Protocol A6181213

RENACALL

Evaluation of the impact of a call center in management of metastatic and/or advanced renal cell carcinoma patients treated with sunitinib (Sutent) in first line

Prospective, multicenter usual care study conducted in mainland France

Statistical analytical plan (SAP)

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Abbreviations

a/mRCC	Advanced/metastatic renal cell carcinoma
AEs	Adverse Events
ALT	Alanine Transaminase
ANOVA	Analysis of variance
AST	Aspartate Transaminase
BMI	Body Mass Index
CATI	Computer-assisted telephone interview
CC	follow-up by a “call center”
CI	Confidence Interval
CRO	Clinical Research Organization
CTCAE	Common Terminology Criteria for Adverse Events
ECG	Electrocardiogram
ECO CRU	Health Economics Clinical Research Unit
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic Case Report Form
GEE	Generalized Estimating Equations
HT	Hypertension
INCA	French National Cancer Institute
INFα	Alpha interferon
ITT	Intention to Treat
IV	Intravenous
MAR	Missing At Random
MedDRA	Medical Dictionary for Regulatory Activities
MMAS	Morisky Medication Adherence Scale
NB	Negative Binomial
ORR	Objective Response Rate
PT	Preferred Term
PV	Pharmacovigilance
QC	Quality Control
RECIST	Response Evaluation Criteria in Solid Tumors
SD	Standard Deviation
SF	Standard follow-up
SmPC	Summary or product characteristics
SOC	System Organ Class
SOP	Standard Operating Procedures
ZIP	Zero-Inflated Poisson
ZNB	Zero-inflated Negative Binomial

1. VERSION HISTORY

Version	Amendments	Date
V6.3	Final version	06/02/2019

2. INTRODUCTION

The introduction to this document briefly summarizes the main features of the RENACALL study on the basis of the amendment to the protocol No. 3.1 of 21 July 2017. Items shown in italics originate from this protocol.

To recall, this last amended version removes of the concept of randomization into two follow-up arms and discontinues the "standard follow-up" arm.

2.1. Justification for the study

Cell therapy treatment requires close patient monitoring to ensure the medicinal product is used correctly, and particularly to prevent and manage adverse events (AEs). Improved management of adverse events helps to optimize the duration of treatment and the clinical benefit of treatment. Most of the targeted therapies are taken orally and the adverse events often occur at home. Regular contact by a treatment management call center could not only reduce the percentage of patients developing a grade 3-4 adverse event but also reduce the number of unplanned hospitalizations and consultations due to poor tolerability.

No studies have assessed the impact of follow-up using a "treatment management call center" on the treatment of patients suffering from metastatic/advanced renal cell carcinomas treated with a targeted oral therapy. Improvement in the care of patients treated with an oral targeted therapy is one of the priorities in the 2nd cancer plan produced by INCa (http://www.plan-cancer.gouv.fr/).

The RENACALL study is designed to assess a method for managing patients under real life conditions which is different from usual follow-up, with no additional interventions of the part of the doctor.

2.2. Plan of the study

- **General plan**

The RENACALL study is a prospective, multicenter, usual care study conducted in Mainland France in adult patients suffering from advanced/metastatic renal cell carcinoma treated first line with sunitinib. The study will be conducted in 10 to 20 centers which look after renal cancer.

The therapeutic management of patients within the facility will not be changed by the study and will follow the recommendations in the SmPC. Patients who are included will receive an additional intervention with follow-up from the treatment management telephone call center. Management through the treatment management telephone call center involves regular telephone calls (cf. Figure 1) *in order to support the patient in his/her home management with sunitinib treatment under real life conditions (prevention, advice and directing patients towards options available).*

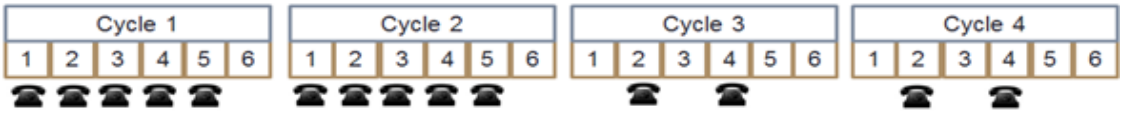


Figure 1. Plan of telephone calls

▪ Populations

- Population of Participating doctors

The study will be proposed to 58 doctors throughout 50 Mainland France oncology centers identified as treating patients suffering from metastatic/advanced renal cell carcinoma. It is planned to identify 20 to 25 doctors liable to take part in the study.

These centers will be selected by the Pfizer Company. They will need to have a number of patients which meet the eligibility criterion which is sufficient to be included (approximately 10 patients per year) and not to have a routine management call center already in place in their facility.

- Patient Population

It is expected to recruit 100 patients for this study, i.e. approximately 10 per center. The patients must meet the following inclusion and non-inclusion criteria.

Table 1: Patient eligibility criteria

Inclusion criteria	Non-inclusion criteria
- Men or women, aged 18 years old or over; - Patients suffering from advanced and/or metastatic renal cell carcinoma treated first line with sunitinib according to the SmPC recommendations; - Starting Sutent® in accordance with the SmPC recommendations (50 mg/day, dosage regimen 4/2); - Resolution (grade ≤ 1 according to CTCAE version 4.03 dated June 2010) of all the acute toxic effects due to previous treatment with radiotherapy or a surgical procedure before starting sunitinib; - Patients who can be followed up for 6 months; - Patients of childbearing potential who must be using a method of contraception throughout the period of treatment with sunitinib and for a minimum of 28 days after stopping treatment with sunitinib; - Patients who have given their signed consent; - Patients belonging to a social security system.	- Patients taking part in a clinical trial during treatment with sunitinib; - Patients managed by a home hospitalization service during treatment with sunitinib; - Patients taking part in therapeutic education programs or receiving a nurse consultation or any other significant support for treatment liable to impact on the management of adverse effects; - Patients suffering from untreated and/or symptomatic cerebral metastases before beginning sunitinib; - Patients who refuse to allow their personal data to be used; - Patients with an ECOG performance index at inclusion > 2; - Patients with a serum creatinine of > 1.5 times the upper limit of normal; - Patients with bilirubin concentrations > 2 mg/dl, aspartate transaminase (AST) or alanine transaminase (ALT) levels > 2.5 times the upper limit of normal value or > 5 times the upper limit of normal in the presence of liver metastases when sunitinib treatment is started; - Patients who are staff members of the center involved in the study or are personal friends to a member of the center directly involved in the management of the study, or patients who are employed by Pfizer and are involved in the conduct of the study.

▪ Data collection

The data collected during the inclusion and follow-up visits are shown in Table 2:

Table 2: Data collected during the RENACALL study inclusion and follow-up consultations

	V0: Inclusion ***T0***	**V1: end of cycle 1** ***W6***	**V2: end of cycle 2** ***W12***	**V3: end of cycle 4** ***W24***
Data completed by the doctor (in the eCRF)				
Meeting the eligibility criteria	x			
ECOG performance index	x	x	x	x
Karnofsky index/Heng criterion risk score	x			
Sociodemographic features	x			
History of the disorder/description of the renal cell carcinoma	x			
Past medical history and comorbidities	x			
Tumor assessment/ Disease assessment		x	x	x
Data from the laboratory, histological or metastatic assessments	x	x	x	x
Conditions for the use of Sunitinib	x			
Change in the conditions of use for Sunitinib		x	x	x
Concomitant treatments	x	x	x	x
Pharmacovigilance data		x	x	x
Medical procedures (telephone calls, consultations, hospitalizations), both planned and unplanned		x	x	x
Issuing of support materials for treatment with sunitinib	x	x	x	x
Data completed by the patient (self-completed questionnaire)				
Adherence to treatment (4 item Morisky questionnaire)		x	x	x
Data completed by the doctor (in the eCRF) and patient (self-completed questionnaire)				
Satisfaction with the telephone call center				x

The following data will be collected by the nurses during the telephone calls (recorded by a CATI - Computer-Assisted Telephone Interview) system:

- Number of attempts and outcome of the call;
- General patient health;
- Administration of treatment;
- Tolerability and onset of AEs (description of the AE: intensity, symptoms, impact on the patient, investigations, action instituted);
- Proposed action.

The investigator characteristics will be obtained from an extraction from the database provided by Pfizer.

2.3. Objectives

Primary objective

- *To assess the impact of a treatment management call center on the treatment of patients suffering from advanced/metastatic renal cell carcinoma (a/mRCC) treated 1st line with sunitinib.*

Secondary objectives

- *To describe and estimate the proportion of patients who have dose reductions, interruptions or discontinuation of treatment (Sutent®),*
- *To estimate the number of unplanned medical procedures, whether or not related to Sutent® (number of unplanned consultations and hospitalizations),*
- *To assess adherence with treatment (Morisky scale [1, 2]),*
- *To estimate the objective response rate (ORR) according to RECIST criteria v1.1.*
- *To assess patient and doctor satisfaction with the telephone call center,*
- *To describe the process of the telephone calls in terms of the number of calls completed and actions taken by the call center and/or the doctor.*

3. INTERIM ANALYSIS AND FINAL ANALYSIS

No interim analysis is planned.

The **final data analysis** will be performed following the data collection and after freezing the database as approved with Pfizer. After the amendment to the protocol (no. 3.1), it was agreed that the statistical analyses be performed on all patients who were followed up by the telephone "Call Center" platform.

Patients initially included in the "standard follow-up" group will be described for informative purposes from their major characteristics at inclusion and during follow-up.

A final statistical report will describe all of the planned analyses in the SAP and any additional analyses requested. This statistical report will not contain any description or comment about the results.

A study report will be written and submitted to Pfizer. This document will provide a discussed overview of the results of the analyses in order to meet the objectives of the study.

The results of the RENACALL study may be discussed in terms of the results of the SANTORIN study [8].

The reports will be written in French.

4. HYPOTHESES AND DECISION-MAKING RULES

4.1. Hypotheses

No statistical tests will be used.

4.2. Decision-making rules

Not applicable.

5. ANALYSIS POPULATION

5.1. Definition of the analysis populations

Reported population All patients reported by the investigators in the non-inclusion register and included in the eCRF.

Safety population Patients treated with Sunitinib.

Full Analysis Set (FAS) Population All patients included by the investigating doctors who meet the study eligibility criteria and have received at least one dose of Sunitinib

NB: Where applicable, the two subgroups of patients will in all cases be distinguished in the populations: firstly patients included in the "Call Center" arm **(main interest population**) and patients included in the "standard follow-up" arm **(exploratory population**) set up as part of the initial study design (before amendment No. 3 to the protocol).

Table 3: Population in each analysis

Analyses		Populations analyzed	Analysis subgroup*
Description at inclusion		Safety population	Call Center /standard follow-up
Description of follow-up	All data Main data	Safety population **Call Center** Safety population **Standard follow-up**	
Primary objective		Safety population	Number of calls made by the call center*
Secondary objectives	Sunitinib treatment details	Safety population	Number of calls made by the call center*
	Planned and unplanned medical procedures	Safety population	Number of calls made by the call center*
	Adherence to treatment	Safety population	Number of calls made by the call center*
	Objective response rate	FAS population	Number of calls made by the call center*
	Telephone calls	Call Center FAS population	
	Patient satisfaction	Call Center FAS population who completed a self-administered satisfaction questionnaire	Number of calls made by the call center*
	Doctor satisfaction	Call Center FAS population for which the Doctors have completed a satisfaction questionnaire	
Pharmacovigilance		Safety population	

* cf. definition §5.2.

5.2. Analysis subgroup

In the assessment of the treatment call center for patient management, analysis of the objectives may be performed overall and according to the number of calls received (two group classification).

