

PHUSE 2026 Paper #DV02

Visualizing Essential Metrics for Assessing Disease Dynamics in Hematologic Oncology Trials: A SAS Graphic Approach

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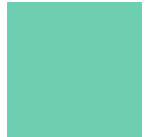
Disclaimer

- All opinions expressed are those of the presenter and do not necessarily reflect the views of Merck & Co. Inc..
- All examples use entirely synthetic data and do not represent any real clinical trial or trial participants.

Agenda



Introduction



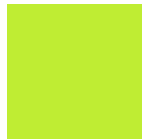
Retrieving Data from SDTM Domain



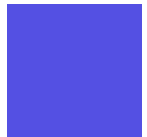
Generating Analysis Value for ADaM



Data Dynamic Visualization



Summary



Acknowledgement

Introduction (1)

- In hematologic oncology trials, Chronic Lymphocyte Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL) are different manifestations of the same disease.
- Absolute Lymphocyte Count (ALC) and Sum of Products of Diameters (SPD) for target lesions are both important metrics for assessing disease dynamics in CLL and SLL.
 - ALC refers to the total number of lymphocytes present in a specific volume of blood.
 - SPD is a method used to quantify tumor burden in tissues based on imaging.

Introduction (2)

- **Challenges/Problems**

Clinical scientists and statistician often view ALC and SPD separately, limiting holistic assessment of disease dynamics.

- **Need**

Monitoring trends in ALC and SPD over time using dual-axis plot.

- **Objective of the paper**

Utilizing SAS graphics to illustrate the trends of ALC and SPD, detailing the processes of data collection and data visualization.

Retrieving Data from SDTM Domain (1)

Data Captured: ALC

- LB domain: captures essential information related to laboratory tests conducted during clinical trials.
- The **ALC** is included in the LB domain when LBTESTCD is equal to “LYM”.



Absolute Lymphocyte	LBORRES when LBTESTCD = 'LYM'
LBTEST	Unit:
	LBORRESU

eCRF for LYM Collection

Generating Analysis Value for ADaM ⁽¹⁾

AVAL Used for Plotting ALC Data

- Customized ADaM dataset: ADLYM (Analysis Dataset of Lymphocyte, derived from SDTM LB domain)
 - PARAM (Analysis parameter): “ACL for CLL/SLL”
 - AVAL (Analysis Value): mapped from LB.LBSTRESN for records where LB.LBTESTCD has a data value of "LYM"
 - Baseline and post-baseline observations are both included

Retrieving Data from SDTM Domain (2)

Data Captured: SPD

- The TR domain includes measurements and/or assessments of the tumors and lesions.
- The calculation of SPD is based on the measurements of the longest diameter (LDi) and the shortest diameter (SDi) obtained from the TR domain.

Longest Diameter	TRTEST	TRORES when TRTESTCD = 'LDIAM'	TRSTRESC	TRSTRESN
Short Axis	TRTEST	TRORES when TRTESTCD = 'LPERP'	TRSTRESC	TRSTRESN

eCRF for LDi and SDi Collection

Generating Analysis Value for ADaM (2)

AVAL Used for Plotting SPD Data

- ADTL (Analysis Dataset of Target Lesions, derived from SDTM TR domain)
 - Analysis Parameter: “Sum of Diameter of Target Lesions per Investigator”
 - AVAL for PARAMCD = “SPD” for target lesions is calculated based on investigator assessments recorded in the TR domain
 - ✓ using the longest and shortest diameters for each target lesion per visit. The per-visit SPD is obtained by summing the products of the longest and shortest diameters across predefined target lesions.

Generating Analysis Value for ADaM₍₃₎

Calculation of SPD for Target Lesion

- Step 1: Identification of target lesions for SPD calculation

DOMAIN	USUBJID	TUGRPID	TUSPID	TULNKID	TUTEST	TUSTRESC	TULOC	TUMETHOD	TUEVAL
TU	1111	LSNHM	1	TN1	Tumor Identification	TARGET	LIVER	CT SCAN	INVESTIGATOR
TU	1111	LSNHM	2	TN2	Tumor Identification	TARGET	MEDIASTINAL LYMPH NODE	CT SCAN	INVESTIGATOR

