



Pan-Canadian Lung Cancer Observational Study (PALEOS): A Multicentre Ambispective Observational Study of Lung Cancer Patients

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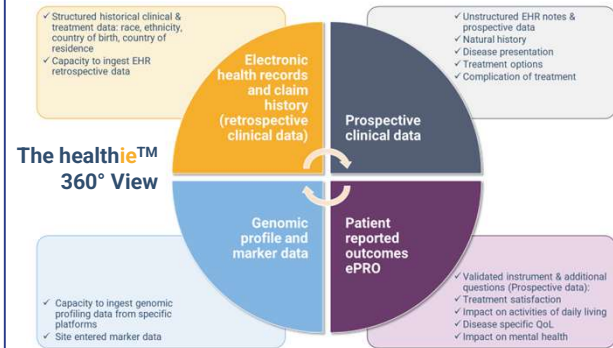
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BACKGROUND

- Healthcare decision-makers and stakeholders are increasingly relying on real-world evidence (RWE) alongside evidence from randomized controlled trials.
- Regulatory bodies such as the FDA, Health Canada and EMA are advocating for increased utilization of RWE to support new indications, signaling a paradigm shift in evidence-based medicine practices.
- Using RWD, PALEOS aims to address key questions regarding the epidemiology and natural history, treatment patterns and effectiveness, safety, patient reported outcomes and health economic impact in Canadian lung cancer patients.

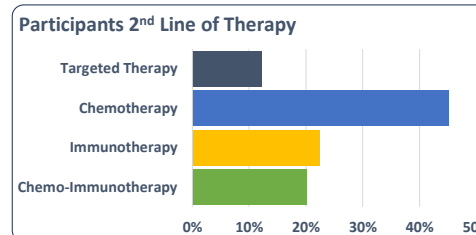
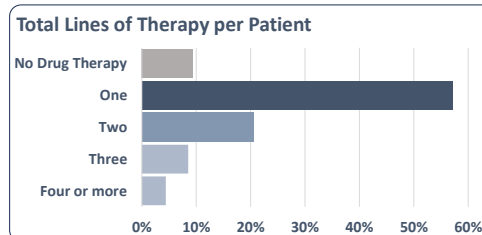
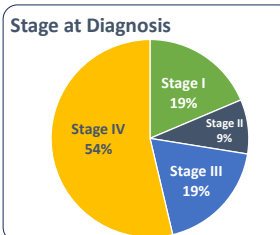
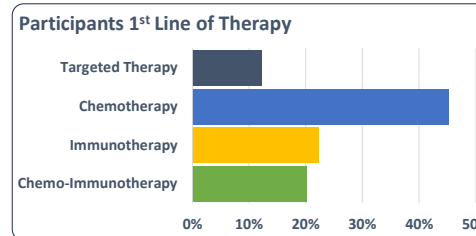
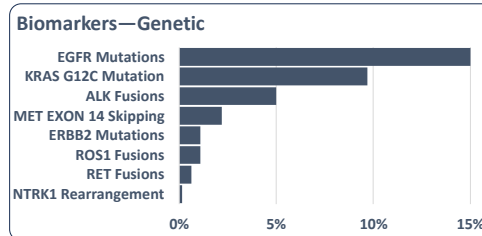
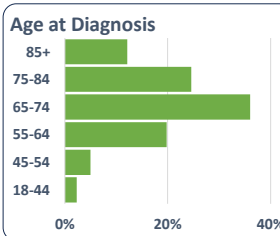
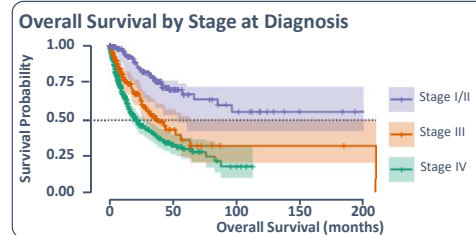
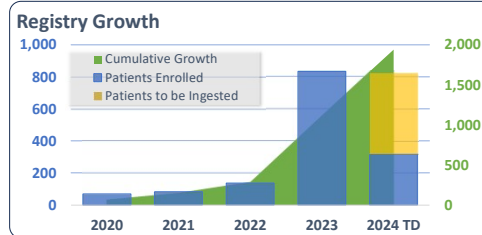
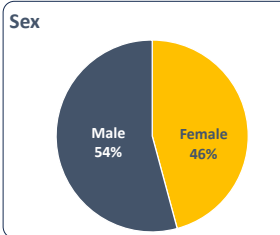
THE HEALTHIE™ 360° VIEW

