

SM07

# An Automated Approach to Generating Call Programs from an Analysis Request

David Maher-McWilliams, [david.maher-mcwilliams@msd.com](mailto:david.maher-mcwilliams@msd.com)

Michael Allie, [michael.allie@msd.com](mailto:michael.allie@msd.com)

Carl Herremans, [carl\\_herremans@merck.com](mailto:carl_herremans@merck.com)

# Agenda

---

Introduction

Call Program Generator Process

Conclusion

# Introduction

# Standardisation

---

Drive to standardize Analysis & Reporting (A&R) process within our team

- Analysis and TLF format

- Analysis request format

Ensure consistency among different submissions

Streamline project delivery

## Reporting Process

## Job Request Document: A&R Grid

AutoSave



AndR+Gri+

Maher-McWilliams, David

File
Home
Insert
Page Layout
Formulas
Data
Review
View
Help
Acrobat
Script Lab

Font
Alignment
Number
Conditional Formatting
Format as Table
Cells
Editing
Ideas
Sensitivity

Clipboard
Styles
Ideas
Sensitivity

|     |        |        |          |                            |                |                                            |        |
|-----|--------|--------|----------|----------------------------|----------------|--------------------------------------------|--------|
| G4  |        |        |          |                            |                |                                            |        |
|     | B      | C      | D        | E                          | F              | G                                          |        |
|     | Values | Review | IDE      |                            |                |                                            |        |
|     | Temp   | name   | Type     |                            |                |                                            |        |
| 2   | P      | REGION | FILETYPE | Parameter Decision by Term | Estimator      | Value Displayed on top of the first column | Output |
| 3   |        | chr04  | Table    | Parameter Decision by Term | Estimator_P01  | COLHEADER                                  | Output |
| 4   |        | chr04  | Table    | Parameter Decision by Term | Estimator_P02  | COLHEADER                                  | Output |
| 5   |        | chr04  | Table    | Parameter Decision by Term | Estimator_P03  | COLHEADER                                  | Output |
| 6   |        | chr04  | Table    | Parameter Decision by Term | Estimator_P04  | COLHEADER                                  | Output |
| 7   |        | chr04  | Table    | Parameter Decision by Term | Estimator_P05  | COLHEADER                                  | Output |
| 8   |        | chr04  | Table    | Parameter Decision by Term | Estimator_P06  | COLHEADER                                  | Output |
| 9   |        | chr04  | Table    | Parameter Decision by Term | Estimator_P07  | COLHEADER                                  | Output |
| 10  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P08  | COLHEADER                                  | Output |
| 11  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P09  | COLHEADER                                  | Output |
| 12  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P10  | COLHEADER                                  | Output |
| 13  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P11  | COLHEADER                                  | Output |
| 14  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P12  | COLHEADER                                  | Output |
| 15  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P13  | COLHEADER                                  | Output |
| 16  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P14  | COLHEADER                                  | Output |
| 17  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P15  | COLHEADER                                  | Output |
| 18  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P16  | COLHEADER                                  | Output |
| 19  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P17  | COLHEADER                                  | Output |
| 20  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P18  | COLHEADER                                  | Output |
| 21  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P19  | COLHEADER                                  | Output |
| 22  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P20  | COLHEADER                                  | Output |
| 23  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P21  | COLHEADER                                  | Output |
| 24  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P22  | COLHEADER                                  | Output |
| 25  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P23  | COLHEADER                                  | Output |
| 26  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P24  | COLHEADER                                  | Output |
| 27  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P25  | COLHEADER                                  | Output |
| 28  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P26  | COLHEADER                                  | Output |
| 29  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P27  | COLHEADER                                  | Output |
| 30  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P28  | COLHEADER                                  | Output |
| 31  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P29  | COLHEADER                                  | Output |
| 32  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P30  | COLHEADER                                  | Output |
| 33  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P31  | COLHEADER                                  | Output |
| 34  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P32  | COLHEADER                                  | Output |
| 35  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P33  | COLHEADER                                  | Output |
| 36  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P34  | COLHEADER                                  | Output |
| 37  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P35  | COLHEADER                                  | Output |
| 38  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P36  | COLHEADER                                  | Output |
| 39  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P37  | COLHEADER                                  | Output |
| 40  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P38  | COLHEADER                                  | Output |
| 41  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P39  | COLHEADER                                  | Output |
| 42  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P40  | COLHEADER                                  | Output |
| 43  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P41  | COLHEADER                                  | Output |
| 44  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P42  | COLHEADER                                  | Output |
| 45  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P43  | COLHEADER                                  | Output |
| 46  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P44  | COLHEADER                                  | Output |
| 47  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P45  | COLHEADER                                  | Output |
| 48  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P46  | COLHEADER                                  | Output |
| 49  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P47  | COLHEADER                                  | Output |
| 50  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P48  | COLHEADER                                  | Output |
| 51  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P49  | COLHEADER                                  | Output |
| 52  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P50  | COLHEADER                                  | Output |
| 53  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P51  | COLHEADER                                  | Output |
| 54  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P52  | COLHEADER                                  | Output |
| 55  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P53  | COLHEADER                                  | Output |
| 56  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P54  | COLHEADER                                  | Output |
| 57  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P55  | COLHEADER                                  | Output |
| 58  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P56  | COLHEADER                                  | Output |
| 59  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P57  | COLHEADER                                  | Output |
| 60  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P58  | COLHEADER                                  | Output |
| 61  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P59  | COLHEADER                                  | Output |
| 62  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P60  | COLHEADER                                  | Output |
| 63  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P61  | COLHEADER                                  | Output |
| 64  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P62  | COLHEADER                                  | Output |
| 65  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P63  | COLHEADER                                  | Output |
| 66  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P64  | COLHEADER                                  | Output |
| 67  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P65  | COLHEADER                                  | Output |
| 68  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P66  | COLHEADER                                  | Output |
| 69  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P67  | COLHEADER                                  | Output |
| 70  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P68  | COLHEADER                                  | Output |
| 71  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P69  | COLHEADER                                  | Output |
| 72  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P70  | COLHEADER                                  | Output |
| 73  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P71  | COLHEADER                                  | Output |
| 74  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P72  | COLHEADER                                  | Output |
| 75  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P73  | COLHEADER                                  | Output |
| 76  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P74  | COLHEADER                                  | Output |
| 77  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P75  | COLHEADER                                  | Output |
| 78  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P76  | COLHEADER                                  | Output |
| 79  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P77  | COLHEADER                                  | Output |
| 80  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P78  | COLHEADER                                  | Output |
| 81  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P79  | COLHEADER                                  | Output |
| 82  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P80  | COLHEADER                                  | Output |
| 83  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P81  | COLHEADER                                  | Output |
| 84  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P82  | COLHEADER                                  | Output |
| 85  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P83  | COLHEADER                                  | Output |
| 86  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P84  | COLHEADER                                  | Output |
| 87  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P85  | COLHEADER                                  | Output |
| 88  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P86  | COLHEADER                                  | Output |
| 89  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P87  | COLHEADER                                  | Output |
| 90  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P88  | COLHEADER                                  | Output |
| 91  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P89  | COLHEADER                                  | Output |
| 92  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P90  | COLHEADER                                  | Output |
| 93  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P91  | COLHEADER                                  | Output |
| 94  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P92  | COLHEADER                                  | Output |
| 95  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P93  | COLHEADER                                  | Output |
| 96  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P94  | COLHEADER                                  | Output |
| 97  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P95  | COLHEADER                                  | Output |
| 98  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P96  | COLHEADER                                  | Output |
| 99  |        | chr04  | Table    | Parameter Decision by Term | Estimator_P97  | COLHEADER                                  | Output |
| 100 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P98  | COLHEADER                                  | Output |
| 101 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P99  | COLHEADER                                  | Output |
| 102 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P100 | COLHEADER                                  | Output |
| 103 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P101 | COLHEADER                                  | Output |
| 104 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P102 | COLHEADER                                  | Output |
| 105 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P103 | COLHEADER                                  | Output |
| 106 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P104 | COLHEADER                                  | Output |
| 107 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P105 | COLHEADER                                  | Output |
| 108 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P106 | COLHEADER                                  | Output |
| 109 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P107 | COLHEADER                                  | Output |
| 110 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P108 | COLHEADER                                  | Output |
| 111 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P109 | COLHEADER                                  | Output |
| 112 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P110 | COLHEADER                                  | Output |
| 113 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P111 | COLHEADER                                  | Output |
| 114 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P112 | COLHEADER                                  | Output |
| 115 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P113 | COLHEADER                                  | Output |
| 116 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P114 | COLHEADER                                  | Output |
| 117 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P115 | COLHEADER                                  | Output |
| 118 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P116 | COLHEADER                                  | Output |
| 119 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P117 | COLHEADER                                  | Output |
| 120 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P118 | COLHEADER                                  | Output |
| 121 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P119 | COLHEADER                                  | Output |
| 122 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P120 | COLHEADER                                  | Output |
| 123 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P121 | COLHEADER                                  | Output |
| 124 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P122 | COLHEADER                                  | Output |
| 125 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P123 | COLHEADER                                  | Output |
| 126 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P124 | COLHEADER                                  | Output |
| 127 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P125 | COLHEADER                                  | Output |
| 128 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P126 | COLHEADER                                  | Output |
| 129 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P127 | COLHEADER                                  | Output |
| 130 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P128 | COLHEADER                                  | Output |
| 131 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P129 | COLHEADER                                  | Output |
| 132 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P130 | COLHEADER                                  | Output |
| 133 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P131 | COLHEADER                                  | Output |
| 134 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P132 | COLHEADER                                  | Output |
| 135 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P133 | COLHEADER                                  | Output |
| 136 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P134 | COLHEADER                                  | Output |
| 137 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P135 | COLHEADER                                  | Output |
| 138 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P136 | COLHEADER                                  | Output |
| 139 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P137 | COLHEADER                                  | Output |
| 140 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P138 | COLHEADER                                  | Output |
| 141 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P139 | COLHEADER                                  | Output |
| 142 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P140 | COLHEADER                                  | Output |
| 143 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P141 | COLHEADER                                  | Output |
| 144 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P142 | COLHEADER                                  | Output |
| 145 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P143 | COLHEADER                                  | Output |
| 146 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P144 | COLHEADER                                  | Output |
| 147 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P145 | COLHEADER                                  | Output |
| 148 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P146 | COLHEADER                                  | Output |
| 149 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P147 | COLHEADER                                  | Output |
| 150 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P148 | COLHEADER                                  | Output |
| 151 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P149 | COLHEADER                                  | Output |
| 152 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P150 | COLHEADER                                  | Output |
| 153 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P151 | COLHEADER                                  | Output |
| 154 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P152 | COLHEADER                                  | Output |
| 155 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P153 | COLHEADER                                  | Output |
| 156 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P154 | COLHEADER                                  | Output |
| 157 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P155 | COLHEADER                                  | Output |
| 158 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P156 | COLHEADER                                  | Output |
| 159 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P157 | COLHEADER                                  | Output |
| 160 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P158 | COLHEADER                                  | Output |
| 161 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P159 | COLHEADER                                  | Output |
| 162 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P160 | COLHEADER                                  | Output |
| 163 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P161 | COLHEADER                                  | Output |
| 164 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P162 | COLHEADER                                  | Output |
| 165 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P163 | COLHEADER                                  | Output |
| 166 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P164 | COLHEADER                                  | Output |
| 167 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P165 | COLHEADER                                  | Output |
| 168 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P166 | COLHEADER                                  | Output |
| 169 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P167 | COLHEADER                                  | Output |
| 170 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P168 | COLHEADER                                  | Output |
| 171 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P169 | COLHEADER                                  | Output |
| 172 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P170 | COLHEADER                                  | Output |
| 173 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P171 | COLHEADER                                  | Output |
| 174 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P172 | COLHEADER                                  | Output |
| 175 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P173 | COLHEADER                                  | Output |
| 176 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P174 | COLHEADER                                  | Output |
| 177 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P175 | COLHEADER                                  | Output |
| 178 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P176 | COLHEADER                                  | Output |
| 179 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P177 | COLHEADER                                  | Output |
| 180 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P178 | COLHEADER                                  | Output |
| 181 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P179 | COLHEADER                                  | Output |
| 182 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P180 | COLHEADER                                  | Output |
| 183 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P181 | COLHEADER                                  | Output |
| 184 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P182 | COLHEADER                                  | Output |
| 185 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P183 | COLHEADER                                  | Output |
| 186 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P184 | COLHEADER                                  | Output |
| 187 |        | chr04  | Table    | Parameter Decision by Term | Estimator_P185 | COLHEADER                                  | Output |
| 188 |        | chr04  | Table    | Parameter Decision by Term |                |                                            |        |

