wcg™ trifecta®

Clinical Trial Training: Value Presentation

Exceptional Site Performance & Satisfaction Starts with an Exceptional Training Experience

ACCELERATED TIMELINES	REDUCE COSTS	IMPROVE QUALITY	INSPECTION READINESS	SPONSOR OF CHOICE
Gain 55 enrollment days through just in time training	**Cut training costs by over 60%** compared to traditional delivery	**Reduce** number of **protocol deviations**	**Avoid the #1 finding** of FDA Audits	Reducing the **burden of Site training by 50%**

Highly Effective

Sites have a clear understanding of requirements and an improved ability to adhere to protocol and trial amendments

Automated Processes

A highly automated system that deploys training quickly, with complete, real time tracking.

Reduced Burden

Reduce the burden on Site staff of unnecessary and/or redundant training

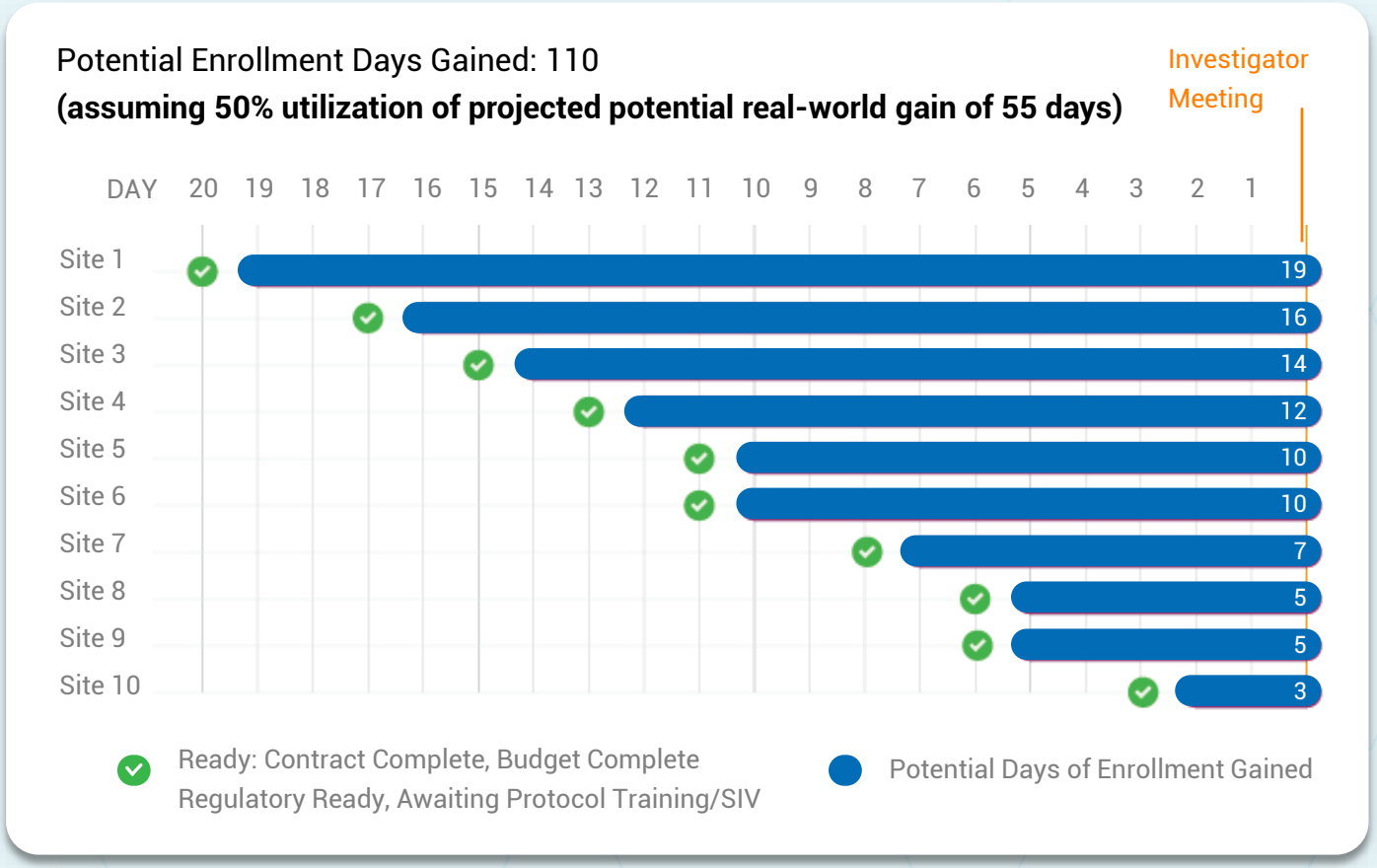
Gain Time for Enrollment Through Just in Time Training

ACCELERATED TIMELINES

With an on-demand training rollout, protocol training is available as soon as the site is ready (contract complete, budget finalized, and regulatory ready).

