COURSE INDEX & PROGRAMME CATALOGUE

Clinical Research Coordinator Programme

Site Operations & Patient Management · **ICH-GCP E6(R3) Aligned** · **20 Modules** · **71 Learning Hours** · **CPD Certified**

20	71	ICH-GCP E6(R3)	US · UK EU
CORE MODULES	LEARNING HOURS	ALIGNED	GLOBAL COVERAGE

PROGRAMME OVERVIEW

The Yoshe Clinical Academy Clinical Research Coordinator (CRC) and Study Coordinator Programme is a comprehensive 71-hour curriculum for professionals co-ordinating clinical trial activities at investigator sites. Spanning 20 structured modules, it covers the complete lifecycle of site-level trial management — from regulatory submissions and patient recruitment through to IMP handling, safety reporting and audit readiness. Region-specific frameworks across the US FDA, UK MHRA/HRA and EU CTR 536/2014 environments equip coordinators to run compliant, efficient and patient-centred trial sites.

COURSE MODULE INDEX — 20 MODULES, 71 HOURS

NO.	MODULE TITLE	DURATION
01	**Introduction to Clinical Trials & Good Clinical Practice** ICH-GCP E6(R3) foundations for site staff	4 hrs
02	**Role & Responsibilities of the CRC / Study Coordinator** Scope, accountability and daily practice	3 hrs
03	**Global Regulatory Landscape for Site Staff** US FDA, UK MHRA/HRA, EU CTR 536/2014 & CTIS	4 hrs
04	**Ethics Committee and IRB / IEC / REC Submissions** Site responsibilities and ongoing reporting	3 hrs
05	**Clinical Trial Protocol & Investigator's Brochure** Review, compliance and amendments	3 hrs
06	**Patient Recruitment, Eligibility Screening & Enrolment** Recruitment strategy and enrolment management	4 hrs
07	**Informed Consent Process** Coordinator role, patient communication and documentation	4 hrs
08	**Subject Scheduling and Visit Management** Including remote and decentralised trial procedures	4 hrs
09	**Source Data and Medical Records Management** Documentation standards and SDV preparation	3 hrs
10	**Electronic Data Capture (EDC) and eCRF Completion** Data entry, query resolution and quality	4 hrs
11	**Safety Reporting — AE, SAE and SUSAR** Collection, documentation and sponsor notification	4 hrs
12	**Protocol Deviations and GCP Breaches** Identification, reporting and CAPA at site level	3 hrs
13	**Clinical Trial Pharmacy / IMP Management** CRC responsibilities and dispensing oversight	4 hrs
14	**Investigator Site File (ISF) and Essential Documents** Filing, completeness and inspection readiness	4 hrs
15	**Clinical Trial Technology for Site Staff** IWRS, eCOA, ePRO, CTMS and eTMF systems	4 hrs
16	**Sample Collection and Laboratory Management** IATA shipments and central lab co-ordination	3 hrs
17	**Delegation of Duties and Site Communication** Stakeholder management and the delegation log	3 hrs
18	**Data Privacy at Site Level** EU GDPR, UK GDPR, HIPAA and patient confidentiality	3 hrs
19	**Monitoring Visits, Sponsor Audits and Inspections** Site preparation and response	4 hrs
20	**Site Budgets, Clinical Trial Agreements & Career Development** Commercial and professional development	3 hrs
TOTAL PROGRAMME — 20 Modules		**71 Hrs**

PARTICIPANT PROFILE & DELIVERY

WHO SHOULD ATTEND

- Clinical Research Coordinators (CRCs)
- Study Coordinators and site research nurses
- Research nurses and allied health professionals
- Site managers and trial administrators
- NHS Clinical Trials Unit staff
- New entrants moving into site-based research

DELIVERY FORMATS

- Live Online — instructor-led sessions
- In-Person — investigator 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, 56 & 312
- **EU** — Clinical Trials Regulation 536/2014 & CTIS
- **UK** — MHRA & HRA, NHS R&D site approvals
- **Data Privacy** — UK/EU GDPR and US HIPAA
- **Logistics** — IATA dangerous goods for biological samples

PROGRAMME NOTES

> All modules are aligned with ICH-GCP E6(R3), EU CTR 536/2014, US FDA 21 CFR Parts 50, 56 & 312, UK MHRA/HRA regulatory frameworks, GDPR and HIPAA. Module 03 provides region-specific tracks for the US, UK and EU regulatory environments. Module durations are confirmed upon programme scheduling.

ENROLMENT & ENQUIRIES

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