Challenges and Opportunities with in-silico Evidence: The Evolving Landscape of RF-Induce Heating of Passive Implants Safety Assessment

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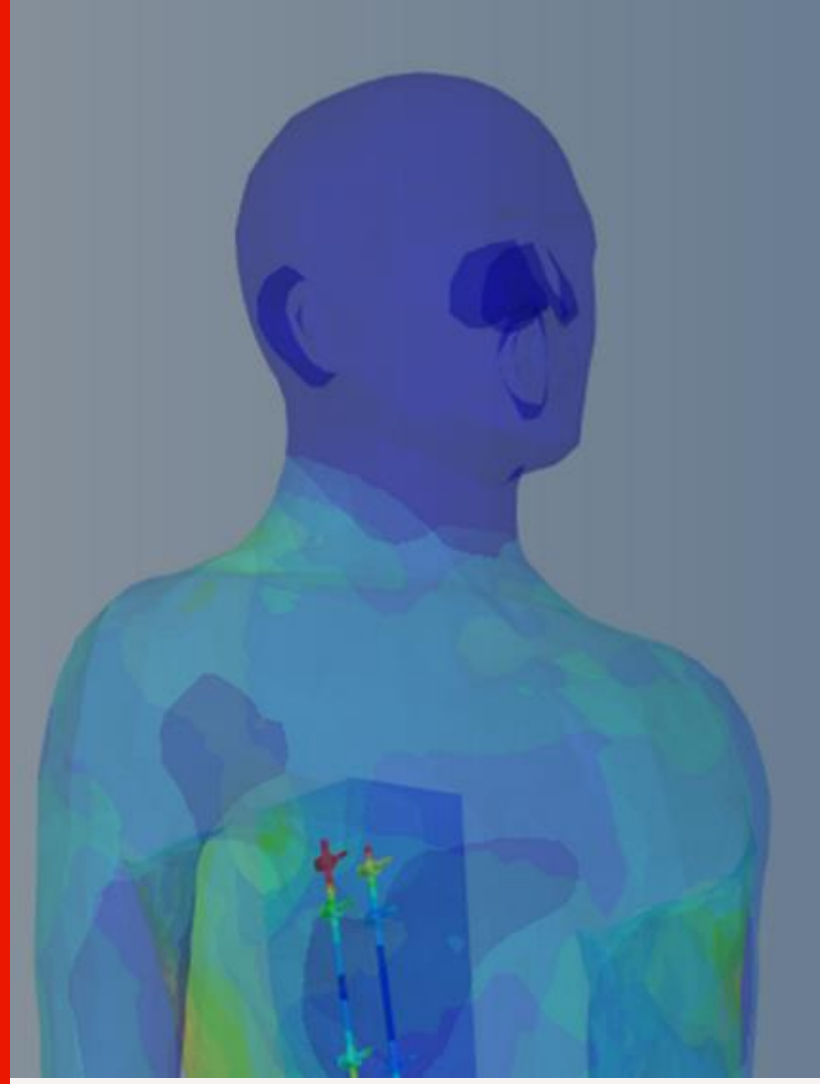
Johnson&Johnson
MedTech



Agenda

This presentation:

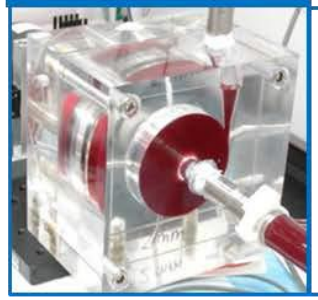
- Is not about the nuts and bolts of RF heating evidence generation.
- Uses the evolution in RF heating evidence acceptability as an analogy for other applications

Regulatory Evidence Generation Paradigms (2017)

animal

- clinical pathology, gross pathology and histopathology assessments
- allows for examination of the biological response to the implant at the cellular level

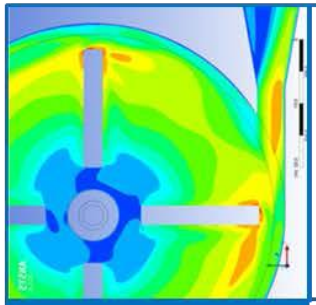
bench



- evaluate device performance in controlled setting
- allows for assessing certain features or the entire device under simulated conditions

- controlled studies with specific inclusion/exclusion criteria for subjects, with specific treatment protocols, and has the clear objectives, in general, to assess safety & effectiveness

