PAREXEL'S EDUCATION SERVICES

2016-2017 COURSE CATALOG

Version 5.0

PAREXEL®
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WELCOME TO PAREXEL'S EDUCATION SERVICES

PAREXEL's Education Services 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 the Perceptive MyTrials® technology platform**
- **Using IMPACT® CTMS**
- **Using Perceptive MyTrials® Data-Driven Monitoring (DDM)**

Education Services provide 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 based on four building blocks as we understand that our clients needs are different. Flexibility and choice is important.

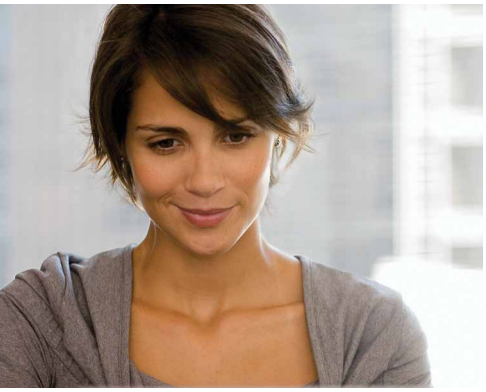
We offer a blended training delivery program including:

- **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.

OUR PORTFOLIO IS MODULAR AND FLEXIBLE



PAREXEL's Education Services 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.

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DATALABS® EDC
COURSES

EDC TRAINING MAP

ILT: Instructor-led training, **E:** eLearning

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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

DATALABS AND DESIGNER ROLES

In DataLabs, each user is assigned to a role in the system. Your role in DataLabs will determine the permissions you will have in the system which in turn drives your training needs. DataLabs user role permissions can be customized during study set-up. Below is a list of typical roles and the associated permissions in DataLabs:

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

STUDY DESIGNERS

The Study Designer role is typically responsible for:

- Designing and building studies in DataLabs EDC

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 Basics (DL001)

DURATION: 15 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	All Roles	Self-Paced eLearning	n/a

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: (ILT) 12 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics Course (DL001) (recommended)	Clinical Research Associates In-house Monitors	Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning	Presentation Participant Guide

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)

DURATION: 30 minutes
CLASS SIZE: (ILT) 12 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	Principal Investigators Study Coordinators Those responsible for reviewing and electronically signing eCRFs	Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning	Presentation Participant Guide

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)

DURATION: 25 minutes
CLASS SIZE: (ILT) 12 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics Course (DL001) (Recommended)	Data Entry Personnel	Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning	Presentation Participant Guide

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)

DURATION: 1 hour
CLASS SIZE: (ILT) 12 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics Course (DL001) (recommended)	Those responsible for Medical review	Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning	Presentation Participant Guide

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)

DURATION: 30 minutes
CLASS SIZE: (ILT) 12 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	Any view only roles, for example: Project Leaders Sponsors Quality Managers and Auditors	Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning	Presentation Participant Guide

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: (ILT) 12 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics Course (DL001) (recommended)	Those responsible for data entry into the eCRF at site	Classroom Instructor-led Virtual Instructor-led Self-Paced eLearning	Presentation Participant Guide

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)

DURATION: 1 hour
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics Course (DL001)	Those assigned the Administrator role	Self-Paced eLearning	n/a

COURSE DESCRIPTION

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 Administrator Certification (DL028)

DURATION: 4 hours
CLASS SIZE: 8 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs Administrator	Those who will be responsible for the DataLabs EDC Administrative activities	Classroom Instructor-led	Presentation Participant Guide

COURSE DESCRIPTION

Certification Track Course*

The DataLabs® EDC Administrator certification course is intended to provide a comprehensive training of the administrator functions within DataLabs EDC. An extensive walkthrough of loading study XMLs, Major and Minor updates to XMLs, Site and User Management and various Study Management activities.

