

# Annotated CRF

CM Pharmaceuticals, Inc.

Subject ID 044 - 1 ☐ ☐

Subject Initials ☐ ☐ ☐

## INCLUS

## Eligibility

### Inclusion Criteria (all answers must be YES to be included in the trial)

	Yes	No	
1 Age 18-45 years, inclusive.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc1
2 Willingness to submit to diagnostic machine testing .....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc2
3 Male or non-pregnant, non-lactating female. Women of reproductive potential must be practicing adequate contraception (e.g., intrauterine device or double barrier device such as a diaphragm or condom plus spermicide). Abstinence is not considered to be an acceptable method of contraception. Additionally, women of reproductive potential must have a negative urine pregnancy at screening and prior to enrollment.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc3
4 In good health as determined by medical history and physical examinations.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc4
5 Capable of understanding and complying with the protocol and has signed the informed consent document.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc5

## EXCLUS

### Exclusion Criteria (all answers must be NO to be included in the trial)

	Yes	No	
1 Pregnant or lactating females.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	exc1
2 History of anaphylaxis.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	exc2
3 History or presence of hepatitis.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	exc3

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subjinit \$3

Demographics/Medical History

DEMO

Demographics	
Sex: sex \$1	Race: race \$9
<input type="checkbox"/> 1 Male	<input type="checkbox"/> 1 Caucasian <input type="checkbox"/> 2 Black <input type="checkbox"/> 3 Hispanic <input type="checkbox"/> 4 Asian
<input type="checkbox"/> 2 Female	<input type="checkbox"/> 5 Other (specify): raceoth \$25
Date of Birth: birthdt	Date Informed Consent Signed : icdt
mm / dd / yy	mm / dd / yy

LABSDONE

Pregnancy test lbdsamp \$42	
Result:	<input type="checkbox"/> 0 Negative lbrescd <input type="checkbox"/> 2 Not applicable

MEDHIST

Medical History		
Body System	Normal	Abnormal (describe)
Neuro mhbodsys \$26	mhstatcd <input type="checkbox"/> 0	mhterm \$200
HEENT	<input type="checkbox"/> 0	
Heart	<input type="checkbox"/> 0	
Lungs	<input type="checkbox"/> 0	
Abdomen	<input type="checkbox"/> 0	
Musculoskeletal	<input type="checkbox"/> 0	
Peripheral Vascular	<input type="checkbox"/> 0	
Skin	<input type="checkbox"/> 0	
Additional Findings: mhafsp \$200		

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Physical Examination

PE

	Study Day 1 <small>peptm \$11</small>		Study Day 2	
Body System	Normal	Abnormal (describe)	Normal	Abnormal (describe)
Neurological <small>pebodsys \$21</small>	<small>pestatcd</small> <input type="checkbox"/> 0	<small>pefind \$160</small>	<input type="checkbox"/> 0	<small>pechgcd</small> <input type="checkbox"/> 1 Unchanged from Study Day 1
HEENT	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Heart	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Lungs	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Abdomen	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Musculoskeletal	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Peripheral Vascular	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Skin	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Additional Findings:			<input type="checkbox"/> 1 Unchanged from Study Day 1	

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	<b>lbptm \$11 Study Day 1</b>	<b>Study Day 2</b>
<b>Name of Lab</b>	<b>lbnamecd lbname \$50</b>	
<b>lbtest \$16 Lab test</b>	<b>Result</b>	<b>Result</b>
	<b>lbstresn</b>	
	<input type="checkbox"/> , Not Done	<input type="checkbox"/> , Not Done
<b>Sodium</b>		
<b>Potassium</b>		
<b>Chloride</b>		
<b>BUN</b>		
<b>Creatinine</b>		
<b>Total Protein</b>		
<b>Albumin</b>		
<b>Direct bilirubin</b>		
<b>Total bilirubin</b>		
<b>ALT/SGPT</b>		
<b>AST/SGOT</b>		
<b>LDH</b>		
<b>WBC</b>		
<b>Neutrophils</b>		
<b>Eosinophils</b>		
<b>Basophils</b>		
<b>Lymphocytes</b>		
<b>Monocytes</b>		
<b>Hct%</b>		
<b>Hgb</b>		
<b>Platelets</b>		
<b>INR</b>		
<b>PT</b>		
<b>PTT</b>		