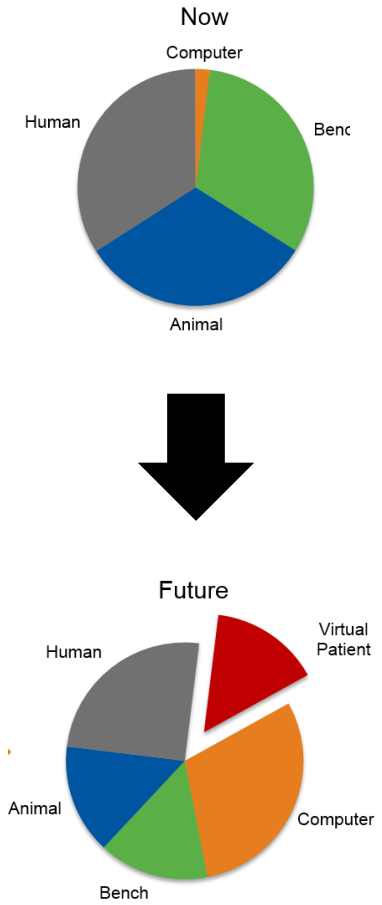
clinical trial



computer

- different aspects of computational modeling in medical devices are provided in the inset below

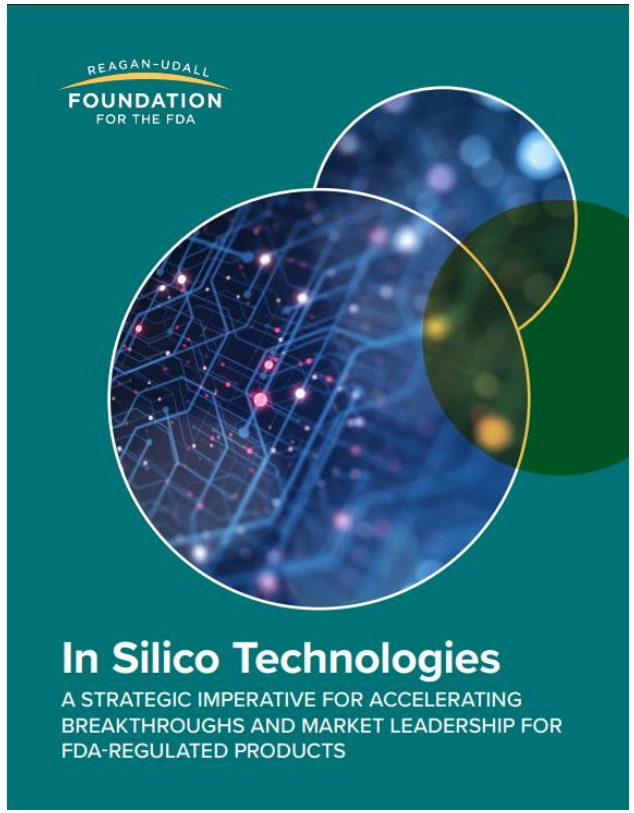
Digital Evidence
In Silico Evidence



Courtesy of Tina Morrison www.fda.gov

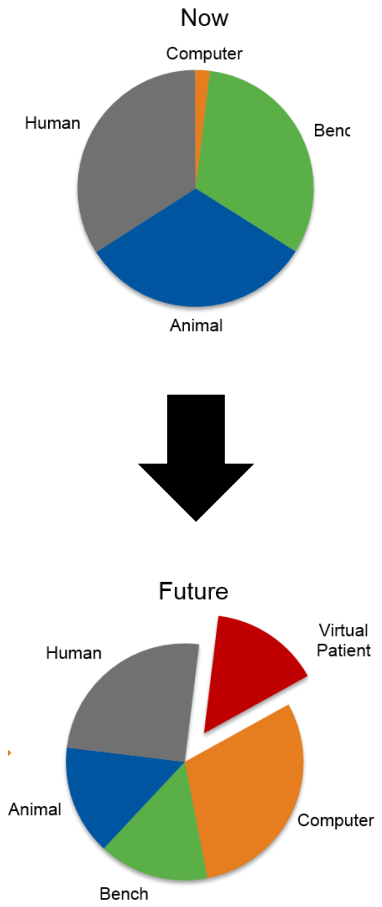
Role of in-silico Evidence: A Status Update

2024 Publication



	Clinical	+ Animal	+ Bench	+ CM&S	TODAY	FUTURE* In Silico Technology
Predictive Capability						
Relevant outcomes to patients/consumers	Good	Minimal	Minimal	Fair		Good
Clinical/real-world performance	Good	Fair	Fair	Fair		Good
Use beyond indications	Minimal	Fair	Good	Good		Good
Investigational Capability						
Represent health condition	Good	Fair	Minimal	Good		Good
Adaptable for patient/consumer specificity	Fair	Minimal	Minimal	Good		Good
Rely on simplifying assumptions	Fair	Fair	Minimal	Minimal		Good
Maintain experimental control	Fair	Fair	Good	Good		Good
Explainability	Minimal	Minimal	Fair	Good		Good
Business Considerations						
Expand COU/Labeling	Good	Minimal	Minimal	Fair		Good
Execution Time (relative)	(Very) High	High	Low	Moderate		Low
Scaling Efficiency	Low	Moderate	High	High		High
Cost (relative)	High	Moderate	Low	Moderate		Low