TU Domain Example for TUTEST = “Tumor Identification” and TUSTRESC = “TARGET”

DOMAIN	USUBJID	TRGRPID	TRSPID	TRLNKID	TRTEST	TRCAT	TRSTRESN	TRSTRESU	TRMETHOD	VISIT
TR	1111	LSNHM	1	TN1	Longest Diameter	TARGET	43	mm	CT SCAN	Screening
TR	1111	LSNHM	1	TN1	Longest Perpendicular	TARGET	32	mm	CT SCAN	Screening
TR	1111	LSNHM	1	TN1	Longest Diameter	TARGET	38	mm	CT SCAN	Cycle 4
TR	1111	LSNHM	1	TN1	Longest Perpendicular	TARGET	28	mm	CT SCAN	Cycle 4
TR	1111	LSNHM	1	TN1	Longest Diameter	TARGET	33	mm	CT SCAN	Cycle 6
TR	1111	LSNHM	1	TN1	Longest Perpendicular	TARGET	29	mm	CT SCAN	Cycle 6
TR	1111	LSNHM	2	TN2	Longest Diameter	TARGET	49	mm	CT SCAN	Screening
TR	1111	LSNHM	2	TN2	Longest Perpendicular	TARGET	39	mm	CT SCAN	Screening
TR	1111	LSNHM	2	TN2	Longest Diameter	TARGET	48	mm	CT SCAN	Cycle 4
TR	1111	LSNHM	2	TN2	Longest Perpendicular	TARGET	32	mm	CT SCAN	Cycle 4
TR	1111	LSNHM	2	TN2	Longest Diameter	TARGET	35	mm	CT SCAN	Cycle 6
TR	1111	LSNHM	2	TN2	Longest Perpendicular	TARGET	26	mm	CT SCAN	Cycle 6

TR Domain Example for TRTEST in (“Longest Diameter” and “Longest Perpendicular”) Where TRCAT = “TARGET”

Generating Analysis Value for ADaM (4)

Calculation of SPD for Target Lesion

- Step 2: Measurement of diameters and calculation of lesion-wise products

DOMAIN	USUBJID	TRGRPID	TRSPID	TRLNKID	TRTEST	TRCAT	TRSTRESN	TRSTRESU	TRMETHOD	VISIT
TR	1111	LSNHM	1	TN1	Longest Diameter	TARGET	43	mm	CT SCAN	Screening
TR	1111	LSNHM	1	TN1	Longest Perpendicular	TARGET	32	mm	CT SCAN	Screening
TR	1111	LSNHM	1	TN1	Longest Diameter	TARGET	38	mm	CT SCAN	Cycle 4
TR	1111	LSNHM	1	TN1	Longest Perpendicular	TARGET	28	mm	CT SCAN	Cycle 4
TR	1111	LSNHM	1	TN1	Longest Diameter	TARGET	33	mm	CT SCAN	Cycle 6
TR	1111	LSNHM	1	TN1	Longest Perpendicular	TARGET	29	mm	CT SCAN	Cycle 6
TR	1111	LSNHM	2	TN2	Longest Diameter	TARGET	49	mm	CT SCAN	Screening
TR	1111	LSNHM	2	TN2	Longest Perpendicular	TARGET	39	mm	CT SCAN	Screening
TR	1111	LSNHM	2	TN2	Longest Diameter	TARGET	48	mm	CT SCAN	Cycle 4
TR	1111	LSNHM	2	TN2	Longest Perpendicular	TARGET	32	mm	CT SCAN	Cycle 4
TR	1111	LSNHM	2	TN2	Longest Diameter	TARGET	35	mm	CT SCAN	Cycle 6
TR	1111	LSNHM	2	TN2	Longest Perpendicular	TARGET	26	mm	CT SCAN	Cycle 6

TR Domain Example for TRTEST in (“Longest Diameter” and “Longest Perpendicular”) Where TRCAT = “TARGET”

