ENHANCED DOCUMENTATION OF CASE REPORT FORMS

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Introduction

“Enhanced documentation” means adding detailed narratives of case reports and modifying forms and reports in many ways, frequently managed using Software packages.

Recently, we have begun to envision all study documentation, including the Manual of Operations, the database of Ocular Hypertension Treatment Study (OHITS), and the Electronic Case Report Form (eCRF). This document provides a brief overview of our efforts to date and a vision for the future of documentation. This document also outlines the study activity to be described.

We describe a model for incorporating in-documentation of study case report forms and sub-elements, including the study documentation. The model integrates the OHITS database and the eCRF. This model encompasses the implementation of the study overview and the study documentation. The documents are designed to provide comprehensive documentation of the study-related activity and detailed narratives.

The OHTS and Database Documentation matrix presents the documentation that is needed to construct, maintain, and analyze data. The matrix also provides specific documentation requirements and describes the documentation that is used in the database.

Menuing Access to Forms and Database Documentation

Annotating Forms

Our annotations are an important part of the documentation. Selecting a form in the navigation pane provides the ability to annotate the form on the screen. The annotation feature is also available on the form itself. Once the form is annotated, it can be saved and accessed at any time.

Detailed Variable Information Page

The detailed variable information page provides a detailed description of the variable, including its name, type, and other relevant information. This page can be used to understand the variable better and make decisions about how to use it.

Detailed Variable Information (Continuous variable available)

The detailed variable information page for continuous variables provides a detailed description of the variable, including its name, type, and other relevant information. This page can be used to understand the variable better and make decisions about how to use it.

Custom Form Library

Selecting “Custom Form Library” retrieves a custom form using the NOTES database. The custom form is then described in detail in the NOTES database. This form is provided by using eCRF in the form. The form is included in the database and can be accessed by users.

Custom Format/Library Sample Page

Selecting “Custom Format/Library Sample Page” retrieves a custom form using the NOTES database. The custom form is then described in detail in the NOTES database. This form is provided by using eCRF in the form. The form is included in the database and can be accessed by users.

Custom Format/Library Sample Page

Selecting “Custom Format” retrieves a custom form using the NOTES database. The custom form is then described in detail in the NOTES database. This form is provided by using eCRF in the form. The form is included in the database and can be accessed by users.

Disclaimer

This document is a work in progress. It includes concepts that have not been fully developed. The document is intended to provide an overview of the project. It is not meant to be an exhaustive guide. The document is subject to change and may be updated at any time.

Future Development

Potential future enhancements include dynamic, interactive links to XML for detailed database specifications.

Technologies Used

Technologies used include Adobe Acrobat Reader™, HTML, XML, and Microsoft Word.

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