CTMS

3.12

NCI / DCTD / CTEP

Clinical Trials Monitoring Service

Case Report Forms

Version 3.12

October 2003

ENROLLMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr)	Protocol #	Institution	Patient ID

Sex (circle): M F	Date of Birth (dy/mth/yr):	Age:

Race: *check one or more* [ ] 01 White [ ] 06 American Indian or Alaska Native [ ] 03 Black or African American [ ] 99 Unknown [ ] 04 Native Hawaiian or Other Pacific Islander [ ] 05 Asian	Ethnicity: [ ] 9 Unknown [ ] 1 Hispanic or Latino [ ] 2 non-Hispanic

Body Weight (kg):	Height (cm):	Body Surface Area (m^2):

CTEP Patient Subgroup:	Institution's Patient ID: *(if different from ID for CTMS)*

Registering Group (CTEP code): *(for inter-group trials only)*	Country Code:	Postal Code:

Registering Institution (CTEP code):	Method of Payment**:

Primary Site:

Stage of Disease:	CTEP Disease Code: *(from CTEP Web Site or Help Desk)*

Histology/Cytopathology:

Date of Confirmation of Histology (dy/mth/yr):	Grade of Histology:

Date of Diagnosis (dy/mth/yr):	Performance Status:

Informed Consent Signature Date (dy/mth/yr):	Registration Date (dy/mth/yr):

Informed Consent Version: _____	Planned Treatment Assignment Code:

**Method of Payment Codes

1 = Private Insurance
2 = Medicare
3 = Medicare and Private Insurance
4 = Medicaid
5 = Medicaid and Medicare
6 = Military or Veterans Sponsored NOS
6a = Military Sponsored (including CHAMPUS &TRICARE)
6b = Veterans Sponsored
7 = Self Pay (No Insurance)
8 = No means of payment (no insurance)
98 = Other
99 = Unknown

ELIGIBILITY CHECKLIST

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Patient ID:
Checklist #:	Effective Date (dy/mth/yr):		Waiver #:

Eligibility Checklist	Yes	No	N/A	
1.	[ ]	[ ]	[ ]	1.
2.	[ ]	[ ]	[ ]	2.
3.	[ ]	[ ]	[ ]	3.
4.	[ ]	[ ]	[ ]	4.
5.	[ ]	[ ]	[ ]	5.
6.	[ ]	[ ]	[ ]	6.
7.	[ ]	[ ]	[ ]	7.
8.	[ ]	[ ]	[ ]	8.
9.	[ ]	[ ]	[ ]	9.
10.	[ ]	[ ]	[ ]	10.
11.	[ ]	[ ]	[ ]	11.
12.	[ ]	[ ]	[ ]	12.
13.	[ ]	[ ]	[ ]	13.
14.	[ ]	[ ]	[ ]	14.
15.	[ ]	[ ]	[ ]	15.
16.	[ ]	[ ]	[ ]	16.
17.	[ ]	[ ]	[ ]	17.
18.	[ ]	[ ]	[ ]	18.
19.	[ ]	[ ]	[ ]	19.
20.	[ ]	[ ]	[ ]	20.
21.	[ ]	[ ]	[ ]	21.
22.	[ ]	[ ]	[ ]	22.
23.	[ ]	[ ]	[ ]	23.
24.	[ ]	[ ]	[ ]	24.
25.	[ ]	[ ]	[ ]	25.
26.	[ ]	[ ]	[ ]	26.
27.	[ ]	[ ]	[ ]	27.
28.	[ ]	[ ]	[ ]	28.
29.	[ ]	[ ]	[ ]	29.
30.	[ ]	[ ]	[ ]	30.
31.	[ ]	[ ]	[ ]	31.
32.	[ ]	[ ]	[ ]	32.
33.	[ ]	[ ]	[ ]	33.
34.	[ ]	[ ]	[ ]	34.
35.	[ ]	[ ]	[ ]	35.
36.	[ ]	[ ]	[ ]	36.
37.	[ ]	[ ]	[ ]	37.
38.	[ ]	[ ]	[ ]	38.
39.	[ ]	[ ]	[ ]	39.
40.	[ ]	[ ]	[ ]	40.

Eligibility: [ ] Patient satisfies all criteria.

