Appendix B

Glossary of Terms

Acronym	Term	Definition
AE	Adverse Event	Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. NOTE: For further information, see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting. "[Modified from ICH E2A]" *Synonyms: side effect, adverse experience. See also serious adverse event, serious adverse experience.* [Source: CDISC 12/06]
	Agent	A pharmaceutical, nutraceutical or other agent used individually or in combination with others that is being tested in a cancer prevention trial.
	Amendment	A written description of a change(s) to, or formal clarification of, a protocol. [Source: CDISC 12/06]
	Audit	A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). [ICH E6 Glossary] [Source: CDISC 12/06]
	Audit Task Manager	An appropriately qualified DCP Monitoring Contractor employee, by training and experience, whose responsibilities include, but are not limited to, DCP project goal planning for on-site monitoring, supervision of staff, assignment of protocol(s) and sites to monitor, assuring compliance with specific SOPs, and assuring that on-site monitoring visits are conducted and site visit reports are recorded appropriately.
	Balanced Study	Trial in which a particular type of subject is equally represented in each study group. [Source: CDISC 12/06]
	Biomarker	A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. [Biomarker definitions working group] [Source: CDISC 12/06]
BGCRG	Breast and Gynecological Cancer Research Group	This group conducts and supports research on the prevention and early detection of breast, cervix, endometrial, and ovarian cancers. Clinical trials and the evaluation of new agents, surrogate biomarkers, and new technologies to identify premalignant lesions are developed and supported. [Source: http://prevention.cancer.gov/programs-resources/groups/bgcrg]

Acronym	Term	Definition
caBIG	Cancer Bioinformatics Grid	An initiative of the NCI to accelerate research discoveries and improve patient outcomes by linking researchers, physicians, and patients throughout the cancer community. caBIG™ serves as the cornerstone of NCI's biomedical informatics efforts to transform cancer research into a more collaborative, efficient, and effective endeavor. [Source: https://cabig.nci.nih.gov/overview]
CB	Cancer Biomarkers Research Group	This group promotes and supports research to identify, develop, and validate biological markers for earlier cancer detection and risk assessment. The group integrates basic and clinical science studies along with computational, statistical and epidemiologic approaches for a comprehensive understanding of biomarkers. It coordinates the Early Detection Research Network. [Source: http://prevention.cancer.gov/programs-resources/groups/cb]
CRF	Case Report Form	1. A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor for each trial subject. 2. A record of clinical study observations and other information that a study protocol designates must be completed for each subject. NOTE: In common usage, CRF can refer to either a CRF page, which denotes a group of one or more data items linked together for collection and display, or a casebook, which includes the entire group of CRF pages on which a set of clinical study observations and other information can be or have been collected, or the information actually collected by completion of such CRF pages for a subject in a clinical study [ICH E6 Glossary] *See also CRF (paper).* [Source: CDISC 12/06]
CCSA	CCS Associates	The DCP Regulatory Contractor who is responsible for assisting the PIO, Organ Site Research Group personnel and study staff with protocol development and management of regulatory issues.
CADRG	Chemopreventive Agent Development Research Group	This group supports scientific and administrative oversight for preclinical chemoprevention agent development up to early phase I chemopreventive agent research using physiological endpoints in healthy volunteers. Research focuses on identifying and developing agents with the potential to block, reverse, or delay early stages of cancer, using a battery of preclinical pharmacology, toxicology, and efficacy tests, and conducting phase 1 pharmacokinetic and safety studies. [Source: http://prevention.cancer.gov/programs-resources/groups/cad]
	Clinical Investigation	*See clinical trial.* [Source: CDISC 12/06]
CRA	Clinical Research Associate	Person employed by a sponsor, or by a contract research organization acting on a sponsor's behalf, who monitors the progress of investigator sites participating in a clinical study. At some sites (primarily in academic settings), clinical research coordinators are called CRAs. [Source: CDISC 12/06]

