Computer Methods in Cardiovascular Device Design & Evaluation: Overview of Regulatory Best Practices

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What Can Computer Methods Be Used For?

- Design & development
- Virtual prototyping
- Parametric studies

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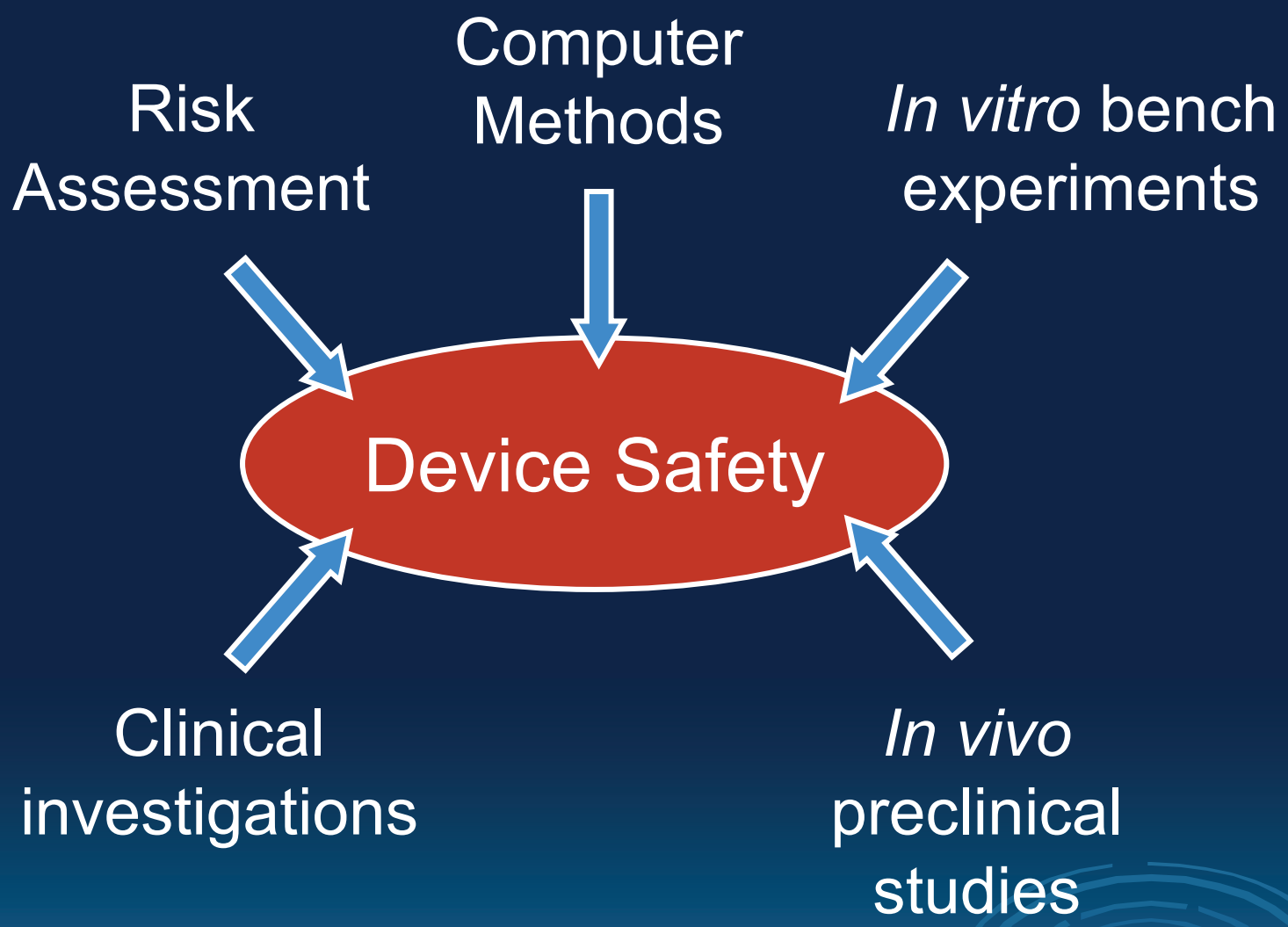
- Regulatory use
- Safety validation?
- Proof of effectiveness???

Computer Methods in Device Regulation

- Computer methods may be a useful tool when part of a complete device application
- Computer methods may enhance, extend, and clarify *in vitro* bench experiments, preclinical *in vivo* studies, and clinical investigations
- Computer methods must be *adapted* from being primarily a design and prototyping tool, to being a safety validation tool


Computer Methods
Risk Assessment
In vitro bench experiments
Device Safety
Clinical investigations
In vivo preclinical studies

Computer Methods Pros and Cons

- Pros
  - Computer methods can provide data that can't be measured directly
    - E.g., stress
  - Computer methods can yield "in between" data, providing details unavailable by experiment
    - E.g., velocities hidden from visualization

Computer Methods Pros and Cons

- Pros
  - Computer methods can give theoretical understanding to mechanisms of device behavior
  - Computer methods allow for performing parametric studies that would be too expensive to do experimentally

Computer Methods Pros and Cons

- Cons
  - Computer methods can be extremely complex and time consuming to perform
  - Computer methods require extensive training and experience

Computer Methods Pros and Cons

- Cons
  - Computer methods can easily generate mountains of data that can't be easily understood
  - Computer methods can generate results that are confusing, misleading, and/or downright erroneous

Computer Methods Pros and Cons

To paraphrase H.L. Mencken:

"Every problem has a solution that is neat

Computer Methods Pros and Cons

To paraphrase H.L. Mencken:

"Every problem has a solution that is neat, plausible

Computer Methods Pros and Cons

To paraphrase H.L. Mencken:

> "Every problem has a solution that is neat, plausible, and *wrong*."

H. L. Mencken, Prejudices: Second Series, 1920

Computer Methods Best Practices

- Have a clear idea of what the computer method is meant to show
- Tie in to the risk assessment
- Perform studies on the final design to be used clinically
- Verify modeling results with experimental data
  - Examples: CFD vs. PIV; CFD vs. *in vivo* preclinical testing

Computer Methods Best Practices

- Make sure the study provides clear evidence for the point that's being made
  - What are you trying to show?
  - How is the point relevant to the FDA?
- Provide a select set of data and clearly explain what the study shows
- Integrate the results with the risk assessment, bench data, and *in vivo* preclinical studies to demonstrate that clinical trials can proceed.

Computer Methods Best Practices

- Data from prototyping or design studies are useful only if they are relevant to the final clinical design, and the relevance is clearly explained
- Don’t present 1000’s of pictures as a substitute for clear and meaningful results
- Remember, computer methods are not required by the agency, nor are they forbidden

FDA Activities

- Critical Path Initiatives
  - Workshops
  - CFD/Blood Damage Round Robin
  - Other research projects
- Standards Activities
  - New AAMI standard under development “Mechanical Circulatory Support Devices Evaluation” will have subsection on flow visualization and CFD
- Guidance Document under development
  - For using CFD in applications

Questions for Discussion

- Should sponsors provide software verification of the programs that they use? What about custom software?
- To what extent should the computer model be validated against experiment?
- Can computer methods really show safety?
  - Proof vs. Comfort Factor
- Can computer methods show anything about *effectiveness?*
  - Or is this in the future?

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