Rapid Training Development & Deployment

Implement your training program **in 5 working days.**



Sponsors Save Over 60% or More in Costs with Training Available to Staff 24/7

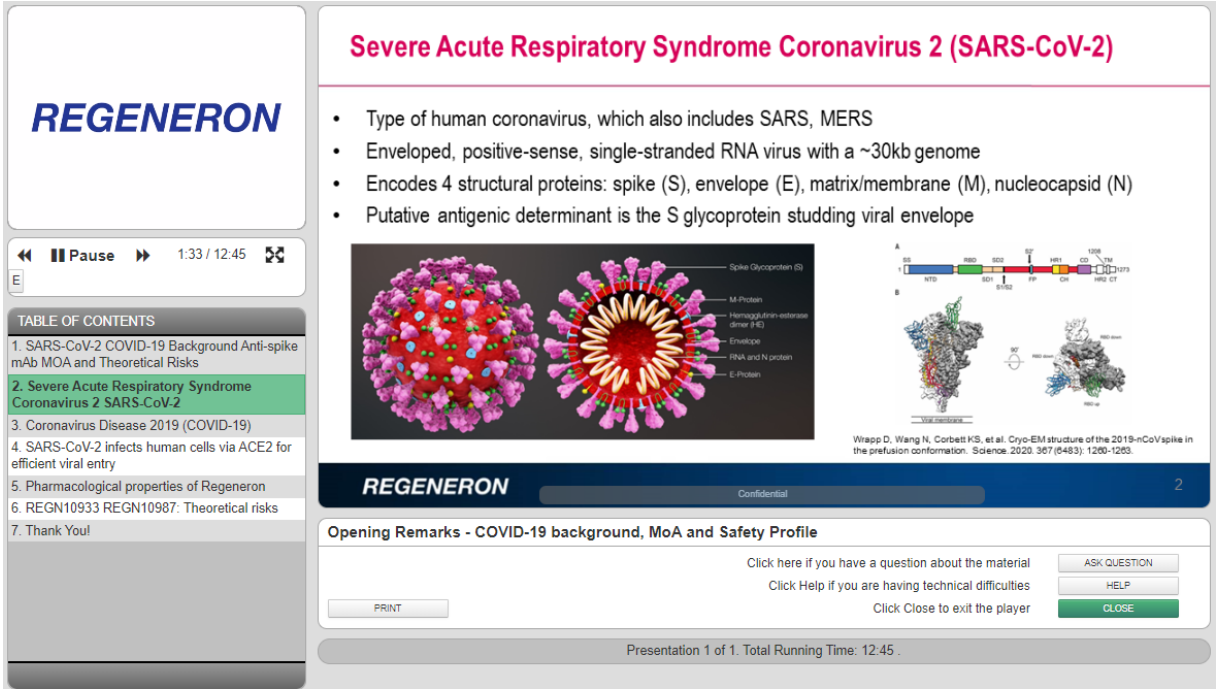
REDUCE COSTS

The ROI for using Trifecta is easily realized based on face-to face investigator meeting costs, but the financial benefits go beyond that:

- Estimated Cost to Attend Investigator Meeting in 2020 - **$2,400 per PERSON**
- Average Investigator Training Cost per site for Trifecta - **$2,500 per SITE**

Reduction in Sponsor/CRO costs, for example:

- **Reduction in overall Monitoring Costs due to less time on site for CRAs**
- **Reduction in Study Management time spent in audit preparation**

