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Systematic Review

A systematic review comparing sex-specific outcomes of prospective clinical trials and subsequent real-world data focusing on systemic treatment options for renal cell cancer

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Short title: Sex-specific outcome in renal cancer treatments: clinical trials vs. real-world

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Abstract
Introduction:
Sex-based differences in enrollment rates in clinical trials and in cancer outcomes are evident. Real-world (RW) results might differ from phase II/III trials. The aim is to compare sex-specific outcomes of RW studies and randomized controlled trials (RCT) in locally advanced or metastasized renal cell cancer (la/mRCC).
Methods:
A systematic search in EMBASE, PubMed, MEDLINE, and Scopus on systemic therapies for la/mRCC was performed. Phase II/III trials, RCT, non-interventional prospective studies, retrospective studies, or case series were included. Data on OS and PFS (DFS for adjuvant therapies), enrollment rates and adverse events were retrieved.
Results
70 studies were included. Females were underrepresented in RCTs. Some RW analyses exceeded the epidemiological benchmark. Outcome analyses exclusively revealed advantages for males: better OS/PFS for Cabozantinib (RW), better OS for Nivolumab (CheckMate025), better PFS for Tivozanib (TIVO-3), better PFS for Nivolumab+Ipilimumab (RW), better OS for Nivolumab+Cabozantinib (CheckMate 9ER), better DFS for adjuvant Pembrolizumab (Keynote-564). No sex-specific toxicity analyses were published in RW studies or RCT.
Conclusion:
This systematic review enlightens sex-specific gaps in enrollment and cancer outcome, as well as the lack of sex-specific toxicity analyses. Balanced enrollment rates and reporting of sex-specific toxicity should be obligate in evaluations of la/mRCC treatments.

Introduction

Individualized and personalized medicine is the main goal for the future of cancer treatment. There is evidence elucidating sex-specific outcomes for different kinds of cancer treatments. This also pertains to urologic malignancies. Thus, during the treatment selection process the biological sex should also play an increasing role next to established factors such as immunohistochemistry markers, volume of metastases or gene mutations.

A recent meta-analysis by Cerrato et al. including 18 randomized controlled trials for renal cancer and urothelial cancer revealed a survival advantage for female patients for adjuvant Atezolizumab for renal cancer and vice versa a survival advantage for male patients for the treatment of urothelial cancer with Nectin-4 targeted ADC (antibody-drug conjugate) [1]. Next to biochemical factors such as pharmacodynamics and pharmacokinetics also statistical bias might lead to these results. Recent reports suggest an underrepresentation of female patients in clinical trials. Sosinsky et al. analyzed more than 1.400 US-based (United States) Phase I-III trials including cardiovascular, psychiatric and cancer diseases. While 51% of the cancer disease population were female, only 41% of the included cancer trial patients were female [2]. Also, our research group highlighted in a recent narrative review that the sex-specific epidemiology rates of urologic malignancies were not necessarily reflected in the enrollment rates of urologic cancer trials [3].

Thus, the aim of systemic review is to further elucidate the sex-gap between participation rates, cancer outcomes, as well as toxicity rates in clinical trials and real-world epidemiology data with a focus on systemic therapies for locally advanced or metastasized renal cell cancer (la/mRCC).

Methods

This review was registered at PROSPERO (number: CRD420251018407) under the following link: https://www.crd.york.ac.uk/PROSPERO/view/CRD420251018407 [4].

The following studies were included: phase II/III trials, randomized-controlled trials, non-interventional prospective studies, retrospective studies, or case series (n>4). All studies except phase II/III trials leading to a drug approval are hereafter referred to as real-world studies. The date of publication had to be between January 2014 and February 2025. The studies had to focus on renal cell cancer treatment and had to be published in English. All other kinds of studies were excluded.

The main databases to be searched were Embase.com, MEDLINE, PubMed and Scopus between August 2024 and February 2025.

Results of individual studies are shown in tables. Each table represents studies dealing with one specific kind of therapy regimen. The top lines of the tables depict the results of the approval studies and the subsequent lines show the results of published real-world data. Each study is cited and its characteristics and results are presented in **Table 1-9**.

Table 10 presents the search strings used in the mentioned databases.

Studies were screened independently by at least two people with a process to resolve differences (MCR, NG and LFS). Data were extracted by one person (MCR) and checked by at least one other person (LFS).

The following outcome parameters were extracted: HR (CI; hazard ratio, 95% confidence interval) for overall survival (OS), HR for progression-free survival (or disease-free survival for adjuvant therapies; PFS and DFS), sex-specific participation rates in all kinds of studies (%), and sex-specific discontinuation rates due to toxic effects or adverse events.

A risk of bias assessment was not performed, as this systematic review does not compare different treatment options. The different study results were only interpreted and characterized.

This systemic review followed PRISMA guidelines.