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VITAL.VSDT

Study Day 1         /      /       
                         mm    dd    yy

Evaluations and Dosing

VITAL

visit \$11

Baseline Vital Signs					
Time (24 Hour)	Temp (°F)	HR (per minute)	RR (per minute)	BP (syst/dia)	O <sub>2</sub> Sat (%)
vsacttm :	temp	heart	resp	sysbp /diabp	o2sat

VITAL

HQSCORE

Weight	Height	Health Questionnaire Score	
weightun weight . ____ Kg	heightun height . ____ inches	Pre mmmptm mmscore	\$24 Post

EXPOSURE

period

Cohort	Infusion Period # 1	Infusion Period # 2
1 <input type="checkbox"/> cohort	modecd mode <input type="checkbox"/> <sub>1</sub> Bottle      12.5 mg/kg	<input type="checkbox"/> <sub>1</sub> Bottle      12.5 mg/kg
	<input type="checkbox"/> <sub>2</sub> Bag      6.25 mg/kg	<input type="checkbox"/> <sub>2</sub> Bag      6.25 mg/kg
	<input type="checkbox"/> <sub>3</sub> Bag, other <u>0</u> . ____	<input type="checkbox"/> <sub>3</sub> Bag, other <u>0</u> . ____
	Amount PROD infused	Amount PROD infused
<input type="checkbox"/> Other ____	proddose ____ . ____ mg	____ . ____ mg

VITALTPT

Study Day 1

Vital Signs

VITALTPT \$31

Timepoint	Time (24 Hour)	HR (per min)	BP (syst/dia)	O <sub>2</sub> Sat (%)
- 5 minutes	vsacttm :	heart	sysbp / diapb	o2sat
0 minutes	:		/	
5 minutes	:		/	
10 minutes	:		/	
15 minutes	:		/	
20 minutes	:		/	
25 minutes	:		/	
30 minutes	:		/	
35 minutes	:		/	
40 minutes	:		/	
45 minutes	:		/	
50 minutes	:		/	
55 minutes	:		/	
60 minutes	:		/	
65 minutes	:		/	
70 minutes	:		/	
End of Infusion Period #2	:			
1 hour after Infusion Period #2	:		/	

CONMEDS

Concomitant Medications

☐ None    cm anycd

Medication		Dose	Unit	Route	Date (mm / dd / yy)	Time (24 Hour)
1	cmterm \$80	cmdose \$10	cmunit \$10	cmroute \$10	cmstdtc \$10 ____/____/____	cmtm : :
2	Coding: cmprefcd \$11 - WHO Drug Code cmdecod \$50 - WHO Drug Preferred Term				____/____/____	:
3	cmatccd \$5 - ATC Code cmatc \$50 - ATC Text				____/____/____	:
4					____/____/____	:
5					____/____/____	:
6					____/____/____	:
7					____/____/____	:
8					____/____/____	:
9					____/____/____	:
10					____/____/____	:
11					____/____/____	:
12					____/____/____	:

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Report all Serious Adverse Events  
IMMEDIATELY

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AE

Adverse Events

☐ None    [aeanycd](#)

