PharmaSUG 2026 - Paper AP-195

Creating Reproducible Clinical Output with SASSY – Reporter Package

Vicky Yuan, Incyte Corporation

ABSTRACT

As the R programming language continues to gain traction in the pharmaceutical and clinical research industries, many SAS® programmers are seeking robust and user-friendly reporting solutions that align with established clinical and company standards. While numerous open-source reporting packages are available in R, identifying one that offers both flexibility and familiarity can be challenging for those transitioning from SAS®. The SASSY-Reporter package stands out as an exceptional choice, particularly for SAS® users, due to its intuitive design and functional similarities to the widely used PROC REPORT procedure in SAS®.

This paper highlights the key features of the SASSY-Reporter package, emphasizing its ease of use, adaptability to clinical reporting requirements, and the convenience it offers to programmers accustomed to SAS®. Through practical examples, we demonstrate how the SASSY-Reporter package streamlines the creation of high-quality, standardized reports, making it an ideal tool for SAS® programmers transitioning to R.

The package's clear syntax and comprehensive functionality not only facilitate a smoother learning curve but also ensure that clinical reporting in R can meet rigorous industry standards with efficiency and confidence.

The R product used in this paper is R **Reporter** package version 1.4.6 running on RStudio environment

INTRODUCTION

The SASSY-**Reporter** package provides an intuitive reporting framework in R, especially for SAS® programmers familiar with PROC REPORT. Its design emphasizes clarity, consistency, and reproducibility, making it an attractive solution for teams modernizing their clinical reporting workflows without compromising quality or compliance.

Key capabilities of the SASSY - **Reporter** Package include:

- **Efficient report creation** with only a few lines of code.
- **Flexible page layout control**, including page header and footer, titles, footnotes, and "Page X of Y" numbering.
- **Automatic handling of pagination,** handle page breaking, page wrapping, and dynamic column width adjustment.
- **Multiple output formats**, such as Word .docx, RFT and PDF, to support diverse clinical reporting needs.

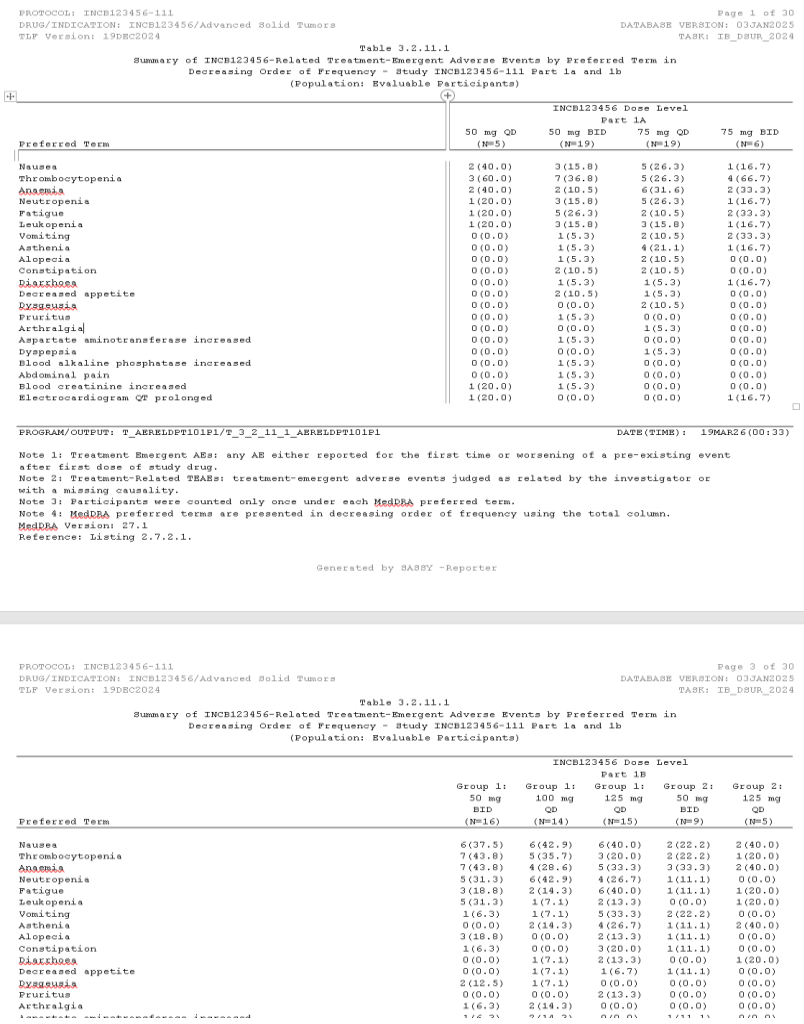
INSTALLATION

The **sassy** Reporter-package is published on CRAN. You can install it with the following console command:

```
Install.packages("reporter")
Library(reporter)
```

To illustrate these capabilities in practice, the following example demonstrates how the SASSY-Reporter package can be used to build a complete clinical table with minimal code. This example highlights how the package manages layout, pagination, formatting, and output generation automatically, showcasing its practicality and efficiency in real clinical reporting workflows.

Example 1. Generating a Multi-page TEAE table with different treatment groups



PROTOCOL: INCB123456-111 Page 1 of 30
DRUG/INDICATION: INCB123456/Advanced Solid Tumors DATABASE VERSION: 03JAN2025
TLF Version: 19DEC2024 TASK: IB_DSUR_2024

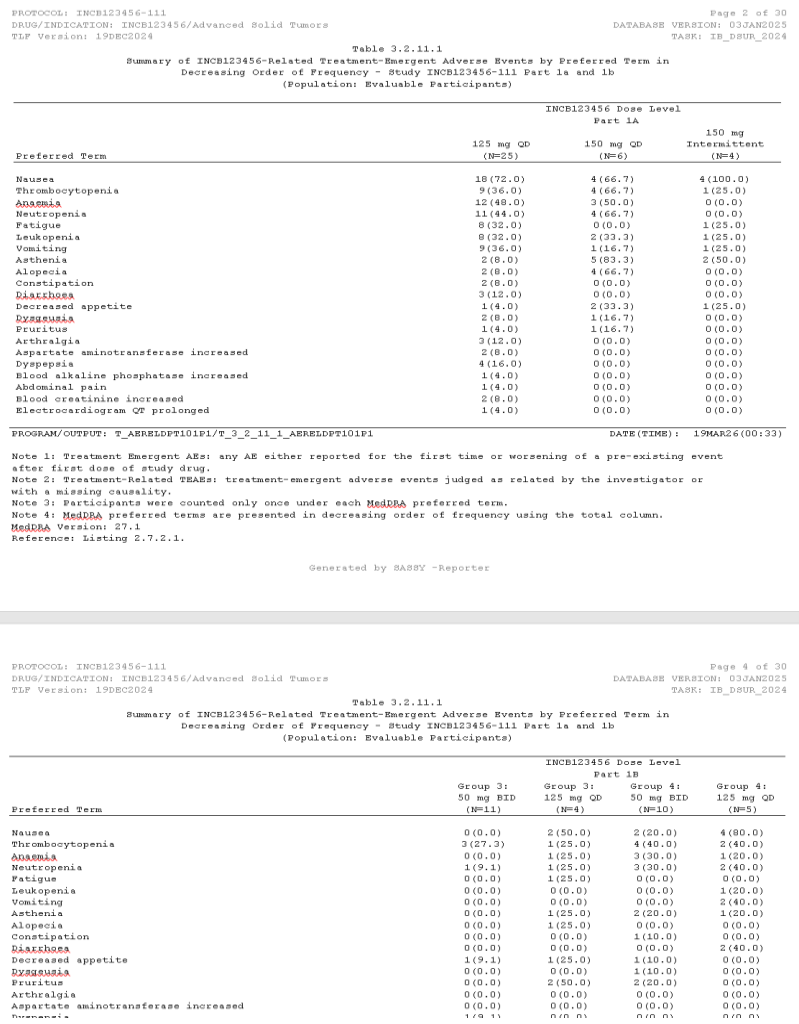
Table 3.2.11.1
Summary of INCB123456-Related Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency - Study INCB123456-111 Part 1a and 1b
(Population: Evaluable Participants)

