SPONSOR:

CicloMed

PROTOCOL NUMBER:

CPX-POM-001

STATISTICAL ANALYSIS PLAN (TFL shells)

Author:	[redacted]
Version:	Version 1.0
Date:	02FEB2018

Cover and signature pages

Sponsor:	CicloMed
Protocol Number:	CPX-POM-001
Study Title:	A Phase 1, First-in-Human, Safety, Dose Tolerance, Pharmacokinetics, and Pharmacodynamics Study of CPX-POM in Patients with Advanced Solid Tumors
Document Version No	Version 1.0

We, the undersigned, confirm that we have read, understood and agree to the content of this document and hereby authorise its approval.

Name **Title, Organisation**	**Signature**	**Date**
[redacted]		
[redacted]		
[redacted]		
[redacted]		

Table of Contents

Table 14.1-1 – Patients disposition
(All patients)

Cycle	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Cycle 1							
Treated	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Completed the cycle [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Discontinued from the cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for discontinuation from the cycle							
Dose Limitimg Toxicity	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Withdrawn Consent	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Percentages are based on the number of patients enrolled.
[a] A patient completed Cycle 1 if s/he attended visit Day 10 (if Cycle 1 was not the last cycle) or Visit Day 22 (if Cycle 1 was the last cycle).

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-1 – Patients disposition
(All patients)

Cycle	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Cycle 2							
Treated	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Completed the cycle [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Discontinued from the cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for discontinuation from the cycle							
Dose Limitimg Toxicity	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Withdrawn Consent	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<repeat until last-1 cycle>

Percentages are based on the number of patients enrolled.
[b] A patient completed Cycle 2 (or any next cycle until last-1 cycle) if s/he attended visit Day 6 (if Cycle 2 or any next cycle was not the last cycle) or Visit Day 22 (if Cycle 2 or any next cycle was the last cycle).

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-1 – Patients disposition
(All patients enrolled)

Cycle	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Last Cycle							
Treated	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Completed the cycle [c]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Discontinued from the cycle	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for discontinuation from the cycle							
Dose Limitimg Toxicity	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Withdrawn Consent	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Attended the follow-up visit (Day 28)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Percentages are based on the number of patients enrolled.
[c] A patient completed the Last Cycle if s/he attended visit Day 22.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Display all the reasons for discontinuation where there is at least one patient within that category

Table 14.1-2 – Number (%) of Patients in the Analysis Populations
(All patients)

	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Safety Population	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Efficacy Population	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PK Population	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Percentages are based on the number of enrolled patients.
The Safety population includes all patients who have received at least one dose of CPX-POM.
The Efficacy population includes all patients who have received at least one dose of CPX-POM, had RECIST measurable disease at baseline and had at least one other post-baseline tumor assessment.
The PK population includes all patients for whom at least one plasma and/or urine sample has been obtained and analyzed for determination of plasma drug and metabolites concentration.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- For the safety population, patients are displayed based on the actually received treatment.

Table 14.1-3 - Summary of Demography
(ITT Population)

	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Age [a] (years)							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX
Age group [n (%)]							
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Sex [n (%)]							
Male	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Female	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Race [n (%)]							
White	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Black or African American	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Asian	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
American Indian or Alaska Native	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Native Hawaiian or Other Pacific Islander	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[a] Age at Screening.
[b] Body mass index (BMI) (kg/m²) = Weight (kg) / (Height (m))^2.
[c] The denominator is the number of females in each dose group.

Table 14.1-3 – Summary of Demography
(ITT Population)

	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Female of child bearing potential [n (%)] [c]							
Yes	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
No	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Country [n (%)]							
XXXXX	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
XXXXX	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
XXXXX	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Height (cm)							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX

[a] Age at Screening.
[b] Body mass index (BMI) (kg/m²) = Weight (kg) / (Height (m))**2.
[c] The denominator is the number of females in each dose group.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.1-3 - Summary of Demography
(ITT Population)

	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Weight (kg)							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX
BMI [b] (kg/m^2)							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX
BSA [d] (kgxm)							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX

[a] Age at Screening.
[b] Body Mass Index (BMI) (kg/m^2) = Weight (kg) / (Height (m))^2.
[c] The denominator is the number of females in each dose group.
[d] Body Surface Area (BSA) (kgxm) = 0.007184 x Weight (kg)^0.425 / (Height (m))^0.725 (Dubois formula).

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Table 14.1-4 – Protocol Deviations
(Safety Population)

Protocol Deviations Category	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Any Protocol Deviations	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Inclusion / Exclusion Criteria							
INCL01	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
<cont.>							
Prohibited Medications	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
<cont.>							

A patient could be counted under more than one category.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Categories are from the protocol deviations criteria form, the table only shows examples.

Table 14.1-5.1 – Disease Characteristics
(Safety Population)

	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Cancer Type? [n (%)]							
Solid Tumor	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lymphoma	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Solid Tumor Organ Site [n (%)]							
Lung	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Breast	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Colon	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Prostate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Time since first diagnosis of Cancer (months)							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX
Disease Stage at the Cancer diagnosis date? [n (%)]							
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Disease Stage at Screening visit date? [n (%)]							
1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)
Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 2 of 2

Table 14.1-5.1 – Disease Characteristics
(Safety Population)

	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Presence of metastases? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Time between date of Metastatic diagnosis and date of Cycle 1 visit Day 1 (months)							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX
Extent of current Metastatic disease							
Bone? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lungs? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Liver? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pelvic Lymph Nodes? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Extrapelvic Lymph Nodes? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Table 14.1-5.2 – Other Medical History
(Safety Population)

System Organ Class/ Preferred Term	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
At least one other previous condition?	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
System Organ Class #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

If there was more than one condition reported under the same System Organ Class and Preferred Term, the patient was counted only once under that System Organ Class and Preferred Term. If there was more than one condition reported under the same System Organ Class, the patient was counted only once under that System Organ Class.
MedDRA version <version number>.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- The Primary System Organ Classes are presented by alphabetical order and the Preferred Terms are sorted within Primary System Organ Classes by alphabetical order.

Table 14.1-6.1.1 – Prior Medications by Therapeutic Class and Preferred Term
(Safety Population)

Therapeutic Class/ Preferred Term	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
At least one prior medication?	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Therapeutic Class #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Therapeutic Class #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

A prior medication is a medication whose end date is before the date of first CPX-POM dose.
If there was more than one prior medication reported under the same Therapeutic Class and Preferred Term, the patient was counted only once under that Therapeutic Class and Preferred Term. If there was more than one prior medication reported under the same Therapeutic Class, the patient was counted only once under that Therapeutic Class.
WHO-DRUG version <version number>.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- The Therapeutic Classes are presented by alphabetical order and the Preferred Terms are sorted within Therapeutic Classes by alphabetical order.
- A medication / therapy can appear within more than one Therapeutic Class.