Event Description		Onset	Resolution	Severity	Relationship to PROD	Actions taken (✓ all applicable)
1	<a href="#">aeterm \$120</a>	Date (mm/dd/yy) <a href="#">aestdt</a> <input type="text"/>	<a href="#">aeendt</a> <input type="text"/>	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe <input type="checkbox"/> 4 Life-threatening <a href="#">aesevcd</a>	<input type="checkbox"/> 1 Unrelated <input type="checkbox"/> 2 Possibly <input type="checkbox"/> 3 Probably <input type="checkbox"/> 4 Definitely <a href="#">aerelcd</a>	<input type="checkbox"/> 0 None <a href="#">aenoatcd</a> <input type="checkbox"/> 1 Treatment <a href="#">aetxcd</a> <input type="checkbox"/> 2 PROD stopped <a href="#">aeprncd</a> <input type="checkbox"/> 3 Discontinued trial <a href="#">aedccd</a> <input type="checkbox"/> 4 SAE Reported <a href="#">aesercd</a>
		Time (24 hour) :	<a href="#">aesttm</a> <input type="text"/> : <input type="checkbox"/> 1 Continuing <a href="#">aeongocd</a>			
2		Date (mm/dd/yy) <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe <input type="checkbox"/> 4 Life-threatening	<input type="checkbox"/> 1 Unrelated <input type="checkbox"/> 2 Possibly <input type="checkbox"/> 3 Probably <input type="checkbox"/> 4 Definitely	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Treatment <input type="checkbox"/> 2 PROD stopped <input type="checkbox"/> 3 Discontinued trial <input type="checkbox"/> 4 SAE Reported
		Time (24 hour) :	<input type="text"/> : <input type="checkbox"/> 1 Continuing			
3		Date (mm/dd/yy) <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe <input type="checkbox"/> 4 Life-threatening	<input type="checkbox"/> 1 Unrelated <input type="checkbox"/> 2 Possibly <input type="checkbox"/> 3 Probably <input type="checkbox"/> 4 Definitely	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Treatment <input type="checkbox"/> 2 PROD stopped <input type="checkbox"/> 3 Discontinued trial <input type="checkbox"/> 4 SAE Reported
		Time (24 hour) :	<input type="text"/> : <input type="checkbox"/> 1 Continuing			
4		Date (mm/dd/yy) <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe <input type="checkbox"/> 4 Life-threatening	<input type="checkbox"/> 1 Unrelated <input type="checkbox"/> 2 Possibly <input type="checkbox"/> 3 Probably <input type="checkbox"/> 4 Definitely	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Treatment <input type="checkbox"/> 2 PROD stopped <input type="checkbox"/> 3 Discontinued trial <input type="checkbox"/> 4 SAE Reported
		Time (24 hour) :	<input type="text"/> : <input type="checkbox"/> 1 Continuing			

Coding: [aeprefcd \\$8 - MEDRA Term](#)

[aedecod \\$100 - Medra Preferred Term](#)

[aesoccd \\$8 - SOC Code](#)

[aesoc \\$100 - SOC Text](#)

Investigator's Signature

Date

☐ 1 Check if subsequent pages



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Study Day 2 VITAL.vsd  
mm / dd / yy Study Completion

Study Completion/Termination VITAL

Vital Signs					
Time (24 Hour)	Temp (°F)	HR (per minute)	RR (per minute)	BP (syst/dia)	O <sub>2</sub> Sat (%)
:				/	

Did the subject complete the trial ? ☐ <sub>1</sub> Yes ☐ <sub>0</sub> No dsstatcd

If No, please complete the following (✓ all applicable) DISPOSIT

Reason for discontinuation		Date mm / dd / yy	
<input type="checkbox"/> <sub>1</sub>	Adverse Event <span>dsaecd</span>	<u>    </u> / <u>    </u> / <u>    </u> <span>dsaedt</span>	event: <span>dsaes</span> \$140
<input type="checkbox"/> <sub>2</sub>	Withdrew consent <span>dswdcd</span>	<u>    </u> / <u>    </u> / <u>    </u> <span>dswddt</span>	reason: <span>dswdsp</span> \$40
<input type="checkbox"/> <sub>3</sub>	Lost to follow up <span>delostcd</span>	<u>    </u> / <u>    </u> / <u>    </u> <span>dslostdt</span>	reason: <span>dslostsp</span> \$140
<input type="checkbox"/> <sub>4</sub>	Blood clot <span>dsclostcd</span>	<u>    </u> / <u>    </u> / <u>    </u> <span>dsshntdt</span>	
<input type="checkbox"/> <sub>5</sub>	Other <span>dsothcd</span>	<u>    </u> / <u>    </u> / <u>    </u> <span>dsothdt</span>	specify: <span>dsothsp</span> \$200

Summary of Protocol Compliance

Was the protocol followed without deviations? ☐ <sub>1</sub> Yes ☐ <sub>0</sub> No departcd

If No, please complete the following (✓ all applicable) SUMMARY

Departures		
<input type="checkbox"/> <sub>1</sub>	Entrance Criteria <span>reascd</span> not met	specify: <span>reassp1</span> \$200
<input type="checkbox"/> <sub>2</sub>	PROD not administered fully	reason: <span>reassp2</span> \$200
<input type="checkbox"/> <sub>3</sub>	Images not obtained	explain:
<input type="checkbox"/> <sub>4</sub>	Safety data not obtained or not collected at scheduled time point	explain:
<input type="checkbox"/> <sub>5</sub>	Other	specify: