Lecture 14:

Ethics, Regulation, and Implementation

Responsible AI in healthcare

Regulatory landscape

Implementation challenges

Introduction to Biomedical Data Science

Lecture Contents

Part 1/3:

Ethics in Biomedical AI

1. Principles and values
2. Practical challenges
3. Governance frameworks

Beneficence Principles

- Do no harm
- Patient benefit
- Risk-benefit analysis
- Unintended consequences
- Precautionary principle

Privacy Concerns

- Data sensitivity
- Re-identification risks
- Genetic privacy
- Family implications
- Data breaches

Informed Consent

- AI transparency
- Data usage
- Future use provisions
- Withdrawal rights
- Capacity issues

Data Ownership

- Patient rights
- Institutional claims
- Commercial interests
- Benefit sharing
- Indigenous data

Algorithmic Bias

Problems	Solutions
Sources of bias	Mitigation strategies
Health disparities	Continuous monitoring
Fairness metrics	Regular auditing

Health Disparities

- Digital divide
- Representation gaps
- Access barriers
- Outcome inequities
- Social determinants

Transparency

- Model explainability
- Decision rationale
- Uncertainty communication
- Audit trails
- Public reporting

Trustworthy AI

Building confidence through openness

Part 2/3:

Regulatory Framework

1. Global regulations
2. Approval pathways
3. Compliance requirements

FDA Regulations

Software as Medical Device

AI/ML-based diagnostic & therapeutic tools

510(k) Process

Substantial equivalence pathway

De Novo Pathway

Novel devices, low-moderate risk

PMA Requirements

High-risk devices, clinical data

Breakthrough Device Designation

Expedited review for devices treating life-threatening conditions • Priority access to FDA experts • Flexible clinical trial designs

CE Marking

MDR Requirements

- Medical Device Regulation 2017/745
- Technical documentation
- Conformity assessment

Risk Classification

- Class I, IIa, IIb, III
- Rule-based classification
- Notified Body involvement

Clinical Evaluation

- Clinical data requirements
- Benefit-risk analysis
- Clinical evaluation report

Post-market Surveillance

- PMS plan & reports
- Vigilance reporting
- PSUR requirements

UKCA Divergence

- Post-Brexit UK requirements • Separate conformity assessment

- UK Approved Body vs. Notified Body • Dual marking considerations

Clinical Validation

Study Design Requirements → **Performance Standards** → **Safety Endpoints** → **Real-world Evidence** → **Post-approval Studies**

Endpoints

Primary & secondary outcomes, statistical power, sample size

Timeline

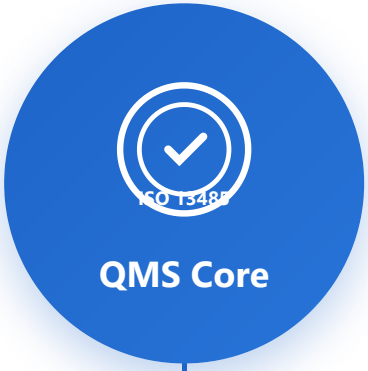
Study duration, follow-up periods, interim analyses

Software as Medical Device

SaMD Framework

- SaMD framework
- Risk categorization
- Quality management
- Cybersecurity
- Updates and modifications