[ ] Patient not formally eligible, but admitted to study because (state reason):

_____

_____

PRIOR TREATMENT SUMMARY

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution	Patient ID:

Type of Therapy	Type Code	Any Therapy? [Y]es [N]o [U]nknown	If Yes, Date of Last Dose (dy/mth/yr)
Chemotherapy single agent systemic	CS	Y / N / U	
Chemotherapy multiple agents systemic	CM	Y / N / U	
Chemotherapy (NOS)	C	Y / N / U	
Hormonal	H	Y / N / U	
Surgery	S	Y / N / U	
Immunotherapy	I	Y / N / U	
Extensive Radiation	ER	Y / N / U	
Limited Radiation	LR	Y / N / U	
Radiation (NOS)	R	Y / N / U	
Bone Marrow Transplant	BM	Y / N / U	
Gene Transfer	G	Y / N / U	
Prior Therapy (NOS)	PT	Y / N / U	
Non – Cytotoxic Chemotherapy	NC	Y / N / U	
Anti – Retroviral	AR	Y / N / U	
Antisense	AS	Y / N / U	
Oncolytic Virotherapy	OV	Y / N / U	
Vaccine	V	Y / N / U	

Details must be provided for the following on the appropriate Supplemental Therapy Case Report Form:

1) The last treatment prior to enrollment.
2) Any prior stem cell toxic therapy (e.g. mitomycin C) or cardiotoxic therapy (e.g. doxorubicin or other anthracycline) if relevant to the study agent.
3) Any therapies used to determine “extensive prior therapy” if specified in protocol.
4) Any therapies restricted by the protocol eligibility criteria, either specific drugs or number of prior therapies (e.g. no more than two prior chemotherapy regimens for metastatic disease).
5) Any therapies that are clinically significant for evaluation of the current study.
6) Additionally as required specifically by the protocol.

PRIOR THERAPY SUPPLEMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Date of First Dose ---(dy/mth/yr)--- Date of Last Dose	Agent ---------- Schedule	Total Dose ---------- Dose Units	Best* Response	Therapy Type Code *(see below)*
1.	----------	----------	----------		
2.	----------	----------	----------		
3.	----------	----------	----------		
4.	----------	----------	----------		
5.	----------	----------	----------		
6.	----------	----------	----------		
7.	----------	----------	----------		
8.	----------	----------	----------		
9.	----------	----------	----------		
10.	----------	----------	----------		

This form is required only when needed to acquire the details of prior therapy, as noted at the bottom of the PRIOR TREATMENT SUMMARY FORM.

*Code "Best Response" as CR, PR, MR, SD, PD, AJ, PA, NE, NA, or UK.

Therapy Type Codes:

CS: chemo single	H: hormonal	BM: bone marrow	AR: anti-retroviral
CM: chemo multiple	I: immunotherapy	G: gene transfer	AS: antisense
C: chemo NOS	V: vaccine	NC: non-cyto chemo	
PT: prior therapy NOS		OV: oncolytic virotherapy	

PRIOR RADIATION SUPPLEMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Radiation Type --- Extent Code*	Date First Dose (dy/mth/yr) --- Date Last Dose (dy/mth/yr)	Site --- Schedule	Dose --- Dose Units	Best** Response
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

This form is required only when needed to acquire the details of prior therapy, as noted at the bottom of the PRIOR TREATMENT SUMMARY FORM.

*Extent: ”LR” = Limited Radiation, “ER” = Extensive Radiation, and “R” = Radiation NOS.

**Code response a CR, PR, MR, SD, PD, AJ, PA, NE, NA or UK.

PRIOR SURGERY SUPPLEMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Date (dy/mth/yr)	Procedure/Site* Findings Residual Disease	Therapeutic ? (Circle One)
1		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Yes --- No
2		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Yes --- No
3		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Yes --- No
4		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Yes --- No
5		Procedure/Site: _____ Findings: _____ Residual Disease: _____	Yes --- No

This form is required only when needed to acquire the details of prior therapy, as noted at the bottom of the PRIOR TREATMENT SUMMARY FORM.

*Procedures for study disease, including diagnosis.

CONCOMITANT MEASURES/MEDICATION

NCI/DCTD/CTMS CASE REPORT FORM

(Include all supportive measures instituted while on study)

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Start Date (dy/mth/yr) ---------- Stop Date (dy/mth/yr)	Agent Or Procedure	Total Daily Dose ---------- Units	Schedule ---------- Reason
1.	----------		----------	----------
2.	----------		----------	----------
3.	----------		----------	----------
4.	----------		----------	----------
5.	----------		----------	----------
6.	----------		----------	----------
7.	----------		----------	----------
8.	----------		----------	----------
9.	----------		----------	----------
10.	----------		----------	----------

*Use “ongoing” if medication started > 1 month prior to study initiation.

