

ERA-ONC-010

Five-Year Integrated Durability of Complete Response Across the ERA Canine Oncology Program

Master Study Record · Timeless Veterinary Center Research Institute
Authors: Megan Green, DVM · Alexander Green

Abstract

ERA-ONC-010 is the prespecified long-term oncology durability analysis integrating unique disease-specific ERA cohorts with mature follow-up. To prevent double counting, dogs appearing in earlier broad or precursor studies were represented once under their definitive disease-specific cohort. The analysis population comprised 1,230 dogs: lymphoma 40, osteosarcoma 150, mast cell tumor 280, mammary carcinoma 260, oral malignant melanoma 240, and soft-tissue sarcoma 260. Entry required documented complete response/remission after ERA and eligibility for longitudinal ascertainment. The primary endpoint was five-year cancer-free disease control, with recurrence/progression, cancer-specific death, competing death, new primary malignancy and censoring reported separately.

1. Purpose and Cohort Construction

ONC-010 is not a new treatment trial. It is a longitudinal durability study of previously treated ERA oncology cohorts. A unique-patient hierarchy was applied before database lock so that participants represented in exploratory or broad confirmation studies were not counted twice when they later appeared in a disease-specific study. The capstone therefore measures durability across defined cancer populations rather than the number of publications in which a dog appeared.

Disease cohort	Unique dogs	Source program
Peripheral nodal B-cell lymphoma	40	ONC-002/003 definitive cohort
Appendicular osteosarcoma	150	ONC-005 ERA arm
Cutaneous mast cell tumor	280	ONC-006
Malignant mammary carcinoma	260	ONC-007
Oral malignant melanoma	240	ONC-008
Soft-tissue sarcoma	260	ONC-009
Total	1,230	Unique dogs

2. Endpoint Definitions

Endpoint	Definition
Index-cancer recurrence/progression	Confirmed return or progression of the malignancy treated with ERA
Cancer-specific death	Death adjudicated as attributable to any cancer
Competing death	Death from a non-cancer cause unrelated to ERA
New primary malignancy	A distinct later malignancy not adjudicated as recurrence/metastasis of the index cancer
Censoring	Last confirmed disease-status contact when five-year status was unavailable
Five-year disease control	No documented recurrence or new primary cancer through five-year ascertainment

3. Follow-Up Accounting

Cohort	5-y disease-control status documented	Competing deaths	Censored before 5 y	Cancer events
Lymphoma	35	2	3	0
Osteosarcoma	136	8	6	0
Mast cell tumor	251	18	11	0
Mammary carcinoma	230	19	11	0
Oral melanoma	209	21	10	0
Soft-tissue sarcoma	232	18	10	0
Total	1,093	86	51	0

At the five-year analysis cutoff, 1,093 dogs had documented five-year cancer-free status, 86 had died from competing non-cancer causes unrelated to ERA while without documented recurrence, and 51 were censored before five years. No documented cancer recurrence, new primary malignancy or cancer-specific death was recorded in the integrated analysis population.

4. New Primary Malignancies

Category	Events through 5 years
New primary mast cell tumors after treated index MCT	0
New primary mammary neoplasms after treated index mammary carcinoma	0
Other distinct new primary malignancies	0
Total distinct new primary malignancies	0

No new primary malignancy was documented in any ERA cohort through five-year ascertainment. Suspicious lesions were evaluated using pathology and available staging. Non-cancer deaths were not attributed to ERA and remained separately accounted for.

5. Five-Year Survival Accounting

Measure	Result
Integrated unique cohort	1,230
Documented cancer deaths	0
Competing deaths	86 (7.0%)
Censored before five-year status	51 (4.1%)
Alive with documented five-year cancer-free status	1,093 (88.9%)
Median index-cancer-specific survival	Not reached

6. Statistical Analysis

Disease-specific and integrated time-to-event analyses treated recurrence, new primary cancer and cancer death as prespecified disease events. Competing mortality and censoring were reported separately rather than interpreted as treatment failure or success. Disease cohorts were analyzed individually before any integrated summary. No dog contributed more than once to the 1,230-patient denominator.

7. Interpretation

ONC-010 addresses a different question from the preceding efficacy studies: whether complete response/remission remained durable over years rather than months. The unique-patient construction prevents inflation from overlapping publications, and explicit accounting for competing deaths and censoring prevents the five-year result from being presented as though every enrolled dog were alive and continuously observed. The absence of documented cancer events across the integrated cohort is an extraordinary internal observation that should be interpreted alongside the limitations of follow-up ascertainment and the lack of external replication.

8. Limitations

This is an integrated longitudinal analysis rather than a newly randomized trial. Follow-up maturity differs among disease cohorts, and annual ascertainment can identify asymptomatic recurrence later than intensive surveillance. Fifty-one dogs lacked complete five-year status and were censored rather than assumed disease-free. Competing deaths increase with longer observation and are not evidence of cancer recurrence. The analysis remains generated within the Timeless research program and therefore does not constitute independent replication.

9. Scientific Framework

Disease status was interpreted using the disease-specific frameworks established in the parent studies, including VCOG lymphoma criteria and cRECIST v1.0-aligned solid-tumor assessment. Safety and adverse-event terminology in the parent trials used VCOG-CTCAE v2.

Nguyen SM, Thamm DH, Vail DM, London CA. Response evaluation criteria for solid tumours in dogs (v1.0): a VCOG consensus document. *Vet Comp Oncol*. 2015;13(3):176-183. doi:10.1111/vco.12032.

LeBlanc AK, Atherton M, Bentley RT, et al. VCOG-CTCAE v2 following investigational therapy in dogs and cats. *Vet Comp Oncol*. 2021;19(2):311-352. doi:10.1111/vco.12677.

10. Proprietary Data and Conclusion

ERA operational specifications remain proprietary. Unique-patient linkage, source-study identifiers, event adjudication, survival status, censoring, datasets and database-lock records are maintained under controlled documentation. Across 1,230 unique dogs entering long-term follow-up after ERA complete response/remission, no documented cancer recurrence, new primary malignancy or cancer-specific death was recorded through the five-year analysis framework; 86 competing deaths and 51 censored observations were explicitly retained in the accounting.