Quality Management



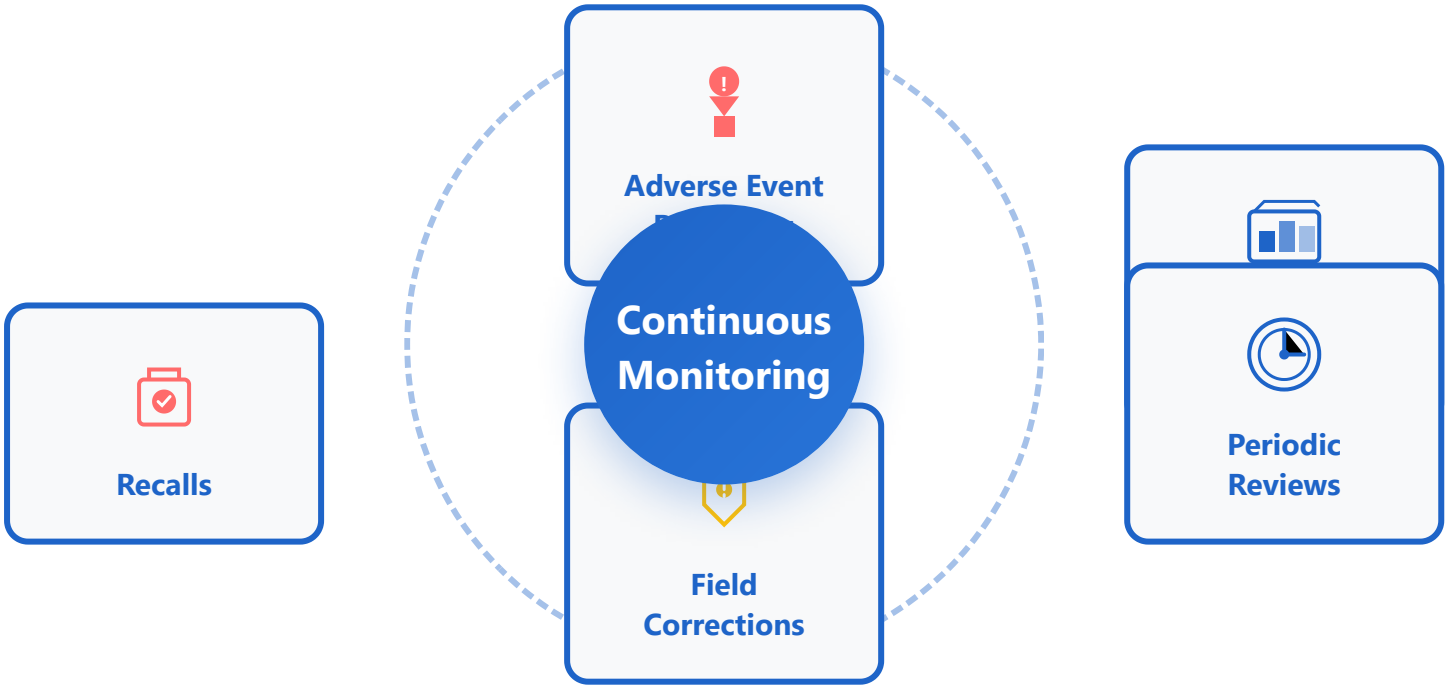
Design Controls

Risk Management

