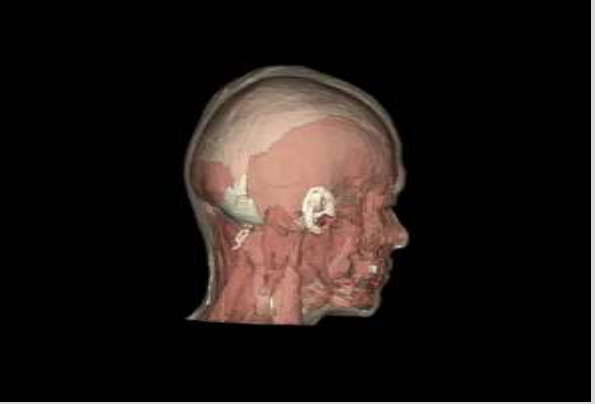


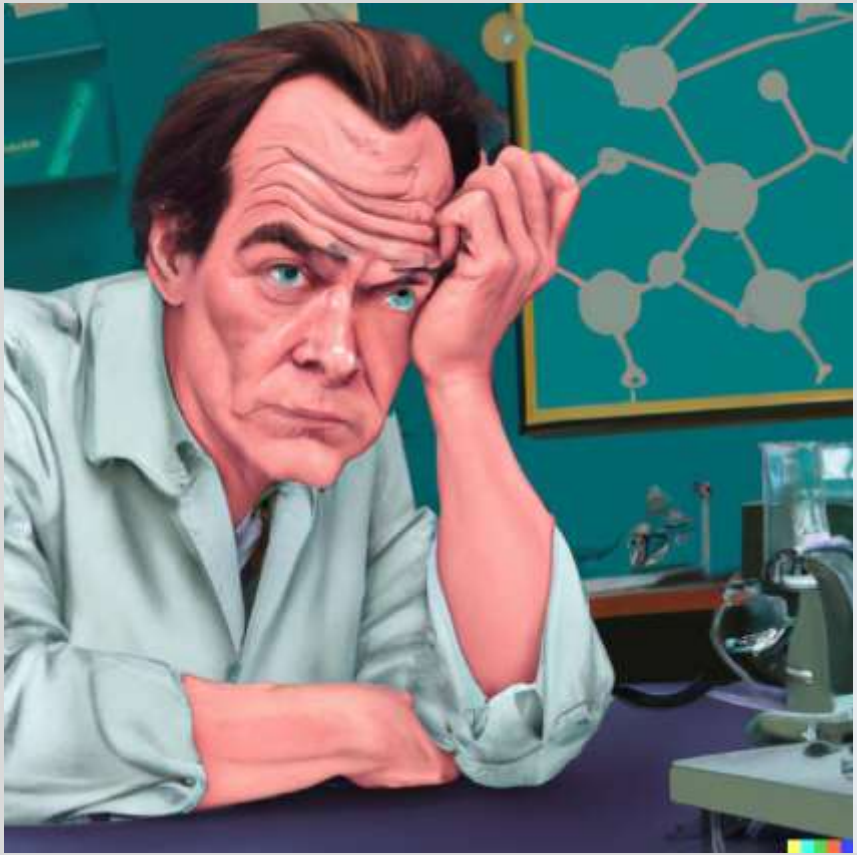
Accelerating Device Innovation Through Regulatory Science

