ANALYSIS DISPLAY PLAN

TABLE and LISTING MOCK-UPs

Compound:	PHA-848125AC
Protocol No.:	CDKO-125a-006
Protocol title:	Phase II Study of Oral PHA-848125AC in Patients with Thymic Carcinoma Previously Treated with Chemotherapy
Clinical phase:	Phase II
Authors:	Miriam Fossati and Anna Petroccione

GENERAL ISSUES

"Page by Regimen" for outputs, in this study one regimen only: 150 mg/day x 7 days q 2 wks.

The outputs will have names starting with "Appendix 1.9.*n.*<*X*> " or "Appendix 2.4.*n.*<*X*> "or "Figure 2.4.*n.*<*X*> ", where *X* will be set to different values according to the subset population described: <x > = 1 for evaluable patients, 2 for treated patients.

APPENDIX 1: STUDY INFORMATION

Appendix 1 – Section 9 – Statistical and Analytical Issues

Appendix 1.9.1.<x> – Treatment Efficacy - Kaplan Meier Estimates for Progression Free Survival
– Treated / Evaluable Patients –

Page by Regimen

Progression Free Survival (days)	Patient No	Number of Patients Failed	Number of Patients Left	Probability	Standard Error	95% CI – LL (**)	95% CI – UL (**)
0		xx	xx	1	0.xxx	0.xx	0.xx
1 *	008	xx	xx	0.xx	0.xxx	0.xx	0.xx

* Censored Observation
** Confidence Intervals around Kaplan Meier estimates

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Descriptive statistics are obtained with SAS PROC LIFETEST considering the Kaplan-Meier method. For Pat-No use ID statement in PROC LIFETEST

Appendix 1.9.2.<x > – Treatment Efficacy - Kaplan Meier Estimates for Overall Survival
– Treated / Evaluable Patients –

Page by Regimen

Overall Survival (months)	Patient No	Number of Patients Failed	Number of Patients Left	Probability	Standard Error	95% CI – LL (**)	95% CI – UL (**)
0		xx	xx	1	0.xxx	0.xx	0.xx
1 *		xx	xx	0.xx	0.xxx	0.xx	0.xx

* Censored Observation
** Confidence Intervals around Kaplan Meier estimates

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Descriptive statistics are obtained with SAS PROC LIFETEST considering the Kaplan-Meier method. For Pat-No use ID statement in PROC LIFETEST

APPENDIX 2: SUMMARY TABLES

Appendix 2 - Section 1 - Patient Disposition

Appendix 2.1.1 - Patient Disposition: Patient Screening
- Screened Patients –

	n	%
Total Patients Screened	xxx	100.0
Patients Screened and not Enrolled	xxx	xxx.x
Patients Enrolled	xxx	xxx.x

%=(n/Total patients screened)*100

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.1.2 - Patient Disposition: Patient Disposition by Investigational Site
- Enrolled Patients –

Page by Regimen

		Enrolled Patients		
		All Enrolled (N=xx)	Treated (N=xx)	Not Treated (N=xx)
		n	n	n
Investigational Site	All Centers	xx	xx	xx
	<Center_1>	xx	xx	xx
	< Center_j>	xx	xx	xx

Treated / Not Treated: patients who received / did not receive at least one treatment dose

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
N=xx: xx is the total number of patients for each distinct patient group (treated, not treated, all enrolled)

Appendix 2.1.3 - Patient Disposition: Study Period Completion and Primary Off Study Reason
- Enrolled Patients –

Page by Regimen

		Enrolled Patients					
		All Enrolled (N=xx)		Treated (N=xx)		Not Treated (N=xx)	
		n	%	n	%	n	%
Off Study Patients	Total Off Study	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Death	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Lost to follow-up	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Reason Not Provided	xx	xxx.x	xx	xxx.x	xx	xxx.x
On Study Patients	Total On Study	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Off Treatment	xx	xxx.x	xx	xxx.x		

%=(n/N)*100
On Study Patients: patients whose Off Study Reason form has not been received and no death is reported.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
N=xx: xx is the total number of patients for each analyzed group (treated, not treated, all enrolled)

Appendix 2.1.4 - Patient Disposition: Treatment Period Completion and Primary Off Treatment Reason
- Treated Patients –

Page by Regimen

		Treated Patients (N=xx)	
		n	%
Off Treatment Patients	Total Off Treatment	xxx	xxx.x
	Adverse Event	xxx	xxx.x
	Lack of Compliance	xxx	xxx.x
	…	xxx	xxx.x
	Reason Not Provided	xxx	xxx.x
On Treatment Patients	Still on Treatment	xxx	xxx.x

%=(n/N)*100
On Treatment Patients: patients whose last available information refers to the study treatment period.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.1.5 – Patient Disposition: Frequency of Patients according to Time on Treatment
- Treated Patients –

Page by Regimen

Time on Treatment	Treated Patients (N=xx)	
	n	%
Less or equal to 2 weeks	xx	xx.x
> 2 - ≤ 6 weeks	xx	xx.x
> 6 - ≤ 12 weeks	xx	xx.x
> 12 - ≤18 weeks	xx	xx.x
> 18 weeks	xx	xx.x

%=(n/N)*100
Time on Treatment: from first dose date to last dose date.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2 – Section 2 – Demography and Pretreatment Characteristics

Appendix 2.2.1 – Demography and Pretreatment: Demography Characteristics
- Treated Patients -

Page by Regimen

		Treated Patients (N=xx)	
		n	%
Gender	Male	xx	xx.x
	Female	xx	xx.x
	Total Reported	xx	xx.x
Race	White	xx	xx.x
	…	xx	xx.x
	Total Reported	xx	xx.x
Age (years)	<40 yrs	xx	xx.x
	40 – 54 yrs	xx	xx.x
	55 – 65 yrs	xx	xx.x
	> 65 yrs	xx	xx.x
	Total Reported	xx	xx.x

%=(n/N)*100

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.2.2 – Demography and Pretreatment: Summary Statistics of Age, Weight and Height
- Treated Patients -

Page by Regimen

		Treated Patients (N=xx)
Age (years)	No. of Pts	xx
	Mean	xx.x
	SD	xx.x
	Median	xx
	Min	xx
	Max	xx
Weight (Kg)	No. of Pts	xx
	Mean	xx.x
	SD	xx.x
	Median	xx
	Min	xx
	Max	xx
Height (cm)	No. of Pts	xx
	Mean	xx.x
	SD	xx.x
	Median	xx
	Min	xx
	Max	xx

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.2.3 – Demography and Pretreatment: Tumor History - Primary Diagnosis and Diagnosis at Study Entry
- Treated Patients –

Page by Regimen

		Treated Patients (N=xx)	
		n	%
Primary Diagnosis made by:	Histological	xx	xxx.x
	Cytological	xx	xxx.x
	Total Reported	xx	xxx.x
WHO Classification	B3 – Well Differenciated Thymic Carcinoma	xx	xxx.x
	C – Thymic Carcinoma	xx	xxx.x
	Total Reported	xx	xxx.x
Tumor Extent at Study Entry	Locally Advanced	xx	xxx.x
	Metastatic	xx	xxx.x
	Total Reported	xx	xxx.x
Metastatic Disease Sites	Liver	xx	xxx.x
	…	…	…
	Other	xx	xxx.x
	Total Reported	xx	xxx.x
Total No. of Recurrence(s)/Progression(s)	1	xx	xxx.x
	2	xx	xxx.x
	>2	xx	xxx.x
	Total Reported	xx	xxx.x
Masaoka Clinical Staging at Study Entry	I	xx	xx
	IIA	xx	xx
	IIB	xx	xx
	IIIA	xx	xx
	IIIB	xx	xx
	IVA	xx	xx
	IVB	xx	xx
	Total Reported	xx	xxx.x

%=(n/N)*100
Metastatic Disease Site: pts with more than 1 metastatic site are counted for each reported site. Total reported: no. of pts. independently of the sites involved
[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.2.4 – Demography and Pretreatment: Tumor History – Time from Primary Diagnosis and Diagnosis at Study Entry to Treatment Start
- Treated Patients –

Page by Regimen

	Treated Patients (N=xx)			
	No. of Pts.	Min	Median	Max
Primary Diagnosis (Months)	xx	xxx.x	xxx.x	xxx.x
Current Diagnosis of locally advanced or metastatic disease (Weeks)	xx	xxx.x	xxx.x	xxx.x

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.2.5 – Demography and Pretreatment: History of Other Cancers
- Treated Patients -

Page by Regimen

Previous History of Other Cancers	Treated Patients (N=xx)	
	n	%
Yes	xx	xxx.x
No	xx	xxx.x
Total Reported	xx	xxx.x

%=(n/N)*100

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.2.6 - Demography and Pretreatment: Tumor History - Prior Antitumor Treatments / Procedures: Type and Setting
- Treated Patients –

Page by Regimen

		Treated Patients (N=xx)	
		n	%
Prior Antitumor Treatments / Procedures	No prior treatments / procedures	xx	xxx.x
	At least one prior treatment / procedure	xx	xxx.x
	Total Reported	xx	xxx.x
Type	Surgery only	xx	xxx.x
	Systemic only	xx	xxx.x
	Radiotherapy only	xx	xxx.x
	Surgery + Systemic	xx	xxx.x
	……	xx	xxx.x
Setting	Neo-Adjuvant	xx	xxx.x
	Adjuvant	xx	xxx.x
	Primary Tumor	xx	xxx.x
	…..	xx	xxx.x

%=(n/N)*100

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Type: Count each pt for each tr. / procedure type (e.g. surgery,…) reported, regardless of how many times the same type of tr. is reported for him. Ex.: A pt with systemic reported 3 times and surgery reported 2 times, will be counted once for "systemic + surgery" in the table.
Setting: Count each pt for each reported setting (e.g. neo-adjuvant,…) regardless of how many times the same setting is reported for him. Ex.: A pt with primary tumor reported once and metastatic reported 3 times, will be counted once for primary tumor and once for metastatic.

Appendix 2.2.7 – Treatment Efficacy: Oncologic Assessment at Study Entry
- Treated Patients –

Page by Regimen

Tumor Lesions	Treated Patients (N= xx)	
	n	%
Total Reported	xx	xxx.x
Patients with Both Target and Non-Target Lesions	xx	xxx.x
Target Lesions only	xx	xxx.x
Non-Target Lesions only	xx	xxx.x

%=(n/N)*100
Tumor Lesions include Lymph Nodes

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.2.8 – Demography and Pretreatment: Signs and Symptoms
- Treated Patients -

Page by Regimen

Treated Patients (N=xx)		Maximum CTC Grade									
		Any Grade		3-4		1		…		Unk	
System Organ Class	Preferred Term	n	%	n	%	n	%	n	%	n	%
Any System	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC 1]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event 1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event i	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC i]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	...	…	…	…	…	…	…	…	…	…	…

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each by group, SOC and AE (i.e. for each Preferred Term), count patients according to the maximum CTC grade reported for that event and sort SOCs by descending frequency of “Any Term” at “Any Grade”.

Appendix 2 – Section 3 – Treatment Exposure

Appendix 2.3.1 – Treatment Exposure: Summary Statistics of the Number of Cycles / Weeks of Treatment
- Treated Patients -

Page by Regimen

Treatment Duration	No. of Patients	Sum.of Cycles/Weeks of Treatment	Min	Median	Max
Cycles	xx	xx.x	xx.x	xx	xx.x
Weeks	xx	xx.x	xx.x	xx	xx.x

Treatment Duration: from the first dose date to end of treatment.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.3.2 - Treatment Exposure: Frequency Distribution of Cycles according to the Percentage of Scheduled Dose Administered
- Treated Patients -

Page by Regimen

No. of Patients	Total No. of Cycles	Dose Administered (as Percentage of the Scheduled Dose)							
		Full Dose		80% - < Full Dose		50% - < 80%		<50%	
		No. of Cycles	%	No. of Cycles	%	No. of Cycles	%	No. of Cycles	%
xx	xxx	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x

Scheduled Dose: assigned dose level (mg/day)*7, where 7 is the per protocol no. of drug administrations per cycle.
Full Dose: greater or equal 95% of Scheduled Dose

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.3.3 – Treatment Exposure: Summary Statistics of Dose Intensity, Relative Dose Intensity and Cumulative Dose
- Whole Treatment Period -
- Treated Patients -

Page by Regimen

No. of Pts	Dose Intensity (mg/wk)			Relative Dose Intensity (%)			Cumulative Dose (mg)					
	Min	Median	Max	Min	Median	Max	Min	Median	Max			
xx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x			
xx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x			
xx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x			
xx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x			

Relative Dose Intensity: the ratio between dose intensity and intended dose intensity x 100.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
The whole stydy period is to be considered for the analysis.

Appendix 2.3.4 - Treatment Exposure: Frequency Distribution of Cycles according to their Duration
- Treated Patients –

Page by Regimen

No. of Patients	Total No. of Cycles	Cycle Duration			
		< 13 Days	13-15 Days	16-28 Days	> 28 Days
		No. of Cycles	No. of Cycles	No. of Cycles	No. of Cycles
xx	xxx	xxx	xxx	xxx	xxx
xx	xxx	xxx	xxx	xxx	xxx

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.3.5 – Treatment Exposure: Frequency Distributions of Patients and Cycles with Treatment Modifications
- Treated Patients -

Page by Regimen

Treated Patients (N=xx)	No. of Patients		No. of Cycles
Treatment Modifications	n	%	n
Any Modification	xx	xxx.x	xx
	xx	xxx.x	xx
	xx	xxx.x	xx
Intra Cycle Modification	xx	xxx.x	xx
	xx	xxx.x	xx
	xx	xxx.x	xx
Treatment Delay	xx	xxx.x	xx
	xx	xxx.x	xx
	xx	xxx.x	xx
Dose Reduction	xx	xxx.x	xx
	xx	xxx.x	xx
	xx	xxx.x	xx

%=(n/N)*100
Dose Reduction : at cycle start

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract].

Programming Notes:
Patients are to be counted just once per tr. modification category. Cycles at which multiple occurrences of the same tr. modification category were reported are to be counted just once per tr. modification category.