	INCB123456 Dose Level Part 1A			
Preferred Term	50 mg QD (N=5)	50 mg BID (N=19)	75 mg QD (N=19)	75 mg BID (N=6)
Nausea	2(40.0)	3(15.8)	5(26.3)	1(16.7)
Thrombocytopenia	3(60.0)	7(36.8)	5(26.3)	4(66.7)
Anaemia	2(40.0)	2(10.5)	6(31.6)	2(33.3)
Neutropenia	1(20.0)	3(15.8)	5(26.3)	1(16.7)
Fatigue	1(20.0)	5(26.3)	2(10.5)	2(33.3)
Leukopenia	1(20.0)	3(15.8)	3(15.8)	1(16.7)
Vomiting	0(0.0)	1(5.3)	2(10.5)	2(33.3)
Asthenia	0(0.0)	1(5.3)	4(21.1)	1(16.7)
Alopecia	0(0.0)	1(5.3)	2(10.5)	0(0.0)
Constipation	0(0.0)	2(10.5)	2(10.5)	0(0.0)
Diarrhoea	0(0.0)	1(5.3)	1(5.3)	1(16.7)
Decreased appetite	0(0.0)	2(10.5)	1(5.3)	0(0.0)
Dysgeusia	0(0.0)	0(0.0)	2(10.5)	0(0.0)
Pruritus	0(0.0)	1(5.3)	0(0.0)	0(0.0)
Arthralgia	0(0.0)	0(0.0)	1(5.3)	0(0.0)
Aspartate aminotransferase increased	0(0.0)	1(5.3)	0(0.0)	0(0.0)
Dyspepsia	0(0.0)	0(0.0)	1(5.3)	0(0.0)
Blood alkaline phosphatase increased	0(0.0)	1(5.3)	0(0.0)	0(0.0)
Abdominal pain	0(0.0)	1(5.3)	0(0.0)	0(0.0)
Blood creatinine increased	1(20.0)	1(5.3)	0(0.0)	0(0.0)
Electrocardiogram QT prolonged	1(20.0)	0(0.0)	0(0.0)	1(16.7)

PROGRAM/OUTPUT: T_AERELDPT101P1/T_3_2_11_1_AERELDPT101P1 DATE(TIME): 19MAR26(00:33)

Note 1: Treatment Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study drug.
Note 2: Treatment-Related TEAEs: treatment-emergent adverse events judged as related by the investigator or with a missing causality.
Note 3: Participants were counted only once under each MedDRA preferred term.
Note 4: MedDRA preferred terms are presented in decreasing order of frequency using the total column.
MedDRA Version: 27.1
Reference: Listing 2.7.2.1.

Generated by SASSY -Reporter



PROTOCOL: INCB123456-111 Page 2 of 30
DRUG/INDICATION: INCB123456/Advanced Solid Tumors DATABASE VERSION: 03JAN2025
TLF Version: 19DEC2024 TASK: IB_DSUR_2024

Table 3.2.11.1
Summary of INCB123456-Related Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency - Study INCB123456-111 Part 1a and 1b
(Population: Evaluable Participants)

	INCB123456 Dose Level Part 1A		
Preferred Term	125 mg QD (N=25)	150 mg QD (N=6)	150 mg Intermittent (N=4)
Nausea	18(72.0)	4(66.7)	4(100.0)
Thrombocytopenia	9(36.0)	4(66.7)	1(25.0)
Anaemia	12(48.0)	3(50.0)	0(0.0)
Neutropenia	11(44.0)	4(66.7)	0(0.0)
Fatigue	8(32.0)	0(0.0)	1(25.0)
Leukopenia	8(32.0)	2(33.3)	1(25.0)
Vomiting	9(36.0)	1(16.7)	1(25.0)
Asthenia	2(8.0)	5(83.3)	2(50.0)
Alopecia	2(8.0)	4(66.7)	0(0.0)
Constipation	2(8.0)	0(0.0)	0(0.0)
Diarrhoea	3(12.0)	0(0.0)	0(0.0)
Decreased appetite	1(4.0)	2(33.3)	1(25.0)
Dysgeusia	2(8.0)	1(16.7)	0(0.0)
Pruritus	1(4.0)	1(16.7)	0(0.0)
Arthralgia	3(12.0)	0(0.0)	0(0.0)
Aspartate aminotransferase increased	2(8.0)	0(0.0)	0(0.0)
Dyspepsia	4(16.0)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	1(4.0)	0(0.0)	0(0.0)
Abdominal pain	1(4.0)	0(0.0)	0(0.0)
Blood creatinine increased	2(8.0)	0(0.0)	0(0.0)
Electrocardiogram QT prolonged	1(4.0)	0(0.0)	0(0.0)

PROGRAM/OUTPUT: T_AERELDPT101P1/T_3_2_11_1_AERELDPT101P1 DATE(TIME): 19MAR26(00:33)

Note 1: Treatment Emergent AEs: any AE either reported for the first time or worsening of a pre-existing event after first dose of study drug.
Note 2: Treatment-Related TEAEs: treatment-emergent adverse events judged as related by the investigator or with a missing causality.
Note 3: Participants were counted only once under each MedDRA preferred term.
Note 4: MedDRA preferred terms are presented in decreasing order of frequency using the total column.
MedDRA Version: 27.1
Reference: Listing 2.7.2.1.

Generated by SASSY -Reporter

PROTOCOL: INCB123456-111 Page 3 of 30
DRUG/INDICATION: INCB123456/Advanced Solid Tumors DATABASE VERSION: 03JAN2025
TLF Version: 19DEC2024 TASK: IB_DSUR_2024

Table 3.2.11.1
Summary of INCB123456-Related Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency - Study INCB123456-111 Part 1a and 1b
(Population: Evaluable Participants)

