



Accelerating Device Innovation Through Regulatory Science

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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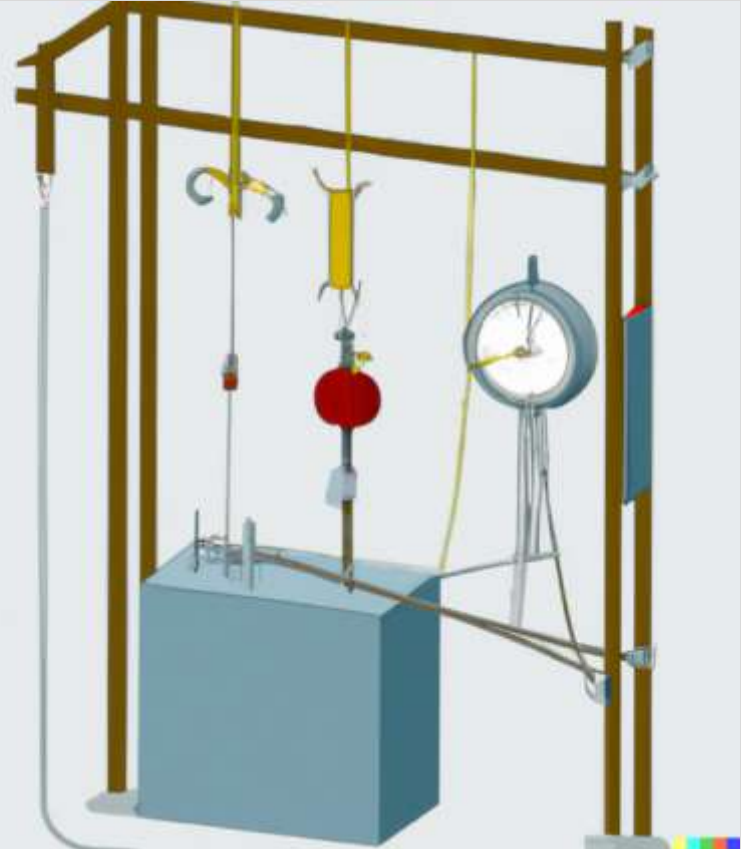
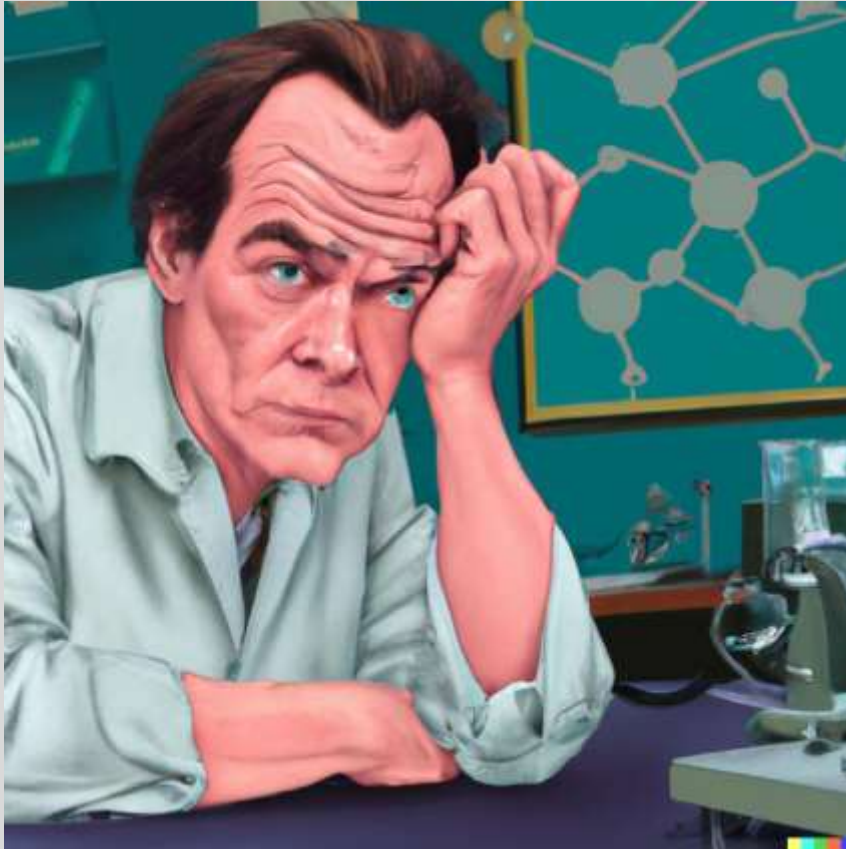
Director

