# Emory University OnCore Dictionary

| **Term or Acronym** | **Definition** | **Context or Field Location** |
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| Accrual | An accrual is the count of subjects on a study. A subject is considered an accrual per the sponsor’s criteria, usually after consent, eligibility and any screening procedures are complete. | Subjects |
| Adjuvant | Study drug is enhancing or otherwise affecting the impact of another drug or treatment. | PC Console |
| Affiliate | Another institution or site that is conducting clinical trials where Emory is the coordinating center. An Institution other than Emory. | PC Console |
| Age | Indicates the age of subject participants. Options are 'Adult', 'Children', or 'Both'. | PC Console |
| AHC | Academic Health Center - represents any non-oncology part of Emory. Also see Organizational Unit, Library,  | PC Console |
| Assigned Subjects | Patients can be assigned to study team members in OnCore. | Subjects |
| Billing Slip | Visit-level accounting of services provided that should be charged to the research study. | Financials |
| BSM Console | Refers to the Biospecimen Management console in OnCore that has the capability to provide information regarding inventory tracking, requisition and distribution management, related document storage, and applicable reports. |  |
| CA | Coverage Analysis | Financials |
| Cancer Center | Winship Cancer Institute  |  |
| Companion Study | A study conducted in conjunction with at least one other study. Enrolling into the companion study can be either "required" or "optional" | PC Console |
| Consent at Age of Majority | Triggers warnings to re-consent subjects at the age of majority when set to 'Yes'. This field is only active when the 'Age' selected is Children or Both. | PC Console |
| Console | An OnCore console is a set of related OnCore pages that are grouped for a particular workflow, function, or type of data.  |  |
| Contact Records | Contact records can be created for any team members who need to be tracked in connection with a protocol, subject, task, audit, or registry. Contacts do not necessarily have access (see User Records).  |  |
| Correlative Study | A correlative study looks at relationships between human biomarkers (e.g. genes, proteins) and something else (e.g. a disease, a treatment). In recent years many biospecimen-based biomarkers have been incorporated into cancer therapeutic trials. In OnCore, a correlative study may be associated with a main study, but does not seek the main outcomes of the main study.  |  |
| Correlatives | Biomarker specimens for correlative studies. |  |
| CRA | Clinical Research Administration | CRA Console |
| CRM | Clinical Research Management |  |
| CRMS | Clinical Research Management System |  |
| CRO | Contract Research Organization or Clinical Research Organization - A company hired by another company or research center to take over certain parts of running a clinical trial. The company may design, manage, and monitor the trial, and analyze the results. |  |
| CRPC | Clinical Research Process Content – an Epic-OnCore interface that allows OnCore calendar and billing grid data to flow from OnCore to Epic. |  |
| CTCAE | Common Terminology Criteria for Adverse Events – The NCI CTCAE is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. |  |
| CTG | Clinical Trials Group (Oncology) |  |
| CTMS | Clinical Trial Management System |  |
| CTO | Clinical Trial Office at the Winship Cancer Center Institute. |  |
| CTRP | NCI's Clinical Trials Reporting Program |  |
| CTSI | Clinical and Translational Science Institute |  |
| Data Table 4 | An NCI report that shows the clinical research trials that are open during a 12-month period at an institution. The report includes data on study type, sponsor type, principal investigator, accruals, etc. |  |
| Department | Identifies the institutional funding body for the study. Fiduciary reporting is available based upon this field. Additionally, the permission scope of Department is driven off of this field.  | PC Console |
| Deviation | A variance from the approved protocol procedures. | Subjects |
| Drug Accountability | Indicates whether drugs are being used and recorded within the protocol. Options are 'Yes', 'No', or 'N/A'. This is an information-only field and does not drive any OnCore functionality. Not a required field at Emory. | PC Console |
| DSMB | Data Safety Management Board |  |
| EMR | Electronic Medical Record |  |
| Enrollment Scope | The general pools into which participants may be enrolled - can be "local", "national", and "international". |  |
| Epic | Emory Healthcare Hospital’s electronic medical record system. |  |
| ePRMS | Electronic Protocol Review and Monitoring System. Also see Protocol Review and Monitoring System. |  |
| FC | Financial Coordinator Role | Access |
| FED | Federal Rate Base | Financials |
| ICF | Informed Consent Form | PC Console, Subjects |
| IDC | Indirect Charges – Overhead costs, Indirect Costs (IDC), and Facilities and Administrative (F&A) costs are terms have been used interchangeably by the federal government as equivalents to describe the same concept. These are actual costs incurred by the university in support of sponsored activities that cannot be identified readily and specifically to a project. Among other expenses, it includes the cost of departmental and central administrative support, building and equipment use, and library services, etc. | Financials |
| IDE | Investigational Device Exemption | PC Console |
| IHE | Integrating the Healthcare Enterprise |  |
| IND | Industry Rate Base | Financials |
| IND | Investigational New Drug Application | PC Console |
| Institution | Institutions are the logical business units of clinical trials that participate in a protocol. | PC Console |
| INV | Investigator Initiated Rate Base | Financials |
