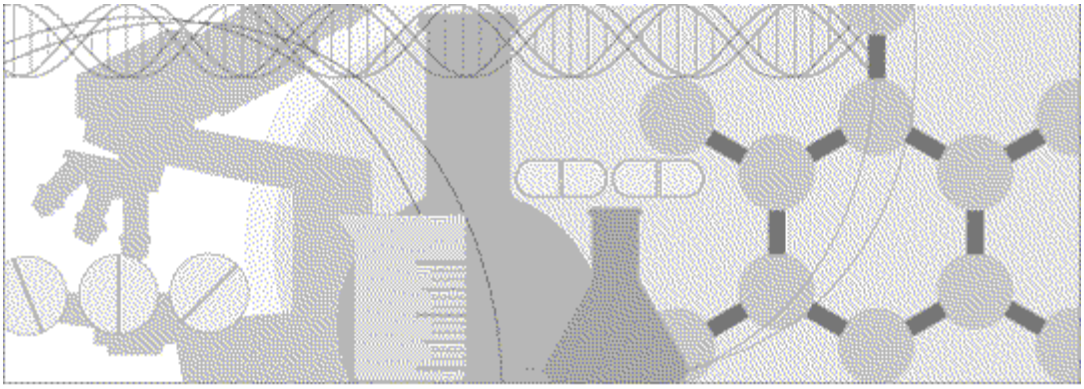
CIS Designer Guide

Clintrial Integration Solution
Release 4.6 SP0



ORACLE

DC-CIS46-002-000

Copyright © 2002 - 2015, Oracle and/or its affiliates. All rights reserved.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs, including any operating system, integrated software, any programs installed on the hardware, and/or documentation, delivered to U.S. Government end users are "commercial computer software" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, use, duplication, disclosure, modification, and adaptation of the programs, including any operating system, integrated software, any programs installed on the hardware, and/or documentation, shall be subject to license terms and license restrictions applicable to the programs. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.

Contents

About this guide vii

Overview of this guide viii
Audience viii
Prerequisites viii
Related information ix
Documentation ix
Training ix
If you need assistance xi

Chapter 1 CIS Overview 1

Integrating InForm and Clintrial software 2
About the InForm software 2
About the Clintrial software 2
Benefits of integration 3
About integrated studies 5
About integrated EDC-only studies 5
About hybrid studies 5
Integrated study workflows 6
Design environment workflow 6
Production environment workflow 6
CIS Administration application 8

Chapter 2 Planning an integrated study 9

Reviewing user scenarios 10
Developing study definitions for a hybrid study 11
Deciding where to develop rules and calculations or derivations 12
Comparison of Central Designer, Clintrial, and InForm rules 12
Options for EDC data validation 13
Validation and InForm enrollment 13
Planning data mappings 15
About data mappings 15
Planning bulk data loads 16
InForm Data Import utility 16
Clintrial Manage or Lab Loader module 16
Study component correspondences 17

Chapter 3 Working with integrated metadata 19

Using integrated study metadata 20
Creating a new hybrid study 20
Adding metadata to an existing integrated study 20
Modifying metadata in an existing hybrid study 20
Clintrial protocol metadata 21
Clintrial data record structure 21
Panel Types and context items 21
Corresponding Clintrial and InForm metadata objects 22
CONTEXT panel items 23
Metadata from an InForm study 25
Metadata in an integrated study 25
Metadata in a hybrid study 25

Data mappings 26
Data type conversions 26
Rules and derivations 28
Codelists 29
Codelists and synchronization 29
Installing a study in the InForm database 30

Chapter 4 Working with data mappings 31

Overview of data mappings 32
What are data mappings? 32
Data mapping components 32
Mapping data to the Clintrial software 35
Setting up Clintrial data transfer processing 35
Mapping considerations—InForm software to Clintrial software 35
Clintrial mappings 38
CIS mapping properties 38
Mapping date time controls—Principles 41
Working with mappings from the Central Designer software 43
Customizing Clintrial mappings 44
Autogenerated codelists and mapping definitions 44
CONTEXT panel mappings 45
Mapping date time controls 45
Creating mappings without a control path 45
Using page keys & block keys 46
Making panel property changes 47
Implementing Clintrial subsets 48
Creating a type 0 panel 48
Mappings and coding targets 49
Maintaining mappings 51
Updating enrollment mappings 51
Viewing data mappings in annotated study design 51

Chapter 5 Creating an integrated protocol 53

Overview of creating an integrated protocol 54
Integrated study development methodology summary 55
Designing with the Central Designer software 55
Clintrial study book autocreation option 55
Clintrial panel and item autocreation option 64
Configuring an integrated Clintrial protocol 66
Required item attribute 66
Rules and derivations 66
DEPPs 67
Page sections and page templates 67
Codelists, aggregated or unaggregated 67
Checklists 67
Panel audit start date 67
Updating a Clintrial protocol 69
Updated protocols and the Resolve module 69
Modifying updated protocols 69

Chapter 6 Entering data in an integrated study 71

Overview of entering data 72
Data transfer 73
Patient number changes and synchronization 74

Data entry in an EDC study 75
Screening and enrollment 75
Entering EDC data 75
Merging EDC data 75
Data entry in a hybrid study 76

Chapter 7 Managing queries and discrepancies 77

Overview of managing queries and discrepancies in an integrated study 78
What are queries and discrepancies? 78
How are queries and discrepancies created? 78
What are query and discrepancy states? 79
How are queries and discrepancies resolved? 79
Storage of query and discrepancy information 83
Queries and discrepancies on frozen or locked forms 84
Queries and discrepancies on an empty form 84
Reopening of automatically closed queries 84
Using rules in an integrated study 85
Effect of rule location 85
Validation and COMMIT statements 85
Managing rules and queries in a hybrid study 86
Duplicating rules 86
Design considerations for creating Clintrial rules for a hybrid study 86
Initial discrepancy status 86
CIS processing for updated rules and derivations 87
CIS processing for updated attachments to rules or derivations 88
Modifying rules to ignore EDC data 88
Placing queries on EDC items 89
Viewing merged query data 91

Chapter 8 Using Clintrial modules in an integrated study 93

Overview of Clintrial modules in an integrated study 94
The Clintrial software in integrated studies 94
Clintrial changes 94
Classify module 95
Omissions status 95
Solution types 95
Design module 96
Protocol design 96
Protocol import and export 96
Changing study mode 96
Enter module 98
Enrollment 98
Data entry 98
Manual discrepancies 98
Flags and notes 98
Lab Loader module 99
Managing queries on batch loaded data 99
Manage module 100
Global Change and Global Delete 100
Batch loading 100
Multisite Distribution module 101
Test environment for Multisite Distribution and CIS 101
Production environment for Multisite Distribution and the CIS software 101
Multisite Distribution and CIS workflow 102

Resolve module 104
Setting up Resolve to return EDC queries 104
Visibility of EDC queries 104

Index **107**

About this guide

In this preface

Overview of this guide viii
Related information ix
If you need assistance xi

Overview of this guide

The *CIS Designer Guide* describes how to design and develop an integrated study that uses the CIS software to transfer metadata and clinical data between an InForm study and a Clintrial protocol.

Audience

This guide is for clinical trial specialists who will be integrating Clintrial studies with InForm EDC capabilities or extending InForm EDC trials to Clintrial software. This includes the following people:

- Clinical study designers
- Application engineers
- Application programmers
- Database administrators
- Database designers
- Data analysts
- Project managers

Prerequisites

You should have experience in the following areas:

- Developing Clintrial studies with the Clintrial Design module.
- Developing InForm trials with the Central Designer software.

Related information

Documentation

In addition to the CIS documentation listed in the following table, the documentation for the following applications provides information about the software products used in a CIS environment:

- Clintrial software
- InForm software
- InForm Adapter software
- Central Designer software

Title	Description	Format
CIS Release Notes	• New features, fixed issues, hardware and software requirements, and upgrade considerations.	PDF. Available from the Phase Forward Download Center.
CIS Known Issues	• Known problems and workarounds (if available).	PDF. Available from the Phase Forward Download Center.
CIS Administrator Guide	• How to use the CIS administration tool (CIS Administration) to manage adapters, load-balanced machines, CIS protocols, and synchronization connections. • Troubleshooting, data transfer and storage, and key database tables.	PDF and HTML. Available from the CIS Administration user interface, the documentation CD, and the Phase Forward Download Center.
CIS Designer Guide	• Integrated study design considerations.	PDF. Available from the documentation CD and the Phase Forward Download Center.
CIS Installation Guide	• Hardware and software requirements. • Product interoperability considerations. • Procedures for installing, configuring, and upgrading the CIS Administration application.	PDF. Available from the documentation CD and the Phase Forward Download Center.
CIS online Help	• Application field definitions. • Procedures for using each page of the CIS Administration application.	HTML. Available from the CIS Administration user interface.

Training

In addition to the CIS training courses listed in the following table, the training courses for the

following applications provide information about the software products used in a CIS environment:

- Clintrial software
- InForm software
- Central Designer software

For information about the following training offerings for CIS, contact Phase Forward.

Title	Description	Format
Clintrial Integration Solution Training	Teaches clinical study specialists to create and manage integrated and hybrid studies using CIS, the Clintrial software, and the InForm software.	Instructor-led training.
Hosting CIS Integrated Studies	Teaches database, network, and web professionals to set up and manage integrated studies, as well as perform general troubleshooting.	Instructor-led training.

If you need assistance

If you are a Phase Forward customer with a maintenance agreement, you can contact the Global Support Center for assistance with product issues.

Your maintenance agreement indicates the type of support you are eligible to receive and describes how to contact Phase Forward. Additionally, the Phase Forward website lists the toll-free support number for your product, location, and support level:

```
http://www.phaseforward.com/support
```

In the event that our toll-free telephone service is interrupted, please use either of the following methods to contact the Global Support Center:

- Email

  customer.support@phaseforward.com

- Telephone

In the US:	781-902-4900
Outside of the US:	+44 (0) 1628 640794

Phase Forward also provides assistance with User Management, Site Assessment, and Provisioning. Please refer to your Master Services Agreement and individual Statement of Work to determine if you are eligible to use these services.

CHAPTER 1

CIS Overview

In this chapter

Integrating InForm and Clintrial software 2

About integrated studies 5

Integrated study workflows 6

CIS Administration application 8

Integrating InForm and Clintrial software

The Clintrial Integration Solution (CIS) software is an application that allows users to integrate the features of the InForm software and the Clintrial software in a complete environment for study development and execution.

About the InForm software

The InForm™ software is an integrated study management system that comprises:

- The InForm software, a web-based electronic data capture (EDC) tool for entering, monitoring, and cleaning data in an ongoing clinical study.
- InForm Reporting and Analysis, a reporting application, developed by Cognos Corporation, which has been customized and integrated into InForm software by Phase Forward.

With the InForm software, you can:

- Enter data remotely into study databases over the Internet.
- Clean and monitor study data.
- Review management and clinical data reports to track the progress of your studies and obtain previews of clinical data trends.
- Produce standard and ad hoc reports on clinical and study management data.

About the Clintrial software

The Clintrial software is a clinical data management system. The Clintrial software consists of a set of integrated modules that can be installed as needed. This modular approach enables you to design study protocols and then collect and manage clinical data according to the needs of your company's processes. The Clintrial software includes the following core modules.

Module	Purpose
Admin	System administration.
Design	Design and creation of the Clintrial database and the study books that you need to enter clinical data.
Enter	Interactive data entry.
Manage	Data management.
Retrieve	Clinical data access and extraction.

In addition to the Clintrial core modules, the following Clintrial extended modules add to the basic functionality of the core modules.

Module	Purpose
Classify	Resolution of omissions (coding failures).

Module	Purpose
Lab Loader	Batch loading of data with screening features not available in the Manage module.
Resolve	Resolution of discrepancies raised when rules run against clinical data fail. **Note:** The Resolve module contains functions that are required in an integrated study with the CIS software.
Multisite	Distribution of clinical data among multiple remote locations.

Benefits of integration

The CIS software enables the integration between the InForm and Clintrial systems. Using the CIS software, you can combine the benefits of both products into a single system for data entry, data management, and study archiving.

Study design and deployment

In a CIS environment, you can design a study using the Central Designer software.

As a result, you can:

- Reuse components in existing studies that were created using the Central Designer software, that are currently deployed with the InForm software.
- Deploy a completed study definition as:
  - A paper-based protocol in the Clintrial software.
  - An EDC study in the InForm software.
  - A study with both paper-based and EDC sites.

Data entry and validation

The CIS software enables you to:

- Transfer EDC clinical data from an InForm study database to tables in a Clintrial protocol database. Users enter data through a web browser by using the InForm software.
- Maintain both paper-based and EDC sites for the same study. Users enter data using either the InForm software (for EDC sites) or the Clintrial Enter module (for a paper-based workflow), and the CIS software transfers the EDC data to the Clintrial database.
- Validate EDC data by using rules created either with the InForm or with the Clintrial software. Users resolve EDC data queries in the InForm software, whether they originated from InForm or Clintrial rules.

Data coding

You can code data using the Central Coding application or the Clintrial Manage and Classify modules. In an integrated study environment with the CIS software, you can use the Clintrial modules with EDC data originating from the InForm software as well as with data originating from the Clintrial software.

Data loading

Both the Clintrial software and the InForm software provide tools for loading batch data such as lab results. In a CIS integrated study environment, you can batch load EDC data in either system (and batch load paper-based data only with the Clintrial tools).

In the Clintrial software, you can:

- Use the batch loading capabilities of the Manage module or the Lab Loader module to load EDC data into the Clintrial database and validate it.
- Resolve discrepancies on batch-loaded EDC data with the Resolve module.

If you prefer to use the InForm Data Import utility, you can:

- Use the InForm Data Import utility to load EDC data into the InForm study database.
- Validate the data by using the InForm user interface.
- Transfer the data to the Clintrial database.

Data storage and analysis

With the CIS software, you can use the extensive data retrieval and reporting features of the Clintrial software for both paper-based and EDC data.

About integrated studies

Studies that are performed using the InForm, Clintrial, and CIS software are integrated studies. Integrated studies are either EDC-only studies or hybrid studies.

About integrated EDC-only studies

In an integrated EDC-only study, users enter data using the EDC capability of the InForm software. Users log on to a study URL using a browser. Data is stored in an InForm study database on a remote server in the same way as in a nonintegrated study.

Users enter data through the InForm user interface defined in the study URL. Data stored in the study database then transfers, through a process called *synchronization,* to a Clintrial protocol database, where it is available for processing and analysis with Clintrial modules.

You can design an integrated EDC-only study to support data validation with:

- InForm rules, query processing, and resolution.
- Clintrial rules and InForm query processing and resolution.
- A combination of the validation processing from both systems.

About hybrid studies

A hybrid study supports data entry from both the InForm (EDC) and Clintrial (paper-based) environments. In a hybrid study:

- Data entered through EDC is stored in an InForm study database and then transferred to a Clintrial protocol database in the same way as in an EDC-only study.
- Data entered through the Clintrial software is stored only in the Clintrial protocol database.

You can design a hybrid study to support data validation with the following scenarios:

- Paper-based data is validated by Clintrial validation processing, and EDC data is validated with InForm validation processing.
- Paper-based data is validated by Clintrial validation processing, and EDC data is validated by both InForm and Clintrial validation processing.

Note: You cannot integrate a study in which data entry is all paper-based. (You cannot transfer data entered with the Clintrial Enter module into an InForm study database for visibility through the InForm user interface.) However, you can convert an all-paper-based study into a hybrid study and introduce the capability to enter data with either the InForm software or the Enter module.

Integrated study workflows

Design environment workflow

The CIS integrated design environment enables you to create study component metadata definitions by using the Central Designer software.

Designing with the Central Designer software

The following steps illustrate a typical integrated design scenario in which the Central Designer software is the primary design tool.

1 Using the Central Designer software, develop a study.

2 Using the Central Designer software, create a deployment package for the study.

3 Deploy the package to the InForm study database.

The deployment process installs the MedML metadata definitions and the CIS mapping definitions in the InForm study database.

4 Using CIS Administration, create a synchronization connection between the InForm study database and the Clintrial clinical database, and transfer the protocol component definitions to the Clintrial database through the synchronization process.

5 Using the Clintrial Design module, refine the protocol component definitions as needed to accommodate paper-based data entry.

For more information, see:

- ***Working with data mappings*** (on page 31) in the *CIS Designer Guide*.
- Central Designer documentation.

Production environment workflow

When study design and development are complete, use the CIS integrated production environment to:

- Test the flow of metadata and clinical data between the product components.
- Run a live integrated study.

The following steps illustrate a typical integrated production environment workflow:

1 Deploy the package to an InForm study database.

2 Create a synchronization connection between the InForm study database and the Clintrial clinical database, and transfer the protocol component definitions to the Clintrial database through the synchronization process.

3 Enter clinical data through the InForm software (storing EDC data in the InForm database) and through the Clintrial Enter module (storing the paper-based data in the Clintrial database).

4 Through a synchronization connection, and using data mapping definitions, transfer the study metadata and the EDC clinical data from the InForm study database to the Clintrial database.

