



Powering Innovation That Drives Human Advancement

The Current State of Standards for Orthopaedic Implant Development

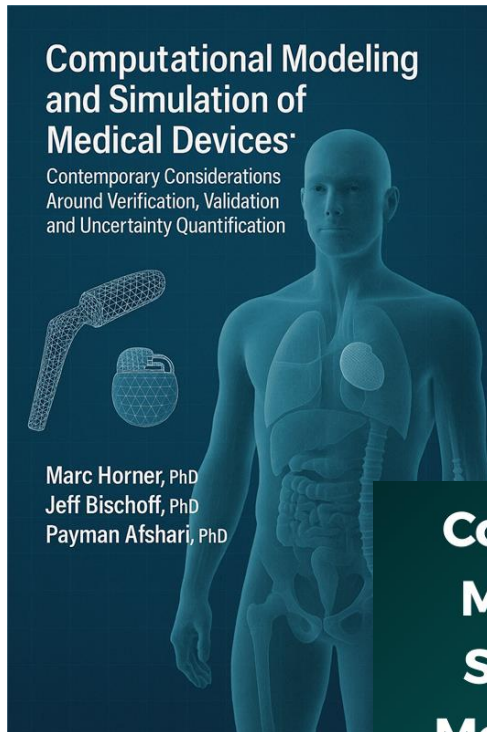
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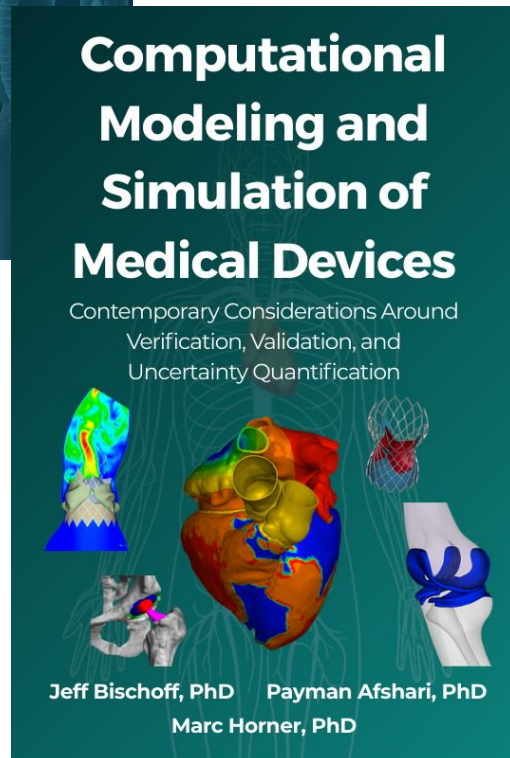
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draft cover art – credit Payman Afshari



draft cover art – credit Jared Garcia

Section 1. Introduction and Fundamentals of Model Credibility (5)

→ background on VVUQ and an ASME VV-40 overview

Section 2. Regulatory Considerations (5)

→ includes FDA, EMA and other considerations

Section 3. Contemporary Applications of CM&S in Medical Device Development (11)

→ includes 5 cardio. chapters and 4 ortho. chapters

Section 4. Emerging Topics around CM&S in Healthcare (3 or 4)

→ SaMD, *in silico* clinical trials, data-based models

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Chapter 6. Regulatory Perspectives and Considerations on the Use of Computational Modeling to Support Medical Device Submissions in the United States

Marc Horner, Ansys, Inc., Evanston, IL, USA
Srinidhi Nagaraja, G.RAU Inc., Scotts Valley, CA, USA

General introduction to the FDA review/approval process in the context of CM&S

Reviews the current state of standardized *in silico* methods supporting medical device evaluation

Chapter 10. Standardized *In Silico* Methodologies to Support Medical Device Design and Evaluation

