

Eligibility criteria

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In case a certain date is unknown, please use the following guidelines:

- In case the month and year are known: 01-mm-yyyy
- In case only the year is known: 01-01-yyyy
- In case the total date is unknown: uk

Metastasis	<input type="radio"/> Yes <input type="radio"/> No (In case of "No" a patient can NOT be enrolled in EuroTARGET)
Date of diagnosis of metastasis	__ __ -- __ __ -- __ __ __ __
Institute of diagnosis (For the Netherlands: according to NKR codes for hospitals)
Date, the informed consent has been signed by the patient	__ __ -- __ __ -- __ __ __ __

General information at diagnosis

Height

Patient's height (in cm)

Bilateral renal cell carcinoma

A patient has bilateral renal cell carcinoma, in case a second tumor in the other kidney was detected within three months. If the patient has bilateral renal cell carcinoma, it is not necessary to fill in the information for both individual tumors.

Bilateral renal cell carcinoma	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
In case of bilateral renal cell carcinoma: Synchronous occurrence?	<input type="radio"/> Synchronous (fill in the form using the first tumor) <input type="radio"/> Non-synchronous (fill in the form using the tumor with the worst prognosis) <input type="radio"/> Unknown

Tumor assessment

Multiple dates should be registered in this form.

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This information should be registered only once for each patient at time of recruitment.

In most cases metastasis will be diagnosed together with the primary tumor.

In case metastasis was diagnosed later, please fill in the information below on the PRIMARY TUMOR.

Date of initial diagnosis of primary tumor	__ __ -- __ __ -- __ __ __ __
Date of surgery / biopsy for primary tumor	__ __ -- __ __ -- __ __ __ __
Tumor sample on which the pathology diagnosis was based comes from	<input type="radio"/> Primary tumor <input type="radio"/> Metastasis <input type="radio"/> No pathology diagnosis
Pathology laboratorium of diagnosis (For the Netherlands: according to NKR codes for hospitals)
Pathology identification number of specimen
Type of renal cell cancer	<input type="radio"/> Clear renal cell carcinoma <input type="radio"/> Chromophobe renal cell carcinoma <input type="radio"/> Collecting duct carcinoma <input type="radio"/> Papillary renal cell carcinoma <input type="radio"/> Non-clear cell renal cell carcinoma <input type="radio"/> Unknown
Papillary type	<input type="radio"/> Papillary type I RCC <input type="radio"/> Papillary type II RCC <input type="radio"/> Unknown
Please specify non-clear cell renal cell carcinoma

Presence of sarcomatoid elements	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Fuhrman grade	<input type="radio"/> Grade I <input type="radio"/> Grade II <input type="radio"/> Grade III <input type="radio"/> Grade IV <input type="radio"/> Unknown
Presence of tumor necrosis	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown

cTNM classification

According to TNM staging system 7 (2009), based on clinical information. For instructions, please see header row.

TNM staging system - clinical

Indicate the TNM stage according to the TNM classification 7 (2009) from clinical information. In case a previous edition of the TNM staging system was used, re-evaluate the TNM stage according to this new edition (2009).

Summary of the changes in the TNM classification 7 (2009)

T2 has been subdivided in:

T2a - Tumor more than 7 cm but not more than 10 cm

T2b - Tumor more than 10 cm, limited to the kidney

T3 and T4 got changes concerning the text:

T3a - Invasion into the adrenal gland is removed from this stage (now T4)

T4 - Tumor invades beyond Gerota fascia (including contiguous extension into ipsilateral adrenal gland)

cT- Primary Tumor	<input type="radio"/> TX <input type="radio"/> T0 <input type="radio"/> T1 <input type="radio"/> T1a <input type="radio"/> T1b	<input type="radio"/> T2 <input type="radio"/> T2a <input type="radio"/> T2b	<input type="radio"/> T3 <input type="radio"/> T3a <input type="radio"/> T3b <input type="radio"/> T3c <input type="radio"/> T4
cN- Regional Lymph Nodes	<input type="radio"/> NX <input type="radio"/> N0 <input type="radio"/> N1 <input type="radio"/> N2		
cM- Distant	<input type="radio"/> M0 <input type="radio"/> M1		

pTNM classification

According to TNM staging system 7 (2009), based on pathology. For instructions, please see the header row.

TNM staging system - pathology

Indicate the TNM stage according to the TNM classification 7 (2009) from the pathology report. In case a previous edition of the TNM staging system was used, re-evaluate the TNM stage according to this new edition (2009). In case a patient did not get surgery the pTNM cannot be assessed, since no pathological grading took place. In this case, indicate the TNM classification based on clinical information.