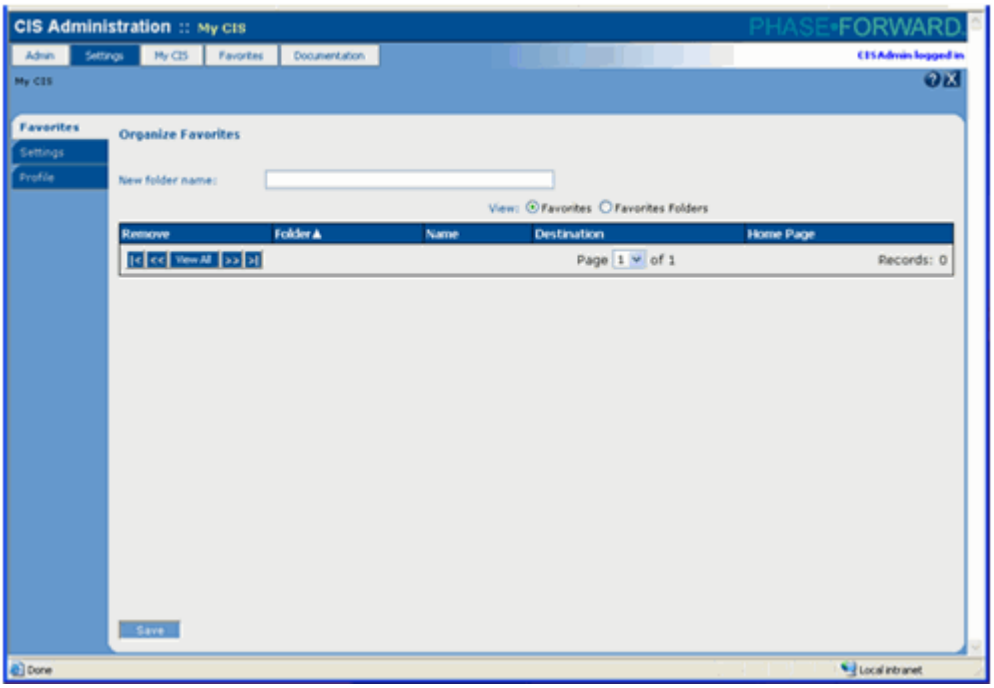
5 Validate entered data by running Clintrial or InForm rules:

- Resolve EDC data queries in the InForm software, whether they originate from rules within the InForm database or the Clintrial database.
- Resolve paper-based data discrepancies by using the Clintrial data validation modules.

6 Archive and manage study data in the Clintrial clinical data management system.

CIS Administration application

The CIS Administration application enables administrative users of the CIS software to manage synchronization connections, CIS users, and load-balancing machines.



CHAPTER 2

Planning an integrated study

In this chapter

Reviewing user scenarios 10

Developing study definitions for a hybrid study 11

Deciding where to develop rules and calculations or derivations 12

Planning data mappings 15

Planning bulk data loads 16

Study component correspondences 17

Reviewing user scenarios

You might want to develop an integrated study if:

- You plan to run an EDC-based study with the InForm software, but you want to take advantage of the coding and data analysis capabilities of the Clintrial software.
- You want to use the visual study design capabilities of the Central Designer software to develop your study, and you want to use the Clintrial database as your study data repository.
- You are running a paper-based study with the Clintrial software, and you want to add EDC-based sites.

This section discusses the issues you should take into consideration when planning an integrated study. For additional information on planning a study, see the following documentation:

- **InForm studies**—*Central Designer User Guide.*
- **Clintrial studies**—Clintrial *Admin and Design.*

Developing study definitions for a hybrid study

For hybrid studies, you will need to work with Clintrial design tools to resolve differences on conversion between the InForm software and the Clintrial software.

Deciding where to develop rules and calculations or derivations

You can develop data validation rules and calculations or derivations in any of the supported design tools.

Comparison of Central Designer, Clintrial, and InForm rules

Characteristic	Central Designer data-entry rules	Clintrial rules and derivations
Written in	Central Designer rule expression language, using the Rule Wizard.	PL/SQL.
Can make calls to	Predefined functions that are included in the Central Designer rule model, or user-defined functions. Central Designer rules can access numerous rule model properties and methods and can include predefined or user-defined constants.	Functions and procedures in PL/SQL packages that are provided with the software or created by the user. These functions include: • **Basic functions**—To investigate the structure of the database. • **String functions**—To manipulate string data. • **User-defined functions**—To use either in a specific protocol or for an entire instance. Instance-wide functions are available to all protocols.
Associated with	Study designs, study elements, study events, forms, and items. A data-entry rule can reference: • A study object and its children. • Properties and values of the study object and its children. If the data-entry rule is designed to generate a query or calculate a value, when a study is deployed to the InForm software, the deployment process creates the InForm structures that determine the item or items to be updated.	A panel within a protocol. Rules and derivations become part of the validation procedure of the panel. If a Clintrial rule fires and fails on EDC data, a query synchronizes back to the InForm software and attaches to an item in the InForm study. The CIS software determines the InForm item on which to place the query by using Clintrial Resolve error items. These items are ordered, and the CIS software evaluates each one in turn, placing the query on the first item that is mapped to a non-calculated InForm item.

Characteristic	Central Designer data-entry rules	Clintrial rules and derivations
Can be used to validate	EDC data only.	EDC or paper-based data, or both. **Note:** To use Clintrial rules and derivations in an integrated study, you must install the Clintrial Resolve module.

For more information, see:

- **Central Designer data-entry rules**—*Central Designer* guide *Working with Rules and Logical Schemas.*
- **Clintrial rules and derivations**—*Clintrial Reference Guide.*

Options for EDC data validation

You can validate paper-based data only with Clintrial rules and derivations. You can validate EDC data with:

- **Central Designer data-entry rules**—After Central Designer data-entry rules are deployed to an InForm study, they fire and update items like InForm rules and calculations. You should consider using Central Designer data-entry rules for EDC data validation if:
  - You desire immediate feedback on data entry.
  - You prefer the flexibility and ease of use of the Central Designer Rule Wizard, rule model, and rule expression language.
- **Clintrial rules and derivations**—When you attach a Clintrial rule to a panel holding an EDC data item, validation runs automatically when the data is synchronized from the InForm software to the Clintrial software. If the rule fails, the discrepancy generated by the Clintrial software synchronizes back to the InForm software as a Clintrial-originating query. Therefore, receipt of the query in the InForm software is not immediate but depends on the timing of synchronization. You should consider using Clintrial rules for EDC validation if:
  - Immediate feedback on data entry is not a priority.
  - You already have a suite of Clintrial rules developed for a paper-based study that you are extending to include EDC sites.
  - You have a library of standard rules based on Clintrial trials.
  - You prefer writing rules with PL/SQL.
- **Both InForm or Central Designer rules and calculations, and Clintrial rules and derivations**.

Validation and InForm enrollment

The InForm screening and enrollment forms process calculation rules but do not allow queries. If you use Clintrial rules and derivations on EDC data:

- Do not create discrepancies for screening and enrollment forms. During synchronization, CIS ignores error items for records in the enrollment table or for records that map to screening and enrollment forms. No queries based on Clintrial discrepancies are placed on screening and

enrollment forms.

- Create derivations for screening and enrollment forms, if needed. CIS installs the derivations into the Clintrial software, where they can populate items in Clintrial panels.

Validation runs on the enrollment panel when CIS moves data from the UPDATE to the DATA tables. (For the enrollment panel, validation runs against the DATA table, not UPDATE table.)

Planning data mappings

Data mappings define how study data in an InForm study is passed to specific table columns in a Clintrial database. Designing and implementing data mappings that meet your data transfer and reporting needs, and updating mapping definitions as necessary when metadata definitions change, are critical to the successful implementation of an integrated or hybrid study.

About data mappings

Mapping definitions specify:

- Where each mapped data point comes from in the source InForm study.
- The CONTEXT data appended to all Clintrial study data panels.
- The target panel and item in the Clintrial database that corresponds to each data point.
- Optional, supplemental text about the design of the components of the Clintrial mapping definition.
- Master-detail relationships.
- Subset items and values.
- Block key and page key values.

When deploying a study from the Central Designer software, you can create multiple mapping definitions and save them. Then, you can specify which set to use when:

- Deploying a package from the Central Designer software.
- Creating a synchronization connection in CIS Administration.

For information about using the Central Designer software to generate CIS-specific mapping definitions, see ***Working with mappings from the Central Designer software*** (on page 43).

Planning bulk data loads

If your study requires the loading of bulk data, such as lab values from an external source, consider the following available tools:

- InForm Data Import utility
- Clintrial Manage module
- Clintrial Lab Loader module

InForm Data Import utility

You can use the InForm Data Import utility to batch-load EDC patient data into an InForm study from which you can synchronize the data to a Clintrial protocol. The InForm Data Import utility enables you to batch-load new patients as well as data for patients who already exist in a study.

Note: You cannot use this tool to load paper-based data into a Clintrial protocol.

For information about the InForm Data Import utility, see the *InForm Utilities Guide*.

Clintrial Manage or Lab Loader module

You can use the Manage or Lab Loader modules of the Clintrial software for batch-loading of either paper-based or EDC data. To use these modules, the:

- Protocol must be defined as hybrid. For more information, see ***About hybrid studies*** (on page 5). Also see ***Changing study mode*** (on page 96).
- EDC patients for which you are batch-loading data must already exist in the Clintrial database through a previous synchronization from the InForm software.
- DB_ID values in the bulk data must match the DB_ID of the database instance.
- Resolve module must be installed to manage queries resulting from batch-loaded EDC data.

For information about these modules, see the following Clintrial documentation:

- *Manage, Classify, and Lab Loader.*
- *Enter, Resolve, and Retrieve.*

Study component correspondences

When developing an integrated study, it is essential to understand how the study components in the Clintrial software correspond to those in the InForm software.

For information about	See
Study components that make up InForm studies.	The Central Designer guide *Working with Study Objects*
Study components that make up Clintrial protocols.	*Clintrial Admin and Design*
• Correspondences between Clintrial and InForm study components. • Changes to study component definitions required when converting from one design environment to the other.	***Working with integrated metadata*** (on page 19)

CHAPTER 3

Working with integrated metadata

In this chapter

Using integrated study metadata 20

Clintrial protocol metadata 21

Metadata from an InForm study 25

Rules and derivations 28

Codelists 29

Installing a study in the InForm database 30

Using integrated study metadata

Study metadata used in an integrated study is the same as metadata used in an EDC-only study, with the addition of mapping information to link the InForm database objects to the associated Clintrial objects. When working with integrated study data, you must ensure that the InForm and Clintrial databases and the mappings between the two remain valid.

Creating a new hybrid study

For a new hybrid study, you can use the Central Designer software to create the trial and the CIS mappings, then create a deployment package. Deploying the package creates the metadata in the InForm database.

Use the Clintrial software to create a study that uses paper-based data entry. Data is entered with the Clintrial Enter module.

For more information, see ***Working with data mappings*** (on page 31).

If you create a hybrid study that uses both EDC and paper-based types of data entry, the resulting protocol requires modification of the display features in the Clintrial database to facilitate data entry with the Enter module.

Adding metadata to an existing integrated study

You can add new metadata objects to an existing integrated study. To add metadata, modify the study using the Central Designer software, then create a new deployment package and deploy it to the InForm database.

Modifying metadata in an existing hybrid study

After a study has been installed in an InForm database, you can modify metadata objects in an existing hybrid study. Changes to the metadata must be reflected in both the InForm database and the Clintrial protocol with which it is integrated. If you modify metadata objects, make sure that the Clintrial mappings remain valid.

Caution: **Avoid modifying mappings that are to be used with an existing Clintrial protocol, such as in a hybrid study. If you must modify these mappings, avoid creating conflicts, such as incompatible item data types.**

Clintrial protocol metadata

Clintrial data record structure

In Clintrial data records, clinical data is categorized to associate subjects (patients) with blocks (visits), blocks (visits) with page templates (forms), page templates (forms) with page sections (sections) and page sections (sections) with items (items). The Clintrial software uses *context items* and *system items* to perform this categorization and to uniquely identify clinical data records. In addition, the context and system items, alone or in combination with other Clintrial study object parameters, associate data items with Clintrial metadata objects and aid in the definition of default data mappings.

Context items

In the Clintrial software, context items identify a specific study object. Typical context items identify a subject (patient), block (visit), and page template (form). The typical context items and corresponding study objects in the InForm software are defined as follows.

InForm study object	CONTEXT item
Patient	Subject ID Item
Visit	Block Key Item
Visit Index (for repeating visits)	Block Repeat Key Item
Form	Page Key Item
Form Index (for repeating forms)	Page Repeat Key Item

System items

The Clintrial software automatically creates system items. For example:

- The **DB_ID** system item identifies the database instance that owns the clinical data record.
- The **CT_RECID** system item uniquely identifies each clinical data record.

For more information, see the *Clintrial Admin and Design* guide.

Panel Types and context items

The Clintrial software uses panels to represent the database tables that store clinical data. Panel types support the data entry activities for a protocol. Panel types, panel and page section attributes, and context parameters are determined during study design using the Clintrial Design module.

The following table lists the Clintrial panel types.

Panel type	Usage	Example
Type 0	Non-subject data	Lab normal ranges
Type 1	1 record per subject	Demography

Panel type	Usage	Example
Type 2	>1 record per subject	Previous Meds
Type 3	1 record per subject visit	Physical Exam
Type 4	>1 record per subject visit	Labs
Type 5	Subject enrollment	Enrollment

Corresponding Clintrial and InForm metadata objects

Clintrial study book attributes, context parameters, system parameters and various object properties correlate Clintrial metadata objects to corresponding InForm metadata objects.

Clintrial metadata object	InForm metadata object
Protocol (type 1 only - clinical data protocol)	Study.
Study book	Study version.
Page template	Form.
Page section (panel types 0, 1, 2, 3, 4)	Section.
Items	Item.
Derived item	Calculated control where the rule defined for the calculated control will reference the name of the DEPP.
Field label	Item question.
Repeating items	Itemset.
Codelist associated with an item (aggregated, unaggregated)	Radio group, checkbox group, or pulldown control, depending on the number of entries contained in the codelist and the options specified when importing the protocol.
Codelist associated with an item (view)	Single radio button with label text Empty View Codelist. The reference to the codelist is preserved in the properties for the item in the data mappings object.
Checklist associated with an item with Override attribute set	Radio group containing: • Pulldown control containing the choices of the checklist. • Text box labeled Other that accepts user input.
In-panel master-detail page section	Itemset.

Clintrial metadata object	InForm metadata object
Cross-panel master-detail page sections	Itemsets (many side) and items (one side) with panels and panel relationships defined through mappings
Date field, complete	Date field.
Date field, incomplete	String field.
Rule or derivations	Rule of type Clintrial Rule or Clintrial Derivation.

CONTEXT panel items

Within a CONTEXT panel, CONTEXT items identify a specific study object in the Clintrial software. Each Clintrial protocol has one CONTEXT panel, and the items in the CONTEXT panel are attached as columns in a panel's clinical data tables when the panel is installed. For more information, see ***CONTEXT panel mappings*** (on page 32).

For more information, see the *Central Designer* guide *Working with Rules and Logical Schemas*, in the chapter ***Grouping data with logical schemas***.

Default CONTEXT panel item names

In the Central Designer software, CONTEXT panel items have the following default names:

- PATNUM
- VISITID
- FORMID
- VISITINDEX
- FORMINDEX

In the Clintrial software, you assign CONTEXT item names when you create the context panel for a protocol. For example, the Medika Clinical sample study has the following CONTEXT panel item names:

- SUBJECT
- VISNO
- PAGENO
- VISRPT
- PAGERPT

Note the following implications of assigning CONTEXT item names:

- When you design a study with the Central Designer software, create a deployment package and deploy it to the InForm database, then synchronize the InForm study to the Clintrial software, the corresponding Clintrial protocol and panels are created automatically using the CONTEXT

panel item RefNames assigned in the mappings in Central Designer custom context panels.

- If you are running a hybrid study or an EDC study that includes components designed in both the Central Designer software and the Clintrial Design module, and the mappings do not match, data entered with InForm software and data entered with the Clintrial Enter module is stored in data tables with different column heading names. You must make sure that data selection for your reports takes this into account.
- If you will be synchronizing to an existing protocol, make sure that the CONTEXT items generated by the Central Designer software match the CONTEXT items in the existing protocol.

Additional CONTEXT panel items

In the Central Designer software you can specify mappings for the CONTEXT panel items, and in a hybrid study the synchronization process populates the corresponding page section CONTEXT items in the Clintrial Enter module with the default values resulting from the mappings.

The Clintrial Design module enables designers to define more CONTEXT panel items in addition to the ones handled by the Central Designer software. For example, you could create a CONTEXT item called PROTOCOL, which would contain the protocol name in each record. Since the Central Designer software does not automatically generate mappings and pass default values for additional CONTEXT panel items, users of the Enter module must manually enter the protocol name for each patient record.

If you want additional CONTEXT items to be populated for EDC patients, you can create a derivation on the CONTEXT panel in the Clintrial software to populate additional context panel items for EDC records.

Metadata from an InForm study

In an EDC-only or hybrid study, the InForm software uses synchronization to update metadata and clinical data in the Clintrial protocol. Synchronizing to the Clintrial protocol is performed through the InForm Adapter and Clintrial Adapter components of the CIS software. Each synchronization connection is associated, within CIS Administration, with a database instance and Clintrial protocol.

Synchronization connection properties in the CIS Administration application allow you to manage metadata changes after the initial synchronization is performed. For more information, see the *CIS Administrator Guide*.

Metadata in an integrated study

In an integrated study, the Clintrial protocol is used primarily to store, merge and analyze clinical data. Verified data enters the Clintrial UDPATE tables with status set to 0 (passed validation) or -1 (failed validation) using the EDC and synchronization capabilities of the InForm software. Rules identified with items in the Clintrial software generate InForm queries after synchronization is completed. These queries are resolved using the InForm software.