	INCB123456 Dose Level Part 1B				
Preferred Term	Group 1: 50 mg BID (N=16)	Group 1: 100 mg QD (N=14)	Group 1: 125 mg QD (N=15)	Group 2: 50 mg BID (N=9)	Group 2: 125 mg QD (N=5)
Nausea	6(37.5)	6(42.9)	6(40.0)	2(22.2)	2(40.0)
Thrombocytopenia	7(43.8)	5(35.7)	3(20.0)	2(22.2)	1(20.0)
Anaemia	7(43.8)	4(28.6)	5(33.3)	3(33.3)	2(40.0)
Neutropenia	5(31.3)	6(42.9)	4(26.7)	1(11.1)	0(0.0)
Fatigue	3(18.8)	2(14.3)	6(40.0)	1(11.1)	1(20.0)
Leukopenia	5(31.3)	1(7.1)	2(13.3)	0(0.0)	1(20.0)
Vomiting	1(6.3)	1(7.1)	5(33.3)	2(22.2)	0(0.0)
Asthenia	0(0.0)	2(14.3)	4(26.7)	1(11.1)	2(40.0)
Alopecia	3(18.8)	0(0.0)	2(13.3)	1(11.1)	0(0.0)
Constipation	1(6.3)	0(0.0)	3(20.0)	1(11.1)	0(0.0)
Diarrhoea	0(0.0)	1(7.1)	2(13.3)	0(0.0)	1(20.0)
Decreased appetite	0(0.0)	1(7.1)	1(6.7)	1(11.1)	0(0.0)
Dysgeusia	2(12.5)	1(7.1)	0(0.0)	0(0.0)	0(0.0)
Pruritus	0(0.0)	0(0.0)	2(13.3)	0(0.0)	0(0.0)
Arthralgia	1(6.3)	2(14.3)	0(0.0)	0(0.0)	0(0.0)

PROTOCOL: INCB123456-111 Page 4 of 30
DRUG/INDICATION: INCB123456/Advanced Solid Tumors DATABASE VERSION: 03JAN2025
TLF Version: 19DEC2024 TASK: IB_DSUR_2024

Table 3.2.11.1
Summary of INCB123456-Related Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency - Study INCB123456-111 Part 1a and 1b
(Population: Evaluable Participants)

	INCB123456 Dose Level Part 1B			
Preferred Term	Group 3: 50 mg BID (N=11)	Group 3: 125 mg QD (N=4)	Group 4: 50 mg BID (N=10)	Group 4: 125 mg QD (N=5)
Nausea	0(0.0)	2(50.0)	2(20.0)	4(80.0)
Thrombocytopenia	3(27.3)	1(25.0)	4(40.0)	2(40.0)
Anaemia	0(0.0)	1(25.0)	3(30.0)	1(20.0)
Neutropenia	1(9.1)	1(25.0)	3(30.0)	2(40.0)
Fatigue	0(0.0)	1(25.0)	0(0.0)	0(0.0)
Leukopenia	0(0.0)	0(0.0)	0(0.0)	1(20.0)
Vomiting	0(0.0)	0(0.0)	0(0.0)	2(40.0)
Asthenia	0(0.0)	1(25.0)	2(20.0)	1(20.0)
Alopecia	0(0.0)	1(25.0)	0(0.0)	0(0.0)
Constipation	0(0.0)	0(0.0)	1(10.0)	0(0.0)
Diarrhoea	0(0.0)	0(0.0)	0(0.0)	2(40.0)
Decreased appetite	1(9.1)	1(25.0)	1(10.0)	0(0.0)
Dysgeusia	0(0.0)	0(0.0)	1(10.0)	0(0.0)
Pruritus	0(0.0)	2(50.0)	2(20.0)	0(0.0)
Arthralgia	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Aspartate aminotransferase increased	0(0.0)	0(0.0)	0(0.0)	0(0.0)

Here is SASSY – Reporter code example

```
library(reporter)
#-----------------------------------------------------------------------------------------------------------
# 1. Create a reporter object with page size and margins
#-----------------------------------------------------------------------------------------------------------
pth <- file.path(tmp, paste0(program.output, ".docx", sep=''))
rpt <- create_report(pth,
                     font = "Courier")  %>%
       options_fixed(font_size = 9)

#-----------------------------------------------------------------------------------------------------------
# 2. Add headers, titles, footnotes, and page numbering
#-----------------------------------------------------------------------------------------------------------
rpt <- rpt %>%
  page_header(
       left = c("PROTOCOL: INCB123456-111",
                "DRUG/INDICATION: INCB123456/Advanced Solid Tumors",
                "TLF Version: 19DEC2024"),
       right =c("Page [pg] of [tpg]",
                "DATABASE VERSION: 03JAN2025",
                "TASK: IB_DSUR_2024")
   ) %>%
  titles(
         "Table 3.2.11.1",
         "Summary of INCB123456-Related Treatment-Emergent Adverse Events by Preferred Term in",
         "Decreasing Order of Frequency - Study INCB123456-111 Part 1a and 1b",
         "(Population: Evaluable Participants)",
         bold = FALSE,
         font_size = 9
  ) %>%
  page_footer(center = "Generated by SASSY-Reporter")%>%
  footnotes("PROGRAM/OUTPUT: " %p% paste(toupper(program.name), "/", toupper(program.output), sep=""),
            paste("DATE(TIME): ", program.timestamp, blank_row=''),
            columns = 2, borders="top", blank_row="none") %>%

  footnotes("Note 1: Treatment Emergent AEs: any AE either reported for the first time or worsening of a pre-
existing event",
            "after first dose of study drug.",
            "Note 2: Treatment-Related TEAEs: treatment-emergent adverse events judged as related by the
investigator or",
```

```
            "with a missing causality.",
            "Note 3: Participants were counted only once under each MedDRA preferred term.",
            "Note 4: MedDRA preferred terms are presented in decreasing order of frequency using the total
column.",
            "MedDRA Version: 27.1",
            "Reference: Listing 2.7.2.1.")

#-----------------------------------------------------------------------------------------------------------
# 3. Create a table object
#-----------------------------------------------------------------------------------------------------------
tbl <- create_table(final, first_row_blank=TRUE, borders = "top", width=9) %>%
  column_defaults(from = 'aedecod', to = 'c21', width=1) %>%
  spanning_header("c1", "c4", label="INCB123456 Dose Level\n Part 1A") %>%
  spanning_header("c5", "c7", label="INCB123456 Dose Level\n Part 1A") %>%
  spanning_header("c8", "c12", label="INCB123456 Dose Level\n Part 1B") %>%
  spanning_header("c13", "c16", label="INCB123456 Dose Level\n Part 1B") %>%
  spanning_header("c17", "c20", label="INCB123456 Dose Level\n Part 1B") %>%

  define(aedecod, label = "Preferred Term", width = 5, id_var = TRUE) %>%
  define("c1", align = "center", label = "50 mg QD",   n= bigN2["1"])  %>%
  define("c2", align = "center", label = "50 mg BID",  n= bigN2["2"])  %>%
  define("c3", align = "center", label = "75 mg QD",   n= bigN2["3"])  %>%
  define("c4", align = "center", label = "75 mg BID",   n= bigN2["4"])  %>%
  define("c5", align = "center", label = "125 mg QD",   n= bigN2["5"], width = 1.3, page_wrap = TRUE)   %>%
  define("c6", align = "center", label = "150 mg QD",   n= bigN2["6"], width = 1.3)  %>%
  define("c7", align = "center", label = "150 mg Intermittent",   n= bigN2["7"], width = 1.3)  %>%
  define("c8", align = "center", label = "Group 1:\n 50 mg BID",   n= bigN2["8"],
         page_wrap = TRUE, width = 0.8)  %>%
  define("c9", align = "center", label = "Group 1:\n 100 mg QD",   n= bigN2["9"], width = 0.8)  %>%
  define("c10", align = "center", label = "Group 1:\n 125 mg QD",   n= bigN2["10"], width = 0.8)  %>%
  define("c11", align = "center", label = "Group 2:\n 50 mg BID",   n= bigN2["11"], width = 0.8)  %>%
  define("c12", align = "center", label = "Group 2:\n 125 mg QD",   n= bigN2["12"], width = 0.8)  %>%
  define("c13", align = "center", label = "Group 3:\n 50 mg BID",   n= bigN2["13"], page_wrap = TRUE)   %>%
  define("c14", align = "center", label = "Group 3:\n 125 mg QD",   n= bigN2["14"])  %>%
  define("c15", align = "center", label = "Group 4:\n 50 mg BID",   n= bigN2["15"])  %>%
  define("c16", align = "center", label = "Group 4:\n 125 mg QD",   n= bigN2["16"])  %>%
  define("c17", align = "center", label = "Group 5:\n 50 mg BID",   n= bigN2["17"],
         page_wrap = TRUE, width = 0.8)  %>%
  define("c18", align = "center", label = "Group 5:\n 125 mg QD",   n= bigN2["18"], width = 0.8)  %>%
  define("c19", align = "center", label = "Group 6:\n 50 mg BID",   n= bigN2["19"], width = 0.8)  %>%
  define("c20", align = "center", label = "Group 6:\n 125 mg QD",   n= bigN2["20"], width = 0.8)  %>%
```

```
  define("c21", align = "center", label = "Total",      n= bigN2["21"], width = 0.8) %>%
  define(ord_layer_index, visible = FALSE) %>%
  define(ord_layer_1, visible = FALSE) %>%
  define(total_n, visible = FALSE)

#-------------------------------------------------------------------------------------------------------------
# 4. Add the table to the report
#-------------------------------------------------------------------------------------------------------------
rpt <- rpt %>%
 add_content(tbl)

#-------------------------------------------------------------------------------------------------------------
# 5. Write the report (handles page wrapping automatically)
#-------------------------------------------------------------------------------------------------------------
write_report(rpt, output_type = "DOCX")
```