Summary of the changes in the TNM classification 7 (2009)

T2 has been subdivided in:

T2a - Tumor more than 7 cm but not more than 10 cm

T2b - Tumor more than 10 cm, limited to the kidney

T3 and T4 got changes concerning the text:

T3a - Invasion into the adrenal gland is removed from this stage (now T4)

T4 - Tumor invades beyond Gerota fascia (including contiguous extension into ipsilateral adrenal gland)

pT- Primary Tumor	<input type="radio"/> TX <input type="radio"/> T0 <input type="radio"/> T1 <input type="radio"/> T1a <input type="radio"/> T1b	<input type="radio"/> T2 <input type="radio"/> T2a <input type="radio"/> T2b	<input type="radio"/> T3 <input type="radio"/> T3a <input type="radio"/> T3b <input type="radio"/> T3c <input type="radio"/> T4
pN- Regional Lymph Nodes	<input type="radio"/> NX <input type="radio"/> N0 <input type="radio"/> N1 <input type="radio"/> N2		
pM- Distant	<input type="radio"/> M0 <input type="radio"/> M1		
	<input type="radio"/> pTNM classification not done		

Co-morbidities at start treatment of metastasis

If co-morbidities exist at the time of start of treatment of metastasis, these co-morbidities should be registered here. A co-morbidity is NOT related to the cancer-specific treatment, and NOT related to the disease itself.

Other malignancy excl. non-melanoma skin cancer and carcinoma in situ of the cervix uteri	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
Diabetes mellitus	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Hypertension	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
in case of "yes", currently treated with medication?	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
Cardiovascular disease e.g. Intermittent claudication, bifurcation prosthesis, percutaneous transluminal angioplasty (PTA), tube prosthesis,	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
abdominal aortic aneurysm, aortic aneurysm, generalized atherosclerosis, peripheral vascular disease, embolectomy, post myocardial infarction, myocardial infarction, angina pectoris, coronary artery bypass graft (CABG), coronary heart disease, percutaneous transluminal coronary angioplasty (PTCA), heart failure, cardiomyopathy, cerebrovascular accident (CVA) in history (not a transient ischemic attack (TIA), cerebral artery disease, cerebral hemorrhage, post carotid endarterectomy, heartvalve prosthesis (aortic valve prosthesis, mitral valve prosthesis), valvular heart disease (mitral, tricuspid, aortic or pulmonary valve stenosis or regurgitation), post heart transplantation, thrombosis, pulmonary embolism, pelvic vein thrombosis, arrhythmias, atrial fibrillation, ventricular fibrillation, AV-block, artificial pacemaker, cardioversion. Although DVT actually falls in this category, we would like to have a separate registration of DVT.	
Deep vein thrombosis Although DVT actually falls in category "cardiovascular diseases", we would like to have a separate registration of DVT.	<input type="radio"/> No <input type="radio"/> Yes, most recent year of diagnosis ____ -- ____ -- ____ <input type="radio"/> Unknown
Other clotting disorder e.g. haemophilia	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown

<p>Lung disease e.g. CARA, emphysema, chronic bronchitis, chronic obstructive pulmonary disease, obstructive</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
<p>pulmonary disease, bronchial hyperreactivity, pulmonary fibrosis, post-lung transplantation.</p>	
<p>Gastro intestinal e.g. peptic ulcer, gastric ulcer, duodenal ulcer, (reflux) esophagitis, post gastrectomy, total or partial (B1, B2-</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
<p>resection), inflammatory bowel disease (Morbis Crohn, CU (Colitis Ulcerosa) (no familial adenomatosis polyposis), liver disease (e.g. cirrhosis, hepatitis A, B, C, non-A and non-B), post liver transplantation, diverticulitis.</p>	
<p>Urinary tract and genital organs e.g. chron. glomerulonephritis (CGN), chron. pyelonephritis (CPN), chronic renal failure, nephrotic syndrome, post</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
<p>kidney transplantation, dialysis (haemodialysis, CIPD, peritoneal dialysis).</p>	
<p>Muscles, joints and connective tissue e.g. connective tissue diseases (e.g., Sarcoidosis = M. Besnier Boeck, Wegener, periarteriitis nodosa (PAN),</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
<p>Systemic lupus erythematosus (SLE), rheumatoid arthritis (RA)</p>	
<p>Central and peripheral NS e.g. dementia, Alzheimer's disease, dementia syndrome, hemiplegic, hemiparesis, quadriplegic, paraplegic,</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
<p>psychiatric disorders (this refers to severe chronic psychiatric problems, e.g. hospitalized in a psychiatric hospital or ward, severe depression, psychosis or schizophrenia), Parkinson's disease.</p>	
<p>Metabolic disease e.g. haemophilia, hypo-/hyperthyreoidia</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
<p>Infectious disease Only chronic infectious diseases, e.g. HIV-positive, AIDS, tuberculosis. No acute infectious diseases, e.g. pneumonia.</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
<p>Congenital disorder e.g. Down syndrome, clubfoot, facial clefts, 18q syndrome, sickle cell disease</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown
<p>Other disorder</p>	<input type="radio"/> No <input type="radio"/> Yes, please specify <input type="radio"/> Unknown

