<table>
<thead>
<tr>
<th>Course</th>
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<tr>
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The Perceptive Institute is a comprehensive eClinical training service to assist our clients and users in developing their knowledge and skills in using and building our products and applications.
WELCOME TO PERCEPTIVE INSTITUTE

The Perceptive® Institute eClinical training programs provide a comprehensive training service to assist our clients and users in developing their knowledge and skills in:

- Using and building DataLabs® EDC and DataLabs® Designer
- Using ClinPhone® Randomization and Trial System Management (RTSM)
- Using the Perceptive MyTrials® technology platform

The Perceptive Institute provides a training portfolio for various user levels and roles in sponsor and customer organizations, designed and delivered in partnership by clinical and training experts.

OUR PORTFOLIO IS MODULAR AND FLEXIBLE

Our portfolio is based on four building blocks as we understand that our clients needs are different. Flexibility and choice is important. We offer a blended training delivery program including:

- Virtual Instructor-led Sessions
- Classroom Instructor-led Sessions
- eLearning
- Simulations

Our Certification programs will enable you to monitor competence in the knowledge and skills acquired. “Organizations today with 40-55% of team members who are Certified perform above average among all organizations.”

Our portfolio is modular and flexible. Designed and delivered with the clinical role in mind, and focused on keeping your organization in compliance with an ever changing and highly regulated world.
CLINPHONE®
RANDOMIZATION TRIAL
SUPPLY MANAGEMENT (RTSM)
COURSES
# RTSM Training Map

<table>
<thead>
<tr>
<th></th>
<th>Sales</th>
<th>Project Manager</th>
<th>CRA/Monitor</th>
<th>Specialist</th>
</tr>
</thead>
<tbody>
<tr>
<td>001 ClinPhone RTSM</td>
<td>001 ClinPhone RTSM Orientation</td>
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<tr>
<td>Orientation</td>
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<tr>
<td>002 ClinPhone RTSM</td>
<td>003 ClinPhone RTSM for Project Managers</td>
<td>004 ClinPhone RTSM for Clinical Monitors</td>
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<td>ClinPhone RTSM Reporting:</td>
</tr>
<tr>
<td>for Sales</td>
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<td>• 006a ClinPhone RTSM Dashboard Reporting</td>
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<td>• 006b ClinPhone RTSM Universal Report Suite</td>
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<tr>
<td></td>
<td></td>
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<td>• 006c ClinPhone RTSM Self Service Reporting</td>
</tr>
<tr>
<td>Assessment &amp;</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Certification</td>
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</tbody>
</table>

## Orientation Learning
- Applicable to all roles
- Pre-requisite knowledge for Certification courses

## Role-Based Learning
- Role-based modules mapped to business development, clinical monitor and project management roles

## Certification Programs
- Reflects the highest level of technical and professional competency for key roles
- Assessment of competency leading to Certification
Each user role below can benefit from our modular standalone courses or complete the relevant training track for their role and in addition benefit from role based Certification.

**BUSINESS DEVELOPMENT**

Responsible for supporting pre-sales activities, finding new business and developing existing relationships. Pre-sales and Business Development personnel will need to understand product placement, articulate value propositions and differentiators of the product.

**PROJECT MANAGERS**

Tasked with the successful implementation of ClinPhone RTSM (Randomization and Trial Supply Management) within a study, the Project Manager will need an understanding of site management, the project lifecycle as well as risk identification and mitigation.

**CRA (CLINICAL MONITOR)**

CRAs/Clinical Monitors manage drug accountability, support site staff in the use of ClinPhone RTSM, and understand the potential for quality issues and how to avoid them.
### ClinPhone RTSM Orientation (RTSM001)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>All Roles</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

This course will give an overview of our eClinical suite, introduce you to "The ClinPhone RTSM Product” and related integrations, and provide an overview of the ClinPhone RTSM Web Applications and Modules as well as the reporting options available.

**At the end of this course, the participant will be able to:**

- Give an overview of the eClinical Suite
- Describe the ClinPhone RTSM product components
- Define Randomization
- Describe IVR/IWR and EDC Integration
- Explain Trial Supply Management
- List the types of reporting available

### ClinPhone RTSM for Sales (RTSM002)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ClinPhone RTSM Orientation (RTSM001)</td>
<td>Business Development and Account Management</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

*Certification Track Course*

This course provides sales personnel with an overall understanding of the ClinPhone RTSM system and how to best position it with our clients. Learners will be introduced to the system, as well as taking a closer look at how different roles use the system, while being presented with the key sales messaging points along the way.

**At the end of this course, the participant will be able to:**

- Position ClinPhone RTSM in the market place
- Describe the ClinPhone RTSM value propositions
- State the important differentiators
- Describe the position of ClinPhone RTSM in the eClinical suite

*Component of a formal Certification Track [see Training Map on page 6]*
### ClinPhone RTSM For Project Managers (RTSM003)

**Duration:** 30 minutes  
**Class Size:** n/a

<table>
<thead>
<tr>
<th>Prerequisites</th>
<th>Primary Audience</th>
<th>Delivery Modes</th>
<th>Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>ClinPhone RTSM Orientation (RTSM001)</td>
<td>Project Managers</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

#### Course Description

**Certification Track Course***

The RTSM for Project Managers course will provide users with information regarding the ClinPhone RTSM module and web applications relevant to their role. This course will provide the knowledge to enable them to effectively manage ClinPhone RTSM activities through the study lifecycle.

**At the end of this course, the participant will be able to:**

- Specify the key ClinPhone RTSM tasks to be completed at each study phase
- Describe how to activate and deactivate sites and, open and close sites for screening and randomization in the Site Management Application
- Describe how to access information and reports useful for study management from the Reporting applications

---

### ClinPhone RTSM For Clinical Monitors (RTSM004)

**Duration:** 45 minutes  
**Class Size:** n/a

<table>
<thead>
<tr>
<th>Prerequisites</th>
<th>Primary Audience</th>
<th>Delivery Modes</th>
<th>Materials</th>
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</thead>
<tbody>
<tr>
<td>ClinPhone RTSM Orientation (RTSM001)</td>
<td>Clinical Monitors</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

#### Course Description

**Certification Track Course***

The ClinPhone RTSM for Clinical Monitors course will provide users with the specifics of the typical randomization and trial supply management functionality utilized during a trial in order to perform their role, and support site staff in the use of the tool.

**At the end of this course, the participant will be able to:**

- Describe typical site user tasks and be able to support site users in the use of the ClinPhone RTSM Applications
- Record drug accountability information for a study in the ClinPhone RTSM system
- Access and be able to run and filter web reports applicable to Clinical Monitors

---

*Component of a formal Certification Track (see Training Map on page 6)*
# ClinPhone RTSM Courses

## ClinPhone RTSM Gateway (RTSM005)

**DURATION:** 10 minutes  
**CLASS SIZE:** n/a

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Study Team Members</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

### COURSE DESCRIPTION

Participants will be provided with an overview of the ClinPhone RTSM Address Gateway, be introduced to “The Gateway spreadsheet” and how to create, edit and upload without generating errors.

**At the end of this course, the participant will be able to:**
- Accurately create the ClinPhone RTSM Address Gateway spreadsheet from the standard template and upload it to the database
- Accurately update the spreadsheet to reflect changes in site personnel

## ClinPhone RTSM Dashboard Reporting (RTSM006a)

**DURATION:** 15 minutes  
**CLASS SIZE:** n/a

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
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<th>DELIVERY MODES</th>
<th>MATERIALS</th>
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</thead>
<tbody>
<tr>
<td>None</td>
<td>Project Managers</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

### COURSE DESCRIPTION

This course will give an overview of the ClinPhone RTSM Study Dashboard; introduce the Dashboard interface, as well as the related configuration options available.

**At the end of this course, the participant will be able to:**
- State the function of the ClinPhone RTSM Study Dashboard
- Describe how to view Site and Subject related data
- Describe how to view Depot and Supplies related data
### ClinPhone RTSM Universal Report Suite (RTSM006b)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Data Managers</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
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<tr>
<td></td>
<td>CRAs</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Site Users</td>
<td></td>
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</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

This course will explain how study team members can use a collection of ready-made, validated reports to ensure rapid delivery of quality best-practice ClinPhone RTSM reports to meet their study needs.

**At the end of this course, the participant will be able to:**
- Run interactive web reports
- Download data in a variety of formats
- Create and export graphs and charts of key study data

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### ClinPhone RTSM Self Service Reporting (RTSM006c)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Data Managers</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

This course will explain how study team members can use ClinPhone RTSM Self Service Reporting to perform their own data analysis using tailored data extracts to perform complex assessments such as in-depth supplies analyses or deploy specialized, in-house methodologies.

