

## **ANovelApproachtoDevelopingaPatientProfileReportingApplication**

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### **ABSTRACT**

This paper describes a novel approach used to develop a patient profile reporting application using Base SAS in the Windows NT Operating System. A patient profile report is a display of the clinical study data that is collected for an individual patient, organized by time and data category. Patient profiles are often used to report clinical study information to the FDA as part of a regulatory submission.

The approach used was to publish the patient profile report as data (to a SAS dataset), containing all of the appropriate titles, data, footnotes and pagination information. This approach is significantly different from using conventional reporting procedures or data null-based reporting.

This paper discusses the development methodology employed in this project, the patient profile report requirements and patient profile application architecture.

### **INTRODUCTION**

This discussion is divided into two sections. The first section reviews the development methodology employed to produce this application; the second section reviews the application. Our development methodology is based upon traditional waterfall methodology. It is centered on a technical specification document that contains detailed descriptions of the application workflow, data structures and processing specifications.

The application target users are SAS programmers who produce patient profile reports that can be different for every clinical study. This requirement necessitated developing the application as a batch process where the patient profile report can be easily and quickly customized for each study. The approach used was to publish the patient profile report as a SAS dataset, containing all of the appropriate titles, data, footnotes and pagination information.

### **DEVELOPMENT METHODOLOGY**

Our development methodology is based upon a traditional waterfall methodology that is centered on a technical specification document. The methodology is as follows:

- The development team reviews report specifications from client;
- analysts write a technical specifications document;
- the development team and client review the technical specifications document;
- developers build and test software modules;
- development team reviews software modules;
- update technical specifications document, team review of technical specifications document and modify/test software (cycle);
- final testing of complete application.

The **technical specifications document** is a detailed description of the application, it contains the following information listed below.

- **System Overview** - A general functional overview of the application, contains key features of the application, system requirements and definitions of terms used in the document.
- **Application Workflow** - A description of the application work processing flow, contains a processing diagram and workflow descriptions.

- **Data Structures** - A detailed description of the data structures, contains an overview of the data structures and the key relationships. For each data file there is a detailed description of the data structure (variable names, description, type, format, default values), its use and relationship with procedures.
- **Application processing** - A description of the application processing, contains an overview of the application architecture, procedures (in this case the procedures are macros), global macro definitions and a sample program. For each procedure (macro), there is a detailed description of the input parameters (names, descriptions, defaults, values), output parameters, data files, processing requirements and processing specifications.
- **Application Testing** - A description of the application testing requirements, contains specifications and location of test data, unit testing requirements and application-level testing requirements.

The technical specification document for this simple application was about 50 pages. For a larger application it can easily grow to over 100 pages. This level of detailed documentation forces the developer to think through the application before starting any coding.

### **REPORT REQUIREMENTS**

The first four pages of a sample patient profile report are contained in Attachment 1. This sample is not an exact specification for the patient profile report, for each study the data being displayed can be different. The requirements for the report and application are listed below.

- Use SAS 6.12 on MS Windows - due to the submission requirements we do not use SAS 8.1. Using SAS 8.1 with ODS may have simplified some of the processing.
- Execute in batch mode - the volume of data requires processing for several hours at off-peak hours.
- Create report as one patient profile or multiple patients per file in ASCII and PDF format.
- Page numbering by patient and overall.
- Format report in a manner where it can be easily be automatically bookmarked by patient and data domain.
- Global, module-specific and patient-specific footnotes.
- Complex column headers that wrap to several lines.
- Continuous output with multiple data domains per page - depending on the amount of data in a domain, the listing of the data may wrap over multiple pages. Also, several domains may fit on one page.
- Allow customizing the display for each study - the titles, column headings and data display requirements may be different for each study.

### **APPLICATION ARCHITECTURE**

The report requirements necessitated developing the application where the patient profile report can be easily and quickly customized for different studies. The approach used was to publish the patient profile report as data (to a SAS dataset), containing all of the appropriate titles, data, footnotes and pagination information. The application consists of the component listed below.

- Titles, footnotes and column header registration file - This

concept there is to separate the page formatting from the data display. All of the titles, footnotes and column headers are registered to a file; this information is used when compiling the report.

- Patient-specific footer registration file - this information can be registered programmatically or manually.
- Procedure to generate the data lines with appropriate wrapping of data. Data lines are stored in a dataset, one dataset per data domain.
- Procedure to combine the page formatting information and data lines and "print" to a single dataset. Use the header information to create the titles and footnotes that are present on all pages. Create the appropriate titles, data and footnotes for each data domain. Perform the appropriate pagination to place multiple CRF modules on one page or break a CRF module over two or more pages. Produces the appropriate patient page numbering.
- Procedure to publish the final patient profile report. Create the appropriate page numbering, print one patient profile or multiple patients per, convert the ASCII output to PDF.

## CONCLUSION

In this paper we try to make two points. The first point is that we used a development methodology that focuses on producing complete specifications before starting any programming. This method tends to increase the up-front analysis and documentation time but greatly decreases the coding time. A large decrease in the coding time can be attributed to little need for revisions of code to specification change cycling. The reduction in coding effort produces an equal reduction in the debugging and testing effort.