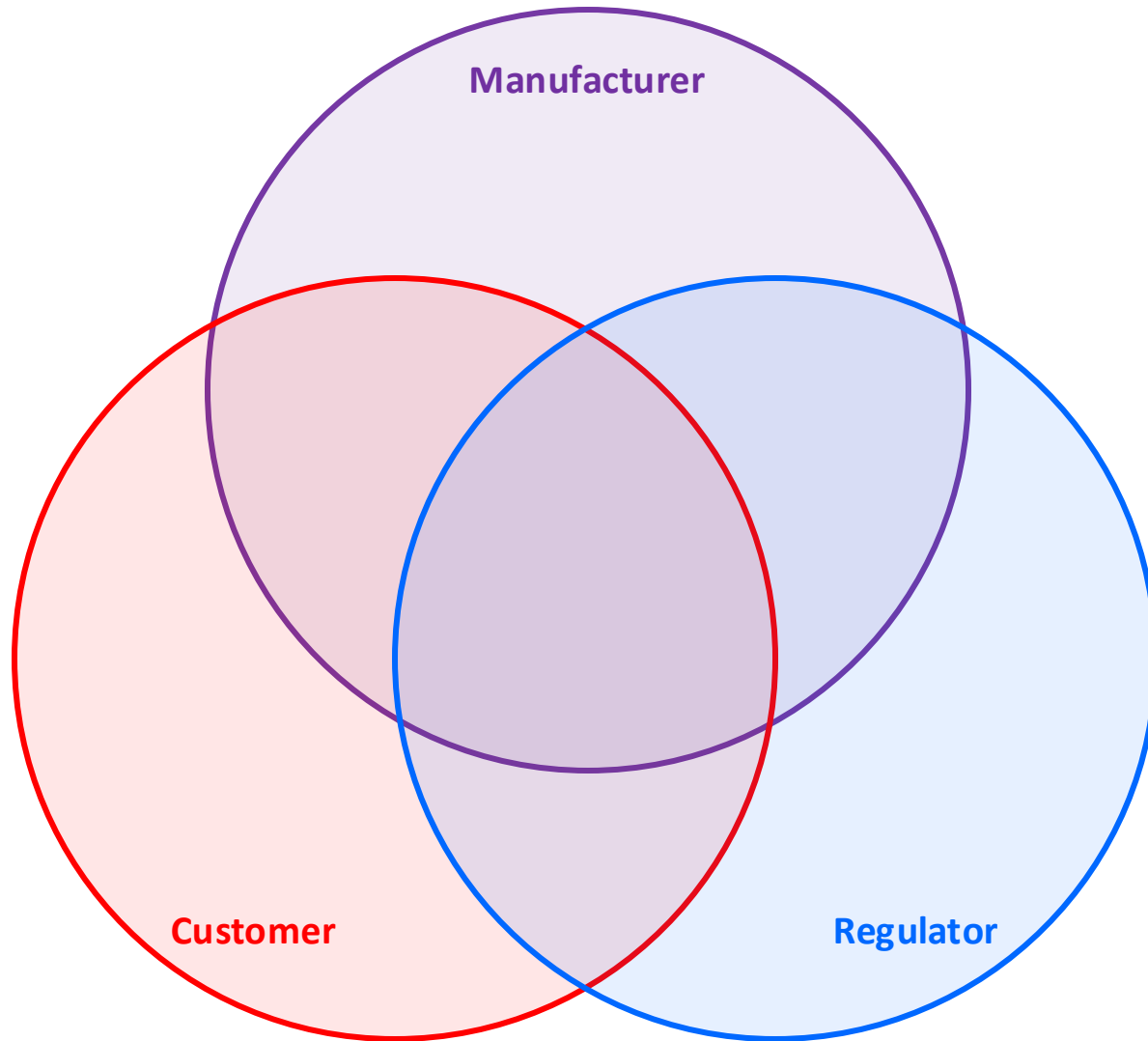
Jeffrey E. Bischoff*, Brandon A. Lurie*, Walter Schmidt#

