SPONSOR:

CicloMed

PROTOCOL NUMBER:

CPX-POM-001

STATISTICAL ANALYSIS PLAN (TFL shells)

Author:	
Version:	Version 2.0
Date:	03Nov2021

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 2.0

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

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	Medical Advisor		

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	Chief Scientific Officer CicloMed LLC		

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	CPX-POM 30 mg/m^2 N=X	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 1 [n (%)]							
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] [c]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cycle 2 [n (%)]							
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] [c]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

<repeat until last cycle>

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).
[b] A patient completed Cycle 2 (or any next cycle) if s/he attended visit Day 6 (if Cycle 2 or any next cycle was not the last cycle).
[c] A patient completed the Last Cycle if s/he attended the last visit of the cycle (visit Day 10 for Cycle 1 or visit Day 6 for Cycle 2 or any next cycle) and if s/he attended the final visit at least 22 days after the first dose in the last cycle.
[d] Calculated as [(Date of end of study – Date of first dose) + 1]/30.4375.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

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	CPX-POM 30 mg/m^2 N=X	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
Reason for end of study [n (%)]							
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Dose Limitimg Toxicity	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)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pregnancy							
Withdrawn Consent	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) [n (%)]	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Time on study (Months) [d]							
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

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).
[b] A patient completed Cycle 2 (or any next cycle) if s/he attended visit Day 6 (if Cycle 2 or any next cycle was not the last cycle).
[c] A patient completed the Last Cycle if s/he attended the last visit of the cycle (visit Day 10 for Cycle 1 or visit Day 6 for Cycle 2 or any next cycle) and if s/he attended the final visit at least 22 days after the first dose in the last cycle.
[d] Calculated as [(Date of end of study – Date of first dose) + 1]/30.4375.
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 Y
Extract date: DDMMMYYYY

Table 14.1-1.2 - Patients disposition
(All Patients Enrolled) - Expansion

	Cisplatin ineligible N=X	Chemotherapy eligible N=X	Overall N=X
Cycle 1 [n (%)])			
Treated	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)
Cycle 2 [n (%)])			
Treated	XX (XX.X)	XX (XX.X)	XX (XX.X)
Completed the cycle [b]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cycle 3 [n (%)] [d]		XX (XX.X)	XX (XX.X)
Treated		XX (XX.X)	XX (XX.X)
Completed the cycle [c]		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 6.
[b] A patient completed Cycle 2 if s/he attended visit Day 26.
[c] A patient completed Cycle 3 if s/he attended visit Day 48.
[d] Applicable to Chemotherapy eligible group only.
[e] A patient completed the study if s/he completed 2 cycles (cisplatin-ineligible patients) or 3 cycles (chemotherapy eligible patients) and had radical cystectomy.
[f] Calculated as [(Date of end of study - Date of first dose) + 1]/30.4375.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

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Table 14.1-1.2 - Patients disposition
(All Patients Enrolled) - Expansion

	Cisplatin ineligible N=X	Chemotherapy eligible N=X	Overall N=X
Completed end of treatment visit (Day 42 or Day 64) [n (%)]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Discontinued from treatment [n (%)]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason for discontinuation from the treatment [n (%)]			
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
Dose Limitimg Toxicity	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)
Withdrawn Consent	XX (XX.X)	XX (XX.X)	XX (XX.X)
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)
Undergone radical cystectomy (Day 56 or Day 78) [n (%)]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Completed the study [e]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Completed at least one follow-up visit [n (%)]	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 6.
[b] A patient completed Cycle 2 if s/he attended visit Day 26.
[c] A patient completed Cycle 3 if s/he attended visit Day 48.
[d] Applicable to Chemotherapy eligible group only.
[e] A patient completed the study if s/he completed 2 cycles (cisplatin-ineligible patients) or 3 cycles (chemotherapy eligible patients) and had radical cystectomy.
[f] Calculated as [(Date of end of study - Date of first dose) + 1]/30.4375.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

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Table 14.1-1.2 - Patients disposition
(All Patients Enrolled) - Expansion

	Cisplatin ineligible N=X	Chemotherapy eligible N=X	Overall N=X
Reason for end of study [n (%)]			
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)
Withdrawn Consent	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)
Time on study (Months) [f]			
n	XX	XX	XX
Mean	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX
Median	XX.X	XX.X	XX.X
Maximum	XX	XX	XX

Percentages are based on the number of patients enrolled.
[a] A patient completed Cycle 1 if s/he attended visit Day 6.
[b] A patient completed Cycle 2 if s/he attended visit Day 26.
[c] A patient completed Cycle 3 if s/he attended visit Day 48.
[d] Applicable to Chemotherapy eligible group only.
[e] A patient completed the study if s/he completed 2 cycles (cisplatin-ineligible patients) or 3 cycles (chemotherapy eligible patients) and had radical cystectomy.
[f] Calculated as [(Date of end of study - Date of first dose) + 1]/30.4375.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

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Table 14.1-2.1 - Number (%) of Patients in the Analysis Populations
(All Patients Enrolled) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X 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)

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.

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

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Table 14.1-2.2 - Number (%) of Patients in the Analysis Populations
(All Patients Enrolled) - Expansion

	Cisplatin ineligible N=X n (%)	Chemotherapy eligible N=X n (%)	Overall N=X n (%)
Safety Population	XX (XX.X)	XX (XX.X)	XX (XX.X)
Efficacy Population	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 and had available tumor tissue at baseline and at the time of radical cystectomy.
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.

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Table 14.1-3.1 - Summary of Demographic and Baseline Characteristics
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
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.
[d] Body Surface Area (BSA) (m^2) = 0.007184 x Weight (kg)^0.425 x (Height (m))^0.725 (Dubois formula).

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

Table 14.1-3.1 - Summary of Demographic and Baseline Characteristics
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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 beari potential [n (%)] [c]							
Able to bear childr	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Premenarche	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Post Menopausal	XX (XX.X)	XX (XX.X)	XX(XX.X)	XX (XX.X)	XX(XX.X)	XX(XX.X)	XX(XX.X)
Sterile - of child bearing age	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.
[d] Body Surface Area (BSA) (m^2) = 0.007184 x Weight (kg)^0.425 x (Height (m))^0.725 (Dubois formula).

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

Table 14.1-3.1 - Summary of Demographic and Baseline Characteristics
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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] (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

[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) (m^2) = 0.007184 x Weight (kg)^0.425 x (Height (m))^0.725 (Dubois formula).

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

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Table 14.1-3.1 - Summary of Demographic and Baseline Characteristics
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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
ECOG [n (%)]							
0 (Fully active)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 (Unable to perform physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2 (Ambulatory and capable of all selfcare but unable to carry out any work activities)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3 (Capable of only limited selfcare)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4 (Completely disabled)	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/m^2) = Weight (kg) / (Height (m))^2.
[c] The denominator is the number of females in each dose group.
[d] Body Surface Area (BSA) (m^2) = 0.007184 x Weight (kg)^0.425 x (Height (m))^0.725 (Dubois formula).

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 14.1-3.2 - Summary of Demographic and Baseline Characteristics
(Safety Population) - Expansion

Replicate of Table 14.1-3.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

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Table 14.1-4.1 - Important Protocol Deviations
(Safety Population) - Dose Escalation

Protocol Deviations Category	CPX-POM 30 mg/m^2 N=X 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 Important 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.
- A last column with the header 'CPX-POM All Doses' will also be displayed.

Table 14.1-4.2 - Important Protocol Deviations
(Safety Population) - Expansion

Replicate of Table 14.1-4.1

PROGRAMMING NOTES:
- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of 4
Extract date: DDMMMYYYY

Table 14.1-5.1.1 - Disease Characteristics
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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
Primary Tumor Site [n (%)]							
Bladder Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Breast Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Colon Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gastric Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Head and Neck Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Liver	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ovarian	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)
…	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 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)
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)

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

Table 14.1-5.1.1 - Disease Characteristics
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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
Extent of Current Metastatic disease							
Abdomen/Viscera? [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)
Adrenals? [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)
Bladder? [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)
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)
Bone Marrow? [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)
Chest Wall? [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)
CNS/Brain? [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)
Kidnet? [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)

Table 14.1-5.1.1 - Disease Characteristics
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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
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)
Lymp 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)
Pancreas? [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)
Peritoneal? [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)
Plura? [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)
Stomach? [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)
Spleen? [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)

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

Table 14.1-5.1.2 - Disease Characteristics
(Safety Population) - Expansion

	Cisplatin ineligible N=X n (%)	Chemotherapy eligible N=X n (%)	Overall N=X n (%)
Dose expansion Arm			
Cisplatin-ineligible patient	XX (XX.X)	XX (XX.X)	XX (XX.X)
Chemotherapy-eligible patient	XX (XX.X)	XX (XX.X)	XX (XX.X)
Reason [a]			
Creatinine clearance < 60 mL/min	XX (XX.X)		XX (XX.X)
Heart failure (NYHA class >=III)	XX (XX.X)		XX (XX.X)
Grade >=2 hearing loss	XX (XX.X)		XX (XX.X)
Grade >=2 neuropathy	XX (XX.X)		XX (XX.X)
Other	XX (XX.X)		XX (XX.X)
Screening eGFR (mL/min/1.73m2)			
n	XX	XX	XX
Mean	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX
Minimum	XX	XX	XX
Median	XX.X	XX.X	XX.X
Maximum	XX	XX	XX

eGFR = estimated Glomerular Filtration Rate.
[a] Applicable to Cisplatin ineligible group only .

