Glossary

Cancer Therapy Evaluation Program Branches:

Clinical Grants and Contracts Branch (CGCB) - The point-of-contact for the extramural community who are engaged in investigator-initiated clinical research.

Clinical Investigations Branch (CIB) – Responsible for scientific oversight and coordination of large, multicenter clinical trials exploring innovative disease therapeutics and biomarkers; partners with public and private entities to expand clinical trial participation to all populations.

Clinical Trials Monitoring Branch (CTMB) - Clinical Trials Monitoring Branch is a branch within CTEP with direct oversight of all quality assurance programs and the audit process and results.

Investigational Drug Branch (IDB) - Implements and oversees an innovative investigational experimental therapeutics program. IDB collaborates with academia and industry through a unique contract and grant NCI funded program to carry out the clinical evaluation of novel anti-cancer agents.

Operations and Informatics Branch (OIB) - Provides support of protocol development and conduct through the Protocol and Information Office, PIO, as the operations hub, processes all submissions and liaisons with all clinical sites. OIB also developed and maintains the CTEP Enterprise System, in use by the NCI as well as the extramural community, to collect, analyze and report a wide variety of protocol, accrual, adverse event and agent information.

Pharmaceutical Management Branch (PMB) **-** Provides pharmaceutical support for clinical trials sponsored by CTEP. Collects and maintains registration documentation for all investigators participating in CTEP clinical trials.

Regulatory Affairs Branch (RAB) -The Regulatory Affairs Branch (RAB) provides IND support and acts as liaison to the FDA for CTEP, DCTD. RAB also fosters pharmaceutical collaboration in evaluating new anti-cancer agents, through the implementation of appropriate agreements.

Contractors:

Capital Technology Information Systems (CTIS) **-** Contractor responsible for maintaining CTEP Enterprise System (ESYS), AdEERS and CDUS AE reporting systems.

Technical Resources International (TRI) **-** Contractor responsible for providing support for CTEP RAB and IDB

EDJ – contractor responsible for managing the Enterprise Core Unit and investigator registration process.

EMMES Corporation - Contractor responsible for providing operational support and data management to the CTEP Clinical trials Information management System (CTIMS), the NCI CIRB, and the AMC.

Theradex - Contractor responsible for administering the Clinical Trials Monitoring Service involving: data management and monitoring of early phase clinical trials (Phase 0, Phase 1 and select Phase 2), co-site visitation for Cooperative Group audits, conducting site visits to cancer centers/single institutions conducting clinical trials of NCI-supplied agents and audit support to International collaborators.

Westat - Primary contractor for the CTSU

Networks:

Adult Brain Tumor Consortium (ABTC) **-** A new multi-institutional consortium created from the consolidation of two previous, separate NCI-funded consortia: the New Approaches to Brain Tumor Therapy (NABTT) and the North American Brain Tumor Consortium (NABTC). The newly formed ABTC permits NABTT and NABTC investigators to continue their research, but focuses management of their clinical program into a single entity.

Aids Malignancy Consortium (AMC) **-** The AIDS Malignancy Consortium (AMC) is a National Cancer Institute-supported clinical trials group founded in 1995 to support innovative trials for AIDS-associated malignancies.

Organ Dysfunction Group (ODG) **-** A CTEP Initiative designed to carry out trials to determine appropriate doses of investigational agents in patients with compromised hepatic and renal function.

Pediatric Brain Tumor Consortium (PBTC) - A multidisciplinary cooperative research organization formed by the NCI in 1999 as a clinical trials organization devoted to the study of correlative tumor biology and new therapies for primary CNS tumors of childhood.

Phase II Consortia (P2C) - CTEP funded contract holders that conduct phase 2 investigational drug studies.

Programs:

Cancer Trials Support Unit (CTSU) - A project sponsored by the NCI for the support of a national network of physicians to participate in NCI-sponsored cancer treatment trials.

Central Institutional Review Board (CIRB) - A NCI-sponsored initiative in consultation with the Office of Human Research Protections (OHRP) that provides an innovative approach to human subject protection through a "facilitated review" process

that streamlines local IRB review of adult and pediatric national multi-center cancer treatment trials.

Clinical Trials Reporting Program (CTRP) - An NCI program is to establish a comprehensive database containing regularly updated information on all NCI-funded clinical trials. The NCI initiated a phased launch of CTRP, which started January 2009 with a focus on registering interventional trials only. The registration of observational, ancillary and correlative studies will begin in 2010.

Systems

Adverse Events Expedited Reporting System (AdEERS) - NCI's web based system for submitting expedited reports for serious and/or unexpected events forwarded to designated recipients and the NCI for all trials using a NCI-sponsored investigational agent/intervention.