In order to define compliance or non-compliance with the intervention, i.e. in order to define the patient as having actually followed the procedure, the scientific committee will define **a minimum number of 7 successful calls out of the planned 14 calls over 4 cycles, with a required minimum of 6 successful calls during the first two treatment cycles, representing at least 3 calls in each of the first two cycles.**

6. END POINTS

6.1. Primary end point

The primary end point is defined as the **percentage of patients with at least one grade 3 or 4 adverse event (whether or not related to Sutent®),** during the first 4 cycles of treatment (study follow-up period) according to the 'Common Terminology Criteria for Adverse Events' (CTCAE) version 4.03 of June 2010).

6.2. Secondary end points

- **Dose reductions, interruptions and discontinuations of treatment (sunitinib)**

  Description of dose reductions:

  - Proportion of patients with at least one dose reduction compared to the initial dose;
  - Reasons for dose reductions;
  - Changes in dose (initial dose or new prescribed dose).

  Description of treatment interruptions:

  - Proportion of patients who temporarily interrupt sunitinib;
  - Mean duration of interruptions;
  - Reasons for interruptions.

  Permanent discontinuation of treatment

  - Proportion of patients who discontinue Sunitinib permanently;
  - Reasons for discontinuations.

- **Unplanned medical procedures:**

  - Average number of unplanned consultations, whether or not related to sunitinib;
  - Average number of unplanned hospitalizations, whether or not related to sunitinib.

- **Treatment adherence**

Adherence to treatment will be assessed from the **mean adherence score** and from the **proportion of "adherent" patients.** These criteria will be determined using the **Morisky scale** (**MMAS-4**: 4-item Morisky Medication Adherence Scale), which consists of 4 items, together with a further question about adverse effects completed by the patient.

- **Response to treatment**

Response to treatment will be assessed from the **objective response rate (ORR)** according to RECIST criteria V1.1.

- **Patient and doctor satisfaction with the telephone call center**

Patient satisfaction with the call center will be assessed by:

- the **mean scores for each dimension on the satisfaction questionnaire;**
- the **proportion of patients/doctors who reported being "satisfied" or "very satisfied"** overall with the management by the telephone call center.

- **Description of telephone calls**

The telephone calls received during the study will be described by:

- the **number of completed calls** (planned and unplanned),
- the **actions taken** by the patient,
- the **actions taken** by the call center,
- the **actions taken** by the doctor,
- and the **declaration of adverse events**.

7. MANAGEMENT OF MISSING VALUES

The data from patients were recorded on an eCRF, except for the paper self-completed adherence and patient satisfaction questionnaires. Mandatory fields and consistency controls will be used to check data registered at the time. This strategy will be used to reduce missing data points or inconsistencies, particularly those concerning the major end points (AE, grades of AE and response to treatment etc.).

The analyses will be performed on the available data ("observed case analysis"), using the assumption that missing data are non-informative. The numbers of missing data points will be presented for each variable.

The response analysis will also be conducted on the FAS population by imputing missing responses as failure (= progression).

8. STATISTICAL METHODOLOGY AND STATISTICAL ANALYSES

The statistical analyses will be performed on SAS software (version 9.4 or subsequent, SAS Institute, North Carolina USA).

8.1. Statistical methods

8.1.1. **Descriptive analyses**

The analysis will be purely descriptive.

The descriptive analysis of qualitative variables will include numbers and frequency of each modality. The analysis of quantitative variables will include mean, standard deviation, values, median and extreme values. The number of missing values or values analyzed will be shown for each variable studied.

Consistency between two qualitative variables (assessment of adherence at W4 and W6 of cycles 1, 2 and 4) will be assessed using the Kappa coefficient [3] (cf. interpretation of the Kappa coefficient in annex 11.1).

8.1.2. **Analysis strategy**

In the principal analysis of the primary objective, all patients included in the "Call Center" arm will be analyzed in this group regardless of the number of calls received and all of their data will be used.

The analysis will be performed on an overall basis and according to the number of calls made by the call center as defined in section §5. Analysis population.

The statistical analyses and tabular models stipulated in this SAP will be used subject to sufficient numbers being available for the expanded analysis for a given variable.

8.2. Statistical analyses

8.2.1. **Numbers**

The numbers of participating investigating doctors will be described, together with the average number of patients included in the study. Participating and non-participating investigators will be described by geographical region (a variable derived from the post code of the investigator: cf. annex 1). The characteristics of active and non-active investigators will be described by geographical region, type of practice, urban or non-urban area and age and sex. The type of center facility will also be described (general hospital, university hospital, cancer center, etc.). These data will be obtained from an extraction from the database provided by Pfizer.

The **patient numbers** during the study will be displayed in a flow chart (cf. Figure 3 on page 35): patients reported, patients included, those followed up, those which leave the study and those who die.

Eligible patients who are not included into the study will be described from the data collected in the non-inclusion register in parallel with the same characteristics as patients who are included: age (derived from date of birth), sex and ECOG performance index. The reasons for non-inclusion will also be presented.

Follow-up of patients who are included will be described by:

- The median follow-up time in weeks: the time between the date of the inclusion visit and the date of the last follow-up consultation (If a patient stops treatment permanently during the follow-up period after the patient has stopped treatment will be included for patients in the CC arm).
- Average number of treatment cycles per patient;
- Average number of follow-up consultations achieved per patient;
- Average number completed calls per patient in the CC arm.

The major inclusion characteristics of patients who were followed up and those who were not followed up will be presented.

8.2.2. **Description of the population when sunitinib treatment is started**

Population analyzed: Included population

Analysis:

The patients will be described when they start treatment with sunitinib from all of the **inclusion data** collected:

- **Patients' sociodemographic characteristics**: Age (calculated as the time in years between date of birth and date of starting sunitinib), and sex;
- **Clinical Characteristics of the patients**: Risk score - Heng et al. criteria, Body Mass Index (BMI), ECOG performance index and Karnofsky index;
- **History of the disorder**: Time since the initial diagnosis of the primary renal cell carcinoma (calculated as the time in years between the date of initial diagnosis and the date of starting sunitinib), histology, stage of the disease, Fuhrman grade, treatment for the primary renal cell carcinoma (nephrectomy, radiotherapy or other), time since diagnosis of the 1st metastases (calculated as the time in years between the date of diagnosis of the 1st metastases and the date of starting sunitinib) and site of the metastases;
- **Past medical history**: Previous or ongoing comorbidities (diabetes, thyroid, etc.);
- **Hematologic and biochemical profile before starting sunitinib**: Time since the laboratory profile (in days), values of indices assessed (hemoglobin, platelets, LDH, etc.), abnormal values for other indices (hematocrit, leucocytes, etc.);
- **Other investigations performed**: Blood pressure, electrocardiogram (ECG), echocardiogram and previous orodental examination;
- **Concomitant symptomatic or preventative treatments**: Antiemetic or anti-diarrheal treatment, anti-neutropenic treatment, etc.;
- **Treatment supportive measures**: Person delivering the information on treatment, issuing of materials/support or document to the patient.

8.2.3. **Description of patients during the follow-up period**

Populations analyzed:

- Safety population: Call Center (all data) and standard follow-up (main data)

Analysis:

On an exploratory basis, before the analysis of the study objectives, the patients will be described from the data completed during the follow-up period by the investigating doctor:

- **Tumor assessment:** Radiologic investigation, response to treatment;
- **Clinical parameters:** ECOG, Karnofsky index and blood pressure;
- **Hematologic and biochemical profile:** Values of the indices measured (hemoglobin, calcium, etc.) and abnormal values for other indices (hematocrit, leucocytes, etc.);
- **Symptoms and tolerability:** Development of AEs: gastrointestinal or cardiac problems, etc.; Description serious AEs and non-serious AEs.
- **Concomitant, symptomatic or preventative treatments:** Prescription of another additional anti-tumor treatment, antiemetic treatment, anti-diarrheal treatment, etc.;
- **Planned and unplanned medical procedures:** number of calls, consultations and hospitalizations performed, specialty of the health professional in the event of calls or consultations, duration of hospitalization, reason for the medical procedure (AE or other) and actions implemented;
- **Measures to support treatment when treatment is continued:** Person delivering the information about treatment, issuing of materials/supports or documents to the patient.

The data listed above will be described for each follow-up time (end of cycle 1, 2 and 4).

8.2.4. **Analysis of the primary end point**

Analysis population: Safety population

The proportion of patients with at least one grade 3 or 4 AE whether or not related to sunitinib, will be estimated.

All of the grades 3 or 4 AEs defined by the 'Common Terminology Criteria for Adverse Events' (CTCAE v4.03 of June 2010), whether or not related to sunitinib, will be included when these occur during the study follow-up period (up to the end of the 4th treatment cycle or until the treatment is stopped if it is discontinued in the 1st, 2nd or 3rd cycle). All of the AEs will be included whether these are declared by the doctor or by the nurse.

The analyses will be performed both on an overall basis and according to the number of calls made by the call center.

Sensitivity analyses:

The sensitivity analyses will be performed:

- Sensitivity to duration of patient treatment: the results will also be expressed as standardized grade 3 or 4 AE rates developed by the patient and reported over the 6 months of treatment. These rates will be defined by each patient as the number of events which occurred/number of treatment months with sunitinib/ 6).

Secondary analysis:

- **The incidence of the main grade 3 or 4 AEs, whether or not related to sunitinib,** will also be presented in these patients according to the MedDRA SOC (System Organ Class) and PT (Preferred Term) classification. Only categories involving at least 2% of patients will be presented.

8.2.5. **Analysis of the secondary end points**

8.2.5.1. Sunitinib treatment

Populations analyzed: Safety population

End points:

The analysis of sunitinib treatment methods will be carried out using the following indicators:

- **Description of dose reductions**
  - Proportion of patients with at least one dose reduction during the period of sunitinib treatment;
  - Reasons for the dose reduction: Proportion of patients involved on at least one occasion for each of the reasons for a dose reduction;
  - Average dose reduction.

- **Description of interruptions to treatment**
  - Proportion of patients who interrupted sunitinib treatment temporarily during treatment (including declared temporary interruptions and cases in which the start of the later cycle was deferred);
  - Mean duration (in days) of interruptions to treatment by patient (declared duration of interruption or number of days delay identified for the start of the subsequent cycle);
  - Reason for interruptions: Proportion of patients involved on at least one occasion for each of the reasons for interruption of treatment (AE, radiotherapy, surgery or other).

- **Description of permanent treatment discontinuations**
  - Proportion of patients who discontinued sunitinib permanently;
  - Reason for discontinuation: proportion of patients involved on at least one occasion for each of the reasons for discontinuation;
  - Duration of treatment with sunitinib: time between starting sunitinib and the notified date to discontinue it or the date of the last consultation if sunitinib treatment was not stopped;
  - Number of treatment cycles before discontinuation.

The analysis will be performed both on an overall basis and according to the number of calls made by the call center.

8.2.5.2. Number of unplanned medical procedures, whether or not related to Sunitinib

Analysis population: Safety population

Analysis:

The purpose of estimating the number of unplanned medical procedures particularly involves those unplanned consultations and hospitalizations, whether or not related to sunitinib and declared at each follow-up visit.

At each theoretical follow-up time (end of cycles 1, 2 and 4 and overall), the following indicators will be described on an overall basis:

- Proportion with at least 1 consultation, at least 1 hospitalization, resulting in at least 1 planned or unplanned call to a health professional;
- Average number of consultations and hospitalizations (two different indicators) both planned and unplanned and the total number per cycle per patient;
- Total number of consultations and hospitalizations (single indicator) by cycle during sunitinib treatment. The number of planned, unplanned and the total number of calls to a health professional by cycle, by patient will also be described for descriptive purposes.

The analysis will be performed on an overall basis and by the number of calls made by the call center.

8.2.5.3. Adherence to treatment

Population analyzed: Safety population

Analysis:

Adherence to sunitinib treatment will be assessed from the standardized, validated, Morisky self-completed questionnaire (MMAS-4: 4-item Morisky Medication Adherence Scale), completed by the patients at the 6 wee follow-up visit in cycles 1, 2 and 4. This questionnaire consists of 4 items each with two response options “Yes” and “No”.