PALEOS is hosted on the healthie™ RWD platform by Pulse Inframe. Pulse Inframe, based in Ontario, has a global reach with over 31,000 patients in registries/studies in 120+ sites, across 87 countries and 13 languages. PALEOS captures close to 500 data elements covering the patient journey from screening, through diagnostics and multiple treatment modalities, to end of life. It uses the OMOP Common Data Model and can collaborate with other national/international registries.



RESULTS

PALEOS annual recruitment rates are growing exponentially, from 69 new cases in 2020 to 1,900 in 2024 to-date including anticipated ingestion for an onboarding site. Median age is 69 years (range 22-97) at diagnosis, 46% were females, and 19%, 9%, 19%, 54% were stages I, II, III, and IV, respectively (n=706). 42% had first-line metastatic treatment initially involving immunotherapy (22% monotherapy; 20% combination chemoimmunotherapy; n=544). Among all patients tested, 15% had EGFR-mutated (n=639) and 5% were ALK-rearranged (n=621) tumors. Median follow-up in Stage I-III patients was 27 months; in Stage IV patients, 16 months. Median overall survival for Stages III and IV were 37.1 and 20.4 months, respectively.



METHODS AND PALEOS STUDY OBJECTIVES

- PALEOS (NCT04706754) is a multicentre, ambispective observational study conducted across multiple sites in Canada in adult patients with a confirmed diagnosis of non-small cell lung cancer.
- The study will recruit 25,000 patients over 20 years, with 6 initial sites that comprise a catchment area of approximately 30% of the Canadian population (mix of urban and rural populations), with plans to expand.
- Descriptive statistics were generated, and survival analysis conducted based on primary and secondary objectives.

PRIMARY OBJECTIVE

- To report on the natural history and treatment patterns of multiple subgroups of lung cancer patients, from 2000 onwards, using a combination of retrospective and prospective methods that includes diagnostic, molecular alterations, treatment, and outcomes.

SECONDARY OBJECTIVES

- To evaluate PROs of different subgroups of lung cancer.
- To understand the incidence, prevalence, and metastatic spread in different subgroups of lung cancer.
- To understand the evolution of clinical implementation of new diagnostic/biomarker tests and new treatments, including rates of adoption into clinical practice, and retention over time.
- To compare the natural history, stage distribution, treatment outcomes such as treatment effectiveness and treatment toxicities across sub-group of patients with tumors that have been molecularly subtyped and identified to have rare molecular alterations.

CONCLUSIONS AND FUTURE DIRECTIONS

- PALEOS provides a comprehensive framework to elucidate natural history, treatment patterns, and outcomes of lung cancer patients. It will facilitate knowledge translation and inform evidence-based decision-making in the management of lung cancer across disciplines
- PALEOS supports health technology assessments for new therapeutics and will have meaningful impact on patient advocacy.
- The RWE generated from PALEOS (clinical, molecular, advanced sequencing techniques) can be used to support biomarker discovery trials.
- In 2024 PALEOS will expand to additional study sites in Canada and the US (New York), and to multiple satellite sites.
- Use of artificial intelligence technology to bridge the different domains will be explored.

ACKNOWLEDGEMENTS AND REFERENCES (at QR code)

We are deeply grateful to our patients, their families and network of passionate collaborators for their invaluable contributions. We thank Pulse Inframe Inc. for partnering to develop the Lung Cancer Platform, and their coordination of the regulatory, operational and financial aspects of this study. Contact sara.kuruvilla@lhsc.on.ca or parneet.cheema@williamoslerhs.ca to learn how to be involved with PALEOS study.



Information about Pulse oncology RWD (lung cancer, melanoma, uveal melanoma, non-melanoma skin cancer), resulting publications, and healthie™ can be found at PulseInframe.com linked through the QR.