



# *Identification of New Information on Data Point Level*



June 2018 / Boubacar Barry / Thomas Binnen /  
Eric Kammer





# Agenda

- // Why highlight **New Information** in the Medical Review Listing?
- // Prerequisites
- // An electronic medical review tool (JReview® ) approach
- // Bayer DRS approach: SAS® based program



# Why highlight **New Information** in the Medical Review Listing?

- // Medical Review is performed on each individual subject on an 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 a 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



# Prerequisites

- // Audit trail: Data available for any given date, time in the past since the beginning of the load process in the database
- // A unique key is defined to identify each record in the database
- // Incremental load of the data with soft delete of inactive records

| KEY | CDR\$CREATION_TS    |  | CDR\$END_TS         |
|-----|---------------------|--|---------------------|
| 62  | 11/09/2017 22:01:54 |  | 15/08/3501          |
| 49  | 11/09/2017 22:01:54 |  | 28/09/2017 13:39:46 |
| 87  | 11/09/2017 22:01:54 |  | 28/09/2017 13:39:45 |
| 72  | 11/09/2017 22:01:54 |  | 28/09/2017 13:39:46 |
| 86  | 11/09/2017 22:01:54 |  | 28/09/2017 13:39:45 |
| 95  | 11/09/2017 22:01:54 |  | 15/08/3501          |

Active record

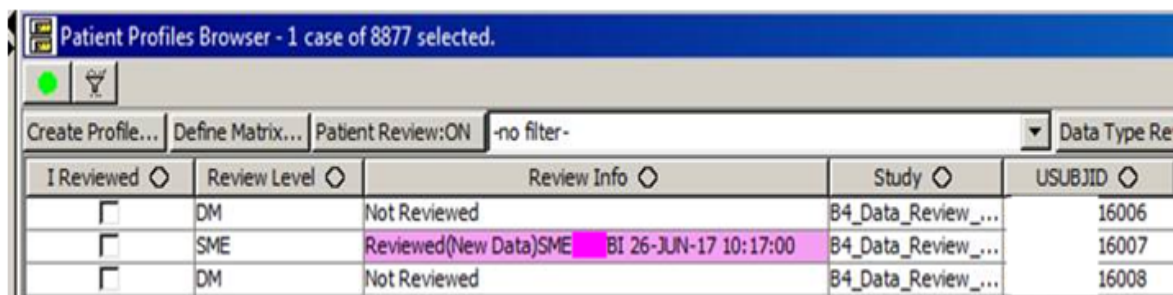
Soft deleted records

Active record



# JReview Approach

- // A review date is noted by the reviewer in the JReview Patient Review Tracker available in the JReview system tables



The screenshot shows a window titled "Patient Profiles Browser - 1 case of 8877 selected." with a menu bar containing "Create Profile...", "Define Matrix...", "Patient Review:ON", and "-no filter-". Below the menu is a table with the following columns: "I Reviewed", "Review Level", "Review Info", "Study", and "USUBJID". The table contains three rows of data.

| I Reviewed               | Review Level | Review Info                                 | Study              | USUBJID |
|--------------------------|--------------|---------------------------------------------|--------------------|---------|
| <input type="checkbox"/> | DM           | Not Reviewed                                | B4_Data_Review_... | 16006   |
| <input type="checkbox"/> | SME          | Reviewed(New Data)SME BI 26-JUN-17 10:17:00 | B4_Data_Review_... | 16007   |
| <input type="checkbox"/> | DM           | Not Reviewed                                | B4_Data_Review_... | 16008   |

- // The application compares this information with the last modification date of the record available in the audit trail columns on subject and record level



