

NATIONAL CANCER INSTITUTE

Clinical Data System (CDS) Web Application

VERSION 3.0 — AUGUST 11, 2006

QUICK REFERENCE GUIDE



PRODUCED BY CAPITAL TECHNOLOGY INFORMATION SERVICES, INC.

The Clinical Data System Web Application Quick Reference Guide was prepared for:

National Cancer Institute (NCI) National Institutes of Health (NIH)

By:

Capital Technology Information Services, Inc.

One Research Court, Suite 200

Rockville, Maryland 20850-3236

Tel: 301-948-3033

Fax: 301-948-2242

Home Page: http://www.ctisinc.com

Under the Information Management and Computer Support Contract N02-CM-27021.

The brand names and product names used in this manual are trade names, service marks, trademarks, or registered trademarks of their respective owners. All designations appearing in this document that are known to be Service Marks, Trademarks, or Registered Trademarks have been appropriately capitalized. CTIS, Inc. is not associated with any product or vendor mentioned in this manual.

The date on the cover of this application guide reflects the document release date, which may differ from the software release date.

Information within this application guide is current as of the date of publication. Software changes and enhancements incorporated into the system after the publication date will be reflected in future releases of the guide.

This application guide contains sample queries and screen examples taken from the CDS Web development database. If you are using the CDS Web production database, your query and screen data may differ from that depicted in this guide.

Contents

Introduction	1
Additional Information	1
Getting Started	3
Logging On	3
Common CDS Features	
Formatting	5
I cons	
Buttons	5
Navigation	6
Error or Warning Messages	6
The Collections Screen	7
Adding a New Collection Record	
The CDS Menu	9
Patient Data	11
Patient Data Entry Screens	11
Patient Demographics	11
Accessing the Patient Data Entry Screens	
Patient Administrative Data	
Baseline Abnormalities	
Prior Therapies	
Treatment Courses	19
Course Agents	21
Adverse Events	
Responses	
Late Adverse Events	
Protocol Data	28
Protocol Data Entry Screens	
Publications	
Authors	
Correlative Studies	
Phase I End Points MTD and Phase I End Points DLT	
Phase I End Points MTD	
Phase I End Points DLT	
Trial Comments	
Submissions and Reports	36
Patient Details Report	
Error Log Report.	
Submitting the Quarterly Clinical Data Update	

Introduction

The purpose of this guide is to provide users of the Clinical Data System (CDS) Web application with concise instructions for accessing and using the system, which replaced the Clinical Data Update System (CDUS) Web application on July 5, 2006.

The guide walks users through the process of accessing a data record, adding a new data record, or updating existing data to include with the Quarterly Clinical Data Update.

The Quarterly Clinical Data Update is a record that includes all the data collected from each screen in the CDS Web application. Once complete, the record is sent to CTEP through the CDS Web application and loaded into the CTEP database (for more information, see the <u>CDUS Instructions and Guidelines v3.0 Release 2</u> available from the CTEP Web site).

Additional Information

The following resources are available to you at the CDUS page of the CTEP Web site:

CDUS Instructions and Guidelines v3.0 Release 2

Provides details regarding CDUS reporting requirements and detailed descriptions of data elements. This document also includes information about the following:

- CTEP Smart Loader Approval, Disapproval and Correction Process.
- *Business Rules*. Business rules are used to validate the entry of appropriate or accurate data prior to being saved in the application.

CTEP Web Site

The CTEP Web site is located at <u>http://ctep.cancer.gov/</u> and can be accessed to obtain a wide variety of information.

• The CDUS page of the CTEP Web site is located at <u>http://ctep.cancer.gov/reporting/cdus.html</u> and provides a link to the CDS Web application, to the documents listed above, and to other documents regarding earlier versions of the CDUS.

NCI CTEP Help Desk

Contact the NCI CTEP Help Desk at <u>ncictephelp@ctep.nci.nih.gov</u> for questions regarding the technical use of the CDS v3.0 Web application or for training information.

Note: The CDS Web application should be accessed via the Internet using Microsoft Internet Explorer version 5.0 or higher. Use of other browsers or older versions of Microsoft Internet Explorer may cause errors within the application and/or difficulty in its use.

This quick reference guide assumes that you have a working knowledge of Microsoft Windows[®] and Microsoft Internet Explorer[®] browser.

Getting Started

This section of the guide provides instruction and information about the general use of the system and its common elements.

Logging On

Follow the instructions below to log on to the CDS Web application.

- 1. Double-click the Internet Explorer (IE) icon on your desktop.
- 2. Click Favorites or select the Favorites menu.
- 3. Select CDS Web from your Favorites list.

Note: If the CDS is not available from Favorites, access the CTEP CDUS page and double-click on the application link. Once the CDS main screen displays, add the application to your Favorites list (see your IE manual or IE Help if you are unfamiliar with the Favorites option in IE).

The Logon screen is displayed (see Figure 1).

ational Cancer Institute	0.5 Hazimal II	institution of linearth () www.carcon.gov
inical Dala System - Web		
Weccome Recklerovice DS - VMb is a web beers application which is the premy resource of clinical hail data field of National Cancel Institute (NCI). CDE reports are admitted for INCI sensered that (Prive 1, 2 and 3). The institutes Add institutes and admitted ad	Olemans. Personal	
Guntad Lin, 1 Privacy Suntar J. Dischainmer, 1. Associability. [1.503.0310 Heat Best.		

Figure 1: Logon Screen

- 4. Enter your User Name and Password.
- 5. Click Log on.

The Warning Notice screen is displayed (see Figure 2).

National Cano	e Institute de la constitute de	WINNLANDIN (CT)
"(Zao		Liser: Allysen Gattle Lagett 1 Hels
	New Yorking Robot for interestion for the Portuge Transment and Polation Determined	
	His system is for the use of authorized source andy, individuals unless this computer system without adventity, or in excess of their authority, are uniques to having all their activities as this system monitored and recented by system presented. In the zones of monitoring individuals improved you have having all their activities and the system monitored and recented by system presented. In the zones of monitoring individuals improved you have having all their activities and a system bar individual and a set of the system presented in the system system presented and a solution do in it system analysis of advectory and and and and a state of the system presented to monitoring to law endercoment afficials.	
	Although decision concerning the applicability and implementation of the HPDA Privary Bale reside with the researcher and his/her institution, ir is important to more that the CDinical Data System (CDS) reporting to permitted without patient anthonication under several permittenes of the HPDA Privacy Bale for example. CDS decisiones are expensely permitted make section 16.5 CDIs for public, brath activities, which include experime for ReV, Nill WD spreames, and where. CDS sense indicators may advect to permitted the when hereight activities works the include to permitted the bale works the include section 2.5 (e.g., and a section 3.5 (
	In addition, to ensure security and adapt of pattern bioinmatice. (CIS uses the lated recorption technique) Ad latel collected free AD COS are stored on a secure that is no recentifie from the homes. Once you be estimisting data to the CDS, the data can and be refoleed with a word D and password. You should take every precasition in elemany to keep the pase code information coefficiential and to avoid distribution of CDS data to suppropriate individuals.	
	Dictant [Diction]	

Figure 2: Warning Notice Screen

6. Click **I** Accept to if you agree to abide by the rules of behavior or **I** Decline if you prefer to exit the system.

If you click I Accept, the Protocol Selection screen is displayed (see Figure 3). The Protocol Number, Title, Current Trial Status, and Current Trial Status Date are displayed for each protocol listed.

The **Protocol Number** is displayed as a link (see the **Navigation** section on page 6 more information on links).

National Cancer	Institute	U.S. Na	itional Institutes of He	alth www.cancer.gov	
CDS WEB				User: Allyson	Gattis
				Logoff	<u>Help</u>
Please select the	Organization: Test University Medical Ce	nter			~
wish to enter data for.	Protocols 🗭				
Organization(s)🏴	Please select the protocol you wish to enter data	for.			
Test University Medica	Protocol Number	Title	Current Trial Status	Current Trial Statu Date	IS
	TRGPROTOCOL1 Phase I Trial and Pharmacokinetic in Childhood Solid Tumors	: Study of Temozolomide and O6-Benzylguanine	Active	07/05/2005	
	TRGPROTOCOL2 Phase I Trial and Pharmacokinetic in Childhood Solid Tumors	; Study of Temozolomide and O6-Benzylguanine	Active	07/05/2005	
	Records 1 to 2 of 2				

Figure 3: Protocol Selection Screen

7. Click on the <u>Protocol Number</u> link for the protocol you wish to access and continue the data entry process.

Note: Only the protocols of the organization for which you have permission will be displayed. This is determined by your User Name and Password. Contact the NCI CTEP Help Desk if there is a discrepancy with the protocols listed from the Protocol Selection screen.