Table 14.1-6.1.2 – Concomitant Medications by Therapeutic Class and Preferred Term
(Safety Population)

Replicate of Table 14.1-6.1.1

PROGRAMMING NOTES:

- Update foootnote: replace 'A prior medication is a medication whose end date is before the date of first CPX-POM dose' by 'A concomitant medication is a medication that started before the date of first dose and stopped on (or is ongoing after) the date of first dose OR a medication whose start date is either the same as (or after) the date of first dose'.
- Update 'At least one prior medication' by 'At least one concomitant medication'.
- The Therapeutic Classes are presented by alphabetical order and the Preferred Terms are sorted within Therapeutic Classes by alphabetical order.
- A medication / therapy can appear within more than one Therapeutic Class.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of 1

Table 14.1-7 - Overall Exposure to Study Drug and Drug Compliance
(Safety Population)

	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Study Drug Exposure (days) [a]							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX
Study Drug Exposure (mg) [b]							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX

[a] The CPX-POM exposure expressed in days is defined as the number of days between the first dose taken date and the last dose taken date + 1 day.
[b] The CPX-POM exposure expressed in mg is defined as: dose per m^2 x Body Surface Area x CPX-POM exposure expressed in days.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of 2

Table 14.2.1 – Patients who have had at least one other post-baseline tumor assessment
(Efficacy Population)

	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
At least one other post-baseline tumor assessment	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary Tumor Site [n (%)]							
Primary Tumor Site #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary Tumor Site #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Primary Tumor Site #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>							

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- **A last column with the header 'CPX-POM All Doses' will also be displayed.**

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of 2

Table 14.2.2 – Summary of Patients Responses
(Efficacy Population)

Visit/ Type of Response	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Cycle 2-Day 1 Visit							
Target Lesion Response [n (%)]							
Complete Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not evaluable	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Non-Target Lesion Response [n (%)]							
Complete Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not evaluable	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Overall Response [n (%)]							
Complete Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Partial Response	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Stable Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not evaluable	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<repeat for Day 1 visit of each cycle from Cycle 3 to last Cycle number over all patients>

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- **A last column with the header 'CPX-POM All Doses' will also be displayed.**

Table 14.3-1.1 – Overview of Adverse Events
(Safety Population)

	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Number of patients with at least one:							
AE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE *	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE leading to discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE leading to discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Serious related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

* A treatment-emergent adverse events (TEAE) is defined as an adverse event which started on or after the first dose of CPX-POM administration.
MedDRA version <version number>.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- "Leading to discontinuation" is derived from action taken = permanently discontinued.
- **A last column with the header 'CPX-POM All Doses' will also be displayed.**

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Table 14.3-1.2 – Number (%) of Patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class/ Preferred Term	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Number of patients with at least one TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>							
System Organ Class #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>							

If there was more than one TEAE reported under the same System Organ Class and Preferred Term, the patient was counted only once under that System Organ Class and that Preferred Term. If there was more than one TEAE reported under the same System Organ Class, the patient was counted only once under that System Organ Class.
MedDRA version <version number>.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- The System Organ Classes are presented by decreasing frequency (within the total column – all CPX-POM doses groups combined – not displayed) and the Preferred Terms within a System Organ Class are presented by decreasing frequency (within the total column – all CPX-POM doses groups combined – not displayed).

Table 14.3-1.3 – Number (%) of Patients with Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population)

Replicate of Table 14.3-1.2

Table 14.3-1.4 – Number (%) of Patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population)

Replicate of Table 14.3-1.2

Table 14.3-1.5 – Number (%) of Patients with Serious Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population)

Replicate of Table 14.3-1.2

Table 14.3-1.6 – Number (%) of Patients with Treatment-Emergent Adverse Events Leading to Discontinuation by System Organ Class and Preferred Term
(Safety Population)

Replicate of Table 14.3-1.2

PROGRAMMING NOTES:

- "Leading to discontinuation" is derived from action taken = permanently discontinued.

Table 14.3-1.7 – Number (%) of Patients with Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximal Severity (Safety Population)

System Organ Class/ Preferred Term/ Maximal severity	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Number of patients with any TEAE							
Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #1							
Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1							
Total	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Mild	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Moderate	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Severe	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

If there was more than one TEAE reported under the same System Organ Class and Preferred Term, the patient was counted only once under the maximal severity for that System Organ Class and Preferred Term. If there was more than one TEAE reported under the same System Organ Class, the patient was counted only once under the maximal severity for that System Organ Class.
MedDRA version <version number>.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Display all severities even if there are no patients.
- The System Organ Classes are presented by decreasing frequency (within the total column – all CPX-POM doses groups combined – not displayed) and the Preferred Terms within a System Organ Class are presented by decreasing frequency (within the

total column – all CPX-POM doses groups combined – not displayed).

Table 14.3-1.8 – Number (%) of Patients with Related Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity (Safety Population)

Replicate of Table 14.3-1.7

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Table 14.3-1.9 – Number (%) of Patients with Treatment-Emergent Adverse Events of Special Interest by System Organ Class and Preferred Term
(Safety Population)

System Organ Class/ Preferred Term	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Number of patients with at least one TEAE of Special Interest	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>							
System Organ Class #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>							

The TEAEs of Special Interest are the clinically significant ophthalmological abnormalities.
If there was more than one TEAE of Special Interest reported under the same System Organ Class and Preferred Term, the patient was counted only once under that System Organ Class and that Preferred Term. If there was more than one TEAE of Special Interest reported under the same System Organ Class, the patient was counted only once under that System Organ Class.
MedDRA version <version number>.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- The System Organ Classes are presented by decreasing frequency for all CPX-POM doses groups combined and the Preferred Terms within a System Organ Class are presented by decreasing frequency for all CPX-POM doses groups combined.
- **A last column with the header 'CPX-POM All Doses' will also be displayed.**

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Table 14.3-2.1.1 – Summary of Hematology Laboratory Data
(Safety Population)

Laboratory Parameter: Hemoglobin (unit)

	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Baseline [a]							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX
Cycle 1-Day 4							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX
Change from Baseline to Cycle 1-Day 4							
n	XX	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX	XX	XX	XX	XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Maximum	XX	XX	XX	XX	XX	XX	XX

<repeat for Cycle 1 Day 10 visit>
<for Cycle 2 to last-1 Cycle, repeat for Day 1 visit and Day 4 visit>
<for the last Cycle, repeat for Day 22 visit and Day 28 follow-up visit>

[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all hematology parameters: Hemoglobin, Hematocrit, Platelet count, RBC count, Reticulocytes, WBC Count with Differential, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils.