Appendix 2.3.6 –Treatment Exposure: Frequency Distributions of Patients by Reasons for Treatment Modifications
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)	No. of Patients	
Reasons for Treatment Modification	n	%
Any Reason	xx	xxx.x
	xx	xxx.x
	xx	xxx.x
Hematological toxicity	xx	xxx.x
	xx	xxx.x
	xx	xxx.x
Non-hematological toxicity	xx	xxx.x
	xx	xxx.x
	xx	xxx.x
Other	xx	xxx.x
	xx	xxx.x
	xx	xxx.x
Unknown Reason	xx	xxx.x
	xx	xxx.x
	xx	xxx.x

%=(n/N)*100

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
n: count patients for each toxicity class (i.e. hematological/non-hematological/other), regardless of what kind of treatment modification is performed; if multiple occurrences of the same toxicity class are reported within a cycle or throughout different cycles patients are to be counted just once per class.

Appendix 2 – Section 4 – Treatment Efficacy

Appendix 2.4.1.<x> – Treatment Efficacy: Progression Free Survival Rate at 3 Months
- Evaluable /Treated Patients –

Page by Regimen

Progression Free Survival at 3 Months	Evaluable Patients/ Treated (N=xx)			
	n	%	95 % CI - LL	95 % CI - UL
Success	xx	xxx.x	xx.xx	xx.xx
Failure	xx	xxx.x		
Total	xx	xxx.x		

%=(n/N)*100. N=no. of treated/evaluable patients
Success: Patients who were progression free for longer than 91 days (i.e. 3 months) and with an overall response at the 3rd month assessment equal to SD or better. Valid assessments were to be within day 134; the outcome of assessments performed outside this time window was considered as failure regardless of the outcome recorded.
Failure: All patients who were not success.
95% CI: Exact Binomial Confidence Limits

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Figure 2.4.1.<x> – Treatment Efficacy: Kaplan-Meier Curve for Progression Free Survival
- Evaluable /Treated Patients –

Page by Regimen

Progression Free Survival (months): from the treatment start date to the date of death from any cause
Median Progression Free Survival (95% CI): xx.xx (xx.xx - xx.xx)

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Create three versions of the graph: the graph automatically created by the SAS proc lifetest - Kaplan-Meier method (.gif format) as control, and two other graphs obtained by plotting the relevant variables with SAS proc gplot (same procedure, two different output file formats: .gif and .pdf)
"General Footnotes" not to be printed for .gif graphs.

Appendix 2.4.2.<x> – Treatment Efficacy: Best Confirmed Tumor Response
- Evaluable/Treated Patients -

Page by Regimen

Best Confirmed Tumor Response	Treated / Evaluable Patients (N=xx)			
	n	%	95 % CI - LL	95 % CI - UL
Objective Response (CR + PR)	xx	xxx.x	xxx.xx	xxx.xx
Disease Control (CR+PR+ SD)	xx	xxx.x	xxx.xx	xxx.xx
Complete Response (CR)	xx	xxx.x		
Partial Response (PR)	xx	xxx.x		
Stable disease (SD)	xx	xxx.x		
Progression of Disease (PD)	xx	xxx.x		
Not Evaluable	xx	xxx.x		

%=(n/N)*100. N=no. of treated (evaluable) patients.
95% CI: Exact Binomial Confidence Limits

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
95% CI: 95% Exact Confidence Limits for tumor response rate.
Valid Response values CR, PR, SD,PD, NE

Appendix 2.4.3.<x> – Treatment Efficacy: Best Unconfirmed Tumor Response
- Evaluable/Treated Patients -

Page by Regimen

Best Unconfirmed Tumor Response	Treated / Evaluable Patients (N=xx)	
	n	%
Overall Response (CR + PR)	xx	xxx.x
Complete Response (CR)	xx	xxx.x
Partial Response (PR)	xx	xxx.x
Stable Disease (SD)	xx	xxx.x
Progression of Disease (PD)	xx	xxx.x
Not Evaluable (NE)	xx	xxx.x

Unconfirmed Tumor Response: for each patient it's the best response reported throughout the study period as overall response, regardless of the confirmation.

%=(n/N)*100. N=no. of treated patients.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Valid Response values CR, PR, SD,PD, NE

Appendix 2.4.4.<x> – Treatment Efficacy: Statistical Analysis of Time-To-Event Endpoints
- Treated / Evaluable -

Page by Regimen

Treated / Evaluable Patients (N=xx)	No. of Pts.	No. of Events	Min	Max	Median	Median 95% CI - LL	Median 95% CI - UL
Progression Free Survival (months)	xx	xx	xxx.xx	xxx.xx +	xxx.xx	xxx.xx	xxx.xx
Overall Survival (months)	xx	xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xxx.xx
Duration of response (months)	xx	xx	xxx.xx	xxx.xx +	xxx.xx	xxx.xx	xxx.xx

N=: no. of treated (evaluable) patients.
No. of Events: the no. of failure patients.for the given endpoint.
Median: estimated by the Kaplan-Meier method.
+: Censored observation
Overall survival: from the treatment start date to the date of death from any cause
Progression free survival: from the treatment start date to the date of objective progression or death from any cause
Duration of response : from the date when response was first assessed to the date of progression or date of censoring,whichever comes first

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Summary statistics are to be calculated by SAS PROC LIFETEST using the Kaplan-Meier method.

Figure 2.4.2..<x> – Treatment Efficacy: Kaplan-Meier Curve for Overall Survival
- Treated / Evaluable Patients–

Page by Regimen

Median Progression Free Survival (95% CI): xx.xx (xx.xx - xx.xx)

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Create three versions of the graph: the graph automatically created by the SAS proc lifetest - Kaplan-Meier method (.gif format) as control, and two other graphs obtained by plotting the relevant variables with SAS proc gplot (same procedure, two different output file formats: .gif and .pdf)
"General Footnotes" not to be printed for .gif graphs.

Appendix 2.4.5 – Treatment Efficacy: ECOG Performance Status: On Treatment Worst Assessment vs. Pretreatment
- Treated Patients with at Least One Assessment On Treatment -

Page by Regimen

Treated Patients (N=xx)	On-Treatment Worst Assessment							
	0		1		…		Total	
Pretreatment Assessment	n	%	n	%	n	%	n	%
Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
2	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
>2	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Unknown	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

%=(n/N)*100.
N = treated patients with at least one Performance Status assessment after treatment start date.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2 – Section 5 – Adverse Events

Appendix 2.5.1 – Adverse Events: Patients with on Treatment AEs by System Organ Class and Maximum CTC Grade
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)	Maximum CTC Grade									
	Any Grade		3-4		1		…		Unk	
System Organ Class	n	%	n	%	n	%	n	%	n	%
Any System	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC 1]	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC n]	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each "by group", sort SOCs by descending frequency of "Any Grade"
For each SOC (System Organ Class), count patients according to the maximum CTC grade reported for that SOC.

Appendix 2.5.2 – Adverse Events: Patients with on Treatment AEs by AE MedDRA Preferred Term and Maximum CTC Grade
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)	Maximum CTC Grade									
	Any Grade		3-4		1		…		Unk	
Preferred Term	n	%	n	%	n	%	n	%	n	%
Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[Term 1]	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[Term i]	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	…	…	…	…	…	…	…	…	…

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each “by group”, sort AEs by descending frequency of “Any Grade”.
For each AE (i.e. for each Preferred Term), count patients according to the maximum CTC grade reported for that event.

Appendix 2.5.3 – Adverse Events: Patients with on Treatment AEs by SOC, AE MedDRA Preferred Term and Maximum CTC Grade
- Treated Patients -

Page by Regimen

Treated Patients (N=xx)		Maximum CTC Grade									
		Any Grade		3-4		1		…		Unk	
System Organ Class	Preferred Term	n	%	n	%	n	%	n	%	n	%
Any System	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC 1]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event 1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event i	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC i]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	...	…	…	…	…	…	…	…	…	…	…

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each by group, SOC and AE (i.e. for each Preferred Term), count patients according to the maximum CTC grade reported for that event and sort SOCs by descending frequency of “Any Term” at “Any Grade”.

Appendix 2.5.4 – Adverse Events: Patients with AEs with Possible to Definite Relationship to Study Treatment by SOC and Maximum CTC Grade
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)	Maximum CTC Grade									
	Any Grade		3-4		1		…		Unk	
System Organ Class	n	%	n	%	n	%	n	%	n	%
Any System	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC 1]	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC n]	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each "by group", sort SOCs by descending frequency of "Any Grade".
For each SOC (System Organ Class), count patients according to the maximum CTC grade reported for that SOC.

Appendix 2.5.5 – Adverse Events: Patients with AEs with Possible to Definite Relationship to Study Treatment by AE MedDRA Preferred Term and Maximum CTC Grade
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)	Maximum CTC Grade									
	Any Grade		3-4		1		…		Unk	
Preferred Term	n	%	n	%	n	%	n	%	n	%
Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[Term 1]	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[Term i]	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	…	…	…	…	…	…	…	…	…

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each "by group", sort AEs by descending frequency of "Any Grade"
For each AE (i.e. for each Preferred Term), count patients according to the maximum CTC grade reported for that event.

Appendix 2.5.6 – Adverse Events: Patients with AEs with Possible to Definite Relationship to Study Treatment by SOC, AE MedDRA Preferred Term and Maximum CTC Grade
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)		Maximum CTC Grade									
		Any Grade		3-4		1		…		Unk	
System Organ Class	Preferred Term	n	%	n	%	n	%	n	%	n	%
Any System	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC 1]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event 1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event i	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC i]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	...	…	…	…	…	…	…	…	…	…	…

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each “by group”, SOC and AE (i.e. for each Preferred Term), count patients according to the maximum CTC grade reported for that event and sort SOCs by descending frequency of “Any Term” at “Any Grade”.

Appendix 2.5.7 – Adverse Events: Patients with on Treatment Serious AEs by SOC, AE MedDRA Preferred Term and Maximum CTC Grade
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)		Maximum CTC Grade									
		Any Grade		3-4		1		…		Unk	
System Organ Class	Preferred Term	n	%	n	%	n	%	n	%	n	%
Any System	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC 1]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event 1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event i	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC i]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	...	…	…	…	…	…	…	…	…	…	…

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each “by group”, SOC and AE (i.e. for each Preferred Term), count patients according to the maximum CTC grade reported for that event and sort SOCs by descending frequency of “Any Term” at “Any Grade”.

Appendix 2.5.8 – Adverse Events: Patients with Serious AEs with Possible to Definite Relationship to Study Treatment by SOC, AE MedDRA Preferred Term and Maximum CTC Grade
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)		Maximum CTC Grade									
		Any Grade		3-4		1		…		Unk	
System Organ Class	Preferred Term	n	%	n	%	n	%	n	%	n	%
Any System	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC 1]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event 1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event i	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC i]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	...	…	…	…	…	…	…	…	…	…	…

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Within each “by group”, SOC and AE (i.e. for each Preferred Term), count patients according to the maximum CTC grade reported for that event and sort SOCs by descending frequency of “Any Term” at “Any Grade”.

Appendix 2.5.9 – Adverse Events: Patients with on Treatment AEs Leading to Withdrawal from Study Treatment by SOC, AE MedDRA Preferred Term and Maximum CTC Grade
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)		Maximum CTC Grade									
		Any Grade		3-4		1		…		Unk	
System Organ Class	Preferred Term	n	%	n	%	n	%	n	%	n	%
Any System	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC 1]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event 1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Event i	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
[SOC i]	Any Term	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	...	…	…	…	…	…	…	…	…	…	…

Only AEs whose Action Taken was “Drug Permanently Withdrawn” are displayed.
%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Select AE with action taken=drug permanently withdrawn.
Within each by group, SOC and AE (i.e. for each Preferred Term), count patients according to the maximum CTC grade reported for that event and sort SOCs by descending frequency of “Any Term” at “Any Grade”

Appendix 2.5.10 – Deaths: Frequency of Death according to Most Probable Cause and Time of Occurence
- Treated Patients –

Page by Regimen

Treated Patients (N=xx)	Total		=<28 Days since Treatment Last Dose		>28 Days since Treatment Last Dose	
Most Probable Cause	n	%	n	%	n	%
Any cause	xx	xx.x	xx	xx.x	xx	xx.x
Progressive Disease	xx	xx.x	xx	xx.x	xx	xx.x
Adverse Event	xx	xx.x	xx	xx.x	xx	xx.x
…….	…	…	…	…	…	…
Unknown	xx	xx.x	xx	xx.x	xx	xx.x

%=(n/N)*100
N = no. of treated patients

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
See ADP for classification of causes of death vs source of info.

Appendix 2 - Section 6 – Laboratory Assessments

Appendix 2.6.1 – Hematology: Frequency Distribution of Patients based on Maximum CTC Grade On Treatment versus Pretreatment
- Treated Patients with at Least One Assessment On Treatment -
- All Cycles, Cycle 1, Cycles > 1-

Page by Regimen / Laboratory Test: < WBC >

		Maximum CTC Grade on Treatment							
		0		…		4		Total	
Study Period	Pretreatment CTC Grade	n	%	n	%	n	%	n	%
All Cycles (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Unknown	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle 1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle >1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

N = treated patients with at least one assessment after treatment start date.
%=(n/N)*100.
Only lab. tests included in the NCI CTCAE v3.0 document. Maximum CTC Grade: the Maximum CTC grade reported for each treated patient and each lab test during the treatment period.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*.
Select collected lab tests listed in NCI CTCAE v3.0.

Appendix 2.6.2 – Hematology: Frequency Distribution of Treatment Cycles based on Maximum CTC Grade On Treatment versus Pretreatment
- Cycles with at Least One Assessment -
- All Cycles, Cycle 1, Cycles > 1 -

Page by Regimen / Laboratory Test: < WBC >

		Maximum CTC Grade on Treatment							
		0		…		4		Total	
Study Period	Pretreatment CTC Grade	n	%	n	%	n	%	n	%
All Cycles (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Unknown	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle 1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle >1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

N = cycles with at least one assessment
%=(n/N)*100.
Only lab. tests included in the NCI CTCAE v3.0 document. Maximum CTC Grade: the Maximum CTC grade reported for each cycle and each lab test during the treatment period.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*.
Select collected lab tests listed in NCI CTCAE v3.0.