Audit Information System (AIS) - An application within the CTEP Enterprise system used to manage Group rosters and audit data.

cancer Adverse Events Reporting System (caAERS) - An open source software tool that is used to collect, process, and report adverse events that occur during clinical trials. This tool supports regulatory and protocol compliance for adverse event reporting and allows local collection, management, and querying of adverse event data, whether routine or serious. This tool also supports service based integration of data from other clinical trials management systems. (See https://cabig.nci.nih.gov/tools/caAERS). On a case-by-case basis this system may be used in place of AdEERS.

Cancer Therapy Evaluation Program (CTEP) Enterprise - All integrated systems used to support CTEP processes.

Cancer Trials Support Unit Enterprise - All integrated systems used to support the CTSU process.

Clinical Data Update System (CDUS) - Clinical Data Update System is the CTEP reporting system for demographic and clinical data.

Clinical Trials Monitoring Service (CTMS)-A service administered by a non-governmental organization under contract with NCI to receive, review, and perform data management and monitoring activities for early phase clinical trials (Phase 0, Phase 1 and select Phase 2 as determined by the Protocol Review Committee, CTEP), conduct Cooperative Group co-site visits, perform monitoring visits to Cancer Centers and other institutions conducting clinical trials involving NCI-supplied investigational agents, and provide audit support to International collaborators.

CTEP Enterprise Services (CES) - CES is a j2ee application under CTEP which facilitates message exchange between CBIIT's COPPA (Correlation of Organizations, People, Protocol Abstraction) Person and Organization (PO) and CTEP's Enterprise Core

Module (ECM). The primary objective of CES is to synchronize data between PO and ECM using JMS technology. CES does not have any database of its own, however has exposed several public APIs and exchanges a small subset of COPPA objects over the wire using web services.

Drug Authorization and Review Tracking System (DARTS) – An application within the CTEP Enterprise system used to track investigational agents.

Enterprise Core Module (ECM) - An application within the CTEP Enterprise system (CTEP ESYS) used to create and maintain institutional (use either both site & institution if applies to both or only one of the terms if applies only to 'site' or only 'institution') code information.

Enterprise Maintenance System (EMS) - A system within the Enterprise application that allows for the owners of applications the ability to update data and run reports based on certain criteria.

Enterprise Query Wizard (EQW) - A data analysis tool within the Enterprise application that provides real-time access to the data stored in the CTEP Enterprise database,conducts queries based on several different criteria i.e. document type, agent, disease, organization, etc., return results as a list of documents and can be exported to Excel or PDF, generates standard reports i.e. Accrual, Adverse Event, Response, etc., generates Protocol Complete Sheets, and integrates with other CTEP apps i.e. PATS, CDUS, DARTS, IR, etc.

JIRA™ - tracking software used by Westat to track development tasks in the CTSU Enterprise services.

NCI Enterprise Services (NES) - An application to collect data that researchers commonly reference in clinical trials applications include organizations (research institutions), people (investigators and patients), and protocols (treatments), and the relationships between and among those entities. The resulting web services began with the name COPPA and evolved to NCI Enterprise Services (NES). It involves numerous internal and external stakeholders, including systems requiring or providing information, to the NCI cancer Biomedical Informatics Grig (caBIG).

Oncology Patient Enrollment Network (OPEN) - The web-based registration system for patient enrollments onto NCI-sponsored Cooperative Group clinical trials. The system is integrated with the CTSU Enterprise System for regulatory and roster data, and with each of the Cooperative Groups' registration/randomization systems for patient registration/ randomization. OPEN provides the ability to enroll patients on a 24/7 basis.

Protocol Abstraction and Tracking System (PATS) - A database module of the CTEP ESYS into which PIO abstracts key data elements from Letters of Intent (LOIs), Concepts, and Protocols, in order to track the progress of solicited and unsolicited proposals from the LOI through the Protocol approval process.

Regulatory Affairs Branch Information Tracking System (RABITS) An application within the CTEP Enterprise system to track CTEP investigational applications and regulatory information.

Regulatory Support System (RSS) - An application created within the CTSU Enterprise system to create and manage institution, person, and regulatory data for CTEP-supported Cooperative Groups, contractors, and grantees. It is also used to manage CTSU-specific enrollment and delinquency tracking data.

Terminology

Accrual Credited Site - A site identified within RSS or another organization's enrollment database that will receive credit for a patient enrollment. In CDUS, this site is not anticipated to be updated.

Affiliate - May be hospitals or community based clinics or offices which have lower accrual rates. Affiliates administratively function and interact with the Cooperative Groups through the Main Member.

Associate – Person integral to the conduct of research that is not a physician. Persons must be registered with CTEP through the CTEP-IAM process.

Auditable Flag - The auditable flag indicates how the CCOP and CCOP components will be audited. The flag applies only to CCOP and CCOP components and can be changed by the Cooperative Groups.

Audited Site - An institution that is identified on the CTMB-AIS roster for auditing purposes.

Common Toxicity Criteria for Adverse Events (CTCAE) - Provides a descriptive terminology that is to be utilized for AE reporting. A grading (severity) scale is provided for each AE term.

