



# **Virtual Human Twins in MedTech: Now and in the Future**

**Michael RS Hill, PhD, MBA**  
**Science Innovations, LLC**



# Disclosures:

**Former Medtronic senior executive (27yrs)**

**Co-Founder, Science Innovations, LLC**

**Co-Founder, ECATE**

**Adjunct Associate Professor, Case Western Reserve University**

**Executive in Residence, EvoNexus**

**Founding Member, Bullpen (BLPN)**

***Investor, ELEM***





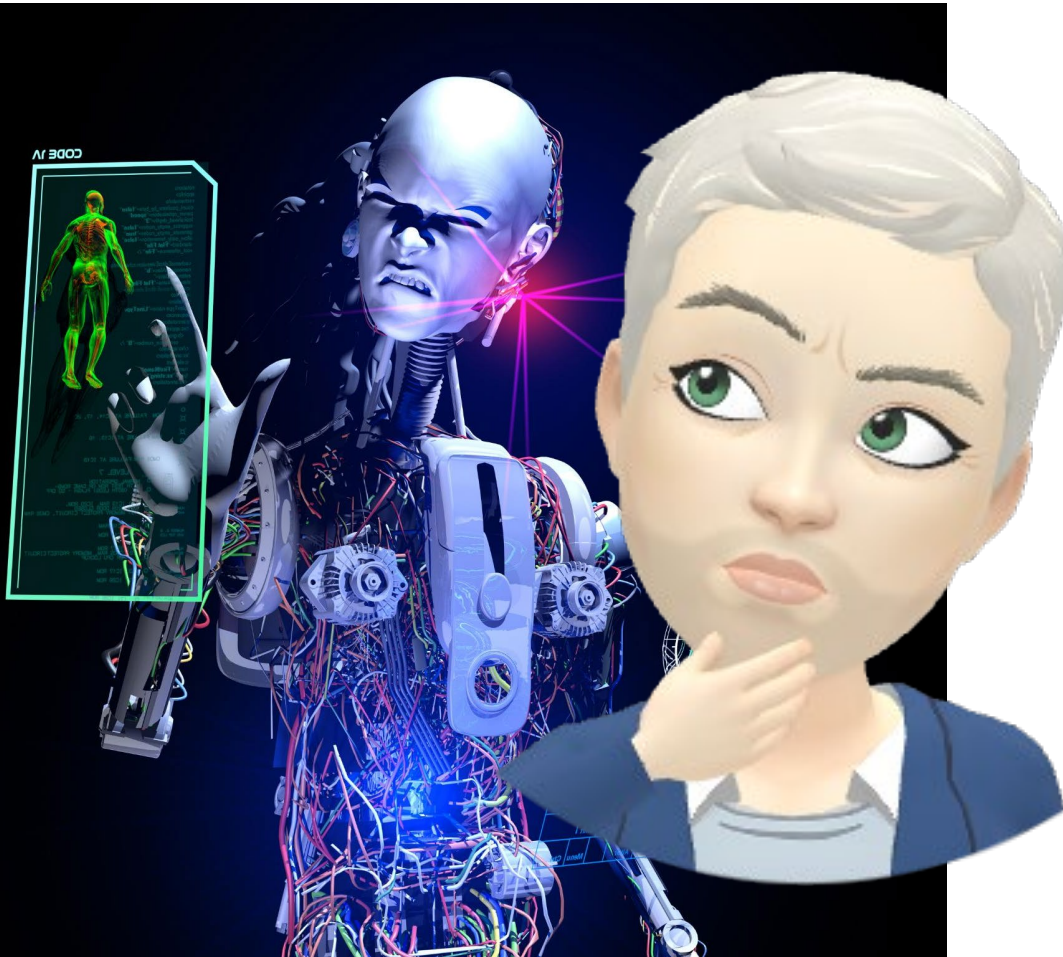
# Drivers for increased use of modeling and simulation

- 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.**







WITHINGS

#Selfcare







Any Questions?



thank  
you