

CTMS

3.10 - 3.12

REVISIONS TO
MANUAL FOR THE COMPLETION
OF THE
NCI/DCTD/CTEP
CLINICAL TRIALS MONITORING SERVICE
CASE REPORT FORMS

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Version 3.12

INTRODUCTION

In October 2003 the Manual for the Completion of the CTMS Case Report Forms (version 3.10) was updated to version 3.12. This document contains the revised sections, which may be used to update a copy of the 3.10 Manual.

The following CRFs were revised, along with the accompanying commentary:

Course Assessment

Off Treatment / Off Study Summary

Common Literal Labs

In addition, a chart for coding adverse events according to the new Common Terminology Criteria for Adverse Events version 3 was added to Appendix II.

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COURSE ASSESSMENT
NCI/DCTD/CTMS CASE REPORT FORM

Date Completed <small>(dy/mth/yr)</small>	Protocol #	Institution	Patient ID
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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 *If YES, you may enter an explanation on the*
- (2) Yes, Unplanned *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)

COURSE ASSESSMENT

Complete one page for each course at the time a course is completed and the patient is evaluated or taken off study.

Start Date of

Course: State the date, in dy/mth/yr format, on which the course was started, i.e., the date on which a protocol stipulated drug was first administered. This date must match the date recorded on the corresponding course initiation form.

Course

Disposition: A "completed" course is one that has been conducted in accordance with the protocol with respect to length including the observation period (two day variance allowed). A course is regarded as "discontinued" if it was shorter than specified in the protocol.

Was Dose Different

From the TAC: Indicate if the patient's treatment was different from that specified by the Treatment Assignment Code for this course as recorded on the Course Initiation CRF

Check "No" if the patient received the treatment described by the TAC.

If the treatment was different, indicate whether this was planned or unplanned, and record the reason, e.g. dose reduction due to toxicity, on the Comments Case Report Form.

Check "Yes, Planned" if the change in treatment had been decided before the start of the course, for example due to toxicity on a previous course.

Check "Yes, Unplanned" if the change was not intended at the start of the course, for example shortening the course (and thus lowering the dose level) due to adverse events.

Check "Unknown" only in when the actual treatment cannot be determined, for example when the patient is uncooperative in reporting self-administration.

Best

Response

Assessment:

Indicate the patient's best disease state as assessed during the course. This determination must be adequately documented. If the response is Not Evaluable, or response was Not Assessed, check the appropriate box and state the reason. If the protocol does not require a response assessment during a specific course, check the box for NP, not applicable per protocol. If it is Too Early to confirm a response, check the TE box.

COURSE ASSESSMENT (cont'd)

Unless the protocol includes specific response evaluation criteria, the following guidelines should be observed:

Responses of PR and MR are assessed relative to the baseline at start of treatment, not to previous courses. They must be confirmed by repeat assessments. Subsequent evaluations at which tumor sizes are substantially unchanged should be assessed again as the same PR/MR.

A response of PD is relative to the best disease status (smallest tumor measurement) since treatment began. Thus a tumor re-growth after a PR would be assessed as PD not an MR. A PR or MR cannot follow a CR.

Stable disease (SD) indicates tumor growth or shrinkage since the start of treatment that is not enough to justify a CR/PR/MR response or a PD progression. Once an actual CR/PR/MR response or PD progression has occurred, an SD assessment is not valid.

Disease Unchanged (DU) indicates that the patient's disease is unchanged relative to the previous assessment. This code may be used when a CR/PR/MR/PD response is not merited but SD is inappropriate.

Date of Evaluation:

Record the date, in dy/mth/yr format, of the earliest evaluation which, upon confirmation, justifies an assessment of CR, PR, MR, or SD/DU.

For NE, record the date the patient's disease was assessed and deemed to be Not Evaluable.

NOTE:

The original date of onset of response should be used for responses that persist through several courses.

Date of Evaluation of Progression:

Record the date, in dy/mth/yr format, of the evaluation used to determine the patient's disease status of progressive disease. A date of progression may be entered if the disease progression occurred after an assessed better response.

Any Toxicity:

If no adverse events occurred during this course, "No" should be checked. If any AE has occurred, "Yes" should be checked and the event must be recorded on the Adverse Events case report form.

COURSE ASSESSMENT (cont'd)

RECIST: Many protocols specify that the following RECIST criteria are to be used in assessing response.

Evaluation of target lesions:

CR	Complete Response	Disappearance of all target lesions.
PR	Partial Response	At least a 30% decrease in the sum of the LD (longest dimension) of target lesions, taking as reference the baseline sum LD.
PD	Progressive Disease	At least a 20% increase in the sum of the LD of target lesions, taking as reference the smallest sum LD recorded since the treatment started or the appearance of one or more new lesions.
SD	Stable Disease	Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum LD since the treatment started.

Evaluation of non-target lesions:

CR	Complete Response	Disappearance of all non-target lesions and normalization of tumor marker level.
SD	Incomplete Response/ Stable Disease	Persistence of one or more non-target lesion(s) or/and maintenance of tumor marker level above the normal limits.
PD	Progressive Disease	Appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions.

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OFF TREATMENT / OFF STUDY
NCI/DCTD/CTMS CASE REPORT FORM

Date Completed <small>dy/mth/yr</small>	Protocol ID	Institution	Patient ID
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Date Last Course Completed: _____ *Last course discontinued or completed including observation period. No further treatment planned.*
(dy/mth/yr)

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:

<input type="checkbox"/>]P Disease Progression On Study **	<input type="checkbox"/>]D Death During Treatment
<input type="checkbox"/>]T Adverse Events/Side Effects	<input type="checkbox"/>]S Complicating Disease / Intercurrent Illness
<input type="checkbox"/>]G Cytogenetic Resistance	<input type="checkbox"/>]A Switched to Alternative Treatment
<input type="checkbox"/>]R Refused Further Participation	<input type="checkbox"/>]I Late Determination of Ineligibility
<input type="checkbox"/>]V Protocol Violation	<input type="checkbox"/>]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:

<input type="checkbox"/>]H Follow-up Period Completed	<input type="checkbox"/>]L Lost to Further Follow-up
<input type="checkbox"/>]W Refused Further Follow-up	<input type="checkbox"/>]E Late Adverse Events/Side Effects
<input type="checkbox"/>]M Death during Follow-up Period	<input type="checkbox"/>]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*

<input type="checkbox"/>] NE all courses Not Evaluable	<input type="checkbox"/>] NP Assessment Not Applicable per protocol
<input type="checkbox"/>] NA all courses Not Assessed	<input type="checkbox"/>] TE all courses Too Early

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

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

Date of Progression: **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*

(dy/mth/yr) _____

OFF TREATMENT / OFF STUDY SUMMARY

This CRF must be completed for each patient coming off study. It should not be used to follow patients' response while still on study. If the protocol includes a specified period of follow-up observation after the last treatment course then this form should be submitted at the end of the period of active treatment and then updated after the follow-up period.

Date

Last Course

Completed:

Record the date, in dy/mth/yr format, when all courses have been completed (including the normal observation period) or discontinued and no further treatment courses are planned. For most protocols this will be the “off-study” date. Ordinarily, the date off study should not intrude on the protocol stipulated observation period.

Reason:

Indicate one reason, as defined below:

Study Completed: The patient's participation has been completed as per protocol, and the protocol does not specify a follow-up observation period. Note that a plan to continue seeing the patient for extended follow-up as a matter of medical practice does not constitute a “follow-up period” in the sense of this CRF.

Patient was Never Treated: the patient was evaluated for entry to the protocol and signed an informed consent form but was not treated – because:

Patient Declined to Participate – before treatment started.

Disease Progression before Treatment.

No Treatment, per protocol.

Other Reasons: please explain.