Document Control

CAPA Systems

Post-market Surveillance

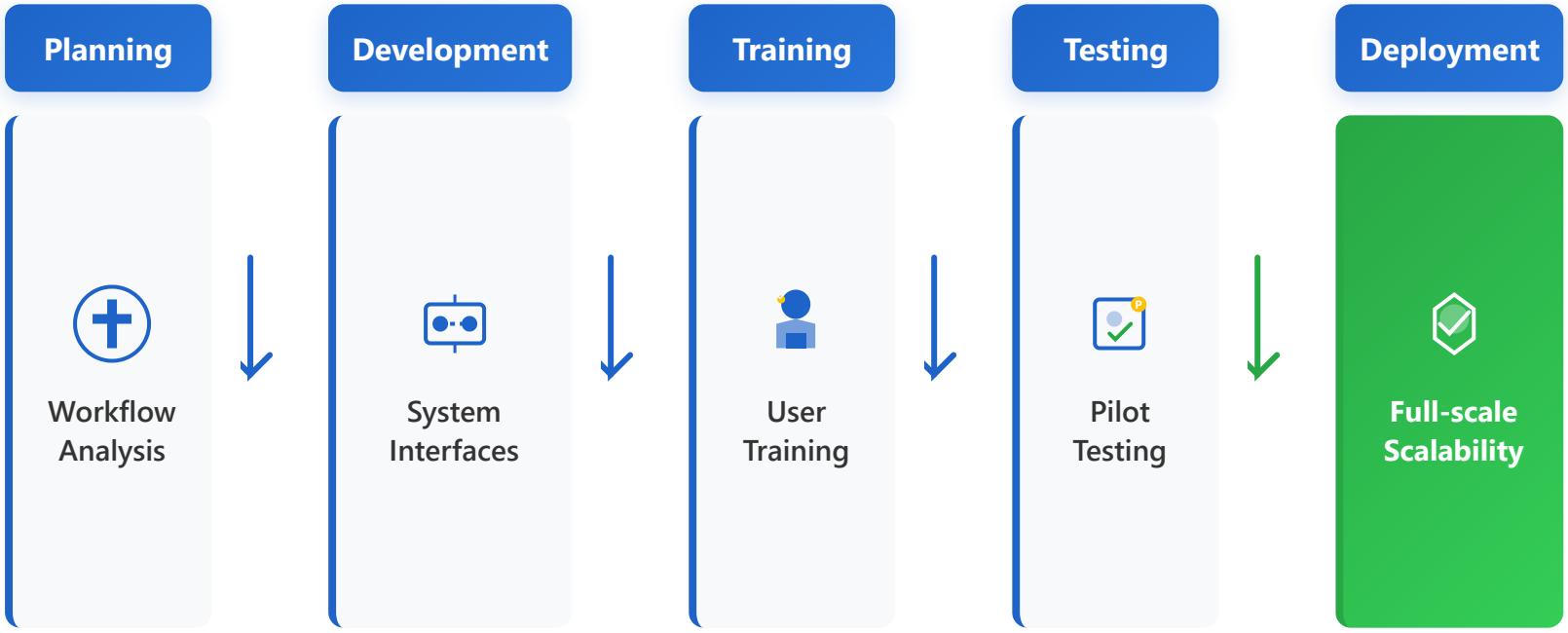


Part 3/3:

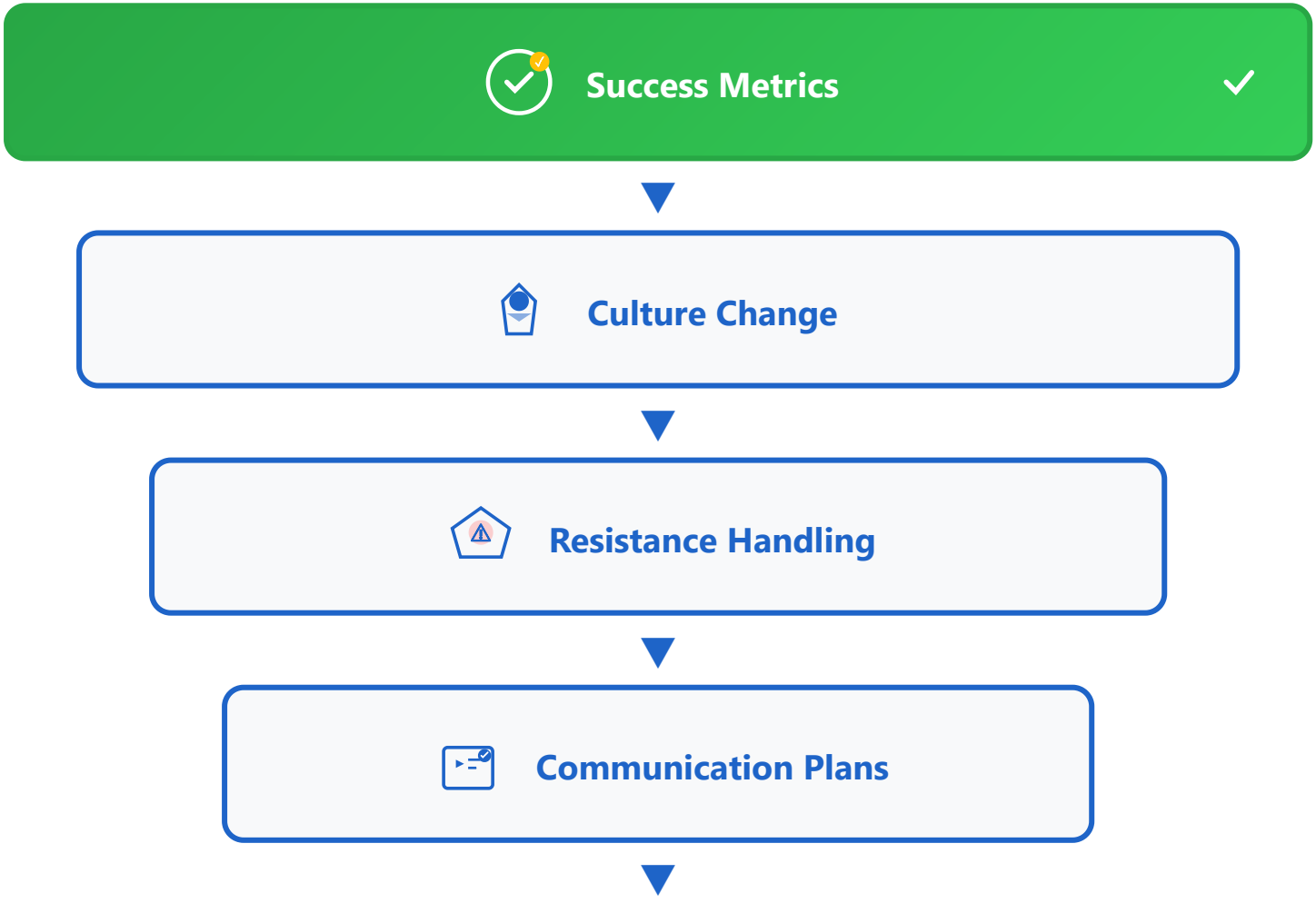
Implementation

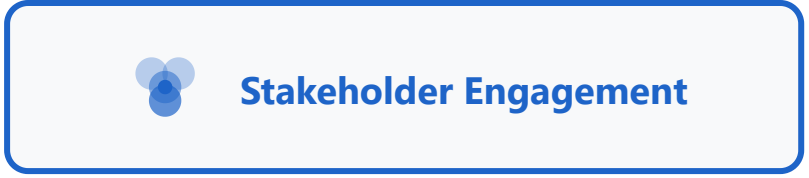
1. Deployment strategies
2. Change management
3. Success factors

