



Virtual Human Twins in MedTech: Now and in the Future

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Disclosures:

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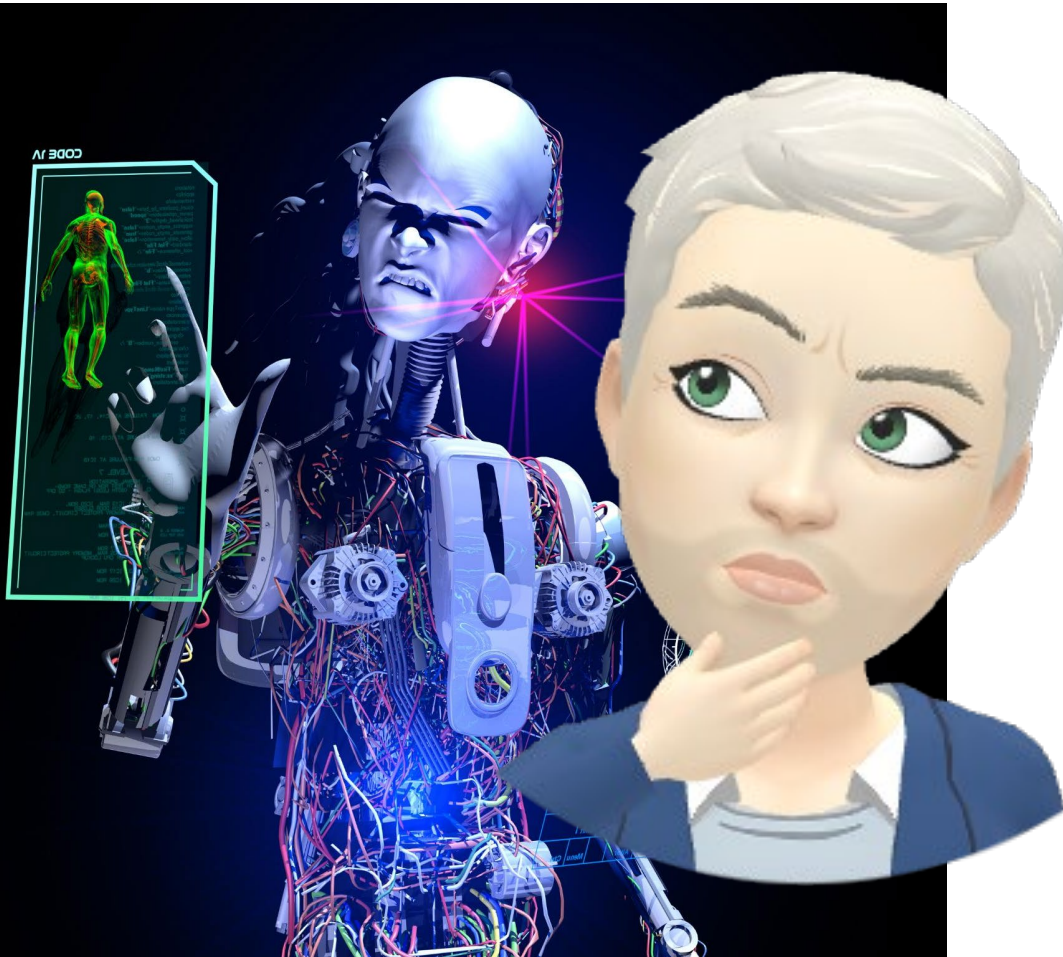




Drivers for increased use of modeling and simulation

- Better problem-solving creates greater value.
- Understanding causative mechanisms enables promising solutions.
- Shift from iterative product development to predictive engineering and human-factors design, reliability and manufacturability for development processes.

How do Virtual Human Models advance innovations in MedTech?