This table contains 21 treatment-group columns. Because only a subset of these columns can fit on a single page, SASSY-Reporter allows you to fine-tune the layout by assigning custom column widths (for example, using width = XX) to improve readability on pages with fewer treatment groups.

The `page_header()` and `page_footer()` functions provide full control over page-level elements, including study identifiers, consistent formatting, and automatic “Page X of Y” numbering. When working with wide tables, setting `page_wrap = TRUE` enables SASSY-Reporter to split columns across multiple pages while preserving alignment and structure. Titles are automatically placed at the top of each page, and footnotes appear at the bottom, ensuring compliance with standard clinical reporting conventions.

Finally, the output format can be easily customized by specifying the desired `output_type`, with support for DOCX, RTF, and PDF, allowing flexibility across different submission or review workflows.

Example 2. Generating a laboratory table

Laboratory summary tables typically present results by treatment group and by laboratory parameter, often across multiple analysis visits. The following example demonstrates how the SASSY-Reporter package can be used to incorporate both the laboratory test parameter and the treatment group directly into the table titles, while also customizing the layout of each page. In this case, we illustrate how to structure the output so that four analysis visits are displayed per page, ensuring a consistent and readable presentation across the entire report.

Table 3.3.1.1
Summary of Laboratory Values - Hematology
(Safety Population)

Laboratory Test (unit): Basophils (GI/L)
Treatment: Ruxolitinib 15 mg BID

		Descriptive Summary							N (%) of Participants		
Visit		N	Mean	STD	Min	Median	Max	Low	Normal	High	Missing
Baseline	Baseline	70	0.0232	0.03712	0.000	0.0000	0.146	0	69(98.6)	1(1.4)	0
Day 2	Measured	2	0.0000	0.00000	0.000	0.0000	0.000	0	2(100.0)	0	0
	Change	2	-0.0210		-0.042	-0.0210	0.000				
	%Change	1	-100.00		-100.0	-100.00	-100.0				
Day 3	Measured	63	0.0382	0.06957	0.000	0.0100	0.400	0	62(98.4)	1(1.6)	0
	Change	60	0.0217		-0.040	0.0000	0.400				
	%Change	22	14.31		-100.0	0.00	300.0				
Day 4	Measured	1	0.0150	NA	0.015	0.0150	0.015	0	1(100.0)	0	0
	Change	1	-0.0270		-0.027	-0.0270	-0.027				
	%Change	1	-64.29		-64.3	-64.29	-64.3				

Program: t_lbsumh.R
DATE(TIME): 02OCT23(21:45)

Note 1: The Change and % Change were based on the number of participants who had both baseline value and post-baseline value at each visit.
Note 2: For N(%) of participants, percentages are calculated with the number of participants measured at each visit as the denominator.
Reference: Listing 2.8.1.1, 2.8.1.2

Table 3.3.1.1
Summary of Laboratory Values - Hematology
(Safety Population)

Laboratory Test (unit): Basophils (GI/L)
Treatment: Ruxolitinib 15 mg BID

		Descriptive Summary							N (%) of Participants		
Visit		N	Mean	STD	Min	Median	Max	Low	Normal	High	Missing
Day 5	Measured	64	0.0294	0.04982	0.000	0.0000	0.240	0	63(98.4)	1(1.6)	0
	Change	61	0.0067		-0.146	0.0000	0.120				
	%Change	25	-9.42		-100.0	0.00	150.0				
Day 6	Measured	3	0.0000	0.00000	0.000	0.0000	0.000	0	3(100.0)	0	0
	Change	3	-0.0140		-0.042	0.0000	0.000				
	%Change	1	-100.00		-100.0	-100.00	-100.0				
Day 7	Measured	50	0.0275	0.04276	0.000	0.0000	0.160	0	49(98.0)	1(2.0)	0
	Change	49	0.0032		-0.112	0.0000	0.110				
	%Change	19	35.26		-100.0	0.00	550.0				
Day 8	Measured	2	0.0285	0.02192	0.013	0.0285	0.044	0	2(100.0)	0	0
	Change	2	-0.0140		-0.030	-0.0140	0.002				
	%Change	2	-32.50		-69.8	-32.50	4.8				

Program: t_lbsumh.R
DATE(TIME): 02OCT23(21:45)

Note 1: The Change and % Change were based on the number of participants who had both baseline value and post-baseline value at each visit.
Note 2: For N(%) of participants, percentages are calculated with the number of participants measured at each visit as the denominator.
Reference: Listing 2.8.1.1, 2.8.1.2

Table 3.3.1.1
Summary of Laboratory Values - Hematology
(Safety Population)

Laboratory Test (unit): Basophils (GI/L)
Treatment: Ruxolitinib 15 mg BID

		Descriptive Summary							N (%) of Participants		
Visit		N	Mean	STD	Min	Median	Max	Low	Normal	High	Missing
Day 9	Measured	52	0.0249	0.04646	0.000	0.0000	0.260	0	51(98.1)	1(1.9)	0
	Change	49	0.0040		-0.106	0.0000	0.160				
	%Change	20	2.75		-100.0	0.00	350.0				
Day 10	Measured	1	0.0560	NA	0.056	0.0560	0.056	0	1(100.0)	0	0
	Change	1	0.0140		0.014	0.0140	0.014				
	%Change	1	33.33		33.3	33.33	33.3				
Day 11	Measured	48	0.0325	0.03874	0.000	0.0195	0.100	0	48(100.0)	0	0
	Change	45	0.0089		-0.117	0.0000	0.100				
	%Change	19	39.62		-100.0	0.00	400.0				
Day 12	Measured	2	0.0440	0.06223	0.000	0.0440	0.088	0	2(100.0)	0	0
	Change	2	0.0230		0.000	0.0230	0.046				
	%Change	1	109.52		109.5	109.52	109.5				

