

# Analysis of cyclin-dependent kinase 4 and 6 inhibitor adverse events in both younger and older adults using the FDA Adverse Event Reporting System database

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## Abstract

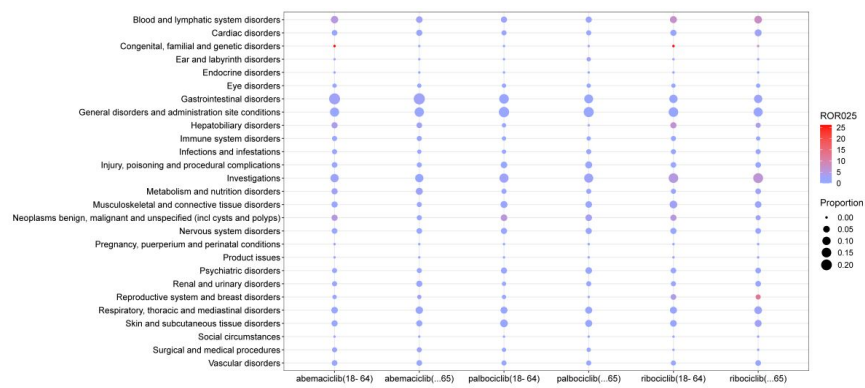
**Abstract Aim** The U.S. Food and Drug Administration (FDA) has granted approval for the use of cyclin-dependent