## Call Program

The screenshot shows a Notepad++ window with the following R code:

```
htha0dichotomous0ae<-data.frame(
  title = sprintf("Summary of Adverse Events by System Organ Class and Preferred Term | (Incidence > 0% in One or More Treatment Groups) | %s", gsmwr_subpopulation_subtitle ),
  preferred_term = sprintf("%s", gsmwr_apat_subtitle ),
  end_nodes = sprintf("%s", sftb | sftc | sftd | sfother ),
  output_filename = sprintf("%s", gsmwr_subpopulation_subtitle ),
  rename_output = "stnum",
  page_orientation = "P",
  debug = A
)

htha0dichotomous0ae$group_by(title, preferred_term, end_nodes) %>%
  summarize(stnum = sum(stnum))
```

## Macro

[illegible]

## TLF

AutoSave ta\_cib... - Saved Maher-McWilliams, David

File Home Insert Design Layout References Mailings Review View Help Script Lab Acrobat

Paste Font Paragraph Styles Editing Adobe Acrobat Dictate Sensitivity

Classification Clipboard Font Voice Sensitivity

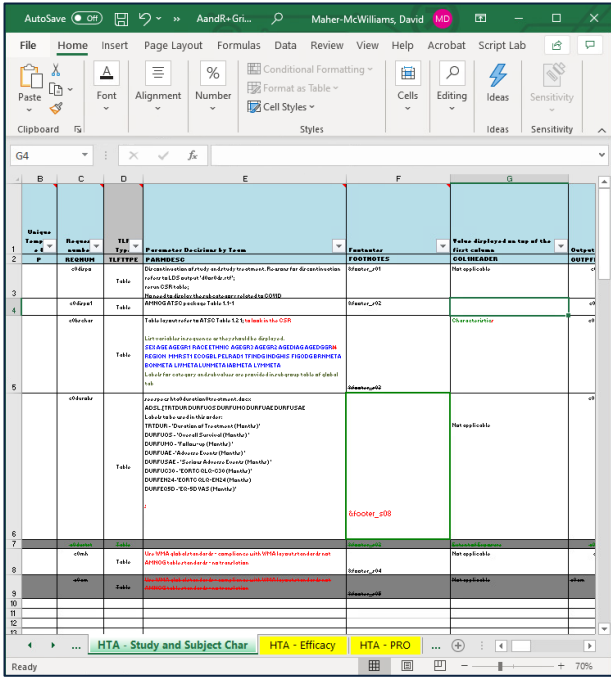
Participant Characteristics  
Population relevant for benefit assessment  
(All-Participants-as-Treated Population)

