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Use of SAS Reports for External Vendor Data Reconciliation

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ABSTRACT

As the adoption of industry data standards grows, organizations must streamline process as to how to manage data effectively with quality often by using various techniques, The main objective of Data Management (DM) is to deliver a qualitative database to SAS Programming , Statistical Analysis teams in a timely manner in turn helps to generate bug-free reports. The ultimate challenge is managing the third party vendor data, which loads into the database, and our aim is to **reconcile** this **Vendor data** (**Lab data**, **SAE Data**) with the related data present in our database. To find out the optimized process in such a way that avoids lot of manual effort, the various challenges, efficient techniques are discussed further in this paper.

INTRODUCTION

In the pharmaceutical industry, carrying clinical trials ethically and fairly is always a challenge because providing quality data for the submission is difficult. DM team reviews multiple numbers of reports on a daily, weekly, and monthly basis or at various frequencies to produce quality data. This data is useful to the Statistics team for their analysis, which includes lots of manual effort. This may lead to failure in submitting quality data. A single step of failure can affect the entire effort of a clinical trial.

There are many challenges in tasks performed by the DM team, but the ultimate challenge is to reconcile the Vendor data (Lab data, SAE Data) with the related data present in the clinical database. A manual reconciliation may cause errors of overlooking the data.

"Reconciliation is the comparison of specific data points associated with third-party data reported to the vendor database and the clinical database".

If one can indulge SAS reports in this area, the following benefits are possible:

- Decreases the reconciliation time
- Increases efficiency and quality by around 60-75%
- Covers the verification of all the parts
- Produces separate outputs in various formats using ODS

OVERVIEW OF DATABASES

There are two different types of databases:

- Clinical Database – Used for a clinical trial and this database uses an electronic CRF or a paper CRF. In both the cases, the relational database allows entry of all data captured on the CRF. Examples of clinical bases are Oracle Clinical, Inform, and Rave etc.
- Vendor Database – An external database, known as Vendor database or Third-party database, is where the collected clinical data is entered and collected samples are tested, analyzed and their results are loaded into Clinical Database.

USUAL APPROACH FOR RECONCILIATION

Reviewers usually perform the reconciliation by manual approach.

To perform manual reconciliation, reviewers:

- Pull clinical data as well as vendor data into excel by using reporting tools like I-Review, J-review, and so on (at times comes in excel from study team).
- Perform manual reconciliation by comparing each and every subject across the vendor data sheet and clinical database data sheet.

Comparison of various data points of vendor database and clinical database is complex and tiresome. The manual reconciliation approach is time consuming and is prone to errors because reviewers may overlook the data. Additionally, the manual tracking of issues is very tedious.

LAB DATA RECONCILIATION

Comparison of specific lab data points associated with lab data reported to the vendor database and the clinical database.

Flow of Lab Data between the Clinical Database and Lab Vendor Database

Flow of Lab Data in the Clinical Database

The data flow in the clinical database is explained in Figure 1.

1. Subject arrives at the investigator site, either on scheduled visit or on unscheduled visit, to give lab samples like blood, urine and so on.
2. The **Lab kit** with a unique Accession Number or Sample ID is assigned to each subject at the investigator site. Lab Kit is consists of all required materials for sample collection like syringes, ampules etc. as well as a Lab Requisition form.
3. The required samples are drawn.
4. **Lab Requisition Form with the Collected Samples is sent to the Vendor.** Lab requisition form which comprises of information like site, subject and visit identifiers, gender, date of birth, Lab test (optional), date of sample collection, time of sample collection (optional) and Sample ID or Accession Number is filled.
5. **Details of the Collected Sample Data is Entered in the Clinical Database** like site, subject and visit identifiers, Lab test (optional), date of sample collection, time of sample collection (optional) and Sample ID or Accession Number.