kinase 4 and 6 inhibitors (CDKIs) in the management of advanced and metastatic breast cancer. We evaluated the real-world data associated with safety in younger and older adults base on Adverse Event Reporting System (FAERS) database of the FDA. **Methods** We conducted disproportionality analysis to detect and compare CDKI-related adverse events (AEs) among the younger and older adults. **Results** The data used were from 3,851, 64,731, and 8,420 case reports on abemaciclib, palbociclib, and ribociclib, respectively. Disproportionality analysis revealed 170, 397, and 626 AEs of abemaciclib, palbociclib, and ribociclib, respectively, in younger adults, and 113, 475, and 557 in older adults. The numbers of system organ classes for abemaciclib, palbociclib, and ribociclib were 27 each among younger adults, and 25, 27, and 27 among older adults. We found several expected AE signals same with drug instructions, such as diarrhea, neutropenia, and thromboembolic events. Furthermore, unexpected AE signals, such as campylobacter sepsis, enterococcal endocarditis, and atrioventricular block were identified. **Conclusion** Our results align with clinical observations, emphasizing possible AEs associated with CDKIs. It is essential to conduct future clinical research to confirm differences in CDKIs among younger and older individuals.

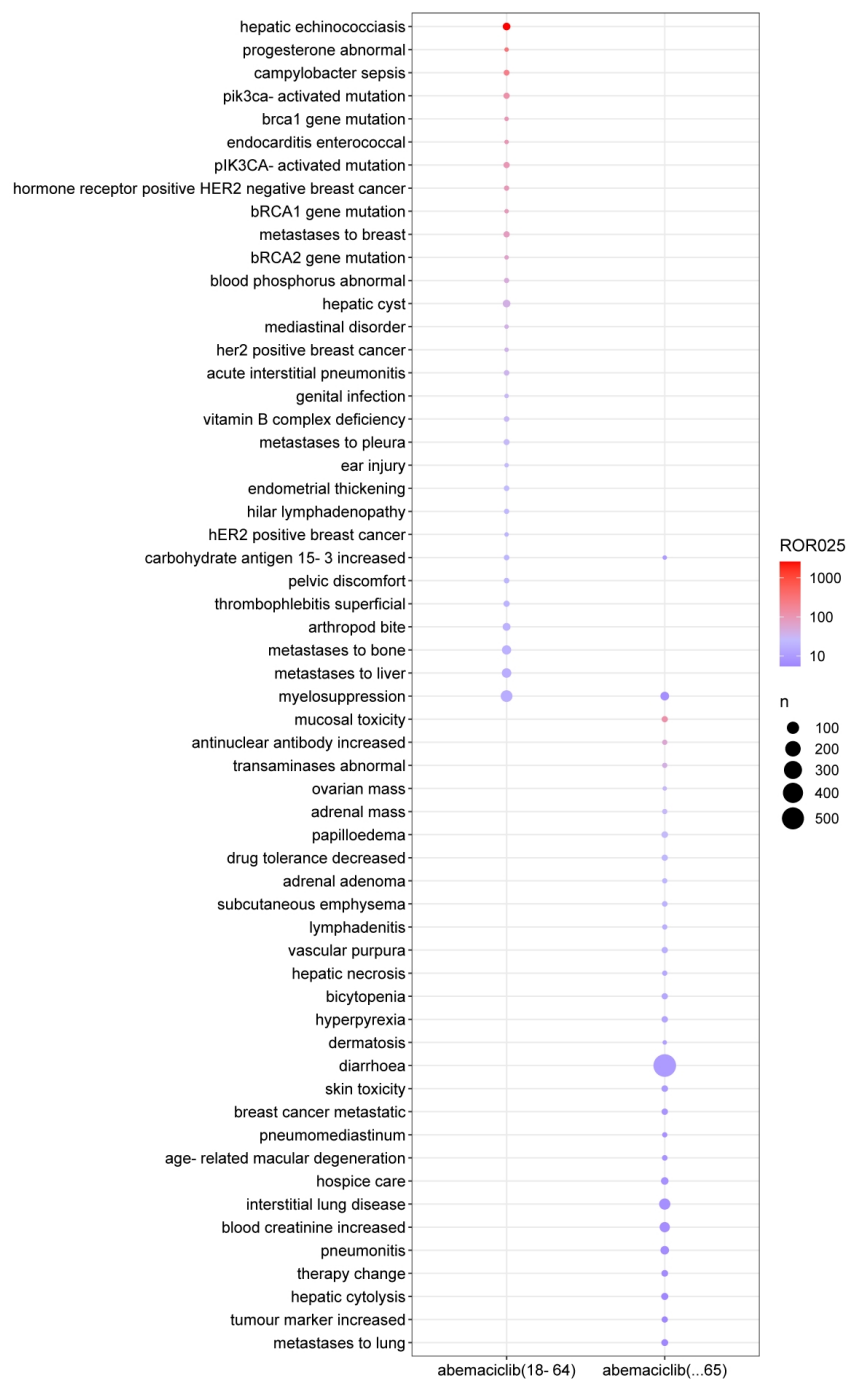
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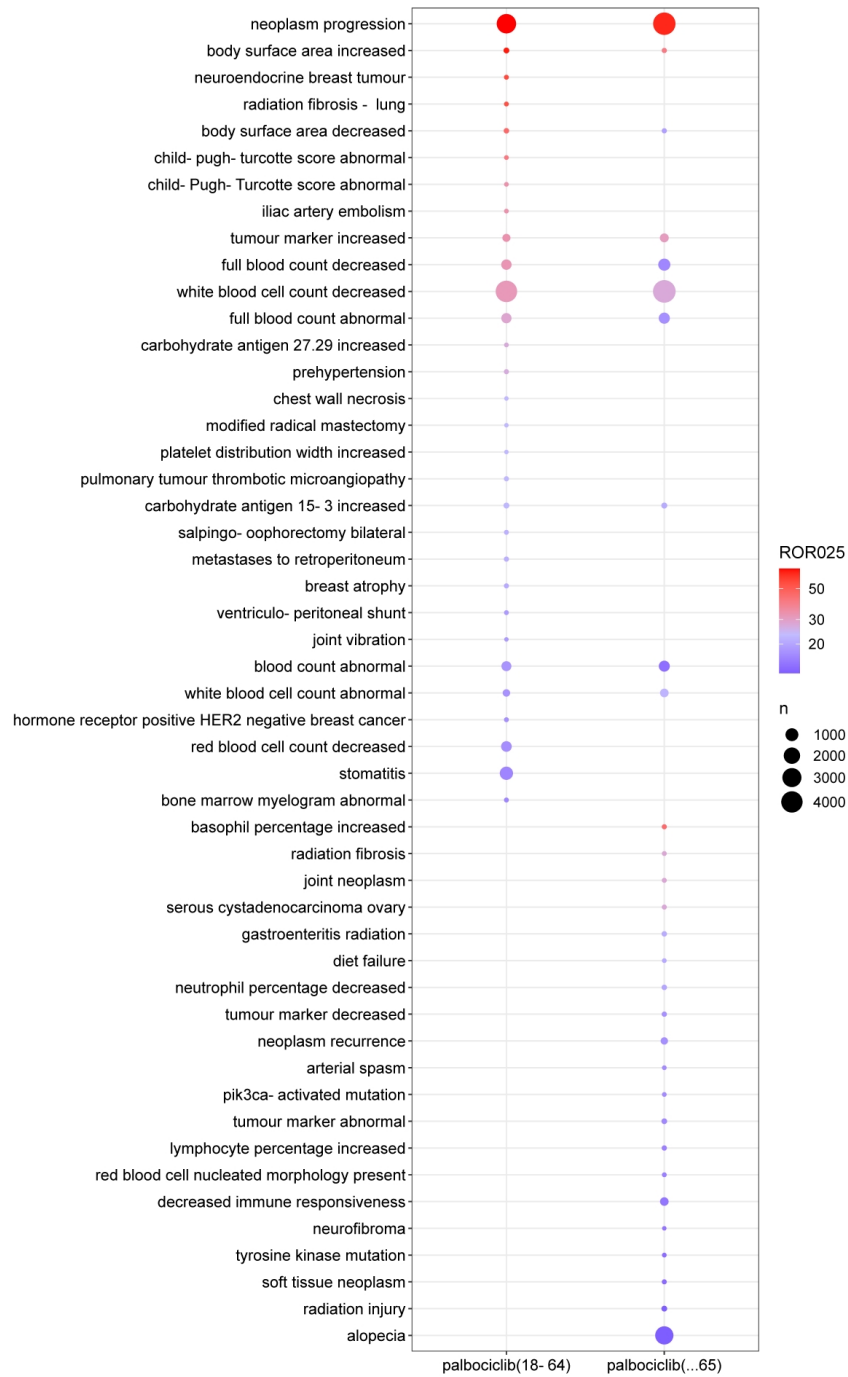
