

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

Laura Marandino ¹, Federica Trastu,² Eleonora Ghisoni,³ Pasquale Lombardi,⁴ Annapaola Mariniello,^{5,6} Maria Lucia Reale ⁵, Giacomo Aimar,⁷ Marco Audisio,⁵ Maristella Bungaro,⁵ Andrea Caglio,² Raimondo Di Liello ⁸, Teresa Gamba,² Piera Gargiulo,⁸ Chiara Paratore ⁵, Alessandro Rossi,⁹ Valentina Tuninetti ², Fabio Turco,^{5,10} Francesco Perrone ⁸, Massimo Di Maio ²

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LM and FT contributed equally.

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For numbered affiliations see end of article.

Correspondence to
Prof Massimo Di Maio;
massimo.dimaio@unito.it

ABSTRACT

Objective To assess time trends in the inclusion of health-related quality of life (QoL) among study endpoints and in the reporting of QoL results in study publications, randomised phase III oncology trials published between 2017 and 2021 were compared with the trials published in the previous 5 years.

Methods and analysis All issues published between 2012 and 2021 by 11 major journals were handsearched for primary publications of phase III trials in adult patients with solid tumours. Trials published in 2017–2021 were compared with trials published in 2012–2016 for three endpoints: (1) proportion of publications including QoL among endpoints out of all the eligible publications; (2) proportion of publications presenting QoL results out of those including QoL among endpoints and (3) proportion of publications presenting QoL data out of all the eligible publications.

Results 388 publications between 2017 and 2021 were eligible and compared with 446 publications between 2012 and 2016. QoL was included among endpoints in 67.8% of trials in 2017–2021 vs 52.9% in 2012–2016 (univariate OR 1.87, 95% CI 1.41 to 2.48, $p < 0.001$). QoL results were available in 52.1% in 2017–2021 vs 62.3% in 2012–2016 of primary publications of trials including QoL among endpoints (OR 0.66, 95% CI 0.46 to 0.94, $p = 0.02$). Overall, QoL was analysed and presented in 35.3% of primary publications in 2017–2021 vs 33.0% in 2012–2016 (OR 1.11, 95% CI 0.83 to 1.48, $p = 0.48$).

Conclusions The proportion of oncology trials including QoL among endpoints increased in 2017–2021 compared with 2012–2016. However, the proportion of primary publications reporting QoL results remains suboptimal.

INTRODUCTION

Patient-reported outcomes (PROs) should play a crucial role in determining the value of treatment for patients with cancer.^{1–3} The subjective nature of PROs, which are evaluated by patients based on their own perceptions, imply per se a more accurate reflection

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Despite the importance of health-related quality of life (QoL) to determine treatment value for patients with cancer, several analyses have shown suboptimal inclusion of patient-reported outcomes and QoL among study endpoints in oncology randomised controlled trials, and suboptimal reporting of QoL results.
- ⇒ Scientific societies and regulatory agencies have recently emphasised the relevance of QoL in oncology trials, but time trends of QoL inclusion among study endpoints and reporting of QoL results in publication have not been formally described.

WHAT THIS STUDY ADDS

- ⇒ In this 10-year analysis, the proportion of oncology randomised phase III trials that included QoL as a study endpoint has increased in recent years, especially in industry-sponsored trials.
- ⇒ In many cases, although collected according to study protocol, QoL data are not presented in the primary publication and this trend is worsening in recent years.
- ⇒ Journals with higher impact factor publish more frequently trials which did include QoL in study protocol, but those journals often do not ask for inclusion of those results in the study publication.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Overall, the proportion of trials reporting QoL results in primary publications remains suboptimal. This should stimulate discussion within investigators, journal editors, peer-reviewers and the whole scientific community.

of the patient's view about the impact of treatment on their symptoms and quality of life (QoL).⁴ The availability of PROs and QoL data helps clinicians to communicate the benefits and the risks of a treatment, beyond

traditional investigator-assessed endpoints. Radiological control of the disease and length of survival, which represent the traditional study endpoints for treatment activity and efficacy, are not the only relevant outcomes for patients, particularly for those with advanced disease.^{5,6}

In a previous systematic review of 446 phase III trials conducted in solid tumours and published in major oncology journals between 2012 and 2016, we found that a relevant proportion of trials did not include QoL among study endpoints.⁷ Namely, QoL was not included among endpoints in 47.1% of all trials, in 40.1% of trials conducted in the advanced/metastatic setting, 39.7% of industry-sponsored trials and 53.6% of academic trials. Furthermore, we found that QoL results, even when collected, were often not reported in the primary publication: out of 231 primary publications of trials with QoL as secondary or exploratory endpoint, QoL results were absent in 38.1% of cases, in 37.6% of publications in the advanced/metastatic setting, in 37.1% of industry-sponsored and 39.3% of academic trials. Disappointingly, the proportion of trials not including QoL as endpoint or not reporting QoL results was relevant in all tumour types and for all treatment categories. In addition, when analysing the timing of secondary publications including QoL results, we frequently observed a relevant delay in the publication.

In recent years, the value of PROs has been repeatedly recognised by regulatory agencies and scientific societies.^{8–11} The European Medicines Agency and the US Food and Drug Administration have both provided guidance for their use specifically in the setting of oncology clinical trials,^{8,9} and some societies incorporated the data into instruments developed to define the value of a treatment, such as the European Society for Medical Oncology -Magnitude of Clinical Benefit Scale.^{10,11} To allow a complete assessment of treatment value, PROs and QoL results should be published concurrently with efficacy and safety data.^{12,13} However, according to our previous analysis⁷ and other studies,¹⁴ this was often not the case, due to the above-described deficiencies in the inclusion of QoL among endpoints and in the reporting of QoL results in the publications.

With the aim of assessing time trends in QoL assessment and reporting, we reviewed phase III oncology trials published in major oncology journals between 2017 and 2021, and compared the results with the previous 5 years. In addition, we analysed the whole 10-year dataset in order to describe the characteristics of the trial and of the journal associated with the inclusion of QoL among endpoints and with the reporting of QoL results in the publication.

METHODS

For this analysis, we chose the same 11 major journals that were included in the previous search to compare the results for the period 2017–2021 with the results for the period 2012–2016 considered in the previously

published report.⁷ All the issues of these journals were screened for primary publications of randomised phase III trials testing anticancer drugs in adult patients with solid tumours (Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart in the online supplemental data). Inclusion criteria were the same as the previous analysis.⁷ Trials testing supportive care drugs were excluded, unless their outcome was anticancer efficacy. Trials testing non-pharmacological interventions were not included, as well as trials conducted in paediatric patients (<18 years old) and in haematological malignancies, and trials testing prevention strategies.

Data were collected using a dedicated electronic form. For each study, details about publication (journal, year, first author, date of definitive and ahead-of-print publication, availability of online supplemental material and/or study protocol) were collected. Impact factor (IF) corresponding to the year of publication was considered, according to the Journal of Citation Reports, and papers were conventionally divided into three IF categories: low (<15), intermediate (15–30) and high (>30). These cut-offs were based on the IQR of the studies included in the 2012–2016 analysis, and for homogeneity, we maintained the same cut-offs for the 2017–2021 period. Among the information recorded about the trial, those included study sponsor (industry-sponsored vs academic), type of primary tumour, disease setting (adjuvant vs neoadjuvant vs advanced/metastatic), study design (superiority vs non-inferiority), masking (open label vs blinded), details of treatment in both experimental and control arms. Trials were considered as industry sponsored when sponsored by the drug company and as academic when sponsored by an academic institution or a cooperative group, even if receiving drug supply and/or economic support from one or more drug companies. Experimental treatments were classified into four main categories (not mutually exclusive): chemotherapy±other drugs; targeted agents±other drugs; hormonal treatment±other drugs; immunotherapy±other drugs.

Endpoint information (primary/secondary/exploratory) was obtained from the paper, the study protocol (when available as online supplemental material), or the ClinicalTrials.gov record (when available). The presence of QoL details in the publication (in the main text and/or in online supplemental appendix) was recorded. For all records, secondary QoL publications were searched in PubMed, by using the name of the drug(s) and/or tumour type and/or the name of authors of the primary publication and/or the study acronym, when available. Time to secondary QoL publication was calculated according to Kaplan-Meier method, from the date of primary publication to the date of secondary QoL publication, if any, or to the date of last PubMed check (15 April 2022).

Results of the 2017–2021 period were compared with trials published in 2012–2016 for three endpoints: (1) proportion of publications including QoL among study endpoints out of all the eligible publications; (2) proportion of publications presenting QoL results out of those

including QoL among endpoints and (3) proportion of publications presenting QoL results out of all the eligible publications. For the main comparison (2017–2021 vs 2012–2016) and for subgroup analysis based on study or publication characteristics (journal IF, study sponsor, type of tumour, disease setting, study design, masking, type of experimental treatment), the three endpoints were expressed in terms of OR with 95% CI. In addition, for each of the three endpoints, multivariate analysis was performed by logistic regression model in the whole 10-year dataset.

Patients and the public were not directly involved in the design and conduct of this research. However, considering the implications of our results for the discussion within scientific community, we plan to interact and cooperate with patients' associations in oncology to disseminate and discuss our results.

All analyses were performed with IBM SPSS Statistics for Windows, V.27.0.

RESULTS

Study characteristics

In total, 388 eligible publications were identified in the 11 journals between 2017 and 2021 (the complete list is reported in online supplemental data). The main characteristics of the eligible publications, compared with the 446 included in the previous review (2012–2016) are reported in [table 1](#). The three most represented journals were *Lancet Oncology* (97 papers, 25.0%) *Journal of Clinical Oncology* (73 papers, 18.8%) and *New England Journal of Medicine* (70 papers, 18.0%). Most trials (270, 69.6%) were conducted in patients with advanced/metastatic disease. Chemotherapy±other drugs (203, 52.3%), targeted therapy±other drugs (180, 46.4%) and immunotherapy±other drugs (86, 22.2%) were the most common experimental treatments. The majority of the trials (226, 58.2%) were sponsored by the drug company, while the remaining (162, 41.8%) were academic.

Inclusion of QoL among study endpoints

QoL was included among study endpoints in 263 (67.8%) trials published in the period 2017–2021 (online supplemental tables 1 and 2). Namely, in these 5 years, QoL was included among endpoints in a higher proportion of industry-sponsored trials (82.3%) compared with academic trials (47.5%), with a higher difference compared with 2012–2016. Like in the previous 5 years, the inclusion of QoL among endpoints was higher in journals with higher IF (high IF 78.5%, intermediate IF 43.4% and low IF 41%) and in the subgroup of trials conducted in patients with advanced/metastatic disease (75.6%) compared with trials conducted in the (neo) adjuvant setting (50.0%).

Overall, the proportion of trials including QoL among endpoints in the period 2017–2021 was significantly higher compared with the period 2012–2016 (67.8% vs 52.9%, OR 1.87, 95% CI 1.41 to 2.48, $p < 0.001$) ([figure 1](#)).

Table 1 Characteristics of the publications included in the analysis

	2012–2016 (n=446)	2017–2021 (n=388)
Year of primary manuscript		
2012	94 (21.1)	–
2013	96 (21.5)	–
2014	87 (19.5)	–
2015	95 (21.3)	–
2016	74 (16.6)	–
2017	–	101 (26.0)
2018	–	76 (19.6)
2019	–	67 (17.3)
2020	–	66 (17.0)
2021	–	78 (20.1)
Primary manuscript journal		
<i>Annals of Oncology</i>	61 (13.7)	41 (10.6)
<i>British Journal of Cancer</i>	8 (1.8)	8 (2.1)
<i>Cancer</i>	7 (1.6)	3 (0.8)
<i>European Journal of Cancer</i>	22 (4.9)	24 (6.2)
<i>JAMA</i>	7 (1.6)	7 (1.8)
<i>JAMA Oncology</i>	1 (0.2)	25 (6.4)
<i>Journal of Clinical Oncology</i>	139 (31.2)	73 (18.8)
<i>Journal of the National Cancer Institute</i>	3 (0.7)	4 (1.0)
<i>Lancet</i>	30 (6.7)	36 (9.3)
<i>Lancet Oncology</i>	123 (27.6)	97 (25.0)
<i>New England Journal of Medicine</i>	45 (10.1)	70 (18.0)
Journals' impact factor		
Low (<15)	101 (22.6%)	61 (15.7%)
Intermediate (15–30)	251 (56.3%)	53 (13.7%)
High (>30)	94 (21.1%)	274 (70.6%)
Study sponsor		
Industry-sponsored	209 (46.9)	226 (58.2)
Academic	237 (53.1)	162 (41.8)
Type of tumour		
Breast	84 (18.8)	88 (22.7)
Lung	83 (18.6)	68 (17.5)
GI	109 (24.4)	92 (23.7)
GU	55 (12.3)	52 (13.4)
Other	115 (25.8)	88 (22.7)
Disease stage		
Localised	124 (27.8)	118 (30.4)

Continued

Table 1 Continued

	2012–2016 (n=446)	2017–2021 (n=388)
Advanced/ metastatic	322 (72.2)	270 (69.6)
Study design		
Superiority	412 (92.4)	355 (91.5)
Non-inferiority	34 (7.6)	33 (8.5)
Masking		
Open label	308 (69.1)	267 (68.8)
Blinded	138 (30.9)	121 (31.2)
Type of experimental therapy*		
Chemotherapy±other	273 (61.2)	203 (52.3)
Targeted therapy±other	210 (47.1)	180 (46.4)
Hormonal therapy±other	43 (9.6)	47 (12.1)
Immunotherapy± other	33 (7.4)	86 (22.2)
Other	8 (1.8)	–

*Categories are not mutually exclusive.
GI, gastrointestinal; GU, genitourinary.

Compared with the previous 5 years, the proportion of trials including QoL among endpoints was higher for all types of tumours, for all types of experimental treatment and in both the localised stages (OR 1.88, 95% CI 1.12 to 3.16) and advanced/metastatic setting (OR 2.07, 95% CI 1.45 to 2.95).

At multivariate analysis (figure 2), the inclusion of QoL among endpoints was significantly higher in journals with higher IF, in non-inferiority studies, in industry-sponsored trials, in studies conducted in patients with advanced disease, in studies conducted in genitourinary tumours and in studies testing immunotherapy.

Presence of QoL results in the primary publication of trials including QoL among endpoints

Out of 263 primary publications of trials published in 2017–2021 with QoL among endpoints, QoL results were available in 137 (52.1%) (online supplemental tables 1 and 3). In these 5 years, the proportion of publications without QoL results was 20.0%, 47.8% and 51.2% among papers published in journals with low, intermediate and high IF, respectively. The proportion of publications without QoL results was 51.6% among industry-sponsored trials and 39.0% among academic trials, and it was 47.5% in localised stages and 48.0% in the advanced setting.

The overall proportion of trials presenting QoL results in the primary publication in the 2017–2021 period was significantly lower compared with the period 2012–2016 (52.1% vs 62.3%, OR 0.66, 95% CI 0.46 to 0.94, $p=0.02$) (figure 3A). Compared with 2012–2016, the proportion of publications reporting QoL results was lower in many

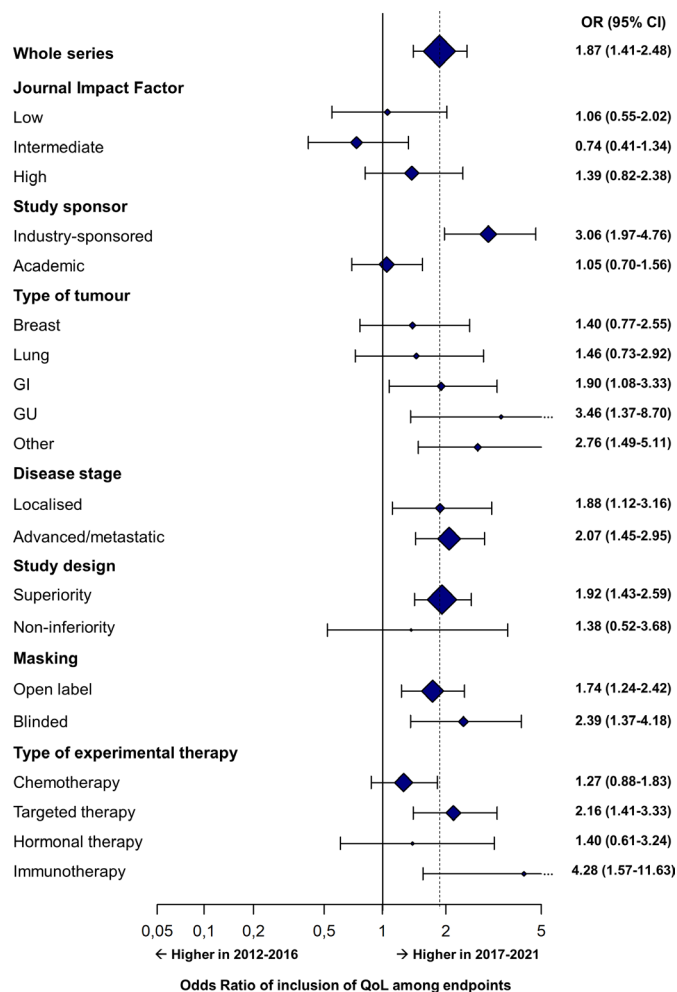


Figure 1 Probability of inclusion of quality of life (QoL) among study endpoints, in the period 2017–2021 (n=388) compared with the period 2012–2016 (n=446), according to characteristics of trial and publication.

types of tumours, for all types of treatment and in both the localised stages and advanced/metastatic setting.

At multivariate analysis, higher journal IF and studies testing immunotherapy were the only variables associated with a lower probability of QoL results (figure 2).

Presence of QoL data in the whole series of primary publications

Overall, QoL was included among endpoints and presented in primary publications in 137 (35.3%) trials in 2017–2021 (online supplemental tables 1 and 4). In these 5 years, QoL was included and presented in 39.8% and 29.0% of publications of industry-sponsored and academic trials, respectively, and in 26.3% and 39.3% of trials conducted in the localised and advanced setting, respectively.

The overall proportion of publications including QoL data in 2017–2021 was not significantly different compared with the period 2012–2016 (35.3% vs 33.0%, OR 1.11, 95% CI 0.83 to 1.48, $p=0.48$) (figure 3B).

At multivariate analysis in the whole series of trials (figure 2), the presence of QoL data was significantly

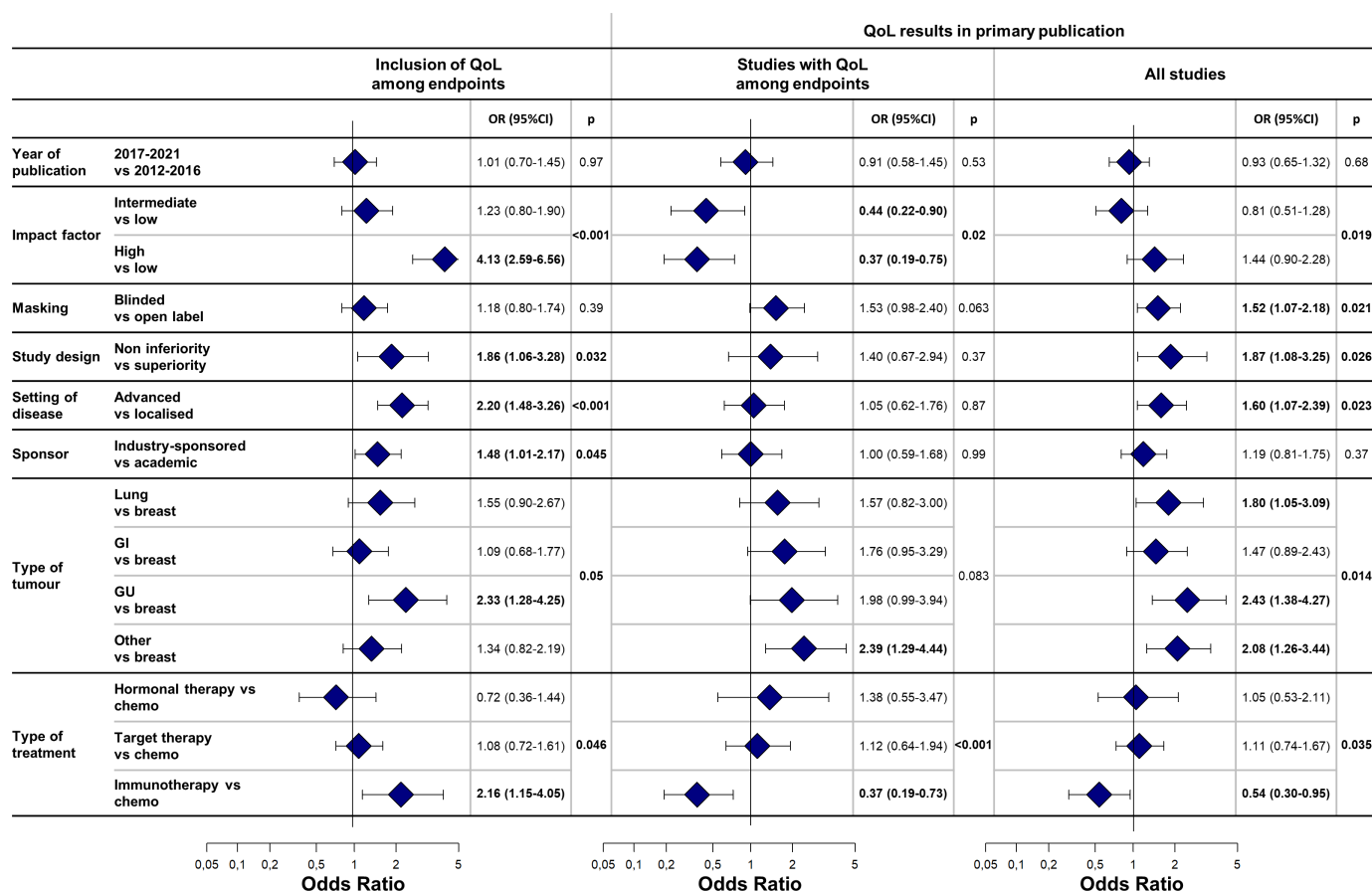


Figure 2 Multivariate analysis of probability of inclusion of quality of life (QoL) among endpoints and probability of presence of QoL results in the primary publication in the whole 10-year series of trials. Bold values identify the statistically significant covariates ($p < 0.05$).

higher in journals with higher IF, in studies with blinded design, in non-inferiority trials, in studies conducted in patients with advanced disease, in tumours different from breast cancer, while it was significantly lower in trials testing immunotherapy.

QoL secondary publications

Overall, out of 126 trials published between 2017 and 2021, including QoL as an endpoint but without any QoL result in the primary publication, 42 secondary QoL publications were found with a median follow-up of 34 months, (the complete list of secondary publications is available in online supplemental data). For these trials, probability of secondary publication was 10.9%, 29.1% and 42.5% at 1, 2 and 3 years respectively (figure 4). These results were similar to those of papers published between 2012 and 2016, included in the previous analysis.

QoL reporting according to study results

According to authors' conclusions about the primary outcomes, studies published between 2017 and 2021 were divided into positive (211, 54.4%) and negative (177, 45.6%). The proportion of publications including QoL results was slightly higher in trials with positive results (83/211, 39.3%) than in trials with negative results (54/177, 30.5%) ($p = 0.07$). For trials including QoL as an

endpoint, but without any QoL result in the primary publication, probability of secondary publication was 12.5%, 39.5% and 59.2% after 12, 24 and 36 months, respectively, in the 75 trials with positive results, and 8.3%, 11.6% and 16.0% after 12, 24 and 36 months, respectively, in the 51 trials with negative results (online supplemental figure 1). These results were similar to those of the 2012–2016 period.

DISCUSSION

In this study, we showed that the proportion of randomised phase III trials that included QoL as a study endpoint has increased in recent years, though it remains suboptimal, particularly in trials promoted by academic sponsors.

In many cases, although collected according to study protocol, QoL data are not presented in the primary publication. This under-reporting was already relevant some years ago,⁷ but the trend is worsening in recent years, with a frequent delay in the availability of QoL results. For instance, even if the rate of industry-sponsored trials including QoL among endpoints has increased in the last 5 years, this was not followed by an increase in reporting of QoL results, which on the contrary has decreased in 2017–2021 compared with the previous 5 years. The same

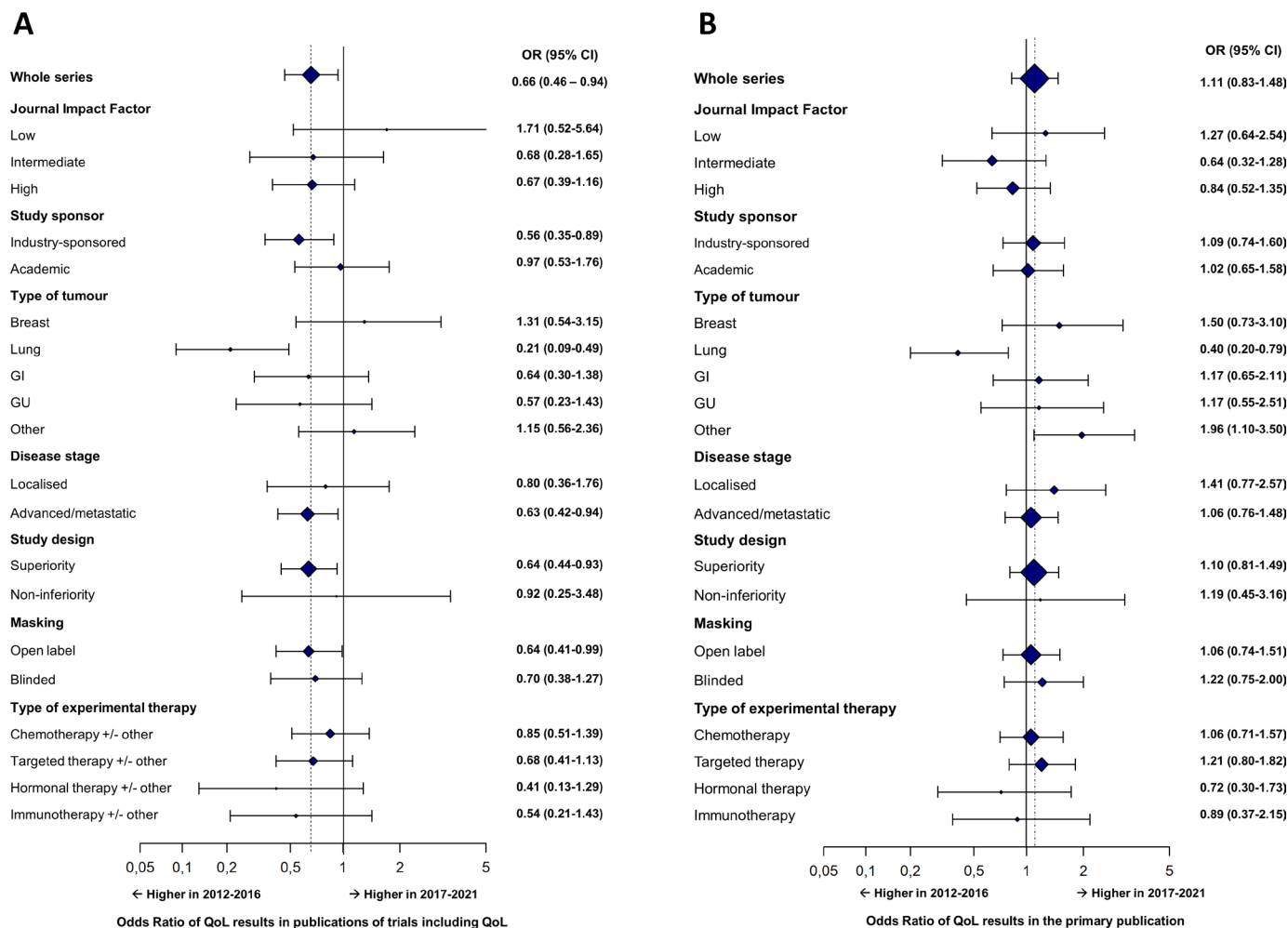


Figure 3 Probability of presence of quality of life (QoL) results in the primary publication, in the period 2017–2021 compared with the period 2012–2016, according to characteristics of trial and publication. (A) Trials including QoL among study endpoints (n=263 for the period 2017–2021 vs n=236 for the period 2012–2016). (B) All trials included in the analysis (n=388 for the period 2017–2021 vs n=446 for the period 2012–2016).

concept also applies to trials testing immunotherapy or conducted in advanced disease, among others. It should be highlighted that the drop in the presence of QoL results in primary publications was particularly relevant for trials

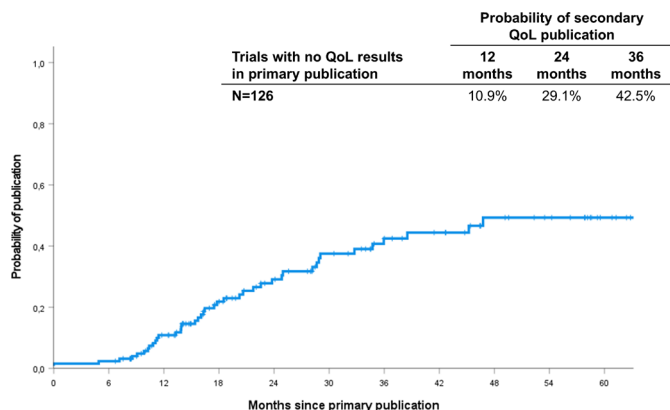


Figure 4 Kaplan-Meier curves of time to secondary publication with quality of life (QoL) results, for trials including QoL as a secondary/exploratory endpoint, but without any QoL result in the primary publication.

including patients with lung cancer (45.8% in 2012–2016 compared with 25.0% in 2017–2021). Of course, regulatory agencies may evaluate QoL results although still unpublished, but we believe that the concomitant publication of QoL results together with other outcomes is very useful not only for decision makers, but for the entire scientific community (including clinicians and patients) to evaluate the value of a new treatment.

By performing a multivariate analysis on the whole 10-year dataset, we investigated the factors (both related to the study and journal characteristics) associated with a higher chance of inclusion of QoL among study endpoints and presence of QoL results in the primary publication. Of note, journal IF was associated with the inclusion of QoL among endpoints and with the presence of QoL results in the first publication. However, these associations were in opposite directions: studies published in journals with higher IF had higher frequency of QoL among endpoints (multivariate OR for journals with high IF compared with those with low IF 4.13, 95% CI 2.59 to 6.56), but higher IF was associated with lower inclusion of QoL results in

the first publication (multivariate OR 0.37, 95% CI 0.19 to 0.75). In other words, if we consider the journal IF as a surrogate of the quality and the relevance of the trial, high-quality trials do include QoL in study protocol, but those journals do not ask for those results when the study is submitted for publication. This is particularly evident for trials testing immunotherapy, as previously shown by a dedicated analysis.¹⁵ In this study, immunotherapy studies confirmed a high rate of inclusion of QoL among endpoints, but a very disappointing rate of presence of QoL data in the primary publication.

As expected, the proportion of trials including QoL among endpoints was significantly lower in trials conducted in early stages compared with advanced disease, although in the last 5 years this proportion showed an improvement in both subgroups. Disease setting showed a significant association at multivariate analysis, with both inclusion of QoL among endpoints and presence of QoL data in the primary publication. The attention to QoL was higher in patients with advanced disease: indeed, in this setting, tumour-related symptoms can have a relevant impact on QoL, and the burden of treatment-related adverse events is not negligible, especially if treatment is associated with a modest efficacy. In patients receiving adjuvant treatment, with a curative aim, investigators often suppose that the benefit in terms of chance of cure should outweigh the negative, hopefully transient, detrimental effect.

We were already disappointed in the previous analysis by the high proportion of academic trials that did not include QoL as a study endpoint. In this update, the gap between industry-sponsored and academic studies was even higher: while the proportion of trials including QoL among industry-sponsored studies significantly improved in recent years (moving from 60.3% to 82.3%, OR 3.06), this was not the case for the academic counterpart (from 46.4% in 2012–2016 to 47.5% in 2017–2021, OR 1.05). In the multivariate analysis conducted over the 10-year period, study sponsor remained statistically significant (OR of QoL inclusion for industry-sponsored vs academic trials 1.48, 95% CI 1.01 to 2.17). In other words, pharmaceutical companies are responding to regulatory agencies' invitation to increase the production of QoL data during a treatment's clinical development, while academic research continues to underestimate the importance of PROs and QoL in clinical trials. We acknowledge that this can be related to technical and methodological challenges: academic trials are often conducted with far less resources compared with industry-sponsored trials, and the administration, collection and analysis of QoL questionnaires could be considered as a 'burden' mining the feasibility of the trial. However, we hope that the increased awareness of the relevance of QoL will determine an improvement also in academic research, coherently with its philosophy, aiming to optimise treatment choices and patients' QoL.

One reason for not including QoL as an endpoint could be the concern that, in order to be methodologically

reliable, QoL data should be generated in a blinded setting rather than in an open-label design.⁹ If this was actually the case, this could partially explain the suboptimal QoL inclusion in academic research, considering that the conduction of placebo-controlled trials can be particularly challenging for academic investigators. In our analysis, masking was significantly associated with the probability of QoL results in the study publication at multivariate analysis (OR 1.52, 95% CI 1.07 to 2.18). However, we believe that QoL data are worth to be collected even if the trial is open-label. In a review of 538 randomised trials with a patient-reported endpoint conducted in the most prevalent cancers, there was no significant association of the treatment concealment (blinded vs open-label) with the proportion of trials favouring the experimental treatment (adjusted OR 1.19, 95% CI 0.79 to 1.79; $p=0.40$).¹⁶ These findings support the validity of QoL results derived from open-label oncology trials.

The limited word-count imposed by most scientific journals may be one of the factors hindering QoL reporting in the primary publication. Limiting the reporting of QoL results to the global/total QoL score due to space restrictions may limit the interpretation of the QoL profile of the treatments under study. In fact, results of the various QoL items and domains, along with different modalities of analysis and presentation of results (eg, mean changes, proportion of responders, time to QoL deterioration), are important to understand treatment impact on QoL and to personalise treatment choices and management. We believe that scientific journals should consider synchronous publications dedicated to PROs, in order to offer a timely and complete evaluation of new treatments. Alternatively, authors should be encouraged to add details of PROs results in the supplemental data, which usually have no word-count restriction, although this solution is at risk of limiting the visibility of PRO results.

We acknowledge some limitations of our study. First, our analysis is limited to 11 major journals and cannot be considered a systematic review of the literature. Some phase III trials published in different journals, even of high relevance and quality, are not considered in our study. However, considering our finding that studies including QoL among endpoints are published more often in journals with higher IF, it is reasonable that the inclusion of other journals (including those with lower IF) could have further reduced the proportion of studies including QoL; therefore, this limitation is conservative as for the matter of the analysis. In addition, we decided to conduct the update on the same 11 journals already included in our previous study, to obtain a homogeneous comparison between the two periods, and the journals included are among those most read by the oncological community. We believe that, despite this important limitation, our review is useful in providing a picture of the relevance of QoL in oncology literature. Second, this analysis, like the previous one, is limited to full text publications. We did not consider the presentation of QoL results as abstracts, posters and/or oral presentations, at scientific

meetings, although those usually precedes the definitive publication and could allow the availability of QoL data for the scientific community for some of the trials classified as under-reported in our analysis. However, we believe that the full text, peer-reviewed publication should be the reference for the evaluation of the methodological quality of a clinical trial. In addition, there is no scientific reason for not including QoL data in the primary study publication, considering that those data are collected during the treatment, and should be mature at the moment of primary analysis. Third, we did not investigate the modality of collection (paper-based vs electronic) within each study. Recent years are witnessing an increasing use of electronic collection of PROs, which allows a prompt availability of data for the analysis. Whether the use of electronic PROs may be associated with higher PROs reporting still needs further investigation. Lastly, we acknowledge that the year of publication is an imprecise surrogate for the year of study design and that the length of accrual for academic trials could be, at least in principle, longer than for industry-sponsored trials due usually to more limited resources. This can affect the comparison of time trends according to sponsorship, at least for the inclusion of QoL among study endpoints, but not for the presentation of results.

In conclusion, we showed that the proportion of oncology trials including QoL among endpoints increased in 2017–2021 compared with 2012–2016, and this is an encouraging result, although QoL remains underrated in many trials. Furthermore, the proportion of trials reporting QoL results in primary publications remains suboptimal, necessitating discussion within the scientific community, which includes not only investigators but also journal editors and peer-reviewers. We believe that more needs to be done to ensure that the scientific community and also patients can access data of PROs and QoL at an appropriate time. At the moment, journal editors, who could make the provision of PROs and QoL for clinical trials a requirement for publication, may hold the key for the improvement of the timely presentation of patient-reported results.

Author affiliations

¹Department of Medical Oncology, IRCCS Ospedale San Raffaele, Milano, Italy

²Department of Oncology, University of Turin, at Ordine Mauriziano Hospital, Torino, Italy

³Department of Oncology, Ludwig Institute for Cancer Research, Lausanne, Switzerland

⁴Phase I Unit, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma, Italy

⁵Department of Oncology, University of Turin, at San Luigi Gonzaga Hospital, Orbassano, Italy

⁶Department of Immunology and Microbiology, Emory University School of Medicine Atlanta, Atlanta, Georgia, USA

⁷Department of Oncology, University of Turin, at Santa Croce e Carle Hospital, Cuneo, Italy

⁸Clinical Trial Unit, Istituto Nazionale Tumori IRCCS Fondazione Pascale, Napoli, Italy

⁹Department of Clinical and Molecular Medicine, "La Sapienza" University of Rome, at Azienda Ospedaliera Sant'Andrea, Rome, Italy

¹⁰Department of Oncology, Oncology Institute of Southern Switzerland, EOC, Bellinzona, Switzerland

Twitter Laura Marandino @LauraMarandino, Maria Lucia Reale @marialuciareale, Valentina Tuninetti @valedoc87, Francesco Perrone @fperrone62 and Massimo Di Maio @MassimoDiMaio75

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ORCID iDs

Laura Marandino <http://orcid.org/0000-0001-7120-2505>

Maria Lucia Reale <http://orcid.org/0000-0001-9210-5149>

Raimondo Di Liello <http://orcid.org/0000-0003-4511-7969>

Chiara Paratore <http://orcid.org/0000-0001-5258-8537>

Valentina Tuninetti <http://orcid.org/0000-0002-7377-0888>

Francesco Perrone <http://orcid.org/0000-0002-9738-0526>

Massimo Di Maio <http://orcid.org/0000-0001-8906-3785>

REFERENCES

- Basch E, Geoghegan C, Coons SJ, *et al*. Patient-Reported outcomes in cancer drug development and US regulatory review: perspectives from industry, the food and drug administration, and the patient. *JAMA Oncol* 2015;1:375–9.
- Di Maio M. Quality of life: an important element of treatment value. *Lancet Oncol* 2017;18:1557–8.
- Kluetz PG, O'Connor DJ, Soltys K. Incorporating the patient experience into regulatory decision making in the USA, Europe, and Canada. *Lancet Oncol* 2018;19:e267–74.
- Di Maio M, Basch E, Bryce J, *et al*. Patient-Reported outcomes in the evaluation of toxicity of anticancer treatments. *Nat Rev Clin Oncol* 2016;13:319–25.
- Gyawali B, Hwang TJ, Vokinger KN, *et al*. Patient-Centered cancer drug development: clinical trials, regulatory approval, and value assessment. *American Society of Clinical Oncology Educational Book* 2019:374–87.

- 6 Silvestri G, Pritchard R, Welch HG. Preferences for chemotherapy in patients with advanced non-small cell lung cancer: descriptive study based on scripted interviews. *BMJ* 1998;317:771–5.
- 7 Marandino L, La Salvia A, Sonetto C, *et al.* Deficiencies in health-related quality-of-life assessment and reporting: a systematic review of oncology randomized phase III trials published between 2012 and 2016. *Ann Oncol* 2018;29:2288–95.
- 8 U.S. Department of Health and Human Services, Food and Drug Administration. Core patient-reported outcomes in cancer clinical trials. draft guidance for industry. 2021. Available: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/core-patient-reported-outcomes-cancer-clinical-trials> [Accessed 11 Oct 2022].
- 9 European Medicines Agency. Appendix 2 to the guideline on the evaluation of anticancer medicinal products in man. the use of patient-reported outcome (PRO) measures in oncology studies. 2016. Available: <https://www.ema.europa.eu/en/news/integrating-patients-views-clinical-studies-anticancer-medicines> [Accessed 11 Oct 2022].
- 10 Schnipper LE, Davidson NE, Wollins DS, *et al.* Updating the American Society of clinical oncology value framework: revisions and reflections in response to comments received. *J Clin Oncol* 2016;34:2925–34.
- 11 Cherny NI, Dafni U, Bogaerts J, *et al.* ESMO-magnitude of clinical benefit scale version 1.1. *Ann Oncol* 2017;28:2340–66.
- 12 Gyawali B, de Vries EGE, Dafni U, *et al.* Biases in study design, implementation, and data analysis that distort the appraisal of clinical benefit and ESMO-magnitude of clinical benefit scale (ESMO-MCBS) scoring. *ESMO Open* 2021;6:100117.
- 13 Di Maio M, Perrone F. Lessons from clinical trials on quality-of-life assessment in ovarian cancer trials. *Ann Oncol* 2016;27:961–2.
- 14 Kyte D, Retzer A, Ahmed K, *et al.* Systematic evaluation of patient-reported outcome protocol content and reporting in cancer trials. *J Natl Cancer Inst* 2019;111:1170–8.
- 15 Servetto A, Salomone F, Di Costanzo F, *et al.* Inadequate health-related quality of life assessment and reporting in phase III clinical trials of immune checkpoint inhibitors in solid cancers: a systematic review. *Crit Rev Oncol Hematol* 2022;172:103649.
- 16 Efficace F, Cella D, Aaronson NK, *et al.* Impact of blinding on patient-reported outcome differences between treatment arms in cancer randomized controlled trials. *J Natl Cancer Inst* 2022;114:471–4.

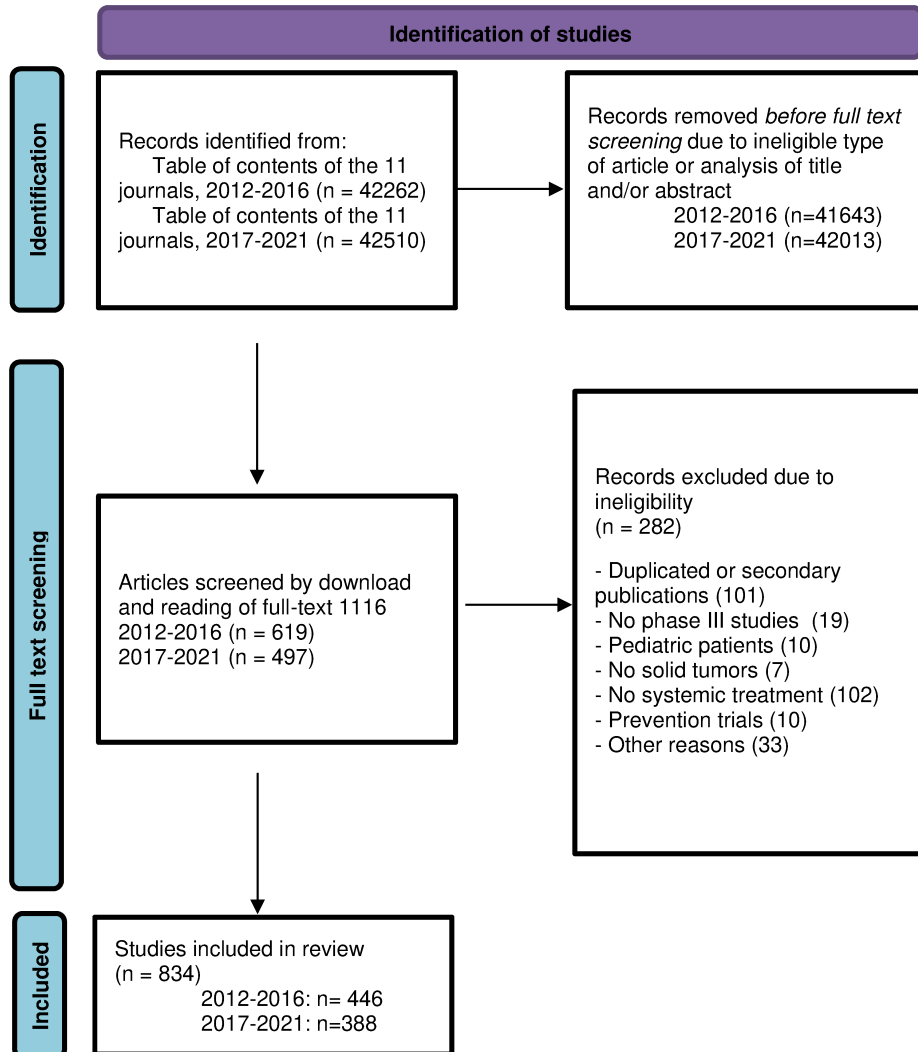
Time trends in health-related quality of life assessment and reporting within publications of oncology randomized phase III trials: a meta-research study.

