



**The CRA Training Institute**  
700 Louisiana Street, Suite 3950  
Houston, Texas 77002, U.S.A  
Website: [www.cratraininginstitute.org](http://www.cratraininginstitute.org)  
Toll-free: 1-866-378-8206 / (281) 616-6771



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## CLINICAL RESEARCH ASSOCIATE (CRA) **ON-BOARDING** TRAINING PROGRAM

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### Course Content

#### MODULE 1

- THE DRUG APPROVAL PROCESS
- OVERVIEW OF THE PHARMACEUTICAL INDUSTRY
- THE CLINICAL RESEARCH PROCESS: DRUG DISCOVERY, DRUG RESEARCH.

#### MODULE 2

- PRE-CLINICAL RESEARCH PRE-CLINICAL STUDIES OF DRUG / PRODUCT CANDIDATES
- INVESTIGATIONAL NEW DRUG APPLICATION (I.N.D.) AND NEW DRUG SUBMISSION (NDS)
- PHASES OF CLINICAL TRIALS

#### MODULE 3

- GOOD CLINICAL PRACTICE & INTERNATIONAL CONFERENCE ON HARMONIZATION
- INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE (IRB/IEC)
- CLINICAL TRIAL INVESTIGATOR

#### MODULE 4

- MONITORING OF CLINICAL INVESTIGATIONS
- STUDY INITIATION
- STUDY MONITORING

#### MODULE 5

- RECRUITMENT, RETENTION AND COMPLIANCE
- STUDY CLOSEOUT
- COMPUTERIZED SYSTEMS USED IN CLINICAL TRIALS

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### MODULE 6

- CHOICE OF CONTROL GROUP IN CLINICAL TRIALS
- CLINICAL TRIAL SPONSOR
- CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT (S)

### MODULE 7

- CLINICAL TRIAL INVESTIGATOR'S BROCHURE
- ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL
- ADVERSE REACTIONS IN CLINICAL TRIALS

### MODULE 8

- INFORMED CONSENT
- SAFETY IN CLINICAL TRIALS
- MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES (MEDDRA)

### MODULE 9

- INSPECTION STRATEGY FOR CLINICAL TRIALS
- AVOIDING FRAUD IN CLINICAL TRIALS
- FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS

### MODULE 10

- SAFETY PHARMACOLOGY STUDIES FOR HUMAN PHARMACEUTICALS
- RECRUITMENT OF VOLUNTEERS FOR CLINICAL TRIALS
- DRUG ADVERTISING

### MODULE 11

- GENERAL PRINCIPLES OF PHARMACOLOGY
- PRINCIPLES OF PHARMACODYNAMICS, TRANSDUCTION AND NEUROTRANSMISSION
- KINETIC PRINCIPLES OF DRUG ADMINISTRATION (Pharmacokinetic)

### MODULE 12

- DRUG INTERACTIONS AND METABOLISM
- DRUGS ACTING ON THE SYMPATHETIC NERVOUS SYSTEM (ADRENERGIC DRUGS)

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- ANTIBIOTICS

### MODULE 13

- DRUGS AFFECTING THE COAGULATION SYSTEM
- DRUGS USED IN TREATMENT OF ALLERGIES
- TREATMENT OF CENTRAL NERVOUS SYSTEM DEGENERATIVE DISORDERS

### MODULE 14

- DRUGS FOR THE TREATMENT OF VIRAL DISEASES
- CHEMOTHERAPY OF NEOPLASTIC DISEASES
- DRUGS ACTING ON THE PARASYMPATHETIC NERVOUS SYSTEM (CHOLINERGIC DRUGS)

### MODULE 15

- DRUGS USED IN DERMATOLOGY
- CARDIAC GLYCOSIDES, ANTIARRHYTHMICS AND DRUGS, USED IN ISCHEMIC HEART DISEASE
- HORMONES, VITAMINS, AND MINERALS.

### MODULE 16

- HYPOTENSIVE DRUGS AND LIPIDS-LOWERING DRUGS
- OPIOID DRUGS
- NSAIDs - NONSTEROIDAL ANTIINFLAMMATORY DRUGS

### MODULE 17

- ONCOLOGICAL CLINICAL TRIALS
- HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Glossary of Terms



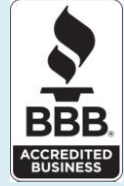
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## Career Opportunities

Clinical Trials is a rapidly expanding field, creating exciting opportunities for trained professionals.

Graduates of this program are employed in both the hospital sector and research industries, and can advance to project management roles. **Both office-based and home-based positions are available.** CRAs work in a broad range of research settings, including:

- Academic health centers
- Government agencies and departments
- Contract research organizations
- Private companies, such as pharmaceutical, biotechnology, and medical device firms

## Course Delivery

This CRA Certificate course can be completed entirely on-line while working with an assigned instructor. All of the materials you will require for the course are delivered online, so there is no need to purchase additional texts. You are at liberty to download and/or print the materials as necessary.