| Characteristic                            | Study            |                  |
|-------------------------------------------|------------------|------------------|
|                                           | XXXXXXXXXX<br>N= | XXXXXXXXXX<br>N= |
| Sex, n (%)                                |                  |                  |
| Female                                    |                  |                  |
| Age (Years)                               |                  |                  |
| Mean (SD)                                 |                  |                  |
| Median (Q1-Q3)                            |                  |                  |
| Min-Max                                   |                  |                  |
| Age (Years), n (%)                        |                  |                  |
| 7-65                                      |                  |                  |
| ≥ 65                                      |                  |                  |
| Race, n (%)                               |                  |                  |
| American Indian Or Alaska Native          |                  |                  |
| Asian                                     |                  |                  |
| Black Or African American                 |                  |                  |
| Multiple                                  |                  |                  |
| Native Hawaiian Or Other Pacific Islander |                  |                  |
| White                                     |                  |                  |
| Unknown                                   |                  |                  |
| Ethnicity, n (%)                          |                  |                  |
| Hispanic Or Latino                        |                  |                  |
| Not Hispanic Or Latino                    |                  |                  |
| Not Reported                              |                  |                  |
| Unknown                                   |                  |                  |
| Age (Years) Group, n (%)                  |                  |                  |
| 7-75                                      |                  |                  |
| ≥ 75                                      |                  |                  |
| Age (Years), n (%)                        |                  |                  |
| 45-65                                     |                  |                  |
| ≥ 65                                      |                  |                  |

Page 1 of 3 776 words English (United States)

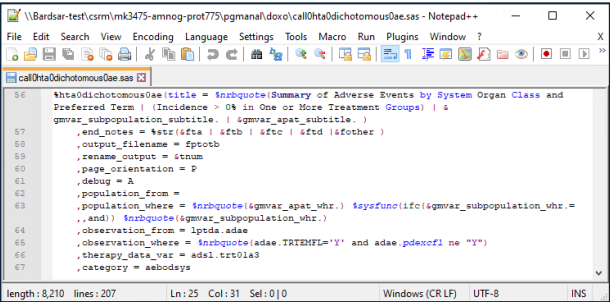
# Reporting Process

## Job Request Document: A&R Grid



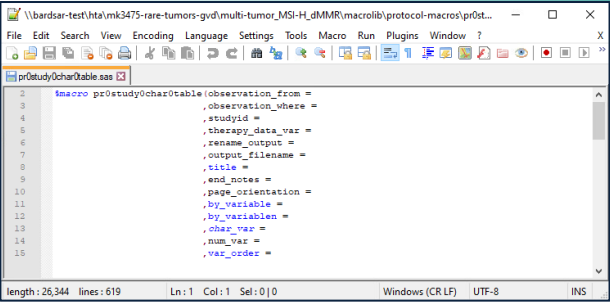
| Study | Request                      | TLF Type                     | Parameter/Decision by Team   | Parameter/Decision by Team   | Parameter/Decision by Team   |
|-------|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| 1     | HTA - Study and Subject Char | HTA - Study and Subject Char | HTA - Study and Subject Char | HTA - Study and Subject Char | HTA - Study and Subject Char |
| 2     | HTA - Efficacy               | HTA - Efficacy               | HTA - Efficacy               | HTA - Efficacy               | HTA - Efficacy               |
| 3     | HTA - PRO                    | HTA - PRO                    | HTA - PRO                    | HTA - PRO                    | HTA - PRO                    |

## Call Program



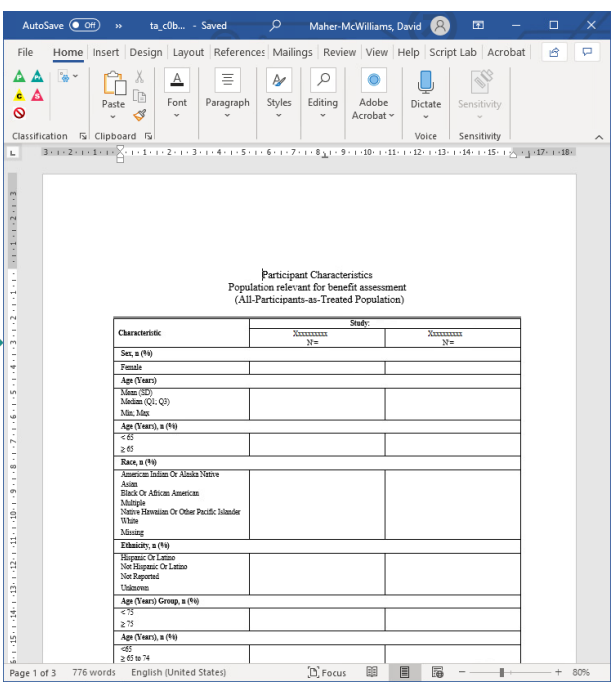
```
htat0dichotomous0ae(title = <tr><td>Summary of Adverse Events by System Organ Class and Preferred Term | (Incidence > 0% in One or More Treatment Groups) | </tr><tr><td>gmvar_subpopulation_subtitle | gmvar_apat_subtitle | </tr><tr><td>end_notes | <tr><td>output_filename | <tr><td>output_output | <tr><td>output_page_orientation | <tr><td>output_debug | <tr><td>output_population_from | <tr><td>output_population_where | <tr><td>output_observation_from | <tr><td>output_observation_where | <tr><td>output_therapy_data_var | <tr><td>output_category | </tr></tr></pre>
```

## Macro



```
pr0study0char0table(observation_from = , observation_where = , studyid = , therapy_data_var = , rename_output = , output_filename = , title = , end_notes = , page_orientation = , by_variable = , by_variable = , char_var = , num_var = , var_order =
```

## TLF



| Characteristic                            | Study | Study |
|-------------------------------------------|-------|-------|
| Sec. a (%)                                | N=    | N=    |
| Female                                    |       |       |
| Age (Years)                               |       |       |
| Age (Years) a (%)                         |       |       |
| Race, a (%)                               |       |       |
| American Indian Or Alaska Native          |       |       |
| Asian                                     |       |       |
| Black Or African American                 |       |       |
| Multiple                                  |       |       |
| Native Hawaiian Or Other Pacific Islander |       |       |
| White                                     |       |       |
| Unknown                                   |       |       |
| Hispanic, a (%)                           |       |       |
| Hispanic Or Latino                        |       |       |
| Not Hispanic Or Latino                    |       |       |
| Not Reported                              |       |       |
| Unknown                                   |       |       |
| Age (Years) Group, a (%)                  |       |       |
| < 15                                      |       |       |
| 15-74                                     |       |       |
| Age (Years), a (%)                        |       |       |
| < 15                                      |       |       |
| 15-74                                     |       |       |

Call Program Generator (CPG) automates this step

# A&R Grid Overview

---

| Tab Name                                                                                                           | Description                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Trial Details                                                                                                      | Overview of Trial details;                                                                                     |
| Global                                                                                                             | Global project conventions; subgroups, populations, subtitles, footnotes, abbreviations                        |
| 4 Outputs tab, split analysis type:<br>HTA – Study and Subject Char<br>HTA – Efficacy<br>HTA – PRO<br>HTA – Safety | One entry (row) per output;<br>Details Titles, Footnotes, Reporting Macro, Call Program name, Output name etc. |
| Issues and Assignments                                                                                             | Detail Project Milestone Assignments and Issues                                                                |

# Call Program Generator

---

## Product

A suite of macros that produce call programs based on Job Request

## Byproduct

During execution of the startup, global macro variables are created based on the project definitions present in the Job Request Document