Table 14.3-2.1.2 – Outside of Normal Range - Shift Table for Hematology Laboratory Parameters
(Safety Population)

Dose group : CPX-POM 30 mg/m^2 (N=1)

Parameter/ Visit	Value at Visit	Baseline [a] value				
		Low n (%)	Normal n (%)	High n (%)	Low/High* n (%)	Total
Hemoglobin (unit)						
Cycle 1-Day 4 (N**=XX)	Low	XX (XXX.X)	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)	XX (XXX.X)
	High	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Low/High*	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Total	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX
Cycle 1-Day 10 (N**=XX)	Low	XX (XXX.X)	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)	XX (XXX.X)
	High	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Low/High*	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Total	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX

<for Cycle 2 to last-1 Cycle, repeat for Day 1 visit and Day 4 visit>
<for the last Cycle, repeat for Day 22 visit and Day 28 follow-up visit>
<repeat for all doses groups>

Percentage was based on the number of patients present at each visit with non-missing results for the considered parameter.
* Included patients with Low or High results. ** Denominator of the percentage.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment intake.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all doses groups.

- Repeat for all hematology parameters: Hemoglobin, Hematocrit, Platelet count, RBC count, Reticulocytes, WBC Count with Differential, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils.

Table 14.3-2.1.3 – Clinician Assessment - Shift Table for Hematology Laboratory Parameters
(Safety Population)

Dose group : CPX-POM 30 mg/m^2 (N=1)

Parameter/ Visit	Value at Visit	Baseline [a] value: Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	Total
Hemoglobin (unit)					
Cycle 1-Day 4 (N*=XX)	Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Abnormal, NCS	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Abnormal, CS	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Total	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX
Cycle 1-Day 10 (N*=XX)	Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Abnormal, NCS	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Abnormal, CS	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Total	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX

<for Cycle 2 to last-1 Cycle, repeat for Day 1 visit and Day 4 visit>
<for the last Cycle, repeat for Day 22 visit and Day 28 follow-up visit>
<repeat for the other hematology parameters>
<repeat for all doses groups>

Percentage was based on the number of patients present at each visit with non-missing results for the considered parameter.
* Denominator of the percentage.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
CS = Clinically Significant; NCS = Not Clinically Significant.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all doses groups.
- Repeat for all hematology parameters: Hemoglobin, Hematocrit, Platelet count, RBC count, Reticulocytes, WBC Count with Differential, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Table 14.3-2.1.4 – On-study Hematology Adverse Events: Worst NCI-CTCAE Grade per patient
(Safety Population)

Parameter/ Worst NCI-CTCAE grade	CPX-POM 30 mg/m^2 N=1 n (%)	CPX-POM [D2] mg/m^2 N=X n (%)	CPX-POM [D3] mg/m^2 N=X n (%)	CPX-POM [D4] mg/m^2 N=X n (%)	CPX-POM [D5] mg/m^2 N=X n (%)	CPX-POM [D6] mg/m^2 N=X n (%)	CPX-POM [D7] mg/m^2 N=X n (%)
Hemoglobin (unit)							
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Grade 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Grade 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Grade 3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Grade 4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Hematocrit (unit)							
Normal	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Grade 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Grade 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Grade 3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Grade 4	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Missing	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<repeat for the other hematology parameters>

For a given laboratory parameter, a patient must have at least one on-study grade assessed to be included.
For a given laboratory parameter, the number of treated patients with at least one on-study grade assessed for that parameter will be used as the denominator for the calculation of percentages.
A patient with multiple results for a parameter will only be counted under the maximum NCI-CTCAE grade for this parameter.
Laboratory ranges are based on NCI-CTCAE version 4.0.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all hematology parameters: Hemoglobin, Hematocrit, Platelet count, RBC count, Reticulocytes, WBC Count with

```
Differential, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils.
```

Table 14.3-2.1.5 – Shift table of Worst NCI-CTCAE Grade for Hematological parameters
(Safety Population)

		Worst NCI-CTCAE grade						
Parameter	Baseline grade	Normal n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Missing n (%)	Total n (%)
Hematocrit (unit)	Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Grade 1	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Grade 2	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Grade 3	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Grade 4	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Missing	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Total	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Hemoglobin (unit)	Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Grade 1	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Grade 2	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Grade 3	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Grade 4	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Missing	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
	Total	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

<repeat for the other hematology parameters>

For a given laboratory parameter, a patient must have at least one baseline and one on-treatment grades assessed to be included.
For a given laboratory parameter, the number of treated patients with at least one baseline and one on-treatment grades assessed for that parameter will be used as the denominator for the calculation of percentages.
A patient with multiple results for a parameter will only be counted under the maximum NCI-CTCAE grade for this parameter.
Laboratory ranges are based on NCI-CTCAE version 4.0.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all hematology parameters: Hemoglobin, Hematocrit, Platelet count, RBC count, Reticulocytes, WBC Count with Differential, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils.

Table 14.3-2.2.1 – Summary of Clinical Chemistry Laboratory Data
(Safety Population)

Replicate of Table 14.3-2.1.1

PROGRAMMING NOTES:
Clinical Chemistry parameters are: Potassium, Sodium, Chloride, Glucose, BUN, Creatinine, Creatinine clearance, ALP, ALT, AST, GGT, Alkaline phosphatase, Direct bilirubin, Indirect bilirubin, Total bilirubin, Total protein, Albumin, Calcium, Bicarbonate, Magnesium, Phosphate, Lipase, Amylase

Table 14.3-2.2.2 – Outside of Normal Range - Shift Table for Clinical Chemistry Laboratory Parameters
(Safety Population)

Replicate of Table 14.3-2.1.2

PROGRAMMING NOTES:
Clinical Chemistry parameters are: Potassium, Sodium, Chloride, Glucose, BUN, Creatinine, Creatinine clearance, ALP, ALT, AST, GGT, Alkaline phosphatase, Direct bilirubin, Indirect bilirubin, Total bilirubin, Total protein, Albumin, Calcium, Bicarbonate, Magnesium, Phosphate, Lipase, Amylase

Table 14.3-2.2.3 – Clinician Assessment - Shift Table for Clinical Chemistry Laboratory Parameters
(Safety Population)

Replicate of Table 14.3-2.1.3

PROGRAMMING NOTES:
Clinical Chemistry parameters are: Potassium, Sodium, Chloride, Glucose, BUN, Creatinine, Creatinine clearance, ALP, ALT, AST, GGT, Alkaline phosphatase, Direct bilirubin, Indirect bilirubin, Total bilirubin, Total protein, Albumin, Calcium, Bicarbonate, Magnesium, Phosphate, Lipase, Amylase

Table 14.3-2.2.4 – On-study Clinical Chemistry Adverse Events: Worst NCI-CTCAE Grade per patient
(Safety Population)

Replicate of Table 14.3-2.1.4

PROGRAMMING NOTES:
Clinical Chemistry parameters are: Potassium, Sodium, Chloride, Glucose, BUN, Creatinine, Creatinine clearance, ALP, ALT, AST,

GGT, Alkaline phosphatase, Direct bilirubin, Indirect bilirubin, Total bilirubin, Total protein, Albumin, Calcium, Bicarbonate, Magnesium, Phosphate, Lipase, Amylase