An **MMAS-4 score** will be calculated as the number of “Yes” responses and will be between 0 and 4, a low score representing improved adherence. The score will be missing if one of the items has not been completed.

A classification using the MMAS-4 score will be used to categorize adherence into levels [3; 4]:

- High adherence: score of 0;
- Average adherence: score of 1 or 2;
- Poor adherence: score of 3 or 4.

At each measurement time (end of cycles 1, 2 and 4), the following indicators will be described:

- **average adherence score;**
- **proportion of patients by a patient adherence level;**
- **the proportion of “adherent” patients,** defined as patients with an MMAS score of 0 and the proportion of “non-adherent” patients as patients with a score of at least 1 [6].
- **An assessment of patient behavior in terms of their treatment when they develop an AE (binary indicator (Yes/No) for reduction or adjustment of treatment).**

In order to examine the change in adherence by patient, the mean difference in patient score between the assessment at the end of cycle 1 and the assessment at cycle 4 will be described.

The analysis will be performed on an overall basis and by the number of calls made by the call center.

In addition and only for informative purposes, the Morisky questionnaire will also be completed through the call center during the call on W4 of cycles 1, 2 and 4 and in the "Call Center" group. This assessment will be used:

- firstly to measure adherence at the end of the 4th week of treatment (immediately before the treatment break) from the derived criteria described above (average score, proportion of adherent patients);

- secondly, to estimate (subject to sufficient numbers being available) good consistency between patient declarations between the measurement on W4 and the consultation on W6 during which the patient will complete his/her self-administered questionnaire.

Concordance will only be measured for informative purposes as the questionnaire has been validated for self-completion by the patient him/herself and not as one administered by a third party (potential declaration bias concerning the issue of adherence).

The MMAS-4 score ranges from 0 to 4 (discrete quantitative variable), and can be considered to be qualitative index. Consistency between adherence at week 4 assessed by telephone and adherence at week 6 assessed in writing will be considered using the Kappa coefficient.

8.2.5.4. Response to sunitinib treatment

Analysis population: FAS population

Analysis:

The response to treatment will be assessed by the investigator based on RECIST v1.1 criteria (complete response, partial response, stable disease or progression) and will be described at each follow-up time (at the end of cycles 1, 2 and 4) (cf. section 8.2.3. Description of patients during the follow-up period).

The best response obtained during treatment with sunitinib will be identified from the responses assessed according to RECIST v1.1 criteria. "Unevaluable" responses will not be included in the definition of the best response.

The proportion of patients with a complete or partial best response during the follow-up period (objective response rate) will be estimated.

The last response assessed during the study will also be estimated.

The analysis will be performed on an overall basis and by the number of calls made by the call center.

Analysis of response will also be assessed on the FAS population imputing missing data points by failure (= progression).

8.2.5.5. Telephone calls made

Analysis population:

- FAS population, regardless of the number of calls completed.
- All calls made.

Analysis:

The average number of planned, unplanned and the total number of calls made per patient will be presented on an overall basis and by treatment cycle.

The conduct of the telephone calls will be described using the following indicators:

- **Action taken by the patient;**
- **And/or action taken by the doctor;**
- **Declaration of adverse events;**
- **Action taken by the call center.**

8.2.5.6. Doctor satisfaction with the call center

Analysis population: FAS population for which the Doctors have completed a satisfaction questionnaire

Analysis:

The doctor's satisfaction with the call center will be assessed from the doctor satisfaction questionnaire which will be completed by the doctors at the end of the follow-up period.

This questionnaire, which has been constructed for the study, is made up of 5 questions with responses in the form of a semantic odd number measurement scale (5 modalities: "Very unsatisfied", "satisfied", "not particularly satisfied", "unsatisfied" and "no opinion"), including 3 satisfaction dimensions (overall satisfaction, satisfaction with the advice given and satisfaction with the management).

Each response is allocated a positive or negative score (+2, +1, -1, -2 and no score) respectively allowing a quantitative score to be established for each item. A score will be calculated for each dimension of the questionnaire by calculating the mean scores obtained for each item if at least 50% of the items for the dimension have been completed (and are not "no opinion").

The doctor's satisfaction with the call center will be assessed from:

- **The mean score for each dimension:** A radar plot with 3 axes will be proposed in order to simultaneously show the mean scores for each dimension. In this type of display, the mean scores are linked together and form a polygon. The area of the polygon will be described and the ratio between the area of the polygon and the ratio of the ideal polygon (complete coverage of the radar plot) will be used to assess the percentage surface area covered. A high area represents better general satisfaction.

- **The proportion of doctors who reported themselves as being "Very satisfied" or "Satisfied"** overall with management by the call center (5^{th} item of the questionnaire).

  These doctors will be described by sex, age and number of patients in the CC arm before being involved with the call center when at least 50% of the planned calls are completed.

8.2.5.7. Patient satisfaction with the call center

Analysis population: FAS population included in the Call Center arm who completed a self-administered satisfaction questionnaire.

Analysis:

The patient satisfaction analysis with the call center will be assessed from the self-administered satisfaction questionnaire completed at the end of the study by each patient in the CC arm. This questionnaire together with the doctor questionnaire has been created for this study.

The questionnaire contains 8 items, and is theoretically completed during the final visit at week 6 of cycle 4. For patients who stop their treatment at the end of cycles 1, 2 or 3, the questionnaire will be completed in the last follow-up visit performed (the visit in which discontinuation of treatment is notified).

Definition of scores by dimension (overall satisfaction with advice, satisfaction with the service and satisfaction with the management) will be similar to what is described in the previous section "doctor satisfaction with the call center".

Patient satisfaction with the call center will be assessed from:

- **The mean scores for each dimension;** a radar plot with 4 axes will be proposed in order to simultaneously represent the mean scores for each dimension. In the same manner as for the assessment of doctor's satisfaction, the area of the polygon and percentage of subjects covered will be described.
- **The proportion of patients who reported themselves as being "Very satisfied" or "Satisfied"** overall with the support offered by the call center (8th item of the questionnaire).

  These patients will be described by their major characteristics when they started sunitinib (sex, age, ECOG score, etc.).

8.2.6. **Pharmacovigilance**

Analysis population: Safety population

Analysis:

The proportion of patients who develop at least one adverse event whether or not related to Sunitinib will be described.

All of the adverse events declared during the study will be described from:

- Their title (coded according to MedDRA);
- The time (in days) between starting sunitinib and the onset of the AE;
- The severity of the adverse effect;
- Its grade;
- Impact on everyday activities;
- Causality;
- Corrective medical action;
- Last actions taken for sunitinib during the AE.

Before the database is frozen, the listing of AEs and SAEs will be provided to the Pfizer Company, in order to undertake a reconciliation between the Kappa Santé and the Pfizer data.

The pharmacovigilance indicators described above will be provided for each of the following AE groups:

- All of the AEs (regardless of severity);
- Non-serious AEs;
- Serious AEs.

8.2.7. **Listings**

Patient listings will be provided in the annex to the statistical report when specific cases exist such as the following situations:

- Patients excluded from the analysis (Patient no. + reason for exclusion);
- Patients with AEs and SAEs;
- Patients with dosage reductions, changes, interruptions or discontinuation.

9. RESULTS

9.1. Numbers

9.1.1. Investigators

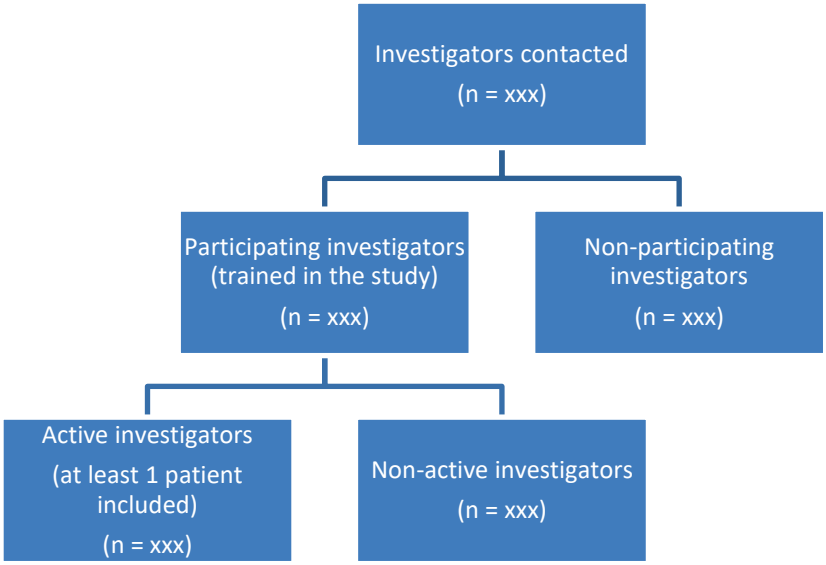


Figure 2: Numbers of investigators

The active centers included an average of xx patients into the study (min: xx; max: xx).

Table 4: Characteristics of participating and non-participating investigators

		Participating investigators	
		Yes (N=xxx)	**No (N=xxx)**
Geographical region*	PPD	xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
Facility	General Hospital	xx (xx%)	xx (xx%)
	University Hospital	xx (xx%)	xx (xx%)
	Private Clinic	xx (xx%)	xx (xx%)
	Cancer Center	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)
	Not stated	xx -	xx -

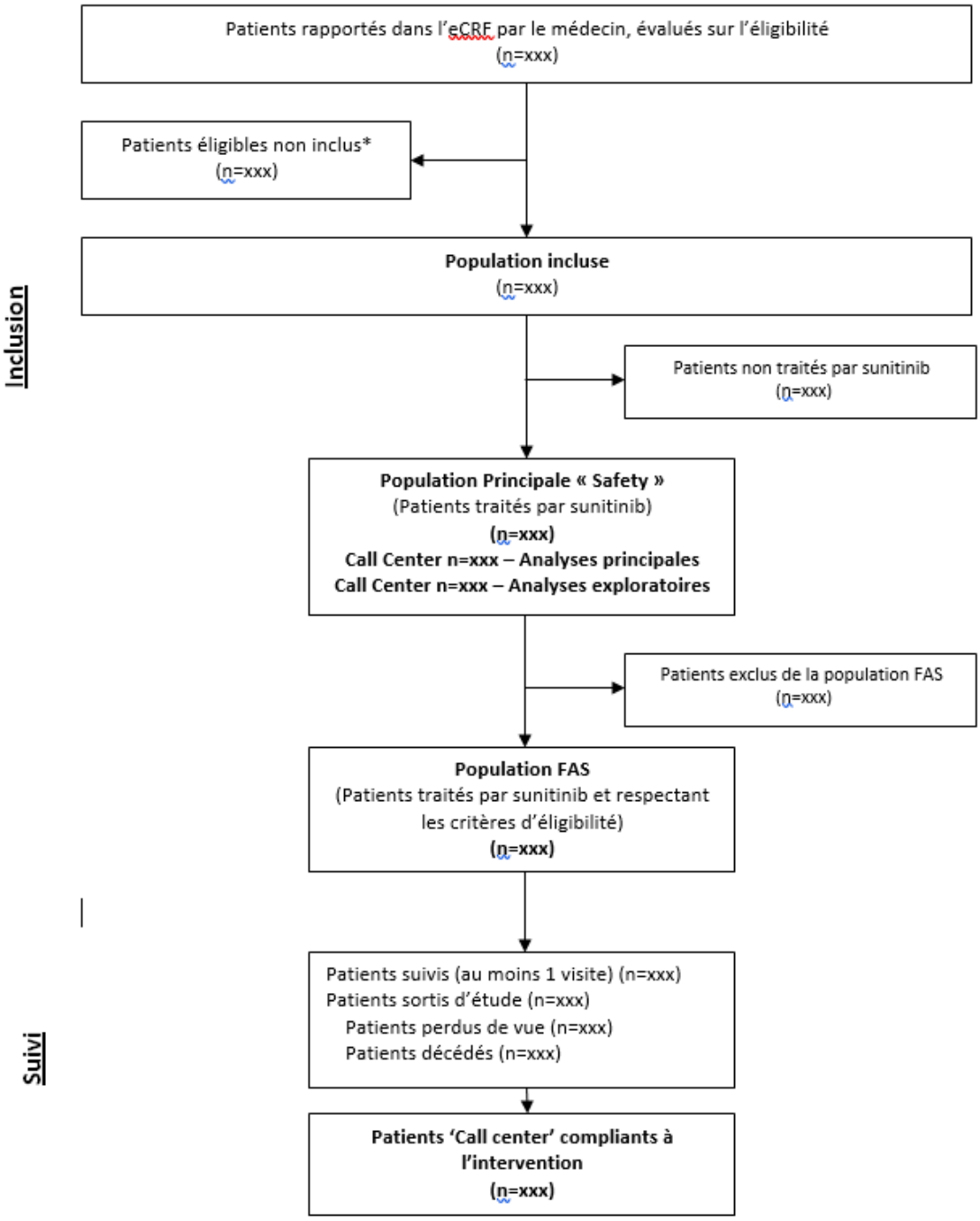
* Derived from the center post code (cf. annex 1)