*Zimmer Biomet, Warsaw, IN

*W.L. Gore & Associates, Flagstaff, AZ

#Stryker, Mahwah, NJ

Standards Development - Stakeholders



Manufacturer

- Medical device designers/manufacturers

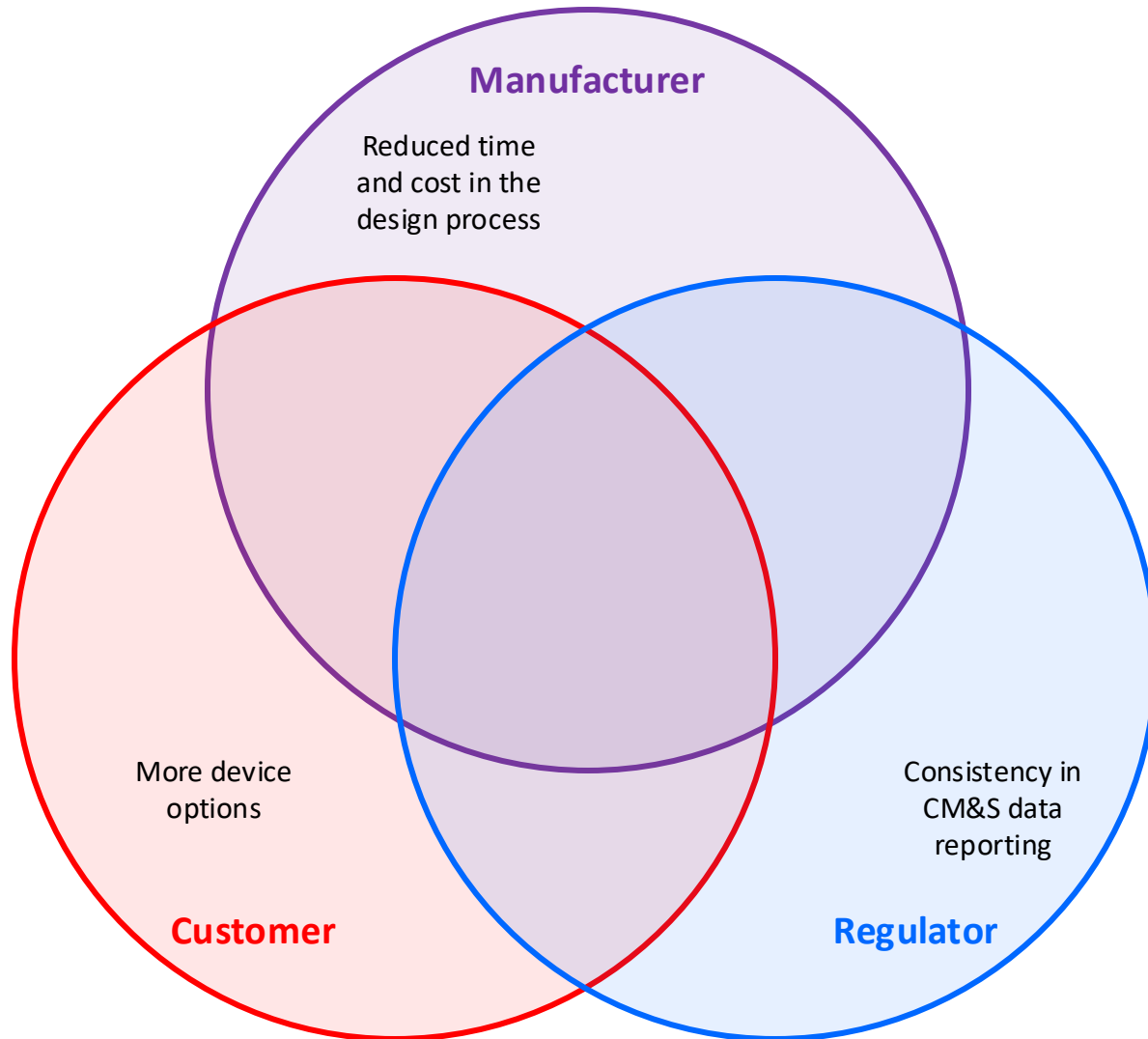
Customer

- Directly involved in the clinical deployment of a device (clinicians, patients, purchasers)

Regulator

- Controls access of medical devices

Standards Development - Benefits



Manufacturer

- Clarity on how to assess device safety/efficacy
- Lowered burden associated with model development

