eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
A		
Ad Hoc Testing	Ad hoc testing is a less formal testing method compared to following test scripts. It involves testing available functionality in a way that may not be detailed in the test script. Results from this exploratory testing may still be recorded during the UAT process.	Lexicon Team
Alarm	An audible or multisensory notification triggered at a pre-defined timepoint intended to remind a participant to complete scheduled PRO measures for device-based eCOA systems.	Lexicon Team
Alert	An automated email, Short Message Service (SMS) text, device, or in-portal notification issued from the eCOA platform when a specific data condition is met.	Lexicon Team
Android Package Kit *(APK)*	The application installation file for Android operating systems.	Lexicon Team
Apple Research Kit *(ARK)*	An open-source framework that allows developers and researchers to create iOS apps for use in medical research.	Adapted from opensource.apple.com

eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Application *(App)*	A type of software that can be installed and run on a smartphone, tablet, computer, or other electronic devices. An app most frequently refers to a mobile application for smartphones or tablets or a piece of software that is installed and used on a computer. Different types of apps include:	

eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Audit Trail	Documentation that allows reconstruction of the course of events. A record of the changes that have been made to a database or file. A process that captures details such as additions, deletions, or alterations of information in an electronic record without obliterating the original record. An audit trail facilitates the reconstruction of the history of such actions relating to the electronic record.	After ICH E6, CSUICI and ICH Glossary
B		
Bluetooth	A short-range wireless technology standard that is used for exchanging data between devices (e.g., fixed and/or mobile) over short distances and building personal area networks.	Adapted from https://en.wikipedia.org/wiki/Bluetooth
Bring Your Own Device *(BYOD)*	The practice of study participants using their own personal devices to collect, record, and transmit eCOA data in clinical trials.	BYOD Project Team
Bring Your Own Wearable *(BYOW)*	The practice of permitting study participants to use personal wearable devices to capture, record, and transmit data in clinical investigations. A subset of BYOD and supports the collection of data more passively.	Lexicon Team
Bug Tracking Tool	Used by the eCOA provider to track errors in code found during testing.	Lexicon Team

eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
C		
Change Control	The process by which changes to a live eCOA study build are implemented in a controlled manner, typically documented in a *Change Control Form.*	Lexicon Team
Clinical Data Repository *(CDR)*	A real time database that consolidates data from a variety of clinical sources to present a unified view of a single participant. Note: Also known as a *Clinical Data Warehouse (CDW)*	Wikipedia - Clinical data repository
Clinical Operations *(ClinOps)*	A team that contributes to and supports an organization's research and development program in order to advance new investigational drugs/devices to commercialization, including designing, planning and executing Phase I through IV clinical trials.	Lexicon Team
Clinical Outcome Assessment *(COA)*	Assessment of a clinical outcome can be made through report by a clinician, a patient, a non-clinician observer, or through a performance-based assessment. Types of COAs include:	

eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Clinical Research Associate *(CRA)*	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.	CDISC Glossary
Clinician-reported Outcome *(ClinRO)*	A type of clinical outcome assessment. A measurement based on a report that comes from a trained health-care professional after observation of a patient's health condition. Most ClinRO measures involve a clinical judgment or interpretation of the observable signs, behaviors, or other manifestations related to a disease or condition. ClinRO measures cannot directly assess symptoms that are known only to the patient.	BEST (Biomarkers, EndpointS, and other Tools) Resource
Cognitive Interview	A qualitative research method used in PRO measure development, linguistic validation of a PRO measure, or comparability testing. It is used to determine whether concepts and items are understood by respondents in the same way that PRO measure developers intend. Cognitive interviews involve incorporating follow-up questions in a field-test interview to gain better understanding of how respondents interpret items and to collect and consider all concepts elicited by an item. Testing the measure on a small group of relevant respondents with the target disease or condition or lay people in order to test alternative wording and to check understandability, interpretation, or cultural relevance of a translation. Note: May also be called *cognitive debriefing*	Adapted from FDA's PRO Guidance Glossary