Common CDS Features

Once you have selected a protocol from the Protocol Selections screen, you will find a variety of features that appear throughout the application to assist you in accurately completing the Quarterly Clinical Data Update. The following provides a description of each.

Formatting

Bold Data Elements: Data elements that appear in bold text are mandatory and must be entered prior to clicking the **Save** button. An error message will display when a mandatory data field is left blank.

Icons

● Protocol Number: The Protocol Number icon is located at the top of each screen and provides access to view a protocol's Organization, Title, CTCAE Version, Status and Status Date information. Click on the to view this information.

The **Help** icon provides access to view additional instruction and step-by-step processes to assist you while you work with the CDS. Click the icon to open the Help window.

The **Calendar** icon is provided as an option for every data element that requires a date and ensures that the date entered is in the correct format. Click the Calendar icon and double click on the day or choose to type the date manually.

Click the **Up Arrow** icon to the right of a data field to a select a value from a List of Values (LOV). Values from the LOV should always be selected, when available, to populate the field.

Click the **Down Arrow** icon to the right of a data field to select values from a drop-down list.

Buttons

Clear The **Clear** button is available to clear the data from one or all data fields prior to saving.

Delete The **Delete** button is used to delete a previously saved data record. A message will display prompting you to confirm the delete before the data is removed.

New The New button is used to create a new data record. Click the button and a new screen is displayed, from which you will begin data entry.

Query The Query button is used to search the application for data that matches specified query criteria.

ReQuery The **ReQuery** button provides a way to refresh the screen and view a list of data records that were successfully saved.

The **Save** button is used to commit data to the application. When the data fields are entered correctly and the button is clicked, the message **Success!** is displayed. An error or warning message will display when mandatory data is missing or when an invalid value is entered (see **Error or Warning Messages** on page 6, for additional information).

Navigation

The CDS Web application uses <u>links</u> to assist you when navigating from one screen to another. <u>Links</u> are presented in blue, underlined text. The <u>links</u> listed on the CDS menu (see The CDS Menu section on page 9 for more information) become activated and display the underlined text when the cursor is placed over the screen name.

Error or Warning Messages

The CDS Web application uses business rules to validate the entry of appropriate or accurate data. Validations occur each time the **Save** button is clicked, when the **Submit Collections** button is clicked, and again, when the data is loaded to the database at CTEP. Data validations at the screen and submission level may result in an Error and/or Warning message. Data validations that occur during the data load at CTEP may result in an Error Log Report (refer to the **Error Log Report** section on page 37).

The following describes the differences between an Error and Warning message. Again, these messages appear at the time the data is being saved in any of the CDS screens or when the Quarterly Clinical Data Update is submitted.

• An Error message is displayed when incomplete or inaccurate data is entered in a **mandatory** data field (see Figure 4). This data must be corrected to commit the data to the application.



Figure 4: CDS Error Message

 A Warning message is displayed when incomplete or inaccurate data is entered in a *requested* data field (see Figure 5). Although correction of the data is preferred, it is not mandatory to complete the submission process.

Success! Row updated
Warning!
Weight(kg): value not in recommended range of 3kg and 120kg

Figure 5: CDS Warning Message

Follow the instructions below to correct the erroneous data:

- 1. Click the **OK** button on the CDS Error Message box or return to the field specified in the Warning Message.
- 2. Complete, update, or modify the specified data element to correct the error.
- 3. Click Save.

Note: Additional Error or Warning messages may appear if multiple data elements are incomplete or inaccurate. Repeat steps 1 through 3 until all the erroneous data are corrected and no further messages are displayed.

The Collections Screen

To access the **Collections** screen from the **Protocol Selection** screen, click on the <u>Protocol Number</u> link for the protocol you wish to view.

The **Collections** screen is displayed (see Figure 6) and provides a summary of the Quarterly Clinical Data Updates created for present and previous quarters.

National Cancer	Institute						U.S. National Institute	is of Health www.can	icer.gov
CDSWEB								User: Al	lyson Gatti
								Log	off Helr
Please select the	Protocol	Number: TF	RGPROTOCOL1						1
wish to enter data for.	Collections	P							
Organization(s)🏴	To enter dat collection , s	a for a partic select the Ad	ular collection, plea I d Collections but	ise select the ton.	collection from the lis	t below. To cre	eate a new collection o	r update an existing	
Test University Medica		Collection Status	Submission Date	Cut-off Date	Last Submission Date	Current Trial Status	Completed By Name	Submitter Phone	Submitt
	□ Submit?	Active	04/30/2006 (Q1)	04/29/2006		Active	Susan Brown	301-948-3033	
		Accepted	01/31/2006 (Q4)	01/30/2006		Active	Susan Brown	301-948-3033	
		Accepted	10/31/2005 (Q3)	09/30/2005	02/15/2006	Active	Susan Brown	301-948-3033	sbrown@
		Accepted	04/30/2005 (Q1)	03/31/2005		Active	Susan Brown	301-948-3033	sbrown@
	Records 1 to	o 4 of 4							
	Note: Active	is open for in t Collections	nsert and/or update Add Colle	e; Submitted a actions	and Approved are close	ed for insert bu	it open for update throu	igh the Active collect	tion.

Figure 6: The Collections Screen

The following functions can be performed on the Collections screen:

• To enter or update data for an existing Quarterly Clinical Data Update, click on the <u>Active</u> link from the **Collection Status** column.

Note: Only those Quarterly Clinical Data Update records that appear with an Active or Rejected **Collection Status** may be accessed for new data entry or data update. Records with a status of Submitted, Processing, or Accepted are not available for data entry or update.

- To create a new Quarterly Clinical Data Update or view previously submitted Quarterly Clinical Data Updates, click the **Add Collections** button.
- To submit a completed Quarterly Clinical Data Update, refer to the **Submitting the Quarterly Clinical Data Update** section on page 39.
- To return to the **Protocol Selection** screen, click the **Organization(s)** name listed in the left frame.

Adding a New Collection Record

A new Quarterly Clinical Data Update record must be created for each quarterly data submission. Follow the instructions below to create a new record.

1. Click the Add Collections button on the Collections screen.

The Collection data entry screen is displayed (see Figure 7).

National Cancer	Institute			U.S. National Institutes of Health	www.cancer.g	ov
CDS WEB					User: Allysa	n Gattis
					<u>Logoff</u>	l <u>Help</u>
Please select the organization you	Collections		Protocol Number: TRGPROTOCOL1			ŕ
for.	Submission Date	Collection Status		Collection		_
Organization(s)	04/30/2006	Active	Submission Date (MM/DD/YYYY):	04/30/2006		
, , , , , , , , , , , , , , , , , , ,	01/31/2006	Accepted	Cut-off Date(MM/DD/YYYY):	04/29/2006		
Test University Medica	10/31/2005	Accepted	Current Trial Status:	Active	•	
	04/30/2005	Accepted	Current Trial Status Date (MM/DD/YYYY):	07/05/2005		
	Record	ls 1 to 4 of 4	Submitter Last Name:	Brown		
	R	eQuery	Submitter First Name:	Susan		
		New	Submitter Middle Name:			
	1	1464	Submitter Phone:	301-948-3033		
	Return to C	Collection Page	Submitter Fax:			
			Submitter E-mail:			
			Any additions or changes since last report:	© Yes C No		
						-

Figure 7: The Collection Data Entry Screen

2. Click the **New** button to create a new Quarterly Clinical Data Update record.

Note: The **Submission Date** field is automatically populated with the submission date of the current or subsequent quarter; no data entry is required.

3. Complete all of the mandatory (bold text) data fields and the requested data fields, if relevant information is available.

🧃 TIP

The **CutOff Date** field is entered with the latest date for which information is known for this record. The application will validate that all date values entered throughout the remainder of the record will be less than or equal to the Submission Date and less than or equal to the **CutOff Date** identified in this present quarter's record. The present quarter's **CutOff Date** must be greater than or equal to the **CutOff Date** in the previous quarter's record.

- 4. Click the **Save** button.
- 5. Click <u>Return to Collection Page</u> link located in the center frame to return to the **Collections** screen.