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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)

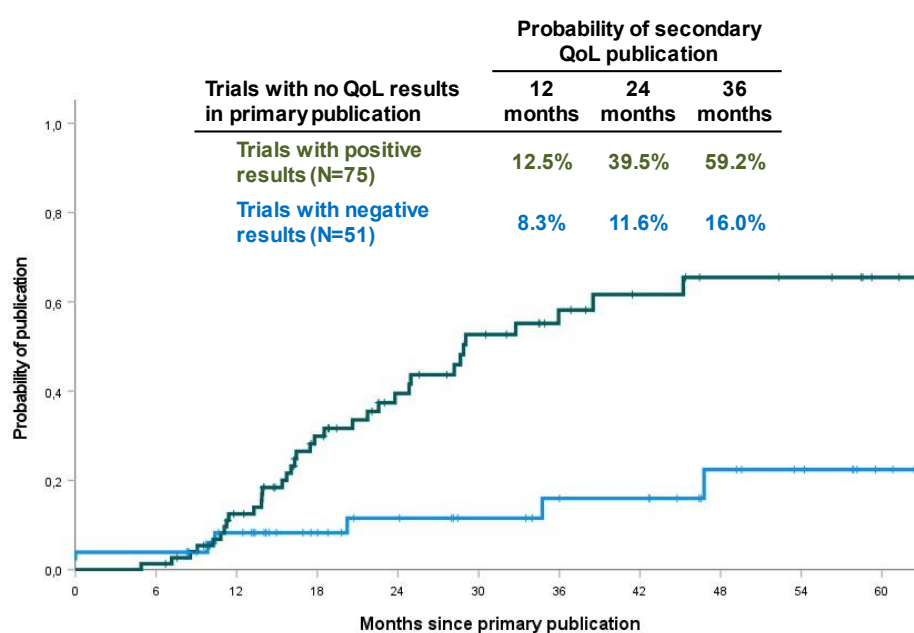
	2012-2016			2017-2021			Odds ratio
	Number of publications	QoI results present	QoI results absent	Number of publications	QoI results present	QoI results absent	
Type of malignancy							
Breast	84	16 (19.0%)	68 (81.0%)	88	23 (26.1%)	65 (73.9%)	1.50 (0.73-3.10)
Lung	83	38 (45.8%)	45 (54.2%)	68	17 (25.0%)	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.
4. Kwakman JJM, Simkens LHJ, van Rooijen JM, van de Wouw AJ, Ten Tije AJ, Creemers GJM, Hendriks MP, Los M, van Alphen RJ, Polée MB, Muller EW, van der Velden AMT, van Voorthuizen T, Koopman M, Mol L, van Werkhoven E, Punt CJA. Randomized phase III trial of S-1 versus capecitabine in the first-line treatment of metastatic colorectal cancer: SALTO study by the Dutch Colorectal Cancer Group. *Ann Oncol*. 2017 Jun 1;28(6):1288-1293. doi: 10.1093/annonc/mdx122. PMID: 28383633.
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.
 10. Shi YK, Wang L, Han BH, Li W, Yu P, Liu YP, Ding CM, Song X, Ma ZY, Ren XL, Feng JF, Zhang HL, Chen GY, Han XH, Wu N, Yao C, Song Y, Zhang SC, Song W, Liu XQ, Zhao SJ, Lin YC, Ye XQ, Li K, Shu YQ, Ding LM, Tan FL, Sun Y. First-line icotinib versus cisplatin/pemetrexed plus pemetrexed maintenance therapy for patients with advanced EGFR mutation-positive lung adenocarcinoma (CONVINCE): a phase 3, open-label, randomized study. *Ann Oncol.* 2017 Oct 1;28(10):2443-2450. doi: 10.1093/annonc/mdx359. PMID: 28945850.
 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.
 12. Frikha M, Auperin A, Tao Y, Elloumi F, Toumi N, Blanchard P, Lang P, Sun S, Racadot S, Thariat J, Alfonsi M, Tuchais C, Cornely A, Moussa A, Guigay J, Daoud J, Bourhis J; GORTEC. A randomized trial of induction docetaxel-cisplatin-5FU followed by concomitant cisplatin-RT versus concomitant cisplatin-RT in nasopharyngeal carcinoma (GORTEC 2006-02). *Ann Oncol.* 2018 Mar 1;29(3):731-736. doi: 10.1093/annonc/mdx770. PMID: 29236943.
 13. Yamada Y, Denda T, Gamoh M, Iwanaga I, Yuki S, Shimodaira H, Nakamura M, Yamaguchi T, Ohori H, Kobayashi K, Tsuda M, Kobayashi Y, Miyamoto Y, Kotake M, Shimada K, Sato A, Morita S, Takahashi S, Komatsu Y, Ishioka C. S-1 and irinotecan plus bevacizumab versus mFOLFOX6 or CapeOX plus bevacizumab as first-line treatment in patients with metastatic colorectal cancer (TRICOLORE): a randomized, open-label, phase III, noninferiority trial. *Ann Oncol.* 2018 Mar 1;29(3):624-631. doi: 10.1093/annonc/mdx816. PMID: 29293874; PMCID: PMC5889030.
 14. Cortes J, Perez-Garcia J, Levy C, Gómez Pardo P, Bourgeois H, Spazzapan S, Martínez-Jañez N, Chao TC, Espié M, Nabholz JM, González Farré X, Beliakouski V, Román García J, Holgado E, Campone M. Open-label randomised phase III trial of vinflunine versus an alkylating agent in patients with heavily pretreated metastatic breast cancer. *Ann Oncol.* 2018 Apr 1;29(4):881-887. doi: 10.1093/annonc/mdy051. PMID: 29481630.

15. Kang YK, Ryu MH, Park SH, Kim JG, Kim JW, Cho SH, Park YI, Park SR, Rha SY, Kang MJ, Cho JY, Kang SY, Roh SY, Ryoo BY, Nam BH, Jo YW, Yoon KE, Oh SC. Efficacy and safety findings from DREAM: a phase III study of DHP107 (oral paclitaxel) versus i.v. paclitaxel in patients with advanced gastric cancer after failure of first-line chemotherapy. *Ann Oncol.* 2018 May 1;29(5):1220-1226. doi: 10.1093/annonc/mdy055. PMID: 29438463.
16. Martin M, Campone M, Bondarenko I, Sakaeva D, Krishnamurthy S, Roman L, Lebedeva L, Vedovato JC, Aapro M. Randomised phase III trial of vinflunine plus capecitabine versus capecitabine alone in patients with advanced breast cancer previously treated with an anthracycline and resistant to taxane. *Ann Oncol.* 2018 May 1;29(5):1195-1202. doi: 10.1093/annonc/mdy063. PMID: 29447329.
17. Novello S, Mazières J, Oh IJ, de Castro J, Migliorino MR, Helland Å, Dziadziuszko R, Griesinger F, Kotb A, Zeaiter A, Cardona A, Balas B, Johannsdottir HK, Das-Gupta A, Wolf J. Alectinib versus chemotherapy in crizotinib-pretreated anaplastic lymphoma kinase (ALK)-positive non-small-cell lung cancer: results from the phase III ALUR study. *Ann Oncol.* 2018 Jun 1;29(6):1409-1416. doi: 10.1093/annonc/mdy121. PMID: 29668860; PMCID: PMC6005013.
18. Gerber DE, Horn L, Boyer M, Sanborn R, Natale R, Palmero R, Bidoli P, Bondarenko I, Germonpre 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. *Ann Oncol.* 2018 Jul 1;29(7):1548-1553. doi: 10.1093/annonc/mdy177. PMID: 29767677; PMCID: PMC6887726.
19. 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, Stoehr 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. *Ann Oncol.* 2018 Sep 1;29(9):1955-1963. doi: 10.1093/annonc/mdy241. PMID: 30010751; PMCID: PMC6158765.
20. 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.
21. Conte P, Frassoldati A, Bisagni G, Brandes AA, Donadio M, Garrone O, Piacentini F, Cavanna L, Giotta F, Aieta M, Gebbia V, Molino A, Musolino A, Ferro A, Maltoni R, Danese S, Zamagni C, Rimanti A, Cagossi K, Russo A, Pronzato P, Giovanardi F, Moretti G, Lombardo L, Schirone A, Beano A, Amaducci L, Bajardi EA, Vicini R, Balduzzi S, D'Amico R, Guarneri V. Nine weeks versus 1 year adjuvant trastuzumab in combination with chemotherapy: final results of the phase III randomized Short-HER study. *Ann Oncol.* 2018 Dec 1;29(12):2328-2333. doi: 10.1093/annonc/mdy414. PMID: 30219886.
22. Gross-Goupil M, Kwon TG, Eto M, Ye D, Miyake H, Seo SI, Byun SS, Lee JL, Master V, Jin J, DeBenedetto R, Linke R, Casey M, Rosbrook B, Lechuga M, Valota O, Grande E, Quinn DI. Axitinib versus placebo as an adjuvant treatment of renal cell carcinoma: results from the phase III, randomized ATLAS trial. *Ann Oncol.* 2018 Dec 1;29(12):2371-2378. doi: 10.1093/annonc/mdy454. PMID: 30346481; PMCID: PMC6311952.

23. Kim ST, Kang JH, Lee J, Lee HW, Oh SY, Jang JS, Lee MA, Sohn BS, Yoon SY, Choi HJ, Hong JH, Kim MJ, Kim S, Park YS, Park JO, Lim HY. Capecitabine plus oxaliplatin versus gemcitabine plus oxaliplatin as first-line therapy for advanced biliary tract cancers: a multicenter, open-label, randomized, phase III, noninferiority trial. *Ann Oncol*. 2019 May 1;30(5):788-795. doi: 10.1093/annonc/mdz058. PMID: 30785198.
24. Kelly RJ, Shepherd FA, Krivoshek A, Jie F, Horn L. A phase III, randomized, open-label study of ASP8273 versus erlotinib or gefitinib in patients with advanced stage IIIB/IV non-small-cell lung cancer. *Ann Oncol*. 2019 Jul 1;30(7):1127-1133. doi: 10.1093/annonc/mdz128. PMID: 31070709; PMCID: PMC6736319.
25. Guo Y, Ahn MJ, Chan A, Wang CH, Kang JH, Kim SB, Bello M, Arora RS, Zhang Q, He X, Li P, Dechaphunkul A, Kumar V, Kamble K, Li W, Kandil A, Cohen EEW, Geng Y, Zografos E, Tang PZ. Afatinib versus methotrexate as second-line treatment in Asian patients with recurrent or metastatic squamous cell carcinoma of the head and neck progressing on or after platinum-based therapy (LUX-Head & Neck 3): an open-label, randomised phase III trial. *Ann Oncol*. 2019 Nov 1;30(11):1831-1839. doi: 10.1093/annonc/mdz388. PMID: 31501887; PMCID: PMC6927323.
26. Morizane C, Okusaka T, Mizusawa J, Katayama H, Ueno M, Ikeda M, Ozaka M, Okano N, Sugimori K, Fukutomi A, Hara H, Mizuno N, Yanagimoto H, Wada K, Tobimatsu K, Yane K, Nakamori S, Yamaguchi H, Asagi A, Yukisawa S, Kojima Y, Kawabe K, Kawamoto Y, Sugimoto R, Iwai T, Nakamura K, Miyakawa H, Yamashita T, Hosokawa A, Ioka T, Kato N, Shioji K, Shimizu K, Nakagohri T, Kamata K, Ishii H, Furuse J; members of the Hepatobiliary and Pancreatic Oncology Group of the Japan Clinical Oncology Group (JCOG-HBPOG). Combination gemcitabine plus S-1 versus gemcitabine plus cisplatin for advanced/recurrent biliary tract cancer: the FUGA-BT (JCOG1113) randomized phase III clinical trial. *Ann Oncol*. 2019 Dec 1;30(12):1950-1958. doi: 10.1093/annonc/mdz402. PMID: 31566666.
27. Moehler M, Maderer A, Thuss-Patience PC, Brenner B, Meiler J, Etrich TJ, Hofheinz RD, Al-Batran SE, Vogel A, Mueller L, Lutz MP, Lordick F, Alsina M, Borchert K, Greil R, Eisterer W, Schad A, Slotta-Huspenina J, Van Cutsem E, Lorenzen S. Cisplatin and 5-fluorouracil with or without epidermal growth factor receptor inhibition panitumumab for patients with non-resectable, advanced or metastatic oesophageal squamous cell cancer: a prospective, open-label, randomised phase III AIO/EORTC trial (POWER). *Ann Oncol*. 2020 Feb;31(2):228-235. doi: 10.1016/j.annonc.2019.10.018. Epub 2019 Dec 16. PMID: 31959339.
28. Planchard D, Reinmuth N, Orlov S, Fischer JR, Sugawara S, Mandziuk S, Marquez-Medina D, Novello S, Takeda Y, Soo R, Park K, McCleod M, Geater SL, Powell M, May R, Scheuring U, Stockman P, Kowalski D. ARCTIC: durvalumab with or without tremelimumab as third-line or later treatment of metastatic non-small-cell lung cancer. *Ann Oncol*. 2020 May;31(5):609-618. doi: 10.1016/j.annonc.2020.02.006. Epub 2020 Feb 20. PMID: 32201234.
29. 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. *Ann Oncol*. 2020 Jul;31(7):942-950. doi: 10.1016/j.annonc.2020.04.001. Epub 2020 Apr 12. PMID: 32294530.

30. Popat S, Curioni-Fontecedro A, Dafni U, Shah R, O'Brien M, Pope A, Fisher P, Spicer J, Roy A, Gilligan D, Gautschi O, Nadal E, Janthur WD, López Castro R, García Campelo R, Rusakiewicz S, Letovanec I, Polydoropoulou V, Roschitzki-Voser H, Ruepp B, Gasca-Ruchti A, Peters S, Stahel RA. A multicentre randomised phase III trial comparing pembrolizumab versus single-agent chemotherapy for advanced pre-treated malignant pleural mesothelioma: the European Thoracic Oncology Platform (ETOP 9-15) PROMISE-meso trial. *Ann Oncol.* 2020 Dec;31(12):1734-1745. doi: 10.1016/j.annonc.2020.09.009. Epub 2020 Sep 22. PMID: 32976938.
31. Yamazaki K, Yamanaka T, Shiozawa M, Manaka D, Kotaka M, Gamoh M, Shiomi A, Makiyama A, Munemoto Y, Rikiyama T, Fukunaga M, Ueki T, Shitara K, Shinkai H, Tanida N, Oki E, Sunami E, Ohtsu A, Maehara Y, Yoshino T. Oxaliplatin-based adjuvant chemotherapy duration (3 versus 6 months) for high-risk stage II colon cancer: the randomized phase III ACHIEVE-2 trial. *Ann Oncol.* 2021 Jan;32(1):77-84. doi: 10.1016/j.annonc.2020.10.480. Epub 2020 Oct 26. PMID: 33121997.
32. Shi M, Gu A, Tu H, Huang C, Wang H, Yu Z, Wang X, Cao L, Shu Y, Wang H, Yang R, Li X, Chang J, Hu Y, Shen P, Hu Y, Guo Z, Tao M, Zhang Y, Liu X, Sun Q, Zhang X, Jiang Z, Zhao J, Chen F, Yu H, Zhang W, Sun J, Li D, Zhou J, Han B, Wu YL. Comparing nanoparticle polymeric micellar paclitaxel and solvent-based paclitaxel as first-line treatment of advanced non-small-cell lung cancer: an open-label, randomized, multicenter, phase III trial. *Ann Oncol.* 2021 Jan;32(1):85-96. doi: 10.1016/j.annonc.2020.10.479. Epub 2020 Oct 29. PMID: 33130217.
33. Dent S, Cortés J, Im YH, Diéras V, Harbeck N, Krop IE, Wilson TR, Cui N, Schimmoller F, Hsu JY, He J, De Laurentiis M, Sousa S, Drullinsky P, Jacot W. Phase III randomized study of tasisib or placebo with fulvestrant in estrogen receptor-positive, PIK3CA-mutant, HER2-negative, advanced breast cancer: the SANDPIPER trial. *Ann Oncol.* 2021 Feb;32(2):197-207. doi: 10.1016/j.annonc.2020.10.596. Epub 2020 Nov 10. PMID: 33186740; PMCID: PMC8457522.
34. Gogas H, Dréno B, Larkin J, Demidov L, Stroyakovskiy D, Eroglu Z, Francesco Ferrucci P, Pigozzo J, Rutkowski P, Mackiewicz J, Rooney I, Voulgari A, Troutman S, Pitcher B, Guo Y, Yan Y, Castro M, Mulla S, Flaherty K, Arance A. Cobimetinib plus atezolizumab in BRAF^{V600} wild-type melanoma: primary results from the randomized phase III IMspire170 study. *Ann Oncol.* 2021 Mar;32(3):384-394. doi: 10.1016/j.annonc.2020.12.004. Epub 2020 Dec 10. PMID: 33309774.
35. Martin M, Zielinski C, Ruiz-Borrego M, Carrasco E, Turner N, Ciruelos EM, Muñoz M, Bermejo B, Margeli M, Anton A, Kahan Z, Csösz T, Casas MI, Murillo L, Morales S, Alba E, Gal-Yam E, Guerrero-Zotano A, Calvo L, de la Haba-Rodríguez J, Ramos M, Alvarez I, Garcia-Palomo A, Huang Bartlett C, Koehler M, Caballero R, Corsaro M, Huang X, Garcia-Sáenz JA, Chacón JI, Swift C, Thallinger C, Gil-Gil M. Palbociclib in combination with endocrine therapy versus capecitabine in hormonal receptor-positive, human epidermal growth factor 2-negative, aromatase inhibitor-resistant metastatic breast cancer: a phase III randomised controlled trial-PEARL. *Ann Oncol.* 2021 Apr;32(4):488-499. doi: 10.1016/j.annonc.2020.12.013. Epub 2020 Dec 29. PMID: 33385521.
36. Wu XH, Zhu JQ, Yin RT, Yang JX, Liu JH, Wang J, Wu LY, Liu ZL, Gao YN, Wang DB, Lou G, Yang HY, Zhou Q, Kong BH, Huang Y, Chen LP, Li GL, An RF, Wang K, Zhang Y, Yan XJ, Lu X, Lu WG, Hao M, Wang L, Cui H, Chen QH, Abulizi G, Huang XH, Tian XF, Wen H, Zhang C, Hou JM, Mirza MR. Niraparib maintenance therapy in patients with platinum-sensitive recurrent ovarian cancer using an individualized starting dose (NORA): a randomized, double-blind, placebo- controlled phase III trial. *Ann Oncol.* 2021 Apr;32(4):512-521. doi: 10.1016/j.annonc.2020.12.018. Epub 2021 Jan 14. PMID: 33453391.

37. 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. *Ann Oncol*. 2021 May;32(5):600-608. doi: 10.1016/j.annonc.2021.01.070. Epub 2021 Feb PMID: 33539945.
38. Spigel DR, Vicente D, Ciuleanu TE, Gettinger S, Peters S, Horn L, Audigier- Valette C, Pardo Aranda N, Juan-Vidal O, Cheng Y, Zhang H, Shi M, Luft A, Wolf J, Antonia S, Nakagawa K, Fairchild J, Baudelet C, Pandya D, Doshi P, Chang H, Reck M. Second-line nivolumab in relapsed small-cell lung cancer: CheckMate 331[☆]. *Ann Oncol*. 2021 May;32(5):631-641. doi: 10.1016/j.annonc.2021.01.071. Epub 2021 Feb 1. PMID: 33539946.
39. Moore KN, Oza AM, Colombo N, Oaknin A, Scambia G, Lorusso D, Konecny GE, Banerjee S, Murphy CG, Tanyi JL, Hirte H, Konner JA, Lim PC, Prasad-Hayes M, Monk BJ, Pautier P, Wang J, Berkenblit A, Vergote I, Birrer MJ. Phase III, randomized trial of mirvetuximab soravtansine versus chemotherapy in patients with platinum-resistant ovarian cancer: primary analysis of FORWARD I. *Ann Oncol*. 2021 Jun;32(6):757-765. doi: 10.1016/j.annonc.2021.02.017. Epub 2021 Mar PMID: 33667670.
40. Miles D, Gligorov J, André F, Cameron D, Schneeweiss A, Barrios C, Xu B, Wardley A, Kaen D, Andrade L, Semiglazov V, Reinisch M, Patel S, Patre M, Morales L, Patel SL, Kaul M, Barata T, O'Shaughnessy J; IMpassion131 investigators. Primary results from IMpassion131, a double-blind, placebo- controlled, randomised phase III trial of first-line paclitaxel with or without atezolizumab for unresectable locally advanced/metastatic triple-negative breast cancer. *Ann Oncol*. 2021 Aug;32(8):994-1004. doi: 10.1016/j.annonc.2021.05.801. Epub 2021 Jul 1. PMID: 34219000.
41. Sugawara S, Lee JS, Kang JH, Kim HR, Inui N, Hida T, Lee KH, Yoshida T, Tanaka H, Yang CT, Nishio M, Ohe Y, Tamura T, Yamamoto N, Yu CJ, Akamatsu H, Namba Y, Sumiyoshi N, Nakagawa K. Nivolumab with carboplatin, paclitaxel, and bevacizumab for first-line treatment of advanced nonsquamous non-small-cell lung cancer. *Ann Oncol*. 2021 Sep;32(9):1137-1147. doi: 10.1016/j.annonc.2021.06.004. Epub 2021 Jun 15. PMID: 34139272.

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1. Lindemann K, Gibbs E, Åvall-Lundqvist E, dePont Christensen R, Woie K, Kalling M, Auranen A, Grenman S, Hoegberg T, Rosenberg P, Skeie-Jensen T, Hjerpe E, Dørum A, Gebski V, Kristensen G. Chemotherapy vs tamoxifen in platinum- resistant ovarian cancer: a phase III, randomised, multicentre trial (Ovaresist). *Br J Cancer*. 2017 Feb 14;116(4):455-463. doi: 10.1038/bjc.2016.435. Epub 2017 Jan 24. PMID: 28118323; PMCID: PMC5318972.
2. Yang JJ, Zhou Q, Yan HH, Zhang XC, Chen HJ, Tu HY, Wang Z, Xu CR, Su J, Wang BC, Jiang BY, Bai XY, Zhong WZ, Yang XN, Wu YL. A phase III randomised controlled trial of erlotinib vs gefitinib in advanced non-small cell lung cancer with EGFR mutations. *Br J Cancer*. 2017 Feb 28;116(5):568-574. doi: 10.1038/bjc.2016.456. Epub 2017 Jan 19. PMID: 28103612; PMCID: PMC5344291.
3. Mavroudis D, Saloustros E, Boukovinas I, Papakotoulas P, Kakolyris S, Ziras N, Christophylakis C, Kentepozidis N, Fountzilias G, Rigas G, Varthalitis I, Kalbakis K, Agelaki S, Hatzidaki D, Georgoulis V. Sequential vs concurrent epirubicin and docetaxel as adjuvant chemotherapy for high-risk, node-negative, early breast cancer: an interim analysis of a randomised phase III study from the Hellenic

Oncology Research Group. *Br J Cancer*. 2017 Jul 11;117(2):164-170. doi: 10.1038/bjc.2017.158. Epub 2017 Jun 22. PMID: 28641315; PMCID: PMC5584474.

4. Aoki Y, Ochiai K, Lim S, Aoki D, Kamiura S, Lin H, Katsumata N, Cha SD, Kim JH, Kim BG, Hirashima Y, Fujiwara K, Kim YT, Kim SM, Chung HH, Chang TC, Kamura T, Takizawa K, Takeuchi M, Kang SB. Phase III study of cisplatin with or without S-1 in patients with stage IVB, recurrent, or persistent cervical cancer. *Br J Cancer*. 2018 Aug;119(5):530-537. doi: 10.1038/s41416-018-0206-7. Epub 2018 Aug 3. PMID: 30072745; PMCID: PMC6162273.
5. Fujiwara Y, Mukai H, Saeki T, Ro J, Lin YC, Nagai SE, Lee KS, Watanabe J, Ohtani S, Kim SB, Kuroi K, Tsugawa K, Tokuda Y, Iwata H, Park YH, Yang Y, Nambu Y. A multi-national, randomised, open-label, parallel, phase III non-inferiority study comparing NK105 and paclitaxel in metastatic or recurrent breast cancer patients. *Br J Cancer*. 2019 Mar;120(5):475-480. doi: 10.1038/s41416-019-0391-z. Epub 2019 Feb 12. PMID: 30745582; PMCID: PMC6461876.
6. Tomita N, Kunieda K, Maeda A, Hamada C, Yamanaka T, Sato T, Yoshida K, Boku N, Nezu R, Yamaguchi S, Mishima H, Sadahiro S, Muro K, Ishiguro M, Sakamoto J, Saji S, Maehara Y. Phase III randomised trial comparing 6 vs. 12-month of capecitabine as adjuvant chemotherapy for patients with stage III colon cancer: final results of the JFMC37-0801 study. *Br J Cancer*. 2019 Apr;120(7):689-696. doi: 10.1038/s41416-019-0410-0. Epub 2019 Mar 5. PMID: 30833647; PMCID: PMC6461756.
7. Groen HJM, van der Heijden EHF, Klinkenberg TJ, Biesma B, Aerts J, Verhagen A, Kloosterziel C, Pieterman R, van den Borne B, Smit HJM, Hoekstra O, Schramel FMNH, van der Noort V, van Tinteren H, Smit EF, Dingemans AC; NVALT Study Group, the Netherlands. Randomised phase 3 study of adjuvant chemotherapy with or without nadroparin in patients with completely resected non-small-cell lung cancer: the NVALT-8 study. *Br J Cancer*. 2019 Aug;121(5):372-377. doi: 10.1038/s41416-019-0533-3. Epub 2019 Jul 24. PMID: 31337877; PMCID: PMC6738047.
8. Mukai H, Uemura Y, Akabane H, Watanabe T, Park Y, Takahashi M, Sagara Y, Nishimura R, Takashima T, Fujisawa T, Hozumi Y, Kawahara T. Anthracycline- containing regimens or taxane versus S-1 as first-line chemotherapy for metastatic breast cancer. *Br J Cancer*. 2021 Oct;125(9):1217-1225. doi: 10.1038/s41416-021-01531-6. Epub 2021 Sep 3. PMID: 34480096; PMCID: PMC8548517.

Cancer

1. Watanabe T, Kuranami M, Inoue K, Masuda N, Aogi K, Ohno S, Iwata H, Mukai H, Uemura Y, Ohashi Y. Comparison of an AC-taxane versus AC-free regimen and paclitaxel versus docetaxel in patients with lymph node-positive breast cancer: Final results of the National Surgical Adjuvant Study of Breast Cancer 02 trial, a randomized comparative phase 3 study. *Cancer*. 2017 Mar 1;123(5):759-768. doi: 10.1002/cncr.30421. Epub 2017 Jan 12. PMID: 28081304; PMCID: PMC6668007.
2. Yu KD, Wu SY, Liu GY, Wu J, Di GH, Hu Z, Hou YF, Chen CM, Fan L, Tang LC, Shen ZZ, Wu KJ, Zhuang ZG, Zhang HW, Shao ZM. Concurrent neoadjuvant chemotherapy and estrogen deprivation in patients with estrogen receptor- positive, human epidermal growth factor receptor 2-negative breast cancer (CBCSG-036): A randomized, controlled, multicenter trial. *Cancer*. 2019 Jul 1;125(13):2185-2193. doi: 10.1002/cncr.32057. Epub 2019 Mar 20. PMID: 30892700.
3. Ito K, Kobayashi M, Komiyama M, Naito S, Nishimura K, Yonese J, Hashine K, Saito S, Arai G, Shinohara M, Masumori N, Shimizu N, Satoh T, Yamauchi A, Tochigi T, Takezawa Y, Fujimoto H, Yokomizo A, Kakimoto KI, Fukui I, Karasawa K, Tsukamoto T, Nozaki M, Hasumi M, Ishiyama H, Ohtani

M, Kuwahara M, Harada M, Ohashi Y, Kotake T, Kakizoe T, Suzuki K, Yamanaka H; National Research Project on Endocrine-Radiation Combination Therapy for Locally Advanced Prostate Cancer Investigators. Oncological outcomes for patients with locally advanced prostate cancer treated with neoadjuvant endocrine and external-beam radiation therapy followed by adjuvant continuous/intermittent endocrine therapy in an open-label, randomized, phase 3 trial. *Cancer*. 2020 Sep 1;126(17):3961-3971. doi: 10.1002/cncr.33034. Epub 2020 Jun 23. PMID: 32573779.

European Journal of Cancer

1. Miles D, Cameron D, Bondarenko I, Manzyuk L, Alcedo JC, Lopez RI, Im SA, Canon JL, Shparyk Y, Yardley DA, Masuda N, Ro J, Denduluri N, Hubeaux S, Quah C, Bais C, O'Shaughnessy J. Bevacizumab plus paclitaxel versus placebo plus paclitaxel as first-line therapy for HER2-negative metastatic breast cancer (MERiDiAN): A double-blind placebo-controlled randomised phase III trial with prospective biomarker evaluation. *Eur J Cancer*. 2017 Jan;70:146-155. doi: 10.1016/j.ejca.2016.09.024. Epub 2016 Nov 4. PMID: 27817944.
2. Marth C, Vergote I, Scambia G, Oberaigner W, Clamp A, Berger R, Kurzeder C, Colombo N, Vuylsteke P, Lorusso D, Hall M, Renard V, Pignata S, Kristeleit R, Altintas S, Rustin G, Wenham RM, Mirza MR, Fong PC, Oza A, Monk BJ, Ma H, Vogl FD, Bach BA. ENGOT-ov-6/TRINOVA-2: Randomised, double-blind, phase 3 study of pegylated liposomal doxorubicin plus trebananib or placebo in women with recurrent partially platinum-sensitive or resistant ovarian cancer. *Eur J Cancer*. 2017 Jan;70:111-121. doi: 10.1016/j.ejca.2016.09.004. Epub 2016 Dec 1. PMID: 27914241.
3. Cao SM, Yang Q, Guo L, Mai HQ, Mo HY, Cao KJ, Qian CN, Zhao C, Xiang YQ, Zhang XP, Lin ZX, Li WX, Liu Q, Qiu F, Sun R, Chen QY, Huang PY, Luo DH, Hua YJ, Wu YS, Lv X, Wang L, Xia WX, Tang LQ, Ye YF, Chen MY, Guo X, Hong MH. Neoadjuvant chemotherapy followed by concurrent chemoradiotherapy versus concurrent chemoradiotherapy alone in locoregionally advanced nasopharyngeal carcinoma: A phase III multicentre randomised controlled trial. *Eur J Cancer*. 2017 Apr;75:14-23. doi: 10.1016/j.ejca.2016.12.039. Epub 2017 Feb 16. PMID: 28214653.
4. Kerbrat P, Desmoulins I, Roca L, Levy C, Lortholary A, Marre A, Delva R, Rios M, Viens P, Brain É, Serin D, Edel M, Debled M, Campone M, Mourret-Reynier MA, Bachelot T, Foucher-Goudier MJ, Asselain B, Lemonnier J, Martin AL, Roché H. Optimal duration of adjuvant chemotherapy for high-risk node-negative (N-) breast cancer patients: 6-year results of the prospective randomised multicentre phase III UNICANCER-PACS 05 trial (UCBG-0106). *Eur J Cancer*. 2017 Jul;79:166-175. doi: 10.1016/j.ejca.2017.03.004. Epub 2017 May 11. PMID: 28501763.
5. Cascinu S, Rosati G, Nasti G, Lonardi S, Zaniboni A, Marchetti P, Leone F, Bilancia D, Iaffaioli RV, Zagonel V, Giordano M, Corsi DC, Ferráú F, Labianca R, Ronzoni M, Scartozzi M, Galli F; GISCAD investigators. Treatment sequence with either irinotecan/cetuximab followed by FOLFOX-4 or the reverse strategy in metastatic colorectal cancer patients progressing after first-line FOLFIRI/bevacizumab: An Italian Group for the Study of Gastrointestinal Cancer phase III, randomised trial comparing two sequences of therapy in colorectal metastatic patients. *Eur J Cancer*. 2017 Sep;83:106-115. doi: 10.1016/j.ejca.2017.06.029. Epub 2017 Jul 20. PMID: 28735067.
6. Ferry D, Billingham L, Jarrett H, Dunlop D, Woll PJ, Nicolson M, Shah R, Thompson J, Spicer J, Muthukumar D, Skales G, Leonard P, Chetiyawardana AD, Wells P, Lewanski C, Crosse B, Hill M, Gaunt P, O'Byrne K. Carboplatin versus two doses of cisplatin in combination with gemcitabine in the treatment of advanced non-small-cell lung cancer: Results from a British Thoracic Oncology Group

- randomised phase III trial. *Eur J Cancer*. 2017 Sep;83:302-312. doi: 10.1016/j.ejca.2017.05.037. Epub 2017 Aug 4. PMID: 28780466; PMCID: PMC5597318.
7. Matsuda C, Ishiguro M, Teramukai S, Kajiwara Y, Fujii S, Kinugasa Y, Nakamoto Y, Kotake M, Sakamoto Y, Kurachi K, Maeda A, Komori K, Tomita N, Shimada Y, Takahashi K, Kotake K, Watanabe M, Mochizuki H, Nakagawa Y, Sugihara K; SACURA Study Group. A randomised-controlled trial of 1-year adjuvant chemotherapy with oral tegafur-uracil versus surgery alone in stage II colon cancer: SACURA trial. *Eur J Cancer*. 2018 Jun;96:54-63. doi: 10.1016/j.ejca.2018.03.009. Epub 2018 Apr 17. PMID: 29677641.
 8. van Rossum AGJ, Kok M, van Werkhoven E, Opdam M, Mandjes IAM, van Leeuwen- Stok AE, van Tinteren H, Imholz ALT, Portielje JEA, Bos MEM, van Bochove A, Wesseling J, Rutgers EJ, Linn SC, Oosterkamp HM; MATADOR Trialists' Group. Adjuvant dose-dense doxorubicin-cyclophosphamide versus docetaxel-doxorubicin- cyclophosphamide for high-risk breast cancer: First results of the randomised MATADOR trial (BOOG 2004-04). *Eur J Cancer*. 2018 Oct;102:40-48. doi: 10.1016/j.ejca.2018.07.013. PMID: 30125761.
 9. Campone M, Lacroix-Triki M, Roca L, Spielmann M, Wildiers H, Cottu P, Kerbrat P, Levy C, Desmoulins I, Bachelot T, Winston T, Eymard JC, Uwer L, Duhoux FP, Verhoeven D, Jaubert D, Coeffic D, Orfeuvre H, Canon JL, Asselain B, Martin AL, Lemonnier J, Roché H. UCBG 2-08: 5-year efficacy results from the UNICANCER- PACS08 randomised phase III trial of adjuvant treatment with FEC100 and then either docetaxel or ixabepilone in patients with early-stage, poor prognosis breast cancer. *Eur J Cancer*. 2018 Nov;103:184-194. doi: 10.1016/j.ejca.2018.06.025. Epub 2018 Sep 26. PMID: 30267987.
 10. Ioka T, Ueno M, Ueno H, Park JO, Chang HM, Sasahira N, Kanai M, Chung IJ, Ikeda M, Nakamori S, Mizuno N, Omuro Y, Yamaguchi T, Hara H, Sugimori K, Furuse J, Maguchi H, Furukawa M, Fukuzawa K, Kim JS, Yukisawa S, Takeuchi M, Okusaka T, Boku N, Hyodo I. TAS-118 (S-1 plus leucovorin) versus S-1 in patients with gemcitabine-refractory advanced pancreatic cancer: a randomised, open-label, phase 3 study (GRAPE trial). *Eur J Cancer*. 2019 Jan;106:78-88. doi: 10.1016/j.ejca.2018.10.004. Epub 2018 Nov 22. PMID: 30471651.
 11. Schneeweiss A, Möbus V, Tesch H, Hanusch C, Denkert C, Lübke K, Huober J, Klare P, Kümmel S, Untch M, Kast K, Jackisch C, Thomalla J, Ingold-Heppner B, Blohmer JU, Rezai M, Frank M, Engels K, Rhiem K, Fasching PA, Nekljudova V, von Minckwitz G, Loibl S. Intense dose-dense epirubicin, paclitaxel, cyclophosphamide versus weekly paclitaxel, liposomal doxorubicin (plus carboplatin in triple-negative breast cancer) for neoadjuvant treatment of high- risk early breast cancer (GeparOcto-GBG 84): A randomised phase III trial. *Eur J Cancer*. 2019 Jan;106:181-192. doi: 10.1016/j.ejca.2018.10.015. Epub 2018 Dec 5. PMID: 30528802.
 12. Retz M, Bedke J, Bögemann M, Grimm MO, Zimmermann U, Müller L, Leiber C, Teber D, Wirth M, Bolenz C, van Alphen R, De Santis M, Beeker A, Lehmann J, Indorf M, Frank M, Bokemeyer C, Gschwend JE. SWITCH II: Phase III randomized, sequential, open-label study to evaluate the efficacy and safety of sorafenib- pazopanib versus pazopanib-sorafenib in the treatment of advanced or metastatic renal cell carcinoma (AUO AN 33/11). *Eur J Cancer*. 2019 Jan;107:37-45. doi: 10.1016/j.ejca.2018.11.001. Epub 2018 Dec 7. PMID: 30529901.
 13. Yuan P, Hu X, Sun T, Li W, Zhang Q, Cui S, Cheng Y, Ouyang Q, Wang X, Chen Z, Hiraiwa M, Saito K, Funasaka S, Xu B. Eribulin mesilate versus vinorelbine in women with locally recurrent or metastatic

- breast cancer: A randomised clinical trial. *Eur J Cancer*. 2019 May;112:57-65. doi: 10.1016/j.ejca.2019.02.002. Epub 2019 Mar 29. PMID: 30928806.
14. Perrone F, De Laurentiis M, De Placido S, Orditura M, Cinieri S, Riccardi F, Ribecco AS, Putzu C, Del Mastro L, Rossi E, Tinessa V, Mosconi AM, Nuzzo F, Di Rella F, Gravina A, Iodice G, Landi G, Pacilio C, Forestieri V, Lauria R, Fabbri A, Ibrahim T, De Maio E, Barni S, Gori S, Simeon V, Arenare L, Daniele G, Piccirillo MC, Normanno N, de Matteis A, Gallo C. Adjuvant zoledronic acid and letrozole plus ovarian function suppression in premenopausal breast cancer: HOBEO phase 3 randomised trial. *Eur J Cancer*. 2019 Sep;118:178-186. doi: 10.1016/j.ejca.2019.05.004. Epub 2019 Jun 1. PMID: 31164265.
 15. D'Hondt V, Canon JL, Roca L, Levy C, Pierga JY, Le Du F, Campone M, Desmoulins I, Goncalves A, Debled M, Rios M, Ferrero JM, Serin D, Hardy-Bessard AC, Piot G, Brain E, Dohollou N, Orfeuvre H, Lemonnier J, Roché H, Delaloge S, Dalenc F. UCBG 2-04: Long-term results of the PACS 04 trial evaluating adjuvant epirubicin plus docetaxel in node-positive breast cancer and trastuzumab in the human epidermal growth factor receptor 2-positive subgroup. *Eur J Cancer*. 2019 Nov;122:91-100. doi: 10.1016/j.ejca.2019.09.014. Epub 2019 Oct 18. PMID: 31634648.
 16. Sharma A, Kalyan Mohanti B, Pal Chaudhary S, Sreenivas V, Kumar Sahoo R, Kumar Shukla N, Thulkar S, Pal S, Deo SV, Pathy S, Ranjan Dash N, Kumar S, Bhatnagar S, Kumar R, Mishra S, Sahni P, Iyer VK, Raina V. Modified gemcitabine and oxaliplatin or gemcitabine + cisplatin in unresectable gallbladder cancer: Results of a phase III randomised controlled trial. *Eur J Cancer*. 2019 Dec;123:162-170. doi: 10.1016/j.ejca.2019.10.004. Epub 2019 Nov 14. PMID: 31707181.
 17. Cortot AB, Audigier-Valette C, Molinier O, Le Moulec S, Barlesi F, Zalcman G, Dumont P, Pouessel D, Poulet C, Fontaine-Delaruelle C, Huret S, Dixmier A, Renault PA, Becht C, Raffy O, Dayen C, Mazieres J, Pichon E, Langlais A, Morin F, Moro-Sibilot D, Besse B. Weekly paclitaxel plus bevacizumab versus docetaxel as second- or third-line treatment in advanced non-squamous non-small-cell lung cancer: Results of the IFCT-1103 ULTIMATE study. *Eur J Cancer*. 2020 May;131:27-36. doi: 10.1016/j.ejca.2020.02.022. Epub 2020 Apr 8. PMID: 32276179.
 18. Eggermont AMM, Rutkowski P, Dutriaux C, Hofman-Wellenhof R, Dzierwulski P, Marples M, Grange F, Lok C, Pennachioli E, Robert C, van Akkooi ACJ, Bastholt L, Minisini A, Marshall E, Salès F, Grob JJ, Bechter O, Schadendorf D, Marreaud S, Kicinski M, Suci S, Testori AAE. Adjuvant therapy with pegylated interferon- α 2b vs observation in stage II B/C patients with ulcerated primary: Results of the European Organisation for Research and Treatment of Cancer 18081 randomised trial. *Eur J Cancer*. 2020 Jul;133:94-103. doi: 10.1016/j.ejca.2020.04.015. Epub 2020 May 26. PMID: 32470710.
 19. Quiox E, Audigier-Valette C, Lavalé A, Molinier O, Westeel V, Barlesi F, Le Treut J, Pichon E, Dauba J, Otto J, Moreau L, Madelaine J, Dumont P, Margery J, Debieuvre D, Renault PA, Pujol JL, Langlais A, Morin F, Moro-Sibilot D, Souquet PJ. Switch maintenance chemotherapy versus observation after carboplatin and weekly paclitaxel doublet chemotherapy in elderly patients with advanced non-small cell lung cancer: IFCT-1201 MODEL trial. *Eur J Cancer*. 2020 Oct;138:193-201. doi: 10.1016/j.ejca.2020.07.034. Epub 2020 Sep 6. PMID: 32898792.
 20. Guarneri V, Giorgi CA, Cinieri S, Bengala C, Mariani G, Bisagni G, Frassoldati A, Zamagni C, De Rossi C, Amoroso V, Andreatta C, Ferro A, Zambelli A, Gori S, Garrone O, Dieci MV, Orlando L, Pastina I, Beninato T, Moretti G, Genovesi E, Cinefra M, Vicini R, Magni G, De Salvo GL, Conte P. Everolimus plus aromatase inhibitors as maintenance therapy after first-line chemotherapy: Final results of the

- phase III randomised MAIN-A (MAINtenance Afinitor) trial. *Eur J Cancer*. 2021 Sep;154:21-29. doi: 10.1016/j.ejca.2021.05.008. Epub 2021 Jul 2. PMID: 34225066.
21. Bianchi S, Mosca A, Dalla Volta A, Prati V, Ortega C, Buttigliero C, Fea E, Vanella P, Valcamonico F, Zamparini M, Sirotova Z, Chiappino I, Dal Canton O, Masini C, Sacco C, Amoroso D, Montagnani F, Comandone A, Bellissimo AR, Ciccone G, Baier S, Gennari A, Tucci M, Berruti A. Maintenance versus discontinuation of androgen deprivation therapy during continuous or intermittent docetaxel administration in castration-resistant prostate cancer patients: A multicentre, randomised Phase III study by the Piemonte Oncology Network. *Eur J Cancer*. 2021 Sep;155:127-135. doi: 10.1016/j.ejca.2021.06.034. Epub 2021 Aug 6. PMID: 34371442.
 22. Guo Y, Luo Y, Zhang Q, Huang X, Li Z, Shen L, Feng J, Sun Y, Yang K, Ge M, Zhu X, Wang L, Liu Y, He X, Bai C, Xue K, Zeng Y, Chang X, Chen W, Lin T. First-line treatment with chemotherapy plus cetuximab in Chinese patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck: Efficacy and safety results of the randomised, phase III CHANGE-2 trial. *Eur J Cancer*. 2021 Oct;156:35-45. doi: 10.1016/j.ejca.2021.06.039. Epub 2021 Aug 18. PMID: 34418665.
 23. Möbus V, Lück HJ, Ladda E, Klare P, Schmidt M, Schneeweiss A, Grischke EM, Wachsmann G, Forstbauer H, Untch M, Marmé F, Blohmer JU, Jackisch C, Huober J, Stickeler E, Reinisch M, Link T, Sinn BV, Janni W, Denkert C, Furlanetto J, Engels K, Solbach C, Schmatloch S, Rey J, Burchardi N, Loibl S; GBG and AGO-B. Phase III randomised trial comparing intense dose-dense chemotherapy to tailored dose-dense chemotherapy in high-risk early breast cancer (GAIN-2). *Eur J Cancer*. 2021 Oct;156:138-148. doi: 10.1016/j.ejca.2021.07.033. Epub 2021 Aug 24. PMID: 34450552.
 24. Go SI, Lee SC, Bae WK, Zang DY, Lee HW, Jang JS, Ji JH, Kim JH, Park S, Sym SJ, Yang Y, Jeon SY, Hwang IG, Oh SY, Kang JH. Modified FOLFIRINOX versus S-1 as second-line chemotherapy in gemcitabine-failed metastatic pancreatic cancer patients: A randomised controlled trial (MPACA-3). *Eur J Cancer*. 2021 Nov;157:21-30. doi: 10.1016/j.ejca.2021.08.002. Epub 2021 Aug 28. PMID: 34464782.