Virtual human modeling can

- **accelerate the cycle of MedTech innovation, and**
- **provide a foundation for discovery and expansion of opportunities**

in many situations in which:

- **the physics are well established,**
- **the biological phenomenon is understood, and**
- **determination within human subjects unnecessarily puts many at increased risk of harm**

Mease Study – MRI-Compatible Active Implantables



MRI affects both internal device components and leads:

- **Electrical or mechanical damage to internal components can lead to device malfunction.**
- **Leads act as antennae; MRI energy can heat lead tips, risking tissue damage and increased pacing threshold or even loss of capture.**

Risk mitigations:

- **Electrical and mechanical solutions exist to protect internal components and maintain functionality.**
- **Physics related to antennae heating in magnetic fields is understood; applied power levels to damage tissue and change pacing thresholds can be measured.**

Data Collection for Modeling

Human anatomy boundaries

- Human MRI scans: 50+ subjects, varied physical features.

Implanted lead boundaries

- X-ray database: 1,000+ RV-ICD implants for lead shapes and placements.

Magnetic field boundaries

- MRI gradient data from various manufacturers.



Simulation & Validation



Extensive Simulations

Hundreds of millions of simulations ran to predict device behavior and risks (safety margins).

FDA Collaboration and Clinical Trial

Collaboration with FDA: 500-patient RV-ICD clinical trial validated model.

Virtual Modeling Benefits

Enabled MRI compatibility labeling for most cardiac and neurological devices/leads.

Avoided need for multiple 3,000+ subject clinical trials.

Saved years of effort and ~\$2B in clinical costs.

Reduced unnecessary patient risk and improved safety margin assessment.

Beyond Randomized Clinical Trials



Advantages

- Reduces patient exposure to unnecessary risk**
- Offers greater and deeper insights into complex scenarios**
- Provides enhanced safety margin assessment and risk management**
- Accelerates product regulatory approval**

Paradigm Shift

VHMs represents a fundamental change in the medical innovation process [discovery, product development, clinical research and regulatory].

The Future of Virtual Human Twins in MedTech

Proactive Health Optimization

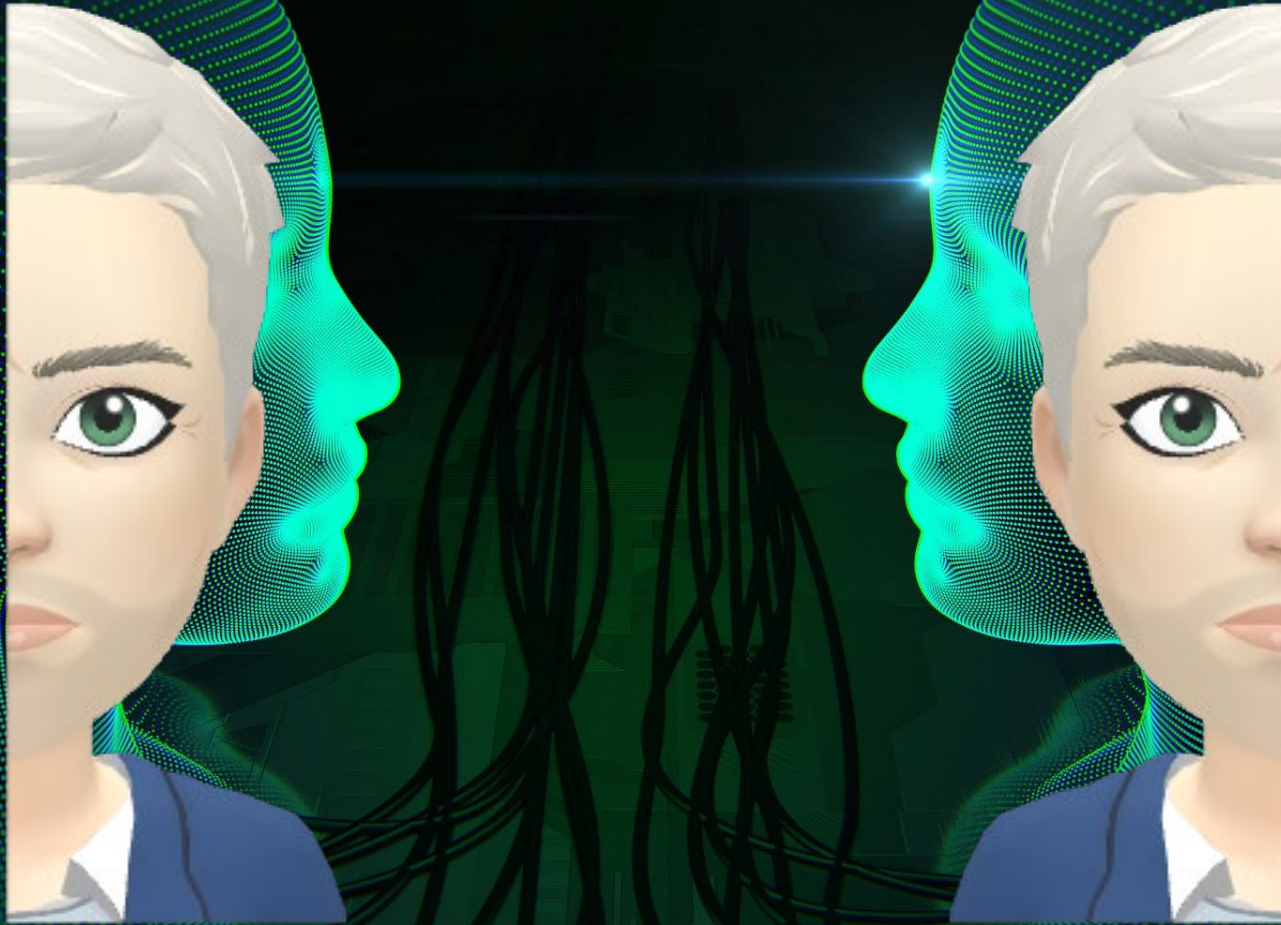
Enable proactive and personalized tracking to optimize individual health and performance.

