Medical Device System Engineering

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In a Digital World

CSDM Paris 2018

Product & Services in a Digital world

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ADN in a Nutshell : LifeScience Compliance

40 Employees

PARIS

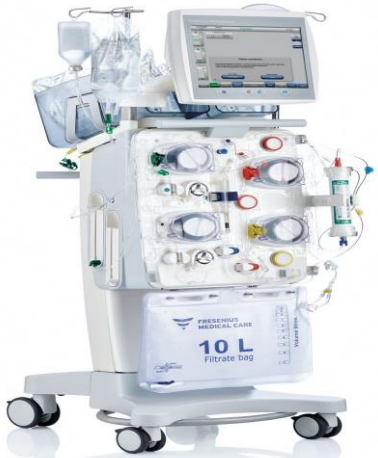
Consultancy

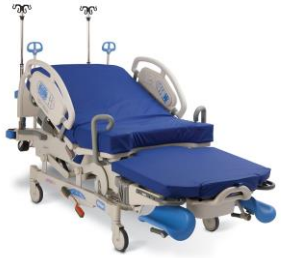
Since 1993

4 M €

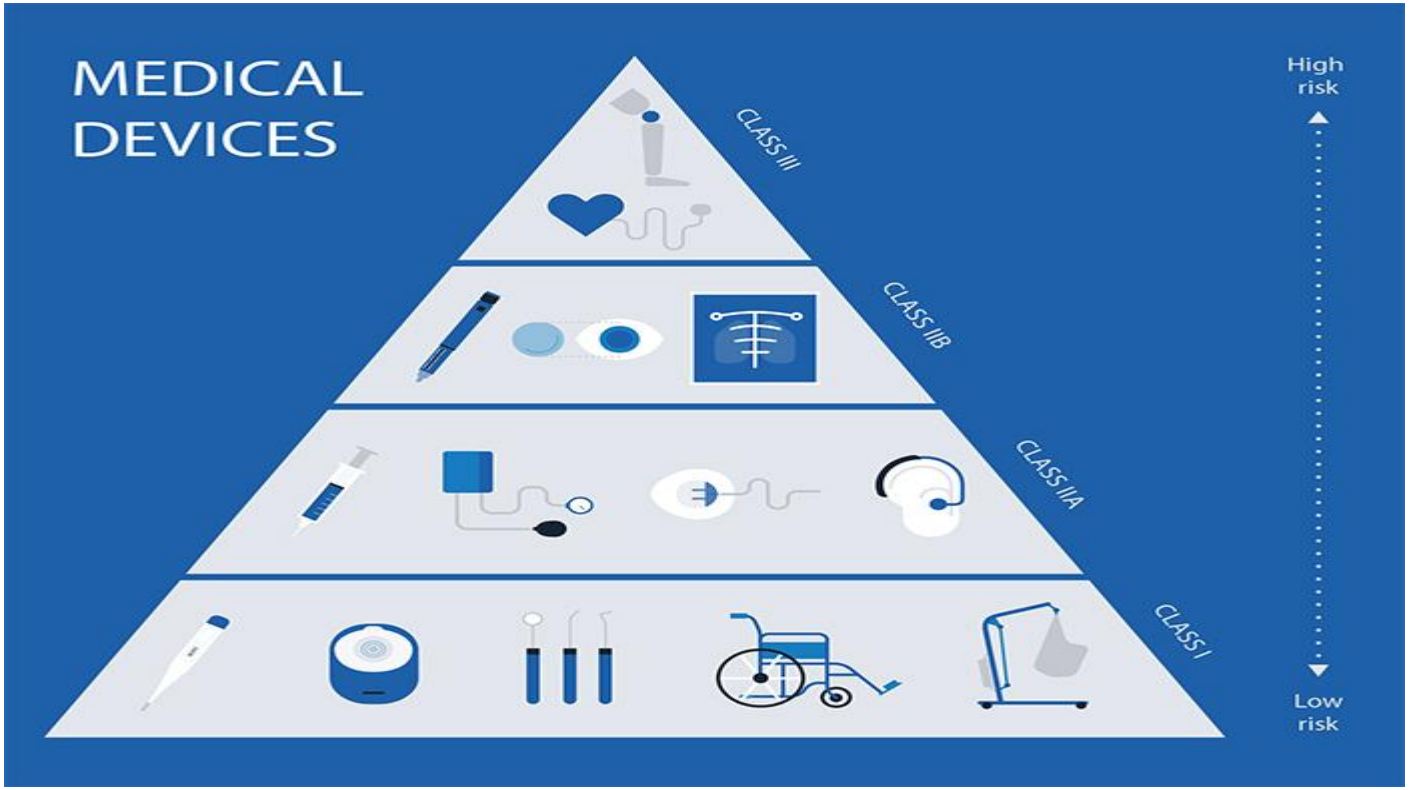
LYON

What is a medical device ?



