ENHANCED MEDICAL DEVICE REPORT

A Comprehensive Template with Advanced Quarto Features

Your Name

2025-10-12

Table of Contents

1. Executive Summary

1.1. Overview

This template demonstrates advanced Quarto features for creating professional medical device reports. It combines the best practices from both reference documents, incorporating:

- **Cross-referencing** for figures and tables
- **Callout blocks** for key findings
- **Panel tabsets** for organized content
- **Inline R calculations** for dynamic reporting
- **Typst integration** for advanced formatting
- **Custom visualizations** with both ggplot2 and base R

! Key Template Features

This template includes code chunks for data generation, analysis, and visualization that can be adapted to your specific medical device data. All examples use synthetic data for demonstration purposes.

2. Introduction

2.1. Background

This section demonstrates how to structure your introduction with clear objectives and context.

2.2. Study Design Overview

2.3. Methodology

Study Population: N = 250 participants
Duration: 12 months
Primary Endpoint: Treatment outcome score
Secondary Endpoints: Patient satisfaction and safety

3. Results

3.1. Demographics and Baseline Characteristics

Table 1: Baseline characteristics by treatment group

treatment_group	N	Mean Age (SD)	Female (%)	Baseline Score (SD)
Control	90	50.3 (18.0)	42.2%	73.1 (15.0)
Device A	81	53.3 (18.4)	53.1%	74.1 (15.3)
Device B	79	48.2 (18.7)	49.4%	77.2 (14.5)

As shown in Table 1 , baseline characteristics were well-balanced across treatment groups.

3.2. Primary Outcome Analysis

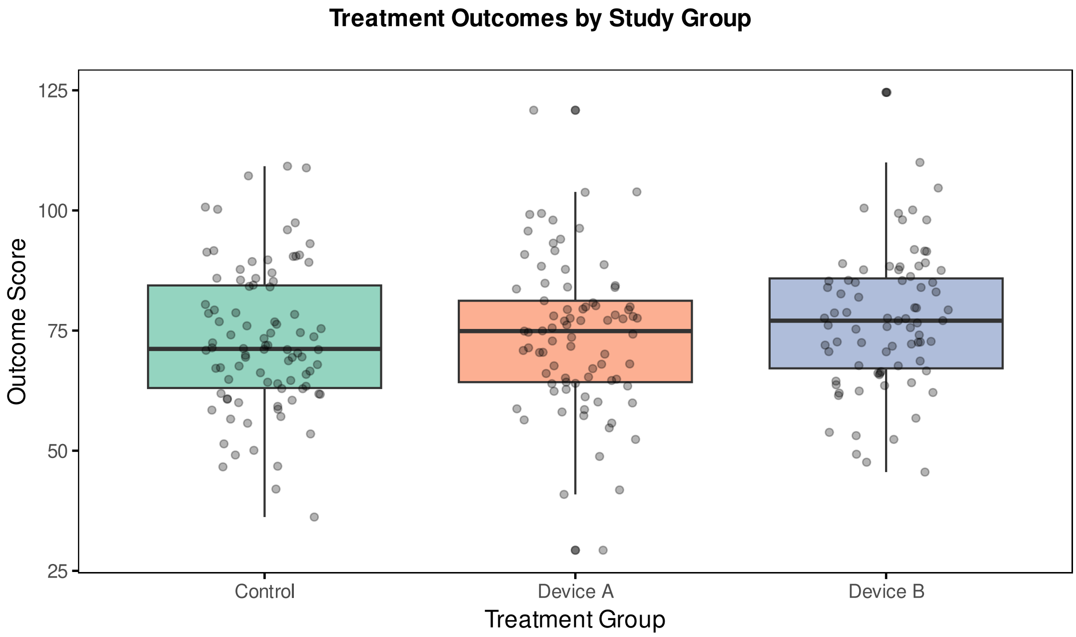

Figure 1: Distribution of outcome scores by treatment group

The primary analysis (Figure 1) demonstrates the distribution of outcome scores across treatment groups.