Appendix 2.6.3 – Blood Chemistry: Frequency Distribution of Patients based on Maximum CTC Grade On Treatment versus Pretreatment (Part I)
- Treated Patients with at Least One Assessment On Treatment -
- All Cycles, Cycle 1, Cycles > 1-

Page by Regimen / Laboratory Test: < AST >

		Maximum CTC Grade on Treatment							
		0		…		4		Total	
Study Period	Pretreatment CTC Grade	n	%	n	%	n	%	n	%
All Cycles (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle 1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle >1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

N = treated patients with at least one assessment after treatment start date.
%=(n/N)*100.
(Part I): Only lab. tests included in the NCI CTCAE v3.0 document and whose abnormality is determined by one-way modifications only.
Maximum CTC Grade: the Maximum CTC grade reported for each treated patient and each lab test during the treatment period.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*.
Select collected lab tests listed in NCI CTCAE v3.0.

Appendix 2.6.4 – Blood Chemistry: Frequency Distribution of Patients based on Maximum CTC Grade On Treatment versus Pretreatment (Part II)
- Treated Patients with at Least One Assessment On Treatment -
- All Cycles –

Page by Regimen / Laboratory Test: < Sodium >

		<Hyper/ Hypo> - Maximum CTC Grade on Treatment							
		1		….		5		Total	
Study Period	Pretreatment CTC Grade	n	%	n	%	n	%	n	%
All Cycles (N=xx)	Total	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x
	4 (H)								
	3 (H)			xx	xx.x	xx	xx.x	xx	xx.x
	2 (H)	…	…	…	…	…	…	…	…
	1 (H)	…	…	…	…	…	…	…	…
	0	…	…	…	…	…	…	…	...
	1 (L)								
	2 (L)	…	…	…	…	…	…	…	…
	3 (L)	…	…	…	…	…	…	…	…
	4 (L)	…	…	…	…	…	…	…	…
	Not Assessed	…	…	…	…	…	…	…	…

N = treated patients with at least one assessment after treatment start date.
%=(n/N)*100.
(Part II): Only lab. tests included in the NCI CTCAE v3.0 document and whose abnormality is determined by two-way modifications.
Maximum CTC Grade: the Maximum treatment emergent CTC grade reported for each treated patient during the treatment period.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*.
Select collected lab tests listed in NCI CTCAE v3.0 for which both 'hyper' and 'hypo' grading is provided. For this study: Magnesium, Potassium, Sodium.

Appendix 2.6.5 – Blood Chemistry: Frequency Distribution of Treatment Cycles based on Maximum CTC Grade On Treatment versus Pretreatment (Part I)
- Cycles with at Least One Assessment -
- All Cycles, Cycle 1, Cycles > 1 -

Page by Regimen / Laboratory Test: < AST >

		Maximum CTC Grade on Treatment							
		0		…		4		Total	
Study Period	Pretreatment CTC Grade	n	%	n	%	n	%	n	%
All Cycles (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Unknown	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle 1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle >1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

N = cycles with at least one assessment.
%=(n/N)*100.
(Part I): Only lab. tests included in the NCI CTCAE v3.0 document and whose abnormality is determined by one-way modifications only.
Maximum CTC Grade: the Maximum CTC grade reported for each cycle and each lab test during the treatment period.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*.
Select collected lab tests listed in NCI CTCAE v3.0.

Appendix 2.6.6 – Blood Chemistry: Frequency Distribution of Treatment Cycles based on Maximum CTC Grade On Treatment versus Pretreatment (Part II)
- Cycles with at Least One Assessment -
- All Cycles-

Page by Regimen / Laboratory Test: < Sodium >

		<Hyper/ Hypo> - Maximum CTC Grade on Treatment							
		1		….		5		Total	
Study Period	Pretreatment CTC Grade	n	%	n	%	n	%	n	%
All Cycles (N=xx)	Total	xx	xx.x	xx	xx.x	xx	xx.x	xx	xx.x
	4 (H)								
	3 (H)			xx	xx.x	xx	xx.x	xx	xx.x
	2 (H)	…	…	…	…	…	…	…	…
	1 (H)	…	…	…	…	…	…	…	…
	0	…	…	…	…	…	…	…	...
	1 (L)								
	2 (L)	…	…	…	…	…	…	…	…
	3 (L)	…	…	…	…	…	…	…	…
	4 (L)	…	…	…	…	…	…	…	…
	Not Assessed	…	…	…	…	…	…	…	…

N = cycles with at least one assessment.
%=(n/N)*100.
(Part II): Only lab. tests included in the NCI CTCAE v3.0 document and whose abnormality is determined by two-way modifications.
Maximum CTC Grade: the Maximum treatment emergent CTC grade reported for each cycle and each lab test during the treatment period.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*.
Select collected lab tests listed in NCI CTCAE v3.0 for which both 'hyper' and 'hypo' grading is provided. For this study: Magnesium, Potassium, Sodium

Appendix 2.6.7 – Coagulation: Frequency Distribution of Patients based on Maximum CTC Grade On Treatment versus Pretreatment
- Treated Patients with at Least One Assessment On Treatment -
- All Cycles, Cycle 1, Cycles > 1 –

Page by Regimen / Laboratory Test: < INR >

Study Period		Maximum CTC Grade on Treatment							
		0		…		4		Total	
	Pretreatment CTC Grade	n	%	n	%	n	%	n	%
All Cycles (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Unknown	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle 1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle >1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	0	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	1	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

N = treated patients with at least one assessment after treatment start date
%=(n/N)*100.
Only lab. tests included in the NCI CTCAE v3.0 document. Maximum CTC Grade: the Maximum CTC grade reported for each treated patient and each lab test during the treatment period.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*.
Select collected lab tests listed in NCI CTCAE v3.0.

Appendix 2.6.8 – Laboratory Tests without a NCI-CTC Grade: Frequency Distribution of Patients Based on On Treatment Worst Assessment versus Pretreatment
- Treated Patients with at Least One Assessment On Treatment -
- All Cycles, Cycle 1, Cycles > 1 –

- <Panel>: e.g. Hematology Laboratory Test: < Eosinophils >

Study Period	Pretreatment Value	On Treatment Worst Assessment							
		Above UNL		Within NLs		Below LNL		Total	
		n	%	n	%	n	%	n	%
All Cycles (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Above ULN	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Within NLs	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Below LLN	xx	xxx.x	xx	xxx.x	xx	xxx.x		
	Not Assessed	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Cycle 1 (N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
	Above ULN	xx	xxx.x	xx	xxx.x	xx	xxx.x		
	Within NLs	xx	xxx.x	xx	xxx.x	xx	xxx.x		
	Below LLN	xx	xxx.x	xx	xxx.x	xx	xxx.x		
	Not Assessed	…	…	…	…	…	…		
Cycle >1 (N=xx)	…..	xx	xxx.x	xx	xxx.x	xx	xxx.x		
	…….	xx	xxx.x	xx	xxx.x	xx	xxx.x		

N = treated patients with at least one assessment after treatment start date
%=(n/N)*100.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*.
< Panel >: Hematology - < Lab Test >: Erythrocytes (RBC), Eosinophils, Basophils, Monocyctes.
Blood Chemistry - < Lab Test >: Blood Urea Nitrogen (BUN), Urea (Carbamide) Blood, Phosporus, IgG, IgM, IgA,GGT, LDH, Creatinine, Total proteins.

Appendix 2.7 – Other Safety Assessments

Appendix 2.7.1 – Other Safety Assessments: Blood Pressure - On Treatment Worst Assessment versus Pretreatment
- Treated Patients with at Least One Assessment On Treatment -

Page by Regimen

Treated Patients (N=xx)	On-Treatment Worst Assessment					
	Normal		Abnormal		Total	
Pretreatment Assessment	n	%	n	%	n	%
Total	xx	xxx.x	xx	xxx.x	xx	xxx.x
Normal	xx	xxx.x	xx	xxx.x	xx	xxx.x
Abnormal	xx	xxx.x	xx	xxx.x	xx	xxx.x
Unknown	xx	xxx.x	xx	xxx.x	xx	xxx.x

Normal: systolic blood pressure < 140 and diastolic blood pressure < 90
Abnormal: systolic blood pressure ≥ 140 or diastolic blood pressure ≥90.
%=(n/N) * 100. N = treated patients with at least one blood pressure measurement after treatment start date.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.7.2 – Other Safety Assessments: ECG - On Treatment Assessment versus Pretreatment Condition
- Treated Patients with at Least One Assessments On Treatment -

Page by Regimen

Treated Patients (N=xx)	On-Treatment ECG Abnormality					
	No		At least One		Total	
Pretreatment ECG Abnormality	n	%	n	%	n	%
Total	xx	xx.x	xx	xx.x	xx	xx.x
No	xx	xx.x	xx	xx.x	xx	xx.x
Yes	xx	xx.x	xx	xx.x	xx	xx.x
Unknown	xx	xx.x	xx	xx.x	xx	xx.x

%=(n/N)*100.
N = treated patients with at least one EGC assesment after treatment start date.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Appendix 2.7.3 – Other Safety Assessments: ECG - On Treatment Abnormality Findings
- Treated Patients with at Least One Assessment On Treatment –

Page by Regimen

Abnormality Category	Treated Patients (N=xx)	
	n	%
Rhythm	xx	xxx.x
P-Wave Morphology	xx	xxx.x
Conduction	xx	xxx.x
QRS	xx	xxx.x
ST-T Wave	xx	xxx.x
----	xx	xxx.x

%=(n/N)*100.
N = treated patients with at least one EGC assessment after treatment start date.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Abnormality categories: count patients within each category. If multiple occurrences of the same abnormality (e.g. conduction) are reported, the patient should be counted only once.

Appendix 2.7.4 – Other Safety Assessments: Funduscopic Examination - On Treatment Worst Assessment versus Pretreatment
- Treated Patients with at Least One Assessment On Treatment -

Page by Regimen

Fundus		Pretreatment Assessment	On-Treatment Worst Assessment							
			Normal		Abnormal, not clinically relevant		Abnormal, clinically relevant		Total	
			n	%	n	%	n	%	n	%
Right Eye	(N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
		Normal	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
		Abnormal, not clinically relevant	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
		Abnormal, clinically relevant	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
		Unknown	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
Leftt Eye	(N=xx)	Total	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
		Normal	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
		Abnormal, not clinically relevant	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
		Abnormal, clinically relevant	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x
		Unknown	xx	xxx.x	xx	xxx.x	xx	xxx.x	xx	xxx.x

%=(n/N)*100.
N = treated patients with at least one assessment after treatment start date.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

APPENDIX 3: INDIVIDUAL DATA LISTINGS

Appendix 3 - Section 1 - Patient Disposition

Appendix 3.1.1 – Patient Disposition: Patient Registration
– Registered Patients –

Enrolled Pt	Treated Pt	Pt. No.	Pt. Screening No.	Center No.	Age /Sex /Race	Date of Birth	Date of Informed Consent	Date of Enrollment
N	N	Sxxx		xxxxx	35/M/W	ddmmmyyyy	ddmmmyyyy	
N	N	Sxxx		xxxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	
Y	N	xxxx	Sxxx	xxxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	ddmmmyyyy
Y	Y	xxxx	Sxxx	xxxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	ddmmmyyyy
Y	Y	xxxx	Sxxx	xxxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	ddmmmyyyy
Y	Y	xxxx	Sxxx	xxxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	ddmmmyyyy

Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by enrolled patients (N, Y), treated patients (N, Y), patient no.
Pt. Screening No.: for enrolled patients it is reported on the patient enrollment page of CRF.
Date of informed consent: it is reported on the demography page of CRF.

Appendix 3.1.2 – Patient Disposition: Registered but Not Enrolled Patients
- Screening Failures -

Pt. No.	Center No.	Date of Informed Consent	Reason for Screening Failure	Other Reason, specify	Comments
Sxxx	xxxxx	ddmmmyy	Inclusion/Exclusion Criteria not fulfilled		
Sxxx	xxxxx	ddmmmyy	Other: …		
Sxxxx	xxxxx	ddmmmyy			
Sxxxx	xxxxx	ddmmmyy			
Sxxxx	xxxxx	ddmmmyy			

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by patient no.
Reason for Screening Failure: it is reported on the screening failure page of CRF

Appendix 3.1.3 – Patient Disposition: Summary of Patient Information
- Enrolled Patients-

Page by Regimen

Pt. No	First Dose Date	Last Dose Date	Cum. Dose (mg	Total No. of Cycles	Tr. Status	Time on Treat. (weeks)	Primary Off Tr. Reason	End of AE Reporting Period	FU Status	Study Status	Last Recorded Date		Time on Study (weeks)	Primary Off Study Reason
xxxx	ddmmmyy	ddmmmyy	xxx.x	1	Off.	xxx.x	AE	ddmmmy	On FU	On	ddmmmyy		xx	xxxxxxxxx
xxxx	ddmmmyy	ddmmmyy	xxx.x	4		xxx.x	Pt's refusal		No FU	Off	ddmmmyy	§	xx	xxxxxxxx
xxxx	ddmmmyy	ddmmmyy	xxx.x	2	Off	xxx.x	Progression	ddmmmy	-	Off	ddmmmyy		xx	xxx xxxxx

Time on Treatment: time from the first dose date to last dose date
Time on Study: time from the informed consent date to the last recorded date
(§) Last Recorded Date is different from Investigator's Decision date or Consent Withdrawn date in the Off Study form

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by patient no.

Cumulative dose: from start to end of treatment.
Usually Time Unit of Time on Study is the same as for Duration of Treatment, but it is not mandatory, i.e. could be weeks and months respectively.