Acronym	Term	Definition
CRC	Clinical Research Coordinator	Person who handles most of the administrative responsibilities of a clinical trial on behalf of a site investigator, acts as liaison between investigative site and sponsor, and reviews all data and records before a monitor's visit. *Synonyms: trial coordinator, study coordinator, research coordinator, clinical coordinator, research nurse, protocol nurse.* [Source: CDISC 12/06]
	Clinical Trial	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one of more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s), and/or to study absorption, distribution, metabolism and excretion of one of more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. [Directive 2001/20/EC; Modified from ICH E6 Glossary] [Source: CDISC 12/06]
CFR	Code of Federal Regulations	The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis. [Source: http://www.gpoaccess.gov/cfr/index.html]
	Commercial Agent	Any agent not supplied under an IND but instead, obtained from a commercial source.
CDE	Common Data Elements	Metadata descriptors used for forms and applications which were developed to promote interoperability among systems developed for NCI-sponsored research.
CTC v.2.0 and CTCAE v.3.0	Common Toxicity Criteria/ Common Terminology Criteria for Adverse Events	The NCI Common Terminology Criteria for Adverse Events v3.0 is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term. [Source: http://ctep.cancer.gov/forms/CTCAEv3.pdf]
	Confidentiality	Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity. [ICH E6 Glossary] [Source: CDISC 12/06]

Acronym	Term	Definition
CF	Consent Form	Document used during the informed consent process that is the basis for explaining to potential subjects the risks and potential benefits of a study and the rights and responsibilities of the parties involved. NOTE: The informed consent document provides a summary of a clinical trial (including its purpose, the treatment procedures and schedule, potential risks and benefits, alternatives to participation, etc.) and explains an individual's rights as a subject. It is designed to begin the informed consent process, which consists of conversations between the subject and the research team. If the individual then decides to enter the trial, s/he gives her/his official consent by signing the document. *Synonym: informed consent form; see also informed consent.* [Source: CDISC 12/06]
CRO	Contract Research Organization	A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. [ICH E6 Glossary] [Source: CDISC 12/06]
	Control Group	The group of subjects in a controlled study that receives no treatment, a standard treatment, or a placebo. [21 CFR 314.126] *See also controls.* [Source: CDISC 12/06]
	Controls	Comparator against which the study treatment is evaluated [e.g., concurrent (placebo, no treatment, dose-response, active), and external (historical, published literature)] 2. Computer: processes or operations intended to ensure authenticity, integrity, and confidentiality of electronic records. NOTE: The protocol incorporates scientific rationale for selection of comparator and describes how the comparator serves as a reference point for the evaluation. [1. After ICH E10. 2. After 21 CFR Part 11; CSUCT] [Source: CDISC 12/06]
CV	Curriculum Vitae	Document that outlines a person's educational and professional history. [Source: CDISC 12/06]
	Data Acquisition	Capture of data into a structured computerized format without a human-computer interface (from another automated or computerized source). Contrast with data entry, electronic data capture. [Source: CDISC 12/06]
	Database Administrator	A systems professional, trained in database administration techniques, who is responsible for utilizing these techniques to manage security and performance of an Oracle database. These responsibilities include: creating and removing user accounts, developing appropriate access roles and profiles, controlling and monitoring user access, identification of security violations, backup and recovery of the database, and monitoring and optimizing performance. There will be a primary and secondary project database administrator for Oracle Clinical databases on the DCP project. A corporate database administrator is responsible for establishing policies and procedures for all Oracle databases at offices of the DCP Monitoring Contractor.