The new record will display an <u>Active</u> link under the **Collection Status** column. You must click on the <u>Active</u> link to access the CDS menu where other screens are available to enter and/or update data.

For detailed information regarding the data elements on the **Collection** screen, refer to the *Data Element Descriptions* section in the <u>CDUS</u> <u>Instructions and Guidelines v3.0 Release 2</u>.

The CDS Menu

The CDS navigation menu resembles a folder directory and lists all of the patient and protocol-specific data entry screens, reports, and navigational links available within the application (see Figure 8).



Figure 8: The CDS Menu

Follow the instructions below to access the CDS menu.

1. From the **Collections** screen, select a Quarterly Clinical Data Update record by clicking on the **Collection Status** <u>Active</u> or Rejected link.

The CDS menu is displayed in the left frame (see Figure 9).

Note: When the **Collection Status** <u>Active</u> or Rejected link is selected and a patient record exists in the CDS, the **Patient Demographic Data** screen is displayed by default (as shown in Figure 9).

DS				0	Logatt 1	
TRGPROTOCOL 1 (84/38/2005)	Patients Select a patient	t to worked	Pretacol Number: TRGPR0T000L(atient Demographics Data		
Authors Constative Moders	Dation f	Birth Date	Deter of the	An own Dataset Doublesseer Outs second		
Phana I End Points MTD	1. ademi itr	(MALININ)	Liter value	e na new Cateria Denjegraphic Data record		
Trial Comments	m OLT PATON 03/1978	03/1955	Patient ID: Enter the unique code asak	ned at the		
Patient Datality	EAT-050	EM/1975	time of registration to the study.			
CTC Application		1.105 M	Sinth Gate (Max 1111):			
View Calection	Ples	orde 1 to 3 of 3	Gender:		_	
Held	PerDucy Overv	Pageony:	Parage		_	
		(Second	HALD.	C American Indian or Alaska Native		
		Query		Differit or Ahiran American	_	
		diame.		Nation Haussian or Other Pacific Islander	_	
		_		P Not Reported	_	
				E Unknown	_	
		Country		E White		
			(Country Name)	Г	1	
			Dip Code:		-	
			Payment Mailand		-	
			Entry Date (MM/DD/YYY):	1	-	
			Registering Group:	1		
			Reg Droup (D.	1		
			Registering Institution:	Ì		
			Rea Inst ID:	1		
			Disease Category:	1	101	
			Disease Sub Category		-	
			Disease Name	-	-	
				1	21	
				Seve Chan		

Figure 9: The CDS Menu Frame

- 2. Click on the folder name to view the screen you wish to access.

If no record exists in the selected screen, only the CDS menu is displayed in the left frame. The **ReQuery** and **New** buttons are displayed in the center frame. You may click the **New** button to view the data fields available on the selected screen.

If a record was previously entered in the selected screen, the record(s) is listed in the center frame and the first record is displayed in the data entry screen (the right frame) by default.

To return to the **Collections** or the **Protocol Selection** screens, click the <u>View Collection</u> or the <u>View Protocol Selection</u> link from the CDS menu.

Patient Data

Patient Data Entry Screens

The CDS Web application provides nine screens to enter patientspecific data and organizes them as follows:

- Demographic Data
- Administrative Data
- Baseline Abnormalities
- Prior Therapies
- Treatment Courses
 - o Course Agents o Adverse Events
- Responses
- Late Adverse Events

Note: A new patient demographic record must be created or an existing patient record must be selected from the center frame to access any of the Patient data entry screens. Once a patient is selected, all patient data screens will be specific to the selected patient.

Patient Demographics

The CDS will provide access to the other patient data entry screens only after the patient demographic record is created. Follow the instructions below to create a new patient demographic record.

Note: Only one Patient Demographic record may be entered per patient.

1. Click on the **Patient** folder from the CDS menu.

Click the **New** button located in the center frame. A blank **Patient Demographics** data record is displayed in the right frame (see Figure 10).

and the state of the state of the state	-					
Patient	Patients		Patient Demographics Data			
Publications Authors	Select a patient	to proceed				
Correlative Studies	Patient ID	Birth Date (MIA/2000)	Enter values for new Patient Demographic Data record			
Phase (Ent Points DLT	CALOU	(04/1966)	Dedage 10. Color Manager and an	and a the second		
Trial Comments	PAL302 03/1973 PAL350 04/1975 Records 1 to 3 of 3	03/1973	time of registration to this atudy.			
Patiero Delara		04/1975	Birth Date (MM/YYYY):			
CTC Apple min		E fo E of F abro	Gender:			
View Protocol Swection		and and a second	Ethnicity:	3		
		Harmany.	Races:	T Americali Indian or Alleska Native T Assan T Black or African American T Native Hewelian or Other Pacific Islander		
		Own/				
		and a				
		Citrar				
				T Not Reported		
				C Unkingwin		
	1			C Wran		
			Country Name			
			Zie Code			
	1		Payment Method:	8		
	1		Entry Date (MM/DD/YYYY):	3		
	1		Registering Group	1		
			Reg Group ID.			
			Registering Institution:	1		
			Reg Inst ID:			
			Disease Category:	te l		
			Disease Sub Category	1		
			Dimon Alana			

Figure 10: The Patient Demographic Data Screen

2. Complete all of the mandatory (bold text) data fields and the requested data fields, if relevant information is available.

Select values from the LOV or the drop down list by clicking either the Up Arrow or Down Arrow buttons.



🌆 TIPS

In the **Patient ID** field, enter the code that uniquely identifies the patient for this protocol. The unique code or ID has been assigned at the time of patient registration. The Patient ID cannot be modified once saved.

You must indicate the patient's ethnicity (i.e., whether or not the patient is Hispanic or Latino, or whether the patient's ethnicity is unknown) within the Ethnicity field.

You may select more than one race from the patient Races field.

If the patient refused to provide his or her race/ethnicity or the site neglected to collect this data, select "Not Reported." If the patient is unsure of his or her race/ethnicity, select "Unknown."

The **Registering Institution** LOV displays institutions alphabetically by name and includes the CTEP ID, City, State, and Zip code of each. Only the institution name can be used to conduct a search

Note: Validate the CTEP ID selected, especially if there is more than one institution name that is worded the same.

Although the Disease block abstraction is optional, the system requires that all three values (i.e., Disease Category, Disease Sub Category, and Disease Name) be provided.

Note: Enter the value '00000' if the patient's U.S. Zip code is unknown.

Note: Enter the value 'Unknown' in the **Payment Method** field if the patient's primary method of payment is unknown.

3. Click the Save button.

If all data elements are entered correctly, the message *Success!* Row inserted will display in the top left of the screen. If a mandatory data field was missed or data were inaccurately entered, an error or warning message will display (see Error or Warning Messages on page 6 for additional information).

For detailed information regarding the Patient Demographic data elements, refer to the *Data Element Descriptions* section in the <u>CDUS</u> <u>Instructions and Guidelines v3.0 Release 2</u>.

Accessing the Patient Data Entry Screens

Once the patient demographic record is saved, the **Patient ID** and **Birth Date** are displayed in the center frame (see Figure 11). The **Patient ID** entered in the **Patient Demographic Data** screen is displayed as a link under the **Patient ID** column. You must click on the <u>Patient ID</u> link to make modifications in **Patient Demographic Data** screen or to access other patient data entry screens.

Patients							
Select a patient to p	proceed						
Patient ID	Birth Date (MM/YYYY)						
PAT-001	04/1956						
PAT-002	03/1973						
PAT-050	04/1975						
Records 1 to 3 of 3 ReQuery Query							
Ν	ew						

Figure 11: The Patients Record (center frame)

When the <u>Patient ID</u> link is selected for a patient, the Patient folder under the CDS menu expands to display the screens available for patient data entry (see Figure 12). The Patient ID and Birth Date are also displayed within parentheses following the Patient folder.



Figure 12: The Patient Folder – Expanded

The center frame is not capable of displaying all the <u>Patient ID</u> links associated with a protocol where a large number of patients are enrolled. In this case, a search must be conducted to access the record of a specific patient. A search can be performed by clicking the **Next Set** and **Last Set** buttons from the center frame or by using the **Patient Demographic Data Query** screen (see Figure 13).



Figure 13: Patient Demographic Data Query Screen

To use the **Patient Demographic Data Query** screen, click the **Query** button from the center frame, enter criteria specific to the patient in any of the available fields, and click the **Find** button. Entry instructions for these fields follow:

Enter a **Patient ID** to search for a patient by ID.

