

## ABET Assignment

1. Desired needs
  - Biopharma hardly targets rare diseases due to small patient populations
  - Cell and drug therapies often fail in formulation and clinical trials
  - Lack of understanding of rare diseases makes identifying drug targets challenging
  - FDA drug approval typically takes more than 10 years
2. Major constraints in project
  - Time - running computational programs to generate data often requires substantial GPU resources and can be time-intensive.
  - Safety of potential users of the product - train model on sufficient, high-quality data, fine-tuning parameters; benchmark predictions against experimental data from collaborating wet labs; conduct a thorough literature review on specific AAVs and their known targets; employ molecular modeling software to simulate and analyze protein interactions
  - Assess the functional and biological relevance of VirCAD - Salve will need to collaborate with a wet lab to obtain experimental validation data
3. Engineering standards
  - Software quality, the ISO/IEC 25000 SQuaRE family is also applicable. ISO/IEC 25000:2014 provides the overall SQuaRE reference framework, while ISO/IEC 25010:2023 defines a product quality model for evaluating system and software quality characteristics
  - Data interoperability standards - FAIR Guiding Principles support findability, accessibility, interoperability, and reuse of digital research assets, with particular emphasis on machine-actionable metadata
  - Model credibility, ASME V&V 40-2018 provides a framework for assessing whether verification and validation activities are sufficient for the intended use of a computational model
  - IEC 62304:2006+A1:2015 defines life cycle requirements for medical device software and would be the key software standard if the platform were treated as software associated with a medical device or as software used in a regulated medical workflow.
  - Viral vector and laboratory standards - FDA Good Laboratory Practice regulations, 21 CFR Part 58
4. Ethical, environmental, or societal concerns
  - Environmental - computational footprint of the platform. Structural prediction and sequence-design workflows can require substantial GPU time, cloud computing, and repeated model runs, which increases energy use and cost
  - Societal - equitable access, VirCAD is intended to support a rare-disease application, which gives it clear social value, but advanced computational tools

are often easier to use at well-funded institutions with access to GPUs, cloud credits, and specialized expertise

- Misuse and overinterpretation - VirCAD is a design tool for viral vectors, there is a nonzero dual-use risk if the software or its outputs are applied irresponsibly; ethical risk in presenting computational predictions as if they were experimentally validated biological truth

5. teamwork/leadership

- a. collaboration and inclusion of diverse opinions
  - i. Discussed during weekly meetings
- b. delegation of leadership on subprojects?
  - i. delegating tasks based on individual strengths
- c. establishing and reaching goals and deadlines?
  - i. Weekly deliverables
- d. received or given constructive feedback?
  - i. Brainstorming alternative strategies and resources
  - ii. For example when a protein docking software did not provide the results we were looking for, we explored other potential tools

6. significant motivating factors that led you to acquire new knowledge, be self-initiating, persist against challenges and setbacks

- e. ReNU conference, hearing feedback from the community helped me realize how much of an impact technology can have on lives

7. What are your most innovative and/or entrepreneurial ideas for this project?

- f. Helping to define the quantitative measures appropriate for project
- g. Helped with the code to mutate proteins based on conservative amino acids