Acronym	Term	Definition
	Data Entry	Human input of data into a structured, computerized format using an interface such as a keyboard, pen-based tablet, or voice recognition. Contrast with data acquisition, electronic data capture. [Source: CDISC 12/06]
	Data Management	Tasks associated with the entry, transfer and/or preparation of source data and derived items for entry into a clinical trial database. NOTE: Data management could include database creation, data entry, review, coding, data editing, data QC, locking, or archiving; it typically does not include source data capture. [Source: CDISC 12/06]
	Data Monitoring	Process by which clinical data are examined for completeness, consistency, and accuracy. [Source: CDISC 12/06]
DMC/ DSMB	Data Monitoring Committee/ Data and Safety Monitoring Board	Group of individuals with pertinent expertise that reviews on a regular basis accumulating data from an ongoing clinical trial. The DMC advises the sponsor regarding the continuing safety of current participants and those yet to be recruited, as well as the continuing validity and scientific merit of the trial. NOTE: A DMC can stop a trial if it finds toxicities or if treatment is proved beneficial. [After FDA guidance on establishment and operation of clinical trial data monitoring committees] [Source: CDISC 12/06]
DESK	DCP Enterprise System Knowledgebase	The DCP Enterprise System Knowledgebase (DESK) supports the NCI Division of Cancer Prevention (DCP) data such as agents and address modules. [Source: http://ncicb.nci.nih.gov/tools/tools_introduction]
	Discontinuation	The act of concluding participation, prior to completion of all protocol-required elements, in a trial by an enrolled subject NOTE: Four categories of discontinuation are distinguished: a) dropout: Active discontinuation by a subject (also a noun referring to such a discontinued subject); b) investigator initiated discontinuation (e.g., for cause); c) loss to follow-up: cessation of participation without notice or action by the subject; d) sponsor initiated discontinuation. Note that subject discontinuation does not necessarily imply exclusion of subject data from analysis. "Termination" has a history of synonymous use, but is now considered non-standard. *See also withdrawal.* [Source: CDISC 12/06]
DCP	Division of Cancer Prevention	The Division of Cancer Prevention (DCP) is the primary unit of the National Cancer Institute devoted to cancer prevention research. DCP provides funding and administrative support to clinical and laboratory researchers, multidisciplinary teams, and collaborative, research-based networks. [Source: http://prevention.cancer.gov/about]
	Drug Accountability	Maintaining current and accurate records showing the quantities of drug received, dispensed, stored at the site, and returned to the sponsor.

Acronym	Term	Definition
DARF	Drug Accountability Report Form	The NCI Drug Accountability Report Form that is used by the site pharmacists to record study agent disposition (receipt, transfer, dispensing and return).
	Effectiveness	The desired measure of a drug's influence on a disease or condition as demonstrated by substantial evidence from adequate and well-controlled investigations. [Source: CDISC 12/06]
	Efficacy	The capacity of a drug or treatment to produce beneficial effects on the course or duration of a disease at the dose tested and against the illness (and patient population) for which it is designed. [Source: CDISC 12/06]
eCRF	Electronic Case Report Form	1. Auditable electronic record designed to capture information required by the clinical trial protocol to be reported to the sponsor on each trial subject. 2. A CRF in which related data items and their associated comments, notes, and signatures are linked electronically. NOTE: eCRFs may include special display elements, electronic edit checks, and other special properties or functions and are used for both capture and display of the linked data. [FDA CSUCT] [Source: CDISC 12/06]
EDC	Electronic Data Capture	The process of collecting clinical trial data into a permanent electronic form. NOTE: "Permanent" in the context of these definitions implies that any changes made to the electronic data are recorded via an audit trail. *Synonym: remote data capture; see also data entry, data acquisition.* [Source: CDISC 12/06]
EC	Ethics Committee	*See institutional review board, independent ethics committee.* [Source: CDISC 12/06]
	Evaluable (for Efficacy and Safety)	Pertains to data or subjects that meet Statistical Analysis Plan criteria for inclusion in Efficacy/Safety datasets. [Source: CDISC 12/06]
	Financial Disclosure Form	Under the applicable regulations (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860), an applicant is required to submit to FDA a list of clinical investigators who conducted covered clinical studies and certify and/or disclose certain financial arrangements as follows: 1. Certification that no financial arrangements with an investigator have been made where study outcome could affect compensation; that the investigator has no proprietary interest in the tested product; that the investigator does not have a significant equity interest in the sponsor of the covered study; and that the investigator has not received significant payments of other sorts; and/or 2. Disclosure of specified financial arrangements and any steps taken to minimize the potential for bias. [Source: http://www.fda.gov/oc/guidance/financialdis.html]

