



PhUSE 2011 - Paper TS10

Alternative Approaches to Creating Disposition Flow Diagrams

**Brian Fairfield-Carter,
ICON Clinical Research,
Redwood City, CA**

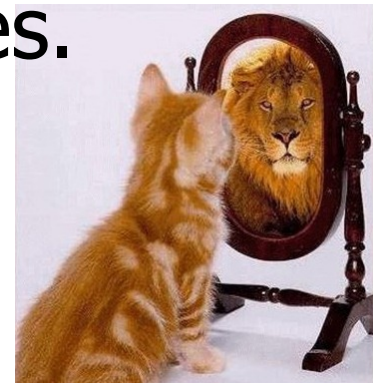
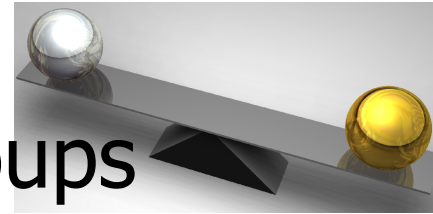
What does ‘disposition’ mean?

- “Predominant tendency”; “propensity”; “final settlement of a matter”
- Screening
- Enrollment
- Randomization
- Completion
- Early discontinuation
 - AE
 - Lack of efficacy
 - Etc.



Why summarize disposition?

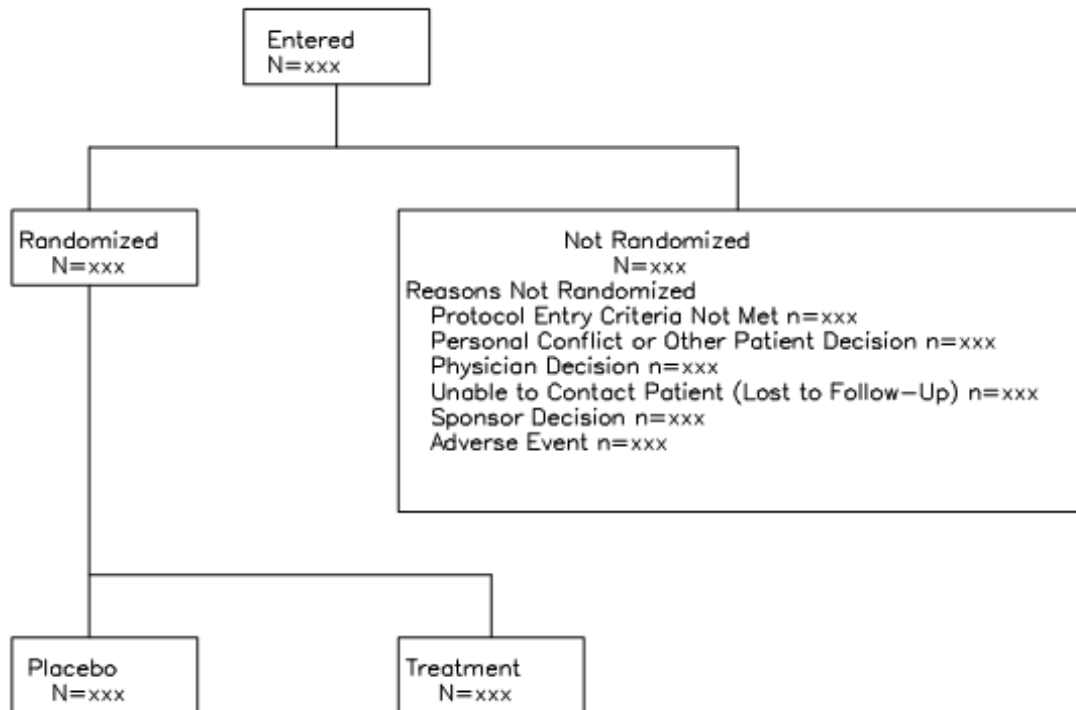
- Check for unbalanced groups
- Effectiveness of recruitment procedures (number of screen failures, etc.)
- Logistical, safety, perception issues.



