Kudo M, Assenat E, Cattani S, Kang YK, Lim HY, Poon RT, Blanc JF, Vogel A, Chen CL, Dorval E, Peck-Radosavljevic M, Santoro A, Daniele B, Furuse J, Jappe A, Perraud K, Anak O, Sellami DB, Chen LT. Effect of everolimus on survival in advanced hepatocellular carcinoma after failure of sorafenib: the EVOLVE-1 randomized clinical trial. JAMA. 2014 Jul 2;312(1):57-67. doi: 10.1001/jama.2014.7189. PMID: 25058218.	This trial did not contribute to FDA approval for the investigated indication.
N-106	NCT02367794	Atezolizumab plus carboplatin and nab-paclitaxel	Non-small cell lung cancer	Jotte R, Cappuzzo F, Vynnychenko I, Stroyakovskiy D, Rodríguez-Abreu D, Hussein M, Soo R, Conter HJ, Kozuki T, Huang KC, Graupner V, Sun SW, Hoang T, Jessop H, McClelland M, Ballinger M, Sandler A, Socinski MA. Atezolizumab in Combination With Carboplatin and Nab-Paclitaxel in Advanced Squamous NSCLC (IMpower131): Results From a Randomized Phase III Trial. J Thorac Oncol. 2020 Aug;15(8):1351-1360. doi: 10.1016/j.jtho.2020.03.028. Epub 2020 Apr 14. PMID: 32302702.	This trial did not contribute to FDA approval for the investigated indication.
N-107	NCT02370498	Pembrolizumab	Gastric cancer	Shitara K, Özgüroğlu M, Bang YJ, Di Bartolomeo M, Mandalà M, Ryu MH, Fornaro L, Olesiński T, Caglevic C, Chung HC, Muro K, Goekkurt E, Mansoor W, McDermott RS, Shacham-Shmueli E, Chen X, Mayo C, Kang SP, Ohtsu A, Fuchs CS; KEYNOTE-061 investigators. Pembrolizumab versus paclitaxel for previously treated, advanced gastric or gastro-oesophageal junction cancer (KEYNOTE-061): a randomised, open-label, controlled, phase 3 trial. Lancet. 2018 Jul 14;392(10142):123-133. doi: 10.1016/S0140-6736(18)31257-1. Epub 2018 Jun 4. PMID: 29880231.	This trial did not contribute to FDA approval for the investigated indication.
N-108	NCT00946712	Cetuximab plus carboplatin, paclitaxel with/without bevacizumab	Non-small cell lung cancer	Herbst RS, Redman MW, Kim ES, Semrad TJ, Bazhenova L, Masters G, Oettel K, Guaglianone P, Reynolds C, Karnad A, Arnold SM, Varella-Garcia M, Moon J, Mack PC, Blanke CD, Hirsch FR, Kelly K, Gandara DR. Cetuximab plus carboplatin and paclitaxel with or without bevacizumab versus carboplatin and paclitaxel with or without bevacizumab in advanced NSCLC (SWOG S0819): a randomised, phase 3 study. Lancet Oncol. 2018 Jan;19(1):101-114. doi: 10.1016/S1470-2045(17)30694-0. Epub 2017 Nov 20. PMID: 29169877; PMCID: PMC5847342.	This trial did not contribute to FDA approval for the investigated indication.