Enter a **Birth Date Range** to search for patients by birth dates.

Enter an Entry Date Range to search for patients by entry dates.

Note: The percentage symbol (%) can be used as a wildcard within the **Patient ID** field only.

Patient Administrative Data

Patient administrative data is mandatory for trials assigned to complete CDS reporting. Follow the instructions below to enter patient-specific administrative data.

Note: Only one Patient Administrative record may be entered per patient.

- 1. Click on the <u>Patient ID</u> link located in the center frame under the **Patient ID** column for the patient record you wish to access.
- 2. Select the <u>Administrative Data</u> link from the CDS menu. The **Patient Administrative Data** screen is displayed for the selected **Patient ID** in the left frame (see Figure 14).

TRGPROTOCOL1 (04/30/2006)	Protocol Number: TROPROTOCOL1
Administralive Data	Patient Administrative Data
Prior Therapies	Patient ID: 042-001 Birth Date: 034/1955
Ele Adverse Eventilia S 🔁 Publications	Subgroup Cotle:
Authors	Subgroup Description
Phase (End Points MTD	Has the Patient had any Baseline Abnormalities? No
Phase End Pointa DLT	Number of Prior Chemo Regimers:
Trial Comments Reputs Provint Ontwis CTC Application	that the patient been declared ineligible?: C Ves C Ves
Wew Collection	is the Patient Evaluable for Response?:
D Hep	Baseline Performance Status Normal Activity, asymptometic
	Is the Patient currently receiving treatment on study?: C No C Yee C Ustroom
	Off Treatment Reason Treatment Completed Perprotocol Criteria
	Last Treatment Date (MM/DD/YYYY): 07/25/2006
	Off Study Reason: Protocol-defined follow-up completed
	Of Study Date (MMODD/YYYY): 07/26/2006
	Serve Cheer

Figure 14: The Patient Administrative Data Screen

3. Complete all of the mandatory (bold text) data fields and the requested data fields, if relevant information is available.

Select values from the LOV or the drop down list by clicking either the **Up Arrow** or **Down Arrow** buttons.



🌆 TIPS

The **Baseline Abnormalities** screen must be completed if 'Yes' is entered in the Has the Patient had any Baseline Abnormalities? field (see the Baseline Abnormalities section on page 16 for more information).

The Off Treatment Reason field becomes mandatory if 'No' is entered in the Is the Patient currently receiving treatment on study? field. If the Off Treatment Reason is 'Death on Study,' then the Off Study Reason must be 'Death' for protocols activated on or after 1/1/2002.

The Last Treatment Date field becomes mandatory when the Off Treatment Reason field is entered. This rule does not apply when an Off Treatment Reason value of 'Patient withdrawal before beginning Active Treatment' or 'Disease Progression before Active Treatment' is entered

Note: The term Active Treatment is considered any form of therapy (including surgery, radiation, commercial chemotherapy agents or investigational agents).

The Off Study Reason field becomes mandatory when the Off Study Date field is entered. The Off Study Reason can only be entered if the patient is not currently receiving treatment on study for protocols activated on or after 1/1/2002.

4. Click the Save button.

For detailed information regarding the Patient Administrative data elements, refer to the Data Element Descriptions section in the CDUS Instructions and Guidelines v3.0 Release 2.

Baseline Abnormalities

The **Baseline Abnormalities** screen is mandatory if you indicated that the patient had baseline abnormalities in the **Patient Administrative Data** screen. Follow the instructions below to enter baseline abnormalities for a selected patient.

Note: Multiple Baseline Abnormality records may be entered per patient.

- 1. Select Baseline Abnormalities from the CDS menu.
- 2. Click the New button. The **Baseline Abnormalities** screen is displayed in the right frame (see Figure 15).

2 S Pasent (PAT-001, 04/1956)	Control and a second second		Restort Alignment in School State		
Administrative Data Baseline Administratives	Category	Adverse Event		Baseline Abnormalities	
Price Therapies	ALLERGY/IMMUNOLOG	ALLERGY/MMUNOLOGY Vavesitie		atient ID: PAT-001	
Responses		reaction/hypersensitik (including drug fever)	8	Inh Date: 04/1956	
E Publications	Appendix IV RTOG/EORTC Late	Brain- Late RT Morbidity Scoring	Category:	ALLERGY/MMUNOLOGY	2
Correlative Studies	Rediction Montidity Scoring Scheme (Use for		Adverse Event:	Masculais	2
Phase I End Ponts MTD Phase I End Ponty DLT	adverse events abouting orgater than 30 days abo		Other Adverse Event (Specif	m [
Thal Comments	(adiation therapy)		Grade;	3 .	

Figure 15: The Baseline Abnormalities Screen

3. Complete all of the mandatory (bold text) data fields and the requested data fields, if relevant information is available.

Select values from the LOV by clicking the Up Arrow button.

TIPS

For studies assigned to CTCAE v3.0, a **Select AE** field is displayed. If you select a Supra-ordinate Term -- indicated by an asterisk (*) -- from the **Adverse Event** field, you must then choose a Select AE from the **Select AE** field's List of Values.

If you select 'Other Specify' for the **Adverse Event** field, you must provide the specific Adverse Event in the **Other Adverse Event (Specify)** field.

For help in locating adverse event terms from both CTC v2.0 and CTCAE v3.0, select <u>CTC Application</u> from the CDS menu to view the Web-based CTCAE dictionary.

4. Click the **Save** button.

The **Category**, **Adverse Event**, and **Grade** of the Baseline Abnormalities record are displayed in the center frame (see Figure 16). If needed, you may click the <u>Category</u> link to access and update the record.

Baseline Abnormalities						
Category	Adverse Event					
ALLERGY/IMMUNOLOGY	Vasculitis					
ALLERGY/IMMUNOLOGY	Allergic reaction/hypersensitiv (including drug fever)					
Appendix IV RTOG/EORTC Late Radiation Morbidity Scoring Scheme (Use for adverse events occurring greater than 90 days after radiation therapy.)	Brain- Late RT Morbidity Scoring					
Records 1 to 3	of 3					
ReQuery						
New						

Figure 16: The Baseline Abnormalities Record (center frame)

5. To enter multiple baseline abnormality records, Click the **New** button and repeat steps 2 through 4 for each record.

For detailed information regarding the Baseline Abnormalities data elements, refer to the *Data Element Descriptions* section in the <u>CDUS</u> <u>Instructions and Guidelines v3.0 Release 2</u>.

Prior Therapies

Prior therapies are mandatory for trials assigned to complete CDS reporting. Follow the instructions below to enter all cancer therapies the patient has received prior to entering the protocol.

Note: Multiple Prior Therapies records may be entered per patient. Up to five therapies can be entered at one time.

- 1. Select the Prior Therapies link from the CDS menu.
- 2. Click the **New** button. The **Prior Therapies** screen is displayed (see Figure 17).

TRGPROTOCOL1 (04/30/2006)	Protocol Number: TRGPROTOCOL1	Prio	or Therapies		
		Patient ID:	PAT-001		
Responses		Birth Date:	04/1956		
Late Adverse Events		-			
🖶 🔁 Publications		Therapy		Insert?	
Authors			•	Clear	
Phase I End Points MTD			•	Clear	1
			•	Clear	1
E A Reports			•	Clear	1
CTC Application			•	Clear	Ĩ
View Collection View Protocol Selection Help		12	Save		
		All data elemen	nts in bold are manda	tory	

Figure 17: The Prior Therapies Screen

- 3. Click the **Down Arrow** button and select a Prior **Therapy** value from the drop down list.
- 4. Click the Save button. The entered therapies are displayed.
- 5. To remove any Prior **Therapy** value from the saved list, click the **Delete** checkbox and click the **Save** button.
- 6. To enter additional prior therapies, click the **New** button and repeat steps 2 through 5 above.

For detailed information regarding Prior Therapies data elements, refer to the *Data Element Descriptions* section in the <u>CDUS Instructions</u> <u>and Guidelines v3.0 Release 2</u>.

Treatment Courses

Treatment course data is mandatory for trials assigned to complete CDS reporting. Follow the instructions below to enter protocol treatment course data.

Note: Multiple Treatment Course records may be entered per patient.

- 1. Select the <u>Treatment Courses</u> link from the CDS menu.
- 2. Click the **New** button. The **Treatment Courses** screen is displayed (see Figure 18).



Figure 18: The Treatment Courses Screen

3. Complete all of the mandatory (bold text) data fields and the requested data fields, if relevant information is available.