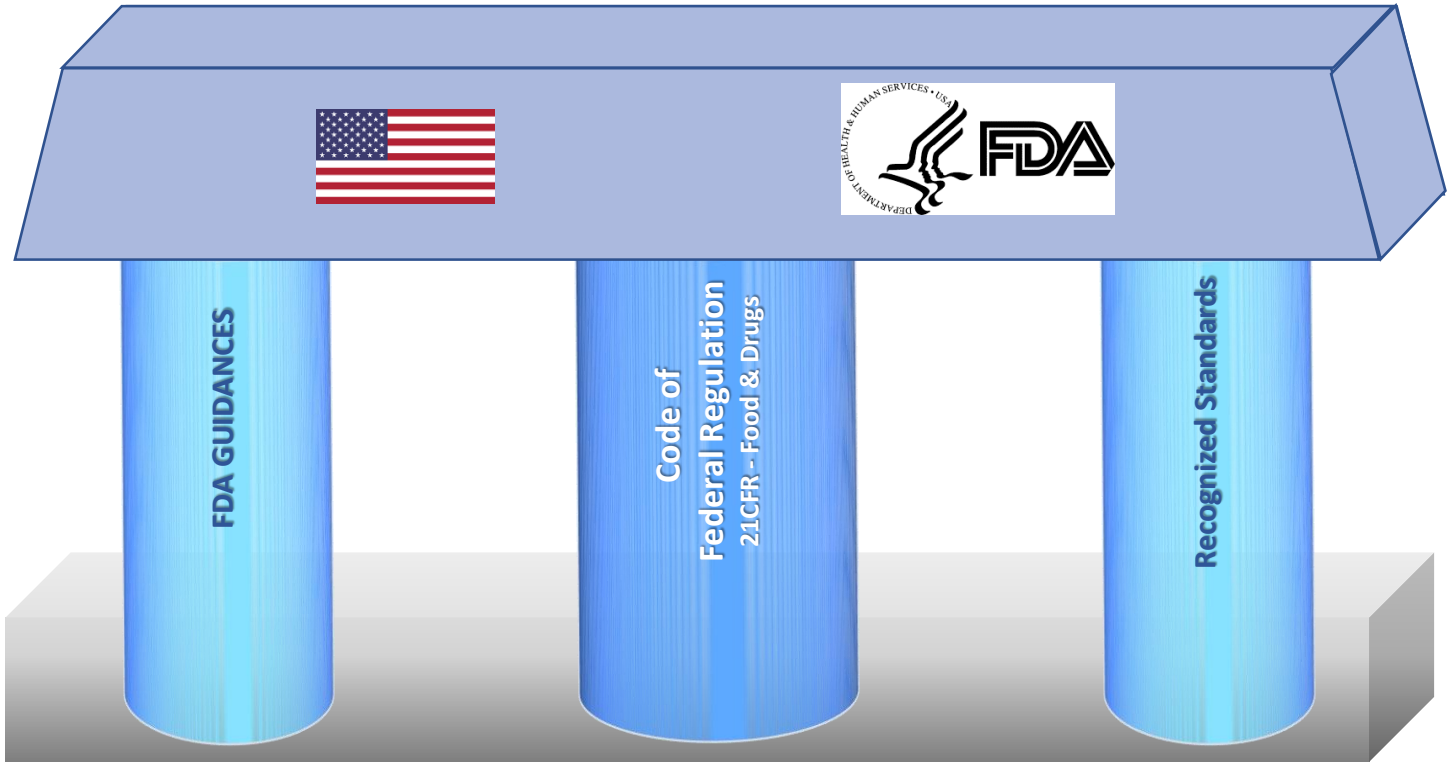


What is a Medical Device Class?