Health Monitoring and Support

Enable continuous health monitoring and support decision-making for better patient outcomes (e.g. diabetes, stroke recovery)

Personal Digital Avatar

Lifelong virtual twin that supports personalized, precise, and predictive relational outcomes.



Trust, Transparency, and Opportunity

Importance of Trust

Trust is essential for public acceptance and success of virtual twin technology in healthcare.

Scientific Rigor and Validation

Accurate and validated models ensure reliability and effectiveness in clinical applications.

Ethical, Secure and Transparent Use

Ethical, secure and transparent application are crucial for responsible use and gaining public confidence.

Expanding Healthcare Opportunities

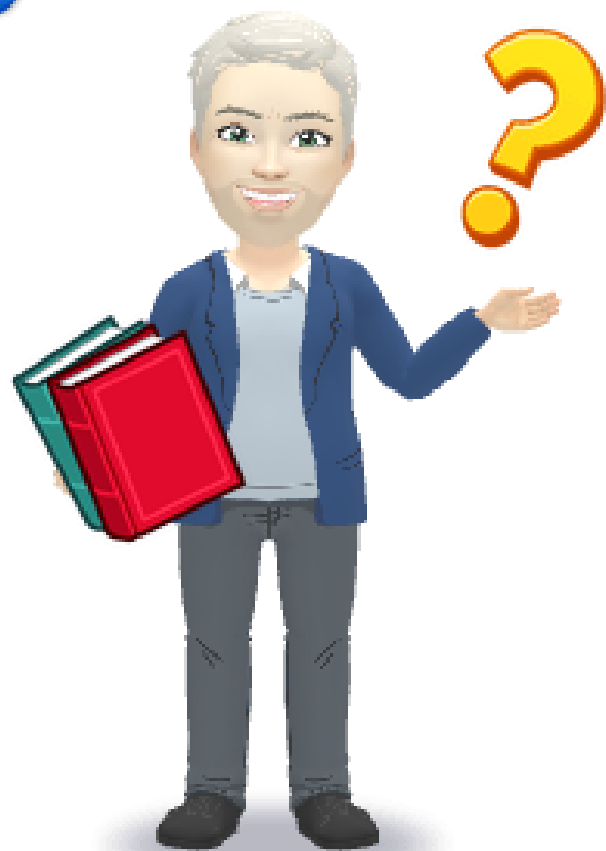
Virtual twins can advance both population health and personalized patient care.







Any Questions?



thank
you