

Patient Narratives (with R)

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WHAT ARE PATIENT NARRATIVES ?

A narrative is a brief summary of the particular events that patients experience in a clinical trial. The narratives facilitate the assessment of the safety profile of the experimental drug under investigation, so the more frequently patient narrative is a summary of AEs occurring in a clinical trial patient/subject. It is generally written for the following criteria:

-death -serious AE (SAE) event(s) of special interest -AE leading to study drug/trial discontinuation -adjudication event(s)

THERAPEUTICS AREAS AND PHASES ?

Patient Narratives included all therapeutic areas and all phases of clinical trials (Phase I–IV) depending on the drug evaluation.

INTERNATIONAL CONFERENCE ON HARMONISATION

International Conference on Harmonisation (ICH) E3 (Section 14.3 Safety Data) we have information about Safety Data which includes 14.3.3 Narratives of deaths, other serious and certain other significant adverse events. There should be brief narratives describing each death, each other serious adverse event, and those of the other significant adverse events that are judged to be of special interest because of clinical importance. In addition on this should be included following information.

- Patient identifier
- Age and sex of patient; general clinical condition of patient, if appropriate
- Disease being treated (if the same for all patients this is not required) with duration (of current episode) of illness
- Relevant concomitant/previous illnesses with details of occurrence/duration
- Relevant concomitant/previous medication with details of dosage
- Test drug/investigational product administered, drug dose, if this varied among patients, and length of time administered.

In the safety data submission to clinical study reporting Patient narrative is playing significant role. With Programs R we can develop an automated narratives report generation tools which will help us to cut the cost and time. The responsibility to create narratives on Medical Writers and they are doing it manually writing in simple text. Using R methods except already mentioned benefit it will save resources for repeated studies too.

CREATION OF NARRATIVE PROGRAM IN R

-First of all we must obtain narrative template from Sponsor and start our annotation to avoid misunderstanding.

-R lets us work with the most useful options and functions within a certain type of work, since there are available packages that allow us to get these relative options and functions from certain packages, e.g. for narratives it is "PatientProfilevis".

-Various visualisation tricks help us not to struggle and loop to achieve the desired result. For example Subjectprofiletext plot allows us to get separate output for each subject, ggplot to create various type of graphs see example below

```
#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
```

The other very useful tool is "RMarkdown":

-R Markdown is a powerful tool for data analysis, scientific research, and data storytelling, as it enables you to combine code, text, and visualizations in a single document, making your work more efficient, transparent, and reproducible.

-R Markdown documents can be exported to a variety of formats, including PDF, HTML, Microsoft Word, and more. This makes it easy to share your work with others, regardless of their preferred file format.

```
---
title: "My R Markdown Document"
author: "Your Name"
date: "March 7, 2023"
output: html_document
---
```

-Code chunk

-Text Part and batch run Code

R Markdown is free and can generate multiple patient narratives in a very short time.

CHALLENGES OF WRITING PATIENT NARRATIVE

1. Data management: Patient narratives require data from various sources, including electronic medical records, surveys, and patient interviews. Managing and merging this data can be challenging, especially if the data is in different formats or has missing values.
2. Text processing: Patient narratives often involve analyzing large amounts of unstructured text data. R has some built-in functions for text processing, but it may be necessary to use additional packages or custom code to perform more complex analyses.
3. Multiple reports: For multiple reports we can use the package (patientprofilevis) and not have to worry about the number of patients, because it automatically works with all those who meet certain criteria.
4. Automation: In report writing is a current trend that every pharmaceutical industry is picking up on to ensure quality and consistency in reports. The tool that helps in automated report writing extracts relevant information for all identified patients in the desired format/template.
5. Formats: For formatting and consistency of the reports provided, which can be solved by using R, where we can specify a unique format and get all the output in a format as desired.

