STATISTICAL ANALYSIS PLAN
SHELLS FOR TABLES, LISTINGS AND FIGURES (TLF SHELLS)

EVEREXES Study

A phase IIIb, multi-center, open-label study of EVERolimus (RAD001) in combination with EXemestane in post-menopausal women with EStrogen receptor positive, human epidermal growth factor receptor 2 negative locally advanced or metastatic breast cancer

(Protocol Number CRAD001JIC06 / NCT03176238, Version 02, 07 Jul 2014)

Final Version 3.0
27 September 2017

DOCUMENT HISTORY

Version Number	Date	Author	Change
0.1	26Aug2013	[redacted]	Initial Release
0.2	10Oct2014	[redacted]	Updated per protocol amendment 2
1.0	6Oct2016	[redacted]	Provide clarification regarding medications considered as prior antineoplastic therapies and the algorithm used to define CR, PR and SD for the calculation of CBR. Interim analysis section updated to provide information about subgroup analyses performed prior to database lock. Update column header of TFL shells including 'Asian' and 'non-Asian' columns in addition to the 'total' column
1.1	30Jan2017	[redacted]	Updated per Novartis comments of previous SAP version V1,0 6Oct2016
2.0	9Feb2017	[redacted]	Updated per [redacted] comments of previous SAP version V1.1 30Jan2017 (internal review)
2.0	14Mar2017	[redacted]	Updated per Novartis comments of previous SAP version V2.0 9Feb2017
2.0	21Mar2017	[redacted]	Updated per [redacted] comments of previous SAP version V2.0 14Mar2017 (internal review)
2.0	2May2017	[redacted]	Updated per [redacted] comments of previous SAP version V2.0 21Mar2017: • Table 2.1.3 updated • Safety tables removed from subgroup analysis 1
3.0	27Sep2017	[redacted]	Updated per [redacted] comments of previous SAP version V2.0 2May2017: • Remove the following 14 tables: T6.6.1, T6.6.2, T6.8.1, T6.8.2, T8.1.3, T8.1.4, T8.1.7, T8.1.8, T8.2.3, T8.2.4, T8.3.3, T8.3.4, T9.1.2, and T9.1.3

SIGNATURES/APPROVALS

Signatures below indicate agreement with the contents of the EVEREXES Shells for tables, listings and figures as an accurate representation of the outputs of the study.

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1 Tables, Figures and Listings (TFLs)

1.1 Reporting Conventions

The following reporting conventions will be adopted for the SAP. These conventions will enhance the review process and help to standardize presentation with common notations. Details regarding the specific TFL numbers, title and body content of the TFL, and any footnote(s) are provided in the section that follows.

- All data listings will be presented in Landscape Orientation.
- Figures will be in black and white, unless otherwise requested. Symbols on figures will not be filled. Lines will be wide enough to see the line after being copied.
- Completely missing values for both numeric and character variables will be explicitly labeled as missing in tables and data listings.
- All analysis programs developed for a table, figure, or data listing will have the name of the program and a date/time stamp on the bottom of each output.
- All analysis programs developed for a table, figure, or data listing display will be self-contained to facilitate transfer of programs. It is recommended that a 1:1 relationship between table and analysis program is used to facilitate this convention.

1.2 TLF Shells

Each table/figure/listing (TFL) produced for the EVEREXES study will have the following general layout. **Bolded text** will appear on each page of the TFL. Details regarding the specific TFL numbers, title and body content of the TFL, and any footnote(s) are provided in the pages that follow.

Novartis
EVEREXES Study

Page x of y

Category/Variable	*Column Header 1* N=XXX	*Additional Column Headers (If Applicable)* N=XXX
Category[a,b], unit		
Observed, n (%)	xx (xx.x)	xx (xx.x)
Sub-category 1	xx (xx.x)	xx (xx.x)
Sub category 2	xx (xx.x)	xx (xx.x)
Sub category 3	xx (xx.x)	xx (xx.x)
Sub category 4	xx (xx.x)	xx (xx.x)
Variable [c]		
Observed, n (%)	xxx (xx.x)	xxx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x
Min, Max	xx, xx	xx, xx

a Footnote.
b Another footnote.
c Yet another footnote.

Source Data:xxxx
Program path: x:\xxx\xxx\xxx.sas (9.2) (ddmmmyyyy hh:mm)

Table 1.1 Population Sets and Screening Failures Overall and in Asian subgroup – All Patients

		Asian (N=xxx)		Non-Asian (N=xxx)		Total (N=xxx)	
	Statistic	**Overall**	**Enrolled on or after 01 July 2014**	**Overall**	**Enrolled on or after 01 July 2014**	**Overall**	**Enrolled on or after 01 July 2014**
Number of Screened Patients	n	xxx	xxx	xxx	xxx	xxx	xxx
Number of Screened Failures	n	xxx	xxx	xxx	xxx	xxx	xxx
Unacceptable past medical history/concomitant diagnosis	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intercurrent medical event	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unacceptable laboratory value	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unacceptable test procedure result(s)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did not meet diagnostic/severity criteria	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unacceptable use of excluded medication/therapies	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient withdrew consent	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Others	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Enrolled Patients	n	xxx	xxx	xxx	xxx	xxx	xxx
Number of Patients in Full Analysis Set	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Patients in Per Protocol Set	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Patients in Safety Set	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.

Table 1.2 Population Sets by Country - All Patients

Country	Enrolled n (%)	Full Analysis Set n (%)	Per Protocol Set n (%)	Safety Set n (%)
TOTAL	XXX	XXX	XXX	XXX
Australia, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
:	:	:	:	:
Vietnam, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Note to programmer: This table will include the following countries in alphabetical order: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan, Jordan, Australia, Morocco, South Africa or Tunisia.

Table 1.3 Patients Disposition Overall and in Asian Subgroup – All patients

Disposition Reason	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xx)
Patients enrolled, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Untreated	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treated	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients treated, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment ongoing	xx (xx.x)	xx (xx.x)	xx (xx.x)
End of treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary reason for end of treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unacceptable adverse events	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal laboratory value(s)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal test procedure result(s)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intercurrent illness that prevent further administration of everolimus treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)
Consent withdrawal	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)
Administrative problems	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment duration completed within the scope of Expanded Access. Program (EAP) (till 31 DEC 2014)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient is switched to commercial drug	xx (xx.x)	xx (xx.x)	xx (xx.x)
General or specific changes in the patient's condition which render the patient unacceptable for further everolimus treatment at the discretion of the investigator	xx (xx.x)	xx (xx.x)	xx (xx.x)
Need for any other types of anticancer therapy, except for palliative radiotherapy for bone lesions	xx (xx.x)	xx (xx.x)	xx (xx.x)
Everolimus dose interruption of > 4weeks	xx (xx.x)	xx (xx.x)	xx (xx.x)
Length of follow-up from screening to end of study (weeks)[a]			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a] Follow-up time: Time from screening visit date to end of study date.

Table 1.4.1 Patients Discontinuing Study Treatment by Visit – Full Analysis Set

STATUS Reason, n (%)	VISIT							
Total (N=xxx)	Baseline	WK 4	WK 10	WK 20	WK 30	WK 40	WK 50	EOT
End of Study Treatment	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Unacceptable adverse events	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal laboratory value(s)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abnormal test procedure result(s)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intercurrent illness that prevent further administration of everolimus treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Consent withdrawal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Administrative problems	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment duration completed within the scope of Expanded Access. Program (EAP) (till 31 DEC 2014)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient is switched to commercial drug	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
General or specific changes in the patient's condition which render the patient unacceptable for further everolimus treatment at the discretion of the investigator	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Need for any other types of anticancer therapy, except for palliative radiotherapy for bone lesions	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Everolimus dose interruption of > 4weeks	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

EOT: End of Treatment.

Table 1.4.2 Patients Discontinuing Study Treatment by Visit for Asian Patients – Full Analysis Set

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
EOT: End of Treatment.

Table 1.4.3 Patients Discontinuing Study Treatment by Visit for Non-Asian Patients – Full Analysis Set

Non-Asian: Australia, Morocco, South Africa or Tunisia.
EOT: End of Treatment.

These tables will be created using the same layout as Table 1.4.1.

Table 1.5.1 Study Evaluation Completion Status by Visit – Full Analysis Set

STATUS Reason, n (%)	VISIT								
Total (N=xxx)	Baseline	WK 4	WK 10	WK 20	WK 30	WK 40	WK 50	EOT	Overall
Study Evaluation Completion	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Patient withdrew consent	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Administrative problems	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
New cancer therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient is switched to commercial drug	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

EOT: End Of Treatment.

Table 1.5.2 Study Evaluation Completion Status by Visit for Asian Patients – Full Analysis Set

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
EOT: End of Treatment.

Table 1.5.3 Study Evaluation Completion Status by Visit for Non-Asian Patients – Full Analysis Set

Non-Asian: Australia, Morocco, South Africa or Tunisia.
EOT: End of Treatment.

These tables will be created using the same layout as Table 1.5.1.

Table 1.6 Major Protocol Deviations Overall and in Asian subgroup – Full Analysis Set

Major Protocol Deviations	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xx)
Major Protocol Violations, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Violation of eligibility criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Violation of any inclusion criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Violation of any exclusion criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)
Informed consent from (ICF) not signed	xx (xx.x)	xx (xx.x)	xx (xx.x)
Date of ICF prior to date of first visit/procedure	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients without metastatic or locally advanced breast cancer	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hormone Receptor non-positive at screening	xx (xx.x)	xx (xx.x)	xx (xx.x)
ECOG performance at baseline status higher than 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient receive a prohibited medication	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.

Table 2.1.1 Patient Demographics Overall and in Asian Subgroup – Full Analysis Set

	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xx)
Age at informed consent (years)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Gender, n (%)			
n	xx	xx	xx
Men	xx (xx.x)	xx (xx.x)	xx (xx.x)
Women	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race, n (%)			
n	---	---	xx
Caucasian	---	---	xx (xx.x)
Asian	---	---	xx (xx.x)
Other[1]	---	---	xx (xx.x)
Ethnicity, n (%)			
n	xx	xx	xx
Hispanic/Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chinese	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indian (Indian subcontinent)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Japanese	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mixed ethnicity	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

CI: Confidence Interval, SD: Standard Deviation.
Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
1. Other includes the sub-categories of Black, Native American, Pacific Islander and Other.

Table 2.1.2 Baseline Clinical Characteristics Overall and in Asian Subgroup – Full Analysis Set

	Asian (N=xxx)	Non-Asian (N=xxx)	Total (N=xxx)
Height, cm			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Weight, kg			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Body Mass Index (BMI), kg/m^2			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Body temperature, ºC			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Heart rate, bpm			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Systolic blood pressure (SBP), mmHg			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Diastolic blood pressure (DBP), mmHg			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x

	Asian (N=xxx)	Non-Asian (N=xxx)	Total (N=xxx)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
ECOG performance status, n (%)			
n	xx	xx	xx
0	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)
>= 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Estrogen receptor, n (%)			
n	xx	xx	xx
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not assessable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Progesterone receptor, n (%)			
n	xx	xx	xx
Positive	xx (xx.x)	xx (xx.x)	xx (xx.x)
Negative	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not assessable	xx (xx.x)	xx (xx.x)	xx (xx.x)
Measurable disease[1] or bone lesions, n (%)			
n	xx	xx	xx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Metastatic sites, n (%)			
n	xx	xx	xx
Lung and/or liver	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone only	xx (xx.x)	xx (xx.x)	xx (xx.x)

CI: Confidence Interval, SD: Standard Deviation, ECOG: Eastern Cooperative Oncology Group, BMI=Weight(kg)/[Height(m)]^2. bpm: beats per minute. CT: Computed Tomography. MRI: Magnetic Resonance Imaging.
Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
1. Measurable disease defined as at least one lesion that can be accurately measured in at least one dimension = 20 mm with conventional imaging techniques or = 10 mm with spiral CT or MRI.

Table 2.1.3 Baseline Prior Treatment Overall and in Asian Subgroup – Full Analysis Set

	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xx)
Sensitivity to previous endocrine therapy[1], n (%)			
n	xx	xx	xx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Purpose of most recent treatment, n (%)			
n	xx	xx	xx
Adjuvant therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapy for advanced/metastatic disease	xx (xx.x)	xx (xx.x)	xx (xx.x)
ANA or LET as most recent treatment, n (%)			
n	xx	xx	xx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Previous tamoxifen treatment, n (%)			
n	xx	xx	xx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Previous fulvestrant treatment, n (%)			
n	xx	xx	xx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any previous use of chemotherapy, n (%)			
n	xx	xx	xx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of prior systemic therapies (in adjuvant or metastatic setting), n (%)			
n	xx	xx	xx
0	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of prior systemic treatment (chemotherapies or hormonal therapies) in metastatic setting (excluding adjuvant and neoadjuvant setting), n (%)			
n	xx	xx	xx
0	xx (xx.x)	xx (xx.x)	xx (xx.x)

	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xx)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior chemotherapies in metastatic setting (excluding adjuvant and neoadjuvant setting), n (%)			
n	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)

ANA: Anastrazole. LET: Letrozole. BC: Breast Cancer.

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.

Non-Asian: Australia, Morocco, South Africa or Tunisia.

1. Defined as at least 24 months of endocrine therapy before recurrence in the adjuvant setting or a response or stabilization for at least 24 weeks of endocrine therapy for advanced disease
2. Prior therapies include those used in the adjuvant setting or to treat advanced disease.

Table 2.2 Prior Antineoplastic Therapy Overall and in Asian Subgroup - Full Analysis Set

Antineoplastic therapy	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Patients with no prior procedures, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients with at least one prior procedure, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Surgery, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lumpectomy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Segmentectomy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mastectomy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Radiotherapy, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medications (solid tumors), n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chemotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hormonal therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Immunotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Targeted therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
1. Including all settings: adjuvant, neoadjuvant, therapeutic, prevention and symptom control.
2. Including all settings: adjuvant, neoadjuvant, therapeutic and prevention.

Table 2.3 Prior Medications Overall and in Asian Subgroup - Full Analysis Set

Anatomic Therapeutic Category (ATC)*/ Preferred Term	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Patients with no prior medications, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients with at least one prior medication, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC CLASSIFICATION, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC CLASSIFICATION, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.			

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
* Prior medications taken within the last 4 weeks prior to day 1 are coded to preferred terms and classifications using the WHO-Drug Dictionary. A patient with more than one medication for a preferred term (PT) or ATC classification is counted only once for that PT or ATC classification.
1. Percentages calculated from patients with at least one prior medication. A patient could show more than one PT within the same ATC classification. These are not exclusive. Consequently, the sum of percentages within an ATC classification could be higher than 100%.

Table 2.4 Concomitant Medications Overall and in Asian Subgroup - Full Analysis Set

Anatomic Therapeutic Category (ATC)*/ Preferred Term	**Asian (N=xx)**	**Non-Asian (N=xx)**	**Total (N=xxx)**
Patients with no concomitant medications, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients with at least one concomitnant medication, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC CLASSIFICATION, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC CLASSIFICATION, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.			

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
* Concomitant medications taken from day 1 are coded to preferred terms and classifications using the WHO-Drug Dictionary. A patient with more than one medication for a preferred term (PT) or ATC classification is counted only once for that PT or ATC classification.
1. Percentages calculated from patients with at least one concomitant medication. A patient could show more than one PT within the same ATC classification. These are not exclusive. Consequently, the sum of percentages within an ATC classification could be higher than 100%.

Table 2.5 Medical History Overall and in Asian Subgroup - Full Analysis Set

System Organ Class*/ Preferred Term	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Patients with no medical history abnormalities, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients with at least one medical history abnormality, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SYSTEM ORGAN CLASS 1, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
SYSTEM ORGAN CLASS 2, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.			

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
*Medical abnormalities are coded using MedDRA version 19.1. A patient with more than one medical condition for a preferred term (PT) or system organ class (SOC) is counted only once for that PT or SOC.
1. Percentages calculated from patients with at least one medical history abnormality. A patient could show more than one PT within the same SOC. These are not exclusive. Consequently, the sum of percentages within a SOC could be higher than 100%.

Table 3.1 Patient Disease History Overall and in Asian Subgroup - Full Analysis Set

	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Primary site of cancer, n (%)			
Breast	xx (xx.x)	xx (xx.x)	xx (xx.x)
Details of tumor histology / cytology, n (%)			
n	xxxx	xxxx	xxxx
Invasive ductal carcinoma	xx (xx.x)	xx (xx.x)	xx (xx.x)
Invasive lobular carcinoma	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
NA	xx (xx.x)	xx (xx.x)	xx (xx.x)
Time since initial diagnosis of cancer (years)[1]			
n	xxxx	xxxx	xxxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Time to first recurrence/metastasis (days)[1]			
n	xxxx	xxxx	xxxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Time since most recent progression/metastasis (days)[1]			
n	xxxx	xxxx	xxxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Current disease status, n (%)			
n	xxxx	xxxx	xxxx
Metastatic	xx (xx.x)	xx (xx.x)	xx (xx.x)
Locally advanced	xx (xx.x)	xx (xx.x)	xx (xx.x)
Current metastatic disease site(s), n (%)[2]			
n	xxxx	xxxx	xxxx
Spinal cord	xx (xx.x)	xx (xx.x)	xx (xx.x)
Brain	xx (xx.x)	xx (xx.x)	xx (xx.x)
Meninges	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pleura	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pleural effusion (malignant)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Lung	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pericardial effusion (malignant)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cervical lymph nodes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Axillary lymph nodes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Thoracic lymph nodes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Para-aortic abdominal lymph nodes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Spleen	xx (xx.x)	xx (xx.x)	xx (xx.x)
Liver	xx (xx.x)	xx (xx.x)	xx (xx.x)
Peritoneum	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ascites (malignant)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ovary	xx (xx.x)	xx (xx.x)	xx (xx.x)
Breast	xx (xx.x)	xx (xx.x)	xx (xx.x)
Skin	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone marrow	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, cervical vertebrae	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, thoracic vertebrae	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, lumbar vertebrae	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, sacrum	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, pelvis	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, femur	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, scapulae and humeri	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, sternum and ribs	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone, other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

SD: Standard deviation. NA: Not applicable.
Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
1. Time is computed from date of initial diagnosis of cancer, date of first recurrence, or date of most recent progression/metastases to date of informed consent.
2. Percentage calculation can sum to > 100% because patients can fall in more than one category.

Table 3.2 Patient Therapeutic History Overall and in Asian Subgroup - Full Analysis Set

	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Prior surgery, n (%)			
n	xxxx	xxxx	xxxx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Surgical procedure, n (%)			
n	xxxx	xxxx	xxxx
Lumpectomy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Segmentectomy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mastectomy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior radiotherapy, n (%)			
n	xxxx	xxxx	xxxx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Radiotherapy setting, n (%)			
n	xxxx	xxxx	xxxx
Adjuvant	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neoadjuvant	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prevention	xx (xx.x)	xx (xx.x)	xx (xx.x)
Symptom control	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior therapy medications (solid tumors), n (%)			
n	xxxx	xxxx	xxxx
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior therapy type, n (%)			
n	xxxx	xxxx	xxxx
Chemotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hormonal therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Immunotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Targeted therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.

Table 4 Concomitant Medications During Treatment Period Overall and in Asian Subgroup - Full Analysis Set

	Asian (N=xx)			Non-Asian (N=xx)			Total (N=xxx)		
Anatomic Therapeutic Category (ATC)*/ Preferred Term	WK 20 (N=xxx)	WK 50 (N=xxx)	End of Treatment (N=xxx)	WK 20 (N=xxx)	WK 50 (N=xxx)	End of Treatment (N=xxx)	WK 20 (N=xxx)	WK 50 (N=xxx)	End of Treatment (N=xxx)
Patients with no concomitant medications, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients with at least one concomitant medication, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC CLASSIFICATION, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC CLASSIFICATION, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
* Concomitant medications taken within the visit window of WK 20, WK 50 and End of treatment are coded to preferred terms and classifications using the WHO-Drug Dictionary. A patient with more than one medication for a preferred term (PT) or ATC classification is counted only once for that PTor ATC classification.
1. Percentages calculated from patients with at least one concomitant medication. A patient could show more than one PT within the same ATC classification. These are not exclusive. Consequently, the sum of percentages within an ATC classification could be higher than 100%.

Table 5 Exposure to Everolimus and Exemestane Overall and in Asian Subgroup - Safety Set

	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
	Everolimus (N=xxx)	Exemestane (N=xxx)	Everolimus (N=xxx)	Exemestane (N=xxx)	Everolimus (N=xxx)	Exemestane (N=xxx)
Type of Exemestane, n (%)						
Generic	NA	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)
Branded	NA	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)
Duration of drug exposure including interruptions (weeks)						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Mean daily dose level, including interruptions[a] (mg/days)						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Absolute dose intensity (mg)						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Relative dose intensity (%)						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Absolute dose intensity including interruptions (mg /week)						
n	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Patients with dose reduction, n (%)						
n	xx	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
	Everolimus (N=xxx)	Exemestane (N=xxx)	Everolimus (N=xxx)	Exemestane (N=xxx)	Everolimus (N=xxx)	Exemestane (N=xxx)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for dose reduction or interruption, n (%)	xx	xx	xx	xx	xx	xx
Per protocol	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adverse event	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dosing error	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lab test abnormality	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Scheduling conflict	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dispensing error	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients with Exemestane dose reduction or interruption due to toxicity, n (%)						
n	NA	xx	NA	xx	NA	xx
Yes	NA	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)
Patients with Everolimus dose reduction or interruption due to toxicity, n (%)						
n	xx	NA	xx	NA	xx	NA
One step	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Two steps	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Everolimus dose interruptions >4 weeks	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Treatment discontinuation	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Primary reason study treatment discontinuation[b], n (%)	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Unacceptable adverse event	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Abnormal laboratory value	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Abnormal test procedure results	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Intercurrent illness that prevents further administration	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Consent withdrawal	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Lost to follow-up	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Administrative problems	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Death due to study indication	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Death due to other cause	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Disease progression	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Treatment duration completed within scope of Expanded Access Program[c]	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Patient switched to commercial drug	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Protocol violation	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Changes in patient's condition (investigator's discretion)	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA

	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
	Everolimus (N=xxx)	Exemestane (N=xxx)	Everolimus (N=xxx)	Exemestane (N=xxx)	Everolimus (N=xxx)	Exemestane (N=xxx)
Need for other types of anticancer therapy (excluding palliative radiation for bone lesions)	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Everolimus dose interruption > 4 wks	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA
Other	xx (xx.x)	NA	xx (xx.x)	NA	xx (xx.x)	NA

NA: Not applicable SD: Standard deviation.
Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a] Days with a zero dose level due are to temporary interruptions caused by safety reasons or patients' non-compliance.
[b] Study treatment discontinuation refers to a patient's withdrawal from everolimus.

Table 6.1 Summary Overview of All Treatment-Emergent Adverse Events Summary, Any CTCAE Grade Overall and in Asian Subgroup - Safety Set

Adverse Event	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Number of patients, n (%)			
With no TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
With at least one TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
With at least one drug-related TEAE[a]	xx (xx.x)	xx (xx.x)	xx (xx.x)
With at least one serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE leading to death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-fatal serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
With at least one serious drug-related TEAE, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AE leading to death	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-fatal serious TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)
TEAE leading to treatment discontinuation, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
With at least one treatment-emergent AESI, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. AESI = Adverse events of special interest.
Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03.
Percentages are based on the number of patients in the Safety Set.
[a]Suspected to be related to study drug as determined by the investigator. Although a patient may have had two or more adverse events the patient is only counted once in a category. The same patient may appear in different categories.

Table 6.2.1 Treatment-Emergent Adverse Events Summary by SOC and PT and CTCAE Grade - Safety Set

System Organ Class Preferred Term	CTCAE Grade 1 n (%)		CTCAE Grade 2 n (%)		CTCAE Grade 3 or Grade 4 n (%)		Total n (%)	
	Patients	Events	Patients	Events	Patients	Events	Patients	Events
Number of patients, n (%)								
With no TEAE	xx (xx.x)		xx (xx.x)		xx (xx.x)		xx (xx.x)	
With at least one TEAE	xx (xx.x)		xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of events		xxx		xxx		xxx		xxx
System Organ Class 1								
Preferred Term 1	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 2	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 3	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
System Organ Class 2								
Preferred Term 1	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 2	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 3	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx

TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03.Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse event the patient is only counted once in a category per System Organ Class (SOC) and Preferred Term(PT). The same patient may appear in different categories per SOC and PT. A patient with a same AE with different grades will be included in the different columns of the corresponding grades for that AE.

