International Journal of Health Sciences and Research
Vol.13; Issue: 3; March 2023
Website: www.ijhsr.org
Review Article *ISSN: 2249-9571*

Delivering a Clinical Trial Study Build in An Electronic Data Capture System for Data Collection

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DOI: https://doi.org/10.52403/ijhsr.20230324

ABSTRACT

All aspects of health, disease, and healthcare, encompass under Health Sciences. It indeed is a large group of disciplines, which through the application of technology, strives to deliver the best health care to humans. Subject data is generated in humongous amounts and data collection is deemed of utmost importance. As focus on patient's experience continues to grow, virtual models for data collection and decentralized components have gained momentum. Electronic Data Capture (EDC) systems help capture clinical data and collect it from any source and harmonize it in a single place. Clinical data collected and captured, provides valuable clinical insights and a data capture system can be utilized for several study designs across various customers.

Keywords: [Electronic Data Capture (EDC), Case Report Form (CRF), User Acceptance Testing (UAT), a Clinical Database Management System (CDMS)]

INTRODUCTION

Various EDC systems are utilized to capture clinical trial data. The best systems are those that help capture the data with ease and are user friendly too. Apart from this, what stands important is the fact that the study design team that builds such a system to capture data, needs to understand the requirements and main objectives for designing and developing such a system. In the days of paper-based data collection, how the data were entered into electronic format, typically in a Clinical Database Management System (CDMS), was not the most important consideration. The CDMS partially automated the workflow of data entry, integration of external data, cleaning and coding, and provided automation for tracking data entry, discrepancy identification, and discrepancy resolution. EDC systems have become essential and effective tools to appropriately capture, review and even present the data accumulated throughout the course of a clinical trial. EDC has become the standard tool for its job in clinical trials across the board. Ever more, sponsors and CROs alike are turning to these systems to ensure the highest quality data, and to save money by reducing trial delays associated with difficulties related to data capture. They should be able to capture data in a manner that it should not only maintain privacy standards that have been set up by regulatory authorities but also must be logical, not duplicated, and consistent.

OBJECTIVES AND SCOPE

A clinical trial is any investigation using human subjects that is intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s); and/or to identify any adverse reactions to an investigational product(s); and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) for the purpose of ascertaining its safety and/or efficacy.

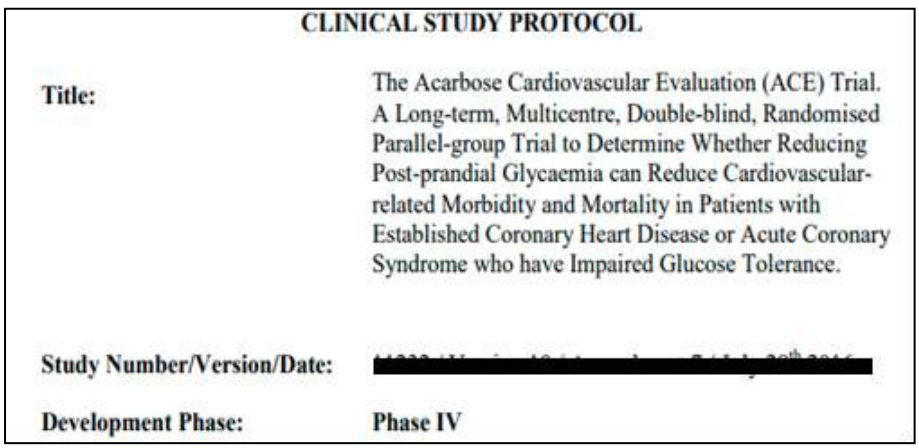
The objective of the project currently undertaken by me, is to describe the process and procedures followed for study build within an EDC system utilized for capturing clinical trial data. This chapter provides information on the design, development, and implementation concepts related to setting-up a study (sometimes called an application) in an EDC system. Practices, procedures, and recommendations are proposed for clinical data managers to design and implement EDC facilitated workflow and data flow for automation, connectivity, decision support, and data mining within and across clinical studies.

MINIMUM STANDARDS

As a mode of data collection and management in clinical studies, EDC systems have the potential to impact human subject protection as well as the reliability of trial results. The E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) contains several passages particularly relevant to use of EDC systems in clinical studies. Section 2.8 "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks".11 Section 2.10, "All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification". 11 Section 5.1.1 states that "The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s)." Additionally, Section 5.1.3 states that "Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly". 11 Section 5.5.3 states that "When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should: a) Ensure and document that the electronic data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e., validation)". 11 Section 5.5.4 under Trial Management, Data Handling and Recordkeeping, states that "If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data"