* With data from all other models w/ AI/ML capabilities

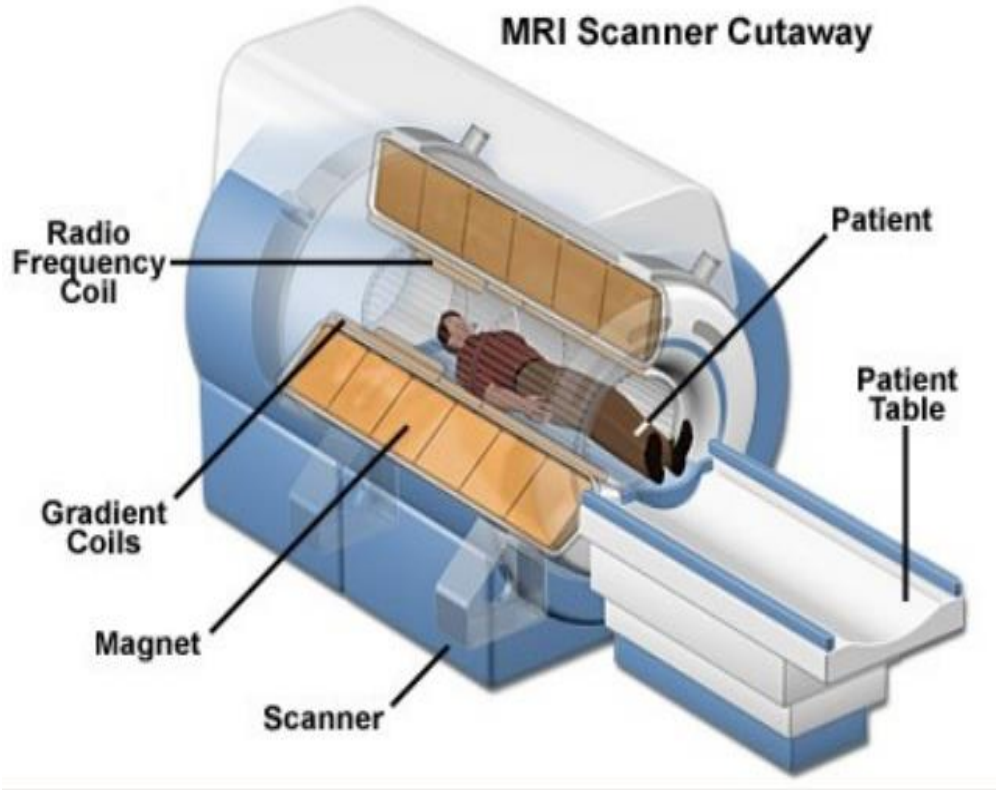


MRI Scanner

Powerful device to non-invasively visualize internal structure, enabling accurate diagnosis, monitoring and treatment planning

Interacts with metallic implants with potential negative consequences

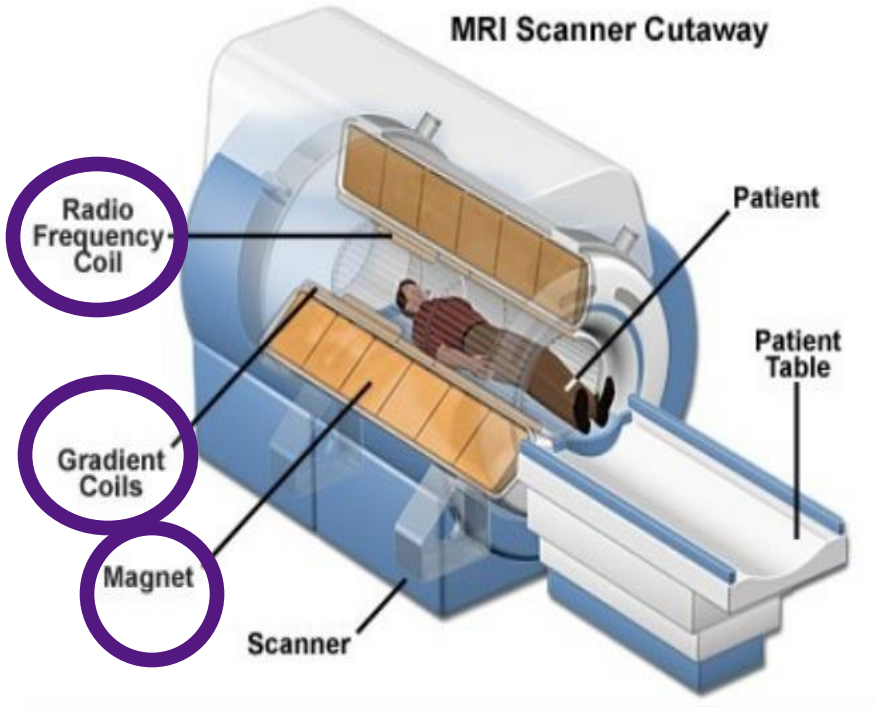
Need to determine safe scanning parameters