Participation Terminated during Treatment Phase – because:

Disease Progression On Study: The patient was taken off study for disease progression. This must be reflected by an increase in the non-measurable or measurable disease state. (See Course Assessment and Extent of Disease Forms). This can be manifested as clinical deterioration. *A Date of Progression must be recorded.*

Death During Treatment: The patient has died during the treatment phase. The date off treatment must coincide with the date of death. The cause of death should be listed on the Adverse Event form.

Adverse Events / Side Effects: The patient experienced any toxicity that was considered related to the study drug which prohibited further protocol treatment. Patients discontinued due to toxicity are evaluable provided the observation period has been completed per protocol. The toxicity must be listed on the Adverse Events form.

OFF TREATMENT / OFF STUDY SUMMARY (cont'd)

Complicating Disease / Intercurrent Illness: Patient was taken off study due to complicating disease not related to malignancy. This should be included in the Adverse Event form by an event not considered to be related to therapy.

Cytogenetic Resistance.

Switched to Alternative Treatment: If patient was removed from study due to a decision to pursue alternative therapy (such as palliative radiation).

Refused Further Treatment: If at any time the patient refused further treatment or follow-up.

Late Determination of Ineligibility: Patient was taken off study following treatment because follow-up tests indicate that patient was not eligible for the study.

Protocol Violation: If a major protocol violation has occurred, the reason must be stated in the Comments form.

Other: Other reasons may be given for taking the patient off treatment, although they may not be included in the protocol stipulated rules. The patient's evaluability will subsequently be determined. Please explain.

Completed Treatment Phase but Patient Refused Protocol-Specified Follow-up.

Began Protocol Specified Follow-up: This is a “place-holder” to indicate that the patient is not off-study yet.

Date Off Protocol Follow-up: Record the date, in dy/mth/yr format, when the patient completes or is removed from the protocol-specified follow-up observation period. This will be the “off-study” date – because:

Follow-up Period Completed: The patient completed the study including the observation period as per protocol, and is off-study.

Lost to Further Follow-up: Follow-up information could not be obtained because contact with the patient was lost.

Refused Further Follow-up: The patient has refused to appear for scheduled appointments or otherwise cooperate in the follow-up phase.

Death during Follow-up Period: The patient has died during the follow-up phase. The date off follow-up must coincide with the date of death. The cause of death should be listed on the Adverse Event form.

OFF TREATMENT / OFF STUDY SUMMARY (cont'd)

Late Adverse Events / Side Effects: The patient experiences any toxicity that prohibited further participation in the observation period. The toxicity must be listed on the Adverse Events form. The patient's evaluability will subsequently be determined.

Other Reasons: Other reasons may be given for taking the patient off follow-up, although they may not be included in the protocol stipulated rules. The patient's evaluability will subsequently be determined. Please explain.

*Note that the “Reasons” are mutually exclusive, so only one can be checked.
Note also that every patient will have a Last Course Completed Date, but the Off-Follow-up Date is appropriate only for certain protocols.*

Best Overall Response to Treatment:

Indicate the best overall response to treatment while on protocol. According to RECIST and WHO guidelines this would be the best response assessed from the start of treatment until disease progression.

Ordinarily this would be the best of the responses reported on the course assessment CRFs. For example, do not enter “SD” if the patient was assessed only with progressive disease.

Please be sure to enter the best response, not necessarily the response on the last course. For example, if the patient was assessed with a PR followed by a PD, enter the “PR”.

If response was not assessed at all during the protocol treatment record the best response as NA; similarly for NE and NP.

RECIST:

Unless the protocol includes specific response evaluation criteria, the following RECIST and WHO guidelines should be observed:

Responses of PR and MR are assessed relative to the baseline at start of treatment, not to previous courses. They must be confirmed by repeat assessments. Subsequent evaluations at which tumor sizes are substantially unchanged should be assessed again as the same PR/MR.

A response of PD is relative to the best disease status (smallest tumor measurement) since treatment began. Thus a tumor re-growth after a PR would be assessed as PD not an MR. A PR or MR cannot follow a CR.

OFF TREATMENT / OFF STUDY SUMMARY (cont'd)

Stable disease (SD) indicates tumor growth or shrinkage relative to the baseline that is not enough to justify a MR/PR/CR response or a PD progression. Consequently it is not a valid assessment once a CR/PR/MR or PD has been assessed. An actual response that persists should continue to be assessed as a response – relative to the baseline.

Date of

Best Response:

Record the date, in dy/mth/yr format, that a response of CR, PR, or MR was first observed, or that an SD response began. This date must be consistent with the date recorded on the Course Assessment form(s) and with evaluations on the Extent of Disease Form.

Date of

Progression:

Record (in dy/mth/yr format) the date that progression (or relapse) was first observed. **This date is required if the Reason Last Course Completed is for Progressive Disease.**

This date must be consistent with the date of progression recorded on the Course Assessment form(s) and with evaluations on the Extent of Disease Form.

Progression is the worsening of disease following a period of stable disease or a response. Relapse is the reoccurrence of disease in a patient with no evaluable disease at enrollment (e.g. on an adjuvant treatment study).

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COMMON LITERAL LABS
NCI/DCTD/CTMS CASE REPORT FORM

Date Completed (dy/mth/yr):		Protocol #:	Institution:	Sheet #:	Patient ID:
	Date (dy/mth/yr)	Test Name Code (See below)	Body Site**	Result <i>(please be concise)</i>	
	Time (hr:min)		Normal/Abnormal		
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.

LL: THX-CTMS-REV.03B

COMMON LITERAL LABS

General: Use this form to record the results of common laboratory or other tests that are literal rather than numeric. Complete and number sequentially additional sheets as required. Enter all dates in dy/mth/yr format.

Lab Date: Record the date that the test done, not the date it was interpreted, e.g. by the radiologist or investigator.

Time: In the event that multiple investigations are obtained on the same date, record the time of the test using hours and minutes (24-hour clock).

Test Name: Record the name of the test as listed at the bottom of the form:

CEKG	Electrocardiogram
CXR	Chest X-ray
BRNCHGRM	Bronchogram
UPGISER	Upper GI Series
LOGISER	Lower GI Series
SKELSURV	Skeletal Survey
HOLTMON	Holter Monitor
BONESCAN	Bone Scan
EEG	Electroencephalogram
BMCELLUTY	Bone Marrow Cellularity
UCASTS	Urine Casts
MUGASCAN	Muga Scan
ULTRASND	Ultrasound
CATSCAN	CAT Scan
MRI	MRI
X-RAY	X-ray
PETSCAN	PET Scan
CULTURE	Culture

Body Site: In the case of tests such as CATSCAN, MRI, and X-RAY record the applicable body site. For CAT Scan and MRI use thorax, abdomen, pelvis or brain. For CULTURE, indicate the cultured specimen, e.g. blood, urine, sputum, etc.

**Normal/
Abnormal:** Circle N or A to indicate if results are normal or abnormal.

Result: Record the results, if abnormal. Please be concise since there is limited space (128 characters) for this entry in the database.