The following tables will follow the format of Table 6.2.1:

Table 6.2.1.1 Treatment-Emergent Adverse Events Summary by SOC and PT and CTCAE Grade of Asian Patients - Safety Set

Table 6.2.1.2 Treatment-Emergent Adverse Events Summary by SOC and PT and CTCAE Grade of Non-Asian Patients - Safety Set

Table 6.2.1A Treatment-Emergent Adverse Events Summary by SOC and PT for CTCAE Grade 1 Overall and in Asian Subgroup - Safety Set

System Organ Class Preferred Term	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
	Patients	Events	Patients	Events	Patients	Events
Number of patients, n (%)						
With no TEAE	xx (xx.x)		xx (xx.x)		xx (xx.x)	
With at least one TEAE	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of events		xxx		xxx		xxx
System Organ Class 1						
Preferred Term 1	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 2	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 3	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
System Organ Class 2						
Preferred Term 1	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 2	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 3	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
TEAE = Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03.Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more adverse events the patient is only counted once in a category per System Organ Class (SOC) and Preferred Term(PT). The same patient may appear in different categories per SOC and PT.

The following tables will follow the format of Table 6.2.1A:

Table 6.2.1B Treatment-Emergent Adverse Events Summary by SOC and PT for CTCAE Grade 2 Overall and in Asian Subgroup - Safety Set

Table 6.2.1C Treatment-Emergent Adverse Events Summary by SOC and PT for CTCAE Grade 3 and 4 Overall and in Asian Subgroup - Safety Set

Table 6.2.1D Treatment-Emergent Adverse Events Summary by SOC and PT for CTCAE Grade 3 Overall and in Asian Subgroup - Safety Set

Table 6.2.1E Treatment-Emergent Adverse Events Summary by SOC and PT for CTCAE Grade 4 Overall and in Asian Subgroup - Safety Set

Table 6.2.2 Treatment-Emergent Adverse Events Summary by SOC and PT and Maximum CTCAE Grade - Safety Set

System Organ Class Preferred Term	CTCAE Grade 1 n (%)		CTCAE Grade 2 n (%)		CTCAE Grade 3 n (%)		CTCAE Grade 4 n (%)	
	Patients	Events	Patients	Events	Patients	Events	Patients	Events
Number of patients with at least one TEAE within each maximum Severity Category, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of events		xxx		xxx		xxx		xxx
System Organ Class 1								
Preferred Term 1	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 2	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 3	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
System Organ Class 2								
Preferred Term 1	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 2	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 3	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx

EAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03.Percentages are based on the number of patients in the Safety Set. The number of patients with one or more events by maximum severity category represents the incidence of patients with at least one event for which the maximum severity is within each corresponding severity category. Patients may be counted in more than one category if they had separate Preferred Terms (PT) with different maximum severities. Although a patient may have had two or more instances of a same adverse event the patient is counted only once within each System Organ Class (SOC) or PT category. Patients are classified by their maximum severity per SOC and PT.

The following tables will follow the format of Table 6.2.2:

Table 6.2.2.1 Treatment-Emergent Adverse Events Summary by SOC and PT and Maximum CTCAE Grade of Asian Patients - Safety Set

Table 6.2.2.2 Treatment-Emergent Adverse Events Summary by SOC and PT and Maximum CTCAE Grade of Non-Asian Patients - Safety Set

Table 6.3 Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug, Any CTCAE Grade Overall and in Asian Subgroup - Safety Set

System Organ Class/ Preferred Term	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Number of patients with no treatment-emergent adverse events leading to permanent discontinuation of study drug, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of patients with at least one treatment-emergent adverse event leading to permanent discontinuation of study drug, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SYSTEM ORGAN CLASS 1, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
SYSTEM ORGAN CLASS 2, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03. Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse event the patient is only counted once in a category per System Organ Class (SOC) and Preferred Term(PT). The same patient may appear in different categories per SOC and PT.

Table 6.4 Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug by CTCAE Grade - Safety Set

System Organ Class Preferred Term	CTCAE Grade 1	CTCAE Grade 2	CTCAE Grade 3	CTCAE Grade 4	CTCAE Grade 3 or 4	Total (N=xxx) n (%)
Number of patients with at least one TEAE leading to permanent discontinuation of study drug, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1						
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 2						
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03. Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse event the patient is only counted once in a category per System Organ Class (SOC) and Preferred Term (PT). The same patient may appear in different categories per SOC and PT. A patient with a same AE with different grades will be included in the different columns of the corresponding grades for that AE.

The following tables will follow the format of Table 6.4:

Table 6.4.1 Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug by CTCAE Grade of Asian Patients - Safety Set

Table 6.4.2 Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug by CTCAE Grade of Non-Asian Patients - Safety Set

Table 6.5 Treatment-Emergent Adverse Events with Suspected Study Drug Relation, Any CTCAE Grade Overall and in Asian Subgroup - Safety Set

System Organ Class/ Preferred Term	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Number of patients with no treatment-emergent adverse events with suspected study drug relation, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of patients with at least one treatment-emergent adverse event with suspected study drug relation, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SYSTEM ORGAN CLASS 1, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
SYSTEM ORGAN CLASS 2, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03. Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse event the patient is only counted once in a category per System Organ Class (SOC) and Preferred Term (PT). The same patient may appear in different categories per SOC and PT.

Table 6.6 Treatment-Emergent Adverse Events with Suspected Study Drug Relation by CTCAE Grade - Safety Set

System Organ Class Preferred Term	CTCAE Grade 1 n (%)		CTCAE Grade 2 n (%)		CTCAE Grade 3 or 4 n (%)	
	Patients	Events	Patients	Events	Patients	Events
Number of patients with at least one TEAE suspected study drug relation, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of events		xxx		xxx		xxx
System Organ Class 1						
Preferred Term 1	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 2	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 3	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
System Organ Class 2						
Preferred Term 1	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 2	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx
Preferred Term 3	xx (xx.x)	xxx	xx (xx.x)	xxx	xx (xx.x)	xxx

TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03. Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse event the patient is only counted once in a category per System Organ Class (SOC) and Preferred Term (PT). The same patient may appear in different categories per SOC and PT. A patient with a same AE with different grades will be included in the different columns of the corresponding grades for that AE.

Table 6.7 Treatment-Emergent Serious Adverse Events, Any CTCAE Grade Overall and in Asian Subgroup - Safety Set

System Organ Class/ Preferred Term	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
	Patients	Events	Patients	Events	Patients	Events
Patients with no treatment-emergent serious adverse events, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Patients with at least one treatment-emergent serious adverse event, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of events		xxx		xxx		xxx
SYSTEM ORGAN CLASS 1, n (%)	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term N	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
SYSTEM ORGAN CLASS 2, n (%)	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term N	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
TEAE = Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03. Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse event the patient is only counted once in a category per System Organ Class (SOC) and Preferred Term (PT). The same patient may appear in different categories per SOC and PT.

Table 6.8 Treatment-Emergent Serious Adverse Events by CTCAE Grade - Safety Set

System Organ Class Preferred Term	CTCAE Grade 1 n (%)		CTCAE Grade 2 n (%)		CTCAE Grade 3 or 4 n (%)	
	Patients	Events	Patients	Events	Patients	Events
Patients with at least one treatment-emergent serious adverse event within each maximum severity category, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of events		xxx		xxx		xxx
System Organ Class 1						
Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 3	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
System Organ Class 2						
Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 3	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03. Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse event the patient is only counted once in a category per System Organ Class (SOC) and Preferred Term (PT). The same patient may appear in different categories per SOC and PT. A patient with a same AE with different grades will be included in the different columns of the corresponding grades for that AE.

Table 6.9 Treatment-Emergent Adverse Events Leading to Death Overall and in Asian Subgroup - Safety Set

System Organ Class/ Preferred Term	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Patients with no treatment-emergent adverse event leading to death, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients with a treatment-emergent adverse event leading to death, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SYSTEM ORGAN CLASS 1, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)
SYSTEM ORGAN CLASS 2, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term N	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03. Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse events the patient is only counted once in a category per per System Organ Class (SOC) and Preferred Term (PT). The same patient may appear in different categories per SOC and PT.

Table 6.10 Listing of Treatment-Emergent Adverse Events Leading to Death - Safety Set

Asian	Patient Number	Site/ Gender/ Race/Age	Verbatim	System Organ Class/ Preferred Term/ Adverse Event	Start Date/ End Date/ Relative Day of Onset[a]	Duration of AE (Days)	Grade/ Relationship to Study Drug	Action Taken (s)	Date of death / Relative Day of Death[b]	Principal Cause of Death

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a]Day of onset relative to the start of study drug.
[b]Day of death relative to the start of study drug.

Table 6.11 Treatment-Emergent Adverse Events of Special Interest, Any CTCAE Grade Overall and in Asian Subgroup - Safety Set

System Organ Class/ Preferred Term	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
	Patients	Events	Patients	Events	Patients	Events
Patients with no treatment-emergent adverse events of special interest, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Patients with at least one treatment-emergent adverse event of special interest, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of events		xxx		xxx		xxx
SYSTEM ORGAN CLASS 1, n (%)	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term N	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
SYSTEM ORGAN CLASS 2, n (%)	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Preferred Term N	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation. Adverse events are coded using MedDRA version 19.1. AEs are assessed using CTCAE version 4.03. Percentages are based on the number of patients in the Safety Set. Although a patient may have had two or more instances of a same adverse event the patient is only counted once in a category per per System Organ Class (SOC) and Preferred Term (PT).The same patient may appear in different categories per SOC and PT.

The following tables will follow the format of Table 6.8:

Table 6.12 Treatment-Emergent Adverse Events of Special Interest by CTCAE Grade - Safety Set

Table 6.12.1 Treatment-Emergent Adverse Events of Special Interest by CTCAE Grade of Asian Patients - Safety Set

Table 6.12.2 Treatment-Emergent Adverse Events of Special Interest by CTCAE Grade of Non-Asian Patients - Safety Set

Table 6.13 Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, any CTCAE Grade Overall and in Asian Subgroup - Safety Set

	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
	Patients	Events	Patients	Events	Patients	Events
Any TEAE	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Stomatitis	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Non-infectious pneumonitis	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Infection (including pneumonia)	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Hyperglycaemia	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Hyperlipidaemia	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Hypophosphataemia	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Rash	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Hypersensitivity	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Increased creatinine/renal failure/proteinuria	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
Cardiac failure congestive	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation.
Note: All percentages (%) are presented with a denominator of the total number of patients in the safety set.

The following tables will follow the format of Table 6.13:

Table 6.13A Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, CTCAE Grade 1 Overall and in Asian Subgroup –Safety Set

Table 6.13B Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, CTCAE Grade 2 Overall and in Asian Subgroup –Safety Set

Table 6.13C Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, CTCAE Grade 3 or 4 Overall and in Asian Subgroup –Safety Set

Table 6.13D Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, CTCAE Grade 3 Overall and in Asian Subgroup –Safety Set

Table 6.13E Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, CTCAE Grade 4 Overall and in Asian Subgroup –Safety Set

Table 6.14 Time to Resolution of Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 3-4 - Safety Set

	Safety Set (N=xxx)		
TEAE	**Number of patients with Grade 3-4 Events**	**n (%) patients with event resolved[a]**	**Median time to resolution, weeks (95% CI)[b]**
Stomatitis	xx	xx (xx.x%)	x.x (x.x, x.x)
Rash	xx	xx (xx.x%)	x.x (x.x, x.x)
Infection (including pneumonia)	xx	xx (xx.x%)	x.x (x.x, x.x)
Pneumonitis	xx	xx (xx.x%)	x.x (x.x, x.x)

CI: Confidence Interval.

TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation.

[a] The denominator of percent of patients resolved is the number of patients with grade 3-4 events.

[b] Median time to resolution based on Kaplan-Meier Estimates. Confidence intervals calculated when at least two patients have event resolved.

Table 6.14.1 Time to Resolution of Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 3-4: Asian vs. Non-Asian – Safety Set

	Asian (N=xxx)			Non-Asian (N=xxx)		
TEAE	**Number of patients with Grade 3-4 Events**	**n (%) patients with event resolved[a]**	**Median time to resolution, weeks (95% CI)[b]**	**Number of patients with Grade 3-4 Events**	**n (%) patients with event resolved[a]**	**Median time to resolution, weeks (95% CI)[b]**
Stomatitis	xx	xx (xx.x%)	x.x (x.x, x.x)	xx	xx (xx.x%)	x.x (x.x, x.x)
Rash	xx	xx (xx.x%)	x.x (x.x, x.x)	xx	xx (xx.x%)	x.x (x.x, x.x)
Infection (including pneumonia)	xx	xx (xx.x%)	x.x (x.x, x.x)	xx	xx (xx.x%)	x.x (x.x, x.x)
Pneumonitis	xx	xx (xx.x%)	x.x (x.x, x.x)	xx	xx (xx.x%)	x.x (x.x, x.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
CI = Confidence Interval.
TEAE: Treatment emergent adverse event. TEAE are defined as any adverse event with a start date on or after the date of the first dose of study drug and within 30 days of treatment discontinuation.
[a] The denominator of percent of patients resolved is the number of patients with grade 3-4 events.
[b] Median time to resolution based on Kaplan-Meier Estimates. Confidence intervals calculated when at least two patients have event resolved.