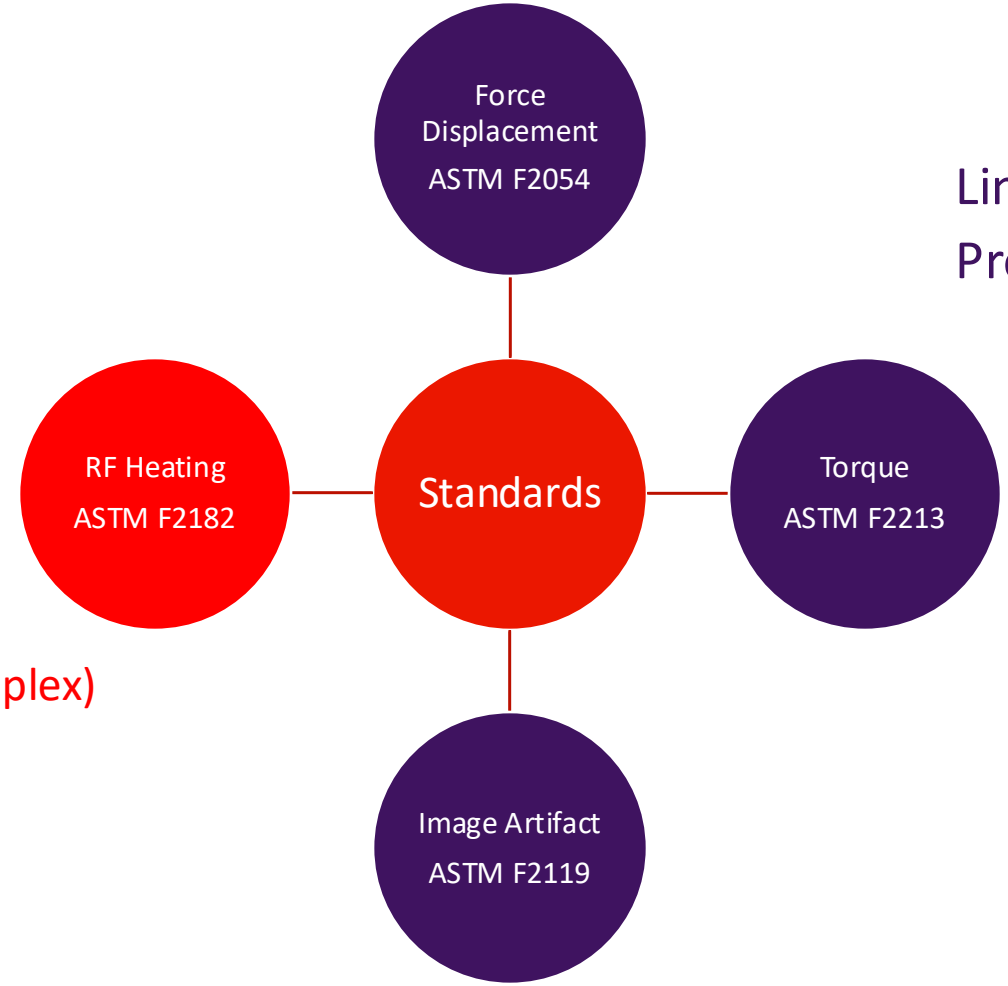
The Evolving Role of In Silico Evidence in RF-Induce Heating of Passive Implants Safety Assessment

Patient at risk due to MRI EM field Interaction with Metallic Device

A. Risk of Movement
B. Image Distortion
C. Risk of Heating



Assessing the interaction Risks Using Standard Tests



Linear: Geometry, Mass, EM Properties

Non-Linear: (complex)

Determining RF Heating Safe Scanning Label for Passive Implants in MRI Scanners

Typical 510k two stage process

1- Worst-Case selection Process:

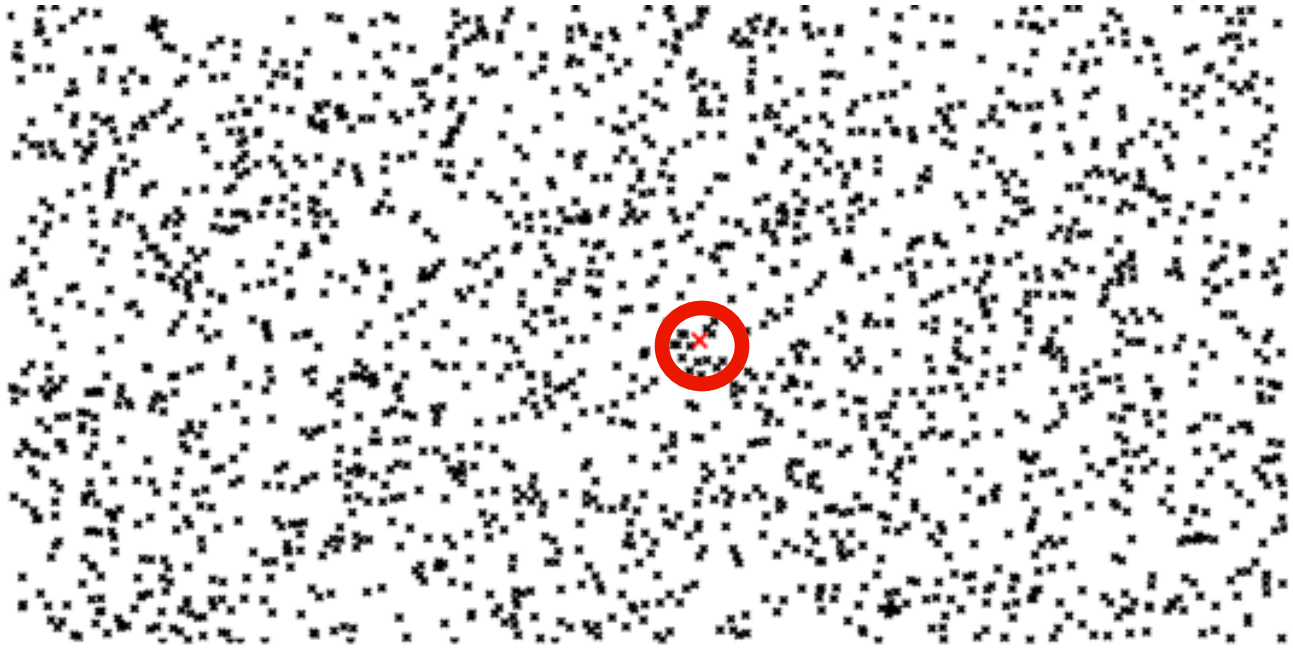
what is the device configuration that creates the highest temperature?

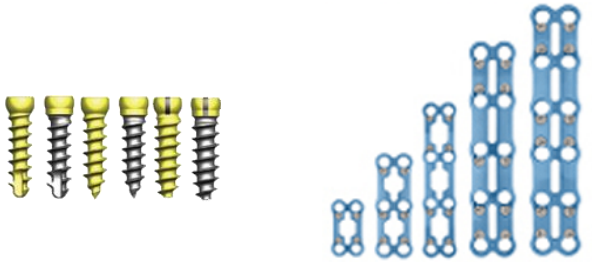
2- Determining the heating Profile of the WC to inform the conditional labeling.

Challenges with Worst-Case identification of Multi Configuration Systems

~20,912,961,780,646,000,000,000,000,000,000,000
Nearly 21 Decillion Combinations!

Finding “the hay” in a haystack.



