The CRA Training Institute
700 Louisiana Street, Suite 3950
Houston, Texas 77002, U.S.A
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Toll-free:1-866-378-8206 / (281) 616-6771

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CLINICAL DATA MANAGEMENT (CDM) CERTIFICATION TRAINING COURSE

To enroll and Start today click to Register Online

The Role of the Clinical Data Manager (CDM)

The role of a **Clinical Data Manager** (CDM) is to track and commit to a database the data gathered from clinical trials of new drugs. They must ensure the completeness, accuracy and consistency of the data so that it meets the standards of quality expected for reporting to regulatory bodies. As such, they are key members of the multidisciplinary teams (often comprising clinicians, statisticians, clinical research associates and quality managers) involved in the setting up, running and reporting of clinical trials.

A clinical data manager processes clinical trial data using a range of computer applications and database systems to support collection, cleaning and management of subject or patient data.

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 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

Accreditation: www.ACCRE-accredit.org - Global Program Code # 463-04-112-GPC02

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- CLINICAL DATA DEFINITIONS, FORMS, AND DATABASE DESIGN IN CLINICAL TRIALS
- DATA ACQUISITION

MODULE 5

- CRF PRINTING AND VENDOR SELECTION
- CLINICAL DATA MANAGER (CDM) PRESENTATION AT INVESTIGATOR MEETINGS
- COMPUTERIZED SYSTEMS USED IN CLINICAL TRIALS

MODULE 6

- DATA STORAGE
- COMPUTERS IN CLINICAL TRIALS: HARDWARE, OPERATING SYSTEMS, AND DATABASE MANAGEMENT SYSTEMS.
- CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)

MODULE 7

- DATABASE VALIDATION, PROGRAMMING AND STANDARDS
- ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL
- DATA ENTRY AND DATA PROCESSING

MODULE 8

- LABORATORY AND OTHER EXTERNAL DATA
- MEASURING DATA QUALITY

MODULE 9

- DATA ENTRY AND DISTRIBUTED COMPUTING
- AVOIDING FRAUD IN CLINICAL TRIALS

MODULE 10

- ASSURING DATA QUALITY
- DATABASE CLOSURE

MODULE 11

- CENTRAL QUALITY CONTROL OF DATA IN CLINICAL TRIALS

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- SOFTWARE TOOLS FOR TRIALS MANAGEMENT

MODULE 12

- **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) - PRIVACY RULE**
- **MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES (MedDRA)**

Course Delivery

This Clinical Data Manager or Coordinator (CDM/CDC) Certificate course can be completed entirely on-line. 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 12 Modules, each of which requires you to complete a multiple-choice exam and/or an assignment allowing us 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 CDM or CDC 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 monitor your performance and provide feedback on your answers. Throughout the course, he/she will get to know each student very well and will be able to make a recommendation on your abilities to prospective employers. All 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$1590.00** (visit website for current promotional discounts)
- Course materials and certificate – **No additional charge**

Training Duration

- Continuing Education Credits: **200 CEUs**
- 100% Online, Self-Paced Training Start Anytime
- Average completion time - **2 to 3 weeks**
- Actual completion time varies depending on your schedule and pace of study.

Target Groups

- Clinical Data Managers, Clinical Data Coordinators, Clinical Research Associates
- Biostatisticians, Statisticians, Bioinformaticians, Data Managers
- IT Professionals, SAS programmers, Oracle DBAs, SQL programmers, Access DBAs

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Career Opportunities

Clinical research 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. CDMs and CDCs 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

Salary Expectations

Typical starting salaries range from **US$70,000 to US$75,000** depending on your background. In some cases, individuals with a higher academic qualification such as a PhD may be able to command a larger salary. Most positions are full-time salaried positions, although some positions are contract hourly paid positions.