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

Table 14.1-5.2.1 - Other Medical History
(Safety Population) - Dose Escalation

System Organ Class/ Preferred Term	CPX-POM 30 mg/m^2 N=X 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.
- A last column with the header 'CPX-POM All Doses' will also be displayed.

Table 14.1-5.2.2 - Other Medical History
(Safety Population) - Expansion

Replicate of Table 14.1-5.2.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.1-5.3.1 - Concomitant Diseases
(Safety Population) - Dose Escalation

Replicate of Table 14.1-5.2.1

PROGRAMMING NOTES:

- Add footnote: 'Events with both start and end dates missing were considered as concomitant.'

Table 14.1-5.3.2 - Concomitant Diseases
(Safety Population) - Expansion

Replicate of Table 14.1-5.3.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

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

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

Therapeutic Class/ Preferred Term	CPX-POM 30 mg/m^2 N=X 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.
- A last column with the header 'CPX-POM All Doses' will also be displayed.

Table 14.1-6.1.2 - Prior Medications by Therapeutic Class and Preferred Term
(Safety Population) - Expansion

Replicate of Table 14.1-6.1.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.1-6.2.1 - Concomitant Medications by Therapeutic Class and Preferred Term
(Safety Population) - Dose Escalation

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.

Table 14.1-6.2.2 - Concomitant Medications by Therapeutic Class and Preferred Term
(Safety Population) - Expansion

Replicate of Table 14.1-6.2.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of 1
Extract date: DDMMMYYYY

Table 14.1-7.1 - Overall Exposure to Study Drug and Drug Compliance
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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 calculated from the dose administration entered in the database as (last dose taken date - first dose taken date + 1) + 16.
[b] The CPX-POM exposure expressed in mg is calculated from the dose per m^2 entered in the database as the sum of all (dose per m^2 x Body Surface Area), using Body Surface Area calculated at baseline for Cycle 1 and Cycle 2 dose administrations, and calculated on Day 1 of every other treatment cycle from Cycle 3 dose administration.

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 14.1-7.2 - Overall Exposure to Study Drug and Drug Compliance
(Safety Population) - Expansion

Replicate of Table 14.1-7.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Tables 14.2

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

Table 14.2-1.1 - Patients who have had at least one other post-baseline tumor assessment
(Efficacy Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X	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 Type [n (%)]							
Bladder Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Breast Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Carcinomatosis	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Colon Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Pancreatic Cancer	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>							

Note: A subject with overall response but no detailed tumor assessments is considered as having tumor assessment in this table.

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
Extract date: DDMMMYYYY

Table 14.2-2.1 - Summary of Patients Responses
(Efficacy Population) - Dose Escalation

Visit/ Type of Response	CPX-POM 30 mg/m^2 N=X	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>

Percentage was based on the number of patients with non-missing tumor assessment at each visit.

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 ----
Extract date: DDMMMYYYY

Table 14.2-3.2 - Recurrence-Free Survival (RFS)
(Efficacy Population) - Expansion

	Cisplatin ineligible N=X	Chemotherapy eligible N=X	Overall N=X
Included in the analysis	XX	XX	XX
No. of events (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No. of censored observations (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Recurrence-Free Survival Time (Months) [a]			
Minimum	XX.X	XX.X	XX.X
25% quartile	XX.X	XX.X	XX.X
Median (95% CI) [b]	XX.X (XX.X; XX.X)	XX.X (XX.X; XX.X)	XX.X (XX.X; XX.X)
75% quartile	XX.X	XX.X	XX.X
Maximum	XX.X	XX.X	XX.X
KM probability estimate for Recurrence-Free Survival rate (95% CI) [c]			
3 months	XX.X (XX.X; XX.X)	XX.X (XX.X; XX.X)	XX.X (XX.X; XX.X)
6 months	XX.X (XX.X; XX.X)	XX.X (XX.X; XX.X)	XX.X (XX.X; XX.X)
12 months	XX.X (XX.X; XX.X)	XX.X (XX.X; XX.X)	XX.X (XX.X; XX.X)
…			

[a] Kaplan-Meier estimates.

[b] 95% confidence interval (CI) for median recurrence-free survival is calculated using the Brookmeyer and Crowley method.

[c] Probability estimates are based upon Kaplan-Meier estimates and 95% CI use the log-log transformation.

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

PROGRAMMING NOTES:

- If the median time to event has not been reached, present as "NR (xx.x, xx.x)" [replacing xx.x with '-' if there is no upper or lower confidence limit].
- Time categories to be updated dependent upon the data.

Table 14.2-4.2 - Overall Survival (OS)
(Efficacy Population) - Expansion

Replicate of Table 14.2-3.2

PROGRAMMING NOTES:

- Replace 'Recurrence-Free Survival' by 'Overall Survival' in the table and footnotes.

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Table 14.2-5.2 - Patients who Undergo Radical Cystectomy
(Efficacy Population) - Expansion

	Cisplatin ineligible N=X n (%)	Chemotherapy eligible N=X n (%)	Overall N=X n (%)
Number of patients who undergo radical cystectomy	XX (XX.X)	XX (XX.X)	XX (XX.X)

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

Tables 14.3

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Extract date: DDMMMYYYY

Table 14.3-1.0 - Dose-Limiting Toxicity (DLT)
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X 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 DLT	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

MedDRA version <version number>.

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 1
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Table 14.3-1.1.1 - Overview of Adverse Events
(Safety Population) - Dose Escalation

	CPX-POM 30 mg/m^2 N=X 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 patie 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 that 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.

Table 14.3-1.1.2 - Overview of Adverse Events
(Safety Population) - Expansion

Replicate of Table 14.3-1.1.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.
- Replace footnote '* A treatment-emergent adverse events (TEAE) is defined as an adverse event that started on or after the first dose of CPX-POM administration' by '* A treatment-emergent adverse events (TEAE) is defined as an adverse event that started on or after the first dose of CPX-POM administration and before the date of the last CPX-POM dose + 30 days or the date of start of a new anti-cancer therapy or the date of radical cystectomy, whichever occurs first.'

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Table 14.3-1.2.1 - Number (%) of Patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Dose Escalation

System Organ Class Preferred Term	CPX-POM 30 mg/m^2 N=X 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) and the Preferred Terms within a System Organ Class are presented by decreasing frequency (within the total column - all CPX-POM doses groups combined).
- A last column with the header 'CPX-POM All Doses' will also be displayed.

Table 14.3-1.2.2 - Number (%) of Patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population) - Expansion

Replicate of Table 14.3-1.2.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-1.3.1 - Number (%) of Patients with Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population) - Dose Escalation

Replicate of Table 14.3-1.2.1

PROGRAMMING NOTES:

- Adjust footnote to mention 'related TEAE' instead of 'TEAE'.

Table 14.3-1.3.2 - Number (%) of Patients with Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population) - Expansion

Replicate of Table 14.3-1.3.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-1.4.1 - Number (%) of Patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population) - Dose Escalation

Replicate of Table 14.3-1.2.1

PROGRAMMING NOTES:

- Adjust footnote to mention 'serious TEAE' instead of 'TEAE'.

Table 14.3-1.4.2 - Number (%) of Patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population) - Expansion

Replicate of Table 14.3-1.4.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-1.5.1 - Number (%) of Patients with Serious Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population) - Dose Escalation

Replicate of Table 14.3-1.2.1

PROGRAMMING NOTES:

- Adjust footnote to mention 'serious related TEAE' instead of 'TEAE'.