# Call Program Generator

---

## Does

- Create a call program based on an A&R Grid selection
- Create numerous call programs at once if requested
- Populate macro parameters that are defined in A&R Grid
- Converts special characters to RTF codes for titles & footnotes
- Mask characters SAS interprets in a special way

## Doesn't

- Create fully executable SAS call programs
- Update call programs when A&R grid is updated
- Populate macro specific parameters

# CPG Inputs & Outputs

|    | A                       | B              | C         | D        | E                                                                                                        | F         | G                                          | H              | I                    | J            | K          | L             |
|----|-------------------------|----------------|-----------|----------|----------------------------------------------------------------------------------------------------------|-----------|--------------------------------------------|----------------|----------------------|--------------|------------|---------------|
| 1  | TLF TITLE               | Unique Temp ID | Requester | TLF Type | Parameter Decisions by Team                                                                              | Footnotes | Value displayed on top of the first column | Output File(s) | Reporting macro Name | Call program | Population | Subpopulation |
| 2  | TITLE                   | P              | REQMNM    | TLF TYPE | PARAMDESC                                                                                                | FOOTNOTES | COLHEADER                                  | OUTFILE        | MACRO                | CALLPGM      | POPDESC    | SUBPOPDESC1   |
| 3  | Disposition of Subjects |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Not applicable                             | c0bschar       | Macro01              | call01dpsg   | ITT        |               |
| 4  | Disposition of Subjects |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Not applicable                             | c0bschar       | Macro01              | call01dpsg   | ITT        |               |
| 5  | Subject Characteristics |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Characteristics                            | c0bschar       | Macro01              | call01dpsg   | ITT        |               |
| 6  | Subject Medical History |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Not applicable                             | c0bschar       | Macro01              | call01dpsg   | ITT        |               |
| 7  | Subject Medical History |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Not applicable                             | c0bschar       | Macro01              | call01dpsg   | ITT        |               |
| 8  | Subject Medical History |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Not applicable                             | c0bschar       | Macro01              | call01dpsg   | ITT        |               |
| 9  | Subject Medical History |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Not applicable                             | c0bschar       | Macro01              | call01dpsg   | ITT        |               |
| 10 | Subject Medical History |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Not applicable                             | c0bschar       | Macro01              | call01dpsg   | ITT        |               |
| 11 | Subject Medical History |                | c0bschar  | Table    | Use VMA global standards: compliance with VMA layout standards not AMNOG table standards: no translation |           | Not applicable                             | c0bschar       | Macro01              | call01dpsg   | ITT        |               |

A&R Grid  
TLF Tab

|     | A                                                                                                                                                                                                                                                                    | B               | C                   | D                                       | E         | F                                       | G                                                     | H                                                                                           | I                                    |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------------|-----------------------------------------|-----------|-----------------------------------------|-------------------------------------------------------|---------------------------------------------------------------------------------------------|--------------------------------------|
| 1   | GLOBAL DISCUSSION                                                                                                                                                                                                                                                    |                 |                     |                                         |           |                                         |                                                       |                                                                                             |                                      |
| 2   | NOTE: Errors are global decisions to be used across all tables (unless otherwise noted). These are not listed as "Parameter Decisions by Team" for each table in the Package Deliverables tab, but should be applied to all tables where this information is needed. |                 |                     |                                         |           |                                         |                                                       |                                                                                             |                                      |
| 3   | PACKAGE                                                                                                                                                                                                                                                              | PARAMETER NAME  | ITEM/PARAM INFO     | TEAM DECISION                           | TEXT/NOTE | SUBTITLE                                | POPUL FOOTER                                          | COMMENTS                                                                                    | Population folder                    |
| 4   | POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION      | ASAT                | ASAT.TRFPL.Y                            | TRT01P    | (Intention-to-Treat Population)         | Number of patients: Intention-to-Treat population     | For all EFF tables - time baseline tables - to be used for all comers run                   |                                      |
| 5   | POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION      | ASAT                | ASAT.TRFPL.Y                            | TRT01P    | (AS Subjects-as-Treated Population)     | Number of patients: AS Subjects-as-Treated population | For all Safety (AE) tables - to be used for all comers run                                  |                                      |
| 6   | POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION      | FAS                 | ASAT.FASPL.Y                            | TRT01P    | (Full Analysis Set Population)          | Number of patients: Full Analysis set population      | For all POC Tables - to be used for all comers run                                          |                                      |
| 7   | POPULATION DEFINITION                                                                                                                                                                                                                                                | SUBPOPULATION   | TPS05S              | ASAT.POL1N1                             |           | Subpopulation of Subjects with TPS <50% | with TPS <50%                                         | This subset for the subpopulation should come before the main population file.              | subpopulation05s<br>subpopulation05s |
| 8   | POPULATION DEFINITION                                                                                                                                                                                                                                                | SUBPOPULATION   | TPS10S              | ASAT.POL1N2                             |           | Subpopulation of Subjects with TPS <50% | with TPS <50%                                         | Subpopulation of Subjects with TPS <50% (Intention-to-Treat Population)                     | subpopulation10s<br>subpopulation10s |
| 9   | POPULATION DEFINITION                                                                                                                                                                                                                                                | SUBPOPULATION   | TPS15S              | ASAT.POL1N3                             |           | Subpopulation of Subjects with TPS <50% | with TPS <50%                                         | Subpopulation of Subjects with TPS <50% (Intention-to-Treat Population)                     | subpopulation15s<br>subpopulation15s |
| 10  | HEADERS                                                                                                                                                                                                                                                              | PARAMETER NAME  | ITEM/PARAM INFO     | Treatment display label                 | FOOTNOTE  | COMMENTS                                | INSTRUCTIONS                                          |                                                                                             |                                      |
| 11  | TREATMENT                                                                                                                                                                                                                                                            | Treatment label | TRT01P=1, TRT01AN=1 | Chemotherapy 200mg                      |           |                                         |                                                       | TRT01P is to be used for ITT and FAS population. TRT01AN is to be used for ASAT population. |                                      |
| 12  | TREATMENT                                                                                                                                                                                                                                                            | Treatment label | TRT01P=2, TRT01AN=2 | Chemotherapy                            |           |                                         |                                                       | TRT01P is to be used for ITT and FAS population. TRT01AN is to be used for ASAT population. |                                      |
| 13  | TREATMENT                                                                                                                                                                                                                                                            | Treatment label | TRT01P=3, TRT01AN=3 | Chemotherapy                            |           |                                         |                                                       | TRT01P is to be used for ITT and FAS population. TRT01AN is to be used for ASAT population. |                                      |
| 14  | STUDY                                                                                                                                                                                                                                                                | Study label     | STUDYID             | KEYNOTE XXX                             |           |                                         |                                                       | Format of the data should be: 25FEB2019                                                     |                                      |
| 15  | Category                                                                                                                                                                                                                                                             | MACRO           | TARGET              | Instructions                            |           |                                         |                                                       |                                                                                             |                                      |
| 16  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | SAFETY              | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 17  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | EFFICACY            | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 18  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 19  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 20  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 21  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 22  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 23  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 24  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 25  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 26  | MACRO                                                                                                                                                                                                                                                                | HTAT01P0100     | PRO                 | X axis: Time in Month display 0-10 by 2 |           |                                         |                                                       |                                                                                             |                                      |
| 27  | AS Selection                                                                                                                                                                                                                                                         | PARAMETER NAME  | ITEM/PARAM INFO     | Treatment display label                 | COMMENTS  |                                         |                                                       |                                                                                             |                                      |
| 28  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 29  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 30  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 31  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 32  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 33  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 34  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 35  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 36  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 37  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 38  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 39  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 40  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 41  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 42  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 43  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 44  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 45  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 46  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 47  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 48  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 49  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 50  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 51  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 52  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 53  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 54  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 55  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 56  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 57  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 58  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 59  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 60  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 61  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 62  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 63  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 64  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 65  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 66  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 67  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 68  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 69  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 70  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 71  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 72  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 73  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 74  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 75  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 76  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 77  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 78  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 79  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 80  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 81  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 82  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 83  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 84  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 85  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 86  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 87  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 88  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 89  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 90  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 91  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 92  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 93  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 94  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 95  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 96  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 97  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 98  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 99  | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |
| 100 | AS Selection                                                                                                                                                                                                                                                         | ASAT            | ASAT                | ASAT                                    |           |                                         |                                                       |                                                                                             |                                      |