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

- Perform all major administrative activities required in DataLabs EDC
- Manage a study XML in DataLabs EDC
- Manage sites, users and permissions
- Manage flags and eSignature attestations
- Produce a database ready to train other team members

DataLabs Data Manager (DL004)

DURATION: 1.5 hours
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics Course (DL001)	Data Managers	Self-Paced eLearning	n/a

COURSE DESCRIPTION

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 4)

IB Reporting Dashboard (DL013)

DURATION: 10 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics Course (DL001) (recommended)	Any role that uses IB Reporting Dashboard functionality	Self-Paced eLearning	n/a

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)

IB Reporting Standard Reports (DL014)

DURATION: 10 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
IB Reporting Dashboard (DL013)	Any role that uses IB Reporting Standard Reports functionality	Self-Paced eLearning	n/a

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)

DURATION: 15 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
IB Reporting Standard Reports (DL014)	Any role that is assigned to creating custom reports	Self-Paced eLearning	n/a

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

Designer Workshop (DL002)

DURATION: 4.5 days
CLASS SIZE: (ILT) 8 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs for Administrators (DL012) DataLabs EDC for Designer Workshop	Programmers Any role that will build DataLabs studies	Classroom Instructor-led	Presentation Participant Guide

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 4)

DataLabs EDC Workshop (DL002a)

DURATION: 2.5 days
CLASS SIZE: 8 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics Course	Those who will be responsible for training in DataLabs for any role	Blended Delivery	Presentation Participant Guide Training Recording

COURSE DESCRIPTION

The DataLabs® EDC Workshop 2.5 Day course is intended to provide a comprehensive training of DataLabs EDC for the end user. An extensive walkthrough of a study from data entry, to verification, queries, freeze, signatures and locking will be provided to all users. Users will become familiar to the administrative functions available in DataLabs EDC in order to prepare a database for a study or training session.

The full program consists of:

- Load & Manage Study XML
- Perform data entry activities,
- Perform study team activities, including data verification, queries and flagging

DataLabs Certified Trainer (DL020a)

DURATION: 2 days
CLASS SIZE: (ILT) 8 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs EDC Workshop (DL002a)	Those who will be responsible for training in DataLabs for any role	Classroom Instructor-led	Presentations Participant Guide

COURSE DESCRIPTION

Certification Track Course*

Participants will have completed a full DataLabs EDC knowledge-based course prior to participation of the DataLabs EDC Certified Trainer course. 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 EDC Train the Trainer Certification Program (2 Days)
- Practical assessment
- Successful completion of this course leads to Certification

*Component of a formal Certification Track (see Training Map on page 4)

Designer Certified Trainer (DL020b)

DURATION: TTT: 2 days
CLASS SIZE: (ILT) 8 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Designer Workshop (DL002)	Those who will be responsible for training others in the Designer tool	Classroom Instructor-led	Presentation Participant Guide

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

DataLabs Designer Version Upgrade Training

DURATION: 10 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Certificate in earlier DataLabs Designer version	Any DataLabs Designer users who require training in an updated DataLabs Designer version	Self-Paced eLearning	n/a

COURSE DESCRIPTION

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

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

- Describe the new features in DataLabs Designer
- Describe how to perform new features in DataLabs Designer

*Component of a formal Certification Track (see Training Map on page 4)

DataLabs Certified Site Trainer (DL023)

DURATION: 2 days
CLASS SIZE: (ILT) 8 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
DataLabs & Designer Basics 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 Participant Guide

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

DataLabs Version Upgrade Training

DURATION: 15-30 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Certificate in earlier DataLabs EDC version	Any DataLabs users who require training in an updated DataLabs version	Self-Paced eLearning	n/a

COURSE DESCRIPTION

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

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

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

*Component of a formal Certification Track (see Training Map on page 4)

Study Archive Utility

DURATION: 10 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	Those who will be responsible for using the Study Archive Utility	Self-Paced eLearning	n/a

COURSE DESCRIPTION

The Study Archive Utility eLearning module explains the study archive process. Starting with generating the archive XML in DataLabs® EDC and continuing on to importing that XML into the Study Archive Utility and generating the archive PDF.

