

Using R to Write Patient Narratives

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ABSTRACT

The Patient Narrative is an impactful document that summarizes and describes a subject's clinical experience resulting from participation in a clinical trial. There are many ways to create this. Let us explore how we can create this document using R. We will identify the packages that are essential to write this program. We will see examples of code and why we chose R instead of traditional methods.

INTRODUCTION

This paper provides information about advantages of using R in specific cases, such as Patient Narratives.

WHAT ARE PATIENT NARRATIVES

A narrative is a brief summary of specific events experienced by patients, during a clinical trial.

Narratives aid in the evaluation of the safety profile of the investigational drug under study.

Patient narratives are written across all therapeutic areas and for all phases of clinical trials (Phase I–IV) depending on the drug under evaluation.

Example of Narratives can be a summary of AEs occurring in a clinical trial patient/subject.

USE OF NARRATIVES IN CLINICAL TRIALS

First, the Narratives are one of the Important parts of Clinical reporting as there we are putting specific info about study patients also, it's one of the topics in the Safety data submission package.

The most frequent information for submission are Serious Adverse event-related topics such as DEATH Life-threatening. Also for Device related studies, we are adding Device related events in the Narrative Such as (Pain in the eye etc.).

CREATION OF NARRATIVE PROGRAM IN SAS

Firstly, we must get the Narrative template in final form from the sponsor and check up on all relative variables and values in specific datasets.

Programming in SAS is a step-by-step procedure so we should specify conditions and variables to be used in Narratives also, we are doing the standardization of variables and values from the raw datasets sent by the sponsor.

We are using a lot of functions in process of creating Narratives such as (Strip, Compbl, catx etc.) as we mostly work with raw datasets there is needed to standardize much.

One of the most difficult parts in the creation of Narratives is visualization as we need to write a dynamic program to create a separate output for each subject and show available info for that specific subject with the output of listings and graphs. So we should be in good relationship with ODS and proc report/template functions and options.

```

proc format;
    value bin
        0="None/Absent"
        1="Trace"
        2="Mild"
        3="Moderate"
        4="Severe"
        5="Present"
    ;
run; ods graphics on / border=off antialiasmax = 8000 width = 8.9in height = 5in;
title3 "Biomicroscopy"; proc sgpanel data=plott; styleattrs
datacolors=(lightgray yellow darkgreen blue red orange); panelby cat / novarname
spacing=10 headerbackcolor=white; heatmapparm x=visit y=Group colorgroup=value /
name='a' ; colaxis display=(nolabel) VALUEATTRS=(size=10) ; rowaxis
display=(nolabel) VALUEATTRS=(size=10) values=("Other" "Corneal Infil" "Chemosis"
"Conj Comp /Indent" "Corneal Vasc" "Stromal Edema" "Epithelial Edema" "Palpebral
Conj Obs" "Conj Stain" "Corneal Stain" "Bulbar Hyper" "Limbal Hyper") ;
keylegend 'a' / valueattrs=(size=9) noborder SORTORDER=ASCENDING; discretelegend
"None/Absent" "Trace" "Mild" "Moderate" "Severe" "Present" ; format value bin.;
run; title3 ' ';
ods graphics off;

```

CREATION OF NARRATIVE PROGRAM IN R

Such visualization can be used to obtain a global view of the subject metadata information, combined with its treatment exposure and concomitant medications, in relation with the adverse events occurring during the trial, and any measurements conducted during a clinical trial (e.g., laboratory, vital signs or ECG). Especially for clinical trial with high number of patients (e.g. phase 3), the creation of the subject profile report can be time-consuming.

Programming in R lets us to work with the most useful options and functions as there are available packages which enable us to get those relative options, and functions from specific packages (eg. for narratives it is "PatientProfilevis").

Different types of visualization tricks help us not struggle and create a loop to get the desired result. For example Subjectprofiletext plot helps us to get separate output with specific info for each subject.

```

#install.packages("ggplot2") library(ggplot2)
data <- read.csv("C:\\Users\\LanaDavtyan\\Desktop\\Works\\1 Week\\NEWW1.csv", header =
TRUE) data$visit <- factor(data$visit, levels=c(0:5), labels =
c("None/Absent", "Trace", "Mild",
"Moderate", "Severe", "Present")) ggp <- ggplot(data, aes(Visit, Group)) +
geom_tile(aes(fill = f)) + ggtitle("Biomicroscopy") + theme(plot.title =
element_text(hjust = 0.5)) + scale_fill_manual(values = c("lightgray",
"darkgreen", "yellow", "orange",
"red", "blue"), name = "Results") + theme(legend.position="bottom") +
theme(axis.title.x=element_blank(),axis.title.y=element_blank())
ggp

```

R provides many functions which can be useful for Specifying colors/shapes, Order of Categories, Palettes, Visualizations aligned across domains and subjects, per subject, only for specific domains.

R provides built in functions/parameters which can help us to create Narratives in a short period of time.

CONCLUSION

Mostly similar outputs will be generated for both, but the difference between these graphs is the time that we have spent for creating.

R gives an opportunity to create the needed graph with the desired view in a shorter period thanks to its specific packages (mostly GGLOT2 Package) which lets us do less research than in SAS to get the desired result.

CONTACT INFORMATION

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