Table 3.3.1.1
Summary of Laboratory Values - Hematology
(Safety Population)

Laboratory Test (unit): Basophils (GI/L)
Treatment: Ruxolitinib 15 mg BID

		Descriptive Summary							N (%) of Participants		
Visit		N	Mean	STD	Min	Median	Max	Low	Normal	High	Missing
Day 13	Measured	46	0.0330	0.04058	0.000	0.0150	0.120	0	45(97.8)	1(2.2)	0
	Change	43	0.0058		-0.102	0.0000	0.100				
	%Change	19	-1.55		-100.0	-25.00	600.0				
Day 14	Measured	2	0.0380	0.03960	0.010	0.0380	0.066	0	2(100.0)	0	0
	Change	2	0.0170		0.010	0.0170	0.024				
	%Change	1	57.14		57.1	57.14	57.1				
Day 15	Measured	41	0.0581	0.09083	0.000	0.0300	0.500	0	39(95.1)	2(4.9)	0
	Change	40	0.0281		-0.094	0.0000	0.500				
	%Change	19	7.01		-64.4	0.00	166.7				
Day 16	Measured	1	0.0600	NA	0.060	0.0600	0.060	0	1(100.0)	0	0
	Change	1	0.0180		0.018	0.0180	0.018				
	%Change	1	42.86		42.9	42.86	42.9				

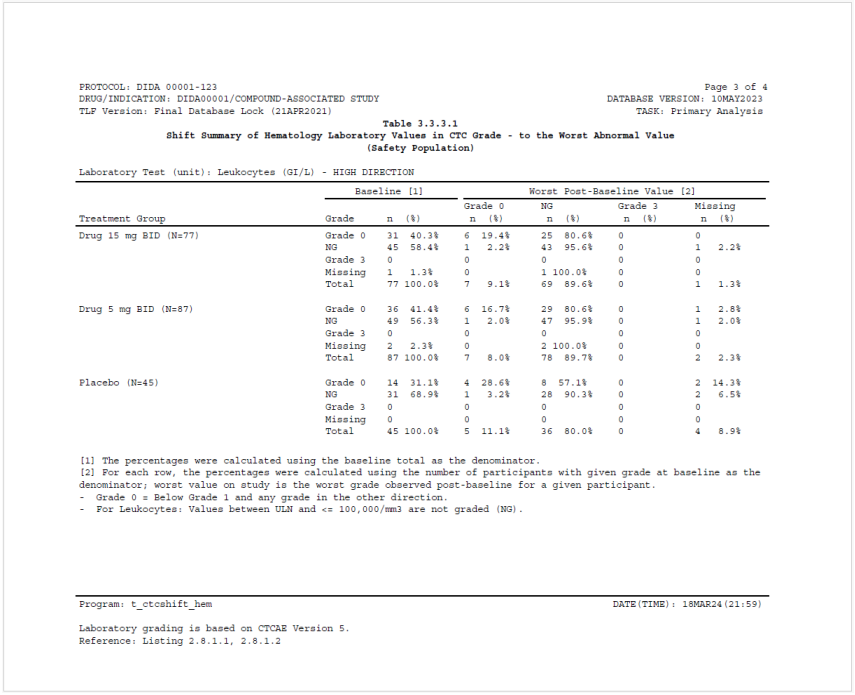
Here is SASSY – Reporter code:

```
library(reporter)
#-----------------------------------------------------------------------------------------------------------
# 1. Create page break
#-----------------------------------------------------------------------------------------------------------
datastep(final, by = c("tr01ag1n", "tr01ag1", "param", "avisitn", "avisit"),
                    retain = list(ptcnt = 0, PG = 1),
                    {
                      if(first.){
                        ptcnt <- ptcnt +1
                      }

                      if (ptcnt == 5){
                        ptcnt <- 1
                        PG <- PG+1
                      }

                     }) -> final.1

final.1 <- final.1 %>%
  arrange(tr01ag1n, tr01ag1, param, avisitn,avisit)
#-----------------------------------------------------------------------------------------------------------
# 2. Create a table object with dynamic column widths
#-----------------------------------------------------------------------------------------------------------
tbl <- create_table(final.1, first_row_blank=TRUE, borders = c("bottom", "top"), width=9) %>%
  page_by(param, label="Laboratory Test (unit): ") %>%
  page_by(tr01ag1, label="Treatment Group: ") %>%

  column_defaults(from = 'avisit', to = 'N_missing') %>%
  spanning_header("N_aval", "aval_max", label="Descriptive Summary") %>%
  spanning_header("N_low", "N_missing", label="N (%) of Participants") %>%
  width(.auto) %>%

  define(avisitn, blank_after = TRUE, visible = FALSE) %>%
  define(PG, page_break = TRUE, visible = FALSE) %>%
  define(variable, align="left", label=" ") %>%
  define(avisit, dedupe = TRUE, align = "left", label = "Visit") %>%
  define(N_aval,      align = "center", label = "N")  %>%
  define(aval_mean,   align = "center", label = "Mean")  %>%
  define(aval_std,    align = "center", label = "STD")  %>%
  define(aval_min,    align = "center", label = "Min")  %>%
```

```
define(aval_median, align = "center", label = "Median")   %>%
define(aval_max,    align = "center", label = "Max")   %>%

define(N_low,       align = "center", label = "Low")   %>%
define(N_normal,    align = "center", label = "Normal")   %>%
define(N_high,      align = "center", label = "High")   %>%
define(N_missing,   align = "center", label = "Missing")
```

In this example, a `retain` statement is used to re-assign page numbers based on user-defined logic, allowing full control over how pages are grouped and displayed. After preparing the data, the `page_by()` function is added within `create_table()` to present both the laboratory test parameter and the treatment group as page-level identifiers, and `width(.auto)` tells the engine to measure column content, adjust widths proportionally and avoid text overflow. All remaining titles, headers, and footnotes follow the same structure demonstrated in the earlier example, ensuring consistent formatting and a reproducible layout across the entire report.

Example 3. Generating a laboratory table in CTC Grade – to the Worst Abnormal Value



PROTOCOL: DIDA 00001-123 Page 3 of 4
DRUG/INDICATION: DIDA00001/COMPOUND-ASSOCIATED STUDY DATABASE VERSION: 10MAY2023
TLF Version: Final Database Lock (21APR2021) TASK: Primary Analysis

Table 3.3.3.1
Shift Summary of Hematology Laboratory Values in CTC Grade - to the Worst Abnormal Value
(Safety Population)

