

Phase Forward – Training Course Catalog

InForm End User Training Courses:

Training Course	Objectives	Audience	Length
InForm™ for CRCs (Site) (max 20 attendees) Hands-On	Use the InForm software to accomplish typical sponsor tasks performed while running a clinical trial.	Clinical trial professionals who enter and update data and respond to queries	5 hours
InForm™ for CRAs (Sponsor) (max 20 attendees) Hands-On	Use the InForm software to accomplish typical sponsor tasks performed while running a clinical trial.	Clinical trial professionals who audit and query data after entry, and sign data entry forms	7 hours
InForm™ for PIs (Investigators) (max 100 attendees) Demonstration Only	Use the InForm software to accomplish typical tasks performed while overseeing a clinical trial.	Clinical trial investigators	30-60 minutes
InForm™ Introduction to New Features (max 20 ppl)	Describe the new features that InForm trials provide for Site and Sponsor users.	Clinical trial professionals who enter, update data, respond to queries, audit and query data after entry, and sign data entry forms	½ day
InForm™ Reporting and Analysis (max 10 attendees)	Use the InForm software to produce reports on electronic clinical data.	Clinical trial professionals who are responsible for producing reports on InForm trial electronic clinical data	1 day
InStruct Online for CDMs (Web-based training)	Use the InForm software to accomplish typical sponsor/data manager tasks performed while running a clinical trial.	Clinical Data Managers	4 hours
InStruct Online for CRAs (Web-based training)	Use the InForm software to accomplish typical sponsor tasks performed while running a clinical trial.	Clinical trial professionals who audit and query data after entry, and sign data entry forms	3 hours
InStruct Online for CRCs (Web-based training)	Use the InForm software to accomplish typical site tasks performed while running a clinical trial.	Clinical trial professionals who enter and update data and respond to queries	3 hours
InStruct Online for PIs - Signature (Web-based training)	Use the InForm software to accomplish typical tasks performed while overseeing a clinical trial.	Clinical trial investigators	30 minutes
InStruct Online for PIs – Data Entry (Web-based training)	Use the InForm software to accomplish typical tasks performed while overseeing a clinical trial.	Clinical trial investigators	3 hours
InStruct Online – View Only (Web-based training)	Use the InForm software to view data while working on a clinical trial.	Clinical trial professionals who only need to view information	45 minutes
InForm™ Portal Administration Recorded Webcast	Basic information needed to navigate the InForm Portal.	All members of the clinical team	1.5 hours

InForm Enterprise Adpotion - Designer/Developer Training Courses:

Training Course	Objectives	Audience	Length
Using InForm™ for Clinical Trials/InForm End user (Site/Sponsor functionality) (max of 20 attendees)	<ul style="list-style-type: none"> Log on to an InForm trial and manage a user profile. Enter, validate, and review clinical data in an InForm trial. 	Clinical trial professionals who enter and update data, respond to queries, audit and query data after entry, and sign data entry forms	1 day
InForm™ Reporting and Analysis (max 10 attendees)	Use the InForm software to produce reports on electronic clinical data.	Clinical trial professionals who are responsible for producing reports on InForm trial electronic clinical data	1 day
Using Central Designer	<ul style="list-style-type: none"> 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. 	All users of Central Designer	2 days
Advanced Designer Workshop	<ul style="list-style-type: none"> 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. 	All programmers and study designers who are responsible for creating data-entry rules using the Central Designer software.	2 days
Central Designer Admin (Web-based training)	<ul style="list-style-type: none"> 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. 	Central Designer Administrators	2 hours
Central Designer Libraries (Web-based training)	<ul style="list-style-type: none"> 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. 	Central Designer Library Administrators	2 hours
Creating Trials Using InForm™ Architect	<ul style="list-style-type: none"> 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 	Designers, Developers, Application Engineers, Clinical Data Managers	3 days

Training Course	Objectives	Audience	Length
	<ul style="list-style-type: none"> • creating forms and items • documenting design decisions online 		
Adding Rules to InForm™ Trials	<ul style="list-style-type: none"> • Define rules, events, contexts, dependencies, and testing 	Designers, Developers, Application Engineers, Clinical Data Managers, Database Administrators	3 days
Releasing an InForm™ Study (for Central Designer users)	<ul style="list-style-type: none"> • 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 	Database Administrators (DBA), Network Administrators, Systems Engineers and Administrators	1/2 day
Installing InForm™ Trials	<ul style="list-style-type: none"> • Prepare server machine for the InForm software. • Install the InForm software. • Install a trial. • Manage and monitor InForm components. • Perform trial decommissioning activities. 	Administrators, System Engineers.	2 Days
CRF Submit	<ul style="list-style-type: none"> • 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. 	CRF Submit End Users, CRF Submit Administrators.	1 day
InForm™ End-User Train-the-Trainer (Min 4/Max 8 attendees)	<ul style="list-style-type: none"> • Prepare trainers to deliver Site/Sponsor InForm training. 	Client Trainers.	3 days

