Statistical Analysis Plan Checklist

Double-Blind Randomized Phase II Trial of Carboplatin and Pemetrexed with or without OGX-427 in Patients with Previously Untreated Stage IV Non-Squamous-Non-Small-Cell Lung Cancer

(The Spruce Clinical Trial)

Sponsor:	**Sarah Cannon Research Institute (SCRI) Development Innovations**
Study Drug:	**OGX-427**
SCRI Protocol Number:	**LUN 229**
Prepared By:	**SCRI Development Innovations (Innovations)**

Statistical Analysis Plan Checklist for Investigator Initiated Trials

History of Changes

This document has undergone the following changes:

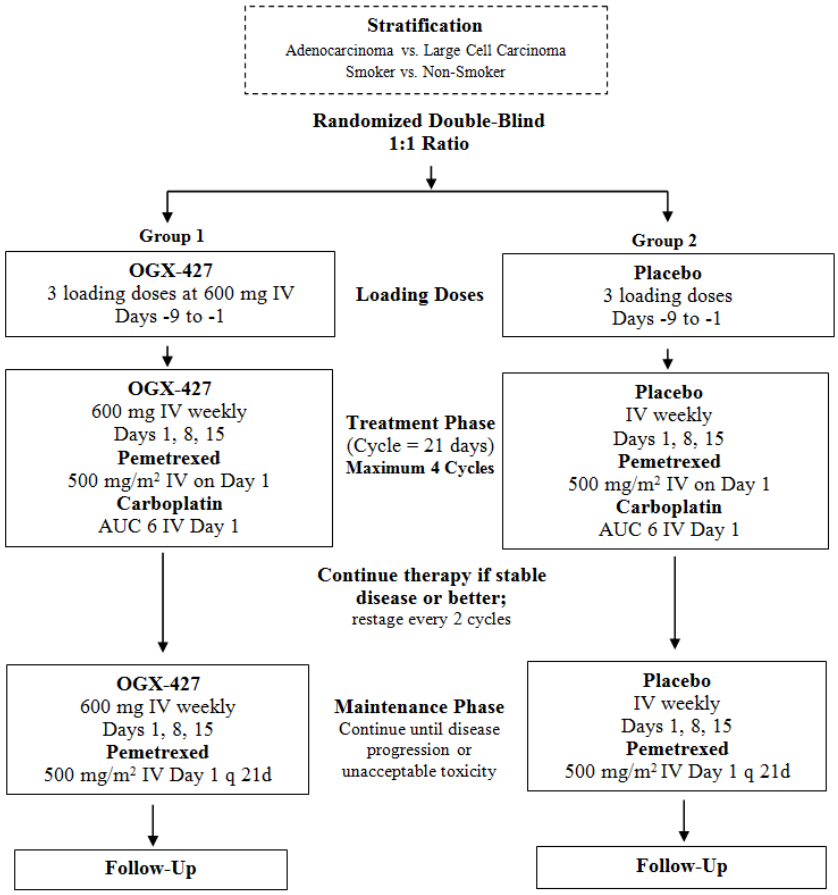
Version Number	Version Date	Description of Changes
Draft 1.0	15JUL2014	Original document [Prepared by Bryan Lange]
Draft 2.0	14AUG2014	Updated based on Dr. Kajdasz's comments [Prepared by Bryan Lange]
Draft 2.1	06FEB2015	Edited and updated by Shuangli Guo
Draft 3.0	21MAY2015	Added clinical benefit rate (CBR) Stratified PFS, OS, ORR and CBR with baseline ECOG performance Added an exploratory objective
Final 1.0	21MAY2015	

1 Introduction	
1.1 Objectives	
Primary Objective:	• To compare the progression-free survival (PFS) of OGX-427 plus carboplatin/pemetrexed therapy versus placebo plus carboplatin/pemetrexed in previously untreated patients with advanced non-squamous NSCLC.
Secondary Objectives:	• To compare the objective response rate (ORR) in each treatment arm. • Objective response rate in a poor performance subgroup (prospectively defined in patients with a baseline ECOG 0 vs.1) • To compare overall survival (OS) in each treatment arm. • Overall survival in a poor performance subgroup (prospectively defined in patients with a baseline ECOG 0 vs.1) • Progression-free survival in a poor performance subgroup (prospectively defined in patients with a baseline ECOG 0 vs.1) • To evaluate safety.
Exploratory Objectives:	• Correlative analyses of serum levels of Hsp27. • Correlative analysis of treatment outcomes with specific biomarkers. • Based on the observations from primary analysis, post *ad hoc* prognostic statistical modeling will be performed, with survival as a function of multiple baseline covariates using proportional hazards regression. Selection of prognostic terms will be based on hierarchical step-down. Note: Interactions were appropriate may be used for inclusion in the model and models with continuous variables dichotomized at median will also be evaluated. Coefficients of the Control Arm model will be used (or carried forward) to compute a "statistical model" score for all patients in the study (both arms). Primary evaluation of the statistical model score will be based on dichotomization at overall median score for all study patients resulting in classifying patients as "poor" versus "good" prognosis.
1.2 Study Design	
Study Type	☐ Non-Randomized ☒ Randomized (Allocation Ratio: 1:1)
Details	This is a randomized, double-blind, placebo-controlled, Phase II trial comparing pemetrexed and carboplatin plus OGX-427 followed by maintenance pemetrexed and OGX-427 versus pemetrexed and carboplatin plus placebo followed by maintenance pemetrexed and placebo in patients with previously untreated advanced non-squamous NSCLC. The patients, investigator, study team members, (except for the mixing pharmacist/nurse), and anyone involved with the conduct of the trial from the time of randomization until database lock for the primary endpoint analysis will be blinded to the identity of the treatment assignment (OGX-427 or placebo). The primary endpoint of the trial is PFS. A total of 155 patients will be randomized in a 1:1 ratio. Randomization will be stratified by histology (adenocarcinoma vs. large cell carcinoma) and smoking status (smoker vs. non-smoker) for the purpose of balance of enrollment and exploratory analysis. **Progression-Free Survival Follow-Up** Patients who discontinue trial treatment prior to the occurrence of disease progression will be followed every 6 weeks from the date of last dose of study drug until disease progression or

for up to 2 years whichever comes first. Assessments at these visits will be performed as described in Protocol **Error! Reference source not found.**. Any subsequent cancer therapy ill be documented.

Survival Follow-Up

After disease progression is documented, patients will be followed every 2 months for survival (e.g., date and cause of death) for up to 2 years or death, whichever comes first. Any subsequent cancer therapy will be documented.



1.3 Randomization	
Randomization Type:	☐ Open-Label ☐ Single Blind ☒ Double-Blind
1.4 Timing of Analysis	
Planned Interim Analysis	☐ Cohort Review / Dose Escalation ☒ Safety Review – Planned after the first 12 patients (6 per arm) have completed 1 cycle of treatment and a second review at 24 patients (12 per arm). DLT's will be assessed in cycle 1 for the first 6 patients and if 2 or more DLT's occur then the dose will be reduced. ☐ Interim Efficacy/Safety Analysis

	☒ Independent DSM ☒ Annual Report ☒ Abstract / Scientific Presentation (Oral/Poster)
Final Analysis	The final analysis will be conducted when 117 progression-free survival events are observed out of approximately 155 randomized patients.
1.5 Responsibilities	
Trial Statistician: Shuangli Guo	Prepare SAP (or SAP check list) and TFL shells Review deliverables produced by Statistical Programmer or other Biostatistician Prepare TFLs for abstract submission and meeting presentation Clinical review The final statistical analysis
PK Statistician:	Not applicable
Independent Statistician: David Bass	Prepare randomization scheme Un-blinded safety delivery review and interim un-blinded analysis Validate statistical analysis methods and TFLs output
1.6 Analysis Software	
Main statistical analysis:	SAS Version 9.3 or above
Other analysis software:	None
1.7 Coding	
☒ Adverse Events ☐ Medical History	☒ MedDRA: ☐ Version 17.0 ☒ Most current release and update coding with new major releases ☒ NCI-CTCAE Version 4.03
☒ Concomitant Medication ☐ Prior Therapy ☐ Subsequent/Further Therapy	☒ WHO-Drug: ☐ Version September 2014 ☒ Most current release and update coding with new major releases
3 Analysis Population	
Intent-To-Treat (ITT) Population definition: Full	☐ All patients who have started treatment in the study ☒ All patients who have been randomized in the study, regardless of whether they have

