

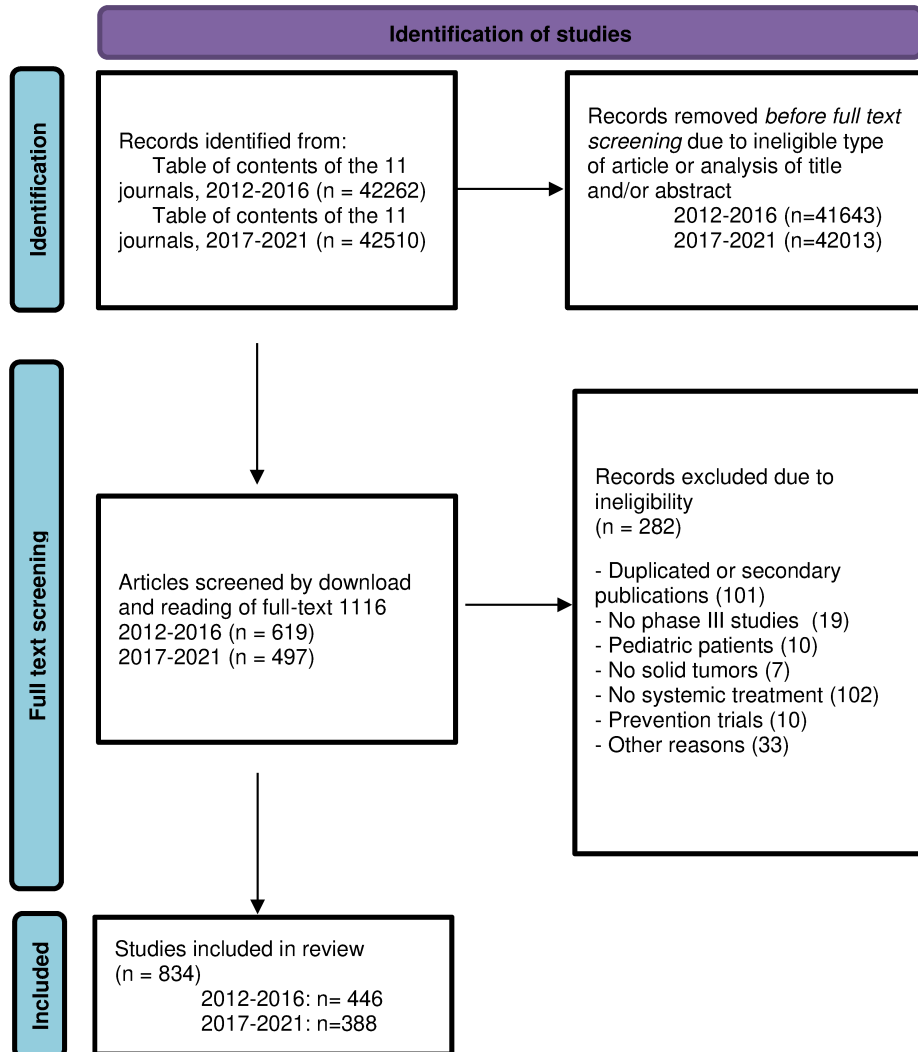
Time trends in health-related quality of life assessment and reporting within publications of oncology randomized phase III trials: a meta-research study.

Supplemental data

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Modified PRISMA 2020 flow diagram



Supplemental Table 1. Inclusion of health-related quality of life (QoL) among study endpoints and presence of QoL data in primary publications.

	2012-2016		2017-2021		Odds ratio (2017-2021 vs 2012-2016)
	N=446		N=388		
QoL included among study endpoints	236	(52.9%)	263	(67.8%)	1.87 (1.41-2.48)
<i>Reported in primary publication</i>	<i>147</i>	<i>(33.0%)</i>	<i>137</i>	<i>(35.3%)</i>	<i>1.11</i> <i>(0.83-1.48)</i>
<i>After a median follow-up (months):</i>	<i>43 months</i>		<i>34 months</i>		
<i>Not reported in primary publication but reported in a later publication</i>	<i>35</i>	<i>(7.8%)</i>	<i>42</i>	<i>(10.8%)</i>	
<i>Neither reported in primary publication nor (yet) in a later publication</i>	<i>54</i>	<i>(12.1%)</i>	<i>84</i>	<i>(21.6%)</i>	
QoL not included among study endpoints	210	(47.1%)	125	(32.2%)	

QoL: health-related quality of life

Supplemental Table 2. Inclusion of health-related quality of life among study endpoints according to characteristics of study and publication.