A&R Grid  
Global Tab

```
%macro reporting0macro(parameter1  
    ,parameter2  
    ,parameter3  
    ,parameter4  
    ,parameter5  
);  
...  
%mend reporting0macro;
```

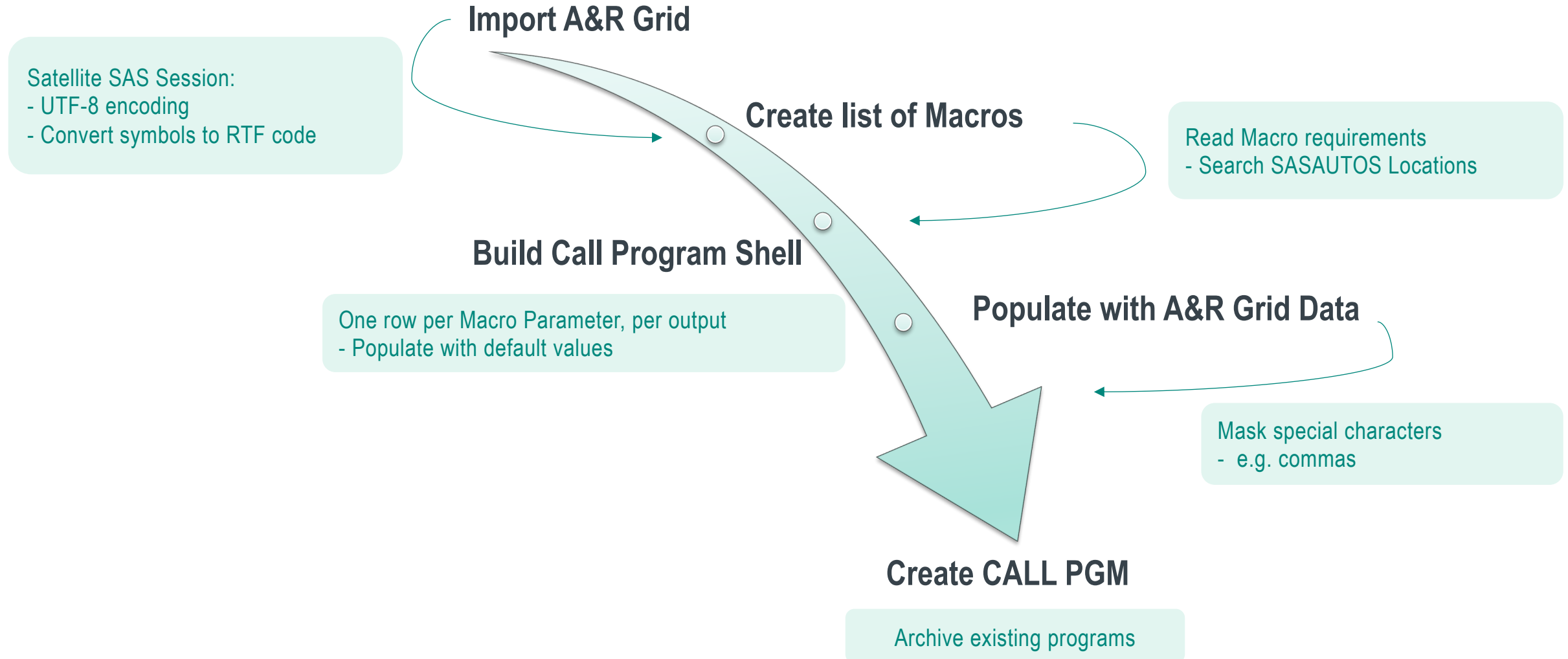
Macro

## Product: Call Program

```
/* REQID: c0bschar  
List variables in sequence as they should be displayed.  
SEX REGION AGEGR1 AGE BSECOG1 STRATIVRS  
Labels for category and subvalues are provided in subgroup table of global tab  
Macro specific notes:  
  
*/  
%hta0baselinechar(population_from=  
    ,population_where=%nrbquote(%gmvar_itt_whr)  
    ,observation_from=  
    ,observation_where=  
    ,therapy_data_var=TRT01P  
    ,rename_output=c0bschar  
    ,output_filename=fptotb  
    ,title=Subject Characteristics(Intention-to-Treat Population)  
    ,end_notes=a: %nrbquote(%gmvar_cutoff) |b: Number of patient..  
    ,page_orientation=p  
    ,first_col_label=Characteristics  
    ,studyid=studyid  
    ,display_totals=  
    ,indata_decode=  
    ,display_variables_label= Gender%str(, ) n (%) | REGION %str(, ) n (%) |  
        Age Group %str(, ) n (%) | Age (Years) | Baseline ECOG %str(, ) n (%) |  
        Strata %str(, ) n (%)  
    ,display_variables= SEX REGION AGEGR1 AGE BSECOG1 STRATAIN  
    ,median_range_decimals= 2  
    ,range_minmax=  
    ,mean_sd_variables= AGE  
    ,mean_sd_decimals= 1  
    ,column_width=  
    ,percent_number_decimals= 2  
    ,pagesize=  
    ,fmt_width=  
    ,median_range_variables= AGE  
    ,debug =A  
);  
  
%-----  
%*- Step 03: Close Proc Printto -*;  
%-----  
  
proc printto;  
run;  
  
%-----  
%*- Step 04: Logchecker -*;  
%-----  
  
%logchecker(input_fileref = fptotlg  
    ,filelist = c0bschar.log  
    ,output_filename = call0c0bschar  
    );  
  
%-----  
%*- END OF PROGRAM:CALL0C0BSCHAR -*;  
%-----
```

# CPG Process

# CPG Process



# CPG Process – Importing A&R Grid

---

# CPG Process – Importing A&R Grid

---

| TLF Title                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Time to Event Analysis for Adverse Events<br>by System Organ Class and Preferred Term<br>(Incidence $\geq$ 10% or (Incidence $\geq$ 1% and in at least 10<br>Participants) in One or More Treatment Groups) |

TLF titles & footnotes regularly contain non-ASCII symbols

# CPG Process – Importing A&R Grid

---

| TLF Title                                                                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Time to Event Analysis for Adverse Events<br>by System Organ Class and Preferred Term<br>(Incidence ≥ 10% or (Incidence ≥ 1% and in at least 10<br>Participants) in One or More Treatment Groups) |

TLF titles & footnotes regularly contain non-ASCII symbols

# CPG Process – Importing A&R Grid



TLF titles & footnotes regularly contain non-ASCII symbols

These **cannot** be represented in latin-1 encoding, but **are** readable in UTF-8 encoding

# CPG Process – Importing A&R Grid



TLF titles & footnotes regularly contain non-ASCII symbols

These **cannot** be represented in latin-1 encoding, but **are** readable in UTF-8 encoding

However, analysis programs must ultimately be executed in a latin-1 environment

# CPG Process – Importing A&R Grid



TLF titles & footnotes regularly contain non-ASCII symbols

These **cannot** be represented in latin-1 encoding, but **are** readable in UTF-8 encoding