The second point is that we needed to develop an application where the patient profile report can be easily and quickly customized for different studies. This was accomplished by using an approach to publish the patient profile report as SAS data. Separating the production of report content from the page formatting and pagination allows us to quickly add or modify data domains to an existing profile and quickly create new profiles for completely different studies.

Your comments and questions are valued and encouraged. Contact the author at:

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## CONTACT INFORMATION

**ATTACHMENT1 -SAMPLE PATIENTPROFILEREPORT**

Company Name  
Project Description

Page 1 of 100

Listing 9  
Safety Subject Profile

Subject Page 1 of 4

Subject: 999-001-0001

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Investigator Name: ABC	Initials: ABC	Age Group: 18-64	Gender: Male	Race: Caucasian
Treatment: Placebo		Weight Category: Obese		Severity of Allergic Rhinitis: N/A

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Summary of Baseline and Treatment Information

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Age (yr): 50	First Dose Date: 25JUL98	Inc/Exc Violation: No
Height (cm): xxxx	Last Dose Date: 08AUG98	Completed Study: Yes
Weight (kg): xxxx	Duration of Rx (days): xxx	Date of Completion/Termination: 09AUG98
	Total Dose (mg): yyyy	Primary Reason for Discontinuation: None
	Daily Dose (mg/kg) zz.zz	Protocol Deviations: None

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Baseline and Concomitant Medication

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ATC Text	WHO Drug Name	Period	Route	Dose	Unit	Frequency	Indication	Start	Stop	Ongoing	AE	Used to Treat
												Pre-Existing Condition
ANTIHIISTAMINES	BENADRYL	Base.	PO									
ANTIHIISTAMINES	BENADRYL	Concom.	PO									

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Optional Domain Specific Footnotes  
Optional Patient Specific Footnotes  
Optional Patient and Domain Specific Footnotes

Listing 9  
Safety Subject Profile

Subject: 999-001-0001

Investigator Name: ABC	Initials: ABC	Age Group: 18-64	Gender: Male	Race: Caucasian
Treatment: Placebo		Weight Category: Obese		Severity of Allergic Rhinitis: N/A

Summary of EKG

EKG	Results Overread or Calculated From Overread	Pre-Dose	Discharge	
			Actual	Change from Pre-dose
Ventricular Rate (bpm)	N/A	999	999	0
R-R Interval (ms)	Yes	999	999	0
P-R Interval (ms)	No	999	999	0
QRS Duration (ms)	No	999	999	0
Q-T Interval (ms)	No	999	999	0
QTc Interval (ms)	No	999	999	0
QTc-B Interval (ms)	Yes	999	999	0
QTc-F Interval (ms)	Yes	999	999	0
QTc-l Interval (ms)	Yes	999	999	0

Abnormal EKG Results

Visit	Date and Time of EKG	Clinical Significance	Description
X	01JUL2000	Yes	????????????????

Optional Domain Specific Footnotes  
Optional Patient Specific Footnotes  
Optional Patient and Domain Specific Footnotes

Listing 9  
Safety Subject Profile

Subject: 999-001-0001

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Investigator Name: ABC	Initials: ABC	Age Group: 18-64	Gender: Male	Race: Caucasian
Treatment: Placebo		Weight Category: Obese		Severity of Allergic Rhinitis: N/A

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Selected Lab Results

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	Pre-Dose		Discharge	
			Actual	Change from Pre-dose
Creatinine (mg/dL)	yyy	Normal	yyyy Normal	zzz
Bun (mg/dL)	yyy	Normal	yyyy Normal	zzz
Alk. Phos (U/L)	yyy	Normal	yyyy Normal	zzz
SGOT (AST) (U/L)	yyy	Normal	yyyy Normal	zzz
SGPT (ALG) (U/L)	yyy	Normal	yyyy Normal	zzz
SGGT	yyy	Normal	yyyy Normal	zzz

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Vital Signs

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	Pre-Dose		Discharge	
			Actual	Change from Pre-dose
Heart Rate (beats/min)				
Systolic BP (mm Hg)				
Diastolic BP (mm Hg)				
Respiratory Rate (breaths/min)				

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Optional Domain Specific Footnotes  
Optional Patient Specific Footnotes  
Optional Patient and Domain Specific Footnotes

Listing 9  
Safety Subject Profile

Subject: 999-001-0001

---

Investigator Name: ABC	Initials: ABC	Age Group: 18-64	Gender: Male	Race: Caucasian
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Adverse Events

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Body System	Preferred Term	Period	Onset Date	Onset Day	Death/ Resol. Date	Death/ Resol. Day	Freq	Outcome	Seve- rity	Action	Relation -ship	Treat -ment	SAE	UAE
Body as a Whole	Headache	SB	1/01/00	1	1/01/00	1	Int	Resolv	Mild	None	Unknown	Other	No	No
Respiratory	Asthma	SB	1/01/00	1	1/01/00	1	Int	Resolv	Mild	None	Unknown	Other	No	No
Nervous System	Headache	SB	1/01/00	1	1/01/00	1	Int	Resolv	Mild	None	Unknown	Other	No	No

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Optional Domain Specific Footnotes

Optional Patient Specific Footnotes

Optional Patient and Domain Specific Footnotes