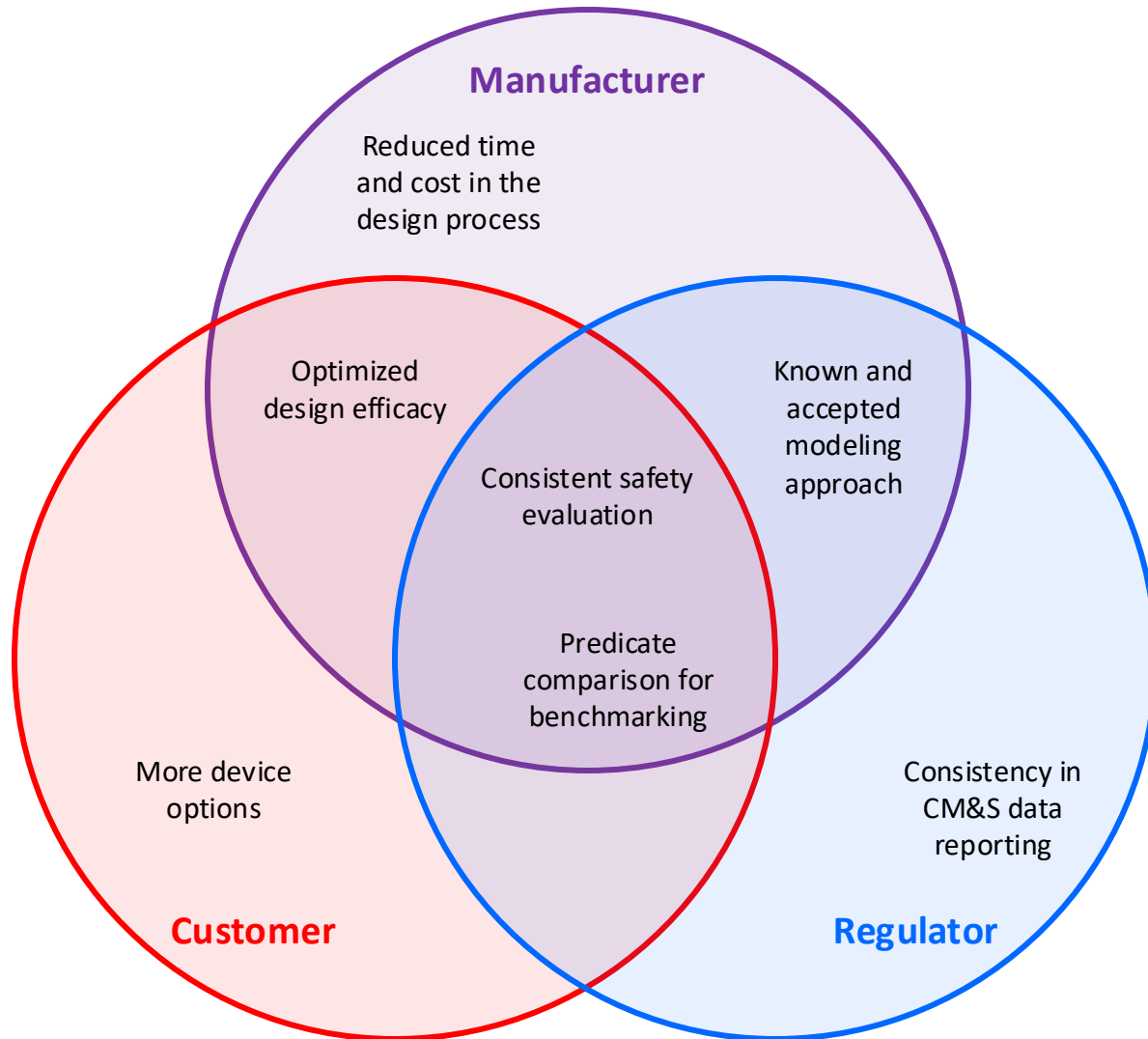
Customer

- Ensure that a device meets technical performance requirements under a range of use conditions
- Ensure ease of use of a new device

Regulator

- Specify conditions that are appropriate for the device's intended use and provide guidance on how to build credibility into the model
- Consistency in the model set-up and reporting can reduce review time and regulatory uncertainty

Standards Development – Benefits (cont'd)



Manufacturer - Customer

- Decreased cost of development

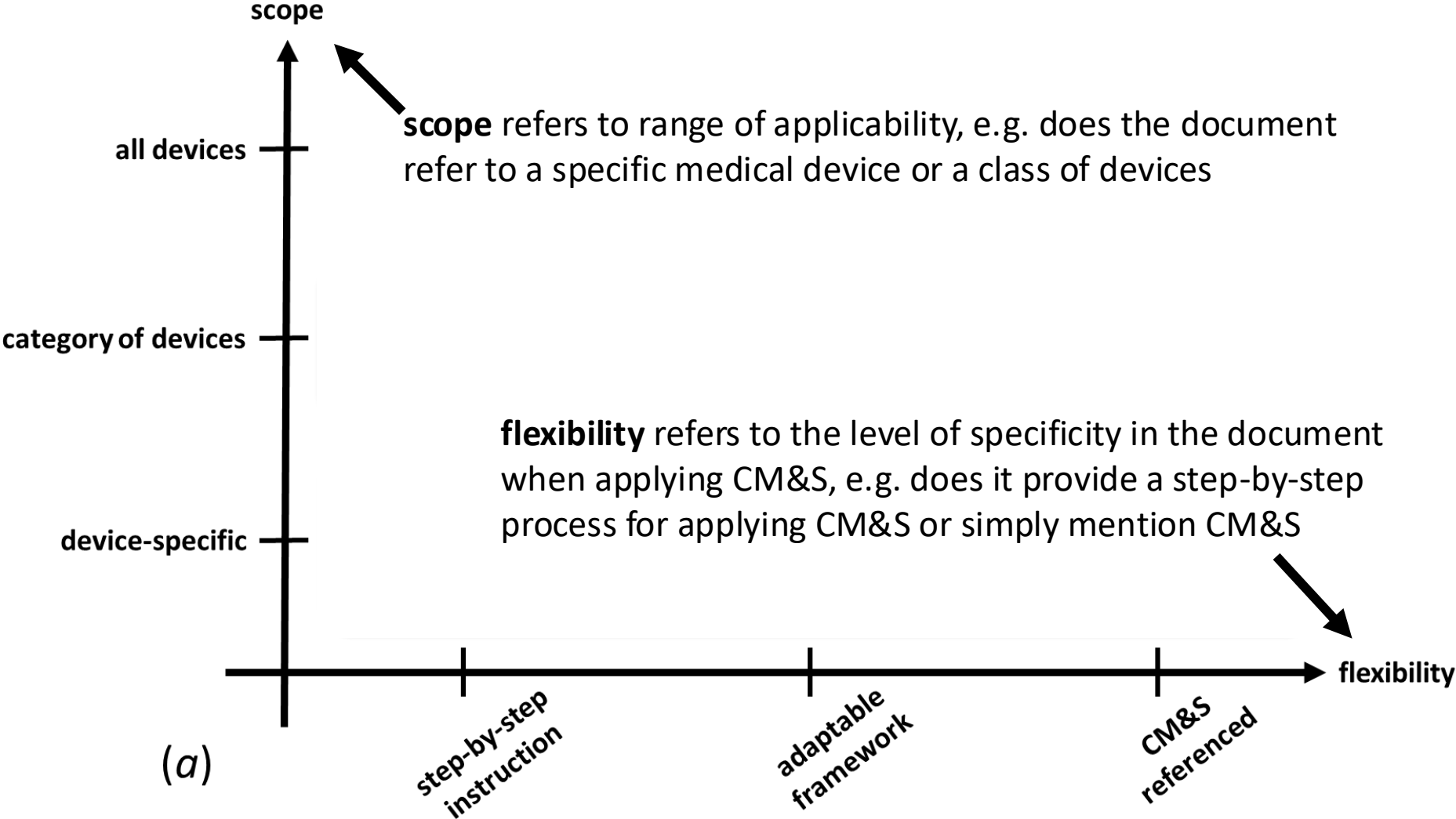
Manufacturer - Regulator

- Increased confidence when incorporating CM&S into regulatory strategies

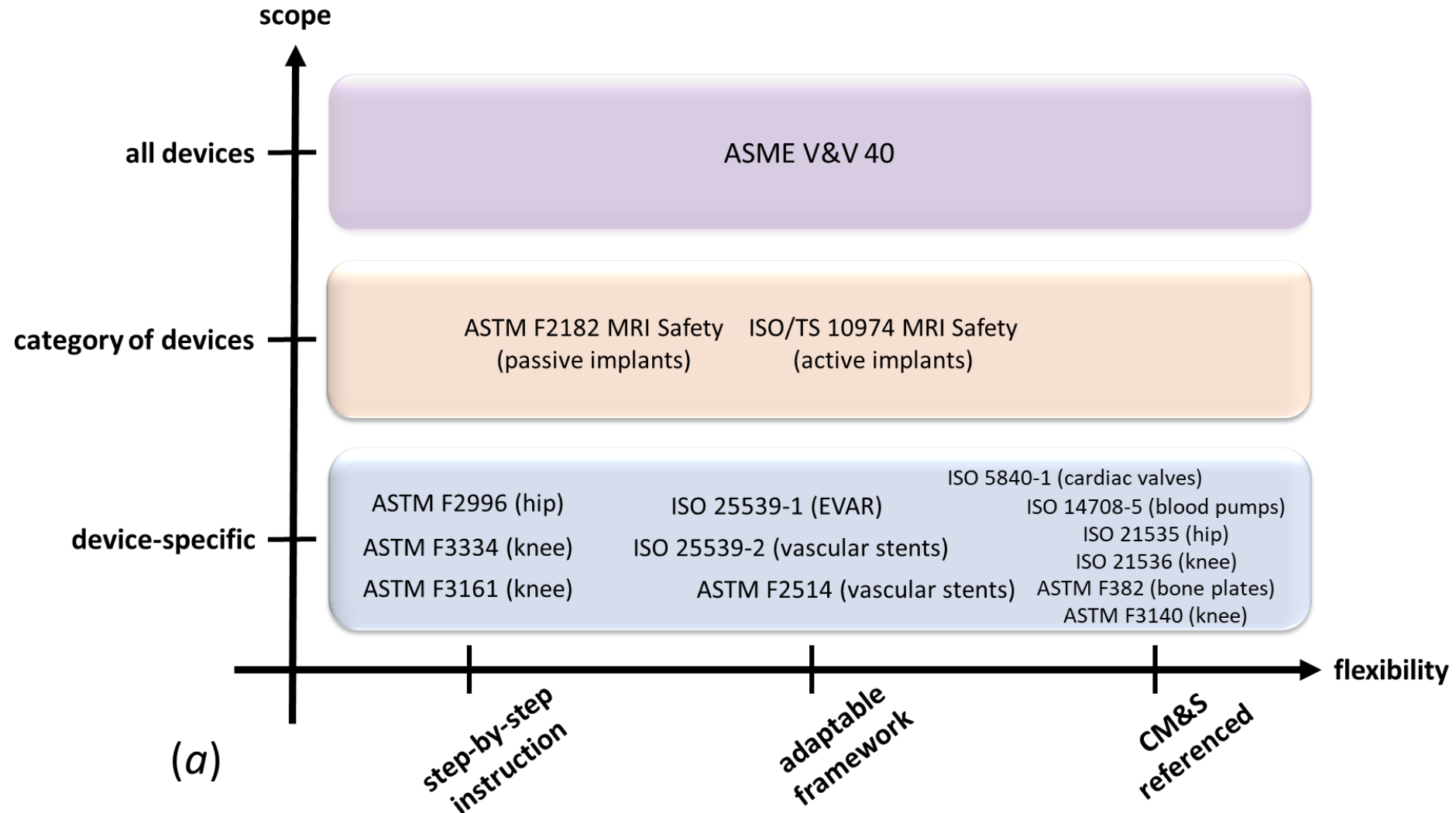