However, analysis programs must ultimately be executed in a latin-1 environment

The solution? A UTF-8 satellite SAS session to convert non-ASCII symbols to RTF text codes

# CPG Process – Importing A&R Grid

---

# CPG Process – Importing A&R Grid

---

CPG Primary session: latin-1 Encoding

# CPG Process – Importing A&R Grid

---

CPG Primary session: latin-1 Encoding

# CPG Process – Importing A&R Grid

---

CPG Primary session: latin-1 Encoding

1. Proc OPTSAVE used to save session options to dataset

# CPG Process – Importing A&R Grid

---

## CPG Primary session: latin-1 Encoding

1. Proc OPTSAVE used to save session options to dataset
2. Supporting macro u0batch93 is called which creates satellite session

# CPG Process – Importing A&R Grid

---

CPG Primary session: latin-1 Encoding

1. Proc OPTSAVE used to save session options to dataset
2. Supporting macro u0batch93 is called which creates satellite session

Satellite session: UTF-8 Encoding



# CPG Process – Importing A&R Grid

---

## CPG Primary session: latin-1 Encoding

1. Proc OPTSAVE used to save session options to dataset
2. Supporting macro u0batch93 is called which creates satellite session

### Satellite session: UTF-8 Encoding

1. Proc OPTLOAD used to retrieve options from primary session

# CPG Process – Importing A&R Grid

---

## CPG Primary session: latin-1 Encoding

1. Proc OPTSAVE used to save session options to dataset
2. Supporting macro u0batch93 is called which creates satellite session

### Satellite session: UTF-8 Encoding

1. Proc OPTLOAD used to retrieve options from primary session
2. A&R Grid imported and non-ASCII symbols converted to macro variable references aligned with standardised reporting macros

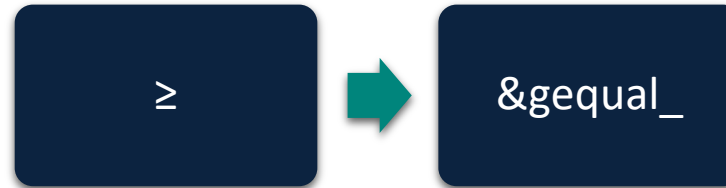
# CPG Process – Importing A&R Grid

## CPG Primary session: latin-1 Encoding

1. Proc OPTSAVE used to save session options to dataset
2. Supporting macro u0batch93 is called which creates satellite session

### Satellite session: UTF-8 Encoding

1. Proc OPTLOAD used to retrieve options from primary session
2. A&R Grid imported and non-ASCII symbols converted to macro variable references aligned with standardised reporting macros



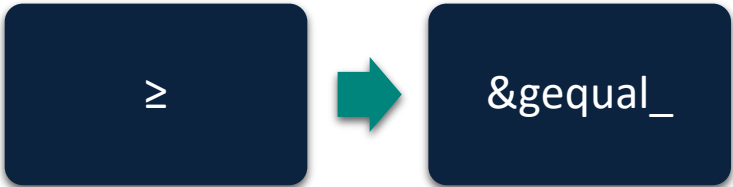
# CPG Process – Importing A&R Grid

## CPG Primary session: latin-1 Encoding

- 1. Proc OPTSAVE used to save session options to dataset
- 2. Supporting macro u0batch93 is called which creates satellite session

### Satellite session: UTF-8 Encoding

- 1. Proc OPTLOAD used to retrieve options from primary session
- 2. A&R Grid imported and non-ASCII symbols converted to macro variable references aligned with standardised reporting macros



- 3. Converted A&R Grid information used to populate template macro call

|   | TITLES                                                                                                                                                                                                                    |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Time to Event Analysis for Adverse Events By System Organ Class and Preferred Term(Incidence <u>&amp;gequal</u> 10% or (Incidence <u>&amp;gequal</u> 1% and in at least 10 Participants) in One or More Treatment Groups) |

# CPG Process – Populating Template Macro Call

---

# CPG Process – Populating Template Macro Call

---

CPG was originally designed to accommodate one output per row in the A&R Grid

This enabled a one-to-one mapping of information from the A&R Grid to macro parameters

# CPG Process – Populating Template Macro Call

CPG was originally designed to accommodate one output per row in the A&R Grid

This enabled a one-to-one mapping of information from the A&R Grid to macro parameters

| TLF Title                                       | Unique Template # | Request number | TLF Type | Parameter Decisions by Team | Footnotes                                                               | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename    | Reporting macro Name | Call program   | Population |
|-------------------------------------------------|-------------------|----------------|----------|-----------------------------|-------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------|----------------------|----------------|------------|
| Analysis of Progression-Free Survival in months |                   | demo           | Table    | ADTTE.PARAMCD="PFSIRC"      | x: &endnotes_km<br>x: &endnotes_Time2cox<br>x: &endnotes_time2wald0test | Progression-Free Survival                                                         | example_tte_output | hta0time2            | call0hta0time2 | ITT        |

1

2

3

4

5

# CPG Process – Populating Template Macro Call

CPG was originally designed to accommodate one output per row in the A&R Grid

This enabled a one-to-one mapping of information from the A&R Grid to macro parameters

| TLF Title                                       | Unique Template # | Request number | TLF Type | Parameter Decisions by Team | Footnotes                                                               | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename    | Reporting macro Name | Call program   | Population |
|-------------------------------------------------|-------------------|----------------|----------|-----------------------------|-------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------|----------------------|----------------|------------|
| Analysis of Progression-Free Survival in months |                   | demo           | Table    | ADTTE.PARAMCD="PFSIRC"      | x: &endnotes_km<br>x: &endnotes_Time2cox<br>x: &endnotes_time2wald0test | Progression-Free Survival                                                         | example_tte_output | hta0time2            | call0hta0time2 | ITT        |

1

2

3

4

5

```
%hta0time2(population_from=  
,population_where=%nrquote(&gmvar_itt_whr)  
,observation_from=  
,observation_where=  
,therapy_data_var=ADSL.TRT71P  
,rename_output=example_tte_output  
,output_filename=fptotb  
,title=Analysis of Progression-Free Survival in months|&nrquote(&gmvar_itt_subtitle)  
,column_width=  
,end_notes=a: &nrquote(&gmvar_cutoff) |b: &nrquote(&gmvar_itt_footer) |c: &nrquote(&gmvar_endnotes_km)  
|d: &nrquote(&gmvar_endnotes_Time2cox) |e: &nrquote(&gmvar_endnotes_time2wald0test)  
,page_orientation=p  
,endpoint_label=Progression-Free Survival  
,studyid=STUDYID  
,reference_therapy_data_varn=  
,maxiter=  
,gconv=  
,debug =A);
```

# CPG Process – Populating Atypical Template Macro Calls

---

# CPG Process – Populating Atypical Template Macro Calls

---

Some macros dynamically create outputs based on the data (such as subgroup interaction tests)

# CPG Process – Populating Atypical Template Macro Calls

Some macros dynamically create outputs based on the data (such as subgroup interaction tests)

While created by a single macro call, these are transcribed in the A&R Grid across two rows to allow title & footnote pairs for each type of output

| TLF Title                                                                                                                                         | <a href="#">Unique Template #</a> | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename             | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2                       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0nsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os                 | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>$< 0.05$                                             | Figure 6.1 1                      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr | hta0plot0km0sub      | call0e0sg0tte | ITT        |

# CPG Process – Populating Atypical Template Macro Calls

Some macros dynamically create outputs based on the data (such as subgroup interaction tests)