Analysis set	received any treatment or not ☐ All patients who have been randomized and have started treatment in the study ☐ Other definition, specify:
Per Protocol (PP) Population to be used in analysis:	☐ Yes ☒ No If yes, please specify the criteria for exclusion from the PP population:
Safety (SAF) Population definition	☒ All patients who have started treatment in the study. Patients will be analysed according to the actual treatment they have received. ☐ Other definition, specify:
Other Analysis Population definition: ECOG Performance Analysis set	A subset of the Full Analysis Set including only patients with a baseline ECOG ≤1
4 Baseline Value Definitions	
	The study-wise baseline value is defined as the most recent value prior to first study drug administration, and the cycle-wise baseline value is the most recent value prior to a given cycle's initial study drug administration. The clinical database has been designed such that both study-wise and cycle-wise baseline values are clearly identifiable and do not require derivation.
5 Efficacy	
Response Criteria Used:	☐ RECIST 1.0 ☒ RECIST 1.1 ☐ Cheson 2007 ☐ Modified RECIST – specify: ☐ Other criteria, Specify:
Efficacy Assessment Timepoints:	Progression-free survival (PFS) and Objective response rate (ORR): Response to treatment will be evaluated every 6 weeks. Overall survival (OS): Survival will be followed from date of randomization to the date of death due to any cause, or the date the patient was known to be alive at the date of cutoff for the analysis. Schedule of assessments are tabulated in protocol Appendix D and descripted in section 7.

<table>
<tr><td>Efficacy Endpoints:</td><td>
<table>
<tr><th></th><th>Endpoint</th><th>Primary Analysis Population</th></tr>
<tr><td>Primary</td><td>Progression-free survival (PFS): death or disease progression via RECIST v1.1</td><td>Full analysis set</td></tr>
<tr><td>Secondary</td><td>Overall Survival (OS): death
Objective Response Rate (ORR), Clinical Benefit Rate (CBR)
Poor performance with OS, ORR, CBR, and PFS: The proportion of patients with a baseline ECOG 0 vs. 1</td><td>Full analysis set
Full analysis set
ECOG Analysis Set (a subset of FAS)</td></tr>
</table>
</td></tr>
<tr><td>Definition of Terms:</td><td></td></tr>
<tr><td>☒ Response</td><td>☒ Complete Response + Partial Response as best observed response
☐ Complete Response + Partial Response, confirmed with weeks apart.
☐ Other criteria, specify:</td></tr>
<tr><td>☒ Clinical Benefit</td><td>☒ Complete Response + Partial Response + Stable Disease ≥ 6 months
☐ Complete Response + Partial Response (confirmed with weeks apart) + Stable Disease (at least weeks from start of treatment)
☐ Other criteria, specify:</td></tr>
<tr><td>☒ Progression</td><td>Target Lesion Progressive Disease
At least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest (nadir) sum while on study (this includes the baseline sum if that is the smallest on study), or the appearance of one or more new lesions. Requires not only 20% increase, but absolute increase of a minimum of 5 mm over sum.
Non-Target Lesion Progressive Disease
Appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions. When the patient also has measurable disease, to achieve “unequivocal progression” on the basis of the non-target disease, there must be an overall level of substantial worsening in non-target disease such that, even in presence of SD or PR in the target disease, the overall tumour burden has increased sufficiently to merit discontinuation of therapy.
Clinical Progression
Documented symptomatic deterioration that is defined as global or severe deterioration of health status such that it requires discontinuation of trial treatment without evidence of RECIST disease progression at that time.</td></tr>
<tr><td>☒ Subsequent Therapy</td><td>Subsequent therapy (subsequent treatment) is defined as therapy that is administered after the last dose of OGX-427/Placebo. This will be collected during follow-up.</td></tr>
<tr><td>☐ Treatment</td><td>Not applicable</td></tr>
</table>

Failure	
Definition of Endpoints:	Start Date: ☒ Date of Randomization ☐ Date of First Treatment End Date (*specify for all pertinent endpoints*): **Progression-Free Survival: Event = Progression or Death**

Situation	Date of Event or Censoring	Outcome
No baseline assessment	Date of randomization	Censored
Progression documented between scheduled visits	First date of evaluated overall response = PD	Event
No progression	Date of last evaluable tumor assessment	Censored
Treatment discontinuation for adverse event or other reason	Date of last evaluable tumor assessment	Censored
Further anti-cancer therapy started	Start date of latest anti-cancer therapy	Censored
Death before first PD assessment	Date of death	Event
Death before the next scheduled tumour assessment	Date of death	Event
Death after one missed tumour assessment but before second missed tumour assessment	Date of death	Event
Death after two or more missed tumour assessment	Date of last evaluable tumour assessment	Censored
Patient experiencing symptomatic deterioration before RECIST PD	Date of clinical disease progression	Event

Overall Survival: Event = Death

Situation	Date of Event or Censoring	Outcome
Death	Date of death	Event
Alive on date of data cut-off	Date of data cut-off	Censored
Alive before date of data cut-off, but status unknown on date of data cut-off (e.g. lost to follow-up)	Date of last contact	Censored
Withdrawal Informed Consent	Date of informed consent withdrawn	Censored

☒ Objective Response Rate (ORR)	Default: Estimates of rates in each treatment arm and associated two-sided exact 95% confidence intervals using the method of Clopper and Pearson. ☒ Difference in ORR & 95% confidence interval between treatment arms ☒ Proportions of complete response (CR), partial response (PR), stable disease (SD), progressive disease (PD) and not evaluable (NE) will be calculated. ☒ p-value, specify statistical test: Fisher's exact test
☐ Disease Control Rate (DCR)	
☐ Clinical Benefit Rate (CBR)	

☐ Time To Progression (TTP) ☒ Progression-Free Survival (PFS) ☒ Overall Survival (OS) ☐ Duration of Response ☐ Duration of Stable Disease ☐ Time To Treatment Failure (TTF)	☒ Kaplan Meier estimates of medians with two-sided 95% confidence interval in each treatment arm, and probability of being alive and/or progression-free at 6 months and one year. ☐ Other quartiles or percentages of survival required, specify: ☒ Hazard ratio and two-sided 95% confidence interval between treatment arms, un-stratified (PFS and OS) ☒ p-value, specify statistical test: the un-stratified log-rank test ☐ Hazard ratio & 95% confidence interval between treatment arms, stratified (specify stratification factor(s)): ☐ p-value, specify statistical test:
☐ Other, Specify:	
6 Safety	
Adverse Events	Definition of Adverse Event: any adverse event (AE) that starts or worsens after the start of the first dose of study treatment up to 30 days post last dose.
Laboratory Data	Data will be summarized by: ☒ NCI-CTCAE for CTCAE-gradable parameters, and H/L for non-CTCAE-Gradable parameter ☐ H/L for all lab parameters

