

Using **R** to Write **Patient Narratives**

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Agenda

Patient
Narrative

Challenges
of writing
Patient
Narratives

Patient
narrative
using R

Q & A

What are Patient Narratives?

Patient 10-11122 , Age 62 with Race of Asian faced Hyphema Serious AE.

Exposure

Eye	Sequence/Treatment	Insertion Date	Removal Date
OD	1	10MAY2019	11MAY2019
	2	13MAY2019	14MAY2019
	3	15MAY2019	16MAY2019
OS	1	01JUN2019	02JUN2019
	2	04JUN2019	05JUN2019
	3	06JUN2019	08JUN2019
OU	1	20JUN2019	21JUN2019
	2	23JUN2019	25JUN2019

Medical History

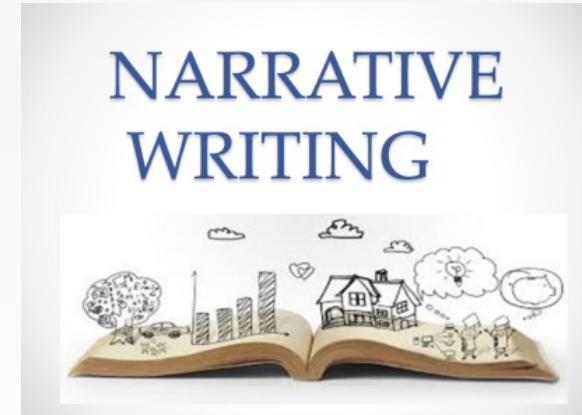
Ocular Medical History			Nonocular Medical History
OD	OS	OU	
Cataract	Cataract	Cataract	
Glaucoma	Strabismus		Diabetes
Amblyopia		Color Blindness	Migraine

Event information for SAE/ADE/Event Leading to DC

PT	Description	Eye	Onset Day	Severity	Duration	Outcome	Action Taken	Treatment Given	Serious?	DC	Related to / Alternate etiology	Serious criteria
Hyphema	XXXX	OD	19MAY2019	Mild	2.5 hours	Recovered	Not applicable	XXX	Y	Headache	Related	Hospitalization
Retinal Tear	XXXX	OS	22MAY2019	Moderate	0.8 hours	Recovered	Not applicable	XXX	N	Drowsy	Not Related	
Cataract	XXXX	OU	01JUN2019	Severe	5 hours	Recovered	Not applicable	XXX	N	Nausea	Not Related	
Reduced VA	XXXX	OD	15JUN2019	Severe	3 hours	Recovered	Not applicable	XXX	N	Emesis	Related	

Use of Narratives in Clinical Trials

- Patient narratives forms an important part of clinical study reporting.
- Patient narratives describe the events of a subject which are of special interest during the study.
 - Serious Adverse Events
 - Device Related Adverse Events
- They are a part of safety data submitted to the regulatory authorities for all phases of clinical trials



Features of R



Open source



Wide Packages



Advanced graphical capabilities



Object-Oriented and functional language



Better option for generating Plots

R Packages

Library(tidyverse) will load the core tidyverse packages



ggplot2 → Data visualisation



dplyr → Data manipulation



tidyr → Data tidying



readr → Data import



tibble → Modern re-imagining of dataframes



stringr → Used for strings



forcats → Used for factors



purrr → Functional programming

Creation of Narrative program in SAS



- Firstly, we must get the Patient Narrative template finalized by the concerned team.



- With SAS, it is a step-by-step process.



- The source datasets are imported into SAS and the program is authored.



- SAS functions such as STRIP, COMPBL, PUT, INPUT, CATX etc., are used for structuring the data as per the template.



- SAS ODS and macros are also used in order to output the narratives and make the programs effective.



- PROC REPORT and PROC TEMPLATE are the procedures which need to be used to create the output and to create the narrative template, respectively.

Creation of Narrative program in R

- R provides packages (ex. "PatientProfileVis") which enables to create subject profile reports of patients/subjects in a clinical trial.
- Different types of visualizations are available via dedicated R functions. Each function creates a separate visualization for each subject available in the dataset.
- 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.

Sample Code

- Screen Shot of sample R code

```
#install.packages("ggplot2")
library(ggplot2)

data <- read.csv("C:\\Users\\XXX\\Desktop\\Works
\\1 Week\\NEWW1.csv", header = TRUE)
data
str(data)

data$f <- factor(data$Value, 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
```

