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Clinical SAS Tutorial

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Clinical SAS Tutorial

In the clinical research sector, there is an increasing need for experts with SAS proficiency. In this Clinical SAS tutorial, let's explore them in detail.

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Introduction to Clinical SAS

Clinical researchers regularly analyze and publish data from clinical studies using clinical SAS (Statistical Analysis System) software. In this Clinical SAS tutorial, we cover the following:

- Overview of Clinical SAS.
- Understanding Clinical Trial Processes and Data Structures
- Understanding of CDMS
- Understanding Discrepancy Management

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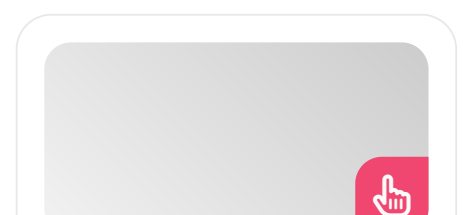
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Overview of Clinical SAS

India's vast patient base, varied gene pool, and affordable infrastructure are making it a growing centre for clinical research.

- Clinical SAS specialists can work in a range of environments, including academic institutions, pharmaceutical corporations, and contract research organizations (CROs).
- Regulatory agencies like the European Medicines Agency and the US Food and Drug Administration mandate that clinical trial data be recorded and analyzed using validated software, like SAS.

Given the increased demand for clinical research specialists and the necessity of regulatory compliance in clinical trials, clinical SAS is projected to have a strong future in India.

Understanding Clinical Trial Processes and Data Structures

Clinical data management (CDM), which generates reliable, high-quality, statistically sound data from clinical trials, is an essential step in clinical research.

This contributes to a significant decrease in the amount of time needed to develop a medicine and commercialize it.

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What is Clinical Trial?

By producing data to support or refute a theory, a clinical trial aims to provide answers to the research issue. The caliber of the data produced has a significant impact on the study's conclusion.

What is CDM or Clinical Data Management?

An essential and pertinent component of a clinical study is clinical data management.

CDM is the process of collecting, cleaning, and maintaining subject data in compliance with regulatory standards.

The main goal of CDM procedures is to deliver high-quality data by minimizing errors and missing data while collecting the most data feasible for analysis.

Tools for CDM

There are some tools that can be used for clinical data management. They are as follows:

- ORACLE CLINICAL
- CLINTRIAL
- MACRO
- RAVE
- eClinical Suite

These software tools are essentially equal in terms of capability; hence, neither system has a clear edge over the other.

The CDM Process

An error-free, valid, and statistically sound database is what the CDM process aims to produce, much as a clinical trial is meant to address the research issue. The CDM process begins early, even before the study protocol is finalized, to achieve this goal.

CRF Design

This phase includes creating the CRF, which directs the gathering of data.

Activities of CRF Design:

- Adverse effect (AE) forms
- Severe adverse effect (SAE) forms
- Concomitant therapy forms
- Eligibility screenings
- Follow-up visits
- Lab test forms
- Medical histories
- Physical exams and vitals
- Randomization
- Status evaluations

Clinical Sas Programmer Salary

Database Design

The study data should be able to fit in the database.

Activities of database design:

- Automated edit checks
- Backend tables
- Data stored in the CDM system (CDMS)
- Study-specific data entry fields and screens

Data Mapping

This stage allows researchers to report continually by combining data that comes in different formats.

Activities of data mapping:

- Evaluation of data entry
- Identification of data inconsistencies
- Testing carried out on the property
- Programming tests and data entry screens utilizing subject data
- Testing and inspections according to the list that the study sponsor has approved.

Study Conduct

The data manager should examine and make any necessary corrections to the actions related to SAEs and possible occurrences at this stage.

Activities of study conduct:

- CRF monitoring
- Data transfer or input from the CRF to the CDMS
- Management of discrepancies
- Data coding
- Review of data and continuous quality assurance
- Data transmission
- Protocols for data import
- Submissions from sponsors
- SAE synchronization

Study Closeout

The data manager should lock the database after a study is over to prevent data changes.

Activities of study closeout:

- Quality control
- Database lock
- Database maintenance and archiving
- Final study report.

CDMS

Clinical research studies can comply with CDM regulations with the aid of clinical data management systems, commonly referred to as clinical trial management systems (CTMS).

A CDMS or CTMS enables internal planning, reporting, and tracking. Clinical research studies can therefore gather data in a more effective, compliant, and successful manner.

