

Opportunities for efficiency gains created by the availability of the Output Delivery System

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Background

- ODS is a major enhancement to SAS
- Project to investigate implementation in a pharma reporting environment
- Intention to integrate ODS with existing process, not to replace
- Focus on report generation, not data manipulation or analysis

The project

- Objective is report-ready RTF tables and listings
- Ideal solution is
 - Generic
 - “One PROC away”
 - Platform independent (Unix and PC)
 - Destination independent (RTF, PDF, etc)
 - Simple

Performance metrics

- Differences from current standards
 - Current standards are not ideal, but they are familiar
- Coding effort required
 - Lines in calling program and generated by macro
 - Complexity
 - Maintenance

Current approach

- RTF files generated by %print [Wehr (1996), SUGI21]
 - Series of complex DATA _NULL_ steps
 - Generate raw RTF (or PDF etc) control code
 - Difficult to generalise
 - Not supported by SAS
 - High maintenance
 - Skill set not widely available

The ideal ODS solution

- Styles define look-and-feel
- Output generated directly from analytical procedures
- ODS statements wrap analysis code to produce output file
- Cost of *presentation* over *analysis* is minimal

What could go wrong with ODS?

- Procedural output is inflexible
 - Generally not true?
 - Training and experience required
 - Pagination remains an issue
 - » More later
- Standards not matched
 - Information vs format
 - “Need” vs “want”

Example 1

Adverse Events by Subject

Center	Subject	Age (years)	Sex	Race	First dose	Last dose
29	748029301	30	Male	Caucasian	17MAY2000	18OCT2000

Event Start Date	Event Stop Date	Day	Week	Duration (days)	Adverse event	Preferred Term	Severity ^a	Serious	Study Drug Related?	Action ^b
17MAY2000	17MAY2000	1	1	1	Vascular Access Thrombosed	Thrombosis Vascular Access	01	No	No	88
07JUN2000	21JUN2000	22	4	15	Bilateral Leg Pain When Walking	Pain Limb	01	No	No	01
04AUG2000	07AUG2000	80	12	4	Hypertension	Hypertension	01	No	No	07
22SEP2000	13OCT2000	129	19	22	Hypertension	Hypertension	01	No	Yes	07 88
06OCT2000	06OCT2000	143	21	1	Cephalea	Headache	01	No	No	01

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Note: . indicates missing

a - Severity: 01=Mild, 02=Moderate, 03=Severe, 04=Life Threatening, 05=Fatal

b - Action: 01=None, 04=Hospitalised, 05=Removed from study, 07=Medication taken, 08=Transfusion performed, 88=Other

Features of the table

- “two tables on a page”
- Superscripts
- Differing alignments
 - Both table entries and footnotes
- Within cell text wrapping
- Pagination

Features of the ODS solution (1)

- Output directly from `PROC REPORT`
 - Easily generalised
 - Core SAS product: \therefore full Tech Support
 - Production in V8
 - Low maintenance
 - Easily customised
 - Minor ODS bugs require small workarounds
- Exact match to current standard

Features of the ODS solution (2)

- Destination independent
- Ideal “one proc away”
- Potential platform independent
- Widely available skill set
- Significantly reduced requirements for
 - Training
 - Validation
 - Maintenance

Comparison of solutions

- ODS version is identical to current standard
- Standard: 250 lines in driver, 14500 lines generated
- ODS v8.2: 49 lines in driver, 8500 lines generated
- ODS v9: 70 lines in total

Example 2

Baseline Demographics by Treatment Group
(Produced by %print)

	Treatment A	Treatment B			Total (N=30)
	600 IU/kg (N=10)	6.5 µg/kg (N=10)	8 µg/kg (N=10)	All (N=20)	
Sex - n(%)					
Female	9 (90)	8 (80)	7 (70)	15 (75)	24 (80)
Male	1 (10)	2 (20)	3 (30)	5 (25)	6 (20)
Race - n(%)					
White or Caucasian	10 (100)	10 (100)	10 (100)	20 (100)	30 (100)

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N=Number of subjects randomized

Program: /statistics/xxxx/new_ind/20010174/analysis/final/tables/ma_t5_demog.sas

Output: t5_demog.rtf (Date Generated: 02MAY02:12:09:39) Source Data: ddin.c_keyvars

Features of the table

- Greek in column headers
- Indentation of some row headers
- Standard code required serious modification to deal with Treatment B subtotal

The ODS version

Demographics by treatment group (Produced by ODS)

	Treatment A				Treatment B				All (N=20)		Total (N=30)	
	600 IU/kg (N=10)		6.5µg/kg (N=10)		8µg/kg (N=10)							
Sex - N (%)												
Female	8	(80)	7	(70)	9	(90)	16	(80)	24	(80)		
Male	2	(20)	3	(30)	1	(10)	4	(20)	6	(20)		
Race - N (%)												
White or Caucasian	10	(100)	10	(100)	10	(100)	20	(100)	30	(100)		

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Features of the ODS solution

- Not identical to standard
- Differences relate only to layout
 - Spacing of column header rows
 - Gap between Treatment A and Treatment B columns
 - Underlining of spanning headers

Comparison of solutions

- Standard: 100 lines in driver, 850 lines generated
- ODS: 22 lines
- ODS uses only `TABULATE`, `TITLE`, `FOOTNOTE`
- Is the difference worth the extra effort?

Pagination (1)

- SAS avoids the issue
 - delegates to Word
 - Titles (footnotes) appear in section headers (footers)
 - Creates problems when importing to multi-element documents
 - Looks wrong for “small” tables

Pagination (2)

- BODYTITLE option places titles (footnotes) in body of text
 - Doesn't work for tables that exceed page size
- Manual pagination often desirable
 - Knowledge of:
 - » Font
 - » Point size
 - » Column widths
 - » Wrapping strategy

The problem with proportional fonts

- Counting characters doesn't work with proportional fonts.
 - The quick brown fox
 - The quick brown fox
- SAS-based solution complex and not generic
 - Is it even possible?

Possible solutions

- Windows API and Java RTE contain the necessary functions
- Interface with SAS by
 - Text file
 - DDE
 - SCL
 - SAS/TOOLKIT®
 - (SAS®9) JAVAOBJ

TITLEs and FOOTNOTEs

- Simplest solution
 - Use SAS default behavior
 - Post process with eg Visual Basic
 - » Other languages possible
- Code is generic and high level
 - Easy to validate

The future

- Three big changes in SAS®9
 - DOCUMENT destination and procedure
 - » Bring much, but not all post processing within SAS
 - RTF destination as tagset
 - » Increases potential for generic customisation
 - JAVAOBJ
 - » Simplified interface with external functionality

What next?

- Analyse once, print many times
 - DOCUMENT
- Automatic bookmarking and hyperlinking
- Compilation of
 - Clinical Study Reports
 - Integrated Summaries of Efficacy and Safety
 - Common Technical Document

Conclusions

- ODS is a realistic, efficient and flexible option for print-ready reporting
- Maximum efficiency requires
 - Wide ranging review of process
 - Entrepreneurial attitude from programming managers
 - Buy in from clients