	2012-2016			2017-2021			Odds ratio
	Number of publications	QoL included among endpoints	QoL not included among endpoints	Number of publications	QoL included among endpoints	QoL not included among endpoints	
Whole series	446	236 (52.9%)	210 (47.1%)	388	263 (67.8%)	125 (32.2%)	1.87 (1.41-2.48)
Year of primary manuscript							
2012	94	49 (52.1%)	45 (47.9%)	-	-	-	Per 1 year: 1.13 (1.07-1.19)
2013	96	43 (44.8%)	53 (55.2%)	-	-	-	
2014	87	51 (58.6%)	36 (41.4%)	-	-	-	
2015	95	44 (46.3%)	51 (53.7%)	-	-	-	
2016	74	49 (66.2%)	25 (33.8%)	-	-	-	
2017	-	-	-	101	64 (63.4%)	37 (36.6%)	
2018	-	-	-	76	50 (65.8%)	26 (34.2%)	
2019	-	-	-	67	47 (70.1%)	20 (29.9%)	
2020	-	-	-	66	45 (68.2%)	21 (31.8%)	
2021	-	-	-	78	57 (73.1%)	21 (26.9%)	
Journal Impact Factor							
Low (<15)	101	40 (39.6%)	61 (60.4%)	61	25 (41.0%)	36 (59.0%)	1.06 (0.55-2.02)
Intermediate (15-30)	251	128 (51.0%)	123 (49.0%)	53	23 (43.4%)	30 (56.6%)	0.74 (0.41-1.34)
High (>30)	94	68 (72.3%)	26 (27.7%)	274	215 (78.5%)	59 (21.5%)	1.39 (0.82-2.38)
Study sponsor							
Industry-sponsored	209	126 (60.3%)	83 (39.7%)	226	186 (82.3%)	40 (17.7%)	3.06 (1.97-4.76)
Academic	237	110 (46.4%)	127 (53.6%)	162	77 (47.5%)	85 (52.5%)	1.05 (0.70-1.56)

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Supplemental Table 2 (continued)

	2012-2016			2017-2021			Odds ratio
	Number of publications	QoL included among endpoints	QoL not included among endpoints	Number of publications	QoL included among endpoints	QoL not included among endpoints	
Type of tumor							
Breast	84	36 (42.9%)	48 (57.1%)	88	45 (51.1%)	43 (48.9%)	1.40 (0.77-2.55)
Lung	83	53 (63.9%)	30 (36.1%)	68	49 (72.1%)	19 (27.9%)	1.46 (0.73-2.92)
GI	112	53 (47.3%)	59 (52.7%)	92	58 (63.0%)	34 (37.0%)	1.90 (1.08-3.33)
GU	57	35 (61.4%)	22 (38.6%)	52	44 (84.6%)	8 (15.4%)	3.46 (1.37-8.70)
Other	110	59 (53.6%)	51 (46.4%)	88	67 (76.1%)	21 (23.9%)	2.76 (1.49-5.11)
Disease stage							
Localized	124	43 (34.7%)	81 (65.3%)	118	59 (50.0%)	59 (50.0%)	1.88 (1.12-3.16)
Advanced / metastatic	322	193 (59.9%)	129 (40.1%)	270	204 (75.6%)	66 (24.4%)	2.07 (1.45-2.95)
Study design							
Superiority	412	217 (52.7%)	195 (47.3%)	355	242 (68.2%)	113 (31.8%)	1.92 (1.43-2.59)
Non-inferiority	34	19 (55.9%)	15 (44.1%)	33	21 (63.6%)	12 (36.4%)	1.38 (0.52-3.68)
Masking							
Open label	308	151 (49.0%)	157 (51.0%)	267	167 (62.5%)	100 (37.5%)	1.74 (1.24-2.42)
Blinded	138	85 (61.6%)	53 (38.4%)	121	96 (79.3%)	25 (20.7%)	2.39 (1.37-4.18)
Type of experimental therapy*							
Chemotherapy +/- other	273	137 (50.2%)	136 (49.8%)	203	114 (56.2%)	89 (43.8%)	1.27 (0.88-1.83)
Targeted therapy +/- other	210	119 (56.7%)	91 (43.3%)	180	133 (73.9%)	47 (26.1%)	2.16 (1.41-3.33)
Hormonal therapy +/- other	43	23 (53.5%)	20 (46.5%)	47	29 (61.7%)	18 (38.3%)	1.40 (0.61-3.24)
Immunotherapy +/- other	33	22 (66.7%)	11 (33.3%)	86	77 (89.5%)	9 (10.5%)	4.28 (1.57-11.63)

*Categories are not mutually exclusive

QoL: health-related quality of life; GI: gastrointestinal; GU: genitourinary.