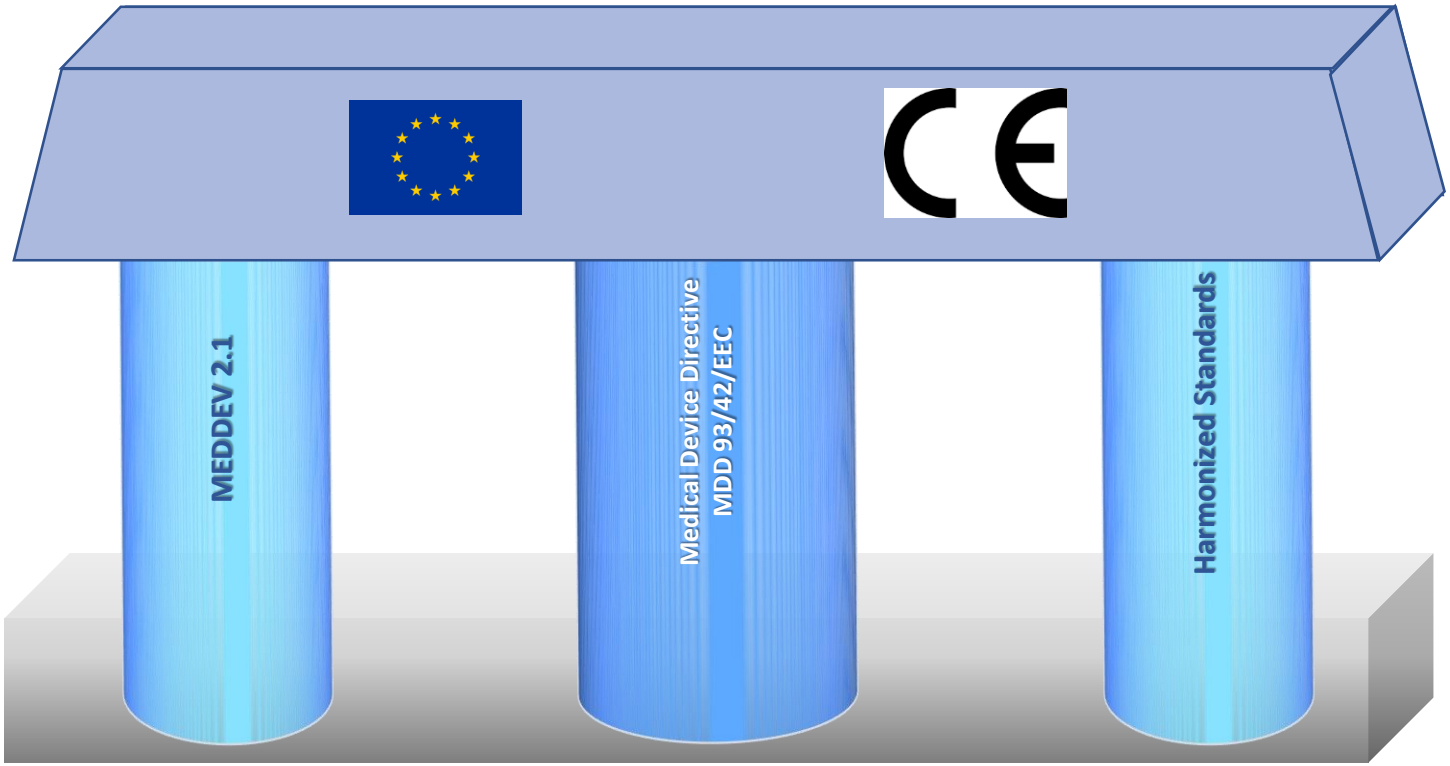


$$Engineering + Quality + Regulatory + Clinical = f\,(Medical\ Device\ Class)$$

US Medical Device Market Authorization



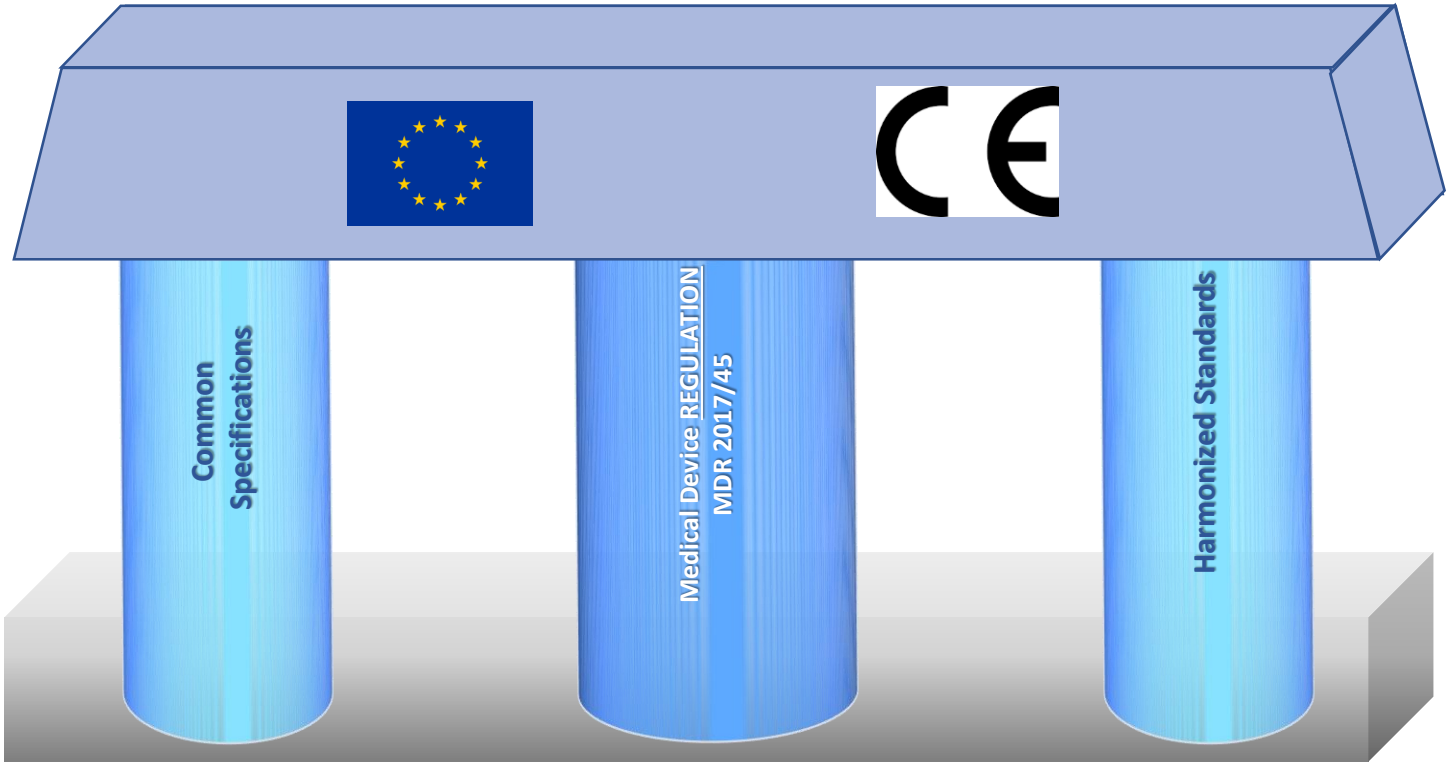
Europe Medical Device Directive



May 2020

MDD MDR

Europe Medical Device Regulation



May 2020

MDD → MDR

Apple Watch 4 Is Now An FDA Class 2 Medical Device: Detects Falls, Irregular Heart Rhythm

1 month FDA PMN

<u>For the App !</u>

CE : Not Yet !

Why ?

Subsystem definiton issue ?

Engineering practices (soft)

- With short product life cycle cycle, digital is one way to differentiate to create a unique experience.
- For medical device startup, they have no chance to raise funds without including IA in there pitch elevator
- Enginnering pratices are governed by standards :

IEC 62 304	**Software developpement**
ISO 13 485	**Quality Management System**
ISO 14 971	**Risk Management**

Engineering practices (system view)

Table 1. Comparison of Healthcare Safety Regulations with ISO/IEC/IEEE 15288 and the INCOSE *SE Handbook*.