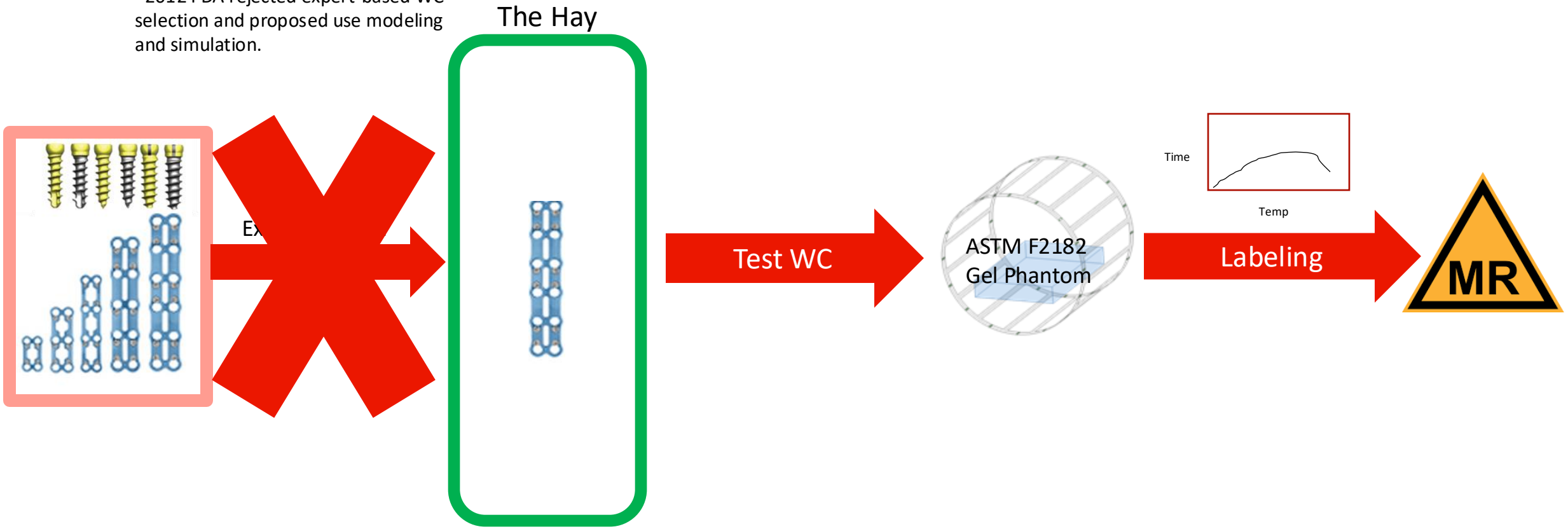


Component	Parameter
Plate	Length
Plate	Levels
Screw	Length
Screw	Diameter
Screw	Tip Shape
Screw	Angulation

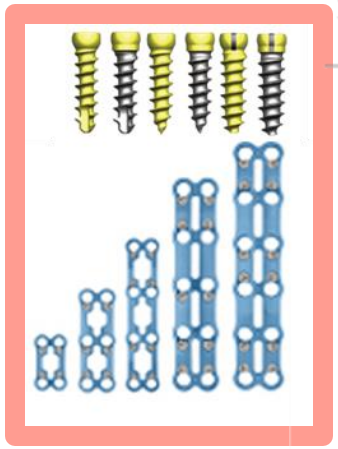
The number of possible configurations are significant

How to find The Hay

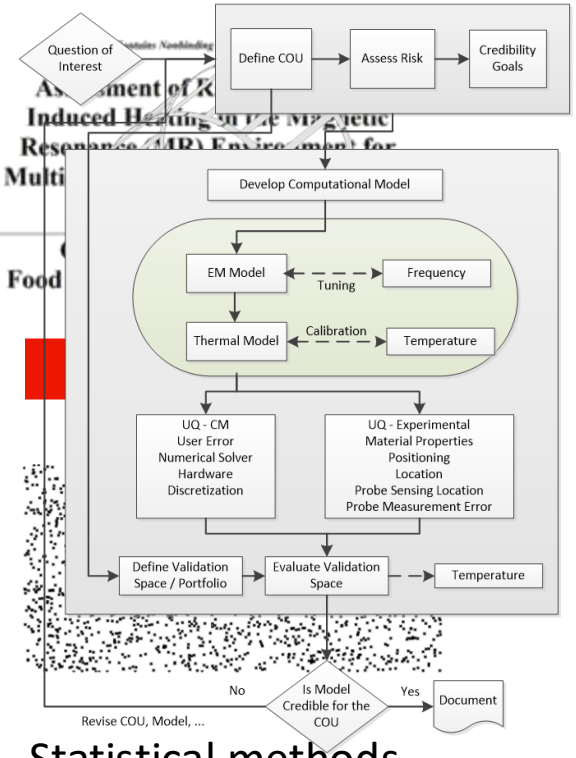
~2012 FDA rejected expert-based WC selection and proposed use modeling and simulation.