While created by a single macro call, these are transcribed in the A&R Grid across two rows to allow title & footnote pairs for each type of output

| TLF Title                                                                                                                                         | <a href="#">Unique Template #</a> | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename             | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2                       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0nsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os                 | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>$< 0.05$                                             | Figure 6.1 1                      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr | hta0plot0km0sub      | call0e0sg0tte | ITT        |

Some enhancements to CPG were needed to account for this scenario, three objectives were outlined:

# CPG Process – Populating Atypical Template Macro Calls

Some macros dynamically create outputs based on the data (such as subgroup interaction tests)

While created by a single macro call, these are transcribed in the A&R Grid across two rows to allow title & footnote pairs for each type of output

| TLF Title                                                                                                                                         | <a href="#">Unique Template #</a> | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename             | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2                       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0nsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os                 | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>$< 0.05$                                             | Figure 6.1 1                      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr | hta0plot0km0sub      | call0e0sg0tte | ITT        |

Some enhancements to CPG were needed to account for this scenario, three objectives were outlined:

1. Identify rows from the A&R Grid related to supplementary outputs

# CPG Process – Populating Atypical Template Macro Calls

Some macros dynamically create outputs based on the data (such as subgroup interaction tests)

While created by a single macro call, these are transcribed in the A&R Grid across two rows to allow title & footnote pairs for each type of output

| TLF Title                                                                                                                                         | <a href="#">Unique Template #</a> | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename                              | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|----------------------------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2                       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0nsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os<br>↑                             | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>$< 0.05$                                             | Figure 6.1 1                      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr<br>↑     ↑     ↑ | hta0plot0km0sub      | call0e0sg0tte | ITT        |

Some enhancements to CPG were needed to account for this scenario, three objectives were outlined:

1. Identify rows from the A&R Grid related to supplementary outputs

There is a standard naming convention for these outputs: [primary table name][subgroup name][selgr]

# CPG Process – Populating Atypical Template Macro Calls

Some macros dynamically create outputs based on the data (such as subgroup interaction tests)

While created by a single macro call, these are transcribed in the A&R Grid across two rows to allow title & footnote pairs for each type of output

| TLF Title                                                                                                                                         | Unique Template # | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename                            | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0nsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os<br>↑                           | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>$< 0.05$                                             | Figure 6.1 1      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr<br>↑    ↑    ↑ | hta0plot0km0sub      | call0e0sg0tte | ITT        |

Some enhancements to CPG were needed to account for this scenario, three objectives were outlined:

1. Identify rows from the A&R Grid related to supplementary outputs

There is a standard naming convention for these outputs: [primary table name][subgroup name][selgr]

2. Do not generate template macro calls for supplementary outputs

# CPG Process – Populating Atypical Template Macro Calls

Some macros dynamically create outputs based on the data (such as subgroup interaction tests)

While created by a single macro call, these are transcribed in the A&R Grid across two rows to allow title & footnote pairs for each type of output

| TLF Title                                                                                                                                         | Unique Template # | Request number | TLF Type | Parameter Decisions by Team                                                                                                                | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename                            | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------|----------|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0sel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os<br>↑                           | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>$< 0.05$                                             | Figure 6.1 1      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                             |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr<br>↑    ↑    ↑ | hta0plot0km0sub      | call0e0sg0tte | ITT        |

Some enhancements to CPG were needed to account for this scenario, three objectives were outlined:

1. Identify rows from the A&R Grid related to supplementary outputs

There is a standard naming convention for these outputs: [primary table name][subgroup name][selgr]

2. Do not generate template macro calls for supplementary outputs

Once #1 is complete, it is simple to programmatically filter out records

# CPG Process – Populating Atypical Template Macro Calls

Some macros dynamically create outputs based on the data (such as subgroup interaction tests)

While created by a single macro call, these are transcribed in the A&R Grid across two rows to allow title & footnote pairs for each type of output

| TLF Title                                                                                                                                         | Unique Template # | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename                            | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0tsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os<br>↑                           | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>$< 0.05$                                             | Figure 6.1 1      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr<br>↑    ↑    ↑ | hta0plot0km0sub      | call0e0sg0tte | ITT        |

Some enhancements to CPG were needed to account for this scenario, three objectives were outlined:

1. Identify rows from the A&R Grid related to supplementary outputs

There is a standard naming convention for these outputs: [primary table name][subgroup name][selgr]

2. Do not generate template macro calls for supplementary outputs

Once #1 is complete, it is simple to programmatically filter out records

3. Retrieve titles & footnotes from supplementary output records and assign values to the correct parameters in the primary output macro call

# CPG Process – Populating Atypical Template Macro Calls

| TLF Title                                                                                                                                         | Unique Template # | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename             | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0nsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os                 | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>< 0.05                                               | Figure 6.1 1      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr | hta0plot0km0sub      | call0e0sg0tte | ITT        |

3. Retrieve titles & footnotes from supplementary output records and assign values to the correct parameters in the primary output macro call

# CPG Process – Populating Atypical Template Macro Calls

| TLF Title                                                                                                                                         | Unique Template # | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename             | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0nsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os                 | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>< 0.05                                               | Figure 6.1 1      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr | hta0plot0km0sub      | call0e0sg0tte | ITT        |

3. Retrieve titles & footnotes from supplementary output records and assign values to the correct parameters in the primary output macro call

The naming convention is used to dynamically create a hash object containing the title & footnotes for the supplementary output

```
dcl hash sel(dataset:catt("__master5 (keep = regnum outfile titles collheader"
                           , " rename = (outfile=sel_outfile titles=g_titles
                                         collheader=g_footnotes)"
                           , " where = (sel_outfile^=", quote(strip(outfile)),
                                         " and index(sel_outfile," , quote(strip(outfile)), ") > 0"
                                         , "and substr(sel_outfile,length(sel_outfile)-4)='selgr'))"
                           ));
sel.defineKey("regnum");
sel.defineData(all:"yes");
sel.defineDone();

if parameter = 'title_graph' then do;
  order=13;
  rc = sel.find();
  if rc=0 then do;
    value=g_titles;
    exclusion_list = catx('|',exclusion_list,sel_outfile);
  end;
end;
else do;
  order=14;
  rc = sel.find();
  if rc=0 then do;
    value=g_footnotes;
    exclusion_list = catx('|',exclusion_list,sel_outfile);
  end;
end;
end;
```

# CPG Process – Populating Atypical Template Macro Calls

| TLF Title                                                                                                                                         | Unique Template # | Request number | TLF Type | Parameter Decisions by Team                                                                                                                 | Footnotes                                                                                              | Value displayed on top of the first column (&endpoint_label) or footnote on graph | Output Filename             | Reporting macro Name | Call program  | Population |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------|----------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------|----------------------|---------------|------------|
| Analysis of Overall Survival for Subgroups<br><With P-value for Interaction test $\geq 0.05$ ><br>/ <With P-value for Interaction test $< 0.05$ > | Table 6.1-2       | e0sg0tte       | Table    | ADTTE.PARAMCD="OS"<br>Macro create 3 tables &rename_output,<br>&rename_output.0nsel, &rename_output.0sel<br>subgroups defined in global tab | &endnotes_km<br>&endnotes_Time2cox0subgroup<br>&endnotes_time2wald0test<br>&endnotes_Time2cox0subgroup | Overall Survival                                                                  | e0sg0tte0os                 | hta0time20sub        | call0e0sg0tte | ITT        |
| Kaplan Meier Curves of Overall Survival<br>by Subgroups With P-value for Interaction test<br>< 0.05                                               | Figure 6.1 1      | e0sg0tte       | Figure   | Triggered by hta0time20sub of e0sg0tte0os0sel -<br>A&Rgrid row ignored by Call Program Generator (CPG)<br>tool                              |                                                                                                        | Mortality                                                                         | e0sg0tte0os0@subgroup@selgr | hta0plot0km0sub      | call0e0sg0tte | ITT        |