Available patient material

Blood sample

In case a certain date is unknown, please use the following guidelines:

- In case the month and year are known: 01-mm-yyyy
- In case only the year is known: 01-01-yyyy
- In case the total date is unknown: uk

Blood sample

☐ Yes

date of venepuncture __ __ -- __ __ -- __ __ __ __

☐ No

Frozen tumor sample

Frozen tumor sample available for EuroTARGET

☐ Yes

☐ No

Available tumor material

☐ Primary tumor

☐ Metastasis

☐ Primary tumor and metastasis

Paraffin-embedded tumor sample

Paraffin-embedded tumor sample available for EuroTARGET

☐ Yes

☐ No

Available tumor material

☐ Primary tumor

☐ Metastasis

☐ Primary tumor and metastasis

Treatment line

Treatment of metastasis

Information collected during treatment regimes for metastasis.

When another drug is administered a new treatment line starts.

Please use one form per treatment line!

"1st line treatment of metastasis" should always be filled in. 2nd, 3rd, 4th and 5th treatment lines should only be filled in in case of (multiple) medication change(s).

Multiple dates should be registered in this form. In case a certain date is unknown, please use the following guidelines:

- In case the month and year are known: 01-mm-yyyy
- In case only the year is known: 01-01-yyyy
- In case the total date is unknown: uk

Treatment line no

- ☐ 1 or palliative care or best supportive care
☐ 2
☐ 3
☐ 4
☐ 5

Clinical data at start of treatment of metastasis

In which hospital is this treatment line administered

.....
(For the Netherlands: according to NKR codes for hospitals)

Weight of the patient

..... (in kg)

WHO performance status

Register the WHO performance status. Copy exactly what is written in the medical record. Do not interpret the performance status yourself. When the WHO performance status cannot be found, but the Karnofsky score is available, the WHO performance status can be derived from the Karnofsky score.

- ☐ 0. Fully active, able to carry on all predisease activities without restrictions
☐ 1. Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature
☐ 2. Ambulatory and capable of all self care but unable to carry out any \ work activities. Up and about more than 50 percent of waking hours
☐ 3. Capable of only limited self-care, confined to bed or chair for 50 percent or more of waking hours
☐ 4. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
☐ Unknown

WHO Karnofsky score

0 100
 0 90
 1 80
 1 70
 2 60
 2 50
 3 40
 3 30
 4 20
 4 10
 4 0

Description

Normal no complaints, no evidence of disease.
 Able to carry on normal activity; minor signs or symptoms of disease.
 Normal activity with effort; some signs or symptoms of disease.
 Cares for self; unable to carry on normal activity or to do active work.
 Requires occasional assistance, but is able to care for most of his personal needs.
 Requires considerable assistance and frequent medical care.
 Disabled; requires special care and assistance.
 Severely disabled; hospital admission is indicated although death not imminent.
 Very sick; hospital admission necessary; active supportive treatment necessary.
 Moribund; fatal processes progressing rapidly.
 Dead

Number of locations with metastases

Number of locations with metastases ☐ 1
 Indicate the number of locations (number of sites) with metastases at the start of this treatment line. Also include lymph node metastases. Regional and distant lymph node metastases count as one site. ☐ 2
☐ 3
☐ 4
☐ > 4

Location of metastases

Location of metastases ☐ Lung
☐ Lymph nodes (regional and/or distant)
☐ Liver
☐ Bone
☐ Brain
☐ Adrenal gland
☐ Other, please specify

Lab values at start of treatment of metastasis

Enter the lab values at the start of this treatment line. Values must not be older than 3 months before start treatment. When necessary, the characters < or > can be used in the fields below.