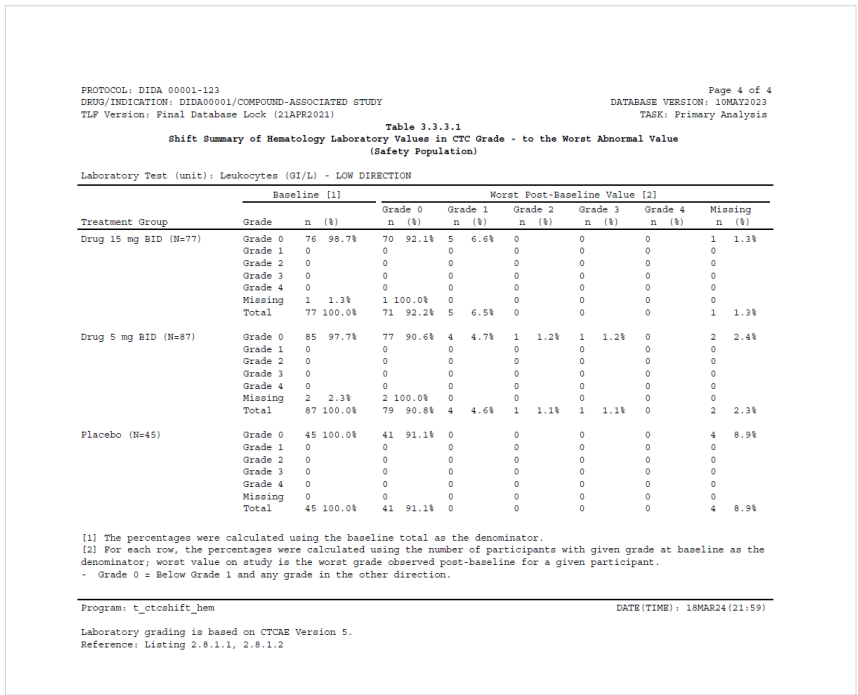
Laboratory Test (unit): Leukocytes (GI/L) - HIGH DIRECTION

		Baseline [1]		Worst Post-Baseline Value [2]							
				Grade 0		NG		Grade 3		Missing	
Treatment Group	Grade	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Drug 15 mg BID (N=77)	Grade 0	31	40.3%	6	19.4%	25	80.6%	0		0	
	NG	45	58.4%	1	2.2%	43	95.6%	0		1	2.2%
	Grade 3	0		0		0		0		0	
	Missing	1	1.3%	0		1	100.0%	0		0	
	Total	77	100.0%	7	9.1%	69	89.6%	0		1	1.3%
Drug 5 mg BID (N=87)	Grade 0	36	41.4%	6	16.7%	29	80.6%	0		1	2.8%
	NG	49	56.3%	1	2.0%	47	95.9%	0		1	2.0%
	Grade 3	0		0		0		0		0	
	Missing	2	2.3%	0		2	100.0%	0		0	
	Total	87	100.0%	7	8.0%	78	89.7%	0		2	2.3%
Placebo (N=45)	Grade 0	14	31.1%	4	28.6%	8	57.1%	0		2	14.3%
	NG	31	68.9%	1	3.2%	28	90.3%	0		2	6.5%
	Grade 3	0		0		0		0		0	
	Missing	0		0		0		0		0	
	Total	45	100.0%	5	11.1%	36	80.0%	0		4	8.9%

[1] The percentages were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of participants with given grade at baseline as the denominator; worst value on study is the worst grade observed post-baseline for a given participant.
- Grade 0 = Below Grade 1 and any grade in the other direction.
- For Leukocytes: Values between ULN and <= 100,000/mm3 are not graded (NG).

Program: t_ctcshift_hem DATE(TIME): 18MAR24(21:59)

Laboratory grading is based on CTCAE Version 5.
Reference: Listing 2.8.1.1, 2.8.1.2



PROTOCOL: DIDA 00001-123 Page 4 of 4
DRUG/INDICATION: DIDA00001/COMPOUND-ASSOCIATED STUDY DATABASE VERSION: 10MAY2023
TLF Version: Final Database Lock (21APR2021) TASK: Primary Analysis

Table 3.3.3.1
Shift Summary of Hematology Laboratory Values in CTC Grade - to the Worst Abnormal Value
(Safety Population)

Laboratory Test (unit): Leukocytes (GI/L) - LOW DIRECTION

		Baseline [1]		Worst Post-Baseline Value [2]											
				Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Missing	
Treatment Group	Grade	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Drug 15 mg BID (N=77)	Grade 0	76	98.7%	70	92.1%	5	6.6%	0		0		0		1	1.3%
	Grade 1	0		0		0		0		0		0		0	
	Grade 2	0		0		0		0		0		0		0	
	Grade 3	0		0		0		0		0		0		0	
	Grade 4	0		0		0		0		0		0		0	
	Missing	1	1.3%	1	100.0%	0		0		0		0		0	
	Total	77	100.0%	71	92.2%	5	6.5%	0		0		0		1	1.3%
Drug 5 mg BID (N=87)	Grade 0	85	97.7%	77	90.6%	4	4.7%	1	1.2%	1	1.2%	0		2	2.4%
	Grade 1	0		0		0		0		0		0		0	
	Grade 2	0		0		0		0		0		0		0	
	Grade 3	0		0		0		0		0		0		0	
	Grade 4	0		0		0		0		0		0		0	
	Missing	2	2.3%	2	100.0%	0		0		0		0		0	
	Total	87	100.0%	79	90.8%	4	4.6%	1	1.1%	1	1.1%	0		2	2.3%
Placebo (N=45)	Grade 0	45	100.0%	41	91.1%	0		0		0		0		4	8.9%
	Grade 1	0		0		0		0		0		0		0	
	Grade 2	0		0		0		0		0		0		0	
	Grade 3	0		0		0		0		0		0		0	
	Grade 4	0		0		0		0		0		0		0	
	Missing	0		0		0		0		0		0		0	
	Total	45	100.0%	41	91.1%	0		0		0		0		4	8.9%

[1] The percentages were calculated using the baseline total as the denominator.
[2] For each row, the percentages were calculated using the number of participants with given grade at baseline as the denominator; worst value on study is the worst grade observed post-baseline for a given participant.
- Grade 0 = Below Grade 1 and any grade in the other direction.

Program: t_ctcshift_hem DATE(TIME): 18MAR24(21:59)

Laboratory grading is based on CTCAE Version 5.
Reference: Listing 2.8.1.1, 2.8.1.2

For shift summaries of laboratory values by CTCAE grade, it is often necessary to display different grade ranges on different pages as table above. CTCAE includes Grades 0 through 5, but not all laboratory parameters use the full range. For example, Leukocytes may have only Grades 0 and 3 for hyper-abnormalities, while the hypo-abnormalities span Grades 0 through 5. To accommodate these variations, the dataset must first be split into smaller data frames—such as lab1, lab2, lab3, and so on—each representing the specific set of parameter with CTCAE grades to be displayed on a single page. After splitting the data, each subset is passed to `create_table()` to generate an individual table object. These tables are then combined in sequence using `add_content()` in `create_report()`, allowing the final report to present the appropriate CTCAE grade columns on each page while maintaining consistent formatting and layout throughout.

