

## Functionality of Existing Adverse Event (AE) Systems

AE System	ACES: Automated Clinical Evaluation System	AdEERS: Adverse Events Expedited Reporting System
Website	<a href="http://www.theradex.com/CTMS/ACES.htm">www.theradex.com/CTMS/ACES.htm</a>	<a href="https://webapps.ctep.nci.nih.gov/openapps/plsql.gadeers_main\$.startup">https://webapps.ctep.nci.nih.gov/openapps/plsql.gadeers_main\$.startup</a>
Developed By	Theradex	Capital Technology Information Services, Inc (CTIS)
Developed For	NCI Cancer Therapy Evaluation Program (CTEP)	NCI Cancer Therapy Evaluation Program (CTEP)
Contact Person		
Conditions Used For	Clinical Trials Monitoring Service (CTMS) Protocols but can also be used for non-CTMS protocols	Protocols using investigational agents supplied under an Investigational New Drug (IND) Application sponsored by NCI Division of Cancer Treatment and Diagnosis (DCTD). An event occurs on arm of a trial using both a Commercial agent and an investigational agent sponsored under an NCI IND. All CTEP-sponsored protocols using any type of agent (commercial, surgical, radiation device). Cooperative Groups - All CTEP sponsored protocols - voluntary usage
Time Requirements for Submission	At least biweekly submissions for timely monitoring of trials in progress.	Initial online notification within 24 hours of an SAE and complete the report within 10 days for Grade 3 Unexpected Event with an Attribution of Possible, Probable, or Definite and Grades 4 and 5 Unexpected Events regardless of Attribution.  Complete report within 10 days for Grade 2 Expected Event with an Attribution of Possible, Probable, or Definite.
Functionality	<p>Routine AE Reporting</p> <p>Captures clinical data including AE and toxicity data to submit to the CTMS - ACES is installed locally. Provides an electronic version of the NCI approved Phase I/II Case Report Form.</p> <p>Data are extracted and uploaded to CTMS using the distributed data transfer system - 'ACESlink'. The data may also be send to CTMS via a diskette.</p> <p>Data transfer between other ACES installations - usable for local and multi-site studies.</p> <p>Incorporates customized electronic Case Report Forms (CRFs).</p> <p>Generates reports</p>	<p>Expedited AE Reporting</p> <p>Collects AE data and death data unrelated to an AE via the web.</p> <p>Surveillance &amp; trend analysis</p> <p>Generates reports</p>
Status	Operational for the last 10 - 15 years	Operational since 1998
caBIG Compliant	To be determined	To be determined

## Functionality of Existing Adverse Event (AE) Systems

AE System	CDUS: Clinical Data Update System	CSAERS: Cancer Serious Adverse Events Reporting System
Website	<a href="http://ctep.cancer.gov">http://ctep.cancer.gov</a>	
Developed By	Capital Technology Information Services, Inc (CTIS)	Booz Allen Hamilton (BAH)
Developed For	NCI Cancer Therapy Evaluation Program (CTEP)	NCI Division of Cancer Prevention (DCP)
Contact Person		
Conditions Used For	CTEP Protocols	Cancer Prevention Protocols
Time Requirements for Submission	<p>Quarterly submissions to CTEP.</p> <p>CDUS Complete - Trial Types - Late Phase 1 and Phase 2 Trials that utilize a DCTD sponsored and supplied investigational agent. Report all Grade 1 - 3 adverse events with an attribution of possible, probable, or definite and all Grade 4 and 5 adverse events regardless of attribution.</p> <p>CDUS Abbreviated - Trial Types - All Phase 3 Trials and Phase 1 and 2 that do NOT utilize a DCTD sponsored and supplied investigational agent.</p>	When the SAE is identified and within the timeframe specified in the protocol.
Functionality	<p>Routine AE Reporting</p> <p>Collects AE data for CTEP sponsored protocols via application to application via CTEP.FTP site <b>or</b> via the web-based data entry application (Internet Explorer only - Does not support MAC) <b>or</b> create a file and send via FTP.</p> <p>Surveillance &amp; trend analysis</p> <p>Generates reports</p>	<p>Routine AE Reporting</p> <p><b>Adverse Events Application</b> Collects SAE Data via Web and application to application</p> <p>Processes SAE information by reviewers</p> <p>Reports to internal &amp; external agencies (HL7 &amp;, XML, CCTD, etc.)</p> <p>Surveillance &amp; trend analysis</p> <p>Toxicity grading &amp; monitoring labs</p> <p>Automated, expert-system based SAE surveillance of clinical information</p> <p><b>Information Clearinghouse</b> Open source platform Integration with a variety of applications and systems Information exchange using multiple standard transmission protocols and coding terminologies (HL7, ICH) Transformation and customization of medical terminologies</p>
Status	Operational since 1997	<b>Currently on Hold - some pilot testing has been done</b>
caBIG Compliant	To be determined	Yes - Silver Level

## Functionality of Existing Adverse Event (AE) Systems

AE System	GeMCRIS: Genetic Modification Clinical Research Information System	MedWatch
Website	<a href="http://www4.od.nih.gov/oba">http://www4.od.nih.gov/oba</a>	<a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a>
Developed By	Stellar Systems	
Developed For	NIH Office of Biotechnology Activities	FDA
Contact Person	Kelly Fennington	
Conditions Used For	Gene Transfer Protocols	Medical Devices in use <b>OR</b> Protocols using Commercial drugs
		NCI Sites and Cooperative Groups using CTEP Protocols are now able to submit AdEERS instead of MedWatch.
Time Requirements for Submission	Immediately upon awareness of the SAE and within the timeframe specified in the protocol	Within 10 days of the AE identification
	The FDA requires a verbal report within 7 days and followed by the written (online) report within 15 days only for SAEs determined to be related or possibly related to the research intervention.	
Functionality	Routine AE Reporting	Routine AE Reporting
	Records trial and product information	Collects AE or Product Problem data - Voluntary Reporting - can submit via paper or via the web. Mandatory Reporting - presently can only submit via paper - web application not yet available
	Collects SAE data or other clinical outcomes and events data related to Gene Transfer research via the Web for reporting to NIH and FDA	Surveillance & trend analysis - to determine if there needs to be: modification the use or design of the product and improve the understanding of the safety profile or device.
	Interfaces with other relevant databases (e.g. AdEERS) (planned - not operational at this time)	Voluntary Reporting by Health Professionals, Consumers, and Veterinary Medicine
	Links to gene sequence databases (GenBank, BLAST) in v2.0 (planned - not operational at this time)	Mandatory Reporting by Health Professionals
	Surveillance & trend analysis	Generates reports
	Analysis of data across all clinical trials	
	Generate reports for diverse user groups - IRBs, IBCs, local DSMBs, investigators, research participants	
	Public queries and reports for gene transfer clinical trial information.	
	Vocabulary reports for gene transfer vocabulary	
Status	Operational for the past several months	Operational with web-based Voluntary Reporting since _____
caBIG Compliant	To be determined	To be determined