



TENALEA eCRF– electronic Case Report Forms for Clinical Trials

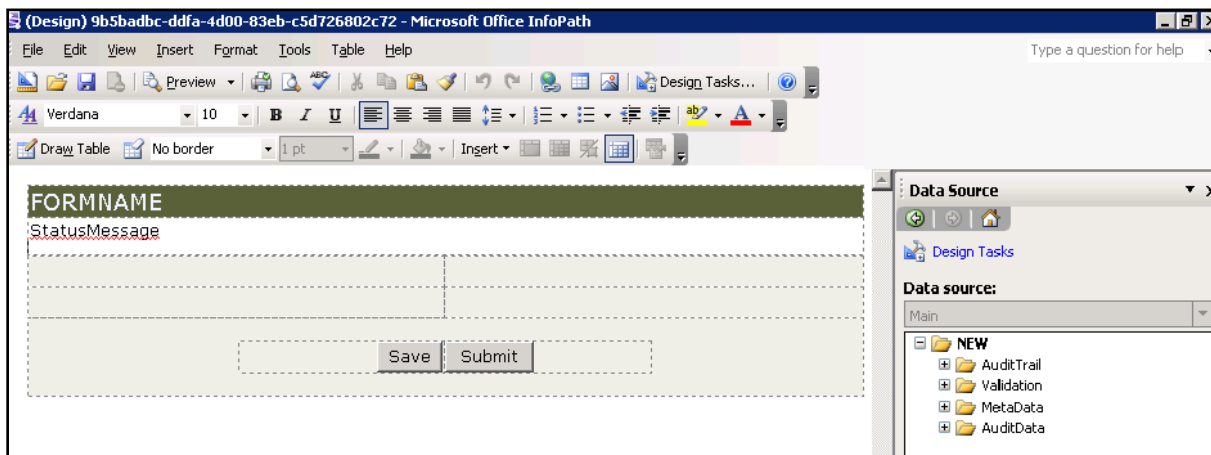
What is TENALEA eCRF?

TENALEA eCRF is an electronic Case Report Forms service for the data collection in clinical trials. It provides a comprehensive, user friendly forms service which can be used with a standard browser running on any computer connected to the internet. The system has been validated, and has been certified by registered auditors to be in compliance with regulation, such as the FDA's CFR 21 Part 11.

TENALEA eCRF was developed to meet the needs of four of the largest Data Centres for cancer trials in Europe and the current service draws on extensive operational experience amassed over the last decade. The current version is suitable for virtually any trial in health care. ALEA has been built as a series of industry grade components from Microsoft, which have been customized for the specific purpose of clinical trials data management. The components make use of a common standard representation of data and metadata: the Operational Data Model of CDISC. Within TENALEA eCRF, the components share a database for storing and retrieving information about the trial, and a separate database for storing and retrieving patient data. The components of TENALEA eCRF are described below.

Study Definition module

The Study Definition Module is a web browser application to design Case Report Forms, define patient visits, manage the participation of sites in trials, and manage information about the status of the trials. Microsoft InfoPath 2007 is integrated into the Study Definition module and provides a standard tool to design the Case Report Forms. Using the Study Definition Module, the Data Collection Items defined on the eCRF can be linked to standard dictionaries such as CTC 3.0 Toxicity Criteria.





The Study Definition Module holds a 'white list' for each trial containing the centres and investigators involved in the trial. This Module is also used to select and design the notifications that can be sent after an event occurs on a participant, such as inclusion of a new subject, adding a patient visit, completing an eCRF or changing data on an eCRF.

In order to facilitate the exchange of study metadata, the Study Definition module supports the import and export of CDISC Operational Data Model (ODM) files (www.cdisc.org).

Data Management Module

The Online Data Management Module is a web browser application that supports online completion of eCRF for healthcare trials. It requires initial login with a username and password, and subsequently provides a navigation menu for all trials to which the account has been granted access, and the selected investigators for which the account has been granted permissions to access eCRFs. This access may allow the user to complete all eCRFs, or may restrict the user access to viewing all or part of the eCRFs.

After completion of an eCRF, the user is prompted for an explanation of all data items which raised validation errors. This enables users to submit data with validation errors, yet providing a comprehensive audit trail in compliance with requirements from regulatory authorities. The Online Data Management Module contains tools to help people monitor and manage the trial. These include comprehensive reporting tools, audit tools, and tools for monitoring operational system components such as print, SMS and email queues.



Reporting options

TENALEA eCRF includes a comprehensive reporting service allowing for on demand, scheduled and triggered reports. For each study a number of standard reports is available, such as various accrual reports, forms overviews and patient overviews. In addition, for each study specific reports can be designed.

TENALEA eCRF reports can be accessed from the Data Management module. Notifications are reports generated and distributed based on specific events, such as the registration of a new subject. And finally, scheduled reports are generated and distributed based on a predefined schedule, such as a study accrual report sent out to all clinicians on the first day of every month.

Data Export

TENALEA eCRF support the worldwide standard CDISC SDTM format for data representation. This format is supported by all major statistical software packages. Study data export requires specific permissions and granted to specifically assigned users. These users may access the Data Management module, and may extract the current, most up to date study data at any moment during the clinical trial.

More information

For further information, please contact the TENALEA Information Desk at +31-20-512.2671 or email info@tenalea.net