3. Retrieve titles & footnotes from supplementary output records and assign values to the correct parameters in the primary output macro call

The naming convention is used to dynamically create a hash object containing the title & footnotes for the supplementary output

This method was selected because it neatly integrated into the data step that was already present in the code

```
dcl hash sel(dataset:catt("__master5 (keep = regnum outfile titles collheader"
                           ", " rename = (outfile=sel_outfile titles=g_titles
                                           collheader=g_footnotes) "
                           ", " where = (sel_outfile^=",quote(strip(outfile)),
                                           " and index(sel_outfile,"",quote(strip(outfile)),") > 0"
                                           , "and substr(sel_outfile,length(sel_outfile)-4)='selgr'))"
                           ));
sel.defineKey("regnum");
sel.defineData(all:"yes");
sel.defineDone();

if parameter = 'title_graph' then do;
  order=13;
  rc = sel.find();
  if rc=0 then do;
    value=g_titles;
    exclusion_list = catx('|',exclusion_list,sel_outfile);
  end;
end;
else do;
  order=14;
  rc = sel.find();
  if rc=0 then do;
    value=g_footnotes;
    exclusion_list = catx('|',exclusion_list,sel_outfile);
  end;
end;
end;
```

# CPG Byproduct – Metadata driven macro variables

---

# CPG Byproduct – Metadata driven macro variables

---

During the development of CPG, it was noticed that information from the A&R Grid could be stored as macro variables

# CPG Byproduct – Metadata driven macro variables

---

During the development of CPG, it was noticed that information from the A&R Grid could be stored as macro variables

A call to the macro which imported the A&R Grid was added to the default startup/autoexec program to be executed each time SAS is opened

# CPG Byproduct – Metadata driven macro variables

During the development of CPG, it was noticed that information from the A&R Grid could be stored as macro variables

A call to the macro which imported the A&R Grid was added to the default startup/autoexec program to be executed each time SAS is opened

- Project-wide macro variables:
- Patient population information
  - Subtitles
  - Footnotes
  - Data selection criteria

| GLOBAL DISCUSSION                                                                                                                                                                                                                                                    |                |                |                 |                    |                                          |                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------|-----------------|--------------------|------------------------------------------|-----------------------------------------------------|
| NOTE: Entries are global decisions to be used across all tables (unless otherwise noted). These are not listed as "Parameter Decisions by Team" for each table in the Package Deliverables tab but should be applied to all tables where this information is needed. |                |                |                 |                    |                                          |                                                     |
| TOPIC                                                                                                                                                                                                                                                                | CATEGORY       | PARAMETER_NAME | VALUE           | TREATMENTVARIABLE  | SUBTITLE                                 | POPN_FOOTER                                         |
| PACKAGE                                                                                                                                                                                                                                                              | PARAMETER_NAME | ITEM/PARM INFO | TEAM DECISION   | TREATMENT VARIABLE | SUBTITLE                                 | POPN_FOOTER                                         |
| POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION     | ITT            | ADSL.ITTFL="Y"  | TRT71P             | (Intention-to-Treat Population)          | Number of participants: intention-to-treat          |
| POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION     | APaT           | ADSL.TRTFL="Y"  | TRT71A             | (All-Participants-as-Treated Population) | Number of participants: all-participants-as-treated |
| POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION     | FAS            | ADPRO.PROFL="Y" | TRT71P             | (Full-Analysis-Set Population)           | Number of participants: full-analysis-set           |

# CPG Byproduct – Metadata driven macro variables

During the development of CPG, it was noticed that information from the A&R Grid could be stored as macro variables

A call to the macro which imported the A&R Grid was added to the default startup/autoexec program to be executed each time SAS is opened

- Project-wide macro variables:
- Patient population information
  - Subtitles
  - Footnotes
  - Data selection criteria

- Output specific macro variables:
- Footnotes

| GLOBAL DISCUSSION                                                                                                                                                                                                                                                    |                |                |                 |                    |                                          |                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------|-----------------|--------------------|------------------------------------------|-----------------------------------------------------|
| NOTE: Entries are global decisions to be used across all tables (unless otherwise noted). These are not listed as "Parameter Decisions by Team" for each table in the Package Deliverables tab but should be applied to all tables where this information is needed. |                |                |                 |                    |                                          |                                                     |
| TOPIC                                                                                                                                                                                                                                                                | CATEGORY       | PARAMETER_NAME | VALUE           | TREATMENTVARIABLE  | SUBTITLE                                 | POPN_FOOTER                                         |
| PACKAGE                                                                                                                                                                                                                                                              | PARAMETER NAME | ITEM/PARM INFO | TEAM DECISION   | TREATMENT VARIABLE | SUBTITLE                                 | POPN_FOOTER                                         |
| POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION     | ITT            | ADSL.ITTFL="Y"  | TRT71P             | (Intention-to-Treat Population)          | Number of participants: intention-to-treat          |
| POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION     | APaT           | ADSL.TRTFL="Y"  | TRT71A             | (All-Participants-as-Treated Population) | Number of participants: all-participants-as-treated |
| POPULATION DEFINITION                                                                                                                                                                                                                                                | POPULATION     | FAS            | ADPRO.PROFL="Y" | TRT71P             | (Full-Analysis-Set Population)           | Number of participants: full-analysis-set           |

| FOOTNOTES | PARAMETER NAME                     | Macro parameter footnote    | Footnote value                                                                                                                                              | scope   |
|-----------|------------------------------------|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| FOOTNOTES | Table 3.1 1                        | &endnotes_KM                | x: From product-limit (Kaplan-Meier) method for censored data                                                                                               | eff/pro |
| FOOTNOTES | Table 3.1 1                        | &endnotes_Time2cox          | Based on Cox regression model with treatment as a covariate stratified by <stratification factors>                                                          | eff/pro |
| FOOTNOTES | Table 3.1 1-f<br>Table 5.1 2-e     | &endnotes_time2wald0test    | Two-sided p-value using Wald test (Score test in case of zero event in one treatment group)                                                                 | eff/pro |
| FOOTNOTES | Table 6.1 2 eff<br>Table 5.1 1 pro | &endnotes_Time2cox0subgroup | Based on Cox model with treatment and subgroup as covariates, and treatment-by-subgroup interaction (p-value of likelihood ratio test for interaction term) | eff/pro |
| FOOTNOTES | Table 4.1 1-d                      | &endnotes_rr0wald0test      | Two-sided p-value based on Wald test                                                                                                                        | eff     |

# Conclusion

## Result & Impact

---

Increased quality of outputs

Less comments received by stakeholders

Reduced time required to produce an analysis request

# Future Development

---

## Create a more dynamic link between Call Programs & Request Form

- Implement “refresh” functionality to update call programs in event of A&R Grid update

## Leverage on information from previous analyses

- Look for correlation between keywords from A&R Grid and analysis-specific information manually entered to predict suitable values and increase proportion of parameter values which are populated at initial call program generation
- Assess suitability of default parameter values based on how frequently they are modified when the macros are called

## Improve user experience

- Increase number of programmatically identified issues within the A&R Grid (minor typos etc.) and generate specific suggestions for corrective action

# Questions



# Thank you

**MSD**

**Tel:** 01234 567 890

**E-mail:** [david.maher-mcwilliams@msd.com](mailto:david.maher-mcwilliams@msd.com), [michael.allie@msd.com](mailto:michael.allie@msd.com), [carl\\_herremans@merck.com](mailto:carl_herremans@merck.com)

**Address:** HTA BARDS, MSD

Copyright © 2022 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.