Table 14.3-1.5.2 - Number (%) of Patients with Serious Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Population) - Expansion

Replicate of Table 14.3-1.5.1

PROGRAMMING NOTES:
- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-1.6.1 - Number (%) of Patients with Treatment-Emergent Adverse Events Leading to Discontinuation by System Organ Class and Preferred Term
(Safety Population) - Dose Escalation

Replicate of Table 14.3-1.2.1

PROGRAMMING NOTES:
- "Leading to discontinuation" is derived from Did AE lead to study discontinuation? = Yes.
- Adjust footnote to mention 'TEAE leading to discontinuation' instead of 'TEAE'.

Table 14.3-1.6.2 - Number (%) of Patients with Treatment-Emergent Adverse Events Leading to Discontinuation by System Organ Class and Preferred Term
(Safety Population) - Expansion

Replicate of Table 14.3-1.6.1

PROGRAMMING NOTES:
- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-1.7.1 - Number (%) of Patients with Related Treatment-Emergent Adverse Events Leading to Discontinuation by System Organ Class and Preferred Term
(Safety Population) - Dose Escalation

Replicate of Table 14.3-1.2.1

PROGRAMMING NOTES:

- "Leading to discontinuation" is derived from Did AE lead to study discontinuation? = Yes.
- Adjust footnote to mention 'related TEAE leading to discontinuation' instead of 'TEAE'.

Table 14.3-1.7.2 - Number (%) of Patients with Related Treatment-Emergent Adverse Events Leading to Discontinuation by System Organ Class and Preferred Term
(Safety Population) - Expansion

Replicate of Table 14.3-1.7.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

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Table 14.3-1.8.1 - Number (%) of Patients with Treatment-Emergent Adverse Events
by System Organ Class, Preferred Term and Maximal Severity
(Safety Population) - Dose Escalation

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

System Organ Class Preferred Term Maximal severity	Any CTC grade n (%)	CTC grade 1 n (%)	CTC grade 2 n (%)	CTC grade 3 n (%)	CTC grade 4 n (%)	CTC grade 5 n (%)
Number of patients with any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #1						
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class #2						
Preferred Term #1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Preferred Term #3	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
<etc>	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 alphabetically.
- 'CPX-POM All Doses' will also be displayed.

Table 14.3-1.8.2 - Number (%) of Patients with Treatment-Emergent Adverse Events
by System Organ Class, Preferred Term and Maximal Severity
(Safety Population) - Expansion

Replicate of Table 14.3-1.8.1

PROGRAMMING NOTES:

- Include three groups: 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-1.9.1 - Number (%) of Patients with Related Treatment-Emergent Adverse Events
by System Organ Class, Preferred Term and Maximum Severity
(Safety Population) - Dose Escalation

Replicate of Table 14.3-1.8

PROGRAMMING NOTES:

- Adjust footnote to mention 'related TEAE' instead of 'TEAE'.

Table 14.3-1.9.2 - Number (%) of Patients with Related Treatment-Emergent Adverse Events
by System Organ Class, Preferred Term and Maximum Severity
(Safety Population) - Expansion

Replicate of Table 14.3-1.9.1

PROGRAMMING NOTES:

- Include three groups: 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

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

Table 14.3-2.1.1.1 - Summary of Hematology Laboratory Data
(Safety Population) - Dose Escalation

Laboratory Parameter: Hemoglobin (unit)

	CPX-POM 30 mg/m^2 N=X	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
BAS [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
C1 TRT D4							
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 BAS to C1 TRT D4							
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 and Differential (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils).
- A last column with the header 'CPX-POM All Doses' will also be displayed.

Table 14.3-2.1.1.2 - Summary of Hematology Laboratory Data
(Safety Population) - Expansion

Replicate of Table 14.3-2.1.1.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

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Table 14.3-2.1.2.1 - Outside of Normal Range - Shift Table for Hematology Laboratory Parameters (Safety Population) - Dose Escalation

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

Parameter/ Visit	Value at Visit	Baseline [a] value				
		Low n (%)	Normal n (%)	High n (%)	Low/High* n (%)	Total
Hemoglobin (unit)						
C1 TRT D4 (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 (XXX.X)
C1 TRT D10 (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 (XXX.X)

<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.
* Includes 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.

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

PROGRAMMING NOTES:

- Repeat for all doses groups, including 'CPX-POM All Doses'.
- Repeat for all hematology parameters: Hemoglobin, Hematocrit, Platelet count, RBC count, Reticulocytes, WBC Count and Differential (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils).

Table 14.3-2.1.2.2 - Outside of Normal Range - Shift Table for Hematology Laboratory Parameters (Safety Population) - Expansion

Replicate of Table 14.3-2.1.2.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

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

Table 14.3-2.1.3.1 - On-treatment Hematology Adverse Events: Worst NCI-CTCAE Grade per patient (Safety Population) - Dose Escalation

Parameter/ Worst NCI-CTCAE grade	CPX-POM 30 mg/m^2 N=X 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>

A patient with multiple results for a parameter will only be counted once under the maximum NCI-CTCAE grade for this parameter.
Laboratory ranges are based on NCI-CTCAE version 4.03.

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

PROGRAMMING NOTES:

- Repeat for all gradable hematology parameters.
- A last column with the header 'CPX-POM All Doses' will also be displayed.

Table 14.3-2.1.3.2 - On-treatment Hematology Adverse Events: Worst NCI-CTCAE Grade per patient (Safety Population) - Expansion

Replicate of Table 14.3-2.1.3.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Protocol: CPX-POM-001
Extract date: DDMMMYYYY --- DELIVERY TYPE ----

Table 14.3-2.1.4.1 - Shift table of Worst NCI-CTCAE Grade for Hematological parameters (Safety Population) - Dose Escalation

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

		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>

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 4.03.

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

PROGRAMMING NOTES:

- Repeat for all doses groups, including 'CPX-POM All Doses'.
- Repeat for all gradable hematology parameters.

Table 14.3-2.1.4.2 - Shift table of Worst NCI-CTCAE Grade for Hematological parameters (Safety Population) - Expansion

Replicate of Table 14.3-2.1.4.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-2.2.1.1 - Summary of Clinical Chemistry Laboratory Data
(Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.1.1

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

Table 14.3-2.2.1.2 - Summary of Clinical Chemistry Laboratory Data
(Safety Population) - Expansion

Replicate of Table 14.3-2.1.1.2

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

Table 14.3-2.2.2.1 - Outside of Normal Range - Shift Table for Clinical Chemistry Laboratory Parameters
(Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.2.1

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

Table 14.3-2.2.2.2 - Outside of Normal Range - Shift Table for Clinical Chemistry Laboratory Parameters (Safety Population) - Expansion

Replicate of Table 14.3-2.1.2.2

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

Table 14.3-2.2.3.1 - On-treatment Clinical Chemistry Adverse Events: Worst NCI-CTCAE Grade per patient (Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.3.1

PROGRAMMING NOTES:
Include all gradable Clinical Chemistry parameters

Table 14.3-2.2.3.2 - On-treatment Clinical Chemistry Adverse Events: Worst NCI-CTCAE Grade per patient (Safety Population) - Expansion

Replicate of Table 14.3-2.1.3.2

PROGRAMMING NOTES:
Include all gradable Clinical Chemistry parameters

Table 14.3-2.2.4.1 - Shift table of Worst NCI-CTCAE Grade for Clinical Chemistry Laboratory parameters (Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.4.1

PROGRAMMING NOTES:
Include all gradable Clinical Chemistry parameters

Table 14.3-2.2.4.2 - Shift table of Worst NCI-CTCAE Grade for Clinical Chemistry Laboratory parameters (Safety Population) - Expansion

Replicate of Table 14.3-2.1.4.2

PROGRAMMING NOTES:
Include all gradable Clinical Chemistry parameters

Table 14.3-2.3.1.1 - Summary of Coagulation Laboratory Data
(Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.1.1

PROGRAMMING NOTES:

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

Table 14.3-2.3.1.2 - Summary of Coagulation Laboratory Data
(Safety Population) - Expansion

Replicate of Table 14.3-2.1.1.2

PROGRAMMING NOTES:

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

Table 14.3-2.3.2.1 - Outside of Normal Range - Shift Table for Coagulation Laboratory Parameters
(Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.2.1

PROGRAMMING NOTES:

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

Table 14.3-2.3.2.2 - Outside of Normal Range - Shift Table for Coagulation Laboratory Parameters (Safety Population) - Expansion

Replicate of Table 14.3-2.1.2.2

PROGRAMMING NOTES:

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

Table 14.3-2.4.1.1 - Summary of Thyroid Panel Laboratory Data
(Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.1.1

PROGRAMMING NOTES:

- Thyroid Panel parameters are TSH, Free T4 and Free and total T3.
- Only Day 1 visit of each cycle.