Tier 1 Study – Tables, Figures & Listings

Standard TFLs			
Table No	**Description**	**Variables/Analyses To Be Included**	**Population**
Table 1	Patient disposition	☐ Number of patients consented ☒ Number of patients randomized ☒ Number of patients treated ☒ Reason for treatment discontinuation ☐ Reason for end of study	All randomized patients
Table 2	Demographic characteristics	☒ Age: Mean, SD, Median, Min, Max ☒ Age group: Senior (>=65) Adult (<65) ☒ Sex ☒ Race ☒ Ethnicity ☒ ECOG ☒ Tobacco use	Full analysis set
Table 3	Disease history	☒ Histology ☒ Disease staging at study entry ☒ Time from initial pathological diagnosis to randomization ☒ Time from most recent recurrence or progression to randomization ☒ EGFR Mutation Status ☒ ALK Translocation ☐ Sites of Metastatic Disease	Full analysis set
Table 4	Prior therapies – Systemic, Radiation, and Surgery	Specify prior therapies groups to be summarized: prior systemic therapy, prior radiation therapy, and prior surgery	Full analysis set
Table 5	Lab parameters at baseline	Specify lab parameters: Haematology: Haemoglobin, Haematocrit, Platelets, White Blood Cells, Neutrophils, Lymphocytes, and Monocytes Chemistry: Albumin, Calcium, Carbon Dioxide, Chloride, Creatinine, Glucose, Potassium, Sodium, Total Protein, and Blood Urea Nitrogen Liver function tests: SGPT/ALT, SGOT/AST, Alkaline Phosphatase, and Total Bilirubin	Safety analysis set
Table 6	Time on treatment and exposure	Initial planned dose, Cumulative actual dose, Actual dose intensity, Planned dose intensity, Relative dose intensity (%) , Duration, Number of cycles treatment and maintenance, Dose modifications	Safety analysis set
Table 7	Progression-free survival	Number of events, Number of censor, Kaplan-Meier estimates of Median PFS [months (95% CI)]	Full analysis set [Safety analysis set will be used if >10% of

Standard TFLs			
Table No	**Description**	**Variables/Analyses To Be Included**	**Population**
		Probability of events at: 6 months and 12 months Hazard ratio and 95% CI between treatment groups using Cox proportional hazards model P-value between arms using log-rank test	randomized patients do not receive study treatment)] ECOG analysis set
Table 8	Overall survival	Number of deaths, Number of censor, Kaplan-Meier curves with Median OS [months (95% CI)] Probability of events at: 6 months and 12 months Hazard ratio and 95% CI between treatment groups using Cox proportional hazards model P-value between arms using log-rank test	Full analysis set [Safety analysis set will be used if >10% of randomized patients do not receive study treatment)] ECOG analysis set
Table 9	Response rates	Best overall response: Complete response (CR), Partial response (PR), Stable disease (SD), RECIST progressive disease (rPD), Clinical progressive disease (cPD), Not evaluable (NE), Unknown Objective response rate (ORR) (CR + PR): ORR, 95% Confidence interval Clinical Benefit Rate (CBR) (CR + PR+SD≥6months): CBR, 95% Confidence interval	Full analysis set [Safety analysis set will be used if >10% of randomized patients do not receive study treatment)] ECOG analysis set
Table 10	AE overview	Number of patient with at least: adverse events, related adverse events, serious adverse events (SAEs), related SAEs, SAE leading to death, related SAE leading to death, AE leading to treatment discontinued, AE leading to treatment interrupted, AE leading to treatment held, AE leading to treatment reduced	Safety analysis set
Table 11	Summary of adverse events	System organ class, Preferred term	Safety analysis set
Table 12	Summary of adverse events by grade	System organ class, Preferred term, CTCAE grade	Safety analysis set
Table 13	Summary of related adverse events	System organ class, Preferred term	Safety analysis set

Standard TFLs			
Table No	**Description**	**Variables/Analyses To Be Included**	**Population**
Table 14	Summary of related adverse events by grade	System organ class, Preferred term, CTCAE grade	Safety analysis set
Table 15	Summary of adverse events leading to treatment discontinuation	Preferred term	Safety analysis set
Table 16	Summary of adverse events leading to dose reduction	Preferred term	Safety analysis set
Table 17	Summary of deaths	Reasons of deaths	Safety analysis set
Table 18	Summary of lab parameters (worst grade post-baseline)	CTCAE grade at baseline and maximum shift post-baseline: Haematology: Haemoglobin, Haematocrit, Platelets, White blood cells, Neutrophils, Lymphocytes, and Monocytes Chemistry: Albumin, Calcium, Carbon dioxide, Chloride, Creatinine, Glucose, Potassium, Sodium, Total protein, and Blood urea nitrogen Liver function tests: SGPT/ALT, SGOT/AST, Alkaline phosphatase, and Total bilirubin	Safety analysis set
Table 19	Summary of follow-up duration	Time (months) for randomization to death, lost to follow-up, or completion of 2 year survival follow-up, whichever comes first.	Full analysis set
Table 20	Summary of serum Hsp27 change from baseline over time	serum Hsp27 level at baseline and protocol timepoint, percentage change of serum Hsp27 level from baseline	FAS, with serum Hsp27 measurement

Figure No	Description	Variables/Analyses To Be Included	Population
Figure 1	Progression-Free Survival	Timescale to be used on horizontal axis: ☐ Day ☐ Week ☒ Month ☐ Year	Full analysis set ECOG analysis set
Figure 2	Overall Survival	Timescale to be used on horizontal axis: ☐ Day ☐ Week ☒ Month ☐ Year	Full analysis set ECOG analysis set

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TFL No.	TLF Title	Analysis Set
Table 1	Patient Disposition	All enrolled patients
Table 2	Demographic Characteristics	Full analysis set
Table 3	Disease History	Full analysis set
Table 4	Prior Therapy	Full analysis set
Table 5.1	Laboratory Parameters at Baseline - Hematology	Full analysis set
Table 5.2	Laboratory Parameters at Baseline - Blood Chemistry	Full analysis set
Table 5.3	Laboratory Parameters at Baseline - Liver Function Test	Full analysis set
Table 6.1	Dose Exposure - Carboplatin	Full analysis set
Table 6.2	Dose Exposure - Pemetrexed	Full analysis set
Table 6.3	Dose Exposure- OGX-427 or Placebo	Full analysis set
Table 6.4	Treatment Modifications - Carboplatin	Full analysis set
Table 6.5	Treatment Modifications - Pemetrexed	Full analysis set
Table 6.6	Treatment Modifications - OGX-427 or Placebo	Full analysis set
Table 7.1	Progression-free Survival	Full analysis set
Table 7.2	Progression-free Survival - Statified by Baseline ECOG Performance	ECOG analysis set
Table 8.1	Overall Survival	Full analysis set
Table 8.2	Overall Survival - Stratified by Baseline ECOG Performance	ECOG analysis set
Table 9.1	Best Overall Response, Objective Response Rate, and Clinical Benefit Rate	Full analysis set
Table 9.2	Best Overall Response, Objective Response Rate, and Clinical Benefit Rate - Stratified by Baseline ECOG Performance	ECOG analysis set
Table 10	Adverse Events Overview	Safety analysis set
Table 11	Adverse Events by System Organ Class and Preferred Term	Safety analysis set
Table 12	Adverse Events by System Organ Class, Preferred Term and Maximum Reported CTCAE Grade	Safety analysis set
Table 13	Treatment-related Adverse Events by System Organ Class and Preferred Term	Safety analysis set
Table 14	Treatment-related Adverse Events by System Organ Class, Preferred Term and Maximum Reported CTCAE Grade	Safety analysis set
Table 15.1	Adverse Events Leading to Carboplatin Discontinuation by Preferred Term	Safety analysis set
Table 15.2	Adverse Events Leading to Pemetrexed Discontinuation by Preferred Term	Safety analysis set

Table 15.3	Adverse Events Leading to OGX-427 Discontinuation by Preferred Term	Safety analysis set
Table 16.1	Adverse Events Leading to Carboplatin Dose Reduction by Preferred Term	Safety analysis set
Table 16.2	Adverse Events Leading to Pemetrexed Dose Reduction by Preferred Term	Safety analysis set
Table 16.3	Adverse Events Leading to OGX-427 Dose Reduction by Preferred Term	Safety analysis set
Table 17	Patient Deaths	All consented patients
Table 18.1	Hematology CTCAE Grade Change from Baseline to Maximum on Treatment	Safety analysis set
Table 18.2	Clinical chemistry CTCAE Grade Change from Baseline to Maximum on Treatment	Safety analysis set
Table 18.3	Elevated AST, ALT, Total Bilirubin, and Alkaline Phosphate	Safety Analysis Set
Table 19	Follow up Duration	Full analysis set
Table 20	Serum Hsp27, Change from Baseline over Time	FAS with serum Hsp27 measurement
Figure 1.1	Progression-free survival, Kaplan-Meier plot, Stratified by Arm	Full analysis Set
Figure 1.2	Progression-free survival, Kaplan-Meier plot, Stratified by Arm and Baseline ECOG Performance	ECOG analysis Set
Figure 2.1	Overall survival, Kaplan-Meier plot, Stratified by Arm	Full analysis Set
Figure 2.2	Overall survival, Kaplan-Meier plot, Stratified by Arm and Baseline ECOG Performance	ECOG analysis Set