Results

General

The search and selection processes are depicted in **Figure 1**. The initial search spanned studies dealing with urothelial cancer and renal cancer (as systemic review articles for both entities are planned). In the beginning, there were 180 studies identified for screening. 171 records entered the step of assessing the full text articles for eligibility. In total, 122 studies were included for systemic

review and among those 70 studies are dealing with renal cancer. The following therapy regimens were included in this review: Cabozantinib, Nivolumab, Lenvatinib + Everolimus, Tivozanib, Pembrolizumab + Axitinib, Nivolumab + Ipilimumab, Nivolumab + Cabozantinib, Pembrolizumab + Lenvatinib, and Pembrolizumab adjuvant. Pembrolizumab as an adjuvant therapy for patients with an increased risk of recurrence after renal surgery (+/- resection of metastatic lesions) was the latest EMA-approved (European Medicines Agency) therapy included in this study (January 2022; [5])

Cabozantinib

The approval studies of Cabozantinib monotherapy for first line or subsequent line therapy (CABOSUN [6] and METEOR [7]) included 21.7% and 24.8% female patients, respectively (**Table 1**). There were no sex-specific study results published. There are 22 real-world studies. The inclusion rates of female patients in the real-world studies ranged from 20.1% to 45.5%. The average rate of included female patients in the real-world studies was 26.7**%,** i.e. higher than the inclusion rates of the approval studies. Only Tomida et al., Sazuka et al., Ishihara et al. and Santoni et al. published sex-specific outcomes [13,16,17,21]. Only the analyses by Santoni et al. revealed statistically significant outcomes: OS and PFS was worse in females compared to males for Cabozantinib as a subsequent line therapy [21] [34338966]. Notably, Santoni et al. included in their multicenter retrospective study 45.5% female patients [21]. There were no sex-specific toxicity analyses published either in the two clinical trials nor in the 22 real-world data.

Nivolumab

In the approval study Checkmate025 for Nivolumab monotherapy 24.6% of the patients were female. Whereas male patients benefitted from Nivolumab regarding OS, female patients did not benefit from Nivolumab (vs. Everolimus). There were no sex-specific toxicity analyses published [30] (**Table 2**). Only two out of the 15 real-world studies—those by Di Giorgi et al. and Vrdoljak et al.—conducted sex-specific cancer outcome analyses; however, neither reported statistically significant results [31,41]. The inclusion rate of female patients in the real-world studies was 24.4 % on average, with a range between 16.7% and 35.0%. Notably, one out of these 15 real-world studies is also listed in **Table 1**.

Lenvatinib + Everolimus

The phase II E7080-G000-205 trial compared Lenvatinib monotherapy vs. Everolimus monotherapy vs. Lenvatinib + Everolimus combination therapy. 26.8% of the included patients were female. There were no sex-specific outcome or toxicity analyses published [45] (**Table 3**). Our study selection process revealed two real-world studies. The study by Hamieh et al. included zero female patients while there were 29.1% female patients in the study by Wiele at al. [46,47]. Also, in these two real-world studies there were no sex-specific outcome or toxicity analyses.

Tivozanib

TIVO-1 and TIVO-3 were the approval studies for Tivozanib in mRCC [48,49] (**Table 4**) with 27.7% and 27.4% female patients, respectively. We identified two succeeding real-world studies with an average inclusion rate of female patients of 30.4% [50,51]. Only TIVO-3 performed a sex-specific analysis revealing a better PFS outcome for male patients than for female patients when taking Tivozanib (vs. Sorafenib) [49].

Pembrolizumab + Axitinib

The approval of Pembrolizumab + Axitinib as first line therapy in mRCC was based on the Keynote-426 trial [52] (**Table 5**). In this trial, 27.1% of the patients were female. Sex-specific toxicity analyses revealed no differences in cancer outcomes. Toxicity analyses were not shown. In the eight listed real-world studies sex-specific analyses were only performed by Guida et al. in the ProPAXI study, however showing no statistically relevant results [60]. The average inclusion rate of female patients was 26.6% and ranged between 19.1% and 32.7% in the real-world data. Sex-specific toxicity analyses were not available in neither of the studies.

Nivolumab + Ipilimumab
The combination therapy Nivolumab + Ipilimumab was approved due to the Checkmate-214 trial [61] (**Table** 6) and is effective in both male and female patients as demonstrated in the sex-specific OS-analysis. 27.4% of the included patients were female in this trial. There are 12 studies examining real-world results of this combination. The mean inclusion rate of female patients among these 12 studies was 24.0% (range 15.3-30.0%). In the sex-specific PFS analysis by Kato et al. the outcome of female patients was significantly worse than for male patients [63]. There are two more real-world studies with sex-specific outcome analyses, however their results were not statistically significant. There were no sex-specific toxicity analyses shown. Notably, four out of these 12 real-world studies are also listed in **Table 5**.

Nivolumab + Cabozantinib
The CheckMate 9ER served as the basis for the approval of Nivolumab + Cabozantib as first line therapy for mRCC [70] (**Table 7**). The inclusion rate of female patients numbered 26.1%. While there was an OS advantage for males receiving Nivolumab + Cabozantinib (vs. Sunitinib), there was no survival advantage for females [70]. Hilser et al. included in their retrospective real-world study 33.3% females. They did not perform sex-specific outcome or toxicity analyses.

Pembrolizumab + Lenvatinib
In consequence of the CLEAR trial, including 25.5% female patients, the combination of Pembrolizumab + Lenvatinib was approved as first line therapy for mRCC [72] (**Table 8**). Sex-specific PFS analysis revealed similar results for male and female patients. In a subsequent real-world analysis by Hara et al. the proportion of female patients was 18.0%. No sex-specific outcome or toxicity analyses were performed.