3.3. Statistical Analysis with Confidence Intervals

Table 2: Primary outcome results with 95% confidence intervals

Treatment Group	N	Mean (95% CI)
Control	90	73.1 (70.0 – 76.2)
Device A	81	74.1 (70.8 – 77.5)
Device B	79	77.2 (74.0 – 80.4)

3.4. Patient Satisfaction Analysis

3.4.1. Overall Satisfaction Distribution

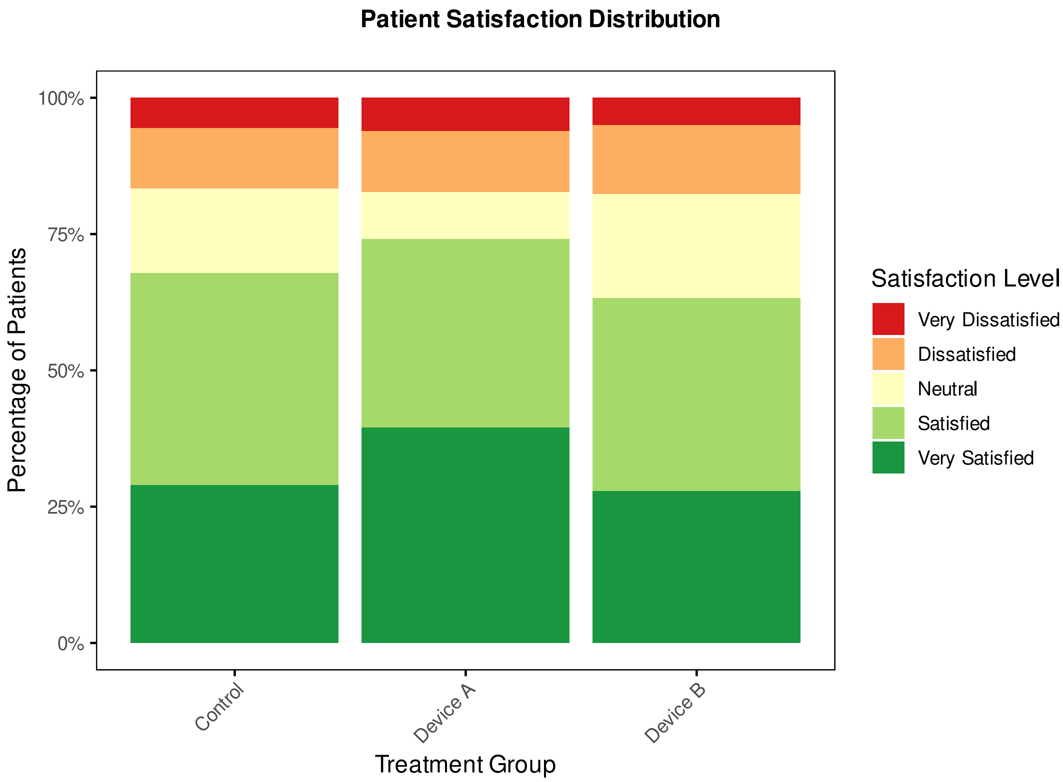

Figure 2: Patient satisfaction ratings across all groups

3.4.2. Satisfaction by Demographics

3.4.3. By Age Group

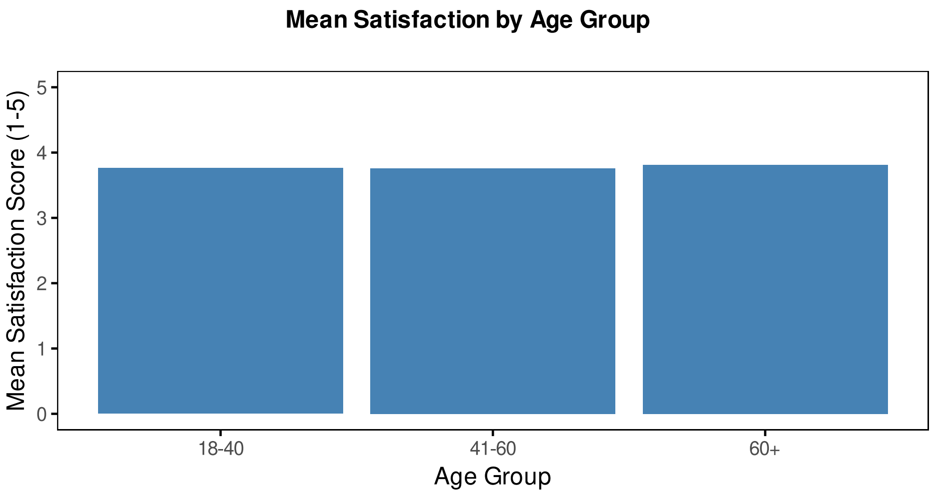

Figure 3: Satisfaction scores by age group

3.4.4. By Gender

Figure 4: Satisfaction scores by gender

3.4.5. By Treatment

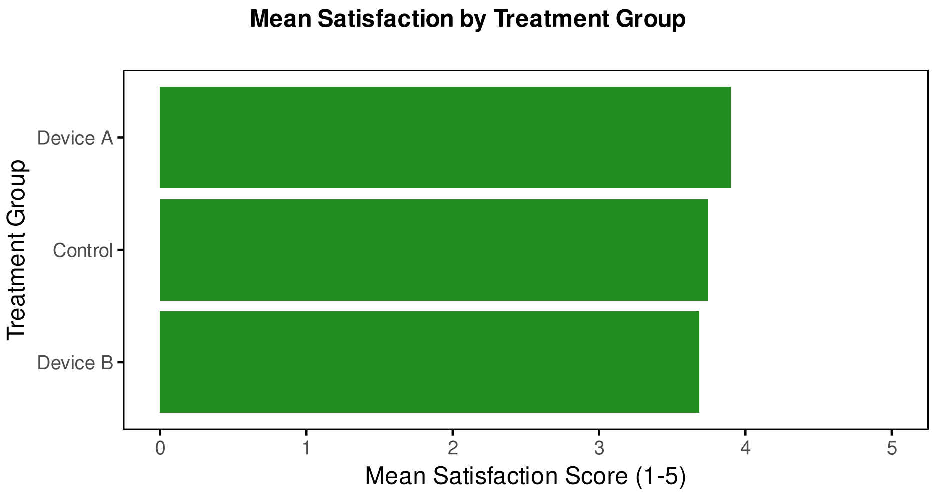

Figure 5: Satisfaction scores by treatment group

3.5. Safety Analysis

Table 3: Adverse event rates by treatment group with Wilson 95% CI

