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

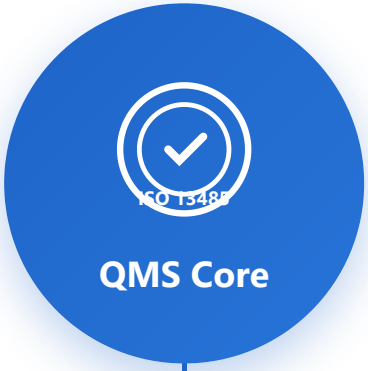
Study duration, follow-up periods, interim analyses

Software as Medical Device

SaMD Framework

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

Quality Management



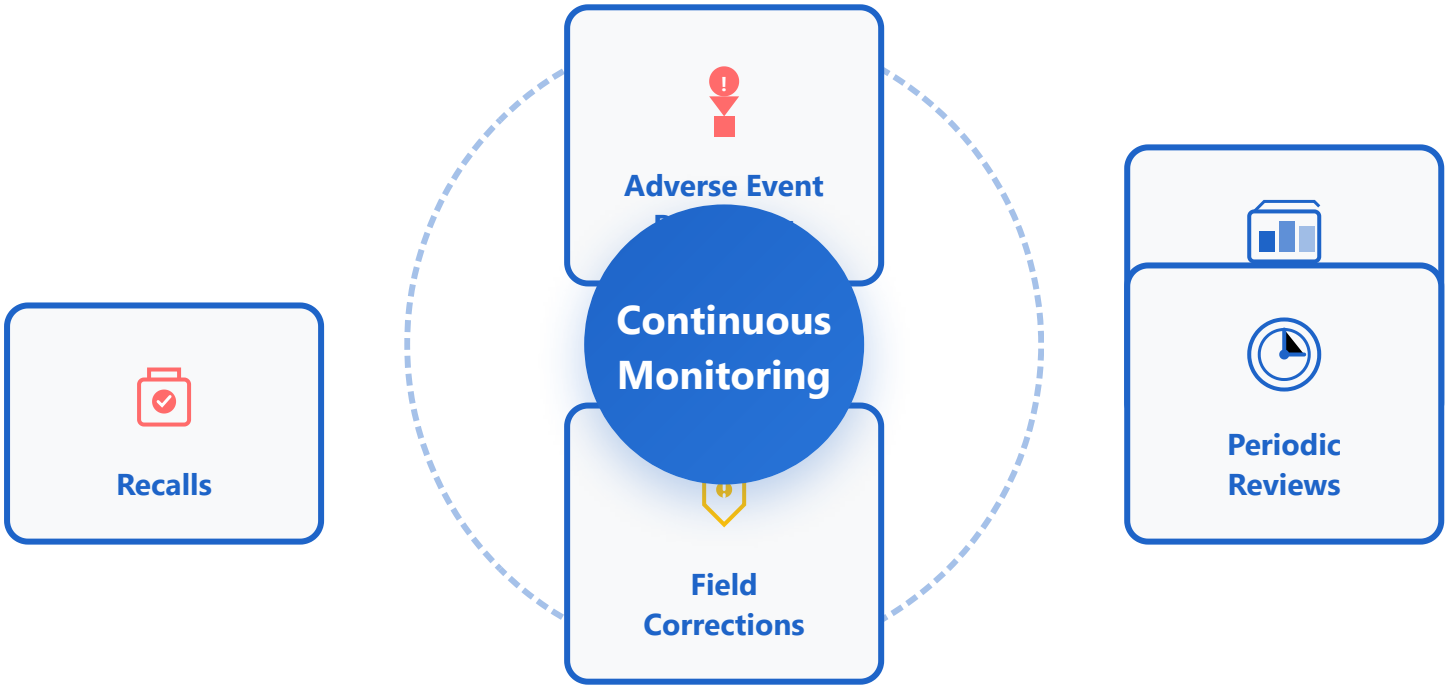
Design Controls

Risk Management

Document Control

CAPA Systems

Post-market Surveillance

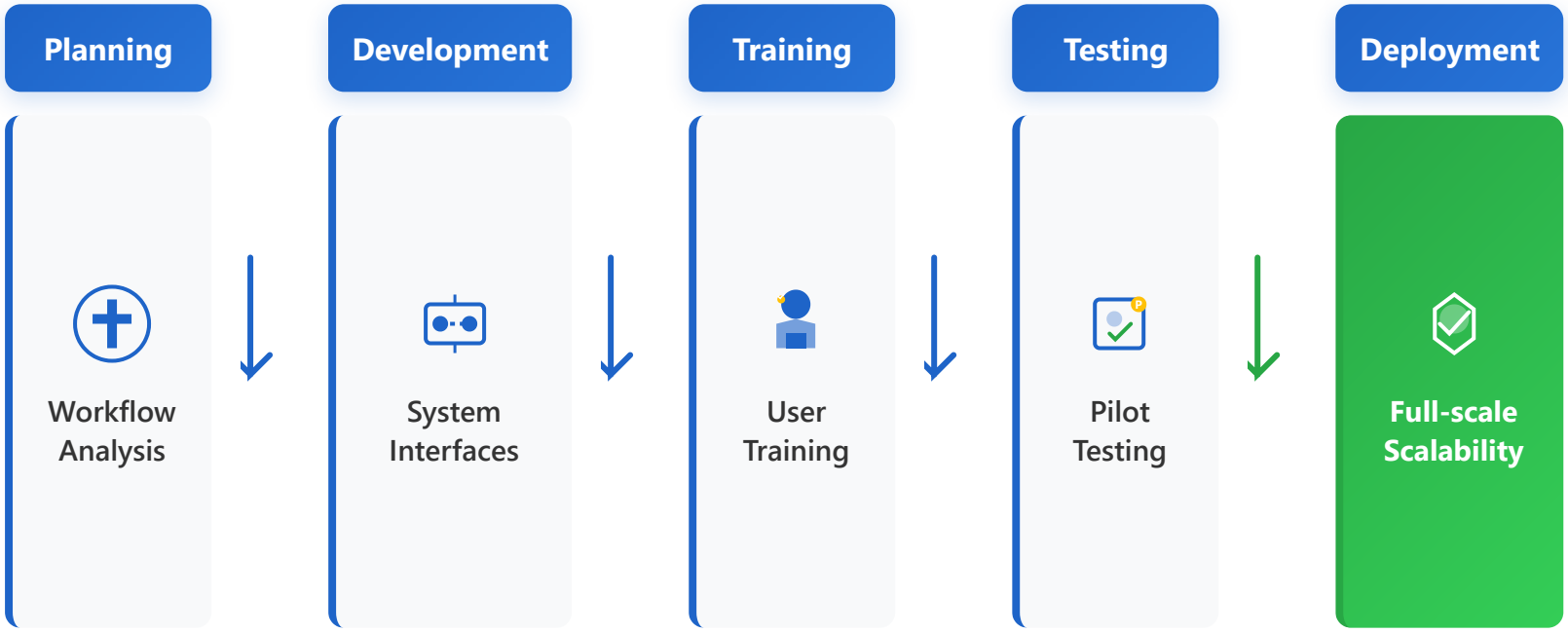


Part 3/3:

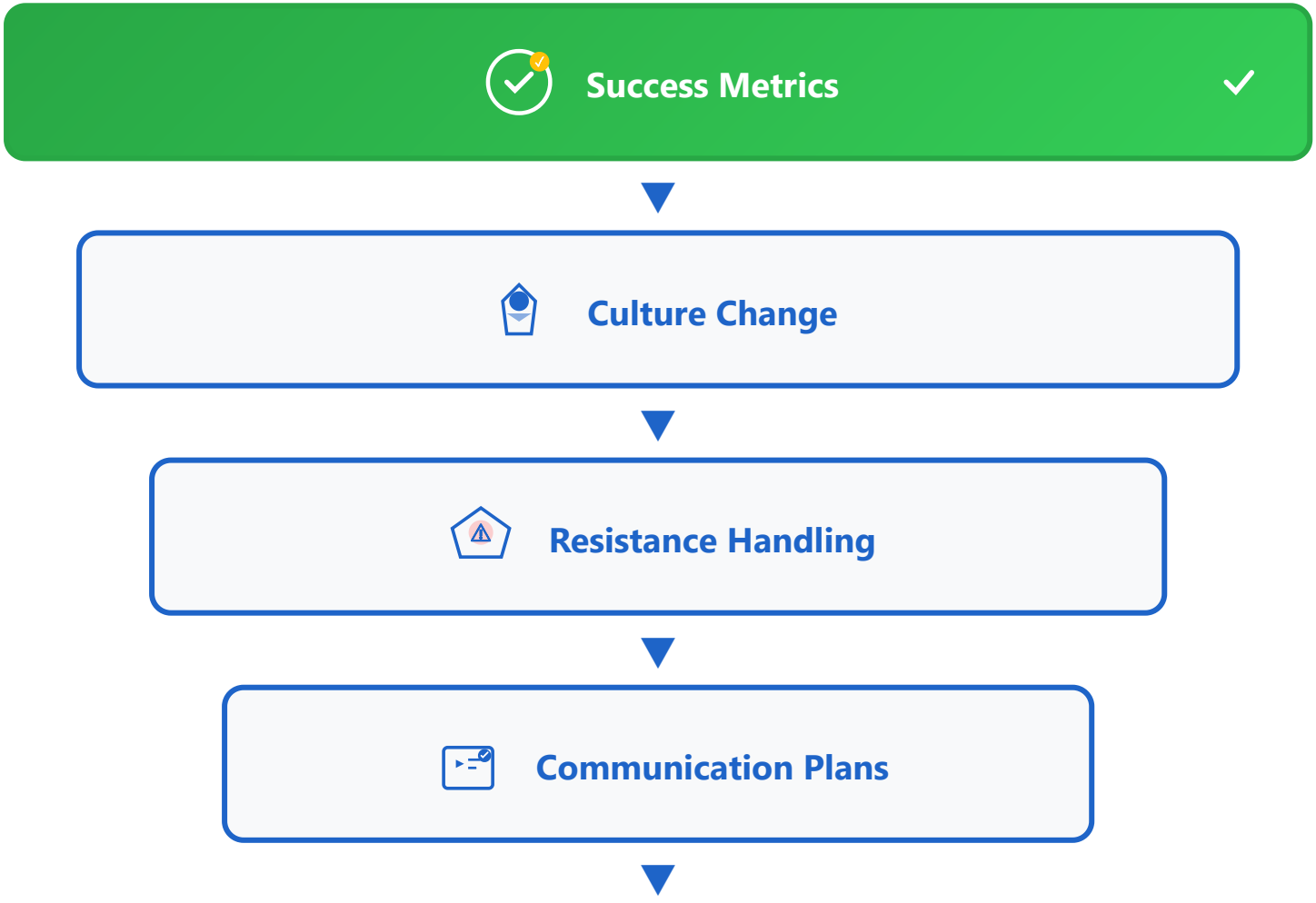
Implementation

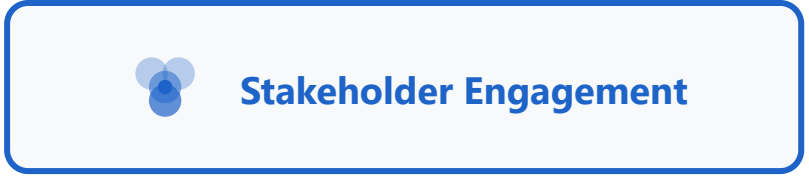
1. Deployment strategies
2. Change management
3. Success factors

Clinical Integration



Change Management




Stakeholder Engagement

Training Requirements

- User competencies
- Training programs
- Certification
- Ongoing education
- Support systems

Cost-benefit Analysis

- ROI calculation
- Productivity impacts
- Quality improvements
- Risk reduction
- Indirect benefits

Reimbursement

- CPT codes
- Coverage decisions
- Evidence requirements
- Pricing strategies
- Value-based contracts

Liability Issues

- Malpractice considerations
- Product liability
- Insurance coverage
- Indemnification
- Risk allocation

Global Perspectives

- Regulatory harmonization
- Cross-border data
- Cultural considerations
- International standards
- Collaboration models

Future Regulations

- AI-specific legislation
- Adaptive regulations
- Sandbox approaches
- International coordination
- Emerging issues

Best Practices

- Governance structures
- Ethics committees
- Documentation standards
- Audit procedures
- Continuous improvement

Case Studies

- Success stories
- Failure analysis
- Lessons learned
- Implementation tips
- Regulatory examples

Discussion Scenarios

- Ethical dilemmas
- Regulatory challenges
- Implementation issues
- Group exercises
- Solution development

Thank you

Key Takeaways & Resources

- Regulatory resources
- Ethics frameworks
- Professional organizations