Pembrolizumab adjuvant
The Keynote-564 trial led to the approval of Pembrolizumab as an adjuvant therapy for patients with an increased risk of recurrence after renal cancer surgery [74] (**Table 9**). 29.0% of the patients were female. Male patients benefitted in this trial from the adjuvant therapy with Pembrolizumab (vs. placebo) in terms of DFS, whereas there was no benefit for the female subgroup. Mattigk et al. performed a retrospective study, which included female patients at a rate of 35.3% [75]. No sex-specific outcome or toxicity analyses were performed in this study.

Discussion
In an epidemiological analysis by Rosiello et al. 34.1% of all mRCC patients in the US were female [76]. Thus, approximately every third patient in prospective clinical trials exploring new systemic therapies for mRCC should be female. None of the mRCC clinical trials included in this systematic review enrolled this proportion of female patients (**Table 1-9**). Notably, among the real-world studies the benchmark of one third was reached and even outperformed by some studies, which vice versa lead to an underrepresentation of male patients in those studies. However, the majority of the averaged enrollment rates of female patients was below one third. As described introductorily, this sex-gap in the enrollment rates for cancer trials was also depicted by Sosinsky et al. [2].
Our review also elucidates a sex-gap in cancer outcome for mRCC patients. In total, we included 11 prospective approval trials in this systematic review. Only seven of these prospective trials performed and published sex-specific outcome analyses. There are some real-world analyses with sex-specific outcome analyses. These are the statistically significant cancer outcomes differences in either approval trials or real-world studies in summary:

- For Cabozantinib monotherapy the real-world analysis by Santoni et al. revealed a better OS and PFS for male patients [21].
- For Nivolumab monotherapy (vs. Everolimus) the approval trial CheckMate025 resulted in a better OS for male patients [30].
- The TIVO-3 trial demonstrated a favorable PFS for male patients taking Tivozanib (vs. Sorafenib) whereas female patients taking Tivozanib did not benefit [49].

- Male patients seemed to have a better PFS than female patients under Nivolumab + Ipilimumab as shown in a real-world study by Kato et al. [63].
- For the combination of Nivolumab + Cabozantinib (vs. Sunitinib) an OS benefit was solely shown for male mRCC patients (see CheckMate 9ER; [70]).
- A DFS benefit was also exclusively seen for the male subgroup in the Keynote-564 trial, examining Pembrolizumab as an adjuvant therapy (vs. placebo) [74].

Taken together, all statistically significant sex-specific cancer outcomes show a better outcome for male patients.

Possible reasons for the sex-based gaps in enrollment rates are non-eligible co-morbidities or medications among female patients or explicit patient preference (to not take part in a clinical trial). Possible reasons for the seen sex-based gaps in cancer outcomes are, e.g., differences in pharmacodynamics or pharmacokinetics [3], differences in dose modifications and differences in the enrollment rates (underpowered cohort). Additionally, maybe only female patients with a higher disease burden receive treatment. Correspondingly, a recent German retrospective real-world analysis of patients with metastatic urothelial cancer by Niegisch et al. revealed that female sex was a risk factor for not receiving treatment [77]. And last but not least, there is a possibility of confounding factors such as socioeconomic status or residential area (rural vs. urban) influencing cancer outcomes.

Meanwhile there was another drug approved for systemic treatment of mRCC in February 2025: the hypoxia-inducible factor 2alpha inhibitor Belzutifan [78]. The approval was based on the LITESPARK-05 trial [79]. In this phase III randomized controlled trials pretreated clear-cell mRCC patients received either Belzutifan or Everolimus. Among 746 included patients 165 were female, i.e. 22.1 % (not meeting above promoted ratio of 2:1 males:females). There exist preliminary sex-specific outcome calculations. In the second interim analysis there was no relevant OS difference between males and females. The final outcome results are eagerly awaited. There are no sex-specific toxicity analyses published so far [79].

The combination Avelumab + Axitinib was also approved long ago in October 2019 for mRCC, however this combination therapy does not play a key role in the treatment of mRCC due to a lacking OS benefit [80-81]. Hence, this therapy regimen was not primarily included in this systematic review. In the approval trial for Avelumab + Axitinib (JAVELIN Renal 101) there were 25.5% female patients included (i.e. below one third). In the PFS subgroup analysis male patients benefitted from Avelumab + Axitinib (vs. Sunitinib) while female patients did not benefit. There were no sex-specific toxicity analyses published [80].

The major limitation of this systematic review is the absence of any sex-specific toxicity analysis which was declared as a main outcome variable for this review. Another restriction is the limited comparability between prospective clinical trials and real-world analyses. On the one hand there is a selection bias in prospective randomized controlled trials due strict inclusion and exclusion criteria which does not pertain to real-world analyses. On the other hand, there is no independent central review of e.g. CT scans in real-world studies as it is in most of the prospective randomized controlled trials. A meta-analysis was not feasible due to different calculations of HRs in prospective clinical trials and real-world analysis (either it is intervention vs. control/placebo with sex-specific subgroup analyses or it is female vs. male in non-interventional observations).