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Comparability	Comparability is a function of the similarity of the psychometric properties of the data obtained via the original and migrated mode. An ePRO measure that has been migrated to a new mode of data collection ought to produce data that are comparable or superior (e.g., higher quality, more complete) to the data produced from the original, source version.	Adapted from Coons et al. 2009
Compliance	Adherence to trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements. In the context of eCOA studies, "compliance" includes respondents completing measures as scheduled per the protocol.	CDISC Glossary as modified from the ICH Glossary
Computerized Adaptive Testing *(CAT)*	"[C]omputerized adaptive testing (CAT) is a computer-based exam that uses special algorithms to tailor test question difficulty to each individual test taker [respondent]. A computer adaptive test means the exam adapts in real time to the test taker's ability level and provides test questions accordingly." Although it is uncommon for exams (i.e., items with correct and incorrect responses) to be administered in the context of a clinical trial, it may be the case when a cognitive test is included as a performance outcome measure, and it is administered using CAT.	What Is Computerized Adaptive Testing (CAT)? — Meaning & Definition (caveon.com)
	A procedure for collecting data in clinical trials, "whereby the next item administered to a respondent depends upon a running estimate of the respondent's status based on the respondent's responses to prior items."	Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
		Assessments (fda.gov)
	"Computer Adaptive Test (CAT): A flexible, computer–driven measure that can use any items (e.g., questions) in an item bank. A CAT selects only those items that sharpen the estimate of a respondent's score on the domain being measured. CAT length varies, but usually includes four to seven items."	https://www.healthmeasures.net/resource-center/measurement-science/glossary
Conditional Branching / Branching Logic	Individualized items that are based on previous answers in a questionnaire. The goal is to reduce respondent burden by skipping irrelevant items. The final set of items can be different for each user. Conditional branching / branching logic requires programming using IF and THEN statements. For example, IF PRO-CTCAE Nausea frequency item 2a= never; THEN skip nausea severity item 2b. The eCOA provider programs branching logic to ensure that irrelevant items are not presented on a user's eCOA device.	Overview of the PRO-CTCAE (cancer.gov) and Conditional statements (tldp.org)
Contract Research Organization (*CRO*)	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 Glossary

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Copyright Holder	The person, organization, or company that owns the copyright to a work and has exclusive rights* to do and to authorize specific actions to the copyrighted work including the licensing of the clinical outcome assessment.	Copyright Law of the United States (Title 17) of the *United States Code* US CODE-2010-title17-chap1-sec106.pdf (govinfo.gov) *Defined in Section 106 of the United States Copyright Act and Lexicon Team
Corrective and Preventative Action *(CAPA)*	A system to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.	US FDA

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
D		
Data Change Form *(DCF)*	The form used to document a trial data change request (DCR) by an investigator. Also known as Data Correction Form. Note: Also see Data Change Request (DCR)	Lexicon Team
Data Change Request *(DCR)*	An action taken by an investigator to request change to trial data. Note: Also see Data Change Form (DCF)	Lexicon Team
Data Loading	The process of copying and loading data or data sets from a source file, folder, or application to a database or similar application. Data loading is not a standard practice in all studies and may be used where manual data entry is not feasible.	Lexicon Team
Data Management (*DM)*	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.	CDISC Glossary; NIA Glossary of Clinical Research Terms

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
	The processes of handling the data collected during a clinical trial from development of the study forms/CRFs through the database locking process and transmission to statistician for final analysis.	
Database Lock *(DBL)*	Action taken to prevent further changes to a clinical trial database or any equivalent clinical data storage system. Note: Locking of a database is done after review, query resolution, and a determination has been made that the database is ready for analysis.	CDISC Glossary
Decommissioning	The process of removing any software from hardware used for the capture or storage of eCOA data, including permanent removal of any data residing on the device. The process includes physical cleaning of the device for potential reuse or onward ethical disposal of the device if at the end of its usable life. The server hosting the database is deactivated at this time and data are moved to archive.	Lexicon Team
Defect Log	A document that lists all defects identified during the UAT phase of eCOA system development, normally including the relevant test script identifier, defect description, severity, and the planned remediation. Note: May also be called *Findings Log* or *Issues Log*	Lexicon Team
Deployment	The process whereby all hardware and materials required to use the eCOA system are shipped to sites.	Lexicon Team

