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Feasibility assessment of a real-world comparator cohort using multiple qualifying index lines of therapy (LOTs) in third-line or later (3L+) Diffuse Large B-Cell Lymphoma (DLBCL)

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Objectives

- Our objective was to explore multi-LOT qualification methods for future comparative analysis to enable appropriate contextualization of RWD study results relative to clinical trial results.

Background

- Real-world data (RWD), including electronic health record (EHR) datasets, are increasingly used to contextualize clinical trial results in a contemporary treatment landscape.
- In clinical trials, patients qualify at enrollment; however, a patient could be eligible in lines of therapy (LOTs) prior to or following enrollment, depending on when trial assessment occurred.
- Given that retrospective EHR data typically include patients' entire treatment history, real-world studies require deliberate choice to determine qualification and index date. (**Figure 1**) Relatedly, results may differ based on which potential qualification date is used.
- It is important to establish optimal methods to determine which LOT serves as the comparison time zero (index) for each eligible patient.

Methods

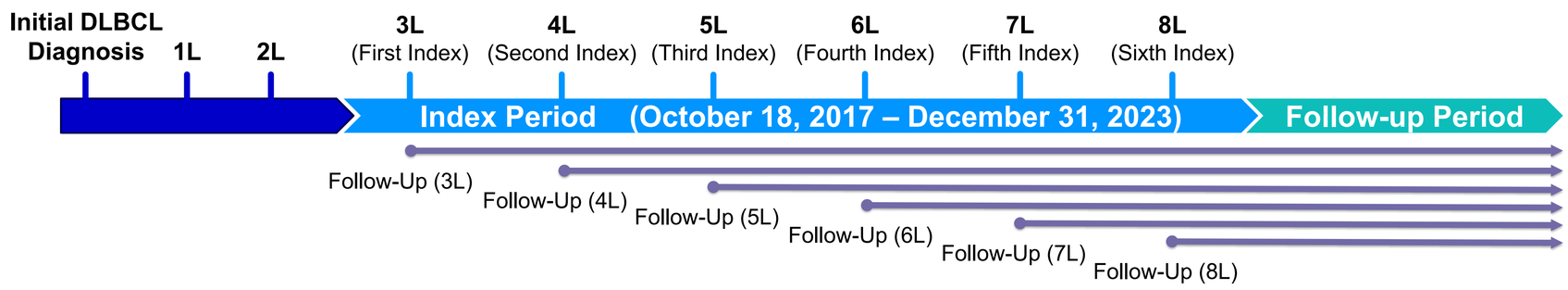
STUDY DESIGN

- Eligibility criteria from ECHELON-3 were adapted and applied to COTA's real-world, EHR-based diffuse large B-cell lymphoma (DLBCL) database.

ELIGIBILITY CRITERIA

- Eligible adult (≥18 years old) patients had received ≥2 prior LOTs for non-primary central nervous system (CNS) DLBCL.
- Eligible patient-LOTs were identified from the following criteria:
  - 3L+ LOT initiation between October 18, 2017 (date of first DLBCL chimeric antigen receptor T-cell therapy (CAR-T) approval) and December 31, 2023 to allow for sufficient follow-up,
  - Excluding patients with a solid tumor malignancy within two years of index date, and
  - Excluding patients with the following treatment history: brentuximab vedotin, CAR-T, hematopoietic stem cell therapy, or investigational therapy at index OR brentuximab vedotin at any point prior to index.
- The baseline window for the study was defined as either a) 30 days prior to index or b) the end of prior LOT, whichever timepoint is earlier. The maximum pre-index baseline period could not exceed 90 days. The baseline period end date was 7 days post-index.
- Results were summarized among unique patients and qualifying patient-LOTs.

Figure 1. Qualification Schema



Abbreviations: 1L = first-line; 2L = second-line; 3L = third-line; 4L = fourth-line; 5L = fifth-line; 6L = sixth-line; 7L = seventh-line; 8L = eighth-line; DLBCL = Diffuse large B-cell lymphoma