In conclusion, this systematic review elucidates (I) sex-based gaps in enrollment rates, (II) sex-specific differences in cancer outcomes, and (III) the lack of any sex-specific toxicity analyses in both retrospective and prospective studies focusing on systemic therapies for la/mRCC. Future clinical trials should increase the enrollment rate for female mRCC patients, e.g. by mandatorily performing a sex-based stratification to ensure a balanced (ratio 2:1) representation of males and females. This measure might already affect the sex-specific cancer outcome. The reporting of sex-specific toxicity analyses should also be mandatory in future phase III trials as dose modifications might also serve as an explanation for sex-specific cancer outcomes. Subsequent real-world studies should follow analogously in their study designs.

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Statement of Ethics
Ethical approval was not required for this study since it is a review of previously published literature.

Conflicts of Interest Statement
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Author contributions
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Writing – review and editing: MCR, NG, DO, ASM
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All authors reviewed the manuscript.

Data Availability Statement

The data that support the findings of this study are not publicly available due to confidentiality restrictions but are available from the corresponding author upon request.

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Figure Legends
Fig. 1. Search and selection process.

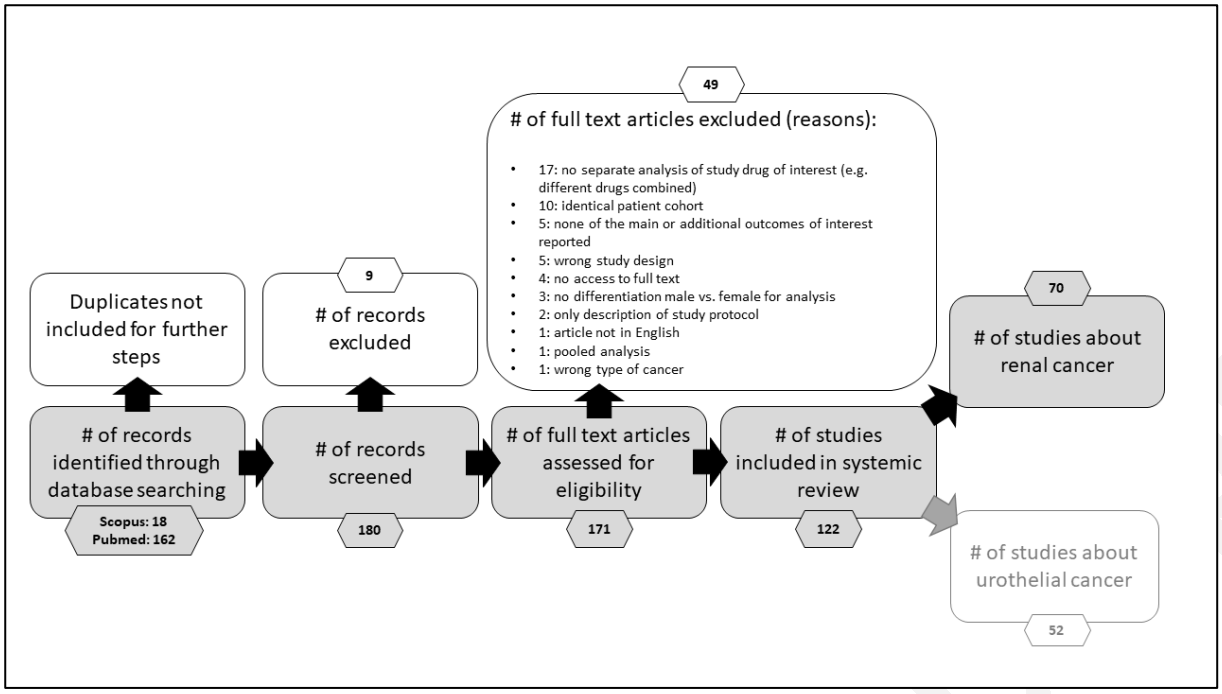

Table 1

Table 1: Cabozantinib in metastatic renal cell cancer

Trial **PMID (or DOI number)**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI[b])**	**Progression-Free Survival** **HR (95% CI)**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
CABOSUN 28199818 [6]	Choueiri TK 2017	Phase II Cabozantinib vs. Sunitinib	All: 157 Female: 34 (21.7)	21.4	Male: n/a[c] Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	1L[d]
METEOR 26406150 [7]	Choueiri TK 2015	Phase III Cabozantinib vs. Everolimus	All: 658 Female: 163 (24.8)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
Real world data								
33463028 [8]	Gan CL 2021	Multicenter Retrospective Cabozantinib	<u>1L</u> All: 34 Female: 4 (11.8) <u>2L</u> All: 143 Female: 28 (19.6) <u>Entire cohort:</u> All: 413 Female: 86 (20.8)	<u>1L</u> 14.7 <u>2L</u> 14.5	<u>1L & 2L</u> Male: n/a Female: n/a	<u>1L & 2L</u> Male: n/a Female: n/a	<u>1L & 2L</u> Male: n/a Female: n/a	1L & >1L
29753637 [9]	Procopio G 2018	Multicenter Retrospective Cabozantinib	All: 96 Female: 23 (24.0)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
39263256 [10]	Narang A 2024	Multicenter Retrospective Cabozantinib	All: 237 Female: 69 (29.1)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
CARINA 39107157 [11]	Nathan P 2024	Multicenter Retrospective Cabozantinib	All: 163 Female: 40 (24.5)	15.7	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
38979548 [12]	Lolli C 2024	Multicenter Retrospective Cabozantinib	All: 113 Female: 29 (25.7)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
38714434 [13]	Tomida R 2024	Multicenter Retrospective Cabozantinib vs. Axitinib	All: 108 Female: 28 (25.9)	14	Male: 0.873 (0.394; 1.934) Female: 1.447 (0.462; 4.528)	Male: 0.791 (0.449; 1.395) Female: 1.133 (0.441; 2.909)	Male: n/a Female: n/a	>1L
38265633 [14]	Brown J 2024	Multicenter Retrospective	All: 1485 Female:	Cabozantinib 25.8	Male: n/a	Male: n/a	Male: n/a	>1L