Businesses utilize these systems to collect, compile, and validate data. Using a CDMS or CTMS has the

following benefits:

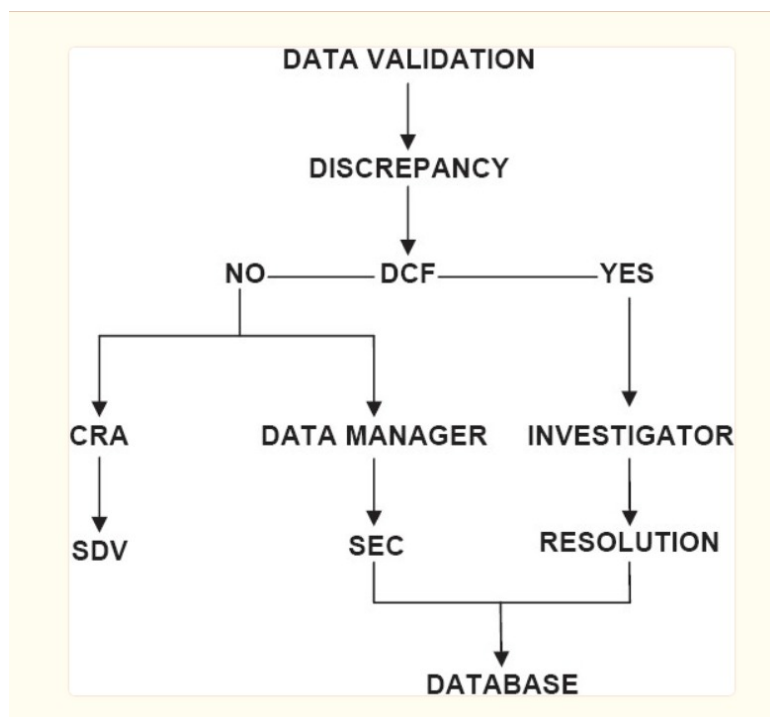
- Develop a rapport with regulatory bodies
- Remotely monitor data
- Include artificial intelligence
- Lead time and risk reduction should be balanced.
- Employ programming that is module-based to provide users with more capabilities.

Discrepancy Management

We also refer to this as query resolution. Managing discrepancies entails examining them, looking into why they occur, and either resolving them with supporting documentation or classifying them as unresolvable.

Discrepancy management assists in sanitizing the data and collects sufficient proof for any deviations found in it.

Discrepancies are either sent to the investigator for explanation based on the types found, or they are closed internally via Self-Evident Corrections (SEC) without requiring DCF to visit the location. Clearly visible spelling mistakes are the most frequent SECs.



Discrepancy management (DCF = Data clarification form, CRA = Clinical Research Associate, SDV = Source document verification, SEC = Self-evident correction)

Clinical Sas Training

Medical Coding

Medical coding facilitates the process of accurately identifying and classifying medical words associated with clinical trials. Online medical dictionaries are used for event classification.

According to technical requirements, this task requires familiarity with medical terminology, comprehension of disease entities and medications, as well as a fundamental awareness of the pathological processes involved.

Medical coding helps in achieving data consistency and preventing needless repetition by categorizing reported medical terms on the CRF into conventional dictionary terms.

Investigators may use more than one term for the same adverse event; nevertheless, all codes must follow the same standard code and the method must remain consistent.

It is essential to properly code and classify adverse events and medications because improper coding can obscure safety concerns or draw attention to unrelated safety issues with the drug.

Database Locking

Following a thorough quality assurance and inspection, the last data validation is performed.

- The statistician is consulted before the SAS datasets are finalized to see if there are any discrepancies.
- The completion of all data management tasks ought to have happened before the database

lock.

- By employing a pre-lock checklist and making sure that every task has been finished, this is sure to happen.
- This is necessary as, once locked, the database cannot be altered in any way.
- After locking, data extraction is completed from the final database.

Modernized Clinical Data Transformation

An essential step in enabling the study of clinical trial data is clinical data transformation.

Transformed data are used to power analyses of both single- and cross-study data.

Traditional Process: Conventional “batch-processing” techniques for data transformation are laborious to set up and don’t always have access to data when a study is being conducted. The inefficiencies of batch processing have become apparent while dealing with the sophisticated clinical trials of today.

Modernized Solution: The ability to consume large volumes of data at rapid speeds is necessary to modernize clinical data transformation.

Data interoperability requires AI/ML-assisted workflows to automate the assignment of semantic meaning and data processing and derivation rules for the various data sources.

Based on trial data, AI/ML technologies can intelligently discover new variables to generate for analytics.

Apply Statistical Procedures to Analyze Clinical Trials Data

The statistical analysis plan (SAP) is a key element of the analysis.

- This strategy guarantees that all decisions are documented and that the analyses to assess all planned study hypotheses are carried out in

a way that is consistent with science.

- It also includes information on the presentation and reporting of the outcomes.

The SAP should specify and approve the following:

- Any primary and important secondary outcome measures are specified in the analysis protocol.
- Techniques for managing several sources of data and missing information.
- Justification for any statistical methods that are not standard.

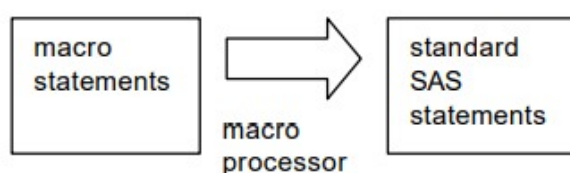
Other crucial factors in statistical analysis are as follows:

- Practical considerations for the trial statistician's blinding.
- Documentation to guarantee the reproducibility of all data modifications and analysis carried out on the original data taken from the data entry system
- Procedures to guarantee that, at trial completion, all pertinent documentation in the statistician's possession is filed in the Trial Master File.