At Screening, the diameter (TN1) = $LD_i * SD_i = 43 * 32 = 1376$ mm

At Cycle 4, the diameter (TN1) = $LD_i * SD_i = 38 * 28 = 1064$ mm

At Cycle 6, the diameter (TN1) = $LD_i * SD_i = 33 * 29 = 957$ mm

At Screening, the diameter (TN2) = $LD_i * SD_i = 49 * 39 = 1911$ mm

At Cycle 4, the diameter (TN2) = $LD_i * SD_i = 48 * 32 = 1536$ mm

At Cycle 6, the diameter (TN2) = $LD_i * SD_i = 35 * 26 = 910$ mm

Generating Analysis Value for ADaM (5)

Calculation of SPD for Target Lesion

- Step 3: Aggregation of lesion-wise products to derive SPD

At Screening, $TN1 + TN2 = 1376 + 1911 = 3287$ mm

At Cycle 4, $TN1 + TN2 = 1064 + 1536 = 2600$ mm

At Cycle 6, $TN1 + TN2 = 957 + 910 = 1867$ mm

USUBJID	PARAMCD	BASE	AVAL	CHG	PCHG	TRDTC	NTLINV	ADT	ADY	ABLFL	ANL01FL
1111	SPDINV	3287	3287	.	.	2022-09-27	2	2022-09-27	-24	Y	
1111	SPDINV	3287	2600	-687	-20.90051719	2023-01-24	2	2023-01-24	96		Y
1111	SPDINV	3287	1867	-1420	-43.20048677	2023-04-04	2	2023-04-04	166		Y

Table 3: Example for SPDINV in ADTL for the Subject Corresponding to Table 2

Generating Analysis Value for ADaM (6)

Calculation of SPD for Target Lesion

- Step 4: Verify that the Total Number of Target Lesions (NTLINV) assessed at each post-baseline visit matches the baseline Total Number of Target Lesions.

DOMAIN	USUBJID	TRSPID	TRLNKID	TRTESTCD	TRCAT	TRSTRESN	TRSTRESU	TRMETHOD	VISIT	TRSTAT	TRREASND	TRDTC
TR	2222	1	TN1	LDIAM	TARGET	24	mm	CT SCAN	Screening			2023-04-18
TR	2222	1	TN1	LPERP	TARGET	20	mm	CT SCAN	Screening			2023-04-18
TR	2222	1	TN1	LPERP	TARGET	.		CT SCAN	Cycle 2	NOT DONE	NOT EVALUABLE	2023-06-07
TR	2222	2	TN2	LDIAM	TARGET	25	mm	CT SCAN	Screening			2023-04-18
TR	2222	2	TN2	LPERP	TARGET	23	mm	CT SCAN	Screening			2023-04-18
TR	2222	2	TN2	LPERP	TARGET	.		CT SCAN	Cycle 2	NOT DONE	NOT EVALUABLE	2023-06-07
TR	2222	3	TN3	LDIAM	TARGET	54	mm	CT SCAN	Screening			2023-04-18
TR	2222	3	TN3	LPERP	TARGET	31	mm	CT SCAN	Screening			2023-04-18
TR	2222	3	TN3	LDIAM	TARGET	43	mm	CT SCAN	Cycle 2			2023-06-07
TR	2222	3	TN3	LPERP	TARGET	27	mm	CT SCAN	Cycle 2			2023-06-07
TR	2222	4	TN4	LDIAM	TARGET	64	mm	CT SCAN	Screening			2023-04-18
TR	2222	4	TN4	LPERP	TARGET	21	mm	CT SCAN	Screening			2023-04-18
TR	2222	4	TN4	LDIAM	TARGET	97	mm	CT SCAN	Cycle 2			2023-06-07
TR	2222	4	TN4	LPERP	TARGET	32	mm	CT SCAN	Cycle 2			2023-06-07
TR	2222	5	TN5	LDIAM	TARGET	70	mm	CT SCAN	Screening			2023-04-18
TR	2222	5	TN5	LPERP	TARGET	36	mm	CT SCAN	Screening			2023-04-18
TR	2222	5	TN5	LPERP	TARGET	.		CT SCAN	Cycle 2	NOT DONE	NOT EVALUABLE	2023-06-07
TR	2222	6	TN6	LPERP	TARGET	69	mm	CT SCAN	Screening			2023-04-18
TR	2222	6	TN6	LPERP	TARGET	40	mm	CT SCAN	Screening			2023-04-18
TR	2222	6	TN6	LPERP	TARGET	.		CT SCAN	Cycle 2	NOT DONE	NOT EVALUABLE	2023-06-07

Table 4: TR Domain Example for Non-evaluable Target Lesion

Data Dynamic Visualization (1)

Key Checks before Plotting

- Standardize a common visit structure across both data endpoints
- Selection of appropriate dual-axis scales to represent trends accurately
- Selection of appropriate statistical procedure for graphical display

Data Dynamic Visualization (2)

- SGPLOT is designed for straightforward, typically single-cell plots (one graph per output)
- GTL offers flexible and powerful capabilities for constructing complex multi-cell layouts with multiple plots arranged in rows/columns.

