

## Swimmer Plots – Some Practical Advice

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### ABSTRACT

Graphs are an integral part of modern data analysis of clinical trials. Viewing data in a graph along with the tabular results of a statistical analysis can greatly improve understanding of the collected data. Visualized data can very often be the most informative way to understand the insights from the results.

Swimmer plots are an effective graphical presentation of subject status and longitudinal data such as duration of treatment, dose changing, occurrences and durations of events. This type of graph is usually very popular in the early phases of drug development (Phase I / Phase II). An essential objective for medical monitors is to make it possible to visually review when specific medications were administered in response to specific safety and efficacy information throughout the study duration. This visual representation is crucial for tracking patient responses and treatment safety/efficacy.

Each subject is represented by an individual horizontal bar (lane). There are many possibilities, with the main restrictions being considerations of readability and not overloading the plot with too much information.

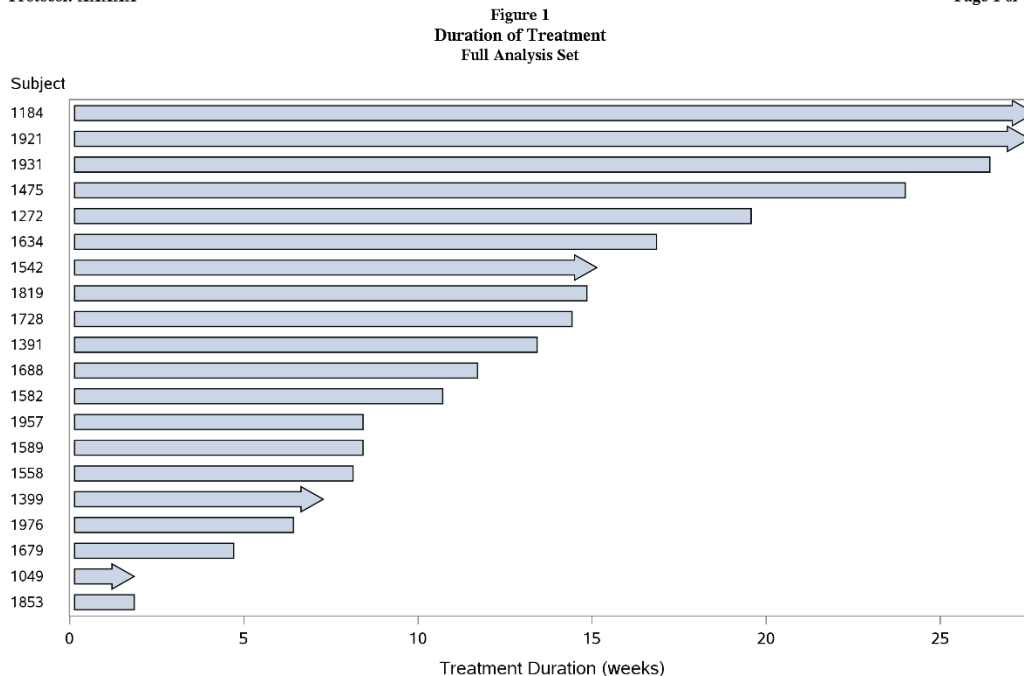
This paper aims to provide some practical advice on how to overcome such restrictions and make enhanced swimmer plots more readable and informative.

### CHAPTER 1. SIMPLE SWIMMER PLOTS

Swimmer plots are easier to create for a relatively small number of subjects. A simple swimmer plot in landscape orientation can be seen in **Figure 1: Simple Swimmer Plot**.

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Source: ADSL

Data cut-off date: yyyy-mm-dd

Arrow at the end of the treatment bar indicates the subject having not discontinued from the treatment.

**Figure 1: Simple Swimmer Plot**

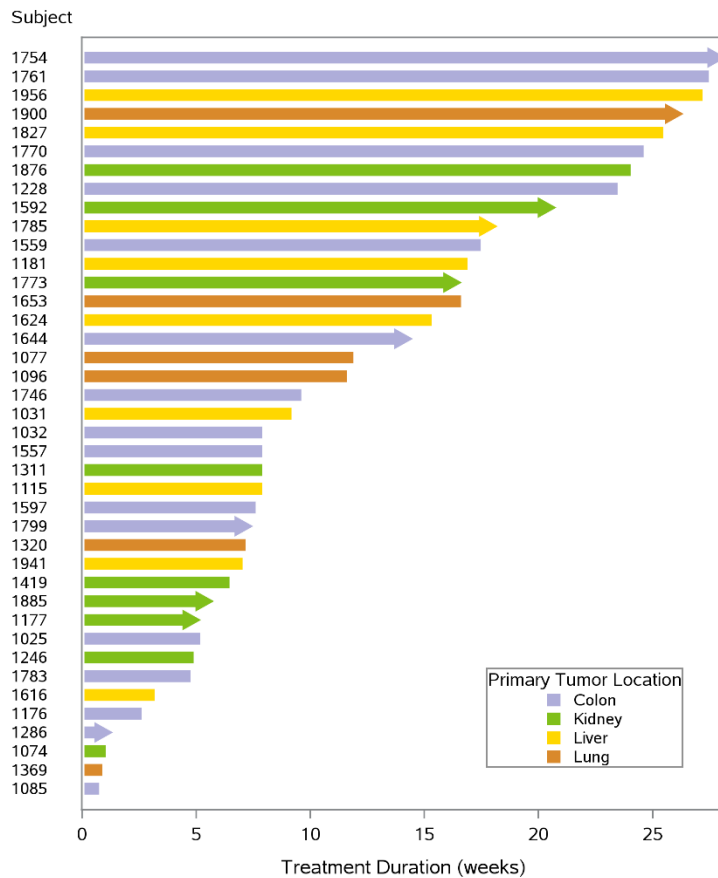
Each bar represents treatment duration; some treatment might be ongoing at the time of data cutoff. Our ongoing treatment is indicated by an arrow at the end of treatment bar. Usually, patients are sorted in descending order based on duration of treatment. We can immediately see a major restriction: the graph is readable and ready for further enhancements if it only contains bars for not more than 20-25 subjects.