Office of Science and Engineering Laboratories

Center for Devices and Radiological Health

U.S. Food and Drug Administration

How Do you Link Innovation and Reg Efficiency?



Learning Objectives

- Describe regulatory science tools (RSTs) and explain why they're important
 - For **innovators**
 - For **product development engineers**
 - For **regulatory reviewers**
- Access the public RST app
- Discuss the scope and framework of context for RSTs

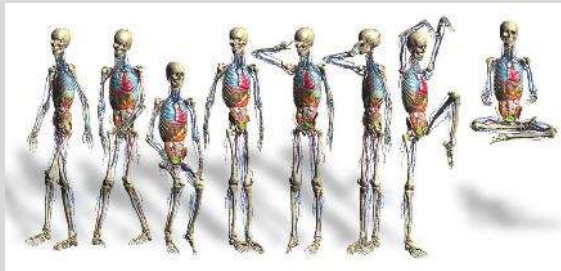
CDRH Regulatory Science Tools

CDRH Regulatory Science

- **Our work product is a collection of Regulatory Science Tools**
 - May be lab methods, AI training data sets, phantoms for medical imaging, computer models
 - Used by innovators and reviewers to standardise the evaluation of safety and effectiveness
 - Publicly available
 - Standardization of methods does not mean a guarantee of medical device quality

Importance of CDRH Regulatory Science

- Proven link between regulatory process efficiency and stimulating upstream innovation
 - 3 NIH Institutes + NSF actively funding tool development
- Organized into 20 programs
 - Some are specific to product areas (such as cardiovascular) or technology (such as AI/ML)
 - Important because many technologies reach across many product areas (such as biocompatibility, cybersecurity)



Impact of RSTs

- **3 years ago, we decided to publish a “catalog”**
 - Tools are now publicly available: cdrh-rst.fda.gov
 - Publications are validation of scientific basis of RSTs, not the work product
- **Early data suggests that product catalog has approx. tripled use of the tools**
 - Adding new tools at the rate of 50 a year
 - Looking to significantly expand capacity
- **RST utility is established upfront through voice of customer**
 - Active portfolio management and alignment with greatest needs

CDRH Tools Catalog



Tools Categories

- ☐ Lab Method (22)
- ☐ Computer Model (25)
- ☐ Device (5)
- ☐ Phantom (2)
- ☐ Physical (1)
- ☐ Clinical Outcome Assessment (1)

Program Areas

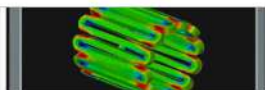
- ☐ Cardiovascular (15)
- ☐ Medical Imaging and Diagnostics (17)
- ☐ Orthopedic Devices (8)
- ☐ Biocompatibility and Toxicology (6)
- ☐ Credibility of Computational Models (5)
- ☐ Materials and Chemical Characterization (5)
- ☐ Neurology (5)
- ☐ AI / Machine Learning (2)
- ☐ Electromagnetic and Electrical Safety (2)
- ☐ Ophthalmology (2)
- ☐ Patient Monitoring and Control (2)
- ☐ Post Market Signal Response (2)
- ☐ Human Device Interaction (1)
- ☐ Medical Extended Reality (1)
- ☐ Sterility and Infection Control (1)



Phantoms for Assessing Image Quality and Dosimetry Performance

This regulatory science tool presents a set of tissue-mimicking phantoms suitable for benchtop performance assessment of photonics imaging (PMI) devices.