The material is divided into 17 Modules, each of which requires you to complete an exam and/or assignment allowing you to assess your comprehension of the material. Your performance will be based on the completion of your assignments, as there will be **no final examinations**. Upon completion of the course of study you will receive your Certificate of completion, which qualifies you for CRA positions in any company in the clinical research industry throughout North America, UK, EU, and Internationally.

You will also have an online instructor who will be monitoring your performance and providing feedback on your answers. Throughout the course, he/she will get to know each student very well and will be in a position to make a recommendation on your abilities to prospective employers. All of our instructors are highly qualified individuals who are currently working in the industry, so this is also an opportunity for you to gain some inside knowledge on how these companies work, how to get through your internship, and how to stay employed after your initial internship/trial period.

## Training Cost

- Tuition fee – **US\$1990.00** ([visit website for current promotional discounts](#))
- Course materials and certificate – **No additional charge**

## Training Duration

- Continuing Education Credits (CEUs): **30 hours**
- 100% Online, Self-Paced Training Start Anytime
- Actual completion time varies depending on your schedule and pace of study

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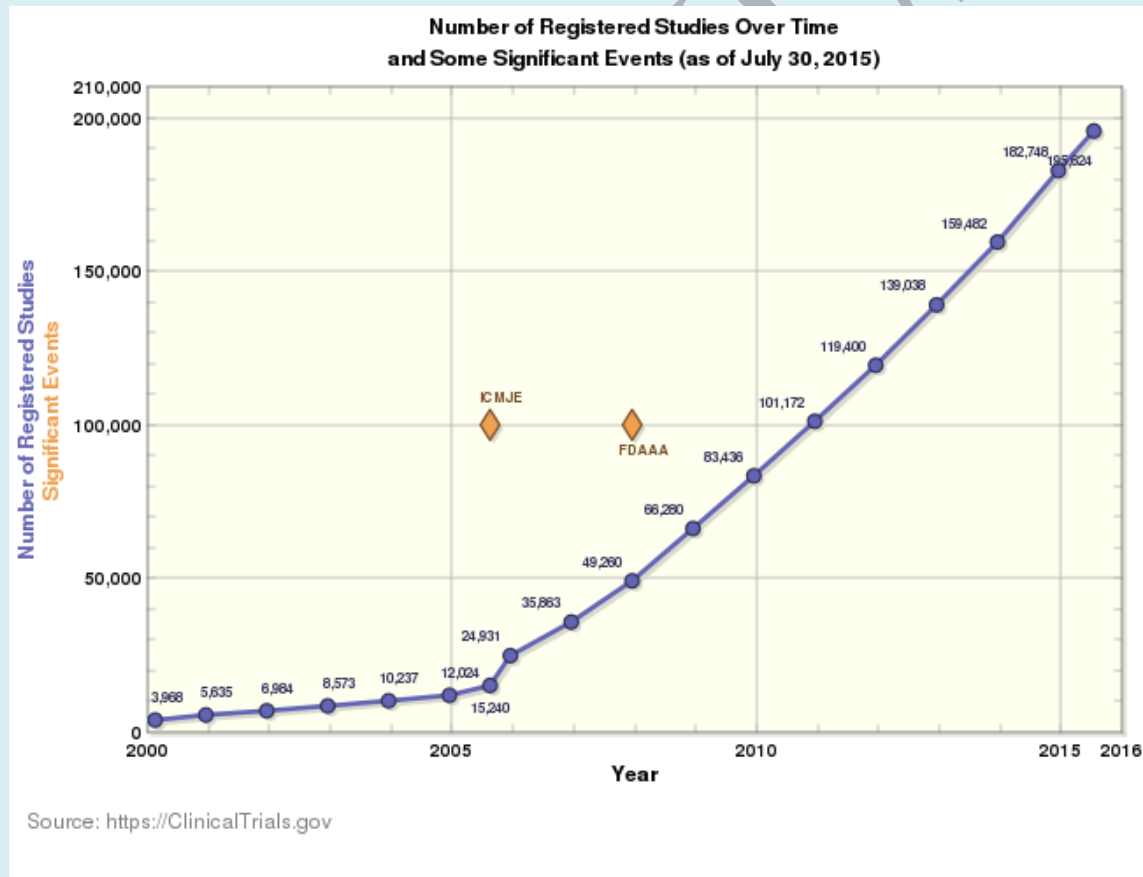
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### Target Groups

- Nurses, Clinical Research Coordinators, Clinical Research Associates
- Physicians, Dentists, Physician Assistants, Medical Monitors, Investigators
- Pharmacists, Pharmacologists, Medical Technologists, Laboratory Technicians
- Physical Therapists, Respiratory Therapists, Psychologists
- Biologists, Chemists, Medical Writers, Data Managers
- Foreign-trained health care professionals from any country



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