A similar graph in portrait orientation (**Figure 2: Simple Swimmer Plot in Portrait Orientation**) allows us to display treatment bars for a larger number of subjects. Some additional information about Primary Tumor Location was also included (the distinct colors of the bars represent different tumor locations—see the legend in the bottom right corner of the figure)

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Figure 2  
Duration of Treatment  
Full Analysis Set



Source: ADSL Data cut-off date: yyyy-mm-dd  
Arrow at the end of the treatment bar indicates the subject having not discontinued from the treatment.

Figure 2: Simple Swimmer Plot in Portrait Orientation

As we can see, there are 4 possible tumor locations, so it might be reasonable to create a plot that occupies 4 separate pages (with one page designated for each Tumor Location) – see **Figure 3: Multipage Simple Swimmer Plot**. A special algorithm was applied in the SAS code to make the width of the bars and horizontal axis scales identical over all these pages.

Sometimes there is a requirement to produce a swimmer plot for a large number of subjects. In general, results from a large number of subjects should not be reviewed visually, but analytically, applying some statistically based conclusions. However, SAS can produce such figures if we change some system options and ODS graphic setup, for example:

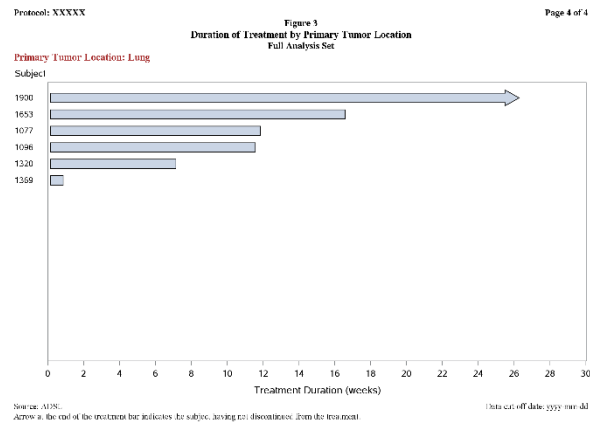
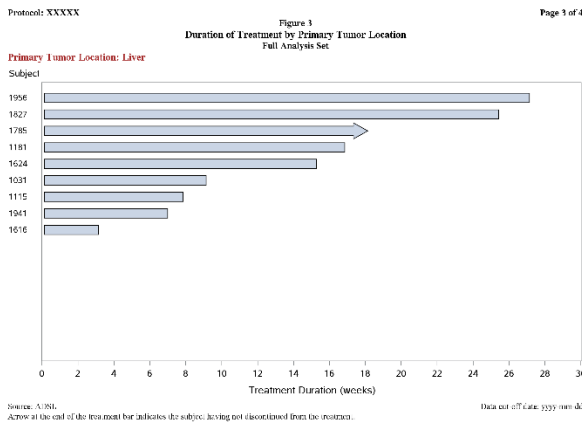
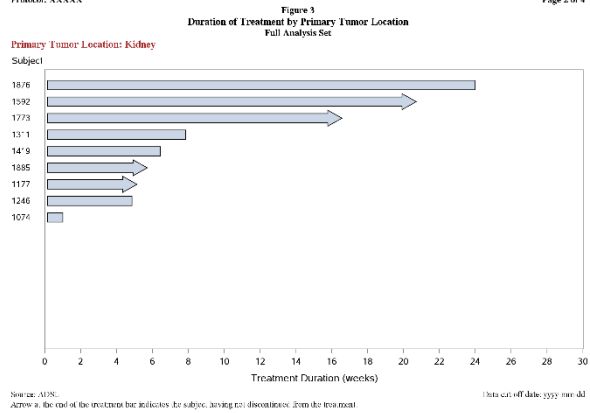
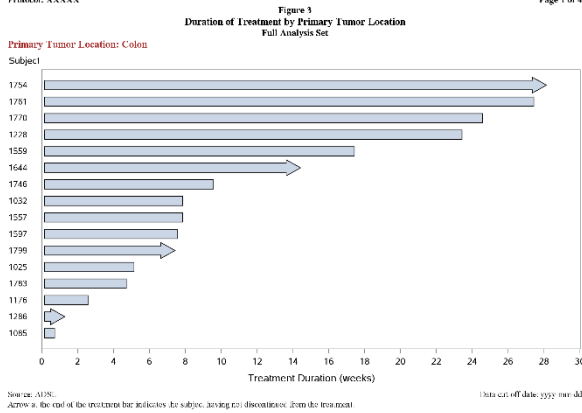


Figure 3: Multipage Simple Swimmer Plot

```
option
  nodate
  nonumber
  orientation = portrait
  papersize = (30in 150in)
;

ods graphics
/
  noborder
  height = 148 in
  width = 28 in
  outputfmt = png
;
```

This setup allowed us to put bars for 500 patients onto the same page. The best ODS destination would be HTML. Obviously, such figures can only be viewed online and only be used for internal company review. The heavily reduced copy of this figure (**Figure 4: Simple Swimmer Plot of 500 Subjects**) clearly demonstrates that the produced graph should only be viewed online.

