

CANADIAN/US INTEGRATIVE ONCOLOGY STUDY (CUSIOS): PROTOCOL AND STUDY STATUS

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BACKGROUND

The Canadian/US Integrative Oncology Study (CUSIOS) is a prospective, observational study designed to document three-year survival outcomes in late stage cancer patients receiving Advanced Integrative Oncology (AIO) care by experienced naturopathic doctors. Three sub-studies will evaluate health-related quality of life, cost-utilization, and the qualitative experience of AIO care in a subset of Canadian participants.

STUDY OBJECTIVES

1. Measure survival of advanced stage breast, colorectal, ovarian and pancreatic cancer patients who receive AIO treatments
2. Describe AIO treatments recommended by naturopathic oncologists
3. Pilot the collection of health-related quality of life (HR-QOL) data
4. Evaluate cost of AIO care
5. Qualitatively describe the experience of AIO Care

STUDY SITES

Clinic name	Location	Site Principal Investigator
CANADIAN SITES		
Ottawa Integrative Cancer Centre	Ottawa, Ontario	Dugald Seely ND, MSc, FABNO
Vital Victoria Naturopathic Clinic Ltd	Victoria, British Columbia	Neil McKinney ND
Integrated Health Clinic Cancer Care Centre	Fort Langley, British Columbia	Gurdev Parmar ND, FABNO
Marsden Centre for Excellence in Integrative Medicine	Maple, Ontario	Eric Marsden ND
Health Source Integrative Medical Centre	Kitchener, Ontario	Michael Reid ND, Rac, FABNO
AMERICAN SITES		
Shelby Naturopathic Clinic	Seattle, Washington	Leanna Standish ND, PhD, LAC, FABNO
Naturopathic Specialists LLC	Scottsdale, Arizona	Dan Rubin ND, FABNO
Salish Care Centre	Fife, Washington	Paul Reilly ND, LAC, FABNO
Lokahi Health Centre	Kailua-Kona, Hawaii	Michael Traub ND, DHANP, CCH, FABNO
Tree of Health Integrative Medicine	Woodenville, Washington	Eleonora Naydis ND, LAC, FABNO
Red Cedar Wellness Center	Bellevue, Washington	Erin Sweet ND, MPH, FABNO

METHODS

Study design: Uncontrolled, prospective observational study
Target sample size: 400 (minimum 80 each in HR-QOL and cost analysis sub-studies)
Eligibility: Adults with confirmed stage IV breast or colorectal cancer, stage III/IV pancreatic or ovarian cancer receiving care from a participating AIO clinic