Disposition Summary: Tabular...

Table 14.1.1.2						
Subject Disposition						
Randomized Set						
	Placebo	2 mg	10 mg	50 mg	Total	P-value (c)
	(N=XXX)	(N=XXX)	(N=XXX)	(N=XXX)	(N=XXX)	
	n (%)	n (%)	n (%)	n (%)	n (%)	
Enrolled Set					XX (XX.X)	
Enrolled but not treated					XX (XX.X)	
Randomized Set	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Full Analysis Set	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Per Protocol Set	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Subjects Completing Treatment (a)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Subjects Discontinuing Treatment	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Reason for Discontinuing Treatment						
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX
Protocol Violation	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX
Subject Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX
Sponsor Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX
Subject's Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX
Clinical Endpoint (ESRD)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	0.XXXXX

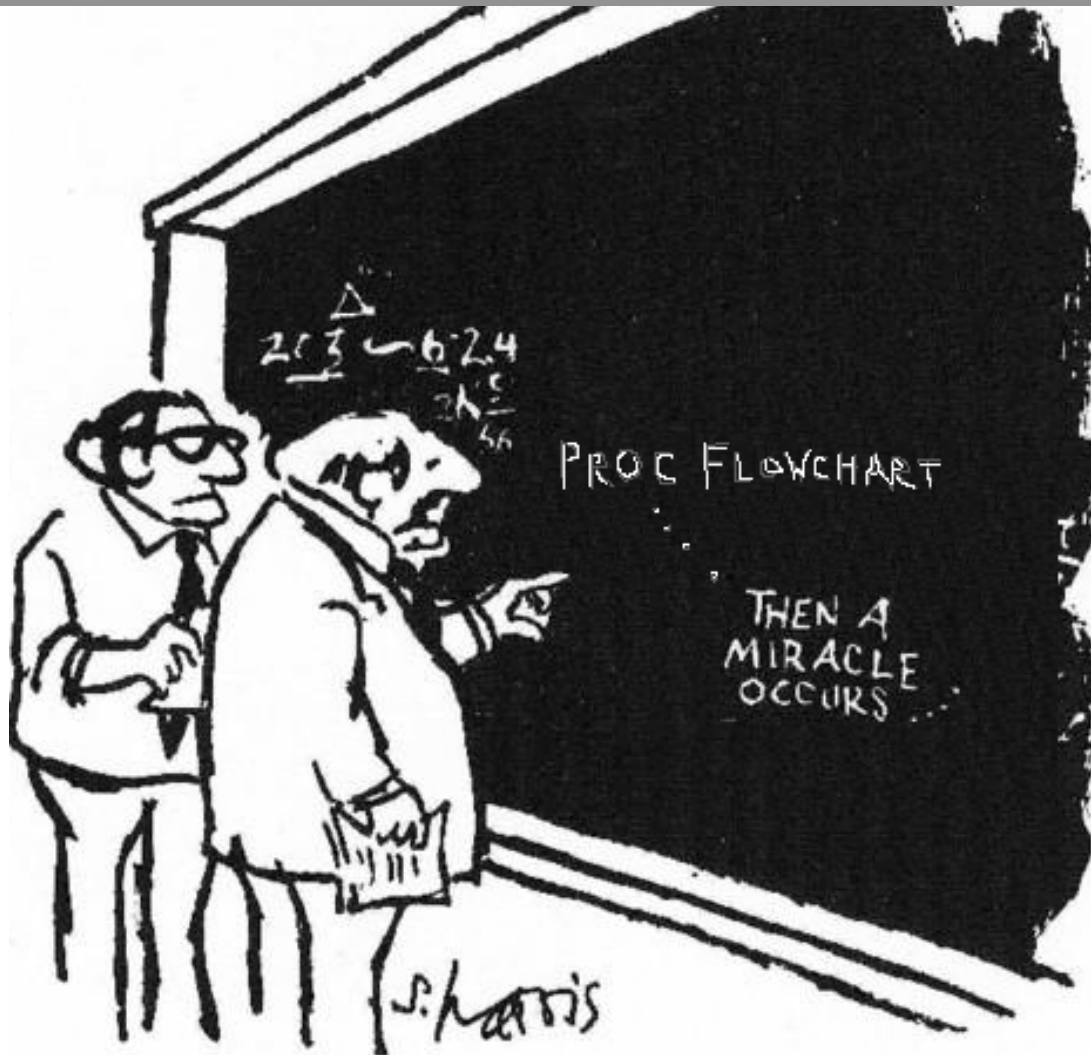
...versus flow diagram



Trade-offs

- Flow diagram *may* be easier to interpret (debatable)...
- ...but more complicated and time-consuming to produce (in fact, just how *do* you program a flow chart?)

The Institute of Imaginary SAS Procedures



Purpose:

Present three alternative methods for disposition flow diagrams.

- Annotate (purely SAS-based)
- Annotate/Excel/Visual Basic (hybrid)
- Word template/script-driven transcription (hybrid)

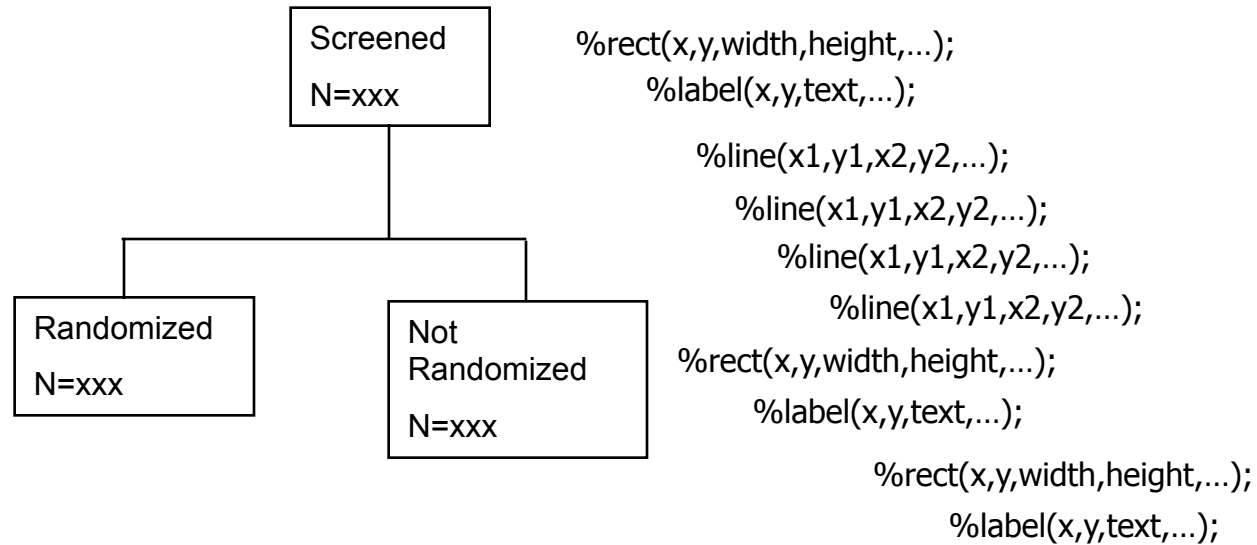
Keeping in mind...

- Validation implications
- Time/effort/cost
- Flexibility
- ‘Interoperability’ (operating system, programming environment, programmer knowledge)

The Annotate Facility

- SAS/Graph ‘drawing tool’
 - Objects (line, rectangle, text)
 - Attributes (color, font)
 - Functions (move, draw)
- Verbose (but consider Annotate macros (%line, %label, etc.))
- A flow diagram is just a collection of objects & attributes...