Medical Imaging and Diagnostics



Workflow for Assessing the Credibility of Patient-Specific Modeling in Medical Device Software

This regulatory science tool presents a method for assessing credibility of patient-specific computational models implemented in medical device software.

Credibility of Computational Models



TEEM Calculator

Get Started

This regulatory science tool is a method that applies the ISO 10603-17 technological risk assessment approach to medical device extractives screening data to assess systematic bias, generalizing, overgeneralization, or reproductive/developmental toxicity in the biocompatibility evaluation of a...

Biocompatibility and Toxicology



Chemicals List for Analytical Performance (CLAP)

Get Started

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Benchmark Validation Dataset for Laminar Flow in an Anatomical Vascular Model of the Inferior Vena Cava

Get Started

This tool provides a benchmark validation data set for laminar flow in an anatomical vascular model of the inferior vena cava (IVC).

Cardiovascular



EEG based Machine or Deep Learning Algorithms for TBI & Stroke Classification (EMATS)

Get Started

This RST contains a set of machine or deep learning algorithms which can be utilized in the development of relevant medical devices to assist in the prediction of traumatic brain injury (TBI) and stroke according to resting electroencephalography (EEG).

Neurology



Mock Circulatory Loop Generated Database for Dynamic Characterization of Pressure-based Cardiac Output Monitoring Systems

Get Started

This RST is a database tool consisting of nine mock circulation loop (MCL) generated datasets for characterizing three dynamic attributes of pressure-based cardiac output monitoring systems that apply an algorithm to intravascular arterial blood pressure waveforms for cardiac output and stroke volume estimation.

Cardiovascular / Patient Monitoring and Control



A "threshold-based" Approach to Determining an Acceptance Criterion for Computational Model Validation

Get Started

This RST, a "threshold-based" validation method, provides a means to determine an acceptance criterion for computational models. A "credible" computational model has the potential to provide a meaningful evaluation of safety in medical device submissions [1, 2].

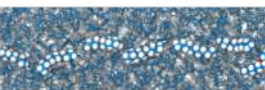
Cardiovascular



Strategy to Estimate Low to High Cycle Fatigue Transition of Nitinol for Fatigue to Fracture Test Planning

Get Started

This RST outlines a strategy for estimating the presence of cyclic phase transformation to aid in the determination of appropriate test levels for fatigue to fracture testing of nitinol components. Specifically, it includes a flowchart (Figure 1 in Appendix) to estimate the low to high cycle fatigue transition using either...



Device and Material Safety Evaluation Library (DAMSEL)

Get Started

The DAMSEL tool is a digital collection of published information related to the safety profile of materials extensively used in the manufacture of medical devices. This interactive application allows users to filter and access key response data for studies relating to material biocompatibility along with hyperlinks to the...



VICTRE: In Silico Breast Imaging Pipeline

Get Started

The Virtual Imaging Clinical Trials for Breast Risk Evaluation (VICTRE) computer modeling pipeline is a set of tools that allow for the replication of clinical trials of in silico breast radiographic images for the evaluation of digital mammography (DM) and digital breast tomosynthesis (DBT) devices.



Targeted Box and Blocks Test (TBBT)

Get Started

A performance based method requiring controlled grasping, transport, and release of objects that can be used to evaluate upper limb functional ability.

Examples of CDRH RSTs

- **iMRMC**
 - Statistical Model Developed for use in imaging and digital pathology
 - To date, has been used in 62 premarket submissions covering 14 different product codes across 4 OHTs, including devices with breakthrough designation

MRMC = multiple readers and multiple cases

OHT = Office of Health Technology

Examples of CDRH RSTs

- **Evaluation of AI-based algorithms and bias**
 - Developed 2 separate approaches to assess bias and evaluate impact on AI algorithm development
 - Tool (DRAGen) is currently being publicly released
 - Used in reducing X-ray dose for CT scanning of susceptible patients including pediatrics