Here is SASSY – Reporter code:

```
library(reporter)
#-----------------------------------------------------------------------------------------------------------
# 1. Leukocytes (10^9/L) - HIGH DIRECTION
#-----------------------------------------------------------------------------------------------------------
table_hemo.3 <- table_hemo %>%
  dplyr::filter(labtest=="Leukocytes (GI/L) - HIGH DIRECTION") %>%
  select(labtest, tmtnc, tmtn, swmgrade,variable, c0,c1,c6,c4,c7,pagebrk) %>%
  arrange(labtest, tmtn, swmgrade) %>%
  mutate(pageby = paste0("Laboratory Test (unit): ", labtest, sep="")) %>%
  select(-labtest)

tb3 <- create_table(table_hemo.3,
                    show_cols = c("none"),  # This will set everything to invisible that is not defined
                    borders = "top",
                    width = 9) %>%
  page_by(pageby, label = "", borders = "bottom") %>%

  footnotes ("[1] The percentages were calculated using the baseline total as the denominator.",
             "[2] For each row, the percentages were calculated using the number of participants with given
grade at baseline as the denominator; worst value on study is the worst grade observed post-baseline for a
given participant.",
             "-  Grade 0 = Below Grade 1 and any grade in the other direction.",
             "-  For Leukocytes: Values between ULN and <= 100,000/mm3 are not graded (NG). ",
             blank_row ="both" ) %>%

  column_defaults(from = tmtnc, to = c7, width=.1) %>%
  spanning_header(variable, c0, label="Baseline [1]") %>%
  spanning_header(c1, c7, label="Worst Post-Baseline Value [2]") %>%

  define(swmgrade, visible=FALSE) %>%
  define(pageby, visible=FALSE) %>%
```

```
  define(tmtnc, dedupe = TRUE, align = "left", label = "Treatment Group", width=2.2) %>%
  define(tmtn, blank_after = TRUE, visible = FALSE) %>%
  define(variable, align="left", label="Grade", width=.8) %>%
  define(c0, align="left", label="n  (%)", width=1) %>%
  define(pagebrk, page_break = TRUE, visible = FALSE) %>%
  define(c1,   align = "left", label = "Grade 0\n n  (%)", width=1.25)  %>%
  define(c6,   align = "left", label = "NG\n n  (%)", width=1.25)  %>%
  define(c4,   align = "left", label = "Grade 3\n n  (%)", width=1.25)  %>%
  define(c7,   align = "left", label = "Missing\n n  (%)", width=1.25)


#-------------------------------------------------------------------------------------------------------
# 2. Leukocytes (10^9/L) - LOW DIRECTION
#-------------------------------------------------------------------------------------------------------
table_hemo.4 <- table_hemo %>%
  dplyr::filter(labtest=="Leukocytes (GI/L) - LOW DIRECTION") %>%
  select(labtest, tmtnc, tmtn, swmgrade,variable, c0,c1,c2,c3,c4,c5,c7,pagebrk) %>%

  arrange(labtest, tmtn, swmgrade) %>%
  mutate(pageby = paste0("Laboratory Test (unit): ", labtest, sep="")) %>%
  select(-labtest)

tb4 <- create_table(table_hemo.4,
                    show_cols = c("none"),  # This will set everything to invisible that is not defined
                    borders = "top",
                    width = 9) %>%

  page_by(pageby, label = "", borders = "bottom") %>%


  footnotes ("[1] The percentages were calculated using the baseline total as the denominator.",
             "[2] For each row, the percentages were calculated using the number of participants with given
grade at baseline as the denominator; worst value on study is the worst grade observed post-baseline for a
given participant.",
             "-  Grade 0 = Below Grade 1 and any grade in the other direction.", blank_row ="both" ) %>%

  column_defaults(from = tmtnc, to = c7, width=.1) %>%
  spanning_header(variable, c0, label="Baseline [1]") %>%
  spanning_header(c1, c7, label="Worst Post-Baseline Value [2]") %>%
```

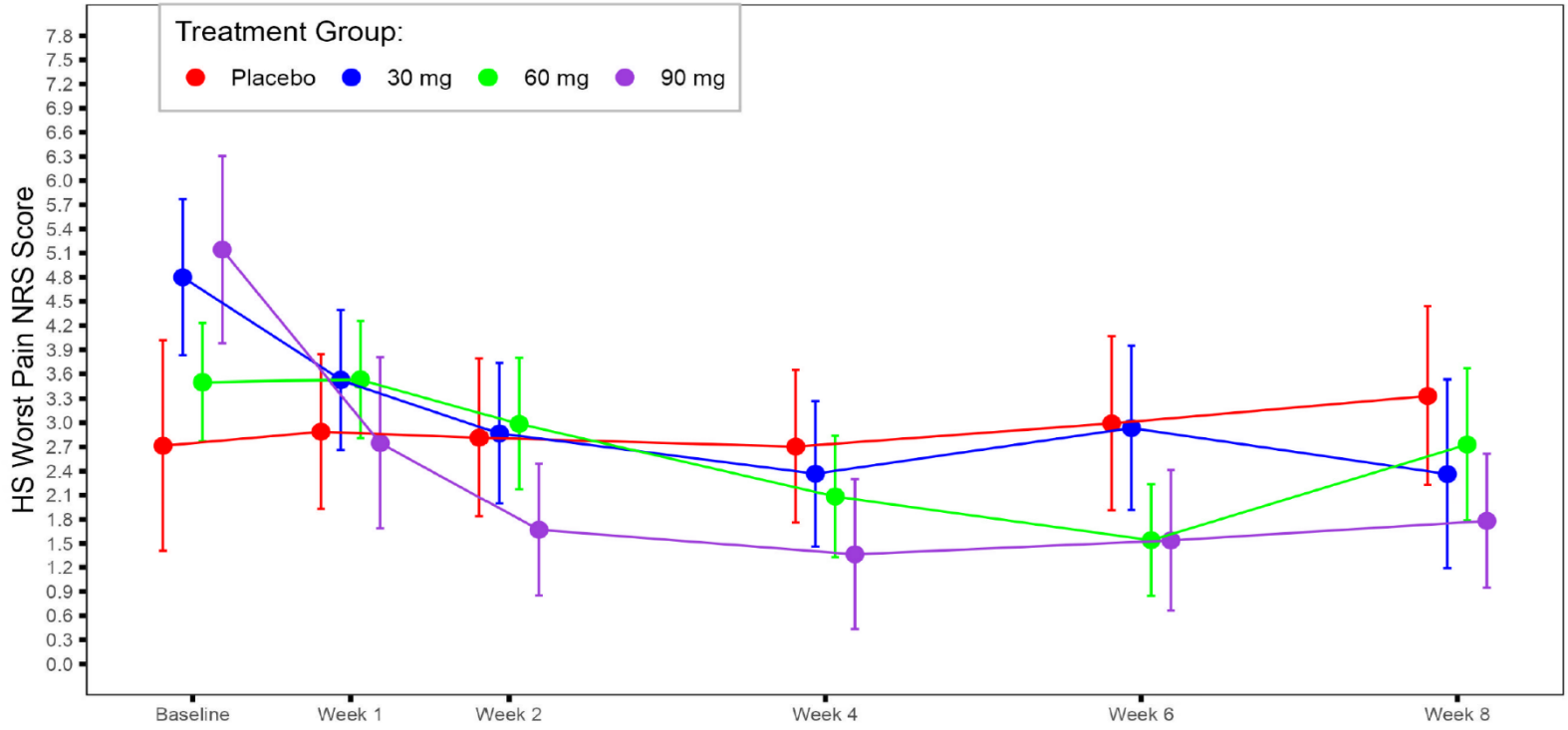
```
  define(swmgrade, visible=FALSE) %>%
  define(pageby, visible=FALSE) %>%
  define(tmtnc, dedupe = TRUE, align = "left", label = "Treatment Group", width=2.2) %>%
  define(tmtn, blank_after = TRUE, visible = FALSE) %>%
  define(variable, align="left", label="Grade", width=.7) %>%
  define(c0, align="left", label="n  (%)", width=.9) %>%
  define(pagebrk, page_break = TRUE, visible = FALSE) %>%
  define(c1,   align = "left", label = "Grade 0\n n  (%)", width=.85)  %>%
  define(c2,   align = "left", label = "Grade 1\n n  (%)", width=.85)  %>%
  define(c3,   align = "left", label = "Grade 2\n n  (%)", width=.85)  %>%
  define(c4,   align = "left", label = "Grade 3\n n  (%)", width=.85)  %>%
  define(c5,   align = "left", label = "Grade 4\n n  (%)", width=.85)  %>%
  define(c7,   align = "left", label = "Missing\n n  (%)", width=.85)

#-------------------------------------------------------------------------------------------------------
# 3. Add the table to the report and write the report
#-------------------------------------------------------------------------------------------------------
rpt <- create_report(pth, font = "Courier", font_size = 9)  %>%
  set_margins(top = 1.0, left = 1, right = 1, bottom = .5) %>%
  options_fixed(line_count = 40) %>%

  add_content(tb3, blank_row = "none") %>%
  add_content(tb4, blank_row = "none")

write_report(rpt, output_type = "DOCX")
```

After running `write_report()`, the output will appear as shown above. The titles, headers, and footnotes follow the same structure used in the earlier example, ensuring consistent formatting and a fully reproducible layout throughout the entire report.