Table 5: Characteristics of active investigators

		Active investigators	
		Yes (N=xxx)	**No (N=xxx)**
Geographical region*	PPD	xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
		xx (xx%)	xx (xx%)
Facility	General Hospital	xx (xx%)	xx (xx%)
	University Hospital	xx (xx%)	xx (xx%)
	Private Clinic	xx (xx%)	xx (xx%)
	Cancer Center	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)
	Not stated	xx -	xx -
Type of practice	Primary Care	xx (xx%)	xx (xx%)
	Hospital	xx (xx%)	xx (xx%)
	Mixed	xx (xx%)	xx (xx%)
	Not stated	xx -	xx -
Urban environment	Yes	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)
	Not stated	xx -	xx -
Sex	Male	xx (xx%)	xx (xx%)
	Female	xx (xx%)	xx (xx%)
	Not stated	xx -	xx -
Age (years)	Number analyzed	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)
	Median	xx	xx
	Min-Max	xx - xx	xx - xx

* Derived from the center post code (cf. annex 1)

9.1.2. **Patients**



*Non-inclusion register

Figure 3: Flow-chart of patient numbers during the study

Table 6: Reasons for non-inclusion of patients entered into the non-inclusion register

		Non-included patients (N=xxx)
Reason for non-inclusion	Patient refusal	xx (xx%)
	Other	xx (xx%)
	Details	xx (xx%)

Table 7: Characteristics of included and non-included patients

		Patients included	
		Yes (N=xxx)	**No (N=xxx)**
Characteristics at inclusion			
Age (years)	Number analyzed	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)
	Median	xx	xx
	Q1-Q3	xx - xx	xx - xx
	Min-Max	xx - xx	xx - xx
Sex	Male	xx (xx%)	xx (xx%)
	Female	xx (xx%)	xx (xx%)
ECOG score	0	xx (xx%)	xx (xx%)
	1	xx (xx%)	xx (xx%)
	2	xx (xx%)	xx (xx%)
	3	xx (xx%)	xx (xx%)
	4	xx (xx%)	xx (xx%)
	Not stated	xx (xx%)	xx (xx%)

Table 8: Description of patient follow-up

		Standard follow-up (N=xxx)	**Call Center (N=xxx)**	**Total (N=xxx)**
Follow-up time (weeks) (time between inclusion and date of last follow-up consultation)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Q1-Q3	xx - xx	xx - xx	xx - xx
	Min-Max	xx - xx	xx - xx	xx - xx
Number of treatment cycles per patient	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Mean duration of cycles 1 (days)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Mean duration of cycles 2 (days)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Mean duration of cycles 3 (days)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Mean duration of cycles 4 (days)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Number of follow-up consultations carried out per patient	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Number of calls	Number analyzed	-	xxx	-
	Mean (±SD)	-	xx (± xx)	-

		Standard follow-up (N=xxx)	Call Center (N=xxx)	Total (N=xxx)
	Median	-	xx	-
	Min-Max	-	xx - xx	-

Table 9: Inclusion characteristics of patients who were followed up and those who were not followed up

		Followed up		Total (N=xxx)
		Yes (N=xxx)	No (N=xxx)	
Characteristics at inclusion				
Age (years)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Sex	Male	xx (xx%)	xx (xx%)	xx (xx%)
	Female	xx (xx%)	xx (xx%)	xx (xx%)
ECOG score	0	xx (xx%)	xx (xx%)	xx (xx%)
	1	xx (xx%)	xx (xx%)	xx (xx%)
	2	xx (xx%)	xx (xx%)	xx (xx%)
	3	xx (xx%)	xx (xx%)	xx (xx%)
	4	xx (xx%)	xx (xx%)	xx (xx%)
	Not stated	xx -	xx -	xx -
Risk score – Heng criteria	Good	xx (xx%)	xx (xx%)	xx (xx%)
	Intermediary	xx (xx%)	xx (xx%)	xx (xx%)
	Poor	xx (xx%)	xx (xx%)	xx (xx%)
	Not available	xx (xx%)	xx (xx%)	xx (xx%)
Fuhrman grade	I	xx (xx%)	xx (xx%)	xx (xx%)
	II	xx (xx%)	xx (xx%)	xx (xx%)
	III	xx (xx%)	xx (xx%)	xx (xx%)
	IV	xx (xx%)	xx (xx%)	xx (xx%)
Metastatic renal cell carcinoma grade	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Previous or current comorbidities	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)

9.2. Description of the population when sunitinib treatment is started

9.2.1. **Sociodemographic characteristics**

Table 10: Sociodemographic characteristics of patients (safety population) at inclusion

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Age (years)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Q1-Q3	xx - xx	xx - xx	xx - xx
	Min-Max	xx - xx	xx - xx	xx - xx
Sex	Male	xx (xx%)	xx (xx%)	xx (xx%)
	Female	xx (xx%)	xx (xx%)	xx (xx%)

9.2.2. **Clinical Characteristics**

Table 11: Clinical characteristics of patients (safety population) at inclusion

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Body Mass Index (BMI)	Lean: < 18,5	xx (xx%)	xx (xx%)	xx (xx%)
	Normal body weight: [18,5; 25[	xx (xx%)	xx (xx%)	xx (xx%)
	Overweight: [25; 30[	xx (xx%)	xx (xx%)	xx (xx%)
	Obese: ≥ 30	xx (xx%)	xx (xx%)	xx (xx%)
ECOG score	0	xx (xx%)	xx (xx%)	xx (xx%)
	1	xx (xx%)	xx (xx%)	xx (xx%)
	2	xx (xx%)	xx (xx%)	xx (xx%)
	3	xx (xx%)	xx (xx%)	xx (xx%)
	4	xx (xx%)	xx (xx%)	xx (xx%)
Karnofsky index scored	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes, Karnofsky index	100%	xx (xx%)	xx (xx%)	xx (xx%)
	90% - 80%	xx (xx%)	xx (xx%)	xx (xx%)
	70% - 60%	xx (xx%)	xx (xx%)	xx (xx%)
	50% - 40%	xx (xx%)	xx (xx%)	xx (xx%)
	30% - 10%	xx (xx%)	xx (xx%)	xx (xx%)
	0%	xx (xx%)	xx (xx%)	xx (xx%)
Risk score – Heng et al. criteria	Good	xx (xx%)	xx (xx%)	xx (xx%)
	Intermediary	xx (xx%)	xx (xx%)	xx (xx%)
	Poor	xx (xx%)	xx (xx%)	xx (xx%)
	Not available	xx (xx%)	xx (xx%)	xx (xx%)

9.2.3. **History of the disorder**

Table 12: Description of the patients' primary renal cell carcinoma (safety population) at inclusion

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Time since initial diagnosis of the primary renal cell carcinoma (years)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Histology	Clear cell carcinoma	xx (xx%)	xx (xx%)	xx (xx%)
	Tubulo-papillary carcinoma	xx (xx%)	xx (xx%)	xx (xx%)
	Type I	xx (xx%)	xx (xx%)	xx (xx%)
	Type II	xx (xx%)	xx (xx%)	xx (xx%)
	Chromophobe cell carcinoma	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)
	…			
Mixed tumor	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes, predominant tumor	Details	xx (xx%)	xx (xx%)	xx (xx%)
	…	xx (xx%)	xx (xx%)	xx (xx%)
Status of disease – TNM Classification	T0	xx (xx%)	xx (xx%)	xx (xx%)
	T1	xx (xx%)	xx (xx%)	xx (xx%)
	T2	xx (xx%)	xx (xx%)	xx (xx%)
	T3	xx (xx%)	xx (xx%)	xx (xx%)
	T4	xx (xx%)	xx (xx%)	xx (xx%)
	Tx	xx (xx%)	xx (xx%)	xx (xx%)
	ND	xx (xx%)	xx (xx%)	xx (xx%)
	N0	xx (xx%)	xx (xx%)	xx (xx%)
	N1	xx (xx%)	xx (xx%)	xx (xx%)
	N2	xx (xx%)	xx (xx%)	xx (xx%)
	Nx	xx (xx%)	xx (xx%)	xx (xx%)
	ND	xx (xx%)	xx (xx%)	xx (xx%)
	M0	xx (xx%)	xx (xx%)	xx (xx%)
	M1	xx (xx%)	xx (xx%)	xx (xx%)
	Mx	xx (xx%)	xx (xx%)	xx (xx%)
	ND	xx (xx%)	xx (xx%)	xx (xx%)
Fuhrman grade	I	xx (xx%)	xx (xx%)	xx (xx%)
	II	xx (xx%)	xx (xx%)	xx (xx%)
	III	xx (xx%)	xx (xx%)	xx (xx%)
	IV	xx (xx%)	xx (xx%)	xx (xx%)

Table 13: Description of the treatment of the patients' primary renal cell carcinoma (safety population) at inclusion

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Nephrectomy	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Radiotherapy	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Other treatment for cancer	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If other, treatment	Details	xx (xx%)	xx (xx%)	xx (xx%)
	…	xx (xx%)	xx (xx%)	xx (xx%)

Table 14: Description of the patients' advanced/metastatic renal cell carcinoma (safety population) at inclusion

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Metastatic renal cell carcinoma grade	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes				
Time since development of 1st metastases (years)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Number of different metastatic sites involved	Number analyzed	xx (xx%)	xx (xx%)	xx (xx%)
	Mean (±SD)	xx (xx%)	xx (xx%)	xx (xx%)
	Median	xx (xx%)	xx (xx%)	xx (xx%)
	Min-Max	xx (xx%)	xx (xx%)	xx (xx%)
Site of metastases	Lung	xx (xx%)	xx (xx%)	xx (xx%)
	Bone	xx (xx%)	xx (xx%)	xx (xx%)
	Mediastinum	xx (xx%)	xx (xx%)	xx (xx%)
	Liver	xx (xx%)	xx (xx%)	xx (xx%)
	Retroperitoneal lymph nodes	xx (xx%)	xx (xx%)	xx (xx%)
	Supra-clavicular lymph nodes	xx (xx%)	xx (xx%)	xx (xx%)
	Adrenal	xx (xx%)	xx (xx%)	xx (xx%)
	Nephrectomy cavity	xx (xx%)	xx (xx%)	xx (xx%)
	Kidney	xx (xx%)	xx (xx%)	xx (xx%)
	Brain	xx (xx%)	xx (xx%)	xx (xx%)
	Skin	xx (xx%)	xx (xx%)	xx (xx%)
	Peritoneum	xx (xx%)	xx (xx%)	xx (xx%)
	Gastro-intestinal	xx (xx%)	xx (xx%)	xx (xx%)
	Pancreas	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)
	…			
If brain metastases, tumor untreated and/or symptomatic	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)

9.2.4. **Past medical history and comorbidities**

Table 15: Past medical history and previous or current comorbidities of patients (safety population) at inclusion