Utilize Macroprogramming for Clinical Trials Data

For automation and efficiency in clinical trials, make use of SAS macros and sophisticated programming approaches.

Report the findings of clinical trials: To effectively convey clinical trial results, provide precise and comprehensible reports, tables, listings, and graphs.



SAS Macro Variables

These are the variables that an SAS application will repeatedly use and hold values for. In an SAS program, they are introduced at the outset and mentioned again later on. Their scope can be local or global.

Global Macro Variable

As any SAS program that is available in the SAS environment can access them, they are known as global macro variables. These are often system-assigned variables that are accessible by various programs. The system date is one example in general.

Example

```
proc print data = sashelp.cars;  
  
where make = 'Audi' and type = 'Sports' ;  
  
    TITLE "Sales as of &SYSDAY &SYSDATE";  
  
run;
```

Local Macro Variable

SAS programs that declare these variables as part of the program can access them. Usually, they are used to provide distinct variables to the same SAS statements so that they may handle various data set observations.

Syntax

```
%LET (Macro Variable Name) = Value;
```

Example

```
%LET make_name = 'Audi';  
  
%LET type_name = 'Sports';  
  
proc print data = sashelp.cars;  
  
where make = &make_name and type =
```

```
&type_name ;
```

```
TITLE "Sales as of &SYSDAY &SYSDATE";
```

```
run;
```

Macro Programs

An SAS statement collection with a name that may be used anywhere in a program is called a macro. A %MACRO statement opens it, while a %MEND statement closes it.

Syntax

```
%MACRO <macro name>(Param1,  
Param2,...Paramn);
```

```
Macro Statements;
```

```
%MEND;
```

```
%MacroName (Value1, Value2,...Valuen);
```

Example

```
%MACRO show_result(make_ , type_);
```

```
proc print data = sashelp.cars;
```

```
where make = "&make_" and type = "&type_" ;
```

```
TITLE "Sales as of &SYSDAY &SYSDATE";
```

```
run;
```

```
%MEND;
```

```
%show_result(BMW,SUV);
```

Report the Findings of Clinical Trials

When conducting a clinical trial, researchers pledge to follow fundamental ethical guidelines in both the study's conduct and the reporting of its results. This entails maintaining the results' accuracy and disclosing both positive and negative findings to the public. It involves the following steps:

1. Review the requirements for reporting results
2. Complete the result modules
3. Upload supplemental documentation
4. Release the record
5. Address the review comments

Validate Clinical Trials Data Reporting

A set of recorded tests of the data is called data validation, and their purpose is to guarantee the accuracy and consistency of the data.

More precisely, four of the eight qualities of high-quality clinical data, which are taken from the first advice and the first additional reference mentioned below, are typically checked during validation. The eight traits are as follows:

- **Attributable:** The data's sources are identified and documented.
- **Legible:** Humans can read the data.
- **Contemporaneous:** As soon as source data is generated, it is documented.
- **Original:** The original source of all data is cited.
 - The data is exact and complete, both in copies and transformations, and they can be tracked back to the original source without erasing any information.
- **Accurate:** The information is true.
- **Durable:** The information is accessible for the duration that it must be retained.
- **Whole:** All information that is at hand is included.
- **Consistent:** Every piece of data is free of contradictions and uses terminology that are consistent.

Tests for data validation typically examine the data's originality, accuracy, consistency, and completeness.

Clinical Data Validation Process

There are numerous alternatives and variations available for the validation process, but it is

complicated and depends on a number of elements, including the data that is recorded, business and regulatory issues, the data management software being used, and several others.

Planning

- The sponsor determines which code lists to use, what checks to do, and what steps to take in the event that an invalid result is obtained.
- Documentation exists for the procedures, code lists, and checks.

Implementation and Testing

- The clinical database management system is used to implement the checks and code lists.
- Typically, database validation involves the creation of test methods and test data for the checks.
- The test protocols are executed.

Data Entry and Validation

- The checks are performed either periodically or as the data is entered.
- The intended methods are used to either allow or repair invalid findings.
- Data cleansing is the term typically used to describe the last round of checks.

Database Locking

- The database is locked when there are no more anticipated updates or modifications to the data.

Analysts may perform additional checks even after the database has been locked to see whether any modifications are required to generate the analytical datasets.

Conclusion

We hope you have gotten the outline of clinical SAS through this comprehensive Clinical SAS tutorial.

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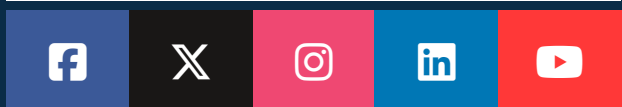
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