

# 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 :: FAST :: FLEXIBLE :: FOCUSED**



To accompany your initial Marvin setup, it is recommended that everyone begins with the "PO3 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.

Prices are included for information purposes, please contact your Account Manager for more details.

# 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

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**Target Group ::** Study/Project Managers and Monitors

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**Type ::** Webcast

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**Duration ::** 1 day via Webcast

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### 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.

Price :: € 2000

## M02 Marvin Roles and Permissions

**Prerequisites ::** P01 Marvin Getting Started Package

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**Target Group ::** Data Managers

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**Type ::** On Site or Webcast

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**Duration ::** 1 day

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### 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.

Price :: € 2000

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## M03 Marvin Database Fundamentals

**Prerequisites ::** P01 Marvin Getting Started Package, SQL experience

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**Target Group ::** Data Managers, Programmers, Statisticians

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**Type ::** On Site

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**Duration ::** 0.5 days

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### 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.

Price :: € 1000

# 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.

Price :: € 2000



## M05 Marvin for Patients (WebPRO)

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

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**Target Group ::** Data Managers, Programmers

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**Type ::** On Site or Webcast

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**Duration ::** 0.5 days

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### 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.

Price :: € 2000

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## M06 Marvin for Paper (DDE)

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

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**Target Group ::** Data Managers

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**Type ::** On Site or Webcast

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**Duration ::** 1 day

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### 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.

Price :: € 2000

## M07 ODM to SDTM with Marvin

<b>Prerequisites ::</b>	P01 Marvin Getting Started Package, SDTM Implementation Guide knowledge
<b>Target Group ::</b>	Data Managers (optional also Statisticians) responsible to define mapping instructions for converting CDISC ODM data into CDISC SDTM or other denormalized datasets
<b>Type ::</b>	On Site
<b>Duration ::</b>	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.

Price :: € 3000

## M08 MedDRA Coder for Marvin

<b>Prerequisites ::</b>	P01 Marvin Getting Started Package, MedDRA Coding knowledge
<b>Target Group ::</b>	Data Managers, (Medical) Coders
<b>Type ::</b>	On Site or Webcast
<b>Duration ::</b>	1 day

### Content

Coder introduction  
 Show complete workflow/link to Marvin  
 Coding with workflow Coder – Reviewer – Data Manager  
 Data import of XML files into Coder

### Goal

After the training the trainees will be able to use the XClinical Coder for MedDRA coding.

Price :: € 2000



# 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

<b>Prerequisites ::</b>	None
<b>Target Group ::</b>	Data Managers, eCRF designers, Programmers
<b>Type ::</b>	On Site
<b>Duration ::</b>	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.

Price :: € 9500

# P02 Marvin Reporting Package

**Prerequisites ::** P01 Marvin Getting Started Package, SQL experience

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**Target Group ::** Data Managers, Programmers

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**Type ::** On Site or Webcast

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**Duration ::** 1.5 days

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## 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.

Price :: € 3000

# P03 Handling Laboratory Data Packages

**Prerequisites ::** P01 Marvin Getting Started Package

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**Target Group ::** Data Managers, Programmers

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**Type ::** On Site or Webcast

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

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## 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.

Price :: € 2000 - 3000

# P04 Marvin Data Import Package

**Prerequisites ::** P01 Marvin Getting Started Package

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**Target Group ::** Data Managers, Programmers

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**Type ::** On Site or Webcast

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**Duration ::** 1 day

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## 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.

Price :: € 2000

# 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.

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

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## W02 Marvin Update Training

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

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### 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.

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## W03 Advanced Marvin Workflows

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

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### 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

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**Target Group ::** Data Managers, Monitors

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**Type ::** On Site

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**Duration ::** flexible

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### 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.

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## W05 Integration with 3rd party systems

**Prerequisites ::** P01 Marvin Getting Started Package

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**Target Group ::** Data Managers, Programmers

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**Type ::** On Site

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**Duration ::** flexible

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### 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

## 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

MedDRA Coder for Marvin 1d

Prerequisite: MedDRA coding

## Workshops

Marvin Update Training flex

Advanced Marvin Workflows flex

Marvin CTMS flex

Integration with 3rd Party Systems flex

Customized Workshops flex



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