- Screen Shot of sample SAS code

```
proc format;
  value bin
    0="None/Absent"
    1="Trace"
    2="Mild"
    3="Moderate"
    4="Severe"
    5="Present"
  ;
run;

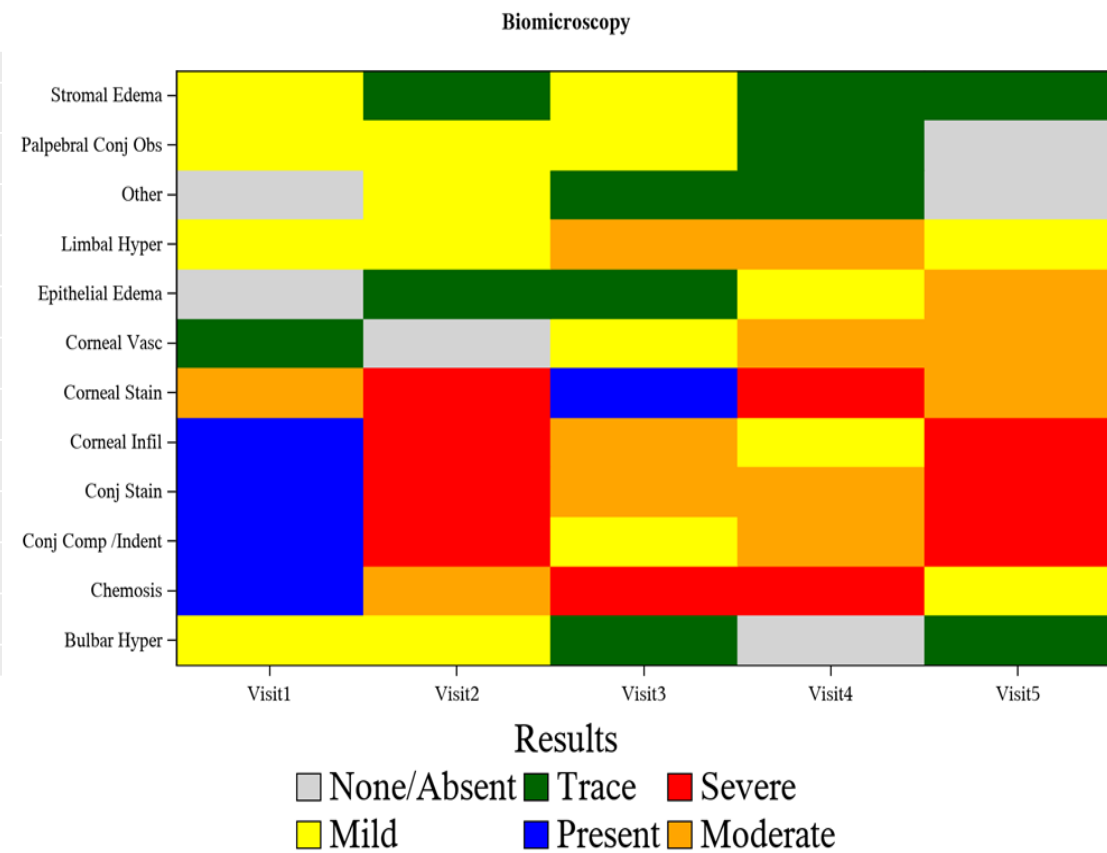
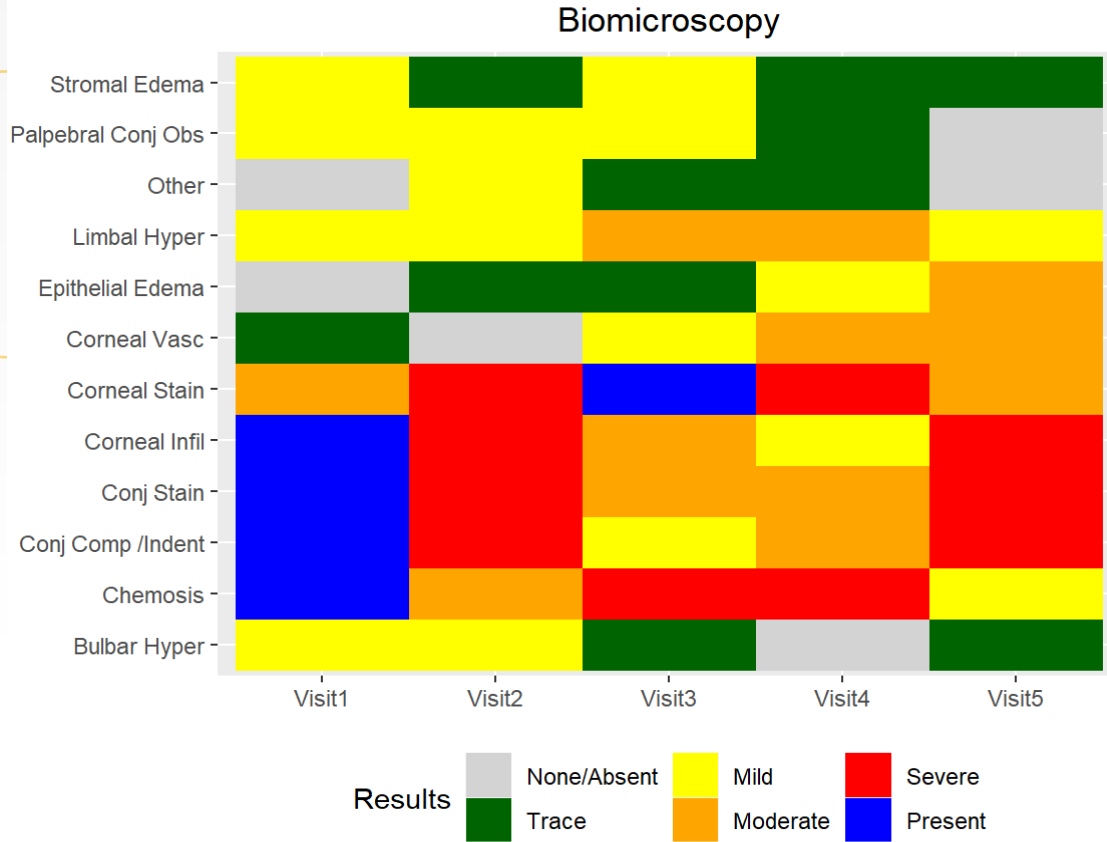
ods graphics on / border=off antialiasmax = 8000
width = 8.9in height = 5in;
title3 "Biomicroscopy";

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;
```

Sample Report

- Screen Shot of sample R report

- Screen Shot of sample SAS report



Challenges of writing Patient Narratives



Large number of resources for the given project



Non standardized data sources for most of the programs



Consistency maintaining due to multiple resources working on the same project



Time and delivery with high quality



High variability in template finalization due to differences in opinion of the reviewers



Possible changes during the intermediate /later stages of the project

Q&A



Thank you for your
ATTENTION

