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SAS Certified Professional: ClinicalTrialsProgramming Using SAS 9.4

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A00-280

- 95-100 multiple-choice and short-answer questions.
(Must achieve score of 70% correct to pass)
- 3 hours to complete exam

Pricing & Discounts

- **\$180** Exam fee in the US and most Other countries

Clinical Trials Programming Using SAS 9.4

Clinical Trials Process

- Describe the clinical research process (phases, key roles, key organizations).
- Interpret a Statistical Analysis Plan.
- Derive programming requirements from an SAP and an annotated Case Report Form.
- Describe regulatory requirements (principles of 21 CFR Part 11, International Conference on Harmonization, Good Clinical Practices).

Clinical Trials Data Structures

- Identify the classes of clinical trials data (demographic, lab, baseline, concomitant medication, etc.).
- Identify key CDISC principals and terms.
- Describe the structure and purpose of the CDISC SDTM data model.
- Describe the structure and purpose of the CDISC ADaM data model.
- Describe the contents and purpose of define.xml.

Import and Export Clinical Trials Data

- Combine SAS data sets.
- Efficiently import and subset SAS data sets.
- Access data in an Excel workbook (LIBNAME and PROC IMPORT/EXPORT).
- Create temporary and permanent SAS data sets.
- Apply regulatory requirements to exported SAS data sets (SAS V5 requirements).

Manage Clinical Trials Data

- Investigate SAS data libraries using base SAS utility procedures (PRINT, CONTENTS, FREQ).
- Access DICTIONARY Tables using the SQL procedure.
- Sort observations in a SAS data set.
- Create and modify variable attributes using options and statements in the DATA step.
- Examine and explore clinical trials input data (find outliers, missing vs. zero values, etc).

Transform Clinical Trials Data

- Process data using DO LOOPS
- Retain variables across observations.
- Use assignment statements in the DATA step.
- Apply categorization and windowing techniques to clinical trials data.
- Use SAS functions to convert character data to numeric and vice versa.
- Use SAS functions to manipulate character data, numeric data, and SAS date values.
- Transpose SAS data sets.
- Apply 'observation carry forward' techniques to clinical trials data (LOCF, BOCF, WOCF).
- Calculate 'change from baseline' results.
- Obtain counts of events in clinical trials.

Apply Statistical Procedures for Clinical Trials

- Use SAS procedures to obtain descriptive statistics for clinical trials data (FREQ, UNIVARIATE, MEANS, SUMMARY).
- Use PROC FREQ to obtain p-values for categorical data (2x2 and NxP test for association).
- Use PROC TTEST to obtain p-values for continuous data (one-sample, paired and two-sample t-tests).
- Create output data sets from statistical procedures.

Macro Programming for Clinical Trials

- Create and use user-defined and automatic macro variables.
- Automate programs by defining and calling macros.
- Use system options to debug macros and display values of macro variables in the SAS log (MPRINT, SYMBOLGEN, MLOGIC, MACROGEN).

Report Clinical Trials Results

- Use PROC REPORT to produce tables and listings for clinical trials reports.
- Use ODS and global statements to produce and augment clinical trials reports.

Validate Clinical Trial Data Reporting

- Explain the principles of programming validation in the clinical trial industry.
- Utilize the log file to validate clinical trial data reporting.
- Use programming techniques to validate clinical trial data reporting (PROC COMPARE, MSGLEVEL).
- Identify and Resolve data, syntax and logic errors

Sample Questions

The following sample questions are not inclusive and do not necessarily represent all of the types of questions that comprise the exams. The questions are not designed to assess an individual's readiness to take a certification exam.

Clinical Trials Programming Using SAS 9

Question 1

What is the main focus of Good Clinical Practices (GCP)?

- A. harmonized data collection
- B. standard analysis practices
- C. protection of subjects
- D. standard monitoring practices

correct_answer = "C"

Question 2

Vital Signs are a component of which SDTM class?

- A. Findings
- B. Interventions
- C. Events
- D. Special Purpose

correct_answer = "A"

Question 3

Which option in the PROC EXPORT procedure overwrites an existing file?

