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NCT #:	NCT02642965
Dataset #:	D1
PMID #:	32401633
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Variable Number	Variable Name	Variable Type	Label	Notes
1	usi	Char	Universal Specimen Identifier	
2	phaseid	Char	Study phase identification	
3	ageyr_ons	Num	Age at study entry in years	
4	cns_stat	Char	Central Nervous System (CNS) status	
5	cytogen	Char	Cytogenetic categories	
6	ds_length_id	Num	Disease status (length of first complete response (CR1))	1= '< 180 days' 2= '180-365 days' 3= '>365 days'
7	prior_sct	Char	Received allogeneic stem cell transplant prior to enrollment	
8	rp1_br	Num	Response at end of cycle 1	1= 'Complete Remission (CR)' 2= 'CR with partial recovery of platelet count (CRp)' 3= 'CR with incomplete blood count recovery (CRi)' 4= 'Partial response (PR)' 5= 'Treatment failure (TF)' 6= 'Unevaluable'
9	rp2_br	Num	Response at end of cycle 2	1= 'Complete Remission (CR)' 2= 'CR with partial recovery of platelet count (CRp)' 3= 'CR with incomplete blood count recovery (CRi)' 5= 'Treatment failure (TF)' 7= 'Withdrawal at end of cycle 1'

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Variable Number	Variable Name	Variable Type	Label	Notes
10	rp_best	Num	Best response	1= 'Complete Remission (CR)' 2= 'CR with partial recovery of platelet count (CRp)' 3= 'CR with incomplete blood count recovery (CRi)' 4= 'Partial response (PR)' 5= 'Treatment failure (TF)' 6= 'Unevaluable'
11	sct_after	Char	Hematopoietic stem cell transplant (HSCT) received after AAML1421 therapy	
12	yrsos	Num	Years to overall survival (OS) from study entry	
13	osi	Num	OS from study entry indicator	0=alive at last contact 1=dead
14	p1anc_achv	Num	Days to absolute neutrophil count recovery >= 1000/microliter (cycle 1)	
15	p2anc_achv	Num	Days to absolute neutrophil count recovery >= 1000/ microliter (cycle 2)	
16	consort_clsf	Char	Consort diagram categories	
17	none_cycle1	Num	CTC version 4: Grade >=3 adverse events during cycle 1: None	0=No, 1=Yes
18	fb_cycle1	Num	CTC version 4: Grade >=3 adverse event during cycle 1: febrile neutropenia (at least one occurrence)	0=No, 1=Yes

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Variable Number	Variable Name	Variable Type	Label	Notes
19	muco_cycle1	Num	CTC version 4: Grade >=3 adverse event during cycle 1: mucositis oral (at least one occurrence)	0=No, 1=Yes
20	fever_cycle1	Num	CTC version 4: Grade >=3 adverse event during cycle 1: fever (at least one occurrence)	0=No, 1=Yes
21	infct_cycle1	Num	CTC version 4: Grade >=3 adverse event during cycle 1: infections and infestations (at least one occurrence)	0=No, 1=Yes
22	ef_cycle1	Num	CTC version 4: Grade >=3 adverse event during cycle 1: ejection fraction decreased (at least one occurrence)	0=No, 1=Yes
23	eqt_cycle1	Num	CTC version 4: Grade >=3 adverse event during cycle 1: electrocardiogram QT corrected interval prolonged (at least one occurrence)	0=No, 1=Yes
24	rash_cycle1	Num	CTC version 4: Grade >=3 adverse event during cycle 1: rash maculo-papular (at least one occurrence)	0=No, 1=Yes
25	none_cycle2	Num	CTC version 4: Grade >=3 adverse events during cycle 2: none	0=No, 1=Yes

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Variable Number	Variable Name	Variable Type	Label	Notes
26	fb_cycle2	Num	CTC version 4: Grade >=3 adverse event during cycle 2: febrile neutropenia (at least one occurrence)	0=No, 1=Yes
27	infct_cycle2	Num	CTC version 4: Grade >=3 adverse event during cycle 2: infections and infestations (at least one occurrence)	0=No, 1=Yes
28	eqt_cycle2	Num	CTC version 4: Grade >=3 adverse event during cycle 2: electrocardiogram QT corrected interval prolonged (at least one occurrence)	0=No, 1=Yes
29	rash_cycle2	Num	CTC version 4: Grade >=3 adverse event during cycle 2: rash maculo-papular (at least one occurrence)	0=No, 1=Yes
30	dlt_id	Char	Dose limiting toxicity (DLT) experienced	
31	rel_wyr	Char	Relapsed within 1 year of initial complete response (CR)?	
32	p1dyshosp	Num	Number of days hospitalized during cycle 1	
33	ef_grade2_id1	Char	Grade 2 reduction in ejection fraction (defined as 40%-50%) during cycle 1	

