COURSE INDEX & PROGRAMME CATALOGUE

CRA Training Programme

Clinical Research Associate · **ICH-GCP Aligned** · **22 Modules** · **53 Learning Hours** · **CPD Certified**

22	53	ICH-GCP Aligned	CPD Certified
EXPERT MODULES	LEARNING HOURS	MONITORING STANDARD	ACCREDITED

PROGRAMME OVERVIEW

The Yoshe Clinical Academy CRA Training Programme is a comprehensive curriculum for clinical research professionals building, strengthening and validating their monitoring competencies. Covering all core disciplines — from ICH-GCP foundations and site visit execution through to advanced regulatory compliance and clinical trial technology systems — this 22-module, 53-hour programme equips Clinical Research Associates to operate at the highest professional standard across global clinical trials.

COURSE MODULE INDEX — 22 MODULES, 53 HOURS

NO.	MODULE TITLE	DURATION
01	**Introduction to Clinical Research** History and evolution of clinical trials	2 hrs
02	**Clinical Trial Types and Phases** Study designs across Phase I–IV	2 hrs
03	**Role, Responsibilities and Functions of a CRA** The monitoring remit end to end	2 hrs
04	**ICH-GCP Guidelines** Principles and glossary	1 hrs
05	**Clinical Study Randomisation** Interactive Web Response Systems (IWRS)	2 hrs
06	**Global Regulatory Requirements** IRB/IEC/REC approvals, EU GDPR and HIPAA compliance	2 hrs
07	**Informed Consent Process** Patient-facing documents and data privacy law	2 hrs
08	**Safety Reporting & Adverse Events** AE, SAE, SUSAR and GCP breaches	2 hrs
09	**Clinical Trial Pharmacy / IMP Management** Accountability, storage and reconciliation	4 hrs
10	**Subject Medical Records and Source Data** Source documentation and SDV	2 hrs
11	**Clinical Trial Site Visit Types** SQV / SSV, SIV, IMV and COV	4 hrs
12	**Site Visit Preparation** Emails, letters, visit reports and escalation	4 hrs
13	**Modernised Monitoring** Remote, risk-based and centralised monitoring	2 hrs
14	**Essential Documents, ISF and TMF** Filing standards and completeness	2 hrs
15	**Clinical Trial Technology Overview** IVRS, CTMS, IWRS, EDC, eCRF, eCOA and eTMF	4 hrs
16	**Data Governance** Investigator and sponsor obligations	2 hrs
17	**Investigator's Brochure and Safety Information** Content, updates and distribution	2 hrs
18	**Protocol, Amendments, Deviations & Violations** Identification, reporting and prevention	2 hrs
19	**Regulatory Audits and Inspections** Sponsor, FDA, MHRA and EMA	2 hrs
20	**Managing Site-Level Issues** Site management and performance	2 hrs
21	**Monitoring & Tracking Protocol Deviations** Potential serious GCP breaches	2 hrs
22	**Clinical Trial Operations Technology Vendors** Vendor oversight and system landscape	4 hrs
TOTAL PROGRAMME — 22 Modules		**53 Hrs**

PARTICIPANT PROFILE & DELIVERY

WHO SHOULD ATTEND

- Clinical Research Associates (CRAs)
- Clinical Research Coordinators (CRCs)
- Clinical operations professionals
- Sponsor and CRO monitoring teams
- Site management personnel
- Aspiring CRAs entering the industry

DELIVERY FORMATS

- Live Online — instructor-led sessions
- In-Person — site or training centre
- Blended — eLearning plus live workshops
- CPD accredited and formally assessed
- Global delivery capability (US, UK, EU, India)
- Certificate of completion with CPD hours recorded

REGULATORY ALIGNMENT

- **ICH-GCP E6(R2)** — Good Clinical Practice
- **US FDA** — 21 CFR Parts 50, 56 & 312
- **EU** — Clinical Trials Regulation 536/2014
- **UK** — MHRA & HRA monitoring expectations
- **Data Privacy** — UK/EU GDPR and US HIPAA
- **Risk-Based Monitoring** — ICH E6 and EMA reflection paper

PROGRAMME NOTES

All modules are aligned with ICH-GCP E6(R2), EU GDPR, HIPAA and applicable national regulatory frameworks. Module durations are confirmed upon programme scheduling and may be extended for in-house cohorts requiring therapeutic-area or sponsor-system specialisation.

ENROLMENT & ENQUIRIES

academy@yosheclinical.com | www.yosheclinical.com

United Kingdom · India · United States