Journal of Clinical Oncology

1. Powles T, Huddart RA, Elliott T, Sarker SJ, Ackerman C, Jones R, Hussain S, Crabb S, Jagdev S, Chester J, Hilman S, Beresford M, Macdonald G, Santhanam S, Frew JA, Stockdale A, Hughes S, Berney D, Chowdhury S. Phase III, Double-Blind, Randomized Trial That Compared Maintenance Lapatinib Versus Placebo After First-Line Chemotherapy in Patients With Human Epidermal Growth Factor Receptor 1/2-Positive Metastatic Bladder Cancer. *J Clin Oncol*. 2017 Jan;35(1):48-55. doi: 10.1200/JCO.2015.66.3468. Epub 2016 Oct 28. PMID: 28034079.
2. 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. *J Clin Oncol*. 2017 Jan;35(1):40-47. doi: 10.1200/JCO.2016.69.1584. Epub 2016 Oct 31. PMID: 28034081.
3. Perez EA, Barrios C, Eiermann W, Toi M, Im YH, Conte P, Martin M, Pienkowski T, Pivot X, Burris H 3rd, Petersen JA, Stanzel S, Strasak A, Patre M, Ellis P. Trastuzumab Emtansine With or Without Pertuzumab Versus Trastuzumab Plus Taxane for Human Epidermal Growth Factor Receptor 2-Positive, Advanced Breast Cancer: Primary Results From the Phase III MARIANNE Study. *J Clin Oncol*. 2017 Jan 10;35(2):141-148. doi: 10.1200/JCO.2016.67.4887. Epub 2016 Nov 7. Erratum in: *J Clin*

- Oncol. 2017 Jul 10;35(20):2342. Erratum in: J Clin Oncol. 2019 Feb 1;37(4):358. PMID: 28056202; PMCID: PMC5455677.
4. Lee SM, Falzon M, Blackhall F, Spicer J, Nicolson M, Chaudhuri A, Middleton G, Ahmed S, Hicks J, Crosse B, Napier M, Singer JM, Ferry D, Lewanski C, Forster M, Rolls SA, Capitano A, Rudd R, Iles N, Ngai Y, Gandy M, Lillywhite R, Hackshaw A. Randomized Prospective Biomarker Trial of ERCC1 for Comparing Platinum and Nonplatinum Therapy in Advanced Non-Small-Cell Lung Cancer: ERCC1 Trial (ET). J Clin Oncol. 2017 Feb;35(4):402-411. doi: 10.1200/JCO.2016.68.1841. Epub 2016 Nov 28. PMID: 27893326.
 5. Spigel DR, Edelman MJ, O'Byrne K, Paz-Ares L, Mocchi S, Phan S, Shames DS, Smith D, Yu W, Paton VE, Mok T. Results From the Phase III Randomized Trial of Onartuzumab Plus Erlotinib Versus Erlotinib in Previously Treated Stage IIIB or IV Non-Small-Cell Lung Cancer: METLung. J Clin Oncol. 2017 Feb;35(4):412-420. doi: 10.1200/JCO.2016.69.2160. Epub 2016 Dec 12. PMID: 27937096.
 6. Agarwala SS, Lee SJ, Yip W, Rao UN, Tarhini AA, Cohen GI, Reintgen DS, Evans TL, Brell JM, Albertini MR, Atkins MB, Dakhil SR, Conry RM, Sosman JA, Flaherty LE, Sondak VK, Carson WE, Smylie MG, Pappo AS, Kefford RF, Kirkwood JM. Phase III Randomized Study of 4 Weeks of High-Dose Interferon- α -2b in Stage T2bNO, T3a-bNO, T4a-bNO, and T1-4N1a-2a (microscopic) Melanoma: A Trial of the Eastern Cooperative Oncology Group-American College of Radiology Imaging Network Cancer Research Group (E1697). J Clin Oncol. 2017 Mar 10;35(8):885-892. doi: 10.1200/JCO.2016.70.2951. Epub 2017 Jan 30. PMID: 28135150; PMCID: PMC5455684.
 7. Smith I, Yardley D, Burris H, De Boer R, Amadori D, McIntyre K, Ejlertsen B, Gnant M, Jonat W, Pritchard KI, Dowsett M, Hart L, Poggio S, Comarella L, Salomon H, Wamil B, O'Shaughnessy J. Comparative Efficacy and Safety of Adjuvant Letrozole Versus Anastrozole in Postmenopausal Patients With Hormone Receptor- Positive, Node-Positive Early Breast Cancer: Final Results of the Randomized Phase III Femara Versus Anastrozole Clinical Evaluation (FACE) Trial. J Clin Oncol. 2017 Apr 1;35(10):1041-1048. doi: 10.1200/JCO.2016.69.2871. Epub 2017 Jan 23. Erratum in: J Clin Oncol. 2019 Feb 1;37(4):359. PMID: 28113032.
 8. Tiseo M, Boni L, Ambrosio F, Camerini A, Baldini E, Cinieri S, Brighenti M, Zanelli F, Defraia E, Chiari R, Dazzi C, Tibaldi C, Turolla GM, D'Alessandro V, Zilembo N, Trolese AR, Grossi F, Riccardi F, Arduzoni A. Italian, Multicenter, Phase III, Randomized Study of Cisplatin Plus Etoposide With or Without Bevacizumab as First-Line Treatment in Extensive-Disease Small-Cell Lung Cancer: The GOIRC-AIFA FARM6PMFJM Trial. J Clin Oncol. 2017 Apr 20;35(12):1281-1287. doi: 10.1200/JCO.2016.69.4844. Epub 2017 Jan 30. PMID: 28135143.
 9. Seckl MJ, Ottensmeier CH, Cullen M, Schmid P, Ngai Y, Muthukumar D, Thompson J, Harden S, Middleton G, Fife KM, Crosse B, Taylor P, Nash S, Hackshaw A. Multicenter, Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Pravastatin Added to First-Line Standard Chemotherapy in Small-Cell Lung Cancer (LUNGSTAR). J Clin Oncol. 2017 May 10;35(14):1506-1514. doi: 10.1200/JCO.2016.69.7391. Epub 2017 Feb 27. PMID: 28240967; PMCID: PMC5455702.
 10. Casali PG, Zalcberg J, Le Cesne A, Reichardt P, Blay JY, Lindner LH, Judson IR, Schöffski P, Leyvraz S, Italiano A, Grünwald V, Pousa AL, Kotasek D, Sleijfer S, Kerst JM, Rutkowski P, Fumagalli E, Hogendoorn P, Litière S, Marreaud S, van der Graaf W, Gronchi A, Verweij J; European Organisation for Research and Treatment of Cancer Soft Tissue and Bone Sarcoma Group, Italian Sarcoma Group, and Australasian Gastrointestinal Trials Group. Ten-Year Progression-Free and Overall Survival in Patients

With Unresectable or Metastatic GI Stromal Tumors: Long-Term Analysis of the European Organisation for Research and Treatment of Cancer, Italian Sarcoma Group, and Australasian Gastrointestinal Trials Group Intergroup Phase III Randomized Trial on Imatinib at Two Dose Levels. *J Clin Oncol*. 2017 May 20;35(15):1713-1720. doi: 10.1200/JCO.2016.71.0228. Epub 2017 Mar 31. PMID: 28362562.

11. Yao JC, Guthrie KA, Moran C, Strosberg JR, Kulke MH, Chan JA, LoConte N, McWilliams RR, Wolin EM, Mattar B, McDonough S, Chen H, Blanke CD, Hochster HS. Phase III Prospective Randomized Comparison Trial of Depot Octreotide Plus Interferon Alfa-2b Versus Depot Octreotide Plus Bevacizumab in Patients With Advanced Carcinoid Tumors: SWOG S0518. *J Clin Oncol*. 2017 May 20;35(15):1695-1703. doi: 10.1200/JCO.2016.70.4072. Epub 2017 Apr 6. PMID: 28384065; PMCID: PMC5455764.
12. Edelman MJ, Wang X, Hodgson L, Cheney RT, Baggstrom MQ, Thomas SP, Gajra A, Bertino E, Reckamp KL, Molina J, Schiller JH, Mitchell-Richards K, Friedman PN, Ritter J, Milne G, Hahn OM, Stinchcombe TE, Vokes EE; Alliance for Clinical Trials in Oncology. Phase III Randomized, Placebo-Controlled, Double-Blind Trial of Celecoxib in Addition to Standard Chemotherapy for Advanced Non-Small-Cell Lung Cancer With Cyclooxygenase-2 Overexpression: CALGB 30801 (Alliance). *J Clin Oncol*. 2017 Jul 1;35(19):2184-2192. doi: 10.1200/JCO.2016.71.3743. Epub 2017 May PMID: 28489511; PMCID: PMC5493050.
13. Shah MA, Xu RH, Bang YJ, Hoff PM, Liu T, Herráez-Baranda LA, Xia F, Garg A, Shing M, Tabernero J. HELOISE: Phase IIIb Randomized Multicenter Study Comparing Standard-of-Care and Higher-Dose Trastuzumab Regimens Combined With Chemotherapy as First-Line Therapy in Patients With Human Epidermal Growth Factor Receptor 2-Positive Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma. *J Clin Oncol*. 2017 Aug 1;35(22):2558-2567. doi: 10.1200/JCO.2016.71.6852. Epub 2017 Jun 2. PMID: 28574779.
14. Jalal SI, Lavin P, Lo G, Lebel F, Einhorn L. Carboplatin and Etoposide With or Without Palifosfamide in Untreated Extensive-Stage Small-Cell Lung Cancer: A Multicenter, Adaptive, Randomized Phase III Study (MATISSE). *J Clin Oncol*. 2017 Aug 10;35(23):2619-2623. doi: 10.1200/JCO.2016.71.7454. Epub 2017 Jun 12. PMID: 28605291.
15. Ejlersen B, Tuxen MK, Jakobsen EH, Jensen MB, Knoop AS, Højris I, Ewertz M, Balslev E, Danø H, Vestlev PM, Kenholm J, Nielsen DL, Bechmann T, Andersson M, Cold S, Nielsen HM, Maae E, Carlsen D, Mouridsen HT. Adjuvant Cyclophosphamide and Docetaxel With or Without Epirubicin for Early TOP2A-Normal Breast Cancer: DBCG 07-READ, an Open-Label, Phase III, Randomized Trial. *J Clin Oncol*. 2017 Aug 10;35(23):2639-2646. doi: 10.1200/JCO.2017.72.3494. Epub 2017 Jun 29. PMID: 28661759.
16. Sledge GW Jr, Toi M, Neven P, Sohn J, Inoue K, Pivot X, Burdaeva O, Okera M, Masuda N, Kaufman PA, Koh H, Grischke EM, Frenzel M, Lin Y, Barriga S, Smith IC, Bourayou N, Llombart-Cussac A. MONARCH 2: Abemaciclib in Combination With Fulvestrant in Women With HR+/HER2- Advanced Breast Cancer Who Had Progressed While Receiving Endocrine Therapy. *J Clin Oncol*. 2017 Sep 1;35(25):2875-2884. doi: 10.1200/JCO.2017.73.7585. Epub 2017 Jun 3. PMID: 28580882.
17. Urruticoechea A, Rizwanullah M, Im SA, Ruiz ACS, Láng I, Tomasello G, Douthwaite H, Badovinac Crnjevic T, Heeson S, Eng-Wong J, Muñoz M. Randomized Phase III Trial of Trastuzumab Plus Capecitabine With or Without Pertuzumab in Patients With Human Epidermal Growth Factor Receptor 2-Positive Metastatic Breast Cancer Who Experienced Disease Progression During or After Trastuzumab-

- Based Therapy. *J Clin Oncol*. 2017 Sep 10;35(26):3030-3038. doi: 10.1200/JCO.2016.70.6267. Epub 2017 Apr 24. PMID: 28437161.
18. 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. *J Clin Oncol*. 2017 Oct 1;35(28):3189-3197. doi: 10.1200/JCO.2016.72.1068. Epub 2017 Jul 28. PMID: 28753384.
 19. Eisenberger M, Hardy-Bessard AC, Kim CS, Géczi L, Ford D, Mourey L, Carles J, Parente P, Font A, Kacso G, Chadjaa M, Zhang W, Bernard J, de Bono J. Phase III Study Comparing a Reduced Dose of Cabazitaxel (20 mg/m²) and the Currently Approved Dose (25 mg/m²) in Postdocetaxel Patients With Metastatic Castration-Resistant Prostate Cancer-PROSELICA. *J Clin Oncol*. 2017 Oct 1;35(28):3198-3206. doi: 10.1200/JCO.2016.72.1076. Epub 2017 Aug 15. PMID: 28809610.
 20. Sinn M, Bahra M, Liersch T, Gellert K, Messmann H, Bechstein W, Waldschmidt D, Jacobasch L, Wilhelm M, Rau BM, Grützmann R, Weinmann A, Maschmeyer G, Pelzer U, Stieler JM, Striefler JK, Ghadimi M, Bischoff S, Dörken B, Oettle H, Riess H. CONKO-005: Adjuvant Chemotherapy With Gemcitabine Plus Erlotinib Versus Gemcitabine Alone in Patients After R0 Resection of Pancreatic Cancer: A Multicenter Randomized Phase III Trial. *J Clin Oncol*. 2017 Oct 10;35(29):3330-3337. doi: 10.1200/JCO.2017.72.6463. Epub 2017 Aug 17. PMID: 28817370.
 21. Pignata S, Scambia G, Bologna A, Signoriello S, Vergote IB, Wagner U, Lorusso D, Murgia V, Sorio R, Ferrandina G, Sacco C, Cormio G, Breda E, Cinieri S, Natale D, Mangili G, Pisano C, Cecere SC, Di Napoli M, Salutari V, Raspagliesi F, Arenare L, Bergamini A, Bryce J, Daniele G, Piccirillo MC, Gallo C, Perrone F. Randomized Controlled Trial Testing the Efficacy of Platinum-Free Interval Prolongation in Advanced Ovarian Cancer: The MITO-8, MaNGO, BGOG-Ov1, AGO-Ovar2.16, ENGOT-Ov1, GCIG Study. *J Clin Oncol*. 2017 Oct 10;35(29):3347-3353. doi: 10.1200/JCO.2017.73.4293. Epub 2017 Aug 21. PMID: 28825853.
 22. 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. *J Clin Oncol*. 2017 Oct 20;35(30):3449-3457. doi: 10.1200/JCO.2016.71.7629. Epub 2017 Aug 30. PMID: 28854067.
 23. Kubota K, Yoshioka H, Oshita F, Hida T, Yoh K, Hayashi H, Kato T, Kaneda H, Yamada K, Tanaka H, Ichinose Y, Park K, Cho EK, Lee KH, Lin CB, Yang JC, Hara K, Asato T, Nakagawa K. Phase III, Randomized, Placebo-Controlled, Double-Blind Trial of Motesanib (AMG-706) in Combination With Paclitaxel and Carboplatin in East Asian Patients With Advanced Nonsquamous Non-Small-Cell Lung Cancer. *J Clin Oncol*. 2017 Nov 10;35(32):3662-3670. doi: 10.1200/JCO.2017.72.7297. Epub 2017 Sep 13. PMID: 28902534.
 24. Goetz MP, Toi M, Campone M, Sohn J, Paluch-Shimon S, Huober J, Park IH, Trédan O, Chen SC, Manso L, Freedman OC, Garnica Jaliffe G, Forrester T, Frenzel M, Barriga S, Smith IC, Bourayou N, Di Leo A. MONARCH 3: Abemaciclib As Initial Therapy for Advanced Breast Cancer. *J Clin Oncol*. 2017 Nov 10;35(32):3638-3646. doi: 10.1200/JCO.2017.75.6155. Epub 2017 Oct 2. PMID: 28968163.

25. Fuchs CS, Niedzwiecki D, Mamon HJ, Tepper JE, Ye X, Swanson RS, Enzinger PC, Haller DG, Dragovich T, Alberts SR, Bjarnason GA, Willett CG, Gunderson LL, Goldberg RM, Venook AP, Ilson D, O'Reilly E, Ciombor K, Berg DJ, Meyerhardt J, Mayer RJ. Adjuvant Chemoradiotherapy With Epirubicin, Cisplatin, and Fluorouracil Compared With Adjuvant Chemoradiotherapy With Fluorouracil and Leucovorin After Curative Resection of Gastric Cancer: Results From CALGB 80101 (Alliance). *J Clin Oncol*. 2017 Nov 10;35(32):3671-3677. doi: 10.1200/JCO.2017.74.2130. Epub 2017 Oct 4. PMID: 28976791; PMCID: PMC5678342.
26. Motzer RJ, Haas NB, Donskov F, Gross-Goupil M, Varlamov S, Kopyltsov E, Lee JL, Melichar B, Rini BI, Choueiri TK, Zemanova M, Wood LA, Reaume MN, Stenzl A, Chowdhury S, Lim HY, McDermott R, Michael A, Bao W, Carrasco-Alfonso MJ, Aimone P, Voi M, Doehn C, Russo P, Sternberg CN; PROTECT investigators. Randomized Phase III Trial of Adjuvant Pazopanib Versus Placebo After Nephrectomy in Patients With Localized or Locally Advanced Renal Cell Carcinoma. *J Clin Oncol*. 2017 Dec 10;35(35):3916-3923. doi: 10.1200/JCO.2017.73.5324. Epub 2017 Sep 13. PMID: 28902533; PMCID: PMC6018511.
27. Xu J, Kim TW, Shen L, Sriuranpong V, Pan H, Xu R, Guo W, Han SW, Liu T, Park YS, Shi C, Bai Y, Bi F, Ahn JB, Qin S, Li Q, Wu C, Ma D, Lin D, Li J. Results of a Randomized, Double-Blind, Placebo-Controlled, Phase III Trial of Trifluridine/Tipiracil (TAS-102) Monotherapy in Asian Patients With Previously Treated Metastatic Colorectal Cancer: The TERRA Study. *J Clin Oncol*. 2018 Feb 1;36(4):350-358. doi: 10.1200/JCO.2017.74.3245. Epub 2017 Dec 7. PMID: 29215955.
28. Aparicio T, Ghiringhelli F, Boige V, Le Malicot K, Taieb J, Bouché O, Phelip JM, François E, Borel C, Faroux R, Dahan L, Jacquot S, Genet D, Khemissa F, Suc E, Desseigne F, Texereau P, Lepage C, Bennouna J; PRODIGE 9 Investigators. Bevacizumab Maintenance Versus No Maintenance During Chemotherapy-Free Intervals in Metastatic Colorectal Cancer: A Randomized Phase III Trial (PRODIGE 9). *J Clin Oncol*. 2018 Mar 1;36(7):674-681. doi: 10.1200/JCO.2017.75.2931. Epub 2018 Jan 18. PMID: 29346040.
29. Carvajal RD, Piperno-Neumann S, Kapiteijn E, Chapman PB, Frank S, Joshua AM, Piulats JM, Wolter P, Cocquyt V, Chmielowski B, Evans TRJ, Gastaud L, Linette G, Berking C, Schachter J, Rodrigues MJ, Shoushtari AN, Clemett D, Ghiorghiu D, Mariani G, Spratt S, Lovick S, Barker P, Kilgour E, Lai Z, Schwartz GK, Nathan P. Selumetinib in Combination With Dacarbazine in Patients With Metastatic Uveal Melanoma: A Phase III, Multicenter, Randomized Trial (SUMIT). *J Clin Oncol*. 2018 Apr 20;36(12):1232-1239. doi: 10.1200/JCO.2017.74.1090. Epub 2018 Mar 12. Erratum in: *J Clin Oncol*. 2018 Dec 10;36(35):3528. PMID: 29528792.
30. Gupta S, Maheshwari A, Parab P, Mahantshetty U, Hawaldar R, Sastri Chopra S, Kerkar R, Engineer R, Tongaonkar H, Ghosh J, Gulia S, Kumar N, Shylasree TS, Gawade R, Kembhavi Y, Gaikar M, Menon S, Thakur M, Shrivastava S, Badwe R. Neoadjuvant Chemotherapy Followed by Radical Surgery Versus Concomitant Chemotherapy and Radiotherapy in Patients With Stage IB2, IIA, or IIB Squamous Cervical Cancer: A Randomized Controlled Trial. *J Clin Oncol*. 2018 Jun 1;36(16):1548-1555. doi: 10.1200/JCO.2017.75.9985. Epub 2018 Feb 12. PMID: 29432076.
31. Tao Y, Auperin A, Sire C, Martin L, Khoury C, Maingon P, Bardet E, Kaminsky MC, Lapeyre M, Chatellier T, Alfonsi M, Pointreau Y, Jadaud E, Géry B, Zawadi A, Tourani JM, Laguerre B, Coutte A, Racadot S, Hasbini A, Malaurie E, Borel C, Meert N, Cornely A, Ollivier N, Casiraghi O, Sun XS, Bourhis J. Improved Outcome by Adding Concurrent Chemotherapy to Cetuximab and Radiotherapy for Locally Advanced Head and Neck Carcinomas: Results of the GORTEC 2007-01 Phase III Randomized Trial. *J*

- Clin Oncol. 2018 Jun 7;JCO2017762518. doi: 10.1200/JCO.2017.76.2518. Epub ahead of print. PMID: 29878867.
32. Ishigami H, Fujiwara Y, Fukushima R, Nashimoto A, Yabusaki H, Imano M, Imamoto H, Kodera Y, Uenosono Y, Amagai K, Kadowaki S, Miwa H, Yamaguchi H, Yamaguchi T, Miyaji T, Kitayama J. Phase III Trial Comparing Intraperitoneal and Intravenous Paclitaxel Plus S-1 Versus Cisplatin Plus S-1 in Patients With Gastric Cancer With Peritoneal Metastasis: PHOENIX-GC Trial. *J Clin Oncol*. 2018 Jul 1;36(19):1922-1929. doi: 10.1200/JCO.2018.77.8613. Epub 2018 May 10. PMID: 29746229.
 33. Attard G, Borre M, Gurney H, Loriot Y, Andresen-Daniil C, Kalleda R, Pham T, Taplin ME; PLATO collaborators. Abiraterone Alone or in Combination With Enzalutamide in Metastatic Castration-Resistant Prostate Cancer With Rising Prostate-Specific Antigen During Enzalutamide Treatment. *J Clin Oncol*. 2018 Sep 1;36(25):2639-2646. doi: 10.1200/JCO.2018.77.9827. Epub 2018 Jul 20. PMID: 30028657; PMCID: PMC6118405.
 34. Miller KD, O'Neill A, Gradishar W, Hobday TJ, Goldstein LJ, Mayer IA, Bloom S, Brufsky AM, Tevaarwerk AJ, Sparano JA, Le-Lindqwister NA, Hendricks CB, Northfelt DW, Dang CT, Sledge GW Jr. Double-Blind Phase III Trial of Adjuvant Chemotherapy With and Without Bevacizumab in Patients With Lymph Node-Positive and High-Risk Lymph Node-Negative Breast Cancer (E5103). *J Clin Oncol*. 2018 Sep 1;36(25):2621-2629. doi: 10.1200/JCO.2018.79.2028. Epub 2018 Jul 24. PMID: 30040523; PMCID: PMC6118403.
 35. Yang H, Liu H, Chen Y, Zhu C, Fang W, Yu Z, Mao W, Xiang J, Han Y, Chen Z, Yang H, Wang J, Pang Q, Zheng X, Yang H, Li T, Lordick F, D'Journo XB, Cerfolio RJ, Korst RJ, Novoa NM, Swanson SJ, Brunelli A, Ismail M, Fernando HC, Zhang X, Li Q, Wang G, Chen B, Mao T, Kong M, Guo X, Lin T, Liu M, Fu J; AME Thoracic Surgery Collaborative Group. Neoadjuvant Chemoradiotherapy Followed by Surgery Versus Surgery Alone for Locally Advanced Squamous Cell Carcinoma of the Esophagus (NEOCRTEC5010): A Phase III Multicenter, Randomized, Open-Label Clinical Trial. *J Clin Oncol*. 2018 Sep 20;36(27):2796-2803. doi: 10.1200/JCO.2018.79.1483. Epub 2018 Aug 8. PMID: 30089078; PMCID: PMC6145832.
 36. Hensley ML, Enserro D, Hatcher H, Ottevanger PB, Krarup-Hansen A, Blay JY, Fisher C, Moxley KM, Lele SB, Lea JS, Tewari KS, Thaker PH, Zivanovic O, O'Malley DM, Robison K, Miller DS. Adjuvant Gemcitabine Plus Docetaxel Followed by Doxorubicin Versus Observation for High-Grade Uterine Leiomyosarcoma: A Phase III NRG Oncology/Gynecologic Oncology Group Study. *J Clin Oncol*. 2018 Oct 5;36(33):JCO1800454. doi: 10.1200/JCO.18.00454. Epub ahead of print. PMID: 30289732; PMCID: PMC6241678.
 37. Qin S, Li J, Wang L, Xu J, Cheng Y, Bai Y, Li W, Xu N, Lin LZ, Wu Q, Li Y, Yang J, Pan H, Ouyang X, Qiu W, Wu K, Xiong J, Dai G, Liang H, Hu C, Zhang J, Tao M, Yao Q, Wang J, Chen J, Eggleton SP, Liu T. Efficacy and Tolerability of First-Line Cetuximab Plus Leucovorin, Fluorouracil, and Oxaliplatin (FOLFOX-4) Versus FOLFOX-4 in Patients With *RAS* Wild-Type Metastatic Colorectal Cancer: The Open-Label, Randomized, Phase III TAILOR Trial. *J Clin Oncol*. 2018 Oct 20;36(30):3031-3039. doi: 10.1200/JCO.2018.78.3183. Epub 2018 Sep 10. PMID: 30199311; PMCID: PMC6324088.
 38. Modest DP, Fischer von Weikersthal L, Decker T, Vehling-Kaiser U, Uhlig J, Schenk M, Freiberg-Richter J, Peuser B, Denzlinger C, Peveling Genannt Reddemann C, Graeven U, Schuch G, Schwaner I, Stahler A, Jung A, Kirchner T, Held S, Stintzing S, Giessen-Jung C, Heinemann V; XELAVIRI/AIO KRK0110 Investigators. Sequential Versus Combination Therapy of Metastatic Colorectal Cancer Using

- Fluoropyrimidines, Irinotecan, and Bevacizumab: A Randomized, Controlled Study- XELAVIRI (AIO KRK0110). *J Clin Oncol*. 2019 Jan 1;37(1):22-32. doi: 10.1200/JCO.18.00052. Epub 2018 Nov 2. PMID: 30388045.
39. Edeline J, Benabdelghani M, Bertaut A, Watelet J, Hammel P, Joly JP, Boudjema K, Fartoux L, Bouhier-Leporrier K, Jouve JL, Faroux R, Guerin-Meyer V, Kurtz JE, Assénat E, Seitz JF, Baumgaertner I, Tougeron D, de la Fouchardière C, Lombard-Bohas C, Boucher E, Stanbury T, Louvet C, Malka D, Phelip JM. Gemcitabine and Oxaliplatin Chemotherapy or Surveillance in Resected Biliary Tract Cancer (PRODIGE 12-ACCORD 18-UNICANCER GI): A Randomized Phase III Study. *J Clin Oncol*. 2019 Mar 10;37(8):658-667. doi: 10.1200/JCO.18.00050. Epub 2019 Feb 1. PMID: 30707660.
40. Walker JL, Brady MF, Wenzel L, Fleming GF, Huang HQ, DiSilvestro PA, Fujiwara K, Alberts DS, Zheng W, Tewari KS, Cohn DE, Powell MA, Van Le L, Davidson SA, Gray HJ, Rose PG, Aghajanian C, Myers T, Alvarez Secord A, Rubin SC, Mannel RS. Randomized Trial of Intravenous Versus Intraperitoneal Chemotherapy Plus Bevacizumab in Advanced Ovarian Carcinoma: An NRG Oncology/Gynecologic Oncology Group Study. *J Clin Oncol*. 2019 Jun 1;37(16):1380-1390. doi: 10.1200/JCO.18.01568. Epub 2019 Apr 19. Erratum in: *J Clin Oncol*. 2019 Sep 1;37(25):2299. PMID: 31002578; PMCID: PMC6544459.
41. Armstrong AJ, Szmulewitz RZ, Petrylak DP, Holzbeierlein J, Villers A, Azad A, Alcaraz A, Alekseev B, Iguchi T, Shore ND, Rosbrook B, Sugg J, Baron B, Chen L, Stenzl A. ARCHES: A Randomized, Phase III Study of Androgen Deprivation Therapy With Enzalutamide or Placebo in Men With Metastatic Hormone-Sensitive Prostate Cancer. *J Clin Oncol*. 2019 Nov 10;37(32):2974-2986. doi: 10.1200/JCO.19.00799. Epub 2019 Jul 22. PMID: 31329516; PMCID: PMC6839905.
42. Argiris A, Li S, Savvides P, Ohr JP, Gilbert J, Levine MA, Chakravarti A, Haigentz M Jr, Saba NF, Ikpeazu CV, Schneider CJ, Pinto HA, Forastiere AA, Burtneess B. Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients With Recurrent or Metastatic Head and Neck Cancer. *J Clin Oncol*. 2019 Dec 1;37(34):3266-3274. doi: 10.1200/JCO.19.00555. Epub 2019 Oct 16. PMID: 31618129; PMCID: PMC6980834.
43. Noronha V, Patil VM, Joshi A, Menon N, Chougule A, Mahajan A, Janu A, Purandare N, Kumar R, More S, Goud S, Kadam N, Daware N, Bhattacharjee A, Shah S, Yadav A, Trivedi V, Behel V, Dutt A, Banavali SD, Prabhash K. Gefitinib Versus Gefitinib Plus Pemetrexed and Carboplatin Chemotherapy in EGFR-Mutated Lung Cancer. *J Clin Oncol*. 2020 Jan 10;38(2):124-136. doi: 10.1200/JCO.19.01154. Epub 2019 Aug 14. PMID: 31411950.
44. Lluch A, Barrios CH, Torrecillas L, Ruiz-Borrego M, Bines J, Segalla J, Guerrero-Zotano Á, García-Sáenz JA, Torres R, de la Haba J, García-Martínez E, Gómez HL, Llombart A, Bofill JS, Baena-Cañada JM, Barnadas A, Calvo L, Pérez-Michel L, Ramos M, Fernández I, Rodríguez-Lescure Á, Cárdenas J, Vinholes J, Martínez de Dueñas E, Godes MJ, Seguí MA, Antón A, López-Álvarez P, Moncayo J, Amorim G, Villar E, Reyes S, Sampaio C, Cardemil B, Escudero MJ, Bezares S, Carrasco E, Martín M; GEICAM Spanish Breast Cancer Group; CIBOMA (Iberoamerican Coalition for Research in Breast Oncology); LACOG (Latin American Cooperative Oncology Group). Phase III Trial of Adjuvant Capecitabine After Standard Neo-/Adjuvant Chemotherapy in Patients With Early Triple-Negative Breast Cancer (GEICAM/2003-11_CIBOMA/2004-01). *J Clin Oncol*. 2020 Jan 20;38(3):203-213. doi: 10.1200/JCO.19.00904. Epub 2019 Dec 5. Erratum in: *J Clin Oncol*. 2020 Mar 10;38(8):847. PMID: 31804894; PMCID: PMC6968797.

45. Kim HA, Lee JW, Nam SJ, Park BW, Im SA, Lee ES, Jung YS, Yoon JH, Kang SS, Lee SJ, Park KH, Jeong J, Cho SH, Kim SY, Kim LS, Moon BI, Lee MH, Kim TH, Park C, Jung SH, Gwak G, Kim J, Kang SH, Jin YW, Kim HJ, Han SH, Han W, Hur MH, Noh WC; Korean Breast Cancer Study Group. Adding Ovarian Suppression to Tamoxifen for Premenopausal Breast Cancer: A Randomized Phase III Trial. *J Clin Oncol*. 2020 Feb 10;38(5):434-443. doi: 10.1200/JCO.19.00126. Epub 2019 Sep 16. PMID: 31518174.
46. Fehrenbacher L, Cecchini RS, Geyer CE Jr, Rastogi P, Costantino JP, Atkins JN, Crown JP, Polikoff J, Boileau JF, Provencher L, Stokoe C, Moore TD, Robidoux A, Flynn PJ, Borges VF, Albain KS, Swain SM, Paik S, Mamounas EP, Wolmark N. NSABP B-47/NRG Oncology Phase III Randomized Trial Comparing Adjuvant Chemotherapy With or Without Trastuzumab in High-Risk Invasive Breast Cancer Negative for HER2 by FISH and With IHC 1+ or 2. *J Clin Oncol*. 2020 Feb 10;38(5):444-453. doi: 10.1200/JCO.19.01455. Epub 2019 Dec 10. PMID: 31821109; PMCID: PMC7007289.
47. 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). *J Clin Oncol*. 2020 Feb 20;38(6):613-622. doi: 10.1200/JCO.19.00816. Epub 2019 Dec 12. PMID: 31829907.
48. Tarhini AA, Lee SJ, Hodi FS, Rao UNM, Cohen GI, Hamid O, Hutchins LF, Sosman JA, Kluger HM, Eroglu Z, Koon HB, Lawrence DP, Kendra KL, Minor DR, Lee CB, Albertini MR, Flaherty LE, Petrella TM, Streicher H, Sondak VK, Kirkwood JM. Phase III Study of Adjuvant Ipilimumab (3 or 10 mg/kg) Versus High-Dose Interferon Alfa-2b for Resected High-Risk Melanoma: North American Intergroup E1609. *J Clin Oncol*. 2020 Feb 20;38(6):567-575. doi: 10.1200/JCO.19.01381. Epub 2019 Dec 27. PMID: 31880964; PMCID: PMC7030886.
49. Seto T, Azuma K, Yamanaka T, Sugawara S, Yoshioka H, Wakuda K, Atagi S, Iwamoto Y, Hayashi H, Okamoto I, Saka H, Mitsuoka S, Fujimoto D, Nishino K, Horiike A, Daga H, Sone T, Yamamoto N, Nakagawa K, Nakanishi Y. Randomized Phase III Study of Continuation Maintenance Bevacizumab With or Without Pemetrexed in Advanced Nonsquamous Non-Small-Cell Lung Cancer: COMPASS (WJOG5610L). *J Clin Oncol*. 2020 Mar 10;38(8):793-803. doi: 10.1200/JCO.19.01494. Epub 2019 Dec 27. PMID: 31880966.
50. Penson RT, Valencia RV, Cibula D, Colombo N, Leath CA 3rd, Bidziński M, Kim JW, Nam JH, Madry R, Hernández C, Mora PAR, Ryu SY, Milenkova T, Lowe ES, Barker L, Scambia G. Olaparib Versus Nonplatinum Chemotherapy in Patients With Platinum-Sensitive Relapsed Ovarian Cancer and a Germline BRCA1/2 Mutation (SOLO3): A Randomized Phase III Trial. *J Clin Oncol*. 2020 Apr 10;38(11):1164-1174. doi: 10.1200/JCO.19.02745. Epub 2020 Feb 19. PMID: 32073956; PMCID: PMC7145583.
51. Delaloge S, Piccart M, Rutgers E, Litière S, van 't Veer LJ, van den Berkmortel F, Brain E, Dudek-Peric A, Gil-Gil M, Gomez P, Hilbers FS, Khalil Z, Knox S, Kuemmel S, Kunz G, Lesur A, Pierga JY, Ravdin P, Rubio IT, Saghatchian M, Smilde TJ, Thompson AM, Viale G, Zoppi G, Vuylsteke P, Tryfonidis K, Poncet C, Bogaerts J, Cardoso F; MINDACT investigators and the TRANSBIG Consortium. Standard Anthracycline Based Versus Docetaxel-Capecitabine in Early High Clinical and/or Genomic Risk Breast Cancer in the EORTC 10041/BIG 3-04 MINDACT Phase III Trial. *J Clin Oncol*. 2020 Apr 10;38(11):1186-1197. doi: 10.1200/JCO.19.01371. Epub 2020 Feb 21. PMID: 32083990; PMCID: PMC7840116.

52. Li J, Yu K, Pang D, Wang C, Jiang J, Yang S, Liu Y, Fu P, Sheng Y, Zhang G, Cao Y, He Q, Cui S, Wang X, Ren G, Li X, Yu S, Liu P, Qu X, Tang J, Wang O, Fan Z, Jiang G, Zhang J, Wang J, Zhang H, Wang S, Zhang J, Jin F, Rao N, Ma B, He P, Xu B, Zhuang Z, Wang J, Sun Q, Guo X, Mo M, Shao Z; CBCSG010 Study Group. Adjuvant Capecitabine With Docetaxel and Cyclophosphamide Plus Epirubicin for Triple-Negative Breast Cancer (CBCSG010): An Open-Label, Randomized, Multicenter, Phase III Trial. *J Clin Oncol*. 2020 Jun 1;38(16):1774-1784. doi: 10.1200/JCO.19.02474. Epub 2020 Apr 10. PMID: 32275467; PMCID: PMC7255982.
53. Kenmotsu H, Yamamoto N, Yamanaka T, Yoshiya K, Takahashi T, Ueno T, Goto K, Daga H, Ikeda N, Sugio K, Seto T, Toyooka S, Date H, Mitsudomi T, Okamoto I, Yokoi K, Saka H, Okamoto H, Takiguchi Y, Tsuboi M. Randomized Phase III Study of Pemetrexed Plus Cisplatin Versus Vinorelbine Plus Cisplatin for Completely Resected Stage II to IIIA Nonsquamous Non-Small-Cell Lung Cancer. *J Clin Oncol*. 2020 Jul 1;38(19):2187-2196. doi: 10.1200/JCO.19.02674. Epub 2020 May 14. PMID: 32407216.
54. Gronchi A, Palmerini E, Quagliuolo V, Martin Broto J, Lopez Pousa A, Grignani G, Brunello A, Blay JY, Tendero O, Diaz Beveridge R, Ferraresi V, Lugowska I, Merlo DF, Fontana V, Marchesi E, Braglia L, Donati DM, Palassini E, Bianchi G, Marrari A, Morosi C, Stacchiotti S, Bague S, Coindre JM, Dei Tos AP, Picci P, Bruzzi P, Casali PG. Neoadjuvant Chemotherapy in High-Risk Soft Tissue Sarcomas: Final Results of a Randomized Trial From Italian (ISG), Spanish (GEIS), French (FSG), and Polish (PSG) Sarcoma Groups. *J Clin Oncol*. 2020 Jul 1;38(19):2178-2186. doi: 10.1200/JCO.19.03289. Epub 2020 May 18. PMID: 32421444.
55. 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 Laurentiis 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. *J Clin Oncol*. 2020 Sep 20;38(27):3138-3149. doi: 10.1200/JCO.20.00147. Epub 2020 Jul 17. PMID: 32678716; PMCID: PMC7499616.
56. Van Cutsem E, Tempero MA, Sigal D, Oh DY, Fazio N, Macarulla T, Hitre E, Hammel P, Hendifar AE, Bates SE, Li CP, Hingorani SR, de la Fouchardiere C, Kasi A, Heinemann V, Maraveyas A, Bahary N, Layos L, Sahai V, Zheng L, Lacy J, Park JO, Portales F, Oberstein P, Wu W, Chondros D, Bullock AJ; HALO 109-301 Investigators. Randomized Phase III Trial of Pegvorhialuronidase Alfa With Nab-Paclitaxel Plus Gemcitabine for Patients With Hyaluronan-High Metastatic Pancreatic Adenocarcinoma. *J Clin Oncol*. 2020 Sep 20;38(27):3185-3194. doi: 10.1200/JCO.20.00590. Epub 2020 Jul 24. PMID: 32706635; PMCID: PMC7499614.
57. Monk BJ, Grisham RN, Banerjee S, Kalbacher E, Mirza MR, Romero I, Vuylsteke P, Coleman RL, Hilpert F, Oza AM, Westermann A, Oehler MK, Pignata S, Aghajanian C, Colombo N, Drill E, Cibula D, Moore KN, Christy-Bittel J, Del Campo JM, Berger R, Marth C, Sehoul J, O'Malley DM, Churrua C, Boyd AP, Kristensen G, Clamp A, Ray-Coquard I, Vergote I. MILO/ENGOT-ov11: Binimetinib Versus Physician's Choice Chemotherapy in Recurrent or Persistent Low-Grade Serous Carcinomas of the Ovary, Fallopian Tube, or Primary Peritoneum. *J Clin Oncol*. 2020 Nov 10;38(32):3753-3762. doi: 10.1200/JCO.20.01164. Epub 2020 Aug 21. PMID: 32822286; PMCID: PMC7655017.