Appendix 3.1.4 – Patient's Survival Status during Follow Up
- Treated Patients-

Page by Regimen

Pt. No	Visit	Status	Alive as of: Date	Last Known Alive Date	Date of Death	Most Probable Cause	Details
xxxx	FU-1	Alive	ddmmmyyyy				
	…	….					
	FU-2	Expired	…	…	ddmmmyyyy	Progressive Disease	xxxxxxxxxxxx
xxxx	FU-1	Lost to FU	…	ddmmmyyyy	…		
		…	…	…	…		

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by patient no., visit
By regimen: in this study one regimen only: 150 mg/day x 7 days q 2 wks

Appendix 3 - Section 2 - Protocol Deviations

Appendix 3.2.1 - Protocol Deviations: Violations of Inclusion / Exclusion Criteria
- Enrolled Patients –

Page by Regimen

Treated Pt.	Pt. No.	Center No.	Criterion Number	Criterion	Y/N	
N	xxxx	xxxx	IC01	……..	Y	
			IC02	……..	N	*
			…	……..	..	
			EC01	……..	Y	*
			EC02	…	N	
			….	…..	…	
Y	xxxx	xxxx	IC01	….	N	*

Only patients with at least one protocol deviation. The * identified the protocol deviation.
IC: Inclusion Criterion; EC: Exclusion Criterion

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by treated patients (N, Y), patient no, Criterion no. (incl., excl.).
Only patients with at least one protocol deviation or missing evaluation and/or waiver granted are to be displayed

Appendix 3 – Section 3 – Patients Evaluability for Efficacy Analysis

Appendix 3.3.1- Patients Evaluability for Efficacy Analysis: Listing of Evaluability Criteria and Individual Evaluability Status
-Treated Patients-

		Dose Cy1+Cy2	Tumor Assessment				
Pt. No	Hystological Confirmation	>/= 80% Cum. Intended Dose	At Pretreat.	On Treat.	Death Before 1st Tumor Assessment	Eval.Pt.	Reasons for Non-Evaluability
xxxx	Y	Y	Y	Y	N	Y	
xxxx	Y	Y	Y	Y	N	Y	
xxxx	N	Y	Y	Y		N	R1
xxxx	Y	Y	N	Y	N	N	R3
xxxx	Y	Y	Y	N	N	N	R4
xxxx	Y	N	Y	Y	N	N	R2
xxxx	Y	Y	Y	N	Y	Y	
xxxx	Y	Y	Y	Y	N	N	R3

Reasons for Non-Evaluability:
R1: the patient did not receive diagnosis confirmation by an Independent Review Committee
R2: the patient didn't receive at least 80% of the intended dose for the first two treatment cycles
R3: the pretreatment oncologic assessment was not performed
R4: no on treatment oncologic assessment was performed and the patient didn't die before the first scheduled (re)assessment

[Protocol No. (Study Description)]
[program path; date/time produced; date data extract]

Programming notes:
Sort by patient no.

Appendix 3 – Section 4 – Demography and Pretreatment

Appendix 3.4.1 - Demography and Pretreatment: Tumor History - Primary Diagnosis
- Treated Patients -

Page by Regimen

Pt. No	Age /Sex /Race	Primary Diagnosis	Type of Diagnosis	Date of Diagnosis	Months to Tr. Start		WHO Classification	Masaoka Stage
xxxx	38/M/W	xxxxxxxxxxxxxxxxxx	Cytological	ddmmmyyyy	xxx.x		B3	II
xxxx	xx/x/x	xxxxxxxxxxxxxxxxxx	Histological	mmmyyyy	xxx.x	*	C	IIB
xxxx	…	……	…	…	…		…	…
xxxx	…	……	…	…	…		…	…
xxxx	…	……	…	…	…		…	…

Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.
B3= Well-differentiated thymic carcinoma, C= Tymic Carcinoma
Months to Tr. Start: From date of primary diagnosis to treatment start date.
*: Estimated time when incomplete date was reported.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt no.

Appendix 3.4.2 - Demography and Pretreatment: Tumor History – Diagnosis at Study Entry
- Treated Patients –

Page by Regimen

Pt. No	Age/Sex /Race	Extent at Study Entry	Date of Current Diagnosis	Weeks to Tr. Start	Masaoka Stage	Total No. of Recurrences /Progression	Sites of Metastatic Disease	Specify	Months from Primary Diagnosis
xxxx	38/M/W	Locally Advanced	ddmmmyyyy	xxx.x	II	1			xxx.x *
xxxx	xx/x/xx	Metastatic	yyyy	xxx.x *	IIB	3	Lung		xxx.x *
					…		Bone		
					…		Brain		
xxxx	xx/x/xx	Metastatic	ddmmmyyyy	xxx.x	…	x	Lymph nodes		xxx.x
							Other	xxxxxxxxxxxx	

Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.
Weeks to Tr. Start: From date of diagnosis to treatment start date.
Total No. of Recurrences /Progression : including current one.
Months from Primary Diagnosis: From initial diagnosis date to current diagnosis date.
*: Estimated time when incomplete date was reported.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt no.

Appendix 3.4.3 - Demography and Pretreatment: Tumor History – Independent Review Committee Confirmation of Diagnosis
- Treated Patients –

Page by Regimen

Pt. No.	WHO Classification by Investigator	Date of Diagnosis by Independent reviewer	Reviewer's Name	Tumor Type at Diagnosis according to Reviewer	Thymic Carcinoma Type Confirmed by Reviewer?		Details of Thymic Carcinoma (C)	Details of Thymic Carcinoma (C), Specify	Other Tumor Type, Specify	Comments
xxxx	B3	ddmmmyyyy	xxxxxxxx	B3	Y		Squamous cell thymic carcinoma			
xxxx	C	ddmmmyyyy	xxxxxxxx	Other	N	*			xxxxxxxxx	
xxxx	C	ddmmmyyyy	xxxxxxxx	C	Y		Other	xxxxxxxx		
xxxx	C	ddmmmyyyy	xxxxxxxx	Other	N	*			xxxxxxxxx	xxxxxxxxx

B3= Well-differentiated thymic carcinoma, C= Tymic Carcinoma
Tumor Type at Diagnosis by Independent Reviewer: * if Other

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt no. , date of diagnosis by independent reviewer.

Appendix 3.4.4 - Demography and Pretreatment: History of Other Cancers
- Treated Patients–

Page by Regimen

Pt. No	Age/Sex/Race	Site of Tumor	Histological Type	Date of Diagnosis	Months to Tr. Start
xxxx	38/M/W	xxxxxxxx	xxxxxxxx	ddmmmyyyy	xxx.x
xxxx	xx/x/xx	xxxxxxxx	xxxxxxxx	yyyy	xxx.x *
xxxx	xx/x/xx	xxxxxxxx	xxxxxxxx	ddmmmyyyy	xxx.x

Only patients with at least one other cancer are displayed.
Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.
Months to Tr. Start: From date of diagnosis of other cancer to treatment start date.
*: Estimated time when incomplete date was reported.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt no., line no. (no print).
Select only patients with Other Cancer = ‘yes’ or derived ‘yes’.

Appendix 3.4.5 - Demography and Pretreatment: Tumor History - Prior Antitumor Treatments/Procedures
- Treated Patients –

Page by Regimen

Pt. No	Primary Diagnosis	Chron. Seq. No.	Start Date	Stop Date	Weeks to Tr. Start	Duration of Antitumor Treatment (months)	Time since Previous Antitumor Treatment (months)	Setting	Type
xxxx	xxxx	1	ddmmmyyyy	NA	xx.x	xx.x		Primary Tumor	Surgery
		2	ddmmmyyyy	mmmyyyy	xx.x *	xx.x *	xx.x *	Adjuvant	Chemotherapy
									Radiation Therapy
xxxx	xxxx	1						....	….
		…						….	…..

Only patients with at least one therapy are displayed.
NA= Not Applicable
Weeks to Tr. Start: from antitumor treatment/procedure stop date to treatment start date.
Duration of Antitumor Treatment (weeks): from start date to stop date.
Time since previous Antitumor Treatment (weeks): from stop date of previous line (chron. seq.) to start date of current line.
*: Estimated time when incomplete date was reported

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt no., chron. seq. number.
Select only patients with prior antitumor treatments/procedures = ‘yes’ or derived ‘yes’ .

Appendix 3.4.6 - Demography and Pretreatment: Tumor History - Prior Systemic Therapies
- Treated Patients –

Page by Regimen

Pt. No.	Chron Seq. No.	Setting	Drug Name	Dose / Unit / Schedule	Start Date	Stop Date	Duration of treatment (months)	Best Response	Response Date	Relapse / Progression Date
xxxx	2	Primary Tumor	xxxxxxxx		ddmmmyyyy	ddmmmyyyy	xxx.x	CR	ddmmmyyyy	ddmmmyyyy
	3	Metastatic	xxxxxxxx	…	ddmmmyyyy	ddmmmyyyy	xxx.x		NA	NA
xxxx	1	Primary Tumor	xxxxxxxx	xxxxxxx	ddmmmyyyy	mmyyyy	xxx.x*	PR	ddmmmyyyy	mmyyyy
	2		xxxxxxxx	xxxxxxx						
	n		…	…						
xxxx	1		xxxxxxxx		ddmmmyyyy	ddmmmyyyy	xxx.x			

Only patients with at least one therapy are displayed.
Best Response: CR= Complete Response, PR= Partial Response, SD= Stable Disease, PD = Progressive Disease, NE=Not Evaluable, NAS= Not Assessed, NA= Not Applicable.
*: Estimated time when incomplete date was reported

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt no., chron. seq. number.
Select only patients with systemic therapy =‘yes’ or derived ‘yes’.
Start/Stop Date: correspond to start/stop date in the header page when for the given Chron. Seq No. the variable Type can be linked to “Systemic Therapy” (see ALG document for derivation)

Appendix 3.4.7 – Demography and Pretreatment: Tumor History - Prior Surgeries
- Treated Patients –

Page by Regimen

Pt. No.	Primary diagnosis	Chron. Seq. No.	Setting	Date	Surgical Procedure
xxxx	xxxx	1	Primary Tumor	ddmmmyyyy	xxxxxxxxxxxxxxxxxxxxx
		2	Locally Advanced	ddmmmyyyy	xxxxxxxxxxxxxxxxxxxxx
xxxx	xxxx				
…		1	…	…	…
		…	….		

Only patients with at least one surgery are displayed.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt no., chron. seq. number.
Select only patients with any prior surgery =‘yes’ or derived ‘yes’.
Date: corresponds to start date in the header page when for the given Chron. Seq No. the variable Type can be linked to “Surgery” (see ALG document for derivation)

Appendix 3.4.8 – Demography and Pretreatment: Tumor History - Prior Radiotherapies
- Treated Patients –

Page by Regimen

Pt. No.	Primary Diagnosis	Chron. Seq. No.	Setting	Irradiated BM (%)	Start Date	Stop Date	Irradiation Site	Best Response	Date of Best Response	Date of Progression
xxxx	xxxx	1	Primary Tumor	xx.x	ddmmmyyyy	ddmmmyyyy	xxxxxxx	CR	ddmmmyyyy	ddmmmyyyy
		2	Adjuvant				xxxxxxx		NA	ddmmmyyyy
							xxxxxxx	PR	ddmmmyyyy	NA
xxxx	xxxx	1	....	xx.x	mmmyyyy	mmmyyyy	xxxxxxx	…		
xxxx	xxxx	…	….	xx.x	ddmmmyyyy	ddmmmyyyy	xxxxxxx	…		

Only patients with at least one radiotherapy are displayed.
Best Response: CR = Complete Response, PR= Partial Response, SD = Stable Disease, PD = Progressive Disease, NE= Not Evaluable, NAS= Not Assessed, NA = Not Applicable

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt no., chron. seq. number.
Select only patients with Prior Radiotherapies ='yes' or derived 'yes'.
Start/Stop Date: correspond to start/stop date in the header page when for the given Chron. Seq No. the variable Type can be linked to "Radiotherapy" (see ALG document for derivation)

Appendix 3.4.9 - Demography and Pretreatment: General Medical History and Physical Examination Findings
- Treated Patients –

Page by Regimen

Pt. No.	Age/Sex/Race	Primary Diagnosis	Medical Conditions / Physical Findings	Status
xxxx	38/M/W	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Active
			xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Controlled
			xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Past
xxxx	xx/x/x	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Past
xxxx	xx/x/x	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Active

Only patients with at least one finding are displayed.
Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt. no, status (Active, Controlled and Past)
Select only patients with medical history/physical findings = ‘yes’ or derived ‘yes’.

Appendix 3 – Section 5 – Treatment Exposure

Appendix 3.5.1 – Treatment Exposure: Treatment Administration Details
- Treated Patients –

Page by Regimen

Pt. No.	Cycle	Tr. Delay	Dose Reduced at Cycle Start	Intra Cycle Modification	Dose Level (mg/day)	BSA (m2)	Day	Taken Dose (mg)	Date of Admin.	Time of Admin.
xxxx	Cy 1			Y	xxx.x	x.xx	1	xxx.x	ddmmmyyyy	hh:mm
							…	xxx.x		hh:mm
							5		ddmmmyyyy	
							….			
							7			
	Cy 2	Y	Y		xxx.x	x.xx	1	xxx.x	ddmmmyyyy	hh:mm
	…	…						…	…	…
xxx	Cy 1					x.xx	1	xxx.x	ddmmmyyyy	hh:mm
	…	…			…		…		…	…

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period, day, date of administration.

Appendix 3.5.2 – Treatment Exposure: Reasons for Treatment Delay, Dose Reduction
- Treated Patients -

Page by Regimen

Pt No.	Cycle	Cycle Duration (weeks)	Trt. Delay	Reason	Specify	Dose Reduced at cycle start	Reason	Specify	Intra-cycle Modification	Reason	Specify	Dose Level (mg/day)	Day	Taken Dose (mg)
xxxx	Cy 1	xx.xx								xxxxxxxxx		xxx.x	1	xxx.x
													…	xxx.x
													5	xxx.x
													….	
	Cy 2	xx.xx				Y	(H)	xxxxxx		xxxxxxxxx		xxx.x	1	xxx.x
		…..				…							.	…
	Cy n	xx.xx (xx.xx)				…							.	…
xxxx	Cy 1	xx.xx	Yes	(N-H)	xxxxxx				Y			…	1	xxx.x
	…	…				…							…	….

Only patients/cycles for whom any treatment modifications are reported.
Duration of the last cycle of treatment is calculated from last cycle start date to end of treatment date; the per-protocol cycle duration is reported within brackets
Reason for Intra Cycle Modification includes Reason for Dose Omitted and Dose Reduced Intra Cycle.
Reasons: H=Hematological toxicity, N-H=Non-Hematological toxicity, O=Other, specify.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period, day. Select only patients for whom any modification applies, i.e. either treatment delay=Y or Dose reduced at cycle start=Y or intra-cycle modification=Y.