Table 6.15 Time to Resolution of Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 2-4 - Safety Set

This table will be created using the same layout as Table 6.14.

Table 6.15.1 Time to Resolution of Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 2-4: Asian vs. Non-Asian: Safety Set

This table will be created using the same layout as Table 6.14.1.

Table 6.16 Time to Resolution of Recurrence After the First Episode of Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 3-4 - Safety Set

This table will be created using the same layout as Table 6.14.

Table 6.16.1 Time to Resolution of Recurrence After the First Episode Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 3-4: Asian vs. Non-Asian: Safety Set

This table will be created using the same layout as Table 6.14.1.

Table 6.17 Time to Resolution of Recurrence After the First Episode of Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 2-4 - Safety Set

This table will be created using the same layout as Table 6.14.

Table 6.17.1 Time to Resolution of Recurrence After the First Episode Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 2-4: Asian vs. Non-Asian: Safety Set

This table will be created using the same layout as Table 6.14.1.

Table 6.18 Time to onset of Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 2-4 - Safety Set

This table will be created using the same layout as Table 6.14.

Table 6.18.1 Time to onset of Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Grade 2-4: Asian vs. Non-Asian: Safety Set

This table will be created using the same layout as Table 6.14.1.

Table 7.1.1 ECOG Performance Status Scores Overall and in Asian Subgroup - Full Analysis Set

		ECOG Performance Status[a], n (%)					
Week	**n**	**0**	**1**	**2**	**3**	**4**	**5**
Total (N=XXX)							
Baseline	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 10	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 20	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 30	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 40	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 50	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
:	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian (N=XXX)							
Baseline	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 10	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 20	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 30	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 40	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 50	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
:	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Asian (N=XXX)							
Baseline	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 4	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 10	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 20	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 30	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 40	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Week 50	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
:	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a]ECOG Performance Status: 0=Fully active, 1=Restricted strenuous activity, but ambulatory, 2= Ambulatory, capable of self-care, but unable to work. 3= Confined to bed >50% day, capable of limited self-care. 4 = Completely disabled. 5 = Dead.

Table 7.1.2 ECOG Performance Status Scores Overall and in Asian Subgroup - Per Protocol Set

This table will be created using the same layout as Table 7.11.

Table 7.2.1 Shift from Baseline to Worst Level in ECOG Performance Status Overall and in Asian Subgroup - Full Analysis Set

Baseline ECOG Performance Status	n[a]	ECOG Performance Status[b], n (%) 0	1	2	3	4	5
Total (N=xxx)							
0	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian (N=xxx)							
0	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-Asian (N=xxx)							
0	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
5	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a]n is the number of patients with baseline and at least one follow-up ECOG performance status data. Shift from baseline to worst level in ECOG performance status is shown.
[b]ECOG Performance Status: 0=Fully active, 1=Restricted strenuous activity, but ambulatory, 2= Ambulatory, capable of self-care, but unable to work. 3 = Confined to bed >50% day, capable of limited self-care. 4 = Completely disabled. 5 = Dead.

Table 7.2.2 Shift from Baseline to Worst Level in ECOG Performance Status Overall and in Asian Subgroup - Per Protocol Set

This table will be created using the same layout as Table 7.2.1.

Table 7.3.1 Time to Deterioration of ECOG Performance Status Overall and in Asian Subgroup - Full Analysis Set

	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
Time to deterioration of performance status[a]	**No. of patients at risk**	**Event-free probability estimates (%)[c]**	**No. of patients at risk**	**Event-free probability estimates (%)[c]**	**No. of patients at risk**	**Event-free probability estimates (%)[c]**
Week 4	xxx	x.x	xxx	x.x	xxx	x.x
Week 10	xxx	x.x	xxx	x.x	xxx	x.x
Week 20	xxx	x.x	xxx	x.x	xxx	x.x
Week 30	xxx	x.x	xxx	x.x	xxx	x.x
Week 40	xxx	x.x	xxx	x.x	xxx	x.x
Week 50	xxx	x.x	xxx	x.x	xxx	x.x
Etc. (as appropriate)	xxx	x.x	xxx	x.x	xxx	x.x
Total number of events, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of censored, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Percentiles (95%CI) (weeks)[b]						
25th percentile	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	
Median	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	
75th percentile	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a]Time to deterioration is the time from date of start of treatment to the date of the event defined as deterioration. Deterioration defined as an increase in performance status from 0 to 2 or greater, an increase in performance status from 1-2 to 3 or greater, or death due to any cause.
[b] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[c] Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. Event-free probability estimates are obtained from the Kaplan-Meier survival estimates.

Table 7.3.2 Time to Deterioration of ECOG Performance Status Overall and in Asian Subgroup - Per Protocol Set

This table will be created using the same layout as Table 7.3.1.

Table 7.3.3 Distribution of Time to Deterioration of ECOG Performance Status Overall and in Asian Subgroup by Analysis Set

	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
	Full analysis set	Per protocol set	Full analysis set	Per protocol set	Full analysis set	Per protocol set
Statistics	Time in weeks (95% CI)	Time in weeks (95% CI)	Time in weeks (95% CI)	Time in weeks (95% CI)	Time in weeks (95% CI)	Time in weeks (95% CI)
25% Deterioration	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
50% Deterioration	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)
75% Deterioration	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)	xx (xx.x, xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
CI: Confidence Interval

Table 8.1.1 Best Overall Response Rate *Overall and in Asian Subgroup* - Full Analysis Set

Everolimus + Exemestane (N=xxx)	**Asian (N=xx)**		**Non-Asian (N=xx)**		**Total (N=xxx)**	
Overall Response rate, overall study period	n(%)	(95% CI)	n(%)	(95% CI)	n(%)	(95% CI)
Best overall response rate[a]	xxx		xxx		xxx	
Complete Response (CR)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Partial Response (PR)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Stable Disease (SD)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Progressive Disease (PD)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Unknown (UNK)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Overall Response Rate (ORR: CR+PR)[b]	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Clinical Benefit Rate (CBR: CR+PR+SD >= 24 weeks)[c]	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Overall Response rate, at Week 20	n(%)	(95% CI)	n(%)	(95% CI)	n(%)	(95% CI)
Best overall response rate[a]	xxx		xxx		xxx	
Complete Response (CR)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Partial Response (PR)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Stable Disease (SD)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Progressive Disease (PD)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Unknown (UNK)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Overall Response Rate (ORR: CR+PR)[b]	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Clinical Benefit Rate (CBR: CR+PR+SD >= 24 weeks)[c]	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Overall Response rate, at Week 50	n(%)	(95% CI)	n(%)	(95% CI)	n(%)	(95% CI)
Best overall response rate[a]	xxx		xxx		xxx	
Complete Response (CR)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Partial Response (PR)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Stable Disease (SD)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Progressive Disease (PD)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Unknown (UNK)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Overall Response Rate (ORR: CR+PR)[b]	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)
Clinical Benefit Rate (CBR: CR+PR+SD >= 24 weeks)[c]	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)	xx (x.x)	(xx.x, xx.x)

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.

[a] Best overall response rate: The best response recorded from baseline assessment until progression. CR: at least two consecutive determinations of CR at least 4 weeks or one determination of CR where confirmation not required prior to PD. PR: at least two consecutive determinations of PR (or better) at least 4 weeks or one determination of PR where confirmation not required prior to PD and not classified as PR. SD: one determination of SD (any duration) prior to PD and not classified as CR or PR. PD: one determination of PD (any duration) and not classified as CR, PR or SD. Unknown: not classified as CR, PR, SD or PD.
[b] Overall response rate: Patients with best overall response rate of CR or PR.
[c] Clinical benefit rate: Patients with best overall response rate of CR (any duration), PR (any duration) and SD with duration of 24 weeks or longer.
N: The total number of patients in the treatment group. It is the denominator for percentage (%) calculation.
n: Number of patients who are at the corresponding category.
CI: Confidence interval. The 95% CI for the frequency distribution of each variable were computed using the Clopper-Pearson method.

Programmer note: This table is not created by Kaplan Meier method. It is a summary of descriptive statistics based on week 20 and week 50 CRF data. n is the number of patients with non-missing data.

Table 8.1.2 Overall Response Rate *Overall and in Asian Subgroup - Per Protocol Set*

This table will be created using the same layout as Table 8.1.1.

Table 8.1.3 Time to Overall Response Overall and in Asian Subgroup – Full Analysis Set

	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
Time to Overall Response[a]	No. of patients at Risk	Event-free probability estimates (%)[c]	No. of patients at Risk	Event-free probability estimates (%)[c]	No. of patients at Risk	Event-free probability estimates (%)[c]
Week 4	xxx	x.x	xxx	x.x	xxx	x.x
Week 10	xxx	x.x	xxx	x.x	xxx	x.x
Week 20	xxx	x.x	xxx	x.x	xxx	x.x
Week 30	xxx	x.x	xxx	x.x	xxx	x.x
Week 40	xxx	x.x	xxx	x.x	xxx	x.x
Week 50	xxx	x.x	xxx	x.x	xxx	x.x
Etc. (as appropriate)	xxx	x.x	xxx	x.x	xxx	x.x
Total number of events, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of censored, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Percentiles (95%CI) (weeks)[b]						
25th percentile	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	
Median	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	
75th percentile	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a] Time to overall response is the time from date of start of treatment to the date of event defined as overall response. Overall response rate: Patients with best overall response rate of CR or PR: CR: At least two consecutive determinations of CR or PR for at least 4 weeks or one determination of CR or PR where confirmation not required prior to PD.
[b] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[c] Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. Event-free probability estimates are obtained from the Kaplan-Meier survival estimates.

Table 8.1.4 Time to Overall Response Overall and in Asian Subgroup – Per Protocol Set

This table will be created using the same layout as Table 8.1.3.

Table 8.1.5 Distribution of Time to Overall Response Overall and in Asian Subgroup by Analysis Set

This table will be created using the same layout as Table 7.3.3.

Table 8.2.1 Duration of Clinical Response Overall and in Asian Subgroup - Full Analysis Set

Overall Response	Statistic	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Duration of overall response (CR+PR) (weeks)[a]	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Proportion with overall response (CR+PR) > 24 weeks	n (%)	xx (xx)	xx (xx)	xx (xx)
	95%CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Duration of clinical benefit (CR+PR+SD >= 24 weeks) (weeks)[b]	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Proportion with clinical benefit (CR+PR+SD >= 24 weeks) > 24 weeks	n (%)	xx (xx)	xx (xx)	xx (xx)
	95%CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Duration of stable disease (weeks)[c]	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Proportion with stable disease > 24 weeks	n (%)	xx (xx)	xx (xx)	xx (xx)
	95%CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
For patients right-censored[d]				
Time elapsed from last tumor evaluation to end of study (weeks)[e]	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

SD: Standard deviation. CI: Confidence interval.
Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a] Duration of overall response: Time from the date of the first of two documented CR or PR for at least 4 weeks or one documented CR or PR where confirmation not required to the date of first documented disease progression or death due to underlying cancer.
[b] Duration of clinical benefit: Time from the date of the first of CR (any duration), PR (any duration) or SD (with duration of 24 weeks) to the date of first documented disease progression or death due to underlying cancer.
[c] Duration of stable disease: Time from the start of treatment date to date of first documented disease progression or death due to underlying cancer.
[d] For effectiveness evaluation (progression-free survival), patients without progression or death are right-censored at the date of their last tumor response evaluation.

[e] Time from the date of last tumor assessment to date of end of study visit. In case of end of study visit date missing, date of last follow-up visit or date of end of treatment, whichever occurs later, will be used.

Table 8.2.2 Duration of Clinical Response Overall and in Asian Subgroup - Per Protocol Set

This table will be created using the same layout as Table 8.2.1.

Table 8.3.1 Progression-Free Survival *Overall and in Asian Subgroup* - Full Analysis Set

	Asian (N=xx)		Non-Asian (N=xx)		Total (N=xxx)	
Progression-free survial (PFS) time[a]	No. of patients at risk	Event-free probability estimates (%)[c]	No. of patients at risk	Event-free probability estimates (%)[c]	No. of patients at risk	Event-free probability estimates (%)[c]
Week 4	xxx	x.x	xxx	x.x	xxx	x.x
Week 10	xxx	x.x	xxx	x.x	xxx	x.x
Week 20	xxx	x.x	xxx	x.x	xxx	x.x
Week 30	xxx	x.x	xxx	x.x	xxx	x.x
Week 40	xxx	x.x	xxx	x.x	xxx	x.x
Week 50	xxx	x.x	xxx	x.x	xxx	x.x
Etc. (as appropriate)						
Total number of events, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Progression, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Death, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Total number of censored, n (%)	xx (xx.x)		xx (xx.x)		xx (xx.x)	
Percentiles (95%CI) (weeks)[b]						
25th percentile	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	
Median	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	
75th percentile	xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)		xx.x (xx.x, xx.x)	

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
[a] PFS is time from date of start of treatment to date of disease progression or death due to any cause, whichever occurs frist.
[b] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[c] Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. Event-free probability estimates are obtained from the Kaplan-Meier survival estimates.

