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Genome analysis

faers: An R Package for Seamlessly Bridging the FAERS Database to R and Delivering Unified Pharmacovigilance Workflows

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Abstract

Motivation: The FDA Adverse Event Reporting System (FAERS) serves as a critical database for monitoring post-marketing drug safety.However, the primary focus on safety signal detection within FAERS has left a significant gap in integrating pharmacovigilance analysis with genetic tools.Thus, we aim to effectively utilize FAERS data to bridge pharmacovigilance with genetic analysis, thereby enhancing the precision of safety assessments and facilitating the development of personalized medicine approaches.
Results: We developed the R package faers, which seamlessly connects the FAERS database to the R programming language and provides a unified approach for the seamless execution of pharmacovigilance analysis and the integration of genetic tools in R.
Availability: faers is available on CRAN and on GitHub at (https://github.com/Yunuuuu/faers).
Contact:212@qq.com
Supplementary information: Supplementary data are available at Bioinformatics Online.

1 Introduction

Cite others using bracket notation (Pepe, 2003). Can also cite with Zou and Hastie (2005).

The FDA Adverse Event Reporting System (FAERS) is the core database for post-marketing safety monitoring of all approved drugs and therapeutic biologics by the FDA. As required by regulations, it consolidates mandatory adverse event reports submitted by pharmaceutical companies, as well as voluntary first-hand information reported by individuals and healthcare professionals. The data, which has been collected since January 2004 and is continuously updated on a quarterly basis, includes eight types of documents: demographic and administrative information, detailed drug information, indications for use, report sources, drug start and end dates, patient outcomes, reports of therapeutic failure, and adverse events. Its core value is reflected in key areas such as early safety signal detection, risk assessment, and drug labeling revisions, providing direct evidence for the FDA to formulate drug safety policies and risk management measures.

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2 Approach

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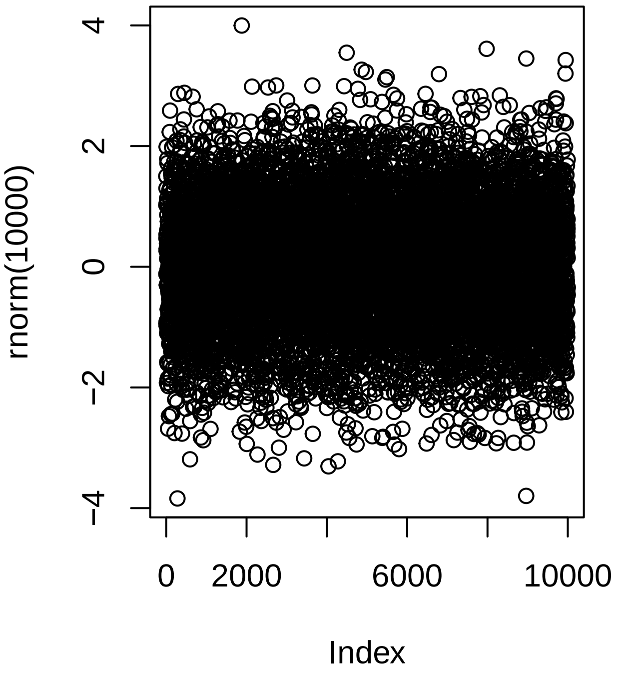

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3 Methods

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5 Conclusion

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Acknowledgements

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Details of all funding sources for the work in question should be given in a separate section entitled ‘Funding’. This should appear before the ‘Acknowledgements’ section.

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- Grant numbers should be given in brackets as follows: ‘[grant number xxxx]’
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