Although you do not typically define blocks (visits), page templates (forms) or page sections (sections) in an integrated study, these elements may exist in the Clintrial protocol. This situation could arise if you synchronized an integrated study to an existing Clintrial protocol rather than creating or updating a new protocol.

All instances of a form within an InForm study store clinical data in one Clintrial panel. Columns in the database table are required to associate the clinical data with a specific patient, visit and form. These columns in the database table consist of either of the following:

- InForm RefNames (subject, visit, form, visit index, and form index). This is the case if study metadata in the InForm software is not based on a Clintrial protocol created with the Clintrial Design module.
- Clintrial context items and system items. This is the case if study metadata in the InForm software is based on a Clintrial protocol in which context and system items are defined and synchronized to an existing or new Clintrial protocol.

  The InForm software may create metadata for items differently than would be the case with the Clintrial software. A checklist with override attribute set in the Clintrial software generates one item, while the InForm software generates two items by default.

  For more information, see ***Corresponding Clintrial and InForm metadata objects*** (on page 22).

  Complex controls in the InForm software can contain nested controls. The controls translate to items in the Clintrial software but the relationship between items is not defined.

Metadata in a hybrid study

In a hybrid study a Clintrial protocol is used to enter clinical data through the Clintrial Enter module as well as to store and validate clinical data through other Clintrial modules. In addition, users can enter validated data to the update table of the Clintrial software by using the EDC and synchronization capabilities of the InForm software. Rules identified with the items in the Clintrial software generate queries that are resolved using the InForm software. You can resolve discrepancies

on data entered through the Clintrial Enter module by using the Clintrial Resolve module.

Blocks, page templates, and page sections in the Clintrial protocol correlate to visits, forms and sections in the InForm study.

Because of minor functionality differences between the InForm and Clintrial design environments, it may be necessary to manage metadata in both environments.

Data mappings

Data mappings define how study data in an InForm study is passed to specific table columns in a Clintrial database. Designing and implementing data mappings that meet your data transfer and reporting needs, and updating mapping definitions as necessary when metadata definitions change, are critical to the successful implementation of an integrated or hybrid study. For more information, see ***Working with data mappings*** (on page 31).

Data type conversions

When you create mapping definitions from the InForm software to the Clintrial database, the data type of the target column should reflect the type of data you expect will be entered through the InForm interface. If the data type of data synchronized to the Clintrial protocol does not match the expected data type in the Clintrial item, the CIS software attempts to convert the data to the data type of that item.

The following table summarizes the data type conversions the CIS software can perform. Incoming (source) data types are listed across the top; target column data types are listed down the side. If the CIS software performs a particular data type conversion, the intersection of those data types is marked **Yes**. If the CIS software does not perform a particular data type conversion, the intersection of those data types is marked **No**, and the attempt to synchronize a piece of data to the target column fails.

Target column data type	Source data type					
	String	Integer	Float	Date	Date time	Date part (year, month, or day)
String	Yes	Yes	Yes	Yes	Yes	Yes
Integer	If no alpha characters	Yes	If all zeros after decimal point	No	No	Yes
Float	If no alpha characters	Yes	Yes	No	No	No
Date	No	No	No	Yes	Yes; time portion dropped	No

Target column data type	Source data type					
	String	Integer	Float	Date	Date time	Date part (year, month, or day)
Date time	No	No	No	Yes; time defaults to midnight	Yes	No

Rules and derivations

Rules of type Clintrial Rule or Clintrial Derivation run only in the Clintrial database once the protocol is recreated there. Similarly, rules of type Form Rule, Conversion, or Calculation run only in the InForm database.

If a rule exists in the Clintrial database, and you want to run an equivalent rule in the InForm database, you must use the Central Designer software to create an InForm rule that uses the same logic as the Clintrial rule.

Clintrial rules and derivations can include calls to functions and procedures in PL/SQL packages that are provided with the software or created by the user. These functions include:

- **Basic functions**—To investigate the structure of the database.
- **String functions**—To manipulate string data.
- **User-defined functions**—To use either in a specific protocol or for an entire instance. Instance-wide functions would be available to all protocols.

In a similar manner, InForm rules can call object methods provided with the Central Designer software that perform various functions. For more information, see the Central Designer guide *Working with Rules and Logical Schema*.

When replicating the behavior of a rule from one scripting language to the other, you must ensure that all functionality contained in outside functions or object calls is re-created in the new language.

Rules that run in the InForm database trigger real-time query messages for EDC data that are immediately visible to the InForm user. However, rules that are triggered by EDC data in the Clintrial database return delayed query messages to the InForm user according to the synchronization schedule. Therefore, it is recommended that as many rules as possible be implemented in the InForm database with Central Designer, rather than in the Clintrial database. For more information, see ***Using rules in an integrated study*** (on page 85).

For hybrid studies, if you want the same validation performed on EDC and paper-based data entry, duplicate sets of rules must exist in both databases unless you perform all validation by using Clintrial rules. If you design a hybrid study with duplicate sets of rules, each must have the proper rule type and use the correct script language. You can prevent an EDC data entry action from generating two queries through the use of the DB_ID parameter value. You can modify the Clintrial software to ignore EDC data - that is data with a DB_ID value of 9999. For more information, see ***Managing rules and queries in a hybrid study*** (on page 86).

Codelists

Codelists and synchronization

When you synchronize an InForm study to the Clintrial software, you can specify that you want the CIS software to generate codelists that correspond to InForm pulldown controls and radio group controls.

If you enable the Auto-Generate Codelists option in your synchronization definition, the CIS software generates a codelist for each InForm pulldown control or radio group control that meets the following criteria:

- The pulldown or radio group control is mapped to a Clintrial item.
- The pulldown or radio group controls have subcontrols that are defined as element controls (PFELEMENT tags in MedML). Each element control in a pulldown or radio group control becomes a codelist entry in the Clintrial software. The CIS software ignores subcontrols that are not defined as element controls, for example, text controls or nested radio, group, or pulldown controls.

If a Clintrial item has only one pulldown or radio group control mapped to it, the CIS software associates the codelist for the control with the Clintrial item. The same InForm pulldown or group control could be mapped to several Clintrial items. In this case, each of those Clintrial items can share the same codelist.

If the Clintrial item has multiple pulldown or radio group controls mapped to it, the CIS software creates the codelist only for that item. The codelist contains values from all of those pulldown or radio group controls, and no other Clintrial items can use it.

To define a synchronization connection and specify the setting of the Auto-Generate Codelists option, use CIS Administration. For more information, see the *CIS Administrator Guide*.

Installing a study in the InForm database

To install a study that was developed with the Central Designer software, create a Central Designer deployment package and deploy it to the InForm database. The deployment process installs study metadata in the InForm study database.

For more information about deploying a Central Designer study, see the Central Designer guide *Working with Study Objects*.

CHAPTER 4

Working with data mappings

In this chapter

Overview of data mappings 32

Mapping data to the Clintrial software 35

Clintrial mappings 38

Working with mappings from the Central Designer software 43

Customizing Clintrial mappings 44

Maintaining mappings 51

Overview of data mappings

What are data mappings?

Data mappings define how study data in an InForm study is passed to specific table columns in a Clintrial database. Designing and implementing data mappings that meet your data transfer and reporting needs, and updating mapping definitions as necessary when metadata definitions change, are critical to the successful implementation of an integrated or hybrid study.

Mapping definitions specify:

- Where each mapped data point comes from in the source InForm study.
- The CONTEXT data appended to all Clintrial study data panels.
- The target panel and item in the Clintrial database that corresponds to each data point.
- Optional, supplemental text about the design of the components of the Clintrial mapping definition.
- Master-detail relationships.
- Subset items and values.
- Block key and page key values.

When deploying a study from the Central Designer software, you can create multiple mapping definitions and save them. Then, you can specify which set to use when:

- Deploying a package from the Central Designer software.
- Creating a synchronization connection in CIS Administration.

For information about using the Central Designer software to generate CIS-specific mapping definitions, see ***Working with mappings from the Central Designer software*** (on page 43).

Note: Before you can synchronize an InForm study to a Clintrial protocol, you must install mappings into the InForm study by executing a Central Designer deployment package. For more information, see the Central Designer guide *Working with Study Objects*.

Data mapping components

When you generate a set of data mapping components, the following mapping components are created:

- CONTEXT panel mappings
- Data panel mappings
- Item mappings
- Control paths

CONTEXT panel mappings

Each Clintrial protocol has one CONTEXT panel. The items in the CONTEXT panel are attached

as columns in a panel's clinical data tables when the panel is installed.

In the Clintrial software, you assign CONTEXT item names when you create the context panel for a protocol. For example, the Medika Clinical sample study has the following CONTEXT panel item names.

CONTEXT panel item name	CONTEXT item
SUBJECT	Subject Item
VISNO	Block Key Item
PAGENO	Page Key Item
VISRPT	Block Repeat Key Item
PAGERPT	Page Repeat Key Item

The CONTEXT panel items created from the mappings have the following default names, established by the RefNames of the CONTEXT panel mapping definitions.

CONTEXT panel item name	Corresponding InForm study object	CONTEXT item
PATNUM	Patient number	Subject Item
VISITID	Visit	Block Key Item
FORMID	Form	Page Key Item
VISITINDEX	Repeating visit index	Block Repeat Key Item
FORMINDEX	Repeating form index	Page Repeat Key Item

Note the following implications of assigning CONTEXT item names:

- When you design a study with the Central Designer software, create a deployment package and deploy it to the InForm database, then synchronize the InForm study to the Clintrial software, the corresponding Clintrial protocol and panels are created automatically using the CONTEXT panel item RefNames assigned in the mappings in Central Designer custom context panels.
- If you are running a hybrid study or an EDC study that includes components designed in both the Central Designer software and the Clintrial Design module, and the mappings do not match, data entered with InForm software and data entered with the Clintrial Enter module is stored in data tables with different column heading names. You must make sure that data selection for your reports takes this into account.
- If you will be synchronizing to an existing protocol, make sure that the CONTEXT items generated by the Central Designer software match the CONTEXT items in the existing protocol.

PANEL mappings

In an automatically generated Clintrial mapping definition, each PANEL mapping definition corresponds to a panel in a Clintrial study and to a form in an InForm study. The RefName specified in a PANEL mapping definition is the panel name in the Clintrial protocol to which it is mapped.

In the Central Designer software, you can also create PANEL mapping definitions that do not correspond directly to an InForm form. For example, you can create a mapping definition that generates a type 0 panel for non-patient data that will be populated from within the Clintrial software. For more information, see the Central Designer guide *Working with Rules and Logical Schemas*, in the section ***CIS mappings for specialized Clintrial panels***.

ITEM mappings

Each ITEM definition in a set of automatically generated Clintrial mappings represents the correspondence between a panel item in the Clintrial software and a form item in the InForm software.

Control paths

A control path mapping definition consists of a concatenated string of RefNames identifying the InForm components that define the physical location of a data point in a study and in the InForm database. In mappings, a control path of a data point consists of its visit, form, section, itemset, item, and controls. The CIS software generates one control path per item.

Mapping data to the Clintrial software

To pass data to a Clintrial database, you must create mapping definitions that show how InForm study objects correspond to Clintrial objects.

Setting up Clintrial data transfer processing

Setting up data transfer to a Clintrial database involves the following steps:

1 Define Clintrial data mappings.

For more information, see the Central Designer guide *Working with Rules and Logical Schemas*, in the section ***Logical schemas and CIS mappings***.

2 Create a deployment package and deploy it to the InForm database.

3 Create a synchronization connection for data transfer. For more information, see the *CIS Administrator Guide*.

Mapping considerations—InForm software to Clintrial software

InForm metadata objects correlate to Clintrial metadata objects. The metadata correlation is performed by CIS server and it occurs as part of the synchronization process. CIS synchronization correlates study structure elements (visits, forms, sections, etc.) if the corresponding metadata (blocks, page templates, page sections, etc.) exist in the Clintrial protocol. The metadata translation always correlates panel and item mappings during synchronization.

Mapping definitions specify how InForm metadata objects correlate to Clintrial metadata objects. The following table describes considerations to be aware of when mapping metadata from an InForm study to a Clintrial protocol in a hybrid study.

For more information, see the Central Designer guide *Working with Study Objects*, in the section ***Central Designer and InForm study component correspondences***.

InForm metadata	Considerations
Association	Associations between forms have no direct corollary in the Clintrial software.
Checkbox group	Maps to a single item for each check box and one additional item for each Other field associated with a check box.
Date field	The following options are available for mapping date fields: • You can specify whether to map a complete InForm date component to a Clintrial date field, individual fields, or both. • You can specify whether to map an incomplete InForm date component to a single Clintrial string field, individual string fields, or both. • If you split the individual parts of the date into separate columns in the Clintrial database, you can choose whether to map them to text or fixed data types.

InForm metadata	Considerations
Design note	The definition of any type of study component can include design notes. These design notes are not translated to the Clintrial protocol. However, when generating mappings for InForm items, the mapping generator populates the Design Note property of the CTITEM mapping definition with the text of the Question property of the item. This value is inserted into the Description field for the Clintrial item.
Form	Maps to a Panel. Special mapping considerations apply if page templates are not unique within the study book**.** For more information, see ***Using page keys and block keys*** (on page 46).
Item	Maps to a Clintrial item. Use the Central Designer Properties browser to set an item as required.
Item question	Maps to a field label (hybrid study only; metadata element may not be defined in an EDC-only study).
Itemset	Each item within an itemset maps to a single item within the panel.
Pulldown control	Maps to a single item within the panel. The item stores the string value associated with the pulldown control.
Radio button	Maps to a single item within the panel. The item stores the numeric value associated with the radio group. The mapping generator automatically calculates the maximum string length of each radio group control.
Radio group/Pulldown consisting of a group of radio buttons or a drop down list and one or more Other fields.	Maps to one item representing the radio group or pulldown list and an additional number of items representing the Other fields.
Repeating form	Corresponds to a single panel with items. The FormIndex value in the Clintrial database table holds form instance information (numeric value).
Repeating visit	Single panels, that comprise forms within visit, contain a VisitIndex value. The Clintrial database table (panel) holds visit instance information (numeric value).
Required item	Items marked as required in the Central Designer software do not translate to required items in the Clintrial software. To force an item to be required in the Clintrial software, set the Item Required property for the item to True in a mapping definition.

InForm metadata	Considerations
Rule	Corresponds to a rule or derivation in the Clintrial software. Rules are maintained separately in the InForm software and the Clintrial software, but the rules created in each application can affect data in the other. Clintrial rules and derivations can run against EDC data in the Clintrial protocol database. For more information, see ***Rules and derivations*** (on page 28).
Section	An InForm section is not related to a Clintrial page section. An InForm section has no corresponding Clintrial element.
Study version	Corresponds to a study book, but CIS does not convert an InForm study book to a Clintrial study version..
Study (Trial)	Corresponds to a protocol (Type 1 - or clinical data protocols - only).
Unit	Controls can be assigned a units property. The units information is not transferred to the Clintrial protocol.

Clintrial mappings

You can create mappings for all objects in an integrated study. You can always modify the mappings after they are initially created.

CIS mapping properties

Use the following custom properties for CIS mappings to specify how the data that is passed from the InForm software should be used in the Clintrial software. The custom properties have default values or are required only when you want to support specific Clintrial software features, such as master-detail panel relationships.

Study object	Option	Description
Study event	Block Key Value	Value of the Clintrial block key. If you specify this value, it overrides the study event RefName as the block key.
Form	Page Key Value	Value of the Clintrial page key. If you specify this value, it overrides the form RefName as the page key.
Data set	Detail Key Item	Name of the item identified as the detail key item, if the panel definition is part of a detail page section.
	Detail Panel	True or False (default), indicating whether the panel definition participates in a detail page section in a master-detail relationship. A master-detail relationship is a relationship between two page sections on a study page, in which each record in one page section (the master page section) can have one or more associated records in the other section (the detail page section). During data entry the displayed records in the detail page section are associated with the selected record in the master page section.
	Master Item	Name of the item on the master panel that corresponds to the detail key item specified in the Detail Key Item property. This property applies only if the value of the Detail Panel property is True.
	Master Panel	Name of the master panel with which this panel definition participates in a master-detail relationship. This property applies only if the value of the Detail Panel property is True.

Study object	Option	Description
	Panel Type	A specification of how the database tables associated with the panel are structured: • **Panel Type 1**—One record per subject, collected once during the study. • **Panel Type 2**—Multiple records for each subject, collected once during the study. • **Panel Type 3**—One record per subject, collected at multiple visits. • **Panel Type 4 (default)**—Multiple records for each subject, collected at multiple visits. • **Context Panel**—One record containing custom context items that are associated with each record in a clinical data table. Use this type to specify a custom context panel. • **Enrollment Panel**—One record of enrollment data for each enrolled subject. • **Non-Patient Data**—Data not related to a study subject, for example, lab normals or standard coding thesauruses.
	Protected	True or False (default), indicating whether access rights to the panel are limited in the Clintrial software.
	SAS Name	Name of the panel when data is sent to SAS through the Clintrial SAS interface. OPTIONAL; if entered, the name must be 8 characters or fewer and conform to SAS naming requirements. **Note:** Panel SAS names must be unique within a protocol.
	Verifiable	True or False (default), indicating whether double-entry of data in panel items is required for verification.
Data series	Checklist	Name of a Clintrial checklist associated with the item. A checklist is a type of codelist used to view suggested entries for a field. The checklist name must be 20 characters or fewer. Checklist and CIS Codelist are mutually exclusive properties.

