Training Concept
# Table of Content

Concept .................................................................................................................. 3

## Training Modules .......................................................................................... 4
  M01  EDC with Marvin ....................................................................................... 4
  M02  Marvin Roles and Permissions .................................................................. 5
  M03  Marvin Database Fundamentals .................................................................. 5
  M04  IWRS & Drug Management in Marvin ....................................................... 6
  M05  Marvin for Patients (WebPRO) ................................................................... 7
  M06  Marvin for Paper (DDE) ............................................................................. 7
  M07  ODM to SDTM with Marvin ...................................................................... 8

## Training Packages ......................................................................................... 9
  P01  Marvin Getting Started Package .................................................................. 9
  P02  Marvin Reporting Package .......................................................................... 10
  P03  Handling Laboratory Data Package ............................................................ 11
  P04  Marvin Data Import Package ........................................................................ 12
  P05  WHODrug and MedDRA Coding Package .................................................. 13

## Workshops ...................................................................................................... 14
  W01  Customized Workshop ............................................................................... 14
  W02  Marvin Update Training ........................................................................... 15
  W03  Advanced Marvin Workflows ..................................................................... 15
  W04  Marvin CTMS .............................................................................................. 16
  W05  Integration with 3rd party systems ............................................................. 16

## Overview ....................................................................................................... 17
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 “P01 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.

<table>
<thead>
<tr>
<th>Target Group</th>
<th>Study/Project/Data Managers, Coders, Statisticians, eCRF designers, Programmers, Monitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Webcast or eLearning or on Site</td>
</tr>
<tr>
<td>Duration</td>
<td>Flexible, from 4 hours to 5 days</td>
</tr>
</tbody>
</table>
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

Modules

- EDC with Marvin 1d
- Marvin Roles & Permissions 1d
- IWRS & Drug Management 1d
- Marvin Database Fundamentals 0,5d
- WebPRO 0,5d
- Marvin for Patients 0,5d
- DDE 1d
- 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

Prerequisites:
- Coding knowledge
- SQL experience
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