CT = computed tomography

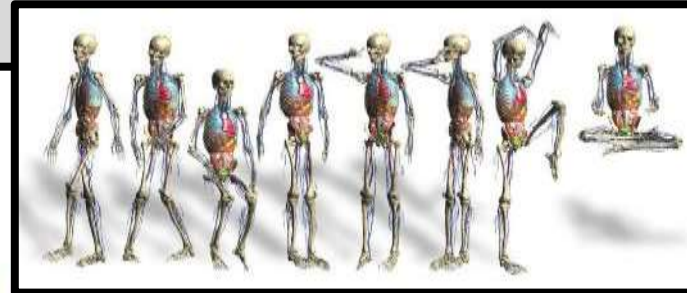
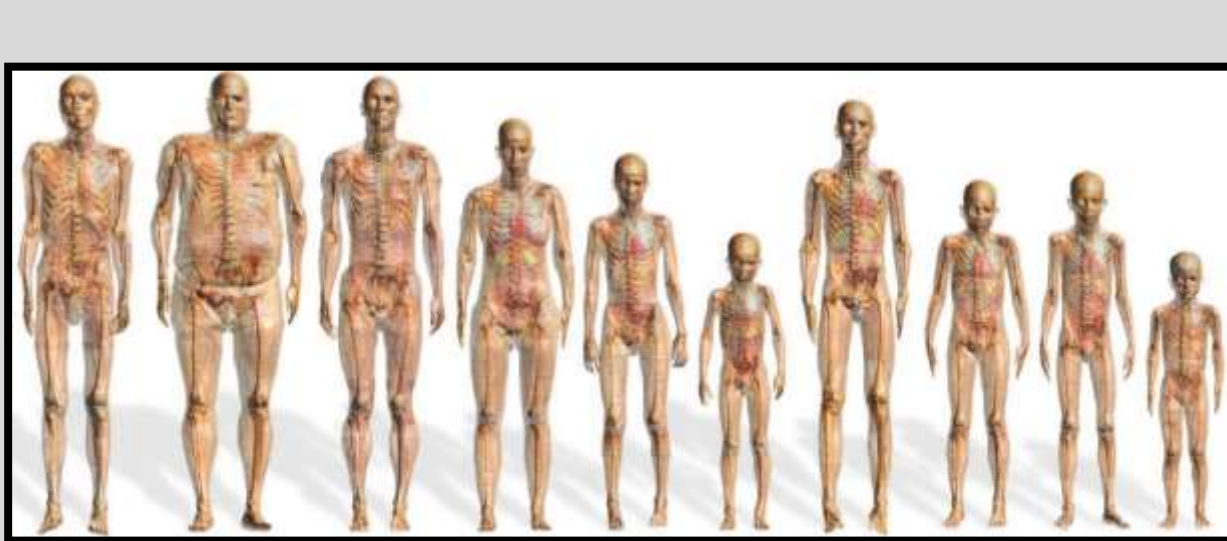
Examples of CDRH RSTs

- **CHRIS Family**
 - Used for early biocompatibility evaluation prior to design freeze
 - Available at the public RST App: cdrh-rst.fda.gov

CHRIS = chemical risk calculators

The Virtual Family

The Virtual Population is a set of anatomically correct whole body models for thermal, electromagnetic, and fluid dynamic simulations