Table 14.3-2.4.1.2 - Summary of Thyroid Panel Laboratory Data
(Safety Population) - Expansion

Replicate of Table 14.3-2.1.1.2

PROGRAMMING NOTES:

- Thyroid Panel parameters are TSH, Free T4 and Free and total T3.
- Only Day 1 visit of each cycle.

Table 14.3-2.4.2.1 - Outside of Normal Range - Shift Table for Thyroid Panel Laboratory Parameters
(Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.2.1

PROGRAMMING NOTES:

- Thyroid Panel parameters are TSH, Free T4 and Free and total T3.
- Only Day 1 visit of each cycle.

Table 14.3-2.4.2.2 - Outside of Normal Range - Shift Table for Thyroid Panel Laboratory Parameters (Safety Population) - Expansion

Replicate of Table 14.3-2.1.2.2

PROGRAMMING NOTES:

- Thyroid Panel parameters are TSH, Free T4 and Free and total T3.
- Only Day 1 visit of each cycle.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of 1
Extract date: DDMMMYYYY

Table 14.3-2.5.1 - Summary of Other Laboratory Data
(Safety Population) - Dose Escalation

Visit/ Parameter	CPX-POM 30 mg/m^2 N=X	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
SCR							
Pregnancy test? [n (%)] [a]							
Negative	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Positive	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
BAS							
Pregnancy test? [n (%)][a]							
Negative	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Positive	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>

[a] Denominator for the percentages was the number of females of child bearing potential.
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 14.3-2.5.2 - Summary of Other Laboratory Data
(Safety Population) - Expansion

Replicate of Table 14.3-2.6.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-3.1.1 - Summary of Vital Signs
(Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.1.1

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 14.3-3.1.2 - Summary of Vital Signs
(Safety Population) - Expansion

Replicate of Table 14.3-2.1.1.2

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.

Protocol: CPX-POM-001 --- DELIVERY TYPE ---- Page 1 of 3
Extract date: DDMMMYYYY

Table 14.3-3.2.1 - Summary of Abnormal Vital Signs
(Safety Population) - Dose Escalation

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=X 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 (%)
Pulse rate (bpm) [b]							
BAS [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)
C1 TRT D2 *	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>

* Total number of abnormal results at each visit, used as the denominator for the percentages.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
[b] Pulse rate: > 150 bpm: Very High values; [101-150] bpm: High values; < 55 bpm: Low values.
[c] Systolic Blood Pressure: >= 161 mmHg: Very High values; [131-160] mmHg: High values; < 95 mmHg: Low values.
[d] Diastolic Blood Pressure: >= 101 mmHg: Very High values; [86-100] mmHg: High values; < 50 mmHg: Low values.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-3.2.1 - Summary of Abnormal Vital Signs
(Safety Population) - Dose Escalation

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=X 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 (%)
Systolic Blooc (mmHg) [c]							
BAS [a] *	XX	XX	XX	XX	XX	XX	XX
>= 161 mmH	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
[131-160] mmHg	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)
C1 TRT D2 *	XX	XX	XX	XX	XX	XX	XX
>= 161 mmH	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
[131-160]	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>

* Total number of abnormal results at each visit, used as the denominator for the percentages.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
[b] Pulse rate: > 150 bpm: Very High values; [101-150] bpm: High values; < 55 bpm: Low values.
[c] Systolic Blood Pressure: >= 161 mmHg: Very High values; [131-160] mmHg: High values; < 95 mmHg: Low values.
[d] Diastolic Blood Pressure: >= 101 mmHg: Very High values; [86-100] mmHg: High values; < 50 mmHg: Low values.
Program: (Program name.sas) (run on: DDMMMYYYY HH:MM) Filename: (Specify file name.rtf)

Table 14.3-3.2.1 - Summary of Abnormal Vital Signs
(Safety Population) - Dose Escalation

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=X 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 (%)
Diastolic Blood Pressure (mmHg) [d]							
BAS [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] mmHg	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)
C1 TRT D2 *	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] mmHg	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>

* Total number of abnormal results at each visit, used as the denominator for the percentages.
[a] Baseline was the last value/result of assessment prior to or on day of first study treatment.
[b] Pulse rate: > 150 bpm: Very High values; [101-150] bpm: High values; < 55 bpm: Low values.
[c] Systolic Blood Pressure: >= 161 mmHg: Very High values; [131-160] mmHg: High values; < 95 mmHg: Low values.
[d] Diastolic Blood Pressure: >= 101 mmHg: Very High values; [86-100] mmHg: High values; < 50 mmHg: Low values.
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 14.3-3.2.2 - Summary of Abnormal Vital Signs
(Safety Population) - Expansion

Replicate of Table 14.3-3.2.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-4.1.1 - Summary of ECG Parameters
(Safety Population) - Dose Escalation

Replicate of Table 14.3-2.1.1.1

PROGRAMMING NOTES:

- Update "laboratory parameter" by "ECG parameter".
- ECG parameters include Heart Rate, PR Interval, RR interval, QRS Duration, QT Interval, QTcF Interval.

Table 14.3-4.1.2 - Summary of ECG Parameters
(Safety Population) - Expansion

Replicate of Table 14.3-2.1.1.2

PROGRAMMING NOTES:

- Update "laboratory parameter" by "ECG parameter".
- ECG parameters include Heart Rate, PR Interval, RR interval, QRS Duration, QT Interval, QTcF Interval.

Table 14.3-4.2.1 - Summary of Abnormal ECG Intervals
(Safety Population) - Dose Escalation

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=X 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 (%)
QTcF interval (msec)							
BAS [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 (CS)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
C1 TRT D5 *	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 C1 TRT D5 *	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 (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 28 follow-up visit>

* Total number of abnormal results at each visit, used as the 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 14.3-4.2.1 - Summary of Abnormal ECG Intervals
(Safety Population) - Dose Escalation

Parameter/ Visit/ Category	CPX-POM 30 mg/m^2 N=X 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 (%)
PR interval							
Percent Change from Baseline to C1 TRT D5 *	XX	XX	XX	XX	XX	XX	XX
≥ 50% increase from baseline if baseline < 200 ms	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
≥ 25% increase from baseline if baseline ≥ 200 ms	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
QRS duration							
Percent Change from Baseline to C1 TRT D5 *	XX	XX	XX	XX	XX	XX	XX
≥ 50% increase from baseline if baseline < 110 ms	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)	XX (XXX.X)
≥ 25% increase from baseline if baseline ≥ 110 ms	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>

* Total number of abnormal results at each visit, used as the 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:

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

Table 14.3-4.2.2 - Summary of Abnormal ECG Intervals
(Safety Population) - Expansion

Replicate of Table 14.3-4.2.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Table 14.3-4.3.1 - Shift Table for ECG Overall Interpretation
(Safety Population) - Dose Escalation

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

		Baseline [a] value			
Visit	Value at Visit	Normal n (%)	Abnormal, CS n (%)	Abnormal, NCS n (%)	Total
C1 TRT D5 (N*=XX)	Normal	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)
	Abnormal, NCS	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)
C2 TRT D1 (N*=XX)	Normal	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)
	Abnormal, NCS	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)
C2 TRT D5 (N*=XX)	Normal	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)
	Abnormal, NCS	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)

<for Cycle 2 to last-1 Cycle, repeat for Day 1 visit and Day 5 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 ECG overall interpretation.
* Denominator of the percentage.
[a] Baseline was the last value 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, including 'CPX-POM All Doses'.