N-109	NCT03302234	Ipilimumab plus pembrolizumab	Non-small cell lung cancer	Boyer M, Şendur MAN, Rodríguez-Abreu D, Park K, Lee DH, Çiçin I, Yumuk PF, Orlandi FJ, Leal TA, Molinier O, Soparattanapaisarn N, Langleben A, Califano R, Medgyasszay B, Hsia TC, Otterson GA, Xu L, Piperdi B, Samkari A, Reck M; KEYNOTE-598 Investigators. Pembrolizumab Plus Ipilimumab or Placebo for Metastatic Non-Small-Cell Lung Cancer With PD-L1 Tumor Proportion Score ≥ 50%: Randomized, Double-Blind Phase III KEYNOTE-598 Study. J Clin Oncol. 2021 Jul 20;39(21):2327-2338. doi: 10.1200/JCO.20.03579. Epub 2021 Jan 29. PMID: 33513313.	This trial did not contribute to FDA approval for the investigated indication.
N-110	NCT02453282	Durvalumab plus tremelimumab	Non-small cell lung cancer	Rizvi NA, Cho BC, Reinmuth N, Lee KH, Luft A, Ahn MJ, van den Heuvel MM, Cobo M, Vicente D, Smolin A, Moiseyenko V, Antonia SJ, Le Moulec S, Robinet G, Natale R, Schneider J, Shepherd FA, Geater SL, Garon EB, Kim ES, Goldberg SB, Nakagawa K, Raja R, Higgs BW, Boothman AM, Zhao L, Scheuring U, Stockman PK, Chand VK, Peters S; MYSTIC Investigators. Durvalumab With or Without Tremelimumab vs Standard Chemotherapy in First-line Treatment of Metastatic Non-Small Cell Lung Cancer: The MYSTIC Phase 3 Randomized Clinical Trial. JAMA Oncol. 2020 May 1;6(5):661-674. doi: 10.1001/jamaoncol.2020.0237. Erratum in: JAMA Oncol. 2020 Nov 1;6(11):1815. PMID: 32271377; PMCID: PMC7146551.	This trial did not contribute to FDA approval for the investigated indication.
N-111	NCT02453282	Durvalumab	Non-small cell lung cancer	Rizvi NA, Cho BC, Reinmuth N, Lee KH, Luft A, Ahn MJ, van den Heuvel MM, Cobo M, Vicente D, Smolin A, Moiseyenko V, Antonia SJ, Le Moulec S, Robinet G, Natale R, Schneider J, Shepherd FA, Geater SL, Garon EB, Kim ES, Goldberg SB, Nakagawa K, Raja R, Higgs BW, Boothman AM, Zhao L, Scheuring U, Stockman PK, Chand VK, Peters S; MYSTIC Investigators. Durvalumab With or Without Tremelimumab vs Standard Chemotherapy in First-line Treatment of Metastatic Non-Small Cell Lung Cancer: The MYSTIC Phase 3 Randomized Clinical Trial. JAMA	This trial did not contribute to FDA approval for the investigated indication.