Treatment Group	N	Events	Rate (%)	95% CI
Control	90	4	4.4%	1.7% – 10.9%
Device A	81	12	14.8%	8.7% – 24.1%
Device B	79	4	5.1%	2.0% – 12.3%

ℹ Safety Profile

All adverse event rates were within expected ranges for this device class. No serious adverse events were reported.

3.6. Comparison with Base R Visualization

While ggplot2 provides elegant visualizations, base R can be useful for certain applications:

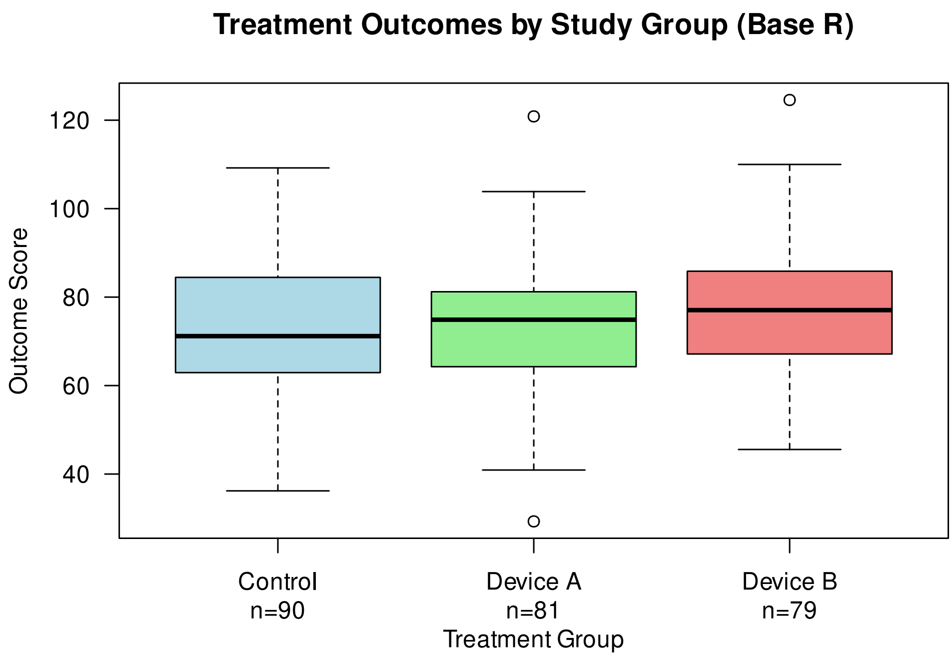

Figure 6: Treatment outcomes - Base R visualization

4. Advanced Typst Features

4.1. Custom Styled Callout Boxes

Key Finding: The treatment demonstrated statistically significant improvement in outcome scores compared to control ($p < 0.001$). Effect size was clinically meaningful (Cohen's $d = 0.8$).