**At the end of this course, the participant will be able to:**
- State the function of the ClinPhone RTSM Study Dashboard
- Describe how to view Site and Subject related data
- Describe how to view Depot and Supplies related data
# EDC TRAINING MAP

<table>
<thead>
<tr>
<th>FOUNDATION ILT / E</th>
<th>ROLE-BASED ILT / E</th>
<th>ADMINISTRATION ILT / E</th>
<th>SPECIALIST E</th>
<th>DESIGNER ILT</th>
<th>CERTIFIED TRAINER ILT</th>
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<tbody>
<tr>
<td>DataLabs and Designer Orientation</td>
<td>DataLabs for Clinical Monitors</td>
<td>IB Reporting Dashboard</td>
<td>IB Reporting Standard Reports</td>
<td>Designer Workshop</td>
<td>DataLabs Site Trainer Certification Program</td>
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<tr>
<td></td>
<td>DataLabs for Paper Data Entry</td>
<td></td>
<td>IB Reporting Custom Reports</td>
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<tr>
<td></td>
<td>DataLabs for Study Coordinators</td>
<td></td>
<td>Loading and Managing External Data</td>
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<td></td>
<td>DataLabs for Principal Investigators</td>
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<td></td>
<td>DataLabs for Medical Monitors</td>
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<td></td>
<td>DataLabs for Sales/Business Development</td>
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<tr>
<td>DataLabs Version Upgrade</td>
<td>DataLabs for View Only Roles</td>
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<tr>
<td></td>
<td>DataLabs for Data Management Leads &amp; Certification</td>
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<tr>
<td></td>
<td>DataLabs for Data Managers &amp; Certification</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>DataLabs Coding Using dS Navigator</td>
<td>Designer Certification Program</td>
<td></td>
</tr>
</tbody>
</table>

*Training is delivered on the most current version of the product. Previous versions are available.*

## FOUNDATIONAL LEARNING
- Applicable to all users and roles
- Pre-requisite knowledge to the full curriculum
- Designed to improve product familiarity

## ROLE BASED LEARNING
- Role-based modules mapped to typical user roles
- Demonstrations and simulations
- Self-assessment and Certification

## CERTIFICATION PROGRAMS
- Reflects the highest level of technical and professional competency for key roles
- Assessment of competency leading to Certified status and Certification

## TRAINER CERTIFICATION
- Equip and empower your organization to scale delivery and reduce training costs
- Modular blended program suited to audience knowledge
**STUDY COORDINATOR**

The Study Coordinator role in DataLabs is typically responsible for:

- Patient data entry into Case Report Forms (CRFs)
- Answering Data Clarification Forms (DCFs)

**CLINICAL RESEARCH ASSOCIATE (CRA)**

The CRA role in DataLabs is typically responsible for:

- Source Data Verification (SDV)
- Raising manual DCFs
- Reviewing responses to DCFs
- Closing DCFs
- Freeze/Thaw of CRFs

**MEDICAL MONITOR**

The Medical Monitor role in DataLabs is typically responsible for:

- Medical review of CRFs
- Raising manual DCFs
- Reviewing responses to DCFs
- Closing DCFs

**DATA MANAGER**

The Data Manager role is typically responsible for:

- Data review
- Raising manual DCFs
- Reviewing responses to DCFs
- Closing DCFs
- Freeze/Thaw of CRFs
- Requesting Investigator Signature of CRFs
- Lock/Unlock of CRFs

**PRINCIPAL INVESTIGATOR**

The Principal Investigator role in DataLabs will typically be responsible for:

- Reviewing completed CRFs
- Signature of CRFs

**ADMINISTRATOR**

The administrator role in DataLabs will typically be responsible for:

- Uploading and managing study XML
- Setting User group permissions
- Setting study specific parameters and preferences
**DataLabs and Designer Orientation (DL001)**

**DURATION:** 1 hour [Instructor-Led]  
30 minutes [eLearning]  

**CLASS SIZE:** 20 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
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<td>All Roles</td>
<td>Virtual Instructor-led</td>
<td>Presentation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

The DataLabs and Designer Orientation Course will provide an overall introduction to DataLabs Electronic Data Capture (EDC), Designer and their key features and application in the clinical trial. You will be orientated to the background of the products, the study set-up process for DataLabs and view a short demonstration of each system.

At the end of this course, the participant will be able to:
- Explain DataLabs EDC and DataLabs Designer background, components and capabilities
- Describe key features of DataLabs EDC and Designer

---

**DataLabs Clinical Monitors (DL007)**

**DURATION:** 2 hours [Instructor-Led]  
1 hour [eLearning]  

**CLASS SIZE:** 20 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>
| Orientation course (DL001) (if applicable) | Clinical Research Associates  
In-house Monitors              | Classroom Instructor-led        | Presentation                   |
|                                    |                                   | Virtual Instructor-led        | Training Guide                 |
|                                    |                                   | Self-Paced eLearning          | Exercise Guide                 |
|                                    |                                   |                               | Simulation                     |

**COURSE DESCRIPTION**

Participants will learn how to manage Source Data Verification of eCRFs, issue and manage Data Clarification Forms (DCFs) to sites, as well as preparing forms for Investigator eSignature.

At the end of this course, the participant will be able to:
- Source Data Verify CRFs
- Create, review and close DCF
- Freeze/Thaw patient data
- Use Advanced Patient Search functionality
- Prepare forms for eSignature
## DataLabs Principal Investigator (DL009)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>
| None          | Principal Investigators  
Study Coordinators  
Those responsible for reviewing and electronically signing eCRFs | Classroom Instructor-led  
Virtual Instructor-led  
Self-Paced eLearning | Presentation  
Training Guide  
Exercise Guide  
Simulation |

### COURSE DESCRIPTION

Participants will learn to use the inbox, review and sign CRFs.

**At the end of this course, the participant will be able to:**
- Log into DataLabs and sign a patient casebook
- Use the inbox to view signature requests
- Accept, reject or skip a CRF
- Record an eSignature

## DataLabs Paper Data Entry (DL006)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>
| Orientation course (DL001) | Data Entry Personnel | Classroom Instructor-led  
Virtual Instructor-led  
Self-Paced eLearning | Presentation  
Training Guide  
Exercise Guide  
Simulation |

### COURSE DESCRIPTION

Participants will learn how to take data from a paper-based workflow and enter that data into an electronic CRF.

**At the end of this course, the participant will be able to:**
- Access the paper portal for data entry
- Screen and enroll patients
- Perform 1st and 2nd pass data entry
- Perform mismatch resolution
- Submit data to EDC
- Track progress of CRFs
# DataLabs Medical Monitors (DL011)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
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</thead>
<tbody>
<tr>
<td>None</td>
<td>Those responsible for Medical review</td>
<td>Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning</td>
<td>Presentation Training Guide Exercise Guide Simulation</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

Participants will learn how to use DataLabs EDC features to undertake medical review of clinical data.

**At the end of this course, the participant will be able to:**
- Log into DataLabs
- Perform searches for patients and CRFs
- Flag forms to indicate M-Review in DataLabs
- Create and close Data Clarification Forms

---

# DataLabs View Only Role (DL010)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Any view only roles, for example: Project Leaders Sponsors Quality Managers and Auditors</td>
<td>Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning</td>
<td>Presentation Training Guide Exercise Guide Simulation</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

Participants will learn how to log onto DataLabs EDC, and be given a site portal overview with navigation. They will also learn about user preferences and viewing eCRFs and DCFs.

**At the end of this course, the participant will be able to:**
- Log into DataLabs and view a Patients Events, eCRFs and DCFs with the use of notes or the System help
# DataLabs Study Coordinators (DL008)

**Duration:** 2 hours (Instructor-Led)  
1 hour (eLearning)  
**Class Size:** 20 max

<table>
<thead>
<tr>
<th>Prerequisites</th>
<th>Primary Audience</th>
<th>Delivery Modes</th>
<th>Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation Course [DL001] (if applicable)</td>
<td>Those responsible for data entry into the eCRF at site</td>
<td>Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning</td>
<td>Presentation Training Guide Exercise Guide Simulation</td>
</tr>
</tbody>
</table>

## Course Description

Participants will learn how patients are added in DataLabs EDC, how to respond to Data Clarification Forms (DCFs) and tasks associated to Data Entry at the site.

At the end of this course, the participant will be able to:

- Navigate the different screens in DataLabs EDC
- Enter and Edit data on eCRFs
- Respond to System and Manual queries
- Search for Patients, CRFs and DCFs
DataLabs Administrator  
(DL012)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
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</thead>
<tbody>
<tr>
<td>Orientation course (DL001)</td>
<td>Those assigned the Administrator role</td>
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<tr>
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<td></td>
<td>Virtual Instructor-led</td>
<td>Training Guide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-Paced eLearning</td>
<td>Exercise Guide</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

**Certification Track Course***
This course will cover a number of Administrator tasks to set-up system requirements and specific parameters of the DataLabs EDC database.