Study object	Option	Description
	CIS Codelist	Name of a Clintrial codelist associated with the item. A codelist encodes entered values. The codelist name must be 20 characters or fewer. Checklist and CIS Codelist are mutually exclusive properties. **Note:** When CIS synchronization processes mapping definitions and autogenerates codelists, it does *not* autogenerate codelists for items that have a value in the Code List property. The CIS Codelist property refers to an existing codelist. Therefore, if you want CIS to autogenerate a codelist for an item, leave the Code List property blank.
	Context Type	Specifies the usage of a user-defined context item: • Not a context item (default). • Subject-related context item. • Visit-related context item. • Page-related context item. • Other context item.
	Copy With Panel	True (default) or False, indicating whether the item should be included with the panel if the panel is copied.
	DB Format Float Precision	Number of characters that can be added after the decimal place in an item with a type of FLOAT. This value can be a number between 1 and 15. The default is 10.
	DB Format Length	Number of characters that can be entered in this item. The default is 2000 for text items, 18 for numeric items.
	Derived	True or False (default), indicating whether the value of the item is determined from a derivation associated with the panel.
	Is Key	True or False (default), indicating whether the item mapped to the data series is a subject key, block key, block repeat key, page key, or page repeat key item in the context panel.
	Item Required	True or False (default), indicating whether the item is required.
	Key Order	The order in which the item appears in the concatenation of key items, if the item is part of the panel's key. 0 (not a key item) is the default.
	Max	Maximum value that can be entered for the value of the item.
	Min	Minimum value that can be entered for the value of the item.
	Repeated	True or False (default), indicating whether an item is one for which multiple values can be entered within a page section.

Study object	Option	Description
	SAS Name	Name of the item when data is sent to SAS through the Clintrial SAS interface. OPTIONAL; if entered, the name must be eight characters or fewer and conform to SAS naming requirements. **Note:** Item SAS names must be unique within a panel.

Mapping date time controls—Principles

How CIS synchronizes date time data to Clintrial database columns depends on how you define the controls and how you define the mappings for the controls in the Central Designer software.

The combination of these specifications provides flexibility in the storage of date time data in the Clintrial database. This section describes:

- Clintrial data types used for mapping date time data.
- Differences in how CIS handles complete and partial date time data, and how to define controls that CIS will consider complete.

The following table describes the Clintrial data types that are used for date time data.

Clintrial data types for dates	Description
DATE	This data type holds a complete date, including month, day, and year. The DATE data type corresponds to the Oracle DATE database format. If you map a complete InForm date time including hours, minutes, seconds to a DATE data type, CIS drops the time portion from the date time when synchronizing.
DATETIME	This data type holds a complete date time, including month, day, year, hour, minute, and second. The DATETIME data type corresponds to the Oracle DATE database format.
FIXED	This data type is an integer, corresponding to the Oracle NUMBER(xx) database format.
TEXT	This data type is a string, corresponding to the Oracle VARCHAR2(n) database format.

When synchronizing date time data to Clintrial, CIS considers it to be complete or partial:

- **Complete**—A date or date time in which all parts are certain to be present. By default, CIS maps a complete date to a Clintrial DATE data type, and maps a complete date time to a DATETIME data type.

To ensure that CIS considers a date time control complete and synchronizes it as a single data item to a DATE or DATETIME column, you must define the control with the Required property set to "True" for all relevant date time parts:

  - For a complete *date*, set the Required property to True for the Month, Day, and Year date time parts.
  - For a complete *date time*, set the Required property to True for all date and time parts.

- **Partial**—All other dates, times, or date times.

  If you define any part of a date time control with the Unknown property set to "True," allowing users to specify UNK as a value of the date time part, CIS treats the control as a partial date, time, or date time.

You can map complete or partial date time controls to any of the following:

- A single Clintrial database column.
- A separate Clintrial database column for each date time part.
- A column for the whole control and a column for each part.

For more information, see the Central Designer guide *Working with Rules and Logical Schema*, in the section ***CIS mappings for date time items***.

Working with mappings from the Central Designer software

When you develop a study with the Central Designer software, you can use a logical schema to generate Clintrial mapping definitions for processing by CIS. (In the Central Designer software, these mapping definitions are called CIS mappings.)

When you create a deployment package and choose one or more logical schemas to use to create CIS mappings, the following mappings are created:

- Each data set becomes a panel, and each data series becomes an item in the panel.
- A custom data dimension on a data set is mapped to the Subset Item in the Clintrial software. Only one custom data dimension is supported for each data set.
- The Panel Type is defined by the value of the Panel Type CIS custom property on the data set.
- Other panel and panel item attributes are defined by the values of CIS custom properties on the study event, form, data set, and data series.
- Only normalized values mapped to the Clintrial software.

For more information, see theCentral Designer guide *Working with Rules and Logical Schemas*.

Customizing Clintrial mappings

Mapping definitions enable you to store data in specific ways in the Clintrial software or to enable Clintrial features through synchronization. The following study component specifications can require mapping customizations:

- Autogenerated codelists.
- CONTEXT panel.
- Date time controls.
- Mappings without a control path.
- Item order in a panel.
- Page keys and block keys.
- Panel properties.
- Subsets.
- Type 0 panels.
- Visits and forms.

Autogenerated codelists and mapping definitions

Note: This feature is available for single language trials.

To autogenerate codelists, the CIS software checks:

- The Code List property of an InForm mapping definition for a Clintrial item.
- New mapping definitions for a pulldown or radio group control.

Autogenerated codelists and the Code List property

In the Central Designer software, when you specify CIS mapping properties, you can specify the name of an existing Clintrial codelist as the target for the data in the item that is being mapped.

When CIS synchronization processes mapping definitions and autogenerates codelists, it does *not* autogenerate codelists for items that have a value in the Code List property, as the Code List property is intended to refer to an existing codelist. Therefore, if you want CIS to autogenerate a codelist for an item, leave the Code List property blank.

Autogenerated codelists and new mappings

When CIS synchronization processes a new mapping definition for autogenerating codelists, it does the following:

- Ignores the mapping definition if the synchronization connection is configured not to autogenerate codelists.
- Ignores the mapping definition if the Code List property of the item has a value.
- Determines which Clintrial codelist to use for the item:
  - If the item has only one pulldown or radio group control mapped to it, CIS creates a codelist if it does not yet exist and attaches the new or existing codelist for that control to the Clintrial item.
  - If the item has multiple pulldown or radio group controls mapped to it, CIS creates a codelist if it does not yet exist.

CONTEXT panel mappings

Context panel item updates

You can change the definition of a CONTEXT panel item by changing its mapping definition in the Central Designer software. Because CONTEXT panel items are appended to all Clintrial data tables, you change only the panel item definition. Changes must follow the standard rules for changing item definitions:

- The new item definition must have the same TYPE property as the previous item
- If you change the item size, you must change it to a larger size.
- When the CIS software receives a valid new CONTEXT panel item during synchronization, it applies the definition to all panels in the Clintrial protocol.

For more information, see the Central Designer guide *Working with Rules and Logical Schemas*, in the section ***CIS mapping properties***.

Mapping date time controls

You can set up CIS mappings for date time items so that:

- The entire data appears in a single database column in the Clintrial database.
- Each date time part appears in a separate database column in the Clintrial database. To split mappings for a date time item into date part components, you define a separate data series and mapping for each date part. The mappings that the Central Designer application generates include the DATEPART attribute of the CTITEM tag.

For more information, see the Central Designer guide Working with Rules and Logical Schema, in the section ***Setting up CIS mappings for date time items***.

Creating mappings without a control path

If you do not map specific items to a data series, the values of the key items are derived from the control path of each InForm transaction as it is processed. The Central Designer software generates

panel mappings for data sets where the data series is created. The item mappings for the Clintrial panel have no control path specifications.

Make sure that items that you create in the Clintrial software do not get their values from items in the InForm software.

For more information, see the Central Designer guide *Working with Rules and Logical Schemas*, in the sections ***Creating a custom Clintrial context panel*** and ***CIS mappings for unmapped items and no items in a data series***.

Using page keys & block keys

Block keys and page keys in CIS mappings

Block keys are identifiers for Clintrial blocks, which correspond to Central Designer study events and InForm visits. Page keys are identifiers for Clintrial pages, which correspond to Central Designer and InForm forms. All data that is synchronized to the Clintrial software must have a block key and a page key associated with it. The context panel in a Clintrial study contains items that hold the values of the block key and page key. These items are called the block key item and the page key item.

In the Central Designer application, the data series in the data set that marked as the context panel (the value of the Panel Type custom property is Context Panel) identify the block key item and the page key item.

How block key values are assigned

Any of the following definitions can be used as the value of the block key item:

- By default, the RefName of the study event.
- If the RefName of the study event contains a double underscore (for example, Week2__21), the value that follows the double underscore.
- The Block Key Value custom property for the study event. If a value is specified for the Block Key Value custom property, that value overrides the block key value formed from all or a part of the RefName.

For common visits, the value of the Shared Form Block Key custom property on the study design becomes the value of the block key in mappings for the internal visit definition (the CommonCRF visit) that the InForm software requires for common forms.

The resulting block key value must conform to the specifications of the data series for the block key item in the context panel:

- The data type must convert to a compatible data type.
- The length must be within the length specified in the DB Format Length CIS custom property.
- If the data type of the data series is float, the precision must be within the precision specified in the DB Format Float Precision CIS custom property.

For example, validation fails if:

- The block key value is First but the block key item has a type of Integer.
- The block key value is 99 but the page key item has a Length of 1.

How page key values are assigned

Any of the following definitions can be used as the value of the page key item:

- By default, the RefName of the study form.
- If the RefName of the study form contains a double underscore (for example, Hema__21), the value that follows the double underscore.
- The Page Key Value custom property for the study form. If a value is specified for the Page Key Value custom property, that value overrides the page key value formed from all or a part of the RefName.

The resulting page key value must conform to the specifications of the data series for the page key item in the context panel:

- The data type must convert to a compatible data type.
- The length must be within the length specified in the DB Format Length CIS custom property.
- If the data type of the data series is float, the precision must be within the precision specified in the DB Format Float Precision CIS custom property.

For example, validation fails if:

- The page key value is First but the page key item has a type of Integer.
- The page key value is 99 but the page key item has a Length of 1.

Making panel property changes

After a panel is installed in the Clintrial software, you can change the following properties by marking the panel for revision in the Design module:

- SAS Name
- Validation Priority
- Verify
- Protected
- Description

To change the panel definition, use the Central Designer software to make changes to the panel mapping properties, create a new deployment package, and deploy it to the InForm software.

Running a CIS synchronization updates the Clintrial software.

Panel properties you can change

You can change the following Clintrial panel properties through CIS synchronization.

- SAS Name
- Verify
- Protected
- Description

Implementing Clintrial subsets

When subsets are used in the Clintrial software, one item in a panel is designated as the subset key item. The value of the subset key item determines the record in which to store a set of subset data.

In the CIS mappings generated by the Central Designer application:

- The panel (CTPanel) mapping definition identifies the subset key item. The Central Designer application obtains the name of the subset key item from the name of a custom dimension defined on a data set. An unmapped item with the name of the custom dimension is added to the mappings for the panel and becomes a column in the panel when synchronized to the Clintrial software.

The item (CTItem) mapping definitions hold the subset value (the value of the subset key item). The Central Designer application obtains the subset value from the custom dimension label that you associate with an item when you map it to a data series within the data set.

For more information, see the Central Designer guide *Working with Rules and Logical Schemas*, in the section: ***Setting up mappings for a Clintrial subset***.

Creating a type 0 panel

A non-patient data panel (Type 0 panel) contains data that is not related to a particular subject or visit. The data series in a non-patient data set must not have any items mapped to them.

For more information, see the Central Designer guide *Working with Rules and Logical Schema*, in the section ***Creating a non-patient data (Type 0) panel***.

Mappings and coding targets

To enable Clintrial coding to function correctly, CIS does not allow synchronized data to update any part of a coding target except the verbatim. When you create Clintrial mappings, make sure that the mappings do not point to any coding items or Central Coding targets.

When receiving mappings or data, CIS rejects mappings or transactions for which the target is any part of a Clintrial coding target other than the verbatim. The value is not placed in the destination field. The CIS software writes a warning to the Event Log to notify you of the issue, and continues the synchronization process.

For Clintrial coding using the Manage module, CIS disallows writing to the following items in the CTSDD.ENCODING_TARGET table:

- CODE1_ITEM
- CODE2_ITEM
- CODE3_ITEM
- WORKFLOW_ITEM
- USER_ITEM
- DATE_ITEM
- AUTO_MATCHES_ITEM
- AUTO_STEP_ITEM
- LANGUAGE_ITEM
- NORMAL_TEXT_ITEM

Correcting a synchronization that generates warnings because of mapping to a Clintrial coding target

If a synchronization generates a warning because CIS has rejected mappings or data designated for a Clintrial coding target, use the following workarounds.

Scenario	Workaround - do one of the following actions
CIS rejects initial mappings on a new synchronization connection.	• In CIS Administration, remove the synchronization connection, and create a new synchronization connection to a new Clintrial protocol that does not have the coding target that causes the mappings to be rejected. • In the Clintrial software, remove the coding target that conflicts with the mapping.
CIS rejects new mappings created after a protocol has been synchronized.	• In CIS Administration, edit the transaction with the mappings. • In the Clintrial software, remove the coding target that conflicts with the mapping.

Scenario	Workaround - do one of the following actions
CIS rejects a data transaction that includes data mapped to a Clintrial coding target.	• In CIS Administration, edit the transaction that has data mapped to a coding target. • In the Clintrial software, remove the coding target that conflicts with the mapping.

Maintaining mappings

Updating enrollment mappings

Before any patients are enrolled in a study, you can update mappings to the enrollment panel as you would to any other.

After patients are enrolled, if you change the mappings to the enrollment panel, subsequent synchronizations of enrollment data reflect the new mappings, but previously synchronized enrollment data does not. This is because the Clintrial software does not allow changes to enrollment data.

If you try to capture pre-existing enrollment data with new mappings by configuring the synchronization connection to replay transactions when a new transaction is received (using the **Replay Sync to gather pre-existing data** synchronization option for new mappings), synchronization stops when the CIS software tries to update the enrollment panel.

To enable synchronization to proceed, you can change the new mappings option for the synchronization connection to **Assume no pre-existing data** and re-synchronize.

Viewing data mappings in annotated study design

In the Central Designer software you can generate an annotated study book. For more information, see the Central Designer guide *Working with Study Objects*, in the section ***Working with projects, studies, and libraries***.

CHAPTER 5

Creating an integrated protocol

In this chapter

Overview of creating an integrated protocol....54

Integrated study development methodology summary....55

Configuring an integrated Clintrial protocol....66

Updating a Clintrial protocol....69

Overview of creating an integrated protocol

Using the CIS application, you can create a Clintrial protocol through the CIS software from integrated metadata and then perform the additional configuration required for EDC and hybrid integrated studies.

The first time that synchronization occurs in an integrated clinical study, the study metadata and mapping information are sent with the data to the Clintrial server. If a protocol for the study does not exist, it is automatically created. During subsequent synchronization transactions, updates to both metadata and clinical data are automatically propagated to the existing Clintrial protocol, along with audit and query information.

Note: The CIS software cannot delete a Clintrial protocol.

Integrated study development methodology summary

You can design an integrated study by using the Central Designer software, the Clintrial Design module, or a combination of the two. Consider the following study development guidelines:

- Design the user interface in the environment in which you have the most expertise or in which there are existing components to leverage first.
- Make sure you understand the conversion issues surrounding each type of study component. For information, see the following resources:
  - ***Working with integrated metadata*** (on page 19).
  - *Clintrial Admin and Design*.

The following sections summarize study development steps for integrated studies developed by using the Central Designer software and by using the Clintrial software. For information about the decisions and actions required at each step, see the referenced documentation.

Designing with the Central Designer software

The following steps illustrate a typical integrated design scenario in which the Central Designer software is the primary design tool.

1 Using the Central Designer software, develop a study.

2 Using the Central Designer software, create a deployment package for the study.

3 Deploy the package to the InForm study database.

The deployment process installs the MedML metadata definitions and the CIS mapping definitions in the InForm study database.

4 Using CIS Administration, create a synchronization connection between the InForm study database and the Clintrial clinical database, and transfer the protocol component definitions to the Clintrial database through the synchronization process.

5 Using the Clintrial Design module, refine the protocol component definitions as needed to accommodate paper-based data entry.

For more information, see:

- ***Working with data mappings*** (on page 31).
- Central Designer documentation.

Clintrial study book autocreation option

Note: This feature is available for single language trials.;

When the CIS software performs a synchronization for the first time, it creates, optionally:

- A Clintrial protocol, panels, and panel items if they do not already exist.
- The study books, page templates, and page sections, either during the initial synchronization or afterwards.

When study book autocreation is enabled, during synchronization, the CIS software:

- Creates new enrollment, non-patient data, and patient data study books in the target protocol if they do not already exist.
- Regenerates study books if they do exist in the target protocol, overwriting the existing study books.

> **Note:** If a non-CIS user, such as a user of the Clintrial Design module, has updated a pre-existing element, the CIS software ignores the element and does not regenerate it during regular synchronization processing. However, if you request immediate study book generation by using the Actions tab of the CIS Synchronizations page, you can specify that the CIS software regenerates elements updated by a non-CIS user and overwrites those elements.