Now we can draw some practical advice from these simple swimmer plots:

- Reduce number of unnecessary titles and footnotes.
- Reduce margins (in cases where there are no strict requirements about margin size).
- If needed, use portrait orientation (instead of more traditional landscape orientation).
- If needed, use custom size as SAS and ODS options.

- If possible, split the chart into several pages by some criteria (for example, by some baseline characteristics). The width of the bars and horizontal axis scale should be identical for all the pages in the same graphic.

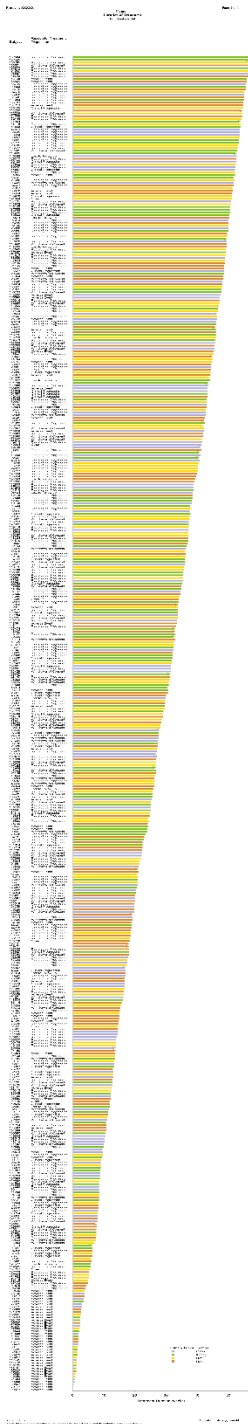


Figure 4: Simple Swimmer Plot of 500 Subjects

## CHAPTER 2. SWIMMER PLOTS WITH DOSING INFORMATION

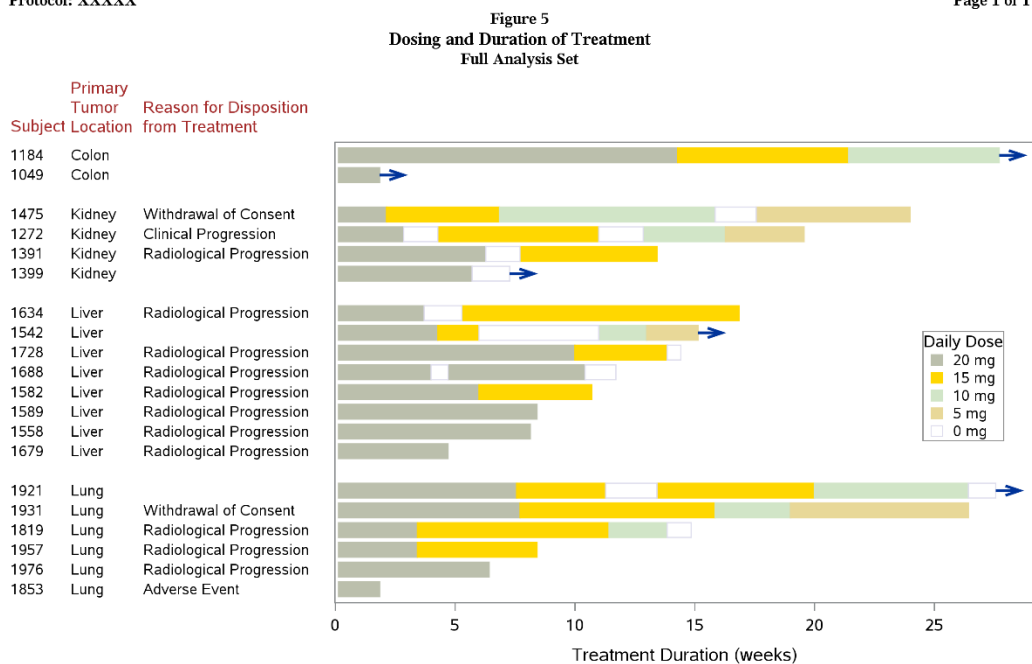
The swimmer plot can be enhanced with dosing information. In this paper, we are going to consider the two most common cases of drug administration: daily oral drug administration and IV (intravenous) drug administration (usually no more often than once a week). Sometimes several study drugs are administered as a combined therapy. The author recommends using time since baseline to disposition from treatment as a source for treatment bar length.

Prescribed dosing may be different than actual dosing, especially for oral treatments, where the patient remains at home during the clinical trial. If both prescribed and actual dosing records are available, it makes sense to contact Study Medical Director to figure out which dosing information should be displayed (prescribed or actual).

In the example (**Figure 5: Swimmer Plot with Daily Dosing Information**) the study oral drug was administered daily. The treatment bars are subdivided into treatment intervals by dose. According to the protocol, a patient can be medicated with daily dosages of 20, 15, 10, or 5 mg; a patient can also be unmedicated for some period(s) of time but stay on the treatment. Data-driven annotation might be needed to indicate ongoing treatment. There was also a requirement from the study team to display Primary Tumor Location and Reason for Disposition from Treatment.