Supplemental Table 3. Presence of QoL results in the publications of trials including QoL among endpoints

	2012-2016			2017-2021			Odds ratio
	Number of publications	QoL results present	QoL results absent	Number of publications	QoL results present	QoL results absent	
Whole series	236	147 (62.3%)	89 (37.7%)	263	137 (52.1%)	126 (47.9%)	0.66 (0.46-0.94)
Year of primary manuscript							
2012	49	32 (65.3%)	17 (34.7%)	-	-	-	Per 1 year: 0.92 (0.86-0.98)
2013	43	26 (60.5%)	17 (39.5%)	-	-	-	
2014	51	33 (64.7%)	18 (35.3%)	-	-	-	
2015	44	27 (61.4%)	17 (38.6%)	-	-	-	
2016	49	29 (59.2%)	20 (40.8%)	-	-	-	
2017	-	-	-	64	38 (59.4%)	26 (40.6%)	
2018	-	-	-	50	26 (52.0%)	24 (48.0%)	
2019	-	-	-	47	26 (55.3%)	21 (44.7%)	
2020	-	-	-	45	19 (42.2%)	26 (57.8%)	
2021	-	-	-	57	28 (49.1%)	29 (50.9%)	
Journal Impact Factor							
Low (<15)	40	28 (70.0%)	12 (30.0%)	25	20 (80.0%)	5 (20.0%)	1.71 (0.52-5.64)
Intermediate (15-30)	128	79 (61.7%)	49 (38.3%)	23	12 (52.2%)	11 (47.8%)	0.68 (0.28-1.65)
High (>30)	68	40 (58.8%)	28 (41.2%)	215	105 (48.8%)	110 (51.2%)	0.67 (0.39-1.16)
Study sponsor							
Industry-sponsored	126	79 (62.7%)	47 (37.3%)	186	90 (48.4%)	96 (51.6%)	0.56 (0.35-0.89)
Academic	110	68 (61.8%)	42 (38.2%)	77	47 (61.0%)	30 (39.0%)	0.97 (0.53-1.76)

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Supplemental Table 3 (continued)

	2012-2016			2017-2021			Odds ratio
	Number of publications	QoI results present	QoI results absent	Number of publications	QoI results present	QoI results absent	
Breast	36	16 (44.4%)	20 (55.6%)	45	23 (51.1%)	22 (48.9%)	1.31 (0.54-3.15)
Lung	53	38 (71.7%)	15 (28.3%)	49	17 (34.7%)	32 (65.3%)	0.21 (0.09-0.49)
GI	53	34 (64.2%)	19 (35.8%)	58	31 (53.4%)	27 (46.6%)	0.64 (0.30-1.38)
GU	35	23 (65.7%)	12 (34.3%)	44	23 (52.3%)	21 (47.7%)	0.57 (0.23-1.43)
Other	59	36 (61.0%)	23 (39.0%)	67	43 (64.2%)	24 (35.8%)	1.15 (0.56-2.36)
Disease stage							
Localized	43	25 (58.1%)	18 (41.9%)	59	31 (52.5%)	28 (47.5%)	0.80 (0.36-1.76)
Advanced / metastatic	193	122 (63.2%)	71 (36.8%)	204	106 (52.0%)	98 (48.0%)	0.63 (0.42-0.94)
Study design							
Superiority	217	134 (61.8%)	83 (38.2%)	242	123 (50.8%)	119 (49.2%)	0.64 (0.44-0.93)
Non-inferiority	19	13 (68.4%)	6 (31.6%)	21	14 (66.7%)	7 (33.3%)	0.92 (0.25-3.48)
Masking							
Open label	151	91 (60.3%)	60 (39.7%)	167	82 (49.1%)	85 (50.9%)	0.64 (0.41-0.99)
Blinded	85	56 (65.9%)	29 (34.1%)	96	55 (57.3%)	41 (42.7%)	0.70 (0.38-1.27)
Type of experimental therapy*							
Chemotherapy +/- other	137	79 (57.7%)	58 (42.3%)	114	61 (53.5%)	53 (46.5%)	0.85 (0.51-1.39)
Targeted therapy +/- other	119	78 (65.5%)	41 (34.5%)	133	75 (56.4%)	58 (43.6%)	0.68 (0.41-1.13)
Hormonal therapy +/- other	23	16 (69.6%)	7 (30.4%)	29	14 (48.3%)	15 (51.7%)	0.41 (0.13-1.29)
Immunotherapy +/- other	22	10 (45.5%)	12 (54.5%)	77	24 (31.2%)	53 (68.8%)	0.54 (0.21-1.43)

*Categories are not mutually exclusive

QoL: health-related quality of life; GI: gastrointestinal; GU: genitourinary.

