

# Phase Forward™ Training Course Catalog



PHASE•FORWARD™

## InForm™ for CRCs

(Site) Hands-on  
Max 20 attendees

### Objectives

Use the InForm software to accomplish typical sponsor tasks performed while running a clinical trial.

### Audience

Clinical trial professionals who enter and update data and respond to queries

**Length** 5 hours

## InForm™ for Delta

(Recorded Webcast)

### Objectives

Describe the new features that InForm trials provide for Site and Sponsor users.

### Audience

Clinical trial professionals who enter, update data, respond to queries, audit and query data after entry and sign data entry forms

**Length** 30 minutes

## InForm™ for CRAs

(Sponsor) Hands-on  
Max 20 attendees

### Objectives

Use the InForm software to accomplish typical sponsor tasks performed while running a clinical trial.

### Audience

Clinical trial professionals who audit and query data after entry and sign data entry forms

**Length** 7 hours

## InForm™ Reporting and Analysis

Max 10 attendees

### Objectives

Use the InForm software to produce reports on electronic clinical data.

### Audience

Clinical trial professionals who are responsible for producing reports on InForm™ trial electronic clinical data

**Length** 1 day

## InForm™ for PIs

(Principal Investigator) Demonstration Only  
Max 100 attendees

### Objectives

Use the InForm software to accomplish typical tasks performed while overseeing a clinical trial.

### Audience

Clinical trial investigators

**Length** 30-60 minutes

## InStruct Online for Sponsors

(Web-based training)

### Objectives

Use the InForm software to accomplish typical sponsor tasks performed while running a clinical trial.

### Audience

Clinical trial professionals who audit and query data after entry and sign data entry forms

**Length** 3 hours

## InStruct Online for CRCs

(Web-based training)

### Objectives

Use the InForm software to accomplish typical site tasks performed while running a clinical trial.

### Audience

Clinical trial professionals who enter and update data and respond to queries

**Length** 3 hours

## InStruct Online for PIs – Signature

(Web-based training)

### Objectives

Use the InForm software to accomplish typical tasks performed while overseeing a clinical trial.

### Audience

Clinical trial investigators

**Length** 30 minutes

## InStruct Online for PIs – Data Entry

(Web-based training)

### Objectives

Use the InForm software to accomplish typical tasks performed while overseeing a clinical trial.

### Audience

Clinical trial investigators

**Length** 3 hours

## InStruct Online – View Only

(Web-based training)

### Objectives

Use the InForm software to view data while working on a clinical trial.

### Audience

Clinical trial professionals who only need to view information

**Length** 45 minutes

## InForm™ Portal Administration

(Recorded Webcast)

### Objectives

Basic information needed to navigate the InForm Portal.

### Audience

All members of the clinical team

**Length** 1.5 hours

### Using InForm™ for Clinical Trials/ InForm End User

(Site/Sponsor functionality)

Max of 20 attendees

#### Objectives

- Log on to an InForm trial and manage a user profile.
- Enter, validate and review clinical data in an InForm trial.

#### Audience

Clinical trial professionals who enter and update data, respond to queries, audit and query data after entry and sign data entry forms

**Length** 1 day

### InForm™ Reporting and Analysis

Max 10 attendees

#### Objectives

Use the InForm software to produce reports on electronic clinical data.

#### Audience

Clinical trial professionals who are responsible for producing reports on InForm trial electronic clinical data

**Length** 1 day

### Using Central Designer™

Max 8 attendees

#### Objectives

- Use Central Designer libraries.
- Work with study objects such as items, forms, study events and study elements.
- Design a study workflow.
- Define data-entry rules.
- Use collaboration features.
- Validate and deploy a study.

#### Audience

All users of Central Designer

**Length** 2 days

### Central Designer™ Rules Workshop

Max 8 attendees

#### Objectives

- Define rule expressions.
- Specify rule actions.
- Create and use constants.
- Import and use functions.
- Create complex data-entry rules.
- Create a logical schema to use in defining rules.
- Validate and deploy a study.

#### Audience

All programmers and study designers who are responsible for creating data-entry rules using the Central Designer software

**Length** 2 days

### Central Designer™ Admin

(Web-based training)

#### Objectives

- Navigate in the Central Designer Administrator software.
- Create and manage users and roles.
- Create and manage supported locales, note and task types, custom properties for Central Designer objects and create form layouts.
- Create keywords and categories and associate keywords and categories with users and study objects.