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Source: ADSL, ADEX

Data cut-off date: yyyy-mm-dd

Duration of Treatment Phase is displayed as horizontal bar from Baseline to the Disposition from Treatment Phase.

For some subjects Treatment Phase was ongoing at time of cut-off. (The right end of the bar for Duration of Treatment Phase is ended with the arrow for these subjects).

**Figure 5: Swimmer Plot with Daily Dosing Information**

In cases of IV drug administration, it is recommended to use markers with the value of administered dose at time of infusion. This approach will help with visually identifying dose irregularities such as dose delay or dose omission. Please see the example (**Figure 6: Swimmer Plot with IV Dosing**) -the IV dose was supposed to be administered once every 3 weeks according to the study protocol.

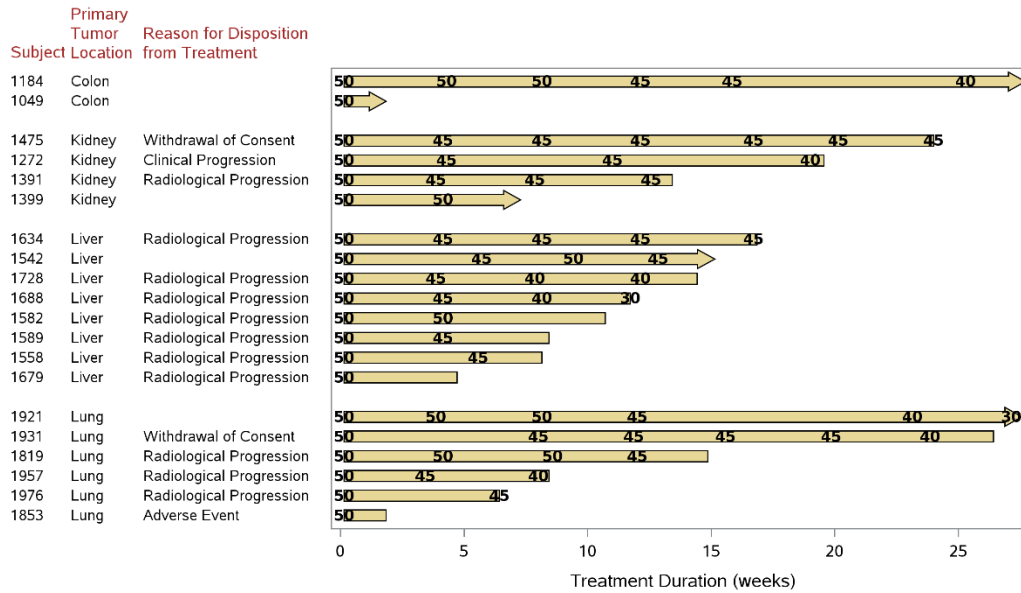
More challenging are cases of combined therapy, where more than one study drug is administered simultaneously. Let us consider an example of combined therapy with two oral drugs. According to the protocol, the second drug treatment (Drug B) should start after 2 weeks of monotherapy by the first drug (Drug A). The second drug may have daily dosages of 125, 100, or 75 mg, or not administered at all (0 mg). In this case, the author recommends using 2 bars (one of the bars is embedded in the other) to make it possible to fully display the dosing information – see **Figure 7: Swimmer Plot for Combined**

# Therapy with Two Oral Drugs.

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Figure 6  
Dosing and Duration of Treatment  
Full Analysis Set



Source: ADSL, ADEX

Data cut-off date: yyyy-mm-dd

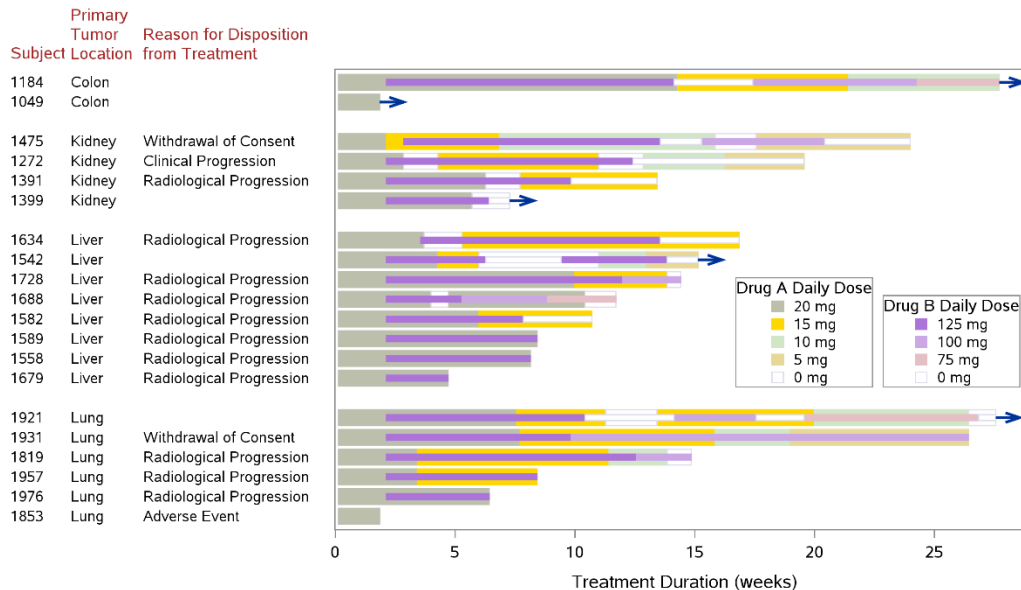
Duration of Treatment Phase is displayed as horizontal bar from Baseline to the Disposition from Treatment Phase. For some subjects Treatment Phase was ongoing at time of cut-off. (The right end of the bar for Duration of Treatment Phase is ended with the arrow for these subjects).