Table 1
Patient Disposition
All enrolleded patients

Disposition	Statistic	Carboplatin Pemetrexed OGX-427	Carboplatin Pemetrexed Placebo	Total
Number of patients enrolled	n			xxx
Number of patients randomised	n	xx	xx	xxx
Number of patients un-treated	n	xx	xx	xxx
Number of patients treated	n	xx	xx	xxx
Number of patients with treatment discontinuation	n	xx	xx	xxx
Disease Progression		xx	xx	xxx
RECIST	n	xx	xx	xxx
Clinical Progression	n	xx	xx	xxx
Adverse Event	n	xx	xx	xxx
Unable to complete at least 3 cycles of at least one chemotherapy agent	n	xx	xx	xxx
Patient requests to discontinue treatment	n	xx	xx	xxx
Patient requests to withdraw consent for the study	n	xx	xx	xxx
Non-compliance	n	xx	xx	xxx
Lost to follow-up	n	xx	xx	xxx
Death on study	n	xx	xx	xxx
Death due to disease progression	n	xx	xx	xxx
Death due to protocol therapy	n	xx	xx	xxx
Death due to AE	n	xx	xx	xxx

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Table 1
Patient Disposition
All consented patients

Disposition	Statistic	Carboplatin Pemetrexed OGX-427	Carboplatin Pemetrexed Placebo	Total
Death, cause unknown	n	xx	xx	xxx
Other	n	xx	xx	xxx
Other	n	xx	xx	xxx

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Table 2
Demographic Characteristics
Full analysis set

Demographic characteristic	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Age (years)				
n	n	xx	xx	xx
Mean	Mean	xx.x	xx.x	xx.x
Standard deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx	xx	xx
Min	Min	xx	xx	xx
Max	Max	xx	xx	xx
Age group (years)				
Adult (<65)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Senior (>=65)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Sex				
Male	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Female	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Race				
White	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Black or African American	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

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Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
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Table 2
Demographic Characteristics
Full analysis set

Demographic characteristic	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Asian	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Race>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Ethnic group				
Hispanic or Latino	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Non-hispanic or Latino	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Unknown	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
ECOG				
0	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Tobacco use				
Smoker	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Non-Smoker	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Unknown	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM

Table 3
Disease History
Full analysis set

Patient characteristics	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Histology				
Adenocarcinoma	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Large Cell Carcinoma	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Unknown	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Stage at study entry				
Stage IV at Initial Diagnosis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Recurrent Stage IV Disease	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Unknown	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
EGFR mutation status				
Positive	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Negative	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Unknown	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
ALK Translocation				
Yes	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
No	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Time from initial diagnosis to randomization (Months) [a]				
N	n	xx	xx	xxx

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[a] Month =(PHFPBDAT-PTRNDT+1)/30.4375.
[b] Month =(PRGDAT-PTRNDT+1)/30.4375.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM

Table 3
Disease History
Full analysis set

Patient characteristics	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Mean	Mean	xx.x	xx.x	xx.x
Standard deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Min	Min	xx.x	xx.x	xx.x
Max	Max	xx.x	xx.x	xx.x
Time from most recent recurrence or progression to randomization (Months) [b]				
N	n	xx	xx	xxx
Mean	Mean	xx.x	xx.x	xx.x
Standard deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Min	Min	xx.x	xx.x	xx.x
Max	Max	xx.x	xx.x	xx.x

[a] Month =(PHFPBDAT-PTRNDT+1)/30.4375.
[b] Month =(PRGDAT-PTRNDT+1)/30.4375.

Program Name: XXXX
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Table 4
Prior Therapy
Full analysis set

	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Prior systemic therapy				
Missing	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Yes	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
No	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of prior systemic regimens				
0	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
>= 3	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Best overall response of prior systemic regimens [a]				
Complete Response	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Partial Response	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Progressive Disease	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Stable Disease	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Not Evaluable	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Not Applicable	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Disease setting [a]				
Neoadjuvant	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

(Continued)

[a] Patients with multiple categories or multiple times in a category will be tabulated one time in each category.
Note: N/A = not applicable

Program Name: XXXX
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Table 4
Prior Therapy
Full analysis set

	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Adjuvant	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
N/A	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Prior surgery				
Missing	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Yes	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
No	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Prior radiotherapy				
Missing	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Yes	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
No	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Patients with multiple categories or multiple times in a category will be tabulated one time in each category.
Note: N/A = not applicable

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM

Table 5.1
Laboratory Parameters at Baseline - Hematology
Full analysis set

Hematology parameter	Arm	Treated,n	Randomized,n	CTCAE grade[a], n(%)				
				G0	G1	G2	G3	G4
Hemoglobin	OGX-427	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	Placebo	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Platelets	OGX-427	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	Placebo	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

<<parameter>>

[a] CTCAE = Common Terminology Criteria for Adverse Events (version 4.03).
Note: The number of randomized patients is the denominator for % calculation in each arm.

Program Name: XXXX
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Table 5.2
Laboratory Parameters at Baseline - Blood Chemistry
Full analysis set

Blood chemistry parameter	Arm	Treated,n	Randomized,n	CTCAE grade[a], n(%)				
				G0	G1	G2	G3	G4
Albumin	OGX-427	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	Placebo	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Glucose	OGX-427	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	Placebo	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

<<parameter>>

[a] CTCAE = Common Terminology Criteria for Adverse Events (version 4.03).
Note: The number of randomized patients is the denominator for % calculation in each arm.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
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Table 5.3
Laboratory Parameters at Baseline - Liver Function Test
Full analysis set

Liver function parameter	Arm	Treated,n	Randomized,n	CTCAE grade[a], n(%)				
				G0	G1	G2	G3	G4
SGPT/ALT	OGX-427	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	Placebo	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
SGOT/AST	OGX-427	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	Placebo	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Alkaline Phosphatase	OGX-427	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	Placebo	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Total bulirubin	OGX-427	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	Placebo	xx	xx	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] CTCAE = Common Terminology Criteria for Adverse Events (version 4.03).
Note: The number of randomized patients is the denominator for % calculation in each arm.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
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Table 6.1
Dose Exposure - Carboplatin
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Total number of treatment cycles started				
0	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
3	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
4	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Cumulative actual dose (AUC)[a]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x
Duration (cycle)[b]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x

(Continued)

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/21.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by 6 multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.1
Dose Exposure - Carboplatin
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x
Actual dose intensity (AUC/cycle)[c]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x
Relative Dose Intensity (%)[d]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x

(Continued)

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/21.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by 6 multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.1
Dose Exposure - Carboplatin
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Maximum	Max	xx.x	xx.x	xx.x

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/21.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by 6 multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.2
Dose Exposure - Pemetrexed
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Total number of treatment phase cycles started				
0	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
3	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
4	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Total number of maintenance phase cycles started				
0	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Number>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Cumulative actual dose (mg/m2)[a]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x

(Continued)

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/21.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by 500 multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.2
Dose Exposure - Pemetrexed
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x
Duration (cycles)[b]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x
Actual dose intensity (mg/m2/cycle)[c]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x

(Continued)

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/21.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by 500 multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.2
Dose Exposure - Pemetrexed
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Relative Dose Intensity (%)[d]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/21.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by 500 multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.3
Dose Exposure- OGX-427 or Placebo
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Number of loading dose				
0	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
3	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of treatment phase cycles started				
0	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
3	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
4	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of maintenance phase cycles started				
0	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Number>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

