Clinical Trial Delivery: Predictive Site Selection, Recruitment Modelling, Oversight Course

10 – 14 May 2027
Tokyo

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Programme Summary

Clinical trial delivery is the subject of this one-week training course for clinical operations leaders, feasibility managers and quality heads, ending in a trial delivery plan for one study. Trials run late when sites are chosen on habit, recruitment is forecast on hope and monitoring effort is spread evenly across risks that are not equal. The programme moves from the delivery problem to predictive site selection, recruitment modelling, risk-based oversight and applied planning on a study the participant selects. Mars Training Centre UK delivers this programme on clinical trial delivery to mixed-organisation cohorts.

The Business Case

Sponsors and research organisations commit budgets before the first participant is enrolled, and delays in enrolment or data quality are costly to recover. Teams that compare site evidence, model recruitment against realistic assumptions and direct oversight at the highest risks can act sooner and explain their choices to study boards. Without that discipline, models are adopted without checks, and teams discover problems only at database lock.

- Enrolment Delays: Fall as site choices and recruitment forecasts rest on tested historical evidence.
- Monitoring Effort: Is directed at critical data and processes instead of being spread evenly across all sites.
- Data Queries: Fall as data quality signals are reviewed during the study rather than after it.

Principles and Evidence Base

- ICH E6R3 Good Clinical Practice: Its emphasis on proportionate, risk-based quality management shapes the oversight design built in Session 4.
- Risk-Based Quality Management: Identifying critical-to-quality factors guides which data and processes receive attention in Sessions 3 and 4.
- Fit-for-Purpose Oversight: Matching the level of control to the risk of a process frames the review of model-supported decisions in Session 4.

Intended Participants

- Clinical operations leaders who own timelines, budgets and delivery of a portfolio of studies.
- Feasibility and site selection managers who decide where studies are placed.
- Quality and monitoring leads who set oversight plans and review study data.
- Data and analytics leaders who build or buy models for trial teams.
- Sponsor representatives who approve study plans and escalations.

Typical settings include pharmaceutical sponsors, contract research organisations, hospital research units and medical device developers.

Learning Outcomes

1. Participants will be able to construct a delivery risk map for a study that links timeline, site and data risks to named decisions.
2. Participants will be able to evaluate site selection scores for bias, data gaps and fit with study needs.
3. Participants will be able to diagnose weaknesses in recruitment forecasts before they enter a study plan.
4. Participants will be able to prioritise monitoring effort against critical data and process risks.
5. Participants will be able to justify an oversight and validation plan for model-supported decisions to a study board.
6. Participants will be able to prepare a delivery plan that a study team can adopt.

Programme Structure

Day 1: Clinical Trial Delivery Risks and Decision Points

Where in clinical trial delivery can better evidence change a decision about time, cost or quality?

- Delivery Risk Map
- Study Milestone Chart
- Decision Point Register
- Historical Data Inventory
- Value and Risk Screening Grid

Day 2: Predictive Site Selection

How are candidate sites compared on evidence rather than habit?

- Site Feasibility Scorecard
- Historical Performance Dataset Review
- Ranking Model Comparison
- Bias and Data Gap Check
- Site Shortlist Rationale Sheet

Day 3: Recruitment Modelling and Forecasting

How realistic is a recruitment forecast, and what happens when it proves wrong?

- Enrolment Curve Model
- Screening Funnel Analysis
- Assumption Stress Test
- Forecast Error Review
- Recovery Action Trigger Table

Day 4: Risk-Based Oversight and Data Quality

How is monitoring directed at critical data, and how are model-supported decisions kept under control?

- Critical-to-Quality Factor List
- Key Risk Indicator Set
- Data Anomaly Review Protocol
- Model Validation Checklist
- Oversight Escalation Matrix

Day 5: Trial Delivery Plan for One Study

Do the site choices, recruitment forecast and oversight rules work together for one study?

- Applying the Session 1 Decision Point Register
- Testing the Session 2 Site Shortlist Rationale Sheet
- Stress-Testing the Session 3 Enrolment Curve Model
- Checking the Session 4 Oversight Escalation Matrix
- Completing the Trial Delivery Plan

Methodology

The programme uses a data workshop method built on a shared case of a multi-site study that is behind its enrolment target, with historical site records and a draft monitoring plan. Participants build each artefact on the case, then on a study from their own portfolio, with written facilitator feedback in every session.

- Suggested activity: Ranking a set of candidate sites and testing how the ranking changes when data gaps are filled.
- Suggested activity: Stress-testing an enrolment forecast against slower screening and higher dropout.
- Suggested activity: Presenting an oversight plan to a mock study board.

Capstone Output

Each participant completes a trial delivery plan for one study. It holds a delivery risk map, a site shortlist and rationale, a recruitment forecast with recovery triggers, a risk-based oversight plan and a model validation note. The plan is used at work to open a feasibility discussion, brief a study board and agree what each team will monitor.

Frequently Asked Questions

Is clinical trial delivery training suitable for leaders without a data science background?

Yes. Clinical trial delivery training uses cases and templates, assuming experience in clinical operations, feasibility, quality or study management, but no earlier work building models.

Which guideline does clinical trial delivery training rest on?

Clinical trial delivery training rests on ICH E6R3 Good Clinical Practice, its risk-based quality management and fit-for-purpose oversight principles.

How is the plan from clinical trial delivery training used at work?

You use the trial delivery plan to open a feasibility discussion, brief a study board and agree what each team monitors.

How does clinical trial delivery training differ from general project management training?

Clinical trial delivery training centres on sites, recruitment and risk-based oversight of study data, while general project management training covers scope, schedule and cost across all industries.