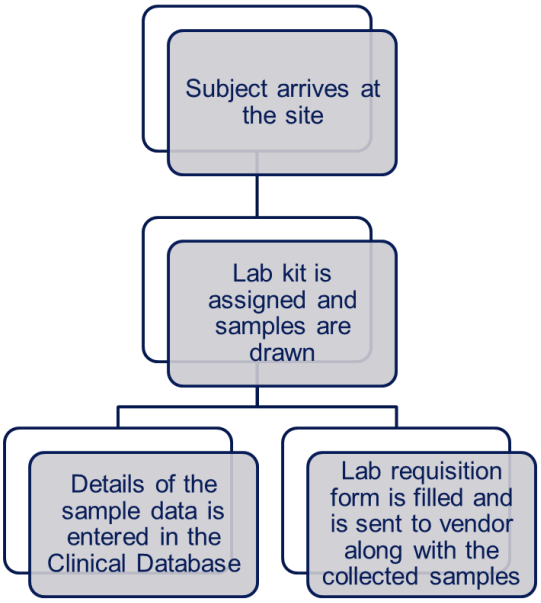

Figure 1. Data Flow in Clinical Database

Flow of Lab Data in the Vendor Database

The data flow in the Vendor database is explained in Figure 2.

Lab vendor provides support for laboratory, biological samples analytics data, collected during the clinical trial. Vendor laboratory data is considered to be very significant for the clinical trial data management process. The reviewer has a significant role to play in effective management of vendor data.

Ex: Biological samples like blood urine etc., ECG core lab, imaging core lab, cardiovascular core lab, biomarkers, genetic testing, isolation of cancer genes etc.

1. Lab samples received from investigator site are analyzed and results collected.

2. Data from Lab requisition form and the collected results are entered in Vendor database.

3. Data is sent to appropriate team per the Data Transfer Agreement (DTA) specification. DTA defines the format of files, frequency of data transfer, file naming conventions, encryption levels, method of transfer, type of transfer (complete versus partial), recipient, test names, formats, high and low value flags or alerts, and any additional information concerning the lab data.

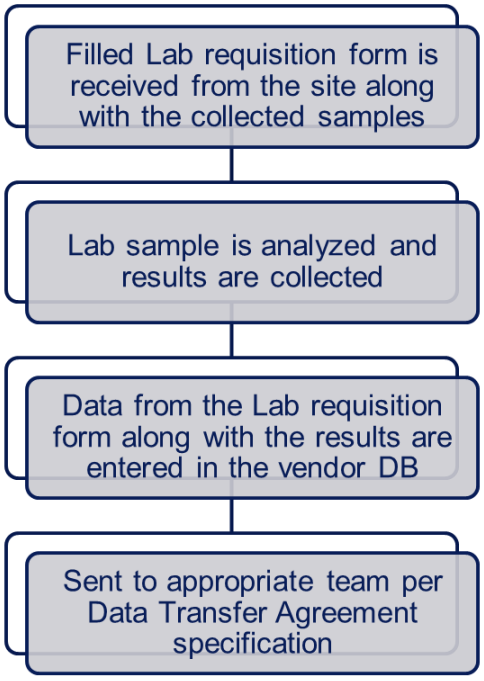

Figure 2. Data Flow in Vendor Database

LIST OF DATA POINTS RECONCILED IN LABORATORY DATA RECONCILIATION

The data points that can be reconciled are namely demographic data and procedural data. These data points are retrieved from vendor databases and clinical databases.

Demographic Data

- Site Identifier
- Subject Identifier
- Gender
- Date of birth

Procedural Data

- Visits for lab sample collected
- Lab test name (Optional)
- Date of lab sample
- Time of lab sample (Optional)

Types of Discrepancies

- Incorrect data loaded for subjects
- Mismatch in dates entered in Vendor and Clinical Databases
- Mismatch in time entered in Vendor and Clinical Databases
- Visits incorrectly loaded
- Visit dates collection mismatches when data is collected in 24-hour format
- Data collected for screen failures

ROLE OF SAS SYSTEM

SAS system plays a vital role in reconciliation. Figure 3 illustrates the steps involved in the SAS system and required data panels that are invoked into the SAS system.

