

## **SM11: Methods of a Fully Automated CONSORT Diagram Macro**

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# Methods of a Fully Automated CONSORT Diagram Macro

Jeffrey Meyers

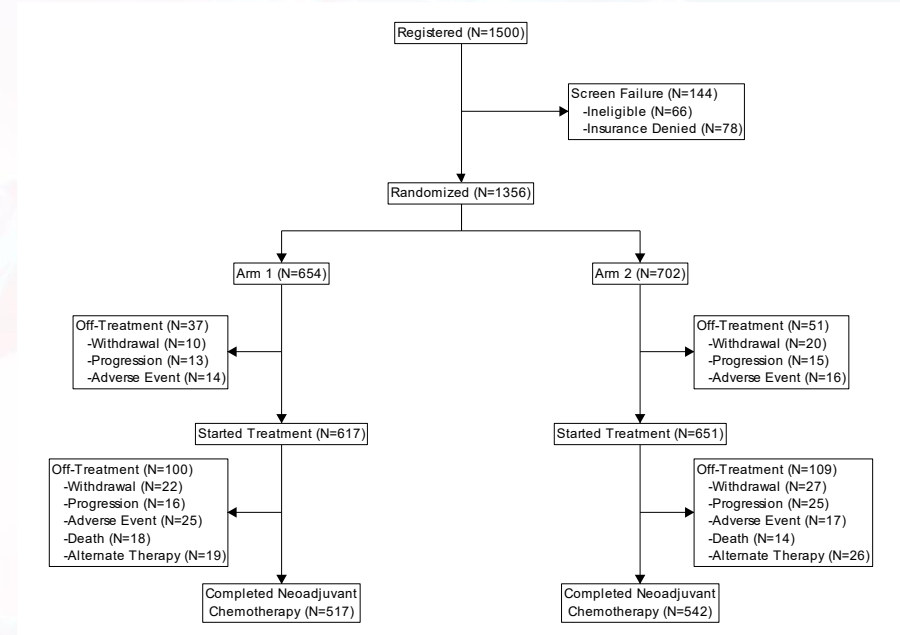
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# Contents

- What is a CONSORT diagram?
- %CONSORT macro features and functionality
- Graphic space and elements setup
- Automation methods

# What is a CONSORT Diagram

- Flow diagram to detail and display the paths that participants take throughout a clinical trial
- Consists of “Nodes” for key clinical trial events such as registration and randomization



# Why Automate

- CONSORT diagrams are very tedious to create manually using software such as Microsoft Visio
- Typically required for publishing final study manuscripts
- Requires calculating and manually entering counts for each node
  - Potential for errors
  - Updating the figure requires manually updating all numbers

# %CONSORT Introduction

- Fully automates creating the CONSORT diagram with user input data
  - Calculates numbers, creates and fills in textboxes, aligns textboxes, and draws connecting lines
- Multiple options for customizing font size/color, textbox outline/fill colors, tweaking alignment, adding annotation

# **%CONSORT Introduction: Required Input**

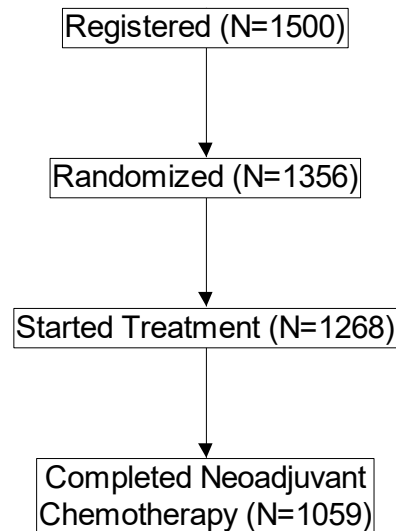
- DATA: input data set name
- ID: variable for unique patient identifier.
  - Only one row-per-patient is allowed in the input data set
- NODE: One or more variables that represent a node of the CONSORT
  - Variables serve two purposes:
    - Acting as a logical operator (missing/non-missing) and
    - Contains the value that will be listed in the textbox
  - Order that variables are listed left-to-right will be printed top-to-bottom in the CONSORT

# %CONSORT Introduction: Example Data Set

| id | Treatment Arm | Sex    | Smoking Status | Screen Failure | reg        | rand       | treated           | neo                                | rt                       | surg              | adj                      | comp                  | Off-Treatment |
|----|---------------|--------|----------------|----------------|------------|------------|-------------------|------------------------------------|--------------------------|-------------------|--------------------------|-----------------------|---------------|
| 1  | Arm 1         | Female | Former         |                | Registered | Randomized | Started Treatment | Completed Neoadjuvant~Chemotherapy |                          | Completed Surgery | Started Adjuvant Therapy | Completed All Therapy |               |
| 2  | Arm 2         | Male   | Current        |                | Registered | Randomized | Started Treatment | Completed Neoadjuvant~Chemotherapy | Completed Neoadjuvant RT | Completed Surgery | Started Adjuvant Therapy | Completed All Therapy |               |
| 3  | Arm 1         | Female | Current        |                | Registered | Randomized | Started Treatment | Completed Neoadjuvant~Chemotherapy |                          | Completed Surgery | Started Adjuvant Therapy |                       | Withdrawal    |
| 4  | Arm 2         | Male   | Current        |                | Registered | Randomized | Started Treatment | Completed Neoadjuvant~Chemotherapy | Completed Neoadjuvant RT | Completed Surgery | Started Adjuvant Therapy | Completed All Therapy |               |
| 5  | Arm 2         | Male   | Current        |                | Registered | Randomized | Started Treatment | Completed Neoadjuvant~Chemotherapy | Completed Neoadjuvant RT | Completed Surgery | Started Adjuvant Therapy | Completed All Therapy |               |