Supplemental Table 4. Presence of QoL data in the whole series of publications

	2012-2016			2017-2021			Odds ratio
	Number of publications	QoL data present	QoL data absent	Number of publications	QoL data present	QoL data absent	
Whole series	446	147 (33.0%)	299 (67.0%)	388	137 (35.3%)	251 (64.7%)	1.11 (0.83-1.48)
Year of primary manuscript							
2012	94	32 (34.0%)	62 (66.0%)	-	-	-	Per 1 year: 1.02 (0.97-1.07)
2013	96	26 (27.1%)	70 (72.9%)	-	-	-	
2014	87	33 (37.9%)	54 (62.1%)	-	-	-	
2015	95	27 (28.4%)	68 (71.6%)	-	-	-	
2016	74	29 (39.2%)	45 (60.8%)	-	-	-	
2017	-	-	-	101	38 (37.6%)	63 (62.4%)	
2018	-	-	-	76	26 (34.2%)	50 (65.8%)	
2019	-	-	-	67	26 (38.8%)	41 (61.2%)	
2020	-	-	-	66	19 (28.8%)	47 (71.2%)	
2021	-	-	-	78	28 (35.9%)	50 (64.1%)	
Journal Impact Factor							
Low (<15)	101	28 (27.7%)	73 (72.3%)	61	20 (32.8%)	41 (67.2%)	1.27 (0.64-2.54)
Intermediate (15-30)	251	79 (31.5%)	172 (68.5%)	53	12 (22.6%)	41 (77.4%)	0.64 (0.32-1.28)
High (>30)	94	40 (42.6%)	54 (57.4%)	274	105 (38.3%)	169 (61.7%)	0.84 (0.52-1.35)
Study sponsor							
Industry-sponsored	209	79 (37.8%)	130 (62.2%)	226	90 (39.8%)	136 (60.2%)	1.09 (0.74-1.60)
Academic	237	68 (28.7%)	169 (71.3%)	162	47 (29.0%)	115 (71.0%)	1.02 (0.65-1.58)

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Supplemental Table 4 (continued)