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Design Specification	An internal document generated by the eCOA provider that details all the information needed to build the required eCOA system. The content is based on the expectations described in the sponsor-approved *Requirements Document.* Note: The Design Specification is not normally subject to sponsor review.	Lexicon Team
Device Accountability Log	A document maintained by the site (or supporting CRA) that tracks the Asset ID of the specific pieces of hardware that are issued to study participants.	Lexicon Team
Device Label	A label that identifies the protocol/study number for which a device is intended for use. The label often incorporates the Helpdesk telephone number, the participant identifier, and the site number.	Lexicon Team
Digital Health Technology *(DHT)*	A system that uses computing platforms, connectivity, software, and/or sensors for healthcare and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products. DHTs may be used to collect clinical outcome assessment data.	Guidance for Industry (fda.gov) and Lexicon Team
Digital Versatile Disc *(DVD)*	A type of compact disc able to store large amounts of data, especially high-resolution audiovisual material.	Lexico

eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
E		
Electronic Case Report Form *(eCRF)*	An auditable electronic record of information that is reported to the sponsor (or sponsor's agent such as an EDC provider) on each trial subject to enable data pertaining to a clinical investigation protocol to be systematically captured, reviewed, managed, stored, analyzed, and reported. The eCRF is a CRF in which related data items and their associated comments, notes, and signatures are linked programmatically.	FDA Guidance on Computerized Systems Used in Clinical Investigations; Revised from FDA Guidance on Electronic Source Data in Clinical Investigations
Electronic Clinical Outcome Assessment *(eCOA)*	A clinical outcome assessment that has been implemented on an electronic data collection platform (e.g., smartphone, tablet, IVR, web, wearable).	Lexicon Team
Electronic Clinical Outcome Assessment System *(eCOA System)*	An electronic system that incorporates technologies that support clinical outcome assessment data capture, transmission, storage and review.	Lexicon Team

eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Electronic Data Capture *(EDC)*	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 with an audit trail.	Lexicon Team
Electronic Device	A piece of hardware loaded with software used for the capture of COAs electronically (e.g., handheld smartphone, tablet, laptop, wearables, and sensors). Often just called a "device."	Lexicon Team
Electronic Patient-Reported Outcome *(ePRO)*	Patient-reported outcome data initially captured electronically. Note: Usually ePRO data are captured as eSource.	Lexicon Team
Electronic Platform	A platform is a group of technologies, including both hardware and software, that are used as a base upon which other applications, processes, or technologies are executed or developed. A platform includes, but is not limited to, the operating system or executive software, communication software, network, input/output hardware, any generic software libraries, database management, and user interface software.	Adapted from Technopedia

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Engagement	The process of building the capacity of patients, families, carers, as well as health care providers, to facilitate and support the active involvement of patients in their own care, to enhance safety, quality and people-centeredness of health care service delivery. eCOA engagement features are elements within an eCOA application that facilitate and support participants' active involvement throughout their clinical trial experience. Ultimately, an engagement feature could be defined as anything that increases compliance and/or retention or anything with a goal of more complete and accurate data, reduced study timelines, and an overall positive participant experience.	

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Ethics Committee *(EC)*	An independent body (a review board or a committee, institutional, regional, national, or supranational) constituted of medical/scientific professionals 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 and to provide public assurance of that protection by, among other things, reviewing and approving/ providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. NOTE: ICH refers to these as "Independent Ethics Committees (IEC)." The legal status, composition, function, operations, and regulatory requirements pertaining to independent ethics committees may differ among countries but should allow the independent ethics committee to act in agreement with GCP as described in the ICH guideline. Note: Also see IRB as the terms are used interchangeably.	ICH Glossary
Equivalence	*See comparability*	

F

Feasibility	In the context of clinical trials, feasibility is a process of evaluating the possibility of conducting a particular clinical program/trial in a particular geographical region with the overall objective of optimum project completion in terms of timelines, targets, and cost. For eCOA studies, evaluation of internet connectivity and comfort with technology may be included.	Conducting Feasibilities in Clinical Trials - PMC

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Findings Log	Used to collate all instances in which the system does not perform as expected and are identified by testers (e.g., sponsor or designee) during UAT. Note: May also be called *Defect Log* or *Issues Log*	Lexicon Team
First Patient First Visit *(FPFV)*	The completion, in accordance with applicable study protocol and regulations, of a first study visit by a human subject in a clinical trial. Note: May also be called *First Participant First Visit*	Law Insider Dictionary FPFV
Fit-for-purpose	A COA is considered fit-for-purpose when "the level of validation associated with a medical product development tool is sufficient to support its context of use."	BEST (Biomarkers, EndpointS, and other Tools) Resource
G		
Go-Live	The timepoint at which all required testing procedures for the eCOA system have been completed, and it is available for the capture of eCOA data into the production database.	Lexicon Team
H		
Helpdesk	A technical support service offered by the eCOA provider or third-party entity that supplies advice and guidance to participants, sites, and CRAs who encounter issues when using the eCOA system. The Helpdesk may be accessed via phone, email, or online chat.	Lexicon Team

eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
I		
Importer of Record *(IoR)*	A company or similar entity that is responsible for ensuring all eCOA hardware intended for use by participants is imported in line with all local laws and regulations. Note: Device-based eCOA only	Lexicon Team
Information Technology *(IT)*	The use of computers to store, retrieve, transmit, and manipulate data or information used within the context of business operations.	Wikipedia - IT
Institutional Review Board *(IRB)*	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. [ICH E6 1.31] Note, also see EC as the terms are used interchangeably.	ICH Glossary
Instrument	A means to capture data (i.e., a questionnaire) plus all the information and documentation that supports its use. Generally, that includes clearly defined methods and instructions for administration or responding, a standard format for data collection, and well-documented methods for scoring, analysis, and interpretation of results in the target patient population. Note: Also see Clinical Outcome Assessment	PRO Guidance 2009

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Instrument developer / measure developer / author	The person(s) or organization that develops and publishes an instrument/measure for use in research, ensuring that it is a valid and reliable measure of a specific concept of interest. Note: May be distinct from copyright holder	Lexicon Team
Interactive Response Technology *(IRT)*	The technologies that research sites use to enroll patients into clinical trials, randomize patients, and manage study drug supplies. Interactive voice response system (IVRS) or interactive web response system (IWRS) falls under the IRT umbrella.	Lexicon Team
Interviewer-administration	Interviewer-administration is a form of respondent self-report that involves a researcher or clinical staff person posing questions or presenting the items and rating scale verbally to the respondent, and the respondent answering verbally while the interviewer records the responses either on paper or on an electronic platform. Note: This refers to completion of a PRO measure and not a ClinRO assessment.	Lexicon Team
ISPOR	A non-profit member-driven organization formed to promote the practice and enhance the science of health economics and outcomes research (formerly the International Society for Pharmacoeconomics and Outcomes Research).	Lexicon Team

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
K		
Kick-off Meeting *(KOM)*	A meeting designed for sponsor, eCOA vendors, and applicable parties to outline timelines, expectations, and introduce key and ancillary team members. This meeting will also include alignment of expectations and timelines of deliverables. Attendance by the person responsible for the protocol would be beneficial to discuss any ambiguity with the protocol.	Lexicon Team
L		
Last Data Available *(LDA)*	The most recent data available. All data available in the analyzable data set from a clinical trial (after last patient last visit). In a clinical study protocol, the last set of outcome measures evaluating the effect of an intervention/treatment.	CDISC Glossary
Last Patient Last Visit *(LPLV)*	The last subject to reach a planned or achieved milestone representing the completion of the trial.	

eCOA: Getting Better Together Initiative

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Lexicon Team	Individuals participating in the eCOA: Getting Better Together Initiative, a pre-competitive collaboration among Critical Path Institute, clinical trial sponsors from the Patient-Reported Outcome (PRO) Consortium, providers of electronic data collection technologies and services from the Electronic Patient-Reported Outcome (ePRO) Consortium, contract research organizations (CROs), and regulators (FDA).	C-Path's PRO Consortium and ePRO Consortium
License Holder	The person, organization, or company that licenses a copyrighted instrument/measure and executes a license agreement granting permission to third parties to use the instrument/measure. This may be the copyright holder or someone working on behalf of the copyright holder.	Lexicon Team
Linguistic Validation	Process by which a COA is simultaneously translated by different translators and reconciled into a single version. This single version is then back-translated by a different translator into the original language in order to evaluate the quality of the reconciled translation in comparison with the source document (also known as dual-forward/single-back). The process of assessing and confirming the conceptual equivalence and content validity of translations of patient-reported outcome (PRO) measures. Usually, linguistic validation refers to a process whereby translated text is actively tested with patients in the target population and target language group through cognitive interviews.	Adapted from Eremenco et al. 2017
Localization	The process of adapting the textual or non-textual content of a COA, or its supporting instructions, to the specific geographical location or culture of planned use.	Lexicon Team

