FDA/MDIC
Symposium on Computational Modeling and Simulation

Generating Regulatory In Silico Evidence

Panel Discussion: Model Credibility Considerations for Different Stages of the Total Product Life Cycle

Tuesday, April 16th
3:30 PM – 4:30 PM

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Today’s panel question:

How do the expectations for model credibility change throughout the product lifecycle?

- Concept selection

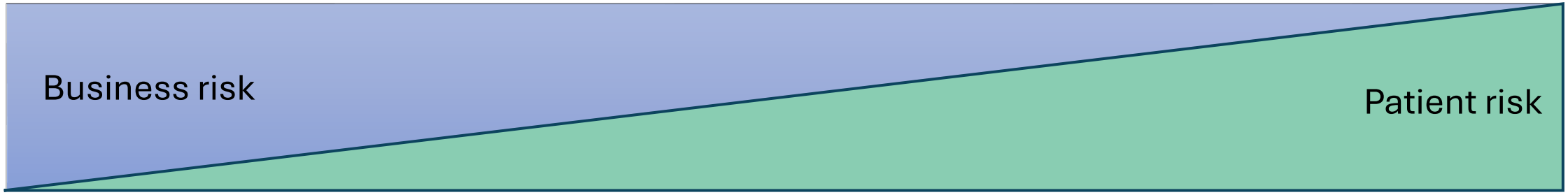
- Design characterization
- Design V&V
- Risk mitigation
- Process development

- In silico trials

- Regulatory evidence

- CAPAs
- Cost-down activities

What exactly is model credibility?

Model credibility is the *trust,* established through the collection of evidence, in the predictive capability of a computational model for a context of use. (Source: ASME V&V40-2018)

Does the type of risk associated with simulation change through the lifecycle?