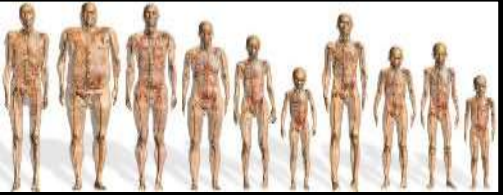
male elderly
1.73m, 65kg

male adult
1.74m, 70kg

11 year old girl
1.46m, 36kg

14 year old boy
1.65m, 50kg

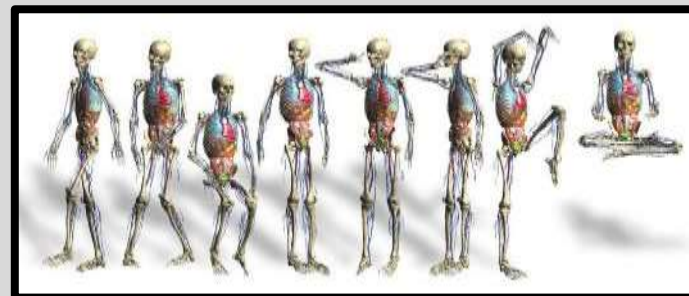
8 year old boy
1.40m, 26kg



The Virtual Family

The Virtual Population is a set of anatomically correct whole body models for thermal, electromagnetic, and fluid dynamic simulations

- Cited in over 850 premarket submissions
- Used in over 450 premarket submissions, including



Drug eluting stents



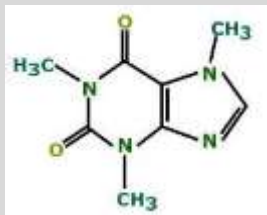
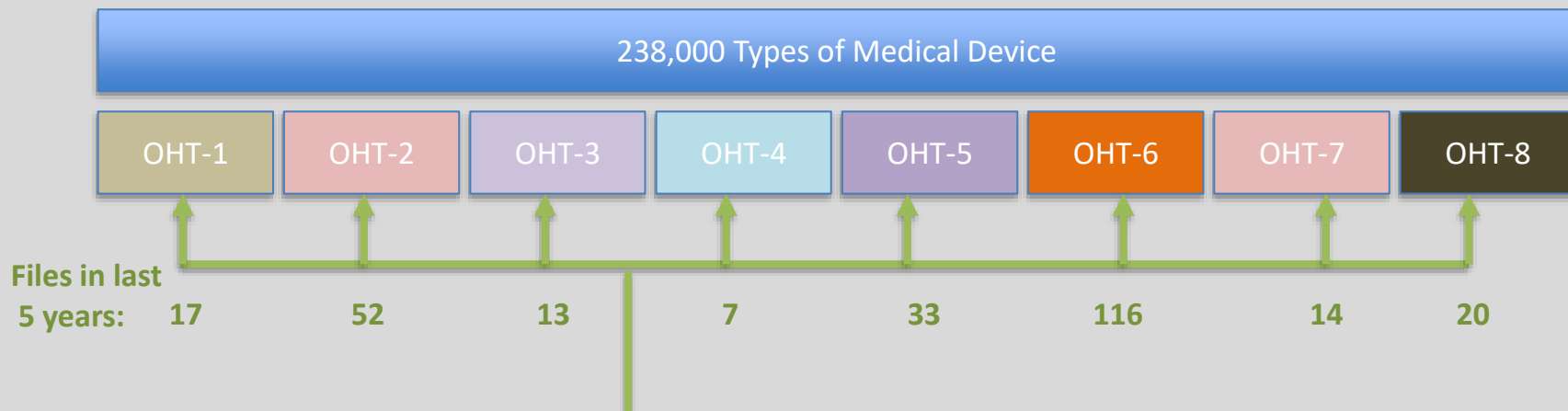
Orthopedic Bone Plates