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NCI/CTEP Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0

Short Abbreviations for the Standard Terms, abstracted from the 10 June 2003 release with "MedDRA-6.0" Codes for submission of AEs to CTMS and CDUS-3.0-r2

for explanation and updates, consult the NCI/DCTD/CTEP website <CTEP.cancer.gov>

== ALLERGY / IMMUNOLOGY

90 004 000 Allergy - Other
10 020 755 Allergic reaction incl drug fever
10 039 087 Allergic rhinitis [12]
10 003 815 Autoimmune reaction
10 040 400 Serum sickness [35]
10 047 128 Vasculitis

== AUDITORY / EAR

90 004 002 Auditory/Ear - Other
10 053 491 Hearing (monitoring prog) [1234]
10 019 245 Hearing (w/o monitoring) [234]
10 052 558 Otitis, external (non-infectious)
10 033 091 Otitis, middle (non-infectious)
10 043 882 Tinnitus [234]

== BLOOD / BONE MARROW

90 004 018 Blood/Bone Marrow - Other
10 005 987 Bone marrow cellularity [1235]
10 007 839 CD4 count
10 050 744 Haptoglobin [135]
10 018 876 Hemoglobin
10 018 914 Hemolysis
10 005 620 Iron overload [2345]
10 024 285 Leukocytes (WBC)
10 025 327 Lymphopenia
10 028 532 Myelodysplasia [345]
10 029 363 Neutrophils (ANC/AGC)
10 035 528 Platelets
10 041 634 Splenic function [1245]

== CARDIAC ARRHYTHMIA

10 003 127 Cardiac Arrhythmia - Other
10 033 557 Palpitations [12]
10 014 387 Prolonged QTc
10 042 777 Vasovagal episode [2345]
select ↓ Conduction abnormality (*)
90 030 002 AV Block-2nd deg Mobitz Type I
90 030 004 AV Block-2nd deg Mobitz Type II
10 003 674 AV Block-First degree
10 003 673 AV Block-Third degree
10 047 284 Asystole
10 003 676 Conduction abnormality NOS
10 040 639 Sick Sinus Syndrome
10 001 115 Stokes-Adams Syndrome
10 048 015 Wolff-Parkinson-White Syndrome
select ↓ Supraventricular arrhythmia (*)
10 003 658 Atrial fibrillation
10 003 662 Atrial flutter
10 003 668 Atrial tachycardia
10 029 458 Nodal/Junctional
10 040 739 Sinus arrhythmia
10 040 741 Sinus bradycardia
10 040 752 Sinus tachycardia
10 042 599 Supraventricular arrhythmia NOS
10 042 602 Supraventricular extrasystoles
10 042 604 Supraventricular tachycardia
select ↓ Ventricular arrhythmia (*)
10 050 779 Bigeminy
10 039 111 Idioventricular rhythm
10 047 289 PVCs
10 044 066 Torsade de pointes
10 050 780 Trigeminy
10 047 282 Ventricular arrhythmia NOS
10 047 290 Ventricular fibrillation
10 047 294 Ventricular flutter
10 047 302 Ventricular tachycardia

== CARDIAC GENERAL

90 004 028 Cardiac General - Other
10 028 600 Cardiac ischemia/infarction
10 007 617 Cardiopulmon arrest non-fatal [4]
10 020 782 Hypertension
10 021 099 Hypotension
10 052 337 Left ventric diastolic dysfunction
10 024 119 Left ventric systolic dysfunction
10 028 613 Myocarditis [345]
10 034 474 Pericard effusion (non-malig) [1345]
10 034 495 Pericarditis
10 037 403 Pulmonary hypertension
10 038 748 Restrictive cardiomyopathy
10 010 971 Right ventricular dysfunction
10 046 972 Valvular heart disease
10 058 268 cTnI Cardiac troponin I [345]
10 058 269 cTnT Cardiac troponin T

== DERMATOLOGY / SKIN

90 004 042 Dermatology/Skin - Other
10 000 510 Acne [1235]
10 001 760 Alopecia [12]
10 040 799 Atrophy, skin [12]
10 016 242 Atrophy, subcutaneous fat [12]
10 014 080 Bruising (no thrombopenia) [12]
90 030 006 Burn
10 008 417 Chelitis [123]
10 011 985 Decubitus [2345]
10 013 786 Dry skin [123]
10 015 218 Erythema multiforme [2345]
10 016 825 Flushing [12]
10 024 772 Hand-foot syndrome [123]
10 040 865 Hyperpigmentation [12]
10 040 868 Hypopigmentation [12]
10 050 207 Induration [123]
10 022 096 Injection site reaction [123]
10 028 696 Nail changes [123]
10 034 973 Photosensitivity
10 037 087 Pruritus [123]
10 012 457 Rash/desquamation
10 040 925 Striae [12]
10 043 189 Telangiectasia [123]
90 030 008 Ulceration [2345]
10 046 749 Urticaria [123]
10 011 642 Wound complication non-infectious
select ↓ Dermatitis (*)
10 037 768 Chemoradiation
10 012 487 Radiation

== ENDOCRINE

90 004 046 Endocrine - Other
10 005 452 ACTH deficiency
10 053 198 ADH abnormality
10 001 369 Adrenal insufficiency
10 011 655 Cushingoid [2]
10 018 429 Diabetes
10 049 290 Feminization of male [3]
10 054 028 Gonadotropin [123]
10 005 572 Growth hormone [12]
10 020 413 Hot flashes [123]
10 043 789 Hyperthyroidism
10 021 041 Hypoparathyroidism [12]
10 021 114 Hypothyroidism
10 047 486 Masculinization of female [3]
10 005 878 Prolactin [1235]

== GROWTH AND DEVELOPMENT

90 030 124 Growth and Development - Other
10 005 954 Bone age [2]
10 012 205 Delayed puberty [23]
10 041 028 Femoral head growth [1234]
10 023 509 Kyphosis/lordosis [1234]
90 030 120 Limb length [1234]
10 036 520 Precocious puberty [2]
90 030 122 Reduction in growth velocity [123]
10 056 811 Short stature [12]

== HEMORRHAGE / BLEEDING

90 004 058 Hem/Bleeding - Other [1345]
10 018 854 Hematoma
10 051 077 Hemorrhage with surgery [345]
10 019 016 CNS hemorrhage
10 034 754 Petechiae [123]
select ↓ Hemorrhage, GI (*)
10 022 729 Abdomen NOS
10 049 555 Anus
90 030 126 Biliary tree
90 030 128 Cecum/appendix
10 009 997 Colon
10 013 829 Duodenum
10 030 172 Esophagus
10 021 301 Ileum
10 023 173 Jejunum
10 019 677 Liver
10 050 953 Lower GI NOS
10 028 024 Oral cavity
10 033 625 Pancreas
10 034 666 Peritoneal cavity
10 038 063 Rectum
10 049 468 Stoma
10 017 788 Stomach
90 030 130 Upper GI NOS
10 030 209 Varices (esophageal)
10 054 787 Varices (rectal)
select ↓ Hemorrhage, GU (*)
10 046 528 Bladder
10 050 468 Fallopian tube
10 038 460 Kidney
90 030 132 Ovary
10 036 960 Prostate
10 038 980 Retroperitoneum
90 030 134 Spermatic cord
90 030 136 Stoma
10 051 877 Testes
90 030 138 Ureter
10 049 710 Urethra
10 050 058 Urinary NOS
10 046 788 Uterus
10 046 910 Vagina
90 030 140 Vas deferens
select ↓ Hemorrhage, pulmonary (*)
90 030 142 Bronchopulmonary NOS
90 030 144 Bronchus
90 030 146 Larynx
10 037 394 Lung
10 056 343 Mediastinum
10 015 090 Nose
90 030 148 Pharynx
10 035 601 Pleura
10 038 729 Respiratory tract NOS
90 030 150 Stoma
90 030 152 Trachea

== COAGULATION

10 009 802 Coagulation - Other
10 013 442 DIC [2345]
10 005 517 Fibrinogen
10 037 063 INR (intl.norm.ratio of PT) [123]
10 000 636 PTT [123]
10 043 646 Thrombotic microangiopath [1345]

== CONSTITUTIONAL SYMPTOMS

90 004 038 Constitutional Symptoms - Other
10 016 256 Fatigue [1234]
10 037 660 Fever
10 021 113 Hypothermia [2345]
10 022 437 Insomnia [1234]
10 029 883 Obesity [234]
10 040 904 Patient odor [12]
10 039 177 Rigors/chills [123]
10 042 667 Sweating [12]
10 047 899 Weight gain [123]
10 047 895 Weight loss [123]

== DEATH

select ↓ Death NOS in CTCAE (*) [5]
10 011 914 Death NOS [5]
10 049 830 Disease progression NOS [5]
10 028 154 Multi-organ failure [5]
10 042 434 Sudden death [5]