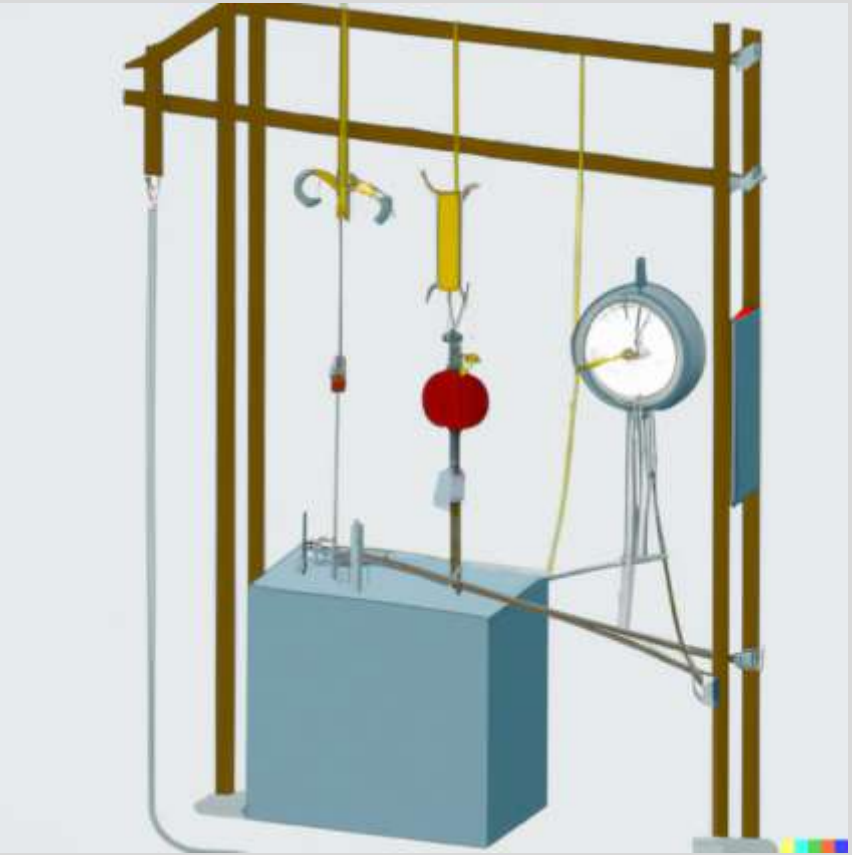
FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