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Logistics	The process of identifying, acquiring qualifying, preparing, shipping, and recovering all eCOA hardware and supporting materials.	Lexicon Team
M		
Method of Administration	The process by which a COA is presented to and answered by the respondent. The methods include self-administration, interviewer-administration, or a combination of both. Note: May also be called *mode of administration (MOA)*	Adapted from FDA COA Qualification Plan content outline: COA Qualification Plan
Mode of Data Collection	The tool with which the COA is administered and responses collected. The modes can include paper-based, computer-assisted (e.g., smartphone/handheld, tablet, web-based), and telephone-based assessments (interactive voice response system) Note: Sometimes referred to incorrectly as *mode of administration (MOA)*	Adapted from FDA COA Qualification Plan content outline: COA Qualification Plan and 2009 PRO Guidance
N		
Notification	An Alarm, Reminder or Alert that provides information and/or prompts users to take action relating to the eCOA system, and which is triggered when certain criteria are met. For example, an Alarm is an audible or multisensory notification triggered at a predefined time point intended to remind a participant to complete scheduled assessments for device-based eCOA systems. An Alert is an automated email, short	Lexicon Team

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
	message service (SMS) text, device or in portal notification issued from the eCOA platform when a specific data condition is met.	
O		
Observer-reported Outcome *(ObsRO)*	A type of clinical outcome assessment. A measurement based on a report of observable signs, events or behaviors related to a patient's health condition by someone other than the patient or a health professional. ObsROs are reported by a parent, caregiver, or someone who observes the patient in daily life and are particularly useful for patients who cannot report for themselves (e.g., infants or individuals who are cognitively impaired). An ObsRO measure does not include medical judgment or interpretation.	BEST (Biomarkers, EndpointS, and other Tools) Resource
P		
Patient-reported Outcome *(PRO)*	A type of clinical outcome assessment.	

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Personal Device	An electronic technology owned by and for use by an individual to collect and transmit study data.	Lexicon Team
Personal Identification Number *(PIN)*	A unique personal identification number selected by a patient, site administrator-anyone with access to data entry; to ensure the attributability of the individual logging in.	Lexicon Team
Pop-up	A message that displays on the screen of a device that typically requires the user to dismiss or confirm the message has been read (e.g., an alarm to complete a daily diary.)	Lexicon Team
Portal	A secure website hosted by the eCOA provider that allows appropriately trained and qualified stakeholders role-based access to eCOA data, reporting functionality, and eCOA management tools and resources.	Lexicon Team
Project Management/ Manager *(PM)*	The eCOA provider project manager (PM) coordinates the team's activities throughout a clinical trial. The PM manages the execution of clinical trials within their role and organizes the work of team members/sub-teams to accomplish a variety of concurrent activities performed in several departments within the organization. The PM is the primary contact for the sponsor and all communications within the trial.	Lexicon Team

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Prompt	See Pop-up	
Protocol Review Committee *(PRC)*	A sponsor cross-functional peer review tasked with a full scientific review of proposed protocols, assessing general feasibility, annual accrual expectations, and competing studies. Monitoring to assure that clinical trials and projects are scientifically sound and that approved studies maintain adequate patient accrual and scientific relevance and progress.	University of Michigan and University of Illinois
Provisioned Device	Electronic device (e.g., a smartphone) supplied to a study participant for the purpose of collecting and transmitting clinical trial data. In contrast to BYOD, these devices are limited in functionality and are normally returned at the end of the trial.	Lexicon Team
Proxy Entry	Data entered by another party on behalf of whomever is usually responsible for data entry, rather than the patient or principal investigator themselves.	Lexicon Team
Q		
Quality Assurance *(QA)*	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 Glossary
Quality Control *(QC)*	The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled.	ICH Glossary

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Questionnaire	A set of questions or items shown to a respondent in order to get answers for research purposes. Note: Also see *Instrument*	CDISC Glossary

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Self-administration	Self-administration is a form of respondent self-report that involves completion of a COA by the respondent on their own. Note: May also be called *self-completion*	Lexicon Team
Site Initiation Visit *(SIV)*	A visit performed to ensure the investigators and study staff at a clinical research site understand the study protocol, that all operational steps are in place, and that everyone is clear and well trained in their specific roles and responsibilities. This visit is conducted prior to the first patient being recruited into the study at the site. The aim is to work with sites to ensure the site's planned operational procedures fit with the requirements of the protocol and will ensure accurate data as well as safe and ethical conduct of the trial.	Process Map TGHN – The Global Health Network
Software Development Life Cycle *(SDLC)*	Process for planning, creating, testing, and deploying software. There are usually six stages in this cycle: requirement analysis, design, development and testing, implementation, documentation, and evaluation.	Lexicon Team
Source Data Verification *(SDV)*	The process of ensuring that data that have been derived from source data accurately represent the source data. Note: Also called *Source Data Review (SDR)*	CDISC Glossary