		Cabozantinib vs. Axitinib	414 (27.9)	Axitinib 30.8	Female: n/a	Female: n/a	Female: n/a	
38239858 [15]	Domanski P 2023	Monocenter Retrospective Cabozantinib	All: 71 Female: 25 (35.2)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
37996622 [16]	Sazuka T 2023	Multicenter Retrospective Cabozantinib	All: 118 Female: 25 (21.2)	10.5	Male: n/a Female: n/a	Male vs. Female (REF[e]) 0.44 (0.17; 1.10)	Male: n/a Female: n/a	>1L
37519060 [17]	Ishihara H 2023	Multicenter Retrospective Cabozantinib	All: 56 Female: 16 (28.6)	10.3	Male: n/a Female: n/a	Male vs. Female (REF) 1.56 (0.63; 3.84)	Male: n/a Female: n/a	>1L
CABOSEQ 35945133 [18]	Navani V 2023	Multicenter Retrospective Cabozantinib	All: 346 Female: 74 (21.4)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
35305916 [19]	Santoni M 2022	Multicenter Retrospective Cabozantinib vs. Nivolumab	All: 343 Female: 95 (27.7)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
CERES 34802966 [20]	Venugopal B 2022	Multicenter Retrospective Cabozantinib	All: 100 Female: 32 (32.0)	10.8	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
34338966 [21]	Santoni M 2021	Multicenter Retrospective Cabozantinib	All: 66 Female: 30 (45.5)	23.7	**Male (REF) vs. Female 2.00 (1.07; 3.73)**	**Male (REF) vs. Female 1.92 (1.03; 3.60)**	Male: n/a Female: n/a	>1L
31905816 [22]	Santoni M 2019	Multicenter Retrospective Cabozantinib	All: 237 Female: 63 (26.6)	182.8	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
31043824 [23]	Stukalin I 2019	Multicenter Retrospective Cabozantinib vs. Nivolumab	All: 278 Female: 56 (20.1)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
30987807 [24]	Bodnar L 2019	Multicenter Retrospective Cabozantinib	All: 115 Female: 31 (27.0)	12.6	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
CABOREAL 33253997 [25]	Albiges L 2021	Multicenter Retrospective Cabozantinib	All: 410 Female: 106 (25.9)	14.4	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
CASSIOPE 39740313 [26]	Staehler M 2025	Multicenter Prospective Cabozantinib	All: 679 Female: 183 (27.0)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
38521648 [27]	Graham J 2024	Multicenter Retrospective Cabozantinib	All: 319 Female: 77 (24.1)	16.4	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L
37926597 [28]	Bruchbacher A 2024	Monocenter Retrospective Cabozantinib	All: 71 Female: 16 (22.5)	14.3	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	1L and >1L
doi.org/10.3233/KCA-210110 [29]	Zhang H 2021	Multicenter Retrospective Cabozantinib	All: 157 Female: 39 (24.8)	9.6	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	>1L

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available, d: L: line, e: REF: reference

Table 2

Table 2: Nivolumab in metastatic renal cell cancer

Trial **PMID**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI)**	**Progression-Free Survival** **HR (95% CI[b])**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
Checkmate025 26406148 [30]	Motzer RJ 2015	Phase III Nivolumab vs. Everolimus	All: 821 Female: 202 (24.6)	minimum 14	**Male: 0.73 (0.58; 0.92)** **Female: 0.84 (0.57; 1.24)**	Male: n/a[c] Female: n/a	Male: n/a Female: n/a	
Real world data								
29956884 [31]	De Giorgi U 2019	Multicenter Prospective Nivolumab	All: 389 Female: 98 (25.2)	11.9	Male vs. Female (REF) 1.18 (0.82; 1.71)	Male: n/a Female: n/a	Male: n/a Female: n/a	
32519026 [32]	Hinata N 2020	Multicenter Retrospective Nivolumab	All: 208 Female: 50 (24.0)	Minimum 9	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
NORA 34953677 [33]	Grimm MO 2022	Multicenter Prospective Nivolumab	All: 228 Female: 65 (28.5)	37	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
35441907 [34]	Uemura H 2022	Multicenter Prospective Nivolumab	All: 555 Female: 123 (22.2)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
35668384 [35]	Waddell T 2022	Multicenter Retrospective Nivolumab	All: 151 Female: 42 (27.8)	15.2	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
36466979 [36]	Rauthan A 2022	Monocenter Retrospective Nivolumab	All: 35 Female: 7 (20.0)	19	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
WITNESS 38897136 [37]	Barthelemy P 2024	Multicenter Prospective Nivolumab	All: 325 Female: 90 (27.7)	12.3	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
POST-NIVO 37248753 [38]	Yonese J 2023	Multicenter Retrospective Nivolumab	All: 208 Female: 50 (24.0)	n/a (36-month follow-up analysis)	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
35907009 [39]	Stühler V 2023	Monocenter Retrospective Nivolumab	All (Nivolumab as ≥2L): 40 Female (Nivolumab as ≥2L): 14 (35.0%)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
33317946 [40]	Verhaart SL 2021	Multicenter Retrospective Nivolumab	All: 264 Female: 64 (24.2)	12.2	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
32940046 [41]	Vrdoljak E 2021	Multicenter Retrospective Nivolumab	All: 87 Female: 18 (20.7)	11	Male (REF[d]) vs. Female 1.01 (0.50-2.05)	Male (REF) vs. Female 0.85 (0.45-1.60)	Male: n/a Female: n/a	