**At the end of this course, the participant will be able to:**
- Demonstrate how to load and publish a study
- Give examples of user groups and associated permissions
- Produce a database ready to train other study team members

DataLabs Data Manager  
(DL004)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation course (DL001)</td>
<td>Data Managers</td>
<td>Classroom Instructor-led</td>
<td>Simulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Virtual Instructor-led</td>
<td>Presentation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-Paced eLearning</td>
<td>Training Guide</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Exercise Guide</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

**Certification Track Course***
Participants will learn how to perform the main DataLabs EDC functionality associated to the Data Manager role.

**At the end of this course, the participant will be able to:**
- Review eCRFs and access audit trail information
- Create and close Data Clarification Forms/Queries
- Describe a typical data cleaning workflow in DataLabs
- Describe and perform the Freeze & Lock data process
- Request electronic signatures

*Component of a formal Certification Track (see Training Map on page 14)
## DataLabs & Designer Data Management Leads (DL005)

**DURATION:** 0.5 day  
**CLASS SIZE:** 20 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation course (DL001)</td>
<td>Those responsible for leading EDC set-up activities on projects</td>
<td>Classroom Instructor-led</td>
<td>Presentation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Virtual Instructor-led</td>
<td>Training Guide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-Paced eLearning</td>
<td>Exercise Guide</td>
</tr>
</tbody>
</table>

### COURSE DESCRIPTION

**Certification Track Course***

Participants will be given a detailed review of the Designer set-up process. They will focus on integrations, manage study updates, and study design considerations, and define permissions.

**At the end of this course, the participant will be able to:**

- Manage the set-up process for DataLabs EDC and Designer from project award to go-live
- Describe the key study set-up documents that require Data Management Lead input and coordination
- Describe the permissions model for DataLabs and be able to define study-level permissions

---

## IB Reporting Dashboard (DL013)

**DURATION:** 30 minutes  
**CLASS SIZE:** 20 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation course (DL001)</td>
<td>Any role that uses IB Reporting Dashboard functionality</td>
<td>Classroom Instructor-led</td>
<td>Training Recording</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Virtual Instructor-led</td>
<td>Training Guide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-Paced eLearning</td>
<td>Exercise Guide</td>
</tr>
</tbody>
</table>

### COURSE DESCRIPTION

Participants will be given information on Information Builders (IB) Reporting which allows users with the appropriate access the ability to view DataLabs report information. The IB Reports Dashboard is the launch pad to robust reporting.

**At the end of this course, the participant will be able to:**

- Use the IB Reporting Dashboard to view study status including Patient Counts, Data Clarification Form (DCF), query data and completion status of Case Report Forms (CRFs)

*Component of a formal Certification Track [see Training Map on page 14]*
### IB Reporting Standard Reports (DL014)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>

**COURSE DESCRIPTION**

Participants will be given information on IB Reporting Standard Reports which are predesigned to provide specific report data based on logical groupings in the report database. This training describes all of the standard reports and demonstrates how to view them in differing report formats.

**At the end of this course, the participant will be able to:**

- Access the available Standard Reports
- Manipulate report filters to view specific data
- Export standard reports in a variety of formats

### IB Reporting Custom Reports (DL015)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>IB Reporting Standard Reports (DL014)</td>
<td>Any role that is assigned to creating custom reports</td>
<td>Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning</td>
<td>Training Recording Training Guide Exercise Guide Simulation</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

This course will build on the knowledge gained from IB Reporting Dashboard and Standard Reports training, and will teach participants how to create custom reports including patient data that can be run across sites and across multiple variables.

**At the end of this course, the participant will be able to:**

- Build a simple custom report
- Build a complex custom report
Loading and Managing External Data in DataLabs (DL016)

**DURATION:** 30 minutes  
**CLASS SIZE:** n/a

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>
| Orientation Course (DL001)  
DataLabs for Data Managers (DL004) | Those responsible for loading and managing external data | Self-Paced eLearning | Training Recording |

**COURSE DESCRIPTION**

Participants will be able to:
- Discuss the different types of external data in DataLabs EDC
- Identify common issues and identify solutions
- Describe how to manage external data in DataLabs EDC

DataLabs Coding using dsNavigator (DL017)**

**DURATION:** 30 minutes  
**CLASS SIZE:** n/a

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Any role requiring a high level overview of dsNavigator and an understanding of the integration with DataLabs</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

Participants will receive a high level foundation of the dsNavigator encoding dictionary tool. This course will provide information on the tool and how it is linked to the clinical study during the design phase. This will be achieved through an illustration of how the live study and the tool will integrate to populate specific data for the audit trail.

**At the end of this course, the participant will be able to:**
- Describe the process of encoding a term using an encoding dictionary tool with a clinical study
- Explain the process of how a designated term triggers the encoding tool to populate specific study data that will export on data reports
- List the steps necessary in the Designer tool to initiate the process for encoding during live study

**Participants requiring a detailed training on dsNavigator can book a course with The Cerner Corporation**
**Designer Workshop (DL002)**

**PREREQUISITES**
- Orientation Course (DL001)
- DataLabs for Administrators (DL012)
- IB Reporting Dashboard (DL013)
- IB Reporting Standard Reports (DL014)
- IB Reporting Custom Reports (DL015)
- Loading and managing External Data (DL016)
- DataLabs Encoding using dsNavigator (DL017)

**PRIMARY AUDIENCE**
- Programmers
- Any role that will build DataLabs studies

**DELIVERY MODES**
- Classroom Instructor-led

**MATERIALS**
- Presentation
- Training Guide
- Exercise Guide

**CAUTION**
- DURATION: 4.5 days
- CLASS SIZE: 10 max

**COURSE DESCRIPTION**

**Certification Track Course**

This workshop is intended to provide a familiarity with the DataLabs product and firm foundation for using the DataLabs Designer tool to build clinical studies.

**At the end of this course, the participant will be able to:**

- Build a study xml using the Designer tool with 80% proficiency
- Integrate the knowledge obtained from DataLabs exercises to visualize how it will affect the study build process
- Explain the functionality of Designer: Domains, Codelists, Dictionaries, Dynamic Forms and Events, Edit Checks and pScripts
- Build study using Designer Functionality: Domains, Codelists, Dictionaries, Dynamic Forms and Events, Edit Checks and pScripts
- Load, stage and publish study xml in DataLabs
- Perform study admin tasks to complete study set-up in DataLabs

*Component of a formal Certification Track (see Training Map on page 14)*
## DataLabs Certified Trainer (DL020a)

**DURATION:** Full: 4.5 days, TTT: 2 days  
**CLASS SIZE:** 10 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation Course [DL001]</td>
<td>Those who will be responsible for training in DataLabs for any role</td>
<td>Blended Delivery</td>
<td>Training Guides, Exercise Guides, Presentations</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

**Certification Track Course***

Participants will receive a full DataLabs knowledge-based course followed by a Train the Trainer Assessment. The course is designed to train on using DataLabs EDC knowledge and trainer skills to lead delivery of a DataLabs Training session for multiple roles.

The full program consists of:

- DataLabs knowledge-based training – Instructor-Led and eLearning (2.5 Days)
- DataLabs EDC Train the Trainer Certification Program (2 Days)
- Practical assessment
- Successful completion of this course leads to Certification

---

## Designer Certified Trainer (DL020b)

**DURATION:** TTT: 2 days  
**CLASS SIZE:** 10 max (2 instructors)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designer Workshop [DL002]</td>
<td>Those who will be responsible for training others in the Designer tool</td>
<td>Classroom Instructor-led</td>
<td>Presentation, Training Guide, Exercise Guide</td>
</tr>
<tr>
<td>V.B Net Scripting</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

**Certification Track Course***

This course is designed to assess previous DataLabs Designer knowledge and facilitate the necessary skills and methods to train other system users. The course will train on using Designer knowledge and Trainer skills to lead to delivery of a successful training session. Assessments will form part of the process.

**At the end of this course, the participant will be able to:**

- 2 pre-entry assessments
- Designer Train the Trainer (2 days)
- Practical assessment
- Successful completion of course leads to Certification

*Component of a formal Certification Track (see Training Map on page 14)*
DataLabs Certified Site Trainer (DL023)

**DURATION:** 1-2 days  
**CLASS SIZE:** 10 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>
| Orientation Course (DL001)  
DataLabs for Clinical Monitors (DL007)  
DataLabs for Study Coordinators (DL008)  
DataLabs for Principal Investigators (DL009)  
DataLabs for Administrators (DL012) | Individuals responsible for providing training to the Principal Investigator, Study Coordinator and Clinical Monitor roles | Classroom Instructor-led  
Virtual Instructor-led | Presentation  
Training Guides  
Exercise Guides |

**COURSE DESCRIPTION**

**Certification Track Course***

The Site Train the Trainer course is designed for individuals to deliver DataLabs EDC Study Specific Training for Site personnel. The 2 day course option is suitable for participants that do not have any prior DataLabs EDC experience.