58. Eisen T, Frangou E, Oza B, Ritchie AWS, Smith B, Kaplan R, Davis ID, Stockler MR, Albiges L, Escudier B, Larkin J, Bex A, Joniau S, Hancock B, Hermann GG, Bellmunt J, Hodgkinson E, Stewart GD, Barber J, Brown J, McMenemin R, Nathan P, Pickering LM, Parmar MKB, Meade A. Adjuvant Sorafenib for Renal Cell Carcinoma at Intermediate or High Risk of Relapse: Results From the SORCE Randomized Phase III Intergroup Trial. *J Clin Oncol*. 2020 Dec 1;38(34):4064-4075. doi: 10.1200/JCO.20.01800. Epub 2020 Oct 14. PMID: 33052759; PMCID: PMC7768344.
59. Zhu J, Liu A, Sun X, Liu L, Zhu Y, Zhang T, Jia J, Tan S, Wu J, Wang X, Zhou J, Yang J, Zhang C, Zhang H, Zhao Y, Cai G, Zhang W, Xia F, Wan J, Zhang H, Shen L, Cai S, Zhang Z. Multicenter, Randomized, Phase III Trial of Neoadjuvant Chemoradiation With Capecitabine and Irinotecan Guided by *UGT1A1* Status in Patients With Locally Advanced Rectal Cancer. *J Clin Oncol*. 2020 Dec 20;38(36):4231-4239. doi: 10.1200/JCO.20.01932. Epub 2020 Oct 29. PMID: 33119477; PMCID: PMC7768334.
60. Kenmotsu H, Niho S, Tsuboi M, Wakabayashi M, Ishii G, Nakagawa K, Daga H, Tanaka H, Saito H, Aokage K, Takahashi T, Menju T, Kasai T, Yoshino I, Minato K, Okada M, Eba J, Asamura H, Ohe Y, Watanabe SI. Randomized Phase III Study of Irinotecan Plus Cisplatin Versus Etoposide Plus Cisplatin for Completely Resected High-Grade Neuroendocrine Carcinoma of the Lung: JCOG1205/1206. *J Clin Oncol*. 2020 Dec 20;38(36):4292-4301. doi: 10.1200/JCO.20.01806. Epub 2020 Nov 2. PMID: 33136471.
61. Johnston SRD, Hegg R, Im SA, Park IH, Burdaeva O, Kurteva G, Press MF, Tjulandin S, Iwata H, Simon SD, Kenny S, Sarp S, Izquierdo MA, Williams LS, Gradishar WJ. Phase III, Randomized Study of Dual Human Epidermal Growth Factor Receptor 2 (HER2) Blockade With Lapatinib Plus Trastuzumab in Combination With an Aromatase Inhibitor in Postmenopausal Women With HER2-Positive, Hormone Receptor-Positive Metastatic Breast Cancer: Updated Results of ALTERNATIVE. *J Clin Oncol*. 2021 Jan 1;39(1):79-89. doi: 10.1200/JCO.20.01894. Epub 2020 Aug 21. PMID: 32822287.
62. Gebre-Medhin M, Brun E, Engström P, Haugen Cange H, Hammarstedt-Nordenvall L, Reizenstein J, Nyman J, Abel E, Friesland S, Sjödin H, Carlsson H, Söderkvist K, Thomasson M, Zackrisson B, Nilsson P. ARTSCAN III: A Randomized Phase III Study Comparing Chemoradiotherapy With Cisplatin Versus Cetuximab in Patients With Locoregionally Advanced Head and Neck Squamous Cell Cancer. *J Clin Oncol*. 2021 Jan 1;39(1):38-47. doi: 10.1200/JCO.20.02072. Epub 2020 Oct 14. PMID: 33052757; PMCID: PMC7771720.
63. Moehler M, Dvorkin M, Boku N, Özgüroğlu M, Ryu MH, Muntean AS, Lonardi S, Nechaeva M, Bragagnoli AC, Coşkun HS, Cubillo Gracian A, Takano T, Wong R, Safran H, Vaccaro GM, Wainberg ZA, Silver MR, Xiong H, Hong J, Taieb J, Bang YJ. Phase III Trial of Avelumab Maintenance After First-Line Induction Chemotherapy Versus Continuation of Chemotherapy in Patients With Gastric Cancers: Results From JAVELIN Gastric 100. *J Clin Oncol*. 2021 Mar 20;39(9):966-977. doi: 10.1200/JCO.20.00892. Epub 2020 Nov 16. PMID: 33197226; PMCID: PMC8078426.
64. Shah MA, Bodoky G, Starodub A, Cunningham D, Yip D, Wainberg ZA, Bendell J, Thai D, He J, Bhargava P, Ajani JA. Phase III Study to Evaluate Efficacy and Safety of Andecaleximab With mFOLFOX6 as First-Line Treatment in Patients With Advanced Gastric or GEJ Adenocarcinoma (GAMMA-1). *J Clin Oncol*. 2021 Mar 20;39(9):990-1000. doi: 10.1200/JCO.20.02755. Epub 2021 Feb 12. PMID: 33577358; PMCID: PMC8078292.

65. Hecht JR, Lonardi S, Bendell J, Sim HW, Macarulla T, Lopez CD, Van Cutsem E, Muñoz Martin AJ, Park JO, Greil R, Wang H, Hozak RR, Gueorguieva I, Lin Y, Rao S, Ryoo BY. Randomized Phase III Study of FOLFOX Alone or With Pegilodocakin as Second-Line Therapy in Patients With Metastatic Pancreatic Cancer That Progressed After Gemcitabine (SEQUOIA). *J Clin Oncol*. 2021 Apr 1;39(10):1108-1118. doi: 10.1200/JCO.20.02232. Epub 2021 Feb 8. PMID: 33555926; PMCID: PMC8078437.
66. Owonikoko TK, Park K, Govindan R, Ready N, Reck M, Peters S, Dakhil SR, Navarro A, Rodríguez-Cid J, Schenker M, Lee JS, Gutierrez V, Percent I, Morgensztern D, Barrios CH, Greillier L, Baka S, Patel M, Lin WH, Selvaggi G, Baudalet C, Baden J, Pandya D, Doshi P, Kim HR. Nivolumab and Ipilimumab as Maintenance Therapy in Extensive-Disease Small-Cell Lung Cancer: CheckMate 451. *J Clin Oncol*. 2021 Apr 20;39(12):1349-1359. doi: 10.1200/JCO.20.02212. Epub 2021 Mar 8. PMID: 33683919; PMCID: PMC8078251.
67. Rosenberg JE, Ballman KA, Halabi S, Atherton PJ, Mortazavi A, Sweeney C, Stadler WM, Teplý BA, Picus J, Tagawa ST, Katragadda S, Vaena D, Misleh J, Hoimes C, Plimack ER, Flaig TW, Dreicer R, Bajorin D, Hahn O, Small EJ, Morris MJ. Randomized Phase III Trial of Gemcitabine and Cisplatin With Bevacizumab or Placebo in Patients With Advanced Urothelial Carcinoma: Results of CALGB 90601 (Alliance). *J Clin Oncol*. 2021 Aug 1;39(22):2486-2496. doi: 10.1200/JCO.21.00286. Epub 2021 May 14. PMID: 33989025; PMCID: PMC8462587.
68. Qin S, Bi F, Gu S, Bai Y, Chen Z, Wang Z, Ying J, Lu Y, Meng Z, Pan H, Yang P, Zhang H, Chen X, Xu A, Cui C, Zhu B, Wu J, Xin X, Wang J, Shan J, Chen J, Zheng Z, Xu L, Wen X, You Z, Ren Z, Liu X, Qiu M, Wu L, Chen F. Donafenib Versus Sorafenib in First-Line Treatment of Unresectable or Metastatic Hepatocellular Carcinoma: A Randomized, Open-Label, Parallel-Controlled Phase II-III Trial. *J Clin Oncol*. 2021 Sep 20;39(27):3002-3011. doi: 10.1200/JCO.21.00163. Epub 2021 Jun 29. PMID: 34185551; PMCID: PMC8445562.
69. Kang YK, George S, Jones RL, Rutkowski P, Shen L, Mir O, Patel S, Zhou Y, von Mehren M, Hohenberger P, Villalobos V, Brahmi M, Tap WD, Trent J, Pantaleo MA, Schöffski P, He K, Hew P, Newberry K, Roche M, Heinrich MC, Bauer S. Avapritinib Versus Regorafenib in Locally Advanced Unresectable or Metastatic GI Stromal Tumor: A Randomized, Open-Label Phase III Study. *J Clin Oncol*. 2021 Oct 1;39(28):3128-3139. doi: 10.1200/JCO.21.00217. Epub 2021 Aug 3. PMID: 34343033; PMCID: PMC8478403.
70. Connolly RM, Zhao F, Miller KD, Lee MJ, Piekarczyk RL, Smith KL, Brown-Glaberman UA, Winn JS, Faller BA, Onitilo AA, Burkard ME, Budd GT, Levine EG, Royce ME, Kaufman PA, Thomas A, Trepel JB, Wolff AC, Sparano JA. E2112: Randomized Phase III Trial of Endocrine Therapy Plus Entinostat or Placebo in Hormone Receptor-Positive Advanced Breast Cancer. A Trial of the ECOG-ACRIN Cancer Research Group. *J Clin Oncol*. 2021 Oct 1;39(28):3171-3181. doi: 10.1200/JCO.21.00944. Epub 2021 Aug 6. PMID: 34357781; PMCID: PMC8478386.
71. 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. *J Clin Oncol*. 2021 Nov 10;39(32):3633-3644. doi: 10.1200/JCO.20.03318. Epub 2021 Aug 26. PMID: 34436928; PMCID: PMC8577684.

72. Hamanishi J, Takeshima N, Katsumata N, Ushijima K, Kimura T, Takeuchi S, Matsumoto K, Ito K, Mandai M, Nakai H, Sakuragi N, Watari H, Takahashi N, Kato H, Hasegawa K, Yonemori K, Mizuno M, Takehara K, Niikura H, Sawasaki T, Nakao S, Saito T, Enomoto T, Nagase S, Suzuki N, Matsumoto T, Kondo E, Sonoda K, Aihara S, Aoki Y, Okamoto A, Takano H, Kobayashi H, Kato H, Terai Y, Takazawa A, Takahashi Y, Namba Y, Aoki D, Fujiwara K, Sugiyama T, Konishi I. Nivolumab Versus Gemcitabine or Pegylated Liposomal Doxorubicin for Patients With Platinum-Resistant Ovarian Cancer: Open-Label, Randomized Trial in Japan (NINJA). *J Clin Oncol*. 2021 Nov 20;39(33):3671-3681. doi: 10.1200/JCO.21.00334. Epub 2021 Sep 2. PMID: 34473544; PMCID: PMC8601279.
73. Kanemitsu Y, Shimizu Y, Mizusawa J, Inaba Y, Hamaguchi T, Shida D, Ohue M, Komori K, Shiomi A, Shiozawa M, Watanabe J, Suto T, Kinugasa Y, Takii Y, Bando H, Kobatake T, Inomata M, Shimada Y, Katayama H, Fukuda H; JCOG Colorectal Cancer Study Group. Hepatectomy Followed by mFOLFOX6 Versus Hepatectomy Alone for Liver-Only Metastatic Colorectal Cancer (JCOG0603): A Phase II or III Randomized Controlled Trial. *J Clin Oncol*. 2021 Dec 1;39(34):3789-3799. doi: 10.1200/JCO.21.01032. Epub 2021 Sep 14. PMID: 34520230.

JNCI (Journal of the National Cancer Institute)

1. Blok EJ, Kroep JR, Meershoek-Klein Kranenbarg E, Duijm-de Carpentier M, Putter H, van den Bosch J, Maartense E, van Leeuwen-Stok AE, Liefers GJ, Nortier JWR, Rutgers EJ, van de Velde CJH; IDEAL Study Group. Optimal Duration of Extended Adjuvant Endocrine Therapy for Early Breast Cancer; Results of the IDEAL Trial (BOOG 2006-05). *J Natl Cancer Inst*. 2018 Jan 1;110(1). doi: 10.1093/jnci/djx134. PMID: 28922787.
2. Strasser-Weippl K, Higgins MJ, Chapman JW, Ingle JN, Sledge GW, Budd GT, Ellis MJ, Pritchard KI, Clemons MJ, Badovinac-Crnjevic T, Han L, Gelmon KA, Rabaglio M, Elliott C, Shepherd LE, Goss PE. Effects of Celecoxib and Low-dose Aspirin on Outcomes in Adjuvant Aromatase Inhibitor-Treated Patients: CCTG MA.27. *J Natl Cancer Inst*. 2018 Sep 1;110(9):1003-1008. doi: 10.1093/jnci/djy017. PMID: 29554282; PMCID: PMC6669949.
3. Gralow JR, Barlow WE, Paterson AHG, M'iao JL, Lew DL, Stopeck AT, Hayes DF, Hershman DL, Schubert MM, Clemons M, Van Poznak CH, Dees EC, Ingle JN, Falkson CI, Elias AD, Messino MJ, Margolis JH, Dakhil SR, Chew HK, Dammann KZ, Abrams JS, Livingston RB, Hortobagyi GN. Phase III Randomized Trial of Bisphosphonates as Adjuvant Therapy in Breast Cancer: S0307. *J Natl Cancer Inst*. 2020 Jul 1;112(7):698-707. doi: 10.1093/jnci/djz215. PMID: 31693129; PMCID: PMC7357327.
4. Yu KD, Ge JY, Liu XY, Mo M, He M, Shao ZM; SPECTRUM Investigators. Cyclophosphamide-Free Adjuvant Chemotherapy for Ovarian Protection in Young Women With Breast Cancer: A Randomized Phase 3 Trial. *J Natl Cancer Inst*. 2021 Oct 1;113(10):1352-1359. doi: 10.1093/jnci/djab065. PMID: 33822134; PMCID: PMC8486325.

JAMA (Journal of the American Medical Association)

1. Jänne PA, van den Heuvel MM, Barlesi F, Cobo M, Mazieres J, Crinò L, Orlov S, Blackhall F, Wolf J, Garrido P, Poltoratskiy A, Mariani G, Ghiorghiu D, Kilgour E, Smith P, Kohlmann A, Carlile DJ, Lawrence D, Bowen K, Vansteenkiste J. Selumetinib Plus Docetaxel Compared With Docetaxel Alone and Progression-Free Survival in Patients With KRAS-Mutant Advanced Non-Small Cell Lung Cancer: The SELECT-1 Randomized Clinical Trial. *JAMA*. 2017 May 9;317(18):1844-1853. doi: 10.1001/jama.2017.3438. PMID: 28492898; PMCID: PMC5815037.

2. Venook AP, Niedzwiecki D, Lenz HJ, Innocenti F, Fruth B, Meyerhardt JA, Schrag D, Greene C, O'Neil BH, Atkins JN, Berry S, Polite BN, O'Reilly EM, Goldberg RM, Hochster HS, Schilsky RL, Bertagnoli MM, El-Khoueiry AB, Watson P, Benson AB 3rd, Mulkerin DL, Mayer RJ, Blanke C. Effect of First-Line Chemotherapy Combined With Cetuximab or Bevacizumab on Overall Survival in Patients With KRAS Wild-Type Advanced or Metastatic Colorectal Cancer: A Randomized Clinical Trial. *JAMA*. 2017 Jun 20;317(23):2392-2401. doi: 10.1001/jama.2017.7105. PMID: 28632865; PMCID: PMC5545896.
3. Li J, Qin S, Xu RH, Shen L, Xu J, Bai Y, Yang L, Deng Y, Chen ZD, Zhong H, Pan H, Guo W, Shu Y, Yuan Y, Zhou J, Xu N, Liu T, Ma D, Wu C, Cheng Y, Chen D, Li W, Sun S, Yu Z, Cao P, Chen H, Wang J, Wang S, Wang H, Fan S, Hua Y, Su W. Effect of Fruquintinib vs Placebo on Overall Survival in Patients With Previously Treated Metastatic Colorectal Cancer: The FRESCO Randomized Clinical Trial. *JAMA*. 2018 Jun 26;319(24):2486-2496. doi: 10.1001/jama.2018.7855. PMID: 29946728; PMCID: PMC6583690.
4. 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. *JAMA*. 2020 Apr 7;323(13):1266-1276. doi: 10.1001/jama.2020.1707. PMID: 32259228; PMCID: PMC7139275.
5. Wang X, Wang SS, Huang H, Cai L, Zhao L, Peng RJ, Lin Y, Tang J, Zeng J, Zhang LH, Ke YL, Wang XM, Liu XM, Chen QJ, Zhang AQ, Xu F, Bi XW, Huang JJ, Li JB, Pang DM, Xue C, Shi YX, He ZY, Lin HX, An X, Xia W, Cao Y, Guo Y, Su YH, Hua X, Wang XY, Hong RX, Jiang KK, Song CG, Huang ZZ, Shi W, Zhong YY, Yuan ZY; South China Breast Cancer Group (SCBCG). Effect of Capecitabine Maintenance Therapy Using Lower Dosage and Higher Frequency vs Observation on Disease-Free Survival Among Patients With Early-Stage Triple-Negative Breast Cancer Who Had Received Standard Treatment: The SYSUCC-001 Randomized Clinical Trial. *JAMA*. 2021 Jan 5;325(1):50-58. doi: 10.1001/jama.2020.23370. Erratum in: *JAMA*. 2022 May 17;327(19):1929. PMID: 33300950; PMCID: PMC7729589.
6. Meyerhardt JA, Shi Q, Fuchs CS, Meyer J, Niedzwiecki D, Zemla T, Kumthekar P, Guthrie KA, Couture F, Kuebler P, Bendell JC, Kumar P, Lewis D, Tan B, Bertagnoli M, Grothey A, Hochster HS, Goldberg RM, Venook A, Blanke C, O'Reilly EM, Shields AF. Effect of Celecoxib vs Placebo Added to Standard Adjuvant Therapy on Disease-Free Survival Among Patients With Stage III Colon Cancer: The CALGB/SWOG 80702 (Alliance) Randomized Clinical Trial. *JAMA*. 2021 Apr 6;325(13):1277-1286. doi: 10.1001/jama.2021.2454. PMID: 33821899; PMCID: PMC8025124.
7. Luo H, Lu J, Bai Y, Mao T, Wang J, Fan Q, Zhang Y, Zhao K, Chen Z, Gao S, Li J, Fu Z, Gu K, Liu Z, Wu L, Zhang X, Feng J, Niu Z, Ba Y, Zhang H, Liu Y, Zhang L, Min X, Huang J, Cheng Y, Wang D, Shen Y, Yang Q, Zou J, Xu RH; ESCORT-1st Investigators. Effect of Camrelizumab vs Placebo Added to Chemotherapy on Survival and Progression-Free Survival in Patients With Advanced or Metastatic Esophageal Squamous Cell Carcinoma: The ESCORT-1st Randomized Clinical Trial. *JAMA*. 2021 Sep 14;326(10):916-925. doi: 10.1001/jama.2021.12836. PMID: 34519801; PMCID: PMC8441593.

JAMA Oncology

1. 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. *JAMA Oncol.* 2017 May 1;3(5):620-627. doi: 10.1001/jamaoncol.2016.5580. PMID: 27918764; PMCID: PMC5824210.
2. Suntharalingam M, Winter K, Ilson D, Dicker AP, Kachnic L, Konski A, Chakravarthy AB, Anker CJ, Thakrar H, Horiba N, Dubey A, Greenberger JS, Raben A, Giguere J, Roof K, Videtic G, Pollock J, Safran H, Crane CH. Effect of the Addition of Cetuximab to Paclitaxel, Cisplatin, and Radiation Therapy for Patients With Esophageal Cancer: The NRG Oncology RTOG 0436 Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2017 Nov 1;3(11):1520-1528. doi: 10.1001/jamaoncol.2017.1598. Erratum in: *JAMA Oncol.* 2017 Nov 1;3(11):1589. PMID: 28687830; PMCID: PMC5710193.
 3. Gianni L, Mansutti M, Anton A, Calvo L, Bisagni G, Bermejo B, Semiglazov V, Thill M, Chacon JI, Chan A, Morales S, Alvarez I, Plazaola A, Zambetti M, Redfern AD, Dittrich C, Dent RA, Magazzù D, De Fato R, Valagussa P, Tusquets I. Comparing Neoadjuvant Nab-paclitaxel vs Paclitaxel Both Followed by Anthracycline Regimens in Women With ERBB2/HER2-Negative Breast Cancer-The Evaluating Treatment With Neoadjuvant Abraxane (ETNA) Trial: A Randomized Phase 3 Clinical Trial. *JAMA Oncol.* 2018 Mar 1;4(3):302-308. doi: 10.1001/jamaoncol.2017.4612. PMID: 29327055; PMCID: PMC5885830.
 4. Joensuu H, Fraser J, Wildiers H, Huovinen R, Auvinen P, Utriainen M, Nyandoto P, Villman KK, Halonen P, Granstam-Björneklett H, Lundgren L, Sailas L, Turpeenniemi-Hujanen T, Tanner M, Yachnin J, Ritchie D, Johansson O, Huttunen T, Neven P, Canney P, Harvey VJ, Kellokumpu-Lehtinen PL, Lindman H. Effect of Adjuvant Trastuzumab for a Duration of 9 Weeks vs 1 Year With Concomitant Chemotherapy for Early Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer: The SOLD Randomized Clinical Trial. *JAMA Oncol.* 2018 Sep 1;4(9):1199-1206. doi: 10.1001/jamaoncol.2018.1380. PMID: 29852043; PMCID: PMC6143012.
 5. Han B, Li K, Wang Q, Zhang L, Shi J, Wang Z, Cheng Y, He J, Shi Y, Zhao Y, Yu H, Zhao Y, Chen W, Luo Y, Wu L, Wang X, Pirker R, Nan K, Jin F, Dong J, Li B, Sun Y. Effect of Anlotinib as a Third-Line or Further Treatment on Overall Survival of Patients With Advanced Non-Small Cell Lung Cancer: The ALTER 0303 Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2018 Nov 1;4(11):1569-1575. doi: 10.1001/jamaoncol.2018.3039. Erratum in: *JAMA Oncol.* 2018 Nov 1;4(11):1625. PMID: 30098152; PMCID: PMC6248083.
 6. Buzdar AU, Suman VJ, Meric-Bernstam F, Leitch AM, Ellis MJ, Boughey JC, Unzeitig GW, Royce ME, Hunt KK. Disease-Free and Overall Survival Among Patients With Operable HER2-Positive Breast Cancer Treated With Sequential vs Concurrent Chemotherapy: The ACOSOG Z1041 (Alliance) Randomized Clinical Trial. *JAMA Oncol.* 2019 Jan 1;5(1):45-50. doi: 10.1001/jamaoncol.2018.3691. PMID: 30193295; PMCID: PMC6331049.
 7. Oudard S, Latorzeff I, Caty A, Miglianico L, Sevin E, Hardy-Bessard AC, Delva R, Rolland F, Mouret L, Priou F, Beuzeboc P, Gravis G, Linassier C, Gomez P, Voog E, Muracciole X, Abraham C, Banu E, Ferrero JM, Ravaud A, Krakowski I, Lagrange JL, Deplanque G, Zylberait D, Bozec L, Houede N, Culine S, Elaidi R. Effect of Adding Docetaxel to Androgen-Deprivation Therapy in Patients With High-Risk Prostate Cancer With Rising Prostate-Specific Antigen Levels After Primary Local Therapy: A Randomized Clinical Trial. *JAMA Oncol.* 2019 May 1;5(5):623-632. doi: 10.1001/jamaoncol.2018.6607. PMID: 30703190; PMCID: PMC6512307.
 8. Nomura H, Aoki D, Michimae H, Mizuno M, Nakai H, Arai M, Sasagawa M, Ushijima K, Sugiyama T, Saito M, Tokunaga H, Matoda M, Nakanishi T, Watanabe Y, Takahashi F, Saito T, Yaegashi N;

- Japanese Gynecologic Oncology Group. Effect of Taxane Plus Platinum Regimens vs Doxorubicin Plus Cisplatin as Adjuvant Chemotherapy for Endometrial Cancer at a High Risk of Progression: A Randomized Clinical Trial. *JAMA Oncol.* 2019 Jun 1;5(6):833-840. doi: 10.1001/jamaoncol.2019.0001. PMID: 30896757; PMCID: PMC6567838.
9. He M, Li Q, Zou R, Shen J, Fang W, Tan G, Zhou Y, Wu X, Xu L, Wei W, Le Y, Zhou Z, Zhao M, Guo Y, Guo R, Chen M, Shi M. Sorafenib Plus Hepatic Arterial Infusion of Oxaliplatin, Fluorouracil, and Leucovorin vs Sorafenib Alone for Hepatocellular Carcinoma With Portal Vein Invasion: A Randomized Clinical Trial. *JAMA Oncol.* 2019 Jul 1;5(7):953-960. doi: 10.1001/jamaoncol.2019.0250. PMID: 31070690; PMCID: PMC6512278.
 10. Burtneess B, Haddad R, Dinis J, Trigo J, Yokota T, de Souza Viana L, Romanov I, Vermorken J, Bourhis J, Tahara M, Martins Segalla JG, Psyrri A, Vasilevskaya I, Nangia CS, Chaves-Conde M, Kiyota N, Homma A, Holeckova P, Del Campo JM, Asarawala N, Nicolau UR, Rauch D, Even C, Wang B, Gibson N, Ehrnrooth E, Harrington K, Cohen EEW; LUX-Head & Neck 2 investigators. Afatinib vs Placebo as Adjuvant Therapy After Chemoradiotherapy in Squamous Cell Carcinoma of the Head and Neck: A Randomized Clinical Trial. *JAMA Oncol.* 2019 Aug 1;5(8):1170-1180. doi: 10.1001/jamaoncol.2019.1146. PMID: 31194247; PMCID: PMC6567846.
 11. Abou-Alfa GK, Shi Q, Knox JJ, Kaubisch A, Niedzwiecki D, Posey J, Tan BR Jr, Kavan P, Goel R, Lammers PE, Bekaii-Saab TS, Tam VC, Rajdev L, Kelley RK, El Dika I, Zemla T, Potaracke RI, Balletti J, El-Khoueiry AB, Harding JJ, Suga JM, Schwartz LH, Goldberg RM, Bertagnolli MM, Meyerhardt J, O'Reilly EM, Venook AP. Assessment of Treatment With Sorafenib Plus Doxorubicin vs Sorafenib Alone in Patients With Advanced Hepatocellular Carcinoma: Phase 3 CALGB 80802 Randomized Clinical Trial. *JAMA Oncol.* 2019 Nov 1;5(11):1582-1588. doi: 10.1001/jamaoncol.2019.2792. Erratum in: *JAMA Oncol.* 2019 Oct 10;: PMID: 31486832; PMCID: PMC6735405.
 12. Yoshino T, Yamanaka T, Oki E, Kotaka M, Manaka D, Eto T, Hasegawa J, Takagane A, Nakamura M, Kato T, Munemoto Y, Takeuchi S, Bando H, Taniguchi H, Gamoh M, Shiozawa M, Mizushima T, Saji S, Maehara Y, Ohtsu A, Mori M. Efficacy and Long-term Peripheral Sensory Neuropathy of 3 vs 6 Months of Oxaliplatin- Based Adjuvant Chemotherapy for Colon Cancer: The ACHIEVE Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2019 Nov 1;5(11):1574-1581. doi: 10.1001/jamaoncol.2019.2572. Erratum in: *JAMA Oncol.* 2019 Nov 1;5(11):1643. Erratum in: *JAMA Oncol.* 2019 Dec 19;: PMID: 31513248; PMCID: PMC6743062.
 13. Okamoto I, Nokihara H, Nomura S, Niho S, Sugawara S, Horinouchi H, Azuma K, Yoneshima Y, Murakami H, Hosomi Y, Atagi S, Ozaki T, Horiike A, Fujita Y, Okamoto H, Ando M, Yamamoto N, Ohe Y, Nakagawa K. Comparison of Carboplatin Plus Pemetrexed Followed by Maintenance Pemetrexed With Docetaxel Monotherapy in Elderly Patients With Advanced Nonsquamous Non-Small Cell Lung Cancer: A Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2020 May 1;6(5):e196828. doi: 10.1001/jamaoncol.2019.6828. Epub 2020 May 14. PMID: 32163097; PMCID: PMC7068674.
 14. 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.
15. 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, Zvirtes 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.
 16. Choueiri TK, Heng DYC, Lee JL, Cancel M, Verheijen RB, Mellempgaard A, Ottesen LH, Frigault MM, L'Hernault A, Szigyarto Z, Signoretti S, Albiges L. Efficacy of Savolitinib vs Sunitinib in Patients With MET-Driven Papillary Renal Cell Carcinoma: The SAVOIR Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2020 Aug 1;6(8):1247-1255. doi: 10.1001/jamaoncol.2020.2218. Erratum in: *JAMA Oncol.* 2020 Sep 1;6(9):1473. PMID: 32469384; PMCID: PMC7260692.
 17. Yu KD, Ye FG, He M, Fan L, Ma D, Mo M, Wu J, Liu GY, Di GH, Zeng XH, He PQ, Wu KJ, Hou YF, Wang J, Wang C, Zhuang ZG, Song CG, Lin XY, Toss A, Ricci F, Shen ZZ, Shao ZM. Effect of Adjuvant Paclitaxel and Carboplatin on Survival in Women With Triple-Negative Breast Cancer: A Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2020 Sep 1;6(9):1390-1396. doi: 10.1001/jamaoncol.2020.2965. PMID: 32789480; PMCID: PMC7426881.
 18. Shitara K, Van Cutsem E, Bang YJ, Fuchs C, Wyrwicz L, Lee KW, Kudaba I, Garrido M, Chung HC, Lee J, Castro HR, Mansoor W, Braghiroli MI, Karaseva N, Caglevic C, Villanueva L, Goekkurt E, Satake H, Enzinger P, Alsina M, Benson A, Chao J, Ko AH, Wainberg ZA, Kher U, Shah S, Kang SP, Tabernero J. Efficacy and Safety of Pembrolizumab or Pembrolizumab Plus Chemotherapy vs Chemotherapy Alone for Patients With First-line, Advanced Gastric Cancer: The KEYNOTE-062 Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2020 Oct 1;6(10):1571-1580. doi: 10.1001/jamaoncol.2020.3370. PMID: 32880601; PMCID: PMC7489405.
 19. Cloughesy TF, Petrecca K, Walbert T, Butowski N, Salacz M, Perry J, Damek D, Bota D, Bettgowda C, Zhu JJ, Iwamoto F, Placantonakis D, Kim L, Elder B, Kaptain G, Cachia D, Moshel Y, Brem S, Piccioni D, Landolfi J, Chen CC, Gruber H, Rao AR, Hogan D, Accomando W, Ostertag D, Montellano TT, Kheoh T, Kabbinar F, Vogelbaum MA. Effect of Vocimogene Amiretrorepvec in Combination With Flucytosine vs Standard of Care on Survival Following Tumor Resection in Patients With Recurrent High-Grade Glioma: A Randomized Clinical Trial. *JAMA Oncol.* 2020 Dec 1;6(12):1939-1946. doi: 10.1001/jamaoncol.2020.3161. PMID: 33119048; PMCID: PMC7596685.
 20. Rugo HS, Im SA, Cardoso F, Cortés J, Curigliano G, Musolino A, Pegram MD, Wright GS, Saura C, Escrivá-de-Romaní S, De Laurentiis M, Levy C, Brown- Glaberman U, Ferrero JM, de Boer M, Kim SB, Petráková K, Yardley DA, Freedman O, Jakobsen EH, Kaufman B, Yerushalmi R, Fasching PA, Nordstrom JL, Bonvini E, Koenig S, Edlich S, Hong S, Rock EP, Gradishar WJ; SOPHIA Study Group. Efficacy of Margetuximab vs Trastuzumab in Patients With Pretreated ERBB2-Positive Advanced Breast Cancer: A Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2021 Apr 1;7(4):573-584. doi: 10.1001/jamaoncol.2020.7932. PMID: 33480963; PMCID: PMC7823434.
 21. Wang J, Lu S, Yu X, Hu Y, Sun Y, Wang Z, Zhao J, Yu Y, Hu C, Yang K, Feng G, Ying K, Zhuang W, Zhou J, Wu J, Leaw SJ, Zhang J, Lin X, Liang L, Yang N. Tislelizumab Plus Chemotherapy vs Chemotherapy Alone as First-line Treatment for Advanced Squamous Non-Small-Cell Lung Cancer: A

Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2021 May 1;7(5):709-717. doi: 10.1001/jamaoncol.2021.0366. PMID: 33792623; PMCID: PMC8017481.

22. Hall PS, Swinson D, Cairns DA, Waters JS, Petty R, Allmark C, Ruddock S, Falk S, Wadsley J, Roy R, Tillett T, Nicoll J, Cummins S, Mano J, Grumett S, Stokes Z, Kamposioras KV, Chatterjee A, Garcia A, Waddell T, Gupta K, Maisey N, Khan M, Dent J, Lord S, Crossley A, Katona E, Marshall H, Grabsch HI, Velikova G, Ow PL, Handforth C, Howard H, Seymour MT; GO2 Trial Investigators. Efficacy of Reduced-Intensity Chemotherapy With Oxaliplatin and Capecitabine on Quality of Life and Cancer Control Among Older and Frail Patients With Advanced Gastroesophageal Cancer: The GO2 Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2021 Jun 1;7(6):869-877. doi: 10.1001/jamaoncol.2021.0848. Erratum in: *JAMA Oncol.* 2021 Aug 1;7(8):1249. PMID: 33983395; PMCID: PMC8120440.
23. Friedl TWP, Fehm T, Müller V, Lichtenegger W, Blohmer J, Lorenz R, Forstbauer H, Fink V, Bekes I, Hober J, Jückstock J, Schneeweiss A, Tesch H, Mahner S, Brucker SY, Heinrich G, Häberle L, Fasching PA, Beckmann MW, Coleman RE, Janni W, Rack B. Prognosis of Patients With Early Breast Cancer Receiving 5 Years vs 2 Years of Adjuvant Bisphosphonate Treatment: A Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2021 Aug 1;7(8):1149-1157. doi: 10.1001/jamaoncol.2021.1854. PMID: 34165508; PMCID: PMC8227465.
24. Coombes RC, Tovey H, Kilburn L, Mansi J, Palmieri C, Bartlett J, Hicks J, Makris A, Evans A, Loibl S, Denkert C, Murray E, Grieve R, Coleman R, Borley A, Schmidt M, Rautenberg B, Kunze CA, Rhein U, Mehta K, Mousa K, Dibble T, Lu XL, von Minckwitz G, Bliss JM; Randomized European Celecoxib Trial (REACT) Trial Management Group and Investigators. Effect of Celecoxib vs Placebo as Adjuvant Therapy on Disease-Free Survival Among Patients With Breast Cancer: The REACT Randomized Clinical Trial. *JAMA Oncol.* 2021 Sep 1;7(9):1291-1301. doi: 10.1001/jamaoncol.2021.2193. PMID: 34264305; PMCID: PMC8283666.
25. 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 S14001 Phase 3 Randomized Clinical Trial. *JAMA Oncol.* 2021 Sep 1;7(9):1368-1377. doi: 10.1001/jamaoncol.2021.2209. PMID: 34264316; PMCID: PMC8283667.

Lancet

1. 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. *Lancet.* 2017 Jan 7;389(10064):56-66. doi: 10.1016/S0140-6736(16)32453-9. Epub 2016 Dec 6. Erratum in: *Lancet.* 2017 Jan 7;389(10064):36. PMID: 27932229.
2. 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. *Lancet.* 2017 Jan 21;389(10066):255-265.

- doi: 10.1016/S0140-6736(16)32517-X. Epub 2016 Dec 13. Erratum in: *Lancet*. 2017 Apr 8;389(10077):e5. PMID: 27979383; PMCID: PMC6886121.
3. Soria JC, Tan DSW, Chiari R, Wu YL, Paz-Ares L, Wolf J, Geater SL, Orlov S, Cortinovis D, Yu CJ, Hochmair M, Cortot AB, Tsai CM, Moro-Sibilot D, Campelo RG, McCulloch T, Sen P, Dugan M, Pantano S, Branle F, Massacesi C, de Castro G Jr. First-line ceritinib versus platinum-based chemotherapy in advanced ALK- rearranged non-small-cell lung cancer (ASCEND-4): a randomised, open-label, phase 3 study. *Lancet*. 2017 Mar 4;389(10072):917-929. doi: 10.1016/S0140-6736(17)30123-X. Epub 2017 Jan 24. Erratum in: *Lancet*. 2017 Mar 4;389(10072):908. PMID: 28126333.
 4. Neoptolemos JP, Palmer DH, Ghaneh P, Psarelli EE, Valle JW, Halloran CM, Faluyi O, O'Reilly DA, Cunningham D, Wadsley J, Darby S, Meyer T, Gillmore R, Anthoney A, Lind P, Glimelius B, Falk S, Izbicki JR, Middleton GW, Cummins S, Ross PJ, Wasan H, McDonald A, Crosby T, Ma YT, Patel K, Sherriff D, Soomal R, Borg D, Sothi S, Hammel P, Hackert T, Jackson R, Büchler MW; European Study Group for Pancreatic Cancer. Comparison of adjuvant gemcitabine and capecitabine with gemcitabine monotherapy in patients with resected pancreatic cancer (ESPAC-4): a multicentre, open-label, randomised, phase 3 trial. *Lancet*. 2017 Mar 11;389(10073):1011-1024. doi: 10.1016/S0140-6736(16)32409-6. Epub 2017 Jan PMID: 28129987.
 5. Hida T, Nokihara H, Kondo M, Kim YH, Azuma K, Seto T, Takiguchi Y, Nishio M, Yoshioka H, Imamura F, Hotta K, Watanabe S, Goto K, Satouchi M, Kozuki T, Shukuya T, Nakagawa K, Mitsudomi T, Yamamoto N, Asakawa T, Asabe R, Tanaka T, Tamura T. Alectinib versus crizotinib in patients with ALK-positive non-small- cell lung cancer (J-ALEX): an open-label, randomised phase 3 trial. *Lancet*. 2017 Jul 1;390(10089):29-39. doi: 10.1016/S0140-6736(17)30565-2. Epub 2017 May 10. PMID: 28501140.
 6. van den Bent MJ, Baumert B, Erridge SC, Vogelbaum MA, Nowak AK, Sanson M, Brandes AA, Clement PM, Baurain JF, Mason WP, Wheeler H, Chinot OL, Gill S, Griffin M, Brachman DG, Taal W, Rudà R, Weller M, McBain C, Reijneveld J, Enting RH, Weber DC, Lesimple T, Clenton S, Gijtenbeek A, Pascoe S, Herrlinger U, Hau P, Dhermain F, van Heuvel I, Stupp R, Aldape K, Jenkins RB, Dubbink HJ, Dinjens WNM, Wesseling P, Nuyens S, Golfopoulos V, Gorlia T, Wick W, Kros JM. Interim results from the CATNON trial (EORTC study 26053-22054) of treatment with concurrent and adjuvant temozolomide for 1p/19q non-co-deleted anaplastic glioma: a phase 3, randomised, open-label intergroup study. *Lancet*. 2017 Oct 7;390(10103):1645-1653. doi: 10.1016/S0140-6736(17)31442-3. Epub 2017 Aug 8. Erratum in: *Lancet*. 2017 Oct 7;390(10103):1644. PMID: 28801186; PMCID: PMC5806535.
 7. Coleman RL, Oza AM, Lorusso D, Aghajanian C, Oaknin A, Dean A, Colombo N, Weberpals JI, Clamp A, Scambia G, Leary A, Holloway RW, Gancedo MA, Fong PC, Goh JC, O'Malley DM, Armstrong DK, Garcia-Donas J, Swisher EM, Floquet A, Konecny GE, McNeish IA, Scott CL, Cameron T, Maloney L, Isaacson J, Goble S, Grace C, Harding TC, Raponi M, Sun J, Lin KK, Giordano H, Ledermann JA; ARIEL3 investigators. Rucaparib maintenance treatment for recurrent ovarian carcinoma after response to platinum therapy (ARIEL3): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2017 Oct 28;390(10106):1949-1961. doi: 10.1016/S0140-6736(17)32440-6. Epub 2017 Sep 12. Erratum in: *Lancet*. 2017 Oct 28;390(10106):1948. PMID: 28916367; PMCID: PMC5901715.
 8. Petrylak DP, de Wit R, Chi KN, Drakaki A, Sternberg CN, Nishiyama H, Castellano D, Hussain S, Fléchon A, Bamias A, Yu EY, van der Heijden MS, Matsubara N, Alekseev B, Necchi A, Géczi L, Ou YC, Coskun HS, Su WP, Hegemann M, Percent IJ, Lee JL, Tucci M, Semenov A, Laestadius F, Peer A, Tortora G, Safina S, Del Muro XG, Rodriguez-Vida A, Cicin I, Harputluoglu H, Widau RC, Liepa AM,

- Walgren RA, Hamid O, Zimmermann AH, Bell-McGuinn KM, Powles T; RANGE study investigators. Ramucirumab plus docetaxel versus placebo plus docetaxel in patients with locally advanced or metastatic urothelial carcinoma after platinum-based therapy (RANGE): a randomised, double-blind, phase 3 trial. *Lancet*. 2017 Nov 18;390(10109):2266-2277. doi: 10.1016/S0140-6736(17)32365-6. Epub 2017 Sep 12. PMID: 28916371.
9. Kang YK, Boku N, Satoh T, Ryu MH, Chao Y, Kato K, Chung HC, Chen JS, Muro K, Kang WK, Yeh KH, Yoshikawa T, Oh SC, Bai LY, Tamura T, Lee KW, Hamamoto Y, Kim JG, Chin K, Oh DY, Minashi K, Cho JY, Tsuda M, Chen LT. Nivolumab in patients with advanced gastric or gastro-oesophageal junction cancer refractory to, or intolerant of, at least two previous chemotherapy regimens (ONO-4538-12, ATTRACTION-2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2017 Dec 2;390(10111):2461-2471. doi: 10.1016/S0140-6736(17)31827-5. Epub 2017 Oct 6. PMID: 28993052.
 10. 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.
 11. Kudo M, Finn RS, Qin S, Han KH, Ikeda K, Piscaglia F, Baron A, Park JW, Han G, Jassem J, Blanc JF, Vogel A, Komov D, Evans TRJ, Lopez C, Dutcus C, Guo M, Saito K, Kraljevic S, Tamai T, Ren M, Cheng AL. Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: a randomised phase 3 non-inferiority trial. *Lancet*. 2018 Mar 24;391(10126):1163-1173. doi: 10.1016/S0140-6736(18)30207-1. PMID: 29433850.
 12. 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.
 13. Mehanna H, Robinson M, Hartley A, Kong A, Foran B, Fulton-Lieuw T, Dalby M, Mistry P, Sen M, O'Toole L, Al Booz H, Dyker K, Moleron R, Whitaker S, Brennan S, Cook A, Griffin M, Aynsley E, Rolles M, De Winton E, Chan A, Srinivasan D, Nixon I, Grumett J, Leemans CR, Buter J, Henderson J, Harrington K, McConkey C, Gray A, Dunn J; De-ESCALaTE HPV Trial Group. Radiotherapy plus cisplatin or cetuximab in low-risk human papillomavirus-positive oropharyngeal cancer (De-ESCALaTE HPV): an open-label randomised controlled phase 3 trial. *Lancet*. 2019 Jan 5;393(10166):51-60. doi: 10.1016/S0140-6736(18)32752-1. Epub 2018 Nov 15. PMID: 30449623; PMCID: PMC6319250.
 14. Gillison ML, Trotti AM, Harris J, Eisbruch A, Harari PM, Adelstein DJ, Jordan RCK, Zhao W, Sturgis EM, Burtneß B, Ridge JA, Ringash J, Galvin J, Yao M, Koyfman SA, Blakaj DM, Razaq MA, Colevas AD, Beitler JJ, Jones CU, Dunlap NE, Seaward SA, Spencer S, Galloway TJ, Phan J, Dignam JJ, Le QT. Radiotherapy plus cetuximab or cisplatin in human papillomavirus-positive oropharyngeal cancer (NRG Oncology RTOG 1016): a randomised, multicentre, non-inferiority trial. *Lancet*. 2019 Jan 5;393(10166):40-50. doi: 10.1016/S0140-6736(18)32779-X. Epub 2018 Nov 15. Erratum in: *Lancet*. 2020 Mar 7;395(10226):784. PMID: 30449625; PMCID: PMC6541928.

