# PHENOTYPE-SPECIFIC SAFETY REPORTING SIGNALS OF ASCIMINIB VERSUS SECOND- AND THIRD-GENERATION TYROSINE KINASE INHIBITORS IN CHRONIC MYELOID LEUKEMIA: A FAERS DISPROPORTIONALITY ANALYSIS

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## INTRODUCTION

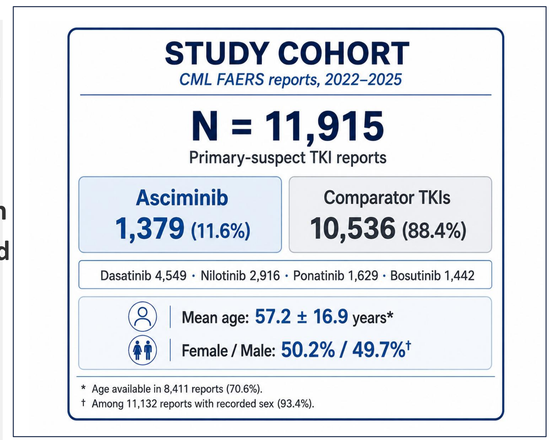
Asciminib is a first-in-class Specifically Targeting the ABL Myristoyl Pocket (STAMP) inhibitor approved in 2021 for chronic myeloid leukemia (CML). Spontaneous reporting systems can be used for signal detection to characterize patterns of disproportionate reporting that may complement established trial and labeling safety data, including warnings for myelosuppression, pancreatic toxicity, hypertension, and cardiovascular toxicity.

## AIM

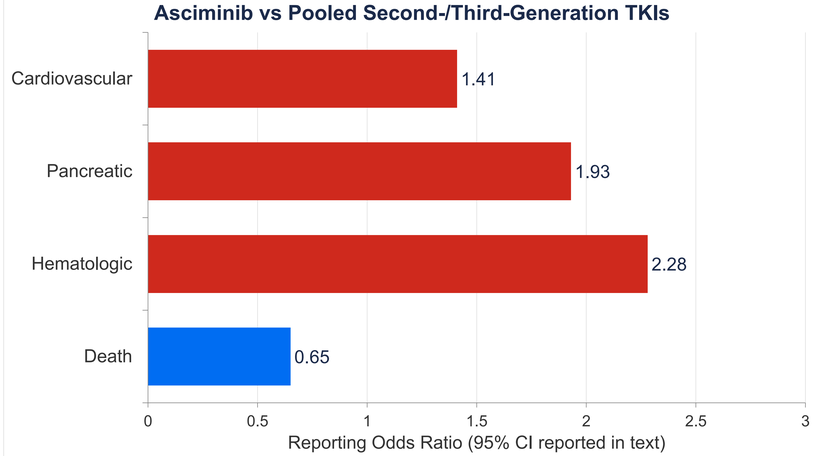
To evaluate whether prespecified cardiovascular, pancreatic, hematologic, and death outcomes demonstrate disproportionate reporting for asciminib compared with second- and third-generation tyrosine kinase inhibitors (TKIs) in the United States Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS).

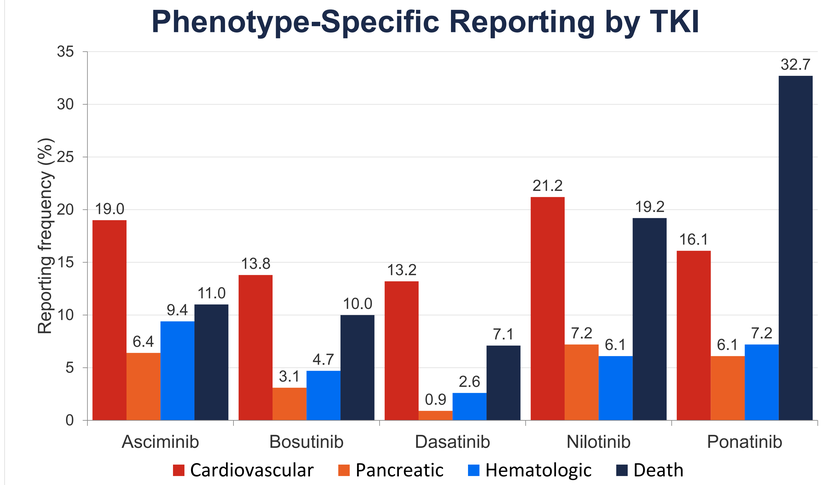
## METHOD

We performed a retrospective disproportionality analysis of FAERS individual case safety reports (ICSRs) from 2022–2025, restricted to CML indications and primary suspect drugs. Asciminib was compared with dasatinib, nilotinib, bosutinib, and ponatinib. Reporting odds ratios (RORs) with 95% confidence intervals (CIs) were calculated for prespecified outcome groupings (cardiovascular, pancreatic, hematologic events defined using MedDRA preferred terms) and death outcomes, using pooled comparator TKIs as the primary reference.




## RESULTS




**FAERS data are reporting signals, not incidence or causality**

## CONCLUSIONS

Asciminib demonstrated disproportionate FAERS reporting of hematologic, pancreatic, and cardiovascular events compared with pooled second- and third-generation TKIs, with the strongest signal observed for hematologic events. Reporting patterns varied substantially across individual TKIs, while death outcomes were less frequently reported with asciminib relative to the pooled comparator. These findings represent pharmacovigilance signals rather than estimates of comparative incidence or causal risk.

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