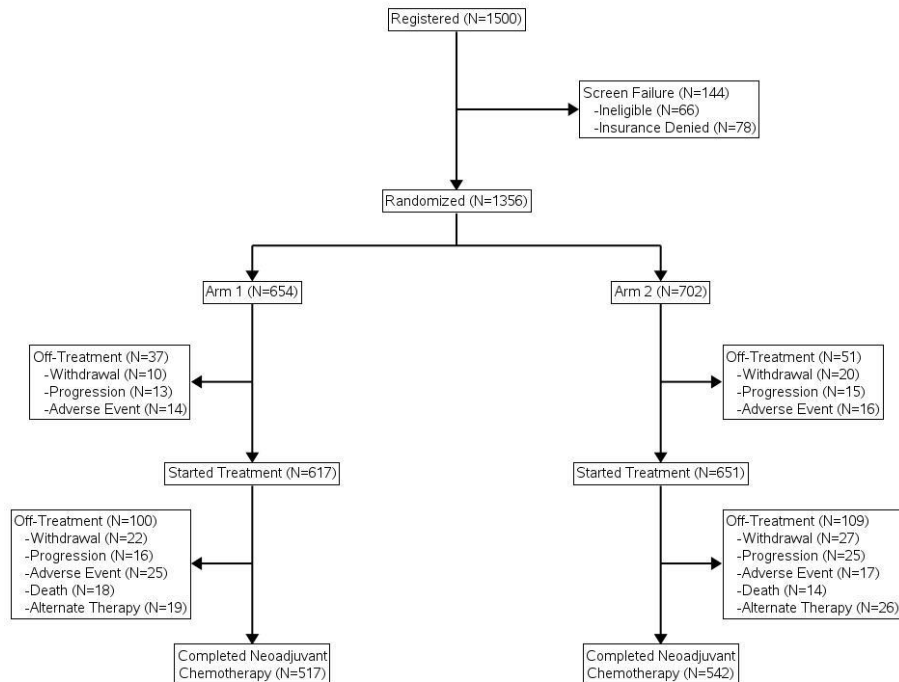
# %CONSORT Introduction: Basic Example

```
%CONSORT (DATA=EXAMPLE  
, ID=ID  
, NODE=REG RAND TREATED NEO  
)
```