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

- Perform an archive export in DataLabs® EDC
- Generate the archive PDF in the Study Archive Utility

IMPACT® CTMS COURSES

TRAINING FOR IMPACT® CTMS EXPRESS IMPLEMENTATION

PAREXEL's Education Services provides online training to enable a streamlined deployment of content to users globally. The role-based curriculum is accessible to learners at any time for initial training, review and reference via a learning portal. Training compliance and completion is tracked, online certificates are available to print and we provide training completion reports to nominated recipients on a regular basis.

We recognize that system administrators require contact with an instructor and so we provide virtual instructor-led, self-paced training to meet this need.

TRAINING MAP

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<tr><th>FOUNDATION</th><th>ROLE-BASED</th><th>ADMINISTRATION</th></tr>
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<tr><td>Managing Clinical Personnel & Centers</td></tr>
<tr><td>Site Monitoring & Management Using MySites*</td><td rowspan="2">IMPACT® Investigator Administration</td></tr>
<tr><td>Site Funds and Payments</td></tr>
</table>

*For Express Premium customers only.

FOUNDATIONAL LEARNING

- Applicable to most users and roles
- Pre-requisite knowledge to most of the IMPACT® Express curriculum

ROLE-BASED LEARNING

- Covering core IMPACT® CTMS functionality

ADMINISTRATION

- Courses to support the personnel administering the system

COURSE/ROLES	MANAGER	TRIAL MANAGER	TRIAL ADMIN.	CRA	MONITOR	IMPACT ADMIN.
IMPACT® CTMS Basics	●	●	●	●		●
Trial Tracking & Management	●	●	●	●		●
Site Monitoring & Management Using MySites*				●	●	●
Managing Clinical Personnel & Centers		●	●	●		●
Site Funds and Payments		●	●	●		●
IMPACT® Administration						●
IMPACT® Investigator Administration						●

*For Express Premium customers only

IMPACT® CTMS EXPRESS USER ROLES

In the IMPACT® CTMS system, each user is assigned to a role in the system. This role 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 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.

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.

IMPACT® CTMS EXPRESS ONLINE TRAINING COURSES

IMPACT® CTMS Basics (PS100)

DURATION: 1.5 hours
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	Manager, Trial Manager, Trial Administrator, Clinical Research Associate (CRA), IMPACT® Administrator	Self-Paced eLearning	n/a

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 (PS120)

DURATION: 3.25 hours
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
IMPACT® CTMS Basics (PS100)	Manager, Trial Manager, Trial Administrator, CRA, IMPACT® Administrator	Self-Paced eLearning	n/a

COURSE DESCRIPTION

This training module is designed for users of the IMPACT Progress module.

This training course comprises the following modules:

- Recording a New Trial
- Trial Level Tasks (Parameters, Design, Vendors and Contacts, New Trial Country, Enrollment Plan, Regulatory References, Protocol Amendments)
- Trial Country Level Tasks (Parameters, Regulatory/IRB/IEC Approval, New Trial Sites, Protocol Amendments)
- Trial Site Level Tasks (Parameters, Clinical Personnel, Contacts, IRB/IEC Approval, Recruitment, Visit Report Review, New Subject, Projecting Subject Visit Dates)
- Subject Level Tasks (Parameters, Visit Dates, Projecting Subject Visit Dates)
- Common IMPACT® Tasks (Company Personnel, Delay/Cancel/Stop, Event Dates)

Managing Clinical Personnel & Centers (IN120)

DURATION: 1 hour
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
IMPACT® CTMS Basics (PS100)	Trial Manager, Trial Administrator, CRA, IMPACT® Administrator	Self-Paced eLearning	n/a

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

Site Monitoring and Management Using MySites (MS100)

DURATION: 2 hours
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	CRA, Monitor, IMPACT® Administrator	Self-Paced eLearning	n/a

COURSE DESCRIPTION

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

This training course comprises the following modules:

- MySites Overview
- Planning & Starting Your Visit
- Working With Subject Data (Properties, Visit Dates, Issues, Withdrawal, New Subject)
- Completing Site Visit Tasks (Clinical Personnel, Issues, Checklists, Recruitment, Event Dates, Current Visit Details)
- Processing Your Visit Report (Narrative, Draft and Formal Report, Visit Report Processing & Finalization)
- Completing Your Site Visit (Visit Completion, Resolution of Data Conflicts)
- Recording Trial Site Contacts

Site Funds and Payments (CT110)

DURATION: 1.5 hours
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
IMPACT® CTMS Basics (PS100)	CRA, Monitor, IMPACT® Administrator	Self-Paced eLearning	n/a

COURSE DESCRIPTION

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

This training course comprises the following modules:

- Recording a New Trial Site Fund (New Funds, Financial Agreements, Subject Fees, Payment Rules, Copy Existing Fund)
- Working With Trial Site Funds (Authorization, Close/Re-open, Fund Adjustment)
- Working With Payment Requests (Subject Fee Pay Status, Review/Authorization/Match)
- Payment Enquiries (Requests, Held Back, Actuals)

IMPACT® CTMS Administration (IA100)

DURATION: Intro. Webinar: 1h
Self-paced: 3.5h
Follow-up Webinar: 1h
CLASS SIZE: 4 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
IMPACT® CTMS Basics (PS100) Trial Tracking & Management (PS120) Managing Clinical Personnel and Centers (IN120) Site Monitoring & Management Using MySites (MS100) Site Funds & Payments (CT110)	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.

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
- Delete data entered in error
- Record and maintain company personnel
- Record and maintain vendor details
- Record investigational products
- Record and maintain payees
- Verify new clinical personnel recorded in MySites
- Record and maintain visit checklists
- Record and maintain currencies
- Record fees
- Record cost areas

IMPACT® CTMS Investigator Administration (IN11)

DURATION: Intro. Webinar: 1h
Self-paced: 2-3h
Follow-up Webinar: 2h
CLASS SIZE: 4 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
IMPACT® CTMS Basics (PS100) Trial Tracking & Management (PS120) Managing Clinical Personnel and Centers (IN120) Site Monitoring & Management Using MySites (MS100) Site Funds & Payments (CT110)	IMPACT® Administrator	Virtual Instructor-led & Self-paced	Word® Documents

COURSE DESCRIPTION

This training module is designed for IMPACT® Administrators 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
- Check for errors, warnings and the status of background processing

TRAINING FOR IMPACT® CTMS FULL IMPLEMENTATION

In addition to the online eLearning curriculum available for IMPACT® CTMS Express/Express Premium, we provide a range of standard training courses suitable for customers who have implemented the full functionality of IMPACT® CTMS.

Reference Data Set-Up and Maintenance (RD01)

DURATION: Classroom: 6h
CLASS SIZE: Classroom: 4 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	System Administrator	Classroom Instructor-led	Presentations Word® Document

COURSE DESCRIPTION

This training is designed for personnel who are involved in setting up and maintaining IMPACT reference data.

This training course includes the following topics:

- Basic reference data
- People and places reference data (medical units, company personnel, vendors, centres, clinical personnel, payees)
- Checklists used in the Progress and Investigator modules
- Investigator Trial File Documents
- Monitoring reference data (visit types, visit report review configuration, visit reports, SOPs and checklists used in MySites)

IMPACT® CTMS Configuration (IC01)

DURATION: Classroom: 4h
CLASS SIZE: Classroom: 4 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	System Administrator	Classroom Instructor-led	Presentations Word® Document

COURSE DESCRIPTION

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

This training course includes the following topics:

- Global settings
- Master events
- Terminology
- Occupation security
- Customer mandatory and required fields
- Additional fields
- "Not Required" functionality and fields
- Trial types
- Automatic reminders

IMPACT® CTMS Investigator Administration (IN11)

DURATION: 3.5h
CLASS SIZE: 4 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	System Administrator	Classroom Instructor-led	Presentations, Word® Document