BASELINE MEDICAL HISTORY

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

Examination Date: (dy/mth/yr)

Body System	History If Abnormal
H/E/E/N/T	
Neck	
Respiratory	
Cardiovascular	
Gastrointestinal	
Musculoskeletal	
Dermatologic	
Hematopoietic/Lymph	
Endocrine/Metabolic	
Urinary	
Genitalia	
Breasts	
Pelvis	
Abdomen	
Neurologic	
Psychologic	
Immune	
Other	

PHYSICAL EXAM

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

Examination Date* (dy/mth/yr): **Baseline and follow-up*

Body System	Normal (N) Abnormal (A) Not Examined (X)	Comment If Any Change From Baseline
H/E/E/N/T		
Neck		
Respiratory		
Cardiovascular		
Gastrointestinal		
Musculoskeletal		
Dermatologic		
Hematopoietic/Lymph		
Endocrine/Metabolic		
Urinary		
Genitalia		
Breasts		
Pelvis		
Abdomen		
Neurologic		
Psychologic		
Other		

BASELINE SYMPTOMS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Onset Date (dy/mth/yr)	Symptom Description ---------- CDUS Toxicity Type Code	Grade*	Related To Disease? [Y]es [N]o [U]nknown
1.		----------		
2.		----------		
3.		----------		
4.		----------		
5.		----------		
6.		----------		
7.		----------		
8.		----------		

*Grade: 1 = Mild, 2 = Moderate, 3 = Severe, and 4 = Life-threatening

EXTENT OF DISEASE

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Lesion #	Lesion #	Lesion #	Lesion #	Lesion #
Organ					
Description of Lesion					
Previously Irradiated (Y/N)					
Measurable/Non-Measurable (M/N)					
Followed For Response (Y/N)					

LS: THX-CTMS-REV.03A

____/____/____ dy / mth / yr	How Measured											
	Measurement(s)											
	*Eval Number	**Eval Code										
____/____/____ dy / mth / yr	How Measured											
	Measurement(s)											
	*Eval Number	**Eval Code										
____/____/____ dy / mth / yr	How Measured											
	Measurement(s)											
	*Eval Number	**Eval Code										
____/____/____ dy / mth / yr	How Measured											
	Measurement(s)											
	*Eval Number	**Eval Code										
____/____/____ dy / mth / yr	How Measured											
	Measurement(s)											
	*Eval Number	**Eval Code										

Enter measurements for 1 (e.g. RECIST), 2, or 3 dimensions, with the largest measurements first.

* Evaluation Number: Number sequentially, 0 = Baseline, 1 = First evaluation, 2 = Second evaluation, etc.

** Evaluation Code: Enter **N** for any New Lesion
For non-measurable disease <u>only</u>, in lieu of dimensions enter
code: **R** = Resolved, **D** = Decreasing, **I** = Increasing, **S** = Stable

COURSE INITIATION

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #	Institution:	Patient ID:
Course #: _____ Start Date of Course: (dy/mth/yr) _____			
Arm: _____ CTEP Treatment Assignment Code *: _____			
Weight: _____ kg	Height: _____ cm	Body Surface Area: _____ m^2	
CTEP Treating Institution Code: _____			

* Normally this TAC will be the same as the one specified on the Enrollment CRF. When the actual treatment does not conform to the TAC, this is reported on the Course Assessment CRF.

STUDY DRUG ADMINISTRATION

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

Start Date (dy/mth/yr) ---------------- Time hr:mn	Course Number	Drug ------------------ Lot #	Dose Level and Units -------------------------------- Actual Dose and Units	Schedule ------------------- Route	Duration -------------- Units
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		
Date			Dose Level Units		
Time			Actual Dose Units		

ADVERSE EVENTS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #	Institution:	Sheet #	Patient ID:

Start Date of Course: (dy/mth/yr) Adverse Event Description --- CDUS Toxicity Type Code	Onset Date (dy/mth/yr) --- Resolved Date (dy/mth/yr)	AER Filed (Y/N/U)	Grade*	Attribution**	Dose Limiting Toxicity (Y/N)	Serious	Action	Therapy	Outcome
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								

*Refer to NCI Common Toxicity Grading Criteria.

**Please provide a comment on the Comment Case Report Form about the likely attribution of the adverse event, if not definitely attributable to the study drug.

Severity Grade

1 = Mild
2 = Moderate
3 = Severe
4 = Life-threatening
5 = Fatal

Attribution: Relation to Study Drug

1 = Unrelated
2 = Unlikely
3 = Possible
4 = Probable
5 = Definite

Serious *(as for MedWatch)*

1 = No
2 = Life-threatening
3 = Death
4 = Disability
5 = Hospitalization
6 = Caused congenital anomaly
7 = Required intervention to prevent permanent impairment

Action

1 = None
2 = Dose reduced
3 = Regimen interrupted
4 = Therapy discontinued
5 = Interrupted and then reduced

Therapy

1 = None
2 = Symptomatic
3 = Supportive
4 = Vigorous supportive

Outcome

1 = Recovered
2 = Still under treatment/ observation
3 = Alive with sequelae
4 = Died

COURSE ASSESSMENT

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr)	Protocol #	Institution	Patient ID

Start Date of Course (dy/mth/yr): _____

Course Disposition: [ ] Completed [ ] Discontinued

Was actual dose of study drug different from that specified
by the Treatment Assignment Code entered on the Course Initiation CRF ?