Clinical Integration

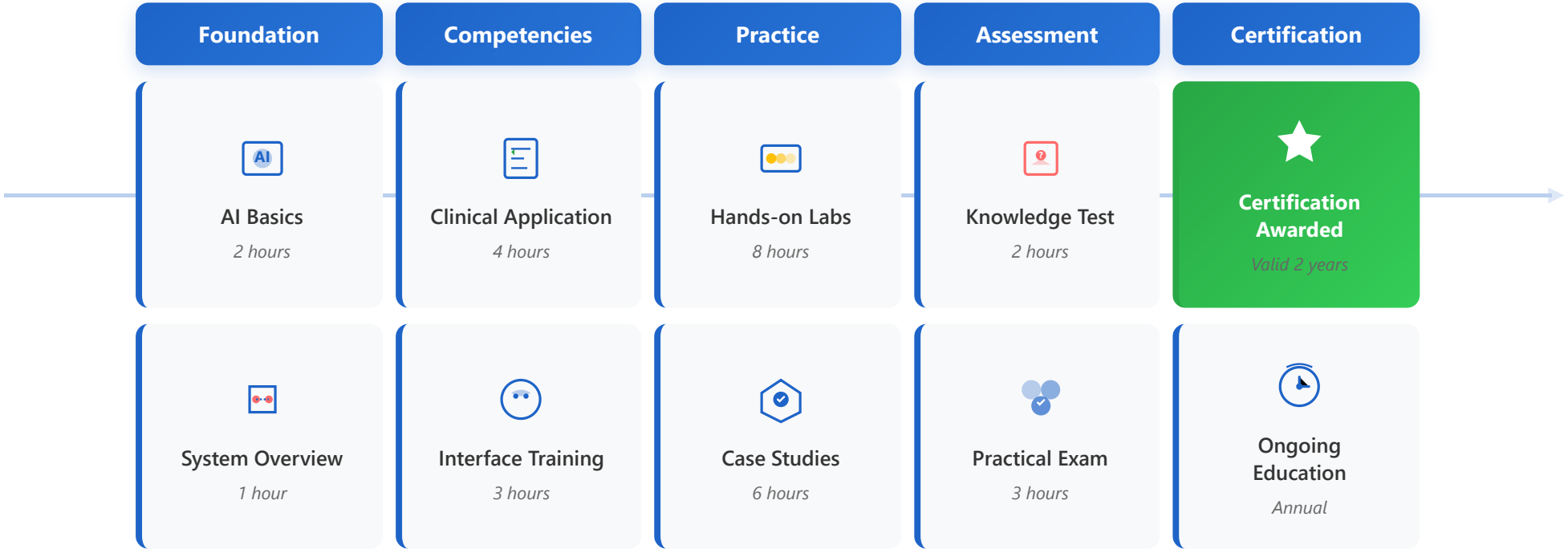


Change Management




Stakeholder Engagement

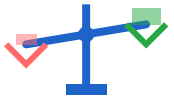
Training Requirements



Cost-benefit Analysis

Costs

Initial Investment	-$500K
Training Time	-$120K
Infrastructure	-$200K
Maintenance	-$80K/yr



ROI
185%
3 years

Payback Period
18 months

Benefits

Productivity Gain	+$450K/yr
Quality Improvement	+$280K/yr
Risk Reduction	+$320K/yr
Indirect Benefits	+$180K/yr

Reimbursement

Step 3

CPT Code Assignment

Category III codes for new technologies

Pricing Strategy

Market analysis & benchmarking

Coverage Determination

Payer review process & negotiations

12-18 months

Evidence Generation

Clinical & economic outcomes data

Value-based Contracts

Performance-based payment models

Liability Issues

	Developer	Healthcare Provider	Clinician	Insurer
Malpractice	Low	Medium	High	Shared
Product Liability	High	Shared	Low	Low
Insurance Coverage	Required	Required	Required	Variable
Indemnification	Negotiated	Negotiated	Partial	Limited
Risk Allocation	Distributed	Distributed	Distributed	Transfer

Global Perspectives

Future Regulations

2024

AI Act Implementation (EU)