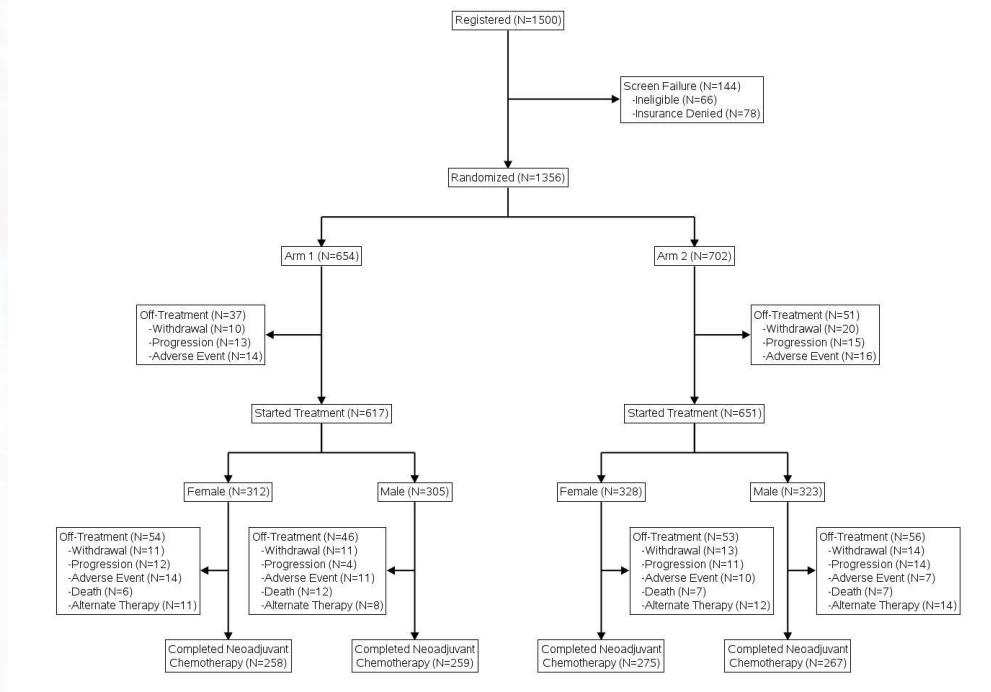


# %CONSORT Introduction: Basic Example 2

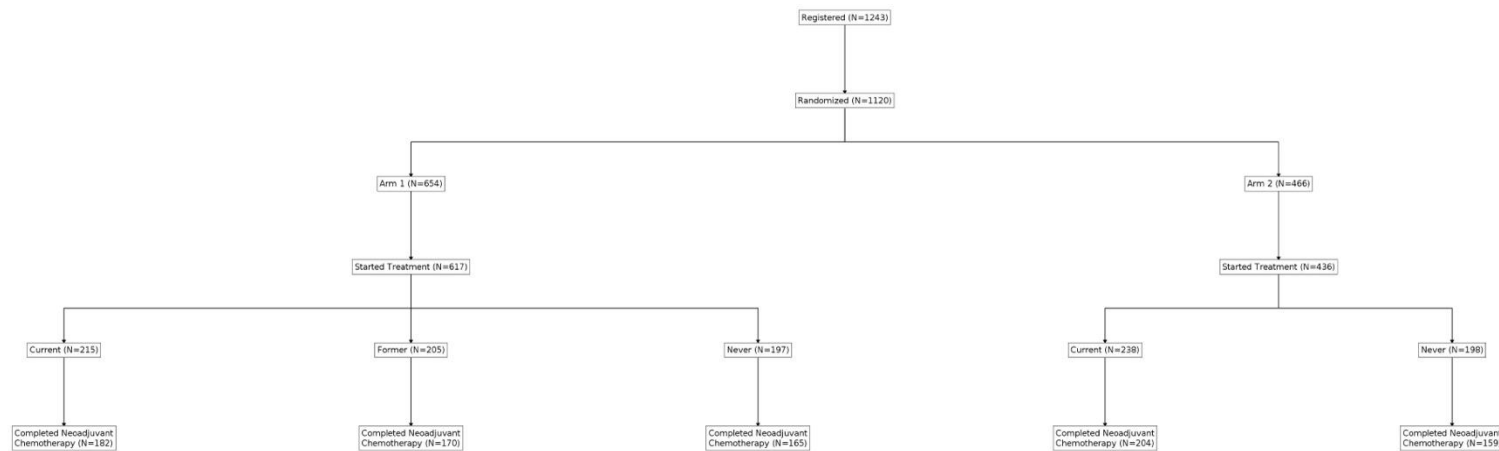
%CONSORT (...  
, SPLIT= | ARM  
, OFFREASON=OFFTRT | OFFTRT2  
)



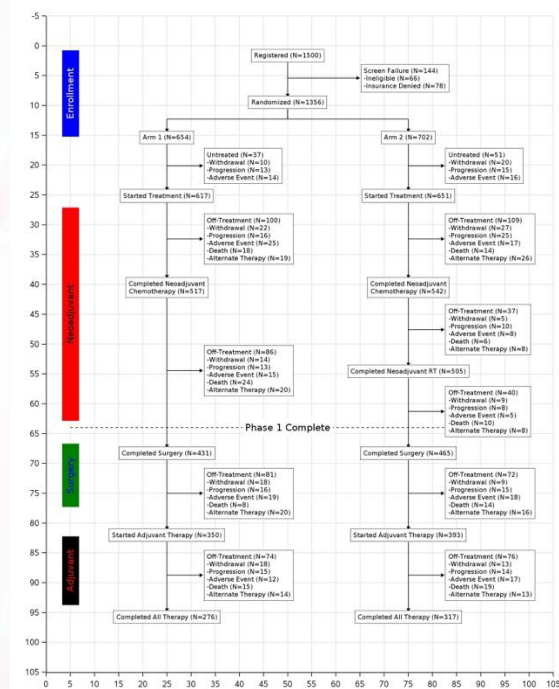
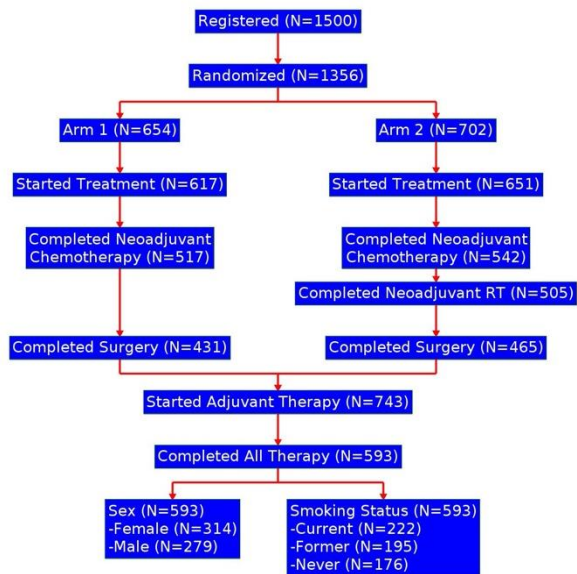
# %CONSORT Introduction: More Examples