Hemoglobin	<input type="radio"/> mmol/L <input type="radio"/> g/dl	(calculated to 1 decimal place)
Leukocytes	x 10 ⁹ /L (=10 ³ /μl)	(calculated to 1 decimal place)
Percentage of neutrophils	%	(calculated to 1 decimal place)
Number of neutrophils	x 10 ⁹ /L	(calculated to 2 decimal places)
Trombocytes (platelets)	x 10 ⁹ /L (=10 ³ /μl)	
Creatinine	<input type="radio"/> μmol/L <input type="radio"/> mg/dl	(calculated to 1 decimal place)
Albumin	g/L	
Calcium	<input type="radio"/> mmol/L	(calculated to 2 decimal places)
Total bilirubin	<input type="radio"/> μmol/L <input type="radio"/> mg/dl	(calculated to 1 decimal place)
Alkaline phosphatase	U/L	
Aspartate aminotransferase (SGOT/ AST/ ASAT)	U/L	
Alanine transaminase (SGPT/GUID/ALT/ALAT)	U/L	
LDH	units/L	

Drug treatment

- Which drug(s) is/are being used
- ☐ None, palliative or best supportive care
 - ☐ Interferon-alpha (IFN-a)
 - ☐ Interferon-alpha (IFN-a) + vinblastine
 - ☐ Interleukin 2
 - ☐ Sunitinib
 - ☐ Sorafenib
 - ☐ Bevacizumab + Interferon-alpha (IFN-a)
 - ☐ Temsirolimus
 - ☐ Everolimus
 - ☐ Pazopanib
 - ☐ Other, please specify
 - ☐ Unknown

Dosing schemes

Please specify dose, frequency etc. in detail below.

A treatment line can consist of different cycles. This is the case for the treatment with Sunitinib. Usually Sunitinib is given during four weeks (weeks on), followed by a two-week rest-period (weeks off). This six-week period is equal to one cycle.

One dosing scheme is a (number of) treatment cycle(s). In case the treatment cycle has been changed (e.g. in case of dose reduction, change in frequency etc.), please fill in the new treatment cycle in dosing scheme 2, 3, etc. You can add extra schemes by clicking on the + button.

A treatment line can also consist of a treatment given during a certain number of weeks/ months. No cycles are involved. This is the case for the treatment with Interferon-alpha, Sorafenib, Everolimus, Pazopanib, Bevacizumab (+ interferon alpha) and Temsirolimus. Use "n/a" in the "weeks on", "weeks off", "total amount per cycle" and "no of cycles with this scheme" fields.

A treatment may consist of a combination of drugs (e.g. Bevacizumab + Interferon alpha). If this is the case, use two schemes for registering this treatment.

In case a new treatment line has started (change of medication), use a new therapy form ("2nd, 3rd, 4th, 5th line treatment of metastasis") for registering this line.

1.	Start Date 1	__ __ -- __ __ -- __ __ __ __		
	Dose 1 <input type="radio"/> mg (calculated to 2 decimal places) <input type="radio"/> million IU <input type="radio"/> ml <input type="radio"/> mmol <input type="radio"/> other, please specify <input type="radio"/> unknown		
	Frequency 1	<input type="radio"/> 0.5 x <input type="radio"/> 1 x <input type="radio"/> 2 x <input type="radio"/> 3 x <input type="radio"/> unknown	per 1	<input type="radio"/> day <input type="radio"/> 3 days <input type="radio"/> week <input type="radio"/> month <input type="radio"/> unknown
	Weeks on treatment 1	Weeks off treatment 1 In case no cycles are involved (eg., interferon alpha) use n/a .
	Total amount per cycle 1	No of cycles with this scheme 1 Please use the unit chosen above. In case no cycles are involved (eg., interferon alpha) use n/a .
	Stop date 1	__ __ -- __ __ -- __ __ __ __		Reason for stop/change 1 <input type="radio"/> toxicity grade 1 or 2 <input type="radio"/> toxicity grade 3 or 4 <input type="radio"/> progression / relapse <input type="radio"/> condition of patient <input type="radio"/> wishes of patient <input type="radio"/> patient has died <input type="radio"/> other, please specify <input type="radio"/> unknown

2.	Start Date 2	__ __ -- __ __ -- __ __ __ __		
	Dose 2 <input type="radio"/> mg (calculated to 2 decimal places) <input type="radio"/> million IU <input type="radio"/> ml <input type="radio"/> mmol <input type="radio"/> other, please specify <input type="radio"/> unknown		
	Frequency 2	<input type="radio"/> 0.5 x <input type="radio"/> 1 x <input type="radio"/> 2 x <input type="radio"/> 3 x <input type="radio"/> unknown	per 2	<input type="radio"/> day <input type="radio"/> 3 days <input type="radio"/> week <input type="radio"/> month <input type="radio"/> unknown
	Weeks on treatment 2	Weeks off treatment 2 In case no cycles are involved (eg., interferon alpha) use n/a .
	Total amount per cycle 2	No of cycles with this scheme 2 Please use the unit chosen above. In case no cycles are involved (eg., interferon alpha) use n/a .
	Stop date 2	__ __ -- __ __ -- __ __ __ __		Reason for stop/change 2 <input type="radio"/> toxicity grade 1 or 2 <input type="radio"/> toxicity grade 3 or 4 <input type="radio"/> progression / relapse <input type="radio"/> condition of patient <input type="radio"/> wishes of patient <input type="radio"/> patient has died <input type="radio"/> other, please specify <input type="radio"/> unknown