COURSE DESCRIPTION

This training module is designed for IMPACT® Administrators 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
- Check for errors, warnings and the status of background processing

Email Notification Set-Up and Maintenance (EN01)

DURATION: Classroom: 2h
Intro. Webinar: 1.5h
Self-paced: 2h
CLASS SIZE: Classroom: (ILT) 4 max
Self-paced: 4 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	System Administrator	Classroom Instructor-led Virtual Instructor-led & Self-paced	Presentations Word® Document

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: (ILT) 8 max
Self-paced: 8 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	System Administrator	Classroom Instructor-led Virtual Instructor-Led & Self-paced	Presentations Word® Document

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

IMPACT® CTMS Trainer (IT10)

DURATION: Classroom: 3.5h–15h
CLASS SIZE: Classroom: (ILT) 8 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Completion of appropriate end user training modules	Super User, Trainer	Classroom Instructor-led	Word® Documents

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 Super User

DURATION: Classroom: 14 hours
CLASS SIZE: Classroom: (ILT) 12 max

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
End user training for all modules to be supported	Super User	Classroom Instructor-led	Word® Documents

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

TRAINING SERVICES

PAREXEL's Education Services has extensive experience in producing training programs to meet the individual requirements of our customers. In addition to our standard courses, we offer a range of training development and consultancy services.

eLEARNING DEVELOPMENT

- Education Service's standard modules are customized to reflect your processes and terminology
- New eLearning modules to your specification

DEVELOPMENT OF MATERIALS FOR CLASSROOM/VIRTUAL CLASSROOM DELIVERY

- PowerPoint® task guides
- Hands-on practice scripts
- Refreshable training delivery database

JOB AID DEVELOPMENT

- Interactive task guides accessible from the IMPACT® CTMS menus/your intranet
- New job aids to your specification

CONSULTANCY

If you prefer to utilize the resource within your own organization or a 3rd-party vendor, PAREXEL's Education Services Instructional Design Specialists and Subject Matter Experts (SMEs) are available to assist you with:

- Developing a training strategy
- Training needs analysis
- Selection of appropriate course content
- Production of a suitable training database
- Training delivery world-wide
- Training support for in-house/external trainers
- Evaluation and feedback for in-house/external trainers

PERCEPTIVE MYTRIALS®
COURSES

PERCEPTIVE MYTRIALS® TRAINING MAP

E: eLearning

TRAINING PROGRAMS E	REPORTS E
Perceptive MyTrials® Basics (MT001)	Perceptive MyTrials® eClinical Metrics (MT004)
Perceptive MyTrials® System Access Process (MT002)	
Perceptive MyTrials® Collaboration Toolbox (MT003)	Perceptive MyTrials® Analytics (MT015)
Perceptive MyTrials® User Maintenance Interface (UMI) (MT006)	

TRAINING PROGRAMS

- Courses to support different roles
- Covers core Perceptive MyTrials® functionality
- Basics course applicable to all roles
- Includes demonstrations, scenarios and hands-on practice

REPORTS

- Covers the standard eClinical metrics reporting feature in Perceptive MyTrials®
- Perceptive MyTrials® Analytics for cross-study analysis of clinical data
- Includes demonstrations and hands-on practice

PERCEPTIVE MYTRIALS® ROLES

Each user role below can benefit from our modular courses or pick and choose the relevant modules from the full suite of PAREXEL's Education Services MyTrials® modules.

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.

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.

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.

PORTFOLIO USERS

Individuals with oversight responsibility who require at a glance, standardized performance metrics across multiple studies in order to identify individual studies with performance issues and address them accordingly.