31043824 [23]	Stukatin I 2019	Multicenter Retrospective Cabozantinib vs. Nivolumab	All: 278 Female: 56 (20.1)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Same study as in Table 1 (Cabozantinib)
35373823 [42]	Ishihara I 2022	Multicenter Retrospective Nivolumab	All: 74 Female: 16 (21.6)	25.8	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
33159426 [43]	Ishihara I 2021	Multicenter Retrospective Nivolumab vs. Targeted Therapy	All: 159 Female: 46 (28.9)	13.2 (Nivolumab Cohort)	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
32048159 [44]	Jose JFM 2020	Multicenter Retrospective Nivolumab	All: 90 Female: 15 (16.7)	8.5	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available, d: REF: reference

Table 3

Table 3: Lenvatinib/Everolimus in metastatic renal cell cancer

Trial **PMID**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI[b])**	**Progression-Free Survival** **HR (95% CI)**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
E7080-G000-205 26482279 [45]	Motzer RJ 2015	Phase II Lenvatinib vs. Everolimus vs. Lenvatinib+Everolimus	All: 153 Female: 41 (26.8)	n/a[c]	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
Real world data								
32291161 [46]	Hamieh L 2020	Monocenter Retrospective Lenvatinib + Everolimus	All: 7 Female: 0 (0%)	n/a (range 4-17)	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
33792094 [47]	Wiele AJ 2021	Monocenter Retrospective Lenvatinib +/- Everolimus	All: 55 Female: 16 (29.1)	n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available

Table 4

Table 4: Tivozanib in metastatic renal cell cancer

Trial **PMID**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI[b])**	**Progression-Free Survival** **HR (95% CI)**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
TIVO-1 24019545 [48]	Motzer RJ 2013	Phase III Tivozanib vs. Sorafenib	All: 517 Female: 143 (27.7)	n/a[c]	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
TIVO-3 31810797 [49]	Rini BI 2020	Phase III Tivozanib vs. Sorafenib	All: 350 Female: 96 (27.4)	19	Male: n/a Female: n/a	**Male: 0.64 (0.47; 0.86)** **Female: 0.72 (0.44; 1.18)**	Male: n/a Female: n/a	
Real world data								
Meet-Uro-16 34583356 [50]	Basso U 2021	Multicenter Retrospective Tivozanib	All: 64 Female: 24 (37.5)	12.5	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
38478923 [51]	Johns AC 2024	Unicenter Retrospective Tivozanib	All: 30 Female: 7 (23.3)	13.9	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available

Table 5

Table 5: Axitinib/Pembrolizumab in metastatic renal cell cancer

Trial **PMID**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI[b])**	**Progression-Free Survival** **HR (95% CI)**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
Keynote-426 30779529 [52]	Rini BI 2019	Phase III Pembrolizumab + Axitinib vs. Sunitinib	All: 861 Female: 233 (27.1)	12.8	Male: 0.54 (0.37; 0.80) Female: 0.45 (0.25; 0.83)	Male: 0.77 (0.61; 0.97) Female: 0.54 (0.37; 0.81)	Male: n/a[c] Female: n/a	
Real world data								
37992086 [53]	Lai GS 2023	Multicenter Retrospective Pembrolizumab + Axitinib vs. IO/IO vs. TKI mono	All: 6297 Female: 1780 (28.3)	Pembrolizumab+Axitinib cohort only 16.7 (Mean)	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
37722984 [54]	Shah NJ 2023	Multicenter Retrospective Pembrolizumab + Axitinib vs. IO/IO	All: 331 Female: 81 (24.5)	Pembrolizumab+Axitinib cohort only 10.1	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
37345413 [55]	Harada KI 2023	Multicenter Retrospective Pembrolizumab + Axitinib	All: 47 Female: 9 (19.1)	14	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
36874600 [56]	Shah NJ 2023	Multicenter Retrospective Pembrolizumab + Axitinib vs. IO/IO vs. TKI mono	All: 1538 Female: 462 (30.0)	Pembrolizumab+Axitinib cohort only 7.2	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
36200791 [57]	Zarrabi KK 2023	Multicenter Retrospective Pembrolizumab + Axitinib vs. IO/IO	All: 1506 Female: 403 (26.8)	Entire cohort 20	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
35664758 [58]	Zakharia Y 2022	Multicenter Retrospective Pembrolizumab + Axitinib	All: 355 Female: 108 (30.4)	9.7	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
35158357 [59]	Hoeh B 2022	Multicenter Retrospective Pembrolizumab + Axitinib vs. IO/IO	All: 104 Female: 34 (32.7)	Pembrolizumab+Axitinib cohort only: 9.2	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
ProPAXI 39405768 [60]	Guida A 2024	Multicenter Prospective Pembrolizumab + Axitinib	All: 170 Female: 35 (20.6)	19.3	Male vs. Female (REF) 0.77 (0.43;1.36)	Male vs. Female (REF) 0.76 (0.47;1.07)	Male: n/a Female: n/a	