== HEPATOBIILIARY / PANCREAS

90 004 062 Hepatobiliary/Pancreas - Other
10 008 619 Cholecystitis
10 019 663 Liver dysfunction [2345]
10 033 622 Pancreas, exocr enzy defic [2345]
10 033 656 Pancreatitis

== METABOLIC / LABORATORY

90 004 074 Metabolic/Laboratory - Other
10 001 551 ALT, SGPT [1234]
10 003 481 AST, SGOT [1234]
10 000 493 Acidosis [1345]
10 059 570 Alkaline phosphatase [1234]
10 001 687 Alkalosis [1345]
10 005 328 Amylase [1234]
10 005 359 Bicarbonate, serum-low
10 005 364 Bilirubin [1234]
10 005 470 CPK
10 020 603 Cholesterol
10 005 483 Creatinine
10 018 355 GFR
10 017 693 GGT [1234]
10 018 906 Hemoglobinuria [15]
10 020 583 Hypercalcemia
10 020 637 Hyperglycemia
10 020 646 Hyperkalemia
10 020 669 Hypermagnesemia [1345]
10 020 679 Hypnatremia
10 020 869 Hypertriglyceridemia
10 020 903 Hyperuricemia [1345]
10 020 942 Hypoalbuminemia [1235]
10 020 947 Hypocalcemia
10 020 996 Hypoglycemia
10 021 015 Hypokalemia [1345]
10 021 027 Hypomagnesemia
10 021 036 Hyponatremia [1345]
10 021 058 Hypophosphatemia
10 024 574 Lipase [1234]
10 037 032 Proteinuria

== INFECTION

90 004 068 Infection - Other
 10 009 655 Colitis, infectious
 10 016 288 Febrile neutropenia [2345]
 10 030 901 Opportunistic infection [2345]
 10 056 885 Viral hepatitis
 select ↓ Infection (clinical) (*) [2345]
 90 030 154 Abdomen NOS [2345]
 90 030 156 Anal/perianal [2345]
 90 030 158 Appendix [2345]
 90 030 160 Artery [2345]
 90 030 162 Biliary tree [2345]
 90 030 164 Bladder (urinary) [2345]
 90 030 166 Bone (osteomyelitis) [2345]
 90 030 168 Brain (encephalitis, infect) [2345]
 90 030 170 Brain/Spi (enceph.myelitis) [2345]
 90 030 172 Bronchus [2345]
 90 030 174 Catheter-related [2345]
 90 030 176 Cecum [2345]
 90 030 178 Cervix [2345]
 90 030 180 Colon [2345]
 90 030 182 Conjunctiva [2345]
 90 030 184 Cornea [2345]
 90 030 186 Dental-tooth [2345]
 90 030 188 Duodenum [2345]
 90 030 190 Esophagus [2345]
 90 030 192 External ear (otitis externa) [2345]
 90 030 194 Eye NOS [2345]
 90 030 196 Fallopian tube [2345]
 90 030 198 Foreign body [2345]
 90 030 200 Gallbladder (cholecystitis) [2345]
 90 030 202 Heart (endocarditis) [2345]
 90 030 204 Ileum [2345]
 90 030 206 Jejunum [2345]
 90 030 208 Joint [2345]
 90 030 210 Kidney [2345]
 90 030 212 Larynx [2345]
 90 030 214 Lens [2345]
 90 030 216 Lip/perioral [2345]
 90 030 218 Liver [2345]
 90 030 220 Lung (pneumonia) [2345]
 90 030 222 Lymphatic [2345]
 90 030 224 Mediastinum NOS [2345]
 90 030 226 Meninges (meningitis) [2345]
 90 030 228 Middle ear (otitis media) [2345]
 90 030 230 Mucosa [2345]
 90 030 232 Muscle (infection myositis) [2345]
 90 030 234 Neck NOS [2345]
 90 030 236 Nerve-cranial [2345]
 90 030 238 Nerve-peripheral [2345]
 90 030 240 Nose [2345]
 90 030 242 Oral cav-gums (gingivitis) [2345]
 90 030 244 Pancreas [2345]
 90 030 246 Paranasal [2345]
 90 030 248 Pelvis NOS [2345]
 90 030 250 Penis [2345]
 90 030 252 Peristomal [2345]
 90 030 254 Peritoneal cavity [2345]
 90 030 256 Pharynx [2345]
 90 030 258 Pleura (empyema) [2345]
 90 030 260 Prostate [2345]
 90 030 262 Rectum [2345]
 90 030 264 Salivary gland [2345]
 90 030 266 Scrotum [2345]
 90 030 268 Sinus [2345]
 90 030 270 Skin (cellulitis) [2345]
 90 030 272 Small bowel NOS [2345]
 90 030 274 Soft tissue NOS [2345]
 90 030 276 Spinal cord (myelitis) [2345]
 90 030 278 Spleen [2345]
 90 030 280 Stomach [2345]
 90 030 282 Trachea [2345]
 90 030 284 Ungual (nails) [2345]
 90 030 286 Upper aerodigestive NOS [2345]
 90 030 288 Upper airway NOS [2345]
 90 030 290 Ureter [2345]
 90 030 292 Urethra [2345]

90 030 294 Urinary tract NOS [2345]
 90 030 296 Uterus [2345]
 90 030 298 Vagina [2345]
 90 030 300 Vein [2345]
 90 030 302 Vulva [2345]
 90 030 304 Wound [2345]
 select ↓ Infection with normal ANC(*) [2345]
 10 056 519 Abdomen NOS [2345]
 10 051 539 Anal/perianal [2345]
 90 030 306 Appendix [2345]
 90 030 308 Artery [2345]
 10 056 523 Biliary tree [2345]
 10 005 048 Bladder (urinary) [2345]
 10 005 977 Bone (osteomyelitis) [2345]
 10 014 601 Brain (encephalitis, infect) [2345]
 10 058 805 Brain/Spi (enceph.myelitis) [2345]
 10 006 461 Bronchus [2345]
 90 030 309 Catheter-related [2345]
 90 030 310 Cecum [2345]
 10 008 331 Cervix [2345]
 90 030 312 Colon [2345]
 90 030 314 Conjunctiva [2345]
 10 011 020 Cornea [2345]
 10 048 762 Dental-tooth [2345]
 90 030 316 Duodenum [2345]
 90 030 318 Esophagus [2345]
 90 030 319 External ear (otitis externa) [2345]
 10 015 936 Eye NOS [2345]
 90 030 320 Fallopian tube [2345]
 10 059 650 Foreign body [2345]
 90 030 322 Gallbladder (cholecystitis) [2345]
 10 014 678 Heart (endocarditis) [2345]
 90 030 324 Ileum [2345]
 90 030 326 Jejunum [2345]
 10 003 259 Joint [2345]
 10 023 429 Kidney [2345]
 90 030 328 Larynx [2345]
 90 030 330 Lens [2345]
 90 030 332 Lip/perioral [2345]
 10 056 522 Liver [2345]
 10 035 725 Lung (pneumonia) [2345]
 10 050 823 Lymphatic [2345]
 10 057 483 Mediastinum NOS [2345]
 10 053 638 Meninges (meningitis) [2345]
 10 033 084 Middle ear (otitis media) [2345]
 10 028 810 Mucosa [2345]
 10 021 918 Muscle (infection myositis) [2345]
 90 030 334 Neck NOS [2345]
 90 030 336 Nerve-cranial [2345]
 90 030 338 Nerve-peripheral [2345]
 10 059 827 Nose [2345]
 10 058 802 Oral cav-gums (gingivitis) [2345]
 10 051 741 Pancreas [2345]
 90 030 340 Paranasal [2345]
 90 030 342 Pelvis NOS [2345]
 10 034 306 Penis [2345]
 90 030 344 Peristomal [2345]
 10 057 262 Peritoneal cavity [2345]
 10 034 835 Pharynx [2345]
 10 051 167 Pleura (empyema) [2345]
 10 050 662 Prostate [2345]
 10 002 579 Rectum [2345]
 90 030 346 Salivary gland [2345]
 10 039 752 Scrotum [2345]
 10 040 756 Sinus [2345]
 10 040 872 Skin (cellulitis) [2345]
 90 030 348 Small bowel NOS [2345]
 10 049 582 Soft tissue NOS [2345]
 10 049 654 Spinal cord (myelitis) [2345]
 10 051 724 Spleen [2345]
 10 056 663 Stomach [2345]
 10 044 303 Trachea [2345]
 10 028 687 Ungual (nails) [2345]
 90 030 350 Upper aerodigestive NOS [2345]
 10 049 083 Upper airway NOS [2345]
 10 051 250 Ureter [2345]
 10 052 298 Urethra [2345]

