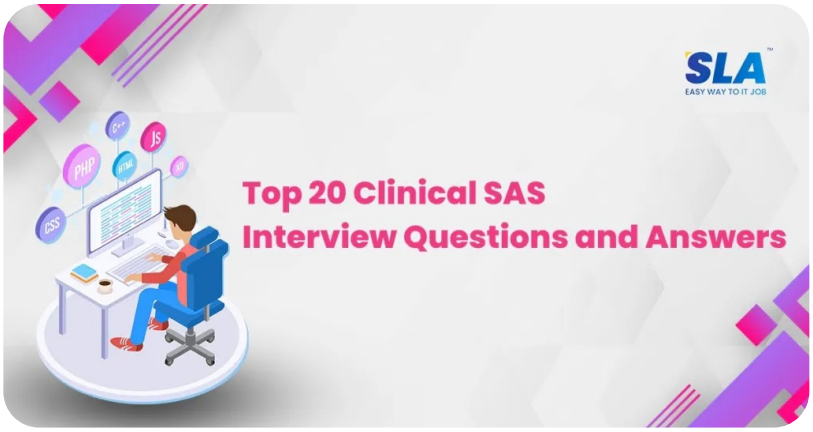

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Top 20 Clinical SAS Interview Questions and Answers

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Clinical SAS Interview Questions and Answers

Top companies around the world are employing certified and skilled clinical SAS professionals to work as clinical SAS developers, clinical SAS programmers, senior SAS administrators, and clinical SAS architects. We have prepared the top 20 clinical SAS interview questions and answers for the aspirants to ace the interviews with big companies.

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1. What is Clinical SAS meant exactly?

SAS (Statistical Analysis System) is applied in clinical trial data analysis for pharmaceutical, biotechnology, and clinical research organizations. It helps clinical research professionals to obtain great speed and accuracy while conducting clinical trials.

2. Define the validation procedure.

The validation procedure is the process used to verify the output of the SAS program that is generated by the programmer. If the output generated by the process validator is the same as the output generated by the SAS programmer, then the program is valid.

3. What is TLG and how is it used in clinical trials?

TLG is the acronym for Table, Listing, and Graph, which helps in performing the validation procedure to check the output of the SAS program.

4. How do you validate the listing of clinical trials that contains 400 pages?

As the validation of a listing that has 400 pages is impossible through a manual process, it is converted to a listing in data sets using PROC REPORT for comparison through PROC COMPARE.

5. How do you generate tables, listings, and graphs?

PROC REPORT is the procedure used to generate the listings; PROC FREQ, PROC MEANS, and PROC TRANSPOSE are the procedures to generate tables; and PROC GPLOT is the procedure for generating graphs in Clinical SAS.

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6. How many tables can be created in a

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VB.Net Interview Questions

day?

It depends on the complexity of the tables. If the tables are the same type, we can generate up to 3 tables in a day.

7. What are the documents to be submitted to the FDA, how can they be submitted to the FDA and who can submit them?

ISS and ISE documents are to be submitted to the FDA. The submission of documents to the FDA is done through e-submission using define.pdf or define.xml formats. A statistician or project manager will submit the documents to the FDA.

8. What is the function of the SAS log and how are errors handled in an SAS program?

Errors, warnings, and notes about how a SAS program was executed are all contained in the SAS log. A SAS program's errors can be managed with conditional processing, the IF-THEN statement, and log review for debugging.

9. Define Clin-trial database and Oracle Clinical.

Clintrial is the popular and leading *Clinical Data Management System (CDMS).* Oracle offers a database management solution called *Oracle Clinical (OC).* They offer data management and data entry, along with data validation functionalities, to the clinical trials process.

10. Explain hard-coding.

When a programmer has to write a report quickly, hard coding is necessary. Hard coding is better to avoid as it overrides the database controls in clinical data management.

11. What are the contents of lab data and what is the goal of the lab data set?

The lab data set consists of SUBJID, week number,

standard units, category of lab test, and lab normal and high range of values. The purpose of the lab data set is to retrieve the difference in the values of key variables after the drug administration.