The CIS software can detect most changes that a user makes to a protocol with the Clintrial Design module. However, some changes are not detectable by the CIS software. If a user of the Design module makes any of the following changes, the CIS software does not detect them and overwrites those changes:

- Deleting the last page template from a block.
- Deleting the last block from a study book.
- Changing the order of page sections in a page template.

You can enable study book autocreation by:

- Creating a synchronization connection with study book autocreation enabled.
- Changing a synchronization connection definition to enable study book autocreation.
- Requesting immediate study book autocreation.

For more information, see the *CIS Administrator Guide*.

Study book autocreation terms

The following table lists definitions of Clintrial terms that are important for understanding how the CIS software automatically creates a study book.

Term	Definition
Block	A group of related study pages in a study book. Blocks usually represent subject evaluation checkpoints, such as subject visits. A Clintrial block corresponds to an InForm visit.
Page section	A part of a study page, corresponding to a section of a CRF. A page section is associated with a panel.

Term	Definition
Page template	An object that consists of one or more page sections and defines the order of page sections in a study page.
Panel	A grouping of logically or clinically related items. A panel is defined by metadata that is stored in data dictionary tables. When you install a panel, three additional database tables are created (the UPDATE table, DATA table, and AUDIT table) for storage of clinical data.
Study book	A representation of a case book. Each study book contains an ordered list of study pages, corresponding to the pages in a paper case book. In addition to clinical study books, Clintrial software also includes enrollment study books, used to enroll study subjects, and non-subject study books, used to enter nonclinical data such as standard coding thesauruses or patient status.
Study page	A data entry window that represents a page in a CRF. A study page in which you can enter clinical data for a subject consists of a context page section (for context items) and one or more additional page sections (for clinical data). A study page is based on a page template.

Enrollment study book generation

To create the enrollment study book for a protocol, the CIS software finds the enrollment panel among the Type 5 panels. The following table describes the study book components the CIS software generates.

Component	Description
Study book	One enrollment study book with the name P_ENROLL.
Block	One block with the block key P_ENROLL and same name as the enrollment panel. The block does not have repeats.
Page template	One page template with the page key P_ENROLL and the same name as the enrollment panel. The page does not have repeats.
Page section	One page section with the same name as the enrollment panel. The page section does not have repeats.
Item	One item for each enrollment panel item.

Note: The study book name, block key, and page key must be exactly the same, including case.

Non-patient data study book generation

The CIS software generates a study book for each Type 0 panel in a protocol. The following table describes the study book components the CIS software generates.

Component	Description
Study book	One non-patient study book with the same name as the Type 0 panel.
Block	One block with a block key and title equal to the Type 0 panel name. The block has no repeats.
Page template	One page template with a page key and title equal to the Type 0 panel name. The page has no repeats.
Page section	One page section with the same name as the Type 0 panel name. The page section has repeats.
Item	One item for each Type 0 panel item.

Patient data study book generation

When the CIS software generates a patient data study book, it makes three passes to collect data from the following locations:

- **InForm study version data**—During this pass, the CIS software converts the structural components of the InForm study to their corresponding Clintrial study elements.
- **INF_PATHMAP table**—During this pass, the CIS software processes the INF_PATHMAP table and finds mapping definitions that involve forms and visits that do not exist in the current InForm study version. It generates the appropriate blocks and pages for these objects and adds them to the study book.
- **Patient data panels (AUDIT, UPDATE, and DATA tables)**—During this pass, the CIS software processes the patient data panels (AUDIT, UPDATE, and DATA tables) and finds mapping targets in the patient data panels that do not exist in the current InForm study version or in the current mapping definitions. It generates the appropriate blocks and pages for these objects and adds them to the study book.

From these sources, the CIS software generates an XML definition for a patient data study book called CISStudyBook.

InForm study version data pass

From the data in the current InForm study version, the CIS software generates XML definitions for the patient data study book and the objects it contains. The following table describes the XML definitions that the CIS software generates.

Component	Description
Study book	One patient data study book with the name **CISStudyBook**.

Component	Description
Block	One block for each FORMSET (visit) in the InForm study version. Blocks have the following attributes: • The ORDER property of the FORMSET determines the order of the blocks in the study version. • If the visit RefName includes a double underscore (__), the block title is the text before the __ and the block key is the text after the __. • If the visit RefName does not include a __, both the block title and the block key are the visit RefName. • If the visit is repeating, the block is repeating. • If the visit has the type **COMMONCRF**, its block key and title are **CommonCRF**. This block is not repeating, and the CIS software adds it to the end of the study book. • If the visit includes a BLOCKKEY value, and the block has not been created, the CIS software adds a block to the end of the study book. The block title and key are the BLOCKKEY value. If the visit is repeating, the block is repeating.
Page	One study page for each FORMREF (form) that has a different combination of panel and page key within a block. **Note:** Master-detail pages are processed differently. For more information, see ***Master-detail relationship generation*** (on page 61). Page keys derive from one of the following: • If the form RefName includes a double underscore (__), the page key is the text after the __. • If the form includes a PAGEKEY value, the page key is the PAGEKEY value. • Otherwise, the page key is the form RefName. Pages have the following attributes: • The page title is the same as the page key. • If the form is repeating, the page is repeating.
Page template	One page template for each study page. The page template has the same name as the panel.
Page section	One context page section with the name **CONTEXT**. The page section is not repeating. It includes a set of context items defined in the InForm mapping definition. One patient data page section with the same name as the panel. It is not repeating unless the form has itemsets. For more information, see ***Itemset generation*** (on page 60).
Item	One item for each item in each InForm form section. For more information, see ***Item generation*** (on page 61).

INF_PATHMAP pass

CIS processes the INF_PATHMAP table to find block key + page key + panel combinations that do not exist in the current InForm study version, and it generates additional definitions for those objects. The following table describes the study book components the CIS software generates.

Component	Description
Block	One block, added to the end of the study book, for each new block key + page key + panel combination found in the INF_PATHMAP table. Block key, title, and repeating attribute are those specified in the INF_PATHMAP table.
Page	One page, added to the end of the block, for each new page key in the block found in the INF_PATHMAP table. Page key and title are those specified in the INF_PATHMAP table.

Patient data panel pass

The CIS software processes the patient data panels (AUDIT, UPDATE, and DATA tables) to find block key + page key + panel combinations that do not exist in the current InForm study version or in the INF_PATHMAP table, and it generates additional definitions for those objects. The following table describes the study book components the CIS software generates.

Component	Description
Block	One block, added to the end of the study book, for each new block key + page key + panel combination found in the patient data panels. Block key and title are those specified in the patient data panels. If the block repeat key in the patient data panels is an integer, the block has repeats.
Page	One page, added to the end of the block, for each new page key in the block found in the patient data panels. Page key and title are those specified in the patient data panels. If the page repeat key in the patient data panels is an integer, the page has repeats.

Itemset generation

InForm itemsets are similar to Clintrial repeating page sections. CIS generates repeating page sections if itemset data is or will be mapped to the panel for the page section.

Subset item generation

Subset items allow the same page section to be added to a page template multiple times based on different values of a subset item. (Each subset value is associated with a different page section instance.)

If the panel for a page section contains a subset item, the CIS software adds the same section to a page template for each unique subset item value specified in the INF_PATHMAP or the AUDIT, UPDATE, or DATA table for the panel.

Master-detail relationship generation

In a page template that includes a cross-panel master-detail relationship, one page section is related to another page section, and the two page sections point to different panels. One panel has a master key item and the other has a detail key item. Clintrial mapping definitions can include master-detail relationships.

When the CIS application identifies a page section involved in a master-detail relationship, it:

- Creates the page template if it does not already exist.
- Creates a context page section in the page template.
- Creates a page section for the master panel and adds it immediately after the context page section.
- Creates a page section for each detail panel and adds them to the page template.
- Adds the page template to the block.

Note: Page keys, master key items, and detail key items must be set up properly, or the detail data in the page may not be displayed. Also, if the CIS application processes a detail panel without a master panel, it does not add a page template with a page section only for the detail panel.

Item generation

When the CIS software adds an item to its page section definition, it applies the following rules:

- Item order is determined by the value of the IORDER column in the CTSDD.ITEM table. This comes from the order in which items occur in the panel mapping definition created in the Central Designer software
- The Label attribute comes from the value of the DESCRIP column in the CTSDD.ITEM table, if a value exists. This value comes from the Design Note property of the item in the panel item mapping definition created in the Central Designer software. If the DESCRIP value is used, the CIS software removes HTML elements such as <br> and   and formatting characters such as .

  If the DESCRIP column is empty, the CIS software uses the value of the ITEM_NAME column in the CTSDD.ITEM table as the Label. This value comes from the RefName property of the item in the panel item mapping definition created in the Central Designer software.

Study book components not created

After processing InForm study version, INF_PATHMAP table, and patient data panel data, CIS has almost all data needed to display patient data in the protocol. However, the following circumstances could cause blocks or pages to be missed:

- Possible reasons for a missing block:
  - The study version has changed over time.
  - The new study version is missing a visit that was in the old study version.
  - The mappings do not specify that visit (they use the Generic Form specification).
  - There is no patient data yet for the visit in any panel tables.

    - There may be patient data in the future if a site is using the old study version.
- Possible reasons for a missing page for a block:
    - The study version has changed over time.
    - The new study version is missing a form that was in the visit in the old study version.
    - The mappings do not specify the visit for the form (they use the Generic Form specification).
    - There is no patient data yet for the form in the visit in any panel tables.
    - There may be patient data in the future if a site is using the old study version.

If any of these circumstances apply, you might need to create the missing blocks or pages manually.

Study book generation

After generating a complete set of XML definitions for the study books of a protocol, the CIS software creates the study books and their components.

Study book autocreation can occur:

- When a user requests study book autocreation by clicking the Create Study Books button on the Actions tab of the CIS Synchronizations page in the CIS Administration application.
- When the CIS software detects that autocreation is necessary. The CIS software determines that autocreation is needed if it processes any of the following types of transactions from the InForm software:
    - STUDYVERSION XML definitions.
    - Data mappings.
    - Any InForm metadata that causes an autogenerated codelist to be attached to a Clintrial item. Examples are metadata definitions for radio controls and dropdown lists.

The CIS software does *not* autocreate study books if any of the following are true:

- The protocol is closed for revision or is locked.
- The synchronization connection is not defined to autocreate study books.

When processing the study book XML created in the first phase of study book autocreation, the CIS software:

- Adds elements that do not exist in the protocol database, if the elements have a valid definition.
- Regenerates elements that already exist in the protocol database, if the elements have a valid definition.

> **Note:** If a non-CIS user, such as a user of the Clintrial Design module, has updated a pre-existing element, the CIS software ignores the element and does not regenerate it during regular synchronization processing. However, if you request immediate study book generation by using the Actions tab of the CIS Synchronizations page, you can specify that the CIS software regenerates elements updated by a non-CIS user and overwrites those elements.

The CIS software can detect most changes that a user makes to a protocol with the Clintrial Design module. However, some changes are not detectable by the CIS software. If a user of the

Design module makes any of the following changes, the CIS software does not detect them and overwrites those changes:

- Deleting the last page template from a block.
- Deleting the last block from a study book.
- Changing the order of page sections in a page template.

- Associates related elements. For example, the CIS software associates page sections with their page templates and page templates with their blocks.
- Truncates block titles to 20 characters, if necessary.
- Truncates page titles to 30 characters, if necessary.

When autocreating page sections, the CIS software:

- Makes the layout of controls horizontal for a repeating page section and vertical for other page sections.
- Does not display the subset item, if one exists.

Possible problems during study book autocreation

Study book autocreation fails if any of the following conditions exist during study book component generation:

- A visit is repeating but has mappings to a non-Type 2, Type 3, or Type 4 panel.
- The repeat value of an existing block does not match the repeat value of the visit to which it corresponds.
- A form is mapped to more than one panel using the same page key (except in the case of master-detail relationships).
- A form is repeating but has mappings to a non-Type 2 or Type 4 panel.
- A block + page key + panel combination in the INF_PATHMAP table would cause duplicate page keys to go to different panels within the same block (except in the case of master-detail relationships).
- A block + page key + panel combination in the AUDIT, UPDATE, and DATA tables would cause duplicate page keys to go to different panels within the same block (except in the case of master-detail relationships).
- A panel containing an itemset is not Type 4.
- A panel containing a subset item in the INF_PATHMAP table is not Type 4.

Clintrial panel and item autocreation option

By default, the CIS software creates a Clintrial protocol, panels, and panel items during synchronization if they do not already exist. If a protocol, panels, and panel items exist, and new metadata is received in mapping definitions, the CIS software updates the protocol, panels, and panel items to match the mapping definitions.

This behavior is optional. When you define or update a synchronization connection, you can specify whether you want the CIS software to create or update the protocol, panels, and panel items.

The following table summarizes the impact of choosing for the CIS software not to create or update Clintrial protocol, panels, and panel items.

Software area	Effect on synchronization if Create panels and items = No
Study book creation	None.
Codelist creation	None.
Mappings	The CIS software does not create the panels and items defined by mapping definitions. However, the following validation occurs to determine whether the Clintrial panels or items match the incoming mappings: • When the CONTEXTPANEL tag is received, the CIS software verifies that a CONTEXT panel exists for the protocol. If a CONTEXT panel does not exist, validation fails. • For CTITEM tags inside the CONTEXTPANEL tag, no additional validation is performed. • When a CTPANEL tag is received, the CIS software verifies that the panel exists and is installed. If the panel does not exist or is not installed, validation fails. • For a CTITEM tag inside the CTPANEL tag, the CIS software verifies that the item exists in the panel. The item type is not checked. If the item does not exist in the panel, validation fails • The CIS software ignores all other properties of the panel from the mappings, including the master-detail information. If validation fails, synchronization stops processing. To continue, make corrections in the Clintrial software or in the mapping definitions and the CIS software: • Alter the protocol in Clintrial Design so it passes the CIS validation. • Remove the synchronization connection in the CIS software, alter the mapping definitions so they will pass validation, and re-create the synchronization connection to the same protocol.
Rules	The CIS software does not create or update Clintrial rules and derivations. No validation checks are performed to verify that rules or derivations exist in the Clintrial protocol.

Software area	Effect on synchronization if Create panels and items = No
Protocols	The CIS software does not create a Clintrial protocol. If the protocol specified in the synchronization connection definition does not exist, synchronization fails.

Configuring an integrated Clintrial protocol

An integrated protocol requires additional configuration to enable certain Clintrial functionality. You may need to manually create, modify, or reconcile the following Clintrial objects:

- Required item attribute.
- Rules and derivations.
- Data entry processing procedures (DEPPs).
- Page sections and page templates.
- Codelists.
- Item and panel attributes.
- Panel keys.
- Panel audit start date.

For information about configuring Clintrial functionality, see *Clintrial Admin and Design* and the *Clintrial Reference Guide*.

Note: For discrepancies to be attached to the correct InForm item, the Resolve module must be installed.

Required item attribute

By default, an item created in an integrated Clintrial protocol does not have its required attribute enabled, even if the corresponding InForm item from which it is mapped is required.

To make a Clintrial protocol item required, you must use the Design module to manually set the required attribute.

Other item attributes may also need to be edited.

Rules and derivations

If you are running a hybrid study with identical rules in both the InForm software and the Clintrial software, you can modify the Clintrial rules to ignore EDC data. To modify a rule to ignore EDC data, include in the rule's PL/SQL script a routine to check for a DB_ID of 9999 or include an exception clause that uses the IS_EDC_RECORD function. This indicates that the record is associated with an EDC subject. For more information, see ***Modifying rules to ignore EDC data*** (on page 88).

For information about using PL/SQL functions in the Clintrial software, see the *Clintrial Reference Guide*.

DEPPs

The InForm software does not support Data Entry Processing Procedures (DEPPs). These operate only within the Clintrial software. You must create or recreate any DEPPs that you want to run for the current protocol.

Page sections and page templates

When a protocol is automatically created in the Clintrial software, only the panels and tables are created. To use the Clintrial Enter module to view data, you must ensure the page section and page template layouts, and their appropriate attributes, are set up. You can do this manually using the Clintrial Design module. Alternatively, you can copy the existing Clintrial protocol to a new protocol and use this new protocol as the synchronization target. If you do not want to use the Enter module, you do not need to create page sections or page templates.

In a hybrid study, you must create page section and page template layouts using the Clintrial Design module before you can use the Enter module to enter data, or you must specify the **Auto-create study book** option of synchronization to enable the CIS software to create study pages for you. For more information, see ***Clintrial study book autocreation option*** (on page 55). Also see the *CIS Administrator Guide*.

Codelists, aggregated or unaggregated

Aggregated and unaggregated codelists in the Clintrial software correspond to InForm pulldown controls and radio group controls. The CIS software enables you to Generate codelists from pulldown controls and radio group controls in the InForm software when you synchronize an InForm study to the Clintrial software.

For more information, see ***Codelists and synchronization*** (on page 29).

Checklists

A checklist is a type of codelist for which no encoding is performed. The issues surrounding metadata transfer between the Clintrial and InForm environments are the same as with codelists with the following exceptions:

- Checklists are represented within the InForm software as pulldown controls.
- Checklists with the override attribute set can also accept input from users. This is implemented in the InForm software as a radio group with the checklist as the top item of the radio group and a second radio item labeled "Other" that has a textbox associated with it.