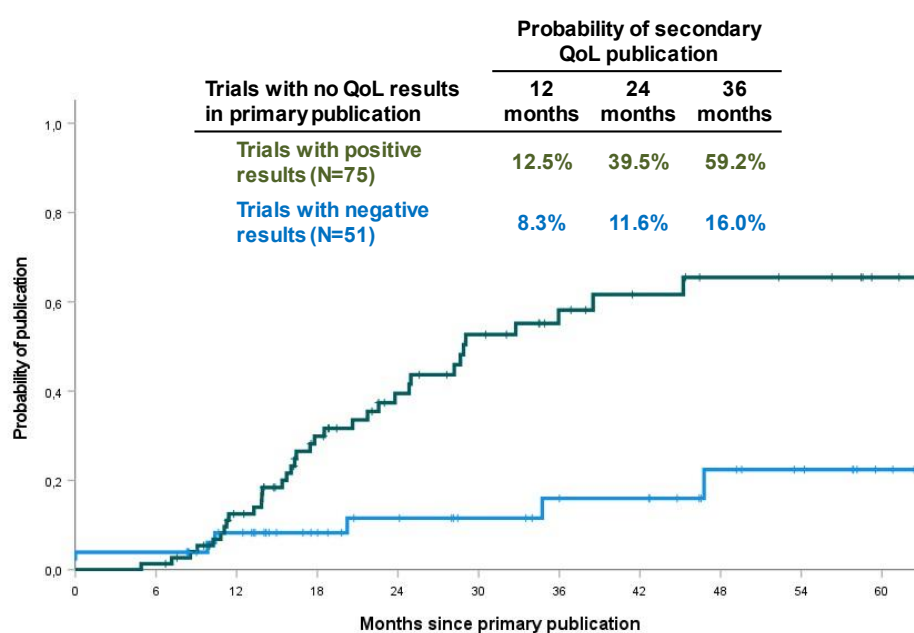
	2012-2016			2017-2021			Odds ratio
	Number of publications	QoI results present	QoI results absent	Number of publications	QoI results present	QoI results absent	
Type of malignancy							
Breast	84	16 (19.0%)	68 (81.0%)	88	23 (26.1%)	65 (73.9%)	1.50 (0.73-3.10)
Lung	83	38 (45.8%)	45 (54.2%)	68	17 (25.0%)	51 (75.0%)	0.40 (0.20-0.79)
GI	112	34 (30.4%)	78 (69.6%)	92	31 (33.7%)	61 (66.3%)	1.17 (0.65-2.11)
GU	57	23 (40.4%)	34 (59.6%)	52	23 (44.2%)	29 (55.8%)	1.17 (0.55-2.51)
Other	110	36 (32.7%)	74 (67.3%)	88	43 (48.9%)	45 (51.1%)	1.96 (1.10-3.50)
Disease stage							
Localized	124	25 (20.2%)	99 (79.8%)	118	31 (26.3%)	87 (73.7%)	1.41 (0.77-2.57)
Advanced / metastatic	322	122 (37.9%)	200 (62.1%)	270	106 (39.3%)	164 (60.7%)	1.06 (0.76-1.48)
Study design							
Superiority	412	134 (32.5%)	278 (67.5%)	355	123 (34.6%)	232 (65.4%)	1.10 (0.81-1.49)
Non-inferiority	34	13 (38.2%)	21 (61.8%)	33	14 (42.4%)	19 (57.6%)	1.19 (0.45-3.16)
Masking							
Open label	308	91 (29.5%)	217 (70.5%)	267	82 (30.7%)	185 (69.3%)	1.06 (0.74-1.51)
Blinded	138	56 (40.6%)	82 (59.4%)	121	55 (45.5%)	66 (54.5%)	1.22 (0.75-2.00)
Type of experimental therapy*							
Chemotherapy +/- other	273	79 (28.9%)	194 (71.1%)	203	61 (30.0%)	142 (70.0%)	1.06 (0.71-1.57)
Targeted therapy +/- other	210	78 (37.1%)	132 (62.9%)	180	75 (41.7%)	105 (58.3%)	1.21 (0.80-1.82)
Hormonal therapy +/- other	43	16 (37.2%)	27 (62.8%)	47	14 (29.8%)	33 (70.2%)	0.72 (0.30-1.73)
Immunotherapy +/- other	33	10 (30.3%)	23 (69.7%)	86	24 (27.9%)	62 (72.1%)	0.89 (0.37-2.15)

*Categories are not mutually exclusive

QoL: health-related quality of life; GI: gastrointestinal; GU: genitourinary.

Supplemental Figure 1. Kaplan-Meier curves of time to secondary publication with quality of life (QoL) results, for trials published between 2017-2021, including QoL among endpoints, but without any QoL result in the primary publication: analysis according to positive or negative results for the primary outcome.

Studies with negative results for the primary outcome (blue line) and studies with positive results for the primary outcome (green line).