Table 14.3-4.3.1 - Shift Table for ECG Overall Interpretation
(Safety Population) - Expansion

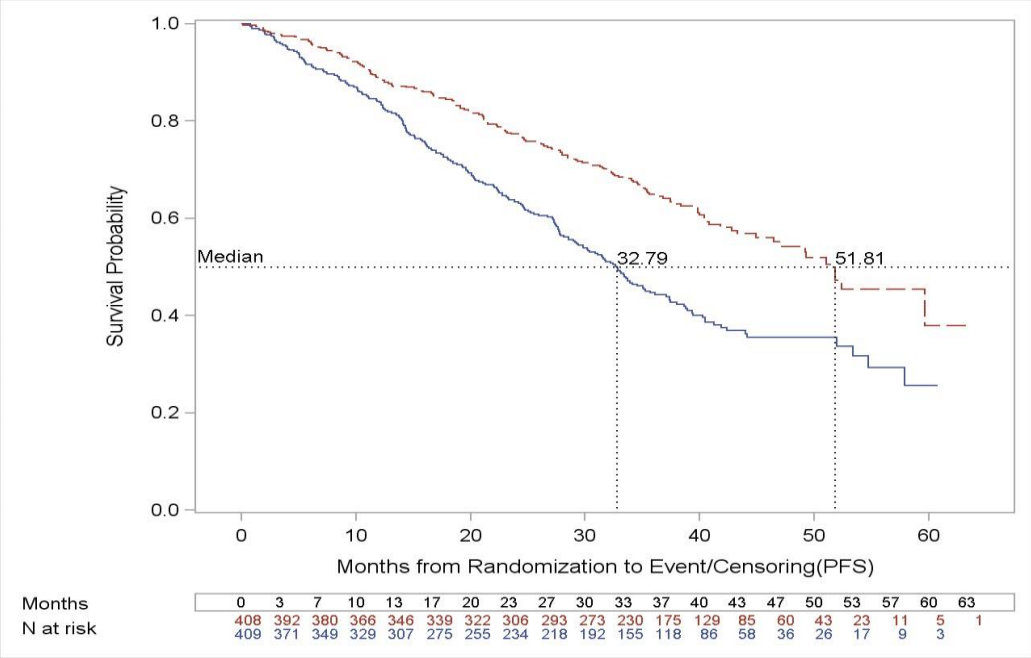
Replicate of Table 14.3-4.3.1

PROGRAMMING NOTES:

- Include three columns for 'Cisplatin ineligible','Chemotherapy eligible','Overall'.

Figures

Figure 14.2-4.2 - Recurrence-Free Survival (RFS)
(Efficacy Population) – Expansion



PROGRAMMING NOTES:

- Add legend for group labels accordingly: 'Cisplatin ineligible','Chemotherapy eligible'.
- X-axis - Label "Recurrence-free survival (months)", Y-axis - Label "Survival probability (%)."
- Legend: "Median" and 95% CI.
- Flag censored observations with '+' and add legend.
- If the median time to event has not been reached, present as "Median (95% CI) NR (xx.x, xx.x)" [replacing xx.x with '-' if there is no upper or lower confidence limit] and add footnote: NR = Median time not reached.

Figure 14.2-5.2 - Overall Survival (OS)
(Efficacy Population) - Expansion

Replicate of Figure 14.2-4.2

PROGRAMMING NOTES:

- Replace 'Recurrence-Free Survival' by 'Overall Survival' in the figure.

Listings

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

Listing 16.2.1-1.1.1 - Preface to Inclusion and Exclusion Criteria - Dose Escalation

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, but all Inclusion / Exclusion criteria for each of the protocol version (initial to last) should be listed.

Listing 16.2.1-1.1.2 - Preface to Inclusion and Exclusion Criteria - Expansion

Replicate of Listing 16.2.1-1.1.1

PROGRAMMING NOTES:

- List all Inclusion / Exclusion criteria as per eCRF.
- Note: as expansion has been added in PA5, all Inclusion / Exclusion criteria for each of the protocol version from PA5 should be listed.
- Add footnote:
  Expansion has been added to the protocol from version 5.0.

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

Listing 16.2.1-1.2.1 - List of Failed Inclusion and Exclusion Criteria
(All Patients) - Dose Escalation

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

<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.

Listing 16.2.1-1.2.2 - List of Failed Inclusion and Exclusion Criteria
(All Patients) - Expansion

Replicate of Listing 16.2.1-1.2.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.1-2.1 - Patient Disposition
(Safety Population) - Dose Escalation

Center/ Patient	Country	CPX-POM Dose group	Did the patient complete a full cycle (including Day 22 assessments) and the Follow Up Visit?	Date (day) of Discontinuation/ Completion	Reason for Discontinuation, specify	Date (day) of Last Dose	Date (day) of Death	Reason for Death
XXXX	XXX	30 mg/m^2	Yes	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		
XXXX	XXX	[D2] mg/m^2	Yes	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		
XXXX	XXX	[D3] mg/m^2	Yes	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		
XXXX	XXX	[D4] mg/m^2	Yes	DDMMMYYYY (XXX)		DDMMMYYYY (XXX)		
XXXX	XXX	[D4] mg/m^2	No	DDMMMYYYY (XXX)	Adverse Event	DDMMMYYYY (XXX)		
XXXX	XXX	[D4] mg/m^2	Yes	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
Extract date: DDMMMYYYY

Listing 16.2.1-2.2 - Patient Disposition
(Safety Population) - Expansion

Center/ Patient	Country	Group	Completed end of Treatment Visit (Day 42 or Day 64)/ Reason for Treatment Discontinuation	Date (day) of Treatment Visit Completion / Discontinuation	Date (day) of Last Dose	Date (day) of End of Study	Reason for End of Study
XXXX	XXX	Cisplatin ineligible	Yes	DDMMMYYYY (XXX)	DDMMMYYYY (XXX)		
XXXX	XXX	Chemotherapy eligible	Yes	DDMMMYYYY (XXX)	DDMMMYYYY (XXX)	DDMMMYYYY (XXX)	Lost to Follow up
XXXX	XXX	Chemotherapy eligible	Yes	DDMMMYYYY (XXX)	DDMMMYYYY (XXX)		
XXXX	XXX	Cisplatin ineligible	Yes	DDMMMYYYY (XXX)	DDMMMYYYY (XXX)		
XXXX	XXX	Chemotherapy eligible	No / Adverse Event	DDMMMYYYY (XXX)	DDMMMYYYY (XXX)	DDMMMYYYY (XXX)	Withdrawn Consent
XXXX	XXX	Cisplatin ineligible	Yes	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
Extract date: DDMMMYYYY

Listing 16.2.2.1 - Protocol Deviations
(Safety Population) - Dose Escalation

Center/ Patient	CPX-POM Dose group	Category	Description	Comment	Leading to Exclusion from Analysis Population(s)	Classification
XXXX	[D4] mg/m^2	Compliance	Not treated	xxxxxxx	Safety / Efficacy	

<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 16.2.2.2 - Protocol Deviations
(Safety Population) - Expansion

Replicate of Listing 16.2.2.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.3.1 - Analysis Populations
(Safety Population) - Dose Escalation

Center/ Patient	Country	CPX-POM Dose group	Safety Population	Efficacy Population
XXXX	XXX	30 mg/m^2	Yes	Yes
XXXX	XXX	[D2] mg/m^2	Yes	Yes
XXXX	XXX	[D3] mg/m^2	Yes	No
XXXX	XXX	[D4] mg/m^2	Yes	Yes
XXXX	XXX	[D4] mg/m^2	No	No
XXXX	XXX	[D4] mg/m^2	Yes	Yes

<etc>

The safety population consists of all patients who received at least one dose of CPX-POM.
The efficacy population consists of 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.

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 - Analysis Populations
(Safety Population) - Expansion

Replicate of Listing 16.2.3.1

PROGRAMMING NOTES:
- Replace definition of efficacy population in footnote by 'The Efficacy population consists of all patients who have received at least one dose of CPX-POM and had tumor tissue at baseline and at the time of RC.'
- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.4-1.1 - Demographic and Baseline Characteristics
(Safety Population) - Dose Escalation

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

<etc>

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 x (Height (cm))^0.725 (Dubois formula).
[a] 0 = Fully active. Able to carry on all pre-disease performance without restriction; 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature e.g. light house work and office work; 2 = Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours; 3 = Capable of only limited selfcare. Confined to bed or chair more than 50% of waking hours; 4 = Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair.