3.	Start Date 3	____ -- ____ -- ____		
	Dose 3 <input type="radio"/> mg (calculated to 2 decimal places) <input type="radio"/> million IU <input type="radio"/> ml <input type="radio"/> mmol <input type="radio"/> other, please specify <input type="radio"/> unknown		
	Frequency 3	<input type="radio"/> 0.5 x <input type="radio"/> 1 x <input type="radio"/> 2 x <input type="radio"/> 3 x <input type="radio"/> unknown	per 3	<input type="radio"/> day <input type="radio"/> 3 days <input type="radio"/> week <input type="radio"/> month <input type="radio"/> unknown
	Weeks on treatment 3		Weeks off treatment 3 In case no cycles are involved (eg., interferon alpha) use n/a .
	Total amount per cycle 3	No of cycles with this scheme 3 Please use the unit chosen above. In case no cycles are involved (eg., interferon alpha) use n/a .
	Stop date 3	____ -- ____ -- ____	Reason for stop/change 3	<input type="radio"/> toxicity grade 1 or 2 <input type="radio"/> toxicity grade 3 or 4 <input type="radio"/> progression / relapse <input type="radio"/> condition of patient <input type="radio"/> wishes of patient <input type="radio"/> patient has died <input type="radio"/> other, please specify <input type="radio"/> unknown

4.	Start Date 4	____ -- ____ -- ____		
	Dose 4 <input type="radio"/> mg (calculated to 2 decimal places) <input type="radio"/> million IU <input type="radio"/> ml <input type="radio"/> mmol <input type="radio"/> other, please specify <input type="radio"/> unknown		
	Frequency 4	<input type="radio"/> 0.5 x <input type="radio"/> 1 x <input type="radio"/> 2 x <input type="radio"/> 3 x <input type="radio"/> unknown	per 4	<input type="radio"/> day <input type="radio"/> 3 days <input type="radio"/> week <input type="radio"/> month <input type="radio"/> unknown
	Weeks on treatment 4		Weeks off treatment 4 In case no cycles are involved (eg., interferon alpha) use n/a .
	Total amount per cycle 4	No of cycles with this scheme 4 Please use the unit chosen above. In case no cycles are involved (eg., interferon alpha) use n/a .
	Stop date 4	____ -- ____ -- ____	Reason for stop/change 4	<input type="radio"/> toxicity grade 1 or 2 <input type="radio"/> toxicity grade 3 or 4 <input type="radio"/> progression / relapse <input type="radio"/> condition of patient <input type="radio"/> wishes of patient <input type="radio"/> patient has died <input type="radio"/> other, please specify <input type="radio"/> unknown

(Concomitant) non drug treatment - Surgery

	<input type="radio"/> No surgery
Date of surgery	__ __ -- __ __ -- __ __ __ __
Surgery type	<input type="radio"/> Open nephrectomy <input type="radio"/> Laparoscopic nephrectomy <input type="radio"/> Open partial nephrectomy <input type="radio"/> Laparoscopic partial nephrectomy <input type="radio"/> Adrenalectomy <input type="radio"/> Lymphadenectomy <input type="radio"/> Thrombectomy <input type="radio"/> Embolisation <input type="radio"/> Radio Frequency Ablation (RFA) <input type="radio"/> Cryosurgery <input type="radio"/> Metastasectomy <input type="radio"/> Nephrectomy + metastasectomy (in one session) <input type="radio"/> Partial nephrectomy + metastasectomy (in one session) <input type="radio"/> Nephrectomy + other (in one session) <input type="radio"/> Partial nephrectomy + other (in one session) <input type="radio"/> Other, please specify <input type="radio"/> Unknown

(Concomitant) non drug treatment - Radiotherapy

	<input type="radio"/> No radiotherapy
Start date	__ __ -- __ __ -- __ __ __ __
Stop date	__ __ -- __ __ -- __ __ __ __
Total dose Gy.
Site of radiotherapy
Subjective (symptomatic) response to radiotherapy	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown

Toxicities

The items in this table must be updated on an ongoing basis.

Please collect only adverse events which are (likely) CAUSALLY related to the treatment.

All grade 3, 4 and 5 toxicities (NOT grade 1 and 2) developed until one month after the last treatment should be reported. Register per treatment line each toxicity only once, with the highest CTC grade reached. If a toxicity existed before the diagnosis of renal cell carcinoma was made, but the CTC grade has increased after diagnosis, this toxicity must also be reported. In this case the starting date is the day that the toxicity worsens.

