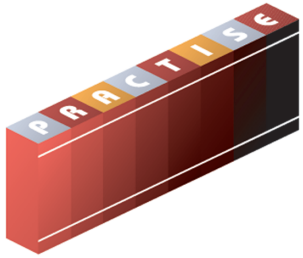


**The program is highly flexible.**
**Tailored teaching modules could be arranged to fit your specific needs.**

**Each teaching module could be supplemented with a practical session (e.g. case studies) if required.**

# Professional Research Accreditation for Clinical Trials Investigative Site Executives

**A comprehensive practical training program specifically designed for clinical investigators and study site personnel worldwide**

- Full coverage for study site personnel
- Make your own program from 25 selective teaching modules
- Complementary practical case studies and discussions
- Translating concepts to practice
- Trainers with hands-on experience in clinical trial management and operations

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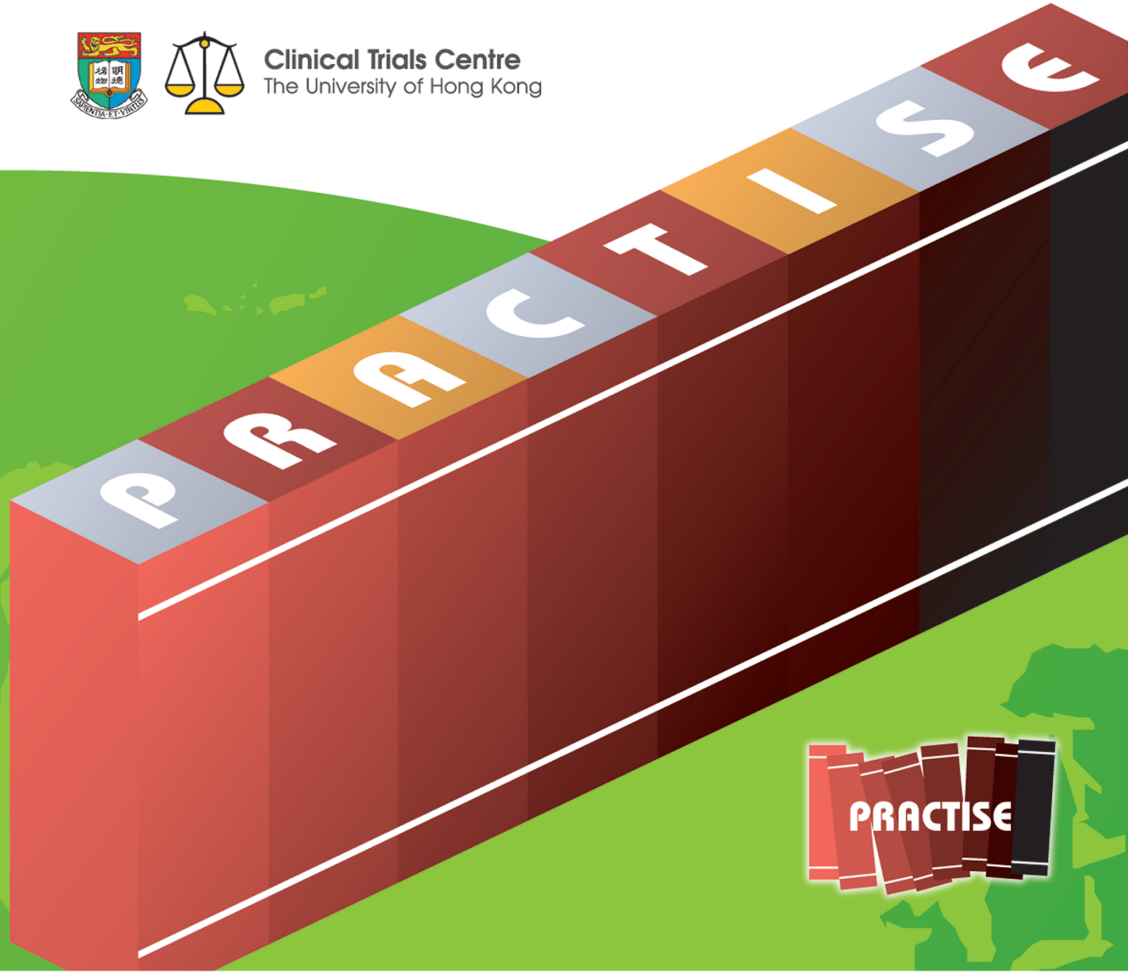


