Modeling Longitudinal Quality of Life Changes in Patients Diagnosed with Lymphomas:
Heatmap Analysis of Electronic Patient-Reported Outcomes (ePRO) Data from the BISON-PRO Quality of Life Study

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BISON·PRO
BLOOD DISORDER SYMPTOMATOLOGY OUTCOMES NETWORK
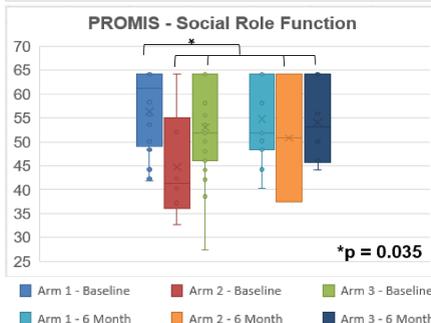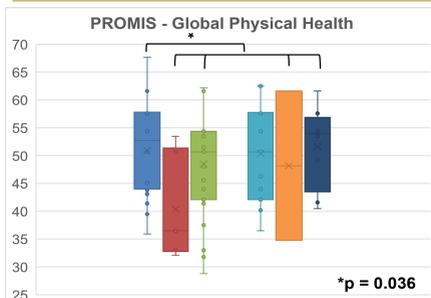PATIENT REPORTED OUTCOMES

Background

- Patient-reported outcomes (PRO) measures are used in lymphoma clinical trials to assess health-related quality of life (QoL) and tolerability of novel treatment regimens, including CAR T-cell and bispecific antibody therapies.
- However, outcomes in the clinical trial setting often differ from those in real-world patient cohorts.
- The **B**lood **DI**sorder **S**ymptomatology **O**utcomes **N**etwork—**P**atient **R**eported **O**utcomes (BISON-PRO) Quality of Life Study prospectively administers longitudinal electronic PRO (ePRO) instruments and is currently enrolling patients with lymphomas and CLL to measure QoL outcomes in the real-world setting.
- This initial study was primarily designed to determine if BISON-PRO can detect meaningful differences in PRO scores and QoL between groups and longitudinally within groups over time.
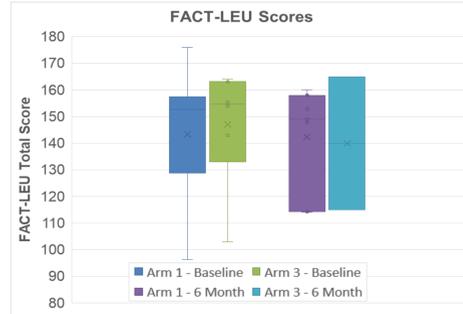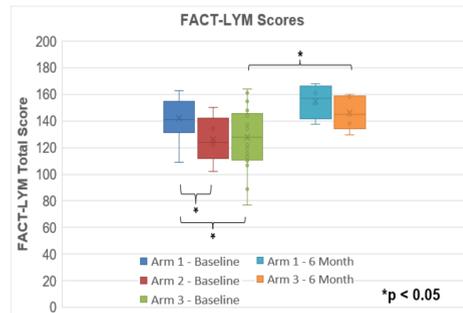
Study Design

BISON-PRO Quality of Life Study

- All patients who present for a new patient visit in the University of Colorado lymphoma and CLL clinics are approached to participate in BISON-PRO.
- Patients are enrolled in 1 of 3 study arms:
  - Arm 1: active surveillance
  - Arm 2: cellular therapies
  - Arm 3: starting active systemic or radiation therapy
- Enrolled patients receive the following ePRO instruments at baseline, 6, and 12 months:
  - PROMIS Global Health 10 and 29+2 Profile
  - FACT-LYM (FACT-LEU if CLL)
  - Acceptability of Intervention Measure (AIM)
  - PROs were also collected at 28 days and 3 months in Arms 2 and 3.
- BISON-PRO enrollment began in May 2023; this analysis was performed over a 6-month time horizon.
- PROMIS T-scores were converted to percentile scores to construct a normal distribution for heatmap analysis. Statistical tests included one-way ANOVA for comparisons between group means.

Results

PROMIS - Global Physical Health
*p = 0.036

PROMIS - Social Role Function
*p = 0.035

- Arm 1 - Baseline
- Arm 2 - Baseline
- Arm 3 - Baseline
- Arm 1 - 6 Month
- Arm 2 - 6 Month
- Arm 3 - 6 Month

Patient Demographics	
Number of patients	
Baseline	65
3 months	20
6 months	19
Age, median (range)	60 (25-85)
Identify as women	49%
Self-identified race/ethnicity	
Non-Hispanic White	88%
Black	8%
Hispanic	4%

- At baseline, patients in active surveillance had higher QoL scores compared with Arms 2 & 3 based on FACT-LYM score.
- Mean PROMIS T-scores were higher over time for global physical health and social role functioning in active surveillance (Arm 1) compared with Arms 2 and 3 (p = 0.036 and p = 0.035, respectively).
- Patients with lymphoma on active treatment had significant improvement in QoL by FACT-LYM (p = 0.048).
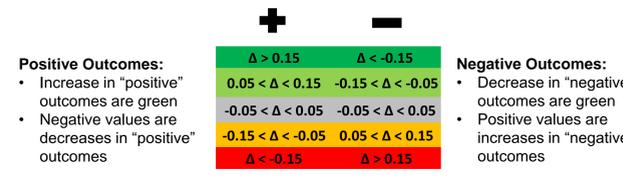- AIM scores at baseline were 4.0, 3.5, and 3.9 for Arms 1, 2, and 3, respectively.