Table 8.3.2 Progression-Free Survival Overall and in Asian Subgroup - Per Protocol Set

Table 8.3.3 Progression-Free Survival Overall and in Asian Subgroup – Sensitivity Analysis

These tables will be created using the same layout as Table 8.3.1.

Table 8.3.4 Distribution of Time to Progression-Free Survival Overall and in Asian Subgroup by Analysis Set

This table will be created using the same layout as Table 7.3.3.

[redacted]

[redacted]

Table 10.1.1 Vital Signs: Observed and Change from Baseline - Safety Set

Visit	Statistic	Body Temperature (°C)	Heart Rate (bpm)	Sitting Systolic Blood Pressure (mmHg)	Sitting Diastolic Blood Pressure (mmHg)
Total (N=xxx)					
Baseline (BL)	n	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 4	n	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 4 Change from BL	n	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 10	n	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 10 Change from BL	n	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Include Weeks 20, 30, 40, 50, etc.	:	:	:	:	:
End of Treatment (EOT)	n	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
EOT Change from BL	n	xx	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

SD: Standard Deviation.

Table 10.1.2 Vital Signs: Observed and Change from Baseline for Asian Patients- Safety Set

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
SD: Standard Deviation.

Table 10.1.3 Vital Signs: Observed and Change from Baseline for Non-Asian Patients- Safety Set

Non-Asian: Australia, Morocco, South Africa or Tunisia.
SD: Standard Deviation.

These tables will be created using the same layout as Table 10.1.1.

Table 10.1.4 Vital Signs: Shift Table Based On Notable Values - Safety Set

		Total (N=xxx)				
		Worst post-baseline value				
Baseline	n (%)	Normal n (%)	High only n (%)	Low only n (%)	High and Low n (%)	Missing n (%)
Temperature (°C)						
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High only	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Low only	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Heart rate (bpm)						
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High only	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Low only	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SBP (mmHg)						
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High only	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Low only	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
DBP (mmHg)						
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High only	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Low only	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

- Notably abnormal vital signs:
  - Systolic blood pressure [mmHg]: >=180 mmHg/<=90 mmHg with increase/decrease from baseline of >=20 mmHg
  - Diastolic blood pressure [mmHg]: >=105 mmHg/<=50 mmHg with increase/decrease from baseline of >=15 mmHg
  - Pulse rate [bpm]: >=120 bpm/<=50 bpm with increase/decrease from baseline of >=15 bpm
  - Temperature(°C): >=39.1°C or <=35°C
- If a patient has both High and Low post baseline values then count in High and Low.
- Baseline is defined as the last non-missing value prior to the first study drug dose.
- Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.1.5 Vital Signs: Shift Table Based On Notable Values for Asian Patients- Safety Set

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
- Notably abnormal vital signs:
  - Systolic blood pressure [mmHg]: >=180 mmHg/<=90 mmHg with increase/decrease from baseline of >=20 mmHg
  - Diastolic blood pressure [mmHg]: >=105 mmHg/<=50 mmHg with increase/decrease from baseline of >=15 mmHg
  - Pulse rate [bpm]: >=120 bpm/<=50 bpm with increase/decrease from baseline of >=15 bpm
  - Temperature(°C): >=39.1°C or <=35°C
- If a patient has both High and Low post baseline values then count in High and Low.
- Baseline is defined as the last non-missing value prior to the first study drug dose.
- Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.1.6 Vital Signs: Shift Table Based On Notable Values for Non-Asian Patients- Safety Set

Non-Asian: Australia, Morocco, South Africa or Tunisia.
- Notably abnormal vital signs:
  - Systolic blood pressure [mmHg]: >=180 mmHg/<=90 mmHg with increase/decrease from baseline of >=20 mmHg
  - Diastolic blood pressure [mmHg]: >=105 mmHg/<=50 mmHg with increase/decrease from baseline of >=15 mmHg
  - Pulse rate [bpm]: >=120 bpm/<=50 bpm with increase/decrease from baseline of >=15 bpm
  - Temperature(°C): >=39.1°C or <=35°C
- If a patient has both High and Low post baseline values then count in High and Low.
- Baseline is defined as the last non-missing value prior to the first study drug dose.
- Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

These tables will be created using the same layout as Table 10.1.4.

Table 10.2.1 Local Hematology Data: Change from Baseline Overall and in Asian Subgroup - Safety Set

Laboratory Test/ Visit	Statistic	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Complete Blood Count (CBC):				
Baseline (BL)	Observed, n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 4 Change from BL	Observed, n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Week 10 Change from BL	Observed, n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Include "Week X Change from BL" where X= 20, 30, 40, 50, Etc.	:			
End of Treatment Change from BL	Observed, n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for other laboratory tests: WBC (total), RBC, Hemoglobin, Hematocrit, Platelet Count, absolute neutrophils, absolute lymphocytes, absolute eosinophils, absolute basophils, absolute monocytes.				

SD: Standard Deviation.
Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.

Table 10.2.2 Hematology shift table based on CTC grade - Safety Set

		Everolimus + Exemestane (N=xxx)					
		Worst post-baseline value					
	Baseline	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Parameter	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Parameter 1							
Grade 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Parameter 2							
Grade 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.							

Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.2.3 Hematology shift table based on CTC grade for Asian Patients - Safety Set

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.2.4 Hematology shift table based on CTC grade for Non-Asian Patients - Safety Set

Non-Asian: Australia, Morocco, South Africa or Tunisia.

Baseline is defined as the last non-missing value prior to the first study drug dose.

Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.2.5 Hematology shift table based on normal range for parameters with no defined CTC grade - Safety Set

		Everolimus + Exemestane (N=xxx)				
		Worst post-baseline value				
	Baseline	Low	Normal	High	Low & High	Missing
Parameter	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Parameter 1						
Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Parameter 2						
Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.						

- Low/High categories defined by normal ranges
- Only the hematology parameters without CTC grades are included
- Baseline is defined as the last non-missing value prior to the first study drug dose.
- Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.2.6 Hematology shift table based on normal range for parameters with no defined CTC grade for Asian Patients- Safety Set

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Low/High categories defined by normal ranges
Only the hematology parameters without CTC grades are included
Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.2.7 Hematology shift table based on normal range for parameters with no defined CTC grade for Non-Asian Patients- Safety Set

Non-Asian: Australia, Morocco, South Africa or Tunisia.
Low/High categories defined by normal ranges
Only the hematology parameters without CTC grades are included
Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.3.1 Blood Chemistry: Observed and Change from Baseline Overall and in Asian Subgroup - Safety Set

Laboratory Test/ Visit	Statistic	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Blood Urea Nitrogen (BUN):				
Baseline (BL)	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Week 4 Change from BL	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Week 10 Change from BL	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Include "Week X Change from BL" where X= 20, 30, 40, 50, Etc.	:			
End of Treatment Change from BL	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Repeat for other laboratory tests: Creatinine, Sodium, Fasting Glucose, Potassium, Uric acid, Calcium, LDH, Total protein, Albumin, SGOT (AST), SGPT (ALT), Alkaline phosphatase, GGT, Total bilirubin,Urea				

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
SD: Standard Deviation.

Table10.3.2 Biochemistry shift table based on CTC grade - Safety Set

		Everolimus + Exemestane (N=xxx)					
		Worst post-baseline value					
	Baseline	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
Parameter	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Parameter 1							
Grade 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Parameter 2							
Grade 0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.							

Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table10.3.3 Biochemistry shift table based on CTC grade for Asian Patients - Safety Set

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table10.3.4 Biochemistry shift table based on CTC grade for Non-Asian Patients - Safety Set

Non-Asian: Australia, Morocco, South Africa or Tunisia.
Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.3.5 Biochemistry shift table based on normal range for parameters with no defined CTC grade - Safety Set

		Everolimus + Exemestane (N=xxx)				
		Worst post-baseline value				
	Baseline	Low	Normal	High	Low & High	Missing
Parameteer	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Parameter 1						
Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Parameter 2						
Low	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
High	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.						

Low/High categories defined by normal ranges.
Only the biochemistry parameters without CTC grades are included.
Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.3.6 Biochemistry shift table based on normal range for parameters with no defined CTC grade for Asian Patients - Safety Set

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Low/High categories defined by normal ranges.
Only the biochemistry parameters without CTC grades are included.
Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.3.7 Biochemistry shift table based on normal range for parameters with no defined CTC grade for Non-Asian Patients - Safety Set

Non-Asian: Australia, Morocco, South Africa or Tunisia.
Low/High categories defined by normal ranges.
Only the biochemistry parameters without CTC grades are included.
Baseline is defined as the last non-missing value prior to the first study drug dose.
Baseline percentage is based on N. Percentage for worst post-baseline value is based on Baseline n.

Table 10.4 Serum Lipids: Observed and Change from Baseline Overall and in Asian Subgroup - Safety Set

Laboratory Test/ Visit	Statistic	Asian (N=xx)	Non-Asian (N=xx)	Total (N=xxx)
Total cholesterol:				
Baseline (BL)	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Week 4 Change from BL	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Week 10 Change from BL	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Include "Week X Change from BL" where X= 20, 30, 40, 50, Etc.				
End of Treatment Change from BL	n	xx	xx	xx
	Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Median	xx	xx	xx
	Min, Max	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Repeat for other laboratory tests: Triglycerides.				

Asian: Indonesia, India, Vietnam, Turkey, South Korea, Thailand, Malaysia, Taiwan or Jordan.
Non-Asian: Australia, Morocco, South Africa or Tunisia.
SD: Standard Deviation.

Tables for Subgroup Analyses

The following subgroups analysis will be performed;

- Patients who received chemotherapy in the metastatic setting versus those who didn't receive chemotherapy in the metastatic setting (**Subgroup 1**):
- Patients who received the combination everolismus and exemestane in first line treatment for metastatic disease versus patients who received it in second line or more. (**Subgroup 2**)
- Patients with visceral metastasis (lung and/or liver) versus patients without visceral metastasis (**Subgroup 3**)
- Hormonal receptor status: Patients with ER+PR+ versus ER+PR- versus ER-PR+ (**Subgroup 4**)

The following table shells will be produced for the subgroup analysis 1 (S1) using the same layout as previous table with the same number and title, and the follsing column header (i.e., Table S1.2.1.1 using the same layout as Table 2.1.1):

	Patients with chemotherapy in the metastatic setting (N=xxx)	Patients without chemotherapy in the metastatic setting (N=xxx)	Total (N=xxx)

Table S1.2.1.1 Patient Demographics – Full Analysis Set

Table S1.2.1.2 Baseline Clinical Characteristics – Full Analysis Set

Table S1.5 Exposure to Everolimus and Exemestane – Safety Set

Table S1.8.1.1 Best Overall Response Rate - Full Analysis Set

Table S1.8.2.1 Duration of Clinical Response - Full Analysis Set

Table S1.8.3.1 Progression-Free Survival - Full Analysis Set

The following table shells will be produced for the subgroup analysis 1 (S2) using the same layout as previous table with the same number and title, and the follsing column header (i.e., Table S2.2.1.1 using the same layout as Table 2.1.1):

	Patients who received the combination EVE+EXE in first line for metastatic disease (N=xxx)	Patients who received the combination EVE+EXE in second line or more for metastatic disease (N=xxx)	Total (N=xxx)

Table S2.2.1.1 Patient Demographics – Full Analysis Set

Table S2.2.1.2 Baseline Clinical Characteristics – Full Analysis Set

Table S2.5 Exposure to Everolimus and Exemestane – Safety Set

Table S2.6.1 Summary Overview of All Treatment-Emergent Adverse Events Summary, Any CTCAE Grade – Safety Set

Table S2.6.2.1 Treatment-Emergent Adverse Events Summary by SOC and PT for Any CTCAE Grade – Safety Set

Table S2.6.2.1A Treatment-Emergent Adverse Events Summary by SOC and PT for CTCAE Grade 1 – Safety Set

Table S2.6.2.1B Treatment-Emergent Adverse Events Summary by SOC and PT for CTCAE Grade 2 - Safety Set

Table S2.6.2.1C Treatment-Emergent Adverse Events Summary by SOC and PT for CTCAE Grade 3 and 4 - Safety Set

Table S2.6.13 Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, Any CTCAE Grade – Safety Set

Table S2.6.13A Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, CTCAE Grade 1 - Safety Set

Table S2.6.13B Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, CTCAE Grade 2 - Safety Set