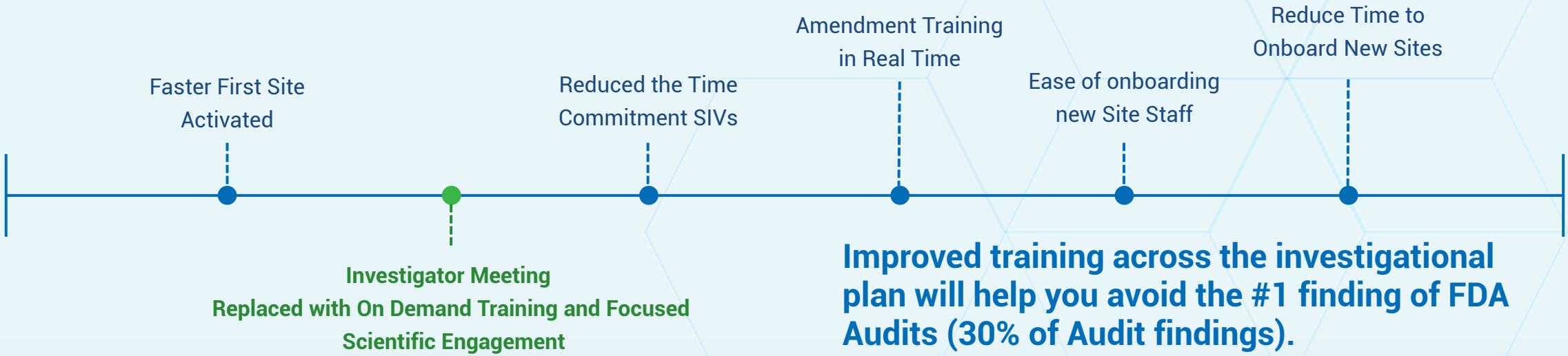


Training is available to site staff throughout the study

Improve Quality With Training That's More Accurate, Immediate, & Easy to Maintain

IMPROVE QUALITY

- Deliver “Just-in-Time" training across the study lifecycle
- Proprietary video-based training production process reduces asset creation time by 90%
- Updates & Amendments produced and available in 24 hours
- Immediate transformation of lessons learned into actionable guidance reduces data queries and data management/monitoring time
- Easy remediation of protocol deviations