Oncol. 2020 May 1;6(5):661-674. doi: 10.1001/jamaoncol.2020.0237. Erratum in: JAMA Oncol. 2020 Nov 1;6(11):1815. PMID: 32271377; PMCID: PMC7146551.

N-112	NCT02853305	Pembrolizumab plus chemotherapy	Urothelial carcinoma	Powles T, Csősz T, Özgüroğlu M, Matsubara N, Géczi L, Cheng SY, Fradet Y, Oudard S, Vulsteke C, Morales Barrera R, Fléchon A, Gunduz S, Lorient Y, Rodriguez-Vida A, Mantani R, Yu EY, Nam K, Imai K, Homet Moreno B, Alva A; KEYNOTE-361 Investigators. Pembrolizumab alone or combined with chemotherapy versus chemotherapy as first-line therapy for advanced urothelial carcinoma (KEYNOTE-361): a randomised, open-label, phase 3 trial. Lancet Oncol. 2021 Jul;22(7):931-945. doi: 10.1016/S1470-2045(21)00152-2. Epub 2021 May 26. PMID: 34051178.	This trial did not contribute to FDA approval for the investigated indication.
N-113	NCT02853305	Pembrolizumab	Urothelial carcinoma	Powles T, Csősz T, Özgüroğlu M, Matsubara N, Géczi L, Cheng SY, Fradet Y, Oudard S, Vulsteke C, Morales Barrera R, Fléchon A, Gunduz S, Lorient Y, Rodriguez-Vida A, Mantani R, Yu EY, Nam K, Imai K, Homet Moreno B, Alva A; KEYNOTE-361 Investigators. Pembrolizumab alone or combined with chemotherapy versus chemotherapy as first-line therapy for advanced urothelial carcinoma (KEYNOTE-361): a randomised, open-label, phase 3 trial. Lancet Oncol. 2021 Jul;22(7):931-945. doi: 10.1016/S1470-2045(21)00152-2. Epub 2021 May 26. PMID: 34051178.	This trial did not contribute to FDA approval for the investigated indication.
N-114	NCT00676507	Belagenpumatucel-L	Non-small cell lung cancer	Giaccone G, Bazhenova LA, Nemunaitis J, Tan M, Juhász E, Ramlau R, van den Heuvel MM, Lal R, Kloecker GH, Eaton KD, Chu Q, Dunlop DJ, Jain M, Garon EB, Davis CS, Carrier E, Moses SC, Shawler DL, Fakhrizadeh H. A phase III study of belagenpumatucel-L, an allogeneic tumour cell vaccine, as maintenance therapy for non-small cell lung cancer. Eur J Cancer. 2015 Nov;51(16):2321-9. doi: 10.1016/j.ejca.2015.07.035. Epub 2015 Aug 14. PMID: 26283035.	This trial did not contribute to FDA approval for the investigated indication.
N-115	NCT00134056	Atrasentan plus docetaxel	Prostate cancer	Quinn DI, Tangen CM, Hussain M, Lara PN Jr, Goldkorn A, Moynihan CM, Garzotto MG, Mack PC, Carducci MA, Monk JP, Twardowski PW, Van Veldhuizen PJ, Agarwal N, Higano CS, Vogelzang NJ, Thompson IM Jr. Docetaxel and atrasentan versus docetaxel and placebo for men with advanced castration-resistant prostate cancer (SWOG S0421): a randomised phase 3 trial. Lancet Oncol. 2013 Aug;14(9):893-900. doi: 10.1016/S1470-2045(13)70294-8. Epub 2013 Jul 17. PMID: 23871417; PMCID: PMC4277263.	This trial did not contribute to FDA approval for the investigated indication.
N-116	NCT00262990	Patupilone	Ovarian cancer	Colombo N, Kutarska E, Dimopoulos M, Bae DS, Rzepka-Gorska I, Bidzinski M, Scambia G, Engelholm SA, Joly F, Weber D, El-Hashimy M, Li J, Souami F, Wing P, Engelholm S, Bamias A, Schwartz P. 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. J Clin Oncol. 2012 Nov 1;30(31):3841-7. doi: 10.1200/JCO.2011.38.8082. Epub 2012 Sep 17. PMID: 22987083.	This trial did not contribute to FDA approval for the investigated indication.
N-117	NCT03043872	Durvalumab plus tremelimumab and platinum-etoposide	Small cell lung cancer	Goldman JW, Dvorkin M, Chen Y, Reinmuth N, Hotta K, Trukhin D, Statsenko G, Hochmair MJ, Özgüroğlu M, Ji JH, Garassino MC, Voitko O, Poltoratskiy A, Ponce S, Verderame F, Havel L, Bondarenko I, Kaźmierz A, Losonczy G, Conev NV, Armstrong J, Byrne N, Thiagarajah P, Jiang H, Paz-Ares L; CASPIAN investigators. Durvalumab, with or without tremelimumab, plus platinum-etoposide versus platinum-etoposide alone in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): updated results from a randomised, controlled, open-label, phase 3 trial. Lancet Oncol. 2021 Jan;22(1):51-65. doi: 10.1016/S1470-2045(20)30539-8. Epub 2020 Dec 4. PMID: 33285097.	This trial did not contribute to FDA approval for the investigated indication.