How to find The Hay

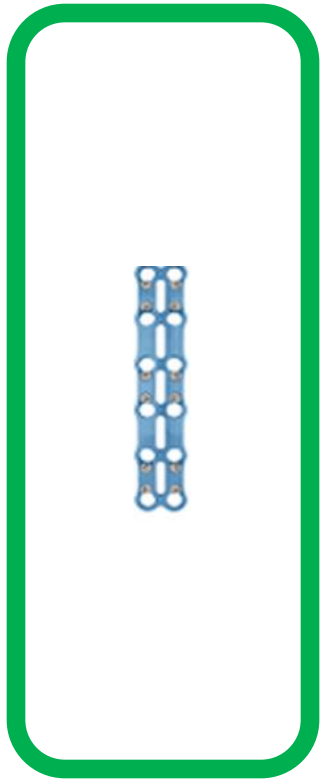


In Silico methods

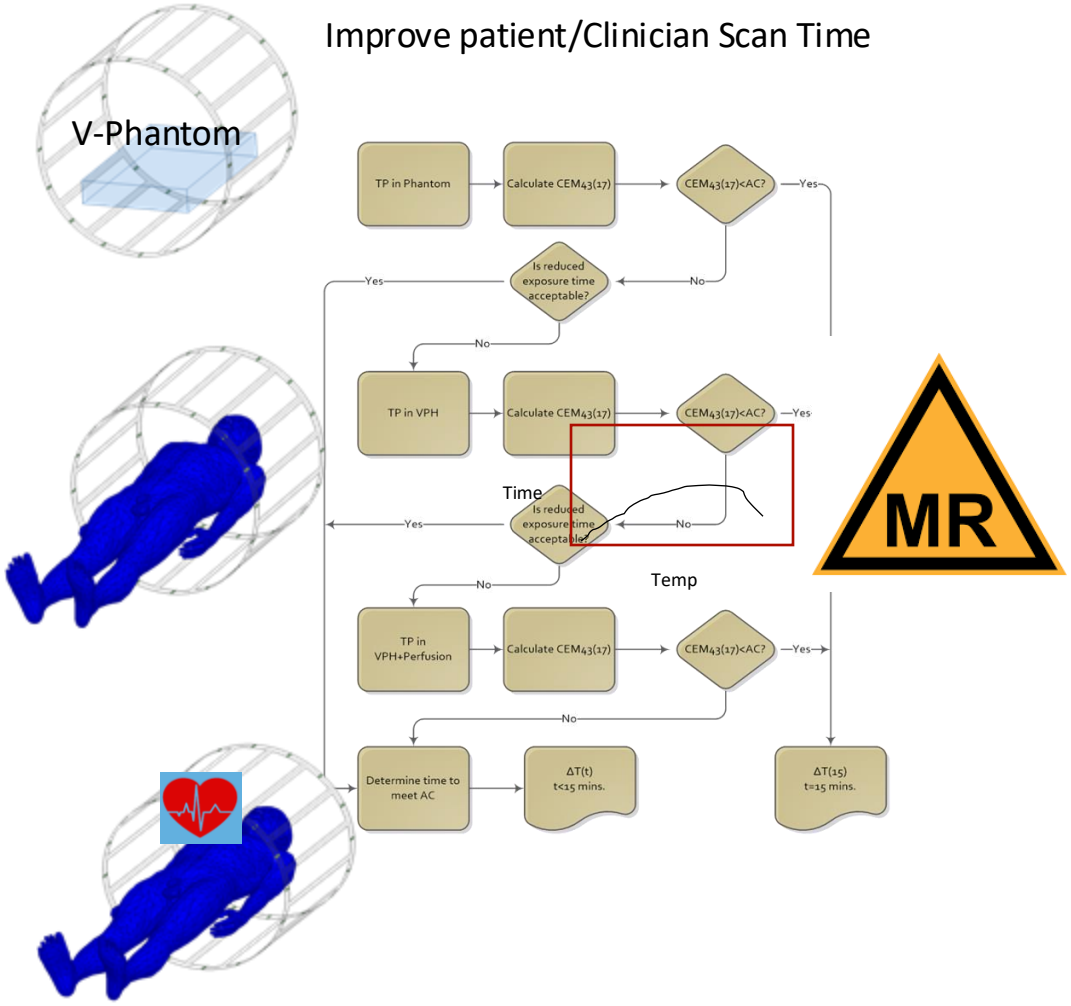


Statistical methods

The WC



Improve patient/Clinician Scan Time



Fast Forward to 2025

Physics based computational models generate the evidence

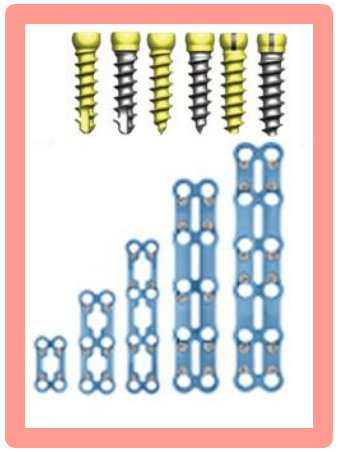
Worst Case Selection:

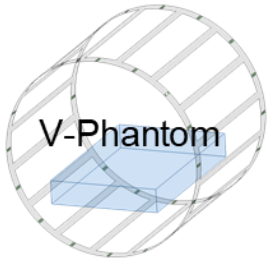
- Depends on where the device is implanted.
  - Speed of EM is medium dependent
  - Resonant length is related to wavelength
- Bone Phantom for WC selection would be appropriate.