15. Cohen EEW, Soulières D, Le Tourneau C, Dinis J, Licitra L, Ahn MJ, Soria A, Machiels JP, Mach N, Mehra R, Burtness 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. *Lancet*. 2019 Jan 12;393(10167):156-167. doi: 10.1016/S0140-6736(18)31999-8. Epub 2018 Nov 30. Erratum in: *Lancet*. 2019 Jan 12;393(10167):132. PMID: 30509740.
16. Herrlinger U, Tzaridis T, Mack F, Steinbach JP, Schlegel U, Sabel M, Hau P, Kortmann RD, Krex D, Grauer O, Goldbrunner R, Schnell O, Bähr O, Uhl M, Seidel C, Tabatabai G, Kowalski T, Ringel F, Schmidt-Graf F, Suchorska B, Brehmer S, Weyerbrock A, Renovanz M, Bullinger L, Galldijs N, Vajkoczy P, Misch M, Vatter H, Stuplich M, Schäfer N, Kebir S, Weller J, Schaub C, Stummer W, Tonn JC, Simon M, Keil VC, Nelles M, Urbach H, Coenen M, Wick W, Weller M, Fimmers R, Schmid M, Hattingen E, Pietsch T, Coch C, Glas M; Neurooncology Working Group of the German Cancer Society. Lomustine-temozolomide combination therapy versus standard temozolomide therapy in patients with newly diagnosed glioblastoma with methylated MGMT promoter (CeTeG/NOA-09): a randomised, open-label, phase 3 trial. *Lancet*. 2019 Feb 16;393(10172):678-688. doi: 10.1016/S0140-6736(18)31791-4. Epub 2019 Feb 14. PMID: 30782343.
17. Mok TSK, Wu YL, Kudaba I, Kowalski DM, Cho BC, Turna HZ, Castro G Jr, Srimuninnimit V, Laktionov KK, Bondarenko I, Kubota K, Lubiniecki GM, Zhang J, Kush D, Lopes G; KEYNOTE-042 Investigators. Pembrolizumab versus chemotherapy for previously untreated, PD-L1-expressing, locally advanced or metastatic non- small-cell lung cancer (KEYNOTE-042): a randomised, open-label, controlled, phase 3 trial. *Lancet*. 2019 May 4;393(10183):1819-1830. doi: 10.1016/S0140-6736(18)32409-7. Epub 2019 Apr 4. PMID: 30955977.
18. Al-Batran SE, Homann N, Pauligk C, Goetze TO, Meiler J, Kasper S, Kopp HG, Mayer F, Haag GM, Luley K, Lindig U, Schmiegel W, Pohl M, Stoehlmacher J, Folprecht G, Probst S, Prasnikar N, Fischbach W, Mahlberg R, Trojan J, Koenigsmann M, Martens UM, Thuss-Patience P, Egger M, Block A, Heinemann V, Illerhaus G, Moehler M, Schenk M, Kullmann F, Behringer DM, Heike M, Pink D, Teschendorf C, Löhr C, Bernhard H, Schuch G, Rethwisch V, von Weikersthal LF, Hartmann JT, Kneba M, Daum S, Schulmann K, Weniger J, Belle S, Gaiser T, Oduncu FS, Güntner M, Hozaeel W, Reichart A, Jäger E, Kraus T, Mönig S, Bechstein WO, Schuler M, Schmalenberg H, Hofheinz RD; FLOT4-AIO Investigators. Perioperative chemotherapy with fluorouracil plus leucovorin, oxaliplatin, and docetaxel versus fluorouracil or capecitabine plus cisplatin and epirubicin for locally advanced, resectable gastric or gastro-oesophageal junction adenocarcinoma (FLOT4): a randomised, phase 2/3 trial. *Lancet*. 2019 May 11;393(10184):1948-1957. doi: 10.1016/S0140-6736(18)32557-1. Epub 2019 Apr 11. PMID: 30982686.
19. Rini BI, Powles T, Atkins MB, Escudier B, McDermott DF, Suarez C, Bracarda S, Stadler WM, Donskov F, Lee JL, Hawkins R, Ravaud A, Alekseev B, Staehler M, Uemura M, De Giorgi U, Mellado B, Porta C, Melichar B, Gurney H, Bedke J, Choueiri TK, Parnis F, Khaznadar T, Thobhani A, Li S, Piau-Louis E, Frantz G, Huseni M, Schiff C, Green MC, Motzer RJ; IMmotion151 Study Group. Atezolizumab plus bevacizumab versus sunitinib in patients with previously untreated metastatic renal cell carcinoma (IMmotion151): a multicentre, open-label, phase 3, randomised controlled trial. *Lancet*. 2019 Jun 15;393(10189):2404-2415. doi: 10.1016/S0140-6736(19)30723-8. Epub 2019 May 9. PMID: 31079938.
20. Earl HM, Hiller L, Vallier AL, Loi S, McAdam K, Hughes-Davies L, Harnett AN, Ah-See ML, Simcock R, Rea D, Raj S, Woodings P, Harries M, Howe D, Raynes K, Higgins HB, Wilcox M, Plummer C, Mansi J,

- Gounaris I, Mahler-Araujo B, Provenzano E, Chhabra A, Abraham JE, Caldas C, Hall PS, McCabe C, Hulme C, Miles D, Wardley AM, Cameron DA, Dunn JA; PERSEPHONE Steering Committee and Trial Investigators. 6 versus 12 months of adjuvant trastuzumab for HER2-positive early breast cancer (PERSEPHONE): 4-year disease-free survival results of a randomised phase 3 non-inferiority trial. *Lancet*. 2019 Jun 29;393(10191):2599-2612. doi: 10.1016/S0140-6736(19)30650-6. Epub 2019 Jun 6. PMID: 31178152; PMCID: PMC6615016.
21. Tap WD, Gelderblom H, Palmerini E, Desai J, Bauer S, Blay JY, Alcindor T, Ganjoo K, Martín-Broto J, Ryan CW, Thomas DM, Peterfy C, Healey JH, van de Sande M, Gelhorn HL, Shuster DE, Wang Q, Yver A, Hsu HH, Lin PS, Tong-Starksen S, Stacchiotti S, Wagner AJ; ENLIVEN investigators. Pexidartinib versus placebo for advanced tenosynovial giant cell tumour (ENLIVEN): a randomised phase 3 trial. *Lancet*. 2019 Aug 10;394(10197):478-487. doi: 10.1016/S0140-6736(19)30764-0. Epub 2019 Jun 19. PMID: 31229240; PMCID: PMC6860022.
 22. 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. *Lancet*. 2019 Nov 23;394(10212):1929-1939. doi: 10.1016/S0140-6736(19)32222-6. Epub 2019 Oct 4. PMID: 31590988.
 23. Burtneß B, Harrington KJ, Greil R, Soulières D, Tahara M, de Castro G Jr, Psyrri A, Basté N, Neupane P, Bratland Å, Fuereder T, Hughes BGM, Mesía R, Ngamphaiboon N, Rordorf T, Wan Ishak WZ, Hong RL, González Mendoza R, Roy A, Zhang Y, Gumuscu B, Cheng JD, Jin F, Rischin D; KEYNOTE-048 Investigators. Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study. *Lancet*. 2019 Nov 23;394(10212):1915-1928. doi: 10.1016/S0140-6736(19)32591-7. Epub 2019 Nov 1. Erratum in: *Lancet*. 2020 Jan 25;395(10220):272. Erratum in: *Lancet*. 2020 Feb 22;395(10224):564. Erratum in: *Lancet*. 2021 Jun 12;397(10291):2252. PMID: 31679945.
 24. Clamp AR, James EC, McNeish IA, Dean A, Kim JW, O'Donnell DM, Hook J, Coyle C, Blagden S, Brenton JD, Naik R, Perren T, Sundar S, Cook AD, Gopalakrishnan GS, Gabra H, Lord R, Dark G, Earl HM, Hall M, Banerjee S, Glasspool RM, Jones R, Williams S, Swart AM, Stenning S, Parmar M, Kaplan R, Ledermann JA. Weekly dose-dense chemotherapy in first-line epithelial ovarian, fallopian tube, or primary peritoneal carcinoma treatment (ICON8): primary progression free survival analysis results from a GCIG phase 3 randomised controlled trial. *Lancet*. 2019 Dec 7;394(10214):2084-2095. doi: 10.1016/S0140-6736(19)32259-7. Epub 2019 Nov 29. PMID: 31791688; PMCID: PMC6902268.
 25. Birtle A, Johnson M, Chester J, Jones R, Dolling D, Bryan RT, Harris C, Winterbottom A, Blacker A, Catto JWF, Chakraborti P, Donovan JL, Elliott PA, French A, Jagdev S, Jenkins B, Keeley FX Jr, Kockelbergh R, Powles T, Wagstaff J, Wilson C, Todd R, Lewis R, Hall E. Adjuvant chemotherapy in upper tract urothelial carcinoma (the POUT trial): a phase 3, open-label, randomised controlled trial. *Lancet*. 2020 Apr 18;395(10232):1268-1277. doi: 10.1016/S0140-6736(20)30415-3. Epub 2020 Mar 5. PMID: 32145825; PMCID: PMC7181180.
 26. Galsky MD, Ariba JÁA, 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. *Lancet*. 2020 May 16;395(10236):1547-1557. doi: 10.1016/S0140-6736(20)30230-0. PMID: 32416780.
27. Gutzmer R, Stroyakovskiy D, Gogas H, Robert C, Lewis K, Protsenko S, Pereira RP, Eigentler T, Rutkowski P, Demidov L, Manikhas GM, Yan Y, Huang KC, Uyei A, McNally V, McArthur GA, Ascierto PA. Atezolizumab, vemurafenib, and cobimetinib as first-line treatment for unresectable advanced BRAF^{V600} mutation- positive melanoma (IMspire150): primary analysis of the randomised, double- blind, placebo-controlled, phase 3 trial. *Lancet*. 2020 Jun 13;395(10240):1835-1844. doi: 10.1016/S0140-6736(20)30934-X. Erratum in: *Lancet*. 2020 Aug 15;396(10249):466. PMID: 32534646.
28. Mittendorf EA, Zhang H, Barrios CH, Saji S, Jung KH, Hegg R, Koehler A, Sohn J, Iwata H, Telli ML, Ferrario C, Punie K, Penault-Llorca F, Patel S, Duc AN, Liste-Hermoso M, Maiya V, Molinero L, Chui SY, Harbeck N. Neoadjuvant atezolizumab in combination with sequential nab-paclitaxel and anthracycline- based chemotherapy versus placebo and chemotherapy in patients with early-stage triple-negative breast cancer (IMpassion031): a randomised, double-blind, phase 3 trial. *Lancet*. 2020 Oct 10;396(10257):1090-1100. doi: 10.1016/S0140-6736(20)31953-X. Epub 2020 Sep 20. PMID: 32966830.
29. Cortes J, Cescon DW, Rugo HS, Nowecki Z, Im SA, Yusof MM, Gallardo C, Lipatov O, Barrios CH, Holgado E, Iwata H, Masuda N, Otero MT, Gokmen E, Loi S, Guo Z, Zhao J, Aktan G, Karantza V, Schmid P; KEYNOTE-355 Investigators. Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for previously untreated locally recurrent inoperable or metastatic triple-negative breast cancer (KEYNOTE-355): a randomised, placebo-controlled, double-blind, phase 3 clinical trial. *Lancet*. 2020 Dec 5;396(10265):1817-1828. doi: 10.1016/S0140-6736(20)32531-9. PMID: 33278935.
30. Baas P, Scherpereel A, Nowak AK, Fujimoto N, Peters S, Tsao AS, Mansfield AS, Popat S, Jahan T, Antonia S, Oulkhovir Y, Bautista Y, Cornelissen R, Greillier L, Grossi F, Kowalski D, Rodríguez-Cid J, Aanur P, Oukessou A, Baudalet 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.
31. Sezer A, Kilickap S, Gümüş M, Bondarenko I, Özgüroğlu M, Gogishvili M, Turk HM, Cicin I, Bentsion D, Gladkov O, Clingan P, Sriuranpong V, Rizvi N, Gao B, Li S, Lee S, McGuire K, Chen CI, Makharadze T, Paydas S, Nechaeva M, Seebach F, Weinreich DM, Yancopoulos GD, Gullo G, Lowy I, Rietschel P. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. *Lancet*. 2021 Feb 13;397(10274):592-604. doi: 10.1016/S0140-6736(21)00228-2. PMID: 33581821.
32. Janjigian YY, Shitara K, Moehler M, Garrido M, Salman P, Shen L, Wyrwicz L, Yamaguchi K, Skocyzlas 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. *Lancet*. 2021 Jul 3;398(10294):27-40. doi: 10.1016/S0140-6736(21)00797-2. Epub 2021 Jun 5. PMID: 34102137; PMCID: PMC8436782.

33. Sweeney C, Bracarda S, Sternberg CN, Chi KN, Olmos D, Sandhu S, Massard C, Matsubara N, Alekseev B, Parnis F, Atduiev V, Buchschacher GL Jr, Gafanov R, Corrales L, Borre M, Stroyakovskiy D, Alves GV, Bournakis E, Puente J, Harle-Yge ML, Gallo J, Chen G, Hanover J, Wongchenko MJ, Garcia J, de Bono JS. Ipatasertib plus abiraterone and prednisolone in metastatic castration-resistant prostate cancer (IPATential150): a multicentre, randomised, double-blind, phase 3 trial. *Lancet*. 2021 Jul 10;398(10295):131-142. doi: 10.1016/S0140-6736(21)00580-8. PMID: 34246347.
34. Chen YP, Liu X, Zhou Q, Yang KY, Jin F, Zhu XD, Shi M, Hu GQ, Hu WH, Sun Y, Wu HF, Wu H, Lin Q, Wang H, Tian Y, Zhang N, Wang XC, Shen LF, Liu ZZ, Huang J, Luo XL, Li L, Zang J, Mei Q, Zheng BM, Yue D, Xu J, Wu SG, Shi YX, Mao YP, Chen L, Li WF, Zhou GQ, Sun R, Guo R, Zhang Y, Xu C, Lv JW, Guo Y, Feng HX, Tang LL, Xie FY, Sun Y, Ma J. Metronomic capecitabine as adjuvant therapy in locoregionally advanced nasopharyngeal carcinoma: a multicentre, open-label, parallel-group, randomised, controlled, phase 3 trial. *Lancet*. 2021 Jul 24;398(10297):303-313. doi: 10.1016/S0140-6736(21)01123-5. Epub 2021 Jun 7. PMID: 34111416.
35. Sun JM, Shen L, Shah MA, Enzinger P, Adenis A, Doi T, Kojima T, Metges JP, Li Z, Kim SB, Cho BC, Mansoor W, Li SH, Sunpaweravong P, Maqueda MA, Goekkurt E, Hara H, Antunes L, Fountzilias C, Tsuji A, Oriden VC, Liu Q, Shah S, Bhagia P, Kato K; KEYNOTE-590 Investigators. Pembrolizumab plus chemotherapy versus chemotherapy alone for first-line treatment of advanced oesophageal cancer (KEYNOTE-590): a randomised, placebo-controlled, phase 3 study. *Lancet*. 2021 Aug 28;398(10302):759-771. doi: 10.1016/S0140-6736(21)01234-4. Erratum in: *Lancet*. 2021 Nov 20;398(10314):1874. PMID: 34454674.
36. Felip E, Altorki N, Zhou C, Csósz T, Vynnychenko I, Goloborodko O, Luft A, Akopov A, Martinez-Marti A, Kenmotsu H, Chen YM, Chella A, Sugawara S, Voong D, Wu F, Yi J, Deng Y, McClelland M, Bennett E, Gitlitz B, Wakelee H; IMpower010 Investigators. Adjuvant atezolizumab after adjuvant chemotherapy in resected stage IB-IIIa non-small-cell lung cancer (IMpower010): a randomised, multicentre, open-label, phase 3 trial. *Lancet*. 2021 Oct 9;398(10308):1344-1357. doi: 10.1016/S0140-6736(21)02098-5. Epub 2021 Sep 20. Erratum in: *Lancet*. 2021 Sep 23;: PMID: 34555333.

Lancet Oncology

1. Azzouzi AR, Vincendeau S, Barret E, Cicco A, Kleinclauss F, van der Poel HG, Stief CG, Rassweiler J, Salomon G, Solsona E, Alcaraz A, Tammela TT, Rosario DJ, Gomez-Veiga F, Ahlgren G, Benzaghoul F, Gaillac B, Amzal B, Debryne FM, Fromont G, Gratzke C, Emberton M; PCM301 Study Group. Padeliporfin vascular-targeted photodynamic therapy versus active surveillance in men with low-risk prostate cancer (CLIN1001 PCM301): an open-label, phase 3, randomised controlled trial. *Lancet Oncol*. 2017 Feb;18(2):181-191. doi: 10.1016/S1470-2045(16)30661-1. Epub 2016 Dec 20. PMID: 28007457.
2. Hickish T, Andre T, Wyrwicz L, Saunders M, Sarosiek T, Kocsis J, Nemecek R, Rogowski W, Lesniewski-Kmak K, Petruzelka L, Apte RN, Mohanty P, Stecher M, Simard J, de Gramont A. MABp1 as a novel antibody treatment for advanced colorectal cancer: a randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Oncol*. 2017 Feb;18(2):192-201. doi: 10.1016/S1470-2045(17)30006-2. Epub 2017 Jan 14. PMID: 28094194.
3. Cunningham D, Stenning SP, Smyth EC, Okines AF, Allum WH, Rowley S, Stevenson L, Grabsch HI, Alderson D, Crosby T, Griffin SM, Mansoor W, Coxon FY, Falk SJ, Darby S, Sumpter KA, Blazeby JM, Langley RE. Peri-operative chemotherapy with or without bevacizumab in operable oesophagogastric adenocarcinoma (UK Medical Research Council ST03): primary analysis results of a multicentre, open-

- label, randomised phase 2-3 trial. *Lancet Oncol.* 2017 Mar;18(3):357-370. doi: 10.1016/S1470-2045(17)30043-8. Epub 2017 Feb 3. PMID: 28163000; PMCID: PMC5337626.
4. Zhang P, Sun T, Zhang Q, Yuan Z, Jiang Z, Wang XJ, Cui S, Teng Y, Hu XC, Yang J, Pan H, Tong Z, Li H, Yao Q, Wang Y, Yin Y, Sun P, Zheng H, Cheng J, Lu J, Zhang B, Geng C, Liu J, Peng R, Yan M, Zhang S, Huang J, Tang L, Qiu R, Xu B; BG01-1323L study group. Utidelone plus capecitabine versus capecitabine alone for heavily pretreated metastatic breast cancer refractory to anthracyclines and taxanes: a multicentre, open-label, superiority, phase 3, randomised controlled trial. *Lancet Oncol.* 2017 Mar;18(3):371-383. doi: 10.1016/S1470-2045(17)30088-8. Epub 2017 Feb 11. PMID: 28209298.
 5. Ladenstein R, Pötschger U, Pearson ADJ, Brock P, Luksch R, Castel V, Yaniv I, Papadakis V, Laureys G, Malis J, Balwierz W, Ruud E, Kogner P, Schroeder H, de Lacerda AF, Beck-Popovic M, Bician P, Garami M, Trahair T, Canete A, Ambros PF, Holmes K, Gaze M, Schreier G, Garaventa A, Vassal G, Michon J, Valteau-Couanet D; SIOP Europe Neuroblastoma Group (SIOPEN). Busulfan and melphalan versus carboplatin, etoposide, and melphalan as high-dose chemotherapy for high-risk neuroblastoma (HR-NBL1/SIOPEN): an international, randomised, multi-arm, open-label, phase 3 trial. *Lancet Oncol.* 2017 Apr;18(4):500-514. doi: 10.1016/S1470-2045(17)30070-0. Epub 2017 Mar 2. PMID: 28259608.
 6. 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. *Lancet Oncol.* 2017 Apr;18(4):473-485. doi: 10.1016/S1470-2045(17)30168-7. Epub 2017 Mar PMID: 28283282.
 7. Dummer R, Schadendorf D, Ascierto PA, Arance A, Dutriaux C, Di Giacomo AM, Rutkowski P, Del Vecchio M, Gutzmer R, Mandala M, Thomas L, Demidov L, Garbe C, Hogg D, Liskay G, Queirolo P, Wasserman E, Ford J, Weill M, Sirulnik LA, Jehl V, Bozón V, Long GV, Flaherty K. Binimetinib versus dacarbazine in patients with advanced NRAS-mutant melanoma (NEMO): a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol.* 2017 Apr;18(4):435-445. doi: 10.1016/S1470-2045(17)30180-8. Epub 2017 Mar 9. PMID: 28284557.
 8. 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.
 9. Ascierto PA, Del Vecchio M, Robert C, Mackiewicz A, Chiarion-Sileni V, Arance A, Lebbé C, Bastholt L, Hamid O, Rutkowski P, McNeil C, Garbe C, Loquai C, Dreno B, Thomas L, Grob JJ, Liskay G, Nyakas M, Gutzmer R, Pikiel J, Grange F, Hoeller C, Ferraresi V, Smylie M, Schadendorf D, Mortier L, Svane IM, Hennicken D, Qureshi A, Maio M. Ipilimumab 10 mg/kg versus ipilimumab 3 mg/kg in patients with unresectable or metastatic melanoma: a randomised, double-blind, multicentre, phase 3 trial. *Lancet Oncol.* 2017 May;18(5):611-622. doi: 10.1016/S1470-2045(17)30231-0. Epub 2017 Mar 27. PMID: 28359784.
 10. Coleman RL, Brady MF, Herzog TJ, Sabbatini P, Armstrong DK, Walker JL, Kim BG, Fujiwara K, Tewari KS, O'Malley DM, Davidson SA, Rubin SC, DiSilvestro P, Basen-Engquist K, Huang H, Chan JK, Spirtos NM, Ashfaq R, Mannel RS. Bevacizumab and paclitaxel-carboplatin chemotherapy and secondary

- cytoreduction in recurrent, platinum-sensitive ovarian cancer (NRG Oncology/Gynecologic Oncology Group study GOG-0213): a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol.* 2017 Jun;18(6):779-791. doi: 10.1016/S1470-2045(17)30279-6. Epub 2017 Apr 21. PMID: 28438473; PMCID: PMC5715461.
11. Earl HM, Hiller L, Howard HC, Dunn JA, Young J, Bowden SJ, McDermaid M, Waterhouse AK, Wilson G, Agrawal R, O'Reilly S, Bowman A, Ritchie DM, Goodman A, Hickish T, McAdam K, Cameron D, Dodwell D, Rea DW, Caldas C, Provenzano E, Abraham JE, Canney P, Crown JP, Kennedy MJ, Coleman R, Leonard RC, Carmichael JA, Wardley AM, Poole CJ; tAnGo trial collaborators. Addition of gemcitabine to paclitaxel, epirubicin, and cyclophosphamide adjuvant chemotherapy for women with early-stage breast cancer (tAnGo): final 10-year follow-up of an open-label, randomised, phase 3 trial. *Lancet Oncol.* 2017 Jun;18(6):755-769. doi: 10.1016/S1470-2045(17)30319-4. Epub 2017 May 4. PMID: 28479233.
 12. Gronchi A, Ferrari S, Quagliuolo V, Broto JM, Pousa AL, Grignani G, Basso U, Blay JY, Tendero O, Beveridge RD, Ferraresi V, Lugowska I, Merlo DF, Fontana V, Marchesi E, Donati DM, Palassini E, Palmerini E, De Sanctis R, Morosi C, Stacchiotti S, Bagué S, Coindre JM, Dei Tos AP, Picci P, Bruzzi P, Casali PG. Histotype-tailored neoadjuvant chemotherapy versus standard chemotherapy in patients with high-risk soft-tissue sarcomas (ISG-ST5 1001): an international, open-label, randomised, controlled, phase 3, multicentre trial. *Lancet Oncol.* 2017 Jun;18(6):812-822. doi: 10.1016/S1470-2045(17)30334-0. Epub 2017 May 9. Erratum in: *Lancet Oncol.* 2017 Jun;18(6):e301. PMID: 28499583.
 13. Baselga J, Im SA, Iwata H, Cortés J, De Laurentiis M, Jiang Z, Arteaga CL, Jonat W, Clemons M, Ito Y, Awada A, Chia S, Jagiello-Gruszfeld A, Pistilli B, Tseng LM, Hurvitz S, Masuda N, Takahashi M, Vuylsteke P, Hachemi S, Dharan B, Di Tomaso E, Urban P, Massacesi C, Campone M. Buparlisib plus fulvestrant versus placebo plus fulvestrant in postmenopausal, hormone receptor-positive, HER2-negative, advanced breast cancer (BELLE-2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2017 Jul;18(7):904-916. doi: 10.1016/S1470-2045(17)30376-5. Epub 2017 May 30. Erratum in: *Lancet Oncol.* 2019 Feb;20(2):e71-e72. PMID: 28576675; PMCID: PMC5549667.
 14. Cameron D, Morden JP, Canney P, Velikova G, Coleman R, Bartlett J, Agrawal R, Banerji J, Bertelli G, Bloomfield D, Brunt AM, Earl H, Ellis P, Gaunt C, Gillman A, Hearfield N, Laing R, Murray N, Couper N, Stein RC, Verrill M, Wardley A, Barrett-Lee P, Bliss JM; TACT2 Investigators. Accelerated versus standard epirubicin followed by cyclophosphamide, methotrexate, and fluorouracil or capecitabine as adjuvant therapy for breast cancer in the randomised UK TACT2 trial (CRUK/05/19): a multicentre, phase 3, open-label, randomised, controlled trial. *Lancet Oncol.* 2017 Jul;18(7):929-945. doi: 10.1016/S1470-2045(17)30404-7. Epub 2017 Jun 7. PMID: 28600210; PMCID: PMC5489700.
 15. Shaw AT, Kim TM, Crinò L, Gridelli C, Kiura K, Liu G, Novello S, Bearz A, Gautschi O, Mok T, Nishio M, Scagliotti G, Spigel DR, Deudon S, Zheng C, Pantano S, Urban P, Massacesi C, Viraswami-Appanna K, Felip E. Ceritinib versus chemotherapy in patients with ALK-rearranged non-small-cell lung cancer previously given chemotherapy and crizotinib (ASCEND-5): a randomised, controlled, open-label, phase 3 trial. *Lancet Oncol.* 2017 Jul;18(7):874-886. doi: 10.1016/S1470-2045(17)30339-X. Epub 2017 Jun 9. PMID: 28602779.
 16. Tap WD, Papai Z, Van Tine BA, Attia S, Ganjoo KN, Jones RL, Schuetze 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.
17. Pujade-Lauraine E, Ledermann JA, Selle F, GebSKI V, Penson RT, Oza AM, Korach J, Huzarski T, Poveda A, Pignata S, Friedlander M, Colombo N, Harter P, Fujiwara K, Ray-Coquard I, Banerjee S, Liu J, Lowe ES, Bloomfield R, Pautier P; SOLO2/ENGOT-Ov21 investigators. Olaparib tablets as maintenance therapy in patients with platinum-sensitive, relapsed ovarian cancer and a BRCA1/2 mutation (SOLO2/ENGOT-Ov21): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2017 Sep;18(9):1274-1284. doi: 10.1016/S1470-2045(17)30469-2. Epub 2017 Jul 25. Erratum in: *Lancet Oncol.* 2017 Sep;18(9):e510. PMID: 28754483.
 18. Alderson D, Cunningham D, Nankivell M, Blazeby JM, Griffin SM, Crellin A, Grabsch HI, Langer R, Pritchard S, Okines A, Krysztopik R, Coxon F, Thompson J, Falk S, Robb C, Stenning S, Langley RE. Neoadjuvant cisplatin and fluorouracil versus epirubicin, cisplatin, and capecitabine followed by resection in patients with oesophageal adenocarcinoma (UK MRC OE05): an open-label, randomised phase 3 trial. *Lancet Oncol.* 2017 Sep;18(9):1249-1260. doi: 10.1016/S1470-2045(17)30447-3. Epub 2017 Aug 4. PMID: 28784312; PMCID: PMC5585417.
 19. 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. *Lancet Oncol.* 2017 Oct;18(10):1373-1385. doi: 10.1016/S1470-2045(17)30517-X. Epub 2017 Aug 23. PMID: 28844499.
 20. Seddon B, Strauss SJ, Whelan J, Leahy M, Woll PJ, Cowie F, Rothermundt C, Wood Z, Benson C, Ali N, Marples M, Veal GJ, Jamieson D, Küver K, Tirabosco R, Forsyth S, Nash S, Dehbi HM, Beare S. Gemcitabine and docetaxel versus doxorubicin as first-line treatment in previously untreated advanced unresectable or metastatic soft-tissue sarcomas (GeDDiS): a randomised controlled phase 3 trial. *Lancet Oncol.* 2017 Oct;18(10):1397-1410. doi: 10.1016/S1470-2045(17)30622-8. Epub 2017 Sep 4. PMID: 28882536; PMCID: PMC5622179.
 21. Wu YL, Cheng Y, Zhou X, Lee KH, Nakagawa K, Niho S, Tsuji F, Linke R, Rosell R, Corral J, Migliorino MR, Pluzanski A, Sbar EI, Wang T, White JL, Nadanaciva S, Sandin R, Mok TS. Dacomitinib versus gefitinib as first-line treatment for patients with EGFR-mutation-positive non-small-cell lung cancer (ARCHER 1050): a randomised, open-label, phase 3 trial. *Lancet Oncol.* 2017 Nov;18(11):1454-1466. doi: 10.1016/S1470-2045(17)30608-3. Epub 2017 Sep 25. PMID: 28958502.
 22. 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. *Lancet Oncol.* 2017 Nov;18(11):1467-1482. doi: 10.1016/S1470-2045(17)30566-1. Epub 2017 Sep 25. PMID: 28958504; PMCID: PMC5898242.

23. Tjan-Heijnen VCG, van Hellemond IEG, Peer PGM, Swinkels ACP, Smorenburg CH, van der Sangen MJC, Kroep JR, De Graaf H, Honkoop AH, Erdkamp FLG, van den Berkmortel FWPJ, de Boer M, de Roos WK, Linn SC, Imholz ALT, Seynaeve CM; Dutch Breast Cancer Research Group (BOOG) for the DATA Investigators. Extended adjuvant aromatase inhibition after sequential endocrine therapy (DATA): a randomised, phase 3 trial. *Lancet Oncol.* 2017 Nov;18(11):1502-1511. doi: 10.1016/S1470-2045(17)30600-9. Epub 2017 Oct 12. Erratum in: *Lancet Oncol.* 2017 Nov;18(11):e642. PMID: 29031778.
24. 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. *Lancet Oncol.* 2017 Nov;18(11):1532-1542. doi: 10.1016/S1470-2045(17)30605-8. Epub 2017 Oct 9. PMID: 29033099.
25. Bang YJ, Xu RH, Chin K, Lee KW, Park SH, Rha SY, Shen L, Qin S, Xu N, Im SA, Locker G, Rowe P, Shi X, Hodgson D, Liu YZ, Boku N. Olaparib in combination with paclitaxel in patients with advanced gastric cancer who have progressed following first-line therapy (GOLD): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2017 Dec;18(12):1637-1651. doi: 10.1016/S1470-2045(17)30682-4. Epub 2017 Nov 2. PMID: 29103871.
26. Wakelee HA, Dahlberg SE, Keller SM, Tester WJ, Gandara DR, Graziano SL, Adjei AA, Leigh NB, Aisner SC, Rothman JM, Patel JD, Sborov MD, McDermott SR, Perez-Soler R, Traynor AM, Butts C, Evans T, Shafqat A, Chapman AE, Kasbari SS, Horn L, Ramalingam SS, Schiller JH; ECOG-ACRIN. Adjuvant chemotherapy with or without bevacizumab in patients with resected non-small-cell lung cancer (E1505): an open-label, multicentre, randomised, phase 3 trial. *Lancet Oncol.* 2017 Dec;18(12):1610-1623. doi: 10.1016/S1470-2045(17)30691-5. Epub 2017 Nov 9. PMID: 29129443; PMCID: PMC5789803.
27. Colleoni M, Luo W, Karlsson P, Chirgwin J, Aebi S, Jerusalem G, Neven P, Hitre E, Graas MP, Simoncini E, Kamby C, Thompson A, Loibl S, Gavilá J, Kuroi K, Marth C, Müller B, O'Reilly S, Di Lauro V, Gombos A, Ruhstaller T, Burstein H, Ribi K, Bernhard J, Viale G, Maibach R, Rabaglio-Poretti M, Gelber RD, Coates AS, Di Leo A, Regan MM, Goldhirsch A; SOLE Investigators. Extended adjuvant intermittent letrozole versus continuous letrozole in postmenopausal women with breast cancer (SOLE): a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol.* 2018 Jan;19(1):127-138. doi: 10.1016/S1470-2045(17)30715-5. Epub 2017 Nov 17. PMID: 29158011.
28. 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.
29. Zhong WZ, Wang Q, Mao WM, Xu ST, Wu L, Shen Y, Liu YY, Chen C, Cheng Y, Xu L, Wang J, Fei K, Li XF, Li J, Huang C, Liu ZD, Xu S, Chen KN, Xu SD, Liu LX, Yu P, Wang BH, Ma HT, Yan HH, Yang XN, Zhou Q, Wu YL; ADJUVANT investigators. Gefitinib versus vinorelbine plus cisplatin as adjuvant treatment for stage II- IIIA (N1-N2) EGFR-mutant NSCLC (ADJUVANT/CTONG1104): a randomised,

- open-label, phase 3 study. *Lancet Oncol.* 2018 Jan;19(1):139-148. doi: 10.1016/S1470-2045(17)30729-5. Epub 2017 Nov 21. PMID: 29174310.
30. Hurvitz SA, Martin M, Symmans WF, Jung KH, Huang CS, Thompson AM, Harbeck N, Valero V, Stroyakovskiy D, Wildiers H, Campone M, Boileau JF, Beckmann MW, Afenjar K, Fresco R, Helms HJ, Xu J, Lin YG, Sparano J, Slamon D. Neoadjuvant trastuzumab, pertuzumab, and chemotherapy versus trastuzumab emtansine plus pertuzumab in patients with HER2-positive breast cancer (KRISTINE): a randomised, open-label, multicentre, phase 3 trial. *Lancet Oncol.* 2018 Jan;19(1):115-126. doi: 10.1016/S1470-2045(17)30716-7. Epub 2017 Nov 23. PMID: 29175149.
31. Di Leo A, Johnston S, Lee KS, Ciruelos E, Lønning PE, Janni W, O'Regan R, Mouret-Reynier MA, Kalev D, Egle D, Csösz T, Bordonaro R, Decker T, Tjan-Heijnen VCG, Blau S, Schirone A, Weber D, El-Hashimy M, Dharan B, Sellami D, Bachelot T. Buparlisib plus fulvestrant in postmenopausal women with hormone-receptor-positive, HER2-negative, advanced breast cancer progressing on or after mTOR inhibition (BELLE-3): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2018 Jan;19(1):87-100. doi: 10.1016/S1470-2045(17)30688-5. Epub 2017 Dec 7. Erratum in: *Lancet Oncol.* 2018 Mar;19(3):e137. PMID: 29223745.
32. de Boer SM, Powell ME, Mileskin L, Katsaros D, Bessette P, Haie-Meder C, Ottevanger PB, Ledermann JA, Khaw P, Colombo A, Fyles A, Baron MH, Jürgenliemk-Schulz IM, Kitchener HC, Nijman HW, Wilson G, Brooks S, Carinelli S, Provencher D, Hanzen C, Lutgens LCHW, Smit VTHBM, Singh N, Do V, D'Amico R, Nout RA, Feeney A, Verhoeven-Adema KW, Putter H, Creutzberg CL; PORTEC study group. Adjuvant chemoradiotherapy versus radiotherapy alone for women with high-risk endometrial cancer (PORTEC-3): final results of an international, open-label, multicentre, randomised, phase 3 trial. *Lancet Oncol.* 2018 Mar;19(3):295-309. doi: 10.1016/S1470-2045(18)30079-2. Epub 2018 Feb 12. Erratum in: *Lancet Oncol.* 2018 Apr;19(4):e184. PMID: 29449189; PMCID: PMC5840256.
33. Maio M, Lewis K, Demidov L, Mandalà M, Bondarenko I, Ascierto PA, Herbert C, Mackiewicz A, Rutkowski P, Guminski A, Goodman GR, Simmons B, Ye C, Yan Y, Schadendorf D; BRIM8 Investigators. Adjuvant vemurafenib in resected, BRAF^{V600} mutation-positive melanoma (BRIM8): a randomised, double-blind, placebo-controlled, multicentre, phase 3 trial. *Lancet Oncol.* 2018 Apr;19(4):510-520. doi: 10.1016/S1470-2045(18)30106-2. Epub 2018 Feb 21. Erratum in: *Lancet Oncol.* 2018 Apr;19(4):e184. PMID: 29477665.
34. De Placido S, Gallo C, De Laurentiis M, Bisagni G, Arpino G, Sarobba MG, Riccardi F, Russo A, Del Mastro L, Cogoni AA, Cognetti F, Gori S, Foglietta J, Frassoldati A, Amoroso D, Laudadio L, Moscetti L, Montemurro F, Verusio C, Bernardo A, Lorusso V, Gravina A, Moretti G, Lauria R, Lai A, Mocerino C, Rizzo S, Nuzzo F, Carlini P, Perrone F; GIM Investigators. Adjuvant anastrozole versus exemestane versus letrozole, upfront or after 2 years of tamoxifen, in endocrine-sensitive breast cancer (FATA-GIM3): a randomised, phase 3 trial. *Lancet Oncol.* 2018 Apr;19(4):474-485. doi: 10.1016/S1470-2045(18)30116-5. Epub 2018 Feb 23. Erratum in: *Lancet Oncol.* 2018 Apr;19(4):e184. PMID: 29482983.
35. Loibl S, O'Shaughnessy J, Untch M, Sikov WM, Rugo HS, McKee MD, Huober J, Golshan M, von Minckwitz G, Maag D, Sullivan D, Wolmark N, McIntyre K, Ponce Lorenzo JJ, Metzger Filho O, Rastogi P, Symmans WF, Liu X, Geyer CE Jr. Addition of the PARP inhibitor veliparib plus carboplatin or carboplatin alone to standard neoadjuvant chemotherapy in triple-negative breast cancer (BrighTNess): a randomised, phase 3 trial. *Lancet Oncol.* 2018 Apr;19(4):497-509. doi: 10.1016/S1470-2045(18)30111-6. Epub 2018 Feb 28. PMID: 29501363.