Acronym	Term	Definition
FDA	Food and Drug Administration	The United States regulatory authority charged with, among other responsibilities, granting IND and NDA approvals. [Source: CDISC 12/06]
	Form FDA 1572	Statement of the investigator that outlines the responsibilities that the investigator agrees to assume in order to conduct the clinical trial.
GOCRG	Gastrointestinal and Other Cancers Research Group	This group conducts and supports research on the prevention and early detection of colorectal, esophageal, liver, pancreatic, skin, and hematolymphoid cancers. Clinical trials and the evaluation of new agents, surrogate biomarkers, and new technologies to identify premalignant lesions are developed and supported. [Source: http://prevention.cancer.gov/programs-resources/groups/gocrg]
	Global Librarian	A person assigned the responsibility of internal administration and change management of the Global Library in an Oracle Clinical database. This person is also assigned the responsibility of granting and revoking access for individual users to specific protocols.
GCP	Good Clinical Practice	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. NOTE: For Guidance on Good Clinical Practice see COMP/ICH/135/95; Declaration of Helsinki; 21 CFR 50, 21 CFR 54, 21 CFR 56, and 21 CFR 312. [ICH] [Source: CDISC 12/06]
HIPAA	Health Insurance Portability and Accountability Act	A federal law that created national standards to protect the privacy of personal health information.
	Human Subject	Individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3]. *Synonym: subject/trial subject.* [Source: CDISC 12/06]
HTML	Hyper Text Markup Language	A specification of the W3C that provides markup of documents for display in a Web browser. [HL7] *Contrast to XML.* [Source: CDISC 12/06]
HTTP	Hyper Text Transfer Protocol	A standard through which a client browser talks to a server to load the requested document.
	Informatics	The design and implementation of complex hardware and software systems for the extraction of knowledge from large databases.

Acronym	Term	Definition
IC	Informed Consent	An ongoing process that provides the subject with explanations that will help in making educated decisions about whether to begin or continue participating in a trial. Informed consent is an ongoing, interactive process, rather than a onetime information session. NOTE: Under 21 CFR 50.20, no informed consent form may include any "language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." [ICH] *See also consent form.* [Source: CDISC 12/06]
	Initiation Visit	A type of site visit conducted to verify that all regulatory and other requirements are in place prior to implementing a study.
IRB	Institutional Review Board	An independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. *Synonyms: independent review board, independent ethics committee, committee for the protection of human subjects.* [Source: CDISC 12/06]
ICH	International Conference on Harmonisation	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. [Source: http://www.ich.org/cache/compo/276-254-1.html]
	Investigational Agent	An agent sponsored under an Investigational New Drug Application (IND).
IND	Investigational New Drug Application	An Investigational New Drug Application (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics/Product License Application. [Source: http://www.fda.gov/cber/ind/ind.htm]