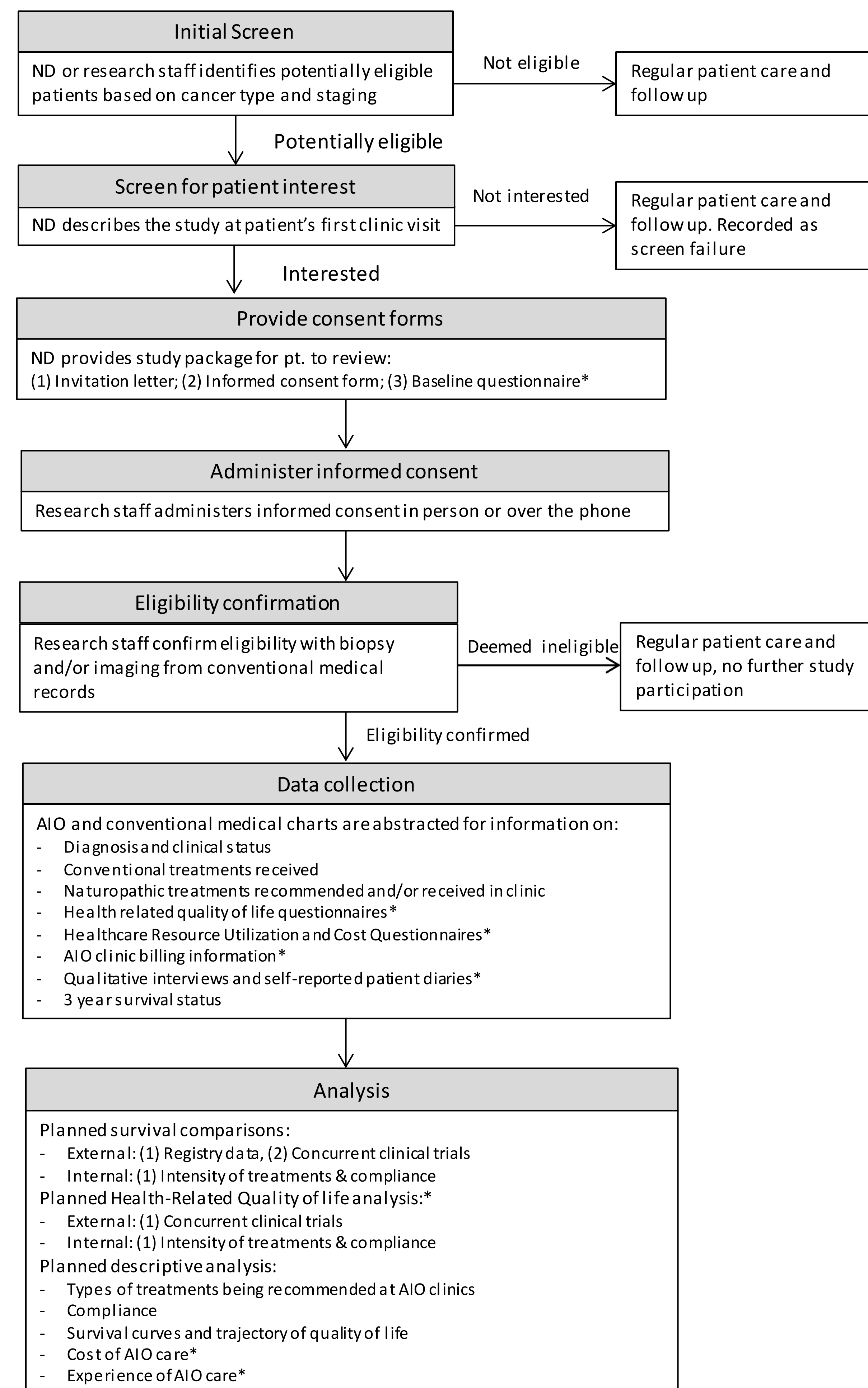


Figure 1: CUSIOS workflow. Items with an asterisks are only performed in a subset of patients from Canadian sites, for the three sub-studies

STUDY STATUS

Study recruitment: began July 2015, with retroactive enrollment to January, 2015
Enrollment as of 10-31-2017: 224 participants (84 in HR-QOL sub-study)
Expected completion: July 2022 (includes 3 year follow up)