Table 14.3-2.2.5 – Shift table of Worst NCI-CTCAE Grade for Clinical Chemistry Laboratory parameters
(Safety Population)

Replicate of Table 14.3-2.1.5

PROGRAMMING NOTES:
Clinical Chemistry parameters are: Potassium, Sodium, Chloride, Glucose, BUN, Creatinine, Creatinine clearance, ALP, ALT, AST, GGT, Alkaline phosphatase, Direct bilirubin, Indirect bilirubin, Total bilirubin, Total protein, Albumin, Calcium, Bicarbonate, Magnesium, Phosphate, Lipase, Amylase

Table 14.3-2.3.1 – Summary of Coagulation Laboratory Data
(Safety Population)

Replicate of Table 14.3-2.1.1

PROGRAMMING NOTES:
- Coagulation parameters are PT and aPTT.
- Only Day 1 visit of each cycle

Table 14.3-2.4 – Summary of Thyroid Panel Laboratory Data
(Safety Population)

Replicate of Table 14.3-2.1.1

PROGRAMMING NOTES:
- Coagulation parameters are TSH, Free T4 and Free and total T3
- Only Day 1 visit of each cycle

Table 14.3-2.5.1 – Summary of Urinalysis Laboratory Data
(Safety Population)

Replicate of Table 14.3-2.1.1

PROGRAMMING NOTES:
- Urinalysis parameters are Color, Turbidity, pH, Specific gravity, Glucose, Ketones, Nitrites, Bilirubin, Urobilirubin, Protein, RBCs, WBCs, Epithelial cells, Casts, Crystals, Bacteria, eGFR (Screening only)
- Replace 'Day 4' by 'Day 5' for each cycle

Table 14.3-2.5.2 – Outside of Normal Range - Shift Table for Urinalysis Laboratory Parameters
(Safety Population)

Replicate of Table 14.3-2.1.2

PROGRAMMING NOTES:
- Urinalysis parameters are Color, Turbidity, pH, Specific gravity, Glucose, Ketones, Nitrites, Bilirubin, Urobilirubin, Protein, RBCs, WBCs, Epithelial cells, Casts, Crystals, Bacteria, eGFR (Screening only)
- Replace 'Day 4' by 'Day 5' for each cycle

Table 14.3-2.5.3 – Clinician Assessment - Shift Table for Urinalysis Laboratory Parameters
(Safety Population)

Replicate of Table 14.3-2.1.3

PROGRAMMING NOTES:
- Urinalysis parameters are Color, Turbidity, pH, Specific gravity, Glucose, Ketones, Nitrites, Bilirubin, Urobilirubin, Protein, RBCs, WBCs, Epithelial cells, Casts, Crystals, Bacteria, eGFR (Screening only)
- Replace 'Day 4' by 'Day 5' for each cycle

Table 14.3-2.5.4 – On-study Urinalysis Adverse Events: Worst NCI-CTCAE Grade per patient
(Safety Population)

Replicate of Table 14.3-2.1.4

PROGRAMMING NOTES:

- Urinalysis parameters are Color, Turbidity, pH, Specific gravity, Glucose, Ketones, Nitrites, Bilirubin, Urobilirubin, Protein, RBCs, WBCs, Epithelial cells, Casts, Crystals, Bacteria, eGFR (Screening only)
- Replace 'Day 4' by 'Day 5' for each cycle

Table 14.3-2.5.5 – Shift table of Worst NCI-CTCAE Grade for Urinalysis Laboratory parameters
(Safety Population)

Replicate of Table 14.3-2.1.5

PROGRAMMING NOTES:

- Urinalysis parameters are Color, Turbidity, pH, Specific gravity, Glucose, Ketones, Nitrites, Bilirubin, Urobilirubin, Protein, RBCs, WBCs, Epithelial cells, Casts, Crystals, Bacteria, eGFR (Screening only)
- Replace 'Day 4' by 'Day 5' for each cycle

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of 1

Table 14.3-2.6 – Summary of Other Laboratory Data
(Safety Population)

Visit/ Parameter	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Screening visit							
HIV? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Hepatitis A? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Hepatitis B? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Hepatitis C? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pregnancy test? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cycle 1-Day 1							
Pregnancy test? [n (%)]							
No	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Yes	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<for Pregnancy test, repeat for Day 1 visit of each cycle>

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-3.1 – Summary of Vital Signs
(Safety Population)

Replicate of Table 14.3-2.1.1

PROGRAMMING NOTES:

- Update "laboratory parameter" by "parameter"
- Vital signs include pulse rate, blood pressure, respiratory rate, oxygen saturation and temperature
- On Days 1 and 5, vital signs are measured at pre-dose and at 6-hour intervals post-dose.

Table 14.3-3.2 – Summary of Abnormal Vital Signs
(Safety Population)

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Pulse rate (bpm)							
Cycle 1							
Baseline [a]*	XX	XX	XX	XX	XX	XX	XX
> 150 bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
[101-150] bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
< 55 bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Cycle 1-Day 2 *	XX	XX	XX	XX	XX	XX	XX
> 150 bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
[101-150] bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
< 55 bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

<repeat for next Cycle 1 visits>
<for Cycle 2 to last-1 Cycle, repeat for Day 1 visit to Day 6 visit>
<for the last Cycle, repeat for Day 1 visit to Day 6 visit, Day 22 visit and Day 28 follow-up visit>

* Denominator for the percentages.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
> 150 bpm: Very High values
[101-150] bpm: High values
< 55 bpm: Low values

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-3.2 - Summary of Abnormal Vital Signs
(Safety Population)

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Systolic Blood Pressure (mmHg)							
Baseline [a]*	XX	XX	XX	XX	XX	XX	XX
>= 161 mmHg	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
[131-160] bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
< 95 mmHg	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Cycle 1-Day 2 *	XX	XX	XX	XX	XX	XX	XX
>= 161 mmHg	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
[131-160] bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
< 95 mmHg	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

<repeat for next Cycle 1 visits>
<for Cycle 2 to last-1 Cycle, repeat for Day 1 visit to Day 6 visit>
<for the last Cycle, repeat for Day 1 visit to Day 6 visit, Day 22 visit and Day 28 follow-up visit>

* Denominator for the percentages.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
>= 161 bpm: Very High values
[131-160] bpm: High values
< 95 bpm: Low values

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-3.2 – Summary of Abnormal Vital Signs
(Safety Population)

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Diastolic Blood Pressure (mmHg)							
Baseline [a]*	XX	XX	XX	XX	XX	XX	XX
>= 101 mmHg	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
[86-100] bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
< 50 mmHg	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Cycle 1-Day 2 *	XX	XX	XX	XX	XX	XX	XX
>= 101 mmHg	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
[86-100] bpm	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
< 50 mmHg	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