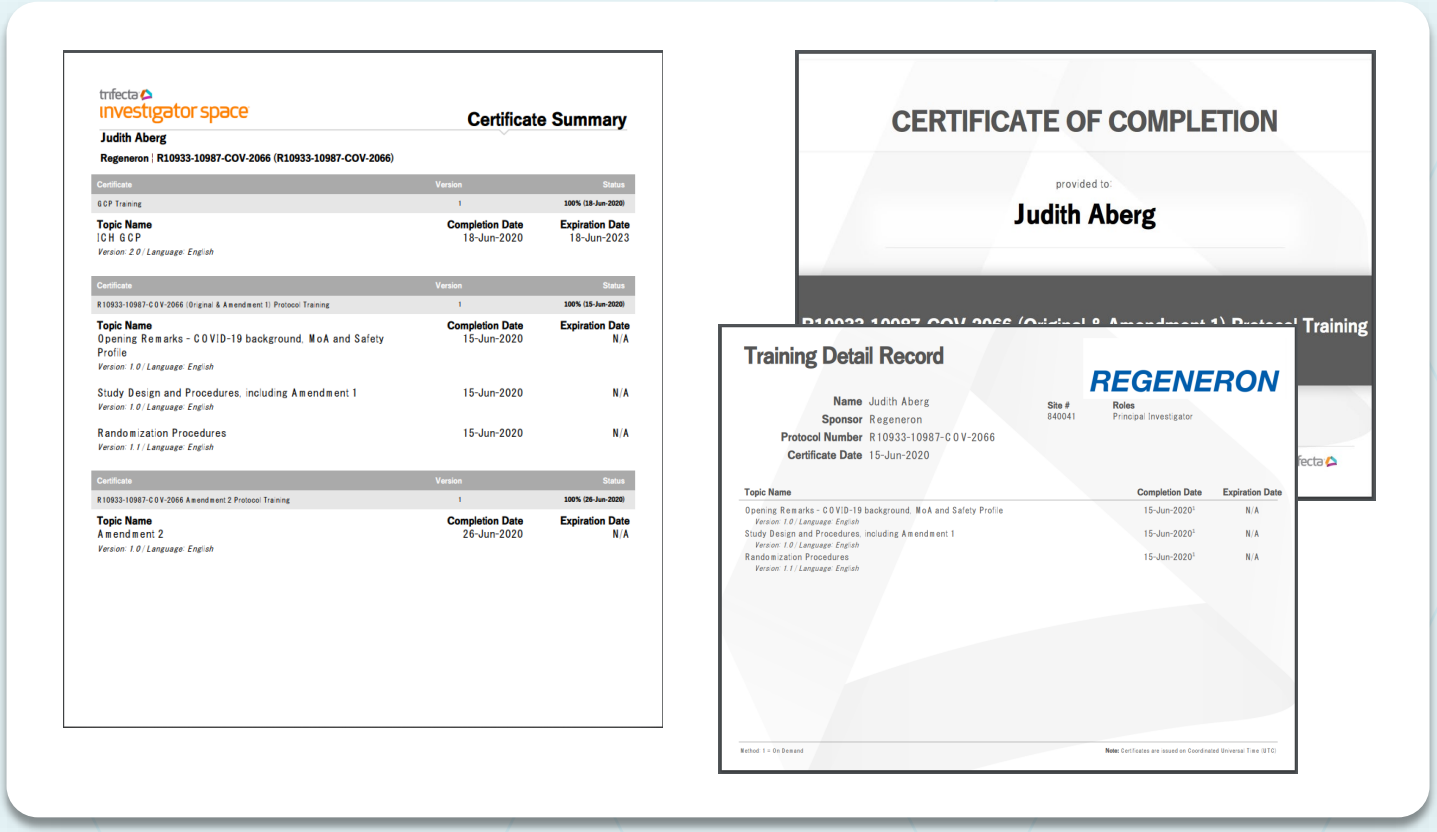


Improved training across the investigational plan will help you avoid the #1 finding of FDA Audits (30% of Audit findings).

Be In a Perpetual State of Inspection Readiness

INSPECTION READINESS

- ✓ Clinical Qualification Management System automates distribution, collection, and maintenance of all training documentation
- ✓ 100% security, auditability, & traceability
- ✓ Real-time compliance reporting provides total training process transparency



trifecta investigator space

Certificate Summary

Judith Aberg

Regeneron | R10933-10987-COV-2066 (R10933-10987-COV-2066)

Certificate	Version	Status
GCP Training	1	100% (18-Jun-2020)

Topic Name ICH GCP — *Version: 2.0 / Language: English* — **Completion Date** 18-Jun-2020 — **Expiration Date** 18-Jun-2023

Certificate	Version	Status
R10933-10987-COV-2066 (Original & Amendment 1) Protocol Training	1	100% (15-Jun-2020)

Topic Name	Completion Date	Expiration Date
Opening Remarks - COVID-19 background, MoA and Safety Profile — *Version: 1.0 / Language: English*	15-Jun-2020	N/A
Study Design and Procedures, including Amendment 1 — *Version: 1.0 / Language: English*	15-Jun-2020	N/A
Randomization Procedures — *Version: 1.1 / Language: English*	15-Jun-2020	N/A

Certificate	Version	Status
R10933-10987-COV-2066 Amendment 2 Protocol Training	1	100% (26-Jun-2020)

Topic Name Amendment 2 — *Version: 1.0 / Language: English* — **Completion Date** 26-Jun-2020 — **Expiration Date** N/A

CERTIFICATE OF COMPLETION

provided to:

Judith Aberg

Training Detail Record

REGENERON

Name Judith Aberg
Sponsor Regeneron
Protocol Number R10933-10987-COV-2066
Certificate Date 15-Jun-2020

Site # 840041 **Roles** Principal Investigator

Topic Name	Completion Date	Expiration Date
Opening Remarks - COVID-19 background, MoA and Safety Profile — *Version: 1.0 / Language: English*	15-Jun-2020[1]	N/A
Study Design and Procedures, including Amendment 1 — *Version: 1.0 / Language: English*	15-Jun-2020[1]	N/A
Randomization Procedures — *Version: 1.1 / Language: English*	15-Jun-2020[1]	N/A

