COURSE INDEX · LAYER 1 FOUNDATION · TRIQ™ CLINICAL OPERATIONS QUALITY SYSTEM

Core Curriculum — Clinical Research

The Foundation Layer · **Mandatory for all clinical research roles** · **14 Modules** · **20.5 CPD Hours** · **1,230 Minutes**

14	20.5	Layer 1 Foundation	80% Pass Mark
FOUNDATION MODULES	CPD LEARNING HOURS	TRIQ™ PATHWAY	ASSESSED

PROGRAMME OVERVIEW

The Core Curriculum is the mandatory foundation of the Yoshe Clinical Academy learning pathway. It equips every member of staff — across all functions and all organisations in the clinical trial ecosystem (Site, CRO and Sponsor) — with the shared regulatory, ethical, quality and safety knowledge required to work compliantly in clinical research. Sitting at Layer 1 (Foundation) of the TriQ™ Clinical Operations Quality System, it is the common baseline completed before, or alongside, any role-specific or higher-layer training, and comprises 14 modules delivering 20.5 CPD learning hours.

MODULE INDEX — 14 FOUNDATION MODULES, 20.5 CPD HOURS

REF	MODULE TITLE	DURATION
CRC-L1-01	**Introduction to Clinical Research and the Drug Development Lifecycle** 90 min · 1.5 CPD hrs	**1.5** hrs
CRC-L1-02	**ICH E6(R3) Good Clinical Practice — Principles and Application** 180 min · 3.0 CPD hrs	**3.0** hrs
CRC-L1-03	**ICH E8(R1) General Considerations and Quality by Design** 90 min · 1.5 CPD hrs	**1.5** hrs
CRC-L1-04	**Research Ethics, Declaration of Helsinki and Human Subject Protection** 90 min · 1.5 CPD hrs	**1.5** hrs
CRC-L1-05	**Informed Consent — Principles, Process and Regulatory Expectations** 90 min · 1.5 CPD hrs	**1.5** hrs
CRC-L1-06	**Data Integrity and ALCOA+ in the Clinical Trial Environment** 60 min · 1.0 CPD hr	**1.0** hrs
CRC-L1-07	**Clinical Data Privacy — UK GDPR, EU GDPR, HIPAA and DPDP Act 2023** 90 min · 1.5 CPD hrs	**1.5** hrs
CRC-L1-08	**Global Regulatory Landscape — FDA, MHRA, EMA, CDSCO, NMPA and PMDA** 120 min · 2.0 CPD hrs	**2.0** hrs
CRC-L1-09	**Adverse Event Awareness and Individual Safety Reporting Obligations** 90 min · 1.5 CPD hrs	**1.5** hrs
CRC-L1-10	**Quality Management System, SOP Compliance and Documentation Practice** 90 min · 1.5 CPD hrs	**1.5** hrs
CRC-L1-11	**Clinical Trial Terminology and Anatomy of a Protocol** 60 min · 1.0 CPD hr	**1.0** hrs
CRC-L1-12	**Inspection Readiness and Behaviour During a Regulatory Inspection** 60 min · 1.0 CPD hr	**1.0** hrs
CRC-L1-13	**Fraud, Misconduct, Serious Breach and Whistleblowing** 60 min · 1.0 CPD hr	**1.0** hrs
CRC-L1-14	**Equality, Diversity and Inclusion in Trial Design and Recruitment** 60 min · 1.0 CPD hr	**1.0** hrs
TOTAL — 14 Modules · 1,230 Minutes		**20.5 Hrs**

PARTICIPANT PROFILE & DELIVERY

WHO SHOULD ATTEND

- Clinical Research Associates and monitoring staff
- Clinical trial coordination and administration
- Site staff — Investigators, Study Coordinators, research nurses
- Data management, pharmacovigilance and drug safety
- Regulatory affairs, quality assurance and quality control
- Study start-up, project management, BD, IT and support functions

DELIVERY FORMATS

- Onsite (classroom) — facilitator-led with group activities
- Remote (virtual) — live tutor-led online sessions
- Self-learning — narrated materials on the TriQ™ platform
- Module-mapped assessment (20 questions × 10 sets)
- Pass mark 80%; learner feedback form on completion
- Course Completion Certificate with CPD hours and unique reference

REGULATORY ALIGNMENT

- **United States** — FDA, 21 CFR Parts 11, 50, 54, 56 & 312
- **United Kingdom** — MHRA, UK Clinical Trials Regulations, UK GCP
- **European Union** — EMA, Regulation (EU) No 536/2014
- **India** — CDSCO / DCGI, NDCT Rules 2019 (as amended)
- **China** — NMPA / CDE, Drug Registration Regulation, China GCP
- **Japan** — PMDA / MHLW, J-GCP (MHLW Ordinance)

PROGRAMME NOTES

Underpinned by ICH E6(R3) and ICH E8(R1), the Declaration of Helsinki and ALCOA+ data-integrity principles, with UK GDPR, EU GDPR, HIPAA and the India DPDP Act 2023, plus 21 CFR Part 11 and EU GMP Annex 11. Where requirements differ, the most stringent standard prevails. Durations are indicative learning time; module references (CRC-L1-nn) belong to the Academy course-module numbering universe and are distinct from operational QMS/SOP numbering. Produced under YCO-SOP-ACAD-001. Retention: 25 years from supersession. Uncontrolled when printed.

ENROLMENT & ENQUIRIES

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