

CTCAE v3.0, AdEERS, MedDRA What's New?

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AdEERS Commercial Agents

- All Cooperative Groups use AdEERS for submitting SAE reports to the FDA for protocols
 - Utilizing commercial agents only
 - With arms utilizing commercial agents only
- No change in that requirement
- Continue to use AdEERS

FDA Discussions with CTEP: AdEERS + Commercial Agents

- Large volume of reports to FDA
- Only Grade 4 & 5 AEs with Attribution to Agent of 'Possible', 'Probable', 'Definite'
- **Do not send Additional Information**
- Electronic data format differences between FDA AERS & CTEP, NCI AdEERS
- Minimize data elements in reports to FDA
- **Do not send Additional Information**

AdEERS For FDA Only

June 2006

- Reformatted report with a subset of AdEERS data elements
- Deactivated 'Additional Information' section of AdEERS (for protocols utilizing commercial agents only)

What Does this Mean for AdEERS Users?

- Protocols that utilize commercial agents only
 - Continue to use AdEERS
 - **Additional Information** section is not available
 - Grade 4 & 5 AEs with Attribution to agent of 'Possible', 'Probable', 'Definite'
 - Automatic distribution to FDA
 - Any AEs other than Grade 4 & 5 with Attribution to agent of 'Possible', 'Probable', 'Definite'
 - 'Send to FDA' default flag is 'No'
 - Submit report to all recipients *except* FDA
 - May change 'Send to FDA' flag to 'Yes'
 - Submit report to all recipients including FDA

What Does this Mean for AdEERS Users?

- FDA requests
 - ONLY the AdEERS report
 - Only Grade 4 & 5 AEs with Attribution to agent of 'Possible', 'Probable', 'Definite'
 - No **Additional Information** is to be submitted unless requested by FDA
- AdEERS Users may view and print
 - Simplified, reformatted report sent to FDA
 - Original AdEERS report


What Does this Mean for AdEERS Users?


- No action required on the part of AdEERS Users
- The AdEERS system automatically distributes appropriate reports to FDA
- This is FYI only

AdEERS User Interface Update

Tentative Release Date July 2006

New look to comply with Federal Regulations


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CAUTION:
AdEERS Training Site





You have accessed the AdEERS Web application *Training* site. Reports entered using this site are for training purposes only and are not submitted to the NCI.
Use the following URL to access the AdEERS Web application *Production* site: [AdEERS Application](#)

Welcome to CTEP AdEERS


- [● Submit an Expedited Report](#)
- [● View NCI Guidelines: Adverse Event Reporting Requirements for NCI Investigational Agents](#)


*Additional AdEERS resources are available on the [AdEERS Home Page](#)
[Frequently Asked Questions FAQ](#)*

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[View CTEP-ES Warning Notice for information on NIH Policies, Disclaimers, and Rules of Behavior](#)

This system is for the use of authorized users only. Individuals using this computer system without authority, or in excess of their authority, are subject to having their activities on this system monitored and recorded by system personnel. In the course of monitoring individuals improperly using this system, or in the course of system maintenance, the activities of authorized users may also be monitored. Anyone using this system expressly consents to such monitoring and is advised that such monitoring reveals possible evidence of criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Although decisions concerning the applicability and implementation of the HIPAA Privacy Rule reside with the researcher and his/her institution, it is important to note that adverse event reporting is permitted without patient authorization under several provisions of the HIPAA Privacy Rule. For example, adverse event disclosures are expressly permitted under section 164.512(b) for public health activities, which include reporting to the FDA, NIH, IND sponsors, and others. Adverse event uses or disclosures may also be permitted for health oversight activities under section 164.512(d).