Central Coding Training Courses:

Training Course	Objectives	Audience	Length
Using Central Coding (End User) (Web-based training)	<ul style="list-style-type: none"> • 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. 	Coding specialists who will be using the Central Coding software.	1.5 hours
Managing Central Coding	<ul style="list-style-type: none"> • 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 stopword 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. 	Coding specialists who will be using the Central Coding user interface to perform system setup and administration tasks.	1 day

Clintrial Training Courses:

Training Course	Objectives	Audience	Length
Using Clintrial™ Enter, Manage, and Retrieve	<ul style="list-style-type: none"> • 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. 	Clinical data managers, Data entry Operators, Programmers, and Study designers	2 days
Clintrial™ Design	<ul style="list-style-type: none"> • 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. 	Study designers, Programmers, System administrators and Data managers	4 days
Clintrial™ Resolve End User and Set Up	<ul style="list-style-type: none"> • Identify, track, review, resolve, and document discrepancies. • Set up protocols for use with Resolve. 	Study designers, Programmers, Data Managers	1 day
Clintrial™ Lab Loader	<ul style="list-style-type: none"> • Batch load data into a lab loader protocol. • Process the data. • Transfer the data into a clinical data protocol. 	Data Managers, Programmers	1 day
Clintrial™ Coding with Classify	<ul style="list-style-type: none"> • 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. 	Coding experts, Dictionary managers	1 day
Clintrial™ Admin	<ul style="list-style-type: none"> • 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. 	System and database administrators	0.5 day
Clintrial™ Multisite	<ul style="list-style-type: none"> • 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. 	Designers, Programmers	2 days
Introduction to SQL	<ul style="list-style-type: none"> • Use basic SQL commands. • Use Query By SQL in Clintrial Retrieve. • Describe the Clintrial database structure. • Use basic SQL functions and table operations. 	Developers who have some acquaintance with basic SQL commands and need to write queries against the Clintrial tables to produce analytical reports.	1 day

Training Course	Objectives	Audience	Length
Writing Clintrial™ Rules and Derivations	<ul style="list-style-type: none"> • 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. 	Designers, Programmers, Data Managers	1 day
Using PL/SQL in the Clintrial™ Environment	<ul style="list-style-type: none"> • 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. 	Clinical Data Managers, Clintrial Programmers and Study Designers	3 days
Implementing CDISC standards in a Clintrial™ Environment	<ul style="list-style-type: none"> • 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). 	Data managers, programmers, study designers, and anyone involved in integrating CDISC standards.	1 day

Empirica Trace Training Courses:

Training Course	Objectives	Audience	Length
Trace™ End User	<ul style="list-style-type: none"> • 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. 	This course is intended for all safety specialists who use the Trace software to enter, manage, and report on adverse event cases.	1 day
Trace™ System Admin	<ul style="list-style-type: none"> • 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. 	This course is intended for safety specialists and administrators who perform Trace system setup and administration tasks.	1 day
Trace™ Reporting Workspace	<ul style="list-style-type: none"> • Describe the Trace Reporting Workspace environment. • Describe the Trace Ad Hoc Reporting data model. • Create reports using the Trace Ad Hoc Reporting tool. 	This course is intended for safety specialists who are responsible for producing administrative reports on Trace data.	1 day
Trace™ Report Distribution	<ul style="list-style-type: none"> • 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. 	Trace administrators responsible for planning, setting up, and maintaining global report distribution.Database personnel.	1 day
Trace™ Producing Trace Reports	<ul style="list-style-type: none"> • Describe the regulatory and internal reports available within Trace • Offers best practices for requesting and producing these reports. • It will assist you in the preparation of periodic reports 	This course is intended for safety specialists responsible for producing, submitting and troubleshooting safety reports.	1 day
Using Empirica Trace (Web-based training)	<ul style="list-style-type: none"> • Launch the Trace application and navigate the user interface. • Enter, edit, code, and review case data. • Evaluate and approve cases and perform regional assessment tasks. • Request and produce internal, regulatory, expedited, and periodic reports. 	This Instruct online course is designed to certify safety experts in the use of Phase Forward's Empirica Trace application.	3 hours