<repeat for next Cycle 1 visits>
<for Cycle 2 to last-1 Cycle, repeat for Day 1 visit to Day 6 visit>
<for the last Cycle, repeat for Day 1 visit to Day 6 visit, Day 22 visit and Day 28 follow-up visit>

* Denominator for the percentages.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
>= 101 bpm: Very High values
[86-100] bpm: High values
< 50 bpm: Low values

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-4.1 – Summary of ECG Parameters
(Safety Population)

Replicate of Table 14.3-2.1.1

PROGRAMMING NOTES:

- Update "laboratory parameter" by "ECG parameter"
- Include all ECG parameters

Table 14.3-4.2 – Summary of Abnormal ECG Intervals
(Safety Population)

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
Heart rate (bpm)							
Baseline [a]*	XX	XX	XX	XX	XX	XX	XX
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Abnormal, NCS	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Abnormal, CS	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Cycle 1-Day 5 *	XX	XX	XX	XX	XX	XX	XX
Normal	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Abnormal, NCS	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Abnormal, CS	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

<for Cycle 2 to last-1 cycle, repeat for Day 1 visit>
<for last cycle, repeat for Day 1 visit and Day 28 follow-up visit>
<repeat for PR interval and QRS interval>

* Denominator for the percentages.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
CS = Clinically Significant; NCS = Not Clinically Significant.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-4.2 – Summary of Abnormal ECG Intervals
(Safety Population)

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=1	CPX-POM [D2] mg/m^2 N=X	CPX-POM [D3] mg/m^2 N=X	CPX-POM [D4] mg/m^2 N=X	CPX-POM [D5] mg/m^2 N=X	CPX-POM [D6] mg/m^2 N=X	CPX-POM [D7] mg/m^2 N=X
QTcB interval (msec)							
Baseline [a]*	XX	XX	XX	XX	XX	XX	XX
> 450 msec	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
> 480 msec	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
> 500 msec	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Cycle 1-Day 5 *	XX	XX	XX	XX	XX	XX	XX
> 450 msec	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
> 480 msec	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
> 500 msec	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
Change from Baseline to Cycle 1-Day 5 *	XX	XX	XX	XX	XX	XX	XX
> 30 msec	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
> 60 msec	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)

<for Cycle 2 to last-1 cycle, repeat for Day 1 visit>
<for last cycle, repeat for Day 28 follow-up visit>
<repeat for QTcF interval>

* Denominator for the percentages.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
CS = Clinically Significant; NCS = Not Clinically Significant.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES: For QTcF interval, the category '> 500 msec' will be replaced by '> 500 msec (CS)' and the category '> 60 msec' will be replaced by '> 60 msec (CS)'.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.1.7-1 – Treatment Administration
(All Patients)

Center/ Patient	Visit	CPX-POM Dose group	CPX-POM Dose Amount per Prot.?	If no, Reason for Adjustment?	Total Inf. Bag vol. of Sal. and CPX-POM (ml)	Was Total Vol. Inf.?	If no, actual Vol. Inf.?	Adm. Date (Day) Inf. Start Time-Inf. End Time	Arm Used for IV	Infusion Interrupted?
XXXXXXXX	BAS	30 mg/m^2	Yes		XXX	Yes		DDMMMYYYY (XX) HH:MM-HH:MM	Right	
	C1 TRT D2	30 mg/m^2	Yes		Yes	Yes		DDMMMYYYY (XX) HH:MM-HH:MM	Right	
	C1 TRT D3	30 mg/m^2	Yes		XXX	Yes		DDMMMYYYY (XX) HH:MM-HH:MM	Right	
	C1 TRT D4	30 mg/m^2	Yes		XXX	Yes		DDMMMYYYY (XX) HH:MM-HH:MM	Right	
	C1 TRT D5	30 mg/m^2	No	Adverse event	XXX	No	XXX	DDMMMYYYY (XX) HH:MM-HH:MM	Right	Yes [a]

<repeat for Days 1,2,3,4 and 5 of next cycles if relevant>

Prot.: Protocol; Inf.: Infusion/Infused; Vol.: Volume; Sal.: Saline; Adm.: Administration; Inter.: Interruption/Interrupted; IV: Intravenous
[a]: see further details regarding the infusion interruption in Listing 16.1.7-2

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:
- Listing to be sorted by increasing CPX-POM dose.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.1.7-2 – Infusion Interruption
(All Patients)

Center/ Patient	Visit	CPX-POM Dose group	Reason for Inf. Inter.?	Specify	Adm. Date (Day) Time Inf. Inter.	Inf. Rest.?	Time Inf. Restarted	Reason for Not Restarting?	Specify	Inf. Site React.?
XXXXXXXX	C1 TRT D5	30 mg/m^2	Infusion reaction	XXXXX	DDMMMYYYY (XX) HH:MM	No		Infusion reaction	XXXXX	Yes
XXXXXXXX	C2 TRT D2	[D2] mg/m^2	Technical problem	XXXXX	DDMMMYYYY (XX) HH:MM	Yes	HH:MM		XXXXX	No

<cont>

Inf.: Infusion; Inter.: Interrupted; Rest.: Restarted; React.: Reaction.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.1-1.1 – Preface to Inclusion and Exclusion Criteria

Protocol Version	Inclusion/ Exclusion No.	Inclusion / Exclusion Text
3.0	INCL01	Patient has histologically- or cytologically- confirmed metastatic or advanced-stage solid malignant tumor that is refractory to standard therapy. Patients should only be included if no therapy exists or if they have received all standard therapies that would be potentially curative or might provide significant benefit.
	INCL02	Patient may have received up to 4 prior lines of cytotoxic chemotherapy or immunotherapy for their metastatic disease (e.g., docetaxel + doxorubicin ± cyclophosphamide), and also may have received additional prior endocrine therapy, as appropriate (e.g., for breast or prostate cancer), or non-myelosuppressive therapy (e.g., bevacizumab, trastuzumab).
	<etc>	
	EXCL01	Patient has a history of risk factors for torsade de pointes (e.g., heart failure, hypokalemia, family history of long QT syndrome) or requires the use of concomitant medications that prolong the QT/QTc interval during study participation.
	EXCL02	Patient has an abnormal cardiac appearance/heart size, as evidenced by chest X-ray or computed tomography (CT) scan.
	<etc>	

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- List all Inclusion / Exclusion criteria as per eCRF.
- Note: Inclusion / Exclusion text displayed in the listing shell is based on the text in Protocol Version 3.0.

