



Development of a Calculator for External Validation Study Sample Size in Radiology AI

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Introduction/Background

External validation of clinical prediction models in radiology AI ensures their performance and generalizability in independent datasets. Accurate estimation of sample sizes for these validation studies is crucial for obtaining precise and unbiased performance metrics, such as the C-statistic and its standard error (SE). This paper introduces a Python-based calculator designed to estimate the required sample size for external validation studies in radiology AI. The tool uses mathematical and statistical methods to provide precise sample size estimations, aiding researchers in designing robust validation studies.

Methods/Intervention

The Python-based tool requires input values for the C-statistic and the outcome event proportion (ϕ) from the validation dataset. It calculates the standard error (SE) of the C-statistic using a specific formula that considers the sample size (n), the C-statistic value, and the outcome event proportion. The SE of the C-statistic is calculated using the formula:

$$SE(C) \approx C(1-C)N\phi(1-\phi)(1+N/2-12-C+N/2-11+C) \approx \frac{C(1-C)}{N\phi(1-\phi)} \left(1 + \frac{N}{2} - 1 \right) \{ 2 - C \} + \frac{N}{2} - 1 \{ 1 + C \}$$

The tool provides two methods for estimating the required sample size for a targeted SE. The first method calculates the sample size directly from the SE formula, while the second method uses a quadratic equation approach. The tool is implemented using the Gradio interface, allowing users to input the C-statistic value, outcome event proportion, and targeted SE, and receive the required sample size.

Results/Outcome

The tool was tested with various C-statistic values and outcome event proportions, demonstrating its accuracy in estimating the required sample size for different scenarios.

Conclusion

The calculator is a valuable tool for researchers conducting external validation studies in radiology AI. It provides accurate sample size estimations, ensuring robust and reliable evaluations of clinical prediction models.

Statement of Impact

The user-friendly interface enables researchers to quickly determine the necessary sample size for their validation studies. The tool ensures that external validation studies are adequately powered, enhancing the reliability and generalizability of AI models in radiology.

Keywords

Classification; External validation; Sample size calculation; Statistics