Table S2.6.13C Treatment-Emergent Adverse Event of Special Interest Associated with mTOR Inhibition, CTCAE Grade 3 or 4 - Safety Set

Table S2.8.1.1 Best Overall Response Rate - Full Analysis Set

Table S2.8.2.1 Duration of Clinical Response - Full Analysis Set

Table S2.8.3.1 Progression-Free Survival - Full Analysis Set

The following table shells will be produced for the subgroup analysis 3 (S3) using the same layout as previous table with the same number and title, and the following column header (i.e., Table S3.8.1.1 using the same layout as Table 8.1.1):

	Patients with visceral metastasis (lung and/or liver) (N=xxx)	Patients without visceral metastasis (lung and/or liver) (N=xxx)	Total (N=xxx)

Table S3.8.1.1 Best Overall Response Rate - Full Analysis Set

Table S3.8.2.1 Duration of Clinical Response - Full Analysis Set

Table S3.8.3.1 Progression-Free Survival - Full Analysis Set

The following table shells will be produced for the subgroup analysis 4 (S4) using the same layout as previous table with the same number and title, and the following column header (i.e., Table S4.8.1.1 using the same layout as Table 8.1.1):

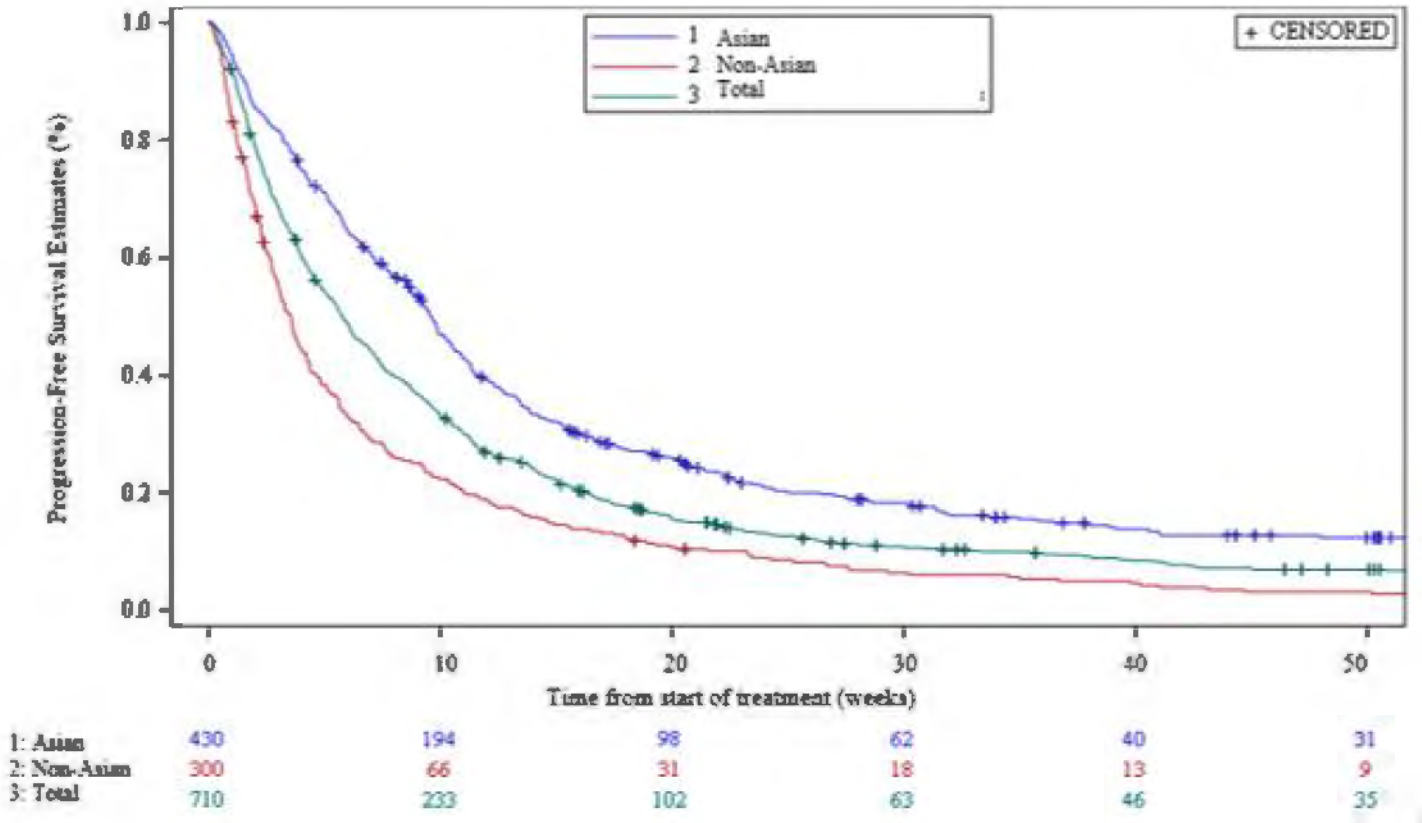
	Patients with ER+ and PR+ (N=xxx)	Patients with ER+ and PR- (N=xxx)	Patients with ER- and PR+ (N=xxx)

Table S4.8.1.1 Best Overall Response Rate - Full Analysis Set

Table S4.8.2.1 Duration of Clinical Response - Full Analysis Set

Table S4.8.3.1 Progression-Free Survival - Full Analysis Set

Figure 1.1 Progression-Free Survival, Asian vs. Non-Asian - Full Analysis Set



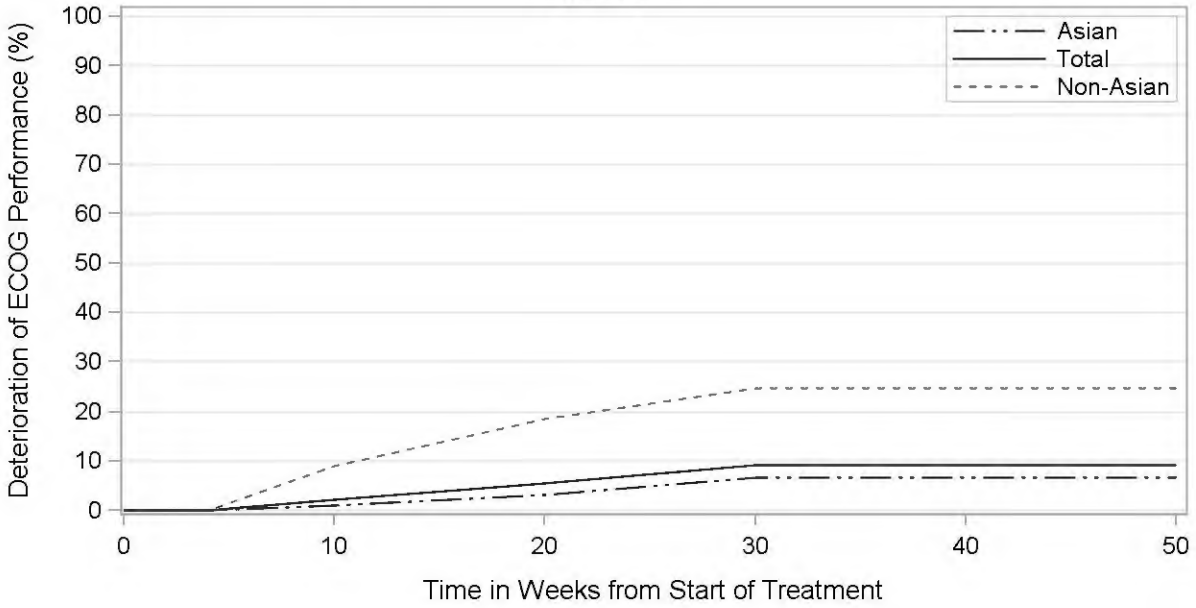
Note that this figure is an example. The ouputs are not real/correct, these were invented.

The following figures will be created using the same layout as Figure 1.1.

Figure 1.2 Progression-Free Survival, Asian vs. Non-Asian - Per Protocol Set

Figure 2.1 Time to Deterioration of ECOG Performance Status, Asian vs. Non-Asian - Full Analysis Set

Figure 2.1
Time to Deterioration of ECOG Performance Status, Asian vs. Non-Asian - Evaluable Patients



Time to deterioration is the time from date of start of treatment to the date of event defined as deterioration.
Deterioration defined as an increase in performance status from 0 to 2 or greater, an increase in performance status from 1-2 to 3 or greater, or death due to any cause.
Kaplan-Meier Estimates

The following figures will be created using the same layout as Figure 2.1.

Figure 2.2 Time to Deterioration of ECOG Performance Status, Asian vs. Non-Asian - Per Protocol Set

Figure 3.1 Cumulative Incidence Estimates for Time to Stomatitis Grade 2-4, Asian vs. Non-Asian - Safety Set

Figure 3.2 Cumulative Incidence Estimates for Time to Rash Grade 2-4, Asian vs. Non-Asian - Safety Set

Figure 3.3 Cumulative Incidence Estimates for Time to Infections Grade 2-4, Asian vs. Non-Asian - Safety Set

Figure 3.4 Cumulative Incidence Estimates for Time to Pneumonitis Grade 2-4, Asian vs. Non-Asian - Safety Set

Listing 1.1 Disposition: Analysis Populations

Country	Site ID	Patient ID	Screen Failure/ Reason for Screen Fail	Screening Date	Informed Consent Date	Eligibility	Full Analysis Set/ Per Protocol Set/ Safety Set	Discontinuation of Study Drug/ Reason	Last Date in Study/ Days in Study
xxx	xxx	xxxx	xxx/xxx	DD-MMM-YYYY	DD-MMM-YYYY	Y	xxx/xxx/xx	xxxx/xxx	DD-MMM-YYYY

Generated with data from all patients, sorted by Site ID and Patient ID

Programmer note: the response to the column Full Analysis Set/Per Protocol Set/Safety Set is Y/N to each of these three sets, e.g., Y/Y/N. Y=Yes, N=No

Listing 1.2 Disposition: End of Study Treatment and Study Evaluation Completion

Page 1 of Listing

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Last Known Date Patient Took Study Drug	Primary Reason for End of Study Treatment	Specify Reason for End of Study Treatment	Principal Cause of Deathh	If Other Cause, Specify Cause of Death	Date of Death	Patient Agrees to be Followed for Post-Treatment Evaluations
			DD-MMM-YYYY	XXXX	XXXX	XXXX	XXXX	DD-MMM-YYYY	Y

Note: Y=Yes, N=No. FAS:Full Analysis Set. PPS: Per Protocol Set. SS:Safety Set.

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Country	Site ID	Patient ID/ FAS/ PPS/ SS	Primary Reason for Study Evaluation Completion	Specify Reason for Study Evaluation Completion	Principal Cause of Death	If Other Cause, Specify Cause of Death	Date of Death
			XXXX	DD-MMM-YYYY	XXXX	XXXX	DD-MMM-YYYY

Listing 2.1 Patients Excluded from Full Analysis Set

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Reasons

Generated with data from eligible patients, sorted by Site ID and Patient ID

Listing 2.2 Patients Excluded from Per Protocol Set (Major Protocol Deviations)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Major Protocol Deviations

Generated with data from eligible patients, sorted by Site ID and Patient ID

Listing 2.3 Patients Excluded from Safety Set

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Reasons

Generated with data from eligible patients, sorted by Site ID and Patient ID

Listing 3 Inclusion/Exclusion Criteria

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Country	Site ID	Patient ID/ FAS/ PPS/ SS	Date Informed Consent Obtained	I1	I2	I3	I4	I5	I6	I7	I2	I8	I9	I10	I11	I12	I13	I14
			DD-MMM-YYYY	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
			DD-MMM-YYYY	Y	Y	Y	Y	N	N	N	N	N	N	N	N	Y	Y	Y

NOTE: Y=Yes, N=No. I=Inclusion I1=Adult women (≥18 years of age) with metastatic, recurrent or locally advanced breast cancer not amenable to curative treatment by surgery or radiotherapy.
I2 = Histological or cytological confirmation of ER+ breast cancer. I3 = Postmenopausal women. I4 = Disease refractory to non-steroidal aromatase inhibitors. I5 = Radiological or objective evidence of recurrence or progression on or after the last systemic therapy prior to enrollment. I6 = Measurable disease or bone lesions. I7 = Adequate bone marrow and coagulation function. I8 = Adequate liver function. I9 = Adequate renal function. I10 = Fasting serum cholesterol ≤ 300 mg/dl or 7.75 mmol/L and fasting triglycerides ≤ 2.5xULN. I11 = ECOG Performance Status ≤2. I12 = Adequate organ function. I13 = Patients with positive HBV-DNA of HBsAg at screening must initiate prophylaxis at least one week prior to treatment start. I14 = Signed informed consent obtained.