[ ] (3) No

[ ] (1) Yes, Planned
[ ] (2) Yes, Unplanned

If YES, you may enter an explanation on the Comments Case Report Form with note type CA

[ ] (9) Unknown

Best Response Assessment on this course:

NP [ ] response assessment Not Applicable – per protocol

else

TE [ ] Too Early to assess, per protocol

else

NA [ ] Not Assessed – reason: _____

else

NE [ ] Not Evaluable – reason: _____

else

CR [ ] Complete Response

or

PR [ ] Partial Response (relative to baseline)

or

MR [ ] Less than Partial Response *(if allowed by protocol's criteria)*

else

PD [ ] Progressive Disease (relative to previous assessment, or baseline)

else

SD [ ] Stable Disease (relative to baseline) *(not after CR/PR/MR or PD)*

or

DU [ ] Disease Unchanged (when SD invalid but PR/MR/PD not warranted)

Date of Evaluation, if CR/PR/MR or SD/DU or NE: (dy/mth/yr):_____

Date of Evaluation of Progression (dy/mth/yr): _____
or of progression subsequent to a better response

Were there any adverse events on this course? [ ] Yes (*see AE CRF*) [ ] No *(no AE CRF)*

LATE ADVERSE EVENTS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #	Institution:	Sheet #	Patient ID:

Start Date of Follow-up: (dy/mth/yr) Adverse Event Description --- CDUS Toxicity Type Code	Onset Date (dy/mth/yr) --- Resolved Date (dy/mth/yr)	AER Filed (Y/N/U)	Grade*	Attribution**	Dose Limiting Toxicity (Y/N)	Serious	Action	Therapy	Outcome
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								
---	---								

*Refer to NCI Common Toxicity Grading Criteria.

**Please provide a comment on the Comment Case report Form about the likely attribution of the adverse event, if not definitely attributable to the study drug.

Severity Grade

1 = Mild
2 = Moderate
3 = Severe
4 = Life-threatening
5 = Fatal

Attribution: Relation to Study Drug

1 = Unrelated
2 = Unlikely
3 = Possible
4 = Probable
5 = Definite

Serious *(as for MedWatch)*

1 = No
2 = Life-threatening
3 = Death
4 = Disability
5 = Hospitalization
6 = Caused congenital anomaly
7 = Required intervention to prevent permanent impairment

Action

1 = None
2 = Dose reduced
3 = Regimen interrupted
4 = Therapy discontinued
5 = Interrupted and then reduced

Therapy

1 = None
2 = Symptomatic
3 = Supportive
4 = Vigorous supportive

Outcome

1 = Recovered
2 = Still under treatment/ observation
3 = Alive with sequelae
4 = Died

COMMENTS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

	Date All notes (dy/mth/yr)	Type*	Notes and Remarks
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			
23.			
24.			
25.			
26.			
27.			
28.			
29.			
30.			

* The following type-codes may be used to link notes to the relevant form, TX = Adverse Events, XT = Extent of disease, MH = Baseline Medical History. For any other sheet to be linked use the two letter identifier given at the bottom of each panel (e.g., PH is used at the bottom of this sheet, so PH is the identifier).

OFF TREATMENT / OFF STUDY

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed dy/mth/yr)	Protocol ID	Institution	Patient ID

Date Last Course Completed: _____ (dy/mth/yr)

Last course discontinued or completed including observation period. No further treatment planned.

Reason (*check one*):

[ ]C Completed Study (study has no Protocol-Specified* Follow-up Phase)

-OR- Patient Not Treated because: [ ]X Declined to Participate [ ]B Disease Progression Before Treatment
[ ]Z No Treatment, per protocol
[ ]U Not Treated – Other Reasons, explain _____

-OR- Participation Terminated during Treatment Phase because:

[ ]P Disease Progression On Study **
[ ]T Adverse Events/Side Effects
[ ]G Cytogenetic Resistance
[ ]R Refused Further Participation
[ ]V Protocol Violation
[ ]D Death During Treatment
[ ]S Complicating Disease / Intercurrent Illness
[ ]A Switched to Alternative Treatment
[ ] I Late Determination of Ineligibility
[ ]O Other; explain _____

Use the following section only for particular studies with a Protocol-Specified Follow-up Phase*