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Variable Number	Variable Name	Variable Type	Label	Notes
34	ef_grade2_id2	Char	Grade 2 reduction in ejection fraction (defined as 40%-50%) during cycle 2	
35	ef_subsq_fup	Char	Subsequent ejection fraction (EF) measurements available demonstrating recovery of EF to >50% during follow-up	0=No, 1=Yes
36	bmblast_id	Char	Bone marrow blast percentage at study entry	
37	flowpf	Char	Location of flow cytometry performed	
38	rd_detected_1	Char	Residual disease (RD) detected at end of cycle 1 only. Only available for patients having a cycle 1 response of either CR or CRp.	
39	rd_detected_2	Char	Residual disease (RD) status at end of cycle 1 for patients who withdrew from therapy or at end of cycle 2 for patients who completed therapy. Only available for patients having a best response of either CR, CRp, or CRi.	
40	inf_path_1	Char	Microbiologically documented infections reported during cycle 1	
41	inf_path_2	Char	Microbiologically documented infections reported during cycle 2	
42	max_anc_1	Char	Maximum absolute neutrophil count (ANC) (K cells/microliter) cycle 1	
43	max_plt_1	Char	Maximum platelets (K cells/microliter) cycle 1	

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Variable Number	Variable Name	Variable Type	Label	Notes
44	rd_cycle1	Char	Residual disease, cycle 1 (%)	
45	max_anc_2	Char	Maximum absolute neutrophil count (ANC) (K cells/microliter) cycle 2	
46	max_plt_2	Char	Maximum platelets (K cells/microliter) cycle 2	
47	rd_cycle2	Char	Residual disease, cycle 2 (%)	
48	pharmck_id	Char	Patient identified in Pharmacokenetics Analysis	
49	bsa	Num	Body Surface Area (m^2)	
50	pc_cytb_nt_0	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose - Nominal Time at 0 hours (ng/mL)	
51	pc_cytb_nt_075	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose - Nominal Time at 0.75 hours (ng/mL)	
52	pc_cytb_nt_15	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 1.5 hours (ng/mL)	
53	pc_cytb_nt_2	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 2 hours (ng/mL)	
54	pc_cytb_nt_5	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at	

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Variable Number	Variable Name	Variable Type	Label	Notes
			5 hours (ng/mL)	
55	pc_cytb_nt_8	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 8 hours (ng/mL)	
56	pc_cytb_nt_12	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 12 hours (ng/mL)	
57	pc_cytb_nt_24	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 24 hours (ng/mL)	
58	pc_cytb_nt_72	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2 m^2/dose - Nominal Time at 72 hours (ng/mL)	
59	pc_cytb_nt_120	Num	Plasma Concentrations of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 120 hours (ng/mL)	
60	pc_dano_nt_0	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 0 hours (ng/mL)	
61	pc_dano_nt_075	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 0.75 hours (ng/mL)	

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Variable Number	Variable Name	Variable Type	Label	Notes
62	pc_dano_nt_15	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 1.5 hours (ng/mL)	
63	pc_dano_nt_2	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 2 hours (ng/mL)	
64	pc_dano_nt_5	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 5 hours (ng/mL)	
65	pc_dano_nt_8	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 8 hours (ng/mL)	
66	pc_dano_nt_12	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 12 hours (ng/mL)	
67	pc_dano_nt_24	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 24 hours (ng/mL)	
68	pc_dano_nt_72	Num	Plasma Concentrations of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 72 hours (ng/mL)	
69	pc_dano_nt_120	Num	Plasma Concentrations of Daunorubicin Following a	

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Variable Number	Variable Name	Variable Type	Label	Notes
			90 Minute IV Infusion of CPX-351 135 Units/ m^2/dose - Nominal Time at 120 hours (ng/mL)	
70	cytb_auc048	Num	Plasma Pharmacokinetic Parameters of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: AUC 0-48 (hours*ng/mL)	
71	cytb_auclast	Num	Plasma Pharmacokinetic Parameters of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: AUC Last (hours*ng/mL)	
72	cytb_cmax	Num	Plasma Pharmacokinetic Parameters of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Unit m^2/dose: CMax (ng/mL)	
73	cytb_tmax	Num	Plasma Pharmacokinetic Parameters of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: tMax (hours)	
74	cytb_t12	Num	Plasma Pharmacokinetic Parameters of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: t1/2 (hours)	
75	cytb_cl	Num	Plasma Pharmacokinetic Parameters of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: CL (mL/hours)	
76	cytb_vss	Num	Plasma Pharmacokinetic Parameters of Cytarabine Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: Vss (mL)	

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Variable Number	Variable Name	Variable Type	Label	Notes
77	dano_auc048	Num	Plasma Pharmacokinetic Parameters of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: AUC 0-48 (hours*ng/mL)	
78	dano_auclast	Num	Plasma Pharmacokinetic Parameters of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: AUC Last (hours*ng/mL)	
79	dano_cmax	Num	Plasma Pharmacokinetic Parameters of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: CMax (ng/mL)	
80	dano_tmax	Num	Plasma Pharmacokinetic Parameters of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: tMax (hours)	
81	dano_t12	Num	Plasma Pharmacokinetic Parameters of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: t1/2 (hours)	
82	dano_cl	Num	Plasma Pharmacokinetic Parameters of Daunorubicin Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: CL (mL/hours)	
83	dano_vss	Num	Plasma Pharmacokinetic Parameters of Daunorubicin Following a	

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Variable Number	Variable Name	Variable Type	Label	Notes
			90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: Vss (mL)	
84	cd_mr_auc048	Num	Plasma Cytarabine:Daunorubicin AUC Ratios Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: Molar Ratio AUC0-48	
85	cd_mr_auclast	Num	Plasma Cytarabine:Daunorubicin AUC Ratios Following a 90 Minute IV Infusion of CPX-351 135 Units/m^2/dose: Molar Ratio AUC Last	