Appendix 3.5.3 – Treatment Exposure: Dose Intensity and Cumulative Dose
- Treated Patients –

Page by Regimen
Intended Dose Intensity (mg/wk): xxx.x

Pt. No.	Age /Sex /Race	Study Period	No. of Days of Treatment	Taken Dose (mg)	BSA (m2)	% Scheduled Dose	Treatment Duration (weeks)	Absolute D.I. (mg/wk)	Relative D.I. (%)	Progressive Cum. Dose (mg)
xxx	38/F/W	Cy 1	xx	xxx.x	x.xx	xx.x	xx.x	xxx.x	xx.x	xxx.x
		Cy 2	xx	xxx.x		xx.x	xx.x	xxx.x	xx.x	xxx.x
		Cy x	xx	xxx.x	x.xx	xx.x	xx.x (3)	xxx.x	xx.x	xxx.x
		Whole Period					xx.x	xxx.x	xx.x	xxx.x
xxxx	xx/x/x	Cy 1	xx	xxx.x	x.xx	xx.x	xx.x	xxx.x	xx.x	xxx.x
		Cy 2	xx	xxx.x		xx.x	xx.x	xxx.x	xx.x	xxx.x
		Cy x	xx	xxx.x	x.xx	xx.x	xx.x (3)	xxx.x	xx.x	xxx.x
		Whole Period					xx.x	xxx.x	xx.x	xxx.x

Race: W= White, B= Black, A= Asian, O= Not listed, N= Not allowed to ask per local regulation.
% Scheduled Dose: the ratio between dose (mg) and intended dose x 100.
Treatment Duration for last cycle and whole period: from the last cycle start date or from first dose date respectively, to end of treatment date. Duration reported in brackets is used for dose intensity calculation and considers the per protocol cycle duration.
Relative D.I.: the ratio between absolute dose intensity and intended dose intensity x 100.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period.

Appendix 3.5.4 – Treatment Exposure: Pharmacokinetics Blood Sampling Time
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Study Period	Tr. Admin Date	Tr. Admin. Time	Study Day	Study Time	Specimen Collection Date	Specimen Collection Time
xxxx	52/F/W	Cy 1	ddmmmyyyy	hh:mm	1	1	ddmmmyyyy	hh:mm
						2	ddmmmyyyy	hh:mm
						3	ddmmmyyyy	hh:mm
			ddmmmyyyy	hh:mm	x	…	…	…
		…	…	…	…	…	…	…
xxxx	xx/x/x	Cy 1	ddmmmyyyy	hh:mm	1	….	ddmmmyyyy	hh:mm
		…	…	…	…	…	…	…

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period, tr. Admin. date, study day, study time, collection date, collection time.
Study day is the one indicated on the PK form of the CRF.

Appendix 3 – Section 6 – Treatment Efficacy

Appendix 3.6.1 - Treatment Efficacy - Target and Non Target Lesions by Assessment Visit
- Treated Patients –

Page by Regimen

Pt. No.	Study Period	Date	Days to/from Tr. Start	Les. Type	Les. No.	Lesion Description	Eval. (Y/N)	Lymph Node	Prior Loco-regionally Treated Lesion	New Les.	N. A.	Method	Target L. Measure (mm)	Target L. % Change from Pretr	Target L. Nadir	Target.L. % Change from Nadir	Non Target L. Status
xxx	Pretr.	ddmmmyyyy	xxx	T	xx	xxxxxxxxxx		Y	Y			xx	xxxx				
					xx	xxxxxxx						xx	xxxx				
						All Target L.							**xxxx**				
				NT	xx	xxxxx						…					
	Onc 1	ddmmmyyyy	xxx	T	xx	xxxxxxxxxx	Y	Y				xx	xxxx				
					xx	xxxxxxx	Y					xx	xxxx	±xxx.x			
					xx	xxxxxxx	Y			Y		xx	xxxx				
						All Target L	**Y**						**xxxx**	±xxx.x	**Y**		
		ddmmmyyyy	xxx	NT	xx	xxxxxxxx											A
	Onc x	ddmmmyyyy	xxx	T	…	…		…				..	….	…….			
						All Target L	**Y**						**xxxx**	±xxx.x		xxxx	
xxx	Pretr.	ddmmmyyyy	xxx	T	xx	xxxxxxxxxx						xx	xxxx				
						All Target L.							**xxxxx**				
	Onc. 1	ddmmmyyyy	xxx	T	xx	xxxxxxxxxx	N					xx*	xxxx				
						All Target L	**N**						**xxxx**				

Lesion Type: T=Target Lesion, NT=Non Target Lesion
Eval (Y/N): a target lesion is not considered as evaluable if missing measure and/or method, or method different from pretreatment assessment; the set of all target lesions is not evaluable if even one only target lesion is not evaluable. N.A.: Not Assessed.
Method: 1=Physical Exam. (measurement by caliper), 2=X-ray, 3=Echo/Ultrasounds, 4=CT scan, 5=Scintigraphy, 6=MRI/NMR, 7=Linear Tomography, 8=Photography, 10=Bronchoscopy, 13=Spiral CT-Scan, 14=PET, 15=MIBG Scan, 16=99tc Scan, 17=MR Spectroscopy, 18=Thallium Spectroscopy, 19=Angiography, 20=Bone Scan, 98=Other, specify in the Physician's Comments page.
Methods different from the pretreatment one are marked by '∗'.
Non Target Lesions: Status: A=Absent (CR); P=Present (Non-CR/Non-PD); UPD=Unequivocal Progressive Disease.
Nadir: lowest value of All Target Lesions throughout the whole study period, baseline included. %Change from Nadir: only for study periods following the period when the nadir is reported.
[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes: Sort by pt. no., study period, les type (T, NT), les. no..

Appendix 3.6.2 - Treatment Efficacy - Response Status by Assessment Visit
- Treated Patients -

Page by Regimen

								If CR or PR	
Pt. No.	Study Period	Assessment Date	Days from Tr. Start	Response	Response Status	Date of Documented PD	Weeks to PD	First Response Date	Response Confirmation Date
xxx	Onc 1	ddmmmyyyy	xxx	Target Lesion	CR				
				Non Target Lesion	NE				
				Overall	PR				
	Onc 1	ddmmmyyyy	xxx	…	…	…	…	…	…
				Overall	PD	ddmmmyyyy	xxx.x		
	Best OR	--		Best Overall	PR			ddmmmyyyy	ddmmmyyyy*
xxx	Onc 1	…	…		xx				
	…	…			…				
	Onc 3	…	…		xx	ddmmmyyyy	xxx.x		
	Best OR	--		Best Overall	CR	…	…	ddmmmyyyy *	ddmmmyyyy

Assessment date: the date of the first tumor lesion assessment in the relevant study period. .
Response Status: CR = Complete Response, PR = Partial Response, SD = Stable Disease, NCR/NPD= Non-CR/Non-PD, UPD= Unequivocal PD, PD = Progressive Disease, NE= Not Evaluable, NA = Not Applicable.
Date of Documented PD was derived as the first tumor lesion assessment date in the relevant study period. Weeks to PD: from the first treatment date to the date of documented PD.
First Response Date: when not recorded on CRF, the * indicates that the date was derived as the latest date among all tumor lesion assessment dates at the first visit when a response (CR or PR) was reported. Response Confirmation Date: when not recorded on CRF, the * indicates that the date was derived as the latest date among all tumor lesion assessment dates at the second visit when a response (CR or PR) was reported.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]
Programming Notes: Sort by pt. no., study period, les type (target, non-target, overall).

Appendix 3.6.3 - Treatment Efficacy – Best Overall Response and Time to Progression, Progression Free Survival, Overall Survival, Response Duration and Stable Disease Duration
- Treated Patients -

Page by Regimen/Assigned Dose Level (mg/m2/day): <xi >

Pt. No	Pt. Evaluable for Efficacy (Y/N)	Tr. Start Date	Total No. of Cycles	Dose Intensity (mg/wk)	Best Overall Response	Date of First Response	Date of PD	Date of Death	Last Onc. Assessment Date	Last Recorded Date	TTP (days)	OS (days)	PFS (days)	Response Duration (days)	Stable Disease Duration (days)
xxx	Y	ddmmmyyyy	4	xxx.x	CR	ddmmmyy		ddmmmyyyy	ddmmmyyyy		xxx.x +		xxx.x	xxx.x +	
xxx	Y	ddmmmyyyy	3	xxx.x	SD		ddmmmyyyy		ddmmmyyyy	ddmmmyyyy	xxx.x	xxx.x +	xxx.x		xxx.x
xxx	Y	ddmmmyyyy	x	xxx.x	PR	ddmmmyy*			ddmmmyyyy	ddmmmyyyy	xxx.x +	xxx.x +	xxx.x +	xxx.x +	
xxx	Y	ddmmmyyyy	x	xxx.x	PD		ddmmmyyyy		ddmmmyyyy	ddmmmyyyy	xxx.x	xxx.x +	xxx.x		
xxx	N	ddmmmyyyy	x	xxx.x	CR	ddmmmyy			ddmmmyyyy	ddmmmyyyy	xxx.x +	xxx.x +	xxx.x +	xxx.x +	
xxx	Y	ddmmmyyyy	x	xxx.x	SD			ddmmmyyyy	ddmmmyyyy		xxx.x		xxx.x		xxx.x
xxx	Y	ddmmmyyyy	x	xxx.x	SD			ddmmmyyyy	ddmmmyyyy		xxx.x +		xxx.x		xxx.x +

Best Overall Response: as reported by the investigator at the completion of treatment; CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE= Not Evaluable.
Date of First Response: when not recorded on CRF, the * indicates that the date was derived as the latest date among all tumor lesion assessment dates at the first visit when a response (CR or PR) was reported.
Last Recorded Date: for patients still alive it is the last available date in CRF.
(+): indicates censored time.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no.
D.I.: the dose intensity to be reported is the one calculated for the whole treatment period.

Appendix 3.6.4 – Treatment Efficacy: ECOG Performance Status
- Treated Patients -

Page by Regimen

Pt. No.	Study Period	Date	Study Day	ECOG PS
xxxxxx	Pretr.	ddmmmyyyy		3 §
	Cy 1	ddmmmyyyy	1	0
	…	….	….	….
	Cy n	ddmmmyyyy	1	

At pretreatment: Performance Status >1 is identified by § (violation of inclusion criterion 05).

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period, date.

Appendix 3 – Section 7 – Adverse Events

Appendix 3.7.1 – Adverse Events: All Reported Adverse Events by Assessment Visit and AE MedDRA Preferred Term
- Treated Patients -

Page by Regimen

Pt. No.	Study Period	Cycle Start Date	Adverse Event	CTC Grade	Serious	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Proc.	Rel. to Study Treat.	Rel. to Study Disease	Action Taken	Outcome
xxxx	Pretr.		xxxxxxxxxx	1	N	ddmmmyyyy		ddmmmyyyy		Y		N		R
			xxxxxxxxxx	1	N		Y		Y	N		N		NR
			xxxxxxxxxx	2	…		Y	ddmmmyyyy		N		Y		R
	Cy 1	ddmmmyyyy	xxxxxxxxxx	x	…		Y		Y		No		No	NR
			xxxxxxxxxx	…	…	ddmmmyyyy			Y		Un	N	No	NR
			xxxxxxxxxx	3	Y	ddmmmyyyy		ddmmmyyyy			Po	Y	D/C	R
	…	…	…	…	…	…	…	…	…		…	…	…	…

AP/SP: Already present/Still present.
Related to Study Treatment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.
Action Taken: No=None; D/C=Dose Delayed/Changed; PW=Drug Permanently Withdrawn.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period, AE MedDRA Preferred Term, AE page no., AE seq no..
Include also records of End of Adverse Events Reporting Period and of Follow-up.

Appendix 3.7.2 - Adverse Events: Adverse Events Related to Study Procedure at Pretreatment
- Treated Patients –

Page by Regimen

Pt. No.	Adverse Event	CTC Grade	Serious	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Procedure	Rel. to Study Disease	Outcome
xxxx	xxxxxxx	x	N	ddmmmyyyy		ddmmmyyyy		Y	N	…
	xxxx	x	N						N	...
	xxxxxxx xxxx xxx	x	N		Y				Y	R
	xxxxxxx	x	N	ddmmmyyyy			Y		…	NR
xxxx	…	…	…	…	…	…	…	…	N	…
…	…	…	…	…	…	…	…	…	Y	…
									…	

Only AEs reported at pretreatment visit and related to study procedure are displayed.
AP/SP: Already present/Still present.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[program path; date/time produced; date data extract]

Programming Notes:
Sort by pt. no., study period, AE MedDRA Preferred Term, AE page no., AE seq. no.
Select only records at pretreatment and with variable “Related to study procedure” =Y or missing

Appendix 3.7.3 – Adverse Events: Serious Adverse Events
- Treated Patients -

Page by Regimen

Pt. No.	Adverse Event	Study Period	Cycle Start Date	Serious	CTC Grade	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Proc.	Rel. to Study Treat.	Rel. to Study Disease	Action Taken	Outcome
xxxx	xxxxxxxxxx	Pretr.			2	ddmmmyyyy		ddmmmyyyy		N		N		R
		Cy 1	ddmmmyyyy		3	ddmmmyyyy					De	Y	D/C	NR
		…	….	Y	4		Y		Y		Pr	Y	D/C	R
		Cy x	ddmmmyyyy	Y	…	…	Y	ddmmmyyyy			…	...	PW	…
	xxxxxxxxxx	Cy 1	ddmmmyyyy		1	ddmmmyyyy		ddmmmyyyy			…	Y	No	NR
		…	…..		…	ddmmmyyyy			Y		Po	…	…	R
		Cy x	ddmmmyyyy	Y	…		Y	ddmmmyyyy			…	…	…	NR
xxxx	…	…	…		…	…	…	…	…		…	…	…	…

All occurrences of AEs that were reported as Serious at least once for the patient in the course of the study are displayed.
AP/SP: Already present/Still present.
Related to Study Treatment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.
Action Taken: No=None; D/C=Dose Delayed/Changed; PW=Drug Permanently Withdrawn.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., AE MedDRA Preferred Term, study period, AE page no., AE seq no..
Select AE Preferred terms that had the variable 'Serious'=Y at least once within the patient in the course of the study, including pretreatment, End of Adverse Events Reporting Period and of Follow-up.

