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On the Integration of Artificial Neural Networks in Clinical Trials

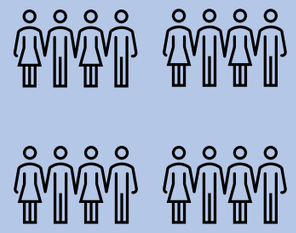
D. Papadopoulos[1], V. Karalis[1]

[1]Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens

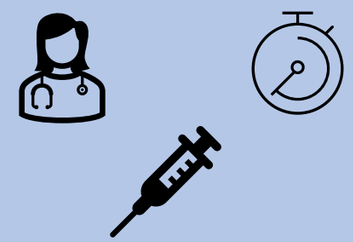
1. Background-Aim

Problem

Clinical trial for two drugs



Need a lot of participants



A lot of other resources as well

Solution

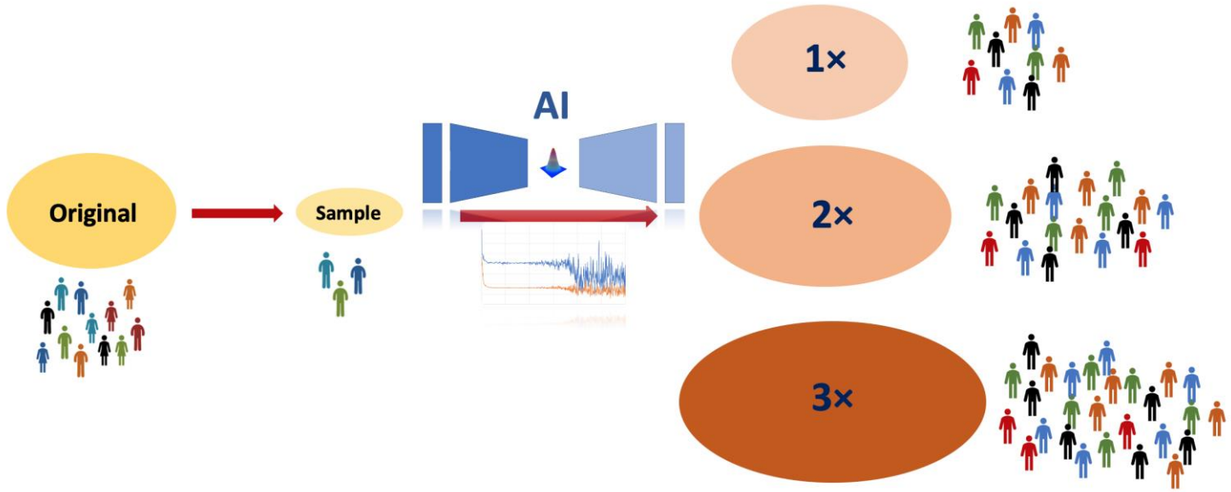
Create virtual subjects from existing ones

2. Materials & Methods - Experimental method

Create virtual subjects from existing ones:

1. From a dataset (i.e. original) we randomly sample a proportion of subjects (i.e. subsampled)
2. Using the subsampled dataset we train a Variational Autoencoder model
3. The trained model is used to generate new data based on the existed ones

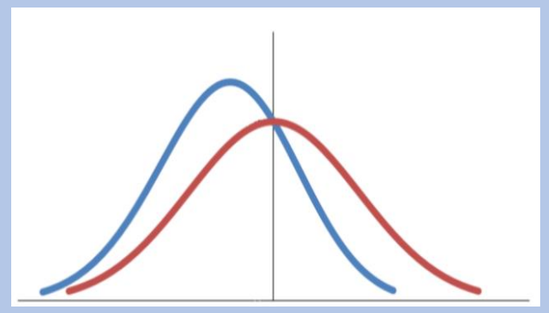
The model allows us to generate as many as we want



2. Materials & Methods - Experimental method

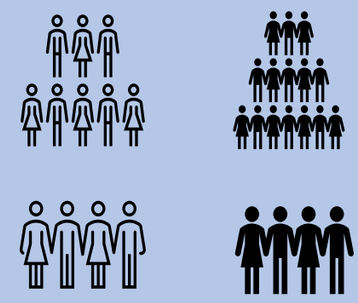
Repeat this many times

1. – Original dataset



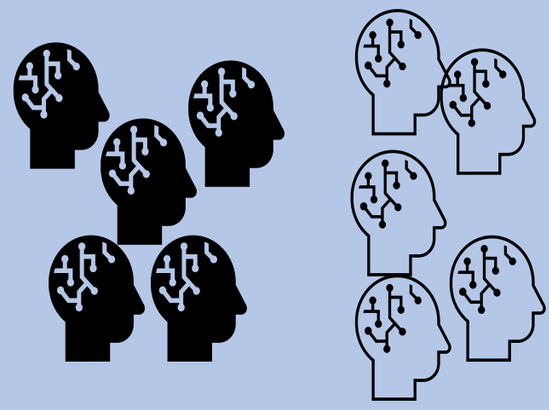
Monte Carlo simulations for both T and R, of N subjects

2. – Subsampled dataset



Subsample T and R

3. – Generated dataset



Create synthetic data for T and R

4. - Evaluation

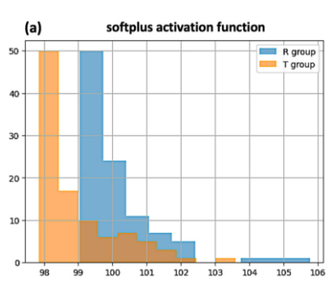
2. Materials & Methods - Experimental method