Figure 6: Swimmer Plot with IV Dosing

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Figure 7  
Dosing and Duration of Treatment  
Full Analysis Set



Source: ADSL, ADEX

Data cut-off date: yyyy-mm-dd

Duration of Treatment Phase is displayed as horizontal bar from Baseline to the Disposition from Treatment Phase. For some subjects Treatment Phase was ongoing at time of cut-off. (The right end of the bar for Duration of Treatment Phase is ended with the arrow for these subjects).

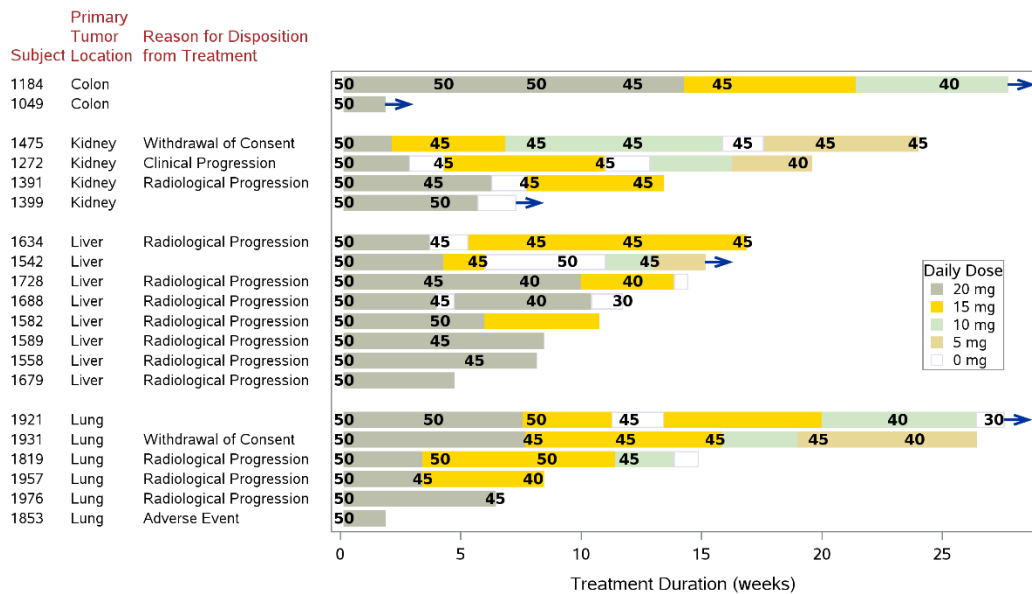
Figure 7: Swimmer Plot for Combined Therapy with Two Oral Drugs

The case of combined therapy with one oral drug and one IV drug is more straightforward, as seen in the **Figure 8: Swimmer Plot for Combined Therapy with Oral and IV Drugs**. Markers showing the values of the IV dose can be placed over the colored bars indicating the values of the daily oral dose.

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Figure 8  
Dosing and Duration of Treatment  
Full Analysis Set



Source: ADSL, ADEX  
Duration of Treatment Phase is displayed as horizontal bar from Baseline to the Disposition from Treatment Phase.  
For some subjects Treatment Phase was ongoing at time of cut-off. (The right end of the bar for Duration of Treatment Phase is ended with the arrow for these subjects).  
Data cut-off date: yyyy-mm-dd

**Figure 8: Swimmer Plot for Combined Therapy with Oral and IV Drugs**

The author suggests using extensively different colors, bar widths, and possibly some other graphical elements to display dosing information. For color selection, the author recommends the website [https://support.sas.com/content/dam/SAS/support/en/books/pro-template-made-easy-a-guide-for-sas-users/62007\\_Appendix.pdf](https://support.sas.com/content/dam/SAS/support/en/books/pro-template-made-easy-a-guide-for-sas-users/62007_Appendix.pdf) from SAS Institute. This guide contains more than ten pages of different available color names.