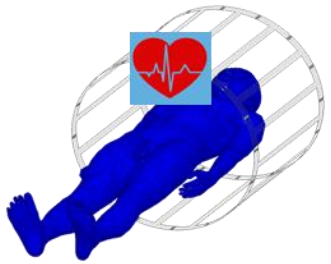
Labeling:

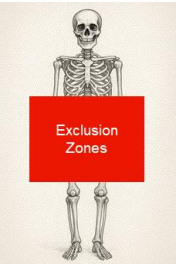
VPH models provides the final thermal profile to inform labeling

- Implant thermal profile depends on the device and its position with respect to the anatomy, and position in the scanner.
- Basal temperature increase can also be accounted for.
- Exposure risk is balanced with a more meaningful exposure time.
  - 15 minutes of scan time was replaced with 60 minutes of procedure time.
  - Risk of heating is stratified <2°C <4°C, <6°C
  - Introduction of the cooling time
  - Exclusion zones



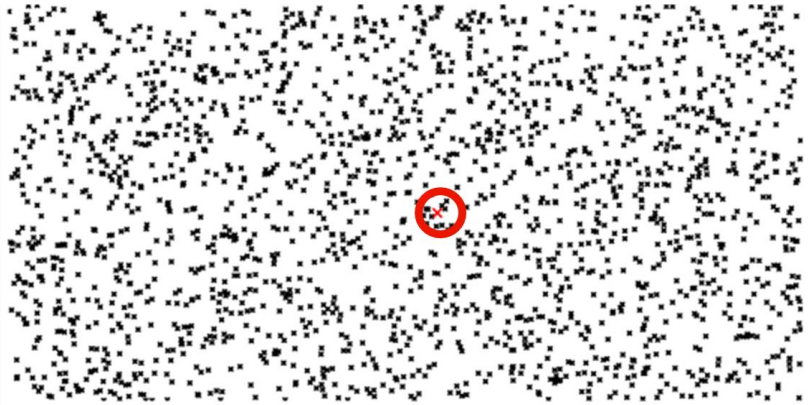


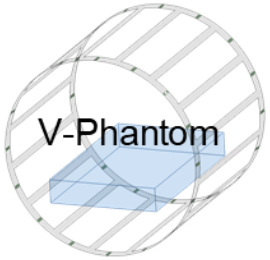


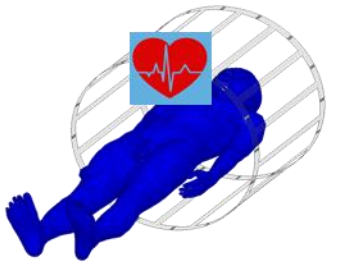


Beyond 2025

- Worst Case selection even in a “bone” like phantom is still a bit problematic due to the variation in anatomical/physiological perfusion rates.
- Perhaps the WC selection and Labeling all informed by the VPH Model.

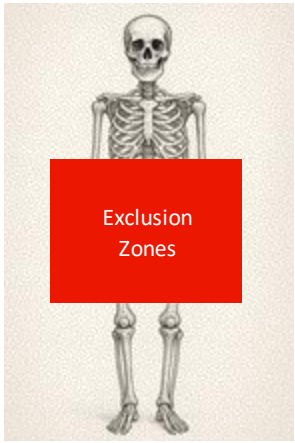


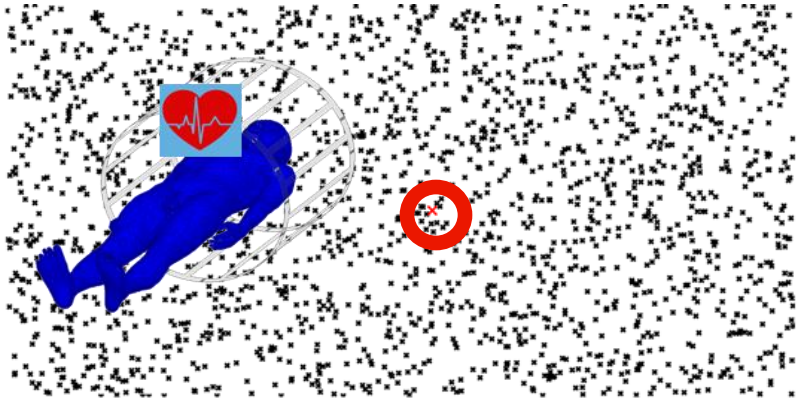




Final Thoughts and Considerations

- Computational models recognized as regulatory tools the WC and provide safe scanning parameters.
- Access (safe) to MRI technology has always been the primary objective.
- WC paradigm is antithetic to this objective.
  - Exclusion zones, exposure time and power limitation are imposed on all patients based on the WC.
- Personalized labeling makes more sense but is that possible or even practical?
- Does artificial intelligence-Machine learning models have a role in this transition from a WC paradigm to a personalized medicine?





The model is credible for the other 21 Decillion-1 configurations.