Select values from the LOV or the drop down list by clicking either the **Up Arrow** or **Down Arrow** buttons.

🏐 TIP

If you enter 'Yes' in the **Adverse Event Experienced** field, you must provide specific Adverse Event data in the **Adverse Events** screen (see **Adverse Events** on page 22).

4. Click the Save button.

Note: Validate the CTEP ID selected, especially if there is more than one institution name that is worded the same.

The **Course ID**, **Course Start Date**, and **Treatment Assignment** of the Treatment Course record are displayed in the center frame (see Figure 19). If needed, you may click the <u>Course ID</u> link to access and update the record.

Treatment Courses								
Please sele	ect a Treatment Cour	se to proceed.						
Course ID Number	Course Start Date (MM/DD/YYYY)	Treatment Assignment						
<u>11</u>	03/03/2006							
1	02/20/2002	LEVEL3						
Records 1 to 2 of 2 ReQuery								
New								

Figure 19: The Treatment Courses Record (center frame)

You can complete the Treatment Courses process by entering information in the **Course Agents** screen and, if you entered 'Yes' in the **Adverse Event Experienced?** field of the **Treatment Courses** screen, in the **Adverse Events** screen. Follow the instructions below to do this.

Course Agents

At the beginning of the new collection period, you may need to enter a new **Course Agents** record to reflect the agents that the patient received in the selected treatment course.

Note: Multiple Course Agent records may be entered per patient.

1. Click the <u>Course ID</u> link in the center frame. The <u>Course Agents</u> and <u>Adverse Events</u> links are displayed on the CDS menu (see Figure 20).



Figure 20: The Course Agents and Adverse Events Links

- 2. Click the Course Agents link from the CDS menu.
- 3. Click the New button located in the center frame. The Course Agents screen is displayed (see Figure 21). The Course ID and Treatment Assignment fields in the right frame are automatically populated.

TRGPROTOCOL1 (04/30/2006)	Course Agents	Protocol Number: TRGPR0T0p0L1			
Administrative Data Baseline Atrummilates Prior Therapies Course Agents Administrative (1, 02002002) Course Agents Responses	Course Agent CPA ST1-579 (5760)(0AP1-ED) CAACSE (Surgemention) Intent E(40%4-6(1-4) Records 1 to 3 of 3		Course Agents Patient ID: PAT-031 Binth Date: OUV1966 Enter values for new Course Agente record		
Late Adverse Events Events Autors Autors	RinGuary	Course ID Number:	1		
Correlative Studies	(Filment)	Treatment Assignment:	LEVEL3-Temozolomide 24 mg/m2 PO qd Days 1-5, wery 28 days 0-6 Benzylguanine 120 mg/m2 /V over 1hr qd Days 1-5, every 28 days		
Phase (End Points DL7	_	Agent Name:	<u></u>		
E Ca Reporte		Dose Changed?:			
CTC Application		Total Dose:	Unit Code:		
View Protocol Selection View Protocol Selection Help			Street Came		

Figure 21: The Course Agents Screen

- 4. Enter the **Agent Name** field and enter the information for the agent the patient received on the selected Treatment Course.
- 5. Click the **Save** button.

The **Course Agent** is displayed as a link in the center frame (see Figure 22). If needed, you may click the <u>Course Agent</u> link to access and update the record.

Course Agents					
Course Agent					
CEA:571-579 (576D)	[CAP1-6D]				
GM-CSF (Sargramos	tim)				
InterLEUKIN-4 (IL-4)					
Records 1 to 3	of 3				
ReQuery					
New					

Figure 22: The Course Agents Record (center frame)

- 6. To enter additional agent records, click the **New** button and follow steps 3 through 5 above.
- 7. Click the <u>Treatment Courses</u> link on the CDS menu to return to the **Treatment Courses** screen or click on the <u>Adverse Events</u> link on the CDS menu to complete the Adverse Event data entry.

Adverse Events

You may need to enter a new Adverse Events record if the patient experienced adverse events on the selected treatment course.

The Adverse Events screen is displayed only when 'Yes' is entered in the Adverse Event Experienced? field of the Treatment Courses screen.

Note: Multiple Adverse Event records may be entered per patient. However, an Adverse Event record can be submitted with only one grade for a patient's treatment course.

- 1. Click the Course ID link from the center frame. The Course Agents and Adverse Events links are displayed on the CDS menu as (see Figure 20).
- 2. Click the Adverse Events link from the CDS menu. The Adverse Events screen is displayed
- 3. Click the New button located in the center frame. The Adverse Events screen is displayed (see Figure 23). The Course ID and Treatment Assignment fields are automatically populated.



Figure 23: The Adverse Events Screen

4. Complete all of the mandatory (bold text) data fields and the requested data fields, if relevant information is available.

Select values from the LOV or the drop down list by clicking either the Up Arrow or Down Arrow buttons.



🎒 TIPS

For studies assigned to CTCAE v3.0, a Select AE field is displayed. If you select a Supra-ordinate Term -- indicated by an asterisk (*) -- from the Adverse Event field, you must then choose a Select AE from the Select AE field's List of Values.

If you select 'Other Specify' for the Adverse Event field, you must provide the specific Adverse Event in the Other Adverse Event (Specify) field.

For help in locating adverse event terms from both CTC v2.0 and CTCAE v3.0, select CTC Application from the CDS menu to view the Web-based CTCAE dictionary.

- 5. Click the **Save** button.
- 6. The **Category**, **Adverse Event**, and **Grade** of the Adverse Event record are displayed as a link in the center frame (see Figure 24). If needed, you may click the <u>Category</u> link to access and update the record.

Adverse Events						
Category	Adverse Event	Grade				
ALLERGY/IMMUNOLOGY	Autoimmune reaction	2				
GASTROINTESTINAL	Dehydration	2				
Records 1 to 2 of 2 ReQuery						
New						

Figure 24: The Adverse Event Record (center frame)

- 7. To enter additional Adverse Event records, click the **New** button and follow steps 3 through 5 above, and enter data for each event.
- 8. Click the <u>Treatment Courses</u> link on the CDS menu to return to the **Treatment Courses** screen.

For detailed information regarding the Treatment Courses, Course Agents, and Adverse Events data elements, refer to the *Data Element Descriptions* section in the <u>CDUS Instructions and Guidelines v3.0</u> <u>Release 2</u>.

Responses

The **Responses** screen provides the capability to enter the observed best response and/or disease progression for a Treatment Course. The screen also enables you to modify existing response status information.

Response data is mandatory when 'Yes' is entered in the **Is the Patient Evaluable for Response?** field from the **Administrative Data** screen. Follow the instructions below to enter response data for the selected patient.

Notes: A Treatment Course record must be created prior to entering response information.

Multiple Response records may be entered per patient. Up to five responses can be entered at one time.

- 1. Select the <u>Responses</u> link from the CDS menu.
- 2. Click the **New** button. The **Responses** screen is displayed (see Figure 25).

IRGPROTOCOL1 (94/30/2006) Administrative Data Datient (PAT-001, 04/1950) Datiente Abnormalities Prior Therapies Prior Therapies Treatmer Courses (1, 02/20/2002) Ourse Agents	B Protocol Number: TROPROTOCOL1	Résp Patient ID: Birth Date:	011565 PAT-001 104/1955	
Adverse Events Responses		Category	Observed Date	Detero?
Late Adverse Events		Less than partial response	03/29/2006	E
Authors		Partial response	04/29/2006	E
Correlative Studies		Complete response	05/31/2006	Π
Authore Concelled Suddes Concelled Suddes Phase I End Fonds WTD Phase I End Fonds WTD Phase I End Fonds OLT That Comments Pasent Details CTC Application View Protocial Selection Help		Record	is 1 to 3 New ReGuery bold are mandet	Plant Denge arts

Figure 25: The Responses Screen

3. Click the **Down Arrow** button and select a Response **Category** value from the drop down list. Enter the **Observed Date**.

🧐 TIPS

Only enter the patient's earliest observed best response.

Progression should be reported even if it is experienced after a better response.

The values entered in the Response **Category** field should not decline except to the value 'Progression.'

Other Response **Category** values will not be accepted if 'Progression' is entered as the initial value.

When 'Other' is entered as the Response **Category** value, the General Response Comments field will be mandatory in the **Trial Comments** (see page 34) screen.