Listing 16.2.1-1.2 – List of Failed Inclusion and Exclusion Criteria
(All Patients)

Center/ Patient	CPX-POM Dose group	Protocol Version	Failed Inclusion / Exclusion
XXXX	[D3] mg/m^2	3.0	INCL01, INCL09 EXCL05, EXCL08, EXCl10
XXXX	[D5] mg/m^2	3.0	INCL02 EXCL03, EXCL07

<to be completed with the other patients having at least one protocol deviation>

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- List all Inclusion / Exclusion criteria that are failed (i.e. 'N' for inclusion and 'Y' for exclusion)
- Listing to be sorted by increasing CPX-POM dose.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.1-2 – Patient Disposition
(All Patients)

Center/ Patient	Country	CPX-POM Dose group	Date (day) of Discontinuation/ Completion	Reason for Discontinuation	Date (day) of Last Dose	Date (day) of Death	Reason
XXXX	XXX	30 mg/m^2	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		
XXXX	XXX	[D2] mg/m^2	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		
XXXX	XXX	[D3] mg/m^2	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		
XXXX	XXX	[D4] mg/m^2	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		
XXXX	XXX	[D4] mg/m^2	DDMMMYYYY (XXX)	Adverse Event	DDMMMYYYY (XXX)		
XXXX	XXX	[D4] mg/m^2	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		

<etc>

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.2 – Protocol Deviations
(All Patients)

Center/ Patient	CPX-POM Dose group	Category	Details	Leading to Exclusion from Analysis Population?	Analysis Population(s)
XXXX	[D4] mg/m^2	Compliance	Not treated	Yes	SAFETY

<to be completed with the other patients having at least one protocol deviation>

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.3-1 – Demographic and Baseline Characteristics
(All Patients)

Center/ Patient	Country	CPX-POM Dose group	Date of Birth	Age (year)	Sex	Race	Weight (kg)	Height (cm)	BMI (kg/m^2)	BSA (kgxm)	Patient of Child Bearing Potential?	Creat. Clear. (unit)
XXXX	XXX	30 mg/m^2	DDMMMYYYY	XX	Male	XXXXX	XXX.X	XXX	XX.X	XX.X		XXX
XXXX	XXX	[D2] mg/m^2	DDMMMYYYY	XX	Female	XXXXX	XXX.X	XXX	XX.X	XX.X	Yes	XXX
XXXX	XXX	[D3] mg/m^2	DDMMMYYYY	XX	Female	XXXXX	XXX.X	XXX	XX.X	XX.X	No	XXX
XXXX	XXX	[D4] mg/m^2	DDMMMYYYY	XX	Male	XXXXX	XXX.X	XXX	XX.X	XX.X		XXX
XXXX	XXX	[D4] mg/m^2	DDMMMYYYY	XX	Male	XXXXX	XXX.X	XXX	XX.X	XX.X		XXX
XXXX	XXX	[D4] mg/m^2	DDMMMYYYY	XX	Female	XXXXX	XXX.X	XXX	XX.X	XX.X	No	XXX

<etc>

Creat. Clear.: Creatinine Clearance.
Dates are displayed as DDMMMYYYY, -- represents an unknown date component. Age was calculated from date of birth and date of screening. BMI (kg/m²)= Weight (kg)/(Height (m)^2. BSA (kgxm) = 0.007184 x Weight (kg)^0.425 / (Height (m))^0.725 (Dubois formula).

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.3-2 – HIV, Hepatitis and Pregnancy Test Results
(All Patients)

Center/ Patient	CPX-POM Dose group	Visit	Parameter	Assessment Performed?	Assessment Date	Study Day	Result
XXXX	30 mg/m^2	SCR	HIV	Yes	DDMMMYYYY	XX	No
			Hepatitis A	Yes	DDMMMYYYY	XX	No
			Hepatitis B	Yes	DDMMMYYYY	XX	No
			Hepatitis C	Yes	DDMMMYYYY	XX	No
			Pregnancy Test	Yes	DDMMMYYYY	XX	No
		BAS	Pregnancy Test	Yes	DDMMMYYYY	XX	No

<repeat for Day 1 of next cycles if relevant>
<cont.>

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.4-1 - Cancer History
(All Patients)

Center/ Patient	CPX-POM Dose group	Cancer Type	If Other, specify	Initial Diagnosis Date (Day)	Disease Stage at Initial Diagnosis	Current Disease Stage	Pres. of Metas.?	Date of Metastatic Diagnosis (Day)	Location	If Other, specify
XXXX	30 mg/m^2	XXXXX		DDMMMYYYY (XXX)	Grade X	Grade X	No			
XXXX	[D2] mg/m^2	XXXXX		DDMMMYYYY (XXX)	Grade X	Grade X	No			
XXXX	[D3] mg/m^2	XXXXX		DDMMMYYYY (XXX)	Grade X	Grade X	Yes	DDMMMYYYY (XXX)	Bone	
XXXX	[D4] mg/m^2	XXXXX		-----YYYY	Grade X	Grade X	No			
XXXX	[D4] mg/m^2	Other	XXXXX	DDMMMYYYY (XXX)	Grade X	Grade X	Yes	DDMMMYYYY (XXX)	Other	XXXXX
XXXX	[D4] mg/m^2	XXXXX		-----YYYY	Grade X	Grade X	Yes	DDMMMYYYY (XXX)	Lungs Liver	

<etc>

Pres.: Presence; Metas.: Mestastases
Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.4-2 – Prior Cancer Therapies
(All Patients)

Center/ Patient	CPX-POM Dose group	Therapy Type	If Radiation, specify	Therapy Name	Line of Therapy	Treatment Setting	Treatment Intent	Start Date (Day) End Date (Day)	Best Response
XXXX	30 mg/m^2	XXXXX		XXXXX	X	XXXXX	XXXXX	DDMMMYYYY(XX) DDMMMYYYY(XX)	XXXXX
XXXX	[D2] mg/m^2	XXXXX		XXXXX	X	XXXXX	XXXXX	DDMMMYYYY(XX) DDMMMYYYY(XX)	XXXXX
XXXX	[D3] mg/m^2	Radiation	XXXXX	XXXXX	X	XXXXX	XXXXX	DDMMMYYYY(XX) DDMMMYYYY(XX)	XXXXX
<etc>									

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.4-3 – Other Medical History
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	System Organ Class/ Preferred Term/ Verbatim	Start Date (Day)	End Date (Day)	Treated with medication?
XXXX	XXXXXX/ XXXXX/ XXXXXXXXXXX	DDMMMYYYY (XXX)	DDMMMYYYY (XXX)	No
XXXX	XXXXXX/ XXXXX/ XXXXXXXXXXX	--MMMYYYY	Ongoing	Yes

<cont.>

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.
MedDRA <version no.>

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.4-4 – Cardiac Function
(All Patients)

Center/ Patient	CPX-POM Dose group	Echocardiogram or MUGA Scan performed?	Method of Assessment	Date of Assessment	Overall Interpretation	If Abnormal CS, specify
XXXX	30 mg/m^2	Yes	Echocardiogram	DDMMMYYYY	XXXXX	
XXXX	[D2] mg/m^2	Yes	MUGA	DDMMMYYYY	Abnormal CS	XXXXX
XXXX	[D3] mg/m^2	Yes	Echocardiogram	DDMMMYYYY	XXXXX	
<etc>						