- A. NEW
- B. OVERWRITE
- C. REPLACE
- D. KEEP

correct_answer = "C"

Question 4

Given the following data set WORK.DEMO:

PTID	Sex	Age	Height	Weight
689574	M	15	80.0	115.5
423698	F	14	65.5	90.0
758964	F	12	60.3	87.0
653347	F	14	62.8	98.5
493847	M	14	63.5	102.5
500029	M	12	57.3	83.0
513842	F	12	59.8	84.5
515151	F	15	62.5	112.5
522396	M	13	62.5	84.0
534787	M	12	59.0	99.5
875642	F	11	51.3	50.5
879653	F	15	75.3	105.0
542369	F	12	56.3	77.0
698754	F	11	50.5	70.0
656423	M	16	72.0	150.0
785412	M	12	67.8	121.0
785698	M	16	72.0	110.0
763284	M	11	57.5	85.0
968743	M	14	60.5	85.0
457826	M	18	74.0	165.0

The following SAS program is submitted:

```
proc print
data=WORK.DEMO (firstobs=5
obs=10);      where Sex='M';
run;
```

How many observations will be displayed?

- A. 4
- B. 6
- C. 7
- D. 8

correct_answer = "B"

Question 5

Given the following partial data set:

SUBJID	SAF	ITT	OTH
101	1	.	1
103	1	1	1
106	1	1	1
107	1	.	1

The following SAS program is submitted:

```

proc format;
value stdypfmt
1="Safety"
2="Intent-to-
Treat"
3="Other";
run;
data test;
set temp (keep=SUBJID ITT
SAF OTH ); by subjid;
length STDYPOP $200;
array pop{*} SAF ITT OTH ;
do i=1 to 3;
if STDYPOP="" and pop{i}=1 then STDYPOP=put(i,
stdypfmt.); else
if STDYPOP^="" and pop{i}=1 then STDYPOP =
trim(STDYPOP)||"/"|| end;
run;

```

What is the value of STDYPOP for SUBJID=107?

correct_answer = "Safety/Other"

Question 6

This question will ask you to provide a line of missing code.

Given the data set WORK.STUDYDATA with the following variable list:

#	Variable	Type	Len	Label
2	DAY	Char	8	Study Day
3	DIABP	Num	8	Diastolic Blood Pressure
1	TRT	Char	8	Treatment

The following SAS program is submitted:

```

proc means data=WORK.STUDYDATA noprint;
<insert code here>
class TRT DAY;
var DIABP;
output out=WORK.DIAOUT mean=meandp;
run;

```

WORK.DIAOUT should contain:

- the mean diastolic blood pressure values for every day by treatment group
- the overall mean diastolic blood pressure for each treatment group

Which statement correctly completes the program to meet these requirements?

- A. where trt or trt*day;
- B. types trt trt*day;
- C. by trt day;
- D. id trt day;

correct_answer = "B"

Question 7

The following SAS program is submitted:

```
%let member1=Demog;
%let member2=Adverse;
%let Root=member;
%let Suffix=2;
%put &&&Root&Suffix;
```

What is written to the SAS log?

- A. &member2
- B. Adverse
- C. &&&Root&Suffix
- D. WARNING: Apparent symbolic reference ROOT2 not resolved.

correct_answer = "B"

Question 8

This question will ask you to provide a line of missing code.

The following SAS program is submitted:

```
proc format ;
  value dayfmt          1='Sunday'
2='Monday'
                        3='Tuesday'
                        4='Wednesday'
                        5='Thursday'
                        6='Friday'
7='Saturday' ;      run ;
proc report data=diary ;
column subject day var1 var2 ;
  <insert code here>
run ;
```

In the DIARY data set, the format DAYFMT is assigned to the variable DAY. Which statement will cause variable DAY to be printed in its unformatted order?

- A. `define day / order 'Day' ;`
- B. `define day / order order=data 'Day' ;`
- C. `define day / order noprint 'Day' ;`
- D. `define day / order order=internal 'Day' ;`

correct_answer = "D"

Question 9

You are using SAS software to create reports that will be output in a Rich Text Format so that it may be read by Microsoft Word. The report will span multiple pages and you want to display a '(Continued)' text at the end of each page when a table spans multiple pages.

Which statement can you add to the SAS program to ensure the inclusion of the '(Continued)' text?

- A. `ods rtf
file='report.rtf';`
- B. `ods tagsets.rtf
file='report.rtf';`
- C. `ods tagsets.rtf file='report.rtf'
break='Continued';`
- D. `ods file open='report.rtf' type=rtf
break=' (Continued) ';`

correct_answer = "B"

Question 10

What is the primary purpose of programming validation?

- A. Ensure that the output from both the original program and the validation program match.
- B. Efficiently ensure any logic errors are discovered early in the programming process.
- C. Justify the means used to accomplish the outcome of a program and ensure its accurate representation of the original data.
- D. Document all specifications pertaining to programmed output and ensure all were reviewed during the programming process.

correct_answer = "C"