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Country	Site ID	Patient ID/ FAS/ PPS/ SS	E1	E2	E3	E4	E5	E6	E7	E8	E9	E10	E11	E12	E13	E14	E15	E16	E17	E18	Patient Meets all Inclusion Criteria and Does Not Meet Any Exclusion Criteria
			N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
			Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N

NOTE: Y=Yes, N=No. E=Exclusion E1 = Patients over expressing HER2. E2 = Patients with only non-measurable lesions other than bone metastasis. E3 = Patients with more than one prior chemotherapy line. E4 = Previous treatment with exemestane or mTOR inhibitors. E5 = Known hypersensitivity to mTOR inhibitors. E6 = Any other malignancy within 5 years prior to enrollment. E7 = Radiotherapy within four wks prior to randomization. E8 = Patient receiving hormone replacement therapy. E9 = History of brain or other CNS metastases. E10 = Treatment with immunosuppressive agents or chronic corticosteroids. E11 = Bilateral diffuse lymphangitic carcinomatosis. E12 = Patients with a known history of HIV seropositivity. E13 = Active, bleeding diathesis. E14 = Any severe and/or uncontrolled medical conditions. E15 = Patients being treated with drugs recognized as being strong inhibitors or inducers of the isoenzyme CYP3A at enrollment. E16 = Patients unwilling to or unable to comply with the protocol. E17 = Patients enrolled in another investigational drug or device study.
E18 = Patients who have discontinued this study may not be re-enrolled.

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Country	Site ID	Patient ID/ FAS/ PPS/ SS	Patient Enrolling in Trial	Primary Reason (s) for Not Enrolling								
				Unacceptable Past Medical History/ Concomitant Diagnosis	Intercurrent Medical Event	Unacceptable Laboratory Value	Unacceptable Test Procedure Result	Did Not Meet Diagnostic/ Severity Criteria	Unacceptable Use of Excluded Medication/ Therapies	Patient Withdrew Consent	Unknown	Other/Specify Reason
			N				Y					Y/XXXXX/XXXXX
			Y									

NOTE: Y=Yes, N=No.

Generated with data from all patients, sorted by Eligibility (Yes first, then No) and Patient ID within a Site ID

Listing 4 Demographics

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Date of Birth	Predominant Race/ Ethnicity	Sex/ Child Bearing Potential	Source of Patient Referral
			DD-MMM-YYYY	XXXX / XXX	XXXX / XXX	XXXX

Generated with data from all patients, sorted by Eligibility (Yes first, then No) and Patient ID within a Site ID

Listing 5 Relevant Medical History and Current Cancer-Related Medical Conditions

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Date of Diagnosis or Surgery	History or Condition	MedDRA System Organ Class/ Preferred Term	Active Problem
			DD-MMM-YYYY	XXXX	XXXX	Y
			DD-MMM-YYYY	XXXX	XXXX	N

NOTE: Y=Yes, N=No. MedDRA vX.X.

Generated with data from all patients, sorted by Eligibility (Yes first, then No) and Patient ID within a Site ID

Listing 6 Diagnosis and Extent of Cancer

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Details of Tumor Histology	Date of Initial Diagnosis of Cancer	Date of First Recurrence	Date of Most Recent Progression	Current Disease Status	Metastatic Disease Site(s)[a]
			XXXX	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	XXXX	XXXXX/XXXXXX/XXXXX
			XXXX	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY	XXXX	

[a] Patients may have several metastatic sites

Generated with data from all patients, sorted by Eligibility (Yes first, then No) and Patient ID within a Site ID

Listing 7 Prior Surgery

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Procedure	Specify Other Procedure	Date of Surgery	Residual Disease	Metastatic Disease Site(s)[a]
			XXXX	XXXX	DD-MMM-YYYY	XXXX	XXXXX/XXXXXX/XXXXX

[a] Patients may have several metastatic sites

Generated with data from all patients, sorted by Eligibility (Yes first, then No) and Patient ID within a Site ID

Listing 8 Prior Radiotherapy

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Location (Site)	Start Date	End Date	Setting
			XXXXXXXXX	DD-MMM-YYYY	DD-MMM-YYYY	XXXXXXXXX
			XXXXXXXXXXX	DD-MMM-YYYY	DD-MMM-YYYY	XXXXXXXXX

Generated with data from all patients, sorted by Eligibility (Yes first, then No) and Patient ID within a Site ID

Listing 9 Prior Medications (Solid Tumors)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Regimen Number	Therapy Type	Medication	Planned dose/ unit	Regimen	Specify Other Regimen	Setting	Number of Cycles	Start Date of First Dose	End Date of last Dose	Date of Progression
			XX	XXXXXX	XXXXXX	XX/XX	XXXXXX	XXXX	XXXXXX	XX	DD-MMM-YYYY	DD-MMM-YYYY	DD-MMM-YYYY

Generated with data from all patients, sorted by Eligibility (Yes first, then No) and Patient ID within a Site ID

Listing 10.1 Prior Medications

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Country	Site ID	Patient ID/ FAS/ PPS/ SS	Anatomic Therapeutic Category	Preferred Name*	Verbatim Term	Single Dose	Unit	Specify other unit	Frequency	Specify Other Frequency	Route
			XXXXXXX	XXXXXXX	XXXXXXXXXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX

Note: Y=Yes, N=No. Medications taken within 4 wks of Day 1 are coded to preferred terms and classifications using the WHO-Drug Dictionary.

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Country	Site ID	Patient ID/ FAS/ PPS/ SS	Anatomic Therapeutic Category	Preferred Name*	Reason (Including Prophylaxis)	Start Date	End Date	Continuing at Final exam
			XXXXXXXX	XXXXXXXX	XXXXXXXX/XXXXXXXX	DD-MMM-YYYY	DD-MMM-YYYY	Y

Note: Y=Yes, N=No. Medications taken within 4 wks of Day 1 are coded to preferred terms and classifications using the WHO-Drug Dictionary.

Listing 10.2.1 Concomitant Medications (Part I)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Anatomic Therapeutic Category	Preferred Name*	Verbatim Term	Single Dose	Unit	Specify other unit	Frequency	Specify Other Frequency	Route
			XXXXXXX	XXXXXXX	XXXXXXXXXXX	XXXX	XXXX	XXXX	XXXX	XXXX	XXXX

Note: Y=Yes, N=No. Medications taken within 4 wks of Day 1 are coded to preferred terms and classifications using the WHO-Drug Dictionary.

Listing 10.2.2 Concomitant Medications (Part II)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Anatomic Therapeutic Category	Preferred Name*	Reason (Including Prophylaxis)	Start Date	End Date	Continuing at Final exam
			XXXXXXXX	XXXXXXX	XXXXXXX/XXXXXXXX	DD-MMM-YYYY	DD-MMM-YYYY	Y

Note: Y=Yes, N=No. Medications taken within 4 wks of Day 1 are coded to preferred terms and classifications using the WHO-Drug Dictionary.

Listing 11.1 Study Drug Administration: Exemestane (Part I)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Planned Dose Administration (mg)	Actual Total Daily Dose Administered (mg)	Regimen	Specify Other Regimen	Type	Dose Change	Specify Reason for Change	Start Date	End Date
			XX	XX	XX	XX	XX	Y/N	XXXXXX	DD-MMM-YYYY	DD-MMM-YYYY

Note: Y=Yes, N=No.

Listing 11.2 Study Drug Administration: Everolimus (Part II)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Planned Dose Administration (mg)	Actual Total Daily Dose Administered (mg)	Regimen	Specify Other Regimen	Type	Dose Change	Specify Reason for Change	Start Date	End Date
			XX	XX	XX	XX	XX	Y/N	XXXXXX	DD-MMM-YYYY	DD-MMM-YYYY

Note: Y=Yes, N=No.

Listing 12 Patient ECOG Performance Status

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Date of deterioration of ECOG performance status	Visit	Date of Assessment	Assessment Not Done	ECOG Performance Status
				Screening	DD-MMM-YYYY		XXXX
				Visit 2		Y	

Note: Y=Yes, N=No. ECOG Performance Status: 0=Fully active. 1=Restricted strenuous activity, but ambulatory. 2= Ambulatory, capable of self-care, but unable to work. 3 = Confined to bed >50% day, capable of limited self-care. 4 = Completely disabled. 5 = Dead.
Deterioration is defined as an increase in performance status from 0 to 2 or greater, an increase in performance status from 1-2 to 3 or greater, or death due to any cause

Listing 13.1 RECIST Solid Tumor Response Assessment - Target Lesion Measurements

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Lesion No.	Describe Location of Lesion	Location Code	Evaluation Method Code	Date of Evaluation	Evaluation (Longest Diameter cm)
			XX	XXXXX	XX	XX	DD-MMM-YYYY	XX

NOTE: Target and non-target lesions must be defined at baseline.

Listing 13.2 RECIST Solid Tumor Response Assessment – Non-Target Lesion Measurements

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Lesion No.	Describe Location of Lesion	Location Code	Evaluation Method Code	Date of Evaluation	Status of Lesion
			XX	XXXXX	XX	XX	DD-MMM-YYYY	XX

NOTE: Target and non-target lesions must be defined at baseline.

Listing 13.3 RECIST Solid Tumor Response Assessment – New Lesions

Country	Site ID	Patient ID/ FAS/ PPS/ SS	New Lesion Present	Lesion No.	Describe Location of Lesion	Location Code	Evaluation Method Code	Date of Evaluation	Evaluation Number at Which Lesion First Appeared
			Y	XX	XX	XX	XX	DD-MMM-YYYY	XX

NOTE: Y=Yes, N=No. New lesions appearing after baseline evaluation.

Listing 13.4 RECIST Solid Tumor Response Assessment – Overall Response Category Evaluation

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Evaluation Number	Date of Response	Overall Lesion Response	Tumor Assessment Comments
			Y	DD-MMM-YYYY	XX	XXXXXXXXXX

Note: Y=Yes, N=No.

Listing 14.1 Treatment-Emergent Adverse Events

Country	Site ID	Patient ID/ FAS/ PPS/ SS	System Organ Class	Preferred Term	Verbatim Term	CTCAE Grade	Start Date	End Date	Serious AE	Relationship to Study Drug	Action(s) Taken
			XXXXXXXX	XXXXXXXX	XXXXXXXXX	3	DD-MMM-YYYY	DD-MMM-YYYY	Y	1	3/4
			XXXXXXXX	XXXXXXXX	XXXXXXXXX	2	DD-MMM-YYYY	DD-MMM-YYYY	N	0	0

Note: MedDRA vX.X. CTCAE v4.03. Y=Yes, N=No. Relationship to Study Drug: 0=Not suspected, 1=Suspected. Action(s) Taken: 0=No action taken. 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this adverse event, 3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/prolonged hospitalization.

Listing 14.2 Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug

Country	Site ID	Patient ID/ FAS/ PPS/ SS	System Organ Class	Preferred Term	Verbatim Term	CTCAE Grade	Start Date	End Date	Serious AE	Relationship to Study Drug	Action(s) Taken
			XXXXXXXX	XXXXXXXX	XXXXXXXXX	3	DD-MMM-YYYY	DD-MMM-YYYY	Y	1	3/4
			XXXXXXXX	XXXXXXXX	XXXXXXXXX	2	DD-MMM-YYYY	DD-MMM-YYYY	N	0	0

Note: MedDRA vX.X. CTCAE v4.03. Y=Yes, N=No. Relationship to Study Drug: 0=Not suspected, 1=Suspected. Action(s) Taken: 0=No action taken. 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this adverse event, 3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/prolonged hospitalization.

Listing 14.3 Serious Treatment-Emergent Adverse Events

Country	Site ID	Patient ID/ FAS/ PPS/ SS	System Organ Class	Preferred Term	Verbatim Term	CTCAE Grade	Start Date	End Date	Serious AE	Relationship to Study Drug	Action(s) Taken
			XXXXXXXX	XXXXXXXX	XXXXXXXXX	3	DD-MMM-YYYY	DD-MMM-YYYY	Y	1	3/4
			XXXXXXXX	XXXXXXXX	XXXXXXXXX	2	DD-MMM-YYYY	DD-MMM-YYYY	Y	0	0

Note: MedDRA vX.X. CTCAE v4.03. Y=Yes, N=No. Relationship to Study Drug: 0=Not suspected, 1=Suspected. Action(s) Taken: 0=No action taken. 1=Study drug dosage adjusted/temporarily interrupted, 2=Study drug permanently discontinued due to this adverse event, 3=Concomitant medication taken, 4=Non-drug therapy given, 5=Hospitalization/prolonged hospitalization.

