

# Title Slide

- **Title:**  
Challenges and Prospects for the Social Implementation of Medical AI:
- **Subtitle:**  
Orthopaedic Applications Using an AI-Assisted Diagnostic System for Osteoporosis as a Case Study
- **Speaker Name:**  
Dr. Toru Moro,  
Project Professor of Division of Science for Joint Reconstruction,  
The University of Tokyo

# Eight Steps Toward Real-World Implementation

**Developing medical AI is not enough  
—implementation requires a structured process:**

1. Idea formulation based on clinical needs
2. Ethics approval and lawful data acquisition
3. Model development and validation with clear metrics
4. Patent filing and IP protection
5. Academic presentation with regulatory risk awareness
6. Industry collaboration and technology transfer (NDA, contracts)
7. Regulatory approval (PMDA classification and review)
8. Reimbursement and integration into clinical workflows

# Essential Literacy in Ethics and Legal Compliance

## Multiple legal layers govern medical AI:

- **Personal Information Protection Law (2022 revision):**  
Understand the difference between pseudonymized and anonymized data
  - **Next-Generation Medical Infrastructure Law:**  
Data must be handled via certified providers
  - **Medical vs. Research Ethics:**  
Define target, purpose, and principles clearly
- **Consent forms, data use scope, and secure handling must be carefully managed.**

# Patent and Regulatory Pitfalls

- Most diagnostic AI falls under SaMD (Software as a Medical Device)
- **Risk of losing patent novelty** through premature disclosure
- **Infringement risk** must be assessed via prior art searches (e.g., J-PlatPat)
- Early dialogue with PMDA and classification assessment is critical for approval strategy

## Key Takeaways and Closing Message

**We live in an era where “anyone can build AI”  
—but responsibility matters.**

### **Keys to real-world adoption:**

1. Prioritize patient safety in technical design
2. Integrate ethics, law, and IP strategy from the outset
3. Anticipate medical device regulations early in development

### **Message:**

AI innovation must go hand in hand with regulatory readiness and clinical relevance.

## Case Example

### – AI-Based Osteoporosis Diagnosis Support (AIBONEX®)

- Osteoporosis affects 15+ million people in Japan, but DXA testing is underused due to cost and limited access.
- We developed AIBONEX, an AI system that estimates BMD from chest or lumbar spine X-rays.
- Based on Vision Transformer, it estimates lumbar and femoral neck BMD (YAM%, T-score, etc.) with high accuracy.
- Performance:
  - Lumbar X-rays:  $r = 0.83\text{--}0.91$ ,  $\text{AUC} = 0.90\text{--}0.95$
  - Chest X-rays:  $r = 0.82\text{--}0.83$ ,  $\text{AUC} = 0.89\text{--}0.91$
- Preparing for regulatory approval and insurance coverage.