May 29, 2024

Ed Margerrison, PhD
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

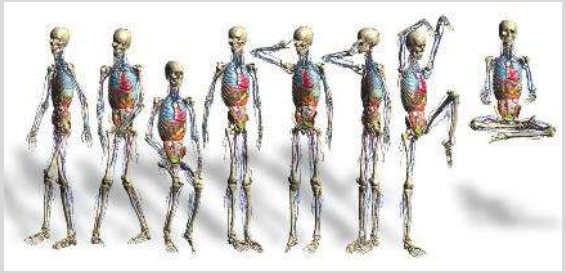
CDRH Regulatory Science Tools

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

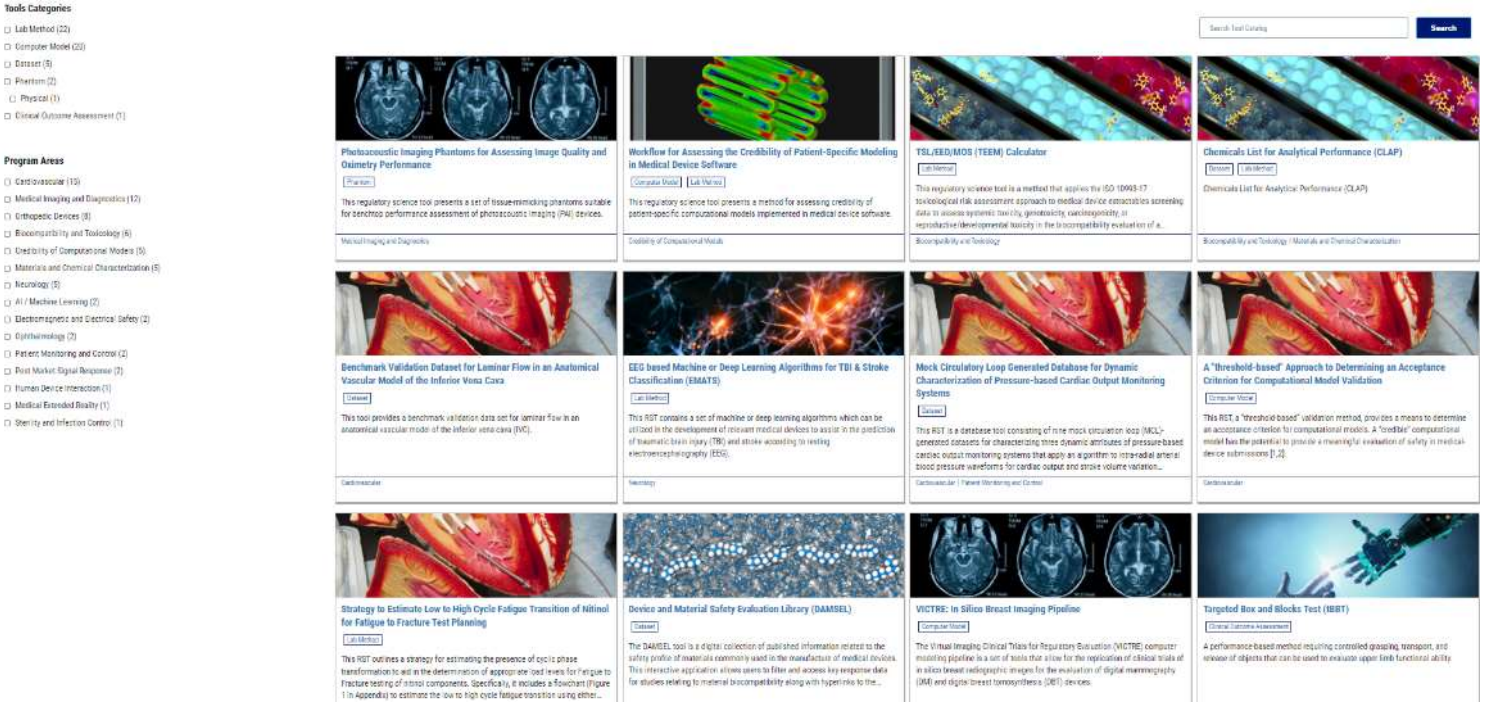
- Proven link between regulatory process efficiency and stimulating upstream innovation
  - 3 NIH Institutes + NSF actively funding tool development
- Organized into 20 programs
  - Some are specific to product areas (such as cardiovascular) or technology (such as AI/ML)
  - Important because many technologies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



