CORE TRAINING WORKSHOP

# Hands-On Training on Artificial Intelligence

## Understanding AI Research Oversight in Healthcare

**Mark Lifson, PhD**

AI Research & Ethics Specialist

Core Training Workshop Series

2025

ML

# Mark Lifson, PhD

## Director, AI/ML Engineering

Mayo Clinic Center for Digital Health

### IMPACT METRICS

EXPERIENCE **15+ Years**

CITATIONS **1300+**

### TECHNICAL EXPERTISE

- Medical AI/ML
- FDA/CE Regulatory
- Diagnostic Biosensors
- Clinical Translation
- Health Equity
- SaMD Governance

### KEY CONTRIBUTIONS

**Regulatory & Oversight**

- AI/ML Expert IRB Reviewer
- FDA/CE-Mark Approvals
- Medical & Scientific Affairs

**Technical Achievements**

- Hematology AI Systems
- Biosensor Platforms
- Point-of-Care Diagnostics

### CAREER IMPACT

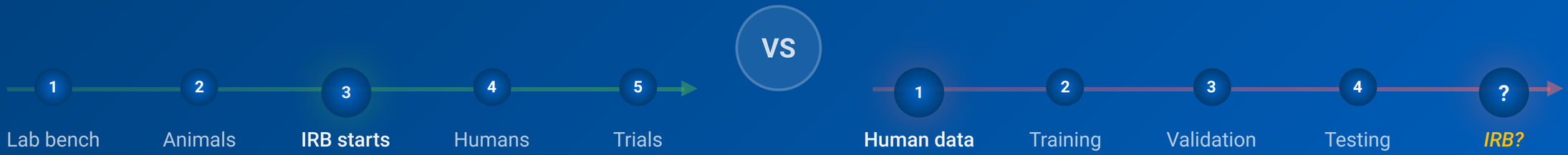
**Biosensor Development**
*Label-free detection platforms*

**AI/ML in Clinical Practice**
*FDA-approved diagnostic algorithms*

**Healthcare Governance**
*Frameworks for responsible AI*

**Regulatory Innovation**
*Automated oversight systems*

# WHAT MAKES AI DIFFERENT? DATA




AI research **starts with human data** - there's no pre-human exploration phase

# Phases of AI Clinical Evaluation

### Exploratory/Discovery

*Pre-clinical*

- Identify study aims & hypotheses
- Literature searches
- Secondary data analysis
- Professional society guidelines
- Initial algorithm development

### Pilot/Validation

*Early feasibility*

- Preliminary safety assessment
- Performance evaluation
- Small study cohorts
- Analytical validation
- Clinical validation metrics

### Intervention/Treatment

*Clinical efficacy*

- Confirms clinical efficacy
- Safety & risk assessment
- Impacts patient care
- Pivotal trials
- Post-market surveillance

**Analytical Validation**
Accuracy, Reliability, Precision

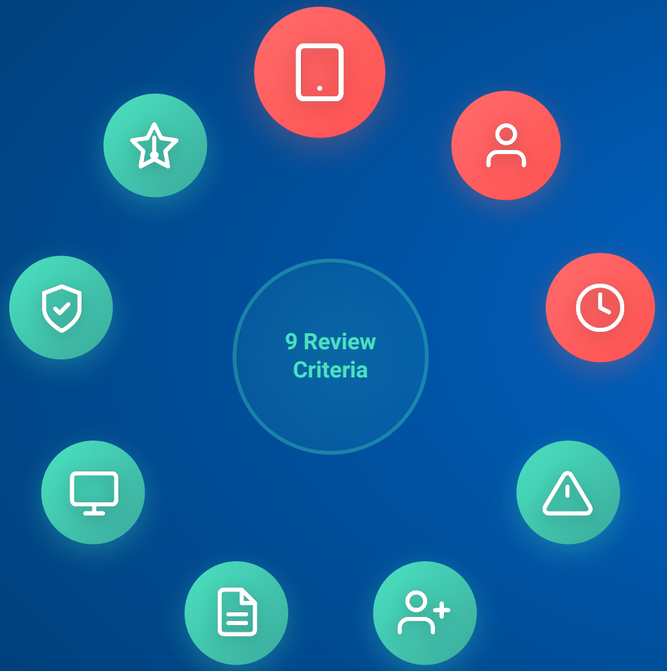
**Clinical Validation**
Sensitivity, Specificity, PPV/NPV

**Performance Monitoring**
Long-term effectiveness & safety

AI requires **three distinct phases** - each with unique validation requirements

# 9 CRITERIA, 1 REVIEW

All Criteria (9) | Research Definition (3) | Risk Management (2) | Subject Protection (4)




## FDA-Regulated Device?

21 CFR 812, 820

Software intended for diagnosis, treatment, prevention, or mitigation of disease

**IRB MUST DETERMINE**

Compliance with FDA Quality System Regulation design controls and determination of significant risk vs non-significant risk device classification.