Annotate



Annotate

```
%annomac;
```

```
%macro add_element(x=,y=,width=,height=,text=);
```

```
%rect(&x,&y,&x+&width,&y+&height,black,1,0.2);
```

```
%let i=1;
```

```
%do %until (%qscan(&text,&i,'|')=);
```

```
%label(&x+0.5,&y+&height-&i,  
        "%qscan(&text,&i,'|')",  
        BLACK,0,0,1,SIMPLEX,6);
```

```
%let i=%eval(&i+1);
```

```
%end;
```

```
%mend add_element;
```

Annotate

```
data final;
  length function color style $8. text $60.;
  retain xsys '6' ysys '6' hsys '6' when 'a'
    line 1 function 'label';
  %add_element(x=20,y=35,width=12,height=3,
    text=%str( Entered | N=xxx));
  %add_element(x=5, y=27,width=12,height=3,
    text=%str(Randomized| N=xxx));
  ... (etc.) ...
  %line(26,35, 26,32.5,BLACK,1,1);
  %line(10,32.5,52,32.5,BLACK,1,1);
  ... (etc.) ...
```

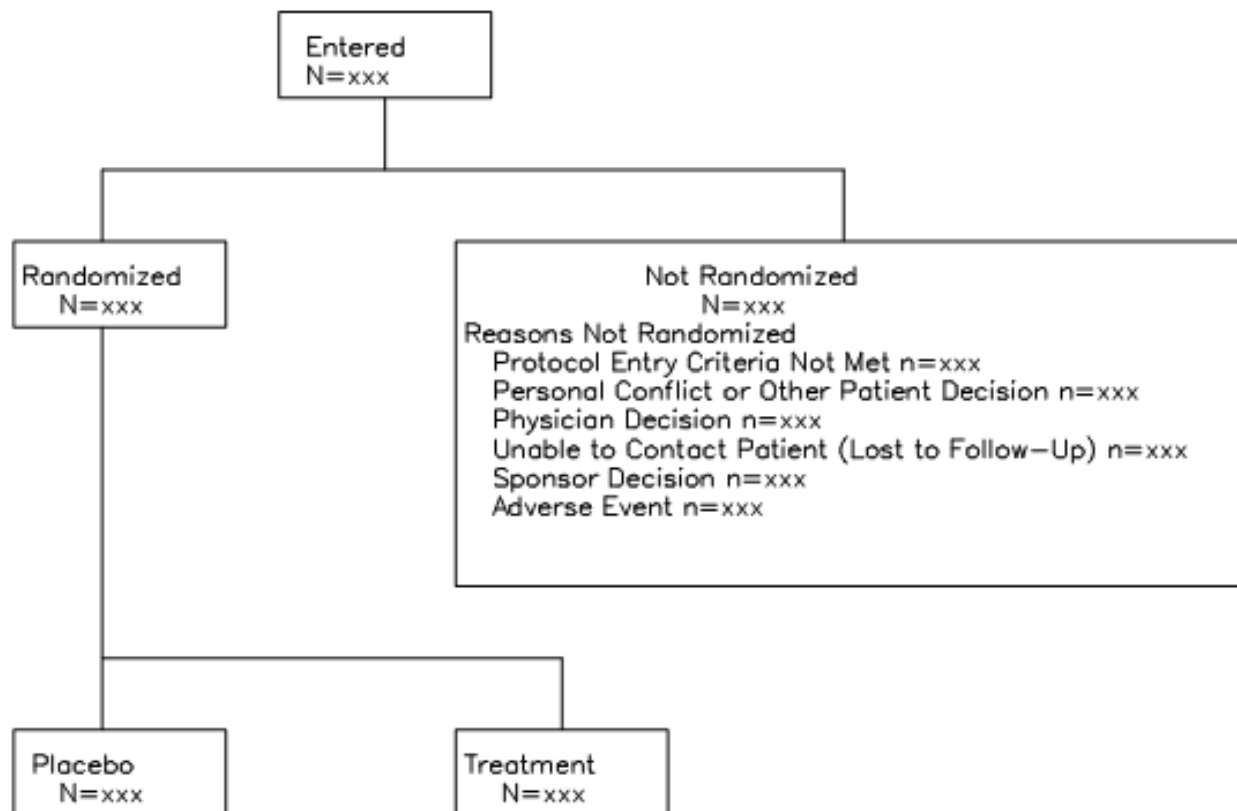
Annotate

FUNCTION	COLOR	STYLE	TEXT	XSYS	YSYS	HSYS	WHEN	LINE	SIZE	X	Y	ANGLE	ROTATE
POLYLINE	black			6	6	6	a	1	0.2	0.0	0	-	-
POLYCONT	black			6	6	6	a	1	0.2	12.0	0	-	-
POLYCONT	black			6	6	6	a	1	0.2	12.0	3	-	-
POLYCONT	black			6	6	6	a	1	0.2	0.0	3	-	-
POLYCONT	black			6	6	6	a	1	0.2	0.0	0	-	-
LABEL	BLACK	SIMPLEX	Entered	6	6	6	a	1	1.0	0.5	2	0	0
LABEL	BLACK	SIMPLEX	N=xxx	6	6	6	a	1	1.0	0.5	1	0	0

Annotate

```
ods rtf file="diagram.rtf";  
  
    proc gslide annotate=final;  
    run;  
    quit;  
  
ods rtf close;
```

