

Introduction

- Primary objective of early phase dose escalation trials: to determine the safety, tolerability, and maximally tolerated dose (MTD) of study drug.
- Graphical presentation of patient profiles facilitates decision making by clinicians in safety data monitoring meetings: escalating, de-escalating, staying the same dose, or stopping study.

SAS GTL

- SAS GTL is flexible for graphing multiple safety endpoints and study drug dosing profile for individual subjects.
- Key GTL statements:
 - LAYOUT LATTICE
 - LAYOUT OVERLAY
 - SERIESPLOT
 - VECTORPLOT
- PROC SGRENDER: for graph template execution

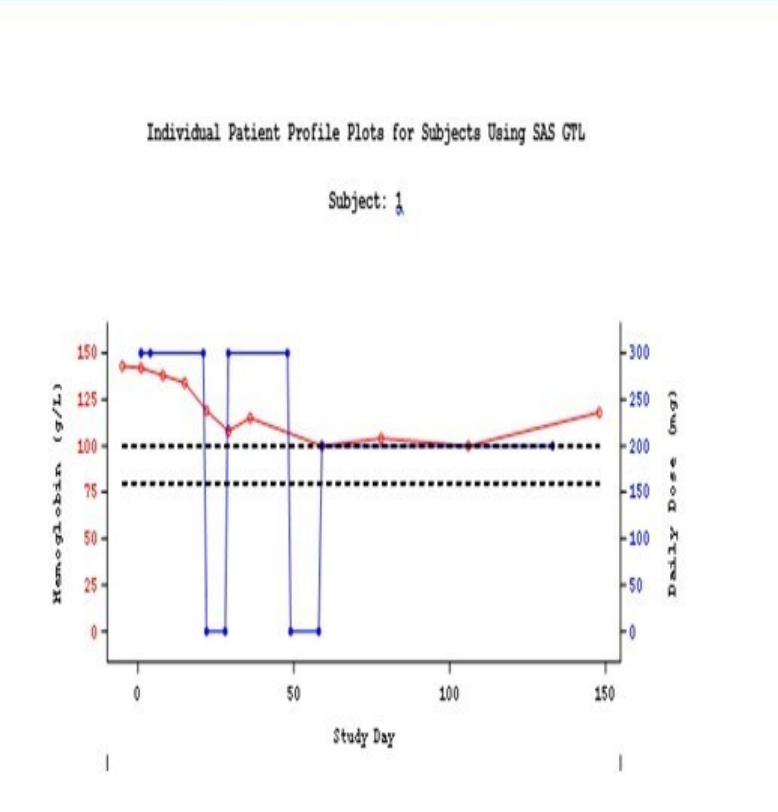
Patient profile

Macro

- Patient profile macro:
- SAS Macro do-loop to subset individual safety data.
 - Nested macro do-loop:
 - to create layout blocks in a graph template
 - To apply graphic elements to specific endpoints.

Plot

- Left axis in red denotes lab assessments.
- Right axis in blue denotes study drug daily dose.
- Bottom axis shows study days from first dose.
- Dotted black lines are lab reference values.



Layout

Plots

Lattice

- SAS PROC TEMPLATE GTL statements create customized graph templates.
 - ROWWEIGHTS option adjust vertical dimension of each graph panel.
- ```
layout lattice /rows=4 rowweights=(0.25 0.25 0.25 0.25);

**additional code here;

endlayout;
```

### Overlay

- LAYOUT OVERLAY block contains elements for 4 graph panels.
  - A macro do-loop iteratively creates 4 layout blocks.
- ```
%do i=1 %to 4;
layout overlay / **additional options;
***
**additional code here;
***
endlayout;
%end;
```

Overlay

- LAYOUT OVERLAY options define graph axes. Macro variable &PARAM is resolved to Hemoglobin (g/L) at &i=1.
- ```
layout overlay /
xaxisopts=(label='Study Day' labelattrs=(family='Courier New' size=6pt)
display=(line label ticks tickvalues) tickvalueattrs=(size=6pt family='Courier New'))
yaxisopts=(display=(line label ticks tickvalues) tickvalueattrs=(size=6pt color=red
family='Courier New') label='%scan(¶m,&i,1)' lineopts=(viewmin=0))
y2axisopts=(label='Daily Dose (mg)' labelattrs=(family='Courier New' size=6pt)
display=(line label ticks tickvalues) tickvalueattrs=(size=6pt color=blue
family='Courier New') lineopts=(viewmin=0));
```

