Designing Clinical SAS Service Request Forms

Sunil Kumar Gupta
Gupta Programming, Simi Valley, CA

ABSTRACT

SAS programmers often have the responsibility of supporting the reporting requirements of the Clinical Affairs Department of Pharmaceutical Companies. This involves interacting with department members to define the report. The SAS programmer's task is to understand the request and to design the program to achieve the desired outcome. This is often the most difficult part of the request.

A SAS Service Request Form should be developed to meet the needs of the department and reflect the type of information available for reporting. The form should be organized to guide the customer through a series of questions. Sections on the form should include who the request is from and the required date, the description of the SAS request with the purpose listed, the selection criteria to identify the population and time period of the report, and the format and organization of the report along with the method of output desired. Finally, the SAS programmer should log the completion date and time.

Proper tools such as a SAS Service Request form should be in place to facilitate the communication and documentation of the customer's requirement and the customer's expectations of the programmer. Establishing standards in service requests will increase efficiency.

INTRODUCTION

One of the primary objectives of the SAS programmer is to generate a variety of reports to provide useful information on the progress of clinical studies. Although some studies will be similar in structure, many are often unique. The purpose of the reports include product approval application, study annual report, and monthly status review.

To expedite the development of a report, the SAS programmer must quickly define the report by having a solid understanding of the type of data available in the database and by having a basic foundation of clinical studies. The desired outcome will be a document reporting the safety and effectiveness measurements of the drug under investigation. The reports to FDA usually have required formats as compared to those for internal use which are designed to support the continuation of the study.

Often, the SAS programmer will spend more time designing the report than programming the report. This is because the programming component is built into the report designing process. A SAS Service Request form is a good tool to address many of the issues the programmer will encounter.

The example form in figure 1 is for a medical device manufacture of hip and knee prosthesis. The options on the form represent typical questions collected in these studies. The questions would have to be modified for drug studies and other medical device studies.

SERVICE REQUEST SECTIONS

The sections presented represent general categories of information and may require modifications for a given department. The objectives are to custom design the form to reflect the type of information available for reporting and to meet the reporting requirements of the department.

Although the end user of the request may know what s/he wants, s/he may not know how to obtain it. S/he may not know how to convey the request to the programmer. By reviewing a series of questions on the request, the communication between the customer and programmer is initiated. Often, this exercise will prevent any misunderstandings between the customer and the programmer. Consequently, additional questions may arise that might not have been addressed earlier.

The sections consist of the following:

- Requester
- Request Description
- Selection Criteria
- Report Heading
- Sort/Rank By
- Output Format
- Completed

REQUESTER SECTION

This section identifies who the request is from, his phone number, the date of the request and the required date of the report. Once the request is submitted to Clinical Data Management, it is assigned a service request number and prioritized with other service requests. The request is then reviewed and assigned to a programmer.

REQUEST DESCRIPTION SECTION

This section forces the requester to think of why and how exactly this report will be useful. How will the report facilitate the review of clinical information? By assessing the utility of the report early, many hours of reprogramming may be saved.

This information informs the programmer of the purpose of the report. Once the programmer understands the request, s/he is better able to plan for similar requests in the future and may establish a system to support the report on a scheduled basis.

These are the three types of service requests: new report, modification of an existing report, and running a report. New reports may require the most amount of time to complete. The

requester may need assistance in designing complex reports. Modifying an existing report is appropriate for duplicating a report from one study to another. Running a report calls for the execution of an existing program. This request takes the least amount of time. The modification of an existing report and running a report options may identify one of the following functional reports: patient listing, patient x-ray log, monitor site visit, and monthly status report.

SELECTION CRITERIA SECTION

This section identifies the population and time period of the report. The study or studies should be identified along with any specific investigator or patient in the study. The population by patient status, diagnosis, sex and age define the health of the patients. The efficacy or safety variables of interest should be stated. The other line may be used for fields not listed on the request. Finally, because clinical studies usually collect similar information over time, it is very important to state the time period of interest. Several of these options include pre-op, operative, post-operative, follow-up period, or most recent follow-up.

These are important factors in extracting and linking tables to obtain a reporting table. This table contains all the identified fields and meets the defined restrictions. If all the data for a given field is to be included in the report, then the outer box should be checked.