Acronym	Term	Definition
	Investigator	1. A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. 2. The individual "under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team". [1. ICH E6 1.35. 2. from 21CFR 50.3] *See also sponsor-investigator.* [Source: CDISC 12/06]
IB	Investigator's Brochure	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects. [Source: CDISC 12/06]
	JavaScript	Lightweight scripting language used at client web browsers to perform basic web page validation and processes.
KA	Knowledge Acquisition	The formalized process of collecting information about business organizational processes necessary for developing requirements.
	Lead Organization	The MAH institution holding the funding agreement with the NCI. This is the institution of the Principal Investigator.
LUACG	Lung and Upper Aerodigestive Cancer Group,	This group conducts and supports research on the prevention and early detection of head and neck and lung cancers. Clinical trials and the evaluation of new agents, surrogate biomarkers, and new technologies to identify premalignant lesions are developed and supported. [Source: http://prevention.cancer.gov/programs-resources/groups/luacrg]
	Marketing Application	An application for a new drug submitted under section 505(b) of the act of biologics license application for a biological product submitted under the Public Health Service Act.
	Medical Monitor	A sponsor representative who has medical authority for the evaluation of the safety aspects of a clinical trial. [Source: CDISC 12/06]
	Monitor	Person employed by the sponsor or CRO who is responsible for determining that a trial is being conducted in accordance with the protocol and GCP guidance. NOTE: A monitor's duties may include, but are not limited to, helping to plan and initiate a trial, assessing the conduct of trials, and assisting in data analysis, interpretation, and extrapolation. Monitors work with the clinical research coordinator to check all data and documentation from the trial. [from ICH E6, 5.18] *See also clinical research associate.* [Source: CDISC 12/06]
	Monitoring	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). [ICH E6 Glossary] [Source: CDISC 12/06]

Acronym	Term	Definition
NCICBIT	National Cancer Institute Center for Bioinformatics and Information Technology	A center within NCI which provides the interoperable biomedical informatics infrastructure, tools, and data that biomedical communities need for cancer research, prevention and care. [Source: http://ncicb.nci.nih.gov/NCICB/about]
	Oracle® Clinical	A software product of the Oracle® Corporation designed to meet the data management needs of the clinical trials industry.
	Organ System Group	The Organ Systems research groups design, develop, implement, and monitor the breadth of cancer prevention research efforts in four major organ sites: Breast and Gynecological, Gastrointestinal, Lung, Head and Neck, and Prostate and Urological. [Source: http://prevention.cancer.gov/programs-resources/groups]
	Participating Organization	Institutions who by arrangement with the NCI/DCP and the lead organization participate in a clinical trial by accruing patients.
PK	Pharmacokinetics	Study of the processes of bodily absorption, distribution, metabolism, and excretion (ADME) of medicinal products. [Source: CDISC 12/06]
	Placebo	A pharmaceutical preparation that does not contain the investigational agent. In blinded studies, it is generally prepared to be physically indistinguishable from the preparation containing the investigational product. [Source: CDISC 12/06]
PI	Principal Investigator	The individual responsible for the conduct of the study at the clinical center and for ensuring the safety of study participants enrolled at that site (i.e., under whose immediate direction the test agent is administered or dispensed to the study participant). If a team of individuals conducts a trial, the principal investigator is the responsible leader of the team.
PUCRG	Prostate and Urologic Cancer Research Group	This group conducts and supports research on the prevention and early detection of prostate and bladder cancer. Clinical trials and the evaluation of new agents, surrogate biomarkers, and new technologies to identify premalignant lesions are developed and supported. [Source: http://prevention.cancer.gov/programs-resources/groups/pucrg]
	Project Director	An appropriately qualified DCP Monitoring Contractor employee, by training and experience, whose responsibilities include, but are not limited to: monitoring project budgets; allocating staff resources; complying with project goals and objectives; evaluating whether the scope of work is being met; serving as official contact for the client, collaborators, and contractors; preparing project progress reports to deliver to the client on a routine basis; and assuming final responsibility for assuring that all project work is completed accurately, on time, and within budget.