### Series

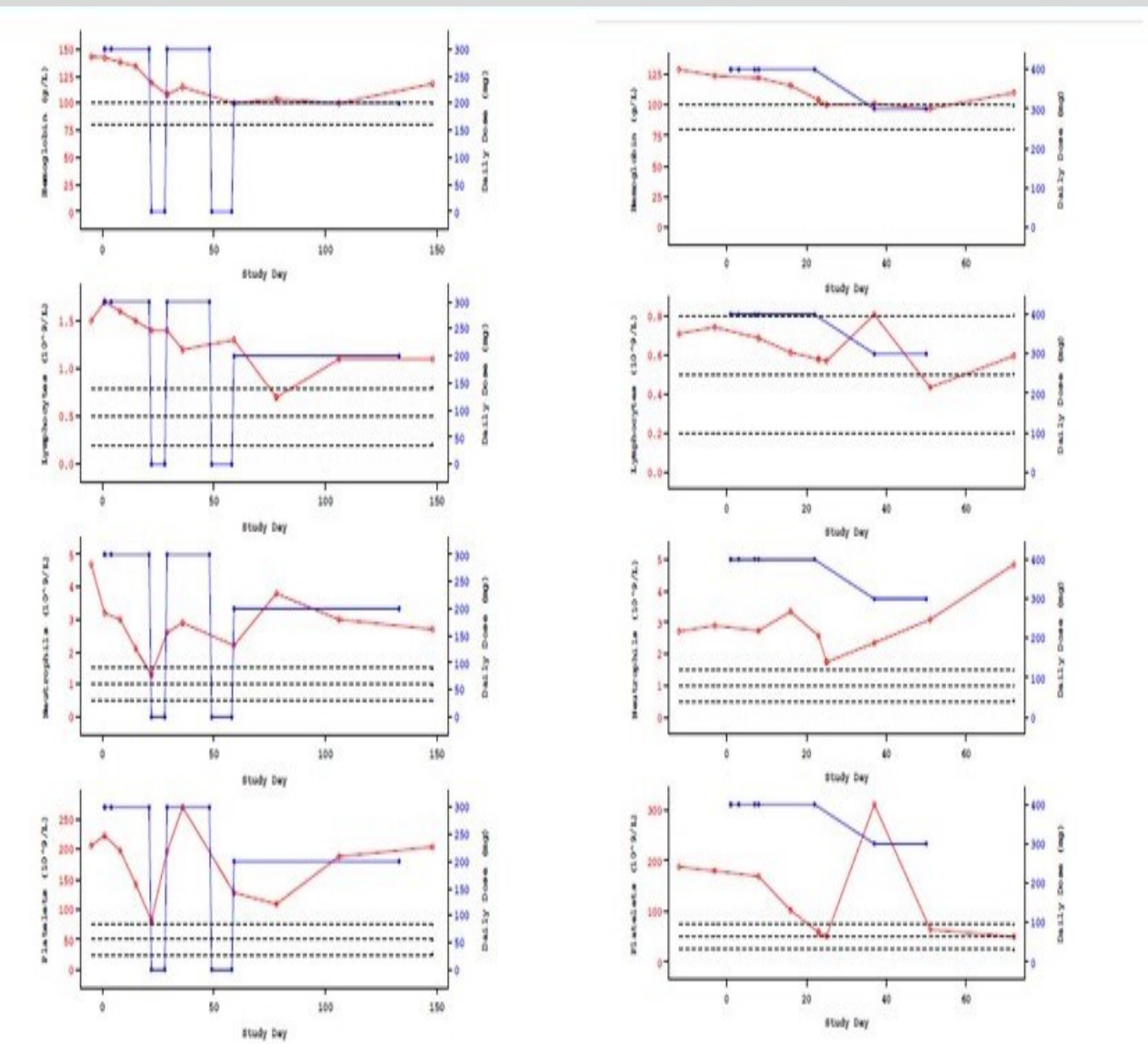
- SERIESPLOT within LAYOUT OVERLAY block displays line plots.
  - Macro variable &PARAMCD is resolved to HGB at &i=1.
- ```
seriesplot x=ady y=%scan(&paramcd,&i)/display=(markers) lineattrs=(color=red)
markerattrs=(symbol=circle color=red size=4pt);
seriesplot x=ady y=%dose/display=(markers) yaxis=2 lineattrs=(color=blue)
markerattrs=(symbol=circlefilled color=blue size=4pt);
```