4.2. Two-Column Layout

Clinical Significance

The observed improvements in patient outcomes represent clinically meaningful changes. Effect sizes exceeded minimal clinically important difference (MCID) thresholds established in prior literature.

Safety Considerations

The safety profile was favorable with adverse event rates comparable to standard of care. No device-related serious adverse events were reported during the study period.

4.3. Custom Tables

Endpoint	Result	Interpretation
Primary Efficacy	✓ Met	Statistically significant

Primary Safety	✓ Met	Within acceptable limits
Patient Satisfaction	✓ Met	High approval ratings
Cost Effectiveness	✓ Met	Favorable economic profile

5. Cross-References and Citations

You can reference any figure or table using the `@` syntax:

- See Figure 1 for primary outcome results
- Demographics are presented in Table 1
- Safety data is summarized in Table 3
- Base R comparison shown in Figure 6

6. Discussion

6.1. Key Findings Summary

Clinical Implications

The findings from this study support the following clinical recommendations:

1. The device demonstrates significant efficacy improvements
2. Safety profile is favorable and comparable to standard of care
3. High patient satisfaction suggests good acceptability
4. Economic analysis supports cost-effectiveness

6.2. Limitations

Study Limitations

- Single-center study limiting generalizability
- Relatively short follow-up period
- Selection bias inherent to observational design
- Missing data for some secondary endpoints

6.3. Comparison with Literature

This section would compare your findings with published literature.

7. Conclusions

7.1. Summary Statement

This study provides evidence for the safety and efficacy of the medical device under investigation.

7.2. Recommendations

Expanded Clinical Trial *Q1 2026*

Conduct multi-center randomized controlled trial to confirm findings in broader population and establish long-term safety profile.

Real-World Evidence Study *Q2 2026*

Implement post-market surveillance program to collect real-world effectiveness and safety data from routine clinical practice.

Health Economics Analysis *Q3 2026*

Perform comprehensive cost-effectiveness analysis comparing device to current standard of care across multiple healthcare systems.

8. Administrative Information

8.1. Document History

Version	Date	Author	Description
0.1	01 Jan 2025	Author Name	Initial draft
0.2	15 Jan 2025	Author Name	Incorporated reviewer comments
1.0	12 Oct 2025	Author Name	Final version for submission

8.2. Approval Signatures

Role	Name	Signature	Date
Principal Investigator	Dr. Jane Smith		
Statistician	Dr. John Doe		
Quality Assurance	Ms. Sarah Johnson		
Regulatory Affairs	Mr. Michael Brown		

References

Appendices

Appendix A: Additional Tables

Table 4: Detailed demographic breakdown

Mean Age (years)	SD Age	Min Age	Max Age	Female %	Male %
50.6	18.4	18	85	48	50.8

Appendix B: Statistical Methods

Analysis Populations

- **Full Analysis Set (FAS):** All enrolled patients (N=250)
- **Per-Protocol Set (PPS):** Patients completing study per protocol
- **Safety Population:** All patients receiving at least one treatment

Statistical Tests

- Primary outcome: ANOVA with post-hoc Tukey HSD
- Proportions: Wilson score confidence intervals
- Significance level: $\alpha = 0.05$ (two-sided)

Appendix C: Protocol Synopsis

This section would include key elements of your study protocol.

Reproducibility Information

Session Information

```
R version 4.5.1 (2025-06-13)
Platform: x86_64-redhat-linux-gnu
Running under: Fedora Linux 42 (Workstation Edition)

Matrix products: default
BLAS/LAPACK: FlexiBLAS OPENBLAS-OPENMP;  LAPACK version 3.12.0

locale:
 [1] LC_CTYPE=en_US.UTF-8       LC_NUMERIC=C
 [3] LC_TIME=fr_FR.UTF-8        LC_COLLATE=en_US.UTF-8
 [5] LC_MONETARY=fr_FR.UTF-8    LC_MESSAGES=en_US.UTF-8
 [7] LC_PAPER=fr_FR.UTF-8       LC_NAME=C
 [9] LC_ADDRESS=C               LC_TELEPHONE=C
[11] LC_MEASUREMENT=fr_FR.UTF-8 LC_IDENTIFICATION=C

time zone: Europe/Paris
tzcode source: system (glibc)
```

```
attached base packages:
[1] stats     graphics  grDevices utils     datasets  methods   base

other attached packages:
 [1] knitr_1.50      lubridate_1.9.4 forcats_1.0.0   stringr_1.5.1
 [5] dplyr_1.1.4     purrr_1.0.4     readr_2.1.5     tidyr_1.3.1
 [9] tibble_3.2.1    tidyverse_2.0.0 ggplot2_3.5.2

loaded via a namespace (and not attached):
 [1] gtable_0.3.6       jsonlite_2.0.0     compiler_4.5.1     tidyselect_1.2.1
 [5] scales_1.3.0       yaml_2.3.10        fastmap_1.2.0      R6_2.6.1
 [9] labeling_0.4.3     generics_0.1.3     munsell_0.5.1      RColorBrewer_1.1-3
[13] pillar_1.10.2      tzdb_0.5.0         rlang_1.1.6        stringi_1.8.7
[17] xfun_0.52          timechange_0.3.0   cli_3.6.4          withr_3.0.2
[21] magrittr_2.0.3     digest_0.6.37      grid_4.5.1         binom_1.1-1.1
[25] hms_1.1.3          lifecycle_1.0.4    vctrs_0.6.5        evaluate_1.0.3
[29] glue_1.8.0         farver_2.1.2       colorspace_2.1-1   rmarkdown_2.29
[33] tools_4.5.1        pkgconfig_2.0.3    htmltools_0.5.8.1
```