In addition, to assure security and safety of patient information, AdEERS uses the latest encryption technology. All data collected through AdEERS are stored on a server that is not accessible from the Internet. Once you have submitted data to AdEERS it can only be retrieved with a combination of three different pass-codes: the patient ID, protocol ID & a random seven character ticket number generated by AdEERS. You should take every precaution necessary to keep the pass-code information confidential and to avoid distribution of AdEERS data to inappropriate individuals.

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AdEERS

Main Menu

- New Expedited Report
 - [AdEERS Report](#)
 - [Death unrelated to an Adverse Event](#)
 - [24-Hour Notification](#)
- Pending Report
 - [Complete Report](#)
 - [Withdraw Report](#)
- Submitted Report
 - [View Report](#)
 - [Copy Report](#)
 - [Amend Report](#)

Protocol Selection

Enter the NCI Protocol Number or the Local Protocol Number for which the New Expedited Report is being created. [Ⓜ]

Search criterion for Protocol Number

All options/pathways on a single menu

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Protocol Selection

All search functionality unchanged

Enter the NCI Protocol Number or the Local Protocol Number for which the New Expedited Report is being created. [Ⓜ]

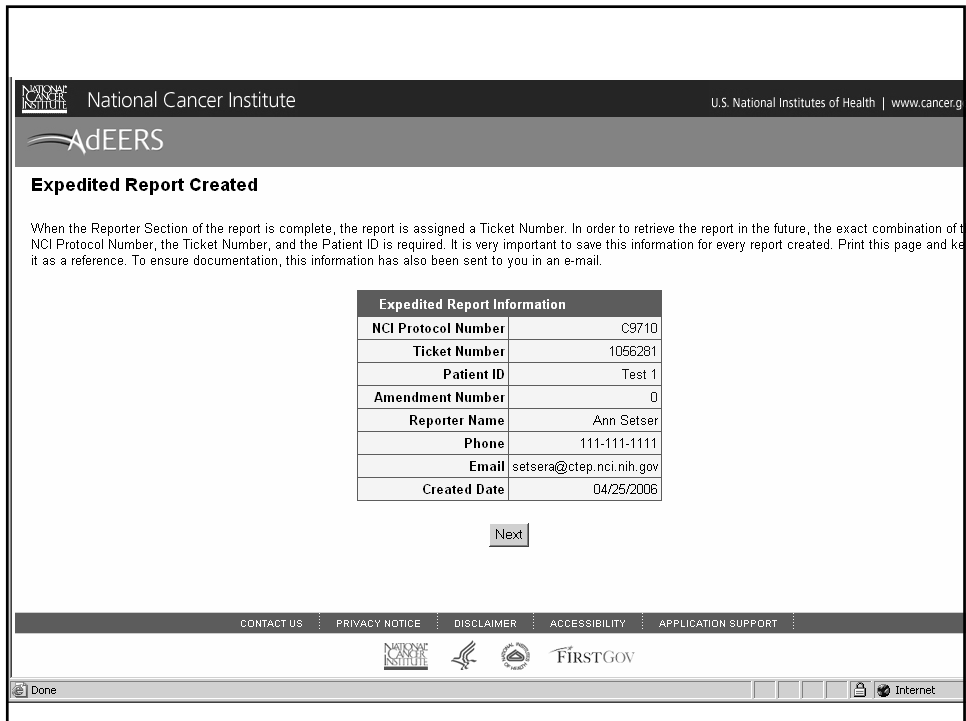
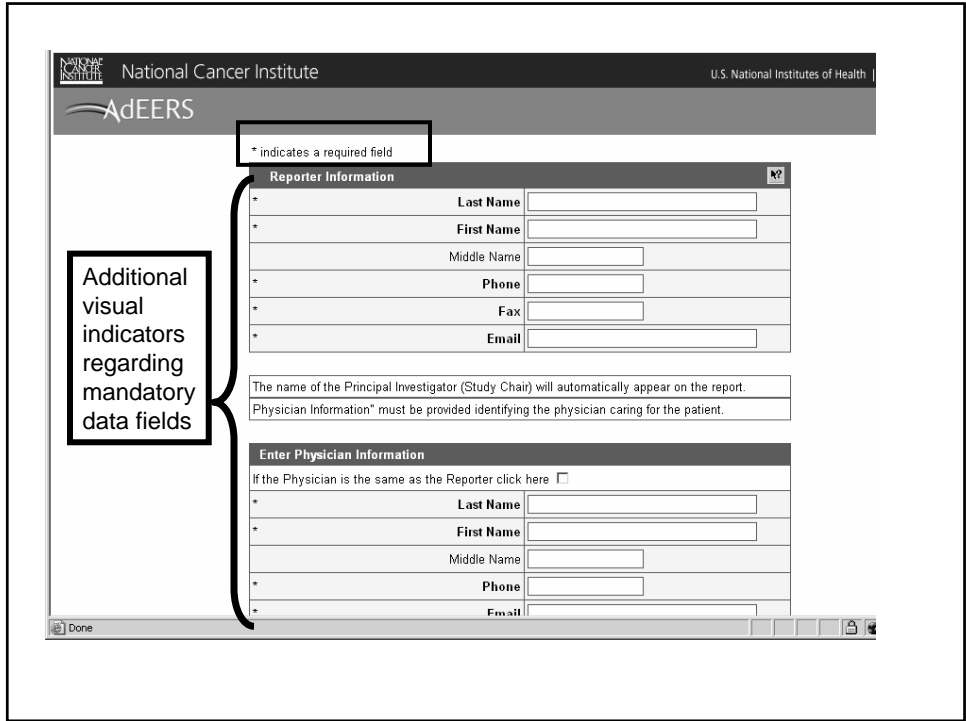
Search criterion for Protocol Number