36. Tang LQ, Chen DP, Guo L, Mo HY, Huang Y, Guo SS, Qi B, Tang QN, Wang P, Li XY, Li JB, Liu Q, Gao YH, Xie FY, Liu LT, Li Y, Liu SL, Xie HJ, Liang YJ, Sun XS, Yan JJ, Wu YS, Luo DH, Huang PY, Xiang YQ, Sun R, Chen MY, Lv X, Wang L, Xia WX, Zhao C, Cao KJ, Qian CN, Guo X, Hong MH, Nie ZQ, Chen QY, Mai HQ. Concurrent chemoradiotherapy with nedaplatin versus cisplatin in stage II-IVB nasopharyngeal carcinoma: an open-label, non-inferiority, randomised phase 3 trial. *Lancet Oncol.* 2018 Apr;19(4):461-473. doi: 10.1016/S1470-2045(18)30104-9. Epub 2018 Feb 28. PMID: 29501366.
37. Iveson TJ, Kerr RS, Saunders MP, Cassidy J, Hollander NH, Tabernero J, Haydon A, Glimelius B, Harkin A, Allan K, McQueen J, Scudder C, Boyd KA, Briggs A, Waterston A, Medley L, Wilson C, Ellis R, Essapen S, Dhadda AS, Harrison M, Falk S, Raouf S, Rees C, Olesen RK, Propper D, Bridgewater J, Azzabi A, Farrugia D, Webb A, Cunningham D, Hickish T, Weaver A, Gollins S, Wasan HS, Paul J. 3 versus 6 months of adjuvant oxaliplatin-fluoropyrimidine combination therapy for colorectal cancer (SCOT): an international, randomised, phase 3, non-inferiority trial. *Lancet Oncol.* 2018 Apr;19(4):562-578. doi: 10.1016/S1470-2045(18)30093-7. PMID: 29611518; PMCID: PMC5883334.
38. Xu RH, Muro K, Morita S, Iwasa S, Han SW, Wang W, Kotaka M, Nakamura M, Ahn JB, Deng YH, Kato T, Cho SH, Ba Y, Matsuoka H, Lee KW, Zhang T, Yamada Y, Sakamoto J, Park YS, Kim TW. Modified XELIRI (capecitabine plus irinotecan) versus FOLFIRI (leucovorin, fluorouracil, and irinotecan), both either with or without bevacizumab, as second-line therapy for metastatic colorectal cancer (AXEPT): a multicentre, open-label, randomised, non-inferiority, phase 3 trial. *Lancet Oncol.* 2018 May;19(5):660-671. doi: 10.1016/S1470-2045(18)30140-2. Epub 2018 Mar 16. PMID: 29555258.
39. Dummer R, Ascierto PA, Gogas HJ, Arance A, Mandala M, Liskay G, Garbe C, Schadendorf D, Krajsova I, Gutzmer R, Chiarion-Sileni V, Dutriaux C, de Groot JWB, Yamazaki N, Loquai C, Moutouh-de Parseval LA, Pickard MD, Sandor V, Robert C, Flaherty KT. Encorafenib plus binimetinib versus vemurafenib or encorafenib in patients with BRAF-mutant melanoma (COLUMBUS): a multicentre, open-label, randomised phase 3 trial. *Lancet Oncol.* 2018 May;19(5):603-615. doi: 10.1016/S1470-2045(18)30142-6. Epub 2018 Mar 21. PMID: 29573941.
40. Rimassa L, Assenat E, Peck-Radosavljevic M, Pracht M, Zagonel 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. *Lancet Oncol.* 2018 May;19(5):682-693. doi: 10.1016/S1470-2045(18)30146-3. Epub 2018 Apr 3. PMID: 29625879.
41. Cats A, Jansen EPM, van Grieken NCT, Sikorska K, Lind P, Nordmark M, Meershoek-Klein Kranenbarg E, Boot H, Trip AK, Swellengrebel HAM, van Laarhoven HWM, Putter H, van Sandick JW, van Berge Henegouwen MI, Hartgrink HH, van Tinteren H, van de Velde CJH, Verheij M; CRITICS investigators. Chemotherapy versus chemoradiotherapy after surgery and preoperative chemotherapy for resectable gastric cancer (CRITICS): an international, open-label, randomised phase 3 trial. *Lancet Oncol.* 2018 May;19(5):616-628. doi: 10.1016/S1470-2045(18)30132-3. Epub 2018 Apr 9. PMID: 29650363.
42. 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 PMID: 29753703.
43. Tripathy D, Im SA, Colleoni M, Franke F, Bardia A, Harbeck N, Hurvitz SA, Chow L, Sohn J, Lee KS, Campos-Gomez S, Villanueva Vazquez R, Jung KH, Babu KG, Wheatley-Price P, De Laurentiis M, Im YH, Kuemmel S, El-Saghir N, Liu MC, Carlson G, Hughes G, Diaz-Padilla I, Germa C, Hirawat S, Lu YS. Ribociclib plus endocrine therapy for premenopausal women with hormone-receptor-positive, advanced breast cancer (MONALEESA-7): a randomised phase 3 trial. *Lancet Oncol.* 2018 Jul;19(7):904-915. doi: 10.1016/S1470-2045(18)30292-4. Epub 2018 May 24. PMID: 29804902.
 44. Dreno B, Thompson JF, Smithers BM, Santinami M, Jouary T, Gutzmer R, Levchenko E, Rutkowski P, Grob JJ, Korovin S, Drucis K, Grange F, Machet L, Hersey P, Krajsova I, Testori A, Conry R, Guillot B, Kruit WHJ, Demidov L, Thompson JA, Bondarenko I, Jaroszek J, Puig S, Cinat G, Hauschild A, Goeman JJ, van Houwelingen HC, Ulloa-Montoya F, Callegaro A, Dizier B, Spiessens B, Debois M, Brichard VG, Louahed J, Therasse P, Debruyne C, Kirkwood JM. MAGE-A3 immunotherapeutic as adjuvant therapy for patients with resected, MAGE-A3-positive, stage III melanoma (DERMA): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2018 Jul;19(7):916-929. doi: 10.1016/S1470-2045(18)30254-7. Epub 2018 Jun 13. PMID: 29908991.
 45. Taberner 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. *Lancet Oncol.* 2018 Oct;19(10):1372-1384. doi: 10.1016/S1470-2045(18)30481-9. Epub 2018 Sep 11. PMID: 30217672.
 46. 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, Eilers-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.
 47. 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, Taberner J. Trifluridine/tipiracil versus placebo in patients with heavily pretreated metastatic gastric cancer (TAGS): a randomised, double-blind, placebo- controlled, phase 3 trial. *Lancet Oncol.* 2018 Nov;19(11):1437-1448. doi: 10.1016/S1470-2045(18)30739-3. Epub 2018 Oct 21. Erratum in: *Lancet Oncol.* 2018 Dec;19(12):e668. PMID: 30355453.
 48. van Ramshorst MS, van der Voort A, van Werkhoven ED, Mandjes IA, Kemper I, Dezentjé VO, Oving IM, Honkoop AH, Tick LW, van de Wouw AJ, Mandigers CM, van Warmerdam LJ, Wesseling J, Vrancken Peeters MT, Linn SC, Sonke GS; Dutch Breast Cancer Research Group (BOOG). Neoadjuvant chemotherapy with or without anthracyclines in the presence of dual HER2 blockade for HER2-positive breast cancer (TRAIN-2): a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol.* 2018 Dec;19(12):1630-1640. doi: 10.1016/S1470-2045(18)30570-9. Epub 2018 Nov 6. PMID: 30413379.
 49. Mamounas EP, Bandos H, Lembersky BC, Jeong JH, Geyer CE Jr, Rastogi P, Fehrenbacher L, Graham ML, Chia SK, Brufsky AM, Walshe JM, Soori GS, Dakhil SR, Seay TE, Wade JL 3rd, McCarron EC, Paik

- S, Swain SM, Wickerham DL, Wolmark N. Use of letrozole after aromatase inhibitor-based therapy in postmenopausal breast cancer (NRG Oncology/NSABP B-42): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2019 Jan;20(1):88-99. doi: 10.1016/S1470-2045(18)30621-1. Epub 2018 Nov 30. Erratum in: *Lancet Oncol.* 2019 Jan;20(1):e10. PMID: 30509771; PMCID: PMC6691732.
50. 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. *Lancet Oncol.* 2019 Feb;20(2):282-296. doi: 10.1016/S1470-2045(18)30937-9. Epub 2019 Jan 18. PMID: 30665869.
51. Fuchs CS, Shitara K, Di Bartolomeo M, Lonardi S, Al-Batran SE, Van Cutsem E, Ilson DH, Alsina M, Chau I, Lacy J, Ducreux M, Mendez GA, Alavez AM, Takahari D, Mansoor W, Enzinger PC, Gorbounova V, Wainberg ZA, Hegewisch-Becker S, Ferry D, Lin J, Carlesi R, Das M, Shah MA; RAINFALL Study Group. Ramucirumab with cisplatin and fluoropyrimidine as first-line therapy in patients with metastatic gastric or junctional adenocarcinoma (RAINFALL): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2019 Mar;20(3):420-435. doi: 10.1016/S1470-2045(18)30791-5. Epub 2019 Feb 1. Erratum in: *Lancet Oncol.* 2019 May;20(5):e242. PMID: 30718072.
52. Smith M, Parker C, Saad F, Miller K, Tombal B, Ng QS, Boegemann M, Matveev V, Piulats JM, Zucca LE, Karyakin O, Kimura G, Matsubara N, Nahas WC, Nolè F, Rosenbaum E, Heidenreich A, Kakehi Y, Zhang A, Krissel H, Teufel M, Shen J, Wagner V, Higano C. Addition of radium-223 to abiraterone acetate and prednisone or prednisolone in patients with castration-resistant prostate cancer and bone metastases (ERA 223): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2019 Mar;20(3):408-419. doi: 10.1016/S1470-2045(18)30860-X. Epub 2019 Feb 6. Erratum in: *Lancet Oncol.* 2019 Oct;20(10):e559. PMID: 30738780.
53. Primrose JN, Fox RP, Palmer DH, Malik HZ, Prasad R, Mirza D, Anthony A, Corrie P, Falk S, Finch-Jones M, Wasan H, Ross P, Wall L, Wadsley J, Evans JTR, Stocken D, Praseedom R, Ma YT, Davidson B, Neoptolemos JP, Iveson T, Raftery J, Zhu S, Cunningham D, Garden OJ, Stubbs C, Valle JW, Bridgewater J; BILCAP study group. Capecitabine compared with observation in resected biliary tract cancer (BILCAP): a randomised, controlled, multicentre, phase 3 study. *Lancet Oncol.* 2019 May;20(5):663-673. doi: 10.1016/S1470-2045(18)30915-X. Epub 2019 Mar 25. Erratum in: *Lancet Oncol.* 2019 Apr 2;: PMID: 30922733.
54. Saito H, Fukuhara T, Furuya N, Watanabe K, Sugawara S, Iwasawa S, Tsunozuka Y, Yamaguchi O, Okada M, Yoshimori K, Nakachi I, Gemma A, Azuma K, Kurimoto F, Tsubata Y, Fujita Y, Nagashima H, Asai G, Watanabe S, Miyazaki M, Hagiwara K, Nukiwa T, Morita S, Kobayashi K, Maemondo M. Erlotinib plus bevacizumab versus erlotinib alone in patients with EGFR-positive advanced non-squamous non-small-cell lung cancer (NEJ026): interim analysis of an open-label, randomised, multicentre, phase 3 trial. *Lancet Oncol.* 2019 May;20(5):625-635. doi: 10.1016/S1470-2045(19)30035-X. Epub 2019 Apr 8. PMID: 30975627.
55. 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. *Lancet Oncol.*

- 2019 Jun;20(6):849-861. doi: 10.1016/S1470-2045(19)30027-0. Epub 2019 Apr 16. Erratum in: *Lancet Oncol.* 2019 Jun;20(6):e293. PMID: 31003911.
56. Jiang Z, Li W, Hu X, Zhang Q, Sun T, Cui S, Wang S, Ouyang Q, Yin Y, Geng C, Tong Z, Cheng Y, Pan Y, Sun Y, Wang H, Ouyang T, Gu K, Feng J, Wang X, Wang S, Liu T, Gao J, Cristofanilli M, Ning Z, Lu X. Tucidostat plus exemestane for postmenopausal patients with advanced, hormone receptor-positive breast cancer (ACE): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2019 Jun;20(6):806-815. doi: 10.1016/S1470-2045(19)30164-0. Epub 2019 Apr 27. PMID: 31036468.
57. Vergote I, Scambia G, O'Malley DM, Van Calster B, Park SY, Del Campo JM, Meier W, Bamias A, Colombo N, Wenham RM, Covens A, Marth C, Raza Mirza M, Kroep JR, Ma H, Pickett CA, Monk BJ; TRINOVA-3/ENGOT-ov2/GOG-3001 investigators. Trebananib or placebo plus carboplatin and paclitaxel as first-line treatment for advanced ovarian cancer (TRINOVA-3/ENGOT-ov2/GOG-3001): a randomised, double-blind, phase 3 trial. *Lancet Oncol.* 2019 Jun;20(6):862-876. doi: 10.1016/S1470-2045(19)30178-0. Epub 2019 May 7. PMID: 31076365.
58. 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. *Lancet Oncol.* 2019 Jul;20(7):924-937. doi: 10.1016/S1470-2045(19)30167-6. Epub 2019 May 20. PMID: 31122901.
59. Long GV, Dummer R, Hamid O, Gajewski TF, Cagle 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. Epcadostat plus pembrolizumab versus placebo plus pembrolizumab in patients with unresectable or metastatic melanoma (ECHO-301/KEYNOTE-252): a phase 3, randomised, double-blind study. *Lancet Oncol.* 2019 Aug;20(8):1083-1097. doi: 10.1016/S1470-2045(19)30274-8. Epub 2019 Jun 17. PMID: 31221619.
60. 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.
61. Nakagawa K, Garon EB, Seto T, Nishio M, Ponce Aix S, Paz-Ares L, Chiu CH, Park K, Novello S, Nadal E, Imamura F, Yoh K, Shih JY, Au KH, Moro-Sibilot D, Enatsu S, Zimmermann A, Frimodt-Moller B, Visseren-Grul C, Reck M; RELAY Study Investigators. Ramucirumab plus erlotinib in patients with untreated, EGFR- mutated, advanced non-small-cell lung cancer (RELAY): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2019 Dec;20(12):1655-1669. doi: 10.1016/S1470-2045(19)30634-5. Epub 2019 Oct 4. PMID: 31591063.
62. Coleman R, Finkelstein DM, Barrios C, Martin M, Iwata H, Hegg R, Glaspy J, Periañez AM, Tonkin K, Deleu I, Sohn J, Crown J, Delaloge S, Dai T, Zhou Y, Jandial D, Chan A. Adjuvant denosumab in early breast cancer (D-CARE): an international, multicentre, randomised, controlled, phase 3 trial. *Lancet*

- Oncol. 2020 Jan;21(1):60-72. doi: 10.1016/S1470-2045(19)30687-4. Epub 2019 Dec 2. PMID: 31806543.
63. Rini BI, Pal SK, Escudier BJ, Atkins MB, Hutson TE, Porta C, Verzoni E, Needle MN, McDermott DF. Tivozanib versus sorafenib in patients with advanced renal cell carcinoma (TIVO-3): a phase 3, multicentre, randomised, controlled, open-label study. *Lancet Oncol.* 2020 Jan;21(1):95-104. doi: 10.1016/S1470-2045(19)30735-1. Epub 2019 Dec 3. PMID: 31810797.
64. Cremolini C, Antoniotti C, Rossini D, Lonardi S, Loupakis F, Pietrantonio F, Bordonaro R, Latiano TP, Tamburini E, Santini D, Passardi A, Marmorino F, Grande R, Aprile G, Zaniboni A, Murgioni S, Granetto C, Buonadonna A, Moretto R, Corallo S, Cordio S, Antonuzzo L, Tomasello G, Masi G, Ronzoni M, Di Donato S, Carlomagno C, Clavarezza M, Ritorto G, Mambrini A, Roselli M, Cupini S, Mammoliti S, Fenocchio E, Corgna E, Zagonel V, Fontanini G, Ugolini C, Boni L, Falcone A; GONO Foundation Investigators. Upfront FOLFOXIRI plus bevacizumab and reintroduction after progression versus mFOLFOX6 plus bevacizumab followed by FOLFIRI plus bevacizumab in the treatment of patients with metastatic colorectal cancer (TRIBE2): a multicentre, open-label, phase 3, randomised, controlled trial. *Lancet Oncol.* 2020 Apr;21(4):497-507. doi: 10.1016/S1470-2045(19)30862-9. Epub 2020 Mar 9. PMID: 32164906.
65. Pfisterer J, Shannon CM, Baumann K, Rau J, Harter P, Joly F, Sehouli J, Canzler U, Schmalfeldt B, Dean AP, Hein A, Zeimet AG, Hanker LC, Petit T, Marmé F, El-Balat A, Glasspool R, de Gregorio N, Mahner S, Meniawy TM, Park-Simon TW, Mouret-Reynier MA, Costan C, Meier W, Reinthaller A, Goh JC, L'Haridon T, Baron Hay S, Kommoss S, du Bois A, Kurtz JE; AGO-OVAR 2.21/ENGOT-ov 18 Investigators. Bevacizumab and platinum-based combinations for recurrent ovarian cancer: a randomised, open-label, phase 3 trial. *Lancet Oncol.* 2020 May;21(5):699-709. doi: 10.1016/S1470-2045(20)30142-X. Epub 2020 Apr 16. Erratum in: *Lancet Oncol.* 2022 Jun;23(6):e248. PMID: 32305099.
66. Abou-Alfa GK, Macarulla T, Javle MM, Kelley RK, Lubner SJ, Adeva J, Cleary JM, Catenacci DV, Borad MJ, Bridgewater J, Harris WP, Murphy AG, Oh DY, Whisenant J, Lowery MA, Goyal L, Shroff RT, El-Khoueiry AB, Fan B, Wu B, Chamberlain CX, Jiang L, Gliser C, Pandya SS, Valle JW, Zhu AX. Ivosidenib in IDH1-mutant, chemotherapy-refractory cholangiocarcinoma (ClarIDHy): a multicentre, randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Oncol.* 2020 Jun;21(6):796-807. doi: 10.1016/S1470-2045(20)30157-1. Epub 2020 May 13. Erratum in: *Lancet Oncol.* 2020 Oct;21(10):e462. PMID: 32416072; PMCID: PMC7523268.
67. Huang J, Xu J, Chen Y, Zhuang W, Zhang Y, Chen Z, Chen J, Zhang H, Niu Z, Fan Q, Lin L, Gu K, Liu Y, Ba Y, Miao Z, Jiang X, Zeng M, Chen J, Fu Z, Gan L, Wang J, Zhan X, Liu T, Li Z, Shen L, Shu Y, Zhang T, Yang Q, Zou J; ESCORT Study Group. Camrelizumab versus investigator's choice of chemotherapy as second-line therapy for advanced or metastatic oesophageal squamous cell carcinoma (ESCORT): a multicentre, randomised, open-label, phase 3 study. *Lancet Oncol.* 2020 Jun;21(6):832-842. doi: 10.1016/S1470-2045(20)30110-8. Epub 2020 May 13. PMID: 32416073.
68. Blay JY, Serrano C, Heinrich MC, Zalcberg J, Bauer S, Gelderblom H, Schöffski P, Jones RL, Attia S, D'Amato G, Chi P, Reichardt P, Meade J, Shi K, Ruiz-Soto R, George S, von Mehren M. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2020 Jul;21(7):923-934. doi: 10.1016/S1470-2045(20)30168-6. Epub 2020 Jun 5. Erratum in: *Lancet Oncol.* 2020 Jul;21(7):e341. PMID: 32511981; PMCID: PMC8383051.

69. Kang YK, Chin K, Chung HC, Kadowaki S, Oh SC, Nakayama N, Lee KW, Hara H, Chung IJ, Tsuda M, Park SH, Hosaka H, Hironaka S, Miyata Y, Ryu MH, Baba H, Hyodo I, Bang YJ, Boku N. S-1 plus leucovorin and oxaliplatin versus S-1 plus cisplatin as first-line therapy in patients with advanced gastric cancer (SOLAR): a randomised, open-label, phase 3 trial. *Lancet Oncol.* 2020 Aug;21(8):1045-1056. doi: 10.1016/S1470-2045(20)30315-6. Epub 2020 Jul 16. PMID: 32682457.
70. Baize N, Monnet I, Greillier L, Geier M, Lena H, Janicot H, Vergnenegre A, Crequit J, Lamy R, Auliac JB, Letreut J, Le Caer H, Gervais R, Dansin E, Madroszyk A, Renault PA, Le Garff G, Falchero L, Berard H, Schott R, Saulnier P, Chouaid C; Groupe Français de Pneumo-Cancérologie 01–13 investigators. Carboplatin plus etoposide versus topotecan as second-line treatment for patients with sensitive relapsed small-cell lung cancer: an open-label, multicentre, randomised, phase 3 trial. *Lancet Oncol.* 2020 Sep;21(9):1224-1233. doi: 10.1016/S1470-2045(20)30461-7. PMID: 32888454.
71. Diéras V, Han HS, Kaufman B, Wildiers H, Friedlander M, Ayoub JP, Puhalla SL, Bondarenko I, Campone M, Jakobsen EH, Jalving M, Oprean C, Palácová M, Park YH, Shparyk Y, Yañez E, Khandelwal N, Kundu MG, Dudley M, Ratajczak CK, Maag D, Arun BK. Veliparib with carboplatin and paclitaxel in BRCA-mutated advanced breast cancer (BROCADE3): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2020 Oct;21(10):1269-1282. doi: 10.1016/S1470-2045(20)30447-2. Epub 2020 Aug 27. PMID: 32861273.
72. Xu J, Shen L, Bai C, Wang W, Li J, Yu X, Li Z, Li E, Yuan X, Chi Y, Yin Y, Lou W, Xu N, Bai Y, Zhang T, Xiu D, Wang X, Yuan Y, Chen J, Qin S, Jia R, Lu M, Cheng Y, Zhou Z, Li J, He J, Su W. Surufatinib in advanced pancreatic neuroendocrine tumours (SANET-p): a randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Oncol.* 2020 Nov;21(11):1489-1499. doi: 10.1016/S1470-2045(20)30493-9. Epub 2020 Sep 20. PMID: 32966810.
73. Xu J, Shen L, Zhou Z, Li J, Bai C, Chi Y, Li Z, Xu N, Li E, Liu T, Bai Y, Yuan Y, Li X, Wang X, Chen J, Ying J, Yu X, Qin S, Yuan X, Zhang T, Deng Y, Xiu D, Cheng Y, Tao M, Jia R, Wang W, Li J, Fan S, Peng M, Su W. Surufatinib in advanced extrapancreatic neuroendocrine tumours (SANET-ep): a randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Oncol.* 2020 Nov;21(11):1500-1512. doi: 10.1016/S1470-2045(20)30496-4. Epub 2020 Sep 20. PMID: 32966811.
74. Smith I, Robertson J, Kilburn L, Wilcox M, Evans A, Holcombe C, Horgan K, Kirwan C, Mallon E, Sibbering M, Skene A, Vidya R, Cheang M, Banerji J, Morden J, Sidhu K, Dodson A, Bliss JM, Dowsett M. Long-term outcome and prognostic value of Ki67 after perioperative endocrine therapy in postmenopausal women with hormone-sensitive early breast cancer (POETIC): an open-label, multicentre, parallel-group, randomised, phase 3 trial. *Lancet Oncol.* 2020 Nov;21(11):1443-1454. doi: 10.1016/S1470-2045(20)30458-7. Erratum in: *Lancet Oncol.* 2020 Dec;21(12):e553. PMID: 33152284; PMCID: PMC7606901.
75. Powles T, van der Heijden MS, Castellano D, Galsky MD, Loriot Y, Petrylak DP, Ogawa O, Park SH, Lee JL, De Giorgi U, Bögemann M, Bamias A, Eigl BJ, Gurney H, Mukherjee SD, Fradet Y, Skoneczna I, Tsiatas M, Novikov A, Suárez C, Fay AP, Duran I, Necchi A, Wildsmith S, He P, Angra N, Gupta AK, Levin W, Bellmunt J; DANUBE study investigators. Durvalumab alone and durvalumab plus tremelimumab versus chemotherapy in previously untreated patients with unresectable, locally advanced or metastatic urothelial carcinoma (DANUBE): a randomised, open-label, multicentre, phase 3 trial. *Lancet Oncol.* 2020 Dec;21(12):1574-1588. doi: 10.1016/S1470-2045(20)30541-6. Epub 2020 Sep 21. Erratum in: *Lancet Oncol.* 2021 Jan;22(1):e5. PMID: 32971005.

76. Bahadoer RR, Dijkstra EA, van Etten B, Marijnen CAM, Putter H, Kranenborg EM, Roodvoets AGH, Nagtegaal ID, Beets-Tan RGH, Blomqvist LK, Fokstuen T, Ten Tije AJ, Capdevila J, Hendriks MP, Edhemovic I, Cervantes A, Nilsson PJ, Glimelius B, van de Velde CJH, Hospers GAP; RAPIDO collaborative investigators. Short-course radiotherapy followed by chemotherapy before total mesorectal excision (TME) versus preoperative chemoradiotherapy, TME, and optional adjuvant chemotherapy in locally advanced rectal cancer (RAPIDO): a randomised, open-label, phase 3 trial. *Lancet Oncol.* 2021 Jan;22(1):29-42. doi: 10.1016/S1470-2045(20)30555-6. Epub 2020 Dec 7. Erratum in: *Lancet Oncol.* 2021 Feb;22(2):e42. PMID: 33301740.
77. Tan AR, Im SA, Mattar A, Colomer R, Stroyakovskii D, Nowecki Z, De Laurentiis M, Pierga JY, Jung KH, Schem C, Hoge A, Badovinac Crnjevic T, Heeson S, Shivhare M, Kirschbrown WP, Restuccia E, Jackisch C; FeDeriCa study group. Fixed-dose combination of pertuzumab and trastuzumab for subcutaneous injection plus chemotherapy in HER2-positive early breast cancer (FeDeriCa): a randomised, open-label, multicentre, non-inferiority, phase 3 study. *Lancet Oncol.* 2021 Jan;22(1):85-97. doi: 10.1016/S1470-2045(20)30536-2. Epub 2020 Dec 21. Erratum in: *Lancet Oncol.* 2021 Feb;22(2):e42. PMID: 33357420.
78. Toi M, Imoto S, Ishida T, Ito Y, Iwata H, Masuda N, Mukai H, Saji S, Shimizu A, Ikeda T, Haga H, Saeki T, Aogi K, Sugie T, Ueno T, Kinoshita T, Kai Y, Kitada M, Sato Y, Jimbo K, Sato N, Ishiguro H, Takada M, Ohashi Y, Ohno S. Adjuvant S-1 plus endocrine therapy for oestrogen receptor-positive, HER2-negative, primary breast cancer: a multicentre, open-label, randomised, controlled, phase 3 trial. *Lancet Oncol.* 2021 Jan;22(1):74-84. doi: 10.1016/S1470-2045(20)30534-9. Erratum in: *Lancet Oncol.* 2022 Oct;23(10):e446. PMID: 33387497.
79. Mayer EL, Dueck AC, Martin M, Rubovszky G, Burstein HJ, Bellet-Ezquerria M, Miller KD, Zdenkowski N, Winer EP, Pfeiler G, Goetz M, Ruiz-Borrego M, Anderson D, Nowecki Z, Loibl S, Moulder S, Ring A, Fitzal F, Traina T, Chan A, Rugo HS, Lemieux J, Henao F, Lyss A, Antolin Novoa S, Wolff AC, Vetter M, Egle D, Morris PG, Mamounas EP, Gil-Gil MJ, Prat A, Fohler H, Metzger Filho O, Schwarz M, DuFrane C, Fumagalli D, Theall KP, Lu DR, Bartlett CH, Koehler M, Fesl C, DeMichele A, Gnant M. Palbociclib with adjuvant endocrine therapy in early breast cancer (PALLAS): interim analysis of a multicentre, open-label, randomised, phase 3 study. *Lancet Oncol.* 2021 Feb;22(2):212-222. doi: 10.1016/S1470-2045(20)30642-2. Epub 2021 Jan 15. PMID: 33460574.
80. 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. *Lancet Oncol.* 2021 Feb;22(2):198-211. doi: 10.1016/S1470-2045(20)30641-0. Epub 2021 Jan 18. Erratum in: *Lancet Oncol.* 2021 Mar;22(3):e92. PMID: 33476593.
81. Quénet F, Elias D, Roca L, Goéré D, Ghouti L, Pocard M, Facy O, Arvieux C, Lorimier G, Pezet D, Marchal F, Loi V, Meeus P, Juzyna B, de Forges H, Paineau J, Glehen O; UNICANCER-GI Group and BIG Renape Group. Cytoreductive surgery plus hyperthermic intraperitoneal chemotherapy versus cytoreductive surgery alone for colorectal peritoneal metastases (PRODIGE 7): a multicentre, randomised, open-label, phase 3 trial. *Lancet Oncol.* 2021 Feb;22(2):256-266. doi: 10.1016/S1470-2045(20)30599-4. Epub 2021 Jan 18. PMID: 33476595.

82. Pignata S, Lorusso D, Joly F, Gallo C, Colombo N, Sessa C, Bamias A, Salutati V, Selle F, Frezzini S, De Giorgi U, Pautier P, Bologna A, Orditura M, Dubot C, Gadducci A, Mammoliti S, Ray-Coquard I, Zafarana E, Breda E, Favier L, Ardizzoia A, Cinieri S, Largillier R, Sambataro D, Guardiola E, Lauria R, Pisano C, Raspagliesi F, Scambia G, Daniele G, Perrone F; MITO16b/MANGO–OV2/ENGOT–ov17 Investigators. Carboplatin-based doublet plus bevacizumab beyond progression versus carboplatin-based doublet alone in patients with platinum-sensitive ovarian cancer: a randomised, phase 3 trial. *Lancet Oncol.* 2021 Feb;22(2):267-276. doi: 10.1016/S1470-2045(20)30637-9. PMID: 33539744.
83. Xu B, Yan M, Ma F, Hu X, Feng J, Ouyang Q, Tong Z, Li H, Zhang Q, Sun T, Wang X, Yin Y, Cheng Y, Li W, Gu Y, Chen Q, Liu J, Cheng J, Geng C, Qin S, Wang S, Lu J, Shen K, Liu Q, Wang X, Wang H, Luo T, Yang J, Wu Y, Yu Z, Zhu X, Chen C, Zou J; PHOEBE Investigators. Pyrotinib plus capecitabine versus lapatinib plus capecitabine for the treatment of HER2-positive metastatic breast cancer (PHOEBE): a multicentre, open-label, randomised, controlled, phase 3 trial. *Lancet Oncol.* 2021 Mar;22(3):351-360. doi: 10.1016/S1470-2045(20)30702-6. Epub 2021 Feb 11. PMID: 33581774.
84. 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. *Lancet Oncol.* 2021 Apr;22(4):499-511. doi: 10.1016/S1470-2045(20)30754-3. Epub 2021 Mar 4. PMID: 33676601.
85. Bellmunt J, Hussain M, Gschwend JE, Albers P, Oudard S, Castellano D, Daneshmand S, Nishiyama H, Majchrowicz M, Degaonkar V, Shi Y, Mariathasan S, Grivas P, Drakaki A, O'Donnell PH, Rosenberg JE, Geynisman DM, Petrylak DP, Hoffman-Censits J, Bedke J, Kalebasty AR, Zakharia Y, van der Heijden MS, Sternberg CN, Davarpanah NN, Powles T; IMvigor010 Study Group. Adjuvant atezolizumab versus observation in muscle-invasive urothelial carcinoma (IMvigor010): a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol.* 2021 Apr;22(4):525-537. doi: 10.1016/S1470-2045(21)00004-8. Epub 2021 Mar PMID: 33721560; PMCID: PMC8495594.
86. Lee NY, Ferris RL, Psyrrri A, Haddad RI, Tahara M, Bourhis J, Harrington K, Chang PM, Lin JC, Razaq MA, Teixeira MM, Lövey J, Chamois J, Rueda A, Hu C, Dunn LA, Dvorkin MV, De Beukelaer S, Pavlov D, Thurm H, Cohen E. Avelumab plus standard-of-care chemoradiotherapy versus chemoradiotherapy alone in patients with locally advanced squamous cell carcinoma of the head and neck: a randomised, double-blind, placebo-controlled, multicentre, phase 3 trial. *Lancet Oncol.* 2021 Apr;22(4):450-462. doi: 10.1016/S1470-2045(20)30737-3. PMID: 33794205.
87. Lamarca A, Palmer DH, Wasan HS, Ross PJ, Ma YT, Arora A, Falk S, Gillmore R, Wadsley J, Patel K, Anthony A, Maraveyas A, Iveson T, Waters JS, Hobbs C, Barber S, Ryder WD, Ramage J, Davies LM, Bridgewater JA, Valle JW; Advanced Biliary Cancer Working Group. Second-line FOLFOX chemotherapy versus active symptom control for advanced biliary tract cancer (ABC-06): a phase 3, open-label, randomised, controlled trial. *Lancet Oncol.* 2021 May;22(5):690-701. doi: 10.1016/S1470-2045(21)00027-9. Epub 2021 Mar 30. PMID: 33798493; PMCID: PMC8082275.
88. Lv X, Cao X, Xia WX, Liu KY, Qiang MY, Guo L, Qian CN, Cao KJ, Mo HY, Li XM, Li ZH, Han F, He YX, Liu YM, Wu SX, Bai YR, Ke LR, Qiu WZ, Liang H, Liu GY, Miao JJ, Li WZ, Lv SH, Chen X, Zhao C, Xiang YQ, Guo X. Induction chemotherapy with lobaplatin and fluorouracil versus cisplatin and fluorouracil followed by chemoradiotherapy in patients with stage III-IVB nasopharyngeal carcinoma: an

- open-label, non-inferiority, randomised, controlled, phase 3 trial. *Lancet Oncol.* 2021 May;22(5):716-726. doi: 10.1016/S1470-2045(21)00075-9. Epub 2021 Apr PMID: 33857411.
89. Conroy T, Bosset JF, Etienne PL, Rio E, François É, Mesgouez-Nebout N, Vendrely V, Artignan X, Bouché O, Gargot D, Boige V, Bonichon-Lamichhane N, Louvet C, Morand C, de la Fouchardière C, Lamfichekh N, Juzyna B, Jouffroy- Zeller C, Rullier E, Marchal F, Gourgou S, Castan F, Borg C; Unicancer Gastrointestinal Group and Partenariat de Recherche en Oncologie Digestive (PRODIGE) Group. Neoadjuvant chemotherapy with FOLFIRINOX and preoperative chemoradiotherapy for patients with locally advanced rectal cancer (UNICANCER- PRODIGE 23): a multicentre, randomised, open-label, phase 3 trial. *Lancet Oncol.* 2021 May;22(5):702-715. doi: 10.1016/S1470-2045(21)00079-6. Epub 2021 Apr 13. PMID: 33862000.
90. Powles T, Csösz T, Özgüroğlu M, Matsubara N, Géczi L, Cheng SY, Fradet Y, Oudard S, Vulsteke C, Morales Barrera R, Fléchon A, Gunduz S, Loriot Y, Rodriguez-Vida A, Mamtani 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.
91. Pujade-Lauraine E, Fujiwara K, Ledermann JA, Oza AM, Kristeleit R, Ray- Coquard IL, Richardson GE, Sessa C, Yonemori K, Banerjee S, Leary A, Tinker AV, Jung KH, Madry R, Park SY, Anderson CK, Zohren F, Stewart RA, Wei C, Dychter SS, Monk BJ. Avelumab alone or in combination with chemotherapy versus chemotherapy alone in platinum-resistant or platinum-refractory ovarian cancer (JAVELIN Ovarian 200): an open-label, three-arm, randomised, phase 3 study. *Lancet Oncol.* 2021 Jul;22(7):1034-1046. doi: 10.1016/S1470-2045(21)00216-3. Epub 2021 Jun 15. PMID: 34143970.
92. Ren Z, Xu J, Bai Y, Xu A, Cang S, Du C, Li Q, Lu Y, Chen Y, Guo Y, Chen Z, Liu B, Jia W, Wu J, Wang J, Shao G, Zhang B, Shan Y, Meng Z, Wu J, Gu S, Yang W, Liu C, Shi X, Gao Z, Yin T, Cui J, Huang M, Xing B, Mao Y, Teng G, Qin Y, Wang J, Xia F, Yin G, Yang Y, Chen M, Wang Y, Zhou H, Fan J; ORIENT-32 study group. Sintilimab plus a bevacizumab biosimilar (IBI305) versus sorafenib in unresectable hepatocellular carcinoma (ORIENT-32): a randomised, open-label, phase 2-3 study. *Lancet Oncol.* 2021 Jul;22(7):977-990. doi: 10.1016/S1470-2045(21)00252-7. Epub 2021 Jun 15. Erratum in: *Lancet Oncol.* 2021 Aug;22(8):e347. PMID: 34143971.
93. Yang Y, Qu S, Li J, Hu C, Xu M, Li W, Zhou T, Shen L, Wu H, Lang J, Hu G, Luo Z, Fu Z, Qu S, Feng W, Chen X, Lin S, Zhang W, Li X, Sun Y, Lin Z, Lin Q, Lei F, Long J, Hong J, Huang X, Zeng L, Wang P, He X, Zhang B, Yang Q, Zhang X, Zou J, Fang W, Zhang L. Camrelizumab versus placebo in combination with gemcitabine and cisplatin as first-line treatment for recurrent or metastatic nasopharyngeal carcinoma (CAPTAIN-1st): a multicentre, randomised, double-blind, phase 3 trial. *Lancet Oncol.* 2021 Aug;22(8):1162-1174. doi: 10.1016/S1470-2045(21)00302-8. Epub 2021 Jun 23. PMID: 34174189.
94. Brose MS, Robinson B, Sherman SI, Krajewska J, Lin CC, Vaisman F, Hoff AO, Hitre E, Bowles DW, Hernando J, Faoro L, Banerjee K, Oliver JW, Keam B, Capdevila J. Cabozantinib for radioiodine-refractory differentiated thyroid cancer (COSMIC-311): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2021 Aug;22(8):1126-1138. doi: 10.1016/S1470-2045(21)00332-6. Epub 2021 Jul 5. PMID: 34237250.

95. Zhang X, Liang H, Li Z, Xue Y, Wang Y, Zhou Z, Yu J, Bu Z, Chen L, Du Y, Wang X, Wu A, Li G, Su X, Xiao G, Cui M, Wu D, Chen L, Wu X, Zhou Y, Zhang L, Dang C, He Y, Zhang Z, Sun Y, Li Y, Chen H, Bai Y, Qi C, Yu P, Zhu G, Suo J, Jia B, Li L, Huang C, Li F, Ye Y, Xu H, Wang X, Yuan Y, E JY, Ying X, Yao C, Shen L, Ji J; RESOLVE study group. Perioperative or postoperative adjuvant oxaliplatin with S-1 versus adjuvant oxaliplatin with capecitabine in patients with locally advanced gastric or gastro-oesophageal junction adenocarcinoma undergoing D2 gastrectomy (RESOLVE): an open-label, superiority and non-inferiority, phase 3 randomised controlled trial. *Lancet Oncol*. 2021 Aug;22(8):1081-1092. doi: 10.1016/S1470-2045(21)00297-7. Epub 2021 Jul 9. Erratum in: *Lancet Oncol*. 2021 Aug;22(8):e347. PMID: 34252374.
96. Monk BJ, Colombo N, Oza AM, Fujiwara K, Birrer MJ, Randall L, Poddubskaya EV, Scambia G, Shparyk YV, Lim MC, Bhoola SM, Sohn J, Yonemori K, Stewart RA, Zhang X, Perkins Smith J, Linn C, Ledermann JA. Chemotherapy with or without avelumab followed by avelumab maintenance versus chemotherapy alone in patients with previously untreated epithelial ovarian cancer (JAVELIN Ovarian 100): an open-label, randomised, phase 3 trial. *Lancet Oncol*. 2021 Sep;22(9):1275-1289. doi: 10.1016/S1470-2045(21)00342-9. Epub 2021 Aug 4. PMID: 34363762.
97. Del Mastro L, Mansutti M, Bisagni G, Ponzzone R, Durando A, Amaducci L, Campadelli E, Cognetti F, Frassoldati A, Michelotti A, Mura S, Urracci Y, Sanna G, Gori S, De Placido S, Garrone O, Fabi A, Barone C, Tamberi S, Bighin C, Puglisi F, Moretti G, Arpino G, Ballestrero A, Poggio F, Lambertini M, Montemurro F, Bruzzi P; Gruppo Italiano Mammella investigators. Extended therapy with letrozole as adjuvant treatment of postmenopausal patients with early-stage breast cancer: a multicentre, open-label, randomised, phase 3 trial. *Lancet Oncol*. 2021 Oct;22(10):1458-1467. doi: 10.1016/S1470-2045(21)00352-1. Epub 2021 Sep 17. PMID: 34543613.

NEJM (New England Journal of Medicine)

1. Strosberg J, El-Haddad G, Wolin E, Hendifar A, Yao J, Chasen B, Mittra E, Kunz PL, Kulke MH, Jacene H, Bushnell D, O'Dorisio TM, Baum RP, Kulkarni HR, Caplin M, Lebtahi R, Hobday T, Delpassand E, Van Cutsem E, Benson A, Srirajaskanthan R, Pavel M, Mora J, Berlin J, Grande E, Reed N, Seregini E, Öberg K, Lopera Sierra M, Santoro P, Thevenet T, Erion JL, Ruzsniowski P, Kwekkeboom D, Krenning E; NETTER-1 Trial Investigators. Phase 3 Trial of ¹⁷⁷Lu- Dotatate for Midgut Neuroendocrine Tumors. *N Engl J Med*. 2017 Jan 12;376(2):125-135. doi: 10.1056/NEJMoa1607427. PMID: 28076709; PMCID: PMC5895095.
2. Shipley WU, Seiferheld W, Lukka HR, Major PP, Heney NM, Grignon DJ, Sartor O, Patel MP, Bahary JP, Zietman AL, Pisansky TM, Zeitzer KL, Lawton CA, Feng FY, Lovett RD, Balogh AG, Souhami L, Rosenthal SA, Kerlin KJ, Dignam JJ, Pugh SL, Sandler HM; NRG Oncology RTOG. Radiation with or without Antiandrogen Therapy in Recurrent Prostate Cancer. *N Engl J Med*. 2017 Feb 2;376(5):417-428. doi: 10.1056/NEJMoa1607529. PMID: 28146658; PMCID: PMC5444881.
3. Mok TS, Wu Y-L, Ahn M-J, Garassino MC, Kim HR, Ramalingam SS, Shepherd FA, He Y, Akamatsu H, Theelen WS, Lee CK, Sebastian M, Templeton A, Mann H, Marotti M, Ghorghiu S, Papadimitrakopoulou VA; AURA3 Investigators. Osimertinib or Platinum-Pemetrexed in EGFR T790M-Positive Lung Cancer. *N Engl J Med*. 2017 Feb 16;376(7):629-640. doi: 10.1056/NEJMoa1612674. Epub 2016 Dec 6. PMID: 27959700; PMCID: PMC6762027.
4. 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. *N Engl J Med.* 2017 Mar 16;376(11):1015-1026. doi: 10.1056/NEJMoa1613683. Epub 2017 Feb 17. PMID: 28212060; PMCID: PMC5635424.
5. Perry JR, Laperriere N, O'Callaghan CJ, Brandes AA, Menten J, Phillips C, Fay M, Nishikawa R, Cairncross JG, Roa W, Osoba D, Rossiter JP, Sahgal A, Hirte H, Laigle-Donadey F, Franceschi E, Chinot O, Golfopoulos V, Fariselli L, Wick A, Feuvret L, Back M, Tills M, Winch C, Baumert BG, Wick W, Ding K, Mason WP; Trial Investigators. Short-Course Radiation plus Temozolomide in Elderly Patients with Glioblastoma. *N Engl J Med.* 2017 Mar 16;376(11):1027-1037. doi: 10.1056/NEJMoa1611977. PMID: 28296618.
 6. Masuda N, Lee SJ, Ohtani S, Im YH, Lee ES, Yokota I, Kuroi K, Im SA, Park BW, Kim SB, Yanagita Y, Ohno S, Takao S, Aogi K, Iwata H, Jeong J, Kim A, Park KH, Sasano H, Ohashi Y, Toi M. Adjuvant Capecitabine for Breast Cancer after Preoperative Chemotherapy. *N Engl J Med.* 2017 Jun 1;376(22):2147-2159. doi: 10.1056/NEJMoa1612645. PMID: 28564564.
 7. Carbone DP, Reck M, Paz-Ares L, Creelan B, Horn L, Steins M, Felip E, van den Heuvel MM, Ciuleanu TE, Badin F, Ready N, Hiltermann TJN, Nair S, Juergens R, Peters S, Minenza E, Wrangle JM, Rodriguez-Abreu D, Borghaei H, Blumenschein GR Jr, Villaruz LC, Havel L, Krejci J, Corral Jaime J, Chang H, Geese WJ, Bhagavatheswaran P, Chen AC, Socinski MA; CheckMate 026 Investigators. First-Line Nivolumab in Stage IV or Recurrent Non-Small-Cell Lung Cancer. *N Engl J Med.* 2017 Jun 22;376(25):2415-2426. doi: 10.1056/NEJMoa1613493. PMID: 28636851; PMCID: PMC6487310.
 8. von Minckwitz G, Procter M, de Azambuja E, Zardavas D, Benyunes M, Viale G, Suter T, Arahmani A, Rouchet N, Clark E, Knott A, Lang I, Levy C, Yardley DA, Bines J, Gelber RD, Piccart M, Baselga J; APHINITY Steering Committee and Investigators. Adjuvant Pertuzumab and Trastuzumab in Early HER2-Positive Breast Cancer. *N Engl J Med.* 2017 Jul 13;377(2):122-131. doi: 10.1056/NEJMoa1703643. Epub 2017 Jun 5. Erratum in: *N Engl J Med.* 2017 Aug 17;377(7):702. Erratum in: *N Engl J Med.* 2018 Oct 18;379(16):1585. PMID: 28581356; PMCID: PMC5538020.
 9. Fizazi K, Tran N, Fein L, Matsubara N, Rodriguez-Antolin A, Alekseev BY, Özgüroğlu M, Ye D, Feyerabend S, Protheroe A, De Porre P, Kheoh T, Park YC, Todd MB, Chi KN; LATITUDE Investigators. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *N Engl J Med.* 2017 Jul 27;377(4):352-360. doi: 10.1056/NEJMoa1704174. Epub 2017 Jun 4. PMID: 28578607.
 10. James ND, de Bono JS, Spears MR, Clarke NW, Mason MD, Dearnaley DP, Ritchie AWS, Amos CL, Gilson C, Jones RJ, Matheson D, Millman R, Attard G, Chowdhury S, Cross WR, Gillessen S, Parker CC, Russell JM, Berthold DR, Brawley C, Adab F, Aung S, Birtle AJ, Bowen J, Brock S, Chakraborti P, Ferguson C, Gale J, Gray E, Hingorani M, Hoskin PJ, Lester JF, Malik ZI, McKinna F, McPhail N, Money-Kyrle J, O'Sullivan J, Parikh O, Protheroe A, Robinson A, Srihari NN, Thomas C, Wagstaff J, Wylie J, Zarkar A, Parmar MKB, Sydes MR; STAMPEDE Investigators. Abiraterone for Prostate Cancer Not Previously Treated with Hormone Therapy. *N Engl J Med.* 2017 Jul 27;377(4):338-351. doi: 10.1056/NEJMoa1702900. Epub 2017 Jun 3. PMID: 28578639; PMCID: PMC5533216.
 11. Robson M, Im SA, Senkus E, Xu B, Domchek SM, Masuda N, Delaloge S, Li W, Tung N, Armstrong A, Wu W, Goessl C, Runswick S, Conte P. Olaparib for Metastatic Breast Cancer in Patients with a Germline BRCA Mutation. *N Engl J Med.* 2017 Aug 10;377(6):523-533. doi: 10.1056/NEJMoa1706450. Epub 2017 Jun 4. Erratum in: *N Engl J Med.* 2017 Oct 26;377(17):1700. PMID: 28578601.