Manufacturer - Regulator - Customer

- Enable comparisons to predicate designs with a proven clinical track record

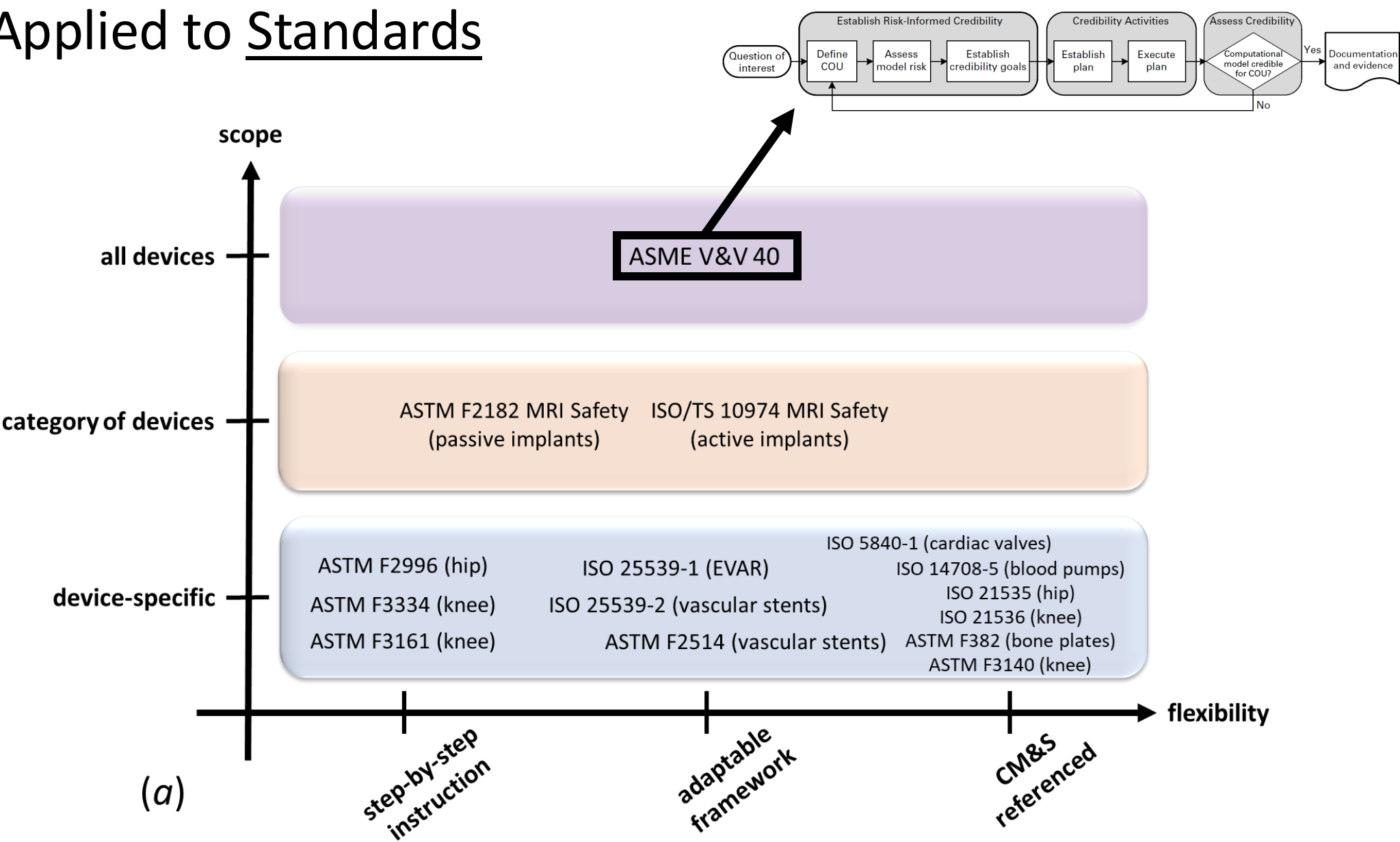
A Rubric for Evaluating Standards and Guidance