Panel audit start date

In the Clintrial software, auditing tracks changes to clinical data and notes associated with clinical data:

- For data entered with the Enter module, study designers can configure the point at which auditing begins, and auditing tracks changes or deletions made to records and notes after the audit start point—Entry, Verification, Validation, Validity, or Merge.
- For EDC data, when you synchronize metadata for an integrated study designed with the Central

Designer software to a Clintrial protocol, the CIS software creates new panels if they do not already exist in the protocol. When the CIS software creates Clintrial panels, it automatically sets the audit start point of each panel to Entry.

Note: If you create a panel with the Design module of the Clintrial software to be used in an integrated or hybrid study, you must manually define the panel with an audit start point of Entry. Similarly, do not change the audit start point for panels created by CIS. Creating or changing a panel to an audit start point other than Entry can result in the inability to reinstate data that has been deleted in the InForm software.

Updating a Clintrial protocol

In addition to creating Clintrial protocols, the CIS software can also update existing protocols. If you are instituting a hybrid study, you may want to use an existing protocol that is already set up for data entry with the Enter module.

Updated protocols and the Resolve module

The Resolve module is required for correct use of the CIS software with a hybrid study. An existing protocol that was created in the Clintrial software can be set up to use the Resolve module. The Resolve module enables you to manage discrepancies that are generated from data entered with the Enter module.

Modifying updated protocols

If you modify a study in the Central Designer software, create a deployment package and deploy it to the InForm server, the changes are automatically updated in the Clintrial software during the next synchronization. If you make changes to the metadata in the Clintrial software, you must be certain that the mappings remain valid.

Note: Updates to metadata made in the Clintrial software using the Design module may be overwritten during the next synchronization, depending on the objects affected.

CHAPTER 6

Entering data in an integrated study

In this chapter

Overview of entering data 72

Data transfer 73

Patient number changes and synchronization 74

Data entry in an EDC study 75

Data entry in a hybrid study 76

Overview of entering data

Entering data in an integrated study requires additional considerations that do not apply to working with either product alone. You may use the CIS software for an EDC-only study, where data entry occurs in the InForm software, or for a hybrid study, where data entry occurs in both the InForm software and the Clintrial Enter module.

Data transfer

The CIS software transfers data between an InForm database and a Clintrial database. Transfer of entered data is one-way only from an InForm study to a Clintrial protocol. Certain query information, however, is exchanged in both directions between the two databases.

The following data is transferred from an InForm database to a Clintrial database:

- Study metadata.
- CIS mapping information.
- Clinical data.
- Query information.
- Site and user data for audit recording.
- Audit information.

The following types of data are not transferred to a Clintrial protocol:

- Form and Case Report Book states (frozen, locked, or SV ready).
- Signature records.
- Visit and form entry metrics.
- Administrative data (other than for audit records).
- Source verification information.

Patient number changes and synchronization

The InForm software uses the current patient number of a patient when creating the enrollment version of the CANDIDATE node in the transaction XML. This form of the node is used by CIS to move the patient record from the UPDATE to the DATA enrollment table in a protocol. Depending on the timing of the change to the patient number, the panels in the Clintrial software can be updated differently:

- If a patient number changes before the CANDIDATE node XML is generated, the CANDIDATE node includes the new ENROLLMENTNUMBER value even though that number is not the number the patient had upon enrollment. When the patient number change transaction eventually is processed by CIS, CIS makes no additional updates because the new patient number is already in all the panels. The following steps summarize:

  1 Screen and enroll a patient.

  2 Before the transaction XML for step 1 is created, change the patient number.

  3 Synchronize.

  Result: Panels show the new patient number but no AUDIT record for the change.

- If the timing is different and the CANDIDATE node XML is created before the patient number changes, the global patient number change code in CIS runs and changes the patient number in all panels. In this scenario, there is one more AUDIT record in every panel for the patient. The following steps summarize:

  1 Screen and enroll a patient.

  2 Synchronize screening and enrollment transactions.

  3 Change the patient number.

  4 Synchronize the new patient number.

  Result: Panels show the new patient number as well as the AUDIT record for the change.

Data entry in an EDC study

In an EDC study, data entry occurs in the InForm software and is transferred to the Clintrial software through the CIS Synchronization Adapter and Clintrial Adapter during synchronization.

Screening and enrollment

Screening information for a patient is transferred to the Clintrial protocol during synchronization. However, the patient is not visible in the protocol until the patient is enrolled in the InForm software. After the patient is enrolled, the data is moved to the enrollment panel of the Clintrial protocol.

Entering EDC data

EDC data is read-only when viewed in the Clintrial Enter module. You cannot modify EDC data in the Enter module, nor can you enter new data for a patient that was created with the InForm software. EDC data from the InForm software is written to the protocol UPDATE tables and is given a record status of 0 (passed validation) or -1 (failed validation).

Merging EDC data

You can merge EDC data, per patient, using the Clintrial Manage module. If previously merged EDC data is modified with the InForm software, all the data associated with that patient is moved back to the UPDATE table and given a record status of 0.

Data entry in a hybrid study

In a hybrid study, data entry occurs in both the InForm software and the Clintrial software. Data entered with the two tools is kept separate in the Clintrial database by use of the DB_ID values associated with each data record. Data entered from InForm software is given a DB_ID value of 9999. Data entered with the Clintrial Enter module is given the DB_ID value assigned during the Clintrial installation.

EDC data entered in the InForm software can be manipulated in the InForm software, but is read only in the Clintrial software. Data entered in the Clintrial Enter module is available for editing in the Clintrial software, but it is not visible to the InForm software.

An individual patient must be enrolled with either the InForm software or the Clintrial Enter module. All subsequent data entry must be accomplished with the application from which that patient was enrolled.

Once the data has been merged with the Clintrial Manage module, the data is available for subsequent Clintrial database operations.

CHAPTER 7

Managing queries and discrepancies

In this chapter

Overview of managing queries and discrepancies in an integrated study....78
Using rules in an integrated study....85
Managing rules and queries in a hybrid study....86

Overview of managing queries and discrepancies in an integrated study

You can create, manage, resolve, and store queries (in the InForm software) and discrepancies (in the Clintrial software) in an integrated study.

What are queries and discrepancies?

Queries and discrepancies arise from real or potential data problems, such as missing values, inconsistencies among entered values, or variation from expected ranges. Queries are handled in the InForm software by alerting the user to a data problem with a query message that describes the problem. The Clintrial software notifies users by creating an error log entry, and, through the Clintrial Resolve module, by creating a discrepancy record.

How are queries and discrepancies created?

You can create queries and discrepancies manually during data review, or they can be generated automatically from the execution of a rule. A rule is a script that is attached to an item that, when run, triggers an *event*, such as the creation of a query message.

Note: You cannot create manual discrepancies in the Clintrial software on EDC data entered with the InForm software.

The InForm software and the Clintrial software have two basic types of rules:

- InForm conversion and calculation rules manipulate data to compute new values. In the Clintrial software, these types of rules are called derivations.
- InForm form rules perform edit checks by comparing or manipulating data values, and evaluating to true or false. The Clintrial software also calls these rules.

In the InForm software, if the Central Designer software is the study design tool, rule scripts are written in the Central Designer rule expression language. Clintrial rule scripts are written in PL/SQL.

The results of a rule can be set up to trigger an event that generates a query message in the InForm software or generates an error log entry or discrepancy record in the Clintrial software.

In an integrated study, rules can reside in either the InForm database or in the Clintrial database. Data entered with the InForm software is subject to the rules in either database. In a hybrid study, data entered with the Clintrial Enter module is subject only to rules and derivations in the Clintrial database.

Note: If you are designing a hybrid study, and you want both EDC and PDC (Paper-based Data Capture) data to be subject to the same validation tests, you must make sure that Clintrial Resolve is installed and you include a duplicate set of rules, unless you choose to have all validation performed by Clintrial rules. For more information, see ***Managing rules and queries in a hybrid study*** (on page 86).

What are query and discrepancy states?

Query and discrepancy states reflect the progression of actions taken to raise and resolve issues with entered data.

In the Clintrial software and the InForm software, queries and discrepancies can exist in several states that indicate whether the data problem is:

- **Proposed**—The query is raised but not yet confirmed by the sponsor.
- **Open**—The data problem has been confirmed but has not yet been answered.
- **Closed**—The data has been changed to an acceptable value, or the existing value is accepted with an explanatory message.

By default, the CIS software maps the Clintrial Ready to Send discrepancy state to the InForm Open query state. All other Clintrial discrepancy states are mapped as InForm Candidate query states.

How are queries and discrepancies resolved?

How queries and discrepancies are resolved depends on where the query resolution takes place. Queries arising from data entered in an EDC study are always resolved in the InForm software, even if the rule that triggered the query resides on the Clintrial server. In a hybrid study, discrepancies arising from data entered with the Clintrial Enter module can only be resolved in the Clintrial software.

Note: Because EDC data that is batch-loaded with the Manage or Lab Loader module is not synchronized from the InForm software to the Clintrial software, managing queries occurs through the Clintrial software even though the data is for EDC patients. For more information, see *Lab Loader module* (on page 99).

Resolving queries in the InForm software and the Clintrial software

In the InForm software, users resolve queries either by:

- Changing the value of the item that created the query such that the new value passes the rule.
- Answering the query with the submission of explanatory text.

In the Clintrial software, users resolve discrepancies with the Clintrial Manage or Resolve modules.

Resolving queries generated by Clintrial rules in the InForm software

You can design a study to validate EDC data by using InForm rules, Clintrial rules, or a combination. In a study designed to validate EDC data with Clintrial rules, the following workflow results:

1 A site user enters data through the InForm software.

2 The next synchronization sends the data to the Clintrial software.

3 Any Clintrial rules on the data item fire. If discrepancies result, the synchronization cycle returns them to the InForm software as queries.

Note: If a Clintrial rule generates a discrepancy, and then a Clintrial user changes the rule and reruns validation before the data is synchronized back to the InForm software, it is possible that the data will pass the changed rule. If it does pass, the discrepancy is opened and closed before synchronization, and the query is never sent to the InForm software.

4 In the InForm software, a query generated by the Clintrial software is in the Open or Candidate state, according to the Data Transfer Option specified for the Clintrial database instance with which the protocol is registered. (By default, Ready to Send Clintrial discrepancies have a state of Open in the InForm software, and all others have a state of Candidate. For more information, see the *CIS Administrator Guide*.)

5 Processing of the resolution of the query depends on how a user responds:

- ***By changing the value of the data item*** (on page 80).
- ***By entering query response text*** (on page 81).

Query response—Changing the data value

When a user responds to a query by changing the value of the data item, the state of the query and its appearance in the InForm software depend on whether the study is configured to close manual queries automatically (Autoclose manual queries option is set to ON).

Note: If the Clintrial rule specifies multiple error items, a query placement algorithm determines on which InForm item the query is placed. The workflow and status information in this section applies only to the item on which the query is placed. For more information, see ***Placing queries on EDC items*** (on page 89).

The following table summarizes the query states that result from a data change.

Query status	Autoclose manual queries = Yes	Autoclose manual queries = No
Open	Query status changes to Closed, and the query text disappears from site view.	Query status remains Open and is visible at the site until synchronization returns the new query status from the Clintrial software.
Candidate	Query status changes to Deleted and is never visible at the site.	Query status remains Candidate and is not visible at the site.
Open query answered (with query response text) and then Reissued as Candidate	Query status changes to Closed, and query text is not visible at the site.	Query status remains Candidate and is not visible at the site.

Note: When CIS automatically closes a query, it also updates the error items for the rule as a signal to reopen the query if a subsequent data change results in the failure of the rule. For more information, see ***Reopening of closed queries*** (on page 84).

Query response—Entering response text

When a user answers a query by entering query response text, the query status is changed to Answered. The query behaves like a manual query in which no Autoclose is available, and a monitor user must review the text and close or reissue the query manually.

When the data synchronizes to the Clintrial software, the Clintrial rule runs again if the user answered the query by changing data. The following table summarizes the query states that result from a data change.

	Original query status	Autoclose manual queries = Yes	Autoclose manual queries = No
New value passes rule	Open, or Open, Answered, then Reissued as Candidate	Query status remains Closed, and no new query is created.	Query status changes to Closed.
	Candidate	Query status remains Deleted, and no new query is created.	Query status changes to Deleted.
New value fails rule	Open, or Open, Answered, then Reissued as Candidate	Status of original query remains Closed. A *new* query with a status of Open synchronizes back to the InForm software.	Query status remains Open.
	Candidate	Status of original query remains Deleted. A *new* query with a status of Candidate synchronizes back to the InForm software.	Query status remains Candidate.

If a user manually answers a query by entering query response text, the Clintrial software does not re-raise the query. The state of the query remains Answered until a monitor user manually responds to the query text.

If the data for a query to which the user originally responded by providing query response text is subsequently changed, the query continues to be treated as a manual query, and its state remains Answered until manual resolution.

Queries and the Resolve module

Although you use the InForm software, and not the Resolve module, to resolve queries generated on EDC data by Clintrial rules, the following must be true for the CIS software to synchronize queries back to the InForm software:

- The Resolve module must be installed as part of your Clintrial installation.
- The Clintrial protocol to which the InForm study synchronizes must be set up to use Resolve. For more information, see ***Setting up Resolve to return EDC queries*** (on page 104).

Clintrial rules that use data from more than one panel

In the Clintrial software, a query can be based on data that resides in two different panels. CIS uses single panel verification; that is, it only fires verification on the panel where the data has changed. This verification method means that if a Clintrial rule on one panel uses data that resides on a different panel, the corresponding query that the user resolves in the InForm software (by correcting the data on the panel that does not contain the rule) will have no effect on the resolution of the query in the second Clintrial panel where the rule is attached.

This issue is evident if you resolve a query in the InForm software by changing the data, but after a subsequent synchronization, the query in InForm continues to be unresolved. To determine whether this situations is caused by data in the Clintrial software, you must use the Clintrial Manage and Resolve modules to revalidate the panels. If the query is resolved after revalidating, the rule is attached to the panel where no data changed.

Handling of conflicts in query states

Query conflicts arise when an InForm user and a Clintrial user act upon the same query prior to synchronization. For example, an InForm user could respond to a query, and a Clintrial user could meanwhile rerun validation, both before synchronization occurs, resulting in the conflicting states of Closed or Answered on the InForm side and Closed on the Clintrial side. The InForm software resolves the states automatically as follows.

Conflict scenario	Resolution
InForm Autoclose, Clintrial Autoclose: 1. An InForm user edits an Open query generated by a Clintrial rule, resulting in a state of Closed. 2. A Clintrial user changes the original rule in such a way that the original data value passes, and after the user reruns validation, the discrepancy state changes to Closed. 3. After synchronization, the query has a conflict state of InForm Closed and Clintrial Closed.	The query state changes to Clintrial Closed.
InForm manual answer, Clintrial Autoclose: 1. An InForm user manually answers an Open query generated by a Clintrial rule by submitting response text, resulting in a state of Answered. 2. A Clintrial user changes the original rule in such a way that the original data value passes, and after the user reruns validation, the discrepancy state changes to Closed. 3. After synchronization, the query has a conflict state of InForm Answered and Clintrial Closed. In another version of this scenario, the original query has a Candidate state when generated by a Clintrial rule. If an InForm monitor user opens the query and a site user responds to it with query response text, the same type of query conflict can occur if a Clintrial user reruns validation before synchronization occurs.	The query state changes to Answered. A monitor user must manually respond to the query response text.

Conflict scenario	Resolution
InForm Delete, Clintrial Autoclose: 1. An InForm monitor user changes the status of a Candidate query generated by a Clintrial rule to Deleted. 2. A Clintrial user changes the original rule in such a way that the original data value passes, and after the user reruns validation, the discrepancy state changes to Closed. 3. After synchronization, the query has a conflict state of InForm Deleted and Clintrial Closed.	The query status changes to Deleted. This state reflects the fact that the query was never opened in the InForm software and thus should not appear to have been closed.

Storage of query and discrepancy information

Query and discrepancy information for an integrated study is stored in the Clintrial database. Query information from EDC data entered with the InForm software is stored both in the InForm database and in a set of query tables in the Clintrial database that have the same structure as the Resolve module tables. The following table shows the Resolve table names, and the equivalent query data table names.

Resolve table	Query table
VCT_ERRORITEM	INF_ERRORITEM
VCT_ERRORSTATUS	INF_ERRORSTATUS

The INF_ query tables only store query information resulting from EDC study data. Discrepancy information resulting from data entered with the Enter module is stored in the Resolve tables if the Resolve module is installed. Updates of the query tables are slightly different for EDC data and data entered with the Enter module:

- When the failure of a rule on EDC data generates a query, the CTS$REASON column of the INF_ERRORITEM and INF_ERRORSTATUS tables is updated with the message **The rule is not satisfied**. When a query is closed, the CTS$REASON column of the INF_ERRORSTATUS table changes to **The rule is satisfied**. The CTS$REASON column of the INF_ERRORITEM table is not updated for the closing action.

  Note: The INF_ERRORSTATUS_AUDIT table is not updated until the query is answered. This is consistent with audit processing for other patient data in Clintrial software. Clintrial software stores data in its UPDATE tables until it has been changed. Then it reflects the change in the corresponding AUDIT table.

- In the Resolve module, the query tables are updated when data entered with the Enter module results in a discrepancy. The CTS$REASON column of the VCT_ERRORSTATUS table is updated with the message **The rule is not satisfied**. When a query is closed, the CTS$REASON column of the VCT_ERRORSTATUS table changes to **The rule is satisfied**. The CTS$REASON column of the VCT_ERRORITEM table is not updated for either action.

Queries and discrepancies on frozen or locked forms

If an InForm item is on a form that is locked or frozen and the data in that item does not pass an existing Clintrial Validation, a query appears on that item in the InForm software after synchronization has occurred.