Example 4. Generating a figure: Mean ± Standard Error Plot in a SASSY-Reporter Output

This example illustrates how to generate a mean and standard error figure, demonstrating how easily the SASSY-**Reporter** package can be used to produce graphics that meet company reporting standards.

Figure 2.1.3.1.1
Mean and Standard Error Plot of HS Worst Pain NRS Score by Visit
Full Analysis Set



Abbreviations: HS = Hidradenitis Suppurativa.

Here is code example: Mean ± Standard Error Plot in a SASSY-Reporter Output

```
library(reporter)
library(ggplot2)


#-----------------------------------------------------------------------------------------------------------
# 1. Prepare analysis dataset
#-----------------------------------------------------------------------------------------------------------

qsset <- qsset %>%
  dplyr::filter(fasfl=='Y' & parcat1n==2.2 & anl01fl=='Y' & avisitn<99) %>%
  dplyr::mutate(
    temp_avisitn = case_when(
      avisitn > 0 ~ as.numeric(readr::parse_number(word(avisit, 2))),
      TRUE~ avisitn
    )
  ) %>%
  arrange(temp_avisitn, avisit, trt01pn)

#-----------------------------------------------------------------------------------------------------------
# 2. Create mean +/- SE figures
#-----------------------------------------------------------------------------------------------------------
graphfinal <- qsset %>%
  group_by(temp_avisitn, avisit, trt01pn) %>%
  summarise(
    tn = n(),
    tmean = mean(aval, na.rm = TRUE),
    tstd = sd(aval, na.rm = TRUE)/sqrt(length(aval)),
    tmin = min(aval, na.rm = TRUE),
    tmedian = median(aval, na.rm = TRUE),
    tmax = max(aval, na.rm = TRUE),
    .groups = "drop"
  ) %>%
  dplyr::mutate(
    low = tmean - tstd,
    high = tmean + tstd
  ) %>%
  arrange(trt01pn, temp_avisitn)
#-----------------------------------------------------------------------------------------------------------
# 3. starting graphic and plot
#-----------------------------------------------------------------------------------------------------------
```

```
ylabel <- "HS Worst Pain NRS Score"
yvalues <- seq(0, 7.8, 0.3)  # adjust based on your scale

color_palette <- c("red", "blue", "green", "#9d3cdb", "black")

mean_plot <- ggplot(graphfinal, aes(x = temp_avisitn, y = tmean, color = factor(trt01pn))) +

   geom_point(position = position_dodge(width = 0.5), size = 3) +

  # Suppress these from creating their own legend
  geom_errorbar(
    aes(ymin = low, ymax = high),
    position = position_dodge(width = 0.5),
    width = 0.2,
    show.legend = FALSE
  ) +

  geom_line(
    aes(group = factor(trt01pn)),
    position = position_dodge(width = 0.5),
    size = 0.5,
    show.legend = FALSE
  ) +

  scale_color_manual(
    values = c("red", "blue", "green", "#9d3cdb"),
    name = "Treatment Group:",
    labels = c("Placebo", "30 mg", "60 mg", "90 mg"),
    guide = guide_legend(nrow = 1)
  ) +

  theme_minimal(base_size = 12) +
  theme(
    legend.position = c(0.05, 1),
    legend.justification = c("left", "top"),
    legend.box = "horizontal",
    legend.title.align = 0,
    panel.background = element_rect(fill = "white", color = "black"),
    panel.grid.major = element_blank(),
    panel.grid.minor = element_blank(),
```

```
    plot.background = element_rect(fill = "white", color = NA),
    legend.background = element_rect(fill = "white", color = "grey"),
    axis.title.x = element_blank(),
    axis.ticks.length = unit(0.1, "cm"),
    axis.text.x = element_text(size = 8),
    axis.text.y = element_text(size = 8),
    axis.ticks = element_line(color = "black", linewidth = 1)
  ) +

  scale_x_continuous(
    breaks = c(0, 1, 2, 4, 6, 8),
    labels = c("Baseline", "Week 1", "Week 2", "Week 4", "Week 6", "Week 8")
  ) +
  scale_y_continuous(
    name = ylabel,
    breaks = yvalues,
    limits = range(yvalues)
  )
#-----------------------------------------------------------------------------------------------------
# 4. Create Report and output report
#-----------------------------------------------------------------------------------------------------
pth <- file.path(tmp)
rpt <- create_report(pth, output_type = "pdf", font = "Courier", font_size = 9)  %>%
  set_margins(top = 1, bottom = 1)  %>%

  page_header(left = c("ROTOCOL: XXXXXXXXX", "DRUG/INDICATION: XXXXXXXXXXXXXX", "TLF Version: Final"),
              right = c("Page [pg] of [tpg]",  "DATABASE VERSION: 09OCT2019", "TASK: Final DB Lock")) %>%

   titles("Figure 2.1.3.1.1", "Mean and Standard Error Plot of HS Worst Pain NRS Score by Visit",
         "Full Analysis Set", bold = TRUE) %>%

  add_content(create_plot(mean_plot, 4.5, 9)) %>%

  footnotes("PROGRAM/OUTPUT: " %p% paste(toupper(program.name), "/", toupper(program.output), sep=""),
            "DATE(TIME): " %p% toupper(fapply(Sys.time(), "%d%h%y(%H:%M)")),
            columns=2, blank_row = "below")

write_report(rpt)
```

The figure was generated using the SASSY-**Reporter** framework, which ensures that the visual output adheres to company formatting standards. Titles, headers, footnotes, and layout conventions are applied consistently, allowing the figure to integrate seamlessly with the rest of the clinical reporting package. This approach supports reproducibility and maintains alignment with established reporting practices across studies.

CONCLUSION

The examples in this paper highlight how the SASSY-**Reporter** package streamlines the creation of complex clinical outputs, including multi-page safety tables, CTCAE shift summaries, and graphical displays such as mean ± standard error plots. By combining flexible data handling with structured layout controls—such as dynamic column management, page-level customization, and consistent titles, headers, and footnotes—SASSY-**Reporter** enables the production of clear, reproducible, and submission-ready reports. Together, these demonstrations show how the package supports a unified, efficient workflow for generating high-quality tables and figures across a wide range of clinical reporting needs.

REFERENCES

Bosak D (2024). *The SASSY System*. R package version 1.2.3, https://github.com/dbosak01/sassy, https://www.r-sassy.org
.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Vicky Yuan
vyuan@incyte.com
Incyte Corporation
1815 Augustine-cutoff, Wilmington, DE 19801
(302) 498-6947