

CompleteClinica [C2]

CompleteClinica is a web-based platform for the Clinical Trial Management System (CTMS). It is used to create, modify, maintain, archive, retrieve, and transmit clinical data intended for submission to the Food and Drug Administration (FDA). These data form the basis for the Agency's decisions regarding the safety and efficacy of new human and animal drugs, biologics, medical devices, and certain food and color additives. It facilitates protocol configuration, the design of Case Report Forms (CRFs), Electronic Data Capture (EDC), retrieval, and clinical data management. CompleteClinica follows the FDA Regulations defined in the Code of Federal Regulations (CFR), ICH GCP Guidelines and HIPAA Guidelines.

Key Benefits

- Centralized trial management database
- Easy and dynamic generation of CRFs
- Supports document attachments
- Generates custom reports
- Produces regulatory output compatible with CTD/eCTD
- Robust and scalable technology
- Supports resource sharing across studies in a secure and transparent
- Extensive tool for data query and retrieval
- Compliance with HIPAA privacy and security guidelines

Business Values

- Real-time sharing and collaboration
- Fewer resources required
- Competitive edge
- Compliance: HIPPA, eCTD, 21CFR Part 11
- Process control
- Communications and alerts
- Instant access of information
- Eliminate or minimize regulatory risks and process delays
- Increases credibility due to regulatory compliance
- Structured and unstructured information is organized and managed
- Enforces best practices for eCTD submission



Industries Served

- Pharmaceuticals
- Life Sciences
- Health Care
- Clinical Research Organization

Contact Us

SoluSoft, Inc.
300 Willow Street South
North Andover, MA
01845
Tel: (978) 681-6600
<http://www.solu-soft.com>

SoluSoft Technologies Pvt. Ltd.
A-704/705, Shapath IV
S.G. Highway
Ahmedabad-380051
Gujarat, India
Tel: (91) 79 - 30073211/12
<http://tech.solusofttech.com>

Key Features

Study Management:

This is an integral module of CTMS, acting as a backbone for clinical studies. Study management defines the guidelines of a study plan. Various aspects of study such as Arm, Site, Therapeutic Area, Indication, Research Organization, Ward, Contact, Organization, etc. are managed using this module.

Subject Management:

Participants of research are referred as Subject. It may comprise of patients or volunteers. This module is capable of managing the entire process of Subject Recruitment and Enrollment. All the subject details such as race, trait, etc. are maintained within the application.

Report Management:

Allows the generation of custom reports using data sets. Queries can be fed into the query builder. Reports can be in the form of tables or graphs. It also allows for subject tracking. The major types of reports generated are as follows:

- **Managerial Reports**
- **Administrative Reports**

Event Management:

The outcome of the study must be documented, both in case of Normal and Adverse Events. It allows eCRF Management. CRF can be created within the application and corresponding data is entered and maintained in CRFs.

User Management:

Clinical studies consist of several participants and stakeholders. This module allows for User Management and User Creation. Corresponding Roles and ACLs can be assigned to users. Functions such as task allocation, task scheduling, signature, etc. can also be performed.

Configuration Management

The Administration module provides various tools for application configuration. Functions such as Audit Trail, Log, Custom Field configuration, Document Attachment, etc. can be specified by the administrator.

