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Identification of new information on data point level

Boubacar Barry, Bayer, Wuppertal, Germany
Thomas Binnen, Bayer, Leverkusen, Germany
Eric Kammer, Bayer, Whippany, NJ, USA

ABSTRACT
One way to identify new information in data is to note time stamps from the audit trail of the clinical database so that these can be compared with a last review date. However, due to the fact that the respective time stamps are typically record-based, previous approaches to identify new information had the limitation that data changes could not be reflected on data point level.

This paper shows a technique developed using a SAS© based approach to overcome this limitation of record based changes.

INTRODUCTION
The review of data for ongoing Clinical Studies is difficult because of the amount of data and its continuous modification. It is important when new data arrives to focus on new information, not yet reviewed.

One way to identify new information is to note time stamps from the audit trial of the clinical database so that these can be compared with a last review date. However, due to the fact that the respective time stamps are typically record-based, previous approaches to identify new information had the limitation that data changes could not be reflected on data point level.

The team at Bayer developed a SAS© based approach within LSH©/JReview© to overcome this important limitation. This approach consists of retrieving the history data at any given review date in the past and compares the result with the current data on record level using a unique record identifier key value. This allows an identification of new information on data point level.

This SAS© based approach considers the subject specific last data review date, documented in Bayer's medical review tool as a basis for the comparison, and subsequently allows the identification of new respectively modified information.

This method is of particular interest for the reviewers which enable them to efficiently perform their tasks by focusing only on new information that is available in the database. This will enable others that the same database access with JReview© and LSH© to use this same method.

DATA CHANGES
Bayer uses JReview© for medical review and for the most part it is sufficient for data review. However, a better way was needed to see changed data that was present. The review of data for ongoing Clinical Studies is difficult because of the amount of data and its continuous modification. It is important when new data arrives to focus on new information, not yet reviewed. The reviewers wanted to focus on new data not yet reviewed in the database. A SAS© program was developed and run in the JReview© environment from LSH© to achieve the desired results.

POTENTIAL PROBLEMS

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- Medical Review is performed on each individual subject on ongoing basis during study conduct and must be completed prior to the declaration of clean database
- Medical reviewers are working on dirty data

- The database is updated on daily basis
- Potentially tens of thousands of records to be reviewed across thousands of pages
- The review process is time consuming and can be irritating sometimes
- Therefore highlighting new or modified information will make the work of the reviewer easier

WHY THE SAS APPROACH?

- ✓ Color coding only possible with current methods on record level which is fine for added new records. For updated records there is no chance to identify at a first glance the item that has been altered
- ✓ Lower performance when executing the affected objects

- A SAS© program is used to read in Bayer's case from the JReview© system tables the panel where the last review date of subjects is documented
- From Oracle LSH© Views, tables of interests are identified by this SAS© Program, using the business area, the schema of the business area, the work area and their respective hierarchies
- For each table of interest following steps are performed
  - ✓ Create a history SAS© dataset of the panel. This history dataset will contain only records that were valid at the date and time of the last review of the subject. Deleted records prior to the review date as well as new or modified records after the review date are excluded
  - ✓ Create a comparison SAS© dataset of the panel. This dataset will contain only valid records at the date and time of the program execution (in other words, current valid records)

SAS© Proc Compare was utilized for changes

- The base SAS© procedure PROC COMPARE is then used in a further step to compare the history dataset to the comparison dataset created in the steps above
- The result of the comparison is analyzed in further steps to flag deleted, new, and altered records and their respective contents are concatenated with **[-R-], [-N-],** and **[-C-]** so that changes become visible on data point level in the underlying SAS dataset

Subject	Change Flag	Last Reviewer	Prev. Review Date	Current DS Date	MedDRA PT	Reported Term	Sequence Number
6017	No Change	BI	24JUL2017	10AUG2017	Chronic obstructive pulmonary disease	COPD exacerbation	
6023	No Change	BI	24JUL2017	10AUG2017	Pneumonia bacterial	BACTERIAL PNEUMONIA	1
6023	No Change	BI	24JUL2017	10AUG2017	Major depression	MAJOR DEPRESSION DISORDER	3
6023	No Change	BI	24JUL2017	10AUG2017	Asthma	INTERMITTENT ASTHMA	2
7005	Changed	BI	24JUL2017	10AUG2017	Hypertension	[-C-] High Blood Pressureexacerbation	2

Changed Cell

```
proc sort data=&&_mb_h&mb_ct presorted;
         by jr_key;
       run;

       proc sort data=&&_mb_c&mb_ct presorted;
          by jr_key;
       run;

proc compare base    = &&_mb_h&mb_ct
     compare = &&_mb_c&mb_ct
     out     = _diff_&&_mb_hc&mb_ct.
     outbase
     outcomp
     outdif
     novalues
     noprint;
        id jr_key;
       run;
```

CONCLUSION

Short Summary of Bayer Data Analytics and Review groups' approach using a SAS© program

While JReview© offers some nice features for data review using JReview© system tables, and reading the PATIENTREVIEW table it was decided that SAS© had to be used to get the format required for record based changes. This required getting data from LSH© audit views, create a history dataset containing only valid records at the time of last review and using the SAS© Compare procedure to perform a comparison between the two snapshots giving a more accurate change indication of records on a data point level.
If you are using an LSH© environment this approach can be helpful in determining new or changed data when making it easier to determine changes for medical review.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Boubacar Barry
Bayer AG
Building 402, 065
Wuppertal, Germany 42096
Work Phone: +49 202 363924
Email: boubacar.barry@bayer.com
Web: www.bayer.com

Thomas Binnen, MD
Bayer AG
Building K 56, 5C145
Leverkusen, Germany 51368
Work Phone: +49 214 3068436
Email: thomas.binnen@bayer.com
Web: www.bayer.com

Eric Kammer
Bayer U.S. LLC
100 Bayer Boulevard
Whippany NJ 07981
Work Phone: +1 8624047649
Email: eric.kammer@bayer.com
Web: www.bayer.com