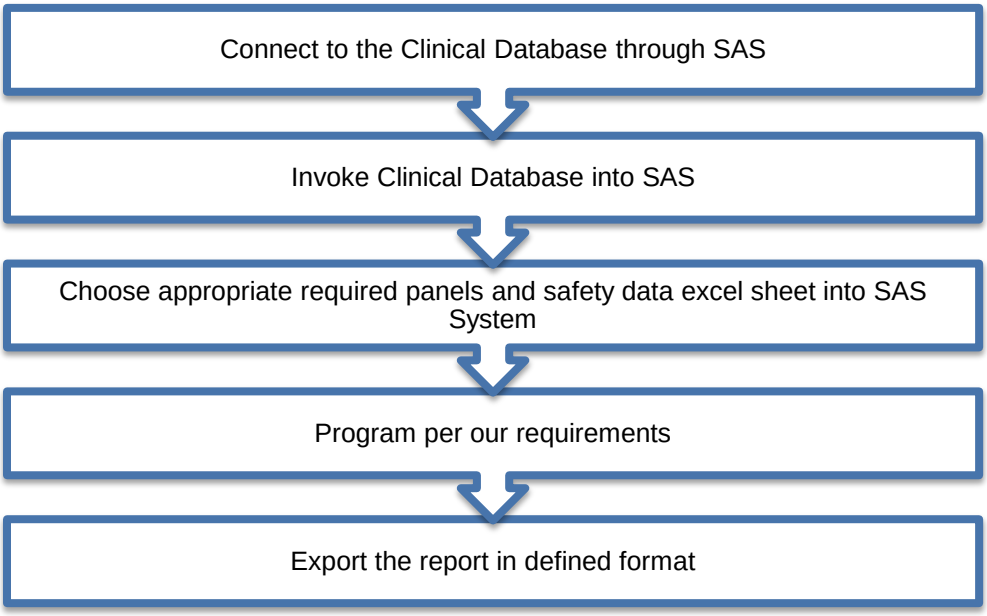

Figure 3. SAS System Process

Once the data are read in SAS, it helps to identify and highlight the discrepant data between both the databases.

EXAMPLE I

```
/*Reading of Input data*/
DATA demog;
 input sdyid $ 1-4 invid  subjid 6. gender$6. DOB$9.;
 cards;
ABCD 123 10000 Female 12Sep99
ABCD 143 10001 Male       12Sep85
ABCD 163 10002 Female 13Sep85
ABCD 183 10003 Male       15Sep85
ABCD 203 10004 Male       16Sep85
ABCD 223 10005 Male       17Sep85
ABCD 243 10006 Male       18Sep85
ABCD 263 10007 Male       19Sep85
;
run;

DATA lab_crf;
input sdyid $1-4 invid  subjid 6.lbvisid 2.lbperfflg
$3.lbtest$3.lbacstdt$9.lbacn 5.;
cards;
ABCD 123 10000 1 Yes HM  12Sep14 234
ABCD 143 10001 2 NO      HM
ABCD 163 10002 3 YES HM  14Sep14 546
ABCD 163 10002 3 YES HM  14Sep14 456
ABCD 183 10003 4 YES HM  16Sep14 4896
ABCD 203 10004 5 YES HM  17Sep14 2589
ABCD 223 10005 6 YES HM  18Sep14 489
ABCD 243 10006 7 YES HM  19Sep14 46
ABCD 263 10007 8 YES HM  20Sep14 123

run;
/*Combing demographic information with CRF lab data*/

proc sql;
 create table lab_crf_demog as
  select a.sdyid,a.invid,a.subjid,b.crf_gender,input(b.crf_dob,date9.) as
crf_dob format=date9.,a.lbvisid as crf_lbvisid,
             a.lbperfflg,a.lbperfflg as crf_lbperfflg,a.lbtest,a.lbtest as
crf_lbtest,input(a.lbacstdt,date9.)as lbacstdt format=date9.,
             input(a.lbacstdt,date9.) as crf_lbacstdt
format=date9.,a.lbacn,a.lbacn as crf_lbacn
  from
     (
        select * from lab_crf )as a
left join
    (
        select sdyid,invid,subjid,gender as crf_gender, dob as crf_dob
         from demog ) as b
on (a.sdyid=b.sdyid and a.invid=b.invid and a.subjid=b.subjid)
;
quit;

DATA lab_vendor1;
```

```
input sdyid $1-4 invid  subjid 6. gender$6. DOB$9. lbvisid 3.lbperfflg$3.
lbtest $3.lbacstdt$9.lbacn 5.;
cards;
ABCD 123 10000 Female 12Sep15 1  Yes HM 12Sep14 234
ABCD 143 10001 Female 12Sep85 2  NO  HM
ABCD 163 10002 Male   13Sep85 3  YES HM 14Sep99 1546
ABCD 163 10002 Male   14Sep85 3.1YES HM 14Sep14 456
ABCD 183 10003 Male   15Sep85 4  YES HM 16Sep14 4896
ABCD 203 10004 Male   16Sep85 5  YES HM 17Sep14 2589
ABCD 223 10005 Male   17Sep85 6  YES HM 18Sep09 1489
ABCD 243 10006 Male   18Sep85 7  YES HM 19Sep14 46
ABCD 263 10007 Male   19Sep85 9  YES HM 20Sep14 123
;
run;

proc sql;
 create table lab_vendor as
  select sdyid,invid,subjid, gender as vendor_gender,input(dob,date9.)as
vendor_dob format=date9.,lbvisid as vendor_lbvisid,
            lbperfflg,lbperfflg as vendor_lbperfflg,lbtest,lbtest as
vendor_lbtest,input(lbacstdt,date9.)as lbacstdt format=date9.,
            input(lbacstdt,date9.) as vendor_lbacstdt
format=date9.,lbacn,lbacn as vendor_lbacn
  from lab_vendor1;
quit;

proc sort data=lab_crf_demog;by sdyid invid subjid lbtest lbacstdt lbacn ;
run;

proc sort data=lab_vendor;by sdyid invid subjid lbtest lbacstdt lbacn ; run;

data vendor_crf;
 merge lab_crf_demog (in=a) lab_vendor (in=b);
 by sdyid invid subjid lbtest lbacstdt lbacn ;
 length comment $50;
 if a and b then do;
  if crf_gender=vendor_gender and crf_dob=vendor_dob and
crf_lbvisid=vendor_lbvisid  then  comment="Complete Match";
   else    if crf_gender^=vendor_gender   then  comment="Gender Mismatch";
   else    if crf_dob^=vendor_dob   then  comment="DOB Mismatch";
    else   if  crf_lbvisid^=vendor_lbvisid  then  comment="Visid Mismatch";
end;
 if a and not b then comment="Clinical Data Base";
 if b and not a then comment="External Data Base";
run;
```