LIST OF PRIMARY PUBLICATIONS

Annals of Oncology

1. Pagani O, Klingbiel D, Ruhstaller T, Nolè F, Eppenberger S, Oehlschlegel C, Bernhard J, Brauchli P, Hess D, Mamot C, Munzone E, Pestalozzi B, Rabaglio M, Aebi S, Ribi K, Rochlitz C, Rothgiesser K, Thürlimann B, von Moos R, Zaman K, Goldhirsch A; Swiss Group for Clinical Cancer Research (SAKK). Do all patients with advanced HER2 positive breast cancer need upfront-chemo when receiving trastuzumab? Randomized phase III trial SAKK 22/99. *Ann Oncol*. 2017 Feb 1;28(2):305-312. doi: 10.1093/annonc/mdw622. PMID: 27998961.
2. Yoshioka H, Katakami N, Okamoto H, Iwamoto Y, Seto T, Takahashi T, Sunaga N, Kudoh S, Chikamori K, Harada M, Tanaka H, Saito H, Saka H, Takeda K, Nogami N, Masuda N, Harada T, Kitagawa H, Horio H, Yamanaka T, Fukuoka M, Yamamoto N, Nakagawa K. A randomized, open-label, phase III trial comparing amrubicin versus docetaxel in patients with previously treated non-small-cell lung cancer. *Ann Oncol*. 2017 Feb 1;28(2):285-291. doi: 10.1093/annonc/mdw621. PMID: 28426104.
3. Shamash J, Sarker SJ, Huddart R, Harland S, Joffe JK, Mazhar D, Birtle A, White J, Chowdhury K, Wilson P, Marshall MR, Vinnicombe S. A randomized phase III study of 72 h infusional versus bolus bleomycin in BEP (bleomycin, etoposide and cisplatin) chemotherapy to treat IGCCCG good prognosis metastatic germ cell tumours (TE-3). *Ann Oncol*. 2017 Jun 1;28(6):1333-1338. doi:10.1093/annonc/mdx071. PMID: 28327896.
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5. Van Cutsem E, Bang YJ, Mansoor W, Petty RD, Chao Y, Cunningham D, Ferry DR, Smith NR, Frewer P, Ratnayake J, Stockman PK, Kilgour E, Landers D. A randomized, open-label study of the efficacy and safety of AZD4547 monotherapy versus paclitaxel for the treatment of advanced gastric adenocarcinoma with FGFR2 polysomy or gene amplification. *Ann Oncol*. 2017 Jun 1;28(6):1316-1324. doi: 10.1093/annonc/mdx107. PMID: 29177434.
6. Möbus V, von Minckwitz G, Jackisch C, Lück HJ, Schneeweiss A, Tesch H, Elling D, Harbeck N, Conrad B, Fehm T, Huober J, Müller V, Bauerfeind I, du Bois A, Loibl S, Nekljudova V, Untch M, Thomssen C; German Breast Group (GBG), the AGO Breast Study Group (AGO-B) and NOGGO Study Groups. German Adjuvant Intergroup Node-positive Study (GAIN): a phase III trial comparing two dose-dense regimens (iddEPC versus ddEC-PwX) in high-risk early breast cancer patients. *Ann Oncol*. 2017 Aug 1;28(8):1803-1810. doi: 10.1093/annonc/mdx203. PMID: 28459941.
7. Ghi MG, Paccagnella A, Ferrari D, Foa P, Alterio D, Codecà C, Nolè F, Verri E, Orecchia R, Morelli F, Parisi S, Mastromauro C, Mione CA, Rossetto C, Polsinelli M, Koussis H, Loreggian L, Bonetti A, Campostrini F, Azzarello G, D'Ambrosio C, Bertoni F, Casanova C, Emiliani E, Guaraldi M, Bunkheila F, Bidoli P, Niespolo RM, Gava A, Massa E, Frattegiani A, Valduga F, Pieri G, Cipani T, Da Corte D, Chiappa F, Rulli E; GSTTC (Gruppo di Studio Tumori della Testa e del Collo) Italian Study Group.

- Induction TPF followed by concomitant treatment versus concomitant treatment alone in locally advanced head and neck cancer. A phase II-III trial. *Ann Oncol.* 2017 Sep 1;28(9):2206-2212. doi: 10.1093/annonc/mdx299. PMID: 28911070.
8. 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. *Ann Oncol.* 2017 Sep 1;28(9):2241-2247. doi: 10.1093/annonc/mdx284. PMID: 28911085; PMCID: PMC5834051.
 9. 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.
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 11. Nokihara H, Lu S, Mok TSK, Nakagawa K, Yamamoto N, Shi YK, Zhang L, Soo RA, Yang JC, Sugawara S, Nishio M, Takahashi T, Goto K, Chang J, Maemondo M, Ichinose Y, Cheng Y, Lim WT, Morita S, Tamura T. Randomized controlled trial of S-1 versus docetaxel in patients with non-small-cell lung cancer previously treated with platinum-based chemotherapy (East Asia S-1 Trial in Lung Cancer). *Ann Oncol.* 2017 Nov 1;28(11):2698-2706. doi: 10.1093/annonc/mdx419. PMID:29045553; PMCID: PMC5834128.
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LIST OF SECONDARY PUBLICATIONS INCLUDING QOL RESULTS

1. Shibahara H, Shiroywa T, Ishiguro M, Nakamura M, Hasegawa J, Yamaguchi S, Masuda Y, Sakamoto J, Tomita N, Fukuda T. Cost-effectiveness of 12 months of capecitabine as adjuvant chemotherapy for stage III colon cancer: preplanned cost-effectiveness analysis of the JFMC37-0801 study. *Eur J Health Econ.* 2022 Sep;23(7):1159-1171. doi: 10.1007/s10198-021-01418-6. Epub 2022 Jan 24. PMID: 35072852; PMCID: PMC9395498.
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