10 046 574 Urinary tract NOS [2345]
 10 050 447 Uterus [2345]
 10 046 915 Vagina [2345]
 10 056 627 Vein [2345]
 10 050 348 Vulva [2345]
 90 030 351 Wound [2345]
 select ↓ Infection w/ unknown ANC(*) [2345]
 90 030 352 Abdomen NOS [2345]
 90 030 354 Anal/perianal [2345]
 90 030 356 Appendix [2345]
 90 030 358 Artery [2345]
 90 030 360 Biliary tree [2345]
 90 030 362 Bladder (urinary) [2345]
 90 030 364 Bone (osteomyelitis) [2345]
 90 030 366 Brain (encephalitis, infect) [2345]
 90 030 368 Brain/Spi (enceph.myelitis) [2345]
 90 030 370 Bronchus [2345]
 10 007 810 Catheter-related [2345]
 90 030 374 Cecum [2345]
 90 030 376 Cervix [2345]
 90 030 378 Colon [2345]
 90 030 380 Conjunctiva [2345]
 90 030 382 Cornea [2345]
 90 030 384 Dental-tooth [2345]
 90 030 386 Duodenum [2345]
 90 030 388 Esophagus [2345]
 10 014 012 External ear (otitis externa) [2345]
 90 030 392 Eye NOS [2345]
 90 030 394 Fallopian tube [2345]
 90 030 396 Foreign body [2345]
 90 030 398 Gallbladder (cholecystitis) [2345]
 90 030 400 Heart (endocarditis) [2345]
 90 030 402 Ileum [2345]
 90 030 404 Jejunum [2345]
 90 030 406 Joint [2345]
 90 030 408 Kidney [2345]
 90 030 410 Larynx [2345]
 90 030 412 Lens [2345]
 90 030 414 Lip/perioral [2345]
 90 030 416 Liver [2345]
 90 030 418 Lung (pneumonia) [2345]
 90 030 420 Lymphatic [2345]
 90 030 422 Mediastinum NOS [2345]
 90 030 424 Meninges (meningitis) [2345]
 90 030 426 Middle ear (otitis media) [2345]
 90 030 428 Mucosa [2345]
 90 030 430 Muscle (infection myositis) [2345]
 90 030 432 Neck NOS [2345]
 90 030 434 Nerve-cranial [2345]
 90 030 436 Nerve-peripheral [2345]
 90 030 438 Nose [2345]
 90 030 440 Oral cav-gums (gingivitis) [2345]
 90 030 442 Pancreas [2345]
 90 030 444 Paranasal [2345]
 90 030 446 Pelvis NOS [2345]
 90 030 448 Penis [2345]
 90 030 450 Peristomal [2345]
 90 030 452 Peritoneal cavity [2345]
 90 030 454 Pharynx [2345]
 90 030 456 Pleura (empyema) [2345]
 90 030 458 Prostate [2345]
 90 030 460 Rectum [2345]
 90 030 462 Salivary gland [2345]
 90 030 464 Scrotum [2345]
 90 030 466 Sinus [2345]
 90 030 468 Skin (cellulitis) [2345]
 90 030 470 Small bowel NOS [2345]
 90 030 472 Soft tissue NOS [2345]
 90 030 474 Spinal cord (myelitis) [2345]
 90 030 476 Spleen [2345]
 90 030 478 Stomach [2345]
 90 030 480 Trachea [2345]
 90 030 482 Ungual (nails) [2345]
 90 030 484 Upper aerodigestive NOS [2345]
 90 030 486 Upper airway NOS [2345]
 90 030 488 Ureter [2345]
 90 030 490 Urethra [2345]

90 030 492 Urinary tract NOS [2345]
 90 030 494 Uterus [2345]
 90 030 496 Vagina [2345]
 90 030 498 Vein [2345]
 90 030 500 Vulva [2345]
 10 048 038 Wound [2345]

== LYMPHATICS

90 004 072 Lymphatics - Other
 90 030 504 Chyle or lymph leakage
 10 025 284 Dermal change [12]
 90 030 506 Edema: head and neck
 90 030 508 Edema: limb
 90 030 510 Edema: trunk/genital
 90 030 512 Edema: viscera
 90 030 514 Lymphedema-related fibrosis [123]
 10 048 642 Lymphocele [123]
 90 030 516 Phlebolympathic cording [123]

== PAIN

90 004 082 Pain - Other [1234]
 select ↓ Pain (*) [1234]
 10 000 085 Abdomen NOS [1234]
 10 052 811 Anus [1234]
 10 003 988 Back [1234]
 10 005 063 Bladder [1234]
 10 006 002 Bone [1234]
 10 006 298 Breast [1234]
 10 048 677 Buttock [1234]
 10 002 383 Cardiac/heart [1234]
 10 008 496 Chest wall [1234]
 10 008 479 Chest/thorax NOS [1234]
 10 044 055 Dental/teeth/peridontal [1234]
 10 030 180 Esophagus [1234]
 90 030 566 External ear [1234]
 10 033 425 Extremity-limb [1234]
 10 015 958 Eye [1234]
 10 016 059 Face [1234]
 10 017 638 Gallbladder [1234]
 10 019 211 Head/headache [1234]
 10 018 000 Intestine [1234]
 10 003 239 Joint [1234]
 10 038 490 Kidney [1234]
 10 054 115 Larynx [1234]
 10 024 561 Lip [1234]
 10 019 705 Liver [1234]
 10 025 182 Lymph node [1234]
 10 014 020 Middle ear [1234]
 10 028 411 Muscle [1234]
 10 028 836 Neck [1234]
 10 029 226 Neuralgia/peripheral nerve [1234]
 10 031 009 Oral cavity [1234]
 10 018 286 Oral-gums [1234]
 10 033 314 Ovulatory [1234]
 10 033 470 Pain NOS [1234]
 10 034 264 Pelvis [1234]
 10 034 310 Penis [1234]
 90 030 568 Pericardium [1234]
 10 034 527 Perineum [1234]
 90 030 570 Peritoneum [1234]
 10 056 238 Phantom (missing limb) [1234]
 10 035 623 Pleura [1234]
 10 036 968 Prostate [1234]
 10 036 772 Rectum [1234]
 90 030 572 Scalp [1234]
 10 039 757 Scrotum [1234]
 10 040 747 Sinus [1234]
 10 033 474 Skin [1234]
 10 042 101 Stomach [1234]
 10 043 345 Testicle [1234]
 10 034 844 Throat/pharynx/larynx [1234]
 10 058 019 Tumor pain [1234]
 10 046 461 Urethra [1234]
 10 046 809 Uterus [1234]
 10 046 937 Vagina [1234]