| Investigator Initiated Protocol | Indicates whether the principal investigator initiated the protocol; options are 'Yes', 'No', or blank. This field is used in the Data Table 4 Revised -- Clinical Research Protocols report. | PC Console |
| IRB | Institutional Review Board, a group of scientists, doctors, clergy, and consumers that reviews and approves the action plan for every clinical trial. | PC Console |
| Library | Determines the Reference Codes, Forms, Protocol Annotations, Notifications and Signoffs available for the protocol. This field cannot be changed once the status of the protocol has changed from 'New'. There are two libraries in Emory OnCore: Winship and Emory Enteprise (non-oncology). | PC Console |
| MRN | Medical Record Number | Subjects |
| NCI | National Cancer Institute |  |
| NCT Number | National Clinical Trials Number in ClinicalTrials.gov | PC Console |
| Objectives | Identifies the objective for the protocol according to your institution's SOPs. Objectives populate to the SIP Console and display on the public website. | PC Console |
| OnCore Administrator | The staff assigned to maintain the OnCore database. | OCR@Emory.edu  |
| Organizational Unit | Organizational Units are used to organize protocols into logical structural divisions, which is useful for reporting purposes and to restrict access to protocols. The permission scope of Organizational Unit is driven off of this field. At Emory University, we have two OUs: Cancer Center or Academic Health Center . | PC Console |
| OU | See Organizational Unit | PC Console |
| PC | Protocol Coordinator Role | Access |
| PC Console | The PC Console displays information about one protocol at a time: details that might be of interest to a Protocol Coordinator. The PC Console includes the protocol number and title, the type of study, the staff assigned to the protocol, the protocol sponsor, and other protocol-related information. | PC Console |
| PDQ | Physician Data Query |  |
| Phase | Indicates the study phase of the protocol. The phase selected here populates to the SIP Console and displays on the public website. Protocol Search provides a Search By Phase option. | PC Console |
| PI | Principle Investigator. A principal investigator is responsible for the overall conduct of the clinical trial at his/her site. | PC Console |
| PRMC | Winship Cancer Institute Protocol Review and Monitoring Committee.  | PC Console |
| PRMC Coordinator | The Protocol Review and Monitoring Committee Coordinator manages the PRMC meeting agendas, tracks submissions, tracks committee decisions, and manages communications between the investigators and the PRMC.  | PC Console |
| PRMS | Protocol Review Meeting System for Cancer studies. | PC Console |
| Protocol No. | A unique, automatically-generated protocol identifier in OnCore. | PC Console |
| QCT | Qualifying Clinical Trial | Financials, Covergae Analysis  |
| RC | Research Center |  |
| Reference Codes | Values that populate drop-down fields throughout OnCore. | Coverage Analysis |
| RR | Re-consent Required - used to indicate a re-consent requirement for enrolled subjects. | Subjects |
| SAE | See Serious Adverse Event | Subjects |
| SC | Study Coordinator Role | Access |
| Scope | Indicates the enrollment scope. Typically, 'Local' indicates the trial will only be open for the research center, 'National' indicates a multi-institutional trial. This is an information-only field and does not indicate scope for Data Table 4 reporting or any other functionality. | PC Console |
| Serious Adverse Event | 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 or requires medical or surgical interventions to prevent any of the above outcomes. | Subjects |
| Short Title | Contains abbreviated version (100 characters maximum) of the protocol title. The short title entered here populates to other screens within OnCore and is displayed in some reports. The Short Title and Title both populate to the SIP Console. | PC Console, SIP Console  |
| Specifications | The base template for a OnCore study calendar. | Calendars |
| Specimen Banking | Using the OnCore BioSpecimen Management system (BSM) | PC Console, BSM Console |
| Sponsor | Organization or company supporting the trial, including financial, drug supply, data management, etc. | PC Console |
| Staff | List of team member contacts for the protocol. | PC Console |
| Study Information Portal (SIP) | Study Information Portal public website.  | SIP Console |
| Study Site | Location associated within an Institution where subjects will be treated. In Emory OnCore, Emory has multiple sites. | PC Console |
| Submitter | The staff (on behalf of a Principal Investigator) entering and submitting a new protocol and associated documents to the PRMC (Protocol Review and Monitoring Committee) or OCR for review. | Staff Role |
| Summary 3 | An NCI report that shows patient accrual data for a 12 month period at an institution. The report includes data on cancer site, demographics, etc. |  |
| Summary Accrual | OnCore protocols can be set up so that patient accrual data is entered periodically “in bulk” rather than as individual patient registration and subject visit tracking. Summary Accrual protocols typically do not have a visit calendar set up. | PC Console |
| Title | Identifies the full-length name of the protocol. The title populates to other pages within OnCore and is displayed in some reports. It is the only title used on the NCI Data Table 4 report. The Title and Short Title both populate the SIP Console. | PC Console, SIP Console  |
| Tolerance | Visit Window | Calendars |
| Toxicity | Refers to harmful side effects caused by the agent or intervention being tested. |  |
| Treating Physician | The physician that is treating the subject while they are on the study. | Staff Role |
| User Record | User Records are activated for team members who need to log into OnCore. | Access |