- 4. Click the **Clear** button if you wish to remove a Response **Category** value from the list.
- 5. Click the **Save** button. The entered responses are displayed.
- 6. To remove any Response value from the saved list, click the **Delete** checkbox and click the **Save** button.
- 7. To enter additional response records, click the **New** button and follow steps 2 through 5 above.

For detailed information regarding Response data elements, refer to the *Data Element Descriptions* section in the *CDUS Instructions and Guidelines v3.0 Release 2*.

Late Adverse Events

Complete the Late Adverse Events screen when an Adverse Event is observed after a patient has completed treatment. Follow the instructions below to enter Late Adverse Events.

Note: Multiple Late Adverse Event records may be entered per patient.

- 1. Select the Late Adverse Events link from the CDS menu.
- 2. Click the New button from the center frame. The Late Adverse Events screen is displayed (see Figure 26).

TRGPROTOCOL1 (84/30/2006)	Late Adverse Events		Protocol Number: TRGEROTOCOL1		
	Calingory ALLERGY/MMUNOLOG GASTRUNTESTINAL	Adverse Event Allensy-Other (Specity) Dysp4pnia/hearthum	Late Adverse Events Patient ID: PAT 001 Birth Date: 04/1956		
Adverse Events	Records 1 to	2#2	Category:		1
Late Adverse Events Service Publications Adverse	Brithman		Adverse Event:	[1
	12mm	Other Adverse Event (Specify)			
Phase (End Points MTD		12mm	Grade:		
Phase End Points DLT			Attribution	-	
Reports		AE Start Date:	AE Start Date:	<u>s</u>	
Papons Papons			All da	Seve Class	

Figure 26: The Late Adverse Events Screen

3. Complete all of the mandatory (bold text) data fields and the requested data fields, if relevant information is available.

Select values from the LOV by clicking the Up Arrow button.

🧐 TIPS

For studies assigned to CTCAE v3.0, a **Select AE** field is displayed. If you select a Supra-ordinate Term -- indicated by an asterisk (*) -- from the **Adverse Event** field, you must then choose a Select AE from the **Select AE** field's List of Values.

If you select 'Other Specify' for the **Adverse Event** field, you must provide the specific Adverse Event in the **Other Adverse Event (Specify)** field.

For help in locating adverse event terms from both CTC v2.0 and CTCAE v3.0, select <u>CTC Application</u> from the CDS menu to view the Web-based CTCAE dictionary.

 The Category, Adverse Event, and Grade of the Late Adverse Event record are displayed as a link in the center frame (see Figure 27). If needed, you may click the <u>Category</u> link to access and update the record.

Late Adverse Events					
Category	Adverse Event				
ALLERGY/IMMUNOLOGY	Allergy-Other (Specify,)				
GASTROINTESTINAL	Dyspepsia/heartburn				
Records 1 to 2 of 2 ReQuery					
New					

Figure 27: The Late Adverse Event Record (center frame)

5. To enter additional Late Adverse Event records, click the **New** button and follow steps 2 through 4 above.

For detailed information regarding Late Adverse Event data elements, refer to the *Data Element Descriptions* section in the <u>CDUS</u> <u>Instructions and Guidelines v3.0 Release 2</u>.

Protocol Data

Protocol Data Entry Screens

The CDS Web application provides six screens to enter protocolspecific data and organizes them as follows:

- Publications
 - o Authors
- Correlative Studies
- Phase I End Points MTD
- Phase I End Points DLT
- Trial Comments

Publications

A publication citation must be provided when data for the study or any associated correlative study is published. Follow the instructions below to enter Publications data.

Note: Multiple Publications records may be entered per protocol.

- 1. Select the <u>Publications</u> link from the CDS menu.
- 2. Click the **New** button from the center frame. The **Publications** screen is displayed (see Figure 28).

TRGPROTOCOL1 (04/30/2006)	Publications		Protocol Humber: TRGPROTOCOL1
Administrative Data	Medline UID	Title	Publications
Prior Therapies	1234	Tels	Enter values for new Publications record
E Course Agents	3343	10014	
Adverse Evonts	Records 1	102:012	Medine UID:
Responses	ReGuery		Title;
Publications			Journal
Authors Correlative Studies			Volume;
Phase I End Points MTD			Year (YYYY)
Phase / End Points DLT Trial Comments			Publishee
Patient Details			Pages
Vew Collection View Collection View Protocol Selection			Save Clear

Figure 28: The Publications Screen

- 3. If the publication has an assigned Medline Unique Identifier (UID), you need only enter the **Medline UID** field. If no Medline UID is available, then all other data fields must be entered to complete the Publications record.
- 4. Click the **Save** button.
- 5. The **Medline UID** or article **Title** of the Publications record is displayed as a link in the center frame (see Figure 29). If needed, you may click the <u>Medline UID</u> or <u>Title</u> link to access and update the record.

Publications	
Medline UID	Title
<u>1234</u>	Title
<u>3343</u>	rggf4
Records 1 to 2 ReQuery New	of 2

Figure 29: The Publications Record (center frame)

6. To enter additional Publications records, click the **New** button and follow steps 2 through 4 above.

To complete the Publications process, you must enter information in the **Authors** screen. Follow the instructions below to complete the data entry process for this screen.

Authors

All authors associated with the article should be entered for each Publication record.

Notes: Multiple Author records may be entered per Publication. Up to five author names may be entered at one time.

Author information is not necessary if the Medline UID was entered.

- 1. On the CDS menu, click on the preceding the <u>Publications</u> folder to expand and view the subfolder.
- 2. Select the <u>Authors</u> link from the CDS menu.
- 3. Click the <u>Medline UID</u> or the article <u>Title</u> link in the center frame to select the Publication record you wish to add authors to.
- 4. Click the **New** button from the right frame. The **Authors** data entry screen is displayed (see Figure 30).

TRGPROTOCOL1 (84/30/2006) Patient (PAT-001, (84/18/56) Administrative Data Bestine Administrative Prior Therapes Treatment Coccuse (1, 02/20/2002) Treatment Coccuse (1, 02/20/2002)	Publications Medline UID Title 1234 Tick 1313 uppt	Protocol Number: TRGPROTOCOL1	Authors Medline UID: 1234 Title: Ta'o	r.c	
Adverse Events	Records 1 to 2 of 2	Last Name	First Name	Middle Name	Insert?
Late Adverse Events	Reducry	1	1		Cluer
Authors		-			Club
Correlative Studies Phase LEnd Points MTD		1	1	1	Clear
Phase I End Points DLT				1	Elenr.
Reports		1	- i		Cieps
Pablet Defails CTD - Application View Calicitian View Potocol Selecton Help			Save	tory	

Figure 30: The Authors Screen

- 5. Enter the Author's last, first, and middle name(s) in the same order as they appear in the selected publication.
- 6. Click the **Clear** button if you wish to remove an Author's name from the list.
- 7. Click the **Save** button. The **Rows inserted successfully** message is displayed.
- 8. To view the entered Authors, click on the <u>Medline UID</u> or the article <u>Title</u> link in the center frame. The Author records are displayed (see Figure 31).

TRGPROTOCOL1 (84/30/2006) Palent (PAT-001, 04/1550) Administrate Data Dissiente Abnormaties Prior Therapies Treatment Courses (1, 0220/2012) Course Agents	Publications Medline UID Title [234 Table 2043 3924	Protocol Number: TRGPROTOCOLI	Authors Mediine UID: 1234 Tide: Tele		
Adverse Events Responses	Records 1 to 2 of 2	Last Name	First Name	Middle Name	Delote?
Late Adverse Events	ReQuery	Perkarton	Robert	JC .	- F
Authors		Mudd	Susan	18	Г
Correlative Studies		Johnson	John	fr	- F
Plane I für Ponis DLT Trai Convents Hapots Pasen Dutits Ch Zelauksen Wew Celleton Wew Celleton Wew Celleton Wew Celleton Wew Celleton Wew Celleton		,	Records 1 to 3	Diuny/	

Figure 31: The Authors Record

- 9. To remove any Author name from the saved list, click the **Delete** checkbox and click the **Save** button.
- 10. To enter additional Author names, click the **New** button and repeat steps 4 through 8 above.

For detailed information regarding Publications data elements, refer to the *Data Element Descriptions* section in the <u>CDUS Instructions and</u> <u>Guidelines v3.0 Release 2</u>.

Correlative Studies

Correlative study data must be provided for each correlative study every quarter when correlative studies are associated with the protocol. Follow the instructions below to enter correlative study data.