Queries and discrepancies on an empty form

In the InForm software, a query can be entered on a form that has no data. If a form does not have any data, the corresponding Clintrial UPDATE table records have not yet been created at the time when CIS receives a query for a location on the form. When CIS receives a query for an InForm location that does not have existing Clintrial records, CIS:

1 Creates a record in the UPDATE table.

2 Processes the query, referring to the UPDATE table record it created.

Reopening of automatically closed queries

Automatic closing of discrepancies can happen when:

- The InForm software automatically closes an EDC query that originated from a Clintrial rule, and CIS automatically closes the corresponding Clintrial discrepancy.
- The InForm software deletes data, and CIS deletes the Clintrial records to which the data is mapped and automatically closes any discrepancies on those Clintrial records.
- The Clintrial software closes a discrepancy as a result of validation.

If a rule runs after a discrepancy is automatically closed (for example, if data changes in one or more items referenced by the rule), and the rule fails, CIS reopens the discrepancy.

To make sure that all of the correct records are processed when a rule runs again, CIS updates the error items when it automatically closes a Clintrial discrepancy or processes the automatic closing of a discrepancy by the Clintrial software. Specifically, CIS changes the value of the INF_ERRORITEMS.CTV_REPEAT_ID column of each error item so that it differs from the value created by the rule. If the INF_ERRORITEMS.CTV_REPEAT_ID column contains data, such as a comment on the error item, CIS overwrites it.

Using rules in an integrated study

Effect of rule location

A rule in an integrated study can reside in the InForm database, in the Clintrial database, or in both. Where the rule resides determines when the resulting query message is displayed:

- Queries produced by rules triggered in the InForm database are immediately visible to the InForm user.
- Query messages produced by rules that are triggered in the Clintrial database appear in the InForm software after synchronization. For more information, see ***Resolving queries generated by Clintrial rules in the InForm software*** (on page 79).

The time interval between data entry and query message display in the InForm software for rules triggered in the Clintrial database depends on the synchronization schedule.

Validation and COMMIT statements

Validation of records synchronized from the InForm software to the CIS software are processed outside of the COM+ transaction that the CIS software creates to process each synchronized InForm transaction. Therefore, COMMIT statements and other data dictionary operations in Clintrial validation routines do not affect processing of synchronization.

When the CIS software processes transactions, it keeps track of the Clintrial records in which data is changed. It stores identifiers for these records in the INF_PENDINGVALIDATIONS table. The class that processes transactions reads records from the INF_PENDINGVALIDATIONS table and calls a COM+ object that does not support transactions to run validation on the records, thereby isolating the validation processing from any COM+ transaction. After validation on a record completes, the CIS software updates the INF_PENDINGVALIDATIONS table to indicate that the record is processed.

The CIS software writes the result of each validation to CTS.JOB_LOG. If errors prevent writing to CTS.JOB_LOG, the CIS software sets the VALIDATIONERROR status to 1 in the INF_PENDINGVALIDATION table and writes an error to the Windows Event Log on the CIS machine.

Managing rules and queries in a hybrid study

Using rules in a hybrid study requires considering the following additional tasks beyond an EDC-only study:

- Ensuring that duplicate rules exist for EDC and PDC data if required.
- Setting the initial discrepancy status.
- Modifying Clintrial rules to ignore EDC data.
- Redirecting queries generated by Clintrial rules to the appropriate items.

Duplicating rules

If you are designing a hybrid study, and you want both EDC and PDC (Paper-based Data Capture) data to be subject to the same validation tests, you must make sure that Clintrial Resolve is installed and you include a duplicate set of rules, unless you choose to have all validation performed by Clintrial rules.

Design considerations for creating Clintrial rules for a hybrid study

- Do not attach a rule to multiple items unless you are sure the rule can work on all panels to which the items map.
- The item to which a rule is attached should map to only one Clintrial panel unless the rule works on all panels to which the item maps.
- Do not specify additional dependencies for the rule.

Note: The set of Clintrial panels to which a rule is applied is determined using the mappings that exist at the time the attachment is processed. If mappings later change, the rule is not moved to different panels based on the new mappings.

Initial discrepancy status

If you do not replicate Clintrial rules in the InForm study, and you use Clintrial rules for both EDC and PDC data, you must consider in what state to send queries back to the InForm study.

The CIS software returns queries from the Clintrial software in either the Candidate or Open state:

- Candidate queries require sponsor action before they are visible to a site for resolution.
- Open queries require site resolution.
- By default, the CIS software returns discrepancies on EDC data to the InForm software as Open queries if they are in Ready to Send state. Ready to Send indicates that it is appropriate for a site to see the query. All other discrepancy states translate as Candidate queries in the InForm software.

Mapping a discrepancy state to the Open InForm query state

Optionally, you can map another discrepancy state as Open in the InForm software by setting the discrepancy initial status.

To set the discrepancy initial status:

1 Edit the Clintrial database instance, and select the discrepancy state you want. For more information, see ***Editing a Clintrial database instance*** (on page 87).

2 For each Clintrial rule that should return an Open query, in the **Modify Rule** dialog box in the Clintrial Design module, set the **Discrepancy Initial Status** value to the same value that is selected on the **Database Settings** tab of CIS Synchronization in CIS Administration.

Editing a Clintrial database instance

1 Log on to CIS Administration.

The home page of CIS Administration appears.

2 If the **CIS Synchronization** page is not your home page, select **Admin** > **CIS Sync**.

The **CIS Synchronization** page appears.

3 Click **Database Settings**.

The **Database Settings** tab appears.

4 In the **Clintrial Database Instance** table, click **Edit** next to the database instance you want to change.

The Instance, CISUSER Password, and Open Query State fields are enabled.

5 In the **Instance** field, type a new tnsname for the instance.

6 In the **CISUSER Password** field, type a new password.

Important: If you want to change this password, you must first change the Clintrial instance password for Oracle. What you specify for the CISUSER password must be the same as the Oracle password for the Clintrial instance.

7 From the **Open Query State** drop-down list, select the Clintrial discrepancy status that corresponds to the InForm open Query status.

Click **Update**.

CIS processing for updated rules and derivations

When the CIS software receives an updated Clintrial rule or derivation script in which the value of the ENABLED attribute is **True**, it applies the updated script to all Clintrial panels to which the rule is attached.

Note: The CIS software does not remove a rule from a panel; if the value of the ENABLED attribute is **False**, it takes no action. To remove a rule from a panel, use Clintrial Design.

When the Clintrial software receives an updated rule or derivation through synchronization, it does *not* automatically run the rule or derivation. After changing the definition of a rule or derivation, you must run validation manually. When validation runs, CIS opens a new query if the rule fails.

CIS processing for updated attachments to rules or derivations

When the CIS software receives an updated Clintrial rule or derivation attachment in which the value of the ACTIVE attribute is **True**, it applies the updated script to all Clintrial panels to which the attachment maps.

Note: The CIS software does not remove a rule from a panel; if the value of the ACTIVE attribute is False, it takes no action. To remove a rule from a panel, use the Clintrial Design module. Also, the set of Clintrial panels to which a rule or derivation is applied is determined by using the mappings that exist at the time the attachment is processed. If mappings later change, CIS does not move the rule or derivation to different panels based on the new mappings.

When the Clintrial software receives an attachment through synchronization, it does *not* automatically run the rule or derivation.

Modifying rules to ignore EDC data

If you replicate Clintrial rules in the InForm study, both sets of rules are eligible to execute on the EDC data. Unless you modify the Clintrial rules to ignore EDC data, the following scenario occurs:

1 A failing EDC rule immediately produces a query in the InForm software.

2 A Clintrial rule failing on the same EDC data also produces a discrepancy that transfers to the InForm software during the synchronization that transfers the original clinical data.

3 Users must resolve both queries in the InForm study.

Generally, making a data change clears the InForm query and the PDC rule discrepancy. However, depending on the timing of synchronizations, a user could have the experience of correcting an EDC data item and clearing the InForm query only to have the Clintrial rule generate a discrepancy on the same item.

To avoid this scenario, you can include an exception clause at the beginning of each Clintrial rule for which an equivalent EDC rule exists in the InForm database. Use the following syntax.

```
(IS_EDC_RECORD (CT_GLOBAL.CTS$PROTOCOL,
CT_GLOBAL.CTS$PANEL, CT_GLOBAL.CTS$CT_RECID)) OR
(original_rule_script)
```

For example, consider the following rule.

```
(this.HT between 50 and 84)
```

To disable the rule if the data source is EDC, make a call to the IS_EDC_RECORD function.

```
(ctproc.ct_edc_event.is_edc_record(ct_global.cts$protocol,ct_global.cts$panel,
ct_global.cts$ct_recid )) OR (this.HT between 50 and 84)
```

The is_edc_record function returns true if the record source is EDC, and the Clintrial rule does not fire.

Placing queries on EDC items

With the InForm software, the definition of rule contexts and dependencies determines the items for which entering or changing a value makes a rule fire and determines which items receive a query if a rule does not pass. In the Clintrial software, rules are attached at the panel level and can apply to several items in the panel, some of which are mapped to the InForm software.

How CIS determines the item on which to place a query

The INF_ERRORITEM table, which identifies items associated with an EDC data entry error, corresponds to the VCT_ERRORITEM table for PDC data. In a CIS environment, if a Clintrial rule fires on EDC data, the CIS software determines the InForm item to which to attach the query by examining the items posted by the rule in the INF_ERRORITEM table in order and doing the following:

1 It places a query on the InForm item corresponding to the first error item in the INF_ERRORITEM table if all of the following are true:

- The error item is mapped to an InForm control.
- The InForm control is not a calculated control.
- The form in which the control appears has been started.

Note: It is not necessary for the item of which the control is a part to have data, but at least one item on the form must have been submitted.

2 If any of these conditions is not true, CIS examines the next error item to determine if it meets the criteria for placing a query in the InForm software.

3 If no error items meet the criteria, CIS does not send a query to the InForm software, and it places a warning in the Windows event log of the CIS machine.

If no error items are set up for a rule, and the rule fails on EDC data, validation fails. To prevent this, include a derivation in the rule that sets the value of the $edc_usect variable to True.

In a protocol that is set up for Resolve:

- If $edc_usect is set to True, and the rule fails on EDC data, validation creates discrepancies in the Resolve tables (VCT_ERRORSTATUS and VCT_ERRORITEM) instead of in the CIS tables (INF_ERRORSTATUS and INF_ERRORITEM). Error items are not required for validation to run, and you can manage the discrepancies through Resolve.
- If $edc_usect is set to False, and the rule fails:
  - If the data comes from the Clintrial software (in a Hybrid protocol), validation creates discrepancies in the Resolve tables (VCT_ERRORSTATUS and VCT_ERRORITEM).
  - If the data comes from the InForm software through synchronization, validation creates discrepancies in the CIS tables (INF_ERRORSTATUS and INF_ERRORITEM) for records that have error items. In this case, validation fails if no error items exist.

The query initial state is taken from the panel to which the rule is attached, not the panel of the first error item.

Loading error items into the INF_ERRORITEM table

You can attach queries to specific items by using the Resolve module CTV_CORE.SETUP_ERRORITEM PL/SQL procedure in a derivation to load records into the INF_ERRORITEM table. Specify every item that is relevant to the rule result; that is, specify all necessary rule dependencies.

These error items are ordered in the INF_ERRORITEM table, and the CIS software uses the order of the error items to determine the InForm item on which to place a query if the rule fails. For more information, see ***How CIS determines the item on which to place a query*** (on page 89).

Use the following syntax.

```
CTV_CORE.SETUP_ERRORITEM(
      'rule-name',
      CTS$PANEL,
      'itemname',
      THIS.CT_RECID,
      THIS.itemname,
      NULL);
```

For example, the following derivation text, used with the AGE_CHECK rule, loads the VCT_ERRORITEM table (for PDC data) or the INF_ERRORITEM table (for EDC data) with records for the CONSDATE and BIRTHDATE items if the CHECK_AGE rule fails.

```
ctv_core.setup_erroritem('CHECK_AGE',cts$panel,'CONSDATE',
this.ct_recid,this.consdate,null);
ctv_core.setup_erroritem('CHECK_AGE',cts$panel,'BIRTHDATE',
this.ct_recid,this.birthdate,null);
If this.age <18 then
CHECK_AGE $msg :='Age is less than 18';
else CHECK_AGE$msg := null;
end if;
```

You can structure the derivation so that the only EDC item for which an error table record is written is the one on which you want the query to appear. For example, you can make sure that only the CONSDATE item has a record written to the INF_ERRORITEM table by using the IS_EDC_RECORD function.

```
ctv_core.setup_erroritem('CHECK_AGE',cts$panel,'CONSDATE',
this.ct_recid,this.consdate,null)
If not (
     (IS_EDC_RECORD (CT_GLOBAL.CTS$PROTOCOL,
     CT_GLOBAL.CTS$PANEL, CT_GLOBAL.CTS$CT_RECID))
ctv_core.setup_erroritem('CHECK_AGE',cts$panel,'BIRTHDATE',
this.ct_recid,this.birthdate,null);
end if;
```

In this version of the derivation, when the CONSDATE item tests true for being an EDC item, only the record for the CONSDATE item is written to the INF_ERRORITEM table, and therefore only the CONSDATE item is available for the InForm software to write the query on.

Validation and InForm enrollment

The InForm screening and enrollment forms process calculation rules but do not allow queries. If you use Clintrial rules and derivations on EDC data:

- Do not create discrepancies for screening and enrollment forms. During synchronization, CIS ignores error items for records in the enrollment table or for records that map to screening and enrollment forms. No queries based on Clintrial discrepancies are placed on screening and enrollment forms.
- Create derivations for screening and enrollment forms, if needed. CIS installs the derivations into the Clintrial software, where they can populate items in Clintrial panels.

Validation runs on the enrollment panel when CIS moves data from the UPDATE to the DATA tables. (For the enrollment panel, validation runs against the DATA table, not UPDATE table.)

Viewing merged query data

By using the Clintrial Resolve module in a hybrid study, you can create a database union of the Resolve module tables with the EDC-only query tables to merge all of the study query data together.

CHAPTER 8

Using Clintrial modules in an integrated study

In this chapter

Overview of Clintrial modules in an integrated study....94
Classify module....95
Design module....96
Enter module....98
Lab Loader module....99
Manage module....100
Multisite Distribution module....101
Resolve module....104

Overview of Clintrial modules in an integrated study

The Clintrial software, when combined with the CIS software, complements the InForm software by:

- Making integrated studies possible.
- Sharing metadata standards.
- Archiving study data in an easily accessible clinical data management system.

The following describes, on a module-by-module basis, the differences between using the Clintrial software in an integrated study and using the Clintrial software independently.

The Clintrial software in integrated studies

You can perform Clintrial data-management operations on data in an integrated study. For example, you can:

- Validate and merge data with the Manage module.
- Perform automatic or interactive coding with the Manage module.
- Resolve coding problems with the Classify module.
- Extract data with the Retrieve module.

Clintrial changes

Clintrial functionality for data entered with the Enter module in a hybrid study is unchanged. However, some Clintrial functionality is not available for use with EDC study data that is entered with InForm software.

An integrated study introduces the following limitations on Clintrial functionality:

- Panels with EDC data cannot be modified.
- New EDC patients cannot be created.
- Enrollment data cannot be modified for EDC patients.
- Flags and notes cannot be created or modified for EDC data.
- EDC data cannot be globally changed or deleted.
- Discrepancies on EDC data cannot be created, managed, or resolved.
- InForm users cannot be created or managed.
- Data can be imported with the Lab Loader module only into a study that has been configured as hybrid.

Note: In some circumstances, it may be necessary to override these restrictions. For more information, see ***Changing study mode*** (on page 96).

Classify module

All Classify module functions are enabled for data entered with the Enter module. For EDC data entered with the InForm software, some functionality differs in:

- Omission status
- Solution types

Omissions status

When the Classify module issues an Omissions request for more information, the query is placed in **Proposed** or **Pending** state once accepted. For EDC data, you must rerun coding from the Manage module to move queries from **Pending** to **Applied** state. Once in the **Applied** state, the Clintrial software creates a query record in the INF_ERRORSTATUS table with a status of **Ready to Send**.

Solution types

In the Propose Solution menu in the Omission Browser for problems in the **Needs Proposal** state, the **Change Verbatim** solution type is not available for coding problems related to EDC data. Only the **Reuse Solution**, **Create Synonym**, and **Request More Info** solution types are available.

For the **Solution Pending**, **Applied**, or **Solved** state, only omission records with a Synonym Solution are displayed in the Omission Browser.

Design module

You can use the Design module to create and modify display features, such as page sections and page templates, for integrated protocols.

The Design module accommodates integrated protocols with changes to the following areas:

- Protocol design
- Protocol import and export
- Hybrid study mode

Protocol design

You cannot modify panels that contain EDC data with the Clintrial Design module. For these panels, the Mark for Revision and Deinstall menu options on the Panel menu in the Panel Browser are disabled. However, you can override this restriction if necessary. For more information, see ***Changing study mode*** (on page 96).

Protocol import and export

Protocol import and export works the same for integrated studies as for nonintegrated studies. For integrated studies, additional CIS tables are created and populated automatically during the import process, and read during the export process.