-OR- [ ]Y Completed Treatment Phase but Refused Protocol-Specified* Follow-up

-OR- [ ]F Began Protocol-Specified* Follow-up *At end of follow-up, please complete:*

Date Off Protocol Follow-up : (dy/mth/yr) _____ Because:

[ ]H Follow-up Period Completed
[ ]W Refused Further Follow-up
[ ]M Death during Follow-up Period
[ ]L Lost to Further Follow-up
[ ]E Late Adverse Events/Side Effects
[ ]K Other; explain _____

** "Protocol-Specified Follow-up" is a specific follow-up phase following the treatment phase that is part of the study design in the protocol. Such protocols will be designated in the CTMS Activation Letter. It does not refer to the normal observation period after the last drug administration or to routine ("30-day") observation after "off-study" or to occasional "follow-up", e.g. for survival tracking.*

Summary of Response Assessments: *must correspond to the responses reported on the Course Assessments*

[ ] NE all courses Not Evaluable
[ ] NA all courses Not Assessed
[ ] NP Assessment Not Applicable per protocol
[ ] TE all courses Too Early

-OR- Best Actual Response:
[ ] CR Complete Response
[ ] PR Partial Response
[ ] MR Less than Partial Response
[ ] SD Stable Disease *(not valid following PD)*
[ ] PD Disease Progression

Date of Best Actual Response: _____ (dy/mth/yr) *(only if CR, PR, MR, SD)*

Date of Progression: (dy/mth/yr) _____

**Required if: *Progression was the best response assessment or Disease Progression followed an actual response or Reason Off Treatment is P = Disease Progression On Study*

SURVIVAL / FOLLOW-UP

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #	Institution:	Patient ID:

Survival

Date of Last Contact: (dy/mth/yr) _____

Date of Death: (dy/mth/yr) _____

[ ] 5 Died
[ ] 1 Alive with disease
[ ] 2 Alive with no evidence of disease
[ ] 3 Alive disease status unknown
[ ] 4 Unknown (explain)

_____

FP: THX-CTMS-REV.03A

Cause of Death (presumed):

[ ] M Malignant Disease
[ ] T Toxicity from Protocol Treatment
[ ] I Infection
[ ] O Other (explain) _____

Autopsy: Yes [ ] No [ ] Unknown [ ]

Cause of Death (Autopsy findings):

[ ] M Malignant Disease
[ ] T Toxicity from Protocol Treatment
[ ] I Infection
[ ] O Other (explain)_____

Sites of Disease at Autopsy:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

DS: THX-CTMS-REV.03A

FLOWSHEET A

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

	Enter Lab Date (dy/mth/yr) →						
	Enter Time (only if needed) hr : min →	:	:	:	:	:	:
	Notes→						
VITAL SIGNS (PL)	Performance Status						
	Height (cm)						
	Weight (kg)						
	Temperature (°C)						
	Pulse (/min)						
	Respiration Rate (/min)						
	Systolic BP (mmHG)						
	Diastolic BP (mmHG)						
TRANSFUSION	Whole Blood – Fresh (U)						
	Whole Blood Stored (U)						
	Packed Red Cells – Fresh (U)						
	Packed Red Cells – Stored (U)						
	Packed White Cells (U)						
	Platelets (U)						
CARDIAC	Pre-Ejection Period (PEP) (msec)						
	LV Ejection Time (msec)						
	LV Ejection Fraction (LVEF) (%)						
HEMATOLOGY (HM)	Hemoglobin (g/dl)						
	Hematocrit (%)						
	WBC (thousands/mm^3)						
	Neutrophils (%)						
	Lymphocytes (%)						
	Basophils (%)						
	Monocytes (%)						
	Eosinophils (%)						
	Bands (%)						
	Blast Cells (%)						
	Atypical Lymphs (%)						
	Other – Differential (%)						
	Platelets (thousands/mm^3)						
	ANC (thousands/mm^3)						
	RBC (thousands/mm^3)						
	Reticulocytes (%)						
	ESR (mm/hr)						
	PT (sec)						
	PTT (sec)						

