# Healthcare Research Project Management: Principles and Practice

14 – 18 June 2027
Tokyo

AGILE LEADERS
Training Center

AGILE LEADERS
Training Center

# Healthcare Research Project Management: Principles and Practice

**Ref:** 921_169076 **Date:** 14 – 18 June 2027 **Location:** Tokyo **Fees:** 10000 Euro

## Overview

Healthcare Research Project Management: Principles and Practice is a one-week course designed for clinical and health sciences professionals seeking to lead research initiatives with disciplined operational control. Healthcare studies frequently encounter protocol deviations, recruitment bottlenecks, budget overruns, and data integrity issues when scientific objectives lack structured project administration. The course bridges clinical governance and project management methodologies, using concrete planning matrices, risk logs, and monitoring frameworks. Healthcare Research Project Management: Principles and Practice is delivered by Agile Leaders Training Center.

## Who Should Attend

- Clinical research coordinators responsible for site operations, patient visit schedules, and protocol adherence
- Principal investigators and academic researchers responsible for project timelines, grant deliverables, and trial governance
- Clinical project managers responsible for resource allocation, vendor contracts, and multi-site milestone tracking
- Research operations managers responsible for institutional trial portfolios, resource forecasting, and compliance oversight
- Biostatistical and data management leads responsible for study data collection workflows and interim analysis schedules

The course assumes participants manage or support clinical, translational, or epidemiological research studies, and it leaves out introductory clinical medicine and laboratory techniques.

## Departments and Industries

The course serves multidisciplinary teams across varied sectors involved in scientific inquiry and health technology evaluation.

- Hospital clinical research centers and trial management offices
- Pharmaceutical clinical operations and medical affairs divisions
- Biotechnology product development and clinical research units
- Academic medical centers and university research institutes
- Contract research organizations supporting health product evaluation
- Medical device clinical evaluation and regulatory affairs departments

## Learning Objectives

By the end of this course, participants will be able to:

- Build a research work breakdown structure aligned with ICH GCP standards
- Prioritize participant recruitment and retention strategies using critical path analysis
- Analyze clinical study budgets using earned value management metrics
- Evaluate clinical protocol risks using failure mode and effects analysis matrices
- Diagnose clinical data quality gaps using statistical process control monitoring plans

AGILE LEADERS
Training Center

## Course Agenda

### Day 1: Research Initiation and Protocol Governance

- Research Project Charter Development and Scope Definition
- ICH GCP Principles and Institutional Governance Integration
- SPIRIT Guidelines Alignment for Protocol Operationalization
- Stakeholder Mapping and RACI Matrix for Clinical Trials
- Institutional Ethics Review Feasibility Checklist

### Day 2: Study Scheduling and Participant Operations

- Clinical Work Breakdown Structure Formulation
- Critical Path Method for Patient Recruitment Timelines
- Subject Enrollment Funnel and Site Activation Milestones
- Resource Allocation Matrix for Multi-Center Studies
- Clinical Trial Supply Logistics and Chain-of-Custody Tracking

AGILE LEADERS
Training Center

## Day 3: Financial Management and Quality Oversight

- Clinical Study Budget Formulation and Milestone Costing
- Earned Value Management for Research Grant Tracking
- Quality by Design Principles in Clinical Protocols
- Failure Mode and Effects Analysis for Trial Risk Logs
- Corrective and Preventive Action Issue Escalation Logs

## Day 4: Data Governance and Vendor Monitoring

- Electronic Data Capture Source Data Verification Protocols
- Good Clinical Data Management Practice Guidelines
- Clinical Vendor Service Level Agreements and Oversight Plans
- Risk-Based Monitoring Matrices and Key Risk Indicators
- Protocol Deviation Tracking Logs and Interim Audit Checklists

## Day 5: Applied Practice and Trial Delivery

- Practical Exercise: Schedule Recovery Plan for Clinical Recruitment Delays
- Practical Exercise: Budget Variance Correction Using Earned Value Analytics
- Practical Exercise: Multi-Site Clinical Audit Finding Remediation
- Practical Exercise: Risk-Based Monitoring Dashboard Configuration
- Capstone Exercise: Integrated Clinical Study Management Plan Simulation

AGILE LEADERS
Training Center

## Practical Exercises

Participants apply core project management frameworks to simulated research scenarios through structured group activities.

- Suggested activity: Construct a study work breakdown structure and critical path schedule for an investigator-initiated clinical trial.
- Suggested activity: Develop a clinical risk register and mitigation matrix addressing site non-compliance and patient retention dropouts.
- Suggested activity: Calculate earned value cost metrics and formulate corrective action plans for a delayed research grant.

## FAQs

### Who should take Healthcare Research Project Management: Principles and Practice, and what experience is expected?

This course suits clinical investigators, research coordinators, and trial managers who oversee health studies. The course assumes familiarity with basic research concepts and active involvement in study operations, focusing on execution frameworks rather than foundational science or laboratory techniques.

### How does healthcare research project management differ from general project management?

Healthcare research project management integrates mandatory bioethics guidelines, participant safety requirements, and data integrity standards into traditional project lifecycles. Standard project management focuses primarily on schedule and cost, whereas healthcare research balances these constraints against protocol adherence and human subject protection.

### Which risk assessment tools are used in healthcare research project management?

Healthcare research project management relies on Failure Mode and Effects Analysis, risk-based monitoring matrices, and centralized risk registers. These tools prioritize hazards to patient safety, protocol compliance, and primary endpoint validity before trial sites begin recruitment.

AGILE LEADERS
Training Center

## How does healthcare research project management support multi-center study tracking?

Multi-center coordination requires standardized Work Breakdown Structures, shared Key Risk Indicators, and unified milestone trackers. These instruments allow project leads to monitor decentralized site activation, subject enrollment velocity, and data quality across disparate clinical environments.

## Conclusion

Participants leave with an operational Clinical Study Management Plan tailored to their organizational research portfolio. This definitive work product standardizes milestone tracking, budget governance, and protocol risk controls across all active study sites. Implementation of this asset reduces study startup delays and ensures rigorous data integrity throughout the trial lifecycle.