CLINICAL TRAILS MANAGEMENT

RAISE YOUR CAREER WITH GLOBALLY ACCLAIMED INSTITUTE

Global Institute Of Health Science™

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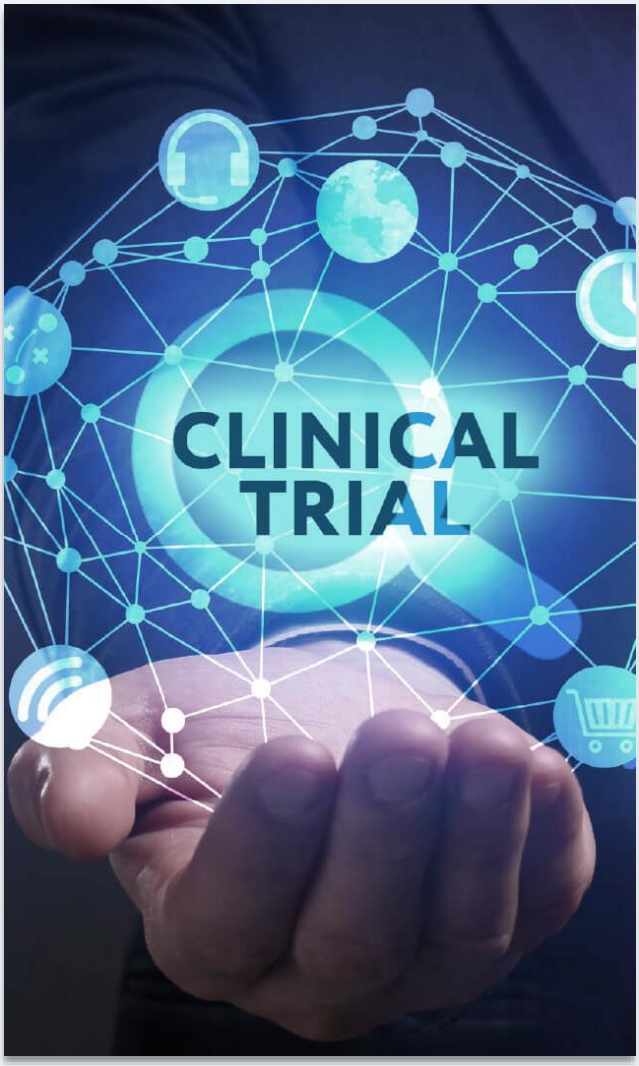
CLINICAL TRAILS MANAGEMENT

Global Institute of Health Science is a pioneer in health science education especially in distance & online education. Global Institute of Health Science is an ISO 21001:2018 Certified health science Institute & globally acclaimed, also certified with copyright approval from IPR Government of INDIA. GIHS have international certification from UASL UK for Quality Control Management System.

WHY CHOOSE US

- *BRINGING EXCELLENCE TO HEALTH PROFESSIONALS*
- *10+ YEARS OF EXPERIENCE WITH INTERNATIONAL EXPOSURE*
- *INTERNATIONAL ACLAIMED WITH ISO & GOVT APPROVED*
- *LIFETIME FREE PERSONALIZED TUTORING FOR SUCCESS*

Clinical Trials Management a branch of medical science and research that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use.
These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.
Clinical Trials is different than clinical practice.
In clinical practice, one used established treatments while in clinical trials evidence is collected to establish a treatment.
This GIHS Clinical Trials Management Program designed to provide total overview and skill globally in the field of Clinical Trials.
It would help professionals to upgrade & develop their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical research & trial management
It can be able applicable to critically appraise the medical scientific literature, including the methodology of published and proposed investigations.