(Continued)

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/7.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by the planned dose intensity multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.3
Dose Exposure- OGX-427 or Placebo
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Cumulative actual dose (mg)[a]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x
Duration (weeks)[b]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x
Actual dose intensity (mg/week)[c]				
n	n	x	x	x

(Continued)

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/7.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by the planned dose intensity multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.3
Dose Exposure- OGX-427 or Placebo
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x
Relative Dose Intensity (%)[d]				
n	n	x	x	x
Mean	Mean	xx.x	xx.x	xx.x
Standard Deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx.x	xx.x	xx.x
Minimum	Min	xx.x	xx.x	xx.x
Maximum	Max	xx.x	xx.x	xx.x

[a] Cumulative actual dose is the sum of the actual daily dose received from cycle 1 day 1 through treatment discontinue.
[b] Duration is calculated as the (last dose date – first dose date +1)/7.
[c] Actual dose intensity is calculated as the cumulative actual dose divided by the duration.
[d] Relative dose intensity is calculated as the actual dose intensity divided by the planned dose intensity multiplied by 100;

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.4
Treatment Modifications - Carboplatin
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Dose reduced				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Infusion stopped/interrupted				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Dose omitted/held				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Discontinued	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.5
Treatment Modifications - Pemetrexed
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Dose reduced				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Infusion stopped/interrupted				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Dose omitted/held				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Discontinued	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 6.6
Treatment Modifications - OGX-427 or Placebo
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Dose reduced				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Infusion stopped/interrupted				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Dose omitted/held				
None	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 1	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 2	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Patients with 3 or more	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Discontinued	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 7.1
Progression-free Survival
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Number of patients progressed or died	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of patients censored	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Progression-free survival (PFS) [a], months				
Median (95% CI)	Median (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
25th Percentile (95% CI)	25th Percentile (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
75th Percentile (95% CI)	75th Percentile (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
Event Rate [a], %				
6 months (95% CI)	Prob.(95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
12 months (95% CI)	Prob.(95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
Hazard Ratio (two-sided 95% CI)				
OGX-427 vs Placebo	x.xxx(x.xxx,x.xxx)	x.xxx(x.xxx,x.xxx)		

(Continued)

[a] Calculated using the Kaplan-Meier technique.
[b] The logrank test.
Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: Progression-free survival (PFS) is defined as the time from the date of radomization until the date of disease progression (RECIST or clinical) or death due to any cause. Patients who have neither progression nor death will be censored.
Note: CI = Confidence Interval
Note: RECIST1.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 7.1
Progression-free Survival
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
p-values[b]				
OGX-427 vs Placebo	p-value	x.xxxx		

[a] Calculated using the Kaplan-Meier technique.
[b] The logrank test.
Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: Progression-free survival (PFS) is defined as the time from the date of radomization until the date of disease progression (RECIST or clinical) or death due to any cause. Patients who have neither progression nor death will be censored.
Note: CI = Confidence Interval
Note: RECIST1.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 7.2
Progression-free Survival - Statified by Baseline ECOG Performance
ECOG analysis set

Parameter	Statistic	Baseline ECOG Performance = 0 (N=xxx)		Baseline ECOG Performance ≥ 1 (N=xxx)	
		Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)
Number of patients progressed or died	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of patients censored	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Progression-free survival (PFS) [a], months					
Median (95% CI)	Median (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
25th Percentile (95% CI)	25th Percentile (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
75th Percentile (95% CI)	75th Percentile (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
Event Rate [a], %					
6 months (95% CI)	Prob.(95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
12 months (95% CI)	Prob.(95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)

(Continued)

[a] Calculated using the Kaplan-Meier technique.
[b] The logrank test.
Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: Progression-free survival (PFS) is defined as the time from the date of radomization until the date of disease progression (RECIST or clinical) or death due to any cause. Patients who have neither progression nor death will be censored.
Note: CI = Confidence Interval
Note: RECIST1.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 7.2
Progression-free Survival - Stratified by Baseline ECOG Performance
ECOG analysis set

		Baseline ECOG Performance = 0 (N=xxx)		Baseline ECOG Performance = 1 (N=xxx)	
Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)
Hazard Ratio (two-sided 95% CI)					
OGX-427 vs Placebo	x.xxx(x.xxx,x.xxx)	x.xxx(x.xxx,x.xxx)		x.xxx(x.xxx,x.xxx)	
p-values[b]					
OGX-427 vs Placebo	p-value	x.xxxx		x.xxxx	

[a] Calculated using the Kaplan-Meier technique.
[b] The logrank test.
Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: Progression-free survival (PFS) is defined as the time from the date of radomization until the date of disease progression (RECIST or clinical) or death due to any cause. Patients who have neither progression nor death will be censored.
Note: CI = Confidence Interval
Note: RECIST1.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 8.1
Overall Survival
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Number of patients died	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of patients censored	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Overall survival (OS) [a], months				
Median (95% CI)	Median (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
25th Percentile (95% CI)	25th Percentile (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
75th Percentile (95% CI)	75th Percentile (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
Event Rate [a], %				
6 months (95% CI)	Prob.(95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
12 months (95% CI)	Prob.(95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
Hazard Ratio (two-sided 95% CI)				
OGX-427 vs Placebo	x.xxx(x.xxx,x.xxx)	x.xxx(x.xxx,x.xxx)		
p-values[b]				

(Continued)

[a] Calculated using the Kaplan-Meier technique.
[b] The logrank test.
Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: Overall survival (OS) is defined as the time from the date of randomization until the date of death due to any cause.
Note: CI = Confidence Interval

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 8.1
Overall Survival
Full analysis set

Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
OGX-427 vs Placebo	p-value	x.xxxx		

[a] Calculated using the Kaplan-Meier technique.
[b] The logrank test.
Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: Overall survival (OS) is defined as the time from the date of randomization until the date of death due to any cause.
Note: CI = Confidence Interval

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 8.2
Overall Survival - Stratified by Baseline ECOG Performance
ECOG analysis set

Parameter	Statistic	Baseline ECOG Performance = 0 (N=xxx)		Baseline ECOG Performance >= 1 (N=xxx)	
		Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)
Number of patients died	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Number of patients censored	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Overall survival (OS) [a], months					
Median (95% CI)	Median (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
25th Percentile (95% CI)	25th Percentile (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
75th Percentile (95% CI)	75th Percentile (95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
Event Rate [a], %					
6 months (95% CI)	Prob.(95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
12 months (95% CI)	Prob.(95% CI)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)	xx.x(xx.x, xx.x)
Hazard Ratio (one-sided 80% CI)					
OGX-427 vs Placebo	x.xxx(x.xxx)	x.xxx(x.xxx)		x.xxx(x.xxx)	

(Continued)

[a] Calculated using the Kaplan-Meier technique.
[b] The logrank test.
Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: Overall survival (OS) is defined as the time from the date of randomization until the date of death due to any cause.
Note: CI = Confidence Interval

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 8.2
Overall Survival - Stratified by Baseline ECOG Performance
ECOG analysis set

		Baseline ECOG Performance = 0 (N=xxx)		Baseline ECOG Performance ≥ 1 (N=xxx)	
Parameter	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)
Hazard Ratio (two-sided 95% CI)					
OGX-427 vs Placebo	x.xxx(x.xxx,x.xxx)	x.xxx(x.xxx,x.xxx)		x.xxx(x.xxx,x.xxx)	
p-values[b]					
OGX-427 vs Placebo	p-value	x.xxxx		x.xxxx	

[a] Calculated using the Kaplan-Meier technique.
[b] The logrank test.
Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: Overall survival (OS) is defined as the time from the date of randomization until the date of death due to any cause.
Note: CI = Confidence Interval

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 9.1
Best Overall Response, Objective Response Rate, and Clinical Benefit Rate
Full analysis set