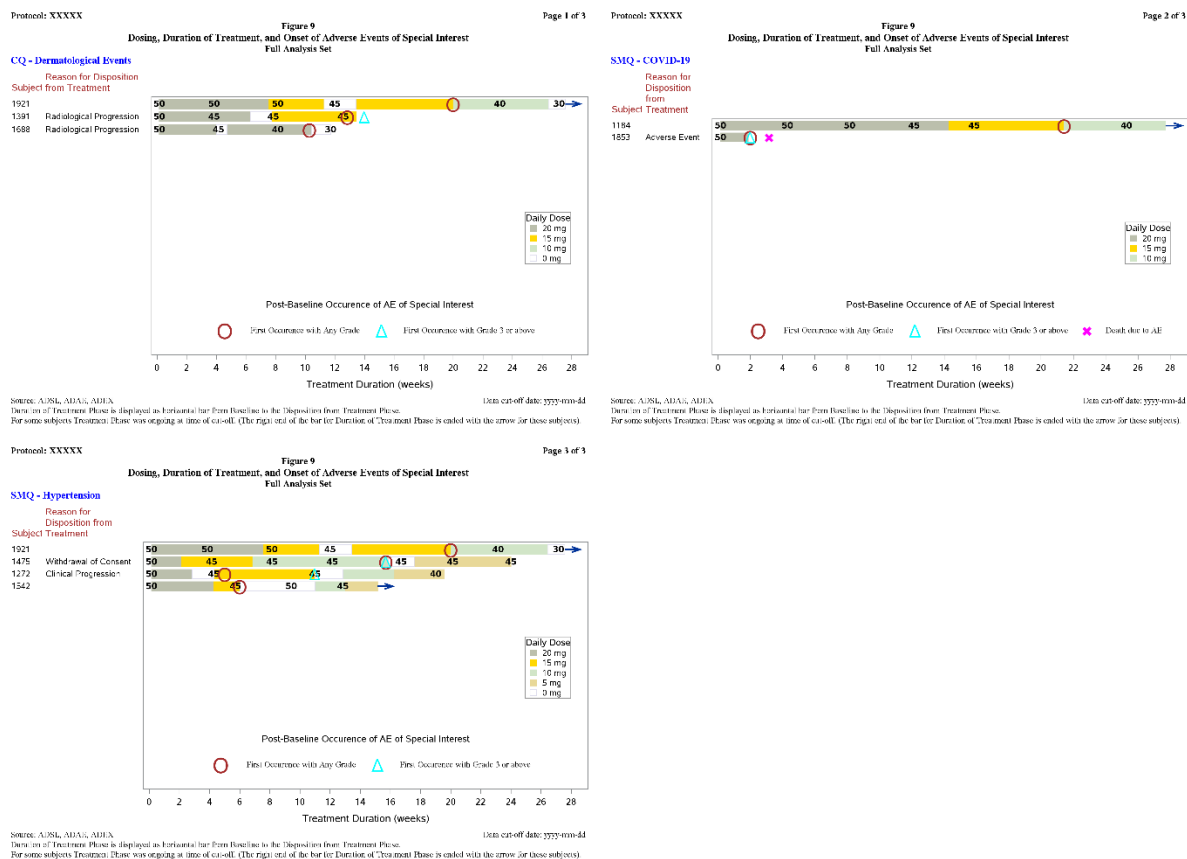
Please contact your study team to inquire what subject-level information they want to see in the columns to the left of the graph area (currently we have Primary Tumor Location and Reason for Disposition from Treatment).

### CHAPTER 3. SWIMMER PLOTS WITH INFORMATION ABOUT ADVERSE EVENTS OF SPECIAL INTEREST

In many cases, the safety reviewer requires information about Adverse Events of Special Interest to be provided parallel with dosing information. Usually, the list of Adverse Events of Special Interest is provided by the Medical Coding Group as a list of SMQ (Standard Medical Queries) or CQ (Custom Queries). It is recommended that each group (SMQ or CQ) of Adverse Events of Special Interest be graphed on a separate page. There is no need to display information for the subjects not affected by these selected Adverse Events of Special Interest. This should dramatically decrease the number of bars. A bar for the same subject may be seen on several pages (if that subject experienced several different Adverse Events of Special Interest), only on one page, or not to be present at all.

Let us consider a case where only 3 categories of Adverse Events of Special Interest (CQ – Dermatological Events, SMQ – COVID-19, and SMQ – Hypertension) were requested to be displayed. The study team wanted to see information about First Post-baseline Occurrence of Adverse Events of

Special Interest, First Occurrence of Serious Adverse Events of Special Interest (in Oncology it can be First Occurrence of Adverse Events of Special Interest with Grade 3 or above), and Death due to Adverse Events of Special Interest. Please see **Figure 9: Swimmer Plot of Dosing Information and Adverse Events of Special Interest**. In addition to the limited number of symbols proposed in SAS documentation (“SAS 9.4 ODS Graphics: Procedure Guide”), some Unicode characters were used as symbols (markers). A special algorithm was applied in the SAS code to make the width of the bars and horizontal axis scales identical over all these pages.



**Figure 9: Swimmer Plot of Dosing Information and Adverse Events of Special Interest**

The author’s practical advice would be:

- Work in close cooperation with the Medical Coding Group to obtain a full list of qualified preferred terms for each SMQ (Standard Medical Query) or CQ (Custom Query)
- Use separate pages for each separate SMQ / CQ
- Display bars only on affected subjects
- If needed, use Unicode characters as symbols (markers)
- The width of the bars and horizontal axis scale should be identical for all the pages in the same figure

## CHAPTER 4. SWIMMER PLOTS IN ONCOLOGY STUDIES WITH EFFICACY INFORMATION

Swimmer plots are very common in oncology studies — investigators are often concerned with whether a subject had a response to the study drug and the timing of that response in relation to the administration of the study drug. A swimmer plot is a graphical way of showing multiple pieces of a subject’s response “story” in one glance; it provides a visual summary of an individual patient’s journey through a clinical study, typically an oncology trial. As we know, in oncology studies the subjects can continue to be

evaluated after discontinuation from the treatment, so we may see that for some subjects, the response is continued for a long time after the last dose of the study drug(s).