Annotate

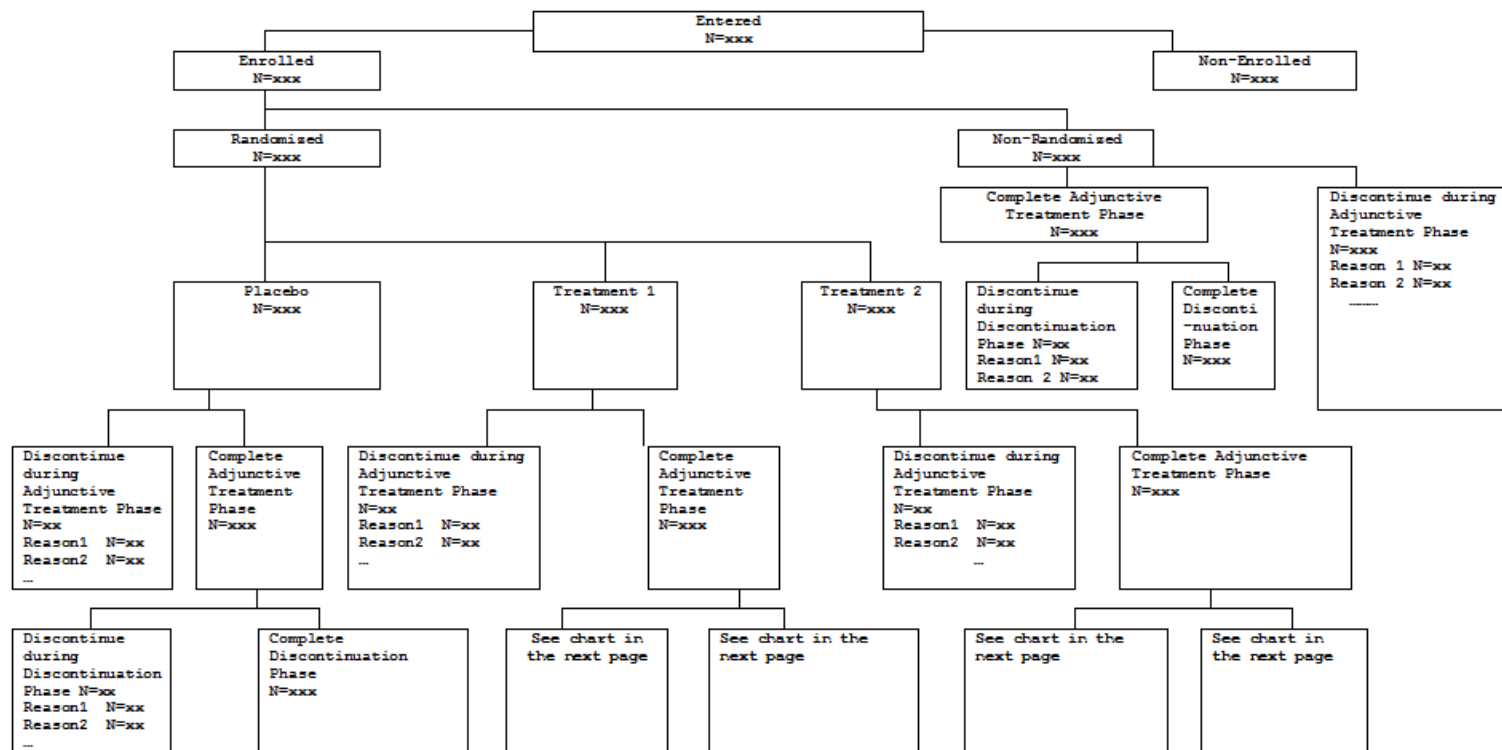


Annotate

- This is ok, but...
 - ‘Dynamic’ positioning of elements? (see instead Saradha & Veeravel (2008))
 - Output file is ‘static’
 - Increase in diagram complexity=increase in code size/complexity...

...alternatives?

Figure 14.1.1
Patient Disposition



‘Hybrid’ approach #1:

- Use Annotate to create rectangle/text elements (as separate graphics files)
- VBA macro or VB script to import, position, and link elements in Excel

Annotate/Excel/VB

SAS

Screened
N=xxx

```
%rect(x,y,width,height,...);  
%label(x,y,text,...);
```

VBScript

Import, position, link

Excel

	A	B	C
1			
2			
3			
4			
5			

Entered
N=xxx

Annotate/Excel/VB

...

```
Set objXLS = WScript.CreateObject("Excel.Application.  
11")
```

...