If the CTC grade was not specified by the physician in the medical record of the patient, specify the grade of each specific toxicity yourself according to CTCAE version 4.0. The CTC grade refers to the severity of the toxicity. For each specific toxicity, the CTCAE guidelines give a unique clinical description which corresponds to the degree of toxicity. You can find the CTCAE at the following page: http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf. Always consult these guidelines to find the specific CTC grade for the toxicity to be reported.

The following symptoms are not required to report as toxicity:

- Symptoms that can be linked to (progress/relapse of) renal cell carcinoma.
- Symptoms that already existed in the same degree of seriousness at the time of diagnosis.
- Symptoms that can be regarded as symptoms of a previously reported other toxicity (e.g. swallowing difficulties due to mucositis).

Fever must be registered. Please also report whether fever is accompanied by neutropenia or not.

Note: If fever occurs as a result of a (allergic) reaction to the medication, the so-called "drug fever", this fever should also be reported as a toxicity.

	Toxicity If not specified by the physician, consult terminology used in the PDF file mentioned above	CTC grade If not specified by the physician, consult the guidelines in the PDF file mentioned above to find the specific CTC grade for the specific toxicity	Determined by	Treatment to which the toxicity is related*	Start date of toxicity	End date of toxicity	Is toxicity treated?
		Grade 3: Serious toxicity: influences general daily life activities, hospitalisation sometimes required Grade 4: Life-threatening toxicity: always requires hospitalization Grade 5: Death due to toxicity	Indicate whether the CTC grade was specified by the physician in the medical record of the patient, or whether the grade was interpreted by the data manager from the medical record (DM)	Report the treatment to which the toxicity is (very likely) related.	Note the date the toxicity has started.	Note the date the toxicity has ended.	Is the toxicity treated?
1.	<input type="radio"/> physician <input type="radio"/> DM	__-__-____	__-__-____	<input type="radio"/> no <input type="radio"/> yes
2.	<input type="radio"/> physician <input type="radio"/> DM	__-__-____	__-__-____	<input type="radio"/> no <input type="radio"/> yes
3.	<input type="radio"/> physician <input type="radio"/> DM	__-__-____	__-__-____	<input type="radio"/> no <input type="radio"/> yes
4.	<input type="radio"/> physician <input type="radio"/> DM	__-__-____	__-__-____	<input type="radio"/> no <input type="radio"/> yes
5.	<input type="radio"/> physician <input type="radio"/> DM	__-__-____	__-__-____	<input type="radio"/> no <input type="radio"/> yes

Response (also in case of non treatment)

Register the response as mentioned in the RADIOLOGY report; as a substitute use the response as indicated by the physician in the medical record.

Information on response is required, and therefore, this part should always be filled out. Details of tumor assessments (in the part 'tumor assessment': 'date tumor assessment', 'target lesions' and 'non-target lesions' below) should be registered if available.

More information on RECIST version 1.1: www.eortc.be/recist/

Date of response assessment	Treatment line	Response*	In case of PR or SD: Decrease according to RECIST	Date of relapse or progression	Further anti cancer treatment	Reason no further treatment**
Date on which the response has been established, within 3 months of treatment. This is the date that the physician recorded the response in the medical record. If this is not listed, then record the date of the investigations that are required for the determination of response. Please note the last date; therefore, the date on which all of the required results were available.	1 = 1 st line 2 = 2 nd line 3 = 3 rd line 4 = 4 th line 5 = 5 th line	0 = no (drug) treatment 1 = CR complete remission 2 = PR partial remission 3 = SD stable disease 4 = PD progressive disease 9 = unknown		Date on which a possible relapse or progress occurs, mostly based on radiology. If no relapse or progress has occurred at end of follow-up, fill in 00-00-0000 (not applicable).	Indicate whether the patient receives active treatment as a result of relapse or progression of disease (or when a previous treatment was ineffective). 0= no (in case of best supportive care).	If a patient does not receive active treatment (anymore), register the reason why. Multiple reasons are possible. If the field code 88 is filled in, a specification must be given in the available field.
1. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
2. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
3. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
4. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
5. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
6. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
7. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
8. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
9. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
10. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	
11. ____ - ____ - ____% ____ - ____ - ____	<input type="radio"/> no <input type="radio"/> yes	