Listing 15 *Physical Examinations*

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date of Assessment	Exam Not Done	General Appearance	Skin	Neck including Thyroid	E.E.N.T	Lungs	Heart	Abdomen	Back	Lymph Nodes	Extremities
			Screening	DD-MMM-YYYY		1	2	3	1	2	3	1	2	3	1
			Visit 2		Y										

Note: Y=Yes, N=No. Examinations: 1=Normal, 2=Abnormal clinically insignificant, 3=Abnormal clinically significant. E.E.N.T.: Eyes, ears, nose, and throat.

Listing 16.1 Vital Signs Assessments

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date of Assessment	Assessment Not Done	Parameter	Value	Notable Criteria
xxxx	xxxx	xxxx/x/x/x	Screening	DD-MMM-YYYY		Weight (kg)	xx.x	
						SBP (mmHg)	xx.x	<90 mmHg
						DBP (mmHg)	xx.x	
						Body Temperature (ºC)	xx.x	
						Pulse rate (bpm)	xx.x	>90 bpm
			Visit 2			SBP (mmHg)	xx.x	<90 mmHg
						DBP (mmHg)	xx.x	
						Body Temperature (ºC)	xx.x	
						Pulse rate (bpm)	xx.x	>90 bpm
			Visit 3		Y			

Note: Y=Yes, N=No. SBP: Systolic Blood Pressure. DBP: Diastolic Blood Pressure.

Listing 16.2 Vital Signs Assessments: Patients with Clinically Notable Vital Sign Abnormalities

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date of Assessment	Assessment Not Done	Parameter	Value	Notable Criteria
xxxx	xxxx	xxxx/x/x/x	Screening	DD-MMM-YYYY		SBP (mmHg)	xx.x	<90 mmHg
						Pulse rate (bpm)	xx.x	>90 bpm
			Visit 2			SBP (mmHg)	xx.x	<90 mmHg
						Pulse rate (bpm)	xx.x	>90 bpm

Note: Y=Yes, N=No. SBP: Systolic Blood Pressure. DBP: Diastolic Blood Pressure.

Listing 17 Patient ECG Evaluations

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date of Assessment	Evaluation Not Done	Clinically Significant ECG Abnormalities Present	Specify Abnormalities
			Screening	DD-MMM-YYYY		N	
			Visit 2			Y	XXXXXXXXX/ XXXXXXXXX/ XXXXXXXXX
					Y		

Note: Y=Yes, N=No.

Listing 18.1.1 Lab Results – Hematology (Part I)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Parameter	Value	Unit	LLN	ULN	CTC grade	Low/Normal/High classification
xxxx	xxxx	xxxx/x/x/x	Screening	DD-MMM-YYYY		CBC						
						WBC						
						RBC						
						Hemoglobin						
						Hematocrit						
						Platelet Count						
						Neutrophils						
						Lymphocytes						
						Basophils						
						Monocytes						
			Visit 2	DD-MMM-YYYY		CBC						
						WBC						
						RBC						
						Hemoglobin						
						Hematocrit						
						Platelet Count						
						Neutrophils						
						Lymphocytes						
						Basophils						
						Monocytes						
			Etc.									
Etc.												

CBC: Complete Blood Count. WBC: White Blood Cells. RBC: Red Blood Cells.
Note: Y=Yes, N=No.

Listing 18.1.2 Lab Results – Hematology values outside the laboratory reference ranges (Part II)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Parameter	Value	Unit	LLN	ULN	CTC grade	Low/Normal/ High classification
xxxx	xxxx	xxxx/x/x/x	Screening	DD-MMM-YYYY		CBC						
						WBC						
						RBC						
						Hemoglobin						
						Hematocrit						
						Platelet Count						
						Neutrophils						
						Lymphocytes						
						Basophils						
						Monocytes						
			Visit 2	DD-MMM-YYYY		CBC						
						WBC						
						RBC						
						Hemoglobin						
						Hematocrit						
						Platelet Count						
						Neutrophils						
						Lymphocytes						
						Basophils						
						Monocytes						
			Etc.									
Etc.												

CBC: Complete Blood Count. WBC: White Blood Cells. RBC: Red Blood Cells.
Note: Y=Yes, N=No.

Listing 18.2.1 Lab Results – Blood Chemistry (Part I)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Parameter	Value	Unit	LLN	ULN	CTC grade	Low/Normal/ High classification
xxxx	xxxx	xxxx/x/x/x	Screening	DD-MMM-YYYY		BUN						
						Creatinine						
						Sodium						
						Fasting Glucose						
						Potassium						
						Uric Acid						
						Calcium						
						LDH						
						Total Protein						
						Albumin						
						AST						
						ALT						
						Alkaline phosphatase						
						GGT						
						Total Bilirubin						
						Urea						
			Visit 2	DD-MMM-YYYY		BUN						
						Creatinine						
						Sodium						
						Fasting Glucose						
						Potassium						
						Uric Acid						
						Calcium						
						LDH						
						Total Protein						
						Albumin						
						AST						
						ALT						
						Alkaline phosphatase						
						GGT						
						Total Bilirubin						

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Parameter	Value	Unit	LLN	ULN	CTC grade	Low/Normal/ High classification
						Urea						
			Etc.									
Etc.												

Note: Y=Yes, N=No.

Listing 18.2.2 Lab Results – Blood Chemistry Values Outside the Laboratory Reference Ranges (Part II)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Parameter	Value	Unit	LLN	ULN	CTC grade	Low/Normal/ High classification
xxxx	xxxx	xxxx/x/x/x	Screening	DD-MMM-YYYY		BUN						
						Creatinine						
						Sodium						
						Fasting Glucose						
						Potassium						
						Uric Acid						
						Calcium						
						LDH						
						Total Protein						
						Albumin						
						AST						
						ALT						
						Alkaline phosphatase						
						GGT						
						Total Bilirubin						
						Urea						
			Visit 2	DD-MMM-YYYY		BUN						
						Creatinine						
						Sodium						
						Fasting Glucose						
						Potassium						
						Uric Acid						
						Calcium						
						LDH						
						Total Protein						
						Albumin						
						AST						
						ALT						
						Alkaline phosphatase						
						GGT						

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Parameter	Value	Unit	LLN	ULN	CTC grade	Low/Normal/ High classification
						Total Bilirubin						
						Urea						
			Etc.									
Etc.												

Note: Y=Yes, N=No.

Listing 18.3 Lab Results – Serum Lipid Profile

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Date Sample Taken	Number of Laboratory	Patient Fasting	Total Cholesterol	Triglycerides
			Screening	DD-MMM-YYYY		DD-MMM-YYYY		N		
			Visit 2		Y					

Note: Y=Yes, N=No.

Listing 18.4 Lab Results – Coagulation Test

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Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Date Sample Taken	Number of Laboratory	INR	aPTT
			Screening	DD-MMM-YYYY		DD-MMM-YYYY			
			Visit 2		Y				

Note: Y=Yes, N=No.

Listing 18.5 Lab Results – Urinalysis

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Visit	Date Sample Taken	Assessment Not Done	Date Sample Taken	Number of Laboratory	Glucose	Protein	Blood	Ketones	Leukocytes
			Screening	DD-MMM-YYYY		DD-MMM-YYYY		Negative/ Trace/ 1+/ 2+/ 3+/ 4+	Negative/ Trace/ 1+/ 2+/ 3+/ 4+	Negative/ Trace/ 1+/ 2+/ 3+/ 4+	Negative/ Trace/ 1+/ 2+/ 3+/ 4+	Negative/ Trace/ 1+/ 2+/ 3+/ 4+
			Visit 2		Y							

Note: Y=Yes, N=No.

Listing 18.6 Lab Results – Hepatitis B Viral Load and Markers

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Assessment Not Done	Date Sample Taken	Number of Laboratory	HBV-DNA	HBSAg	HBsAb	HBcAb
				DD-MMM-YYYY			Negative/ Positive	Negative/ Positive	Negative/ Positive
			Y						

Note: Y=Yes, N=No.

Listing 18.7 Lab Results – Hepatitis C Viral Load and Markers

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Assessment Not Done	Date Sample Taken	Number of Laboratory	HCV-RNA
				DD-MMM-YYYY		
			Y			

Note: Y=Yes, N=No.

Listing 19 Body Imaging

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Assessment Not Done	Date of Scan	Location (Site)	Specify Other Location	Scan Type	Specify Other Scan Type
				DD-MMM-YYYY	Chest/ Abdomen/ Pelvis/ Spine/ Head/ Neck/ Abdomen and pelvis/ Bone/ Chest and abdomen/ Chest, abdomen, and pelvis/ Other	XXXX	CT/ Gd-MRI/ CT Scan (with contrast)/ CT Scan (without contrast)/ Spiral CT (with contrast)/ Spiral CT (without contrast)/ MRI (with contrast)/ MRI (without contrast)/ Dynamic Contrast Enhanced-MRI/ PET Scan (18-FDG-PET)/ PET Scan (11-C-Methionine)/ PET Scan (other agent)/ Other	XXXX
			Y					

Note: Y=Yes, N=No.

Listing 20 Brain Scan

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Assessment Not Done	Date of Scan	Scan Type	Specify Other Location	Overall Interpretation	Specify Clinically Significant Abnormalities
				DD-MMM-YYYY	CT/ Gd-MRI/ CT Scan (with contrast)/ CT Scan (without contrast)/ Spiral CT (with contrast)/ Spiral CT (without contrast)/ MRI (with contrast)/ MRI (without contrast)/ Dynamic Contrast Enhanced-MRI/ PET Scan (18-FDG-PET)/ PET Scan (11-C-Methionine)/ PET Scan (other agent)/ Other	XXXX	Normal/ Clinically insignificant abnormality/ Clinically significant abnormality/	XXXX/XXXX/XXX
			Y					

Note: Y=Yes, N=No.

Listing 21 Skeletal Survey

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Assessment Not Done	Date of Skeletal Survey	Bone Assessment Method	Specify Other Bone Assessment Method	Number of Lesions
				DD-MMM-YYYY	CT/ MRI Scan/ Bone Scan/ PET Scan/ X-Ray/ Other	XXXX	None/ 1-3/ More than 3
			Y				

Note: Y=Yes, N=No.

[redacted]

Listing 23 Broncho-Alveolar Lavage (BAL)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Date of Assessment	Clinically Significant Abnormalities Present
			DD-MMM-YYYY	Y

Note: Y=Yes, N=No. BAL Test not required, performed as clinically indicated.

Listing 24.1 Pulmonary Function Tests (Part I)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Date of Test	Total Lung Capacity	Forced Vital Capacity	FEV1	Functional Residual Capacity	Residual Capacity	DLCO Done	Date of DLCO Test	DLCO	DLCO unit
			DD-MMM-YYYY						Y	DD-MMM-YYYY		mL/min/torr// mL/min/mmHg// Mmol/min/KPa

Note: Pulmonary function tests not required, performed as clinically indicated. Y=Yes, N=No. FEV1: Forced Expiratory Volume in One Second. DLCO: Diffusion Capacity for CO.

Listing 24.2 Pulmonary Function Tests (Part II)

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Pulse Oximetry Done	Date of Pulse Oximetry	% Inspired Oxygen	%Oxygen Saturation	Clinically Significant Abnormalities Present
			Y	DD-MMM-YYYY			Y

Note: Pulmonary function tests not required, performed as clinically indicated. Y=Yes, N=No.

Listing 25 Study Visit Dates

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Screening	Baseline	WK 4	WK 10	WK 20	WK 30	WK 40	WK 50	WK 60	WK 70	WK 80	WK 90	WK 100	Other WKs	End of Treatment	Date of last contact

Listing 26 Hormonal Receptor Status

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Date of test	Estrogen Receptor	Progesterone Receptor
xxxx	xxxx	xxxx/x/x/x	DDMMYYY	xx	xx
xxxx	xxxx	xxxx/x/x/x	DDMMYYY	xx	xx
ETC.					

Listing 27 Progression-free Survival – Full Analysis set

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Start date	End date	Days	Event (PD/Censor)	Censoring reason
xxxx	xxxx	xxxx/x/x/x	DDMMYYY	DDMMYYY	xx	PD	
xxxx	xxxx	xxxx/x/x/x	DDMMYYY	DDMMYYY	xx	Censor	xxxx
ETC.							

Listing 28 Time to Definitive Deterioration of ECOG Performance Status – Full Analysis set

Country	Site ID	Patient ID/ FAS/ PPS/ SS	Start date	End date	Days	Event (Deterioration/Censor)	Censoring reason
xxxx	xxxx	xxxx/x/x/x	DDMMYYY	DDMMYYY	xx	Deterioration	
xxxx	xxxx	xxxx/x/x/x	DDMMYYY	DDMMYYY	xx	Censor	xxxx
ETC.							