Notes: A separate Correlative Study record is automatically created for each correlative study associated with the protocol.

Only one Correlative Study record is available per correlative study.

1. Select the <u>Correlative Studies</u> link from the CDS menu. The **Correlative Studies** screen is displayed (see Figure 32).

RGPR0TOCOL1 (04/30/2006)	Correlative Studies	Protocol Number: 1180PR010C0L1			
Administrative Data Baseline Ateromatilitys	Study Title	Correlative Studies			
Dvior Thetapies	PO-1 Tumor levels of	Study Code: PD-1			
Course Agents	AGT in prior tumo:	Title: Tumor levels of AGT in prior tumor blocks and tumor bropsies after C688 therapy			
Adverse Events	biopsies after	Patients Collected Number:			
Responses Lats Adverse Events Patiestons Autors Correlative Studies	C686 therapy	Patients Analyzed Number:			
	of 06-	Samples Collected Number:			
	Exclosure and B-orb-of benzydygusine EX:2 Planarockinetico oftemozohomude Records 1 to 3 of 3 Bat2unny	Samples Analyzed Number:			
Phase (End Points MTC) Phase (End Points D) T		Pindings:			
hial Comments					
Patient Details Patient Details CTC-Application View Protocol Bellocion Help		All date elements in bold are mandatory			

Figure 32: The Correlative Studies Screen

- 2. Click on the <u>Study Code</u> link in the center frame for the Correlative Study record you wish to access.
- 3. Complete all of the mandatory (bold text) data fields and the requested data field, if relevant information is available.
- 4. Click the **Save** button.

For detailed information regarding Correlative Studies data elements, refer to the *Data Element Descriptions* section in the <u>CDUS</u> <u>Instructions and Guidelines v3.0 Release 2</u>.

Phase I End Points MTD and Phase I End Points DLT

Phase I end points include the recommended Phase 2 dose or maximum tolerated dose (MTD) and dose limiting toxicity (DLT)

information. This information is mandatory for Phase I studies assigned to complete CDS reporting.

The Phase I End Points MTD and DLT are identified by the subgroup and treatment assignment for which the DLT occurred and the MTD determined. This data combination creates a unique data key, which assists CTEP in further understanding the agent's abilities. The MTD and DLT information is expected towards the completion of the trial.

Follow the instructions below to enter Phase I End Points data.

Phase I End Points MTD

Note: Multiple Phase I End Points MTD records may be entered per protocol.

- 1. Select the <u>Phase I End Points MTD</u> link from the CDS menu.
- 2. Click the New button. The Phase I End Points MTD screen is displayed (see Figure 33).



Figure 33: The Phase I End Points MTD Screen

- 3. Complete all of the mandatory (bold text) data fields by clicking the **Up Arrow** button and entering values from the LOV.
- 4. Click the **Save** button.
- 5. The **Subgroup Code** and **Treatment Assignment** of the **Phase I** End Points MTD record are displayed as a link in the center frame (see Figure 34). If needed, you may click the <u>Subgroup Code</u> link to access and update the record.

Phase I End Points MTD					
Subgroup Code	Treatment Assignment Code				
<u>SG1</u>	LEVEL9				
Re	ecord 1 of 1 ReQuery				
	New				

Figure 34: The Phase I End Points MTD Record (center frame)

6. To enter additional Phase I End Points MTD records, click the **New** button and follow steps 2 through 4 above.

Phase I End Points DLT

Note: Multiple Phase I End Points DLT records may be entered per protocol.

- 1. Select the Phase I End Points DLT link from the CDS menu.
- 2. Click the **New** button. The **Phase I End Points DLT** screen is displayed (see Figure 35).



Figure 35: The Phase I End Points DLT Screen

3. Complete all of the mandatory (bold text) data fields by clicking the **Up Arrow** button and entering values from the LOV.

TIPS

For studies assigned to CTCAE v3.0, a **Select AE** field is displayed. If you select a Supra-ordinate Term -- indicated by an asterisk (*) -- from the **Adverse Event** field, you must then choose a Select AE from the **Select AE** field's List of Values.

If you select 'Other Specify' for the **Adverse Event** field, you must provide the specific Adverse Event in the **Other Adverse Event (Specify)** field.

For help in locating adverse event terms from both CTC v2.0 and CTCAE v3.0, select <u>CTC Application</u> from the CDS menu to view the Web-based CTCAE dictionary.

- 4. Click the Save button.
- 5. The **Subgroup Code**, **Treatment Assignment**, and **Adverse Event** of the Phase I End Points DLT record are displayed as a link in the center frame (see Figure 36). If needed, you may click the <u>Subgroup Code</u> link to access and update the record.

Phase I End Points DLT						
Treatment Assignment Code	Adverse Event					
LEVEL9	Alkaline phosphatase					
Record 1 of ReQuery	1					
New						
	Treatment Assignment Code LEVEL9 Record 1 of ReQuery New					

Figure 36: The Phase I End Points DLT Record (center frame)

6. To enter additional Phase I End Points DLT records, click the **New** button and follow steps 2 through 4 above.

Trial Comments

The **Trial Comments** screen is used to provide a general data summary by subgroup and treatment assignment. This screen is optional. Follow the instructions below to enter Trial Comments data.

- 1. Click the Trial Comments link from the CDS menu.
- 2. Click the **New** button. The **Trial Comments** screen is displayed (see Figure 37).

RGPROTOCOL1 (04/30/2006)	Trial Cor	nments	Protoco	I Number: TRGPROTOCOLI		
Administrative Data Baseline Abnormalities Prior Therapies Treatment Courses (1, 02/20/2002)	Subgroup Code	Treatment Assignment Code		Enter val	Trial Comments	ints record
Course Agents				Subgroup Code:	- B	
Presenterse Processors Puter actions Puter actions Processors Processors Processors Processors Processors Prisel Find Points DLT Trial Commertia	Re	Record 1 of 1 Recisenty		Treatment Assignment: General Response Comments General Adverse Events Comments		ज ज ज ज
Patent Decision CtC Application Wew Collection Wew Protocol Selection Help				All data	Seve Clear	sandiatony

Figure 37: The Trial Comments Screen

3. Complete all of the mandatory (bold text) data fields by clicking the **Up Arrow** button and entering values from the LOV. Complete the requested data fields, if relevant information is available.



TIPS

When 'Other' is entered as the Response **Category** value in the **Responses** screen (see page 24), the General Response Comments field will be mandatory in the **Trial Comments** screen.

4. The **Subgroup Code** and **Treatment Assignment** of the Trial Comments record are displayed as a link in the center frame (see Figure 38). If needed, you may click the <u>Subgroup Code</u> link to access and update the record.

Trial Comments						
Subgroup Code	Treatment Assignment Code					
<u>SG1</u>	LEVEL9					
Reco	rds 1 to 2 of 2 ReQuery					
	New					

Figure 38: The Trial Comments Record (center frame)

5. To enter additional Trial Comments records, click the **New** button and follow steps 2 through 4 above.

For detailed information regarding Trial Comments data elements, refer to the *Data Element Descriptions* section in the <u>CDUS</u> <u>Instructions and Guidelines v3.0 Release 2</u>.

Submissions and Reports

Patient Details Report

The **Patient Details Report** provides the current data for each patient enrolled on the protocol and entered in the Quarterly Clinical Data Update. Because the report is cumulative, it includes all new patient records entered for the quarter and any modifications made to existing patient data. The report does not show original or previous data once the data is modified. Follow the instructions below to generate the **Patient Details Report**.

- 1. On the CDS menu, click on the preceding the <u>Reports</u> folder to expand and view the subfolders.
- 2. Select the <u>Patient Details</u> link from the CDS menu. The **Patient Details Report** generation screen is displayed (see Figure 39).



Figure 39: The Patient Details Report Generation Screen

3. Enter the quarterly submission due date that the Quarterly Clinical Data Update was submitted or will be submitted in the **Submission Date** field.

- 4. Select a source patient in the **Source Patient ID** list. To select more than one patient, select a patient, and then hold down the CTRL key while you click other patients that you want to select. To select all patients, click 'ALL.'
- 5. Click the **Run Report** button.

The **Patient Details Report** is displayed as an Adobe Acrobat PDF file (see Figure 40).

