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Challenges and Opportunities in Generating Robust Real-World Evidence from Real-World Data: A Statistical Perspective in the Era of GDPR

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Introduction

The recent European Union's General Data Protection Regulation (GDPR) is one example of a concept that has been defined in numerous ways. "Any information relating to an identified or identifiable natural person" is the definition of personal data in this. "racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, health data or data concerning the individual's sex life or sexual orientation" are all examples of sensitive data in this set. It is against the law to use automated means to process these kinds of data for any purpose at all without the explicit consent of the subject. The generation of robust real-world evidence (RWE) from real-world data (RWD) and its integration into drug development and regulatory review poses a significant challenge for biostatisticians. Mapping RWE to substantial evidence description requires a rigorous analytical approach that takes into account the quality, validity, and relevance of the RWE generated from RWD. To achieve this, it is essential to apply appropriate statistical methods and data science techniques to analyse the RWD and generate reliable and actionable RWE [1,2].

Description

This requires the application of appropriate study design and analysis methods that take into account potential sources of bias and confounding, such as selection bias, measurement error, and unmeasured confounding. In addition, the analysis must be tailored to the specific research question and context, taking into account differences in patient populations, treatment regimens, and clinical outcomes. Overall, the goal of mapping RWE to substantial evidence description is to generate reliable and actionable evidence that can be used to inform drug development and regulatory decision-making. This requires a collaborative effort between biostatisticians, data scientists, clinicians, and regulatory authorities to ensure that the RWE generated from RWD is of sufficient quality, validity, and relevance to be considered as substantial evidence. For more robust features, a hybrid DL model incorporating CNNs and LSTM was developed. CNNs, which extract convolutional maps with more discriminative features, and RNNs, which process features as temporal sequences, were combined in the proposed model. One of the key challenges is to ensure the quality of the RWD used to generate RWE. The data must be accurate, complete, and collected in a standardized manner, so it can be analyzed and compared across different sources. This requires careful attention to data collection, management, and processing, as well as the use of appropriate quality control procedures to identify and correct errors and inconsistencies in the data. Another challenge is to ensure the validity and relevance of the RWE generated from RWD [3].

This is, to our knowledge, the first mobile gait verification method that takes into account privacy-preserving techniques trained unsupervised .One of the most common methods of authentication for mobile devices is the use of biometrics. Particularly, smart devices, such as accelerometer and gyroscope data, make passive recognition possible with behavioural biometrics, which are based on how subjects perform actions like writing and walking. Even though mobile behavioural biometrics are becoming increasingly popular, the data that is collected may contain a substantial amount of personal and sensitive information, such as demographics or the subject's activity. As a result, it's possible that this technology amounts to an invasion of personal privacy. The databases for Motion Sense and Mobi Act; and) the database OU-ISIR. The obtained experimental results indicate that Gait Privacy on may be able to maintain user authentication results above 96.6% AUC while significantly enhancing the subject's privacy.

However, it has been demonstrated that biometric system-associated learning processes may reveal sensitive personal information about subjects. A novel mobile gait biometrics verification method that provides accurate authentication results while safeguarding the subject's sensitive information, is the idea presented in this study. It is made up of two convolutional auto encoders with shared weights that turn the biometric raw data into a new privacy-preserving representation of things like gender and activity ;and ii) a Siamese-architecture mobile gait verification system built on a Siamese architecture of Convolutional Neural Networks (CNNs) and Recurrent Neural Networks (RNNs).The fact that the first module of Gait Privacy ON—convolutional auto encoders—is trained without supervision and without specifying the subject's sensitive characteristics is the main benefit. Examined experimental studies include. The use of biometrics on mobile devices for authentication has already been demonstrated in a number of studies published in the literature [4,5].

Conclusion

For model training, the authors wanted to avoid having to collect a lot of sensitive data. Unsupervised learning training for the privacy-preserving task was carried out for this purpose. Data transformation and noise addition using an Auto encoder and a CNN were used to treat the frame work. While the activity recognition task remained virtually unchanged, gender classification yielded results with an accuracy of 56.79 percent. Their system, which was based on Generative Adversarial Networks (GANs), achieved a 45.8% accuracy reduction in the gender classification task while only a 1.37 percent accuracy reduction in the activity recognition task.

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Conflict of Interest

The Author declares there is no conflict of interest associated with this manuscript.

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