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available

Table 6

Table 6: Ipilimumab + Nivolumab in metastatic renal cell cancer

Trial **PMID**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI[b])**	**Progression-Free Survival** **HR (95% CI)**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
Checkmate-214 29562145 [61]	Motzer RJ 2018	Phase III Ipilimumab + Nivolumab vs. Sunitinib	Intermediate/poor IMDC[d] All: 847 Female: 232 (27.4)	25.2	Intermediate/poor IMDC Male: 0.71 (0.55; 0.92) Female: 0.52 (0.34; 0.78)	Male: n/a[c] Female: n/a	Male: n/a Female: n/a	
Real world data								
32893401 [62]	Tanaka T 2020	Multicenter Retrospective Ipilimumab + Nivolumab	All: 52 Female: 11 (21.2)	16	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
34848474 [63]	Kato R 2021	Multicenter Retrospective Ipilimumab + Nivolumab	All: 45 Female: 9 (20.0)	1-year-follow-up	Male: n/a Female: n/a	**Male (REF) vs. Female 5.546 (2.092;14.704)**	Male: n/a Female: n/a	
35024632 [64]	Meerveld-Eggink 2022	Multicenter Retrospective Ipilimumab + Nivolumab	All: 71 Female: 14 (19.7)	11.5	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
38345708 [65]	Ishihara H 2024	Multicenter Retrospective Ipilimumab + Nivolumab vs. TKI[e]/IO[f]	All: 175 Female: 47 (26.9)	Entire cohort 15	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
38251783 [66]	Ishihara H 2024	Multicenter Retrospective Ipilimumab + Nivolumab	All: 56 Female: 16 (28.6)	34.4	Male vs. Female (REF) 0.92 (0.38; 2.26)	Male: n/a Female: n/a	Male: n/a Female: n/a	
37992086 [53]	Lai GS 2023	Multicenter Retrospective Ipilimumab + Nivolumab vs. Axitinib + Pembrolizumab vs. TKI mono	All: 6297 Female: 1780 (28.3)	Ipilimumab + Nivolumab cohort only 19.7 (Mean)	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Same study as in Table 5 (Pembrolizumab/ Axitinib)
37722984 [54]	Shah NJ 2023	Multicenter Retrospective Ipilimumab + Nivolumab vs. Axitinib + Pembrolizumab	All: 331 Female: 81 (24.5)	Ipilimumab + Nivolumab cohort only 10.7	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Same study as in Table 5 (Pembrolizumab/ Axitinib)

36874600 [56]	Shah NJ 2023	Multicenter Retrospective Ipilimumab + Nivolumab vs. Axitinib + Pembrolizumab vs. TKI Mono	All: 1538 Female: 462 (30.0)	Ipilimumab + Nivolumab cohort only 8.5	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Same study as in Table 5 (Pembrolizumab/ Axitinib)
36200791 [57]	Zarrabi KK 2023	Multicenter Retrospective Ipilimumab + Nivolumab vs. Axitinib + Pembrolizumab	All: 1506 Female: 403 (26.8)	Entire cohort: 20	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	Same study as in Table 5 (Pembrolizumab/ Axitinib)
35831538 [67]	Kato T 2022	Multicenter Retrospective Ipilimumab + Nivolumab	All: 72 Female: 11 (15.3)	16.1	Synchronous M1[g] disease: Male (REF) vs. Female 1.327 (0.305;4.098)	Synchronous M1 disease: Male (REF) vs. Female 0.764 (0.181;2.210)	Male: n/a Female: n/a	
35115252 [68]	Thana M 2022	Multicenter Retrospective Ipilimumab + Nivolumab	All: 195 Female: 49 (25.1)	10.6	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	
39727706 [69]	Taniguchi T 2024	Multicenter Retrospective Ipilimumab + Nivolumab	All: 84 Female: 18 (21.4)	18,3	Male: n/a Female: n/a	Male: n/a Female: n/a	Male: n/a Female: n/a	

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available, d: IMDC: International Metastatic Renal Cell Carcinoma Database Consortium, e: TKI: tyrosine kinase inhibitor, f: IO: immune-oncology therapy, g: M1: distant metastases