Perceptive MyTrials® Basics (MT001)

DURATION: 15 minutes approx
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
None	All Roles	Self-Paced eLearning	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)

DURATION: 10 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001)	All Roles	Self-Paced eLearning	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: 25 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001) Perceptive MyTrials® System Access Process (MT002)	Any role with write access	Self-Paced eLearning	n/a

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® eClinical Metrics (MT004)

DURATION: 20 minutes approx
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001) Perceptive MyTrials® System Access Process (MT002)	CRA Data Manager Any Project Team Member	Self-Paced eLearning	n/a

COURSE DESCRIPTION

This course will explain how study team members can use the Perceptive MyTrials® eClinical Metrics 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® User Maintenance Interface (UMI) (MT006)

DURATION: 20 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001) Perceptive MyTrials® System Access Process (MT002)	Data Managers Project Managers Any Project Team Member	Self-Paced eLearning	n/a

COURSE DESCRIPTION

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

Perceptive MyTrials® Analytics (MT015)

DURATION: 15 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001)	Any role that requires access to cross-study analysis of clinical data to identify key trends	Self-Paced eLearning	n/a

COURSE DESCRIPTION

This course is intended for those who are responsible for reviewing and analyzing data trends and performing cross study analysis of clinical data. This course will introduce how to leverage predictive analytics to proactively respond to issues before they occur. Users can focus on a single study or for trend analysis, users can examine data across multiple studies. Using defined milestones, reports and visualizations, users can quickly identify and mitigate issues, improve patient safety and data quality.

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

- Navigate the Perceptive MyTrials® Analytics dashboards
- Describe the system benefits of Perceptive MyTrials® Analytics
- Utilize the predictive analytics to identify issues

PERCEPTIVE MYTRIALS® DATA-DRIVEN MONITORING (DDM) COURSES

PERCEPTIVE MYTRIALS® DATA-DRIVEN MONITORING TRAINING MAP

E: eLearning

FOUNDATION E	ROLE-BASED E	ADMINISTRATION E
Perceptive MyTrials® Data-Driven Monitoring Basics (DDM001)	Perceptive MyTrials® Data-Driven Monitoring for Clinical Monitors (DDM003)	Perceptive MyTrials® Data-Driven Monitoring for Study Administrator (DDM005)
Perceptive MyTrials® Data-Driven Monitoring Dashboard (DDM002)	Perceptive MyTrials® Data-Driven Monitoring for Clinical Oversight (DDM004)	
Completion Certificate	Completion Certificate	Completion Certificate

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

PERCEPTIVE MYTRIALS® DATA-DRIVEN MONITORING ROLES

Each user role below can benefit from our modular standalone courses or complete the relevant training track for their role. In addition, each user can benefit from role based completion certification.

CLINICAL OVERSIGHT

Clinical Oversight roles include Clinical Operations Leaders, Project Managers, and those responsible for ensuring effective study oversight. Typically these users evaluate study progress and manage risk and workload.

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.

STUDY ADMINISTRATOR

The Study Administrator role will be assigned to a study team member who has extensive knowledge and experience in clinical monitoring and oversight, such as a Clinical Lead or Lead Clinical Monitor. The core responsibilities of this role will be to participate in the Data-Driven Monitoring configuration set-up, to manage the configuration throughout the life of the trial, and customize study preferences. Based on the data in the application and recommendations from Clinical Monitors and Oversight, the Study Administrator may apply manual overrides to site-specific risk status and workload hours.

Perceptive MyTrials® Data-Driven Monitoring Basics (DDM001)

DURATION: 10 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001)	All Roles	Self-Paced eLearning	n/a

COURSE DESCRIPTION

This course will introduce users to the Data-Driven Monitoring solution and how it assists in the planning and execution of clinical monitoring and oversight. Users will learn about both the Data-Driven Monitoring methodology, how risk and workload are calculated, and how to action monitoring activities in the application. Users will also learn about the multiple reporting capabilities that can be used to track and justify remediation actions to regulatory agencies.

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

- Explain the Data-Driven Monitoring methodology
- Explain how the application calculates metrics and generates data visualizations to show where risk is occurring

Perceptive MyTrials® Data-Driven Monitoring Dashboard (DDM002)

DURATION: 15 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001) Perceptive MyTrials® DDM Basics (DDM001)	All Roles	Self-Paced eLearning	n/a

COURSE DESCRIPTION

This course will navigate users through the DDM Dashboard, navigation techniques, data displays, and visualizations.