Acronym	Term	Definition
	Project Manager	An appropriately qualified DCP Monitoring Contractor employee, by training or experience, whose responsibilities include, but are not limited to: project goal planning, supervision of staff, and evaluation and assessment of project activities. The project manager's responsibilities may also include conducting on-site monitoring visits.
	Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments. NOTE: Present usage can refer to any of three distinct entities: 1) the plan (i.e., content) of a protocol, 2) the protocol document and 3) a series of tests or treatments (as in oncology). [ICH E6 Glossary] [Source: CDISC 12/06]
PIMS	Protocol Information Management System	A component of the DCP Enterprise Knowledgebase System (DESK).
PIO	Protocol Information Office	The central office for all protocol-related information management for DCP sponsored trials. The mission of the PIO is to coordinate all administrative aspects related to clinical trial development to assure that quality protocols are developed in the most expeditious and efficient manner possible. Towards that end, the PIO collects, processes, tracks, and monitors all protocol-related information between DCP, the study site staff, DCP Monitoring Contractor, and the DCP Regulatory Contractor.
QA	Quality Assurance	All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with good clinical practice (GCP) and the applicable regulatory requirement(s). [ICH] [Source: CDISC 12/06]
QOL	Quality of Life	A broad ranging concept that incorporates an individual's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationships to salient features of the environment. NOTE: Quality of Life is one way to measure the benefits or negative impacts of an "improvement" measured in terms of a physiological or psychological symptom. QOL research seeks to quantify what an intervention means to a patient's sense that their life has changed. [WHO Group, 1994] [Source: CDISC 12/06]

Acronym	Term	Definition
	Randomization	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. NOTE: Unequal randomization is used to allocate subjects into groups at a differential rate; for example, three subjects may be assigned to a treatment group for every one assigned to the control group. [ICH E6 1.48] *See also balanced study.* [Source: CDISC 12/06]
	Regulatory Binder	The Regulatory Binder contains all study-specific information and regulatory documentation. This Binder (or series of files) does not include completed CRFs or signed informed consent forms. While the site must keep all original informed consents that have been signed by participants, it is recommended that these be maintained in separate binders or files as directed by the policies of the clinical site. The Regulatory Binder may take the form of file folders, one or more three-ring binders, a filing system, or a combination of these organizational methods. *Synonyms: Study Binder, Investigator Binder, Administrative Binder, Regulatory Files, and Investigator's Study Files*
RDC/RDE	Remote Data Capture/Remote Data Entry	*See electronic data capture.*
SAE/ Serious ADR	Serious Adverse Event/ Serious Adverse Drug Reaction	Any untoward medical occurrence that at any dose: results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. [ICH] See also adverse experience. [Source: CDISC 12/06]
SAE	Serious Adverse Experience	Any experience that suggests a significant hazard, contra-indication, side effect or precaution. *See also serious adverse event.* [Source: CDISC 12/06]
	Site Coordinator	The responsible person at the clinical site who is the primary contact and ensures that the studies are conducted appropriately. Also called Study Coordinator.
	Sponsor	1. An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. 2. A corporation or agency whose employees conduct the investigation is considered a sponsor and the employees are considered investigators. [1. ICH. 2. 21 CFR 50.3] [Source: CDISC 12/06]
	Sponsor-investigator	An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. NOTE: The term does not include any person other than an individual (i.e., it does not include a corporation or an agency). The obligations of a sponsor investigator include both those of a sponsor and those of an investigator. [21 CFR 50.3f] [ICH] [Source: CDISC 12/06]

Acronym	Term	Definition
SOPs	Standard Operating Procedures	Detailed, written instructions to achieve uniformity of the performance of a specific function. [ICH] [Source: CDISC 12/06]
	Study Coordinator	*See clinical research coordinator.* [Source: CDISC 12/06]
	Sub-investigator	Any member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows) [ICH] *See also investigator.* [Source: CDISC 12/06]
URL	Uniform Resource Locator	Address of a Web page, actmagazine.com, for example. [Source: CDISC 12/06]
	Visit	A clinical encounter that encompasses planned and unplanned trial interventions, procedures and assessments that may be performed on a subject. A visit has a start and an end, each described with a rule. NOTE: For many domains each visit results in one record per visit. [SDTM, Trial Design Model] [Source: CDISC 12/06]
	Withdrawal	The act of reducing the degree of participation by a subject in a clinical trial. Subjects may withdraw permission for Sponsor use of data derived from study participation, privacy waivers, informed consent, or they may withdraw from the active treatment component of a clinical trial but continue to be observed. Withdrawal from participation in a study is called discontinuation. *See also discontinuation.* [Source: CDISC 12/06]