Select the protocol (below) on which the Adverse Event occurred for this report.

NCI Protocol Number	CTC/CTCAE Version	Local Protocol Number [Ⓜ]	Title	NCI Investigation Agent [Ⓜ]
C9710	2.0	C9710	Phase III Randomized Study of Concurrent Tretinoin and Chemotherapy with or without Arsenic Trioxide (AS203) (NSC # 706363) as Initial Consolidation Therapy Followed by Maintenance Therapy with Intermittent Tretinoin Versus Intermittent Tretinoin Plus Mercaptopurine and Methotrexate for Patients with Untreated Acute Promyelocytic Leukemia	Yes
5322	2.0	97100	Phase II Studies of Donepezil and Ginkgo Biloba in Irradiated Brain Tumor Patients.	No
CCG-09710	2.0	CCG-09710	Treatment of recurrent CD7 Antigen Positive Leukemia with TXU (Anti-CD7)-Pokeweed Antiviral Protein (PAP) Immunotoxin	No
T98-0045	2.0	9710-07	A PHASE II trial of PERILLYL ALCOHOL in patients with	No

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AdEERS

Sections of the Report

Indicate sections appropriate for this report. [ⓧ]

AE Sections	Select values from the list
Patient Information	Mandatory Section
Course Information	Mandatory Section
Medical Device	Yes ▾
Description of Event	Mandatory Section
Prior Therapies	Mandatory Section
Protocol Agents	Mandatory Section
Pre-Existing Conditions	Yes ▾
Sites of Metastatic Disease	Yes ▾
Concomitant Medications	Yes ▾
Other Contributing Causes	Yes ▾
Adverse Events (CTC)	Mandatory Section
Attribution for Adverse Events	Mandatory Section
Abnormal and Relevant Normal Lab Results	Yes ▾
Additional Information	Yes ▾

Next

Done

No changes

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AdEERS

Menu options collapse/expand

OPEN ALL | CLOSE ALL | HIDE MENU

* indicates a required field

AdEERS Help

- Sections
 - Reporter Information
 - Patient Information
 - Course Information
 - Medical Device
 - Description of Event
 - Prior Therapies
 - Protocol Agents
 - Pre-Existing Conditions
 - Sites of Metastatic Disease
 - Concomitant Medications
 - Other Contributing Causes
 - Adverse Events (CTC)
 - Attribution for Adverse Events
 - Abnormal and Relevant Normal Lab Results
 - Additional Information
- Review/Submit AE
- Withdraw AE
- Return Links
- Training

Course Information

Treatment Assignment Code [ⓧ]

Describe Treatment Assignment or Dose Level (Include Agent Name(s), Dose, Route and Schedule) [ⓧ]

* Start date of first course (MM/DD/YYYY)

* Start date of course associated with Expedited Report (MM/DD/YYYY)

* Course number on which event occurred

* Total number of courses to date

* Was an investigational agent(s) administered on this protocol? [ⓧ]

Save Clear

[View Crossover Studies Information](#)

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Submit Expedited Report

Expedited Report Information	
NCI Protocol Number	C9710
Ticket Number	1056281
Patient ID	Test 1
Amendment Number	0

Select the recipients for this report

Recipient Type	Recipients	Send	Name	Email	Phone
Lead Group	Cancer and Leukemia Group B	<input checked="" type="checkbox"/>	Joshua Yoder	josh.yoder@duke.edu.x	(919) 668-9312
		<input type="checkbox"/>	Sally Scherer	centraloffice@calgb.org.x	(773) 702-9973
		<input type="checkbox"/>	Darrin Brandon	darrin.brandon@duke.edu.x	(919) 286-0045
		<input type="checkbox"/>	Rena Williams	williamr@uchicago.edu.x	(773) 702-9860
		<input type="checkbox"/>	Gabrielle Dye	centraloffice@calgb.org.x	(773) 834-2545
		<input type="checkbox"/>	Debbie Sawyer	debbie.sawyer@duke.edu.x	919-286-0045
Participant Group	Children's Cancer Group	<input checked="" type="checkbox"/>	Janet Klufft	jkluft@childrensoncologygroup.org.x	(240) 235-2223
		<input type="checkbox"/>	Susan Caso	scaso@childrensoncologygroup.org.x	626-447-0664 ext 115
Participant		<input checked="" type="checkbox"/>			

Done

Internet

Group			Nickey McCasland	nmccasland@swog.org.x	210-677-8808
Participant Group	Children's Oncology Group	<input checked="" type="checkbox"/>	Janet Klufft	jkluft@childrensoncologygroup.org.x	(240) 235-2223
		<input type="checkbox"/>	Karen Reed	kreed@childrensoncologygroup.org.x	(352) 392-5198 x 310
		<input type="checkbox"/>	Beverly Watson	dwatson@childrensoncologygroup.org.x	(352) 392-5198 x 328
		<input type="checkbox"/>	Tim Peters	tpeters@childrensoncologygroup.org.x	(626) 241-1519
		<input type="checkbox"/>	Loran Lord	llord@childrensoncologygroup.org.x	(626) 447-0064 ext 1545
		<input type="checkbox"/>	Susan Caso	scaso@childrensoncologygroup.org.x	626-447-0664 ext 115
Submitter	Blanchfield Army Hospital	<input checked="" type="checkbox"/>	Ann Setser	setsera@ctep.nci.nih.gov	111-111-1111
Physician	Blanchfield Army Hospital	<input checked="" type="checkbox"/>	Mary Smith	smithm2@ctep.nci.nih.gov	123-123-1233
PI	Cancer and Leukemia Group B	<input checked="" type="checkbox"/>	Bayard Powell	bpowell@wfubmc.edu.x	(336) 716-2946
Cc	To send this report to others, enter the email addresses in the field below. Multiple email addresses can be entered separated by a comma. Example: jsmith@cbon.com,alvincent@cox.org				
	<input type="text"/>				
<input type="button" value="Send"/>					

MedDRA

Medical Dictionary for Regulatory Affairs Terminology

CTEP, NCI Data Systems Lists of Values
July 1, 2006

MedDRA History

Growing need for a single, globally accepted terminology for

- use by regulatory and industry alike
- all communication associated with registering, documenting, and safety monitoring of medical products.

MedDRA History

1992

International Conference on International
Harmonization of Technical Requirements
of Registration of Pharmaceuticals for
Human Use

ICH

2006 - Rigorously refined, expanded, tested

MedDRA Translations

- Currently MedDRA is available in:
 - Dutch
 - English
 - French
 - German
 - Italian
 - Japanese
 - Portuguese
 - Spanish

MedDRA Translations (cont.)

- Translations include terms and all documentation
- With the release of MedDRA 9.0, French and German LLTs will also be translated
- The Czech Republic regulator is developing a translation

CTEP, NCI's Use of MedDRA

- Background of data systems
- Lists of Values in AdEERS
 - Diseases
 - Prior Therapies
 - Pre-existing conditions

CTEP, NCI's Use of MedDRA

- Nothing New to Application Users
- No Changes to AdEERS Users
- No New Terminology to Learn
- Only standard language apparent to CTEP collaborators continues to be CTCAE

The screenshot shows the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) website. The browser window title is "Cancer Therapy Evaluation Program - Microsoft Internet Explorer". The address bar shows "http://ctep.cancer.gov/". The website header includes the NCI logo, the text "National Cancer Institute", "Cancer Therapy Evaluation Program", and "U.S. National Institutes of Health | www.cancer.gov". A navigation menu contains links for Resources, Funding Opportunities, Guidelines & Tools for Protocol Development, Regulation of Agents, Reporting Guidelines, Monitoring of Clinical Trials, Industry Collaborations, and Human Research Protections. The main content area is divided into several sections: Resources (listing Clinical Trial Sources, Clinical Trials Plan, Cooperative Group Guidelines, etc.), Reporting Guidelines (listing Clinical Data Update System, CTCAE, etc.), Monitoring of Clinical Trials (listing Office for Human Research Protections, etc.), and Industry Collaborations (listing CTEP Interaction with Industry, etc.). A "Scroll down" button is visible on the right side of the page.

Internet Explorer browser window showing the CTEP website (http://ctep.cancer.gov/).

Navigation menu: Back, Forward, Home, Search, Favorites, Go, Links.

Page Content:

- Contracts Funding**
 - Plans and Priorities for Cancer Research
 - Surgical Oncology and Gynecologic Oncology Funding and Training Opportunities
 - Translational Research Initiative (formerly Translational Research Fund)
- Guidelines and Tools for Protocol Development and Review**
 - Investigators' Handbook
 - Letter of Intent (LOI)
 - Recent Solicitations for letters of intent for investigational agents available through CTEP
 - Concept Submission
 - List of Codes and Values
 - Protocol Templates and Applications
 - Organ Dysfunction Studies Information
 - CTEP Amendment Requests
 - NCI Standard Protocol Language for Collaborative Agreements
 - Patient Confidential Disclosure Agreement
 - Non-Protocol Access to Experimental Agents
 - Correlative Science Guidelines
- Requisition and Management of Agents**
 - Policies and Guidelines
 - Clinical Drug Request (NIH-986) Form
 - NCI Investigational Drug Accountability Form
 - NCI Transfer Investigational Agent Form
 - NCI Return Investigational Agent Form
 - Links to Commercial Drug Shortage Recourses
- Human Research Protections**
 - Office for Human Research Protections
 - Institution Review Board (IRB) Guidelines
 - Central IRB Project
- (CTISU)**
- Investigators' Handbook**
- Cooperative Group Guidelines** (Update Coming Soon)
- Cooperative Group Semi-Annual Meeting Schedule** (MS Word)
- CTEP Forms**
- Office of AIDS Malignancy Program**
- Clinical Trial Resources:**
 - List of Codes and Values
 - (Ad)FERS: Adverse Event Expedited Reporting System
 - CTCAE (formerly known as CTC) v2.0 and v3.0: Common Terminology Criteria for Adverse Events v3.0 and Common Toxicity Criteria v2.0
 - (CDUS): Clinical Data Update

An arrow points from the "List of Codes and Values" link in the Clinical Trial Resources section to the right.