**For further details, please contact**
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# Professional Research Accreditation for Clinical Trials Investigative Site Executives

| Module No. | Topic | Key Contents | Duration (Mins) | Credits |
|---|---|---|---|---|
| **Part A : Clinical Trial Concepts and Compliance** | | | | |
| A01 | Clinical Trial Concepts & Clinical Development Prcoess | • Clinical Practice & Clinical Research<br>• History of Clinical Research<br>• Clinical Development Process<br>• Classifcation of Clinical Studies | 30 | 2 |
| A02 | Clinical Research Compliance | • What is compliance?<br>• Clinical Research Compliance : The 3 Pillars<br>• 6-dimensional Compliance in Clinical Research | 30 | 2 |
| A03 | International Clinical Research Guidelines | • Nuremberg Code<br>• Declaration of Helsinki<br>• Belmont Report | 30 | 2 |
| A04 | ICH GCP : Overview & Principles | • Background of ICH GCP<br>• ICH GCP : What is it about?<br>• ICH GCP Principles & The 3 Pillars of Clinical Trials | 45 | 3 |
| A05 | ICH GCP : Insight for Investigators & Study Site Personnel | • The Roles of Investigators & Study Site Personnel<br>• Responsibilities : Subject Protection<br>• Responsibilities : Data Integrity<br>• Responsibilities : Science | 30 | 2 |
| A06 | ICH GCP : Roles & Responsibilities of Sponsors & CROs | • The Roles of Sponsors & CROs<br>• Responsibilities : Subject Protection<br>• Responsibilities : Data Integrity<br>• Responsibilities : Science | 30 | 2 |
| A07 | Ethics Committees : ICH GCP & Beyond | • Concepts of Clinical Research Ethics<br>• Mission, Authority & Setup of IRBs<br>• IRBs' Responsibilities under ICH GCP<br>• Key Research Ethics Aspects | 30 | 2 |
| A08 | Quality Management at Study Sites | • Concepts of Quality Assurance & Quality Control<br>• Quality Assurance for Clinical Study Sites | 30 | 2 |
| A09 | Study Site Standard Operating Procedures | • Development of Study Site SOPs<br>• Key Elements of Study Site SOPs<br>• Maintenance of Study Site SOPs | 30 | 2 |
| **Part B : CLinical Trial Preparation** | | | | |
| B01 | Confidentiality Agreements | • Confidential Information & Confidentiality Agreements<br>• Key Contents of Confidentiality Agreements | 15 | 1 |
| B02 | Study Planning | • Recruitment Planning<br>• Operational Planning<br>• Manpower Planning<br>• Time Planning<br>• Budget Planning<br>• Quality Management Planning | 30 | 2 |
| B03 | Ethics Submissions | • Understand of Local Ethics Committees' SOPs<br>• Initial & Subsequent Ethics Submissions<br>• Progress Reports & Final Reports | 30 | 2 |
| B04 | Budgeting & Payment Management | • Costing Concepts<br>• Concept of Fair Market Value<br>• Common Cost Items<br>• Payment Management | 30 | 2 |
| B05 | Clinical Trial Agreements | • Principles of Clinical Trial Agreements<br>• Key Contents of Clinical Trial Agreements<br>• Management of Clinical Trial Agreements | 30 | 2 |
| B06 | Common Legal Documents (I) | • Form FDA 1572 : Statement of Investigator<br>• Conflicts of Interest & Financial Disclosure Statement | 30 | 2 |
| B07 | Common Legal Documents (II) | • Personal Data Disclosure Statement<br>• Anti-bribery and Anti-corruption Statement | 30 | 2 |

# Professional Research Accreditation for Clinical Trials Investigative Site Executives

| Module No. | Topic | Key Contents | Duration (Mins) | Credits |
|---|---|---|---|---|
| **Part C : Clinical Trial Process** | | | | |
| C01 | Subject Recruitment & Retention | • Subject Recruitment & Subject Protection<br>• Subject Recruitment Strategies<br>• Subject Retention Strategies<br>• Subject Protection in Subject Recruitment | 30 | 2 |
| C02 | Informed Consent | • Principles of Informed Consent<br>• Contents of Informed Consent<br>• Informed Consent Process<br>• Enrolling Subjects Incapable of Giving Consent through a Normal Informed Consent Process | 60 | 4 |
| C03 | Case Report Forms & Source Documents | • Completion of Paper CRFs & eCRFs<br>• Source Data & Source Documents<br>• Clinical Notes versus Clinical Research Source Documents<br>• Retention of Source Documents | 30 | 2 |
| C04 | Investigational Product Management | • Principles of Investigational Product Management<br>• Receipt of Products<br>• Storage of Products & Inventory Control<br>• Handling & Dispensing of Products<br>• Return of Products<br>• Disposal of Products | 30 | 2 |
| C05 | Biological Specimen Management | • Principles of Biological Specimen Management<br>• Specimen Collection<br>• Specimen Processing<br>• Specimen Storage & Archiving<br>• Specimen Shipment<br>• Specimen Disposal | 30 | 2 |
| C06 | Safety Management & Reporting | • Investigators' Responsibilities in Safety Management<br>• Defintion of Safety Events<br>• Reporting of SAEs & SUSARs | 30 | 2 |
| C07 | Essential Document Management | • The Concepts of Essential Documents<br>• Essential Documents & Management | 30 | 2 |
| C08 | Facilitation of Site Monitoring | • Site Initiation Visit<br>• Study Monitoring<br>• Source Data Verification and Data Queries<br>• Investigational Products Accountability<br>• Study Closure Visit | 30 | 2 |
| C09 | Facilitation of Audits & Inspections | • Overview of Audits & Inspections<br>• Purposes of Audits & Inspections<br>• Preparation for Audits & Inspections<br>• Audit / Inspection Process<br>• Common Audit / Inspection Findings | 30 | 2 |

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