Vector

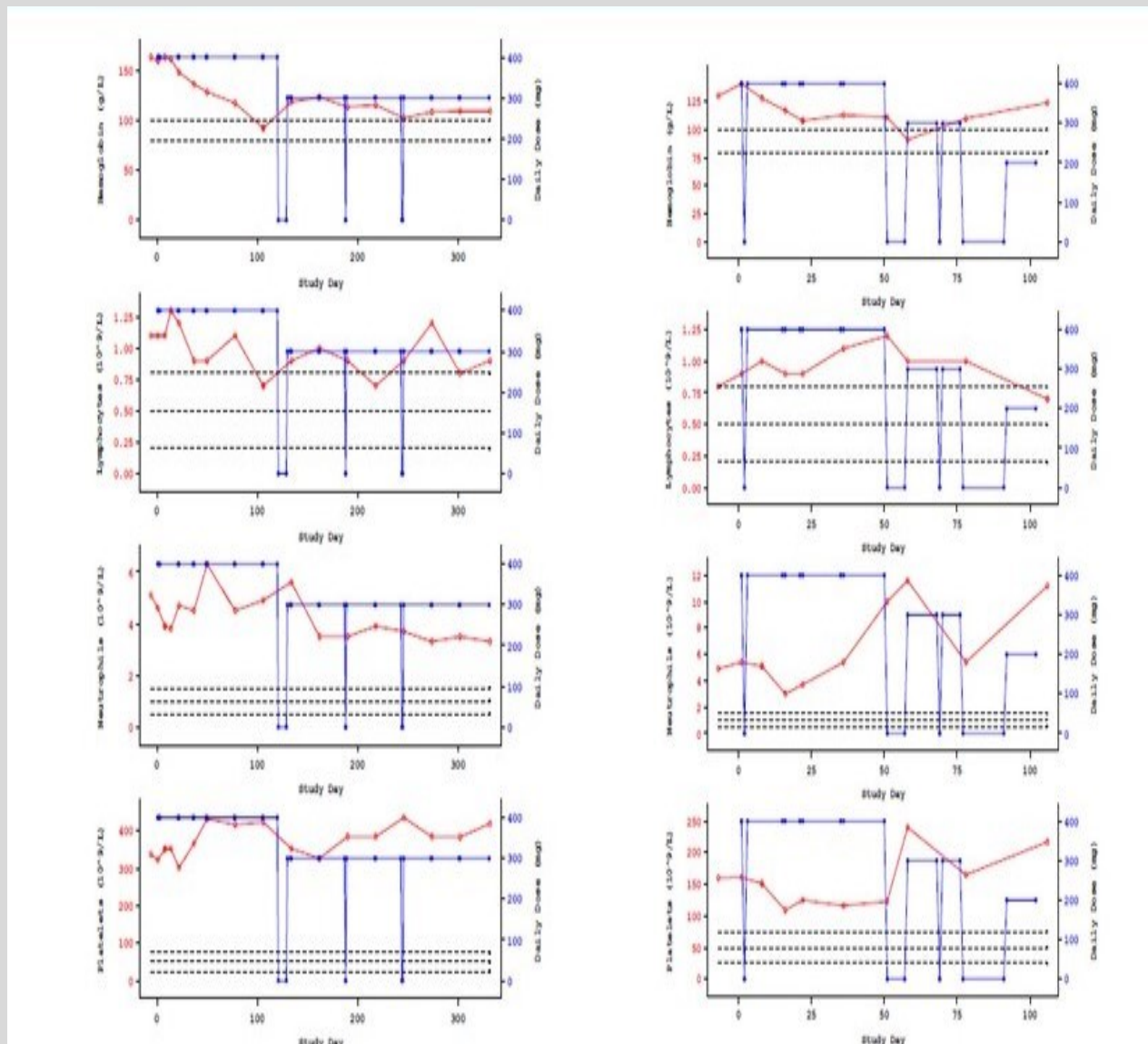
- VECTORPLOT within LAYOUT OVERLAY block displays dotted horizontal lines at Y values.
 - Within a nested do-loop, Y%SCAN(&PARAMCD,&i)&j is resolved to YHGB1 at &i=1, &j=1, and YHGB2 at &i=1, &j=2.
- ```
%do j=1 %to 2;
vectorplot x=xmax y=y%scan(¶mcd,&i)&j xorigin=xmin
yorigin=y%scan(¶mcd,&i)&j/ lineattrs=(color=black pattern=2) arrowheads=false;
%end;
```