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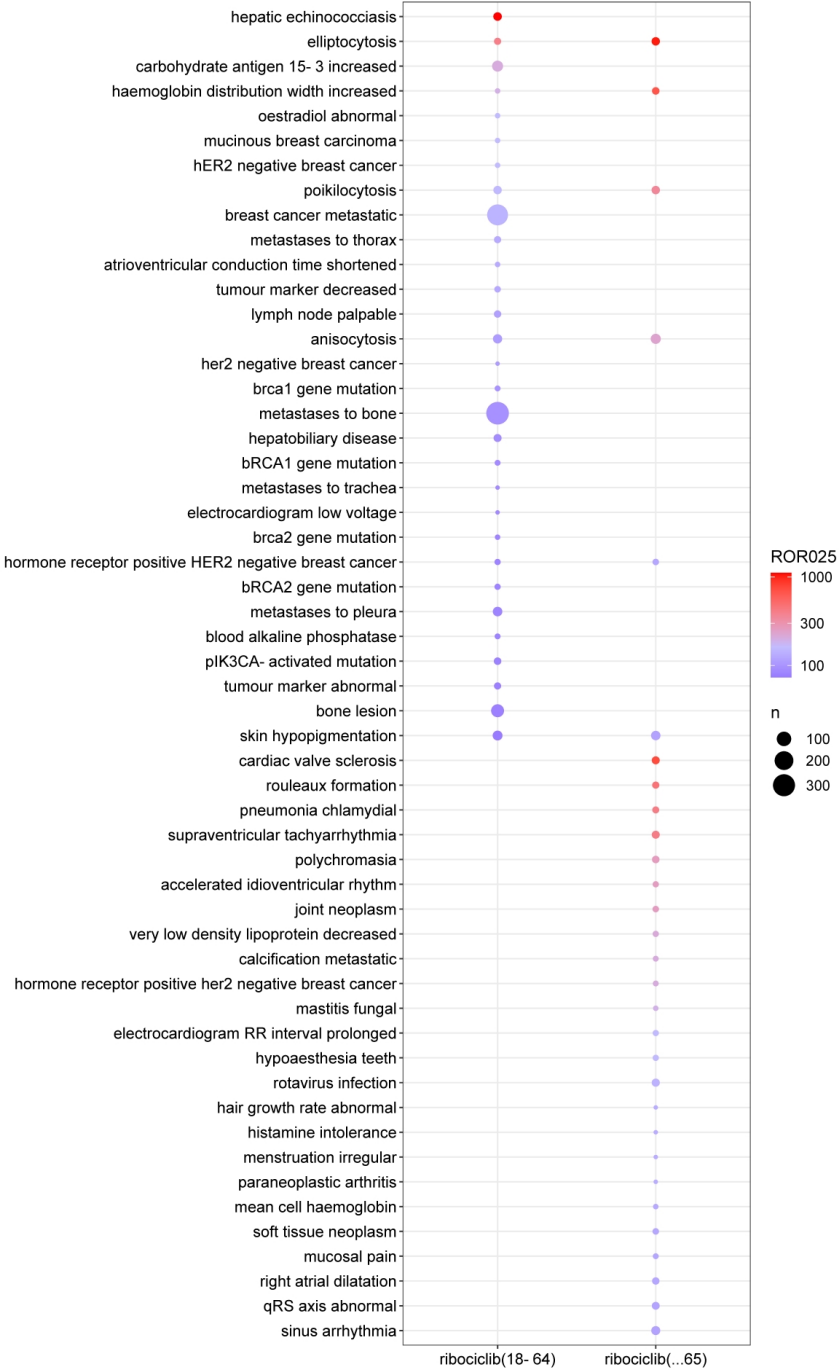
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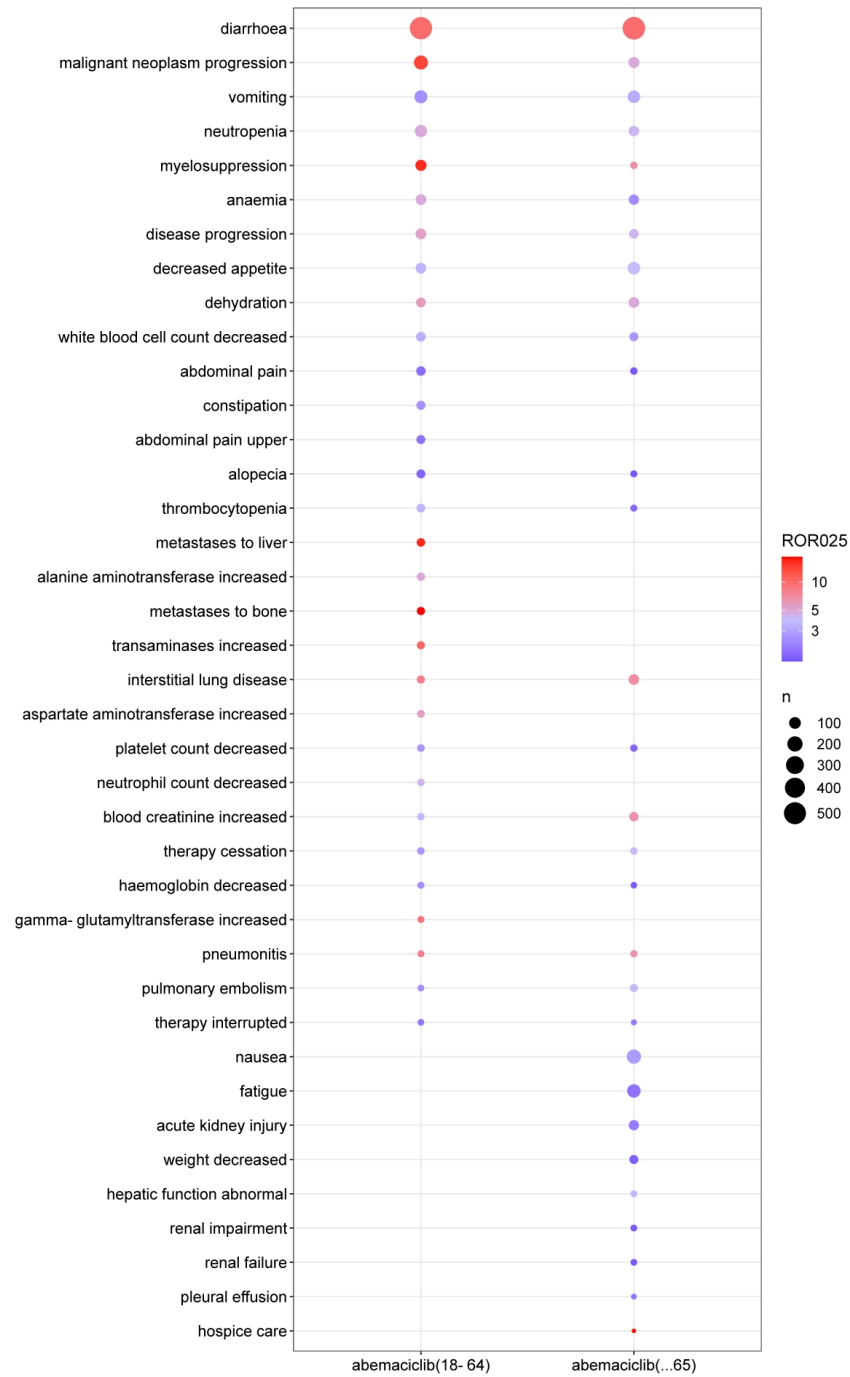
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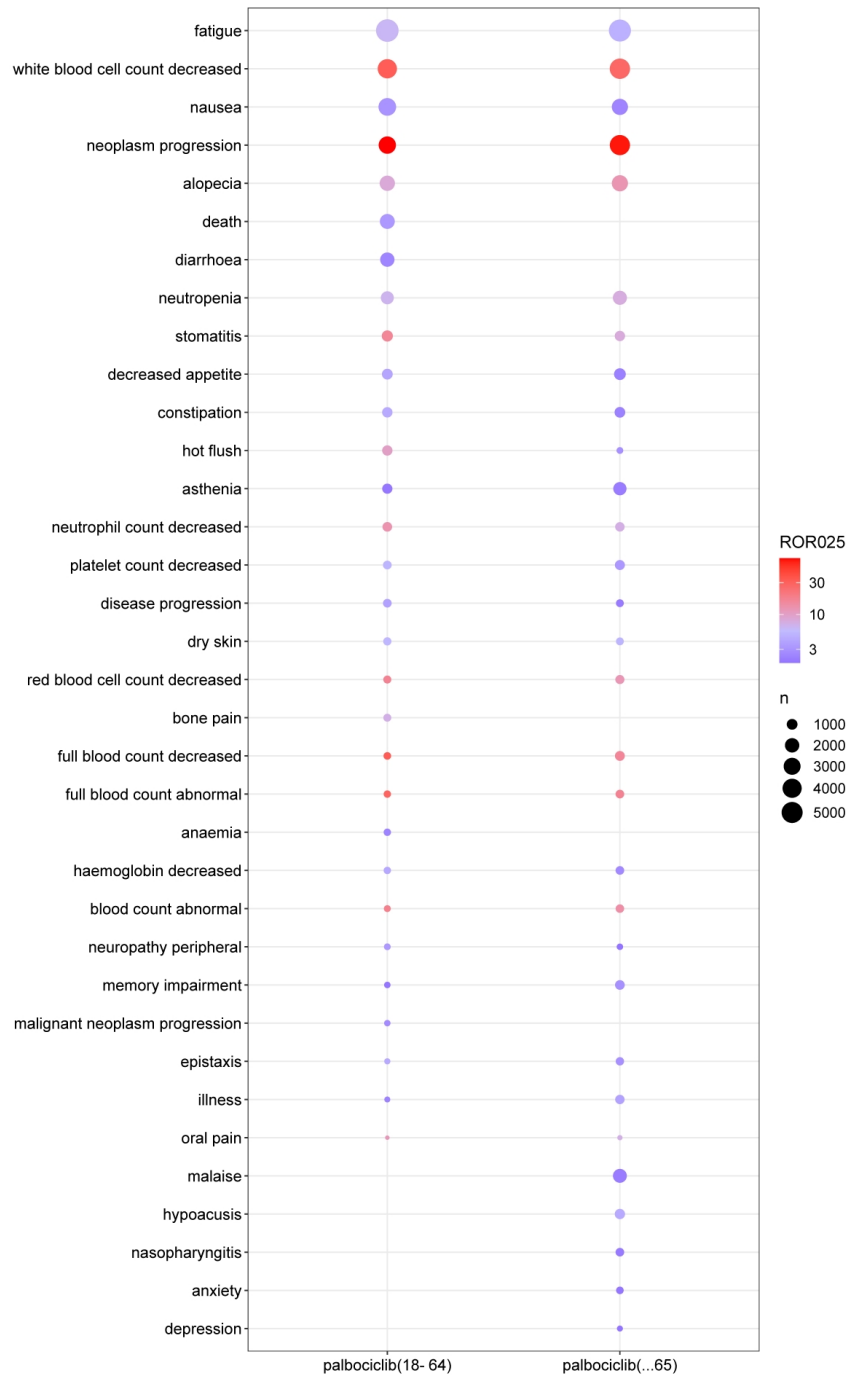


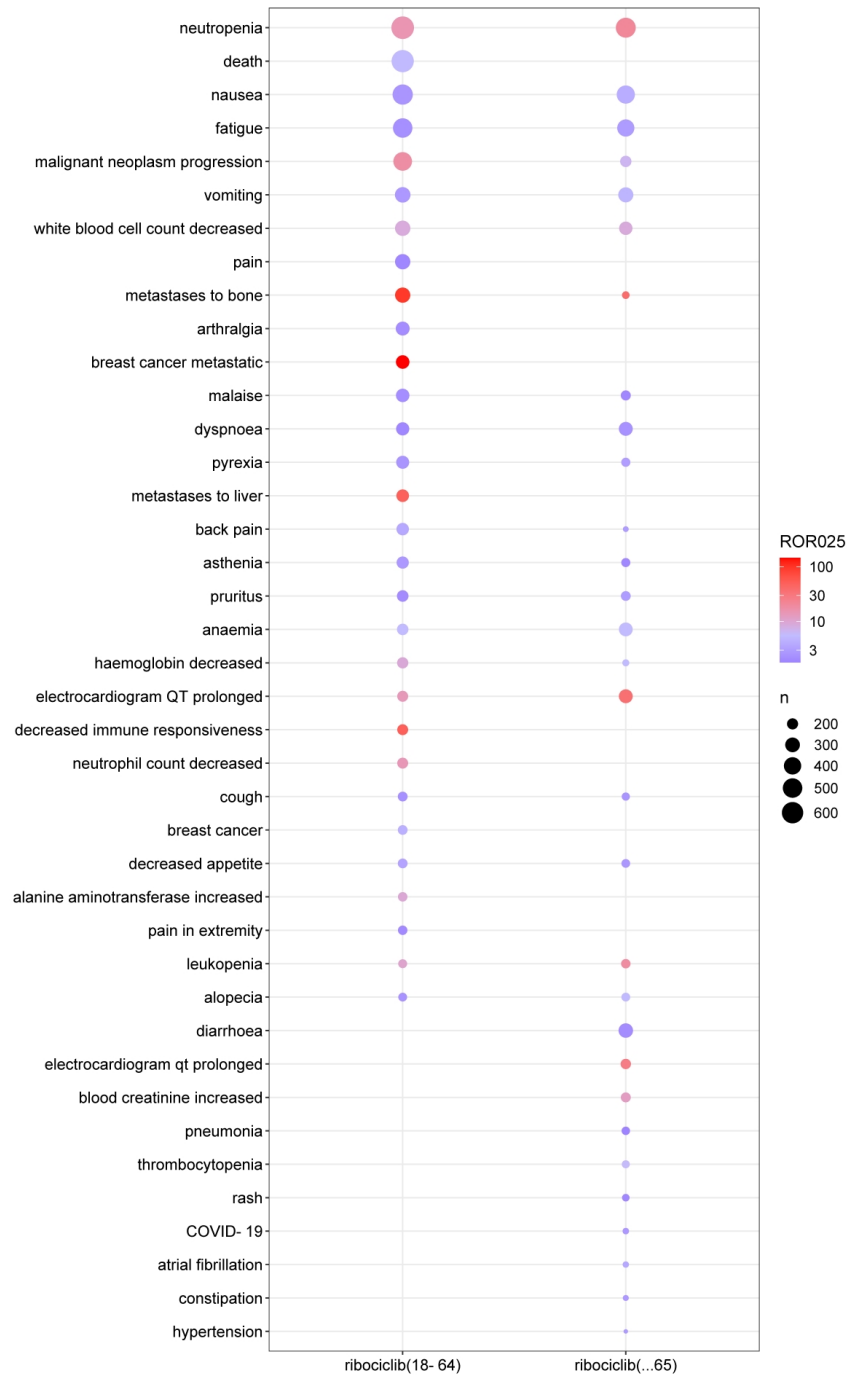












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