STUDY BUILD

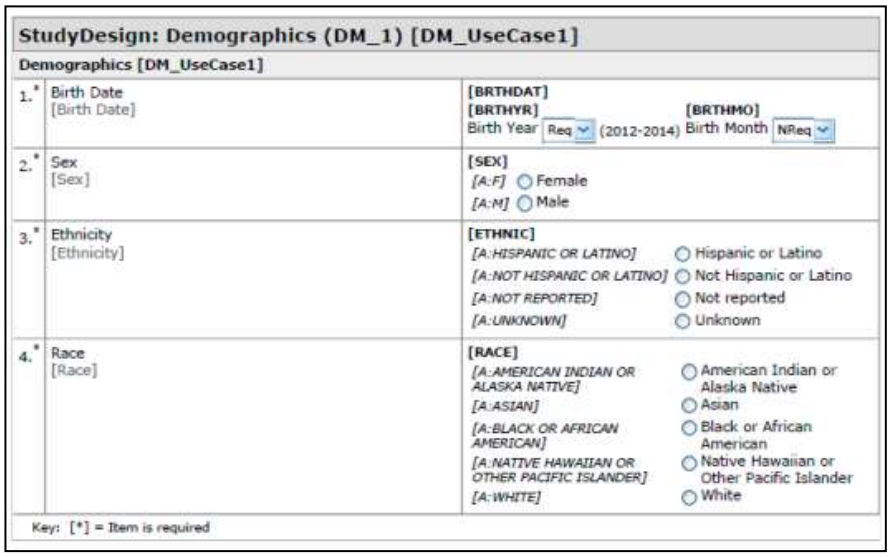
Requirement Gathering is the task of requirement gathering is one of the most important and very crucial steps towards successful design finalization for study build. Study build related documents that are essential to finalize the design of the study design. These include the Study Protocol, the mock Case Report Form (Figure 1 and Figure 2) and the Events Schedule (Figure 3)



CLINICAL STUDY PROTOCOL

Title:	The Acarbose Cardiovascular Evaluation (ACE) Trial. A Long-term, Multicentre, Double-blind, Randomised Parallel-group Trial to Determine Whether Reducing Post-prandial Glycaemia can Reduce Cardiovascular-related Morbidity and Mortality in Patients with Established Coronary Heart Disease or Acute Coronary Syndrome who have Impaired Glucose Tolerance.
Study Number/Version/Date:	[redacted]
Development Phase:	**Phase IV**

Figure 1: An illustrative representation of the Protocol



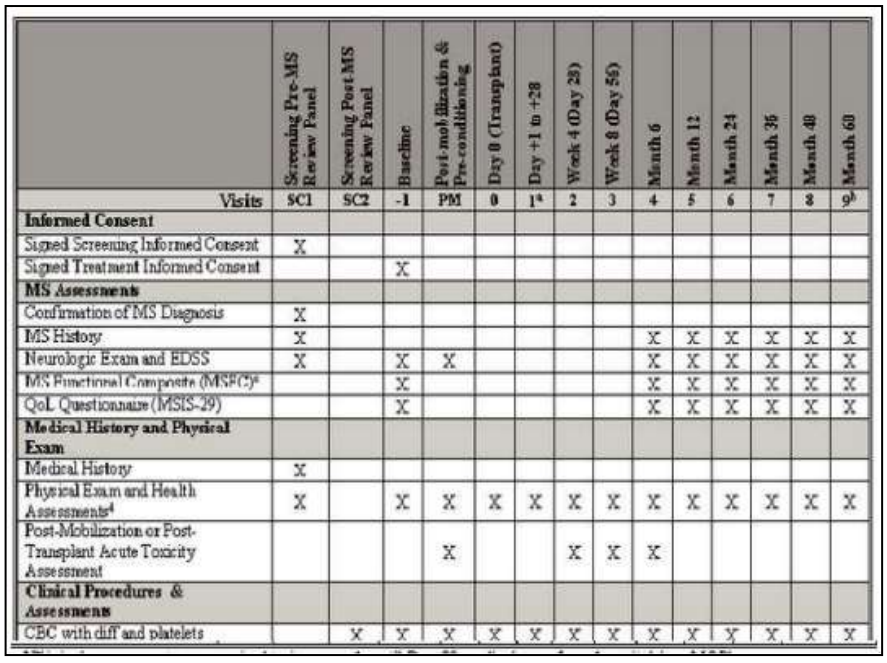
StudyDesign: Demographics (DM_1) [DM_UseCase1]

Demographics [DM_UseCase1]

1.*	Birth Date [Birth Date]	[BRTHDAT] [BRTHYR] Birth Year Req (2012-2014) [BRTHMO] Birth Month NReq
2.*	Sex [Sex]	[SEX] [A:F] Female [A:M] Male
3.*	Ethnicity [Ethnicity]	[ETHNIC] [A:HISPANIC OR LATINO] Hispanic or Latino [A:NOT HISPANIC OR LATINO] Not Hispanic or Latino [A:NOT REPORTED] Not reported [A:UNKNOWN] Unknown
4.*	Race [Race]	[RACE] [A:AMERICAN INDIAN OR ALASKA NATIVE] American Indian or Alaska Native [A:ASIAN] Asian [A:BLACK OR AFRICAN AMERICAN] Black or African American [A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER] Native Hawaiian or Other Pacific Islander [A:WHITE] White