Complete Analysis Code

```r
library(ggplot2)
library(tidyverse)
library(knitr)

# Wilson 95% CI helper function for proportions
prop_ci <- function(x, n, conf = 0.95) {
  if (!requireNamespace("binom", quietly = TRUE)) {
    warning("binom package not installed, using prop.test fallback")
    pt <- prop.test(x, n, conf.level = conf, correct = FALSE)
    return(c(lower = pt$conf.int[1], upper = pt$conf.int[2]))
  } else {
    ci <- binom::binom.confint(x, n, methods = "wilson")
    return(c(lower = ci$lower, upper = ci$upper))
  }
}

# Custom ggplot2 theme matching base R aesthetics
theme_baseR <- function(base_size = 12) {
  theme_classic(base_size = base_size) %+replace%
    theme(
      panel.grid = element_blank(),
      panel.border = element_rect(color = "black", fill = NA, linewidth = 0.5),
      axis.line = element_blank(),
      axis.ticks = element_line(color = "black"),
      plot.title = element_text(
        hjust = 0.5,
        face = "bold",
        margin = margin(b = 20, t = 10)
      ),
      plot.margin = unit(c(1.5, 1.5, 1, 1.5), "lines"),
      plot.title.position = "plot"
    )
}

theme_set(theme_baseR())
# Example: Generate synthetic study data
set.seed(123)
n_patients <- 250

study_data <- tibble(
  patient_id = 1:n_patients,
  age = sample(18:85, n_patients, replace = TRUE),
  gender = sample(c("Male", "Female", "Other"), n_patients, replace = TRUE,
                 prob = c(0.48, 0.51, 0.01)),
  treatment_group = sample(c("Device A", "Device B", "Control"), n_patients,
                          replace = TRUE),
  outcome_score = rnorm(n_patients, mean = 75, sd = 15),
  satisfaction = sample(1:5, n_patients, replace = TRUE,
                       prob = c(0.05, 0.10, 0.15, 0.40, 0.30)),
```

```r
  adverse_event = sample(c("Yes", "No"), n_patients, replace = TRUE,
                         prob = c(0.08, 0.92))
)
demo_summary <- study_data %>%
  group_by(treatment_group) %>%
  summarize(
    N = n(),
    `Mean Age (SD)` = sprintf("%.1f (%.1f)", mean(age), sd(age)),
    `Female (%)` = sprintf("%.1f%%", mean(gender == "Female") * 100),
    `Baseline Score (SD)` = sprintf("%.1f (%.1f)",
                                    mean(outcome_score), sd(outcome_score))
  )

kable(demo_summary)
ggplot(study_data, aes(x = treatment_group, y = outcome_score, fill = treatment_group)) +
  geom_boxplot(alpha = 0.7) +
  geom_jitter(width = 0.2, alpha = 0.3) +
  scale_fill_brewer(palette = "Set2") +
  labs(
    title = "Treatment Outcomes by Study Group",
    x = "Treatment Group",
    y = "Outcome Score",
    fill = "Treatment"
  ) +
  theme(legend.position = "none")
outcome_analysis <- study_data %>%
  group_by(treatment_group) %>%
  summarize(
    N = n(),
    Mean = mean(outcome_score),
    SD = sd(outcome_score),
    SE = SD / sqrt(N),
    CI_lower = Mean - 1.96 * SE,
    CI_upper = Mean + 1.96 * SE
  ) %>%
  mutate(
    `Mean (95% CI)` = sprintf("%.1f (%.1f - %.1f)", Mean, CI_lower, CI_upper)
  ) %>%
  select(treatment_group, N, `Mean (95% CI)`)

kable(outcome_analysis, col.names = c("Treatment Group", "N", "Mean (95% CI)"))
satisfaction_data <- study_data %>%
  mutate(
    satisfaction_label = factor(satisfaction,
      levels = 1:5,