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 16.2.4-1.2 - Demographic and Baseline Characteristics
(Safety Population) - Expansion

Replicate of Listing 16.2.4-1.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.4-2.1 - Pregnancy Test Results
(Safety Population) - Dose Escalation

Center/ Patient	CPX-POM Dose group	Visit	Parameter	Assessment Performed?	Assessment Date	Study Day	Result
XXXX	30 mg/m^2	SCR	Pregnancy Test	Yes	DDMMMYYYY	XX	Negative
		BAS	Pregnancy Test	Yes	DDMMMYYYY	XX	Positive

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

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.
Only females are included in this listing.
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 16.2.4-2.2 - Pregnancy Test Results
(Safety Population) - Expansion

Replicate of Listing 16.2.4-2.1

PROGRAMMING NOTES:
- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.4-3.1 - Cancer History
(Safety Population) - Dose Escalation

Center/ Patient	CPX-POM Dose group	Primary Tumor Type	Initial Histological or Cytological Diagnosis Date (Day)	Disease Stage at Screening	Presence of Metastases?	Location
XXXX	30 mg/m^2	XXXXX	DDMMMYYYY (XXX)	Grade X	No	
XXXX	[D2] mg/m^2	XXXXX	DDMMMYYYY (XXX)	Grade X	No	
XXXX	[D3] mg/m^2	XXXXX	DDMMMYYYY (XXX)	Grade X	Yes	Adrenals/ Bone
XXXX	[D4] mg/m^2	XXXXX	- --- YYYY	Grade X	No	
XXXX	[D4] mg/m^2	Other, XXXXX	DDMMMYYYY (XXX)	Grade X	Yes	Liver/ Other, XXXXX
XXXX	[D4] mg/m^2	XXXXX	- --- YYYY	Grade X	Yes	Lungs
<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
Extract date: DDMMMYYYY

Listing 16.2.4-4.1 - Prior Cancer Therapies
(Safety Population) - Dose Escalation

Center/ Patient	CPX-POM Dose group	Therapy Type	Therapy Name	Line of Therapy	Treatment Setting	Treatment Intent	Start Date (Day)/ End Date (Day)	Best Response	Reason for discontinuation
XXXX	30 mg/m^2	XXXXX	XXXXX	X	XXXXX	XXXXX	DDMMMYYYY(XX)/ DDMMMYYYY(XX)	XXXXX	XXXXX
XXXX	[D2] mg/m^2	XXXXX	XXXXX	X	XXXXX	XXXXX	DDMMMYYYY(XX)/ DDMMMYYYY(XX)	XXXXX	XXXXX
XXXX	[D3] mg/m^2	Radiation, XXXXX	XXXXX	X	XXXXX	XXXXX	DDMMMYYYY(XX)/ DDMMMYYYY(XX)	XXXXX	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
Extract date: DDMMMYYYY

Listing 16.2.4-5.1 - Medical History and Concomitant Disease
(Safety Population) - Dose Escalation

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

Center/ Patient	System Organ Class/ Preferred Term/ Verbatim	Start Date (Day)	End Date (Day)	Any medication/non-drug therapies currently being taken for this condition?
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 16.2.4-5.2 - Medical History and Concomitant Disease (Safety Population) - Expansion

Replicate of Listing 16.2.4-5.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.4-6.1 - Cardiac Function
(Safety Population) - Dose Escalation

Center/Patient	CPX-POM Dose group	Visit	Echocardiogram or MUGA Scan performed?	Method of Assessment	Date of Assessment	Left ventricular ejection fraction (%)	Overall Interpretation	If Clinically Significant, specify
XXXX	30 mg/m^2	C1 TRT D1	Yes	Echocardiogram	DDMMMYYYY	XX	XXXXX	
XXXX	[D2] mg/m^2	C1 TRT D1	Yes	MUGA	DDMMMYYYY	XX	Abnormal CS	XXXXX
XXXX	[D3] mg/m^2	C1 TRT D1	Yes	Echocardiogram	DDMMMYYYY	XX	XXXXX	
<etc>								

NCS: Not Clinically Significant; 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 16.2.4-6.2 - Cardiac Function
(Safety Population) - Expansion

Replicate of Listing 16.2.4-6.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Listing 16.2.4-7.1 - Ophthalmologic Exam
(Safety Population) - Dose Escalation

Center/ Patient	CPX-POM Dose group	Visit	Ophthalmology Assessments performed?	Assessment performed by a qualified Ophthalmologist?	Use of Corrective Lenses?	Date of Assessment	Overall Interpretation	If Abnormal CS, specify
XXXX	30 mg/m^2	C1 TRT D1	Yes	Yes	Yes	DDMMMYYYY	XXXXX	
XXXX	[D2] mg/m^2	C1 TRT D1	Yes	No	No	DDMMMYYYY	Abnormal CS	XXXXX
XXXX	[D3] mg/m^2	C1 TRT D1	Yes	Yes	No	DDMMMYYYY	XXXXX	
<etc>								

NCS: Not Clinically Significant; 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
Extract date: DDMMMYYYY

Listing 16.2.4-8.1.1 - Prior and Concomitant Medications
(Safety Population) - Dose Escalation

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

Center/ Patient	Category	Therapeutic Class Preferred Term Verbatim	Start Date (Day)/ End Date (Day)	Dose (unit)/ Frequency/ Route	Prophylaxis?/ Reason
XXXX	Prior	XXXXXX/ XXXXX/ XXXXXXXXXXX	DDMMMYYYY (-180)/ DDMMMYYYY (XXX)	XXXXXXXX (XXX)/ Once/ Inhalation	Yes/ XXXXXXXXXXX
	Conc.	XXXXXX/ XXXXX/ XXXXXXXXXXX	--MMMYYYY/ Ongoing	Other, XXXX/ bid/ Cutaneous	No/ XXXXXX
XXXX	Prior	XXXXXX/ XXXXX/ XXXXXXXXXXX	--MMMYYYY/ DDMMMYYYY (XXX)	200 mg/ tid/ Other, XXXXX	Yes/ XXXXXXXXXXXXXXXXX

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. = concomitant = 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.

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 16.2.4-8.1.2 - Prior and Concomitant Medications
(Safety Population) - Expansion

Replicate of Listing 16.2.4-8.1.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.4-8.2.2 - Chemotherapy
(Safety Population) - Expansion

Center/ Patient	Name of Medication	Start Date (Day)/ End Date (Day)	Dose (unit)/ Route
XXXX	Gemcitabine	DDMMMYYYY (XXX)/ DDMMMYYYY (XXX)	XXXXXXXX (XXX)/ XXXXXXXX
	Cisplatin	--MMMYYYY/ Ongoing	XXXXXXXX (XXX)/ XXXXXXXX
XXXX	XXXXXXXX	--MMMYYYY/ DDMMMYYYY (XXX)	XXXXXXXX (XXX)/ XXXXXXXX

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.
Only patients from Chemotherapy eligible group are included in this listing.
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
Extract date: DDMMMYYYY

Listing 16.2.4-9.1 - Surgeries and Procedures
(Safety Population) - Dose Escalation

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

Center/ Patient	System Organ Class/ Preferred Term/ Verbatim	Start Date (Day)
XXXX	XXXXXX/ XXXXX/ XXXXXXXXXXX	DDMMMYYYY (XXX)
XXXX	XXXXXX/ XXXXX/ XXXXXXXXXXX	--MMMYYYY

<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 16.2.4-9.2 - Surgeries and Procedures
(Safety Population) - Expansion

Replicate of Listing 16.2.4-9.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.5-1.1 - Treatment Administration
(Safety Population) - Dose Escalation

Center/ Patient	Visit	CPX-POM Dose group	CPX-POM Dose Amount per Protocol?/ If no, Reason for Adjustment?	Total Infusion Bag Volume of Saline and CPX-POM (ml)	Was Total Volume Infused?/ If no, actual Volume Infused (ml)?	Administration Date (Day) Infusion Start Time- 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	XXX	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>

IV: Intravenous.
[a] See further details regarding infusion interruption in Listing 16.2.5-2.1.

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 16.2.5-1.2 - Treatment Administration
(Safety Population) - Expansion

Replicate of Listing 16.2.5-1.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.
- In footnote [a], replace 'Listing 16.2.5-2.1' by 'Listing 16.2.5-2.2'.

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

Listing 16.2.5-2.1 - Infusion Interruption
(Safety Population)- Dose Escalation

Center/ Patient	Visit	CPX-POM Dose group	Reason for Infusion Interrupted?	Administration Date (Day) Time Infusion Interrupted	Infusion Restarted?	Time Infusion Restarted	Reason for Not Restarting?	Infusion Site Reaction?
XXXXXXXX	C1 TRT D5	30 mg/m^2	Infusion reaction	DDMMMYYYY (XX) HH:MM	No		Other, XXXXX	Yes
XXXXXXXX	C2 TRT D2	30 mg/m^2	Other, XXXXX	DDMMMYYYY (XX) HH:MM	Yes	HH:MM		No

<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.
- Include only patients with infusion interruption.

Listing 16.2.5-2.2 - Infusion Interruption
(All Patients Enrolled) - Expansion

Replicate of Listing 16.2.5-2.1

PROGRAMMING NOTES:
- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Listing 16.2.5-3.1 - Drug Exposure
(Safety Population) - Dose Escalation

Center/ Patient	CPX-POM Dose group	Date of first dose administration	Visit of last dose administration	Date of last dose administration	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: (last dose taken date - first dose taken date +1) + 16 days.
The CPX-POM exposure expressed in mg is defined as: sum of all (dose per m^2 x Body Surface Area), using Body Surface Area calculated at baseline for Cycle 1 and Cycle 2 dose administrations, and calculated on Day 1 of every other treatment cycle from Cycle 3 dose administration.