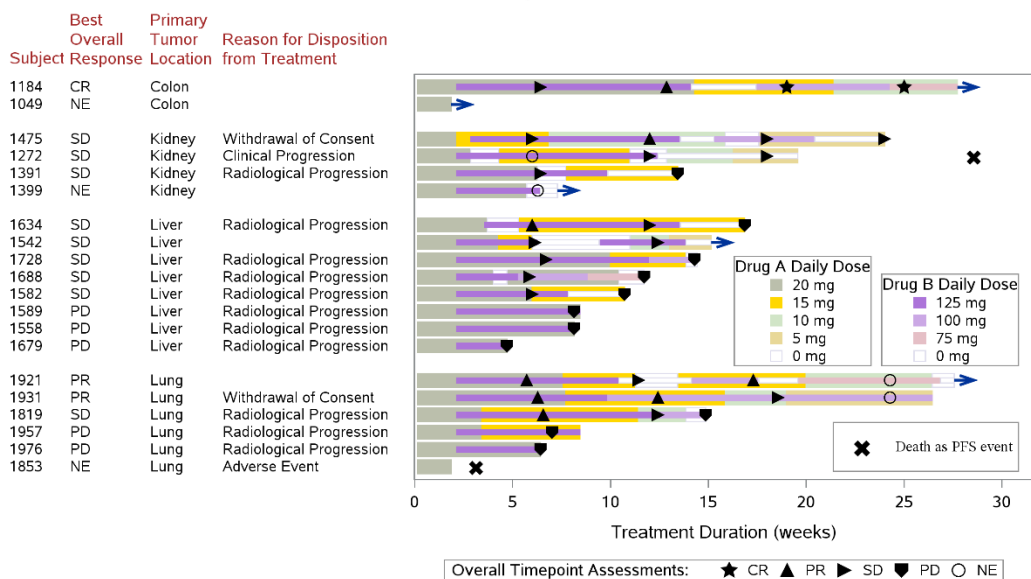
The simplest way to provide the necessary graph for the study team is to mark the results of overall timepoint assessments on top of each bar. If a subject is evaluated by RECIST 1.1 criteria, there can only be a limited number of results of overall timepoint assessments: Complete Response (CR), Partial Response (PR), Stable Disease (SD), or Progressive Disease (PD). Occasionally, for some subjects not having target lesions at baseline, the result of overall timepoint assessment is recorded as Non-CR/Non-PD. In addition to displaying the results of timepoint assessments, a common request can be to provide derived value of Best Overall Response (BOR). The algorithm for derivation of such statistics depends on if the study protocol/Statistical Analysis Plan (SAP) required confirmation of response in derivation of Best Overall Response. Such requirement should be mentioned in a footnote. We also might be required to display death if it is an observed Progression Free Survival (PFS) event.

This figure (**Figure 10: Swimmer Plot of Dosing Information and Results of Overall Time-point Assessments**) uses different markers to display the results of overall timepoint assessments or death.

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**Figure 10**  
Dosing, Duration of Treatment, and Efficacy Results  
Full Analysis Set



Source: ADSL, ADEX, ADTR, ADEF, ADYTE

Data cut-off date: yyyy-mm-dd

Duration of Treatment Phase is displayed as horizontal bar from Baseline to the Disposition from Treatment Phase.

For some subjects Treatment Phase was ongoing at time of cut-off. (The right end of the bar for Duration of Treatment Phase is ended with the arrow for these subjects).

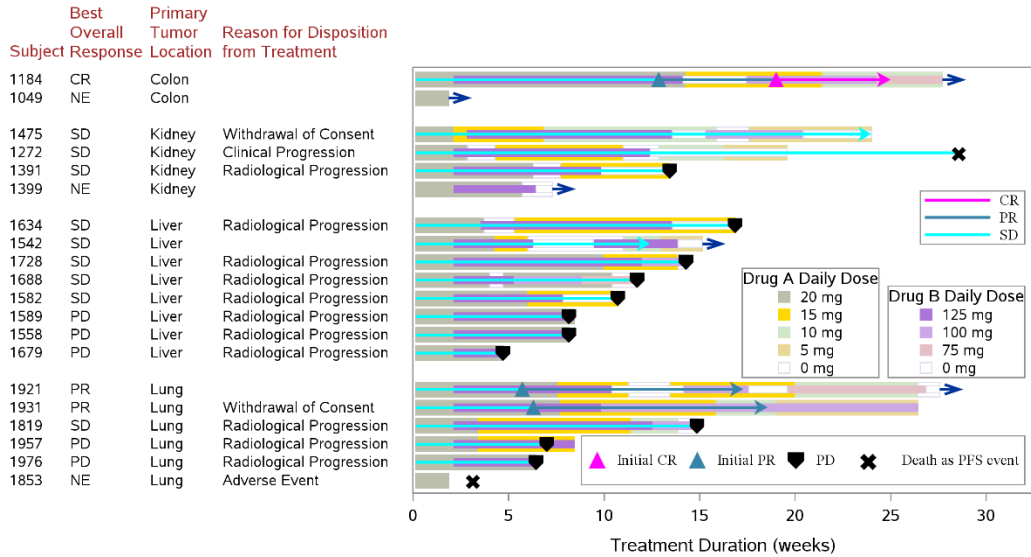
BOR (Best Overall Response) was derived with confirmation of response.