CS: Clinically Significant. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.4-5 – Ophthalmologic Exam
(All Patients)

Center/ Patient	CPX-POM Dose group	Ophthalmology Assessments performed?	Use of Corrective Lenses?	Date of Assessment	Overall Interpretation	If Abnormal CS, specify
XXXX	30 mg/m^2	Yes	Yes	DDMMMYYYY	XXXXX	
XXXX	[D2] mg/m^2	Yes	No	DDMMMYYYY	Abnormal CS	XXXXX
XXXX	[D3] mg/m^2	Yes	No	DDMMMYYYY	XXXXX	
<etc>						

CS: Clinically Significant. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.4-6 – RECIST Target Lesions
(All Patients)

Center/ Patient	CPX-POM Dose group	Visit/ Target Lesions Identified at Screening Visit?	Date of Scans review	Lesion Number	Organ Site	Specific Location within the Organ Site	Lymph Node Type	Method	Lesion Diameter (mm)
XXXX	30 mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
				T02	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
			DDMMMYYYY	T02	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C3 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX

<etc>

CS: Clinically Significant. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.4-7 - RECIST Non-Target Lesions
(All Patients)

Center/ Patient	CPX-POM Dose group	Visit/ Non-Target Lesions Identified at Screening Visit?	Date of Scans review	Lesion Number	Organ Site	Specific Location within the Organ Site	Lymph Node Type	Method	Result
XXXX	30 mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
				NT02	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
				NT02	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
				NT03	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C3 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX

<etc>

CS: Clinically Significant. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.4-8 – Prior and Concomitant Medications
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	Type of Medication	Therapeutic Class Preferred Term Verbatim	Start Date (Day)/ End Date (Day)	Total Daily Dose (unit)/ Frequency/ Route	Reason/ Indication
XXXX		XXXXXX/ XXXXX/ XXXXXXXXXXX	DDMMMYYYY (<-180)/ DDMMMYYYY (XXX)	XXXXXXXX (XXX)/ Once/ Inhalation	XXXXXXXXXXXX
	Conc.** Proh. [a]	XXXXXX/ XXXXX/ XXXXXXXXXXX	--MMMYYYY/ Ongoing	Other, XXXX/ bid/ Cutaneous	XXXXXX
XXXX	Prior*	XXXXXX/ XXXXX/ XXXXXXXXXXX	--MMMYYYY/ DDMMMYYYY (XXX)	200 mg/ tid/ Other, XXXXX	XXXXXXXXXXXXXXXXXX

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.
* Prior = any medication whose end date is before the date of first dose.
** Conc. = any medication that started before the date of first dose and stopped on (or is ongoing after) the date of first dose OR any medication whose start date is either the same as (or after) the date of first dose.
[a] Proh. = Prohibited medication.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.
- Use abbreviations or codes to present data if not enough space (and add appropriate abbreviations / codes in footnotes).

Listing 16.2.5 – Drug Exposure
(All Patients)

Center/ Patient	CPX-POM Dose group	Date of first dose admnistration	Visit of last dose admnistration	Date of last dose admnistration	Exposure (days)	Exposure (mg)
XXXX	30 mg/m^2	DDMMMYYYY	C1 TRT D5	DDMMMYYYY	XX	XX
XXXX	[D2] mg/m^2	DDMMMYYYY	C2 TRT D5	DDMMMYYYY	XX	XX

<cont.>

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY.
The CPX-POM exposure expressed in days is defined as the number of days between the first dose taken date and the last dose taken date + 1 day.
The CPX-POM exposure expressed in mg is defined as: dose per m^2 x Body Surface Area x CPX-POM exposure expressed in days.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Listing to be sorted by increasing CPX-POM dose.

Listing 16.2.6-1 – Urine concentrations of CPX-POM and Metabolites
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	Parameter (Unit)	Visit	Assessment Sample	___Assessment__ Date	Time	Study Day	Urine Volume (mL)	CPX-POM Conc. (ng/mL)	CPX Conc. (ng/mL)	CPX-G Conc. (ng/mL)
	CPX-POM									
XXXX	(XXXX)	C1 TRT D1	Pre-Dose	DDMMMYYYY	HH:MM		XX	XX	XX	XX
			Post-Dose [0-12]	DDMMMYYYY	HH:MM		XX	XX	XX	XX
			Post-Dose [12-24]	DDMMMYYYY	HH:MM		XX	XX	XX	XX
		C1 TRT D5	Post-Dose [0-12]	DDMMMYYYY	HH:MM	XX	XX	XX	XX	XX
			Post-Dose [12-24]	DDMMMYYYY	HH:MM	XX	XX	XX	XX	XX

Conc.: Concentration.
Study Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component. Baseline was the last non-missing assessment prior or on the first dose date. SI units and results presented.
ND = Not Done.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

-

Listing 16.2.6-2 – Plasma concentrations of CPX-POM and Metabolites
(All Patients)

Replicate of Listing 16.2.6-1

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.6-3 – Plasma concentrations of Biomarkers Assays
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	Parameter (Unit)	Visit	Assessment Sample	Assessment Date	Assessment Time	Study Day	VEGF Conc. (pg/mL)	Percent change from Baseline	IL-6 Conc. (pg/mL)	Percent change from Baseline	IL-8 Conc. (pg/mL)	Percent change from Baseline
XXXX	CPX-POM(XXXX)	C1 TRT D1	Pre-Dose	DDMMMYYYY	HH:MM		XX		XX		XX	
		C1 TRT D5	Pre-Dose	DDMMMYYYY	HH:MM	XX	XX	XX.X	XX	XX.X	XX	XX.X

<repeat for Day 1 and Day 5 visits of next cycles if relevant>
<repeat for Day 22 visit of last cycle>

Conc.: Concentration.
The Baseline concentrations are the concentrations obtained at Day 1 Visit of Cycle 1.
Study Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component. Baseline was the last non-missing assessment prior or on the first dose date. SI units and results presented.
ND = Not Done.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all doses groups.