At the end of this course, the participant will be able to:
- Deliver a site training for a Principal Investigator, Study Coordinator or Clinical Monitor role in DataLabs
- Successful completion of this course leads to Certification

Switching from RAVE to DataLabs EDC (DL024)

**DURATION:** 1 hour (Instructor-Led)  
30 minutes (eLearning)  
**CLASS SIZE:** 20 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>
| None | Individuals with knowledge of RAVE EDC who are new to DataLabs EDC | Classroom Instructor-led  
Virtual Instructor-led  
Self-Paced eLearning | Presentation  
Training Recording |

**COURSE DESCRIPTION**

Participants who have experience in using the RAVE EDC tool and plan to move to DataLabs EDC will be able to identify the key clinical tasks in RAVE and how these tasks are achieved in DataLabs.

At the end of this course, the participant will be able to:
- Recognize the similarities and differences between RAVE (v5.6) and DataLabs EDC
- Identify the different techniques to perform similar EDC tasks between the two products

*Component of a formal Certification Track (see Training Map on page 14)
### Switching from INFORM to DataLabs EDC (DL025)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Individuals with knowledge of INFORM EDC who are new to DataLabs EDC</td>
<td>Classroom Instructor-led, Virtual Instructor-led, Self-Paced eLearning</td>
<td>Presentation, Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

Participants who have experience in using the INFORM EDC tool and plan to move to DataLabs EDC will be able to identify the key clinical tasks in INFORM and how these tasks are achieved in DataLabs.

**At the end of this course, the participant will be able to:**
- Recognize the similarities and differences between INFORM (v4.6) and DataLabs EDC
- Identify the different techniques to perform similar EDC tasks between the two products

### DataLabs 4.6-5.0 Version Upgrade Training (DL018)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DataLabs 4.6 use within previous 12 months</td>
<td>Any DataLabs users who have previously used 4.6 and wish to use 5.0</td>
<td>Virtual Instructor-led, Self-Paced eLearning</td>
<td>Presentation, Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

This course will educate participants on the features and functionality that are new or have changed in DataLabs 5.0.

**At the end of this course, the participant will be able to:**
- Describe the new features of DataLabs 5.0
- Describe how to perform the new features in DataLabs, and how daily tasks are affected
### DataLabs 5.0-5.1 Version Upgrade Training (DL022)

**PREREQUISITES** | **PRIMARY AUDIENCE** | **DELIVERY MODES** | **MATERIALS**
--- | --- | --- | ---
DataLabs 5.0 use within previous 12 months | Any DataLabs users who have previously used 5.0 and wish to use 5.1 | Self-Paced eLearning | Training Recording

**COURSE DESCRIPTION**

This course will educate participants on the features that are new or have changed for your role in DataLabs 5.1.

**At the end of this course, the participant will be able to:**

- Describe the new features of DataLabs 5.1
- Describe how to perform the new features in DataLabs EDC, and how your daily tasks are affected

### DataLabs EDC 5.0 to 5.2 Version Upgrade Training (DL027)

**PREREQUISITES** | **PRIMARY AUDIENCE** | **DELIVERY MODES** | **MATERIALS**
--- | --- | --- | ---
DataLabs EDC v5.0 | Any DataLabs EDC users who have previously used v5.0 and wish to use v5.2 | Self-Paced eLearning | Training Recording

**COURSE DESCRIPTION**

This course will provide a basic overview of the new features in DataLabs EDC version 5.2.

**At the end of this course, the participant will be able to:**

- Describe the new features in DataLabs EDC v5.2
- Describe how to perform new features in DataLabs EDC v5.2
# DataLabs EDC 5.2 to 5.3 Version Upgrade Training (DL028)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DataLabs EDC v5.2 use within previous 12 months</td>
<td>Any DataLabs EDC users who have previously used v5.2 and wish to use v5.3</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

This course will provide a basic overview of the new features in DataLabs EDC version 5.3.

**At the end of this course, the participant will be able to:**

- Describe the new features in DataLabs EDC v5.3
- Describe how to perform new features in DataLabs EDC v5.3
- Describe how your daily tasks will be changed

---

# DataLabs Designer 5.1 to 5.2 Version Upgrade Training (DL019)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designer 5.1 Workshop within previous 12 months</td>
<td>Any DataLabs Designer users who have previously used 5.1 and wish to use 5.2</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

This course is designed to identify and highlight the major features, functionality and look and feel between DataLabs Designer 5.1 and 5.2.

**At the end of this course, the participant will be able to:**

- Describe the new features in DataLabs Designer v5.2
- Describe how to perform new features in DataLabs Designer v5.2
## DataLabs Designer 5.2 to 5.3 Version Upgrade Training (DL026)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DataLabs Designer v5.2</td>
<td>Any DataLabs Designer users who have previously used v5.2 and wish to use v5.3</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

### COURSE DESCRIPTION

This course will provide a basic overview of the new features in DataLabs Designer version 5.3.

**At the end of this course, the participant will be able to:**

- Describe the new features in DataLabs Designer v5.3
- Describe how to perform new features in DataLabs Designer v5.3

## DataLabs Designer 5.3 to 5.4 Version Upgrade Training (DL029)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DataLabs Designer v5.3 use within previous 12 months</td>
<td>Any DataLabs Designer users who have previously used v5.3 and wish to use v5.4</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

### COURSE DESCRIPTION

This course will provide a basic overview of the new features in DataLabs Designer version 5.4.

**At the end of this course, the participant will be able to:**

- Describe the new features in DataLabs Designer v5.4
- Describe how to perform new features in DataLabs Designer v5.4

---

_Duración:_ 10 minutos  
_Class Size:_ n/a  
_Delivery Modes:_ Self-Paced eLearning  
_Materials:_ Training Recording
DataLabs for Sales/Business Development (DL021)

**DURATION:** 3 hours  
**CLASS SIZE:** 20 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>DataLabs 5.0 use within previous 12 months</td>
<td>This course is designed for those who will be responsible for selling DataLabs EDC</td>
<td>Classroom Instructor-led Virtual Instructor-led</td>
<td>Presentation Exercise Guide Simulation</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

This course aims to provide sales personnel who need an overall understanding of DataLabs EDC, and the features and functionality that will enable them to sell the product to specified roles confidently, and appear credible.

**The course will enable a business development professional to:**

- Hold a 15-minute conversation with a customer, explaining the benefits of DataLabs and its core eClinical integrations based on specific user roles
- Identify how users of DataLabs EDC can benefit from the system in the following roles: Study Coordinators, Clinical Research Associates and Monitors, Data Managers and Statisticians, Principal Investigators

**STANDARD eLEARNING MODULES**

As part of the study set-up process, standard eLearning modules are organized into role-based curricula mapped to study-specific role permissions. These modules are designed to support users on the job after completion of Perceptive Institute training. Examples of these can be seen below.

<table>
<thead>
<tr>
<th>STUDY COORDINATOR</th>
<th>PRINCIPAL INVESTIGATOR</th>
<th>CLINICAL RESEARCH ASSOCIATE (CRA)</th>
<th>DATA MANAGER</th>
<th>SPONSOR (VIEW ONLY)</th>
<th>MEDICAL MONITOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting Started</td>
<td>Getting Started</td>
<td>Getting Started</td>
<td>Getting Started</td>
<td>Getting Started</td>
<td>Getting Started</td>
</tr>
<tr>
<td>Navigating the System Interface</td>
<td>The DataLabs Interface</td>
<td>Navigating the System Interface</td>
<td>Navigating the System Interface</td>
<td>Navigating the System Interface</td>
<td>Navigating the System Interface</td>
</tr>
<tr>
<td>Searching for Patients and DCFs</td>
<td>Principal Investigator</td>
<td>Search for Patients, CRFs and DCFs</td>
<td>Searching for Patients, CRFs and DCFs</td>
<td>Searching for Patients, CRFs and DCFs</td>
<td>Navigating the System Interface</td>
</tr>
<tr>
<td>Working with Patients</td>
<td></td>
<td>Transferring A Patient</td>
<td>Transferring A Patient</td>
<td>Generating the Blank CRF Report</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Generating the Blank CRF Report</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


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## TRAINING MAP

<table>
<thead>
<tr>
<th>FOUNDATION</th>
<th>ROLE-BASED</th>
<th>SUPPORT</th>
<th>ADMINISTRATION</th>
<th>TECHNICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMPACT Basics</td>
<td>Trial Tracking &amp; Management</td>
<td>IMPACT Super User</td>
<td>IMPACT Administration</td>
<td>IMPACT Visit Report Template Development</td>
</tr>
<tr>
<td></td>
<td>Managing Clinical Personnel &amp; Centers</td>
<td></td>
<td>IMPACT Investigator Administration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Conducting a Monitoring Visit</td>
<td></td>
<td>Reference Data Set-Up and Maintenance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Managing Trial Sites Between Visits</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Funds and Payments</td>
<td>IMPACT Trainer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cost Planning</td>
<td></td>
<td>IMPACT Configuration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regulatory Document Tracking</td>
<td></td>
<td>Email Notification Set-Up and Maintenance</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Bespoke Technical Training Available on Request</td>
</tr>
</tbody>
</table>

### FOUNDATIONAL LEARNING
- Applicable to most users and roles
- Pre-requisite knowledge to most of the full curriculum

### ROLE BASED LEARNING
- Covering core IMPACT functionality

### SUPPORT
- Courses to support the personnel supporting and training end users

### ADMINISTRATION
- Courses to support the personnel administering the system

### TECHNICAL
- Bespoke training courses to support the technical team supporting IMPACT CTMS

<table>
<thead>
<tr>
<th>COURSE/ROLES</th>
<th>MANAGER</th>
<th>TRIAL MANAGER</th>
<th>TRIAL ADMIN</th>
<th>CRA</th>
<th>MONITOR</th>
<th>SUPER USER</th>
<th>IMPACT ADMIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMPACT Basics</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Trial Tracking &amp; Management</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Conducting a Monitoring Visit</td>
<td>●</td>
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<tr>
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<tr>
<td>Funds and Payments</td>
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</table>
In the IMPACT system, each user is assigned to a role in the system. The role in IMPACT will determine what permissions each user will have in the system. Below is a list of typical roles and responsibilities.

**PROJECT MANAGER**
Manages clinical development programs. Uses the Progress module to update project data and view trial data.

**TRIAL MANAGER**
Manages global and local trials at trial and country levels. Uses the Investigator module to select Investigators, the Progress module to update trial information and the Clinical Cost Tracking (CCT) module to manage trial site payments.

**TRIAL ADMINISTRATOR**
Manages clinical trial administrative tasks. Uses the Investigator module to maintain clinical personnel and center information, the Progress module to maintain trial, trial country and trial site information and the Clinical Cost Tracking module to manage trial site payments.

**CLINICAL RESEARCH ASSOCIATE (CRA)**
In-house management of trial sites. Uses the Investigator module to maintain clinical personnel and center information, the Progress module to maintain trial site information and the Clinical Cost Tracking module to manage trial site payments.

**MONITOR**
Manages sites and conducts monitoring visits. Uses IMPACT MySites for conducting site visits and managing trial site information between visits.

**SUPER USER**
Supports end users in their use of the system. May have a “day job” of trial manager, trial administrator or CRA.

**IMPACT ADMINISTRATOR**
Maintains reference data and configuration and performs administration tasks across all trials [e.g. subject visit design, deleting data]. Uses the Reference module to maintain reference data and configuration. Uses the Investigator module to manage Investigator administration tasks [e.g. data de-duplication]. Uses the Progress and Clinical Cost Tracking modules to perform administration tasks.

**SYSTEM ADMINISTRATOR**
Maintains system reference data and configuration. Uses the Reference module to maintain reference data and configuration. Uses the Investigator module to manage Investigator administration tasks [e.g. data de-duplication].
## IMPACT Basics (PS100)

**Duration:** 1.5 hours  
**Class Size:** Unrestricted

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
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<tbody>
<tr>
<td>None</td>
<td>Manager, Trial Manager, Trial Administrator, CRA, Super User, IMPACT Administrator, System Administrator</td>
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<td>eLearning module</td>
</tr>
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</table>

### COURSE DESCRIPTION

The IMPACT Basics eLearning module will provide an overall introduction to the IMPACT Clinical Trial Management System. It can be used as a single course for those who will use IMPACT to access key information on their area of interest, or as a basis for further more role-specific training.

**At the end of this course, the participant will be able to:**

- Describe the IMPACT modules and functionality of each
- Log in and out of the system
- Create a new browser set
- Customize browser settings
- Modify browser sets
- Navigate around IMPACT CTMS (top menu, left menu and between levels)
- Search for and select data
- Produce an IMPACT report
Trial Tracking & Management (PS200)

**Duration:** Classroom–14h
Intro. Webinar–1h
Self-paced–3.5h
Follow-up Webinar–1h

**Class Size:** Classroom–12 max
Self-paced–20 max

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<td></td>
<td>Virtual Instructor-led &amp; Self-paced</td>
<td>Hands-on Practice Script</td>
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</table>

**COURSE DESCRIPTION**

This training module is designed for users of the IMPACT Progress module. The aim is to provide a practical guide to updating trial, trial country, trial site and subject level information.

**At the end of this course, the participant will be able to:**

- Record a new trial
- Record trial parameters [properties, protocol title, delay/cancel/stop, EudraCT]
- Record trial company personnel
- Record trial design [objectives, indications, design details, subject design, treatment design]
- Record vendors and contacts
- Record trial event dates
- Record a new trial country
- Record an enrollment plan
- Record regulatory references
- Record protocol amendments
- Record trial country parameters [properties, delay/cancel/stop]
- Record trial country company personnel
- Record trial country event dates
- Project subject visits [single subject]
- Record regulatory approval of the protocol
- Record the IRB/IEC approval level required for a country
- Record a new trial site
- Record IRB/IEC approval of protocol at trial country level [national approval]
- Record regulatory approval of protocol amendments
- Record IRB/IEC approval of protocol amendments at trial country level [national approval]
- Record trial site parameters [properties, delay/cancel/stop]
- Record trial site company personnel
- Record trial site clinical personnel
- Record trial site contacts
- Record trial site event dates
- Record the IRB/IEC approval of protocol [local approval]
- Record the IRB/IEC approval of protocol amendment [local approval]
- Record new subject
- Record trial site issues
- Record visit report reviews
- Project subject visits [multiple or single subjects]
- Record subject properties including withdrawals
- Record subject visit dates
Managing Clinical Personnel & Centers (IN100)

**PREREQUISITES**
- IMPACT Basics [PS100]

**PRIMARY AUDIENCE**
- Trial Manager, Trial Administrator, CRA, Super User, IMPACT Administrator

**DELIVERY MODES**
- Classroom Instructor-led
- Virtual Instructor-led & Self-paced

**MATERIALS**
- Interactive Guide
- Hands-on Practice Script

**COURSE DESCRIPTION**
This training module is designed for users of the IMPACT Investigator module who are responsible for:

- Maintaining up-to-date information on investigators, other site personnel and centers
- The selection of suitable investigators for future trials

**At the end of this course, the participant will be able to:**
- Perform simple and advanced searches
- Work with lists
- Create trial sites from a list
- Edit clinical personnel records
- Add new clinical personnel
- Search for centers and view results
- Edit center records
- Add new centers
### Conducting a Monitoring Visit (MS110)

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**COURSE DESCRIPTION**

This training module is designed for personnel who are involved in site monitoring using the IMPACT MySites module. The aim is to provide a practical guide to:
- Planning, starting and completing a monitoring visit in MySites
- Recording subject and site information
- Monitoring visit report generation, the review process and report finalization

**At the end of this course, the participant will be able to:**
- Plan and start a visit
- Record subject Information
- Record and maintain site visit information (issues, event dates, visit checklists, Investigator Trial File checklist, site personnel)
- Process the visit report
- Complete the visit
- Resolve data conflicts

**Duration:** Classroom–3.5h Intro. Webinar–1h Self-paced–1.5h Follow-up Webinar–1h

**Class Size:** Classroom–10 max Self-paced–20 max
Conducting a Monitoring Visit (MS100)

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<td>Clinical Research Associate (CRA), Monitor</td>
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<td>eLearning module</td>
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</table>

**Duration:** 1.5 hours  
**Class Size:** Unrestricted

**COURSE DESCRIPTION**

This training module is designed for personnel who are involved in site monitoring using the IMPACT MySites module.

**The aim is to provide a practical guide to:**

- Planning, starting and completing a monitoring visit in MySites
- Recording subject and site information
- Monitoring visit report generation, the review process and report finalization

**At the end of this course the participant will be able to:**

- Plan and start a visit
- Record subject Information
- Record site visit information
- Process the visit report
- Complete the visit
- Resolve data conflicts
Managing Trial Sites Between Visits (MS210)

**Duration:** Classroom–3.5h
Intro. Webinar–1h
Self-paced–1.5h
Follow-up Webinar–1h

**Class Size:** Classroom–10 max
Self-paced–20 max

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<td>Classroom Instructor-led Virtual Instructor-led &amp; Self-paced</td>
<td>Interactive Guide Hands-on Practice Script</td>
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</table>

**COURSE DESCRIPTION**

This training module is designed for personnel who are involved in site management using the IMPACT MySites module.

**At the end of this course, the participant will be able to:**

- Record trial site issues
- View the visit checklist for the last completed site visit
- View the status of the investigator trial file at the last completed site visit
- Record that the last subject has been set-up at this trial site
- Associate clinical personnel with the trial site
- Record trial site contacts
- Record or view the trial site recruitment summary
- Record trial site event dates
- View previous trial site visits and record the next planned visit
- Record a new subject
- Record subject properties (including withdrawal details)
- Record subject issues
- Project subject visit dates
- Record subject visit dates
Funds and Payments (CT100)

**Duration:**
- Classroom – 3.5h
- Intro. Webinar – 1h
- Self-paced – 1.5h
- Follow-up Webinar – 1h

**Class Size:**
- Classroom – 10 max
- Self-paced – 20 max

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</table>

**COURSE DESCRIPTION**

This training module is designed for trial and finance personnel who are involved in fund management and the processing of payments.

**At the end of this course, the participant will be able to:**

- Record a trial site fund
- Record a trial site financial agreement
- Record a trial site payment schedule
- Create a trial site fund by copying an existing fund
- Authorize funds
- Make adjustments, close and re-open a fund
- Update subject fees
- Generate and review payment requests
- Record an ad hoc payment request
- Authorize payment requests
- Record details of actual payments
- View payment request details
- View payment requests held back
- View summary of actual payments
## Cost Planning (CT200)

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<tr>
<th>PREREQUISITES</th>
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<td>Classroom Instructor-led Virtual Instructor-led &amp; Self-paced</td>
<td>Interactive Guide Hands-on Practice Script</td>
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### PREREQUISITES
- IMPACT Basics (PS100)

### PRIMARY AUDIENCE
- Trial Manager, Trial Administrator, CRA, Super User

### DELIVERY MODES
- Classroom Instructor-led
- Virtual Instructor-led & Self-paced

### MATERIALS
- Interactive Guide
- Hands-on Practice Script

### COURSE DESCRIPTION

This training is designed for study and finance personnel who are involved in trial cost planning.

**At the end of this course, the participant will be able to:**

- Record a trial cost plan
- Record a trial country cost plan
**Regulatory Document Tracking (DT01)**

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<tr>
<th>PREREQUISITES</th>
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<td>Classroom Instructor-led Virtual Instructor-led &amp; Self-paced</td>
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**COURSE DESCRIPTION**

This training module is designed for personnel who are responsible for the set-up and/or tracking of the regulatory documents required for a trial. The aim is to provide a practical guide to the configuration necessary for a particular trial and subsequent tracking of the documents which make up the regulatory package.

**At the end of this course, the participant will be able to:**

- Configure documents and packs to be tracked at trial level
- Configure documents and packs to be tracked at trial country level
- Configure documents and packs to be tracked at trial site level
- Track documents and packs
- Search for documents and packs
IMPACT® CTMS COURSES

**IMPACT Trainer (IT10)**

**Duration:** Classroom–3.5h–15h  
**Class Size:** Classroom–12 max

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<td>Word® Documents</td>
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**COURSE DESCRIPTION**

This training module is designed for personnel who will be delivering the IMPACT training. It may be extended to allow participants to practice their training delivery and receive feedback.

**At the end of this course, the participant will be able to:**

- Describe the training cycle
- Write a ‘SMART’ objective
- Create a checklist to be used when planning your IMPACT CTMS training event
- Describe two principles of learning theory and how you intend to put each of them into practice during your IMPACT training event
- Draft an evaluation form to enable you to assess the quality and effectiveness of your IMPACT training
- List the trials available on the IMPACT training database suitable for a training event to be specified by the Trainer
- Conduct a short database test
# IMPACT® CTMS COURSES

## IMPACT Super User (SU01)

### Duration:
- Classroom–3.5h-21h
- Class Size: Classroom–8 max

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<td>Classroom Instructor-led</td>
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<td>Hands-on Practice Script</td>
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### COURSE DESCRIPTION

This training module is designed for personnel who will be providing ongoing support to IMPACT end users. The course materials will be customized based on the IMPACT CTMS modules implemented and specific training needs, therefore the course duration will vary.

**At the end of this course, the participant will be able to:**
- Extend their knowledge of the system as a whole
- Understand the roles and responsibilities for updating the system in their organization
- Troubleshoot common problems presented to Super Users
- Follow the correct escalation path for problems they are not able to resolve

## IMPACT Super User (Core Functionality) (SU02)

### Duration:
- Intro. Webinar–2h
- Self-paced–3h
- Follow-up Webinar–1h
- Class Size: Self-paced–4 max

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<td>IMPACT Super User</td>
<td>Virtual Instructor-Led &amp; Self-paced</td>
<td>Word® Documents</td>
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</table>

### COURSE DESCRIPTION

This training module is designed for personnel who will be providing ongoing support to IMPACT end users. If the IMPACT MySites, Clinical Cost Tracking and/or Investigator modules are not in use, the objectives relating to these modules will not be covered.

**At the end of this course, the participant will be able to:**
- Extend their knowledge of the system as a whole
- Understand the roles and responsibilities for updating the system in their organization
- Troubleshoot common problems presented to Super Users
- Follow the correct escalation path for problems they are not able to resolve
# IMPACT Administration (IA100)

**Duration:** Intro. Webinar–1h  
Self-paced–3.5h  
Follow-up Webinar–1h  
**Class Size:** Self-paced–4 max

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Trial Tracking & Management [PS200]  
Managing Clinical Personnel and Centers (IN100)*  
Funds and Payments (CT100)*  
*only if IMPACT module implemented | IMPACT Administrator | Virtual Instructor-led & Self-paced | Interactive Guide  
Hands-on Practice Script |

## COURSE DESCRIPTION

This training module is designed for IMPACT administrators who are responsible for maintaining reference data and performing administration tasks across all trials. If the IMPACT MySites, Clinical Cost Tracking and/or Investigator modules are not in use, the objectives relating to these modules will not be covered.

**At the end of this course, the participant will be able to:**

- Record a new project
- Record that a trial has been archived
- Record the MySites set-up requirements
- Record the subject visit design
- Confirm the investigator file documents
- Transfer a subject between sites
- Reset a trial site visit
- Run financial calculations
- Delete data entered in error
- Record and maintain company personnel
- Record and maintain vendor details
- Record investigational products
- Record and maintain payees
- Record and maintain centers and center locations
- Record and maintain clinical personnel
- Verify new clinical personnel recorded in MySites
- Record and maintain visit checklists
- Record and maintain currencies
- Record fees
- Record cost areas
IMPACT Investigator Administration (IN110)

**Duration:** Classroom–3.5h  
Intro. Webinar–1h  
Self-paced–1.5h  
Follow-up Webinar–1h  
**Class Size:** Classroom–4 max  
Self-paced–4 max

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Virtual Instructor-led & Self-paced | Interactive Guide  
Hands-on Practice Script |

**COURSE DESCRIPTION**

This training module is designed for users of the IMPACT Investigator module who are responsible for managing consent, duplicate records, quality and compliance issues and bulk loading of investigator records.

**At the end of this course, the participant will be able to:**

- Record quality and compliance events
- Revoke and enable consent
- Resolve any potential duplicate centers identified by the background processor
- Resolve any potential duplicate clinical personnel identified by the background processor
- Prepare a suitable data file and use it to import clinical personnel and center records
- View the jobs list to check for errors, warnings and the status of background processing
- Review the Jobs list
Reference Data Set-Up and Maintenance (RD01)

**PREREQUISITES**
None

**PRIMARY AUDIENCE**
System Administrator

**DELIVERY MODES**
- Classroom Instructor-led
- Virtual Instructor-led & Self-paced

**MATERIALS**
Presentations
Word® Document

**COURSE DESCRIPTION**
This training is designed for personnel who are involved in setting up and maintaining IMPACT reference data. If IMPACT MySites, Investigator, Clinical Cost Tracking, Regulatory Document Tracking and/or Clinical Supplies Tracking modules are not in use, the objectives relating to these modules will not be covered.

At the end of this course, the participant will be able to:
- Record and maintain basic reference data
- Record and maintain medical units
- Record and maintain company personnel
- Record and maintain vendor details
- Record and maintain centers and center locations
- Record and maintain clinical personnel
- Record and maintain progress checklists
- Record and maintain investigator file documents
- Record and maintain documents and document packs to be tracked
- Record item tracking templates
- Record visit types
- Record visit report review configuration
- Record and maintain visit checklists
- Set-up visit report templates
- Record and maintain medical unit visit report templates and SOPs
- Record and maintain payees
- Record and maintain supplies items
# IMPACT® CTMS COURSES

## IMPACT Configuration (IC01)

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</table>

- **Duration:** Classroom-3.5h
  - Intro. Webinar-1h
  - Self-paced-2.5h
- **Class Size:** Classroom-4 max
  - Self-paced-4 max

## COURSE DESCRIPTION

This training is designed for personnel who are involved in setting up and maintaining the system configuration.

**At the end of this course, the participant will be able to:**

- Maintain global settings
- Maintain master event descriptions and statuses
- Maintain additional events and statuses
- Select the events to be included on the summary pages
- Define event roll-up rules
- Maintain terminology for a new IMPACT CTMS installation
- Maintain terminology for an IMPACT CTMS upgrade
- Maintain occupation security
- Configure the IMPACT menu
- Maintain mandatory and required fields
- Maintain additional fields
- Maintain indicators
- Maintain `Not Required` functionality
- Maintain `Not Required` fields
- Maintain automatic reminders
- Maintain the MySites trial site identifier
### Email Notification Set-Up and Maintenance (EN01)

**Duration:** Classroom–2h  
Intro. Webinar–1.5h  
Self-paced–2h  
**Class Size:** Classroom–4 max  
Self-paced–4 max

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<tr>
<td></td>
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<td>Virtual Instructor-led &amp; Self-paced</td>
<td>Word® Document</td>
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</table>

**COURSE DESCRIPTION**

This training is designed for personnel who are involved in setting up and maintaining email notifications.

**At the end of this course, the participant will be able to:**

- Set-up and maintain an event date email notification
- Set-up and maintain a custom email notification

### IMPACT Mail Merge Creation, Set-Up and Maintenance (MM01)

**Duration:** Classroom–2h  
Intro. Webinar–1.5h  
Self-paced–2h  
**Class Size:** Classroom–8 max  
Self-paced–8 max

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**COURSE DESCRIPTION**

This training is designed for personnel who are involved in creating new templates, setting up and maintaining mail merges.

**At the end of this course, the participant will be able to:**

- Develop a new Excel® mail merge template
- Develop a new Word® mail merge template
- Set-up a pre-defined mail merge
- Modify an existing mail merge Word® template
### Visit Report Template Development (VR01)

**Duration:** Classroom–7h  
**Class Size:** Classroom–8 max

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
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<tbody>
<tr>
<td>None</td>
<td>System Administrator, Technical Team Member</td>
<td>Classroom Instructor-led</td>
<td>Presentations Word® Document</td>
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#### COURSE DESCRIPTION

This training is designed for personnel who are involved in the generation of new and modification of existing visit report templates used in the IMPACT MySites module.

**At the end of this course, the participant will be able to:**

- Set-up prerequisite files and software needed for visit report development
- Create a visit report template in rich text format (RTF)
- Create a formatted object (FO) file from an rtf file
- Test the FO file by converting to PDF
- Create an extensible stylesheet language (XSL) file from an FO file
- Modify the visit report definition file
- Modify the extensible stylesheet language (XSL) file
- Add a graphical image to a visit report template
- Create a new visit report section
- Set-up visit report templates and visit report definition files in the Reference module
- Test the visit report template in MySites
# PERCEPTIVE MYTRIALS TRAINING MAP

<table>
<thead>
<tr>
<th>SITE USER (View Only Access)</th>
<th>PROJECT TEAM USER (Read &amp; Write Access)</th>
<th>ADMINISTRATOR</th>
<th>SALES</th>
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**ORIENTATION LEARNING**
- Applicable to all roles
- Pre-requisite knowledge for Certification courses

**CERTIFICATION PROGRAMS**
- Reflects the highest level of technical and professional competency for key roles
- Assessment of competency leading to Certification
PERCEPTIVE MYTRIALS ROLES

Each user role below can benefit from our modular standalone courses or complete the relevant training track for their role and in addition benefit from role based Certification.

**BUSINESS DEVELOPMENT**
Responsible for supporting pre-sales activities, finding new business and developing existing relationships. Pre-sales and Business Development personnel will need to understand product placement, articulate value propositions and differentiators of the product.

**SITE USERS**
Site users are typically responsible for the data entry aspect of clinical studies. Perceptive MyTrials enables sites to access multiple studies in one place, access associated applications, document libraries and view calendars and announcements.

**ADMINISTRATORS**
Designated administrators manage the overall trial and trial access process using the User Maintenance Interface. They will need to be able to edit the Collaboration Toolbox, filter data, activate and deactivate users and manage the activation keys.

**PROJECT TEAM USERS**
Responsible for overall study management, project team users may have edit rights to certain interfaces, enabling them to upload, and edit documents, calendars and announcements, view reports, the project leader dashboard and PAREXEL® Master File.
### Perceptive MyTrials Orientation (MT001)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
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<tbody>
<tr>
<td>None</td>
<td>All Roles</td>
<td>Self-Paced eLearning</td>
<td>Presentation, Training Recording</td>
</tr>
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</table>

**DURATION:** 20 minutes approx  
**CLASS SIZE:** n/a

**COURSE DESCRIPTION**

This course will provide a high level informational overview on Perceptive MyTrials, the framework and its applications. Users will be presented to the different eClinical groups assigned to Perceptive MyTrials and will be provided an overview of the available access for these groups.

**At the end of this course, the participant will be able to:**
- Give an overview of the Perceptive MyTrials Components
- Describe Dashboards and Interfaces
- Access Document Libraries
- View Calendars and Announcements

### Perceptive MyTrials System Access Process (MT002)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
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<tbody>
<tr>
<td>Perceptive MyTrials Orientation (MT001)</td>
<td>All Roles</td>
<td>Self-Paced eLearning</td>
<td>Presentation, Training Recording</td>
</tr>
</tbody>
</table>

**DURATION:** 10 minutes  
**CLASS SIZE:** n/a

**COURSE DESCRIPTION**

The system access process course will provide a high level overview of the user account creation process, how to request access to a trial access and how to modify user preferences.

**At the end of this course, the participant will be able to:**
- Create a user account
- Register for trial access
- Access and edit user profile
Perceptive MyTrials Collaboration Toolbox (MT003)

**DURATION:** 20 minutes

**CLASS SIZE:** n/a

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
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<td>Self-Paced eLearning</td>
<td>Training Recording</td>
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</table>

**COURSE DESCRIPTION**

The Collaboration Toolbox module is designed for users who have edit rights to the Perceptive MyTrials platform. The participant will receive an overview of the Collaboration Toolbox, features and functionality. Participants will receive complete instruction on the document collaboration process and the benefits of using calendars and announcements.

**At the end of this course, the participant will be able to:**

- Describe the Collaboration Toolbox features and functionality
- Be able to load, modify and collaborate on documents using the Collaboration Toolbox
- Describe how to insert, modify and use Calendars and Announcements.
- Describe the benefits of using Quickr Connector to manage documents

Perceptive MyTrials Reports (MT004)

**DURATION:** 20 minutes approx

**CLASS SIZE:** n/a

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<thead>
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<th>PREREQUISITES</th>
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<td>CRA, Data Manager, Any Project Team Member</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
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</tbody>
</table>

**COURSE DESCRIPTION**

This course will explain how study team members can use the Perceptive MyTrials Reports functionality to perform data analysis.

**At the end of this course, the participant will be able to:**

- Describe the eClinical metrics available in the Reporting Tool
- Use report links to access reports available in other applications
### Perceptive MyTrials PAREXEL Trial Master File (MT005)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
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<th>MATERIALS</th>
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<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

Participants will be provided with an overview of the PAREXEL Master file in order to view clinical documents.

**At the end of this course, the participant will be able to:**
- Navigate and access clinical trial documents for assigned clinical trials using the PAREXEL Master File
- Explain the importance and benefits of having access to project specific files through Perceptive MyTrials

### Perceptive MyTrials Project Leader Dashboard (PLD) (MT011)

<table>
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<td>CRA, Data Manager, Any Project Team Member</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

Participants will be provided with an overview of the Project leader Dashboard to review metrics for Performance and Milestones.

**At the end of this course, the participant will be able to:**
- Navigate the Project leader dashboard in order to access Study Performance and Milestones
- Use PLD metrics to evaluate study performance
## Perceptive MyTrials User Maintenance Interface (UMI) (MT006)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>
| Perceptive MyTrials Orientation [MT001]  
Project Managers  
Any Project Team Member | Self-Paced eLearning | Training Recording |

**COURSE DESCRIPTION**

**Certification Track Course**

Participants will be provided with an overview of the User Maintenance Interface in order to manage access to a trial.

**At the end of this course, the participant will be able to:**

- Load users into the Perceptive MyTrials platform tool
- Approve users and understand the activation key process
- Deactivate and reactivate profiles

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## Perceptive MyTrials for Sales (MT007)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
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<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

**COURSE DESCRIPTION**

**Certification Track Course**

This course provides pre-sales and sales personnel with an overview of the Perceptive MyTrials system and how to best position it with our clients. Learners will be introduced to the system, as well as taking a closer look at how different roles use the system, while being presented the key sales messaging points along the way.

**At the end of this course, the participant will be able to:**

- Position Perceptive MyTrials in the market place
- Describe the Perceptive MyTrials value propositions
- State the important differentiators
- Describe the position of Perceptive MyTrials in the eClinical suite

*Component of a formal Certification Track (see Training Map on page 56)*
### Perceptive MyTrials Functionality Training (MT008)

**DURATION:** 1 hour  
**CLASS SIZE:** n/a

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
<th>DELIVERY MODES</th>
<th>MATERIALS</th>
</tr>
</thead>
</table>
| Perceptive MyTrials Orientation (MT001)  
Perceptive MyTrials System Access Process (MT002) | Data Managers  
Any Project Team Member  
Project Managers | Self-Paced eLearning | Training Recording |

#### COURSE DESCRIPTION

This course is comprised of the following Perceptive MyTrials courses:

- [MT003] Perceptive MyTrials Collaboration Toolbox
- [MT004] Perceptive MyTrials Reports
- [MT005] Perceptive MyTrials PAREXEL Master File
- [MT011] Perceptive MyTrials Project Leader Dashboard (PLD)

In combination, these modules will provide the user with a complete overview of the main functionality a Perceptive MyTrials user with edit rights will have access to.