Method: 1 = On Demand

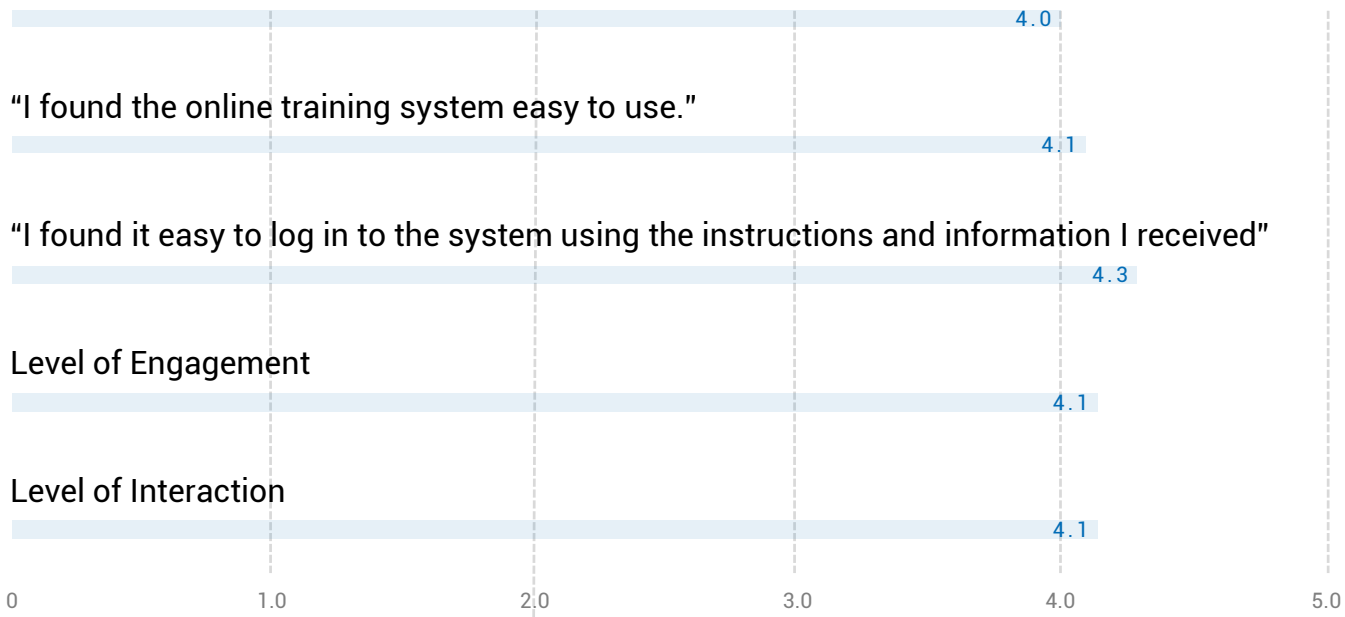
Note: Certificates are issued on Coordinated Universal Time (UTC)

Improve Site Satisfaction, Eliminate Redundant Training

SPONSOR OF CHOICE

N=3,866 responses

Exceptional Feedback on Trifecta Training in 2020



STRONGLY DISAGREE — STRONGLY AGREE

Site Investigator Training Requirements

STUDY 1
Protocol W32
Mechanism of Action
SCORAD
GCP

STUDY 2
Protocol M91
GCP
SCORAD
eClinRO

STUDY 3
Protocol ZYY
Imaging Criteria
COX-2 Inhibition
GCP

STUDY 4
Protocol 45W
GCP
SCORAD
eCOA Tablet

Training Taken in Study 1 Automatically Credited for Any Additional Studies

In one year, more than 50% of Investigators were exempt from redundant GCP training.

CASE STUDY: Stop Redundant Training

Background

Large biopharma Sponsor seeking clinical site staff to able to be “exempted” from the completion of certain training topics when training was managed in a system that applied topic equivalency rules to site personnel training history information retained in the system between and across studies.

Action

Over four years of use, and with an average of 15 minutes of training time for each topic, clinical site staff working on studies for this sponsor were “exempted” from redundant training

Results

Reduction of **98,166** hours of redundant training, freeing significant time for clinical site teams to use on other important work.

CASE STUDY: Secure GCP Training Documentation Quickly

Background

Biopharma client required documentation of ICH-GCP training for all site staff associated with the execution of the protocol (2000+ user base for the 3-study program).

Action

Biopharma client required documentation of ICH-GCP training for all site staff associated with the execution of the protocol (2000+ user base for the 3-study program).

