

## Midterm assignment

Read the article “Toward trustworthy medical device in silico clinical trials: a hierarchical framework for establishing credibility and strategies for overcoming key challenges”, by Aycock et al. (available on Moodle with its appendix and online <https://www.frontiersin.org/articles/10.3389/fmed.2024.1433372/full>).

Explain in your own words the five steps to assess the credibility of numerical models for medical devices. Mention explicitly which of these steps concerns the VVUQ.

Explain which kind of submodel applies to your project, and how these five steps should be applied. Propose a strategy for a full ISCT.

Submit this report as a two-page pdf, one for each of the two points above.

You can try the help of chatGPT, but I’m afraid that you might lose more time, for a weaker result, than using your own brain. Besides, the main objective of this exercise (test) is that you learn something.

## Grading

Each P1-P5 of the 5 steps, and P6 for the application to the project, is worth 1 point.

### Step 0: Summary of hierarchical credibility assessment approach

- Set a hierarchical, or building block, approach with 6 (potential) submodels, and full model.
  - Device model
  - Patient model
  - Coupled device-patient model
  - Virtual patient cohort model
  - Clinician model
  - Clinical outcome mapping model
  - Full in silico clinical trial (ISCT)
- Methodically considering the evidence needs for each submodel
- Get data
- Set verification, validation, and uncertainty quantification (VVUQ)
- Document

### Step 1: Question of interest

- Identify a specific question, decision, or concern that is being addressed, in terms of a decision that is to be informed.

### Step 2: Context of use

- Identify a statement that defines the specific role and scope of the computational model used to address the question of interest.

### Step 3: Model risk assessment

- From steps 1 and 2, perform a model risk assessment
- Consider 2 independent factors:
  - Model influence (e.g. 5 levels)
  - Decision consequence (e.g. 5 levels)
- Model risk → VVUQ

### Step 4: Credibility evidence

- Plan and execute activities to generate the credibility evidence
- Depends on the 6 types of submodels and full model
- Mapping simulation output to clinical outcome

### Step 5: Adequacy assessment (Final step)

- Evaluate credibility evidence of ISCT
- Sufficient to support using the model for the COU given the risk assessment?