	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Complete response (CR)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Partial response (PR)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Stable disease (SD months)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Stable disease (SD<6 months)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Progressive disease (PD)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Clinical progression	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
RECIST progression	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Not evaluable (NE)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Objective response rate (CR+PR, ORR)				
ORR	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
95% CI[a]	%, %	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Odds Ratio for ORR (two-sided 95% CI)				
OGX-427 vs Placebo	%(%,%)			xx.x(xx.x, xx.x)
p-value for ORR[b]				
OGX-427 vs Placebo	p-value			x.xxxx

(Continued)

Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: CI = Confident Interval
[a] Two sided exact 95% CI using the method of Clopper Pearson.
[b] Fisher's exact test.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 9.1
Best Overall Response, Objective Response Rate, and Clinical Benefit Rate
Full analysis set

	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Clinical benefit rate (CR+PR+SD≥months, CBR)				
CBR	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
95% CI[a]	%, %	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Odds Ratio for CBR (two-sided 95% CI)				
OGX-427 vs Placebo	%(%,%)			xx.x(xx.x, xx.x)
p-value for CBR[b]				
OGX-427 vs Placebo	p-value			x.xxxx

Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: CI = Confident Interval
[a] Two sided exact 95% CI using the method of Clopper Pearson.
[b] Fisher's exact test.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 9.2
Best Overall Response, Objective Response Rate, and Clinical Benefit Rate - Stratified by Baseline ECOG Performance
ECOG analysis set

		Baseline ECOG Performance = 0 (N=xxx)		Baseline ECOG Performance ≥ 1 (N=xxx)	
	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)
Complete response (CR)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Partial response (PR)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Stable disease (SD months)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Stable disease (SD<6 months)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Progressive disease (PD)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Clinical progression	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
RECIST progression	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Not evaluable (NE)	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Objective response rate (CR+PR, ORR)					
ORR	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
95% CI[a]	%, %	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Odds Ratio for ORR (two-sided 95% CI)					
OGX-427 vs Placebo	%(%,%)	xx.x(xx.x, xx.x)		xx.x(xx.x, xx.x)	

(Continued)

Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: CI = Confident Interval
[a] Two sided exact 95% CI using the method of Clopper Pearson.
[b] Fisher's exact test.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 9.2
Best Overall Response, Objective Response Rate, and Clinical Benefit Rate - Stratified by Baseline ECOG Performance
ECOG analysis set

		Baseline ECOG Performance = 0 (N=xxx)		Baseline ECOG Performance >= 1 (N=xxx)	
	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)
p-value for ORR[b]					
OGX-427 vs Placebo	p-value	x.xxxx		x.xxxx	
Clinical benefit rate (CR+PR+SD months, CBR)					
CBR	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)	xx(xx.x)
95% CI[a]	%, %	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Odds Ratio for CBR (two-sided 95% CI)					
OGX-427 vs Placebo	%(%,%)	xx.x(xx.x, xx.x)		xx.x(xx.x, xx.x)	
p-value for CBR[b]					
OGX-427 vs Placebo	p-value	x.xxxx		x.xxxx	

Note: The denominator for the percentage calculation is the total number of patients who were assigned to the specific arm.
Note: CI = Confident Interval
[a] Two sided exact 95% CI using the method of Clopper Pearson.
[b] Fisher's exact test.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 10
Adverse Events Overview
Safety analysis set

	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Number of patients with at least one:				
Adverse event				
Grade 1 / Mild	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Grade 2 / Moderate	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Grade 3 / Severe	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Grade 4 / Life Threatening	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Grade 5 / Fatal	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Treatment-related adverse event				
Grade 1 / Mild	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Grade 2 / Moderate	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Grade 3 / Severe	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Grade 4 / Life Threatening	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Grade 5 / Fatal	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Serious adverse event	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Treatment-related serious adverse event	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Serious adverse event leading to death	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

(Continued)

[a] Patients with multiple events in the same category are counted only once in that category.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: CTCAE = Common Terminology Criteria for Adverse Events (version 4.03).

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 10
Adverse Events Overview
Safety analysis set

	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Treatment-related serious adverse event leading to death	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Adverse events leading to treatment discontinued	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Adverse events leading to treatment stopped/interrupted	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Adverse events leading to treatment omitted/held	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Adverse events leading to treatment reduced	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Patients with multiple events in the same category are counted only once in that category.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: CTCAE = Common Terminology Criteria for Adverse Events (version 4.03).

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 11
Adverse Events by System Organ Class and Preferred Term
Safety analysis set

MedDRA system organ class Preferred term	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any AE [a]	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Infections and infestations	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Respiratory tract infection NOS	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pharyngitis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Influenza	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Nervous system disorders	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Headache	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Dizziness	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert System organ class>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Number (%) of patients with AEs, sorted on international order for system organ class and alphabetical order for preferred term
Note: A patient can have one or more preferred terms reported under a given system organ class.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 12
Adverse Events by System Organ Class, Preferred Term and Maximum Reported CTCAE Grade
Safety analysis set

MedDRA system organ class Preferred term	Maximum CTCAE grade	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any AE [a]	Total	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	1	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	2	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	3	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	4	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	5	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
Infections and infestations	Total	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	1	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	2	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	3	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	4	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	5	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
Respiratory tract infection NOS	Total	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	1	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	2	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	3	n(%)	x(xx.x)	x(xx.x)	x(xx.x)

(Continued)

[a] Each patient has only been represented with the maximum reported CTCAE grade for each system organ class / preferred term.
Number (%) of patients with AEs, sorted by international SOC order and alphabetical PT and then maximum grade.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1
Note: CTCAE = Common Terminology Criteria for Adverse Events (version 4.03)

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 12
Adverse Events by System Organ Class, Preferred Term and Maximum Reported CTCAE Grade
Safety analysis set

MedDRA system organ class Preferred term	Maximum CTCAE grade	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
	4	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	5	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
<insert Preferred term>					
<insert System organ class>					
<insert Preferred term>					

[a] Each patient has only been represented with the maximum reported CTCAE grade for each system organ class / preferred term.
Number (%) of patients with AEs, sorted by international SOC order and alphabetical PT and then maximum grade.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1
Note: CTCAE = Common Terminology Criteria for Adverse Events (version 4.03)

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 13
Treatment-related Adverse Events by System Organ Class and Preferred Term
Safety analysis set

MedDRA system organ class Preferred term	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any treatment-related AE [a]	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Infections and infestations	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Respiratory tract infection NOS	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pharyngitis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Influenza	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Nervous system disorders	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Headache	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Dizziness	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert System organ class>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Number (%) of patients with AEs, sorted on international order for system organ class and alphabetical order for preferred term
Note: A patient can have one or more preferred terms reported under a given system organ class.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 14
Treatment-related Adverse Events by System Organ Class, Preferred Term and Maximum Reported CTCAE Grade
Safety analysis set

MedDRA system organ class Preferred term	Maximum CTCAE grade	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any treatment-related AE [a]	Total	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	1	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	2	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	3	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	4	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	5	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
Infections and infestations	Total	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	1	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	2	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	3	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	4	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	5	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
Respiratory tract infection NOS	Total	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
	1	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	2	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	3	n(%)	x(xx.x)	x(xx.x)	x(xx.x)

(Continued)

[a] Each patient has only been represented with the maximum reported CTCAE grade for each system organ class / preferred term.
Number (%) of patients with AEs, sorted by international SOC order and alphabetical PT and then maximum grade.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1
Note: CTCAE = Common Terminology Criteria for Adverse Events (version 4.03)

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 14
Treatment-related Adverse Events by System Organ Class, Preferred Term and Maximum Reported CTCAE Grade
Safety analysis set

MedDRA system organ class Preferred term	Maximum CTCAE grade	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
	4	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
	5	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
<insert Preferred term>					
<insert System organ class>					
<insert Preferred term>					

[a] Each patient has only been represented with the maximum reported CTCAE grade for each system organ class / preferred term.
Number (%) of patients with AEs, sorted by international SOC order and alphabetical PT and then maximum grade.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1
Note: CTCAE = Common Terminology Criteria for Adverse Events (version 4.03)

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 15.1
Adverse Events Leading to Carboplatin **Discontinuation by Preferred Term**
Safety analysis set

