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Comparison of Adverse Event Reporting Between Adolescent and Young Adults and Older Adults with Cancer Enrolled in Phase II/III Clinical Trials.

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INTRODUCTION

Momentum to improve cancer outcomes in adolescents and young adults (AYAs, diagnosed between 15-39 years of age) has been growing in recent years. However, there remains to be significant barriers to understanding differences in treatment response in AYAs compared with younger and older patients. Currently, it is unknown the extent to which AYA adverse event data is reported separately in oncology clinical trials that enroll AYAs and older adults. For this reason, this study investigates not only the reporting of disaggregated AYA clinical trial data in published oncology trials, but also the differences in treatment-related adverse events experienced by AYAs.

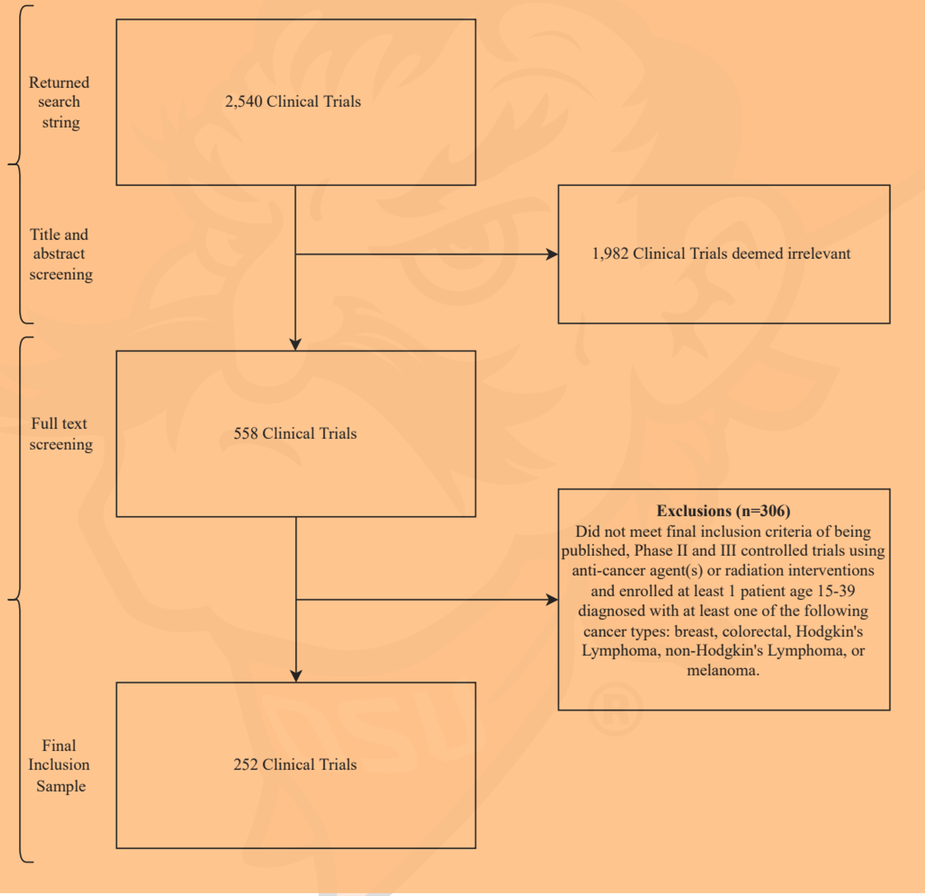
METHODS

In our cross-sectional analysis, we performed a comprehensive search using PubMed (which includes Medline) to identify all clinical trials that met eligibility criteria published from January 1, 2021 to December 31, 2021. Two independent investigators title and abstract screened, full-text screened, and extracted data from the final study sample using Google Forms. In addition to obtaining demographic data for each included trial, a further assessment was made to see if the trial distinguished outcomes between AYAs and older adults. Microsoft Excel was used for summary data and measures of central tendency. No further statistical analyses were planned.

Characteristic	n/N (%)
Cancer	
Breast	111/252 (44.0%)
Colorectal	53/252 (21.0%)
Non-Hodgkin's Lymphoma	47/252 (18.7%)
Melanoma	26/252 (10.3%)
Hodgkin's Lymphoma	13/252 (5.2%)
Hodgkin's and non-Hodgkin's Lymphoma	2/252 (0.8%)
Trial Phase	
II	128/252 (50.8%)
III	124/252 (49.2%)

Characteristic	n/N (%)
Studies that reported adverse events stratified by age, including AYA as an age group.	0/252 (0.0%)

Figure 1. PRISMA Flow Diagram of Study Selection



RESULTS

A total of 572 Phase II and Phase III cancer trials evaluating anti-cancer agent(s) or radiation interventions in either breast, colorectal, Hodgkin's lymphoma, non-Hodgkin's lymphoma, or melanoma met the inclusion criteria. Of these included trials, zero (0/572, 0.00%) disaggregated adverse event AYA clinical trial data.

CONCLUSION

There remains a substantial gap in understanding the adverse event profile regarding anti-cancer agent(s) or radiation interventions in the AYA population with either breast, colorectal, Hodgkin's lymphoma, non-Hodgkin's lymphoma, or melanoma. We recommend future clinical trials evaluate and disaggregate AYA adverse event clinical trial data from other age groups to assess the differences in treatment-related adverse events in AYAs and to improve guidelines and treatment protocols for AYA patients with cancer.

OUTCOMES

The primary outcome of this study is to determine the proportion of Phase II and Phase III cancer trials that report adverse events for AYAs.

Secondary endpoints include a comparison of adverse event rates between AYAs and older adults with cancer and to determine whether these adverse events lead to different rates of dose-reduction or treatment discontinuation.

REFERENCES

RESEARCH