with objXLS

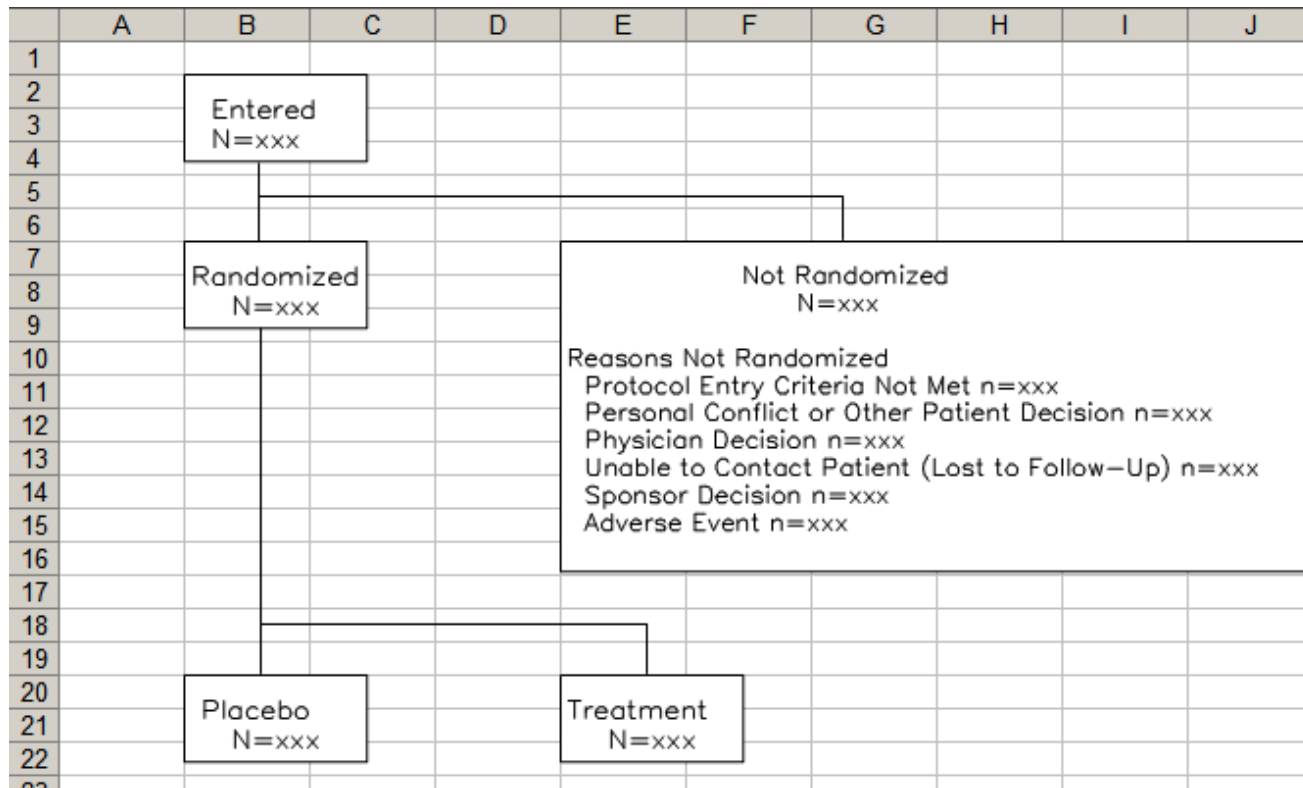
```
.Range("B2").Select
```

```
.ActiveSheet.Pictures.Insert(f & "_1.emf").Select
```

... (etc.) ...

```
AddLine(76.5, 46.5, 76.5, 76.5).Select
```

Annotate/Excel/VB



Annotate/Excel/VB

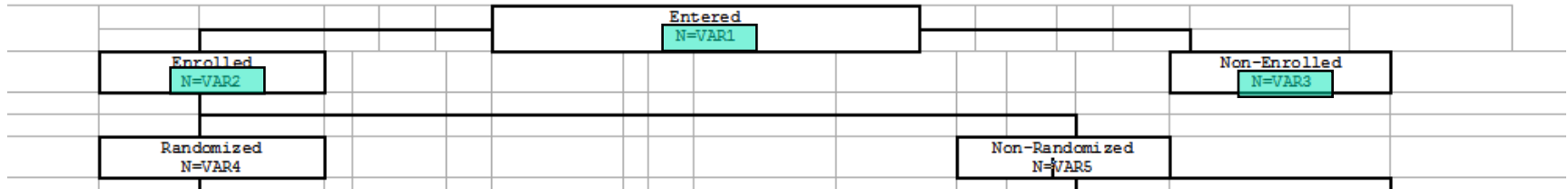
- This is OK, but...
 - Determining target cells for placing rectangle/text elements is a pain
 - Determining coordinates for connecting lines is a pain
- Generate code automatically by recording a VBA macro while importing, positioning and linking.

‘Hybrid’ approach #2

- Calculate values in SAS, and output to a text file
- Use the flow-diagram mock-up as a template, replacing ‘N=xxx’ placeholders with the actual values

Word template, transcription

Figure 14.1.1
Patient Disposition



Word template, transcription

```
data _null_;  
  set disposition;  
  file "replacevalue.txt";  
  put "VAR" || put(_n_,best.) || " " || put(count,best.) ;  
  
run;
```

```
VAR1 | 200  
VAR2 | 180  
VAR3 | 20  
VAR4 | 150  
VAR5 | 30  
--- (etc.) ---
```

Word template, transcription

- *Script*: read the varname/value list, and do an iterative search/replace in Word...