# %CONSORT Introduction: More Examples



# %CONSORT Introduction: More Examples



# Graphics Setup: Creating a Textbox

- SGPLOT procedure's TEXT statement works well
  - BACKFILL and OUTLINE options create an opaque bordered box
  - SPLITJUSTIFY, SPLITCHAR, SPLITPOLICY=ALWAYS allow appropriately aligned text with controllable line breaks
  - Textbox is automatically sized by SGPLOT to match the text
  - POSITION allows user specified anchor point for the box at the x/y-coordinates
  - Requires variables X, Y and TEXT

# Graphics Setup: Creating the Connecting Lines

- SGPLOT procedure's SERIES statement works well
  - Two different series plots: one with and one without arrowheads
  - Unique ID variable for each line segment is used with the GROUP option
  - Requires X and Y variables for coordinates

## Graphics Setup: Graph Space

- X and Y axes are set from 0-100
- Columns and rows are allocated a percentage of the space
- All graph borders, axes, and labels are turned off

# Automation Methods: What is Needed

- There are four primary data items to be automated
  - Determine the unique patient paths through the trial
  - Derive the text and counts for each textbox
  - Determine the parent-child links between textboxes
  - Determine the x/y coordinates of each textbox

# Automation Methods: Patient Paths

| ID | Arm   | Reg        | Rand       | Treated           | Neo | Offrsn     |
|----|-------|------------|------------|-------------------|-----|------------|
| 19 | Arm 2 | Registered | Randomized | Started Treatment |     | Withdrawal |



| ID | Node | Phase | Order | Label             | Split1 | Offrsn     | Off_order | Off_trt |
|----|------|-------|-------|-------------------|--------|------------|-----------|---------|
| 19 | 1.01 | 1     | 1     | Registered        |        |            |           | 0       |
| 19 | 2.01 | 1     | 1     | Randomized        |        |            |           | 0       |
| 19 | 3.02 | 2     | 2     | Started Treatment | Arm 2  |            |           | 0       |
| 19 | 4.02 | 2     | 2     | Arm 2             | Arm 2  |            |           | 0       |
| 19 | 5.02 | 2     | 2     | Off-Treatment     | Arm 2  | Withdrawal | 1         | 1       |

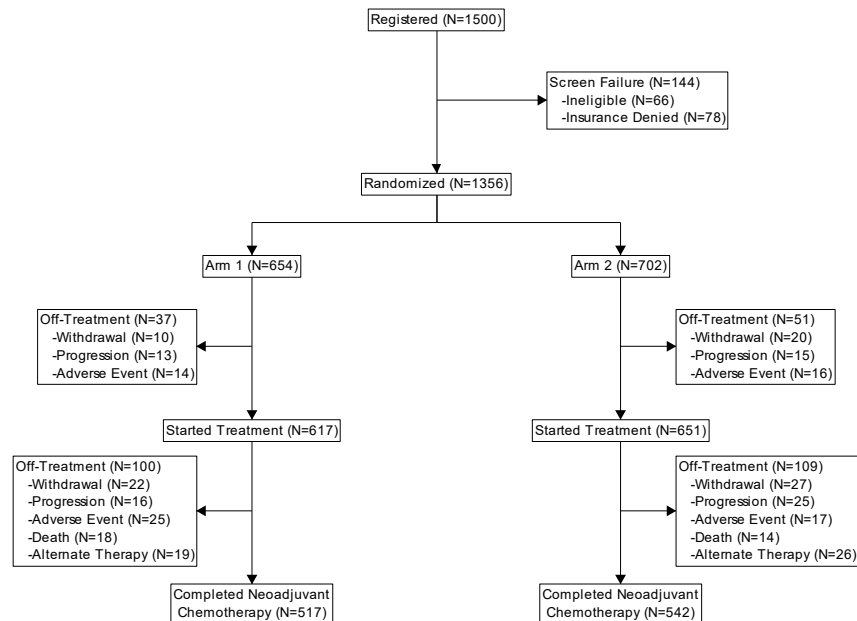
# Automation Methods: Patient Paths

Unique paths through entire study

| Path | Step1 | Step2 | Step3 | Step4 | Step5 | Last_step |
|------|-------|-------|-------|-------|-------|-----------|
| 1    | 1.01  | 3.01  | 4.02  | 6.02  | 8.02  | 8.02      |
| 2    | 1.01  | 3.01  | 4.03  | 6.03  | 8.03  | 8.03      |