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Sponsor	In the conduct of	

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
T		
Test Script	A document specifying one or more test procedures. The term normally applies to manually executed testing rather than the execution of an automated script. Test scripts are developed based on a Test Plan and are executed to confirm a specific piece of expected functionality of an eCOA system is operating as per design requirements.	Adapted from ISO/ IEC/IEEE 29119-1; 2022. Software and systems engineering
Trial Master File *(TMF)*	The trial master file shall consist of essential documents, which enable both the conduct of a clinical trial and the quality of the data produced to be evaluated. Those documents shall show whether the investigator and the sponsor have complied with the principles and guidelines of good clinical practice.	The EU Commission's Directive 2005/28/EC 63 Chapter 4
Translation Migration	Process by which an existing COA translation is moved into an electronic system. The text of the COA translation (e.g., instructions) may be modified, as needed, by a translation provider based on the approved English source screenshots. The translation provider issues certificates of translation documenting the conformity of the translation screenshots.	Lexicon Team
U		
Understandability	The property of a COA item to be interpreted as intended by a respondent (this is an aspect of content validity).	Lexicon Team

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
Universal Serial Bus *(USB)*	A common interface that enables communication between devices and a host controller such as a personal computer (PC). It connects peripheral devices such as digital cameras, mice, keyboards, printers, scanners, media devices, external hard drives and flash drives.	Techopedia-USB
Usability Testing	Examines whether respondents from the target population are able to use the software and the device appropriately. This process includes formal documentation of respondents' ability to navigate the electronic platform, follow instructions, and answer questions. The overall goal is to demonstrate that respondents can complete the computerized assessment as intended.	Coons 2009
User Acceptance Testing *(UAT)*	The last phase of the system testing process. System users (e.g., the sponsor or its designee) use test cases and test scripts written against the requirements document to test the eCOA system in order to ensure it performs as expected. Any testing that takes place outside of the developer's-controlled environment. Note: Recognize that in other industries, this term refers to the end user.	FDA General Principles of Software Validation - Final Guidance Document
User Design *(UD)*	Also called User interface (UI) design, is the process of making interfaces in software or computerized devices with a focus on looks or style. Designers aim to create designs users will find easy to use and pleasurable. UI design typically refers to graphical user interfaces but also includes others, such as voice-controlled ones.	Interaction-Design-UI Design
User Guide	A document or webpage that provides instruction to different user types (e.g., site staff, participant) on how to use the eCOA system.	Lexicon Team

eCOA Lexicon v3.0

May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
User Interface *(UI)* **/ User Experience** *(UX)*	"[T]he user interface (UI) is the series of screens, pages, and visual elements—like buttons and icons—that enable a person to interact with a product or service [in this case an electronic screen-based device used for data collection in clinical trials]. User experience (UX), on the other hand, is the internal experience that a person has as they interact with every aspect of a company's products and services. 'User experience' encompasses all aspects of the end-user's interaction with the company, its services, and its products." In this case, the user experience would be related to the eCOA system, including the hardware, software, and any devices or web-based portals used to access and interact with the system during the conduct of a clinical trial. End users include study participants, site staff, clinician research organization staff, clinical research associates, monitors, and other sponsor representatives.	UI vs UX | Difference Between UI and UX | What is UX or UI (usertesting.com)
V		
Validation Pop-up	A conditional pop-up alert presented in screen-based eCOA systems that either informs the user of an error on the page or form being completed or indicates the need for confirmation of a recorded response.	Lexicon Team
W		
Wearable Device	A small electronic device containing one or more sensors that are integrated into clothing or other accessories that can be worn on the body, such as on a wristband, belt, headband, adhesive patch, contact lens, or glasses. Common sensors used in wearable devices include those for measuring movement and position, such as accelerometers, gyroscopes, magnetometers, and global positioning systems, or sensors for assessing electrophysiological and	Adapted from Byrom et al. 2018

eCOA Lexicon v3.0
May 2023

A B C D E F G H I K L M N O P Q R S T U V W

Term	Definition	Definition Source
	chemophysiological function or other physiological properties such as body temperature.	
Web Backup	A web-based system for patients and sites to enter and submit eCOA data if the primary eCOA system is not available.	Lexicon Team