Display 1 shows the SAS output lab reconciliation, which indicates the mismatches between lab data reported in both clinical database and vendor database.

LAB DATA RECONCILIATION

sdyid	invid	subjid	crf_sex	crf_lbvisid	crf_lbperfflg	crf_lbacstdt	crf_lbacn	vendor_sex	vendor_lbvisid	Vendor_lbperfflg	vendor_lbacstdt	vendor_lbacn	Findings
XXX	123	10000	Female	1	Yes	12-Sep-14	234	Female	1	Yes	12-Sep-14	234	DOB Mismatch
XXX	163	10002	Female	3	YES	14-Sep-14	456	Male	3.1	YES	14-Sep-14	456	Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	163	10002	Female	3	YES	14-Sep-14	546						Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	163	10002						Male	3	YES	14-Sep-99	1546	Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	223	10005						Male	6	YES	18-Sep-09	1489	Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	223	10005	Male	6	YES	18-Sep-14	489						Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	**343**	**10011**	**Female**	**12**	**YES**	**25-Sep-14**	**910**	**e**	**12.1**	**YES**	**25-Sep-14**	**910**	**DOB Mismatch,Visid Mismatch**
XXX	403	10014						Female	15	NO			Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	403	10014	Female	15	NO	28-Sep-14	123						Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	423	10015						Male	16	NO			Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	423	10015	Male	16	NO	29-Sep-14	1456						Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	443	10016						Male	17	NO			Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	443	10016	Male	17	NO	30-Sep-14	158						Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	463	10017						Female	18	NO			Sex Mismatch,DOB Mismatch,Visid Mismatch
XXX	463	10017	Female	18	NO	1-Oct-14	1239			NO			Sex Mismatch,DOB Mismatch,Visid Mismatch

Display 1. SAS output for Lab Data Reconciliation

SERIOUS ADVERSE EVENT (SAE) RECONCILIATION

A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening

  NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event, which hypothetically might have caused death if it were more severe.
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect

Note: Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening, result in death, or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious.

SAE that take place during clinical trials are reported in two databases—Clinical database and Safety database. SAE data present in clinical database is used for analysis, reports, and new drug applications to regulatory agencies.

SAFETY DATABASE

SAEs from clinical trials and marketed products are reported directly to a safety group or safety coordinator. A specialized system is used for processing and management of SAE data.

PROCESS

Once we receive the First Subject, First Visit (FSFV) information then we can start the process of SAE reconciliation. If a serious event is reported to the clinical database, then the reviewer may request reconciliation between the databases.

The assigned reviewer begins by extracting listings of fields to be reviewed from the safety database and the clinical database. Per DTA document; frequency of reconciliation between databases is based on visit dates and data loads, and frequency of reports and reporting milestones with frequent communication/issues log and documentation.