Unique paths through going off-treatment

| Step1 | Step2 | Step3 | Step4 | Step5 | Last_step | Connect_backwards |
|-------|-------|-------|-------|-------|-----------|-------------------|
| 1.01  | 2.01  |       |       | 2.01  | 1.01      |                   |
| 1.01  | 3.01  | 4.02  | 5.02  | 5.02  | 4.02      |                   |
| 1.01  | 3.01  | 4.03  | 5.03  | 5.03  | 4.03      |                   |
| 1.01  | 3.01  | 4.02  | 6.02  | 7.02  | 7.02      | 6.02              |
| 1.01  | 3.01  | 4.03  | 6.03  | 7.03  | 7.03      | 6.03              |



# Automation Methods: Calculating Patient Counts

```
select phase,node,label,'BOTTOM' as position,
count(distinct id) as n,
case(missing(label))
when 0 then strip(label)||'(N='||
strip(put(calculated n,12.0))||')'
else '' end as text length=1000
from _temp4 where off_trt<1
group by phase,node,label,position
```

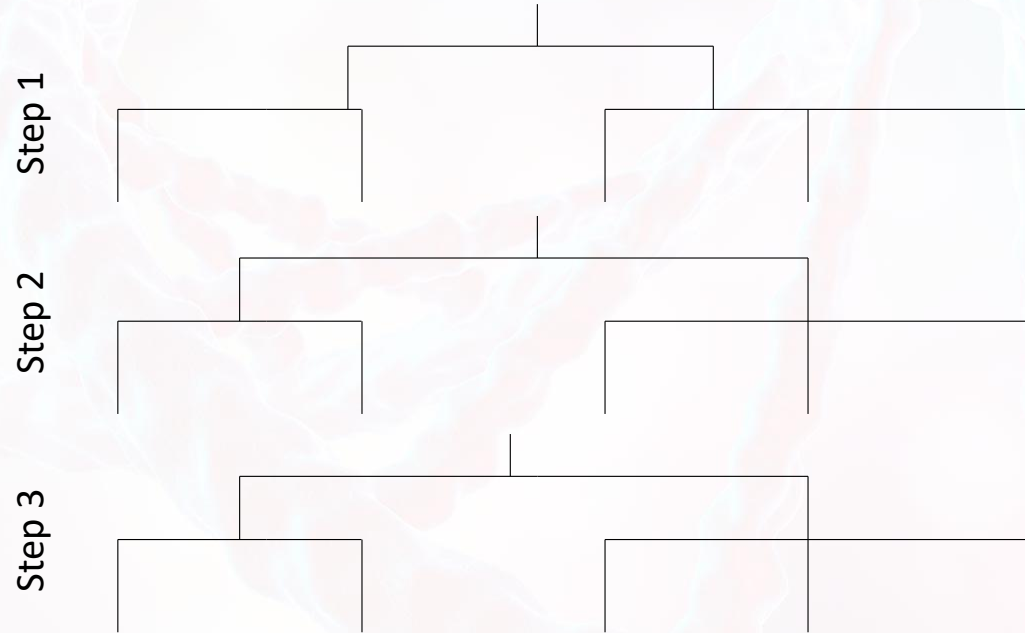
| Phase | Node | Label                              | Position | N    | Text                                       | Off_trt | Off_order | Offrsn            |
|-------|------|------------------------------------|----------|------|--------------------------------------------|---------|-----------|-------------------|
| 1     | 1.01 | Registered                         | BOTTOM   | 1500 | Registered (N=1500)                        |         |           |                   |
| 1     | 2.01 | Screen Failure                     | RIGHT    | 144  | Screen Failure (N=144)                     | 1       |           |                   |
| 1     | 2.01 |                                    | RIGHT    | 66   | -Ineligible (N=66)                         | 1       | 1         | Ineligible        |
| 1     | 2.01 |                                    | RIGHT    | 78   | -Insurance Denied (N=78)                   | 1       | 2         | Insurance Denied  |
| 1     | 3.01 | Randomized                         | BOTTOM   | 1356 | Randomized (N=1356)                        |         |           |                   |
| 2     | 4.02 | Arm 1                              | BOTTOM   | 654  | Arm 1 (N=654)                              |         |           |                   |
| 2     | 4.03 | Arm 2                              | BOTTOM   | 702  | Arm 2 (N=702)                              |         |           |                   |
| 2     | 5.02 | Off-Treatment                      | LEFT     | 37   | Off-Treatment (N=37)                       | 1       |           |                   |
| 2     | 5.02 |                                    | LEFT     | 10   | -Withdrawal (N=10)                         | 1       | 1         | Withdrawal        |
| 2     | 5.02 |                                    | LEFT     | 13   | -Progression (N=13)                        | 1       | 2         | Progression       |
| 2     | 5.02 |                                    | LEFT     | 14   | -Adverse Event (N=14)                      | 1       | 3         | Adverse Event     |
| 2     | 5.03 | Off-Treatment                      | RIGHT    | 51   | Off-Treatment (N=51)                       | 1       |           |                   |
| 2     | 5.03 |                                    | RIGHT    | 20   | -Withdrawal (N=20)                         | 1       | 1         | Withdrawal        |
| 2     | 5.03 |                                    | RIGHT    | 15   | -Progression (N=15)                        | 1       | 2         | Progression       |
| 2     | 5.03 |                                    | RIGHT    | 16   | -Adverse Event (N=16)                      | 1       | 3         | Adverse Event     |
| 2     | 6.02 | Started Treatment                  | BOTTOM   | 617  | Started Treatment (N=617)                  |         |           |                   |
| 2     | 6.03 | Started Treatment                  | BOTTOM   | 651  | Started Treatment (N=651)                  |         |           |                   |
| 2     | 7.02 | Off-Treatment                      | LEFT     | 100  | Off-Treatment (N=100)                      | 1       |           |                   |
| 2     | 7.02 |                                    | LEFT     | 22   | -Withdrawal (N=22)                         | 1       | 1         | Withdrawal        |
| 2     | 7.02 |                                    | LEFT     | 16   | -Progression (N=16)                        | 1       | 2         | Progression       |
| 2     | 7.02 |                                    | LEFT     | 25   | -Adverse Event (N=25)                      | 1       | 3         | Adverse Event     |
| 2     | 7.02 |                                    | LEFT     | 18   | -Death (N=18)                              | 1       | 4         | Death             |
| 2     | 7.02 |                                    | LEFT     | 19   | -Alternate Therapy (N=19)                  | 1       | 5         | Alternate Therapy |
| 2     | 7.03 | Off-Treatment                      | RIGHT    | 109  | Off-Treatment (N=109)                      | 1       |           |                   |
| 2     | 7.03 |                                    | RIGHT    | 27   | -Withdrawal (N=27)                         | 1       | 1         | Withdrawal        |
| 2     | 7.03 |                                    | RIGHT    | 25   | -Progression (N=25)                        | 1       | 2         | Progression       |
| 2     | 7.03 |                                    | RIGHT    | 17   | -Adverse Event (N=17)                      | 1       | 3         | Adverse Event     |
| 2     | 7.03 |                                    | RIGHT    | 14   | -Death (N=14)                              | 1       | 4         | Death             |
| 2     | 7.03 |                                    | RIGHT    | 26   | -Alternate Therapy (N=26)                  | 1       | 5         | Alternate Therapy |
| 2     | 8.02 | Completed Neoadjuvant~Chemotherapy | BOTTOM   | 517  | Completed Neoadjuvant~Chemotherapy (N=517) |         |           |                   |
| 2     | 8.03 | Completed Neoadjuvant~Chemotherapy | BOTTOM   | 542  | Completed Neoadjuvant~Chemotherapy (N=542) |         |           |                   |