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Comorbidities either previously or at the time of inclusion	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes, type (several options possible)	Diabetes	xx (xx%)	xx (xx%)	xx (xx%)
	Thyroid	xx (xx%)	xx (xx%)	xx (xx%)
	Hypothyroidism	xx (xx%)	xx (xx%)	xx (xx%)
	Hyperthyroidism	xx (xx%)	xx (xx%)	xx (xx%)
	CVA	xx (xx%)	xx (xx%)	xx (xx%)
	Hypertension	xx (xx%)	xx (xx%)	xx (xx%)
	Myocardial infarction	xx (xx%)	xx (xx%)	xx (xx%)
	Deep venous thrombosis	xx (xx%)	xx (xx%)	xx (xx%)
	Angina pectoris	xx (xx%)	xx (xx%)	xx (xx%)
	Renal impairment	xx (xx%)	xx (xx%)	xx (xx%)
	Hepatic impairment	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)
Comorbidities ongoing at the time inclusion	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes, type (several options possible)	Diabetes	xx (xx%)	xx (xx%)	xx (xx%)
	Thyroid	xx (xx%)	xx (xx%)	xx (xx%)
	Hypothyroidism	xx (xx%)	xx (xx%)	xx (xx%)
	Hyperthyroidism	xx (xx%)	xx (xx%)	xx (xx%)
	CVA	xx (xx%)	xx (xx%)	xx (xx%)
	Hypertension	xx (xx%)	xx (xx%)	xx (xx%)
	Myocardial infarction	xx (xx%)	xx (xx%)	xx (xx%)
	Deep venous thrombosis	xx (xx%)	xx (xx%)	xx (xx%)
	Angina pectoris	xx (xx%)	xx (xx%)	xx (xx%)
	Renal impairment	xx (xx%)	xx (xx%)	xx (xx%)
	Hepatic impairment	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)

Table 16: Treatments being received at inclusion for ongoing comorbidities (safety population)

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Ongoing treatments (several options possible)	For:			
	Diabetes	xx (xx%)	xx (xx%)	xx (xx%)
	Thyroid	xx (xx%)	xx (xx%)	xx (xx%)
	Hypothyroidism	xx (xx%)	xx (xx%)	xx (xx%)
	Hyperthyroidism	xx (xx%)	xx (xx%)	xx (xx%)
	CVA	xx (xx%)	xx (xx%)	xx (xx%)
	Hypertension	xx (xx%)	xx (xx%)	xx (xx%)
	Myocardial infarction	xx (xx%)	xx (xx%)	xx (xx%)
	Deep venous thrombosis	xx (xx%)	xx (xx%)	xx (xx%)
	Angina pectoris	xx (xx%)	xx (xx%)	xx (xx%)
	Renal impairment	xx (xx%)	xx (xx%)	xx (xx%)
	Hepatic impairment	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)

9.2.5. **Hematologic and biochemical profile**

Table 17: Hematologic profile before starting the Sunitinib (safety population)

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Length of history (in months) from the last laboratory assessment	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Hematologic profile				
Hemoglobin	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (g/dL)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Neutrophils	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (mm^3)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Platelets	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (10^9/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx

Table 18: Biochemical profile before starting Sunitinib (safety population)

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Length of history (in months) from the last laboratory assessment	Number analyzed	xx (xx%)	xx (xx%)	xx (xx%)
	Mean (±SD)	xx (xx%)	xx (xx%)	xx (xx%)
	Median			
	Min-Max			
Biochemical profile				
Creatinine, (mg/dL)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
ALT (SGPT) (U/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
AST (SGOT) (U/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Bilirubin (mg/dL)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Calcium	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (mmol/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Albumin	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (g/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
LDH	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (IU/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx

Table 19: Abnormal values for other hematologic and biochemical indices before starting Sunitinib (safety population)

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Abnormal values for biological indices	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes,				
Hematologic profile				
Hematocrit	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (%)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Leucocytes	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (10^9/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Biochemical profile				
Alkaline phosphatase	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (U/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
TSH	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (mU/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
fT3	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (pmol/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
fT4	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (pmol/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Sodium	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (mmol/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Potassium	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (mmol/L)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx

9.2.6. **Other investigations**

Table 20: Other patient investigations (safety population) at inclusion

		Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Blood pressure	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes,		xxx	xxx	xxx
Systolic value (mmHg)	Number analyzed			
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Diastolic value (mmHg)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Electrocardiogram (ECG)	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes,				
Result normal	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If abnormal,	Atrial fibrillation (AF)	xx (xx%)	xx (xx%)	xx (xx%)
(several responses are possible)	Ventricular dysrhythmias	xx (xx%)	xx (xx%)	xx (xx%)
	Atrio-ventricular block (AVB)	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)
	…			
Echocardiography	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes,				
Result normal	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If abnormal,	Details	xx (xx%)	xx (xx%)	xx (xx%)
	…			
Orodental examination	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes,		xx (xx%)	xx (xx%)	xx (xx%)
Result	Normal	xx (xx%)	xx (xx%)	xx (xx%)
	Abnormal	xx (xx%)	xx (xx%)	xx (xx%)

9.2.7. **Concomitant treatments at inclusion**

Table 21: Symptomatic or preventative treatments prescribed (safety population) at inclusion

	Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Symptomatic or preventative treatments prescribed in the 1st visit			
Antiemetic treatment	xx (xx%)	xx (xx%)	xx (xx%)
Anti-diarrheal treatment	xx (xx%)	xx (xx%)	xx (xx%)
Anti-neutropenic treatment	xx (xx%)	xx (xx%)	xx (xx%)
Anti-hypertensive treatment	xx (xx%)	xx (xx%)	xx (xx%)
Mouthwashes and local anesthetics	xx (xx%)	xx (xx%)	xx (xx%)
Emollients, moisturizing creams	xx (xx%)	xx (xx%)	xx (xx%)
Analgesics	xx (xx%)	xx (xx%)	xx (xx%)
Anti-gastro-esophageal reflux treatment	xx (xx%)	xx (xx%)	xx (xx%)
Bisphosphonates	xx (xx%)	xx (xx%)	xx (xx%)
Other additional anti-tumor treatment	xx (xx%)	xx (xx%)	xx (xx%)
Details	xx (xx%)	xx (xx%)	xx (xx%)
…			
Other prescriptions	xx (xx%)	xx (xx%)	xx (xx%)
Details	xx (xx%)	xx (xx%)	xx (xx%)
…			

9.2.8. **Supportive measures for sunitinib treatment at initiation**

Table 22: Supportive measures for sunitinib treatment (safety population) at initiation

	Call Center (N=xxx)	Standard (N=xxx)	Total (N=xxx)
Information received by the patient when sunitinib treatment was started (several options possible)			
By the investigator him/herself	xx (xx%)	xx (xx%)	xx (xx%)
By the care team	xx (xx%)	xx (xx%)	xx (xx%)
Nurse	xx (xx%)	xx (xx%)	xx (xx%)
Pharmacist	xx (xx%)	xx (xx%)	xx (xx%)
Intern	xx (xx%)	xx (xx%)	xx (xx%)
CRA	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)
By an information leaflet or other support/material/document given to the patient	xx (xx%)	xx (xx%)	xx (xx%)
Details of support	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)
Details	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)

9.3. Description of patients during the follow-up period

9.3.1. **Change in treatment with sunitinib (dose/dosage regimen)**

Table 23: Description of changes to treatment with sunitinib in terms of dosage and dosage regimen (safety population - Call Center)

		Cycle 1 (N=xxx)	Cycle 2 (N=xxx)	Cycle 3 (N=xxx)	Cycle 4 (N=xxx)	Call center (N=xxx)
At least 1 change in dose during treatment with sunitinib	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Type (several options possible)	Reduction	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Increase	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
At least 1 change in dosage regiment during treatment with sunitinib	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
New regimen	Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	…	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Reasons for changing (patients involved at least once for each of the possible reasons)	AE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

9.3.2. **Tumor assessments during the follow-up period**

Table 24: Tumor assessments (safety population - Call Center) during the follow-up period

		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
Tumor assessment since the last visit	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
<u>If yes,</u>				
Radiologic investigation (several options possible)	CT	xx (xx%)	xx (xx%)	xx (xx%)
	MRI	xx (xx%)	xx (xx%)	xx (xx%)
	PET scan	xx (xx%)	xx (xx%)	xx (xx%)
	radiography	xx (xx%)	xx (xx%)	xx (xx%)
	Ultrasound	xx (xx%)	xx (xx%)	xx (xx%)
Response to treatment (RECIST v1.1 criteria)	CR (Complete response)	xx (xx%)	xx (xx%)	xx (xx%)
	PR (Partial response)	xx (xx%)	xx (xx%)	xx (xx%)
	SD (Stable disease)	xx (xx%)	xx (xx%)	xx (xx%)
	PD (Progressive disease)	xx (xx%)	xx (xx%)	xx (xx%)
	NE (Not evaluable)	xx (xx%)	xx (xx%)	xx (xx%)
<u>If not evaluable,</u> reason	Details	xx (xx%)	xx (xx%)	xx (xx%)
	…			

The assessment of the best response during treatment is shown in part 9.5.4., Response to treatment.

9.3.3. **Clinical indices during the follow-up period**

Table 25: Clinical indices (safety population - Call Center) during the follow-up period

		inclusion (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
ECOG performance index assessed	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
<u>If yes,</u> ECOG score	0	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	1	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	2	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	3	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	4	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Karnofsky index scored	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
<u>If yes,</u> Karnofsky index	100%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	90% - 80%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	70% - 60%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	50% - 40%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	30% - 10%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	0%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Blood pressure	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
<u>If yes,</u>					
Systolic value (mmHg)	Number analyzed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Mean (±SD)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Median	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Min-Max	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Diastolic value (mmHg)	Number analyzed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Mean (±SD)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Median	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Min-Max	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

9.3.4. **Hematologic and biochemical profile during the follow-up period**

Table 26: Hematologic and biochemical profile (safety population - Call Center) during the follow-up period

		inclusion (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
Hematologic profile					
Hemoglobin	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (g/dL)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Neutrophils	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (mm^3)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Platelets	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (10^9/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Biochemical profile					
Creatinine	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (mg/dL)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
ALT (SGPT)	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (U/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
AST (SGOT)	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

		inclusion (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
If value obtained, Value (U/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Calcium	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (mmol/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Albumin	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (g/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
LDH	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, Value (IU/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx

Table 27: Abnormal values for other hematologic and biochemical indices (safety population - Call Center) during the follow-up period

Patient in Call Center group		inclusion (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
Abnormal values for biological indices	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If yes,					
Hematologic profile					
Hematocrit	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (in%)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx

Patient in Call Center group		inclusion (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
Leucocytes	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (in 10^9/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Biochemical profile					
Alkaline phosphatase	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (in U/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Bilirubin	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (in mg/dL)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
TSH	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (in mU/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
fT3	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal,					

Patient in Call Center group		inclusion (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
Value (in pmol/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
fT4	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (in pmol/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Sodium	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (in mmol/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Potassium	Value obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Value not obtained	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Not performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If value obtained, abnormal result	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If result abnormal, Value (in mmol/L)	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx

9.3.5. **Symptoms during the follow-up period**

Table 28: Symptoms of patients who were followed up (safety population - Call Center) during the follow-up period

		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)	Overall during follow-up
Symptoms develop (several options possible)	Skin reactions or disorder	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Gastrointestinal disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Cardiac disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Bleeding disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Hematologic disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Infectious problems	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Pain	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Site	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	…				
	Endocrine disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Inflammatory disorders (mucitis, etc.)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	General disorders (asthenia, anorexia, etc.)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Development of other AE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	…				

9.3.6. **Supportive measures during follow-up period**

Table 29: Supportive measures for sunitinib treatment (safety population - call center follow-up) during the follow-up period, instituted by the doctor