## Patient Profile Plots

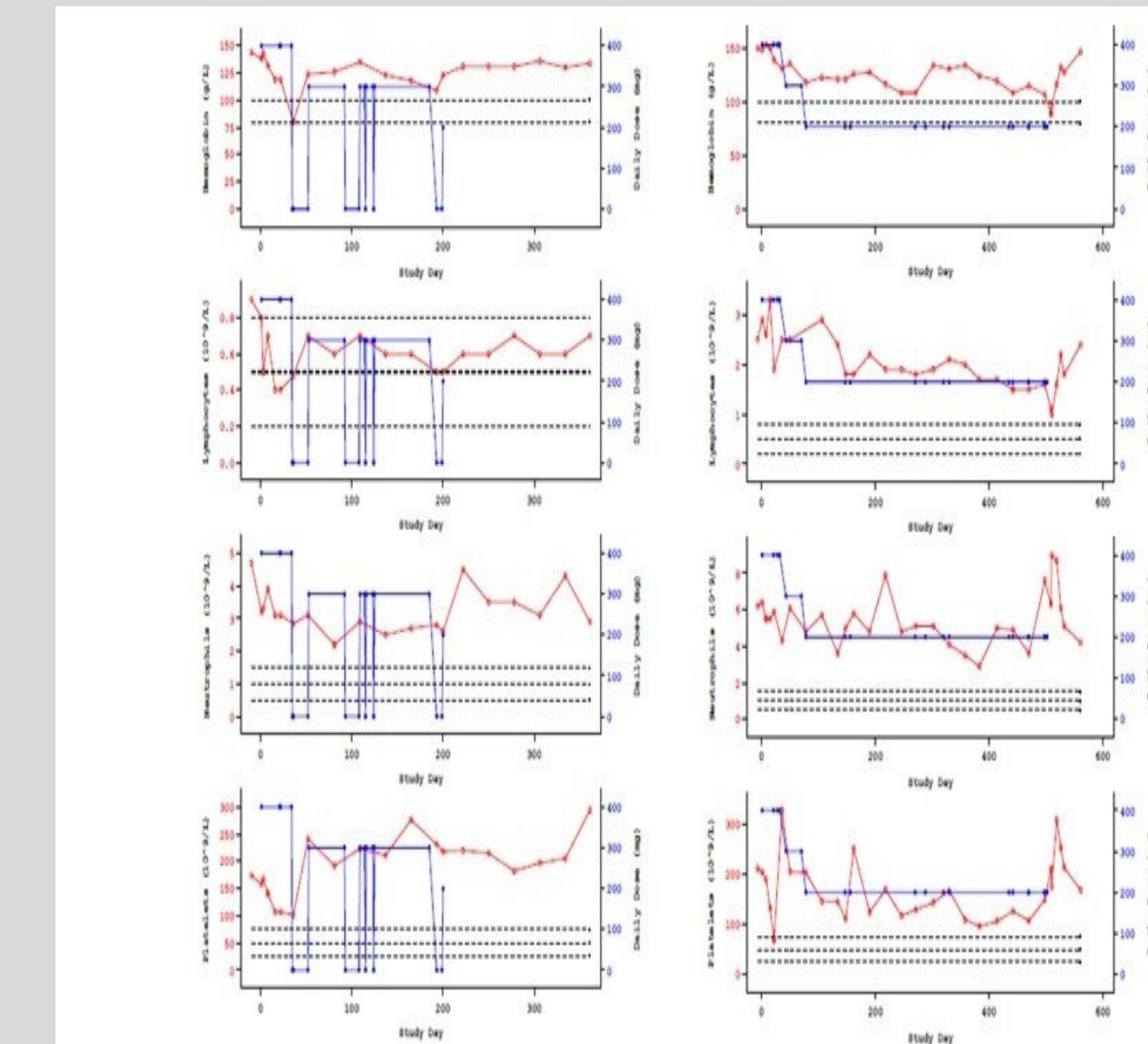
1



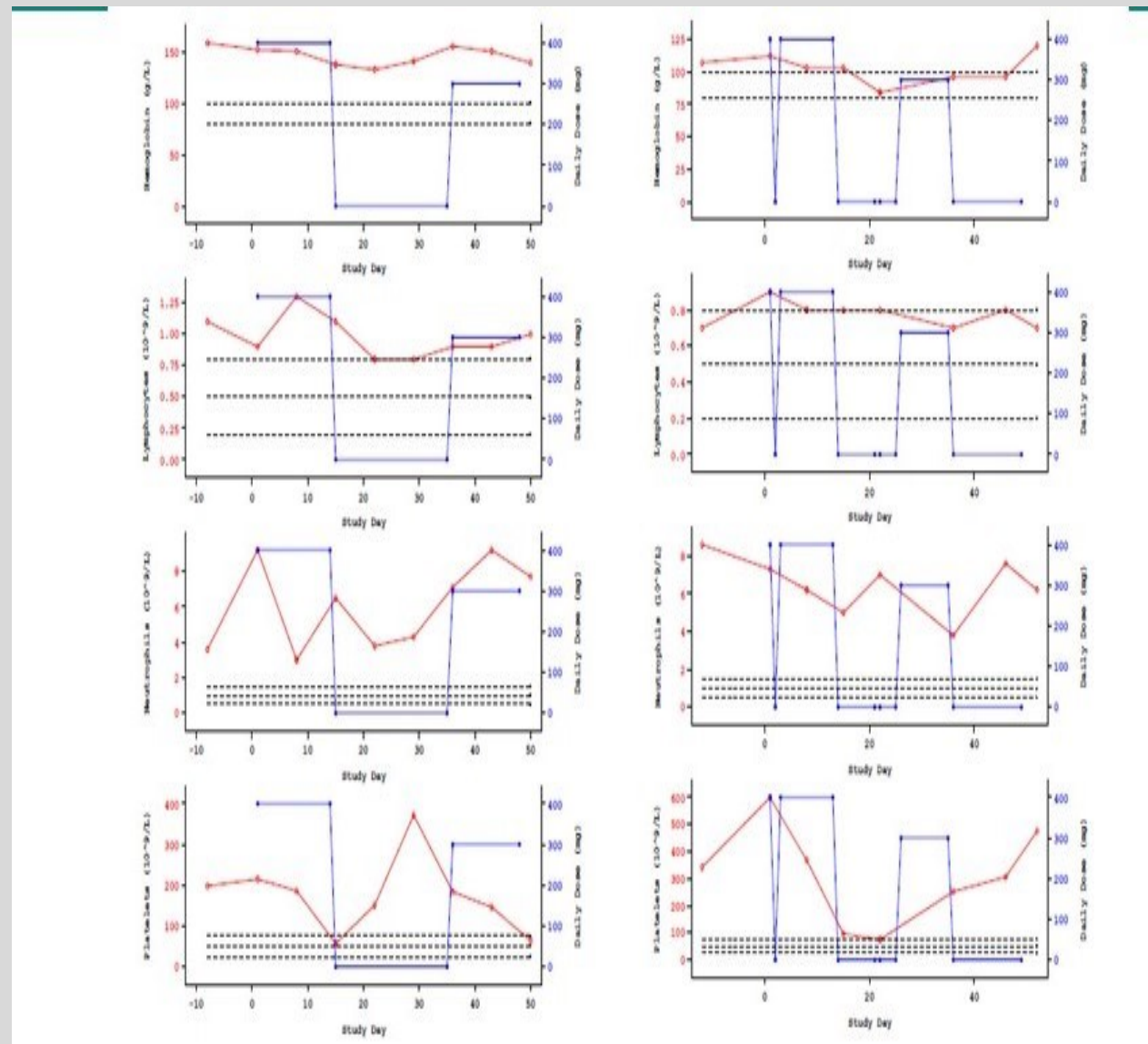
2



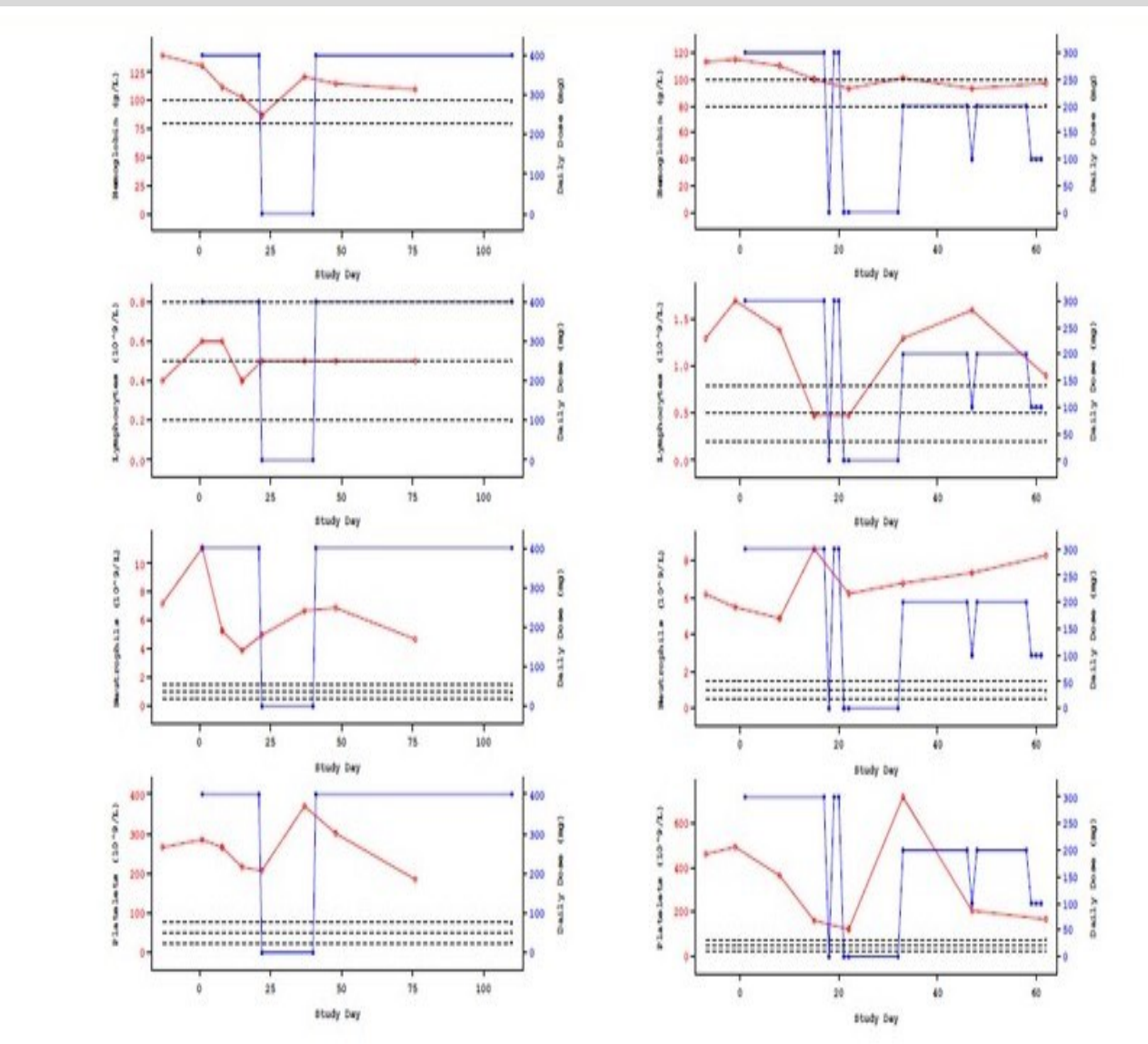
3