12. What are the macro libraries?

Macro libraries have all the macros needed for developing TLGs for clinical trials and these are important to control and manage with the help of the %INLUDE statement. It is automatically called whenever required.

Clinical Sas Programmer Salary

Clinical SAS Interview Questions and Answers for Experienced

13. What are the phases in clinical trials?

There are four major phases in clinical trials, as follows:

Phase 1: Testing a new treatment or drug on a small group of people (20–80) to evaluate its safety.

Phase 2: Experiment with a drug or treatment with a large group of people (100–300) to validate whether the drug is effective or not.

Phase 3: Experiment with a treatment or drug with a large group of people (1000–3000) to check its actual effectiveness, monitor side effects, and compare with previous drugs.

Phase 4: Submit the study results for post-marketing that include the risks and benefits of the proposed drug or treatment.

14. Describe CRT and CRF

A pharmaceutical business must submit a CRT, or case report tabulation, as part of an NDA to the FDA.

Annotated CRFs (Case Report Form) are the variable names next to spaces to offer to the

investigator. These act as a link between the raw data and the queries to CRF. It is a useful tool for statisticians and programmers.

15. Define verification and program validation.

The work of verification is to ensure the quality of the SAS programs that have created the final tables and the accuracy of the final tables.

Program validation is the same as macro validation in that the SAS programmer has to validate the programs as per the rule of SOP to determine the result of the program, such as by creating a validation document and monitoring the status of pass or fail.

16. What is the Clinical Study Team and what is the main responsibility of a Clinical SAS programmer?

The Clinical Study Team provides information on safety and efficacy findings as per the requirements, along with periodic reporting.

A clinical SAS programmer has to develop programming for report formats such as ISS and ISE Shell that are required by regulatory authorities and update them whenever they are needed.

17. What are the things to be given in adverse events, and what are the things to be given in vitals?

Adverse Events is applicable for Protocol No., Patient ID, Preferred Term, Investigator No., Investigator Term, severity, seriousness, seriousness type, visit number, start time, stop time, and study drug.

Vital variables include subject number, procedure time, study date, sitting blood pressure, visit number, sitting cardiac rate, change from baseline to abnormal, dose of treatment, BMI, diastolic blood pressure, and systolic blood pressure.

18. Mention the things to be given in the PhysicalExam variable, ECG variable, and lab variable.

PhysicalExam should contain subject no., exam date, exam time, reason for exam, visit number, body system, findings, abnormalities, change from baseline, and comments.

ECG variables should contain study data, study time, subject no., visit no., PR interval, QRS duration, QT interval, ventricular rate, abnormal QTc interval, and change from baseline.

The lab variable should contain subject no., study day, lab parameter, lab units, ULN (upper limit of normal), LLN (lower limit of normal), change from baseline, visit number, medical condition, date of diagnosis, past condition, years of onset, or occurrences, and current condition.

19. Define PROC CDISC and explain what can be done with the Proc Life Test.

It is one of the SAS procedures that is available as a hotfix for the SAS 8.2 version and comes with the SAS 9.1.3 version. It allows the programmers to import or export XML files.

PROC LIFETEST is used to retrieve Kaplan-Meier and life table survival estimates that compare with different groups.

20. Define SDTM, ADAM, and DEFINE in clinical SAS.

SDTM is an acronym for '*Study Data Tabulation Model*' that has been built to standardize the submitted document to the FDA.

Clinical trial statistical analysis is conducted using ADAM (Analysis Data Model) datasets, which are obtained from SDTM datasets.

In SDTM and ADAM datasets, variables are defined with the DEFINE statement, which also specifies their

forms and properties.

Clinical SAS Training

Conclusion

We hope these clinical SAS interview questions and answers will be helpful to you in preparing for clinical SAS jobs. Explore a wide range of opportunities by enrolling in our **clinical SAS training in Chennai**.

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