# Automation Methods: Determine the X/Y Coordinates of Each Textbox

- X-coordinates are the difficult coordinate
  - Properly spacing and aligning different branching paths
- Y-coordinates are mostly straightforward with two different methods:
  - Allocate equal space to each row of the CONSORT and center the textboxes
  - Give each row of the CONSORT a proportionate space depending on how many lines of text exist and center the textboxes

| Path | Phase | Node | Row | Row_link | Connect_forward | Connect_backward |
|------|-------|------|-----|----------|-----------------|------------------|
| 1    | 1     | 1.01 | 1   | 1        | 3.01            | 1.01             |
| 1    | 1     | 3.01 | 3   | 1        | 4.02            | 1.01             |
| 1    | 2     | 4.02 | 4   | 3        | 6.02            | 3.01             |
| 1    | 2     | 6.02 | 6   | 4        | 8.02            | 4.02             |
| 1    | 2     | 8.02 | 8   | 6        |                 | 8.02             |
| 2    | 1     | 1.01 | 1   | 1        | 3.01            | 1.01             |
| 2    | 1     | 3.01 | 3   | 1        | 4.03            | 1.01             |
| 2    | 2     | 4.03 | 4   | 3        | 6.03            | 3.01             |
| 2    | 2     | 6.03 | 6   | 4        | 8.03            | 4.03             |
| 2    | 2     | 8.03 | 8   | 6        |                 | 6.03             |

# Automation Methods: Determine the X-Coordinates



# Final Steps: Collapsing Text

```
Data _temp9;
set _temp8;
by y x;
  where ^missing(x) and ^missing(y);
  length _temp_text $10000;
  if first.x then call missing(_temp_text);
  if ^(first.x and last.x) then do;
    _temp_text=catx('~',_temp_text,text);
  if last.x then do;
    text=_temp_text;
    output;
  end;
end;
else output;
retain _temp_text;
Run;
```