While reconciling, reviewers look for below points:

- Cases found in the SAE system but not in the clinical database system
- Cases found in the clinical database system but not in the SAE system
- Deaths reported in one but not the other, perhaps because of updates to the SAE report
- Cases where the basic data matched up but where there are differences, such as in onset date

Of these fields, some will require a one-to-one match with no exception, while some may be deemed as acceptable discrepancies based on logical match. The fields that require an exact match or logical determination are listed in Table 1.

Field	Match
Demographics	1:1 match
Event Term	Rational match verbatim to preferred terms
Onset Date	Rational match first onset of symptoms versus date event becomes serious
Outcome	Rational match to subject summary or final page
Resolved Date	Rational match to outcome and summary pages
Causality	1:1 match
Study Drug Start Date	1:1 match
Study Drug Stop Date	1:1 match
Date of Death	1:1 match
Cause of Death	Rational match to causality
Action Taken regarding Study Drug	Action taken in response to SAE; rational check to dosing data

Table 1. Patient and Case Identifiers

Case report forms are used for clinical database and Adverse Event monitoring forms are used for safety database and database are being created by entering data into these forms respectively. The data is processed in the safety database on a case number basis and in the clinical database through data collection modules (DCMs).

Consequently, data may be captured with different field names in both databases due to data capture/protocol conventions/CRF design or medical review:

Some examples of data capture variations may be:

- During the safety medical review process, terms may be added resulting in additional SAEs in the safety database that may not be in or are non-serious in the project database.
- CRF design – Captures study drug action “no action” or “permanently discontinued,” or reports action for continuation in the study.
- Protocol convention – Safety database captures the event as “dose not changed” and clinical database captures pre-rand action as permanently discontinued.
- Data capture conventions – Events in the clinical database may start as non-serious, become serious and resolve as non-serious, resulting in the appearance of event date discrepancies.

As reconciliation is not an automated process between the safety and clinical databases, it takes much time to reconcile between two databases.

DIFFICULTIES OF DATA RECONCILIATION

The data reported in clinical database (For example, Oracle Clinical) data is collected to meet the requirements of a specific protocol while the safety database (For example, ARGUS) is collected to meet regulatory reporting requirements. The CRF forms could vary depending on the disease under study even when working on the same family of drugs. It is important to define how the data will be reviewed prior to the reconciliation in order to have guidelines consistent across the entire study.

When preparing for the data extractions, it is important to map the data fields in the safety database that mirror those data fields in clinical database to ensure an accurate comparison of the data. This can best be accomplished by reviewing the actual CRF page in the clinical database to establish the appropriate field name and by data handling guidelines for the study under review.

In this paper, safety database is referred as ARGUS and Clinical database as Oracle Clinical. In Table 1**Error! Reference source not found.**, the data points collected against Argus and Oracle Clinical are listed.

ARGUS Data Elements	**Oracle Clinical Data Elements**
Protocol Number	Protocol Number
Actual Report	Seriousness of AE
Case Number AE	Case ID-FUL
Center ID-Patient ID	Patient
DOB	Date of Birth-FUL
Sex	Sex
Race	Race-FUL
Race	Ethnicity-FUL
Reported Term	Investigator Event Term
Preferred Term	Preferred Term (PT)
Onset Date	Start Date-FUL
Outcome	Recovered with Sequelae-FUL
Outcome	AE Still Present
Cessation Date	Stop Date-FUL
Outcome	AE Action Study Drug Dose-FUL
Outcome	AE Action Wdrn from Study
Investigator Causality	Reasonable Poss. AE Related Study Drug
Case Causality	
Case Narrative	AE Causality
Case Narrative	AE Causality Specify-FUL
Suspect Product Trade Name (Generic Name)	Study Drug Name-FULL
Therapy Start Date	Start Date-FUL
Therapy Stop Date	Stop Date-FUL
Total Daily Dose	Total Daily Dosage-FUL
Date of Death	Date of Death-FUL
Cause of Death	Cause of Death-FUL
Case Narrative	Reason for Withdrawal-FUL