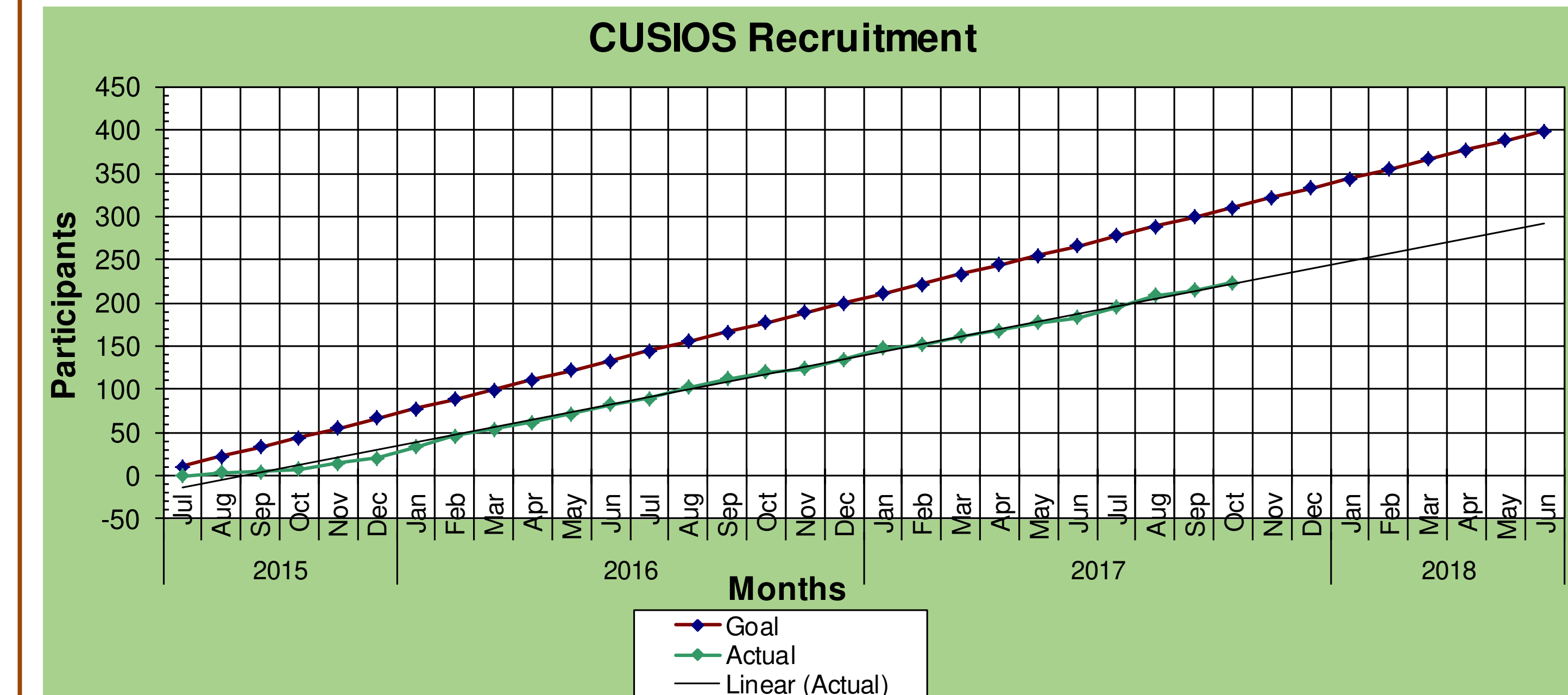


Figure 2: Graph of monthly enrollment compared to target enrollment

CUSIOS enrollment by cancer type

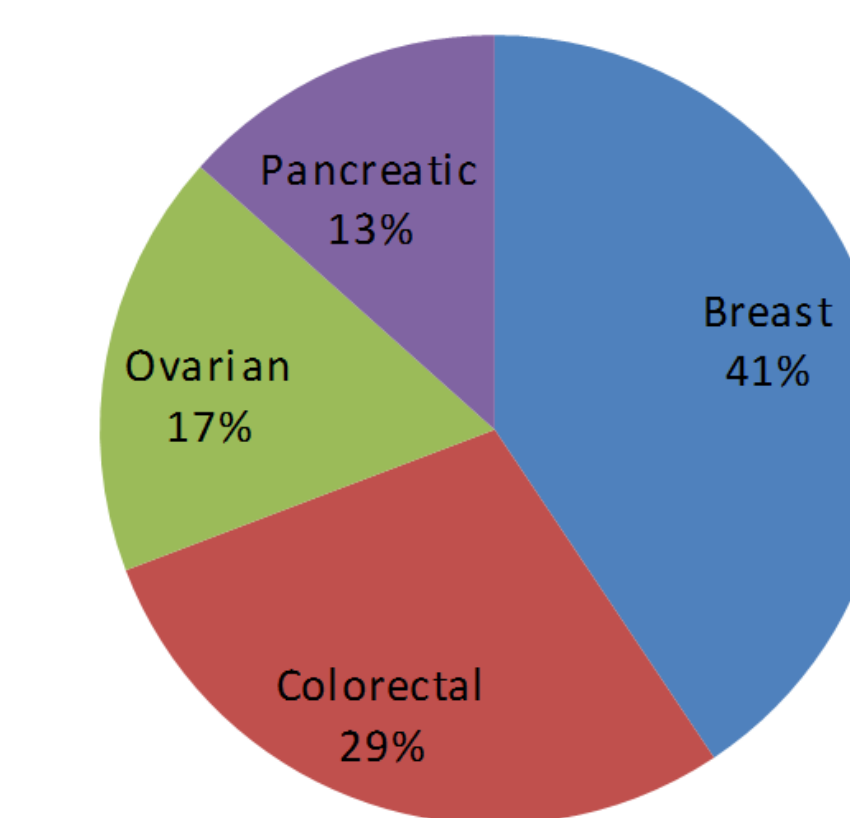


Figure 3: CUSIOS enrollment by cancer type, as of 10-31-2017

NEXT STEPS

- Initiate cost-analysis sub-study
- Conduct qualitative interviews to describe the experience of AIO care

SIGNIFICANCE

This is the first multi-centre, prospective observational study evaluating survival outcomes for patients receiving advanced AIO care in North America. Findings from the study will inform the profession and public of the potential impact that AIO has on survival and quality of life. In addition, this research will provide a thorough description of the range of therapies provided by experienced naturopathic oncologists, cost utilization by patients, and a longitudinal analysis of patient experience.



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