# What Both Sides Want

IRB SPECIALISTS

## Speaking Regulatory

> "Per 45 CFR 46.111(a)(2), risks must be reasonable in relation to anticipated benefits..."

Need: Complete documentation demonstrating compliance with Common Rule, FDA regulations, and institutional policies

TRANSLATION GAP

AI RESEARCHERS

## Speaking Technical

> "Our CNN achieves 94% AUC with cross-validation on the hold-out test set..."

Want: Clear guidance on what's needed without having to learn regulatory frameworks

**The Challenge:** How do we bridge this gap without requiring either side to become experts in the other's domain?

# DETERMINING CLINICAL INTENT

The same technology described differently triggers different regulatory pathways

## ⚠ Clinical Trigger Words

diagnose | treat | screen | detect | clinical decision | deployed | patient care

## Research Indicators

investigate | analyze | explore | retrospective | patterns | correlations | hypotheses

**STUDY OBJECTIVES**

The primary objective is to develop a deep learning model that will **diagnose** pneumonia from chest X-rays with accuracy comparable to board-certified radiologists. The system will be **deployed in emergency departments** to **expedite treatment decisions** for patients with respiratory symptoms.

CLINICAL INTENT - FDA PATHWAY LIKELY

**RESEARCH AIMS**

This study will **investigate** novel biomarkers in retinal images by **analyzing patterns** across large retrospective datasets. We aim to **explore correlations** between retinal features and cardiovascular risk factors to **generate hypotheses** for future prospective studies.

EXPLORATORY RESEARCH - IRB FOCUS ON DATA PRIVACY

**METHODOLOGY**

Our AI platform will **analyze** patient data to **predict** 30-day readmission risk. Results will be **provided to clinicians** for **evaluation** of potential **treatment modifications**. The system will **support** clinical teams in **decision-making processes**.

MIXED SIGNALS - CONTAINS BOTH CLINICAL AND RESEARCH LANGUAGE

**DATA ANALYSIS PLAN**

The AI algorithm will **screen** mammography images to **identify suspicious lesions** requiring immediate radiologist review. Cases flagged as high-risk will **trigger automatic scheduling** for follow-up imaging, with the AI assessment **documented in patient records**.

CLINICAL INTENT - DIRECT PATIENT IMPACT

# IMPACT SPECTRUM & OVERSIGHT REQUIREMENTS

Patient impact level determines IRB oversight requirements

Minimal | Moderate | Significant

## Silent/Shadow Mode

AI runs in background without clinical use

***Example:*** *Algorithm validation study*

***IRB Oversight:*** *Standard data review + annual reports*

## Advisory Mode

AI provides recommendations for review

***Example:*** *Risk scores shown in EHR*

***IRB Oversight:*** *Performance monitoring + quarterly safety reviews*

## Active Intervention

AI triggers actions or alerts directly

***Example:*** *Auto-schedules follow-ups*

***IRB Oversight:*** *Real-time monitoring + DSMB + FDA consultation*

**Oversight Intensity:** Proportional to the degree of patient care impact

# RISK CONTROL PRIORITIZATION MATRIX

Q2: Patient Impact

| | Exploratory | Translational | Clinical |
|---|---|---|---|
| Direct Care | Enhanced Review<br>**Medium-High Risk**<br>Exploratory with direct impact | Full IRB<br>**High Risk**<br>Translational affecting patients | Full IRB + Monitoring<br>**Critical Risk**<br>Clinical deployment to patients |
| Indirect | Standard Review<br>**Low-Medium Risk**<br>Exploratory with indirect effects | Enhanced Review<br>**Medium Risk**<br>Translational validation phase | Full IRB<br>**Medium-High Risk**<br>Clinical decision support |
| No Impact | Minimal<br>**Low Risk**<br>Pure research, no patient involvement | Standard Review<br>**Low-Medium Risk**<br>Algorithm development phase | Enhanced Review<br>**Medium Risk**<br>Clinical readiness testing |

Q1: Clinical Intent

## Q3 Technology Characteristics

Select technology features to determine appropriate controls

ML/Predictive Models

- ☐ **Autonomous operation** — Operates without human input
- ☐ **Clinical decision influence** — Outputs used in care decisions
- ☐ **Continuous learning** — Updates from new data
- ☐ **Age extremes included** — Users <10 or >80 years
- ☐ **Patient data usage** — Processes medical records

Complexity Score 0/ 17

*Based on ISO 14971 Risk Management*