Appendix 3.7.4 – Adverse Events: Adverse Events with CTC Grade 3 to 5
- Treated Patients -

Page by Regimen

Pt. No	Adverse Event	Study Period	Cycle Start Date	CTC Grade	Serious	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Proc	Rel. to Study Treat.	Rel. to Study Disease	Action Taken	Outcome
xxxx	xxxxxxxxxx	Pretr.		3	N	ddmmmyyyy		ddmmmyyyy			No	Y	No	R
	xxxxxxxxxx	Cy 1	ddmmmyyyy	3	N		Y		Y		Un	Y	D/C	NR
		…		…	Y	…	…		…		Pr	N	…	…
		Cy x	ddmmmyyyy	...	...		Y		Y		Pr	N	No	NR
	xxxxxxxxxx	Cy 1	ddmmmyyyy	…	...	ddmmmyyyy			Y		Un	Y	No	NR
		…		4	Y	ddmmmyyyy		ddmmmyyyy			De	Y	D/C	R
		Cy x	ddmmmyyyy										…	…

Only AE occurrences at the time when CTC grade > 2 are displayed.
AP/SP: Already present/Still present.
Related to Study Treatment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.
Action Taken: No=None; D/C=Dose Delayed/Changed; PW=Drug Permanently Withdrawn.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract

Programming Notes:
Sort by pt. no., study period, AE MedDRA Preferred Term, AE page no., AE seq. no..
Selct only the occurrences of AEs when CTC grade > 2. Include also occurrences reported with grade > 2 at pretreatment or at End of Adverse Events Reporting Period or at Follow-up.

Appendix 3.7.5 – Adverse Events: Patients with Adverse Events Leading to Withdrawal from Study Treatment
- Treated Patients -

Page by Regimen

Pt. No.	Adverse Event	Study Period	Cycle Start Date	CTC Grade	Serious	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Proc.	Rel. to Study Treat.	Rel. to Study Disease	Action taken	Outcome
xxxx	xxxxxxxxxx	Pretr.		2		ddmmmyyyy		ddmmmyyyy		N		N		R
		Cy 1	ddmmmyyyy	3	Y	ddmmmyyyy					De	Y	D/C	NR
		…	….	4	Y		Y		Y		Pr	Y	D/C	R
		Cy x	ddmmmyyyy	…	N	…	Y	ddmmmyyyy			…	...	PW	…
	xxxxxxxxxx	Cy 1	ddmmmyyyy	1	…	ddmmmyyyy		ddmmmyyyy			…	Y	No	NR
		…	…..	…	…	ddmmmyyyy			Y		Po	…		R
		Cy x	ddmmmyyyy	…	…		Y	ddmmmyyyy			…	…		NR
xxxx	…	…	…	…		…	…	…	…		…	…		…

Only patients that had at least one AE whose Action Taken was Drug Permanently Withdrawn are displayed.
AP/SP: Already present/Still present.
Related to Study Treatment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.
Action Taken: No=None; D/C=Dose Delayed/Changed; PW=Drug Permanently Withdrawn.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by, pt. no., study period, AE MedDRA Preferred Term, AE page no., AE seq no..
Select patients that had at least one AE whose Action Taken was Drug Permanently Withdrawn. Of these patients report all AEs.
Include also records of End of Adverse Events Reporting Period and of Follow-up.

Appendix 3.7.6 – Adverse Events: End of AE Reporting Period and Follow-Up
- Treated Patients –

Page by Regimen

Pt. No	Tr. Last Date	Study Period	Adverse Event	CTC Grade	Serious	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Treat.	Rel. to Study Disease	Outcome	If Ongoing
xxxx	ddmmmyyyy	AE End	xxxxxxxxxx	x	N		Y		Y	No	N	NR	Chronic/Stable
			xxxxxxx	x	N		Y		Y	Un	Y	NR	Continue to follow
			xxxxxxxxxx	x	...	ddmmmyyyy			Y	Po	N	NR	New Anticancer therapy
xxxx	ddmmmyyyy	AE FU1	§ xxxxxxx	x	…		Y		Y	De	N	NR	Chronic/Stable
		…											

AEs not recovered in Follow-up are identified by §.
AP/SP: Already present/Still present.
Related to Study Treatment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract

Programming Notes:
Sort by pt. no., study period, AE MedDRA Preferred Term, AE page no., AE seq. no..
Select AEs with study period = 'End of AE reporting period' or 'Follow-up'.

Appendix 3.7.7 – Adverse Events: All Reported Adverse Events by System Organ Class, AE MedDRA Preferred Term and Investigator's Term
- Treated Patients -

Page by Regimen

Pt. No.	System Organ Class	Adverse Event	Investigator's Term	Study Period	Cycle Start Date	CTC Grade	Serious	Rel. to Study Proc.	Rel. to Study Treat.	Rel. to Study Disease
xxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	Pretr.		x	N	N	De	…
		xxxxxxxxxxxxx	xxxxxxxxxxxxx	Cy 1	ddmmmyyyy	x	Y		Pr	Y
		xxxxxxxxxxxxx	xxxxxxxxxxxxx	Cy x	ddmmmyyyy	x	N		…	...
			xxxxxxxxxxxxx	Cy x	ddmmmyyyy	x	N		…	Y
		…	…	Cy 1	ddmmmyyyy	x	…		Po	
		…	…	Cy x	ddmmmyyyy	x	…		…	
xxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	…		x	…			
		xxxxxxxxxxxxx	xxxxxxxxxxxxx	…		x	…			

Related to Study Treatment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., System Organ Class, AE MedDRA Preferred Term, AE Investigator's Term, study period, AE page no., AE seq no..

Appendix 3.7.8 – Adverse Events: Hospitalization
- Treated Patients -

Page by Regimen

Pt. No.	Age/Race /Sex	Tr. Start Date	Tr. Last Date	Reason	Description	Date of Admission	Date of Discharge	Ongoing	Duration (days)	Weeks from Tr. Start
xxxx	35/W/M	ddmmmyyyy	ddmmmyyyy	Adverse event		ddmmmyyyy	ddmmmyyyy		xxx	xxx
				Progressive Disease		ddmmmyyyy		Y		xxx
xxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	Instrumental procedure		ddmmmyyyy		Y		xxx
xxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	Other	xxxxxxxxxxxxx	ddmmmyyyy	ddmmmyyyy		xxx	xxx

Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.
Duration (days): from date of admission to date of discharge.
Weeks from Tr. Start: from treatment start date to date of admission.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., admission date, seq. no.

Appendix 3.7.9 – Deaths
- Treated Patients -

Page by Regimen

Pt. No.	Age /Sex /Race	Tr. Start Date	Tr. Last Date	Total No. of Cycles	Cumulative Dose (mg/m2)	Date of Death	CRF Source	Days from Tr. Last Date	Most Probable Cause	Details	Investigator Causality Assessment
xxxx	38/M/W	ddmmmyyyy	ddmmmyyyy	2	xxxx.x	ddmmmyyyy	FU	xxx	PD		Un
xxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	x	xxxx.x	ddmmmyyyy	Death	xxx*	AE	xxxxxxxxxx	No
xxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	x	xxxx.x	ddmmmyyyy	Death	xxx	Other	xxxxxxxxxx	Po
xxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	x	xxxx.x	ddmmmyyyy	AE	xxx	AE	xxxxxxxxx	Pr
xxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	x	xxxx.x	ddmmmyyyy	AE	xxx	AE		…
xxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy	x	xxxx.x	ddmmmyyyy	AE	xxx			…

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
CRF Source: (Death): Death date reported in Death Form, (FU): Death date reported in Survival Follow-up Form, (AE): Death date reported in AE Form.
Days from treatment last date: * if <= 28 days.
Investigator Causality Assessment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no..

Appendix 3.7.10 – Deaths: Autopsy Result
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Days from Tr. Last Date to Death Date	Most Probable Cause	Details	Investigator Causality Assessment	Autopsy Performed	Autopsy Date	Autopsy Result
xxxx	38/M/W	xxx	Progressive Disease		Pr	Y	ddmmmyyyy	xxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxx
xxxx	xx/x/x	xxx*	Adverse Event		Po	Y	ddmmmyyyy	…
xxxx	xx/x/x	xxx	Other	xxxxxxxxxxx	…	N		
xxxx	xx/x/x	xxx	…		…	N		

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Days from treatment last date to death date: * if <= 28 days.
Investigator Causality Assessment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no..

Appendix 3 - Section 8 – Laboratory Assessments

Appendix 3.8.1 – Laboratory Assessments: Hematology by Laboratory Test, Patient and Study Period
- Treated Patients -

Page by Regimen /Laboratory Test: < e.g. Neutrophils >

Pt. No.	Age /Sex /Race	Study Period	Cycle Start Date	Date of Sampling	Study Day	Collected Value	Collected Unit	L/H	Converted Value	Converted Unit	CTC Grade
xxxx	52/F/W	Pretr.		ddmmmyyyy	-xx	xxx.xx	xxxx	L	xxx.xx	xxxx	x
		Cy x	ddmmmyyyy	ddmmmyyyy	xx	…	…	…	…	…	3 *
					xx	…	…	…	…	…	4 *
		…	…	…	...	…	…	…	…	…	...
xxxx		Pretr.		ddmmmyyyy	xx	…	…	…	…	…	2
…		…	…	…		…	…	…	…	…	…

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Converted Unit: either the unit reported in the NCI CTCAE v3.0 or the Conventional Unit, depending on the analyzed lab test.
CTC Grade - NCI CTCAE v3.0: N= Not Applicable, U= Unknown. The '*' identifies the occurrence(s) of CTC grades= 3 or 4.
L/H: Below/Above Normal Limits.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*, pt. no, study period, date of sampling, study day. If feasible lab test is to be ordered as per CRF appearance.
The listing must include all the hematological labs (including also the ones that are not listed in the NCI CTCAE v.3.0).
Each assessment (i.e. record) is to be displayed only if date is not missing or collected value is not missing.

Appendix 3.8.2 – Laboratory Assessments: Blood Chemistry by Laboratory Test, Patient and Study Period
- Treated Patients -

Page by Regimen /Laboratory Test: < e.g. ALT >

Pt. No.	Age /Sex /Race	Study Period	Cycle Start Date	Date of Sampling	Study Day	Collected Value	Collected Unit	Collected Lower Limit	Collected Upper Limit	L/H	Converted Value	Converted Unit	CTC Grade
xxxx	52/F/W	Pretr.		ddmmmyyyy	- xx	xxx.xx	xxx.xx	xxx.xx	xxx	L	xxx.xx	xxxx	N
				…….		xxx.xx	xxx.xx	xxx.xx	xxx		…	…	N
		Cy x	ddmmmyyyy	ddmmmyyyy	xx	xxx.xx	xxx.xx	xxx.xx	xxx	H	…	…	3*
						…	…	…	…		…	…	
						…	…	…	…	…	…	…	
				ddmmmyyyy	xx	…	…	…	…	L			4*
						…	…	…	…	…			
…		…	…	…	…	…	…	…	…	…			

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Converted Unit: either the unit reported in the NCI CTCAE v3.0 or the Conventional Unit, depending on the analyzed lab test.
CTC Grade - NCI CTCAE v3.0: N= Not Applicable, U= Unknown. The '*' identifies the occurrence(s) of CTC grades= 3 or 4.
L/H: Below/Above Normal Limits.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*, pt. no, study period, date of sampling, study day.
If feasible lab test is to be ordered as per CRF appearance.
The listing must include all the biochemistry labs (including also the ones that are not listed in the NCI CTCAE v.3.0).
Each assessment (i.e. record) is to be displayed only if date is not missing or collected value is not missing.

Appendix 3.8.3 – Laboratory Assessments: Coagulation by Patient, Study Period and Laboratory Test
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Study Period	Cycle Start Date	Date of Sampling	Study Day	Laboratory Test	Collected Value	Collected Unit	Collected Lower Limit	Collected Upper Limit	L/H	Converted Value	Converted Unit	CTC Grade
xxxx	52/F/W	Pretr.		ddmmmyyyy	- xx	aPTT	xxx.xx	xxx.xx	xxx.xx	xxx	L	xxx.xx	xxxx	2
						INR	xxx.xx	xxx.xx	xxx.xx	xxx		…	…	1
				ddmmmyyyy		aPTT	xxx.xx	xxx.xx	xxx.xx	xxx	H	…	…	2
						INR	xxx.xx	xxx.xx	xxx.xx	xxx	H	…	…	2
		Cy x	ddmmmyyyy	ddmmmyyyy	xx	…	…	…	…	…		…	…	
						…	…	…	…	…	…	…	…	
				ddmmmyyyy	xx	…	…	…	…	…	…			
						…	…	…	…	…	…			
…		…	…	…	…	…	…	…	…	…	…			

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Converted Unit: either the unit reported in the NCI CTCAE v3.0 or the Conventional Unit, depending on the analyzed lab test.
CTC Grade - NCI CTCAE v3.0: N= Not Applicable, U= Unknown. The '*' identifies the occurrence(s) of CTC grades= 3 or 4.
L/H: Below/Above Normal Limits.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no, study period, date of sampling, study day, lab test.
If feasible lab test is to be ordered as per CRF appearance.
The listing must include all the coagulation labs (including also the ones that are not listed in the NCI CTCAE v.3.0).
Each assessment (i.e. record) is to be displayed only if date is not missing or collected value is not missing.

Appendix 3.8.4 – Laboratory Assessments: Urinalysis
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Study Period	Cycle Start Date	Date of Sampling	Study Day	Laboratory Test	Collected Value
xxxx	52/F/W	Pretr.		ddmmmyyyy	- xx	ph	xx
						glucose	negative
						…	trace
		Cy. 1	ddmmmyyyy	ddmmmyyyy	xx	ph	
						…	
						protein	1+

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no, study period, date of sampling, study day, lab test.
If feasible lab test is to be ordered as per CRF appearance.
Each assessment (i.e. record) is to be displayed only if date is not missing or collected value is not missing.