N-118	NCT01188187	Custirsen plus docetaxel and prednisone	Prostate cancer	Chi KN, Higano CS, Blumenstein B, Ferrero JM, Reeves J, Feyerabend S, Gravis G, Merseburger AS, Stenzl A, Bergman AM, Mukherjee SD, Zalewski P, Saad F, Jacobs C, Gleave M, de Bono JS. Custirsen in combination with docetaxel and prednisone for patients with metastatic castration-resistant prostate cancer (SYNERGY trial): a phase 3, multicentre, open-label, randomised trial. <i>Lancet Oncol.</i> 2017 Apr;18(4):473-485. doi: 10.1016/S1470-2045(17)30168-7. Epub 2017 Mar 8. PMID: 28283282.	This trial did not contribute to FDA approval for the investigated indication.
N-119	NCT00825955	Brivanib plus BSC	Hepatocellular carcinoma	Llovet JM, Decaens T, Raoul JL, Boucher E, Kudo M, Chang C, Kang YK, Assenat E, Lim HY, Boige V, Mathurin P, Fartoux L, Lin DY, Bruix J, Poon RT, Sherman M, Blanc JF, Finn RS, Tak WY, Chao Y, Ezzeddine R, Liu D, Walters I, Park JW. Brivanib in patients with advanced hepatocellular carcinoma who were intolerant to sorafenib or for whom sorafenib failed: results from the randomized phase III BRISK-PS study. <i>J Clin Oncol.</i> 2013 Oct 1;31(28):3509-16. doi: 10.1200/JCO.2012.47.3009. Epub 2013 Aug 26. PMID: 23980090.	This trial did not contribute to FDA approval for the investigated indication.
N-120	NCT02807636	Atezolizumab plus platinum-based chemotherapy	Urothelial carcinoma	Galsky MD, Ariba JAA, Bamias A, Davis ID, De Santis M, Kikuchi E, Garcia-Del-Muro X, De Giorgi U, Mencinger M, Izumi K, Panni S, Gumus M, Özgüroğlu M, Kalebasty AR, Park SH, Alekseev B, Schutz FA, Li JR, Ye D, Vogelzang NJ, Bernhard S, Tayama D, Mariathasan S, Mecke A, Thåström A, Grande E; IMvigor130 Study Group. Atezolizumab with or without chemotherapy in metastatic urothelial cancer (IMvigor130): a multicentre, randomised, placebo-controlled phase 3 trial. <i>Lancet.</i> 2020 May 16;395(10236):1547-1557. doi: 10.1016/S0140-6736(20)30230-0. PMID: 32416780.	This trial did not contribute to FDA approval for the investigated indication.