REPORT HEADING SECTION

This section defines the format and organization of the report. The fields are listed in the order requested along with any calculations. Attachment of a sample layout is suggested for custom or complex requests.

SORT/RANK BY SECTION

This section defines the list sorting or ranking by variable. Options include all or top x patients in decreasing or increasing order based on a given variable. A ranking list assigns a numeric value to each patient.

OUTPUT FORMAT SECTION

This section defines one or more of the following methods of report output: printed copy, letterhead paper, and ascii file. The type of report output can drive the structure of the program.

COMPLETED SECTION

It is important to track the request completion date and time. This information will be helpful to estimate completion times of similar requests.

It is a good idea to show a sample of the report to the requester as the report development continues. There are often changes to the original request based on the progress of the report. It is important to document these changes and note the additional amount of time required to complete the assignment.

SUMMARY

A substantial amount of time and efficiency can be saved by providing an effective method of communication between the customer's requirements and the programmer's expectations of the service request. By establishing a service request system, end user training will be improved with each service request. The requester will become more knowledgeable about the type of information available for review. Initially, a separate user instructions document should be provided to the requester to assist in the completion of the request.

The programmer will become more productive because the report specifications will be understandable.

Finally, the service request form can be continually improved with new studies and standards.

TRADEMARK INFORMATION

AUTHOR

The author welcomes your comments & suggestions.

Sunil Gupta
Gupta Programming
213 Goldenwood Circle
Simi Valley, CA 93065-6772
(805) 577-8877
Sunil@GuptaProgramming.com
http://www.GuptaProgramming.com

ACKNOWLEDGMENTS

The author would like to thank Dr. Fred Hoehler of Data Management Center, Santa Ana, CA and Kirk Paul Lafler of Software Intelligence Corporation, Spring Valley, CA for their invaluable assistance in the preparation of this paper.

CLINICAL AFFAIRS DEPARTMENT
SAS Service Request Form

I. Requester

Initiator: _____ Phone: _____.
Date: _____ Required Date: _____.
Approval: _____ SR #_____ Date: _____.

II. SAS Request Description

Report Title: _____.
Description: _____.
Purpose: _____.
_____.

Type: ❑ New Report ❑ Modify Existing Report ❑ Run Report

Functional Reports:
❑ Patient Listing ❑ Patient X-ray Log ❑ Monitor Site Visit
❑ Monthly Status Report ❑ Other Custom Report (Attach a sample layout)

III. Selection Criteria

Study: ❑ Hip - ❑ 9501 ❑ 9502 ❑ 9503
❑ Knee - ❑ 9501 ❑ 9502 ❑ 9503

❑ Investigator ❑ Patient #: _____.

Population:
❑ Patient Status: ❑ Active ❑ Dead ❑ Other _____.
❑ Diagnosis: ❑ OA ❑ RA ❑ PT
❑ Sex: ❑ Male ❑ Female
❑ Age: _____

❑ Efficacy ❑ Safety Variables: _____.
❑ Other: _____.

❑ Time Period: ❑ Pre-Op ❑ Operative ❑ Post-Operative
❑ Follow-up Interval: _____ ❑ Most Recent Follow-Up
❑ Custom Dates: _____-_____.

IV. Report Heading Information (order #)

❑ Investigator ❑ Patient #: _____.
Population:
❑ Patient Status: ❑ Active ❑ Dead ❑ Other _____.
❑ Diagnosis: ❑ OA ❑ RA ❑ PT
❑ Sex: ❑ Male ❑ Female
❑ Age: _____

❑ Efficacy ❑ Safety Variables: _____.
❑ Other: _____.
❑ Statistics: ❑ Count ❑ Mean ❑ Median ❑ Minimum ❑ Maximum ❑ STDV ❑ Range

V. Sort / Rank By

❑ Efficacy ❑ Safety Variables: _____.
❑ Other: _____.
❑ All ❑ Top: _____ ❑ Decreasing ❑ Increasing

VI. Output Format

❑ Printed Copy ❑ Letterhead ❑ ASCII File

VII. Completed

Programmer: _____ Date: _____ Hours:_____.

Figure 1