FLOWSHEET B

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

	Enter Lab Date (dy/mth/yr)→						
	Enter Time (only if needed) hr : min →	:	:	:	:	:	:
	Notes →						
BLOOD CHEMISTRIES (BC)	BUN (mg/dl)						
	Creatinine (mg/dl)						
	Sodium (mEq/l)						
	Potassium (mEq/l)						
	Chloride (mEq/l)						
	Magnesium (mg/dl)						
	Bicarbonate (mEq/l)						
	Uric Acid (mg/dl)						
	Bilirubin (total) (mg/dl)						
	Alkaline Phosphate (U/l)						
	SGOT (AST) (U/l)						
	SGPT (ALT) (U/l)						
	SGGT (U/l)						
	LDH (U/l)						
	Total Protein (g/dl)						
	Albumin (g/dl)						
	Globulin (g/dl)						
	Calcium (mg/dl)						
	Inorganic Phosphorus (mg/dl)						
	Blood Glucose – Fasting (mg/dl)						
	Blood Glucose – Non – Fasting (mg/dl)						
	Cholesterol (mg/dl)						
	Amylase (U/l)						
	5’ Nucleotidase (U/l)						
	Creatinine Phosphokinase (CPK) (U/l)						
URINALYSIS (US)	Creatinine Clearance (ml/min)						
	Acidity (pH)						
	Specific Gravity (decimal ratio)						
	White Blood Cells (coded, 0-4)						
	Red Blood Cells (coded, 0-4)						
	Casts (8 char)						
	Glucose (mg/dl)						
	Protein (mg/dl)						
	Ketones (coded, 0-4)						
	Bile (coded, 0-4)						
	Urinary Creatinine (mg/dl)						
	Volume (ml/24 hr)						
	Collection Period (hr)						

FLOWSHEET C

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

	Enter Lab Date (dy/mth/yr) →						
	Enter Time (only if needed) hr : min →	:	:	:	:	:	:
	Notes →						
BONE MARROW (BM)	Myeloblasts (%)						
	Promyelocytes (%)						
	Myelocytes: Neutros (%)						
	Eosinos (%)						
	Basos (%)						
	Metamyelocytes (%)						
	Polymorphs: Neutros (%)						
	Eosinos (%)						
	Basos (%)						
	Lymphocytes (%)						
	Plasma Cells (%)						
	Monocytes (%)						
	Reticulum Cells (%)						
	Megakaryocytes (%)						
	Pronormoblasts (%)						
	Normoblasts (%)						
	Cellularity (8 char)						
	M Rating (integer part: 1-7)						
Serology (SR)	PSA (ng/ml)						
	CA125 (U/ml)						
	CEA (ng/ml)						
	CA19-9 (U/ml)						
	CA15-3 (U/ml)						
	CA27, 29 (U/ml)						
	AFP (ng/ml)						
	HCG (ng/ml)						
	HIV (code 0=negative, 1=positive)						
	HbsAg (code 0=negative, 1=positive)						
	Pregnancy (code 0=negative, 1=positive)						
	Stool Guaiac (code 0=negative, 1=positive)						
Other Serum Chemictries (SC)	Aldolase (U/l)						
	Ammonia (μmol/l)						
	Calcium – Ionized (mg/dl)						
	Copper (μg/dl)						
	Ferritin (ng/ml)						
	HDL (mg/dl)						
	Insulin (μU/ml)						
	Iron (μg/dl)						
	Iron Binding Capacity (μg/dl)						
	Iron Saturation (%)						
	LDL (mg/dl)						
	Lipase (U/l)						
	Osmolality (mOsm/kg)						
	Acid Phosphatase (U/l)						
	Transferrin (mg/dl)						
	Triglycerides (mg/dl)						
	T3 (ng/dl)						
	T4 (μg/dl)						
	TSH (μg/ml)						

FLOWSHEET D

NCI/DCTC/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr) :	Protocol #:	Institution:	Sheet #:	Patient ID:

	Enter Lab Date (dy/mth/yr) →						
	Enter Time (only if needed) hr : min →	:	:	:	:	:	:
	Notes →						
BLOOD GASES (RF) RESPIRATORY FUNC.	pH (pH)						
	pCO_2 (mmHg)						
	pO_2 (mmHg)						
	Bicarbonate (mEq/l)						
	Base Excess (mmol/l						
	Base Deficit (mmol/l)						
	Oxygen Saturation (%)						
	CO (%)						
	Methemoglobin (% total hgb)						
	Vital Capacity (l)						
	Expiratory Volume (FEV1) (%/sec)						
	Maximum Capacity (l)						
	Residual Volume (l)						
	Tidal Volume (l)						
	Functional Residual Capacity (l)						
	Pulmonary Compliance (dV/dP)						
	Diffusing Capacity (DLCO) (ml/min/torr or %pred)						
	Maximum EXP. FLOW (l/sec)						
	Maximum Mid – Exp.Flow (l/sec)						
RED CELL INDICES (RC)	MCH (pg)						
	MCHC (%)						
	MCV (fl)						
	Bleeding Time (min)						
	Clot Retraction Screen (hr)						
	Semi Quant (%)						
	Quantitative (mg)						
	Clotting Time (min)						
	FDP (µg/ml)						
	Fibrinogen (mg/dl)						
	Thrombin Time (sec)						
	Nucleated RBCs (%)						
	Complement (U/ml)						
	Coombs Test (code 0=negative, 1=positive)						
	Antinuclear Factor (ANF) (ratio)						
OTHER URINARY RESULTS (OU)	Calcium (mg/24 hr)						
	Chloride (mg/24 hr)						
	Osmolality (m0sm/kg)						
	Oxalate (mg/24 hr)						
	Potassium (mEq/24 hr)						
	Protein – Albumin (g/dl)						
	alpha 1 (%)						
	alpha 2 (%)						
	beta (%)						
	gamma (%)						
	Sodium (mEq/24 hr)						
	Urea Nitrogen (g/24 hr)						
	Uric Acid (mg/24 hr)						

