



# QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER LLC

Somerset New Jersey USA

Private Vocational School

Training Division of Qtech Solutions Inc.



## Clinical Research Associate [ CRA ]

*In-House / Monitor*

### Our Mission

Our mission is to provide the best-in-class job oriented career development Elearning training courses and programs in Clinical research, SAS data management and business analysis for students and professionals requiring a skills refresh – or the development of new skills and experience for job entry, advancement, and placement



Clinical Research Associate / Clinical Research Coordinator professional training program is approved by State of New Jersey, Department of Education and Department of Labor and Workforce Development and listed on Eligible Training Provider List



STATE OF NEW JERSEY  
DEPARTMENT OF EDUCATION



STATE OF NEW JERSEY  
DEPARTMENT OF LABOR  
AND WORKFORCE DEVELOPMENT

# ABOUT CLINICAL RESEARCH



Clinical research is a rapidly expanding field, creating exciting job opportunities. Clinical Research Associates / Clinical Research Coordinator work in a broad range of research settings, including: academic health centers, government agencies and departments, contract research organizations, pharmaceutical, biotechnology and medical device firms.

## OVERVIEW OF THE CURRICULUM

Program was designed by industry experts for students and young professionals. The training provides in depth knowledge of roles and responsibilities of Clinical Research Associate/ Clinical Research Coordinator, including theoretical aspect of the field and exposure to variety exercises based on industry requirements.

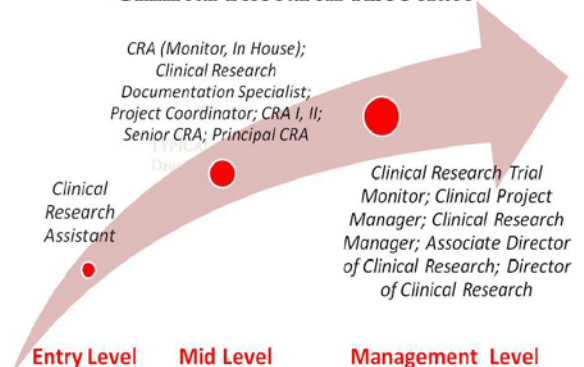
### LIST OF TOPICS: THEORETICAL ASPECT OF THE FIELD

1. Drug Discovery and Research Process
2. Pre-Clinical Research
3. Introduction to Clinical Trials
4. Role of Clinical Research Associate
5. Phase I Clinical Trials
6. Phase II Clinical Trials
7. Phase III Clinical Trials
8. Phase IV Clinical Trials
9. Good Clinical Practice and ICH Guidelines
10. FDA Regulations
11. Institutional Review Board (IRB)
12. Overview of Clinical Protocol
13. Clinical Protocol Design and Development
14. SOP Development
15. Case Report Form (CRF) Design and Data Capture
16. Clinical Trial Budget
17. Conducting Multinational Clinical Trials
18. Communication with Cross Functional Team
19. Clinical Research Associate / Coordinator In House Responsibilities
20. Selection of Investigator
21. Vendor Selection and Management
22. Informed Consent Preparation
23. Roles and Responsibilities of Investigator
24. Investigator Meetings and Timelines
25. Selection of Investigator Site
26. Study Initiation
27. In-House Monitoring and Reporting
28. Trial Master File (TMF)
29. Introduction to Adverse Events (AE) Reporting and Classification
30. Preparation for Internal Audit

### LIST OF REAL TIME CASES: PRACTICAL EXPOSURE TO DAILY ROLES AND REPOSIBILITIES

- Case 1: Introduction To Clinical Trial
- Case 2: FDA EMEA Regulations
- Case 3: Institutional Review Board (IRB)
- Case 4: Protocol Design and Development
- Case 5: Clinical Trial Budget
- Case 6: Case Report Form (CRF) Design
- Case 7: Investigator Meeting
- Case 8: Site Management and Initiation
- Case 9: Informed Consent Preparation
- Case 10: Trial Master File
- Case 11: Adverse Event Monitoring and Reporting
- Case 12: Audit

### TYPICAL CAREER PATH OF Clinical Research Associate



## Main Roles and Responsibilities of Clinical Research Associate - CRA/ CRC

- ✓ Writes, edits and assists in writing protocols
- ✓ Coordinates protocol review for clinical studies
- ✓ Writes and reviews patient informed consents
- ✓ Designs and develops case report forms (CRFs)
- ✓ Helps, writes, assembles, and distributes investigator brochures, SOP documents and study/CRF instruction manuals
- ✓ Prepares and submits documents required to meet regulatory, GCP, and SOP requirements
- ✓ Determines order, ships, and tracks investigational drug supplies
- ✓ Evaluates and selects investigators (sites), plans and conducts investigator meetings
- ✓ Develops study budgets and grant payment schedules
- ✓ Sends study packages such as protocols, brochures, and contracts/agreement letters to field monitors for site initiation
- ✓ Assures all adverse events (AEs) are reported according to regulation and company policy
- ✓ Prepares final study reports and assist in the response or reporting to any FDA inspections

### Do You Know...?

#### Hiring CRA professionals:

- ✓ 99% of the employers choose candidates with **clinical research** degree or experience
- ✓ 75% of the employers choose candidates with **pharmacology or toxicology** degree
- ✓ 80% of the employers choose candidates with **nursing** degree
- ✓ 40% of the employers choose candidates with **Biological Science** degree
- ✓ 80% of the employers choose candidates with **public health** degree
- ✓ 65% of the employers choose candidates with **Biotechnology** degree
- ✓ 90% of the employers choose candidates with **Medicine** degree

**Do you want to know more? Call us!**

#### Contact Information

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