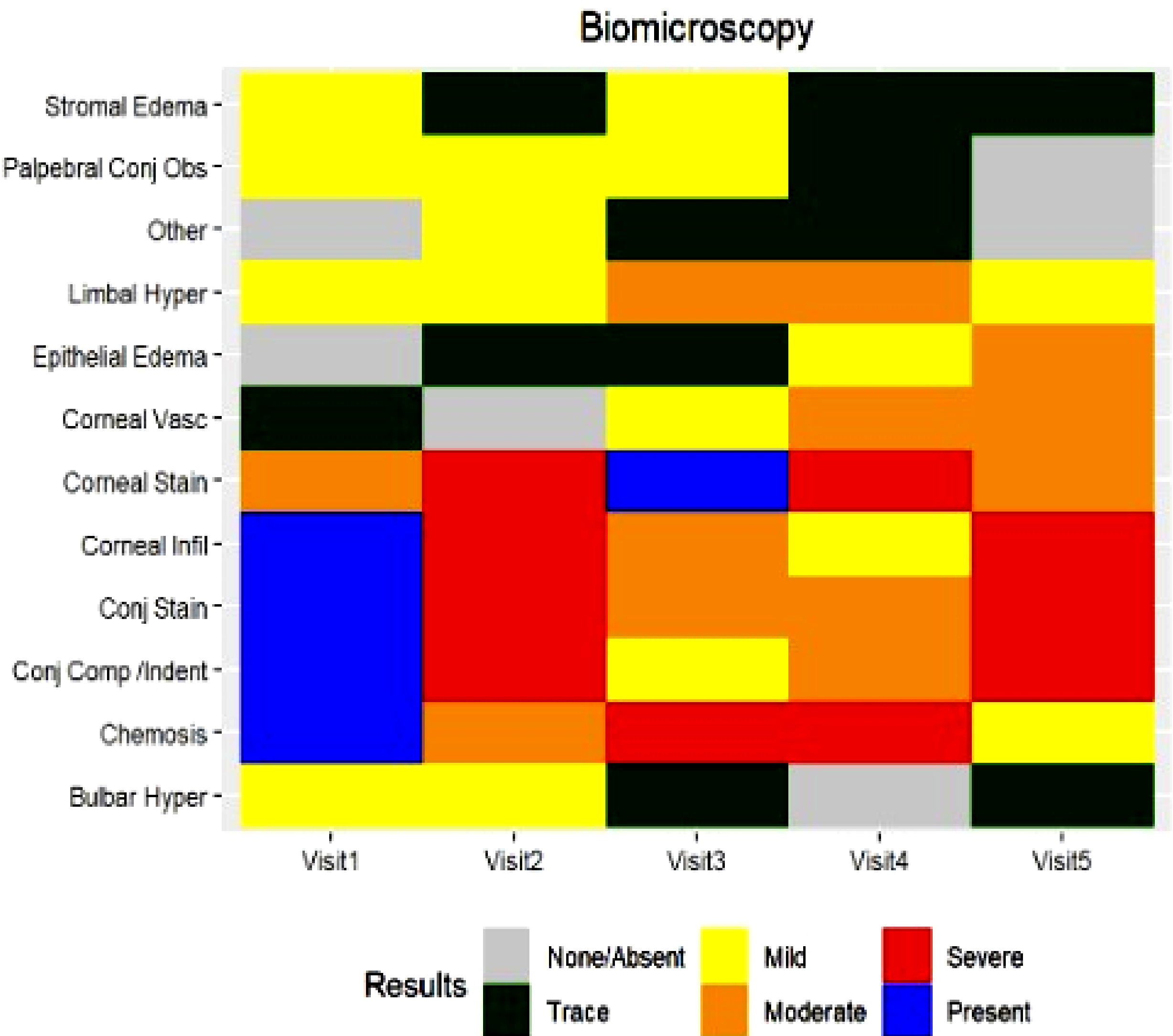
USE OF NARRATIVES IN CLINICAL TRIALS

Narratives are often used in clinical trials to provide a more detailed and nuanced understanding of the effects of a particular treatment or intervention. While traditional clinical trial data often focuses on quantitative measures such as clinical endpoints, laboratory results, and adverse event rates, narratives allow for a more comprehensive examination of the patient experience.

Narratives can help researchers gain insights into the patient's experience of the treatment, including subjective experiences such as quality of life, symptom relief, and changes in physical or emotional functioning. These insights can be particularly valuable in exploring how the treatment affects patient outcomes beyond just clinical metrics.

In addition, narratives can help researchers identify unanticipated or rare adverse events that may not be captured through more traditional data collection methods. By gathering detailed patient accounts of their experiences, researchers can better understand the potential risks and benefits of the treatment being studied.

Overall, narratives provide a more complete picture of the patient experience, and can help researchers develop more patient-centered and effective treatments.



CONCLUSION

The use of R packages/R Markdown can give us high quality patient narratives.

Main reason for using R instead of other programming languages is the wide range of packages that allow us to complete certain tasks in short time. And one more important thing ITS cost effective.