SYLLABUS

Clinical Trails Management

Introduction of clinical research

- Clinical Trial Phases / Pharmacological Principal of Clinical Research
- Drug Development and Launch

Indian Regulation (domestic regulation)

- ICH GCP / Schedule Y / ICMR / Indian GCP

Key Stakeholders in Clinical Research

- Ethics Committees and Institutional Review Board
- Responsibilities of Sponsor / Responsibilities of Investigator
- Responsibilities of Sponsor – Investigator / Responsibilities of Sponsor – Vendor

Clinical Trial Design and Project Managements

- Clinical Trial Design / Vendor Selection and Managements
- Project Planning / Project Managements

Principles of good clinical practices

- Protocol Design / CRF Design

Essential documents in clinical research and regulatory requirements

- Essential Documents / IND Application / Clinical Study Report
- NDA Application / Informed Consent Process and Documentation

Study setup process

- Site Selection and Pre- Study Visits
- Site Initiation / Subject Recruitment and Retention Planning
- Site Contract and Budgeting

QC, Compliance & Auditing in Clinical Research

- 21 CRF Part 11 / Site Auditing
- Sponsor Compliance and Auditing / SOP for Clinical Research

Clinical Monitoring

- CRF Review & Source Data Verification
- Drug Safety Reporting / Drug Accountability Work
- Routine Site Monitoring / Site Close Out Visit

Introduction of Pharmacovigilance

- Overview of Pharmacovigilance
- Standard Terms and Terminology in Pharmacovigilance

Medical Evaluation of Adverse Events in Pharmacovigilance

- Adverse Event Reporting System and Form
- Diagnosis and Managements of ADRs / Medical Evaluation of AE

Case Processing

- Global Perspective of Pharmacovigilance
- Single Case Processing / Case Narrative Writing

Pharmacovigilance Reporting Database, Signal Detection, Managements and Risk Assessments & Evaluation

- Quality System in PV / Expedited Reporting Criteria
- PSUR & PBRER / PV Database and Signal Detection
- Risk Assessments & Management

Medical Dictionary for Regulatory Activities medDRA

- medDRA

PV laws and Guideline

- Regulatory Guideline @ Laws in PV / SOPS in PV / PV Auditing And Inspection
- Regulatory Aspects In PV

ADMISSION PROCEDURE

- *Enrollment online: www.gihsonline.com / Apply Online*
- *Online Access for Study Content within 48 Hours of enrollment*
- *Shipping of books with Latest updates with every enrollment (optional)*
- *Will Assign Personalized Professional Expert for Lifetime with no COST*
- *Online exam and Project submission*
- *Will award and ship two international certificates*

FEES DETAILS (All modes of payment available)

- *Post Graduate Diploma Program (One Year) – 32000/- INR & Fees for International Candidates – 699 $ USD*
- *Fast Track PG Diploma Program (4 Months) – 36000/- INR & Fees for International Candidates – 750 $ USD*

STUDY METHODOLOGY

- Freelance method of study
- Read the books
- Make notes of your queries
- Need to mail or contact to our expert
- Experts will resolve... via mail or via call or Can arrange Session based on your queries
- Experts will support for lifetime to raise your knowledge & Expertise
- Our content is totally based on live cases and Industries best practices

MODE OF EXAMS

- Login Details for online examinations after completion of the duration.
- 7 days to appear in online exams.
- Examination pattern would be Multiple Choice question MCQ
- PowerPoint project of minimum 30 pages of your own selected topic
- Successful Candidates would award with two certifications (DEGREE & TRANSCRIPTIONAL Degree)

PLACEMENT SUPPORT

Will Share your profile globally for career growth. With the support of GIHS programs more than 2000 professionals are working in healthcare industry and having strong student & professional base in India, UK, USA, Canada, UAE, Russia, Australia and more.

India UK USA Australia Canada Russia New Zealand UAE Africa Europe

Global Institute Of Health Science

Certificate

This is to certify that

Saswata Banerjee

completed the one year programme of

Post Graduate Diploma in

Clinical Trials Management

offered by

Global Institute of Health Science.

during September 2020 to August 2021

Upon successful completion of the programme

POST GRADUATE DIPLOMA

IN

CLINICAL TRIALS MANAGEMENT

is awarded to him/her this day the 07th September 2021.