FACT-LYM Scores
*p < 0.05
- Arm 1 - Baseline
- Arm 1 - 6 Month
- Arm 2 - Baseline
- Arm 3 - 6 Month
- Arm 3 - Baseline

FACT-LEU Scores
- Arm 1 - Baseline
- Arm 3 - Baseline
- Arm 1 - 6 Month
- Arm 3 - 6 Month

Heatmap Results

		Global Mental Health	Global Physical Health	Physical Function	Social Role Function	Cognitive Function
Positive Outcome Measures						
Surveillance	0 to 6 Months	0.018	-0.019	-0.077	-0.059	-0.041
Cellular Therapies	0 to 28 Days	0.005	-0.032	-0.143	-0.093	-0.144
	28 Days to 3 Months	0.264	0.120	0.220	0.294	0.111
	0 to 3 Months	0.269	0.088	0.077	0.201	-0.033
	3 Months to 6 Months	-0.179	0.172	0.018	0.030	0.074
	0 to 6 Months	0.090	0.260	0.095	0.231	0.041
Systemic Therapy / Radiotherapy	0 to 3 Months	-0.033	-0.043	-0.081	-0.053	0.055
	3 Months to 6 Months	0.085	0.168	0.193	0.146	-0.156
	0 to 6 Months	0.052	0.125	0.112	0.093	-0.101

		Anxiety	Depression	Fatigue	Sleep Disturbance	Pain Impacting Activity
Negative Outcome Measures						
Surveillance	0 to 6 Months	-0.138	-0.147	0.033	0.009	0.020
Cellular Therapies	0 to 28 Days	-0.392	-0.023	0.086	-0.213	-0.165
	28 Days to 3 Months	0.152	0.087	-0.196	0.080	-0.238
	0 to 3 Months	-0.240	0.065	-0.110	-0.133	-0.403
	3 Months to 6 Months	-0.034	0.036	-0.079	-0.311	0.236
	0 to 6 Months	-0.274	0.101	-0.189	-0.445	-0.167
Systemic Therapy / Radiotherapy	0 to 3 Months	-0.121	0.013	-0.087	-0.044	-0.089
	3 to 6 Months	-0.033	0.015	-0.043	-0.031	-0.046
	0 to 6 Months	-0.154	0.028	-0.130	-0.075	-0.135

- Large increases in global physical health and social role function were seen in Arms 2 and 3 at 6 months compared to baseline, while Arm 1 had virtually no change in physical health and a decrease in social role functioning.
- Cognitive function remained similar at 6 months compared to baseline for Arms 1 and 2; however, Arm 3 saw an approximately 10 percentile point drop in function at 6 months.
- Global mental health at 6 months improved modestly for Arms 2 and 3 compared with baseline, but Arm 1 saw virtually no change.

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Positive Outcomes:	Δ > 0.15	Δ < -0.15	Negative Outcomes:
• Increase in "positive" outcomes are green	0.05 < Δ < 0.15	-0.15 < Δ < -0.05	• Decrease in "negative" outcomes are green
• Negative values are decreases in "positive" outcomes	-0.05 < Δ < 0.05	-0.05 < Δ < 0.05	• Positive values are increases in "negative" outcomes
	-0.15 < Δ < -0.05	0.05 < Δ < 0.15	
	Δ < -0.15	Δ > 0.15	

- Anxiety improved in all arms at 6 months compared with baseline.
- Fatigue levels improved in Arms 2 and 3 at 6 months relative to baseline, but there was no change in Arm 1.
- Similarly, there were lower levels of sleep disturbance and pain impacting daily activity in Arms 2 and 3 at 6 months compared to baseline, but Arm 1 had similar levels of both at the same time points.

Conclusions

- In the BISON-PRO Quality of Life Study, meaningful differences in PROs were detected between study cohorts, with higher QoL (measured by FACT and PROMIS) in patients undergoing surveillance as compared to active therapies.
- Interestingly, patients with lymphoma who underwent systemic or radiation therapies had significant improvement in lymphoma-related QoL on FACT-LYM by 6 months, which was not seen in patients with CLL receiving therapy when measured by FACT-LEU.
- Heatmap modeling enabled discrete tracking of longitudinal changes in these QoL domains, revealing improvements in physical health, social role functioning, anxiety, pain, and fatigue in patients receiving cellular and other active therapies, but worsening cognitive function in the active therapy cohort.
- High patient-reported acceptability of the BISON-PRO platform (AIM scores approaching 4) demonstrates the utility of ePRO platforms to collect real-world QoL and treatment tolerability data.

Limitations and Future Directions

- The primary limitation of this preliminary analysis is the small cohort size and limited follow-up.
- Use of BISON-PRO for further study of subgroups at risk for inferior QoL trajectories is feasible and warranted based on these results.
- Comparison of psychometric properties of PROMIS versus FACT instruments in patients receiving novel therapies is also feasible using BISON-PRO data.
- Heatmap analysis will be expanded in future work to create a functional model for predicting QoL outcomes in lymphoma patients undergoing treatment

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906. Outcomes Research: Lymphoid Malignancies Excluding Plasma Cell Disorders: Poster III

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