"تحسين محركات البحث لإدارة البحوث السريرية والتجارب السريرية: دليل شامل"

Duration: 10 Days

Language: ar

Course Code: IND5 - 172

Objective

:By the end of this course, participants will be able to

- .Understand the phases and structure of clinical trials
- .Identify the ethical principles and regulatory standards in clinical research
- .Discuss the roles and responsibilities of key personnel involved in trials
- .Explain how to design a clinical trial protocol and manage informed consent
- .Analyze how data is collected, stored, and monitored during trials
- .Recognize the importance of Good Clinical Practice (GCP) and safety reporting

Audience

:This course is ideal for

- .Pharmacy, medical, or life sciences graduates
- .Clinical research assistants or coordinators
- .Nurses and healthcare providers working on trials
- .Quality officers and regulatory staff
- .Anyone seeking to start a career in clinical research

Training Methodology

Participants will learn through a blended and engaging approach that includes instructor-led sessions supported by easy-to-follow visuals, allowing for clear understanding of key concepts. The course incorporates real-world case studies from clinical trial settings to provide practical context. To reinforce learning, participants will engage in practice quizzes and work with simplified protocol documents. Interactive discussions will explore ethical considerations and trial design principles, encouraging active participation and critical thinking. Additionally, learners will receive downloadable checklists, templates, and study aids to support their application of course .content beyond the training

Summary

Clinical research plays a crucial role in advancing medical knowledge and ensuring that new treatments are safe and effective. This course offers a structured introduction to how clinical trials are designed, managed, and monitored. It also introduces the regulatory, ethical, and .operational aspects of clinical research in both academic and industry settings

Whether you're new to the field or looking to expand your understanding, this training will help you grasp the essential concepts of clinical trial phases, protocol development, participant safety, data management, and regulatory compliance. It is a solid foundation for anyone interested in .clinical research as a career or in supporting roles

Course Content & Outline

Section 1: Introduction to Clinical Research

- ?What is clinical research
- .Purpose and value of clinical trials
- .Differences between observational and interventional studies
- .Key stakeholders in clinical trials

Section 2: Clinical Trial Phases

- .Overview of Phase I, II, III, and IV trials
- .Purpose and timeline of each phase
- .Examples of trials in different phases

Section 3: Trial Design and Protocol Development

- .Core elements of a clinical trial protocol
- .Defining study objectives, endpoints, and methodology
- .Writing clear inclusion/exclusion criteria
- .Designing informed consent forms

Section 4: Roles in Clinical Trial Management

- .Principal Investigator (PI), Study Coordinator, CRA
- .Trial Sponsor responsibilities
- .Site selection and site initiation visits
- .Communication and documentation

Section 5: Ethical and Regulatory Considerations

- .(Introduction to Good Clinical Practice (GCP
- .Institutional Review Boards (IRB) / Ethics Committees
- .Informed consent and participant rights
- .Reporting adverse events and maintaining transparency

Section 6: Data Management and Monitoring

- .(Data collection methods (eCRF, paper-based, EDC systems
- .Data cleaning, validation, and analysis basics
- .Trial monitoring and quality control procedures
- .Common challenges in clinical data handling

Section 7: Safety, Compliance, and Risk Management

- .Pharmacovigilance overview and adverse event reporting
- .Managing protocol deviations and compliance issues

- Audit readiness and inspection basics.
- Risk-based monitoring in clinical trials.

Section 8: Closing and Reporting

- Trial close-out procedures.
- Preparing the final study report.
- Publishing results and data sharing.
- Importance of transparency in clinical trials.

Certificate Description

عند إتمام هذه الدورة التدريبية بنجاح، سيحصل المشاركون على شهادة إتمام التدريب من Holistique Training. (e-Certificate) وبالنسبة للذين يحضرون ويكملون الدورة التدريبية عبر الإنترنت، سيتم تزويدهم بشهادة إلكترونية من Holistique Training.

شهادات Holistique Training معتمدة من المجلس البريطاني للتقييم (BAC) وخدمة اعتماد التطوير المهني المستمر (CPD)، كما أنها معتمدة وفق معايير ISO 9001 وISO 21001 وISO 29993.

لهذه الدورة من خلال شهاداتنا، وستظهر هذه النقاط على شهادة إتمام (CPD) يتم منح نقاط التطوير المهني المستمر واحدة عن كل ساعة CPD يتم منح نقطة، CPD ووفقًا لمعايير خدمة اعتماد Holistique Training. التدريب من لأي دورة واحدة نقدمها حاليًا CPD حضور في الدورة. ويمكن المطالبة بحد أقصى قدره 50 نقطة.

Categories

الصحة والسلامة والبيئة, الرعاية الصحية والصيدلانية

Related Articles

ما هي أهمية التعاطف في القيادة؟

في عالم القيادة الحديث، يتزايد الاهتمام بأهمية صفات القائد، ومن بين هذه الصفات الرئيسية تبرز بشكل لافت صفة التعاطف. فالتعاطف لا يقتصر على مجرد مظهر إنساني، بل يمتد ليكون أحد العوامل الحيوية في تحقيق القيادة الفعالة.