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MHRD (Higher Education)
Reg No: SW - 12032/2018
CR Act 1957

UASL
Quality Control Certification

ISO 21001:2018

Cert. ID :630791bd37cb4

Academic Head

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Global Institute Of Health Science

POST GRADUATE DIPLOMA
IN
Clinical Trials Management
(September 2020 to August 2021)

Saswata Banerjee

GRADE SHEET & TRANSCRIPT

Introduction | Clinical Trial Phases | Principal | Drug Development And Launch | ICH GCP | Schedule Y
Indian Regulation (domestic regulation) | ICMR | Indian GCP | Key Stakeholders
Ethics Committees And Institutional Review Board | Vendor Selection And Managements
Responsibilities Of Sponsor, Investigator, Sponsor – Investigator & Sponsor – Vendor
Clinical Trial Design And Project Managements & Planning | Principles of good clinical practices
Protocol Design | CRF Design | Essential documents | Clinical Study Report | NDA Application
Informed Consent process And Documentation | Study Setup process | Site Selection And Pre- Study VIsits
Subject Recruitment And Retention Planning | Site Contract And Budgeting | 21 CRF Part 11 | Site Auditing
QC, Compliance & Auditing in Clinical Research | Sponsor Compliance And Auditing | Clinical Monitoring
CRF Review & Source Data Verification | Drug Safety Reporting | Drug Accountability Work
Routine Site Monitoring | Site Close Out Visit
Overview & Standard Terms And Terminology | Medical Evaluation Of Adverse Events
Adverse Event Reporting System And Form | Diagnosis And Managements Of ADRs
Medical Evaluation Of AE | Case Processing |Global Perspective | Single Case Processing
Case Narrative Writing | Reporting Database, Signal Detection | Managements And Risk Assessments & Evaluation
Quality System In PV | Expedited Reporting Criteria | PSUR & PBRER | Database And Signal Detection
Risk Assessments & Management | Medical Dictionary For Regulatory Activities medDRA
PV laws And Guideline | Regulatory Guideline @ Laws | SOPS | PV Auditing & Inspection | Regulatory Aspects

Examination: 41/50 **Project Work: 43/50**

Total: 84/100

GRADE: A+

ISO 21001:2018

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07/09/2021

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GIHS ADVANTAGE

GIHS provides best courses helps to get the start up in the healthcare field. These courses are ad-hoc to professional career and provides the additional benefit to be the part of an organization.

OTHER PROGRAMS

Health Management Programs

• Health Informatics	• Hospital Administration
• Pharma Management	• Hospital Planning & Management
• Healthcare Management	• Nursing Management
• Public Health Administration	• Health Insurance
• Blood Banking Management	• Medico-Legal Systems
• Medical Laboratory Technology	• Medical Radiology Technology
• Quality management for Hospital and healthcare organizations	
• Disaster management for hospitals and healthcare organizations	
• Hospital Infection Control & Patient Safety	

Clinical Research Programs

• Clinical Research & Quality Assurance GCP Audits / Inspections	• Pharmacovigilance & Medical/Scientific Writings
• Clinical Research & Pharmacovigilance	• Clinical Data Management & SAS
• Regulatory affairs IPR & Patent	• Clinical Trials Management

Allied Medical Programs

• Mother & Child Health	• Mental Health & Addictions
• Nutrition & Dietetics	• Medical Transcription
• Pregnancy Education	• Gynaecology & Obstetrics
• Electroencephalogram (EEG)	• Nuclear Medicine Technology
• Anaesthesia Management	• First AID (CPR/Emergency Care)

Environment Health & Safety Programs

• Industrial Health & Hygiene	• Environment Health Safety & RM
• Occupational Health & Safety	• Industrial Safety
• Food Safety & Quality Management	• Oil & Gas Safety Engineering
• Process Safety & Engineering	• Fire & Industrial Safety MGT

Ayurveda & Homeopathic Programs

• Panchkarma: Ayurveda	• Garbhsanskar: Ayurveda
• Naturopathy & Yoga	• Siddha: Medicine
• Ksharsutra: Ayurveda	• Classical Homeopathy
• Materia Medica: Homeopathy	• Repertory: Homeopathy

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