Word template, transcription

**Open the mockup
in Word**

**Open the text file,
read the first line,**

(Grab 'VAR1' as the
search-string, and
'200' as the replace-
string)

**Execute the
search-replace**

Repeat...

Figure 14.1.1
Patient Disposition

Enrolled N=200	Entered N=200	Non-Enrolled N=20
Randomized N=150	Non-Randomized N=30	

VAR1 | 200

VAR2 | 180

VAR3 | 20

VAR4 | 150

VAR5 | 30

Figure 14.1.1
Patient Disposition

Entered N=VAR1



Figure 14.1.1
Patient Disposition

Entered N=200

VAR1 | 200

VAR2 | 180

VAR3 | 20

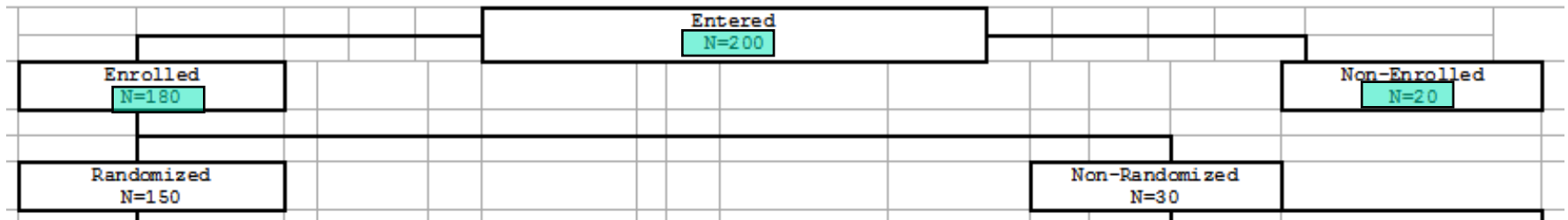
VAR4 | 150

VAR5 | 30

Save the final product

Word template, transcription

Figure 14.1.1
Patient Disposition



Word template, transcription

Figure 14.1.1
Patient Disposition

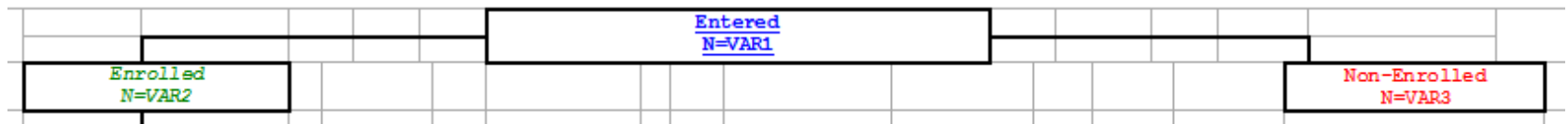
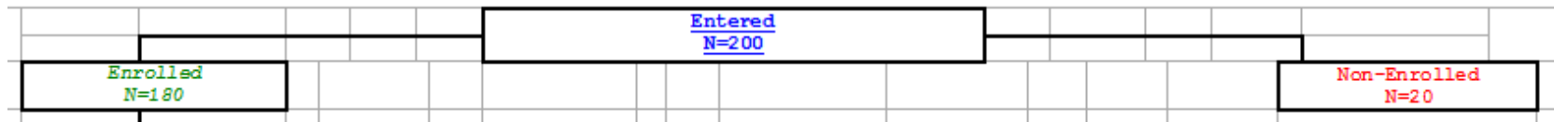


Figure 14.1.1
Patient Disposition



In Summary...

- Annotate – avoids ‘hybrid’ solution, is platform-independent, but may require a lot of code



In Summary...

- Annotate/Excel/VB – reduces coding overhead, but sacrifices platform independence.
- Word template/transcription - demands a well-developed template but little code; sacrifices platform independence.