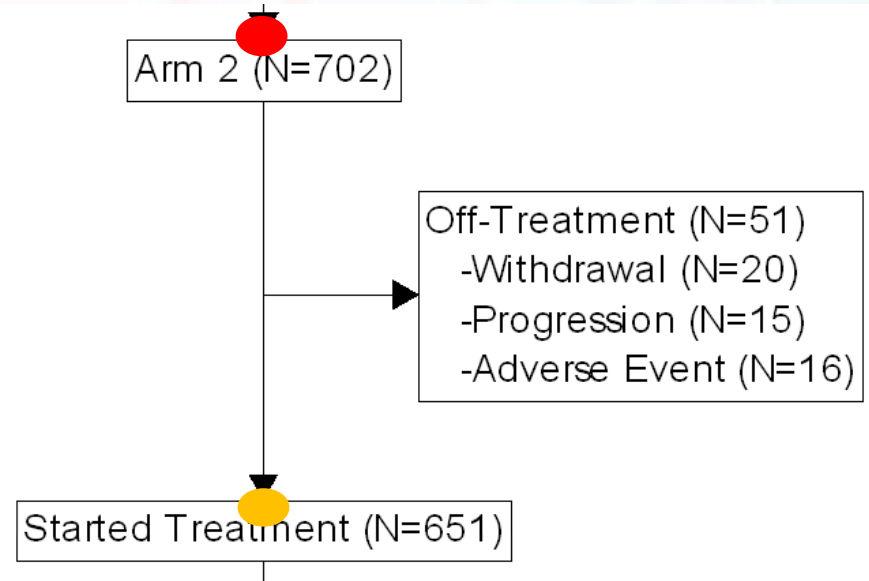
| phase | node | position | text                                                                                                                             | off | trt | n | off | order | connect | backward | connect | forward | x    | y | column |
|-------|------|----------|----------------------------------------------------------------------------------------------------------------------------------|-----|-----|---|-----|-------|---------|----------|---------|---------|------|---|--------|
| 1     | 1.01 | BOTTOM   | Registered (N=1500)                                                                                                              |     |     |   |     |       | 1.01    |          | 3.01    |         | 50.0 | 1 | 3      |
| 1     | 2.01 | RIGHT    | Screen Failure (N=144)~ -Ineligible (N=66)~ -Insurance Denied (N=78)                                                             | 1   | 1   | 2 |     |       | 1.01    |          | 3.01    |         | 65.0 | 2 | 4      |
| 1     | 3.01 | BOTTOM   | Randomized (N=1356)                                                                                                              |     |     |   |     |       | 1.01    |          | 4.03    |         | 50.0 | 3 | 3      |
| 2     | 4.02 | BOTTOM   | Arm 1 (N=654)                                                                                                                    |     |     |   |     |       | 3.01    |          | 6.02    |         | 25.0 | 4 | 2      |
| 2     | 4.03 | BOTTOM   | Arm 2 (N=702)                                                                                                                    |     |     |   |     |       | 3.01    |          | 6.03    |         | 75.0 | 4 | 5      |
| 2     | 5.02 | LEFT     | Off-Treatment (N=37)~ -Withdrawal (N=10)~ -Progression (N=13)~ - Adverse Event (N=14)                                            | 1   | 1   | 3 |     |       | 4.02    |          | 6.02    |         | 17.5 | 5 | 1      |
| 2     | 5.03 | RIGHT    | Off-Treatment (N=51)~ -Withdrawal (N=20)~ -Progression (N=15)~ - Adverse Event (N=16)                                            | 1   | 1   | 3 |     |       | 4.03    |          | 6.03    |         | 82.5 | 5 | 6      |
| 2     | 6.02 | BOTTOM   | Started Treatment (N=617)                                                                                                        |     |     |   |     |       | 4.02    |          | 8.02    |         | 25.0 | 6 | 2      |
| 2     | 6.03 | BOTTOM   | Started Treatment (N=651)                                                                                                        |     |     |   |     |       | 4.03    |          | 8.03    |         | 75.0 | 6 | 5      |
| 2     | 7.02 | LEFT     | Off-Treatment (N=100)~ -Withdrawal (N=22)~ -Progression (N=16)~ - Adverse Event (N=25)~ -Death (N=18)~ -Alternate Therapy (N=19) | 1   | 1   | 5 |     |       | 6.02    |          | 8.02    |         | 17.5 | 7 | 1      |
| 2     | 7.03 | RIGHT    | Off-Treatment (N=109)~ -Withdrawal (N=27)~ -Progression (N=25)~ - Adverse Event (N=17)~ -Death (N=14)~ -Alternate Therapy (N=26) | 1   | 1   | 5 |     |       | 6.03    |          | 8.03    |         | 82.5 | 7 | 6      |
| 2     | 8.02 | BOTTOM   | Completed Neoadjuvant~Chemotherapy (N=517)                                                                                       |     |     |   |     |       | 6.02    |          |         |         | 25.0 | 8 | 2      |
| 2     | 8.03 | BOTTOM   | Completed Neoadjuvant~Chemotherapy (N=542)                                                                                       |     |     |   |     |       | 6.03    |          |         |         | 75.0 | 8 | 5      |