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

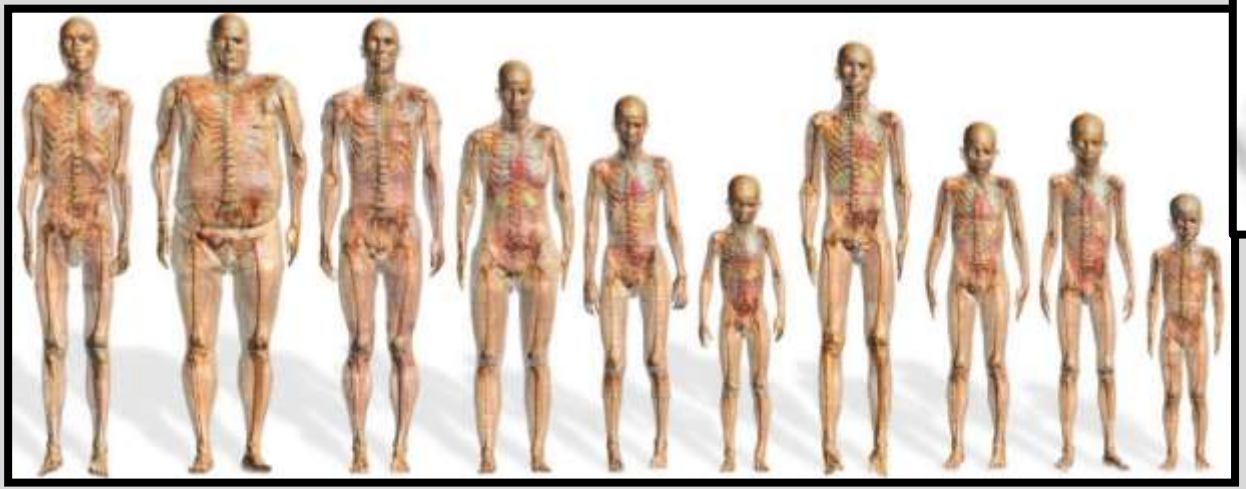
Examples of CDRH RSTs

- **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



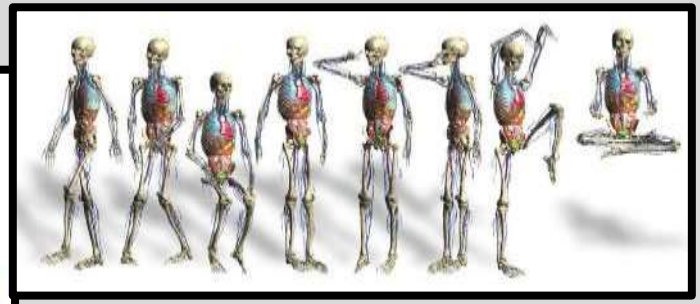
male elderly
1.73m, 65kg

male adult
1.74m, 70kg

11 year old girl
1.46m, 36kg

14 year old boy
1.65m, 50kg

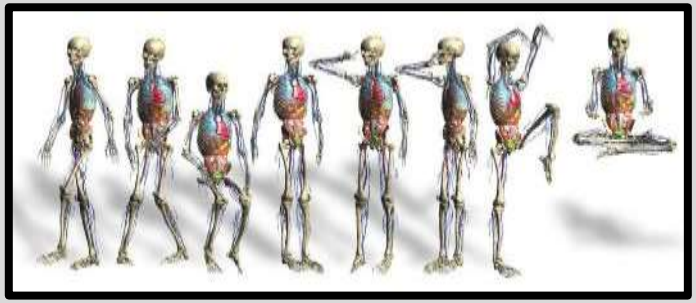
8 year old boy
1.40m, 26kg



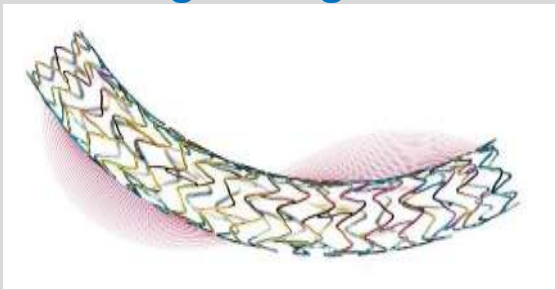
The Virtual Family

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

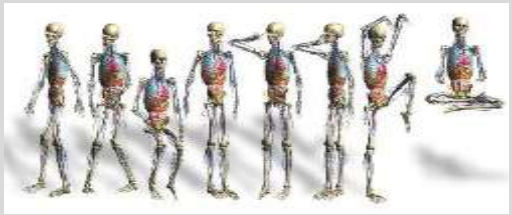
World's First 7T MRI Scanner

Tools Impact Multiple Product Areas

238,000 Types of Medical Device

OHT-1	OHT-2	OHT-3	OHT-4	OHT-5	OHT-6	OHT-7	OHT-8
Files in last 5 years: 17	52	13	7	33	116	14	20

CHRIS



Virtual Family

ViCTRE

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

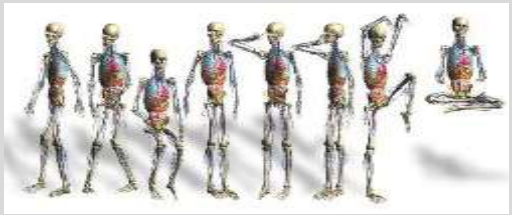
iMRMC

Tools Impact Multiple Product Areas

257,400 Types of Medical Device

OHT-1 | OHT-2 | OHT-3 | OHT-4 | OHT-5 | OHT-6 | OHT-7 | OHT-8

CHRIS



Virtual Family

ViCTRE

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

iMRM
C

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