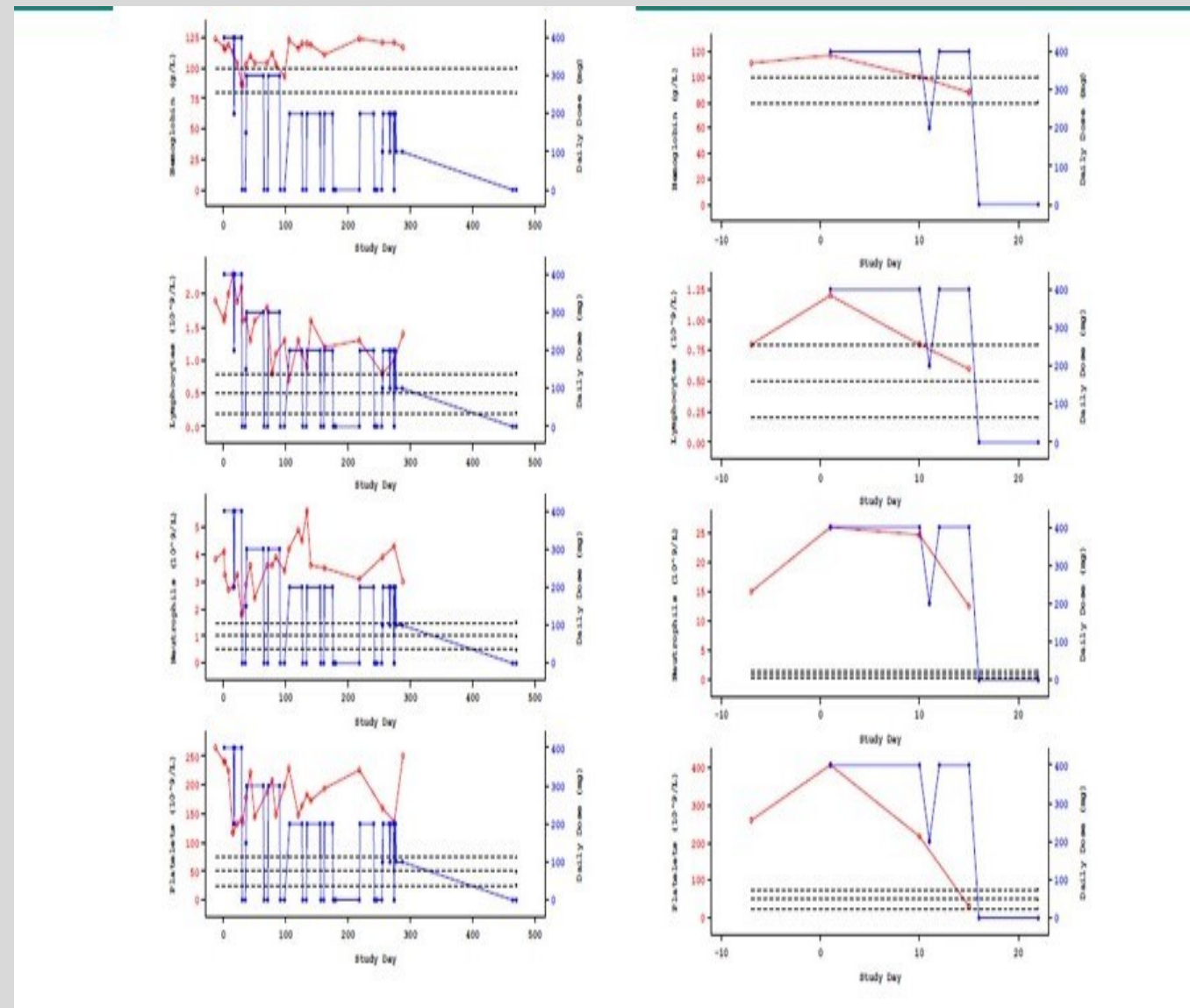
4



5



6



## Conclusion

- SAS PROC TEMPLATE GTL statements create customized graph templates.
- A macro do-loop subset individual data for graph template execution using PROC SGRENDER.
- A nested macro do-loop dynamically assigns graphic elements to specific lab parameters.

## Reference

- SAS Institute Inc. (2014), "SAS 9.4 Graph Template Language: User's Guide, Third Edition", Cary, NC, USA

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