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 16.2.5-3.2 - Drug Exposure
(Safety Population) - Expansion

Replicate of Listing 16.2.5-3.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.6-1.1 - RECIST Target Lesions
(Efficacy Population) - Dose Escalation

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)	Split or coalesced?
XXXX	30 mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
				T02	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
			DDMMMYYYY	T02	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
		C3 TRT D1 / Yes	DDMMMYYYY	T01	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX

<etc>

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
Extract date: DDMMMYYYY

Listing 16.2.6-2.1 - RECIST Non-Target Lesions
(Efficacy Population) - Dose Escalation

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
XXXX	30 mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX
				NT02	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX
				NT02	XXXXX	XXXXX	XXXXX	XXXXX
				NT03	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX
		C3 TRT D1 / Yes	DDMMMYYYY	NT01	XXXXX	XXXXX	XXXXX	XXXXX

<etc>

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
Extract date: DDMMMYYYY

Listing 16.2.6-3.1 - RECIST response
(Efficacy Population) - Dose Escalation

Center/ Patient	CPX-POM Dose group	Visit	Sum of diameters (mm)	Target Lesion Response	Non-Target Lesion Response	Unequivocal new lesions	Overall Response
XXXX	30 mg/m^2	C1 TRT D1	DDMMMYYYY	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1	DDMMMYYYY	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1	DDMMMYYYY	XXXXX	XXXXX	XXXXX	XXXXX
XXXX	[D2] mg/m^2	C1 TRT D1	DDMMMYYYY	XXXXX	XXXXX	XXXXX	XXXXX
		C2 TRT D1	DDMMMYYYY	XXXXX	XXXXX	XXXXX	XXXXX
		C3 TRT D1	DDMMMYYYY	XXXXX	XXXXX	XXXXX	XXXXX

<etc>

CR = Complete response; PR = Partial response; SD = Stable disease; PD = Progressive disease; NE = Not evaluable.
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
Extract date: DDMMMYYYY

Listing 16.2.6-4.1 - Tumor Marker
(Efficacy Population) - Dose Escalation

Center/ Patient	CPX-POM Dose group	Visit	Tumor marker assessment performed?	Date of assessment	Type of sample	Tumor marker	If other, specify	Result	Unit
XXXX	30 mg/m^2	C1 TRT D1	Yes	DDMMMYYYY	XXXXX	XXXXX		XX.X	XXX
					XXXXX	XXXXX		XX.X	XXX
XXXX	[D2] mg/m^2	C1 TRT D1	Yes	DDMMMYYYY	XXXXX	XXXXX		XX.X	XXX
		C2 TRT D1	Yes	DDMMMYYYY	XXXXX	XXXXX		XX.X	XXX
XXXX	[D2] mg/m^2	C1 TRT D1	Yes	DDMMMYYYY	XXXXX	Other	XXXXX	XX.X	XXX
		C2 TRT D1	No						
		C3 TRT D1	Yes	DDMMMYYYY	XXXXX	XXXXX		XX.X	XXX

<etc>

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
Extract date: DDMMMYYYY

Listing 16.2.6-5.2 - Evaluable TURBT Results
(Efficacy Population) - Expansion

Center/ Patient	Group	TURBT performed within 8 weeks prior to cycle 1 Day 1?	Initial or repeat TURBT	Date of procedure	Tumor tissue sample obtained from a referring institution?	Tumor tissue sample obtained from TURBT?	Highest Viable Tumor content in TURBT (%)	Pathological confirmation of Muscularis Propria Invasion?	Archived tumor tissue from TURBT used?
XXXX	Cisplatin ineligible	Yes	Initial	DDMMMYYYY	Yes	Yes	XX	Yes	Yes
XXXX	Chemotherapy eligible	Yes	Repeat	DDMMMYYYY	Yes	No		Yes	Yes
XXXX	Cisplatin ineligible	No							

<etc>

TURBT = Transurethral resection of bladder tumour.
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
Extract date: DDMMMYYYY

Listing 16.2.6-6.2 - Radical Cystectomy
(Efficacy Population) - Expansion

Center/ Patient	Group	Formalin-fixed, paraffin-embedded bladder tumor tissue obtained at time of RC	Date of procedure	Tumor tissue sample obtained from cystectomy used?	Highest Viable Tumor content from cystectomy (%)
XXXX	Cisplatin ineligible	Yes	DDMMMYYYY	Yes	XX
XXXX	Chemotherapy eligible	Yes	DDMMMYYYY	No	
XXXX	Cisplatin ineligible	Yes			

<etc>

RC = Radical cystectomy.
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
Extract date: DDMMMYYYY

Listing 16.2.6-7.2 - Determination of Recurrence and Survival
(Efficacy Population) - Expansion

Center/ Patient	Group	Attend any follow-up visits (includes phone calls)?	If no, reason	Date of Death	Cause of Death	Physician Decision, specify	Other, specify	Date of study completion	Date of last contact with patient
XXXX	Cisplatin ineligible	No	Death	DDMMMYYYY	XXXXXX			DDMMMYYYY	DDMMMYYYY
XXXX	Chemotherapy eligible	Yes						DDMMMYYYY	DDMMMYYYY
XXXX	Cisplatin ineligible	No	Physician Decision			XXXXXX		DDMMMYYYY	DDMMMYYYY
XXXX	Cisplatin ineligible	No						DDMMMYYYY	DDMMMYYYY

<etc>

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
Extract date: DDMMMYYYY

Listing 16.2.6-8.2 - Recurrence-Free Survival and Overall Survival
(Efficacy Population) - Expansion

Center/ Patient	Group	Date of first CPX-POM Infusion (Day)	Date of Recurrence (Day)	Date of Death (Day)	Start Date of First Further Anti-cancer Therapy (Day)	Date of Last Contact (Day)	RFS (month)	Censoring / Event for RFS	OS (month)	Censoring/ Event for OS
XXXX	Cisplatin ineligible	DDMMMYYYY (XX)	DDMMMYYYY (XX)	DDMMMYYYY (XX)		DDMMMYYYY (XX)	XX.X	Event	XX.X	Event
XXXX	Chemotherapy eligible	DDMMMYYYY (XX)	DDMMMYYYY (XX)	DDMMMYYYY (XX)	DDMMMYYYY (XX)	DDMMMYYYY (XX)	XX.X	Censoring	XX.X	Event
XXXX	Cisplatin ineligible	DDMMMYYYY (XX)	DDMMMYYYY (XX)	DDMMMYYYY (XX)		DDMMMYYYY (XX)	XX.X	Event	XX.X	Event
XXXX	Cisplatin ineligible	DDMMMYYYY (XX)	DDMMMYYYY (XX)	DDMMMYYYY (XX)		DDMMMYYYY (XX)	XX.X	Censoring	XX.X	Censoring

<etc>

Day was from the date of first dose of CPX-POM administration. Dates are displayed as DDMMMYYYY, -- represents an unknown date component.
RFS = Recurrence Free Survival, OS = Overall Survival.

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

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

Listing 16.2.7-1.1 - Dose-Limiting Toxicity
(Safety Population) - Dose Escalation

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/ Grade/ Relationship	SAE?
XXXX	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX	DDMMMYYYY (XXX)/ DDMMMYYYY (XXX)	None/ No	XXXXXXXX/ Grade 1/ Not related	No
	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX	DDMMMYYYY (XXX)/ Ongoing	Dose Adjusted/ Yes	Resolved/ Grade 3/ Definitely related	Yes
XXXX	XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXX	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.
- Select all AEs where DLT= Yes.

Listing 16.2.7-2.1 - Adverse Events
(Safety Population) - Dose Escalation

Replicate of Listing 16.2.7-1.1

PROGRAMMING NOTES:

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

Listing 16.2.7-2.2 - Adverse Events
(Safety Population) - Expansion

Replicate of Listing 16.2.7-2.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Listing 16.2.7-3.1 - Serious Adverse Events
(Safety Population) - Dose Escalation

Replicate of Listing 16.2.7-1.1

PROGRAMMING NOTES:

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

Listing 16.2.7-3.2 - Serious Adverse Events
(Safety Population) - Expansion

Replicate of Listing 16.2.7-3.1

PROGRAMMING NOTES:
- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Listing 16.2.7-4.1 - Adverse Events Leading to Discontinuation
(Safety Population) - Dose Escalation

Replicate of Listing 16.2.7-1.1

PROGRAMMING NOTES:
- Repeat for the other CPX-POM doses by increasing order.
- Select all AEs where action taken = Drug Withdrawn.