Patient in Call Center group	Start of sunitinib (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
Information received by the patient when treatment with sunitinib was started (several options possible)				
No new information leaflet	--	xx (xx%)	xx (xx%)	xx (xx%)
By the investigator him/herself	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
By the care team	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Nurse	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Pharmacist	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Intern	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
CRA	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
by an information leaflet or any other support/material/ document given to the patient	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Details of support	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)			
Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

9.4. Analysis of the primary end point

Table 30: Development of AEs during the follow-up period (safety population)

		Number of calls received < xx (N=xxx)	Number of calls received ≥ xx (N=xxx)	Call center (N=xxx)
At least 1 grade 3 or 4 AE whether or not related to Sunitinib	Yes	xx (xx%) [xx; xx]	xx (xx%) [xx; xx]	xx (xx%) [xx; xx]
	No	xx (xx%)	xx (xx%)	xx (xx%)
Number of grade 3 or grade 4 AEs, whether or not related to Sunitinib per patient	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Standardized grade 3 or 4 AEs, whether or not related to Sunitinib per patient, reported over the 6 months of treatment	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx

Table 31: Description of grade 3 and 4 AEs related or unrelated to sunitinib recorded during the follow-up period (safety population)

		Number of calls received < xx (N=xxx)	Number of calls received ≥ xx (N=xxx)	Call center (N=xxx)
Type of grade 3 or 4 AEs, whether or not related to Sunitinib (SOC – MedDRA category)*	xxxx	xx (xx%)	xx (xx%)	xx (xx%)
	xxxx	xx (xx%)	xx (xx%)	xx (xx%)
	xxxx	xx (xx%)	xx (xx%)	xx (xx%)
Type of grade 3 or 4 AEs, whether or not related to Sunitinib (PT – MedDRA category)*	xxxx	xx (xx%)	xx (xx%)	xx (xx%)
	xxxx	xx (xx%)	xx (xx%)	xx (xx%)
	xxxx	xx (xx%)	xx (xx%)	xx (xx%)

* Categories involving at least 2% of patients

These tables are described for patients under standard follow-up also for exploratory purposes.

9.5. Analysis of the secondary end points

9.5.1. **Sunitinib treatment**

9.5.1.1. Dose reductions

Table 32: Description of dose reductions (safety population)

		Cycle 1 (N=xxx)	Cycle 2 (N=xxx)	Cycle 3 (N=xxx)	Cycle 4 (N=xxx)	Call center (N=xxx)
At least 1 dose reduction during treatment with sunitinib	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Reason for dose reductions (patients involved on at least 1 occasion for each of the possible reasons)	AE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

The average dose reductions were xx mg/day (+/- xx).

Table 33: Dose reductions made depending on the number of calls received (safety population)

		Number of calls received < xx (N=xxx)	Number of calls received ≥ xx (N=xxx)	Call center (N=xxx)
At least 1 dose reduction during treatment with sunitinib	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Reason for dose reductions (patients involved on at least 1 occasion for each of the possible reasons)	AE	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)

9.5.1.2. Temporary interruptions of sunitinib treatment

Table 34: Description of temporary interruption of sunitinib treatment during the follow-up period (safety population)

		Cycle 1 (N=xxx)	Cycle 2 (N=xxx)	Cycle 3 (N=xxx)	Cycle 4 (N=xxx)	Call Center (N=xxx)
At least 1 temporary interruption of sunitinib treatment	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Mean duration of interruption (in days)	Number analyzed	xxx	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
Reason for interruption (patients involved once for each of the possible reasons)	AE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Radiotherapy	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Surgery	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Table 35: Temporary interruption of sunitinib treatment during the follow-up period depending on number of calls received (safety population)

		Number of calls received < xx (N=xxx)	Number of calls received ≥ xx (N=xxx)	Call center (N=xxx)
At least 1 temporary interruption of sunitinib treatment	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Reason for interruption (patients involved once for each of the possible reasons)	AE	xx (xx%)	xx (xx%)	xx (xx%)
	Radiotherapy	xx (xx%)	xx (xx%)	xx (xx%)
	Surgery	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)

9.5.1.3. Discontinuation of sunitinib treatment

Table 36: Description of discontinuations of sunitinib treatment during the follow-up period (safety population)

		Number of calls received < xx (N=xxx)	Number of calls received ≥ xx (N=xxx)	Call center (N=xxx)
Patients who stopped sunitinib	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Reason for stopping sunitinib	Progressive disease	xx (xx%)	xx (xx%)	xx (xx%)
	Toxicity	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)
	Intercurrent disease	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)
	Patient choice	xx (xx%)	xx (xx%)	xx (xx%)
	Doctor choice	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)
	Died	xx (xx%)	xx (xx%)	xx (xx%)
	Other	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)
Number of cycles before discontinuation	1	xx (xx%)	xx (xx%)	xx (xx%)
	2	xx (xx%)	xx (xx%)	xx (xx%)
	3	xx (xx%)	xx (xx%)	xx (xx%)
	4	xx (xx%)	xx (xx%)	xx (xx%)
Duration of treatment (months)	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Duration of treatment <u>if stopped (months)</u>	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx

9.5.2. **Number of unpredicted medical procedures either related or unrelated to sunitinib**

Table 37: Requirements for medical procedures by cycle during the follow-up period (safety population)

		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)	Call Center (N=xxx)
At least 1 consultation	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If yes, at least 1	Planned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Unplanned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
At least 1 hospitalization	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If yes, at least 1	Planned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Unplanned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
At least 1 hospitalization and 1 consultation	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
At least 1 call to a health professional	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If yes, at least 1	Planned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Unplanned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Table 38: Number of medical procedures per cycle during the follow-up period (safety population)

Subject to sufficient numbers		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)	Call Center (N=xxx)
Requirement for consultations					
Number of planned consultations performed per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Number of unpredicted consultations performed per cycle	**Number analyzed**	**xxx**	**xxx**	**xxx**	**xxx**
	Mean (±SD)	**xx (± xx)**	**xx (± xx)**	**xx (± xx)**	**xx (± xx)**
	Median	**xx**	**xx**	**xx**	**xx**
	Min-Max	**xx - xx**	**xx - xx**	**xx - xx**	**xx - xx**
Total number of consultations performed per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Requirement for hospitalizations					
Number of planned hospitalizations performed per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Total number of hospitalizations performed per cycle	**Number analyzed**	**xxx**	**xxx**	**xxx**	**xxx**
	Mean (±SD)	**xx (± xx)**	**xx (± xx)**	**xx (± xx)**	**xx (± xx)**
	Median	**xx**	**xx**	**xx**	**xx**
	Min-Max	**xx - xx**	**xx - xx**	**xx - xx**	**xx - xx**

Subject to sufficient numbers		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)	Call Center (N=xxx)
Number of planned consultations and hospitalizations performed per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Requirement for consultations AND hospitalizations					
Number of planned consultations AND hospitalizations performed per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Total number of consultations AND hospitalizations performed per cycle	**Number analyzed**	**xxx**	**xxx**	**xxx**	**xxx**
	Mean (±SD)	**xx (± xx)**	**xx (± xx)**	**xx (± xx)**	**xx (± xx)**
	Median	**xx**	**xx**	**xx**	**xx**
	Min-Max	**xx - xx**	**xx - xx**	**xx - xx**	**xx - xx**
Total number of consultations AND hospitalizations performed per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Requirement for calls to a health professional					
Total number of planned calls made per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Number of unplanned calls made per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx
Total number of calls made per cycle	Number analyzed	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx

9.5.3. **Adherence to treatment**

Table 39: Morisky scale items during the follow-up period (safety population)

		End of cycle 1 (N=xxx)	End of cycle 2 (N=xxx)	End of cycle 4 (N=xxx)
Morisky questionnaire items				
Has already forgotten to take treatment	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Occasionally has difficulty remembering to take treatment	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Occasionally stops taking treatment when he/she feels better	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Occasionally stops taking treatment when he/she feels less well	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Additional question about the AEs				
Occasionally reduced or adjusts treatment when an adverse event develops	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)

Table 40: Assessment of adherence during the follow-up period (safety population)

		End of cycle 1 (N=xxx)	End of cycle 2 (N=xxx)	End of cycle 4 (N=xxx)
MMAS-4 score (adherence score)*	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Level of adherence	High: 0	xx (xx%)	xx (xx%)	xx (xx%)
	Mean: 1 or 2	xx (xx%)	xx (xx%)	xx (xx%)
	Low: 3 or 4	xx (xx%)	xx (xx%)	xx (xx%)
	Missing value	xx -	xx -	xx -
"Adherent" patient	Yes: 0	xx (xx%)	xx (xx%)	xx (xx%)
	No: >=1	xx (xx%)	xx (xx%)	xx (xx%)
	Missing value	xx -	xx -	xx -
Difference in adherence score between the end of C1 and C4	Number analyzed	-	-	xxx
	Mean (±SD)	-	-	xx (± xx)
	Median	-	-	xx
	Min-Max	-	-	xx - xx
Difference in adherence score between the end of C1 and C4	Improvement	-	-	xx (xx%)
	Stable score	-	-	xx (xx%)
	Deterioration	-	-	xx (xx%)
	Missing value	-	-	xx -

* From 0 to 4: a low score represents improved adherence.

- **Assessment of adherence in week 4 of cycles 1, 2 and 4 by telephone in patients in the CC arm**

Table 41: Morisky scale items in week 4 of cycles 1, 2 and 4 (safety population)

Carried out by telephone		Call, W4 cycle 1 (N=xxx)	Call, W4 cycle 2 (N=xxx)	Call, W4 cycle 4 (N=xxx)
Morisky questionnaire items:				
Has already forgotten to take treatment	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Occasionally has difficulty remembering to take treatment	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Occasionally stops taking treatment when he/she feels better	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Occasionally stops taking treatment when he/she feels less well	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Additional question about the AE				
Occasionally reduced or adjusts treatment when an adverse event develops	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)

Table 42: Assessment of adherence in week 4 of cycles 1, 2 and 4 (safety population)

Carried out by telephone		Call, W4 cycle 1 (N=xxx)	Call, W4 cycle 2 (N=xxx)	Call, W4 cycle 4 (N=xxx)
MMAS-4 score (adherence score)*	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Level of adherence	High: 0	xx (xx%)	xx (xx%)	xx (xx%)
	Moderate: 1 or 2	xx (xx%)	xx (xx%)	xx (xx%)
	Low: 3 or 4	xx (xx%)	xx (xx%)	xx (xx%)
	Missing value	xx -	xx -	xx -
"Adherent" patient	Yes: 0	xx (xx%)	xx (xx%)	xx (xx%)
	No: >=1	xx (xx%)	xx (xx%)	xx (xx%)
	Missing value	xx -	xx -	xx -

From 0 to 4: a low score represents improved adherence.