Key: [*] = Item is required

Figure 2: An illustrative representation of the mock Demography Case Report Form



Visits	Screening Pre-MS Review Panel SC1	Screening Post-MS Review Panel SC2	Baseline -1	Post-mobilization & Pre-conditioning PM	Day 0 (Transplant) 0	Day +1 to +28 1[a]	Week 4 (Day 28) 2	Week 8 (Day 56) 3	Month 6 4	Month 12 5	Month 24 6	Month 36 7	Month 48 8	Month 60 9[b]
Informed Consent														
Signed Screening Informed Consent	X													
Signed Treatment Informed Consent			X											
MS Assessments														
Confirmation of MS Diagnosis	X													
MS History	X								X	X	X	X	X	X
Neurologic Exam and EDSS	X		X	X					X	X	X	X	X	X
MS Functional Composite (MSFC)[c]			X						X	X	X	X	X	X
QoL Questionnaire (MSIS-29)			X						X	X	X	X	X	X
Medical History and Physical Exam														
Medical History	X													
Physical Exam and Health Assessments[d]	X		X	X	X	X	X	X	X	X	X	X	X	X
Post-Mobilization or Post-Transplant Acute Toxicity Assessment				X			X	X	X					
Clinical Procedures & Assessments														
CBC with diff and platelets		X	X	X	X	X	X	X	X	X	X	X	X	X

Figure 3: An illustrative representation of the Events Schedule.

The design of the study build follows CRF design, programming Data Validation Checks and performing testing (User Acceptance Testing). The approach can also be customized based on study build specific needs.

CRF DESIGN

Most study builds start with the CRFs (eCRFs) design, i.e., the data elements or fields to be collected, their definition, valid response values, layout on the screen, and their organization into forms and visits. Likewise, the fields may differ from form to form, and the contents of forms may differ from visit to visit. Thus, eCRF design requires a thorough understanding of the relationship between data definition, grouping, layout, and data storage structure in the specific EDC system. When designing an eCRF, it is often not known what type of computer(s) will be used for data entry by the end-user.

The most basic function of EDC software is the ability to build and deploy web-based electronic forms for the entry of data and to

store the entered data. In most EDC systems, data elements are associated with a data collection structure when they are first added to the system. Common data collection structures in EDC systems include free text, many options for semi-structured text, radio buttons, dropdown lists, and checklists. The use of pre-defined answer choices such as those in radio buttons, checklists, and dropdown lists provides constraints during entry and free text fields allow the user easiness in data collection.

DATA VALIDATION CHECKS

Data Validation Checks which also known as Edit checks. Data validation checks are algorithms that are used to screen data for invalid, questionable, or anomalous values entered in the Case report forms. They are sometimes referred to as edit checks, query rules, or error checks. Data validation checks that identify problems as data are entered in EDC systems are also referred to as on-screen checks. Edit checks should be developed concurrently as part of the eCRF with the eCRF specifications. Edit checks in EDC can be classified into two broad categories, "hard" edits and "soft" edits. Soft edits identify discrepant data and usually prompt the site for data correction but allow the data to be confirmed as is and saved so that entry can continue. Whereas hard edit checks also identify discrepant data but prevent the identified data from being saved.

USER ACCEPTANCE TESTING

Data validation is the process of testing the validity of data into the system. A team of testers perform User Acceptance Testing. User testing with comprehensive test cases is recommended for EDC studies. UAT documents should include a UAT test plan, test scripts, findings log, a summary of issues and resolutions (e.g., UAT Summary Report), and lastly, a UAT approval form. The User Acceptance Testing are by entering dummy data into the system. Discrepancy is defined as a data point that fails to pass a validation check. Discrepancy may be due to inconsistent data, missing data, range checks, and deviations. In eCRF based studies, data validation process will be run frequently for identifying discrepancies. These discrepancies will be highlighted in the system and recorded in the finding log.

Figure 4: An illustrative representation of the UAT Process.

Study ID		System/Software Name		Name of Tester (Print)	
Form	Field	Script	Result	Comments (required for failure)	Initial & Date
Screening	History (has the subject had a heart attack in the last 5 years?)	If you click "Yes" a date field to enter the event date will appear.	❑ Pass ❑ Fail		

Figure 5: An illustrative representation of the Testing Results Log.

CONCLUSION

In the drug development process, the value report and data ensure the accurate drug evaluation and full fill the regulatory authorities' expectations for getting NDA approval from FDA. Data Capture and Data

Evaluation is essential for evaluating one or more interventions aimed at identifying or diagnosing a particular disease or condition. Due to the development of the information technology, data management assessment and evaluation became easy with quality data. Pharmaceutical companies and sponsor research are encouraging EDC tools for high-speed data capture, generation, and high-quality reports. Well-designed CRF offers the opportunity to minimize data processing. EDC system is one of the best tools for clinical trial data collection and data management. It enhances in monitoring and data management, saving time duration, minimal error and query rates, quick assessment, and reliable results.

Declaration by Authors

Ethical Approval: Not Applicable
Acknowledgement: None
Source of Funding: None
Conflict of Interest: The authors declare no conflict of interest.

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How to cite this article: Prashanth Kumar Alay. Delivering a clinical trial study build in an electronic data capture system for data collection. *Int J Health Sci Res.* 2023; 13(3):229-233.
DOI: *https://doi.org/10.52403/ijhsr.20230324*

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