

GBIO0033 – Advances in In Silico Medicine

Project Report Outline

1. Explanation model
 - a. Biological context
 - b. Equations > *explain*
 - c. Parameters > *where did they get these values from? Experiments, literature? other models? Discuss!*
 - d. Description (and discussion) of analyses performed in the paper > *what is missing?*
2. Credibility assessment
 - a. Question of interest, context of use
 - b. Analysis of risk & acceptability criteria
 - c. Verification > *platform related verification & user related verification*
 - d. Validation > *what is the comparator data available? How to do the comparison?*
 - e. Uncertainty quantification > *as discussed, not necessary for all parameters. Explain selection of parameters, explain technology used to perform UQ*
3. Credibility matrix & Discussion
 - a. Credibility matrix > *complete summary table of the credibility assessment (cfr 3 examples at the end of the paper <https://ascpt.onlinelibrary.wiley.com/doi/10.1002/psp4.12669>)*

Drug	
Type of model	
Scientific Question(s) of interest (QOI)	
Context of use	
Acceptability criteria (Precision level)	
Regulatory impact	
Risk based analysis of decision consequence	
Credibility activities results	
Model informed decision	

- b. General discussion > *limitations of the models, limitations of the data,*
4. Towards In silico clinical trials
 - a. Creation of digital population *(is information on relevant variability in the population available in the literature? If no real world data is available, the results of the sensitivity analysis can be used to find relevant parameters to vary to generate the virtual cohort)*
 - b. Therapy to be tested *(+ biological & experimental background)*

- c. Design of the in silico clinical trial
- 5. Execution of the in silico clinical trial & discussion
 - a. Execute in silico clinical trial
 - b. Discuss the outcome of the trial : *effectiveness, subpopulations with different degrees of responsiveness. Limitations of the trials, missing data etc.*
- 6. Conclusion