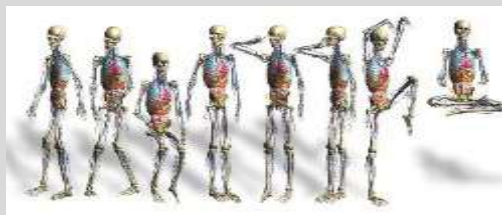
World's First 7T MRI Scanner



Tools Impact Multiple Product Areas



CHRIS



Virtual Family

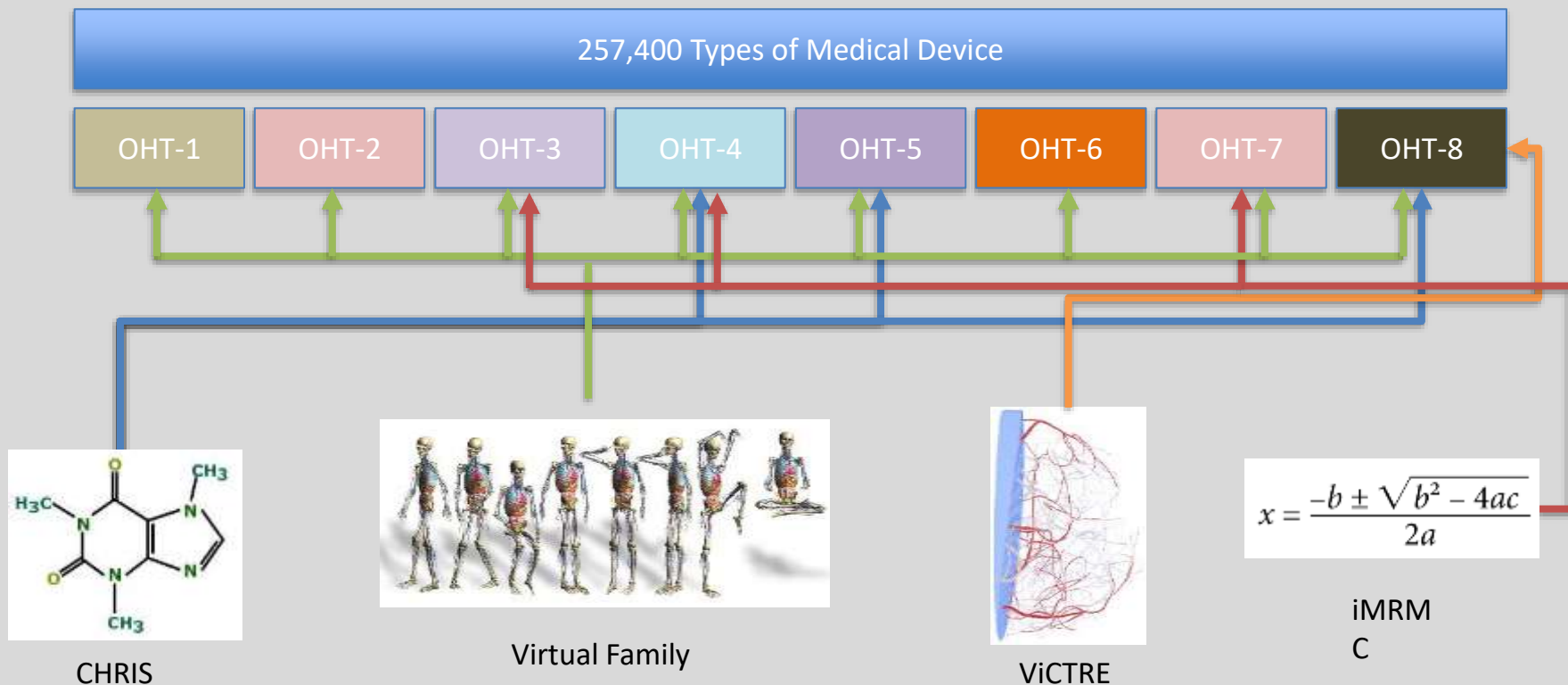


ViCTRE

$$x = \frac{-b \pm \sqrt{b^2 - 4ac}}{2a}$$

iMRMC

Tools Impact Multiple Product Areas



Knowledge Check

Who can use regulatory science tools?

1. Researchers in academia
2. Industry product development teams
3. CDRH reviewers
4. All of the above



Knowledge Check

True or False: Regulatory Science Tools guarantee FDA clearance or approval of your medical device application?

1. True
2. False



Summary

- Regulatory science tools are publicly available
- They help **innovators**, by allowing them to focus on how good the technology or product is, and not how well is it tested
- They help **product development teams** by allowing easier benchmarking of a product early in development
- They help **CDRH reviewers** through familiarity with evaluation methods

Questions



Your Call to Action

- **Learn more about regulatory science tools**
 - Start by going to catalog
- **Explore where you may put RSTs to use**
 - Let us know what is needed