# JReview Approach

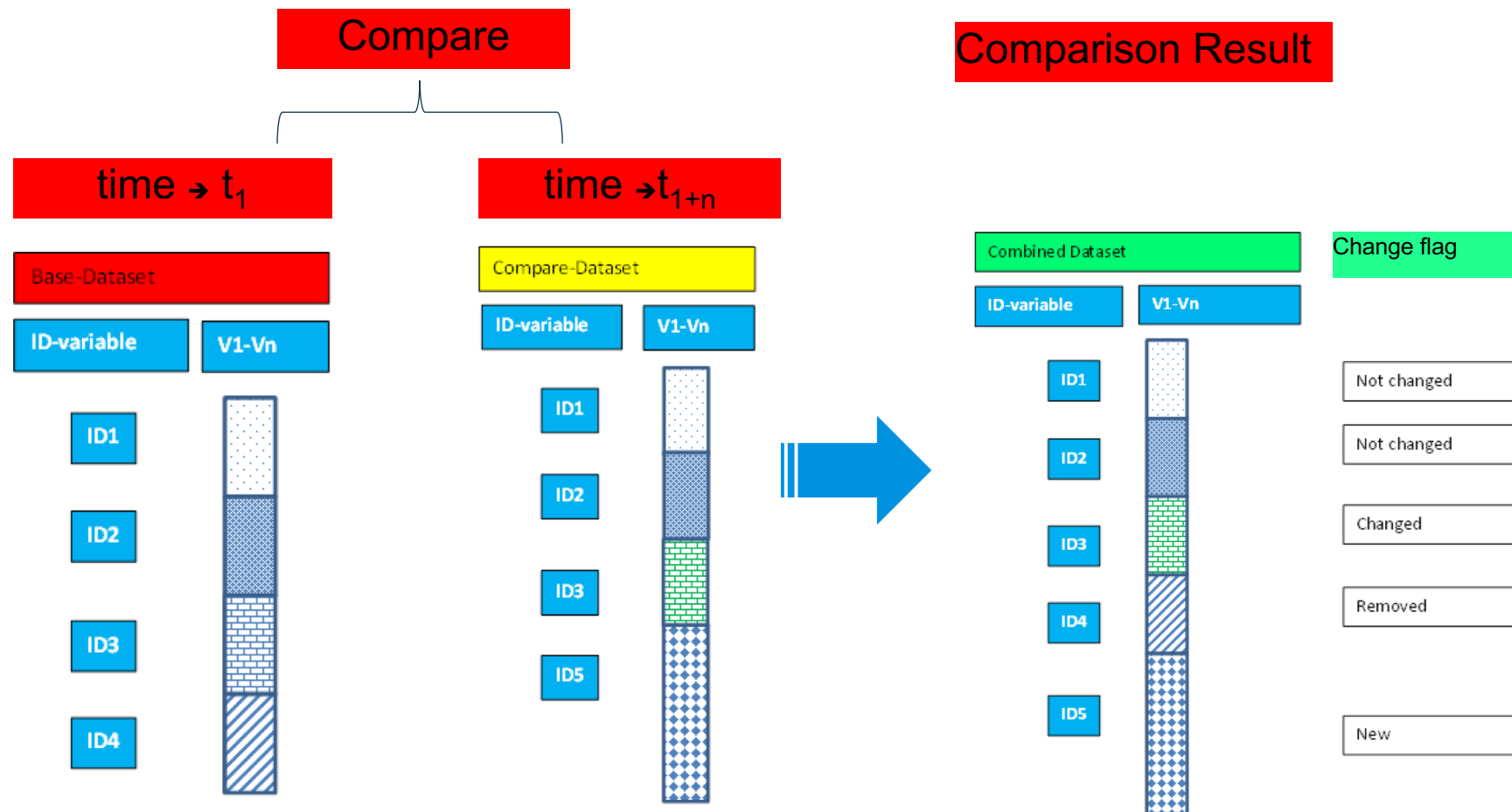
- // The result of the comparison is displayed in the JReview listings and Patient Profiles in form of color coding
- // Any row that has been newly added or modified since last review date will be highlighted automatically

| Adverse Events - All Patients / Output Filter applied |         |                                           |                                  |                 |
|-------------------------------------------------------|---------|-------------------------------------------|----------------------------------|-----------------|
| Show Filter Refresh                                   |         |                                           |                                  |                 |
|                                                       | Subject | MedDRA PT                                 | Reported Term                    | Start Date/Time |
| 1                                                     |         | 6003 Dermatitis                           | Skin Inflammation right shin     | 2017-02-13      |
| 2                                                     |         | 6003 Skin abrasion                        | Graze right shin                 | 2017-02-13      |
| 3                                                     |         | 6006 Erectile dysfunction                 | erectile dysfunction             | 2017-01-18      |
| 4                                                     |         | 6006 Hyperuricaemia                       | worsening of hyperuricaemia      | 2016-04-11      |
| 5                                                     |         | 6007 Atrioventricular block second degree | atrioventricular block grade 2   | 2017-08-02      |
| 6                                                     |         | 6007 Diarrhoea                            | diarrhea                         | 2016-09-27      |
| 7                                                     |         | 6007 Subcutaneous abscess                 | Skin Abscess on the right arm    | 2016-10-09      |
| 8                                                     |         | 6007 Urinary tract infection              | Urinary tract infection          | 2016-12-07      |
| 9                                                     |         | 6007 Vomiting                             | vomit                            | 2016-09-27      |
| 10                                                    |         | 16009 Gingivitis                          | gingivitis                       | 2017-07-12      |
| 11                                                    |         | 16009 Hyperuricaemia                      | Worsening of hyperuricemia       | 2017-07-26      |
| 12                                                    |         | 16009 Pharyngeal erythema                 | Throat lateral funiculus redness | 2017-07-12      |