Appendix 3.8.5 – Laboratory Assessments: Laboratory Normal Ranges of Hematological Tests

Laboratory Test Description	Laboratory Test Code	Sex	Age Min (years)	Age Max (years)	Lower Limit	Upper Limit	Unit
xxxxx		Both			xxx.xx	xxx.xx	xxxxx
xxxxx		…			…	…	…
xxxxx		Male			…	…	…
xxxxx		Both			…	…	…
…		Female			…	…	…
…		…			…	…	…
…		…			…	…	…
…		…			…	…	…

Normal ranges are not collected for hematological tests, Standard Normal Ranges expressed in Conventional Unit are used.
Age class: age range 0-150 is a conventional range when lab. test normal ranges are valid for all ages

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by lab. Test (description, code), sex.
For each test belonging to WBC, report the unit expressed both in percentage and absolute count.

Appendix 3.8.6 – Laboratory Assessments: Laboratory Normal Ranges of Non-Hematological Tests
- Treated Patients -

Page by: Laboratory Code: <xxxxx> Laboratory Name: <xxxxxxxxxx>.

Laboratory Class	Assay	Initial Set (Y/N)	Date of Change	Sex	Age Min (years)	Age Max (years)	Lower Limit	Upper Limit	Unit
Blood Chemistry	xxxxx	Y		Male	xx	xx	xxx.xx	xxx.xx	…
					…	…	…	…	…
				Female	xx	xx	…	…	…
					…	…	…	…	…
xxxxxxxxxxxx	xxxxx	N	ddmmmyyyy	Both	xx	xx	…	…	…
…	…			…	…	…	…	…	…
	xxxxx	…	…	…	…	…	…	…	…
	…	…	…	…	…	…	…	…	…

Units are not converted, they are listed according to CRF reported units.
Age class: age range 0-150 is a conventional range when lab. test normal ranges are valid for all ages.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*, laboratory class, assay, date of change, sex, age min.
Lab test ranges are not to be converted; they are to be listed according to the units reported on CRF.

Appendix 3 - Section 9 – Other Safety Assessments

Appendix 3.9.1 – Other Safety Assessments: Vital Signs
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Study Period	Date	Height (cm)	Weight (kg)	Temperature (°C).	Route	Syst. B.P. (mmHg)		Diast. B.P. (mmHg)		Pulse (bpm)
xxxx	35/M/W	Pretr.	ddmmmyyyy	xxx.x	xxx.x	xxx.x	xxxx	170	*	100	*	xxx
		Cy 1	ddmmmyyyy		xxx.x	xxx.x	xxxx	164	*	xxx		xxx
		Cy 2	ddmmmyyyy		xxx.x	xxx.x	xxxx	xxx		110	§	xxx
xxxx		…..	….	…				….		….		…..

Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.
(*) Systolic Blood Pressure ≥140 mmHg or Diastolic Blood Pressure ≥ 90 mmHg.
(§) Increase from pretreatment: Systolic BP≥20; Diastolic BP ≥10 mmHg.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt. no., study period, date.

Appendix 3.9.2 – Other Safety Assessments: ECG
- Treated Patients –

Page by Regimen

Pt. No.	Age/Sex /Race	Study Period	ECG Date	Ventricular Rate (bpm)	Tracing Abnormalities	Category		Specific Abnormality	Further Details
xxxx	35/M/W	Pretr.	ddmmmyyyy	xxx	N				
					Y	Rhythm		Sinus Tachicardia	
		Cy 1	ddmmmyyyy	xxx		QRS		xxxxxxxxxxxx	
		Cy 2	ddmmmyyyy	xxx			*	xxxxxxx	
								xxxxxxx	
		Cy 3	ddmmmyyyy	xxx				xxxxxxx	
			ddmmmyyyy					xxxxxxx	
xxxx	xx/x/x	Pretr.	ddmmmyyyy	xxx	Y	ST-T Wave		Other	xxxxxxxx
		Cy 1	ddmmmyyyy	…	N	…		…	…

Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.
(*) Specific Abnormality not present at pretreatment.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period.

Appendix 3.9.3 – Other Safety Assessments: Visual Acuity and Funduscopic Examination
- Treated Patients –

Page by Regimen

Pt. No.	Study Period	Cumulative Dose (mg)	Date of Visual acuity Assessment	Snellen Equivalent Right Eye	Snellen Equivalent Left Eye	Date of Funduscopic Examination	Right Eye	Left Eye
xxxx	Pretr.		ddmmmyyyy	20/xx	20/xx	ddmmmyyyy	Normal	Normal
	Cy 1	xxxx.x	ddmmmyyyy	20/xx	20/xx	ddmmmyyyy	Abnormal, clinically relevant	Abnormal, clinically relevant
	…	…	ddmmmyyyy	20/xx	20/xx	ddmmmyyyy	Abnormal, not clinically relevant	Abnormal, not clinically relevant
	Cy j	xxxx.x	ddmmmyyyy			ddmmmyyyy	Normal	Normal
	…	xxxx.x	ddmmmyyyy	20/xx	20/xx	ddmmmyyyy	Abnormal, not clinically relevant	Abnormal, not clinically relevant
xxxx	…	….	….	…	…	…	…	…

Cumulative dose (mg) : from treatment start up to end of relevant treatment cycle

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt. no., study period.

Appendix 3.9.4 – Other Safety Assessments: Chest X-Ray
- Treated Patients –

Page by Regimen

Pt. No	Age/Sex/Race	Date	Days to/from Tr. Start	Study Period	Results
xxxx	38/M/W	ddmmmyyyy	-1	Pretr.	Normal
		ddmmmyyyy	4	Cy 1	Normal
		ddmmmyyyy	20		Abnormal; not clinically relevant
xxxx	xx/x/x	…	…	Pretr.	Abnormal; clinically relevant
…	…	…		…	…

Only patients with chest x-ray performed are displayed
Race: W= White, B= Black, A= Asian, O= Not listed, N= Not allowed to ask per local regulation.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt. no., date, study period.

Appendix 3.9.5 – Other Safety Assessments: Pregnancy Test
- Treated Patients –

Page by Regimen

Pt. No	Age/Sex/Race	Study Period	Date	Method	Result	Reason for Not Performing
xxxx	38/F/W	Pretr.				Surgically sterile
xxxx	41/F/W	Pretr.	ddmmmyyyy	Serum	Negative	
xxxx	43/F/W	…	ddmmmyyyy	Urine	Negative	
xxxx	47/F/W		ddmmmyyyy	Urine	Positive *	
xxxx	57/F/W					Postmenopausal

All female patients are displayed.
Race: W= White, B= Black, A= Asian, O= Not listed, N= Not allowed to ask per local regulation.
Result: Positive results are marked by a *.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt. no., study period.
All female patients are to be displayed in the listing, including those for whom pregnancy test section is not present in the database.

Appendix 3.9.6 – Other Safety Assessments: Physical Examination
- Treated Patients -

Page by Regimen

Pt. No.	Age /Sex /Race	Study Period	Physical Examination (including neurological status evaluation) Performed?	Date of Physical Examination
xxxxxx	35/M/W	Cy 1	Y	ddmmmyyyy
		Cy 2	Y	ddmmmyyyy
		Cy i	Y	ddmmmyyyy
xxxxxx	50/M/W	Cy 1	Y	ddmmmyyyy
		Cy n	N	

Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt. no., study period.

Appendix 3 – Section 10 – Other Information

Appendix 3.10.1 - Other Information: Concomitant Medications
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Tr. Start Date	Tr. Last Date	Trade / Generic Name	Reason for Use	Start Date	Stop Date	Ongoing at Final Visit (Y/N)	Duration (days)	Weeks from Tr. Start
xxxx	35/M/W	ddmmmyyyy	ddmmmyyyy	xxxxxxxxxxx	xxxxxxxxxxx	ddmmmyyyy		Y		xxx.x
				xxxxxxxxxxx	xxxxxxxxxxx	ddmmmyyyy	ddmmmyyyy		xxx	xxx.x
				xxxxxxxxxxx	xxxxxxxxxxx	ddmmmyyyy		Y		xxx.x
xxxx	50/M/W	ddmmmyyyy	ddmmmyyyy	xxxxxxxxxxx	xxxxxxxxxxx	ddmmmyyyy	ddmmmyyyy		xxx	xxx.x

Only patients with at least one concomitant medication are displayed
Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.
Duration (days): from start date to stop date.
Weeks from Tr. Start: from treatment start date to start date of concomitant medication.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt. no., start date.
Select only patients with concomitant medication=’yes’ or derived ‘yes’

Appendix 3.10.2 – Other Information: Concomitant Radiotherapies
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Tr. Start Date	Tr. Last Date	Lesion Number	Lesion Description	% Bone Marrow Irradiated	Start Date	Stop Date	Duration (days)	Weeks from Tr. Start
xxxx	35/M/W	ddmmmyyyy	ddmmmyyyy	xxxx		xx.xx	ddmmmyyyy			xxx.x
				xxxx		……..	ddmmmyyyy	ddmmmyyyy	xxx	xxx.x
						……..	ddmmmyyyy			xxx.x
xxxx	xx/x/x	ddmmmyyyy	ddmmmyyyy			……..	ddmmmyyyy	ddmmmyyyy	xxx	xxx.x

Only patients with at least one concomitant radiotherapy are displayed.
Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Duration (days): from start date to stop date.
Weeks from Tr. Start: from treatment start date to start date of concomitant radiotherapy.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt no., start date.
Select only patients with concomitant radiotherapy = ‘yes’ or derived ‘yes’.

Appendix 3.10.3 – Other Information: Blood Derivatives
- Treated Patients -

Page by Regimen

Pt. No.	Age /Sex /Race	Date	Weeks from Tr. Start	Type	Description	No. of Units
xxx	35/M/W	ddmmmyyyy	xx.x	Whole Blood		xx
				Packed RBC		…
		…		Packed WBC		…
xxx	xx/x/x	ddmmmyyyy	xx.x	Platelets		…
		ddmmmyyyy	xx.x	Other	xxxxxxxxxxxxxxxxxxxxxx	…

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation..
Weeks from Tr. Start: from treatment start date to date of blood derivatives.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no, date.

Appendix 3.10.4 - Other Information: Other Anti-Tumor Therapies at Follow-up
- Treated Patients –

Page by Regimen

Pt. No.	Age/Sex/Race	Visit	Start Date	Days from Tr. Last Date	Description
xxxx	35/M/W	FU-1	ddmmmyyyy	xxx	xxxxxxxxxxxxxxx
			ddmmmyyyy	xxx	xxxxxxxxxxxxxxx
			ddmmmyyyy	xxx	xxxxxxxxxxxxxxx
xxxx	xx/x/x	FU-2	ddmmmyyyy	xxx	xxxxxxxxxxxxxxx

Only patients with at least one therapy are displayed.
Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation..
Days from Tr. Last: from treatment last date to start date of anti-tumor therapy.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., start date.
Select only patients with antitumor therapy ='yes' or derived 'yes'.

Appendix 3.10.5 - Other Information: Physician's Comments
- Treated Patients -

Page by Regimen

Pt. No.	Age/Sex/Race	Section	Visit	Page	Date	Comments
xxxx	35/M/W	xxxxx	xxxxxxx	xx	ddmmmmyyyy	xxx xxxxx xxxxxxx xxxxxxxxxxxxxxxxxxx xxxxx
		xxxxx	xxxxxxx	xx	ddmmmmyyyy	xxx xxxxx xxxxxxx xxxxxxxxxxxxxxxxxxx xxxxx
xxxx	xx/x/x	…	…	…	…	…
…		…	…	…	…	…
xxxx		…	…	…	…	…

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation..

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., section, visit, page, date.

ADDITIONAL DISPLAYS

Listing 3.3.1 – Patients Evaluability for Efficacy Analysis: Patients not Included in the Efficacy Analysis of Evaluable Patients
- Enrolled Patients -

Page by Regimen

Pt. No	First Dose Date	Total Administered Dose in Cy1+Cy2	Date of Last Tumor Assessment	Days from First Dose	Date of Death	Days from First Dose	Confirmation of Diagnosis (Y/N)	Reasons for Non-Evaluability
xxxx			ddmmmyyyy		ddmmmyyyy			Patient not treated
xxxx	ddmmmyyyy	xxx.x	ddmmmyyyy	-xx				Less than 80% of Intended Dose at Cy1+Cy2) / No tumor assessment at pretreatment
xxxx	ddmmmyyyy	xxx.x						No tumor assessment at pretreatment / No on treatment oncologic assessment nor death before (re)assessment
xxxx	ddmmmyyyy	xxx.x	ddmmmyyyy	xx	ddmmmyyyy	xx		No tumor assessment at pretreatment
xxxx	ddmmmyyyy	xxx.x	ddmmmyyyy	xx	ddmmmyyyy	xx	N	Diagnosis not confirmed

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by patients no.. Report all reasons for non-evaluability.

Listing 3.4.1 – Demography and Pretreatment: Tumor History - Summary of Prior Antitumor Treatment Procedure
- Treated Patients –

Page by Regimen

Pt. No.	Age/Sex /Race	Any Surgery ?	Any Radiotherapy ?	Any Systemic Therapy ?
xxxx	38/M/W	Y		Y
xxxx	xx/x/x	Y		
xxxx	xx/x/x		Y	
xxxx	xx/x/x			Y
xxxx	xx/x/x	Y		

Race: W= White, B= Black, A= Asian, O= Not Listed, N= Not Allowed to ask per local regulation.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming notes:
Sort by pt. no.