Table 43: Consistency between assessment of adherence at W4 (telephone) and W6 (self-completed questionnaire) in each cycle 1, 2 and 4 (safety population)

Cycle 1		Level of adherence at W6 (MMAS-4) Self-completed paper questionnaire			Coefficient Kappa
		High: 0 (N=xxx)	Moderate: 1 or 2 (N=xxx)	Low: 3 or 4 (N=xxx)	
Level of adherence at W4 (MMAS-4) (telephone)	High: 0	xx (xx%)	xx (xx%)	xx (xx%)	xx
	Moderate: 1 or 2	xx (xx%)	xx (xx%)	xx (xx%)	
	Low: 3 or 4	xx (xx%)	xx (xx%)	xx (xx%)	
	Missing value	xx -	xx -	xx -	
Cycle 2		**Level of adherence at W6 (MMAS-4) Self-completed paper questionnaire**			**Coefficient Kappa**
		High: 0 (N=xxx)	**Moderate: 1 or 2 (N=xxx)**	**Low: 3 or 4 (N=xxx)**	
Level of adherence at W4 (MMAS-4) (telephone)	High: 0	xx (xx%)	xx (xx%)	xx (xx%)	xx
	Moderate: 1 or 2	xx (xx%)	xx (xx%)	xx (xx%)	
	Low: 3 or 4	xx (xx%)	xx (xx%)	xx (xx%)	
	Missing value	xx -	xx -	xx -	
Cycle 4		**Level of adherence at W6 (MMAS-4) Self-completed paper questionnaire**			**Coefficient Kappa**
		High: 0 (N=xxx)	**Moderate: 1 or 2 (N=xxx)**	**Low: 3 or 4 (N=xxx)**	
Level of adherence at W4 (MMAS-4) (telephone)	High: 0	xx (xx%)	xx (xx%)	xx (xx%)	xx
	Moderate: 1 or 2	xx (xx%)	xx (xx%)	xx (xx%)	
	Low: 3 or 4	xx (xx%)	xx (xx%)	xx (xx%)	
	Missing value	xx -	xx -	xx -	

9.5.4. **Response to the sunitinib treatment**

Table 44: Response to sunitinib treatment (FAS population)

		Number of calls received < xx (N=xxx)	Number of calls received ≥ xx (N=xxx)	Call center (N=xxx)
Best response obtained during treatment according to RECIST v1.1 criteria	CR (Complete response)	xx (xx%)	xx (xx%)	xx (xx%)
	PR (Partial response)	xx (xx%)	xx (xx%)	xx (xx%)
	SD (Stable disease)	xx (xx%)	xx (xx%)	xx (xx%)
	PD (Progressive disease)	xx (xx%)	xx (xx%)	xx (xx%)
	Missing value	xx -	xx -	xx -
Best complete or partial response (Objective response rate)	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
	Missing value	xx -	xx -	xx -

9.5.5. Patient support

9.5.5.1. Number of calls

Table 45: Frequency of calls made during sunitinib treatment by cycle and overall (FAS population)

		Patients per sunitinib treatment cycle				Total (N=xxx)
		1 (N=xxx)	2 (N=xxx)	3 (N=xxx)	4 (N=xxx)	
Number of planned completed calls per patient	Number analyzed	xxx	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
Number of unplanned completed calls per patient	Number analyzed	xxx	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx
Total number of completed calls per patient	Number analyzed	xxx	xxx	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx	xx - xx	xx - xx

9.5.5.2. Actions by doctors and patients

Table 46: Actions by doctors and patients assessed during the first call (FAS population)

According to the patient, at the time of the first call:		1st Call (N=xxx)
Action by doctor		
The doctor clearly explained how to take the treatment	Yes	xx (xx%)
	No	xx (xx%)
The patient was given documentation about the treatment by the doctor or medical team	Yes, information leaflet	xx (xx%)
	Yes, Sutent® diary	xx (xx%)
	No	xx (xx%)
The doctor explained how to manage any side effects due to treatment which could occur	Yes	xx (xx%)
	No	xx (xx%)
Prescriptions or orders for supportive medical treatments by the doctor	Yes	xx (xx%)
	No	xx (xx%)
Action by patient		
Sutent® taken	Yes	xx (xx%)
	No	xx (xx%)
If no, reason	Forgot to start	xx (xx%)
	Stressed/worried about the idea of taking the drug	xx (xx%)
	Other reason	xx (xx%)
	Details	

Table 47: Actions by doctors and patients assessed during the first call in cycles 2, 3 and 4 (FAS population)

According to the patient, at the time of the first call in cycles 2, 3 and 4:		1st call, cycle 2 (N=xxx)	1st call, cycle 3 (N=xxx)	1st call, cycle 4 (N=xxx)
Actions by patient				
A new cycle of Sutent® was due to be started:	Yes	xx (xx%)	xx (xx%)	xx (xx%)
restarted Sutent®	No	xx (xx%)	xx (xx%)	xx (xx%)
If no, reason	Planned restart	xx (xx%)	xx (xx%)	xx (xx%)
	Forgot to restart	xx (xx%)	xx (xx%)	xx (xx%)
	Stressed/worried about the idea of taking the drug	xx (xx%)	xx (xx%)	xx (xx%)
	Development of an AE	xx (xx%)	xx (xx%)	xx (xx%)
	Treatment delayed or interrupted temporarily by the doctor	xx (xx%)	xx (xx%)	xx (xx%)
	Other reason	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)
Action by doctor				
Dose and/or dosage regimen amended by the doctor in the last visit	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
Prescription or order for supportive medicinal products by the doctor	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)

9.5.5.3. Advice delivered

Table 48: Advice given during calls by the support call center by cycle and overall (FAS population)

Advice delivered during calls (several options possible)	N=Patients who were called at least once				Total Patients (N=xxx)
	Cycle 1 (N=xxx)	Cycle 2 (N=xxx)	Cycle 3 (N=xxx)	Cycle 4 (N=xxx)	
Advice about managing the treatment					
Advice about taking Sutent®	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Advice about using the Sutent® follow-up diary	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Reporting any AE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
General preventative advice					
Advice about taking preventative systemic treatments	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Lifestyle advice	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Food/dietetic advice	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Oro-dental hygiene advice	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Specific preventative advice for a type of AE					
Prevention of skin toxicities	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Prevention of gastrointestinal disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Prevention of cardiac disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Prevention of infectious/inflammatory problems	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other preventative advice	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Actions recommended to patient					
Do not forget the planned consultation with the oncologist	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Get the additional investigations requested performed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

9.5.6. **Satisfaction with the call center**

9.5.6.1. Doctors' satisfaction with the call center

Table 49: Satisfaction of doctors who included patients followed up by the call center with the patient treatment management call center

Satisfaction assessed at the end of the patient follow-up period		Doctors who included at least 1 patient into the Call Center arm (N=xxx)
Satisfaction with the advice		
- **In terms of the reduction in the number and/or frequency of grade 3/4 AEs as a result of the advice delivered during the support process**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
- **With the improvement in adherence to treatment through the support**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
- **With the change in patient's quality of life through the advice delivered by the call center**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
Satisfaction with care		
- **Feeling that the treatment management call center care reduced workload**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
Overall satisfaction of patient care with the call center	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
Overall satisfaction: Doctor "satisfied" or "very satisfied"	Yes	xx (xx%)
	No	xx (xx%)
Desire to continue this type of support	Yes	xx (xx%)
	No	xx (xx%)

A 3 axis radar plot shows the mean satisfaction scores for each dimension. The area of the polygon and percentage surface area covered are shown on the plot. A high represents greater general satisfaction.

Table 50: Characteristics of doctors who were satisfied or very satisfied with the support from the patient treatment management call center

		Overall satisfied or very satisfied with the support	
		Yes (N=xxx)	**No (N=xxx)**
Age of doctor	Number analyzed	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)
	Median	xx	xx
	Min-Max	xx - xx	xx - xx
Sex	Male	xx (xx%)	xx (xx%)
	Female	xx (xx%)	xx (xx%)
Number of patients who used the call center for at least 50% of the planned calls	Number analyzed	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)
	Median	xx	xx
	Min-Max	xx - xx	xx - xx
Average number of planned and unplanned calls received by the patients	Number analyzed	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)
	Median	xx	xx
	Min-Max	xx - xx	xx - xx

9.5.6.2. Patient satisfaction with the call center

Table 51: Satisfaction of patients included in the Call Center arm with the call center (FAS Call Center population)

Patient satisfaction assessed at the end of their follow-up in the study (end of cycle 4 or end of treatment)		Total (N=xxx)
Satisfaction with the advice		
- **With the preventative advice given to avoid sunitinib related complications**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
- **With the advice given to reduce/resolve side effects due to sunitinib**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
- **With the capacity of the call center to direct the patient to a general practitioner/oncologist when the situation required this**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
Satisfaction with care		
- **With the explanations given about the disease, treatment and/or their side effects**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
Satisfaction with the service		
- **With the response given to questions, problems and/or about the patient him/herself**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
- **With the frequency and duration of calls received from the patient's perspective**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
- **Availability of nurses from the call center through the toll free number available**	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
Overall satisfaction with support in management of sunitinib treatment	Very satisfied	xx (xx%)
	Satisfied	xx (xx%)
	Not particularly satisfied	xx (xx%)
	Not satisfied	xx (xx%)
	No opinion	xx (xx%)
Overall satisfaction: Patient "satisfied" or "very satisfied"	Yes	xx (xx%)
	No	xx (xx%)

A 4 axes radar plot simultaneously shows the mean scores for each satisfaction dimension. The area of the polygon and percentage of the surface area covered will be shown on this plot. A higher area represents greater general satisfaction.

Table 52: Other satisfaction indicators for patients included in the Call Center arm with the call center (FAS Call Center population)

Satisfaction assessed at the end of the final visit at 6 weeks in cycle 4 or in the treatment discontinuation visit		Total (N=xxx)
Desire to continue this type of support	Yes, completely	xx (xx%)
	Possibly	xx (xx%)
	Not really	xx (xx%)
	Not at all	xx (xx%)
	No opinion	xx (xx%)
Liable to recommend this type of follow-up to a member of the family circle	Yes, completely	xx (xx%)
	Possibly	xx (xx%)
	Not really	xx (xx%)
	Not at all	xx (xx%)
	No opinion	xx (xx%)
Need experienced during the study for actions proposed by the call center	Yes	xx (xx%)
	No	xx (xx%)

The comments given by patients in the self-completed satisfaction questionnaires will also be provided in this section.

Table 53: Characteristics of patients who were satisfied or very satisfied with the support, in patients in the Call Center arm (FAS Call Center population)

		Overall very satisfied or very satisfied with the support	
		Yes (N=xxx)	**No (N=xxx)**
Characteristics at inclusion			
Age (years)	Number analyzed	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)
	Median	xx	xx
	Min-Max	xx - xx	xx - xx
Sex	Male	xx (xx%)	xx (xx%)
	Female	xx (xx%)	xx (xx%)
ECOG score	0	xx (xx%)	xx (xx%)
	1	xx (xx%)	xx (xx%)
	2	xx (xx%)	xx (xx%)
	3	xx (xx%)	xx (xx%)
	4	xx (xx%)	xx (xx%)
	Not stated		
Risk score – Heng et al. criteria	Good	xx (xx%)	xx (xx%)
	Intermediary	xx (xx%)	xx (xx%)
	Poor	xx (xx%)	xx (xx%)
	Not available	xx (xx%)	xx (xx%)
Fuhrman grade	I	xx (xx%)	xx (xx%)
	II	xx (xx%)	xx (xx%)
	III	xx (xx%)	xx (xx%)
	IV	xx (xx%)	xx (xx%)
Metastatic renal cell carcinoma grade	Yes	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)
Previous or current comorbidities	Yes	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)
Concomitant treatment	Yes	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)
Characteristics during the follow-up period			
Number of calls achieved	Number analyzed	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)
	Median	xx	xx
	Min-Max	xx - xx	xx - xx
Development of AEs	Yes	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)
Development of grade 3/4 AEs	Yes	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)

9.6. Pharmacovigilance

Note: The pharmacovigilance analysis will be described both according to severity (AE/SAE) and overall.