AVISITC	AVISIT	N1	MEDIAN1	P251	P751	N2	MEDIAN2	P252	P752	GROUPCD	GROUPCD	COUNT1	COUNT2
BL	BL	92	0	0	0	91	0	0	0	ALC	SPD	92	91
1	Month 1	87	97.3513	-25.2703	275.0418	6	-29.2636	-79.8576	-12.5062	ALC	SPD	87	6
2	Month 2	81	214.2961	71.71748	329.4458	3	52.54443	-93.2917	58.28468	ALC	SPD	81	3
3	Month 3	75	182.2604	15.71703	331.7468	69	9.488875	-67.7971	53.17379	ALC	SPD	75	69
4	Month 4	69	240.471	83.55525	336.6376	7	-19.969	-52.584	25.91491	ALC	SPD	69	7
5	Month 5	62	242.5988	63.79369	352.4564	21	-30.0867	-54.5043	22.45496	ALC	SPD	62	21
6	Month 6	55	136.8807	-5.8317	286.8924	41	-7.18848	-47.4888	48.8586	ALC	SPD	55	41

Example Input Dataset for Creating the Graph

Data Dynamic Visualization (3)

SAS SGPLOT

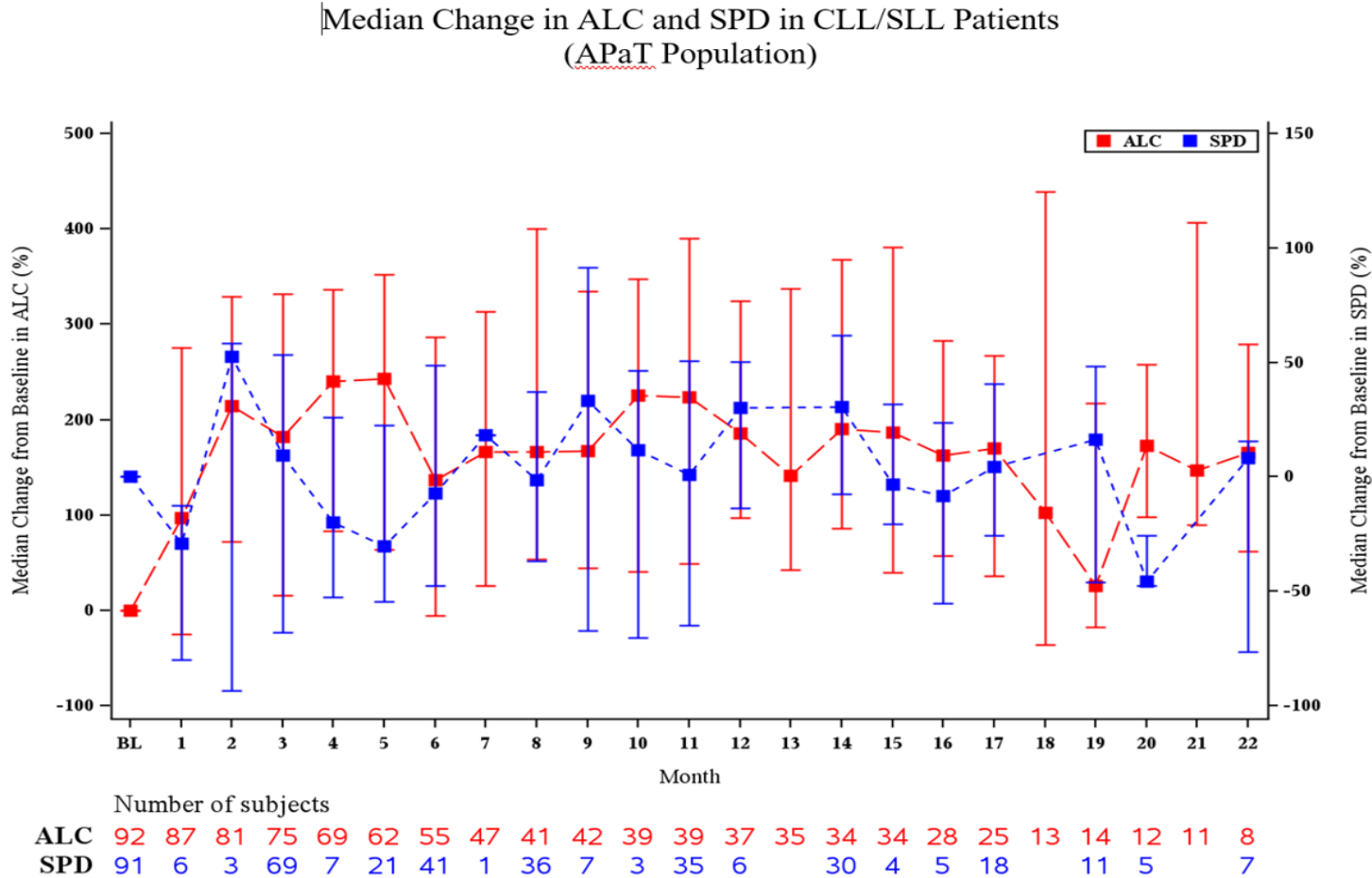


Figure 3: SGPLOT Dual-axis Graph for ALC and SPD

SGPLOT CODE

```
proc sgplot data=for_graph;
  yaxis label="Median Change from Baseline in ALC (%)"
    values=(-100 to 500 by 100);
  y2axis label="Median Change from Baseline in SPD (%)"
    values=(-100 to 150 by 50);
  xaxis label="Month" type=discrete;
  scatter x=avisitc y=median1/yerrorlower=p251 yerrorupper=p751
.....;
  series x=avisitc y=median1/lineattrs=(pattern=mediumdash
    color=red);
  scatter x=avisitc y=median2/y2axis yerrorlower=p252 yerrorupper=p752
.....;
  series x=avisitc y=median2/y2axis
    lineattrs=(pattern=shortdash
    color=blue);
  keylegend "s1" "s2"/location=inside position=topright across=2;
  xaxistable count1/labelattrs=(weight = bold size = 10) label="ALC"
.....;
  xaxistable count2/labelattrs=(weight = bold size = 10) label="SPD"
.....;
run;
```

Data Dynamic Visualization (4)