Results

44+ of site staff auto-exempted

794 unique clinicians

30 min of redundant GCP training

397 hours saved

> *Thank you both for an outstanding second IM. The amount of questions and participation in the case studies proved how engaged the site staff was. It has been a wonderful partnership with Trifecta and look forward to the next IM!*
>
> **-Rashmi Shah, Senior Clinical Trial Associate, Insmed**

Thank You

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Training Content Offerings

Beyond Protocol Specific Training

Clinical Research Industry

What is it?

- An FDA-adopted, Part 11-compliant training program for clinical research professionals.
- Designed by experts in clinical research and adult learning, the WCG Academy curriculum is interactive and role-based, helping adults to retain more information than any other learning solution.
- WCG Academy also provides robust dashboards and metrics to foster compliance and efficiency.

Who can benefit?

- Sponsors, CROs and CRAs or Clinical Investigative Site Staff

Clinical Research Industry – WCG Academy (UL Compliance Wire)

- GCP/ICH Obligations of Sponsors, Monitors & Investigators
- Obligations of Investigators in Conducting Medical Device Trials
- HIPAA – The Impact on Clinical Trials
- Ethics as the Foundation to Clinical Research
- Overview of the Clinical Research Process
- Selecting and Managing Clinical Contract Research Organizations (CROs)
- Informed Consent
- Ethical Review Boards
- Drug Safety & Adverse Event Reporting
- The Role of the Clinical Research Associate
- The Role of the Clinical Research CoordinatorISO 14155: Obligations of Sponsors and Monitors
- Clinical Trial Audits and Consequences of Non-Compliance
- Aspects of Regulatory History
- Investigational Product Development
- Financial Disclosure by Clinical Investigators
- Laboratory Specimens for Clinical Research
- The Clinical Development Process: Investigational Product, Plan, and Data Manager
- ISO 14155: Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice
- Good Clinical Practices (GCPs) for New Product Investigations
- Protection for Human Subjects in Clinical Trials
- Management Responsibility for Quality: What FDA Expects
- A Tour of FDA
- GxPs
- A Tour of Health Canada

Investigative Site Support

What is it?

- The CRC Trainers are interactive eLearning courses that highlight and reinforce the information from The CRC's Guide to Coordinating Clinical Research. These courses are designed to be used in tandem with the book, giving the user the opportunity to apply what he or she learns in a practical, thoughtful manner.
- Currently there are 6 eLearning courses in the catalog.

Who can benefit?

- Clinical Investigative Site Staff
  - Specifically beneficial for those site staff that may be research-naïve or at Institutions that do no supply their own clinical research SOP training

Investigator Site Support – CenterWatch CRC Training Topics

THE CRC TRAINER

MODULE 1

CRC roles and responsibilities, regulatory history and compliance, principles of good clinical practice, and good documentation practices.

MODULE 2

The clinical research process, clinical trial site quality systems, SOPs and IRBs

MODULE 3

Informed consent, preparing for a study

MODULE 4

Protocols, case report forms, electronic data capture and investigational drug accountability

MODULE 5

Working with trial participants, study closure, adverse events and safety monitoring, and audits and inspections

MODULE 6

Final Assessment — review and test on the previous five modules

Clinical Research Associate (CRA) Support

What is it?

- The CRA Trainers are interactive eLearning courses that highlight and reinforce the information from The CRA's Guide to Monitoring Clinical Research. These courses are designed to be used in tandem with the book, giving the user the opportunity to apply what he or she learns in a practical, thoughtful manner.
- Currently there are 6 eLearning courses in the catalog.

Who can benefit?

- Clinical Research Associates (CRAs)
  - Specifically beneficial for those CRAs that may be new to the monitoring role.
- CRO/Sponsor Organizations managing CRAs –provides a baseline training curriculum to newly onboarded CRAs

Investigator Site Support – CenterWatch CRA Training Topics

THE CRC TRAINER

MODULE 1

CRA roles and responsibilities, regulatory history and compliance, principles of good clinical practice.

MODULE 2

The clinical research process, device and biologics trials, globalization, IRBs and data safety monitoring boards.

MODULE 3

Informed consent, preparing for a study, clinical investigators.

MODULE 4

Study initiation, study monitoring, adverse events and safety monitoring, recruitment, retention and compliance.

MODULE 5

Study closeout, quality management, audits, errors and misconduct, the future for CRAs.

MODULE 6

Final Exam — review and test on the previous five modules.