12. Peters S, Camidge DR, Shaw AT, Gadgeel S, Ahn JS, Kim DW, Ou SI, Pérol M, Dziadziuszko R, Rosell R, Zeaiter A, Mityr E, Golding S, Balas B, Noe J, Morcos PN, Mok T; ALEX Trial Investigators. Alectinib versus Crizotinib in Untreated ALK-Positive Non-Small-Cell Lung Cancer. *N Engl J Med.* 2017 Aug 31;377(9):829-838. doi: 10.1056/NEJMoa1704795. Epub 2017 Jun 6. PMID: 28586279.
13. Long GV, Hauschild A, Santinami M, Atkinson V, Mandalà M, Chiarion-Sileni V, Larkin J, Nyakas M, Dutriaux C, Haydon A, Robert C, Mortier L, Schachter J, Schadendorf D, Lesimple T, Plummer R, Ji R, Zhang P, Mookerjee B, Legos J, Kefford R, Dummer R, Kirkwood JM. Adjuvant Dabrafenib plus Trametinib in Stage III BRAF-Mutated Melanoma. *N Engl J Med.* 2017 Nov 9;377(19):1813-1823. doi: 10.1056/NEJMoa1708539. Epub 2017 Sep 10. PMID: 28891408.
14. Weber J, Mandala M, Del Vecchio M, Gogas HJ, Arance AM, Cowey CL, Dalle S, Schenker M, Chiarion-Sileni V, Marquez-Rodas I, Grob JJ, Butler MO, Middleton MR, Maio M, Atkinson V, Queirolo P, Gonzalez R, Kudchadkar RR, Smylie M, Meyer N, Mortier L, Atkins MB, Long GV, Bhatia S, Lebbé C, Rutkowski P, Yokota K, Yamazaki N, Kim TM, de Pril V, Sabater J, Qureshi A, Larkin J, Ascierto PA; CheckMate 238 Collaborators. Adjuvant Nivolumab versus Ipilimumab in Resected Stage III or IV Melanoma. *N Engl J Med.* 2017 Nov 9;377(19):1824-1835. doi: 10.1056/NEJMoa1709030. Epub 2017 Sep 10. PMID: 28891423.
15. 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, Hirt 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. *N Engl J Med.* 2017 Nov 16;377(20):1919-1929. doi: 10.1056/NEJMoa1709937. Epub 2017 Sep 8. PMID: 28885881.
16. Wick W, Gorlia T, Bendszus M, Taphoorn M, Sahm F, Harting I, Brandes AA, Taal W, Domont J, Idbaih A, Campone M, Clement PM, Stupp R, Fabbro M, Le Rhun E, Dubois F, Weller M, von Deimling A, Golfopoulos V, Bromberg JC, Platten M, Klein M, van den Bent MJ. Lomustine and Bevacizumab in Progressive Glioblastoma. *N Engl J Med.* 2017 Nov 16;377(20):1954-1963. doi: 10.1056/NEJMoa1707358. PMID: 29141164.
17. Soria JC, Ohe Y, Vansteenkiste J, Reungwetwattana T, Chewaskulyong B, Lee KH, Dechaphunkul A, Imamura F, Nogami N, Kurata T, Okamoto I, Zhou C, Cho BC, Cheng Y, Cho EK, Voon PJ, Planchard D, Su WC, Gray JE, Lee SM, Hodge R, Marotti M, Rukazenzov Y, Ramalingam SS; FLAURA Investigators. Osimertinib in Untreated EGFR-Mutated Advanced Non-Small-Cell Lung Cancer. *N Engl J Med.* 2018 Jan 11;378(2):113-125. doi: 10.1056/NEJMoa1713137. Epub 2017 Nov 18. PMID: 29151359.
18. van Driel WJ, Koole SN, Sikorska K, Schagen van Leeuwen JH, Schreuder HWR, Hermans RHM, de Hingh IHJT, van der Velden J, Arts HJ, Massuger LFAG, Aalbers AGJ, Verwaal VJ, Kieffer JM, Van de Vijver KK, van Tinteren H, Aaronson NK, Sonke GS. Hyperthermic Intraperitoneal Chemotherapy in Ovarian Cancer. *N Engl J Med.* 2018 Jan 18;378(3):230-240. doi: 10.1056/NEJMoa1708618. PMID: 29342393.
19. 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.
20. Smith MR, Saad F, Chowdhury S, Oudard S, Hadaschik BA, Graff JN, Olmos D, Mainwaring PN, Lee JY, Uemura H, Lopez-Gitlitz A, Trudel GC, Espina BM, Shu Y, Park YC, Rackoff WR, Yu MK, Small EJ; SPARTAN Investigators. Apalutamide Treatment and Metastasis-free Survival in Prostate Cancer. *N Engl J Med.* 2018 Apr 12;378(15):1408-1418. doi: 10.1056/NEJMoa1715546. Epub 2018 Feb 8. PMID: 29420164.
21. Eggermont AMM, Blank CU, Mandala M, Long GV, Atkinson V, Dalle S, Haydon A, Lichinitser M, Khattak A, Carlino MS, Sandhu S, Larkin J, Puig S, Ascierto PA, Rutkowski P, Schadendorf D, Koornstra R, Hernandez-Aya L, Maio M, van den Eertwegh AJM, Grob JJ, Gutzmer R, Jamal R, Lorigan P, Ibrahim N, Marreaud S, van Akkooi ACJ, Suci S, Robert C. Adjuvant Pembrolizumab versus Placebo in Resected Stage III Melanoma. *N Engl J Med.* 2018 May 10;378(19):1789-1801. doi: 10.1056/NEJMoa1802357. Epub 2018 Apr 15. PMID: 29658430.
22. Hellmann MD, Ciuleanu TE, Pluzanski A, Lee JS, Otterson GA, Audigier-Valette C, Minenza E, Linardou H, Burgers S, Salman P, Borghaei H, Ramalingam SS, Brahmer J, Reck M, O'Byrne KJ, Geese WJ, Green G, Chang H, Szustakowski J, Bhagavatheeswaran P, Healey D, Fu Y, Nathan F, Paz-Ares L. Nivolumab plus Ipilimumab in Lung Cancer with a High Tumor Mutational Burden. *N Engl J Med.* 2018 May 31;378(22):2093-2104. doi: 10.1056/NEJMoa1801946. Epub 2018 Apr 16. PMID: 29658845; PMCID: PMC7193684.
23. 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. *N Engl J Med.* 2018 May 31;378(22):2078-2092. doi: 10.1056/NEJMoa1801005. Epub 2018 Apr 16. PMID: 29658856.
24. Socinski MA, Jotte RM, Cappuzzo F, Orlandi F, Stroyakovskiy D, Nogami N, Rodríguez-Abreu D, Moro-Sibilot D, Thomas CA, Barlesi F, Finley G, Kelsch C, Lee A, Coleman S, Deng Y, Shen Y, Kowanetz M, Lopez-Chavez A, Sandler A, Reck M; IMpower150 Study Group. Atezolizumab for First-Line Treatment of Metastatic Nonsquamous NSCLC. *N Engl J Med.* 2018 Jun 14;378(24):2288-2301. doi: 10.1056/NEJMoa1716948. Epub 2018 Jun 4. PMID: 29863955.
25. Hussain M, Fizazi K, Saad F, Rathenborg P, Shore N, Ferreira U, Ivashchenko P, Demirhan E, Modolska K, Phung D, Krivoschik A, Sternberg CN. Enzalutamide in Men with Nonmetastatic, Castration-Resistant Prostate Cancer. *N Engl J Med.* 2018 Jun 28;378(26):2465-2474. doi: 10.1056/NEJMoa1800536. PMID: 29949494; PMCID: PMC8288034.
26. Abou-Alfa GK, Meyer T, Cheng AL, El-Khoueiry AB, Rimassa L, Ryoo BY, Cicin I, Merle P, Chen Y, Park JW, Blanc JF, Bolondi L, Klumpen HJ, Chan SL, Zagonel V, Pressiani T, Ryu MH, Venook AP, Hessel C, Borgman-Hagey AE, Schwab G, Kelley RK. Cabozantinib in Patients with Advanced and Progressing Hepatocellular Carcinoma. *N Engl J Med.* 2018 Jul 5;379(1):54-63. doi: 10.1056/NEJMoa1717002. PMID: 29972759; PMCID: PMC7523244.

27. Sparano JA, Gray RJ, Makower DF, Pritchard KI, Albain KS, Hayes DF, Geyer CE Jr, Dees EC, Goetz MP, Olson JA Jr, Lively T, Badve SS, Saphner TJ, Wagner LI, Whelan TJ, Ellis MJ, Paik S, Wood WC, Ravdin PM, Keane MM, Gomez Moreno HL, Reddy PS, Goggins TF, Mayer IA, Brufsky AM, Toppmeyer DL, Kaklamani VG, Berenberg JL, Abrams J, Sledge GW Jr. Adjuvant Chemotherapy Guided by a 21-Gene Expression Assay in Breast Cancer. *N Engl J Med.* 2018 Jul 12;379(2):111-121. doi: 10.1056/NEJMoa1804710. Epub 2018 Jun 3. PMID: 29860917; PMCID: PMC6172658.
28. Litton JK, Rugo HS, Ettl J, Hurvitz SA, Gonçalves A, Lee KH, Fehrenbacher L, Yerushalmi R, Mina LA, Martin M, Roché H, Im YH, Quek RGW, Markova D, Tudor IC, Hannah AL, Eiermann W, Blum JL. Talazoparib in Patients with Advanced Breast Cancer and a Germline BRCA Mutation. *N Engl J Med.* 2018 Aug 23;379(8):753-763. doi: 10.1056/NEJMoa1802905. Epub 2018 Aug 15. PMID: 30110579.
29. Paz-Ares L, Luft A, Vicente D, Tafreshi A, Gümüş M, Mazières J, Hermes B, Çay Şenler F, Csösz 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. *N Engl J Med.* 2018 Nov 22;379(21):2040-2051. doi: 10.1056/NEJMoa1810865. Epub 2018 Sep 25. PMID: 30280635.
30. Camidge DR, Kim HR, Ahn MJ, Yang JC, Han JY, Lee JS, Hochmair MJ, Li JY, Chang GC, Lee KH, Gridelli C, Delmonte A, Garcia Campelo R, Kim DW, Bearz A, Griesinger F, Morabito A, Felip E, Califano R, Ghosh S, Spira A, Gettinger SN, Tiseo M, Gupta N, Haney J, Kerstein D, Popat S. Brigatinib versus Crizotinib in ALK-Positive Non-Small-Cell Lung Cancer. *N Engl J Med.* 2018 Nov 22;379(21):2027-2039. doi: 10.1056/NEJMoa1810171. Epub 2018 Sep 25. PMID: 30280657.
31. 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.
32. Horn L, Mansfield AS, Szczyńska 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, Kabbinnavar F, Lin W, Sandler A, Liu SV; IMPower133 Study Group. First-Line Atezolizumab plus Chemotherapy in Extensive-Stage Small-Cell Lung Cancer. *N Engl J Med.* 2018 Dec 6;379(23):2220-2229. doi: 10.1056/NEJMoa1809064. Epub 2018 Sep 25. PMID: 30280641.
33. Gounder MM, Mahoney MR, Van Tine BA, Ravi V, Attia S, Deshpande HA, Gupta AA, Milhem MM, Conry RM, Movva S, Pishvaian MJ, Riedel RF, Sabagh T, Tap WD, Horvat N, Basch E, Schwartz LH, Maki RG, Agaram NP, Lefkowitz RA, Mazaheri Y, Yamashita R, Wright JJ, Dueck AC, Schwartz GK. Sorafenib for Advanced and Refractory Desmoid Tumors. *N Engl J Med.* 2018 Dec 20;379(25):2417-2428. doi: 10.1056/NEJMoa1805052. PMID: 30575484; PMCID: PMC6447029.
34. Conroy T, Hammel P, Hebbbar M, Ben Abdelghani M, Wei AC, Raoul JL, Choné L, Francois E, Artru P, Biagi JJ, Lecomte T, Assenat E, Faroux R, Ychou M, Volet J, Sauvanet A, Breysacher G, Di Fiore F, Cripps C, Kavan P, Texereau P, Bouhier- Leporrier K, Khemissa-Akouz F, Legoux JL, Juzyna B, Gourgou S, O'Callaghan CJ, Jouffroy-Zeller C, Rat P, Malka D, Castan F, Bachet JB; Canadian Cancer Trials Group and the Unicancer-GI-PRODIGE Group. FOLFIRINOX or Gemcitabine as Adjuvant Therapy for Pancreatic Cancer. *N Engl J Med.* 2018 Dec 20;379(25):2395-2406. doi: 10.1056/NEJMoa1809775. PMID: 30575490.

35. Moore K, Colombo N, Scambia G, Kim BG, Oaknin A, Friedlander M, Lisysanskaya A, Floquet A, Leary A, Sonke GS, Gourley C, Banerjee S, Oza A, González-Martín A, Aghajanian C, Bradley W, Mathews C, Liu J, Lowe ES, Bloomfield R, DiSilvestro P. Maintenance Olaparib in Patients with Newly Diagnosed Advanced Ovarian Cancer. *N Engl J Med.* 2018 Dec 27;379(26):2495-2505. doi: 10.1056/NEJMoa1810858. Epub 2018 Oct 21. PMID: 30345884.
36. von Minckwitz G, Huang CS, Mano MS, Loibl S, Mamounas EP, Untch M, Wolmark N, Rastogi P, Schneeweiss A, Redondo A, Fischer HH, Jacot W, Conlin AK, Arce-Salinas C, Wapnir IL, Jackisch C, DiGiovanna MP, Fasching PA, Crown JP, Wülfing P, Shao Z, Rota Caremoli E, Wu H, Lam LH, Tesarowski D, Smitt M, Douthwaite H, Singel SM, Geyer CE Jr; KATHERINE Investigators. Trastuzumab Emtansine for Residual Invasive HER2-Positive Breast Cancer. *N Engl J Med.* 2019 Feb 14;380(7):617-628. doi: 10.1056/NEJMoa1814017. Epub 2018 Dec 5. PMID: 30516102.
37. Rini BI, Plimack ER, Stus V, Gafanov R, Hawkins R, Nosov D, Pouliot F, Alekseev B, Soulières D, Melichar B, Vynnychenko I, Kryzhaniivska A, Bondarenko I, Azevedo SJ, Borchiellini D, Szczylik 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.
38. 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. *N Engl J Med.* 2019 Mar 21;380(12):1103-1115. doi: 10.1056/NEJMoa1816047. Epub 2019 Feb 16. PMID: 30779531; PMCID: PMC6716603.
39. Fizazi K, Shore N, Tammela TL, Ulys A, Vjaters E, Polyakov S, Jievaltas M, Luz M, Alekseev B, Kuss I, Kappeler C, Snapir A, Sarapohja T, Smith MR; ARAMIS Investigators. Darolutamide in Nonmetastatic, Castration-Resistant Prostate Cancer. *N Engl J Med.* 2019 Mar 28;380(13):1235-1246. doi: 10.1056/NEJMoa1815671. Epub 2019 Feb 14. Erratum in: *N Engl J Med.* 2022 Sep 1;387(9):860. PMID: 30763142.
40. André F, Ciruelos E, Rubovszky G, Campone M, Loibl S, Rugo HS, Iwata H, Conte P, Mayer IA, Kaufman B, Yamashita T, Lu YS, Inoue K, Takahashi M, Pápai Z, Longin AS, Mills D, Wilke C, Hirawat S, Juric D; SOLAR-1 Study Group. Alpelisib for *PIK3CA*-Mutated, Hormone Receptor-Positive Advanced Breast Cancer. *N Engl J Med.* 2019 May 16;380(20):1929-1940. doi: 10.1056/NEJMoa1813904. PMID: 31091374.
41. 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. *N Engl J Med.* 2019 Jul 4;381(1):13-24. doi: 10.1056/NEJMoa1903307. Epub 2019 May 31. PMID: 31150574.
42. Davis ID, Martin AJ, Stockler MR, Begbie S, Chi KN, Chowdhury S, Coskinas X, Frydenberg M, Hague WE, Horvath LG, Joshua AM, Lawrence NJ, Marx G, McCaffrey J, McDermott R, McJannett M, North SA, Parnis F, Parulekar W, Pook DW, Reaume MN, Sandhu SK, Tan A, Tan TH, Thomson A, Tu E,

- Vera-Badillo F, Williams SG, Yip S, Zhang AY, Zielinski RR, Sweeney CJ; ENZAMET Trial Investigators and the Australian and New Zealand Urogenital and Prostate Cancer Trials Group. Enzalutamide with Standard First-Line Therapy in Metastatic Prostate Cancer. *N Engl J Med.* 2019 Jul 11;381(2):121-131. doi: 10.1056/NEJMoa1903835. Epub 2019 Jun 2. PMID: 31157964.
43. Golan T, Hammel P, Reni M, Van Cutsem E, Macarulla T, Hall MJ, Park JO, Hochhauser D, Arnold D, Oh DY, Reinacher-Schick A, Tortora G, Algül H, O'Reilly EM, McGuinness D, Cui KY, Schlienger K, Locker GY, Kindler HL. Maintenance Olaparib for Germline *BRCA*-Mutated Metastatic Pancreatic Cancer. *N Engl J Med.* 2019 Jul 25;381(4):317-327. doi: 10.1056/NEJMoa1903387. Epub 2019 Jun 2. PMID: 31157963; PMCID: PMC6810605.
44. Zhang Y, Chen L, Hu GQ, Zhang N, Zhu XD, Yang KY, Jin F, Shi M, Chen YP, Hu WH, Cheng ZB, Wang SY, Tian Y, Wang XC, Sun Y, Li JG, Li WF, Li YH, Tang LL, Mao YP, Zhou GQ, Sun R, Liu X, Guo R, Long GX, Liang SQ, Li L, Huang J, Long JH, Zang J, Liu QD, Zou L, Su QF, Zheng BM, Xiao Y, Guo Y, Han F, Mo HY, Lv JW, Du XJ, Xu C, Liu N, Li YQ, Chua MLK, Xie FY, Sun Y, Ma J. Gemcitabine and Cisplatin Induction Chemotherapy in Nasopharyngeal Carcinoma. *N Engl J Med.* 2019 Sep 19;381(12):1124-1135. doi: 10.1056/NEJMoa1905287. Epub 2019 May 31. PMID: 31150573.
45. 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.
46. González-Martín A, Pothuri B, Vergote I, DePont Christensen R, Graybill W, Mirza MR, McCormick C, Lorusso D, Hoskins P, Freyer G, Baumann K, Jardon K, Redondo A, Moore RG, Vulsteke C, O'Ceirbhail RE, Lund B, Backes F, Barretina-Ginesta P, Haggerty AF, Rubio-Pérez MJ, Shahin MS, Mangili G, Bradley WH, Bruchim I, Sun K, Malinowska IA, Li Y, Gupta D, Monk BJ; PRIMA/ENGOT-OV26/GOG-3012 Investigators. Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer. *N Engl J Med.* 2019 Dec 19;381(25):2391-2402. doi: 10.1056/NEJMoa1910962. Epub 2019 Sep 28. PMID: 31562799.
47. Coleman RL, Fleming GF, Brady MF, Swisher EM, Steffensen KD, Friedlander M, Okamoto A, Moore KN, Efrat Ben-Baruch N, Werner TL, Cloven NG, Oaknin A, DiSilvestro PA, Morgan MA, Nam JH, Leath CA 3rd, Nicum S, Hagemann AR, Littell RD, Cella D, Baron-Hay S, Garcia-Donas J, Mizuno M, Bell-McGuinn K, Sullivan DM, Bach BA, Bhattacharya S, Ratajczak CK, Ansell PJ, Dinh MH, Aghajanian C, Bookman MA. Veliparib with First-Line Chemotherapy and as Maintenance Therapy in Ovarian Cancer. *N Engl J Med.* 2019 Dec 19;381(25):2403-2415. doi: 10.1056/NEJMoa1909707. Epub 2019 Sep 28. PMID: 31562800; PMCID: PMC6941439.
48. Ray-Coquard I, Pautier P, Pignata S, Pérol D, González-Martín A, Berger R, Fujiwara K, Vergote I, Colombo N, Mäenpää J, Selle F, Sehouli J, Lorusso D, Guerra Alía EM, Reinthaller A, Nagao S, Lefevre-Plesse C, Canzler U, Scambia G, Lortholary A, Marmé F, Combe P, de Gregorio N, Rodrigues M, Buderath P, Dubot C, Burges A, You B, Pujade-Lauraine E, Harter P; PAOLA-1 Investigators. Olaparib plus Bevacizumab as First-Line Maintenance in Ovarian Cancer. *N Engl J Med.* 2019 Dec 19;381(25):2416-2428. doi: 10.1056/NEJMoa1911361. PMID: 31851799.

49. de Wit R, de Bono J, Sternberg CN, Fizazi K, Tombal B, Wülfing C, Kramer G, Eymard JC, Bamias A, Carles J, Iacovelli R, Melichar B, Sverrisdóttir Á, Theodore C, Feyerabend S, Helissey C, Ozatilgan A, Geffriaud-Ricouard C, Castellano D; CARD Investigators. Cabazitaxel versus Abiraterone or Enzalutamide in Metastatic Prostate Cancer. *N Engl J Med*. 2019 Dec 26;381(26):2506-2518. doi: 10.1056/NEJMoa1911206. Epub 2019 Sep 30. PMID: 31566937.
50. Schmid P, Cortes J, Puzstai L, McArthur H, Kümmel S, Bergh J, Denkert C, Park YH, Hui R, Harbeck N, Takahashi M, Foukakis T, Fasching PA, Cardoso F, Untch M, Jia L, Karantza V, Zhao J, Aktan G, Dent R, O'Shaughnessy J; KEYNOTE-522 Investigators. Pembrolizumab for Early Triple-Negative Breast Cancer. *N Engl J Med*. 2020 Feb 27;382(9):810-821. doi: 10.1056/NEJMoa1910549. PMID: 32101663.
51. 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. *N Engl J Med*. 2020 May 14;382(20):1894-1905. doi: 10.1056/NEJMoa1915745. PMID: 32402160.
52. de Bono J, Mateo J, Fizazi K, Saad F, Shore N, Sandhu S, Chi KN, Sartor O, Agarwal N, Olmos D, Thiery-Vuillemin A, Twardowski P, Mehra N, Goessl C, Kang J, Burgents J, Wu W, Kohlmann A, Adelman CA, Hussain M. Olaparib for Metastatic Castration-Resistant Prostate Cancer. *N Engl J Med*. 2020 May 28;382(22):2091-2102. doi: 10.1056/NEJMoa1911440. Epub 2020 Apr 28. PMID: 32343890.
53. Shore ND, Saad F, Cookson MS, George DJ, Saltzstein DR, Tutrone R, Akaza H, Bossi A, van Veenhuyzen DF, Selby B, Fan X, Kang V, Walling J, Tombal B; HERO Study Investigators. Oral Relugolix for Androgen-Deprivation Therapy in Advanced Prostate Cancer. *N Engl J Med*. 2020 Jun 4;382(23):2187-2196. doi: 10.1056/NEJMoa2004325. Epub 2020 May 29. PMID: 32469183.
54. Powles T, Park SH, Voog E, Caserta C, Valderrama BP, Gurney H, Kalofonos H, Radulović S, Demy W, Ullén A, Lorient Y, Sridhar SS, Tsuchiya N, Kopyltsov 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. *N Engl J Med*. 2020 Sep 24;383(13):1218-1230. doi: 10.1056/NEJMoa2002788. Epub 2020 Sep 18. PMID: 32945632.
55. Herbst RS, Giaccone G, de Marinis F, Reinmuth N, Vergnenegre A, Barrios CH, Morise M, Filip E, Andric Z, Geater S, Özgüroğlu M, Zou W, Sandler A, Enquist I, Komatsubara K, Deng Y, Kuriki H, Wen X, McClelland M, Mucci 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.
56. Wu YL, Tsuboi M, He J, John T, Grohe C, Majem M, Goldman JW, Laktionov K, Kim SW, Kato T, Vu HV, Lu S, Lee KY, Akewanlop C, Yu CJ, de Marinis F, Bonanno L, Domine M, Shepherd FA, Zeng L, Hodge R, Atasoy A, Rukazenkova Y, Herbst RS; ADAURA Investigators. Osimertinib in Resected EGFR-Mutated Non-Small-Cell Lung Cancer. *N Engl J Med*. 2020 Oct 29;383(18):1711-1723. doi: 10.1056/NEJMoa2027071. Epub 2020 Sep 19. PMID: 32955177.
57. Shaw AT, Bauer TM, de Marinis F, Filip E, Goto Y, Liu G, Mazieres J, Kim DW, Mok T, Polli A, Thurm H, Calella AM, Peltz G, Solomon BJ; CROWN Trial Investigators. First-Line Lorlatinib or Crizotinib in Advanced ALK-Positive Lung Cancer. *N Engl J Med*. 2020 Nov 19;383(21):2018-2029. doi: 10.1056/NEJMoa2027187. PMID: 33207094.

58. André T, Shiu KK, Kim TW, Jensen BV, Jensen LH, Punt C, Smith D, Garcia- Carbonero R, Benavides M, Gibbs P, de la Fouchardiere C, Rivera F, Elez E, Bendell J, Le DT, Yoshino T, Van Cutsem E, Yang P, Farooqui MZH, Marinello P, Diaz LA Jr; KEYNOTE-177 Investigators. Pembrolizumab in Microsatellite- Instability-High Advanced Colorectal Cancer. *N Engl J Med.* 2020 Dec 3;383(23):2207-2218. doi: 10.1056/NEJMoa2017699. PMID: 33264544.
59. Choueiri TK, Powles T, Burotto M, Escudier B, Bourlon MT, Zurawski B, Oyervides Juárez VM, Hsieh JJ, Basso U, Shah AY, Suárez C, Hamzaj A, Goh JC, Barrios C, Richardet M, Porta C, Kowalyszyn R, Feregrino JP, Żołnierek J, Pook D, Kessler ER, Tomita Y, Mizuno R, Bedke J, Zhang J, Maurer MA, Simsek B, Ejzykowicz F, Schwab GM, Apolo AB, Motzer RJ; CheckMate 9ER Investigators. Nivolumab plus Cabozantinib versus Sunitinib for Advanced Renal-Cell Carcinoma. *N Engl J Med.* 2021 Mar 4;384(9):829-841. doi: 10.1056/NEJMoa2026982. PMID: 33657295; PMCID: PMC8436591.
60. 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. *N Engl J Med.* 2021 Mar 25;384(12):1125-1135. doi: 10.1056/NEJMoa2035807. Epub 2021 Feb 12. PMID: 33577729; PMCID: PMC8450892.
61. Kelly RJ, Ajani JA, Kuzdzal J, Zander T, Van Cutsem E, Piessen G, Mendez G, Feliciano J, Motoyama S, Lièvre A, Uronis H, Elimova E, Grootsholten C, Geboes K, Zafar S, Snow S, Ko AH, Feeney K, Schenker M, Kocon P, Zhang J, Zhu L, Lei M, Singh P, Kondo K, Cleary JM, Moehler M; CheckMate 577 Investigators. Adjuvant Nivolumab in Resected Esophageal or Gastroesophageal Junction Cancer. *N Engl J Med.* 2021 Apr 1;384(13):1191-1203. doi: 10.1056/NEJMoa2032125. PMID: 33789008.
62. Motzer R, Alekseev B, Rha SY, Porta C, Eto M, Powles T, Grünwald V, Hutson TE, Kopyltsov E, Méndez-Vidal MJ, Kozlov V, Alyasova A, Hong SH, Kapoor A, Alonso Gordoia T, Merchan JR, Winquist E, Maroto P, Goh JC, Kim M, Gurney H, Patel V, Peer A, Procopio G, Takagi T, Melichar B, Rolland F, De Giorgi U, Wong S, Bedke J, Schmidinger M, Dutcus CE, Smith AD, Dutta L, Mody K, Perini RF, Xing D, Choueiri TK; CLEAR Trial Investigators. Lenvatinib plus Pembrolizumab or Everolimus for Advanced Renal Cell Carcinoma. *N Engl J Med.* 2021 Apr 8;384(14):1289-1300. doi: 10.1056/NEJMoa2035716. Epub 2021 Feb 13. PMID: 33616314.
63. Bardia A, Hurvitz SA, Tolaney SM, Loirat D, Punie K, Oliveira M, Brufsky A, Sardesai SD, Kalinsky K, Zelnak AB, Weaver R, Traina T, Dalenc F, Aftimos P, Lynce F, Diab S, Cortés J, O'Shaughnessy J, Diéras V, Ferrario C, Schmid P, Carey LA, Gianni L, Piccart MJ, Loibl S, Goldenberg DM, Hong Q, Olivo MS, Itri LM, Rugo HS; ASCENT Clinical Trial Investigators. Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer. *N Engl J Med.* 2021 Apr 22;384(16):1529-1541. doi: 10.1056/NEJMoa2028485. PMID: 33882206.
64. Bajorin DF, Witjes JA, Gschwend JE, Schenker M, Valderrama BP, Tomita Y, Bamias A, Lebret T, Shariat SF, Park SH, Ye D, Agerbaek M, Enting D, McDermott R, Gajate P, Peer A, Milowsky MI, Nosov A, Neif Antonio J Jr, Tupikowski K, Toms L, Fischer BS, Qureshi A, Collette S, Unsal-Kacmaz K, Broughton E, Zardavas D, Koon HB, Galsky MD. Adjuvant Nivolumab versus Placebo in Muscle-Invasive Urothelial Carcinoma. *N Engl J Med.* 2021 Jun 3;384(22):2102-2114. doi: 10.1056/NEJMoa2034442. Erratum in: *N Engl J Med.* 2021 Aug 26;385(9):864. PMID: 34077643; PMCID: PMC8215888.

65. Tutt ANJ, Garber JE, Kaufman B, Viale G, Fumagalli D, Rastogi P, Gelber RD, de Azambuja E, Fielding A, Balmaña J, Domchek SM, Gelmon KA, Hollingsworth SJ, Korde LA, Linderholm B, Bandos H, Senkus E, Suga JM, Shao Z, Pippas AW, Nowecki Z, Huzarski T, Ganz PA, Lucas PC, Baker N, Loibl S, McConnell R, Piccart M, Schmutzler R, Steger GG, Costantino JP, Arahmani A, Wolmark N, McFadden E, Karantza V, Lakhani SR, Yothers G, Campbell C, Geyer CE Jr; OlympiA Clinical Trial Steering Committee and Investigators. Adjuvant Olaparib for Patients with BRCA1- or BRCA2-Mutated Breast Cancer. *N Engl J Med.* 2021 Jun 24;384(25):2394-2405. doi: 10.1056/NEJMoa2105215. Epub 2021 Jun 3. PMID: 34081848; PMCID: PMC9126186.
66. Gnant M, Fitzal F, Rinnerthaler G, Steger GG, Greil-Ressler S, Balic M, Heck D, Jakesz R, Thaler J, Egle D, Manfreda D, Bjelic-Radisic V, Wieder U, Singer CF, Melbinger-Zeinitzer E, Haslbauer F, Sevelde P, Trapl H, Wette V, Wimmer K, Gampenrieder SP, Bartsch R, Kacarovsky-Strobl S, Suppan C, Brunner C, Deutschmann C, Soelkner L, Fesl C, Greil R; Austrian Breast and Colorectal Cancer Study Group. Duration of Adjuvant Aromatase-Inhibitor Therapy in Postmenopausal Breast Cancer. *N Engl J Med.* 2021 Jul 29;385(5):395-405. doi: 10.1056/NEJMoa2104162. PMID: 34320285.
67. Choueiri TK, Tomczak P, Park SH, Venugopal B, Ferguson T, Chang YH, Hajek J, Symeonides SN, Lee JL, Sarwar N, Thiery-Vuillemin A, Gross-Goupil M, Mahave M, Haas NB, Sawrycki P, Gurney H, Chevreau C, Melichar B, Kopyltsov E, Alva A, Burke JM, Doshi G, Topart D, Oudard S, Hammers H, Kitamura H, Bedke J, Perini RF, Zhang P, Imai K, Willemann-Rogerio J, Quinn DI, Powles T; KEYNOTE-564 Investigators. Adjuvant Pembrolizumab after Nephrectomy in Renal-Cell Carcinoma. *N Engl J Med.* 2021 Aug 19;385(8):683-694. doi: 10.1056/NEJMoa2106391. PMID: 34407342.
68. 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.
69. Nathan P, Hassel JC, Rutkowski P, Baurain JF, Butler MO, Schlaak M, Sullivan RJ, Ochsenreither S, Dummer R, Kirkwood JM, Joshua AM, Sacco JJ, Shoushtari AN, Orloff M, Piulats JM, Milhem M, Salama AKS, Curti B, Demidov L, Gastaud L, Mauch C, Yushak M, Carvajal RD, Hamid O, Abdullah SE, Holland C, Goodall H, Piperno- Neumann S; IMCgp100-202 Investigators. Overall Survival Benefit with Tebentafusp in Metastatic Uveal Melanoma. *N Engl J Med.* 2021 Sep 23;385(13):1196-1206. doi: 10.1056/NEJMoa2103485. PMID: 34551229.
70. Colombo N, Dubot C, Lorusso D, Caceres MV, Hasegawa K, Shapira-Frommer R, Tewari KS, Salman P, Hoyos Usta E, Yañez E, Gümüş M, Olivera Hurtado de Mendoza M, Samouëlian V, Castonguay V, Arkhipov A, Toker S, Li K, Keefe SM, Monk BJ; KEYNOTE-826 Investigators. Pembrolizumab for Persistent, Recurrent, or Metastatic Cervical Cancer. *N Engl J Med.* 2021 Nov 11;385(20):1856-1867. doi: 10.1056/NEJMoa2112435. Epub 2021 Sep 18. PMID: 34534429.

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.
2. Majem M, Goldman JW, John T, Grohe C, Laktionov K, Kim SW, Kato T, Vu HV, Lu S, Li S, Lee KY, Akewanlop C, Yu CJ, de Marinis F, Bonanno L, Domine M, Shepherd FA, Atagi S, Zeng L, Kulkarni D, Medic N, Tsuboi M, Herbst RS, Wu YL. Health- Related Quality of Life Outcomes in Patients with Resected Epidermal Growth Factor Receptor-Mutated Non-Small Cell Lung Cancer Who Received Adjuvant Osimertinib in the Phase III ADAURA Trial. *Clin Cancer Res.* 2022 Jun 1;28(11):2286-2296. doi: 10.1158/1078-0432.CCR-21-3530. PMID: 35012927.
3. Kawahara T, Taira N, Shiroywa T, Hagiwara Y, Fukuda T, Uemura Y, Mukai H. Minimal important differences of EORTC QLQ-C30 for metastatic breast cancer patients: Results from a randomized clinical trial. *Qual Life Res.* 2022 Jun;31(6):1829-1836. doi: 10.1007/s11136-021-03074-y. Epub 2022 Jan 4. PMID: 34982354; PMCID: PMC9098551.
4. Rischin D, Harrington KJ, Greil R, Soulières D, Tahara M, de Castro G Jr, Psyrri A, Braña I, Neupane P, Bratland Å, Fueeder T, Hughes BGM, Mesía R, Ngamphaiboon N, Rordorf T, Ishak WZW, Hong RL, Mendoza RG, Jia L, Chirovsky D, Norquist J, Jin F, Burtness B. Pembrolizumab alone or with chemotherapy for recurrent or metastatic head and neck squamous cell carcinoma: Health-related quality-of-life results from KEYNOTE-048. *Oral Oncol.* 2022 May;128:105815. doi: 10.1016/j.oraloncology.2022.105815. Epub 2022 Apr 2. PMID: 35381576.
5. Scherpereel A, Antonia S, Bautista Y, Grossi F, Kowalski D, Zalcman G, Nowak AK, Fujimoto N, Peters S, Tsao AS, Mansfield AS, Popat S, Sun X, Lawrance R, Zhang X, Daumont MJ, Bennett B, McKenna M, Baas P. First-line nivolumab plus ipilimumab versus chemotherapy for the treatment of unresectable malignant pleural mesothelioma: patient-reported outcomes in CheckMate 743. *Lung Cancer.* 2022 May;167:8-16. doi: 10.1016/j.lungcan.2022.03.012. Epub 2022 Mar 21. PMID: 35367910.
6. Shitara K, Ajani JA, Moehler M, Garrido M, Gallardo C, Shen L, Yamaguchi K, Wyrwicz L, Skoczylas T, Bragagnoli AC, Liu T, Tehfe M, Elimova E, Bruges R, Zander T, de Azevedo S, Kowalyszyn R, Pazo-Cid R, Schenker M, Cleary JM, Yanez P, Feeney K, Karamouzis MV, Poulart V, Lei M, Xiao H, Kondo K, Li M, Janjigian YY. Nivolumab plus chemotherapy or ipilimumab in gastro-oesophageal cancer. *Nature.* 2022 Mar;603(7903):942-948. doi: 10.1038/s41586-022-04508-4. Epub 2022 Mar 23. PMID: 35322232; PMCID: PMC8967713.