## Final Steps: Calculating x/y values for connecting lines

- A one row data set containing all x/y coordinates and positions for each textbox is saved out
- This data set is then merged to every row of the data set on the previous slide
- This gives each row access to the attributes of each textbox for use in array functions
  - Using the row/column indexes previously calculated
  - The row/column indexes for forward/backward connecting nodes are also merged into the data set

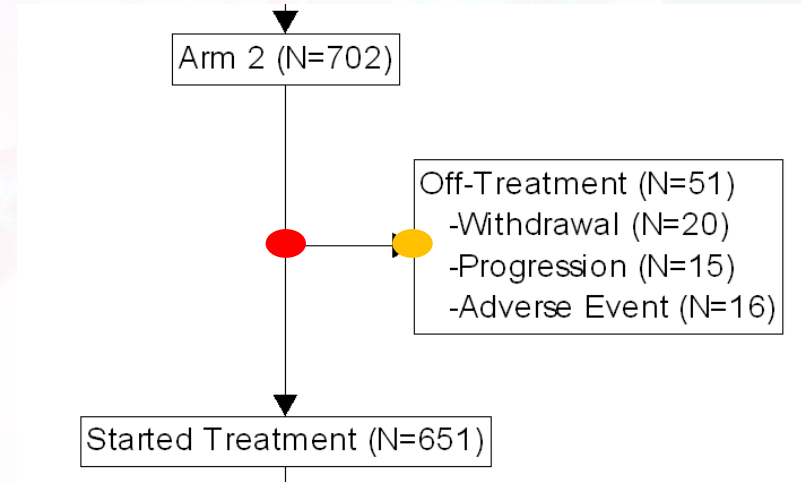
## Final Steps: Linking textboxes in the same column

- Most straightforward
  - Origin: x/y of previous textbox
  - Finish: x/y of current textbox



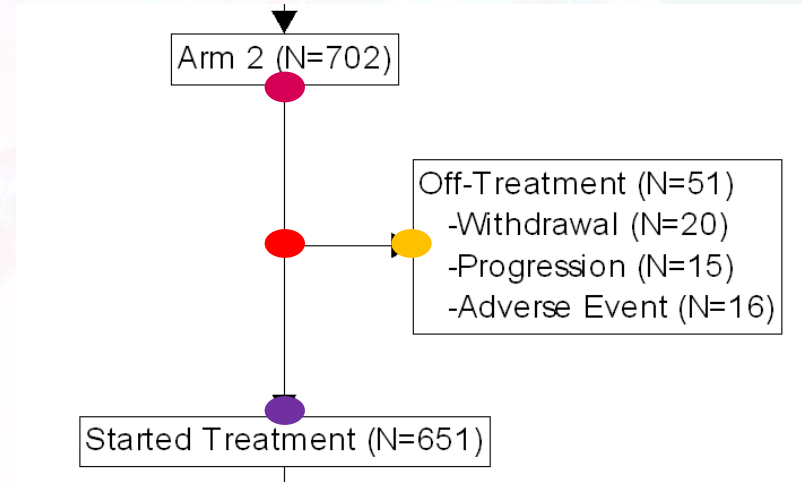
# Final Steps: Linking Off-Treatment Textboxes

- Y-coordinates are tricky
  - **Origin:**
    - X-coordinate of previous textbox
    - Y-coordinate is midpoint of previous textbox and next textbox
  - **Finish:**
    - X-coordinate of current textbox
    - Y-coordinate is midpoint of previous textbox and next textbox



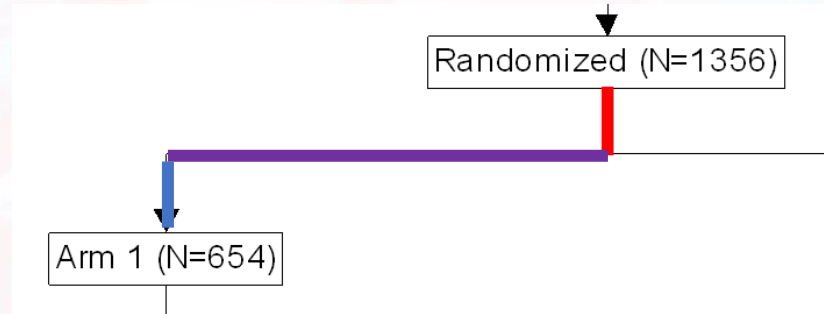
# Final Steps: Linking Off-Treatment Textboxes

- Midpoint is calculated from *bottom* of previous textbox and the top of current
  - Top of the next is known
  - Bottom of previous must be approximated
    - Macro has an adjustable parameter (&MULTILINE\_ADJUST) to give space for each line of text



## Final Steps: Linking Textboxes not in the Same Column

- Three separate lines to calculate
  - Line coming down from previous textbox
  - Horizontal line between textboxes
  - Line connecting to current textbox



# Conclusion

- These methods can be used outside of a macro to programmatically create a CONSORT
  - There are many different preferences and styles of CONSORT depending on journal and employer
- More complicated methods can be derived for paths combining instead of splitting, merging nodes together, and other annotations

## Contact Information

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