Listing 16.2.7-4.2 - Adverse Events Leading to Discontinuation
(Safety Population) - Expansion

Replicate of Listing 16.2.7-4.1

PROGRAMMING NOTES:
- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Listing 16.2.7-5.1 - Adverse Events Leading to Death
(Safety Population) - Dose Escalation

Replicate of Listing 16.2.7-1.1

PROGRAMMING NOTES:

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

Listing 16.2.7-5.2 - Adverse Events Leading to Death
(Safety Population) - Expansion

Replicate of Listing 16.2.7-5.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.8-1.1 - Patients Laboratory Profile: Hematology
(Safety Population) - Dose Escalation

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	CS?
XXXX	BAS	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX	Grade 1		
	C1 TRT D1	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX L/H	Grade 2	XXXX	
	C1 TRT D4	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX L/H	Grade 2	XXXX	
	C1 TRT D10	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX L/H	Grade 3	XXXX	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.
Laboratory ranges are based on NCI-CTCAE version 4.03.

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 16.2.8-1.2 - Patients Laboratory Profile: Hematology
(Safety Population) - Expansion

Replicate of Listing 16.2.8-1.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Listing 16.2.8-2.1 - Patients Laboratory Profile: Clinical Chemistry
(Safety Population) - Dose Escalation

Replicate of Listing 16.2.8-1.1

PROGRAMMING NOTES:

- Listing to be sorted by increasing order.

Listing 16.2.8-2.2 - Patients Laboratory Profile: Clinical Chemistry
(Safety Population) - Expansion

Replicate of Listing 16.2.8-2.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Listing 16.2.8-3.1 - Patients Laboratory Profile: Coagulation (Safety Population) - Dose Escalation

Replicate of Listing 16.2.8-1.1

PROGRAMMING NOTES:

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

Listing 16.2.8-3.2 - Patients Laboratory Profile: Coagulation (Safety Population) - Expansion

Replicate of Listing 16.2.8-3.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Listing 16.2.8-4.1 - Patients Laboratory Profile: Thyroid Panel (Safety Population) - Dose Escalation

Replicate of Listing 16.2.8-1.1

PROGRAMMING NOTES:

- Listing to be sorted by increasing order.
- Only Day 1 of each cycle.
- Remove CTCAE column and footnote.

Listing 16.2.8-4.2 - Patients Laboratory Profile: Thyroid Panel (Safety Population) - Expansion

Replicate of Listing 16.2.8-4.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.8-5.1 - Patients Laboratory Profile: Urinalysis
(Safety Population) - Dose Escalation

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

Center/ Patient	Visit	Assessment Date	Assessment Time	Study Day	Parameter (Unit)	Normal Range	Result	CS?
XXXX	BAS	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX	
	C1 TRT D1	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX	
	C1 TRT D4	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX	
	C1 TRT D10	DDMMMYYYY	HH:MM	XXX	XXXXXXXX (XXXX)	XXXXXX	XX	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.
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 16.2.8-5.2 - Patients Laboratory Profile: Urinalysis
(Safety Population) - Expansion

Replicate of Listing 16.2.8-5.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.9-1.1 - Vital Signs
(Safety Population) - Dose Escalation

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

Center/ Patient	Visit	Assessment Date	Assessment Time	Study Day	Timepoint	Parameter (unit)	Result	Change from Baseline
XXXX	BAS	DDMMMYYYY	HH:MM	XXX		Pulse Rate (bpm)	XXX L	
						Respiratory Rate (bpm)	XXX	
						Systolic BP (mmHg)	XXX	
						Diastolic BP (mmHg)	XXX	
						Oxygen Saturation (%)	XXX	
						Body Weight (kg)	XXX.X	
						Temperature (C)	XX.X	
	C1 TRT D1	DDMMMYYYY	HH:MM	XXX	6 hours Post Dose	Pulse Rate (bpm)	XXX H	XX
						Respiratory Rate (bpm)	XXX	XX
						Systolic BP (mmHg)	XXX VH	XX
						Diastolic BP (mmHg)	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.
L = Low; H = High; VH = Very High; BP = Blood Pressure; bpm = beats per minute; ND = Not Done.
Pulse Rate: L: <55 bpm; H: 101-150 bpm; VH: >150 bpm.
Systolic BP: L: <95 mmHg; H: 131-160 mmHg; VH: >=161 mmHg.
Diastolic BP: L: <50 mmHg; H: 86-100 mmHg; VH: >=101 mmHg.
R = repeated/ unscheduled assessment.

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

PROGRAMMING NOTES:

- Include all parameters: blood pressure, respiratory rate, pulse, oxygen saturation, temperature, BSA, BMI and height.
- Repeat for all doses groups

Listing 16.2.9-1.2 - Vital Signs
(Safety Population) - Expansion

Replicate of Listing 16.2.9-1.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

Protocol: CPX-POM-001
Extract date: DDMMMYYYY --- DELIVERY TYPE ----

Listing 16.2.9-2.1 - ECG Results
(Safety Population) - Dose Escalation

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

Center/ Patient	Visit	Assessment Date (Day)	Parameter (unit)	Result	Change from baseline
XXXX	BAS	DDMMMYYYY (XXX)	Heart Rate (bpm)	XXX	XX
			PR interval (msec)	XXX	XX
			RR interval (msec)	XXX	XX
			QRS duration (msec)	XXX	XX
			QT interval (msec)	XXX	XX
			QTcF interval (msec)	XXX	XX
			Overall Interpretation	Normal	
	C1 TRT D5	DDMMMYYYY (XXX)	Heart Rate (bpm)	XXX ++	XX *
			PR interval (msec)	XXX	XX
			RR interval (msec)	XXX	XX
			QRS duration (msec)	XXX	XX
			QT interval (msec)	XXX	XX
			QTcF interval (msec)	XXX +	XX
			Overall Interpretation	Abnormal, CS	

<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.
QTcF: +: >450 msec; ++: > 480 msec; +++: >500 msec; *: > 30 msec above baseline; **: > 60 msec above baseline.
R = repeated/ unscheduled assessment. 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 dose groups.

Listing 16.2.9-2.2 - ECG Results
(Safety Population) - Expansion

Replicate of Listing 16.2.9-2.1

PROGRAMMING NOTES:

- Change label from 'CPX-POM Dose group' to 'Group' and populate with 'Cisplatin ineligible'/'Chemotherapy eligible'.

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

Listing 16.2.9-3.1 - Digital Holter Monitoring
(Safety Population) - Dose Escalation

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

Center/ Patient	Visit	Assessment Start Date	Assessment Start Time	Assessment End Date	Assessment End Time	Study Day	Any Alert Flags?	Timepoint	Alert Flag Type	Specify
XXXX	BAS	DDMMMYYYY	HH:MM	DDMMMYYYY	HH:MM	xx	Yes	Pre-dose	> 60 ms increase from baseline	
								0.25	Other (specify)	xxxxx
…										

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

PROGRAMMING NOTES:

- Repeat for all dose groups.

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Certificate Of Completion

Envelope Id: 58ECCD3CFEAF44899B59B738DF5CCA50
Status: Completed
Subject: Please DocuSign: CPX-POM-001 Shells v2.0
Source Envelope:
Document Pages: 125
Signatures: 3
Envelope Originator:
Certificate Pages: 5
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
IP Address: 89.80.168.70
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Record Tracking

Status: Original
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Signer Events	Signature	Timestamp
		Sent: 03-Nov-2021 | 16:55 Viewed: 03-Nov-2021 | 18:49
Security Level: Email, Account Authentication (Required)		Signed: 03-Nov-2021 | 18:50
	Signature Adoption: Pre-selected Style Signature ID: C379E80D-7E44-4D7C-93C1-912BBD696B8A Using IP Address: 136.32.172.207 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	
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Biostatistics Cmed (Clinical Research Services) Limited Security Level: Email, Account Authentication (Required)	Signature Adoption: Pre-selected Style Signature ID: 47FCB0F5-C810-4908-9B4A-6F3E0911DFD3 Using IP Address: 89.80.168.70 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Signed: 03-Nov-2021 | 16:56
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Editor Delivery Events	Status	Timestamp

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Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

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Envelope Sent	Hashed/Encrypted	03-Nov-2021 | 16:55
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