- Monte Carlo simulations
  - Utilizing the normal distribution
  - Several levels of variability were used for the creation of virtual subjects
  - Several average endpoint ratios were explored between R and T (R/T)
  - Half of the subjects are considered to receive T and the other half R

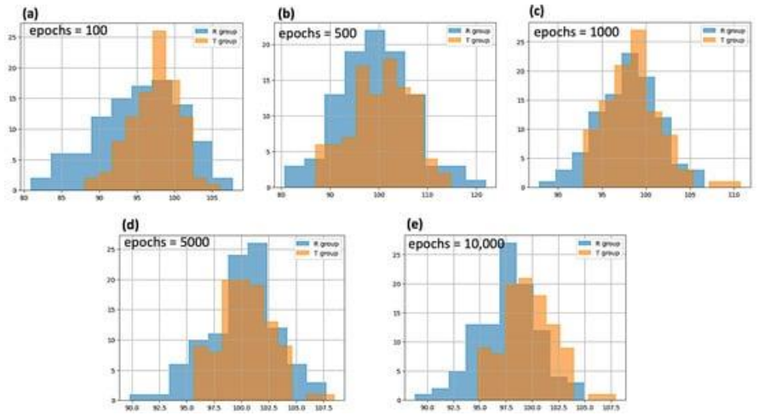
3. Results – Hyperparameter tuning

The Deep Learning model first needed to hypertuned

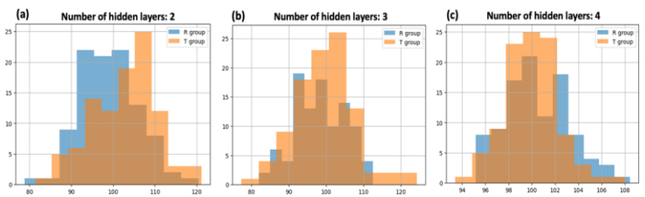
Activation function for the output layer



Epochs



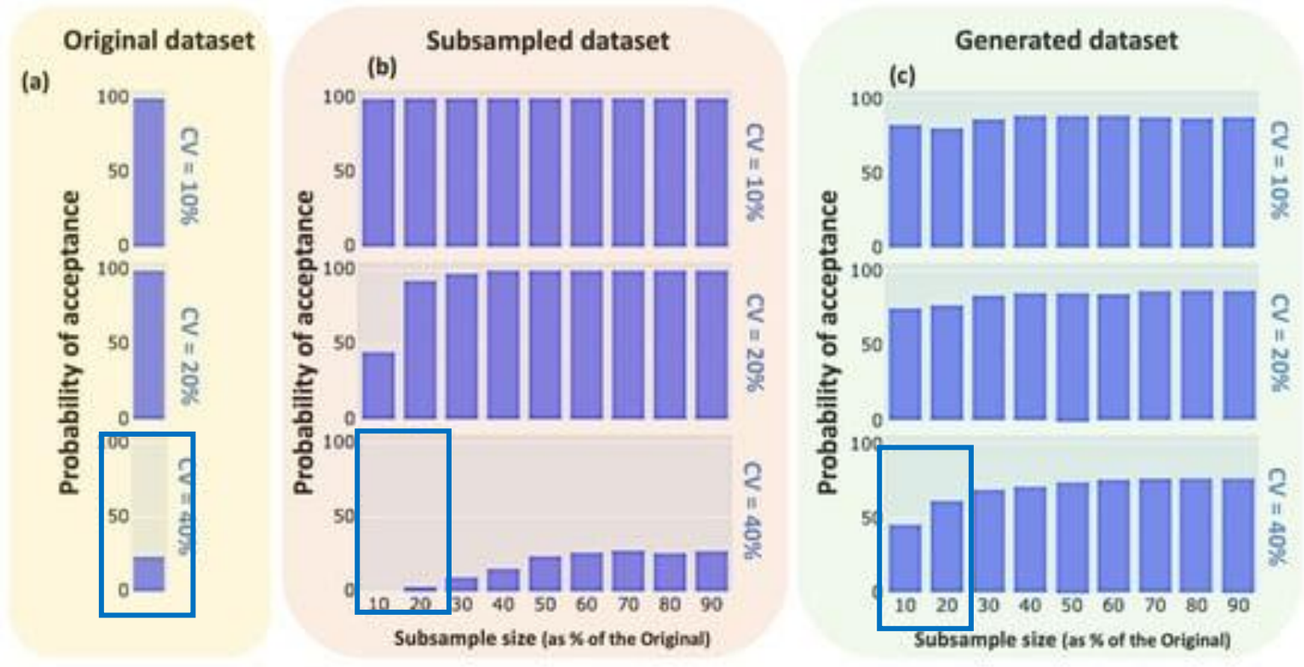
Number of hidden layers



3. Results – Acceptance rates

Probability of accepting equivalence between the test and reference groups for the original (a), subsampled (b), and generated (c) datasets

By taking less participants and using VAE, we can achieve the same acceptance rates as if we had more real participants



4. Conclusions

- Our study is the first one to introduce the use of deep learning (particularly variational autoencoders) for data augmentation in clinical studies
- The optimal structure of the neural network was investigated
- It was shown that using VAEs resulted in an increase of statistical power
- The biggest improvement was in high variability cases
- This study is a cornerstone in using AI, for data augmentation in clinical studies, which demonstrated the desired performance and at the same time leading to less human exposure and significantly reduced resources

Thank you for your attention