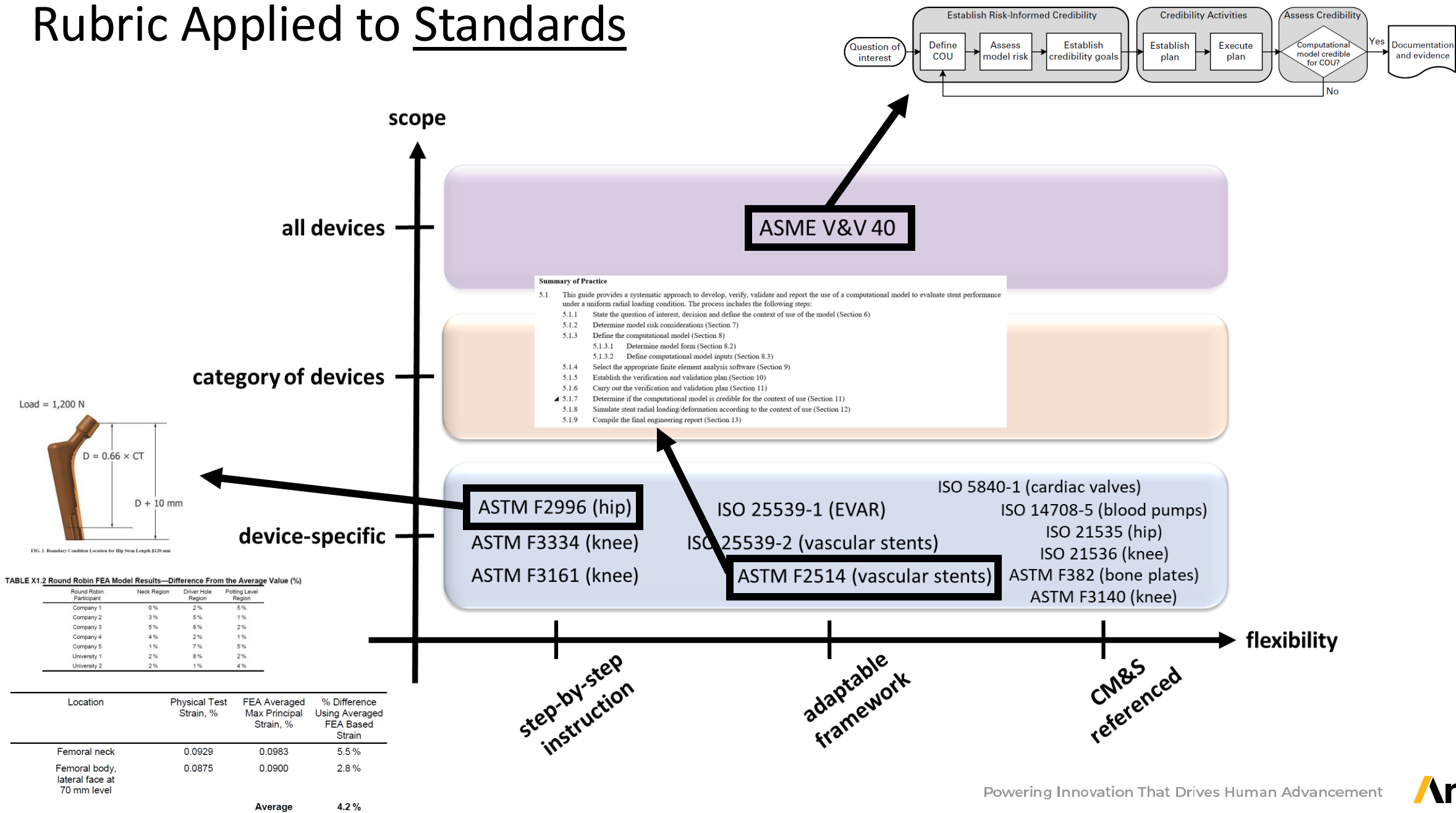
Rubric Applied to Standards



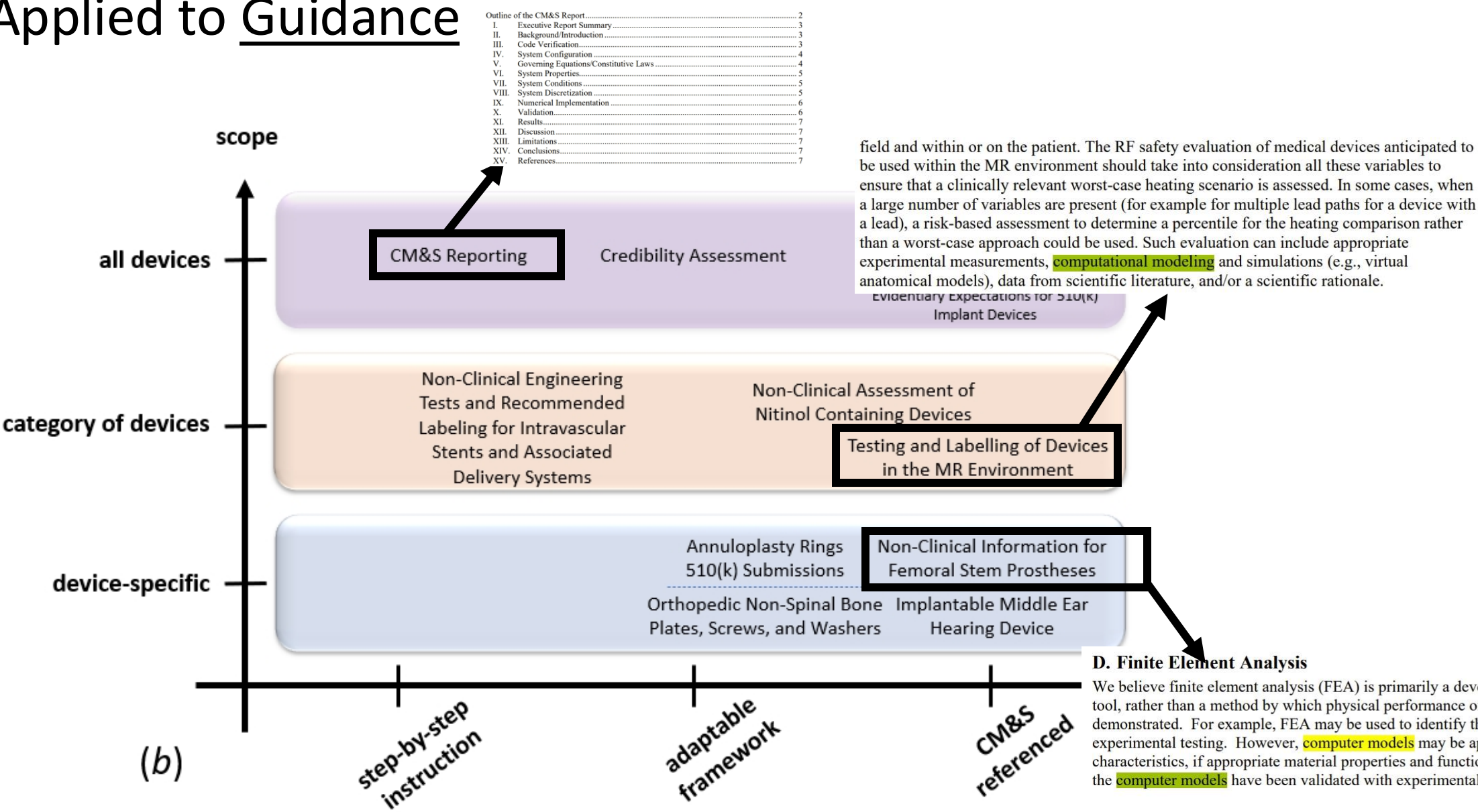
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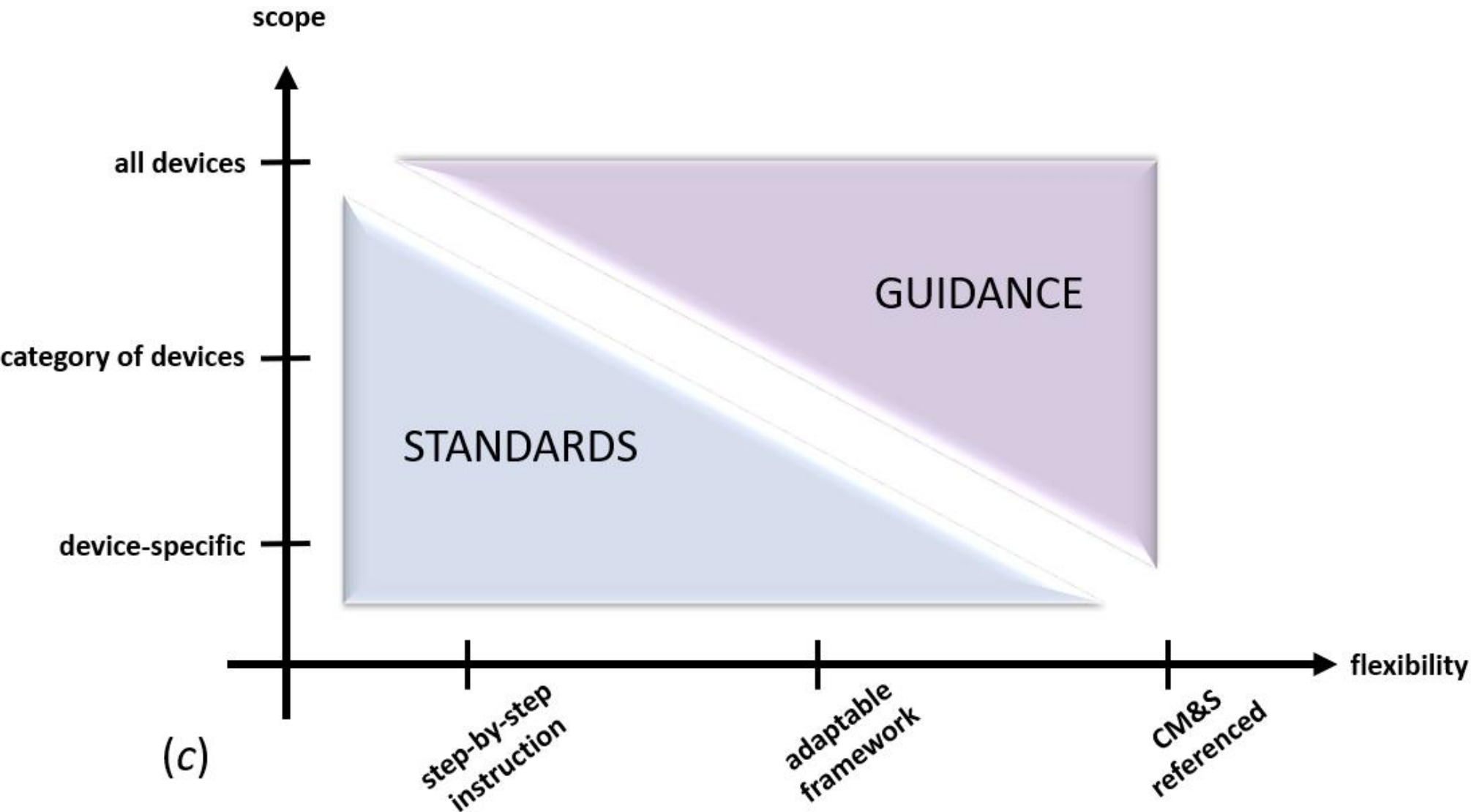
Rubric Applied to Standards



Rubric Applied to Guidance



Comparing the Scope and Flexibility of Guidance and Standards



(c)

The Future

- Standards that address efficacy
- Assessing absolute device performance
- Incorporating increased model complexity