Community Clinical Oncology Program (CCOP) - A community based administrative and financial unit, designated by the Division of Cancer Prevention (DCP), funded by a peer-reviewed cooperative agreement to participate in NCI sponsored cancer treatment, prevention, and controlled clinical trials. It usually consists of community hospitals, clinics, HMOs or private physician practices. A CCOP and its components must accrue at least 50 participants to treatment trials and 50 participants to cancer prevention and control trials annually. The CCOP may actively accrue participants or may be a "storefront" that only enrolls participants for its components.

Community Clinical Oncology Program Components (CCOP Components) - Groups of community hospitals, university hospitals, clinics, HMOs or group of physicians and private practice belonging to a specific CCOP, they actively enroll participants onto NCI sponsored cancer Treatment, Prevention, and cancer control trials. These hospitals,

clinics, HMOs and physician practices are all considered CCOP components within the AIS. Components must be included in the Cooperative Group roster and are held to the same standards as other clinical participants.

Center for Biomedical Informatics and Information Technology (CBIIT) - NCI program that provides interoperable biomedical informatics infrastructure tools, applications and activities to support research initiatives.

Certification & Accreditation (C&A) - a process that ensures that systems and applications adhere to formal and established security requirements that are documented. It is required by the Federal Information Security Management Act (FISMA).

Code Management Committee - committee developed to discuss difficult site code issues and resolve coding disputes.

CTEP Institution (Site) Code - A unique ID assigned at the time an institution is initially created and used to identify that institution across all CTEP and CTSU applications.

CTEP Investigator –must be alicensed medical doctor whom has registered with CTEP to conduct CTEP-supported treatment protocols, or other research personnel leading prevention or ancillary protocols.

CTMB Roster Flag - A flag in the Regulatory Support System on the institution roster screens that is set by the Cooperative Group designee to request an institution be added to the CTMB roster.

Drug Shipment Site - A site identified by an NCI-registered investigator on their Supplemental Investigator Data Form, which will be responsible for the receipt, maintenance, and dispensing of investigational agent received from the Pharmaceutical Management Branch.

Enterprise Core Unit (ECU) - Contractor assigned to process and maintains site code related requests for the CTEP Enterprise system.

Enterprise Change Management Committee (ECMC)

electronic Case Report Form (eCRF)

Grantees - CTEP-funded entities provided funds through a grant mechanism.

Institution - A distinct physical location where research is conducted under Health and Human Services regulations by an investigator responsible for the oversight of patients. The term institution is synonymous with site.

Investigator Registration (IR) – CTEP process to register investigators, collect mandatory regulatory information, and supplemental information for agent shipping.

Institutional Review Board (IRB) - Any board committee, or other group formally designated by an institution to review biomedical research involving human subjects, to

approve the initiation of, and conduct periodic review of such research. The term is synonymous with *institutional review committee* (FDA 21 CFR 50, ICH 6A).

Main Member - Academic or medical center that makes significant contributions to Group activities and provide significant accrual to Group protocols. If the main member has affiliates, they shall contribute, oversee and hold responsibility for mentoring and monitoring them.

Membership Type – term that describes the institution's role on a roster. Terms may vary from dependent on the roster owner. Terms used within the CTMB AIS include: Main Member, Affiliate, CCOP, or CCOP Component.

Membership Status – term used to define an institution's status on a roster. Terms may vary dependent on roster owner. Terms used within the CTMB AIS include Active, Withdrawn, or Terminated.

Membership Status Date - Date status (active, withdrawn, or terminated) and/or other changes to the membership, such as change of membership role, change of Main Member/CCOP, name, address, or audit flag. The roster owner determines when the change is effective.

Membership Start Date - Date first joined Group. The audit history indicates changes regarding participation in the Group; therefore the original start date is a firm date.

Membership Study Type - Designation of a specific roster type based on a study category such as Treatment, Prevention, UCOP, STAR, SELECT, CICRS, etc.

Privacy Impact Assessment (PIA) – a decision-making tool used to identify and mitigate privacy risks at the beginning of and throughout the development life cycle of a program or system.

Plan Of Action and Milestone (POA&M) – federal system reporting requirements outlined by the Department of Health and Human Services to ensure initial and ongoing compliance of federal systems with FISMA and Office of Management and Budget requirements.

Protocol Submission Worksheet (PSW) – worksheet used at the time a protocol is submitted to CTEP for review.

Record – r entry into a database; can reflect an institution, person, protocol, etc.

Record Effective Date - Date record was changed in AIS.

Record Status - Roster entry status

- Active – current roster entry
- Inactive – past roster entries

Roster History - A list of all changes made to a record in a database.

Satellite Location – A health care facility that provides a component of the research process under agreement with a rostered instititution.

Site Code Update (SCU) – changes to CTEP assigned institution code.

Service Oriented Architecture (SOA) – a flexible set of design principles used during systems development.

Special Member - Non-member, participant has specific limitations set by the Group regarding their function within that Group. Examples include provisional status, restrictions related to Group activities, protocol participation, atypical auditing situations, etc.