7. van Amelsfoort RM, Walraven I, Kieffer J, Jansen EPM, Cats A, van Grieken NCT, Meershoek-Klein Kranenbarg E, Putter H, van Sandick JW, Sikorska K, van de Velde CJH, Aaronson NK, Verheij M; CRITICS Investigators. Quality of Life Is Associated With Survival in Patients With Gastric Cancer: Results From the Randomized CRITICS Trial. *J Natl Compr Canc Netw*. 2022 Mar;20(3):261-267. doi: 10.6004/jnccn.2021.7057. PMID: 35276669.
8. Thiery-Vuillemin A, de Bono J, Hussain M, Roubaud G, Procopio G, Shore N, Fizazi K, Dos Anjos G, Gravis G, Joung JY, Matsubara N, Castellano D, Degboe A, Gresty C, Kang J, Allen A, Poehlein C, Saad F. Pain and health-related quality of life with olaparib versus physician's choice of next-generation hormonal drug in patients with metastatic castration-resistant prostate cancer with homologous recombination repair gene alterations (PROfound): an open-label, randomised, phase 3 trial. *Lancet Oncol*. 2022 Mar;23(3):393-405. doi: 10.1016/S1470-2045(22)00017-1. Epub 2022 Feb 11. Erratum in: *Lancet Oncol*. 2022 Apr;23(4):e161. PMID: 35157830.
9. Cella D, Motzer RJ, Suarez C, Blum SI, Ejzykowicz F, Hamilton M, Wallace JF, Simsek B, Zhang J, Ivanescu C, Apolo AB, Choueiri TK. Patient-reported outcomes with first-line nivolumab plus cabozantinib versus sunitinib in patients with advanced renal cell carcinoma treated in CheckMate 9ER: an open-label, randomised, phase 3 trial. *Lancet Oncol*. 2022 Feb;23(2):292-303. doi: 10.1016/S1470-2045(21)00693-8. Epub 2022 Jan 12. PMID: 35032437; PMCID: PMC9479564.
10. Kawashima Y, Fukuhara T, Saito H, Furuya N, Watanabe K, Sugawara S, Iwasawa S, Tsunozuka Y, Yamaguchi O, Okada M, Yoshimori K, Nakachi I, Seike M, Azuma K, Kurimoto F, Tsubata Y, Fujita Y, Nagashima H, Asai G, Watanabe S, Miyazaki M, Hagiwara K, Nukiwa T, Morita S, Kobayashi K, Maemondo M. Bevacizumab plus erlotinib versus erlotinib alone in Japanese patients with advanced, metastatic, EGFR-mutant non-small-cell lung cancer (NEJ026): overall survival analysis of an open-label, randomised, multicentre, phase 3 trial. *Lancet Respir Med*. 2022 Jan;10(1):72-82. doi: 10.1016/S2213-2600(21)00166-1. Epub 2021 Aug 26. PMID: 34454653.
11. Wang J, Yu X, Barnes G, Leaw S, Bao Y, Tang B. The effects of tislelizumab plus chemotherapy as first-line treatment on health-related quality of life of patients with advanced squamous non-small cell lung cancer: Results from a phase 3 randomized clinical trial. *Cancer Treat Res Commun*. 2021 Dec 17;30:100501. doi: 10.1016/j.ctarc.2021.100501. Epub ahead of print. PMID: 34952253.
12. Yang Q, Xia L, Lin M, Zhang MX, Duan CY, Liu YP, Xie YL, Wang ZQ, You R, Zou X, Hua YJ, Huang PY, Sun R, Hong MH, Chen MY. The impact of induction chemotherapy on long-term quality of life in patients with locoregionally advanced nasopharyngeal carcinoma: Outcomes from a randomised phase 3 trial. *Oral Oncol*. 2021 Oct;121:105494. doi: 10.1016/j.oraloncology.2021.105494. Epub 2021 Aug 20. PMID: 34425533.
13. Kahan Z, Gil-Gil M, Ruiz-Borrego M, Carrasco E, Ciruelos E, Muñoz M, Bermejo B, Margeli M, Antón A, Casas M, Csöszi T, Murillo L, Morales S, Calvo L, Lang I, Alba E, de la Haba-Rodríguez J, Ramos M, López

- IA, Gal-Yam E, Garcia-Palomo A, Alvarez E, González-Santiago S, Rodríguez CA, Servitja S, Corsaro M, Rodrigálvarez G, Zielinski C, Martín M. Health-related quality of life with palbociclib plus endocrine therapy versus capecitabine in postmenopausal patients with hormone receptor-positive metastatic breast cancer: Patient-reported outcomes in the PEARL study. *Eur J Cancer*. 2021 Oct;156:70-82. doi: 10.1016/j.ejca.2021.07.004. Epub 2021 Aug 20. PMID: 34425406.
14. Denda T, Takashima A, Gamoh M, Iwanaga I, Komatsu Y, Takahashi M, Nakamura M, Ohori H, Sakashita A, Tsuda M, Kobayashi Y, Baba H, Kotake M, Ishioka C, Yamada Y, Sato A, Yuki S, Morita S, Takahashi S, Yamaguchi T, Shimada K. Combination therapy of bevacizumab with either S-1 and irinotecan or mFOLFOX6/CapeOX as first-line treatment of metastatic colorectal cancer (TRICOLORE): Exploratory analysis of RAS status and primary tumour location in a randomised, open-label, phase III, non-inferiority trial. *Eur J Cancer*. 2021 Sep;154:296-306. doi: 10.1016/j.ejca.2021.06.013. Epub 2021 Jul 22. PMID: 34304054.
 15. Van Cutsem E, Valderrama A, Bang YJ, Fuchs CS, Shitara K, Janjigian YY, Qin S, Larson TG, Shankaran V, Stein S, Norquist JM, Kher U, Shah S, Alsina M. Quality of life with first-line pembrolizumab for PD-L1-positive advanced gastric/gastroesophageal junction adenocarcinoma: results from the randomised phase III KEYNOTE-062 study. *ESMO Open*. 2021 Aug;6(4):100189. doi: 10.1016/j.esmoop.2021.100189. Epub 2021 Aug 7. PMID: 34371381; PMCID: PMC8358416.
 16. Van De Sande M, Tap WD, Gelhorn HL, Ye X, Speck RM, Palmerini E, Stacchiotti S, Desai J, Wagner AJ, Alcindor T, Ganjoo K, Martín-Broto J, Wang Q, Shuster D, Gelderblom H, Healey JH. Pexidartinib improves physical functioning and stiffness in patients with tenosynovial giant cell tumor: results from the ENLIVEN randomized clinical trial. *Acta Orthop*. 2021 Aug;92(4):493-499. doi: 10.1080/17453674.2021.1922161. Epub 2021 May 12. PMID: 33977825; PMCID: PMC8382018.
 17. Gogas H, Dummer R, Ascierto PA, Arance A, Mandalà M, Liskay G, Garbe C, Schadendorf D, Krajsová I, Gutzmer R, Sileni VC, Dutriaux C, Yamazaki N, Loquai C, Queirolo P, Jan de Willem G, Sellier AT, Suissa J, Murriss J, Gollerkeri A, Robert C, Flaherty KT. Quality of life in patients with BRAF-mutant melanoma receiving the combination encorafenib plus binimetinib: Results from a multicentre, open-label, randomised, phase III study (COLUMBUS). *Eur J Cancer*. 2021 Jul;152:116-128. doi: 10.1016/j.ejca.2021.04.028. Epub 2021 Jun 4. Erratum in: *Eur J Cancer*. 2022 Jan;160:287-288. PMID: 34091420.
 18. Galle PR, Finn RS, Qin S, Ikeda M, Zhu AX, Kim TY, Kudo M, Breder V, Merle P, Kaseb A, Li D, Mulla S, Verret W, Xu DZ, Hernandez S, Ding B, Liu J, Huang C, Lim HY, Cheng AL, Ducreux M. Patient-reported outcomes with atezolizumab plus bevacizumab versus sorafenib in patients with unresectable hepatocellular carcinoma (IMbrave150): an open-label, randomised, phase 3 trial. *Lancet Oncol*. 2021 Jul;22(7):991-1001. doi: 10.1016/S1470-2045(21)00151-0. Epub 2021 May 27. PMID: 34051880.
 19. Moy B, Oliveira M, Saura C, Gradishar W, Kim SB, Brufsky A, Hurvitz SA, Ryvo L, Fagnani D, Kalmadi S, Silverman P, Delaloge S, Alarcon J, Kwong A, Lee KS, Ang PCS, Ow SGW, Chu SC, Bryce R, Keyvanjah K,

- Bebchuk J, Zhang B, Oestreicher N, Bose R, Chan N. Neratinib + capecitabine sustains health-related quality of life in patients with HER2-positive metastatic breast cancer and ≥ 2 prior HER2-directed regimens. *Breast Cancer Res Treat.* 2021 Jul;188(2):449-458. doi: 10.1007/s10549-021-06217-4. Epub 2021 Apr 28. PMID: 33909203; PMCID: PMC8260518.
20. Thiery-Vuillemin A, Fizazi K, Sartor O, Oudard S, Bury D, Ozatilgan A, Poole EM, Eisenberger M, de Bono J. Post Hoc Health-Related Quality of Life Analysis According to Response Among Patients with Prostate Cancer in the PROSELICA and FIRSTANA Studies. *Oncologist.* 2021 Jul;26(7):e1179-e1188. doi: 10.1002/onco.13803. Epub 2021 May 21. PMID: 33904646; PMCID: PMC8265338.
21. Bines J, Clark E, Barton C, Restuccia E, Procter M, Sonnenblick A, Fumagalli D, Parlier D, Arahmani A, Baselga J, Viale G, Reaby LL, Frank E, Gelber RD, Piccart M, Jackisch C, Petersen JA. Patient-reported function, health-related quality of life, and symptoms in APHINITY: pertuzumab plus trastuzumab and chemotherapy in HER2-positive early breast cancer. *Br J Cancer.* 2021 Jul;125(1):38-47. doi: 10.1038/s41416-021-01323-y. Epub 2021 Apr 7. PMID: 33828257; PMCID: PMC8257679.
22. Garon EB, Cho BC, Reinmuth N, Lee KH, Luft A, Ahn MJ, Robinet G, Le Moulec S, Natale R, Schneider J, Shepherd FA, Garassino MC, Geater SL, Szekely ZP, Van Ngoc T, Liu F, Scheuring U, Patel N, Peters S, Rizvi NA. Patient-Reported Outcomes with Durvalumab With or Without Tremelimumab Versus Standard Chemotherapy as First-Line Treatment of Metastatic Non-Small-Cell Lung Cancer (MYSTIC). *Clin Lung Cancer.* 2021 Jul;22(4):301-312.e8. doi: 10.1016/j.clc.2021.02.010. Epub 2021 Feb 19. PMID: 33775558.
23. Ciruelos EM, Rugo HS, Mayer IA, Levy C, Forget F, Delgado Mingorance JI, Safra T, Masuda N, Park YH, Juric D, Conte P, Campone M, Loibl S, Iwata H, Zhou X, Park J, Ridolfi A, Lorenzo I, André F. Patient-Reported Outcomes in Patients With PIK3CA-Mutated Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer From SOLAR-1. *J Clin Oncol.* 2021 Jun 20;39(18):2005-2015. doi: 10.1200/JCO.20.01139. Epub 2021 Mar 29. PMID: 33780274; PMCID: PMC8210974.
24. Yokomizo A, Koga H, Ito K, Takezawa Y, Komiyama M, Nishimura K, Yonese J, Hashine K, Masumori N, Arai G, Saito S, Shinohara M, Shimizu N, Yamauchi A, Satoh T, Tochigi T, Kobayashi M, Fujimoto H, Kakimoto KI, Fukui I, Tsukamoto T, Nozaki M, Karasawa K, Hasumi M, Ohtani M, Ishiyama H, Kuwahara M, Harada M, Ohashi Y, Kotake T, Kakizoe T, Suzuki K, Naito S, Yamanaka H; National Research Project on Endocrine-Radiation Combination Therapy for Locally Advanced Prostate Cancer investigators. Patient-reported outcomes following neoadjuvant endocrine therapy, external beam radiation, and adjuvant continuous/intermittent endocrine therapy for locally advanced prostate cancer: A randomized phase III trial. *Cancer Med.* 2021 May;10(10):3240-3248. doi: 10.1002/cam4.3895. Epub 2021 May 1. PMID: 33932114; PMCID: PMC8124125.
25. Friedlander M, Moore KN, Colombo N, Scambia G, Kim BG, Oaknin A, Lisianskaya A, Sonke GS, Gourley C, Banerjee S, Oza A, González-Martín A, Aghajanian C, Bradley WH, Liu J, Mathews C, Selle F,

- Lortholary A, Lowe ES, Hettle R, Flood E, Parkhomenko E, DiSilvestro P. Patient-centred outcomes and effect of disease progression on health status in patients with newly diagnosed advanced ovarian cancer and a BRCA mutation receiving maintenance olaparib or placebo (SOLO1): a randomised, phase 3 trial. *Lancet Oncol.* 2021 May;22(5):632-642. doi: 10.1016/S1470-2045(21)00098-X. Epub 2021 Apr 13. PMID: 33862001.
26. Bottomley A, Coens C, Mierzynska J, Blank CU, Mandalà M, Long GV, Atkinson VG, Dalle S, Haydon AM, Meshcheryakov A, Khattak A, Carlino MS, Sandhu S, Puig S, Ascierto PA, Larkin J, Lorigan PC, Rutkowski P, Schadendorf D, Koornstra R, Hernandez-Aya L, Di Giacomo AM, van den Eertwegh AJM, Grob JJ, Gutzmer R, Jamal R, van Akkooi ACJ, Krepler C, Ibrahim N, Marreaud S, Kicinski M, Suciú S, Robert C, Eggermont AMM; EORTC Melanoma Group. Adjuvant pembrolizumab versus placebo in resected stage III melanoma (EORTC 1325-MG/KEYNOTE-054): health-related quality- of-life results from a double-blind, randomised, controlled, phase 3 trial. *Lancet Oncol.* 2021 May;22(5):655-664. doi: 10.1016/S1470-2045(21)00081-4. Epub 2021 Apr 12. PMID: 33857414.
27. Andre T, Amonkar M, Norquist JM, Shiu KK, Kim TW, Jensen BV, Jensen LH, Punt CJA, Smith D, Garcia-Carbonero R, Sevilla I, De La Fouchardiere C, Rivera F, Elez E, Diaz LA Jr, Yoshino T, Van Cutsem E, Yang P, Farooqui M, Le DT. Health- related quality of life in patients with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer treated with first-line pembrolizumab versus chemotherapy (KEYNOTE-177): an open-label, randomised, phase 3 trial. *Lancet Oncol.* 2021 May;22(5):665-677. doi: 10.1016/S1470-2045(21)00064-4. Epub 2021 Apr 1. PMID: 33812497.
28. Yang JC, Mok TSK, Lu S, Nakagawa K, Yamamoto N, Shi YK, Zhang L, Soo RA, Morita S, Tamura T. Efficacy and Safety of S-1 Compared With Docetaxel in Elderly Patients With Advanced NSCLC Previously Treated With Platinum-Based Chemotherapy: A Subgroup Analysis of the EAST-LC Trial. *JTO Clin Res Rep.* 2021 Jan 7;2(3):100142. doi: 10.1016/j.jtocrr.2021.100142. PMID: 34590001; PMCID: PMC8474214.
29. Paty J, Sandin R, Reisman A, Wu YL, Migliorino MR, Zhou X, Cheng Y, Lee KH, Nakagawa K, Niho S, Corral J, Płuzański A, Linke R, Meyers O, Mok TS. The patient's perspective on treatment with dacomitinib: patient-reported outcomes from the Phase III trial ARCHER 1050. *Future Oncol.* 2021 Mar;17(7):783-794. doi: 10.2217/fon-2020-0888. Epub 2020 Nov 9. PMID: 33164569.
30. Harrington KJ, Soulières D, Le Tourneau C, Dinis J, Licitra LF, Ahn MJ, Soria A, Machiels JH, Mach N, Mehra R, Burtness B, Ellison MC, Cheng JD, Chirovsky DR, Swaby RF, Cohen EEW. Quality of Life With Pembrolizumab for Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinoma: KEYNOTE-040. *J Natl Cancer Inst.* 2021 Feb 1;113(2):171-181. doi: 10.1093/jnci/djaa063. PMID: 32407532; PMCID: PMC7850527.
31. Takahashi M, Kato K, Okada M, Chin K, Kadowaki S, Hamamoto Y, Doki Y, Kubota Y, Kawakami H, Ogata T, Hara H, Muto M, Nakashima Y, Ishihara R, Tsuda M, Motoyama S, Kodani M, Kitagawa Y. Nivolumab versus chemotherapy in Japanese patients with advanced esophageal squamous cell carcinoma: a

- subgroup analysis of a multicenter, randomized, open-label, phase 3 trial (ATTRACTION-3). *Esophagus*. 2021 Jan;18(1):90-99. doi: 10.1007/s10388-020-00794-x. Epub 2020 Nov 10. PMID: 33170461; PMCID: PMC7794205.
32. Koole SN, Kieffer JM, K Sikorska, Schagen van Leeuwen JH, Schreuder HWR, Hermans RH, de Hingh IH, van der Velden J, Arts HJ, van Ham MAPC, Aalbers AG, Verwaal VJ, Van de Vijver KK, Sonke GS, van Driel WJ, Aaronson NK. Health- related quality of life after interval cytoreductive surgery with or without hyperthermic intraperitoneal chemotherapy (HIPEC) in patients with stage III ovarian cancer. *Eur J Surg Oncol*. 2021 Jan;47(1):101-107. doi: 10.1016/j.ejso.2019.05.006. Epub 2019 May 13. PMID: 31128948.
33. Zeng J, Mao WM, Chen QX, Luo TB, Wu YL, Zhou Q, Yang XN, Yan HH, Zhong WZ, Wang Q, Xu ST, Wu L, Shen Y, Liu YY, Chen C, Cheng Y, Xu L, Wang J, Fei K, Li XF, Li J, Huang C, Liu ZD, Xu S, Chen KN, Xu SD, Liu LX, Yu P, Wang BH, Ma HT. Quality of life with adjuvant gefitinib versus vinorelbine plus cisplatin in patients with completely resected stage II-IIIa (N1-N2) EGFR-mutant non-small- cell lung cancer: Results from the ADJUVANT (CTONG1104) study. *Lung Cancer*. 2020 Dec;150:164-171. doi: 10.1016/j.lungcan.2020.09.027. Epub 2020 Oct 8. PMID: 33186858.
34. Goldman JW, Garassino MC, Chen Y, Özgüroğlu M, Dvorkin M, Trukhin D, Statsenko G, Hotta K, Ji JH, Hochmair MJ, Voitko O, Havel L, Poltoratskiy A, Losonczy G, Reinmuth N, Patel N, Laud PJ, Shire N, Jiang H, Paz-Ares L. Patient- reported outcomes with first-line durvalumab plus platinum-etoposide versus platinum-etoposide in extensive-stage small-cell lung cancer (CASPIAN): a randomized, controlled, open-label, phase III study. *Lung Cancer*. 2020 Nov;149:46-52. doi: 10.1016/j.lungcan.2020.09.003. Epub 2020 Sep 10. PMID: 32961445.
35. Fizazi K, Kramer G, Eymard JC, Sternberg CN, de Bono J, Castellano D, Tombal B, Wülfing C, Lontos M, Carles J, Iacovelli R, Melichar B, Sverrisdóttir Á, Theodore C, Feyerabend S, Helissey C, Oudard S, Facchini G, Poole EM, Ozatilgan A, Geffriaud-Ricouard C, Bensfia S, de Wit R. Quality of life in patients with metastatic prostate cancer following treatment with cabazitaxel versus abiraterone or enzalutamide (CARD): an analysis of a randomised, multicentre, open-label, phase 4 study. *Lancet Oncol*. 2020 Nov;21(11):1513-1525. doi: 10.1016/S1470-2045(20)30449-6. Epub 2020 Sep 11. PMID: 32926841.
36. Litton JK, Hurvitz SA, Mina LA, Rugo HS, Lee KH, Gonçalves A, Diab S, Woodward N, Goodwin A, Yerushalmi R, Roché H, Im YH, Eiermann W, Quek RGW, Usari T, Lanzalone S, Czibere A, Blum JL, Martin M, Ettl J. Talazoparib versus chemotherapy in patients with germline BRCA1/2-mutated HER2-negative advanced breast cancer: final overall survival results from the EMBRACA trial. *Ann Oncol*. 2020 Nov;31(11):1526-1535. doi: 10.1016/j.annonc.2020.08.2098. Epub 2020 Aug 20. PMID: 32828825.
37. Camidge DR, Kim HR, Ahn MJ, Yang JCH, Han JY, Hochmair MJ, Lee KH, Delmonte A, García Campelo MR, Kim DW, Griesinger F, Felip E, Califano R, Spira A, Gettinger SN, Tiseo M, Lin HM, Gupta N, Hanley MJ, Ni Q, Zhang P, Popat S. Brigatinib Versus Crizotinib in Advanced ALK Inhibitor-Naive ALK-Positive Non- Small Cell Lung Cancer: Second Interim Analysis of the Phase III ALTA-1L Trial. *J Clin Oncol*. 2020

- Nov 1;38(31):3592-3603. doi: 10.1200/JCO.20.00505. Epub 2020 Aug 11. PMID: 32780660; PMCID: PMC7605398.
38. Oza AM, Lorusso D, Aghajanian C, Oaknin A, Dean A, Colombo N, Weberpals JI, Clamp AR, Scambia G, Leary A, Holloway RW, Gancedo MA, Fong PC, Goh JC, O'Malley DM, Armstrong DK, Banerjee S, García-Donas J, Swisher EM, Cella D, Meunier J, Goble S, Cameron T, Maloney L, Mörk AC, Bedel J, Ledermann JA, Coleman RL. Patient-Centered Outcomes in ARIEL3, a Phase III, Randomized, Placebo-Controlled Trial of Rucaparib Maintenance Treatment in Patients With Recurrent Ovarian Carcinoma. *J Clin Oncol*. 2020 Oct 20;38(30):3494-3505. doi: 10.1200/JCO.19.03107. Epub 2020 Aug 24. PMID: 32840418; PMCID: PMC7571791.
39. Yoh K, Atagi S, Reck M, Garon EB, Ponce Aix S, Moro-Sibilot D, Winfree KB, Frimodt-Moller B, Zimmermann A, Visseren-Grul C, Nakagawa K; RELAY investigators. Patient-reported outcomes in RELAY, a phase 3 trial of ramucirumab plus erlotinib versus placebo plus erlotinib in untreated EGFR-mutated metastatic non-small-cell lung cancer. *Curr Med Res Opin*. 2020 Oct;36(10):1667-1675. doi: 10.1080/03007995.2020.1808781. Epub 2020 Aug 28. PMID: 32780643.
40. Stenzl A, Dunshee C, De Giorgi U, Alekseev B, Iguchi T, Szmulewitz RZ, Flaig TW, Tombal B, Morlock R, Ivanescu C, Ramaswamy K, Saad F, Armstrong AJ. Effect of Enzalutamide plus Androgen Deprivation Therapy on Health-related Quality of Life in Patients with Metastatic Hormone-sensitive Prostate Cancer: An Analysis of the ARCHES Randomised, Placebo-controlled, Phase 3 Study. *Eur Urol*. 2020 Oct;78(4):603-614. doi: 10.1016/j.eururo.2020.03.019. Epub 2020 Apr 23. PMID: 32336645.
41. Goetz MP, Martin M, Tokunaga E, Park IH, Huober J, Toi M, Stoffregen C, Shekarriz S, Andre V, Gainford MC, Price GL, Johnston S. Health-Related Quality of Life in MONARCH 3: Abemaciclib plus an Aromatase Inhibitor as Initial Therapy in HR+, HER2- Advanced Breast Cancer. *Oncologist*. 2020 Sep;25(9):e1346-e1354. doi: 10.1634/theoncologist.2020-0084. Epub 2020 Jun 24. PMID: 32536013; PMCID: PMC7485333.
42. Earl H, Hiller L, Vallier AL, Loi S, McAdam K, Hughes-Davies L, Rea D, Howe D, Raynes K, Higgins HB, Wilcox M, Plummer C, Mahler-Araujo B, Provenzano E, Chhabra A, Gasson S, Balmer C, Abraham JE, Caldas C, Hall P, Shinkins B, McCabe C, Hulme C, Miles D, Wardley AM, Cameron DA, Dunn JA. Six versus 12 months' adjuvant trastuzumab in patients with HER2-positive early breast cancer: the PERSEPHONE non-inferiority RCT. *Health Technol Assess*. 2020 Aug;24(40):1-190. doi: 10.3310/hta24400. PMID: 32880572; PMCID: PMC7505360.
43. Zhu AX, Nipp RD, Finn RS, Galle PR, Llovet JM, Blanc JF, Okusaka T, Chau I, Cella D, Girvan A, Gable J, Bowman L, Wang C, Hsu Y, Abada PB, Kudo M. Ramucirumab in the second-line for patients with hepatocellular carcinoma and elevated alpha-fetoprotein: patient-reported outcomes across two randomised clinical trials. *ESMO Open*. 2020 Aug;5(4):e000797. doi: 10.1136/esmooopen-2020-000797. PMID: 32817068; PMCID: PMC7437873.

44. Climans SA, Brandes AA, Cairncross JG, Ding K, Fay M, Laperriere N, Menten J, Nishikawa R, O'Callaghan CJ, Perry JR, Phillips C, Roa W, Wick W, Winch C, Mason WP. Temozolomide and seizure outcomes in a randomized clinical trial of elderly glioblastoma patients. *J Neurooncol.* 2020 Aug;149(1):65-71. doi: 10.1007/s11060-020-03573-x. Epub 2020 Jul 6. PMID: 32632894.
45. Reck M, Wehler T, Orlandi F, Nogami N, Barone C, Moro-Sibilot D, Shtivelband M, González Larriba JL, Rothenstein J, Früh M, Yu W, Deng Y, Coleman S, Shankar G, Patel H, Kelsch C, Lee A, Piau E, Socinski MA. Safety and Patient-Reported Outcomes of Atezolizumab Plus Chemotherapy With or Without Bevacizumab Versus Bevacizumab Plus Chemotherapy in Non-Small-Cell Lung Cancer. *J Clin Oncol.* 2020 Aug 1;38(22):2530-2542. doi: 10.1200/JCO.19.03158. Epub 2020 May 27. PMID: 32459597; PMCID: PMC7392741.
46. Harbeck N, Franke F, Villanueva-Vazquez R, Lu YS, Tripathy D, Chow L, Babu GK, Im YH, Chandiwana D, Gaur A, Lanoue B, Rodriguez-Lorenc K, Bardia A. Health-related quality of life in premenopausal women with hormone-receptor-positive, HER2-negative advanced breast cancer treated with ribociclib plus endocrine therapy: results from a phase III randomized clinical trial (MONALEESA-7). *Ther Adv Med Oncol.* 2020 Jul 26;12:1758835920943065. doi: 10.1177/1758835920943065. PMID: 32782490; PMCID: PMC7385843.
47. Conte P, Schneeweiss A, Loibl S, Mamounas EP, von Minckwitz G, Mano MS, Untch M, Huang CS, Wolmark N, Rastogi P, D'Hondt V, Redondo A, Stamatovic L, Bonnefoi H, Castro-Salguero H, Fischer HH, Wahl T, Song C, Boulet T, Trask P, Geyer CE Jr. Patient-reported outcomes from KATHERINE: A phase 3 study of adjuvant trastuzumab emtansine versus trastuzumab in patients with residual invasive disease after neoadjuvant therapy for human epidermal growth factor receptor 2-positive breast cancer. *Cancer.* 2020 Jul 1;126(13):3132-3139. doi: 10.1002/cncr.32873. Epub 2020 Apr 14. PMID: 32286687; PMCID: PMC7317721.
48. Taberero J, Alsina M, Shitara K, Doi T, Dvorkin M, Mansoor W, Arkenau HT, Prokharau A, Ghidini M, Faustino C, Gorbunova V, Zhavrid E, Nishikawa K, Ando T, Yalçın Ş, Van Cutsem E, Sabater J, Skanji D, Leger C, Amellal N, Ilson DH. Health-related quality of life associated with trifluridine/tipiracil in heavily pretreated metastatic gastric cancer: results from TAGS. *Gastric Cancer.* 2020 Jul;23(4):689-698. doi: 10.1007/s10120-020-01053-9. Epub 2020 Mar 4. PMID: 32128634; PMCID: PMC7305098.
49. Atkins MB, Rini BI, Motzer RJ, Powles T, McDermott DF, Suarez C, Bracarda S, Stadler WM, Donskov F, Gurney H, Oudard S, Uemura M, Lam ET, Grüllich C, Quach C, Carroll S, Ding B, Zhu QC, Piau-Louis E, Schiff C, Escudier B. Patient- Reported Outcomes from the Phase III Randomized IMmotion151 Trial: Atezolizumab + Bevacizumab versus Sunitinib in Treatment-Naïve Metastatic Renal Cell Carcinoma. *Clin Cancer Res.* 2020 Jun 1;26(11):2506-2514. doi: 10.1158/1078-0432.CCR-19-2838. Epub 2020 Mar 3. PMID: 32127394; PMCID: PMC8407399.
50. Adams S, Diéras V, Barrios CH, Winer EP, Schneeweiss A, Iwata H, Loi S, Patel S, Henschel V, Chui SY, Rugo HS, Emens LA, Schmid P. Patient-reported outcomes from the phase III IMpassion130 trial of

- atezolizumab plus nab- paclitaxel in metastatic triple-negative breast cancer. *Ann Oncol*. 2020 May;31(5):582-589. doi: 10.1016/j.annonc.2020.02.003. Epub 2020 Feb 20. PMID: 32178964.
51. Garassino MC, Gadgeel S, Esteban E, Felip E, Speranza G, Domine M, Hochmair MJ, Powell S, Cheng SY, Bischoff HG, Peled N, Reck M, Hui R, Garon EB, Boyer M, Wei Z, Burke T, Pietanza MC, Rodríguez-Abreu D. Patient-reported outcomes following pembrolizumab or placebo plus pemetrexed and platinum in patients with previously untreated, metastatic, non-squamous non-small-cell lung cancer (KEYNOTE-189): a multicentre, double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol*. 2020 Mar;21(3):387-397. doi: 10.1016/S1470-2045(19)30801-0. Epub 2020 Feb 6. PMID: 32035514.
52. Kaufman PA, Toi M, Neven P, Sohn J, Grischke EM, Andre V, Stoffregen C, Shekarriz S, Price GL, Carter GC, Sledge GW Jr. Health-Related Quality of Life in MONARCH 2: Abemaciclib plus Fulvestrant in Hormone Receptor-Positive, HER2-Negative Advanced Breast Cancer After Endocrine Therapy. *Oncologist*. 2020 Feb;25(2):e243-e251. doi: 10.1634/theoncologist.2019-0551. Epub 2019 Oct 24. PMID: 32043763; PMCID: PMC7011625.
53. Mansfield AS, Kazarnowicz A, Karaseva N, Sánchez A, De Boer R, Andric Z, Reck M, Atagi S, Lee JS, Garassino M, Liu SV, Horn L, Wen X, Quach C, Yu W, Kabbinar F, Lam S, Morris S, Califano R. Safety and patient-reported outcomes of atezolizumab, carboplatin, and etoposide in extensive-stage small-cell lung cancer (IMpower133): a randomized phase I/III trial. *Ann Oncol*. 2020 Feb;31(2):310-317. doi: 10.1016/j.annonc.2019.10.021. Epub 2019 Dec 9. PMID: 31959349.
54. Mazieres J, Kowalski D, Luft A, Vicente D, Tafreshi A, Gümüş M, Laktionov K, Hermes B, Cicin I, Rodríguez-Cid J, Wilson J, Kato T, Ramlau R, Novello S, Reddy S, Kopp HG, Piperdi B, Li X, Burke T, Paz-Ares L. Health-Related Quality of Life With Carboplatin-Paclitaxel or nab-Paclitaxel With or Without Pembrolizumab in Patients With Metastatic Squamous Non-Small-Cell Lung Cancer. *J Clin Oncol*. 2020 Jan 20;38(3):271-280. doi: 10.1200/JCO.19.01348. Epub 2019 Nov 21. PMID: 31751163.
55. Leigh NB, Karaseva N, Nakagawa K, Cho BC, Gray JE, Hovey T, Walding A, Rydén A, Novello S. Patient-reported outcomes from FLAURA: Osimertinib versus erlotinib or gefitinib in patients with EGFR-mutated advanced non-small-cell lung cancer. *Eur J Cancer*. 2020 Jan;125:49-57. doi: 10.1016/j.ejca.2019.11.006. Epub 2019 Dec 12. PMID: 31838405.
56. Jones DA, Mistry P, Dalby M, Fulton-Lieuw T, Kong AH, Dunn J, Mehanna HM, Gray AM. Concurrent cisplatin or cetuximab with radiotherapy for HPV-positive oropharyngeal cancer: Medical resource use, costs, and quality-adjusted survival from the De-ESCALaTE HPV trial. *Eur J Cancer*. 2020 Jan;124:178-185. doi: 10.1016/j.ejca.2019.10.025. Epub 2019 Nov 30. PMID: 31794928; PMCID: PMC6947474.
57. Petrylak DP, de Wit R, Chi KN, Drakaki A, Sternberg CN, Nishiyama H, Castellano D, Hussain SA, Fléchon A, Bamias A, Yu EY, van der Heijden MS, Matsubara N, Alekseev B, Necchi A, Géczi L, Ou YC, Coskun HS, Su WP, Bedke J, Gakis G, Percent IJ, Lee JL, Tucci M, Semenov A, Laestadius F, Peer A, Tortora G, Safina S, Garcia Del Muro X, Rodriguez-Vida A, Cicin I, Harputluoglu H, Tagawa ST, Vaishampayan U, Aragon-

- Ching JB, Hamid O, Liepa AM, Wijayawardana S, Russo F, Walgren RA, Zimmermann AH, Hozak RR, Bell-McGuinn KM, Powles T; RANGE study investigators. Ramucirumab plus docetaxel versus placebo plus docetaxel in patients with locally advanced or metastatic urothelial carcinoma after platinum-based therapy (RANGE): overall survival and updated results of a randomised, double-blind, phase 3 trial. *Lancet Oncol*. 2020 Jan;21(1):105-120. doi: 10.1016/S1470-2045(19)30668-0. Epub 2019 Nov 18. PMID: 31753727; PMCID: PMC6946880.
58. Schadendorf D, Di Giacomo AM, Demidov L, Merelli B, Bondarenko I, Ascierto PA, Herbert C, Mackiewicz A, Rutkowski P, Guminski A, Goodman GR, Simmons B, Ye C, Hong A, Lewis K; BRIM8 Investigators. Health-related quality of life in patients with fully resected BRAF^{V600} mutation-positive melanoma receiving adjuvant vemurafenib. *Eur J Cancer*. 2019 Dec;123:155-161. doi: 10.1016/j.ejca.2019.09.019. Epub 2019 Nov 5. PMID: 31704549.
59. Pérol M, Pavlakis N, Levchenko E, Platania M, Oliveira J, Novello S, Chiari R, Moran T, Mitry E, Nüesch E, Liu T, Balas B, Konopa K, Peters S. Patient-reported outcomes from the randomized phase III ALEX study of alectinib versus crizotinib in patients with ALK-positive non-small-cell lung cancer. *Lung Cancer*. 2019 Dec;138:79-87. doi: 10.1016/j.lungcan.2019.10.002. Epub 2019 Oct 11. PMID: 31654838.
60. Hui R, Özgüroğlu M, Villegas A, Daniel D, Vicente D, Murakami S, Yokoi T, Chiappori A, Lee KH, de Wit M, Cho BC, Gray JE, Rydén A, Viviers L, Poole L, Zhang Y, Dennis PA, Antonia SJ. Patient-reported outcomes with durvalumab after chemoradiotherapy in stage III, unresectable non-small-cell lung cancer (PACIFIC): a randomised, controlled, phase 3 study. *Lancet Oncol*. 2019 Dec;20(12):1670-1680. doi: 10.1016/S1470-2045(19)30519-4. Epub 2019 Oct 7. PMID: 31601496.
61. Hammel P, Kindler HL, Reni M, Van Cutsem E, Macarulla T, Hall MJ, Park JO, Hochhauser D, Arnold D, Oh DY, Reinacher-Schick A, Tortora G, Algül H, O'Reilly EM, McGuinness D, Cui KY, Joo S, Yoo HK, Patel N, Golan T; POLO Investigators. Health-related quality of life in patients with a germline BRCA mutation and metastatic pancreatic cancer receiving maintenance olaparib. *Ann Oncol*. 2019 Dec 1;30(12):1959-1968. doi: 10.1093/annonc/mdz406. PMID: 31562758; PMCID: PMC6938600.
62. Perez EA, Barrios C, Eiermann W, Toi M, Im YH, Conte P, Martin M, Pienkowski T, Pivot XB, Burris HA 3rd, Petersen JA, De Haas S, Hoersch S, Patre M, Ellis PA. Trastuzumab emtansine with or without pertuzumab versus trastuzumab with taxane for human epidermal growth factor receptor 2-positive advanced breast cancer: Final results from MARIANNE. *Cancer*. 2019 Nov 15;125(22):3974-3984. doi: 10.1002/cncr.32392. Epub 2019 Jul 18. PMID: 31318460.
63. Coleman RL, Spirtos NM, Enserro D, Herzog TJ, Sabbatini P, Armstrong DK, Kim JW, Park SY, Kim BG, Nam JH, Fujiwara K, Walker JL, Casey AC, Alvarez Secord A, Rubin S, Chan JK, DiSilvestro P, Davidson SA, Cohn DE, Tewari KS, Basen-Engquist K, Huang HQ, Brady MF, Mannel RS. Secondary Surgical Cytoreduction for Recurrent Ovarian Cancer. *N Engl J Med*. 2019 Nov 14;381(20):1929-1939. doi: 10.1056/NEJMoa1902626. PMID: 31722153; PMCID: PMC6941470.

64. Agarwal N, McQuarrie K, Bjartell A, Chowdhury S, Pereira de Santana Gomes AJ, Chung BH, Özgüroğlu M, Juárez Soto Á, Merseburger AS, Uemura H, Ye D, Given R, Cella D, Basch E, Miladinovic B, Dearden L, Deprince K, Naini V, Lopez- Gitlitz A, Chi KN; TITAN investigators. Health-related quality of life after apalutamide treatment in patients with metastatic castration-sensitive prostate cancer (TITAN): a randomised, placebo-controlled, phase 3 study. *Lancet Oncol.* 2019 Nov;20(11):1518-1530. doi: 10.1016/S1470-2045(19)30620-5. Epub 2019 Sep 29. PMID: 31578173.
65. Weller J, Tzaridis T, Mack F, Steinbach JP, Schlegel U, Hau P, Krex D, Grauer O, Goldbrunner R, Bähr O, Uhl M, Seidel C, Tabatabai G, Brehmer S, Bullinger L, Galldiks N, Schaub C, Kebir S, Stummer W, Simon M, Fimmers R, Coch C, Glas M, Herrlinger U, Schäfer N. Health-related quality of life and neurocognitive functioning with lomustine-temozolomide versus temozolomide in patients with newly diagnosed, MGMT-methylated glioblastoma (CeTeG/NOA-09): a randomised, multicentre, open-label, phase 3 trial. *Lancet Oncol.* 2019 Oct;20(10):1444-1453. doi: 10.1016/S1470-2045(19)30502-9. Epub 2019 Sep 2. PMID: 31488360.
66. Robson M, Ruddy KJ, Im SA, Senkus E, Xu B, Domchek SM, Masuda N, Li W, Tung N, Armstrong A, Delaloge S, Bannister W, Goessl C, Degboe A, Hettle R, Conte P. Patient-reported outcomes in patients with a germline BRCA mutation and HER2-negative metastatic breast cancer receiving olaparib versus chemotherapy in the OlympiAD trial. *Eur J Cancer.* 2019 Oct;120:20-30. doi: 10.1016/j.ejca.2019.06.023. Epub 2019 Aug 22. PMID: 31446213; PMCID: PMC6836724.
67. Reck M, Schenker M, Lee KH, Provencio M, Nishio M, Lesniewski-Kmak K, Sangha R, Ahmed S, Raimbourg J, Feeney K, Corre R, Franke FA, Richardet E, Penrod JR, Yuan Y, Nathan FE, Bhagavatheswaran P, DeRosa M, Taylor F, Lawrance R, Brahmer J. Nivolumab plus ipilimumab versus chemotherapy as first-line treatment in advanced non-small-cell lung cancer with high tumour mutational burden: patient-reported outcomes results from the randomised, open-label, phase III CheckMate 227 trial. *Eur J Cancer.* 2019 Jul;116:137-147. doi: 10.1016/j.ejca.2019.05.008. Epub 2019 Jun 11. PMID: 31195357.
68. Ribi K, Luo W, Colleoni M, Karlsson P, Chirgwin J, Aebi S, Jerusalem G, Neven P, Di Lauro V, Gomez HL, Ruhstaller T, Abdi E, Biganzoli L, Müller B, Barbeaux A, Graas MP, Rabaglio M, Francis PA, Foukakis T, Pagani O, Graiff C, Vorobiof D, Maibach R, Di Leo A, Gelber RD, Goldhirsch A, Coates AS, Regan MM, Bernhard J; SOLE Investigators. Quality of life under extended continuous versus intermittent adjuvant letrozole in lymph node-positive, early breast cancer patients: the SOLE randomised phase 3 trial. *Br J Cancer.* 2019 May;120(10):959-967. doi: 10.1038/s41416-019-0435-4. Epub 2019 Apr 10. Erratum in: *Br J Cancer.* 2020 Jan 16;: PMID: 30967649; PMCID: PMC6734915.
69. Schadendorf D, Hauschild A, Santinami M, Atkinson V, Mandalà M, Chiarion- Sileni V, Larkin J, Nyakas M, Dutriaux C, Haydon A, Robert C, Mortier L, Lesimple T, Plummer R, Schachter J, Dasgupta K, Manson S, Koruth R, Mookerjee B, Kefford R, Dummer R, Kirkwood JM, Long GV. Patient-reported outcomes in patients with resected, high-risk melanoma with BRAF^{V600E} or BRAF^{V600K} mutations treated with adjuvant dabrafenib plus trametinib (COMBI-AD): a randomised, placebo-

- controlled, phase 3 trial. *Lancet Oncol.* 2019 May;20(5):701-710. doi: 10.1016/S1470-2045(18)30940-9. Epub 2019 Mar 27. PMID: 30928620.
70. Tombal B, Saad F, Penson D, Hussain M, Sternberg CN, Morlock R, Ramaswamy K, Ivanescu C, Attard G. Patient-reported outcomes following enzalutamide or placebo in men with non-metastatic, castration-resistant prostate cancer (PROSPER): a multicentre, randomised, double-blind, phase 3 trial. *Lancet Oncol.* 2019 Apr;20(4):556-569. doi: 10.1016/S1470-2045(18)30898-2. Epub 2019 Feb 12. PMID: 30770294.
71. Cella D, Grünwald V, Escudier B, Hammers HJ, George S, Nathan P, Grimm MO, Rini BI, Doan J, Ivanescu C, Paty J, Mekan S, Motzer RJ. Patient-reported outcomes of patients with advanced renal cell carcinoma treated with nivolumab plus ipilimumab versus sunitinib (CheckMate 214): a randomised, phase 3 trial. *Lancet Oncol.* 2019 Feb;20(2):297-310. doi: 10.1016/S1470-2045(18)30778-2. Epub 2019 Jan 15. Erratum in: *Lancet Oncol.* 2019 Jun;20(6):e293. PMID: 30658932; PMCID: PMC6701190.
72. Saad F, Cella D, Basch E, Hadaschik BA, Mainwaring PN, Oudard S, Graff JN, McQuarrie K, Li S, Hudgens S, Lawson J, Lopez-Gitlitz A, Yu MK, Smith MR, Small EJ. Effect of apalutamide on health-related quality of life in patients with non-metastatic castration-resistant prostate cancer: an analysis of the SPARTAN randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2018 Oct;19(10):1404-1416. doi: 10.1016/S1470-2045(18)30456-X. Epub 2018 Sep 10. PMID: 30213449.
73. Strosberg J, Wolin E, Chasen B, Kulke M, Bushnell D, Caplin M, Baum RP, Kunz P, Hobday T, Hendifar A, Oberg K, Sierra ML, Thevenet T, Margalet I, Ruzsiewicz P, Krenning E; NETTER-1 Study Group. Health-Related Quality of Life in Patients With Progressive Midgut Neuroendocrine Tumors Treated With ¹⁷⁷Lu-Dotatate in the Phase III NETTER-1 Trial. *J Clin Oncol.* 2018 Sep 1;36(25):2578-2584. doi: 10.1200/JCO.2018.78.5865. Epub 2018 Jun 7. PMID: 29878866; PMCID: PMC6366953.
74. Friedlander M, GebSKI V, Gibbs E, Davies L, Bloomfield R, Hilpert F, Wenzel LB, Eek D, Rodrigues M, Clamp A, Penson RT, Provencher D, Korach J, Huzarski T, Vidal L, Salutari V, Scott C, Nicoletto MO, Tamura K, Espinoza D, Joly F, Pujade-Lauraine E. Health-related quality of life and patient-centred outcomes with olaparib maintenance after chemotherapy in patients with platinum-sensitive, relapsed ovarian cancer and a BRCA1/2 mutation (SOLO2/ENGOT Ov-21): a placebo-controlled, phase 3 randomised trial. *Lancet Oncol.* 2018 Aug;19(8):1126-1134. doi: 10.1016/S1470-2045(18)30343-7. Epub 2018 Jul 17. PMID: 30026002; PMCID: PMC7869962.
75. Lee CK, Novello S, Rydén A, Mann H, Mok T. Patient-Reported Symptoms and Impact of Treatment With Osimertinib Versus Chemotherapy in Advanced Non-Small-Cell Lung Cancer: The AURA3 Trial. *J Clin Oncol.* 2018 Jun 20;36(18):1853-1860. doi: 10.1200/JCO.2017.77.2293. Epub 2018 May 7. PMID: 29733770.
76. Vaughn DJ, Bellmunt J, 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, Li H, Perini RF, Bajorin DF, de

- Wit R. Health-Related Quality-of-Life Analysis From KEYNOTE-045: A Phase III Study of Pembrolizumab Versus Chemotherapy for Previously Treated Advanced Urothelial Cancer. *J Clin Oncol*. 2018 Jun 1;36(16):1579-1587. doi: 10.1200/JCO.2017.76.9562. Epub 2018 Mar 28. PMID: 29590008.
77. Piccirillo MC, Scambia G, Bologna A, Signoriello S, Vergote I, Baumann K, Lorusso D, Murgia V, Sorio R, Ferrandina G, Sacco C, Cormio G, Breda E, Cinieri S, Natale D, Mangili G, Pisano C, Cecere SC, Di Napoli M, Salutati V, Raspagliesi F, Arenare L, Bergamini A, Bryce J, Daniele G, Gallo C, Pignata S, Perrone F. Quality-of-life analysis of the MITO-8, MaNGO, BGOG-Ov1, AGO- Ovar2.16, ENGOT-Ov1, GCIG study comparing platinum-based versus non-platinum- based chemotherapy in patients with partially platinum-sensitive recurrent ovarian cancer. *Ann Oncol*. 2018 May 1;29(5):1189-1194. doi: 10.1093/annonc/mdy062. PMID: 29462248.
78. Chi KN, Protheroe A, Rodríguez-Antolín A, Facchini G, Suttman H, Matsubara N, Ye Z, Keam B, Damião R, Li T, McQuarrie K, Jia B, De Porre P, Martin J, Todd MB, Fizazi K. Patient-reported outcomes following abiraterone acetate plus prednisone added to androgen deprivation therapy in patients with newly diagnosed metastatic castration-naive prostate cancer (LATITUDE): an international, randomised phase 3 trial. *Lancet Oncol*. 2018 Feb;19(2):194-206. doi: 10.1016/S1470-2045(17)30911-7. Epub 2018 Jan 8. PMID: 29326030.
79. de Boer SM, Powell ME, Mileskin L, Katsaros D, Bessette P, Haie-Meder C, Ottevanger PB, Ledermann JA, Khaw P, Colombo A, Fyles A, Baron MH, Kitchener HC, Nijman HW, Kruitwagen RF, Nout RA, Verhoeven-Adema KW, Smit VT, Putter H, Creutzberg CL; PORTEC study group. Toxicity and quality of life after adjuvant chemoradiotherapy versus radiotherapy alone for women with high-risk endometrial cancer (PORTEC-3): an open-label, multicentre, randomised, phase 3 trial. *Lancet Oncol*. 2016 Aug;17(8):1114-1126. doi: 10.1016/S1470-2045(16)30120-6. Epub 2016 Jul 7. PMID: 27397040.
80. Shimozuma K, Ohashi Y, Takeuchi A, Aranishi T, Morita S, Kuroi K, Ohsumi S, Makino H, Katsumata N, Kuranami M, Suemasu K, Watanabe T, Hausheer FH. Taxane- induced peripheral neuropathy and health-related quality of life in postoperative breast cancer patients undergoing adjuvant chemotherapy: N-SAS BC 02, a randomized clinical trial. *Support Care Cancer*. 2012 Dec;20(12):3355-64. doi: 10.1007/s00520-012-1492-x. Epub 2012 May 15. PMID: 22584733.