Date of response assessment	Treatment line	Response*	In case of PR or SD: Decrease according to RECIST	Date of relapse or progression	Further anti cancer treatment	Reason no further treatment**
12. ____ - ____ - ____% ____ - ____ - ____		<input type="radio"/> no <input type="radio"/> yes
13. ____ - ____ - ____% ____ - ____ - ____		<input type="radio"/> no <input type="radio"/> yes
14. ____ - ____ - ____% ____ - ____ - ____		<input type="radio"/> no <input type="radio"/> yes
15. ____ - ____ - ____% ____ - ____ - ____		<input type="radio"/> no <input type="radio"/> yes
16. ____ - ____ - ____% ____ - ____ - ____		<input type="radio"/> no <input type="radio"/> yes
* Response 0 = No (drug) treatment, adjuvant treatment or palliative treatment whereby the patient has died before the first evaluation time, therefore not applicable 1 = Complete remission (CR): Disappearance of all (target and non-target) lesions 2 = Partial remission (PR): At least 30% decrease in longest diameter (LD) of single tumor or sum of LDs of multiple masses (specify the decrease according to RECIST version 1.1) 3 = Stable disease (SD): Neither PR nor PD criteria met (specify the decrease (if any) according to RECIST version 1.1) 4 = Progressive disease (PD): Greater than 20% increase in LD of single tumor or the sum of LDs in multiple masses, or appearance of new lesions 9 = unknown (also when treatment was not completed)				** Reason no further treatment 00 = new treatment starts, so n.a. 01 = no further treatment possibilities 02 = wait-and-see policy 03 = refusal patient / family 04 = co morbidity 05 = functional status 06 = age 07 = short life expectancy 08 = patient has died 88 = other, please specify below 99 = unknown		
Reason no further treatment, option 88, specification:						
.....						
.....						
.....						

Tumor assessment (also in case of non treatment)

Details on 'tumor assessment', in the parts 'date tumor assessment', 'target lesions' and 'non-target lesions' should be filled out, if available. So please fill out the dates on which tumor assessments were performed in this treatment line and provide detailed information on target and non-target lesions. Click on the + buttons to add a new assessment.

Date tumor assessment

		Date
1.	Baseline assessment	__ __ -- __ __ -- __ __ __ __ __
2.	Tumor assessment 2	__ __ -- __ __ -- __ __ __ __ __
3.	Tumor assessment 3	__ __ -- __ __ -- __ __ __ __ __
4.	Tumor assessment 4	__ __ -- __ __ -- __ __ __ __ __
5.	Tumor assessment 5	__ __ -- __ __ -- __ __ __ __ __
6.	Tumor assessment 6	__ __ -- __ __ -- __ __ __ __ __
7.	Tumor assessment 7	__ __ -- __ __ -- __ __ __ __ __
8.	Tumor assessment 8	__ __ -- __ __ -- __ __ __ __ __
9.	Tumor assessment 9	__ __ -- __ __ -- __ __ __ __ __
10.	Tumor assessment 10	__ __ -- __ __ -- __ __ __ __ __
11.	Tumor assessment 11	__ __ -- __ __ -- __ __ __ __ __
12.	Tumor assessment 12	__ __ -- __ __ -- __ __ __ __ __
13.	Tumor assessment 13	__ __ -- __ __ -- __ __ __ __ __
14.	Tumor assessment 14	__ __ -- __ __ -- __ __ __ __ __
15.	Tumor assessment 15	__ __ -- __ __ -- __ __ __ __ __
16.	Tumor assessment 16	__ __ -- __ __ -- __ __ __ __ __

Target Lesions

All measurable lesions up to a maximum of 5 lesions (2 per organ) representative of all involved organs should be identified as target lesions and be recorded and measured at baseline. These 5 lesions should be selected on the basis of their size (lesions with the longest diameter) and their suitability for accurate repetitive measurements (either by imaging techniques or clinically). A sum of the longest diameter (LD) for all target lesions will be calculated and reported as the baseline sum LD. The baseline sum LD will be used as reference to further characterize the objective tumor response of the measurable dimension of the disease. If there are >5 measurable lesions, those not selected as target lesions will be considered together with non-measurable disease as non-target lesions.

Kidney-ipsilateral = side of primary tumor

For lymph nodes: Take shortest diameter

	Location /type	Target lesion 1	Target lesion 2	Target lesion 3	Target lesion 4	Target lesion 5	Sum of lesion diameters	Overall Response
1	Location /type ipsi = ipsilateral con = contra-lateral adrenal g = adrenal gland	Okidney ipsi Okidney con Olung Olymphnode Oliver Obrain Oadrenal g Oother* On.a.	Okidney ipsi Okidney con Olung Olymphnode Oliver Obrain Oadrenal g Oother* On.a.	Okidney ipsi Okidney con Olung Olymphnode Oliver Obrain Oadrenal g Oother* On.a.	Okidney ipsi Okidney con Olung Olymphnode Oliver Obrain Oadrenal g Oother* On.a.	Okidney ipsi Okidney con Olung Olymphnode Oliver Obrain Oadrenal g Oother* On.a.		CR (complete remission) PR (partial remission) SD (stable disease) PD (progressive disease) U (unknown)
2	Baseline assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
3	Tumor 2 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
4	Tumor 3 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
5	Tumor 4 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
6	Tumor 5 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
7	Tumor 6 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
8	Tumor 7 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
9	Tumor 8 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
10	Tumor 9 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
11	Tumor 10 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD

12	Tumor 11 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
13	Tumor 12 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
14	Tumor 13 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
15	Tumor 14 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
16	Tumor 15 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
17	Tumor 16 assessment mm mm mm mm mm mm	<input type="radio"/> CR <input type="radio"/> PD <input type="radio"/> PR <input type="radio"/> U <input type="radio"/> SD
*Target lesion other		

Non-Target Lesions

All non-measurable lesions (or sites of disease) plus any measurable lesions over and above the 5 listed as target lesions. Measurements are not required but these lesions should be noted at baseline and should be followed as "equal", "increase" or "decrease".

	Location /type	Non-target lesion 1	Non-target lesion 2	Non-target lesion 3	Non-target lesion 4	Non-target lesion 5
1	Location /type ipsi = ipsilateral contr = contra-lateral adrenal gl = adrenal gland	<input type="radio"/> kidney ipsi <input type="radio"/> kidney contr <input type="radio"/> lung <input type="radio"/> lymphnodes <input type="radio"/> liver <input type="radio"/> bone <input type="radio"/> brain <input type="radio"/> adrenal gl <input type="radio"/> other* <input type="radio"/> n.a.	<input type="radio"/> kidney ipsi <input type="radio"/> kidney contr <input type="radio"/> lung <input type="radio"/> lymphnodes <input type="radio"/> liver <input type="radio"/> bone <input type="radio"/> brain <input type="radio"/> adrenal gl <input type="radio"/> other* <input type="radio"/> n.a.	<input type="radio"/> kidney ipsi <input type="radio"/> kidney contr <input type="radio"/> lung <input type="radio"/> lymphnodes <input type="radio"/> liver <input type="radio"/> bone <input type="radio"/> brain <input type="radio"/> adrenal gl <input type="radio"/> other* <input type="radio"/> n.a.	<input type="radio"/> kidney ipsi <input type="radio"/> kidney contr <input type="radio"/> lung <input type="radio"/> lymphnodes <input type="radio"/> liver <input type="radio"/> bone <input type="radio"/> brain <input type="radio"/> adrenal gl <input type="radio"/> other* <input type="radio"/> n.a.	<input type="radio"/> kidney ipsi <input type="radio"/> kidney contr <input type="radio"/> lung <input type="radio"/> lymphnodes <input type="radio"/> liver <input type="radio"/> bone <input type="radio"/> brain <input type="radio"/> adrenal gl <input type="radio"/> other* <input type="radio"/> n.a.
2	Baseline assessment	<input type="radio"/> no <input type="radio"/> yes	<input type="radio"/> no <input type="radio"/> yes	<input type="radio"/> no <input type="radio"/> yes	<input type="radio"/> no <input type="radio"/> yes	<input type="radio"/> no <input type="radio"/> yes
3	Tumor 2 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
4	Tumor 3 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
5	Tumor 4 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
6	Tumor 5 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
7	Tumor 6 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
8	Tumor 7 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
9	Tumor 8 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
10	Tumor 9 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
11	Tumor 10 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
12	Tumor 11 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease

	Location /type	Non-target lesion 1	Non-target lesion 2	Non-target lesion 3	Non-target lesion 4	Non-target lesion 5
13	Tumor 12 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
14	Tumor 13 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
15	Tumor 14 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
16	Tumor 15 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
17	Tumor 16 assessment	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease	<input type="radio"/> equal <input type="radio"/> increase <input type="radio"/> decrease
*Target lesion other	

New Lesions	
New lesion during this treatment line?	<input type="radio"/> no <input type="radio"/> yes
Date new lesion	__ __ __ __ __ __

Final information on patient

Final information on patient

This form should be filled in when a patient has died or is lost to follow up

At which date has the final information (toxicities, treatment, etc.) been collected	__ __ -- __ __ -- __ __ __ __
Reason for last registration	<input type="radio"/> Lost to follow up (e.g., referral to another hospital, registration impossible) <input type="radio"/> Patient has died <input type="radio"/> Unknown
In case the patient is lost to follow up, last date patient was known to be alive	__ __ -- __ __ -- __ __ __ __
In case the patient has died, date of death	__ __ -- __ __ -- __ __ __ __
In case the patient has died, cause of death	<input type="radio"/> As a result of the malignancy <input type="radio"/> Due to toxicity (specify in "toxicities and response") <input type="radio"/> Other, please specify below <input type="radio"/> Unknown
Other cause of death, option 8
Remarks