== GASTROINTESTINAL

90 004 050 Gastrointestinal - Other
 10 002 646 Anorexia
 10 003 445 Ascites
 10 009 898 Colitis
 10 010 774 Constipation
 10 012 174 Dehydration
 10 050 857 Dentures [123]
 10 012 745 Diarrhea
 10 000 060 Distension/bloating [123]
 10 013 781 Dry mouth [123]
 10 013 950 Dysphagia
 10 014 866 Enteritis
 10 030 220 Esophagitis
 10 016 766 Flatulence [12]
 10 017 869 Gastritis
 10 013 946 Heartburn [123]
 10 019 022 Hemorrhoids
 10 021 333 Ileus
 10 016 092 Incontinence, anal
 10 025 476 Malabsorption [2345]
 10 028 813 Nausea
 10 034 537 Periodontitis [123]
 10 036 782 Proctitis
 90 030 110 Prolapse of stoma, GI
 10 039 405 Salivary gland changes [1234]
 10 013 911 Taste alteration [12]
 10 044 035 Teeth [123]
 10 044 030 Teeth development [123]
 10 006 919 Typhlitis
 10 047 706 Vomiting
 select ↓ Perforation, GI (*)
 90 030 108 Appendix
 10 034 405 Biliary tree
 10 049 873 Cecum
 10 010 001 Colon
 10 013 832 Duodenum
 10 030 181 Esophagus
 10 017 639 Gallbladder
 10 021 305 Ileum
 10 023 174 Jejunum
 10 038 073 Rectum
 10 041 104 Small bowel NOS
 10 017 815 Stomach
 select ↓ Leak, GI (*)
 90 030 022 Biliary tree
 90 030 024 Esophagus
 90 030 026 Large bowel
 90 030 028 Leak NOS
 10 050 457 Pancreas
 90 030 030 Pharynx
 10 054 119 Rectum
 90 030 032 Small bowel
 90 030 034 Stoma
 90 030 036 Stomach
 select ↓ Mucositis (clinical exam) (*)
 90 030 038 Anus
 90 030 040 Esophagus
 90 030 042 Large bowel
 90 030 044 Larynx
 90 030 045 Oral cavity
 90 030 046 Pharynx
 90 030 048 Rectum
 90 030 050 Small bowel
 90 030 052 Stomach
 90 030 054 Trachea
 select ↓ Mucositis (symptomatic) (*)
 90 030 056 Anus
 90 030 058 Esophagus
 90 030 060 Large bowel
 90 030 062 Larynx
 10 042 128 Oral cavity
 90 030 064 Pharynx
 90 030 066 Rectum
 90 030 068 Small bowel
 90 030 070 Stomach
 90 030 072 Trachea

select ↓ Necrosis, GI (*) [345]
 90 030 074 Anus [345]
 10 014 878 Colon/cecum/appendix [345]
 90 030 076 Duodenum [345]
 90 030 078 Esophagus [345]
 90 030 080 Gallbladder [345]
 10 019 692 Hepatic [345]
 90 030 082 Ileum [345]
 90 030 084 Jejunum [345]
 10 055 670 Oral [345]
 10 033 654 Pancreas [345]
 90 030 086 Peritoneal cavity [345]
 90 030 088 Pharynx [345]
 90 030 090 Rectum [345]
 90 030 092 Small bowel NOS [345]
 90 030 094 Stoma [345]
 10 049 150 Stomach [345]
 select ↓ Obstruction, GI (*)
 90 030 096 Cecum
 10 010 000 Colon
 10 013 830 Duodenum
 10 030 178 Esophagus
 10 017 636 Gallbladder
 90 030 098 Ileum
 90 030 100 Jejunum
 90 030 102 Rectum
 10 041 108 Small bowel NOS
 90 030 104 Stoma
 90 030 106 Stomach
 select ↓ Stricture, GI (*)
 10 002 176 Anus
 10 051 341 Biliary tree
 10 022 700 Cecum
 10 010 004 Colon
 10 013 834 Duodenum
 10 030 195 Esophagus
 10 021 307 Ileum
 10 023 176 Jejunum
 90 030 112 Pancreas/pancreatic duct
 10 050 028 Pharynx
 10 038 079 Rectum
 10 041 106 Small bowel NOS
 90 030 114 Stoma
 10 017 819 Stomach
 select ↓ Fistula, GI (*)
 90 030 010 Abdomen NOS
 10 002 156 Anus
 10 004 665 Biliary tree
 10 009 995 Colon/cecum/appendix
 10 013 828 Duodenum
 10 000 582 Esophagus
 10 017 631 Gallbladder
 90 030 012 Ileum
 90 030 014 Jejunum
 90 030 016 Oral cavity
 10 049 192 Pancreas
 90 030 018 Pharynx
 10 038 062 Rectum
 10 039 411 Salivary gland
 10 022 647 Small bowel NOS
 90 030 020 Stomach
 select ↓ Ulcer, GI (*)
 10 002 180 Anus
 90 030 116 Cecum
 10 023 799 Colon
 10 013 836 Duodenum
 10 030 201 Esophagus
 10 021 309 Ileum
 10 023 177 Jejunum
 10 038 080 Rectum
 10 041 109 Small bowel NOS
 90 030 118 Stoma
 10 017 822 Stomach

Note: in some categories the CTCAE criteria only allow certain grades, not all 1,2,3,4,5.

== RENAL / GENITOURINARY

90 004 086 Renal/Genitourinary - Other
 10 048 994 Bladder spasms [1234]
 10 011 798 Cystitis
 10 046 543 Incontinence, urinary [1234]
 90 030 652 Prolapse stoma, GU
 10 038 448 Renal failure [345]
 10 052 607 Urinary electrolyte wasting [123]
 10 036 018 Urinary frequency [123]
 10 046 555 Urinary retention
 10 008 796 Urine color change [1]
 select ↓ Fistula, GU (*)
 10 047 363 Bladder
 10 016 393 Genital tract-female
 10 051 985 Kidney
 10 046 404 Ureter
 10 046 451 Urethra
 90 030 590 Uterus
 90 030 592 Vagina
 select ↓ Leak, GU (*)
 90 030 594 Bladder
 90 030 596 Fallopian tube
 90 030 598 Kidney
 90 030 600 Spermatic cord
 90 030 602 Stoma
 90 030 604 Ureter
 90 030 606 Urethra
 90 030 608 Uterus
 90 030 610 Vagina
 90 030 612 Vas deferens
 select ↓ Obstruction, GU (*)
 10 005 060 Bladder
 90 030 614 Fallopian tube
 10 055 026 Prostate
 90 030 616 Spermatic cord
 90 030 618 Stoma
 90 030 620 Testes
 10 046 406 Ureter
 10 046 459 Urethra
 90 030 622 Uterus
 90 030 624 Vagina
 90 030 626 Vas deferens
 select ↓ Perforation, GU (*)
 90 030 628 Bladder
 90 030 630 Fallopian tube
 90 030 632 Kidney
 90 030 634 Ovary
 90 030 636 Prostate
 90 030 638 Spermatic cord
 90 030 640 Stoma
 90 030 642 Testes
 90 030 644 Ureter
 90 030 646 Urethra
 10 046 810 Uterus
 90 030 648 Vagina
 90 030 650 Vas deferens
 select ↓ Stricture, anastomotic, GU (*)
 10 005 082 Bladder
 90 030 654 Fallopian tube
 90 030 656 Prostate
 90 030 658 Spermatic cord
 90 030 660 Stoma
 90 030 662 Testes
 10 046 411 Ureter
 10 046 466 Urethra
 90 030 664 Uterus
 10 053 496 Vagina
 90 030 666 Vas deferens

(*) The notation "select ↓" designates a "supra-ordinate" group term. Report these by combining the group term with one of the specific qualifiers below it.

Where this is the case, the allowable grades are indicated in brackets, thus "[123]".

