

Training Concept



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XClinical Training Concept

Training Modules :: Training Packages :: Workshops

The XClinical training concept is simple – to focus on our customer's needs. To get you up and running quickly, we offer standalone Modules, pre-defined Training Packages and customized Workshops on demand.

Most trainings can be conducted either on-site or via web conference.

XCLINICAL :: MARVIN YOUR STUDY



To accompany your initial Marvin setup, it is recommended that everyone begins with the "PO1 Marvin Getting Started Package". After completing this first set of training modules, you may add other training courses like "Marvin Roles and Permissions" depending on your training plan.

All costs for trainings are based on 1 – 6 trainees and 1 trainer. For each batch of 6 students, XClinical will provide an additional trainer at the contracted price. Travel costs, accommodation and meal allowance are generally excluded from the given costs and will be charged separately.

Please contact your Account Manager for more details and pricing information.

Training Modules

The training modules listed below are standard trainings that may contain prepared exercises. If study specific requests should be covered please contact your Account Manager to discuss the details and prepare a workshop if necessary.

M01 EDC with Marvin

Prerequisites :: None

Target Group :: Study/Project Managers and Monitors

Type :: Webcast or eLearning

Duration :: 1 day via Webcast

Content

Marvin navigation basics
User and site management
Assignment of users and sites to studies
Data entry and Marvin icons
Dynamics (conditional navigation)
Roles and workflows
Query handling/ query workflow/ source data verification
Patient data and patient status
Communication tools (info page, messages within Marvin, emails, ...)

Goal

After the training the trainee knows how Marvin is used for daily study management, data management and monitoring tasks.

M02 Marvin Roles and Permissions

Prerequisites :: P01 Marvin Getting Started Package

Target Group :: Data Managers

Type :: On Site or Webcast

Duration :: 1 day

Content

Role concept in Marvin

Permissions and permission sets

Roles/permissions specification sheet

How to change, grant/remove permissions

How to define different permissions for different parts of the eCRF (security categories)

Permissions for receiving emails from Marvin

Goal

After the training the trainee understands Marvin's powerful and fine-grained permissions system. The trainee will be able to set up user roles. This training is obligatory if you want to set up permissions yourself.

M03 Marvin Database Fundamentals

Prerequisites :: P01 Marvin Getting Started Package, SQL experience

Target Group :: Data Managers, Programmers

Type :: On Site

Duration :: 0.5 days

Content

Marvin databases (core, blinder, ident, report) and their structure

Simple clinical data SQL statements on the core database

How to handle administrative protocol data (optional)

Goal

After the training the trainee knows the structure of the Marvin database and how to create SQL statements.

M04 IWRS & Drug Management in Marvin

Prerequisites :: P01 Marvin Getting Started Package, M02 Marvin Roles and Permissions

Target Group :: Data Managers, Statisticians

Type :: On Site or Webcast

Duration :: 1 day

Content

File-based, block-wise randomization
 Randomization algorithms: variance minimization & CARA
 Multi-phase randomization
 Blind vs. open randomization
 Material handling in Marvin
 Drug management in Marvin
 Randomization and materials action
 Configuration of Marvin
 Relevant permissions for IWRS & drug management

Goal

After the training the trainee can set-up different randomization options in Marvin.



M05 Marvin for Patients (WebPRO)

Prerequisites :: P01 Marvin Getting Started Package, M02 Marvin Roles and Permissions

Target Group :: Data Managers, Programmers

Type :: On Site or Webcast

Duration :: 0.5 days

Content

Understand different WebPRO workflows
WebPRO eCRF Design
Relevant permissions for WebPRO
How to handle identifying data

Goal

After the training the trainee knows how to setup the Marvin system for WebPRO users.

M06 Marvin for Paper (DDE)

Prerequisites :: P01 Marvin Getting Started Package, M02 Marvin Roles and Permissions

Target Group :: Data Managers

Type :: On Site or Webcast

Duration :: 1 day

Content

Double Data Entry (DDE) workflow in Marvin
DDE eCRF Design
Relevant permissions for DDE
Best practices
DDE Standard Reports

Goal

After the training the trainee knows how to set up a complete eCRF or parts of the eCRF for Double Data Entry and is educated on the challenges of DDE.