21CFR820.30	ISO/IEC/IEEE 15288:2015	INCOSE *SE Handbook*
(b) Design and development planning	6.3.1 Project Planning Process	5.1 Project Planning Process
(c) Design input.	6.4.2 Stakeholder needs and requirements definition process 6.4.3 Systems requirements definition process	4.2 Stakeholder needs and requirements definition process 4.3 Systems requirements definition process
(d) Design output	6.4.5 Design definition process 6.4.7 Implementation process	4.5 Design definition process 4.7 Implementation process
(e) Design review	6.3.2 Project Assessment and Control process	5.2 Project Assessment and Control process
(f) Design verification	6.4.9 Verification Process	4.9 Verification Process
(g) Design validation	6.4.11 Validation Process	4.11 Validation Process
(h) Design transfer	6.4.10 Transition Process	4.10 Transition Process
(i) Design changes	6.3.5 Configuration Management Process 6.4.13 Maintenance Process	5.5 Configuration Management Process 4.13 Maintenance Process
(j) Design history file	6.2.6 Knowledge Management Process	5.6 Information Management Process

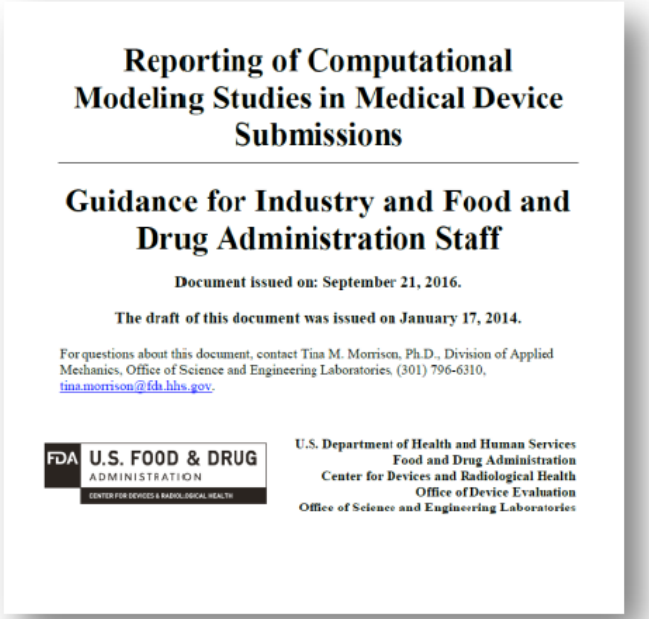
Document oriented for very large number of Medical Device Compagnies
Even for some software pure player …
Disconnected Processes … Change and Configuration challenges !

System Engineering

- The complexity of the Experience – versus solution – services – product – justifies the SE approach. MD shares the same challenges !
- However this regulated sector is controlled by **Norms** acting as market access gate.
- Nowdays regulation slows dow innovation in europe … US FDA is unlocking, hoping incumbent actors will be challenged or disrupted to reduce healthcare cost .

Digital System Engineering

- Microsoft is dominating the SE tool market with 4 best sellers : Excel, Word, Windows Server, and Outlook ! with Azure and Git becoming more and more popular …
- With a clear Cyber-Physical experience trend, the medical device sector needs also a reliable and secure digital system engineering framework .
- Automotive and Aerospace are driving the initiative.



Reporting of Computational Modeling Studies in Medical Device Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on: September 21, 2016.

The draft of this document was issued on January 17, 2014.

For questions about this document, contact Tina M. Morrison, Ph.D., Division of Applied Mechanics, Office of Science and Engineering Laboratories, (301) 796-6310, tina.morrison@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Office of Science and Engineering Laboratories

Reporting on Computational Modeling Studies in Medical Device Submissions

FDA Seminar

BMES/FDA Frontiers Conference

Tina Morrison

Guidance Lead

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM381813.pdf

ASME V&V 40

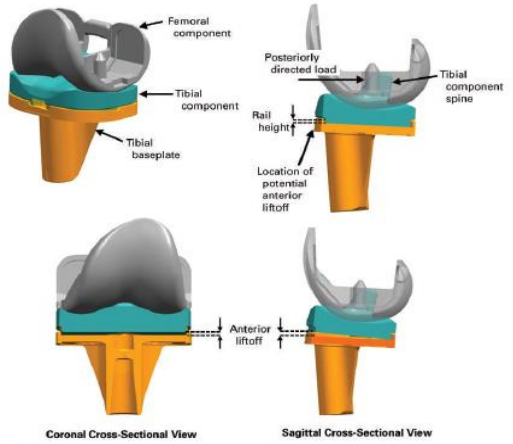
ASME V&V 40-2018

Assessing Credibility of Computational Modeling Through Verification and Validation: Application to Medical Devices

AN INTERNATIONAL STANDARD

The American Society of Mechanical Engineers

Figure B-2.5.1-1 Schematic of a Posterior-Stabilized TKA Assembly



GENERAL NOTES:
(a) This Figure shows illustrations of an anterior liftoff test to assess the strength of the locking mechanism between the polyethylene tibial component and the metal tibial baseplate in total knee arthroplasty, in which a posteriorly directed load on the spine of the tibial component results in anterior liftoff of the component from the tibial baseplate.
(b) Courtesy of Zimmer Biomet, Warsaw, IN.