== NEUROLOGY

90 004 078 Neurology - Other
 10 002 974 Apnea [345]
 10 003 074 Arachnoiditis
 10 003 591 Ataxia
 10 037 778 Brachial plexopathy
 10 008 120 CNS ischemia [2345]
 90 030 560 CNS necrosis
 10 008 164 CSF leak
 10 057 668 Cognitive disturbance
 10 010 305 Confusion
 10 013 573 Dizziness [1234]
 10 014 625 Encephalopathy [2345]
 10 020 510 Hydrocephalus
 10 015 832 Involuntary movement
 10 022 998 Irritability [123]
 90 030 562 Laryngeal nerve
 10 024 832 Leukoencephalopathy [123]
 10 027 175 Memory impairment [1234]
 10 048 294 Mental status [23]
 10 018 526 Myelitis
 10 034 580 Neuropathy: motor
 10 034 620 Neuropathy: sensory
 10 034 719 Personality
 10 012 725 Phrenic nerve
 10 048 343 Psychosis [2345]
 10 020 745 Pyramidal tract dysfunction
 10 010 922 Seizure [2345]
 10 012 373 Somnolence [2345]
 10 041 466 Speech impairment [234]
 10 042 772 Syncope (fainting) [345]
 10 044 565 Tremor [1234]
 select ↓ Mood alteration (*)
 10 001 497 Agitation
 10 002 855 Anxiety
 10 012 378 Depression
 10 015 535 Euphoria
 select ↓ Neuropathy: cranial (*)
 10 056 388 CN I Smell
 10 030 932 CN II Vision
 10 030 073 CN III Pupil, upper eyelid
 10 044 691 CN IV Down/in, movement of eye
 10 018 389 CN IX Motor-pharynx; Sensory-ear
 10 044 647 CN V Motor-jaw; Sensory-facial
 10 053 646 CN VI Lateral deviation of eye
 10 016 051 CN VII Motor-face; Sensory-taste
 90 030 564 CN VIII Hearing and balance
 10 046 966 CN X Motor-palate; pharynx, larynx
 10 000 365 CN XI Motor-sternomast, trapezius
 10 020 991 CN XII Motor-tongue

== OCULAR / VISUAL

90 004 080 Ocular/Visual - Other
 10 047 513 Blurred vision [1234]
 10 007 739 Cataract [123]
 10 013 036 Diplopia [1234]
 10 013 775 Dry eye [123]
 10 015 986 Eyelid dysfunction [123]
 10 034 962 Flashing lights [1234]
 10 018 326 Glaucoma [1234]
 10 023 332 Keratitis [1234]
 10 000 573 Nyctalopia [1234]
 10 029 868 Nystagmus [1234]
 10 010 741 Ocular surface disease [123]
 10 030 916 Optic disc edema [1234]
 10 034 960 Photophobia [1234]
 10 036 905 Proptosis/enophthalmos [123]
 10 038 848 Retinal detachment [1234]
 10 048 487 Retinopathy [1234]
 10 039 697 Scleral necrosis [1234]
 10 046 855 Uveitis [1234]
 10 047 655 Vitreous hemorrhage [123]
 10 023 644 Watery eye [123]

For example, "Watery eye" can only be assigned grade 1 or 2 or 3.

== MUSCULOSKEL / SOFT TISSUE

90 004 076 Musculoskeletal - Other
 10 003 263 Arthritis
 90 030 518 Cervical spine ROM [123]
 90 030 526 Device/prosthesis related
 10 015 688 Exostosis
 90 030 520 Extremity-upper (function) [1234]
 90 030 522 Fibrosis-cosmesis [123]
 90 030 524 Fibrosis-deep connective tissue
 10 017 089 Fracture
 10 017 574 Gait/walking [1234]
 10 023 215 Joint-effusion
 10 023 212 Joint-function [1234]
 90 030 528 Lumbar spine ROM [123]
 90 030 546 Muscular/skel hypoplasia [1234]
 10 028 653 Myositis
 10 031 264 Osteonecrosis
 10 031 284 Osteoporosis
 10 039 722 Scoliosis
 10 040 102 Seroma [123]
 10 044 684 Trismus [123]
 select ↓ Muscle weakness (*)
 10 053 635 Extraocular
 90 030 530 Extremity-lower
 90 030 532 Extremity-upper
 90 030 534 Facial
 90 030 536 Left-sided
 90 030 538 Ocular
 90 030 540 Pelvic
 90 030 542 Right-sided
 90 030 544 Trunk
 10 028 351 Whole body/generalized
 select ↓ Soft tissue necrosis (*) [2345]
 90 030 548 Abdomen [2345]
 90 030 550 Extremity-lower [2345]
 90 030 552 Extremity-upper [2345]
 90 030 554 Head [2345]
 90 030 556 Neck [2345]
 90 030 558 Pelvic [2345]
 10 043 881 Thorax [2345]

== VASCULAR

90 030 982 Vascular - Other
 10 007 196 Acute vascular leak synd [2345]
 10 034 576 Peripheral arterial ischemia [2345]
 10 034 902 Phlebitis [2]
 10 036 200 Portal flow [23]
 10 051 094 Thrombos/embol (vasc acc) [2345]
 10 043 607 Thrombos/thrombus/embol [2345]
 10 047 503 Visceral arterial ischemia [2345]
 select ↓ Artery injury (*)
 90 030 956 Aorta
 90 030 958 Carotid
 90 030 960 Extremity-lower
 90 030 962 Extremity-upper
 90 030 964 Other NOS
 90 030 966 Visceral
 select ↓ Vein injury (*)
 90 030 968 Extremity-lower
 90 030 970 Extremity-upper
 90 030 972 IVC
 90 030 974 Jugular
 90 030 976 Other NOS
 90 030 978 SVC
 90 030 980 Viscera

== SECONDARY MALIGNANCY

90 004 088 Secondary Malig - Other [345]

== PULMONARY / UPPER RESP

90 004 084 Pulmonary/Upper Resp - Other
 10 001 052 ARDS [345]
 10 003 504 Aspiration
 10 003 598 Atelectasis
 10 006 485 Bronchospasm
 90 030 586 Chest tube drainage or leak [2345]
 10 051 228 Chylothorax
 10 011 224 Cough [123]
 10 037 388 DLco
 10 013 968 Dyspnea
 10 023 845 Edema, larynx
 10 016 984 FEV(1)
 10 020 039 Hiccoughs [123]
 10 021 143 Hypoxia [2345]
 90 030 582 Nasal/paranasal reactions
 10 035 598 Pleural effusion
 10 035 755 Pneumonitis
 10 035 762 Pneumothorax
 90 030 588 Prolonged intubation [2345]
 10 037 383 Pulmonary fibrosis
 10 047 582 Vital capacity
 10 023 879 Voice changes
 select ↓ Airway obstruction (*)
 10 006 487 Bronchus
 10 023 862 Larynx
 90 030 584 Pharynx
 10 050 816 Trachea
 select ↓ Fistula, pulmonary (*)
 10 006 437 Bronchus
 90 030 574 Larynx
 90 030 576 Lung
 90 030 578 Oral cavity
 10 034 825 Pharynx
 10 053 481 Pleura
 90 030 580 Trachea

== SEXUAL / REPROD FUNCTION

90 004 092 Sexual/Reproductive - Other
 90 030 668 Breast function [12]
 10 049 070 Breast volume [123]
 10 014 327 Ejaculatory dysfunction [12]
 10 052 003 Erectile dysfunction [123]
 10 018 800 Gynecomastia [23]
 10 021 930 Infertility/sterility [23]
 10 027 339 Irregular menses [123]
 10 024 419 Libido [12]
 90 030 670 Nipple/areolar [123]
 10 031 085 Orgasmic function [123]
 10 046 901 Vaginal discharge [12]
 10 047 791 Vaginal dryness [12]
 90 030 672 Vaginal mucositis [1234]
 10 046 879 Vaginal stenosis [123]
 10 046 950 Vaginitis [1234]

