AI in Pharma Pipelines Training: Drug Discovery Choices, Trial Evidence and Oversight

26 – 30 October 2026
Rome

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Ref: 760_36315 **Date:** 26 – 30 October 2026 **Location:** Rome **Fees:** 5500 GBP

Programme Summary

AI in pharma pipelines is the subject of this one-week training course for research, development and portfolio leaders at managerial level, ending in a pipeline AI decision pack for one drug candidate. Medicine developers receive many offers of AI for target selection, molecule design and trial planning, yet few can judge which claims rest on evidence. The programme moves from scientific principles to data diagnosis, trial evidence design and oversight, using case analysis throughout. Mars Training Centre UK delivers this programme on AI in drug discovery to mixed-organisation cohorts.

The Business Case

Pipeline decisions are costly to reverse. A model that ranks targets or selects patients on weak data can send a candidate into late development before the flaw is clearly seen, and a purchased platform can bind an organisation to claims that were never tested. Leaders who question the evidence behind a model protect capital, scarce research time and patients alike.

- Development Cycle Time: Falls where AI is used only for steps with a tested benefit and a clear owner.
- Late-Stage Attrition Exposure: Is reduced as weak candidates are challenged earlier with stronger evidence.
- Regulatory and Data Risk: Is lowered as records, validation and human review are agreed before a submission is prepared.

Principles and Evidence Base

- ICH E6R3 Good Clinical Practice: Frames risk-proportionate trial conduct, applied in Session 3 to AI-supported trial decisions.
- GAMP 5 Risk-Based Approach to Computerised Systems: Guides the classification and validation of software used in regulated work, applied in Session 4.
- GxP Data Integrity Principles: Set expectations for traceable records, applied in Session 2 to training data.

Intended Participants

- Research and development leaders who decide which AI tools enter discovery work.
- Portfolio and pipeline managers who rank candidates and allocate budgets.
- Clinical development managers who plan trials and read their evidence.
- Quality and data managers who must defend model-supported decisions.

Typical settings include pharmaceutical companies, biotechnology firms, contract research organisations and hospital research units.

Learning Outcomes

1. Participants will be able to evaluate claims about AI in drug discovery against the evidence supplied.
2. Participants will be able to diagnose data weaknesses that limit a model.
3. Participants will be able to construct an evidence grid for an AI-supported trial decision.
4. Participants will be able to prioritise AI opportunities using value, risk and readiness.
5. Participants will be able to design a validation and human review plan for a model.
6. Participants will be able to justify a build, buy or partner choice to an executive committee.

Programme Structure

Day 1: AI in Drug Discovery and the Pipeline Map

Where does AI in drug discovery add evidence, and where does it only add speed?

- Discovery to Development Stage Map
- Target Identification Evidence Ladder
- Generative Molecule Design Claim Check
- Build, Buy or Partner Decision Matrix
- Pipeline AI Opportunity Long-List

Day 2: Data and Model Diagnosis

Is the data behind a model good enough to support the decision it informs?

- Assay and Omics Data Quality Review
- GxP Data Integrity Principles Checklist
- Bias and Coverage Gap Test
- Training Data Provenance Record
- Model Performance Claim Audit

Day 3: Designing AI-Supported Trial Evidence

How can AI help plan a trial without weakening the evidence it produces?

- Patient Selection and Enrolment Modelling
- ICH E6R3 Risk Proportionality Grid
- External and Synthetic Control Caveats
- Trial Site Feasibility Scoring
- Endpoint Signal Review Protocol

Day 4: Validation and Oversight Controls

What must be in place before a model is relied on in regulated work?

- GAMP 5 Software Category Mapping
- Model Validation Plan Template
- Human Review and Override Rules
- Model Drift Monitoring Log
- Submission Evidence Dossier Outline

Day 5: Pipeline AI Decision Pack

Do the earlier tools combine into one decision that a committee can approve?

- Applying the Session 1 Opportunity Long-List
- Testing the Session 2 Data Quality Review
- Checking the Session 3 Evidence Grid
- Rehearsing the Session 4 Validation Plan
- Completing the Pipeline AI Decision Pack

Methodology

The programme uses case analysis built on prepared files for a small-molecule candidate and a biologic candidate, each with vendor claims, assay summaries, trial design drafts and a sample validation record. Participants work in small groups of four, test the claims against the evidence, and defend their conclusions to peers in each session.

- Suggested activity: Ranking three AI target proposals by the strength of their evidence.
- Suggested activity: Finding the data gaps in a supplied patient selection model.
- Suggested activity: Arguing a build, buy or partner choice before a mock committee.

Capstone Output

Each participant completes a pipeline AI decision pack for one drug candidate. It holds an opportunity ranking, a data quality finding, a trial evidence grid, a validation plan and a build, buy or partner recommendation. The pack is used at work to brief a committee.

Frequently Asked Questions

Is a course on AI in drug discovery suitable for leaders without a data science background?

Yes. AI in drug discovery is taught through prepared cases and checklists. It assumes experience in research, development, portfolio or quality work, but no coding.

Which standards does AI in pharma pipelines rest on?

AI in pharma pipelines is examined against ICH E6R3 for good clinical practice, GAMP 5 for computerised systems and GxP data integrity principles.

How is the decision pack on AI in drug discovery used at work?

You use the decision pack to brief your committee and set the rule for whether an AI tool enters the pipeline.

How does AI in drug discovery differ from a course on regulatory affairs?

AI in drug discovery concentrates on judging models, data and trial evidence, while a regulatory affairs course concentrates on submissions and procedures.