M07 ODM to SDTM with Marvin

Prerequisites :: P01 Marvin Getting Started Package, SDTM Implementation Guide knowledge

Target Group :: Data Managers (optional also Statisticians) responsible to define mapping instructions for converting CDISC ODM data into CDISC SDTM or other denormalized datasets

Type :: On Site

Duration :: 1.5 days

Content

Introduction (CDISC, SDTM)

Usage of define.xml libraries

Create define.xml with the Composer

eCRF SDTM annotation

Mapping (ODM <-> SDTM)

Goal

After the training the trainee can define mapping instructions for converting CDISC ODM data into CDISC SDTM or other denormalized datasets. The trainee will understand how the setup of the study definition can facilitate the setup of mapping rules for SDTM.

Training Packages

A training package includes one or multiple modules which usually should be trained in combination. The duration is always including all modules trained in the package.

P01 Marvin Getting Started Package

Prerequisites ::	None
Target Group ::	Data Managers, eCRF designers, Programmers
Type ::	On Site
Duration ::	3 days

Day 1 :: Modul M01 and the following topics:

How to configure a Marvin instance (application configuration)
How to upload files into Marvin for the instance configuration
How to set up news-page (= first page visible in Marvin after login)
Marvin transforms for CRFs as PDF

Goal :: After day one of the training, the trainee knows how Marvin is used for daily study management, data management and monitoring tasks. Furthermore, the trainee will have a deeper understanding on the technical side of Marvin and will know how to configure the Marvin instance for the specific study. The trainee will be able to train Study Managers and Monitors.

Day 2 :: Working with the Composer

Introduction into CDISC ODM
How to set up an eCRF and program actions (dynamics, edit checks) with the Composer
Other actions in Marvin
Upload of the study definition in Marvin

Goal :: The trainee will be able to set-up the eCRF and to program the dynamics and edit checks with the Composer.

Day 3 :: Set up of eCRF amendments with the Composer

How to apply the amendment in Marvin
Amendment validation
How to generate aCRF, blank CRF and DVP
Standard data export from Marvin (CDISC ODM XML)

Goal :: The trainee knows how to set up an amendment with the Composer and to handle different change scenarios on his own.

P02 Marvin Reporting Package

Prerequisites :: P01 Marvin Getting Started Package, SQL experience

Target Group :: Data Managers, Programmers

Type :: On Site or Webcast

Duration :: 1.5 days

Content

Modul M03 Marvin Database Fundamentals and the following topics:

- Working with the report DB (standard tabulation)
- Further explanation on status information tables
- High-performance SQL statements
- How to publish listing reports in Marvin ("ERML")
- How to create simple graphical reports ("BIRT tool")
- Filter BIRT reports with report parameters
- Implement a chart in the BIRT report
- How to export the report results in different formats

Goal

After the training the trainee knows how to program online reports for Marvin.

P03 Handling Laboratory Data Packages

Prerequisites :: P01 Marvin Getting Started Package

Target Group :: Data Managers, Programmers

Type :: On Site or Webcast

Duration :: 1 day for each option separately / 1.5 days for both options combined

Content

Modul M03 Marvin Database Fundamentals and one of the following options:

Option 1: Lab Data Import

This option is useful if complete laboratory data sets including the results, measurement units and valid laboratory ranges have to be imported into Marvin. The different approaches to import bulk data or increment files are explained and covered with exercises

Option 2: Lab Normal Ranges entered in Marvin per center

This option explains how to setup laboratory normal ranges for central or smaller site labs in Marvin. It should be used if the laboratory test results are entered by the site personnel.

Goal

After the training the trainee knows how to set up Marvin to handle laboratory data.

P04 Marvin Data Import Package

Prerequisites :: P01 Marvin Getting Started Package

Target Group :: Data Managers, Programmers

Type :: On Site or Webcast

Duration :: 1 day

Content

Modul M03 Marvin Database Fundamentals and the following topics:

- Different possibilities to import data into Marvin
- General configuration for data import
- How does the import of data via the Web-UI works
- How to use the tool "TXT2ODM" that is needed to import data from CSV files into Marvin
- Automatic data import via TXT2ODM job

Goal

After the training the trainee is aware of all different data import possibilities in Marvin and understands advantages/ disadvantages of different import options as well as the setup.

P05 WHODrug and MedDRA Coding Package

Prerequisites ::	P01 Marvin Getting Started Package, Coding knowledge
Target Group ::	Data Managers, (Medical) Coders
Type ::	On Site or Webcast
Duration ::	0,5 day for each option separately or 1 day for both options combined

Content Option 1 Coder (MedDRA)

Marvin Coder (MedDRA) introduction
Integration with Marvin
Workflow: Coder – Reviewer – Data Manager
Data import of XML files into Marvin Coder

Content Option 2 Coder 2 (WHODrug)

Marvin Coder 2 (WHODrug) introduction
Integration with Marvin
Workflow: Coder – Reviewer – Data Manager

Goal

After the training the trainee is aware of all XClinical coding options and the integration with Marvin.

Workshops

A workshop depends on the customer's requirements.

Therefore, no fix price or duration is available for those trainings.

W01 Customized Workshops

In general, any customer-specific process could be trained as a workshop. These workshops emphasize particular areas of interest, a particular project, or combinations of our modules which are not included in our standardized trainings.

Please contact your Account Manager for more information if you are interested in a customized workshop.

We will assess your specific needs in order to design a tailored training seminar.

Target Group ::	Study/Project/Data Managers, Coders, Statisticians, eCRF designers, Programmers, Monitors
Type ::	Webcast or eLearning or on Site
Duration ::	Flexible, from 4 hours to 5 days

W02 Marvin Update Training

Prerequisites ::	P01 Marvin Getting Started Package
Target Group ::	Data Managers, eCRF designers, Programmers
Type ::	On Site or Webcast
Duration ::	2 hours to 1 day (depends on last trainings)

Content

New features since last training depending on the trained modules and Marvin version.

Goal

The workshop focuses on the existing Marvin knowledge of the participant and trains new system capabilities.

W03 Advanced Marvin Workflows

Prerequisites ::	P01 Marvin Getting Started Package, M02 Marvin Roles and Permissions
Target Group ::	Data Managers, Monitors, Study Managers
Type ::	On Site
Duration ::	flexible

Content

The workshop could contain one or more of the following workflows:

- Advanced query workflow ("Noteflags")
- Advanced data review workflow ("Elementflags")
- Signature workflows
- Advanced SDV workflow (risk-based monitoring, optional SDV, etc.)

Goal

After the training the trainee knows how to set up advanced workflows in Marvin.

W04 Marvin CTMS

Prerequisites :: P01 Marvin Getting Started Package

Target Group :: Data Managers, Monitors

Type :: On Site

Duration :: flexible

Content

The workshop covers one or more of the following topics:

- Setup of center specific forms to e.g. track monitoring visits
- Setup of reporting based on center specific information

Goal

The participant works together with the trainer to create a customized CTMS solution within Marvin.

W05 Integration with 3rd party systems

Prerequisites :: P01 Marvin Getting Started Package

Target Group :: Data Managers, Programmers

Type :: On Site

Duration :: flexible

Content

The workshop covers one or more of the following topics:

- eCRF integration (external data call/ external soap call)
- Data transfer between Marvin instances
- Extract of single data points from 3rd party systems
- Export of bulk data via web services

Goal

The training participant works together with the trainer to create an integration to a 3rd party system in Marvin via web services.

Overview

Packages

Marvin Getting Started 3d

Marvin Reporting 1,5d

Handling Laboratory Data 1-1,5d

Marvin Data Import 1d

WHODrug and MedDRA Coding 0,5-1d

Prerequisite: Coding knowledge

Modules

EDC with Marvin 1d

Marvin Roles & Permissions 1d

IWRS & Drug Management 1d

Marvin Database Fundamentals 0,5d

Prerequisite: SQL experience

WebPRO Marvin for Patients 0,5d

DDE Marvin for Paper 1d

ODM to SDTM with Marvin 1,5d

Workshops

Marvin Update Training flex

Advanced Marvin Workflows flex

Marvin CTMS flex

Integration with 3rd Party Systems flex

Customized Workshops flex

Please contact us at training@xclinical.com for more information.

XClinical GmbH

Arnulfstrasse 19

80335 Munich

Germany

Tel :: +49 89 452 27 75 000

Fax :: +49 89 452 27 75 900

Email :: info@xclinical.com

www :: xclinical.com



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