		Patier	Clinical Data S at Details Report	System as ol 04/30/2006			Page 1 of 4
Protocol Number :	TRGPROTOCOL1				Run By:	FBUSER1 (08/01/2006)	
Title :	Phase I Trial and Pharmacok	netic Study of Temozolomide and	l O6-Benzylguanine	in Childhood Solid T	umors		
Patient ID :	PAT-001	Birth Date : 04/1956		Eatry Date :	02/04/2002		
Gender :	Male	Ethnicity : Not Hispani	c or Latino	Country :	United States		
Registering Group	: -			Zip Code :	20999		
Registering Institut	tion : NC010 - Test University	Medical Center		Payment Method :	Medicare and Priv	ate Insurance	
Subgroup:	-						
Disease :	Chondrosarcoma NOS						
Has the patient bee	n declared ineligible ?:	No	Is the patient eva	luable for Response?	: Үсз		
Is the patient curre	atly receiving treatment on st	ady?: Yes	Off Treatment Re	eason :			
Last Treatment Da	te:		Off Study Reason	& Date :	-		
Number of Prior Cl	hemo Regimens :	3	Baseline Abnorm	ality Flag :	Yes		
Performance Status		Normal Activity, asymp	tomatic				
Races American Indian or A Patient Responses Category Complete response Less than partial resp Partial response	Alaska Native <u>Observed Date</u> 03/31/2006 03/29/2006 03/29/2006						
Anti-retroviral Thera	py						
Chemotherapy (NOS)						
Chemotherapy non-o	ytotoxic						
Hematopoietic Stem	Cell Transplantation						
Baseline Abnormal Category ALLERGY/IMMU ALLERGY/IMMU Appendix IV RTOG Morbidity Scoring S events occurring gre radiation therapy.)	lities NOLOGY NOLOGY /BORTC Late Radiation teheme (Use for adverse ater than 90 days after	Adverse Events Vasculitis Allergic reaction/hypersensitivity (including drug fever) Brain- Late RT Morbidity Scoring	<u>Gr</u> .	<u>ade AE Oth</u> 3 2 4	er Specify		
Note: Because the rep the data is modified.	ort is cumulative, it includes al	l new patient records entered for t	the quarter and any	modifications made to	existing patient date	s. The report does not show original or p	revious data once

Figure 40: The Patient Details Report

The report uses the assigned Patient ID to organize the report data and displays the patient records in alphanumeric order.

Error Log Report

The **Error Log Report** displays all errors generated for the latest submission. For each error, the report shows the Error ID, the screen name and on which the error occurred, the field name, and the unique identifier field and value. The **Error Log Report** can be generated only via a rejected collection. Follow the instructions below to generate the **Error Log Report**.

1. On the **Collections** screen, click on the <u>Rejected</u> link to view the CDS menu for the rejected collection (see Figure 41).

organization you wish to	Protocol N	lumber: TROPA	(locol)						
enter data for.	Collections								
Organization	To enter data	for a platicular o	methon, please select	the collection from	m the list bulles. To create a	new collection is up	sale an existing collection , i	Heat the Add Collection	6 billio:
ten University Minlie II Care	11	Collection	Submission Date	Cut off Date	Last Submission Date	Current Trial Status	Completed By Name	Submitter Phane	Submitte
	C Submit?	Rejected 🛋	- 17/91/2006 (02)	07/30/2006	07/14/2006	Active	Sus in Brown	301-945-3033	Howng
	C Submit?	Fightlet	(M/30/200E (01)	04/29/2006		Active	Brown Susse	301-948-3033	-
		Accepted Accepted Accepted Accepted	(11/31/2006 (04) 10/31/2006 (03) 07/31/2005 (02) 14/30/2005 (07)	01/30/2006 10/30/2006 07/30/2005 04/30/2005		Active Active Active Active	Susan Brown Susan Brown Susan Brown Susan Brown	301-948-3033 301-948-3033 301-548-3033 301-948-3033	ebiown() ebiown() ebiown()
	Resards 3 to 4	346							
	Note Activity	opin fer insurf	ind/m indute, Susnifie India Comerciani	ed and Approved	are broad for insert but open	for uptime through i	he Active collaman		
				1					

Figure 41: Collections Screen with "Rejected" Link

- 2. On the CDS menu, click on the preceding the <u>Reports</u> folder to expand and view the subfolders.
- 3. Click on the Error Logs link (see Figure 42).

Note: The Error Logs link appears only if the selected collection was rejected.

TRGPROTOCOL2 (07/31/2006)	Patients Select a patient	to proceed	Protocol Number: TROPROTOCOL2	tient Demographic Data		
Phase Lend Pends MTD Phase Lend Pends MTD Phase Lend Points DLT	Patient ID	Hinh Date (MM/YYYY)	Patient ID: Enter the unique code assigned the of reportation to this attudy	d at the PATION		
That Commette	PATIO2	09/1979	Birth Date (MM/YYYY):	03/1975		
Patienttesia	STALINA	0001000	Genden	Mate -		-1
CTC Application	Rec	teds 1 to 2 of 2	Ethnicity:	Hispanicor Leino		-
View Collection		PieCasery.	Races:	R American Indian or Alaska Native	_	-
View Philbola Develophi	-			E Asser	-	_
-		Chairy .		Elack or African American		-
		(Instant)		Thative Havanan ar Other Pacific Isl	ander	
		(Control)		T Nat Reported		
				L. Usknown		_
			the second second	E White		
			Country Name	United Strates		
			Zip Code	29879		-
			Payment Method	1	18	
			Entry Date (MM/DD/YYYY):	08/01/1980		
			Registering Group			1
			Reg Group ID			-
			Registering Institution:	A.C. Camergo Hospital		10
			Rug Inst ID:	08017		
			Disease Calegory:	1	161	-
			Disease Sub Category	- í	141	-
			Disease Name			-
			Sin All data	elements in bold are mandatory		

Figure 42: The Error Log Report Generation Screen

The **Error Log Report** is displayed in a separate window (see Figure 43).

S.		Nistonal Cancer Ine futor Log Report For Submissio	16da n Date 07/31/2006	National Casoar Middle National Casoar Middle National Casoar Middle
Document I Tille:	tumber: TRGPHOTOCOL. Phase I Trial and) Pharmácsikinetis: Study of Tensonolounde and	Run Dy: #10 I Of-Benardytamor in Childrood Solid Tumors	USERI (06/07/2006)
Error Cate	pary: REJECTION			
Error II)	Screen Name	Field Name	Unique Identifier Field	Unique Identifier Values
R0022	Collections	Current Trial Status	Submatrion Date, Cutoff Date	[20060601,20060601]
R0092	Patient Demographic Data	Entry Date	Patient ID	[PAT102]
80092	Panent Demographic Data	Entry Date	(Panent II)	[PAT102]
80092	Patient Demographic Data	Entry Date	Patient ID	[PAT101]
R0092	Patient Demographic Data	Entry Date	Paternt ID	[PA7102]
R0092	Patient Demographic Data	Entry Date	Patient ID	[PAT101]
<u>R0092</u>	Patient Demographic Data	Entry Date	(Patient II)	[PAT101]
E Litter Cate	OUT CUMULARYE	-		
Error ID	Streen Name	Field Name	Unique Identifier Field	Unique Identifier Values
Farter Cate	gary: CAUTION			
Error ID	Screen Name	Field Name	Unique Identifier Field	Unique Identifier Values
\$5010	Treatment Courses	Weight	Patiens ID, Course ID	[PAT101,1]

Figure 43: The Error Log Report

On the Error Log Report, click on the

 <u>■</u> preceding the <u>Error</u>
 <u>Category</u> headings to expand and view the errors and their
 description. The report displays the errors by category (Rejection,
 Cumulative, and Caution) and error ID. Each error category is
 sorted by screen name.

For more detailed information regarding CDS Error Notices and Error Log Reports, refer to the *Interpreting the CDUS Error Reports* section in the <u>CDUS Instructions and Guidelines v3.0</u> <u>Release 2</u>.

Submitting the Quarterly Clinical Data Update

Once all the data are entered for the Quarterly Clinical Data Update, it is submitted to the Cancer Therapy Evaluation Program (CTEP). Follow the instructions below to submit the Quarterly Clinical Data Update.

- 1. Update and/or enter new data in all Patient and Protocol screens. Review the data for accuracy.
- 2. Select the protocol to access the **Collections** screen.
- 3. Check the **Submit**? checkbox located in the first column of the table.
- 4. Click the Submit Collections button.

The Quarterly Clinical Data Update is now submitted to CTEP. If an Error Message is displayed, correct the error by following the instructions provided in the **Error or Warning Messages** section on page 6.