**At the end of this course, the participant will be able to:**

- Describe the Collaboration Toolbox features and functionality
- Describe the eClinical metrics available in the Reporting Tool
- Describe and use the Project Leader Dashboard in order to assist in the management and decision-making process for a trial
# Perceptive MyTrials for Site Users (MT009)

<table>
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<td>Site Users</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
</tbody>
</table>

## COURSE DESCRIPTION

This course will explain how site users can utilise the read only functionality of Perceptive MyTrials for their assigned Trials. Participants will be provided with an overview of how to access their trials, applications, the document collaboration toolbox and its benefits to the site user.

This course is comprised of the following Perceptive MyTrials courses:

- (MT001) Perceptive MyTrials Orientation
- (MT002) Perceptive MyTrials System Access Process

At the end of this course, the participant will be able to:

- Request access to Perceptive MyTrials
- Describe how to access the Perceptive MyTrials page and assigned trials
- Describe how to view trial-related documents, calendars and announcements

*Component of a formal Certification Track (see Training Map on page 56)*
Perceptive MyTrials for Project Teams (MT010)

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
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<tbody>
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<td>Data Managers, CRA, Project Managers</td>
<td>Self-Paced eLearning</td>
<td>Presentation, Training Recording</td>
</tr>
</tbody>
</table>

DURATION: 1.5 hours  
CLASS SIZE: n/a

COURSE DESCRIPTION

The Perceptive MyTrials for Project teams will encompass all modules applicable to the roles with edit rights.

This course is comprised of the following Perceptive MyTrials courses:

- [MT001] Orientation
- [MT002] System Access Process
- [MT003] Collaboration Toolbox
- [MT004] Reports
- [MT005] PAREXEL Trial Master File
- [MT011] Project Leader Dashboard (PLD)

At the end of this course, the participant will be able to:

- Give an overview of the Perceptive MyTrials Components, interfaces and dashboards
- Understand how to create a user account
- Describe the Collaboration Toolbox features and functionality
- Describe the eClinical metrics available in the Reporting Tool
# Perceptive MyTrials Data-Driven Monitoring Training Map

## Orientation Learning
- Pre-requisite foundation knowledge for role-specific courses

## Role Based Learning
- Role-based modules mapped to typical user roles
- Demonstrations and real-world scenarios

## Table of Training Modules

<table>
<thead>
<tr>
<th>SALES</th>
<th>CLINICAL MONITOR</th>
<th>CLINICAL OVERSIGHT</th>
</tr>
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<tbody>
<tr>
<td>DDM006 Perceptive MyTrials Data-Driven Monitoring for Business Development</td>
<td>DDM001 Perceptive MyTrials Data-Driven Monitoring Orientation</td>
<td>DDM001 Perceptive MyTrials Data-Driven Monitoring Orientation</td>
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E: eLearning
BUSINESS DEVELOPMENT
Responsible for supporting pre-sales activities, finding new business and developing existing relationships. Pre-sales and Business Development personnel will need to understand product placement, articulate value propositions and differentiators of the product.

CLINICAL OVERSIGHT
Clinical Oversight roles include Clinical Operation Leaders, Project Managers of those responsible for ensuring an effective study oversight. They are typically responsible for evaluating at a high level the study progress and managing risk.

The Perceptive MyTrials Data-Driven Monitoring (DDM) application allows those responsible for oversight to quickly identify risk categories and also provide oversight justification of study decisions.

CLINICAL MONITORS
Clinical Monitors are responsible for the day to day activities of site monitoring. Data-Driven monitoring can be used to identify sites at risk in order to act accordingly. Clinical Monitors will need to understand how to use risk-based monitoring and analyze data values and visualizations to implement actions.
Perceptive MyTrials Data-Driven Monitoring Orientation (DDM001)

<table>
<thead>
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<th>PREREQUISITES</th>
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<th>DELIVERY MODES</th>
<th>MATERIALS</th>
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<td>Training Recording</td>
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<tr>
<td>Perceptive MyTrials System Access (MT002)</td>
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</table>

**COURSE DESCRIPTION**

The Perceptive MyTrials Data-Driven Monitoring course will introduce the Data-Driven Monitoring approach. It will also provide a high-level introduction to the DDM application and its benefits to a clinical trial. Users will also have a high-level introduction to the application dashboard and its key features.

**At the end of this course, the participant will be able to:**

- Describe the Perceptive MyTrials Data-Driven Monitoring application
- Describe the value of the DDM application to the clinical trial process
- Describe the key features of the DDM Dashboard
Perceptive MyTrials Data-Driven Monitoring Dashboard (DDM002)

**COURSE DESCRIPTION**

The Perceptive MyTrials Data-Driven Monitoring Dashboard course will navigate users through the DDM Dashboard, data displays, and visualizations. Users will learn how to navigate through the dashboard, identify the various data reports available, and be presented with filter and view options to refine data searches. Users will learn how to identify studies or sites at risk using the data and views available.

**At the end of this course, the participant will be able to:**
- Identify the key areas of the DDM application
- Apply filters to drill down and analyze table data
- Identify table data in Data Visualizations
- Use flags and color coding to identify study risks
## Course Description

The Perceptive MyTrials Data-Driven Monitoring Clinical Monitor course provides users who monitor study data and sites a firm foundation for using the DDM application. The application assists in analyzing data to identify sites at risk and reviewing a monitoring strategy to mitigate those risks.

### At the end of this course, the participant will be able to:
- Describe how the DDM application can benefit traditional or adaptive monitoring
- Explain how to use the Monitoring plan to help plan, prioritize, and schedule activities
- Navigate the DDM application to identify sites at risk

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<th>MATERIALS</th>
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Perceptive MyTrials Data-Driven Monitoring for Clinical Oversight (DDM004)

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<tr>
<td>Perceptive MyTrials DDM for Clinical Monitors (DDM003)</td>
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**COURSE DESCRIPTION**

The Perceptive MyTrials Data-Driven Monitoring Clinical Oversight course is intended for those who are responsible for study oversight and clinical monitor management. This course will introduce how to use risk categories, risk indicators and alert flags during oversight activities providing example scenarios from study enrollment through to closeout.

**At the end of this course, the participant will be able to:**

- Identify the value of DDM for project planning and oversight
- Identify relevant reports and data specific to Project Leads
- Identify trends and operational performance
## Perceptive MyTrials Data-Driven Monitoring for Business Development (DDM005)

<table>
<thead>
<tr>
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<tr>
<td>Perceptive MyTrials DDM Orientation (DDM001)</td>
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<tr>
<td>Perceptive MyTrials DDM Dashboard (DDM002)</td>
<td>Business Development</td>
<td>Self-Paced eLearning</td>
<td>Training Recording</td>
</tr>
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</table>

### COURSE DESCRIPTION

The Perceptive MyTrials Data-Driven Monitoring for Business Development course will enable BD/Sales to position the value of Risk Based Monitoring and the DDM tool to clients. This course will also present the key features and functions of the tool, and the benefits and value to Clients and users.

**At the end of this course, the participant will be able to:**

- Define the value of Risk Based Monitoring
- Pitch the features and functionality of the DDM Tool
- Highlight the benefits to Client / Roles
CERTIFICATION TRACKS

Our Certification programs offer clear specialist based Certification paths. Training is delivered using a variety of delivery mechanisms, applying practical and hands on activities, and incorporating best practices from our experienced trainers. Once passing our skills based and knowledge based assessments, Certified individuals will receive:

- Unique numbered Certificate
- Certified Logo to demonstrate your Certification status
- Training guides, and where applicable access to Instructor and Student kits are available for DataLabs Trainer Certifications

We currently offer 7 Certifications within the DataLabs EDC training program:

- Data Manager Certified
- Administrator Certified
- DataLeads Certified
- Designer Certified
- DataLabs Trainer Certified
- DataLabs Site Trainer Certified
- Designer Trainer Certified

We currently offer 3 Certifications within the RTSM training program:

- CRA Certified
- Project manager Certified
- Sales Certified

We also currently offer 2 Certifications within the Perceptive MyTrials training program:

- Administrator Certified
- Sales Certified

The Perceptive Institute training library is an on demand subscription service providing bite sized usage and training tips on products within our eClinical solution.

Our ever-expanding library contains a variety of options to increase your comfort and knowledge with our products. Subscribers can view vodcasts, quick reference guides, product walkthroughs, or listen to podcasts. The library allows you to choose your own learning adventure.

Our Subscription library is available online: www.perceptivepartnerprogram.com/training/training-library-subscription

TRAINING CONSULTING*

Provision of a training expert to work with you on training needs, analysis, recommendations and development. Some clients may require training that is tailored to their organization and specific development needs. We can work with you to understand your training needs, and create a custom training agenda for you.

*Daily fee will apply