Changing study mode

When an integrated study is EDC only, or when a hybrid study contains EDC data, some restrictions apply. For more information, see ***Clintrial changes*** (on page 94). However, in some circumstances you may need to change the mode in which a study is operating. The **Hybrid** and **Enable Modifications to EDC panels** options accommodate these needs. These options are on the Modify Protocol screen. To activate either:

1 In Clintrial Design, open the **Protocol Browser** window for the protocol you want to modify.

2 From the right-click menu of the **Protocol Browser** window, select **Modify**.

The Modify Protocol window appears.

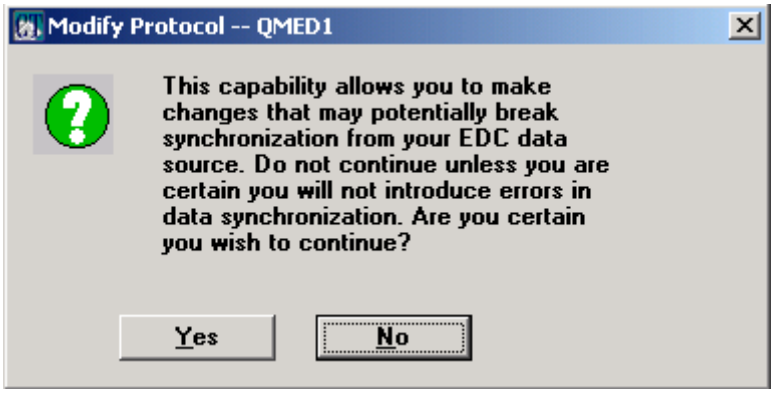
3 Select the option you require:

- **Hybrid**—Converts an EDC-only study to hybrid mode. This option is available in an EDC-only study in which no EDC data has been synchronized to the Clintrial software. In this mode, the restrictions placed on EDC-only trials are removed.

  Note: This conversion is one-time only and cannot be reversed. Once you select Hybrid and save, this option does not appear on the Modify Protocol screen.

- **Enable Modifications to EDC panels**—Re-enables the ability to revise or deinstall a panel. This option is available in a hybrid study where some EDC data has been synchronized to the Clintrial software.

Caution: Make sure that you update mappings appropriately and do not cause data type mismatches with any changes you introduce. Test changes thoroughly in a test environment before enabling them in production. The following message warns of the possibility of introducing errors.



4 Save the protocol.

Enter module

You can use the Enter module to enroll patients and to enter and edit data in hybrid studies. However, patients enrolled with the Clintrial software are not visible to the InForm software, and you cannot use the Enter module to modify EDC data entered from the InForm software.

Enrollment

Enter module users are not permitted to enroll EDC patients. For EDC patients in an integrated study, the enrollment pages are protected from data entry, and the New Subject menu option on the File menu is disabled.

When you create a protocol for a hybrid study by synchronizing a study from the InForm software, the CIS software automatically assigns an enrollment panel. Therefore, when you create a study book for the protocol, the Clintrial software does not ask which enrollment study book to use.

Data entry

EDC data entered with the InForm software is read-only in the Enter module. Also, data entered with the Enter module is visible only in the Clintrial software.

Manual discrepancies

You cannot create manual discrepancies on EDC data from within the Clintrial software. On pages that have discrepancies for EDC data, the View menu, the Discrepancies menu, and the Print Discrepancies menu options on the File menu are disabled. These functions are enabled only for data entered with the Enter module.

Flags and notes

You cannot attach flags or notes to items with EDC data in them.

Lab Loader module

You can use the Lab Loader module with EDC data, provided that the protocol has been configured as a hybrid protocol and the Resolve module is installed. The EDC subject must already exist in the Clintrial software, through a previous synchronization between the InForm software and the Clintrial software, before the Lab Loader module can be utilized for EDC data. For both EDC and non-EDC subjects, the DB_ID data values in the source protocol must use the DB_ID of the database instance.

The enhanced transfer functionality within the Lab Loader module automatically updates the DB_ID values for EDC subjects to 9999. Data records transferred by the Lab Loader module are re-validated in the destination protocol if the data record is being updated. New data records are not validated in the destination protocol.

Managing queries on batch loaded data

Because EDC data loaded with Lab Loader is not synchronized from the InForm software to the Clintrial software, managing queries occurs through the Resolve module of the Clintrial software even though the data is for EDC patients. The workflow is as follows:

1 Synchronization of a study that is designed with the Central Designer software results in the creation of a destination protocol. Enroll EDC patients using the InForm software and synchronize the data into the destination protocol.

2 Create a Lab Loader source protocol, and map the source and destination protocol panels to use for batch-loaded data.

3 Use the Lab Loader module to load EDC patient data into the Lab Loader source protocol.

4 Screen and validate the records.

5 Transfer the data to the destination protocol.

6 Use the Manage module to re-validate the EDC data, which has a DB_ID value of 9999.

7 Use the Resolve module to handle any resulting queries.

Manage module

You can validate and merge all data in an integrated study, regardless of their source. However, some Manage module functionality is restricted for EDC data.

Global Change and Global Delete

You cannot perform Global Change or Global Delete functions on EDC data. These options on the Manage menu are disabled for EDC-only studies. The Global Change Log and Global Delete Log options from the Reports menu are also not available. These functions are enabled only for data entered with the Enter module.

Batch loading

Data can be batch-loaded into an integrated protocol. The EDC subject must already exist in the Clintrial software, through a previous synchronization between the InForm software and the Clintrial software, before you can perform batch loading of EDC data. For both EDC and non-EDC subjects, the DB_ID data values in batch-loaded data files must be assigned the DB_ID of the database instance.

Enhanced screening functionality, within the Manage module, automatically updates the DB_ID values for EDC subjects to 9999. The software validates batch-loaded data that is successfully screened.

Managing queries on batch-loaded data

Because EDC data loaded with the batch loading functionality of the Manage module is not synchronized from the InForm software to the Clintrial software, managing queries occurs through the Resolve module of the Clintrial software even though the data is for EDC patients. The workflow is as follows, use the:

1 Manage module to batch load EDC patient data into the UPDATE tables in the Clintrial database.

2 Manage module to validate the EDC data, which has a DB_ID value of 9999.

3 Resolve module to handle any resulting queries.

Multisite Distribution module

You can use the Multisite Distribution module with CIS to distribute EDC protocol design changes developed with the Central Designer software from a test environment to a production environment.

Test environment for Multisite Distribution and CIS

The test environment using Multisite Distribution to distribute metadata updates to a production Clintrial protocol consists of:

- The Central Designer software and a test InForm study.
- The CIS software.
- A test Clintrial protocol defined as a Multisite *master* protocol.

Note: The master protocol must be set up to use Resolve for query processing. For more information, see ***Setting up Resolve to return EDC queries*** (on page 104).

Production environment for Multisite Distribution and the CIS software

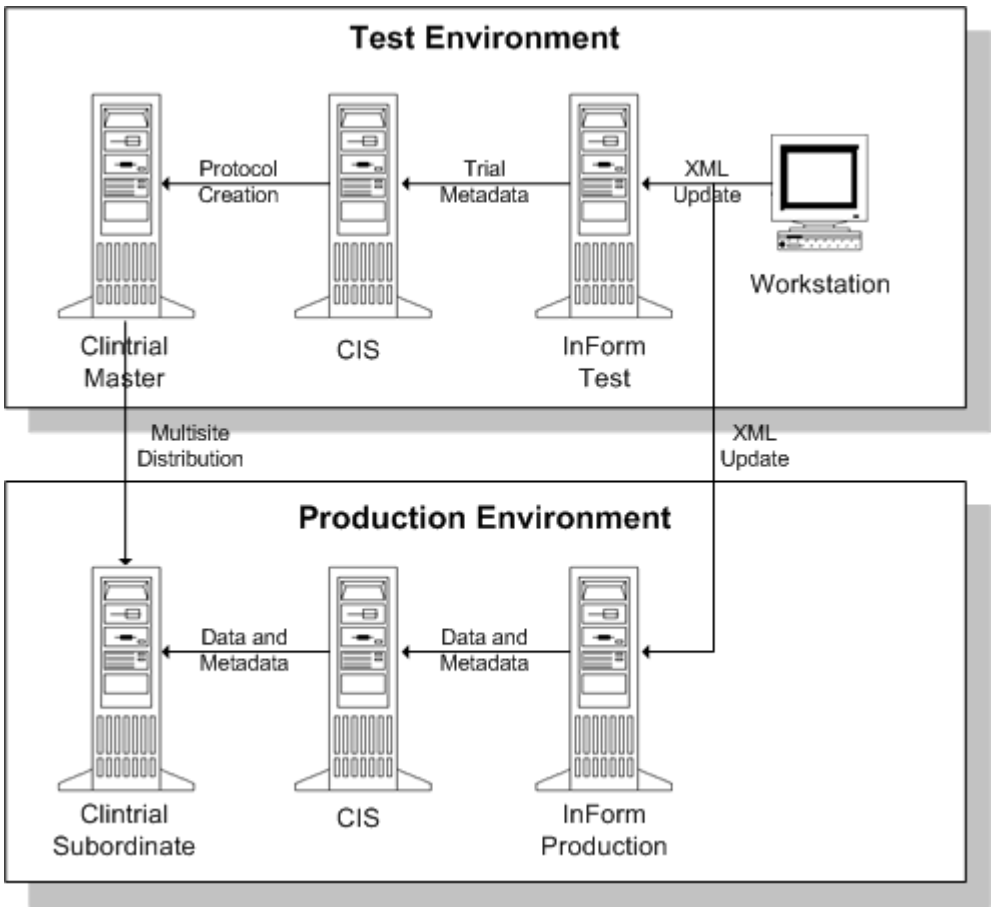
The production environment using Multisite Distribution to distribute metadata updates to a production Clintrial protocol consists of:

- A production InForm study.
- The CIS software.
- A production Clintrial protocol defined as a Multisite *subordinate* protocol.

Note: The subordinate protocol must be set up to use Resolve for query processing. You can do this at the subordinate protocol, or you can set up the master protocol for Resolve and use Multisite Distribution and Replication to pass the settings to the subordinate protocol. For more information, see ***Setting up Resolve to return EDC queries*** (on page 104).

Multisite Distribution and CIS workflow

The following diagram illustrates the workflow between the InForm software, the CIS software, and Clintrial Multisite Distribution when distributing protocol metadata from a design to a production environment:



To use Multisite Distribution for distributing metadata updates from test to production environments:

1 Using the Central Designer software, develop an InForm study, make a deployment package, and install the package to the InForm test server.

2 Create a Clintrial protocol and initial metadata in the test environment (Clintrial Master). You can do this by:

- Synchronizing the InForm study metadata from the InForm software to the Clintrial software. If no protocol exists in the Clintrial software, the CIS synchronization creates it.

  or

- Using the Design module to create the protocol and then synchronizing the InForm study metadata to that protocol.

3 Using Multisite, create the subordinate protocol in the production environment (Clintrial Subordinate).

4 Deploy the deployment package (created in Step 1) to the InForm server in the production environment (InForm Production).

5 Synchronize the production study to the production protocol.

6 Iteratively create or alter the metadata as needed (these steps can occur any number of times):

   a Open the test (master) protocol for revision in Clintrial Multisite.

   b Using the Central Designer software, make any necessary changes to the InForm test study, create a new deployment package and install the package to the InForm test server.

   c Using the CIS software, synchronize the metadata changes to the test protocol.

   d Close the test protocol for revision.

   e Distribute the metadata changes from the test protocol to the production (subordinate) protocol.

   f Accept the metadata changes at the production protocol.

   g Install the deployment package to the production InForm study.

   h Synchronize the production study to the production protocol.

Caution: The order of this workflow is important. The workflow requires that the subordinate Clintrial protocol receives changes from the test protocol before the changes are synchronized from the production InForm study. This is because the CIS software cannot update the subordinate protocol through synchronization; it can only be updated by Multisite Distribution. If a production synchronization contains metadata changes that are not already reflected in the production Clintrial protocol, the CIS software stops the synchronization and reports an error.

Resolve module

Resolve is an extended module of the Clintrial software. It *must* be included in your Clintrial installation if you want to use the CIS software.

Setting up Resolve to return EDC queries

If you want the CIS software to synchronize back to the InForm software any queries that were generated on EDC data by Clintrial rules, the Clintrial protocol to which the InForm study synchronizes must be set up for Resolve.

To set up a protocol for Resolve:

1 Login to Resolve.

2 Click **File** > **Set Protocol**.

The Set Protocol dialog box appears.

3 Select the protocol you want and click **OK**.

The name of the protocol you selected appears in the title bar of the main Resolve window and the Selected Discrepancies window appears.

4 Close the **Selected Discrepancies** window.

5 Click **Setup** > **Setup for Resolve**.

Note: If you are using the Clintrial Multisite Distribution module to distribute EDC protocol design changes developed with the Central Designer software from a test environment to a production environment, both the master and subordinate protocols must be set up for Resolve. For more information, see ***Multisite Distribution module*** (on page 101).

Visibility of EDC queries

Except for the following cases, the Resolve module is only available for discrepancies associated with data entered with the Enter module. Queries generated on EDC data, other than batch loaded data, are not visible in Resolve.

Queries generated on EDC data are visible in Resolve if either of the following is true:

- They apply to data loaded with the Lab Loader module or with the batch loading functionality of the Manage module. For more information, see ***Manage module*** (on page 100). Also see ***Lab Loader module*** (on page 99).
- The rule that generates a query includes a derivation that sets the value of the $edc_usect variable to True. In a protocol that is set up for Resolve:
  - If $edc_usect is set to True, and the rule fails on EDC data, validation creates discrepancies in the Resolve tables (VCT_ERRORSTATUS and VCT_ERRORITEM) instead of in the CIS tables (INF_ERRORSTATUS and INF_ERRORITEM). Error items are not required for validation to run, and you can manage the discrepancies through Resolve.
  - If $edc_usect is set to False, and the rule fails:
    - If the data comes from the Clintrial software (in a Hybrid protocol), validation creates

discrepancies in the Resolve tables (VCT_ERRORSTATUS and VCT_ERRORITEM).

- If the data comes from the InForm software through synchronization, validation creates discrepancies in the CIS tables (INF_ERRORSTATUS and INF_ERRORITEM) for records that have error items. In this case, validation fails if no error items exist.

The EDC table data is used to synchronize a query back to the InForm software. The Resolve panels enable you to view and manage the discrepancy through the Resolve module.

Index

$

$edc_usect • 89

A

Admin module • 2

B

bulk data loads, planning • 16, 100

C

Classify module • 95
    Omissions status • 95
    solution types • 95
Clintrial software
    batch loading • 100
    changes to • 94
    Classify module • 95
    data entry in • 98
    Design module • 96
    enrollment • 98
    Enter module • 98
    flags and notes • 98
    global change and delete • 100
    import/export • 96
    in an integrated study • 94
    Lab Loader module • 99
    Manage module • 100
    manual discrepancies • 98
    protocol design • 96
    Resolve module changes • 104
context items • 21
CONTEXT panel • 45
CTV_CORE.SETUP_ERRORITEM • 90

D

data entry
    and merging • 75
    in a hybrid study • 76
    in an EDC study • 75
    screening and enrollment • 75
data transfer • 73
data type conversions • 26
Design module • 96

E

enrollment study book • 57
enrollment, InForm • 13
Enter module • 98
entering data • 72

F

flags and notes • 98
frozen Case Book • 73

G

global change and delete • 100

H

hybrid study
    and data entry • 76

I

INF_PATHMAP and study book autocreation • 60
InForm
    enrollment • 13
InForm Data Import • 16
initial discrepancy status • 86
integrated study
    and Clintrial software • 94
    creating • 54
    data transfer • 73
    modifying metadata • 20
IS_EDC_RECORD function • 88, 90

L

Lab Loader module • 16, 99
locked Case Book • 73
locked forms and queries • 84
locked protocol • 73

M

Manage module • 16, 100
mappings
    enrollment • 51
    overview • 32
    planning • 15
    updating • 51
merging EDC and PDC query data • 91
metadata translation
    items • 21
    protocols • 21
    studybooks • 21
modifying
    metadata in an integrated study • 20

N

non-patient data study book • 58

O

Omissions status, Classify • 95

P

panel
    types • 21, 63
patient data study book • 58
patient number changes • 74
planning
    bulk data loads • 16
    rules • 12
protocol
    creating • 54
    locked • 73
    updating • 69
protocol configuration
    checklists • 67
    codelists • 67
    general • 66
    required attribute • 66

Q

queries
    batch loaded data and • 100
    Clintrial rules and • 79
    conflicts • 82
    database tables • 83
    definition • 78
    initial discrepancy status and • 86
    on an empty form • 84
    on EDC data • 89
    on frozen or locked forms • 84
    reopening • 84
    Resolve and • 104
    resolving • 79
    states • 79
    storing information • 83
    viewing merged EDC and PDC • 91

R

Resolve module
    and updated protocols • 69
    EDC queries and • 104
    tables • 83
resolving queries • 79
rules
    ignoring EDC data • 88
    in a hybrid study • 86
    in an integrated study • 85
    planning • 12
    queries on EDC data • 89

S

screening and enrollment • 75
SETUP_ERRORITEM procedure • 90
solution types, Classify • 95
storing query information • 83
study book autocreation
    INF_PATHMAP and • 60
    patient data panel and • 60
    study book generation • 62
    terms • 56
    troubleshooting • 63
    XML generation • 57, 58, 60, 61
study mode, changing • 96
synchronization connections
    patient number changes and • 74

U

updating an existing protocol • 69

V

validation and COMMIT statements • 85
validation and InForm enrollment • 13
VCT_ERRORITEM table • 83, 89
VCT_ERRORSTATUS table • 83

X

XML for study book autocreation • 57, 58, 60, 61