Users will will be presented with 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:

- Navigate the Data-Driven Monitoring dashboard
- Recognize the standard icons and data visualizations
- Customize viewable data using the application filters and User Preferences

Perceptive MyTrials® Data-Driven Monitoring for Clinical Monitors (DDM003)

DURATION: 20 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001) Perceptive MyTrials® DDM Basics (DDM001) Perceptive MyTrials® DDM Dashboard (DDM002)	Clinical Monitors	Self-Paced eLearning	n/a

COURSE DESCRIPTION

This course instructs users on how Data-Driven Monitoring enables more effective site monitoring. Users will be presented with the key features and functionality to identify sites at risk, analyze available data, and prioritize site and monitoring activities using scenarios.

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

- Describe how Data-Driven Monitoring enables more effective clinical monitoring
- Explain how the key features and functionality maximize the effectiveness of all monitoring efforts.
- Practice using the application to analyze data and prioritize site and monitoring activities.

Perceptive MyTrials® Data-Driven Monitoring for Clinical Oversight (DDM004)

DURATION: 20 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001) Perceptive MyTrials® DDM Basics (DDM001) Perceptive MyTrials® DDM Dashboard (DDM002) Perceptive MyTrials® DDM for Clinical Monitors (DDM003)	Project Leaders Clinical Operations Leaders Project Managers Any role involved in Clinical Oversight	Self-Paced eLearning	n/a

COURSE DESCRIPTION

This 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 to help identify trends and operational performance areas. Users will be able to practice Data-Driven Monitoring Oversight using real-world scenarios.

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

- Describe how Data-Driven Monitoring enables more effective clinical oversight
- Explain how the key features and functionality benefit clinical oversight and support regulatory compliance
- Use the application to analyze data and generate reports

Perceptive MyTrials® Data-Driven Monitoring for Administrators (DDM005)

DURATION: 20 minutes
CLASS SIZE: n/a

PREREQUISITES	PRIMARY AUDIENCE	DELIVERY MODES	MATERIALS
Perceptive MyTrials® Basics (MT001) Perceptive MyTrials® DDM Basics (DDM001) Perceptive MyTrials® DDM Dashboard (DDM002) Perceptive MyTrials® DDM Clinical Monitor (DDM003) Perceptive MyTrials® DDM Clinical Oversight (DDM004)	Administrators	Self-Paced eLearning	n/a

COURSE DESCRIPTION

This course is intended for those who have been selected for the role of Study Administrator and who may also be responsible for study oversight and clinical monitor management. This course will introduce the study administrator role in a Data-Driven Monitoring study and how to perform the assigned tasks. Tasks include management of study-specific Site Measures, management of the Data-Driven Monitoring study configuration template, and applying site-specific manual overrides. Users will be able to practice study administration tasks using real-world scenarios.

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

- Describe the role of the Study Administrator in a Data-Driven Monitoring study
- Navigate the Study Administration Dashboard to perform the required study administration tasks
- Practice using the application with real world scenarios

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 offer the following certifications within the DataLabs training program.

- **Administrator Certified**
- **Designer Certified**
- **DataLabs Trainer Certified**
- **DataLabs Site Trainer Certified**
- **Designer Trainer Certified**

Our IMPACT CTMS Certifications include:

- **IMPACT Trainer**
- **IMPACT Administrator**

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

TRAINING COMPLIANCE

PAREXEL's Education Services can help you effectively manage your eClinical training for your next trial. We can offer a scalable clinical training service to automatically manage and track training and maintain regulatory compliance. Whether you want to host your own training content or wish to leverage our full catalog of market-ready courses, our solution is designed to protect your eClinical investments and simplify your training needs.

To find out more, please refer to our training compliance brochure available at **www.PAREXEL.com/education-services**

FOR MORE INFORMATION

www.PAREXEL.com/education-services
EducationServices@PAREXEL.com

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