CTEP website header: National Cancer Institute, Cancer Therapy Evaluation Program, Developing Cancer Therapies.

Navigation menu: Home | Contact | Help | Search.

Menu items: Resources, Funding Opportunities, Guidelines & Tools for Protocol Development, Requisition of Agents, Reporting Guidelines, Monitoring of Clinical Trials, Industry Collaborations, Human Research Protections.

List of Codes and Values

- Disease Codes**
The CTEP Simplified Disease Classification (CTEP SDSC), is a restructured, more intuitive classification of diseases, designed to meet the needs of CTEP while still allowing reporting based on the Medical Dictionary for Drug Regulatory Reporting (MedDRA) terminology. MedDRA is used as the global standard for reporting to regulatory authorities within the U.S., Europe, and Japan.
- CTC v2.0/CTCAE v3.0 Codes**
Common Toxicity Criteria (CTC v2.0) and the Common Terminology Criteria for Adverse Events (CTCAE v3.0) are based on MedDRA and are used for reporting adverse events experienced by patients enrolled in clinical trials.
- Pre-Existing Condition Codes**
The CTEP Pre-Existing Condition Codes are based on MedDRA and are used for reporting pre-existing patient conditions for patients enrolled in clinical trials.
- Therapy Codes**
The CTEP Therapy Classification has been simplified for use in reporting clinical trial therapy types (i.e., non-drug, drug, and/or immunotherapy).
- Agent NSC Numbers**
Unique identifiers to be used when identifying agents when submitting clinical trial data to CTEP
- Country Codes**
Unique identifiers for countries to be used when submitting clinical trial data to CTEP
- Cooperative Group Codes**
Unique identifiers for the Cooperative Groups to be used when submitting clinical trial data to CTEP
- Institution Codes**

An arrow points from the "CTC v2.0/CTCAE v3.0 Codes" link to the text below it.

Footer: Done, Internet

CF GUIDELINES AND TOOLS FOR PROTOCOL DEVELOPMENT - MICROSOFT INTERNET EXPLORER

Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Print Mail News RSS Feeds

Address: http://ctep.cancer.gov/guidelines/codes.html#ctc

CTEP Simplified Disease Classification v1.0 (Updated July 5, 2005)				
Medical Dictionary for Regulatory Activities (MedDRA) Codes v6.0 (Effective October 1, 2003)				
Medical Dictionary for Regulatory Activities (MedDRA) Codes v5.0 (Effective July 1, 2002)				

CTCAE/CTC Codes Additional mapping files are available on the CTCAE Web page.

Title	Help (.pdf file)	Text (.txt file)	Excel (.xls file)	Mapping Version Excel (.xls file)
CTCAE v3.0 (MedDRA v6.0) (Effective October 1, 2003)				
CTCAE v3.0 (MedDRA v6.0) (with Grades) (Effective October 1, 2003)				
Notice of MedDRA Code Modifications (Effective October 1, 2003)				
CTC v2.0 Codes (MedDRA v6.0) (Effective October 1, 2003)				
CTC v2.0 Codes (MedDRA v5.0) (Effective July 1, 2002)				

re-existing Condition Codes

Title	Text (.txt file)	Excel (.xls file)	Mapping Version Excel (.xls file)
Medical Dictionary for Regulatory Activities (MedDRA) Codes v6.0 (Effective October 1, 2003)			
Medical Dictionary for Regulatory Activities (MedDRA) Codes v5.0 (Effective July 1, 2002)			

therapy Codes