- // Limitation:
  - // Color coding is only possible on record level. This is fine for newly added records. For updated records there is no chance to identify at a first glance the item that has been altered



# Bayer DRS Approach: SAS based program





# Bayer DRS Approach: SAS based program

// 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

```
PROC COMPARE BASE = &base_dset.  
              COMPARE = &comp_dset.  
              OUT = _diff_&dset.  
              OUTBASE  
              OUTCOMP  
              OUTDIF  
              NOVALUES  
              NOPRINT;  
  
ID &key_var;  
RUN;
```

// The result of the comparison is analyzed in further steps to flag deleted [-R-], new [-N-], and altered [-C-] records and their respective contents are concatenated with these flags so that changes become visible on data point level in the electronic data review tools

| 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



# Bayer DRS Approach: SAS based program

// Using the inline formatting, we can replace in the SAS based reports the pattern '[-N-]' new and '[-C-]' altered with the super script 'n' and 'c' and select a green foreground to make the changes visible

```
DATA work.cs_ae;
SET work.ae;
ARRAY all_var {*} $ _character_;
DO var_ct=1 TO dim(all_var);
  IF prxmatch("m/[-C-]/i", strip(all_var(var_ct))) THEN
    DO;
      all_var(var_ct)=prxchange("s/[-C-]/i", -1, strip(all_var(var_ct)));
      all_var(var_ct)= cat('^S={color=green}', compl(strip(all_var(var_ct))), ' ^{style[color=green] ^{super c}}');
    END;
  IF prxmatch("m/[-N-]/i", strip(all_var(var_ct))) THEN
    DO;
      all_var(var_ct)=prxchange("s/[-N-]/i", -1, strip(all_var(var_ct)));
      all_var(var_ct)= cat('^S={color=green}', compl(strip(all_var(var_ct))), ' ^{style[color=green] ^{super n}}');
    END;
END;
RUN;
```

// Patient Profiles

Previous date: 02FEB2018

Current date: 09MAY2018

| Adverse Events Report                                                                                                                               |                         |                     |                |                         |                          |                   |                |                               |                                    |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------|----------------|-------------------------|--------------------------|-------------------|----------------|-------------------------------|------------------------------------|
| MedDRA PT/Rep. Term                                                                                                                                 | Start Date/Time         | Rel S/E             | TEAE?          | End Date/Time           | Relation to SD?          | Intensity         | Seriousness    | Action taken                  | Outcome                            |
| Abdominal discomfort / gastrointestinal upset                                                                                                       | 2018-01-01              | 14/ -               | Y              | 2018-02-03 <sup>c</sup> | Rel. SD1: N              | MILD              | N              | DOSE NOT CHANGED              | RECOVERED/ RESOLVED <sup>c</sup>   |
| Oedema peripheral / edema of the lower limbs <sup>n</sup>                                                                                           | 2018-04-01 <sup>n</sup> | 104/ - <sup>n</sup> | Y <sup>n</sup> | <sup>n</sup>            | Rel. SD1: N <sup>n</sup> | MILD <sup>n</sup> | N <sup>n</sup> | DOSE NOT CHANGED <sup>n</sup> | RECOVERING/ RESOLVING <sup>n</sup> |
| ( <sup>n</sup> ) New records since the previous review date (02FEB2018) - ( <sup>c</sup> ) Changed items since the previous review date (02FEB2018) |                         |                     |                |                         |                          |                   |                |                               |                                    |



# Forward-Looking Statements

This website/release/presentation may contain forward-looking statements based on current assumptions and forecasts made by Bayer management.

Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at <http://www.bayer.com/>.

The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.



*Thank you!*



**Bye-Bye**