- **With 3 or more years of experience, the typical salary range is US$85,000 to US$95,000**
- **Typical starting salaries for Entry-level positions range from US$55,000 to US$65,000 per year.**

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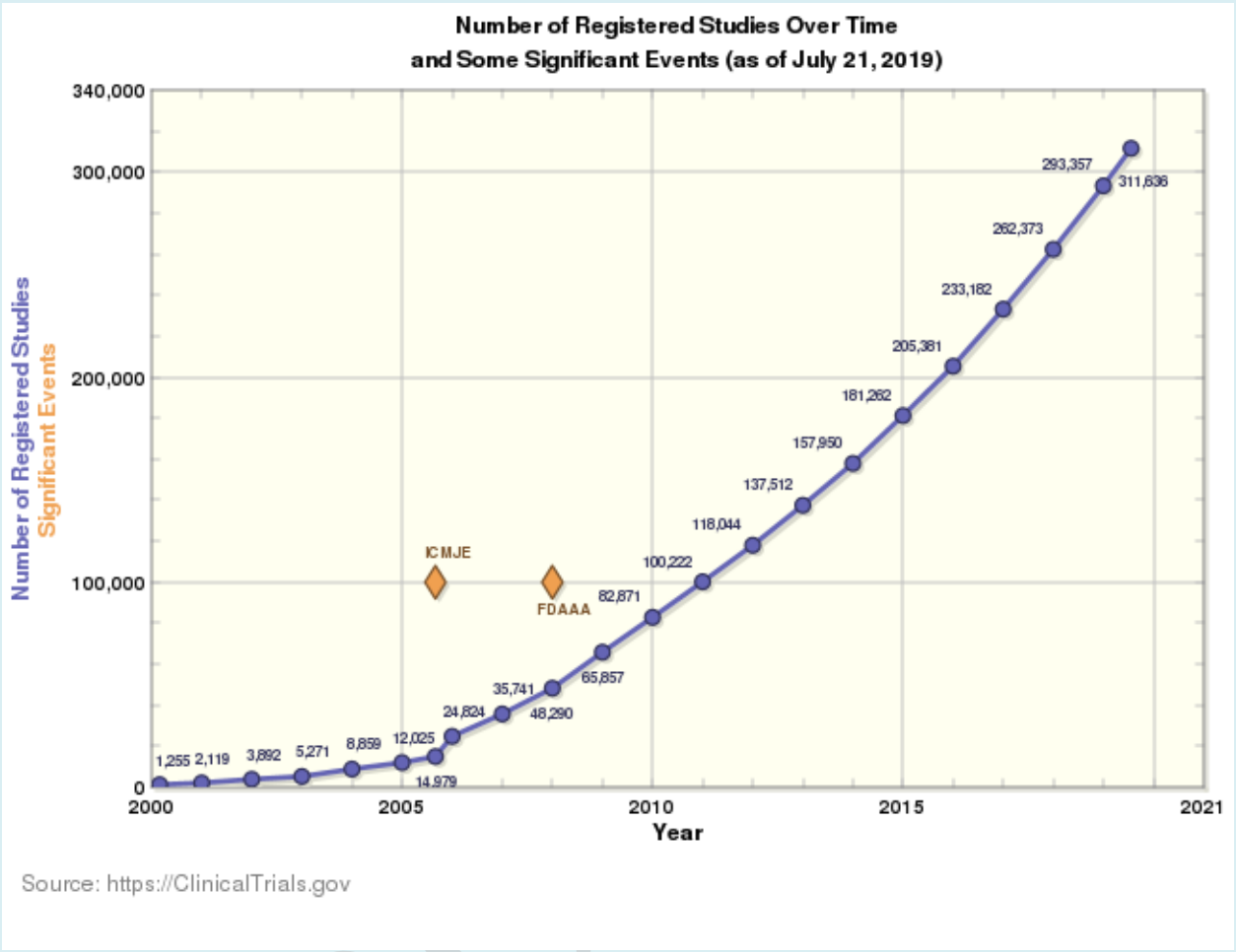

To search for Clinical Trials in your Location – **Click here**

To Enroll and Start Today click to Register Online

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