Table 7

Table 7: Nivolumab + Cabozantinib in metastatic renal cell cancer

Trial **PMID**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI[b])**	**Progression-Free Survival** **HR[a] (95% CI[b])**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
CheckMate 9ER 33657295 [70]	Choueiri TK 2021	Phase III Nivolumab + Cabozantinib vs. Sunitinib	All: 651 Female: 170 (26.1)	18,1	**Male: 0.59 (0.40; 0.85)** **Female: 0.68 (0.39; 1.18)**	Male: 0.48 (0.37; 0.62) Female: 0.61 (0.40; 0.94)	Male: n/a[c] Female: n/a[c]	
Real world data								
39272856 [71]	Hilser T 2024	Multicenter Retrospective Nivolumab + Cabozantinib	All: 96 Female: 32 (33.3)	12.7	Male: n/a[c] Female: n/a[c]	Male: n/a[c] Female: n/a[c]	Male: n/a[c] Female: n/a[c]	

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available

Table 8: Pembrolizumab + Lenvatinib in metastatic renal cell cancer

Trial **PMID**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI[b])**	**Progression-Free Survival** **HR[a] (95% CI[b])**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
CLEAR 33616314 [72]	Motzer RJ 2021	Phase III Pembrolizumab + Lenvatinib vs. Lenvatinib + Everolimus vs. Sunitinib	Entire cohort: All: 1069 Female: 273 (25.5)	Entire cohort: 26.6	Male: n/a[c] Female: n/a[c]	Pembrolizumab + Lenvatinib vs. Sunitinib: Male: 0.38 (0.30; 0.49) Female: 0.42 (0.27; 0.66)	Male: n/a[c] Female: n/a[c]	
Real world data								
39472358 [73]	Hara T 2024	Multicenter Retrospective Pembrolizumab + Lenvatinib	All: 50 Female: 9 (18.0)	n/a[c]	Male: n/a[c] Female: n/a[c]	Male: n/a[c] Female: n/a[c]	Male: n/a[c] Female: n/a[c]	

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available

Table 9

Table 9: Pembrolizumab adjuvant in renal cell cancer

Trial **PMID**	**First Author** **Year of publication**	**Study Design** **Study drug(s)**	**Patient numbers** **All [n]** **Female [n;%]**	**Follow-Up (median) [months]**	**Overall Survival** **HR[a] (95% CI[b])**	**Progression-Free Survival** **HR[a] (95% CI[b])**	**Discontinuation of treatment** **Male** **Female** **[%]**	**Annotation**
Approval studies								
Keynote-564 34407342 [74]	Choueiri TK 2021	Phase III Pembrolizumab vs. Placebo	All: 994 Female: 288 (29.0)	24.1	Male: n/a[c] Female: n/a[c]	**DFS[d]:** **Male: 0.66 (0.49; 0.89)** **Female: 0.75 (0.48; 1.16)**	Male: n/a[c] Female: n/a[c]	DFS[d] instead of PFS[e]
Real world data								
39719131 [75]	Mattigk A 2024	Multicenter Retrospective Pembrolizumab	All: 51 Female: 18 (35.3)	6	Male: n/a[c] Female: n/a[c]	Male: n/a[c] Female: n/a[c]	Male: n/a[c] Female: n/a[c]	

a: HR: hazard ratio, b: CI: confidence interval, c: n/a: not available, d: DFS: disease-free survival, e: PFS: progression-free survival

Table 10

Table 10: Search Strings

cabozantinib AND (CABOSUN) cabozantinib AND (CABOSUN) AND (real world) cabozantinib AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma)) AND (first line) AND (real world)
cabozantinib AND (METEOR) cabozantinib AND (METEOR) AND (real world) cabozantinib AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma)) AND (second line) AND (real world)
nivolumab AND (checkmate-025) nivolumab AND ((checkmate-025) OR (CA209-025)) AND (real world) nivolumab AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma)) AND (second line) AND (real world)
lenvatinib AND everolimus AND motzer [first author] lenvatinib AND everolimus AND (E7080-G000-205) AND (real world) (lenvatinib plus everolimus) AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma)) AND (real world)
tivozanib AND motzer [first author] tivozanib AND (tivo-3) (tivozanib) AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma)) AND (real world) (tivozanib [title]) AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma))
axitinib AND pembrolizumab AND (keynote 426) axitinib AND pembrolizumab AND (keynote 426) AND (real world) (axitinib AND pembrolizumab) AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma)) AND (real world)
nivolumab AND ipilimumab AND checkmate-214 nivolumab AND ipilimumab AND checkmate-214 AND (real world)
nivolumab AND cabozantinib AND (checkmate 9ER) nivolumab AND cabozantinib AND (checkmate 9ER) AND (real world) (cabozantinib AND nivolumab) AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma)) AND (real world)
lenvatinib AND pembrolizumab AND (CLEAR) lenvatinib AND pembrolizumab AND (CLEAR) AND (real world) (lenvatinib AND pembrolizumab) AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma)) AND (real world) (lenvatinib AND pembrolizumab [title]) AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma))

pembrolizumab AND (keynote 564)
pembrolizumab AND (keynote 564) AND (real world)
(adjuvant AND pembrolizumab [title]) AND ((kidney cancer) OR (renal cancer) OR (renal carcinoma) OR (renal cell cancer) OR (renal cell carcinoma))