

Review 100 Tables  
in 1 Day???

| Most Common Treatment Emergent Adverse Events Reported in 10% or more subjects in any treatment group for Safety Set Population |                            |                         |                         |
|---------------------------------------------------------------------------------------------------------------------------------|----------------------------|-------------------------|-------------------------|
| Preferred term                                                                                                                  | Placebo<br>Subjects (N=30) | TrtA<br>Subjects (N=28) | TrtB<br>Subjects (N=20) |
| Subjects with any events                                                                                                        | 20 ( 66.7)                 | 15 ( 53.6)              | 15 ( 75.0)              |
| Alanine aminotransferase increased                                                                                              | 1 ( 3.4)                   | 1 ( 3.6)                | 4 ( 20.0)               |
| Arthralgia                                                                                                                      | 4 ( 13.4)                  | 0                       | 1 ( 5.0)                |
| Headache                                                                                                                        | 1 ( 3.4)                   | 2 ( 7.2)                | 4 ( 20.0)               |
| Multiple sclerosis relapse                                                                                                      | 3 ( 10.0)                  | 3 ( 10.8)               | 1 ( 5.0)                |
| Nasopharyngitis                                                                                                                 | 2 ( 6.7)                   | 2 ( 7.2)                | 1 ( 5.0)                |
| Urinary tract infection                                                                                                         | 3 ( 10.0)                  | 3 ( 10.8)               | 2 ( 10.0)               |

D:\Study123\Development\Primary\Tables\programs\T\_ae\_mc10.sas  
Dictionary Coding: MedDRA version 13.0  
Preferred terms are sorted alphabetically.  
A subject with multiple occurrences of an AE under one treatment is counted only once in the AE category a  
Adverse events recorded during follow-up period are not included

Table Review Tool

Report Inspector Tool

Input File(s) Path

Output File Path

☐ Formatting Checks ☐ Value Checks

TOOL BENEFITS

- Review Process Easier
- Saves Time
- Provide Additional Time For Complex Checks

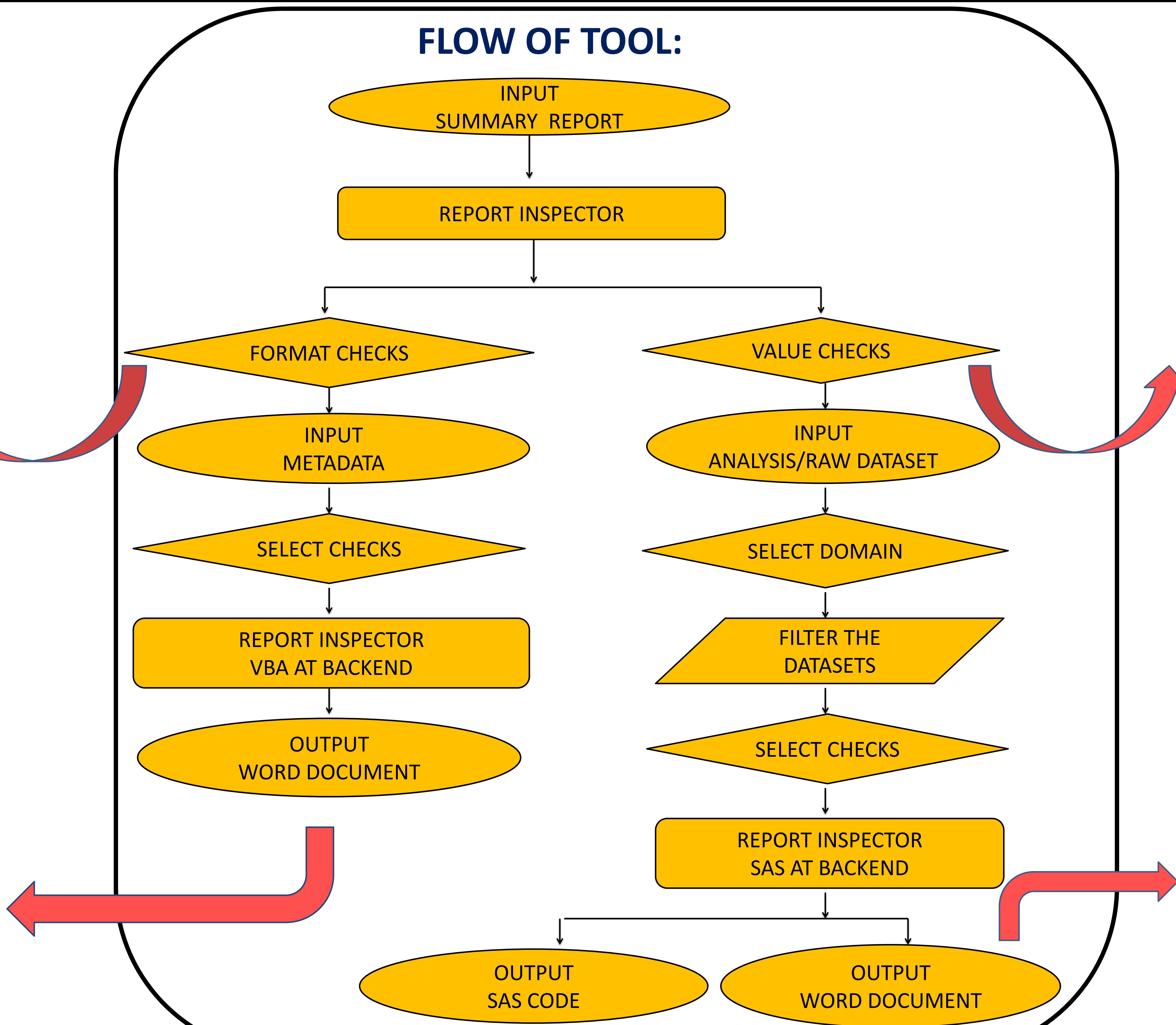
LIST OF FORMAT CHECKS IN TOOL:

1. Spell Check
2. Blank Page
3. Page Size
4. Page Number
5. Decimal Precision
6. Full Stop After Each Footnote
7. Title Case
8. Header Case
9. Line Size
10. Zero Display
11. Footnote Truncation
12. Font Checks

FORMAT CHECK OUTPUT FROM TOOL :

| No. | Checks                   | Output                                      |
|-----|--------------------------|---------------------------------------------|
| 1   | Footnote Truncation      | <b>Footnote 4</b> is Truncated              |
| 2   | Full Stop After Footnote | Full-Stop Not Present For <b>Footnote 5</b> |
| 3   | Blank Page               | Blank Page : <b>Page Number 3</b>           |

FLOW OF TOOL:



LIST OF VALUE CHECKS IN TOOL (AE Domain):

1. Total Adds To All Treatments (N)
2. Ascending Order Of Preferred Terms
3. #Subjects Having Any AEs Not Exceeding “N”
4. Per Column Counts Of PTs >= Counts of SOC's
5. Check On Most Common Treatment Emergent Adverse Event
6. #Subject/Events Under All Arms Add Up To “Total Column”
7. Cross Check The Counts Across Two Tables

VALUE CHECK OUTPUT FROM TOOL :

| Sr.No. | Checks                                              | Output                                                                             |
|--------|-----------------------------------------------------|------------------------------------------------------------------------------------|
| 1      | Preferred Term less Than 10% in Any Treatment Group | Preferred Terms With Less Than 10% in Any Treatment Group : <b>Nasopharyngitis</b> |

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