Listing 16.2.6-4 – PBMC Biomarkers Assays
(All Patients)

Replicate of Listing 16.2.6-3

PROGRAMMING NOTES:

- PBMC Biomarkers are Notch 1, surviving, cyclin D, c-Myc and Hes 1 using RT-PCR.
- Repeat for all doses groups.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.6-5 – Urine beta-glucuronidase activity
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	Parameter (Unit)	Visit	Assessment Sample	___Assessment__ Date	Time	Study Day	Urine beta-glucuronidase activity (U/mL)
XXXX	CPX-POM (XXXX)	C1 TRT D1	Post-Dose [0-12]	DDMMMYYYY	HH:MM		XX
			Post-Dose [12-24]	DDMMMYYYY	HH:MM		XX
		C1 TRT D5	Post-Dose [0-12]	DDMMMYYYY	HH:MM	XX	XX
			Post-Dose [12-24]	DDMMMYYYY	HH:MM	XX	XX

Study Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component. Baseline was the last non-missing assessment prior or on the first dose date. SI units and results presented. ND = Not Done.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all doses groups.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.7-1 – Adverse Events
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	System Organ Class/ Preferred Term/ Verbatim	Start Date (Day)/ End Date (Day)	Action Taken/ Medication or Therapies Taken?	Outcome/ Severity/ Relationship	SAE?
XXXX	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXX	DDMMMYYYY (XXX)/ DDMMMYYYY (XXX)	None/ No	XXXXXXXX/ Mild/ Not related	No
	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXX	DDMMMYYYY (XXX)/ Ongoing	Dose Adjusted/ Yes	Resolved/ Moderate/ Definitely related	Yes
XXXX	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXX	DDMMMYYYY (XXX)/ --MMMYYYY		XXXXXXXX/ XXXXXX/ XXXXXXX	No

<cont.>

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.
MedDRA version <version #>.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for the other CPX-POM doses by increasing order.

Listing 16.2.7-2 – Serious Adverse Events
(All Patients)

Replicate of Listing 16.2.7-1

PROGRAMMING NOTES:

- Repeat for the other CPX-POM doses by increasing order.
- Select all AEs where SAE = Yes.
- Remove column 'SAE' and remove SAE from footnote.

Listing 16.2.7-3 – Adverse Events Leading to Discontinuation
(All Patients)

Replicate of Listing 16.2.7-1

PROGRAMMING NOTES:

- Repeat for the other CPX-POM doses by increasing order.
- Select all AEs where action taken = permanently discontinued.

Listing 16.2.7-4 – Adverse Events Leading to Death
(All Patients)

Replicate of Listing 16.2.7-1

PROGRAMMING NOTES:

- Repeat for the other CPX-POM doses by increasing order.
- Select all AEs where outcome = Fatal

Listing 16.2.8-1 – Patients Laboratory Profile: Hematology
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	Visit	Assessment Date	Assessment Time	Study Day	Parameter (Unit)	Normal Range	Result	CTCAE grade	Change from Baseline	Clinical Interpretation
XXXX	BAS	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX	Grade 1		Normal
	C1 TRT D1	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX L/H	Grade 2	XXXX	Abnormal, NCS
	C1 TRT D4	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX L/H	Grade 2	XXXX	Abnormal, NCS
	C1 TRT D10	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX L/H	Grade 3	XXXX	Abnormal, CS

<for Cycle 2 to last-1 cycle, repeat for Day 1 visit and Day 4 visit if relevant>
<for the last cycle, repeat also for Day 22 visit and Day 28 visit>

Study Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component. Baseline was the last non-missing assessment prior or on the first dose date. SI units and results presented. L/H = low/high value based upon normal ranges. R = repeat/unscheduled assessments. CS = Clinically Significant; NCS = Not Clinically Significant; ND = Not Done.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for the other CPX-POM doses by increasing order.

Listing 16.2.8-2 – Patients Laboratory Profile: Clinical Chemistry
(All Patients)

Replicate of Listing 16.2.8-1

PROGRAMMING NOTES:
- Listing to be sorted by increasing order.

Listing 16.2.8-3 – Patients Laboratory Profile: Coagulation and Thyroid Panel
(All Patients)

Replicate of Listing 16.2.8-1

PROGRAMMING NOTES:
- Listing to be sorted by increasing order.
- Only Day 1 of each cycle.

Listing 16.2.8-4 – Patients Laboratory Profile: Urinalysis
(All Patients)

Replicate of Listing 16.2.8-1

PROGRAMMING NOTES:
- Listing to be sorted by increasing order.
- Replace 'Day 4' by 'Day 5' for each cycle.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.8-5 – Vital Signs
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	Visit	___Assessment__ Date Time	Study Day	Parameter (unit)	Position	Result	Change from Baseline
XXXX	BAS	DDMMMYYYY HH:MM	XXX	Pulse Rate (bpm)	Supine	XXX +	
				Respiratory Rate (bpm)	Supine	XXX	
				Systolic BP (mmHg)	Supine	XXX	
				Diastolic BP (mmHg)	Supine	XXX	
				Oxygen Saturation (mmHg)		XXX	
				Body Weight (kg)		XXX.X	
				Temperature (C)		XX.X	
	C1 TRT D2	DDMMMYYYY HH:MM	XXX	Pulse Rate (bpm)	Supine	XXX +	XX
				Respiratory Rate (bpm)	Supine	XXX	XX
				Systolic BP (mmHg)	Supine	XXX	XX
				Diastolic BP (mmHg)	Supine	XXX	XX
				Oxygen Saturation (mmHg)		XXX	XX
				Body Weight (kg)		XXX.X	X.X
				Temperature (C)		XX.X	X.X

<repeat for Day 3, Day 4, Day 5, Day 6 and Day 10 visits of Cycle 1>
<for Cycle 2 to last-1 cycle, repeat from Day 1 to Day 6 visits if relevant>
<for the last cycle, repeat also for Day 22 visit and Day 28 follow-up visit>

Study Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY. Baseline was the last non-missing assessment prior or on the first dose.
+ Results of clinical importance (see SAP). BP = Blood Pressure; bpm = beats per minute; ND = Not Done.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all doses groups

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of X

Listing 16.2.8-6 – ECG Results and Interpretation
(All Patients)

CPX-POM Dose Group: 30 mg/m^2

Center/ Patient	Visit	Assessment Date (Day)	Parameter (unit)	Clinician Interpretation	Result	Change from baseline
XXXX	BAS	DDMMMYYYY (XXX)	Heart Rate (bpm)	Normal	XXX	
			PR interval (msec)	Normal		
			QRS duration (msec)	Normal		
			QT interval (msec)	Normal		
			QTcB interval (msec)	Normal		
			QTcF interval (msec)	Normal		
	C1 TRT D5	DDMMMYYYY (XXX)	Heart Rate (bpm)	Abnormal, Clinical Significant	XXX ++	XX *
			PR interval (msec)	Normal		
			QRS duration (msec)	Normal		
			QT interval (msec)	Normal		
			QTcB interval (msec)	Abnormal, Not Clinical Significant	XXX +	
			QTcF interval (msec)	Abnormal, Not Clinical Significant	XXX +	

<for Cycle 2 to last-1 cycle, repeat for Day 1 visit if relevant>
<for the last cycle, repeat also for Day 28 follow-up visit>

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY. Baseline was the last non-missing assessment prior or on the first dose date.
QTcB and QTcF: +: >450 msec; ++: > 480 msec; +++: >500 msec; *: > 30 msec above baseline; **: > 60 msec above baseline.
R = repeated/ unscheduled assessment.

Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

PROGRAMMING NOTES:

- Repeat for all dose groups.