Listing 3.7.1 - Adverse Events: All Reported Adverse Events by AE MedDRA Preferred Term and Assessment Visit
- Treated Patients –

Page by Regimen

Pt. No.	Adverse Event	Study Period	Cycle Start Date	CTC Grade	Serious	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Proc.	Rel. to Study Treat.	Rel. to Study Disease	Action Taken	Outcome
xxxx	xxxxxxxxxx	Pretr.		2		ddmmmyyyy		ddmmmyyyy		N		N		R
		Cy 1	ddmmmyyyy	3		ddmmmyyyy					De	Y	D/C	NR
		…	….	4	Y		Y		Y		Pr	Y	D/C	R
		Cy x	ddmmmyyyy	…	Y	…	Y	ddmmmyyyy			…	...	PW	…
	xxxxxxxxxx	Cy 1	ddmmmyyyy	1		ddmmmyyyy		ddmmmyyyy			…	Y	No	NR
		…	…..	…		ddmmmyyyy			Y		Po	…	…	R
		Cy x	ddmmmyyyy	…	Y		Y	ddmmmyyyy			…	…	…	NR
xxxx	…	…	…	…		…	…	…	…		…	…	…	…

AP/SP: Already present/Still present.
Related to Study Treatment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.
Action Taken: No=None; D/C=Dose Delayed/Changed; PW=Drug Permanently Withdrawn.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by AE MedDRA Preferred Term, AE page no., AE seq no, pt. no., study period
Include also records of End of Adverse Events Reporting Period and of Follow-up.

Listing 3.7.2 – Adverse Events: AEs with Possible/Probable/Definite Relationship to Study Treatment
- Treated Patients -

Page by Regimen

Pt. No	Study Period	Cycle Start Date	Adverse Event	CTC Grade	Serious	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Treat.	Rel. to Study Disease	Action Taken	Outcome
xxxx	Cy 1	ddmmmyyyy	xxxxxxxxxx	1	N	ddmmmyyyy		ddmmmyyyy		Po	N	…	R
			xxxxxxxxxx	1	N		Y		Y	Pr	N	…	NR
			xxxxxxxxxx	2	…		Y	ddmmmyyyy		De	Y	…	R
	Cy 2	ddmmmyyyy	xxxxxxxxxx	x	…		Y		Y	Po	…	No	NR
			xxxxxxxxxx	…	…	ddmmmyyyy			Y	De	N	No	NR
			xxxxxxxxxx	3	Y	ddmmmyyyy		ddmmmyyyy		De	Y	D/C	R
…	…	…	…	…	…	…	…	…	…	…	…	…	…

AP/SP: Already present/Still present.
Related to Study Treatment: Po=Possible, Pr=Probable, De=Definite.
Action Taken: No=None; D/C=Dose Delayed/Changed; PW=Drug Permanently Withdrawn.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period, AE MedDRA Preferred Term, AE page no., AE seq. no.
Only AEs with possible/probable/definite relationship to study treatment are to be selected.

Listing 3.7.3 – Adverse Events: AEs Leading to Dose Delay or Change
- Treated Patients -

Page by Regimen

Pt. No	Study Period	Cycle Start Date	Adverse Event	CTC Grade	Serious	Start Date	A. P.	Stop Date	S. P.	Rel. to Study Treat.	Rel. to Study Disease	Outcome
xxxx	Cy 1	ddmmmyyyy	xxxxxxxxxx	1	N	ddmmmyyyy		ddmmmyyyy		Po	N	R
			xxxxxxxxxx	1	N		Y		Y	Pr	N	NR
			xxxxxxxxxx	2	…		Y	ddmmmyyyy		De	Y	R
	Cy 2	ddmmmyyyy	xxxxxxxxxx	x	…		Y		Y	Po	…	NR
			xxxxxxxxxx	…	…	ddmmmyyyy			Y	De	N	NR
			xxxxxxxxxx	3	Y	ddmmmyyyy		ddmmmyyyy		De	Y	R
	…	…	…	…	…	…	…	…	…	…	…	…

Only AE occurrences at the time when Action Taken was Dose Delay or Change are displayed.
AP/SP: Already present/Still present.
Related to Study Treatment: No=Unrelated, Un=Unlikely, Po=Possible, Pr=Probable, De=Definite.
Outcome: R=Recovered; RS=Recovered with sequelae; D=Death; Un=Unknown; NR=Not recovered.

[Protocol No. (Study Description)]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no., study period, AE MedDRA Preferred Term, AE page no., AE seq. no..
Selct only the occurrences of AEs when variable Action Taken= ‘Dose Delayed/Changed’.

Listing 3.8.1 - Laboratory Assessments: Hematology by Patient, Study Period and Laboratory Test
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Study Period	Cycle Start Date	Date of Sampling	Study Day	Lab. Test	Collected Value	Collected Unit	L/H	Converted Value	Converted Unit	CTC Grade
xxxx	52/F/W	Pretr.	ddmmmyyyy	ddmmmyyyy	-xx	Hemoglobin	xxx.xx	xxxx	L	xxx.xx	xxxx	x
						Platelet	…	…	…	…	…	3 *
						WBC	…	…	…	…	…	4 *
						…	…	…	…	…	…	...
		Cycle x	ddmmmyyyy	ddmmmyyyy	xx	Hemoglobin	…	…	…	…	…	2
…	…	…	…	…		Platelet	…	…	…	…	…	…
…	…	…	…	…	…	…	…	…	…	…	…	…

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Converted Unit: either the unit reported in the NCI CTCAE v3.0 or the Conventional Unit, depending on the analyzed lab test.
CTC Grade - NCI CTCAE v3.0: N= Not Applicable, U= Unknown. The '*' identifies the occurrence(s) of CTC grades= 3 or 4.
L/H: Below/Above Normal Limits.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no, study period, date of sampling, study day, lab test. If feasible lab test is to be ordered as per CRF appearance.
The listing must include all the hematological labs (including also the ones that are not listed in the NCI CTCAE v.3.0).
Each assessment (i.e. record) is to be displayed only if date is not missing or collected value is not missing.

Lisring 3.8.2 – Laboratory Assessments: Hematology by Laboratory Test, Patient and Study Periods with More than One Assessment
- Treated Patients -

Page by Regimen /Laboratory Test: < Neutrophils >

Pt. No.	Age /Sex /Race	Study Period	Cycle Start Date	Cycle Total Dose (mg)	Date of Sampling	Study Day	Collected Value	Collected Unit	L/H	Converted Value	Converted Unit	CTC Grade
xxxx	52/F/W	Pretr.			ddmmmyyyy	-xx	xxx.xx	xxxx	L	xxx.xx	xxxx	x
		Cy x	ddmmmyyyy	xxxx.xx	ddmmmyyyy	xx	…	…	…	…	…	3 *
						xx	…	…	…	…	…	4 *
		…	…		…	...	…	…	…	…	…	...
xxxx		Pretr.			ddmmmyyyy	xx	…	…	…	…	…	2
…		…	…		…		…	…	…	…	…	…

Only study periods with more than one assessment for the test are displayed
Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Converted Unit: either the unit reported in the NCI CTCAE v3.0 or the Conventional Unit, depending on the analyzed lab test.
CTC Grade - NCI CTCAE v3.0: N= Not Applicable, U= Unknown. The '*' identifies the occurrence(s) of CTC grades= 3 or 4.
L/H: Below/Above Normal Limits.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*, pt. no, study period, date of sampling, study day. If feasible lab test is to be ordered as per CRF appearance.
The listing must include all the hematological labs (including also the ones that are not listed in the NCI CTCAE v.3.0).
Each selected assessment (i.e. record) is to be displayed only if date is not missing or collected value is not missing.

Listing 3.8.3 – Laboratory Assessments: Hematology – Maximum CTC Grade by Laboratory Test, Patient and Time Window
- Treated Patients –

Page by Regimen

Laboratory Test	Pt. No.	Maximum CTC Grade at Pretr.	Cycle 1	Cycles >1	All Cycles
Neutrophils	xxxx	3	2	4 *	4 *
	xxxx	1	2 *	1	2 *
	xxxx	x	x	x	x
	xxxx	x	x	x	x
…	xxxx	x	x	x	x
…	…	…	…	…	

Only lab. test included in the NCI CTCAE v3.0 document are displayed.
Pretreatment Value: the most recent value among the pretreatment assessment(s).
CTC Grade - NCI CTCAE v3.0: U= Unknown. The '*' identifies CTC grades higher than Pretreatment grade.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by lab test, pt. no. If feasible lab test is to be ordered as per CRF appearance.
Select collected lab tests listed in NCI CTCAE v3.0.

Listing 3.8.4 - Laboratory Assessments: Blood Chemistry by Patient, Study Period and Laboratory Test
- Treated Patients –

Page by Regimen

Pt. No.	Age /Sex /Race	Study Period	Cycle Start Date	Date of Sampling	Study Day	Lab. Test	Collected Value	Collected Unit	Collected Lower Limi	Collected Upper Limit	L/H	Converted Value	Converted Unit	CTC Grade
xxxx	52/F/W	Pretr.	ddmmmyyyy	ddmmmyyyy	-xx	ALT	xxx.xx	xxxx	xxx.xx	xxx.xx	L	xxx.xx	xxxx	x
						AST	…	…			…	…	…	3 *
						Albumin	…	…			…	…	…	4 *
						…	…	…			…	…	…	...
	…	Cycle x	ddmmmyyyy	ddmmmyyyy	xx	ALT	…	…			…	…	…	2
…		…	…	…		AST	…	…			…	…	…	…
…	…	…	…	…	…	…	…	…			…	…	…	…

Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Converted Unit: either the unit reported in the NCI CTCAE v3.0 or the Conventional Unit, depending on the analyzed lab test.
CTC Grade - NCI CTCAE v3.0: N= Not Applicable, U= Unknown. The '*' identifies the occurrence(s) of CTC grades = 3 or 4.
L/H: Below/Above Normal Limits.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by pt. no, study period, date of sampling, study day, lab test. If feasible lab test is to be ordered as per CRF appearance.
The listing must include all the blood chemistry labs (including also the ones that are not listed in the NCI CTCAE v.3.0).
Each assessment (i.e. record) is to be displayed only if date is not missing or collected value is not missing.

Listing 3.8.5 – Laboratory Assessments: Blood Chemistry by Laboratory Test, Patient and Study Periods with More than One Assessment
- Treated Patients -

Page by Regimen /Laboratory Test: < ALT >

Pt. No.	Age /Sex /Race	Study Period	Cycle Start Date	Cycle Total Dose (mg)	Date of Sampling	Study Day	Collected Value	Collected Unit	Collected Lower Limit	Collected Upper Limit	L/H	Converted Value	Converted Unit	CTC Grade
xxxx	52/F/W	Pretr.			ddmmmyyyy	- xx	xxx.xx	xxx.xx	xxx.xx	xxx	L	xxx.xx	xxxx	N
					…….		xxx.xx	xxx.xx	xxx.xx	xxx		…	…	N
		Cy x	ddmmmyyyy	xxxx.xx	ddmmmyyyy	xx	xxx.xx	xxx.xx	xxx.xx	xxx	H	…	…	3*
							…	…	…	…		…	…	
							…	…	…	…	…	…	…	
					ddmmmyyyy	xx	…	…	…	…	L			4*
							…	…	…	…	…			
…		…	…		…	…	…	…	…	…	…			

Only study periods with more than one assessment for the test are displayed
Race: W=White, B=Black, A=Asian, O=Not listed, N=Not allowed to ask per local regulation.
Converted Unit: either the unit reported in the NCI CTCAE v3.0 or the Conventional Unit, depending on the analyzed lab test.
CTC Grade - NCI CTCAE v3.0: N= Not Applicable, U= Unknown. The '*' identifies the occurrence(s) of CTC grades= 3 or 4.
L/H: Below/Above Normal Limits.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by *"page by variables"*, pt. no, study period, date of sampling, study day.
If feasible lab test is to be ordered as per CRF appearance.
The listing must include all the biochemistry labs (including also the ones that are not listed in the NCI CTCAE v.3.0).
Each selected assessment (i.e. record) is to be displayed only if date is not missing or collected value is not missing.

Listing 3.8.6 – Laboratory Assessments: Blood Chemistry - Maximum CTC Grade by Laboratory Test, Patient and Time Window (Part I)
- Treated Patients -

Page by Regimen

Laboratory Test	Pt. No.	Maximum CTC Grade at			
		Pretr.	Cycle 1	Cycles >1	All Cycles
ALT	xxxx	3	2	4 *	4 *
	xxxx	1	2 *	1	2 *
	xxxx	x	x	x	x
	xxxx	x	x	x	x
…	xxxx	x	x	x	x
Albumin	xxxx	0	1*	2*	2*

Only lab. tests included in the NCI CTCAE v3.0 document and whose abnormality is determined by one-way modifications only, are displayed.
Pretreatment Value: the most recent value among the pretreatment assessment(s).
CTC Grade - NCI CTCAE v3.0: U= Unknown. The '*' identifies CTC grades higher than Pretreatment grade.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by lab test, pt. no. If feasible lab test is to be ordered as per CRF appearance.
Select collected lab tests listed in NCI CTCAE v3.0.

Listing 3.8.7 – Laboratory Assessments: Blood Chemistry - Maximum CTC Grade by Laboratory Test, Patient and Time Window (Part II)
- Treated Patients -

Page by Regimen

Laboratory Test	Pt. No.	Maximum CTC Grade at											
		Pretreatment			Cycle 1			Cycles >1			All Cycles		
		L	N	H	L	N	H	L	N	H	L	N	H
Calcium	xxxx		0		2			2		1	2		1
	xxxx		0			0				3			3
	xxxx		0			0			0			0	
	xxxx	1			2			3			3		
…	xxxx												
Sodium	xxxx												

Only lab. tests included in the NCI CTCAE v3.0 document and whose abnormality is determined by two-way modifications (L = value lower than normal range, H = value higher than normal range, N= value within normal range), are displayed.
Pretreatment Value: the most recent value among the pretreatment assessment(s).
CTC Grade - NCI CTCAE v3.0: U= Unknown.

[Protocol No.; Study Description]
[Program Path; Date/Time Produced; Date Data Extract]

Programming Notes:
Sort by lab test, pt. no. If feasible lab test is to be ordered as per CRF appearance.
Select collected lab tests listed in NCI CTCAE v3.0 for which both ‘hyper’ and ‘hypo’ grading is provided. For this study: Magnesium, Potassium, Sodium.

REVISION HISTORY

Version	Date	Reviewed by: *(Printed name)*	Reason for change
1.0	**8th July 2013**		**Initial version**

Reviewed and Approved by:

Role	Printed Name	Signature	Date
Statistician	**Anna Petroccione**		
CL	**Marcella Martignoni**		