B-2.5.2 Question of Interest. Does the locking mechanism of a posterior-stabilized TKA design have sufficient strength to withstand posteriorly directed loads?

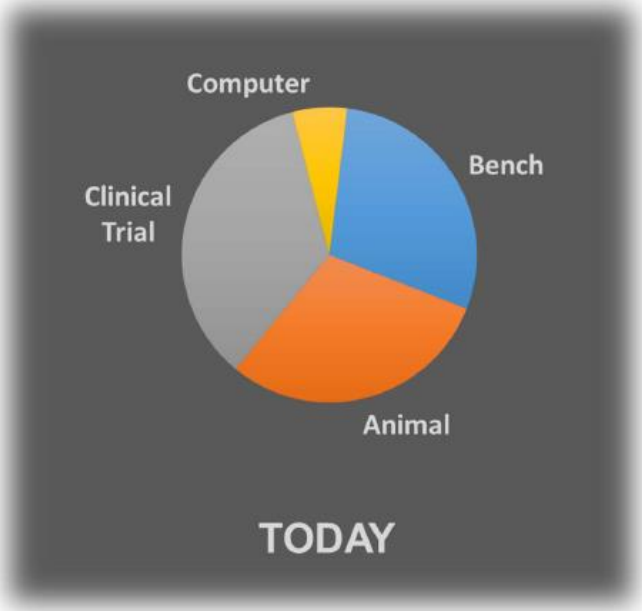
B-2.5.3 Contexts of Use. Several COUs for a model of tibial component liftoff are described in Figure B-2.5.3-1. These COUs are differentiated *not* based on intrinsic model assumptions (e.g., mesh size, loading conditions) but rather based on the extent to which there is additional information, outside of the computational model, that can be used to inform the necessary decision about the device — namely, does the locking mechanism have sufficient strength to withstand posteriorly directed load? Such additional information could include the extent to which benchtop testing of the proposed device will be performed, as well as whether the proposed device is evaluated relative to an existing (predicate) device with sufficient locking mechanism strength, as demonstrated through benchtop testing, in vivo data, or other means.

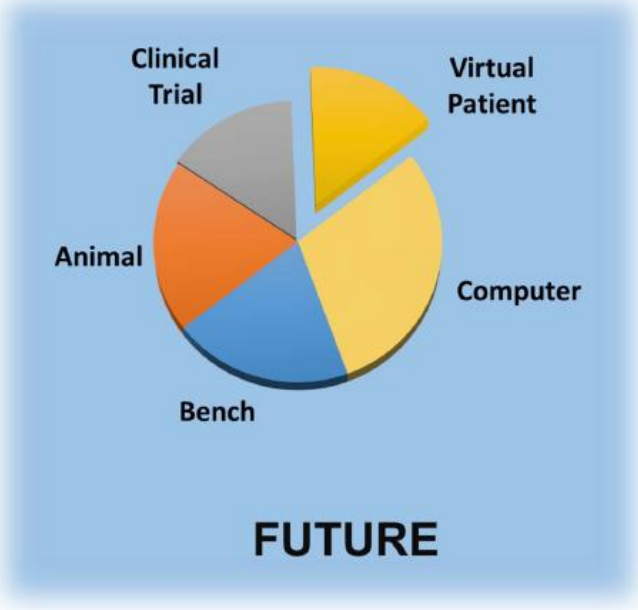
B-2.5.3.1 COU1: Performance Evaluation Without Testing. The tibial component anterior liftoff is evaluated exclusively using the computational model.

B-2.5.3.2 COU2: Performance Evaluation With Testing. The computational model is used to predict the worst-case size across the proposed product portfolio in terms of tibial component anterior liftoff, and this worst case is then physically tested.

Digital Evidence vs Clinical Evidence

Reliance on Evidence from Different Models





Summary

- Regulatory Framework is evolving to address patient safety
- Digital System Engineering can reduce the cost of experience development by leveraging in medical device, technics and processes used in other industries
- However, there are scientifics challenges as we are probably one of the most complex system !