Enacted

First comprehensive AI regulation framework enacted

2025

Adaptive Regulations

In Progress

Real-time learning systems, continuous monitoring frameworks

2026

Regulatory Sandboxes

Planned

Protected innovation spaces for testing novel AI applications

2027

International Coordination

Proposed

Global harmonization standards for AI in healthcare

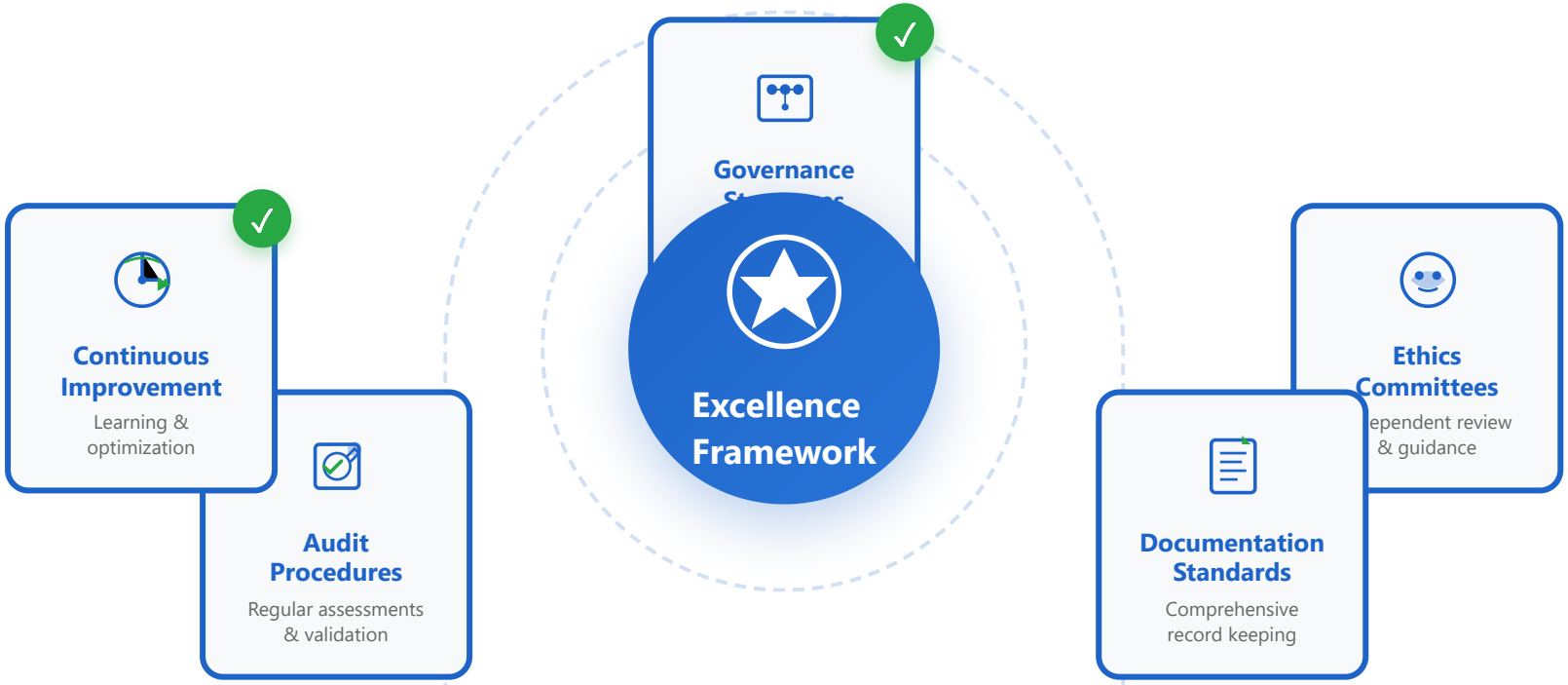
2028+

Emerging Issues Framework

Horizon

Quantum AI, synthetic data, autonomous clinical decisions

Best Practices



Case Studies

SUCCESS

Diabetic Retinopathy AI

Google Health / Screening Tool

90%	98%	50K+
Sensitivity	Specificity	Patients

- Strong clinical validation across populations
- Clear regulatory pathway (FDA approved)
- Effective provider training program

LESSONS

Watson for Oncology

IBM / Treatment Recommendations

Limited	High	Variable
Adoption	Cost	Results

- Insufficient local data adaptation
- Over-promised capabilities
- Poor integration with workflows

EVOLVING

Sepsis Prediction Model

Epic Systems / Risk Alert

63%	Wide	Mixed
PPV	Deploy	Reviews

- Alert fatigue concerns addressed
- Continuous model improvement
- Need for local calibration

LANDMARK

IDx-DR

First Autonomous AI / FDA De Novo

1st	87%	2018
FDA AI	Accuracy	Approved

- Clear intended use definition
- Robust clinical trial design
- Set regulatory precedent

Discussion Scenarios

COMPLEX

Ethical Dilemma: Bias in AI Diagnosis

Your AI system shows 95% accuracy overall but only 70% for minority populations. The hospital wants to deploy immediately due to staffing shortages.

What ethical principles guide your decision?

20 min

MODERATE

Regulatory Challenge: Cross-Border Data

Your AI needs training data from EU, US, and Asia. Each region has different privacy laws. How do you ensure compliance?

Design a compliant data strategy

15 min

MODERATE

Implementation: Resistance to Change

Senior physicians refuse to use the new AI system, citing trust issues. Junior staff are enthusiastic but lack authority.

Create a change management plan

15 min

COLLABORATIVE

Group Exercise: ROI Calculation

Calculate the 5-year ROI for an AI radiology system. Consider costs, benefits, and risks.

Teams present business case

30 min

ADVANCED

Solution Development: Complete AI Governance Framework

Design a comprehensive governance framework for a multi-site healthcare system implementing various AI tools. Address ethics committees, audit procedures, liability allocation, training requirements, and continuous improvement processes. Consider stakeholder engagement, regulatory compliance across jurisdictions, and long-term sustainability.

Develop full implementation roadmap with milestones and success metrics

45 min

Thank you

Key Takeaways & Resources

- Regulatory resources
- Ethics frameworks
- Professional organizations