N-121	NCT02807636	Atezolizumab	Urothelial carcinoma	Galsky MD, Ariba JAA, Bamias A, Davis ID, De Santis M, Kikuchi E, Garcia-Del-Muro X, De Giorgi U, Mencinger M, Izumi K, Panni S, Gumus M, Özgüroğlu M, Kalebasty AR, Park SH, Alekseev B, Schutz FA, Li JR, Ye D, Vogelzang NJ, Bernhard S, Tayama D, Mariathasan S, Mecke A, Thåström A, Grande E; IMvigor130 Study Group. Atezolizumab with or without chemotherapy in metastatic urothelial cancer (IMvigor130): a multicentre, randomised, placebo-controlled phase 3 trial. <i>Lancet.</i> 2020 May 16;395(10236):1547-1557. doi: 10.1016/S0140-6736(20)30230-0. PMID: 32416780.	This trial did not contribute to FDA approval for the investigated indication.
N-122	NCT01662869	Onartuzumab plus mFOLFOX6	Gastric cancer	Shah MA, Bang YJ, Lordick F, Alsina M, Chen M, Hack SP, Bruey JM, Smith D, McCaffery I, Shames DS, Phan S, Cunningham D. Effect of Fluorouracil, Leucovorin, and Oxaliplatin With or Without Onartuzumab in HER2-Negative, MET-Positive Gastroesophageal Adenocarcinoma: The METGastric Randomized Clinical Trial. <i>JAMA Oncol.</i> 2017 May 1;3(5):620-627. doi: 10.1001/jamaoncol.2016.5580. PMID: 27918764; PMCID: PMC5824210.	This trial did not contribute to FDA approval for the investigated indication.
N-123	NCT00085124	Oblimersen plus chemotherapy	Acute myeloid leukemia	Walker AR, Marcucci G, Yin J, Blum W, Stock W, Kohlschmidt J, Mrózek K, Carroll AJ, Eisfeld AK, Wang ES, Jacobson S, Kolitz JE, Thakuri M, Sutamtewagul G, Vij R, Stuart RK, Byrd JC, Bloomfield CD, Stone RM, Larson RA. Phase 3 randomized trial of chemotherapy with or without oblimersen in older AML patients: CALGB 10201 (Alliance). <i>Blood Adv.</i> 2021 Jul 13;5(13):2775-2787. doi: 10.1182/bloodadvances.2021004233. PMID: 34251414; PMCID: PMC8288671.	This trial did not contribute to FDA approval for the investigated indication.
N-124	NCT00128102	Vorinostat	Mesothelioma	Krug LM, Kindler HL, Calvert H, Manegold C, Tsao AS, Fennell D, Öhman R, Plummer R, Eberhardt WE, Fukuoka K, Gaafar RM, Lafitte JJ, Hillerdal G, Chu Q, Buikhuisen WA, Lubiniecki GM, Sun X, Smith M, Baas P. Vorinostat in patients with advanced malignant pleural mesothelioma who have progressed on previous chemotherapy (VANTAGE-014): a phase 3, double-blind, randomised, placebo-controlled trial. <i>Lancet Oncol.</i> 2015 Apr;16(4):447-56. doi: 10.1016/S1470-2045(15)70056-2. Epub 2015 Mar 20. Erratum in: <i>Lancet Oncol.</i> 2015 May;16(5):e199. PMID: 25800891.	This trial did not contribute to FDA approval for the investigated indication.