MedDRA Preferred term	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any AE leading to Carboplatin dose discontinuation [a] [b]	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Respiratory tract infection NOS	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pharyngitis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Influenza	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Number (%) of patients with an AE leading to discontinuation of Carboplatin, sorted by alphabetically for preferred term. Patients with multiple AEs leading to discontinuation are counted once for each preferred term.
[b] Action taken, Carboplatin discontinued.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 15.2
Adverse Events Leading to Pemetrexed Discontinuation by Preferred Term
Safety analysis set

MedDRA Preferred term	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any AE leading to Pemetrexed dose discontinuation [a] [b]	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Respiratory tract infection NOS	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pharyngitis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Influenza	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Number (%) of patients with an AE leading to discontinuation of Pemetrexed, sorted by alphabetically for preferred term. Patients with multiple AEs leading to discontinuation are counted once for each preferred term.
[b] Action taken, Pemetrexed discontinued.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 15.3
Adverse Events Leading to OGX-427 Discontinuation by Preferred Term
Safety analysis set

MedDRA Preferred term	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any AE leading to OGX-427 dose discontinuation [a] [b]	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Respiratory tract infection NOS	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pharyngitis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Influenza	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Number (%) of patients with an AE leading to discontinuation of OGX-427, sorted by alphabetically for preferred term. Patients with multiple AEs leading to discontinuation are counted once for each preferred term.
[b] Action taken, OGX-427 discontinued.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 16.1
Adverse Events Leading to Carboplatin Dose Reduction by Preferred Term
Safety analysis set

MedDRA Preferred term	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any AE leading to Carboplatin dose reduction [a] [b]	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Respiratory tract infection NOS	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pharyngitis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Influenza	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Number (%) of patients with an AE leading to reduction of Carboplatin, sorted by alphabetically for preferred term.
Patients with multiple AEs leading to reduction are counted once for each preferred term.
[b] Action taken, Carboplatin reduced.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 16.2
Adverse Events Leading to Pemetrexed Dose Reduction by Preferred Term
Safety analysis set

MedDRA Preferred term	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any AE leading to Pemetrexed dose reduction [a] [b]	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Respiratory tract infection NOS	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pharyngitis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Influenza	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Number (%) of patients with an AE leading to reduction of Pemetrexed, sorted by alphabetically for preferred term.
Patients with multiple AEs leading to reduction are counted once for each preferred term.
[b] Action taken, Pemetrexed reduced.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 16.3
Adverse Events Leading to OGX-427 Dose Reduction by Preferred Term
Safety analysis set

MedDRA Preferred term	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Patients with any AE leading to OGX-427 dose reduction [a] [b]	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Respiratory tract infection NOS	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Pharyngitis	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Influenza	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
<insert Preferred term>	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

[a] Number (%) of patients with an AE leading to reduction of OGX-427, sorted by alphabetically for preferred term.
Patients with multiple AEs leading to reduction are counted once for each preferred term.
[b] Action taken, OGX-427 reduced.
Note: Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of study treatment.
Note: MedDRA version 17.1

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 17
Patient Deaths
All enrolled patients

Category	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Total number of alive	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Total number of deaths	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Death due to disease progression	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Death due to protocol therapy	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Death due to AE	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Death, cause unknown	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)
Other	n(%)	xx(xx.x)	xx(xx.x)	xx(xx.x)

Note: Rows are mutually exclusive, patients are only reported in one category.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM

Table 18.1
Hematology CTCAE Grade Change from Baseline to Maximum on Treatment
Safety analysis set

Hematology Variable	Arm	Baseline CTCAE grade[a]	Patients at baseline[b] n(%)	Maximum overall CTCAE grade during treatment (%)[c]					
				Grade 0 n(%)	Grade 1 n(%)	Grade 2 n(%)	Grade 3 n(%)	Grade 4 n(%)	Total n(%)
Hemoglobin	OGX-427 (N=xx)	0	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		1	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		2	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		3	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		4	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		Total evaluable	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Placebo (N=xx)	0	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		1	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		2	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		3	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		4	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		Total evaluable	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)

<<Variable >>

[a] Baseline is defined as the last result obtained prior to the start of study treatment
[b] Patients with a baseline value and at least one on-treatment value. Percentages have been calculated using the number of patients with a baseline value and a post baseline value.
[c] Derived from laboratory assessments between the start of treatment and 30 days following the date of last dose of study medication and is the maximum CTCAE grade.
Note: CTCAE Common Terminology Criteria for Adverse Events version 4.03.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 18.2
Clinical chemistry CTCAE Grade Change from Baseline to Maximum on Treatment
Safety analysis set

Hematology Variable	Arm	Baseline CTCAE grade[a]	Patients at baseline[b] n(%)	Maximum overall CTCAE grade during treatment (%)[c]					
				Grade 0 n(%)	Grade 1 n(%)	Grade 2 n(%)	Grade 3 n(%)	Grade 4 n(%)	Total n(%)
Albumin	OGX-427 (N=xx)	0	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		1	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		2	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		3	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		4	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		Total evaluable	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)
	Placebo (N=xx)	0	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		1	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		2	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		3	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		4	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	x(x.x)	xx(x.x)
		Total evaluable	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)	xx(x.x)

<<Variable >>

[a] Baseline is defined as the last result obtained prior to the start of study treatment
[b] Patients with a baseline value and at least one on-treatment value. Percentages have been calculated using the number of patients with a baseline value and a post baseline value.
[c] Derived from laboratory assessments between the start of treatment and 30 days following the date of last dose of study medication and is the maximum CTCAE grade.
Note: CTCAE Common Terminology Criteria for Adverse Events version 4.03.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 18.3
Elevated AST, ALT, Total Bilirubin, and Alkaline Phosphate
Safety analysis eet

Parameter Abnormality	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
AST				
N	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
3x - <5x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
5x - <10x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
10x - <20x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
>=20x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
ALT				
N	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
3x - <5x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
5x - <10x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
10x - <20x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
>=20x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
AST or ALT				
N	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
3x - <5x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
5x - <10x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
10x - <20x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
>=20x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)

(Continued)

Note: ULN = upper limit of normal; AST = Aspartate transaminase; ALT = Alanine transaminase; Tbili = Total Bilirubin.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 18.3
Elevated AST, ALT, Total Bilirubin, and Alkaline Phosphate
Safety analysis eet

Parameter Abnormality	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Total Bilirubin				
N	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
>2x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
Alkaline Phosphatase				
N	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
>1.5x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
(AST or ALT) and Total Bilirubin				
N	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
(AST or ALT >3x ULN) and 2xULN > Tbili > 1.5x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)
(AST or ALT >3x ULN) and Tbili >= 2x ULN	n(%)	x(xx.x)	x(xx.x)	x(xx.x)

Note: ULN = upper limit of normal; AST = Aspartate transaminase; ALT = Alanine transaminase; Tbili = Total Bilirubin.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Table 19
Follow up Duration
Full analysis set

	Statistic	Carboplatin Pemetrexed OGX-427 (N=xx)	Carboplatin Pemetrexed Placebo (N=xx)	Total (N=xxx)
Follow up duration (months)				
n	n	xx	xx	xx
Mean	Mean	xx.x	xx.x	xx.x
Standard deviation	SD	xx.xx	xx.xx	xx.xx
Median	Median	xx	xx	xx
Min	Min	xx	xx	xx
Max	Max	xx	xx	xx