RESULTS

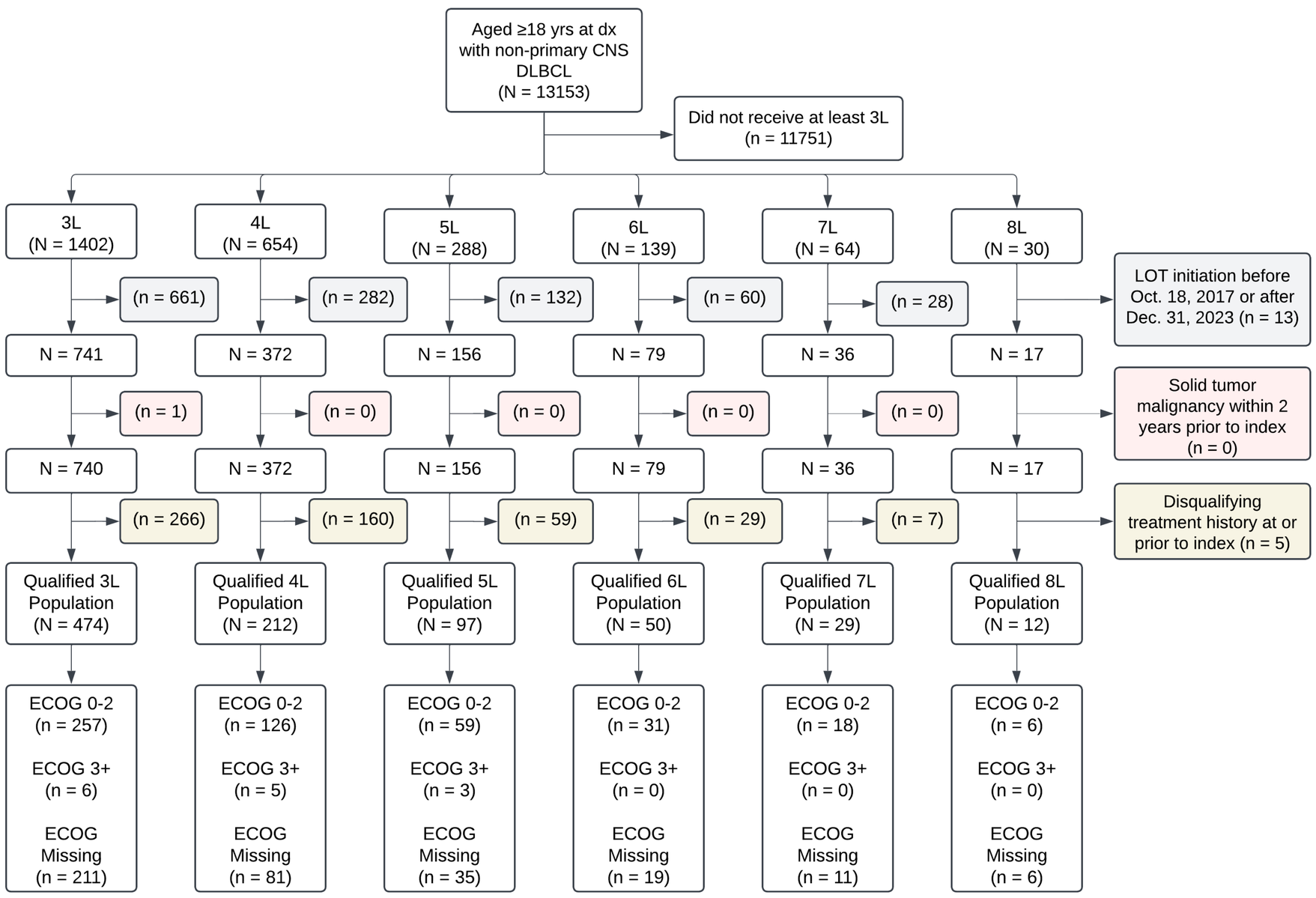
- In total, 585 unique records had at least one qualifying index-LOT. (**Table 1**) There were 880 qualifying index-LOTs identified (3L = 474; 4L = 212; 5L = 97; 6L = 50; 7L = 29; 8L = 12; 9L+ = 6). (**Figure 2**)
- The median number of qualifying LOTs per patient was 1 (min=1, max=7).
- The majority of qualifying index-LOTs occurred at 3L (n=474; 53.9%), and 24.1% and 11.0% of qualifying patient-LOTs occurred at 4L and 5L, respectively, representing nearly 90% of qualifying index-LOTs between 3L-5L.
- Among unique records, 206 (35.2%) had unknown ECOG scores in all qualifying-LOT baseline periods, and 9 (1.5%) had at least one ECOG score of ≥ 3 without any scores 0-2 across qualifying LOTs.
- Only 2.5% and 3.4% of qualifying index-LOTs had missing race and ethnicity data, respectively. All patients had complete age, sex, and practice setting data.

Table 1. Qualification Summary

Number of qualifying patient-LOTs	880
Number of unique patients that qualify	585
ECOG 0-2 in baseline period for at least one qualifying LOT	370
ECOG unknown for all qualifying LOTs	206
ECOG 3+ at least once and no ECOG 0-2 across qualifying LOTs	9
Number of qualifying LOTs per patient, median (min, max)	1 (1, 7)
Among unique qualifying patients, number with positive CNS biopsy prior to first qualifying index	5
Among unique qualifying patients, number with CNS radiation prior to first qualifying index	6
Data missingness among all qualifying patient-LOTs, n (%)	
Race	22 (2.5)
Ethnicity	30 (3.4)

Abbreviations: CNS = Central Nervous System; ECOG = Eastern Cooperative Oncology Group; LOT = Line of therapy

Figure 2. Attrition Diagram



Abbreviations: 3L = third-line; 4L = fourth-line; 5L = fifth-line; 6L = sixth-line; 7L = seventh-line; 8L = eighth-line; CNS = Central Nervous System; DLBCL = Diffuse large B-cell lymphoma; Dx = Diagnosis; ECOG = Eastern Cooperative Oncology Group; LOT = Line of Therapy

CONCLUSIONS

- Among 585 unique patients, there was a 50% increase in qualifying index-LOTs when assessing each LOT independently for qualification, demonstrating that choice of index LOT in retrospective real-world studies in not trivial.
- This analysis demonstrates an ability to assess qualification across a patient journey, and future research is needed to understand the sensitivity of real-world results based on the selected index date, specifically as it relates to outcomes analyses.

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