

1. *Drug Discov Today*. 2011 Aug;16(15-16):697-703. doi: 10.1016/j.drudis.2011.05.007. Epub 2011 May 20.

## FDA-approved drug labeling for the study of drug-induced liver injury.

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Drug-induced liver injury (DILI) is a leading cause of drugs failing during clinical trials and being withdrawn from the market. Comparative analysis of drugs based on their DILI potential is an effective approach to discover key DILI mechanisms and risk factors. However, assessing the DILI potential of a drug is a challenge with no existing consensus methods. We proposed a systematic classification scheme using FDA-approved drug labeling to assess the DILI potential of drugs, which yielded a benchmark dataset with 287 drugs representing a wide range of therapeutic categories and daily dosage amounts. The method is transparent and reproducible with a potential to serve as a common practice to study the DILI of marketed drugs for supporting drug discovery and biomarker development.

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