FLOWSHEET E

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

	Enter Lab Date (dy/mth/yr) →						
	Enter Time (only if needed) hr : min →	:	:	:	:	:	:
	Notes →						
IMMUNE PARAMETERS (IP)	Lymphocyte Blasts						
	B – Cell Level						
	T – Cell Total						
	Helper						
	Suppressor						
	DTH						
	CTL						
	NK Activity						
	ADCC						
	Macrophage Cytotoxicity						
	Macrophage Cytostasis						
	Peroxide Generation						
	Serum Interferon						
SERUM ELECTRO. (SE)	Ig A (mg/dl)						
	Ig D (mg/dl)						
	Ig E (mg/dl)						
	Ig G (mg/dl)						
	Ig M (mg/dl)						
	Monoclonal (0 or #)						
	Polyclonal (0 or #)						
	Kappa (0 or mg/dl)						
	Lambda (0 or mg/dl)						
	Bence – Jones (0 or #)						
URINE IMMUNE ELECTRO. (UE)	Ig A (mg/dl)						
	Ig D (mg/dl)						
	Ig E (mg/dl)						
	Ig G (mg/dl)						
	Ig M (mg/dl)						
	Monoclonal (0 or #)						
	Polyclonal (0 or #)						
	Kappa (0 or mg/dl)						
	Lambda (0 or mg/dl)						
	Bence – Jones (0 or #)						
ELECTRO. (RC)	Total Serum Protein (g/dl)						
	Albumin (g/dl)						
	ALPHA 1 (%)						
	ALPHA 2 (%)						
	Beta (%)						
	Gamma (%)						

COMMON LITERAL LABS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

	Date (dy/mth/yr) / Time (hr:min)	Test Name Code (See below)	Body Site** / Normal/Abnormal	Result *(please be concise)*
1.	_____ :		_____ N / A	
2.	_____ :		_____ N / A	
3.	_____ :		_____ N / A	
4.	_____ :		_____ N / A	
5..	_____ :		_____ N / A	
6.	_____ :		_____ N / A	
7.	_____ :		_____ N / A	
8.	_____ :		_____ N / A	

Use this form only for the following tests

Test Name Code		Test Name Code	
EKG or CEKG	Electrocardiogram	EEG	Electroencephalogram
CXR	Chest X-ray	BMCELLTY	BM Cellularity
BRNCHGRM	Bronchogram	UCASTS	Urine Casts
UPGISER	Upper GI Series	MUGASCAN	Muga Scan
LOGISER	Lower GI Series	ULTRASND	Ultra Sound
SKELSURV	Skeletal Survey	CATSCAN	CAT Scan
HOLTMON	Holter Monitor	MRI	MRI
BONESCAN	Bone Scan	XRAY	X-ray
PETSCAN	PET Scan	CULTURE	Culture

**For CAT Scan and MRI please use the following body sites where applicable: Thorax, Abdomen, Pelvis, Brain.

SPECIAL NUMERIC LABS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr)	Protocol #	Institution	Sheet #	Patient ID

PANEL #		DATE	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr	__/__/__ dy/mth/yr
ASSIGNED TEST		TIME (if needed)	:	:	:	:	:	:
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
21.								
22.								
23.								
24.								
25.								

***This form is to be used only for specific lab test names assigned by CTMS for this protocol.**

SPECIAL LITERAL RESULTS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed	Protocol	Institution	Sheet #	Patient ID

PANEL # / ASSIGNED TEST NAME*		DATE (dy/mth/yr)	TIME (hr:mn)	RESULT
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

***This form is to be used only for specific lab test names assigned by CTMS for this protocol.**

UNANTICIPATED LAB DATA

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #	Institution	Sheet #	Patient ID

Date (dy/mth/yr) / Time (hr:min)	Lab Test	Body Site *	Normal or Abnormal	Result and Type
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________
/ / ------------ :			N A	[ ] Literal or [ ] Numeric: Units ____________

* Enter UNAVAIL if not known or not applicable.

