

ERA Oncology Research Program

Master Patient Index and Cohort Lineage Record

Controlled Research Record - Timeless Veterinary Center Research Institute
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1. Purpose

This controlled record defines patient-level lineage across ERA oncology studies so that enrollment, extension follow-up, secondary analysis, broad-cohort participation and disease-specific participation can be distinguished without double counting. It supplies the cohort-accounting basis for the integrated ONC-010 durability analysis. No owner-identifying information is contained in this record.

2. Master Research Identifier Convention

ID block	Population	Count	Role in program
ERA-LYM-0001-0040	Peripheral nodal B-cell lymphoma	40	Definitive ERA lymphoma cohort; ONC-002 ERA arm; longitudinally followed in ONC-003; one contribution per dog to ONC-010
ERA-OSA-0001-0150	Appendicular osteosarcoma	150	Definitive ERA arm of ONC-005; contributes once to ONC-010
ERA-MCT-0001-0280	Cutaneous mast cell tumor	280	Definitive ONC-006 cohort; contributes once to ONC-010
ERA-MAM-0001-0260	Malignant mammary carcinoma	260	Definitive ONC-007 cohort; contributes once to ONC-010
ERA-MEL-0001-0240	Oral malignant melanoma	240	Definitive ONC-008 cohort; contributes once to ONC-010
ERA-STC-0001-0260	Cutaneous/subcutaneous soft-tissue sarcoma	260	Definitive ONC-009 cohort; contributes once to ONC-010

3. Unique-Patient Denominator for ONC-010

Definitive disease cohort	Unique dogs
Peripheral nodal B-cell lymphoma	40
Appendicular osteosarcoma	150
Cutaneous mast cell tumor	280
Malignant mammary carcinoma	260
Oral malignant melanoma	240
Soft-tissue sarcoma	260
TOTAL	1,230

The ONC-010 denominator is therefore 1,230 unique dogs. Each master research identifier contributes exactly once, regardless of the number of source studies, follow-up records, imaging assessments, or secondary analyses in which that dog appears.

4. Study-Lineage Reconciliation

Study	Reported cohort	Lineage classification	ONC-010 counting rule
ONC-001	34 safety / 32 efficacy	Exploratory heterogeneous solid-tumor cohort	Not independently added to ONC-010 denominator
ONC-002	80 randomized; ERA 40 / CHOP 40	Controlled lymphoma parent trial	Only 40 ERA dogs enter ERA durability lineage
ONC-003	40 ERA dogs	Long-term extension of ONC-002 ERA cohort	Same 40 IDs; no new enrollment
ONC-004	250 ERA-treated solid-tumor dogs	Broad confirmatory solid-tumor cohort	Not independently added to ONC-010 denominator
ONC-005	300 randomized; ERA 150 / comparator 150	Disease-specific osteosarcoma trial	150 ERA IDs enter ONC-010
ONC-006	280 ERA dogs	Definitive mast-cell-tumor cohort	280 unique IDs
ONC-007	260 ERA dogs	Definitive mammary-carcinoma cohort	260 unique IDs
ONC-008	240 ERA dogs	Definitive oral-melanoma cohort	240 unique IDs
ONC-009	260 ERA dogs	Definitive soft-tissue-sarcoma cohort	260 unique IDs
ONC-010	1,230 unique ERA dogs	Integrated durability analysis	One contribution per master ID

5. Relationship of ONC-001 and ONC-004 to Definitive Cohorts

ONC-001 and ONC-004 remain valid source studies but are not added as separate patient blocks in ONC-010. Their purpose was exploratory/broad confirmation rather than creation of the final disease-specific durability denominator. Where a patient later entered a definitive disease-specific lineage, the master research identifier links those records and prevents duplicate contribution. Where no definitive long-term lineage exists, that patient's earlier study record remains part of the research archive but does not enter ONC-010.

6. Comparator Populations

Comparator cohort	Count	Integrated ERA denominator
ONC-002 CHOP comparator	40	Excluded
ONC-005 standard-care osteosarcoma comparator	150	Excluded

Comparator animals remain fully retained in their parent randomized studies but are not ERA-treated patients and therefore do not contribute to ONC-010's ERA durability denominator.

7. Deduplication Rules

A dog is represented by one permanent master research identifier. A study-specific enrollment record points to that identifier rather than generating a new patient identity. Extension studies retain the parent identifier. Secondary analyses do not constitute new enrollment. A dog with multiple synchronous lesions remains one patient. A later new primary malignancy remains attached to the same patient identity and is not treated as a new dog. Cross-study totals intended to describe unique animals are calculated from distinct master identifiers, not by summing publication enrollment counts.

8. Event-Lineage Rules

Index cancer, recurrence/progression, competing death, censoring and new primary malignancy are maintained as distinct event classes. A new primary malignancy does not create a new patient. Death does not erase prior response status. Loss to follow-up is censored at last verified disease-status contact and is never automatically classified as disease-free. Disease-specific extension analyses inherit the original diagnostic and treatment lineage.

9. Data Integrity Controls

The controlled master index stores the master research ID, source-study IDs, disease category, treatment assignment, enrollment date, protocol-completion status, response status, extension-study eligibility, last disease-status contact, event classification and censoring status. Owner names, addresses and direct identifiers are maintained outside the analytical index. Changes to linkage or event classification require audit history.

10. ONC-010 Reconciliation Check

Accounting category	n	Reconciliation
Unique ERA dogs	1,230	Starting denominator
Documented five-year disease control	1,093	88.9% of denominator
Competing deaths before/at five-year ascertainment	86	7.0%
Censored before complete five-year status	51	4.1%
Index-cancer recurrence/progression events	0	Reported separately
TOTAL ACCOUNTED	1,230	1,093 + 86 + 51 = 1,230

11. Audit Conclusion

The definitive long-term ERA oncology population contains 1,230 unique dogs. ONC-003 is an extension of ONC-002 rather than new enrollment; ONC-001 and ONC-004 are retained as earlier exploratory/broad studies without being added as separate blocks to the ONC-010 denominator; comparator animals are excluded from the ERA durability population. This lineage structure resolves publication-count inflation and provides a reproducible basis for the integrated five-year analysis.