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Employing "FDAlabel" Database to Extract Pharmacogenomics Information from FDA Drug Labeling to Advance the Study of Precision Medicine

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Uber, Ryley B.; Fang, Hong; Liu, Zhichao; Xu, Joshua; Thakkar, Shraddha; Amur, Shashi; Mummaneni, Padmaja; Chen, Minjun;
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Presenters

Ryley B. Uber, Hong Fang, Zhichao Liu, Joshua Xu, Shraddha Thakkar, Shashi Amur, Padmaja Mummaneni, Minjun Chen, Baitang Ning, Steve Harris, Guangxu Zhou, Leihong Wu, Paul Howard, and Weida Tong

Employing "FDAlabel" Database to Extract Pharmacogenomics Information from FDA Drug Labeling to Advance the Study of Precision Medicine

Pharmacogenomics (PGx) focuses on how genomics and genetic variants (inherited and acquired) affect drug response. A better understanding of the association between genetic markers and individual phenotypes may improve therapy by enhancing drug efficacy, safety, and advance precision medicine. The FDALabel database (https://rm2.scinet.fda.gov/druglabel/#simsearch-0) was developed from the FDA's Structured Product Labeling (SPL) repository to allow users to perform full-text and customizable searches of the labeling section {e.g. Boxed Warning, Warning and Precautions, Adverse Reaction (AR) sections}. In this study, 48 known biomarkers were used to query PGx relevant contents from the FDALabel database, including Indication, Clinical Pharmacology, Clinical Studies, and Use in Specific Populations. As a result, we identified 162 drugs out of 1129 small molecule drugs with PGx biomarker information. Furthermore, statistical analysis, pattern recognition, and network visualization were applied to investigate association of drug efficacy and severe ARs with PGx biomarkers and subpopulation. The results indicated that these drugs have a higher association with certain ARs in specific patient subpopulations (e.g., a higher association between CYP2D6 poor metabolizers and ARs caused by drugs for the treatment of psychiatric disorders), and cover a broad range of therapeutic classes (e.g., Psychiatry, Cardiology, Oncology, and Endocrinology). FDALabel database (free publicly available) provides a convenient tool to navigate and extract PGx information from FDA-approved drug. The knowledge gained from these drugs and biomarkers in this study will enhance the understanding of PGx to advance precision medicine.

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