COURSE INDEX & PROGRAMME CATALOGUE

Principal Investigator Programme

Clinical Trial Leadership & Site Governance · **ICH-GCP E6(R3) Aligned** · **18 Modules** · **60 Learning Hours** · **CPD Certified**

18	60	ICH-GCP E6(R3)	US · UK EU
EXPERT MODULES	LEARNING HOURS	ALIGNED	GLOBAL COVERAGE

PROGRAMME OVERVIEW

The Yoshe Clinical Academy Principal Investigator (PI) Programme is a rigorous 60-hour curriculum developed for physicians, specialists and senior clinicians assuming the role of Principal Investigator in interventional and observational clinical trials. Spanning 18 structured modules, the programme equips Principal Investigators with comprehensive knowledge of their regulatory obligations, ethical duties, protocol governance responsibilities and inspection-readiness requirements. Covering global regulatory frameworks across the US FDA, UK MHRA/HRA and EU CTR 536/2014, the programme enables Principal Investigators to lead trial sites with confidence, accountability and full GCP compliance.

COURSE MODULE INDEX — 18 MODULES, 60 HOURS

NO.	MODULE TITLE	DURATION
01	**Introduction to Clinical Research** History, Ethics & the Role of the Principal Investigator	**3** hrs
02	**ICH-GCP E6(R3)** Principles, Responsibilities and Obligations of the Investigator	**3** hrs
03	**Clinical Trial Protocol** Review, Implementation, Amendments & Deviation Management	**4** hrs
04	**Global Regulatory Landscape** US FDA (IND / Form FDA 1572), UK MHRA & HRA, EU CTR 536/2014 & CTIS	**4** hrs
05	**Ethics Committee & IRB / IEC / REC Submissions** Responsibilities of the Principal Investigator	**3** hrs
06	**Informed Consent Process** PI Oversight, Vulnerable Populations & Re-Consent	**4** hrs
07	**Delegation of Duties** Delegation Logs, Site Staff Authorisation & Supervision	**3** hrs
08	**Subject Safety** Adverse Event & SAE Reporting Obligations (US, UK & EU Frameworks)	**4** hrs
09	**SUSAR Reporting, DSUR & Annual Safety Reviews** Principal Investigator Responsibilities	**3** hrs
10	**Investigational Medicinal Product (IMP) Management** PI Accountability & Pharmacy Oversight	**3** hrs
11	**Source Data, EHR & Data Integrity** Investigator Obligations and ALCOA+ Principles	**3** hrs
12	**Investigator Site File (ISF) & Trial Master File (TMF)** PI Sign-Off Requirements	**3** hrs
13	**Site Activation, Green Light Approvals & Site Readiness** US, UK & EU Region-Specific Requirements	**3** hrs
14	**Protocol Deviations, GCP Breaches & CAPA** Investigator-Level Reporting & Escalation	**3** hrs
15	**Clinical Trial Monitoring** Managing CRA Visits, Sponsor Oversight & Corrective Actions	**3** hrs
16	**Regulatory Audit & Inspection Readiness** FDA, MHRA, EMA & Sponsor Audits	**4** hrs
17	**Data Privacy in Clinical Trials** GDPR (EU / UK), HIPAA and Investigator Obligations	**3** hrs
18	**PI Leadership & Site Performance Metrics** Multi-Site Trial Co-ordination & Site Governance	**4** hrs
TOTAL PROGRAMME — 18 Modules		**60 Hrs**

PARTICIPANT PROFILE & DELIVERY

WHO SHOULD ATTEND

- Principal Investigators (MD / PhD) in interventional trials
- Sub-Investigators and Co-Investigators
- Clinicians entering the PI role for the first time
- Academic and NHS researchers conducting CTIMP studies
- Senior site physicians in CRO / SMO-supported trials
- Hospital-based research leads (US, UK & EU)

DELIVERY FORMATS

- Live Online — instructor-led sessions
- In-Person — hospital, 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(R3)** — Good Clinical Practice
- **US FDA** — 21 CFR Parts 50, 54, 56 & 312
- **EU** — Clinical Trials Regulation 536/2014 & CTIS
- **UK** — MHRA & HRA, UK Policy Framework for Health Research
- **Data Privacy** — UK/EU GDPR and US HIPAA
- **Safety** — ICH E2A / E2F pharmacovigilance reporting

PROGRAMME NOTES

All modules are aligned with ICH-GCP E6(R3), EU CTR 536/2014, US FDA 21 CFR Parts 50, 54, 56 & 312, UK MHRA/HRA regulations, GDPR and HIPAA. Region-specific modules (**04, 05, 13, 16**) include separate US FDA, UK MHRA/HRA and EU CTR tracks. Module durations are confirmed upon programme scheduling and may be extended for in-house cohorts requiring therapeutic-area specialisation.

ENROLMENT & ENQUIRIES

academy@yosheclinical.com | www.yosheclinical.com

United Kingdom · India · United States