

PROGRAM SYLLABUS · 2026

# OCREA™ Clinical Development Capability Platform

Standardizing clinical decision-making across oncology development for sponsor-side professionals — Medical Monitors, Clinical Scientists, and Clinical Science Liaisons.

<b>51</b> MODULES	<b>9</b> TOOLS	<b>9</b> TRACKS	<b>3</b> CERT LEVELS	<b>12–20</b> WEEKS	<b>16</b> FRAMEWORKS
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## Who this program is for

OCREA™ is the first training system built specifically for the sponsor-side professionals who drive clinical drug development decisions. Most pharmaceutical training is designed for site investigators. OCREA is the opposite — it addresses the decisions made by Medical Monitors reviewing SAEs, Clinical Scientists designing amendments, and Clinical Science Liaisons preparing regulatory submissions.

<b>Medical Monitor (MM)</b>	Safety oversight, eligibility decisions, dose escalation, SAE adjudication, regulatory response authoring.
<b>Clinical Scientist (CS)</b>	Protocol design, amendment strategy, CRF development, data review framework, CSR construction.
<b>Clinical Science Liaison (CSL)</b>	Cross-functional integration, investigator engagement, scientific communication, site strategy.
<b>Organizations</b>	Pharma, biotech, CROs — onboarding, capability building, standardization, regulatory readiness.

## What makes OCREA different

**Decision-level, not knowledge-level.** Every module and every tool addresses the specific judgment calls that define high-quality clinical development — not abstract knowledge tests. Frameworks for SAE attribution, eligibility waivers, signal detection, dose optimization, AdCom preparation, and CRL response are taught as structured decisions with documented rationale.

**Sponsor-side operational realism.** OCREA was designed by an oncology Medical Monitor with 16+ years of senior clinical development experience at Pfizer across Phase 1 through Phase 4 and global submissions (including Besponsa, Lorlatinib, Aromasin programs). The content reflects how decisions are actually made in sponsor organizations — not site-facing adaptations of GCP training.

**Regulatory-grade alignment.** Aligned with ICH E6(R3), ICH E2A/E2B safety reporting, ICH E9(R1) estimands, FDA Oncology guidance (current), EMA guidelines, EU HTA Regulation (JCA), Project Optimus, and FDORA post-approval requirements.

TRAINING PRODUCT · 51 MODULES

# The 9-Track Curriculum

Fifty-one modules organized across nine content tracks. Each track is sequenced from foundational to advanced. Modules combine conceptual instruction with applied scenario-based knowledge checks. Total curriculum duration: 12–20 weeks.

<b>Track 1</b>	<b>Oncology Science Foundation</b>	<b>4</b>	Cancer biology & hallmarks, drug classes & mechanisms of action, tumor immunology & IO principles, biomarkers & precision oncology.
<b>Track 2</b>	<b>Clinical Trial Methodology</b>	<b>8</b>	Endpoints (OS, PFS, ORR, DOR), RECIST & iRECIST, CTCAE, trial design Phase 1–3, non-RECIST response, special populations, RBQM, ongoing eligibility & medical waivers.
<b>Track 3</b>	<b>Clinical Development Phases</b>	<b>7</b>	DLT framework (BOIN, MTD, RP2D), combination attribution, FIH consent & pediatric Phase 1, Phase 2 single-arm & go/no-go, Phase 3 RCT design, Phase 4 & RWE, site start-up.
<b>Track 4</b>	<b>Safety Operations</b>	<b>5</b>	Individual SAE 6-Step Framework, Signal Detection 4-Move Framework, irAEs & immune-mediated toxicities, safety in combination regimens, dose interruption/reduction/re-challenge.
<b>Track 5</b>	<b>Data Review &amp; Benefit-Risk</b>	<b>6</b>	Efficacy data review, DSMB package construction, benefit-risk with imperfect data, program-level benefit-risk, estimands & missing data, database lock & pre-analysis data review.
<b>Track 6</b>	<b>Regulatory Strategy</b>	<b>5</b>	FDA pathways & FDORA, EMA/HTA/JCA, NMPA & China strategy, submission strategy & label negotiation, CSR medical writing & Clinical Overview.
<b>Track 7</b>	<b>Field Excellence</b>	<b>4</b>	KOL management & scientific exchange, site selection & trial readiness, competitive landscape intelligence, medical communication in the field.
<b>Track 8</b>	<b>Leadership &amp; Strategy</b>	<b>8</b>	MM leadership & conflict resolution, program strategy & drug lifecycle, safety data management, investigator management, agency interaction & ODAC prep, market access & HTA, scientific/regulatory writing, ISS/ISE & submission integration.
<b>Track 9</b>	<b>Expert Practice</b>	<b>4</b>	Advanced clinical decision-making, advanced data interpretation, protocol design workshop, Clinical Reality Layer.

## Module architecture

Each of the 51 modules contains: (1) conceptual instruction with explicit regulatory anchors, (2) operational frameworks for the key decisions in that content area, (3) applied scenario-based knowledge checks with immediate educational feedback, and (4) role-specific filters so MM / CS / CSL audiences see only what applies to their responsibilities. Progress tracking is automatic across sessions.