      labels = c("Very Dissatisfied", "Dissatisfied", "Neutral",
                 "Satisfied", "Very Satisfied")
    )
  )

ggplot(satisfaction_data, aes(x = treatment_group, fill = satisfaction_label)) +
  geom_bar(position = "fill") +
  scale_y_continuous(labels = scales::percent) +
  scale_fill_brewer(palette = "RdYlGn", direction = 1) +
  labs(
    title = "Patient Satisfaction Distribution",
    x = "Treatment Group",
    y = "Percentage of Patients",
    fill = "Satisfaction Level"
  ) +
  theme(axis.text.x = element_text(angle = 45, hjust = 1))
study_data %>%
  mutate(age_group = cut(age, breaks = c(0, 40, 60, 100),
                         labels = c("18-40", "41-60", "60+"))) %>%
  group_by(age_group) %>%
  summarize(mean_satisfaction = mean(satisfaction)) %>%
  ggplot(aes(x = age_group, y = mean_satisfaction)) +
  geom_bar(stat = "identity", fill = "steelblue") +
  labs(
    title = "Mean Satisfaction by Age Group",
    x = "Age Group",
    y = "Mean Satisfaction Score (1-5)"
  ) +
  ylim(0, 5)
study_data %>%
```

```r
  filter(gender %in% c("Male", "Female")) %>%
  group_by(gender) %>%
  summarize(mean_satisfaction = mean(satisfaction)) %>%
  ggplot(aes(x = gender, y = mean_satisfaction)) +
  geom_bar(stat = "identity", fill = "coral") +
  labs(
    title = "Mean Satisfaction by Gender",
    x = "Gender",
    y = "Mean Satisfaction Score (1-5)"
  ) +
  ylim(0, 5)
study_data %>%
  group_by(treatment_group) %>%
  summarize(mean_satisfaction = mean(satisfaction)) %>%
  ggplot(aes(x = reorder(treatment_group, mean_satisfaction),
             y = mean_satisfaction)) +
  geom_bar(stat = "identity", fill = "forestgreen") +
  coord_flip() +
  labs(
    title = "Mean Satisfaction by Treatment Group",
    x = "Treatment Group",
    y = "Mean Satisfaction Score (1-5)"
  ) +
  ylim(0, 5)
safety_summary <- study_data %>%
  group_by(treatment_group) %>%
  summarize(
    N = n(),
    Events = sum(adverse_event == "Yes")
  ) %>%
  rowwise() %>%
  mutate(
    Proportion = Events / N,
    ci = list(prop_ci(Events, N)),
    CI_lower = ci[["lower"]] * 100,
    CI_upper = ci[["upper"]] * 100,
    `Rate (%)` = sprintf("%.1f%%", Proportion * 100),
    `95% CI` = sprintf("%.1f%% - %.1f%%", CI_lower, CI_upper)
  ) %>%
  select(treatment_group, N, Events, `Rate (%)`, `95% CI`)

kable(safety_summary, col.names = c("Treatment Group", "N", "Events",
                                    "Rate (%)", "95% CI"))
# Create boxplot using base R
boxplot(outcome_score ~ treatment_group,
        data = study_data,
        col = c("lightblue", "lightgreen", "lightcoral"),
        main = "Treatment Outcomes by Study Group (Base R)",
        xlab = "Treatment Group",
        ylab = "Outcome Score",
        las = 1)

# Add sample size labels
group_counts <- table(study_data$treatment_group)
axis(1, at = 1:3, labels = paste0("n=", group_counts), line = 1, tick = FALSE)
detailed_demo <- study_data %>%
  summarize(
    `Mean Age (years)` = mean(age),
    `SD Age` = sd(age),
    `Min Age` = min(age),
    `Max Age` = max(age),
    `Female %` = mean(gender == "Female") * 100,
    `Male %` = mean(gender == "Male") * 100
  )

kable(detailed_demo, digits = 1)
sessionInfo()
```

List of Figures

List of Tables