N-125	NCT02017717	Nivolumab	Glioblastoma	Reardon DA, Brandes AA, Omuro A, Mulholland P, Lim M, Wick A, Baehring J, Ahluwalia MS, Roth P, Bähr O, Phuphanich S, Sepulveda JM, De Souza P, Sahebjam S, Carleton M, Tatsuoka K, Taitt C, Zwirter R, Sampson J, Weller M. Effect of Nivolumab vs Bevacizumab in Patients With Recurrent Glioblastoma: The CheckMate 143 Phase 3 Randomized Clinical Trial. JAMA Oncol. 2020 Jul 1;6(7):1003-1010. doi: 10.1001/jamaoncol.2020.1024. PMID: 32437507; PMCID: PMC7243167.	This trial did not contribute to FDA approval for the investigated indication.
N-126	NCT01440088	Evofosfamide plus doxorubicin	Soft tissue sarcoma	Tap WD, Papai Z, Van Tine BA, Attia S, Ganjoo KN, Jones RL, Schuetz S, Reed D, Chawla SP, Riedel RF, Krarup-Hansen A, Toulmonde M, Ray-Coquard I, Hohenberger P, Grignani G, Cranmer LD, Okuno S, Agulnik M, Read W, Ryan CW, Alcindor T, Del Muro XFG, Budd GT, Tawbi H, Pearce T, Kroll S, Reinke DK, Schöffski P. Doxorubicin plus evofosfamide versus doxorubicin alone in locally advanced, unresectable or metastatic soft-tissue sarcoma (TH CR-406/SARC021): an international, multicentre, open-label, randomised phase 3 trial. Lancet Oncol. 2017 Aug;18(8):1089-1103. doi: 10.1016/S1470-2045(17)30381-9. Epub 2017 Jun 23. Erratum in: Lancet Oncol. 2018 Feb;19(2):e78. PMID: 28651927; PMCID: PMC7771354.	This trial did not contribute to FDA approval for the investigated indication.
N-127	NCT02420821	Atezolizumab plus bevacizumab	Renal cell carcinoma	Motzer RJ, Powles T, Atkins MB, Escudier B, McDermott DF, Alekseev BY, Lee JL, Suarez C, Stroyakovskiy D, De Giorgi U, Donskov F, Mellado B, Banchereau R, Hamidi H, Khan O, Craine V, Huseni M, Flinn N, Dubey S, Rini BI. Final Overall Survival and Molecular Analysis in IMmotion151, a Phase 3 Trial Comparing Atezolizumab Plus Bevacizumab vs Sunitinib in Patients With Previously Untreated Metastatic Renal Cell Carcinoma. JAMA Oncol. 2022 Feb 1;8(2):275-280. doi: 10.1001/jamaoncol.2021.5981. PMID: 34940781; PMCID: PMC8855230.	This trial did not contribute to FDA approval for the investigated indication.
N-128	NCT03038100	Atezolizumab plus bevacizumab and chemotherapy	Ovarian cancer	Moore KN, Bookman M, Sehouli J, Miller A, Anderson C, Scambia G, Myers T, Taskiran C, Robison K, Mäenpää J, Willmott L, Colombo N, Thomes-Pepin J, Lontos M, Gold MA, Garcia Y, Sharma SK, Darus CJ, Aghajanian C, Okamoto A, Wu X, Safin R, Wu F, Molinero L, Maiya V, Khor VK, Lin YG, Pignata S. Atezolizumab, Bevacizumab, and Chemotherapy for Newly Diagnosed Stage III or IV Ovarian Cancer: Placebo-Controlled Randomized Phase III Trial (IMagyn050/GOG 3015/ENGOT-OV39). J Clin Oncol. 2021 Jun 10;39(17):1842-1855. doi: 10.1200/JCO.21.00306. Epub 2021 Apr 23. Erratum in: J Clin Oncol. 2021 Jul 20;39(21):2420. PMID: 33891472; PMCID: PMC8189598.	This trial did not contribute to FDA approval for the investigated indication.
N-129	NCT02928224	Encorafenib plus binimetinib and cetuximab	Colorectal cancer	Kopetz S, Grothey A, Yaeger R, Van Cutsem E, Desai J, Yoshino T, Wasan H, Ciardiello F, Loupakakis F, Hong YS, Steeghs N, Guren TK, Arkenau HT, Garcia-Alfonso P, Pfeiffer P, Orlov S, Lonardi S, Elez E, Kim TW, Schellens JHM, Guo C, Krishnan A, Dekervel J, Morris V, Calvo Ferrandiz A, Tarpgaard LS, Braun M, Gollerkeri A, Keir C, Maharry K, Pickard M, Christy-Bittel J, Anderson L, Sandor V, Tabernero J. Encorafenib, Binimetinib, and Cetuximab in BRAF V600E-Mutated Colorectal Cancer. N Engl J Med. 2019 Oct 24;381(17):1632-1643. doi: 10.1056/NEJMoa1908075. Epub 2019 Sep 30. PMID: 31566309.	This trial did not contribute to FDA approval for the investigated indication.