#### Audience

Central Designer Administrators

**Length** 2 hours

### Creating Trials Using InForm™ Architect

#### Objectives

- Present the concepts and procedures needed to create forms using InForm Architect; including initiating a trial in Architect.
- Setting up the trial structure (forms and visits) in Architect.
- Implementing naming conventions.
- Creating forms and items.
- Documenting design decisions online.

#### Audience

Designers, Developers, Application Engineers, Clinical Data Managers

**Length** 3 days

### Central Designer™ Libraries

(Web-based training)

#### Objectives

- Create a library project and a library.
- Set library deployment properties and specify library form layouts.
- Assign users to library teams.
- Import functions and add constants to a library.
- Import a study into a library.
- Create templates and types in a library.
- Create and manage study objects in a library.
- Generate library reports.

#### Audience

Central Designer Library Administrators

**Length** 2 hours

### Adding Rules to InForm™ Trials

(for Architect users)

#### Objectives

- Define rules, events, contexts, dependencies and testing.

#### Audience

Designers, Developers, Application Engineers, Clinical Data Managers, Database Administrators

**Length** 3 days

### Releasing an InForm™ Study

(for Central Designer™ users)  
(Live Webcast)

#### Objectives

- Identify the tasks associated with preparing a study for production.
- Work with XML files and use the MedML Installer.
- Configure administrative data for a study.
- Configure study-wide system settings.
- Enable electronic signatures.
- Set up a home page.
- Manage study versions.
- Prepare the final build of a study for production.

#### Audience

Database Administrators (DBA), Network Administrators, Systems Engineers and Administrators

**Length** ½ day

### Installing InForm™ Trials

- Prepare server machine for the InForm software.
- Install the InForm software.
- Install a trial.
- Manage and monitor InForm components.
- Perform trial decommissioning activities.

#### Audience

Administrators, System Engineers

**Length** 2 Days

### CRF Submit

#### Objectives

- Understand the functionality, architecture, request process and workflow of CRF Submit.
- Generate and interpret PDFs and the trial data included in the PDFs.
- Administer and configure CRF Submit users, parameters and settings.
- Troubleshoot the application for known problems and recommended solutions.

#### Audience

CRF Submit End Users, CRF Submit Administrators

**Length** 1 day

### InForm™ End-user Train-the-trainer

*Min 4/Max 8 attendees*

#### Objectives

- Prepare trainers to deliver Site/Sponsor InForm training.

#### Audience

Client Trainers

**Length** 3 days

## Using Central Coding™ (End User)

(Web-based training)

### Objectives

- Launch the Central Coding software and navigate the user interface.
- Understand how synonyms, stopwords and coding algorithms are used in Central Coding.
- Use assignment rules and coding.
- Interactively code requests using the Coding Browser.
- Approve and disapprove coding requests.
- Create coding queries.

### Audience

Coding specialists who will be using the Central Coding software

### Length

1.5 hours

## Managing Central Coding™

### Objectives

- Launch the Central Coding software and navigate the user interface.
- Create and manage roles, work teams and user accounts.
- Manage coding dictionaries; Create and manage synonym lists.
- Create and manage stopwords lists.
- Create and manage autocoding algorithms.
- Create and manage coding definitions; Create and manage assignment rules.
- Work with administrative reports.
- Manage system configuration options, job queues and coding requests.

### Audience

Coding specialists who will be using the Central Coding user interface to perform system set-up and administration tasks.

### Length

1 day

## Using Clintrial™ Enter, Manage and Retrieve

### Objectives

- Understand key concepts and define key terms needed when using Clintrial.
- Perform data-entry tasks using Clintrial Enter.
- Perform data-management tasks using Clintrial Manage.
- Query the database using Clintrial Retrieve.

### Audience

Clinical Data Managers, Data Entry Operators, Programmers and Study Designers

**Length** 2 days

## Clintrial™ Design

### Objectives

- Create protocols.
- Create codelists.
- Define the structure of the Oracle® tables.
- Create electronic representation of CRFs (study books), including dynamic blocks and pages.
- Create flags and notes.
- Set up coding thesauruses.
- Transfer protocol accounts and codelists.
- Manage metadata through revision control and protocol release management.
- Work with PL/SQL packages.

### Audience

Study Designers, Programmers, System Administrators and Data Managers

**Length** 4 days

## Clintrial™ Resolve End User and Set Up

### Objectives

- Identify, track, review, resolve and document discrepancies.
- Set up protocols for use with Resolve.

### Audience

Study Designers, Programmers, Data Managers

**Length** 1 day

## Clintrial™ Lab Loader

### Objectives

- Batch load data into a lab loader protocol.
- Process the data.
- Transfer the data into a clinical data protocol.