**Sample frameworks developed across the program:** SAE 6-Step Review, Signal Detection 4-Move, DLT BOIN/MTD/RP2D framework, irAE organ-system classification, Hy's Law detection, estimand framework per ICH E9(R1), benefit-risk with imperfect data, 3-Question Eligibility framework, FDORA post-approval diligence, ODAC 7-step preparation, CTD Module 2.5/2.7 architecture, ISS/ISE integration.

TOOLS PRODUCT · 9 INSTRUMENTS

# The 9-Phase Tools Hub

Nine operational tools mapped to the nine phases of the Medical Monitor workflow — from protocol design through post-approval lifecycle. Structured decision frameworks with interactive checklists, classification trees, and documented rationale templates. Each tool prints as a professional PDF.

<b>Phase 1</b>	<b>Protocol Review Checklist</b>	Protocol Development & Study Design — pre-submission design review across 6 domains: eligibility, endpoints, DLT & dose, safety plan, statistical design, ICF scientific content (48 verification items).
<b>Phase 2</b>	<b>Site Activation Readiness</b>	Site Start-up & Trial Activation — essential docs review, IRB/EC strategy with modification classification, SIV clinical content delivery, FPI readiness 5-domain framework, site signal recognition (36 verification items).
<b>Phase 3</b>	<b>Eligibility Decision Tool</b>	Enrollment & Eligibility Review — 3-Question Framework for waiver requests, 5 edge case types with drill-down guidance, pattern monitoring across sites, amendment trigger identification.
<b>Phase 4</b>	<b>Safety Monitoring Command</b>	Active Trial Conduct — SAE 6-Step Framework, Signal Detection 4-Move Framework, causality attribution discipline, protocol deviation tracking, DSMB preparation, cross-site pattern recognition.
<b>Phase 5</b>	<b>Oncology Data Review</b>	Database Lock & Pre-Analysis — day-to-day CRF review across 13 CRF domains, Hy's Law detection, cardiac monitoring, efficacy verification, narrative thread construction.
<b>Phase 6</b>	<b>Tables &amp; Listings Review</b>	CSR Preparation — TLF medical review for CSR construction, what to check, flag framework, sign-off documentation.
<b>Phase 7</b>	<b>IND / NDA / BLA Submission</b>	Submission Package — CTD Module 2.5 Clinical Overview, Module 2.7 Clinical Summary, ISS/ISE integration, submission architecture & MM sign-off.
<b>Phase 8</b>	<b>IR Response &amp; AdCom Prep</b>	Regulatory Review Response — FDA/EMA Information Requests, AdCom/ODAC 7-step preparation timeline, label negotiation across sections, CRL response framework.
<b>Phase 9</b>	<b>PMR/PMC Lifecycle Tracker</b>	Post-Approval Lifecycle — PMR vs PMC distinction, confirmatory trials under FDORA, PSUR/PBRER framework, REMS compliance, label expansion pathways.

## Tool features

- Interactive** Checklists with saved state, decision trees with drill-down, classification frameworks with documented rationale.
- Printable** Every tool prints as a professional PDF (clean or with checklist state). Portable deliverable for meetings, audits, and regulatory inspections.
- Regulatory-anchored** Each framework cites the specific regulatory reference (ICH E6(R3), FDA guidance, EMA guideline, FDORA) that governs the decision.

## CERTIFICATIONS · LICENSING · ACCESS

# How to Engage

OCREA is available for individual learners, teams, and enterprise deployments. Access is licensed and code-protected. Certificates are issued upon completion of track or full-program assessments.

## Three certification levels

<b>Level 1 · Foundation</b>	Completion of Tracks 1–2 plus three selected tracks aligned with the learner's role. Assessment at Kirkpatrick Level 1–2. Suitable for new MM/CS/CSL onboarding.
<b>Level 2 · Proficient</b>	Full 9-track curriculum plus integrated case work across the Clinical Reality Layer. Applied decision-making assessment with scenario-based knowledge checks.
<b>Level 3 · Advanced</b>	Level 2 plus capstone — original clinical development decision memo or protocol design deliverable reviewed by program faculty.

## Licensing models

**Individual license** — single user, full Training Program and Tools Hub access, 12-month term, no redistribution. Includes certification upon completion.

**Team license** — defined seat count (typically 5–25 users), 12-month term, admin tracking, shared standardization across a team or function.

**Enterprise license** — company-wide deployment (25+ users), 12 or 24-month term, custom track selection possible, branded certifications, LMS integration support, annual strategy review with the founder. Pricing reflects seat count and deployment complexity.

## Regulatory & methodological alignment

- ICH E6(R3) — Good Clinical Practice (2023 update)
- ICH E2A / E2B — Safety reporting standards
- ICH E9(R1) — Estimand framework
- FDA Oncology Center of Excellence guidance (current)
- FDA Project Optimus — Dose optimization
- FDA Project Confirm — Accelerated Approval diligent pursuit (FDORA 2022)
- EMA Scientific Advice / CHMP guidelines
- EU HTA Regulation — Joint Clinical Assessment (JCA)
- NMPA regulatory framework (for global development programs)
- Kirkpatrick Levels 1–2 (assessment methodology)

## Request access or schedule a demo

**Email** [info@ocreaacademy.com](mailto:info@ocreaacademy.com)

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