Table 1. Comparison of Data Fields using Argus and Oracle Clinical

EXAMPLE II

```
data lss ;
input sitemnemonic $ 1-3      subjectnumberstr $ 5-10 LSS_TERM $ 13-21
      pf_term     $ 23-31 LSS_PREFERRED_TERM    $ 33-41
LSS_DEATH $ 43-46       LSS_LIFE_THREATENING $ 49-52  LSS_DISABLING $ 53-56
      LSS_HOSPITALIZATION $ 57-60
 LSS_CONGENITAL_ANOMALY  $ 61-64 LSS_OTHER $ 65-68          LSS_CAUSALITY $
73-76 lss_sex $77-78 lss_DOB $ 79-88;
length all_val $500;
all_val=strip(sitemnemonic)|| strip(subjectnumberstr)|| strip(LSS_TERM)||
strip(pf_term)|| strip(LSS_PREFERRED_TERM)||
strip(LSS_DEATH)|| strip(LSS_LIFE_THREATENING)|| strip(LSS_DISABLING)||
strip(LSS_HOSPITALIZATION)||
strip( LSS_CONGENITAL_ANOMALY)|| strip(LSS_OTHER)|| strip(LSS_CAUSALITY)||
strip(lss_sex)|| strip(lss_DOB);
cards;
748   105178      Fall    FALL          Fall      No  No    Yes   Yes   No
      No          No  F 01JAN1985
748   105364      anxiety       ANXIETY   Anxiety       No  No    No    Yes
      No    No          No  M 09SEP1990
748   105366      ANEMIA        ANAEMIA   Anaemia   No      No    No    Yes
      No    No          No  F 10JUL1978
748   105360      Asthenia  ASTHENIA      Asthenia  No      No    No    Yes
      No    No          No
run;


data ae;
input sitemnemonic $ 1-3      subjectnumberstr $ 5-10 cb_CTTERM $ 13-21
      cb_pf_term $ 23-31      cb_PREFERRED_TERM $ 33-41
      cb_CAUSALITY $ 45-48    cb_CONGENITAL_ANOMALY $ 49-52 cb_DEATH $ 53-56
      cb_DISABLING $ 57-60
cb_HOSPITALIZATION $ 60-63    cb_LIFE_THREATENING $ 65-68   cb_OTHER $ 69-72
cb_sex $ 73-74 cb_DOB $ 75-84;
length all_val $500;
all_val=strip(sitemnemonic)|| strip(subjectnumberstr)|| strip(cb_CTTERM)||
strip(cb_pf_term)|| strip(cb_PREFERRED_TERM)||
          strip(cb_DEATH)|| strip(cb_LIFE_THREATENING)||
strip(cb_DISABLING)||strip(cb_HOSPITALIZATION)||

      strip(cb_CONGENITAL_ANOMALY)||strip(cb_OTHER)||strip(cb_CAUSALITY) ||
strip(cb_sex)|| strip(cb_DOB);
cards;
748   105178      Fall    FALL          Fall          No    No    No    Yes
      Yes   No    No  F 01JAN1985
748   105364      Fever   Fever         Fever         No    No    No    Yes
      No    No    No  F 01FEB1980
748   105366      ANEMIA        ANAEMIA   Anaemia           No    No    No
      Yes   No    No    No  M 01MAR1986
748   105369      Asthenia  ASTHENIA      Asthenia    No    No    No    Yes
      No    No    No  F 01JAN1967
run;

proc sort data=lss;
  by all_val;
run;
```

```
proc sort data=ae;
  by all_val;
run;

data ae_lss;
  merge ae(in=a) lss(in=b);
  by all_val;
  length comment $100;
  if a and not b then comment="Clinical Data Base";
  if b and not a then comment="Safety Data Base";
  if a and b then comment="Both Databases";
run;
```

BENEFITS AND ADVANCEMENTS

- Decreases the turnaround time of review by 70-75%
- Identifies the appropriate data issues
- Helps attain better quality increasing it by 10-15%
- Earlier issues are tracked easily

You can program above-mentioned piece of SAS codes in a way that is more robust and use alternative methods too.

CONCLUSION

This paper covered two types of external reconciliations and SAS system that makes review easier.

- Reviewers can easily compare the external data with Clinical data within the stringent timelines or while reviewing overall data.
- Tracking or following up of discrepancies will be easier and efficient as it gives the clear picture about the issues.
- Ability to easily assess the metrics of report and calculate the percentage of the database cleaned. This in turn, decreases the manual efforts and duplicate reviews.
- Reconcile all external data with Clinical data. For example: IVRS, PK-PD, Biomarkers reconciliations and so on.

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RECOMMENDED READING

Base SAS® Procedures Guide

SAS® For Dummies®

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