### Audience

Data Managers, Programmers

**Length** 1 day

## Clintrial™ Coding with Classify

### Objectives

- Track, review and find solutions for values that fail automatic coding.
- Build and test effective coding thesaurus algorithms.
- Create coding thesaurus protocols.
- Set up coding targets and coding related items in a clinical data protocol.

### Audience

Coding Experts, Dictionary Managers

**Length** 1 day

## Clintrial™ Admin

### Objectives

- Create user accounts and user groups.
- Assign access rights to users and user groups.
- Set system parameters and Oracle® storage parameters.
- Monitor database storage and space utilization.
- View system administration reports.

### Audience

System and Database Administrators

**Length** ½ day

## Clintrial™ Multisite

### Objectives

- Understand Multisite concepts including sites, distribution and replication.
- Configure sites in a distribution environment and in a replication environment.
- Perform basic data-entry operations in a replicated environment.

### Audience

Designers, Programmers

### Length

2 days

## Introduction to SQL

### Objectives

- Use basic SQL commands.
- Use Query By SQL in Clintrial Retrieve.
- Describe the Clintrial database structure.
- Use basic SQL functions and table operations.

### Audience

Developers who have some acquaintance with basic SQL commands and need to write queries against the Clintrial tables to produce analytical reports

### Length

1 day

## Writing Clintrial™ Rules and Derivations

### Objectives

- Create derivations in Clintrial Design.
- Create rules in Clintrial Design.
- Test derivations and rules by running validation in Clintrial Manage.
- View discrepancies in Clintrial Resolve.

### Audience

Designers, Programmers, Data Managers

### Length

1 day

## Using PL/SQL in the Clintrial™ Environment

### Objectives

- Use SQL\*Plus.
- Describe how PL/SQL works with Clintrial validation.
- Use basic PL/SQL syntax, create and use stored functions and procedures.
- Create and use packages.
- Set up data checks.
- Write value changed procedures.

### Audience

Clinical Data Managers, Clintrial Programmers and Study Designers

### Length

3 days

## Implementing CDISC Standards in a Clintrial™ Environment

### Objectives

- Build an SDTM version 3.1 library of Clintrial Panels and construct a sample trial database.
- Import lab data in the LAB model format and converting to SDTM in CDISC\_Medika.
- Understand the basic principles of XML.
- Generate an ODM XML file from CDISC\_Medika (using the Phase Forward ODM Export Tool).

### Audience

Data Managers, Programmers, Study Designers, and anyone involved in integrating CDISC standards

### Length

1 day

## Empirica™ Trace End User

### Objectives

- Launch the Trace software and navigate the user interface.
- Enter, edit, code and review case data.
- Enter and edit triage data.
- Evaluate and approve cases.
- Work with drug, medical device and vaccine data.
- Create and manage queries.
- Generate and manage reports.

### Audience

This course is intended for all safety specialists who use the Trace software to enter, manage and report on adverse event cases

**Length** 1 day

## Empirica™ Trace System Admin

### Objectives

- Describe the Trace system administration environment.
- Set up and manage user accounts.
- Create and manage reporters and codelists.
- Maintain product and reporting information.
- Manage coding and coding dictionaries.
- Upgrade the MedDRA coding dictionary.
- Configure E2B settings.
- Manage the Reporting Workspace.
- Run administrative reports.

### Audience

This course is intended for safety specialists and administrators who perform Trace system set-up and administration tasks

**Length** 1 day

## Empirica™ Trace Reporting Workspace

### Objectives

- Describe the Trace Reporting Workspace environment.
- Describe the Trace Ad Hoc Reporting data model.
- Create reports using the Trace Ad Hoc Reporting tool.

### Audience

This course is intended for safety specialists who are responsible for producing administrative reports on Trace data

**Length** 1 day

## Empirica™ Trace Report Distribution

### Objectives

- Describe the global report distribution process and requirements.
- Set up product profiles, recipient contacts and report recipients.
- Manage case selection rules.
- Manage the distribution matrix.
- Perform release management.

### Audience

Trace administrators responsible for planning, setting up and maintaining global report distribution

**Length** 1 day

## Producing Empirica™ Trace Reports

### Objectives

- Describe the regulatory and internal reports available within Trace.
- Offers best practices for requesting and producing these reports.
- Review and rehearse the preparation of periodic reports.

### Audience

This course is intended for safety specialists responsible for producing, submitting and troubleshooting safety reports

**Length** 1 day

## Phase Forward Headquarters

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