Table S 2 Search parameters for ClinicalTrials.gov	
Items	Employed search parameters
Search Terms	Condition or disease: [Blank]
	Other terms: [Blank]
	Country: [Blank]
	Outcome measure: Survival
Study Type	Interventional
Study Phase	Phase 3
Study Status	Active, not recruiting; Completed; Suspended; Terminated; Withdrawn
Time Frame	Study start date from January 1, 1990, to January 1, 2021

Table S 3 Adjusted pooled effect sizes for OS hazard ratio following trim-and-fill sensitivity analysis

	FDA approved drugs (Observed: 79, Imputed: 19)	FDA non-approved drugs (Observed: 129, Imputed 40)	Relative disparity between FDA approved and non-approved drugs
Observed (n=208)	HR 0.703 (95% CI: 0.681- 0.725)	HR 0.948 (95% CI: 0.927- 0.970)	HR 0.245
Observed and Imputed (n=267)	HR 0.667 (95% CI: 0.644- 0.690)	HR 0.900 (95% CI: 0.877- 0.924)	HR 0.233
Difference	HR 0.036	HR 0.048	HR 0.012

The symbol n represents the number of arm-level comparisons. These comparisons were derived from 189 unique clinical trials.

Table S 4 Drugs for which FDA convened ODAC

NCT number	NCT02039726	NCT00065442	NCT02370498	NCT02807636	NCT02807636	NCT02425891
Study name	QuANTUM-R	IMPACT	KEYNOTE-061	IMvigor130	IMvigor130	IMpassion130
Study drug	Quizartinib	Sipuleucel-T	Pembrolizumab	Atezolizumab plus platinum-based chemotherapy (Gemcitabine plus Carboplatin or Cisplatin)	Atezolizumab	Atezolizumab plus nab-paclitaxel
Control drug	Salvage chemotherapy (LoDAC, MEC, or FLAG-IDA)	Placebo	Paclitaxel	Placebo plus platinum-based chemotherapy	Placebo plus platinum-based chemotherapy	Placebo plus nab-paclitaxel
Cancer type	Acute myeloid leukemia	Prostate cancer	Gastric cancer	Urothelial carcinoma	Urothelial carcinoma	Breast cancer (TNBC)
Treatment line	2L+	1L	2L	1L	1L	1L
Median OS of control [95% CI] (month)	4.7 [4.0 - 5.5]	21.7	8.3 [7.6 - 9.0]	13.4 [12.0-15.2]	13.1 [11.7 - 15.1]	18.7 [16.9 - 20.3]
Median OS of the study drug [95% CI] (month)	6.2 [5.3 - 7.2]	25.8	9.1 [6.2 - 10.7]	16.0 [13.9 - 18.9]	15.7 [13.1 - 17.8]	21.0 [19.0 - 22.6]
Extension of median OS (month)	1.5	4.1	0.8	2.6	2.6	2.3
Hazard ratio for OS [95% CI]	0.76 [0.58 - 0.98]	0.78 [0.61 - 0.98]	0.82 [0.66 - 1.03]	0.83 [0.69 - 1.00]	1.02 [0.83 - 1.24]	0.86 [0.72 - 1.02]
p-value for OS	0.02 ^{a)}	0.03 ^{b)}	0.0421 ^{c)}	0.027 ^{d)}	NA	0.078
Median PFS/EFS of control [95% CI] (month)	0.9 [0.1 - 1.3]	3.6	4.1 [3.1 - 4.2]	6.3 [6.2 - 7.0]	NA	5.5 [5.3 - 5.6]
Median PFS/EFS of the study drug [95% CI] (month)	1.4 [0.0 - 1.9]	3.7	1.5 [1.4 - 2.0]	8.2 [6.5 - 8.3]	NA	7.2 [5.6 - 7.4]
Extension of median PFS/EFS (month)	0.5	0.1	-2.6	1.9	NA	1.7
Hazard ratio for PFS/EFS [95% CI]	0.90 [0.70 - 1.16]	0.95 [0.77 - 1.17]	1.27 [1.03 - 1.57]	0.82 [0.70 - 0.96]	NA	0.80 [0.69 - 0.92]
p-value for PFS/EFS	0.11 ^{a)}	0.63	NA	0.007 ^{d)}	NA	0.0021
FDA approval status	Non-approved	Approved	Non-approved	Non-approved	Non-approved	Approved

^{a)} One-sided, stratified log-rank test, ^{b)} Two-sided Wald's test, ^{c)} One-sided, ^{d)} One-sided

Table S 5 Odds ratio for ODAC risk by efficacy in OS

	Whether the observed HR for OS is in boundary area or not (HR 0.74 - 0.86) n(%)		
	Yes	No	Total
FDA consulted with ODAC	5 [11.9%]	1 [0.6%]	6
FDA did not consult with ODAC	37 [88.1%]	165 [99.4%]	202
Total	42 [100%]	166 [100%]	208
Odds ratio		22.3	
p-value (Pearson's chi-squared test)		0.0001	

The symbol n represents the number of arm-level comparisons. These comparisons were derived from 189 unique clinical trials.

Table S 6 Comparison of logistic regression results between the primary and GEE models

	Primary model (Logistic regression using arm-paired samples)			GEE model (Logistic regression accounting for trial-level clustering)		
Number of arm-pairs	208			208		
Number of trial groups	—			189		
	Coefficient	Standard Error	p-value	Coefficient	Standard Error	p-value
OS hazard ratio	-24.56	3.54	< 0.001	-24.50	5.24	< 0.001
Constitant	19.75	2.87	< 0.001	19.70	4.33	< 0.001

Abbreviations: GEE, generalized estimating equation.