Graph Template Language

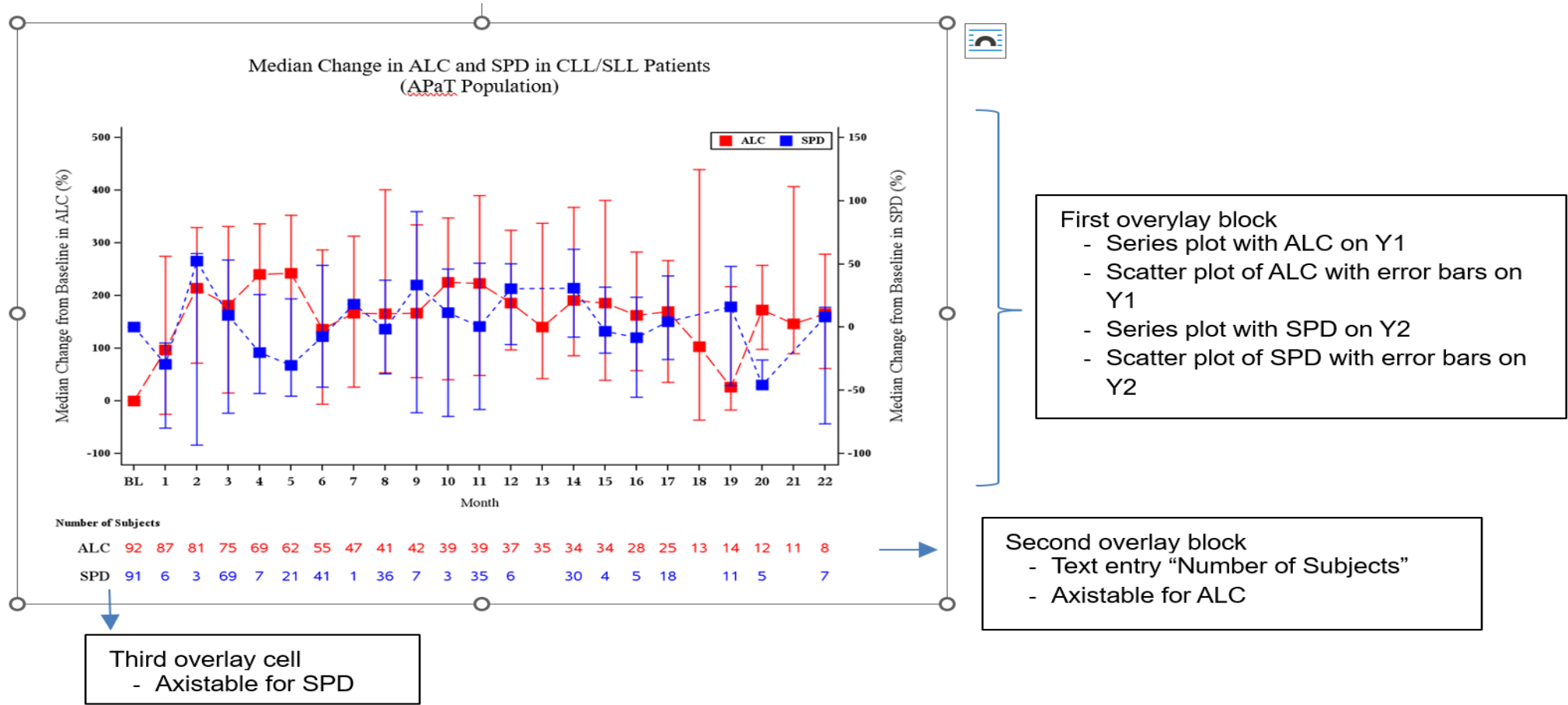


Figure 4: Dual-axis Graph for ALC and SPD by Using GTL

GTL CODE

```
proc template;
  define statgraph overtime;
    begingraph;
      layout lattice/columns=1 rows=3 rowweights=(0.86 0.09 0.05) rowgutter=5pt;

      ***First layout block***;
      layout overlay /xaxisopts=(Label="Month" type=discrete
        discreteopts=(tickvaluefitpolicy=splitrotate )
        .....
        yaxisopts=(label="Median Change from Baseline in
          ALC(%)" labelattrs=(size=10pt)
        .....
        y2axisopts=(label="Median Change from Baseline in
          SPD (%)" labelattrs=(size=10pt) type=linear
        .....;
      scatterplot x=avisitc y=median1/yaxis=y
        .....;
      seriesplot x=avisitc y=median1/yaxis=y
        .....;
      scatterplot x=avisitc y=median2/yaxis=y2
        .....;
      seriesplot x=avisitc y=median2/yaxis=y2
        .....;

      discretelegend "s1" "s2"/
        location=inside across=2
      .....;
    endlayout;

    ***Second layout block***;
    layout overlay/xaxisopts=(display=none);
    entry halign=left "Number of Subjects"/location=outside
      valign=top;
    axistable value=count1 x=avisitc/label="ALC"
    .....;
    endlayout;

    ***Third layout block***;
    layout overlay/xaxisopts=(display=none);
    axistable value=count2 x=avisitc/label="SPD"
    .....;
    endlayout;

  endlayout;
endgraph;

end;
run;

proc sgrender data=for_graph template=overtime;
run;
```

Summary

- Both the SGPLOT procedure and the Graph Template Language (GTL) effectively produce a dual-axis plot to track ALC and SPD trends over time for assessing disease dynamics in CLL and SLL, and each supports clear visual representation of data.
- SGPLOT is preferable when its visual styling and spacing meet the requirements and rapid development and execution are priorities.
- When finer layout control and a standardized, reusable template are required, GTL is the better choice.
- Prioritizing a thorough understanding of the underlying data and the intended analytical objective will enable more effective use of these tools.

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Thank you