PHARMACOKINETICS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:
Study Drug	Date (dy/mth/yr) of Drug Administration	Time (hr:min) of Drug Administration		Type of Specimen*

Time Interval After Start of Dosing (min)	Parent Drug Assay 1 /ml**	Parent Drug Assay 2 /ml**	Parent Drug Mean Conc. /ml**	Metabolite Assay 1 /ml**	Metabolite Assay 2 /ml**	Metabolite Mean Conc. /ml**

*Enter: B = Whole Blood; S = Serum; P = Plasma; C = CSF. If other, write in.

**Enter concentration units: mcg/ml, ng/ml, mcmoles/ml, or other conventional abbreviation.

URINARY EXCRETION

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Sheet #:	Patient ID:

Date (dy/mth/yr) of Drug Administration	Time (hr:min) of Drug Administration	Study Drug:

Date (dy/mth/yr)	Time Start	Time Stop	Urine Volume ml	Parent Drug Assay 1 /ml*	Parent Drug Assay 2 /ml*	Parent Drug Mean Conc. /ml*	Parent Drug Amt in Void ( )**	Metabolite Assay 1 /ml*	Metabolite Assay 2 /ml*	Metabolite Mean Conc. /ml*	Metabolite Amt in Void ( )**

*Enter concentration units: (mg/ml), (mcg/ml), (ng/ml), (mcmoles/ml), or other conventional abbreviation.

**Enter units: mg, mcg, ng, mcmoles, or other conventional abbreviation.

SCINTIGRAPHY

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:	Patient ID:
Trial #:		Date (dy/mth/yr):	

#1 Nuclide Name: _____	#2 Nuclide Name: _____
Aliquot count (ml): _____	Aliquot Count (ml): _____
#1 Antibody Name: _____	#2 Antibody Name: _____
Corrected/Aliquot CPM: _____	Corrected/Aliquot CPM: _____
Total Administered (ml): _____	Total Administered (ml): _____

SH: THX-CTMS-REV.03A

Sample I.D. #	Source Organ	Gamma Scan Positive**	Surgical Follow-Up *** Biopsied (Yes), Identified But Not Biopsied, Not Found	WT. of Sample (grams)	Percent Tumor	Corrected CPM of #1 Nuclide
*Tissue Class	Description of Sample	CT Scan Positive**				#2 Nuclide
		Y / N / E	Y INB NF			
N / T		Y / N / E				
		Y / N / E	Y INB NF			
N / T		Y / N / E				
		Y / N / E	Y INB NF			
N / T		Y / N / E				
		Y / N / E	Y INB NF			
N / T		Y / N / E				
		Y / N / E	Y INB NF			
N / T		Y / N / E				

Circle the appropriate item in the asterisked columns.

*N = Normal; T = Tumor **Y = Yes; N = No, E = Equivocal ***Y = Yes; INB = Identified but not biopsied; NF = Not found

SS: THX-CTMS-REV.03A

INFECTION EPISODE

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed: (dy/mth/yr)	Protocol #:	Institution:	Sheet #:	Patient ID:

Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ______________________ Infectious Agent: ___________________	Treatments: ______________________ ________________________________ Outcome: ________________________ ________________________________
Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ______________________ Infectious Agent: ___________________	Treatments: ______________________ ________________________________ Outcome: ________________________ ________________________________
Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ______________________ Infectious Agent: ___________________	Treatments: ______________________ ________________________________ Outcome: ________________________ ________________________________
Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ______________________ Infectious Agent: ___________________	Treatments: ______________________ ________________________________ Outcome: ________________________ ________________________________
Onset Date (dy/mth/yr) Resolved Date (dy/mth/yr)	Infection Type: ____________________ Primary Site: ______________________ Infectious Agent: ___________________	Treatments: ______________________ ________________________________ Outcome: ________________________ ________________________________

This form required only if mandated by the protocol.

STUDY CONCLUSIONS

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):	Protocol #:	Institution:
CTEP Patient Subgroup:	The Maximum Tolerable Dose Level Has Treatment Assignment Code:	

1	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____
2	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____
3	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____
4	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____
5	Dose Limiting Toxicity: _____ CDUS Toxicity Type Code: _____

Use this form to record the investigator's findings as to the Maximum Tolerable Dose Level for the indicated patient Subgroup, and the Dose Limiting Toxicities on which that finding is based.

CORRELATIVE STUDIES

NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr)	Protocol #	Institution	CTEP ID for Correlative Study

Title: _____

Number of Patients: _____ from whom samples have been collected _____ from whom samples have been analyzed

Number of Samples: _____ collected (total) _____ analyzed (total)

Brief Summary of Findings: *(at completion of study)*

_____

_____

_____

_____

_____

_____

_____

_____

CS: THX-CTMS-REV.03A