== SURGERY / INTRA-OP INJURY

90 030 952 Intra-operative Injury - Other [1234]
 select ↓ Intra-Op injury (*) [1234]
 90 030 674 Abdomen NOS [1234]
 90 030 676 Adrenal gland [1234]
 90 030 678 Anal sphincter [1234]
 90 030 680 Anus [1234]
 90 030 682 Appendix [1234]
 90 030 684 Artery NOS [1234]
 90 030 686 Artery-aorta [1234]
 90 030 688 Artery-carotid [1234]
 90 030 690 Artery-cerebral [1234]
 90 030 692 Artery-extremity (lower) [1234]
 90 030 694 Artery-extremity (upper) [1234]
 90 030 696 Artery-hepatic [1234]

90 030 698 Artery-maj visceral artery [1234]
 90 030 700 Artery-pulmonary [1234]
 90 030 702 Biliary tree NOS [1234]
 90 030 704 Biliary tree-cmn bile duct [1234]
 90 030 706 Biliary tree-cmn hepat duct [1234]
 90 030 708 Biliary tree-left hepat duct [1234]
 90 030 710 Biliary tree-right hepat duct [1234]
 90 030 712 Bladder [1234]
 90 030 714 Bone [1234]
 90 030 716 Brain [1234]
 90 030 718 Breast [1234]
 90 030 720 Bronchus [1234]
 90 030 722 Cartilage [1234]
 90 030 724 Cecum [1234]
 90 030 726 Cervix [1234]
 90 030 728 Colon [1234]
 90 030 730 Conjunctiva [1234]
 90 030 732 Cornea [1234]
 90 030 734 Duodenum [1234]
 90 030 736 Esophagus [1234]
 90 030 738 Extremity-lower [1234]
 90 030 740 Extremity-upper [1234]
 90 030 742 Eye NOS [1234]
 90 030 744 Face NOS [1234]
 90 030 746 Fallopian tube [1234]
 90 030 748 Gallbladder [1234]
 90 030 750 Gingiva [1234]
 90 030 752 Heart [1234]
 90 030 754 Ileum [1234]
 90 030 756 Inner ear [1234]
 90 030 758 Jejunum [1234]
 90 030 760 Joint [1234]
 90 030 762 Kidney [1234]
 90 030 764 Larynx [1234]
 90 030 766 Lens [1234]
 90 030 768 Ligament [1234]
 90 030 770 Lip/perioral area [1234]
 90 030 772 Liver [1234]
 90 030 774 Lung [1234]
 90 030 776 Mediastinum [1234]
 90 030 778 Meninges [1234]
 90 030 780 Middle ear [1234]
 90 030 782 Muscle [1234]
 90 030 834 Nails [1234]
 90 030 836 Nasal cavity [1234]
 90 030 838 Nasopharynx [1234]
 90 030 840 Neck NOS [1234]
 90 030 842 Nose [1234]
 90 030 844 Oral [1234]
 90 030 846 Oral cavity NOS [1234]
 90 030 848 Outer ear NOS [1234]
 90 030 850 Outer ear-Pinna [1234]
 90 030 852 Ovary [1234]
 90 030 854 Pancreas [1234]
 90 030 856 Pancreatic duct [1234]
 90 030 858 Parathyroid [1234]
 90 030 860 Parotid gland [1234]
 90 030 862 Pelvis NOS [1234]
 90 030 864 Penis [1234]
 90 030 866 Peritoneal cavity [1234]
 90 030 868 Pharynx [1234]
 90 030 870 Pituitary [1234]
 90 030 872 Pleura [1234]
 90 030 874 Prostate [1234]
 90 030 876 Rectum [1234]
 90 030 878 Retina [1234]
 90 030 880 Salivary duct [1234]
 90 030 882 Salivary gland [1234]
 90 030 884 Scrotum [1234]
 90 030 886 Sinus [1234]

90 030 888 Skin [1234]
 90 030 890 Small bowel NOS [1234]
 90 030 892 Soft tissue NOS [1234]
 90 030 894 Spinal cord [1234]
 90 030 896 Spleen [1234]
 90 030 898 Stoma (Gl) [1234]
 90 030 900 Stomach [1234]
 90 030 902 Teeth [1234]
 90 030 904 Tendon [1234]
 90 030 906 Testis [1234]
 90 030 908 Thoracic duct [1234]
 90 030 910 Thyroid [1234]
 90 030 912 Tongue [1234]
 90 030 914 Trachea [1234]
 90 030 916 Upper aerodigestive NOS [1234]
 90 030 918 Upper airway NOS [1234]
 90 030 920 Ureter [1234]
 90 030 922 Urethra [1234]
 90 030 924 Urinary conduit [1234]
 90 030 926 Urinary tract NOS [1234]
 90 030 928 Uterus [1234]
 90 030 930 Vagina [1234]
 90 004 030 Vein NOS [1234]
 90 030 932 Vein-extremity (lower) [1234]
 90 030 934 Vein-extremity (upper) [1234]
 90 030 936 Vein-hepatic [1234]
 90 030 938 Vein-inferior vena cava [1234]
 90 030 940 Vein-jugular [1234]
 90 030 942 Vein-major visceral vein [1234]
 90 030 944 Vein-portal vein [1234]
 90 030 946 Vein-pulmonary [1234]
 90 030 948 Vein-superior vena cava [1234]
 90 030 950 Vulva [1234]
 select ↓ Intra-Op nerve injury (*) [1234]
 90 030 784 Brachial plexus [1234]
 90 030 786 CN I (olfactory) [1234]
 90 030 788 CN II (optic) [1234]
 90 030 790 CN III (oculomotor) [1234]
 90 030 792 CN IV (trochlear) [1234]
 90 030 794 CN IX (glossophary) motor [1234]
 90 030 796 CN IX (glossophary) sensor [1234]
 90 030 798 CN V (trigeminal) motor [1234]
 90 030 800 CN V (trigeminal) sensory [1234]
 90 030 802 CN VI (abducens) [1234]
 90 030 804 CN VII (facial) motor [1234]
 90 030 806 CN VII (facial) sensory [1234]
 90 030 808 CN VIII (vestibulocochlear) [1234]
 90 030 810 CN X (vagus) [1234]
 90 030 812 CN XI (spinal accessory) [1234]
 90 030 814 CN XII (hypoglossal) [1234]
 90 030 816 Cranial nerve/branch NOS [1234]
 90 030 818 Lingual [1234]
 90 030 820 Lung thoracic [1234]
 90 030 822 Peripheral motor NOS [1234]
 90 030 824 Peripheral sensory NOS [1234]
 90 030 826 Recurrent laryngeal [1234]
 90 030 828 Sacral plexus [1234]
 90 030 830 Sciatic [1234]
 90 030 832 Thoracodorsal [1234]

== SYNDROMES

90 004 094 Syndromes - Other
 10 001 598 Alcohol intolerance syndrome [35]
 10 052 015 Cytokine release syndrome
 10 022 004 Flu-like syndrome
 10 038 921 Retinoic acid syndrome
 10 045 169 Tumor flare
 10 045 170 Tumor lysis syndrome [35]

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SUMMARY OF CHANGES

Course Assessment

Two new response codes are allowed:

TE “Too Early” may be used if it is too soon, per protocol, to assess a response.

DU “Disease Unchanged” may be used if the extent of disease is unchanged from the previous assessment and the CR/PR/MR or PD or SD codes are not appropriate, per protocol.

A description of the RECIST response criteria was added to the notes.

Comments on when SD is appropriate were added.

Off Treatment / Off Study

The layout of the CRF has been improved to emphasize that some of the reasons off-study are only appropriate for particular studies as designated by CTMS.

A new Reason (and code) Off-Study is allowed, and one code is revised.

Z = “No Treatment, per Protocol” is self-descriptive.

U = “Not Treated – Other Reasons” is a new code for this term, since “per protocol” has now been split out into a specific category.

Two new response codes are allowed:

NP “Not Applicable Per Protocol” is used if the protocol does not include the assessment of responses.

TE “Too Early” is used if all the Course Assessments were coded as Too Early.

Common Literal Labs

Two new lab test names are allowed:

PETSCAN may be used for PET scans.

CULTURE may be used for any culture, e.g. blood, urine.

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