### Figure 10: Swimmer Plot of Dosing Information and Results of Overall Time-point Assessments

There is another way to provide a swimmer plot with efficacy information in oncology. According to RECIST 1.1 criteria, Stable Disease is measured from the start of the treatment (in randomized trials, from date of randomization) until the criterion for progression is met. For some subjects, the Stable Disease can be changed later with a Partial or Complete Response. The response continues until criterion for progression is met. The Partial Response by itself can be changed later to Complete Response. If the criterion of progression is not met, the subject has ongoing response with a censored PFS date (the derivation of this date should be done according to instruction from the Statistical Analysis Plan). We also need to see when response started and if the end of response was observed or was censored. The author can recommend the provided figure (**Figure 11: Swimmer Plot of Dosing Information and Response Results**) as answering all these questions.

Similar figure (**Figure 12: Swimmer Plot of Dosing Information and Response Results in Case of Combinational Treatment of Oral and IV Drugs**) can be produced in case of combined therapy with oral and IV drugs.

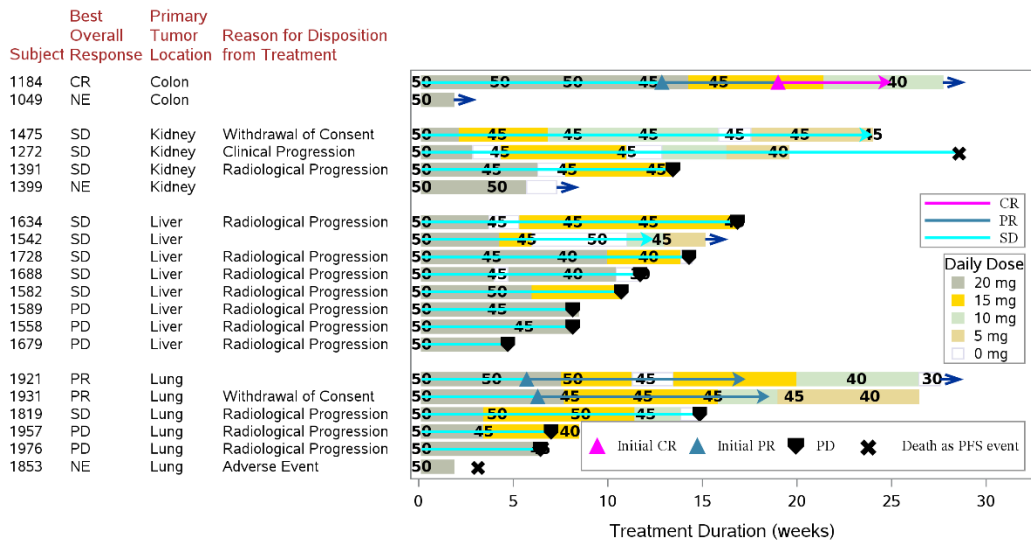
**Figure 11**  
Dosing, Duration of Treatment, and Efficacy Results  
Full Analysis Set



Source: ADSL, ADEX, ADTR, ADEF, ADTTE  
 Duration of Treatment Phase is displayed as horizontal bar from Baseline to the Disposition from Treatment Phase.  
 For some subjects Treatment Phase was ongoing at time of cut-off. (The right end of the bar for Duration of Treatment Phase is ended with the arrow for these subjects).  
 BOR (Best Overall Response) was derived with confirmation of response.  
 Response line is provided for subjects having BOR other than NE. Arrow at the end of response line indicates censored PFS date

**Figure 11: Swimmer Plot of Dosing Information and Response Results**

**Figure 12**  
Dosing, Duration of Treatment, and Efficacy Results  
Full Analysis Set



Source: ADSL, ADEX, ADTR, ADEF, ADTTE  
 Duration of Treatment Phase is displayed as horizontal bar from Baseline to the Disposition from Treatment Phase.  
 For some subjects the Treatment Phase was ongoing at time of cut-off. (The right end of the bar for Duration of Treatment Phase is ended with the arrow for these subjects).  
 BOR (Best Overall Response) was derived with confirmation of response.  
 Response line is provided for subjects having BOR other than NE. Arrow at the end of response line indicates censored PFS date

**Figure 12: Swimmer Plot of Dosing Information and Response Results in Case of Combinational Treatment of Oral and IV Drugs**

This design has some advantages over the design of the previous figure:

- We can see when the Response started. Time to Response is one of the statistics that is analyzed in most oncology clinical trials.
- Duration of Response is one of the statistics that is analyzed in most oncology clinical trials. We can see where response was ended and if the end of response was observed or was censored.
- This design can tremendously reduce the number of markers, especially in studies with long Progression Free Survival and big number of overall timepoint assessments.

## CONCLUSION

SAS has provided us with powerful tools to generate graphs using **PROC SGPLOT**. This paper shows how to make different swimmer plots while working around some of the common restrictions for these types of graphs. The plot should not be overcrowded with information. Different techniques considered in this paper can be applied to make plot readable. Equivalent results can be achieved using the Graph Template Language technique. The selection of information that needs to be displayed should be provided by a medical director and statistician, and this information is study specific.

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<https://pharmasug.org/proceedings/2024/DV/PharmaSUG-2024-DV-380.pdf>

## CONTACT INFORMATION

Your comments and questions are valued and encouraged. The full SAS code and data sets used for this presentation are available upon request. Contact the author at:

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