Table 54: Description of all of the AEs declared during the study (Safety population)

		Safety population (N=xxx)
Type of AEs (SOC – MedDRA category)*	xxxx	xx (xx%)
	xxxx	xx (xx%)
	xxxx	xx (xx%)
Type of AEs (PT – MedDRA category)*	xxxx	xx (xx%)
	xxxx	xx (xx%)
	xxxx	xx (xx%)
cycle	cycle 1	xx (xx%)
	cycle 2	xx (xx%)
	cycle 3	xx (xx%)
	cycle 4	xx (xx%)
Severity	Non-serious	xx (xx%)
	Serious	xx (xx%)
If serious, severity criteria	Fatal	xx (xx%)
	Life-threatening	xx (xx%)
	Hospitalization/prolongation of hospitalization	xx (xx%)
	Congenital abnormality/ malformation	xx (xx%)
	Permanent or severe invalidity/ incapacity	xx (xx%)
	Significant medical event	xx (xx%)
Grade	1	xx (xx%)
	2	xx (xx%)
	3	xx (xx%)
	4	xx (xx%)
	5	xx (xx%)
	Not applicable	xx (xx%)
Causality of the AEs with sunitinib	Related to administration of Sutent®	xx (xx%)
	Related to a concomitant medicinal product	xx (xx%)
	Related to Sutent and another concomitant medicinal product	xx (xx%)
	Related neither to Sutent nor another medicinal product	xx (xx%)
	Unknown	xx (xx%)
Outcome	Recovered	xx (xx%)
	Recovered with sequelae	xx (xx%)
	Currently recovering	xx (xx%)
	Not recovered	xx (xx%)
	Unknown	xx (xx%)
Corrective medical action	Prescription of a treatment	xx (xx%)
	Medical consultation	xx (xx%)
	Hospitalization	xx (xx%)
	Other	xx (xx%)
	Not applicable	xx (xx%)
Last action undertaken for Sutent during the AE	Discontinuation (temporary or permanent, or dose delayed)	xx (xx%)
	Increased dosage	xx (xx%)
	Reduced dosage	xx (xx%)
	Unchanged dosage	xx (xx%)

		Safety population (N=xxx)
	Change in dosage regimen	xx (xx%)
	Unknown	xx (xx%)
	Not applicable	xx (xx%)
Specific situation	No specific situation	xx (xx%)
	Exposure during pregnancy	xx (xx%)
	Overdose	xx (xx%)
	Medication error/Risk of medication error	xx (xx%)
	Exposure during breast-feeding	xx (xx%)
	Misuse	xx (xx%)
	Lack of efficacy	xx (xx%)
	Off-label use	xx (xx%)
	Extravasation	xx (xx%)
	Occupational exposure	xx (xx%)

* Categories involving at least 2% of patients

Table 55: Description of all AEs related to sunitinib declared during the follow-up period (Safety population)

AEs related to sunitinib*		Safety population (N=xxx)
Type of AE (SOC – MedDRA category)**	xxxx	xx (xx%)
	xxxx	xx (xx%)
	xxxx	xx (xx%)
Type of AE (PT – MedDRA category)**	xxxx	xx (xx%)
	xxxx	xx (xx%)
	xxxx	xx (xx%)
Cycle	cycle 1	xx (xx%)
	cycle 2	xx (xx%)
	cycle 3	xx (xx%)
	cycle 4	xx (xx%)
Severity	Non-serious	xx (xx%)
	Serious	xx (xx%)
If serious, severity criteria	Fatal	xx (xx%)
	Life-threatening	xx (xx%)
	Hospitalization/prolongation of hospitalization	xx (xx%)
	Congenital abnormality/ malformation	xx (xx%)
	Permanent or severe invalidity/ incapacity	xx (xx%)
	Significant medical event	xx (xx%)
Grade	1	xx (xx%)
	2	xx (xx%)
	3	xx (xx%)
	4	xx (xx%)
	5	xx (xx%)
	Not applicable	xx (xx%)
Causality of the AEs with sunitinib	Related to administration of Sutent®	xx (xx%)
	Related to a concomitant medicinal product	xx (xx%)
	Related to Sutent and another concomitant medicinal product	xx (xx%)
	Related neither to Sutent nor another medicinal product	xx (xx%)
	Unknown	xx (xx%)
Outcome	Recovered	xx (xx%)

AEs related to sunitinib*		Safety population (N=xxx)
	Recovered with sequelae	xx (xx%)
	Currently recovering	xx (xx%)
	Not recovered	xx (xx%)
	Unknown	xx (xx%)
Corrective medical action	Prescription of a treatment	xx (xx%)
	Medical consultation	xx (xx%)
	Hospitalization	xx (xx%)
	Other	xx (xx%)
	Not applicable	xx (xx%)
Last action undertaken for Sutent during the AE	Discontinuation (temporary or permanent, or dose delayed)	xx (xx%)
	Increased dosage	xx (xx%)
	Reduced dosage	xx (xx%)
	Unchanged dosage	xx (xx%)
	Change in dosage regimen	xx (xx%)
	Unknown	xx (xx%)
	Not applicable	xx (xx%)
Specific situation	No specific situation	xx (xx%)
	Exposure during pregnancy	xx (xx%)
	Overdose	xx (xx%)
	Medication error/Risk of medication error	xx (xx%)
	Exposure during breast-feeding	xx (xx%)
	Misuse	xx (xx%)
	Lack of efficacy	xx (xx%)
	Off-label use	xx (xx%)
	Extravasation	xx (xx%)
	Occupational exposure	xx (xx%)

* AE related to sunitinib if the relationship is entered as “Related to taking Sutent®” or “Related to Sutent® and another concomitant medicinal product”.

** Categories involving at least 2% of patients

9.7. Supplementary analysis: Patient follow-up "Standard follow-up"

9.7.1. **Tumor assessment during the follow-up period**

Table 56: Tumor assessments (safety population- standard follow-up) during the follow-up period

		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
Tumor assessment since the last visit	Yes	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)
If yes,				
Radiologic investigation (several possible options)	CT	xx (xx%)	xx (xx%)	xx (xx%)
	MRI	xx (xx%)	xx (xx%)	xx (xx%)
	PET scan	xx (xx%)	xx (xx%)	xx (xx%)
	Radiography	xx (xx%)	xx (xx%)	xx (xx%)
	Ultrasound	xx (xx%)	xx (xx%)	xx (xx%)
Response to treatment (RECIST v1.1 criteria)	CR (Complete response)	xx (xx%)	xx (xx%)	xx (xx%)
	PR (Partial response)	xx (xx%)	xx (xx%)	xx (xx%)
	SD (Stable disease)	xx (xx%)	xx (xx%)	xx (xx%)
	PD (Progression)	xx (xx%)	xx (xx%)	xx (xx%)
	NE (Not evaluable)	xx (xx%)	xx (xx%)	xx (xx%)
If not evaluable, reason	Details	xx (xx%)	xx (xx%)	xx (xx%)
	…			

9.7.2. **Clinical indices during the follow-up period**

Table 57: Clinical indices (safety population- standard follow-up) during the follow-up period

		inclusion (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
ECOG performance index assessed	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If yes, ECOG score	0	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	1	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	2	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	3	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	4	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Karnofsky index scored	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If yes, Karnofsky index	100%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	90% - 80%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	70% - 60%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	50% - 40%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	30% - 10%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	0%	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Blood pressure	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

		inclusion (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
<u>If yes,</u>					
Systolic value (mmHg)	Number analyzed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Mean (±SD)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Median	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Min-Max	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Diastolic value (mmHg)	Number analyzed	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Mean (±SD)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Median	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Min-Max	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

9.7.3. **Symptoms during the follow-up period**

Table 58: Symptoms (safety population- standard follow-up) during the follow-up period

		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)	Overall during follow-up
Symptoms develop (several options possible)	Skin reactions or disorder	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Gastrointestinal disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Cardiac disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Bleeding disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Hematologic disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Infectious problems	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Pain	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Site	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	…				
	Endocrine disorders	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Inflammatory disorders (mucitis, etc.)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	General disorders (asthenia, anorexia, etc.)	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Development of other AE	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	…				

9.7.4. **Supportive measures during the follow-up period**

Table 59: Supportive measures for sunitinib treatment (safety population- standard follow-up) during the follow-up period, instituted by the doctor

	Start of sunitinib (N=xxx)	V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)
Information received by the patient when treatment with sunitinib was started (several options possible)				
No new information leaflet	--	xx (xx%)	xx (xx%)	xx (xx%)
By the investigator him/herself	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
By the care team	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Nurse	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Pharmacist	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Intern	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
CRA	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
By an information leaflet or any other support/materials/ document given to the patient	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Details of the support	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
Other	xx (xx%)			
Details	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
…	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

9.7.5. **Study criteria**

Table 60: Follow-up data (safety population- standard follow-up)

		Standard follow-up (N=xxx)
At least 1 grade 3 or 4 AE whether or not related to Sunitinib	Yes	xx (xx%)
	No	xx (xx%)
At least 1 dose reduction during treatment with sunitinib	Yes	xx (xx%)
	No	xx (xx%)
Reason for dose reductions (patients involved on at least 1 occasion for each of the possible reasons)	AE	xx (xx%)
	Other	xx (xx%)
	Details	xx (xx%)
At least 1 temporary interruption of sunitinib	Yes	xx (xx%)
	No	xx (xx%)
Reason for interruption (patients involved once for each of the possible reasons)	AE	xx (xx%)
	Radiotherapy	xx (xx%)
	Surgery	xx (xx%)
	Other	
	Details	
Best response obtained during treatment	CR (Complete response)	xx (xx%)
	PR (Partial response)	xx (xx%)
	SD (Stable disease)	xx (xx%)
	PD (Progressive disease)	xx (xx%)
	Missing value	xx -
Best complete or partial response (Objective response rate)	Yes	xx (xx%)
	No	xx (xx%)
	Missing value	xx -

Table 61: Requirement for medical procedures (safety population- standard follow-up)

		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)	Standard follow-up (N=xxx)
At least 1 consultation	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If yes, at least 1	Planned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Unplanned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
At least 1 hospitalization	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
If yes, at least 1	Planned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Unplanned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
At least 1 hospitalization AND 1 consultation	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
At least 1 call to a health professional	Yes	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	No	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

		V1 - End of cycle 1 (N=xxx)	V2 - End of cycle 2 (N=xxx)	V3 - End of cycle 4 (N=xxx)	Standard follow-up (N=xxx)
If yes, at least 1	Planned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)
	Unplanned	xx (xx%)	xx (xx%)	xx (xx%)	xx (xx%)

Table 62: Patient adherence with treatment (safety population- standard follow-up)

		End of cycle 1 (N=xxx)	End of cycle 2 (N=xxx)	End of cycle 4 (N=xxx)
MMAS-4 score (adherence score)*	Number analyzed	xxx	xxx	xxx
	Mean (±SD)	xx (± xx)	xx (± xx)	xx (± xx)
	Median	xx	xx	xx
	Min-Max	xx - xx	xx - xx	xx - xx
Level of adherence	High: 0	xx (xx%)	xx (xx%)	xx (xx%)
	Mean: 1 or 2	xx (xx%)	xx (xx%)	xx (xx%)
	Low: 3 or 4	xx (xx%)	xx (xx%)	xx (xx%)
	Missing value	xx -	xx -	xx -
"Adherent" patient	Yes: 0	xx (xx%)	xx (xx%)	xx (xx%)
	No: >=1	xx (xx%)	xx (xx%)	xx (xx%)
	Missing value	xx -	xx -	xx -

10. REFERENCES

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11. Annexes

11.1. Interpretation of the Kappa coefficient

Accord	*Kappa*
Excellent	³ 0,81
PPD	0,80 - 0,61
	0,60 - 0,41
	0,40 - 0,21
	0,20 - 0,0
	< 0,0

Sources:

Landis JR, Koch G.G. The Measurement of Observer Agreement for Categorical Data, *Biometrics*, 1977a, **33**, 159-174.

http://kappa.chez-alice.fr/Kappa_2juges_Def.htm

11.2. Definition of region indicators

Figure 4: Definition of region indicators

Region (Insee 2016)	*Département*
PPD	01, 03, 07, 15, 26, 38, 42, 43, 63, 69, 73, 74
PPD	21, 25, 39, 58, 70, 71, 89, 90
PPD	22, 29, 35, 56
PPD	18, 28, 36, 37, 41, 45
PPD	20
PPD	08, 10, 51, 52, 54, 55, 57, 67, 68, 88
PPD	02, 59, 60, 62, 80
PPD	91, 92, 75, 93, 77, 94, 95, 78
PPD	14, 27, 50, 61, 76
PPD	16, 17, 19, 23, 24, 33, 40, 47, 64, 79, 86, 87
PPD	09, 11, 12, 30, 31, 32, 34, 46, 48, 65, 66, 81, 82
PPD	44, 49, 53, 72, 85
PPD	04, 06, 13, 05, 83, 84, 980 (Monaco)