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM

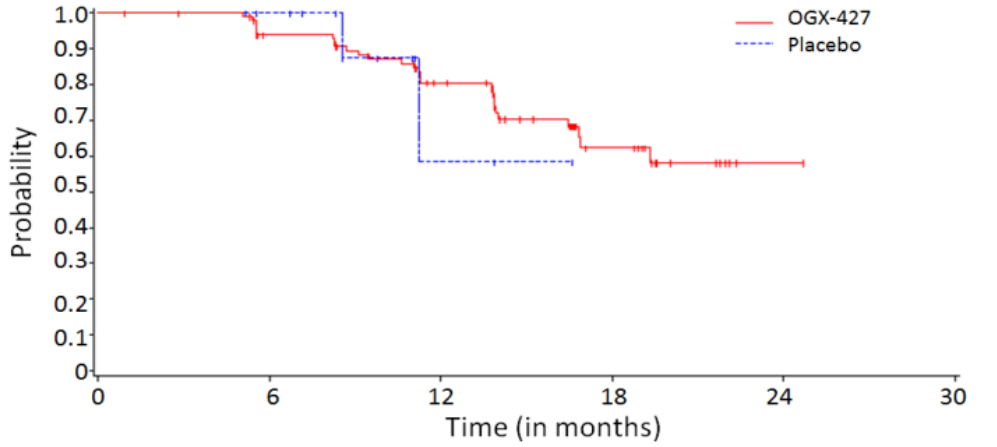
Table 20
Serum Hsp27, Change from Baseline over Time
FAS with serum Hsp27 measurement

		Observed Results						% Change from Baseline					
Arm	Protocol Timepoint	N	Mean	SD	Min	Median	Max	N	Mean	SD	Min	Median	Max
OGX427 (N=xx)	Pre-treatment	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx						
	Pre-loading dose	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx						
	Cycle 1 day 1	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx
	Cycle n day 1	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx
	End of Treatment	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx
Placebo (N=xx)	Pre-treatment	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx						
	Pre-loading dose	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx						
	Cycle 1 day 1	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx
	Cycle n day 1	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx
	End of Treatment	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx	xx	xx.xx	xx.xxx	xx.xx	xx.xx	xx.xx

Note: Baseline is defined as the last value observed before the administration of study treatment.
Note: % Change from baseline = 100* (related protocol timepoint value - baseline value)/(baseline value).

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time : YYYY-MM-DD/HH:MM

Figure 1.1
Progression-free survival, Kaplan-Meier plot, Stratified by Arm
Full analysis Set

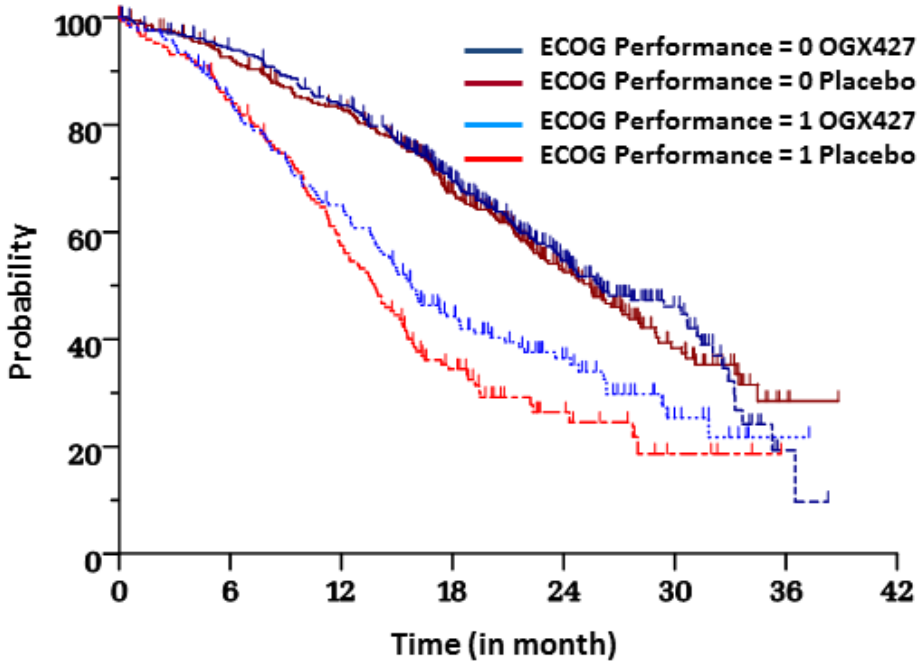


N at Months	0	6	12	18	24	30
OGX-427	xx	xx	xx	xx	xx	xx
Placebo	xx	xx	xx	xx	xx	xx

Note: + indicates a censored observation.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM

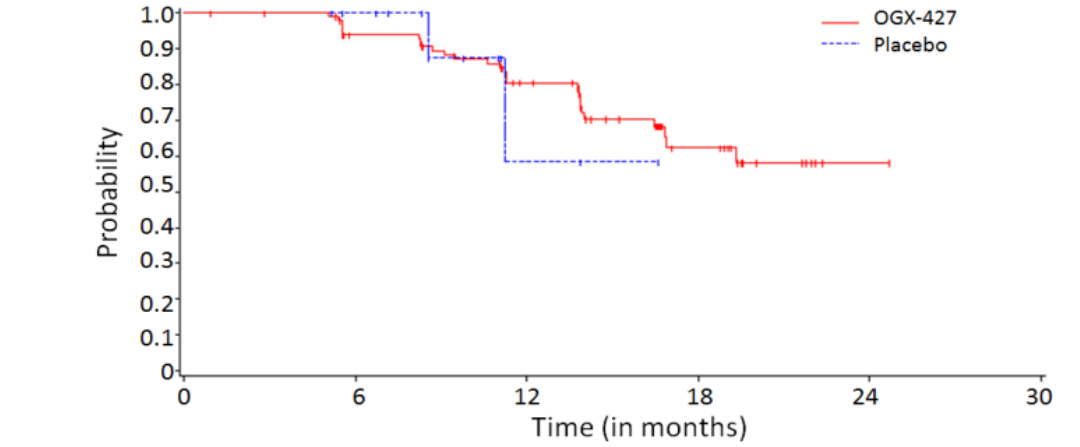
Figure 1.2
Progression-free survival, Kaplan-Meier plot, Stratified by Arm and Baseline ECOG Performance
ECOG analysis Set



Note: + indicates a censored observation.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM

Figure 2.1
Overall survival, Kaplan-Meier plot, Stratified by Arm
Full analysis Set

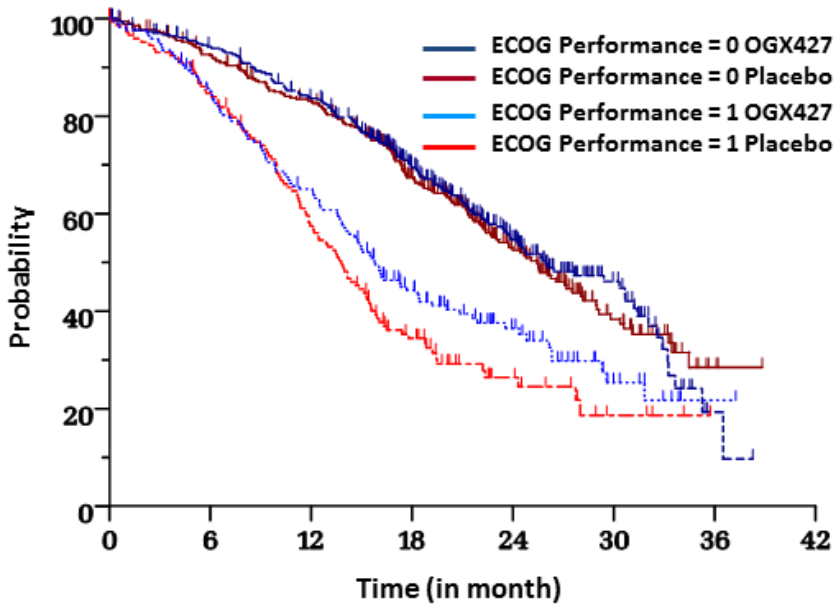


N at Months	0	6	12	18	24	30
OGX-427	xx	xx	xx	xx	xx	xx
Placebo	xx	xx	xx	xx	xx	xx

Note: + indicates a censored observation.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM

Figure 2.2
Overall survival, Kaplan-Meier plot, Stratified by Arm and Baseline ECOG Performance
ECOG analysis Set



Note: + indicates a censored observation.

Program Name: XXXX
Datasets(date): X_XXX.XX, X_XXX.XXX (DDMMMYYYY)
Generation Date/Time: YYYY-MM-DD/HH:MM